EUROPEAN COMMISSION
Directorate-General for Trade

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

Brussels,
USA and Canada

Meeting with EPFIA on TTIP

09/03/2015

Participants:

Richard Bergstrom (EFPIA DG)

Art. 4.1 b (International Affairs)

Art. 4.1 b (TRADE)

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Summary: EFPIA presented a possible new issue to include in the pharmaceutical regulatory cooperation part of TTIP. This is about upstream cooperation on research and innovation – essentially to match the EU's Innovative Medicines Initiative with the US "Precision Medicines Initiative" announced in SOTU 2015, for which a Congressional bill entitled *21st century cures* is on its way. HH invited EFPIA to come back with more detail on the idea once they had consulted further.

Detail:

- EFPIA explained their recent communications activity on TTIP, including publication of new factsheets and meetings in the European Parliament. They noted that they would like to pursue the SME angle further, given the broad industry supply chain. An EFPIA member represents the interests of SMEs in the pharma industry and they intend to consult further.

- EFPIA explained that they would like to see a stronger focus on innovation in TTIP ''convergence trough regulatory science''. Recent positive developments in the US innovation ecosystem for pharmaceuticals: in particular the "Precision Medicines Initiative" as announced in State of the Union 2015. This is directly modelled on the EU's Innovative Medicines Initiative (IMI) which has existed for some years. Its purpose is to ensure that regulatory cooperation moves along with scientific development. For example:

- Breakthrough designation. If an emerging compound is designated as a potential medical breakthrough, it can be fast-tracked through the various regulatory processes in order to get to market as quickly as possible.
- Joint scientific advice.
- Common assessment.

- EMA in London is strongly involved on scientific aspects/innovation discussions (SANTE is regulator but main activity is led by EMA).
  This issue is currently not being addressed in the TTIP negotiations. EU and US regulators would have to be consulted on the opportunity (or not) to do so

- EFPIA would like to see if EU-US cooperation on IMI/PMI could be formalised in TTIP. The purpose would be to create a formal channel to advance swift transatlantic cooperation on highly innovative high-potential medicines, through the systems already established in each territory via IMI/PMI. So for example, if a compound is designated as a breakthrough in one market, could also be in the other market. EFPIA do not believe this would require any changes in law.

- Art. 4.1 b invited EFPIA to come back with more detail on the idea once they had consulted further.