CIVIL SOCIETY DIALOGUE

AD HOC MEETING – TRADE INSTRUMENTS TO IMPROVE ACCESS TO AFFORDABLE MEDICINES IN DEVELOPING AND LEAST-DEVELOPED COUNTRIES

Date: 28th November 2013
Time: 10h-12h30
Location: Auditorium, Breydel building, Rue Belliard 248, 1040 Brussels

Lead speakers

Mr Anders Jessen, Head of Unit Intellectual Property and Public Procurement, Directorate-General for Trade

Ms Isabel Fezas Vital, Policy Officer, Unit Market Access, Industry, Energy and Raw Materials, Directorate-General for Trade

Ms Helle Aagaard, EU Policy and Advocacy Advisor, Médecins Sans Frontières – Access Campaign.

Ms Leïla Bodeux, Policy Officer Essential Services, Oxfam Solidarité.

Mr Sergio Napolitano, Trade Policy Officer, European Generic Medicines Association (EGA).

Commission opening remarks

DG Trade (AJ) referred to the many recent studies and trade cases on the issue at stake, as well as the trilateral report of the WHO, the WTO and WIPO. He also set the framework of the dialogue, i.e. a discussion of the wider range of trade instruments that affect access to medicines, such as procurement policies, competition policy, tariffs and non-tariff measures, services and investment among others. DG Trade invited the stakeholders to widen the debate on access to medicines and to go beyond the uni-dimensional debate that tends to focus on intellectual property rights as an obstacle to wider access. DG Trade declared that it shares stakeholders' concern about the unaffordability of medicines in developing countries and would be ready to use all trade instruments at its disposal to improve access to medicines. Hence, it encouraged the participants to share their views and experiences in developing countries and least developing countries on other trade-related obstacles to access affordable pharmaceutical products.
Stakeholders’ presentations

*Médecins Sans Frontières (HA)* stated its belief that the patent system would be the key-problem that hinders access to medicines, as it restricts generic competition and increases prices of medicines. MSF urged the European Commission not to impose TRIPS+ provisions in its FTAs. Referring to the Eli Lilly vs. Canada case, MSF was concerned that companies’ investment claims might conflict with public health interests. Therefore they asked for cautiousness on the Investor-State Dispute Settlement (ISDS) provisions in the EU’s FTAs.

On the EU-Thailand FTA, MSF rejected the inclusion of the patent term extension, the specific data exclusivity provisions and the IP enforcement principles of the EU proposal. Furthermore, MSF expressed its doubts on tiered pricing as a means to deliver sustainable access. For MSF it is a form of harmful competition, whereas (generic) competition should be the default option for achieving affordability, as it has proven superior to tiered pricing for reliably achieving the lowest sustainable prices. MSF encouraged the use of the “de-linkage” policy to finance medical R&D instead of the current patent system that is needed to recover investments.

*Oxfam Solidarité (LB)* underlined the importance of the Policy Coherence for Development principle in the Lisbon Treaty under article 208 TFEU. It was noted that 2/3 of the world’s pharmaceuticals are paid directly by the patient and that 1/3 of the population has no access to medicines. The EU does play a positive role in developing and least-developed countries through its development aid policy as well as its research and development policy; however, some FTA provisions and strict IP rules may harm the access to affordable and quality generic medicines.

Oxfam expressed its concern about data exclusivity provisions, Supplementary Protection Certificates (SPC) and other TRIPS+ provisions in the FTAs with India and Thailand as well as about ISDS provisions in the investment chapter of the EU’s FTAs. It also advocated for extending the TRIPS waiver for LDCs, as they need the space to implement IP systems appropriate to their development needs, to their policy priorities and to their level of economic development. Oxfam considered that the Commission was putting pressure on LDCs to reduce their demands and hoped the EU would take a more flexible approach in 2016 (extension for pharmaceutical products) and 2021.

*EGA (SG)* referred to various variables that undermine effective access to medicines, such as diffused poverty, lack of infrastructures, low level of regulatory capacities, lack of pharmaceutical production and political instability, which have led to the dependence on sub-standard medicines in many developing countries. EGA therefore suggested allowing European generic companies to manufacture for export during the SPC period to create a level-playing-field with other generic companies outside the EU; this could generate more jobs in the EU, increase growth and exports, and reduce the dependence on sub-standard medicines in developing and LDC markets.

The presentations are available at the dedicated webpage of the meeting.

**Roundtable discussion**

*DG Trade (IFV)*, referred to the wide range of barriers encountered on market access issues for pharmaceutical products, which were not related to IPR, such as registration and certification procedures, the requirement of conducting clinical trials locally, custom control measures, TBT and NTB barriers, cuts in health expenditure, cultural barriers, and additional GMP requirements of third countries administrations that can lead to significant delays.
DG Trade (AJ) addressed some of the issues raised in the presentations.

DG Trade assured the participants that there is always an interservice consultation process in the European Commission that ensures policy coherence.

On patents, it was flagged that most of the drugs on the essential medicines list are off-patent. Nonetheless, large price differences continue to exist on these medicines. Therefore it would be necessary to think about explanations which go beyond IP.

On the tiered-pricing mechanism, DG Trade noted that it is currently under review. An independent policy study will be conducted next year. It was underlined that the tiered pricing mechanism should be regarded as an efficient temporary solution during the patent term protection period, where there is not yet generic competition. Moreover, governments should put in place public health systems and use their power to negotiate reasonable low priced medicines by securing sustainable supply.

DG Trade clarified that, on the trade agreements with India and Thailand, the European Commission would include clear language on the TRIPS flexibilities that apply to the whole agreement, i.e. including the investment chapters. In the negotiations with Thailand, the Commission would not impose a patent term restoration system. Concern was expressed about the current backlog in Thailand’s patent system. It should be kept in mind that Thailand’s impressive economic performance should bring it up to par with a number of EU Member States within a few years and that it is rapidly developing public health care.

On the LDC extension for the TRIPS waiver, DG Trade observed that it has not put excessive pressure on the LDCs. Its aim has been to establish a debate on the current status and needs of different LDCs, considering, inter alia that several of them have ambitious IP objectives in their own development goals. Therefore it would have been useful to see what could be done to fill IP gaps. Hence, the EU is not against the extension per se, but it should not be done automatically, unilaterally and without dialogue about the ways to address the specific and differentiated problems of the countries concerned. For DG Trade the de-linkage proposal is valuable particularly in areas where other mechanisms are not effective, such as in the financing of innovation in the treatment of neglected diseases; however, it is not convinced that the system can replace the IP system for innovative medicines. Public and private funding are complementary to each other. Moreover, the European public budgets are already under enormous pressure and the question would be how to finance such de-linked mechanisms.

Health Action International (HAI) agreed that there are other barriers to access to medicines that go beyond IPR and stated that substandard medicines are one of their main concerns. Nevertheless, they did not believe that the problem would be solved through stronger IP rules, but rather by increasing the controls on the quality of medicines in developing and least developed countries.

European Federation of Pharmaceutical Industries and Associations (EFPIA) noted that many of the issues at stake could not be solved by the European Commission but should be discussed at a much broader level. A substantial part of the global population has an affordability problem, not only on pharmaceuticals, but just about on any other basic needs. Therefore, the discussion would not be about re-engineering the IP system, but about governments investing in public health coverage. EFPIA was sceptical about the de-linkage system and expressed their doubts on how this could work as an innovation mechanism.

HAI added that governments already use the de-linkage system through e.g. the EDCTP and the IMI. Governments should, however, be more critical when investing in innovative medicines and impose –price- conditions upon their funding.
DG Trade thanked the participants for their interest and active participation, and observed that it might be useful that civil society organisations discussed the issues raised during the meeting with their colleagues working on the field.

A follow-up event can be organised in the near future if civil society organisations are interested.