Response to the EC consultation on counterfeit medicines for human use: Key ideas for better protection of patients against the risk of counterfeit medicines

Joint Submission by the Irish Pharmaceutical Healthcare Association (IPHA) and PharmaChemical Ireland (PCI)

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Introduction

The **Irish Pharmaceutical Healthcare Association (IPHA)** and **PharmaChemical Ireland (PCI)**, the bodies which together represent the various substantial interests of the pharmaceutical and chemical sectors in Ireland, welcome the European Commission's legal proposal to combat counterfeit medicines for human use.

Ireland is the largest net exporter of pharmaceuticals in the world.[1] In 2007, pharmaceutical and chemical exports valued at €42.7 billion making up almost half of all Irish exports.[2] One hundred and twenty pharmaceutical and chemical companies have operations in Ireland, including fourteen of the top fifteen worldwide. Twelve of the world's top 25 medicines are manufactured in Ireland.[3] IDA Ireland, Ireland's foreign direct investment authority, has estimated that the replacement value of the investment by the sector in the Irish economy exceeds €40 billion.

We believe that patients have a legitimate need for, and right to, high quality, safe medicinal products. However, decisive and urgent action is required to enhance medicinal product security and protect European patients.

We welcome the prospect of new legislation however we strongly advocate more stringent enforcement globally of existing regulations. We believe that such stricter enforcement, if coupled with severe penalties for offenders, would significantly reduce the risk posed by the increasingly global nature of trade. Presently, there is little or no deterrent to ensure at least a reasonable level of compliance thus increasing the risk of counterfeit medicines reaching the EU market. The protection of EU citizens must be ensured by adequate EU-based systems of oversight and enforcement throughout the supply chain. The recent heparin case (the FDA has reported 62 heparin related deaths in the USA since 2007) all too clearly demonstrates the catastrophic consequences when counterfeit medicines enter the supply chain.

The three central objectives of any legislative proposal should be:

Health & Safety - Protection of the health and safety of EU citizens;

Competitiveness - Ensuring the competitiveness of the EU manufacturing sector by removing illegal players from the supply chain;

Security of supply - Guaranteeing European wide security of supply at a time of crisis.

In order to maximise the security of the global supply chain there is a need for an improved harmonised regulatory framework, in addition to increased enforcement - we fully support the following statement in the legal proposal:

> *"Any legislative measure needs to be complemented by appropriate supervision and enforcement. Any legislation can only be fully effective if it is thoroughly enforced by the competent authorities of the member states"*

We support an increase in the number of "*risk based"* (deploying resources to areas of high concern where counterfeiting has been detected or a strong suspicion thereof exists) inspections. Areas in which lower GMP standards have been identified should be prioritised by inspectorates, as lower standards are not alone putting EU citizens at risk but also creating an uneven playing field for EU manufacturers (through financially penalising those in GMP compliance) and adversely impacting on EU competitiveness.

The only way to combat this is through increased GMP inspections in third countries both scheduled and unannounced.

The objective of policy should be to prevent counterfeit medicines from entering the EU market. In order to do this it is necessary to define a "*counterfeit medicine"*. We support the following definition:

> *"A counterfeit API is one for which the source and/or quality are falsely represented on the label, on the Certificate of Analysis or otherwise. A medicine that contains a counterfeit API is a counterfeit medicine"*[4]

<u>Technology to ensure pack integrity</u>

The focus of the legislative reform should be to ensure that the integrity of original package is guaranteed along the entire supply chain, from the point where it leaves the original manufacturer to its receipt by the end user.

We support the proposed measure in section 4.1.3 requiring the use of tamper-evident packaging. However, this should be applicable to every prescription pharmaceutical product

rather than only those identified via a risk-based system. Additionally, the use of overt and covert authentication features should be specific to each manufacturer (in order to reduce risk of copy) rather than having universal features.

We support strengthening product identification at individual pack level as proposed in section 4.1.5. However, this would be best achieved by implementing an end to end product verification system for each individual unit at the point of dispensation (i.e. pharmacy) rather than a full track and trace system such as a pedigree. To this end we support the European Federation of Pharmaceutical Industries and Associations (EFPIA)'s proposal to harmonise pharmaceutical coding and identification systems in Europe around the existing GS1 open standard[5] and the use of the Data Matrix code ECC200 as described in EFPIA's previous submission to the European Commission titled '*Towards safer medicines supply - A vision for the coding and identification of pharmaceutical products in Europe".* Such harmonisation of the coding rules across Europe is essential to guarantee a safe supply chain.

Strengthening the integrity of the supply chain

We support the ban on repackaging as proposed in section 4.1.3. If products are repackaged, any anti-counterfeit features incorporated into the original packaging are rendered ineffective. This makes it more difficult to detect counterfeits. The ban on repackaging should help address the fact that sub-standard medicines are found in the (parallel) supply chain not only in counterfeit products.

We also support auditing of the supply chain as proposed in section 4.1.1. While basic regulations to prevent parallel traders from causing safety problems exist, these need to be more strictly enforced.

Additionally criminal sanctions should be introduced to act as a deterrent against the crime of counterfeiting medicines.

The current system of GMP (Good Manufacturing Practices) audits should be extended to GDP (Good Distribution Practice) audits, as well as to the entire supply chain to assure that measures taken with respect to product protection, packaging practices and distribution practices are properly used and followed.

Conclusion

In conclusion we would emphasise the following points:

- A more tightly controlled and shorter distribution chain will reduce the risk of interception by counterfeiters. A ban on repackaging, the proper enforcement of legislation and the introduction of severe penalties will act as a significant deterrent.

- Counterfeiting not only directly affects patient health it also reduces patients confidence in medicines as a whole. This can have a negative effect on population health.

- A tightened regulatory framework, greater enforcement and enhanced international cooperation combined with improved awareness are needed to combat the risks of counterfeit medicines.

- We commend the Commission's commitment to international cooperation. It is a global problem and therefore requires a global solution. Regulation needs to be enforced throughout the global supply chain.

- We strongly advocate prioritising global risk-based inspections of API manufacturers and the introduction of a licensing system for traders and brokers.

- We also support adequately resourcing Customs through the provision of an IT system to help prevent the movement of counterfeit medicines.

PharmaChemical Ireland and the **Irish Pharmaceutical Healthcare Association** welcome the opportunity to comment on the Commission initiative to combat the provision of counterfeit medicines for human use and believe that the elements highlighted above could contribute to identifying and eliminating the factors facilitating the increase in counterfeiting.

[1] IPHA Healthcare Facts and Figures 2008
[2] Central Statistics Office data
[3] IDA Ireland data
[4] European Federation of Pharmaceutical Industries and Associations (EFPIA)
[5] http://www.gs1.org