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

***10 December 2013***

**List of attendees:**

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

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**Summary:**

On 10 December 2013, the European Commission met with representatives of the medical technology industry association EUCOMED and the European Diagnostic Manufacturers Association (EDMA) to discuss the Transatlantic Trade and Investment Partnership (TTIP). The European Commission provided a general overview of the timing and the content of the negotiations. The industry associations expressed their interest in discussing issues related to tariffs, the Unique Device Identification (UDI), the Regulatory Product Submission (RPS) and the Single Audit Program.

Unique Device Identification (UDI)

The Commission noted that the general UDI principles existing in the draft Regulation are not being questioned in the Council and Parliament discussions. On the content, US has based its rules (adopted in September 2013) on International Medical Device Regulators Forum (IMDRF) Guidance (they are though not identical). EU will do the same when it regulates (Delegated act). As regards the UDI database the industry calls for close cooperation between the EU and the US and this is considered to be an urgent matter given that the Food and Drugs Administration (FDA) is already developing a database (industry was engaged in testing it). It would be important that IT specialists from both sides are brought together to ensure compatibility. Industry fears that the existing guidance is not detailed enough to ensure compatibility.

Regulatory Product Submissions (RPS)

The industry brought up this issue as allowing similar evidence and similar data submission (forms) would help reducing the regulatory burden. Devices are sometimes classified differently in the EU and the US and the levels of details of data that have to be submitted vary between the different classes. The industry is following the progress of the work done by the IMDRF on the use of electronic formats for Regulatory Product Submissions (RPS) and feels that both format (table of contents) and substance (e.g. information details to be provided) issues need to be considered. The industry would welcome the adoption of the IMDRF RPS guidance by both Parties in order to allow submission of common data sets and asks the regulators from both sides to carefully integrate electronic information exchange and safeguards for intellectual property in the context of ongoing regulatory revisions.

Single Audit of Manufacturer Quality Management Systems (QMS)

The industry reported similar but not identical current regulatory requirements in the two Parties. In the EU, the medical Devices Directive (and future Regulation) QMS requirements are based on the ISO 13485 but compliance with ISO 13485 is not sufficient. In the US the situation is similar. FDA has established its 21 CFR 820 Quality System Regulation which is based on ISO standard but not identical. The industry noted that it would be important to pursuit the single audit concept where a Notified Body would be able to audit facilities according to EU and US requirements and that audit would be accepted by both jurisdictions. The industry welcomes the efforts of the IMDRF in this field and in particular the pilot recently launched (in which the US would welcome the EU's involvement). The industry also informed the Commission that the initial audit is important but the follow-up audit is even more important and that EU Notified Bodies can currently subcontract parts of the audit but not its totality.

Finally, the industry referred to the confidentiality provisions and the issue of sharing information (either accepting the certificates or exchanging full details) between regulators.