[redacted] (GROW)

From: [redacted] (ENTR)
Sent: 27 September 2013 17:25
To: [redacted] (ENTR); [redacted] (ENTR); [redacted] (ENTR); [redacted] (ENTR)
Cc: [redacted] (ENTR); [redacted] (ENTR)
Subject: TTIP- EFPIA meeting

Dear all,

I have participated on 25 September to the meeting between Commission services (DG TRADE F3 CDF) and EFPIA in order to discuss issues related to TTIP.

- COM informed about the status of negotiations with US: 1st round in July; the next round is scheduled for October.
- The aim of the meetings with US is to determine the objectives: what each party seeks to achieve; which are the areas which require further work. The aim of the negotiations is to be feasible on the deliverables.
- Issues for discussions identified by COM: exchange of confidential information; authorization of biosimilars; paediatrics; harmonization of terminology.
- The technical details remain to be discussed between experts between October-December
- The industry showed their support and pointed out that they are ready to discuss the technical details. They identified 3 areas of interest: IPR; regulatory convergence and issues on reimbursement (transparency).
- With regard to the issues related to transparency, the industry asked whether there will be an annex containing provisions on transparency. COM replied indeed in the negotiations with Korea there is such annex, however it was pointed out that it would be more difficult to interfere in the reimbursement process with regard to US. It was mentioned that COM will be looking at this aspect.
- US industry informed about the preliminary discussions with FDA – nothing is off the table.
- With regard to paediatrics, it was pointed out that both regulators consider their system as appropriate and it would be important to determine what is the best solution
- With regard to biosimilars, EU authorized several biosimilars while US did not grant any authorization. Industry pointed out the potential to create a model.
- Industry asked the question whether there is willingness for collaboration between EMA and FDA as lot of money are wasted for the US/EU approval.
- Questions about what would be MS role in the process were raised. COM replied that MS remain the regulators as the Council has to agree and pointed out that MS will be involved once things become more concrete.

Kind regards,

[redacted]