From: Giovanna.Tromby@sicor.it

Sent: jeudi 8 mai 2008 19:12

To: ENTR PHARMACEUTICALS COUNTERFEIT

Subject: Public consultation in preparation of a legal proposal to combat counterfeit medicines for human use

With API production facilities throughout Italy, TEVA PFC S.r.l. and Sicor S.r.l. sell to pharmaceutical companies throughout the world APIs of various classes used for oral, respiratory and injectable therapeutic products.

TEVA PFC S.r.l. and Sicor S.r.l. agree with the concerns of the European Commission and the European Parliament about the increasing threat to public health and safety arising from the counterfeiting of medicinal products.

Tightening requirements for manufacture, placing on the market of active substances are essential parts of the comprehensive strategy for combating such counterfeiting.

In particular, we agree with concerns of the European Commission about the introduction into the market of APIs coming from countries, where the compliance to cGMP quality standards is not verified by a "trustable" regulatory authority. It must be recognized that there can be significant potential risks for human health in case of a self-certified, but not verified "on site" compliance to the requested quality standards (i.e. ICH Q7a).

TEVA PFC S.r.l. and Sicor S.r.l. therefore recommend that legislation be enacted, at Community level, to fully addess these concerns.

In this sense, TEVA PFC S.r.l. and Sicor S.r.l. ask that the Written Declaration on active pharmaceutical ingredients, approved on November 30th 2006 by European Parliament, will be taken into consideration - with the below modification:.

 Mandatory inspections carried out by an European regulatory authority or US FDA , will be considered valid for the purpose of GMP certificate

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