[All redactions are made under Art. 4.1 (b)]

EUROPEAN COMMISSION
Directorate-General for Trade

Directorate E - Neighbouring countries, USA and Canada
USA and Canada

Brussels,
USA and Canada

TTIP Meeting with Johnson & Johnson
19 January 2015

Participants:

[redacted] (CAB-MALMSTROM)
[redacted] (TRADE F.3)

[redacted] - Johnson &Johnson [redacted]

Summary:

Johnson & Johnson produces a wide range of pharmaceutical products, medical devices and cosmetics/consumer products. J&J mission is to provide high quality health care around the world. Sales: over $71 billion in worldwide sales in 2013 ($28.1 billion on pharmaceuticals, $28.5 billion on medical devices and $14.7 billion on the consumer products segment). 45% of business takes place in the EU. J&J has 47 manufacturing sites in the EU and 8 R&D centres. There are 130.000 employees globally amongst those 30.000 in the EU.

J&J noted strong support for TTIP agenda and in particular for the regulatory convergence objective. J&J is seeking increased efficiency in product approvals on both sides of the Atlantic and improved access to innovation. TTIP is seen as a unique opportunity. In this context, J&J would like to see:

<u>On pharmaceuticals:</u>

- Mutual Recognition Agreement on Good Manufacturing Practices (GMP) inspections
- Harmonization of Clinical Trials Data fields (EU and US data bases are slightly different)
- Harmonization of Paediatrics study Plans (to avoid duplication of clinical trials)
- Provisions on transparency of pricing and reimbursement decisions
- Reiteration of IPR protection principles

<u>On Medical Devices:</u>

- Work on Unique Device Identification (UDI) (in particular EU to follow international practice in this area – IMDRF)
- Work on Data Submission (notably common interoperable data bases - increased level of ambition)
- Recognition of international standards and processes – quality management systems

On Cosmetics:

- Collaboration (and recognition) of ingredients safety assessment
- Recognition of ingredients testing results
- Approximation/harmonization of labelling requirements
- Possible work on the definition of cosmetics (some products are considered cosmetics in the EU and in the US are classified as Over The Counter (OTC) Drugs which has regulatory consequences)

COM noted that regulatory component of TTIP is very important and work is going in several areas. COM is engaged with a number of stakeholders from Industry to NGOs, Members of the European Parliament and civil society in general. Transparency efforts have been stepped up and a number of position papers are available to the public in the web site. Commissioner Malmström is heavily involved in TTIP and is engaging in many EU Member States with civil society and business organisations to explain the state of play of negotiations and discuss concerns around TTIP.

There are some areas where work between regulators is progressing well and concrete outcomes are expected (e.g. GMP). However, there are other areas where a concrete outcome would be difficult (if they require legislative changes in one of the parties). There are also areas which are politically sensitive and COM does not anticipate any outcome in TTIP in this respect (e.g. pricing and reimbursement).