
From: Michelangelo Leoni [Michelangelo.Leoni@acsdobfar.net]
Sent: mardi 29 avril 2008 11:17
To: ENTR PHARMACEUTICALS COUNTERFEIT
Cc:
Subject: PUBLIC CONSULTATION - ACS DOBFAR

TO THE ATTENTION: EUROPEAN COMMISSION - ENTERPRISE AND INDUSTRY DIRECTORATE GENERAL

CONSUMER GOODS - PHARMACEUTICALS

OBJECT: PUBLIC CONSULTATION IN THE PREPARATION OF A LEGAL PROPOSAL TO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE

Dear Sirs,

ACS DOBFAR is a privately owned Italian Company. Being one of the major producers of Bulk Cephalosporins and Penicillin both oral and for injection and exporting its APIs all over the world, ACS DOBFAR is among the top five Chemical Pharmaceutical Companies in the world.

The Italian Group owns 13 Production Sites and 7 of them are US FDA inspected. ACS DOBFAR is one of the leading exporters to the US market as well as an important supplier to many companies in the world, who currently export their Finished Dosage Forms to the US market, using ACS DOBFAR Active Pharmaceutical Ingredients. Group turnover 2007: 250 Million Euro. Human Resources: more than 1.300.

Despite constant and strong competition in the market from companies in new growing economies, ACS DOBFAR retains an important share in the global market thanks to strict quality control, investment in R&D know-how expertise, human resources as well as vertical and international integration.

Considering the above, ACS DOBFAR shares the European Commission's concerns related to the introduction into the market of APIs, especially coming from the extra-EU countries, that can harm the human health, as not in compliance with the quality GMPa standard, applied in the Community (i.e. ICHQ7A). At present such situations are more and more likely for lacking of the necessary controls.

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

- 1) Mandatory inspections performed by European regulatory Authority on production sites that exports APIs into the EU.**
- 2) Traceability of APIs (i.e. the possibility to locate the source).**

Thanks for your cooperation and Best Regards,

Michelangelo Leoni

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