Dear Contractor

Falsified Medicines Directive: If you have not registered - do it now – it's the law!

As you know, the Falsified Medicines Directive is now in force.

From **9th February 2019**, market authorisation holders have been required to place two safety features on all prescription medicines distributed in Europe:

(1) a unique identifier (UI) in the form of a 2D data matrix (barcode) which contains the batch number, expiry date, product identifier and a unique serial number for the pack; and

(2) an anti-tampering device (ATD).

From **9th February 2019,** community pharmacy teams have been required as part of the dispensing process to:

(1) check the anti-tampering device to ensure it is intact prior to dispensing; and

(2) check the status of the pack ('verification') in the UK's National Medicines Verification System (the UK hub) and change it from "active" to "inactive—supplied" ('decommissioning'). This involves scanning the 2D barcode on each pack.

Registration

The law requires you to comply with the Directive and registering with the UK's National Medicines Verification Organisation (**SecurMed UK)** is the first step in getting ready for the implementation of FMD.

IF YOU HAVE NOT REGISTERED – DO IT NOW BY FOLLOWING THIS LINK

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

Once the request is verified, access credentials will be sent back via both email and postal mail in 10 to 15 days. The content of **both** will need to be used in conjunction to validate connection. There is no fee associated with the registration process.
For those pharmacies already fully engaged with the process or for those just starting off, the following links may be of help:

An introduction to FMD

This will give you the background to the Directive:
https://fmdsource.co.uk/introduction-to-fmd/

FAQs and practical implications for FMD

This will help you deal with some of the more common questions raised by community pharmacists:
https://fmdsource.co.uk/faqs/fmd-faqs-practical-implications-for-community-pharmacies/

How to report a falsified pack

Any instances of suspected falsification (including physical signs of tampering) is to be reported in the usual way via the yellow card reporting system:

https://yellowcard.mhra.gov.uk/

Standard Operating Procedures

It is important that you have appropriate SOPs in place which include the FMD processes. Links to some of the organisations that can help you with this include:
https://www.npa.co.uk/login/
https://www.uca.org.uk/members-home

Flow Charts: Community pharmacy aggregation, verification and decommissioning

This links to a handy flow-chart dealing with the dispensing process:
https://developer.nhs.uk/wpcontent/uploads/2018/11/FMD_Community_Process_DNv1.pdf

Guidance for dealing with FMD alerts

In the early stages of roll out, the system may generate a significant number of alerts. This will help you deal with them. The updated wording of the 11 Alert messages and 1 related system message produced by the UK NMVS can be found at this link:
https://www.securmed.org.uk/wp-content/uploads/2019/02/Changes-to-UK-NMVS-Alerts-wording-26-02-19.pdf

Community pharmacies holding a wholesaler dealers licence

For those pharmacies holding a wholesale dealers licence, information on what you should have in place can be found here:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/769581/MHRA-guidance_for_wholesalers.pdf

Funding

Applications for funding to assist implementation of FMD in Northern Ireland can be made by accessing this link:
http://www.hscboard.hscni.net/download/PUBLICATIONS/pharmacy_and_medicines_management/correspondence/Transformation-Funding-Allocations2.pdf

Kind Regards,

SENT FOR AND BEHALF OF GERARD GREENE | Chief Executive

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Gerard