**Meeting with the Association of the European Self-Medication Industry (AESGP)**

***7 February 2014***

**List of attendees:**

[ ART. 4.1b ] (AESGP); [ ART. 4.1b ] (AESGP);

KAIZELER Ivone (DG TRADE); SELLES Laurent (SANCO); GOUX Sebastien (DG SANCO); FEZAS VITAL Isabel (DG TRADE); VELASCO MARTINS Pedro (DG TRADE); SUAREZ SANCHEZ Elena (TRADE); INNOCENTE Francesca (DG TRADE)

**Summary:**

On 7 February, the European Commission met with the Association of the European Self-Medication Industry (AESGP) to discuss the Transatlantic Trade and Investment Partnership (TTIP). The Commission gave a general overview of the content and timing of the negotiations and the Association expressed the interest in discussing topics related to both the medical devices and the pharmaceutical sector.

*Medical devices*

The Commission had an exchange of views with the AESGP on the revision of the EU legislation on Medical Devices and on the developments in the TTIP negotiations given that the work items currently discussed in the bilateral negotiations are also treated in the framework of the International Medical Device Regulators Forum (IMDRF).

When discussing the Unique Device Identification (UDI), the Commission stated that the IMDRF Guidance is the best approximation of what the EU is willing to achieve in this field. The AESGP referred to the final rule on UDI adopted by the US Food and Drug Administration (FDA) in September 2013. The AESGP noted that the latter deviates from the IMDRF 2012 proposed rule insofar it will limit the proposed exemption for medical devices sold at retail to class I devices bearing a Universal Product Code on their labels and device packages. The Commission, however, noted that application of UDI to Class I devices is foreseen in about 5 years and this leaves plenty of time for changes to the FDA rule. The EU has not decided on exemptions yet and therefore feels no need to raise this detailed issue for the time being also considering that there are more pressing issues to be solved. The industry also reported that the Global Medical Device Nomenclature (GMDN) Agency has agreed to provide free access to its nomenclature within the context of the GUDID data submission process. The Commission and the industry agreed to further investigate the recent developments in the GMDN business model by enquiring the Agency, the Policy Advisers Group and the FDA. The Commission and the industry agreed that accessibility to the UDI system should be different for different categories of users (e.g. bearing in mind for example that GMDN codes are bought by industry). Even though these issues will not be tackled in the TTIP draft, the Commission agrees to discuss them bilaterally with the FDA during the upcoming meetings.

*Pharmaceuticals*

The AESGP raised the issues of market exclusivity, manufacturing audits and the acceptance of foreign data for marketing authorisation applications.

As ingredients used in the self-medication sector are usually not under protection of a patent any more, the issue of market exclusivity is very important for the industry. In the US, 3 years of data protection are granted for relevant scientific work in the context of reclassification of an ingredient from prescription to non-prescription, whereas the current European regime offers only one year exclusivity period. The self- medication industry would welcome an alignment with the US provision in this field. The Commission, however, does not feel that TTIP is the right forum to address the aforementioned concern as the EU Exclusivity Provisions are set in Directive 2001/83/EC. Industry request would require changing the EU legislation.

As for manufacturing audits, the AESGP urges the EU and the US to reduce duplication of inspections. The Commission confirmed that recognition of Good Manufacturing Practice (GMP) inspections is the first area where regulatory convergence is being pursued during the negotiations. The recently enacted Food and Drug Administration Safety and Innovation Act (FDASIA) would provide a basis for the FDA to commit in this sense. The only concern relates to the level of ambition.

When discussing Data Acceptance for Marketing Authorisation Applications, the Association reported that while US patient data is widely accepted as a basis for European authorisation, the FDA does not accept bibliographical data thus creating the need for unnecessary expensive and ethically questionable (e.g. in the case of nicotine replacement products) clinical trials. [ **NOT RELEASABLE** ].