EUROPEAN COMMISSION
Directorate-General for Trade

Directorate F - WTO, Legal Affairs and Trade in Goods
TRADE F.3 Tariff and Non–Tariff Negotiations, Rules of Origin

Meeting with GIRP (European Association of Pharmaceutical Full-line Wholesalers) on TTIP regulatory issues

09/04/2015

Participants:

- Art. 4.1b , Art. 4.1b (DG TRADE); Art. 4.1b (DG GROW)
- Monika Derecque-Pois, Director General (GIRP); Art. 4.1b , Deputy Director General (GIRP); Art. 4.1b , Head of Corporate Legal (Celesio); Art. 4.1b (GIRP)

Summary:

On the 9th of April 2015, the European Commission met with the European Association of Pharmaceutical Full-line Wholesalers (GIRP) to discuss the ongoing negotiations for the Transatlantic Trade and Investment Partnership (TTIP).

The members of the GIRP expressed their interest in discussing the potential impact of TTIP on issues such as access to medicines, medical devices as well as quality and safety standards.

GIRP representatives gave some background information on the daily business of the Association as well as on pharmaceutical wholesaling. GIRP represents the national associations of over 750 pharmaceutical full-line wholesalers serving 32 European countries, including major pan-European pharmaceutical full-line wholesaling companies. (e.g. Celesio). GIRP members create a vital link in healthcare by providing to pharmacies a full range of product including medical devices, food supplements, cosmetics as well as medicines. Furthermore, GIRP members play a substantial role in safeguarding European citizens from medicines shortages in cases of threat.

COM gave a general overview of the content and the state of play of TTIP negotiations. It was explained that several sectors are being negotiated including the health care sector, which is deemed to be particularly challenging as health related aspects could appear in different chapters of the agreement. A number of position papers have already been issued (available in web). Those resulted from a close cooperation among stakeholders of the area, including pharmaceutical and health regulators of both Parties (contributions from several stakeholders have been assessed by COM based on feasibility and reasonability). COM noted that food supplements have not been discussed under TTIP and are not on the discussion table.

Several questions were raised by GIRP among them on the ***timing of the finalisation of TTIP*** negotiations. COM answered that negotiations are unlikely to be finalised by the end of this year.

On the question of whether EU legislation can be influenced by TTIP, COM answered that the final decision making fall within the competence of the EU regulators. Any future revision of EU Regulations/Directives has to go through the normal EU legislative process.

As regards ***the potential prospects of harmonisation***, COM explained giving the example of GMP inspections that in several areas mutual recognition agreement can be concluded after an assessment of equivalence. However, as regards medical product authorisations the concept of a product already authorised in one region being automatically authorised in the other one is not possible nor being discussed.

Regarding ***TTIP's potential effects on the parallel trade market and*** on the guidelines ***on Good Distribution Practice of medicinal product for human use (GDP)***, COM clarified that nothing is going to be changed in these areas.

As regards the ***potential inclusion of pricing and reimbursement transparency provisions in TTIP***, COM underlined that this issue Art. 4.1(a) third indent is not endorsed by the EU. Art. 4.1(a) third indent .

With regard to ***the potential legal provisions to be made for the delivery of health care services***, COM informed the attendees about the publicly available comprehensive documents (e.g. fact sheet on services) regarding the handling of services. COM mentioned that given the sensitivity of the health care services they are exempted from the national treatment obligations hence the EU and its MS have the right to restrict the provision of cross-border health services.

On ***Unique Device Identification (UDI)*** and ***interoperability of databases*** for medical devices, COM explained that both the EU and the US side are committed to develop their UDI systems aligned to IMDRS guidelines. The US has already developed and implemented their US UDI system as well as their database that are in application since September 2014. The EU has intention to implement its own compatible system but that requires the EU Regulation on medical devices to be adopted. In addition, GIRP has ***expressed its concern about*** the potential growing role of serialisation, namely ***taking serialisation approach to all classes of medical devices*** is not endorsed by the industry.

Finally, **GIRP informed COM about a conference on health care** organised by GIRP on the 13th of November 2015 in Brussels with the presence of several stakeholders from the industry. GIRP noted that any representatives of COM dealing with health care in the frame of TTIP would be welcome in this event. **COM noted** that **a public debate on TTIP and health is expected to be organised on the 27th of May in Brussels**, where several questions can be asked by the attendees to the TTIP negotiators.