EU FMD for Hospital Pharmacists

YOUR TOP 10 QUESTIONS

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CONTENTS

Introduction

The EU Falsified Medicines Directive (FMD) aims to eliminate falsified medicines by implementing uniform product identification and verification requirements across the pharmaceutical supply chain, from manufacturer to pharmacist. A falsified medicine is one whose ingredients may be different, of poor quality, or incorrect dosage compared to the authorized medicine.

From February 2019, every pack of in-scope medicines must bear safety features, consisting of an anti-tamper device and a 2D Data Matrix code containing a unique product identifier. The pharmacist or dispensing doctor must scan and verify that an in-scope medicine is genuine, and decommission it before dispensing it to a patient.

In preparing for EU FMD, hospitals need to assess the equipment and software they will need, and implement new processes for verifying and decommissioning medicines. In this eBook, we answer the top questions they have about how FMD will impact their operations.

Key Terms

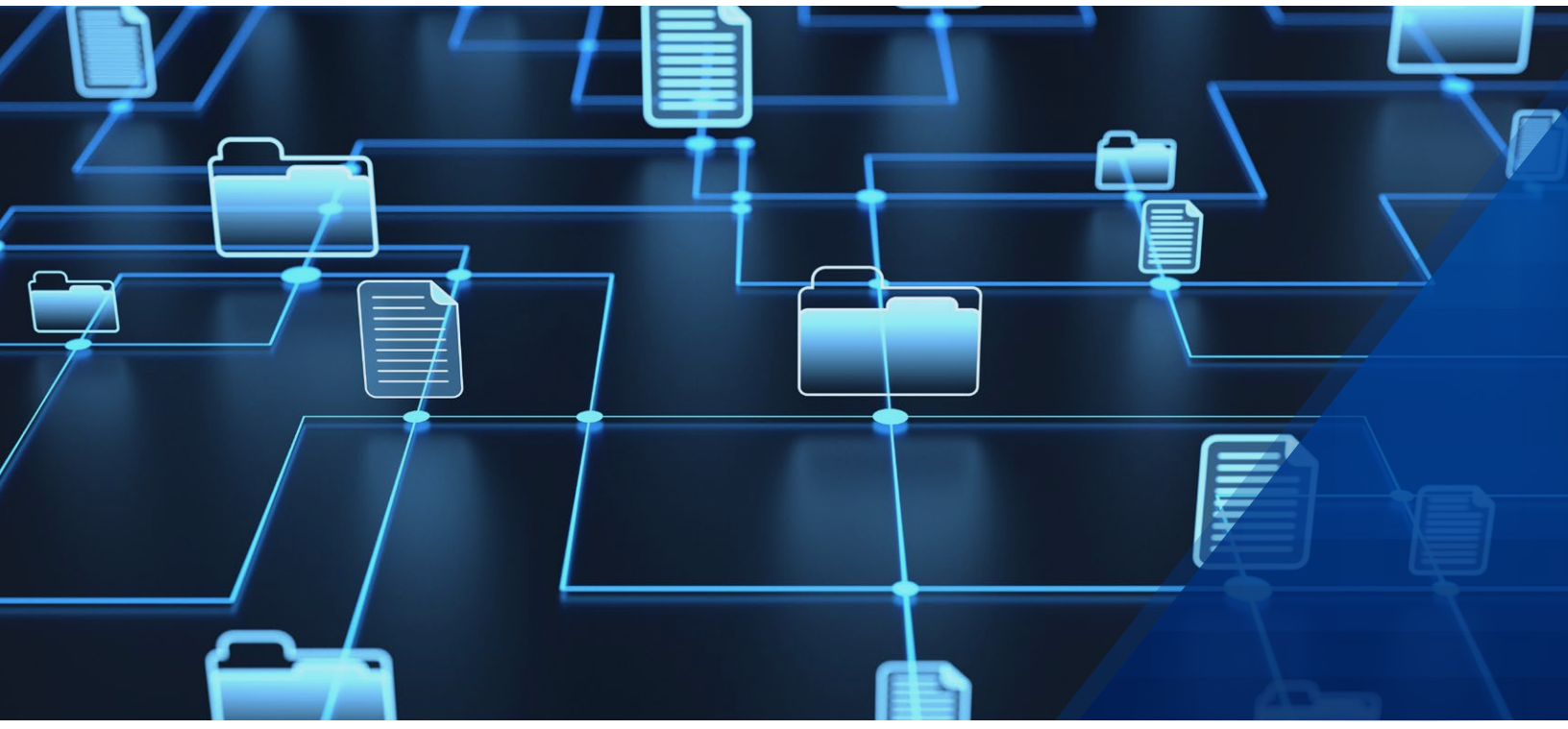
- Before shipping a medicine, the manufacturer uploads the product data to the **EU Hub**, which routes it to the target market's **National System**.
- Each National System is governed by a **National Medicines Verification Organization (NMVO)**. This is a separate entity from the **National Competent Authority (NCA)**.
- Checking a pack's unique identifier against a country's National System is known as **verification**.
- **Decommissioning** deactivates the pack's unique identifier against the National System, effectively removing it from the supply chain.
- Reactivating the pack's unique identifier against the National System after it has been decommissioned is known as **recommissioning**. This can only be done in specific circumstances (see question 5).

1 | Will I need additional software to connect to National Systems?

Yes. Hospitals will need a solution that has a secure connection to the National System and can complete the required transactions. National Systems are a new concept specific to EU FMD, so this capability does not exist in current pharmacy software.

In order to support compliance, a solution must be able to:

- Receive input from 2D barcode scanners in order to verify, decommission, and—when necessary—recommission packs.
- Operate in accordance with industry security standards in order to ensure compliance and patient safety.
- Securely transmit the scanned data and receive the ensuing confirmation or alert from the National System.
- Accept manual data entry, in case the 2D Data Matrix code is damaged and can't be read by a scanner.
- Provide offline functionality, so that medicines can continue to be supplied to patients in the case of a connection or system failure. The solution must then be able to process outstanding requests on reconnection to the National System.



2 | How do I know if a pack has already been verified?

There is no way of telling by looking at a pack if it has already been verified, but some EU FMD solutions can detect that, though it's not a mandatory feature.

Hospitals will need to ensure that their staff receive adequate training to comply with the verification requirements, and then build it into their workflow. There are benefits of verifying packs as soon as you receive them, even though this means scanning the packs twice—once to verify and again to decommission.

Verifying upon receipt:

1. Provides staff with clarity on at what point packs should be verified, reducing the risk of packs not being verified until point of dispense—or at all.
2. Allows you to deal with any issues early, reducing the risk of shortages and having potentially unsafe medicines in your hospital.

3 | Where is the best place to verify and decommission medicines?

Hospitals can use their discretion to determine the best point to decommission medicines, but should consider several factors, including:

- **Shortages and non-availability:** With early decommissioning, there is the risk that the pack's status could then change between the time you decommission it and when you dispense it to a patient. In that period, for example, the manufacturer or wholesaler could issue a recall. Decommissioning at or close to point of dispense would reduce this risk, but it could increase the risk of medicine shortages or non-availability if an error or failure is returned upon decommissioning.
- **Stock and supplier management:** Decommissioning at goods-in would allow you to reject any packs that fail immediately, so you eliminate any chance of having suspect stock on your premises. However, for larger hospital systems with a central receiving facility, transporting decommissioned medicines between locations could have an impact on logistics.
- **Wastage:** Decommissioning can only be reversed (referred to as recommissioning) within 10 days, so decommissioning early could result in wastage.
- **Staff clarity and compliance:** Decommissioning all packs in one place—such as the hospital pharmacy or at goods-in—would limit the number of staff who need to be trained on the decommissioning process. Decommissioning at goods-in would give your staff the confidence that stock on-site has already been verified and decommissioned.

4 | What is the impact on workflows with satellite or decentralized dispensing?

If you have multiple points of dispense—whether they are within the same building or different buildings—you will need to equip all of those locations with the ability to verify and decommission packs and to report any issues. EU FMD requires that any FMD solution be able to trace the scanning activity back to the corresponding location and sync the transactions with the National System.

5 | Can we return a medicine to stock if it has already been decommissioned?

If packs are decommissioned but not dispensed or collected, this could increase waste and cost. To reduce this risk, Article 13 of EU FMD allows for the reversal of decommissioning—called recommissioning—in order to return a medicine to stock under the following circumstances:

1. It takes place within 10 days (240 hours) of decommissioning.
2. It is performed by the same organization that decommissioned it, and in the same location.
3. The pack has not been marked as recalled, stolen, or expired since being decommissioned.

To recommission a pack, you scan it to inform the National System that the pack is effectively re-entering the supply chain. Your FMD solution must check the product data to make sure it hasn't expired or been recalled, before informing you of a successful recommission. It can then be returned to stock.

A pack that was decommissioned longer than 10 days ago can only be dispensed within your hospital or wider hospital group, or safely destroyed.

6 | What information will I get back from the National System when I scan a medicine?

The National System will return one or more of the following statuses, depending on the transaction chosen:

- **For verification**
  - The pack's current status: active, recalled, expired, or decommissioned. Only an active product can be dispensed.
- **For decommissioning or recommissioning**
  - Success
  - Error: for example, unable to read the 2D code.
  - Failure: for example, the unique identifier has already been decommissioned or, in the case of recommissioning, more than 10 days have passed since the pack was decommissioned.

7 | What do I do if I receive an error message on verification or decommissioning?

There are a number of reasons why the National System may return an error message when you scan a medicine. These are the most common:

REASON	2D Data Matrix code is damaged or smeared	MAH has not followed EU FMD rules for the product identifier	MAH has not uploaded the pack's product data to the EU Hub	System error
DETAILS	If the code is damaged, your barcode scanners will not be able to read it.	Product identifiers have strict formatting requirements—if the manufacturer has not followed these, the National System will not be able to read it.	The National System receives product data from the EU Hub, which is reliant on MAHs uploading their data before shipping the product.	As with any IT system, there is a possibility of downtime or connectivity issues.
WHAT DO I HAVE TO DO?	Find the HRI (human readable information) on the pack and manually enter it into your system.	Find the HRI (human readable information) on the pack and manually enter it into your system, to check that the issue isn't just with the 2D Data Matrix code.	If the product identifier does not exist in the National System, you cannot verify it.	Check with your NMVO for any reported system errors and expected downtime.
CAN I STILL DISPENSE IT?	If the error message persists, you cannot verify or decommission the pack, and it cannot be dispensed to the patient.	If the error message persists, you cannot verify or decommission the pack, and it cannot be dispensed to the patient.	No.	Yes—your EU FMD solution must be capable of keeping track of dispensed packs, and syncing with the National System once back online.
DO I HAVE TO REPORT IT TO MY NCA?	Yes.	Yes.	Yes.	No.

8 | What do I do if I receive a failure message on verification or decommissioning?

Failure messages indicate that there is a problem with the pack itself, rather than error messages that indicate a problem with the system or code.

Decommissioning fails when the pack's unique identifier has been marked with one of four statuses:

PACK STATUS	Already decommissioned	Stolen	Recalled	Expired
DETAILS	This raises the alarm that the pack could be falsified, as it is bearing a product identifier that has already been decommissioned.	Manufacturers and wholesalers are required to report stolen packs to the EU Hub.	When a manufacturer or wholesaler needs to recall a pack, they have to report it to the EU Hub.	The pack has exceeded its expiry date.
CAN I STILL DISPENSE IT?	No.	No.	No.	No.
DO I HAVE TO REPORT IT TO MY NCA?	Yes.	Yes.	No.	No.

9 | What do I do with stock bearing a 2D Data Matrix code before my National System is live?

If manufacturers are already producing packs bearing the safety features, they are obligated to upload that data to the EU Hub, even though EU FMD is not yet in effect. However, the EU Hub cannot pass that data on if the National System of the country in which they are destined to be sold is not yet live.

As of late summer 2018, 22 National Systems were already live, and experts deemed only 3 National Systems to be at risk of not being ready by February 2019.

If you scan packs that were manufactured prior to your local National System going live, you could receive an error message. This gap in readiness is a concern that the European Medicines Verification Organization (EMVO) and National Medicines Verification Organizations (NMVOs) are already discussing, and guidance to hospitals will be released nearer to February 2019.

10 | What criteria should I use when choosing an EU FMD solution?

In addition to all of the mandatory functionality outlined in Question 1, hospitals should look for an EU FMD solution that:

1. Minimizes disruption to their workflow.
2. Has the potential to provide increased visibility of your inventory and other business values.
3. Provides a connection to the National System and subsequent response time that is as rapid as possible, to avoid delaying your staff and patients.
4. Requires a minimal IT footprint, since every verification and decommissioning location needs to be equipped with an EU FMD solution.

The TraceLink Pharmacy Application provides pharmacists with a secure and easy-to-use method for complying with EU FMD requirements while offering enhanced visibility into stock control and reordering processes. TraceLink's Pharmacy Application adds scanned packs to your inventory dashboard once you have verified them, allowing you to track product disposition and better manage product exceptions (product expiry, recall notifications, product alerts, etc.) that have been issued by the manufacturer. TraceLink also supports unique dispensing solutions, including centralized fill locations where individual medicines are aggregated, split packs and unit dose dispensing. The cloud-based solution can be accessed via mobile or tablet, or integrated with your existing pharmacy software.

Contact us to find out more about TraceLink's solutions for hospital pharmacists.