

## **Meeting with the European Consumers' Organisation (BEUC)**

**29 January 2014**

### **List of attendees:**

[ ART. 4.1b ] (BEUC); [ ART. 4.1b ] (BEUC)

KAIZELER Ivone (DG TRADE); SUAREZ SANCHEZ Elena (TRADE) EMBERGER Geraldine (DG TRADE); INNOCENTE Francesca (TRADE); MOKRY Roman (DG SANCO).

### **Summary:**

On 29 January 2014, the European Commission met with two representatives of the European Consumers' Organisation (BEUC) to discuss the ongoing negotiations for a Transatlantic Trade and Investment Partnership (TTIP). The Commission welcomed BEUC engagement in the dialogue and gave a general overview of the timing and content of negotiations.

BEUC expressed its interest in discussing sectorial issues related to the medical devices, pharmaceuticals and cosmetics sectors. COM noted that while understanding that an umbrella organisation is likely to provide comments of a more horizontal nature (transparency, consultation, consumer health and safety, etc) more detailed position papers per sector would be very welcome.

### Medical Devices:

- BEUC sees the system of pre-market authorisation for medical devices in place in the United States as a model and would welcome EU to take the same approach. COM clarified that TTIP will not interfere on EU Medical Devices Regulation discussions nor aim at changing the EU system towards the EU one.
- Agrees with the topics currently being discussed (Unique Device Identification (UDI), Common Data Template and common approach on Quality Management Systems/Single Audit) and does not expect negative impact of them on consumers.
- Sees the requirements for clinical evidence for manufacturers not sufficiently high in Europe if compared to those required to place a device in the US market. Proposed to include clinical evidence/investigation as another topic for discussion in TTIP, which would increase the requirements for manufacturers in the EU.
- Is in favour of exchange of confidentiality data between the EU and the US and of public access to certain data (e.g. in order to avoid duplication of clinical trials).
- Would like to see TTIP to discuss regulatory issues in the future such as the classification of borderline products classified (e.g. cosmetic fillers) in the EU and the US, where more harmonisation (within the EU and also across the Atlantic) should be achieved. BEUC would prefer legally binding decisions in the EU on classification of medical devices, cosmetics etc., rather than EU guidelines.

### Cosmetics:

BEUC is still shaping its position on cosmetics and TTIP. A more detailed position is expected. Three issues were highlighted:

- Differences in regulatory frameworks: BEUC has some concerns that the approximation of the two frameworks could lead to reduction of consumer protection in the EU. COM clarified that this will not be the case.
- Different approaches in specific areas - product notification, nano definition, labelling requirements.
- Endocrine disruptors: The US does not want to impose regulation in this area. COM noted that discussions on the horizontal criteria for the identification of endocrine disruptors are going on in the EU and that an Impact Assessment will be launched soon.

#### Pharmaceuticals:

A meeting with DG SANCO dedicated to pharmaceuticals would be organised in the next days

- BEUC is in favour of recognition of GMP inspections
- Welcomes closer cooperation between the European Medicines Agency and the Food and Drug Administration.
- Inquired about pricing and reimbursement provisions. COM noted that this issue has not yet been discussed in detail in TTIP but it is likely that US comes up with a proposal.
- Favours transparency and data disclosure both towards the public and between regulators, notes that EU is ahead of US in terms of public data disclosure which is good for consumers and is somehow concerned about the definition of commercial confidentiality. COM noted that exchange of confidential information between regulators is being discussed in TTIP as an enabler for bilateral work between EMA, FDA and EU Member States on pharmaceutical products.