

Pharmaceutical piracy Tracking and Tracing and Anti-Counterfeiting

It is estimated that in 2010, counterfeit drug sales will reach 75 billion US dollars globally, an increase of more than 90 percent from 2005. This figure is highly alarming. But most worryingly, we must realise that this is no long-term prediction anymore. The pharmaceutical industry, politics, organisations and associations not only need to get plans going for an effective protection of medical products - a prompt implementation is also necessary as soon as possible.

According to the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) a medical product is counterfeit "when there is a false representation in relation to its identity, history or source. This applies to the product, its container or other packaging or labelling information."

Pharmaceutical counterfeits often cannot be recognised at first, and sometimes not even at second sight – the counterfeit drug, its primary and secondary packaging are just too true to the original. Besides enormous losses for the pharmaceutical industry, the immediate danger for consumers is more and more prevalent. The forecast of global counterfeit drug sales reaching 75 billion US dollars next year asks for quick action; a demand that is not easily met. Pharmaceutical companies are well aware of the threat and many have already – more or less efficiently – put security measures into place to stop counterfeiting of their products. Also, political and industrial organisations, associations and institutions have reacted to the problem by initiating projects and publishing drafts and proposals for national or international guidelines or legislation changes. Yet, up to the present, no common solution has been found and the fight against counterfeiting still seems to be at its very beginning, different attempts and experiments often leading to no clear results.

From RFID to SNI

In the middle of 2006, FDA abandoned its

original concept to combat counterfeits and ensure traceability with Radio Frequency Identification (RFID). Recently new developments have been introduced at FDA in order to establish standards for a unique standardised numerical identifier (SNI) for prescription drug packaging. The FDA Amendments Act of 27th September 2007 (FDAAA) imposes March 2010 as the deadline for developing or adopting an SNI. In January 2009 draft guidance was issued by FDA, requesting comments and questions from the industry. In a first step, FDA has defined a package-level SNI that consists of the serialised National Drug Code (sNDC) and is composed of the National Drug Code combined with a unique

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8-digit serial number for each individual package. This guidance is considered as an "initial step to facilitating other measures for securing the drug supply chain" and is only to be viewed as a recommendation. Standards for track and trace, authentication and validation are not included, but will be dealt with in one of several announced guidances and regulations. Californian ePedigree, the last remnant of the ambitious FDA plans for the US-wide implementation of RFID, is an electronic record to trace every step taken by a retail package of prescription drugs throughout the supply chain. The initial proposal envisaged 2009 as the deadline. This deadline was initially

delayed until 2011, and now even until 2015, to give the involved parties more time to prepare for the implementation.

European Commission on the move

While the draft guidance of FDA does not yet include the topic of traceability, the European Commission is engaged in finding a method to protect pharmaceutical products against counterfeiting and at the same time assuring the traceability of these products. In March last year, the European Commission therefore launched a public consultation in preparation of a legal proposal to combat counterfeit medicines for human use. The Commission observes that "there is evidence that Member States are starting to consider taking unilateral action to address the problem". For this reason, a consensus needs to be found for pack-specific tracing and mass serialisation. In its consultation, the EC specifies: "Mass serialisation is based on a code on the outer packaging which 'individualises' the pack. The code is read with a reading device. Currently, various tamper-proof technologies to implement such a concept are under discussion by the industry." Datamatrix and 2D barcoding are considered to be such technologies; other devices are not ruled out. One of the 123 responses from stakeholders to the European Commission's public consultation was issued by the European Association of Pharmaceutical Industries and Associations. EFPIA, amongst others, argues that "a risk-based approach may no longer be appropriate to apply these measures, as counterfeiters are now targeting a growing range of medicines and will simply move to target any weaknesses in the supply chain." EFPIA is decidedly in favour of the proposed ban on repackaging because "it provides an open door for any illegitimate party to infiltrate the legitimate supply chain with potentially dangerous products". One exception should be made to the ban on repackaging: "Any legislation will have to make provision to



ensure that clinical trials and other research activities are clearly out of scope of any legislation arising out of the Commission's initiative".

Initial first layer of security

The UK's Medicines and Healthcare products Regulatory Agency (MHRA), as well as other respondents, raises concerns over a possible general repackaging ban at European level. Such a regulation would imply that importers could no longer comply with the requirements of supplying products placed on the UK market with an English leaflet and English labelling of the primary and secondary packaging. Many stakeholders emphasised the importance of cooperation with the American FDA, and of following a multi-layer approach, meaning a consideration of many different aspects and a bundle of methods. The majority of the respondents opined that it would be

"premature, ineffective and even counter-productive" to decide on only one specific safety feature. Some respondents also stressed the necessity of sufficiently long implementation times and warned against an increase in bureaucracy. Changes in the legislation "should not lead to an overhaul of the existing legal system". A stepwise approach seems to be most effective. One of the most important points in this discussion is that no government or international institution has yet found a mutual consent as far as the technology for counterfeiting and/or tracking & tracing is concerned. As required by many respondents to the European Commission's consultation, a choice of different security and traceability features should be possible. EFPIA brings it to the point when emphasising that "while tamper evident features and the use of authentication technologies present an initial first layer of

security, it must be noted that these features can potentially be copied and alone do not constitute an absolute barrier to reduce counterfeits". Traceability devices do not necessarily guarantee the authenticity of the traceable product. Although very sophisticated in their development, RFID tags and datamatrix codes are still far from being reliable security features. As for many anti-counterfeit features, some recent cases have repeatedly shown that these security measures can be copied almost as quickly as they enter the market for the protection of pharmaceuticals. What is more, counterfeiters are even ahead of the game. They apply security features to products that, in their original state, have no such feature. New implementations of anti-counterfeiting devices are often not communicated to the public for fear of them being copied. Counterfeiters profit from this lack of communication.

Vulnerable distribution chain

The pharmaceutical supply chain may consist of twenty or more different steps before the drug reaches the patient. The production of each active pharmaceutical ingredient (API) is the first step of the distribution chain which has to combat counterfeiting. If not produced at the company's own laboratory, each active ingredient will reach the production site through a network of suppliers. The different chemical substances are then combined to a pure drug substance to produce the final medicinal product. The European Commission confirms the risk of fake APIs: "Already the active pharmaceutical ingredients entering the manufacturing process may be false representations of the original API." Therefore, choosing reliable manufacturers is, of course, an important prerequisite. The more people in contact with the drug, the greater the chance of an infiltration of counterfeits. The next step in the drug chain includes packing or filling. Additionally, secondary packaging and patient information leaflets are required before the medicinal product can finally be delivered to distributors or vendors. This rather simplified description of the pharmaceutical supply chain already reveals numerous steps which allow counterfeit drugs or packaging to enter the distribution

chain, not forgetting the different routes travelled by the product to reach its final destination. Depending on the number of distributors and interim storages as well as on the number of countries or even continents, the product has to be dispatched by air, road or sea. Each mode of transport is exposed to the potential risk of counterfeiting. Pharmaceutical packaging is particularly prone to counterfeiting. The need for a technology that not only secures the primary and secondary packaging of medical products, but also ensures the authenticity of the traceability code and the information provided within is obvious.

Colour-coded security

One example for such combined technology is a system based on micro colour code technology to ensure a counterfeit-free legal supply chain. These micro colour codes with a size of 8 to 90 micrometers consist of four to eleven different colour-layers. The individual user code, which is exclusively allocated to and produced for the products of a specific brand-owner, is based on the combination of different colour-layers and their sorting order. A unique industry solution on the basis of these colour codes is now available for the combined tracing and securing of pharmaceutical products and constitutes an essential step towards improved security for the drug supply chain. The product, its primary or secondary packaging, its labels and seals can be kept secure by means of individualised colour codes. For example, secondary packaging is marked with a datamatrix code printed on a label to be used for tracking purposes. The colour code is also applied onto the label, thereby authenticating both the traceability code and the product. The same applies to primary packaging like tubes or blisters. In this example, the traceability code is now scanned with a 2D scanner and verified in worldwide existing databases. The product ID is checked and matched to the information provided in the database. However, even if the data and the information in the database coincide, the originality of the product is not yet guaranteed. If data verification reveals that the product has already been scanned, it is almost certainly a fake. Here, the authenticity of colour-coded products can immediately be verified by the use of a simple standard microscope. Manufacturers, distributors,

police and customers are able to clearly distinguish between fake or original products and traceability codes. High costs of legal proceedings are avoided and customer trust in the company's products is maintained. The complete solution is obtainable from one single source and allows pharmaceutical companies to combine the logistic advantages of traceability with counterfeit-resistance and easy integration into the production process.

2010 is approaching fast. And so is the predicted rise in counterfeited pharmaceutical products. American authorities revealed another alarming increase in fake pharmaceuticals: in 2008 a rise of more than 100 percent in comparison to 2007. The seizure of such high amounts of counterfeits is partly due to better collaboration among federal agencies. But it is mainly due to the overall increase in pharmaceutical counterfeits entering the legal supply chain. Much has already been done in order to find a solution to the growing problem. Yet even more still remains to be done. The different guidance drafts and public consultations are only the first step in a long discussion, decision and implementation process. Many different viewpoints and diverse conflicts of interest arise from this debate. No matter which codes or features pharmaceutical companies and national or international legislative bodies will opt for in the future, micro colour codes will contribute their share to the worldwide issue of tracking and tracing and anti-counterfeiting ■

For further information, please visit www.3SGmbH.com.

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