

CIVIL SOCIETY LETTER

Drop TRIPS-plus Demands from Malaysia-EU Free Trade Agreement (MEUFTA)

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Maroš Šefčovič
Commissioner for Trade and Economic Security
European Commission

Bernd Lange
Chair, Committee on International Trade
European Parliament

Adam Jarubas
Chair, Committee on Public Health
European Parliament

António Costa
President of the European Council

We, the undersigned civil society from around the world, including from Malaysia and the European Union (EU), are writing to call on the EU to drop all its TRIPS-plus demands from the MEUFTA.

We are extremely concerned about the EU's proposals¹ on intellectual property (IP) in the MEUFTA that go beyond the requirements of the WTO-TRIPS Agreement and are thus TRIPS-plus, including obligations in relation to:

- data and market exclusivity
- patent term extension for medicines for delays in marketing approval
- trade secret and industrial design protection
- intellectual property (IP) enforcement such as the application of border measures to all IP.

TRIPS-plus proposals prolong IP monopolies and erect barriers to market competition, thereby deterring or delaying generic competition, keeping prices of medical products prohibitively high and undermining affordable access and the sustainability of Malaysia's public health system.

Numerous European Parliament resolutions have urged the Commission to oppose IP proposals that adversely impact access to medicines in trade negotiations (see Annex).

The UN Special Rapporteur on the Right to Health² in his report on the implications of the TRIPS Agreement and bilateral and regional free trade agreements, for the right to health recommended that developing countries refrain from adopting TRIPS-plus requirements, finding that "TRIPS and FTAs have had an adverse impact on prices and availability of

medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfil the right to health". The Report also explicitly recommended that "Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health."

The report further emphasizes that the developed countries have a responsibility to support the realization of the Right to Health and that State Parties to the International Covenant on Economic, Social and Cultural Rights have a legal obligation not to interfere with the rights conferred under the Universal Declaration of Human Rights and the Covenant, including the Right to Health.

Similarly, the UN Secretary-General's High Level Panel on Access to Medicines recommended that 'Governments engaged in bilateral and regional trade and investment treaties should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health'.³

General Comment 14⁴ of the Committee on Economic, Social and Cultural Rights underscores that to comply with the Right to Health, "States parties have to respect the enjoyment of the right to health in other countries", and that "In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact upon the right to health". General Comment 24 states that "States parties should ensure that intellectual property rights do not lead to denial or restriction of everyone's access to essential medicines necessary for the enjoyment of the right to health".

Accordingly, the EU's pursuit of TRIPS-plus provisions in its trade negotiations with Malaysia raises serious concerns regarding the compliance of EU Member States with their human rights responsibilities, including their obligation to respect and promote the right to health.

There is significant evidence that EU's proposed TRIPS-plus measures are damaging for access to affordable medical products.

A 2022 review of 91 studies of the impact of intellectual property provisions on medicine prices found 'that the stronger pharmaceutical monopolies created by TRIPS-plus intellectual property rules are generally associated with increased drug prices, delayed availability and increased costs to consumers and governments'.⁵

Even within the EU, the experience with patent term extension, implemented through Supplementary Patent Certificates (SPC), has raised concerns about their impact on medicines prices and affordability. For example, a report examining the impact of SPC in the Netherlands found that the cumulative costs of delayed competition due to supplementary protections to the Dutch healthcare system for medicines Lipitor (atorvastatin, used to prevent cardiovascular disease) and Losec (omeprazole, used to treat gastrointestinal illnesses) were estimated to have been over €600m for each medicine.⁶

Medicine prices were significantly lower in countries that did not grant SPC compared to those that did. For example, Truvada (30 tablets), a fixed-dose combination of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) used for the treatment and prevention of HIV, reportedly costs around €30 in the Netherlands, which did not grant an SPC for the product, compared to approximately €800 in Switzerland, where SPC protection applied.⁷

The EU's application of border measures to various types of IP beyond counterfeit trademark and pirated copyright has resulted in the seizure or transit detention of legitimate generic medicines, affecting access to affordable treatment in developing countries. Between 2008 and 2010, European customs authorities seized multiple shipments of generic medicines in transit from India to developing countries, on allegations of patent or trademark infringement, disrupting access to essential medicines.⁸

The negative effects of TRIPS-plus measures within the EU and beyond are thus well-documented.

Malaysia is a developing country facing rising health-care needs from an ageing population and non-communicable diseases (NCDs). NCDs already impose an estimated annual cost of RM64.3 billion—exceeding the Ministry of Health's 2026 allocation of RM46.52 billion.⁹ Within these finite resources, Malaysia's commitment to universal health coverage depends on affordable medicines, including robust generic competition.

By proposing the adoption of TRIPS-plus measures in the trade agreement, the EU risks exacerbating the challenges already confronting Malaysia's public health system and undermining its ability to provide affordable healthcare for all. Measures that restrict competition, delay generic and biosimilar entry and prolong pharmaceutical monopolies will keep medicine prices higher for longer, placing an additional and potentially unsustainable burden on Malaysia's public health system.

The human cost will be severe. Higher medicine prices and delayed access to affordable alternatives would place many Malaysians at risk of financial hardship and could deny patients access to essential treatment. For those who cannot afford life-saving medicines, the consequences will not merely be financial but a matter of life and death.

The EU's TRIPS-plus demands on industrial design protection will adversely affect disabled people in Malaysia. Around 160,000 of Malaysia's current population of 32 million need prosthetic or orthotic devices. Lengthy industrial design protection, as well as giving protection to unregistered designs, both of which are TRIPS-plus, will result in high prices for medical devices such as prostheses, imposing a financial burden on a significant percentage of amputees, which will eventually inhibit their rehabilitation progress.

The Convention on the Rights of Persons with Disabilities requires State Parties to ensure access to affordable, high-quality assistive products, including prostheses and orthoses. EU's

TRIPS-plus demands will adversely affect Malaysia's ability to fulfil its obligations under the Convention.

In conclusion, empirical evidence, including the European Commission's own research¹⁰, demonstrates the anti-competitive effects of extending patent protection and creating additional layers of exclusivity around pharmaceutical products. The proposed TRIPS-plus measures would not only risk delaying generic and biosimilar competition in Malaysia and keeping medicine prices higher for longer; they also disadvantage generic and biosimilar manufacturers from the EU by creating additional barriers to their entry into the Malaysian market.¹¹

The EU must immediately:

1. **Drop all TRIPS-plus demands** from the MEUFTA
2. **Ensure that no IP obligation is subject to state-to-state dispute settlement** where it would expose Malaysia to enforceable FTA claims for measures that are permitted under TRIPS or necessary to protect public health, ensure equitable access, regulate medicines, remedy anti-competitive conduct, or respond to an emergency.

A modern EU–Malaysia partnership should promote public health, resilient supply chains, local productive capacity, scientific cooperation and affordable access to health technologies. It should not make access to medicines or medical devices contingent on monopoly periods that exceed the TRIPS Agreement. The EU has both the opportunity and the responsibility to ensure that the final agreement matches its own parliamentary resolutions and its stated commitments to human rights, global health and sustainable development.

Annex

The European Parliament (EP) has also repeatedly urged the Commission to reject IP proposals that adversely impact access to medicines in trade negotiations:

- In 2007, an EP Resolution called on “the Council to meet its commitments to the Doha Declaration and to restrict the Commission's mandate so as to prevent it from negotiating pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation on grounds of compulsory licences, within the framework of [...] bilateral and regional agreements with developing countries”.¹²
- In 2011 in a resolution on EU FTA with India, the EP asked the Commission not to request data exclusivity in the context of negotiations, and to recognise that data exclusivity would have far-reaching consequences for the production of generic medicines and is therefore detrimental to developing countries' access to medicines and public health policy.¹³
- In 2021, an EP Parliament resolution called on the Commission to oppose the inclusion of TRIPS-plus measures in free trade agreements with middle-income developing countries to ensure that all HIV antiretroviral treatments are affordable, with full respect for the Doha Declaration on TRIPS and Public Health.¹⁴

SIGNATORIES

Malaysian Organizations

1. Acacia Forest Industries Sdn Bhd
2. Agora Society Malaysia
3. AiGro
4. Colorectal Cancer Survivorship Malaysia
5. Crisis Home
6. DIRIBUMI
7. Eatcious Solutions 202503124632 (JM1022611-V)
8. Justice for Sisters
9. Kiro Studio
10. KOKORIU
11. Kuala Lumpur Aids Support Services Society
12. Lelaki Positif Malaysia
13. Lil Fierra Wellness
14. Malaysian Agroecology Society – SRI-Mas
15. Malaysian AIDS Council
16. Malaysian AIDS Foundation
17. Malaysian Food Sovereignty Forum (FKMM)
18. Malaysian Rare Disorders Society
19. Médecins Sans Frontières (MSF)-Malaysian chapter
20. My Starfish Foundation
21. PACOS
22. Penggerak
23. Peribadi
24. Persatuan Pendidikan Dan Kebajikan Jaringan Nelayan Pantai Malaysia (Jaring)
25. Persatuan Pengguna Islam Malaysia
26. Persatuan Pengguna Luar Bandar dan Ekologi Malaysia (Rural Malaysia)
27. Persatuan Pengguna-Pengguna Pulau Pinang (Consumers' Association of Penang) - CAP
28. Persatuan Prihatin Anak Jati Johor
29. Persatuan Wecarejourney
30. Pertubuhan Alam Sekitar Sejahtera Malaysia-GRASS
31. Pertubuhan Idris
32. Pertubuhan Persaudaraan Pesawah Malaysia (PeSAWAH)
33. Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
34. PT Foundation
35. Sahabat Alam Malaysia (Friends of the Earth) – SAM
36. Stono Farms KKB Sdn. Bhd
37. Suara Mahasiswa (SMUMS)
38. Terabai Kenyalang Heritage Association of Sarawak
39. The Hope Village, Tuaran, Sabah

40. Together Against Cancer Association
41. Third World Network

European & Other Organizations

42. *Æqua, Switzerland & Global*
43. Association For Promotion of Sustainable Development, *India*
44. Centre for Health Science and Law (CHSL), *Canada and Global*
45. Fundación Grupo Efecto Positivo, *Argentina*
46. Fundación IFARMA, *Colombia*
47. Global Humanitarian Progress Ghp Corp, *Colombia & Global*
48. Health Action International (HAIAP), *Asia Pacific*
49. Health Global Access Project (Health GAP) *United States & Global*
50. Indian Institute of Technology Kharagpur, *India*
51. Indian Social Action Forum, *India*
52. Indonesia for Global Justice (IGJ), *Indonesia*
53. International Treatment Preparedness Coalition, *South Africa & Global*
54. JSA, *India*
55. Medical Impact, *Mexico*
56. PF AGEPC, *Kazakhstan*
57. Pharmaceutical Accountability Foundation, *Netherlands*
58. Policies for Equitable Access to Health, *Italy*
59. Princess of Africa Foundation, *South Africa*
60. Public Eye, *Switzerland & Global*
61. Public Health Association of Australia, *Australia*
62. Salud por Derecho, *Spain & Global*
63. Salud y Fármacos, *United States*
64. WomanHealth, *Philippines*
65. Woodseer Resources, *France*
66. Consumers Association of Bangladesh (CAB)
67. Health Action International, *Netherlands & Global*
68. AIDS Healthcare Foundation, *Netherlands (Europe)*
69. Global Policy Forum Europe, *Germany*
70. Wemos, *Netherlands & Global*
71. Association Burkinabè d'Action Communautaire, *Burkina Faso*
72. Consultancy Bureau voor Strategisch Management CBSM, *Netherlands*
73. Society for International Development (SID), *Italy & Global*
74. Geneva Global Health Hub (G2H2), *Switzerland & Global*

Notes

- ¹ <https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/ed8ac59f-9b06-41f5-8627-47f098baa2a7/details?download=true>
- ² https://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A_HRC.11.12_en.pdf
- ³ <https://www.unsgaccessmeds.org/final-report>
- ⁴ <https://www.refworld.org/legal/general/cescr/2000/36991>
- ⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9013034/>
- ⁶ See 'Supplementary Protection Certificates in the European Union: Briefing Document available at <https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Supplementary-Protection-Certificates.pdf>
- ⁷ See 'Supplementary Protection Certificates in the European Union: Briefing Document available at <https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Supplementary-Protection-Certificates.pdf>
- ⁸ See <https://twm.my/title2/wto.info/2009/twninfo20090203.htm>; <https://twm.my/title2/wto.info/2010/twninfo100509.htm>;
<https://twm.my/title2/wto.info/2009/twninfo20090213.htm>; <https://www.twm.my/title2/resurgence/2009/228-229/health1.htm>
- ⁹ <https://www.malaymail.com/news/malaysia/2026/02/08/malaysia-faces-rm642b-ncd-economic-burden-shifts-focus-from-sick-care-to-prevention-says-health-minister/208509>
- ¹⁰ European Commission, Pharmaceutical Sector Inquiry, 2009, https://competition-policy.ec.europa.eu/sectors/pharmaceuticals-health-services/pharmaceutical-sector-inquiry_en
- ¹¹ International Generic and Biosimilar Association (IGBA) (2025), 'Gaming the system: An overview of originator companies' evergreening strategies used to hinder access to generic and biosimilar products', https://www.igbamedicines.org/doc/IGBA_IP&Comp_Report-v20250123.pdf
- ¹² https://www.europarl.europa.eu/doceo/document/TA-6-2007-0353_EN.html
- ¹³ https://www.europarl.europa.eu/doceo/document/TA-7-2011-0224_EN.html
- ¹⁴ https://www.europarl.europa.eu/doceo/document/TA-9-2021-0250_EN.html