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Sent: Monday, January 14, 2013 4:10 PM
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Subject: HLWG; reg issues; meeting with COCIR , Eucomed and EDMA

TRADE and ENTR met today with COCIR **[Art. 4.1(b)]**, Eucomed **[Art. 4.1(b)]** and **[Art. 4.1(b)]** (EDMA) to discuss the joint COCIR – MITA submission and follow-up. Businesses conveyed a joint message that they are aligned on the main objectives for the future FTA, which in their view were "achievable" albeit not necessarily low-hanging fruits. They also confirmed that priorities are aligned with their US counterparts. At the same time, COCIR flagged that some of their members remained sceptical in view of past failures as regards regulatory cooperation. Questions were also raised as to the cooperation between USTR and agencies and how far the US side was in mobilising its regulators and Congress.

TRADE and ENTR provided short update on HLWG and preparations for the Forum meeting and industry participation. We also asked for some clarifications on the substance of the proposal.

It was agreed that businesses would submit by mid- February more detailed information on the three priorities mentioned, i.e. **CA and joint audits for factories, UDI and harmonization of a single model for a medical device marketing application**, including

- Steps, which would be necessary on US and EU side to move to more coherence
- Possible (legal) obstacles on both sides
- Tentative time table for achievement
- Possible delivery mechanisms
- Information on how this would relate to on-going regulatory activities such as the draft MD Directive and rulemaking by FDA and other relevant US agencies.

Main messages from business:

- EDMA confirmed that **Advamed and Eucomed could possibly submit a joint paper**, since Eucomed fully supports Advamed's position. Reason why this has not been done yet was rather due to time constraints.

- All businesses highlighted **positive impact on third countries** of a possible EU-US initiative.

- COCIR: **Single audits for medical device auditing systems are high on the priority list**– at present some manufacturing units could be subjected to as many as 70 audits within a month. EU and US need to recognise each other's quality systems. Between EU and CN there is on-going cooperation and CN is using some of the same bodies EU uses; this has led in practice to single inspections. BSI for example has a Canadian office and its inspections are recognised by EU and CN. There is also cooperation between CN and the

US in this field. Single audits are also discussed at international level in IMDRF, the WG is led by US and NBs as well as industry participates, for EU Sanco is in the lead.

- EDMA: **Companies are aiming at a single quality system in EU and US** allowing testing of individual products rather than batches. This could be an ISO or mixed standard, or one could take an extended ISO standard. The Commission's draft directive on MDs now with Council and EP, foresees additional criteria for full quality assessment, which requires companies do carry out additional exercises.

- **UDI** is another top priority for businesses, where both EU and US are about to regulate (apart from the identification issue there is also the issue of how information is treated). On UDI Cocir and EDMA stressed the **need for a single system in the EU** and showed concern as regards possible attempts by Member States to establish national systems. Sanco will issue a recommendation soon to maintain coherence pending the entry into force of the MD Directive. But in addition **businesses would welcome a message/statement by EU and US officials after the meeting of the HLRCF that EU an US are considering cooperation in this field**, to discourage unilateral moves.