SecurMed
The UK Medicines Verification Organisation

14th December 2020

Important communication for End Users regarding changes under the Falsified Medicines Directive (FMD) for Great Britain and Northern Ireland with effect from January 2021

Future of the 'safety features' measures under FMD

The United Kingdom formally departed from the European Union on 31st January 2020, entering into a Transition Period lasting until 31st December 2020. During the Transition Period the UK remained in the single market and consequently remained fully aligned to EU Law. This means that the Falsified Medicines Directive (FMD) and associated Delegated Regulation (DR) applies to all in the UK supply chain until 31st December 2020, as if the UK were still a member of the EU.

The United Kingdom comprises of Great Britain and Northern Ireland. The Great Britain countries are England, Scotland, Wales together with the Crown Dependencies of Isle of Man and Channel Islands. At the end of the Transition Period, 23.00 GMT on 31st December 2020, GB countries will no longer be subject to the 'safety features' elements of the EU Falsified Medicines Directive (FMD, 2011/62/EU) and the Delegated Regulation (EU/2016/161). However, under the Northern Ireland Protocol, the FMD and Delegated Regulation continue to apply in Northern Ireland.

The UK FMD Working Group for Community Pharmacy released a communication clarifying the position for pharmacies and other end users, such as wholesalers and distributors, hospitals, dispensing doctors and others handling or supplying medicines on 16th November 2020.

Update from UK FMD Working Group for Community Pharmacy

Community Pharmacy, Wholesalers, Distributors, Hospitals, GP Practices, Health Centres, In-/Out-Patient Clinics in Great Britain

- 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. Operators in these sectors and system suppliers need to check that any integrated 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 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.**

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Community Pharmacy, Wholesalers, Distributors, Hospitals, GP Practices, Health Centres, In-/Out-Patient Clinics 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 into 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 1st January 2022. The UK published a statement, agreed with the EU, on 5th November 2020 confirming a phased implementation of up to 12 months of the Falsified Medicines Directive and regulatory importation requirements for medicines moving from GB to NI. Work is continuing with the EU and the regulators to agree operational specifics. Please check the latest UK Government guidance on www.gov.uk .

Actions to take:

Great Britain: End users should check that any integrated 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 2020.

Software suppliers to end users acting as registration contacts with SecurMed UK, should notify their GB end users of the disconnection.

Northern Ireland: End users should ensure they are registered with SecurMed UK (www.securmed.org.uk), if they have not already done so.

Help with the system:

In the first instance please contact your Software Supplier.

Yours sincerely

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