Falsified Medicines Directive (FMD)

Leyla Hannbeck  MRPharmS, MBA, MSc, MA
NPA Chief Pharmacist and Director of Pharmacy
Falsified medicines: the facts

• Falsified medicines may:
  – Be fraudulently mislabelled
  – Contain low quality ingredients
  – Contain the wrong dose
  – Contain wrong ingredients
  – Have fake packaging

• Falsified medicines do **not** pass efficacy, evaluation, quality and safety required for EU authorisation and MHRA authorisation
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

[Diagram showing anti-tampering device, safety features, and unique identifier with images of a product label and a QR code with data: NDC: 59148 011 13, SN: 100000000001, EXP: AUG 22 2015, Lot: AB100613]
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:
  - 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

- “Active”
- “Inactive”
  - Cannot be supplied
  - Additional messages include “already dispensed”, “recalled”, “withdrawn”, “stolen” or “locked”
Decommissioned medicines

- Decommissioned medicine status change from:
  - “Active”
  - “Inactive – dispensed”

- 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
Decommissioning points and patient safety concerns

During assembly or during accuracy check

- Additional step/increase workload
- Time period between assembly and handing out
- Increased pressure/distraction
Decommissioning points and patient safety concerns

At point of hand out with/without aggregated code

- Prescription bags need to be re-opened
- Training required for all support staff
- Increased workload/pressure
How close are we to implementing FMD?

• The UK FMD Working Group for Community Pharmacy work ongoing to ensure the implementation within the time frame

• Brexit – questions over how Brexit will affect the implementation of FMD
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
Can we still dispense PI medicines?

• Yes
• PIs will be re-packaged and re-labelled for the intended country
• This includes a new UI and barcode and ATD (if required)
• Brexit may impact the position of parallel traded products
I have a Wholesale Dealers License – do I have additional FMD requirements?

- Pharmacies with a WDL will be required to meet both the requirements for pharmacies and wholesalers
- This will require a number of additional steps
- It is advisable to become familiar with the Deregulated Regulation (2016/161)
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
Questions