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Sent: Wednesday, September 26, 2012 2:01 PM
To: GARCIA BERCERO Ignacio (TRADE)
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Subject: meeting with EFPIA of 25 September (report)

DG ENTR, Sanco and TRADE met yesterday with EFPIA (s Art 4.1(b) Art 4.1(b) ii).
to provide an update on the work of the HLWG and learn about industry discussions (also in view of a forthcoming mission in the week of 8th October to DC) and preparation of a reply to the public consultation on the IA and the joint solicitation. The meeting took place in a friendly atmosphere and confirmed that industry is getting ready to submit concrete input, although the first submission is likely to be EFPIA only. EFPIA used the occasion to also press a few more general points and to make some requests in relation to the EU framework (which will not necessarily be dealt with in the context of the FTA but are useful to bear in mind when looking at the overall situation in the sector).

Points raised by EFPIA

General:

- **Regulations and Science**: In general, EFPIA considers that the regulatory framework is not fit for what "goes on the real world" – EFPIA would support a healthy debate about how to ensure the regulations are in sync with science. In this context, EFPIA pointed to a study run by RTD on NTMs. It will be important when producing new standards and regulations to bear in mind the global dimension of the industry. We need appropriate regulatory frameworks and standards for biosimilars, biologics and compete on generics.

- **Importance of third country dimension**: ICH: Important to rethink our strategy. The "International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use" is a forum where science and peer pressure could be used to communicate with emerging economies. EFPIA informs about the ICH Steering Committee meeting in November and the usefulness to have a letter by Sanco and other associated services to the FDA ahead of the meeting to pass a few policy messages. EFPIA has already shared some ideas with Sanco (who also has their own position paper).

- **Cooperation EMA-FDA and attitude towards the growth and jobs initiative**: Positive attitude in general of EMA on the Growth initiative. Important to convince FDA: Risk of regulatory capture and difficulty to change well-established habits. Capture of the "regulated " (i.e. industry) – sometimes also an issue. There are good contacts FDA-EMA including informal contacts, but need to go beyond that.

Possible targets for a joint submission with PHRMA:

- One objective would be to have a **coordinated assessment of the data submitted by companies,** i.e. regulators should work together.
- **Inspections** is another area where improvement could be made. While inspection reports are being shared between the agencies, full mutual recognition of inspections would be a clear improvement.
- FTA negotiations could provide the opportunity to **make the 1995 MRA work in practice**. This could be a quick win.
- **MR of Good Manufacturing Practices** (GMP) should also be within reach. EFPIA notes that FDA and EMA have slightly different attitudes to the way they see enforcement (FDA "very far away from the market" while EMA is more prescriptive. FDA "really gets into the data".
- MR of regulations is an objective for the future.

Possible targets to be part of a unilateral submission by EFPIA

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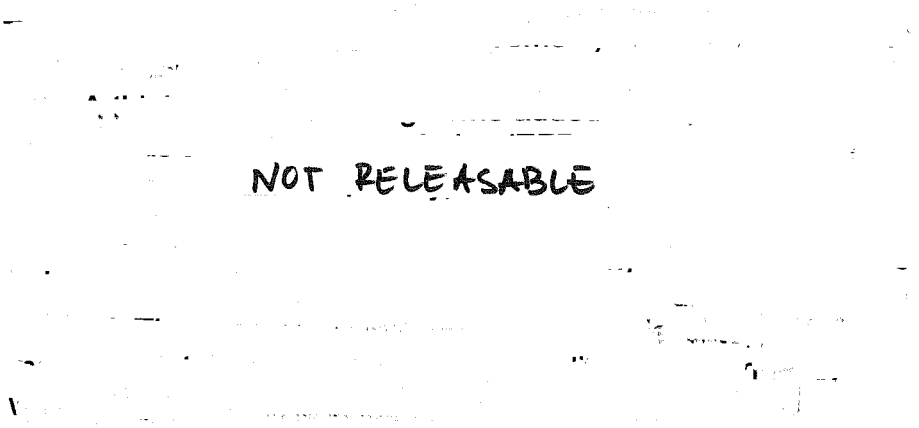

- IPR: EFPIA would like to seek [redacted] M.R. [redacted] for biologics (which is the time frame granted to firms in the US). EFPIA hopes this will be part of the "EU policy initiative for the pharma sector"