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To
Directorate General Enterprise and Industry
EUROPEAN COMMISSION

Labochim is an Italian API producer, based in Segrate (Milan), with over 40 years experience at the service of the pharmaceutical, nutritional and healthcare industry

Labochim is undergoing regular AIFA, US FDA and Australian FGA inspections since 1978.

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Reference is made to the document drafted by the European Commission – Enterprise and Industry Directorate-General "Public consultation in preparation of the proposal to compact counterfeit medicines for human use – Key ideas for better protection of patients against the risk of counterfeit medicines" and more in particular to paragraph 4.3 "Tightening requirements for manufacture, placing on the market of active substances and inspections".

We share the European Commission's concerns, analyses and proposals related to the introduction into the market of medicines containing counterfeited and harmful APIs, mostly deriving from extra-EU countries which are not abiding to EU rules and not complying with the quality GMPs standard, applied in the Community (i.e. ICHQ7A). We indeed stress the importance that human health be safeguarded by a homogeneous trustworthy network supported by a equally reliable supply chain, to overcome this problem.

We believe that a system of mandatory inspections of manufacturing sites that export APIs into EU, would be the most reliable and suitable mean to warrant and guarantee end-users. Accordingly, we deem that these inspections and audit must be carried out by Governmental bodies in order to avoid any conflict of interest.

We therefore support the introduction of new rules and laws, at Community level (i.e. Directives), governing this subject matter. This solution is not meant to hamper good quality non-EU manufacturers, but is targeted to exclude manufacturers not in compliance with cGMPs in view of safeguarding the citizens, who have the right to use safe drugs and to know the origin of the active principle of the drug, and have the absolute guarantee and trust that this compound is made according to the highest possible standards set forth

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by EU directives. To this end, it is our opinion that drug packages should bear indication of the API manufacturer (using a code in order to safeguard privacy and confidentiality laws) and the country of origin, as it happens in the food market.

In fact, as the European consumer is able to know the origin of the food he buys at the supermarket or eats in a restaurant, in the same way he should be equally in the position to know where molecules contained in medicines, and where medicines themselves, are manufactured and come from.

Accordingly I would kindly ask you to consider the Written Declaration on active pharmaceutical ingredients, approved on November 30th 2006 by European Parliament, and more in particular: 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).

In faith,

Daniele Cardoso
President
Labochim S.p.A.