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

9 December 2013

List of attendees:

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

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

Summary:

On 9 December 2013, 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 timing of negotiations, the representatives of EFPIA expressed its interest in discussing several important issues for the pharmaceutical sector including Good Manufacturing Practices (GMP) and parallel scientific advice.

The pharmaceutical industry sees mutual recognition of GMP inspection findings as a key objective of TTIP and calls for a political support for a Mutual Recognition Agreement for GMP and Good Clinical Practices (GCP) inspections. The agreement should be legally binding for both sides. EPFIA noted interest that batch testing is also waived.

The industry reported a convergence of inspection capacities of Member States over the past years, thanks to the Joint Audit Programme established by the European Medicines Agency (EMA) (where a same facility would be inspected by different Member States), peer reviews in between Member States, twining programmes before accession to the EU of new Member States and accession of Member States to PICs (Pharmaceutical Inspection Convention the Pharmaceutical Inspection Co-operation Scheme).

The industry welcomed the 2012 enacted FDA Safety and Innovation Act (FDASIA) (legal basis for FDA being able to accept foreign GMP inspections) but considers that reassessing all Member States inspection capacities is unnecessary due to the already existing cooperation the EU Member States, EMA and FDA and also participation of EU Member States and US in PICs. FDA will likely not have enough resources to audit all Member States (inspection systems assessment). A way forward could be for the US to rely on the Member States system assessments conducted by Canada in the context of the EU-Canada MRA. It is however uncertain if FDA would accept that.

As regards information to be shared, industry noted that in all MRAs EU has in place only the GMP certificate is exchanged and that would be the preferred practice. The old US MRA of

1998 required however the exchange of full inspections reports (which is legally more challenging).

When discussing Parallel Scientific Advice, the EFPIA stated that the program established by the FDA and EMA has only a limited scope and does not grant sponsors the right to receive parallel scientific advice upon request. Moreover, there is no guarantee that the independent advices provided by the two agencies will be the same. Ideally agencies should provide Joint advice. It would be important to determine if PSA should work better (e.g. in which aspects?) and whether in the long run agencies could agree on Joint Scientific Advice instead of Parallel Scientific Advice.

Finally, the industry mentioned paediatric medicines and clinical testing requirements (under the ICH E5) as areas where the EMA and FDA could further collaborate under ICH to avoid divergences and encourage greater regulatory compatibility.