

## NEWS RELEASE

### EFCG AND APIC WELCOME THE DRAFT DIRECTIVE FOR COUNTERFEIT MEDICINES AND APPLAUD THE NEW INTERNATIONAL API INSPECTION PROGRAMME

*Brussels, 12 December 2008.*

EFCG - the European Fine Chemicals Group and APIC – the Active Pharmaceutical Ingredients Committee – are pleased with the European Commission’s draft amending Directive to combat counterfeit medicines published on 10<sup>th</sup> December. We appreciate that it addresses our main concerns by recognising the need to defend public health by legislating to prevent the supply into Europe of substandard, counterfeit active pharmaceutical ingredients (rogue APIs), originating in 3<sup>rd</sup> countries in especially Asia.

While not in the amending Directive, we especially applaud the establishment of the International Cooperative API Inspection Programme that has been designed to coordinate the use of limited inspection resources, drawn from Europe, USA, and Australia, in higher risk 3<sup>rd</sup> countries in the immediate short term. This extended, global API inspection activity, especially if targeted on higher-risk geographical areas, should begin to stop the inflow of rogue APIs into Europe in the short term for the benefit of EU patients.

The cornerstone of the Commission’s proposed approach in the amending Directive is the requirement of equivalence to EU GMP standards, inspection and enforcement systems in countries where APIs are manufactured. Such equivalence must be secured by these countries for APIs exported to the EU. It will be checked by the EU on a regular basis whether equivalence is in place and whether this is maintained thereafter. We believe that this approach represents a considerable political challenge, and without details of how it is to be accomplished, we reserve final judgement on the workability of the proposals. For example, we are expecting that the contents of the yet-to-be compiled accompanying guidelines will secure full enforcement and control of equivalence, resulting in a system that will be guaranteed against false and / or misleading statements.

Special consideration of current, highly compliant API supply situations that would be unnecessarily hampered by this new approach will probably be needed.

Nevertheless, we feel that the publication of this draft Directive sends a strong signal to all 3<sup>rd</sup> countries that, unless they begin now to harmonise their standards and oversight to the EU level within the proposed timetable, they will not be allowed to sell their APIs, or medicines containing them, into the EU. This should provide them with a vital incentive to comply and we assume that the EU authorities will be offering them help to do so.

The majority of pharmaceuticals worldwide are now off patent and the industry has become intensely global and hypercompetitive. Never has the need for tougher laws and effective law enforcement been more compelling to ensuring the safety of APIs 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. Most of the APIs consumed in Europe now come from Asia.

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### Note to Editors

For further information:

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