



## **EFCG ENDORSES THE EUROPEAN COMMISSION'S NEW PHARMACEUTICAL LEGISLATION INITIATIVE, AS LIFE-THREATENING, SUBSTANDARD APIS BECOMES A REALITY GLOBALLY**

**Brussels, 12<sup>th</sup> March 2008:**

The heparin scare in the USA is now spreading to Europe and Japan. This is precisely what EFCG – The European Fine Chemicals Group - has been working hard to avoid over the past 4 years.

Nevertheless, EFCG welcomes the news that the FDA is making urgent investigations into the cause of the scare after they admitted never having inspected the Chinese factory making the heparin, and which they now suspect is the cause.

Meanwhile, heparin-based products are being recalled from the US market where the FDA has estimated that the deaths of 19 patients could be connected with the use of heparin produced by Baxter International using a substandard, contaminated active pharmaceutical ingredients (APIs) sourced in China. As serious side effects have been reported also in Germany, heparin products worldwide are being subjected to additional testing. In Japan, supplies of heparin-based products are also being withdrawn as a precaution.

Since 2004, EFCG has advocated tougher enforcement of existing laws and new, harmonised international laws to combat substandard APIs, especially those originating in China. Whereas pharmaceuticals in the past could afford a safety margin, today there are not enough profit margins to guarantee safety and the risks that competitive pressures drive in off-patent medicines are no longer acceptable.

The majority of pharmaceuticals worldwide are now off patent and this industry has become intensely global and hyper competitive. Never has the need for enforcement been more compelling at ensuring quality and a level playing field. Weak enforcement has encouraged the growth of severely non-compliant manufacture and sourcing of substandard APIs with fatal effects not only to patients but also to the competitiveness of EU manufacturers of APIs. The majority of APIs sold in the EU now comes from Asia.

The European Commission coincidentally made an important announcement on 5<sup>th</sup> March. The Commission now accepts that the risks from severely non-compliant counterfeit pharmaceutical products and APIs in Europe has worsened significantly, and new legislation to deal with the issue is now required as a matter of urgency.

While applauding the Commission's announcement, EFCG feels that the enforcement strategies in place are inadequate. The 21st century demands a new approach to law making and enforcement, one that is based on international cooperation by the major authorities, on joint enforcement actions at an international level and on strict sanctions that drive effective deterrence.

## Notes for Editors

For further information, please contact:

Mr Tony Scott  
Adviser – European Fine Chemicals Group, Cefic  
[tscott@tsassoc.eu](mailto:tscott@tsassoc.eu), +44 (0) 1428 641 168

Mr Pieter van der Hoeven  
Manager - Active Pharmaceutical Ingredients Committee, Cefic  
[pvd@cefic.be](mailto:pvd@cefic.be) +32 (0) 2 676 7202

**EFCG – the European Fine Chemicals Group**, [www.efcg.cefic.org](http://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.