Frequently Asked Questions – Secondary care services and the Falsified Medicines Directive (FMD) Version 2

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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/EU[1]) 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 (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. This update includes new questions raised to the above email address plus other forums including the Welsh pharmacy FMD working group.

It should be noted that NHS Digital are currently working alongside the NHS (NHS E and NHS I), DHSC, 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.

[1] Falsified Medicines Directive [FMD] (Directive 2011/62/EU)
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf
[2] Full list available with Article 23 of the Commission Delegated Regulation (EU 2016/161)

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Version 2 – additional Questions

2.1) Are NHS Ambulance trusts considered Healthcare Institutions or are they under article 23 flexibilities?

Subject to public consultation, the current government position for the purposes of FMD is to consider Ambulance Trusts as healthcare institutions and therefore they are required to decommission. In terms of individuals working within an emergency setting but either working in a healthcare institution (i.e. paramedics) or out of a healthcare institution, they are currently considered to fall under the Article 23 definition and therefore government is proposing, subject to public consultation, that wholesalers will decommission on their behalf. We would welcome consultation responses to support or challenge this position.

2.2) Do the Falsified Medicines Directive requirements apply to Mental Health trusts who do not have pharmacy supply services?

All NHS trusts are classified as Healthcare Institutions therefore all must ensure that they comply with the full regulations. Article 23 flexibilities do not apply.

2.3) Clinical trials that use existing medicinal products as part of trial protocols – who is responsible for decommissioning the licensed medicine? The company developing the trial, the hospital supplying the medicine or both? Plus would all of the product packs need decommissioning at the same time?

Where a hospital pharmacy is providing a licensed medicine as part of a clinical trial being undertaken within the hospital, the licensed medicine (if it were in scope for FMD) would need to be decommissioned either when re-packaged by the hospital pharmacy or when supplied to the patient if no repackaging is needed. If the Hospitals has not already decommissioned the stock on receipt then it should decommission when the pharmacy repackages and or labels it for use in a trial where there is no patient. Alternatively, if it is not already decommissioned decommission it when dispensed to the patient.

2.4) How will SecurMed make contact with hospitals to create their National Medicines Verification System (NMVS)? Who will be the contact (concern if just sent to CEO as will get 'lost' in trust systems) When will this happen? Will there need to be individual log-ins for any system or is it an organisation wide log in?

SecurMed are contacting stakeholders to support the on-boarding process but it is the responsibility of individual organisations to ensure their arrangements for on-boarding and FMD compliance are in place, not SecurMed's. For more information please contact SecurMed directly- info@securmed.org.uk.

2.5) Which scanner should I be purchasing?

The 2D barcode must meet the standards set out in the Delegated Regulation so that it can 'be correctly recognised and decoded throughout the Union by commonly-used scanning equipment'. To scan 2D barcodes you will require an optical image scanning (Camera) type scanner. These range in price from £37 upwards depending on the manufacturer and features. They will usually require a Windows computer with a USB connection. Further recommendations are being sought from standards bodies (GS1)

2.6) Will my automated pharmacy storage system be able to handle 2D barcodes?

The main system suppliers (BD and Omnicell) have confirmed that they are developing solutions to support decommissioning of medicines as required by the Falsified Medicines Directive. A range of installations will require upgrades to their scanning technology which will result in additional costs to trusts. BD have provided this information across all sites in the UK. Individual trusts that will require scanner upgrades have also been communicated with by BD. Pharmacy stock control system software enhancements are being developed to communicate directly with the NMVO's Arvato system.

2.7) My Healthcare Institution is supplied with small quantities of stock medicines across multiple sites by my third-party supplier. Why can they not decommission medicines used in my organisation?

In the Delegated Regulation, the Commission have stipulated that decommissioning should be completed as close to the time of dispensing as possible for safety purposes such as to ensure incidents of falsification are flagged and to aid with product recalls. As a healthcare institution it is not acceptable for hospitals/hospital pharmacies to subcontract their decommissioning obligations to wholesalers as the process is not in line with the provisions of Regulation (EU) No 2016/161: as they are not part of the same legal entity. Since the decommissioning would happen through the wholesaler's computer using the wholesaler's log-in ID, the decommissioning operation would be recorded in the system and in the audit trail as an operation performed by the wholesaler, and not by the hospital. This is not acceptable as the audit trail would not reflect the reality of the supply chain, as required by Article 35(1)(g) of the Regulation. Articles 23 and 26 of Regulation (EU) No 2016/161 are explicit about those cases where wholesalers are entitled to decommission the safety features on behalf of hospitals.

However, there is a scenario, compatible with Regulation (EU) No 2016/161, where wholesalers could facilitate the decommissioning operation of hospitals. The Delegated Regulation sets out that wholesalers could scan the packs in the hospital consignment to acquire the information on the UIs and encode such information into an aggregated code. Decommissioning would then be performed by the hospital by scanning the aggregated code. The only equipment needed for this operation would be a hand-held scanner and a computer (connected to the national repository).

****Further discussions on aggregation continue with the EU**

2.8) Will we be provided with software to support verification and decommissioning of medicines as required under the Falsified Medicines Directive?

No. Individual organisations are responsible for their local implementation of the regulations. Any software systems must be chosen and implemented locally to ensure compliance. Work is ongoing nationally to co-ordinate developments within the main systems (JAC & EMIS) through the NHS England Digital Medicines Programme. Other stand-alone software may be commissioned/developed by third parties to make verification and/or decommissioning easier (e.g. for bulk decommissioning of out-patient items awaiting collection or healthcare institution decommissioning of stock supplies from a third party when that healthcare institution does not have a pharmacy).

2.9) Cardiac arrest boxes may be assembled by 1 organisation but then sold to other organisations. Can the supplier decommission the medicines contained in the box?

DHSC and MHRA are continuing to develop a response to this question.

2.10) Where Community Interest Companies such as "not-for-profit" social enterprises exist will they have article 23 flexibilities? Some of these can be significant size healthcare providers.

This is dependant of whether or not they are classified as healthcare institutions. Further details as to the legal classifications are being sought.

2.11) As some Healthcare Institutions do not have the necessary infrastructure to decommission medicines received – as they have outsourced their stock supply to 3rd parties. Can selected staff in the supplying third-party be given formal honorary contracts from the receiving Healthcare Institution to allow them to decommission the drugs on the behalf of that organisation?

Given that the Delegated Regulation provides healthcare institutions with flexibility around where they decommission, as long as the supplying 3rd party is within the same legal entity as the healthcare institution who owns the stock then they can be given a contract to decommission on behalf of the organisation. However, if the 3rd party is not within the same legal entity and therefore transferring medicines to them would mean that ownership of the stock would change then no, they cannot be given a contract to decommission on their behalf.

2.12) If a drug shows up as falsified do we assume that the first barcode decommissioned from SecurMed was the authentic product and that the one we hold is then falsified? How can we be sure?

Not necessarily but the focus should be on the product in your possession and if it is showing as falsified it should not be dispensed to a patient and should be reported to the national competent authority, in the UK's case, the Medicines and Healthcare products Regulatory Agency (MHRA).

2.13) If we have used a medication that then proves to be falsified would we as healthcare professionals be held accountable?

Further information on sanctions and enforcement will be published as part of the Government's consultation on the implementation of 'safety features'. Under the Delegated Regulation the obligations on those who supply medicines to the public are to verify and decommission medicinal products.

2.14) What if there is an occasion when there was a clinical need for the patient to be treated with something and all the stock we hold we cannot verify?

If you cannot verify the stock because the IT system is down, as stated in the Delegated Regulation (Article 29), you are to record the details of the unique identifier and, once the technical problems are resolved, verify the products authenticity and decommission accordingly. The responsibility for developing Standards of Practise will lie with the profession and will need to reflect and depend on critical clinical need. It is also worth noting that SecurMed are looking at options for how data can be cached to remove the need for manual entry. For more information, please contact SecurMed directly via mailto:info@securmed.org.uk

2.15) As of Feb 9th 2019 all stock received by us will be verified one way or another but what about the stock we currently hold, how can that be verified?

The FMD 'safety features' system is not a track-and-trace system, it is an end-to-end verification system and therefore it is possible for stock to reach hospitals without verification. For instance, if a wholesaler receives stock directly from a manufacturer or from their designated manufacturer they do not have an obligation to verify that product.
Under the Delegated Regulation, from 9 February 2019 medicinal products released for sale or distribution must bear the safety features and must be verified and decommissioned. Whilst manufacturers have begun the process to add safety features, compliant FMD products can only be released from 9 February 2019 when they can be entered into the system. Products already on the market may not bear the safety features but do not have to be withdrawn and can be supplied to patients after this date and the same goes for packs already on the market with the safety features but not in the repository.
Further information on what is understood by "released for sale" can be found in the EU Commission Q&A document, question 7.13
https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_v9.pdf

2.16) What happens if the pharmacy system/SecurMed is down for reasons other than routine maintenance? We can still maintain the supply chain but would we need to verify retrospectively and again what happens if we've already used it and it cannot be verified?

See answer to 2.13 above. SecurMed are exploring options in this regard and they should be contacted directly.

2.17) If a product has an EU licence and so would be entered onto the central database but does not have a UK licence, would we be able to decommission it?

All products should be uploaded on to the system centrally via the European Medicines Verification Organisation (EMVO) - https://emvo-medicines.eu/pharmaceutical-companies/. Centrally authorised products are licensed for use across all EU member states. Data on packs intended for the UK market will be transmitted from the EU Hub to the UK National Medicines Verification System in line with the provisions in the Delegated Regulation.

2.18) Do you need to recommission when part packs are returned in order to decommission at the point of resupply to another point?

The Delegated Regulation takes into account the need for part packs to be supplied. Verification and decommissioning of the unique identifier must take place the first time the pack is opened. Reverting the status of split packs is not required for decommissioning against future prescriptions.

Also, if you are using the robot technology to decommission, would it cause issues being loaded multiple times and accessing the central database?

We were not clear on this question but it sounds like it is to do with access to the repository system and we would therefore recommend that you contact SecurMed directly.

2.19) Can a hospital that has a wholesaler dealer's licence, and supplies to hospitals without a pharmacy in another health board, decommission for them?

Under the obligations in the Delegated Regulation (Article 25) the current understanding is that persons supplying to the public must verify the safety features and decommission at any time the product is in the physical possession of the healthcare institution (provided no sale happens in between this process). As Article 23 highlights it is clear that wholesalers cannot decommission for those operating in a healthcare institution and therefore if establishments are not part of the same legal entity (i.e. a hospital in another health board) then they cannot have another entity decommission on their behalf and would need to make their own arrangements before supplying to patients. However, we are currently exploring at a European level what is understood 'by sale of product' and will share this update accordingly via guidance (these Secondary Care FAQs) when we have a clearer definition.

2.20) I have read the EU safety features for medicinal products for human use Questions and Answers Version 9 (https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_v9.pdf) Specifically:

2.20.1) Question: Once Regulation (EU) No 2016/161 applies, can manufacturers place the safety features, on a voluntary basis, on medicinal products not required to bear the safety features?

Answer: No. Once Regulation (EU) No 2016/161 applies, manufacturers cannot place the safety features on medicinal products not required to bear the safety features, unless the Member States have extended the scope of application of the unique identifier or of the anti-tampering device to those medicinal products in accordance with Article 54a(5) of Directive 2001/83/EC.

2.20.2) Question: Certain medicinal products are currently bearing an anti-tampering device on a voluntary basis. Are those products allowed to maintain the anti-tampering device once Regulation (EU) No 2016/161 applies, if they are not required to bear the safety features?

Answer: Once Regulation (EU) No 2016/161 applies, medicinal products can only bear an anti-tampering device if they are in the scope of Article 54a(1) of Directive 2001/83/EC (i.e. if they are medicinal products subject to prescription or medicinal products listed in Annex II of Regulation (EU)

No 2016/161) or if the Member State(s) where they are placed on the market extended the scope of the anti-tampering device to those medicinal products.

2.20.3) Does this mean that GSL and Pharmacy only medicines will not be allowed to have tamper evident safety features?

No, these areas relate to the flexibilities included within the Delegated Regulation and the DHSC/MHRA public consultation will identify that, under those flexibilities, the UK proposes to continue to allow anti-tampering devices to be added to products. However, the UK will not be intending on extending the scope of the Unique Identifier to include GSL, P and other medicines not specifically included in the Regulation (EU) No 2016/161.

2.21) Will the format of the barcodes to be printed on packaging be in GS1 format?

The requirement in the Delegated Regulations is that the coding complies with the ISO standard. GS1 coding is one such system which meets the standard. However other coding systems are available and also meet the standards. The likelihood is that the NHS procurement strategy will require all medicines to include a GS1 code if they are to be supplied to the NHS and this may drive the use of GS1 coding.

You may find this link useful: https://www.gs1uk.org/our-industries/healthcare/recent-legislation/the-falsified-medicines-directive

Version 1

1.1) 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.

1.2) 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

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

1.3) 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.

1.4) 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.

1.5) How should I manage items dispensed as "owing's" as patients may not collect them? Do I decommission when checked?

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.

1.6) 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.

1.7) 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.

1.8) 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.

1.9) 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.

1.10) 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.

1.11) 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.

1.12) 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.

1.13) 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.

1.14) 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.

1.15) 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.

1.16) 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.

1.17) 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.

1.18) 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.

1.19) 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.

1.20) 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.

1.21) 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.

1.22) 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.