

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".<sup>1</sup> The Commission IPR Report, however, conflates counterfeiting<sup>2</sup> and piracy<sup>3</sup> 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>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>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](https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#fnt-13)

<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](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 Commission 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"<sup>6</sup> 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."<sup>7</sup>

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.<sup>8</sup> 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"<sup>9</sup>. The Treaty of Lisbon commits the European Union to advancing the "principles of equality and solidarity"<sup>10</sup> 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.

## Co-signatories

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<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](http://trade.ec.europa.eu/doclib/docs/2004/march/tradoc_113230.pdf)

<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>6</sup> Article 7, Agreement on Trade-Related Aspects of Intellectual Property, [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_03\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm)

<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](https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm)

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

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

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

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BUKO Pharma-Kampagne  
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)  
Médecins du Monde  
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  
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STOPAIDS  
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