Ref. Ares(2015)1077544 - 11/03/2015

Annual Conference on EU Law in the Pharmaceuticals Sector in 2015
26-27/02/2015

Panel on EU pharmaceuticals law

"The negotiation of a Transatlantic Trade and Partnership: Implications for the pharmaceuticals sector" - [Art. 4.1(b)]

Presentation

The presentation touched upon the following aspects: TTIP objectives, TTIP negotiation structure and negotiation team, consultation and information mechanisms and details on 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).

Negotiations are organised around tree pillars: Market access (tariffs, Services, Investment, Public Procurement, etc.), Regulatory Component (Regulatory coherence, TBT,SPS, Sectors (9)) and Rules (IPR, RoO, Dispute Settlement, Sustainable Development, Customs, Energy and raw materials, SMEs, GIs). There is a strong presence of regulators (DG SANTE, DG GROWTH, DG AGRI, DG TAXUD, COMP, etc.) in the negotiations (co-leadership).

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.

Pharmaceuticals: is an important sector in our 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) but a lot can still be done. Main priorities being discussed are:

- the recognition of Good Manufacturing Practice's inspections,
- collaboration on innovative areas – Biosimilars and Generics – shape int. practice.
- Increased exchange of conf. information between regulators
- Paediatrics
- Collaboration on state of the art – latest science available

An update of the state of play of the pharmaceuticals regulatory discussions on GMP, Biosimilars and generics was provided

Discussion

There were only few questions asked. One was on impact of TTIP on the provision of public health services. The participant was referred to the letter from the Chief negotiators to UK on the matter. The letter explains COM stance on the matter.
On pricing and reimbursement provisions, there was a question on why this area was not being considered by the Commission in TTIP. An explanation on why the COM considers that TTIP should not contain provisions on transparency of pricing and reimbursement was provided.