



EUROPEAN FINE CHEMICALS GROUP EXPECTS A MORE EFFICIENT FOREIGN DRUG INSPECTION PROGRAMME

Brussels, 12th November 2007:

Because of the paper published in October 2006 by the European Fine Chemicals Group (EFCG) and the Synthetic Organic Chemicals Manufacturers Association (SOCMA), EFCG - a Cefic sector group - was invited to give testimony to a sub-committee of the US Congress who are investigating the risks associated with lack of foreign facility inspections by the FDA.

The joint EFCG/SOCMA paper highlighted the risks to EU and US citizens from off-patent Active Pharmaceutical Ingredients (APIs) and medicines made in foreign factories, especially in China and India, that have never been inspected by either EU or US authorities.

These findings have since been confirmed by a US government audit report published on 1st November 2007. This states that the FDA inspects only 7% of an estimated 3250 foreign drug manufacturers supplying the USA each year, and that in 2007, the FDA will inspect only 13 of the 714 Chinese sites eligible for inspection.

Representing EFCG, Mr Guy Villax, CEO of Hovione, told the sub-committee "80% of the API volume used to make EU medicines comes from abroad, and not everyone plays by the rules. This is putting the safety of our citizens at risk. Globalisation makes it harder to enforce the rules and this has resulted in the emergence of off-patent API production in the low cost economies where regulations and Good Manufacturing Practices (GMP) requirements are very limited compared to those in the EU."

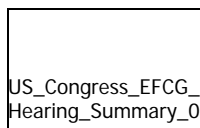
He added, "Oddly, the EU inspects API plants based in proximity not risk. Per year, the EU authorities may inspect 30-50 plants in Asia, when Italy and France inspect a greater number in their own country. The few foreign inspections by the European Directorate of Quality of Medicines (EDQM) tell us something is broken as all suspended approvals were related to production in Asia. None were in the EU"

The sub-committee chairman (Bart Stupak, Michigan) wondered whether "We can have any confidence FDA is truly managing the risk that may come from foreign-made drug products if the FDA doesn't know the exact number or location of foreign drug manufacturers".

At the hearing, the FDA said it was seeking to verify the existence of the several thousand foreign drug facilities for which they do not have verified data. EFCG is of the opinion that this is precisely the kind of international enforcement collaboration on which the FDA and the EMEA, its EU counterpart, should work together to share costs and to free up resources for more inspections along the supply chain where the risks of unlawful activity are greater.

Notes for Editors

A copy of the EFCG Hearing Summary Testimony is attached.



A copy of the full Testimony is available on the EFCG website at http://efcg.cefic.org/isoFILES/publications/items/DOWNLOAD_129.pdf

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EFCG – the European Fine Chemicals Group, www.efcg.cefic.org. Provides a forum where European Fine Chemical manufacturers, including those making APIs and excipients, discuss their competitiveness issues and agree on actions to deal with them.

Cefic – European Chemical Industry Council - is the Brussels-based organisation representing national chemical federations and chemical companies in Europe. Cefic represents directly or indirectly around 29,000 large, medium and small companies in Europe, which employ about 2 million people and account for more than 30% of world chemicals production. www.cefic.org