

THE COUNTERFEIT CRISIS

In the age of internet connectivity, it is not only online fraudsters putting the public at risk from bogus pharmaceuticals. Colin Mackay of EFPIA looks at how the supply chain needs to be strictly monitored and what technologies should be implemented to give the best results.

Counterfeiting is one of the oldest criminal activities and one of the major risks comes from counterfeit pharmaceutical products being passed off as genuine versions of real medicines. These may contain substandard or below therapeutic levels of active ingredient, no active ingredient at all or even dangerous, toxic substitutes. They can range from crude, amateur copies to highly sophisticated duplicates, increasingly difficult to differentiate from the genuine article. Counterfeiting is a big business and growing bigger; in some developing countries the infiltration of counterfeit medicines is estimated as high as 50%, a situation fuelled by weak law enforcement of supply chain legislation and inappropriate product registration. The tempting combination of high potential for profit and a low risk of being caught make it an attractive area for criminals.

Europe: a prime target

Counterfeiters have shown their flexibility to seize opportunities; the threat of H1N1 influenza has allowed Tamiflu to surpass Viagra as the most counterfeited medicine in Europe. The internet is not the only source of counterfeit medicine. Presumably encouraged by the promise of substantial returns, the legitimate supply chain is increasingly becoming a target. The European Commission has recognised the need for legislation, and included counterfeiting as part of the 2008 'Pharmaceutical Package' of measures designed to ensure the industry remained competitive and generated safe, innovative and accessible medicines. The third element of the package was a 'proposal aimed at strengthening EU legislation' by 'protecting the legal distribution chain from infiltration'. Counterfeit medicines are a growing problem everywhere, and if public confidence in the supply chain is undermined, the consequences could be severe.

If public awareness of the threat within the legitimate supply chain is low, it is partly because the number of counterfeits entering by this route is relatively low; at least in comparison to internet-based sources. However, the UK Government's Medicines and Healthcare products Regulatory Agency (MHRA) has presided over nine batch recalls of counterfeit medicines in the last five years, with counterfeit versions of products including Casodex, Lipitor, Plavix and Zyprexa all found the legitimate supply chain. These are not treatments that can be classified as 'lifestyle' treatments, such as those for weight loss or erectile dysfunction; these are therapies for life-threatening conditions like cancers and serious mental health problems. The potential consequences of this are very serious

Contributor profile



Colin Mackay is the Director of Communications and Partnerships for EFPIA, the Brussels-based European Federation of the Pharmaceutical Industries and Associations. He is involved in the pilot EFPIA coding project, validating the concept of an end-to-end verification system based on a 2D data matrix, to reduce counterfeiting.

indeed. The problem is not limited to Europe; in 2006 alone, the US Food and Drug Administration (FDA) investigated more than 50 cases of counterfeit medical products.

Supply chain solutions

The Commission proposes two key elements as a solution; firstly, the need to guarantee the integrity of product packs throughout the supply chain. This introduces a requirement to apply safety features such as overt, covert and/or forensic devices on packaging, allowing authenticity checks. However, these features alone would be ineffective unless they are combined with tamper-evident features that can guarantee the integrity of the product itself. Clearly, tamper-evident features and the use of authentication technologies can only provide a primary layer of security. They can still be copied – and modern scanning and printing technologies facilitate this – so in isolation do not provide an insurmountable barrier to the determined counterfeiter. The European Federation of Pharmaceutical Industries and Associations (EFPIA) has argued for a total ban of repackaging. However, the proposal does not support this approach. The other strand of the Commission's proposal is to ensure traceability through individual product codes (product serialisation) on the packaging. These will be read by legal actors in the distribution chain, including pharmacies. Sophisticated traceability systems will need to form a key part of any effective and comprehensive anti-counterfeiting strategy. At the moment, it is not possible to guarantee identification of individual packs, with product traceability only feasible at batch level. Where it does happen, the dispensing pharmacist scans a standard (one-dimensional or linear) barcode, which supplies limited information.

Harmonisation required?

The reality of the procedure that applies across Europe is that it varies by country, with each national system using its own codes and own system. With the lack of a harmonised system, and with substantial movements of goods between countries via parallel trade, traceability across Europe is a considerable

challenge. There is an absence of direction from the Commission's proposal, and alongside member states' unique systems, this has encouraged the European research-based pharmaceutical industry to put forward its own proposal for a harmonised system. The proposal, led by EFPIA, recommends developing a system based on a 2D data matrix code (ECC 200), containing a randomised serial number to enable the unique identification of each unit. The code would also include the existing product code (identifying the product and its manufacturer), the expiry date and the batch number. The data matrix is ideal for use with small packs, as it can encode up to 50 characters readable at 2 or 3mm. It also works well in low-contrast situations. Such an approach would mean minimal changes to existing packaging.

Other traceability solutions are available, including RFID, but this remains a high-cost solution. There are also some doubts over whether such systems are capable of functioning at such a granular level. In EFPIA's analysis, the 2D barcode solution is a proportionate response. To effectively minimise the risk of substandard or counterfeit products reaching the patient, there is one crucial juncture at which it is vital to know that the product is precisely what it is supposed to be. This is at the final link in the supply chain, where the product passes from the pharmacist – retail or hospital – to the patient. This, EFPIA believes, can be achieved by a systematic control of the serial number at the point of dispensing, checking against the relevant manufacturer's database via a web-based service.

Traceable technology

EFPIA is in the process of developing an end-to-end product verification that will achieve this objective. By scanning each 2D barcode pack at the point of dispensing, the pharmacist will be able to see whether that individual product has been dispensed before. This will verify the authenticity of each dispensing unit before it reaches the patient. Unlike an electronic system that permits the tracking and tracing of each pack throughout the supply chain, this end-to-end product verification system cannot guarantee the genuine nature of the product contained within the coded product pack. However, it can provide a method by which the product information, including expiry date and batch codes, can be tracked, minimising the risks of counterfeiting or tampering.

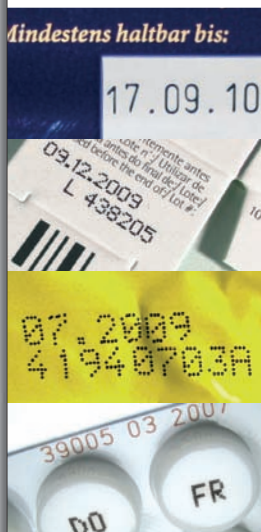
Realistically, this is the only type of traceability technology that could feasibly be implemented in any reasonable timeframe – around three to four years – at anything approaching a reasonable cost. EFPIA is conducting a pilot version in Sweden to verify the practicality of the system. The eventual aim would be to integrate the system into pharmacy software. While this system cannot and will not be able to fully prevent counterfeiting or make the supply chain 100% secure, it can go a long way towards providing high standards of security, integrity and safety. It would also improve patient safety in other ways, such as detecting out-of-date packs and could also significantly reduce dispensing errors. Most importantly, it offers increased security benefits for patients, helping to deliver the right product to the right patient. That should be the ultimate concern for all stakeholders. **WPF**



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