Medicines & Healthcare products Regulatory Agency

MHRA

FMD Safety Features – Wholesale Dealers Guidance

The following message is being sent to all UK Licensed Wholesale dealers, to support you in meeting the new FMD requirements.

The 'Safety Features' Delegated Regulation comes into force on 9 February next year. The Medicines and Healthcare products Regulatory Agency (MHRA) is continuing to work with stakeholders from across the supply chain to support implementation to the right standard and on time. We can reassure you that the MHRA does not underestimate the challenge and complexity of implementing FMD, not least the tight time-frame stakeholders have been working to.

The MHRA has been clear that its priority is to seek compliance, working pragmatically with suppliers to ensure that implementation doesn't prevent medicines from reaching the patients that need them. Our number one priority is the safety of the public.

All UK Wholesalers for Prescription Only Medicines holding WDA(H) licences are obliged to be able to verify and decommission medicine packs using the UK Medicines Verification System (UK MVS) under the EU Falsified Medicines Directive (FMD) from 9 February 2019, when the 'Safety Features' Delegated Regulation (2016/161/EU) comes into force. Wholesalers will need to consider the following messages from SecurMed UK, and further guidance from MHRA and Department of Health and Social Care (DHSC).

Please note there are no charges for wholesalers to use the UK MVS and the licence granted is free.

Further guidance and information

For a broader update on progress with the implementation of the Delegated Regulation, please see the attached newsletter (if you would like to sign up to future editions please email fmd.safetyfeatures@mhra.gov.uk, which is also used for addressing any questions about FMD in general to MHRA).

All available, relevant FMD information will be hosted or signposted on the following central webpage: https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features
Further guidance is expected to be issued by the Government in coming weeks.

SecurMed

The following message is from SecurMed UK, which is the UK's National Medicines Verification Organisation (UK MVO), a non-profit company set up to establish the UK Medicines Verification System (UK MVS) for the UK.

The advice to wholesalers is to progress the following four steps urgently, if you haven't done so already:

1. Prepare your IT solution and business for the FMD change
2. Review your operations and number of locations needing to comply
3. Register with SecurMed UK either as a single entity or in bulk (multiple locations)
4. Receive your user credentials and connect.

1. **Preparing a wholesaler IT solution and preparing for change**

Wholesalers will need to consult their IT department or IT service provider to make changes to their IT systems and business working practices; this includes establishing a connection to the UK MVS.

Arvato Systems, who is the IT provider sub-contracted by SecurMed UK to deliver the UK IT solution, provides a software developers' toolkit (SDK) to enable 3rd parties to create local connections to the UK MVS. The SDK contains a full set of technical documentation, a test environment enabling generation of sample pack serialisation numbers, sample code, test plans/test scripts and a technical helpdesk. The SDK is provided free of charge.

Wholesalers, or their IT providers, can register for this toolkit at www.sws-nmvs.eu. SecurMed UK will perform legitimacy (aka Bone fide) checks to verify that the wholesaler is a genuine organisation and their IT provider is authorised to act on their behalf. This is required under the 'Safety Features' Delegated Regulation, before granting access to this toolkit.

Alternatively for those who do not have an IT service provider, SecurMed UK provides a list of those registered suppliers offering solutions on their website at www.securmed.org.uk. It is up to the wholesaler to choose the supplier most suited to their needs.

2. **Reviewing operational locations needing to comply**

The 'Safety Features' Delegated Regulation requires the ability to carry out verification/decommissioning of medicines in scope at each of the wholesaling business locations that manages medicines. For businesses with more than one location, consideration needs to be given to which location(s) needs to be registered with SecurMed UK.

3. **Registering with SecurMed UK either as a single entity or in bulk (multiple locations)**

Wholesalers will need to register with SecurMed UK separately, as well as establishing their own local IT solution, to gain access to the UK MVS. Each wholesaler will need to submit registration details and sign up to an End User Licence Agreement (EULA). Wholesalers can submit registrations for a single location or in bulk for organisations with multiple locations.

Please note there are no charges for wholesalers to use the UK MVS and the licence granted under the EULA is free.

The SecurMed user registration process can be found at https://www.securmed.org.uk/register/end-user-registration.

Registration is now open and there is no deadline by which registration need to be completed.

4. **Receiving credentials and connecting**

Once a registration submission is completed, SecurMed UK will verify each applicant as required under the FMD Delegated Regulation, before issuing their user credentials. The user credentials will be sent back in two separate communications. These user credentials must be configured into the wholesaler IT solution to enable access to the UK Medicines Verification System. IT software providers should be in a position to assist in getting wholesalers connected.

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.

Where to find more information

For more information on SecurMed UK, the software developers' toolkit and user registration processes please visit the SecurMed website at www.securmed.org.uk and for links to other information https://www.securmed.org.uk/useful-links. For more information from SecurMed please email info@securmed.org.uk.

Further guidance update

The following message is the NCA response to common queries, further information has been provided with regards to: i) definition of legal entity; ii) designated wholesalers; iii) aggregated codes.

1. Definition of legal entity in relation to wholesalers
A Legal entity is a separate entity which operates in their own right. Examples of legal entity include but are not limited to:

- Limited companies,
- Unlimited companies,
- Private companies,
- Public companies,
- Companies limited by guarantee and having share capital or community interest
- Companies registered under the Companies Act 2006.
- A health centre,
- NHS primary dental services,
- NHS primary medical services maintained under the National Health Service Act 2006; the National Health Service (Wales) Act 2006; the National Health Service (Scotland) Act 1978; or the Health and Personal Social Services (Northern Ireland) Order 1972.
- Separate NHS secondary care providers

Example scenarios for existing business models:

Scenario #		**IF**	**Verification required upon receipt?**
1	An organisation with one WDA(H) and one Companies House number – supplies medicines to its own pharmacies.	The wholesale hub and pharmacies are all part of the same legal entity;	No Verification upon receipt is not required. products being moved to pharmacies will then need to be verified and decommissioned at the point of supply.
Scenario #		IF	Verification required upon receipt?
2	An organisation has a number of subsidiary companies (a), (b), etc each having their own WDA(H)	Company (a) are not designated by the original Marketing Authorisation Holder (MAH).	YES Verification upon receipt is required.

	and Companies House numbers. Product is supplied by company (a) to a different subsidiary company (b) (i.e. different legal entities)	Company (a) are designated by the original Marketing Authorisation Holder (MAH).	NO Verification upon receipt is not required.
3	An organisation moves products between two warehouses belonging to the same WDA(H) and same Companies House number. No sale takes place.	Same legal entity and no sale takes place.	NO Verification upon receipt is not required.
4	Organisation (c) with one WDA(H) and one Companies House number Has medicines stored by a third-party contractor – Organisation (d) No sale takes place Organisation (d) is contracted to hold medicines on behalf of Organisation (c). Organisation (d) hold a WDA(H) and separate Companies House number Organisation (d) is not designated.	Organisation (c) IS a designated wholesaler	No Verification upon receipt is not required by organisation (d).
		Organisation (c) is NOT a designated wholesaler.	YES Verification upon receipt is required by organisation (d).
		Products are physically returned to Organisation (c) from Organisation (d).	YES Verification upon receipt is required by organisation (d).
		Other wholesalers buy stock and receive it directly from organisation (d).	YES Verification upon receipt is required by other wholesalers

MAH – Marketing Authorisation Holder; MIA – Manufacturer / Importer Authorisation (licence); WDA(H) – Wholesale Dealers Authorisation for Human medicines (licence);

2. 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.

3. 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.
- 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 suppling 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.