From: Russolo, Paolo [Paolo.Russolo@cambrex.com]

Sent: mardi 6 mai 2008 16:50

To: ENTR PHARMACEUTICALS COUNTERFEIT

Subject: 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.

Dear Sirs,

Cambrex Profarmaco Milano (CPM) is the Italian subsidiary of the multinational group Cambrex, listed in the New York Stock Exchange.
Cambrex provides products and services to accelerate the development and commercialization of small molecule APIs, advanced intermediates and other products for branded and generic pharmaceuticals. The Company currently employs approximately 850 people worldwide.
Its Italian subsidiary manufactures Active Pharmaceuticals Ingredients (APIs) since 1946 and it is recognized worldwide as one of the most serious and reliable companies in the field.
CPM firmly believes that the way pharmaceutical companies purchase APIs to be used in human medicines has to be harmonized worldwide with the most possible strict rules. The APIs are the ingredients that perform the terapeutic action on the patients and it is not acceptable that patients are not aware of the nature and the origin of the medicines.
There are APIs manufacturers 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.
The concern of the European Commission on APIs coming into the market without verification of GMPs standard is fully justified and cannot be eliminated if not establishing new rules that
a) impose mandatory inspections by European Health Authorities to all the APIs manufacturers that want to sell their products into the European Union
b) assure the traceability of the API available to the patient.
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.

Milano, May 6, 2008