

PRESS RELEASE
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**EUROPEAN FINE CHEMICALS GROUP PROPOSES CERTIFIABLE
STANDARDS FOR EXCIPIENTS USED IN PHARMACEUTICAL PRODUCTS**

Brussels, 3rd October 2007:

The European Fine Chemicals Group (EFCG), a Cefic sector group, has developed a Position Paper¹ on excipients used in pharmaceutical manufacturing. The paper explains that the manufacture of excipients destined for use in European medicines is neither regulated nor controlled as it should be and that regulations and standards should be enforced to avoid any potential risk to the health of EU patients and consumers.

With the implementation of the EU Directive 2001/83/EC (amended by Directive 2004/27/EC) into national law, it is now mandatory that all active pharmaceutical ingredients (APIs), and the yet-to-be-defined list of *Certain Excipients* used in pharmaceutical manufacturing, must be produced in compliance with current Good Manufacturing Practice (cGMP).

EFCG's Position Paper builds on this expectation and proposes (1) that all common excipients, by far the largest grouping, conform to General Chapter <1078> USP, including certified ISO requirements; (2) that all Specific (includes *Certain Excipients*) and Novel Excipients, a much smaller defined group, are covered by EC Directive 2001/83 (amended by Directive 2004/27/EC); and (3) that all these requirements are certified and effectively enforced.

EFCG believes that the consequences of the full implementation of their proposals not only supports the need to better protect the health of EU citizens, but it would also bring into law what is already the accepted practice for a wide range of reputable suppliers in the Far East, N America and Europe. As such, it should have an insignificant effect on product prices.

Dr Arnulf Heubner, Chairman of the EFCG Pharmaceuticals Business Committee said,

“By far the largest volume and weight of any medicine consists of a range of excipients, the manufacture of which varies, is covered by limited regulation and lacks legal enforceability. I am, therefore, concerned that by allowing this situation to prevail we could be putting the health of European citizens at risk”.

EFCG made public the Position Paper during a press conference held on 3rd October 2007 at the CPhI Exhibition in Milan. At the press conference, Mr Guy Villax, past-Chairman of the EFCG Pharmaceuticals Business Committee, provided an update on EFCG's progress and plans to help minimise the presence of GMP non-compliant APIs in European medicines.

¹Reference: "EFCG Position Paper: Excipients Used in Pharmaceutical Manufacturing"



"EFCG Excipients
Position Paper 07092

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Notes for Editors

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

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.

Excipients – are pharmaceutically inactive substances that are physically mixed with active pharmaceutical ingredients (APIs) to form pharmaceutical final dosage forms (medicines). The most common functionalities of excipients include fillers, binders, disintegrants, solubilisers and coatings.