EUROPEAN COMMISSION
Directorate-General for Trade

Directorate F - WTO, Legal Affairs & Trade in Goods
Unit F3: Tariff and Non-Tariff Negotiations, Rules of Origin

AMCHAM EU PLENARY MEETING

Medical Devices
Tuesday 16 June 2015, Brussels

Key note speaker:

Thomas Huszak – Head of Cabinet of Commissioner Elzbieta BIENKOWSKA

Panellists:

- Céline Bourguignon, *Director, Worldwide Government Affairs & Policy, Johnson & Johnson*
- [redacted] *CEPS*
- [redacted] *Tariff and Non-Tariff Negotiations, Rules of Origin Unit, DG Trade*

Summary:

Thomas Huszak opened the plenary meeting by mentioning that on 26 September 2012, the European Commission adopted a Proposal for a Regulation of the European Parliament and of the Council on medical devices and in vitro diagnostic medical devices aiming to ensure that patients can reap benefits of safe and innovative products. On 18 and 19 June 2015 the Council (*Employment, Social Policy, Health and Consumer Affairs Council*) will be called on to agree its stance on the two draft regulations. Commission hopes that a compromise is reached as it is important that the regulations are finally adopted. There are a number of challenges and opportunities faced by the medical devices sector such as demographic factors (e.g. ageing population, increase rate of chronic diseases), economic factors (pressure on public health budgets) and emerging technologies (for the prevention and monitoring of diseases). Enterprises need to have a solid legal framework and to get support to growth and remain competitive. He highlighted some factors in the revised draft Regulations of importance for the MedTech sector: harmonized rules on reprocessing of single used medical devices, proper functioning of notified bodies and conformity assessment, clinical investigations aligned with international guidance as well as reinforced market surveillance and governance.

Céline Bourguignon continued the discussions by presenting the business perspectives of medical devices within TTIP. The economic importance of the MedTech sector was highlighted: 25 000 companies of which 95% are SMSs, 575 000 employees and total sales of around €100 billion. Johnson & Johnson supports the regulatory convergence between the EU and the US. The importance of the implementation of the UDI system, the need for RPS and a formal recognition of QMS were highlighted. A study on the EU medical device approval safety assessment conducted by Boston Consulting Group in 2011 revealed there is no significant difference in safety between the EU-US systems. Johnson and Johnson calls on EU for an offensive agenda on medical devices in TTIP leading to significant cost savings for the industry by means of cutting red-tape and over-regulation.

[redacted] pointed out that there are problems arising from several misunderstandings among public opinion on TTIP. Public opinion is focusing on less important elements of TTIP that are possibly even not in the TTIP negotiation agenda. While a number of arguments pro TTIP can be set out such as increased level of economic activity and productivity gains, TTIP cannot serve as solution for all of the problems existing in Europe. Finally, he mentioned enhanced regulatory cooperation as being essential if the EU and the US wish to play a leading role in developing international regulations and standards based on the highest levels of protection.

[redacted] gave a brief overview of the content of TTIP negotiations focusing on the medical devices sector. While TTIP will be an ambitious and balanced agreement dismantling both tariff and non-tariff barriers, in this area the main benefits are expected to come from the latter, as the existing tariffs on medical devices are already mostly zero. She highlighted the high level of transparency provided by COM in terms of TTIP. Among others the Advisory Group with several representatives from very diverse sectors, a number of events taking place during and after each round of talks with several hundred representatives of civil society attending as well as comprehensive materials on all aspects of the negotiations posted on the website. She emphasized that no legal text is available yet regarding medical devices, pharmaceuticals and cosmetics regulatory aspects. Finally the most important possible elements for a medical devices annex in TTIP were explained such as Quality Management system Audits (QMS), Unique Device Identification (UDI) and interoperable databases as well as the Regulated Product Submission (RPS).

After the panel discussions several **questions** were raised, among them:

- To what extent can the public debates influence the negotiations?
- Is further cooperation foreseen in new/emerging areas ("living agreement")?
- Is the above mentioned study publicly available and what kind of methodology was followed in the analysis?

On the first question [redacted] answered that basically the Commission follow the public debates but those do not focus on the aspects dealt in the technical discussions. As regards the

possible cooperation in new areas, similarly to the pharmaceuticals, both Parties could co-operate on new issues and consider developing disciplines and principles aimed at good regulatory practices specific to the medical device sector. **Ms Bourguignon** clarified that the results unveiled in the study are based on the comparison of the absolute number of annual recalls over a given period in the EU and the US and the study is available for the public.