FUEHRING Stefan (ENTR)

From: Jim Whittle [jwhittle@NANOINK.net]
Sent: mardi 18 mars 2008 17:02
To: ENTR PHARMACEUTICALS COUNTERFEIT
Subject: RE: NanoInk Response to EU's request for Public Consultation (Below)

Dear Directorate-General,

I applaud the EU's effort to launch a concerted effort to combat counterfeit drugs and problems created by parallel trade activities. However any security measure or tracking feature that is applied at the package level only, will continue to leave the EU at risk of allowing dangerous medicines to be distributed to patients. The stakes are high for the criminal elements that make a living substituting medicines without active ingredient (or with the wrong levels of active ingredient), or who play the illegal diversion arbitrage game of moving medicines from lower value markets to higher value markets. Certainly the repackaging of products will defeat 'package' level security measures. And RFID or 2 D bar coding with mass serialization is really only a first level of defense and more of a supply chain efficiency measure, and not an adequate anti-counterfeiting measure. What the EU needs is protection down to the individual dosage level: down to the tablet, down to the capsule and down to the vial. In this way individual dosages could be authenticated regardless or repackaging, or how they move from country to country. Insisting on pharmaceutical product protection that extends from the package (where it is relatively easy fake) down to the individual dosage, is the surest approach to securing the EU's supply chain, and ultimately the patients who rely on pharmaceutical products to maintain their health. My company, NanoInk has a unique technology that protects from plant to patient called Nanoencryption™ technology. You can read more about this technology in our website at www.nanoink.net. We are working with all of the global pharmaceutical companies to launch this technology into the supply chain.

With regards,

Jim Whittle
Vice President, Business Development
NanoInk, Inc.
312-286-4346 (C)
847-745-3623 (O)
847-679-8767 (F)
jwhittle@nanoink.net

www.nanoink.net

http://www.pharmatimes.com/WorldNews/article.aspx?id=13080

EU launches public consultation on counterfeit drugs

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The European Commission has launched a public consultation on the dangers of counterfeit drugs, and is asking all stakeholders and interested parties to submit key ideas for regulatory reform by May 9.

Counterfeit medicines have become an increasing threat for patients, healthcare professionals and the industry, and a concern for European Union and national policymakers, says the Commission. In particular, it notes the following "worrying" trends: a sharp increase in seized fake medicines at EU customs borders; the counterfeiting of life-saving drugs; targeting by counterfeiters of the "classical" supply chain; and a "blurred line" between counterfeit and substandard active substances in medicines.

This growing problem may have been facilitated by deficiencies in supply chain integrity, says the Commission, noting that

there is “uncertainty as to whether certain participants in the distribution chain (eg, brokers, traders, business-to-business platforms) are subject to pharmaceutical legislation.' It also cites: a lack of transparency as to whether wholesalers and others in the distribution chain comply with Good Distribution Practice (GDP); shortcomings in product integrity, especially when packs are opened for repackaging and changed for relabeling purposes; difficulties in conducting targeted recalls, especially for counterfeits; legal uncertainty and differing practices between EU member states concerning the application of legislation to “imports for the purpose of export;” and the fact that active substances may not be manufacturing in compliance with Good Manufacturing Practice (GMP) standards, at declared sites and in accordance with declared procedures.

In addition, member states are starting to consider taking unilateral actions to address these problems, and while the Commission acknowledges that these are motivated by justifiable concerns, it warns that they may create issues of compatibility with EU internal market rules. These varying approaches may also lead to different levels of protection for public health and safety, it adds, and cautions: “indirectly, this kind of way forward could encourage counterfeiters to target member states with lower levels of protection of the legal distribution chain.” Therefore, “the EU must act firmly.”

The EU’s plans to prioritise and speed up moves to tackle counterfeits were first announced in January, when Commission Vice President Guenter Verheugen told Parliament that the initial findings of a study into drug distribution had shown that parallel imports pose a “considerable” risk for patient safety for “numerous” reasons.

The consultation - to be conducted by the Commission’s Directorate-General (DG) Enterprise and Industry, which is headed by Commissioner Verheugen and has responsibility for the pharmaceutical industry - will focus on the manufacture and marketing of active substances and finished medicines, plus related inspections, and on the import, export and transhipment of drugs. Improvements to the regulatory framework in these areas could make a “real contribution” to protecting patients, it says.

As a result of the Commission’s concerns, there has been a major change to the DG’s work programme, and it plans to introduce legislative proposals after the summer break.

Positive reponse
The European Federation of Pharmaceutical Industries and Associations (EFPIA) welcomed the consultation, pointing out that the Commission’s findings corroborate its own evidence on prevalence of counterfeits, including the increasing penetration in the EU legitimate supply chain.

As long as repackaging and breaking of seals in the distribution chain is allowed, patient safety will be highly at risk, says the EFPIA, which is calling for: a ban on repackaging; clearly defined liabilities for all involved in the distribution chain (including brokers, traders and agents); stricter auditing rules and controls of the supply chain; and penalties for trafficking in counterfeits.

The industry is investing in anti-counterfeiting technologies to enhance product security, and the EFPIA plans to launch a pilot project in the area of mass serialization (2D barcoding system) towards the end of this year, it adds.

DG Enterprise and Industry is calling for responses to the consultation to be sent by e-mail to entr-pharmaceuticals-counterfeit@ec.europa.eu by 9 May 2008
By Lynne Taylor