Pharmaceutical Piracy Colour-Coded Security and Traceability

PEER REVIEWED

The problem of counterfeit medicines was first addressed at the international level at a World Health Organization (WHO) conference in 1985. Things have come a long way from there, and much has been undertaken to combat the growing threat of fake medication. Yet, while governments and organisations are discussing the implementation of a uniform definition into their respective legislations, and guidance is being published for mass serialisation of prescription medicines, the counterfeiting 'business' is shifting to new markets.

In just two months, 34 million counterfeit tablets were seized by customs authorities in all European Union member countries. "This exceeded our worst fears," former European industry commissioner Gunter Verheugen told the German daily 'Die Welt'. But what exactly is a counterfeit medicine? Up to now, no uniform definition has yet been agreed upon. In the WHO Factsheet on counterfeit medicines, we read: "Counterfeit medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source." The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) carries on: "Their quality is unpredictable as they may contain the wrong amount of active ingredients, wrong ingredients or no active ingredients. In all cases counterfeit medicines are manufactured in clandestine laboratories with no possibility of control." Additionally, primary or secondary packaging, patient information leaflets or labels and documentation accompanying the medicines are prone to counterfeiting.

"A First Step"

The first definition intended for international use was formulated by the WHO in 1992. In the Declaration of Rome from 18th February 2006, newly-founded IMPACT stated that "counterfeiting medicines is widespread and has escalated to such an extent that effective coordination and cooperation at the international level are necessary for regional and national strategies to be more effective." Yet, neither a common definition nor a common solution in the fight against counterfeit medicines has yet been found. The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) also observes that "the absence of a universally accepted definition makes information exchange between countries very difficult, limits the ability to understand the true extent of the problem at global level, and hinders the development of global strategies to combat the problem".

The American Food and Drug Administration (FDA) Amendments Act of 27th September 2007 imposed March 2010 as the deadline for developing or adopting a standardised numerical identifier (SNI) for prescription drug packaging. The guidance is compatible with the California e-pedigree law, which has been delayed until 2015/2017. The final guidance for a standardised numerical identification recommends the introduction of a serialised National Drug Code (sNDC), "composed of the National Drug Code (NDC) that corresponds to the specific drug product combined with a unique serial number, generated by manufacturer or repackager for each individual package." The FDA is still far from implementing any rules into legislation: "defining the SNI is expected to be a first step to facilitate the development of other standards and systems for securing the drug supply chain".

A Highly Profitable Market

In 2008, the European Commission went a lot further into the question with its public consultation in preparation of a legal proposal to combat counterfeit medicines for human use. 128 responses from stakeholders were received and considered in the impact assessment leading to the current proposal amending Directive 2001/83/EC. The proposal has been submitted to the European Parliament and the Council, where it will be discussed and voted in a co-decision procedure. Nearly three years ago, the Commission was already aware of the fact that "Member States are starting to consider taking unilateral action to address the problem". Some countries are already implementing their own national solutions while industry-based tests are being carried out in others. A subsequent unification of these different schemes further complicates

the implementation of international standards.

The pharmaceutical industry is moving fast, and counterfeiters have discovered a new and highly profitable market to distribute their products: the internet. A Pfizer-sponsored survey indicates that Western Europeans spend approximately 10.5 billion euros a year on illicit medicines, of which many are believed to be counterfeits. Nearly half of the transactions are for weight-loss medicines, followed by prescription drugs for flu treatment. The WHO has been warning about the risks of online pharmacies for quite some time: "In over 50 percent of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit." A study released by the European Alliance for Access to Safe Medicines (EAASM) provides even more worrying figures. Of the over 100 online pharmacies tested, 84.5 per cent do not physically exist; only 6.2 per cent are linked to a named, verifiable pharmacist. Laboratory analysis revealed that 62 per cent of all products ordered online by the research team were counterfeit, substandard or unapproved generic.

No Prescription Required

For the third time in three years, Interpol conducted their Operation Pangea, "an international week of action tackling the online sales of counterfeit and illicit medicine". 45 countries took part in 2010, leading to the seizure of 2.6 million US Dollars worth of illicit and counterfeit pills. Among these were antibiotics, steroids, anti-cancer, anti-depression and anti-epileptic, as well as slimming or food supplement pills. 694 websites were found to be engaged in illegal activity; 290 were shut down. These figures clearly show how illegal internet sales of medicines are developing. But they also highlight how difficult it is for authorities to intervene in the long term. Prescription drugs can be obtained online without difficulty. Patients no longer need a valid prescription from an accredited practitioner. The prescription is either issued by an online doctor or is not required at all. The EAASM study found that in 90.3 per cent of all cases, no prescription was required for prescription-only drugs.

So how can patients find out whether they have bought a substandard or counterfeit medicinal product? The Royal Pharmaceutical Society of Great Britain (RPSGB), now replaced by the General Pharmaceutical Council, has developed guidelines for what legitimate online pharmacies should do: name, address and owner must be clearly displayed; patients must be required to provide a medical history evaluation and a prescription signed by a registered national doctor before purchasing medicines; the pharmacy must have a physical address in the country in which it claims to carry out its business, as well as a telephone number and a privacy and security policy. All registered pharmacies can be found on the website of the General Pharmaceutical Council, and must display a logo containing its unique seven-digit number on its website.

Data Security at Risk

Only 4.4 per cent of the websites checked by EAASM are listed as legitimate websites, while 20 per cent bear a logo or stamp of approval from a recognised society. From these 20, nearly 86 per cent were found to link to a bogus website. Counterfeiting logos on products and packaging is not too hard, as customs statistics demonstrate every year. But implementing a fake logo on a website is a piece of cake for anyone who has worked with a graphic program a few times. The user needs to know how to distinguish false from original: original logos must link to the website of the issuing society. But so many organisations, associations and societies worldwide supply online shops with security seals that, here again, it is difficult to feel reassured. Even if the medicines bought online are not dangerous, the transaction itself reveals many personal details like medical and financial information to dubious traders.

The EAASM expert panel states that "while several of the medicines bought online were considered highly likely to be substandard and/or counterfeit, the vast majority of typical European consumers would be unable to detect this". This surely is one of the main issues with the online purchase of medicines: many patients are not aware of the threats that counterfeit medicines impose on their health. If a website looks trustworthy, the medicines are promptly delivered and the pills, syrups and syringes look authentic, most consumers will not check the packaging for evidence of tampering. This leads many experts to the opinion that online sales of medicines should be banned immediately, and especially that prescription drugs should only be sold to patients in physically existing pharmacies. Yet, it is far too late for such steps. Online sales are rising continuously, and it would simply be impossible to put a ban on internet sales into practice in the near future.

Multi-Layer Approach

On one point, nearly all experts agree: a so-called multi-layer or multi-level approach is needed. A study by Cambridge Consultants names three different types of technologies, i.e. tamper-evident, serialisation and authentication features. Tamper-evident packaging or closures are seen as the first layer of protection, and can include security features like perforation or seals integrated into the packaging design. Serialisation implies a unique serial number to be printed on each package. Each pharmaceutical product needs to be traceable along the entire supply chain, to ensure that only originals are being sold to the end-customer. Authentication can be overt, like holograms and watermarks, or covert, like micro colour-codes. Because many security features are counterfeited in next to no time, different technologies must be combined, and more than one layer should be used.

One example for such combined technology is a system based on micro colour-codes. These codes, with a size of 8 to 90 micrometres, are manufactured in four to ten different colour layers. An individual user code is exclusively allocated to the products of a specific brand-owner. For example, secondary packaging is marked with a data matrix code printed onto a label used for tracking purposes. This label can also be tamper-evident, e.g. when applied over the closure of the packaging, and reveals at first sight whether the pack has been opened. It may also include, for example, a hologram as an overt authentication feature. The colour-code is applied onto this label, providing, in a first step, covert authentication. In a second step, it not only secures the product and its packaging, but also the

label or seals and the traceability code. Additionally, patient information leaflets and authentication certificates can be secured with micro colour-codes.

Double-Checking Information

Many technology companies advertise their track & trace solutions as counterfeit-proof. Yet, with a little knowledge of the printing business, counterfeiters can easily print their own fake data matrix codes or copy existing ones from solution providers which they multiply thousands-fold. As soon as a code has been checked in the corresponding database, the next code with the same specifications will be identified as fake. But what if the first code was copied and the second or third one is the original? To ensure that these problems do not hinder the supply chain of original medicines, another code needs to be applied to the traceability label, making the label and the product identifiable as originals. The information sent to the databases needs to be double-checked. This can be done by applying a micro colour-code to the traceability device. The producer-inherent code is deposited in the databases and can be verified by use of a simple microscope.

Internet sales of pharmaceutical products have risen so fast over the past years that it would be impossible to forbid them altogether. To get to the heart of the problem, better patient education must prevent unknowing purchases of fake medicine. Patients who consciously buy their medication from unreliable sources need to be warned about the dangers they expose themselves to. The adoption of a uniform definition and international protection standardisation would greatly assist the fight against counterfeiters. Activities like Operation Pangea or international seizure operations need to be enhanced in order to get to the operators of bogus online pharmacies and the producers of counterfeit or illicit medicines. A multi-layer approach consisting of authentication, serialisation and tamper-evident features can help secure the products along the entire supply chain. In all aspects, micro colour-code technology can decisively contribute to the success of all these endeavours ■

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