



Welcome to the first edition of the Safety Features newsletter.

Background

In February 2016 the European Parliament and Council published the Delegated Regulation on the 'Safety Features' aspects of the Falsified Medicines Directive (https://ec.europa.eu/health/human-use/falsified_medicines_en). This introduces two mandatory changes that will allow medicines to be verified and authenticated. The delegated regulation comes into force in the UK in 2019. The safety features are:

- a unique identifier (a 2D data matrix code and human readable information) to be placed on medical products that can be scanned at fixed points along the supply chain
- tamper evident features on the pack

Our work to date

Since the publication, MHRA and the Department of Health have been working with stakeholders from throughout the medicines supply chain on implementation. Two key aspects of this work have been:

- (a) the impact assessment – an evidence-based assessment which considered the costs and benefits of implementing this policy
- (b) the UK position on the small number of flexibilities given in the Regulation to allow countries to adapt it to the characteristics of their supply chain.

Your views on both of these aspects of work will be gathered through a formal public consultation which will be launched later in 2017. If you have specific questions, please send them to our mailbox - engagement@mhra.gsi.gov.uk.

Get involved with the National Medicines Verification System

An end-to-end verification system requires the setting up a repositories IT system. The UK system will be linked to a pan-European repository, which will enable the verification of prescription medicines at the time of supply to UK patients.



SecurMed UK has been established as the UK Medicines Verification Organisation, and as a not for profit organisation it will deliver the UK Medicines Verification System. SecurMed UK has been incorporated by the principle representative supply chain stakeholder associations (Association of British Pharmaceutical Industry, British Association of European Pharmaceutical Distributors, British Generics Manufacturers Association, Company Chemists Association, Healthcare Distribution Association and National Pharmacy Association) as required by the EU Falsified Medicines Directive. Jerome Bertin was appointed as UK General Manager from 1 January 2017; he will be responsible for the implementation of the UK repository and interfaces to time, and to budget, using an IT service provider (Blueprint Service Provider, or BSP) selected by the SecurMed UK Board. If you have any specific questions relating to SecurMed, please contact Jerome Bertin - jerome.bertin@securmed.org.uk.

Registering to receive updates

Please help us reach as many stakeholders as possible by forwarding this newsletter to others you think may be interested.

This newsletter will be sent out on a regular basis with helpful information for all stakeholders, and aims to keep you updated on the latest developments with implementation. For further information, visit our [webpages](#), which contain all currently available information.

To register to receive this newsletter directly in future, please email by return with the following:

Your name

Your organisation (if applicable)

Your title (if applicable)

Best regards,

MHRA Safety Features team