



EUROPEAN COMMISSION
Directorate-General for Trade

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

Participation as speaker on the 2nd Annual EU-US Trade Conference

Sector-specific breakout session: Chemicals and Pharmaceuticals

Brussels, 5th February 2015

Participants:

[redacted] (Grayling), [redacted] (DG TRADE), [redacted] (DG GROW), [redacted] (US Food and Drug Administration), [redacted] (Pharmaceutical Group of the European Union (PGEU)), [redacted] (Pfizer), [redacted] (Cefic).

Summary:

The 2nd Annual EU-US Trade Conference on TTIP was organised by "Forum Europe" on 5th February 2015. The conference featured a combination of plenary sessions and sector-specific breakouts and brought around 250 stakeholders together. I attended the breakout session on chemicals and pharmaceuticals where the following issues were discussed:

- To what extent is regulatory convergence in the area of chemicals and pharmaceuticals possible, and what challenges remain for this to become a reality?
- Where this is not possible, how can negotiators work to allow mutual recognition of standards within existing regulatory frameworks?
- What will be the impact of easier market access on both American and European SMEs?
- How will the potential convergence of regulation affect consumers, in terms of both standards and prices?

I have provided a general introduction on the TTIP negotiations and current state of play, 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.

I noted that in the pharmaceutical sector regulatory cooperation between EU and US is very well established both at bilateral level as well as at multilateral level, notably via the ICH. Many regulatory aspects are already aligned. However there are still many areas

that can be tackled. The different topics that are part of the negotiation were briefly presented: Good Manufacturing Practices (GMP) inspections, Biosimilars, exchange of confidential/trade secret information, generics and paediatrics. Finally, I noted that the regulatory power will remain in the hands of the regulators.

██████████ (US Food and Drug Administration) reiterated historical cooperation between EU and US and FDA engagement in the negotiations. He noted that horizontal provisions are the foundation for ensuring opportunities for stakeholders to comment on regulations and standards and therefore permit that more issues will be aligned in the future. The objective of TTIP is to increase regulatory compatibility, regulatory efficiencies while upholding to high level of health protection. He noted that we are looking into our practices and on how to align existing and new regulatory areas (e.g. biosimilars). As regards GMP, both sides are assessing equivalence of the systems. How to better cooperate within ICH is also in the radar. For the US, an important area is the transparency on pricing and reimbursement decisions. Discussions are going well but there are no legal texts available (looking into what would be the appropriate legal obligations).

██████████ (Pharmaceutical Group of the European Union (PGEU)) noted TTIP was not the good instrument to deal with transparency on pricing and reimbursement decisions. Therefore, PGEU and many other stakeholders strongly object to transparency provisions on pricing being included in TTIP. Affordability of medicines is a very important issue for many stakeholders as well as the EMA policy on disclosure of clinical trials data (TTIP should not interfere/damage this process).

██████████ (Pfizer), presented EPFIA priorities for TTIP notably mutual recognition of GMP inspections, paediatrics (timing of clinical trials submission), new emerging areas (keep structure in place to allow evolution of science), IPR (promote IPR principles globally), early resolution mechanism (patents) and market access (transparency on pricing and reimbursement decisions).