

EFCG AND APIC WELCOME ADOPTION OF NEW FALSIFIED MEDICINES DIRECTIVE

Brussels, February 22, 2011 – The Active Pharmaceutical Ingredients Committee (APIC) and the European Fine Chemicals Group (EFCG) welcome the overwhelming support given on February 16 by the European Parliament for the Falsified Medicines Directive.

“We consider it to be a major step forward in the fight against falsified active pharmaceutical ingredients (APIs), and excipients in European medicines. However, as we do have some reservations about how it will work out exactly, we will be closely following the implementation by the Member States,” says Dr Chris Oldenhof, APIC president and a board member of EFCG, both sector groups of Cefic – the European Chemicals Industry Council.

Dr Oldenhof added: “We are pleased that the focus on APIs has dramatically increased and that is a good thing. If the total package of new initiatives worldwide results in adequate coverage of global API manufacture by thorough inspection to EU standards, then we are on the right track. As disappointingly, the new directive fell short of our wish for mandatory inspections by Europe of API producers in third countries, we will be vigilant to see how things progress”.

EFCG is pleased to note that the inclusion of pharma excipients in the new directive is a very positive aspect and fits well with development plans for the international voluntary certification project for pharma excipients – Excipact – which they initiated and which will open for public consultation in March.

The new directive is just one piece in a set of national and international developments (see note three below) to deal with falsified medicines and counterfeiting so it should not be seen in isolation. A point of concern is still the vagueness of current definitions of falsified or counterfeit medicines with regards to falsified APIs. The two groups believe definitions should be made unambiguously clear that a medicine that contains a falsified API is a falsified medicine.

Oldenhof concluded: “Our biggest concern remains the lack of enforcement, so we are considering what further actions are needed to ensure optimal oversight and enforcement. Weak enforcement has encouraged the growth of severely non-compliant manufacture and the entry of falsified APIs into the legal supply chain, putting the health of patients at risk and at the same time undermining the competitiveness of compliant EU manufacturers.”

Notes for editors:

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1. APIC – the Active Pharmaceutical Ingredients Committee was formed in 1992 as a sector group of CEFIC and represents the producers of APIs and API intermediates in Europe. See www.apic.cefic.org
2. EFCG – the European Fine Chemicals Group was formed in 2004 as a sector group of Cefic and represents fine chemical manufacturers in Europe. See www.efcg.cefic.org

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