EUROPEAN COMMISSION
Directorate-General for Trade

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

MISSION REPORT

Subject: **Participation as speaker in the Lubeck Summer Academy on Medical Technology - Benefit Assessment of Medical Devices, 15 September 2015**

Participants: [redacted] **(TRADE F3)**

Summary:

The mission to Lubeck (Germany) aimed at delivering a speech on TTIP and medical devices and pharmaceuticals at a conference on "Medical Technology - Benefit Assessment of Medical Devices". The conference was organised by FFM (Forum for Medical Technology) with the support of the Lubeck chamber of commerce. Most presentations were about health technology assessment.

The conference was attended by around 90 participants.

Presentation:

The presentation touched upon the following aspects: TTIP objectives, consultation and information mechanisms, health aspects of TTIP and details on medical devices and pharmaceuticals – regulatory component.

As regards general objectives, it was noted that TTIP will be an ambitious but balanced agreement (tariff and non-tariff aspects). It will strengthen the economic partnership (growth and job creation). It is expected that TTIP will positively influence the development of regulations and standards worldwide based on high levels of consumer and environmental protection. As the tariffs are very low in average - most TTIP benefits will steam from reducing Non-Tariff Barriers (NTBs).

Extensive consultation and information mechanisms have been developed. Member States are informed/consulted before and after each negotiation round, European Parliament is keep regularly informed and Advisory Group has been established (consumer and health organisations are represented). In addition civil society meetings and stakeholder events (at margins of negotiations sessions) take place as well as meetings with different stakeholders and participation of negotiators in conferences and seminars. Finally there is extensive information available in the Web site including position papers, fact sheets and legal texts.

TTIP and health: It was noted that although there is no specific health chapter in TTIP negotiations, a number of negotiation sessions touch upon health related aspects (services, IPR, regulatory aspects of pharmaceuticals and medical devices, etc.)

Medical Devices: an important sector in EU-US bilateral trade (*8.1% of EU imports from US (19.9 b) and 4.1 % of US imports from EU (11.4 b*). Most medical devices are already at 0% tariff (WTO agreement) - TTIP added value lies on regulatory convergence. There is a long tradition of regulatory cooperation at international and bilateral level. Negotiations are centered on existing transatlantic cooperation under the auspices of the International Medical Device Regulators Forum (IMDRF) and focus on:

- Quality Management System (QMS) Audits,
- Unique Device Identification (UDI) (traceability)
- Regulated Product Submission (RPS) (data submission)

Pharmaceuticals: an important sector in EU-US bilateral trade (*13.1% of EU imports from US (21 b) and 10.6% of US imports from EU (29.5 b*). Most pharma products already at 0% tariff (WTO Pharmaceuticals agreement) - TTIP added value lies on regulatory convergence. There is a long tradition of regulatory cooperation at international (ICH) and bilateral level (EMA/FDA). Main priorities being discussed are:

- the recognition of Good Manufacturing Practice's inspections,
- collaboration on innovative areas – Biosimilars and Generics – shape international practice
- Increased exchange of confidential information between regulators
- ICH matters such as paediatrics

Discussion:

There were a number of questions on the draft medical devices Regulation (state of play) and how that would impact TTIP negotiations, progress on Quality Management System audits at IMDRF level (i.e. Medical Devices Single Audit Pilot) and COM and MS involvement in the international process, progress on UDI (i.e. how and when UDI will be implemented in the EU), public debate on TTIP and how COM deals with it, ISDS, etc.

All in all participants noted the need for Commission negotiators to reach specialised audience and explain in detail what is being negotiated in TTIP.

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