Ms. Cecilia Malmström Commissioner, Trade European Commission

## CC:

Head of Cabinet, Ms. Maria Åsenius Deputy Head of Cabinet, Mr. Miguel Ceballos Barón Member of Cabinet, Ms. Nele Eichhorn Member of Cabinet, Mr. Pedro Velasco Martins Assistant to the Commissioner, Ms. Helen Cogels

Mr. Neven Mimica Commissioner, International Cooperation and Development European Commission

Mr. Vytenis Andriukaitis Commissioner, Health & Food Safety European Commission

16 April 2018

Dear Commissioner Malmström,

We write to you to express our concerns regarding the European Commission's recent announcement on 12 March 2018 to create a "Counterfeiting and Piracy Watch-List" to target third countries for allegedly failing to provide adequate and effective protection of intellectual property rights. We understand that the "Commission Staff Working Document: Report on the protection and enforcement of intellectual property rights in third countries" (hereinafter referred to as the "Commission IPR Report"), published on 21 February 2018, is intended to "identify third countries in which the state of IPR protection and enforcement gives rise to the greatest level of concern and thereby to establish an updated list of so called "priority countries". The Commission IPR Report, however, conflates counterfeiting and piracy with the legitimate use of the flexibilities of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

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<sup>&</sup>lt;sup>1</sup> China remains chief concern in latest EU report on the protection and enforcement of intellectual property rights, 12 March 2018. http://trade.ec.europa.eu/doclib/press/index.cfm?id=1813

<sup>&</sup>lt;sup>2</sup> Under the TRIPS Agreement, counterfeit trademark goods are defined as "any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation." Article 51, Footnote 13, Agreement on Trade-Related Aspects of Intellectual Property, https://www.wto.org/english/docs\_e/legal\_e/27-trips\_05\_e.htm#fnt-13

<sup>&</sup>lt;sup>3</sup> The TRIPS Agreement defines pirated copyright goods as "any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation. Article 51, Footnote 14, TRIPS Agreement, https://www.wto.org/english/docs\_e/legal\_e/27-trips\_05\_e.htm#fnt-14

Despite the European Union's public pledge<sup>4</sup> of support for third countries' right to use the flexibilities of the TRIPS Agreement and the support of an indefinite exemption for least-developed countries on implementing WTO intellectual property rules for pharmaceuticals<sup>5</sup>, the EU Watch-List will chill third countries' efforts to protect public health and to promote access to medicines as reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health. The Commision IPR report singles out third countries for enacting policies on: 1) strict patentability criteria (Argentina, Brazil, India, Indonesia, and Russia), 2) local working provisions (Ecuador and Indonesia), and 3) compulsory licensing (Ecuador, India and Ukraine). In addition, the EU IPR Report alleges that Argentina, China, India, Indonesia, Mexico and Ukraine provide insufficient regulatory data protection for pharmaceuticals. The EU's proposed Watch-List vitiates the spirit of the Doha Declaration. The creation of a Watch-List would undermine the objectives of the TRIPS Agreement which speak to a "balance of rights and obligations" and the fundamental principles which provide countries the policy space to "adopt measures necessary to protect public health" and undertake appropriate measures to "prevent the abuse of intellectual property rights."

An EU Watch-List would encourage the implementation of TRIPS-plus measures in third countries (such as narrowing the grounds for compulsory licensing, introduction of regulatory data exclusivity and patent term extension or promoting lax patentability criteria). Under the International Covenant on Economic, Social and Cultural Rights (ICESCR), states have an obligation, predicated upon human rights principles, not to support, adopt or accept TRIPS-plus provisions that would impede states from using exclusions, exceptions and flexibilities. Target 3.B of the SDG recognizes the importance of the "Doha Declaration and the right of countries to use to the full the provisions in the Agreement on TRIPS regarding flexibilities to protect public health, and, in particular, provide access to medicines for all" The Treaty of Lisbon commits the European Union to advancing the "principles of equality and solidarity" and fostering the "sustainable economic, social and environmental development of developing countries"; let not these principles ring hollow.

The Commission's Strategy for the Enforcement of Intellectual Property Rights in Third Countries is in dire need of course correction. We urge you to stop targeting the legitimate use of public health-sensitive TRIPS flexibilities in your objective to create a Counterfeiting and Piracy Watch List.

We request to meet with you and your Cabinet to discuss this matter further.

https://www.wto.org/english/docs e/legal e/27-trips 03 e.htm

<sup>&</sup>lt;sup>4</sup> Communication from the EC to the TRIPs Council on the implementation of the Doha Declaration on the TRIPs Agreement and Public health (ref. Doc. 282/03), 2 June 2003, http://trade.ec.europa.eu/doclib/docs/2004/march/tradoc 113230.pdf

<sup>&</sup>lt;sup>5</sup> European Commission supports better access to medicines in poorest countries, 10 September 2015,

http://trade.ec.europa.eu/doclib/press/index.cfm?id=1363

<sup>&</sup>lt;sup>6</sup> Article 7, Agreement on Trade-Related Aspects of Intellectual Property,

<sup>&</sup>lt;sup>7</sup> Article 8, Agreement on Trade-Related Aspects of Intellectual Property, https://www.wto.org/english/docs\_e/legal\_e/27-trips\_03\_e.htm

<sup>&</sup>lt;sup>8</sup> Report to the General Assembly of UN, A/70/279, 4 August 2015, ¶, 104

<sup>&</sup>lt;sup>9</sup> Sustainable Development Goal 3.B, https://sustainabledevelopment.un.org/sdg3

<sup>&</sup>lt;sup>10</sup> Chapter 1, Article 10 A, Treaty of Lisbon, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:12007L/TXT

## **Co-signatories**

Access to Medicines Ireland

AIDS Access Foundation, Thailand

Alianza LAC - Global por el Acceso a Medicamentos, Regional

All India Drug Action Network (india)

Associação Brasileira Interdisciplinar de AIDS (ABIA), Brazil

BioThai, Thailand

Commons Network

Drug Study Group, Thailand

Foundation for AIDS Rights, Thailand

Foundation for Consumers, Thailand

FTA Watch, Thailand

Fundación Grupo Efecto Positivo (FGEP), Argentina

Fundación IFARMA, Colombia

Health Action International (HAI)

Health and Trade Network

Health GAP (Global Access Project)

Initiative for Health and Equity in Society (india)

International Treatment Preparedness Coalition Latin American and Caribbean ITPC-LATCA

Just Treatment

Knowledge Ecology International Europe (KEI Europe)

Misión Salud, Colombia

ONG Políticas Farmacéuticas (Chile)

Oxfam

People's Health Systems Movement, Thailand

Prayas Centre for Health Equity (India)

Red Latinoamericana por el Acceso a Medicamentos, RedLAM

Salud por Derecho

Stop Drink Network, Thailand

STOPAIDS

Sustainable Agriculture Network, Thailand

Thai Network of People Living with HIV/AIDS (TNP+), Thailand

The All-Ukrainian Network PLWHA

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