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

TTIP Meeting with MedTech and Cocir on Medical Devices 28/04/2015

Participants:

- [redacted], [redacted] (DG TRADE); [redacted], [redacted] (DG GROW)
- [redacted], [redacted], [redacted] (COCIR);

Summary:

On the 28th of April 2015, the European Commission met with MedTech and Cocir to discuss the state of play of TTIP negotiations as well as the EU position paper on Medical Devices published in the web on April 2015.

COM gave a brief summary on discussions and outcome of the TTIP 9th round.

COM noted that the position paper on medical devices resulted in some misunderstanding regarding the mutual recognition of **Quality Management System audits (QMS)**. Apparently US industry believes that the international pilot Medical Device Single Audit Programme (MDSAP) is sufficient to avoid double inspections. COM noted that despite being committed to MDSAP, a legal basis needs to be established for the EU to be able to accept audit reports carried out by foreign inspectors. TTIP could provide for such legal basis. Furthermore, COM explained that TTIP cannot provide for the acceptance of QMS audits conducted under the authority of all the other different jurisdictions involved in MDSAP (e.g. Canada, Australia, Brazil) given that it is a bilateral agreement.

COM noted also that the MDSAP pilot project does not provide for the legal certainty that TTIP would provide for. Also should an MRA be negotiated between EU and US in this matter, the number of EU Notified Bodies allowed to carry the single audit would have to be increased on the basis of their competencies/accreditation (few NB are currently eligible under the MDSAP pilot: 6 out of 14 eligible ones can be considered to be at an advanced stage of the application –5 out of 6 and 12 out of 14 are European). Finally the scope of the MRA would have to be discussed as currently US FDA accepts only routine/post market inspections under the pilot MDSAP.

MedTech noted that the wording mutual recognition ('MRA') might be interpreted in such a way that it goes beyond the framework of the MDSAP meaning any audit done by a notified body in the EU or done by FDA would be recognised on either side.

COM noted that the EU legislation and legal constraints regarding acceptance of QMS audits have to be explained to the US industry.

- It was agreed that the EU industry will liaise with the US industry

On **Unique Device Identification (UDI)** system and database, COM explained that the EU IT expert's will study the technical dossier for the implementation of the UDI sent by the US and will come back to the US FDA with questions if necessary. COM noted that while the EU is committed to implement its UDI system, the adoption of the EU Regulation on Medical Devices is needed preliminarily.

With regard to the **Regulated Product Submission (RPS)**, COM noted that no specific discussions were held on this point. MedTech asked for clarification on the current pilots conducted both at regional (EU) and at global (IMDRF) level. COM explained that the regional pilot is supposed to focus on the low and medium risk level medical devices and eventually it may feed into the global project.

Regarding the question on the **exchange of confidential information** between EU Notified Bodies/EU institutions and FDA COM clarified that all of the existing Confidential Arrangements have already expired hence they need to be renewed in the future.

In relation to the point **on reinforce bilateral regulatory cooperation** in new areas COM explained that this area has not been discussed yet precisely but it would aim at providing provision for reinforce cooperation between the regulatory authorities.