The Falsified Medicines Directive -
Supply chain and packaging requirements

The objective of the Falsified Medicines Directive (FMD) is to protect patients from falsified medicines which might make their way into the legal distribution chain. Falsified medicines are 'fake' medicines which pass themselves off as authorised medicines – they may contain low quality ingredients or wrong doses, fake packaging or wrong ingredients or have their identity or source deliberately misrepresented. The Directive does not cover 'unintentional' quality defects.

The FMD introduces stricter controls, tightens the supply chain and requires additional outer packaging safety features in order to exclude falsified medicines from the supply chain. The dates for the introduction of the various requirements are set out below.

Safety features

Marketing authorisation holders will be required to place safety features on the outer packaging of most prescription medicines. These consist in a 2D data matrix code with a unique identifier and an anti-tampering device. The safety features are combined with an end-to-end, EU-wide verification system (referred to as the repositories system) under which authenticity will generally be checked by the dispensing pharmacist at the point of supply and, in some cases, also at the wholesale level. The intended effect of this verification system is to exclude unauthorised medicines from the legal market for medicines. The safety features and repositories system should be fully implemented by 9 February 2019.

EU-wide logo for online sales

An EU-wide logo to identify legal online pharmacies. The logo includes embedded cryptography linking through to a list of authorised pharmacies. All online pharmacies or retailers legally operating in the EU should register with the MHRA and display the logo from 1 July 2015. Read more

Import controls on active substances

Imports of active substances must be accompanied by a certificate from the competent authority of the exporting third country confirming that the standards of good manufacturing and control of the plant are equivalent to those in the EU. (This is waived for some countries.) This requirement has applied since 2 July 2013. Read more

Manufacturing guidelines

EU Member States must ensure that manufacturers in their territories comply with principles and guidelines on good manufacturing practice for active substances. Such principles and guidelines have been defined by the EU Commission and have applied by regulation since 25 May 2015. Read more

Going forward, only the first item above – safety features – remains to be implemented.

The repositories system is being set up and managed by not-for-profit legal entities in the EU Member States. These entities are to be established by manufacturers and marketing authorisation holders of products bearing the safety features. The UK entity is Securmed UK. The cost of the repositories system is to be borne by manufacturers.

Market authorisation holders are obliged to implement the safety features on the packaging by 19 February 2019. These safety features are likely to affect product information requirements. The European Medicines Agency has published guidance for market authorisation holders. Read more

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