From: Petraroja Adelaide [A.Petraroja@biosint.it]
Sent: jeudi 8 mai 2008 12:14
To: ENTR PHARMACEUTICALS COUNTERFEIT
Subject: Answer to a public consultation

Dear Sirs,

Making reference to the "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" and to the "Written declaration on pharmaceutical active principles", please find enclosed the position of our Company.

Biosint S.p.A., a privately owned Italian Company belonging to Sigma-Tau group, is a manufacturer of APIs, whose plant is located in Sermoneta, near Latina. The Production Site is regularly inspected by AIFA and FDA.

Its leader products, Carnitine Base and its derivatives, are approved and marketed all over the world.

For this reason, Biosint had to adopt high quality standards for its production, according to the cGMPs rules (ICH Q7A), that implies a continuous improvement and care of its facilities, a continuous evaluation and growing of its control systems together with strong investments in R&D, in order to increase the reliability of its processes.

Biosint fully agrees with the concerns expressed by the European Commission about the hazard of the introduction into the European market of active ingredients manufactured in extra-EU countries in which the compliance to cGMPs rules is not verified by an EU Regulatory Authority, in order to avoid a potential risk for the public health.

Biosint believes reasonable, rational and ethic that any APIs' manufacturer, which put into the market products for human use, complies with the same rules that guarantee the proper quality and safety of the same products, despite their nationality and geographical position.

Therefore Biosint strongly support the content of the Written Declaration on active pharmaceutical ingredients, and asks for the necessity of:

1) successful inspections performed by European Regulatory Authorities on Production Sites as mandatory condition for exporting their APIs into the European market.

2) traceability of APIs, with indication of their origin (Country, Company, Site of production).

Best Regards.

Dr. Adelaide Petraroja

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