From: Salghetti Drioli [salghetti@procos.it]

Sent: mardi 6 mai 2008 8:58

To: ENTR PHARMACEUTICALS COUNTERFEIT

Cc:

Subject: I: testo per la consultazione

Dear sirs,
below plase find the CBC Procos position regarding the Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use
Best regards
Roberto Salghetti Drioli
CBC Procos Qualified Person

CBC Procos, a wholly-owned subsidiary of CBC Co. Ltd Group, is a manufacturer of bulk active ingredients (API's) and advanced intermediates for the life-science industry.

The Firm is present in the field of chemical intermediates and APIs since 1945 and exports in all the main markets all over the world (Europe, America, Far and Middle East).

Procos is regularly inspected by AIFA and by FDA.

The Company fully agrees with the European Commission's concerns about the introduction into the market of APIs coming from extra-European countries, where the compliance to cGMPs quality standards is not verified by an European Regulatory Authority. The Company shares the concerns relevant to such potential risk for human health due to a declared, but not verified "on site" compliance to the requested quality standards (i.e. ICH Q7a).

Therefore CBC PROCOS suggests and strongly recommends to prepare a legislation, at Community level (that means Directive), which rules the matter. In this way CBC PROCOS asks to consider what it's requested with the Written Declaration on active pharmaceutical ingredients, approved on November 30th 2006 by European Parliament, that is:

a) mandatory inspections performed by European regulatory Authority on production sites that export APIs into the EU;

b) traceability of APIs (i.e. the possibility to locate the source).