INFOGRAPHIC

FMD: HOW IT WILL WORK

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.

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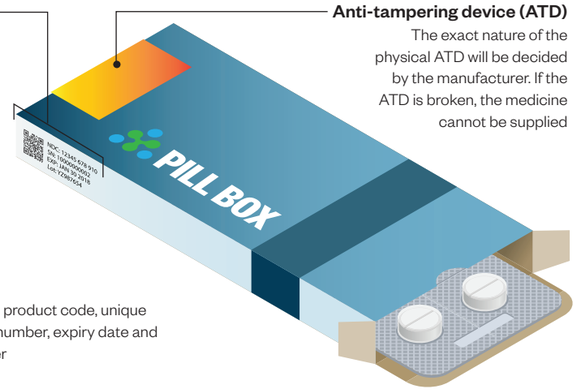
SAFETY FEATURES

Under the FMD, all new packs of prescription medicines put on the market from February 2019 will have to have two safety features: a unique identifier (UI) and an anti-tampering device (ATD)

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

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



NDC: 12345 678 910
SN: 100000002
EXP: JAN 30 2018
Lot: YZ987654

The FMD 2D barcode is a data matrix, similar to the QR code shown above

Must include: product code, unique serialisation number, expiry date and batch number

1 MANUFACTURERS

Manufacturers apply the unique identifier (UI) code to their pack labelling (see 'safety features'), add the anti-tampering device (ATD) and upload the UI code to the European Medicines Verification System (EMVS)

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)

2 PRE-WHOLESALER

Manufacturers store medicines in a pre-wholesaler, which then sells them on to the wholesaler

3 WHOLESALERS

Wholesalers only scan and verify medicines that do not come directly from a 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

NATIONAL MEDICINES VERIFICATION SYSTEM

When a medicine is scanned, 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 (Medicines and Healthcare products Regulatory Agency) if a potential falsified medicine is identified

UI code is scanned at the community pharmacy and verified by the NMVS

4 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

UI code is scanned at the hospital pharmacy and verified by the NMVS

5 HOSPITAL PHARMACY

The product follows the same process as in community pharmacy, but can be decommissioned at any time after verification

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

Infographic: Mark Watkinson

Editorial advisers: Jerome Bertin, UK general manager, SecurMed, and Martin Sawer, executive director, Healthcare Distribution Association (HDA UK)

Sources: Association of the British Pharmaceutical Industry, Healthcare Distribution Association, National Pharmacy Association, Pharmaceutical Services Negotiating Committee, Royal Pharmaceutical Society, SecurMed UK, TraceLink, UK FMD Working Group for Community Pharmacy, *J Generic Med* 2014;11:169