To: [redacted] (TRADE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE)

Cc: TRADE TTIP TRANSPARENCY

Subject: TTIP Meeting with IFHA International Federation for Animal Health Europe on 10/11/2015

DG TRADE and DG SANTE officials meet on 10/11/2015 with the International Federation for Animal Health Europe (IFHA)

IFAH-Europe is the federation representing manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It represents both corporate members and national animal health associations in Europe. These associations comprise both local medium-size enterprises (SMEs) and international companies. IFAH-Europe's membership covers 90% of the European market for veterinary products.

- IFHA enquired about progress in the TTIP pharmaceuticals regulatory discussions and whether there are still opportunities for specific provisions on veterinary medicines
- IFHA referred to **VICH** which is a trilateral (EU-Japan-USA) programme. The role of VICH is to harmonise technical requirements for data necessary for the marketing authorisation of a veterinary medicinal product. This is achieved by developing harmonised guidelines on the studies to be submitted in a marketing authorisation application. VICH exists since 1996. IFHA enquired whether TTIP might replace some vICH activities.
- IFHA inquired whether the EU-US recognition of GMP inspections for human medicines could be expanded to veterinary medicines
- IFHA showed interest in the EU proposal to include an Article on Anti-Microbial Resistance (AMR) in the SPS Chapter of TTIP (IFHA will take contact with the SPS unit)
- COM noted that a detailed report of Round 11 is available online. It includes details on pharmaceuticals regulatory discussions as well as on SPS discussions.
- As regards GMP, the modalities and scope (type of products to be covered) of the GMP provisions has not yet been discussed. The focus of the works has been so far on human medicines but other products are not excluded (EU-US 1998 MRA covered veterinary medicines)
- COM supports (including through TTIP) the works of International fora such as vICH and ICH. Wherever possible, harmonisation activities on technical requirements for authorisation of medicinal and veterinary products will continue to be deferred to these fora that are working well.

- IFHA would need to specify its position (e.g. are there any other matters not covered in VICH that would require specific attention/action)
- IFHA will consult members and decide whether a joint EU-US position will be put forward

Participants:
[redacted] (TRADE)
[redacted], [redacted], [redacted], [redacted], [redacted], [redacted] (IFHA)

[redacted]
European Commission
Directorate General for Trade
[redacted]