State Secretary Helene Budliger Artieda
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Remove TRIPS+ demands from the EFTA-Malaysia Free-Trade Agreement

Dear State Secretary Budliger Artieda,

We are writing to express our deepest concerns about damaging provisions on intellectual property (IP) in relation to the Malaysia-European Free Trade Association (EFTA) Economic Partnership Agreement (MEEPA), according to the leaked text of its annex XIX on the protection of intellectual property. We understand that MEEPA is currently in the final stages of finalisation before signature.

The undersigned Swiss NGOs are urging the Swiss government to actively engage within EFTA to drop these provisions which go beyond the requirements of the World Trade Organization (WTO) rules contained in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) – known as TRIPS+ – that are hampering farmers' rights and the right to health.

1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV 1991)

Art. 3.3 of the Annex XIX includes a reference to Malaysia joining or making "*all reasonable efforts*" to accede to the 1991 Act of UPOV. The latter grants extensive breeder's rights but restricts farmers' right to save, exchange and sell farm saved seeds/propagating materials. This reference should be withdrawn for the following reasons:

- EFTA itself declared in a letter dated December 2020 that "*EFTA does not make the accession to UPOV or the adherence to its rules a prerequisite for the conclusion of an FTA"*, further stating that *"The objective of any FTA negotiated by EFTA is to provide the best possible solution for **all** stakeholders concerned."* Additionally, Liechtenstein is not a party to any UPOV Convention, and Norway is not party to its 1991 Act. Any commitment to join or make efforts to join UPOV 1991 means that Malaysia is getting a worse deal than some EFTA member countries.
- Malaysia already operates an effective plant variety protection (PVP) system under its Protection of New Plant Varieties (PNPV) Act 2004 in full compliance with the requirements of the World Trade Organization's Intellectual Property Agreement (TRIPS). Notably, approximately 63.31% of PVP applications are submitted by foreign entities, reflecting strong international confidence in Malaysia's system. There are also applications from foreign universities and government research institutions, underscoring the broad recognition of Malaysia's unique and inclusive approach to PVP. By contrast, we have observed dysfunctional UPOV based PVP systems in many developing countries.

- A report from 2023 titled *"The Potential Impact of UPOV 1991 on the Malaysian Seed Sector, Farmers, and Their Practices"* clearly demonstrates that the UPOV 1991 system is not suitable for Malaysia. Experts are also explicit of the inappropriateness of the UPOV system for developing countries.
- Michael Fakhri, the UN Special Rapporteur on the right to food, in a report to the UN Human Rights Council, recommended that *"[b]eing a party to that [UPOV 1991] Convention should no longer be required as part of bilateral or regional agreements. Member States are strongly encouraged to remove such requirements from current agreements"*. In a letter to all EFTA countries in 2024, Mr Fakhri stressed that such demand would jeopardize the right to food.
- EFTA made no requirement of acceding to UPOV 1991 in their latest free-trade agreements with Thailand and India.

In view of the objection by Malaysian stakeholders, we urge you to fulfil your commitment in EFTA's letter and to withdraw all references to UPOV in MEEPA. We are of the strong view that nothing in the MEEPA trade agreement must affect Malaysia's sovereignty and its full flexibility to implement any effective sui generis PVP system as appropriate for Malaysia's agricultural system.

TRIPS-plus intellectual property provisions regarding access to medicines

The leaked Annex XIX of MEEPA contains several TRIPS+ intellectual property (IP) provisions that will hinder access to affordable medicines and undermine the viability of the domestic generic pharmaceutical industry. Among the TRIPS+ provisions are:

Art. 7.1 (Patents) is restricting the use of TRIPS Flexibilities like Compulsory licences (CL): a CL is a legal mechanism that allows a State to authorize the exploitation of a patent by a third party without the holder's consent (but with remuneration provided). For Malaysia, CLs are an important tool from the perspective of national security, i.e. ensuring that Malaysia is not import dependent. This provision in MEEPA aims to exclude the granting of a CL for failure to produce the patented product (e.g. medicine) locally, whereas the TRIPS Agreement allows CLs for failure to work the patent locally. Adopting such TRIPS+ rules would limit Malaysia's ability to respond to future crises and undermine its pharmaceutical industry, which supplies over a third of national needs and can manufacture most essential drugs.

Art. 7.3a (Patents) is weakening patentability exclusions, allowing for more patent evergreening: TRIPS allows each Party to exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' (Art. 27.3a). However, a provision in MEEPA is attaching a condition that narrows what can be excluded from patentability, by stating that the exclusion "*shall not apply to products, in particular substances or compositions, for use in any of these methods*". Its effect will be to reinforce the granting of patents on uses of pharmaceutical substances, including new uses of old medicines, although the condition is not required under the WTO rules. The practice known as 'patent evergreening' is a common strategy of the pharmaceutical companies, consisting of applying for different patent claims around a known medicine to extend their market monopoly and charge very high prices for a much longer period. It is an abuse of the patent system. Furthermore, CAR-T cell therapies – such as Novartis' Kymriah, which are a method of treatment – may also be caught by such a condition and may have to be considered patentable in Malaysia, resulting in much higher prices.

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Art. 8 (Undisclosed Information) is undermining Malaysia's Directive on data exclusivity (DE): DE requirement is an additional layer of IP monopoly in addition to patent monopoly. DE is not required by WTO rules. It can significantly increase the price of medicines and prevent the use of TRIPS flexibilities such as compulsory licensing. Malaysia has implemented data exclusivity through a directive that includes safeguards to protect public health, including the right to use compulsory license and to take other action to protect public health. The Directive could be undermined by the proposed TRIPS+ provision in MEEPA, which ignores the existing public health safeguards.

The TRIPS+ provisions contained in the leaked Annex XIX of MEEPA will tie the hands of the government, prolong IP monopolies and increase the price of pharmaceutical products, affecting the sustainability of public health budgets and hindering access to affordable treatments for Malaysians. They must therefore be dropped.

As a host country to many multilateral organisations such as the WTO or WHO that are nowadays increasingly challenged, Switzerland must uphold and respect the requirements established multilaterally and refrain from exceeding them bilaterally. We thus call on Switzerland to take immediate steps to ensure that MEEPA does not contain any TRIPS+ provision and respect human rights such as the right to health as well as farmers' rights.

SIGNATORIES:

1. Public Eye
2. Alliance Sud
3. Swissaid
4. Fastenaktion / Action de Carême
5. HEKS / EPER
6. Bruno Manser Fonds

C.C.:

Federal Councillor Guy Parmelin (Economic Affairs / Agriculture)
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Federal Councillor Beat Jans (Justice & Police / Intellectual property)

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