11th September 2018

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Dear Sir/Madam,

Re: Concerns about TRIPS-plus provisions impacting Access to Medicines in Indonesia

We are extremely concerned that TRIPS-plus provisions that adversely impact access to medicines may be included in the European Free Trade Association (EFTA)-Indonesia Comprehensive Economic Partnership Agreement (CEPA).

We would like to strongly urge the EFTA states to ensure that the CEPA does not include any of the TRIPS-plus provisions that may hinder access to affordable medicines in Indonesia such as data and/or market exclusivity on pharmaceutical products, patent linkage (the practice of linking marketing approval for generic products to the patent status of the originator product) or patent term extensions for pharmaceutical products for delays in marketing approval and/or delays in granting the patent.

In this context, the EFTA states – and in particular Switzerland who is leading the negotiations on those issues – should NOT put any pressure on the Indonesian Government to adopt and lock-in any requirements beyond the TRIPS Agreement (TRIPS-plus) in CEPA.

Indonesia has a population of 261 million, with a GNI per capita of US$3,540 compared to EFTA's US$83,420 (24 times greater than Indonesia's). Even at purchasing power parity rates, 62% of Indonesia's population lives on less than US$5.50 per day[1].

Indonesia suffers from double disease burden of communicable and non-communicable disease with access to medicines representing a huge challenge. For example, about 620,000 people are living with HIV with only about 12% of the adult population on treatment. Hepatitis C affects about 3 million people in Indonesia and yet to date, due to the high prices of medicines, treatment has been limited. Indonesia is also one of the 30 high tuberculosis (TB) burden countries worldwide, with TB incidence of 1,020,000 cases with an estimate of 32,000 patients having drug resistant-TB (DR-TB). It is estimated that 2.8% of new TB cases and 16% of previously treated cases in Indonesia? are DR-TB. In addition, every year in Indonesia about 300,000 people are newly diagnosed with cancer with about 200 000 deaths annually. Access to cancer treatment is limited due to the exorbitant costs of such treatments.

Robust generic competition is key to improving access to affordable medicines. For example, due to generic competition, prices of HIV/AIDS have dropped from US$15,000 per person per year to $67 per person per year[2], greatly improving access to HIV treatment globally.

TRIPS-plus provisions erect barriers to entry of generic competition, allowing the intellectual property holder to maintain market monopoly. Consequently, prices remain high, adversely impacting the health system in Indonesia as well as the lives of Indonesian patients in need of treatment.

A TRIPS-plus provision that is of great concern is data/market exclusivity. The TRIPS Agreement does not require countries to provide data/market exclusivity. This TRIPS-plus provision deters and considerably delays the entry of generic medicines even when there is no patent. During the exclusivity period, a generic competitor may not obtain marketing approval relying on or referring to the data that has been submitted by the originator company, unless the generic company produces independent data which costs time and money. The repeating of full clinical trials also raises serious ethical concerns related to patients.

There is significant evidence about the effect of data exclusivity on access to affordable medicines, including the significant budgetary implications for the public sector. For example, in Jordan, data exclusivity delayed the introduction of cheaper generic alternatives of 79% of medicines between 2002 and 2006 and ultimately the higher medicine prices are threatening the financial sustainability of government public health programs.[3] Medicine prices in Jordan are also 800% higher than in Egypt[4] due to introduction of data exclusivity. In Colombia, as a result of data exclusivity, the costs to the public health system increased by US$396 million between 2003 and 2011.[5] In Peru the adoption of data exclusivity measures is expected to contribute to an increase of about US$459 million to the country's total pharmaceutical expenditure in 2025.[6] In Guatemala, a study found that the data exclusivity duration of 15 years significantly reduced competition, as a result medicines that were readily available in most countries at affordable prices were simply not available in Guatemala.[7]

Another worrying TRIPS-plus provision is patent linkage (i.e. refuse the granting of marketing approval until the patents expire). Such a provision would require the drug regulatory authority (DRA) to take on the role of 'patent police' although such a role would be against the statutory mandate, capacity and expertise of the DRA. As a result, it is likely that they will enforce all patents including the non-blocking/invalid/expired patents, thereby creating additional and unnecessary hurdles for generic competition to the derogation of the public welfare and interest.

A fundamental, well-established principle of intellectual property recognised in the Preamble of the WTO-TRIPS Agreement, is that 'intellectual property rights are private rights'. Hence it is the responsibility of the right holder to enforce its own private rights.

This means that if a patent holder is of the view that there is infringement of its patents, it has the right to institute court proceedings against any person who has infringed or is infringing the patent. In turn, the alleged infringer may argue that its product is not infringing the patent or dispute the validity of the patent. The court will scrutinise the patent and determine whether or not the patent should be enforced. It is not the responsibility of the DRA to 'police' private patents.

It is important to note that the drug marketing approving authority under the EU law i.e. the European Medicines Agency (EMEA) does not allow patent linkage. Neither does Switzerland have provisions of patent linkage in its own legislation. Even in the United States, where such provisions exist, the Food and Drug Administration has stated that it does not have the expertise or resources to review patents.[8] A United States Federal Trade Commission study showed that the United States linkage system is subject to substantial abuse by patent holders.[9] The Canadian Federal Government and Supreme Court have also recognized that companies had been using the Canadian linkage system to evergreen their patents[10], maintain market monopoly and high prices.

These and other TRIPS plus provisions also hinder the effective use of TRIPS flexibilities such as compulsory licenses. In this context it should be recalled that the UN High Level Panel Report on Access to Medicines (UNHLP) has recommended that "Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities."[11]

Further the United Nations Special Rapporteur on the Right to Health has recommended that 'Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs' and 'Developing countries and LDCs should not introduce TRIPS-plus standards in their national laws.'[12]

The UNHLP recommends 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."[13] **EFTA countries and Indonesia have ratified human rights treaties which include the right to health which are violated by the adoption of TRIPS-plus provisions such as data/market exclusivity, patent linkage, patent term extensions etc. [14]**

Furthermore, such provisions will make it extremely difficult for Indonesia to achieve the United Nations Sustainable Development Goals (SDGs) Goal 3 on health which were agreed to by all EFTA countries and Indonesia[15] and includes:[16]

- 'By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases'
- 'By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment'
- access to affordable essential medicines and vaccines.

We are also disturbed by the lack of transparency of the EFTA negotiations with Indonesia. The right to information and to participate in the decision-making process are essential for the enjoyment of the right to health.[17] Concerns have been expressed by various UN human rights bodies about the secrecy of trade negotiations.[18] It is worth recalling that the European Union (EU) has released their proposals to Indonesia in their FTA negotiations, including on intellectual property[19] and Norway[20] and Switzerland[21] have released their proposals in the Trade in Services Agreement (TISA) negotiations.

Therefore, we call on the EFTA countries to release their proposals in their FTA negotiations, including with Indonesia.

Given the above, we demand that EFTA removes from the CEPA with Indonesia all TRIPS-plus provisions such as data/market exclusivity, patent linkage, patent term extensions etc.

Please do not hesitate to contact Patrick Durish (Public Eye) at patrick.durisch@publiceye.ch for more information.

Signatories

- Public Eye (formerly Berne Declaration), Switzerland
- Alliance Sud (Swiss Alliance of Development Organizations), Switzerland
- Medicus Mundi Schweiz (Network of Swiss organizations active in international health cooperation), Switzerland
- Médecins du Monde (Doctors of the World), Switzerland
- Universities Allied for Essential Medicines (UAEM), Switzerland
- The Norwegian Trade Campaign

[i] https://data.worldbank.org/indicator/SI.POV.UMIC?view=chart
[ii] http://www.doctorswithoutborders.org/publications/reports/2011/MSF_Access_Report_13th_edition.pdf and http://aids2012.msf.org/wp-content/uploads/2012/07/MSF_Access_UTW_15th_Edition_2012_webres.pdf
[iii] Malpani, R. All costs, no benefits: how the US-Jordan free trade agreement affects access to medicines, Journal of Generic Medicines (2009) 6(3):206-217, Available from: http://jgm.sagepub.com/content/6/3/206.short.
[iv] Malpani, R. All costs, no benefits: how the US-Jordan free trade agreement affects access to medicines, Journal of Generic Medicines (2009) 6(3):206-217, Available from: http://jgm.sagepub.com/content/6/3/206.short.
[v] Cortés Gamba M, Rossi Buenaventura F, Vásquez Serrano M. Impacto de 10 Años de Proteccion de Datos en Medicamentos en Colombia, IFARMA and Fundación Misión Salud; Bogotá D.C., Colombia (2012), Available from: http://www.mision-salud.org/wp-content/uploads/2013/02/IMPACTO-DE-10-A%C3%91OS-DE-PROTECCION-DE-DATOS-EN-COLOMBIA.pdf .
[vi] IFARMA. Impact of the EU-Andean Trade Agreement on Access to Medicines in Peru, Health Action International Europe and IFARMA Foundation (2009), Available from: http://haieurope.org/wp-content/uploads/2010/12/11-Nov-2009-Report-IFARMA-Impact-Study-on-EU-Andean-Trade-Agreement-in-Peru-EN.pdf.
[vii] Shaffer E, Brenner J. A trade agreement's impact on access to generic drugs, Health Affairs (2009)28(5):w957-w968. Available from: https://doi.org/10.1377/hlthaff.28.5.w957.
[viii] "FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims." 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994). See "Generic drug entry prior to patent expiration: an FTC study", Federal Trade Commission, July 2002, p. 44
[ix] *ibid*
[x] T.A. Faunce and J. Lexchin, "Linkage in pharmaceutical evergreening in Canada and Australia", Australia and New Zealand Health Policy, vol. 4, (2007), p. 8, referring to the two following sources: Government of Canada. Canada Gazette Part II Regulations amending the patented medicines (notice of comp liance) regulations 2006, 140 (21): 1503-1525; AstraZeneca Canada Inc. v. Canada (Minister of Health), 2006 SCC 49.
[xi] https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf
[xii] www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf
[xiii] https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf
[xiv] Eg see Parties to the Convention on the Rights of the Child and the International Covenant on Economic, Social and Cultural Rights, http://indicators.ohchr.org/ which include the right to health in Article 12 and 24 respectively.
[xv] https://www.un.org/sustainabledevelopment/blog/2015/09/historic-new-sustainable-development-agenda-unanimously-adopted-by-193-un-members/
[xvi] https://sustainabledevelopment.un.org/post2015/transformingourworld
[xvii] A/69/299
[xviii] See for example: A/HRC/28/57, E/CN.4/2005/51/Add., A/69/299, A/69/299
[xix] http://trade.ec.europa.eu/doclib/press/index.cfm?id=1620
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