

**To:** (TRADE); (TRADE);  
 (GROW); (GROW); (TRADE)  
**Cc:** (TRADE); (TRADE); TRADE  
 TTIP TRANSPARENCY  
**Subject:** TTIP Meeting with BEUC on TTIP & Health 10/07/2015  
**Attachments:** 2015 06 23 ttip\_health\_beuc\_position.pdf

DG TRADE, SANTE and GROW met with BEUC on TTIP & Health on 10/07/2015

BEUC is the European Consumer organisation and is part of TTIP Advisory Group

- BEUC submitted a position paper on TTIP and health on 23/06/2015 (attached)
- BEUC noted that there is no particular need to promote regulatory cooperation in this area in TTIP given the fact that in many aspects the EU and the US are already engaged in global or bilateral cooperation. COM noted that despite the existing regulatory cooperation there are a number of areas that have not yet been fully explored such as biosimilars and generics. TTIP could serve as an impetus for the existing cooperation without replacing it.
- BEUC expressed support for the mutual recognition of Good Manufacturing Practices (GMP) (more effective use of regulatory resources). COM noted that intensive work is taking place in order to assess the equivalence of EU and US GMP systems. Legal texts have not yet been drafted.
- BEUC enquired whether clinical trials data received or held by the EMA will continue being subject to European legislation or will be treated by the US legal environment in terms of disclosure. COM indicated that the EMA policy and the implementation of the clinical trial regulation will not be negotiated in TTIP. More specifically, COM clarified that information received from a US manufacturer for the purposes of a marketing authorization in the EU will be treated in line with EU rules on the matter and vice versa. COM highlighted that clear distinction has to be made between exchange of information among regulators and data disclosure to the public.
- BEUC opposes any potential extension of the intellectual property protection as well as wants to see the high-level of EU standards maintained. COM noted that IP on pharmaceuticals do not constitute areas

of possible offensive interest to the EU contrary to the issues of geographical indications or copyright where EU has offensive interests. COM highlighted that issues that would require changes to EU law such as patent linkage should not be discussed in TTIP. There is no legal text available and EU position is expressed in the IPR position paper and fact sheet available on the web.

- BEUC reiterated that EU governments should maintain full autonomy to make pricing and reimbursement decisions about medicines and medical devices. COM underlined that EU has no intention to include transparency provisions within the TTIP given the diverging health care systems.
- BEUC noted that it does not want to see the EU approaches to the promotion of pharmaceuticals changed according to US-style medicine promotion. COM noted that medicinal products advertising is not being discussed within TTIP.
- BEUC welcomed the main elements of possible cooperation on medical devices as outlined in the EU position paper but expressed concerns about the fact that harmonisation of the approval systems being ruled out. According to BEUC US has a safer marketing authorisation system compared to the EU especially in terms of the high risk devices. COM noted that EU system is very solid, provides for adequate consumer protection and provides for wide access to innovative products.

Participants:

[REDACTED], [REDACTED], [REDACTED] (DG TRADE);  
[REDACTED] (DG SANTE);  
[REDACTED]; [REDACTED] (DG GROW)  
[REDACTED]; [REDACTED] (BEUC)