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NCHA Position Statement

Implementation of Falsified Medicines Directive in Clinical Homecare - The Way Forward

History

Version	Date	Reason for change
v1	5 Dec 18	New

Scope:

The implementation of the Falsified Medicines Directive (FMD) will create significant work for homecare providers and will require processes to be re-engineered in most organisations. This implementation comes alongside several other major implementations within the Homecare Industry, therefore homecare providers are seeking to plan a phased implementation.

Homecare providers are subject to a complex regulatory regimen that was designed to work in other settings. Homecare providers therefore often find themselves working in grey areas where the activities being undertaken were not foreseen and are either not covered or there is conflicting advice from different regulators leading to operational inefficiency and potential patient safety issues. Implementation of the Falsified Medicines Directive in Clinical Homecare has the potential to significantly increase the operational cost of providing Clinical Homecare Services and magnify wastage of high cost medicines often associated with these services – costs that will eventually be borne by the NHS as more than 90% of Clinical Homecare Services are provided to NHS patients.

FMD guidelines are available for other sectors of the pharmaceutical supply chain. This document does not seek to duplicate information provided elsewhere, so will focus on implementation of FMD in the homecare provider's pharmacy. Homecare providers who are registered wholesale dealers should also review the FMD guidance for wholesale dealers and should review their systems and practices to ensure clear demarcation between their wholesale and pharmacy activities.

While the regulation is clear, there is the need for further scoping work which continues as detailed information about the FMD implementation becomes available.

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

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Disclaimer

Background to Falsified Medicines Directive implementation in the UK.

MHRA (Medicines and Healthcare products Regulatory Agency) and the Department of Health and Social Care (DHSC) are leading an FMD Implementation Steering Group comprising key stakeholders including NCHA. Statements have been made by the UK Government (DHSC and MHRA) to stakeholders over their wish to be part of an EU regulatory system which includes FMD, and that they are continuing their preparations to introduce FMD in line with the expected timescales, even as the UK prepares to leave the EU (Brexit). In the unlikely event of no-deal 'exit' they have said that it would be common sense to build on existing the FMD implementation in developing a UK solution. However, we are assuming that the UK will be considered, for the purposes of interpreting the FMD Delegated Regulations, still to be "inside the EU", now and in the future, so medicines received in the UK from manufacturers and wholesalers in the EU will not already be decommissioned (or treated as exports under Article 22).

The UK Government (DHSC and MHRA) is currently consulting on regulatory changes needed to implement FMD. However, this consultation will only focus on a few flexibilities available to Member States as well as the sanctions behind any breaches as most elements of FMD are already binding through the Delegated Regulation process. There will in future be an impact assessment of the expected costs of FMD for all parts of the medicines supply chain. It will be vital that homecare providers and commissioners provide a robust response to this consultation. The consultation was delayed and closed 23 September 2018.

The DHSC and MHRA are jointly responsible as the National Competent Authority (NCA) for the implementation and enforcement of FMD in the UK.

Introduction

Implementation is required under Delegated Regulation 2016/161 from 9th February 2019, although there is ongoing uncertainty caused by Brexit. UK Pharmaceutical supply chain including homecare providers are mandated to comply however, given the uncertainty proceeding with appropriate caution is recommended.

In order to comply with the requirements of FMD, homecare providers pharmacies will be required (for products that bear "safety features") to:

1. Check the anti-tamper device (ATD) of each and every pack to ensure it is intact prior to dispensing or splitting the pack for dispensing. This is a simple visual inspection.
2. Change the status of the pack in the UK's National Medicines Verification System (NMVS) from "active" to "inactive—supplied". This involves scanning

the 2D barcode on each pack, which will communicate electronically with the NMVS.

The 'safety features' are the last in a series of measures introduced in the wider Falsified Medicines Directive aimed at fighting medicines falsification and securing the supply chain to ensure that medicines are safe. The detail of 'safety features' was laid out in the EU Delegated Regulation [Article 25(1)] state that these steps must take place "at the time of supplying the medicine to the public" although there is no further clarification of this definition

The UK's National Medicine Verification System (NMVS) is run by a not-for-profit industry organisation SecurMed UK, the National Medicines Verification Organisation (NMVO) which is supervised by MHRA and DHSC. Further guidance on their role can be found on their new website https://www.securmed.org.uk/

A more detailed but still understandable description of FMD prepared for community pharmacies can be found here https://ukfmdworkinggroup.files.wordpress.com/2016/11/fmd-wg-for-community-pharmacy-jargon-buster-nov-16-final.docx

It will be for each homecare provider to determine the best FMD process for their operation. FMD 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, including simultaneously with decommissioning. It in itself does not change the status of the pack
- **Decommissioning** – this has to be undertaken by the organisation supplying the medicine to the patient. There is an automatic verification of the pack's status and then changes it to "inactive" to prevent other packs with the same unique identifier being dispensed.
- **Re-Commissioning** – this reverses the decommissioning scan where it occurs within a 10-day time period after the pack was made "inactive". After 10 days re-commissioning is not possible and therefore those previously decommissioned pack(s) cannot be returned to the wider supply chain.

It is not clear what the costs will be of implementing FMD in Clinical Homecare, but as >90% of homecare patients are NHS funded, increased costs will, either directly or indirectly, impact NHS budgets. The majority of homecare services commissioned by the NHS are via tender processes which have not foreseen the costs of FMD implementation. Recent data from NCHA members shows approximately 3% of packs issued are not dispensed as original packs. Of all medicines dispensed, 5% are returned to the pharmacy (e.g. failed deliveries) and more than 97% of those medicines are assessed as suitable for re-issue to patients. Homecare medicines are typically high cost medicines, so any increase in wastage due to implementation of FMD will add significant cost. Any reduction in the ability of homecare providers to re-use previously dispensed (i.e. decommissioned) medicines would be unwarranted

as procedures already ensure assessment of the quality of medicines and audit trails are kept for re-dispensed medicines. It is clear that decommissioned medicines past the 10 day rule cannot be returned to the legal supply chain, as others would see the products as 'closed' and would not be able to meet their legal obligations to decommission medicines.

Patient safety may be compromised if unforeseen FMD implementation costs or increased waste adversely impact the financial viability of Clinical Homecare Providers. Furthermore, it is important that implementation of FMD does not provide a perverse incentive that blocks the achievement of the current NHS 5 Year Forward View or future initiatives on moving healthcare closer to patients rather than delivering care in high cost hospital settings

There is much work to do to ensure the Clinical Homecare Providers are ready for FMD and timelines are now very short. Clarity is urgently needed on what exactly is required of Homecare Providers and by when.

NCHA believes the approach outlined in this guideline will allow FMD to be implemented at a pace that allows the benefits of FMD to be achieved whilst minimising any adverse cost impacts and transition risks. There are still significant concerns about the costs of implementation and ongoing costs of FMD; risks of synchronised system changes across the entire pharmaceutical supply chain and further clarity is needed on the benefits that will be realised within the homecare setting.

Homecare Industry Level Risks

In Homecare, 95% of medicine packs are of are sourced direct from the manufacturer's and/or Marketing Authorisation Holder's supply chain. For FMD implementation, this means that the homecare supply route has a lower risk of falsified medicines.

NCHA has significant concerns that the FMD implementation is another significant system change for the bespoke systems that are used by most homecare providers. FMD implementation is running in parallel to the GDPR implementation and implementation of national standard homecare activity and key performance indicator reporting. Running three significant change projects in homecare in parallel poses particular complexity and risk of unforeseen system errors and other consequences which may impact patient safety. There are also concerns about the risks associated with significant system changes being enacted by all parties across the entire medicines supply chain which are being synchronised due to the availability of the central databases and SecurMed system only being available in summer 2018; February 2019 deadline for FMD; and the fact that system changes do not take place within the medicine supply chain in the run up to the Christmas activity peak.

MHRA and DHSC have been clear that patient safety must come first in respect to FMD implementation.

Homecare FMD Challenges

IT implications for homecare pharmacy systems

There are no "off-the-shelf" systems available to run homecare services. Homecare Providers each use different bespoke end-to-end IT solutions or different combinations of proprietary systems with/without bespoke elements. Each Homecare Provider will need to plan FMD implementation in their own system.

Where the homecare provider uses a bespoke system, they (or, if IT is outsourced, their relevant IT system partner) will need to register with SecurMed as a system provider. After registration, technical details relating to interfacing with SecurMed system will be provided. There is an expectation that SecurMed will need to verify the legitimacy of the system users to protect the integrity of the National Medicines Verification System.

Where the homecare pharmacy uses a proprietary Patient Medication Record (PMR) system, suppliers are adding FMD capability, but this may not be available by February 2019.

Homecare providers may instead opt for a stand-alone FMD system that is not linked to the main homecare systems. This means batch and serial numbers dispensed will not be automatically recorded against a patient delivery and the manual entry of batch data would need to continue as it does today. If homecare providers opt for a stand-alone FMD system as an interim solution, extra costs, disruption and operational inefficiency will be incurred.

Clarity in requirements for FMD system compatibility is needed for robust decision making on IT systems and hardware changes. Clarity on messages that will be received from verification and decommissioning scans is needed before standard operating procedures can be updated and users trained. There is considerable concern within homecare providers that continuing uncertainty means the timescale for implementation is very challenging.

Definition of the point of supply

Definition of the point of supply is not an instant but a period of time, from when a pack is selected for a patient or group of patients to when the delivery to the patient (or their representative) takes place. Decommissioning should happen as close to the time of supply to the patient as possible. In homecare, depending on the systems and processes in operation in each organisation, this can be anytime from receipt of the packs into the pharmacy to the time the consignment is handed to the patient[1].

[1] *"The sale and supply of Pharmacy (P) medicines and Prescription Only Medicines (POMs) must only happen at or from a registered pharmacy under the supervision of a pharmacist, even when the sale or supply is made on the internet."* Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet GPhC April 2015.

When to scan, verify and decommission packs

The precise process and timing of the check for evidence of tampering and decommissioning will depend on the homecare provider's standard operating procedures and may vary between homecare services and occur at different times in the pharmacy process. The decommissioning should happen as close as possible to the hand-over of medicines to the patient, but there are other important considerations in the homecare setting. Disruption to the dispensing, despatch and delivery workflows could jeopardise patient safety and confidentiality. As many homecare medicines are high cost, processes must not unnecessarily increase waste particularly due to the 10 day re-commissioning restriction.

Interpretation of FMD System Messages including Error Messages

At the time of writing, the messages that will be generated by the UK medicines repository are still to be determined.

Implementation of FMD should not change the liability of the Marketing Authorisation Holder to reimburse costs associated with recalls etc. whether supply was via a wholesaler or direct.

Receiving aggregated codes

Stock being received from the Pharmaceutical manufacturer or a wholesaler approved by the manufacturer do not need to be verified at goods-in. Where verification at goods-in is needed for bulk shipments, the suppliers can facilitate verification of stocks during the goods-in process through aggregation. Aggregation should be based on a contract between the homecare provider and the manufacturer or wholesaler. Whilst aggregation is allowed by FMD it is not a legal requirement. Organisations supplying medicines to the public bear the ultimate responsibility for verifying and decommissioning medicines. . If aggregation is agreed, additional checks will be needed to ensure that there is match to the products received. Coding labels need to be readable by the Homecare Provider systems and should be based on the GS1 coding system including data from all the packs contained in the outer or provide a link to the data stored in an accessible FMD-capable system.

Generating Aggregated codes

Aggregated codes can be generated by pharmacy IT systems to link several pack identifiers together. They are not mandatory. Aggregated codes may be printed on external consignment labels to facilitate decommissioning later in the homecare supply process. Aggregated barcodes on patient consignments cannot contain all

of the data of the pack identifiers but should simply provide a link to the data stored on the homecare providers FMD-capable system. This is because external labels on patient consignments should not contain information about the medicines contained in order to maintain patient confidentiality and GDPR compliance for delivery sub-contractors who do not handle "sensitive" personal data.

Specials

Manufactured specials are out-of-scope of FMD, but any registered medicinal product used in the production of a manufactured special will need to be decommissioned by the specials manufacturer.

Early days of implementation

Homecare providers will be within the first wave of FMD implementation as stockholding is commonly less than 1 month and replenishment stocks are received direct from the manufacturer, so most stock received by Homecare Providers after 9th Feb 2019 will have safety features. Homecare Providers will have existing stock without safety features and there may additionally be packs that bear a 2d-barcode but are pre-FMD stock. Confusion may arise as in some, but not all cases, the manufacturer may have uploaded them to the database anyway.

In excess of 90% of homecare services are manufacturer funded, so homecare providers will be subject to the additional contractual requirements imposed by the manufacturer (or marketing authorisation holder) in relation to FMD implementation.

High Level FMD process for Clinical Homecare

Homecare pharmacies will be required to decommission medicines themselves. While the regulation is clear that pharmacies must decommission medicines at the point of supply to the patient there are additional flexibilities for 'healthcare institutions' e.g. hospitals and GPs, who can decommission at any time once it's in their possession. However, in reality despite having registered pharmacy premises homecare providers fall between the two because of the way they operate. Therefore, in considering the period of time from when a pack is picked to the patient, homecare providers should aim to decommission as close to the patients accepting there will be limitations on what is practical in terms of their business processes. In some organisations these will be separate sites or areas within the same site. If the demarcation between the wholesale and pharmacy areas is not clear there may be regulatory challenges arising from different regulatory requirements and regulatory audit regimens of GPhC who regulate pharmacies and MHRA who regulate wholesalers.

The use of verification scans within the homecare medicines supply process should be risk based. If decommissioning is performed at assembly or delivery stage, a verification scan may be appropriate during the pharmacy goods-receiving process or earlier e.g. within wholesale goods-in process. It is recommended that either a

verification scan or decommissioning is performed early in the process when the medicines are received by the homecare provider so that any FMD coding errors are identified at the earliest opportunity ensuring liability for products that failed FMD scans remains with the supplier. Using the risk based approach however, it may not be necessary to perform a verification scan on products received direct from the manufacturer.

Each item's Anti-Tamper Device will be checked during assembly or dispensing of the individual patient order. This is the only time during the homecare process when each individual pack is handled.

Medicines supplied to homecare provider's healthcare professionals "for use in practice" will be decommissioned at the time of issue to the healthcare professional e.g. anaphylaxis kits.

Implementation of FMD must not undermine existing recall processes which are tried and tested.

MHRA have confirmed that the responsibility for reconciliation of FMD coding information in the European Database rests with the Marketing Authorisation Holder. However, there are concerns over the implementation of additional regulatory expectations for reconciliation of medicines within homecare providers to serial number level.

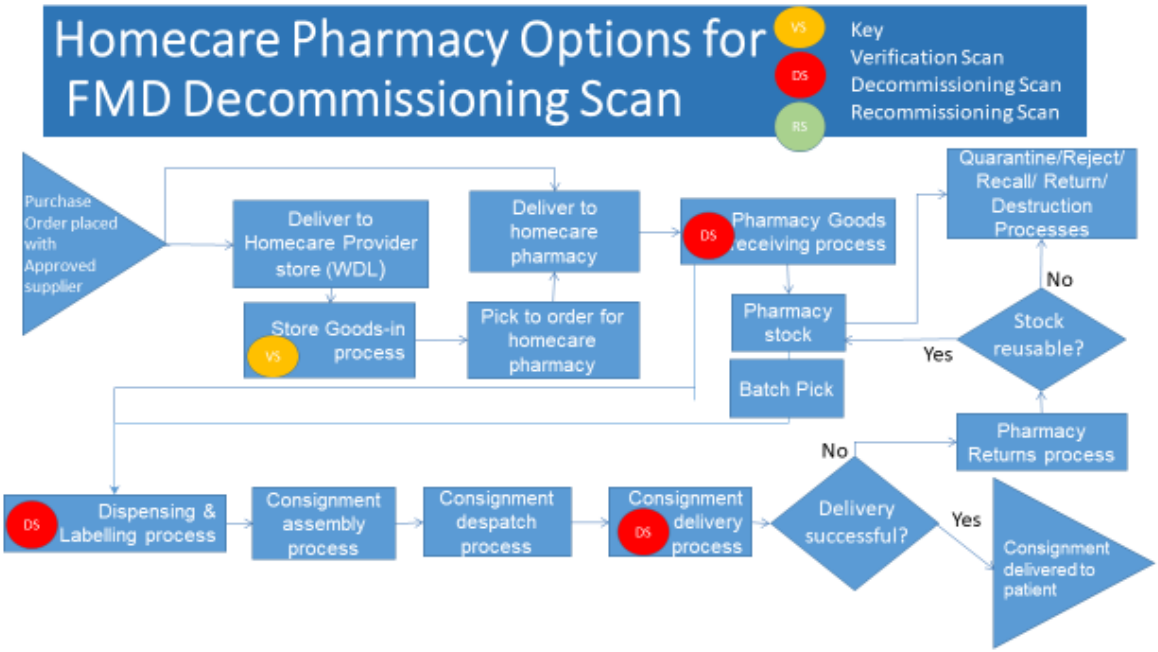

Figure 1: Homecare Pharmacy Options for FMD Decommissioning Scan

Risks and benefits of decommissioning at Pharmacy Goods-receiving stage

Benefits	Risks
Least impact on operational processes providing aggregated FMD coding is available from the manufacturers and is readable by the homecare provider systems	Pharmacy stock is not available tor wholesale transaction.
May be cheaper and quicker to implement in system terms as a stand-alone system could easily be used	Will not facilitate additional functions such as integrated accuracy checks
Minimal efficiency impact on dispensing and assembly process	Will not automatically link and record FMD batch number/ expiry dates dispensed for each patient in the patient record
Split packs are not an issue as all packs are decommissioned on arrival at the pharmacy	Risk of medicines that would fail FMD scan remaining in pharmacy stock until the medicine's expiry date.
Returns can be processed as per current processes – no increase in waste providing manufacturer credits stock failing FMD checks.	Homecare provider may have increased liability in case or products which would fail FMD scan being dispensed.
Allows low risk stock to be decommissioned early in the life-cycle of the medicine allowing detection earlier of alternative counterfeit packs in the wider supply chain.	
Identifies FMD coding issues early giving time for resolution so continuity of patient supply is not impacted.	

Risks and benefits of decommissioning at Dispensing / Assembly stage

Benefits	Risks
Maintains relationship of FMD batch/expiry information with the individual patient record	May be more expensive to implement
Possibility of linking FMD information to an accuracy check at a future date	The pharmacy may need to be reconfigured to accommodate more scanners and terminals in the dispensary

Benefits (continued)	**Risks (continued)**
If aggregated codes are not available this is the only time individual packs are routinely handled within the homecare supply	The assembly process is likely to need to be amended
	Split packs will be scanned multiple times
	Returns will need to be re-commissioned within 10 days for wholesale supply
	Systems will need to cope with returns that have already been decommissioned being returned to pharmacy stock and issued at a later date

Risks and benefits of decommissioning at Handover of consignment to the patient Stage

Benefits	**Risks**
Decommissioning at latest time point in the homecare medicine supply chain	Requires anonymised aggregated codes on consignments,
	Would require verification scan at dispensing / assembly stage to provide information for aggregated codes for patient consignments
	Systems must be able to produce aggregated code labels for patient consignments linking to a secure database with medicine information
	Functionality not available with many delivery sub-contractors, so would only be possible for a proportion of deliveries.
	May cause patient safety issues if scan fails and medicine cannot be supplied

IT systems – expected standard requirements

An overview of user requirements for an FMD compliant system is provided below for more information see URS Lite[2]. The full 'URS heavy' is only available from SecurMed on signing an NDA.

The FMD compliant system must:

- Perform verification scans
- Perform decommissioning scans
- Perform automated expiry date checking using information from the 2d code. This applies to all 3 scan types – verification, decommissioning and re-commissioning
- Allow re-commissioning i.e. allow reversal of decommissioning within the 10-day period permitted.
- Have a suitable offline feature to ensure continuity of medicine supply to patients.
- No user action should be needed to go offline/online. FMD-capable systems will automatically deal with outstanding FMD requests including highlighting negative scan results on reconnection to NMVS.
- Manual (keyboard) entry of the unique identifier must be supported (for exceptional circumstances such as where the pack is damaged)
- Enable split pack dispensing with check the tamper-evident seal/s, decommission on first use, then further use as required without any requirement to scan and suitable messaging if scanning is performed on a previous used split pack.
- The system must allow the connection of sufficient scanners or terminals and must be able to process multiple decommissioning requests and their results simultaneously. It must be clear which NMVS feedback message corresponds to which scan activity.
- The system should provide management information relating to FMD activity.

The FMD compliant system should where appropriate:

- Link FMD scan results made during goods-in processes to the supplier's order.
- Interface with automated assembly systems (robots) as appropriate.
- Interface with the patient record system to store FMD requests/results against the patient record which may support recalls/decommissioning failure identified after reconnection to the NMVS.
- Check that pack product data (e.g. Global Trade Item Number (GTIN)) matches equivalent information on prescriptions (potentially using dm+d codes) during verification or decommissioning scans (i.e. automated accuracy checking)

[2] https://www.emvo-medicines.eu/wp-content/uploads/2016/09/EMVS-URS-Lite.pdf

- Interface with homecare provider stock control systems
- Provide detailed management information – terminals/ users who conducted the scan, proportion of items dispensed, scans conducted, etc.
- 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 be able to print aggregated codes with despatch labels identifying the contents of each consignment and part thereof.

The FMD compliant system must allow feedback to the user:

- Current pack status for verification scans
- Successful decommissioning
- Decommissioning "errors"
- Successful re-commissioning where appropriate
- Where possible, visual and audible feedback differentiating positive and negative scan results (and associated messages) should be harmonised across different operating locations and homecare providers
- Audible warning should be able to be turned off if required.

Scanners

The scanners used must be able to scan:

- Barcodes on medicine packs
- FMD unique identifier 2D data matrix codes
- Aggregated barcodes (if used)

The scanners used should be able to scan:

- Barcodes on prescriptions
- Existing linear barcodes on other stock items (and possibly QR or other information codes)
- Using wired and/or wireless scanners.

Scanners in automated warehousing and/or dispensing systems or robots

Response to negative or failed scans and decommissioning errors

"Error messages" that should be anticipated are:-

- "not detected on system" for those items which did not have their data uploaded before 9th Feb 2019
- "failures" (i.e., pack identifier previously dispensed in same pharmacy, another location, another country, product past expiry date)
- other system errors, including temporary lack of connection to NMVS

Error messages should help identify where the product was received from to facilitate further processing in accordance with the homecare provider's processes in case of an FMD error message.

Using a risk based approach, some "error messages" will be for information and some will require action. If a scan results in an "error message" that cannot be readily explained and dealt with, the homecare pharmacy may need to report to the manufacturer or MHRA. For example a stolen or already used pack message for a pack received direct from the manufacturer would need reporting, but an out of date message means the pack cannot be used.

The process for responding to negative or failed scans is yet to be determined but should be risk based. The proposed flow chart for responding to negative or failed scans or decommissioning errors in homecare pharmacies is below.

Homecare organisations will need to consider processes to be followed if the FMD system is not available, whether local systems being "down", connection issues or unresponsive National Medicine Verification System. It is also likely that homecare providers will, at some point, take a risk based decision to dispense and deliver to patients, medicines that have inconclusive or failed FMD scans. Homecare provider Responsible Pharmacists will need to be supported to take these decisions by their Superintendent pharmacist via approved standard operating procedures.

The way forward for FMD in community pharmacy3 contains a proposed scanning and error messages flowchart for use by community pharmacies in Appendix D which can be used as a reference A specific scanning and error message flowchart will be prepared for homecare pharmacies when the detail of the error messages are known.

Immediate Actions to be taken by Homecare Providers for the implementation of FMD

Actions are outlined in the following list and further details provided below.

- Assess need to update IT systems and associated hardware
- Connecting homecare pharmacies to the National Medicine Verification System (NMVS "on-boarding")
- Check internet data connection
- Assess impact of FMD on workflows and standard operating procedures
- Develop user/staff training

Assess need to update IT systems and associated hardware

It is anticipated that all homecare providers will need to make IT system and hardware changes to ensure FMD compatibility. Homecare providers should assess their current IT systems and hardware to ensure FMD data fields are included in relevant databases and hardware is capable of scanning FMD compliant barcodes. The scale of system changes required will vary between organisations.

[3] https://pharmacyfmd.files.wordpress.com/2018/08/fmd-cp-working-group-way-forward-paper-jan-18-public-v1-0-final.pdf

Connecting to the National Medicine Verification System (NMVS)

Each homecare provider pharmacy will need to connect to the NMVS 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 "on-boarding" or "registration" and will need to be completed well before 9th February 2019. SecureMed UK and/or Arvato have yet to determine the process that pharmacies will need to undertake to complete their on-boarding. Due to the 2018/2019 festive period, and staff training requirements, on-boarding should be completed at the earliest opportunity.

Check Internet Data Connection

The homecare provider will need to ensure that their internet data connection is appropriate in terms of speed, capacity and latency.

Assess impact of FMD on workflows and standard operating procedures

Implementation of the Falsified Medicines Directive will have a direct impact the operational processes within each homecare provider. Workflows and standard operating procedures should be updated to include verification scans, decommissioning and procedures to be followed when FMD "error messages" are received when the detail of the error messages are known and the scanning and error messages flowchart for use by homecare pharmacies is available.

User training

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 homecare provider. This will include training on the revised standard operating procedures.

Recommendations

Implementation Phasing within and between homecare providers

Homecare systems are unlikely to be fully compliant by Feb 2019 and a transition period is suggested to stagger the implementation and minimise risk of all homecare providers making significant system changes concurrently.

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

Error messages

The FMD error messages and standard audible warnings need piloting.

When error messages occur, among the issues to be clarified are:

- Who is responsible for investigating negative or failed scans – homecare provider, wholesaler, manufacturer/Marketing Authorisation Holder, SecurMed or the National Competent Authority?
- The information that is required to be supplied to the investigating body from the homecare provider and how that data is transferred.
- The process for refunding the cost of the pack to the homecare provider in the event of a failed scan (which has been bought in good faith). This would not include a failed scan due to expired stock (unless received expired which would be covered by the current process).
- The timescales during which the above must be carried out

When the detail of the error messages is known a scanning and error messages flowchart for use by homecare pharmacies is to be prepared.

User training

Consideration should be given to provision of a national training programme to explain FMD to homecare pharmacy staff with individual organisations providing training on their own internal processes.

Patient information

Given the substantial interest and potential disruption that the introduction of FMD will cause, DH, MHRA and SecurMed UK should work with the FMD Working Groups in each of the medicines supply chain sectors to produce consistent information materials for patients, customers and carers that contractors can use to explain the implementation and benefits of FMD.

Stakeholders

NCHA should engage at the earliest opportunity with BGMA, APBI and NHMC to ensure expectations of pharma manufacturers and NHS are managed and implementation of FMD is co-ordinated with all key stakeholders.

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 possible that GPhC (General Pharmaceutical Council) will have a role in the enforcement of the FMD regulations in homecare pharmacies. The regulatory position must be clarified.

In order to ensure patient safety in clinical homecare services, regulators must all accept processes for business continuity on an "as usual" basis when FMD systems are not available.

Conclusion

NCHA will to continue engagement with MHRA and DHSC to plan implementation of FMD and assess the impact on regulatory compliance of Homecare providers with the new regulations during the implementation phase.

Whilst the situation is open to interpretation, it is not unreasonable to conclude that in relation to clinical homecare services:-

- Implementation of FMD within the timescales envisaged will be very challenging.
- Engagement with pharmaceutical manufacturers and market authorisation holders supplying homecare medicines will be critical to successful implementation.

References and Useful links

What you need to know about FMD - Jargon Buster

Ref https://ukfmdworkinggroup.files.wordpress.com/2016/11/fmd-wg-for-community-pharmacy-jargon-buster-nov-16-final.docx from www.fmdsource.co.uk 23/11/2016

EMVO https://emvo-medicines.eu/

FMD source www.fmdsource.co.uk

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

https://www.securmed.org.uk/

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