EUROPE

INTERNATIONAL PHARMACEUTICAL EXCIPIENTS COUNCIL

9 May 2008

Dear Sir/Madam,

Subject: IPEC Europe's reply to the European Commission's document "Public consultation in preparation of a legal proposal to combat counterfeit medicines for human use - Key ideas for better protection of patients against the risk of counterfeit medicines"

IPEC Europe would like to thank the European Commission for this initiative. We acknowledge that the counterfeiting of medicines for human use is a significant threat to patient safety and that the issue transcends national borders. IPEC Europe would welcome clarification of the regulatory framework for medicinal products with regard to counterfeiting. However we note that counterfeiting is by definition a criminal activity and any revised regulation must not disadvantage ethical manufacturers and suppliers.

IPEC Europe notes that **Excipients** are not expressly in the scope for this consultation document as written. We would appreciate that inclusion and/or exclusion of excipients be explicitly mentioned in the text to avoid any misunderstanding. Over the past years, IPEC Europe has been proactive in developing industry guidelines aiming at reinforcing excipients quality, traceability and safety, such as the joint IPEC-PQG Good Manufacturing Practices (GMP) Guide, and the IPEC Good Distribution Practices Guide (GDP) on the supply chain security (both attached).

IPEC Europe fully supports the application of some key principles highlighted in this proposal to medicinal products and Active Pharmaceutical Ingredients (APIs) as they are already embodied in IPEC Europe guides, in particular:

- **4.1.1. Subject all actors of the distribution chain to pharmaceutical legislation**
  "... acceptance of third party audits by accredited companies could be considered":
  IPEC supports the acceptance of third party audits by accredited bodies who have demonstrated that their auditors are competent to assess the GDP and GMP status of organisations.
- **4.1.3. Improving product integrity through a unique seal from the manufacturer to the retailer or wholesaler, using a risk-based approach, supported by a ban on repackaging**
  The IPEC-PQG GMP Guide already requires the application of tamper evident seals to excipient packaging.
- **4.1.4. Centrally accessible record to facilitate traceability of batches throughout the distribution chain**
  The principles of being able to trace a material's pedigree are embodied in the IPEC GDP Guide.

- **4.3.2. Enhancing audit and enforceability of GMP**
  As already mentioned, IPEC supports the acceptance of third party audits by accredited bodies who have demonstrated that their auditors are competent to assess the GDP and GMP status of organisations.

We thank you very much for your attention to our reply and remain at your disposal, should you wish to further discuss it with us.

Yours sincerely

IPEC Europe

About IPEC-Europe

IPEC Europe, the International Pharmaceutical Excipients Council Europe, is an international industry association formed in 1991 that serves the interests of producers, distributors and users of pharmaceutical excipients. Together with its sister associations, IPEC Americas and IPEC Japan (JPEC), the Council is a member of TriPEC whose global membership extends to more than 200 companies. IPEC's objectives are to contribute to the development and harmonization of international excipient standards, the introduction of useful new excipients to the marketplace and the development of good manufacturing practice for excipients.

IPEC has published internationally accepted guidelines concerning the manufacture and supply of excipients, most notably the IPEC-PQG GMP Guide and the IPEC GDP Guide.

For further information please visit our website at www.ipec-europe.org

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