EUROPABIO
The European Association for Bioindustries

European Commission
Counterfeit Medicines for Human Use Consultation
B232 8/102
B-1049 Brussels
Belgium

13 May 2008

Re: PUBLIC CONSULTATION IN PREPARATION OF A LEGAL PROPOSAL TO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE

To whom it may concern

Thank you very much for the opportunity to input into the above consultation.

EuropaBio is the European Association for Bioindustries, solely and uniquely bringing together bioscience companies from all fields of research and development, testing, manufacturing and distribution of biotechnology products. It has 84 corporate members operating worldwide, 8 associate members, 6 BioRegions and 25 national biotechnology associations representing some 1800 small and medium sized enterprises involved in research. Its mission is to promote an innovative and dynamic biotechnology-based industry in Europe.

Healthcare biotechnology, in particular, is already having a tremendous impact on our lives, and biotech therapies will continue to represent the state-of-the-art evolution of science as applied to human medicine. They present novel approaches to patient disease management, and the technology itself is providing us with a better understanding on the course and mechanisms of disease. Innovative European biotechnology companies are now defining diseases at a molecular level, distinguishing between different disease states, and connecting genomics-identified targets with particular disease pathologies.

As such, we take the issue of counterfeit drugs very seriously and we therefore applaud the efforts of the Commission to increase the protection of patients from the acts of criminals and others that would attempt to insert counterfeit or substandard products into the medicine supply. Counterfeit biologics may be extremely difficult to detect before they do damage Most often these medicines are administered as injections. They have the appearance of either a clear or white liquid or powder. Oft times, the patient does not see the medicine and cannot perceive the taste – a sensation which has led to the detection of other counterfeit medicines in the past.

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Another element is that biologics may be administered to healthy individuals as a preventative measure such as a flu vaccine and as a consequence, the effects of the product are not immediately apparent. A counterfeiter can substitute the product by sterile water knowing that his actions will not be detected for months since any given patient may or may not develop the flu. Such biologics, in particular vaccinations, are often given to a large number of persons at one event increasing the potential for a catastrophic event. For example, from 100 up to 200 persons could be inoculated at a school or a nursing home. So the potential impact of a counterfeit biologic is magnified as a large number of multiple adverse reactions would result from one incident.

Every counterfeit biologics incident is significant because the probability of a counterfeiter successfully creating a biologic with any therapeutic value is remote and virtually non-existent, because manufacturing biologics is a complex, exacting procedure as is also seen from the debate on biosimilars. Incident data suggest that the most common illegal schemes involved the following practices:

- Recycling of expired products by altering the expiry date;
- Refilling discarded vials recovered from hospitals and/or clinics;
- Up-labeling low dose medicines to high dose versions, or
- Purchasing stolen and illegally diverted biologics.

We suggest that any measures against counterfeit medicines take these practices into account with the aim to eliminate or minimize them.

Based on the above, we specifically, we would suggest that sealing the outer packaging of a medicine and ensuring that there is no intrusion into, or over-packaging or repackaging of, its contents is an essential element in preventing a range of counterfeiting attacks. While EuropaBio believes that this approach should be legally required for all medicines, we think it is imperative in the case of injectable biological medicines. Additionally, we support the ultimate adoption of a "sealed and serialized" approach based on the use of legally protected sealing of outer packaging to ensure the physical integrity of the packaged medicine, and serialization of the package to ensure the source and authenticity of the packaged product.

We would also strongly recommend putting strict controls on Internet Pharmacies, and checking for the above issues.

Of course, there are a number of other important measures that are needed to further ensure the safety of medicines from counterfeiters. We see that the Commission has identified a number of these and we support their adoption, together with certain additional steps that were not raised in the Consultation document, which are set out below.

EuropaBio Supports the Use of Legally Protected Tamper-evident Security Seals on the Outer Packaging of Medicines (Section 4.1.3)

By adopting legislation that prohibits the intrusion or obscuring of this feature, sealed products would be better protected in two ways. First, medicines would be protected against counterfeiting by helping to ensure that the security features remain visible and that tampered product is not substituted for genuine. Second the quality is protected, by discouraging opening of Dispensing Packs and exposure of vials and syringes of medicine to excessive heat and vibration as they are over-label or repackaged.

We therefore endorse the proposed key ideas listed under Section 4.1.3 and believe that any legislation should specifically prohibit repackaging, over-boxing and intrusive over-labeling of biological and other medicinal products.

EuropaBio supports the Serialization of Seal Packs of Biological Medicines according to Harmonized International Standards (Section 4.1.5)

We endorse the ultimate adoption of a "sealed and serialized" approach to protecting biological medicines based on legally protected sealed outer packages that are serialized to ensure the source and authenticity of the packaged product.

Section 4.1.5 of the Consultation document seeks comments on mass serialization for pack-tracing and authenticity checks. EuropaBio believes that any EC legislation on this topic should harmonize internationally and especially with ongoing US efforts. However, the technical solutions to achieve these means need to be adapted to the type of products and take into account the limitations with respect to their implementation in the special context of SMEs.

Specifically, the US Food and Drug Administration is also currently seeking input into the use of serialization to protect medicines.[1] Its authorizing legislation instructs the Agency to develop "numerical identifiers (which, to the extent practicable, shall be harmonized with the international consensus standards for such an identifier)."

At present, the basic approaches being developed by the two jurisdictions are different:

- Europe appears more committed to pursuing an end-to-end authentication approach that involves manufacturers serializing individual packs, and pharmacies verifying the pack numbers at the point of dispensing;

[1] "Technologies for Prescription Drug Identification, Validation, Track and Trace, or Authentication; Request for Information," Docket No. FDA-2008-N-0121 (http://www.fda.gov/OHRMS/DOCKETS/98fr/E8-5599.htm); and "Standards for Standardized Numerical Identifiers, Validation, Track and Trace, and Authentication for Prescription Drugs; Request for Comments," Docket No. FDA-2008-N-0120 (http://www.fda.gov/OHRMS/DOCKETS/98fr/E8-5597.htm).

- The US may be more committed to a full track and trace (or pedigree) model, where the manufacturer applies the unique serial number and the product's chain of custody is verified and recorded at each step in its distribution.

Respecting these potential differences, we support strengthening product identification at individual pack level through serialization of products using a unique identification number, established at the point of manufacture, contained within a standardized non-proprietary data format and architecture (e.g., according to the GS1 standards). To the maximum extent possible coding legislation should be harmonized.

Finally, biological medicines are extremely vulnerable to environmental degradation. The proper handling of biologics is critical to their efficacy and retention of therapeutic properties. In many incidents of illegal diversion, the biologics are shipped around the world with little care or understanding of the impact that the multiple temperature changes at different destinations have on the medicine.

We suggest that measures are being put in place to follow up and control the correct handling of biologics.

General Comments in Support of Public Consultation

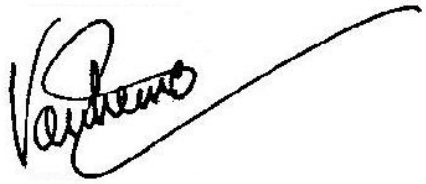
Broadly speaking EuropaBio supports the Commission's approach and the set of measures proposed to address the problems related to counterfeit medicines in Europe. We join in support of the comments filed by the European Federation of Pharmaceutical Industry Associations (EFPIA).

We would also like to stress that the proposed measures should be considered as whole rather than individually or 'a la carte'. The proposed set of key ideas should be considered as part of a comprehensive strategy focused on ensuring that only the safest products reach the patient by strengthening the integrity of the supply chain and by adopting a number of additional, complementary measures in order to address the different aspects of this serious criminal activity

Other controls the Commission should consider include the following: increased criminal sanctions, limiting sales of counterfeits over the internet and enhanced law enforcement.

Thank you very much again for the opportunity to comment, and we look forward to being involved in the next stages of this process.

Yours sincerely



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