



November 2018

## FMD Safety Features – Newsletter 12

### **Public Consultation**

The public consultation on the flexibilities within the Delegated Regulation on Safety Features closed on 23 September, with more than 50 responses received from a wide range of stakeholders. Analysis of all consultation responses is currently underway with the aim to publish the final Government response later this year.

### **FMD Communications Group**

MHRA and DHSC re-launched the Communications Group through a productive workshop in July, which identified existing information and guidance, explored the gaps, and agreed who would fill them.

In future, all stakeholders impacted by the implementation will be able to find guidance related to their position in the supply chain of medicines in the UK, whether produced by the Government or stakeholder-led, through Gov.uk, which can be found [here](#), and representatives on the Comms group will be working to promote this to others. Further guidance will be issued by the Government in coming weeks, which will also be available here.

Please email [fmd.safetyfeatures@mhra.gov.uk](mailto:fmd.safetyfeatures@mhra.gov.uk) to suggest posting additional guidance that you have found useful.

### **Designated wholesalers**

It is important to be clear that MHRA cannot compel an MAH or manufacturer to designate any wholesalers, Wholesalers must consider all requirements of the Delegated Regulation when seeking designation by a manufacturer or Marketing Authorisation Holder (MAH).

The European Medicines Verification Organisation (EMVO) has produced guidance: <https://emvo-medicines.eu/new/wp-content/uploads/FMD-Workshop-130718-Ai2a-Designated-Wholesaler-v1.pdf>.

The key point is that any designated wholesaler must have a written contract with the MAH or manufacturer to cover the storage and distribution of their product.

Further queries should be directed to EMVO, which may also have system constraints regarding the number of wholesalers designated by each MAH or manufacturer.

### **Aggregated Codes**

We understand various parts of the supply chain are interested in the use of aggregated codes for the scanning of medicines under the new FMD requirements.

Aggregation is allowed under the FMD Regulation, however there is nothing legally binding that requires wholesalers or manufacturers to supply aggregate codes for batches of medicines, in addition to the mandatory unique identifier on each pack of medicine in scope of the new requirements. This is not a flexibility in the Regulation and therefore we cannot mandate its use.

The UK has inputted into the recent EU process to publish some guidance on implementing FMD in the hospital setting. We are clear that to protect the integrity of FMD system aggregation must be fully integrated into the EU repository system. Any short-term solutions adopted while a fully-integrated system is developed must fully protect the integrity of the FMD. The document published was adopted by the EU expert group on safety features: [https://ec.europa.eu/health/sites/health/files/files/falsified\\_medicines/2018\\_hospitalsetting\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/2018_hospitalsetting_en.pdf).

It is important to note that organisations supplying medicines to the public bear the ultimate responsibility for verifying and decommissioning medicines. We are encouraging those supplying medicines to the public to work with their suppliers to seek agreement in their contracts about when and where aggregation can be used.

Stakeholders may wish to consider circumstances when the use of aggregation can be agreed, for example a hospital operating with a wholesale dealers licence supplying another hospital which is a separate legal entity.

#### **Message on aggregated codes from the UK Healthcare Distribution Association (HDA):**

Wholesalers and distributors understand the benefits of aggregation of data, but note that the FMD verification system, as currently configured, does not allow for aggregated verification and decommissioning of the Unique Identifiers.

Therefore, any aggregation will have to be separate, and outside of, the remit of both the National Medicines Verification System (NMVS) and The National Medicines Verification Organisation (NMVO).

The necessary investment, operational changes and technologies will not be in place for this to be routinely available for NHS Secondary Care by February 2019.

### **SecurMed UK Update**

SecurMed have now opened End User registration for FMD. All end user organisations will be able to register as either a single location or via a bulk registration for larger

organisations; and will need to sign up to an end use license agreement. There are no charges to use the system for wholesalers, pharmacies, hospitals and GP/ health centres.

The UK test system is now connected to the European Medicines Verification System (EMVS) and business proving is in progress. Recently two parallel distributors (PDs) were able to load data via EMVS into the UK system and an NHS hospital pharmacy was able to verify and decommission packs from those PDs.

The UK Medicines Verification System (UK MVS) is now connected to EMVS and operationally live.

The SecurMed UK Annual MAH Operational Fee for 2019 will be GBP £20,000.

Please refer to the updated SecurMed UK website at [www.securmed.org.uk](http://www.securmed.org.uk) for more details on end user registration, the FMD implementation and information for MAHs and IT software providers. Questions relating to FMD process or compliance should be addressed to [FMD.safetyfeatures@mhra.gov.uk](mailto:FMD.safetyfeatures@mhra.gov.uk)

### **Error messages and alerts**

Stakeholders have worked collaboratively to produce the attached charts, which intend to capture the key error messages and resulting actions that may need to be taken by those scanning products throughout the supply chain. There is a clean version and one with explanatory comments, as well as a separate guidance document.

Ahead of finalising this guide for use across the system, any feedback or comments would be very welcome – please contact Jonathan directly [Jonathan.Buisson@wba.com](mailto:Jonathan.Buisson@wba.com)

### **NHS Digital**

#### ***FMD Google+ forum for NHS staff***

NHS Digital welcomes anyone with an NHS email address to join their FMD online discussion forum. This forum can be used to ask questions, start debates, share ideas, solve problems and promote learning and change. If you would like to join please email [fmd@nhs.net](mailto:fmd@nhs.net) with google+ in the title and they will set you up.

#### ***FMD toolkit for secondary care***

The first of the FMD toolkits is now available here: <https://developer.nhs.uk/learn/falsified-medicines-directive-fmd-implementation-toolkits/>

Toolkits for community pharmacy and GP practices will be available shortly. If you have any suggestions or any additional information that would help improve the toolkit you can email the NHS Digital team at [fmd@nhs.net](mailto:fmd@nhs.net)

## **Mailbox**

MHRA will continue to answer your questions about FMD through our dedicated mailbox, [FMD.safetyfeatures@mhra.gov.uk](mailto:FMD.safetyfeatures@mhra.gov.uk) Please send queries to this mailbox rather than other MHRA email addresses.

The mailbox is monitored daily and we aim to issue a response as quickly as we can; thank you for bearing with us during the consultation period. If you don't currently receive a copy of the newsletter and would like to, please email by return with the following – your name, your organisation (if applicable) and your title (if applicable).

## **Our privacy policy**

At the Medicines and Healthcare products Regulatory Agency, we have recently published our new privacy policy in line with the new requirements of the General Data Protection Regulation. You can view this at the following link:

<https://www.gov.uk/government/publications/mhra-privacy-notice>

We retain your email address so that you and other stakeholders impacted by FMD can continue to receive the newsletter. If you wish to continue receiving the newsletter, no action is required. If you would like to unsubscribe from our mailing list, please reply with 'Unsubscribe' in the subject line.

Kindest Regards

MHRA Safety Features team