



EUROPEAN COMMISSION
Directorate-General for Trade

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

Brussels,
Trade /F3/IK

MISSION REPORT

Subject: Participation as speaker in a Conference on the impact of TTIP in the health care industry (Berlin, 12th March 2015)

Participants: [REDACTED] (TRADE)

Summary:

The mission to Berlin aimed at delivering a speech at a conference on TTIP negotiations and in particular on regulatory aspects of relevance for pharmaceuticals and medical devices. The conference was organised by Germany Trade & Invest (the foreign trade and inward investment agency of the Federal Republic of Germany) and Spectaris (German association for the high-tech industry). A round table discussion on TTIP involving representatives of Carl Zeiss Mediatec, Lilly Europe, European Social Insurance Platform and Institut der deutschen Wirtschaft Köln e.V. took also place.

The conference was attended by around 60 stakeholder's.

Presentation:

I have provided a general introduction on the TTIP negotiations, highlighted consultation mechanisms in place (EP, MSs, advisory group, industry and civil society, etc.), transparency provisions (position papers in the web), gave an overview of the structure of the negotiations (the three pillars), the role of the regulators in the negotiations and stressed the importance for the EU of the sectoral aspects of the negotiations – non-tariff barriers.

All aspects related to pharmaceuticals and the different topics that are part of the negotiation were covered in detail: GMP inspections, Biosimilars, exchange of confidential/trade secret information, generics and paediatrics. The regulatory aspects linked to medical devices were also explained in detail: Quality Management Systems, Regulated Product Submission and Unique Device Identification.

Discussion:

Participants welcomed the three priorities for medical devices identified for discussion under TTIP and the intention of the EU to become observer at the MDSAP (Medical Devices Single Audit Programme). In this respect they asked why EU would be only observer and not full member. They cautioned Commission to the fact that MDSAP is only a pilot and that FDA has the tendency to not implement commitments taken at international level. Important to guarantee that after the pilot there will be a commitment to accept in each jurisdiction the QMS audits results. For the benefits to be meaningful, legal commitments should be established.

It was also asked how negotiations can be seen (and progress) in a context where the EU legislation on medical devices is being revised and whether TTIP would interfere in any way with the EU internal process.

The SME angle was highlighted by one participant. US is a major market, many products are sent in small quantities so any harmonisation/administrative facilitation (e.g. data submission) would play a very important role in improving access to the US market. The same applies to QMS audits. There is however no question/intention from the industry to lower health and safety provisions.

Commission was asked to explain why an agreement on recognition of Good Manufacturing Practices inspections (Pharma) that has not worked in 1998/1999 would work now.

There was a question on the ratification process and the level of involvement of national parliaments in that process and a question on the eventuality of decisions on health care service providers being challenged via ISDS provisions.

I have noted that TTIP will not interfere with the EU legislative process but that progress on several of TTIP priorities depends on the adoption of the medical devices regulation. There is no legal basis for the EU neither to be full member of MDSAP nor to accept QMS audits carried by foreign inspectors (for that a mutual recognition agreement has to be established). On pharma, GMP discussions with FDA are progressing well. Commission is confident but the final outcome is not yet certain. It is too early to determine how TTIP will be ratified as it depends if it will be a mixed agreement or not. ISDS discussions have been very extensive and information is available in the web.

[REDACTED]

Cc: I. García Bercero, [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED].