Meeting with the Trans-Atlantic Business Council (TABC) Life Sciences Working Group

29 November 2013

List of attendees:

[ART. 4.1b] (TABC); [ART. 4.1b] (Pfizer); [ART. 4.1b] (Siemens); [ART. 4.1b] (ASTM International)

KAIZELER Ivone (TRADE); GOUX Sebastien (SANCO); FEZAS VITAL Isabel (TRADE); VELASCO MARTINS Pedro (TRADE); HEYNISCH Thomas (ENTR); EMBERGER Geraldine (TRADE); SELLES Laurent (SANCO)

Summary:

On 29 November 2013, the European Commission met with the Life Sciences Working Group of the Trans-Atlantic Business Council (TABC) to discuss the ongoing negotiations for the Transatlantic Trade and Investment Partnership (TTIP).

The members of the TABC Life Science Working Group expressed interest in discussing pharmaceuticals and medical devices in particular regulatory issues, market access issues, Intellectual Property Rights and international standards.

First of all, the TABC representatives noted that the recognition of Good Manufacturing Practices, parallel scientific advice and fostering ICH[1] related work are important TTIP objectives. COM noted that several issues are being assessed and encouraged the industry to show its support for sharing information between regulators as this matter is tightly linked with the issue of recognising GMP inspection results. TABC explained the problems that the industry is facing in the field of parallel scientific advice as the latter involves a heavy bureaucratic procedure, it is not applicable to all medicines and there is no guarantee that the different agencies will arrive to the same conclusions. Furthermore, the industry seeks consistency with the provisions of the EU-Korea Free Trade Agreement in terms of pricing and reimbursement for medicines. However, COM noted that being based on a privately funded system, the reality of healthcare in the US is very different from the EU and that this is a sensitive issue considering the positions adopted by Member States in the Council (revision of Council Directive 89/105/EEC). When discussing matters related to Intellectual Property Rights (IPRs), the TABC Working Group called for harmonising protection and ensuring sufficient IP incentives for the development of paediatric medicines.

The European and the American industry associations for medical technology jointly support the Unique Device Identifier (UDI), harmonized format for product registration submission and a Single Audit process as priorities for the TTIP negotiations. They call for both parties developing UDI system based on IMDRF guidelines that would allow data interoperability. The issue of how the Food and Drugs Administration (FDA) sometimes deviates from or adds on international standards was then brought up and discussed. COM finally noted that in the EU competence is shared with Member

[1] ICH - International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

States and that the current revision of the regulatory framework for Medical Devices should also be taken into account.