Falsified Medicines Directive update

The UK FMD Working Group for Community Pharmacy has issued an update on the Falsified Medicines Directive (FMD). Now that the UK has left the EU and the Transition Period ends on 31 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.

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, including dispensing doctors) will no longer be required by law to verify and decommission unique identifiers on prescription medicine packs.

The working group has advised end users to check that any integrated pharmacy systems are no longer actively connecting to or seeking a response from UKMVS from the end of 2020.

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 1 January 2021.

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 31 December 2020 for end users in Great Britain.

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

The FMD will still apply in Northern Ireland, for at least four years (until the NI Protocol is due to be reviewed).

Future national falsified medicines system

The **Medicines and Medical Devices Bill** 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.