Meeting with Health Action International and Public Citizen

2 February 2015

Subject: Transatlantic Trade and Investment Partnership, Trans Pacific Partnership – impact on the access of affordable medicine

Participants:

DG TRADE, DG GROW, , , , , DG SANTE

, , Health Action International, , Public Citizen

Summary

In this meeting, Health Action International and Public Citizen voiced concerns about the TTIP's impact on the access to affordable medicine in the EU. US-based Public Citizen reported about lessons learned from the TPP negotiations in this regard. The Commission representatives welcomed the information and recalled the Commission position on the various points discussed.

1. Pricing and reimbursement of pharmaceuticals

Health Action International and Public Citizen voiced concerns about the TTIP's impact on the pricing and reimbursement of pharmaceuticals in the EU. In particular, HAI is worried about the inclusion of a transparency annex in the agreement. Public Citizen stressed that is the first priority of US industry that is making active lobbying on this matter in D.C., notably by claiming that the EU does not currently contribute in a fair way to innovation. It is also very high on USTR agenda for TTIP. Based on previous trade agreement with Korea and Singapore, this annex could lead to a situation where the ability of the European Member States to regulate prices would be limited, and the power of multinational drug companies in price-setting would increase. As drug companies might ask for a greater compensation of innovations, drug prices might increase in the EU. The reimbursement of pharmaceuticals could be affected and patient co-payments might increase. HAI believes that government pricing policies are important to keep drugs affordable and ensure access. The value of a drug should not be determined by whether or not it is under patent. Rather, the therapeutic value of a drug should determine its price.

The **Commission** reminded current EU Transparency Directive (89/105/EEC) and repeated the commitment to ensuring that neither the TTIP nor any other trade agreement will infringe upon the competences of Member States as stipulated by Article 168 (TFEU). Moreover, EC explained in what way the situation described for trade agreement with Korea was not applicable to the US as there is no universal health coverage in the US and no price setting by the public authorities.

Public Citizen reported on experience with the **Transatlantic-Pacific Partnership** negotiations. The negotiations are almost completed and the agreement may be used by the US to impose similar standards on the EU. Public Citizen believes that the bargaining power of multinational drug companies is likely to increase with the TPP and sees a similar risk in the EU.

Following this meeting, Public Citizen will provide the Commission with papers on the TPP debate.

2. Release of data from clinical trials and exchange of confidential information

HAI raised concerns that the TTIP could undermine EMA's policy on publishing data from clinical trials. In the view of HAI, clinical trial data should be shared to spread knowledge about the safety and efficacy of drugs as well as to ensure innovation. But trade secret protection and commercial confidentiality agreements could jeopardize access to data from clinical trials. Public Citizen expressed the view that FDA policy on public access is too restrictive and that legal cases against FDA often allow to gain access to more information.

The Commission clarified that a clear distinction has to be made between public access to information on clinical trials and exchange of information amongst regulators. As far as clinical trial data are concerned, the EMA policy and the EU Regulation will be implemented. There is no interest from the EU to pursue discussions in the TTIP on this point. By contrast, the EU has interest to facilitate exchange of information amongst regulators on confidential information and trade secrets (e.g. inspection reports, safety data) that support regulatory cooperation. HAI was supportive of this second objective. The Directive on Trade secret protection is still being discussed within the EU and there is no intention from the Commission that this Directive will affect public access to clinical trial information.

3. Intellectual property (IP)

HAI and Public Citizen voiced concerns that the TTIP could **reduce access** to affordable **generics**, if it leads to a higher protection of IP than currently in place in the EU and in the US. Stricter IP rules would imply longer monopoly periods, higher prices and more new drugs with only limited therapeutic value.

EC stressed that IP rules will not change in the EU.

ISDS was only mentioned as there was no time to discuss it and HAI gave us a copy of their response to the consultation.