The way forward for FMD in community pharmacy

Introduction

This document represents the consolidated views of the UK FMD Working Group for Community Pharmacy on the implementation of the "safety features" elements of the EU Falsified Medicines Directive (FMD) [Directive 2011/62/EU] in the UK. Under EU Delegated Regulation 2016/161, implementation is required to start in all Member States, including the UK, from 9th February 2019, although ongoing concerns about what the UK's exit from the European Union will mean for FMD add a level of complexity that is yet to be resolved. Within this document the term "FMD" generally refers to the safety features elements of the wider Directive.

There is much work still to do to ensure community pharmacy is ready. That includes:

- Updating IT systems and associated hardware
- Connecting community pharmacies to the verification system ("registration/on-boarding")
- Revising workflows and standard operating procedures
- Training staff
- Providing patient information

Appendix C contains a glossary of terms relating to FMD. The key terms are "safety features" – whereby each individual pack of a prescription medicine will have a randomised unique identifier and an anti-tampering device to prevent against falsification – and the associated processes of "verification", "authentication" and "decommissioning" by checking the unique identifiers against secure national and European databases.

The UK FMD Working Group for Community Pharmacy brings together the main trade and negotiating bodies representing community pharmacies. It works closely with the Department of Health and Social Care (DHSC) and the Medicines and Healthcare products Regulatory Agency (MHRA) to develop pragmatic solutions to aid the implementation of FMD in the UK. This guidance has been produced to help community pharmacy owners understand what is required and the options for their businesses.

What will contractors have to do?

In order to comply with the requirements of FMD, pharmacy contractors will be required as part of the dispensing process (from 9th February 2019 and for products that bear "safety features") to:

1. Check the anti-tampering device (ATD) to ensure it is intact prior to dispensing. This is a simple visual inspection
2. Change the status of the pack in the UK's National Medicines Verification System* from "active" to "inactive—supplied". This involves scanning the 2D barcode on each pack and communicating with the National Medicine Verification System (NMVS)

The Delegated Regulations [Article 25(1)] state that these steps should occur "at the time of supplying it to the public".

* The UK's National Medicines Verification Organisation (NMVO) is SecurMed UK. It has selected Arvato as the IT company to provide the NMVS.

Key assumptions

- **Brexit** – The DHSC and MHRA have made statements that the UK will maintain "high regulatory alignment" with the EU and that this includes FMD. We are assuming for the time being that the UK will be considered, for the purposes of interpreting the FMD Delegated Regulation, still to be "inside the EU", now and in the future, so medicines received in the UK from the EU will **not** already be decommissioned (or treated as exports under Article 22).
- **Scanning** – this may be undertaken using a stand-alone FMD (only) system or an FMD-capable PMR system. It will be for contractors to determine the best process for their pharmacies. Scanning can be used for three purposes:
    - **Verification** – an ad-hoc check that the pack is still "active" and that no alerts or recalls have be raised. This is optional and can be undertaken at any time that the pack is in the contractor's possession. It does not change the status of the pack
    - **Decommissioning** – this has to be undertaken as part of the dispensing process, before the pack is handed to a patient or their representative. It checks the pack status and then changes it to "inactive" to prevent other (potentially falsified) packs with the same unique identifier being dispensed.
    - **Re-Commissioning** – this reverses the decommissioning scan if it occurs within a 10-day time period after the pack was made "inactive". This will be used if a pack has been decommissioned but has not been used or given to the patient.
- **Aggregated codes** – these are not required under the Delegated Regulation but may be generated by pharmacy IT systems to link several pack identifiers together, if this functionality has been provided by the IT supplier. They are not mandatory, but may be used to facilitate decommissioning. Aggregated codes may be printed directly on dispensing bags, or on a separate adhesive label to be applied to dispensing bags, and then scanned at the time of supply. Aggregated barcodes could either contain all of the data of the pack identifiers or simply provide a link to the data stored on the pharmacy IT system.
- **Time of supply** – This is not an instant but a period of time, from when a pack is picked, to when the patient (or their representative) has the pack. The ATD check must take place during that period, as must the decommissioning. It may be that during assembly, the barcodes are scanned and linked to an aggregated barcode placed on the dispensing bag. Decommissioning can then be accomplished by scanning the aggregated barcode before hand-over to the patient (or their representative). The precise process will depend on each contractor's SOPs and may vary depending on whether the patient (or their representative) is present or not. It is important to note that the check of the ATD and the decommissioning scan may occur at different points in that process. Decommissioning should happen as close to the time of supply to the patient as possible, but there are other important considerations. Disruption to the dispensing workflow could jeopardise safety. Emptying out bags to scan packs in front of the patient could compromise patient privacy and poses problems if any pack fails to authenticate for any reason.
- **Deliveries to patients** – if not completed during the dispensing process, the decommissioning scan should be completed before hand-over to the driver/courier.
- **Government consultation** – The UK Government (DHSC and MHRA) has committed to consult on any regulatory changes needed to implement FMD. However, this consultation will only focus on a small number of flexibilities where there is legal scope for Member States to make changes as most elements of FMD are already binding through the Delegated Regulation process and not subject to change. These flexibilities do not primarily impact community pharmacy dispensing but may have some impact on pharmacies that hold wholesale dealer's licenses. The consultation has been delayed and is currently expected to be published by the end of April 2018. Due to the considerable delay, and approaching deadline for implementation of FMD, we continue to urge the UK Government to publish the consultation and subsequent outcomes as swiftly as possible.

Costs of implementation and operation

Under the Delegated Regulation, each sector, including pharmacy, is responsible for its own costs for connecting to the NMVS. Each of the four national community pharmacy negotiators will work to ensure that contractors' FMD-related costs are recognised in future NHS funding settlements. Some of the costs involved include initial set-up, IT, both software and hardware, plus ongoing operational costs.

High level process

Pharmacies will be able to conduct an optional verification scan, if desired, as stock enters the pharmacy (or at any other time). This process is outlined in Appendix A.

More detail is given regarding the assembly workflow process in Appendix B. It is envisaged that, for all relevant products, each item's ATD will be checked during assembly or dispensing.

If not using aggregated codes:

- At the time of supply to the patient/their representative/the driver/courier, conduct a decommissioning scan that may involve opening the dispensing bag and scanning each pack's 2D data matrix (barcode) if the scanning was not done at assembly

If using aggregated codes (on the bag):

- During assembly each item's unique identifier (in 2D barcode) will be:
  - scanned
  - optionally verified to reduce later scan failures (configurable by contractor)
  - Unique identifier data will be stored in the system (PMR system or stand-alone FMD system that may be middleware) and associated with an aggregated code. This code can be printed on the dispensing bag or affixed by means of an adhesive label
  - The pharmacy must store assembled bags in a secure area prior to hand-over
- At hand-over to the patient/their representative, or before hand-over to the driver/courier:
  - the aggregated code will be scanned, and
  - the system will disaggregate the unique identifiers and forward them to the NMVS for decommissioning

NB. Each pharmacy's standard operating procedures (SOPs) will need to be updated to reflect the approach adopted by the contractor.

Verification and decommissioning may fail for a variety of reasons – see Appendix D

Implementation and transition

The EU Delegated Regulation only applies to new stocks of products released to the market on or after 9th February 2019. Older packs do **not** have to be withdrawn and can still be supplied to patients after this date. Manufacturers are beginning to change production to incorporate the new 2D data matrix barcodes on their packs but it is expected that there will still be a considerable volume of older products in stock and in the supply chain and a long transition period is expected.

Levels of FMD-compliant stock will increase over time and the amount of verification, authentication and decommissioning to be carried out in pharmacies will increase in proportion until all stock is fully compliant. FMD does not apply to OTC products, medical devices and some specialist products.

At the time FMD comes in to force, there may be existing products in the system that bear 2D data matrix barcodes but which have not had their unique identifier data uploaded in to the verification system, or where data uploads take place retrospectively. Pharmacy teams will need to take great care in dispensing these products.

It is expected that during the transition period all new stock will bear 2D data matrix barcodes and so the older linear barcodes will gradually disappear from prescription medicines.

IT system requirements

Registration of community pharmacies

Each community pharmacy in the UK will need to connect to the NMVS being set up by SecurMed UK so that FMD verification scanning and decommissioning can occur. The process of identifying legitimate pharmacies and granting them an account to connect is known as "registration" (or sometimes as "on-boarding") and will need to be completed well before 9th February 2019.

SecurMed UK and Arvato are expected to produce guidance on how pharmacies can register in 2018. In order to avoid disruptions during the Christmas and New Year period and to allow time for staff training, the UK FMD Working Group has urged SecurMed UK to produce its guidance as soon as possible and for pharmacy contractors to plan to complete registration by 31st October 2018, wherever possible.

Time to develop and deploy

We are informed by PMR system suppliers that adding FMD capability to PMR systems will take some time. Pharmacies may instead opt for a stand-alone FMD system that might be available sooner. As FMD capable PMR systems become available, pharmacies may prefer that option. Any pharmacy switching between approaches will incur extra cost and disruption.

Stand-alone FMD system or FMD-capable PMR?

Each contractor will need to decide which system best serves their needs. Some of the pros and cons of each system are outlined below.

Stand-alone FMD system

Pros	Cons
May be cheaper and quicker to implement in the first instance	Would need the provision of power and network connection at the point of use
If scanning at the counter, it has less of an effect on assembly (unless verification is also done in the dispensary)	If scanning at the counter, it takes time, plus it reduces patient privacy/confidentiality unless the counter is reconfigured
	Less likely to provide additional functions (such as integrated accuracy checks) than integrated systems
	May introduce another IT supplier to the pharmacy
	If scanning in the dispensary (for verification or decommissioning), then the system needs to be accommodated there. If it comprises middleware that utilises the existing PMR PC

	and existing scanner it would take no extra space. Conversely, if it required its own hardware, it would occupy some space
	Additional costs might be incurred if the pharmacy then moves back to using an integrated PMR at a later date

FMD-capable PMR system

Pros	Cons
Possibility of generating aggregated codes	May be more expensive
Maintains relationship with PMR provider	The pharmacy may need to be reconfigured to accommodate more PMR terminals in the dispensary and at its counter, with associated costs.
Possibility of linking to an accuracy check at a future date	The assembly process is likely to need to be amended

IT systems – expected standard requirements

The following requirements reflect the expectations of the UK FMD Working Group for Community Pharmacy of what suitable FMD-compliant systems should be capable of delivering. Reference should also be made to the User Requirement Specification produced by the EMVO and any guidance produced by SecurMed UK and/or Arvato Systems. Minimum requirements to meet obligations under the Delegated Regulation are indicated thus [Minimum]:

- The scanners used must be able to scan:
    - Barcodes on prescriptions or tokens (including on a smartphone screen)
    - FMD unique identifier 2D data matrix codes [Minimum]
    - Aggregated barcodes (if used)

  Ideally, the system should be able to cope with wired and/or wireless scanners. It should also be able to scan existing linear barcodes on other pharmacy stock (and possibly QR or other information codes)

  Where possible, existing scanners (if able to scan 2D barcodes) should be reused. Changing scanners in automated systems or robots may be problematic.
- The system must allow [Minimum]:
    - Verification scans
    - Decommissioning scans
    - Re-commissioning
- The system must allow feedback to the user [Minimum]:
    - Current pack status for verification scans
    - Successful decommissioning
    - Decommissioning "errors" (including "not detected on system" for those items which did not have their data uploaded before 9th Feb 2019)
    - Decommissioning "failures" (i.e., pack identifier previously dispensed in same pharmacy, another location, another country)
    - Other system errors, including temporary lack of connection to NMVS
    - Successful re-commissioning where appropriate

  Where possible, visual and audible feedback (and associated messages) should be harmonised across different operating locations in the same country. Audible warning should be able to be

turned off if required. See Appendix D - error messages flowchart. A success sound is to be added too. The sounds and error messages need piloting.

- FMD-capable systems need to have a suitable offline feature to ensure continuity of medicine supply to the public. No user action should be needed to go offline/online. FMD-capable systems will deal with outstanding FMD requests on reconnection to the NMVS. [Minimum]
- Alert the user on detection of falsified, expired or recalled medicines (either at the time of scanning, or as soon as the NMVS connection is restored). [Minimum]
- Manual (keyboard) entry of the unique identifier must be supported (for exceptional circumstances such as where the pack is damaged). [Minimum]
- In the UK we do not exclusively use whole pack dispensing. Packs of medicines can be legitimately split within the pharmacy to allow for dispensing a different number of tablets to the number within the pack, or to allow hydration/dilution, or to dispense a measured dose of a liquid for supervised consumption, or for MDS (monitored dosage system), or for pouching etc. The system must support pack splitting. If a prescription needs you to split a pack, check the tamper-evident seals, decommission, open the pack, then use it as required without any further requirement to scan.
- The software must allow reversal of decommissioning within the 10-day period permitted. [Minimum]
- The system should allow an option to not use aggregated codes and to decommission during assembly. The option must be available for each prescription, and as a system configuration setting for each terminal.
- The system should allow the connection of multiple scanners or terminals and be able to process multiple decommissioning requests and their results simultaneously. It must be clear which NMVS feedback message corresponds to which user/scan activity when multiple users are using the same terminal.
- The system should be able to print multiple aggregated bag labels for the same patient and link them together. This could be used, for example:
    - Where prescription items include a fridge line or Controlled Drug
    - Where prescription items are split across a number of bags due to their size

  Where a bag is one of many for the same patient, the system should warn when there are more bags to retrieve and scan – where possible this should incorporate a configurable “chaos storage” solution which contractors can use if they wish.
- The system must also be able to carry out automated expiry date checking using information from the 2D code. This applies to all three scan types – verification, decommissioning and re-commissioning
- The contractor will need to ensure that their broadband connection is appropriate in terms of speed, capacity and latency. This will need NHS involvement for the SWAN connections in Scotland (and possibly similar for the other home countries.)
- The system should provide limited management information, eg, simple number of scans conducted in a given period. This should be accessible from Head Offices where appropriate.

IT systems – optional requirements

- FMD-capable PMR systems may store FMD requests/results against the patient record which may support recalls. At this stage this does not imply an automated accuracy check between prescription and patient, or patient level recalls, but they may be future developments.
- FMD-capable PMR systems may use FMD requests/results stored against the patient record to support recalls/decommissioning failure identified after reconnection to the NMVS.
- The pharmacy IT system may check that pack product data (eg, Global Trade Item Number, GTIN) matches equivalent information on prescriptions (potentially using dm+d codes) during verification or decommissioning scans (ie, automated accuracy checking)
- The system may co-operate with EPOS (electronic point of sale) modules or systems.

- The system may use product data from unique identifiers gathered from scans to aid stock control and re-ordering.
- Detailed management information – terminals/users who conducted the scan, proportion of items dispensed, scans conducted, etc.
- The ability for contractors to link verification scans on receipt of an order into the pharmacy to the wholesaler the product was received from to facilitate any returns due to negative or failed scans

Phasing

It is likely that the IT system development will be phased. The initial version will support the minimum requirements for decommissioning and many of the other features listed above as expected standard requirements. Aggregation might be delayed until a later version, followed by the features listed above as optional requirements, such as management information.

EMVO user requirement specification

Details of the EMVO user requirement specification can be found here:
https://www.emvo-medicines.eu/wp-content/uploads/2016/09/EMVS-URS-Lite.pdf
The full version, known as "URS heavy", is available from the EMVO through non-disclosure agreements.

Automated systems

Scanners within automated assembly systems (robots) should be able to use FMD-compliant unique identifier data to assist loading and retrieval of relevant products.

User training

IT system suppliers should provide training materials and easily accessible online help pages regarding the operation of their systems. All members of staff in the pharmacy who are involved with prescription assembly and delivery (including counter assistants and drivers) will need to be trained on the FMD process that is adopted by their pharmacy. This will include training on the revised SOPs.

Response to negative or failed scans

If a scan gives an error, then the pharmacy may need to contact the National Competent Authority (in the UK this will be the MHRA) in some circumstances – see Appendix D. For instance, a stolen or already-dispensed pack would need reporting, but an out-of-date one could not be used but would not need reporting.

The process for responding to negative or failed scans is yet to be determined. Further guidance is expected from the MHRA later in 2018. Among the issues to be clarified are:

- Responsibilities for investigating negative or failed scans between pharmacy contractors, wholesalers, manufacturers, SecurMed and the MHRA
- The information that is required to be supplied to the investigating body from the pharmacy contractor and how that data is transferred
- The timescales during which the above must be carried out

Separate to this, a process for refunding the cost of the pack (which has been bought in good faith) to the contractor in the event of a failed scan. This would not include a failed scan due to expired stock (unless received expired from the wholesaler, which would be covered by the current process).

Patient safety implications

The Community Pharmacy Patient Safety Group, comprising of Medication Safety Officers from across the sector, was consulted on a draft version of this guidance. The Patient Safety Group has raised a number of issues that will need to be considered by community pharmacy owners, superintendent pharmacists and responsible pharmacists when FMD is being implemented.

The Patient Safety Group supports the driving principles and intentions of the Falsified Medicines Directive and recognises that falsification presents a threat to patient safety. However, it is also cognisant that any changes to established operating procedures also in themselves increase risks to patients and will place a significant burden on pharmacy teams, at the very least in the short term. This comes at a time when dispensary teams are at full stretch with limited time and space to introduce any additional steps to the dispensing process.

Because the implementation of FMD will be mandatory for all UK pharmacies, pharmacy owners and all those responsible for patient safety will need to balance these risk and work to reduce overall avoidable harm to patients wherever possible. Key points to be considered include:

- **Integration** – FMD processes need to be integrated within existing dispensing processes and risks attributed to any additional steps around verification, authentication, decommissioning (or reversing decommissioning) must be considered. Integrating FMD in to current pharmacy systems would be preferable to stand-alone systems, from a safety point of view
- **Operations** – Care must be taken to ensure that any new equipment, including scanners or screens, does not crowd existing workspace. Standard operating procedures need to be updated to take account of FMD processes
- **Continuity** – Processes for dealing with issues caused by losing connection to the NMVS must be considered, including what to do if a product subsequently fails authentication and in which circumstances medicines would or would not be supplied to patients pending authentication
- **Recommissioning** – Processes for handling the recommissioning of products (as required) within the 10-day period allowed need to be put in place so that there is clarity across pharmacy teams, especially where products are decommissioned in advance of being supplied to patients
- **Training** – All staff should receive sufficient training to understand the principles and operations relating to FMD, especially during the transition phase
- **Errors** – Processes for handling errors, including near-miss errors, and dealing with products that fail to authenticate must be put in place, including notifying relevant authorities
- **Aggregation** – If aggregated codes and labels are being used, additional care must be taken to ensure that these are applied correctly to the right products, avoiding any mis-matches, and that they are then used to decommission all relevant products. Processes and systems should quickly and clearly identify which products are involved if any negative response or alert is received
- **Accuracy** – Where possible, systems should make use of machine-readable data derived from scanning packs to increase accuracy and safety checks. At a basic level, this should start with expiry date checks and batch-level recalls. In later phases, data from packs picked could be cross-checked with prescription information for accuracy and, in due course, stored in appropriate patient records

Patient information

Given the substantial interest that the introduction of FMD will cause, DHSC, MHRA and SecurMed UK should work with the UK FMD Working Group for Community Pharmacy to produce consistent information materials for patients, customers and carers that contractors can use to explain the implementation and benefits of FMD.

Enforcement

The DHSC and MHRA are jointly responsible as the National Competent Authority (NCA) for the implementation and enforcement of FMD in the UK. It is likely that the GPhC (General Pharmaceutical Council) and the PSNI (Pharmaceutical Society of Northern Ireland) and the inspectorate of the Department of Health (Northern Ireland) will have a role in the enforcement of the FMD regulations in community pharmacies. Issues around sanctions and enforcement should be clarified in the forthcoming Government consultation.

Useful links

EMVO: https://emvo-medicines.eu/

SecurMed UK: https://www.abpi.org.uk/what-we-do/collaboration-and-partnership/manufacturing-and-supply/securmed-uk/

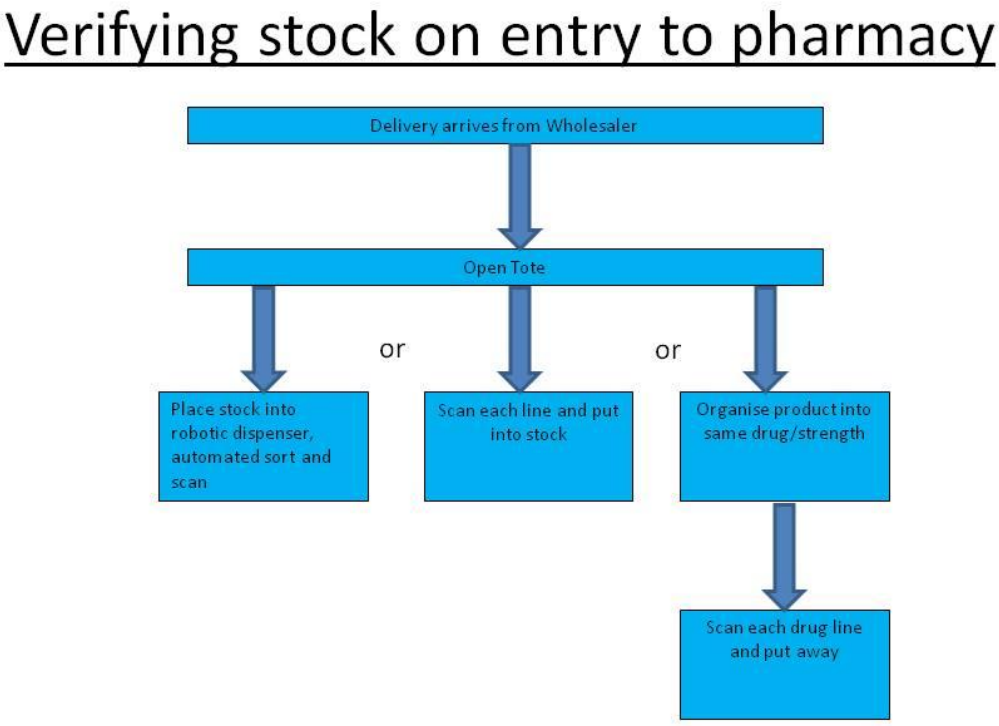
FMD source (the UK FMD Working Group for Community Pharmacy's website): www.fmdsource.co.uk

https://www.gov.uk/government/news/new-rules-to-help-fight-falsified-medicines

Appendix A

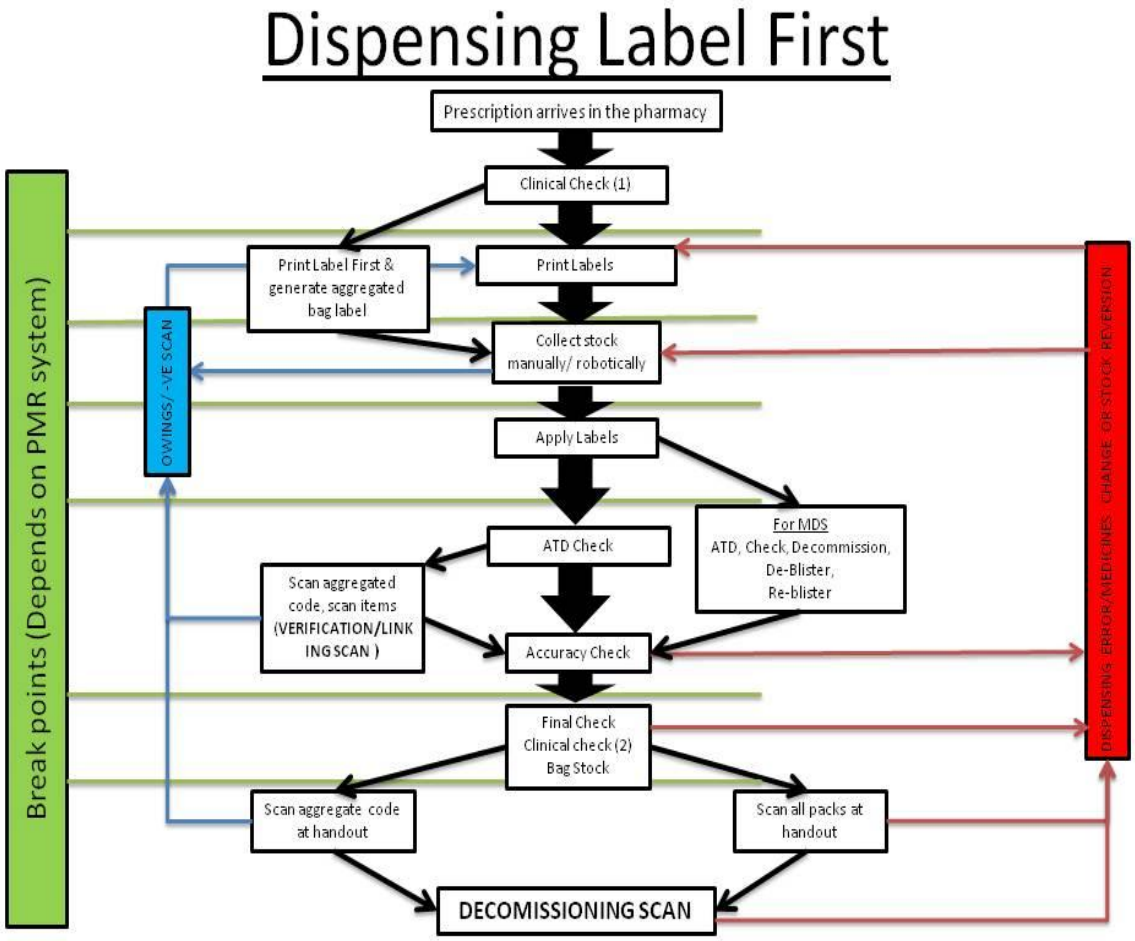
Verifying stock on entry to pharmacy

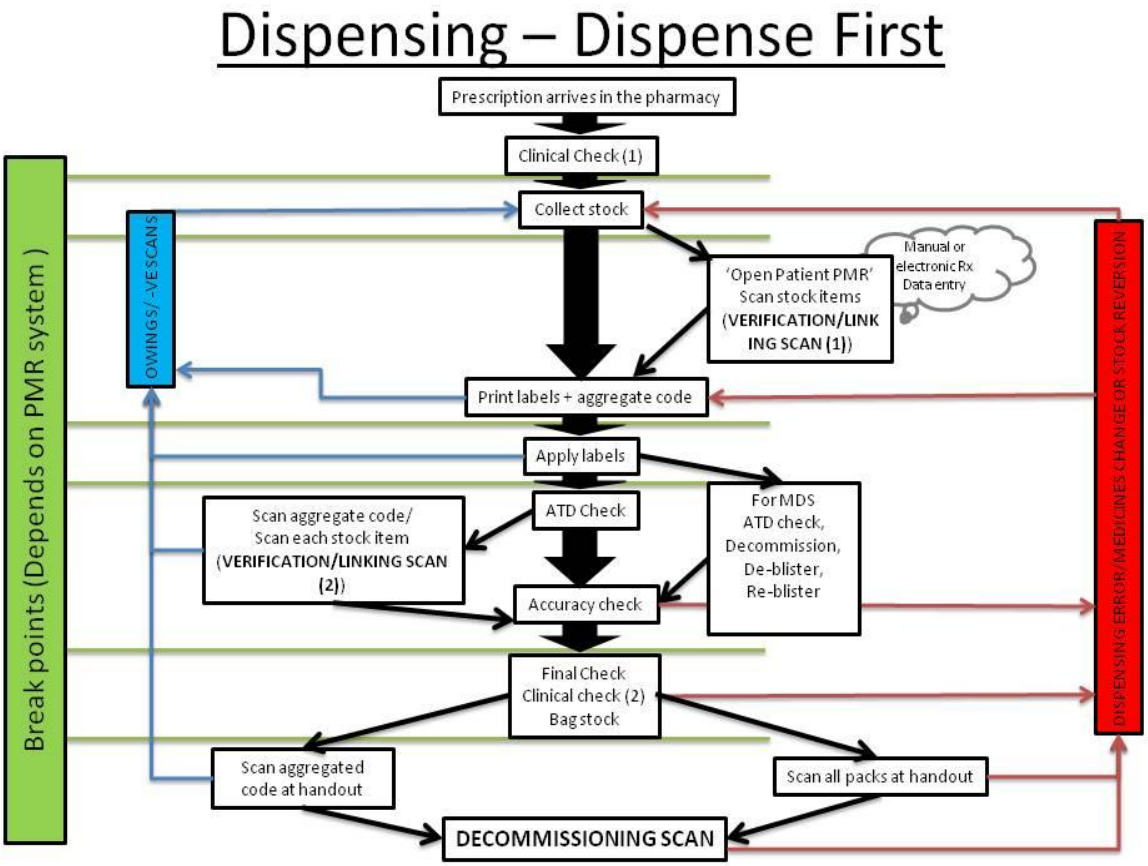
With OPTIONAL validation on entry, there are three options that can be taken once the delivery arrives from the wholesaler.



Appendix B

Suggested workflows using aggregated codes either 'dispensing label first' or 'dispense first'




Dispensing – Dispense First
Prescription arrives in the pharmacy
Clinical Check (1)
Collect stock
'Open Patient PMR'
Scan stock items
(VERIFICATION/LINKING SCAN (1))
Manual or electronic Rx Data entry
Print labels + aggregate code
Apply labels
ATD Check
Scan aggregate code/
Scan each stock item
(VERIFICATION/LINKING SCAN (2))
For MDS
ATD check,
Decommission,
De-blister,
Re-blister
Accuracy check
Final Check
Clinical check (2)
Bag stock
Scan aggregated code at handout
Scan all packs at handout
DECOMMISSIONING SCAN
Break points (Depends on PMR system)
OWINGS/ -VE SCANS
DISPENSING ERROR/ MEDICINES CHANGE OR STOCK REVERSION

Appendix C – FMD glossary

FMD jargon buster

*This jargon buster explains some of the terms commonly associated with the European Falsified Medicines Directive (FMD) and its operation. Short explanations are given for items in **bold text**.*

Section 1: FMD legislation and organisations

FMD: Falsified Medicines Directive (FMD). **FMD** is often used as shorthand for the scanning and **verification** of medicines (see Section 2), but can also refer legally to the European Directive on Falsified Medicinal Products [2011/62/EU] which amended the European Directive on Medicinal Products for Human Use [2001/83/EC]. The legal requirements for FMD have been transposed in to UK law through the Human Medicines Regulations 2012 (as amended).

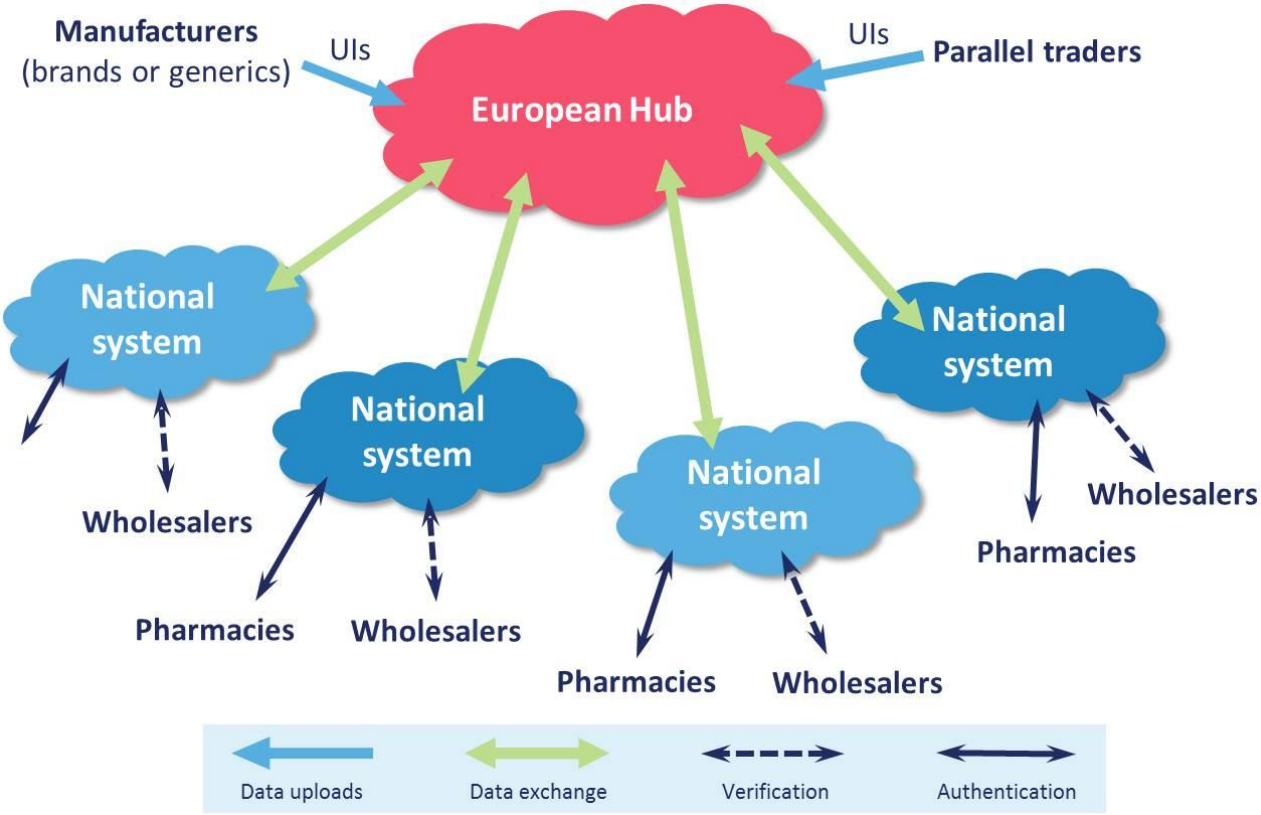
Delegated Regulation: Directive 2011/62/EU set out an overall requirement for prescription medicines to bear **safety features** and for these to be **authenticated** through the use of a **repositories** system. The technical details for these requirements are set out in **Delegated Regulation** 2016/161. The Regulation is binding on all Member States from 9th February 2019, three years after it was published in the *Official Journal of the European Union*. References to "Articles" in this jargon buster are to Article numbers in the Delegated Regulation (DR).

EMVO: European Medicines Verification Organisation. The **EMVO** is the not-for-profit organisation responsible for setting up and running the **European Medicines Verification System** (EMVS). The EMVO was established under the "European Stakeholder Model" by the five European trade bodies representing research-led manufacturers (EFPIA), generic and biosimilar manufacturers (Medicines for Europe), parallel distributors (EAEPC), wholesalers (GIRP) and pharmacies (PGEU). The EMVO is responsible for the "User Requirement Specifications" (URS) that **National Medicines Verification Systems** will have to meet. It has also established the **Blueprint model** for setting up **National Medicines Verification Organisations** and for appointing **Blueprint Service Providers** to run each NMVS.

EMVS/European Hub: European Medicines Verification System or "European Hub". The **EMVS** lies at the heart of the **repositories system** (see diagram below). It provides a system though which manufacturers and parallel distributors can upload active **unique identifiers**, which are then shared with relevant national systems. The EMVS also synchronises data, so that once a pack of medicine is **decommissioned** in one EU Member State, all other national verification systems can be made aware of this. The EMVS holds "master data" about products (ie, the name, strength, pack size, etc) but does not keep records of unique identifiers once this data has been transmitted to the relevant national systems. The EMVS is a cloud-based system operated by **Solidsoft Reply**, one of the two **Blueprint Service Providers**, on behalf of EMVO.

NMVO: National Medicines Verification Organisation. Each Member State is required to have an **NMVO** to establish and run an **NMVS** in its country (although multi-country regional NMVOs are possible). These are generally incorporated under the **Blueprint model** by representatives of national organisations representing research-led manufacturers, generic and biosimilar manufacturers, parallel distributors, wholesalers and pharmacies, although the exact nature of the governing boards and the number of directors can vary from country to country. The key task of the NMVO is to appoint a **Blueprint Service Provider** to operate the NMVS.

NMVS: National Medicines Verification System**.** The **NMVS** holds details of the **unique identifiers** for all medicinal products subject to FMD and which are intended for sale in that Member State (including multi-market packs licensed for sale in more than one country). Wholesalers and **persons authorised to supply medicines to the public** (including community pharmacies) will connect to the NMVS in their country and will use this to **authenticate** medicine packs in their possession by scanning packs' unique identifiers and comparing this with data held on the NMVS.



Blueprint model: A generic model for establishing **National Medicines Verification Organisations** in each Member State, providing draft memorandums of understanding and other documentation, aimed at speeding up the process and achieving equality of status for all of the main sectors in the medicines supply chain, including wholesalers and pharmacies.

Blueprint Service Provider: Under the **Blueprint model**, three large IT providers pre-qualified to compete for the right to establish NMVS in each Member State. The aim is to bring a degree of harmonisation between NMVSs while introducing some competition in order to keep costs down and ensure that future tenders will also attract competitive bids. Three companies were initially selected: **Aegate**, **Arvato** and **Solidsoft Reply**, but Aegate is no longer active. Each has experience in managing large-scale serialisation projects.

National Competent Authority: A generic European term covering Government or Ministerial functions and bodies responsible for licensing, inspecting, regulating and legislating around the medicines supply chain. In the UK, the National Competent Authorities are the **Department of Health and Social Care** (DHSC) and the **Medicines and Healthcare products Regulatory Agency** (MHRA), for manufacturers and wholesalers, with lesser roles for the Health Departments of devolved administrations, and the General Pharmaceutical Council (GPhC) and Pharmaceutical Society of Northern Ireland (PSNI) with respect to pharmacies.

Persons authorised to supply medicines to the public: A generic European term covering community pharmacies, as well as other healthcare professions and organisations that use, administer or supply medicines to patients and the public as part of their work.

Repositories system: A generic term used in Delegated Regulation covering all parts of the verification system, including EMVO and NMVOs and the associated EMVS and NMVSs, as well as parties that are connected to them.

Healthcare institutions: A generic European term covering hospitals (including hospital pharmacies), in- and out-patient clinics, and health centres.

End users: A generic term for all organisations, institutions or locations that are handling medicines and which will need to be connected to the NMVS for their country. These include individual community pharmacies (even if part of a larger chain), hospital pharmacies, wholesale service centres, etc.

Onboarding: The process through which each end user location has its identity verified and is then connected securely to the NMVS for their country. Identity verification may use existing official lists or registers as well as the generation and use of software security certificates. NMVOs (and their BSPs) will be responsible for onboarding end users in their countries (eg, pharmacies, hospitals and wholesalers). The EMVO is responsible for onboarding manufacturers to the European hub (EMVS) so that they can upload master data and unique identifiers relating to their products.

White List/Black List: The requirement for **safety features** applies to all prescription medicines placed on the market in Europe on or after 9th February 2019. Non-prescription medicines, unlicensed products and "specials" are excluded.

- **White List** – Certain other products or product categories normally subject to prescription are excluded under Article 45(1). Examples include medical gases, homoeopathic medicines, radionuclide kits and generators and some parenteral nutrition products. These are all normally subject to specialist handling and logistics and are not considered to be at high risk of falsification. They are listed in Annex 1 of the DR, commonly referred to as the **White List**
- **Black List** – Under Article 45(2), some non-prescription medicine packs are required to bear **safety features**, particularly if they have been subject to falsification in the past. These are listed in Annex 2 of the DR, commonly referred to as the **Black List**. Only two products – omeprazole 20mg and 40mg gastro-resistant hard capsules – are currently listed in this way.

Section 2: FMD operations

Safety features: Under FMD, all new packs of prescription medicines placed on the market from 9th February 2019 onwards are required to bear **safety features** in order to reduce the risk of falsified products reaching patients. These features are the serialised **unique identifiers** and an **anti-tampering device**.

Unique identifiers: (UI). Each and every pack of prescription medicine will have to carry its own **unique identifier**, encoded in a machine-readable 2D data matrix (or barcode) that meets ISO standards. Unless the packaging is very small, part of this information will also appear in printed human-readable form. The unique identifier will contain the following information [Article 4]:

- ***Product code***: the name, common name, pharmaceutical form, strength, pack size and pack type

- ***Serial number***: randomised numeric or alphanumeric sequence of up to 20 characters
- ***National reimbursement number***: national identifying code, if required by Member State
- ***Batch number***: up to 20 characters
- ***Expiry date***: in YYMMDD form

Anti-tampering device: (ATD). Every pack has to have some sort of **anti-tampering device** which allows visual identification as to whether the pack may have been tampered with since it was originally manufactured (or repacked, for parallel traded products). Neither the Directive nor the Delegate Regulation specifies the nature of the ATDs that can be used, but typical devices could include glued-down flaps, seals or labels that have to be broken when opening, shrink or film wraps, breakable or tear-away closures, film or foil blister packs, and blow-fill-seal unit packs. Because of the variable type and locations for ATDs, inspection of them is always likely to be a human activity that would be difficult to automate.

Verify/verification: In order to **verify** a product in their possession, the person holding the medicine (normally a wholesaler or pharmacy) scans the **unique identifier** and then uses the **NMVS** to compare the data in the pack UI with corresponding data held in the NMVS. If the two match, and the **anti-tampering device** is still intact, then the pack is considered authentic. As long as it still has an **active** status, it can be moved through the supply chain or supplied to a patient (after **decommissioning**). Packs can be verified multiple times as they pass through the supply chain, as long has the person doing the verification has the product in their possession. Packs must be verified at certain points – if they have been bought from a secondary supplier rather than the original manufacturer or their agent; before they are repackaged for parallel trading; if they have been returned from a pharmacy back to a wholesaler.

Authentication: The processes of **verification** and **authentication** are closely linked and involve similar steps. In practice, authentication generally refers to the final step in the process, leading to **decommissioning**. Under Article 25, **persons authorised to supply medicines to the public** must authenticate the product by **verifying** the **unique identifier** using a **NMVS** and check that the **anti-tampering device** is still intact. This needs to be done "at the time of supplying it to the public", although in practice it is likely that authentication will take place during the assembly and dispensing of prescribed medicines, rather than in front of the patient at the point of hand-over.

Decommissioning: Once the product has been **authenticated** during the dispensing process, it must have its status in the **NMVS** changed from **active** to **inactive – decommissioned/supplied**. This indicates that it has been dispensed and prevents any other pack bearing the same **unique identifier** from being dispensed, as the second attempt to **verify** the product would fail. This process of decommissioning underpins the operation of the **repositories system** and is aimed at preventing falsified products from reaching patients.

Active/inactive status: Each **unique identifier** that is uploaded to the **repositories system** has a status associated with it. Products with an **active** status can be dispensed or moved through the supply chain. Products with an **inactive** status cannot be supplied further, other than in certain circumstances (set out in Article 12), such as the product is intended for export from the EU, it is intended for destruction, or that it has been taken as a sample for official purposes. Packs can have an **inactive** status for several reasons – the product has been withdrawn from the market; the product (or a batch) has been recalled; the pack has already been dispensed, exported, repacked, supplied as a sample, destroyed or is part of a consignment known to have been stolen. If a product passes its expiry date, it will also have its status set to **inactive** automatically.

"10-day rule": Once a pack has been **decommissioned** and had its status set to **inactive – decommissioned/supplied** there is a short period of 10 days during which this process can be reversed and the pack status set back to **active**. Reversal of decommissioning is only permitted [under Article 13] when:

- ***Same location*** – The reversal is undertaken by the same "person" (ie, organisation) as the original decommissioning and from the same set of premises
- ***10-day rule*** – The reversal takes place not longer than 10 days (240 hours) after the decommissioning
- ***Not expired*** – The product has not expired since the decommissioning
- ***Not recalled*** – The pack has not been registered as recalled, withdrawn, intended for destruction or stolen during the intervening period
- ***Not supplied*** – The product was not supplied to the public (and thus has not left the premises)

The **10-day rule** is crucial to the smooth operation of assembly and dispensing within pharmacies. If products are decommissioned at an early stage, there is a risk that they might not be collected or handed over within the 10-day period. After this, decommissioning cannot be reversed and the product "shall not be returned to saleable stock" [Article 13] which could massively increase wastage. One potential way around this is the use of **aggregated codes** generated within pharmacies' dispensing systems.

Aggregated codes: Each pack will have a **unique identifier** that refers only to that pack and which is used for **verification** and **decommissioning**. However, it would be possible to capture the data from the UIs of one or more packs and to incorporate this within a single **aggregated code** generated by the pharmacy dispensing system. This aggregated code could be printed as a linear or 2D data matrix on a dispensing or address label applied to the outside of a dispensing bag holding all the items for one patient. During handover to the patient, it should be possible to scan the aggregated code and to use this data to trigger the decommissioning of all the products simultaneously. Aggregated codes may also have a function earlier in the supply chain when they could be used to transfer batch/expiry or UI data relating to multiple packs or products during shipment from manufacturers to wholesalers, reducing the need to scan many different packs, but this is not mandated by the Delegated Regulation.

Article 23 groups: As well as community and hospital pharmacies, and dispensing medical practices, many other healthcare professionals and institutions are entitled to use, administer or supply medicines to the public as part of their normal work. Such use may not be a core part of their work and may be infrequent or unpredictable. In such circumstances, having a connection to the **NMVS** might be difficult or disproportionately expensive. **Article 23** recognises that Member States may need flexibility to take these different organisations (collectively referred to as "Article 23 groups") in to account. Under Article 23, wholesalers can undertake **verification** and **decommissioning** on their behalf. It should be noted that persons operating within a **healthcare institution** or a pharmacy are specifically excluded from this. The groups covered by Article 23 are:

- Veterinarians and retailers of veterinary medicinal products (in relation to human medicines for veterinary use)
- Dental practitioners
- Optometrists and opticians
- Paramedics and emergency medical practitioners

- Armed forces, police and other governmental organisations maintaining stocks of products for the purposes of civil protection and disaster control
- Universities and other higher education establishments using medicinal products for research and education
- Prisons
- Schools
- Hospices
- Nursing homes

Note that where pharmacies supply these organisations (or patients resident within them) with medicines supplied under a prescription, then the pharmacy would undertake the decommissioning as part of the normal dispensing process.

Accumulators/concentrators: These are hardware devices that will streamline the way in which **end users** are connected to each NMVS. **Accumulators** can be used within individual locations (eg, pharmacies) to connect multiple terminals. The accumulator would also synchronise messages to and from the NMVS to ensure that they are presented and received in the correct order. They may also temporarily hold messages if the connection to the NMVS is lost. **Concentrators** can be used by larger organisations, such as pharmacy chains or national wholesalers, to connect multiple locations through a single gateway to the NMVS. Each location within the chain would retain its own secure identity for purposes of auditing and alert monitoring. Smaller locations, such as an individual community pharmacy business, may use an accumulator but would probably have a direct connection to the NMVS without needing a concentrator.

Appendix D – error messages flow chart

This chart gives an initial indication of negative responses ("error messages") that might be generated by systems connected to the NMVS and the ways these might be reported to users. Note that suggested wording and confirmations are not final and are intended to prompt further discussion between pharmacy contractors and their IT systems suppliers, within an overall aim of harmonising responses across the sector where possible.