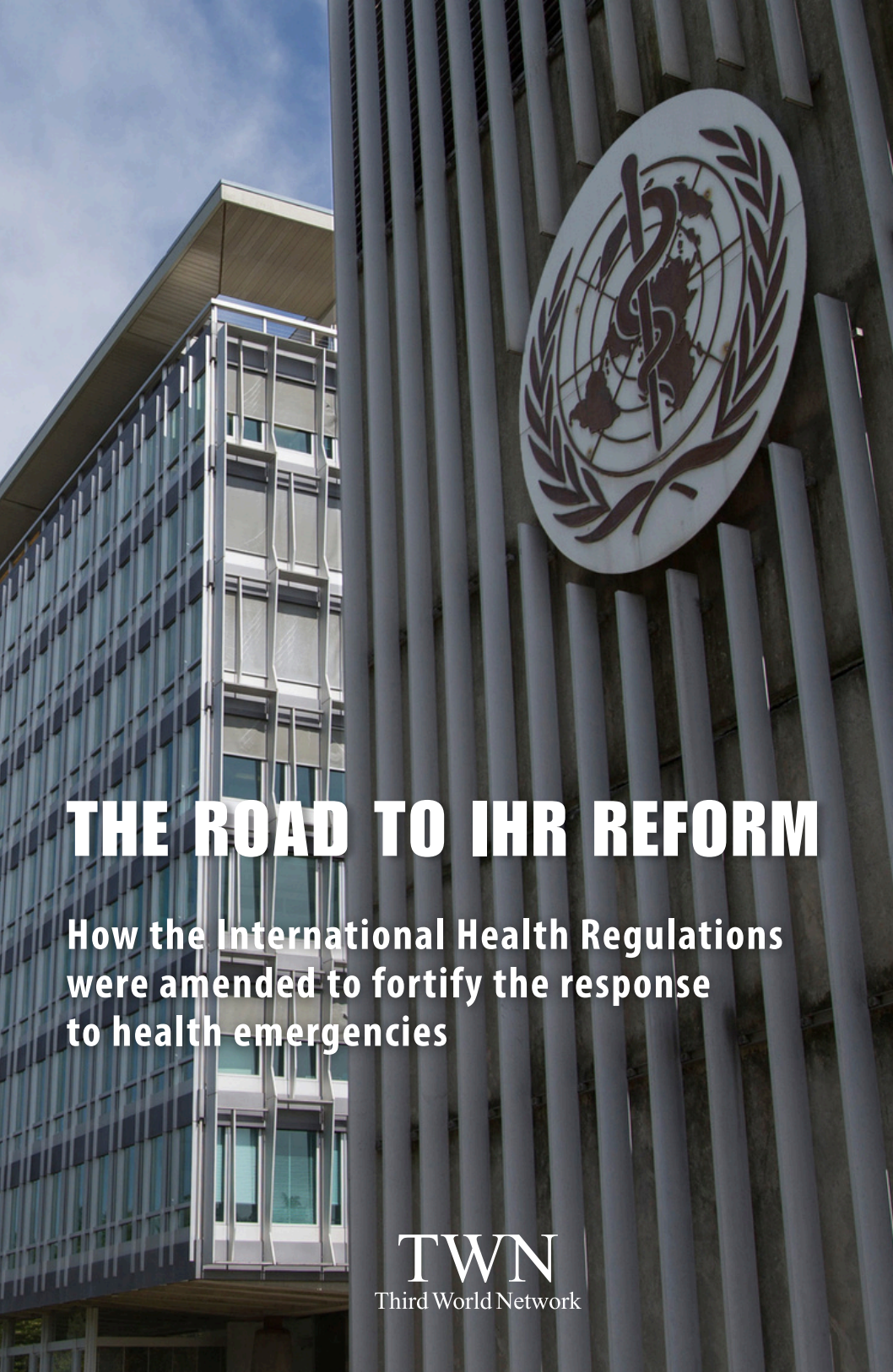

THE ROAD TO IHR REFORM

How the International Health Regulations were amended to fortify the response to health emergencies

TWN
Third World Network

The Road to IHR Reform

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Introduction

IN 2020, the unprecedented scale of the COVID-19 pandemic laid bare the systemic inequities embedded in the global health regime and, differently from previous pandemics, like H1N1, and public health emergencies of international concern, like Ebola, had far-reaching impacts on the entire world. Disparities in access to vaccines, treatments, diagnostics, and other critical health tools during the pandemic underscored the need for a comprehensive and equitable approach to public health emergencies. While high-income countries had vaccinated 68% of their populations, only 2.31% of people in low-income countries had received a dose by October 2021. After a mass vaccination rollout, rates picked up in 2022, but still lagged far behind.

However, the devastation caused by COVID-19 was not solely due to vaccine shortages. The pandemic's true toll was further obscured by a severe lack of diagnostic capacity, particularly in Africa. The World Health Organization (WHO) estimated that only one in seven COVID-19 cases was detected across the continent. A stark example comes from a 2022 study by the Boston University School of Public Health, which found that nearly 90% of deceased individuals at a morgue in Lusaka, Zambia, had been infected with COVID-19 during peak transmission periods (July 2020–June 2021) – yet only 10% had tested positive while alive. This, we should not forget, led to 18.2 million excess deaths globally by 2021, with Southern Sub-Saharan Africa holding one of the highest excess mortality rates: 309 deaths per 100,000.

Various initiatives to prevent such inequalities in future health emergencies were launched. During the 73rd World Health Assembly held in November 2020, WHO adopted a resolution to strengthen preparedness during health emergencies through implementation of the International Health Regulations 2005 (IHR), and the WHO Director-General requested the convening of the IHR Review Commit-

tee. In its turn, the Committee published in 2021 a report highlighting the lack of a mechanism within the IHR to secure equitable sharing of health products and to diversify and foster local production, among other issues like financing, surveillance, and notification. This was followed by other reports by the Independent Oversight and Advisory Committee and the Independent Panel for Pandemic Preparedness and Response, which touched on the same issues but differed on how to tackle inequitable access to health products – with one report recommending voluntary and the other report, binding mechanisms.

The inequalities seen during the COVID-19 pandemic, and the various recommendations emanating from the abovementioned review reports, led to the establishment of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) to consider these recommendations and propose the way forward.

The WGPR process further initiated two WHO-Member-State-driven processes for legal reforms to strengthen preparedness and response during health emergencies. The first was the establishment of an intergovernmental negotiating body (INB) to draw up a new international legal instrument dealing with prevention, preparedness and response to pandemics (pandemic instrument). Secondly, the WGPR was reconvened as a Working Group on Amendments to the IHR 2005 (WGIHR) to amend the IHR. The decision to amend the IHR followed the United States' proposals for amendment.

The WGIHR negotiating process culminated in amendments to the IHR which were adopted by the 77th World Health Assembly in May 2024, marking a significant milestone in global health governance, especially the governance of cross-border health emergencies.

Concerns over IHR implementation

The IHR, which originally emerged from the 19th-century International Sanitary Conferences, became a cornerstone of international health cooperation when they were formalized as the International Sanitary Agreement and later revised into the International Health Regulations in 1969. These regulations were further revamped

in 2005 under the WHO Constitution to establish a framework obligating Member States to notify WHO of potential public health emergencies of international concern (PHEICs). Article 2 of the IHR states: *"The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."*

To fulfil their purpose, the IHR create three important obligations on State Parties. First, State Parties are to inform of any event which may constitute a PHEIC and the measures implemented in response to the event. To determine whether an event constitutes a PHEIC, the IHR provide a decision instrument as an Annex. Second, the IHR obligate State Parties to maintain core capacities on surveillance and response to an event, which is to facilitate the fulfilment of the first obligation. Third, State Parties are under an obligation to maintain capacities in designated ports of entry such as airports, ports and ground crossings and also to ensure compliance with measures taken under the IHR.

Though the IHR contain obligations on maintaining public health responses, they lacked any concrete provisions on assistance, especially in facilitating access to relevant health products required for prevention of and response to PHEICs. As a result, the IHR were criticized for perpetuating a one-way flow of information from the Global South, where many disease outbreaks originate, to the Global North, without creating reciprocal obligations, and for failing to address the stark developmental divide between countries, particularly in terms of access to health resources and financial or technical support. This growing criticism regarding the silence of the IHR on access to health products played a major role in driving the IHR amendments.

Similarly, the IHR also lacked a financial mechanism providing support to developing countries to build the capacities mentioned above. Though there were provisions providing for collaboration and assistance to developing countries in building capacities and mobilizing financial resources for the same, they were limited to best-en-

deavour clauses. This resulted in uneven implementation of capacity building, with response capacities lagging behind considerably. These disparities between surveillance and response capacities also played a major role in setting the tone in the IHR amendment process.

Also, the governance over IHR implementation rested with the World Health Assembly, the top decision-making body of WHO. However, since the WHA has to address all other issues under WHO's scope of work, there was never enough time allocated to examine in detail the challenges and opportunities in IHR implementation. Hence, many Member States considered developing a distinct body or committee to look into IHR implementation.

Amendment process

As mentioned above, by 2022, the WGPR process had resulted in two parallel negotiation tracks: one to amend the IHR, and the other to develop a pandemic instrument. The establishment of the formal process for amendment of the IHR had been set in motion by a US initiative. In fact, a part of the US' amendment proposals dealing with the procedure and timelines for the coming into force of IHR amendments was adopted during the 75th World Health Assembly in 2022 itself; thus, even before the establishment of the WGIHR, the 75th WHA had formally adopted a process for amendment of the IHR.

Prior to the decision of the 75th WHA (WHA75(9)), the 150th meeting of the WHO Executive Board (EB) had adopted a decision (EB150(3)) outlining the scope of amendments to the IHR. This EB decision urged *"Member States to take all appropriate measures to consider potential amendments to the International Health Regulations (2005), with the understanding that this would not lead to reopening the entire instrument for renegotiation. Such amendments should be limited in scope and address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance*

of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner". Subsequently, WHA 75(9) established the WGIHR by renaming the WGPR and tasked it with working on amendments to the IHR for the consideration of the 77th WHA in 2024. Further, it set a timeline for Member States to submit amendment proposals for the WGIHR's consideration, and also mandated the establishment of an IHR Review Committee to make technical recommendations on the proposed amendments.

Following the WHA decision, 16 Member States submitted proposed amendments. (Out of these 16, four submissions were made on behalf of regions.) These proposals clearly reflected a North-South divide over the orientation of the IHR. While the proposals from the North primarily focused on strengthening information-sharing aspects, the amendments sought by developing countries mainly addressed equity concerns, especially inequitable access to health products.

The WGIHR formally started the negotiations on the amendment proposals in its second session in February 2023, following the submission of the technical recommendations of the IHR Review Committee.

Over the next 15 months, the WGIHR conducted more than 10 rounds of negotiations, including eight formal rounds and two informal rounds. As the deadline for the IHR amendments neared in early 2024, the negotiations intensified, but by the time of the 77th WHA in May 2024, the amendments package was still not completely ready. Since the mandate of the WGIHR ended before the WHA, a drafting group was set up at the 77th WHA to conclude the negotiations, and the amendments were finally adopted during the WHA session.

Amendments

The IHR amendments incorporated several significant changes, especially from an equity perspective. For the first time, equity

and solidarity are incorporated as core principles, which will shape the implementation of obligations of both Member States and WHO. Amended provisions under Article 13 and Annex 1 obligate States Parties and WHO to facilitate equitable access to health products and technologies by building national core capacities and expanding or diversifying the manufacturing of these products. Furthermore, Articles 44 and 44 *bis* under the amendments aim to enable access to financial resources to address the needs and priorities of developing countries. Finally, the amendments established the Committee for the Implementation of the International Health Regulations (2005), tasked with overseeing implementation efforts, particularly through international collaboration and assistance, as stipulated in Article 54 *bis*.

These changes represent a shift from treating equitable access as a matter of charity to recognizing it as a binding obligation. However, the amendments stop short of providing detailed provisions for implementation. Further, some of the equity-related amendments are qualified with terms such as "subject to applicable law and available resources" or "to the extent possible". This may pose challenges related to implementation. There might also be a possibility of Member States ratifying the amendments with reservations or opting out altogether.

Despite these challenges, the amendments hold a critical merit: they establish a legal framework to advance equity and embed accountability in WHO's work on health emergencies. This includes leveraging coordinated mechanisms and networks. The framework also provides a platform to assess barriers to implementation and to develop effective solutions to ensure equitable access.

By embedding equity into the core framework of the IHR, the amendments provide a foundation for more just and effective responses to health emergencies. However, their success will depend on the commitment of Member States, the vigilance of civil society, and the outcomes of the pandemic instrument negotiations, which offer an opportunity to further strengthen the global health architecture.

Entry into force

The amendments entered into force for WHO Members on 19 September 2025. However, they did not enter into force for Members that notified the WHO Director-General of their rejection within the applicable period, i.e., for Argentina, Austria, Brazil, Canada, the Czech Republic, Germany, Israel, Italy, the Netherlands, the Philippines and the United States. While some rejections, by Argentina and the US, appear to have been politically motivated, others, like those by Brazil and Germany, were necessary to complete domestic constitutional or parliamentary approval procedures before accepting the amendments in the near future. Iran, the Netherlands, New Zealand and Slovakia had rejected or reserved against amendments to Article 59 and related provisions (resolution WHA75.12) that shortened the default rejection and entry into force period, during an earlier 2022 amendment. As a result, for these four WHO Members, the previous IHR timelines continue to apply, meaning that the 2024 IHR amendments are expected to enter into force only on 19 September 2026.

Organization of the book

This book brings together around 50 articles published by the Third World Network (TWN) between October 2021 and June 2024 chronicling the process that led to the adoption of the IHR amendments. In addition to these articles, the collection includes as annexes key documents related to the negotiations. The objective of the book is to provide readers with a sense of the state of play of the negotiations that resulted in the amendments, the North-South divide, the tactics used during the negotiations against an equity approach to the IHR, as well as the resistance by developing countries.

The materials are arranged chronologically and divided into parts reflecting the various stages of the negotiation process: the period before formal negotiations began, followed by the successive meetings of the WGIHR.

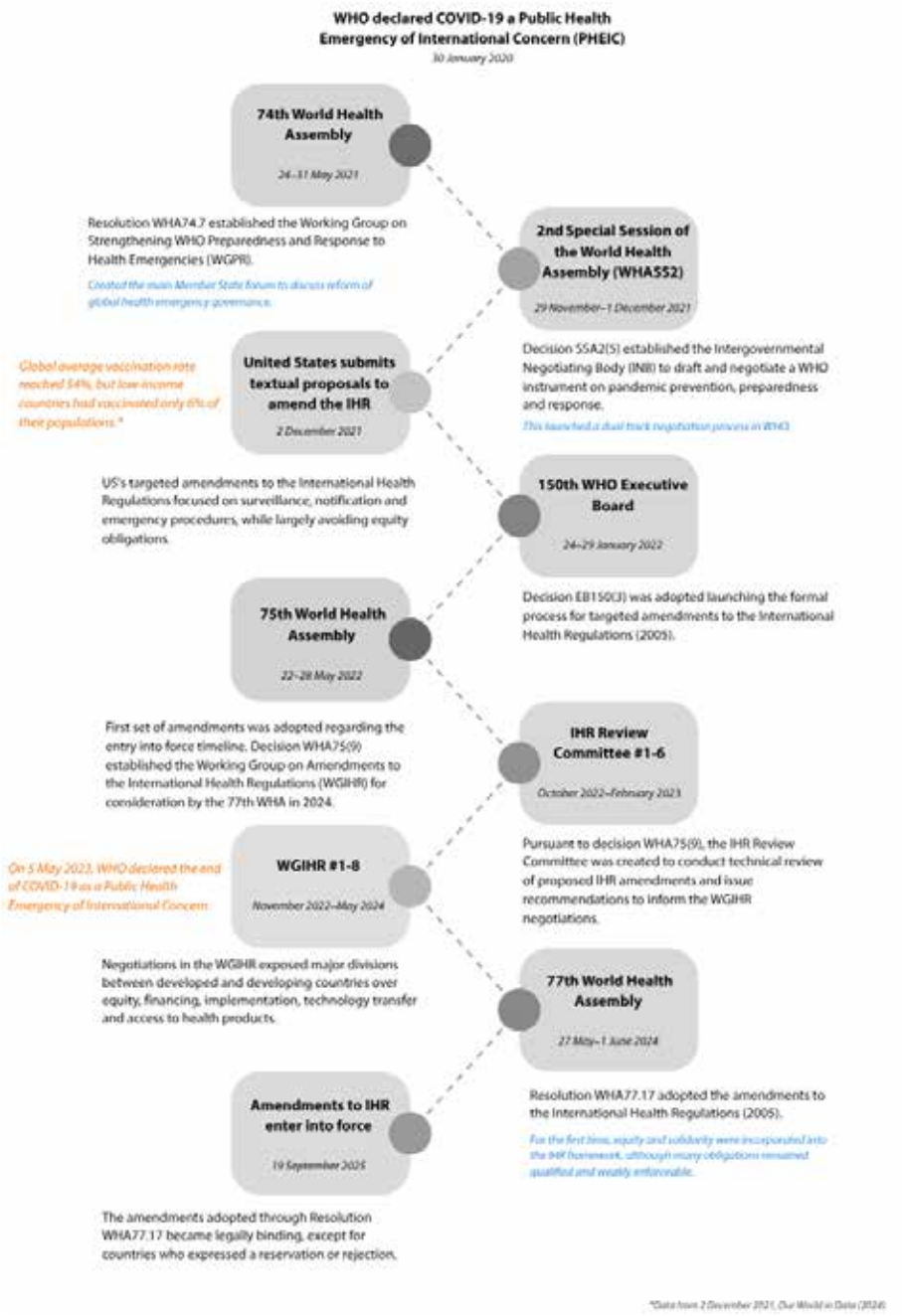
In the first part of this book, entitled “Setting the stage”, write-ups from October 2021 to May 2022 document the preamble to the

amendment process. The second part of the book delves into the beginning of the text-based negotiations, and covers the period from May 2022 to January 2023. During this period, Member States submitted their proposals to amend the IHR. But there was an attempt to skew the Member-State-led negotiations by constituting an IHR Review Committee, comprised of experts, on the amendment proposals submitted by the Member States. Draft terms of reference for the IHR Review Committee exceeding its mandate under WHA75(9) and Article 50 of the IHR 2005 were drawn up, even calling for "proposals for reformulation" of the amendment texts submitted by Member States.

The write-ups included in Parts 3–11 capture the state of play of each round of negotiations that happened during the eight formal meetings of the WGIHR. A key trait of the negotiations was the insistence by some quarters on sidelining equity provisions. In December 2023, at the end of the 6th WGIHR meeting, it was promised that the subsequent session would focus on equity. But as the work resumed, countries found that equity-related articles had been erased from the agenda of the 7th WGIHR meeting in February 2024. The WGIHR Bureau quickly sensed that a deterioration of trust might ensue if they followed said programme of work, and rejected secretariat proposals to sideline, if not avoid, equity-related amendments. There was sustained resistance from developed countries against substantive equity measures, with efforts to weaken binding obligations. Despite these tensions, developing countries, backed by civil society, eventually secured critical language reinforcing the principle of equitable access.

The WGIHR negotiations were conducted away from the spotlight of the media and various non-State actors, compared with the INB negotiations on the pandemic instrument. We hope this compilation will fill the information gap and serve as an informal history of the IHR amendment process.

Timeline


WHO declared COVID-19 a Public Health Emergency of International Concern (PHEIC)
30 January 2020
74th World Health Assembly
24–31 May 2021
Resolution WHA74.7 established the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR).
Created the main Member State forum to discuss reform of global health emergency governance.
2nd Special Session of the World Health Assembly (WHASS2)
29 November–1 December 2021
Decision SSA2(5) established the Intergovernmental Negotiating Body (INB) to draft and negotiate a WHO instrument on pandemic prevention, preparedness and response.
This launched a dual track negotiation process in WHO.
Global average vaccination rate reached 54%, but low-income countries had vaccinated only 6% of their populations.*
United States submits textual proposals to amend the IHR
2 December 2021
US's targeted amendments to the International Health Regulations focused on surveillance, notification and emergency procedures, while largely avoiding equity obligations.
150th WHO Executive Board
24–29 January 2022
Decision EB150(3) was adopted launching the formal process for targeted amendments to the International Health Regulations (2005).
75th World Health Assembly
22–28 May 2022
First set of amendments was adopted regarding the entry into force timeline. Decision WHA75(9) established the Working Group on Amendments to the International Health Regulations (WGIHR) for consideration by the 77th WHA in 2024.
IHR Review Committee #1-6
October 2022–February 2023
Pursuant to decision WHA75(9), the IHR Review Committee was created to conduct technical review of proposed IHR amendments and issue recommendations to inform the WGIHR negotiations.
On 5 May 2023, WHO declared the end of COVID-19 as a Public Health Emergency of International Concern
WGIHR #1-8
November 2022–May 2024
Negotiations in the WGIHR exposed major divisions between developed and developing countries over equity, financing, implementation, technology transfer and access to health products.
77th World Health Assembly
27 May–1 June 2024
Resolution WHA77.17 adopted the amendments to the International Health Regulations (2005).
For the first time, equity and solidarity were incorporated into the IHR framework, although many obligations remained qualified and weakly enforceable.
Amendments to IHR enter into force
19 September 2025
The amendments adopted through Resolution WHA77.17 became legally binding, except for countries who expressed a reservation or rejection.
*Data from 2 December 2021, Our World in Data (2024)

Part 1 – **Setting the stage**

TWN Info Service on Health Issues (Oct21/03)
4 October 2021

"Significant divergence" among Member States on proposed pandemic treaty and IHR strengthening

Kochi/New Delhi, 4 October (Nithin Ramakrishnan and K.M. Gopakumar) – There are "real differences" of views among World Health Organization Member States with regard to the possibility of a pandemic treaty proposed by the European Union and strengthening of the existing International Health Regulations (IHR).

This emerged at the second meeting of the Working Group on Strengthening WHO Preparedness and Response To Health Emergencies (WGPR) and is recorded in the WGPR Bureau's summary of the records.

The second WGPR meeting was held on 1–3 September at WHO headquarters in hybrid (online and onsite) mode, and the next one will start today (4 October).

[The WGPR was established by the World Health Assembly Resolution WHA74.7 in May this year, with the mandate to assess the benefits of developing a new pandemic treaty under WHA 74(16). The first meeting of the WGPR was held on 15–16 July.]

The draft summary of the second meeting states: *"While discussing agenda items 4 and 5, Member States engaged in a rich and substantive discussion that identified several areas of clear priority both where there is significant convergence of views and where real differences remain."*

The summary was released on 1 October, just three days before the third meeting of the WGPR. Several documents as discussed below have also been circulated over the past week, giving Member States very little time to analyze and prepare for the third meeting. At the same time, some steps taken by the WHO Secretariat do not reflect the divergent views of Member States.

The two relevant items on this matter in the second WGPR meeting were as follows:

Item No. 4: *Consideration of the findings and recommendations of the Independent Panel for Pandemic Preparedness and Response, the IHR Review Committee and the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme, taking into account relevant work of WHO, including that stemming from resolution WHA73.1 (2020) and decision EB148(12) (2021), as well as the work of other relevant bodies, organizations, non-State actors and any other relevant information.*

Item No. 5: *Prioritization of the assessment of the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response.*

Sources disclosed to TWN that both the United States and China opposed the idea of a new pandemic treaty during the recent WGPR meeting. The US position was already clear prior to the meeting. In a viewpoint published in the *Journal of the American Medical Association (JAMA)*, the US Secretary of State stated:

"Some major strides to advance global health security may take years to accomplish, for example, the creation of a new international instrument on preparedness and response, which the WHO and a number of other countries have endorsed. But it is not necessary to choose between a new instrument and a revised standing legal framework; immediate steps can make a meaningful difference. One is strengthening the WHO's International Health Regulations (IHR), adopted by the World Health Assembly in 1969 and revised in 2005."

The Bureau's summary provides a snapshot of discussions on several thematic areas: strengthening the effectiveness and implementation of, and compliance with, the IHR (2005); governance; finance; equity; benefits of a new treaty; and coordination with other UN agencies.

Regarding the strengthening of the IHR, the summary states: *"There is significant divergence on how best to accomplish this goal, and it will require more work to find consensus. Potential challenges of amending the International Health Regulations (2005), including areas that cannot be covered in the Regulations, should be explored."*

Regarding governance, the summary notes that there is convergence on the potential improvements in WHO governance focusing on the Executive Board and its sub-committees and also the need to link the improvements of WHO to an effort to improve the global health architecture.

On finance, the summary states that there is a convergence of views that the current model of WHO financing is inadequate for effective preparedness and response to a pandemic. It further identifies *"a clear direction that the WGPR needs to coordinate its work with the Working Group on Sustainable Financing to promote sustainable and flexible financing for WHO".* Thus, the finance discussion will now effectively take place in the Working Group on Sustainable Financing.

Though the summary notes the agreement of Member States to address equity, including the supply of countermeasures, there is no clarity with regard to the way forward. It states: *"... Member States agreed that equity, both within and between countries, is a critical principle for success in improving global pandemic preparedness and response. It will require more work to develop specific measures to address inequalities in access by WHO and its Member States."*

An analytical paper was prepared earlier by the WHO Secretariat (A/WGPR/2/3) compiling all the recommendations from various committees such as the Independent Panel for Pandemic Preparedness and Response (IPPPR), the International Health Regulations Review Committee (IHR Review Committee), the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme (IOAC) and the Global Preparedness and Monitoring Board (GPMB) under three categories, i.e., leadership and governance, systems and tools, and finance.

The summary also notes that the Universal Health Preparedness Review (UHPR) has strong support across Member States and regions, and is currently being piloted by WHO and several Member States. The idea of a universal periodic review (based on the current human rights mechanism), i.e., to have periodic reviews of IHR core capacities, is touted as a new idea to ensure reporting and peer review regarding the implementation of the IHR.

However, it is interesting to note that there is already an obligation on WHO Member States to report annually on IHR implementation. Apart from the reporting requirements set out in Article 54 of the IHR, Article 62 of the WHO Constitution obligates Member States to report to WHO on the actions taken with respect to recommendations given by the Organization.

[Article 62 states: *"Each Member shall report annually on the action taken with respect to recommendations made to it by the Organization and with respect to conventions, agreements and regulations."*]

The IHR are a set of regulations adopted under Article 21 of the WHO Constitution and therefore Member States are already under a legal obligation to submit the annual report regarding the implementation of the IHR. However, there is no evidence of proper implementation of Article 62 in the IHR context. Thus, there are already two legally established mechanisms to report the implementation of the IHR (Article 54 of the IHR and Article 62 of the WHO Constitution) yet there is no transparency with regard to their implementation.

The UHPR mechanism presently being tried is a model based on the Universal Periodic Review Mechanism (UPR) of the implementation of human rights obligations of parties to various human rights treaties. The UPR was established under 2006 United Nations General Assembly Resolution 60/251. That mechanism is more elaborate by which the progress and the fulfilment by each State of its human rights obligations and commitments is peer-reviewed through an interactive dialogue between the State concerned and other UN Member States. The State declares its actions and then questions based on the declaration as well as information collected from other stakeholders can be raised to the State. Following the discussions, recommendations are made to the State concerned. The actions undertaken to implement these recommendations shall then be reviewed in the second review meeting. Also, the international community will assist in implementing the recommendations and conclusions regarding capacity-building and technical assistance, in consultation with the country concerned.

In contrast, the UHPR mechanism piloted in WHO cannot ensure the achievement of core capabilities without international financing to establish such capability in developing country Member States. The majority of developing countries lack functional health systems. Further, strengthening and sustainable financing of WHO are also required for the proper monitoring of IHR implementation.

It is also interesting to note that while the WGPR Bureau's draft summary was being finalized, the WHO Secretariat had already moved ahead with forming the panel of experts for the pilot UHPR. A call for experts has been issued and the last date for application was 17 September.

Despite the clear admission of significant divergence on the idea of a pandemic treaty, the summary states: *"There is strong support for exploring the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response that could complement existing instruments, including the International Health Regulations (2005). In developing such a convention, agreement or other international instrument on pandemic preparedness and response, a cautious approach should be taken, recognizing both potential benefits and potential challenges."*

The draft summary also contains a list of identified gaps which includes:

(a) funding gaps at both domestic and global level;

(b) building core capacities for the implementation of and compliance with IHR at national and subnational levels, and strengthening mutual accountability, through regular country reviews and potential mechanisms like a Universal Health Preparedness Review;

(c) surveillance and early warning systems;

(d) zoonotic and environmental risks prevented and managed as part of a One Health approach;

(e) regional capacity on preparedness and response;

(f) strengthening laboratory capacities, enabling transparent immediate sharing of data on outbreaks, sharing pathogens, and promoting equitable sharing of benefits arising from shared information and resources;

(g) *strengthening WHO's authority, including for access to outbreak sites with due regard to and respect for the sovereignty of states;*
(h) *clear guidelines for action when a public health emergency of international concern is declared with potential to establish intermediate alerts issued at global or regional levels;*
(i) *interdisciplinary health emergency workforce, immediately deployable, to identify health emergencies and respond;*
(j) *digital systems to enable direct exchange of data and genetic sequence data;*
(k) *zoonotic and environmental risks prevented and managed as part of a One Health approach including for global surveillance systems and processes;*
(l) *national commitment on investment in inter-ministerial planning and preparedness, including precautionary measures to acquire and stockpile resources and on financing health systems;*
(m) *national, regional and global capacities to develop, produce and distribute vaccines, diagnostics, therapeutics and medical supplies;*
(n) *improving equitable access to countermeasures, through knowledge and technology sharing, better governance of intellectual property rights on pandemic/epidemic countermeasures and supply chain systems.*

The summary was released on 1 October, just three days before the third meeting of the WGPR that begins on 4 October. The summary states that *"the Bureau will investigate the possibility for thematic deep dive sessions focused on the priority areas described in paragraph 2 and on the gaps in paragraph 3, taking into account challenges for all countries in the virtual setting".* However, one of the deep dive sessions was already over on 30 September. This delay in releasing the Bureau's report that shows lack of consensus over the proposed pandemic treaty raises concerns on the transparency of the process.

Further, the Secretariat also released the following documents between 29 September and 1 October, giving very little time for

Member States to carry out a proper analysis of the content of these documents:

- WHO collaboration with United Nations entities that operate during a health emergency, with a focus on the COVID-19 response (A/WGPR/3/3);
- Secretariat analysis for consideration by the Working Group to further identify the incentives for a new instrument on pandemic preparedness and response and the options for strengthening the effectiveness of the International Health Regulations (2005), including a consideration of the benefits, risks and legal implications (A/WGPR/3/6);
- Funding streams for health emergency preparedness and response in the context of COVID-19 (A/WGPR/3/4);
- Update of the preliminary findings from COVID-19-related recommendation mapping (A/WGPR/3/5).

A Twitter message was also posted that published the guiding questions prepared by the Bureau for the deep dive session on IHR strengthening and a potential new WHO instrument. These questions were leading questions aimed at compromising objective discussions, according to observers.

TWN Info Service on Health Issues (Oct21/08)
9 October 2021

No consensus yet but two-track approach on IHR amendment and pandemic treaty proposed

Geneva, 8 October (TWN) – Despite lack of consensus, the Bureau of the WHO Member State Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) proposed a work plan with a two-track approach of amending the international Health Regulations (IHR) and having a pandemic treaty.

The two-track approach is to keep the proposal of a pandemic treaty alive, which failed to gain consensus even after the third meeting of the WGPR that took place in Geneva on 4–6 October.

The open sessions were concluded by 5 October and the Bureau circulated a draft "way forward" work plan text. However, on 6 October the Bureau amended the text and provided time till the evening of 7 October for Member States to provide comments.

According to the work plan, the Bureau will develop a zero draft of the report to be submitted to the Special Session of the World Health Assembly (WHASS) scheduled for 29 November to 1 December 2021. Further, it proposes to organize intersessional meetings before the 4th WGPR meeting to be held on 1–3 November. These intersessional meetings are to focus on the topics as scheduled:

- 18 October: Equity and medical countermeasures and sample sharing and the benefits derived thereof; Member State Dialogue with non-state actors (NSAs)
- 20 October: New instrument deep dive
- 25 October: Architecture deep dive including governance, financing, One Health and leading role of WHO; Member State Dialogue with NSAs.

Apart from the above intersessional meetings, the work plan anticipates such further meetings after the 4th WGPR meeting prior to the WHASS. However, the work plan does not indicate that there would be a 5th WGPR meeting.

The work plan also proposes that *"following WHASS, the negotiations take areas by topic (for example, gaps listed in para 3 of A/WGPR/2/4) and cover all aspects of our mandate as we look at each topic including both how to use existing tools to close gaps and make proposal for the potential benefit of a new WHO Convention, Agreement and Instrument".*

This clearly indicates the Bureau's preference to follow a two-track approach even if there is no consensus at the WHASS. This goes against the mandate of the WGPR.

Earlier, the 74th World Health Assembly (WHA) in May had adopted decision WHA74(16) which mandated the WGPR *"to prioritize the assessment of the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response and to provide a report to be considered at*

the special session of the Health Assembly referred to in paragraph 2 of this decision".

Paragraph 2 of said decision requested the WHO Director-General *"to convene a special session of the World Health Assembly in November 2021, and to include on the agenda of the special session only one item, dedicated to considering the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response with a view towards the establishment of an intergovernmental process to draft and negotiate such a convention, agreement or other international instrument on pandemic preparedness and response, taking into account the report of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies referred to in paragraph 1".*

Thus, it is clear that the mandate of the WGPR is to prepare a report on the *"assessment of the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response".* This means that the report of the WGPR is expected to state whether there is a benefit of a new WHO convention, agreement or other international instrument, to enable the WHASS to take the decision on whether to launch negotiations on said instrument.

The proposal of the Bureau is to keep alive the discussion on the pandemic treaty even after the WHASS, which would otherwise be impossible to continue due to the lack of consensus among Member States.

Member States are also asked to provide guidance to the zero draft report to the WHASS by 25 October. The Bureau while preparing this zero draft will *"draw from discussions in the first three meetings of the WGPR, non-papers submitted by Member States or groups of Member States as well as observations of non-state actors and observers".* The report may also contain a draft resolution or decision for the consideration of the WHASS.

However, according to diplomatic sources, Russia opposed the idea for the WGPR to prepare a draft resolution or decision. Many other Member States including France, Norway, Spain and Indonesia wanted the WGPR to develop such drafts to be adopted by the

WHASS. In the proposed method of work and terms of reference of the WGPR, paragraph 10 states that the WGPR will conduct its business (including, for the avoidance of any doubt, the activities of subgroups, if any) on the basis of consensus.

Some Member States, including Brazil, questioned the Bureau's interest in pushing ahead solutions which do not form part of the consensus in the WGPR meeting, if any. China and Russia have strongly raised their concerns and said that the WGPR Bureau should strictly adhere to the mandate provided by decision WHA74(16). Brazil agreed that the IHR need improvements, but questioned whether a new treaty is the best way to get the improvements done. There appears to be significant divergence on this question even as the 3rd WGPR meeting concluded.

The US has submitted a non-paper to strengthen WHO and revise the IHR, while the Group of Friends of a Pandemic Treaty has submitted a non-paper highlighting the benefits of a treaty.

The US proposal is based on objectives and targets set by a virtual Global COVID-19 Summit: Ending the Pandemic and Building Back Better held on 22 September. Three critical areas are identified: vaccinate the world; save lives now; and build back better. It is argued that the targets set under these areas raise a fundamental question on the principle of equity. However, the paper adopts a business-as-usual approach and seeks to promote market options or solutions rather than legal and governmental obligations to address the issues.

The non-paper of the Group of Friends of a Pandemic Treaty sets out the principal benefits of a new legally binding international instrument on pandemic preparedness and response: (1) elevating attention to the high-level political heads, (2) cross-sectoral coherence and mobilization, (3) global inclusivity, (4) improving coherence in a fragmented global health architecture. Other benefits include: equitable access to quality medical countermeasures; sharing of data, samples, technology and benefits; One Health approach; and health system capability.

However, the paper fails to explain why any of these benefits cannot be achieved through IHR amendments or implementation.

From the very beginning in May 2021, the proposals of the Group of Friends of a Pandemic Treaty have not addressed the question of why only a new treaty can accord these benefits.

New Zealand, Switzerland and Monaco are also reported to have submitted separate non-papers. New Zealand's non-paper presented a draft collection of legal principles to be adhered to in pandemic preparedness and response.

Switzerland's non-paper is reported as containing some targeted IHR amendments. Nevertheless, these suggestions are reportedly absent of any solid obligations on equitable access to health care, or other countermeasures and capacities to deal with pandemics.

Monaco proposed to study the possibility of setting up an inter-agency standing committee for equity issues such as setting up emergency stockpiles, private sector engagement for the production and distribution of pharmaceutical products, upstream preparation, exchange of information required for R&D etc on the model of the Codex Alimentarius.

Even amongst the countries which accept a new treaty alongside the IHR, there seems to be a difference of opinion as to the role of the new instrument. For instance, Indonesia, New Zealand, South Africa, Botswana, Algeria, Ghana, Kenya, Zambia and the rest of the Africa Group believe a new instrument should contain issues relating to equity, especially those relating to equitable access to diagnostics, treatments and vaccines, their local production and manufacturing capacity building, and the related technology transfer.

Singapore said the new instrument can have provisions for sustainable finance and equitable countermeasures. Thailand said that the new instrument should help access to health services and countermeasures.

Spain and Costa Rica looked at the benefits of new legal instruments, including equitable access, but want voluntary mechanisms and best-endeavour clauses for sharing intellectual property or enhancing production capacity or for other equity measures.

However, the rest of the supporters of a treaty who took the floor during WGPR meetings such as the Republic of Korea, Swit-

zerland, France, Norway, the United Kingdom, Colombia, Monaco and Chile are not seen as stressing on equity issues.

The WHO Secretariat has already highlighted that equity issues have always been dealt with using non-binding mechanisms in the past. It must be kept in mind that, so far, no one has explained why legal obligations of equity cannot be strengthened under the IHR. It is also an intriguing question whether developed countries would still become party to the treaty or new instrument they have proposed if equity considerations become obligations.

TWN Info Service on Health Issues (Nov21/05)
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Two-track approach proposed for pandemic preparedness and response

Geneva, 11 November (TWN) – The fourth meeting of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) finalized its report to the World Health Assembly Special Session (WHASS) which proposes a two-track approach as a way forward.

The proposal comprises a WHO convention, agreement or other international instrument on pandemic preparedness and response, and strengthening the International Health Regulations (IHR) including implementation, compliance, support for IHR core capacities, and potential targeted amendments to the IHR. However, there is no clarity at this stage on whether the new instrument would be a WHO convention or agreement under Article 19 of the WHO Constitution.

[The WHASS is to take place at the WHO headquarters in Geneva in hybrid mode from 29 November to 1 December. According to WHA Decision 74(16), the WHASS is dedicated to considering the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response with a view towards the establishment of an intergovernmental process to draft and negotiate such a convention, agreement or other

international instrument on pandemic preparedness and response, taking into account the report of the WGPR.]

The fourth WGPR meeting took place 1–4 November in hybrid mode, after being extended by one day to finalize its report. Throughout the four days, delegates debated a zero draft of the report released on 28 October 2021. The new finalized text was placed under a "silence procedure" until 7 pm of 7 November, meaning that in the absence of any objection during this period, there is presumed to be agreement.

The WGPR established by WHA Resolution 74.7 has two mandates, the first stemming from the resolution and the second from WHA Decision 74(16): (1) to consider the findings and recommendations of independent panels and review committees established for reviewing the function of WHO and Member States and to submit a report on proposed actions for the consideration of WHA75; (2) to prioritize assessment of the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response and to submit a report for the consideration of the WHASS.

The present report pertains to the second mandate and, once adopted, shall be considered during the WHASS on 29 November – 1 December. The WGPR will continue its work under WHA Resolution 74.7, i.e., to consider the recommendations of independent review panels/committees, such as the Independent Panel on Pandemic Preparedness and Response (IPPPR), the Review Committee on the functioning of the IHR during the COVID-19 response (IRC), the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme (IOAC), and other relevant bodies.

The 1–4 November WGPR meeting witnessed the lack of good-faith support from developed country members of the Group of Friends of a Pandemic Treaty to the Group's developing country members' efforts to advance the normative value of "equity in health emergency preparedness and response". On the third day of the meeting, a few developed country delegations (US, Canada, UK, Germany, EU) sat together to develop compromise paragraphs to be tabled during the meeting. The only developing country from the

Group invited to discuss the text along with them was Chile, which is an OECD member. Indonesia and South Africa registered their discontent.

The way forward and the role of the WGPR

On the way forward, paragraph 29 of the WGPR report avoids the word "recommendations" and keeps three compromise proposals:

"The WGPR proposes for consideration of the WHASS the following:

a) Establish an intergovernmental negotiating body in charge of developing a WHO Convention, Agreement or other international instrument on pandemic preparedness and response;

b) Outline a clear, efficient, effective, Member State led, transparent and inclusive process for how to identify and develop the substantive elements and a zero draft of a new instrument, the modalities of negotiation of the instrument, and on what timelines;

c) To support the WGPR to continue its work under resolution WHA 74.7, including to identify the tools to implement the recommendations that fall under the technical work of WHO and further develop proposals to strengthen the IHR (2005), including potential targeted IHR (2005) amendments, and elements that may most effectively be addressed in other venues."

It is not clear whether the instrument to be developed in the first proposal above would be an instrument under Article 19 of the WHO Constitution, as publicly called for by the Group of Friends of a Pandemic Treaty. However, a non-paper by the Group avoids any reference to Article 19. An instrument under Article 19 would be based on an opt-in process, i.e., the obligations under the instrument would be legally binding only on those WHO Member States that ratify the instrument. As a result, many Member States may not opt in for the new instrument. Further, developed countries may use this as a threat to prevent the inclusion of legally binding provisions on equity in the new instrument. The proponents of the treaty have also projected the need for creating a separate decision-making body, like

a Conference of Parties. This further indicates a need for an additional budget to administer the instrument.

In contrast, a new instrument under Article 21 of the WHO Constitution would be based on an opt-out option. This means that a Member State which does not want to be party to the instrument has to inform the WHO Director-General of its decision. Otherwise, the adoption of the instrument by the WHA will itself bring the instrument into force without need for a ratification process. The present instrument under Article 21, the IHR, does not require any additional body to administer the treaty; such a mandate is given to the WHA.

The second proposal put forward by the WGPR report is to outline a *"process for how to identify and develop the substantive elements and a zero draft of a new instrument, the modalities of negotiation of the instrument, and on what timelines".* However, it is not clear whether it is the abovementioned intergovernmental negotiating body that is to develop the elements, zero draft and modalities of negotiation. It is doubtful whether the WGPR will work on this. During the negotiations, a proposal to add the terms "negotiating body" and "WGPR" into subparagraph (b) was rejected. Since the WGPR's mandate to work on the instrument ends with the preparation of the report to the WHASS, there is a need to either launch a negotiating body or mandate the WGPR to carry forward the work.

The concern is that a new process outside the WGPR, whether a negotiating body or another process, would compromise the effective participation of the majority of the WHO membership, especially developing countries which have small delegations. The WHASS resolution/decision is expected to clarify the process. Chile is expected to circulate the draft WHASS resolution/decision to kickstart the negotiations for the finalization of the outcome document.

According to the third proposal in the WGPR report, the WGPR is to continue the work on strengthening the IHR, including the targeted amendments. If the abovementioned intergovernmental negotiating body is launched to work on the new instrument, and the IHR amendment work remains with the WGPR, there is a risk of fragmentation of participation. This may also result in lack of coherence since both the instruments (a potential new instrument and

the IHR) may undergo changes simultaneously. It may also result in reduced attention by the developing countries in either or both of the processes, especially by those countries that maintain smaller delegations to WHO.

It is interesting to trace the evolution of the compromise text in paragraph 29 of the WGPR report. Paragraph 35 of the zero draft in its conclusions and recommendations section had sought endorsement from the WHASS for two WGPR recommendations:

"Therefore, the WGPR seeks the endorsement by WHASS of the following recommendations.

(a) To task the WGPR to identify the tools to implement the recommendations that fall under the technical work of WHO, further develop targeted IHR (2005) amendments, and further identify and develop the elements of a potential WHO instrument and modalities of its negotiations.

(b) Towards this, the WGPR may draft and negotiate possible Health Assembly resolutions and decisions to implement the recommendations in order to strengthen WHO preparedness and response to health emergencies."

As mentioned above, the word "recommendations" was removed in the final report. Further, the proposed mandate of the WGPR to identify and develop elements of the potential new instrument has also been removed.

Reference to Article 19 of WHO Constitution removed

Before finalization of the text, paragraph 33 of the zero draft in its conclusion and recommendations section had stated: *"The WGPR assesses that* ***in order to be successful****, the way forward should include both the initiation of a new instrument negotiation* ***on the basis of Article 19*** *and strengthening the International Health Regulations (2005), including implementation, compliance and targeted amendments to the Regulations, as part of a comprehensive approach"* (emphasis added).

In the final report of the WGPR, the corresponding text is split into two paragraphs 26 and 27:

"Member States agree that there are benefits to developing a new instrument, while also acknowledging that the IHR currently remains the key legally binding instrument for pandemic preparedness. The WGPR has confirmed the importance of a number of topics, as identified in subparagraphs 8 a – i that might be better addressed by a new instrument under the auspices of WHO.

"The WGPR assesses, for consideration by WHASS, that the way forward should include as part of a comprehensive and coherent approach a process or processes for: i) developing a WHO Convention, Agreement or other international instrument on pandemic preparedness and response, and ii) strengthening the IHR (2005) including implementation, compliance, support for IHR core capacities, and potential targeted amendments to the IHR."

There is no more explicit mention of Article 19 of the WHO Constitution in the recommendation. While the US has succeeded in getting the reference out, many countries including Brazil, Russia, India and Japan argued that there is no consensus on an Article 19 instrument.

However, paragraph 10 of the report in its section enumerating the benefits of a new instrument states thus: *"Many Member States emphasized that developing a new instrument on pandemic preparedness and response under Article 19 of the WHO constitution could offer a number of benefits. An Article 19 instrument under the WHO constitution would be legally binding on State Parties that* ***opt to ratify it****, and this legally binding status offers the potential for greater sustained attention, both political and normative, to the critical issue of a pandemic preparedness and response,* ***than a non-binding act****"* (emphasis added).

It might be noted that neither this paragraph nor the report compares an Article 19 instrument with an Article 21 instrument. An Article 21 instrument has greater potential of binding more States and can address Member States' concerns recorded in paragraph 18 *"over how the 'opt-in' nature of an Article 19 convention* ***might reduce the effectiveness of the instrument*** *due to the insufficient signatories"* (emphasis added).

The language of paragraph 10 is also ambiguous. It begins with a sentence on Member States emphasizing that a new instrument under Article 19 could offer a number of benefits. Later it goes on to assert that only Article 19 has benefit such as the potential for greater sustained attention. The sentence structure now gives the impression that Member States have such a consensus. This is reportedly incorrect as many Member States very clearly stated that benefits relating to a new instrument under Article 19 are generic and similar to other instruments such as those under Article 21.

Fight for equity

Developed countries had sought to limit the scope of "equity" to pandemic preparedness and response in paragraph 8 of the report. Some developing countries, though part of the Friends of a Pandemic Treaty group, have not gained the wholehearted support of the EU and other developed countries in the group to realize equity in health emergency prevention, preparedness and response.

The Brazilian delegation reportedly warned the WGPR that it will not join the consensus if there is no commitment to address the concerns of equity in general. It stressed that equity is the single issue that must be addressed first in any future discussions on a WHO convention or instrument. This was the spirit in which "equity" was moved up to paragraph 8(a) from paragraph 8(b).

The support of the following countries resulted in expanding the scope of equity to all health emergencies: Ghana, India, Chile, Paraguay, Indonesia, Botswana, Iran and Dominica.

The US proposal to insert the phrase "in pandemic preparedness and response" after "equity" in paragraph 8(a) was finally rejected on the extended day of the meeting. Certain editorial inputs made by Monaco, the US and the EU to dilute the reference to equity were also successfully modified by the delegations from developing countries to make the reference to equity even stronger.

Paragraph 22 of the zero draft had stated: *"(b) Equity, including universal health coverage and equitable access to health countermeasures, and issues such as research and development, intellectual*

property, technology transfer and empowering regional manufacturing capacity during emergencies to discover, develop and deliver effective tools and technologies. While each of these areas are complex, equity is at the core of the breakdown in the current system and is ideally suited for negotiation under the umbrella of a potential new instrument."

During the negotiations the Co-Chair, working upon suggestions from the US and the EU, proposed the following text on equity: *"(b) Equity in pandemic preparedness and response, including capacity building and equitable and timely access to and distribution of medical countermeasures and addressing barriers, and related issues such as research and development, intellectual property, technology transfer and empowering/scaling up regional manufacturing capacity during emergencies to discover, develop and deliver effective medical countermeasures and other tools and technologies. While each of these areas are complex, equity is at the core of the breakdown in the current system. Despite unprecedented developments of medical countermeasures, the challenge remains to ensure their universal and equitable access and distribution. This is an issue that could be meaningfully addressed under the umbrella of a potential new instrument and through discussions in several other relevant global fora."*

However, paragraph 8 of the report, which outlines the issues which may not be solely addressed only through the IHR or may be best dealt with through the new instrument, finally states thus: *"(a) Equity. Member States agree that equity is critically important for global health both as a principle and an outcome. Member States emphasized that equity, including capacity building and equitable and timely access to and distribution of medical countermeasures and addressing barriers to timely access to and distribution of medical countermeasures, and related issues such as research and development, intellectual property, technology transfer and empowering/scaling up local and regional manufacturing capacity during emergencies to discover, develop and deliver effective medical countermeasures and other tools and technologies, is essential, in particular in prevention, preparedness and response to health emergencies.*

While each of these areas are complex, equity is at the core of the breakdown in the current system. Despite unprecedented developments of medical countermeasures, the challenge remains to ensure their universal and equitable access and distribution, with a view to achieving universal health care. This is an issue that could be meaningfully addressed under the umbrella of a potential new instrument and through discussions in several other relevant global fora."

The new formulation, unlike in the case of the zero draft, ignores elements such as health system, universal health coverage or health system strengthening under equity. A reference to universal health care is in paragraph 8(a), but only as a challenge, while certain other elements are identified as essential.

Interestingly, paragraph 9 which outlines the benefits of the new instrument speaks very little about equity and does not refer to all those elements mentioned in paragraph 8(a). The references to equity in subparagraphs (e) and (f) are noteworthy. Paragraph 9(e) recognizes the importance of the principles of the WHO Constitution in advancing equity, whereas paragraph 9(f) states thus: *"Addressing equitable access to countermeasures such as vaccines, therapeutics and diagnostics. A framework could facilitate concrete measures and long-term mechanisms to develop, manufacture and scale up countermeasures through increasing local production, sharing of technology and know-how for broadening manufacturing capacity, and strengthening regulatory systems."*

Concerns still remain

Uncertainty over the scope and nature of the new instrument: Under WHA Decision 74(16), the WGPR has the mandate to prioritize the assessment of the benefits of developing a new instrument for pandemic preparedness and response. Ideally it should have assessed the need for a specific instrument for pandemic preparedness and response in the first place. It should have also identified the type of legal instrument for this purpose, if found necessary. Unfortunately, the WGPR discussions and its report are not reflective of any such specific understanding. There is no substantive discussion as to how

pandemic preparedness and response differs from health emergency preparedness and response, or forms a specialized category within the latter.

The WGPR report simply takes note of the recommendation for a pandemic treaty from the Independent Panel for Pandemic Preparedness and Response. When it comes to its own proposals, the WGPR report uses the generic term "a new instrument". While a new instrument could mean any type of legal instrument available under the WHO Constitution, the WGPR report indicates additionally it could also involve *"policy or programmatic tools"* available to WHO. This implication is quite concerning as issues of equity in financing health emergency preparedness and response may be pushed into these non-normative tools.

The European Commission's reflection paper on an international agreement for pandemic preparedness and response had earlier proposed to use a flexible and open participation model for the agreement and a mix of soft-law and hard-law mechanisms in the new agreement. There was no reference to equity in it. Regarding access to health care products and services, it suggested incentive-based models and also stockpiling.

It must be noted that, on the third day of the WGPR meeting, the Co-Chair's proposal for establishing an intergovernmental negotiating body had a mandate to negotiate specifically for a "legally binding instrument". To get the US on board, this was later changed to the present compromise text of paragraph 29(a), which allows negotiating on any type of instrument. The change of language now also opens possibilities for non-normative, non-legal programmatic schemes as implementation vehicles for many of the concerns raised on pandemic preparedness and response.

Scope of equity: Equity is very relevant in IHR implementation, but the present narratives effectively drive it away from the IHR. Although the delegation from Brazil succeeded in bringing equity to the top of the list in paragraph 8 and in resisting the attempt from the US and the EU to limit the scope of equity to pandemic preparedness and response, equity is now placed for a better consideration in a "potential" new instrument. Paragraph 8(a) of the WGPR

report states thus: *"[Equity] is an issue that could be meaningfully addressed under the umbrella of a potential new instrument and through discussions in several other relevant global fora."*

The developing countries therefore need to continue efforts to ensure that equity is included in the IHR and implemented. A new instrument solely for pandemic preparedness and response cannot help them to ensure equity for the total implementation of law relating to health emergencies. Presently the paragraph in the WGPR report speaking about strengthening the IHR does not explicitly refer to equity. This may be used against addressing equity-related issues within the IHR. In the absence of implementation of equity provisions such as Article 44 of the IHR, these regulations effectively remain as a unilateral legal obligation on developing countries to inform on the outbreak of diseases with the potential of emerging as a "public health emergency of international concern", without any corresponding effective legal obligation on developed countries and WHO to provide the required assistance, including supply of needed health products for the prevention and containment of health emergency and building of core capabilities.

A related concern is the narrow approach on equity. Currently the text is heavily focused on access to countermeasures, and marginalizes the fundamental equity issues related to health system strengthening, and capacity building in health emergency preparedness and response such as for IHR core capacities. Iran's proposal to include funding and financing for building of IHR core capacities in paragraph 24(b)(i) was accepted only after significant resistance from the developed countries. It was noteworthy that Iran insisted on this point from day 1 to the last day of the fourth WGPR meeting.

Pathogen sharing: There is a concern that the new instrument may be used to overcome existing rules in treaties such as the Convention on Biological Diversity and its Nagoya Protocol on benefit sharing. Paragraph 9(g) which states the benefits reads: *"Sharing of data, samples, technology and benefits in the context of pandemic preparedness and response. There are some legally binding agreements relating to pathogen sharing, but no comprehensive framework within WHO, either for sharing of pathogens or for sharing of*

the benefits derived therefrom, which takes into account the reality and needs of pandemic preparedness and response."

Though this paragraph recognizes the existence of treaty obligations on access and benefit sharing, it fails to state that the proposed WHO framework should comply with the provisions of these existing treaty obligations. Paragraph 8(g) speaks about *"the openness to explore a more comprehensive mechanism under the auspices of WHO"*. There again the existing instruments are not mentioned.

Fragmentation of financial resources and norms: The WGPR discussions did not focus on the crucial issue of fragmentation of resources, the method of financing of institutional requirements that a new instrument shall entail, and the uneven norms it may create. As a result, the risks involved in the new instrument relating to fragmentation are not fully recognized in the report. It refers only to fragmentation of negotiating resources due to multiple tracks of negotiation, such as one for a new instrument and the other for strengthening existing instruments. However, fragmentation of financial resources and norms that comes after the adoption of a new instrument is more problematic. It may lead to further draining of the scarce resources that are available in health emergencies in general. It also has the potential to create confusion in the compliance with obligations arising from multiple instruments, especially if they are uneven for Member States.

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US proposal on IHR amendment pursues health security agenda

Geneva, 3 December (Nithin Ramakrishnan) – The United States has submitted a proposal to amend the International Health Regulations 2005 (IHR) that pursues a health security agenda without paying any attention to the issue of equity.

The US has invited WHO Member States to informally negotiate on amendments to Articles 11, 12 and 59 of the IHR that it has submitted to the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR).

The US is organizing two informal consultations of Member States on 2 and 16 December to reach a consensus. It is also interesting to note that these informal consultations are much ahead of the WGPR that is mandated to examine the findings and recommendations of various expert panels which had reviewed the COVID-19 pandemic response. The WGPR is yet to have a focused discussion on the required changes to the IHR.

The US submission to the WGPR contains a resolution for the adoption of the amendment and an annex containing the proposed amendments to Articles 11, 12 and 59 of the IHR. Article 11 governs the information provided by Member States to WHO to help the assessment of whether a particular health event constitutes a public health emergency of international concern (PHEIC). Article 12 deals with the determination of a PHEIC. Article 59 sets out the rules for the entry into force of the IHR, and also on rejection or reservations.

Article 11 and the proposed changes

Article 11 of the IHR, as mentioned above, provides for the handling of information by WHO. Paragraph 1 of the Article allows WHO, subject to paragraph 2, to share the relevant public health information which is necessary to respond to the public health risk to all State Parties and relevant intergovernmental organizations, as appropriate and in confidence. WHO may also share information that might help State Parties in preventing the occurrence of events that may pose public health risks.

Paragraph 2, however, is worded negatively, i.e., that WHO shall not share information it received under Articles 6, 8 and 9(2) unless otherwise agreed upon by the Member States until such time:

(a) a PHEIC is declared under Article 12; or
(b) information evidencing an international spread of disease is confirmed by WHO; or

(c) evidence shows that control measures are not likely to succeed against the international spread or (affected) State Parties lack sufficient capacities to carry out necessary measures; or
(d) the infection or contamination requires the immediate application of international control measures.

The US proposal attempts to alter the measured approach of Article 11 and make it obligatory on WHO to share the information it has received on outbreaks or public health risks with all Member States if any of the conditions above is satisfied.

It also proposes to expand the scope of information to be shared under Article 11 by adding an overarching condition as sub-paragraph (e): "WHO determines it is necessary that such information be made available to other States Parties to make informed, timely risk assessments."

[A general understanding of the scope of information that is involved in this process is available in Article 6(2) of the IHR and it includes: case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed, and report, when necessary, the difficulties faced and support needed in responding to a potential PHEIC.]

The net effect of the changes proposed in Article 11 is that WHO is made obligated to share all the information that it receives, with every Member State, irrespective of the source, on a precautionary basis.

Further, the US proposal to create the obligation to share information has left open the exception in Article 11, i.e., "unless otherwise agreed upon by other Member States".

As a result, this exception will help powerful countries to still guard against proactive sharing of information by WHO against their interests.

There is also a significant proposal to alter Article 11(3), where the US proposes to replace the word "consultation" with "information". This means WHO would only need to inform the State Party about its intent to make the information available to others under the Article. This takes away the opportunity for the State Parties to raise

their concerns at the international forum. Moreover, a consultation is a significant tool that can help assess the ground realities.

Another problem with the proposed targeted amendment is that in the text of Article 11(2), a designated authority is identified only with regard to Article 11(2)(a). The rest of the sub-paragraphs of Article 11(2), including the newly proposed sub-paragraph (e), do not specify any authority within WHO in charge of providing information. The provisions simply say "WHO". The definition of WHO in Article 1 also only says "World Health Organization".

Therefore, it could mean that any organ, committee, or an official/personnel in some of the relevant offices of authority, such as the World Health Emergencies Programme, can invoke this provision and proactively share information with all State Parties. They can also invoke the wide discretion provided by the proposed changes to protect themselves, while acting in excess of the authority.

In short, the US-proposed text could create a problem of accountability in WHO's handling of public health information and its confidentiality.

Article 12 and the proposed changes

Article 12 is one of the most important provisions of the IHR. It deals with the determination of the PHEIC status of events coming under the scope of the IHR. It already gives high-level authority and far-reaching powers to the WHO Director-General to determine and declare a PHEIC, read along with Article 49.

The US proposal will further enhance the power in the hands of the Director-General.

In the existing provision, the Director-General has to consult with affected State Parties in whose territory the event is happening before (s)he convenes an Emergency Committee (EC). Under paragraphs 2 and 3 of Article 12, a timeline of 48 hours has also been accorded to the Director-General to convene a meeting of the EC after consulting with the State Party concerned, with a view to reaching agreement between him/her and the State Party. The Director-Gener-

al may also convene an EC after 48 hours even if the affected State Party does not agree with WHO.

The Director-General has further powers to make the determination that a PHEIC has ended after consultation with the State Parties in whose territories the PHEIC has occurred, under paragraph 5 of the Article.

The US proposal indicates four important changes, among many others.

Firstly, it introduces new concepts like "public health emergency of regional concern" and "intermediary health alert" to be determined by the Regional Director or the Director-General, as the case may be.

Secondly, it removes the process of consultation with Member States and the 48-hour timeframe for reaching a consensus.

Thirdly, it proposes to give notification to all State Parties even before an EC is called to convene, and fourthly, it proposes to have consultations with all relevant State Parties, which may include State Parties which are not affected by the spread of disease or PHEIC, in order to determine if the PHEIC has ended.

All the suggested changes promote the health security agenda of the US at the expense of the developing countries' interests and creatively pave the way for escaping the obligations to collaborate and assist.

Already, the definition of PHEIC in the IHR is very narrow; the further differentiations can create more fragmentation of the IHR obligations. It is highly probable that with each of the intermediary health alerts, unwanted interruptions in international traffic and trade can happen, as was the case with Southern African countries immediately after their notification of the Omicron variant of the COVID-19 virus.

On the other hand, a public health emergency of regional concern can be used to differentiate many outbreaks or events from a PHEIC and thereby escape most of the obligations laid down for PHEICs under the IHR, especially the duty to collaborate and provide assistance to affected States.

An important textual change sought by the US on Article 12(2) and 12(3) of the IHR seeks to avoid the 48-hour timeframe for the Director-General to reach an agreement with the affected State Party regarding the preliminary determination of a PHEIC in order to convene an EC. It also seeks to obligate the Director-General to notify all State Parties of the event and the preliminary determination of a potential or actual PHEIC even before convening an EC.

Article 12(2) and (3) of the IHR presently read as follows:

"2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State Party in whose territory the event arises regarding this preliminary determination. If the Director-General and the State Party are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the 'Emergency Committee') on appropriate temporary recommendations.

"3. If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49."

The US proposal deletes paragraph 3 and for paragraph 2, it proposes the following text:

"2. If the Director-General considers, based on an assessment under these Regulations, that a potential or actual public health emergency of international concern is occurring, the Director-General shall notify all States Parties and seek to consult with the State Party in whose territory the event arises regarding this preliminary determination and may, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the 'Emergency Committee'). If the Director-General determines that the event constitutes a public health emergency of

international concern, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the 'Emergency Committee' on appropriate temporary recommendations."

Article 59 and the proposed changes

The US proposal to amend Article 59 of the IHR is with a view to improving the agility of the IHR. It proposes to add paragraph 1 *bis* to Article 59: "The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, an amendment to these Regulations shall be 6 months from the date of the notification by the Director-General of the adoption of an amendment to these Regulations by the Health Assembly."

However, limiting the time for reservations and rejections to 6 months effectively reduces the time for the Member States to conduct inter-ministerial meetings and analyze the implications of amendments suggested in the IHR. It must be noted that amendments to the IHR may involve elements of national security, as seen in this very proposal by the US to amend the IHR.

The US proposal also says that "amendments to these Regulations shall enter into force 6 months after the date of notification referred to in paragraph 1 *bis* of this Article".

Such a limited time could compromise informed decision making at the national level. The 18-month timeframe given in the present text of the IHR helps the various departments or ministries under national governments to coordinate and take an informed decision.

Therefore, it is important that Member States go with a pragmatic timeline and not a hasty approach.

It is learnt that while this report was being prepared, the US has proposed further amendments to many more Articles in the IHR. A commentary on those proposals will follow.

TWN Info Service on Health Issues (Dec21/09)
16 December 2021

US pushes onerous IHR obligations on developing countries

Geneva, 15 December (Nithin Ramakrishnan and K.M. Gopakumar) – The United States is seeking to push onerous obligations on developing countries through its proposals to amend the World Health Organization's International Health Regulations 2005 (IHR).

On 2 December, prior to the first informal consultation on IHR amendments, the US circulated its consolidated proposed amendments. It had earlier tabled amendments to Articles 11, 12 and 59 of the IHR. The consolidated proposal now contains amendments to Articles 5, 6, 9, 10, 11, 12, 13, 15, 18, 48, 49, 53 and 59. Amendments to these 13 articles would substantially change the characteristics of the IHR.

The US has reportedly asked WHO Member States to respond to the proposal on or before the second informal consultation, to be held on 16 December.

The proposal pushes onerous obligations in the following five areas:

- Accelerated sharing of information, both to and from WHO;
- Sharing of genetic sequence information;
- Compulsion to accept WHO's offer of assistance or collaboration in preparedness and response;
- Opening of outbreak sites for international assessment; and
- Promotion of multi-stakeholder approaches.

All these proposals, if accepted, would undermine the sovereignty of developing countries and force them to provide information to developed countries without any assurance of predictable and sustainable assistance to meet health emergency challenges.

The main criticism against the functioning of the IHR is that WHO and developed countries often use the IHR mechanism to seek information from developing countries, where disease outbreaks often take place, without fulfilling the corresponding duty

to cooperate and assist these countries. Any assistance provided is mostly inadequate and carried out outside the framework of the IHR as bilateral or unilateral measures, and not as a legal entitlement of developing countries.

Accelerated sharing of information

The US has kept proposals to speed up sharing of information both to and from WHO. Amendments, including timeframes, have been proposed in Articles 5, 6, 9, 10 and 11 for rapid sharing of information.

In Article 5, the US tries to incorporate an early warning system by introducing a new provision Article 5(5) and providing for sharing risk assessment on events of unknown causes on an early basis.

In Article 6(1), the US proposes a 48-hour timeframe within which a State Party should assess the events upon receiving the information and then share the information with WHO within another 24 hours. The existing Article 6(1) fixes the timeframe for sharing of information with WHO after the assessment, but not for the assessment itself.

In Article 9(1), the proposal seeks to do away with the obligation to consult and verify information received from other sources, with the concerned State Parties. Under Article 10(1), it is proposed that WHO has to request the relevant State Party for verification of the information it receives from other sources within 24 hours. The US has also proposed that WHO should offer collaboration to assess the events within 24 hours of receiving information in Article 10(3), i.e., when WHO receives information of an event that may constitute a public health emergency of international concern. The US also proposes that State Parties should accept or reject the same within 48 hours by suggesting to incorporate a new paragraph (3 *bis*) in Article 10. In the same paragraph, the US proposes to obligate WHO to share such information with all State Parties immediately, once the relevant State Party rejects the offer of collaboration or does not make a decision within 48 hours.

While it is proposed under the new Article 5(5) that WHO shall convey risk assessment with State Parties, the phrase used is any "local, national and global risks", not just "public health risks". The US proposal therefore expands the scope of the information to be shared.

In another attempt to accelerate information sharing by WHO, the US further proposes to remove or dilute the requirement of prior WHO consultation with State Parties on whose territory events are occurring, from various provisions of the IHR such as Articles 9(1), 11(3) and 12(2). For instance, according to the US proposal for Article 12, if the WHO Director-General in his/her preliminary determination considers that a potential or actual public health emergency of international concern is occurring, then he/she shall notify all the State Parties, even before he/she seeks to consult the State Party on whose territory the potential or actual outbreak is happening or he/she convenes an emergency committee.

The US also proposes to delete the phrase "taking into account the views of the State Party concerned" from Article 10(4), where it is further proposed that WHO share information with other State Parties immediately after rejection or non-acceptance of WHO's offer of collaboration in assessment.

It is unfortunately forgotten that rapid sharing of information requires large investments in building nationwide surveillance capacities. Studies report that countries have been improving in terms of *surveillance* capacities over the past decade, while they lack significantly in *response* capacities. The US proposal, if adopted, would again frontload investments in surveillance capacities. It will alter related donor preferences to the detriment of attention required for resilience and surge capacities of the health systems in developing countries.

More problematically, several US-proposed amendments seek to obligate WHO to share public health information received by it from various sources proactively to all IHR State Parties and to the public, and limit the discretion currently available to WHO under the IHR with regard to sharing the information. Earlier, the independent panel for pandemic preparedness and response (IPPPR), in its May

2021 report, had recommended empowering WHO to publish the information without requiring prior approval of national governments. The US proposal goes even further and will end up with WHO sharing information even without consulting the State Parties providing such information.

In short, it can be said the US proposal goes much beyond the precautionary approach. It wants WHO to be always keyed-up rather than exercise precaution. It seeks almost real-time, rapid and open access to information without a substantial screening by WHO or by affected State Parties. It goes without saying that such an approach is antithetical to the purpose and scope of the IHR, i.e., *"to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade".*

Indiscriminately wide dissemination of such information would affect the economy negatively as credit rating agencies, standard-setting organizations, donors and financiers can all use this information to pressure or secure concessions from developing countries. This also entails national security concerns.

It is interesting to note that while the US is pushing for accelerated sharing of information from State Parties, it had put the following reservation to the current Article 9, which obligates State Parties to inform WHO as far as possible within 24 hours of receipt of evidence of a public health risk identified outside their territory:

"Article 9 of these Regulations obligates a State Party 'as far as practicable' to notify the World Health Organization (WHO) of evidence received by that State of a public health risk occurring outside of its territory that may result in the international spread of disease. Among other notifications that could prove to be impractical under this article, ***it is the United States' understanding that any notification that would undermine the ability of the US Armed Forces to operate effectively in pursuit of US national security interests would not be considered practical for purposes of this Article"*** (emphasis added).

Sharing of genetic sequence information of pathogens

Currently when the IHR speak about sharing of public health information, it does not include sequenced genetic information of pathogens or other relevant biological materials.

Article 6(2) of the IHR, which provides the scope of information to be shared with WHO, states thus: *"... a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern."*

The US seeks to add the term "genetic sequence data (GSD)" to this list. Such an addition would obligate all State Parties including developing countries to share genetic sequence information of pathogens with WHO and the rest of the world therefrom. This would frustrate developing countries' interest in establishing an effective and legally enforceable "access and benefit-sharing mechanism". For example, any mechanism like the Pandemic Influenza Preparedness (PIP) Framework would then be undermined, even made irrelevant. A 2019 study by Edward Hammond for the Third World Network reported how sequenced genetic information shared in open platforms like GenBank can be used to bypass the requirements of benefit-sharing mechanisms under relevant national or international laws.

It must be noted that the WHO Secretariat, by developing programmatic tools such as the Global Genomic Surveillance Strategy and voluntary mechanisms like BioHub, is already promoting de facto sharing of pathogens and genetic sequence information without concrete and meaningful commitments to equitably share the benefits derived from the same at appropriate levels.

GSD should not be treated as mere public health information. In most cases, it is used in lieu of biological sample sharing as it avoids the complexities of sharing biological materials. Therefore,

sharing of genetic sequence information must be subject to the laws and regulations applicable to the access and benefit sharing of genetic resources.

The US proposals to amend Articles 6 and 11 further seek to obligate WHO to share information with all relevant entities and the public, which can include private sector undertakings as well. Such information, according to the proposed amendment to Article 6(2), will include sequenced genetic information.

The argument advanced for the proposal is that such proactive sharing of resources makes it easier for researchers and industry partners to access the required information and develop or produce relevant health care products and technologies. But the same also makes it easier for such industrial actors to overcome national legislation and international laws providing for equitable sharing of the benefits developed out of such resources, and to instead monopolize them using patents or other forms of intellectual property.

Compulsion to accept or reject WHO's offer of assistance

According to the US proposals, a State Party will be required to either accept or reject the offer by WHO for collaboration or assistance within 48 hours of the offer. If the offer is not accepted, then the State Party shall also be mandated to provide reasons for the same. Moreover, WHO is to be obligated to share the information it has received from various sources immediately upon the rejection of the offer by the State Party or non-acceptance within 48 hours.

Currently, under Article 10(3) of the IHR, WHO shall offer collaboration with concerned State Parties in verifying the information or assessing the related events. When such an offer is not accepted by State Parties, WHO may at its discretion share the relevant information with other State Parties, if the same is found justified by the magnitude of public health risk. However, the US proposal seeks to require WHO to offer collaboration within 24 hours of receiving information. It then proposes in Article 10(4) to obligate WHO to share the information if the concerned State Party does not accept the offer in 48 hours. It proposes to replace "may" with "shall", indicating

such sharing of information shall become obligatory in nature and not discretionary.

The US proposes to add a new paragraph 3 *bis* to Article 10 which states: *"... When 48 hours have elapsed since the initial WHO offer of collaboration, failure by the State Party to accept the offer of collaboration shall constitute rejection for the purposes of sharing available information with States Parties under Paragraph 4 of this section."*

Such compulsive language is also proposed in Article 13, which deals with public health response to events covered under the scope of the IHR.

These proposals by the US pressurize developing countries to accept the offer of assistance, even if it entails opening outbreak sites to the international community or international expert teams at the cost of national security. Such pressure expands the inequities and security concerns facing developing countries vis-a-vis developed countries, because most outbreaks happen in developing countries and, in any case, developed countries can muscle their way out of recommendations or offers from WHO. It must be kept in mind that often "international expert teams" are constituted on a case-by-case basis from rosters maintained by the WHO Secretariat and which are often dominated by experts from developed countries. This compromises not only the accountability of WHO as an organization, but also the sovereign interests of State Parties, especially developing countries.

It is interesting to note, in contrast, that there is no proposal by the US to amend Article 13(5). This provision requires all State Parties, including unaffected States, to support WHO-coordinated public health response activities to a public health emergency of international concern (PHEIC) when called upon by WHO. In this case, the US proposes no timeframe or compulsion on the State Parties to respond to such a call by WHO.

Access to outbreak sites

The US proposal seeks to add provisions for deployment of international expert teams to the outbreak sites of State Parties, in particular under Article 15 of the IHR.

Article 15 provides for issuance of temporary recommendations during a PHEIC by the WHO Director-General after the meeting of the Emergency Committee, which is convened under Articles 49 and 12 of the IHR. Article 15(2) states: *"Temporary recommendations may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic."*

The US proposal seeks to include the words "the deployment of expert teams, as well as" before "health measures". If accepted, the revised paragraph 2 will read: *"Temporary recommendations may include the deployment of expert teams, as well as health measures to be implemented by the State Party experiencing the public health emergency of international concern…."*

Though Article 15(2) appears to provide a certain degree of discretion with regard to temporary measures, there are concerns that such discretion will be used against the weaker State Parties, considering the institutional weakness of WHO stemming primarily from its lack of financial independence.

The US also proposes to require State Parties to provide reasons if they deny WHO access to outbreak sites under Article 13(4). It further seeks to obligate State Parties "to make reasonable efforts to facilitate short-term access to relevant sites." As mentioned above, this is not in the interest of developing countries, while developed countries themselves can be expected to not comply with impunity.

It must be noted that under Article 49(5), the WHO Director-General is the one who makes the final determination on these matters. Therefore the US proposal is very excessive in burdening a single person with the decision-making authority of deploying

international expert teams. Considering the dependency on voluntary financial contributions from the developed countries or entities in the developed countries, the office of the WHO Director-General can be compromised and pressurized by these countries and entities to make recommendations to deploy external teams.

Promotion of multi-stakeholder approaches

The US proposal seeks to incorporate different types of stakeholders into the international public health response system. In its proposals on Article 6(1), the US seeks to obligate WHO to provide information to "other relevant entities" alongside the International Atomic Energy Agency (IAEA), the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (OIE) and the UN Environment Programme (UNEP).

While all the entities specifically mentioned are international intergovernmental organizations, "other relevant entities" is an open category which can include stakeholders ranging from private persons and loose associations to international non-State actors. It can include standard-setting organizations, credit rating agencies, potential development donors and financiers, research organizations, academic institutions, production and manufacturing companies of health care products etc.

Over and above this, the US proposal also seeks to establish a compliance committee under the IHR. The proposed Article 53 *bis* (2)(d) says the compliance committee can "seek the services of experts and advisers, including representatives of NGOs or members of the public, as appropriate". This is a highly intrusive multi-stakeholder approach. Issues like compliance and dispute settlement are at the very core of the international legal order. A multi-stakeholder approach in the same will compromise not only the State's sovereign rights and interests, but also the stability and sustainability of international relations.

No proposals for promoting the interests of developing countries

The US proposal does not address any concerns of developing countries, such as financial and technical assistance to build surveillance and response capabilities to deal with health emergencies including resilient health systems, timely and equitable access to health products, checks on unilateral measures, social and economic security during health emergencies, and access and benefit sharing for pathogens or sequenced genetic information.

TWN Info Service on Health Issues (Jan22/06) 14 January 2022

Proposed standing committee on health emergency raises concerns

Kochi, 14 January (Nithin Ramakrishnan and K.M. Gopakumar) – The Austrian proposal for the establishment of a Standing Committee on Pandemic and Emergency Preparedness and Response (SCPPR) consisting of select members of the WHO Executive Board (EB) raises concerns on health emergency governance.

The proposal (EB150/17) contains a White Paper describing the SCPPR details, a draft decision of the EB for the establishment of the SCPPR and its terms of reference (ToR). The 150th session of the EB is scheduled to consider the proposal when it meets on 24–29 January.

Though the proposal is now part of the official documentation of the 150th EB, Austria had already organized an informal discussion in December 2021. The second informal discussion was to take place on 13 January.

According to the ToR, the SCPPR will have the following wide-ranging functions:

(a) Review, provide guidance and, as appropriate, make recommendations to the Executive Board on ongoing work regard-

ing policy proposals on pandemic and emergency preparedness and response;

(b) Consider information provided by the Director-General about events that have been declared as a public health emergency of international concern pursuant to the International Health Regulations (2005), provide guidance to the Executive Board and, acting on behalf of the Executive Board, make recommendations to the Health Assembly on policy and related matters regarding the event and, upon request, provide advice to the Director-General to consider with respect to temporary recommendations in the event of a public health emergency of international concern.

The ToR proposed that the SCPPR be composed of 12 EB members, i.e., two Member States from each WHO region as a "committee of limited membership" as referred to in Rule 18 of the EB Rules and Procedures. Although other WHO Member States shall have the right to participate without a vote in the SCPPR meetings, the Chair is empowered to limit attendance at the Standing Committee meetings, or parts thereof, to members of the Standing Committee and essential Secretariat staff.

The SCPPR should have at least two regular meetings every year. Further, the EB can recommend convening extraordinary meetings. Most importantly, the Director-General of WHO should convene *"an extraordinary meeting of the Standing Committee within 24 hours from a declaration of a public health emergency of international concern pursuant to the International Health Regulations (2005) in order for the Standing Committee to consider information provided by the Director-General about events that have been declared as a public health emergency of international concern pursuant to the International Health Regulations (2005) and, as appropriate, provide guidance to the Executive Board, make recommendations to the Health Assembly on policy and related matters regarding the event and, upon request, provide advice to the Director-General to consider with respect to temporary recommendations in the event of a public health emergency of international concern".*

The decisions of the SCPPR are to be based on consensus. If consensus is not arrived at, then the difference of views will be reported to the EB or World Health Assembly (WHA) as appropriate.

Interfering with IHR process

The most important concern is that the SCPPR is provided with powers to interfere with the implementation of the International Health Regulations 2005 (IHR), a legally binding instrument, and the entire health emergency programme of WHO.

As mentioned above, upon request from the Director-General, the SCPPR is to provide advice on temporary recommendations under the IHR. It must be noted that Article 15 of the IHR, on the other hand, not only obligates but also empowers the Director-General to issue temporary recommendations in the event of a public health emergency of international concern in accordance with the procedure set out in Article 49 of the IHR.

Under Article 49(5), the Director-General is the final authority to make a decision on the temporary recommendations after considering the views of the Emergency Committee. The recommendations under Article 15(2) may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease.

Article 49 of the IHR further provides for the Director-General to convene an Emergency Committee, which shall be composed of experts selected from the IHR expert roster before the issuance of temporary recommendations. The Director-General is required to provide relevant information to the Emergency Committee including the temporary recommendation he or she proposes to issue. The Director-General is further obligated to invite the State Party in whose territory the event arises to present its views to the Emergency Committee. After considering the views of the Emergency Committee that were forwarded to him/her, the Director-General shall make decisions.

The proposal now seeks to interfere with this power and functions of the Director-General. It proposes to incorporate a handful of Member State representatives in the process, and also to empower the Chair of such a committee to exclude participation of other Member States. The effect of the proposal will indirectly alter the implementation of the IHR without an amendment to the IHR. This will make the Director-General's decision susceptible to the undue influence of powerful Member States. Also, the proposal allows scope for the SCPPR to make decisions without consulting the affected States or other relevant States.

Though the SCPPR is to provide guidance upon request from the Director-General, the power dynamics at the WHO, especially the dependence of WHO on voluntary contributions from developed countries, would force the Director-General to seek and follow the advice from the SCPPR. This would compromise the independence of the office of the Director-General.

There is another procedural issue of concern with the Austrian proposal on the SCPPR. It seeks to alter the effect of a legally binding instrument adopted by the WHA, the IHR, through an EB resolution. Therefore, the legitimacy of a decision adopting such a proposal by the EB would be questionable.

The IHR are a legal instrument adopted by the WHA under Article 21 of the WHO Constitution. Article 21 says that the WHA shall have authority to adopt such regulations. The EB, on the other hand, under Article 28 of the Constitution, is required to give effect to WHA decisions and policies. It should act as an executive organ of the WHA. This means that the EB cannot act in ways which are not consistent with laws and regulations adopted by the WHA, although under Article 28(i), it may authorize the Director-General to take the necessary steps to combat epidemics. Furthermore, the EB cannot, by its own motion, seek to limit or interfere with the powers conferred on the Director-General by the WHA. However, the SCPPR proposal does both: firstly, it is inconsistent with the IHR process; and secondly, it interferes with the powers and functions of the Director-General.

Concerns on compromising scientific advice

According to the proposal's White Paper, the establishment of the SCPPR could improve WHO's operations, and the role of its Member States therein, in the most critical moments of global health response to health emergencies, including by:

(a) strengthening the role of Member States in guiding the Director-General;
(b) narrowing the gap between WHO's scientific advice (given by the Secretariat and Expert Committees) and actual policies in Member States; and
(c) overcoming the structural shortcomings that have manifested themselves during the current (COVID-19) pandemic.

Though the SCPPR proposal strengthens the role of selected Member States, it could result in conflict between the scientific advice and actual policies of WHO, and further worsen the coordination problem manifested during the COVID-19 pandemic response. Both the Emergency Committee acting under the IHR and the proposed SCPPR are advisory bodies to the Director-General. The possibility of delivering conflicting or contradictory advice to the Director-General is greater because the bodies differ in their priorities.

The principles under which they make decisions shall also differ. This would compromise the capacity of the Director-General's office and WHO, which need coherent policy suggestions to act swiftly during an emergency. Further, there is a real danger of undermining scientific advice for political reasons.

Exclusive club of powerful Member States

Though the SCPPR would allow for the attendance of WHO Member States in its meetings, the Chair of the SCPPR can exclude the participation of other WHO Member States under paragraph 3 of the ToR. Towards this purpose, paragraphs 2 and 3 of the proposed draft decision also seek to amend Rules 3 and 18 of the EB Rules of Procedure respectively. The amended rules will allow the Chairs of the Committees established under Rule 18 to exclude participation

of the Member States of WHO in the committee meetings. It must be noted that earlier in the month of December 2021, Austria circulated another draft decision text, which proposed to suspend Rule 3 and the third sentence of Rule 18.

Rule 3 of the EB Rules of Procedure reads: *"All Member States not represented on the Board and Associate Members may designate a representative who shall have the right to participate without vote in the deliberations of meetings of the Board and of committees of limited membership (as defined in Rule 18) established by it. ... Representatives of Member States and Associate Members participating in meetings under this Rule shall have the following rights: (a) the right to speak after members of the Board; (b) the right to make proposals, and amendments to proposals, which shall be considered by the Board only if seconded by a Board member; and (c) the right of reply."*

The third sentence of Rule 18 states: *"All Member States and Associate Members shall have the right to attend such committees in accordance with Rule 3."*

In its current proposal, Austria seeks to add the following clause towards the end of the third sentence of Rule 18: "unless the Chair of the committee decides otherwise, the reason for which must be presented to the next session of the Executive Board". In Rule 3, it proposes to include the words "pursuant to" before the words "as defined in Rule 18".

The Austrian proposal thus turns the third sentence of Rule 18 into the following: *"All Member States and Associate Members shall have the right to attend such committees in accordance with Rule 3 unless the Chair of the committee decides otherwise, the reason for which must be presented to the next session of the Executive Board."*

The proposed amendments to Rules 3 and 18 mean that the Chair of the Committee shall have capacity to exclude participation of other Member States if required by providing a reason. The proposed Standing Committee can therefore function as an "exclusive club", where only 12 Member States acting on behalf of the EB advise and make recommendations to the constitutional organs of WHO such as the Secretariat, Director-General, Executive Board and WHA.

According to the experts and delegates who spoke to the Third World Network, the proposal is an attempt by developed countries to indirectly legitimize some of the activities carried out by the WHO Secretariat at their behest. For example, developed countries fund many programmatic tools and schemes of the WHO Secretariat, such as the WHO BioHub, Hub for Pandemic and Epidemic Intelligence, and Genomic Surveillance Strategy, which ignore policy inputs from the developing countries and their special needs or requirements. A major criticism against such initiatives is that they are not Member-State-led and are not based on decisions of the WHA or EB. The proposed Standing Committee can therefore be used to legitimize such initiatives, bypassing a substantive discussion in the WHA.

In short, the new proposal for the SCPPR, if adopted, effectively means that 12 Member States will have the power to take decisions relating to pandemic and emergency preparedness and response, with no transparency. They can act as an exclusive club vested with wide-ranging powers, even to provide recommendations to the Director-General, EB and WHA.

TWN Info Service on Health Issues (Jan22/09)
24 January 2022

Health emergency preparedness and response initiatives serve the interest of developed countries

New Delhi/Kochi, 24 January (K.M. Gopakumar and Nithin Ramakrishnan) – The WHO Director-General's report to the Executive Board (EB) reveals that WHO's health emergency preparedness and response initiatives compromise principles of accountability and participatory governance, to serve the interest of developed countries.

The 150th session of the EB is taking place from 24 to 29 January at the WHO headquarters in Geneva in hybrid mode.

The report (EB150/15) is mandated under resolution WHA74.7 adopted at the 74th session of the World Health Assembly. This res-

olution requested the Director-General to submit a report to the 75th WHA regarding the implementation progress of WHA74.7.

According to the report, *"in resolution WHA74.7, the Health Assembly, having taken note of the recommendations of reviews, including those of the Independent Panel for Pandemic Preparedness and Response, requested the Director-General to strengthen the Organization's capacity to prepare for and respond to health emergencies in key areas"*.

The report is divided into two parts. The first part reports on WHO's initiatives to strengthen preparedness and response to health emergencies in the light of COVID-19. The second part provides the details of the WHO Secretariat's assistance to the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR).

The report claims that in the area of health emergency preparedness and response *"the Secretariat has built on the existing framework of the three outcomes for achieving the target of one billion people better protected from health emergencies"*. The expected outcomes are: countries prepared for health emergencies; epidemics and pandemics prevented; and health emergencies rapidly detected and responded to.

However, various initiatives cited in the report compromise the principles of accountability and participatory governance, which in turn reinforces the status quo to serve the interest of developed countries.

There are three initiatives listed under the first two outcomes, viz., countries prepared for health emergencies; and epidemics and pandemics prevented. These are:

- WHO Hub for Pandemic and Epidemic Intelligence based in Berlin;
- WHO BioHub facility; and
- A new Scientific Advisory Group for the Origins of Novel Pathogens.

Though there's a "WHO" prefix for the first two initiatives, they are not accountable to WHO governing bodies. Further, there is no approval from Member States to start these hubs.

WHO Hub for Pandemic and Epidemic Intelligence: This was inaugurated on 1 September 2021 in Berlin. According to the WHO press release, *"The WHO Hub is part of WHO's Health Emergencies Programme and will be a new collaboration of countries and partners worldwide, driving innovations to increase availability of key data; develop state of the art analytic tools and predictive models for risk analysis; and link communities of practice around the world."*

The pandemic intelligence hub was established with initial funding of 100 million euros from the German government. This initiative marks a shift from the traditional disease surveillance and laboratory results to gather information from multiple sources and following an interdisciplinary approach, to obtain a more robust understanding to enable better decision-making based on better data and analyses.

The hub works on the basis of collaborative intelligence involving partners including the private sector. The strategy paper concerned envisages a multi-stakeholder decision-making mechanism in relation to the collaborative intelligence framework, including its trust architecture. This means that non-State actors including the private sector, such as pharmaceutical companies, will be on an equal footing in the decision making of the trust architecture. It also means that the hub will not be accountable to WHO governing bodies. The participation of "all WHO Member States" in the hub is also doubtful.

WHO BioHub system: This joint initiative between WHO and Switzerland was launched on 24 May 2021, i.e., ahead of adoption of resolution WHA74.7. The Swiss government is providing the infrastructure support to the BioHub through the Swiss biosafety laboratory in Spiez. According to the press release, *"Currently, most pathogen sharing is done bilaterally between countries and on an ad hoc basis, which can be slow, and leave some countries without access to the benefits and tools. The BioHub will enable Member States to share biological materials with and via the BioHub under pre-agreed conditions, including biosafety, biosecurity, and other*

applicable regulations. This will ensure timeliness and predictability in response activities."

In fact, operational paragraph 9.15 of resolution WHA74.7 requested the DG *"to work together with Member States, the medical and scientific community, and laboratory and surveillance networks, to promote early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens of pandemic and epidemic, or other high-risk, potential, taking into account relevant national and international laws, regulations, obligations and frameworks, including, as appropriate, the International Health Regulations (2005), the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and the Pandemic Influenza Preparedness Framework and the importance of ensuring rapid access to human pathogens for public health preparedness and response purposes."*

WHA74.7 was adopted after the launch of the BioHub and there was no move on the part of the WHO Secretariat to involve the Member States and governing bodies to take a decision with regard to the architecture of the BioHub. The Secretariat is organizing a series of multi-stakeholder consultations in a way to show compliance with the WHA resolution. Paragraph 13 of the DG's report states, *"The BioHub is now at the start-up phase for sustainable pathogen-sharing, and is expected to be further developed, through its system design phase, in 2022, in consultation with Member States."* In WHO parlance, the term "in consultation with Member States" does not mean that governing bodies need to approve the mechanism. The current arrangement, i.e., a Swiss biosafety laboratory, is not accountable to WHO Member States though its governing bodies.

The guiding principles of the WHO BioHub as prepared by the WHO Secretariat contain 10 principles, but do not even use the phrase "benefit sharing". The language of benefit sharing is conspicuously absent in the commentary to the principles as well. Although the two standard material transfer agreements (SMTAs) used in the BioHub (currently in pilot phase) recognize benefit sharing, the language

used is very ambiguous and not indicative of how fair and equitable benefit sharing would play out in future.

For example, in one of the SMTAs, Article 5 merely states: *"In furtherance of the aims set out in the Recitals of this Agreement, the WHO BioHub System aims to provide to all Member States and relevant partners, access to a range of public health information, tools, and products that may arise from the sharing of BMEPP [biological materials with epidemic or pandemic potential] with the WHO BioHub System. This Agreement covers the Pilot Testing Phase and period of the WHO BioHub System project, only, and that Pilot Testing Phase is not designed or intended to result in the creation of material benefits from the BMEPP. In the event that the use of BMEPP results in the creation of such material benefits, all Parties will engage with WHO to distribute and provide such benefits on a fair and equitable basis."*

Such initiatives bypassing WHO governing bodies serve the interest of developed countries by facilitating access to pathogen samples and genetic sequence information (GSI) contrary to the corresponding obligation to share the benefits on a fair and equitable basis. Paragraph 9 of the DG's report states: *"... technologies have not only the potential to transform the speed at which we recognize and communicate threats but also the speed at which, and depth to which, we understand the natural history of infectious pathogens, their transmission dynamics, and their susceptibility over time to public health and biomedical interventions."* Thus it is clear that such initiatives would be dealing with data on pathogens and there is no clarification on benefit sharing with countries that are the source of the data.

Similarly, paragraph 13 of the DG's report states: *"This [BioHub] System is intended to be an essential element of a global mechanism for the standardized collection, characterization and archiving of viruses, other pathogens with pandemic potential and specimens to facilitate and accelerate the development of diagnostics, therapeutics and vaccines."*

The SMTAs of the BioHub cover only BMEPP and not GSI. However, Article 3.1.3 of SMTA 1 requires the uploading of BMEPP

genetic sequence data to various databases. From these databases, the sequence may be used for the development of diagnostics and vaccines, without any commitment to fair and equitable benefit sharing. Therefore any party accessing GSI from such databases may not be under any benefit-sharing obligation.

Under the Convention on Biological Diversity and its Nagoya Protocol on Access and Benefit Sharing, the recipients of biological materials or their genetic sequence information are under an obligation to share the benefits of the R&D outcomes in a fair and equitable manner with the providers of such materials. However, pharmaceutical companies refuse to share benefits with providers of pathogen samples and GSI and instead monopolize the products through intellectual property protection to maximize their profits. As a result, developing countries which promptly share samples of pathogens or GSI are often unable to access the diagnostics, vaccines or therapeutics developed using such samples or GSI.

WHO is reinforcing the status quo and defying the provisions of the Convention on Biological Diversity and Nagoya Protocol.

Epidemic Intelligence from Open Sources (EIOS): Paragraph 17 of the DG's report refers to the role of the EIOS initiative in rapid detection and response to health emergencies. According to the EIOS webpage: *"Creating a community of practice for public health intelligence (PHI) that includes Member States, international organisations, research institutes and other partners and collaborators is at the heart of the initiative; saving lives through early detection of threats and subsequent intervention its ultimate goal."*

It also states: *"The EIOS system builds on a long-standing collaboration between WHO and the Joint Research Centre (JRC) of the European Commission (EC) to develop a system for public health intelligence and responds to the need for a global initiative to bring together PHI efforts."* The IT system functioning behind EIOS is developed under the technical lead of the JRC. EIOS has staff working in all the WHO regional offices.

The Coordination Group of EIOS does include the European Commission. Other members are the Africa Centres for Disease Control and Prevention (Africa CDC), Public Health England, Food

and Agriculture Organization of the United Nations (FAO), European Commission – Joint Research Centre, Global Outbreak Alert and Response Network, European Centre for Disease Prevention and Control, National Institute of Infectious Diseases Japan, Centres for Disease Control and Prevention (CDC, US), World Organisation for Animal Health (OIE), Ministry of Health Mexico, WHO and Public Health Agency Canada. Thus the governance is controlled by agencies of developed countries, and EIOS is not reporting or accountable to any of the WHO governing bodies.

Access to COVID-19 Tools (ACT) Accelerator: According to paragraph 14 of the DG's report: *"WHO's research and development blueprint for action to prevent epidemics and the three vertical product pillars of the Access to COVID-19 Tools (ACT) Accelerator provide a foundation on which to build a transparent and coordinated global mechanism whereby research and innovation priorities are set upstream."* It further states: *"WHO continues to explore with partners ways in which the successes of the ACT Accelerator can be institutionalized and built on over the coming months and years."*

The ACT Accelerator, a mechanism based on a white paper of the Bill and Melinda Gates Foundation, was launched on 24 April 2020 to facilitate the development and equitable distribution of tests, treatments and vaccines for COVID-19. This initiative has three pillars for vaccines, therapeutics and diagnostics. The lead organizations for the vaccine pillar are Gavi, the Vaccine Alliance, Coalition for Epidemic Preparedness Innovations (CEPI) and WHO. Wellcome Trust and UNITAID are leading the therapeutics pillar, while the Foundation for Innovative New Diagnostics (FIND) and the Global Fund are the leads for diagnostics. Apart from these three pillars, there is a Health System Connector pillar working to ensure the tools reach the people in need. WHO also hosts the ACT Accelerator secretariat known as ACT-A Hub.

Each pillar has its own workstreams with participation of industry and selected civil society organizations. Though there is an ACT-A facilitation council for governance purposes, the mandate of the council is to address the strategic, policy and financial issues and political advocacy for the ACT Accelerator. There is no mandate for

the council to take any substantive decision with regard to the ACT Accelerator such as the intellectual property protection of R&D outcomes or licensing of products developed through the Accelerator, as this is within the purview of each pillar consisting of a few actors including certain donors.

The ACT Accelerator could not make any significant impact to address the inequitable access to COVID-19 health products, especially in addressing intellectual property barriers to scale up production.

As the WHO EB meets this week, developing country Member States need to take full cognizance that the manner in which WHO is seeking to strengthen preparedness and response to health emergencies favours developed countries and their pharmaceutical corporations, undermining the WHO governing bodies and accountability to Member States.

TWN Info Service on Health Issues (Jan22/10)
24 January 2022

EB Members decide to establish Standing Committee on Health Emergency amidst concerns

Geneva, 24 January (TWN) – WHO Member States have reportedly arrived at a consensus to establish a Standing Committee on Health Emergency (Pandemic) Prevention, Preparedness and Response (SCPPR) of the Executive Board of the Organization.

A draft decision in this regard was circulated on 21 January ahead of the 150th session of the WHO Executive Board (EB) that is taking place on 24–29 January in hybrid mode.

However, Member States could not reach a consensus on the terms of reference (ToR) of the SCPPR. Therefore, the draft decision requests the WHO Director-General to facilitate informal consultations with Member States, with a view to submitting the revised ToR to the 151st meeting of the EB.

In accordance with Rule 18 of the Rules of Procedure of the EB, the SCPPR will be a standing committee of limited membership. However, the first meeting of the committee will only happen after EB151 adopts the revised ToR. Paragraph 2 of the draft decision requests the Director-General:

"(a) to facilitate further informal consultations in an inclusive, transparent manner among Member States to finalize the draft terms of reference of the Standing Committee on Health Emergency (Pandemic) Prevention, Preparedness and Response, taking into account the deliberations at the 150th Executive Board, with a view to submit the terms of reference for consideration by the 151st Executive Board in May 2022; and

"(b) to report on the functions and impact of the Standing Committee and present the results and possible recommendations based thereon for the consideration of the Executive Board at its 156th meeting in January 2025."

This means that the SCPPR's scope and functions are yet to be decided by the EB. The Director-General is tasked to facilitate informal consultations amongst Member States to finalize the draft ToR. The finalized draft then needs to be adopted by the EB by virtue of paragraph 1(a) of the decision.

The ToR as proposed by Austria have several issues; the Third World Network has previously published on these. Austria has sought to establish a non-inclusive process and an exclusive club in the name of a "standing committee" of the EB. The proposed process of the SCPPR would have interfered with the International Health Regulations process and the authority of the Director-General, and ultimately it would have compromised the significance of the scientific advice in the Director-General's response to a public health emergency of international concern. Several of these issues have stalled the process of convening the first meeting of the SCPPR up until EB151.

Nevertheless, the language of the draft decision itself raises serious concerns. Firstly, although paragraph 1(a) envisages that EB151 will look into the adoption of the revised ToR, paragraph 2(a) can reduce the role of EB151 to a namesake authority. Secondly, it

contributes to the further fragmentation of ongoing negotiations on health emergency preparedness and response and the required legal and policy changes.

Under paragraph 1 of the draft decision, the EB has to adopt the ToR. However, paragraph 2(a) entrusts the Director-General to facilitate informal meetings of the Member States with a view to submitting the ToR for consideration by EB151. It is not clear whether it is the Secretariat or the Member States that will prepare the ToR. The term "consideration" may not necessarily mean that there will be a substantive discussion during EB151. The EB may simply take note of the report submitted by the Director-General or Secretariat, which shall then be considered as approval by the EB.

There is at least one such precedent in WHO when the language was twisted to get things approved by the World Health Assembly (WHA) and EB. In the case of the development and adoption of "criteria and principles for secondments from nongovernmental organizations, philanthropic foundations and academic institutions", resolution WHA69.10 had requested the Director-General *"to develop, in consultation with Member States, a set of criteria and principles for secondments from nongovernmental organizations, philanthropic foundations and academic institutions and to submit the criteria and principles for the consideration of and establishment by, as appropriate, the Seventieth World Health Assembly, through the Executive Board, taking into account …"*

The criteria and principles were later incorporated in WHO's human resource policies and procedures after WHA70, but without any formal adoption. The EB and WHA simply took note of reports submitted by the Director-General and the Secretariat and it was considered as approval by the WHA. In connection with this, during the WHA70 session, the WHO legal counsel explained the practice as follows:

"… resolution WHA69.10 requested the Director-General to develop a set of criteria and principles for secondments and to submit those criteria and principles for the consideration of and establishment by, as appropriate, the Seventieth World Health Assembly. The inclusion of the words 'as appropriate', allowed the Health As-

sembly either to take note of the principles and criteria or to take other actions. The Executive Board had decided only to take note of the principles and criteria. If the Health Assembly took note of the report, the criteria and principles would be incorporated in WHO's human resources policies and procedures; a number of other WHO policies had been established in that manner. As no other course of action had been proposed by the Executive Board, it would be appropriate for the Health Assembly merely to take note of the report."

Following this explanation, though countries such as Brazil and Somalia asked for further clarifications from the WHO Secretariat, the reports submitted were nonetheless "noted" by WHA70 without waiting for the Secretariat's substantive response. It must be pointed out that the legal counsel patently erred in saying the EB can decide what is appropriate for the WHA.

Further, the draft SCPPR decision requests the Director-General to conduct informal consultations on the issue. There is no reference to the ongoing process on the issue of health emergency (pandemic) preparedness and response, namely (1) the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies; and (2) the intergovernmental negotiating body on a proposed pandemic instrument. The process of finalizing the ToR of the SCPPR will take place separately from these other processes. This would further fragment the already fragmented negotiations and could create issues of (in)coherence among the outcomes of the various processes.

TWN Info Service on Health Issues (Jan22/11) 26 January 2022

Member States agree to work on International Health Regulations amendments

Geneva, 26 January (TWN) – WHO Member States agree to start the process within the Member States Working Group on Strengthening WHO Preparedness and Response to Health (WGPR) to amend the International Health Regulations (IHR) of 2005.

A draft decision (EB150/CONF./3) in this regard is circulated for consideration and adoption at the 150th session of the WHO Executive Board (EB150) that is taking place this week from 24 to 29 January.

The draft decision titled "Strengthening of the International Health Regulations (2005) through a process for revising the regulations through potential amendments" was uploaded to the EB150 documents page on 24 January.

The draft is proposed by Albania, Australia, Canada, Colombia, India, Japan, Monaco, Montenegro, Norway, Peru, the Republic of Korea, the United Kingdom and Northern Ireland, the United States of America, Uruguay and Member States of the European Union.

The draft is proposed under agenda item 15.1 on the consideration of the interim report of the WGPR and the report of the Director-General on strengthening WHO preparedness and response to health emergencies.

The draft decision text has been finalized through a series of informal negotiations on an initial text circulated by the US. The US had earlier circulated substantive proposals to amend the IHR provisions and organized at least two informal consultations in this regard. These proposals seek to impose onerous obligations on developing countries. However, the draft decision for consideration by EB150 provides some clarity on the purpose and scope of any amendments to the IHR.

Operative paragraph (OP) 1.2 provides some explanation to the term "potential amendments". It states that amendments should be limited and address specific and clearly identified issues or challenges such as equity, technological or other developments. They could also address the gaps that cannot be addressed otherwise but are critical to supporting effective implementation and compliance of the IHR, and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner. The potential amendments, thus, would not lead to opening the entire instrument for renegotiation.

The OPs stress on insufficient global solidarity and collaboration, while requiring Member States to take all appropriate

measures to consider the potential amendments to the IHR. The OPs are as follows:

"(OP1) Noting the urgent need to further strengthen implementation of, and compliance with, the IHR (2005), and mindful that Member States face challenges, including inter alia, due to capacity constraints and insufficient global solidarity and collaboration, decided:

"(OP1.1) To note that the WGPR will include, as part of its ongoing work, dedicated time to allow for discussions on strengthening of the IHR (2005), including through implementation, compliance and potential amendments.

"(OP1.2) To urge Member States to take all appropriate measures to consider potential amendments to the IHR (2005), with the understanding that this would not lead to reopening the entire instrument for renegotiation. Such amendments should be limited in scope and address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the IHR (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner."

OP1.2 recognizes equity both as a central issue and as a cross-cutting issue across the whole implementation of the IHR. This is in line with views of the Member States of the African region, which had requested the WGPR to study the issue of equity in both dimensions.

The preamble of the decision further underscores *"the importance of States Parties' implementation of and compliance with the IHR (2005), including regarding collaboration and international cooperation, and developing, maintaining and strengthening core capacities"*.

It also emphasizes *"the importance of solidarity and equitable access to and distribution of medical countermeasures in the context of health emergencies as well as strengthening the health and care workforce and addressing access concerns"*.

However, the decision has not provided any timeline or other details of the amendment process/negotiations.

The adoption of the decision would pave the way for initiating discussions within the WGPR to amend the IHR. It also provides an opportunity to all Member States to submit their proposals for the potential amendments of the IHR.

TWN Info Service on Health Issues (Mar22/01)
2 March 2022
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African Region calls for amendment of IHR to address equity

Geneva, 1 March (TWN) – Member States from the WHO African Region called for the inclusion of equity provisions within the potential amendments to the International Health Regulations 2005 (IHR) during the 7th meeting of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR).

The meeting took place on 21–23 February at the WHO headquarters in Geneva in a hybrid mode.

Following decision EB150(3) adopted at the 150th session of the Executive Board, the WGPR is now discussing potential targeted amendments to the IHR.

Botswana, who spoke on behalf of 47 States from the WHO African Region, stated that "it is critical that the IHR (2005) address the current inequities in order to ensure balanced rights and obligations in health emergency response including to facilitate availability and affordability of health products, and to address the unilateral decisions like travel bans, restrictions on movement [of] goods, and information on diseases outbreaks that has been reported under the IHR (2005)."

The African Region recommended that "equity should be addressed both within the potential IHR (2005) amendments as well as

the new international [pandemic] instrument. Therefore, equity provisions proposed in the IHR (2005) should be complemented in zero draft prepared by the INB with cross referencing to relevant IHR provisions. Therefore, we share the views as were just expressed by the distinguished colleague from Indonesia."

[The INB is the Intergovernmental Negotiating Body mandated to develop a new WHO instrument on pandemic prevention, preparedness and response. It started its work on 24 February. Indonesia has also reportedly sought a division of work on equity between the WGPR and the INB.]

The African Region submitted an indicative list of proposals on improving equity under the IHR as follows:

1. Equity in obligations on prevention, detection and control of pandemic threats;
2. Provision of financial assistance and technology transfer to developing countries;
3. Subjecting all WHO actions in a pandemic under the provisions of the IHR and a complementary future international instrument;
4. Obligation to provide support to WHO to coordinate the response;
5. Obligations to facilitate production, availability and access to medical countermeasures;
6. Ensuring equal footing of pathogen and genomic sequence sharing and benefit sharing.

Decision EB150(3) has urged Member States to consider potential targeted IHR amendments including for improving equity.

Operative paragraph 2 of EB150(3) specifically requires Member States to consider amendments to the IHR which *"address specific and clearly identified issues, challenges, **including equity**, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner"* (emphasis added).

Several developed countries including Canada, the Netherlands and Denmark requested for the written statement of the African Region to study further the elements of their proposal.

Japan reportedly asked Botswana to detail further on how they intend to achieve equity through amendments to the IHR.

Several delegates involved in the proceedings raised a concern about the work of the Bureau trying to treat equity outside the workstream relating to IHR amendments, as well as to lead the discussions of the WGPR based on a survey conducted by the Bureau and Secretariat in which more than 60% of the Member States did not participate.

Botswana has squarely rejected any prioritization based on the results of such a survey, while several other countries expressed their reservations on the way the survey results have been handled by the Bureau and the Secretariat.

While making it clear that the survey results on priority recommendations cannot be generalized across all regions for implementation, Botswana stressed that any work in modernizing the notification and alert systems for enhanced sharing of information, including genome sequences, must adhere to the principles of the Nagoya Protocol on access and sharing of benefits derived from genetic resources. It also called for increased capacity building in relation to genomic sequencing.

It must be noted that some developed countries reportedly moved to park equity issues for future work of the INB, exactly opposite to what Botswana has proposed on behalf of the African Region, i.e., to adopt amendments to the IHR on equity, and then cross-refer the same in the new instrument being developed by the INB.

The World Health Assembly Special Session decision WHASS2(5), which provides the mandate for the INB, supports the view of the African Region. Operative paragraph 1.4 of the decision reads: *"... the process referred to in paragraph 1(3) [INB] should be informed by evidence and should take into account the discussions and outcomes of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies [WGPR], considering the need for coherence and complementarity between*

the process of developing the new instrument and the ongoing work under resolution WHA 74.7, particularly with regard to implementation and strengthening of the IHR (2005)".

Currently, the United States is the only Member State which has proposed amendments to the IHR along with draft textual changes. The US proposals have nothing concrete on issues relating to equity. Nevertheless, the US is aggressively promoting its proposed amendments through both formal discussions in the WGPR and informal consultations with Member States, with a view to getting them adopted at the 75th session of the World Health Assembly (WHA75) that will take place on 22–28 May.

According to Article 55(2) of the IHR, the text of any proposed amendment needs to be communicated to all State Parties by the WHO Director-General at least four months before the WHA at which it is proposed for consideration. Although the WGPR received its mandate to discuss potential targeted IHR amendments only on 26 January, the US is relying on its early circulation of its text of proposed amendments to argue that WHA75 can consider its proposal, according to some delegates.

On the other hand, these delegates also reported that Article 55 of the IHR has been repeatedly brought into the discussion to discourage immediate proposals from other countries. At one point in the meeting, there were even suggestions to submit the US proposal to WHA75 for consideration, and for other proposals to be tabled for WHA76 to be held in 2023. Nevertheless, Member States like Botswana (on behalf of the African Region), China and India reportedly opposed such moves.

China highlighted the legally binding nature of the IHR and stated that any proposal to amend must happen through a collective process, and after Member States sit together on the same. The process should allow for proposals from all Member States.

India said that a piecemeal process which compartmentalizes certain IHR amendments to one period and others to another period is not desirable.

Botswana made it very clear by saying that going forward, the WGPR should establish a process with a timeframe for receiving

textual proposals on targeted IHR amendments, to develop a consolidated draft text with attributions to Member States, and that all proposals should be treated on an equal footing. "Only after this process can the substantial discussions commence," said Botswana.

Algeria, supporting the African Region statement, also said there will be some amount of duplication of work between the WGPR and the INB on equity, and that is quite obvious given equity is the central issue.

TWN Info Service on Health Issues (Mar22/09)
28 March 2022

WGPR Bureau marginalizes International Health Regulations amendment process

Geneva, 28 March (Nithin Ramakrishnan and K.M. Gopakumar) – The Bureau of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) is marginalizing the IHR amendment process.

The Bureau's Summary Report on the 7th WGPR session and its draft programme of work for the 8th session are clear indications of this direction.

The WHO Executive Board (EB) in its decision EB150(3) (2022) dated 26 January had required the WGPR to provide dedicated time to allow for discussions on strengthening of the IHR, including through implementation, compliance and potential amendments. However, the Summary Report and draft programme of work neglect to implement this mandate.

[The WGPR was established in 2021 by World Health Assembly (WHA) resolution 74.7 to consider the findings and recommendations of the Independent Panel for Pandemic Preparedness and Response, the IHR Review Committee and the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme, taking into account relevant work of WHO, including that stemming from resolution WHA73.1 (2020) and decision EB148(12)

(2021), as well as the work of other relevant bodies, organizations, non-State actors and any other relevant information.

[The functions of the WGPR Bureau include: (a) to propose working methods of the Working Group; (b) to draw up the provisional agenda of Working Group meetings; (c) to consider documents prepared in advance of Working Group meetings, including to facilitate the timely dispatch of working documents; (d) to coordinate work among subgroups, if any; (e) to propose to Member States for their consideration ways forward on substantive matters, including, for example, through "Chair proposals" (but not to decide substantive matters); and (f) to prepare the draft reports of the Working Group, based on the proceedings and discussions during the Working Group sessions.]

The 7th session of the WGPR was held on 21–23 February. The Bureau's Summary Report was published on 18 March.

The draft programme of work for the 7th session, published on 16 February, had a clear agenda item on the "consideration of Member States' proposals for action, including at the 150th session of the Executive Board". There was a repeated demand from several developing countries for a process to submit proposals for amending the IHR, based on the EB150(3) decision. Nevertheless, the Co-Chairs, who presided over the meeting, did not make any effort to drive this demand from developing countries to a decision point.

Furthermore, the Bureau's Summary Report does not report anything on this agenda item, especially the demand for a timeline to carry out discussion on the IHR amendment. The report only mentions the critical role of strengthening the IHR.

In comparison, during the previous meeting of the WGPR, the US was pushing ahead an agenda for taking into consideration its own IHR amendment proposals circulated before the EB decision in January. The US is insisting that its proposals should be taken on a priority basis to facilitate their consideration at the upcoming WHA75 in May. This means the amendment proposals of other Member States will not be treated on an equal footing with the US proposals and will be considered only during WHA76 in 2023.

If the US has its way, it then gets an edge to press other countries to discuss its proposals without any alternative texts, thus blocking the adoption of other amendment proposals. It must be noted that the US amendment proposals have nothing to address concerns of equity in health emergency preparedness and response.

In contrast, the EB decision has given a specific mandate to address the issue of equity within the scope of amendments. It states: *"Such amendments should be limited in scope and address specific and clearly identified issues, challenges, including equity, technological or other developments…."*

The US strategy seems to be to fast-track its own amendment proposals and then block proposals for equity-related amendments which may come from developing country Member States. The US is relying on Article 54 of the IHR, which states that text proposals for amending the IHR must be submitted four months prior to the WHA session at which the proposals will be considered.

The WGPR Bureau's Summary Report of the 7th WGPR session and the organization of the intersessional informal meetings between the 7th and 8th sessions are essentially promoting the US approach.

Despite the calls by several developing countries for the WGPR to adopt a timeline and process for submitting proposals for amending the IHR for its consideration, the Bureau's Summary Report is devoid of any mention of such calls. Member States such as India also raised a concern in the WGPR meeting against compartmentalization of the proposals to amend IHR, i.e., for WHA75 and for WHA76. Even this is not reflected in the Summary Report.

Nigeria had asked for a timeline for other Member States to submit the proposals.

Paragraph 4 of the Bureau's Summary Report simply states: *"Member States also requested the Bureau to provide a clearer timeline of WGPR's activities until the Seventy-fifth World Health Assembly, taking into account other processes such as the deliberations of the Working Group on Sustainable Financing and the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic preven-*

tion, preparedness and response."

There is no mention of decision EB150(3) in the Summary Report. The Bureau's reluctance to fix or propose a timeline for submission of IHR amendments is thus delaying the submission of amendment proposals pursuant to decision EB150(3) and is serving the US interest.

The US is one of the Vice-Chairs of the WGPR Bureau.

Meanwhile, on 25 March, the draft programme of work for the 8th WGPR session, scheduled for 28–30 March, was published. On strengthening the IHR, it reads as follows:

"d) Discussion on strengthening the International Health Regulations (IHR) (2005)

- *Capturing progress so far, including potential amendments to the IHR (2005) with a focus on enabling the rapid sharing of information*
- *Discussion of a possible inclusive, transparent path forward for negotiations on strengthening the IHR (2005), to be potentially included as a proposed action in the report discussed in (3) below*
- *Efforts to strengthen country core capacities and compliance*
- *Follow-up on discussion of the Universal Health and Preparedness Review."*

The draft programme of work contains no indication on establishing a timeline or process inviting proposals for amending the IHR in the WGPR as per the 150th EB decision. It merely indicates a possibility of having a path forward for negotiations on "strengthening the IHR" as a proposed action in the WGPR's "final outcome report". On the other hand, it is not clear whether the mandate of the WGPR will be extended beyond WHA75.

The strengthening of the IHR according to the 150th EB decision includes strengthening through implementation, compliance and potential amendments. Thus, amendment of the IHR is one of the ways of strengthening the regulations. However, fixing a timeline for the amendment process now depends on the persistence of the Member States since the Bureau is clearly abdicating its responsibil-

ity of taking the mandate of the EB decision to its logical conclusion. As of now, it is not very clear that there would be a transparent process, including a timeline and opportunity for all Member States to submit their proposals on IHR amendments to the WGPR.

There might be proposals to shift IHR amendment to the mandate of the international negotiating body (INB) established to negotiate the proposed new pandemic instrument. The Bureau's proposal for the outline of the final report of the WGPR to the 75th WHA states: *"... proposed recommendations to be taken up by the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (INB)."*

This may be an indication of shifting IHR amendment to the INB, but the critical question is whether the US amendment proposals will also be shifted to the INB. Such a shift of forum could result in the marginalization of the IHR amendment agenda due to the already prioritized timeline for the new instrument in the INB.

While there is no mention of the EB150(3) mandate in the draft programme of work for the 8th WGPR session, it is interesting to note that the draft purports to capture the progress of negotiations on potential amendments to the IHR "with a focus on enabling rapid sharing of information", meaning the US proposals. In comparison, decision 150(3) has called for amendments with a few other focus areas, including "equity". In other words, the WGPR Bureau is ignoring its mandate from the EB, and is acting according to the interests of the US.

Guiding questions disregard the legitimate interests of developing countries

Meanwhile, on 15 March the Bureau circulated a set of guiding questions to shape the agenda of the intersessional informal meetings of the WGPR on 18 and 24 March on four themes: equity, leadership and governance, systems and tools and finance. Strengthening the IHR is addressed under the theme of "leadership and governance".

The second question on strengthening the IHR conspicuously disregards the views expressed by several Member States during the 7th session of the WGPR on prioritizing certain IHR amendment proposals against others: *"Some amendments currently before the WHA in May address these high priority areas such as notification and alerts, risk assessments and information sharing. Do those proposed amendments address the gaps raised by the recommendations or can they be improved? Are there other relevant aspects of these high priority areas that should be addressed by WHA75 in some other way?"*

The term "some amendments currently before the WHA" refers to the US proposals submitted before the EB mandate to the WGPR. Ideally this question should have come after the start of the process for submission and consideration of IHR amendment proposals.

It is noteworthy that EB decision 150(3) clearly stipulates the primacy of "equity" and "the universal application [of the IHR] for the protection of all people of the world from the international spread of disease in an equitable manner". However, the guiding questions on IHR amendment do not address the issue of equity at all.

The other guiding questions on "strengthening the IHR" include:

- *"Based on the recommendations from the panels/committee and the survey results, IHR strengthening in these areas was identified as a high priority and feasibility item: Role and functioning of NFPs; Core capacity requirements for preparedness, surveillance and response; National notification and alert system; Risk assessment and information sharing. Are there any concrete ideas on how to implement the recommendations either through WHO's normative work and/or IHR amendment?*
- *"Many Member States, both through WGPR statements and survey responses have prioritized in particular for States Parties to share the relevant public health information needed by WHO to assess the public health risk and for WHO to be empowered to respond effectively to outbreaks, while some Member States have expressed caution that such efforts should not*

compromise national sovereignty. How should we finalize recommendations on this critical area?

- *"What obstacles need to be addressed and/or support required in order to strengthen national and regional core capacities that could improve IHR (2005) implementation and compliance?"*

Similarly, the guiding questions on the "equity" theme also do not cross-refer to the need for amending the IHR in realizing equity in health emergency preparedness and response.

The guiding questions on IHR strengthening also explain, in the fifth bullet point, that *"the Bureau intends to propose a way forward through its final report so there will be agreement and clarity on how the IHR strengthening work will be taken forward, and we continue to seek Member State input to inform that proposal"*.

While it is not for the WGPR Bureau to decide on the way forward, by postponing the development of a way forward for the work related to strengthening the IHR, to its final outcome report, the Bureau is effectively delaying the submission of proposals from developing countries to ensure equity in the IHR, and prioritizing the US amendments instead.

The guiding questions are also seen as aggressively promoting WHO's programmatic tools such as the ACT Accelerator and WHO BioHub, undermining the need for translating equity into legal commitments and obligations under the IHR. It must be noted that the structural and working principles of these programmatic tools are not prepared through a Member-State-led process. The WGPR Bureau's actions also undermine several areas of priority such as diversification and promotion of local production of health products, and fair and equitable sharing of the R&D outcomes etc.

Furthermore, the agenda of the WGPR meetings is often published a few days ahead of a meeting without giving much time for the countries to prepare. There is no clarity on the process by which guiding questions are drafted and agreed upon. In their current form, such questions are clearly leading questions soliciting Member States to respond in a particular way which promotes the priorities of the developed countries to the detriment of the legitimate needs of the developing countries.

TWN Info Service on Health Issues (May22/04)
5 May 2022

WGPR draft report seeks endorsement of US IHR amendment proposals

by Nithin Ramakrishnan and K.M. Gopakumar

The draft report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) dated 3 May seeks the endorsement of the United States' proposals to amend the International Health Regulations 2005 (IHR).

The 9th WGPR meeting is taking place 4–6 May at the WHO headquarters in Geneva. This meeting is to finalize the WGPR's report to the 75th session of the World Health Assembly (WHA) to be held 22–28 May in Geneva.

Though the draft report was circulated to WHO Member States for them to submit their comments, the published version of 3 May has hardly incorporated comments from the feedback.

[Resolution WHA74.7 (2021) constituted the WGPR as the intergovernmental Member State process to discuss the findings and recommendations of various expert and review committees established pursuant to resolution WHA73.1 (2020). There were the IHR Review Committee on the functioning of the IHR during the COVID-19 response; the Independent Oversight and Advisory Committee for the WHO Emergencies Programme; and the Independent Panel for Pandemic Preparedness and Response.]

The draft report contains a draft decision of the WHA on the process of IHR amendment and a set of recommendations to strengthen WHO's preparedness and response to health emergencies. Its recommendations addressing Member States, the WHO Secretariat and non-State actors are categorized under the following headings: political leadership; cooperation and collaboration; WHO at the centre; financing; sustainability of COVID-19 innovative mechanisms; global surveillance; strengthening IHR implementation, compliance and potential amendments; universal health and preparedness review pilot; travel measures; and equity.

Fast track for US proposals for IHR amendments?

Backdoor endorsement of the US IHR amendment proposals is sought by mentioning these proposals as "recommendations" under the heading of strengthening IHR implementation, compliance and potential amendments. Such recommendations and the corresponding US amendment proposals are listed below.

No.	Technical Recommendation	US Proposal to Amend IHR
1	Table 7 C recommendation No 25 *WHO Secretariat, in accordance with Article 11 of the IHR, to share information about public health risks with States Parties and report annually to the Health Assembly on how it has complied with the implementation of Article 11*	US proposal to include new paragraph 5 in Article 11 of the IHR reads as follows: **5. WHO shall annually report to the Health Assembly on all activities under Article 11, including instances of sharing information that has not been verified by a State Party on whose territory an event that may constitute a public health emergency of international concern is or is allegedly occurring with States Parties through alert systems**
2	Table 7 E recommendation No 38 *MS to accept the Secretariat's offer of immediate technical support in outbreak investigations and risk assessments and where such offers are not accepted by MS, the latter should*	Amendment proposed to Article 13(3) and 13(4): 3. ~~At the request of a State Party,~~ WHO shall **offer assistance** ~~collaborate~~ **to a State Party** in the response to public health risks and other events by providing technical guidance and assistance and by assessing the effectiveness of the control

	promptly provide a written explanation of their position.	measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary. **The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which the WHO shall share with other States Parties.** 4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it **shall** ~~may~~ offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer. **The State Party shall accept or reject such an offer of assistance within 48 hours and, in the case of rejection of such an offer, shall provide to WHO its rationale for the rejection, which the WHO shall share with other States Parties. Regarding on-**

		site assessments, a State Party shall make reasonable efforts to facilitate short-term access to relevant sites; in the event of a denial, it shall provide its rationale for the denial of access.
3	Table 7 E recommendation No 39 *WHO Secretariat to publish information about outbreaks with pandemic potential on an immediate basis*	US proposal to amend Article 11(2): WHO shall use information received under Articles 6, ~~and~~ 8 and ~~paragraph 2 of Article~~ 9 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, **when** ~~until such time as~~: a. the event is determined to constitute a public health emergency of international concern in accordance with Article 12; or … **new e. WHO determines it is necessary that such information be made available to other States Parties to make informed, timely risk assessments.**

4 & 5	Table 7 F recommendation No 45 *MS to continue to discuss the feasibility of an intermediate and/or regional public health emergency of concern* Table 7 F recommendation No 46 *WHO Secretariat to support MS in the discussion, including involvement of the Regional Office*	Proposal to incorporate new paragraph 7 in Article 12 of the IHR: **7. A Regional Director may determine that an event constitutes a Public Health Emergency of Regional Concern and provide related guidance to States Parties in the region either before or after notification of an event that may constitute a public health emergency of international concern is made to the Director-General, who shall inform all States Parties.**
6	Table 7 G recommendation No 47 *MS to consider adopting amendment to Article 59 of the IHR at the Seventy-fifth World Health Assembly*	Proposal to incorporate new paragraph 1 *bis* in Article 59 of the IHR: **The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, an amendment to these Regulations shall be 6 months from the date of the notification by the Director-General of the adoption of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.**

The adoption of these recommendations would effectively result in the endorsement of the US amendment proposals and prejudge the IHR amendment process that is to be Member-State-driven. It would go against the consensus of treating all amendment proposals on an equal footing. Russia has already submitted proposals for IHR amendments; other Member States especially developing countries are expected to follow suit.

Further, the draft WHA decision in the WGPR draft report seeks the adoption of any amendments to the IHR ready for adoption. The US is pressing for the adoption of an amendment to Article 59 of the IHR dealing with the entry into the force of amendments to the IHR. It proposes different timelines for the entry into force of amendments. First, the amendment proposes to reduce the time for the rejection or reservation of the amendment to nine months from 18 months. Second, the timeline for the entry into force of the amendment to be reduced to 12 months from 24 months. Third, it provides an extra timeline of six months to make the domestic legal or administrative adjustments after entry into force of an amendment.

The US is also seeking amendments to Articles 55, 61, 62 and 63 of the IHR. These were not part of the amendment proposals that the US had circulated in January 2022, and are projected as "technical confirming adjustments" that are only procedural. However, a clear reading of the proposed amendments to Article 62(4)(c) and 62(5) shows that these proposals go beyond technical confirmation as they actually seek to substantially change the IHR provisions concerned.

The proposed Article 62(4)(c) creates a new substantive provision which allows any State Party to notify objections to the reservation to IHR amendments along with reasons given. The proposed amendment to Article 62(5) puts a condition that the reservation to the amendments would come into force only in the absence of objection from one-third of the State Parties.

In contrast, the existing Article 62(6) obligates the WHO Director-General to notify State Parties to consider the withdrawal of a reservation to the IHR in the event of objection from one-third of State Parties. The proposed amendments from the US will extend

State Parties' objection to reservations made on *amendments* to the IHR as well. This is not a technical or procedural matter.

But the most important question is whether these proposed amendments to Articles 55, 61, 62 and 63 – which are not part of the proposal circulated by the US on 20 January 2022 – can be considered for adoption during the upcoming 75th WHA. Article 55(2) requires that all textual proposals to amend the IHR must be circulated through the DG "four months ahead of the WHA" which is to consider the proposals. Privileging the select US proposed amendments over other Member States would not be fair if adoption is pushed for at the 75th WHA.

Marginalization of equity through a Member State process

As mentioned earlier, the draft report also contains a draft decision on the IHR amendment process. The draft decision text proposes a Member State process to *"convene between the Seventy-fifth and Seventy-sixth World Health Assemblies to take forward work on all proposed IHR-targeted amendments"*. Thus the mandate is with the Member State process and not with the WGPR. The Executive Board (EB) in decision EB150(3) of 26 January 2022 entrusted the WGPR *"to allow for discussions on strengthening of the International Health Regulations (2005), including through implementation, compliance and potential amendments"*.

Interestingly, the draft decision is silent on decision EB150(3). The EB took this decision on the basis of the interim report of the WGPR submitted to the EB, which sought time to address its primary mandate, viz., WHA resolution 74.7 (2021), to develop recommendations for strengthening WHO's preparedness and response to health emergencies after examining the findings and recommendations of various expert and review committees which reviewed the functioning of WHO and its Member States.

Decision EB150(3) clearly spells out the scope of amendment and it includes equity: *"Such amendments should be limited in scope and address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could*

not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner."

The draft decision is silent not only about decision EB150(3) but also on equity. The mandate of the Member State process, according to the draft decision, is to "take forward work on all proposed IHR-targeted amendments". This means the Member State process mandate, if this draft decision is adopted, will not include the scope under decision EB150(3) and therefore efforts to incorporate equity provisions in the IHR could be neglected. In the absence of reference to decision EB150(3), the US and other developed countries who are opposed to the inclusion of equity provisions in the IHR may argue that the WHA decision overrides the EB decision because WHA is the highest decision-making body of WHO.

One delegate familiar with the discussions said that many Member States are not very comfortable with the US co-chairing of the WGPR and cited examples of pushing the US amendment proposals as part of the recommendations for strengthening the IHR. According to an observer, there should be selection of new Co-Chairs for the working group once the mandate of the WGPR is extended to discuss IHR amendment proposals, because the current Co-Chairs' mandate ends with the 75th WHA.

Another IHR Review Committee?

The WGPR draft report seeks to establish another IHR Review Committee to further provide technical recommendations on IHR amendments. Sceptics of the proposal for the appointment of such a committee point out that Member States had arrived at the decision to amend the IHR during the WGPR deliberations and incorporated this as part of the WGPR report to the WHA Special Session. Further, the WGPR had considered reports of various committees and panels including the IHR Review Committee appointed pursuant to WHA resolution 73.1, which reviewed the functioning of the IHR

during the COVID-19 response. Thus the proposal for a new IHR Review Committee amounts to a reinvention of the wheel, according to critics, and also creates a situation where amendment proposals of Member States may not be treated equally in light of the US push for its amendment proposals to be considered first.

Some observers view this as an attempt by the WHO Secretariat to have control on the Member-State-driven IHR amendment process. These observers cite the fact that the suggestion to appoint a new IHR Review Committee came from the WHO legal advisor during the 8th session of the WGPR.

The draft decision for the WHA states: *"Proposed amendments to be submitted by 30 June, 2022. All such proposed amendments will be distributed by the Director-General to all States Parties without delay."* It further states: *"An IHR Review Committee to be established by the Director-General in accordance with Article 50(1)(a) of the IHR, with particular attention to be paid to the fulfilment of the letter and spirit of Article 51(2)."*

Article 50(1)(a) allows the IHR Review Committee to *"make technical recommendations to the Director-General regarding amendments to these regulations"*. There is no clarity regarding the term "technical recommendations". There is also no clarity on whether this IHR Review Committee would examine the proposals submitted by Member States. Such an exercise would go against Member States' prerogative to propose amendments. There is nothing in the IHR on all amendment proposals requiring technical recommendations from an IHR Review Committee.

It must be noted that Article 51(2) provides that: *"The Director-General shall invite the Member States, the United Nations, and its specialized agencies and other relevant intergovernmental organizations or non-governmental organizations in official relations with WHO to designate representatives to attend the Committee sessions. Such representatives may submit memoranda and, with the consent of the Chairperson, make statements on the subjects under discussion. They shall not have the right to vote."*

This could be used to legitimize the IHR Review Committee process and then pressurize Member States to drop proposals which

are not part of the recommendations of the Committee. There are also concerns that such an IHR Review Committee can undermine the interests of developing countries in the name of technical recommendations and promote the interests of developed countries instead.

The draft decision in the WGPR's draft report states that the IHR Review Committee is to submit its report to the Director-General by October 2022. However, the Member State process is to be convened no later than September 2022. With this timeline, the Member State process may not have much time left for textual negotiations on the IHR amendment proposals since there should be at least another round of discussions on the technical recommendations provided by the IHR Review Committee (if such a Committee is to be set up). This is one of the practical concerns which will affect developing country participation.

Other concerns

Promotion of summary discussions and the undermining of developing country interests: The WGPR piggybacking on the lack of time not only promotes summary and accelerated discussions on its draft decision text for the 75th WHA at the last minute, but is also seen as promoting the interests of select Member States such as the US and other developed countries to the detriment of developing country Member States' interests. This is well evident from the way several recommendations have been included in the draft report which had undergone very little discussion. For example, inclusion of strengthening ("harmonization") of regulatory systems under the recommendations for equity has never generated any sort of convergence; only developed countries like the US and European Union countries have been promoting this as an element of equity.

Use of the term "pandemic" instead of "health emergencies": The WGPR draft report uses the term "pandemic" in several instances, a term that is not found in the IHR. This will limit the application of the technical recommendations to only public health emergencies of international concern (the term used in the IHR) that are pandemic in scale, whereas the mandate of the WGPR according to WHA

resolution 74.7 is strengthening WHO preparedness and response to "health emergencies". This narrowing of the scope of the new recommendations is a serious concern, because developing countries require international assistance and WHO-coordinated responses to non-pandemic-scale emergencies like Ebola.

Promotion of WHO initiatives such as WHO BioHub and Hub for Pandemic and Epidemic Intelligence without referring to an access and benefit-sharing (ABS) mechanism: During the COVID-19 response, several initiatives such as the WHO BioHub and the Hub for Pandemic and Epidemic Intelligence were launched by the WHO Secretariat without adequate Member State involvement. The draft report seeks to have Member States discuss the sustainability of these "innovative mechanisms" beyond a COVID-19 response, without referring to the development of a comprehensive WHO ABS mechanism which should ensure that these new mechanisms abide by the objectives and principles of the Convention on Biological Diversity and its Nagoya Protocol, especially the obligation to fairly and equitably share the benefits arising from the utilization of genetic resources.

Promotion of multi-stakeholder engagement without reference to the FENSA principles: The draft report not just promotes but intensively focuses on multi-stakeholder engagement, including with the private sector, in health emergency preparedness and response. Unfortunately, there is no reference to the WHO Framework of Engagement with Non-State Actors (FENSA), which would help avoid conflicts of interest among the non-State actors who are engaged in health emergency preparedness and response.

No reference to the existing provisions of the IHR which can enhance Member State cooperation and collaboration: Though it has several recommendations which require good-faith cooperation and collaboration from Member States, the draft report hardly refers to IHR Articles such as Articles 5(3), 13(3), 13(5), 42 and 44. A recommendation to WHO to actively use these provisions or other provisions like Article 43(4) and 43(5) would have been very effective in strengthening WHO preparedness and response to health emergencies, as well as Member State cooperation and collaboration in health emergency preparedness and response.

TWN Info Service on Health Issues (May22/07)
23 May 2022

EU says "no" to equity in health emergencies in the WGPR recommendations

Geneva, 23 May (TWN) – The European Union has said no to expanding the scope of equity-related measures to "health emergencies" and insisted on limiting it to "pandemics" as part of the recommendations of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR).

Differences over this matter blocked consensus on the adoption of the WGPR report, which was subjected to the "silence procedure". TWN learnt that two Member States broke the silence and blocked its adoption. As a result, the WGPR Bureau carried out a few more textual edits and placed the document for another round of silence procedure.

[The "silence procedure" was first introduced in the United Nations General Assembly as a temporary method to accommodate decision-making during the COVID-19 period when intergovernmental negotiations were forced to be held in virtual format. The usual process is that a draft of a decision or resolution is circulated to all Member States, allowing at least 72 hours for raising any objection. In the absence of an objection, the draft is considered to be adopted.]

The 9th session of the WGPR was held on 4–6 May to finalize its report to the 75th World Health Assembly (WHA) as mandated under resolution WHA74.7. Failing to reach a consensus on the draft report, the session was suspended without finalization of the text. Resumed meetings spread across the last two weeks were concluded on 17 May.

The replacement of the word "pandemic" with "health emergency" would expand the scope of equity and have the potential to address the current inequities in the global health emergency regime. Limiting to pandemics will reduce the scope to only extreme health emergencies of the scale of COVID-19, which occur rarely. Pandem-

ics occur much more infrequently when compared with the frequency of public health emergencies in general. Capacities developed solely for pandemic response cannot therefore be put in use regularly and this will result in the deterioration of the capacities as well.

Contrary to the consensus reached on the first day of the 9th session to replace "pandemics" with "health emergencies", except in the paragraphs relating to a new pandemic instrument being developed in the WHA-mandated intergovernmental negotiating body (INB), the EU refused to use the term "health emergencies" in several crucial parts of the WGPR report. Interestingly, the WGPR Bureau also supported the EU and asked developing countries not to press their demand, citing the lack of time. Several Member States (both developed and developing countries) recalled that the mandate of the WGPR was "health emergencies", not just "pandemics". As a result, Brazil kept a reservation on two paragraphs, 3 and 4(a), of the report. These paragraphs refer to the tables containing possible actions that are recommended for further consideration by Member States, the WHO Secretariat and non-State actors. They read as follows:

"(3) To encourage Member States to continue reviewing the actions contained in Tables XX, including through relevant ongoing WHO governing body processes.

"(4) To request the Director-General to: (a) submit a report to the Seventy-sixth World Health Assembly on (i) the Secretariat's progress to implement actions which have been previously mandated by WHO's Governing Bodies and which are related to the activities mentioned in paragraph 3, in accordance with existing reporting requirements; and (ii) as appropriate, views from the WHO Secretariat on possible modalities for carrying forward the activities mentioned in paragraph 3 which are not presently under implementation; and…."

The EU's opposition to the term "health emergencies" casts doubt on its professed intentions behind its advocacy for addressing equity through a new instrument specifically for pandemics. The intention of the EU is now clear, in that it wants to limit equity by using the language of "pandemic" such that several other health emergency

events like Ebola or Zika virus outbreaks can be excluded from the scope of equity provisions of the new instrument.

The Zero Draft report and state of play during the 9th WGPR

The Zero Draft report from the WGPR Bureau had been circulated to Member States for their written inputs from 19 to 26 April, with a view to incorporating the comments and making the draft report fit for negotiations during the 9th session of the WGPR. However, many Member States, especially developing countries, noted that their written inputs were not yet incorporated into the text of the published draft on 3 May.

The Zero Draft had four sections and two annexes. The sections were on: (1) background, mandate and scope of the WGPR; (2) short summary of process and analysis, including pathways for implementation of recommendations; (3) recommendations to WHA75; and (4) the decision point. The annexes provided some inferences from a WGPR survey, which was another attempt by the WGPR Bureau and developed country Member States to blindside deliberations in the WGPR. It must be noted that these annexes carry no significance since the WGPR survey failed to be truly representative of Member State opinions.

The third section contained various recommendations addressing Member States, the WHO Secretariat and non-State actors under the following headings: (1) political leadership, (2) cooperation and collaboration; (3) WHO at the centre; (4) financing; (5) sustainability of the WHO initiatives during the COVID-19 response: (6) global surveillance; (7) strengthening the International Health Regulations (IHR); (8) universal health and preparedness review; (9) travel measures; and (10) equity. Under each heading, there were paragraphs describing the general understanding on the recommendations and then tables reflecting specific actions that are proposed for the consideration of WHA75.

However, many of the recommendations prepared by the WGPR Bureau in the Zero Draft favoured the interests of developed countries. For instance, recommendations under the strengthening of

the IHR reflected the IHR amendment proposals of the US, currently separately considered.

Other shortcomings of the Zero Draft were as follows:

- Many recommendations were limited to "pandemics", inconsistent with the mandate of the WGPR, which requires the Working Group to address health emergencies.
- The report did not contain any reference to WHO Executive Board (EB) decision 150(3), which describes the nature of the IHR amendments to be pursued.
- It promoted several WHO Secretariat initiatives such as the WHO BioHub and Hub for Pandemic and Epidemic Intelligence without adequate reference to the requirement of fair and equitable benefit sharing under the Convention on Biological Diversity and its Nagoya Protocol.
- It promoted multi-stakeholder engagement without adequate reference to the principles of the WHO Framework of Engagement with Non-State Actors (FENSA).
- Many recommendations on equity were general in nature and did not contain concrete deliverables. Above all, according to EB decision 150(3), one of the identified issues to be addressed in the IHR amendments is the equity issue. However, not only were the recommendations on equity half-baked but the reference to this decision was also conspicuously absent in the draft report.

During the first day of the 9th WGPR session, almost all developing countries took the floor to reiterate the need to stick to the WGPR's mandate, i.e., to replace "pandemics" with "health emergencies" and thus expand the scope of the applicable recommendations from pandemics to health emergencies.

The WGPR Bureau then sought to discuss other topics and promised to change the language in the revised version. The developing countries, believing the Bureau, continued their efforts to make other textual edits and submit new textual suggestions to the report in order to make it a true reflection of their recommendations. They were able to place specific discussion and action points for the

future to buy time for submitting IHR amendment proposals, and pushed back on several recommendations favouring the US and EU.

The developed country Member States, especially the EU and US, were alarmed at seeing developing countries from various regions speaking with one voice, and cited lack of time to argue that there should be very minimal negotiations on the report. This led to the opening up of two parallel tracks of work in the WGPR, after initial inputs by the Member States. Colin McIff, the US Co-Chair of the WGPR Bureau, along with a few others, reportedly worked on the basis of inputs received from Member States and revised the tables containing the possible actions, while the rest of the WGPR negotiated on the report, excluding the tables.

EU's opportunism

When the resumed sessions continued on 12, 13 and 17 May, a revised text of the draft report was circulated which was substantially altered based on inputs received from Member States during the initial three days. The major negotiations continued to focus on the parts other than the revised tables on the first two days. It was only on the last day, 17 May, that the tables and the corresponding decision points were brought into the discussion. Member States were generally accommodative of the draft tables produced under the Bureau leadership; however, they were later moved from the main text to Annex 3.

Though these amended tables contained various suggestions of developing countries, in certain crucial recommendations, such as on equity, the scope of the recommendation was again limited to the pandemic context. On 17 May, many developing countries, including Brazil, Bangladesh, India, Paraguay, Argentina, China and the whole of the African Region, demanded the replacement of the term "pandemic" with "health emergency" in those recommendations as well. They requested the Bureau to keep to its word. Russia too reportedly supported this stance.

The EU, however, stormed the floor with opposition. The EU said that in order to address concerns over "lack of time", the lan-

guage developed by the Bureau in the tables must be adopted into the report without negotiations. According to the EU, the Bureau had done a fabulous job of taking into account various suggestions made by all countries in the initial days and the tables represented a decent capture of "possible actions" that could be further discussed. The US and other developed countries extended support to the EU.

Brazil pointed out at least two specific actions mentioned in the report to stress upon the need to change the wording – they were actions affecting equity, transparency, solidarity, research collaboration and cooperation. It requested the Bureau to review the table text once again to carry out the changes which should have been made even before the negotiations began on 17 May. The two actions pointed out by Brazil in the table were:

Table 2a, Action 8: "WHO to develop or strengthen guidelines to promote transparency in public funding research and development related to pandemics to promote measures to support technology transfer and commitment to voluntary licensing."

Table 5, Action 3: "R&D and all other relevant processes in Member States to be driven by a goal and strategy to rapidly and effectively respond to health emergencies in a manner that prevents pandemics and promotes equitable and effective access at national and international levels, especially in developing countries."

Some other actions in the tables also used "pandemics" instead of "health emergencies", such as:

Table 3, Action 1: "Member States to support research efforts to inform and expand capacity for effective public health and social measures during pandemics to underpin preparedness & readiness efforts, including in the formulation of emergency guidance and advice."

Table 3, Action 4: "WHO Secretariat to facilitate and support efforts to build evidence and research on the effectiveness of public health and social measures and non-pharmaceutical interventions during pandemics to underpin preparedness and readiness efforts, including the formulation of emergency guidance and advice."

Table 2a was on "equity", Table 5 on "sustainability of WHO innovative mechanisms", and Table 3 on "cooperation and collaboration".

However, immediately after the Brazilian request, the EU took the floor and said that the text inside the table could not be altered at any cost. The US, Monaco, Australia and the UK supported the EU.

A developing country delegate reported that the WGPR Bureau behaved as if they were helpless on the last day. "If this was their capacity, they should have let us know in the initial days itself; we would have marked all the references to pandemics in the report and ensured the changes are made in the meeting room itself," the delegate remarked.

India, supporting Brazil, stated that there was nothing wrong in altering the text in the table, because it would only be consistent with other paragraphs which were already agreed upon. India also pointed out that to use "pandemics" inside the table would create inconsistencies between the two parts of the report. The EU then came up with a suggestion to acknowledge the said inconsistency in the chapeau to the tables.

Brazil finally requested the Bureau to add a sentence in the chapeau that the word "pandemics" in Table 2(a) Action 8 and Table 5 Action 3 may also be read as "health emergencies". Russia supported Brazil and said incorporating "for example" before the sentence suggested by Brazil could solve the concern. However, the EU and the WGPR Bureau reportedly pushed to delete that sentence as well.

The chapeau after negotiations read as follows: *"The section below is provided for further consideration for action by Member States, the WHO Secretariat, and non-State actors, especially ones that could be taken up, as appropriate, through MS-led processes and through the technical work of WHO. The WGPR recognized that these actions need to take into account national context, addressing conflicts of interests and the application of FENSA for WHO-related actions. The WGPR emphasized that the tables represent a snapshot of the progress made as a work product of the bureau, they may have differences with the language in the main body of the report and acknowledged that a number of issues identified below will require*

more discussion by Member States through relevant ongoing WHO governing bodies processes including in the INB (on a new pandemic instrument) and WGIHR (Working Group on IHR amendments).”

Bangladesh reportedly pointed out that countries from more than three regions were making their request to abide by the consensus. It further explained that these countries covered more than 60% of the world population, and in the interest of providing them equity, the WGPR must stick to the consensus and its mandate. The EU reportedly responded by saying that “population size does not make any country or region right or correct in their argument”.

The Vice-Chair of the WGPR Bureau, a representative of France, suggested asking the floor whether there was any opposition to altering the text, and that changes should not be made if there was a single Member State opposing it. The WGPR Co-Chair quickly asked the question and the EU opposed. Russia told the Co-Chair and Vice-Chair that the question asked was wrong, explaining that the question should have been whether there was any Member State wishing to go back on the consensus made on the first day. The WGPR Bureau reportedly did not respond to Russia at this instance.

Brazil eventually kept its reservation on the paragraphs in the decision point pertaining to the tables, paragraphs 3 and 4(a). The report was therefore finalized without obtaining consensus and put into the silence procedure. Reportedly two countries broke the silence, and a second round of silence procedure was initiated until 5:30 PM CET on 21 May.

According to sources, the WGPR Bureau reconvened itself and has since circulated a revised chapeau to the tables as well as paragraph 3 of the decision point.

The revised chapeau now includes a footnote which reads: *“The WGPR noted that some of the terms used in the tables, including inter alia ‘health emergencies’ and ‘pandemics’, have not been defined for the purposes of this report.”*

The chapeau also additionally contains a clause which says the language of the tables does not prejudge the results of discussions that may happen in relevant governing bodies or other forums such

as the intergovernmental negotiating body on a new pandemic instrument or the Working Group on IHR amendments (WGIHR).

The revised decision point further reads as follows: *"Ad ref (3) To encourage Member States to continue to review and consider the possible actions contained in Annex 3, in relation to health emergency prevention preparedness and response, including through relevant ongoing WHO governing body processes, while noting that those possible actions are complementary and additional to existing mandates already under implementation by the Secretariat"*.

At the time of publishing this article, it is reported that the second silence procedure was completed without challenges, and the final report is now available in the WHA75 documents webpage. The phrase *"ad ref"* qualifying paragraphs 3 and 4(a), indicating Brazil's reservations, has been removed in the final report.

TWN Info Service on Health Issues (May22/08) 23 May 2022

Attempt to limit equity in health emergency to pandemics

Geneva, 23 May (TWN) – The survey on an indicative list of substantive elements for a new pandemic instrument raises concerns that it strengthens attempts to limit equity to a pandemic context and thus generally legitimizes existing inequities in the global health emergency preparedness and response regime.

The Bureau of the Intergovernmental Negotiating Body (INB) established pursuant to the World Health Assembly (WHA) Special Session decision WHASS2(5) had initiated the survey. The questionnaire sought the response of WHO Member States and non-State actors in official relation with WHO on 58 substantive elements and the deadline for response was 29 April.

These 58 elements in the survey are categorized as follows: (1) 16 elements on "equity", (2) 10 on "leadership and governance", (3) 20 on "systems and tools", (4) five on "finance", and (5) seven as "elements from other WHO instruments".

The equity elements are limited to the pandemic context. This raises concern on whether the proposed pandemic instrument is another attempt to limit the equity question only to pandemics and thus whitewash the failure to address issues related to equity in other health emergencies.

The WHO deliberations on the scope of a new instrument are limited to a new pandemic instrument. Though relevant bodies such as the INB or the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) have not provided any clarity on the precise scope and meaning of the term "pandemic", the limited scope of "pandemic" would limit the preparedness and response elements of a new instrument to pandemics or potential pandemics. As a result, the equity elements contained in the new pandemic instrument may not be applicable to other health emergencies including public health emergencies of international concern (PHEIC) that are the basis of the International Health Regulations (IHR).

The following 16 equity-related elements are listed in the survey:

1. Access to lifesaving, scalable and safe clinical care, including mental health care
2. Access to quality, agile, and sustainable health services for universal health coverage
3. Access to technology and know-how
4. Affordability of pandemic response products, including medical countermeasures
5. Availability of and timely access to pandemic response products, including medical countermeasures
6. Equitable access to emergency financial mechanisms
7. Equitable gender, geographical and socioeconomic status representation and participation in global and regional decision-making processes
8. Equitable representation in global networks and technical advisory groups

9. Increased national, sub-regional and regional manufacturing capacity for pandemic response products, including medical countermeasures
10. National capacity strengthening to prevent, prepare for and respond to epidemics and pandemics, including for R&D
11. Pandemic countermeasure strategic stockpiles and their equitable distribution
12. Policy to safeguard vulnerable populations most affected by pandemics
13. Prioritize access to pandemic response products, including medical countermeasures for healthcare workers
14. Rapid, regular and timely pathogen and genomic sequence sharing and related benefit sharing, including for the development and use of diagnostics, vaccines and therapeutics
15. Scalable scientific and technical cooperation and collaboration
16. Strengthened national regulatory authority capacity on licensing medical countermeasures.

The equity elements listed above do not take into consideration the developmental divide existing between Member States and are couched in general language without any specific reference to the special needs of developing countries. Though the IHR recognize the needs of developing countries, this is in a vague and limited fashion and fails to translate the equity elements into concrete deliverables.

There are no specific, differentiated and concrete obligations in the IHR for the developed countries to provide financial and technological assistance to developing countries, either to build health emergency preparedness and response capacities or to strengthen their health systems' resilience to infectious disease outbreaks. Moreover, the provisions for collaboration and assistance in the IHR are triggered only when there is a chance of international spread of infectious diseases, leaving Member States without adequate assistance to address their local outbreaks of disease. Interestingly, the preamble of the WHO Constitution states that *"the achievement of any State in the promotion and protection of health is of value to all"* and identifies *"unequal development in different countries in the*

promotion of health and control of disease, especially communicable disease", as a common danger.

Nevertheless, the IHR failed to recognize the common value and common danger except for Article 44(2)(c) wherein WHO is required to collaborate with State Parties upon request in mobilization of financial resources specifically for developing countries for capacity building in the core areas identified in the IHR. The indicative list of the equity elements in the INB survey is no different and does not rectify the existing failure. There is absolutely nothing indicative of more binding concrete commitments from developed countries.

The WHO Executive Board (EB) decision 150(3) requires issues of equity to be addressed in the IHR amendments, and this was reinforced in certain Member State statements in the WGPR sessions following the EB150 session.

For instance, during the 8th session of the WGPR, Botswana on behalf of 47 African States reiterated the African Region's position expressed during the 7th session. It stated: *"As we have indicated during the 7th meeting of the WGPR, the Africa Member States propose that equity should be addressed both within the IHR (2005) amendments as well as the new international instrument (INB). Therefore equity provisions proposed in the IHR (2005) should be complemented in zero draft prepared by the INB with cross referencing to relevant IHR (2005) provisions. It is critical that the IHR (2005) address the current inequities in order to ensure balanced rights and obligations in health emergency response including to facilitate accessibility, availability and affordability of health products including the sharing of technology and know-how for scaling up local production, as well to address the unilateral decisions like travel bans, restrictions on movement of goods and information on diseases outbreaks that has been reported under the IHR (2005)."*

However, the list of equity elements in the survey shows no preference to cross-refer to the IHR or to public health emergencies of international concern. This shows the new pandemic instrument is being envisaged as a super-specialized instrument dealing with only pandemic-scale health emergencies, further verticalizing the public

health policy of WHO. This is alarming as it would further earmark and fragment the financial, technical and technological resources available with WHO to address public health emergencies.

The highly inadequate response of the international community to health emergencies like Ebola and COVID-19, and their near-neglect of regional or small-scale outbreaks of disease are well documented. When the Ebola outbreak in the Democratic Republic of Congo was declared a "PHEIC", after the fourth Emergency Committee meeting, one of the major considerations was that the global community has not contributed sustainable and adequate technical assistance, human or financial resources for outbreak response, despite previous recommendations for increased resources by the Committee. The Committee specifically stated that the declaration of a PHEIC is a measure that recognizes "the need for intensified and coordinated action to manage them".

It must be noted that a pandemic is much beyond an extraordinary event with potential risk of international spread of disease, and it requires presence of disease in multiple regions of the world, perhaps an intercontinental spread of disease. Amongst the six PHEICs declared after the adoption of the IHR 2005, only H1N1 and SARS-CoV-2 were identified as pandemic. A pandemic instrument without adequate reference to the IHR is going to create an entire new set of governing institutions, systems and tools, and financial mechanisms to be earmarked and untouched except for rare outbreaks.

Limiting equity to pandemic or potential pandemic outbreaks would directly legitimize the existing inequities in the health emergency preparedness and response regime, including the lack of legal obligations on common but differentiated responsibilities, access to medical and health products, finance etc. Accordingly, the efforts to incorporate equity in the health emergency regime would be limited in scope and ignore the urgent needs of developing countries to address health emergencies other than pandemics and potential pandemics.

TWN Info Service on Health Issues (May22/11)
27 May 2022

Proposed new standing committee usurps powers of IHR 2005

Geneva, 27 May (Nithin Ramakrishnan) – The terms of reference (ToR) proposed for a new WHO Executive Board Standing Committee on Health Emergency Prevention, Preparedness and Response (SCHEPPR) raise concern as they seek to usurp powers of the International Health Regulations 2005 (IHR).

The proposed ToR text marked as "Chairs Draft after Informal Cons. April 1, 2022" had been informally circulated amongst Member States since 25 April. On 9 May, Austria organized an informal meeting at which several small delegations expressed their reservations. It is understood that the above version was "greened" (finalized) in the 9 May meeting with some changes, despite several countries' silence and non-participation.

The draft decision text that was finalized through the informal meeting was then opened until 12 May for Member States to become co-sponsors of the text. This decision text is currently available in the EB151 dashboard as a conference paper (EB151/CONF./1) dated 27 May 2022. According to operative paragraph 2, the 151st session of the WHO Executive Board (EB151) on 30 May is expected to approve the ToR text tabled after the 9 May informal meeting. The ToR are annexed to the draft decision text.

It is further understood that there was a suggestion from several Member States to consider the recommendation for a standing committee under the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) in order to bring coherence and to avoid too thin a spread. This was however not given attention by developed countries, including Austria, the originator of the SCHEPPR proposal.

According to the proposed functions under paragraph 5 of the ToR, the SCHEPPR, which will act as a standing committee of the EB, will have powers over cases that have not been determined as

public health emergencies of international concern (PHEICs) under the IHR. Also, in cases where a public health event is deemed a PHEIC, the proposal now requires the WHO Director-General to hold an extraordinary meeting of the SCHEPPR, as early as possible, in order to seek guidance and advice, through the EB.

Paragraph 5 of the ToR in the annex of the draft decision text states:

"The Standing Committee shall:

"a) In the event a PHEIC is determined pursuant to the International Health Regulations (2005): Consider information provided by the Director-General about the event that has been determined to constitute a public health emergency of international concern ('PHEIC') and, as appropriate, provide guidance to the Executive Board and advice to the Director-General, through the Executive Board, on matters regarding health emergency prevention, preparedness and response, and immediate capacities of the World Health Organization Emergencies Programme; and

"b) Outside of the cases where a PHEIC is determined pursuant to the IHR (2005): Review, provide guidance and, as appropriate, make recommendations to the Executive Board regarding the strengthening and oversight of the WHO Health Emergencies Programme and for effective health emergency prevention, preparedness and response."

The draft decision is sponsored by Austria, Canada, the European Union and its Member States, Japan, Moldova, Switzerland, the UK, the US and Vanuatu.

SCHEPPR seeks powers beyond the constitutional mandate

The EB itself does not have such wide-reaching powers under the WHO Constitution. Under Article 28 of the WHO Constitution, the functions of the EB are limited as an executive organ of the World Health Assembly, except for taking up some emergency functions as mentioned in clause (i) of Article 28. Even there, the Article limits EB functions to certain specific purposes.

Article 28(i) of the WHO Constitution states: *"(i) to take emergency measures within the functions and financial resources of the Organization to deal with events requiring immediate action. In particular it may authorize the Director-General to take the necessary steps to combat epidemics, to participate in the organization of health relief to victims of a calamity and to undertake studies and research the urgency of which has been drawn to the attention of the Board by any Member or by the Director-General."*

The EB thus has power to combat epidemics or address victims of calamities and to undertake research. But through paragraph 5(b) of the ToR, the newly proposed SCHEPPR can act over any public health event, not just an epidemic, and also even if the event is not determined as a PHEIC under the IHR. This far exceeds the functions under Article 28(i) of the WHO Constitution.

It must be noted that WHO, right from its establishment, was dealing with only specific infectious diseases, until the IHR 2005 were adopted. The IHR 2005 are the revised version of the IHR 1969 which dealt with specific diseases. WHO Member States which revised the IHR were very careful not to accord WHO and the international community excessive power to intervene in the health affairs and policy of the Member States. The definition of PHEIC was therefore adopted under Article 1 and the criteria for determining the PHEIC status of any public health event were laid down in Article 12 of the IHR 2005.

The actions of WHO and the international community in the area of health emergencies are therefore limited and bound by the legal instrument, the IHR 2005. It must be noted that WHO's functions on sharing of information are also governed by Article 11 and there are very limited actions which WHO can pursue itself in non-PHEIC events.

Furthermore, the IHR 2005 authorize the WHO Director-General to take actions in the event of a PHEIC. The EB is not actually bestowed with such specific authorizations. For example, Article 15 of the IHR 2005 authorizes the DG to make temporary recommendations during a PHEIC to effectively respond to the PHEIC. The term "Executive Board" is mentioned only once in the IHR 2005, and

that too, only to receive the reports from the IHR review committee through the DG under Article 52(3). The DG is also not required to call an extraordinary EB meeting or a sub-committee meeting of the EB under the IHR 2005.

For all these reasons, the functions of the EB under Article 28(i) can only be delivered by the EB in a manner not prejudicial to the processes under the IHR 2005. However, paragraph 5 of the proposed ToR of the SCHEPPR is an attempt by the EB to acquire authority in an area in which it has no mandate provided either by the World Health Assembly or by the legal instruments of WHO, including its Constitution. The proposed paragraph 5(b) of the ToR, in particular, bypasses the limitations laid down by the IHR 2005 and allows the standing committee to provide guidance and to make recommendations to the EB *even when cases are outside the scope of the IHR 2005*.

Further, paragraph 8 of the ToR reads: *"In the event a PHEIC is determined pursuant to the International Health Regulations (2005), the Director-General shall convene an extraordinary meeting of the Standing Committee as soon as reasonably practicable, and ideally within 24 hours following the determination of the PHEIC."*

However, it must be noted that there is no requirement for the DG to hold an extraordinary or special session of the EB under the IHR 2005 in response to a PHEIC. Therefore, such a mandate can only be effective after amendment of the IHR 2005. The EB cannot suo moto acquire powers in the subject matter which are already decided by the World Health Assembly.

Further, paragraph 8 of the ToR means, in effect, that the work and advice of the SCHEPPR will have influence on the DG, even before the EB deliberates upon such advice. For example, if a PHEIC is determined in the month of February, a SCHEPPR meeting will be organized in the same month, but the EB will be meeting only in May if an extraordinary meeting is not called for. This will result in the DG looking to the SCHEPPR for all practical and immediate purposes until the EB is constituted. This is inconsistent with paragraph 5(a) of the ToR, which says the SCHEPPR may provide advice to DG "through the EB".

These are serious interferences with the DG's powers and these changes can only be made by suitable amendment of the IHR 2005 by the World Health Assembly. In a way, the proposed SCHEPPR is expanding WHO's role and authority over public health events beyond the scope of the IHR 2005, to which Member States in the World Health Assembly have not given their consent.

Under Article 38 of the WHO Constitution, the EB has powers to establish committees on its own initiative (as in the case of the SCHEPPR) but they must be considered desirable to serve any purpose "within the competence of the Organization."

When the World Health Assembly has exercised its authority and established a mechanism to deal with a subject, that settles the boundaries of the competence of the Organization. The EB, therefore, cannot on its own initiative expand the scope of the competence or alter the method of exercise of the authority which was decided by the Health Assembly. Unfortunately, the proposed ToR for the SCHEPPR do exactly this. They propose to the EB to appropriate or usurp powers and roles in health emergency governance, which is a matter in which the Health Assembly has already developed methods for exercising the power and authority of WHO.

Imbalanced composition of the SCHEPPR

Paragraph 1 of the ToR sets out the composition of the proposed SCHEPPR: *"The Standing Committee on Health Emergency Prevention, Preparedness and Response ('the Standing Committee') shall be composed of 14 members, two from each region, selected from among Executive Board members, as well as the Chair and a Vice-Chair of the Board, ex officio, in line with the principles set out in Rule 18 of the Rules of Procedure of the Executive Board, reflecting a balanced representation of developed and developing countries. Members of the Standing Committee shall serve for two years."*

To have a balanced geographical representation between developed and developing countries, a 12-strong membership would be better suited, i.e., two from each of the WHO regions. Inclusion of the Chair and Vice-Chair of the EB as ex-officio members not

only creates an imbalance in the composition but also provides a potential added advantage to the developed countries. As far as the current system of representation in the EB is concerned, the US has almost a permanent representation on the Board and the EU has a disproportionate representation too. This may result in the SCHEPPR tilting towards the interests of developed countries.

Although meetings of the SCHEPPR would be open to Member States according to paragraph 11 of the ToR, the extent of their participation is not clear. Paragraph 4 only states that "Member States in whose territory an event arises shall be invited to present their views to the Standing Committee." Nevertheless, there is no mandate for the SCHEPPR to take into account the views of such affected Member States. Paragraph 6 only says: "In performing its functions, the Standing Committee shall take into account the work of other relevant WHO instruments and bodies, as appropriate."

Further, it must be noted that while the SCHEPPR is mandated to be respectful of the scientific evidence provided by the IHR Emergency Committee in its actions, there is no corresponding requirement in the ToR to take into account "issues of equity" in the implementation of recommendations of the Emergency Committee or of the DG.

Participation of observers and experts in the committee

According to paragraph 3 of the ToR, the Chair and the Vice-Chair of the proposed SCHEPPR, in consultation with the DG, "may invite observers" to "attend a meeting of the Standing Committee without the right to vote", if they consider that this would enhance the work of the Standing Committee on a specific item or items on the agenda of the meeting.

Further, according to the same paragraph, the Chair and the Vice-Chair, in consultation with the DG, "may invite experts" to attend a meeting of the Standing Committee "to provide advice", as appropriate.

The word "observers" is explained in a footnote, according to which not all organizations in official relationship with WHO are included. The footnote reads: *"For the purposes of attending and addressing the Standing Committee reference to 'observers' is understood as referring to the Holy See; Palestine; Gavi, the Vaccine Alliance; the Order of Malta; the International Committee of the Red Cross; the International Federation of Red Cross and Red Crescent Societies; the Inter-Parliamentary Union; the Global Fund to Fight AIDS, Tuberculosis and Malaria; the United Nations and other intergovernmental organizations with which WHO has established effective relations under Article 70 of the Constitution; the European Union; and any other body so authorized for these purposes by the Executive Board."*

Accordingly, though civil society organizations and other non-State actors would be excluded from SCHEPPR meetings, representatives from multi-stakeholder entities like Gavi, the Vaccine Alliance and the Global Fund may be invited to attend. This approach will promote multi-stakeholderism in health emergency governance and compromise the leading and central role of WHO in health emergency preparedness and response.

DG's white paper seeks to legitimize the SCHEPPR proposal along with GHEC and UHPR

On 4 May, the WHO DG had issued a white paper for consultation titled "Strengthening the Global Architecture for Health Emergency Preparedness, Response and Resilience", with an objective to "support and contribute to decision-making in the various fora within and beyond WHO that will determine the future global architecture of HEPR."

The DG's first proposal on governance is to have a Global Health Emergency Council (GHEC) which will complement the proposed SCHEPPR. The DG proposes that creation of the GHEC could "be linked with the creation of a Standing Committee on Health Emergencies as a sub-committee of the Executive Board. In considering

this proposal, Member States may wish to consider establishing this alternatively as a committee of the World Health Assembly to:

- Review the work of WHO under GPW-13 Pillar 2: One billion more people better protected from health emergencies
- Act as a conference of State Parties to the International Health Regulations
- Act as the peer review mechanism for the Universal Health and Preparedness Review (UHPR)."

It must be noted that neither the GHEC nor the Standing Committee, be it of the EB or the World Health Assembly, especially with a limited membership, can be a legitimate body to act as a conference of State Parties to the IHR, or as a peer review mechanism for the UHPR. In such an arrangement, a small number of States, especially developed countries, can exercise their influence on or pressure other State Parties to the IHR, especially developing countries.

Part 2 – **Text-based negotiations**

TWN Info Service on Health Issues (Oct22/01)
6 October 2022

DG aims to control IHR amendment content through IHR Review Committee

Geneva/Kochi, 6 October (Nithin Ramakrishnan and K.M. Gopakumar) – The World Health Organization Director-General (DG) is aiming to control the content of the amendment of the International Health Regulations (IHR) 2005 through the IHR Amendments Review Committee (RC).

The draft terms of reference (ToR) provide a wide-ranging mandate to the Committee, to even reformulate the amendments proposed by IHR States Parties. This is inconsistent with the World Health Assembly (WHA) decision WHA75(9) and Article 50 of the IHR 2005. WHA75(9) requested the DG to convene an IHR Review Committee to make "technical recommendations on the amendments" proposed by various States Parties in accordance with the scope of Article 50(1)(a) of the IHR 2005 and to submit its report no later than 15 January 2023.

The proposed scope of work in the draft ToR for the Review Committee allows the RC to reformulate the amendments proposed by WHO Member States, including by partially or totally removing Member States' text proposals. The draft ToR also propose an extended timeline to submit its final report in January 2024, i.e., long after the negotiations began between Member States. Thus, there are concerns that the proposed ToR reflect an attempt to prejudge the outcome as well as process of IHR amendment.

WHA75(9) also invited States Parties to submit their proposals for amending the IHR 2005 before 30 September 2022. As of that date, several States Parties had proposed amendments, including Armenia; Bangladesh; Brazil; Czech Republic on behalf of the Member States of the European Union; Eswatini on behalf the WHO African Region Member States; India; Indonesia; Japan; Namibia; New Zealand; Russian Federation on behalf of the Member States of the Eurasian Economic Union; Switzerland; United States of Amer-

ica; and Uruguay on behalf of MERCOSUR. It is learnt that a good number of developing countries' proposals stress the importance of advancing obligations of States and WHO for realizing equitable access to health products and technologies required for public health emergency preparedness and response.

However, the draft ToR attempt to limit such proposals being taken forward by raising leading questions as to the compatibility of the proposals with the objective and scope of the IHR 2005 as well as with other international legal instruments both within and outside of WHO. Interestingly, some of the ToR corresponds to work in progress in other forums and documents which have no Member State consensus.

According to WHA75(9), the RC is to function *"in accordance with Part IX, Chapter III, of the International Health Regulations (2005), in particular Article 50, paragraphs 1(a) and 6, with particular attention to be paid to the fulfilment of the letter and spirit of Article 51, paragraph 2, to make technical recommendations on the proposed amendments referred to in sub-paragraph (c) below, with a view to informing the work of the WGIHR [Working Group on Amendments to the International Health Regulations 2005]".*

[Article 50(1)(a) of the IHR 2005 states: *"The Director-General shall establish a Review Committee, which shall carry out the following functions: (a) make technical recommendations to the Director-General regarding amendments to these Regulations."*

[Article 50(6) states: *"The Director-General shall select the members of the Review Committee on the basis of the principles of equitable geographical representation, gender balance, a balance of experts from developed and developing countries, representation of a diversity of scientific opinion, approaches and practical experience in various parts of the world, and an appropriate interdisciplinary balance."*

[Article 51(2) states: *"The Director-General shall invite Member States, the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO to designate representatives to attend the Committee sessions. Such representatives may submit*

memoranda and, with the consent of the Chairperson, make statements on the subjects under discussion. They shall not have the right to vote."]

Accordingly, the WHO DG will be convening the IHR RC on 6 October 2022. The list of members of the RC will only be published after its first meeting. It will be a "closed virtual meeting to elect Chair, Vice-Chair, and Rapporteur of the IHR Amendments RC, and define the Methods of Work".

Draft ToR: RC to do much more than provide "technical recommendations"

The proposed scope of work in the ToR contains the following four elements:

(1) Analysis of each of the proposed amendments to the IHR submitted no later than 30 September 2022;
(2) Proposals for reformulation and/or clarification;
(3) Analysis of the remaining provisions of the IHR;
(4) Overall consistency analysis, including of definition of terms.

The text explaining the four elements is as follows:

"i. Analysis of each of the proposed amendments to the IHR submitted no later than 30 September 2022 in terms of:

– *Consistency across proposed amendments in case multiple proposals are submitted to the same article;*
– *Pertinence vis-à-vis the purpose and scope of the IHR, as defined in Article 2;*
– *Pertinence vis-à-vis the article intended to be amended;*
– *Consistency with the Constitution of WHO;*
– *Consistency, where applicable, with other provisions contained in the article intended to be amended;*
– *Consistency with any other provisions of the IHR;*
– *Compatibility and consistency with provisions of other relevant WHO frameworks and relevant international legal instruments*

under the auspices of other intergovernmental and international organizations, such as:

- *the Pandemic Influenza Preparedness (PIP) Framework;*
- *the International Food Safety Authorities Network (INFOSAN, under the auspices of the Food and Agriculture Organization (FAO) and WHO);*
- *the WHO Global Surveillance and Monitoring System for substandard and falsified medical products (GSMS);*
- *Convention on Biological Diversity (CBD), relevant legal instruments of the following UN agencies: International Atomic Energy Agency (IAEA), International Civil Aviation Organization (ICAO), International Maritime Organization (IMO), Organization for the Prohibition of Chemical Weapons (OPCW), United Nations Human Rights Council (HRC), United Nations Office for Disarmament Affairs (UNODA), World Organization for Animal Health (OIE), World Trade Organization (WTO);*

– *Compatibility and consistency with the Working Draft of a WHO Convention, Agreement, or other International Instrument on Pandemic Prevention, Preparedness and Response (Document A/INB/2/3).*

"ii. Proposals for reformulation and/or clarification; e.g., rewording, rephrasing, inclusion of cross-references to other relevant articles of the IHR, inclusion of compliance monitoring elements – and/or consolidation, if/when necessary, of the text of the article intended to be amended, as well as of the text of any other article of the Regulations that needs amendments for the article intended to be amended to be applicable. Such proposals shall ensure the internal consistency, integrity, and robustness of the text of the IHR, as well as the compatibility and consistency with any other relevant international legal instrument under the auspices of intergovernmental and international organizations. Each of the above-mentioned proposals for reformulation and/or refinement by the IHR Amendments RC shall be accompanied by its rationale, including the reason/s why amendments proposed by States Parties

have not been totally or partially retained, or have been reallocated to an article different from the one initially intended to be amended.

"iii. Analysis of the remaining provisions of the IHR: for provisions that were not subject to proposals for amendments – to identify internal inconsistencies, inconsistencies vis-à-vis other international legal instruments

"iv. Overall consistency analysis, including of definition of terms: to advise on definitions of terms, either new or existing terms the meaning of which might be changed following the proposed amendments, to ensure clarity and consistency; as well as to advise on whether the inclusion, in the text of the IHR, of an explicit taxonomy related to the nature of amendments (e.g., targeted amendments, conforming amendments, technical adjustments, updates, 'reopening the instrument') is warranted and, if so, to formulate a proposal in that respect."

Thus, the draft ToR propose a clear mandate to the RC not only to examine the proposed amendments technically but also to undertake "reformulation and/or clarification; e.g., rewording, rephrasing, inclusion of cross-references to other relevant articles of the IHR". This goes beyond the mandate of decision WHA75(9). Further, the draft ToR state: "Each of the above-mentioned proposals for reformulation and/or refinement by the IHR Amendments RC shall be accompanied by its rationale, including the reason/s why amendments proposed by States Parties have not been totally or partially retained."

If the draft ToR are accepted, the RC will be able to reformulate the amendment proposals of the Member States. It can even partially or totally remove Member States' text proposals from the negotiating table in the Working Group on Amendments to the IHR 2005. This effectively creates a situation wherein only those proposals that pass the RC's scrutiny could be discussed within the WGIHR. The draft ToR therefore definitely go beyond the common understanding of the term "technical recommendations" used in Article 50(1)(a). Moreover, the power imbalances between developed and developing country Member States would most likely influence this decision

making about which proposals need to be on the negotiating table and how.

[The Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) was renamed the WGIHR to undertake the work on IHR 2005 amendments.]

The draft ToR also undermine the Member-State-led process of IHR amendment and even infringe upon the sovereign right of an IHR State Party to propose amendments. According to Article 55, which deals with amendments: *"Amendments to these Regulations may be proposed by any State Party or by the Director-General. Such proposals for amendments shall be submitted to the Health Assembly for its consideration."* There is no requirement under the IHR 2005 that the amendments proposed by any State Party should be submitted to the scrutiny of the RC.

In addition, WHA75 adopted part of the amendment proposals from the US without the scrutiny of the RC. The WHA decision 75(9), as mentioned above, also does not provide any mandate to the RC other than making "technical recommendations".

Prejudging scope of amendment and limiting Member States' prerogative

According to the draft ToR, the RC is to examine a proposed amendment's "pertinence vis-à-vis the purpose and scope of the IHR, as defined in Article 2" as well its "pertinence vis-à-vis the article intended to be amended", among other things.

This is under the presumption that there will not be any State Party proposal to change or expand the scope and objective of the IHR 2005. However, it was learnt that there have been a few proposed amendments to Article 2, which contains the purpose and scope of the IHR. The draft ToR thus limit the freedom to States Parties to change the status quo and propose amendments which expand or alter the scope of the current IHR articles.

The draft ToR further propose that the RC analyze the compatibility and consistency of proposed amendments with provisions of other relevant WHO frameworks and relevant international legal instruments under the auspices of other intergovernmental and international organizations. The RC is also to study "the compatibility and consistency with the Working Draft of a WHO Convention, Agreement, or other International Instrument on Pandemic Prevention, Preparedness and Response (Document A/INB/2/3)".

While the former gives a presumption that the IHR 2005 in their amended version should not seek to alter the impact of existing legal instruments, the latter seeks to limit the IHR amendment process by referring to a working document which does not have Member State consensus. Document A/INB/2/3 is not even a negotiated document and there is no Member State consensus on the working draft of a new pandemic instrument contained in the said document. It is only a compilation of ideas by the Intergovernmental Negotiating Body (INB) Bureau and WHO Secretariat. It is not even a Zero Conceptual Draft for the new pandemic instrument. Member States have only submitted their comments to A/INB/2/3 and these are being studied by the INB Bureau; an advance copy of the Zero Conceptual Draft will only be released in the month of November. The INB will have to convene its 3rd session in the second week of December and see whether the Zero Conceptual Draft gets consensus or not. It is also noteworthy that the scope of the proposed instrument under document A/INB /2/3 is limited to pandemics and does not cover all types of public health emergency of international concern (PHEIC) as is covered by the IHR 2005.

The mandate of the RC is only to provide technical recommendations and there is no mandate to coordinate with the INB. Coordination with the INB is left to the WGIHR. According to a WHA Special Session 2 decision, the INB is to take into account the discussions of the WGPR (now renamed the WGIHR). The relevant part of the decision reads: "… the process referred to in paragraph (3) should be informed by evidence and should take into account the discussions and outcomes of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emer-

gencies (WGPR), considering the need for coherence and complementarity between the process of developing the new instrument and the ongoing work under resolution WHA74.7, particularly with regard to implementation and strengthening of the IHR (2005)".

While consistency with existing legal instruments is a good characteristic of any new legal reform, this cannot limit the freedom of States Parties to move away from pre-existing law if needed. It is against the basic principles of international treaty making, which allow States to develop subsequent treaties which may differ from existing treaties. For instance, the Vienna Convention on the Law of Treaties – which reflects the application of *lex posterior derogat legi priori* (later law supersedes the earlier law) – and the International Law Commission, which elaborates on this principle in its extensive study report and conclusions on the fragmentation of international law, have made no remark that limits the freedom of States to enter into two or more incompatible treaties.

Yet, the IHR amendment proposals are now sought to be reformulated by the RC to be consistent and compatible with existing international legal instruments.

Draft ToR prolong duration of RC

According to WHA75(9) paragraph 2(e), the RC is requested to "submit its report to the Director-General no later than 15 January 2023, with the Director-General communicating it without delay to the WGIHR". Thus, there is no mandate for the RC beyond 15 January 2023. However, the draft ToR set a much later deadline of January 2024 before the package of amendment proposals is forwarded to the WGIHR. The RC report, if such a process is allowed, can influence the negotiations within the WGIHR and frustrate the freedom of Member States to negotiate. Further, the timeline collides with pressures of the Executive Board meeting that will precede WHA77. Therefore, this attempt has no legal backing, nor is it a legitimate move in supporting a Member State process for amending the IHR 2005.

Silence on the mandate of EB150(3) and WGPR final report

The 150th meeting of the Executive Board adopted the decision to amend the IHR. Paragraph 2 of decision EB150(3), which sets the scope of the IHR amendments, explicitly states that the amendments should *"address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner".*

Nevertheless, the draft ToR do not require the RC to look at the relevance/compatibility of the IHR amendment proposals with this EB150(3) mandate. On the other hand, they enable the RC to define "targeted amendments", which is the term used in decision WHA75(9) to refer to the potential amendments as identified by Member States in EB150. EB150(3), in paragraph 2 quoted above, clearly defines the scope of the proposed amendments. No expert committee can have the authority to interpret what the Member States meant by this term in decision WHA75(9). This is another attempt to create new filters to limit the amendment proposals.

Meanwhile the WGPR final report is the outcome of Member States' deliberations over the recommendations and suggestions made by three important expert committees which studied the functioning of WHO, Member States and the IHR 2005 during the COVID-19 response. The report could serve as a checkpoint for analyzing whether the IHR amendment proposals are in the right direction as envisaged by the Member States. Unfortunately, the draft ToR do not make any reference to it.

WHO Secretariat is behind idea of RC

The decision to have an IHR Review Committee looking at the amendment proposals by States Parties arose from a WHO Secretariat idea during a WGPR meeting in May 2022. Such a proposal by

the WHO Secretariat was unusual as there has already been an IHR Review Committee on the COVID-19 response that made technical recommendations as to what needs to be changed in the functioning of WHO and Member States as well as the IHR.

Article 50(1)(a) was intended to support the DG if he/she intends to make a proposal for amending the IHR 2005 under Article 55(1). It could never have been meant as the basis for an expert committee appointed by an international civil servant making remarks on text proposals made by States Parties.

The previous amendments to the IHR had not been subjected to RC intervention as envisaged by the current draft ToR. It must be noted that the WHO Secretariat is at the forefront of promoting a new legal instrument in WHO which is seen by many as a competing process against the IHR amendment process.

Amidst the negotiations in the WGPR and WHA75, the developed countries were making clear attempts to use the IHR amendment process to advance more obligations on information sharing and surveillance without any corresponding obligations on finance and resources for the health emergency preparedness and response of developing countries. Further, there was no willingness on their part to address the issue of equitable access to health products required for health emergency response. The only promise from the developed countries like those from the European Union was to address equity in the context of pandemics (not all types of health emergencies) and that too only in the new instrument.

The draft ToR now developed by the WHO DG show all the potential signs of facilitating use of the RC by vested interests to delegitimize the proposals from developing countries to amend the IHR 2005, especially those requiring equitable access to health products and technologies for addressing PHEICs.

Geneva Health Files, Newsletter Edition #008 [Treaty Talks] 17 October 2022

The Review Committee on the IHR amendments: Questions on fairness of content and procedure

by K.M. Gopakumar and Nithin Ramakrishnan

Many developing country Member States and observers were caught by surprise earlier this year when the WHO Secretariat suggested that the IHR amendment proposals can be referred to an IHR Review Committee (Review Committee). This was during the discussions on the timeline of the IHR amendment process, at the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR). There are a few reasons for their surprise.

First, whenever amendment proposals to international legal instruments are submitted by sovereign States, it is not the practice to allow a panel of experts acting in their individual capacity to offer comments on such proposals. The normal practice is that such proposals are treated on an equal footing and opened for negotiations to find a consensus.

Second, Article 55 of the IHR deals with the amendment process and there is no such requirement to submit the amendment proposals to the scrutiny of any Review Committee. Article 55(1) reads: "Amendments to these Regulations may be proposed by any State Party or by the Director-General. Such proposals for amendments shall be submitted to the Health Assembly for its consideration." Article 55(2) states that the Director-General should communicate the amendment texts to all State Parties at least four months before the Health Assembly at which it is proposed for consideration.

Article 50(1)(a) states that "The Director-General shall establish a Review Committee, which shall carry out the following functions: (a) make technical recommendations to the Director-General regarding amendments to these Regulations". However, it is understood that such technical recommendations are generally after the

adoption of amendments or whenever any amendment proposals come from the DG. The word used in Article 50(1) is "amendments" and not "amendment proposals". The 75th World Health Assembly (WHA) adopted the amendment proposed by the US without referring to the IHR Review Committee, for example.

While many Member States welcomed the Secretariat's suggestion in good faith to appoint an IHR Review Committee, they also insisted that the mandate of the Review Committee should be under Articles 50 and 51. However, many seasoned negotiators and observers viewed this unprecedented suggestion from the Secretariat as a move to rig the process and content of the EB150 decision [EB150(3)] to amend the IHR.

The battle lines on the discussions around the IHR amendments were already drawn when developed countries proposed more stringent obligations on preparedness, especially surveillance, without any corresponding obligations on various aspects of health response. There is no clarity on the obligations for predictable availability of health products required for response to a public health emergency of international concern (PHEIC), and obligations for access and benefit sharing emanating from the utilization of pathogen samples collected from humans. Developed countries like the EU want to limit the equity elements in a health emergency only to the pandemic context and therefore do not want such obligations to include the IHR amendments.

DG exceeds the WHA mandate?

The Terms of Reference (ToR) of the IHR Review Committee bear out the abovementioned apprehensions. The mandate emanating from decision WHA75(9) provides for technical recommendations on the proposed amendments. It states: "in accordance with Part IX, Chapter III, of the International Health Regulations (2005), in particular Article 50, paragraphs 1(a) and 6, with particular attention to be paid to the fulfilment of the letter and spirit of Article 51, paragraph 2, to make technical recommendations on the proposed

amendments referred to in sub-paragraph (c) below, with a view to informing the work of the WGIHR".

It appears that DG Tedros has stretched the mandate under Article 50(1)(a) and entrusts the mandate to the IHR Review Committee to pass judgment on the proposals from State Parties.

Setting boundaries

The ToR prima facie set boundaries on the scope of the amendments. For instance, the first task – analysis of each of the proposed amendments to the IHR submitted no later than 30 September 2022 – has many variables. As per this mandate, the IHR Review Committee is expected to carry out an analysis of the pertinence of the amendment proposals vis-à-vis the purpose and scope of the IHR, as defined in Article 2. This raises the interesting question on how the Review Committee would carry out such an exercise on a proposal to amend Article 2 of the IHR itself.

(Article 2 of the IHR: "The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.")

The Review Committee is also expected to check the "compatibility and consistency with the Working Draft of a WHO Convention, Agreement, or other International Instrument on Pandemic Prevention, Preparedness and Response" (Document A/INB/2/3). This is quite a baffling assignment because the said document is not even a negotiated document and only a compilation by the Secretariat and the Bureau of the INB. This proposed instrument is expected to deal with only pandemics – a subset of PHEICs. It can be inferred that examining the compatibility of amendment proposals with a document where there is no consensus or clarity regarding the normative content is an attempt to limit the inclusion of equity provisions in the IHR by stating that equity will be addressed in the new pandemic instrument.

This move sets a de facto scope for amendment proposals by overruling the decision of the World Health Assembly and the Executive Board. EB150(3) sets the scope of the IHR amendments, explicitly stating that the amendments should "address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner."

Surprisingly, the ToR do not even refer to the EB150 decision in the scope of work which really sets the boundary for the amendment proposals.

A mandate to override the prerogative of State Parties?

The mandate of the Review Committee as per WHA75(9) is "to make technical recommendations on the proposed amendments". However, the ToR also give a mandate for reformulation and/or clarification.

The ToR mandate includes proposals for "rewording, rephrasing, inclusion of cross-references to other relevant articles of the IHR, inclusion of compliance monitoring elements – and/or consolidation, if/when necessary, of the text of the article intended to be amended, as well as of the text of any other article of the Regulations that needs amendments for the article intended to be amended to be applicable. Such proposals shall ensure the internal consistency, integrity, and robustness of the text of the IHR, as well as the compatibility and consistency with any other relevant international legal instrument under the auspices of intergovernmental and international organizations. Each of the abovementioned proposals for reformulation and/or refinement by the IHR Amendments RC shall be accompanied by its rationale, including the reason/s why amendments proposed by States Parties have not been totally or partially retained, or have been reallocated to an article different from the one initially intended to be amended."

This gives a clear mandate to the Review Committee to even recommend the deletion of an amendment proposed by States Parties. This could vitiate the negotiating process. By commenting on the proposals of States Parties, the Review Committee can potentially be seen as exercising power.

Similarly, the ToR also task the Review Committee "to advise on definitions of terms, either new or existing terms the meaning of which might be changed following the proposed amendments, to ensure clarity and consistency; as well as to advise on whether the inclusion, in the text of the IHR, of an explicit taxonomy related to the nature of amendments (e.g., targeted amendments, conforming amendments, technical adjustments, updates, 'reopening the instrument') is warranted and, if so, to formulate a proposal in that respect".

This is an attempt to classify the proposals based on whether they fall within the definition of "targeted amendments". This could discredit progressive proposals that do not fall within this category.

Extended timeline

Though WHA75(9) sets the timeline for the Review Committee to submit its report to the Director-General no later than 15 January 2023, the ToR extend this further to January 2024. While the mandate of WHA75(9) only requires providing technical recommendations on the proposed amendments submitted before 30 September 2022, the ToR are asking the Review Committee to review "the package of amendments agreed by the WGIHR" later in December 2023–January 2024. This backdoor extension of the duration of the Review Committee bears the danger of unduly influencing the negotiations.

The ToR show that the Review Committee is a ploy to reinforce the status quo in the IHR regime by discrediting the proposals of developing countries aiming to bring equity and justice in the international public health emergency regime. The ToR clearly move away from the spirit of WHA decision 75(9), which agreed in good

faith to refer the amendment proposals to the Review Committee for technical recommendations.

Such a process may create a trust deficit in the functioning of the Working Group on Amendments to the IHR 2005 (WGIHR), the State Party mechanism to lead the amendment process. It may also create trust deficits even before negotiations on the amendments begin. We would wait to see if the process will be fair and legitimate.

Part 3 **– 1st meeting of the WGIHR**

TWN Info Service on Health Issues (Jan23/02)
11 January 2023

Developing countries focus on equity in IHR amendment proposals

Kochi/Delhi, 11 January (Nithin Ramakrishnan and K.M. Gopakumar) – Proposals from developing countries to amend the International Health Regulations (IHR) 2005 focus on facilitating equity in health emergency preparedness and response.

The Working Group on Amendments to the IHR (WGIHR) is to negotiate various amendment proposals submitted by States Parties to the IHR 2005.

Sixteen States Parties, including four on behalf of four different groups of states, have submitted amendment proposals. These are Armenia, Bangladesh, Brazil, the Czech Republic on behalf of the Member States of the EU, Eswatini on behalf of the WHO African Region Member States, India, Indonesia, Japan, Malaysia, Namibia, New Zealand, the Republic of Korea, the Russian Federation on behalf of the Member States of the Eurasian Economic Union, Switzerland, the United States, and Uruguay on behalf of MERCOSUR (Argentina, Brazil, Paraguay and Uruguay). All the proposed amendments are publicly available except for the proposals from Japan.

The WHO Executive Board decision 150(3) titled "Strengthening the International Health Regulations (2005): a process for their revision through potential amendment", which provides for the IHR amendment process, has emphasized the need for addressing equity. It states that the IHR amendments *"should be limited in scope and address specific and clearly identified issues, challenges, including* ***equity****, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease* ***in an equitable manner****"* (emphasis added),

Nevertheless, there is very little, if at all, on realizing equity in the developed country proposals to amend the IHR 2005. This resonates with the EU's stated policy to narrow down the application of equity principles only to pandemic-scale health emergencies. Instead, the developed countries seek to further entrench information-sharing obligations and the promotion of a securitization agenda.

On the other hand, the proposals from developing countries seek to ensure equity in health emergency preparedness and response in a comprehensive manner. They seek to address issues such as scope, principles, capacity building including for surveillance and health systems strengthening, equitable access to health products, technologies and know-how, international financial assistance, implementation oversight, regulation of unilateral measures, and actions of non-State actors, each targeting the realization of equity in health emergency preparedness and response. These equity proposals have the backing of a total of 55 developing countries.

The main equity elements reflected in the proposals outlined below are:

- inclusion of equitable access to health products, in the part on scope;
- common but differentiated responsibilities, in the part on principles;
- health systems strengthening;
- concrete proposals to ensure equitable access to health products, technologies and know-how;
- establishment of an international financial mechanism;
- access and benefit-sharing mechanism.

(1) Scope of IHR 2005

One of the important critiques of the IHR concerns its silence on equitable access to health products. Article 2, which explains the purpose and scope of the IHR 2005, reads: *"The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health*

risks, and which avoid unnecessary interference with international traffic and trade."

Developing countries like India, Bangladesh and the African Region States seek to amend Article 2 to incorporate not only equitable access but also other equity concerns such as interference with livelihood and health systems strengthening. The text to be negotiated is as follows:

"The purpose and scope of these Regulations are to prevent, protect against, ***prepare****, control and provide a public health response to the international spread of disease****s*** ***including through health systems readiness and resilience*** *in ways that are commensurate with and restricted to* ~~*public health risk*~~ ***all risks with a potential to impact public health****, and which avoid unnecessary interference with international traffic,* ~~*and*~~ *trade,* ***livelihoods, human rights, and equitable access to health products and health care technologies and know how.****"* (Bold and underline corresponds to new text additions and strikethrough corresponds to deletion.)

(2) Inclusion of equity, solidarity and common but differentiated responsibilities as principles

Article 3 of the IHR 2005 currently sets out the principles to be applied while implementing the Regulations, and these include human rights, dignity, fundamental freedoms, principles from the WHO Constitution and UN Charter, sovereignty and universal application.

Developing country States Parties like India, Bangladesh, Malaysia and the WHO African Region States seek to amend Article 3. The proposed additions include principles of equity, solidarity, common but differentiated responsibilities and respective capabilities, prioritization of establishment and strengthening of health systems capacities, and peaceful purposes. Meanwhile the EU has sought to incorporate the precautionary approach in dealing with unknown pathogens.

(3) Capacity building and health systems strengthening

Developing countries like Bangladesh, Malaysia, India and the WHO African Region States have submitted proposals to ensure the IHR 2005 mandate not only establishment and maintenance of surveillance capacities, but also the strengthening of health systems capacities. They have also sought to incorporate international financial, technical and technological assistance for the achievement of the same.

It must be noted that the developed countries' interests in developing country capacities are limited to surveillance and reporting capacities. The health securitization agenda of developed countries has narrowed the focus of IHR implementation without focusing on health system strengthening.

Bangladesh's proposals focusing on the need for strengthening health systems are key in reversing this agenda in international health law. It has proposed amendments to incorporate health systems capacities in Annex 1 of the IHR 2005 which currently lists only health emergency capacities. Further, its proposal to amend the Article 3 principles seeks prioritization of health systems strengthening in the implementation of the IHR 2005.

Malaysia, India, Indonesia and the WHO African Region States also seek the improvement of capacity-building provisions in the IHR 2005 and to incorporate wide-ranging health systems capacities within Annex 1. Bangladesh and Malaysia have explicitly called for developed country assistance to the developing countries.

Developed countries like the US, New Zealand and the EU, on the other hand, call for an assessment mechanism for capacity building and preparedness but fail to take note of the gaps in the list of capacities identified in Annex 1 of the IHR 2005.

(4) Access to health products, technologies and know-how

The most glaring inequity during the COVID-19 response was experienced in access to health products such as diagnostics, therapeutics and vaccines. While these health products had been re-

searched and developed in the fastest possible timelines, scaling up of the production and distribution of the products was extraordinarily lagging. African Region States, Bangladesh, India, Malaysia, Indonesia and Russia on behalf of the Eurasian Economic Union have therefore proposed amendments resolving this concern for future "public health emergencies of international concern" (PHEICs), the term used in the IHR 2005.

The 47 Member States of the WHO African Region have made a compelling, clear and straightforward amendment proposal which would enable access to health products, technologies and know-how required for a public health response to all on an equitable basis. So has Bangladesh. Both proposed to have an additional Article 13A which could establish obligations for States Parties and WHO to ensure equitable access to health products and technologies.

The African Region States Parties' proposed new Article 13A is titled "Access to Health Products, Technologies and Know-How for Public Health Response". This new provision would require:

(a) the WHO Director-General to:
    (i) make an immediate assessment about availability and affordability of required health products for public health response; and
    (ii) make recommendations including an allocation mechanism to avoid any potential shortage.
(b) States Parties to:
    (i) cooperate with each other and WHO in complying with such recommendations made by the WHO DG and to take measures to ensure equitable access to health products and technologies;
    (ii) include in their intellectual property legislations a provision for waiving or suspending intellectual property rights protection during a PHEIC;
    (iii) share the rights over products developed in the course of research partially or wholly funded by public sources;
    (iv) share regulatory dossiers with developing countries to kickstart local production in their territories; and

(v) ensure non-State actors and manufacturers do not act contrary to the IHR 2005, recommendations and actions taken pursuant to the IHR provisions.

The new Article 13A proposed by Bangladesh is titled "WHO-led International Public Health Response". Bangladesh envisages WHO as the central and coordinating authority for international public health response to PHEICs and it proposes beginning with an assessment by WHO of the availability and affordability of health products such as vaccines, diagnostics and therapeutics. Bangladesh further proposes:

(a) WHO to develop an allocation mechanism in cases of expected shortages and, in doing so, identify and prioritize recipients of the health products and determine the required quantity of health products to meet the needs of those recipients;
(b) WHO to develop and maintain databases which contain information required by potential manufacturers in order to start manufacturing in their facilities;
(c) States Parties with production capacities to diversify production including to developing countries upon request of WHO; and
(d) States Parties to ensure that the manufacturers operating from their territories shall supply WHO the requested quantities of health products in a timely manner.

The African Region States Parties and Bangladesh have also suggested some minimal changes to Article 13, which currently deals with public health response to public health risks and PHEICs. These aim to create two obligations on IHR States Parties: to provide support and assistance to affected States Parties when requested by WHO, and also to ensure that health response measures of one State Party do not affect another's ability to respond to health emergencies.

Complementing the proposals by Bangladesh and the African Region States Parties, India, Malaysia, Indonesia and Russia also seek to address issues relating to access to health products.

With the aim of achieving equitable access to health products, Indonesia has proposed to amend Article 44 which currently deals with collaboration and assistance. India, Russia and Malaysia propose to amend Articles relating to WHO's power to make recom-

mendations during a PHEIC to address issues relating to equitable access.

India, Bangladesh and the African Region States Parties also seek to incorporate production and supply capacities within the scope of Annex 1 of the IHR 2005 such that international financial and technological resources can be mobilized for the establishment and development of such capacities.

With regard to WHO's authority to make recommendations, India has proposed to incorporate a new paragraph 2 *bis* to Article 15 of the IHR 2005, which reads as follows:

"Temporary recommendations should be evidence based as per real time risk assessment of a potential or declared PHEIC, and the immediate critical gaps to be addressed for an optimal public health response, that shall be fair and equitable. The recommendations based on these assessments shall include:

"a. support by way of epidemic intelligence surveillance, laboratory support, rapid deployment of expert teams, medical countermeasures, finance as well as other requisite health measures to be implemented by the State Party experiencing the Public Health Emergency of International Concern, or

"b. prohibitive recommendations to avoid unnecessary interference with international traffic and trade."

(5) Financial mechanism

The IHR Review Committee that reviewed the COVID-19 response had stressed the lack of sufficient funding. Its report stated: *"All previous IHR Review Committees have highlighted the need for sufficient resources to be allocated to the implementation of the Regulations. This includes national funding for strengthening detection and response capacities in the context of building resilient health systems. It also includes funding for WHO to enable it to lead an effective, coordinated, multisectoral and evidence-based global effort to protect humanity against public health risks. Financial support mechanisms are also needed for some countries."*

Bangladesh, Malaysia, the African Region States Parties and MERCOSUR have proposed amendments to address this gap. MERCOSUR seeks to include specific mention of international financial assistance to prevent international spread of disease. In paragraph 3 of Article 13, MERCOSUR proposes that WHO cooperate with Member States in seeking support and international financial assistance to facilitate the containment of risks at source.

Bangladesh and Malaysia further suggest having a dedicated international financial mechanism to support the implementation of health emergency preparedness and response under Article 44. The WHO African Region States Parties, on their part, seek to incorporate a new financial mechanism under Article 44A. This fund, which is proposed to provide grants and concessional loans to developing countries, shall operate under the guidance of, and be accountable to, States Parties of the IHR 2005. States Parties shall decide and review its policies, programme priorities and eligibility criteria on a periodic basis. A proposal is also made to mandate the World Health Assembly to set up this fund within 24 months of the adoption of the provision. Amongst the funding priorities, the following are explicitly mentioned:

"(i) building, developing, strengthening, and maintaining of core capacities mentioned in Annex 1;

"(ii) strengthening of health systems including its functioning capacities and resilience;

"(iii) building, developing and maintaining research, development, adaptation, production and distribution capacities for health care products and technologies, in the local or regional levels as appropriate; and

"(iv) addressing the health inequities existing both within and between States Parties such that health emergency preparedness and response is not compromised".

These proposals for a financial mechanism aim to address the gaps and deficiencies associated with the pandemic fund constituted at the World Bank. The Pandemic Fund is primarily managed by a group of donors and a group of recipients with no accountability to the World Health Assembly.

India has also proposed to strengthen WHO's capacity to provide sustainable financing for managing health emergencies by suggesting that global-level capacities be incorporated in Annex 1 of the IHR 2005.

(6) No sharing of genetic resources without guarantee on benefit sharing

The 47 African Region States Parties and Namibia in particular, India and Malaysia call for access and benefit sharing for genetic resources, including genetic materials and sequence information. India and Malaysia have called for access and benefit-sharing capacities in the Annexures to the IHR 2005.

The EU and the Republic of Korea have shown some interest in addressing this subject matter. The EU, without using the words "benefit sharing", has stated that the sharing of information shall be based on modalities agreed by the World Health Assembly in that regard. The Republic of Korea, on the other hand, emphasized the need for establishing a system for sharing benefits derived from the sharing of genetic information.

Nevertheless, the African Region States Parties and Namibia in particular have indicated there shall be no sharing of genetic sequence information without guarantees on fair and equitable sharing of benefits derived therefrom. The African Region in its proposal seeks to incorporate an explicit paragraph 3 which states:

"No sharing of genetic sequence data or information shall be required under these Regulations. The sharing of genetic sequence data or information shall only be considered after an effective and transparent access and benefit sharing mechanism with standard material transfer agreements governing access to and use of biological material including genetic sequence data or information relating to such materials as well as fair and equitable sharing of benefits arising from their utilization is agreed to by WHO Member States, is operational and effective in delivering fair and equitable benefit sharing."

Namibia, in its communication sent to WHO, takes note of the ongoing discussions under the Convention on Biological Diversity and has stated that it "therefore reserves its right to introduce additional proposals on ABS and GSD/GSI at a later stage, if needed. Namibia is of the view that nothing is agreed until everything is agreed."

Uncertainty over IHR Review Committee's approach to equity

The IHR Review Committee established by the WHO DG is expected to submit its report to the WGIHR in mid-January. The terms of reference of the committee came under severe criticism by the States Parties and civil society in the first face-to-face meeting. The method of work adopted by the IHR Review Committee has also attracted criticism as it seeks to examine the appropriateness and consistency of the IHR amendment proposals submitted by States Parties by asking questions such as (i) whether the proposed amendment is suitable for achieving the "intended purpose" of the Article and other related IHR provisions; and (ii) whether the proposed amendment "is in line with the scope, purpose and other IHR provisions, the WHO Constitution and relevant existing" international legal instruments.

Though the Executive Board decision 150(3) stressed the need for addressing equity issues as part of the amendments, the WHO DG has requested the Review Committee "to advise on definitions of terms, either new or existing terms the meaning of which might be changed following the proposed amendments, to ensure clarity and consistency; as well as to advise on whether the inclusion, in the text of the IHR, of an explicit taxonomy related to the nature of amendments (e.g., targeted amendments, conforming amendments, technical adjustments, updates, 'reopening the instrument') is warranted and, if so, to formulate a proposal in that respect." The apprehension is that the IHR Review Committee may use these reference questions to make adverse recommendations on equity-related proposals or limit such proposals' scope.

Therefore, it would be interesting to see the approach of the Review Committee towards the amendment proposals made by developing countries that emphasize equity in health emergency preparedness and response. However, according to several observers and government delegations, States Parties are free to pursue their IHR amendment proposals during the negotiations and have full freedom to reject the recommendations of the Review Committee.

TWN Info Service on Health Issues (Jan23/07)
30 January 2023

DG's proposals for global health emergency architecture skip critical issues

Geneva/Kochi, 30 January (K.M. Gopakumar and Nithin Ramakrishnan) – The World Health Organization's Director-General (DG) has made proposals to strengthen the global architecture for health emergency preparedness, response and resilience (EB152/12). However, these skip critical issues required for strengthening the health emergency regime, especially to address the needs of developing countries.

Document EB152/12 on "Strengthening WHO preparedness for and response to health emergencies" will be discussed today under agenda item 12.1 of the Executive Board's 152th meeting that takes place from 30 January to 7 February in Geneva.

The document contains 10 proposals to strengthen the global architecture for health emergency preparedness, response and resilience (HEPR). It was initially presented to the 75th World Health Assembly (WHA) in May 2022 to be taken note of. The EB152/12 document is now reporting on the progress in the discussions on those 10 proposals from WHA75. There are some changes in the headlines of these proposals, but the central ideas remain more or less similar.

Paragraph 4 of the document says these proposals are *"designed to strengthen HEPR under the aegis of a new WHO con-*

vention, agreement or other international instrument on pandemic prevention, preparedness and response (hereafter referred to as the pandemic accord), which is currently being developed by Member States through the Intergovernmental Negotiating Body established by the Second special session of the World Health Assembly in decision SSA2(5) (2021) (the 'INB').''

Below are the 10 proposals, out of which nine are classified into three pillars of the global architecture, i.e., governance, systems and finance.

Governance:

1. *Establish a Global Health Emergency Council, to complement the Standing Committee of the Executive Board, and a main committee on emergencies of the World Health Assembly*
2. *Make targeted amendments to the International Health Regulations (2005)*
3. *Scale up Universal Health and Preparedness Reviews (UHPR) and strengthen independent monitoring*

Systems:

4. *Strengthen the health emergency workforce*
5. *Strengthen health emergency coordination through standardized approaches to the strategic planning, financing, operations and monitoring of health emergency preparedness and response*
6. *Expand partnerships and strengthen networks for a whole-of-society approach to collaborative surveillance, community protection, safe and scalable care, access to medical countermeasures and emergency coordination*

Finance:

7. *Enhance coordination between finance and health decision-makers*
8. *Strengthen and fully finance the Pandemic Fund to provide catalytic and gap-filling funding*

9. *Expand the funds available for rapidly scalable and sustainable emergency response, including at-risk financing for the rapid development of and access to medical countermeasures*

Equity, inclusion and coherence:

10. *Strengthen WHO at the centre of the global HEPR architecture.*

The EB152 is invited to answer the following two questions:

a) How can the Secretariat best work with Member States to advance the 10 proposals contained in the report?
b) What gaps are there that require further work by the Secretariat with Member States?

These questions attempt to seek endorsement from Member States for the proposals for which there was no earlier endorsement from the WHO governing bodies. Most importantly, these proposals on the global architecture for HEPR are premature because fora like the INB and the Working Group on Amendments to the International Health Regulations 2005 (WGIHR) are negotiating several important building blocks of the very same global architecture. To date, there is no consensus among WHO Member States regarding those building blocks in these fora.

There are concerns that the 10 proposals "handpicked" by the DG effectively undermine the Member States' negotiations to set the architecture by promoting certain ideas and neglecting some others. In-depth discussions should take place within fora like the INB and WGIHR, and their recommendations should then be forwarded to the governing bodies. If required, any other proposals or building blocks of the global architecture that are not addressed by the INB or WGIHR may then be considered by the governing bodies alongside the INB and WGIHR recommendations. However, seeking collaboration from Member States on the DG's proposals at this point in time is sidestepping the role of Member States in shaping the global architecture.

Apart from this problematic process, the DG's proposals fail to address the following critical building blocks for a resilient global HEPR architecture:

(1) Equity

Though the document identifies equity as one of the purposes and principles of the global architecture, it does not consider it to be one of the pillars of the global architecture. Further, there are no specific proposals on equity under any of the three pillars, viz., governance, systems and finance. This goes against the recommendations in the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR). Many developing country Member States during the WGPR meetings demanded that equity be treated as one of the main pillars along with governance, systems and finance, and that specific proposals on equity be developed in each of the other pillars.

The current proposals pay lip service to equity by recognizing it as a purpose and principle in the introductory part, but there are very limited proposals to ensure the operationalization of equity. The proposals assume that giving WHO a central role in coordinating the HEPR work alone will suffice to meet the needs of equity. However, in several other proposals, it can be seen that the role of WHO is getting further constrained by other agencies and institutions.

Further, while discussing the IHR amendments, the DG's proposals draw attention away from the need for equity within the IHR 2005, which is one of the most explicit gaps mandated by EB150 to be addressed through the IHR amendment process.

(2) Health system strengthening

Paragraph 35 of the document reads: *"A strong HEPR architecture must be built on a foundation of strong national health systems centred on primary health care. High-quality health services and public health capacities are necessary to detect, prevent and respond to health emergencies. Resilient health systems have the resources to reorganize and redeploy existing resources in response to shocks such as health emergencies, while at the same time maintaining essential health services."*

However, when it comes to the foundational idea behind these proposals, the DG suggests as follows: *"Investing in health security strengthens primary health care and health promotion, and vice versa, within the broader health system and multisectoral landscape".* The proposals are silent on investing in primary health care. For example, the DG's proposal No. 4 deals only with strengthening the "health emergency workforce and corps", but not strengthening of health systems in general, maintenance of adequate numbers of health workers in the facilities and all parts of the country and protection of their rights. Investing in the latter would naturally generate co-benefits for health emergency response. Yet the DG's proposal is in the reverse direction.

On financing, the DG's proposals allow for external agencies such as the World Bank to determine health priorities, which would in turn prioritize health security ideas over health systems strengthening.

(3) Equitable access to health products

When it comes to equitable access to health products, the DG's proposals seek to legitimize business-as-usual and market-based mechanisms, and fail to recognize the importance of establishing legal obligations to ensure universal equitable access. The proposals seek to promote failed models such as the ACT Accelerator. Before proposing to *"expand partnerships and strengthen networks for a whole-of-society approach to ... access to medical countermeasures and emergency coordination"* (proposal No. 6), the DG highlights *"more recently, the ACT Accelerator was established in April 2020 to support the end-to-end process of rapid development and equitable deployment of COVID-19 vaccines, tests, treatments and personal protective equipment".*

Proposal No. 9 further calls for expanding the *"funds available for rapidly scalable and sustainable emergency response, including at-risk financing for the rapid development of and access to medical countermeasures".*

This proposal is to reform *"the WHO Contingency Fund for Emergencies (CFE) to expand the size and scope of the fund to enable direct financing to facilitate rapid deployment of health work force and emergency supply chain"*. Further, it also calls for *"sufficient at-risk financing [to be] available early in the pandemic response cycle to ensure the timely development, production and procurement of medical countermeasures"*.

These proposals do not make any calls for addressing structural determinants of equitable access, establishing a legally binding allocation mechanism or for mechanisms to diversify production within and outside the borders of the countries having capacity to produce.

(4) Access and benefit sharing

It is quite clear from the various public health emergencies of international concern such as Ebola, COVID-19 and monkeypox that unless a comprehensive framework is built for sharing of pathogens and their genetic sequence information, wherein utilizers of such pathogens and information are required to share fairly and equitably the benefits arising from these shared resources, there will be very little room for ensuring equitable access to health products such as diagnostics, vaccines and therapeutics.

However, the DG's proposals fail to consider this as an important element. Earlier, paragraph 28(iv) of the DG's proposals to WHA75 understood "pre-negotiated benefit sharing agreements" as an integral component to equitable access to health products. Such an understanding seems to be strangely quite diluted in the EB152 document.

(5) Relationship between IHR and new pandemic instrument

Paragraphs 4 and 13 of EB152/12 clearly emphasize the importance of the INB process and the new pandemic instrument being negotiated there. For instance, paragraph 13 states: *"The three proposals for strengthening the global governance of HEPR outlined below have been requested by, and are driven by, WHO Member States in*

alignment with the development of a new WHO pandemic accord, through the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (INB).”

However, a pandemic instrument as currently envisaged only applies to a health emergency of “pandemic” scale, with no common understanding yet on what that means. Therefore, the basic structure of the global architecture for HEPR must emanate from the IHR 2005 – it is where the HEPR capacities are delineated and basic functions of the countries and WHO are delineated. The new instrument for pandemics will address the enhanced level of coordination and enhanced equity and other mechanisms that may be triggered during a pandemic-scale emergency.

Proper management of the relationship between the IHR 2005 and the pandemic instrument is critical; otherwise, accountability of actors such as Member States and WHO will slip into gaps between the two instruments. Not addressing this structural concern could generate a sense of near-impunity to the stakeholders in HEPR for their actions and omissions.

Call for strengthening WHO and the promotion of multi-stakeholderism

As mentioned above, the only one of the DG’s proposals which envisages equity as a direct outcome is proposal No. 10 to strengthen WHO’s central role. However, this is quite inconsistent with several other proposals such as proposals Nos. 1, 3, 6, 7 and 8 which seek to maximize multi-stakeholder approaches. While multi-stakeholder platforms are openly promoted in several of the 10 proposals, it is astonishing to see that the DG fails to speak about the accountability of WHO and its partnerships or collaborative initiatives.

The approach is stated in paragraph 40 of the document: *“WHO initiated an outreach process to bring together a broad range of partners and stakeholders to further develop the proposals and their application across the five Cs (collaborative surveillance, community protection, countermeasures, care and coordination) and ensure co-*

herence, strict alignment, and open and intensive collaboration with relevant global and regional partners, initiatives and mechanisms."

Proposal 6 further elaborates on this approach: *"Expand partnerships and strengthen networks for a whole-of-society approach to collaborative surveillance, community protection, safe and scalable care, access to medical countermeasures and emergency coordination."* Furthermore, proposal No. 3 that calls for review and monitoring mechanisms again prominently describes the role of various stakeholders. Unfortunately, conflict-of-interest rules or the WHO Framework on Engagement with Non-State Actors do not get mentioned even once.

In short, the DG has not incorporated into his proposals calls made by developing countries over the last two years. Despite the several calls for common but differentiated responsibilities in the health regime, the DG's proposals do not explicitly address the needs and requirements of the developing countries.

Instead, most of the proposals encompass the ideas advanced by countries like the United States, the European Union and other developed countries. The most glaring example would be the prioritization of the health security agenda over health systems strengthening, and also the neglect of the critical importance of access and benefit-sharing mechanisms.

TWN Info Service on Health Issues (Jan23/08)
31 January 2023

EB Members express reservations on DG's proposals on global health emergency architecture

31 January (TWN) – The WHO Executive Board (EB) Members have expressed their reservations over the Director-General's proposals for a global architecture for health emergency preparedness, response and resilience.

Many EB Members reiterated that the DG's proposals must be deliberated by all WHO Member States at appropriate forums such

as the Intergovernmental Negotiating Body (INB) or the Working Group on Amendments to the International Health Regulations 2005 (WGIHR).

The proposals are contained in the DG's report on "Strengthening WHO preparedness for and response to health emergencies" (EB152/12). The report was discussed on the first day of the 152nd session of the EB, which is taking place at the WHO headquarters in Geneva from 30 January to 7 February. The EB is requested to guide the WHO Secretariat on the following two questions: (1) How can the Secretariat best work with Member States to advance the 10 proposals contained in the report? (2) What gaps are there that require further work by the Secretariat with Member States?

In response, several EB Members reminded the Secretariat on the role of Member States in shaping the global health emergency architecture. They also stated that currently the Member States are taking part in such discussions at the WGIHR and at the INB for the new pandemic instrument. Apart from the process issues, EB Members also expressed concerns on the substantive elements of the 10 proposals.

Denmark, who spoke on behalf of the European Union (EU), stated that Member States will ultimately decide whether and how to take any of these individual topics forward in collaboration with concerned government sectors. The EU called for in-depth discussion on selected topics before further steps are taken.

Denmark also reminded the DG that the global health architecture should not only focus on health security. It also needs to support Member States in advancing, as appropriate, the strengthening of national health systems including the essential public health functions.

The UK, while commending the DG's report for covering a lot of ground, stated that the devil will be in the details. It also stated that the One Health approach is missing in the DG's proposals.

China said that the 10 proposals are related to the discussions at the INB and WGIHR and require cooperation of "other Member States" to improve global health security. It called for the use of the WGIHR and INB to further examine the detailed content of the 10 proposals, adding that the work must not be rushed.

Brazil highlighted that though the DG's proposals provide food for thought, the interests of developing countries as well as issues relating to delivery of equity are not properly addressed. It concluded its statement by saying: "[T]he substance of the proposals is an integral part of the ongoing discussion at the INB and the WGIHR, with the difference that these processes have been developing in a much more transparent and inclusive way, with clear participation by non-State actors and guidance offered by Member States. Both of these workstreams are entering into critical phases this year. Now it is the time to concentrate our efforts to have meaningful debates within those two mechanisms in order to come up with innovative and game-changing norms. For this reason, we believe that the proposals should be referred to the relevant governing and negotiating bodies, including the WGIHR and the INB, where they can be thoroughly discussed and further developed if agreed upon by Member States, and not be the subject of specific consultations."

Stating that the INB and WGIHR are working to strengthen the global architecture and the two processes are complementary, Paraguay reminded that "multiplying spaces for the debate will not help substantive discussions." Therefore, it said, "we think that exchanges on global architecture need to be focused on these two processes and these two forums, which have proven how they stick to the value of transparency and inclusiveness."

The United States maintained the position that "it should be really up to the Member States to determine what elements go forward and what elements are held back." It added that the ongoing negotiations may be used as a vehicle or a platform for discussions in this regard.

The Maldives reminded the meeting that "while we [Member States] work together to apply various global mechanisms in preventing, detecting and responding to emergencies, we must be worried of the risks of overlapping, fragmenting or duplicating responsibilities, efforts and the conflicts of interests."

Japan also reminded EB Members that the discussions should not be duplicated.

Russia, calling out the proposal to create more committees as "premature", reiterated its stance against the DG's proposals that endanger or might cause fragmentation of the global health architecture, that might duplicate current processes and overburden the participants of these forums, especially small delegations.

The discussions on this agenda item are expected to resume at the current session and the non-EB Member States are expected to make their comments on the DG's proposals in the coming days.

TWN Info Service on Health Issues (Feb23/04)
20 February 2023

IHR Review Committee fails to make meaningful technical recommendations

Geneva, 20 February (K.M. Gopakumar and Nithin Ramakrishnan) – The Review Committee on Amendments to the International Health Regulations (IHR) 2005 fails to make any meaningful technical recommendations.

Its report is sending out an overall message of resisting major changes to the status quo. In other words, the Review Committee (RC) wants to maintain the IHR 2005 as an instrument mainly focused on information sharing on potential health emergency outbreaks and ignores the demand for equity in the Regulations. Acceptance of the recommendations of the report therefore would maintain existing inequities in the international health emergency regime.

The RC was appointed with the mandate to make technical recommendations on the various IHR amendment proposals submitted by 16 Member States under the 150th Executive Board decision to carry out targeted amendments including equity. The Committee's terms of reference were however criticized for their potential to enable a situation where the amendment proposals would be discredited prior to the initiation of the negotiations. The RC report now clearly bears out those concerns.

Using the terms of reference by the WHO Director-General and Secretariat as a pretext, the RC offers "commentary" on the Member State proposals rather than providing "technical recommendations" in accordance with its mandate under Article 50(1)(a) of the IHR 2005. It must be noted that there have been IHR amendments made in the past without a Review Committee having even been constituted. According to some developing country delegates, several of the questions raised by the WHO Secretariat in the terms of reference were not even discussed during negotiations of the previous amendments.

Furthermore, most of the time, the RC ended up making remarks on the Member State proposals such as "unnecessary" – an explicit contravention of its assurance that it will not prejudice any Member State proposals. What is unfortunate here is that Member States were not given a chance to offer feedback to the Committee's report before it was finalized.

The report consists of a preface, executive summary and four chapters. The first chapter is an introduction, and the second chapter describes the method of work. The third chapter summarizes the general considerations behind the amendment proposals. The fourth chapter analyzes the 300 amendment proposals and also contains the RC's technical recommendations. This chapter contains a summary of the existing IHR Articles and corresponding amendment proposals, and the RC's technical recommendations.

In the preface, the RC claims to have identified the values that underpin most of the proposals: (1) equity, solidarity and international cooperation, (2) trust and transparency, and (3) sovereignty. However, it is doubtful whether the Committee has really understood these values. Most of its recommendations are inconsistent with these values or fall short of fully reflecting these values. The RC records that there is divergence among its members on several issues relating to the above values, but fails to examine whether this divergence can be substantiated on the basis of a sound technical analysis.

At the beginning of its report, the RC calls on Member States to *"focus on the fundamentals. Capture this unique moment of possibility. Be bold in thinking and in action. Develop and prioritize amend-*

ments to the International Health Regulations (2005) that will fundamentally improve global public health protection and help create a more equal, just and resilient world – and a better prepared one."

However, the rest of the report shows that the RC itself was not bold enough in thinking about equity and justice. The Eurocentric, conservative approach to the duty to cooperate dilutes all the major proposals for IHR reforms and offers a skewed view about the practicality and feasibility of such proposals. For the RC, what the international law scholars from developed countries think as international law appears "practical and feasible", while what the developing countries want from the IHR reforms appears "unnecessary". In effect, the equity proposals are compromised by the RC.

The equity-related proposals mainly relate to the following areas:

- Common but differentiated responsibility (CBDR)
- Access and benefit sharing (ABS)
- Equitable access
- Disciplining of unilateral actions
- Financial mechanism.

CBDR: There are three Member State proposals to incorporate CBDR as part of Article 3 on the principles of the IHR. This incorporation would then not only provide a tool for interpretation but also become a basis for various legal provisions on equity. The CBDR principle, by acknowledging the greater obligations of developed countries and broader policy choice for the developing countries, paves the way for burden sharing in the pursuit of the common goal of health emergency preparedness and response. It is key to ensuring the "equal, just and resilient world" which the RC calls for. However, the RC, after supporting the spirit of these proposals, sows seeds of doubt about the applicability of CBDR in international health law.

In the report, some RC members question the conceptual and factual application of CBDR to public health risks that may constitute a public health emergency of international concern (PHEIC). The sceptics within the RC then proceed to question whether the concept can be captured differently. However, the report does not

reveal any reasons for its members' doubts on the non-applicability of CBDR in heath emergencies.

The Committee acknowledges that *"there are differences across States Parties in, among others, the level of social and economic development (e.g. small island developing States), which can influence the level of implementation of the Regulations in some circumstances"*. It is interesting that it says the differences across States Parties influence implementation in "some" circumstances. Experience so far clearly shows that IHR implementation has been lagging behind in the developing world and the priorities of developed countries and donors are driving the developing countries to vertically focus more on surveillance capacities rather than holistically developing their response capacities and health systems.

Out of all the amendment proposals on Article 3, the RC is explicitly positive on including phrases such as "equity", "inclusivity", "coherence" and "solidarity" as a constructive contribution, but maintains a silence on CBDR, which has the potential to fix the existing inequity in the international health emergency regime.

The report nonetheless notes that there exist some differentiated responsibilities in the IHR 2005 as opposed to the principle of universal application in paragraph 3 of Article 3. It states that *"Other than rejections (Article 61), reservations (Article 62) and extensions (Articles 5 and 13), the Regulations do not explicitly provide for differentiated responsibilities of States Parties"*.

Access and benefit sharing (ABS): There are a few proposals under Article 6 to incorporate the transfer of genetic sequence data (GSD). Some of these seek mandatory transfer of GSD, while other proposals make it contingent upon the equitable sharing of benefits.

The Committee recommends that *"States Parties outline a coherent, principled, efficient and pragmatic multilateral mechanism for GSD and benefit-sharing. In this regard consideration should be given to coherence with the Nagoya Protocol to the Convention on Biological Diversity which many States Parties to the International Health Regulations (2005) are parties to. The Committee also discussed the Pandemic Influenza Preparedness (PIP) Framework as an example of multilateral collaboration in this area. Furthermore,*

a standardization of terminology may be warranted (e.g. genomic vs. genetic sequencing data; the Committee recommends the use of 'genetic sequence data')".

However, the RC, while discussing Article 44 amendment proposals on including sharing of samples and data within the duty to cooperate, makes the following remarks: *"The Committee acknowledges the importance of both information sharing (including biological specimens and GSD) and access to benefits derived from the use of shared pathogens. Both principles are vital but do not need to be implemented in a transactional manner."*

In the preface, where the RC offers a blueprint on the IHR amendment process, it states: *"While open science is not currently part of the International Health Regulations (2005), their chief aim will be advanced with the full and open exchange of all relevant scientific information. The amended Regulations should promote open and full exchange of all relevant scientific data. The corollary to this is the equally fulsome exchange of benefits that may be derived from such data. One of these essential values should not be traded for the other."*

The RC therefore falls short in its attempt to send out the message that sharing of pathogens, genetic sequence information and benefits are equally important. The overall take of the RC on access and benefit sharing of pathogens including GSD is confusing and lacks direction. The Committee clearly fails to examine the relevance and importance of the ABS mechanism not only in ensuring equitable access to health products and technologies but also in mobilizing funds for preparedness and response. It fails to take note that benefit sharing is a concrete, measurable and objective legal obligation unlike most of the soft law obligations in the IHR 2005 and other forms of duty to cooperate. ABS therefore is one of the most effective methods to create legal obligations to ensure equity – but its effectiveness comes from the linkage between "access" and "benefit sharing". Unfortunately, the RC uses subtle language to delink access and benefit sharing.

By taking the view that access and benefit sharing should not be transactionally linked, the RC in effect aligns with the positions

of the developed countries and their industries. In Chapter 2, while setting the key values underpinning the amendment proposals, the RC claims that *"there is convergence across proposed amendments on the sharing of GSD, with some making it conditional on having access to benefits deriving from their use".* This is clearly nudging Member States to create an obligation on sharing of pathogens and genetic sequence information – violating the principle of sovereignty of States over their genetic resources – and also inconsistent with the principle that access to genetic resources should be subject to a commitment to fairly and equitably share benefits arising from their utilization.

The RC, in other words, "traded off" the public interest in the concrete obligation of benefit sharing, and instead promotes the commercial interests of the pharmaceutical industries in the ABS regime.

Equity: The RC acknowledges the need to address equity in Chapter 3 and states: *"Although the term 'equity' is not used in the Regulations, this value is crucial to the promotion of global health to the extent that it guides the international response to public health risks, events that may constitute a PHEIC, and a PHEIC itself."* The report also acknowledges the inequity during the COVID-19 pandemic and structural barriers to access such as intellectual property rights and lack of diversified manufacturing. It is also of the view that *"equity as a value and principle extends well beyond access to medical countermeasures, knowledge and technology transfer".* This pro-equity view however is not reflected in the RC's technical recommendations on the proposals to facilitate equitable access to health products in the context of PHEIC. Equitable access proposals are reflected in a concrete way in the proposed Article 13A and Annex 10. The RC's analysis and technical recommendations effectively rejected those proposals without even proper reasoning. For instance:

(i) Assessment of shortage: One of the proposals from the Africa Group is to create an obligation on WHO to ascertain whether there is a shortage of health products to address the PHEIC in question immediately after the declaration of PHEIC. The proposed

amendment states: *"Immediately after the determination of a public health emergency of international concern under Article 12, the Director-General shall make an immediate assessment of availability and affordability of required health products and make recommendations, including an allocation mechanism, to avoid any potential shortages of health products and technologies pursuant to Article 15 or 16 as appropriate."*

The RC rejects this most pragmatic approach to addressing shortage, by citing feasibility and workload of WHO during the initial stages of a health emergency. The report reads: *"The Committee recognizes the critical importance of ensuring that health products are affordable and available to every State Party. However, the requirement in paragraph 1 for the Director-General to make an 'immediate assessment of availability and affordability of required health products' may not be feasible due to the magnitude of such a list implied by the proposed amendment and the very high workload imposed on WHO during the initial stages of determining a PHEIC."*

It is quite strange that the RC thinks management of accessibility of the health products required for an emergency response is a deferable function of WHO during a PHEIC. As noted by an observer, this is one of the crudest reflections of colonial understanding of international health law in the report. It is indeed bewildering that the RC states that the terms "availability" and "affordability" are relative and complex and hence require clarity, despite WHO having conducted several projects assessing both availability and affordability of medicines. There are operational definitions used in these projects which the RC may have offered as technical suggestions to Member States.

(ii) Allocation mechanism: There are at least two proposals, supported by more than 40 developing countries, to develop legally binding allocation mechanisms. It is clear from the proposals that an allocation mechanism is required only to address potential shortages and is not required in the absence of a shortage.

Though there was an allocation mechanism for COVID-19 vaccines, which was developed in pursuance of a World Health Assembly resolution, the majority of Member States did not follow it.

This is because a multi-stakeholder institution later developed this mechanism, and the same could not be issued under the legal authority of WHO under either the IHR 2005 or the WHO Constitution. This worsened the vaccine scarcity. Thus, it is clear that in the absence of legal backing, such a mechanism does not work.

According to the RC's report, *"The Committee has concerns regarding the proposal in paragraph 1 to use Article 15 (temporary recommendations) for the purposes of establishing an 'allocation mechanism.' Temporary recommendations, as defined under Article 1, are 'non-binding advice' and do not authorize WHO to direct States. Temporary recommendations may also be 'risk-specific', that is, individualized to areas or States with particular risk profiles. A different mode of authority may be required to establish an allocation mechanism. The Committee notes that the proposed amendment to Article 17 may be more feasible, as it requires WHO to take into account 'equitable access to and distribution of medical countermeasures i.e. vaccines, therapeutics and diagnostics for optimal public health response' when issuing, modifying or terminating temporary or standing recommendations."*

The RC in this analysis completely fails to consider that an "allocation mechanism" developed in an ad hoc manner through participation of multi-stakeholder platforms which are not accountable to Member States is much worse than an allocation mechanism developed by WHO within its mandate under the IHR 2005 and WHO Constitution. The RC argues that the IHR 2005 definition of temporary recommendations does not "authorize WHO to direct States". The RC derives this inference based on its understanding of the term "non-binding advice" used in the definition. While it is true that the term compromises WHO's ability to coordinate international public health response to PHEICs, the authority of WHO to direct States is not derived from Articles 15 and 16 (on standing recommendations).

Article 2(1)(a) of the WHO Constitution identifies WHO as the directing and coordinating authority of international health work, while Article 2(1)(g) requires WHO to stimulate and advance work to eradicate epidemic, endemic and other diseases. Furthermore, Article 28 endorses the WHO Executive Board to take up emergency

actions in this regard and the Director-General, subject to authority of the Board, may very well perform such actions under Article 31 of the Constitution. Articles 12, 15 and 16 of the IHR 2005 are operational reflections of this legal authority of WHO.

Moreover, the use of the word "non-binding" in Article 1 of the IHR 2005 definition of recommendations is not a bar on the States Parties to specifically identify one or more types of recommendations (if issued under Article 15) as binding by virtue of another provision. This is exactly what the Africa Group is trying to do. For instance, the Group's proposals seek to create an obligation to comply with recommendations to facilitate availability and affordability, including an allocation mechanism, through the proposed paragraphs 2 of Article 13A and 3 *bis* of Article 43. The Africa Group proposal states: *"States Parties shall co-operate with each other and WHO to comply with such recommendations pursuant to paragraph 1 and shall take measures to ensure timely availability and affordability of required health products such as diagnostics, therapeutics, vaccines, and other medical devices required for the effective response to a public health emergency of international concern."*

There are similar proposals from Bangladesh. Malaysia has also proposed to improve the effectiveness of the implementation of health measures pursuant to WHO recommendations by suggesting amendments to Article 42 of the IHR 2005. Despite all these jurisdictional provisions and clear direction provided by developing countries from the Africa Group, Bangladesh and Malaysia, the RC argues that the proposal to delete the word "non-binding" will raise questions of feasibility without clearly explaining what those questions are. Deleting the adjective "non-binding" would in fact provide clarity and can avoid potential conflicts with the amendment proposals making "selected recommendations" more consequential than being merely advisory.

(iii) Guidelines for regulatory approval: Another important proposal from the Africa Group is the creation of an obligation on WHO to develop guidelines for accelerated approvals of medical products to facilitate their affordability and availability. It reads: *"develop appropriate regulatory guidelines for the rapid approval of*

health products of quality including development of immunogenicity co-relative protection (ICP) for vaccines".

The RC rejects this proposal with the following logic: *"It may be inadvisable from a legal perspective to require that WHO develops such regulatory guidelines, as the liability in the event of a significant safety flaw that appears post-marketing of the product will then fall chiefly on the Organization."* The purpose of this proposal is to accelerate the regulatory approval without compromising on safety and efficacy. That is clear from the word "quality". The RC's rejection ignores the constitutional function of WHO in Article 2(w) "to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products". All these years WHO has issued various guidelines for the production and distribution of medicines, vaccines and biotherapeutics.

(iv) WHO database: Bangladesh has proposed a legal obligation on WHO to establish a database wherein all the required products for a PHEIC can be listed along with the specifications. Such a database would help Member States to scale up production in needy situations. The proposal reads: *"WHO shall develop and maintain a database containing details of the ingredients, components, design, know-how, manufacturing process, or any other information required to facilitate manufacturing of health products required for responding to the potential public health emergencies of international concern. Within two years of the entry into force of this provision, WHO shall develop this database for all PHEICs declared so far, including for the diseases identified in the IHR 1969."*

The RC recognizes the utility of such a database but raises doubts on the feasibility of its implementation, saying that this will need additional resourcing from States Parties to WHO. The Committee then casts doubts on the proposal: *"It remains unclear from this paragraph which entities would help WHO populate this database, given that much of the information called for in this database is not in the public domain but rather privately held by entities operating within States Parties. ... WHO would need the help of States Parties to render this database operational, but there is no corresponding obligation on States Parties to help WHO in this regard. In that*

same vein, the effectiveness of such a database would be limited by the various laws and agreements that govern proprietary commercial data and patents, including the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights and domestic intellectual property laws of individual States."

This clearly raises serious questions on the RC's integrity in calling for open access to information. The RC, when aligning with the call for an obligation to share information on genetic resources, does not see that such information is also accumulated through immense public and private investments such as ground-level collection of pathogens, safe transport and undertaking of risks involved, laboratory analysis, digital capture of information etc. The RC has even called for delinking access and benefit sharing, inconsistent with the Convention on Biological Diversity and its Nagoya Protocol, in order to promote rapid sharing of genetic information. However, when it comes to information regarding manufacture of products required for responding effectively to health emergencies, the RC starts to see obstacles, including limitations posed by WTO rules.

The fundamental problem seems to be lack of understanding by the RC of Member States' proposals. Its face-to-face meetings with Member States were limited and most of them ended up as briefing sessions with one-way communication. The RC did not discuss with the Member States what it thought about the latter's proposals. Even with regard to proposals which the RC felt were necessary to be clarified by Member States, the Committee sent out questions seeking clarifications via email.

In conclusion, the RC, which acknowledges "inequities in access to medical countermeasures manifested in myriad ways during pandemic", not only fails to provide technical recommendations to improve equitable access, but also discourages the creative proposals coming from the Member States.

Disciplining of unilateral measures: Two amendment proposals on paragraphs 4 and 6 of Article 43 aim at disciplining unilateral measures. For this, a quasi-judicial process is proposed to roll back unilateral measures without any scientific/public health backing. The RC states: *"The proposed amendments in general reflect a le-*

gitimate concern to strike a better balance between implementing health measures at the national level and avoiding disproportionate and unnecessary repercussions for other States Parties. The proposals in paragraphs 4 and 6 establish a quasi-judicial process with tight deadlines and binding effects for recommendations, with the Emergency Committee having the final authority to decide on the appropriateness of health measures. This Committee is concerned that these proposals may unduly impinge on the sovereignty of States Parties and give binding effects to what are supposed to be recommendations."

Apart from this remark, the RC also applies similar reasoning on the United States' proposal to provide a written explanation for rejecting WHO's offer to assist under Article 13. The fundamental fact about international lawmaking is the acceptance of limits on sovereignty, which is a political call to be left to the Member States. Thus these comments cannot be considered as purely technical recommendations. Once again, the Committee fails to see the sovereign policy space accorded under the WHO Constitution in implementing the recommendations.

Duty to cooperate: The RC takes a very narrow view on amendment proposals on Article 44 though it *"supports the affirmative idea of tangible assistance and, moreover, emphasizes that such assistance should be viewed as an act of mutual responsibility to fulfil this Article. Alternative formulations in this regard may be considered to convey this sense of partnership and mutual responsibility. Given the emphasis put on assistance in the chapeau of paragraph 1, by adding the verb 'assist' and removing the qualifier 'undertake to', States Parties may wish to reflect on the desirability of retaining the existing wording of 'to the extent possible' at the end of that paragraph".*

It is not clear why the RC wants States Parties to retain the phrase "to the extent possible" in the said provision. Does it want States Parties to demonstrate that the assistance is provided to the fullest extent possible, or does it want to allow States a discretionary choice to provide assistance or not? Even if the former is the case, the Committee then indirectly rejects the proposals to enhance the scope of WHO's duty to cooperate. It reasons: *"The numerous*

proposed amendments to paragraphs 2 and 3 introduce many new functions for WHO to fulfil, which would have serious implications for WHO in terms of human, financial and other resources." Any reasonable person would have expected the technical experts in the Committee to suggest creative ways of mobilizing such resources, rather than simply becoming a red-flag bearer.

Financial mechanism: An important shortcoming of the IHR is the absence of a financial mechanism to assist needy Member States and WHO to implement its provisions. To address this, the Africa Group has proposed a new Article 44A. Here again, though the RC recognizes the need for financing, it cautions against the creation of any such mechanism: *"The Committee is aware that the World Bank recently established the Financial Intermediary Fund, known now as the Pandemic Fund, to enhance financing for pandemic prevention, preparedness and response, for which WHO acts as Lead of the Technical Advisory Board, and has a role within the broader secretariat. ... under Article 44, WHO already has a role, in collaboration with States Parties, to mobilize financial resources, and cautions against creating an explicit financing function for WHO under the Regulations."*

Unfortunately, while drawing the attention of Member States to the Pandemic Fund facility managed by the World Bank, the RC ignores the shortcoming of the fund, where the role of WHO is limited only to technical advice and there is no role for developing countries in the management of the fund. Participation of WHO in the broader secretariat is also not helpful as the secretariat is mandated to work in accordance with the policies of the World Bank. Further, the fund is not accountable to the Member States of the IHR or WHO and it clearly allows donor priorities to shape health policy choices. The RC thus ignores the long history of World Bank funds that largely prioritize needs of donors and developed countries.

The first call from the Pandemic Fund for expression of interest (EOI) for funds is a clear demonstration that this new fund is no different in this regard. The call prioritizes health security functions such as surveillance and laboratory capacities. A State is therefore denied the opportunity to apply funds for improving its health sys-

tem or primary health care facilities, even if its health system suffered shocks during the COVID-19 response or lacks resilience to health emergencies. It must be noted that in the IHR implementation, scores for surveillance capacities stand much higher compared with other capacities like emergency coordination or infection control. Countries were seen scrambling for ventilators and oxygen cylinders during the COVID-19 shock. However, the Pandemic Fund's call for EOI provides no policy space for countries to apply for funds addressing such issues. A WHO fund accountable to the World Health Assembly would not make such wrong priorities for its Member States.

Thus, the RC, by cautioning against creation of a WHO financial mechanism, fails to consider the relevance of having a financial mechanism within the IHR 2005. Not only would such a financial mechanism be accountable to the IHR membership, but WHO would also remain as the central authority to set health policy goals.

Overall, the technical recommendations contained in the RC report maintain the status quo of the IHR 2005 which carry the colonial baggage of being a health security instrument for protecting developed countries from diseases emerging from other parts of the world. The report clearly reflects thinking that urgently needs to be changed.

Part 4 – 2nd meeting of the WGIHR

TWN Info Service on Health Issues (Feb23/06)
26 February 2023

Secretariat attempts to influence IHR amendment negotiations using Review Committee

Geneva, 26 February (Nithin Ramakrishnan) – There are concerns that negotiations to amend the International Health Regulations (IHR) 2005 may be inappropriately influenced by a review committee that was initiated by the WHO Secretariat.

At the 2nd meeting of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR) that ended on 24 February, the Secretariat proposed that the IHR Review Committee may be reconvened "at any time during the negotiations" to provide assistance if required.

This suggestion was in response to a question from the delegation from China on how Member States could benefit from the IHR Review Committee in going forward with the negotiations. According to some close to the negotiations, there was also a move to request the presence of the Review Committee members in the meetings of the Working Group, which was not accepted.

The WGIHR meeting took place from 20 to 24 February at the WHO headquarters in Geneva. The Working Group was not only discussing the IHR amendment proposals made by the States Parties to the IHR 2005, but also considered a few other agenda items, including a report by the IHR Review Committee constituted to provide technical recommendations to amendment proposals made by the States Parties.

[The IHR Review Committee was constituted at the suggestion of the WHO Secretariat. This was pushed ahead by several States Parties who feared faster progress in the Working Group would make the negotiations for a new pandemic instrument partly redundant. The terms of reference were accordingly prepared by the Secretariat leading the Review Committee to produce "legal opinions" instead of "technical" recommendations.]

According to a deeply disappointed delegate, "This sets a wrong precedent on international lawmaking negotiations. It challenges the principles of State sovereignty. Experts in international law handpicked by an international organization's Secretariat should not have passed judgements on Member States' text proposals, no matter how their work is balanced and unbiased. In being balanced and unbiased – there is a bias."

Concerns had previously been raised over this irregular procedure and the IHR Review Committee's terms of reference. These concerns have been affirmed as the Review Committee came out with a report that failed to make meaningful technical recommendations but instead made conservative remarks more or less aligning with the status quo.

Though Member States expressed appreciation for the work of the Review Committee, countries like the United States, Brazil, Namibia, Kenya and Bangladesh questioned the work of the Committee and the resulting report.

The US asked whether there was a reference to previous review committees' work on IHR implementation, referring to IHR review committees that had reviewed the technical aspects of IHR implementation previously during H1N1, Ebola and COVID-19 outbreaks as well as the review committee on establishment of national public health capacities mentioned in Annex 1 of the IHR 2005.

Brazil stated that the Member States had not been given ample opportunity to interact with the IHR Review Committee, and Member States who proposed amendments should especially have had opportunities to fully explain their proposals to the Committee or to respond to questions or provide clarifications on proposals which might not have been understood properly by the Committee. Brazil also reminded other States Parties that any decision on these proposals was not necessarily technical but political – indicating the limits of the Review Committee's mandate.

Namibia questioned the doubts cast by some of the Review Committee members on the applicability of the principle of common but differentiated responsibilities (CBDR) in health emergency law. It pointed to the continued neglect of the principle of solidarity

and international cooperation by States and told the Review Committee that the CBDR principle had become relevant in this context in order to translate the political commitment of solidarity into a legal obligation to cooperate and provide assistance. Namibia also questioned the Review Committee's remark against the creation of a WHO financial mechanism to provide financial assistance to Member States on health emergency capacities and response. It stressed that the Review Committee's remark could be inconsistent with the provisions of the WHO Constitution and raised the question whether the Committee's advice could be reconciled with Article 58 of the Constitution.

[Article 58 reads: *"A special fund to be used at the discretion of the Board shall be established to meet emergencies and unforeseen contingencies."*]

Kenya welcomed some of the recommendations of the Review Committee and criticized others. It specifically called out the Review Committee's analysis on the proposed Annex 10 on duty to cooperate as "humdrum". Kenya explained that Annex 10 would help build health emergency preparedness and response capacities including health systems strengthening. It reminded the Review Committee and States Parties that "difficulty to implement" (the remark of the Committee on Annex 10) did not mean "impossibility". Kenya also reminded that all proposals must be discussed by the WGIHR, indirectly indicating that the Review Committee's recommendations should not be the basis to reject proposals.

According to many familiar with the negotiations, the WHO Secretariat is trying to constrain the IHR amendment negotiations from several sides. This comes from fear that new legal instruments, and the facilities and funds that would follow therefrom, will be lost if Member States after amending the IHR 2005 find a new instrument redundant. This fear is misplaced because countries clearly know that a new pandemic instrument is inevitable, not to fill in the gaps of the IHR 2005, but to augment the obligations of the IHR 2005 – to prevent, prepare, respond and recover from pandemic emergencies.

Sources following the negotiations indicate that some developed countries wanting to restrict the IHR amendments to not include

provisions on equitable access are more likely to press for continued engagement with the Review Committee. In contrast, several developing countries are clear that they would not want such interferences from the Review Committee in the negotiations.

The Secretariat will prepare a tabulated document of IHR amendment proposals and respective comments from the Review Committee. On the final day of the WGIHR meeting on 24 February, developing countries suggested that this document be marked as a "reference/information" document, meaning the text will not form the basis of negotiations.

Developed countries, speaking through Monaco, tried to oppose this move, but did not succeed. Monaco indicated that the Review Committee report was very useful in terms of understanding the "feasibility" of the amendment proposals.

Since the Review Committee had cast doubts on the feasibility of several amendment proposals for enriching equity on flimsy grounds, it is becoming apparent that the Committee's recommendations are an additional battle front for developing countries which have proposed amendments to operationalize equity.

TWN Info Service on Health Issues (Mar23/02)
13 March 2023

Text negotiations on equity proposals for International Health Regulations to start in April 2023

Geneva, 12 March (K.M. Gopakumar and Nithin Ramakrishnan) – The Working Group on Amendments to the International Health Regulations (2005) (WGIHR) has decided to start text-based negotiations on proposals addressing equity during its third session, which will take place on 17 to 20 April.

This decision was taken at the second meeting of the Working Group on 20 to 24 February at the World Health Organization headquarters in Geneva.

The Working Group was set up under a World Health Assembly resolution in 2022 to carry out amendments to the International Health Regulations (IHR). The second meeting started to consider amendment proposals. Sixteen countries have submitted amendment proposals, including from the Africa Group, European Union (EU) and MERCOSUR (South American grouping of countries). Developing countries such as India, Malaysia and Bangladesh have pressed for common but differentiated responsibilities in the IHR 2005, while countries from the Africa Group and Bangladesh have extensive proposals on equitable access to health products and health systems strengthening.

Immediately after the conclusion of the general discussion in the February meeting, the Working Group started the first reading of amendments in the drafting group. Drafting group meetings are not webcast to the public and are not open to non-State actors. At the first reading, Member States explained the rationale of their amendment proposals with respect to specific IHR articles, followed by discussions. After the completion of the first reading, there was a consensus to cluster the proposals and take these up for text-based negotiations.

The proposed clusters are:

- Cluster 1: Definitions, purpose and scope, principles (Articles 1, 2 and 3)
- Cluster 2: Responsible authorities (Article 4)
- Cluster 3: Notifications, verification and provision of information (Articles 6–11, Annex 2)
- Cluster 4: Public health response and core capacities (Articles 5, 13 and new 13A, Annex 1 and new Annex 10)
- Cluster 5: Collaboration and coordination (Articles 44 and 44A)
- Cluster 6: The Emergency Committee (Articles 48 and 49)
- Cluster 7: Determination of public health emergency of international concern and standing recommendations (Articles 12, 15, 16, 17 and 18)
- Cluster 8: Points of entry, provisions for conveyances, provisions for travellers (Articles 19, 23, 24, 27, 28 and 31, Annexes 3 and 4)

- Cluster 9: Health documents, additional health measures (Articles 35, 36, 42, 43, 45 and 56, Annexes 6 and 8)
- Cluster 10: Compliance and implementation (new Article 53A, 53 *ter*, 54A, 54 *bis*).

At the time of writing, the meeting report is not available yet, but a screenshot of paragraph 10 of the draft report that was displayed on screen reads as follows:

"The Bureau presented a proposal for grouping of the proposed amendments in relevant clusters, based on discussions during the first reading session (Annex 1). There was general support for the proposed groupings and three groups of proposed amendments to be considered at the third meeting of the WGIHR with the understanding that the considerations of the groupings remain flexible and that Articles 2 and 3 will be considered throughout the discussions.

"It was stressed that amendments should be examined holistically and with due consideration to related articles and the outcome of the negotiations will be presented as a package of targeted amendments in alignment with decision WHA 75 (9)."

It was not clear which three groups of proposed amendments (clusters) would be discussed during WGIHR3. The on-screen text of the draft report did not show this list. The full list of clusters and the three priority clusters are expected to be annexed to the final report, which will be released in the coming days. However, according to some delegates, proposals in cluster 4 – public health response and core capacities (Articles 5, 13 and new 13 A, Annex 1 and new Annex 10) – will be taken up for negotiations in April. This is expected to be mentioned in Annex 1 of the report, which was not shown on screen during the discussion. An email from the WHO Secretariat to non-State actors in official relationship with WHO states that clusters 10 (Articles 53A, 53 *ter*, 54A and 54 *bis*) and 5 (Articles 44 and 44A) will also be discussed in WGIHR3 along with cluster 4.

The intersessional meetings of the WGIHR may also follow similar cluster-based discussions and prioritization of the clusters on equity. Nevertheless, the nature of the intersessional meetings is not yet clear. Russia has emphatically said the results of intersessional meetings cannot be binding. Nigeria and Namibia sought the inclu-

sion of various actors and stakeholders in the intersessional meetings. In response, the Secretariat urged Member States to consider the intersessional meetings as drafting work and suggested they need not be made open to non-State actors.

Discussion on the term "package"

During the discussion on the finalization of the WGIHR2 report, Brazil proposed the following sentence towards the end of paragraph 10: *"It was stressed that amendments should be examined holistically and as a package."*

The US opposed the term "package" and proposed its deletion. It said the term prejudged the outcome of the negotiations. Brazil then proposed the phrase *"without prejudice to the outcome of the negotiations"* to convey the idea that nothing is agreed until everything is agreed. This proposal was supported by Bangladesh.

This was followed by a request from India to retain the term "package". China also supported this and cited decision WHA75(9) of the 75th World Health Assembly which stated: *"... taking into consideration the report of the IHR Review Committee, to propose a package of targeted amendments, for consideration by the Seventy-seventh World Health Assembly, in accordance with Article 55 of the International Health Regulations (2005)"*. China said that the term "package" was used in the decision and therefore should be retained.

At this stage, the Co-Chair, Dr Ashley Bloomfield, proposed compromise text, which then formed the basis for the following paragraph: *"It was stressed that amendments should be examined holistically and with due consideration to related articles and the outcome of the negotiations will be presented as a package of targeted amendments in alignment with decision WHA 75 (9)."*

Demand for "equity" in the text on scope and purpose

Apart from various developing country demands for the principle of common but differentiated responsibilities (CBDR), a mech-

anism for access and benefit sharing (ABS), and solutions for equitable access to health products such as medicines in the IHR, there were also proposals to amend the text on the scope and purpose of the IHR 2005 contained in Article 2 to better reflect equity and health systems readiness.

Currently Article 2 states: *"The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."*

The Africa Group, Bangladesh and India have proposed amendments to Article 2. India proposed two amendments. The first is to add the term "prepare" immediately after the term "protect against". This is to explicitly mention preparedness as part of the scope and purpose of the IHR. The second is to replace the words "public health risks" with "all risks with a potential to impact public health". This phraseology would allow for health measures to be applied to all forms of risks that would affect public health.

Bangladesh proposed the insertion of the phrase "including through health systems readiness and resilience" after the words "international spread of disease". This proposal emphasizes the health system approach towards health emergency preparedness and response.

The Africa Group proposed to add the following towards the end of Article 2: "livelihood, human rights and equitable access to health products and health care technologies and know- how". The Group wants to ensure that the prevention, protection, control and public health response measures to health emergencies shall not unnecessarily interfere with not only international travel and trade but also livelihood and human rights, and shall provide equitable access to health products and health care technologies and know-how. Some States like Namibia have highlighted the need to explicitly provide for "equitable access to health products" as a necessary change to not repeat the mistakes of the COVID-19, monkeypox and Ebola responses.

During the discussion, many developing countries supported the expansion of the IHR 2005 scope and purpose. Botswana proposed the inclusion of solidarity in Article 2. Kenya supported the idea of equity. Eswatini and Peru supported the Bangladeshi proposal of strengthening of readiness and resilience of the health system.

Developed countries including the US opposed all the proposals under Article 2 except the insertion of the word "preparation". Australia and the United Kingdom also supported the inclusion of "preparation".

Kenya, in the plenary on behalf of the Africa Group, however stated: "There is a longstanding history of States Parties expanding the scope of IHRs. Such expansion should be guided by lessons learnt, and in our case, … the EB [Executive Board] Decision paved the way for this amendment."

Call for "common but differentiated responsibilities"

Bangladesh, India and Malaysia proposed CBDR as part of the principles of the IHR under Article 3. One of the major shortcomings of the IHR 2005 is that they do not effectively recognize the development divide, and they treat developing and developed countries on an equal footing, thus treating unequal State Parties equally.

CBDR is a principle which recognizes the common but differentiated responsibilities of developed and developing countries under international environmental law, and is operationalized in, for example, climate change and biodiversity treaties. In the climate change context, the principle of "CBDR and respective capabilities" (CBDR-RC) recognizes that while responding to climate change is a common responsibility of all countries, developed countries, owing to their enormous economic and technological capacity and their historical contribution to the emission and accumulation of greenhouse gases, have to take up additional responsibilities. For instance, they agreed to take on additional responsibility in reducing carbon footprints and also provide new and additional financial resources to developing countries to assist them to meet their obligations under the UN Framework Convention on Climate Change.

Applying the CBDR principle to international health emergency law requires focus on operationalizing concepts of equity and fairness, and providing the means of implementation to developing countries.

Equity: To reflect equity, the IHR 2005 and the new pandemic instrument should not consider developed and developing countries as being equal in their respective capacities to implement obligations. This means that there must be some level of differentiation between developed and developing countries in terms of what obligations both sets of countries would be subject to and what obligations would be applicable only to developed countries.

Fairness: Developing countries need policy space and fiscal space to enable them to invest in public health infrastructure facilities based on their own priorities and not those set by international donors. Temporal flexibility for developing countries is needed to achieve their full capacities under the IHR 2005, allowing them policy choice to prioritize those capacities, and requiring developed countries to not place conditionalities that alter developing countries' self-determined public health priorities, while providing financial and technological resources to them.

Means of implementation: These should be provided by developed countries, sharing more technologies, supporting endogenous technology development in developing countries, and providing financial resources to help them meet their obligations. An article in the 2020 *Netherlands Yearbook of International Law* states: "[A] more compelling need is the operational mechanisms and the corresponding legal arrangements under the more practical and normative principle of CBDR-RC. Namely, without reforming the current international health system and revising the corresponding legal tools, the concept of solidarity remains a holy yet hollow concept. To reform the entire international health regime is a huge project and is beyond the scope of this chapter. Nevertheless, to substantiate the principle of solidarity with more detailed and practical meaning, the CBDR-RC principle may serve as the first step of rebuilding the international health regime…."

During the first reading, Bangladesh, India and Malaysia explained the rationale behind their proposals for the inclusion of CBDR as a principle. During the discussion, Brazil stated that inclusion of CBDR does not differentiate countries but makes them equal.

As expected, most developed countries such as Australia, Japan, New Zealand, Norway, the European Union, the UK and the US opposed the inclusion of CBDR as a principle under Article 3. However, the US recognized in principle the "different responsibilities and the different capacities", and expressed its commitment to addressing challenges that need to be addressed, and to talk honestly to address them.

Discussions on access and benefit sharing

Discussions on ABS took place during the first reading of proposed amendments to Article 6. There are three proposals – from the Africa Group, India and Malaysia – on the sharing of pathogens or their genetic sequence data (GSD) and the benefits arising from their utilization. Additionally, the US, Indonesia and the EU proposed sharing of genetic sequence information without referring to the benefit-sharing aspects.

The Africa Group's proposal clearly states that there is no obligation to share GSD, and links such sharing with the prior establishment of an ABS system to facilitate access to pathogens and GSD, and the fair and equitable sharing of benefits emerging from such access. The proposal reads: *"No sharing of genetic sequence data or information shall be required under these Regulations. The sharing of genetic sequence data or information shall only be considered after an effective and transparent access and benefit sharing mechanism with standard material transfer agreements governing access to and use of biological material including genetic sequence data or information relating to such materials as well as fair and equitable sharing of benefits arising from their utilization is agreed to by WHO Member States, is operational and effective in delivering fair and equitable benefit sharing."*

Malaysia also proposed that the sharing of GSD be subject to the capacity of the country involved and national legislation.

According to the Convention on Biological Diversity and its Nagoya Protocol on ABS, access to genetic materials is conditional upon willingness to share the benefits emerging out of access in a fair and equitable manner. However, in practice, although sharing of pathogens or their GSD takes place, pharmaceutical companies do not share the products – such as vaccines, therapeutics and diagnostics – developed using the pathogen samples or GSD, nor the technology to produce such products. Further, these companies use intellectual property rights to legally block developing country companies from producing generic versions of those products.

During the discussion, many Africa Group Member States including Ethiopia, Ghana and Namibia made it clear that there will not be any sharing of pathogens or GSD without an ABS mechanism. China also stressed the need for an ABS system. Similarly, Brazil supported the need for sharing of benefits arising from the sharing of pathogens and GSD. The relationship with a proposed WHO Pathogen Access and Benefit Sharing mechanism as mentioned in the Zero Draft of the new pandemic instrument was also explored by the Member States.

Part 5 – 3rd meeting of the WGIHR

TWN Info Service on Health Issues (Apr23/03)
17 April 2023

Negotiations on equity proposals for IHR amendments to start

Geneva, 17 April (K.M. Gopakumar and Nithin Ramakrishnan) – The third meeting of the Working Group on Amendments to the International Health Regulations (WGIHR3) started today to negotiate proposals on equity.

The meeting is in hybrid mode from 17–20 April at the WHO headquarters in Geneva.

According to the provisional agenda, WGIHR3 is to consider amendment proposals, which include amendments to existing provisions as well as new articles. These have been submitted by the Africa Group, Bangladesh, India, Malaysia, MERCOSUR countries, Russia, the European Union and the US. Some of the key proposals cover:

- Establishment of implementation committee (Article 53A)
- The compliance committee (new Articles 53 *bis*, 53 *ter*, 53 *quater*)
- Amendments to Article 5 on surveillance
- Amendments to Article 13 on public health response
- New Annex 1A on core capacity requirements for surveillance and health response
- New Annex 10 on obligations of duty to cooperate
- New Article 13A to facilitate equitable access to medical products, technologies and know-how
- Amendment to Article 44 on collaboration and assistance
- New Article 44A to establish a financial mechanism for equity in health emergency preparedness and response.

Equitable access to health products

The most important shortcoming of the International Health Regulations (IHR) 2005 is the absence of any provision to facilitate access to health products required for preparedness and response to a public health emergency of international concern (PHEIC).

The IHR obligate a State Party to inform on all disease outbreaks "which may constitute a public health emergency of international concern within its territory" or any unusual public health events that occur within its territory but might have originated from elsewhere. This sharing of information would facilitate the WHO Director-General to take a decision on whether to declare such an event as a PHEIC.

However, there is no clear provision to guarantee assistance to provide access to health products to State Parties to effectively respond to PHEICs. As a result, the IHR effectively function as a mechanism to inform other State Parties regarding the outbreak of a potential PHEIC and to facilitate those State Parties having access to required health products to protect their own populations. This leaves the State Parties providing information through the IHR with no legally guaranteed assistance.

Since most of the disease outbreaks that fall within the scope of the IHR occur in developing countries, the information helps the developed countries to take measures to prevent spread. Thus, the IHR system practically functions as a mechanism to inform the North about outbreaks of diseases in the South without any corresponding obligation to provide the latter with access to health products.

Proposals by the Africa Group and Bangladesh to introduce a new Article 13A aim to address the issue of equitable access through diversification of production. Proposals under Article 13 would create the following obligations on WHO and State Parties:

- WHO to make an assessment of the availability and affordability of PHEIC-related health products and develop an allocation mechanism to facilitate equitable access in case of a potential shortage;

- WHO to publish a list of PHEIC-related products required for various PHEICs and maintain a database containing the detailed specifications of those products to facilitate manufacturing of those products without formal technology transfer by those manufacturers having skill in the art;
- WHO to also establish:
    - Database of raw materials for the known PHEIC products
    - Repository of cell lines to facilitate rapid non-originator production of vaccines and biotherapeutics
    - Appropriate regulatory pathway to facilitate non-originator/generic production of relevant PHEIC health products;
- State Parties to compulsorily cooperate to follow WHO recommendations on access to health products including adherence to the WHO allocation mechanism;
- State Parties to provide a temporary exemption to intellectual property protection on PHEIC-related health products;
- State Parties to share the regulatory dossiers at the request of another State Party to facilitate the scaling up of production of health products required for PHEIC response. This would help to overcome the trade-secret barrier around health products, especially vaccines and biotherapeutics like monoclonal antibodies;
- State Parties to license publicly funded technologies on PHEIC-related products, especially to manufacturers from the developing countries;
- State Parties to ensure adherence to WHO recommendations by the manufacturers of PHEIC-related health products, including sharing regulatory dossiers and deposit of cell lines.

Assistance to build core capacities

To have the ability to provide timely information to WHO on potential PHEIC events such as disease outbreaks and nuclear or chemical accidents, State Parties are under an obligation to maintain core capacities on surveillance (Article 5) and public health response (Article 13).

These core capacities are elaborated under Annex 1 of the IHR. Article 5.1 obligates all State Parties to *"develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1".*

Similarly, under Article 13.1, *"Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the capacity to respond promptly and effectively to public health risks and public health emergencies of international concern as set out in Annex 1."*

The obligations under Articles 5 and 13 ignore the development divide existing between developing and developed country State Parties, especially in terms of finance and technology. Though Article 5 creates an obligation on WHO to assist State Parties upon their request in achieving core capacity in surveillance, there are no corresponding provisions on core capacity in public health response. Thus, the obligation of WHO to assist is very generic in nature and limited to Article 5.

Another provision under Article 44.2(c) states that WHO, upon request from State Parties and to the extent possible, shall assist in *"the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1"*. However, the qualification in the provision makes it ineffective. Further, WHO is an organization that always struggles for financial resources and would not be in a position to assist developing countries without the cooperation of developed countries.

Malaysia has proposed under Articles 5 and 13 to create a moderate obligation on developed countries and WHO to assist developing countries to achieve the core capacities under Annex 1. The proposal reads: *"Developed State Parties and WHO shall offer assistance to developing State Parties depending on the availability of finance, technology and know-how for the full implementation of this article, in pursuance of Article 44."*

Though the proposal still contains qualifications like "availability of finance, technology and know-how", it clearly sets out the obligations of WHO and developed countries to assist developing countries to achieve the capacities. In the absence of effective assistance to build the core capacities, the global average capacity remains at 66%, based on the reports of State Parties.

The silence on addressing the development divide and lack of core capacities goes against the spirit of the WHO Constitution. The preamble of the Constitution reads: *"The achievement of any State in the promotion and protection of health is of value to all. Unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger."*

Apart from the abovementioned amendment proposal, the scope of core capacities would also be expanded under various proposed amendments to Annex 1. India has proposed to expand the scope of the Annex from core capacity requirements for surveillance and response, to core capacity requirements for disease detection, surveillance and health emergency response. Further, India has proposed many elements under the public health response provision.

Similarly, the Africa Group has proposed changes in core capacity related to both surveillance and response, including the health system's capacity to respond to PHEICs.

Bangladesh proposes health system strengthening as part of the core capacity under Annex 1. This would effectively expand the scope of required assistance under Articles 5 and 13, which has the potential to change the IHR from an instrument facilitating information provision from South to North, to a system based on mutual cooperation.

Duty to cooperate

Various State Parties including the Africa Group, Bangladesh, Russia and MERCOSUR countries have proposed amendments to Article 44. This Article contains obligations on the duty to cooperate between State Parties as well as between WHO and State Parties, in-

cluding on mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1.

The Africa Group has proposed a dedicated new Annex 10 to govern the assistance under Article 44. The proposal by Bangladesh is for equitable access to health products within the scope of Article 44.

New financial mechanism

The Africa Group has proposed the creation of a financial mechanism to provide assistance to developing country State Parties and WHO for the effective implementation of the IHR. This proposal resembles the Green Climate Fund established under the United Nations Framework Convention on Climate Change (UNFCCC). If agreed, it could provide the needed support to developing countries and WHO to build core capacities.

The World Bank has set up a Pandemic Fund which emerged from G20 initiatives but this is still based on voluntary contributions mainly from developed countries. The apprehension about the Pandemic Fund is that it may not serve the purpose of IHR implementation and priorities identified by IHR State Parties.

Proposals to subvert technical assistance

Developed countries led by the US and the EU have proposed further conditions for obtaining assistance under the IHR. Currently, provisions for assistance under Articles 5.3, 13.3 and 44 are based upon request from the concerned State Party. There is a burden of proof on the State Party requesting the assistance to show the need for support.

The US has proposed the following amendment to Article 5.1: *"This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism, in replacement of the Joint External Evaluation that began in 2016. Such review shall / Should such review identify resource constraints and other challenges in at-*

taining these capacities, WHO and its Regional Offices shall, upon the request of a State Party, provide or facilitate technical support and assist in the mobilization of financial resources to develop, strengthen and maintain such capacities."

Thus the proposal restricts the scope of obligation to assist developing country State Parties to only WHO. Further, it makes this conditional upon the findings of the Universal Health Periodic Review mechanism.

It is understood that the US has informally made a revised proposal on the Compliance Committee with dedicated articles on the Universal Health and Preparedness Review (UHPR), changing the term contained in its proposal to amend Article 5.1, i.e., Universal Health Periodic Review. According to the US proposal, the aim of the UHPR is to *"serve as a State Party-to-State Party intergovernmental dialogue to review and assess capacities and identify needs for assistance"*.

This would effectively institutionalize the norms on limited assistance, which is to be available upon request and to be conditional on the findings of the UHPR. Further, the proposal explaining the UHPR procedure states:

"The UHPR mechanism shall base its work on the following documentation, among others, as available:

(a) the State Party Annual Self-Assessment Report (SPAR);
(b) the Joint External Evaluation;
(c) National Action Plan for Health Security, as well as a report, to be drawn up by the Secretariat pursuant to its responsibility, based on the information available to it provided by the State Party or States Parties concerned. The Secretariat should seek clarification from the State Party or States Parties concerned of their health and preparedness policies and practices;
(d) Simulation Exercises;
(e) Intra- and After-Action Reviews; and
(f) The reports by the State Party under review and by the Secretariat, together with the minutes of the respective meeting of the UHPR, shall be published promptly after the review."

Thus, State Parties will have to undergo various evaluation initiatives currently carried out by the WHO Secretariat to obtain assistance. Further, such proposed amendments would also institutionalize all such initiatives except SPAR wherein participation is voluntary.

The EU also circulated a draft titled "Compliance and Implementation Committee" containing almost the same proposal, which makes assistance on core capacity conditional upon various evaluations.

TWN Info Service on Health Issues (May23/02)
8 May 2023

Member States to engage in equity proposals on IHR 2005 amendment

Geneva, 4 May (Nithin Ramakrishnan and K.M. Gopakumar) – WHO Member States expressed their willingness to engage in amendment proposals on the International Health Regulations (IHR) 2005, focusing on the delivery of equity, at the third meeting of the Working Group on Amendments to the IHR 2005 (WGIHR3).

WGIHR3 took place in hybrid mode on 17–20 April at the WHO headquarters in Geneva. Though the report of the meeting was discussed and adopted on 20 April, it is yet to be posted on the WGIHR webpage.

Member States adopted the report, which sets out the way forward, after three-and-a-half days of detailed substantive discussions on the IHR amendment proposals. States have agreed to hold intersessional meetings in the following format till the fourth meeting of the WGIHR (24–28 July 2023):

- Further discussions between proponents of amendment proposals,
- Facilitated informal consultations open to all drafting group members, and

- Information briefings on specific topics open to all drafting group members and other relevant stakeholders.

Further, there is an agreement on a joint meeting between the WGIHR and the Intergovernmental Negotiating Body (INB) that is developing the pandemic instrument, but this is not yet scheduled. The report states that many countries expressed interest in scheduling the meeting after the 76th session of the World Health Assembly in the last weeks of May and before the INB drafting group meeting during the week of 2 June.

WGIHR3 began with discussions on newly proposed Articles 53A, 53 *bis–quart* and 54A on implementation. Articles 5.1–5.3 and 13.1–13.4 were also discussed which mainly addressed surveillance and response capacities and offers of assistance.

Proposals on Articles 13.5, newly proposed Articles 13.7, 13A and some parts of Annex 1 were discussed on the second day, focusing more on equitable access to health products and WHO's centrality in international public health response.

On the third day, proposals on Articles 44 and 44A were discussed along with the remaining parts of Annex 1 proposals, i.e., on coordination and collaboration and the establishment of a new WHO financial mechanism accountable to WHO for the implementation of the IHR 2005.

On the final day, there was a brief discussion on newly proposed Annex 10 and then the process for the way forward was outlined in the report of the meeting. A lengthy debate occurred on the way forward and the inclusion of WHO National Focal Point experts.

According to many delegates, the WGIHR3 discussions are a precursor to text-based negotiations. Member States focused on the amendment proposals and suggested additions and deletions, rather than trying to reach consensus on the textual proposals during WGIHR3.

The European Union's proposal to mandate the WGIHR Bureau to develop streamlined text for negotiations did not find much support. The WGIHR negotiations would instead be based on the textual proposals from the Member States.

Another proposal from the WGIHR Bureau to have technical inputs from National IHR Focal Point experts during drafting group meetings received a mixed response. This was finally withdrawn, and it was agreed that there will be informational briefings involving National IHR Focal Points, regarding implementation and governance.

This is "how the negotiations should progress", according to a developing country delegate, pointing towards the process and the faith it keeps with Member States' text proposals. It shows Member States are working together despite their differences. When their text proposals are on the table, there is a lot more clarity on the content and the context. States know each other's political situation, legal tradition, political economy outlook, their ambitions and interests. It is much easier to negotiate in this way than negotiating on text that comes from a third party, whereby it is difficult to assess the intent of the text, in turn making it difficult to find common ground.

According to a senior diplomat from a developed country, it is heartening and absolutely positive that even delegations with drastically opposite views have found ways to engage with each other. "We are hopeful the intersessional work will begin to show convergences between Parties," the diplomat added.

Day 1: Debates on implementation and compliance

After the first plenary session, in which the Co-Chair requested Member States to remain focused on equity, deliberations began on the amendment proposals made by the Africa Group, the United States and the EU to establish implementation/compliance committees for improving the IHR 2005 implementation.

The US and EU proposals sought to establish an expert committee of limited Member States with quasi-judicial powers, such as calling for more information from States Parties and conducting fact-finding missions in the territories of the affected States Parties.

Developing countries, on the other hand, were asking for an implementation committee, inclusive of all Member States, which would regularly monitor and provide guidance on the functioning of the IHR 2005, establishment and development of capacities, extent

and quality of international assistance provided, actual realization of equity etc.

The US and Switzerland apparently tried to incorporate an assessment mechanism that could conditionalize financial and technical assistance following the framework of the IHR 2005. The US, which had proposed a universal periodic review on IHR core capacities establishment in its written submissions to WGIHR3, sought to circulate a new text proposal containing details of the review process, mostly adapting from WHO's pilot projects on Universal Health Preparedness Review. This proposal would convert existing voluntary assessment mechanisms into obligatory processes imposed on a State Party to the IHR.

The EU wants the implementation committee to be the part of the World Health Assembly (WHA) or to meet during the Assembly. Countries with smaller delegations are quite unhappy with this suggestion since during the WHA, there would be several agenda items going on and the discussions on IHR implementation would then not get the required time to address the details and nuances.

The Africa Group delivered a statement in the closing session reasserting its position that any committee the WGIHR may agree upon to promote compliance and assistance should have universal membership. It called on the US, the EU and Malaysia to take forward discussions on composition, structure and functioning of the committee through informal consultations during the intersessional period. It is learnt that Malaysia was previously involved in the informal discussions between the US, the EU and the Africa Group on the implementation of the IHR 2005, although it has not proposed any text itself.

Meanwhile, another crucial debate at WGIHR3 was on the use of the phraseology "developed countries" and "developing countries". Many amendments proposed to the IHR 2005 seek to create specific obligations on developed countries to provide assistance and support to other States Parties and WHO. Developed countries, especially the EU, wanted to alter these amendment proposals using the World Bank classification of countries based on income status such as high-income, upper-middle-income, lower-middle-income

and low-income countries. Developing countries opposed the move and pointed out that several other organizations including the United Nations and World Trade Organization were continuing to use the words "developed" and "developing". It is understood that Russia had questioned which were the developed and developing countries, and whether WHO had previous understanding of these terms.

In fact, Article 50.6 of the IHR 2005 uses both terms and Article 44.2(c) uses "developing countries", both obligating WHO to perform certain functions. The operations of WHO for the last 15 years under the IHR 2005 clearly indicate that there is no problem in continuing with this terminology. Moreover, it is important to understand that income-based classification of countries is not a fully relevant classification for the purposes of the IHR 2005. The indicators of development included in the UN classification, on the other hand, are appropriate for public health purposes.

Discussions on accountability on technical assistance

According to the current text of Article 13.4 of the IHR 2005, WHO is given a discretionary authority to offer assistance in terms of on-site assessment of disease/emergency outbreak by international experts, in addition to any support WHO may provide to the countries affected by the outbreak pursuant to Article 13.3. States Parties are free to accept or reject such offers of assistance. But once WHO decides to invoke Article 13.4, developing countries are more susceptible to such offers. Developed countries which are not dependent on WHO do not feel the pressure to accept any such offers.

This provision allows for intrusion into the internal affairs of the developing country States Parties by coupling "technical assistance" with "on-site assessment of outbreaks", forcing them to open their borders to international assessment teams, which could also at times involve security or defence personnel from other countries. This provision usually does not affect developed countries since they customarily do not seek assistance from WHO.

[Article 13.3 reads: *"At the request of a State Party, WHO shall collaborate in the response to public health risks and other events*

by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary."

[Article 13.4 reads: *"If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer."*]

The US in its proposals has sought to remove the clause that says "At the request of a State Party" in Article 13.3, and convert "it [WHO] may offer" to "it shall offer" in Article 13.4. This means Article 13.3 and 13.4 would both trigger mandatory proactive offers of assistance from WHO. Further, the US proposed that a country must either accept or reject such an offer of assistance within 48 hours and, in case of rejection, such country shall provide WHO with its rationale for the rejection. The proposal in turn mandates WHO to share the same with other States Parties.

Further, the proposal seeks to append another sentence to Article 13.4: *"Regarding on-site assistance, in compliance with its national law, a State Party shall make reasonable efforts to facilitate short-term access to relevant sites; in the event of a denial, it shall provide its rationale for the denial of access."*

All this shows that the real US interest in offering proactive assistance is to gain access to outbreak sites and pressurize countries that seek assistance to open their borders to international assessment teams.

Interestingly, when the Africa Group sought to amend Article 13.5 that deals with the obligation of States Parties to support WHO-coordinated public health response activities in a similar fashion, the

US, the EU and other developed countries opposed such a proposal. The Africa Group had proposed to create an obligation on States Parties to provide support to WHO's coordinated public health response to public health emergencies of international concern (PHEICs), when requested by WHO. Under the proposal, the support shall include supply of health products and technologies, especially diagnostics and other devices, personal protective equipment, therapeutics and vaccines. The proposal further wants to extend the obligation that the States Parties must also give reasons to WHO if they are unable to provide the required support to WHO.

The Africa Group has also proposed to introduce a new Annex 10 to the IHR 2005, wherein paragraph 1 sets a similar obligation to provide collaboration and assistance or to provide reasons in cases where collaboration or assistance is not provided. Unlike in the US proposal on offers of assistance, there is no timeline set in the Africa Group's proposal for responding to requests from WHO or from other States Parties, yet developed countries opposed the proposal, arguing that it is invasive of national policy space. It is learnt that several developing countries, on the other hand, supported the Africa Group's proposal. The double standards maintained by the developed countries including the US thus got exposed in the meetings.

A developing country delegate said that the developing countries have legitimate reasons to oppose the amendments sought by the US, while the rich developed countries have no moral or political reasoning to oppose the Africa Group proposal.

The developed countries' stance starkly contrasts with various international agreements that promote a duty to respond promptly to the request for assistance in an emergency. Examples include the International Civil Defence Organization (ICDO)'s Framework Convention on Civil Defence Assistance 2000, the ASEAN (Association of Southeast Asian Nations) Agreement on Disaster Management and Emergency Response 2005 and the SAARC (South Asian Association for Regional Cooperation) Agreement on Rapid Response to Natural Disasters 2011.

Such norms and rules have become part of the UN International Law Commission's work recently. Article 12.2 of the draft

articles on the protection of persons in the event of disasters 2016 states: *"When external assistance is sought by an affected State by means of a request addressed to another State, the United Nations, or other potential assisting actor, the addressee shall expeditiously give due consideration to the request and inform the affected State of its reply."*

The Africa Group's proposal to include an obligation to provide support to WHO-coordinated activities in Article 13.5 and to provide collaboration and assistance in Annex 10 is thus important and consistent with international law in this regard.

Paragraph 1 of Annex 10 reads: *"States Parties may request collaboration or assistance from WHO or from other States Parties in any of the activities mentioned in paragraph 2 or any other activities in which collaboration or assistance with regard to health emergency preparedness and response become necessary. It shall be (the) obligation of the WHO and States Parties, to whom such requests are addressed to respond to such request, promptly and to provide collaboration and assistance as requested. Any inability to provide such collaboration and assistance shall be communicated to the requesting States and WHO along with reasons."*

Days 2 and 3: Equitable access to health products, technologies and finance

On the second day of WGIHR3, developed countries initially opposed the proposals of the Africa Group and Bangladesh for a new Article 13A in the IHR 2005. Both the proposals seek to address the issue of equitable access to health products through a WHO-mediated allocation plan and diversification of production.

The developed countries, despite their failure to provide for equitable access to health products for responding to the COVID-19 pandemic, continued to oppose these proposals with arguments on the scope of the IHR 2005 and WHO's constitutional mandate. While making such arguments, they totally ignored the *travaux preparatoires* (negotiation history) and current practice of the IHR 2005 that suggest the scope of the IHR 2005 to be inclusive of equitable

access to health products required for responding to PHEICs. It is understood that WHO legal counsel Steven Solomon clarified that these proposals could fall within the scope of WHO's mandate. The WHO Secretariat was commended for its "wise interventions" by Brazil during the closing session.

Following detailed interventions by the Africa Group and Bangladesh, Member States decided to further engage in informal consultations on the proposals. Similarly, after initial resistance to developing country proposals for amendments to Article 44 on coordination and assistance, and a new Article 44A establishing a financial mechanism for IHR 2005 implementation, the discussions ended on a positive note, where Member States agreed to further consider the proposals through intersessional work. It was learnt that developing country Member States cited the example and modalities of the contingency fund established at WHO by the Executive Board decision following the Ebola outbreak and response.

Although certain developed countries belonging to the Group of Friends of a Pandemic Treaty continue to be sceptical on the scope of the IHR 2005, there is a clear understanding emerging that the IHR 2005's scope is amenable to Member States' interpretation.

On the last day of WGIHR3, Brazil emphasized the need to balance the possibility of enlarging the minimum requirements of surveillance under the IHR with equitable and timely access to pandemic response products. Brazil reasserted that the equity discussions should take place in the WGIHR and INB, while Indonesia acknowledged there will be some duplication in both instruments.

During the opening plenary of WGIHR3, Indonesia had stated that "synergy and coherence means not only the avoidance of duplication; perhaps, some duplication is necessary, but synergy and coherence could be in the form of cross-referencing among the two documents or in other forms that may be necessary".

During the closing plenary, Tanzania stressed the need for equity in the IHR 2005, while Kenya stated that it was looking forward to a strengthened IHR 2005 that addresses the equity-related gaps identified by several expert review panels.

Ethiopia said it was optimistic on the equity pillar.

The US called for “tangible outcomes”, while China remarked on the constructive engagement of Member States and said that it was improving when compared with past negotiations. The Africa Group stressed the need for an implementation committee that is inclusive of all States Parties to the IHR 2005 and highlighted the importance of health systems strengthening.

Part 6 – 4th meeting of the WGIHR

TWN Info Service on Health Issues (Jul23/04)
24 July 2023

North's proposals to take centrestage in IHR working group meeting

Geneva, 24 July (TWN) – The fourth meeting of the Working Group on Amendments to the International Health Regulations (WGIHR4) is to discuss various developed country amendment proposals focusing on accelerated information sharing and compliance.

These proposals are from the US, the European Union (EU), Switzerland and New Zealand.

WGIHR4 will take place at the WHO headquarters in Geneva on 24–28 July in a hybrid mode.

According to the WGIHR4 draft programme of work, amendment proposals to the following articles will be considered:

- Responsible authorities – Article 4
- Notification, verification and provision of information – Article 5 (paragraph 4 and new paragraph 5). Articles 6–11, Annex 2 and new Annex 2 as an alternative
- The Emergency Committee – Articles 48 and 49
- Determination of a public health emergency of international concern – Article 12
- Temporary and standing recommendations – Articles 15–18.

The third meeting of the WGIHR had focused on amendment proposals on Article 13 (public health response), new article 13A (equitable access to health products, technologies and know-how), 43 (additional health measures), 44 (collaboration and cooperation), new article 44A (financing mechanism) and new Article 53A (implementation and compliance).

This week the majority of the amendment proposals under consideration are from developed countries. Many of these aim at enhancing the obligations on information sharing and compliance, which may seem reasonable on the surface but can be negative for developing countries. It is noteworthy that none of the developed

country proposals focus on equitable access to medical products (such as diagnostics, medicines, vaccines or therapeutics) required for preparedness and response to public health emergencies of international concern.

Some of these proposals raise the following concerns:

- Creating obligations to have a vertical approach on emergencies;
- Classifying emergencies of international concern into national, regional and global risks, thereby abdicating from international responsibilities;
- Creating obligations on States Parties and WHO to share more information including genetic sequence data;
- Reducing policy space and discretion of States Parties in the name of accountability and time constraints, including in obligations to share information;
- Making available the information shared with WHO to other agencies, including international organizations like the IAEA, FAO, WTO and international financial institutions and to all States Parties and their national entities;
- Empowering WHO to take actions without consulting with affected States Parties.

Responsible authorities (Article 4)

There are five amendment proposals under this article. Two of them are from Russia and another two from Switzerland. The fifth amendment proposal is from the Africa Group and would obligate WHO to provide technical assistance to National Focal Points.

The first Russian proposal seeks to designate or establish an "entity" as the IHR Focal Point. Under the current provision, each State Party shall either designate or establish a National IHR Focal Point. The proposal aims to change the current obligation from the designation or establishment of an "entity" as National IHR Focal Point to the creation of an independent or separate institution as IHR Focal Point.

The second proposal from Russia aims to provide legal authority to the National IHR Focal Point and reads: *"States Parties shall / ALT may enact or adapt legislation to provide National IHR Focal Points with the authority and resources to perform their functions, clearly defining the tasks and function of the entity with a role of National IHR Focal Point in implementing the obligations under these Regulations."*

Switzerland's first proposal also requires the States Parties to establish a National Competent Authority responsible for IHR implementation. It states: *"In addition, each State Party should inform WHO about the establishment of its National Competent Authority responsible for overall implementation of the IHR that will be recognized and held accountable for the NFP's functionality and the delivery of other IHR obligations."*

The second Swiss proposal seeks to create an obligation on States Parties to provide the contact details of National Competent Authorities (replacing the current National IHR Focal Points) to WHO.

These four amendment proposals aim to create independent authorities in charge of IHR implementation and to convert the current National IHR Focal Point into a larger, free-standing institution. This could result in creating silos in the health system by taking away the emergency preparedness and response functions from the authority in charge of health system administration. Such an approach may result in the flow of international assistance directly to such IHR authorities, limiting the resources available for strengthening broader health systems. The health system is the backbone of a broad emergency response system, and in the absence of health system resilience, emergency preparedness and response will be compromised.

Further, it would result in the fragmentation and duplication of scarce domestic health finance. It is interesting to note that the Swiss proposal is not accompanied by any proposals on technical and financial assistance to implement the IHR in developing countries.

Creation of such authorities at the national level and adoption of national legislation may also lead to the harmonization of health emergency preparedness and actions, constraining the policy space

for States Parties through international networks, as happened in the case of networks of economic regulators. Thus, these proposals bear the danger of verticalization of health emergency preparedness and response work at the national level and of fragmenting the health system.

Surveillance (Article 5)

Since WGIHR3 had discussed amendment proposals on paragraphs 1, 2 and 3 of Article 5, WGIHR4 will discuss amendment proposals on paragraph 4, including a new proposed paragraph and three other amendment proposals for a new paragraph 5.

The US proposes a new paragraph 5 which reads: *"WHO shall develop early warning criteria for assessing and progressively updating the national, regional, or global risk posed by an event of unknown causes or sources and shall convey this risk assessment to States Parties in accordance with Articles 11 and 45 where appropriate. The risk assessment shall indicate, based on the best available knowledge, the level of risk of potential spread and risks of potential serious public health impacts, based on assessed infectiousness and severity of the illness."*

This proposal alters the IHR's approach to risk assessment and divides it into national, regional and global levels. The proposed US approach is followed up with amendment proposals to declare a public health emergency of regional concern and intermediate health alert under Article 12. [Article 12 deals with the declaration of a public health emergency of international concern (PHEIC).]

This type of grading of emergencies based on the geographical spread provides a justification for the developed countries to abdicate from their responsibilities in international/global health by classifying an emergency as regional. Further, this approach may keep certain regions under a health emergency for a long time, with adverse implications for trade and travel.

Notifications (Article 6)

The US proposes an amendment to paragraph 1 of Article 6 which obligates States Parties to complete the assessment of a public health event within 48 hours using the decision instrument included in Annex 2. This proposal overlooks the asymmetries existing in terms of technical and resource capabilities among States Parties. Like Switzerland, the US is also not offering any assistance to comply with such obligations. It must be also noted that States Parties already have an obligation to develop capacities to conduct the assessment of all urgent events within 48 hours under the existing Annex 1. As such, the US proposal is redundant.

Further, the US also proposes an amendment to the last sentence of paragraph 1, which currently obligates WHO to notify the International Atomic Energy Agency (IAEA) if the notification from the State Party falls within the competency of the Agency. The proposal expands the scope of this obligation to include the UN Food and Agriculture Organization (FAO), World Organisation for Animal Health (OIE), UN Environment Programme (UNEP) and other relevant entities. This proposal thus brings the One Health approach to the IHR without directly mentioning it. Such wide sharing of information with these organizations even before assessing the information shared by State Parties scientifically, bears the risk of adverse economic implications for the affected countries.

In paragraph 2, the US and the EU propose that sharing genetic sequence data be made part of the obligation to share public health information. Currently the scope of public health information includes *"case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern"*.

The EU's proposal even goes beyond genetic sequence data as follows: *"... epidemiological and clinical data, as well as microbial and genomic data in case of an event caused by an infectious agent,*

genome sequencing data if available" as well as *"implemented and other related information as per request of WHO"*.

The EU also has a proposal under Article 7 which has complementary interests to the Article 6 proposals, which would obligate States Parties to share genetic materials, but without any mention of benefit sharing.

The EU and its Member States are Parties to the Convention on Biological Diversity (CBD) and its Nagoya Protocol on access and benefit sharing (ABS), and thus have existing international obligations on ABS. The US is not a Party but was nevertheless heavily involved in the CBD negotiations; though it did not ratify the CBD, it is a signatory. As such, international law requires the US to still act in good faith and to refrain from acts which would defeat the object and purpose of CBD.

[Article 18 of the Vienna Convention on the Law of Treaties requires a State to refrain from acts which would defeat the object and purpose of a treaty "when it has signed the treaty, subject to ratification, acceptance or approval, until it shall have made its intention clear not to become a party to the treaty". The US so far, as the UN Treaties webpage shows, has not made any declaration regarding its intention not to ratify the CBD. It continues to actively participate as an "observer State" in the Conference of the Parties to the CBD and in many other meetings of its subsidiary bodies.]

The international ABS regime imposes an obligation on Parties and entities accessing pathogens or related information to fairly and equitably share the benefits emerging from the use of such pathogens or related information, including health products such as vaccines, diagnostics and therapeutics. For instance, WHO's Pandemic Influenza Preparedness Framework (which the US does support) establishes a benefit-sharing mechanism to smoothen the sharing of pandemic influenza virus or related information.

The EU, however, also proposes the following language which could be seen as an indirect recognition for setting up ABS rules for genetic sequence data of pathogens: *"With the aim of fostering event related research and assessment, the WHO shall make the information received available to all Parties in accordance with modalities to be adopted by the Health Assembly."*

Developing countries, on the other hand, have submitted some proposals which seek to have a responsible regime of information sharing which takes into account the need for benefit sharing and balancing the health security agenda of developed countries with equity for developing countries.

The Africa Group clearly proposes that the sharing of genetic materials and genetic sequence data should be based on a Standard Material Transfer Agreement (SMTA) developed by Member States. The proposal reads: *"No sharing of genetic sequence data or information shall be required under these Regulations. The sharing of genetic sequence data or information shall only be considered after an effective and transparent access and benefit sharing mechanism with standard material transfer agreements governing access to and use of biological material including genetic sequence data or information relating to such materials as well as fair and equitable sharing of benefits arising from their utilization is agreed to by WHO Member States, is operational and effective in delivering fair and equitable benefit sharing."*

Malaysia made a proposal pointing to the need for taking into account the capacities of States Parties in sharing genetic sequence data. It also proposed that WHO shall not transfer public health information received pursuant to Article 6 *"to establishments, personnel, non-state actors or any recipient whatsoever engaging directly or indirectly with conflict and violence elements. WHO shall also handle the information in a manner designed to avoid such actors accessing the information, directly or indirectly"*.

Removal of consultation (Article 9)

Article 9 allows WHO to "take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring".

Under this Article, WHO is under an obligation to consult the State Party in whose territory the event is allegedly occurring and

also to attempt to verify the information obtained from other sources. The details of the consultation with the State Party are contained in Article 10.

The US proposes to delete the mandatory consultation from Article 9. This would give WHO the power to proceed with actions based on the information received without consultation with the concerned State Party. As shown below, the US proposes mandatory sharing of such information, without consultation and verification with concerned States Parties, to other State Parties under Articles 10 and 11.

Verification (Article 10)

The US has proposed several amendments under Article 10 which essentially take away the process of consultation prior to verification of information, and also set a narrow timeframe to accept or reject the offer of collaboration from WHO in assessing potential for international disease spread, possible interference with international traffic and the adequacy of control measures including through on-site assessments.

Firstly, in Article 10.1 the US proposes to set a 24-hour timeline for WHO to request for the verification of information from other sources with the concerned State Party without undergoing a consultation process under Article 9.

Secondly, the US proposes to remove the reference to Article 9 in paragraph 2, which deals with the timeline and list of information to be verified. It further adds references to paragraphs 1 and 2 of Article 6, thereby ensuring the duty of States Parties to provide verification on specific components of public health information as listed in Article 6.2. It must be noted that this proposal will empower WHO to require genetic sequence data of pathogens or other biological information from States Parties.

Thirdly, the proposal sets a 24-hour timeline for WHO to offer assistance to collaborate with the concerned State Party. Currently there is no such time limit. Such assistance is primarily for *"assessing the potential for international disease spread, possible interfer-*

ence with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments".

Fourthly, a new paragraph 3 *bis* has been proposed which sets a strict timeline of 24 hours for the State Party to request clarifications on the offer to collaborate. Failure to respond within 48 hours from WHO's initial offer of collaboration will be deemed as a rejection of the offer. The proposed paragraph reads: *"Within 24 hours of receiving a WHO offer of collaboration, the State Party may request additional information supporting the offer. WHO shall provide such information within 24 hours. When 48 hours have elapsed since the initial WHO offer of collaboration, failure by the State Party to accept the offer of collaboration shall constitute rejection for the purposes of sharing available information with States Parties under Paragraph 4 of this section."*

Fifthly, the proposal seeks to amend paragraph 4 to remove the discretion of WHO to share the information immediately after the non-acceptance of the offer of collaboration (i.e., 48 hours) with other State Parties, without taking into account the views of the concerned State Party. The current paragraph 4 provides discretion to WHO by using the verb "may" and also requires WHO to take into account the views of the State Party concerned. The US seeks to replace "may" with "shall" and to delete the clause requiring WHO to take into account the views of the State Party concerned.

Apart from the US, New Zealand also proposes two amendments to paragraphs 1, 2 and 3 which aim to speed up the verification process, and offer for collaboration, as soon as possible without any specific timeline. It must be noted that the timeframe proposed by the US is highly impractical, because both the State Party and WHO are given only 24 hours each to request clarifications or offer of collaboration, and to respond respectively. This means by the time States Parties receive clarifications from WHO, the time for accepting or rejecting the offer will have lapsed. WHO will then be free to take actions based on the claim that it deems the concerned State Party has rejected the collaboration offer.

Provision of information by WHO (Article 11)

Article 11 of the IHR sets the contours of information obtained from States Parties and other sources by WHO. Paragraph 1 of Article 11 allows WHO, subject to paragraph 2, to share with all States Parties, and with relevant intergovernmental organizations as appropriate, public health information which it has received under Articles 5–10 and which is necessary to enable the States Parties to respond to a public health risk. WHO may also share information that might help States Parties in preventing the occurrence of similar events.

Paragraph 2, however, is worded in the reverse, i.e., that WHO shall not share information it received under Articles 6, 8 and 9.2 unless otherwise agreed upon by the Member States, until such time as:

(a) a PHEIC is declared under Article 12; or
(b) information evidencing an international spread of disease is confirmed by WHO; or
(c) evidence shows that control measures are not likely to succeed against the international spread or the affected States Parties affected lack sufficient capacities to carry out necessary measures; or
(d) the infection or contamination requires the immediate application of international control measures.

The US proposal attempts to alter the measured approach of Article 11 in the reverse direction. It seeks to make it obligatory on WHO to share the information under any of the above situations. It also proposes to expand the scope of the situation under which information is to be shared under Article 11 by adding an overarching condition as sub-paragraph (e), which says: *"WHO determines it is necessary that such information be made available to other States Parties to make informed, timely risk assessments."*

Meanwhile the EU has proposed to change the title of this provision from "Provision of Information by WHO" to "Exchange of Information".

The net effect of the changes proposed to Article 11 is that WHO is obligated to share all the information that it receives, with every Member State, irrespective of the source, on a precautionary

basis. The US proposal to create the obligation to share information has retained the exception in Article 11, i.e., "unless otherwise agreed upon by other Member States". This exception will help powerful countries to still guard against proactive sharing of information by WHO against their interests.

In another interesting proposal, the US seeks to alter WHO's obligation to consult the affected State Party under Article 11.3 to inform the affected State Party of its intent to make the information available. This takes away the opportunity of States Parties to raise their concerns at the international forum. Moreover, a consultation is a significant tool that can help assess the ground realities.

Another problem with the proposed amendment is that in the text of Article 11.2, a designated authority is identified only with regard to Article 11.2(a). The other sub-paragraphs of Article 11.2, including the newly proposed sub-paragraph (e), do not specify any authority within WHO in charge of providing information. The provisions simply say "WHO". The definition of WHO in Article 1 also only says "World Health Organization".

Determination of PHEIC (Article 12)

Under Article 12, the WHO Director-General has to consult with affected States Parties in whose territory the event is happening before (s)he convenes an Emergency Committee (EC). Under paragraphs 2 and 3 of Article 12, a timeline of 48 hours has been accorded to the Director-General to convene a meeting of the EC after consulting with the affected State Party, with a view to reaching agreement between him/her and the State Party. The Director-General may also convene an EC after 48 hours even if the affected State Party does not agree with WHO.

The US has proposed several changes to this provision. The proposal seeks four important changes, among many others.

Firstly, it proposes to give notification to all States Parties even before an EC is called to convene, when the WHO Director-General considers that a potential or actual public health emergency of international concern is occurring.

Secondly, it introduces new concepts like "public health emergency of regional concern" and "intermediary health alert" to be determined by the Regional Director or the Director-General.

Thirdly, it proposes to remove the 48-hour gap provided for the consultation process with Member States for the establishment of the EC.

Fourthly, it proposes to have consultations with all relevant States Parties, which may include States Parties which are not affected by the spread of disease or PHEIC, in order to determine if the PHEIC has ended.

It is highly probable that with each of the intermediary health alerts, unwanted interruptions in international traffic and trade can happen, as recently experienced by Southern African countries immediately after their notification of the Omicron variant of the COVID-19 virus.

Further, a public health emergency of regional concern can be used to differentiate many outbreaks or events from a PHEIC, and consequently developed countries could abdicate from their responsibility and duty to collaborate and provide assistance to affected States.

TWN Info Service on Health Issues (Aug23/01)
14 August 2023

IHR amendments on "surveillance" and "intermediate alert" move to informal meetings

Geneva, 14 August (TWN) – The fourth meeting of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR4) decided to hold informal meetings to discuss amendment proposals on surveillance (Article 5) and the determination of a public health emergency of international concern (PHEIC) (Article 12).

Although Article 12 primarily deals with the determination of a PHEIC, the proposals for amendments are mostly related to eliminating consultations between WHO and the concerned State Party and

introducing intermediate alerts as well as emergencies of regional concern.

WGIHR4 took place from 24 to 28 July at the WHO headquarters in Geneva.

As reported earlier, the work of WGIHR4 substantially focused on amendment proposals made by developed countries on issues including National Focal Points (Article 4), surveillance (Article 5), notification and sharing of information (Article 6), sharing of genetic materials (Article 7), consultation, verification and information from WHO (Articles 8–11), and regional and intermediate alerts (Article 12).

Several of the proposals from the developing countries had been discussed during WGIHR3, including equitable access to health products, a financial mechanism and strengthening of health systems capacities.

During WGIHR4, developing countries questioned how the abovementioned proposals on Articles 4 to 12, essentially initiated by the US, would improve the current functioning of the IHR 2005 or the delivery of equity, which is an unequivocal mandate of the amendment process. They argued that several of the proposals substantially alter the obligations on information sharing between WHO and Member States, as well as with other entities, and that such changes are inconsistent with the stated purpose and scope of the IHR 2005. Following this, several of the proposals were pushed to informal consultations for further discussions and consensus building, with an understanding that no informal meetings will take place during the month of August.

The report of WGIHR4 reads: *"The Working Group agreed that efforts should continue during the intersessional period, including as follows:*

- *Discussions between proponents of various proposed amendments, with a view to presentation of any outcomes for the consideration of the drafting group.*
- *Intersessional briefings and facilitated informal consultations, in a hybrid format open to all drafting group members, as well as joint intersessional work with the INB at dates and times to*

be announced, covering Articles and Annexes discussed during the fourth meeting of the WGIHR, including those that have been the subject of intersessional work…"

The report does not specifically identify the amendment proposals or provisions that would be dealt with in the informal intersessional work. However, according to a few developing country delegates, the Bureau Co-Chairs will intimate the proposals and provisions to be taken up during the intersessional informals; nevertheless, Articles 5 and 12 will definitely be discussed.

Under Article 5, the US has proposed that WHO shall develop an early warning criterion for assessing and progressively updating the national, regional or global risk posed by an event of unknown causes or sources and shall convey this risk assessment to States Parties.

Under Article 12, the US proposal seeks to eliminate the obligation of WHO to seek consultation with States Parties on whose territories the event is occurring before the determination of a PHEIC as well as notifying other States Parties. On the other hand, to determine the termination of a PHEIC, the US wants WHO to consult "relevant States Parties", i.e., not just the States Parties on whose territories the events are occurring.

Further, the US wants to enable WHO to declare public health emergencies of regional concern and an intermediate alert during events which do not constitute a PHEIC but need a potential international health response. Some countries such as the Republic of Korea, New Zealand, Russia and India also have similar proposals on early warning and localization of health emergency concerns.

The US proposals on Article 12 need to be read along with other US proposals related to Articles 6, 10 and 11, where States Parties and WHO will have to work within a very short span of time to make and communicate decisions. There again the US has proposed to increase the scope of information to be shared and eliminate consultation. At the same time, the US proposals contain nothing on sharing of benefits derived from such sharing of information, or on forging a better international public health response. For instance, under Article 12, after proposing intermediate alert and emergencies of region-

al concern, the US fails to provide for "actions" or "international public health response" that will need to follow.

The US proposals faced opposition not only from developing countries, but also from some other developed countries which were also of the opinion that regional alerts and intermediate alerts could affect the fabric of international health regulations and politicize the determination of PHEICs.

No informal consultation on Article 4 and Co-Chairs prepare text for negotiations

Interestingly, with an intent to push forward a low-hanging-fruit approach, the WGIHR Bureau initiated a more text-based approach when it came to the proposals on national authorities, surveillance and other related provisions on information sharing, determination of PHEICs and notification.

Currently Article 4 provides for responsible authorities for the implementation of health measures under the IHR 2005 though specifics are only provided for having National IHR Focal Points (NFPs) and their functions. Switzerland and Russia have proposed to establish a "National Competent Authority" for overall implementation of the IHR 2005 and adoption of national legislation respectively.

Although there were several conceptual issues relating to a variety of the institutions proposed under Article 4, the Co-Chairs produced new text with the help of the secretariat that substantially alters the existing Article 4. The new text proposed for Article 4 seeks to establish two or more entities in States Parties to the IHR in addition to National Focal Points, i.e., National IHR Authority and other competent authorities. According to the new proposal, the major function of NFPs will be communication with WHO IHR Focal Points. The National Authority will look after the overall implementation of the IHR 2005, and the competent authorities will take up their respective functions as listed in Article 22 such as monitoring persons, cargo and conveyances so that they remain uninfected and free from sources of infection or contamination. Another function is supervising service providers concerning travellers, cargo and con-

veyances including through conduct of inspections and medical examination.

As in the current text, National Focal Points are, under the Co-Chairs' proposal, specifically obligated to send out communications to WHO under various provisions from Articles 6 to 12. They are also required to collect information as well as send information to various administrative departments including points of entry health departments. Further, the Co-Chairs' proposal assigns all obligations not specifically assigned to NFPs or other competent authorities to the National IHR Authority's portfolio.

States Parties are further required to provide adequate financial and human resources to these entities as well as to consider enacting or adapting legislation providing for the functioning of these entities. It is also provided that States Parties will share with WHO the contact information of NFPs and National IHR Authorities, and WHO will in turn share with all States Parties the contact information thus collected. The Co-Chairs' proposal also stipulates obligations on WHO IHR Focal Points to send out urgent communications to NFPs under Articles 6 to 12.

It was decided that the Co-Chairs' text proposal would be taken up for discussion in the morning session of the last day of WGIHR4, along with text on Article 13A on equitable access to health products and technologies developed by the co-facilitators of the informal meetings, i.e., Bangladesh and Botswana. Article 4 was extensively discussed during the last day, but delegations refrained from making textual suggestions. The discussions took up most of the scheduled time, resulting in no negotiation engagement on Article 13A.

The implication of this new Article 4 proposal is that States Parties to the IHR would be obligated to establish a National IHR Authority and share the contact details with WHO. Currently certain States Parties have National IHR Focal Points in a department or a section office and are free to choose where they want to establish, terminate or restructure these points as needed. If this new proposal goes through, a substantial amount of resources must be set aside in the national health budget to maintain such an office, diverting limited resources available for broader health systems strengthening.

There are concerns that donor countries will place such conditionalities through WHO and other institutions like the World Bank when providing financial resources.

Furthermore, while National IHR Focal Points are explicitly obligated to share information and provide response to communications sent by the WHO IHR Focal Points, no corresponding obligations are placed on the WHO IHR Focal Points to provide responses to requests for assistance from Member States under Article 13 on public health response. For all these reasons, the Co-Chairs' proposal invited criticism.

US calls for consideration of joint meeting of WGIHR and INB on governance

Amongst various other developments during the week of WGIHR4, the US called for joint work of the WGIHR and the Intergovernmental Negotiating Body developing a new pandemic instrument (INB) on governance mechanisms. According to a developing country delegate, the US stated that there are many co-benefits to be realized by having "a governing body" that could provide guidance to both the IHR and the new pandemic instrument.

The US further suggested that issues relating to Articles 53 and 54 of the IHR 2005 could be discussed in conjunction with Chapter III on governance being discussed in the INB. Other co-facilitators who engaged in the informal consultations regarding the subject matter, i.e., the EU, Malaysia and the Africa Group, seemed to have agreed to this call. "There was no objection to the proposal," said the delegate.

WGIHR's informal meetings in stark contrast with INB

While it is a concern that Member States are constantly pushed to discuss proposals informally, the WGIHR does it in a more transparent way by placing Member States' text proposals on the negotiating draft and then inviting proponents of the proposals to facilitate informal consultations and discussions. The informal consultations

at the WGIHR after the launch of formal negotiations are mostly led by proponents of text themselves, although one of the informals on Article 44A (WHO financial mechanism) was facilitated by Saudi Arabia, which was not a proponent of the text in question.

At the INB, in comparison, Member States are pressured into informals without the adoption of the formal negotiating text. These informals are facilitated by volunteer delegations rather than the proponents of the text. It is of concern that the INB mandates these delegations who co-facilitate informal meetings to develop text based on the discussions to be formally incorporated in the Bureau's text for the new pandemic instrument. This essentially makes States compromise on their text proposals even before the launch of formal negotiations.

Regulation of information sharing gets attention

Malaysia had proposed to obligate WHO to ensure that information shared with them is not transferred to entities engaging in conflict settings or performing violent activities as well as to take precautions such that it is not reaching such entities otherwise. Although this was initially opposed, later during the discussions, several countries expressed second thoughts on the need for disciplined sharing of information under WHO.

It must be noted that the new proposals from developed countries make information sharing under the IHR 2005 a broad mechanism whereby not only the scope of information shared but also the number of actors with which information is shared is increased. Much of health information, including the genetic sequence information of pathogens, is very sensitive information and could be misused by actors that perpetrate illegality. It could cause national security concerns. Therefore, Malaysia submitted this proposal that the information shared with WHO should be handled with due diligence so that WHO should know who is using their data and for what purposes.

Some of the developing country delegates indicated that they are waiting for a revised text proposal from Malaysia, as they find it

critical and useful to have a trustworthy environment for sharing of information.

TWN Info Service on Health Issues (Aug23/02) 14 August 2023

South calls for "equity across the board" in joint WGIHR/ INB meeting

Geneva, 14 August (Nithin Ramakrishnan) – Developing countries called for equity across the board during a joint plenary meeting of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR) and the Intergovernmental Negotiating Body (INB) on the new pandemic instrument.

The call is to incorporate equity in both the new pandemic instrument as well as in the amended International Health Regulations. In particular, developing countries strongly urged the inclusion of provisions to facilitate equitable access to health products and technologies in both instruments given the development divide between developing and developed countries.

Although developed countries like Monaco, Switzerland, Japan, Canada and the UK attempted to park equity issues in the new pandemic instrument, Australia and the US indicated the possibility and the need to address equity in both instruments. The EU acknowledged that there is no constitutional barrier to accommodating equity in both instruments, without explicitly recognizing the need for equity in the IHR 2005.

The first joint plenary meeting of the WGIHR and INB took place on 21 and 24 July 2023 at the WHO headquarters in Geneva, in hybrid mode. As reported earlier, the joint meeting was primarily organized to deliberate upon the relationship between the two instruments on the following agenda: objectives and scope of both instruments (agenda item 2), and a list of topics which are of common interest to both the INB and WGIHR (agenda item 3). The list includes

(i) equity, (ii) common but differentiated responsibilities between developed and developing countries (CBDR), (iii) surveillance, (iv) review and reporting, (v) access to health products, (vi) access and benefit sharing, (vii) financing, (viii) capacity building/collaboration and cooperation, and (ix) preparedness and health systems resilience.

Ethiopia, speaking on behalf of 47 Member States in the Africa Group, in the opening statement explained the need to address equity within both instruments for the following reasons:

"… the African Member States recognize that building resilient core capacities for effective implementation of the IHR is a necessary prerequisite for the realization of the objectives of the IHR and that fit for purpose IHR implementation is critical to the aspirational objective of the WHO CA+.

"We therefore view the two instruments as being part of the same continuum and serving the same overall purpose but at varying degrees. Hence there is a need to ensure the maximum level of complementarity and synergy between the two instruments to ensure that they individually and collectively deliver on their respective objectives.

"The mandate from the 150th Session of the Executive Board urged WHO Member States to take all appropriate measures to propose amendments that address equity, technological or other developments that are critical to supporting effective implementation and compliance of the International Health Regulations. It is for these reasons that the African Member States proposed amendments to the IHR, which are focused on delivering on this equity mandate … the African Member States seek to address equity related gaps within both instruments."

["WHO CA+" is the term used for "WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response", as the legal nature of the instrument has not been decided yet.]

Kenya reiterated that the IHR are the foundational instrument and fully supported strengthening of the IHR through amendments in the WGIHR. It stated that the "major role of the WHO CA+ is to augment the IHR in the unfortunate event a PHEIC becomes Pan-

demic and this complementarity needs to be maintained with overlaps where necessary".

Brazil stated that "it is crucial to ensure that both instruments are coherent, complementary, mutually reinforcing and guided by equity in order to address gaps identified in the COVID-19 pandemic and in other PHEICs. In our view some elements should remain in the IHR such as surveillance, notification of potential public health emergencies of international concern, health documents, recommendations of public health measures related to persons and cargo, including on the points of entry … Each instrument has its own specificity and scope. However, equity is a key concept and should be present in both the pandemic instrument and the IHR. The same is true for access to health products, technologies, implementation support measures, resources and international cooperation".

Argentina said it was convinced that both the processes have to be complementary. However, this should not weaken the IHR to prevent the spread of a disease. It stressed the need to protect and strengthen the IHR and keep in mind the legal nature of the instrument. According to the delegation, "containment effort was the main justification for having IHR 2005, so that we could have a concerted response" that would prioritize the international community's effort and focus on the source of the potential propagation event.

The Philippines stated that the IHR and the WHO CA+ have similar goals, and continuum of the PHEIC and pandemic response naturally leads to crossovers in both the processes. It further stated that equity is the core principle and the desired outcome of the WHO CA+ and amended IHR. The delegation called upon Member States to resist the urge to compartmentalize prematurely and warned about the loss of useful proposals altogether otherwise. "When we have greater certainty over the form that each instrument takes, we can begin to identify where duplications serve to reinforce and where they create conflict and confusion that need to be resolved."

Fiji stated that "complementarity does not mean that a certain issue cannot be reflected in both instruments where necessary as long as it is not contradictory … With a pandemic being a level up from the PHEIC, we therefore agree with the Africa Group that certain

provisions of the WHO CA+ must also apply to PHEIC to prevent escalation to pandemic, for example access to pandemic-related products, technology transfer and financing etc".

Indonesia, which cautioned against making the joint WGIHR-INB meeting a third track of negotiations, stated that the IHR and the pandemic instrument are two equal-footing instruments of different scope. It stated that the two instruments "should ensure that the next pandemic is addressed in a more equitable manner" and argued that equity should guide the discussion and its operationalization should be one of the main goals of the processes.

China argued that the IHR and WHO CA+ are two stages of the same thing and are interrelated and inseparable. The delegation stressed on a few requirements. First, equity should be fully discussed and fully reflected in both instruments. Second, duplication should be reduced in the institutional governance arrangements, including evaluation and reporting, such that it "should be an arrangement that does not create a dual track that burdens Member States' compliance and implementation". Third, it wanted to settle the definition of pandemic and determination mechanism for pandemic, as soon as possible. Fourth, China expressed support for continued meetings of the joint session of the WGIHR and INB.

Rebuttal on "technical" and "universal" nature of IHR 2005

Certain countries such as Monaco, Chile, Switzerland and Canada referred to the technical nature of the IHR 2005 and claimed it cannot address issues like equitable access to health products and technologies. Some of them also referred to the principle of universality in Article 3 of the IHR 2005 and asserted that the CBDR principle cannot be incorporated within the IHR 2005.

By invoking the technical nature of the IHR 2005, some of these countries intend to argue that it is an international instrument to set up surveillance, detect disease, assess, notify WHO, determine whether or not a disease is an emergency of international concern, and, if a disease is spreading across borders, ensure quarantine and sanitary measures. Although Article 13 clearly provides for adopting

"public health measures" and other provisions speak about issues relating to access to medical care and facilities (limited to international travellers), these countries tend to argue that access to medicines and other health supplies is beyond the scope of the IHR 2005.

Switzerland argued that only the issues already covered under the present provisions of the IHR 2005 can be dealt with and therefore amendments should pertain to such issues only. New ideas should be kept in the INB. In this regard, Switzerland went ahead to pick up issues to be allocated between the WGIHR and INB from the document containing the list of topics of common interest. It said that only topics 3, 4 and 8 on the list – surveillance, review and reporting, and capacity building/collaboration and cooperation respectively – can be discussed under the IHR. It stated that topics like equity, access to health products, access and benefit sharing, reviews and reports specifically those related to universal health preparedness and review, financing, and health systems resilience, could be dealt with in the INB.

Canada was of the opinion that amendments to the IHR should be targeted and based on the existing scope, and that any proposed amendments should follow the scope of Article 21(a). It stressed the need to be cognizant that the IHR provide the authority for the existing programme about what happens when there is a public health emergency, while the WHO CA+ addresses systemic acts, prevention and preparedness specifically when a pandemic is declared.

Monaco, one of the delegations actively criticizing developing country proposals on equity in both the WGIHR and INB, argued that the IHR 2005's stated purpose, scope and principles cannot be changed. Ignoring the mandate of the WGIHR under the WHO Executive Board Decision EB150(3) and World Health Assembly Decision WHA75(9), which were agreed in 2022, it argued that topics such as equity cannot be considered as subject matter to be dealt with under the IHR 2005.

The UK stated that the IHR's scope and purpose are clearly stated in Article 2 and based on this it asserted: "We believe the purpose and scope of the IHR as the technical framework for a broader range of public health events remain valid and should not be expand-

ed. These regulations are broadly fit for purpose and its strength is in setting out required course valence and response capacities for State Parties. We believe that implementation, especially related to surveillance and information sharing are the primary issues that must be addressed through targeted amendments."

For Japan, it is surveillance and information sharing that should be in both instruments, while equitable access should be in the new instrument.

It must be noted that none of these arguments can be sustained as the WGIHR has a clear mandate from EB150(3) to address equity through the IHR 2005 amendments. Reiterating this mandate, the Africa Group said at the 24 July joint meeting: "Africa Member States continue to advocate for equity as a principle, objective as well as an outcome … The decision of the Second Special Session of the World Health Assembly as well as that by the 150th Executive Board puts equity at the centre of both the WHO CA+ and WGIHR (2005) amendment process. As such, the success of these two processes will be judged or evaluated by how much the operationalization of equity has found itself in the two instruments. It is for these reasons that the African Member States made submission to propose amendments to the IHR, which are focused on delivering on this equity mandate."

Countries such as Kenya, Botswana and Uganda supported the statement made by the Africa Group.

Bangladesh in its statement said the "remit of WHO Constitution, current IHR and principles of human rights, as a matter of fact, empower us to set the right direction for both instruments. Application of equity for both instruments is exigent to produce efficacy. If we have a close look at the IHR of 1969 vis-à-vis the IHR of 2005, we see how the IHR has gone through changes: first, in structure, second, in scope, and third, in terms of actions and deliverables. We have to repeat the same in order to take it to the next higher level with required changes for realizing equity".

It added: "… the two processes are envisaged for dealing with two different levels of health emergency situation. Our journey should be to stop the PHEIC so that it does not escalate to a pandemic situation. Towards that, it would be seminal first to mobilize

resources for the countries in need of support, assistance and cooperation to strengthen their health systems, and second, to make relevant PHEIC products available at an affordable cost in the market. The whole efforts should be premised upon equity."

The Philippines said: "It would be more practical at this point to approach the common issues with a greater focus on ensuring how effectively and efficiently the instruments can be operationalized to achieve their desired outcome, which is preparing States to ensure early detection and a timely, coordinated, and effective response to health emergencies, all while adhering to the principles of solidarity, equity, accountability, and transparency.

"For the Philippines, overcoming differences in capacities that affect the level of implementation of the obligations would be very important for lower- and middle-income countries, and operationalizing equity through enhanced cooperation and coordination must be reflected throughout the many components of both instruments."

Malaysia also insisted that equity should be addressed by both instruments. Regarding access to health products, it argued that access must be ensured for pandemic-related products as well as PHEIC-related products. It also reasoned that a financial mechanism should be established in the IHR 2005 and could be linked to the pandemic instrument by citing the need for finance to establish the core capacities mentioned in the IHR 2005 and the universal membership of the IHR 2005.

Interestingly, the EU made it clear that there is no constitutional barrier against including equity in the IHR 2005. Although it preferred to see equitable access to health products in the new pandemic instrument, it stated on 24 July: "When it comes to the scope, from a legal point of view, the proposals made for both the pandemic agreement and the IHR fall within the constitutional mandate of WHO as set out in Article 19 and Article 21(a) respectively. We do not see any constitutional requirement that would clearly indicate the choice of the pandemic agreement or IHR for any particular issue. Such a choice may be influenced by other policy considerations such as differences between the two instruments in terms of ratification, entry into force or participation. It may be of particular relevance

when deciding on the allocation of issues under the two instruments to reply to the following question: how important the universality of the certain obligation and their rapid entry into force are perceived to be for the effective implementation of the instrument."

However, the EU also stated that the objectives of the IHR are established while the objective of the WHO CA+ is yet to be determined. According to the EU, the objectives of the IHR focus on preparedness, early detection, surveillance during outbreaks including PHEIC and containment "including through public health measures". The objective of the pandemic agreement is to set out provisions aimed at addressing pandemic situations across the prevention, preparedness and response cycle.

Earlier, on 21 July, the EU had called upon States not to debate about what issue should be discussed under which process.

The principle of universality is taken from Article 3 of the IHR 2005 which states that "the implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease". Several developed countries cite this to argue that there is no place for CBDR either in the IHR 2005 or in the new pandemic instrument. This would leave populations in many developing countries susceptible to international spread of disease without adequate and equitable access to vaccines and other health products, as seen in the COVID-19 response.

Monaco opposed CBDR, referring to inconsistency with the principle of universality of IHR implementation. It stated: "We are not prepared to amend the principle of universality under IHR 2005 and therefore mention of CBDR as issue 2 in the list of the topics of common interest is not appropriate."

Namibia called out the Member States that continue to insist on pushing equity proposals out of the IHR negotiations notwithstanding the clear legal mandate from the World Health Assembly and the Executive Board to incorporate equity under both workstreams. It also expressed regret that some other Member States are proposing alternative, indirect methods which will lead to the same negative result of distributing elements between the two instruments.

It further substantiated the importance of incorporating equity under both instruments by pointing out that it might take longer for some Member States to ratify the envisaged pandemic treaty while others may not even ratify the treaty. It questioned the application of the principle of universality, pointing to reservations made by certain countries which have altered the scope and nature of information sharing for those countries. It categorically stated universality is a fallacy and it should not be cited as a reason not to incorporate CBDR.

Malaysia argued that recognizing the developmental divide in both instruments is important to operationalize equity.

Chile, a member of the Group of Friends of a Pandemic Treaty and of the Group for Equity, supported the statement of Monaco and Switzerland on the scope of the IHR 2005 on 21 July. However, subsequently on 24 July, following many of the abovementioned interventions by other developing countries, Chile stepped back from that support and proposed that equity should be addressed in both the IHR 2005 and a new pandemic instrument.

The US and Australia indicated the possibility of accommodating equity in both instruments.

The US not only welcomed the discussion at the joint session, but also called for future joint work as appropriate to consider substantive areas of overlap and how best to address them to protect people and lives. Referring to the list of topics of common interest between the WGIHR and INB, the US regarded equity as the underlying concept of both processes and as something that should be accomplished through both instruments.

Speaking through the virtual platform, the US Ambassador stated: "We could continue to hold formal joint sessions of WGIHR and INB, but also understand very real capacity constraints put on the delegations and want to work in a way that is acceptable for all. Alternatively, and in the interests of focusing on substance first, we would like to suggest assigning specific topics to a specific negotiating track, being clear that doing so would not prejudice any outcomes in the other track. We could then invite members of the other negotiation track to participate as appropriate, facilitating fuller and

more efficient negotiations while reducing the overall burden on our delegations. Later we would decide on the most appropriate placement for specific provisions. It could be that one provision on one topic might end up in the IHR and another provision on the same topic in the accord, or perhaps, the same provision could end up in both instruments. This process could potentially be supported by the joint discussion."

Australia, recognizing explicitly the importance of equity, stated: "Viewing prevention, preparedness and response as a continuum the IHR largely focuses on the middle of that continuum, addressing detection, assessment and initial response to disease events. In our view, the pandemic agreement should focus on aspects of the continuum beyond the scope of the IHR, at one end prevention measures to reduce the risk of dangerous pathogens emerging or re-emerging, and at the other, cooperation and coordination for sustained and effective public health response and recovery, while also reinforcing preparedness commitments under the IHR. Equity is fundamental across the entire continuum."

No decision and report adoption

The joint plenary meeting of the WGIHR and INB was "closed" on 24 July without a report for adoption. It requested States to submit in writing how they would like to organize further joint meetings until the end of that week.

Part 7 – 5th meeting of the WGIHR

TWN Info Service on Health Issues (Oct23/02)
3 October 2023

WGIHR to discuss health emergency measures and unilateral actions

Geneva, 3 October (TWN) – The 5th meeting of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR5), scheduled for 2–6 October, will discuss health emergency measures and unilateral actions.

WGIHR5 will be considering the IHR amendment proposals placed by both developed and developing countries addressing the implementation of health measures and the obligations to initiate and complete them. Various developing country proposals focus on the need for checks and balances and other necessary safeguards that must be in place in order to ensure that the health measures are applied in a transparent, equitable and non-discriminatory manner.

WGIHR5 will take place at the WHO headquarters in Geneva in hybrid mode. The agenda provides three groups of IHR amendment proposals for consideration this week and these proposals relate to the following articles:

Group 8:*
- Article 19 General obligations
- Article 23 Health measures on arrival and departure
- Article 24 Conveyance operators
- Article 27 Affected conveyances
- Article 28 Ships and aircraft at points of entry
- Article 31 Health measures relating to entry of travellers
- Annexes 3 and 4

Group 9:*
- Article 35 General rule
- Article 36 Certificates of vaccination or other prophylaxis
- Article 42 Implementation of health measures

- Article 43 Additional health measures
- Article 45 Treatment of personal data
- Article 56 Settlement of disputes
- Annexes 6 and 8

Group 1:*
- Article 1 Definitions
- Article 2 Purpose and scope
- Article 3 Principles.

* Numbers 8, 9 and 1 are based on a grouping system that was accepted at WGIHR2.

The group of proposals relating to Articles 19–31 will be considered first, then proposals relating to Articles 35–56 followed by proposals on Articles 1–3.

Health measures at points of entry and conveyances

Article 19 of the IHR 2005 identified certain general obligations of States Parties relating to points of entry, amongst other obligations provided in other provisions of the IHR. These deal with capacity building, identifying competent authorities and sharing of information at the points of entry.

MERCOSUR countries have proposed to include an obligation to develop bi-national contingency plans that deal especially with plans of action relating to land borders.

Japan has proposed to obligate States to ensure that the conveyance operators also "implement quarantine promptly on board as necessary" under Article 24. It further proposes to empower competent authorities to "demand the conveyance operators, the pilot in command of the aircraft or the officer in command of the ship to take practicable measures on the conveyance" under Article 27, and also to "notify health measures applicable to a ship or an aircraft as necessary" under Article 28.

Some of these proposals, if adopted, could be interpreted in a manner allowing the countries concerned to impose quarantine on board itself, without allowing the ships to dock or the passengers to disembark. Such an interpretation will be inconsistent with human rights of the passengers as well as the rights of the seafarers that require quarantining and/or medical care to be provided in on-shore facilities as far as possible. Thus, the proposals from Japan may involve human rights implications, especially the proposals to have quarantine on board conveyances.

During the COVID-19 pandemic, Japan received international criticism about its varying and inconsistent approaches towards ships approaching its territorial waters and coasts. While a ship carrying a significant number of Japanese passengers was allowed to dock, a ship which carried fewer Japanese passengers was not permitted to dock and disembark its passengers. Further, it executed on-board quarantining for the ship that it allowed to dock and this led to cluster infections on board. For several weeks passengers were not able to disembark.

Japanese law allows for its officials to take up this varying approach and quarantine persons on board with the consent of the captain of the vessel, while Japan had only limited on-shore facilities to be provided for passengers and crew arriving at its borders. Therefore, in a sense, it is possible that Japan could be seeking to legitimize or create a basis in international law to justify its actions and national laws. Unfortunately, its proposals provide power to national authorities to demand the captain of a vessel to take measures, and there is no clear guidance as to how this power could be exercised.

Meanwhile Malaysia has proposed changes to Article 42 which provides for the general rule regarding the implementation of health measures. Article 42 currently provides that health measures taken pursuant to regulations will be initiated and completed in a transparent and non-discriminatory manner. The Malaysian proposal makes it an explicit obligation of the States Parties that their health measures will be implemented not only in a prompt, transparent and non-discriminatory manner but also in an equitable manner. The proposal also seeks to have States Parties ensure that the non-State actors

within their territories comply with such health measures. Although these proposals provide a general protection against abuse of authority by national authorities at points of entry as well as conveyance operators, it would be better if additional and specific safeguards are mentioned under Articles 24, 27 and 28.

Digitalization of health documents and the need for protection of data

Both developing and developed countries such as Brazil, Indonesia, Russia and the European Union have proposed digitalization of health documents. The proposals have been made to various articles such as Articles 23, 31, 35 and 36. However, the approach towards digitalization varies significantly between developed and developing country proposals. The EU prefers digital documents to paper format and wants to employ interoperability of data etc, while developing countries treat both the digital and paper formats on par.

Under Article 23, the EU has proposed the following text for a new paragraph 6: *"... documents containing information concerning traveller's destination (hereinafter Passenger Locator Forms, PLFs) should preferably be produced in digital form, with paper form as a residual option. Such information should not duplicate the information the traveller already submitted in relation to the same journey, provided the competence authority can have access to it for the purpose of contact tracing. The Health Assembly may adopt, in cooperation with the International Civil Aviation Organization (ICAO) and other relevant organisations, the requirements that documents in digital or paper form shall fulfil with regard to interoperability of information technology platforms, technical requirements of health documents, as well as safeguards to reduce the risk of abuse and falsification and to ensure the protection and security of personal data contained in such documents. Documents meeting such requirements shall be recognized and accepted by all Parties. Specifications and requirements for PLFs in digital or paper form shall take into account existing widely used systems established at the regional or international level for the issuance and verification of documents.*

Parties which are low and lower middle-income countries shall receive assistance in accordance with Article 44 for the implementation of this provision."

Under Article 35, a new paragraph 2 has been proposed by the EU as a general rule: *"Health documents may be produced in digital or paper form, subject to the approval by the Health Assembly of the requirements that documents in digital form have to fulfil with regard to interoperability of information technology platforms, technical requirements of health documents, as well as safeguards to reduce the risk of abuse and falsification and to ensure the protection and security of personal data contained in the health documents. Health documents meeting the conditions approved by the Health Assembly shall be recognized and accepted by all Parties. Specifications and requirements for certificates in digital form shall take into account existing widely used systems established at the international level for the issuance and verification of digital certificates. Parties which are low and lower middle-income countries shall receive assistance in accordance with article 44 for the implementation of this provision."*

The proposal under Article 23 pertains to passenger locator forms, while Article 35 deals with health documents in general. There is a difference in the two proposals. While both promote digitalization of health, the proposal under Article 23 simply says that safeguards against risk of abuse, falsification and infringement of the right to privacy "may" be adopted by the World Health Assembly. Further, the EU also makes a mention of existing systems established at the international level for issuance and verification of digital certificates and the need to take them into account. Thus the EU's proposal is to clearly expand and promote continuation of digitalization of health, whether there is development of safeguards or not.

It is important to establish systems for verification of health documents without necessarily transferring data from one jurisdiction to another. Developed countries or other agencies while providing assistance to low- and lower-middle-income countries should not use the opportunity to establish systems that automatically transfer data from these countries. Otherwise, national sovereignty in data governance may be compromised.

Under Article 45, which deals with treatment of personal data, Japan, Indonesia and the Africa Group have however proposed certain safeguards. Irrespective of digital or paper format, Japan would require all States Parties receiving information from WHO and other States Parties to seek consent of the provider State Party before the disclosure of personal data is made to a third party. Further, such disclosures must only be made where it is essential.

Indonesia proposes that the information be shared with only internal and relevant personnel. The Africa Group seeks to limit cross-border data transfers by proposing that States Parties processing the personal data have to do so without duplicating or storing data, unless they have obtained permission from the provider States Parties. It is important that these proposals be extended to all health data and not just personal data.

Additional health measures and the need for discipline

Article 43 of the IHR 2005 allows for States Parties to take additional health measures over and above what is recommended by WHO; nevertheless there should be a sound scientific and public health rationale behind such measures. This is one of the provisions significantly abused by developed countries against developing countries for restraining the entry of persons and goods coming from developing countries to developed countries during public health emergencies or disease outbreaks. Although Article 43 empowers WHO to assess the additional health measures and to issue recommendations or requests to the implementing States Parties for necessary adjustments, this does not bind the States Parties. There is no guarantee that WHO will exercise this authority in a prompt manner.

To overcome these shortcomings, the Africa Group has made some significant amendment proposals to Article 43. Firstly, a new paragraph 3 *bis* is sought to be introduced which could reduce the risk of additional health measures causing impediments to WHO's allocation mechanism or any other State Party's access to health products, technologies and know-how.

Secondly, changes are proposed to paragraphs 4 and 6 by which a time-bound process is designed for the assessment of additional health measures and making any necessary modifications such that other States Parties' rights or the human rights of the people are not unduly affected.

Brazil has proposed resolving disputes relating to additional health measures through a process under Article 56 for settlement of disputes.

The EU also has a proposal under Article 43; however, it is specifically limited to set certain standards to be applied for employing additional health measures. According to the EU, such measures shall be based on regular risk assessments, provide a proportionate response to the specific public health risks, and be reviewed on a regular basis. It also proposes that additional health measures should not be more invasive or intrusive to persons than reasonably available alternatives that would achieve or attain the appropriate highest achievable level of health protection.

Amendment proposals to Article 1 – definitions

There are two important categories of proposals to amend Article 1 on definitions: first, to incorporate definitions for health products and technologies, and second, to modify the definitions of temporary and standing recommendations.

Malaysia and the Africa Group propose the definition of health products to be incorporated under Article 1. Though their proposals differ slightly, they rely on an adaptation of the definition as used in WHA Resolution 72.8. Malaysia prefers to define this phrase alongside "health technologies".

An amendment proposal to Article 1 in the second category is made by Bangladesh and it is to modify the definition of temporary and standing recommendations. Currently, they are defined as "non-binding advice", and Bangladesh proposes to delete the term "non-binding".

This proposal is important in the light of a combined proposal by the Africa Group and Bangladesh for a new provision, Article

13A, which employs temporary or standing recommendations to facilitate equitable access to health products and technologies. Under this proposal on Article 13A, States Parties are required to comply with recommendations issued for ensuring equitable access to health products and technologies.

Retaining the word "non-binding" before "advice" in the definition of recommendations would cause interpretative inconsistency between Articles 1 and 13A. The proposal to delete "non-binding" will avoid this inconsistency and at the same time will maintain the non-binding nature of the other temporary and standing recommendations issued by WHO, because "advice" is in general "non-binding" under international law. The deletion of "non-binding" would however enable States Parties to make binding selected recommendations, such as for equitable access, or attach legal consequences to the non-performance of these recommendations.

Proposals for restating the scope and purpose of the IHR 2005

Currently Article 2 of the IHR 2005 states: *"The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."*

Although the IHR 2005 address internationally coordinated approaches towards health emergency preparedness and response, the experiences of the past decade-and-a-half are very clear that the IHR 2005 continue to operate in a manner which does not ensure equity. Therefore, countries like India, Bangladesh and the Africa Group have proposed changes to Article 2. While India wants an explicit mention of the need for "preparedness", Bangladesh wants to include "health systems readiness and resilience" and the Africa Group seeks an explicit clause for "equitable access to health products and technologies" within the text of Article 2.

It must be noted that these proposals would not expand the scope of the IHR 2005 or go beyond the scope of Article 21 of the

WHO Constitution under which the IHR 2005 were adopted by the WHA. They merely bring certain aspects to proper attention and visibility such that the importance of those elements is no longer neglected. It is simply a restatement of the existing purpose and scope of the IHR 2005.

Proposals to incorporate principles of CBDR and peaceful purposes

Article 3 of the IHR 2005 currently has four paragraphs and delineates principles to be applied while implementing the regulations. However, there are several proposals from India, Malaysia, Bangladesh and the UK to incorporate more principles into the provision. While the UK wants to incorporate a precautionary approach towards the diseases caused or events relating to unknown pathogens, others want to incorporate principles of equity, fairness, common but differentiated responsibilities (CBDR), as well as prioritization of health systems strengthening in capacity building.

CBDR as a principle becomes important given the resource-intensive nature of the capacity-building obligations identified in the IHR 2005 and also certain new proposals expanding the scope of such capacities. Application of this principle has become a necessity on the part of the developed countries, given the neo-colonial trends in the implementation of the IHR 2005 in the last decade or so.

Disparities in surveillance and response capacities, weakened health systems and inequitable access to health products and technologies are the results of an international health emergency law that is blind to the development divide between countries and the non-binding approach it employs in the provisions addressing international cooperation.

The only way out from this conundrum is by developing legally binding obligations to address health inequities within the IHR 2005 and with a reasonable differentiation between the obligations to be discharged by the developed and developing countries. Since the IHR 2005 are the only existing legal instrument, addressing this gap within the IHR 2005 is important.

The principle of CBDR is gaining acceptance beyond international environmental law especially among Global South leaders. In the Inaugural Leaders' Session of the Voice of Global South Summit 2023, Indian Prime Minister Narendra Modi called on other leaders to recognize that the CBDR principle applies to "all global challenges".

Malaysia additionally has proposed to incorporate a peaceful purposes clause on the exchange of information. Given developed country proposals for IHR 2005 amendments which promote rapid and indiscriminate sharing of information with multiple actors, it is important that the data provided are used only for public health purposes. The peaceful purposes proposal has become more important than ever given that the US has also proposed to consider genetic sequence information of pathogens as part of the public health information to be shared under Article 6 of the IHR 2005.

It must be noted that ever since the advancement of synthetic biology, and recent developments such as DNA printers, the risk of misutilization of genetic information contributing to proliferation of biological weapons as well as bioterrorism has increased. Not only exchange of biological materials but also biological information needs to be protected in this scenario.

A possible attempt at an early harvest approach by the Bureau

At the time of writing of this article, it is reported that the WGIHR Bureau has circulated Co-Chairs' text relating to Articles 4, 5, 18, 48, 49 and Annex 2. They have requested the Member States to be prepared to negotiate on the said text as well in the coming week. A developing country delegate who spoke to TWN in this regard said, "This is the approach we were fundamentally against from the beginning. The gaps identified in the COVID-19 pandemic response were that of equity; it seems like the North wants to force a consensus on all other issues except equity."

TWN Info Service on Health Issues (Oct23/03)
5 October 2023

"Early harvest" to sideline negotiations on equity proposals in IHR through Co-Chair proposals

Geneva, 3 October (TWN) – There is an attempt, through Co-Chairs' proposals, to press for an early harvest approach to sideline negotiations on equity proposals to amend the International Health Regulations 2005 (IHR).

The Co-Chairs of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR), the negotiating body mandated to consider IHR amendment proposals, have made proposals on Article 4 during the 5th session that is currently taking place in Geneva from 2 to 6 October. On 29 September, Member States had received the Co-Chairs' proposals on five Articles and one Annex:

Article 4: Responsible authorities
Article 5: Surveillance
Article 18: Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels
Article 48: Terms of reference and composition
Article 49: Procedure
Annex 2: Decision instrument for assessment and notification

These proposals from the Co-Chairs are seen as part of an attempt to exert pressure on developing countries to agree to an early harvest, on grounds that the mandate of the WGIHR is to submit its report to the World Health Assembly through the Executive Board. The Secretariat cited on the first day of WGIHR5 that amendment proposals are to be submitted four months prior to the WHA under Article 55. However, what is not stated clearly is that Article 55 does not require consensus among Member States to submit amendment proposals to the WHA. It merely requires an amendment proposal to be submitted to the WHA and it must be circulated to Member States

at least four months prior to the WHA session at which it is proposed for consideration.

The early harvest approach takes away the pressure on developed country Member States to engage in equity proposals because it provides an opportunity to postpone such negotiations and slowly undermine consensus within the WGIHR. It is noteworthy that many developed countries, especially the US and the EU, have stated many times that it is important to maintain the technical nature of the IHR and that they prefer to address equity under the proposed pandemic instrument which is currently also under negotiation.

This approach is problematic due to two reasons. First, the scope of the pandemic instrument is limited to pandemics and excludes all other emergencies of international concern, which occur more frequently than pandemics. Thus, the exclusion of equity provisions, especially those related to equitable access to health products, would leave a big hole in health emergency response.

Second, the legal nature of the pandemic instrument is still not clear, and a considerable number of Member States are pushing for adopting the instrument under Article 19 of the WHO Constitution, which requires ratification. The ratification requirement would allow developed countries to not abide by their responsibility by not ratifying the instrument. On the other hand, the IHR are an existing legal instrument to which 196 WHO Member States are parties and the amendments, if any, do not require ratifications to come into force.

Further, sidelining of equity violates the letter and spirit of the Executive Board decision which provides the mandate for the IHR amendment process. EB150(3) states: *"Such amendments should be limited in scope and address* ***specific and clearly identified issues, challenges, including equity****, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner"* (emphasis added).

Thus, it is mandatory to address equity as one of the issues and early harvest undermines the mandate.

As shown below, some of the proposals of the Co-Chairs camouflage developed country proposals as technical and minor in nature even though they would substantially change the nature of the IHR.

Article 4

The Co-Chairs have proposed two important changes to Article 4. First, States Parties would be obligated to either create or designate national IHR authorities and competent authorities in accordance with national circumstances and laws along with the national IHR focal point. The national IHR authority is the "the entity responsible for the overall coordination of the implementation of these Regulations by the State Party".

Second, there would be an obligation on States Parties to provide financial and human resource support for all the three institutions without creating obligations on developed countries to make any commitments to provide financial and technical assistance.

The proposal reads: *"States Parties shall, as necessary and appropriate, take measures to enable the above-referenced entities to discharge their responsibilities effectively, including by providing them with adequate financial and human resources and enacting or adapting existing domestic legislation or administrative arrangements, as necessary and appropriate. WHO shall provide technical assistance and capacity building to States Parties, upon their request, to support these entities, in particular in support of the National IHR Focal Points, through training and regular exercises."*

Article 5

The Co-Chairs' text proposal for Article 5 replaces the proposal from Malaysia to obligate developed country State Parties to assist developing countries to build surveillance capacity. Malaysia's proposal is based on the principle of common but differentiated responsibilities (CBDR) by imposing a concrete obligation on developed countries. The proposal states: *"Developed State Parties and WHO*

shall offer assistance to developing State Parties depending on the availability of finance, technology and know-how for the full implementation of this article, in pursuance of Article 44."

The new proposal from the Co-Chairs removes the CBDR element and reads: *"Pursuant to Article 44, State Parties and WHO shall, to the extent possible and upon request, collaborate and assist each other in developing, strengthening and maintaining this capacity."* The offer of assistance is also made subject to the qualification "to the extent possible".

Another detrimental change in Article 5 is that the Co-Chairs propose to delete paragraph 3 that obligates WHO to provide assistance upon request. Paragraph 3 reads: *"WHO shall assist States Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph 1 of this Article."* It must be noted that this is an existing legal provision in the IHR 2005 which imposes a concrete obligation on WHO without any qualification.

Article 18

The Co-Chairs' textual proposals add three new paragraphs to Article 18, which is about recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels. The Co-Chairs, taking into account the discussions, propose to have an enabling clause such that the "WHO DG may consult with relevant international organizations, as appropriate, in order to avoid unnecessary interference with international traffic and trade" while developing the recommendations.

The Co-Chairs also propose to add paragraphs 4 and 5, the first of which suggests WHO recommendations to take into account the need for ensuring unrestricted international movement of certain categories of persons such as health workers and the need to maintain uninterrupted international supply chains for essential medical products and food supplies. Paragraph 5 would require States Parties to develop contingency arrangements for the purposes of paragraph 4.

Article 48

The Co-Chairs under Article 48 take into account the calls made to avoid conflict of interests and to address gender balance in the composition of the Emergency Committee. However, on addressing "conflict of interests" directly, the Co-Chairs propose to make the Regulations for Expert Advisory Panels and Committees applicable to the selection process of the members of the Emergency Committee. This in turn addresses the issue of conflict of interests.

Article 49

There are two major proposals in the Co-Chairs' text about Article 49 which deal with the procedure of the Emergency Committee. First, it mandates the WHO Director-General to provide a detailed agenda to the committee, and to include a recurrent set of standard items for consideration of the committee aimed at ensuring specificity, completeness and coherence of the advice provided.

Secondly, a new paragraph 3 *bis* is proposed by which, if the Emergency Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views, anonymously, in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Emergency Committee's report.

Annex 2

The Co-Chairs' text proposal in Annex 2 is to ensure mandatory reporting of severe acute respiratory disease of unknown cause, irrespective of domestic assessment on whether there is potential for the disease to become a public health emergency of international concern or not.

Equity first approach vs early harvest approach

The Co-Chairs were keen to initiate negotiation based on the above text proposals either under agenda item 2 or after the completion of other agenda items, with a view to achieving consensus. However, developing countries firmed up their "equity first" approach, i.e., the need to negotiate IHR amendment proposals for achieving equity first.

Kenya delivered the Africa Group statement on behalf of its 47 Member States. It stated: "As we move closer to the deadline set by the Assembly for conclusion of our work, the Africa Group wishes to reiterate that, in view of the interrelated nature of the IHR articles and annexes, the comprehensive discussion and adoption of a single package of amendments by the Health Assembly remains our preferred approach. This will ensure that we address the equity gaps identified, in line with this Working Group World Health Assembly mandate."

Ethiopia, calling for "equity first" negotiations, explained thus: "We want to be very cautious that we started with very important articles at first, but we are not moving that fast as we wished on those articles which very much relate with equity. Then our mandate for this working group includes specifically the amendments which should be including the equity-related provisions which were lacking from previous IHR and also, it's very clear from the working group that was established before WGIHR and also every works of independent organs in this process. So I think it's the right time to focus on the remaining equity-related articles first … if we put those major amendments for latter stage then I think in my country's capacity it will be very much challenging to accept."

South Africa's intervention aligning with the statement of the Africa Group stated: "Having listened carefully to the advice of the legal counsel, and looking what do we have to do as member states in terms of coming up with what is required of us, one, update or amend the IHR and secondly, consider including issues of equity, which was the most missing link that made the world not be able to really implement IHR quite well even during the pandemic. We therefore

would like to support the proposal by Ethiopia that we might have to even work smartly and address the mandate that this committee has. The mandate on issues including issues of equity and we therefore propose that articles that have got equity in it be reviewed first. We finalize them first, that at the end of the work, if there's anything that would have been achieved, is to ensure that equity is included in the new IHR. That is a mandate that we have and … by ensuring that equity is addressed will not just be addressing for one country but addressing for all countries across the board. Because equity affects us all."

Nigeria pointed out that the WGIHR is "aware that the main challenge that necessitated the review of the amendment of the IHR is the lack of compliance and implementation by some parties. And so as a result of this, it's very important that those areas that cover, like some colleagues have mentioned, equity, financing, and of course the issues of core capacities … are addressed … forefront. Because that will enable countries that are unable to implement and comply with relevant outlines of IHR, in particular capacities for many of the developing countries that have been unable to comply with all of the provisions."

Nigeria further drew attention to some amendments proposed by the delegation of the United States in December 2021 and stated that "in approaching that [the US proposals], so many members mentioned the need to have a holistic approach and that prompted the need for other member states to bring forward their proposals". Nigeria reiterated that it is important for the WGIHR to continue to work and look at the proposals as a package.

Namibia expressed concern that the WGIHR might be headed towards an early harvest approach for some proposed amendments, "whilst significant progress is lacking on some of the proposed amendments, especially those that seek to mainstream equity into the International Health Regulations. Co-Chair, there was broad support for the inclusion of proposals that seek to operationalize equity under both instruments, i.e., the pandemic accord and the International Health Regulations. To quote my distinguished colleagues from the European Union, they said that there is no constitutional barrier

to accommodate equity in both instruments. Even [with] this broad consensus among member states, we need to see significant progress on the equity proposals. To this end we know that at the second meeting of the working group, we agreed to follow a certain structure when we started these discussions.

"I think we started with a consideration of proposed amendments to Article 53, Article 13A, 44 and 44A, among others. We believe that there was a reason why we decided to follow the structure for the formal meetings of the working group. This reason was to ensure adequate consideration for all proposed amendments and to try and avoid what the Africa Group at the time termed as a low-hanging fruit approach. The similar consideration should therefore apply to proposed amendments for the second round of negotiations. We therefore urge the bureau to take this into consideration in the development of work programmes and the agenda for subsequent meetings of the formal meetings of the working group."

Bangladesh recalled that the IHR amendment process was triggered by the lessons learnt during the COVID-19 pandemic. It said they were not looking forward to any kind of status quo.

Responding to some of these proposals, WGIHR Co-Chair Dr Ashley Bloomfield of New Zealand said, "If we agree to continue our work beyond January or beyond our scheduled meeting in December, that does not mean we slow down or take our eye off the ball. We need to keep making progress … and I've heard the interventions from member states of the African region, from Bangladesh, we need to make progress on those challenging issues. And we will make time to make sure we discuss them further this week."

The floor generally accepted the call made by certain developing countries, and Co-Chair Dr Abdullah Asiri of Saudi Arabia concluded the agenda item by saying: "From now until the deadline is there, then we'll have to report whatever we agree on, whether it is preferably a consensus on the amendments or report that concludes the work of the WGIHR to the World Health Assembly. However, we will all agree what should be amended in the IHR. I think the question now is how to address these – I mean proposed amendments – how to make them or to include them or to reach a consensus on

including them into the IHR. Everybody agrees on equity. Everybody agrees on the importance of addressing financing and addressing benefit sharing and all these difficult issues that we were really afraid at the beginning of this process that they will not go forward but luckily with your support and understanding, we are now at an advanced stage of understanding your position on including them into the IHR. So I would urge all of us to continue the momentum discussing what we have on the plate."

Despite these statements, the Co-Chairs circulated their text proposals and have a plan to undertake discussions in WGIHR5.

TWN Info Service on Health Issues (Oct23/04) 13 October 2023

IHR amendments deadline extended to May 2024; Bureau mandated to draft text

Geneva, 13 October (TWN) – The deadline to conclude negotiations on the amendment of the International Heath Regulations 2005 (IHR) has been extended to May 2024.

This was decided at the 5th meeting of the Working Group on Amendments to the IHR (WGIHR5), the mandated negotiating body, that took place on 2–6 October 2023 in hybrid format at the WHO headquarters in Geneva.

The WGIHR5 meeting report states: "…The Co-Chairs noted that, in reference to Decision WHA75(9), it appeared unlikely that the package of amendments would be ready by January 2024. In this regard, the Working Group agreed to continue its work between January and May 2024. The Director-General will submit to the 77th Health Assembly the package of amendments agreed by the Working Group."

WGIHR Co-Chair Dr Ashley Bloomfield, while opening the closing plenary, stated: "What I can say without any doubt to all our relevant stakeholders, and I am sure that this view would be shared

in the room, is that we have a shared and clear understanding of our mandate which is twofold, first to come up with a set of targeted amendments, but secondly, and these are interlinked, to reorient the IHR towards equity.

"We have made progress this week on that topic, perhaps not as much as, definitely not as much as, we intend to. But we have intercessional plans to keep progress going on both parts of our mandate, both the technical amendments but also the reorientation towards equity, and that remains a very strong focus for our work here. And we'll continue. We will continue our work between now and our next meeting in December and as a working group we have also agreed that we will need to continue our work in the new year between January and May 2024."

According to the World Health Assembly decision WHA75(9), the WGIHR is "to establish a programme of work, consistent with decision EB150(3), and taking into consideration the report of the IHR Review Committee, to propose a package of targeted amendments, for consideration by the Seventy-seventh World Health Assembly, in accordance with Article 55 of the International Health Regulations (2005)".

[Article 55 of the IHR states, in paragraph 2: "The text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which it is proposed for consideration."]

The WHO's Principal Legal Officer suggested the way forward by stating that though the WGIHR is a subsidiary body working under the WHA, the WHO Director-General needs to fulfil the obligation under Article 55.2 by circulating the amendment proposal to Member States in January 2024. This would allow the WGIHR to continue to work prior to WHA 2024 in May and directly submit the package of amendments to the WHA.

The Principal Legal Officer stated, "Article 55 of the IHR, including this four-month requirement, has never been applied to amendments submitted collectively by a subdivision of the Health Assembly – which is exactly what the WGIHR is. The WGIHR is a subdivision of the Health Assembly under Rule 41 of the Rules of

Procedure of the Health Assembly. Thus, there are no precedents to rely on, with respect to the manner in which the four-month requirement set out in Article 55 should be satisfied. That is to say, Article 55 has been applied to amendments proposed by the State Party or by the Director General, but never by a subdivision of the Health Assembly…

"This is a first. Accordingly, an option for consideration by the Working Group would be for the Director General to communicate in January 2024 the following documents to all States Parties: first, the proposed amendments as originally submitted by Member States, and already communicated by the Secretariat to all States Parties by email. And second, the proposed amendments as they might be shown on the screen at the closure of WGIHR6. This approach would allow work to continue in the WGIHR, if necessary, up until the 77th Health Assembly itself, recognizing the importance of complementarity with the INB process which as we know is mandated to work up until the 77th WHA...

"This approach just outlined for your consideration would fulfil the four-month requirement in its purpose as prescribed by Article 55 of the IHR … at the same time, allowing the Working Group to continue its consideration and negotiation of the proposed amendments including possible modifications to the package that would be communicated to States Parties. Should this approach be considered satisfactory, … the Working Group may wish to consider reflecting it in the report of this session of the WGIHR."

[The INB is the Intergovernmental Negotiating Body mandated to develop a new pandemic instrument in a parallel process.]

According to the WGIHR5 report, apart from the scheduled work programme, WGIHR5 also discussed "a consolidated proposal of proposed amendments, by proponent States Parties, to Article 13A Equitable Access to Health Products, Technologies and Know-How for Public Health Response, as well as Article 8 Consultation".

However, many developing country delegates told TWN that developed countries followed a non-engagement policy during the discussions on equitable access.

Bureau to prepare text

The Bureau of the WGIHR is now empowered, with the assistance of the Secretariat, to prepare draft text proposals based on the discussion so far. This is a major departure from the existing practice. Usually, the Chair or Co-Chairs may suggest a text in their individual capacity based on the various positions that have emerged during the negotiations, to move forward in the negotiations.

When the Bureau takes over the role of the Chair or Co-Chairs to propose text during negotiations, there are two types of risks. First, it puts the Bureau members under pressure to own the text and compromises their national position during the negotiations. Second, historically the Secretariat is mostly aligned with the developed countries and developing country delegates face stiff resistance inside the Bureau to push their case.

The WGIHR5 report states: "Preparation, as relevant, by the Bureau with the assistance of the Secretariat, of draft text proposals based on the discussions so far, for consideration by the Working Group at the Sixth Meeting, without prejudice to the status of the proposed amendments by States Parties."

Initially, the European Union proposed this paragraph without the qualification "without prejudice to the status of the proposed amendments by States Parties". Developing countries like Malaysia proposed to include such a clause. The EU concurred and this was added to the end of the paragraph.

There are serious concerns that this text-drafting role given to the Bureau also impinges on the effectiveness of other processes such as intersessional briefings and intersessional consultations set out in the report to reduce the differences among the Member States on various issues. According to the WGIHR5 report: "Discussions between proponents of various proposed amendments, with a view to presentation of any outcomes for the consideration of the drafting group.

"Intersessional briefings and facilitated intersessional consultations, in a hybrid format, open to all drafting group members, as well as joint intersessional work with the INB at dates and times to be announced, covering Articles, Annexes and topics discussed during this and previous meetings of the WGIHR, including those that have been the subject of intersessional work. Work will also continue on financing for public health emergencies and IHR implementation, and the Public Health Alert-PHEIC-pandemic continuum, including definitions, criteria and the process for determining each. The outcomes of facilitated intersessional consultations are understood not to constitute agreed text and will be made available in advance of the next WGIHR meeting in December 2023."

Since the Bureau has the mandate to draft the text, the intersessional processes are now reduced to providing input to the Bureau instead of finding consensus or bridging divergences in country or group positions. The experience of Bureau text on the pandemic instrument shows that such text has left out many crucial proposals of developing countries aiming to achieve equity in the international health emergency regime.

Part 8 – 6th meeting of the WGIHR

TWN Info Service on Health Issues (Dec23/03)
7 December 2023

WGIHR Bureau's proposals raise concerns on early harvest approach at the cost of equity

Geneva, 7 December (TWN) – Proposals on various textual amendments to the International Health Regulations (IHR) from the Bureau of the working group mandated to negotiate the amendments raise concerns on an early harvest approach at the cost of excluding proposals on equity, especially those on equitable access.

The 5th meeting of the WGIHR (2–6 October 2023) empowered the Bureau of the Working Group on Amendments to the IHR to produce the textual proposals with assistance from the Secretariat. The report of the meeting stated that there will be "preparation, as relevant, by the Bureau, with the assistance of the Secretariat, of draft text proposals based on the discussions so far, for consideration by the Working Group at its sixth meeting, without prejudice to the status of the proposed amendments by States Parties".

The 6th meeting of the WGIHR (7–8 December) is to discuss the Bureau's proposals. According to the draft programme, discussions are to take place on the Bureau's proposals on the following Articles and Annexes: Articles 4–9, 15–19, 23, 24, 27, 28, 31, 35, 36, 42, 43, 45, 56, and Annexes 3, 4, 6 and 8.

Interestingly, proposals of the Bureau are silent on equity-related proposals, especially on the proposed new Article 13A, Article 44 *bis* and proposed changes to Annex 1 and a new Annex 10. The draft programme states that Member States are invited to update on the proposals on the following Articles:

- Article 13A on equitable access to health products, technologies and know-how for public health response (Africa Group and Bangladesh);
- Articles 44 and 44A, and Annexes 1 and 10 – current technical support, capacity building and collaborative activities undertaken (Saudi Arabia);

- Article 53A on establishment of an implementation committee (Africa Group);
- Article 53 *bis–quater* on the Compliance Committee (United States);
- Article 54 on reporting and review (Malaysia) and Article 54 *bis* on implementation (European Union).

The apprehension is that the Bureau's text may lead to demands for an early harvest from developed countries and the Secretariat, which would lead to the effective marginalization of negotiations on equity-related proposals. Equity is one of the issues identified to be addressed as part of the IHR amendment. The WHO Executive Board decision 150(3), which sets the scope of the IHR amendment, states: *"... to urge Member States to take all appropriate measures to consider potential amendments to the International Health Regulations (2005), with the understanding that this would not lead to reopening the entire instrument for renegotiation. Such amendments should be limited in scope and address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner."*

Important proposals of the Bureau

The Bureau has circulated its own textual proposals for amending various provisions, taking into account the proposals made by States to amend the IHR 2005. It has provided much more limited and streamlined textual proposals for a number of provisions, attempting to forge an early convergence.

The Bureau has also provided reasons and explanations on how its text proposals seek to be inclusive of proposals made by States Parties and if not, how its proposals differ from such proposals, and how they serve the objectives of the States who proposed the excluded proposals.

Article 4: Creation of National IHR Authority

The Bureau proposes the creation of two more institutions other than the IHR focal point for the implementation of the IHR at the national level, viz., a National IHR Authority and a Competent Authority. The proposal provides an option to States Parties to implement the functions of these three institutions through any one institution. However, the proposal does not offer any effective solution to address the financial and technical assistance required for the effective functioning of either the National IHR Authority or the Competent Authority.

Regarding assistance, paragraph 3 of the Bureau's text reads: *"States Parties shall, as necessary and appropriate, enable the above-referenced entities to discharge their responsibilities effectively, including by providing them with adequate financial and human resources and enacting or adapting existing national law. WHO shall, in accordance with Article 44, collaborate with States Parties, upon request, to support the implementation of this Article."*

However, in Article 44 the obligation of WHO to provide assistance is qualified by the words "to the extent possible". Article 44.2 states: *"WHO shall collaborate with States Parties, upon request, to the extent possible, in:*

(a) the evaluation and assessment of their public health capacities in order to facilitate the effective implementation of these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support to States Parties; and

(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1."

The proposed roles of the National IHR Authority and the Competent Authority are as follows:

"The National IHR Authority shall:

(i) coordinate the implementation of these Regulations within the territory of the State Party;

(ii) oversee the National IHR Focal Point and Competent Authority in the performance of their functions; and

(iii) perform any other function that is not explicitly attributed to either the National IHR Focal Point or the Competent Authority in these Regulations…

"The Competent Authority shall:

(i) be responsible for the implementation and application of health measures under these Regulations pursuant to Article 22;

(ii) identify the competent authorities at each designated point of entry in its territory pursuant to indent (b) of Article 19; and

(iii) implement other relevant provisions related to conveyance operators and travellers."

Articles 15 to 18: Recommendations of WHO Director-General

Article 15 provides authority to the WHO Director-General to issue temporary recommendations, while Article 16 provides for issuance of standing recommendations. Article 17 lists certain considerations the DG has to make for issuing recommendations, and Article 18 provides an inclusive list of issues on which recommendations may be issued by the DG.

The amendment proposals from States Parties included explicit authority to issue recommendations regarding access to health products and technologies required to respond to public health emergencies of international concern in Articles 15 and 16. These proposals have been diluted in the Bureau's proposal. The Bureau's proposal is to add an additional paragraph in Articles 15 and 16 where the DG may provide "guidance on access to, and allocation of, health products, technologies and know-how through WHO-coordinated mechanisms" while he/she issues recommendations.

The proposal is vague and does not clarify the need for qualifying the recommendations with regard to access to health products as "guidance". There is no explanation why the DG cannot issue recommendations instead regarding access to and allocation of health products. The Bureau's proposal is against the current practice as well, since several times during the COVID-19 pandemic and mon-

keypox outbreak, the DG had issued recommendations on the very same issue. There is no reason to alter this practice.

The Bureau's proposals for Articles 17 and 18 streamline the proposals made by various States Parties. The Bureau proposes to take into account the "availability of relevant health products, technologies and know-how, including in the context of a WHO-coordinated mechanism for access to and allocation of health products", as a consideration while issuing recommendations. A similar proposal is made to Article 18 as well, such that the recommendations are qualified in a way that must take into account the need for "essential international travel, including movement of essential health workers", and "international supply chains, including for essential health products and food supplies".

Furthermore, the Bureau's proposal for Article 15 authorizes the DG to offer States Parties assistance in mobilizing an international team of experts for on-site assistance. However, this is redundant because WHO is already able to offer such assistance upon request by States Parties under Article 13.

Articles 19 to 31: Amendments to provisions relating to traffic and trade

There were few amendment proposals from States Parties associated with these Articles. Primarily, the proposals relate to bringing more order to cross-border transport by making a few changes including:

(i) bi-national contingency plans;
(ii) legitimizing on-board quarantine and isolation; and
(iii) use of digital documents for clearance of immigration or related travel processes.

The Bureau however proposes not to adopt all such proposals, asserting that these are part of discretionary powers already recognized with regulatory authorities. With regard to use of digital documents, the Bureau proposed to address the same in Articles 35 and 36 where health documents as such are regulated.

Nevertheless, a dangerous proposal from the Bureau is that it empowers conveyance operators to implement measures such as isolation and quarantine in Article 24. The proposal obligates States Parties to take all practicable measures to ensure conveyance operators comply with health measures such as quarantine and isolation on board. Although worded as an obligation under Article 24, the implication is that this enables conveyance operators to implement measures such as isolating passengers etc. This empowerment must be strictly circumscribed with obligations to be fair, proportionate and reasonable. Measures taken by conveyance operators should be subject to human rights law and standards.

The Bureau, however, argues this is not important because human rights apply as a general principle under Article 3 of the IHR 2005. This reasoning shows low ambition to maintain human rights standards, since Article 3 only applies to States Parties while Article 24 actions are implemented by conveyance operators who are not necessarily government officials.

Articles 35 and 36: Health documents

Article 35 is currently a general rule relating to health documents, while Article 36 deals with certificates of vaccination or other prophylaxis. Countries like Argentina, Brazil, Bolivia, Uruguay and Paraguay wanted to expand Article 36 to other documents in line with their proposals relating to Articles 19 to 31. They wanted to enable the World Health Assembly to review and approve the document formats for these documents, in both paper form as well as digital form.

However, the Bureau is of the opinion that Article 35 as the general provision relating to health documents is the best place to address some of these proposals, and has proposed the following language as an alternative to various proposals from States Parties relating to documents mentioned in Articles 19 to 31 as well as Article 36:

"Health documents issued under these Regulations may be issued on paper, digital format or any other possible formats, subject

to obligations regarding format of any State Party deriving from other international agreements.

"Regardless of the format in which health documents have been issued, each State Party shall accept as valid the health documents issued by other States Parties, as long as measures for ascertaining their authenticity are provided in the documents.

"WHO, in consultation with States Parties, shall develop and update, as necessary, technical recommendations including specifications or standards related to the issuance and ascertainment of authenticity of health documents in digital format. Such specifications shall be in accordance with Article 45 regarding treatment of personal data."

The Bureau's approach is that the issue relating to specifications and standards of such documents can be left to the WHO Secretariat and there is no need for an intergovernmental negotiation to adopt such standards. While this may be the current practice in WHO, especially as the World Health Assembly has very limited time to go into technical issues such as health documents, it must be noted that, under both the IHR 2005 and the proposed new pandemic instrument, there are proposals to have annual meetings of governing bodies for the instruments and these bodies may allocate time to engage in these issues.

Articles 42 and 43: Implementation of health measures

Article 42 maintains a general obligation to implement health measures pursuant to the IHR 2005. Article 43 provides for implementing additional health measures other than those recommended by WHO and certain limitations to employing such additional measures.

Several developing countries wanted to improve the language of Articles 42 and 43. The problem with Article 42 is that it lacks specific mention about who is obligated to implement the measures. Developing countries thus proposed that "States Parties" will be responsible for implementing measures. They also proposed that implementation of health measures must be not only transparent and

non-discriminatory but also equitable. They further proposed to specifically mention the measures taken for ensuring equitable access to health products and technologies and also that States Parties must ensure the non-State actors under their jurisdiction also act consistently with these measures.

The Bureau, however, ignored all of these proposals except for the last proposal. It now suggests including an additional sentence to Article 42 which reads: *"States Parties shall take all practicable measures, consistent with relevant national law, to ensure that non-State actors operating in their respective jurisdictions comply with and implement health measures taken pursuant to these Regulations."*

Similarly, for Article 43, there is a detailed proposal from the Africa Group which gained support from several other countries such as Bangladesh, Egypt, Iran, Brazil, Indonesia, Colombia and Malaysia. The proposal provides for an aggrieved State Party to approach WHO if the additional health measures taken by other States Parties affect it or its people and a time-bound process by which a solution has to be arrived at. The Bureau's proposal however does not include such a process. Its proposal is to make WHO merely an information channel between the States Parties in this regard.

Further, the Bureau's proposal maintains a position that additional health measures should not interfere with access to health products required for responding to a public health risk.

Articles 45 and 56: Bureau retains original text

Article 45 currently deals with treatment of personal data and Article 56 deals with dispute settlement. There were proposals from Japan and a few other countries to allow sharing of personal data in certain situations under Article 45. The Africa Group has proposed to limit cross-border data transfer while providing for access to data. In Article 56, Brazil alongside the MERCOSUR region has proposed some amendments to deal with issues relating to additional health measures.

The Bureau however proposes to avoid all these amendments and seeks to retain the original text. With regard to Article 45, the claim is that the proposed ideas are still doable within the existing text. With respect to Article 56, the Bureau makes a claim that Article 43 already addresses the issue.

TWN Info Service on Health Issues (Jan24/01) 9 January 2024

Upcoming IHR amendment negotiations to focus on equity proposals

Geneva, 9 January (TWN) – The 6th meeting of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR6) decided to focus on equity and allocate more time to the discussions on amendment proposals relating to equity in the Working Group's upcoming 7th meeting, to be held on 5–9 February 2024.

Attempts to push for an early harvest approach on amendment proposals relating to surveillance, sanitary and quarantine measures, and the structure and role of national authorities were dropped due to resistance from developing countries.

WGIHR6 was held on 7-8 December 2023 at the WHO headquarters in Geneva in hybrid mode. The report of the meeting was adopted on 8 December.

During the adoption of the report, the Co-Chair from New Zealand reaffirmed the commitment to the need for the amended International Health Regulations (IHR) to address equity. He stated: "It's heart, and it's really the key purpose and part of our original mandate." The Co-Chair also clarified that the WGIHR will continue its work up until May 2024, with an aim to reach consensus on a package of amendment proposals which could be transmitted to the World Health Assembly (WHA) that will take place then.

While some developed countries had an interest in transmitting an early selection of amendment proposals to the WHO Director-General relating to surveillance and to implementation of health

measures through national authorities and conveyance operators, such an attempt did not garner much support.

The 7th Working Group meeting is expected to take up amendment proposals relating to Articles 13, 13A, 44, 44A, 53A and 53 *bis–quater* and Annexes 1 and 10 with more focus. These proposals relate to equity, financing, implementation and compliance, core capacities and duty to cooperate. According to the report of WGIHR6, the Bureau of the Working Group has undertaken responsibility to facilitate informal consultations during the intersessional period with a view to sharing a revised text ahead of WGIHR7.

In this regard, the report states:

"6. Member States and regional groups shared updates on text proposals related to the following articles: Article 13, Article 13A, Article 53A, 53 bis–quarter, 54 and 54 bis, and; Article 44; Article 44A; and Annexes 1 and 10. The drafting group agreed that the Bureau would consider the proposals and share proposed text with the drafting group ahead of the seventh meeting of the WGIHR in February 2024 (WGIHR7).

"7. Regarding the proposed amendments to Articles 13, 13A, 44, 44A, Annex 1, new Annex 10 relating broadly to equity, capacity building and financing to support capacity building and IHR implementation, the Bureau will consider the proposals and facilitate informal consultations during the intersessional period with a view to sharing a revised text ahead of WGIHR7. The drafting group also supported the suggestion for Bureau members to attend related INB subgroup discussions."

Bangladesh, one of the proponents of major equity-related IHR amendment proposals, requested discussion of Articles 13 and 13A on equitable access to health products and technologies required to respond to public health emergencies of international concern (PHEICs), along with Articles 44 and 44A and Annexes 1 and 10, in the beginning of the next meeting. The Co-Chair agreed to the request and indicated in the concluding session that these Articles will be placed upfront for discussion on the WGIHR7 agenda.

Monaco expressed doubts regarding the process, which stipulates that the IHR amendment proposals must be circulated at least

four months ahead of the WHA. However, the Co-Chair pointed out that the legal counsel had already advised that this stipulation was met with when the compilation of IHR amendment proposals was first transmitted by the WHO Director-General to all Member States.

After taking updates from the Member States and regional groups on their proposed amendments, WGIHR6 discussed amendment proposals relating to Articles 15–18 on temporary and standing recommendations, as well as Articles 19, 23–24, 27–28, 31 and 35–36 on health measures at points of entry, affected conveyances, role of conveyance operators, health documents etc. It also discussed Articles 42–43, 45 and 56 on implementation of health measures, treatment of personal data, and settlement of disputes respectively.

Developed countries' indifference towards equity

Several countries such as Japan, Australia, Norway and the European Union have been trying to dilute, if not avoid, IHR amendment proposals relating to equitable access to health products by citing comments of the IHR Review Committee on equity-related amendment proposals. The Committee had termed some of the proposals as complex and therefore not targeted amendments.

At one instance, relating to discussions on the amendment proposals in Articles 13A, 15–18 and 42, Japan questioned whether the WHO Director-General can issue recommendations on equitable access to health products and technologies. The major proposal from the developing countries spreading across all these Articles requires authorizing the Director-General to issue recommendations to States Parties on realizing equitable access to health products such as vaccines, therapeutics and diagnostics during a PHEIC.

Under Article 13, the proposal is to empower WHO to request all States Parties to support the WHO Coordinated Activities against a PHEIC, including for equitable access to health products. Articles 15 to 18 are also proposed to be amended for enabling WHO to issue recommendations for equitable access such as temporary or standing instructions, after taking into account the status of demand and supplies of health products.

Operationalization of these functions of WHO and the States Parties' obligation to implement such recommendations are dealt with in detail under the Article 13A proposal.

Accordingly, WHO has to assess the potential shortage of supplies during a PHEIC and has to make recommendations to the States Parties to promote equitable access including any allocation plans if required. The States are also to be mandated to follow those recommendations, through scaling up production within their territories, diversifying production to developing countries and adhering to allocation plans developed by WHO. Under proposals for Articles 13A and 42, States are also required to ensure that non-State actors acting from their territories act consistently with WHO recommendations and health measures taken pursuant to the IHR 2005, respectively.

The Bureau, in the context of Articles 15–18, has proposed textual suggestions which state that while issuing "recommendations", the Director-General can provide "guidance" to States Parties on access to and allocation of health products, technologies and know-how through WHO-coordinated mechanisms, as appropriate.

Since such text formulation can potentially create ambiguity as to the authority of the Director-General to make recommendations, certain developing countries, including the Africa Group, insisted on using language which makes it clear and straightforward that the Director-General can make recommendations for equitable access. Japan and other developed countries, on the other hand, do not want WHO or the Director-General to have such functions. They also do not want to take up "obligations" to cooperate and assist in this regard.

The WHO Secretariat, however, showed examples during the COVID-19 pandemic when the Director-General made recommendations relating to equitable access to health products. This has strengthened the developing countries' proposition that equity and equitable access to health products are matters within the scope of the IHR 2005.

Technical amendments without adequate safeguards on human rights

WGIHR6 discussed the Bureau's textual proposals for amending the IHR 2005 in areas such as health measures to be undertaken in vessels and points of entry and health documents (format and standards).

Relating to vessels, the Bureau's proposal took inputs from developed countries' proposals seeking to empower conveyance operators to implement health measures, including onboard quarantining, under Article 24. The proposals also seek to empower competent authorities of port States to implement additional health measures, including quarantine of conveyances to prevent international spread of disease under Article 27.

Further, under Article 35, the Bureau proposed that health documents can be in either paper or digital format, and also that WHO, in consultation with States, can develop standards and specifications, including for interoperability.

(Interoperability generally refers to the ability of two or more systems to work together. In the current context, it refers to computer systems, programs or other digital tools interacting or working with each other, using a common data format or communication protocol which enhances the speed of data sharing and ease of processing. While this may contribute to increased data transfers across national borders, there are implications on sovereign control by States over the data generated or stored in their territories.)

Interestingly, the WGIHR seems to be generating some form of convergence and consensus on the abovementioned amendment proposals in the IHR 2005 relating to on-board quarantining and use of digital health documents.

In Article 24, the proposal is to obligate States Parties to take practicable measures such that the conveyance operators comply with and implement health measures recommended by WHO and adopted by a State Party, including on-board quarantining, and other measures upon embarkation and disembarkation. The proposal is getting some convergence across WGIHR members.

However, the proposals from certain developing countries to balance such a proposal with inclusion of human rights standards were not accepted by several States and the Bureau. In fact, the Bureau was assisted by the WHO legal counsel to argue that recommendations developed by WHO and health measures adopted by the State Party consistent with such recommendations will meet human rights standards by virtue of Article 3 of the IHR 2005.

It is learnt that some developing countries expressed dissatisfaction with this explanation as Article 3 speaks only on general principles, with nothing explicit on non-State actors' obligation to act consistently with human rights standards. They argued that health measures like on-board quarantine pose several risks and challenges in safeguarding human rights and that therefore there is a need to specifically mention human rights standards when the IHR enable conveyance actors to implement such measures. They continue to insist on their proposal that would obligate States Parties to ensure conveyance operators who are implementing such health measures act consistently with human rights standards.

Similarly, there are several proposals to explicitly include digital health documents within the IHR. Some of them are gaining acceptance in the WGIHR discussions. Nevertheless, in the name of emergency operations and interoperability, the proposals seek to dilute the right to privacy of the individuals as well as data sovereignty of the States Parties. The proposals from the Bureau on accepting digital health documents are largely welcomed by the States Parties. At the same time, the Africa Group's proposal on safeguarding data through regulating the secondary storage and duplication of data under Article 45 has reportedly been withdrawn.

However, certain countries like India, Indonesia and Botswana have questioned the stress on interoperability and how interoperable systems can be developed while respecting the right to privacy of individuals and sovereignty of the States Parties over the data of their residents and citizens. On enquiry, some of the Africa Group delegations indicated that the group may propose revised amendment language to Article 45.

WGIHR to coordinate with INB on definition of pandemic, public health alerts and financing approaches

It was agreed by Member States at WGIHR6 that there will be increased coordination with the Intergovernmental Negotiating Body (INB) that is working on a proposed pandemic instrument, in areas relating to public health alerts, definition of pandemic, PHEIC and pandemic continuum and financing approaches to meet the needs and mandates of both instruments, i.e., the IHR 2005 and the proposed pandemic instrument.

In this regard, the WGIHR6 report states:

"5. Following an initial discussion on the proposed amendments held in an open session, the Working Group transitioned into a drafting session and proceeded with a discussion on financing mechanisms. The drafting group agreed to continue discussions during the intersessional period, in coordination with the INB, to develop an approach to financing that meets the needs and mandates of both processes…

"9. Regarding proposed amendments related to the public health alert – PHEIC – pandemic continuum, including definitions, criteria and the process for determining each, the drafting group agreed to form a subgroup, convened by the Bureau and open to all drafting group members, and in coordination with the INB, to move the discussions forward and to provide an update at the WGIHR7."

In addition, the WGIHR6 report also states that "the drafting group also supported the suggestion for Bureau members to attend related INB subgroup discussions" in matters relating to equity and capacity building.

However, Botswana told the WGIHR Bureau that this increased coordination must result in specific drafting outcomes for both the WGIHR and the INB, indicating that the IHR and the new pandemic instrument are two different international instruments. Developing a financing solution or solutions for challenges to equitable access in any one of the instruments cannot suffice, with similar requirements needed in the other instrument.

According to the Africa Group, it is crucial to address equity gaps through both instruments since equity was the most critical gap experienced during the COVID-19 pandemic and other PHEICs such as monkeypox or Ebola which were not pandemics. Botswana was endorsing the general position of the Africa Group. At the concluding session, the WGIHR Co-Chair said the WGIHR Bureau had specifically noted the suggestion by the Botswanan delegation.

Part 9 – **7th meeting of the WGIHR**

TWN Info Service on Health Issues (Feb24/01)
5 February 2024

WGIHR7 agenda proposes inequitable treatment for equity proposals

Geneva, 5 February (Nithin Ramakrishnan and K.M. Gopakumar) – The provisional agenda and programme of work for the 7th meeting of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR7) do not treat amendment proposals for operationalizing equity in the IHR 2005 on the same footing as other amendment proposals that are either technical in nature or in the interests of the developed countries.

It is not clear whether there will be negotiations on equity-related provisions and others of interest to developing countries, because the Bureau has not circulated the text on equity-related provisions.

This is a backtracking from the commitment made by the Co-Chair during the last day of the 6th meeting of the WGIHR held in December 2023 and goes against the mandate of the Bureau to work during the intersessional period on these equity-related proposals.

In this regard, the WGIHR6 report reads: *"Regarding the proposed amendments to Article 13, Article 13A, Article 44, Article 44A, Annex 1 and new Annex 10 relating broadly to equity, capacity-building and financing to support capacity-building and the implementation of the International Health Regulations (2005), the Bureau will consider the proposals and facilitate informal consultations during the intersessional period with a view to sharing a revised text ahead of the seventh meeting of the WGIHR."*

TWN learnt that the WHO Secretariat had communicated textual proposals on equity-related proposals on 2 February for the consideration of the Bureau, which has yet to take a decision regarding the circulation of the text as the Bureau's text. A couple of developing country delegates also confirmed that there was no intersessional work or informal consultations on most of these Articles. (The proposed text concerned Articles 13, 13A, 44 and 44A, Annex 1 and Annex 10.)

WGIHR7 will take place on 5–9 February 2024 at the WHO headquarters in hybrid mode.

The draft programme of work for WGIHR7 does not envisage discussions on equity-related amendment proposals such as those related to Articles 2, 3, 13 and 44 and Annex 1, as well as proposed new Articles 13A and 44A.

(Article 2 deals with the purpose and scope of the IHR 2005, Article 3 is on principles, and Article 13 is on public health response. The new amendment proposals are as follows: Article 13A on equitable access to health products, technologies and know-how, Article 44 on collaboration and assistance, Article 44A on financial mechanism, and Annex 1 on health emergency preparedness and response capacities.)

According to the draft programme of work, agenda item no. 3 is "Consideration of proposed amendments including text proposals from the Bureau and the outcome of intersessional discussions". However, this agenda item is divided into two sub-items:

"• The Co-Chairs will introduce the updated Bureau's text on proposed amendments related to the following articles and annexes:
  - *Articles 4; 5; 8; 9; 15–18; 24; 35; 36; 37; 42; 43; 45; 56; and Annexes 2–4; 6; and 8*
- *The Co-Chairs will provide an update on the Bureau's text proposals related to the following articles and annexes, including updates on the facilitated discussions on these proposals during the intersessional period:*
  - *Articles 6; 7; 10–13; 13A; 44; 44A; 48; 49; 53A; 53 bis–quater; 54; 54 bis; and Annex 1; and new Annex 10"*

Thus, the first sub-item will introduce and discuss the updated Bureau's text on the proposed amendments. Subject matters covered in this sub-item are responsible authorities (Article 4), surveillance (Article 5), consultation and reports (Articles 8 and 9), temporary and standing recommendations (Articles 15–18), conveyance operators (Article 24), health documents (Articles 35–37), implementation of health measures (Article 42), additional health measures (Article 43), treatment of personal data (Article 45), settlement of disputes

(Article 56), decision instrument for assessment of public health events (Annex 2), model ship sanitation control exemption certificate/ship sanitation control certificate (Annex 3), technical requirements pertaining to conveyances and conveyance operators (Annex 4), vaccination, prophylaxis and related certificates (Annex 6), and model of maritime declaration of health (Annex 8).

However, the second sub-item, which contains major amendment proposals with respect to achieving equity, would only "provide an update on the Bureau's text proposals". This means the Bureau does not propose a text-based discussion on equity-related amendment proposals, quite contrary to the commitment given by the Bureau Co-Chair during WGIHR6.

During the concluding session of WGIHR6, one of the Co-Chairs had responded affirmatively to Bangladesh, which had requested: "Still we have to make progress on Articles 13, 13A, 44, 44A and Annex 1 … so we request you to consider that at the beginning in the next round of discussions. I think it is important to ensure that all articles are on equal footing. Because of your intention … our intention as well is to advance equity as the prime focus of the amendments."

The Co-Chair replied: "… as you see that our commitment would be to put those upfront on the agenda for our next meeting to make sure we really are going through them in detail and having a good discussion on those articles that are seen through to delivering on equity."

Bangladesh had also asked when the Bureau's textual proposals would be circulated for the discussions in WGIHR7 as per the mandate reiterated in the report of WGIHR6. The Co-Chair had then said the text proposals would be circulated as and when they were prepared with the support of the WHO Secretariat.

By devoting the dedicated discussions on the Bureau's text to various other Articles, the Bureau and the WHO Secretariat seem to be attempting to shift the focus from the various proposals from Member States to incorporate equity-related provisions in the IHR 2005.

For WGIHR7, the Bureau has circulated its proposals for around 17 Articles and five Annexes. Amongst these, on Articles relating to surveillance, verification of external reports, certificates of vaccination or other prophylaxis and health measures, i.e., Articles 5, 9, 36 and 42 respectively, the Bureau has proposed to retain the current IHR 2005 text. Regarding Article 24, on conveyance operators, the Bureau agrees to continue with the text proposals that were on the screen during the last discussion on 8 December.

However, on Articles 4, 8, 15, 16, 17, 18, 35, 43, 45 and 56, the Bureau has amended the texts that were shown on screen at the last meeting. These proposals, as well as proposals on five Annexes, are up for discussion in WGIHR7.

Thus, most of the initial discussions under agenda item 3 will focus on technical matters such as health documents, operations of conveyance operators, responsible authorities etc, although certain Articles like Articles 15–18, 42 and 43 reflect some elements of equity. The most crucial elements of equity, i.e., financing for core capacity building (Article 44A) and equitable access to health products, technologies and know-how (Article 13A), are however not included in the list of Articles which will be discussed under the first agenda sub-item. These Articles are mentioned under the second sub-item, but there is no mention of consideration of any textual proposals, neither from the Bureau nor from the States Parties to the IHR 2005.

Bureau's text proposals for Articles 4 and 5 ignore equity

The Bureau's text proposals for Articles 4 and 5 have conspicuously avoided elements of equity. Article 4, which deals with responsible authorities, originally contained obligations to establish and maintain responsible authorities in the States Parties for implementation of the IHR 2005, and in particular, National Focal Points which shall communicate and coordinate with the WHO focal point in the implementation of the IHR 2005. Article 5 deals with the establishment of surveillance capacities, detection and assessment of public health events that may potentially become a PHEIC.

The Bureau's textual proposal on Article 4 compromises equity on two fronts.

Firstly, the text proposal envisages creating a network of national authorities of technical expertise and bypassing national discretion in sharing information about public health events. This could create several economic repercussions for developing countries, including low credit rating profiles in the financial market.

It must be noted that the proposal from the Bureau to establish a National IHR Authority, National IHR Focal Point and National IHR Competent Authority is not limited to national context and law, as it appears from the proposed paragraph 1 of Article 4. A newly proposed paragraph 5 to Article 4 seeks to obligate States Parties to amend their national law to enable them to allocate adequate human and financial resources to these entities. Although the establishment of these entities appears to be an obligation which is domestic in nature, there is another proposal which seeks to share contacts of these entities with all States Parties and WHO. This would establish a de facto international network of technical authorities that could eventually sideline political entities' discretionary authority over health emergency affairs, resulting in unnecessary interference with trade and traffic. This defeats the very purpose of the IHR 2005 which seeks to avoid such unnecessary interference.

Secondly, the text proposal falls short of taking into account the importance of WHO States Parties' communication regarding a coordinated public health response to PHEICs or need for assistance in responding to PHEICs. It is interesting to see that while the Bureau's textual proposal is aligned with certain developed countries' proposal to alter paragraph 2 of Article 4 to convert the functions of National IHR Focal Points into obligations of National IHR Focal Points, the proposal does not make efforts to expand the role of focal points to communicate on issues associated with public health response, support and assistance. They continue to be obligated for communications pursuant to Articles 6 to 12. Thus, there is no guarantee that a State Party will respond to a WHO request under Article 13.5 to provide support for WHO-coordinated activities to help another State Party where a PHEIC is prevalent.

The Bureau's text does not refer to Article 13 or 13A on equity in the proposed amendment for Article 4.2 for creation of a National IHR Authority. Similarly, it makes no effort to ensure that WHO's focal point has an obligation to respond to communications (requests for support) made to WHO by States Parties under Article 13 and the newly proposed Article 13A.

Therefore, the Bureau's proposal for Article 4 perpetuates the inherent inequity of international health emergency law, where communication and coordination are obligatory only for sharing of information about potential public health events. There is not even a guarantee that a State Party's request for assistance in responding to a disease outbreak will be responded to by WHO or by other States Parties.

In addition, the Bureau's proposal to retain the original text of Article 5 also avoids the proposal to incorporate differential treatment of the obligation of developing countries in establishing surveillance capacities. Countries like Malaysia have proposed changes to Article 5 to this effect, with support from a larger number of developing countries, but the text is not reflected in the Bureau's proposal for Article 5 in any manner whatsoever. This will further force developing countries to invest more in surveillance, even when they lack primary health care facilities.

TWN Info Service on Health Issues (Feb24/02)
6 February 2024

WGIHR Bureau's push for two new national institutions for IHR implementation raises concerns

New Delhi/Geneva, 5 February (K.M. Gopakumar and Nithin Ramakrishnan) – The continued push of the Bureau of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR) for the creation of two additional institutions at the national level to implement the regulations raises concerns of institutional and financial fragmentation.

The latest version of the Bureau's text on amending Article 4, which sets out the details of responsible authorities for the implementation of the IHR, proposes the creation of a National IHR Authority and a National IHR Competent Authority.

(This proposal will be discussed at the 7th meeting of the WGIHR, which is taking place on 5–9 February at WHO headquarters in Geneva. The idea for two more new institutions was first tabled in October and again in December, by the Co-Chairs and Bureau respectively.)

Paragraph 2 of the Bureau's text sets out the function of the proposed National IHR Authority as follows: *"The National IHR Authority shall coordinate the implementation of these Regulations within the territory of the State Party, including Article 54 and those provisions that do not explicitly refer to the National IHR Focal Point or the National IHR Competent Authority."*

Functions of the proposed National Competent Authority are set out in paragraph 4 of the Bureau's text: *"... (a) guide and oversee the implementation of provisions of these Regulations that are related to points of entry and/or conveyance operators and/or travellers; and (b) identify the competent authorities at points of entry in its territory."*

Under the current Article 4 of the IHR, each State Party shall "designate or establish a National IHR Focal Point and the authorities responsible" for the implementation of health measures. It is left to the States Parties to determine the nature of the authorities, even though Article 4 sets out the functions of National IHR Focal Points as follows:

"... (a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and

(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments."

Thus, National IHR Focal Points of States Parties are envisaged as the only entity to be in communication with WHO on IHR implementation especially in relation to Articles 6 to 12. The current proposal seeks to create two more institutions, which will not only fragment the institutional arrangement for domestic implementation but also create fragmentation of finance and technical resources.

Institutional fragmentation

To avoid criticisms of institutional fragmentation, the proposed obligation to create another two institutions at the national level is spelled out with two qualifications. Paragraph 1 of the Bureau's text reads:

"Each State Party shall, ***in accordance with its national law and context****, designate or establish* ***the following responsible authorities: a National IHR Authority****, a National IHR Focal Point and* ***a National IHR Competent Authority****.* ***The aforementioned responsible authorities*** ~~*the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations*~~ ***shall act on the State Party's behalf, and in close coordination, through a single entity or up to one entity for each of these authorities.****"*

(The words in bold indicate the proposed text addition, and those in strikethrough are proposed for deletion.)

Thus, it is clear that States Parties have no choice in terms of creation of the two new authorities in addition to the existing National IHR Focal Point. However, there is a choice in designing the work and structure of these authorities, i.e., whether they have to act in close coordination within a single entity or as three separate entities.

Though the proposal for the creation of these authorities is qualified by the words "in accordance with its national law and context", the subsequent paragraphs setting out the functions clearly show that there is little policy space for States Parties in this regard. Though several countries have national IHR authorities, there are no national IHR competent authorities.

Further, proposed amendments to paragraph 4 (renumbered as 7 in the Bureau's text) state: *"States Parties shall provide* ***to*** *WHO* ~~*with*~~ ***the*** *contact details of thei*~~*r*~~ ***National IHR Authority, National IHR Focal Point and National IHR Competent Authority*** ~~*National IHR Focal Point*~~ *and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make available to all States Parties the contact details of* ***the National IHR Authority, National IHR Focal Point and National IHR Competent Authority [, noting that, in accordance with paragraph 1 of this Article, these may be a single entity or up to three separate entities.]****"*

Although it may seem to be an innocent and neutral proposal to share contacts between authorities for administrative ease, the proposal implies that there will be a network of national authorities established in the near future.

Furthermore, the Bureau's text spells out functions of these institutions in such a way as to make it clear that States Parties have no choice but to create two more institutions at the national level. For some larger countries and those with a federal system of government, these institutions could be additional to similar institutions set up by provincial or sub-national governments.

The Bureau gives the following rationale for its proposal: *"In light of the experience gained with the implementation of the Regulations until now, the proposed allocation of responsibilities across three authorities would seem more adequate than maintaining only a National IHR Focal Point (which has appeared to be insufficient to comply with all IHR provisions in several States Parties). The overall rationale is to facilitate the attribution of responsibilities at the domestic level for the implementation of all the provisions of the Regulations – spanning from obligation with a more political connotation to obligations of a more operational nature – thereby enhancing accountability. By outlining in more granular terms each of the three authorities' responsibilities, this Article ultimately intends to facilitate the allocation of responsibilities at the hierarchically most appropriate domestic level. This will help to support full implemen-*

tation and ensure National IHR Focal Points are not assumed to be the 'default' implementing entity for provisions that they have neither the mandate nor resources for."

This institutional fragmentation would create a risk of resource diversion to support the new institutions. The lack of financial resources in developing countries could see developed countries and the WHO Secretariat attempt to create a network of these institutions and effectively bypass the authority of the health ministries of developing countries. Furthermore, it will create confusion of authority and in the line of communication since all the three entities are national-level authorities. This can in fact cause further delays in communications about health emergencies, and thus has the potential to worsen the very problem which States Parties are seeking to address.

It is understood that the WHO Secretariat explained the need to the WGIHR delegations, and that they would recommend creation of the National IHR Authority outside the health ministry at the country level.

Financial fragmentation

To address concerns on the additional financial and technical resources required for the creation/designation of two more institutions, a new paragraph 5 is proposed which states: *"States **Parties shall take measures to implement paragraphs 1 to 4 of this Article, including by allocating human and financial resources, and adjusting its national law in accordance with paragraph 3 of Article 59, as necessary.**"*

Though this clause creates an optics of relating the legal obligations on technical and financial assistance, it does not specify the differentiated responsibilities of actors to provide such assistance. Since it is a general obligation on States Parties, it gives an easy way out for developed countries, which have the financial and technical means at their disposal to assist developing countries. Further, it also allows WHO to abdicate its responsibility.

The proposal to amend Article 4 initially came from Switzerland and Russia. Switzerland wanted to obligate States Parties "to

inform WHO about the establishment of its National Competent Authority responsible for overall implementation of the IHR that will be recognized and held accountable for the NFP's [National Focal Point] functionality and the delivery of other IHR obligations". It also wanted States Parties to share contacts of such National IHR Competent Authority with WHO.

Russia, on the other hand, wanted to amend Article 4 such that the National IHR Focal Point will be an "entity" (institution) rather than a single-person office as is the case for many resource-poor countries. It also wanted to obligate States Parties to amend or adapt national legislation so as to provide the National IHR Focal Point with authority and resources.

Therefore, it is clear that what has been proposed by the WGIHR Bureau goes far beyond what was asked by the initial proponents.

Proposals receive mixed response

The proposals received mixed response during the first day of WGIHR7 on 5 February. Several countries including the United States, the European Union, Botswana, Bangladesh and Malaysia questioned the need for three national entities.

TWN learnt that a few developing countries proposed to delete the proposed paragraph that imposes an obligation to adjust national laws. Also, the EU, the US and Bangladesh questioned the creation of a National IHR Competent Authority just to coordinate other competent entities functioning at the ground level.

In addition, the delegations have explained how the national institutions work and why WHO cannot intervene in national administrative structures.

On another note, Bangladesh proposed to expand the obligation of National IHR Focal Points and WHO contact point to communicate not only on disease detection and information sharing, but also on the needs for coordinating any public health response measure, including request for support and assistance. The Bureau Co-Chair, however, tried to downplay this proposal, citing it as a new proposal. The proposal is surprisingly under "reservation" from the Bureau.

TWN Info Service on Health Issues (Feb24/03)
8 February 2024

Bureau rejects Secretariat's proposal to delete equity-related IHR amendment proposals

Geneva, 7 February (TWN) – The Bureau of the Working Group on Amendments to the International Health Regulations (WGIHR) rejected the WHO Secretariat's proposal to delete equity-related amendment proposals (Article 13A, Article 44A and Annex 10).

The Bureau did not circulate the Secretariat's proposals as the Bureau's text.

The Secretariat had prepared the draft Bureau text following the decision of the 6th meeting of the WGIHR, wherein Member States entrusted the Bureau to prepare a revised text on equity-related proposals. The report of WGIHR6 states: "Regarding the proposed amendments to Article 13, Article 13A, Article 44, Article 44A, Annex 1 and new Annex 10 relating broadly to equity, capacity-building and financing to support capacity-building and the implementation of the International Health Regulations (2005), the Bureau will consider the proposals and facilitate informal consultations during the intersessional period with a view to sharing a revised text ahead of the seventh meeting of the WGIHR."

As is the practice in most of the WHO processes, the Secretariat prepared the documents for the Bureau.

The Secretariat communicated textual proposals on these equity-related proposals on 2 February for the consideration of the Bureau. The Bureau circulated textual proposals on Articles 13 and 44, and Annex 1, but had yet to take a decision regarding the circulation of the Secretariat's text as the Bureau's text on Articles 13A and 44A.

Article 13A: Equitable access to health products, technologies and know-how

The Africa Group and Bangladesh had proposed insertion of a new Article 13A titled "Equitable access to health products, technol-

ogies and know-how for public health response" to address a glaring gap in the IHR, i.e., the silence on access to health products required for preparedness and response to public health emergencies including public health emergencies of international concern (PHEICs). As a result of this gap, the IHR function as a mechanism to provide information on disease outbreaks and help WHO and those Member States with financial and technological abilities to take measures to protect their own population, but without any legal obligation to help the Member State providing the information. Since most disease outbreaks are happening in developing countries, the IHR work as a mechanism for developed countries to obtain information without any legal obligation to assist the developing countries which face PHEICs.

Article 13A proposes a series of measures to facilitate diversified manufacturing of health products required to respond to PHEICs, including the use of exceptions and limitations on intellectual property protection and enforcement, transfer of publicly funded technologies for the production of PHEIC products etc. Further, it also proposes the following obligations on WHO to facilitate diversified production:

(a) develop and publish a list of required health products,
(b) develop and publish specifications for the production of required health products,
(c) develop appropriate regulatory guidelines for the rapid approval of health products of quality including development of immune correlate of protection (ICP) for vaccines,
(d) develop and maintain a database containing the details of the raw materials, ingredients, components, design, know-how, manufacturing process or any other information required to facilitate manufacturing and equitable access of health products required for responding to public health emergencies of international concern,
(e) establish a repository for cell lines to accelerate the production and regulation of similar biotherapeutic products and vaccines,
(f) review and regularly update WHO listed authorities so as to facilitate appropriate regulatory approvals,

(g) any other measures required for the purposes of this provision.

The Secretariat, however, suggested against including a dedicated Article 13A, but instead including elements proposed in Article 13A in other provisions of the IHR or cross-referring to provisions of the pandemic instrument being negotiated in the parallel WHO Intergovernmental Negotiating Body (INB). However, it did not show any such mapping except for one or two elements. Neither has the Secretariat proposed any textual language on Article 13A elements in other provisions of the IHR.

Article 44A: Financial mechanism for equity in health emergency preparedness and response

Article 44.2(c) currently mandates WHO to collaborate with States Parties to the extent possible for "the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1".

Further, the World Health Assembly Resolution 58.3 in 2005 which adopted the IHR also requests the WHO Director-General to work with States Parties to mobilize financial resources to assist developing countries to meet the IHR obligations. Paragraph 6.6 of the resolution requests the Director-General "to collaborate with States Parties to the extent possible in the mobilization of financial resources to provide support to developing countries in building, strengthening and maintaining the capacities required under the International Health Regulations (2005)".

However, so far there is no dedicated fund or a financial mechanism to provide financial assistance within the IHR framework.

The IHR Review Committee's report on the functioning of the IHR during the COVID-19 response stated: "States Parties should ensure adequate and sustained financing for IHR implementation at the national and subnational levels and provide adequate and sustained financing to the WHO Secretariat for its work on preventing, detecting and responding to disease outbreaks…."

To address this glaring gap, the Africa Group proposed a new article, i.e., Article 44A, to create a financial mechanism to provide

financial assistance to developing countries for the implementation of IHR-related obligations. The proposed Article 44A reads:

"1. A mechanism shall be established for providing the financial resources on a grant or concessional basis to developing countries. Such financial mechanism shall provide the financial assistance to achieve the following purposes:

(i) building, developing, strengthening, and maintaining of core capacities mentioned in Annex 1;

(ii) strengthening of Health Systems including its functioning capacities and resilience;

(iii) building, developing and maintaining research, development, adaptation, production and distribution capacities for health care products and technologies, in the local or regional levels as appropriate;

(iv) addressing the health inequities existing both within and between States Parties such that health emergency preparedness and response is not compromised;…."

The Africa Group further proposed that the mechanism function under the guidance of States Parties and the World Health Assembly.

The Secretariat proposed to not retain this new Article 44A, reasoning that the INB is making great progress to adopt a financial mechanism in the pandemic instrument under negotiation, which in the Secretariat's opinion will cover not only pandemics but also health emergencies. However, the Secretariat was not clear about why an existing legal instrument should refer to something that might be established in a future instrument whose fate is in fact not yet decided.

Annex 10: Obligations of duty to cooperate

The existing language under Article 44 of the IHR 2005 which speaks about collaboration and assistance is not sufficiently legally binding to ensure assistance to States Parties in need or their populations. For example, there is not even an obligation on States Parties to respond to a request for assistance from another country. The forms of collaboration and assistance could vary significantly, and

therefore there is no guarantee that the requested help would flow to the requesting party without any conditions attached.

To avoid perpetuating this uncertainty, the Africa Group proposed a non-exhaustive list of activities in which collaboration or assistance could be undertaken. This list, which brings some predictability and specificity into activities that will fall under the scope of Article 44, is then supported by an obligation to collaborate or provide assistance "as requested". Inability to provide assistance or collaboration as requested must be communicated to the requesting States Parties with reasons.

The Secretariat has suggested to not retain this provision, citing the analysis made by the IHR Review Committee on Amendments to IHR 2005, although the Review Committee's mandate was not to evaluate any of the amendment proposals made by sovereign States.

Faulty reasoning

The rationale of the Secretariat is faulty and ignores the demand to address equity in the IHR and to create a health emergency regime based on mutual cooperation and trust. To the Secretariat, the possibility of equity in the pandemic instrument would seem to be a substitute for the lack of equity in the IHR. This ignores the fact that the former is an international legal instrument to address prevention, preparedness and response to a pandemic, an extreme form of PHEIC, whereas the IHR are the legal instrument to address all types of PHEIC. Poor implementation of the IHR would lead to a greater risk of a pandemic.

The Secretariat's proposed treatment of States Parties' equity-related proposals completely disregards WHO Executive Board decision EB 150(3) which mandated issues of equity to be addressed as part of the IHR amendments. Paragraph 2 of EB150(3) is explicit and unambiguous: "Such amendments should be limited in scope and address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting

effective implementation and compliance of the International Health Regulations (2005)...."

Pointing out that major equity-related proposals, i.e., Article 13A and Article 44A, have not been discussed yet, a developing country diplomat said, "We know what is being played out here is delay tactics. The Secretariat holds the INB process as hostage for opposing almost all equity-related [IHR] amendment proposals. They are giving signals [that] if we make good progress on equity in the IHR 2005, then the pandemic treaty agenda will fall apart. The Bureau is being told by the Secretariat what to do and what not to do. At times, it becomes difficult to understand whom we are negotiating with – with the States Parties or with the Secretariat."

TWN Info Service on Health Issues (Feb24/04) 12 February 2024

Bureau's text suggestion for "pre-qualification" raises concerns of vaccine supply concentration

New Delhi/Geneva, 12 February (K.M. Gopakumar and Nithin Ramakrishnan) – Text has been proposed by the Bureau of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR) that seeks to make WHO-prequalified vaccines a compulsory requirement for the issuance of vaccine or prophylaxis certificates, raising concerns of vaccine supply concentration.

This took place at the recent 7th meeting of the WGIHR held from 5 to 9 February 2024.

Vaccine certificates are used as evidence of vaccination to facilitate international travel. Article 36 of the IHR states that travellers in possession of a vaccine certificate should not be denied entry unless the competent authority has verifiable indications and/or evidence that the vaccination or other prophylaxis was not effective.

Article 36 obligates States Parties to issue vaccine certificates as per the conditions mentioned in Annex 6 and Annex 7. Annex 6 sets out the general conditions and model certificates for vaccination/

prophylaxis certificates. Annex 7 sets out the conditions and model certificates for vaccination/prophylaxis certificates for specific diseases. Currently Annex 7 lists only yellow fever vaccines.

The contentious proposal is to amend paragraphs 1 and 3 of Annex 6. These paragraphs currently state that only those vaccines or prophylaxis designated or approved by WHO should be used.

Paragraph 1 states: *"Vaccines or other prophylaxis specified in Annex 7 or recommended under these regulations shall be of suitable quality; those vaccines and prophylaxis designated by WHO shall be subject to its approval. Upon request, the State Party shall provide to WHO appropriate evidence of the suitability of vaccines and prophylaxis administered within its territory under these Regulations."*

Paragraph 3 states: *"Certificates under this Annex are valid only if the vaccine or prophylaxis used has been approved by WHO."*

The amendment proposals replace "approval" with WHO "prequalification".

The Bureau's proposal on paragraph 1 states: *"Vaccines or other prophylaxis specified in Annex 7 or recommended under these Regulations shall be of suitable quality; those vaccines and prophylaxis designated by WHO shall be* ***prequalified or listed for emergency use by WHO*** ~~*subject to its approval*~~*. Upon request, the State Party shall provide to WHO appropriate evidence of the suitability of vaccines and prophylaxis administered within its territory under these Regulations."*

The proposal on paragraph 3 states: *"Certificates under this Annex are valid only if the vaccine or prophylaxis used has been* ***prequalified or listed for emergency use*** ~~*approved*~~ *by WHO."*

The proposal to introduce these phrases came during the December 2023 meeting from the United States, which is not an original proponent of the amendments to Annex 6. The Bureau Co-Chair, who was keen to avoid equity-related proposals coming from non-original proponents, showed no hesitance in adopting this proposal from the US.

Countries like Malaysia, Mexico, Brazil, Indonesia and Colombia indicated that "approval of WHO" under Annex 6 should not be modified to make it too prescriptive about the scheme of approval.

According to them, the language in Annex 6 should be generic in nature to include any modified or new processes that may be developed in the future. Brazil has suggested incorporating "safety and efficacy" along with "suitable quality" in paragraph 1 as compromise language in exchange for retaining the original language relating to WHO's approval. However, the Co-Chairs reserved against Brazil's proposal on the ground that it is a new proposal and did not allow further discussion on it.

It is learnt that the WHO Secretariat itself offered to come up with an explanation or definition of the phrase "subject to its approval" in Annex 6 and discussions were accordingly suspended.

It is important to note that the existing condition mentioned in Annex 6, i.e., the vaccine is subject to WHO approval, does not necessarily mean that it is a WHO-prequalified product. WHO prequalification is a specific form of product marketing approval that involves evaluation of data and inspection of the manufacturing facility concerned by WHO. In contrast, a WHO-approved vaccine means a vaccine which complies with the WHO-specified safety and efficacy specifications.

The rationale provided by the Bureau is as follows: *"WHO prequalification and emergency use listing procedures for vaccines and medicines are intended to ensure that a common set of requirements regarding quality, safety and efficacy are met. The Bureau maintains that it is desirable to preserve the integrity of these mechanisms as those underpinning the use of vaccines and medicines in international travelers. Therefore, the Bureau proposes not to retain the proposed reference to the competent national / regional regulatory authority of the State Party in which territory the vaccine was administered."*

However, this rationale totally undermines the need for diversified production and adequate availability. Further, this amendment, if adopted, will make it compulsory to use only vaccines or prophylaxis that are WHO-prequalified or listed for emergency use by WHO to issue vaccine/prophylaxis-related certificates. In current practice, only WHO-prequalified vaccines or prophylaxis can be used to issue vaccine certificates for yellow fever and any other public health

emergency of international concern (PHEIC) requiring issuance of certificates under the IHR such as COVID-19.

The insistence on prequalified or emergency-use-listed vaccines or prophylaxis effectively institutionalizes monopoly because usually only a few producers can obtain the prequalification or emergency use listing. For instance, according to the WHO pre-qualification vaccines list, only four yellow fever vaccines from two manufacturers are prequalified to date: Institut Pasteur de Dakar has three prequalified products and Sanofi Pasteur has one. Similarly, out of 15 COVID-19 emergency-use-listed vaccines from 12 manufacturers, only five are from developing countries. These five manufacturers are Beijing Institute of Biological Products Co, Ltd and Sinovac Life Sciences Co, Ltd from China, and Bharat Biotech International Ltd, Serum Institute of India Pvt Ltd and Biological E. Limited from India. However, the supply from Bharat Biotech International Ltd is listed as suspended. It is pertinent to note that the Secretariat did not respond to a question on how many developing countries have stringent regulatory authorities (SRAs) or WHO listed authorities which play a significant role in this process.

A recent report of the US International Trade Commission (ITC) observes that prequalification is expensive and delays access. It states: "These procurement agencies, however, rely on WHO prequalification (or emergency use listing) and guidance issuance for all tests and treatments, which were reported to have caused delays. In the case of some therapeutics, such as remdesivir, WHO recommendation and prequalification came a full two years after US authorization and the first VLs [voluntary licences] were signed. This means that although treatments were available, many countries were not immediately able to access them. WHO prequalification, which is also required for certain MPP [Medicines Patent Pool] sublicensing agreements, requires significant effort by manufacturers in order to complete the application requirements and address data standards, which may be challenging for some manufacturers. It can also be costly. As noted in chapter 2, a one-time application fee of $25,000 is required in addition to a $20,000 annual fee for a full product assessment. Industry representatives have noted that these fees may be

too expensive for smaller manufacturers in many LMICs [low- and middle-income countries]."

When asked about the application cost and annual fee, the WHO Secretariat, which had made an expert presentation, did not provide a direct answer. "They were very reluctant to spell out the application fee and annual fee," a delegate told TWN. Instead, the audience were told that 60% of the cost for evaluation work by WHO is to be borne by the manufacturers and the remainder through contributions from the Gates Foundation, GAVI and UNITAID.

The ITC report also notes that the standard timeline for prequalification is 270 days, excluding the time for manufacturers to respond to evaluators' questions.

The report also states: "In the case of diagnostics, WHO Emergency Use Listing Procedure (EUL) and official guidance delays were a significant factor for access to rapid antigen tests. The WHO issued its first two EULs for rapid antigen tests in September and November 2020, but the initial guidance did not recommend their use. The guidance in late December 2020 only recommended the use of rapid antigen tests in limited circumstances where molecular testing was unavailable. … The delays in EULs and guidance from the WHO likely reduced demand for rapid antigen tests in LMIC markets, despite the ample supply."

The delay in the prequalification process is also cited as a reason for the underperformance of efforts to facilitate COVID-19 diagnostics through the Access to COVID-19 Tools Accelerator (ACT-A), a multistakeholder platform set up under the aegis of WHO. The Strategic Review of ACT-A states: "Although progress has been made in lowering the price of tests, internal stakeholders expressed dismay that the price had not yet fallen further, citing below one dollar to be the critical threshold for expanding access and uptake. Currently, despite over 1,000 COVID-19 tests being commercially available, only four rapid tests have the necessary Emergency Use Listing (EUL) for WHO procurement (two of which are variations from the same manufacturer)."

The External Evaluation of ACT-A observes: "Access to certain diagnostic types was delayed due to late WHO clearance (es-

pecially for self-tests). Diagnostics are usually less complex to develop than drugs and vaccines. They are very important throughout the pandemic, especially at the beginning of pandemics when other MCMs [medical countermeasures] are not available."

There is a difference in timeframe between prequalification of a product approved by a stringent regulatory authority and a product approved by a regulatory authority of a developing country. In current practice, "WHO's work is essentially an abridged procedure to verify that the product submitted to WHO [prequalification] is indeed the one approved by the SRA".

Thus, insistence on WHO prequalification essentially facilitates products approved by a limited number of SRAs, bearing the danger of concentration of supply and undermining efforts to diversify manufacturing.

TWN Info Service on Health Issues (Feb24/06) 19 February 2024

WGIHR to hold dedicated session on equity-related amendment proposals

Geneva, 16 February (TWN) – The Working Group on Amendments to the International Health Regulations (IHR) 2005 (WGIHR) suspended its 7th meeting on 9 February as the Bureau proposed to hold a dedicated session on equity-related amendment proposals in March.

This will be soon after the 8th meeting of the Intergovernmental Negotiating Body (INB) that is working in parallel on a pandemic instrument. The Working Group welcomed this proposal.

The Bureau could not conduct informal consultations and circulate textual proposals on amendments relating to equity before the 7th meeting of the WGIHR (WGIHR7) that took place on 5–9 February. The textual proposals relating to Articles 13, 13A, 44 and 44A were supposed to be circulated before the beginning of WGIHR7, but this was not done. The Bureau, however, managed to circulate

and discuss text on Articles 13 and 44 during the second week of February.

The Co-Chairs have now promised to come up with text proposals addressing Articles 13A and 44A and a resumed session will be conducted sometime between 4 and 15 March to discuss these. Although there are certain equity-related elements in other amendment proposals with respect to Articles 15–18, 42 and 43, the major equity-related proposals pertain to Articles 13, 13A, 44 and 44A. The former category of amendment proposals was discussed during WGIHR7.

WGIHR7 adopted an interim report on 9 February which reads thus: *"The Working Group further agreed that a dedicated session should be held to discuss the Bureau's textual proposals on Article 13A and 44A and other Articles addressing equity not covered during the week. The Working Group supported the Bureau proposal to suspend this seventh meeting of the WGIHR and to hold a resumed session ahead of its 8th meeting. The date which is proposed to be during the period 4–15 March 2024 and the modalities would be determined and announced by the WHO Secretariat as soon as possible. Article 13A and 44A will also be considered by the Drafting Group on the first day of WGIHR8, taking into account the discussions in INB8 and INB9."*

TWN reported during WGIHR7 that the WHO Secretariat had drafted certain text proposals on Articles 13A and 44A, mainly recommending deletion of the proposals by suggesting that the elements proposed under these Articles be linked to various other provisions in the IHR 2005 and also to provisions that are being currently negotiated in the INB in the development of a proposed pandemic instrument. However, the Bureau rejected these proposals as the recommendation was not supplemented with a mapping of the elements proposed under Articles 13A and 44A to the existing IHR 2005 provisions.

When the Co-Chairs consulted the proponents of these amendments about the text developed by the Secretariat, the proponents clearly conveyed that the Secretariat or Bureau cannot suggest deleting the textual proposals in exchange for a promise that

some of these ideas will be dealt with in the new pandemic instrument being developed. The two instruments differ significantly in scope and therefore elements of equity should be substantively addressed in the IHR 2005. The proponents also referred to the mandate under the Executive Board decision EB150(3) which requires States Parties to amend the IHR 2005 to address equity gaps.

Although the Bureau managed to come back to the proponents with a text proposal relating to Article 44A, the proponents are not fully convinced about that text. Article 13A, on the other hand, is still pending in the drafting stage. Therefore, both the text proposals were not circulated during the 5–9 February session. The way forward is that these text proposals will be circulated in the coming days and will be negotiated through a dedicated resumed session of WGIHR7.

Further, according to the interim report, the intersessional period will be used by the Working Group, with the support of the Bureau and WHO Secretariat, to conduct the following:

(a) Discussions amongst various proponents of the amendment proposals, with the aim to present outcomes to the next meeting;
(b) Discussions with relevant subgroups of the INB developing a new international legal instrument on pandemic prevention, preparedness and response on issues of common interest;
(c) Intersessional briefings, facilitated intersessional consultations, and joint intersessional work with the INB;
(d) Preparation by the Bureau, with the assistance of the Secretariat, of draft text proposals for consultation at the 8th meeting of the WGIHR, without prejudice to the status of the amendment proposals made by the States; and
(e) WGIHR-INB joint plenary session at the 8th meeting of the INB.

Egypt, on behalf of the Group of Equity Member States, reminded the floor about the mandate of the WGIHR under decision EB150(3) which requires it to address the gaps relating to equity, and welcomed the Bureau's proposal to have a dedicated session on equity-related amendment proposals.

India, on behalf of the South-East Asian Region countries, supported the statement made by the Group of Equity and welcomed the Bureau's proposal to have the dedicated session, and suggested that additional informal sessions could be organized if required.

Ethiopia, on behalf of 47 Member States of the African Region and Egypt, said that they remain committed to having meaningful amendments to the IHR 2005, which would include equity. They also requested constructive engagement for all delegations in pushing the equity agenda to the last mile.

The European Union, the United States and Norway took the floor to promise constructive engagement, while Switzerland reminded the floor that the WGIHR is only working on targeted amendments and cannot reopen the scope of the IHR 2005.

Geneva Health Files, Newsletter Edition #67 [Treaty Talks] 27 February 2024

On the brink of legitimizing inequity: Negotiations at WHO for a pandemic instrument and amending the IHR

by K.M. Gopakumar

Equity is listed as a "guiding principle and approach" in the current proposed negotiating text for a new pandemic instrument.

"Equity is at the centre of pandemic prevention, preparedness and response, both at the national level within States, among and within countries or regions, and at the international level between States…," as per Article 3 of the negotiating text that elaborates on the principle of equity.

Similarly, EB decision 150(3), which spells out the scope of the amendment of the International Health Regulations 2005 (IHR), also mandates addressing the issue of equity. It states: "Such amendments should be limited in scope and address specific and identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical

to supporting effective implementation and compliance of the International Health Regulations (2005)."

Despite the loud and clear mandate to address equity within the international health emergency regime, the negotiations in both processes are moving towards the opposite direction that legitimizes inequity.

Inequitable international health emergency regime: The limitations of the IHR (2005)

One of the glaring gaps in the international health emergency regime is the legal vacuum in providing predictable financial assistance for effective response during outbreaks of diseases. The IHR is the only legally binding instrument setting out the obligations for countries "to prevent, protect against, control and provide a public health response to the international spread of disease".

It effectively obligates its 194 Member States (who are State Parties to the IHR) to assess public health events and inform WHO within 24 hours if such a public health event has the potential to become a public health emergency of international concern (PHEIC). The Director-General of WHO is to act upon this information and make a decision on whether to declare the outbreak a PHEIC.

However, there is no explicit legally binding provision in the IHR to facilitate availability and access to required health products to contain the international spread of diseases. Thus, the IHR effectively operates as an instrument only to provide information about potential PHEICs without any corresponding obligations on State Parties or WHO to guarantee assistance in public health response.

Though the IHR recognizes the need to assist its State Parties, it fails to effectively address the prevailing development divide. Provisions on technical assistance are framed without recognizing the special needs of developing countries.

Articles 5 and 13 setting the obligations on surveillance and public health response obligate WHO to assist State Parties as a general obligation. For instance, Article 5.5 states: "WHO shall assist

States Parties, upon request, to develop, strengthen and maintain the capacities referred to in paragraph 1 of this Article." The IHR refers to the special needs of developing countries only once.

Article 44.2(c) obligates WHO to collaborate with State Parties to the extent possible in "the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1". There are no specific obligations on developed countries, which possess the technological capabilities in the pharmaceutical sector to assist in the response to a PHEIC, to help developing countries.

The lack of obligations on developed countries and for WHO in assisting the implementation of the IHR and facilitating access to health products makes the IHR an inequitable regime. This is especially true in the light of the fact that these health products are developed from information, including from pathogens, shared by developing countries.

The IHR amendment process

Developed countries are making all efforts to undermine the equity-related amendment proposals by putting forth an argument that the pandemic instrument is the best place to address equity and also stressing the need to preserve the current version of the IHR. The WHO Secretariat is toeing the same line and made several attempts to reject the amendment proposals contained in Article 13A on equitable access to medical products and Article 44A on the proposed financial mechanism for IHR implementation.

Shifting equity provisions from the IHR to the pandemic instrument would undermine the need for equity in health emergencies because the scope of the pandemic instrument is very limited, i.e., pandemics and not PHEIC. Hence, preserving the status quo of the IHR would create an equity vacuum in addressing PHEIC situations.

Marginalization of equity in the INB

Common but differentiated responsibilities (CBDR)

Recognition of the development divide among WHO Member States is a prerequisite to addressing equity.

In this regard, the negotiation text brings back the principle of common but differentiated responsibilities (CBDR) as a guiding principle and approach in Article 3. It states: "Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures. Given the unequal global development in the promotion of health and control of diseases, especially communicable diseases, which is a common danger, developed countries that hold more capacities and resources relevant to pandemics should bear a commensurate degree of differentiated responsibility regarding global pandemic prevention, preparedness, response and recovery through effective means of implementation, such as technology transfer and know-how as well as financial resources."

However, none of the subsequent Articles propose specific obligations on developed countries to assist developing countries.

Equitable access

Proposed articles on equitable access from Articles 9 to 11 and 13 deal with R&D, production and distribution and are mostly stated in "best endeavour" language. For instance, Article 10's (sustainable production) chapeau reads: "… thereby reducing the potential gap between supply and demand, shall endeavour to". Similarly, the article on technology transfer is qualified with terms including promoting, encouraging etc. Technology transfer is proposed through mutually agreed terms. There is nothing in these articles which offers predictable access through diversified production.

Except Article 13, no mechanism at the international level is envisaged in either Article 10 or Article 11 to facilitate technology transfer and sustainable production. The only reference in Article 11

is to "develop and strengthen multilateral mechanisms, as appropriate, that facilitate the transfer of technology and know-how for pandemic-related products on voluntary and mutually agreed terms".

This provision is a non-starter.

Existing obligations on cooperation

The reluctance of developed countries to share technologies is a convenient ignorance of their obligations under the Biological Weapons Convention, which creates an obligation on State Parties to cooperate with other states or international organizations in the field of bacteriology for the prevention of disease or for other peaceful purposes. Article X.1 states: " … Parties to the Convention in a position to do so shall also co-operate in contributing individually or together with other States or international organizations to the further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease, or for other peaceful purposes."

Higher standards on regulations and their potential impact on access

There are proposals to push the pharmaceutical monopoly agenda through regulatory strengthening. For instance, the proposed Article 14 on regulatory strengthening proposes strengthening WHO prequalification and compliance with ICH standards. For instance, Article 14.7 states: "Each Party shall consider adopting and implementing, when practicable and consistent with national law and procedures, guidance and technical documents concerning medical products developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the International Medical Device Regulators Forum (IMDRF) or their successor organizations."

Most ICH and IMDRF standards are beyond the reach of most of the developing country manufacturers. This mandatory consideration of ICH and IMDRF standards would threaten the demand

for diversified production of pandemic-related health products. The following remark from the report of a WHO-convened meeting of regulatory officials in 2001 is still relevant: "Public health implications of the application of guidelines of greater technical complexity in developing countries may be far reaching … If these suppliers are unable to meet what may be unsubstantiated quality standards, the adverse impact of the withdrawal of these drugs on the health of the population might well be far more dramatic than that of any hypothetical risk posed by failing to achieve the ICH standards."

Access and benefit sharing

Developed countries especially the EU are trying to undo international obligations on access and benefit sharing as described under the Convention on Biological Diversity and its Nagoya Protocol. This is reflected in Article 12 on pandemic access and benefit sharing (PABS). The EU tabled a proposal that makes access to the pathogen a legal obligation but makes benefit sharing an option. The EU approach serves the purposes of developed countries, which have already invested in the data harvest by establishing the BioHub and the Hub for Pandemic and Epidemic Intelligence.

There is a concerted attempt to accommodate the EU proposal through a subgroup proposal by marginalizing a comprehensive proposal from the Africa Group and Group of Equity that treats access and benefit sharing with equal importance.

Hesitation on financing commitments

The lack of adequate finance is another major inequity existing in the context of the IHR. It is important to address this glaring gap through the establishment of a financial mechanism including a fund. However, the negotiations in the WGIHR on financing have not made much progress.

Article 20 of the draft text of the pandemic instrument proposes the establishment of a financial mechanism along with a pooled fund. The pooled fund is "to provide targeted, supplementary financing to

support, strengthen and expand capacities for pandemic prevention, preparedness and response, and as necessary for day zero surge response, in Cooperating Parties when other resources are not accessible through existing financing entities".

Thus, the pooled fund is envisaged as a last resort to obtain financial assistance for the implementation of the pandemic instrument including prevention, preparedness, response and recovery. The financial mechanism is envisaged to "increase the effectiveness and efficiency of existing and future financial mechanisms, within or outside WHO, including by providing additional financial resources".

However, it is obvious that existing and future financial mechanisms are not under any legal obligations to follow the directions of the financial mechanism under the pandemic instrument. For the moment, there is no proposed obligation or even a nudge to developed countries to provide financial resources for the implementation of the IHR or in the pandemic instrument. This will contribute to existing inequities in availing finance for pandemic preparedness and response.

A motivation for data extraction?

While the provisions on equity are proposed as "best endeavour", the language in the negotiating text contains concrete obligations on surveillance and data transfer. The proposed obligations under Article 4.3 extend surveillance obligations not only to public health but also to zoonotic diseases. Further, parties are to commit to taking measures to prevent zoonotic spillovers.

The negotiating text also proposes obligations on Member States to comply with various international guidelines including guidelines on health and antimicrobial resistance. Some of these guidelines require an exchange of data, such as the One Health Joint Plan of Action developed by WHO, FAO, OIE and UNEP. Similarly, the inclusion of antimicrobial resistance would expand the scope of the instrument and make international guidelines like the Global Action Plan on Antimicrobial Resistance legally binding, which would then also impose surveillance obligations. Once surveillance is in place, data transfer is a logical conclusion.

Legitimizing inequity?

The IHR and INB processes bear the danger of limiting the legal obligations on equity to "best endeavours" and at the same time expanding the obligations on surveillance and data transfer. A "managed" process which prevented text-based negotiations since the publication of the Zero Draft in February 2023 is now shifting gears. Member States are now reminded that they must conclude the negotiations prior to the World Health Assembly in May 2024. This means they will be under pressure to end the negotiations within three months (March–May). There is already speculation that during the 9th INB meeting, where text-based negotiations are expected to begin, both the Bureau and the Secretariat would likely actively discourage Member States from proposing textual suggestions to the negotiating text. This unrealistic timeline and approach would be used to reinforce and legitimize inequity through the IHR amendments and a new pandemic instrument.

TWN Info Service on Health Issues (Mar24/05)
11 March 2024

Developed countries push to dilute WGIHR Bureau's half-hearted equity text

Kochi/New Delhi, 11 March (Nithin Ramakrishnan and K.M. Gopakumar) – Developed countries are pushing to dilute proposed equity-related text to amend the International Health Regulations (IHR) 2005.

The proposed new provisions, Article 13A and Article 44A, were tabled by the Bureau of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR) at the resumed session of the 7th meeting of the WGIHR. This took place in hybrid mode on 8 March.

Article 13A deals with equitable access to health products, technologies and know-how. Article 44A deals with the financing of

IHR implementation. The resumed WGIHR7 was organized based on a WGIHR decision of 9 February.

The original proposals for these new provisions came primarily from the Africa Group and Bangladesh, with the aim to address the equity gaps in health emergency preparedness and response. Egypt also co-sponsored these proposals.

WGIHR6 entrusted the Bureau to develop the text based on the discussions on these text proposals that took place during various WGIHR meetings. As reported earlier, the Secretariat had advised the Bureau to delete such proposals. Sensing that this would create problems, the Bureau decided not to circulate the recommendation of the Secretariat. Since WGIHR7 could not discuss the Bureau's proposed text, it was decided that the Bureau would prepare a new text and the WGIHR would hold a one-day resumed meeting to discuss the text concerned.

The newly circulated Bureau's text, however, ended up as a half-hearted proposal with several missing equity elements. It also contains loopholes which undermine the delivery of equity during health emergencies.

Nevertheless, during the resumed WGIHR7, developed countries still tried to dilute the Bureau's text proposal further, as well as push the negotiations to the Intergovernmental Negotiating Body (INB) tasked to develop a new pandemic instrument. They continued to disregard the WGIHR's mandate arising from the WHO Executive Board Decision 150(3) to tackle equity gaps in the IHR 2005. The United States, the European Union, Norway and other developed countries attempted to dilute the entire text and find excuses to shift the provisions to the INB.

Developing countries have stated clearly that the INB and WGIHR processes are two separate processes addressing different subject matters: the INB focuses on pandemic prevention, preparedness and response, while the IHR 2005 deal with all types of public health emergencies, pandemic or non-pandemic in nature.

Additionally, with the pandemic instrument being developed by the INB, there are other concerns like ambiguity over its entry into force and the States which will eventually become parties to the

instrument. (Countries like Switzerland and the United States have still not ratified the Framework Convention on Tobacco Control, the only other legal instrument adopted under Article 21 of the WHO Constitution.) Therefore, it is important to ensure equity through both instruments.

Bureau's text on Article 13A: content, gaps and discussion

The Bureau's text on Article 13A contains three paragraphs, with two containing several sub-paragraphs.

The first paragraph states that WHO shall support States Parties and coordinate international public health response efforts by striving to ensure equitable access to health products, technologies and know-how.

The second paragraph speaks about certain measures that will be taken up by the WHO Director-General once a public health emergency of international concern (PHEIC) is announced. These include assessing availability and affordability of the health products and technologies required to respond to the PHEIC; publishing a list of the health products along with such assessment; activating or establishing an allocation mechanism; supporting States Parties to further support scaling up and diversification of production; sharing regulatory dossiers with national regulatory authorities upon request; and supporting States Parties to strengthen local production, and achieve quality assurance and regulatory approvals etc.

The third paragraph outlines the obligations of States Parties to collaborate and support WHO-coordinated public health responses. However, the actions set out in the sub-paragraphs are vague and cannot facilitate meaningful equitable access. They require States Parties to support WHO's actions to the extent possible, engage and encourage non-State actors to contribute, and publish terms of government-funded research agreements, including pricing policies, to support equitable access.

Moreover, the third paragraph is qualified with best-endeavour-type clauses such as "to the extent possible" and "in accordance

with national law". Consequently, there are no legally binding obligations in any of the provisions under paragraph 3, making the delivery of equity uncertain.

Furthermore, there are several missing links in the Bureau's text, making the proposal for Article 13A a wool-gathering exercise. For example, it is unclear how WHO will source health products for distribution through the allocation mechanism. Similarly, while regulatory dossiers are proposed to be shared with national regulatory authorities, it is not mentioned that the dossiers will be shared with manufacturers for diversification of production during a PHEIC. It is also not clear how WHO will obtain possession of these dossiers in the first place. Interestingly enough, States Parties are requested to publish terms of government-funded research, but they are not required to assign rights over the outcomes of such resources to other manufacturers to diversify production.

Several other developing country proposals are not included in the Bureau's proposed text. These include the establishment of a database for product specifications and method of processing of the required health products, and the establishment of a repository for biological starting materials such as cell lines that are required for development and production of health products. Most importantly, an obligation to share a portion of health products during PHEICs is not explicitly mentioned in Article 13A.

A developing country delegate told the Third World Network that the discussions on loopholes in the Bureau's text resulted in the insertion of textual suggestions by developing countries within brackets for discussion at the next WGIHR session.

While developing countries like Bangladesh, Malaysia, Iran, Indonesia and Nigeria attempted to improve the Bureau's text, developed countries like Norway sought to water down the equity provisions. The Africa Group and several other developing countries, including Pakistan, Brazil, Colombia, Syria and Ethiopia, voiced out against further dilution.

Norway argued that WHO has no capacity to ensure equitable access to health products and that there is no allocation mechanism

within the IHR 2005. It claimed a range of stakeholders need to act in order to address the issue of equity and wanted to shift the discussion on health technologies and equitable access to the INB.

Though the European Union joined Norway to express concerns about the abilities of WHO to ensure equitable access or to activate allocation mechanisms, it engaged with the text and proposed a few changes and deletions.

Pakistan challenged this logic by questioning developed countries as to why they believe WHO can perform many actions related to pandemics in the ongoing discussions on a pandemic instrument but doubt its ability to take similar actions for PHEICs.

Nigeria also proposed that the Director-General shall at all times cooperate with regional production centres to ensure readiness in scaling up and diversifying production.

The United States said the proposals duplicate the proposals under the INB and reserved its position on the entire text.

Monaco repeated its argument that the WGIHR has no mandate to discuss these provisions, pointing to the scope of the IHR 2005. However, it neglected its own practice of reporting on capacities for addressing access to health products under the IHR 2005 for several years. For instance, Monaco has consistently marked a 100% score in its capacity for Emergency Logistics and Supply Chain Management Systems and Mechanism under the State Party Self-Assessment and Reporting Tool. The explanation of the system and mechanism under the tool explicitly covers emergency kits, protective equipment, diagnostics, medical consumables, therapeutics, drugs and biomedical equipment, beds and stockpiles.

Germany, on the other hand, acknowledged equity is important, but at the same time proposed to delete diversification of production from the proposal.

Mexico, Botswana, China and Malaysia however explained about WHO's current practices and existing mechanisms such as vaccine standardization, international pharmacopoeia, local production and assistance units, stressing that WHO is well positioned to support Member States in the matters being discussed under Article 13A. Some of these developing countries pointed out that codifica-

tion and legal backing are needed to infuse legitimacy and accountability to many of these mechanisms.

Bureau's text on Article 44A: content, gaps and discussion

The Bureau's text on Article 44A adopted an approach significantly different from the proposed text by the Africa Group but incorporated several ideas currently under discussion at the INB.

A few developing countries have been pointing out that the right place for a financial mechanism serving capacity building is the IHR 2005 and that the new pandemic instrument can refer to the mechanism under the IHR 2005 to develop additional categories to serve the specialized purposes of pandemic prevention, preparedness and response.

Although the Bureau's text proposal reflected the linkages between financing in the IHR 2005 and the new pandemic instrument, it currently refers to the proposed coordinating financial mechanism within the draft negotiating text of the pandemic instrument, i.e., it is referring to a currently non-existing instrument in an existing legal instrument, making financial assistance for IHR implementation conditional upon the entry into force of the pandemic instrument.

Further, the Bureau's text converted the Africa Group proposal for a dedicated financial mechanism under the IHR 2005 into a supplementary fund that might be used when all other existing sources, both within and outside WHO, including the coordinating financial mechanism under the INB, are exhausted. Developing countries said this is unacceptable, and they argued particularly that the coordinating financial mechanism under the INB falls short in many respects.

The Bureau's text on Article 44A has six paragraphs. The first paragraph mentions an obligation to work together to sustainably finance the full implementation of the IHR 2005.

The second paragraph refers to the need for prioritizing domestic finance, while the third paragraph speaks about the obligation of States Parties to collaborate to mobilize finance to support developing countries, to encourage existing financial mechanisms to be responsive to the needs and priorities of developing countries, and to

support the coordinating financial mechanism being developed under the proposed pandemic instrument.

The fourth paragraph mandates the WHO Director-General to support States Parties in implementing the obligations pursuant to paragraph 3, and to report the outcomes to the World Health Assembly.

The fifth paragraph calls for an IHR implementation fund which will provide supplementary finance to address the gaps identified in the financing of IHR implementation, and the sixth paragraph discusses sources of financial resources and governance of the fund entrusted with the World Health Assembly.

The fifth paragraph reads thus: *"States Parties also agree to the establishment of, within 24 months of the adoption of this provision, a dedicated IHR Implementation Fund ('the Fund') within the WHO, governed by and accountable to States Parties through the World Health Assembly, to provide targeted, supplementary financing in particular to developing countries, as necessary, to build, strengthen and maintain the capacities required under these Regulations. The purpose of the Fund is to address identified gaps in financing of IHR implementation in particular in developing countries that are not met by domestic funding, existing and new bilateral, sub-regional, regional and multilateral funding mechanisms, or the Coordinating Financial Mechanism established under the WHO Pandemic Agreement."*

Bangladesh, calling for non-debt-generative grants and funds, argued that the above fund should not be supplementary, but rather should serve the purposes of full IHR implementation and address gaps in IHR implementation that are self-identified by recipient or applicant countries.

Nigeria attempted to elevate the standard of financing obligations from "strengthening" sustainable financing to "ensuring" sustainable financing.

Malaysia referred to the five-year financial strategy being developed under the proposed pandemic instrument, and recommended incorporating a similar provision in Article 44A, should the pandemic instrument fail to enter into force within a stipulated time. Ac-

cording to the delegation, such a strategy helps in ensuring that the donor countries align with the broad strategy developed by the WHO Member States while providing financial resources both within and outside WHO.

Countries like Norway, Israel, Australia, the UK and Monaco wanted a joint approach in financing the INB and the IHR.

The Africa Group at the same time is keen to see a dualistic approach to financing both instruments, according to sources.

The WGIHR concluded its resumed 7th meeting and adopted the meeting report. IHR States Parties are requested to provide further written inputs to the Bureau on or before 15 March.

Part 10 – 8th meeting of the WGIHR

TWN Info Service on Health Issues (Apr24/05)
22 April 2024

WGIHR Bureau's text recognizes equity without effective implementation means

Geneva, 22 April (K.M. Gopakumar) – A consolidated text on proposals to amend the International Health Regulations (IHR) 2005 recognizes the promotion of equity and solidarity as a principle of IHR implementation but undermines it with the absence of effective means of implementation.

The text was produced by the Bureau of the Working Group on Amendments to the International Health Regulations 2005 (WGIHR) and is hereby referred to as "the Bureau's text".

The Bureau's proposals undermine equity by placing the responsibility of financial investment on States Parties without considering the existing development divide among WHO Member States.

The Bureau's text is to be discussed during the 8th meeting of the WGIHR, which will take place on 22–26 April at the WHO headquarters in Geneva in hybrid mode.

Though the Co-Chairs and Bureau have previously prepared text of specific articles, this is the first time the Bureau developed a consolidated text. This is a practice imported from the Bureau of the Intergovernmental Negotiating Body (INB) on a pandemic instrument, which is currently under criticism for undermining the textual proposals of Member States, especially developing countries.

The consolidated text removes all the textual proposals of Member States and proposes amendments to around 25 articles including the article dealing with definitions as well as annexes. The substantial amendments are confined only to a few articles and Annex 1.

The Bureau proposes to amend paragraph 1 of Article 3 as follows: *"The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons, and shall promote equity and solidarity among States Parties."*

An accompanying document on the rationale of the Bureau's proposal explains the inclusion of equity in paragraph 1 by citing the Technical Recommendation of the Review Committee on Amendments to the International Health Regulations (2005): "The Committee also notes that, as referred to in the proposed amendment to paragraph 1 and new paragraph 5, inclusivity, coherence and particularly equity and solidarity are important principles underpinning the Regulations, and also reflect important lessons from the COVID-19 pandemic."

One of the important shortcomings of the IHR 2005 is the absence of equity, reducing it to an instrument to provide information on disease outbreaks with potential to become a public health emergency of international concern (PHEIC) without any legal guarantee of obtaining assistance for effective response. Though there is recognition of the need for assistance for IHR States Parties, especially developing countries, there are no provisions to translate this into reality, particularly into assistance to facilitate access to health products required for PHEIC preparation and prevention. Therefore, the WHO Executive Board decision EB150(3), which set the scope of the IHR amendments, provided a clear mandate to address equity.

EB150(3) states: *"Such amendments should be limited in scope and address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005) and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner."*

The Bureau however dropped the principle of common but differentiated responsibilities (CBDR) by citing the differing views on its inclusion among Member States.

Equitable access

The Bureau's text recognizes the need for equitable access for effective PHEIC response. In this regard, the text proposes an amendment to the title of Article 13 on public health response, by adding the phrase "including access to health products". The proposed title now reads: "Public health response, including access to health products".

Further, the text proposes three more paragraphs to Article 13, viz., 7, 8 and 9. The rationale for the inclusion of the three new paragraphs is to merge some of the ideas proposed as Article 13A by Bangladesh and the Africa Group. The rationale document of the Bureau states: "The proposed new Paragraphs intend to operationalize the principles of equity and solidarity that the Bureau proposes to include in Article 2. They focus on the critical role of health products, and, where applicable, technology transfer, in response efforts."

The proposed paragraph 7 of Article 13 obligates WHO to support and coordinate response activities during PHEICs and pandemic emergencies. Among the supporting activities is facilitating equitable access through equitable allocation and distribution of health products, including through technology transfer. It reads:

"WHO shall support States Parties and coordinate response activities during public health emergencies of international concern, including pandemic emergencies. To facilitate equitable access to health products, this support shall include, as necessary, coordinating with mechanisms and networks that facilitate equitable allocation and distribution of health products, including through technology transfer on mutually agreed terms. The aforesaid mechanisms and networks may include, but are not limited to, regional ones and those established under relevant international agreements."

Paragraph 8 proposes to obligate the Director-General of WHO to take the following measures after the determination of a PHEIC to facilitate equitable access:

- To conduct and periodically review and update an assessment of the availability and affordability of health products need-

ed for the public health response and consider the assessment while making recommendations under Articles 15, 17, 18 and 49;

- To make use of existing or new WHO-coordinated allocation mechanism(s) to assist States Parties to access relevant health products based on public health risks and needs;
- To support efforts by States Parties to scale up and diversify, as appropriate, the production of relevant health products;
- To facilitate the sharing of dossiers with the consent of manufacturers for the purpose of facilitating regulatory authorization by the national regulatory authority;
- To support States Parties to strengthen local production including technology transfer on mutually agreed terms.

The Bureau's rationale behind paragraph 8 is as follows: "Through the proposed New Paragraph 8, the Bureau intends to introduce more specific obligations than those detailed in the proposed New Paragraph 7, for the WHO Secretariat to ensure equitable access." Further, it cites various World Health Assembly resolutions and ongoing WHO programmes to show the existing mandate and rationale behind its proposals under paragraph 8.

Paragraph 9 proposes obligations on States Parties to cooperate among themselves to the fullest extent possible as per their national law and available resources, and to collaborate with WHO and other States Parties to support WHO-coordinated response activities.

These include:

- To support WHO in implementing actions outlined in paragraph 8;
- To engage and encourage non-State actors to contribute towards equitable access to health products needed to respond to a public health emergency of international concern;
- To maintain transparency by publishing relevant terms of government-funded research agreements for PHEIC health products such as pricing policies regarding these products and technologies, to support equitable access.

According to the Bureau: "Through the proposed New Paragraph 9, the Bureau intends to outline the nature of the collaboration that

States Parties may undertake under these Regulations to contribute to response efforts, and to equitable access to health products under those circumstances."

Further, the Bureau's text proposes the inclusion of "availability of, and accessibility to, relevant health products" under Article 17 as one of the criteria for making recommendations.

It also proposes an obligation on States Parties to take all practical steps while taking additional measures under Article 43 to facilitate access to health products to other countries. This reads:

"When implementing additional health measures referred to in paragraph 1 of this Article, States Parties shall take all practicable measures to facilitate other States Parties in accessing health products relevant for responding to a public health risk or a public health emergency of international concern."

Another relevant proposal on equitable access in the Bureau's text relates to Article 44 dealing with collaboration and alliance. The Bureau proposes to include the facilitation of access to health products, including through WHO-coordinated mechanisms, as an area of collaboration and assistance. Similarly, the Bureau's text also proposes "facilitating equitable access to health products through WHO-coordinated mechanisms" as an area of collaboration between WHO and Member States.

However, these proposals, especially those under Article 13, lack effective means of implementation. They do not provide any direction or indication on how the WHO Secretariat and Director-General are to facilitate equitable access.

For instance, the Bureau's proposal on Article 13.7 states: "… To facilitate equitable access to health products, this support shall include, as necessary, coordinating with mechanisms and networks that facilitate equitable allocation and distribution of health products, including through technology transfer on mutually agreed terms." Similarly, the proposed Article 13.8(e) states: "support States Parties, upon their request, to strengthen local production; achieve quality assurance through regulatory approval of locally manufactured products; and facilitate research and development and technology transfer on mutually agreed terms".

However, there is no indication of the means to achieve these. In the absence of such direction, it gives enough room for WHO and the Director-General to bypass accountability on this important issue.

There is also a lack of clarity on the trigger for activities mentioned under the proposed Article 13.8. Following the chapeau of paragraph 8 that reads "After the determination of a public health emergency of international concern, pursuant to Article 12 of these Regulations, the Director-General shall...", there is a list of four actions by the Director-General. This implies that the Director-General has to take those measures – which include supporting States Parties, upon their request, to strengthen local production – only after the determination of a PHEIC. That would be too late to act. Support for local production and equitable access should be an ongoing mandate and its trigger should not be limited to the determination of a PHEIC.

While framing these proposals, the Bureau has ignored the specific proposals made jointly by the Africa Group and Bangladesh to facilitate technology transfer. For instance, Bangladesh made the following proposal:

"WHO shall develop and maintain a database containing details of the ingredients, components, design, know-how, manufacturing process, or any other information required to facilitate manufacturing of health products required for responding to the potential public health emergencies of international concern. Within two years of the entry into force of this provision, WHO shall develop this database for all PHEICs declared so far, including for the diseases identified in the IHR 1969."

Similarly, the Africa Group proposed to facilitate local production of health products required for PHEICs, as follows:

"WHO shall take measures to ensure availability and accessibility through the local production of required health products including:

a) develop and publish a list of required health products,

b) develop and publish specifications for the production of required health products,

c) develop appropriate regulatory guidelines for the rapid approval of health products of quality, including development of immunogenicity co-relative protection (ICP) for vaccines,

d) establish a database of raw materials and their potential suppliers,

e) establish a repository for cell lines to accelerate the production and regulatory of similar biotherapeutics products and vaccines,

f) review and regularly update WHO Listed Authorities so as to facilitate appropriate regulatory approvals."

Further, the Bureau's proposals on equitable access under Articles 13.8 and 9 as well as in Article 44 are marred with multiple qualifications. This would seriously undermine the effective implementation of equity.

Moreover, a proposal of the Bureau to add a footnote to Annex 6 (on vaccination, prophylaxis and related certificates) effectively neutralizes equitable access especially through local production. Paragraph 3 of Annex 6 states: "Certificates under this Annex are valid only if the vaccine or prophylaxis used has been approved by WHO." The proposed footnote to this paragraph now states: "Approved by WHO refers to health products evaluated and listed by WHO under the WHO Prequalification (PQ) procedures, applicable to medicines, vaccines, in-vitro diagnostics, vector control products, immunisation devices; and inspection services; and Emergence Use Listing (EUL) procedures, applicable to medicines, vaccines, in-vitro diagnostics." A similar footnote is also proposed to the model international vaccination and prophylaxis certificate, which is part of Annex 6. This means that vaccination, prophylaxis or related certificates under the IHR will be recognized for international travel and related purposes only when the product used is prequalified by WHO.

This restricts the number of products which can be used for diagnosis, vaccination and treatment. The insistence on WHO prequalified products would result in concentration and monopoly. Further, the compliance cost of WHO prequalification is high and only a few manufacturers from developing countries can meet the WHO prequalification standards. The WHO prequalification process also

systematically discriminates against regulatory approval by developing country authorities. As per the current practice, it is almost an automatic approval for products approved by WHO listed authorities formerly known as stringent regulatory authorities. If an independent WHO evaluation is required for products approved by regulatory authorities, this would require time and resources.

A recent report of the US International Trade Commission (ITC) observes that prequalification is expensive and delays access. It states: "These procurement agencies, however, rely on WHO prequalification (or emergency use listing) and guidance issuance for all tests and treatments, which were reported to have caused delays. In the case of some therapeutics, such as remdesivir, WHO recommendation and prequalification came a full two years after US authorization and the first VLs [voluntary licences] were signed. This means that although treatments were available, many countries were not immediately able to access them. WHO prequalification, which is also required for certain MPP [Medicines Patent Pool] sublicensing agreements, requires significant effort by manufacturers in order to complete the application requirements and address data standards, which may be challenging for some manufacturers. It can also be costly. As noted in chapter 2, a one-time application fee of $25,000 is required in addition to a $20,000 annual fee for a full product assessment. Industry representatives have noted that these fees may be too expensive for smaller manufacturers in many LMICs [low- and middle-income countries]."

Similarly, the External Evaluation of WHO's Access to COVID-19 Tools (ACT) Accelerator or ACT-A observes: "Access to certain diagnostic types was delayed due to late WHO clearance (especially for self-tests). Diagnostics are usually less complex to develop than drugs and vaccines. They are very important throughout the pandemic, especially at the beginning of pandemics when other MCMs [medical countermeasures] are not available."

The Bureau provided the following comment for the footnote without examining the implications of its suggestion: "The Bureau notes the diverse positions of Member States with respect to the term 'approval' ('subject to its approval' in Paragraph 1, 'approved by

WHO' in Paragraph 3 and the first paragraph following the table in the Model ICVP) and its possible replacement with the terms 'pre-qualification' and 'emergency use listing'."

Finance

The Bureau's text on finance for the implementation of the IHR 2005 follows the proposal of the INB Bureau on the pandemic instrument and drops the Africa Group proposal for the creation of a dedicated fund. Instead, it proposes to use the fund to be created under the pandemic instrument. The proposal states: *"... secure the financial resources necessary to support the implementation of these Regulations through coordination and/or funding mechanisms that may be established in future International Agreement(s) related to pandemic prevention, preparedness and response."* However, the latest INB Bureau text on the pandemic instrument does not contain any proposal to create a fund.

Further, the Bureau proposes to explore the idea of the creation of funds at a future date. The proposal in this regard states: *"... review the effectiveness of the provisions in this paragraph two years from their entry into force, and address identified gaps in financing IHR implementation that are not being met by current or future domestic funding, existing and new bilateral, sub-regional, regional and multilateral funding mechanisms, including, if necessary, through the establishment of a dedicated financing mechanism to provide targeted, supplementary financing, in particular to developing countries, to build, strengthen and maintain the capacities required under these Regulations."*

Instead of offering a solution to the lack of predictable and sustainable financial resources for implementation of the IHR, the Bureau's text shifts the burden to States Parties to make the required investment for the implementation, especially to achieve core capacities mentioned under Annex 1. It proposes the creation of national IHR authorities under Article 4 and puts the responsibility of implementation solely on States Parties without offering any assistance.

A new paragraph 2 *bis* is proposed to Article 4 which states: *"States Parties shall take measures to implement paragraphs 1, 1 bis, and 2 of this Article, including, as appropriate, by allocating human and financial resources, as well as by adjusting their domestic legislative and administrative arrangements."*

Similarly, a proposed new paragraph 1 *bis* of Article 13 reads: *"Each State Party shall, within the means and resources at its disposal, provide sustainable domestic funding to build, strengthen and maintain the core capacities required under these Regulations."* This creates a burden of proof on a country seeking assistance for the implementation of core capacities under the IHR to prove that it has already exhausted domestic funding "within the means and resources at its disposal". This proposal would institutionalize the development-blind approach to IHR implementation and constitute a departure from the Bureau's proposal for Article 3, i.e., that the implementation of the IHR 2005 shall promote equity and solidarity among States Parties.

The rationale provided by the Bureau is silent on the implications of this proposal. It only states that it simply shifted a proposal that obtained wide support during the discussions on Article 44. The rationale states: "This paragraph is an updated Bureau proposal based on Paragraph 2 of the Bureau's proposal for Article 44A, related to domestic financing for IHR implementation, which received good support during the discussion at WGIHR7. The Bureau proposes to move this paragraph to Article 13 alongside other domestic obligations, as the Bureau considers this is a more appropriate place for such a provision, rather than as part of Article 44, which relates to collaboration between States Parties."

However, the fact is that there was no amendment proposal to Article 44 submitted by any Member State proposing such language.

Further, this proposal is to promote the new co-funding model, an approach to legitimize the abdication of the responsibility of developed countries to provide financial resources to address global concerns such as health emergency preparedness and preparation.

Access and benefit sharing (ABS)

The Bureau's text fully ignores the sharing proposal made by the Africa Group. The Group had proposed the insertion of the following paragraph to Article 6 of the IHR 2005: *"No sharing of genetic sequence data or information shall be required under these Regulations. The sharing of genetic sequence data or information shall only be considered after an effective and transparent access and benefit sharing mechanism with standard material transfer agreements governing access to and use of biological material including genetic sequence data or information relating to such materials as well as fair and equitable sharing of benefits arising from their utilization is agreed to by WHO Member States, is operational and effective in delivering fair and equitable benefit sharing."*

The absence of a fair and equitable benefit-sharing mechanism under the IHR 2005 undermines equity by giving a free-riding possibility to pharmaceutical companies, especially those based in developed countries, to make use of pathogen samples or their sequence information without any corresponding obligation to share the benefits emanating from their research and development. Though there was discussion on applying the pandemic instrument's Pathogen Access and Benefit Sharing (PABS) system to include benefit sharing during PHEICs, the latest INB Bureau text limits the benefit sharing only to the duration of a pandemic outbreak. This means there would not be any obligation to share benefits by contributing health products during a PHEIC. This goes against the EB150(3) mandate of addressing equity.

It is clear that though the WGIHR Bureau recognizes equity as a principle under Article 3 of the IHR 2005, its text requires further amendment and clarifications to operationalize equity into concrete deliverables.

TWN Info Service on Health Issues (Apr24/07)
24 April 2024

Developed countries push for dilution of WGIHR Bureau's text proposal on equity

Geneva, 24 April (TWN) – Developed countries are pushing to dilute the proposal on equity from the Bureau of the Working Group on Amendments to the International Health Regulations 2005 (WGHIR).

The Bureau's proposal is itself already weak as it lacks effective implementation means to address the lack of equity in the IHR, as reflected in its silence on access to health products and the lack of a financial vehicle to assist the implementation.

The 8th meeting of the WGIHR is taking place from 22 to 26 April at the WHO headquarters in hybrid mode.

The first day of WGIHR8 discussed the Bureau's proposals on Articles 13 and 44 immediately after the opening plenary. There were no statements from the regional groups or individual Member States.

Article 13: Equitable access

The Bureau proposed three new specific paragraphs focusing on equitable access, viz., paragraphs 7, 8 and 9.

Paragraph 7 states: "WHO shall support States Parties and coordinate response activities during public health emergencies of international concern, including pandemic emergencies. To facilitate equitable access to health products, this support shall include, as necessary, coordinating with mechanisms and networks that facilitate equitable allocation and distribution of health products, including through technology transfer on mutually agreed terms. The aforesaid mechanisms and networks may include, but are not limited to, regional ones and those established under relevant international agreements."

While the majority of Member States support the retention of the text, developed countries proposed textual suggestion aiming to dilute the Bureau's proposal. The group of developing countries include Ethiopia, Fiji, Malaysia, the Africa Group, Brazil, Mexico, the Dominican Republic, India, Saudi Arabia, Brunei, Qatar and the United Arab Emirates, among others.

Australia and the United Kingdom proposed to add the word "relevant" before "health products", which will limit the scope of health products. It will impose the burden of proof on WHO to show the relevance of the product for response to a public health emergency of international concern (PHEIC).

Another suggestion from Australia, Israel, Japan, the European Union, the UK and the US is to insert the word "voluntary" before "technology transfer". The Bureau's proposal to provide a mandate to WHO on technology transfer under paragraph 7 is already qualified with the words "mutually agreed terms".

On paragraph 8(a), Japan, Monaco and New Zealand put a reservation on the term "affordability". Under the Bureau's text, the WHO Director-General is to carry out an "assessment of the availability and affordability of health products needed for the public health response". Deletion of the term "affordability" will limit the scope of assessment only to availability in the market. In the absence of an assessment on affordability, it would be extremely difficult to initiate steps to facilitate equitable access.

According to the proposed paragraph 8(b), the Director-General is to "make use of existing WHO-coordinated allocation mechanism(s) and networks, or facilitate their establishment as needed, to assist States Parties to access relevant health products based on public health risks and needs".

The US, the EU, Canada and Monaco proposed to do away with the mandate to WHO to make use of the existing coordination mechanism by proposing the deletion of the following words from paragraph 8(b): "make use of existing WHO-coordinated". The US and Monaco proposed a substitution of those words with "coordinate with existing distribution". This effectively means the Director-General is left with only a coordination role and cannot really use WHO's

existing coordination mechanism like the International Coordinating Group (ICG). According to the WHO webpage on the ICG, its core mandate is "to make available and ensure equitable access to licensed vaccines for cholera, meningitis, yellow fever, and Ebola virus disease during outbreaks". The proposal from the US will thus weaken an existing mechanism.

Further, Japan proposed the deletion of the words "facilitate their establishment as needed" from paragraph 8(b).

The proposed paragraph 8(e) mandates the Director-General to take measures to "support States Parties, upon their request, to strengthen local production; achieve quality assurance through regulatory approval of locally manufactured products; and facilitate research and development and technology transfer on mutually agreed terms".

The EU proposed to insert the term "voluntary" before "technology transfer" to further limit the mandate. The insertion would limit WHO's freedom to carry out certain ongoing activities which have the potential to contribute to technology transfer, such as the International Pharmacopeia, WHO Reference Cell Banks, vaccine standardization etc.

Bangladesh, Brazil, China, Indonesia and Malaysia called for the retention of the Bureau's text.

Paragraph 9 deals with the obligation of States Parties to support WHO's efforts to facilitate equitable access under paragraphs 7 and 8. The chapeau of paragraph 9 reads: "Pursuant to paragraph 5 of this Article, and paragraph 1 of Article 44 of these Regulations, States Parties shall, to the fullest extent possible, according to their national law and available resources, and upon request of other States Parties or WHO, undertake to collaborate with each other and to support WHO-coordinated response activities, including through …".

Developed countries added textual suggestions to qualify the chapeau further, making the obligation ineffective. For instance, the US proposed deletion of the word "fullest" before "extent". Japan proposed addition of the word "policy" before "law". Australia and Monaco proposed replacing the words "available resources" with "circumstances".

With all these changes, the chapeau may read as follows: "Pursuant to paragraph 5 of this Article, and paragraph 1 of Article 44 of these Regulations, States Parties shall, to the extent possible, according to their national policies and law and circumstances …".

The US proposed changes to the proposed paragraph 9(a), which currently reads: "… supporting WHO in implementing actions outlined in paragraph 8 of this Article". The suggestion from the US is to change it as follows: "supporting the implementation of this Article".

Paragraph 9(b) proposes that States Parties engage with, and encourage, "relevant non-State actors operating in their respective jurisdictions, to contribute towards equitable access to health products needed to respond to a public health emergency of international concern". The US proposed to replace the words "non-State actors" with "stakeholders", and "contribute towards" with "facilitate".

Another target for dilution is paragraph 9(c), which reads: "… publishing relevant terms of government-funded research agreements for health products needed to respond to a public health emergency of international concern, as well as information, where relevant, on pricing policies regarding these products and technologies, in order to support equitable access".

The US and Japan proposed to add the word "considering" before "publishing". This would make the whole paragraph a best-endeavour provision. Nevertheless, the US and Japan suggested further qualification by suggesting addition of the words "as appropriate" after "publishing". Both countries also proposed a few more suggestions. Under their suggestions, the paragraph would read as follows: "… considering publishing, as appropriate, relevant terms that promote timely and equitable access in government-funded research and development agreements related to promoting equitable and timely access to health products relevant to respond to a public health emergency of international concern, as well as where relevant, on affordable pricing policies regarding these products in order to support equitable access, subject to applicable law".

Nigeria and Bangladesh proposed a new paragraph 9(d) to address the challenges posed to equitable access by intellectual prop-

erty. It reads: "… providing exemptions in their intellectual property laws and related laws and regulations, to the exclusive rights of intellectual property holders to facilitate the manufacturing, export and import of the required health products, including their materials and components".

Interestingly, Japan, Switzerland and Russia called for the deletion of the entire paragraph 9. Australia, the Africa Group, Egypt, Brazil, Uruguay, Fiji, Malaysia, Mexico, Colombia and the UAE called for the retention of the entire paragraph.

The Bureau's proposal contains a clear mandate to WHO to assist States Parties in the facilitation of equitable access. In Article 44 also, the Bureau suggested an additional sub-paragraph (e): "… facilitating equitable access to health products through WHO-coordinated mechanisms". However, the US proposed deletion of the reference to WHO-coordinated mechanisms in favour of "known mechanisms and networks for allocation and distribution".

Article 44.2 *bis*: Financial assistance

The Bureau's text proposed a change to the title of Article 44 from "collaboration and assistance" to "collaboration and assistance including financial assistance". Japan, Switzerland, the US, the Republic of Korea and Israel proposed the deletion of the proposed change.

Further, on the proposed new paragraph 2 *bis*(a) of Article 44, the US has proposed the deletion of the words "in particular developing countries". This would undermine the very purpose of financial assistance for IHR implementation. Similarly, in sub-paragraph 2 *bis*(b), the US proposed the deletion of "developing countries", when it was originally proposed as follows: "Encourage governance and operating models of existing financing entities and funding mechanisms to be responsive to the needs and national priorities, related to these Regulations, of developing countries; …".

Paragraph 2 *bis*(c) proposes the possibility of linking the financial assistance with funds to be established under the pandemic instrument. It reads: "… secure the financial resources necessary to

support the implementation of these Regulations through coordination and/or funding mechanisms that may be established in future International Agreement(s) related to pandemic prevention, preparedness and response".

The EU proposed mainly two changes in this sub-paragraph to oppose the establishment of any dedicated fund for the implementation of the IHR and the pandemic instrument. Firstly, it proposed the deletion of the word "funding" and thus opposed reference to creating a funding mechanism for the implementation of the IHR. Secondly, it proposed the replacement of the word "established" with "defined".

Further, Canada, Japan, Switzerland, the EU, the US, the UK, Australia, the Republic of Korea and Israel proposed substantial deletions in paragraph 2 *bis*(d), which proposes a process to establish a dedicated fund within the IHR framework for its implementation. It reads: "Review the effectiveness of the provisions in this paragraph two years from their entry into force, and address identified gaps in financing IHR implementation that are not being met by current or future domestic funding, existing and new bilateral, sub-regional, regional and multilateral funding mechanisms, including, if necessary, through the establishment of a dedicated financing mechanism to provide targeted, supplementary financing, in particular to developing countries, to build, strengthen and maintain the capacities required under these Regulations".

These countries sought to retain only the review mandate in paragraph 2 *bis*(d). Developing countries, on the other hand, proposed the establishment "of a fund under the WHO to provide financing to support, strengthen and expand IHR core capacities as well as capacities needed for preventing, and responding to health emergencies, particularly in developing countries".

According to a developing country delegate, "It's surprising that developed countries speak about compliance and international review of core capacities. But they don't want to commit to any obligation to provide financial assistance or technology transfer. At first, they wanted us to go to external financial agencies and were telling us they will work with external agencies to look into our priorities,

but now they don't even want to commit that they will encourage external agencies to do so."

A communication from the Bureau to Member States after the conclusion of the first day of the WGIHR8 discussions stated that the Bureau would review the feedback and update the text on Articles 13 and 44 by 25 April. This unilateral revision of the negotiating text by the Bureau would be problematic because it may lead to further dilution of the equity provisions.

TWN Info Service on Health Issues (May24/10)
16 May 2024

Switzerland rejects proposals for equity in International Health Regulations

Geneva, 16 May (TWN) – Switzerland has rejected outright equity-related amendment proposals in the International Health Regulations 2005.

In its written submission to the Bureau of the Working Group on Amendments to the International Health Regulations (WGIHR), Switzerland stated: "We would like to request the deletion of all other mentions of health products in the proposed Bureau's text, namely in Articles 15, 16, 17, 18, 43, 44, Annex 1."

The only other country that supports such a blanket deletion of the proposals relating to equitable access to health products is Israel.

The WGIHR has circulated the consolidated text of the IHR amendment proposals, which includes the Bureau's proposals on equitable access to health products and finance. These proposals will be negotiated during the resumed 8th session of the WGIHR, which is taking place on 16–17 May at the WHO headquarters in hybrid mode.

It is learnt that other developed countries such as the European Union, the United States, Japan, Australia and Canada are trying to work through the Bureau's proposals on the issue, even though they are also making efforts to dilute the Bureau's already diluted pro-

posals on equity. The Bureau has made proposals relating to equity without retaining several important amendment proposals placed by developing countries.

Switzerland requests the Bureau to keep two short paragraphs in Article 13 which refer to public health response and equitable access to health products, and remove all other references to health products as proposed by the Bureau. The proposed two paragraphs from Switzerland are as follows:

"WHO shall support States Parties and coordinate response activities during public health emergencies of international concern, including pandemic emergencies. This support may include, as necessary, coordinating with mechanisms and networks that facilitate equitable allocation and distribution of relevant health products."

"Pursuant to paragraph 5 of this Article, and paragraph 1 of Article 44 of these Regulations, States Parties shall undertake to collaborate with, and assist each other, as appropriate, to support WHO-coordinated response activities. This support may include, as appropriate, the facilitation of access to relevant health products, in accordance with applicable international law, including through WHO-coordinated mechanisms."

These two paragraphs are proposed in lieu of the Bureau's proposals for paragraphs 7 to 9, which read as follows:

"7. WHO shall support States Parties and coordinate response activities during public health emergencies of international concern, including pandemic emergencies, after their determination pursuant to Article 12 of these Regulations.

"8. WHO shall facilitate equitable access by States Parties to relevant health products after the determination of a public health emergency of international concern, including a pandemic emergency. To that effect, the Director-General shall:

(a) conduct, and periodically review and update, assessments of the public health needs, as well as of the availability and accessibility, including affordability, of relevant health products for the public health response; publish such assessments; and consider the available assessments while issuing, modifying, extending or terminating

temporary recommendations pursuant to Articles 15, 17, 18, and 49 of these Regulations;

(b) make use of existing WHO-coordinated mechanisms, or facilitate their establishment as needed, and coordinate, as appropriate, with other allocation and distribution mechanisms and networks that facilitate equitable and unobstructed access to relevant health products based on public health needs;

(c) collaborate with relevant stakeholders to support States Parties, upon their request, in scaling up and diversifying, as appropriate and in accordance with relevant international law, the production of relevant health products;

(d) share with a State Party, upon its request, the product dossier related to a specific relevant health product, as provided to WHO by the manufacturer for approval and where the manufacturer has consented, within 30 days of receiving such request, for the purpose of facilitating regulatory evaluation and authorization by the State Party;

(e) support States Parties, upon their request, and, as appropriate, in collaboration with relevant stakeholders pursuant to sub-paragraph (c) of this paragraph, to strengthen local production; achieve quality assurance for the evaluation and regulatory approval of locally manufactured relevant health products; and facilitate the [voluntary] transfer of technology, know-how and expertise [on mutually agreed terms], including for research and development purposes.

"9. Pursuant to paragraph 5 of this Article and paragraph 1 of Article 44 of these Regulations, States Parties shall undertake to collaborate with, and assist each other, to the extent possible, and, upon request of other States Parties or WHO, support WHO-coordinated response activities, including facilitating equitable access to

relevant health products, in accordance with applicable law. To that effect, States Parties shall:

(a) support WHO in implementing actions outlined in this Article;

(b) engage with and encourage relevant stakeholders operating in their respective jurisdictions, to facilitate equitable access to relevant health products for responding to a public health emergency of international concern, including a pandemic emergency;

(c) publish, as appropriate, relevant terms of government-funded research and development agreements for relevant health products related to promoting equitable access to such products during a public health emergency of international concern, including a pandemic emergency."

It must be noted that the Bureau's proposal is in itself a dilution of the Africa Group and Bangladesh proposal for a new Article 13A which specifically deals with access to health products, technologies and know-how. There is no more proposal for Article 13A, which initially had eight key paragraphs.

The proposal on intellectual property law exemptions as proposed by the Africa Group and Bangladesh has disappeared from the negotiating table, unless some States bring it back to the discussions.

Regarding technology transfer and sharing of know-how, the Bangladesh proposals on timely development and sharing of pharmacopoeia monographs as well as sharing of biological starting materials are not taken into account.

Countries like the US and those from the EU are already pushing for "voluntary" and "mutually agreed terms" clauses regarding technology transfer. The US reportedly has attempted to threaten negotiators in the WGIHR that if voluntary and mutually agreed terms have to be removed from the IHR 2005, then technology transfer should also be removed.

Further proposals for effective pathogen access and benefit sharing now seem to be parked in the negotiations for the WHO pandemic agreement.

In short, there is no provision for consideration at the WGIHR which would promote diversification of production in different regions and thereby ensure equitable access promptly or predictably.

It is unfortunate to note that colonial and Eurocentric international law narratives still cloud the current negotiations. For example, while States Parties are obligated to respond to offers of assistance or collaboration from WHO, there is no corresponding obligation on the States Parties to respond to requests for assistance from WHO. It is even more unfortunate that although the current amendment proposal for new IHR authorities is all colour-coded green, except for one sentence in Article 4, there is no corresponding obligation on the WHO contact point to provide a response to requests for surveillance. (The green colour code means there is an in-principle consensus on the text.)

It is at this stage that Switzerland is proposing the blanket deletions for IHR 2005 amendments wherever "relevant health products" is mentioned, and Israel is backing the same. These proposals from Switzerland, if accepted, mean the WGIHR would be going against the WHO Executive Board's Decision EB150(3), which provides a clear mandate to address equity issues in the IHR.

EB150(3) states: *"Such amendments should be limited in scope and address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner."*

Part 11 – 77th WHA and the adoption of the IHR amendments

TWN Info Service on Health Issues (May24/16)
27 May 2024

Ministers to weigh unfinished business of pandemic agreement, IHR negotiations

Geneva, 27 May (Nithin Ramakrishnan) – The 77th session of the World Health Assembly (WHA77) that will take place this week will look into the unfinished business of the Intergovernmental Negotiating Body (INB) developing a new pandemic instrument under the aegis of WHO, and the Working Group on Amendments to the International Health Regulations 2005 (WGIHR).

WHA77, an annual meeting of health ministers, will be held in Geneva from 27 May to 1 June 2024.

Both the INB and the WGIHR were not able to complete their work since developed countries continue to refuse to draft and adopt legally binding provisions which would ensure equitable access to medicines, diagnostics and vaccines to developing countries to respond to public health emergencies of international concern (PHEICs) and pandemics such as COVID-19.

Developed countries want developing countries to take on legally binding obligations on various types of surveillance and rapid information-sharing systems in the name of pandemic prevention, without taking into account the lack of health systems and other basic health facilities in the developing countries.

The G7 countries specifically intervened in both processes to oppose calls for a new financing facility, accountable to Parties to the instruments, which can provide financial assistance to establish the core capacities for prevention, preparedness and response. They are continually persuading developing countries to rely on existing financing arrangements, which are established outside WHO governance. These existing facilities often prioritize surveillance-related capacities over prevention and response capacities.

According to the provisional agenda of WHA77, the outcome documents of the INB and the WGIHR are submitted through docu-

ments A77/10 and A77/9 respectively. The reports will be discussed under agenda items 13.4 and 13.3.

The draft final report of the resumed 9th session of the INB (A/INB/9/5) reads: "The INB decided to submit to the Seventy-seventh World Health Assembly the draft text of the WHO Pandemic Agreement reflecting progress up to Friday 24 May at 12:00 CEST, and an accompanying covering note."

Another draft document seen by TWN, marked as A77/10, also indicates the same. It states: "Following its mandate as set out in SSA2(5), the INB drafted and negotiated the text of the WHO Pandemic Agreement, the draft of which, as of the conclusion of its ninth meeting, is contained in the Appendix. The INB did not reach consensus on the text."

The document also says that the draft text reflecting progress up to Friday, 24 May at 12:00 CEST will be integrated into the file prior to online posting for WHA77.

The draft text begins with an explanation as follows:

"Recalling that the INB did not reach consensus on the text of the WHO Pandemic Agreement, and worked on the basis of the principle that 'nothing is agreed until everything is agreed', highlighting and brackets in the text indicate the following:

- *Green highlighting: text for which initial agreement was reached;*
- *Yellow highlighting: text for which initial convergence was reached;*
- *Text without highlighting: text for which no convergence was reached;*
- *Text in [brackets]: text with respect to which there were divergent views."*

The report of the WGIHR follows a similar approach. However, the colour codes are different and the WGIHR Bureau has also attempted to propose some updated language on contentious text, wishing to undertake some more discussions to conclude by WHA77.

The Bureau also expressed a commitment to supporting the next steps agreed by the WHA. A proposed note from the WGIHR Bureau for the outcome report states as follows: "The Bureau's view

is that the Working Group is close to agreeing a consensus package of amendments to the IHR and that there is a strong willingness to conclude the process successfully. The mandate of the WGIHR Co-Chairs and Bureau has now finished, but we stand ready to support the next steps agreed by the Health Assembly, including facilitating any further discussions during the Seventy-seventh World Health Assembly if that is the path decided on."

Options for way forward under consideration for continuing INB work

Delegations are presented with a decision tree outlining the way forward for negotiating the WHO pandemic agreement in the INB. The decision tree has two main suggestions: first, to negotiate during WHA77, and second, to continue negotiations after WHA77.

The second suggestion further includes three options:

1. Suspend WHA77 and continue INB negotiations with the goal of reporting to a resumed WHA77;
2. Conclude WHA77 with a decision to hold a WHA Special Session to consider the outcomes of the INB negotiations, and continue negotiations until this Special Session;
3. Conclude WHA77 with a mandate to negotiate the pandemic instrument in the INB until the next WHA in 2025.

Member States are presented with the above choices and requested to discuss the chance of a successful negotiation in the given timelines and the changing political context, in case they choose the second suggestion of negotiating the pandemic instrument beyond WHA77. However, no such question is presented for the first suggestion; instead, five days from 28 May to 1 June are marked as negotiating days in such a case.

However, several negotiators from both developed and developing countries told TWN that they are already exhausted with accelerated negotiations conducted by the INB for the past one year and the marathon negotiations over the last six weeks. Negotiators from small-sized delegations have been working even through weekends, deprived of their personal and family time, challenging their endurance.

For this reason, negotiating through WHA77 or negotiating in a rushed manner by suspending WHA77 for a few days seems to not be a preferred option for many delegations. They prefer six months to one year to complete the negotiations.

Moreover, it is clear that if the INB negotiations continue during WHA77 or if WHA77 is suspended for weeks, then developing countries will be under severe pressure not only to postpone negotiations for the pathogen access and benefit sharing (PABS) system but also to accept the new European Union call for a One Health instrument for pandemic prevention. This is because the current proposal of the INB Bureau and WHO Secretariat is to adopt a half-baked pandemic agreement and continue negotiating additional international legal instruments on PABS and One Health to supplement the same. According to sources, the French delegation has already indicated that negotiations for the PABS instrument can start only if there are concurrent negotiations for the One Health instrument. TWN has reported on how the proposed solution of adopting a pandemic agreement at WHA77 and attempting to develop additional instruments will fragment the health emergencies regime.

A developing country delegate told TWN: "Several of us cannot understand the logic being presented to us – [that] the conservative political parties are going to come into power in the upcoming elections [in the United States] and therefore we should adopt the pandemic treaty now. For that to happen, developing countries have to compromise the call for a new fund, technology transfer and the benefits under the PABS system.

"Developed countries can hold on to their demands, and they haven't committed to any legally binding obligation to deliver equitable access to health products during PHEICs or pandemics. All these are understandable, but how on earth are they expecting us to adopt a pandemic instrument the way the North wants and continue negotiating on issues that are important for us later? Will these so-called conservative parties who they fear will block the pandemic agreement block the PABS instrument? Will they grant us all benefits including technology transfer?"

TWN Info Service on Health Issues (May24/18)
30 May 2024

Drafting group starts negotiations on IHR amendments

Geneva, 30 May (TWN) – A drafting group of the ongoing World Health Assembly (WHA) has started negotiations on the pending amendment proposals to the International Health Regulations (IHR) 2005.

The drafting is largely focused on Article 13 on equitable access to relevant health products, Article 44 on collaboration, assistance and financing, and Article 54 on a committee for the effective implementation of the IHR 2005.

The drafting group was set up by the President of the WHA's Committee A, which deals with technical health issues. (Committee B is responsible for finance and administrative issues.)

On 28 May, when Committee A took up the agenda item on matters related to the pandemic instrument and IHR 2005 amendments, the President announced the establishment of the drafting group and requested the WHO Secretariat to provisionally include the work of the drafting group in the daily journal of the WHA. Prior to the announcement, the following white paper was circulated to Member States explaining the modalities of the drafting group:

"The Chair of Committee A proposes that Committee A establish a single drafting group, to be Co-Chaired by one Bureau member from, respectively, the Intergovernmental Negotiating Body (INB) and the Working Group on Amendments to the International Health Regulations (2005) (WGIHR), to consider the matters related to agenda item 13.3 and the matters related to agenda item 13.4, including further work with respect to the proposed amendments to the IHR (2005). Further, the Chair proposes that the drafting group first consider matters under item 13.3 (WGIHR), to be followed by consideration of matters under 13.4 (INB).

"It is proposed that the drafting group begin its work at 9am on Wednesday, 29 May, with further details to be provided in the Journal.

"This arrangement would promote predictability, transparency and inclusivity. It would also assist to avoid parallel meetings.

"It is properly within the role of the Chair to present this proposal, and within the prerogative of the Committee to accept it. The support of all Member States for the predictable handling of this matter, through this arrangement, is appreciated."

Wide support to wrap up WGIHR's work

Several developing country negotiators embraced the idea of finalizing amendments to the IHR 2005.

Saudi Arabia, on behalf of the EMRO (Eastern Mediterranean) region, stated: "[W]e are committed to reaching an acceptable compromise throughout the process of work to find common ground. We urge all Member States to seize this historic opportunity to protect future generations from the impact of the pandemic and epidemic by lending their support to the amendments."

Kenya, on behalf of the Africa Group, stated: "[T]he Africa Member States proposed the inclusion of a new Article 13A highlighting the importance of technologies and know-how in terms of public health response. Another Article 44 *bis* addresses the findings of the IHR committee on the need for financing of co-capacities. It proposes supporting the IHR at global and regional and national levels. Such a mechanism will contribute to enhancing greater equity in preparedness efforts … We remain committed to the issues and reiterate the importance of mainstreaming equity in both the IHR and the pandemic agreement in order to ensure that the world is better prepared to deal with the health emergencies in a fair and more equitable manner. We stand ready to engage and present a consensus package to the assembly for adoption."

Bangladesh said: "We would like to highlight that the failure to deliver on Article 13 on public health response and Article 44 on collaboration, assistance and financing, prior to and during the COVID-19 pandemic, triggered the amendment of the IHR. Therefore, it would be crucially important to amend Articles 13 and 44, taking into account the concern of developing countries. In going

forward, the whole set of amendments proposed by the Member States are to be treated as a package with the caveat that nothing is agreed until everything is agreed. We have already agreed to promote equity and solidarity in Article 3 on principles. Now we need to be bold and courageous to finalize the text in Articles 13 and 44 showing equity and solidarity in the spirit of achieving health equity for everyone, everywhere."

Botswana expressed concerns over the delay in finalization of the articles designed to increase compliance with the Regulations and render equity, i.e., Articles 13, 44 and 54.

Malaysia, too, expressed its concern that "the World Health Assembly schedule is already fully packed and for smaller delegations, this would be a constraint. A fully agreed package of amendments will need the consensus of all the Member States and we recognize the fact that throughout these Member State–led negotiations the principle of nothing is agreed until everything is agreed has been upheld".

Switzerland, one of the major countries blocking consensus on the amendment provisions relating to equitable access to health products in the WGIHR, said that it seeks only targeted amendments, which will preserve the universality and technical nature of the IHR 2005. Switzerland was of the view that incorporating provisions relating to equitable access would risk them having to take the amended IHR 2005 for a deliberative process within their national government, which could be ambivalent and may make Switzerland reject the amendment proposals. However, the Swiss delegation had last week expressed its commitment towards finding creative ways to address equity within the IHR 2005.

Contentious issues

Despite widespread support for the negotiations, there is no guarantee that they would lead to the successful conclusion of the amendment process. Three major issues are yet to find a solution: finance, the governance mechanism and technology transfer.

Finance

There is no convergence between developing country and developed country Member States, with the latter unwilling to create any new funds for the implementation of the IHR 2005. The G7 developed countries want IHR States Parties to seek funds from external financing institutions, which often prioritize donor interests. During discussions, the United States categorically stated that it "does not support the establishment of a new fund".

Norway suggested that the WGIHR should explore if consensus can be found to have periodic reviews to address gaps in financing and enable access to financing by addressing such gaps, rather than establishing a new fund.

According to the Africa Group, its proposal for a new financial mechanism currently reflected under Article 44 is based on the findings of the IHR Review Committee that highlighted the need for more financial resources to address the gaps in IHR 2005 implementation.

Reiterating the position of the Africa Group, Nigeria stated that it "does see the overarching necessity for a financial mechanism established under the IHR. Such fund along with other vital equity considerations in the amendment process will ensure the mistakes of the past are not repeated. It would address the implementation and compliance of the IHR".

Negotiations within the drafting group have yet to find a solution on the proposal to create a new fund for IHR implementation. The state of play regarding the text on the fund stands as follows:

Proposal of the Africa Group under Article 44.2 *ter* (c):

"[establish a fund, under WHO and that would commence on 1 October 2030, to provide financing to develop, strengthen and maintain the core capacities set out in Annex 1, particularly in developing countries.]"

(Brackets around negotiation text indicate lack of consensus.)

Alternative proposal of the EU supported by the US and Iraq:

"[(c) to establish a Coordinating Financing Mechanism aimed to:

(i) increase the efficient utilization of existing financing instruments relevant to supporting the effective implementation of these Regulations, and in particular to develop, strengthen and maintain core capacities set out in Annex 1[ADD A IRQ], with special attention to the diverse needs of developing countries, and

(ii) work towards mobilizing further financial resources.

The Mechanism shall function under the guidance of the World Health Assembly and be accountable to it. Its operation shall be supported by one or more existing international entities to be selected by the Assembly by consensus. The Assembly is encouraged to enter into the necessary working arrangements with the selected entity or entities within 24 months of the 77th WHA.]"

Governance mechanism

While there is more or less a consensus to establish a committee to facilitate and oversee the effective implementation of the IHR 2005, there is no consensus to create a sub-committee to directly report to the WHA, an idea opposed by many Member States. According to these countries, the sub-committee would be able to bypass the implementation committee, which consists of all IHR States Parties. The drafting group discussion could not reach a consensus on this issue on the first day.

Article 54 *bis* currently reads as follows:

"1. The States Parties Committee for the [Effective (DEL CHN)] Implementation of the International Health Regulations (2005) is hereby established to facilitate and oversee the effective implementation of these Regulations, in particular of Article 44, and perform any other functions entrusted to it by the Health Assembly. The Committee shall be facilitative and consultative in nature only, and function in a non-adversarial, non-punitive, assistive and transparent manner, guided by the principles set out in Article 3. To this effect:

(a) The Committee shall have the aim of promoting and supporting learning, exchange of best practices, and cooperation among States Parties [for the effective implementation of these Regulations (CHN)];

(b) The Committee shall establish a Subcommittee to provide technical advice and report to the Committee.

2. The Committee shall be comprised of all States Parties and shall meet at least once every two years. Terms of reference for the Committee, including the way that the Committee conducts its business, and for the Subcommittee shall be adopted at the first meeting of the Committee by consensus.

3. The Committee shall have a Chair and a Vice-Chair, elected by the Committee from among its State Party members, who shall serve for two years and rotate on a regional basis."

(CHN: China)

Technology transfer

Discussions on technology transfer under Article 13.8(e) are yet to find a consensus. The discussions are centred around the use of the terms "voluntary" and "mutually agreed". While developed countries, especially the US, insist on retention of these terms, developing countries argue for their deletion. The US proposed a footnote during the last round of negotiations on 16–17 May. However, consensus is yet to be reached on the paragraph and the footnote.

After the first day of negotiations within the drafting group, the text stands as follows:

"[(e) support States Parties, upon their request, [and, DEL EU] as appropriate, [and, EU] subject to Article 2 of these Regulations, through relevant WHO-coordinated and other networks and mechanisms, [pursuant to subparagraph 8(c) of this paragraph Article DEL EU,] to strengthen local production of [quality assured DEL EU][safe and effective EU] relevant health products, and facilitate the [voluntary AF + EGY] transfer of technology, [know-how DEL RUS][relevant skills and knowledge, RUS] and [as mutually

agreed AF + EGY] expertise [on mutually agreed terms, AF + EGY], including for research and development purposes. DEU, KEN]

[For greater certainty, the reference to voluntary transfer of technology, know-how and expertise on mutually agreed terms is without prejudice to other measures that States Parties may take, consistent with the rights, obligations, and flexibilities that Members of the World Trade Organization have under the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including those reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health.]"

(EU: European Union; EGY: Egypt; AF: Africa Group; KEN: Kenya; RUS: Russia)

TWN Info Service on Health Issues (Jun24/01) 7 June 2024

IHR 2005 amendments adopted, include equity-related provisions

Kochi/Geneva, 3 June (Nithin Ramakrishnan and K.M. Gopakumar) – The WHO Member States at the 77th session of the World Health Assembly (WHA77) adopted a package of amendments to the International Health Regulations (IHR) 2005 that included equity-related provisions.

These provisions attempt to address concerns on lack of equitable access to health products such as vaccines, therapeutics and diagnostics for health emergency preparedness and response.

WHA77 took place at the Palais de Nations in Geneva from 27 May to 1 June 2024.

The adoption of the IHR amendments concludes a two-year process initiated in 2022. The purpose and the scope of this process was set out in a decision of the WHO Executive Board (EB) in 2022.

Decision EB150(3) urged Member States *"to take all appropriate measures to consider potential amendments to the Interna-*

tional Health Regulations (2005), with the understanding that this would not lead to reopening the entire instrument for renegotiation. Such amendments should be limited in scope and address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner".

This decision was reiterated in a WHA75 decision, which was followed by a call for written submissions on amendment proposals. Several States Parties proposed amendments to the IHR 2005, including Armenia, Bangladesh, Brazil, the Czech Republic on behalf of the Member States of the European Union, Eswatini on behalf of the WHO African Region Member States, India, Indonesia, Japan, New Zealand, the Russian Federation on behalf of the Member States of the Eurasian Economic Union, Switzerland, the United States, and Uruguay on behalf of MERCOSUR.

The proposals from the developing countries stressed on developing legal obligations and mandates on States Parties and WHO respectively, to enable equitable access to health products and technologies required for public health emergency preparedness and response for all populations.

The Africa Group and Bangladesh also proposed expansion of Annex 1 of the IHR 2005, i.e., core capacities for health preparedness and response, which was supplemented with demands for a financial mechanism accountable to IHR States Parties. Certain other countries like India and Malaysia also proposed amendments for expansion of Annex 1. Several of these proposals and demands have been accommodated in the final package of IHR amendments, albeit not in the form originally proposed by the proponents.

The Working Group on Amendments to the IHR (WGIHR) held, based on the compiled text proposals from States Parties, several rounds of negotiations from 2023 to May 2024. The Co-Chairs and the WGIHR Bureau also proposed meaningful alternative text

proposals to bring diverging States Parties closer and to arrive at consensus. Since the WGIHR failed to arrive at a full consensus before WHA77, a WHA drafting group further discussed the amendment proposals with the aim to build a final consensus. The drafting group worked on the basis of document A77/9, submitted by the WGIHR for the consideration of the WHA, which contained the text of amendment proposals reflecting initial consensus and convergences arrived during the WGIHR meetings.

The WGIHR Co-Chairs, along with the Co-Chairs from the Intergovernmental Negotiating Body (INB) working in parallel to develop a WHO Pandemic Agreement, convened the drafting group meetings during WHA77 and submitted a consensus package of amendments to the WHA as contained in the conference paper A77/A/CONF./14. This package of amendments, as finalized by the drafting group, was annexed to a draft resolution co-sponsored by France, Indonesia, Kenya, New Zealand, Saudi Arabia and the US which was adopted without any objections.

These amendments, among others, create legal obligations on WHO to take measures to address equitable access and also establish a financial mechanism to mobilize resources for the implementation of the IHR. A new implementation committee has also been established consisting of all States Parties to discuss issues related to implementation.

Major amendments targeting equity

(a) Access to health products

Article 13 is amended to provide for international assistance to facilitate equitable access to health products such as diagnostics, vaccines and therapeutics for responding to public health emergencies of international concern (PHEICs) as well as pandemic emergencies. There are three newly added paragraphs to Article 13 providing for such support.

The new paragraph 7 makes it a mandate of WHO to support IHR States Parties in general during PHEICs, including pandemic

emergencies. WHO is mandated to coordinate international response activities.

The new paragraph 8 further explains the role of WHO in facilitating timely and equitable access by States Parties to relevant health products. Under this paragraph, it is the mandate of WHO to facilitate access as well as work towards removing barriers to such access. In this regard, WHO shall periodically assess the public health needs as well as the availability and accessibility including affordability of relevant health products, publish these assessments, and take the assessments into account while issuing recommendations pursuant to Articles 15–18.

Further under paragraph 8, WHO is mandated to use coordinated mechanisms and networks for allocation and distribution, coordinated by WHO as well as others, to facilitate equitable access. It should also provide support to States Parties, upon their request, in scaling up and geographically diversifying the production of relevant health products. In doing so, WHO should promote research and development and strengthen local production of quality, safe and effective relevant health products, and facilitate other measures for full implementation of the provision. WHO has also gotten a mandate to share product dossiers with States Parties for the purpose of facilitating regulatory evaluation and authorization of health products.

The obligation under this paragraph is further strengthened under the amended paragraph 2(d) of Article 44 which now reads: *"WHO shall collaborate with, and assist, States Parties, upon their request, to the extent possible, in … (d) the facilitation of access to relevant health products, in accordance with paragraph 8 of Article 13."* This will help States Parties to seek assistance from WHO in addressing barriers to equitable access.

Interestingly, under paragraph 9, States Parties are also obligated, subject to applicable law and available resources, to support WHO in implementing the actions outlined in Article 13 (on equitable access to health products and technologies). They are further mandated to engage with and encourage relevant stakeholders operating in their respective jurisdictions to facilitate equitable access to relevant health products for responding to a PHEIC and a pandemic

emergency. They are also required to make available the relevant terms of their research and development agreements for relevant health products related to promoting equitable access to such products during PHEICs and pandemic emergencies.

The term "relevant health products" is defined in Article 1 as *"those health products needed to respond to public health emergencies of international concern, including pandemic emergencies, which may include medicines, vaccines, diagnostics, medical devices, vector control products, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-based therapies, and other health technologies"*.

The most striking feature of the definition of health products is that it now includes health technologies as well. More importantly, Annex 1 of the IHR 2005, which provides for the IHR core capacities, now explicitly recognizes "access to health services and health products" as core capacity at both the national and sub-national (intermediate) levels. This would allow the developing countries to claim more support and assistance in building, maintaining, developing and strengthening capacities for local production, procurement, storage and distribution of medical products as well as primary health care capacities.

Articles 15–18 and 49 are also amended, enabling the WHO Director-General to issue temporary and standing recommendations relating to relevant health products. For instance, the amended Article 15 states:

"… 2. Temporary recommendations may include health measures to be implemented by the State(s) Party(ies) experiencing the public health emergency of international concern, including a pandemic emergency, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods, including relevant health products, and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

"2 bis. The Director-General, when communicating to States Parties the issuance, modification or extension of temporary

recommendations, should provide available information on any WHO coordinated mechanism(s) concerning access to, and allocation of, relevant health products, as well as on any other allocation and distribution mechanisms and networks…"

The incorporation of principles of equity and solidarity under Article 3.1 ensures that the implementation of the IHR should promote equity and solidarity and this would in turn be considered as playing a significant interpretative role in the provisions of Articles 13 and 15–18.

(Article 13 is on "Public health response including equitable access to relevant health products"; Article 15 "Temporary recommendations"; Article 16 "Standing recommendations"; Article 17 "Criteria for recommendations"; and Article 18 "Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels".)

(b) Access to financing

Article 44 has been amended to increase international collaboration and assistance including for mobilization of additional financial resources. The States Parties and WHO are mandated to collaborate and assist to strengthen sustainable financing to support the implementation of the IHR.

The States Parties have undertaken to encourage governance and operating models of existing financing entities and funding mechanisms to be responsive to the needs and national priorities of developing countries. More importantly, they agree to identify and enable access to financial resources necessary to equitably address the needs and priorities of developing countries, including for developing, strengthening and maintaining core capacities, including through the establishment of a Coordinating Financial Mechanism (CFM) pursuant to Article 44 *bis*.

The new Article 44 *bis* has been incorporated into the IHR 2005 to define the CFM. The functions of the CFM are threefold:

"(a) promote the provision of timely, predictable, and sustainable financing for the implementation of these Regulations in order to develop, strengthen, and maintain core capacities as set out in Annex 1 of these Regulations, including those relevant for pandemic emergencies;

(b) seek to maximize the availability of financing for the implementation needs and priorities of States Parties, in particular of developing countries; and

(c) work to mobilize new and additional financial resources, and increase the efficient utilization of existing financing instruments, relevant to the effective implementation of these Regulations."

The CFM will function under the authority and guidance of the World Health Assembly and is accountable to the Assembly. The terms of reference of this mechanism, and modalities for its operationalization and governance are yet to be decided. A newly formed States Parties Committee for the Implementation of the IHR 2005 is mandated to adopt these under Article 54 *bis* of the Regulations.

(c) Governance

One of the major demerits of the implementation of the IHR 2005 was that there was no appropriate forum to discuss in detail the challenges, strengths and weaknesses in the implementation. All that was allotted were some sessions during the annual WHA meetings.

The newly incorporated Article 54 *bis* establishes the States Parties Committee for the Implementation of the IHR 2005, which will meet at least once in two years. It will work with the aim of promoting and supporting learning, exchange of best practices, and cooperation among States Parties for the effective implementation of the Regulations, in particular of Article 44 and 44 *bis*. The work of the Committee is also aided by a sub-committee for providing technical advice.

The Committee is therefore able to give directions and guidance as to international collaboration and assistance, and other coordinated activities of WHO to improve the implementation of the IHR 2005.

The refreshed Annex 1 of the IHR 2005 has added new capacities to be developed by the States Parties, and the prime focus of Article 44 is to provide support and assistance in building, maintaining and developing these capacities. Previously, technical support and international assistance focused more on surveillance capacities as, among all the capacities contained in Annex 1, they are the donor priorities. However, with the new mandate under Article 44 *bis* and the effective governance oversight by the States Parties Committee for the Implementation of the IHR 2005 under Article 54 *bis*, international assistance and cooperation can now be channelled to realize developing country priorities too.

The Committee can also look into the implementation of Article 13 that includes provisions for equitable access to health products and technologies, as discussed above.

Other (selected) amendments

(a) Pandemic emergency as a new category of PHEIC

Article 1 incorporates a new category of PHEIC identified as pandemic emergency, which is defined as follows: *"a public health emergency of international concern that is caused by a communicable disease and: (i) has, or is at high risk of having, wide geographical spread to and within multiple States; and (ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and (iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and (iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches".*

The definition is further supplemented by a process under Article 12 enabling the WHO Director-General to determine the pandemic emergency status of a public health event.

Most of the provisions on taking measures to prevent, prepare for and respond to PHEICs have been revised to incorporate an explicit mention of pandemic emergency. This enables better coherence of WHO's emergency activities as the IHR can apply to pandemic emergencies, irrespective of the outcome of the INB process for a new pandemic agreement.

(b) Expansion of national authorities

Article 4 of the IHR 2005 has been amended to ensure that there is both a National IHR Authority and a National Focal Point. The amendment is augmented by incorporation of a new paragraph 2 *bis* which provides that *"States Parties shall take measures to implement paragraphs 1, 1 bis, and 2 of this Article, including, as appropriate, adjusting their domestic legislative and/or administrative arrangements"*.

The amendments also involve sharing of contacts between National IHR Authorities and WHO. This could possibly end up creating a network of regulatory authorities that could bypass political scrutiny of the WHO activities within each country relating to health emergency preparedness and response.

(c) Accelerated information sharing from WHO with other intergovernmental organizations

Article 6 of the IHR 2005 has been amended to accelerate the sharing of information by WHO with other international organizations. Up to now, paragraph 1 of Article 6 has provided for immediate sharing of information with the International Atomic Energy Agency (IAEA) if the subject matter involves the IAEA's competency. In the case of other intergovernmental organizations, there is no immediate sharing of information. Such organizations could get

information from WHO following the triggering points available under other provisions of the IHR 2005.

However, this has now been amended by modifying Article 6.1. The amended part of Article 6.1 reads as follows: *"If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA) or other intergovernmental organization(s), WHO shall, pursuant to paragraph 1 of Article 14, immediately notify the IAEA or, as appropriate, the other competent intergovernmental organization(s)."*

(d) Digitalization of health documents

Article 35 of the IHR 2005 has been drastically amended to specifically provide that digital documents could also be considered as health documents, and it sets some conditions for such documents. The newly added paragraph 3 of Article 35 reads: *"Regardless of the format in which health documents under these Regulations have been issued, said health documents shall conform to the Annexes, referred to in Articles 36 to 39, as applicable, and their authenticity shall be ascertainable."*

Further, WHO is empowered to develop and update, as necessary, in consultation with States Parties, technical guidance, including specifications or standards related to the issuance and ascertainment of authenticity of health documents, in both digital format and non-digital format.

According to an observer of the amendment process: "The adopted amendments are incremental steps towards enabling equity in health emergency preparedness and response. Some of them really try to address the gaps in equity as mandated in the EB Decision 150(3).

"Nevertheless, the provisions still do not provide for concrete obligations on the developed countries to provide financial or technological resources to the developing countries to prepare for and respond effectively to PHEICs. What they do is entrust certain functions to WHO to enable access to such resources, especially for

developing countries. If WHO is adequately supported by the Member States in rendering these functions, then the current amendments can deliver equity.

"More importantly, the amendments have also established an implementation committee which would meet periodically and can contribute towards effective implementation of the Regulations."

For the amended International Health Regulations (IHR 2005), refer to Annex 4 below.

Annexes

Annex 1

WHO Executive Board Decision EB150(3): Strengthening the International Health Regulations (2005): a process for their revision through potential amendment

DECISIONS

EB150(1) Special procedures to regulate the conduct of hybrid meetings of the Executive Board at its 150th session[1]

The Executive Board, having considered the report by the Director-General,[2]

Decided to adopt the special procedures set out in Annex 2 in order to regulate the conduct of hybrid meetings of the Executive Board at its 150th session, opening on 24 January 2022 and closing no later than 29 January 2022.

(First meeting, 24 January 2022)

EB150(2) Mandate of the Working Group on Sustainable Financing

The Executive Board, having considered the report of the Working Group on Sustainable Financing,[3] and having also considered the associated recommendations contained in the report of the Programme, Budget and Administration Committee of the Executive Board,[4]

Decided to extend the mandate of the Working Group on Sustainable Financing with a view to having it report to the Seventy-fifth World Health Assembly, through the thirty-sixth meeting of the Programme, Budget and Administration Committee, acting on behalf of the Executive Board.

(Fourth meeting, 25 January 2022)

EB150(3) Strengthening the International Health Regulations (2005): a process for their revision through potential amendment[1]

The Executive Board, having considered the interim report of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies[5] and the report by the Director-General;[6] recognizing the critical importance of the International Health Regulations (2005) in preventing, preparing for, and responding to health emergencies; underscoring the importance of States Parties' implementation of and compliance with the International Health Regulations (2005), including regarding collaboration and international cooperation, and development, maintenance and strengthening of core capacities required by the International Health Regulations (2005); emphasizing the importance of solidarity and equitable access to and distribution of medical countermeasures in the context of health emergencies, as well as the importance of strengthening the health and care workforce and addressing access concerns; noting with concern the negative effects of discrimination, misinformation, disinformation and stigmatization on public health emergency prevention, preparedness and response,

[1] See Annex 6 for the financial and administrative implications for the Secretariat of this decision.

[2] Document EB150/2.

[3] Document EB150/30, Annex.

[4] Document EB150/5, paragraph 35.

[5] Document EB150/16.

[6] Document EB150/15.

as well as unnecessary interference with international traffic and trade, and recognizing the need for strengthened coordination; noting the recommendations aimed at strengthening implementation of compliance with and modernization of the International Health Regulations (2005) from the main report of the Independent Panel for Pandemic Preparedness and Response,[1] the report of the Review Committee on the Functioning of the International Health Regulations (2005) during the COVID-19 response,[2] the report of the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme,[3] and the annual reports of the Global Preparedness Monitoring Board for 2019, 2020 and 2021,[4] as well as the recommendations from the report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response,[5] the report of the Ebola Interim Assessment Panel[6] and the report of the High-level Panel on the Global Response to Health Crises;[7] bearing in mind the importance of ensuring coherence, complementarity and communication between different processes that will run in parallel, including the process for developing the new instrument on pandemic prevention, preparedness and response and the ongoing work under resolution WHA74.7 (2021), and ensuring coordination between those processes in order to avoid creating an excessive burden on Member States; noting the urgent need to further strengthen implementation of and compliance with the International Health Regulations (2005), and mindful that Member States face challenges due to, inter alia, capacity constraints and insufficient global solidarity and collaboration,

Decided:

(1) to note that the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies will include, as part of its ongoing work, dedicated time to allow for discussions on strengthening of the International Health Regulations (2005), including through implementation, compliance and potential amendments;

(2) to urge Member States[8] to take all appropriate measures to consider potential amendments to the International Health Regulations (2005), with the understanding that this would not lead to reopening the entire instrument for renegotiation. Such amendments should be limited in scope and address specific and clearly identified issues, challenges – including equity, technological or other developments – or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005) and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner.

(Sixth meeting, 26 January 2022)

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[1] Document A74/INF./2.

[2] Document A74/9 Add.1.

[3] Document A74/16.

[4] A world at risk: annual report on global preparedness for health emergencies. Geneva: World Health Organization; 2019 (https://www.gpmb.org/docs/librariesprovider17/default-document-library/annual-reports/gpmb-2019-annualreport-en.pdf?sfvrsn=d1c9143c_30, accessed 26 January 2022); A world in disorder: Global Preparedness Monitoring Board annual report 2020. Geneva: World Health Organization; 2020 (https://www.gpmb.org/docs/librariesprovider17/default-document-library/annual-reports/gpmb-2020-annualreport-en.pdf?sfvrsn=bd1b8933_36, accessed 26 January 2022); and From worlds apart to a world prepared: Global Preparedness Monitoring Board report 2021. Geneva: World Health Organization; 2021 (https://www.gpmb.org/docs/librariesprovider17/default-document-library/gpmb-annual-report-2021.pdf?sfvrsn=44d10dfa_9, accessed 26 January 2022).

[5] Document A69/21.

[6] Report of the Ebola Interim Assessment Panel. Geneva: World Health Organization (https://www.who.int/publications/m/item/report-of-the-ebola-interim-assessment-panel---july-2015, accessed 6 May 2022).

[7] United Nations General Assembly document A/70/723.

[8] And, where applicable, regional economic integration organizations.

Annex 2

World Health Assembly Decision WHA75(9): Strengthening WHO preparedness for and response to health emergencies

World Health Organization

SEVENTY-FIFTH WORLD HEALTH ASSEMBLY **WHA75(9)**
Agenda item 16.2 **27 May 2022**

Strengthening WHO preparedness for and response to health emergencies

The Seventy-fifth World Health Assembly, having considered the report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies,[1]

Decided:

(1) to welcome the report;

(2) with respect to targeted amendments to the International Health Regulations (2005):

(a) to continue the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, with a revised mandate, including as appropriate and if agreed within each region, the rotation of the Bureau, and name (the "Working Group on Amendments to the International Health Regulations (2005)" (WGIHR)) to work exclusively on consideration of proposed targeted amendments to the International Health Regulations (2005), consistent with decision EB150(3) (2022), for consideration by the Seventy-seventh World Health Assembly in 2024;

(b) to request the Director-General to convene a Review Committee on the International Health Regulations (2005) (IHR Review Committee), as early as possible but no later than 1 October 2022, in accordance with Part IX, Chapter III, of the International Health Regulations (2005), in particular Article 50, paragraphs 1(a) and 6, with particular attention to be paid to the fulfilment of the letter and spirit of Article 51, paragraph 2, to make technical recommendations on the proposed amendments referred to in subparagraph (c) below, with a view to informing the work of the WGIHR;

(c) to invite proposed amendments to be submitted by 30 September 2022, with all such proposed amendments being communicated by the Director-General to all States Parties without delay;

(d) to request the WGIHR to convene its organizational meeting no later than 15 November 2022, and to coordinate with the process of the Intergovernmental Negotiating Body (INB) to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, including through regular coordination between the two Bureaus and alignment of meeting schedules and workplans, as both the International Health Regulations (2005) and the new instrument are expected to play central roles in pandemic prevention, preparedness and response in the future;

[1] Document A75/17.

(e) to request that the IHR Review Committee submit its report to the Director-General no later than 15 January 2023, with the Director-General communicating it without delay to the WGIHR;

(f) to request the WGIHR to establish a programme of work, consistent with decision EB150(3), and taking into consideration the report of the IHR Review Committee, to propose a package of targeted amendments, for consideration by the Seventy-seventh World Health Assembly, in accordance with Article 55 of the International Health Regulations (2005);

(3) to encourage Member States to continue to review and consider the possible actions contained in Appendix 3 of document A75/17, in relation to health emergency prevention, preparedness and response, including through relevant ongoing WHO governing bodies processes, while noting that those possible actions are complementary and additional to existing mandates already under implementation by the Secretariat;

(4) to request the Director-General:

(a) to submit a report to the Seventy-sixth World Health Assembly, under a substantive agenda item, on:

(i) the Secretariat's progress to implement actions that have been previously mandated by WHO's governing bodies and that are related to the activities mentioned in paragraph 3, in accordance with existing reporting requirements;

(ii) as appropriate, views from the WHO Secretariat on possible modalities for carrying forward the activities mentioned in paragraph 3 that are not presently under implementation;

(b) to support the WGIHR, by:

(i) convening its first meeting no later than 15 November 2022, and subsequent meetings at the request of the co-chairs as frequently as necessary;

(ii) providing the WGIHR with the necessary services and facilities for the performance of its work, and complete, relevant and timely information and advice.

Seventh plenary meeting, 27 May 2022
A75/VR/7

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Annex 3

World Health Assembly Resolution WHA75.12: Amendments to the International Health Regulations (2005)

World Health Organization

SEVENTY-FIFTH WORLD HEALTH ASSEMBLY **WHA75.12**
Agenda item 16.2 **28 May 2022**

Amendments to the International Health Regulations (2005)

The Seventy-fifth World Health Assembly,

Having considered the Proposal for amendments to the International Health Regulations (2005),[1] which includes in its Annex proposed amendments submitted by the United States of America in accordance with paragraph 1 of Article 55 of the International Health Regulations (2005);

Recalling decision EB150(3) (2022) on Strengthening the International Health Regulations (2005): a process for their revision through potential amendment, which noted the discussions of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies related to strengthening the International Health Regulations (2005), including through implementation, compliance and potential amendments, and urged Member States to take all appropriate measures to consider potential amendments to the International Health Regulations (2005), with the understanding that this would not lead to reopening the entire instrument for renegotiation;

Expressing appreciation for the work of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies in developing an inclusive Member State-led process for considering amendments to the International Health Regulations (2005);

Welcoming decision WHA75(9) (2022) on Strengthening WHO preparedness for and response to health emergencies, in which Member States decided to commence a Member State-led process to consider proposed amendments[2] to the International Health Regulations (2005) beyond those adopted below;

Recalling that Member States decided to establish the Working Group on Amendments to the International Health Regulations (2005) (WGIHR), through the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, to discuss targeted amendments to address specific and clearly identified issues, challenges, including equity, technological or other developments, or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation of and compliance with the International Health Regulations (2005), and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner;

Noting States Parties' right to notify the Director-General of rejections or reservations, pursuant to Articles 61 and 62, of the below amendments of the International Health Regulations (2005),

[1] Document A75/18.

[2] Including the other proposed amendments set out in the Annex to document A75/18, as well as other amendments which have or may be submitted by other States Parties to the International Health Regulations (2005) or the Director-General, including through the above-mentioned Member State-led process.

1. ADOPTS, in accordance with paragraph 3 of Article 55 of the International Health Regulations (2005), the amendments to Article 59, and the consequent necessary updates to Articles 55, 61, 62, and 63 of the International Health Regulations (2005) set out in the Annex below;

2. URGES States Parties, consistent with Article 44 of the International Health Regulations (2005), to collaborate with each other in the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under the International Health Regulations (2005).

CERTIFIED TRUE COPY

Derek Walton
LEGAL COUNSEL

ANNEX

Article 59: Entry into force; period for rejection or reservations

1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

1bis The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, an amendment to these Regulations shall be 10 months from the date of the notification by the Director-General of the adoption of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, and amendments to these Regulations shall enter into force 12 months after the date of notification referred to in paragraph 1bis of this Article, except for:

(a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61;

(b) a State that has made a reservation, for which these Regulations or an amendment thereto shall enter into force as provided in Article 62;

(c) a State that becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of this Article, and which is not already a party to these Regulations, for which these Regulations shall enter into force as provided in Article 60; and

(d) a State not a Member of WHO that accepts these Regulations, for which they shall enter into force in accordance with paragraph 1 of Article 64.

3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations or an amendment thereto within the period set out in paragraph 2 of this Article, as applicable, that State shall submit within the applicable period specified in paragraph 1 or 1bis of this Article a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than 12 months after the entry into force of these Regulations or an amendment thereto for that State Party.

Article 55: Amendments

1. Amendments to these Regulations may be proposed by any State Party or by the Director-General. Such proposals for amendments shall be submitted to the Health Assembly for its consideration.

2. The text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which it is proposed for consideration.

3. Amendments to these Regulations adopted by the Health Assembly pursuant to this Article shall come into force for all States Parties on the same terms, and subject to the same rights and obligations, as provided for in Article 22 of the Constitution of WHO and Articles 59 to 64 of these Regulations, subject to the periods provided for in those Articles with respect to amendments to these Regulations.

Article 61 Rejection

If a State notifies the Director-General of its rejection of these Regulations or of an amendment thereto within the applicable period provided in paragraph 1 or 1bis of Article 59, these Regulations or the amendment concerned shall not enter into force with respect to that State. Any international sanitary agreement or regulations listed in Article 58 to which such State is already a party shall remain in force as far as such State is concerned.

Article 62 Reservations

1. States may make reservations to these Regulations or an amendment thereto in accordance with this Article. Such reservations shall not be incompatible with the object and purpose of these Regulations.

2. Reservations to these Regulations or an amendment thereto shall be notified to the Director-General in accordance with paragraphs 1 and 1bis of Article 59 and Article 60, paragraph 1 of Article 63 or paragraph 1 of Article 64, as the case may be. A State not a Member of WHO shall notify the Director-General of any reservation with its notification of acceptance of these Regulations. States formulating reservations should provide the Director-General with reasons for the reservations.

3. A rejection in part of these Regulations or an amendment thereto shall be considered as a reservation.

4. The Director-General shall, in accordance with paragraph 2 of Article 65, issue notification of each reservation received pursuant to paragraph 2 of this Article. The Director-General shall:

(a) if the reservation was made before the entry into force of these Regulations, request those Member States that have not rejected these Regulations to notify him or her within six months of any objection to the reservation, or

(b) if the reservation was made after the entry into force of these Regulations, request States Parties to notify him or her within six months of any objection to the reservation, or

(c) if the reservation was made to an amendment to these Regulations, request States Parties to notify him or her within three months of any objection to the reservation.

States Parties objecting to a reservation to an amendment to these Regulations should provide the Director-General with reasons for the objection.

5. After this period, the Director-General shall notify all States Parties of the objections he or she has received with regard to reservations. In the case of a reservation made to these Regulations, unless by the end of six months from the date of the notification referred to in paragraph 4 of this Article a reservation has been objected to by one third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and these Regulations shall enter into force for the reserving State, subject to the reservation. In the case of a reservation made to an amendment to these Regulations, unless by the end of three months from the date of the notification referred to in paragraph 4 of this Article, a

reservation has been objected to by one third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and the amendment shall enter into force for the reserving State, subject to the reservation.

6. If at least one third of the States referred to in paragraph 4 of this Article object to the reservation to these Regulations by the end of six months from the date of the notification referred to in paragraph 4 of this Article or, in the case of a reservation to an amendment to these Regulations, by the end of three months from the date of the notification referred to in paragraph 4 of this Article, the Director-General shall notify the reserving State with a view to its considering withdrawing the reservation within three months from the date of the notification by the Director-General.

7. The reserving State shall continue to fulfil any obligations corresponding to the subject matter of the reservation, which the State has accepted under any of the international sanitary agreements or regulations listed in Article 58.

8. If the reserving State does not withdraw the reservation within three months from the date of the notification by the Director-General referred to in paragraph 6 of this Article, the Director-General shall seek the view of the Review Committee if the reserving State so requests. The Review Committee shall advise the Director-General as soon as possible and in accordance with Article 50 on the practical impact of the reservation on the operation of these Regulations.

9. The Director-General shall submit the reservation, and the views of the Review Committee if applicable, to the Health Assembly for its consideration. If the Health Assembly, by a majority vote, objects to the reservation on the ground that it is incompatible with the object and purpose of these Regulations, the reservation shall not be accepted and these Regulations or an amendment thereto shall enter into force for the reserving State only after it withdraws its reservation pursuant to Article 63. If the Health Assembly accepts the reservation, these Regulations or an amendment thereto shall enter into force for the reserving State, subject to its reservation.

Article 63 Withdrawal of rejection and reservation

1. A rejection made under Article 61 may at any time be withdrawn by a State by notifying the Director-General. In such cases, these Regulations or an amendment thereto, as applicable, shall enter into force with regard to that State upon receipt by the Director-General of the notification, except where the State makes a reservation when withdrawing its rejection, in which case these Regulations or an amendment thereto, as applicable, shall enter into force as provided in Article 62. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59 and in no case shall an amendment to these Regulations enter into force in respect to that State earlier than 12 months after the date of notification referred to in paragraph 1bis of Article 59.

2. The whole or part of any reservation may at any time be withdrawn by the State Party concerned by notifying the Director-General. In such cases, the withdrawal will be effective from the date of receipt by the Director-General of the notification.

Eighth plenary meeting, 28 May 2022
A75/VR/8

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Annex 4

World Health Assembly Resolution WHA77.17: Strengthening preparedness for and response to public health emergencies through targeted amendments to the International Health Regulations (2005)

World Health Organization

SEVENTY-SEVENTH WORLD HEALTH ASSEMBLY **WHA77.17**
Agenda item 13.3 **1 June 2024**

Strengthening preparedness for and response to public health emergencies through targeted amendments to the International Health Regulations (2005)

The Seventy-seventh World Health Assembly,

Having considered the report by the Director-General;[1]

Recalling resolution WHA58.3 (2005) adopting the International Health Regulations (2005), as subsequently amended through resolutions WHA67.13 (2014) and WHA75.12 (2022);

Recalling also decisions EB150(3) (2022) and WHA75(9) (2022);

Acknowledging with appreciation the work of the Review Committee regarding amendments to the International Health Regulations (2005) convened by the Director-General pursuant to decision WHA75(9) (2022);

Expressing appreciation for the work of the Working Group on Amendments to the International Health Regulations (2005) and acknowledging with appreciation the leadership of its Bureau;

Recognizing States Parties' right to notify the Director-General of rejections or reservations, pursuant to Articles 59, 61 and 62 of the International Health Regulations (2005), to the amendments to the International Health Regulations (2005) annexed to this resolution,

1. ADOPTS, in accordance with Article 55 of the International Health Regulations (2005), the amendments to the International Health Regulations (2005) annexed to this resolution (hereinafter referred to as the "amended International Health Regulations (2005)";

2. DECIDES:

(1) in accordance with paragraph 2 of Article 54 of the amended International Health Regulations (2005), that a review of the functioning of the amended International Health Regulations (2005) shall be made by the Eightieth World Health Assembly;

(2) that amendments to the Model International Certificate of Vaccination or Prophylaxis contained in Annex 6 to the amended International Health Regulations (2005) will only apply to

[1] Document A77/9.

certificates issued after the date of the entry into force of the amended International Health Regulations (2005);

(3) that future instruments on public health emergencies or pandemic prevention, preparedness and response, adopted pursuant to the Constitution of the World Health Organization, may utilize the Coordinating Financial Mechanism contained in Article 44 bis of the amended International Health Regulations (2005) to serve the implementation of such instruments;

3. REQUESTS the Director-General:

(1) to give prompt notification of the amendments to the International Health Regulations (2005) adopted through this resolution, in accordance with paragraph 1 of Article 65 of the International Health Regulations (2005), on the understanding that, prior to such notification, the Director-General shall ensure the uniformity of the Arabic, Chinese, English, French, Russian and Spanish texts of the amendments, allowing for State Party review and input on language conformity and accuracy;

(2) to inform other competent intergovernmental organizations or international bodies of the amendments to the International Health Regulations (2005) adopted through this resolution, including specifically the International Maritime Organization regarding amended Article 37 and Annexes 3, 4 and 8 to the International Health Regulations (2005);

(3) to commence work, in advance of the entry into force of the amendments adopted through this resolution, on matters addressed in all amended Articles, and to prepare and publish a consolidated version of the amended International Health Regulations (2005);

(4) to collaborate with States Parties, to the extent possible, in the mobilization of predictable, sustainable and timely financial resources to support developing countries in developing, strengthening and maintaining the capacities required under the amended International Health Regulations (2005);

(5) to facilitate the process for the Eightieth World Health Assembly to review the functioning of the amended International Health Regulations (2005), in accordance with paragraph 2 of Article 54 of the amended International Health Regulations (2005);

(6) to facilitate the convening of the first meeting of the States Parties Committee for the Implementation of the International Health Regulations (2005), in accordance with Article 54 bis of the amended International Health Regulations (2005), no later than one year after entry into force of the amended International Health Regulations (2005);

(7) to develop, and regularly review in consultation with Member States, the risk assessment approach to inform the determination of public health emergencies of international concern, including pandemic emergencies.

ANNEX

AMENDMENTS TO THE INTERNATIONAL HEALTH REGULATIONS (2005)

PART I – DEFINITIONS, PURPOSE AND SCOPE, PRINCIPLES AND RESPONSIBLE AUTHORITIES

Article 1 Definitions

1. For the purposes of the International Health Regulations (hereinafter "the IHR" or "Regulations"):

"affected" means persons, baggage, cargo, containers, conveyances, goods, postal parcels or human remains that are infected or contaminated, or carry sources of infection or contamination, so as to constitute a public health risk;

"affected area" means a geographical location specifically for which health measures have been recommended by WHO under these Regulations;

"aircraft" means an aircraft making an international voyage;

"airport" means any airport where international flights arrive or depart;

"arrival" of a conveyance means:

(a) in the case of a seagoing vessel, arrival or anchoring in the defined area of a port;

(b) in the case of an aircraft, arrival at an airport;

(c) in the case of an inland navigation vessel on an international voyage, arrival at a point of entry;

(d) in the case of a train or road vehicle, arrival at a point of entry;

"baggage" means the personal effects of a traveller;

"cargo" means goods carried on a conveyance or in a container;

"competent authority" means an authority responsible for the implementation and application of health measures under these Regulations;

"container" means an article of transport equipment:

(a) of a permanent character and accordingly strong enough to be suitable for repeated use;

(b) specially designed to facilitate the carriage of goods by one or more modes of transport, without intermediate reloading;

(c) fitted with devices permitting its ready handling, particularly its transfer from one mode of transport to another; and

(d) specially designed as to be easy to fill and empty;

"container loading area" means a place or facility set aside for containers used in international traffic;

"contamination" means the presence of an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk;

"conveyance" means an aircraft, ship, train, road vehicle or other means of transport on an international voyage;

"conveyance operator" means a natural or legal person in charge of a conveyance or their agent;

"crew" means persons on board a conveyance who are not passengers;

"decontamination" means a procedure whereby health measures are taken to eliminate an infectious or toxic agent or matter on a human or animal body surface, in or on a product prepared for consumption or on other inanimate objects, including conveyances, that may constitute a public health risk;

"departure" means, for persons, baggage, cargo, conveyances or goods, the act of leaving a territory;

"deratting" means the procedure whereby health measures are taken to control or kill rodent vectors of human disease present in baggage, cargo, containers, conveyances, facilities, goods and postal parcels at the point of entry;

"Director-General" means the Director-General of the World Health Organization;

"disease" means an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans;

"disinfection" means the procedure whereby health measures are taken to control or kill infectious agents on a human or animal body surface or in or on baggage, cargo, containers, conveyances, goods and postal parcels by direct exposure to chemical or physical agents;

"disinsection" means the procedure whereby health measures are taken to control or kill the insect vectors of human diseases present in baggage, cargo, containers, conveyances, goods and postal parcels;

"event" means a manifestation of disease or an occurrence that creates a potential for disease;

"free pratique" means permission for a ship to enter a port, embark or disembark, discharge or load cargo or stores; permission for an aircraft, after landing, to embark or disembark, discharge or load

cargo or stores; and permission for a ground transport vehicle, upon arrival, to embark or disembark, discharge or load cargo or stores;

"goods" mean tangible products, including animals and plants, transported on an international voyage, including for utilization on board a conveyance;

"ground crossing" means a point of land entry in a State Party, including one utilized by road vehicles and trains;

"ground transport vehicle" means a motorized conveyance for overland transport on an international voyage, including trains, coaches, lorries and automobiles;

"health measure" means procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures;

"ill person" means an individual suffering from or affected with a physical ailment that may pose a public health risk;

"infection" means the entry and development or multiplication of an infectious agent in the body of humans and animals that may constitute a public health risk;

"inspection" means the examination, by the competent authority or under its supervision, of areas, baggage, containers, conveyances, facilities, goods or postal parcels, including relevant data and documentation, to determine if a public health risk exists;

"international traffic" means the movement of persons, baggage, cargo, containers, conveyances, goods or postal parcels across an international border, including international trade;

"international voyage" means:

(a) in the case of a conveyance, a voyage between points of entry in the territories of more than one State, or a voyage between points of entry in the territory or territories of the same State if the conveyance has contacts with the territory of any other State on its voyage but only as regards those contacts;

(b) in the case of a traveller, a voyage involving entry into the territory of a State other than the territory of the State in which that traveller commences the voyage;

"intrusive" means possibly provoking discomfort through close or intimate contact or questioning;

"invasive" means the puncture or incision of the skin or insertion of an instrument or foreign material into the body or the examination of a body cavity. For the purposes of these Regulations, medical examination of the ear, nose and mouth, temperature assessment using an ear, oral or cutaneous thermometer, or thermal imaging; medical inspection; auscultation; external palpation; retinoscopy; external collection of urine, faeces or saliva samples; external measurement of blood pressure; and electrocardiography shall be considered to be non-invasive;

"isolation" means separation of ill or contaminated persons or affected baggage, containers, conveyances, goods or postal parcels from others in such a manner as to prevent the spread of infection or contamination;

"medical examination" means the preliminary assessment of a person by an authorized health worker or by a person under the direct supervision of the competent authority, to determine the person's health status and potential public health risk to others, and may include the scrutiny of health documents, and a physical examination when justified by the circumstances of the individual case;

"National IHR Authority" means the entity designated or established by the State Party at the national level to coordinate the implementation of these Regulations within the jurisdiction of the State Party;

"National IHR Focal Point" means the national centre, designated by each State Party, which shall be accessible at all times for communications with WHO IHR Contact Points under these Regulations;

"Organization" or "WHO" means the World Health Organization;

"pandemic emergency" means a public health emergency of international concern that is caused by a communicable disease and:

(i) has, or is at high risk of having, wide geographical spread to and within multiple States; and

(ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and

(iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and

(iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches.

"permanent residence" has the meaning as determined in the national law of the State Party concerned;

"personal data" means any information relating to an identified or identifiable natural person;

"point of entry" means a passage for international entry or exit of travellers, baggage, cargo, containers, conveyances, goods and postal parcels as well as agencies and areas providing services to them on entry or exit;

"port" means a seaport or a port on an inland body of water where ships on an international voyage arrive or depart;

"postal parcel" means an addressed article or package carried internationally by postal or courier services;

"public health emergency of international concern" means an extraordinary event which is determined, as provided in these Regulations:

(i) to constitute a public health risk to other States through the international spread of disease; and

(ii) to potentially require a coordinated international response;

"public health observation" means the monitoring of the health status of a traveller over time for the purpose of determining the risk of disease transmission;

"public health risk" means a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger;

"quarantine" means the restriction of activities and/or separation from others of suspect persons who are not ill or of suspect baggage, containers, conveyances or goods in such a manner as to prevent the possible spread of infection or contamination;

"recommendation" and "recommended" refer to temporary or standing recommendations issued under these Regulations;

"relevant health products" means those health products needed to respond to public health emergencies of international concern, including pandemic emergencies, which may include medicines, vaccines, diagnostics, medical devices, vector control products, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-based therapies, and other health technologies;

"reservoir" means an animal, plant or substance in which an infectious agent normally lives and whose presence may constitute a public health risk;

"road vehicle" means a ground transport vehicle other than a train;

"scientific evidence" means information furnishing a level of proof based on the established and accepted methods of science;

"scientific principles" means the accepted fundamental laws and facts of nature known through the methods of science;

"ship" means a seagoing or inland navigation vessel on an international voyage;

"standing recommendation" means non-binding advice issued by WHO for specific ongoing public health risks pursuant to Article 16 regarding appropriate health measures for routine or periodic application needed to prevent or reduce the international spread of disease and minimize interference with international traffic;

"surveillance" means the systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary;

"suspect" means those persons, baggage, cargo, containers, conveyances, goods or postal parcels considered by a State Party as having been exposed, or possibly exposed, to a public health risk and that could be a possible source of spread of disease;

"temporary recommendation" means non-binding advice issued by WHO pursuant to Article 15 for application on a time-limited, risk-specific basis, in response to a public health emergency of international concern, so as to prevent or reduce the international spread of disease and minimize interference with international traffic;

"temporary residence" has the meaning as determined in the national law of the State Party concerned;

"traveller" means a natural person undertaking an international voyage;

"vector" means an insect or other animal which normally transports an infectious agent that constitutes a public health risk;

"verification" means the provision of information by a State Party to WHO confirming the status of an event within the territory or territories of that State Party;

"WHO IHR Contact Point" means the unit within WHO which shall be accessible at all times for communications with the National IHR Focal Point.

2. Unless otherwise specified or determined by the context, reference to these Regulations includes the annexes thereto.

Article 2 Purpose and scope

The purpose and scope of these Regulations are to prevent, **prepare for,** protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risk and which avoid unnecessary interference with international traffic and trade.

Article 3 Principles

1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons, **and shall promote equity and solidarity**.

2. The implementation of these Regulations shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization.

3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease.

4. States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so, they should uphold the purpose of these Regulations.

Article 4 Responsible authorities

1. Each State Party shall designate or establish, **in accordance with its national law and context, one or two entities to serve as National IHR Authority and** ~~a~~ National IHR Focal Point, ~~and~~ **as well as** the authorities responsible within its respective jurisdiction for the implementation of health measures under these Regulations.

1 bis. The National IHR Authority shall coordinate the implementation of these Regulations within the jurisdiction of the State Party.

2. National IHR Focal Points shall be accessible at all times for communications with the WHO IHR Contact Points provided for in paragraph 3 of this Article. The functions of National IHR Focal Points shall include:

(a) sending to WHO IHR Contact Points, on behalf of the State Party concerned, urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12; and

(b) disseminating information to, and consolidating input from, relevant sectors of the administration of the State Party concerned, including those responsible for surveillance and reporting, points of entry, public health services, clinics and hospitals and other government departments.]

2 bis. States Parties shall take measures to implement paragraphs 1, 1 bis, and 2 of this Article, including, as appropriate, adjusting their domestic legislative and/or administrative arrangements.

3. WHO shall designate IHR Contact Points, which shall be accessible at all times for communications with National IHR Focal Points. WHO IHR Contact Points shall send urgent communications concerning the implementation of these Regulations, in particular under Articles 6 to 12, to the National IHR Focal Point of the States Parties concerned. WHO IHR Contact Points may be designated by WHO at the headquarters or at the regional level of the Organization.

4. States Parties shall provide WHO with contact details of their **National IHR Authority and their** National IHR Focal Point and WHO shall provide States Parties with contact details of WHO IHR Contact Points. These contact details shall be continuously updated and annually confirmed. WHO shall make the contact details available to all States Parties.

PART II – INFORMATION AND PUBLIC HEALTH RESPONSE

Article 5 Surveillance

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the **core** capacity**ies** to **prevent,** detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1.

2. Following the assessment referred to in paragraph 2 Part A of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances, and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall make the decision, taking into account the technical advice of the Committee established under Article 50 (hereinafter the "Review Committee"). After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.

3. WHO shall assist States Parties, upon request, to develop, strengthen and maintain the **core** capacities referred to in paragraph 1 of this Article.

4. WHO shall collect information regarding events through its surveillance activities and assess their potential to cause international disease spread and possible interference with international traffic. Information received by WHO under this paragraph shall be handled in accordance with Articles 11 and 45 where appropriate.

Article 6 Notification

1. Each State Party shall assess events occurring within its territory by using the decision instrument in Annex 2. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within 24 hours of assessment of public health information, of all events which may constitute a public health emergency of international concern within its territory in accordance with the decision instrument, as well as any health measure implemented in response to those events. If the notification received by WHO involves the competency of the International Atomic Energy Agency (IAEA) **or other intergovernmental organization(s),** WHO shall, **pursuant to paragraph 1 of Article 14,** immediately notify the IAEA **or**, as appropriate, **the other competent intergovernmental organization(s)**.

2. Following a notification, a State Party shall continue to communicate to WHO timely, accurate and sufficiently detailed public health information available to it on the notified event, where possible including case definitions, laboratory results, source and type of the risk, number of cases and deaths, conditions affecting the spread of the disease and the health measures employed; and report, when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern.

Article 7 Information-sharing during unexpected or unusual public health events

If a State Party has evidence of an unexpected or unusual public health event within its territory, irrespective of origin or source, which may constitute a public health emergency of international concern, it shall provide to WHO all relevant public health information. In such a case, the provisions of Article 6 shall apply in full.

Article 8 Consultation

In the case of events occurring within its territory not requiring notification as provided in Article 6, in particular those events for which there is insufficient information available to complete the decision instrument, a State Party **should** nevertheless keep WHO advised thereof through the National IHR Focal Point and consult with WHO on appropriate health measures **in a timely manner**. Such communications shall be treated in accordance with paragraphs 2 to 4 of Article 11. The State Party in whose territory the event has occurred may request WHO assistance to assess any epidemiological evidence obtained by that State Party.

Article 9 Other reports

1. WHO may take into account reports from sources other than notifications or consultations and shall assess these reports according to established epidemiological principles and then communicate information on the event to the State Party in whose territory the event is allegedly occurring. Before taking any action based on such reports, WHO shall consult with and attempt to obtain verification from the State Party in whose territory the event is allegedly occurring in accordance with the procedure set forth in Article 10. To this end, WHO shall make the information received available to the States Parties

and only where it is duly justified may WHO maintain the confidentiality of the source. This information will be used in accordance with the procedure set forth in Article 11.

2. States Parties shall, as far as practicable, inform WHO within 24 hours of receipt of evidence of a public health risk identified outside their territory that may cause international disease spread, as manifested by exported or imported:

(a) human cases;

(b) vectors which carry infection or contamination; or

(c) goods that are contaminated.

Article 10 Verification

1. WHO shall request, in accordance with Article 9, verification from a State Party of reports from sources other than notifications or consultations of events which may constitute a public health emergency of international concern allegedly occurring in the State's territory. In such cases, WHO shall inform the State Party concerned regarding the reports it is seeking to verify.

2. Pursuant to the foregoing paragraph and to Article 9, each State Party, when requested by WHO, shall verify and provide:

(a) within 24 hours, an initial reply to, or acknowledgement of, the request from WHO;

(b) within 24 hours, available public health information on the status of events referred to in WHO's request; and

(c) information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article.

3. ~~When WHO receives~~ **Upon receiving** information of an event that may constitute a public health emergency of international concern, ~~it~~ **WHO** shall offer to collaborate with the State Party concerned in assessing the potential for international disease spread, possible interference with international traffic and the adequacy of control measures. Such activities may include collaboration with other standard-setting organizations and the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.

4. If the State Party does not accept the offer of collaboration, and when justified by the magnitude of the public health risk, WHO **should** share with other States Parties the information **about the event** available to it, whilst encouraging the State Party to accept the offer of collaboration by WHO, taking into account the views of the State Party concerned.

Article 11 Provision of information by WHO

1. Subject to paragraph 2 of this Article, WHO shall send to all States Parties and, as appropriate, to relevant intergovernmental organizations, as soon as possible and by the most efficient means available, in confidence, such public health information which it has received under Articles 5 to 10 inclusive and

which is necessary to enable States Parties to respond to a public health risk. WHO should communicate information to other States Parties that might help them in preventing the occurrence of similar incidents.

2. WHO shall use information received under Articles 6 and 8 and paragraph 2 of Article 9 for verification, assessment and assistance purposes under these Regulations and, unless otherwise agreed with the States Parties referred to in those provisions, shall not make this information generally available to other States Parties, until such time as:

(a) the event is determined to constitute a public health emergency of international concern, **including a pandemic emergency,** in accordance with Article 12; or

(b) information evidencing the international spread of the infection or contamination has been confirmed by WHO in accordance with established epidemiological principles; or

(c) there is evidence that:

(i) control measures against the international spread are unlikely to succeed because of the nature of the contamination, disease agent, vector or reservoir; or

(ii) the State Party lacks sufficient operational capacity to carry out necessary measures to prevent further spread of disease; or

(d) the nature and scope of the international movement of travellers, baggage, cargo, containers, conveyances, goods or postal parcels that may be affected by the infection or contamination requires the immediate application of international control measures.

3. WHO shall consult with the State Party in whose territory the event is occurring as to its intent to make information available under this Article.

4. When information received by WHO under paragraph 2 of this Article is made available to States Parties in accordance with these Regulations, WHO may also make it available to the public if other information about the same event has already become publicly available and there is a need for the dissemination of authoritative and independent information.

Article 12 Determination of a public health emergency of international concern, ***including a pandemic emergency***

1. The Director-General shall determine, on the basis of the information received, in particular from the State**(s)** Party**(ies)** within whose territory**(ies)** an event is occurring, whether an event constitutes a public health emergency of international concern, **including, when appropriate, a pandemic emergency,** in accordance with the criteria and the procedure set out in these Regulations.

2. If the Director-General considers, based on an assessment under these Regulations, that a public health emergency of international concern is occurring, the Director-General shall consult with the State**(s)** Party**(ies)** in whose territory**(ies)** the event **is occurring** ~~arises~~ regarding this preliminary determination. If the Director-General and the State**(s)** Party**(ies)** are in agreement regarding this determination, the Director-General shall, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee") on appropriate temporary recommendations.

3. If, following the consultation in paragraph 2 above, the Director-General and the State**(s)** Party**(ies)** in whose territory**(ies)** the event **is occurring** ~~arises~~ do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49.

4. In determining whether an event constitutes a public health emergency of international concern, **including, when appropriate, a pandemic emergency,** the Director-General shall consider:

(a) information provided by the State**(s)** Party**(ies)**;

(b) the decision instrument contained in Annex 2;

(c) the advice of the Emergency Committee;

(d) scientific principles as well as the available scientific evidence and other relevant information; and

(e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.

4 bis. If the Director-General determines that an event constitutes a public health emergency of international concern, the Director-General shall further determine, having considered the matters contained in paragraph 4, whether the public health emergency of international concern also constitutes a pandemic emergency.

5. If the Director-General, **having considered the matters contained in subparagraphs (a), (c), (d) and (e) of paragraph 4 of this Article, and** following consultations with the State**(s)** Party**(ies)** within whose territory**(ies)** ~~the~~ **a** public health emergency of international concern, **including a pandemic emergency,** has occurred, considers that a public health emergency of international concern, **including a pandemic emergency,** has ended, **because it no longer meets the relevant definition in Article 1,** the Director-General shall take a decision in accordance with the procedure set out in Article 49.

*Article 13 Public health response, **including equitable access to relevant health products***

1. Each State Party shall develop, strengthen and maintain, as soon as possible but no later than five years from the entry into force of these Regulations for that State Party, the **core** capacit~~y~~**ies** to **prevent, prepare for, and** respond promptly and effectively to public health risks and public health emergencies of international concern, **including a pandemic emergency, including in fragile and humanitarian settings,** as set out in Annex 1. WHO shall publish, in consultation with Member States, guidelines to support States Parties in the development of public health response **core** capacities.

2. Following the assessment referred to in paragraph 2 Part A of Annex 1, a State Party may report to WHO on the basis of a justified need and an implementation plan and, in so doing, obtain an extension of two years in which to fulfil the obligation in paragraph 1 of this Article. In exceptional circumstances and supported by a new implementation plan, the State Party may request a further extension not exceeding two years from the Director-General, who shall make the decision, taking into account the technical advice of the Review Committee. After the period mentioned in paragraph 1 of this Article, the State Party that has obtained an extension shall report annually to WHO on progress made towards the full implementation.

3. At the request of a State Party **or following its acceptance of an offer by WHO,** WHO shall collaborate in the response to public health risks and ~~other~~ events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary.

4. If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern, **including a pandemic emergency,** is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State**(s)** Party**(ies)**, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer.

5. When requested by WHO, States Parties should provide, to the extent possible, support to WHO-coordinated response activities.

6. When requested, WHO shall provide appropriate guidance and assistance to other States Parties affected or threatened by the public health emergency of international concern, **including a pandemic emergency**.

7. WHO shall support States Parties, upon their request or following acceptance of an offer from WHO, **and coordinate international response activities during public health emergencies of international concern, including pandemic emergencies, after their determination pursuant to Article 12 of these Regulations.**

8. WHO shall facilitate, and work to remove barriers to, timely and equitable access by States Parties to relevant health products after the determination of and during a public health emergency of international concern, including a pandemic emergency, based on public health risks and needs. To that effect, the Director-General shall:

(a) conduct, and periodically review and update, assessments of the public health needs, as well as of the availability and accessibility including affordability of relevant health products for the public health response; publish such assessments; and consider the available assessments while issuing, modifying, extending or terminating recommendations pursuant to Articles 15, 16, 17, 18, and 49 of these Regulations;

(b) make use of WHO-coordinated mechanisms, or facilitate, in consultation with States Parties, their establishment as needed, and coordinate, as appropriate, with other allocation and distribution mechanisms and networks that facilitate timely and equitable access to relevant health products based on public health needs;

(c) support States Parties, upon their request, in scaling up and geographically diversifying the production of relevant health products, as appropriate, through relevant WHO-coordinated and other networks and mechanisms, subject to Article 2 of these Regulations, and in accordance with relevant international law;

(d) share with a State Party, upon its request, the product dossier related to a specific relevant health product, as provided to WHO by the manufacturer for approval and where

the manufacturer has consented, within 30 days of receiving such request, for the purpose of facilitating regulatory evaluation and authorization by the State Party.; and

(e) support States Parties, upon their request, and, as appropriate, through relevant WHO-coordinated and other networks and mechanisms, pursuant to subparagraph 8(c) of this Article, to promote research and development and strengthen local production of quality, safe and effective relevant health products, and facilitate other measures relevant for the full implementation of this provision.

9. Pursuant to paragraph 5 of this Article and paragraph 1 of Article 44 of these Regulations, and upon request of other States Parties or WHO, States Parties shall undertake, subject to applicable law and available resources, to collaborate with, and assist each other and to support WHO-coordinated response activities, including through:

(a) supporting WHO in implementing actions outlined in this Article;

(b) engaging with and encouraging relevant stakeholders operating in their respective jurisdictions to facilitate equitable access to relevant health products for responding to a public health emergency of international concern, including a pandemic emergency; and

(c) making available, as appropriate, relevant terms of their research and development agreements for relevant health products related to promoting equitable access to such products during a public health emergency of international concern, including a pandemic emergency.

Article 14 Cooperation of WHO with intergovernmental organizations and international bodies

1. WHO shall cooperate and coordinate its activities, as appropriate, with other competent intergovernmental organizations or international bodies in the implementation of these Regulations, including through the conclusion of agreements and other similar arrangements.

2. In cases in which notification or verification of, or response to, an event is primarily within the competence of other intergovernmental organizations or international bodies, WHO shall coordinate its activities with such organizations or bodies in order to ensure the application of adequate measures for the protection of public health.

3. Notwithstanding the foregoing, nothing in these Regulations shall preclude or limit the provision by WHO of advice, support, or technical or other assistance for public health purposes.

PART III – RECOMMENDATIONS

Article 15 Temporary recommendations

1. If it has been determined in accordance with Article 12 that a public health emergency of international concern, **including a pandemic emergency,** is occurring, the Director-General shall issue temporary recommendations in accordance with the procedure set out in Article 49. Such temporary recommendations may be modified or extended as appropriate, including after it has been determined that a public health emergency of international concern, **including a pandemic emergency,** has ended, at which time other temporary recommendations may be issued as necessary for the purpose of preventing or promptly detecting its recurrence.

2. Temporary recommendations may include health measures to be implemented by the State**(s)** Party**(ies)** experiencing the public health emergency of international concern, **including a pandemic emergency,** or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods, **including relevant health products,** and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.

2 bis. The Director-General, when communicating to States Parties the issuance, modification or extension of temporary recommendations, should provide available information on any WHO-coordinated mechanism(s) concerning access to, and allocation of, relevant health products, as well as on any other allocation and distribution mechanisms and networks.

3. Temporary recommendations may be terminated in accordance with the procedure set out in Article 49 at any time and shall automatically expire three months after their issuance. They may be modified or extended for additional periods of up to three months. Temporary recommendations may not continue beyond the second World Health Assembly after the determination of the public health emergency of international concern, **including a pandemic emergency,** to which they relate.

Article 16 Standing recommendations

1. WHO may make standing recommendations of appropriate health measures in accordance with Article 53 for routine or periodic application. Such measures may be applied by States Parties regarding persons, baggage, cargo, containers, conveyances, goods **including relevant health products,** and/or postal parcels for specific, ongoing public health risks in order to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic. WHO may, in accordance with Article 53, modify or terminate such recommendations, as appropriate.

2. The Director-General, when communicating to States Parties the issuance, modification or extension of standing recommendations, should provide available information on any WHO-coordinated mechanism(s) concerning access to, and allocation of, relevant health products as well as on any other allocation and distribution mechanisms and networks.

Article 17 Criteria for recommendations

When issuing, modifying or terminating temporary or standing recommendations, the Director-General shall consider:

(a) the views of the States Parties directly concerned;

(b) the advice of the Emergency Committee or the Review Committee, as the case may be;

(c) scientific principles as well as available scientific evidence and information;

(d) health measures that, on the basis of a risk assessment appropriate to the circumstances, are not more restrictive of international traffic and trade and are not more intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection;

(d bis) availability of, and accessibility to relevant health products;

(e) relevant international standards and instruments;

(f) activities undertaken by other relevant intergovernmental organizations and international bodies; and

(g) other appropriate and specific information relevant to the event.

With respect to temporary recommendations, the consideration by the Director-General of subparagraphs (e) and (f) of this Article may be subject to limitations imposed by urgent circumstances.

Article 18 Recommendations with respect to persons, baggage, cargo, containers, conveyances, goods and postal parcels

1. Recommendations issued by WHO to States Parties with respect to persons may include the following advice:

- no specific health measures are advised;
- review travel history in affected areas;
- review proof of medical examination and any laboratory analysis;
- require medical examinations;
- review proof of vaccination or other prophylaxis;
- require vaccination or other prophylaxis;
- place suspect persons under public health observation;
- implement quarantine or other health measures for suspect persons;
- implement isolation and treatment where necessary of affected persons;
- implement tracing of contacts of suspect or affected persons;
- refuse entry of suspect and affected persons;
- refuse entry of unaffected persons to affected areas;
- implement exit screening and/or restrictions on persons from affected areas.

2. Recommendations issued by WHO to States Parties with respect to baggage, cargo, containers, conveyances, goods and postal parcels may include the following advice:

- no specific health measures are advised;
- review manifest and routing;
- implement inspections;

- review proof of measures taken on departure or in transit to eliminate infection or contamination;
- implement treatment of the baggage, cargo, containers, conveyances, goods, postal parcels or human remains to remove infection or contamination, including vectors and reservoirs;
- the use of specific health measures to ensure the safe handling and transport of human remains;
- implement isolation or quarantine;
- seizure and destruction of infected or contaminated or suspect baggage, cargo, containers, conveyances, goods or postal parcels under controlled conditions if no available treatment or process will otherwise be successful;
- refuse departure or entry.

3. Recommendations issued by WHO to State Parties shall, as appropriate, take into account the need to:

(a) facilitate international travel, particularly of health and care workers and persons in life-threatening or humanitarian situations. This provision is without prejudice to Article 23 of these Regulations; and

(b) maintain international supply chains, including for relevant health products and food supplies.

PART IV – POINTS OF ENTRY

Article 19 General obligations

Each State Party shall, in addition to the other obligations provided for under these Regulations:

(a) ensure that the **core** capacities set forth in Annex 1 for designated points of entry are developed within the **time frame** provided in paragraph 1 of Article 5 and paragraph 1 of Article 13;

(b) identify the competent authorities at each designated point of entry in its territory; and

(c) furnish to WHO, as far as practicable, when requested in response to a specific potential public health risk, relevant data concerning sources of infection or contamination, including vectors and reservoirs, at its points of entry, which could result in international disease spread.

Article 20 Airports and ports

1. States Parties shall designate the airports and ports that shall develop the **core** capacities provided in Annex 1.

2. States Parties shall ensure that Ship Sanitation Control Exemption Certificates and Ship Sanitation Control Certificates are issued in accordance with the requirements in Article 39 and the model provided in Annex 3.

3. Each State Party shall send to WHO a list of ports authorized to offer:

(a) the issuance of Ship Sanitation Control Certificates and the provision of the services referred to in Annexes 1 and 3; or

(b) the issuance of Ship Sanitation Control Exemption Certificates only; and

(c) extension of the Ship Sanitation Control Exemption Certificate for a period of one month until the arrival of the ship in the port at which the Certificate may be received.

Each State Party shall inform WHO of any changes which may occur to the status of the listed ports. WHO shall publish the information received under this paragraph.

4. WHO may, at the request of the State Party concerned, arrange to certify, after an appropriate investigation, that an airport or port in its territory meets the requirements referred to in paragraphs 1 and 3 of this Article. These certifications may be subject to periodic review by WHO, in consultation with the State Party.

5. WHO, in collaboration with competent intergovernmental organizations and international bodies, shall develop and publish the certification guidelines for airports and ports under this Article. WHO shall also publish a list of certified airports and ports.

Article 21 Ground crossings

1. Where justified for public health reasons, a State Party may designate ground crossings that shall develop the **core** capacities provided in Annex 1, taking into consideration:

(a) the volume and frequency of the various types of international traffic, as compared to other points of entry, at a State Party's ground crossings which might be designated; and

(b) the public health risks existing in areas in which the international traffic originates, or through which it passes, prior to arrival at a particular ground crossing.

2. States Parties sharing common borders should consider:

(a) entering into bilateral or multilateral agreements or arrangements concerning prevention or control of international transmission of disease at ground crossings in accordance with Article 57; and

(b) joint designation of adjacent ground crossings for the **core** capacities in Annex 1 in accordance with paragraph 1 of this Article.

Article 22 Role of competent authorities

1. The competent authorities shall:

(a) be responsible for monitoring baggage, cargo, containers, conveyances, goods, postal parcels and human remains departing and arriving from affected areas, so that they are maintained in such a condition that they are free of sources of infection or contamination, including vectors and reservoirs;

(b) ensure, as far as practicable, that facilities used by travellers at points of entry are maintained in a sanitary condition and are kept free of sources of infection or contamination, including vectors and reservoirs;

(c) be responsible for the supervision of any deratting, disinfection, disinsection or decontamination of baggage, cargo, containers, conveyances, goods, postal parcels and human remains or sanitary measures for persons, as appropriate under these Regulations;

(d) advise conveyance operators, as far in advance as possible, of their intent to apply control measures to a conveyance, and shall provide, where available, written information concerning the methods to be employed;

(e) be responsible for the supervision of the removal and safe disposal of any contaminated water or food, human or animal dejecta, wastewater and any other contaminated matter from a conveyance;

(f) take all practicable measures consistent with these Regulations to monitor and control the discharge by ships of sewage, refuse, ballast water and other potentially disease-causing matter which might contaminate the waters of a port, river, canal, strait, lake or other international waterway;

(g) be responsible for supervision of service providers for services concerning travellers, baggage, cargo, containers, conveyances, goods, postal parcels and human remains at points of entry, including the conduct of inspections and medical examinations as necessary;

(h) have effective contingency arrangements to deal with an unexpected public health event; and

(i) communicate with the National IHR Focal Point on the relevant public health measures taken pursuant to these Regulations.

2. Health measures recommended by WHO for travellers, baggage, cargo, containers, conveyances, goods, postal parcels and human remains arriving from an affected area may be reapplied on arrival, if there are verifiable indications and/or evidence that the measures applied on departure from the affected area were unsuccessful.

3. Disinsection, deratting, disinfection, decontamination and other sanitary procedures shall be carried out so as to avoid injury and as far as possible discomfort to persons, or damage to the environment in a way which impacts on public health, or damage to baggage, cargo, containers, conveyances, goods and postal parcels.

PART V – PUBLIC HEALTH MEASURES

Chapter I – General provisions

Article 23 Health measures on arrival and departure

1. Subject to applicable international agreements and relevant articles of these Regulations, a State Party may require for public health purposes, on arrival or departure:

(a) with regard to travellers:

(i) information concerning the traveller's destination so that the traveller may be contacted;

(ii) information concerning the traveller's itinerary to ascertain if there was any travel in or near an affected area or other possible contacts with infection or contamination prior to arrival, as well as review of the traveller's health documents if they are required under these Regulations; and/or

(iii) a non-invasive medical examination which is the least intrusive examination that would achieve the public health objective; **and**

(b) inspection of baggage, cargo, containers, conveyances, goods, postal parcels and human remains.

2. On the basis of evidence of a public health risk obtained through the measures provided in paragraph 1 of this Article, or through other means, States Parties may apply additional health measures, in accordance with these Regulations, in particular, with regard to a suspect or affected traveller, on a case-by-case basis, the least intrusive and invasive medical examination that would achieve the public health objective of preventing the international spread of disease.

3. No medical examination, vaccination, prophylaxis or health measure under these Regulations shall be carried out on travellers without their prior express informed consent or that of their parents or guardians, except as provided in paragraph 2 of Article 31, and in accordance with the law and international obligations of the State Party.

4. Travellers to be vaccinated or offered prophylaxis pursuant to these Regulations, or their parents or guardians, shall be informed of any risk associated with vaccination or with non-vaccination and with the use or non-use of prophylaxis, in accordance with the law and international obligations of the State Party. States Parties shall inform medical practitioners of these requirements in accordance with the law of the State Party.

5. Any medical examination, medical procedure, vaccination or other prophylaxis which involves a risk of disease transmission shall only be performed on, or administered to, a traveller in accordance with established national or international safety guidelines and standards so as to minimize such a risk.

Chapter II – Special provisions for conveyances and conveyance operators

Article 24 Conveyance operators

1. States Parties shall take all practicable measures consistent with these Regulations to ensure that conveyance operators:

(a) comply with the health measures recommended by WHO and adopted by the State Party, **including for application on board as well as during embarkation and disembarkation**;

(b) inform travellers of the health measures recommended by WHO and adopted by the State Party, **including for application on board as well as during embarkation and disembarkation**; and

(c) permanently keep conveyances for which they are responsible free of sources of infection or contamination, including vectors and reservoirs. The application of measures to control sources of infection or contamination may be required if evidence is found.

2. Specific provisions pertaining to conveyances and conveyance operators under this Article are provided in Annex 4. Specific measures applicable to conveyances and conveyance operators with regard to vector-borne diseases are provided in Annex 5.

Article 25 Ships and aircraft in transit

Subject to Articles 27 and 43 or unless authorized by applicable international agreements, no health measure shall be applied by a State Party to:

(a) a ship not coming from an affected area which passes through a maritime canal or waterway in the territory of that State Party on its way to a port in the territory of another State. Any such ship shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies;

(b) a ship which passes through waters within its jurisdiction without calling at a port or on the coast; and

(c) an aircraft in transit at an airport within its jurisdiction, except that the aircraft may be restricted to a particular area of the airport, with no embarking and disembarking or loading and discharging. However, any such aircraft shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies.

Article 26 Civilian lorries, trains and coaches in transit

Subject to Articles 27 and 43 or unless authorized by applicable international agreements, no health measure shall be applied to a civilian lorry, train or coach not coming from an affected area which passes through a territory without embarking, disembarking, loading or discharging.

Article 27 Affected conveyances

1. If clinical signs or symptoms and information based on fact or evidence of a public health risk, including sources of infection and contamination, are found on board a conveyance, the competent authority shall consider the conveyance as affected and may:

(a) disinfect, decontaminate, disinsect or derat the conveyance, as appropriate, or cause these measures to be carried out under its supervision; and

(b) decide in each case the technique employed to secure an adequate level of control of the public health risk as provided in these Regulations. Where there are methods or materials advised by WHO for these procedures, these should be employed, unless the competent authority determines that other methods are as safe and reliable.

The competent authority may implement additional health measures, including isolation **and quarantine** of the conveyances, as necessary, to prevent the spread of disease. Such additional measures should be reported to the National IHR Focal Point.

2. If the competent authority for the point of entry is not able to carry out the control measures required under this Article, the affected conveyance may nevertheless be allowed to depart, subject to the following conditions:

(a) the competent authority shall, at the time of departure, inform the competent authority for the next known point of entry of the type of information referred to under subparagraph (b); and

(b) in the case of a ship, the evidence found and the control measures required shall be noted in the Ship Sanitation Control Certificate.

Any such conveyance shall be permitted to take on, under the supervision of the competent authority, fuel, water, food and supplies.

3. A conveyance that has been considered as affected shall cease to be regarded as such when the competent authority is satisfied that:

(a) the measures provided in paragraph 1 of this Article have been effectively carried out; and

(b) there are no conditions on board that could constitute a public health risk.

Article 28 Ships and aircraft at points of entry

1. Subject to Article 43 or as provided in applicable international agreements, a ship or an aircraft shall not be prevented for public health reasons from calling at any point of entry. However, if the point of entry is not equipped for applying health measures under these Regulations, the ship or aircraft may be ordered to proceed at its own risk to the nearest suitable point of entry available to it, unless the ship or aircraft has an operational problem which would make this diversion unsafe.

2. Subject to Article 43 or as provided in applicable international agreements, ships or aircraft shall not be refused free pratique by States Parties for public health reasons; in particular, they shall not be prevented from embarking or disembarking, discharging or loading cargo or stores, or taking on fuel, water, food and supplies. States Parties may subject the granting of free pratique to inspection and, if a

source of infection or contamination is found on board, the carrying out of necessary disinfection, decontamination, disinsection or deratting, or other measures necessary to prevent the spread of the infection or contamination.

3. Whenever practicable and subject to ~~the previous~~ paragraph 2 **of this Article**, a State Party shall authorize the granting of free pratique by radio or other communication means to a ship or an aircraft when, on the basis of information received from it prior to its arrival, the State Party is of the opinion that the arrival of the ship or aircraft will not result in the introduction or spread of disease.

4. Officers in command of ships or pilots in command of aircraft, or their agents, shall make known to the port or airport control, as early as possible before arrival at the port or airport of destination, any cases of illness indicative of a disease of an infectious nature or evidence of a public health risk on board, as soon as such illnesses or public health risks are made known to the officer or pilot. This information must be immediately relayed to the competent authority for the port or airport. In urgent circumstances, such information should be communicated directly by the officers or pilots to the relevant port or airport authority.

5. The following shall apply if a suspect or affected aircraft or ship, for reasons beyond the control of the pilot in command of the aircraft or the officer in command of the ship, lands elsewhere than at the airport at which the aircraft was due to land or berths elsewhere than at the port at which the ship was due to berth:

(a) the pilot in command of the aircraft or the officer in command of the ship or other person in charge shall make every effort to communicate without delay with the nearest competent authority;

(b) as soon as the competent authority has been informed of the landing, it may apply health measures recommended by WHO or other health measures provided in these Regulations;

(c) unless required for emergency purposes or for communication with the competent authority, no traveller on board the aircraft or ship shall leave its vicinity and no cargo shall be removed from that vicinity, unless authorized by the competent authority; and

(d) when all health measures required by the competent authority have been completed, the aircraft or ship may, so far as such health measures are concerned, proceed either to the airport or port at which it was due to land or berth, or, if for technical reasons it cannot do so, to a conveniently situated airport or port.

6. Notwithstanding the provisions contained in this Article, the officer in command of a ship or pilot in command of an aircraft may take such emergency measures as may be necessary for the health and safety of travellers on board. He or she shall inform the competent authority as early as possible concerning any measures taken pursuant to this paragraph.

Article 29 Civilian lorries, trains and coaches at points of entry

WHO, in consultation with States Parties, shall develop guiding principles for applying health measures to civilian lorries, trains and coaches at points of entry and passing through ground crossings.

Chapter III – Special provisions for travellers

Article 30 Travellers under public health observation

Subject to Article 43 or as authorized in applicable international agreements, a suspect traveller who on arrival is placed under public health observation may continue an international voyage, if the traveller does not pose an imminent public health risk and the State Party informs the competent authority of the point of entry at destination, if known, of the traveller's expected arrival. On arrival, the traveller shall report to that authority.

Article 31 Health measures relating to entry of travellers

1. Invasive medical examination, vaccination or other prophylaxis shall not be required as a condition of entry of any traveller to the territory of a State Party, except that, subject to Articles 32, 42 and 45, these Regulations do not preclude States Parties from requiring medical examination, vaccination or other prophylaxis or proof of vaccination or other prophylaxis:

(a) when necessary to determine whether a public health risk exists;

(b) as a condition of entry for any travellers seeking temporary or permanent residence;

(c) as a condition of entry for any travellers pursuant to Article 43 or Annexes 6 and 7; or

(d) which may be carried out pursuant to Article 23.

2. If a traveller for whom a State Party may require a medical examination, vaccination or other prophylaxis under paragraph 1 of this Article fails to consent to any such measure, or refuses to provide the information or the documents referred to in paragraph 1(a) of Article 23, the State Party concerned may, subject to Articles 32, 42 and 45, deny entry to that traveller. If there is evidence of an imminent public health risk, the State Party may, in accordance with its national law and to the extent necessary to control such a risk, compel the traveller to undergo or advise the traveller, pursuant to paragraph 3 of Article 23, to undergo:

(a) the least invasive and intrusive medical examination that would achieve the public health objective;

(b) vaccination or other prophylaxis; or

(c) additional established health measures that prevent or control the spread of disease, including isolation, quarantine or placing the traveller under public health observation.

Article 32 Treatment of travellers

In implementing health measures under these Regulations, States Parties shall treat travellers with respect for their dignity, human rights and fundamental freedoms and minimize any discomfort or distress associated with such measures, including by:

(a) treating all travellers with courtesy and respect;

(b) taking into consideration the gender, sociocultural, ethnic or religious concerns of travellers; and

(c) providing or arranging for adequate food and water, appropriate accommodation and clothing, protection for baggage and other possessions, appropriate medical treatment, means of necessary communication if possible in a language that they can understand, and other appropriate assistance for travellers who are quarantined, isolated or subject to medical examinations or other procedures for public health purposes.

Chapter IV – Special provisions for goods, containers and container loading areas

Article 33 Goods in transit

Subject to Article 43 or unless authorized by applicable international agreements, goods, other than live animals, in transit without transhipment shall not be subject to health measures under these Regulations or detained for public health purposes.

Article 34 Container and container loading areas

1. States Parties shall ensure, as far as practicable, that container shippers use international traffic containers that are kept free from sources of infection or contamination, including vectors and reservoirs, particularly during the course of packing.

2. States Parties shall ensure, as far as practicable, that container loading areas are kept free from sources of infection or contamination, including vectors and reservoirs.

3. Whenever, in the opinion of a State Party, the volume of international container traffic is sufficiently large, the competent authorities shall take all practicable measures consistent with these Regulations, including carrying out inspections, to assess the sanitary condition of container loading areas and containers in order to ensure that the obligations contained in these Regulations are implemented.

4. Facilities for the inspection and isolation of containers shall, as far as practicable, be available at container loading areas.

5. Container consignees and consignors shall make every effort to avoid cross-contamination when multiple-use loading of containers is employed.

PART VI – HEALTH DOCUMENTS

Article 35 General rule

1. No health documents, other than those provided for under these Regulations or in recommendations issued by WHO, shall be required in international traffic, provided however that this Article shall not apply to travellers seeking temporary or permanent residence, nor shall it apply to document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements. The competent authority may request travellers to complete contact information forms and questionnaires on the health of travellers, provided that they meet the requirements set out in Article 23.

2. Health documents under these Regulations may be issued in non-digital format or digital format, subject to the obligations of any State Party regarding the format of such documents deriving from other international agreements.

3. Regardless of the format in which health documents under these Regulations have been issued, said health documents shall conform to the Annexes~~,~~ referred to in Articles 36 to 39, as applicable, and their authenticity shall be ascertainable.

4. WHO, in consultation with States Parties, shall develop and update, as necessary, technical guidance, including specifications or standards related to the issuance and ascertainment of authenticity of health documents, both in digital format and non-digital format. Such specifications or standards shall be in accordance with Article 45 regarding treatment of personal data.

Article 36 Certificates of vaccination or other prophylaxis

1. Vaccines and prophylaxis for travellers administered pursuant to these Regulations, or to recommendations and certificates relating thereto, shall conform to the provisions of Annex 6 and, when applicable, Annex 7 with regard to specific diseases.

2. A traveller in possession of a certificate of vaccination or other prophylaxis issued in conformity with Annex 6 and, when applicable, Annex 7, shall not be denied entry as a consequence of the disease to which the certificate refers, even if coming from an affected area, unless the competent authority has verifiable indications and/or evidence that the vaccination or other prophylaxis was not effective.

*Article 37 ~~Maritime~~ **Ship** Declaration of Health*

1. The master of a ship, before arrival at its first port of call in the territory of a State Party, shall ascertain the state of health on board, and, except when that State Party does not require it, the master shall, on arrival, or in advance of the vessel's arrival if the vessel is so equipped and the State Party requires such advance delivery, complete and deliver to the competent authority for that port a ~~Maritime~~ **Ship** Declaration of Health, which shall be countersigned by the ship's surgeon, if one is carried.

2. The master of a ship, or the ship's surgeon if one is carried, shall supply any information required by the competent authority as to health conditions on board during an international voyage.

3. A ~~Maritime~~ **Ship** Declaration of Health shall conform to the model provided in Annex 8.

4. A State Party may decide:

(a) to dispense with the submission of the ~~Maritime~~ **Ship** Declaration of Health by all arriving ships; or

(b) to require the submission of the ~~Maritime~~ **Ship** Declaration of Health under a recommendation concerning ships arriving from affected areas or to require it from ships which might otherwise carry infection or contamination.

The State Party shall inform shipping operators or their agents of these requirements.

Article 38 Health Part of the Aircraft General Declaration

1. The pilot in command of an aircraft or the pilot's agent, in flight or upon landing at the first airport in the territory of a State Party, shall, to the best of his or her ability, except when that State Party does not require it, complete and deliver to the competent authority for that airport the Health Part of the Aircraft General Declaration which shall conform to the model specified in Annex 9.

2. The pilot in command of an aircraft or the pilot's agent shall supply any information required by the State Party as to health conditions on board during an international voyage and any health measure applied to the aircraft.

3. A State Party may decide:

(a) to dispense with the submission of the Health Part of the Aircraft General Declaration by all arriving aircraft; or

(b) to require the submission of the Health Part of the Aircraft General Declaration under a recommendation concerning aircraft arriving from affected areas or to require it from aircraft which might otherwise carry infection or contamination.

The State Party shall inform aircraft operators or their agents of these requirements.

Article 39 Ship sanitation certificates

1. Ship Sanitation Control Exemption Certificates and Ship Sanitation Control Certificates shall be valid for a maximum period of six months. This period may be extended by one month if the inspection or control measures required cannot be accomplished at the port.

2. If a valid Ship Sanitation Control Exemption Certificate or Ship Sanitation Control Certificate is not produced or evidence of a public health risk is found on board a ship, the State Party may proceed as provided in paragraph 1 of Article 27.

3. The certificates referred to in this Article shall conform to the model in Annex 3.

4. Whenever possible, control measures shall be carried out when the ship and holds are empty. In the case of a ship in ballast, they shall be carried out before loading.

5. When control measures are required and have been satisfactorily completed, the competent authority shall issue a Ship Sanitation Control Certificate, noting the evidence found and the control measures taken.

6. The competent authority may issue a Ship Sanitation Control Exemption Certificate at any port specified under Article 20 if it is satisfied that the ship is free of infection and contamination, including vectors and reservoirs. Such a certificate shall normally be issued only if the inspection of the ship has been carried out when the ship and holds are empty or when they contain only ballast or other material, of such a nature or so disposed as to make a thorough inspection of the holds possible.

7. If the conditions under which control measures are carried out are such that, in the opinion of the competent authority for the port where the operation was performed, a satisfactory result cannot be obtained, the competent authority shall make a note to that effect on the Ship Sanitation Control Certificate.

PART VII – CHARGES

Article 40 Charges for health measures regarding travellers

1. Except for travellers seeking temporary or permanent residence, and subject to paragraph 2 of this Article, no charge shall be made by a State Party pursuant to these Regulations for the following measures for the protection of public health:

(a) any medical examination provided for in these Regulations, or any supplementary examination which may be required by that State Party to ascertain the health status of the traveller examined;

(b) any vaccination or other prophylaxis provided to a traveller on arrival that is not a published requirement or is a requirement published less than 10 days prior to provision of the vaccination or other prophylaxis;

(c) appropriate isolation or quarantine requirements of travellers;

(d) any certificate issued to the traveller specifying the measures applied and the date of application; or

(e) any health measures applied to baggage accompanying the traveller.

2. States Parties may charge for health measures other than those referred to in paragraph 1 of this Article, including those primarily for the benefit of the traveller.

3. Where charges are made for applying such health measures to travellers under these Regulations, there shall be in each State Party only one tariff for such charges and every charge shall:

(a) conform to this tariff;

(b) not exceed the actual cost of the service rendered; and

(c) be levied without distinction as to the nationality, domicile or residence of the traveller concerned.

4. The tariff, and any amendment thereto, shall be published at least 10 days in advance of any levy thereunder.

5. Nothing in these Regulations shall preclude States Parties from seeking reimbursement for expenses incurred in providing the health measures in paragraph 1 of this Article:

(a) from conveyance operators or owners with regard to their employees; or

(b) from applicable insurance sources.

6. Under no circumstances shall travellers or conveyance operators be denied the ability to depart from the territory of a State Party pending payment of the charges referred to in paragraphs 1 or 2 of this Article.

Article 41 Charges for baggage, cargo, containers, conveyances, goods or postal parcels

1. Where charges are made for applying health measures to baggage, cargo, containers, conveyances, goods or postal parcels under these Regulations, there shall be in each State Party only one tariff for such charges and every charge shall:

(a) conform to this tariff;

(b) not exceed the actual cost of the service rendered; and

(c) be levied without distinction as to the nationality, flag, registry or ownership of the baggage, cargo, containers, conveyances, goods or postal parcels concerned. In particular, there shall be no distinction made between national and foreign baggage, cargo, containers, conveyances, goods or postal parcels.

2. The tariff, and any amendment thereto, shall be published at least 10 days in advance of any levy thereunder.

PART VIII – GENERAL PROVISIONS

Article 42 Implementation of health measures

Health measures taken pursuant to these Regulations shall be initiated and completed without delay, and applied in a transparent and non-discriminatory manner.

Article 43 Additional health measures

1. These Regulations shall not preclude States Parties from implementing health measures, in accordance with their relevant national law and obligations under international law, in response to specific public health risks or public health emergencies of international concern, which:

(a) achieve the same or greater level of health protection than WHO recommendations; or

(b) are otherwise prohibited under Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1(c) of Article 31 and Article 33,

provided such measures are otherwise consistent with these Regulations.

Such measures shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection.

2. In determining whether to implement the health measures referred to in paragraph 1 of this Article or additional health measures under paragraph 2 of Article 23, paragraph 1 of Article 27, paragraph 2 of Article 28 and paragraph 2(c) of Article 31, States Parties shall base their determinations upon:

(a) scientific principles;

(b) available scientific evidence of a risk to human health, or where such evidence is insufficient, the available information, including from WHO and other relevant intergovernmental organizations and international bodies; and

(c) any available specific guidance or advice from WHO.

3. A State Party implementing additional health measures referred to in paragraph 1 of this Article which significantly interfere with international traffic shall provide to WHO the public health rationale and relevant scientific information for it. WHO shall share this information with other States Parties and shall share information regarding the health measures implemented. For the purpose of this Article, significant interference generally means refusal of entry or departure of international travellers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24 hours.

4. After assessing information provided pursuant to paragraph 3 and 5 of this Article and other relevant information, WHO may request that the State Party concerned reconsider the application of the measures.

5. A State Party implementing additional health measures referred to in paragraphs 1 and 2 of this Article that significantly interfere with international traffic shall inform WHO, within 48 hours of implementation, of such measures and their health rationale unless these are covered by a temporary or standing recommendation.

6. A State Party implementing a health measure pursuant to paragraph 1 or 2 of this Article shall within three months review such a measure, taking into account the advice of WHO and the criteria in paragraph 2 of this Article.

7. Without prejudice to its rights under Article 56, any State Party impacted by a measure taken pursuant to paragraph 1 or 2 of this Article may request the State Party implementing such a measure to consult with it, **either directly, or through the Director-General, who may also facilitate consultations between the States Parties concerned.** The purpose of such consultations is to clarify the scientific information and public health rationale underlying the measure and to find a mutually acceptable solution. **Unless otherwise agreed with the State Parties involved in the consultation, information shared during the consultation must be kept confidential.**

8. The provisions of this Article may apply to implementation of measures concerning travellers taking part in mass congregations.

*Article 44 Collaboration ~~and~~, assistance **and financing***

1. States Parties shall undertake to collaborate with each other, to the extent possible in:

(a) the detection and assessment of, **preparedness for,** and response to, events as provided under these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the ~~public health~~ **core** capacities required under **Annex 1 of** these Regulations;

(c) the mobilization of financial resources, **including through relevant sources and funding mechanisms** to facilitate implementation of their obligations under these Regulations **in particular to address the needs of developing countries**;

(d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations; **and**

2. WHO shall collaborate with, **and assist,** States Parties, upon **their** request, to the extent possible, in:

(a) the evaluation and assessment of their ~~public health~~ **core** capacities in order to facilitate the effective implementation of these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support to States Parties; ~~and~~

(c) the mobilization of financial resources to support developing countries in ~~building~~ **developing,** strengthening and maintaining the **core** capacities provided for in Annex 1~~.~~; **and**

(d) the facilitation of access to relevant health products, in accordance with paragraph 8 of Article 13.

2 bis. States Parties, subject to applicable law and available resources, shall maintain or increase domestic funding, as necessary, and collaborate, including through international cooperation and assistance, as appropriate, to strengthen sustainable financing to support the implementation of these Regulations.

2 ter. Pursuant to subparagraph (c) of paragraph 1, States Parties shall undertake to collaborate, to the extent possible, to:

(a) encourage governance and operating models of existing financing entities and funding mechanisms to be regionally representative and responsive to the needs and national priorities of developing countries in the implementation of these Regulations;

(b) identify and enable access to financial resources, including through the Coordinating Financial Mechanism, established pursuant to Article 44 bis, necessary to equitably address the needs and priorities of developing countries, including for developing, strengthening and maintaining core capacities.

2 quater. The Director-General shall support the collaboration work in paragraph 2 bis of this Article, as appropriate. The States Parties and the Director-General shall report on its outcomes as part of the reporting to the Health Assembly.

3. Collaboration under this Article may be implemented through multiple channels, including bilaterally, through regional networks and the WHO regional offices, and through intergovernmental organizations and international bodies.

Article 44 bis – Coordinating Financial Mechanism

1. A Coordinating Financial Mechanism (the Mechanism) is hereby established to:

(a) promote the provision of timely, predictable, and sustainable financing for the implementation of these Regulations in order to develop, strengthen, and maintain core capacities as set out in Annex 1 of these Regulations, including those relevant for pandemic emergencies;

(b) seek to maximize the availability of financing for the implementation needs and priorities of States Parties, in particular of developing countries; and

(c) work to mobilize new and additional financial resources, and increase the efficient utilization of existing financing instruments, relevant to the effective implementation of these Regulations.

2. In support of the objectives set out in Paragraph 1 of this Article, the Mechanism shall, inter alia:

(a) use or conduct relevant needs and funding gap analyses;

(b) promote harmonization, coherence and coordination of existing financing instruments;

(c) identify all sources of financing that are available for implementation support and make this information available to States Parties;

(d) provide advice and support, upon request, to States Parties in identifying and applying for financial resources for strengthening core capacities, including those relevant for pandemic emergencies;

(e) leverage voluntary monetary contributions for organizations and other entities supporting States Parties to develop, strengthen and maintain their core capacities, including those relevant for pandemic emergencies.

3. The Mechanism shall function, in relation to the implementation of these Regulations, under the authority and guidance of the Health Assembly and be accountable to it.

Article 45 Treatment of personal data

1. Health information collected or received by a State Party pursuant to these Regulations from another State Party or from WHO which refers to an identified or identifiable person shall be kept confidential and processed anonymously, as required by national law.

2. Notwithstanding paragraph 1, States Parties may **process and** disclose ~~and process~~ personal data where essential for the purposes of assessing and managing a public health risk, but State Parties, in accordance with national law, and WHO must ensure that the personal data are:

(a) processed fairly and lawfully, and not further processed in a way incompatible with that purpose;

(b) adequate, relevant and not excessive in relation to that purpose;

(c) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete are erased or rectified; and

(d) not kept longer than necessary.

3. Upon request, WHO shall as far as practicable provide an individual with his or her personal data referred to in this Article in an intelligible form, without undue delay or expense and, when necessary, allow for correction.

Article 46 Transport and handling of biological substances, reagents and materials for diagnostic purposes

States Parties shall, subject to national law and taking into account relevant international guidelines, facilitate the transport, entry, exit, processing and disposal of biological substances and diagnostic specimens, reagents and other diagnostic materials for verification and public health response purposes under these Regulations.

PART IX – THE IHR ROSTER OF EXPERTS, THE EMERGENCY COMMITTEE AND THE REVIEW COMMITTEE

Chapter I – The IHR Roster of Experts

Article 47 Composition

The Director-General shall establish a roster composed of experts in all relevant fields of expertise (hereinafter the "IHR Expert Roster"). The Director-General shall appoint the members of the IHR Expert Roster in accordance with the WHO Regulations for Expert Advisory Panels and Committees (hereinafter the "WHO Advisory Panel Regulations"), unless otherwise provided in these Regulations. In addition, the Director-General shall appoint one member at the request of each State Party and, where appropriate, experts proposed by relevant intergovernmental and regional economic integration organizations. Interested States Parties shall notify the Director-General of the qualifications and fields of expertise of each of the experts they propose for membership. The Director-General shall periodically inform the States Parties, and relevant intergovernmental and regional economic integration organizations, of the composition of the IHR Expert Roster.

Chapter II – The Emergency Committee

Article 48 Terms of reference and composition

1. The Director-General shall establish an Emergency Committee that at the request of the Director-General shall provide its views on:

(a) whether an event constitutes a public health emergency of international concern, **including a pandemic emergency**;

(b) the termination of a public health emergency of international concern, **including a pandemic emergency**; and

(c) the proposed issuance, modification, extension or termination of temporary recommendations.

1 bis. The Emergency Committee shall be considered an ~~Expert Committee~~ expert committee and shall be subject to the WHO Advisory Panel Regulations, unless otherwise provided for in this Article.

2. The Emergency Committee shall be composed of experts selected by the Director-General from the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization. The Director-General shall determine the duration of membership with a view to ensuring its continuity in the consideration of a specific event and its consequences. The Director-General shall select the members of the Emergency Committee on the basis of the expertise and experience required for any particular session and with due regard to the principles of equitable geographical representation. ~~At least one member~~ **Members** of the Emergency Committee should **include at least one** ~~be an~~ expert nominated by ~~a~~ State**(s)** Party**(ies)** within whose territory the event ~~arises~~ **is occurring**.

3. The Director-General may, on his or her own initiative or at the request of the Emergency Committee, appoint one or more technical experts to advise the Committee.

Article 49 Procedure

1. The Director-General shall convene meetings of the Emergency Committee by selecting a number of experts from among those referred to in paragraph 2 of Article 48, according to the fields of expertise and experience most relevant to the specific event that is occurring. For the purpose of this Article, "meetings" of the Emergency Committee may include teleconferences, videoconferences or electronic communications.

2. The Director-General shall provide the Emergency Committee with the agenda and any relevant information concerning the event, including information provided by the States Parties, as well as any temporary recommendation that the Director-General proposes for issuance.

3. The Emergency Committee shall elect its Chairperson and prepare following each meeting a brief summary report of its proceedings and deliberations, including any advice on recommendations.

4. The Director-General shall invite the State**(s)** Party**(ies)** in whose territory the event ~~arises~~ **is occurring** to present its **(their)** views to the Emergency Committee. To that effect, the Director-General shall notify to it the dates and the agenda of the meeting of the Emergency Committee with as much advance notice as necessary. The State**(s)** Party**(ies)** concerned, however, may not seek a postponement of the meeting of the Emergency Committee for the purpose of presenting its views thereto.

5. The views of the Emergency Committee shall be forwarded to the Director-General for consideration. The Director-General shall make the final determination on these matters.

6. The Director-General shall communicate to **all** States Parties the determination and the termination of a public health emergency of international concern, **including a pandemic emergency**, any health measure taken by the State**(s)** Party**(ies)** concerned, any temporary recommendations, **including the supporting evidence,** and the modification, extension and termination of such recommendations, together with the **composition and** views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination.

The Director-General shall subsequently make such information and recommendations available to the general public.

7. States Parties in whose territories the event has occurred may propose to the Director-General the termination of a public health emergency of international concern, **including a pandemic emergency,** and/or the temporary recommendations, and may make a presentation to that effect to the Emergency Committee.

Chapter III – The Review Committee

Article 50 Terms of reference and composition

1. The Director-General shall establish a Review Committee, which shall carry out the following functions:

(a) make technical recommendations to the Director-General regarding amendments to these Regulations;

(b) provide technical advice to the Director-General with respect to standing recommendations, and any modifications or termination thereof; **and**

(c) provide technical advice to the Director-General on any matter referred to it by the Director-General regarding the functioning of these Regulations.

2. The Review Committee shall be considered an expert committee and shall be subject to the WHO Advisory Panel Regulations, unless otherwise provided in this Article.

3. The Members of the Review Committee shall be selected and appointed by the Director-General from among the persons serving on the IHR Expert Roster and, when appropriate, other expert advisory panels of the Organization.

4. The Director-General shall establish the number of members to be invited to a meeting of the Review Committee, determine its date and duration, and convene the Committee.

5. The Director-General shall appoint members to the Review Committee for the duration of the work of a session only.

6. The Director-General shall select the members of the Review Committee on the basis of the principles of equitable geographical representation, gender balance, a balance of experts from developed and developing countries, representation of a diversity of scientific opinion, approaches and practical experience in various parts of the world, and an appropriate interdisciplinary balance.

Article 51 Conduct of business

1. Decisions of the Review Committee shall be taken by a majority of the members present and voting.

2. The Director-General shall invite Member States, the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO to designate representatives to attend the Committee sessions. Such representatives may submit memoranda and, with the consent of the Chairperson, make statements on the subjects under discussion. They shall not have the right to vote.

Article 52 Reports

1. For each session, the Review Committee shall draw up a report setting forth the Committee's views and advice. This report shall be approved by the Review Committee before the end of the session. Its views and advice shall not commit the Organization and shall be formulated as advice to the Director-General. The text of the report may not be modified without the Committee's consent.

2. If the Review Committee is not unanimous in its findings, any member shall be entitled to express his or her dissenting professional views in an individual or group report, which shall state the reasons why a divergent opinion is held and shall form part of the Committee's report.

3. The Review Committee's report shall be submitted to the Director-General, who shall communicate its views and advice to the Health Assembly or the Executive Board for their consideration and action.

Article 53 Procedures for standing recommendations

When the Director-General considers that a standing recommendation is necessary and appropriate for a specific public health risk, the Director-General shall seek the views of the Review Committee. In addition to the relevant paragraphs of Articles 50 to 52, the following provisions shall apply:

(a) proposals for standing recommendations, their modification or termination may be submitted to the Review Committee by the Director-General or by States Parties through the Director-General;

(b) any State Party may submit relevant information for consideration by the Review Committee;

(c) the Director-General may request any State Party, intergovernmental organization or nongovernmental organization in official relations with WHO to place at the disposal of the Review Committee information in its possession concerning the subject of the proposed standing recommendation as specified by the Review Committee;

(d) the Director-General may, at the request of the Review Committee or on the Director-General's own initiative, appoint one or more technical experts to advise the Review Committee. They shall not have the right to vote;

(e) any report containing the views and advice of the Review Committee regarding standing recommendations shall be forwarded to the Director-General for consideration and decision. The Director-General shall communicate the Review Committee's views and advice to the Health Assembly;

(f) the Director-General shall communicate to States Parties any standing recommendation, as well as the modifications or termination of such recommendations, together with the views of the Review Committee; **and**

(g) standing recommendations shall be submitted by the Director-General to the subsequent Health Assembly for its consideration.

PART X – FINAL PROVISIONS

Article 54 Reporting and review

1. States Parties and the Director-General shall report to the Health Assembly on the implementation of these Regulations as decided by the Health Assembly.

2. The Health Assembly shall periodically review the functioning of these Regulations, including financing for their effective implementation. To that end it may request the advice of the Review Committee, through the Director-General. The first such review shall take place no later than five years after the entry into force of these Regulations.

3. WHO shall periodically conduct studies to review and evaluate the functioning of Annex 2. The first such review shall commence no later than one year after the entry into force of these Regulations. The results of such reviews shall be submitted to the Health Assembly for its consideration, as appropriate.

Article 54 bis States Parties Committee for the Implementation of the International Health Regulations (2005)

1. The States Parties Committee for the Implementation of the International Health Regulations (2005) is hereby established to facilitate the effective implementation of these Regulations, in particular of Article 44 and 44 bis. The Committee shall be facilitative and consultative in nature only, and function in a non-adversarial, non-punitive, assistive and transparent manner, guided by the principles set out in Article 3. To this effect:

(a) The Committee shall have the aim of promoting and supporting learning, exchange of best practices, and cooperation among States Parties for the effective implementation of these Regulations;

(b) The Committee shall establish a Subcommittee to provide technical advice and report to the Committee.

2. The Committee shall be comprised of all States Parties and shall meet at least once every two years. Terms of reference for the Committee, including the way that the Committee conducts its business, and for the Subcommittee shall be adopted at the first meeting of the Committee by consensus.

3. The Committee shall have a Chair and a Vice-Chair, elected by the Committee from among its State Party members, who shall serve for two years and rotate on a regional basis.[1]

4. The Committee shall adopt, at its first meeting, by consensus, terms of reference for the Coordinating Financial Mechanism, established in Article 44 bis, and modalities for its operationalization and governance and may adopt necessary working arrangements with relevant international bodies, which may support its operation as appropriate.

[1] For the purposes of this provision, the Holy See and Liechtenstein shall be regarded as belonging to the European Region of WHO, it being understood that this arrangement is without prejudice to their status as States Parties to the International Health Regulations (2005) that are not Members of WHO.

Article 55 Amendments
[Amendments to this Article will enter into force on 31 May 2024]

1. Amendments to these Regulations may be proposed by any State Party or by the Director-General. Such proposals for amendments shall be submitted to the Health Assembly for its consideration.

2. The text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which it is proposed for consideration.

3. Amendments to these Regulations adopted by the Health Assembly pursuant to this Article shall come into force for all States Parties on the same terms, and subject to the same rights and obligations, as provided for in Article 22 of the Constitution of WHO and Articles 59 to 64 of these Regulations.

Article 56 Settlement of disputes

1. In the event of a dispute between two or more States Parties concerning the interpretation or application of these Regulations, the States Parties concerned shall seek in the first instance to settle the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation or conciliation. Failure to reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.

2. In the event that the dispute is not settled by the means described under paragraph 1 of this Article, the States Parties concerned may agree to refer the dispute to the Director-General, who shall make every effort to settle it.

3. A State Party may at any time declare in writing to the Director-General that it accepts arbitration as compulsory with regard to all disputes concerning the interpretation or application of these Regulations to which it is a party or with regard to a specific dispute in relation to any other State Party accepting the same obligation. The arbitration shall be conducted in accordance with the Permanent Court of Arbitration Optional Rules for Arbitrating Disputes between Two States applicable at the time a request for arbitration is made. The States Parties that have agreed to accept arbitration as compulsory shall accept the arbitral award as binding and final. The Director-General shall inform the Health Assembly regarding such action as appropriate.

4. Nothing in these Regulations shall impair the rights of States Parties under any international agreement to which they may be parties to resort to the dispute settlement mechanisms of other intergovernmental organizations or established under any international agreement.

5. In the event of a dispute between WHO and one or more States Parties concerning the interpretation or application of these Regulations, the matter shall be submitted to the Health Assembly.

Article 57 Relationship with other international agreements

1. States Parties recognize that the IHR and other relevant international agreements should be interpreted so as to be compatible. The provisions of the IHR shall not affect the rights and obligations of any State Party deriving from other international agreements.

2. Subject to paragraph 1 of this Article, nothing in these Regulations shall prevent States Parties having certain interests in common owing to their health, geographical, social or economic conditions,

from concluding special treaties or arrangements in order to facilitate the application of these Regulations, and in particular with regard to:

(a) the direct and rapid exchange of public health information between neighbouring territories of different States;

(b) the health measures to be applied to international coastal traffic and to international traffic in waters within their jurisdiction;

(c) the health measures to be applied in contiguous territories of different States at their common frontier;

(d) arrangements for carrying affected persons or affected human remains by means of transport specially adapted for the purpose; and

(e) deratting, disinsection, disinfection, decontamination or other treatment designed to render goods free of disease-causing agents.

3. Without prejudice to their obligations under these Regulations, States Parties that are members of a regional economic integration organization shall apply in their mutual relations the common rules in force in that regional economic integration organization.

Article 58 International sanitary agreements and regulations

1. These Regulations, subject to the provisions of Article 62 and the exceptions hereinafter provided, shall replace as between the States bound by these Regulations and as between these States and WHO, the provisions of the following international sanitary agreements and regulations:

(a) International Sanitary Convention, signed in Paris, 21 June 1926;

(b) International Sanitary Convention for Aerial Navigation, signed at The Hague, 12 April 1933;

(c) International Agreement for dispensing with Bills of Health, signed in Paris, 22 December 1934;

(d) International Agreement for dispensing with Consular Visas on Bills of Health, signed in Paris, 22 December 1934;

(e) Convention modifying the International Sanitary Convention of 21 June 1926, signed in Paris, 31 October 1938;

(f) International Sanitary Convention, 1944, modifying the International Sanitary Convention of 21 June 1926, opened for signature in Washington, 15 December 1944;

(g) International Sanitary Convention for Aerial Navigation, 1944, modifying the International Sanitary Convention of 12 April 1933, opened for signature in Washington, 15 December 1944;

(h) Protocol of 23 April 1946 to prolong the International Sanitary Convention, 1944, signed in Washington;

(i) Protocol of 23 April 1946 to prolong the International Sanitary Convention for Aerial Navigation, 1944, signed in Washington;

(j) International Sanitary Regulations, 1951, and the Additional Regulations of 1955, 1956, 1960, 1963 and 1965; and

(k) the International Health Regulations of 1969 and the amendments of 1973 and 1981.

2. The Pan American Sanitary Code, signed at Havana, 14 November 1924, shall remain in force with the exception of Articles 2, 9, 10, 11, 16 to 53 inclusive, 61 and 62, to which the relevant part of paragraph 1 of this Article shall apply.

Article 59 Entry into force; period for rejection or reservations
[Amendments to this Article will enter into force on 31 May 2024]

1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations or an amendment thereto, shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations or of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, except for:

(a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61;

(b) a State that has made a reservation, for which these Regulations shall enter into force as provided in Article 62;

(c) a State that becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of this Article, and which is not already a party to these Regulations, for which these Regulations shall enter into force as provided in Article 60; and

(d) a State not a Member of WHO that accepts these Regulations, for which they shall enter into force in accordance with paragraph 1 of Article 64.

3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations within the period set out in paragraph 2 of this Article, that State shall submit within the period specified in paragraph 1 of this Article a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than 12 months after the entry into force of these Regulations for that State Party.

Article 60 New Member States of WHO

Any State which becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of Article 59, and which is not already a party to these Regulations, may communicate its rejection of, or any reservation to, these Regulations within a period of **12** months from the date of the notification to it by the Director-General after becoming a Member of WHO. Unless rejected, these Regulations shall enter into force with respect to that State, subject to the

provisions of Articles 62 and 63, upon expiry of that period. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59.

Article 61 Rejection
[Amendments to this Article will enter into force on 31 May 2024]

If a State notifies the Director-General of its rejection of these Regulations or of an amendment thereto within the period provided in paragraph 1 of Article 59, these Regulations or the amendment concerned shall not enter into force with respect to that State. Any international sanitary agreement or regulations listed in Article 58 to which such State is already a party shall remain in force as far as such State is concerned.

Article 62 Reservations
[Amendments to this Article will enter into force on 31 May 2024]

1. States may make reservations to these Regulations in accordance with this Article. Such reservations shall not be incompatible with the object and purpose of these Regulations.

2. Reservations to these Regulations shall be notified to the Director-General in accordance with paragraph 1 of Article 59 and Article 60, paragraph 1 of Article 63 or paragraph 1 of Article 64, as the case may be. A State not a Member of WHO shall notify the Director-General of any reservation with its notification of acceptance of these Regulations. States formulating reservations should provide the Director-General with reasons for the reservations.

3. A rejection in part of these Regulations shall be considered as a reservation.

4. The Director-General shall, in accordance with paragraph 2 of Article 65, issue notification of each reservation received pursuant to paragraph 2 of this Article. The Director-General shall:

(a) if the reservation was made before the entry into force of these Regulations, request those Member States that have not rejected these Regulations to notify him or her within six months of any objection to the reservation; or

(b) if the reservation was made after the entry into force of these Regulations, request States Parties to notify him or her within six months of any objection to the reservation.

States objecting to a reservation should provide the Director-General with reasons for the objection.

5. After this period, the Director-General shall notify all States Parties of the objections he or she has received with regard to reservations. Unless by the end of six months from the date of the notification referred to in paragraph 4 of this Article a reservation has been objected to by one-third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and these Regulations shall enter into force for the reserving State, subject to the reservation.

6. If at least one-third of the States referred to in paragraph 4 of this Article object to the reservation by the end of six months from the date of the notification referred to in paragraph 4 of this Article, the Director-General shall notify the reserving State with a view to its considering withdrawing the reservation within three months from the date of the notification by the Director- General.

7. The reserving State shall continue to fulfil any obligations corresponding to the subject matter of the reservation, which the State has accepted under any of the international sanitary agreements or regulations listed in Article 58.

8. If the reserving State does not withdraw the reservation within three months from the date of the notification by the Director-General referred to in paragraph 6 of this Article, the Director-General shall seek the view of the Review Committee if the reserving State so requests. The Review Committee shall advise the Director-General as soon as possible and in accordance with Article 50 on the practical impact of the reservation on the operation of these Regulations.

9. The Director-General shall submit the reservation, and the views of the Review Committee if applicable, to the Health Assembly for its consideration. If the Health Assembly, by a majority vote, objects to the reservation on the ground that it is incompatible with the object and purpose of these Regulations, the reservation shall not be accepted and these Regulations shall enter into force for the reserving State only after it withdraws its reservation pursuant to Article 63. If the Health Assembly accepts the reservation, these Regulations shall enter into force for the reserving State, subject to its reservation.

Article 63 Withdrawal of rejection and reservation
[Amendments to this Article will enter into force on 31 May 2024]

1. A rejection made under Article 61 may at any time be withdrawn by a State by notifying the Director-General. In such cases, these Regulations shall enter into force with regard to that State upon receipt by the Director-General of the notification, except where the State makes a reservation when withdrawing its rejection, in which case these Regulations shall enter into force as provided in Article 62. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59.

2. The whole or part of any reservation may at any time be withdrawn by the State Party concerned by notifying the Director-General. In such cases, the withdrawal will be effective from the date of receipt by the Director-General of the notification.

Article 64 States not Members of WHO

1. Any State not a Member of WHO, which is a party to any international sanitary agreement or regulations listed in Article 58 or to which the Director-General has notified the adoption of these Regulations by the World Health Assembly, may become a party hereto by notifying its acceptance to the Director-General and, subject to the provisions of Article 62, such acceptance shall become effective upon the date of entry into force of these Regulations, or, if such acceptance is notified after that date, three months after the date of receipt by the Director-General of the notification of acceptance.

2. Any State not a Member of WHO which has become a party to these Regulations may at any time withdraw from participation in these Regulations, by means of a notification addressed to the Director-General which shall take effect six months after the Director-General has received it. The State which has withdrawn shall, as from that date, resume application of the provisions of any international sanitary agreement or regulations listed in Article 58 to which it was previously a party.

Article 65 Notifications by the Director-General

1. The Director-General shall notify all States Members and Associate Members of WHO, and also other parties to any international sanitary agreement or regulations listed in Article 58, of the adoption by the Health Assembly of these Regulations.

2. The Director-General shall also notify these States, as well as any other State which has become a party to these Regulations or to any amendment to these Regulations, of any notification received by WHO under Articles 60 to 64 respectively, as well as of any decision taken by the Health Assembly under Article 62.

Article 66 Authentic texts

1. The Arabic, Chinese, English, French, Russian and Spanish texts of these Regulations shall be equally authentic. The original texts of these Regulations shall be deposited with WHO.

2. The Director-General shall send, with the notification provided in paragraph 1 of Article 59, certified copies of these Regulations to all Members and Associate Members, and also to other parties to any of the international sanitary agreements or regulations listed in Article 58.

3. Upon the entry into force of these Regulations, the Director-General shall deliver certified copies thereof to the Secretary-General of the United Nations for registration in accordance with Article 102 of the Charter of the United Nations.

ANNEX 1

~~A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE~~

CORE CAPACITIES

1. States Parties shall utilize existing national structures and resources to meet their core capacit~~y~~**ies** requirements under these Regulations, including with regard to:

(a) their **prevention** surveillance, reporting, notification, verification, **preparedness,** response and collaboration activities; and

(b) their activities concerning designated airports, ports and ground crossings.

2. Each State Party shall assess, within two years following the entry into force of these Regulations for that State Party, the ability of existing national structures and resources to meet the minimum requirements described in this Annex. As a result of such assessment, States Parties shall develop and implement plans of action to ensure that these core capacities are present and functioning throughout their territories as set out in paragraph 1 of Article 5, ~~and~~ paragraph 1 of Article 13 **and subparagraph (a) of Article 19**.

3. States Parties and WHO shall support assessments, planning and implementation processes under this Annex.

4. Pursuant to Article ~~4~~4, States Parties shall undertake to collaborate with each other, to the extent possible, in developing, strengthening and maintaining core capacities.

A. CORE CAPACITIES REQUIREMENTS FOR PREVENTION, SURVEILLANCE, PREPAREDNESS AND RESPONSE

41. At the local community level and/or primary public health response level **(hereinafter the "Local level"), each State Party shall develop, strengthen and maintain** ~~T~~the **core** capacities:

(a) to detect events involving disease or death above expected levels for the particular time and place in all areas within the territory of the State Party; and

(b) to report all available essential information immediately to the appropriate level of health-care response. At the community level, reporting shall be to local community health-care institutions or the appropriate health personnel. At the primary public health response level, reporting shall be to the intermediate or national response level, depending on organizational structures. For the purposes of this Annex, essential information includes the following: clinical descriptions, laboratory results, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed; ~~and~~

(c) to **prepare for the implementation of, and** implement **immediately,** preliminary control measures ~~immediately.~~;

(d) to prepare for the provision of, and facilitate access to health services necessary for responding to public health risks and events; and

(e) to engage relevant stakeholders, including communities, in preparing for and responding to public health risks and events.

~~5~~**2**. At the intermediate public health response levels **(hereinafter the "Intermediate level"), where applicable,[1], each State Party shall develop, strengthen and maintain** ~~T~~**the core** capacities:

(a) to confirm the status of reported events and to support or implement additional control measures; and

(b) to assess reported events immediately and, if found urgent, to report all essential information to the national level. For the purposes of this Annex, the criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread.; **and**

(c) to coordinate with and support the Local level in preventing, preparing for and responding to public health risks and events, including in relation to:

(i) surveillance;

(ii) on-site investigations;

(iii) laboratory diagnostics, including referral of samples;

(iv) implementation of control measures;

(v) access to health services and health products needed for the response;

(vi) risk communication, including addressing misinformation and disinformation;

(vii) logistical assistance (e.g. equipment, medical and other relevant supplies and transport); and

~~6~~**3**. At the national level

Assessment and notification. **Each State Party shall develop, strengthen and maintain** ~~T~~**the core** capacities:

(a) to assess all reports of urgent events within 48 hours; and

(b) to notify WHO immediately through the National IHR Focal Point when the assessment indicates the event is notifiable pursuant to paragraph 1 of Article 6 and Annex 2 and to inform WHO as required pursuant to Article 7 and paragraph 2 of Article 9.

[1] In States Parties where, because of their administrative structure, an Intermediate level either absent or not clearly identifiable, the core capacities listed in subparagraphs (a) through (e) of this paragraph shall be understood to be developed, strengthened or maintained either at the Local level or at the National level, as appropriate, in accordance with national laws and context.

Public health ***prevention, preparedness and*** *response.* **Each State Party shall develop, strengthen and maintain the core** capacities **for**:

(**a bis**) ~~to~~ **rapidly** determin**e**ing ~~rapidly the~~ control measures required to prevent domestic and international spread;

(b) surveillance;

(~~b~~**c**) **deploying** specialized staff~~;~~

(d) laboratory analysis of samples (domestically or through collaborating centres) ~~and~~**;**

(e) logistical assistance (e.g. equipment, **medical and other relevant** supplies and transport);

(~~e~~**f**) ~~to~~ provid**e**ing on-site assistance as required to supplement local investigations;

(g) developing and/or disseminating guidance for clinical case management and infection prevention and control;

(h) access to health services and health products needed for the response;

(i) risk communication, including addressing misinformation and disinformation;

(~~d~~**j**) ~~to~~ provid**e**ing a direct operational link with senior health and other officials to approve rapidly and implement containment and control measures;

(~~e~~**k**) provi**d**ing direct liaison with other relevant government ministries;

(~~f~~**l**) ~~to~~ provid**e**ing, by the most efficient means of communication available links with hospitals, clinics, airports, ports, ground crossings, laboratories and other key operational areas for the dissemination of ~~information and~~ recommendations received from WHO regarding events in the State Party's own territory and in the territories of other States Parties;

(~~g~~**m**) ~~to~~ establishing, operat**e**ing and maintaining a national public health emergency response plan, including the creation of multidisciplinary/multisectoral teams to respond to events that may constitute a public health emergency of international concern;

(m bis) coordinating activities nationally and supporting Local and Intermediate levels, where applicable, in preventing, preparing for and responding to public health risks and events; and

(~~h~~**n**) providing the foregoing on a 24-hour basis.

B. CORE CAPACITY~~Y~~IES REQUIREMENTS FOR DESIGNATED AIRPORTS, PORTS AND GROUND CROSSINGS

1. At all times, **each State Party shall develop, strengthen and maintain** ~~T~~**the core** capacities:

(a) to provide access to (i) an appropriate medical service, including diagnostic facilities located so as to allow the prompt assessment and care of ill travellers, and (ii) adequate staff, equipment and premises;

(b) to provide access to equipment and personnel for the transport of ill travellers to an appropriate medical facility;

(c) to provide trained personnel for the inspection of conveyances;

(d) to ensure a safe environment for travellers using point of entry facilities, including potable water supplies, eating establishments, flight catering facilities, public washrooms, appropriate solid and liquid waste disposal services and other potential risk areas, by conducting inspection programmes, as appropriate; and

(e) to provide as far as practicable a programme and trained personnel for the control of vectors and reservoirs in and near points of entry.

2. For responding to events that may constitute a public health emergency of international concern, **each State Party shall develop, strengthen and maintain** ~~T~~**the core** capacities:

(a) to provide appropriate public health emergency response by establishing and maintaining a public health emergency contingency plan, including the nomination of a coordinator and contact points for relevant point of entry, public health and other agencies and services;

(b) to provide assessment of and care for affected travellers or animals by establishing arrangements with local medical and veterinary facilities **and laboratories,** for their isolation~~,~~ **and** treatment**, the analysis of their samples,** and other support services that may be required;

(c) to provide appropriate space, separate from other travellers, to interview suspect or affected persons;

(d) to provide for the assessment and, if required, quarantine of suspect travellers, preferably in facilities away from the point of entry;

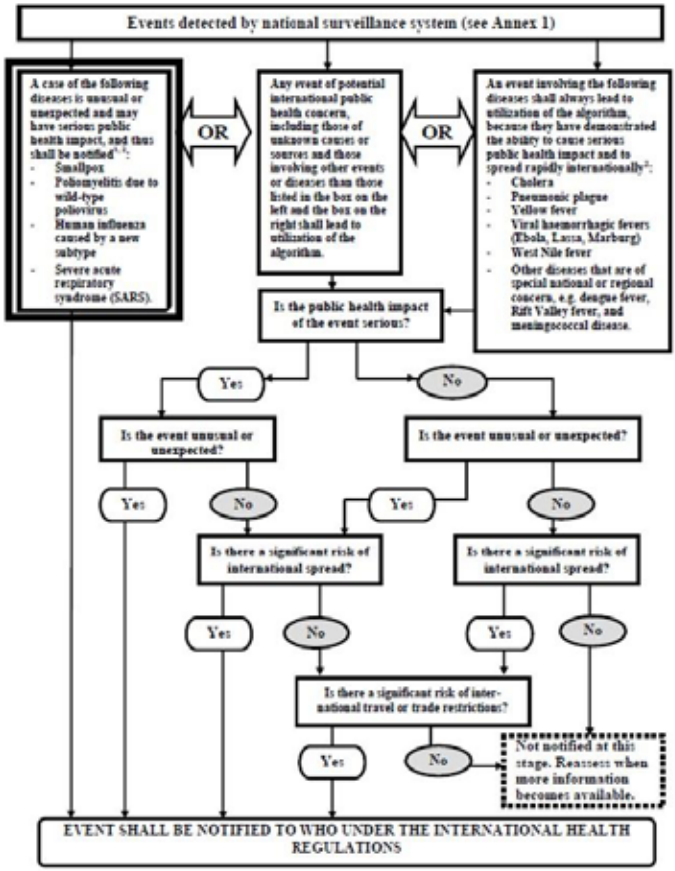
(e) to apply recommended measures to disinsect, derat, disinfect, decontaminate or otherwise treat baggage, cargo, containers, conveyances, goods or postal parcels, including, when appropriate, at locations specially designated and equipped for this purpose;

(f) to apply entry or exit controls for arriving and departing travellers; and

(g) to provide access to specially designated equipment, and to trained personnel with appropriate personal protection, for the transfer of travellers who may carry infection or contamination.

ANNEX 2

DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN



[1] As per WHO case definitions.
[2] The disease list shall be used only for the purposes of these Regulations.

{LEFT BOX}

A case of the following diseases is unusual or unexpected and may have serious public health impact, and thus shall be notified:[1,2]

- Smallpox
- Poliomyelitis due to ~~wild-type~~ polioviruses
- Human influenza caused by a new subtype
- Severe acute respiratory syndrome (SARS).

{MIDDLE BOX}

Any event of potential international public health concern, and those of unknown causes or sources, **in particular clusters of cases of severe acute respiratory disease of unknown or novel cause**, and those involving other events or diseases than those listed in the box on the left and the box on the right shall lead to utilization of the algorithm.

EXAMPLES FOR THE APPLICATION OF THE DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN

The examples appearing in this Annex are not binding and are for indicative guidance purposes to assist in the interpretation of the decision instrument criteria.

DOES THE EVENT MEET AT LEAST TWO OF THE FOLLOWING CRITERIA?

Is the public health impact of the event serious?	**I. Is the public health impact of the event serious?**
	1. *Is the number of cases and/or number of deaths for this type of event large for the given place, time or population?*
	2. *Has the event the potential to have a high public health impact?* THE FOLLOWING ARE EXAMPLES OF CIRCUMSTANCES THAT CONTRIBUTE TO HIGH PUBLIC HEALTH IMPACT: ✓ Event caused by a pathogen with high potential to cause epidemic (infectiousness of the agent, high case fatality, multiple transmission routes or healthy carrier). ✓ Indication of treatment failure (new or emerging antibiotic resistance, vaccine failure, antidote resistance or failure). ✓ Event represents a significant public health risk even if no or very few human cases have yet been identified. ✓ Cases reported among health staff. ✓ The population at risk is especially vulnerable (refugees, low level of immunization, children, elderly, low immunity, undernourished, etc.). ✓ Concomitant factors that may hinder or delay the public health response (natural catastrophes, armed conflicts, unfavourable weather conditions, multiple foci in the State Party). ✓ Event in an area with high population density. ✓ Spread of toxic, infectious or otherwise hazardous materials that may be occurring naturally or otherwise that has contaminated or has the potential to contaminate a population and/or a large geographical area.
	3. *Is external assistance needed to detect, investigate, respond and control the current event, or prevent new cases?* THE FOLLOWING ARE EXAMPLES OF WHEN ASSISTANCE MAY BE REQUIRED: ✓ Inadequate human, financial, material or technical resources – in particular: – insufficient laboratory or epidemiological capacity to investigate the event (equipment, personnel, financial resources); – insufficient antidotes, drugs and/or vaccine and/or protective equipment, decontamination equipment, or supportive equipment to cover estimated needs; – existing surveillance system is inadequate to detect new cases in a timely manner.
	IS THE PUBLIC HEALTH IMPACT OF THE EVENT SERIOUS? **Answer "yes" if you have answered "yes" to questions 1, 2 or 3 above.**

Is the event unusual or unexpected?	II. Is the event unusual or unexpected?
	4. Is the event unusual? THE FOLLOWING ARE EXAMPLES OF UNUSUAL EVENTS: ✓ The event is caused by an unknown agent or the source, vehicle, route of transmission is unusual or unknown. ✓ Evolution of cases more severe than expected (including morbidity or case-fatality) or with unusual symptoms. ✓ Occurrence of the event itself unusual for the area, season or population.
	5. Is the event unexpected from a public health perspective? THE FOLLOWING ARE EXAMPLES OF UNEXPECTED EVENTS: ✓ Event caused by a disease/agent that had already been eliminated or eradicated from the State Party or not previously reported.
	IS THE EVENT UNUSUAL OR UNEXPECTED? **Answer "yes" if you have answered "yes" to questions 4 or 5 above.**

Is there a significant risk of international spread?	III. Is there a significant risk of international spread?
	6. Is there evidence of an epidemiological link to similar events in other States?
	7. Is there any factor that should alert us to the potential for cross border movement of the agent, vehicle or host? THE FOLLOWING ARE EXAMPLES OF CIRCUMSTANCES THAT MAY PREDISPOSE TO INTERNATIONAL SPREAD: ✓ Where there is evidence of local spread, an index case (or other linked cases) with a history within the previous month of: – international travel (or time equivalent to the incubation period if the pathogen is known); – participation in an international gathering (pilgrimage, sports event, conference, etc.); – close contact with an international traveller or a highly mobile population. ✓ Event caused by an environmental contamination that has the potential to spread across international borders. ✓ Event in an area of intense international traffic with limited capacity for sanitary control or environmental detection or decontamination.
	IS THERE A SIGNIFICANT RISK OF INTERNATIONAL SPREAD? **Answer "yes" if you have answered "yes" to questions 6 or 7 above.**

Risk of international restrictions?	IV. Is there a significant risk of international travel or trade restrictions?
	8. Have similar events in the past resulted in international restriction on trade and/or travel?
	9. Is the source suspected or known to be a food product, water or any other goods that might be contaminated that has been exported/imported to/from other States?
	10. Has the event occurred in association with an international gathering or in an area of intense international tourism?
	11. Has the event caused requests for more information by foreign officials or international media?
	IS THERE A SIGNIFICANT RISK OF INTERNATIONAL TRADE OR TRAVEL RESTRICTIONS? **Answer "yes" if you have answered "yes" to questions 8, 9, 10 or 11 above.**

States Parties that answer "yes" to the question whether the event meets any two of the four criteria (I-IV) above, shall notify WHO under Article 6 of the International Health Regulations.

ANNEX 3

MODEL SHIP SANITATION CONTROL EXEMPTION CERTIFICATE/SHIP SANITATION CONTROL CERTIFICATE

Port of ..... Date: .....

This Certificate records the inspection and 1) exemption from control or 2) control measures applied

Name of ship or inland navigation vessel .....Flag ..... Registration/IMO No. .....

At the time of inspection the holds were unladen/laden with ..... tonnes of ..... cargo

Name and address of inspecting officer .....

Ship Sanitation Control Exemption Certificate

Areas, [systems, and services] inspected	Evidence found[1]	Sample results[2]	Documents reviewed
Galley			Medical log
Pantry			Ship's log
Stores			Other
Hold(s)/cargo			
Quarters:			
- crew			
- officers			
- passengers			
- deck			
Potable water			
Sewage			
Ballast tanks			
Solid and medical waste			
Standing water			
Engine room			
Medical facilities			
Other areas specified - see attached			
Note areas not applicable, by marking N/A.			

No evidence found. Ship/vessel is exempted from control measures.

Name and designation of issuing officer .....

Ship Sanitation Control Certificate

Control measures applied	Re-inspection date	Comments regarding conditions found

Control measures indicated were applied on the date below.

Signature and seal ..... Date .....

[1] (a) Evidence of infection or contamination, including vectors in all stages of growth; animal reservoirs for vectors; rodents or other species that could carry human disease, microbiological, chemical and other risks to human health; signs of inadequate sanitary measures. (b) Information concerning any human cases (to be included in the ~~Maritime~~ **Ship** Declaration of Health).

[2] Results from samples taken on board. Analysis to be provided to ship's master by most expedient means and, if re-inspection is required, to the next appropriate port of call coinciding with the re-inspection date specified in this certificate.

Sanitation Control Exemption Certificates and Sanitation Control Certificates are valid for a maximum of six months, but the validity period may be extended by one month if inspection cannot be carried out at the port and there is no evidence of infection or contamination.

ATTACHMENT TO MODEL SHIP SANITATION CONTROL EXEMPTION CERTIFICATE/SHIP SANITATION CONTROL CERTIFICATE

Areas/facilities/systems inspected[1]	Evidence found	Sample results	Documents reviewed	Control measures applied	Re-inspection date	Comments regarding conditions found
Food						
Source						
Storage						
Preparation						
Service						
Water						
Source						
Storage						
Distribution						
Waste						
Holding						
Treatment						
Disposal						
Swimming pools/spas						
Equipment						
Operation						
Medical facilities						
Equipment and medical devices						
Operation						
Medicines						
Other areas inspected						

[1] Indicate when the areas listed are not applicable by marking N/A.

ANNEX 4

TECHNICAL REQUIREMENTS PERTAINING TO CONVEYANCES AND CONVEYANCE OPERATORS

Section A Conveyance operators

1. Conveyance operators shall **prepare for, as appropriate, and** facilitate:

   (a) inspections of the cargo, containers and conveyance;

   (b) medical examinations of persons on board;

   (c) application of other health measures under these Regulations, **including on board as well as during embarkation and disembarkation**; and

   (d) provision of relevant public health information requested by the State Party.

2. Conveyance operators shall provide to the competent authority a valid Ship Sanitation Control Exemption Certificate or a Ship Sanitation Control Certificate or a ~~Maritime~~ **Ship** Declaration of Health, or the Health Part of an Aircraft General Declaration, as required under these Regulations.

Section B Conveyances

1. Control measures applied to baggage, cargo, containers, conveyances and goods under these Regulations shall be carried out so as to avoid as far as possible injury or discomfort to persons or damage to the baggage, cargo, containers, conveyances and goods. Whenever possible and appropriate, control measures shall be applied when the conveyance and holds are empty.

2. States Parties shall indicate in writing the measures applied to cargo, containers or conveyances, the parts treated, the methods employed, and the reasons for their application. This information shall be provided in writing to the person in charge of an aircraft and, in case of a ship, on the Ship Sanitation Control Certificate. For other cargo, containers or conveyances, States Parties shall issue such information in writing to consignors, consignees, carriers, the person in charge of the conveyance or their respective agents.

ANNEX 5

SPECIFIC MEASURES FOR VECTOR-BORNE DISEASES

1. WHO shall publish, on a regular basis, a list of areas where disinsection or other vector control measures are recommended for conveyances arriving from these areas. Determination of such areas shall be made pursuant to the procedures regarding temporary or standing recommendations, as appropriate.

2. Every conveyance leaving a point of entry situated in an area where vector control is recommended should be disinsected and kept free of vectors. When there are methods and materials advised by the Organization for these procedures, these should be employed. The presence of vectors on board conveyances and the control measures used to eradicate them shall be included:

(a) in the case of aircraft, in the Health Part of the Aircraft General Declaration, unless this part of the Declaration is waived by the competent authority at the airport of arrival;

(b) in the case of ships, on the Ship Sanitation Control Certificates; and

(c) in the case of other conveyances, on a written proof of treatment issued to the consignor, consignee, carrier, the person in charge of the conveyance or their agent, respectively.

3. States Parties should accept disinsecting, deratting and other control measures for conveyances applied by other States if methods and materials advised by the Organization have been applied.

4. States Parties shall establish programmes to control vectors that may transport an infectious agent that constitutes a public health risk to a minimum distance of 400 metres from those areas of point of entry facilities that are used for operations involving travellers, conveyances, containers, cargo and postal parcels, with extension of the minimum distance if vectors with a greater range are present.

5. If a follow-up inspection is required to determine the success of the vector control measures applied, the competent authorities for the next known port or airport of call with a capacity to make such an inspection shall be informed of this requirement in advance by the competent authority advising such follow-up. In the case of ships, this shall be noted on the Ship Sanitation Control Certificate.

6. A conveyance may be regarded as suspect and should be inspected for vectors and reservoirs if:

(a) it has a possible case of vector-borne disease on board;

(b) a possible case of vector-borne disease has occurred on board during an international voyage; or

(c) it has left an affected area within a period of time where on-board vectors could still carry disease.

7. A State Party should not prohibit the landing of an aircraft or berthing of a ship in its territory if the control measures provided for in paragraph 3 of this Annex or otherwise recommended by the Organization are applied. However, aircraft or ships coming from an affected area may be required to land at airports or divert to another port specified by the State Party for that purpose.

8. A State Party may apply vector control measures to a conveyance arriving from an area affected by a vector-borne disease if the vectors for the foregoing disease are present in its territory.

ANNEX 6

VACCINATION, PROPHYLAXIS AND RELATED CERTIFICATES

1. Vaccines or other prophylaxis specified in Annex 7 or recommended under these Regulations shall be of suitable quality; those vaccines and prophylaxis designated by WHO shall be subject to its approval. Upon request, the State Party shall provide to WHO appropriate evidence of the suitability of vaccines and prophylaxis administered within its territory under these Regulations.

2. Persons undergoing vaccination or other prophylaxis under these Regulations shall be provided with an international certificate of vaccination or prophylaxis (hereinafter the "certificate") in the form specified in this Annex. No departure shall be made from the model of the certificate specified in this Annex.

3. Certificates under this Annex are valid only if the vaccine or prophylaxis used has been approved by WHO.

4. Certificates **under this Annex issued in non-digital format** must be signed ~~in the hand of~~ **by** the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. Such certificates must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature. **Regardless of the format in which they have been issued, certificates must bear the name of the clinician supervising the administration of the vaccine or prophylaxis, or of the relevant authority responsible for issuing the certificate or overseeing the administering centre.**

5. Certificates shall be fully completed in English or in French. They may also be completed in another language, in addition to either English or French.

6. Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.

7. Certificates are individual and shall in no circumstances be used collectively. Separate certificates shall be issued for children.

8. **For certificates under this Annex issued in non-digital format,** Aa parent or guardian shall sign the certificate when the child is unable to write. ~~The signature of an illiterate~~ **A person who is unable to sign** shall be indicated in the usual manner by the person's mark and the indication by another that this is the mark of the person concerned, **which shall be considered their signature. With respect to persons with a guardian, the guardian shall sign the certificate on their behalf.**

9. If the supervising clinician is of the opinion that the vaccination or prophylaxis is contraindicated on medical grounds, the supervising clinician shall provide the person with reasons, written in English or French, and where appropriate in another language in addition to English or French, underlying that opinion, which the competent authorities on arrival should take into account. The supervising clinician and competent authorities shall inform such persons of any risk associated with non-vaccination and with the non-use of prophylaxis in accordance with paragraph 4 of Article 23.

10. An equivalent document issued by the Armed Forces to an active member of those Forces shall be accepted in lieu of an international certificate in the form shown in this Annex if:

(a) it embodies medical information substantially the same as that required by such form; and

(b) it contains a statement in English or in French and where appropriate in another language in addition to English or French recording the nature and date of the vaccination or prophylaxis and to the effect that it is issued in accordance with this paragraph.

MODEL INTERNATIONAL CERTIFICATE OF VACCINATION OR PROPHYLAXIS

This is to certify that [name] ....., date of birth ....., sex .....,

nationality ....., national identification document, if applicable .....

whose signature follows[1] ……....., **or, if applicable:**

name of the parent or guardian ……..**and**

signature of the parent or guardian[1] ……..

has on the date indicated been vaccinated or received prophylaxis against:

(name of disease or condition) ……

in accordance with the International Health Regulations.

Vaccine or prophylaxis	Date	Name, ~~signature and professional status~~ of supervising clinician, or relevant authority responsible for issuing this certificate, or for overseeing the administering centre	Signature of supervising clinician[1]	Manufacturer and batch No. of vaccine or prophylaxis	Certificate valid from ..... until	Official stamp of administering centre[1]
1.						
2.						

This certificate is valid only if the vaccine or prophylaxis used has been approved by the World Health Organization.

This certificate **in non-digital format** must be signed ~~in the hand of~~ **by** the clinician, who shall be a medical practitioner or other authorized health worker, supervising the administration of the vaccine or prophylaxis. The certificate must also bear the official stamp of the administering centre; however, this shall not be an accepted substitute for the signature. **Regardless of the format in which this certificate has been issued, it must bear the name of the clinician supervising the administration of the vaccine or prophylaxis, or of the relevant authority responsible for issuing the certificate or overseeing the administering centre.**

Any amendment of this certificate, or erasure, or failure to complete any part of it, may render it invalid.

The validity of this certificate shall extend until the date indicated for the particular vaccination or prophylaxis. The certificate shall be fully completed in English or in French. The certificate may also be completed in another language on the same document, in addition to either English or French.

[1] **Only applies to certificates issued in non-digital format.**

ANNEX 7

REQUIREMENTS CONCERNING VACCINATION OR PROPHYLAXIS FOR SPECIFIC DISEASES[1]

1. In addition to any recommendation concerning vaccination or prophylaxis, the following diseases are those specifically designated under these Regulations for which proof of vaccination or prophylaxis may be required for travellers as a condition of entry to a State Party:

Vaccination against yellow fever.

2. Recommendations and requirements for vaccination against yellow fever:

(a) For the purpose of this Annex:

(i) the incubation period of yellow fever is six days;

(ii) yellow fever vaccines approved by WHO provide protection against infection starting 10 days following the administration of the vaccine;

(iii) this protection continues for the life of the person vaccinated; and

(iv) the validity of a certificate of vaccination against yellow fever shall extend for the life of the person vaccinated, beginning 10 days after the date of vaccination.

(b) Vaccination against yellow fever may be required of any traveller leaving an area where the Organization has determined that a risk of yellow fever transmission is present.

(c) If a traveller is in possession of a certificate of vaccination against yellow fever which is not yet valid, the traveller may be permitted to depart, but the provisions of paragraph 2(h) of this Annex may be applied on arrival.

(d) A traveller in possession of a valid certificate of vaccination against yellow fever shall not be treated as suspect, even if coming from an area where the Organization has determined that a risk of yellow fever transmission is present.

(e) In accordance with paragraph 1 of Annex 6 the yellow fever vaccine used must be approved by the Organization.

(f) States Parties shall designate specific yellow fever vaccination centres within their territories in order to ensure the quality and safety of the procedures and materials employed.

[1] Amended by the Sixty-seventh World Health Assembly as to subparagraphs (iii) and (iv) of Section 2(a) in WHA67.13, 24 May 2014. This amendment entered into force for all IHR (2005) States Parties as of 11 July 2016.

(g) Every person employed at a point of entry in an area where the Organization has determined that a risk of yellow fever transmission is present, and every member of the crew of a conveyance using any such point of entry, shall be in possession of a valid certificate of vaccination against yellow fever.

(h) A State Party, in whose territory vectors of yellow fever are present, may require a traveller from an area where the Organization has determined that a risk of yellow fever transmission is present, who is unable to produce a valid certificate of vaccination against yellow fever, to be quarantined until the certificate becomes valid, or until a period of not more than six days, reckoned from the date of last possible exposure to infection, has elapsed, whichever occurs first.

(i) Travellers who possess an exemption from yellow fever vaccination, signed by an authorized medical officer or an authorized health worker, may nevertheless be allowed entry, subject to the provisions of the foregoing paragraph of this Annex and to being provided with information regarding protection from yellow fever vectors. Should the travellers not be quarantined, they may be required to report any feverish or other symptoms to the competent authority and be placed under surveillance.

ANNEX 8

MODEL OF ~~MARITIME~~ SHIP DECLARATION OF HEALTH

To be completed and submitted to the competent authorities by the masters of ships arriving from foreign ports.
Submitted at the port of ..... Date .....
Name of ship or inland navigation vessel ..... Registration/IMO No ..... arriving from ..... sailing to .....
(Nationality)(Flag of vessel) ..... Master's name .....
Gross tonnage (ship) .....
Tonnage (inland navigation vessel) .....
Valid Sanitation Control Exemption/Control Certificate carried on board? Yes ..... No ..... Issued at ..... date .....
Re-inspection required? Yes ..... No .....
Has ship/vessel visited an affected area identified by the World Health Organization? Yes ..... No .....
Port and date of visit .....
List ports of call from commencement of voyage with dates of departure, or within past thirty days, whichever is shorter:

Upon request of the competent authority at the port of arrival, list crew members, passengers or other persons who have joined ship/vessel since international voyage began or within past thirty days, whichever is shorter, including all ports/countries visited in this period (add additional names to the attached schedule):

(1) Name ..... joined from: (1) ..... (2) ..... (3) .....
(2) Name ..... joined from: (1) ..... (2) ..... (3) .....
(3) Name ..... joined from: (1) ..... (2) ..... (3) .....

Number of crew members on board .....
Number of passengers on board .....

Health questions

(1) Has any person died on board during the voyage otherwise than as a result of accident? Yes ..... No .....
If yes, state particulars in attached schedule. Total no. of deaths: .....

(2) Is there on board or has there been during the international voyage any case of disease which you suspect to be of an infectious nature? Yes ..... No ..... If yes, state particulars in attached schedule.

(3) Has the total number of ill passengers during the voyage been greater than normal/expected? Yes ..... No .....
How many ill persons? .....

(4) Is there any ill person on board now? Yes ..... No ..... If yes, state particulars in attached schedule.

(5) Was a medical practitioner consulted? Yes ..... No ..... If yes, state particulars of medical treatment or advice provided in attached schedule.

(6) Are you aware of any condition on board which may lead to infection or spread of disease? Yes ..... No .....
If yes, state particulars in attached schedule.

(7) Has any sanitary measure (e.g. quarantine, isolation, disinfection or decontamination) been applied on board? Yes ..... No .....
If yes, specify type, place and date .....

(8) Have any stowaways been found on board? Yes ..... No ..... If yes, where did they join the ship (if known)? .....

(9) Is there a sick animal or pet on board? Yes ..... No .....

Note: In the absence of a surgeon, the master should regard the following symptoms as grounds for suspecting the existence of a disease of an infectious nature:

(a) fever, persisting for several days or accompanied by (i) prostration; (ii) decreased consciousness; (iii) glandular swelling; (iv) jaundice; (v) cough or shortness of breath; (vi) unusual bleeding; or (vii) paralysis.

(b) with or without fever: (i) any acute skin rash or eruptions; (ii) severe vomiting (other than sea sickness); (iii) severe diarrhoea; or (iv) recurrent convulsions.

I hereby declare that the particulars and answers to the questions given in this Declaration of Health (including the schedule) are true and correct to the best of my knowledge and belief.

Signed .....
Master

Countersigned .....
Ship's Surgeon (if carried)

Date .....

ATTACHMENT TO MODEL OF ~~MARITIME~~ **SHIP** DECLARATION OF HEALTH

Name	Class or rating	Age	Sex	Nationality	Port, date joined ship/vessel	Nature of illness	Date of onset of symptoms	Reported to a port medical officer?	Disposal of case[1]	Drugs, medicines or other treatment given to patient	Comments

[1] State: (1) whether the person recovered, is still ill or died, and (2) whether the person is still on board, was evacuated (including the name of the port or airport), or was buried at sea.

ANNEX 9

THIS DOCUMENT IS PART OF THE AIRCRAFT GENERAL DECLARATION, PROMULGATED BY THE INTERNATIONAL CIVIL AVIATION ORGANIZATION

HEALTH PART OF THE AIRCRAFT GENERAL DECLARATION[1]

Declaration of Health

Name and seat number or function of persons on board with illnesses other than airsickness or the effects of accidents, who may be suffering from a communicable disease (a fever – temperature 38°C/100 °F or greater – associated with one or more of the following signs or symptoms, e.g. appearing obviously unwell; persistent coughing; impaired breathing; persistent diarrhoea; persistent vomiting; skin rash; bruising or bleeding without previous injury; or confusion of recent onset, increases the likelihood that the person is suffering a communicable disease) as well as such cases of illness disembarked during a previous stop ……

……

Details of each disinsecting or sanitary treatment (place, date, time, method) during the flight. If no disinsecting has been carried out during the flight, give details of most recent disinsecting

……

……

…… Signature, if required, with time and date _____

Crew member concerned

Eighth plenary meeting, 1 June 2024
A77/VR/8

= = =

[1] This version of the Aircraft General Declaration entered into force on 15 July 2007. The full document may be obtained from the website of the International Civil Aviation Organization at http://www.icao.int.

Annex 5

Joint letter signed by over 800 individuals and organizations from Latin America led by the Feminists for a People's Vaccine campaign and sent in July 2023 to the WGIHR Co-Chairs requesting that equity provisions be guaranteed in the IHR amendments

FEMINISTS FOR A PEOPLE'S VACCINE

We, the undersigned civil society organizations (CSO) and individuals strongly urge you to learn from the lessons of the COVID-19 pandemic and achieve a stronger collective response that upholds human rights, equity, and solidarity.

In light of this, we request you to fully support the amendment proposals on the International Health Regulations (IHR) that promote equitable access to health products and other equity issues, such as financial mechanisms at the upcoming meeting of the Working Group on International Health Regulations (WGHIR) scheduled to take place between July 24 and 28, 2023.

As you are aware, at the ongoing IHR amendment process, the global North is pushing an agenda to create onerous obligations on the global South without facilitating equitable access to health products required for the preparedness and response of a public health emergency of international concern (PHEIC). IHR also allows parties to take additional measures, which are often misused by the North and take unilateral measures like travel bans, as happened during the Omicron outbreak.

IHR 2005 is a highly inequitable regime which effectively institutionalises an one-way traffic of information on disease outbreaks from the global South to the global North, which leaves out any obligation on them to facilitate equitable access to health products. Further, IHR 2005 does not take into account the development divide and treats all countries equally. This equal treatment of unequal countries should be rectified urgently by incorporating the principle of common but differentiated responsibilities (CbDR).

Similarly, it is important to address access and benefit sharing to facilitate fair and equitable benefits emerging from the sharing of pathogens or their genetic sequence data. IHR also requires establishing its own financial mechanism to assist developing countries in effectively implementing IHR obligations.

Against this background, we request you to support the following proposals.

• *Article 3: Principles - New paragraph proposals for Paragraphs 2 bis and 5.*

• *Article 5 Paragraph 1, Article 13 Paragraph 1, and Annex 1 New Paragraph 1 bis - On CBDR application*

• *Article 6 New Paragraph 3 - on Access and Benefit Sharing Mechanism*

• *Article 13(5) and New Article proposed on Article 13A - on Equitable access to health products and technologies*

• *Article 43, new paragraph 3 bis, and text edits to paragraph 4, 5 and 6 - On disciplining additional health measures such as excessive or discriminatory travel bans etc.*

• *Article 44A - On establishing a new financial mechanism.*

• *Article 53A - On establishing an implementation committee open to all Member States.*

We also take note of a possible proposal from the global North to address these issues in a new Instrument for Pandemic Prevention, Preparedness and Response being developed in another parallel process at the Intergovernmental Negotiating Body (INB), popularly known as the Pandemic Treaty. However, we would like to reiterate that IHR 2005 is the only existing legal instrument and it has universal membership, which cannot be guaranteed by this new pandemic instrument.

In solidarity,

FEMINISTS FOR A PEOPLE'S VACCINE

Annex

Article 3: Principles - New paragraph proposals for Paragraphs 2 bis and 5.

On Paragraphs 2 and 5 being proposed, the principles of equity and solidarity are reiterated and the principle of Common But Differentiate Responsibilities and Respective Capabilities (CBDR-RC) is introduced attached to international financial assistance, tech transfer and public health systems resilience in accordance to respective level of development.

> Article 3, Paragraphs 2 bis, regarding Principles, it is proposed "Common But Differentiate Responsibilities and Respective Capabilities (CBDR-RC), availability of international financial assistance and shared technological resources, and in this regard, primary preference shall be given to the establishment of functioning public health systems resilient to public health emergencies".
>
> On new Article 5 being proposed, States shall follow the regulations "on the basis of equity, solidarity as well as and in accordance with their common but differentiated responsibilities and respective level of development of the State Parties".

Article 5 : Surveillance - Paragraph 1 and Article 3

On Paragraph 1, establishing concrete language on the application of the principle of CBdR, it is proposed that developed countries and WHO shall offer assistance and, upon the request of State Parties, provide or facilitate technical support and assist in mobilization of financial resources to develop, strengthen and maintain capacities in regards to surveillance.

> "Developed State Parties and WHO shall offer assistance to developing State Parties depending on the availability of finance, technology and know-how for the full implementation of this article, in pursuance of the Article 44. This capacity will be periodically reviewed through the Universal Health Periodic Review mechanism, in replacement of the Joint External Evaluation that began in 2016. Such review shall / ALT Should such review identify resource constraints and other challenges in attaining these capacities, WHO and its Regional Offices shall, upon the request of a State Party, provide or facilitate technical support and assist in mobilization of financial resources to develop, strengthen and maintain such capacities."

On Article 3, attributes to developed State Parties the duty to assist upon request to build capacity on surveillance.

Article 13: Public health response

Paragraph 1

On Paragraph 1, establishing concrete language on the application of the principle of CBdR, it is proposed that developed countries and WHO shall offer assistance and, upon the request of State Parties, provide or facilitate technical support and assist in mobilization of financial resources to develop, strengthen and maintain capacities to respond promptly and effectively to public health risks and public health emergencies of international concern.

Paragraph 5 and Article 13A

On Paragraph 5 and New Article proposed on Article 13A, it is proposed that State Parties have the duty to collaborate on promoting equitable access to health products and technologies and explain when they do not, while establishing a mandate to the WHO on an allocation mechanism, that must assess and correct the availability and affordability of necessary health products.

> "When requested by WHO, States Parties should shall provide, to the extent possible, support to WHOcoordinated response activities, including supply of health products and technologies, especially diagnostics and other devices, personal protective equipment, therapeutics, and vaccines, for effective response to PHEIC occurring in another State Party's jurisdiction and/or territory, capacity building for the incident management systems as well as for rapid response teams. Any State Party unable to fulfil such requests shall inform the reasons for the same to WHO and the Director General shall include the same in the report submitted to WHA under Article 54 of these Regulations. , including supply of health products and technologies especially diagnostics and other devices, therapeutics, and vaccines for effective response to PHEIC".

Annex 1: Core capacity requirements - Paragraph 1 bis

Developed Countries States parties shall provide financial and technological assistance to the Developing Countries States Parties in order to ensure state-of-the-art facilities in developing countries States Parties, including through international financial mechanism as envisaged in Article 44.

Article 6: Access and Benefit Sharing Mechanism - New Paragraph 3

> "No sharing of genetic sequence data or information shall be required under these Regulations. The sharing of genetic sequence data or information shall only be

considered after an effective and transparent access and benefit sharing mechanism with standard material transfer agreements governing access to and use of biological material including genetic sequence data or information relating to such materials as well as fair and equitable sharing of benefits arising from their utilization is agreed to by WHO Member States, is operational and effective in delivering fair and equitable benefit sharing."

Article 43: Additional health measures - New Paragraph 3 bis, 4, 5 and 6

On the implementation and disciplining of additional health measures, such as travel bans, State Parties shall ensure that such measures do not harm the WHO-led allocation mechanism and must explain their enactment. Then, WHO must assess it in terms of proportion and possible discriminatory character and can recommend its rescission.

New Article 44A - Financial Mechanism for Equity in Health Emergency Preparedness and Response

A mechanism shall be established for providing the financial resources on a grant or concessional basis to developing countries. Such financial mechanism shall provide the financial assistance to build and maintain core capacities, strengthen health systems, invest in research, development, adaptation, production and distribution capacities for health care products and technologies and adress inequalities.

Article 53A: Establishment of an Implementation Committee

The IHR and its amendments would be under annual evaluation by all State Parties to be gathered during the World Health Assembly regarding its implementation and obligations observance.

Annex 6

Other relevant documents

Consolidated proposed amendments to the IHR led by the US: https://twn.my/files/20211202_USA%20Proposal%20for%20IHR%20Targeted%20Amendments.pdf
Draft resolution led by the US submitted to WHA75 on amendments to the IHR: https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_ACONF7-en.pdf
Interim report of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies: https://apps.who.int/gb/ebwha/pdf_files/EB150/B150_16-en.pdf
Final report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies: https://apps.who.int/gb/ebwha/pdf_files/WHASSA2/SSA2_3_E.pdf
Member States' proposals for amendments to the IHR: https://twn.my/files/20220901_Member%20States%20Amendments%20Proposals%20(1).pdf
Terms of reference of the IHR Review Committee regarding amendments to the International Health Regulations (2005): https://cdn.who.int/media/docs/default-source/international-health-regulations/terms-of-reference_ihr-amendments-rc_for-web_rev-221024.pdf
Report of the Review Committee regarding amendments to the International Health Regulations (2005): https://apps.who.int/gb/wgihr/pdf_files/wgihr2/A_WGIHR2_5-en.pdf

As the COVID-19 pandemic left a devastating human and economic toll in its wake, multiple efforts to shore up preparedness and response to public health emergencies were initiated. One of the most significant of these was the move to reform the International Health Regulations, which govern the management of cross-border health crises.

This book tracks the intergovernmental negotiating process that took place under the aegis of the World Health Organization (WHO) to amend the IHR. Bringing together contemporaneous articles published by the Third World Network, it documents the various twists and turns in the talks and the key issues that were at stake – including developing countries' calls for equitable access to health products and for financial support in implementing the Regulations.

The Road to IHR Reform **chronicles how the negotiations navigated a raft of challenges to eventually deliver a landmark set of amended rules aimed at enhancing international health cooperation.**

"[A]n absolute tour de force. It is easily the most comprehensive and insightful analysis of IHR amendments ever written. It combines academic rigour with penetrating analysis."
Lawrence O. Gostin, Distinguished University Professor at Georgetown University and Director of the WHO Center on Global Health Law

"I witnessed the valuable role played by TWN in supporting developing countries... through technical analysis, policy advice, and comprehensive reporting... This publication... will be a valuable resource for future practitioners, researchers, and policymakers."
Dr Boitumelo Tau, Health Attaché of the Permanent Mission of Botswana to the United Nations

"Through its meticulous analysis, this publication offers profound insight into the conduct of negotiations behind closed doors, while standing as a meaningful testament to the shared commitment that ultimately brought this milestone to fruition."
Nurhafiza Hamzah, former Minister Counsellor (Health) of the Permanent Mission of Malaysia to the United Nations and Other International Organizations

TWN
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