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May 9, 2008

European Commission
Enterprise and Industry Directorate-General
Consumer Goods, Pharmaceuticals
Brussels, Belgium

Re: "Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use: Key Ideas for Better Protection of Patients against the Risk of Counterfeit Medicines"

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the European Commission for the opportunity to submit comments on *Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use: Key Ideas for Better Protection of Patients against the Risk of Counterfeit Medicines*. BIO and its member companies work closely with international regulatory bodies to ensure that the biopharmaceutical supply is safe, secure, and reliable, and that patients can be confident that when they use an approved prescription drugs, the medicine will be safe and effective and work as intended. In light of the unique nature of biologic medicines, BIO supports the efforts of the Commission to further secure the biopharmaceutical supply chain, in a manner that does not inadvertently impede the free flow of legitimate medicines, through the use of sealed tamper resistant packaging and internationally harmonized serialization of sealed packs.

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology technologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

BIO members are committed to making the biopharmaceutical distribution system the most secure in the world and thanks to the ongoing efforts of international legislative bodies, regulators, drug manufacturers, and distributors, patients can continue to have high confidence that the drugs they are prescribed are safe and efficacious. Nevertheless, the presence of any amount of fake, adulterated, sub-potent, or super-potent drugs in the biopharmaceutical distribution system poses a threat to the public health. The actual prevalence of criminal counterfeiting is difficult to quantify, but the World Health Organization estimates that less than 1% of sales in developed countries and more than 10% in developing countries are counterfeit or adulterated. Biopharmaceutical manufacturers currently deploy a wide variety of sophisticated, multilayered anti-counterfeiting strategies, but also recognize that there are additional ongoing steps that can be taken to further secure the supply chain and enhance inventory management.

BIOLOGICS OFTEN REQUIRE UNIQUE CARE AND HANDLING:

While counterfeiting any type of pharmaceutical product can pose a serious threat to the public health, BIO feels biotechnology-based medicines, such as recombinant proteins, need special attention when it comes to designing anti-counterfeiting measures, for a number of reasons. For example biotechnology medicines typically treat serious, often life threatening diseases and there may be fatal consequences for patients that receive a counterfeit copy and receive no therapeutic benefit. Often biotechnology medicines are of high value, and therefore may be a particularly attractive target for criminal counterfeiters. Additionally, many biologics are sensitive to potential degradation if not properly handled and must be maintained in a cold chain environment. Finally, biologics are generally clear liquid injectables, making it virtually impossible to determine whether the active ingredient is present or whether the product may be contaminated. The product's identity is assured primarily by the delivery devices and packaging materials, making the protection of these features all the more essential for patient safety.

To prevent a range of counterfeiting attacks, BIO believes it is important to seal the outer packaging of a medicine and ensure that there is no intrusion into, over-packaging or repackaging of its contents. While BIO believes that this approach should be legally protected for all medicines, we think it is imperative in the case of injectable biological medicines. Additionally, we support the ultimate adoption of serialization of the package based on international consensus standards to ensure the source and authenticity of the packaged product.

TAMPER EVIDENT SECURITY SEALS WILL ENHANCE PATIENT SAFETY:

BIO supports the proposed legislative provision (Sect. 4.1.3) to establish a unique seal from the manufacturer to the retailer or wholesaler, using a risk-based approach, supported by a ban on repackaging. This approach offers several advantages with regards to biologics. First, legal protection of sealed biologics packaging would protect patients by helping to ensure that the security features remain visible and that counterfeit or

tampered products are not substituted in the packaging. Secondly, the quality of the biologic product would be protected by discouraging to opening of packages in the supply chain thereby exposing vials and syringes to potential degradation from environmental exposures. Therefore, any proposed legislation should specifically prohibit repackaging, over-boxing and intrusive over-labeling of biologics. However, certain exemptions may be necessary during clinical testing when a product may be re-packaged and de-identified to ensure proper blinding during the trial.

SEAL PACKS OF BIOLOGICAL MEDICINES SHOULD BE SERIALIZED CONSISTENT WITH INTERNATIONAL STANDARDS:

Product serialization is a promising approach to help authenticate the identity of biologics and other prescription drug products and BIO is supportive of a "sealed and serialized" approach which would legally protect sealed outer packages of serialized products to ensure their identity and authenticity. BIO believes that is important to affirm the need to ban repackaging and guarantee product integrity before serialization can be successfully introduced.

As the EC explores options for product serialization (Section 4.1.5), BIO encourages the Commission to work with other international regulatory bodies wherever possible and appropriate to encourage the international harmonization of serialization standards. BIO member companies conduct business in the global marketplace and recognize that counterfeiting and criminal tampering is a global problem, and as such, should be addressed from both a regional and international perspective. BIO believes that any legislation on this topic should attempt to harmonize internationally, and especially with ongoing U.S. efforts. The U.S. Food and Drug Administration is also currently soliciting comment on serialization standards and has been directed by authorizing legislation to develop a serialization standard "which, to the extent practicable, shall be harmonized with the international consensus standards."

BIO is concerned that the approaches being developed in Europe and in the U.S. are diverging. For example, Europe appears to be pursuing an end-to-end authentication approach that involves manufacturers serializing individual packs, and pharmacies verifying the pack numbers at the point of dispensing. The U.S., on the other hand, 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, BIO supports strengthening product identification at individual pack level through risk-based serialization of products using a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture (e.g., according to the GS1 standards). To the maximum extent possible, coding should be harmonized across the EU and also with the U.S. and other counties, to optimize interoperability between regions.

THE EC PROPOSALS COMPRISE AN IMPORTANT PART OF A COMPREHENSIVE RESPONSE TO CRIMINAL COUNTERFEITING:

In general, BIO supports the Commission's approach and the set of measures proposed to address the problems of criminal counterfeiting, tampering, and diversion in Europe. BIO also expresses support for the comments filed by the European Federation of Pharmaceutical Industry Associations (EFPIA). We also stress that the Commission and member states should pursue a robust and comprehensive anti-counterfeiting strategy rather than implementing these proposals provisions on a partial basis. The EC proposals should be viewed as a significant element of a larger, comprehensive strategy aimed at strengthening the integrity of the supply chain to ensure that patients receive safe, secure, and reliable biopharmaceuticals. For example, continuing to incorporate risked-based principles into the EC's statutory scheme for inspections, auditing, and certification will serve to ensure that enforcement resources are directed to those areas where they are most productive. Other complementary steps can also be taken to reduce counterfeiting, including increased criminal sanctions, limiting sales of counterfeits over the internet and enhanced law enforcement.

CONCLUSION:

BIO appreciates this opportunity to comment on the *Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use: Key Ideas for Better Protection of Patients against the Risk of Counterfeit Medicines*. BIO applauds the efforts of the Commission to increase the protection of patients from the acts of criminals and others that attempt to introduce counterfeit or adulterated products into the medicine supply. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
Director for Science and Regulatory Affairs
Biotechnology Industry Organization