Counterfeit Medicines

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The counterfeiting of medicinal products is a growing concern for patients, the pharmaceutical industry and national policy-makers worldwide. EU internal market rules for medicinal products for human use coupled by wide-ranging International cooperation, and proposed European legislative reforms are hoped to have a positive impact against the problem of counterfeit medicines – one of the greatest current threats to public health and safety.

The WHO defines counterfeit medicines as "medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source".[1] Since the first international initiative that addressed the problem of counterfeit medicines at the Conference of Experts on the Rational Use of Drugs in Nairobi in 1985, the worldwide import and export of counterfeit medicines has become a highly sophisticated criminal enterprise and a major public health concern. The astronomical 118% increase in the number of medicinal products detained by customs authorities in 2008 makes medicines the third largest specific product category in terms of quantities of intercepted counterfeit articles.[2] This increase in customs discovery was largely due to the EU coordinated 'MEDI-FAKE' action which targeted customs control of counterfeit medicines over a two-month period in 2008 and led to the seizure of 34 million tablets, including antibiotics, antineoplastic, anti-malaria and lipid-regulating medicines, as well as painkillers,and drug precursors. This by far exceeded any previous results.[3]

This growing global problem is being counteracted by international endeavours of the WHO and the pharmaceutical industry, and through European legislative reforms. In 2006 the WHO launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) which is a partnership comprising several stakeholders including international non-governmental organizations, regulatory authorities, enforcement agencies and pharmaceutical manufacturers associations. Furthermore, the European Directorate for the Quality of Medicines and Health care of The Council of Europe has set up a Committee of Experts aimed at minimizing the public health risk posed by counterfeit medicinal products and related crimes; whilst the US Food and Drug Administration (FDA) launched its Counterfeit Drug Task Force in July 2003 to receive proposals from security experts, Federal and State law enforcement officials, technology developers, manufacturers, wholesalers, retailers, consumer groups, and the general public, in order to help deter counterfeit medicines. The European Medicines Agency (EMEA) also collaborates with member states in combating counterfeit medicinal products and has recently issued a warning about counterfeit medicines for the treatment of H1N1 influenza being sold over theinternet.[4]

Directive 2001/83/EC on medicinal products for human use, as amended[5] includes provisions for manufacturing, importation, placing on the market, and wholesale distribution of medicinal products in the Community, as well as rules relating to active pharmaceutical ingredients used as starting materials. The Commission's proposal to amend this Directive[6] aims to further optimise the functioning of the internal market for medicinal products while ensuring a high level of protection of public health in the EU.

The proposed amendments include:

- Obligations for stakeholders, acting in the distribution chain and involved in the transactions but who do not actually handle the products;
- A legal basis for the Commission to introduce obligatory safety-features (such as a serialisation number or a seal) on the packaging of prescription medicines;
- Prohibition of manipulating (i.e. removing and tampering with the packaging, or over-labelling) safety features on the packaging by intermediaries between the original manufacturer and the last stakeholder in the distribution chain (pharmacist/doctor/patient);
- Obligatory audits of supplying wholesale distributors in order to ensure reliability of business partners;
- Strengthened requirements for the importation of active pharmaceutical ingredients from third countries, if the regulatory framework in the respective third country does not ensure a sufficient level of protection of human health for products imported into the EU;
- Audits of manufacturers of API;
- Strengthened mandate for inspections including increased transparency of inspection results through publication in the EudraGMP database managed by the EMEA.

The European Patients' Forum has published a Position Paper[7] supporting the Commission's legislative proposal, focusing principally on patient-centred health care and patient involvement in counteracting the public health threat of counterfeit medicinal products. The European Federation of Pharmaceutical Industries and Associations (EFPIA) has however expressed concern that the patient safety would not be fully secured through the Commission's current proposals.[8] EFPIA has recommended a technological anti-counterfeiting strategy based on the integrity of the product packaging through the use of tamper-evident packaging or tamper-resistant closures for all medicines, the use of overt, covert and forensic authentication features, and better product identification through one harmonized European coding of each individual pack. EFPIA has advocated the prohibition of repackaging in order to guarantee the integrity of the product throughout the entire supply chain. The latter proposal is highly controversial as it would severely limit parallel importation. Parallel importation of a medicinal product is a lawful form of trade within the Internal Market based on article 28 of the EC Treaty and subject to the derogations provided by article 30 of the EC Treaty.[9]

Increasing product safety is also a key priority in the US, with the focus being on the physical-chemical identifiers (PCIDs) in medicinal products. The FDA issued a Draft Guidance for Industry on Drug Anti-counterfeiting[10] in July 2009 on the use of inks, pigments, flavours, and other PCIDs by manufacturers to make medicinal products more difficult to duplicate by counterfeiters, and to make it easier to identify the genuine version of the medicinal product. This is an important collaborative step between the FDA and drug manufacturers in making medicinal products more difficult to counterfeit.

It is clear that the eradication of counterfeit medicines is a challenging undertaking which requires multi-disciplinary collaboration between national governments, the pharmaceutical industry and international bodies; structured cooperation between regulatory authorities and national law enforcement agencies such as the police and customs officials; as well as rigorous information campaigns directed at consumers.

continues on page 22

continued from page 6

Counterfeit Medicines

The commitment to continuously improve the availability and affordability of medicines on a national and European level should be recognized as a cornerstone of healthcare in Europe if the problem is to be adequately addressed. It is essential that medicines legislation is strictly enforced and that Court cases involving counterfeit medicines are adjudicated without undue delay. Counterfeit medicines do not only affect 'the weak consumer' but impact the health and well-being of the public as a whole. Medicines legislation must therefore reflect the seriousness of public health violations as a matter of public policy.

The author is currently reading for a Doctor of Laws degree at the University of Malta, with a special interest in Medical and Pharmaceutical Law. She is currently researching the EU and US legal frameworks for medicines and their impact on the pharmaceutical industry and public health.

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