Meeting with the European Federation of Pharmaceutical Industries and Associations (EPFIA) on TTIP Regulatory issues

19 February 2014

List of attendees:

[**ART 4.1b**] (EFPIA), [**ART 4.1b**] (EFPIA); [**ART 4.1b**] (Eli Lilly); [**ART 4.1b**] (EFPIA), [**ART 4.1b**] (Roche),

PERREAU DE PINNINCK Fernando (DG TRADE); KAIZELER Ivone (DG TRADE); EMBERGER Geraldine (DG TRADE); GOUX Sebastien (DG SANCO); FEZAS VITAL Isabel (DG TRADE); INNOCENTE Francesca (DG TRADE)

Summary:

On 19 February 2014, the European Commission met with the European Federation of Pharmaceutical Industries and Associations (EPFIA) to discuss regulatory issues in the context of the Transatlantic Trade and Investment Partnership (TTIP). After being updated by the Commission on the general outline of negotiations, the representatives of EFPIA expressed its interest in discussing several important issues for the pharmaceutical sector.

One of the most pressing issues for the pharmaceutical sector concerns paediatrics. Companies would benefit from the possibility to submit the clinical data to both Agencies at the same time. The EFPIA feels that this would be possible within the current legal framework and proposed to provide a more detailed legal analysis. The industry would like to submit one proposal that can be used in both jurisdictions, preferably along the line of the US model. The companies believe that the end of phase 2 is the most appropriate time to discuss paediatrics development with both Agencies. Many drugs do not arrive to phase 2, so providing data before that is in their view not necessary. Therefore, they would like the TTIP to call for alignment in this area as a long-term aspirational goal that can be accompanied with a pilot phase starting immediately.

As for clinical data, the EFPIA reported that companies are currently required to provide different data in the two jurisdictions and they would prefer to have one data set for both. The EFPIA representatives stated that often different names are used to define the same thing thus creating confusion also for patients looking for information on the internet. The data asked by both regulators is substantially the same, but items are often labelled differently (e.g. adverse events/severe adverse reactions). The industry considers the US website to be IT-friendly and would welcome alignment to it. The EFPIA also urged the EU and US regulators to agree on a common view on what is commercial confidentiality. The Commission informed the industry representatives that the regulators are engaged in a dialogue too see what is feasible in this area. The EFPIA is aware of this dialogue which has been going on for a long time and feels that the TTIP provides the political support needed to bring this process forward.

When discussing variations, the EFPIA shared figures collected among its members that report discrepancy (very high number of type II changes in Europe) and urged EU and US

regulators to harmonise the classification of manufacturing changes. The Commission invited the EFPIA to give a clearer presentation of the figures gathered and the association agreed to provide new data. The two months discrepancy in the time allowed for submission between the EU (12 months) and the US (12 + 2 months for submission) force companies to run two production processes at the same time (with risk of shortage). Anyway, with this respect, the industry stated that having greater predictability is more important than having greater time. The Commission, however, noted that the Member States have a great say in relation to this classification and therefore any change to it would constitute a very difficult exercise.

The EFPIA met with the European Medicines Agency (EMA) in July and this helped the industry to have a clearer picture of the scope of the Parallel Scientific Advice (PSA). The association revised its initial position on PSA, stating that this is no longer a priority for the industry in relation to TTIP. This advice is given for a single product and is not binding so the companies can deviate from it if they provide solid scientific evidence. The industry reported that divergences in advices given by the two Agencies vary very much depending on the therapeutic area (ex. FDA interested in cardiovascular toxicity of medicines for diabetes). What is of greater interest to the pharmaceutical companies is a common discussion of regulatory guidance for drug development which covers a whole area and not a single product.

The EFPIA is in close contact with the association representing the pharmaceutical industry in the US. They clarified that a slightly lower engagement from their side with regulators in the US is rather due to capacity issues of the trade association rather than a lack of interest as the American companies fully share the priorities outlined by the European pharmaceutical sector.

The Commission invited the EFPIA to share their view with regard to the involvement of stakeholders in the adoption of legislative acts. The EFPIA stated that there is room for improvement, especially in the uncertainty due to changes proposed by the European Parliament and the Member States which are not assessed. However, if the association felt that this was an issue, it would have included it in its position paper. The representatives of Eli Lilly also reported that large US companies with a representation office in Brussels have a good understanding of how the system functions and do not necessarily share the US government's concerns with this regard.