

TTIP Meeting with EPFIA and EGA 16/07/2015

Participants:

I. Garcia Bercero,  (DG TRADE)

 (USTR)

EPFIA (European Federation of Pharmaceutical Industries and Associations)

EGA (European Generic and Biosimilar Medicines Association)

Summary:

- EPFIA and EGA requested a joint meeting (EU and US) in order to discuss regulatory cooperation in TTIP related to the pharmaceutical sector.
- COM provided a general update on state of play of TTIP negotiations in general and pharmaceutical regulatory discussions in particular.
- EPFIA and EGA noted that when it comes to the benefits, TTIP can bring to patients and industry, the originator pharmaceutical industry and the generic and biosimilar medicines manufacturers have a number of shared objectives in the area of regulatory cooperation. They noted that TTIP can ensure quicker access to medicines for patients by creating greater compatibility between EU and us regulatory systems and removing unnecessary and burdensome bureaucracy. For example, mutual recognition of Good Manufacturing Practices inspections could reduce inspections by around 40% on both sides of the Atlantic. This would significantly increase regulator efficiency and generate significant cost-savings for all parties, where industry saving could be-used for future transatlantic investment opportunities.
- Industry noted that the expected TTIP outcome would be "mutual recognition" of GMP inspections and not "reliance" as this later concept is much vaguer.
- EPFIA noted that there are several other areas of interest for the industry (such as Paediatrics, compatibility of clinical trials data bases, etc).
- EGA reiterated interest to step up EU-US regulatory cooperation on generics and biosimilars.
- Industry expectations on TTIP are very high and industry is ready to provide any information, data or studies the regulators would deem important.