

**From Acting Chief Pharmaceutical Officer
Mrs Cathy Harrison**



To: Community Pharmacy Contractors

[By email]

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Dear Colleague,

FALSIFIED MEDICINES DIRECTIVE (FMD)

The Falsified Medicines Directive (Directive 2011/62/EU) was published on 1 July 2011 and has applied since 2 January 2013. Its aim is to prevent the entry into the legal supply chain of falsified medicinal products. The Commission Delegated Regulation (EU) 2016/161 also sets out detailed rules for new safety features to appear on the packaging of medicinal products intended for human use.

From **9 February 2019**, marketing authorisation holders are required to place safety features on all new packs of prescription medicines placed on the market in Europe:

- a **unique identifier** (UI) in the form of a 2D data matrix (barcode) which can be scanned at various points along the supply chain to determine its authenticity; and
- an **anti-tamper device** (ATD).

Products currently available that do not have the safety features can continue to be dispensed. However, in order to comply with the requirements of the FMD, community pharmacy contractors are required as part of the dispensing process (from 9 February 2019 and for products that bear safety features) to:

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

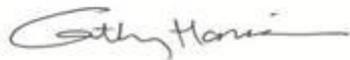
barcode on each pack and communicating with the National Medicine Verification System (NMVS).

SecurMed UK is a not-for-profit company set up to establish the UK Medicines Verification System as required under the Delegated Regulation of the EU Falsified Medicines Directive. If you have not already registered with SecurMed it is important that you do so at the earliest opportunity. Further details on the registration process is available from: **www.securmed.org.uk**

A UK FMD Working Group was established to bring together the main pharmacy bodies representing community pharmacy to influence and inform the implementation of the FMD in the UK. Community Pharmacy Northern Ireland (CPNI) has been a member of the group which has produced helpful guidance and resources for contractors available from - **<https://fmdsource.co.uk>**

You will also be aware of the funding that has been made available to contractors to support implementation of the FMD and the Health and Social Care Board has communicated separately on how to access that funding.

Yours sincerely,



Mrs Cathy Harrison
Acting Chief Pharmaceutical Officer