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From: NEIRA Pablo (TRADE)
Sent: 03 December 2012 10:06
To: PERREAU DE PINNINCK Fernando (TRADE)
Cc: GARCIA BERCERO Ignacio (TRADE); KAIZELER Ivone (TRADE); EMBERGER Geraldine (TRADE); FEZAS VITAL Isabel (TRADE); ROELAND Christophe (ENTR); HEYNISCH Thomas (ENTR); GOUX Sebastien (SANCO)
Subject: US-EU HLWG - Meeting wiht EGA 30/11/2012

Dear all,

See below a report from the meeting with EGA last Friday.
Thank you Ivone for your help.

Regards,

Pablo

Attendants: EGA Generics: E Art 4.1b

Commission: F. Perreau de Pinninck, I. Kaizeler, G. Emberger, I. Fezas and P. Neira (TRADE); C. Roeland and T. Heynisch (ENTR); and S. Goux (SANCO)

- COM explained the current status of the process.
- EGA highlighted the importance of the process, in particular for their multinational members. They also highlighted the impact on the efficiency gains for regulators.
- Key element is to improve the information exchange between the US and the EU.
- Biosimilars:
  - Key issue: Avoid repetition of clinical trials (in particular if the reference product is the same). Clinical trials and the purchase of the reference product are the biggest cost for biosimilars registration.
  - EGA notes recent developments on both sides of the Atlantic on acceptance of applications based on reference products not locally sourced (EMA is revising the biosimilars guideline as well as the US but important that both sides implement the recognition process at the same time).The process is sufficiently advanced but they see an opportunity to speed it up.
  - A coordinated EU/US approach would have a significant global effect: S. Korea, with other APEC countries (Singapore, etc) is working to define the international standards in this area. EU and US need to make sure that the existing ICH standards are adopted by other countries.
  - Recommendations:
    - Strengthen the existing EMA/FDA biosimilars cluster.
    - Reinforce regulatory exchanges.

        - Obtain clear commitment from the US on use of non-US sourced reference products (i.e. concrete implementation of the draft US guideline that foresses that).

- Generics:
    - Recommendations:
        - Create a US/EU generics cluster in order to foster cooperation, discussion and alignment.
        - Possibility to use the same reference products in the applications: need modification of the guideline (EU) or changes or re-interpretation of the legislation (US).
        - Harmonization of data requirements, harmonization of assessment criteria and sharing of assessment reports (data base available to EU MS could also be extended to US)
        - Only one assessment for active substance in order to avoid duplications (SANCO & ENTR questioned the feasibility of this point, given that most generics are approved via decentralized procedure)
        - Pharmacopea: they suggest recognition of monographs that do not exist in one of the pharmacopeia, and setting up collaboration for elaboration of new monographs.
        - Cooperation on the planning and prioritization of inspections and information sharing: Sharing of the EMA GMP database with the US is already foreseen. US has also a public repository of GMP reports (additional non-public info can be exchanged with MS on basis of confidentiality agreements)
        - Revision and activation of the (dormant) MRA, in their opinion in the current situation an MRA would be helpful in particular on falsified medicines.

- EGA raised the point of necessary legal modifications of the IPR regime: to allow advanced manufacturing (COM noted no interest to tackle contentious issues).

- Obstacles:
    - Some obstacles for the implementation of the ideas presented could come from the EU and US 'originator' Industry. However, in areas such as pharmacopeia and GMP inspections the interest is common. Furthermore, part of the industry is nowadays both originator and biosimilars/generics producer.