From: Federica Feltre [FFEL@Lundbeck.com]
Sent: mercredi 7 mai 2008 14:39
To: ENTR PHARMACEUTICALS COUNTERFEIT
Subject: Contribution to public consultation in preparation of a legal proposal to combat counterfeit medicines for human use

Der Sirs,
Lundbeck Pharmaceuticals Italy S.p.A. (acronym LUPI) was founded in 1929 with the name of "VIS Farmaceutici SpA".
LUPI is an independent business unit owned by the Danish pharmaceutical group H. Lundbeck A/S. Offices, laboratories and production plants are located in the industrial area of Padova. The total turnover in 2007 was more than 22 Million Euro with around 120 employees.
Main activities are:
- Contract manufacturing activity of New Chemical Entities.
- From laboratory to industrial scale production of APIs and Intermediates for the pharmaceutical industry. LUPI is also actively involved in the supply chain of H. Lundbeck A/S.
The company is regularly, successfully inspected by AIFA, US FDA (since 1972), Japanese Ministry of Health and other international authorities.

LUPI firmly believes that a strict control on APIs should be considered mandatory and absolutely necessary for assuring quality of medicines in order to guarantee a proper surveillance on European citizens' health. It is not acceptable that some of APIs manufacturers are regularly inspected by Health Authorities while others can sell their APIs without any inspection, often supported by the Certificate of Suitability to the European Pharmacopoeia, that do not provide any inspection as well.

Therefore, sharing the European Commission's concerns in relation to the introduction into the European market of APIs which are not proved to be in compliance with cGMP standard applied in the Community (i.e. ICHQ7A), LUPI strongly supports the proposal for the preparation of an EC Directive that rules the matter and considers as mandatory:
- Regular inspections by European Health Authorities on all production sites that exports APIs into the European Union.
- Traceability of the APIs with the clear intent to locate the real source of them To be noted that the Written Declaration on active pharmaceutical ingredients, approved by the European Parliament on November 30, 2006, already contains similar rules, that could avoid introduction of counterfeit medicines in the EU, but, after 17 months, nothing has been yet translated into any directive.

Giulio Volpe
Operations Director
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