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Sifavitor s. r. l.
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6th May, 2008

To
Directorate General Enterprise and Industry
EUROPEAN COMMISSION

Sifavitor, was founded in 1966 in Lodi (Italy) as a producer of active ingredients for the pharmaceutical industry. The production site main policy has always been focused on high quality standards. Since 1977 its quality system has been verified by the US FDA and periodically inspected by AIFA. In 1998 Sifavitor has been ISO 9000 certified, now 9001:2000

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With reference to the European Communty document "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 would like to submit the following considerations.

SIFAVITOR shares the European Commission's concerns related to the introduction into the market of APIs, mainly of extra-EU countries origin, that can harm human health, being not in compliance with the quality GMPs standard, applied in the Community (i.e. ICHQ7A).

We believe that this situation is mainly due to the lack of controls. We therefore suggest the introduction of mandatory audits to be carried out by qualified personnel solely belonging by the competent bodies.

We therefore suggests to prepare a legislation, at Community level (that means Directive), which ruling this issue and we would be grateful if you could consider the contents of the Written Declaration on active pharmaceutical ingredients, approved on November 30th 2006 by European Parliament, and more in particular the introduction of (a) mandatory inspections performed by European regulatory Authority on production sites that export APIs into the EU; and (b) traceability of APIs (i.e. the possibility to locate the source).

In faith,

Livio Nani
Managing Director
Sifavitor Srl