



Boehringer Ingelheim
Bidachem

Bidachem S.p.A.

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The Company Bidachem S.p.A., a Boehringer Ingelheim GmbH affiliated, which has been fighting against counterfeit medicines for human use for years, 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, likely for lacking of the necessary controls.

Therefore the company Bidachem suggests to prepare a legislation, at Community level (that means Directive), which rules the matter.

In this way the company Bidachem asks 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).

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