

From: NEIRA Pablo (TRADE)
Sent: Wednesday, September 19, 2012 9:45 AM
To: PERREAU DE PINNINCK Fernando (TRADE)
Cc: HERBERT Didier (ENTR); ROELAND Christophe (ENTR); SELLES Laurent (SANCO); EMBERGER Geraldine (TRADE); GARCIA BERCERO Ignacio (TRADE); SACCHETTI Fabrizio (ENTR)
Subject: Meeting with EDMA/COCIR/EUCOMED - US EU HLWG

EDMA: { Art 4.16 }
 COCIR: [Art 4.16]
 EUCOMED: [Art 4.16]
 EUCOMED/EDMA: [Art 4.16]

Commission: Didier Herbert and Christophe Roeland (ENTR), Laurent Selles (SANCO), Geraldine Emberger and Pablo Neira (TRADE)

- Industry welcomes de initiative and requests additional information on timing in order to assess which deliverables would be achievable in that time frame.
- They put forward five areas in which would be worth working:
 - Unique Device Identification: they believe that an agreement US-EU would be highly desirable: lower costs and third country effect. There is no legislation yet and the FDA is slightly ahead having proposed a draft text. There has been international cooperation in the issue, and guidelines have been agreed. SANCO already has a WG. They believe that an agreement could be easily achieved.
 - Medical software: There is already regulation in the US, but the issue is still not harmonised in Europe, where only a Guidance document exists produced by a SANCO WG.
 - Standardisation: General concern, international standards should be more widely used.

- Conformity assessment procedures: In particular Joint Audits, factories are subject to different inspections. If mutual recognition of the results of the inspections cannot be achieved (at least in the short term), at least a better coordination of visits would be desirable.
- New emerging technologies: SANCO has a WG working on these new technologies, if it were possible to identify a similar mechanism in the US and coordinate their works, this would ease the way for future regulatory convergence.

Follow up: Industry will cooperate to produce a joint paper by October, if possible with their US counterparts. They will send a few main elements of their submission by end of September.