The Falsified Medicines Directive (FMD) will be rolled out in Europe from February 2019 to address the threat of fake medicines and will impact the entire supply chain.

JULIA ROBINSON

The National Medicines Verification System (NMVS) will send back the status of the product as either “active”, meaning it can go on to be distributed or dispensed, or “inactive”, meaning it cannot be distributed or dispensed. This might happen if the pack has been withdrawn, stolen or already dispensed. The NMVS will raise an alert to authorities if a potential falsified medicine is identified.

EUROPEAN MEDICINES VERIFICATION SYSTEM

The European Medicines Verification System (EMVS) is a data repository that stores the identification data of all medicines packs in the European Union. It transmits data from manufacturers to all of the National Medicines Verification Systems (NMVS).

WHOLESALEs

Wholesalers only scan and verify medicines that do not come directly from the manufacturer or pre-wholesaler. This is called risk-based verification, and means that a high percentage of medicines will not need to be verified or decommissioned by wholesalers. However, they do decommission medicines on behalf of other suppliers, such as dentists and care homes.

COMMUNITY PHARMACY

On receiving medicines, pharmacy staff check the anti-tampering device (ATD) is intact. The UI code is scanned and verified against the NMVS. Only once verified can the medicine be decommissioned, meaning its status in the NMVS is changed from “active” to “inactive – dispensed”. This prevents the same UI being verified more than once. The medicine is decommissioned at the time of supplying it to the patient.

FMD: HOW IT WILL WORK

WHO WILL BE IMPACTED BY THE FMD IN THE UK?

15,000 community pharmacies
260 acute NHS hospitals
190 private hospitals
1,200 dispensing doctors
7,500 GP practices and surgeries
1,500 authorised wholesalers/distributors
790 market authorisation holders
66 million patients

SAFETY FEATURES

Unique identifier (UI)

The UI is a unique 2D barcode made up of four key elements (shown below). If the pack size permits, it will also carry the same information printed in text adjacent to the barcode.

- Must include: product code, unique serialisation number, expiry date and batch number
- NDC: 12345 678 910
- SN: 100000002
- EXP: JAN 30 2018
- Lot: YZ987654

Anti-tampering device (ATD)
The exact nature of the physical ATD will be decided by the manufacturer. If the ATD is broken, the medicine cannot be supplied.

This might happen if the pack has been withdrawn, stolen or already dispensed. The NMVS will raise an alert to authorities if a potential falsified medicine is identified.