EUROPEAN COMMISSION
Directorate-General for Trade

Directorate F - WTO, Legal Affairs and Trade in Goods
TRADE F.3 Tariff and Non–Tariff Negotiations, Rules of Origin

Meeting with EGA on TTIP
26/05/2015

Participants:

- EGA: [redacted], [redacted]
- COM: [redacted], [redacted] (TRADE), [redacted] (SANTE)

The purpose of the meeting was to discuss the EU (EGA) and US (GPhA) industry joint submission on generics and next steps. There was also an exchange of views on progress so far on TTIP on other topics of interest to EGA: GMP and Biosimilars.

COM provided an overview of the state-of-play of the negotiations and informed that a TTIP stocktaking is planned for October 2015.

Generics

The EU and US generics industry, EGA and GPhA, submitted a position paper on *''the use of a single reference product as enabler to single clinical development programmes for generics medicines*'' on 17 April 2015.

Industry expectation is that EU and US allow the single development of complex generics in the same way than for biosimilars i.e. that both jurisdictions accept the sourcing of reference products from outside the EU and US for certain studies. This would allow avoiding duplication of clinical trials. According to EGA, this would require adaptation of EU and US guidelines on generics but changes in the basic legislation would not be needed. Industry indicated estimated savings which are more substantial for complex generic products such as transdermal patches.

COM indicated that it is assessing industry proposals. COM has the intention submit a paper to the US with concrete ideas on generics collaboration ahead of next negotiation round in July.

GMP inspections

COM noted that the work of the GMP task force in charge of assessing the equivalence of EU and US GMP systems is progressing well. A number of audits of Member States inspectorates by other MS and observed by US took take place and will continue during 2015. EU inspectors will also audit the US GMP system in 2015.

Biosimilars

EGA welcomed the fact that FDA issued the final guidance on biosimilars approval and other FDA draft guidance currently under public consultation. The FDA guidance on naming of biosimilars and the one on labelling is expected to be announced still in 2015. EGA reiterated its views that it is important that US policy on naming is aligned to the EU. It is very important that Industry reacts under the notice and comment process.

India

EGA informed COM that they increased their activities with respect to India and the Indian drug controller. EGA works in close liaison with four Indian companies and would like to organise a conference on GCP matters in the coming months.