Falsified Medicines Directive (FMD)

WHAT IS THE FMD?

The FMD comes into effect in Europe on 9th February 2019 to ensure that medicines in the EU are safe and that trade in medicines is properly controlled

From 9th February 2019, under the European FMD, market authorisation holders are required to place two safety features on all new packs of prescription medicines placed on the market in Europe:

- an anti-tamper device (ATD)
- each packet of medication from a manufacturer will have a unique identifier (UI) in the form of a 2D data matrix (barcode), which will be scanned at various fixed points along the supply chain to determine its authenticity:

This will be scanned out of manufacturers' and wholesalers' and into dispensaries

The person supplying the medicine to the patient will scan the pack during the dispensing process, verifying the pack as a legitimate item and decommissioning it (from a Europe-wide list and making the code number no longer viable).

WHAT DO THE CHANGES MEAN IN PRACTICE?

Dispensing contractors are required to comply as part of the dispensing process for products that bear safety features:

- **check the anti-tampering device (ATD)** to ensure it is intact prior to dispensing
- **change the status of the pack in the UK's National Medicines Verification System (NMVS)** from "active" to "inactive—supplied". This involves scanning the 2D barcode on each pack and electronically communicating with the NMVS.

For more information on the implementation of FMD please see the following links;

Gov.uk
https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features

Pharmaceutical Services Negotiating Committee (PSNC)
https://psnc.org.uk/contract-it/pharmacy-regulation/falsified-medicines-directive/

The Pharmaceutical Journal
https://www.pharmaceutical-journal.com/your-rps/what-is-the-falsified-medicines-directive/20201820.article?firstPass=false