

Health Series 2015- Multi-stakeholder debate on regulatory convergence aspects of the TTIP

26/05/2015

The Permanent Representation of Denmark to the European Union organised on 26/05/2015 a Multi-stakeholder debate on regulatory convergence aspects of the TTIP with a focus on pharmaceuticals.

The debate comprised:

- A short status on the Pharma chapter in TTIP provided by USTR and European Commission, DG TRADE
- The perspectives from the regulators provided by US FDA and European Commission (DG SANTE) and European Medicines Agency (EMA).
- Industry reflections on the following topics: Mutual recognition of GMP/GCP inspections, Harmonisation of paediatrics requirements (format, plan and timelines), Scientific advice (joint/parallel) and Medicines pathways.
- Short discussion on priorities and opportunities moving forward

COM provided a state of play of negotiations Round 9 that had taken place in April 2015. The EU priorities are the ones as set in the publically available position paper (Good manufacturing practices, biosimilars, generics, exchange of regulatory information between regulators, paediatrics, etc). COM reiterated that regulators (SANTE and EMA and US FDA) are at the negotiation table. A lot of work has taken place on GMP but there is still considerable work to be done in 2015. Legal texts are not yet available nor being discussed. COM expects to have concrete deliverables in certain areas and establish the cooperation path in other areas. There is also the intention to continue commitment on cooperation at international level in fora such as ICH as well as reinforcing exiting bilateral EU-US cooperation.