Future of the 'safety features' measures under FMD in Great Britain and Northern Ireland

Update from UK FMD Working Group for Community Pharmacy

Now that the UK has left the EU and the Transition Period ends on 31st December 2020, some regulatory requirements will no longer apply. However, certain EU legislation will continue to have effect in Northern Ireland under the Northern Ireland Protocol.

Pharmacies in Great Britain

The 'safety features' elements of the EU Falsified Medicines Directive (FMD, 2011/62/EU) and Delegated Regulation (2016/161) cease to have effect in Great Britain from 31st December 2020. This means that pharmacies (and other end users such as wholesalers, hospitals and others handling or supplying medicines) will no longer be required by law to verify and decommission unique identifiers on prescription medicine packs.

- End users in Great Britain will be disconnected automatically from the UK National Medicines Verification System (UKMVS) run by SecurMed UK. This means that it will no longer be possible to verify and authenticate packs from 1st January 2021. Pharmacy operators and system suppliers need to check that any integrated pharmacy systems with FMD functions are no longer actively connecting to or seeking a response from the UKMVS after the end of 2020. Stand-alone FMD systems can simply be turned off.
- Integrated pharmacy systems can still use batch details, expiry dates or product details (GTINs) from packs' 2D barcodes while these packs are still in circulation. However, pack serial numbers no longer have any function. These packs remain valid and can be dispensed for as long as they are still in date.
- SecurMed UK will continue to provide end user registration and necessary support up to 31st December 2020 for end users in Great Britain.

Pharmacies in Northern Ireland

Under the terms of the Northern Ireland Protocol, part of the UK's Withdrawal Agreement with the EU, FMD will still apply in Northern Ireland, for at least four years (until the NI Protocol is due to be reviewed).

- End users in Northern Ireland will remain connected to the UKMVS. They need to continue to verify and decommission any packs with the FMD safety features (unique identifiers and anti-tamper devices) in line with the requirements of relevant EU and UK medicines legislation.
- SecurMed UK will continue to provide end user registration and necessary support to enable Northern Ireland end users to decommission packs with FMD identifier features in to 2021 and beyond.

The UK participated in discussions with the EU to agree a phased implementation of medicines regulations in Northern Ireland, under the NI Protocol, by 1 Jan 2022. The UK published a statement, agreed with the EU, on 5 Nov 2020 confirming a 12-month phased implementation of the Falsified Medicines Directive and regulatory importation requirements for medicines moving from GB to NI. Work is continuing with the EU to agree operational specifics. Please check the latest guidance for industry, the first version of which was due to be published soon after the release of this document.

https://www.gov.uk/government/news/irelandnorthern-ireland-specialised-committee-05- november-2020

Future national falsified medicines system

The Medicines and Medical Devices Bill (progressing through Parliament) would enable the Government to make regulations aimed at preventing falsified medicines from entering the medicine supply chain. This could include establishing a national system based on the unique identification of individual packs that enables medicines to be authenticated and identified if tampered with. The Government will have to consult with industry stakeholders, including pharmacy organisations, before introducing any new Regulations. No timetable has been set by the Government for consultation.

Actions to take

Great Britain: End users should check that any integrated pharmacy systems are no longer actively connecting to or seeking a response from UKMVS from the end of 2020. Turn off or disconnect any stand-alone FMD systems after 31st December.

Northern Ireland: End users should ensure they are registered with SecurMed UK (www.securmed.org.uk), if they have not already done so. Pharmacy teams should continue to verify and decommission FMD-compliant packs of prescription medicines. Refresher training should be carried out if needed.

Q&A

How do I register for access to the UKMVS?

https://securmed.org.uk/what-do-you-want-to-do/registration-process/

How do I get help?

In the first instance please contact your Software Supplier. Check the SecurMed UK website: www.securmed.org.uk

Further information is available on FMD Source (fmdsource.co.uk).

The UK FMD Working Group for Community Pharmacy brings together the main pharmacy bodies representing community pharmacy to influence and inform the implementation of FMD in the UK

16.11.2020

Revision History

Version Number	Date	Revision Details	Author(s)
1.0	16 November 2021		Joanne Hibbert-Gorst

Contact us

For more information contact:
Telephone: 0344 209 2601