52

From: EMBERGER Geraldine (TRADE)
Sent: Thursday, July 19, 2012 8:11 PM
To: PERREAU DE PINNINCK Fernando (TRADE); ROELAND Christophe (ENTR)
Cc: GARCIA BERCERO Ignacio (TRADE); RYS Andrzej Jan (SANCO); HERBERT Didier (ENTR); SIEBERT Christian (ENTR); DUPUIS Philipp (TRADE); SORENSEN Carsten (TRADE); NEIRA Pablo (TRADE); DE LUSIGNAN Paul (TRADE)
Subject: HLWG; regulatory issues; meeting with EGA today

Participants from EGA: [Art 4.1b]

Meeting with EGA showed high level of preparedness of the industry.

EGA underlined **strong interest from both EU and US membership** (many are active on both sides of the Atlantic). EGA believes that EU and US companies would probably be very much aligned in their interests, although there may be differences (i.e. advanced manufacturing) demands are unlikely to be conflicting. EGA may submit a common position on global development of bio-similars and generics any time soon. Bio-tech companies can be expected to oppose this.

EGA pointed to the fact that **EU and US are still the largest generic** markets in terms of sales, although markets in Latin America and Asia are growing at a stronger pace. US alone will account for 1/3 of global sales in 2015. But at the same time, the debate (among OECD members) **is increasingly about access to the emerging economies** – this can be seen from recent discussions in WTO, and WIPO in particular.

EGA confirmed they are **not worried about tariffs** as they have been largely eliminated but want to **focus their attention on NTBs**.

EAG informed that most of the "asks" of the generics industry would **not require changes in our respective legislations**, except for advanced manufacturing.

EGA is preparing a **joint / coordinated submission** with their US counterparts.

Among the offensive issues EGA mentioned were

- **General NTBs** (barriers to public procurement market, although EGA does not have specific problems with Buy America – by contrast, this is an approach they would like to see even replicated in the EU- (!); nor with Medicare; but will double-check).

- **Mutual Recognition of compliance inspections**: EU-US MRA was signed in 1999 but never implemented and FDA is reluctant to come on board. Result is the high number of inspections in transatlantic market but also in third country markets, which in EGA's view could be avoided because EU and US operate on the basis of similar standards or even the same standards. One problem is that FDA does not recognise inspections as

equivalent for all EU Member States. The objective would be to update, revive and modernise the existing MRA – as it provides the necessary legal framework, which cannot be substituted by other forms of cooperation (such as international collaboration on API GMP and pilot projects).

- **Global Development for bio-similars :** EU is world-leader; aim is to allow for a single development programme for bio-similars (and the same for genercis) and get US to accept data from tests with reference products not sourced in the EU and vice – versa. There were promising steps on the EU side noted when Commissioner Dalli declared in June that Commission would apply a more flexible interpretation to the existing legislation allowing for acceptance of data from tests where ref products have not been sourced in the EU – this is seen by the industry as an important break-through; FDA has started a draft guidance which does not go as far but provides for the possibility of using representative products sourced elsewhere for parts of the programme. EGA is concerned that the guidance would move slowly or could get stuck and would like to use HLWG and possible negotiations to advance this guidance.

- **Generic Medicines:** EGA wants to test the idea to intensify bilateral work on harmonising the approach to requested studies as regards those generics, which are more difficult to make (with a view to accelerating work on-going at multilateral level and motivate other partners to come on board); EGA also advocates for harmonisation of "pharmacopoeias" (although very ambitious) and for the creation of a cluster EMA-FDA for biosimilars (this could be of interest for both sides).

- **IPR**: EGA warned of any attempt to "mix" or merge EU and US approaches to IPR BUT). But they want to be able to produce generics in the EU for export purposes when patent protection has elapsed in third countries, even if the SPC is still active in the EU (something they currently cannot do without breaking EU law). The current situation hinders EU producers to export to important third country markets while foreign companies can take their place at the front of the queue and this negatively impinged on the EU producers' competitiveness.

Geraldine Emberger