The state of play with FMD

With less than 18 months to go before the main provisions of the EU Falsified Medicines Directive come into force, writing on behalf of the UK FMD Working Group for Community Pharmacy, **Jonathan Buisson** examines the current state of play with FMD, including issues resulting from the confusion around Brexit

RIGHT ACROSS EUROPE, plans are being put in place to implement the medicines verification systems that lie at the heart of the EU Falsified Medicines Directive (FMD). With less than 18 months to go until the verification systems are due to go live, on February 9 2019, there is a real focus on the practical issues around FMD across the entire medicines supply chain.

Falsification of medicines is still an issue in the EU, with falsified products being discovered recently by authorities in Cyprus. There have also been issues raised by medicines regulators in the UK and Ireland around diversion of products from the legitimate supply chain.

Since the FMD Delegated Regulation [2016/161] was published last year, most Member States in the EU and EEA have set up National Medicines Verification Organisations (NMVOs) to oversee the process of establishing their national verification systems. These generally mirror the already established European Medicines Verification Organisation (EMVO) in having five "constituencies" as core members – research-based manufacturers, generic manufacturers, parallel traders, wholesalers and "dispensing entities" (ie, community and hospital pharmacies, and dispensing medical practices).

The UK has SecurMed, with its core members of ABPI, BGMA, BAEPD, HDA and a "dispensing entity" seat held jointly by NPA and CCA. SecurMed has recently signed a Letter of Intent with Arvato, a major European software company, to be its Blueprint Service Provider (BSP). The role of the BSP is to set up and run a National Medicines Verification System (NMVS), to connect this to the central European hub run by the EMVO, and to put in place links that will allow pharmacies, wholesalers and other organisations that legitimately supply medicines to connect to the NMVS. Arvato has begun discussing the technical details of this with the IT suppliers who provide pharmacies and wholesalers with their internal systems.

A lack of clarity

It will come as no great surprise to read that the UK's decision to leave the European Union is raising many questions around FMD, as it is with most other aspects of Government policy. In theory, FMD implementation will occur before Brexit (early February vs late March 2019 on current timescales), and therefore will be incorporated into UK legislation at the time of departure. However, no-one seems to have a crystal ball that still sees that clearly up to that point, or beyond, so there's a high degree of uncertainty.

At this stage, the main problems have been the lack of real clarity about what happens to FMD (and everything else) before and after Brexit, and the knock-on effects on the Department of Health and MHRA plans to consult on details of FMD. This consultation, initially due in January was on the verge of being signed off in April when the unexpected general election pushed it in to purdah. A post-election reshuffle at DH, caused by the previous pharmacy minister losing his seat, didn't help either and the consultation is now expected "in the autumn".

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Medicines packaging showing the proposed new 2D barcode

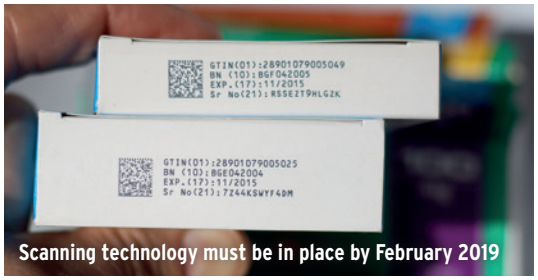
What pharmacies will have to do

Under FMD, community pharmacies will be required to authenticate all prescription medicines bearing the safety features "at the time of supplying them to the public." Authentication involves two steps:

- Checking that the anti-tamper device (ATD) sealing the bottle, pack or carton is still intact at the start of the dispensing process. This is a simple visual check.
- Scanning the 2D barcode on the pack, comparing the unique identifier data contained in it with data originally uploaded by manufacturers, and decommissioning the pack. This involves connecting to the National Medicines Verification System (NMVS) through either a stand-alone interface or through the PMR system.

If the data from the pack scan matches that held in NMVS then the decommissioning scan will change the pack's status to 'inactive—supplied'. This will prevent other packs that might have the same unique identifier from being dispensed, thereby reducing the risk that falsified products are handed to patients.

However, if the NMVS returns a negative message, such as that the product in question has been recalled by the manufacturer, then the pharmacy will need to take appropriate action in response.



Scanning technology must be in place by February 2019

Of equal interest to the consultation itself – which will only cover some minor details of FMD and not whether the whole thing should go ahead – will be a long-awaited impact assessment on the expected costs of FMD for the whole medicines supply chain. Pharmacy organisations, through the UK FMD Working Group for Community Pharmacy [see panel], have fed in their views. The bigger picture of costs will be pored over by negotiators on all sides, once it is published. Strong representations and responses to the consultation are expected, when it does finally appear.

What happens next?

Assuming that the DH/MHRA consultation goes ahead – itself a statement of intent – all parties and their IT suppliers will be looking to engage with SecurMed and Arvato to understand the finer details of what will be required to upgrade their software. Pharmacies will also be looking for clarity on what kind of scanners they might need to install, and how many.

The next steps will be a prototype or "test rig" UK medicines verification system (UKMVS) and an initial phase of pilot projects. These are likely to involve selected manufacturers, wholesalers and both independent and multiple pharmacies. Some European markets expect to start pilots in early 2018 but this may be slightly later in the UK.

At the same time, pharmacies will gradually see products bearing the two FMD "safety features" – 2D barcodes with unique identifiers, and anti-tamper devices (ATDs) – appearing on their shelves as manufacturers gear up. There will be no legal requirement to authenticate these products until February 2019.

As we move closer to the start, SecurMed and Arvato will begin an "onboarding" stage as each location that will be connected to the NMVS goes through a process of authenticating its identity and establishing a secure connection. There are tens of thousands of locations to connect, not just community pharmacies but also hospitals, GP surgeries, prisons and many other locations supplying medicines to patients.

Not all users of medicines will need to be connected, though. Some groups that use only small quantities of medicines – known as "Article 23 organisations" – will have their products authenticated by their wholesalers, but this doesn't include pharmacies, hospitals or GP surgeries. The expected DH/MHRA consultation will set out which groups will be covered in the UK.

FMD-related activity will increase as 2018 progresses as most organisations will want to be broadly ready ahead of the Christmas rush. This will include having upgraded PMR software (or installing stand-alone verification systems), installing new scanners as needed, and updating standard operating procedures in the light of experience from the pilot phase, as well as training for staff.

Clearly there are costs to pharmacy operators and our negotiators will be pressing the Government for clarity and funding to support this.

Although the full process of authentication and decommissioning of packs will start formally on February 9 2019, it will be something of a rolling start. There is no requirement to withdraw existing stock (that does not have safety features) until it expires, so pharmacies will have to use both the old and new processes for some time until all the older stock has been replaced. It's difficult to know how long this transition will last, but it could be a couple of years for slow-moving items.

The detailed information that will be carried on all new packs has the potential to be used to improve some pharmacy operations, including date and accuracy checks, and stock management, as well as ensuring patient safety. In time, FMD authentication should become a normal part of pharmacy operations.

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UK FMD Working Group for Community Pharmacy

The FMD Working Group was established in 2015 to bring together all the bodies representing community pharmacy owners in order to discuss the practical implementation of FMD within community pharmacies across the UK, and to influence the Government to seek cost-effective solutions to the issues raised by it.

The Working Group consists of representatives from NPA, AIMp, CCA, PSNC, CPW, CPS and CPNI. It meets regularly with DH and MHRA and with the main IT system suppliers for pharmacies in the UK.

In order to help community pharmacies understand what will be required, the Working Group has established **FMD Source** (www.fmdsource.co.uk) as a detailed and authoritative information hub. The site contains articles, diagrams and FAQs aimed at community pharmacists and their teams.

UKFMD
Working Group for Community Pharmacy

About the author

Jonathan Buisson leads the UK FMD Working Group for Community Pharmacy's communications sub-group and the development of **FMD Source**. He is International Pharmacy & Policy Manager at Walgreens Boots Alliance and an expert on FMD and its implications for the entire medicines supply chain.