To: [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (GROW); [redacted] (GROW)
Cc: [redacted] (TRADE)
Subject: TTIP meeting with TUV on medical devices 23/09/2015
Attachments: 2015 07 08 TUV Position Paper_Limits and opportunities with respect to medical devices.pdf

DG TRADE and GROW officials met with TUV on TTIP and medical Devices on 23/09/2015

TUV is a service provider for testing, inspection, certification, consulting and training. It employs around 19.500 employees and is present in 69 countries.

- TUV submitted a position paper *''Limits and opportunities in TTIP with respect to Medical devices (08.07.2015)''*.
- TUV noted that there should be no mutual recognition of products approvals (EU and US systems are different – for higher risk products, pre-market approval in US vs CE mark with the intervention of a Notified Body in the EU. Both EU and US should keep their systems)
- The recognition of Quality Management System Audits could be done provided that the frequency of inspections + surveillance requirements are equivalent as well as level of specialisation of auditors
- Important to cooperate in other areas at international level– e.g. UDI (Unique Device identification –traceability) and RPS (Regulated Product Submission)
- TUV is part of the MDSAP (Medical Devices Single Audit Pilot). It has been accredited by Health Canada and also audited by US FDA and Australia. In that condition TUV has participated already in some joint inspections of given manufacturing facilities.
- EU Notified Bodies experts are highly specialised and the teams are composed with different expertise (e.g. experts auditing a RX Machine manufacturer are different than the ones auditing a pacemaker manufacturer) as in the EU the Notified Body does also the technical file assessment. Facilities are audited frequently (annually)
- In the EU around 80% of the inspection/certification activity on Medical devices is carried out by 20% of the existing Notified Bodies.
- Clinical studies (US studies are accepted in the EU but EU studies are not always accepted in the US for the market authorization)

Participants:

[redacted], [redacted] and [redacted] (TRADE)
[redacted] (GROW)
[redacted] (TUV)
[redacted] (TUV)
[redacted] (TUV)

[redacted]
European Commission
Directorate General for Trade
Tariff and Non-Tariff Negotiations, Rules of Origin (TRADE F3)
[redacted]