



Falsified Medicines Directive ('FMD'): Refresher and update on recent developments

LEONIE CLARKE MPSI

IIOP 'IN CONVERSATION WITH ...' SERIES

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Outline

- ▶ Recap of FMD
- ▶ Where are we now?
- ▶ Practical tips for FMD
- ▶ PSI FMD inspections
- ▶ New IMVO Corporate Strategy 2025-2027
- ▶ Revision of EU pharma legislation
- ▶ Support available from IMVO
- ▶ Q&A
- ▶ Back-up slides
 - ▶ *NMVS Alerts*
 - ▶ Common causes of alerts





Recap of FMD

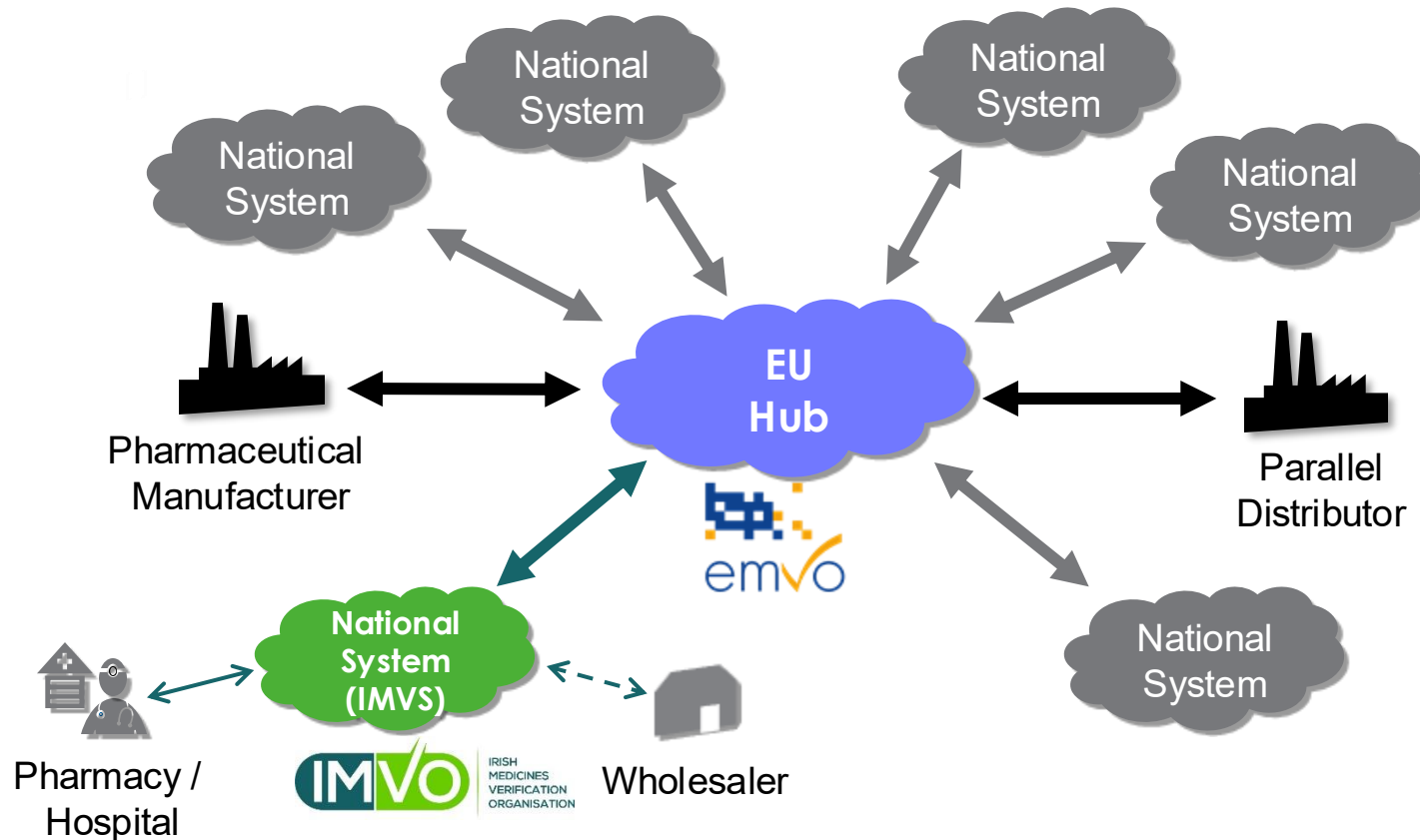
Falsified Medicines Directive (FMD)

- ▶ Falsified Medicines Directive (2011/62/EU) introduced several measures to tackle growing threat of falsified medicines and ensure trade in medicines is rigorously controlled
 - ▶ Obligatory **safety features** on outer packaging of medicines – 2D barcode and anti-tamper device
 - ▶ Common, **EU-wide logo** to legal online pharmacies and medicines retailers
 - ▶ Tighter controls on and inspections of producers of **active pharmaceutical ingredients**
 - ▶ Additional requirements for **wholesalers**, included extra record-keeping
- ▶ Commission Delegated Regulation (EU) 2016/161 (**'DR'**) sets out:
 - ▶ Details about safety features and how European Medicines Verification System was to operate
 - ▶ Obligations of national medicines verification organisations (NMVOs), manufacturers/marketing authorisation holders (MAHs), wholesalers, pharmacies and hospitals



 Click to verify
if this website
is operating
legally

European Medicines Verification System (EMVS)



Covers 30 countries:

- 26 EU (IT due to join later this year)
- 3 EEA
- Switzerland (have joint system with Liechtenstein)
- UK system was disconnected on 31 Dec 2024 due to Windsor Framework

Roles and responsibilities

► IMVO:

- Manages Irish Medicines Verification System (IMVS) and ensures it operates smoothly as part of European EMVS
- Supports pharmacies, hospitals and wholesalers ('end-users') to connect to the IMVS and assist with any problems that arise
- Works with end-users and marketing authorisation holders (MAHs) to minimise avoidable alerts
- Provides for the immediate investigation of all alerts that represent potential incidents of falsification and ensure the HPRA, European Medicines Agency and EU Commission are notified should the falsification be confirmed

Roles and responsibilities (ctd)

- ▶ **Department of Health (DoH)** – responsible for legislation and policy relating to safety features where there is scope for national decisions; accountable to EU Commission for any non-compliance with EU legislation
- ▶ **National competent authorities (NCAs)** – responsible for supervising the IMVS and ensuring that all parties comply with their obligations
 - ▶ **HPRA:**
 - ▶ Oversees compliance by manufacturers, MAHs, wholesalers and IMVO
 - ▶ Leads investigation if falsified medicines are identified
 - ▶ Also takes lead in detaining and closing down suppliers of illegal medicines (and other healthcare products) working with Garda Síochána, Revenue etc.
 - ▶ **PSI:**
 - ▶ Oversees compliance by retail pharmacy businesses and pharmacists
 - ▶ Maintains register of online retailers of medicines

Roles and responsibilities (ctd)

Manufacturers/MAHs

- ▶ Manufacture packs with 2D barcodes and anti-tampering devices
- ▶ Ensure data is correctly uploaded to EMVS for all markets in which products are marketed
- ▶ Involved in investigation of alerts on their products and follow-up with HPRA in case of falsifications

Roles and responsibilities (ctd)

Wholesalers

- ▶ Not required to verify every pack that passes through their warehouses, only the following:
 - ▶ Returns from customers – can't return decommissioned packs to stock (which is why it is important to recommission packs that are not needed by patients – can only be done within 10-day window after decommissioning)
 - ▶ Packs received from a supplier other than manufacturer/MAH or their designated wholesaler
- ▶ Decommission packs as destroyed / stolen / locked as appropriate
- ▶ Decommission packs supplied to 'Article 23 locations', e.g. GPs, prisons, vets, etc. 'Article 23 locations' are those defined in EU and national law as being exempt from the requirement to do their own decommissioning
- ▶ Investigate alerts generated in their warehouses

Roles and responsibilities (ctd)

Pharmacies and hospitals

- ▶ Authenticate packs prior to supply to patients by scanning 2D barcode and checking anti-tampering device
- ▶ If the scan generates an 'alert', follow-up action is required and the pack must be withheld from supply until falsification has been ruled out
- ▶ If the pack appears to have been tampered with, do not supply the pack and report your concern to the HPRA (as a suspected quality defect) via [HPRA's online reporting system](#)
- ▶ Risk of falsified pack entering legal supply chain in Ireland is low but it is a real risk

Scan responses

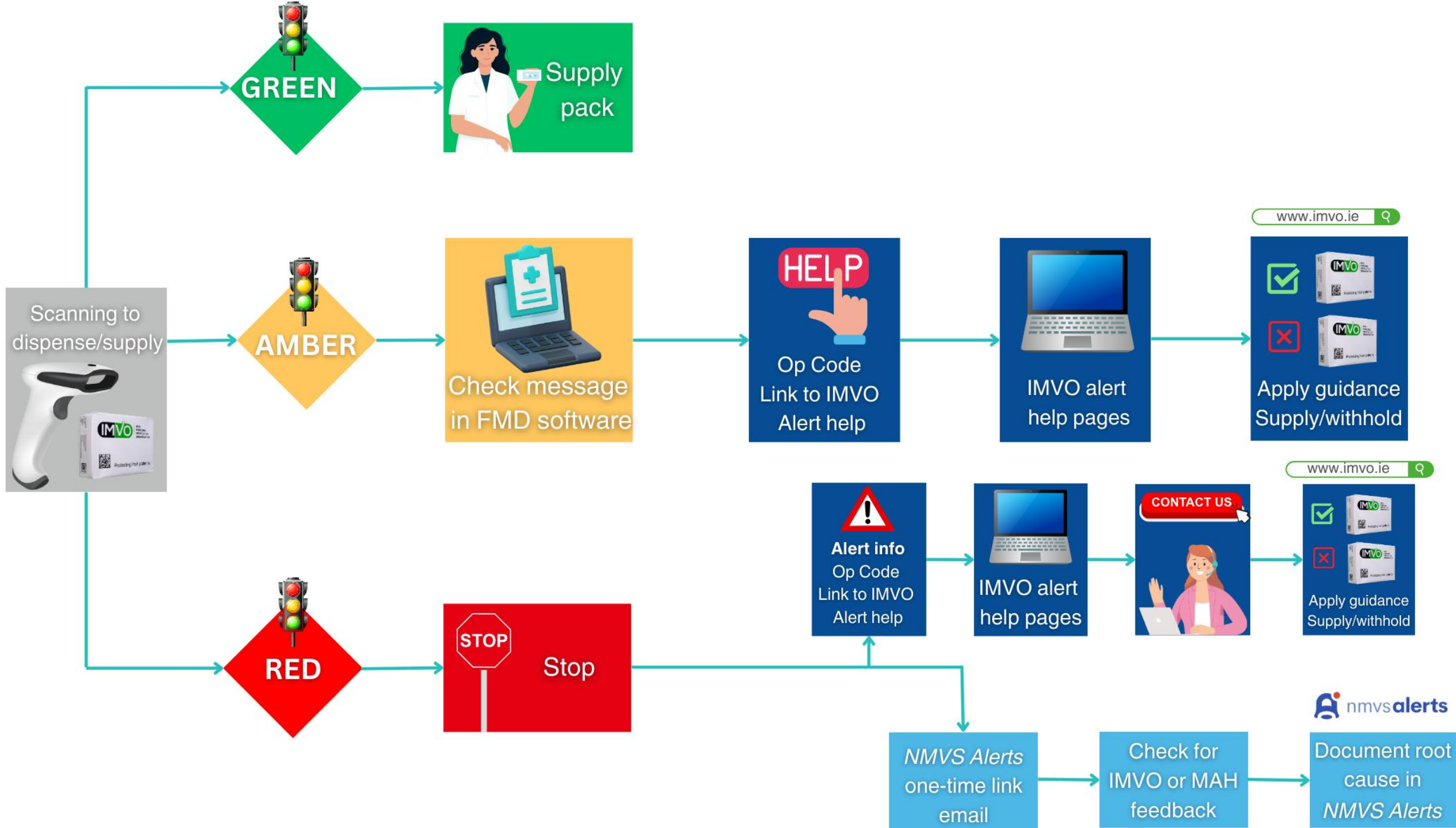
- ▶ When you verify or decommission a pack, your FMD software displays a response which contains text and is colour coded (**green/amber/red**) depending on the outcome of the scan
- ▶ **Amber** and **red** responses require attention
- ▶ **Alerts (i.e. potential falsifications)**
 - ▶ Certain **red** or **amber** responses represent potential falsifications and are known as '**alerts**'
 - ▶ Alerts can be recognised as follows:
 - ▶ The message returned by your FMD software will include the words 'An alert has been raised'
 - ▶ The alert will have unique Alert ID, e.g. IE-LJB-AGR-34G-R3A-VG3
 - ▶ You will receive an email from IMVO's alert management system - *NMVS Alerts* - for these alerts
 - ▶ All alerts are automatically notified to IMVO, the MAH for the product and the HPRA
 - ▶ These alerts must be investigated to establish a root cause and falsification ruled out before the pack can be supplied
- ▶ All other scan responses are known as '**exceptions**'

Examples of amber 'exceptions'

Scan message	Likely root cause (other than falsification)	What to do next?
Product code not known	Barcode on non-FMD pack was scanned, e.g. medical device, OTC, EMP/ULM from outside EU	- Follow advice in IMVO 'Help' page (linked from your FMD software) - Contact IMVO if you need any further assistance - NB – you will not receive any NMVS Alerts emails about these exceptions and don't need to notify IMVO of the outcome of your own investigation
Batch is recalled	Pack has been recalled	
Pack cannot be reactivated – time limit exceeded	More than 10 days have elapsed since pack was decommissioned in your pharmacy	
'The product code or batch is unknown locally. Inter-market communication error. Do not retry' <i>New message from 1 Jan 2025 linked with Windsor Framework</i>	You have scanned a UK pack previously uploaded to the UK system (prior to 1 Jan 2025)	Supply the pack unless you have overriding concerns that it may be falsified or has been tampered with or it has expired

Examples of red 'alerts'

Alert message	Likely root cause (other than falsification)	What to do next?
Batch not found	- Scanner or software issue - Data not uploaded by MAH UK pack placed on market in UK <u>since</u> 1 Jan 2025	<u>UK packs only:</u> Supply the pack unless you have overriding concerns that it may be falsified or has been tampered with or it has expired <u>All other packs:</u> - Follow advice in IMVO 'help' page (linked from your FMD software) - If you identify a root cause in the pharmacy, notify IMVO via NMVS Alerts - If you can't identify a root cause: - Set pack aside until you are informed of outcome of MAH's investigation - Keep pack in pharmacy/ hospital until the MAH or HPRA advises you what to do next with it. Do not supply it to a patient - Contact IMVO if you need any further assistance
Pack not found / serial number is unknown	- Scanner or software issue - Data not uploaded by MAH (least likely)	
Pack already decommissioned in another location	Procedural error - decommissioned pack received from another pharmacy or wholesaler	
Pack already decommissioned (bulk/split pack)	- Procedural error (most likely) - Scanner or software issue	
Batch ID mismatch	Scanner or software issue	





Where are we
now?

In summary ...

- ▶ **Continuous improvement** of EMVS (including IMVS) to enhance user experience, performance and eliminate system-related alerts – system is very stable, with very few delays or downtime
- ▶ **Alert rate** in Ireland has increased since the start of Jan 2025, due to impact of Windsor Framework
- ▶ Decommissioning rates are improving but **still not close to full scanning**
- ▶ **Continuous communication** by IMVO to pharmacies, hospitals, wholesalers and MAHs on most common issues seen by us in order to help prevent further alerts
- ▶ Pharmacy and hospital **engagement with IMVO has increased** significantly
- ▶ Usage of the '**NMVS Alerts**' **alert management system** by pharmacies and hospitals to provide feedback on alerts is steadily increasing

European Medicines Verification System



**14 billion
transactions
per year across
Europe**



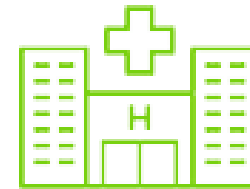
**115,000 community
pharmacies**



**4,000
wholesalers**



2,900 MAHs
*(marketing authorisation
holders)*



6,000 hospitals
*(pharmacies,
labs & stores)*

IMVS users (Sept 2025)

Marketing authorisation holders (MAHs)

- ▶ 375 MAHs

End-users (total 2101)

- ▶ 1902 pharmacies
- ▶ 101 hospitals
- ▶ 96 wholesalers
- ▶ 2 other



Analysis of alerts – 1 Oct 2024 to 30 Sept 2025

Alert to Scan Ratio for End-users



Summary of alerts

- ▶ Increased alert rate is driven by scanning of UK single market packs as these packs all generate alerts or exceptions since Windsor Framework took effect on 1 Jan 2025
- ▶ End-user alert rate excluding EMPs/ULMs and occasional procedural error 'spikes' is consistently in region of 0.01-0.02% as controllable factors are now well managed
- ▶ Medicines shortages / availability issues are driving alerts
 - ▶ Reliance on packs sourced from UK
 - ▶ Borrowings between pharmacies
- ▶ See some alerts due to wholesaler errors e.g. hospital aggregation, repeated scanning
- ▶ More information about common causes of alerts is included in back-up slides

Scanning activity in Ireland – Jan-Sept 2025

Scans Over Time



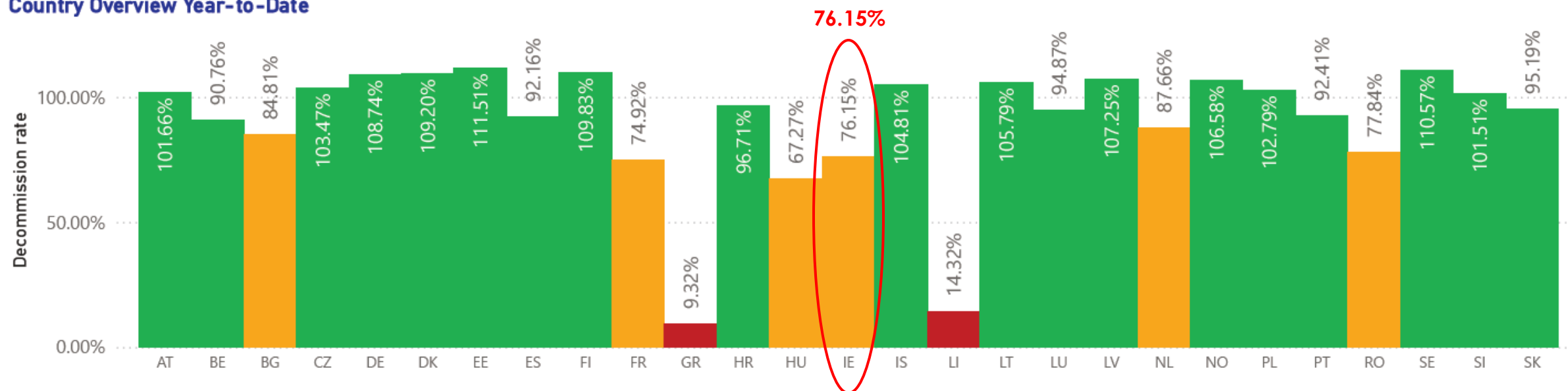
Decommissioning activity across Europe YTD 2025

Source: EMVO Monitoring
Report July 2025



Decommission Rate

Country Overview Year-to-Date





Practical tips for FMD

IMVO/HPRA guidance on scanning unlicensed medicines

Developed by IMVO and HPRA in 2022 to prevent scanning issues with EMPs/ULMs (which are out of scope of FMD) – also relevant to UK packs

- ▶ If you know the pack is a ULM, don't scan it as the IMVS may not recognise the pack
- ▶ If you inadvertently scan a ULM and get an alert, you may supply the pack unless:
 - ▶ you have overriding concerns that a falsified medicine is involved or believe the pack has been interfered with or
 - ▶ the pack is flagged as expired, recalled, withdrawn, stolen or destroyed
- ▶ Always check the anti-tampering device (if there is one) – if you have any reason to believe the pack has been interfered with, please report this to the HPRA as a product quality defect and do not supply the pack

[Note: *When you scan a ULM, the product name may not display on screen*]

UK packs

- ▶ Ensure your teams are aware that all UK packs will generate alerts/exceptions if scanned and that the only way to prevent these is not to scan them
- ▶ IMVO sent out A5 guidance cards about the Windsor Framework last December – have these to hand in the dispensary (these cards are available to download [here](#))
- ▶ Contact our service desk if you have any queries

‘Decommissioned at another location’ alerts

- ▶ There are a number of root causes for this type of alert, including the following ‘red flag’ causes:
 - ▶ The same serial number being used on different falsified packs by counterfeiters, where another pack with the same number was previously decommissioned somewhere else
 - ▶ Packaging of legitimate decommissioned packs is stolen, filled with fake medicines and reintroduced into the supply chain
- ▶ If you see these alerts in your pharmacy:
 - ▶ You won’t sufficient information to be able to draw any conclusions about the authenticity of the pack and must contact IMVO for assistance
 - ▶ Packs that generate these responses must be quarantined until a genuine reason for the prior decommissioning has been established and falsification has been ruled out
 - ▶ The only exception would be where the pack has been borrowed from another pharmacy or hospital and they can definitively tell you the pack was decommissioned by them

Borrowings

FMD - Lending packs

I am lending a pack to another pharmacy, what should I do?



1
CONFIRM THE PACK'S
FMD STATUS

If you are unsure of the pack's FMD status, you can do a verification scan



2
REACTIVATE THE
PACK IF NEEDED

If the 10 day window for reactivating it has not passed



3
INCLUDE A NOTE
WITH THE PACK

If the pack's FMD status is 'supplied', include a note to indicate this



FMD - Borrowing packs

I am borrowing a pack from another pharmacy, what do I need to do?



1
CONFIRM THE PACK'S
FMD STATUS

When you receive a pack, its FMD status should be 'Active'



2
IF UNSURE OF THE
PACK'S FMD STATUS,
VERIFY THE PACK

Carry out a verification scan. This will indicate the current FMD status of the pack. If the pack is 'Active', decommission it and supply it to the patient



3
IF THE PACK'S STATUS IS NOT
'ACTIVE', CONFIRM WITH THE
LENDING PHARMACY THAT
THEY HAVE ALREADY
DECOMMISSIONED IT

If they can't confirm that they decommissioned the pack then withhold the pack and contact IMVO for advice



4
IF THE LENDING PHARMACY
CONFIRMS THEY HAVE
DECOMMISSIONED THE
PACK

The pack can be supplied to the patient. Do not scan it again as this will generate an alert



NMVS Alerts

- ▶ Please use the '**NMVS Alerts' alert management system** to provide feedback on alerts – use the one-time link emailed to you or login into your NMVS Alerts account if you have one
- ▶ Make your comments as precise as possible, e.g. “procedural error – scanned pack twice”
- ▶ If you can't identify a root cause for the alert on your side, please give this feedback as it is very helpful
- ▶ NMVS Alerts is the preferred communications tool for alerts, but you may also provide feedback by email to alert.support@imvo.ie or by phone 01-575320

Scanning

- ▶ Plan your **scanner numbers and locations** to facilitate optimal workflow in the dispensary
- ▶ If using a **wireless scanner**, need to be close enough to device with FMD software so the scan is picked up
- ▶ **Ensure 'Caps lock' is not switched on, on your keyboard** – if this is the case, batch IDs containing caps will be misread by your scanner causing an alert
- ▶ **Scanner issues** - visit [Scanner help - IMVO](#) for details of how to identify and fix the problem. Next step is to contact your FMD software supplier for support
- ▶ **Ensure you're in the right scanning mode in your FMD software**
 - ▶ **Verification:** A medicine may be scanned to verify it is in the IMVS and its status, i.e. is it 'active' or marked as expired or decommissioned as supplied, recalled, locked, exported, stolen etc.
 - ▶ **Decommissioning:** 'Decommission' means changing the status of a pack from active in the supply chain to e.g. supplied, destroyed, sample etc.



Software

- ▶ Ensure that the response returned on screen by the FMD software is visible to the person scanning the pack so they know if any follow-up action is needed
- ▶ If you need to take action when your FMD software is being updated, please do this as soon as possible – older versions can lead to alerts
- ▶ Be aware that new software and other software updates could impact FMD software
- ▶ Contact your software provider for support in first instance
- ▶ If you're changing software provider, please contact us if you need any support



Vaccines

- ▶ Covid vaccines are all decommissioned by NCCS as indicated by sticker – if you try to decommission them in the pharmacy, this will cause an alert



**Decommissioned for
FMD by NCCS**



The Pharmacy Regulator
An Rialtóir Cógaisíochta

FMD-themed inspections

Learnings from PSI inspections

- ▶ PSI publishes learnings and insights - see [Inspection Findings - Overview](#)
- ▶ Based on inspections between Jan and June 2025, the PSI has recommended targeted improvements in the following areas:

1. **SOPs and staff training**

- ▶ A comprehensive **SOP for FMD Operational Management** that accurately reflects the pharmacy's operations is essential. It promotes consistent practice and ensures the team works in line with both internal procedures and legislative requirements
- ▶ It is important that **locums** are familiar with the pharmacy's FMD procedures to maintain consistent compliance with legislative requirements
- ▶ Regular, role-specific **training** and up-to-date records will ensure staff competence and correct system use.
- ▶ **Strong governance** underpins FMD compliance. The supervising pharmacist is responsible for ensuring that all systems and procedures, such as SOPs and training, are implemented and followed consistently in daily practice.

Learnings from PSI inspections

2. Dispensary Workflow and Software Issues

- ▶ **Strong governance and proactive operational management** are key to maintaining compliance with FMD scanning. We would encourage individuals in pharmacy governance roles to proactively review their practices and take corrective action when needed to ensure compliance with the FMD legislative requirements.
- ▶ It is important that **locums** are familiar with the pharmacy's dispensary workflow and FMD software to ensure medicines are dispensed safely and in compliance with the legislative requirements.
- ▶ Ensuring that an **adequate number of scanners** are available and that these are located in convenient locations helps embed the FMD system into the daily workflow, making it easier for staff to comply with scanning requirements.
- ▶ Regular maintenance and prompt communication and troubleshooting with **your software provider** are essential for consistent system performance.

Responding to PSI queries re your FMD activity

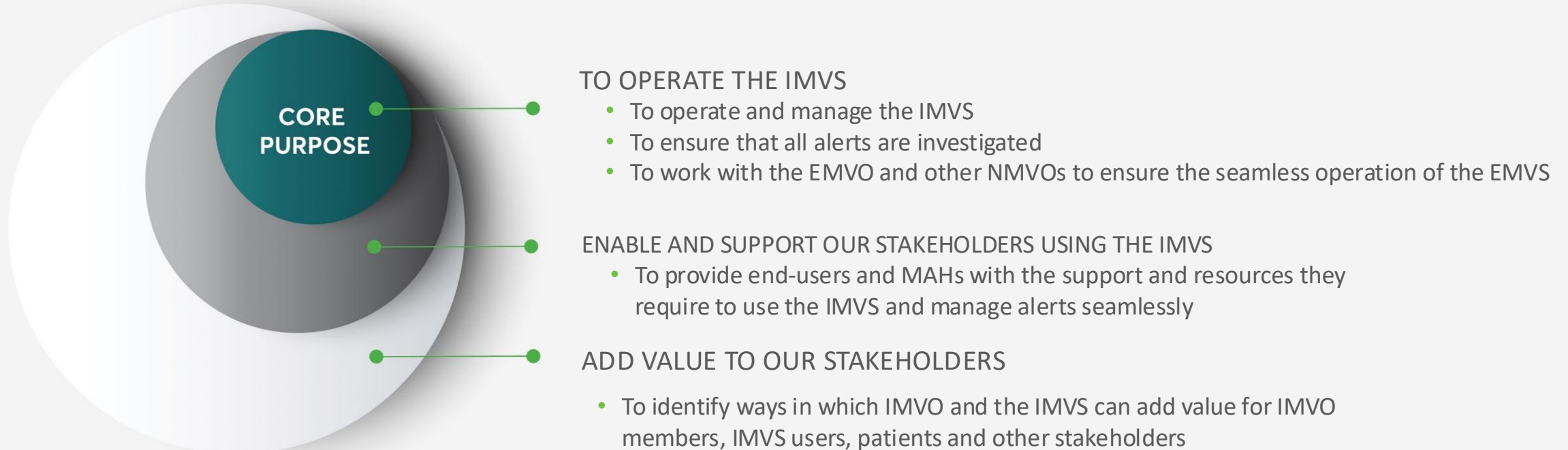
- ▶ Legal obligation is to decommission all packs of prescription medicines bearing safety features that are authorised for sale in Ireland prior to supply to patients (look for PA or EU marketing authorisation number)
- ▶ If you are asked to explain your decommissioning activity to the PSI, need to analyse your daily audit report to reconcile it with the PSI numbers having regard to the following:
 - ▶ Packs can only be decommissioned as supplied once and this must be done when the pack is first opened – you may have several dispensings from that pack but only one decommissioning transaction will be recorded in the IMVS
 - ▶ If your scanner is used in verification mode, none of the scans will be recorded as decommissioning scans
 - ▶ Some of the items dispensed will be medical devices and reimbursable OTCs that are not subject to FMD. If you scan these, the barcode will not be recognised by the IMVS and they cannot be decommissioned
 - ▶ The numbers of EMPs/ULMs used in your pharmacy and whether they are scanned or not
 - ▶ EMPs/ULMs from EU countries will be decommissioned if scanned
 - ▶ ULMs/EMP sourced from the UK will **not** be decommissioned if scanned



New IMVO Corporate Strategy 2025-2027

Our Purpose

Protecting Ireland's patients from falsified medicines by operating the IMVS



Our Corporate Strategy Summary

PURPOSE: Protecting patients in Ireland from falsified medicines by operating the IMVS

VISION: A secure and sustainable supply chain where patients are confident about the authenticity of prescription medicines they receive in the Irish healthcare system

MISSION: We manage the IMVS to assure patients in Ireland about the authenticity of their prescription medicines and we harness IMVO's potential to enhance the security and sustainability of the medicines supply chain

STRATEGIC PILLARS:

Patient Safety	Partnership	Leadership	Excellence
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VALUES:

Trust	Collaboration	Ambition	Agility	Innovation
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What's new

- ▶ Focus on leveraging our knowledge of medicines supply chain and our experience rolling out a major IT project and collaborating closely with counterparts across Europe to benefit IMVS users, our members and patients
- ▶ Example of planned initiatives:
 - ▶ Explore how IMVO can contribute to addressing the problem of medicines shortages
 - ▶ Share our expertise in change management and digital transformation projects to support the rollout of the Digital Health Framework for Ireland and ICT initiatives in the healthcare system
 - ▶ Establish a multi-stakeholder supply chain forum to identify and advocate for enhancements in supply chain security, efficiency and sustainability
 - ▶ Work with policy makers, EMVS colleagues and other stakeholders to explore the use of barcodes for the benefit of supply chain partners and patients



Changes in EU pharma legislation

Proposals relevant to FMD

- ▶ EU pharma legislation is under revision at moment – see [here](#) for updates
- ▶ From an FMD perspective, the key proposals in the latest drafts are:
 1. **Purposes for which competent authorities may access data in the system**
 - ▶ Currently they may access the data for purposes of investigating suspected falsifications, reimbursement, pharmacovigilance and pharmacoepidemiology
 - ▶ Proposal is to extend this to include *“monitor[ing] any expected potential or actual shortage of a medicinal product, as well as to assess the general supply situation to avoid shortages”*

Proposals relevant to FMD

2. Electronic package leaflets

- ▶ Proposal is that companies must provide package leaflets in electronic form as well as paper format
- ▶ Lot of interest in how package leaflet would be made available electronically
- ▶ EMA issued a [Reflection paper on linking to electronic product information \(ePI\) from EU medicine packages](#) in March which outlined a proposal for accessing the ePI of a medicine by using a smart phone to scan the 2D barcode printed on medicine packages



Integration of FMD into HMMS

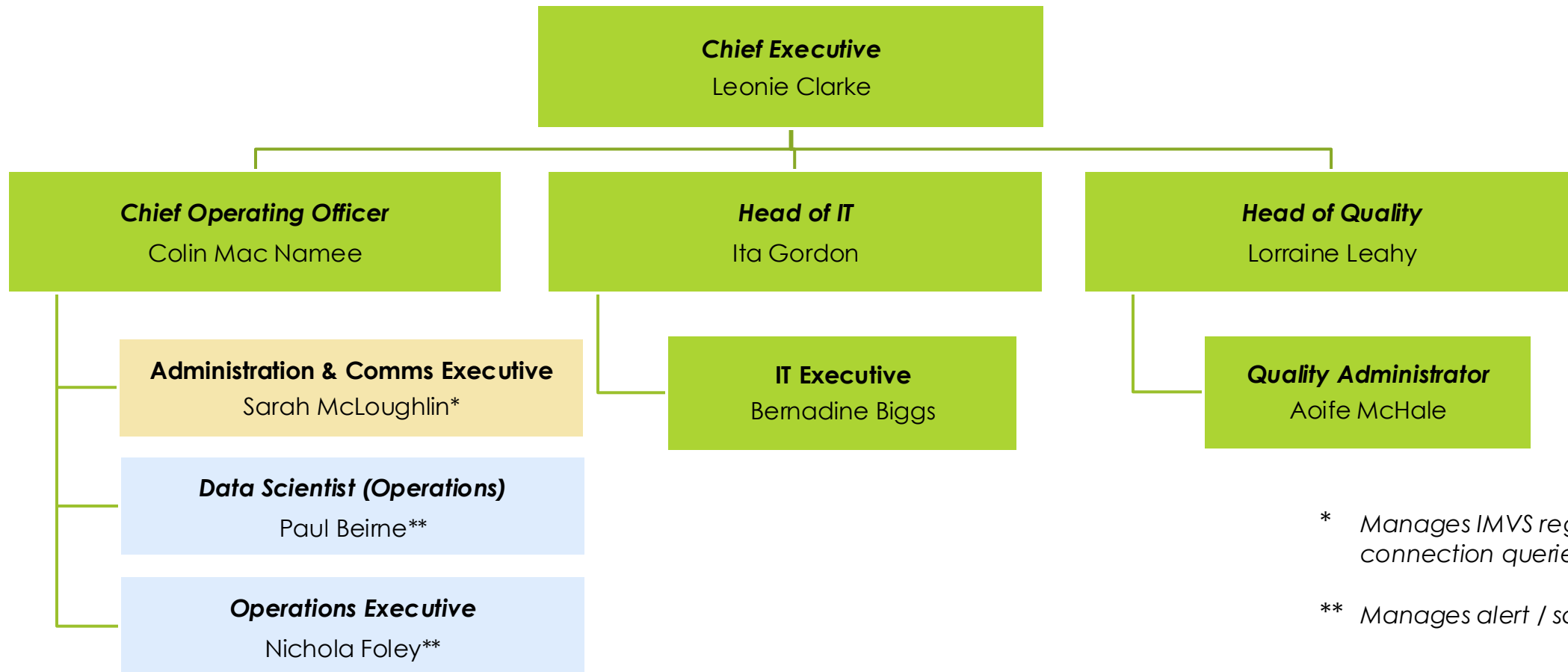
Integration of FMD into HMMS

- ▶ The Hospital Medicines Management System (HMMS) is being rolled-out by the HSE in acute and non-acute hospital pharmacy departments as part of overall plans to improve e-health service delivery in Ireland
- ▶ There is now an interface from the FMD software used in the HSE (ezFMD) and HMMS
- ▶ When a HMMS hospital completes the FMD scan, it receives the product into stock as well as verifying the product, integrating FMD scanning and barcode receipt of drugs
- ▶ Seven hospitals are live with HMMS and using the interface daily. Phase 1 is on track to finish this year and Phase 2 commences in Jan 2026
- ▶ Queries about HMMS should be referred to hmms.contact@hse.ie



Support
available
from
IMVO

Meet the team



* Manages IMVS registration / connection queries

** Manages alert / scanning queries

What support is available?

- ▶ Contact **our service desk**

- ▶ Tel: +353-1-5715320

- ▶ Email: info@imvo.ie

- ▶ Opening hours:

- Weekdays: 08.00-20.00

- Saturday: 09.00-18.00

- Sun/public holidays: 11.00-18.00

- ▶ To contact us about an **alert**, use *NMVS Alerts* or email alert.support@imvo.ie

What support is available? (ctd)

- ▶ **Visit our website** www.imvo.ie
 - ▶ FAQs: <https://www.imvo.ie/support/faqs/>
- ▶ Guidance videos on a range of topics, including *NMVS Alerts* are available on IMVO's **YouTube channel**: <https://www.youtube.com/@irishmedicinesverification5361>
- ▶ **Live IMVS status** is available at: <https://status.nmvo.eu/> (link is accessible from home page of our website)
- ▶ **Bespoke support sessions for pharmacies** by phone, Zoom or Teams or in-person – email info@imvo.ie if you want to book a session
- ▶ **FMD reference cards** – previously sent out by post; further copies available on request

FMD - Out of scope

Products that are out of scope
of FMD requirements include:



**UNLICENSED MEDICINES
(ULMs)/
EXEMPT MEDICINAL
PRODUCTS (EMPs)**

These packs don't
need to be
scanned for FMD



MEDICAL DEVICES

These devices don't
need to be scanned
for FMD



**OTC PACKS THAT
CARRY 2D BARCODES**

These packs don't
need to be
scanned for FMD



IRISH
MEDICINES
VERIFICATION
ORGANISATION



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alert.support@imvo.ie

FMD reference cards

FMD - Destroying packs

Don't decommission a pack as destroyed if:



EXPIRED

THE PACK HAS
ALREADY EXPIRED

The system will
automatically
decommission
this pack



THE PACK WAS
ALREADY
DECOMMISSIONED AS
SUPPLIED

This will
raise an alert



YOU ARE UNSURE OF
THE PACK'S FMD
STATUS

You can do a
verification scan
to check the
pack's FMD status



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ORGANISATION



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alert.support@imvo.ie

FMD reference cards

For more information ...

► Follow us on social media

- LinkedIn: [IMVO | Irish Medicines Verification Organisation](#)

► PSI

- [Falsified Medicines Directive](#)
- Queries: info@psi.ie

► HPRA

- [How to report a quality defect for a medicine for human use](#)
- [Questions and answers on the Windsor Framework](#)

► Legislation:

- [Falsified Medicines Directive 2011/62/EU](#)
- [Commission Delegated Regulation on Safety Features \(EU\) 2016/161](#)
- [S.I. No. 36/2019 - Medicinal Products \(Safety Features On Packaging\) Regulations 2019](#)
- [S.I. No. 270/2022 - Medicinal Products \(Safety Features on Packaging\) Regulations 2022](#)







BACKUP SLIDES





NMVS Alerts – alert management system

- ▶ *NMVS Alerts* is name of the online alert management system used by IMVO and 13 other NMVOs
- ▶ When an alert is generated in your FMD software, an automated email will be issued to you with a link to the alert record in *NMVS Alerts*
 - ▶ Please use this to provide feedback if you have identified a root cause on your side
 - ▶ Check to see if IMVO or the MAH have added information about the alert and closed it; if so, you can go ahead and supply the pack
- ▶ If IMVO or MAH cannot find a root cause and we haven't heard from you, a reminder to provide feedback will be sent to you after 2 working days and again after 4 further working days

NMVS Alerts account

- ▶ You have the option to create an account in *NMVS Alerts* free of charge which allows you to:
 - ▶ log in to see a list of all your alerts
 - ▶ report any information you have to add about an alert generated in your pharmacy (e.g. 'our scanner wasn't working'; 'we accidentally decommissioned the pack several times')
- ▶ Useful way of keeping records of your alert investigations as justification for your decision to supply a pack that generated an alert
- ▶ Email alert.support@imvo.ie to set up an account



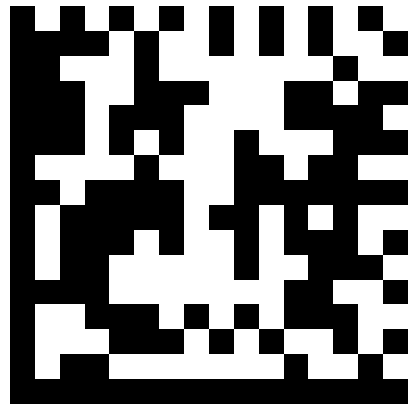
Common causes of alerts

Technical and procedural issues

- ▶ Decommissioning borrowed packs that were already decommissioned by lending location – most common procedural issue now
- ▶ Misconfigured scanners, 'caps lock' on when scanning
- ▶ FMD software bugs – not very common
- ▶ Impact of changes to other software on computer, e.g. anti-virus software
- ▶ Scanning 2D barcode that is very close to linear barcode – please let us know if you see these happening a lot with a product
- ▶ Repeatedly scanning bulk/split packs causes alerts ('double-decommissioning')

Other

- ▶ **Scanning unlicensed medicines** (EMPs/ULMs), particularly UK packs
- ▶ **Data issues** – now relatively uncommon:
 - ▶ Data for packs has not been uploaded by manufacturer to IMVS or the upload failed
 - ▶ Data uploaded to IMVS does not match what's in 2D barcodes (either data uploaded is incorrect or the barcode details are incorrect)
- ▶ **System issues**, i.e. some issue with EMVS/IMVS – not very common
- ▶ **Pack is falsified** – very rare but has to be considered if no plausible root cause can be identified



IRISH
MEDICINES
VERIFICATION
ORGANISATION

www.imvo.ie