

Meeting with EGA on TTIP – 17/07/2014

Participants

EGA: [Art. 4.1b], [Art. 4.1b], [Art. 4.1b], [Art. 4.1b]

GPhA: [Art. 4.1b]

COM: [Art. 4.1b] (SANCO), [Art. 4.1b] (SANCO), [Art. 4.1b] (TRADE), [Art. 4.1b] (TRADE)

EMA: Emer Cooke

The purpose of this meeting was to exchange information on the current state-of-play and their expectations regarding the TTIP.

Biosimilars

COM provided an outline on the non paper that presents the EU objectives on biosimilars and indicated that exchange of information on the two legislative frameworks and their implementation was ongoing.

EGA thanked the EU for its engagement on this topic. It was acknowledged that the matter was primarily to be handled through collaboration by regulators and that their primary expectation from the TTIP was to put pressure on FDA for further collaboration with EMA. It was considered that the TTIP had already contributed to positive developments.

EGA provided the following information regarding the state-of-play in the US. Over 50 pre-submission meetings took place with FDA and there are indications that applications from two companies are closed to filing. The submissions will in all likelihood be limited to the highly similar status and not to interchangeability.

EGA committed to inform COM on announcements of applications submitted under the abbreviated pathway.

The FDA guidance on naming of biosimilars is expected to be announced in the next two months. GPhA reiterated its wish that the INN will be used.

On a side-note, EGA indicated its concerns regarding recent Communication of Canada with respect to extrapolation of indications. Although Canada uses the same approach than the EU based on totality of evidence, its communication would not reflect adequately this global approach and focusses on the use of clinical trials.

GMP inspections

COM called the attention of EGA to the public announcement of FDA regarding mutual reliance of inspections and stressed that it was a positive development towards the EU objective of mutual recognition of inspections. The current efforts are related to four areas: conflicts of interest, consistency of MS inspectorates, sharing of inspection reports, and GMP technical guidances.

COM outlined that a first short-term objective was to obtain unredacted inspection reports from FDA and enquired whether EGA would be supportive to an approach

where inspected manufacturers would provide their agreement to FDA to share the inspection reports prior the inspections.

EGA/GPhA indicated that their companies were positive towards this approach provided that it is also used for the benefits of their members. The purpose of the pre-inspection agreement will thus need to be clearly established.

Generics

COM indicated that while generics were amongst the topics identified for regulatory cooperation under the TTIP, no detailed discussions were taking place at this stage. International cooperation on generics is currently focussed on IGDRP in which, as far as information sharing of application is concerned, FDA is not currently engaged.

EGA acknowledged the positive developments in IGDRP but pointed out that they are limited to simple generics. Their expectations from the TTIP is to allow the single development of complex generics in the same way than for biosimilars.

While the current understanding is that the US legal framework would not allow such development, GPhA committed to further investigate the matter.

Communication on TTIP

EGA indicated that it is providing publicly positive messages on the TTIP and that DGTRADE are welcomed to use their statements.

SPC – Export provision

EGA reiterated its wish to keep IP rules on pharmaceuticals outside of the TTIP. It however pointed out its wish for rapid positive signals regarding the revision of the SPC rules since a wave of investment for biosimilars is going to be decided soon.

COM indicated that this matter was indeed currently discussed amongst Commission services.