CIVIL SOCIETY LETTER
Reject TRIPS-Plus Provisions in Ongoing Trade Negotiations with the European Union to Safeguard Access to Affordable Pharmaceutical Products

URGENT

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Dear Honorable Ministers,

We the undersigned civil society and patient-advocacy organizations are writing to express our concerns with Intellectual Property (IP) Chapter proposals that the European Union (EU) has published[i] in the negotiations for a comprehensive trade agreement between Malaysia and the EU. We understand that the next round of negotiations is likely to take place from 9-12 June 2026.

In this letter, we highlight our serious concerns regarding several TRIPS-plus proposals advanced by the EU, which would prolong monopolies over pharmaceutical products and create further barriers to market entry for domestic manufacturers and generic competition.

We emphasize that it is imperative for the Malaysia government to reject all TRIPS-plus provisions in the proposed EU FTA. It is equally important that the government conduct the negotiations in a transparent and accountable manner.

Malaysia Must Avoid All TRIPS-plus Requirements To Protect it National Interests

The Malaysian government has identified the generic pharmaceutical industry as a strategic priority under the New Industrial Master Plan (NIMP) 2030. The Plan seeks to strengthen the industry in order to improve the affordability and accessibility of medicines, enhance national self-sufficiency, support domestic economic development, and reduce the country's pharmaceutical trade deficit. At the same time, Malaysia has adopted important public health policies aimed at facilitating access to affordable medicines, including

the National Generic Medicines Framework, which is grounded in the Malaysian National Medicines Policy and promotes the use of quality-assured generic medicines.

These strategies and policies are critical both for advancing public health through lower medicine prices and for supporting the growth of the domestic generic industry through timely generic market entry. However, adoption of TRIPS-plus measures in upcoming trade negotiations risks undermining these objectives by prolonging monopolies and creating additional barriers to legitimate generic competition.

This concern is even more pressing in light of reductions in the budget of the Ministry of Health. At a time of increasing fiscal constraints, Malaysia cannot afford policies that delay access to affordable medicines, increase pharmaceutical expenditure, and weaken competition in the pharmaceutical market.

Malaysia remains predominantly a net importer of intellectual property (IP), particularly in sectors such as pharmaceuticals and high technology. For e.g. in 2023, net IP royalty outflows were approximate US$2.7 billion while receipts were a mere US$282 million[ii]. This means that the economic costs associated with stronger and longer IP protection—including higher royalty payments, prolonged monopolies, and increased prices for technology-intensive products are significant. In such circumstances, adopting TRIPS-plus standards that expand or extend IP protection primarily advantages foreign multinational corporations, while increasing costs for Malaysian consumers, public health programmes, local manufacturers, and technology users. As a developing economy seeking to strengthen domestic industrial capacity and technological self-reliance, Malaysia should preserve its policy space and maintain a balanced IP system.

The European Parliament has repeatedly passed resolutions against the EU Commission promoting TRIPS-plus measures.[iii] In 2021 EU Parliament resolution stated "Calls on the Commission to oppose the inclusion of TRIPS-plus measures in free trade agreements with middle-income developing countries in order to ensure that all HIV antiretroviral treatments are affordable, with full respect for the Doha Declaration on TRIPS and Public Health".[iv]

If possible, Malaysia should aim for a trade agreement with the EU without an IP chapter or a cooperation only IP chapter, for when TRIPS provisions are included in the FTA, they are enforceable via the FTA's dispute settlement chapter. Presently the TRIPS Agreement is not enforceable at the WTO due to the paralysis of the Appellate Body. Although Malaysia has joined the Multi-Party Interim Appeal Arbitration Arrangement (MPIA), it retains the option, in a dispute brought by the EU at the WTO, not to use the MPIA mechanism. However, if TRIPS obligations are incorporated into the EU FTA and made subject to the FTA's dispute settlement provisions, the EU would gain a direct and binding avenue to enforce TRIPS obligations against Malaysia through the FTA framework.

Below we highlight the public health impact of certain TRIPS-plus provisions proposals published by the EU.

1. Extending Data And Marketing Exclusivity

The EU´s proposal in Article X.49 aims to extend data exclusivity and marketing exclusivity in Malaysia, far beyond Malaysia's Directive on Data Exclusivity (DE), and this should not be accepted. Malaysia's DE

Directive is already TRIPS-plus. But it has built-in some safeguards such as to obtain DE an application has to be made, such application has to be made within a specific time-frame following approval in country of origin or in any recognised country, and the duration runs from the time of that registration. Further the government has discretion not to grant DE and the Directive will not apply when measures are taken in the interest of public health etc.

The example of access to treatment for Hepatitis C virus (HCV) clearly shows why Malaysia should not follow the pathway of the EU. In 2016 HCV originator treatment was available in Europe at a price of around € 50,000 for a 12-week treatment. Because of the data and market exclusivity granted in the EU, generic entry was not possible until 2024.[v] In comparison, Malaysia through its use of government use license in 2017 and safeguards in the DE Directive, managed to import and access generic versions for less than US$300 for a treatment course and consequently roll-out free treatment in public hospitals.

It is important to note that recent EU trade agreements with Mercosur and India do not contain any requirements on data and marketing exclusivity.

2. Patent Term Extensions (PTEs): Lengthening Monopolies

Art. X.45 of the EU proposal provides for PTE, which aims to extend the patent protection period for up to five years beyond the standard TRIPS 20-year term, due to delays in the granting of marketing authorization. The effect of this TRIPS-plus provision combined with the extensive problem of patent evergreening in Malaysia will be to extend the market monopolies of the patent holder for a substantial period of time.

Evidence shows that the impact of PTE on public health is disastrous. For e.g. in Korea, a three year PTE, result of US trade agreement is calculated to have costs Korea US$1billion in lost savings from when it was implemented in 2012 to 2020 (US$250million in 2018 alone), while EU-Korea FTA which required 5-year PTE has resulted in lost cost savings of US$592million in Korea between 2015-2020.[vi] The Canadian government calculated that PTE implemented because of EU trade agreement will add an average of 2.66 years to the existing patent monopoly period and increase Canadian medicine costs by $795million-$1.95billion each year.[vii]

Even in the EU, the experience with PTE, implemented through Supplementary Patent Certificates (SPC) has been negative. For example, a report examining the impact of SPC in 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), are estimated to have been over €600m for each medicine.[viii]

Studies have also found that medicine prices were significantly lower in European 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.[ix] Studies have also found that SPC did not incentivise R&D in Europe.[x]

It should be noted that neither the EU-Mercosur FTA nor the EU-India FTA requires PTE.

3. Trade Secret

EU has proposed several articles on the protection of trade secret. These provisions should be scrutinized very carefully. Overly restrictive provisions can hamper the government's ability to protect national interests, public health such as in situations of health emergency, to remedy anti-competitive behavior or to make available life-saving treatments.

During COVID-19, major manufacturers refused to reveal trade secrets in manufacturing to prevent competition, although such manufacturers were unable to satisfy the demand for supplies. For e.g. in Netherlands, Roche was only able to supply 30% of the orders and yet refused to release its secret recipe for a solution used in its COVID-19 tests. However, once Roche was threatened with investigation by the EU Competition Commission, Roche quickly agreed to share the recipe with the government.[xi]

Increasingly as well trade secrets play a particularly important role in the development and manufacturing of complex biologic medicines, including gene therapies, where much of the value lies in proprietary know-how, cell lines, manufacturing processes, and quality control methods that are not fully disclosed in patents. As a result, market competition remains limited and prices of treatments prohibitively high.

For reasons mentioned above, it is crucial that any commitment, does not go beyond requirements of the TRIPS Agreement. Further it should be noted, that EU's proposals require far more extensive commitments than in the EU-India FTA. For e.g. the scope of protection in Article X.47(2) of EU's proposal for Malaysia covers "civil procedures, measures and remedies", which is much broader for it can include pre-emptive measures. In contrast, Article 13.37 of the EU-India FTA only covers "civil procedures and remedies". EU's proposal for Malaysia also sets out criteria that should be applicable to "civil procedures, measures and remedies". EU-India FTA is silent on this. The scope of exceptions proposed by the EU for Malaysia is narrower than exceptions agreed in the India FTA which also includes a broad exception in Article 10.37 (para 4)– "any other practice which, under the circumstances, is in conformity with honest commercial practices".

It is imperative to note that the European Union Trade Secrets Directive[xii] contains important public interest exceptions that do not appear to be reflected in the proposed text. These include safeguards preserving the authority of governments, regulators, courts, and public bodies to require disclosure of trade secret information for public interest purposes or in the exercise of their legal duties and powers.

Exceptions provided in the EU text are insufficient. The omission of safeguards and exceptions risks creating an overly broad and rigid trade secret regime that will undermine regulatory transparency, public oversight, and access to information necessary for national security, the protection of public health and other public interests.

It is imperative to ensure that there are broad exceptions to trade secret protection including a concrete exception that allows disclosure in the public interest including for providing timely access to affordable pharmaceutical products and to operationalize the use of TRIPS flexibilities.

4. Border Measures & Enforcement

EU's proposal on border measures is in Article X.66. It requires customs authorities to implement border measures (seems to apply to import, export and transit) with regards to goods suspected to be violating intellectual property including patents, industrial designs etc. EU's proposal is TRIPS-plus.

Article 51 of TRIPS only requires border measures to be applicable for the *"importation of counterfeit trademark goods or pirated copyright goods"* (as defined in footnote 14 of the TRIPS Agreement). Border measures are not required for other IP violations. The reason for this differentiation is that infringement in the case of trademark counterfeiting and copyright piracy may be determined with ease on the basis of visual inspection of imported goods since the infringement will be apparent "on its face". This is not the case for other IP infringements such as patents, where more expertise and investigation is necessary to determine whether infringement has taken place. TRIPS also does not require border measures to be applied to goods-in-transit or for export.

Agreeing to extend border measures to patents, industrial designs, and other forms of IP can also have serious adverse consequences for development. Unlike trademarks and counterfeit goods, disputes involving patents, industrial designs and other IP are often highly technical and legally complex, requiring detailed judicial assessment before any determination of infringement can reasonably be made. Allowing border authorities to detain goods on the basis of mere allegations of infringement risks disrupting legitimate trade including exports, delaying access to essential products, and creating uncertainty for domestic manufacturers, importers, and exporters.

Such measures have, in several instances, 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.[xiii]

Extending border enforcement to patents and other IP, beyond TRIPS, can therefore be used strategically to hinder legitimate competition, interfere with supply chains, and increase the costs and risks of trade and industrial activity. It will also place significant administrative and financial burdens on customs authorities, requiring them to adjudicate complex private intellectual property disputes for which they often lack the technical expertise.

EU proposals in Article X.66 also undermines the safeguards allowed by TRIPS. For e.g. Article 60 of TRIPS allows de minimis exception in small consignments but this is disallowed by Art. X.66.11. TRIPS also requires the IP holder initiating the border measure to prove prima facie infringement, to provide security or equivalent assurance to protect the defendant, to initiate legal proceedings within 10 working

days of receiving the suspension notice, to indemnify the importer for any wrongful detention etc. but these safeguards are absent from the EU's proposal.

Instead incredibly, the EU is suggesting that the customs authorities should not charge a fee to cover the administrative costs, meaning that the tax-payer should bear the cost of such enforcement of private rights.

For developing countries seeking to promote industrialisation and development of a technological base, public health, and participation in global value chains, overly expansive border enforcement measures can undermine policy space, discourage local production and innovation, and tilt the balance excessively in favour of private rights holders at the expense of broader development objectives.

Thus it is of utmost importance that Malaysia does not agree to any TRIPS-plus provisions on enforcement including border measures.

5. Industrial Design (ID) Protection

The EU proposal on IDs is also unacceptable. It calls for 25 year protection for registered designs and 3 years of protection for "unregistered designs", both of which are TRIPS-plus. The longer the protection, the greater the negative impact on access to affordable medical devices, as market competition is excluded or delayed e.g. for prosthetic limbs for diabetic amputees. For instance, around 160,000 of Malaysia's current population of 32 million need prosthetic or orthotic devices.[xiv] However, the cost of a prosthesis typically varies between RM 4,000 to RM 15,000 and is higher if advanced components or computerized systems are used.[xv] The high price of prostheses imposes a financial burden on a significant percentage of amputees in Malaysia. Consequently, many of them are left with the choice of lower-priced prosthetics that are less effective and inhibit their rehabilitation progress. The cost of prostheses is a major issue, especially in East Peninsular and East Malaysia.

While Malaysian law seems to allow ID monopolies for up to 25 years, if not locked into a FTA, Malaysia can choose to reduce that in future. It is noteworthy that Australia reduced its ID period from 16 years to 10 years as it determined that it would not be in Australia's interest to provide a period of registration in excess of its international obligations, as Australia is a net importer of IP.[xvi]

Protection should not be granted to unregistered industrial designs because registration is essential to provide legal certainty, transparency, and clear notice to the public regarding the existence and scope of the claimed rights. Without registration, businesses, designers, and competitors may have no reliable way of determining whether a design is protected, increasing the risk of inadvertent infringement and costly disputes. Registration also helps ensure that only designs meeting the required standards of novelty and originality receive protection. Extending exclusive rights to unregistered designs can therefore create uncertainty, hinder legitimate competition, and impose unnecessary barriers on local manufacturers, small enterprises, and follow-on innovation.

It should be noted that there is no definite commitment to provide ID protection to unregistered designs in the EU-India and EU-Mercosur FTAs and the duration of protection in both these trade agreements is

limited to 15 years. Malaysia must not agree to provide greater level of protection than the 10 years required by TRIPS.

Based on the above, we respectfully call on the Malaysian government to:

(a) Reject all TRIPS-Plus IP provisions in the EU-Malaysia trade agreement, including data exclusivity, patent term extension, excessive trade secret and industrial design protection as well as enforcement measures and to provide a commitment of the same to civil society and patient advocacy organizations.

(b) Be transparent and accountable:

- **To conduct information sessions after every round of negotiation with the EU, informing civil society and patient advocacy organizations about the outcome of negotiations;**
- **To undertake meaningful consultations with civil society and patient advocacy organizations in advance of the EU negotiations, especially on proposals that have an impact on generic competition and access to affordable pharmaceutical products.**

Malaysians' Constitutional Right to Health and Access to Affordable Medicines must not be sacrificed in the EU FTA or any other trade negotiations.

Yours sincerely,
Signed by the organizations listed below.

SIGNATORIES

Malaysia

1. Consumers' Association of Penang (CAP)
2. Federation of Malaysian Consumers Associations
3. Forum Kedaulatan Makanan Malaysia (FKMM) - Malaysian Food Sovereignty Forum
4. Health Action International Asia Pacific (HAIAP)
5. Health Equity Initiatives (HEI)
6. Kuala Lumpur AIDS Support Services Society
7. Lelaki Positif Malaysia
8. Malaysian Women's Action for Tobacco Control and Health (MyWATCH)
9. Médecins Sans Frontières Malaysia (MSF)
10. Pertubuhan Kebajikan Ar Riqab Kuala Lumpur
11. Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)
12. Prostate Cancer Society Malaysia
13. PT Foundation
14. Sahabat Alam Malaysia
15. Together Against Cancer (TAC)
16. Third World Network (TWN)
17. Usrah Fitrah Klang

International

19. Association For Promotion Sustainable Development, India
20. Association for Proper Internet Governance, Switzerland
21. BUKO Pharma-Kampagne, Germany

22. Campaign for Human Rights Accountability and Democracy (CHRAD), Malawi
23. Cancer Alliance National, South Africa
24. Development Alternatives with Women for a New Era (DAWN), Global
25. Equidad de Género: Ciudadanía, Trabajo y Familia National, Mexico
26. Fundación para Estudio evInvrdyigsvion de la Mujer, Argentina
27. Governance Links, Tanzania
28. Handelskampanjen, Norway
29. Health Action International (HAI) International, The Netherlands
30. Health Global Access Project, USA
31. Indonesia AIDS Coalition (IAC), Indonesia
32. Indonesia for Global Justice (IGJ), Indonesia
33. International Treatment Preparedness Coalition (ITPC), South Africa
34. Jamia Hamdard, India
35. JSA Chhattisgarh, India
36. Misión Salud, Colombia
37. NALSAR University of Law Hyderabad, India
38. Peoples Health Movement (PHM), Global
39. Public Eye, Switzerland
40. Red de Acceso a Medicamentos, Guatemala
41. Salud por Derecho (SpD), Spain
42. Society for International Development (SID), Global
43. Treatment Action Campaign (TAC), South Africa
44. UBINIG (Policy Research for Development Alternative), Bangladesh
45. Wemos International, The Netherlands
46. Women and Media Collective, Sri Lanka
47. Yolse Santé Publique et Innovation, Global

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[i] https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/ed8ac59f-9b06-41f5-8627-47f098baa2a7/details?download=true

[ii] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/W721.pdf&Open=True

[iii] The European Parliament has repeatedly passed resolutions including specifically with respect to trade relations with ASEAN which pointed out that 'nothing in the agreement should create legal or practical obstacles to . . . access to medicines' and calling on the European Commission's negotiators 'to take full account of the points set out in its above mentioned resolution of 12 July 2007 on this topic' which included calling on the Council to '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' in its 'bilateral and regional agreements with developing countries' and encourages developing countries to use TRIPS flexibilities and asks the European Council to support them in doing so. See https://www.europarl.europa.eu/doceo/document/TA-6-2008-0195_EN.html and http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN&language=EN

[iv] https://www.europarl.europa.eu/doceo/document/TA-9-2021-0250_EN.pdf

[v] See https://medicineslawandpolicy.org/wp-content/uploads/2019/06/European-Union-Review-of-Pharma-Incentives-Data-Exclusivity.pdf

[vi] https://igbamedicines.org/doc/IQVIA-IGBA_Impact%20of%20FTAs%20on%20generic%20and%20biosimilar%20markets_Final%20Deck%20-%20October%202020.pdf

[vii] https://www.cbc.ca/news/politics/canada-eu-drug-patent-demand-in-trade-talks-costs-almost-2b-1.1217626

[viii] 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

[ix] ibid, n. viii

[x] ibid, n.viii

[xi] https://www.ftm.eu/articles/roche-releases-recipe-after-public-pressure-while-european-commission-considers-intervention-due-to-coronavirus-test

[xii] See Article 1 at https://eur-lex.europa.eu/eli/dir/2016/943/oj/eng

[xiii] See https://twn.my/title2/wto.info/2009/twninfo20090203.htm; https://twn.my/title2/wto.info/2010/twninfo100509.htm; https://twn.my/title2/wto.info/2009/twninfo20090213.htm; https://www.twn.my/title2/resurgence/2009/228-229/health1.htm

[xiv] https://pmc.ncbi.nlm.nih.gov/articles/PMC5772821/

[xv] https://pmc.ncbi.nlm.nih.gov/articles/PMC5772821/

[xvi] https://www.ipaustralia.gov.au/about-us/public-consultations/consultation-hague-agreement-designs