

FMD: What you need to know & do

Issue 1: Intro & overview



About the Falsified Medicines Directive (FMD)

17th October 2018

- FMD comes into effect across the UK and the rest of Europe on 9th February 2019.
- It aims to prevent the supply of falsified medicines – i.e. medicines that may contain the wrong active ingredients, or the wrong amount of the correct active ingredients.
- Medicines placed on the market from 9th February will feature an Anti-Tampering Device (ATD) and a Unique Identifier (UI). (Manufacturers will have six months from the date of approval of variation to exhaust their 'old' stock and have 'new' stock ready for the market with the ADT and UI.)
- Community pharmacies need to be compliant with the new rules – this means registering with SecurMed UK, checking your IT systems are compliant, and changing SOPs and processes.

**16 weeks
to go!**

Implications for pharmacies

Pharmacy teams will be required to:

- Check the Anti-Tampering Device (ATD) is intact "at the time of supply to the patient". ATDs will vary but could include shrink-wrapping, tamper-proof labels and glue. (You can check ATDs when medicines arrive in your pharmacy but must then check them again at the time of supply.)
- Scan the Unique Identifier (UI) on each medicine "at the time of supply to the patient" to verify it is registered on the UK's national medicines verification system (SecurMed UK), which will be linked to the EU-wide verification system.
- Scan the UI again to 'decommission' the medicine just before handing it over to the patient / delivery driver. The medicine's status on SecurMed UK will change from 'Active' to 'Inactive – Supplied'.

Examples of ATDs & UIs

This graphic from the FMD Source website shows what medicine packets are likely to look like from February 2019.

Image from <https://fmdsource.co.uk>



*Note: This is just a summary. Please visit <https://fmdsource.co.uk> for the full official guidance

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What does “at the time of supply” mean?

It covers the supply process, i.e. from selecting the packet/bottle to handing it over to the patient or delivery driver. Checking and verification can be done at any point in this process but decommissioning (i.e. changing the status to ‘Inactive – Supplied’) should be done at the latest possible moment before handover to the patient/driver.

Monitored Dosage Systems, splitting packs & dispensing multiple medications

Pharmacies will still be able to split packs and prepare compliance aids e.g. Monitored Dosage Systems (MDS) when FMD comes into effect. Pharmacy teams will need to check the ATD and UI when the pack is opened and first dispensed. When preparing MDS trays, pharmacy teams will need to check the ATD and UI, and decommission each medicine when placing it into the tray. The MDS tray won't need to be scanned / decommissioned again at the point it is handed over to the patient / delivery driver. Pharmacies will be able to use aggregated barcodes when dispensing multiple medicines for the same patient **if your IT system allows this** i.e. you could check the ATD and verify the UI for each medicine being dispensed, then create an aggregated barcode for the whole bag and scan this to decommission all medicines supplied.

What about Brexit?

Pharmacies are being advised to make sure they are compliant with FMD by 9th February 2019, regardless of Brexit. The NPA is currently advising its members not to sign long-term contracts.

Actions your pharmacy needs to take

- **Visit the FMD Source website.** This is the [official guidance for community pharmacies](#) from the UK FMD Working Group for Community Pharmacy, which includes representatives from CCA, NPA and AIMp and PSNC, as well as the representative bodies for Scotland, Wales and Northern Ireland.
- **Check your IT systems will be compliant.** You may need additional IT hardware & software. There are [lots of suppliers](#) and many PMR providers are adding FMD functions. There are also some apps. Speak to providers and decide which system is best for you.
- **Register with SecurMed UK when registration opens** for community pharmacies. [Registration is likely to open shortly](#). We will keep you posted via the GMLPC newsletter and these FMD updates.
- **Develop new SOPs & ensure staff are trained** in the new processes in time for February 2019. We will produce further updates between now and February 2019.

FMD Briefing and Q&A Event: Thursday 22nd November, 6.30pm-9.30pm

Join us at the **AJ Bell Stadium**, M30 7EY for this event with **Raj Patel, Chair of the UK FMD Working Group for Community Pharmacy**. <https://psnc.org.uk/greater-manchester-lpc/our-events/fmd-quality-payments-ig-everything-you-need-to-know/> **Send questions for Raj to enquiries@gmlpc.org.uk**.

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