Implementation of Falsified Medicines Directive in Clinical Homecare

Frequently Asked Questions

This FAQ document supplements the NCHA Position Statement Implementation of Falsified Medicines Directive in Clinical Homecare - The Way Forward" (version 1 dated 5th December 2018).

The position statement concludes that while the regulation is clear, there is the need for further scoping work which continues as detailed information about the FMD implementation becomes available. These answers to Frequently Asked Questions set out the NCHA's views on the interpretation of the FMD requirements and will be updated as further information becomes available.

Please note in order to aid reading, key sections have been identified. However, we advise readers to review all the questions and answers in their entirety as we have tried to avoid duplication of information across multiple answers.

Sections are as follows:

- General Questions
- Decommissioning
- Managing Returns and Recommissioning
- Error Messages

For comments, questions or requests for further information please contact info@clinicalhomecare.co.uk.

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General Questions

1. **Do I have to have separate systems for decommissioning or can my pharmacy system decommission items?**

Pharmacy system suppliers are looking at the implementation of FMD. It is entirely possible that a commercial pharmacy system could decommission the Unique Identifier from the repository automatically. NHS Digital has a programme within Domain E looking at potential options and guidance as to how this can be achieved and this may also align with the Department of Health's the NHS Scan4Safety work. Homecare Providers using bespoke systems will need work with their in-house team or system suppliers to develop this functionality where it is required.

2. **Who is going to pay for software and hardware changes -and how much will it cost?**

Each healthcare institution, including homecare providers, will need to purchase the equipment required to enable it to scan the unique identifier and undertake verification and decommissioning. This will require the development of software to link through to the repository system via software changes and/or stand-alone systems depending on how systems are configured and the support provided by your software supplier.

There is no standard or fixed cost. The cost of the required hardware and software changes will vary depending on the state of the relevant healthcare institutions existing systems/software and the extent of the changes required.

3. **If an existing licensed drug is used in a clinical trial, when would it need to be decommissioned?**

When a licensed medicine is intended to be used as an investigational medicinal product it must be decommissioned before it leaves the supply chain and becomes part of the clinical trial medication stock.

4. **How does FMD link to dm+d and GS1?**

The information stored in the 2D data matrix bar code will include a product code. The product code is likely to comprise the Global Trade Identification Number (GTIN). This will be a GS1 code and will make reference to the ISO IDMP coding system. There will be a mechanism put in place for the GTIN data to map across directly to the dm+d coding system and NHS Digital is looking at this in more detail.

5. **Am I allowed to use the Unique Identifier and other information to support tracking of my controlled drugs?**

Yes. Whilst the unique identifier will be removed from the FMD repository, the data contained within it will be mapped across to GTIN/ISO IDMP/dm+d and will still be readable within the 2D data matrix code. It will be able to be used within local IT systems as required locally to support medicines administration, closed loop checking, billing systems etc.

6. **All our stock is delivered to one site. When we supply to our other sites can the originating site decommission the drugs?**

Yes -providing the other sites are part of the same legal entity and there is no sale between the product being received and supplied to the public. Otherwise the receiving organisation will need to undertake the decommissioning.

7. **Do all homecare providers fall within the definition of a healthcare institution?**

All homecare Providers with a registered pharmacy or holding a wholesale dealer's licence fall within the definition of a healthcare institution. Homecare Providers who do **not** have a registered pharmacy may be eligible for exemption under Article 23 e.g. clinical service providers supplying anaphylaxis kits to nurses where prescribed patient medicines are supplied by another healthcare organisation. The wholesaler or pharmacy who is supplying the Article 23 organisation with the already decommissioned medicines will need to verify article 23 status of their customer.

8. **If I supply to other wholesalers, community pharmacy, hospices, or community hospitals does Article 23 apply? What will I have to do?**

As Homecare Providers hold both Wholesale Dealer's License and registered pharmacy status you will need to consider which stock will be subject to wholesaler dealing and which stock will be supplied to patients within your own legal entity acting as a pharmacy. Where a medicine is supplied labelled for administration to an individual patient, the FMD processes relating to dispensing should be followed, irrespective of whether the organisation is subsequently invoiced for the medicines under the provisions of your Wholesale Dealer's Licence.

Where a medicines is supplied via a wholesale transaction to another organisation as "stock" which that organisation then administers or supplies to an individual patient the FMD processes relating to wholesaling should be followed. All Healthcare institutions (includes all registered pharmacies and hospitals) must have their own processes for decommissioning products they supply to patients. If you supply any healthcare institution that is not part of the same legal entity as your organisation you would not be able to decommission on their behalf - they would need to make their own arrangements to decommission products that they supply to patients.

Work continues looking to adopt the flexibility afforded by Article 23 within the delegated regulation and the current proposed position (subject to a public consultation) is that wholesalers, including pharmacies with Wholesale Dealer's License's will be required to decommission products on behalf of a number of organisations that are not required to decommission products themselves - hospices would be one such organisation. A full list of the groups being considered under this flexibility can be found in the Delegated Regulation - https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf.

9. Can I track information about patients using the system?

Verification and decommissioning only provides information on the product. No patient related data is held or reported into the central FMD database. However local systems (such as ePrescribing, dispensing, patient records, billing/stock management) may be redesigned to utilise the unique identifier locally to link products to patients, however, this is not part of the regulatory requirements for FMD.

Decomissioning

10. What is the difference between decommissioning and verification?

Verification is a process that can take place at any time during movement of the medicine through the supply chain. It checks the Unique Identifier of the product against the repository to verify that there is a corresponding number within the repository placed there by the manufacturer indicating that a pack of the product was placed on the market by the manufacturer and that Unique Identifier has not already been decommissioned.

Decommissioning happens once only (unless a product's status is reverted) and takes place at the end of the supply chain close to the point of supply to an individual patient or when the product otherwise leaves the "controlled supply chain" (e.g. anaphylaxis medicines carried by a homecare nurse making home visits). Decommissioning removes the Unique Identifier from the repository. If a product is decommissioned in error, then it can be recommissioned within 10 calendar days. In this case, the product's status is reverted and it will need to be decommissioned again once supplied to the patient.

11. At what point can the medicines be decommissioned?

Generally there is no requirement for products to be decommissioned at the point of administration to the patient. The delegated regulation allows for the decommissioning of products within a healthcare institution to take place at any point whilst the product is in the possession of the institution provided that no sale takes place between the organisation who receives the product and the organisation who supplies to the public (Article 25(2)). It would therefore be for the healthcare institution to consider, given the operational procedures within its organisation, when it would be best for products to be scanned and decommissioned. Within a Homecare Provider this could be as they arrive in the on-site pharmacy or as they are moved to the dispensary, recognising that once decommissioned they cannot be "returned" to saleable stock after 10 days. It is preferable to ensure that decommissioning happens as close as possible to the patient use to ensure that the checks are current.

12. Where is the best place to decommission stock?

This is for individual healthcare institutions to determine given the operational procedures within the institution. Each institution would need to consider where

decommissioning fits best so that it has the minimum impact on the business processes.

Whilst the homecare provider's legal entity often holds both Wholesale Dealer's License and Pharmacy registration, it is unlikely that it would be appropriate for decommissioning to be performed as part of the wholesaler process applied to bulk stockholdings within the homecare provider. It would be possible for verification to take place as part of your organisations wholesale "goods-in" processes. It may be appropriate for decommissioning to take place at the point of replenishment of pharmacy stocks from the organisation's wholesale stock. Local assessment would be required.

Managing Returns & Recommissioning

13. We recycle medicines though our returns process –won't FMD prevent me from doing this?

Providing the product remains in the possession of the same legal entity, there is no FMD block to it being returned to the pharmacy and then going into local pharmacy stock before being supplied to another patient. All existing GDP good practice processes must still be followed and decisions documented.

Returns do not need to be recommissioned unless they are to be sold to another wholesaler or pharmacy. Returns cannot be recommissioned if more than 10 days has elapsed since the original decommissioning.

Error Messages

14. What happens if a staff member scans an ancillary, GSL or P pack to decommission it -when it doesn't need decommissioning?

The system will be designed to provide an appropriate message if a product is scanned that doesn't need to be. If Homecare Providers choose to train staff in which items to scan rather than scanning all items, adequate control process must be in place to ensure all Prescription Only medicines are decommissioned.

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History

Version	Date	Reason for change	Author
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