Meeting with EGA on TTIP
02/03/2015

Participants:

- EGA: [redacted], [redacted], [redacted], other EGA members
- COM: [redacted] (TRADE)

The purpose of the meeting was to exchange information on the current state-of-play of TTIP negotiations. COM gave a general overview of issues discussed at the 8th round under the pharmaceuticals regulatory discussions and next steps.

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. An extensive exchange of documentary information (applicable legislation and guidelines, GMP reports, conflict of interest rules and so on) took place. This information is being assessed. A number of audits of Member States inspectorates by other MS and observed by US will take place during 2015. EU inspectors will also audit the US GMP system in 2015.

EGA noted that there is substantial production of generics in Poland and other countries that joined the EU in 2004. It is therefore fundamental that inspections of all MS inspectorates are accepted by US. EGA noted also that FDA has agreements with certain EU MS.

Biosimilars

COM noted that the exchange of information on the two legislative frameworks and their implementation is ongoing. The FDA guidance on naming of biosimilars and the one on labelling is expected to be announced in 2015. It is very important that Industry reacts under the notice and comment process.

EGA noted that there is one biosimilar product close to be authorized by FDA (following positive assessment by the scientific committee) and other products are in pre-approval process.

EGA wishes that FDA guidance on naming of biosimilars is similar to the EU one (i.e. use of INN) and that it is finalised asap. As regards the guideline on use of reference products sourced outside the US, EGA would also like to see the draft guideline formally adopted.

EGA is organising a Conference on Biosimilars in London (April 2015). FDA will be attending.

Generics

COM indicated that generics were amongst the topics identified for regulatory cooperation under TTIP. However no detailed discussions took place yet. COM has the intention submit more concrete ideas at next negotiation round.

EGA expectation is to allow the single development of complex generics in the same way than for biosimilars (i.e. acceptance of sourcing of reference products from outside the EU/US). This would require adapting EU and US guidelines but not the basic legislation. EGA committed to further investigate the matter and to submit (with its US counterpart, GPhA) a paper to EU and US regulators.

Other

- EGA asked for biosimilars to be considered in Japan FTA negotiations
- EGA noted that it will comment on TTIP regulatory cooperation papers
- Contacts with EP Parliament members and consumer organisation are planned/on-going