

This guide is intended to support contractors in explaining what Falsified Medicines Directive (FMD) is, its implications and what you need to consider.

The information contained has been collated from the PSNC and FMD Source websites for Contractors in the LPC.

## What is the Falsified Medicines Directive?

- FMD comes into effect across the UK and the rest of Europe on 9<sup>th</sup> 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 9<sup>th</sup> 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 ATD 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.

## What are the implications for Community Pharmacy?

### 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’.

## What about Brexit?

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

## 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>

## 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.

## 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.** [Register here](#)
- **Develop new SOPs & ensure staff are trained** in the new processes in time for February 2019.
- **Watch the FMD webinar from PSNC** available now on the [PSNC website](#).

## Choosing an FMD IT supplier

Pharmacies may need new IT hardware/software to meet the requirements of the Falsified Medicines Directive (FMD). You will need IT that enables you to scan the Unique Identifier – a barcode unique to each medicine package/bottle – and connect to SecurMed UK (the UK's national medicines verification system) to verify that the medicine can be dispensed and then 'decommission' it from the system when you supply it to the patient.

### There are two types of FMD IT supplier:

- Standalone options – these are separate from your PMR
  - Integrated options – some PMR suppliers are offering FMD solutions integrated with their PMR There are pros and cons to both, so the best thing is to speak to a range of providers and decide what is best for your pharmacy.

## Useful tips & guidance

**Don't rush into a decision.** Although you need to choose a system before you can register with SecurMed UK, you still have time to explore your options carefully so there is no need to panic.

**Avoid signing long-term contracts if possible.** Pharmacies do need to comply with FMD by 9<sup>th</sup> February 2019, regardless of Brexit, but it is less clear whether things will change in future years although it is likely the UK will continue to have some form of medicines verification system.

**Use the information & guidance available.** The FMD Source website has a [list of suppliers](#). The NPA has published a [comparison of several standalone FMD suppliers](#). The [NPA website](#) features a recorded webinar and information about two standalone options: FMD IT Limited and Tracelink.

## What is SecurMed UK? (national medicines verification system)

SecurMed UK is the national medicines verification system that will enable your pharmacy to scan, check and decommission medicines at the time of supply to the patient. Your pharmacy must be connected to SecurMed UK before FMD comes into effect on 9<sup>th</sup> February 2019.

## Before you register with SecurMed UK

- Check whether you will need additional hardware / software to connect to SecurMed UK (e.g. a system that can read barcodes).
- Choose your IT system – e.g. IT integrated with your PMR or a standalone option that will let you scan barcodes and communicate with SecurMed UK. There is a [list of suppliers on the FMD Source website](#). The NPA website has a [sheet that compares various standalone FMD solutions](#).
- You must know what IT system you will use to connect to SecurMed UK before you register with them.
- Create an account on the SecurMed UK website by [signing up here](#). You will need to

enter your

**'End User Location' (i.e. your pharmacy location), an 'End User Location Contact' (i.e. the person SecurMed UK should liaise with), and your Software Supplier. You don't need to register individuals who will be using the system.**

- Download a copy of the [Registration Guidance](#), which explains more about the fields you need to complete and how the registration process works.

## How to register with SecurMed UK

- You register your pharmacy location(s), not the individual(s) who will be using the system.
- There are different processes, depending on whether you are registering one location or multiple locations. SecurMed UK recommends that anyone who needs to register **1 to 5 locations** does them individually using the **Single Registration** process. If you need to register **more than 5** locations, SecurMed UK recommends using the Bulk Registration process.
- If your pharmacy also has a wholesaling function, you will need to complete a separate registration process for that as well as one for your dispensing registration.
- You will need the following information to hand before you can complete registration. You can save draft versions, though, and return to it later if you don't have all the details to hand. The [Registration Guidance](#) explains what these terms mean. We have copied the information below from the [registration portal on the SecurMed UK website](#):
  - Name of Legal Entity, as it appears in the Authorising or Registration database
  - Registered Address for the End User Location
  - End User Location Function(s)
  - Authorising or Registration Body for the Location and Registration ID
  - Name, Email and Business Phone for the End User Location Primary Contact
  - Name and Email for an End User Location System Contact
  - Your Software Supplier Name, Software Name and Version

## Single Registration (for 1-5 pharmacies):

- Open the [registration portal](#).
- Click the Single Registration box at the bottom of that page.
- Sign into your SecurMed UK account.
- Follow the instructions, entering the requested information.
- Agree to the [End User Licence Agreement](#) terms and conditions – make sure you are authorised to do this on behalf of your pharmacy.

- Complete registration.
- SecurMed UK will verify the information you have submitted. This usually takes 10-15 working days. SecurMed UK will contact you if they have any queries about your submission. Otherwise, you will receive your access credentials by email and by post within 10-15 working days.
- SecurMed UK will upload your pharmacy's data onto the national medicines verification system.
- You then need to use information from both the email and the postal information to validate your connection to SecurMed UK. This will include a username, a password and a web link so you or your software supplier can download your software certificate. Your username and password will be sent by post to your pharmacy's End User Location Contact. The link will be sent to the email address you have registered on the system.
- Once you have received your username, password and the email, follow the instructions in that email to download and install your certificate. Then log in using your username and password.
- Contact [registration@securmed.org.uk](mailto:registration@securmed.org.uk) if you have not received your username, password and emailed link within 15 working days of registration.

### **Bulk Registration (for more than 5 pharmacies):**

- Open the [registration portal](#).
- Click the Bulk Registration box at the bottom of that page.
- Sign into your SecurMed UK account.
- Follow the instructions, entering the requested information.
- SecurMedUK will check your bulk upload for formatting and data integrity.
- A member of their customer service team will contact you within 10-15 working days to explain what happens next, including how and when you should expect to receive your access credentials.
- Once your data has been verified, SecurMed UK will send you a username, password and a link to download a certificate for each of your locations.
- Contact SecurMed UK on [registration@securmed.org.uk](mailto:registration@securmed.org.uk) if you have not heard from their customer service team within 15 working days of registration.

**Note:** This is a summary of the full guidance from SecurMed UK. We strongly advise that you read the full guidance carefully on the [End User Registration page of their website](#)