Meeting with Eucomed, Johnson & Johnson, COCIR and the European Diagnostic Manufacturers Association (EDMA)

7 February 2014

List of attendees:

[ART. 4.1b] (EUCOMED); [ART. 4.1b] (EDMA); [ART. 4.1b] (COCIR); [ART. 4.1b] (Johnson & Johnson)

KAIZELER Ivone (DG TRADE); SELLES Laurent (SANCO); MOKRY Roman (SANCO); SUAREZ SANCHEZ Elena (TRADE); SCALZO Salvatore (SANCO); INNOCENTE Francesca (DG TRADE)

Summary:

On 7 February 2014, the European Commission met with representatives of the medical technology industry to discuss the ongoing negotiations for a Transatlantic Trade and Investment Partnership (TTIP). The Unique Device Identification (UDI), the Regulatory Product Submission (RPS) and the Single Audit Program remain the priorities for the medical devices industry. The Commission explained that the aim of the current talks with the US are to identify commitments that can be achieved already at the end of the negotiations and to identify more long term objectives as for instance a commitment to cooperate when issuing future regulations in order to ensure regulatory coherence.

The Commission provided a general update on the work done in the context of the International Medical Device Regulators Forum (IMDRF). IMDRF Guidance on the Unique Device Identification (UDI) – Labelling part is finalised. US rule published in September 2013 is aligned with IMDRF guidance (it is not identical but almost identical). In the EU, the Commission issued a Recommendation on UDI for Member States (non-legally binding) in April 2013. EU UDI system (legally binding) will be established through a Delegated Act following the adoption of the new Medical Devices Regulation.

The industry noted that the establishment of a EU UDI system aligned with IMDRF is crucial (need to avoid different systems across the Member States) and expressed clear and full support for resuming IMDRF efforts and to speed up the drafting of an IMDRF Guidance on the UDI Implementation (common data sets in the UDI database, definitions of access for the different categories of users). The European UDI Database shall in particular be compatible with the Global Unique Device Identification Database (GUDID) being created by the Food and Drug Administration (FDA) in the US. Ensuring the interconnection between the US and the European database is of crucial importance for the industry as this could create a domino effect on databases of other countries such as Canada, Brazil and Australia. The representatives of the industry feel that such a global alignment would be beneficial both for the manufacturers (when submitting data) and the regulators (when analysing the data).

The industry questioned whether Member States will be willing to accept the IMDRF Guidance - implementation part as such. The Commission reported that there were some

discussions with Members States as regards compatibility of existing Members States data bases and EU future data base EUDAMED which will have a module on UDI. On UDI, the fact that some of Member States (e.g. Germany) are directly involved in IMDRF work is believed to have a positive effect on how the IMDRF Guidance on UDI implementation will be accepted in the EU (through the Delegated Act). Given the reserves expressed during the IMDRF teleconference by Japan and Canada on extending the UDI work item to implementation/data base, the idea is to form a smaller group that would agree to bring this forward. If harmonisation (notably on UDI data base interoperability) is agreed at international level, the industry sees the added value of TTIP in providing an example to third countries.

- **All in all Work achievements in IMDRF could be facilitated by the TTIP political support**

The industry welcomes the work done on IMDRF on the electronic format for Regulatory Product Submissions (RPS) but would like to see more clearly the concrete usability of the outcomes of this Group. IMDRF RPS work has focused on elaborating an HL7 Message Standard for harmonised submission and on drafting a Table of Contents in which each jurisdiction listed the contents it would require for internal products submission. In the context of the Table of Contents industry would wish that the submission structure/contents would concretely satisfy all jurisdictions requirements and is concerned that RPS could finally turn into different submissions, one for each jurisdiction, for a given product.

Commission made clear that it is actively involved in RPS IMDRF discussions. The Tables of Contents are structured according to a two-column structure containing common and regional contents for each relevant common heading and subheading (a harmonised structure has been agreed), regional classification matrixes and Implementation Guides at both IMDRF and regional level will help all users to deal with this table appropriately. Moreover a pilot test is foreseen in all jurisdictions.

It was finally noted that the TTIP could provide the legal basis which is needed for recognising Good Manufacturing Practice (GMP) inspections from US and vice versa but that taking into account that the revision of the EU Regulation is not finalised, discussions with US are still preliminary (on hold).