Tackling the problem of falsified medicines in the UK

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The problem of falsified medicines entering the supply chain has grown in recent years, including in the UK. However, new initiatives such as the EU Falsified Medicines Directive are attempting to confront the issue.

If a medicine isn’t what it says it is, the risks to patient can be significant. Falsified medicines may look like the real thing, but inside the packaging, the products are unlikely to be correct. They may contain the wrong active ingredient or no active at all; and even if there is some of the right drug, the dose might be too low or the quality poor.

It used to be that most falsified medicines – at least in developed countries such as the UK – were lifestyle drugs like Viagra, hormones for bodybuilders and those designed to promote weight loss. But the problem has grown in recent years, with many expensive medicines now targeted by criminals looking for a quick profit.

In legal terms, there is a difference between a falsified medicine and a counterfeit medicine. Falsified medicines are fakes that pass themselves as the real thing; counterfeits are those that contravene patent or trademark rules.

The size of the problem in the UK

There have been big seizures in recent years. As part of Interpol’s global Operation Pangea in 2015,¹ for example, nearly £16 million of falsified medicines and medical devices were seized in the UK. That haul of more than six million doses included slimming pills, erectile dysfunction tablets and narcolepsy treatments, but also drugs for diseases as diverse as depression, cancer and epilepsy. Most originated from China, India, Hong Kong and Singapore.

While most falsified medicines are found in places such as unlicensed online pharmacies, they do occasionally make it into the legitimate supply chain. “The instances of falsified medicines infiltrating the authorised UK supply chain are extremely rare – since 2011 there have been nine occasions,” says a spokesman for the Medicines and Healthcare products Regulatory Agency (MHRA). “We remain alert and have strategies in place for such an occurrence. Arrangements are in place with Border Force to seize medicines that are identified as suspicious and pass them to the MHRA for investigation.”
The Falsified Medicines Directive

However, just because the problem is rare, doesn’t mean there is no risk. According to Anabela Marçal, Head of Committees and Inspections at the European Medicines Agency (EMA), it is estimated that more than 30 million counterfeit medicines were seized at EU borders between 2010 and 2015. Growing concerns about the incidence of falsified medicines in the legitimate supply chain led the EU to introduce the Falsified Medicines Directive (FMD) in 2011.2

Some of its measures are already in effect, including stricter regulations for active ingredients, and new rules for internet pharmacies. But the biggest change for prescribers and pharmacists is set to go live on 9 February 2019. The new medicine verification system is designed to ensure the integrity of products, and authenticate medicines at the time of supply to the patient.

All medicine packs will have to have a 2D matrix code printed on them by the manufacturer. These will contain four pieces of information: the product code, batch number and expiry date that packs already carry, and also a serialisation number that is unique to that pack.

Serialisation means that each individual pack can be tracked on its entire journey, from factory to patient. Just before it is given to the patient, the pack’s 2D code will be scanned by the dispenser. This will verify that it is authentic, and the code will be ‘decommissioned’ from the system’s database. It will prevent the empty carton being re-used or otherwise sold on, as that individual code no longer exists on the system.

“The manufacturers will upload all that pack information onto the European Medicines Verification System (EMVS) and, once it has been uploaded there, the system will determine what country or countries the pack data applies to, and send the information to the relevant national systems,” says Graham Smith, General Manager of Healthcare and Pharmacy at serialisation specialist TraceLink.

“If it identifies that the pack doesn’t exist when they try to decommission it, the system will raise an alert to the European Medicines Verification Organisation, and also the manufacturer and the MHRA, to notify of a possible issue of falsification,” says Jerome Bertin, General Manager of SecurMed, the non-profit organisation that has been established in the UK to run the national verification system. “That will institute a set of processes at the MHRA and the manufacturer to identify where it entered the supply chain, and therefore they can focus on which organisation the medicine came from so they can put a stop to it.”

Every pack will also require an anti-tampering device to be applied to stop fraudsters breaking into stolen legitimate packs and replacing the medicine with something else, allowing them to sell on both the genuine pack with fake contents masquerading as the real thing, and also the legitimate medicine. Manufacturers will be able to use any form of anti-tamper technology, as long as it irreversibly shows that the pack has been opened.

What if hackers were able to access the European system and add new, fake serialisation numbers so their falsified medicines appeared legitimate? Blockchain, the technology that underpins digital currencies such as bitcoin, could one day provide an additional layer of security. A traditional database is held on a centralised server, where all parties – manufacturer, distributor, wholesaler and pharmacist – share their data. Blockchain makes it almost impossible to tamper with the data.

Data are added in ‘blocks’, and each block contains the new information, a timestamp, and all the data from the previous block in encrypted form. Once the block has been added, its data can’t be changed without changing all the subsequent blocks too. The blocks are stored across a peer-to-peer network, and can run on a simple laptop or desktop computer.

Importantly, every participant accessing the data has a full, duplicated version of the whole ledger, and every time someone adds something, it is encrypted and added to everyone’s copy. Although it is not required by the Falsified Medicines Directive (FMD), if it were implemented, this extra layer of security would make it virtually impossible for fraudsters to alter the database.

“A pharma company could put in blockchain for its supply chain and start tracking pharma products tomorrow,” says Pieter Vandevelde, Chief Executive Officer of Melbourne-based TBSx3, which specialises in supply chain security.

“Our founder survived cancer a couple of years ago, and wanted to do something about the stories of fake chemotherapy and kids dying as a result. The large pharma companies already have technology in place to comply with the regulation, and we are talking to their innovation people about what will be the next generation, so they are ready for the future.”

Box 1. The potential of blockchain

Decommissioning and recommissioning

It is possible to ‘recommission’ a scanned pack if it is no longer required by the patient or is not collected from the pharmacy. This must be done within 10 days of the decommissioning scan, and at the same place where it was decommissioned as part of the dispensing process.

But this produces another knock-on issue for dispensers, claims independent community pharmacist and Royal Pharmaceutical Society spokesman Sid Dajani. “At the moment, we dispense repeat prescriptions during quiet periods so we can keep a steady workflow going throughout the day. But because we cannot recommission medicines to put them back in stock after 10 days, the danger is that if the patient doesn’t collect them we cannot put them back in the system.

“We argued that we needed at least three months for recommissioning, and we managed to push it back up to 10 days from the proposed three days. But it could be a huge cost to the pharmacist...
and the NHS if we end up dispensing and not giving out medicines in time, as they would have to be thrown out.”

The changes that pharmacists and other dispensers will need to make are not insignificant. “We need three things to make this work: broadband, software and hardware,” Dajani says. “We also need the time to train our staff. What happens if there is an exceptional event? What about our pre-existing workstreams? Do we need extra staff?”

The changes will also come at a cost. Although the system up to the pharmacy wall will be paid for by industry, this is not the case for the pharmacy itself. “In many instances, pharmacists currently have the facility to scan linear barcodes that help in the identification of the medicine,” says The Association of the British Pharmaceutical Industry’s (ABPI’s) Director of Distribution and Supply, Rick Greville. “It can be straightforward to modify this, depending on what system they have. But the costs of modifying the tools falls on the pharmacy, and it is also inevitably going to mean a change of work practice.

“They may already scan a barcode, but probably not at the time of supply to the patient. The scan should also be captured in the pharmacy’s patient record system. I know some pharmacists see this as being more difficult, and there is no point in hiding the fact that for some pharmacies this is going to be a significant change, but it’s the nature of the regulations. I’m confident that pharmacy is a progressive enough profession that they will be able to keep on top of the obligations that they have as pharmacists.”

**Additional benefits – and problems**

However, the new system will bring some additional benefits. “It will help with accuracy checking and expiry date checking,” Dajani explains. “It can also help us find patients if there are faulty batches that are nothing to do with falsified medicines. In the event that there is a recall, we can find everyone who might have had that medicine. There is far greater scope to cut down on human error.” Patients need to be made aware that the additional step in the dispensing process may cause slight delays, he adds.

Brexit has, perhaps unsurprisingly, caused further problems – the date set for the UK exit from the EU is just seven weeks after the verification system goes live. “To have a system built for implementation for seven weeks is a bit of a no-no,” Greville says. “We have been reassured that the EU and the UK have agreed a transition period, so at the very least this system is expected to be operable for a period of about two years.”

But it will be important to have an effective system in place after this – whether that means staying in the EMVS or something new. The danger is that if the UK has weaker controls than the rest of Europe, it will become a prime target for fraudsters frustrated by their inability to access the EU market.

“[UK Health Minister] Lord O’Shaughnesssey has publicly stated that the UK is implementing the FMD in full,” says TraceLink’s Smith. “This makes absolute sense; we do not want to be the one country in Europe that is not implementing it. If the UK leaves, we don’t want to become the dumping ground in Europe for counterfeit medicines – the burglar will go to the house without an alarm.”

Dajani thinks it is very likely the February 2019 deadline will be missed. “It won’t be impossible to meet it, but it will be implausible,” he says. “It would be ridiculous to think we could get more than 11,000 pharmacies and their staff all across the UK up and ready by February 2019. We’ve got no information on the ground about end-user agreements, software updates, standard operating procedures, what to do if something is flagged up on the system, or what to do if our system goes down because of hardware issues.”

The EMA’s Marçal doesn’t believe it will be possible to completely eliminate falsified medicines, but the FMD represents a great advance. “There are additional guarantees to ensure patients are given a medicine that is safe and effective, and has been produced and distributed according to the legal requirements,” she says. “Independently of the legal requirements, what is important is that we are sure that what arrives at the patient is safe and effective.”

And patients are indeed at the heart of the reasons behind the new system. “The risks of implementing are far outweighed by the risks of not implementing it,” Dajani concludes. “It is open heart surgery for community pharmacy. It’s going to be very painful in the short term, but it will have long-term benefits.”

**References**


**Declaration of interests**

None to declare.

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