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Directorate-General for Trade

Directorate B - Services and Investment, Intellectual Property and Public Procurement
Intellectual Property and Public Procurement

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Trade Policy Committee

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NOTE FOR THE ATTENTION OF THE TRADE POLICY COMMITTEE

SUBJECT: LETTER COMMISSION TO CALL FOR CONTRIBUTIONS UNITED NATIONS HIGH LEVEL PANEL ON ACCESS TO MEDICINES

***ORIGIN*:** COMMISSION DG TRADE, UNIT B.3 INTELLECTUAL PROPERTY AND PUBLIC PROCUREMENT

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OBJECTIVE: ***For information***

REMARKS:

Please find attached a letter the Commission sent on Tuesday 16 February 2016 in response to a call for contributions by a United Nations High Level Panel on Access to Medicines. The letter has also been circulated to Member States delegations to the World Health Organisation in Geneva.

United Nations Secretary-General Ban Ki-moon in November 2015 established this panel to present a set of recommendations in June 2016, coinciding with a UN high level meeting on HIV/AIDS.

The Commission welcomes the opportunity to contribute to this very important debate and therefore prepared a detailed submission. However, regarding one particular issue, the role of IPR, we would like to call the attention of the Member States to the following:

The Panel's Terms of Reference start from the assumption that IP rules are in contradiction with fundamental rights, and even with trade rules and focusing only on the price variations caused by patents as the main barrier to access to medicines.

The Commission does not share the starting assumption of the call for contributions as many studies show lack of access to medical technologies is not due to a single isolated factor. As a 2012 WHO-WTO-WIPO study notes, the "*lack of access to medical technologies is rarely due to a single isolated factor*". There are many factors affecting access, but mostly unrelated to IPRs, such as lack of access to quality health care, poor infrastructure, lack of distribution and supply systems, and lack of quality control..

The Panel's documents are on-line: http://www.unsgaccessmeds.org/

The Commission was informed that the United Nations has invited UN Member States to make representations at a Hearing of the High-Level Panel in Johannesburg, 16 March 2016.

The Hearings provide the High-Level Panel and its Expert Advisory Group an opportunity to engage with short-listed contributors, stakeholders and Member States who so wish on matters that have relevance to the deliberations of the panel.

UN Member States were also invited to participate in one of two Global Dialogues where a broad range of stakeholders, including but not limited to Member States, academia, civil society, private sector and patient rights groups, will engage and be afforded the opportunity to provide input on the Contributions received.

Below are the details of the two Global Dialogues the UN announced will be taking place:

- 10 March 2016, The Kingsway Hotel, London, United Kingdom
- 17 March 2016, Holiday Inn Rivonia Road, Johannesburg, South Africa

Should Member States decide to participate in such hearings, the Commission consider s that the attached submission would be useful reference material.

Attachments: 1) Letter Commission to call for contributions United Nations High Level Panel on Access to Medicines

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels,
SANTE/B2/CN/jp Ares(2016)808196

Dear Sirs,

Subject: Contribution submission to the Panel on Access to Medicines

The European Commission welcomes the opportunity to address comments to the High Level Panel on Access to Medicines. Access to medicines is a complex issue with a multitude of factors affecting the accessibility, availability and affordability of safe quality medicines to patients around the world. The European Commission addresses the access to medicines agenda with a health-in-all-policies approach and through various initiatives, programmes, and policy and financial support.

Currently, European Commission engagement and support for access to medicines addresses a wide range of issues including basic and applied research for neglected and orphan diseases, regulatory capacity building, health systems strengthening, transparent public procurement systems, increased capacities for local production and for detection of falsified medicines, support for measures to root out corruption and to improving supply and distribution chains for pharmaceuticals. The Commission also supports the work of the WHO, including its normative work, on its lists of Essential Medicines and its guidance on rational use. This includes the implementation of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (GSPOA) adopted by the World Health Assembly in 2008.

Other initiatives put in place in relation to affordability include the elimination of import tariffs for medicines and the encouragement of actions that provide economies of scale such as joint procurement actions for medicines and vaccines both directly at EU Member States level and indirectly though the significant contributions it makes to the Global Fund to Fight AIDS, Tuberculosis and Malaria and to GAVI, The Vaccine Alliance. The EU is a major contributor to health-related aid. Against this background the Commission wishes to point out the importance of EU support to such projects and initiatives. The EU has also initiated the European and Developing Countries Clinical

United Nations Secretary-General's
High-Level Panel on Access to Medicines

Trials Partnership to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria as well as other poverty-related and neglected infectious diseases in sub-Saharan Africa.

Within this broad picture, the Commission encourages the Panel to adopt a holistic approach to the problem so that it can make a valuable contribution to the wider debate on access to medicines. In this context, the European Commission does not share the starting assumption of the call for contributions - presented as a definitive conclusion - that there is a "misalignment between the rights of inventors, international human rights law, trade rules and public health where it impedes the innovation of and access to health technologies". Indeed, this assumption that the rights of inventors are the single or even the main impediment to innovation and access to health overlooks a key finding of the 2012 joint WHO-WTO-WIPO study on "Promoting Access to Medical Technologies and Innovation" that the "lack of access to medical technologies is rarely due entirely to a single determinant." As also reflected in the WHO access framework for essential medicines, there are many factors affecting access which are not related to intellectual property, such as lack of access to quality health care, poor infrastructure, lack of distribution and supply systems, and lack of quality control. Such a narrow starting point also ignores all the efforts and verifiable progress that have been made on the link between patents and access to medicines in the last 15 years.

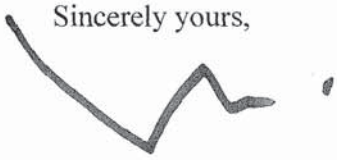
Intellectual property is a driver of innovation for new medicines and new uses for medicines. The question the Panel will face is how to balance the need for incentives for innovation with ensuring equitable access for patients. There is a significant amount of work going on globally in this area and the Commission urges the Panel to build on the work conducted by international organisations such as the WHO, the WTO, and WIPO on this issue. The Commission also draws the Panel's attention to the ongoing comprehensive evaluation and review of the above-mentioned GSPOA that will take into account relevance, effectiveness, efficiency and sustainability.

The Commission also wishes to recall that the international IP regime foresees a number of exceptions and options that can be used to improve access to medicines, as clarified notably in the 2001 Doha Declaration on TRIPS and public health. Key options include transition periods for least developed countries (LDCs) and a recent example of putting this into practice was the 6 November 2015 decision of the WTO's Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) that LDCs will be exempt from WTO obligations to provide patent protection for pharmaceutical products to support access to medicines until at least 2033, which was fully supported by the European Union. Another important step was the decision by WTO members in 2003 to propose amending the TRIPS Agreement to make it easier for countries to import medicines produced under compulsory licensing if they are unable to manufacture the medicines themselves ("Paragraph 6 System"). The Commission would suggest the potential contribution of these measures is taken into account.

The Commission would encourage the Panel to assess the increased use of voluntary license agreements (e.g. through the Medicines Patent Pool) as a tool to increase the affordability of medicines, as well as to consider recent initiatives such as the WIPO initiative "Re:Search" – a consortium through which public and private sector organizations share valuable intellectual property and expertise with the global health research community to promote development of new drugs, vaccines, and diagnostics in the fight against neglected tropical diseases, malaria, and tuberculosis.

Finally, the European Commission would like to express its availability to work constructively with the Panel in the coming months as part of the broader debate on access to medicines but would insist that this, like all the work of the Panel, should be done in a transparent manner.

Sincerely yours,



Xavier Prats Monné