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PhRMA

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Sabine Atzor
European Commission
Enterprise and Industry DG
Pharmaceuticals Unit
European Commission, BREY 10/069
B - 1049 Bruxelles

Dear Ms. Atzor,

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is pleased to comment on the consultation document *Key Ideas for Better Protection of Patients Against the Risk of Counterfeit Medicines*.

PhRMA is the principal trade association for the innovative pharmaceutical industry in the United States. In 2007, PhRMA member companies invested an estimated $44.5 billion in discovering and developing new medicines. Patients and their health care providers quite reasonably expect these medicines to safely and effectively treat the diagnosed medical condition. Most, if not all, of our members are also active in Europe and they are directly affected by the increasing availability of counterfeit medicines.

Counterfeiting of medicines presents a serious risk for patients and public health. PhRMA and its members are committed to be active participants in addressing counterfeit medicines and the threat to public health and safety they pose. We fully support the aim of the Commission and agree that there is an urgent need to prevent as much as possible any counterfeiting of medicines. We would like to specifically highlight the following elements and also include some additional suggestions:

- Improving product integrity through a unique seal that remains visible at all times will provide a major deterrent to the introduction of counterfeit products (and other products that have been tampered with) from successfully entering the normal distribution chain.

  The unique, visible seal could be applied by the original marketing authorisation holder (and entities instructed by it) and only the original marketing authorisation holder (and entities instructed by it) and the final user (patient and healthcare professional) would be entitled to open the package and break the seal.

  PhRMA thus actively supports the proposed key ideas listed under section 4.1.3 of the consultation document and believes that the legislation should prohibit any acts involving opening the packaging during the distribution chain, including the

repackaging and intrusive over-labelling of products. In addition, over-boxing would also undermine the informative value of the original seal, which would be covered by an additional outside packaging.

- Experience has shown that the more stops in a product's distribution chain, the more opportunities exist for counterfeit products to be inserted into the system. The public consultation acknowledges that "counterfeiters seem to veil the source of the product by selecting highly complicated distribution concepts". One effective way of reducing the risk of counterfeits is thus to, as the public consultation notes, to subject all parties in the distribution chain to pharmaceutical legislation.

  Original marketing authorisation holders should also have flexibility to independently structure their distribution arrangements as they consider most appropriate, taking into account, amongst others, the need to minimize the risks that counterfeit goods will enter the legitimate distribution chain.

- A clearer and stricter application of the rules governing wholesale licenses will contribute to more effective control of the distribution chain. It will help ensure that dealers, brokers and agents marketing products through business-to-business platforms, are regulated. However, in establishing the rules, special attention should be given to situations where there is a separation between the physical flow of the goods and the title (ownership) flow through entities that belong to the same corporate group. Such separation is routine practice in all industries, including the pharmaceutical industry, and there may in those cases normally be no need to impose additional regulatory burdens that go beyond what is required.

- Criminal sanctions and prosecution should be increased with regards to counterfeiting medicines. The European Court of Justice has recognised (in *Commission v Council* Case C-176/03 and *Commission v Council* Case C-440/05) that Community law can require Member States to impose criminal penalties "when the application of effective, proportionate and dissuasive criminal penalties by the competent national authorities is an essential measure for combating serious … offences." This is only exceptionally needed, but counterfeiting in the pharmaceutical sector is a problem that requires a strict and well harmonised approach throughout the entire Community, especially in light of the serious risks to patients and the practical problems in bringing perpetrators to justice purely on a national basis. Common standards for criminal sanctions and prosecution should be laid down in Community rules to provide an effective protection.

- Increased inspections and audits, especially of distributors, can also play a useful role in combating counterfeiting. It should, however, be clear that audits by others than public authorities should only be possible with the agreement of the entity

that is audited. This is necessary to protect the commercial independence and general business confidentiality.

- Mass serialisation of medicines, allowing the tracking of individual packages, would increase transparency of the distribution chain. It would, however, constitute a major change and would require significant technological advances. Any technologies used for serialisation must be readable and useable for all entities in the distribution system and at the stage of final use or dispensing. This presents logistical challenges throughout the chain, but especially for the final stage of dispensing, where each Member State operates its own rules that are also intrinsically linked with the system for reimbursement of products, and these rules may be in conflict. Finally, any system ultimately selected could, in practice, not be easily changed in the future.

  If serialisation is considered useful, it should only be decided after a very careful analysis of the impacts and especially of the benefits and disadvantages. This will require significant time and it is better to first adopt the other measures against counterfeits.

The proposed measures should be considered as a 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.

We hope that these comments will be useful to you and remain available to discuss them in more detail.

Sincerely,

Brian C. Toohey
Vice President, International Affairs
Pharmaceutical Research and
Manufacturers of America (PhRMA)