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“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”

PRODOTTI CHIMICI E ALIMENTARI S.p.A.’s POSITION

Prodotti Chimici e Alimentari S.p.A. is an Italian Company manufacturer of bulk active ingredients for pharmaceutical use. The Firm is present in the field of chemical intermediates and APIs since 1946 and it is leader for sales volumes and product range in the production of bile acids and derivatives. The Company invests in human and technological resources to improve its know-how and to be in the vanguard of its field. Our customers are important national and international Pharmaceutical Groups and market areas occur through Europe, America, Far and Middle East. P.C.A. is regularly inspected by AIFA and inspected by FDA, too.

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).

P.C.A. would underline how it is important a change of the current laws in force concerning the medicinal products and the need of preparation of an over-country legislation, a Community Directive, that rules the matter tightening the requirements for APIs manufacturing and the relevant controls by means of inspections “on site”.

As mentioned above, Prodotti Chimici e Alimentari S.p.A. asks to consider what's requested with the Written Declaration on active pharmaceutical ingredients, approved on November 30th 2006 by European Parliament, more precisely:

- 1) introduction of mandatory inspections to manufacturing sites that export APIs into EU, carried out by the European Regulatory Authority
- 2) traceability of APIs in order to identify the source

In conclusion, Prodotti Chimici e Alimentari S.p.A. thinks that it is indispensable to take measures against counterfeit of medicines and against the import into the European Community of active ingredients manufactured without any controls carried out by the European Authority, whose priority should be the setting up of an European Inspection Team.