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Garbaganate M.se, May 7, 2008

For the attention of the European Commission - Enterprise and Industry Directorate General - Consumer Goods -Pharmaceuticals

Solmag is a privately owned Italian Company producing APIs and advanced intermediates, exporting products for generic drug producers in Europe, US, Asia and Australia.

The Company has three Manufacturing Sites in Italy with about three hundred employees. Solmag is mainly involved in the manufacturing, by chemical synthesis, of Retinoids, Controlled substances, Antivirals and Anticancers.

The company is fully committed with GMP respect and all the Sites are regularly ispected by AIFA and two of them are regularly inspected by FDA.

Solmag bears with the European Commission's concerns related to the introduction into the market of APIs, especially coming from extra-EU countries, that can threat the public health, if not produced in compliance with the quality GMPs standard, applied in the Community (i.e. ICHQ7A).

Therefore Solmag strongly suggests the preparation and the officialization of a legislation, at Community level, which rules the matter taking in consideration 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).

Hoping this proposal will soon be implemented , we remain Best Regards

Claudia Maurogiovanni

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