

Open Letter to EU Commission "Drop TRIPS Plus Provision on Indonesia-EU CEPA"

Dear Commissioner Valdis Dombrovkis,

We are extremely concerned about EU's proposals on intellectual property (IP)¹ in the Indonesia-European Union Comprehensive Economic Partnership Agreement (CEPA) that *inter alia* include:

- limiting of parallel importation to national or regional exhaustion of rights;
- patent term extension for medicines for delays in marketing approval, with further extension for pediatrics;
- data and market exclusivity requirements including for new uses of older medicines
- extensive requirements on IP enforcement (such as application of border measures to all IP)

These and other proposals of the EU are TRIPS-plus (i.e. beyond TRIPS requirements of TRIPS) with disastrous consequences for access to medicines in Indonesia. For example in Jordan, data exclusivity (DE) delayed the introduction of cheaper generic alternatives of 79% of medicines between 2002 and 2006, threatening the financial sustainability of government public health programs.² Medicine prices in Jordan are also 800% higher than in Egypt³ due to introduction of DE. In Colombia, as a result of DE, the costs to the public health system increased by US\$396 million between 2003 and 2011.⁴ In Guatemala, a study found that as a result of DE medicines that were readily available in most countries at affordable prices were simply not available in Guatemala.⁵ Patent term extension has been calculated by the Korean National Health Insurance Corporation to cost US\$757 million for a 4 year extension.⁶

Indonesia has a population of 274 million, with a GNI per capita of US\$3,870 compared to EU's US\$35,806 (11 times greater than Indonesia's).⁷ Even at purchasing power parity rates, 52% of Indonesia's population lives on less than US\$5.50 per day.⁸

Indonesia suffers from multiple communicable and non-communicable disease (NCD) burdens. It has been struggling with the effects of the WTO-TRIPS Agreement for the monopoly conferred by the Agreement has made medicines unaffordable. For example, Hepatitis C affects about 3 million people in Indonesia and yet to date, due to the high prices of medicines has meant that treatment has been limited. Similarly cancer causes 19% of NCD deaths in Indonesia. In 2018 there were 350,000 cancer cases with

¹ EU's proposals available at <https://trade.ec.europa.eu/doclib/press/index.cfm?id=1620?>

² 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>.

³ *ibid*

⁴ Cortés Gamba M, Rossi Buenaventura F, Vásquez Serrano M. Impacto de 10 Años de Protección 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>

⁵ 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>.

⁶ http://english.hani.co.kr/arti/english_edition/e_business/165065.html

⁷ <https://data.worldbank.org/indicator/NY.GNP.PCAP.CD>

⁸ <https://data.worldbank.org/indicator/SI.POV.UMIC?view=chart>

207,000 cancer deaths. Access to cancer treatment is limited due to the exorbitant costs, for instance 12 months of treatment of trastuzumab costs US\$20000.⁹

COVID-19 has aggravated the situation in Indonesia. It is one of the worst hit countries in South East Asia with 142,026 deaths. Access to critical medical products needed to contain the spread the infection has been difficult due to monopolies and high prices. Vaccinating 70% of Indonesia's population is expected to cost 22% of Indonesia's current health expenditure.¹⁰ This is not taking into account boosters and additional vaccinations needed in the coming years.

Against this background, the EU's proposals will only further worsen the socio-economic consequences facing Indonesia, exacerbated by COVID-19.

In TRIPS Council discussions, the EU claims to support the use of TRIPS flexibilities and yet IP proposals of the EU in the CEPA negotiations aims to extend IP monopolies and undermine TRIPS flexibilities.

Human rights experts have denounced TRIPS-plus provisions for their impact on access to medicines. The United Nations Special Rapporteur on the Right to Health has recommended that "Developed countries should not encourage developing countries to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health."¹¹

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 2008 an EP Resolution on EU relations with ASEAN Countries (which Indonesia is a part of), it recalled EU's commitment to support the Doha Declaration and the use of TRIPS flexibility in supporting public health and access to medicines in developing countries; therefore, asks the Commission not to do anything that could undermine the Thai government's efforts to ensure access to medicines for all its citizens. The Resolution also states 'nothing in the agreement should create legal or practical obstacles to the maximum use of flexibilities set out in the Declaration amending the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS agreement) and access to medicines.
- 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

⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5494230/>

¹⁰ Cost of vaccinating 70% of population as percent of current health expenditure at \$35, available at <https://data.undp.org/vaccine-equity/affordability/>

¹¹ <https://digitallibrary.un.org/record/652915?ln=en>

¹² https://www.europarl.europa.eu/doceo/document/TA-6-2007-0353_EN.html

far-reaching consequences for the production of generic medicines and is therefore detrimental to developing countries' access to medicines and public health policy¹³

- 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 in order to ensure that all HIV antiretroviral treatments are affordable, with full respect for the Doha Declaration on TRIPS and Public Health¹⁴

Therefore, we strongly urge the EU to ensure that the CEPA does not include any provisions that may in any way hinder access to affordable medicines in Indonesia including any TRIPS-plus provisions as mentioned in this letter.

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