

## Using Information Technology to Combat Counterfeiting in the EU

*Gary Noon* explains how using information technology to enhance communications can help industry better deliver quality assured medicines in the European Union.

The advent of information technology has had a profound impact on industry and the pharmaceutical community is no exception. With a complex supply chain and a growing need to guarantee the safety and well-being of consumers, information technology is a powerful enabler. Increasingly, technology is critical to ensure all industry stakeholders are kept up-to-date with the latest regulatory and legislative changes.

As the last point of professional contact between the patient and the industry, pharmacists are on the front line when it comes to ensuring patient safety. The quality and timeliness of information flowing to pharmacists about medicines is vital in this endeavour.

Providing the pharmacist with information in real-time – as the medication is dispensed – creates the opportunity to provide new levels of patient safety previously not available. Implementing a communications network between pharmacies, manufacturers and regulatory authorities that operates in real time on a pan-European basis will revolutionise the pharmaceutical industry.

### What is the issue?

The threat of patients receiving substandard or counterfeit medicines is a clear and present danger. This multibillion dollar global industry is accountable for an estimated half a million deaths a year, and continues to rise at an alarming rate<sup>1</sup>. In 2005, 500,000 single doses of fake medicines were discovered across Europe. The following year that number escalated to 2.5 million. The World Health Organization estimates the trade in fake drugs to represent as much as 10% of all pharmaceutical sales worldwide. The WHO also believes that up to 30% of medicines in Russia and in some countries in Africa, Asia and Latin America are counterfeit. However, quantification of a true figure is almost impossible as often the evidence has been swallowed.

Indeed, even in Europe, as Jean-Francois Dehecq, chairman of pharmaceutical firm sanofi-aventis acknowledges, counterfeits are now starting to appear in the legitimate supply chain – in pharmacies as well as distributors and wholesalers. Dr Dehecq estimates that counterfeit medicine affects around 2-3% of sanofi-aventis's own products in Europe<sup>2</sup>.

In December 2008, the European Commission announced its health package, which contains legislative proposals relating to several pressing industry issues, one of which is counterfeit medicines<sup>3</sup>; true recognition that drug counterfeiting is a serious and growing problem.

However, this is a complex area and will be the subject of much debate before legislation can be agreed.

With re-elections to the European Parliament due to take place in the summer of 2009, the dates of a unified

course of action for the industry to follow are unlikely to materialise this year – time that industry and patients can ill afford as drug counterfeiting becomes ever more embedded in society.

### What are the challenges?

The primary challenge for industry has been the inherent complexity of the pharmaceutical supply chain. As many as 20 different parties can become involved in the distribution of medicines before they reach the pharmacist, and this gives counterfeiters numerous opportunities to penetrate the chain. As ownership and title of goods passes to the purchaser as soon as the medicine is sold, the original manufacturer cannot completely control the quality in which the product finally reaches the patient. Each stakeholder must take liability for the part they play in the transit of medicines.

When quality issues occur, it is also extremely important to be able to efficiently and effectively withdraw affected products. However, such products are often difficult to locate, which raises another patient safety issue. As an example, the UK's Medicines and Healthcare products Regulatory Agency in June 2007 issued three emergency drug recall notices<sup>4</sup> relating to the medicines Casodex (bicalutamide), Plavix (clopidogrel bisulfate) and Zyprexa (olanzapine). Out of the 70,000 packs that were distributed to pharmacies and wholesalers, only 40,000 were effectively recalled, meaning up to 30,000 of these drugs may have still not been recovered.

In May 2009, Glaxo SmithKline and the MHRA issued a recall for a batch of Seretide (salmeterol xinafoate and fluticasone propionate) 250 Evohalers, which are used to treat asthma, because of possible interference by counterfeiters in the plastic inhalers themselves<sup>5</sup>. It was reported this product had reached patients through the legitimate supply chain, resulting in a nationwide withdrawal.

The costs and time involved in a full global product recall are vast. The risk associated with the loss of public confidence in a manufacturer's products is probably immeasurable.

In addition, in some countries – such as Turkey – pharmacists are liable for the quality of the medicines they sell and can be imprisoned for dispensing a counterfeit drug, even if this is done so unknowingly.

This example highlights that speed of communication is vital; if information reaches the pharmacy quickly enough it can act as an effective barrier between patients and medicine that is unsafe for public use.

Technological intervention would be helpful as, until now, the method of communicating regulatory and product

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changes (including recalls and suspect counterfeits) to the pharmacist has been fax or email, or even post. Given the time constraints pharmacists are often operating under, these notifications might not get picked as quickly as they need to and inadvertently compromise the well-being of the patient.

### **An available solution**

Both the product licence holder and pharmacists, when faced with ever-changing status relating to the quality of medicines supply – such as notification of a product withdrawal, product expiry or changes in a dosing schedule – want to be in a position to assure the patient of the quality of the product they are about to receive. To achieve this pharmacists require the very latest on the product as it is being dispensed. This requires input from the pharmaceutical manufacturer and regulatory agency and participation from the pharmacists themselves.

One method that uses technology to improve communication in the pharmacy is authentication. This method has proved to be effective in improving the speed of recalls and protecting against counterfeiting trade.

Authentication involves setting up an open, direct communications link between the pharmacy, the manufacturer and the regulatory body by simply installing broadband connectivity and upgrading the existing pharmacy software with an authentication system. Pharmaceutical manufacturers need to add to every pack of medicine before distribution a mass serialisation code (a “passport” number), which is effectively a unique machine readable number. With authentication installed, pharmacists are alerted rapidly to any issues relating to products they are about to dispense.

Every time the passport number of the medicinal item is scanned by the pharmacist, he or she receives relevant messages from the pharmaceutical manufacturer or regulatory body directly into his or her computer screen before passing the item to the patient. If there are issues, the system will “freeze” and the manufacturer can immediately relay any important instructions, such as “hold the product” directly to the pharmacist.

### **Benefit**

Effective authentication systems limit the negative publicity associated with drug scares and minimise the threat of litigation if patients suffer as a result of taking fake or unsafe medicines.

An authentication system that uses mass serialisation technology allows manufacturers and regulators to recall batches or sub-batches of fake or substandard drugs quickly and efficiently before they reach the patient.

Using a dedicated communications channel, pharmacists can play a key role on behalf of the manufacturer in the intervention of the prescribed drug before it reaches the patient. Pharmacists who have already installed this infrastructure have seen a change in how their role relates to the patient. Historically, the pharmacist was seen as a “shopkeeper”, an individual whose function it was to sell medicines, but this is evolving. The pharmacist is now reminded to be a “consultant”, offering patients relevant, timely advice relating to the treatment they are receiving.

Beyond the operational benefits that technology offers pharmacists, there is a strong case for technology within the pharmacy to assure patients of the quality of medicines they receive. Perhaps this will also discourage patients from accessing medicines from more dubious and risky sources via the internet, where as much as 60% of medicines purchased may be counterfeit<sup>6</sup>.

The pharmaceutical industry can gain a significant amount of goodwill by being able to demonstrate that it has taken every reasonable care to protect consumers. There is widespread acknowledgement that efforts to promote public safety generate a positive return on investment<sup>7</sup>.

### **Staying one step ahead**

In a world where counterfeits have no borders, solutions to combat the trade in counterfeits must be applied across all markets and not just nationally.

Implementing a communications network that operates in real time on a pan-European basis could revolutionise the European pharmaceutical industry. With a concrete effort from all stakeholders to embrace the technology available, pharmacists can assure the level of quality and regulatory compliance sought by industry as patients receive their medication.

The challenge that industry and governmental organisations face is to convert collective responsibility into decisive action.

In the economics of the counterfeiting industry, using technology that collectively addresses the issue and erects an even greater barrier for the entry of counterfeits to the market will lead even the most persistent counterfeiters to acknowledge that their money spinning days might be numbered.

#### *References*

1. *The Daily Telegraph*, 5 April 2008, Counterfeit medicines – the pills that kill, [www.telegraph.co.uk/health/3354135/Counterfeit-medicines-the-pills-that-kill.html](http://www.telegraph.co.uk/health/3354135/Counterfeit-medicines-the-pills-that-kill.html)
2. *Outsourcing Pharma*, 23 June 2008, EFPIA says traceability pilot will start next year, [www.outsourcing-pharma.com/On-your-radar/Patient-safety/EFPIA-says-traceability-pilot-will-start-next-year](http://www.outsourcing-pharma.com/On-your-radar/Patient-safety/EFPIA-says-traceability-pilot-will-start-next-year)
3. *The Regulatory Affairs Journal – Pharma*, 2009, **20**(1), 47-49
4. BBC News online, 3 February 2009, Thousands “have taken fake drugs”, <http://news.bbc.co.uk/1/hi/health/7865246.stm>
5. *Chemist & Druggist*, 13 May 2009, Counterfeit fears prompt Serotide Evohaler batch recall, [www.chemistanddruggist.co.uk/c/portal/layout?p\\_1\\_id=259751&CMPI\\_SHARED\\_articleId=2462900&CMPI\\_SHARED\\_ImageArticleId=2462900&CMPI\\_SHARED\\_articleIdRelated=2462900&CMPI\\_SHARED\\_ToolsArticleId=2462900&CMPI\\_SHARED\\_CommentArticleId=2462900&articleTitle=Counterfeit%20fears%20prompt%20Serotide%20Evohaler%20batch%20recall](http://www.chemistanddruggist.co.uk/c/portal/layout?p_1_id=259751&CMPI_SHARED_articleId=2462900&CMPI_SHARED_ImageArticleId=2462900&CMPI_SHARED_articleIdRelated=2462900&CMPI_SHARED_ToolsArticleId=2462900&CMPI_SHARED_CommentArticleId=2462900&articleTitle=Counterfeit%20fears%20prompt%20Serotide%20Evohaler%20batch%20recall)
6. European Alliance for Access to Safe Medicines, The Counterfeiting Superhighway, 2008, [http://v35.pixelcms.com/ams/assets/312296678531/455\\_EAASM\\_counterfeiting%20report\\_020608.pdf](http://v35.pixelcms.com/ams/assets/312296678531/455_EAASM_counterfeiting%20report_020608.pdf)
7. Frost and Sullivan, Working together on mass serialisation; Whose responsibility is ensuring patient safety?, 28 April 2008, [www.aegate.co.uk/assets/\\_files/documents/aug\\_08/aeg\\_1219846309\\_FrosSullivanexesummarywhitepap.pdf](http://www.aegate.co.uk/assets/_files/documents/aug_08/aeg_1219846309_FrosSullivanexesummarywhitepap.pdf)