CECILIA MALMSTRÖM
MEMBER OF THE EUROPEAN COMMISSION

Brussels, 15 MAI 2018

Dear Mr Balasubramaniam,
Dear Mr Vidal,
Dear Co-signatories,

We thank you for having brought to our attention your concerns about the Counterfeit and Piracy Watch List (the "Watch List") and our intellectual property enforcement policy.

As you know, the Watch List initiative is part of the Commission's Strategy announced in the 2017 Communication "*A balanced intellectual property enforcement system responding to today's societal challenges*"[1], which was designed to step up efforts to combat counterfeiting and piracy. With the planned Watch List the Commission intends to identify concrete physical and online marketplaces, located outside the EU, which engage in or facilitate IP infringements, in particular counterfeiting and piracy. The Watch List will not list countries, but only concrete online and physical marketplaces (websites, market halls, street markets).

Counterfeiting and piracy cause significant financial losses for right holders and legitimate businesses in developed and developing countries alike. The lost sales and revenues result in lost jobs, lost government revenues due to the tax evasion (i.e. VAT, revenue taxes, customs duties) and undermine local innovation. Counterfeit goods also constitute a real threat for consumers' health and safety (i.e. pharmaceuticals, toys and spare parts) and the environment (i.e. pesticides) and contribute to organised crime. The recent OECD-EUIPO study on the economic impact of trade in counterfeit and pirated goods showed that international trade in counterfeit and pirated goods represents up to 2.5% of world trade, or as much as EUR 338 billion. In the EU context counterfeit and pirated goods amounted up to 5% of imports or as much as EUR 85 billion[2]. Regarding pharmaceuticals, according to the OECD-EUIPO (2016) study, global trade in counterfeit pharmaceuticals was up to EUR 11.9 billion in 2013. This represents more than 3.3% of total trade in pharmaceutical products.

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[1] http://europa.eu/rapid/press-release_IP-17-4942_en.htm
[2] https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/documents/Mapping_the_Economic_Impact_study/Mapping_the_Economic_Impact_en.pdf

The objective of the Watch List is to bring about the improvement of IP enforcement by, for instance, encouraging the operators of the marketplaces to take measures to reduce the availability of counterfeit and pirated goods and content on their platforms. Nothing in the Watch List will have a negative effect on the access to genuine medicines, whether those are generics or products of the originator.

Unlike the Watch List, the Commission's Report on the protection and enforcement of intellectual property rights (IPR) in third countries (Third Country Report), which was published on 21 February 2018, identified countries outside the European Union, where the level of intellectual property protection and enforcement gives rise to the greatest level of concern, with the aim of improving IPR protection and enforcement worldwide. The Third Country Report was based on a variety of information sources, including for instance stakeholder input, customs data received from the EU Member States' customs authorities, statistical data collected by the EUIPO and the OECD, WTO Trade Policy Reviews, IPR Dialogues with third countries and data on actions against IPR infringements published by third country governments. The wide range of data sources used for the preparation of the Report makes it highly reliable.

We would like to underline that nothing in the Third Country Report can be interpreted as restricting the TRIPS flexibilities or limiting access to medicines. On the contrary, the Commission points at measures introduced by third countries, undermining the current international legal framework, which safeguards access to genuine medicines.

For instance, some of the listed countries apply a controversial local working requirement, which requires all foreign pharmaceutical companies to manufacture the patented medicines or use the patented process in their territory. These rules appear to discriminate imported patented products against domestically produced goods under patent protection. Also, some of the listed countries exclude from patentability certain classes of medicinal products or apply additional patentability criteria, which are questionable under the TRIPS Agreement. These legislative practices undermine incremental innovation and research in, *inter alia*, new uses of already known medicines (follow-up pharmaceuticals, new uses, new combinations), which can provide benefits to patients. Finally, a number of the listed countries apply criteria for the issuance of compulsory licences which seem not to respect the international legal framework on access to medicines and public health. These controversial legal practices applied by the countries mentioned in the Third Country Report seriously undermine incentives for innovation and research, or even to place the products on the respective markets, with detrimental effects for patients in need. We believe that the Third Country Report can be used as a tool to address these practices.

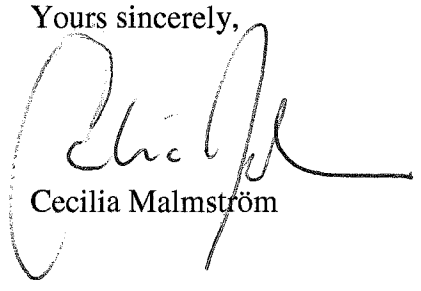
Furthermore, the European Commission is committed to promoting an ambitious global health agenda and better access to medicines, including through a permanent waiver for least developed countries (LDCs) for pharmaceutical products under the TRIPS Agreement. In addition, the European Commission always takes into account the level of development of its trading partners and also aims at preserving the balance between economic opportunities in the knowledge economy and the pursuit of public policy objectives (i.e. biodiversity, sustainability and public health). Consequently, the EU - in negotiations with its trading partners - insists on consistency with the international legal framework on access to medicines. Effective enforcement to stop the flow of counterfeit medicines is equally crucial – substandard and falsified medicines pose a tremendous health risk to patients in need that have to rely on life-saving treatment. According to a WHO study, with regard to pneumonia alone, 72,000 to 169,000 children are dying each year due to substandard and falsified antibiotics[3].

[3] http://www.who.int/en/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified

The European Commission has been also consistently promoting the agenda of access to medicines through various initiatives and financial support, seeking to strike the right balance between, on the one hand, the need to promote and fund research into new and better medicines and, on the other hand, to ensure that medicines are accessible and affordable. The EU and its Member States have financed, for instance, the Global Fund, which distributes medicines to patients in need in developing countries with diseases such as HIV or malaria drugs with over 19 billion EUR from 2001-1016. For the period of 2017-2019 the EU and its Member States will finance the Global Fund with around 15 billion (out of the 29 billion EUR pledged by all countries). This has allowed saving approximately 22 million lives.

We are looking forward to meeting your representatives in Brussels on 16 May 2018 and to discussing these issues in a greater detail.

Yours sincerely,



Cecilia Malmström