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PSNC Briefing 058/18: Getting ready for FMD – a quick guide for the pharmacy team

In this briefing we answer common questions about the practicalities of complying with the FMD legislation.

The Falsified Medicines Directive (FMD) aims to prevent the entry of 'fake' medicines into the legal supply chain. From 9th February 2019, market authorisation holders must place two safety features on all prescription medicines distributed in Europe:

- a **unique identifier** (UI) in the form of a 2D data matrix (barcode) which contains the batch number, expiry date, product identifier and a unique serial number for the pack; and
- an **anti-tampering device** (ATD).

What will community pharmacy's role be?

Community pharmacy teams will be required as part of the dispensing process to:

- check the anti-tampering device to ensure it is intact prior to dispensing; and
- check the status of the pack in the UK's National Medicines Verification System (the UK hub) and change it from "active" to "inactive—supplied". This involves scanning the 2D barcode on each pack.

Which medicines will we need to authenticate?

Almost all prescription-only medicines, including generics, have to be authenticated; the exceptions include specials and several products which community pharmacies are unlikely to dispense. Non-prescription medicines do not need to be authenticated unless specified; the only OTC product currently specified is omeprazole.

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What happens when we scan a medicine?

When the barcode is scanned, the unique identifier is checked in the UK hub to see if it is a valid serial number and if it is marked as previously dispensed, recalled or expired; this is known as **verifying** the pack.

If the medicine is to be supplied to the patient, the system will then send another message to the UK hub to change the status of the product to "Inactive – decommissioned". This process is known as **decommissioning** and it prevents any other pack with the same unique identifier from being authenticated – duplication of packs being a sign that falsification might have occurred.

During dispensing, there will also be a check that the pack still has an intact anti-tampering device.

What if we dispense and decommission a medicine, but the patient doesn't return to collect it?

Once you have decommissioned a medicine, you can change its status in the UK hub back to active within ten days of decommissioning it; this is called **recommissioning**. After that time, the product cannot be recommissioned, and the legislation requires that any medicines which are not collected by the patient must be disposed of; they cannot be supplied to another patient. Note – this does not apply to split packs which have been decommissioned, but which the pharmacy has not yet dispensed.

Due to this "**ten-day rule**" most pharmacies will want to use a system which allows the product to be decommissioned at the point it is handed out to the patient. Many system suppliers have developed FMD software products which allow scanning of the unique identifier at the time of dispensing, but the products are not decommissioned until the medicines are collected by the patient.

When do we scan a medicine?

This will vary from pharmacy to pharmacy, depending on what best suits the workflow of the pharmacy and how the FMD software system has been designed; it can be when preparing a prescription or at handover to the patient, but the decommissioning of the product should normally occur at the time of handing the product to the patient, as this avoids problems related to the ten-day rule.

What about medicines licensed in other EU countries, but not here?

If the system cannot find the medicine's unique serial number in the UK hub, it will then check the EU-wide system to see if it appears on any other Member States' system.

What do we do about split packs?

When you part-dispense a medicine from a pack, you should decommission the pack when part of it is first supplied to a patient. The next time you dispense from this part-pack, you do not need to authenticate it again. However, since you are not scanning the pack on subsequent dispensings, you will not be alerted to recalls or expired medicines, so this will need to be checked manually.

How will the system deal with product recalls?

If a medicine is recalled, the manufacturer or parallel distributor will update the system, marking the relevant batch numbers as being recalled. If a pharmacy scans the barcode of a recalled medicine, the system will indicate that the product has been recalled.

How will the system deal with out-of-date medicines?

The 2D barcode contains the expiry date of the product. If you attempt to dispense the product after the expiry date has passed, the system will alert you to the fact that the medicine has expired.

What happens if a potential falsified medicine is detected?

You will get a message to say the medicine has already been marked as "inactive – supplied" and it is therefore a suspected falsified medicine. If this happens, you will need to contact the MHRA and the supplier of the product. You

may also want to verify any other packs of the same product which you have in stock.

What happens if a product does not have a 2D barcode?

In the first couple of years following implementation of FMD, there will be many medicines in the supply chain, in both wholesale and pharmacies, that are not FMD-compliant and do not have a 2D barcode. These medicines can continue to be dispensed until such supplies are exhausted or the items reach their expiry date. Some products may have a 2D barcode, but their details are not contained within the UK hub, as they were released into the market before the start of FMD.

Learn more about FMD

You can find out more about the detail of FMD, guidance on implementation and a list of system suppliers at: **fmdsource.co.uk**

FMD webinar: PSNC will be holding a webinar about FMD on Wednesday 7th November at 7.00pm. Book your place now: **psnc.org.uk/webinar**

If you have queries on this PSNC Briefing or you require more information please contact Daniel Ah-Thion, Community Pharmacy IT Lead.