FMD: What you need to know & do
Issue 3: Registering with SecurMed UK

GMLPC — Supporting Community Pharmacy in Greater Manchester

About the Falsified Medicines Directive (FMD)

7th November 2018

13 weeks to go!

- 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). (Manufactures 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.

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 9th 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 <u>before</u> 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 <u>don't</u> 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.

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

- 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 <u>and</u> 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 if you have not received your username, password and emailed link within 15 working days of registration.

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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 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, either on the End User Registration page of their website or by downloading their Registration Guidance.

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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