
Medicines are the most common intervention made across the NHS. It is essential that patient can have confidence in the medicines they are supplied and that systems are in place to prevent counterfeit or ‘Falsified Medicines’ that might contain ingredients, including active ingredients, which are not of a pharmaceutical grade or incorrect strength or indeed may contain no active ingredient. Falsified medicines are considered a major threat to public health with seizures by regulators increasing annually across the globe.

The Falsified Medicines Directive [FMD] (Directive 2011/62/EU1) was published on 1 July 2011 introducing a range of safety measures to ensure that Prescription Only Medicines in the EU are safe and that the trade in medicines is properly controlled. Its aim was to significantly reduce the risk of counterfeit medicines reaching patients.

The introduction of addition of safety features on to the outer packaging of medicines is the most significant change within the directive. The regulation obliges those supplying medicines to the public to verify authenticity of the product via the placement of a unique identifier (UI) barcode on each pack to allow verification of medicines throughout the supply chain and the addition of an anti-tamper evidence device (ATD). The requirements around the safety features apply from 9 February 2019.

The FMD applies all organisations supplying Prescription Only Medicines to the NHS (including manufacturers, wholesalers & parallel Importers) and all those who supply medicines to patients (e.g. community pharmacies, hospital pharmacies, general practice). Holders of MHRA Wholesale Dealers Authorisations will have to verify authenticity of any product not received directly from the manufacturers and will not be able to decommission products on behalf of healthcare institutions or pharmacies. Wholesalers may be permitted to decommission products for supplied to organisations that are NOT healthcare institutions (e.g. dentists, opticians, paramedics, etc.).2 This decision is subject to a public consultation on the Article 23 flexibility. Organisations including community pharmacies, hospital pharmacies and Dispensing doctors will be required to decommission products at the point of supply to a patient.

The MHRA produces a monthly newsletter about progress towards UK implementation of EU Falsified Medicines Directive. The newsletter is available by email request only to FMD.safetyfeatures@mhra.gov.uk.

The following Frequently Asked Questions have been produced to help raise awareness and understanding across secondary care.

It should be noted that NHS Digital are currently working alongside the NHS (NHS E and NHS I), DH, MHRA and SecurMed (the not for profit organisation that will establish and maintain the UK FMD repository) to scope out the end to end implementation of FMD and gain a greater understanding of business change implications. SecurMed are also leading a series of system supplier engagement sessions to help raise awareness in the supplier community.

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2 Full list available with Article 23 of the Commission Delegated Regulation (EU 2016/161)  
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1) 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 the product is authentic.

**Decommissioning** happens once only (unless a product’s status is reverted) and takes place at the end of the supply chain when the product is supplied to the patient or otherwise leaves control of the pharmacy (e.g. ward stock supply). Decommissioning removes the Unique Identifier (UI) from the repository.

If a product is decommissioned in error, then it can be recommissioned within 10 days. In this case, the product’s status is reverted and it will need to be decommissioned again once supplied to the patient.

2) I supply a hospice and community hospitals that are part of other organisations using my WDA - what will I have to do?

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) it that wholesalers, including hospitals with WDA’s will be required to decommission products on behalf of a number of groups - 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](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf)

Therefore if the Article 23 flexibility is adopted you, acting as a wholesaler, would be required to decommission products you supply to the hospice. However, if you supply any hospital (defined as a 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.

Where you have a WDA 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 section 10 pharmacy.

It is important that any organisation with a WDA adheres to the obligations in the delegated regulation.

3) Will nurses have to scan the barcode to decommission drugs?

Generally there is no requirement for nurses to decommission products. 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 an acute hospital this could be as they arrive in the on-site pharmacy or as they are moved to the ward, recognising that once removed from the repository they cannot be returned after 10 days. It may also be preferable to ensure that decommissioning happens as close as possible to the patient use to ensure that the checks are current.

4) Can I scan everything as I get it and then not decommission at the point of dispensing?

See above. As a hospital pharmacy is part of a healthcare institution then this would be possible, however this may not be the best option. Local assessment would be required.

5) How should I manage items dispensed as “owing’s” as patients may not collect them? Do I decommission when checked?

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This would depend on the processes in place around decommissioning within your organisation. Where decommissioning happens as close to the point of supply as possible then such products awaiting collection would be best decommissioned when collected by the patient. If products are decommissioned as they arrive at the healthcare institution there is no difficulty with these not collected “owings” being returned to stock and used for another patient.

6) 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.

7) How will all my robot stock get decommissioned - do I have to scan every pack after it leaves the robot?

Again this is for your organisation to determine where decommissioning takes place so that it has the minimum impact on the business processes within the organisation. If the software permits, the robot could decommission the stock on receipt or when the product is dispensed. This may involve changes to the automated systems software to decommission packs when issued from the robot.

8) Who is going to pay for software and hardware changes - and how much will it cost?

Each healthcare institution 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.

9) 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 problem with it being returned from a ward/other site to the pharmacy and then going into stock before being supplied to another ward. It does not need to be recommissioned (and cannot be if more than 10 days has elapsed since decommissioning). Software systems would require designing to either be able to ‘know’ that the pack has already been decommissioned by the organisation OR be able to handle the ‘already decommissioned’ message returned from the repository when decommissioning is reattempted.

10) Who will have to decommission my homecare supplied drugs?

Where medicines are dispensed on a “named patient” basis the medicines would be decommissioned by the organisation who supplies the medicine – i.e. the homecare company.

11) We have a Wholly Owned Subsidiary. Can the main pharmacy decommission the drugs used in this entity?

A Wholly Owned Subsidiary is a separate legal entity for tax purposes therefore that entity would be required to decommission any products supplied that are subject to the Falsified Medicines Directive.

12) What happens if a non-qualified staff member scans a 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. Adequate systems will be required in organisations to ensure all Prescription Only medicines are decommissioned. This may include ‘all stock’ type arrangements to prevent legal breaches.

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13) Can I track information about patients using the system?

Verification and decommissioning only provides information on the authenticity of the product in the system. No patient related data is held or reported into this system. However local systems (such as ePrescribing, billing/stock management) may be redesigned to utilise the UI locally to link products to patients outside the scope of the system.

14) Do I have to have separate systems for decommissioning or can my pharmacy system decommission items?

It is entirely possible that your pharmacy system could decommission the Unique Identifier (UI) from the repository. NHS Digital has a programme within Domain E looking at potential options and guidance as to how this can be achieved. Individual IT system suppliers may also develop tools to support this process. It may also align with the Department of Health’s the NHS Scan4Safety work.

15) Can a BD automated pharmacy robot decommission items directly?

The software changes required to support automated systems will need to be developed by the relevant system suppliers.

16) We are planning to introduce ward order assembly with a 3rd party providing the majority of stock items how will these medicines be decommissioned?

Local legal advice would be required to allow the organisation to determine the legal position taking into consideration who is the legal owner of the product and how decommissioning can take place so that it has the minimum impact on the business processes within the organisation. Where a separate legal entity is supplying a healthcare institution, the decommissioning will be the responsibility of the healthcare institution i.e. the hospital receiving the supplies. It would be potentially possible for this process to be supported by technological solutions using data provided by the 3rd party – i.e. all Unique Identifiers could be scanned by the 3rd party as part of the supply process and a software solution could support the healthcare institution to bulk decommission the medicines.

17) 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.

18) We outsource our compliance devices to Lloyds. Can they decommission the drugs even though the MCAs are returned to us to supply to the patient?

Lloyds will be “dispensing” the medicine against a prescription and will need to undertake the decommissioning of the medicine.

19) We are a hospital providing healthcare. We are not registered as a pharmacy nor do we have a WDA. Do we have to do anything?

Yes. As a healthcare institution you are required to decommission products that you supply to patients. This cannot be done by a wholesaler on your behalf.

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20) Does FMD apply to clinical trials materials? 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 trial medication stock.

21) 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 GTIN (Global Trade Identification Number). 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.

22) Am I allowed to use the Unique Identifier (UI) and other information to support tracking of my controlled drugs?

Yes. Whilst the UI 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.

While the scoping work commences there is limited information available about the details of the FMD implementation. However, if you have any further questions please email them to psc.su@nhs.net and they will be included in future updates to these FAQ’s.