Falsified Medicines Directive

PURPOSE

This document is to provide a brief consolidated view of the implementation of the Falsified Medicines Directive (FMD), primarily for GP representative organisations such as the BMA, and RCGP.

WHAT IS THE FALSIFIED MEDICINES DIRECTIVE?

The EU Falsified Medicines Directive (2011/62/EU) (FMD) was adopted in 2011 and introduced new harmonised measures to ensure that medicines in the European Union (EU) are safe and that trade in medicines is properly controlled.

The final part of the Directive, the 'safety features' Delegated Regulation (EU) 2016/161) came into force on 9 February 2019, this applies to almost all prescription-only medicines and selected others.

These safety features are:

- a unique identifier (a 2D data matrix code and human readable information) which will be placed on medical products that can be scanned at fixed points along the supply chain
- tamper evident features (anti-tampering devices) on the pack

The unique identifier comprises:

- a product code which allows the identification of at least the name of the medicine, the common name, the pharmaceutical form, the strength, the pack size, and the pack type
- a serial number which is a numeric or alphanumeric sequence of a maximum of 20 characters randomly generated
- a batch number
- an expiry date who If the member state to which the medicine is being supplied requires it, the unique identifier will also need to include the national reimbursement number (note that this is not applicable in the UK). The unique identifier must be printed on the pack in a 2D data-matrix code and be printed in a way in which the information can be read by the human eye.

A full explanation and further guidance is available from the Medicines and Healthcare products Regulatory Agency (MHRA) - https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features

GP Specific implementation

The 'Safety Features' Delegated Regulation, part of the EU Falsified Medicines Directive (FMD), came into force in the UK on 9 February 2019. NHS Digital have produced some sector specific guidance in the form of internet-based toolkits, available at the in the 'Links' section below. General Practices, as healthcare institutions, are legally required to comply.

Additional software and hardware will be required to meet these new requirements. This will apply to

- All practices (approximately 7,200) where medications are personally administered (e.g. vaccinations) – the software and the supporting GP IT enabling requirements are a core & mandated requirement. Designated GP IT funding sources i.e. GP IT Futures nominal CCG allocations, GP IT Revenue and GP IT Capital can be used to support these requirements as appropriate.
- Dispensing practices (approximately 1,000) operating under pharmaceutical dispensing regulations will be required to meet this capability. As this is part of the dispensing function the software and the supporting enabling requirements are a practice responsibility to provide.

End User Registration

In order to connect to the UK's National Medications Verification System (NMVS), GP practices will need to register with SecurMed via the link below:

https://www.securmed.org.uk/register/end-user-registration/

SecurMed is a not-for-profit organisation that runs the NMVS and is overseen by the DHSC and the MHRA.

Useful Links

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

FMD compliance progress - https://www.securmed.org.uk/nmvs-progress/

GP & Dispensing Doctors' toolkit

- https://digital.nhs.uk/services/falsified-medicines-directive-fmd

Government statement relating to Brexit (Section 1.11 for falsified medicines) - https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal