From: emilio buscaini [ebuscaini@yahoo.it]

Sent: mardi 6 mai 2008 11:27

To: ENTR PHARMACEUTICALS COUNTERFEIT

Subject: Public consultation in preparationof a legal proposal to combat counterfeit medicines for human use – Key ideas for better protection of patients against the risk of counterfeit

I undersigned Emilio Buscaini shares the European Commission's concerns related to the introduction into the market of APIs, especially coming from extra-EU countries, that can harm the human health, as not in compliance with the quality GMPs standard, applied in the Community (i.e. ICHQ7A).. At present such situations are more and more likely for lacking of the necessary controls.
Therefore I suggest to prepare a legislation, at Community level (that means Directive), which rules the matter. In this way I ask to consider what it's requested with 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)(for example: through the indication on the medicinal packaging of the name of the manufacture of the active ingredient

Emilio Buscaini