Meeting with the German Pharmaceutical Industry Association (BPI)

5 December 2013

List of attendees:

[ART. 4.1b] (BPI); [ART. 4.1b], Schwabe GmbH, (BPI); [ART. 4.1b] (EUCOPE)

KAIZELER Ivone (DG TRADE); FEZAS VITAL Isabel (DG TRADE); INNOCENTE Francesca (DG TRADE)

Summary:

On 5 December 2013, the European Commission met with the German Pharmaceutical Industry Association (BPI). The Commission gave a general overview of the timing and the content of the Transatlantic Trade and Investment Partnership (TTIP) negotiations. The BPI expressed its interest in discussing regulatory convergence and issues related to the definition of food supplements in the US.

The BPI fully supports mutual recognition of GMP inspection findings. The issue of the FDA being able to accept foreign inspections following the enactment of the FDA Safety and Innovation Act (FDASIA) was discussed with reference to the failure of the previous Mutual Recognition Agreement (MRA) agreed by the Parties in the past.

The BPI sees the TTIP as an opportunity to address the industry's concerns on finding ways to disclose data while ensuring a certain level of protection for commercial confidentiality as data protection is the only way to protect products for companies that do not have patents protected in foreign countries. To this end, the German association calls for a common approach on what is considered confidential information – on the basis of a case-by-case analysis. There are some concerns on the European Medicines Agency (EMA)'s stand on this subject.

The BPI then raised the issue of food supplements. The industry association reported that the concentrations of substances (e.g. vitamins) allowed in food supplements in the US would qualify such products as pharmaceuticals in the EU and stated that an alignment to the EU system would be welcomed. According to the BPI, manufacturers of food supplements use images of herbs (e.g. Ginkgo leafs) to attract consumers that know these ingredients from herbal medicines but these dietary supplement are not subject to pharmacovigilance. In the EU, Member States have the right to regulate maximum levels and the BPI would like to see harmonisation at the EU level.

As regards health claims, US system is more flexible than the EU one i.e. in the US even if there is no scientific proof that the health claim is substantiated, Industry can still say that a given product may have a given health effect. Industry noted however that EU system where a health claim can be used only after being approved by the European Food Safety Agency (EFSA) is preferable (level playing field). The BPI would welcome assessments by EFSA on

health claims of botanicals as claims made regarding possible health benefits of products that are on the market have often not been proved. The BPI would welcome a renewed effort by the EU in this field to ensure the safety and protection of consumers.

The Commission reported that these items have not been touched upon during the negotiations so far but it would welcome more information from the industry shall this concern be brought to the table by the other Party.