Falsified Medicines Directive (FMD)

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FMD: background

Aims to prevent falsified medicines entering the supply chain

- Approved by European Parliament
- Two mandatory safety features
- Allows medicines to be verified and authenticated
- To be implemented from **9 February 2019**
  - The impact of Brexit is currently unknown

FMD: background

- FMD requires :
  - Mandatory safety features on medicine packaging; **an anti-tamper device (ATD) and unique identifier (UI)** in the form of a 2D barcode
  - All online pharmacies register and display an EU wide logo
  - Restrictions on the import of active ingredients
  - Heightened record keeping requirements for wholesalers

FMD medicine safety features

Anti-tampering device

Safety features

Unique Identifier

Verifying and authenticating medicines

Manufacturers enter each medicines UI code to the **National Medicines Verification System** (SecurMed UK)

Pharmacies will be required to authenticate medicines "*at the time of supplying it to the public*"

This includes checking the **ATD** is still intact

And **scanning the UI** on the medicines outer packaging – referred to as '**decommissioning**'

Verifying and authenticating medicines

- There are two potential messages displayed once the UI has been scanned:

"Active"

- Medicine can be dispensed as long as the ATD is undamaged
- If the ATD is broken in order to dispense the medicine, this is exempt
- Successfully **decommissioned**

"Inactive"

- **Cannot** be supplied
- Additional messages include "already dispensed", "recalled", "withdrawn", "stolen" or "locked"

Decommissioned medicines

- Decommissioned medicine status change from:

wholesalers will verify the status of any product returned and any products with an "active" status will not be accepted

- If the product is not supplied, the status can be reversed

Reversing the medicine status

- Reversing the "*decommissioned*" status of a medicine can only occur if:
  - It takes place at the **same pharmacy** it was decommissioned
  - It occurs no more than **10 days** after decommissioning
  - The product has **not expired**
  - The product has not been recalled, withdrawn, stolen or intended for destruction
  - The medicine has **not been supplied** to a patient

Enforcement and monitoring

Department of Health	• Update legislation and set penalties
Medicines and Healthcare products Regulatory Agency (MHRA)	• Enforcement for manufacturers and wholesalers
General Pharmaceutical Council (GPhC) and Pharmaceutical Society of Northern Ireland (PSNI)	• Enforcement for community pharmacies

Implications for pharmacy contractors

- All community pharmacies will be required to:
  - Connect to the UK National Medicines Verification System
  - Update software
  - Obtain scanners
  - Introduce SOPs

Scanning and decommissioning medicines

"At the time of supplying it to the public" *is not defined but the FMD process must be completed before the medicine is released to the patient*

- **'Aggregated barcodes'** may can be used where more than one medicine is dispensed
  - This code links multiple items together and allows decommissioning of all items in one go by scanning the aggregated code on the bag label
- **'10 day' rule**

Split packs and MDS

Split packs

- Check the ATD and scan UI when **first opening** a pack
- Remainder of pack does **not** require further checks before use

MDS

- Before dispensing into an MDS, ATDs must be checked and UI scanned to decommission the product

Potential decommissioning points

During assembly

During accuracy check

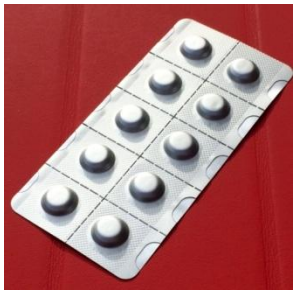
At point of hand out

At point of hand out with aggregated code

FAQs

Do GSL and P medicines need to be decommissioned before supplying?

- Non-prescription medicines are **not** included under FMD
- Therefore do **not** require decommissioning
  - The only exception is OTC omeprazole
- Unlicensed specials and appliances/devices do **not** require decommissioning



How do I deal with medicines that do not have a UI code?

- There may be medicines in the supply chain which do not have a 2D barcode by **February 2019**
- These can still be dispensed
- They are **not** required to be decommissioned

Who will pay for the additional equipment and training required?

- Pharmacies will be responsible for any costs associated with obtaining or updating software and hardware
- Total costs unknown