IRISH MEDICINES VERIFICATION ORGANISATION

FMD 5 years on – where are we now?

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IIOP 'IN CONVERSATION WITH …" SERIES

27 NOVEMBER 2024

Outline

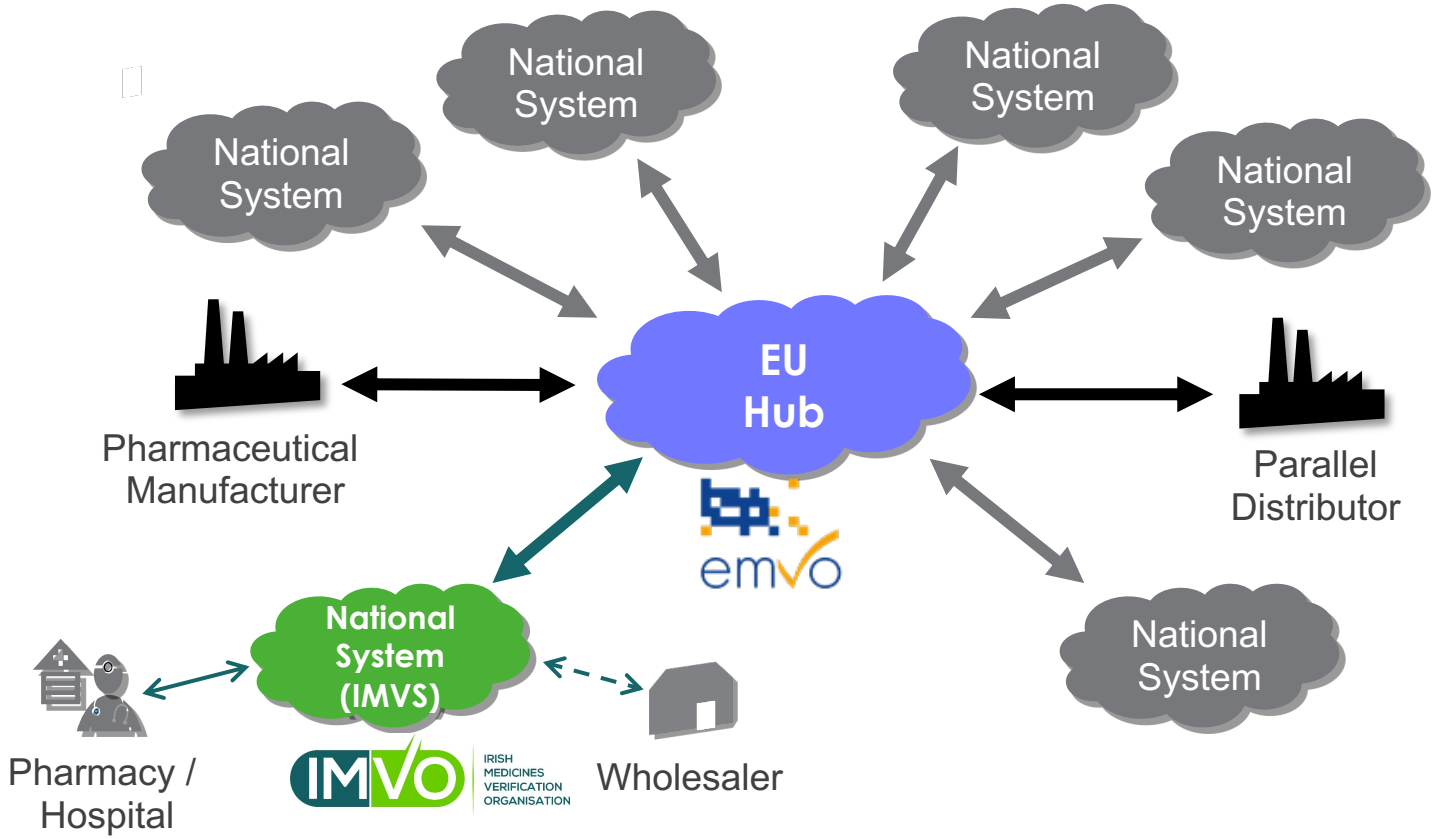
- Recap of FMD
- Where are we now?
- Is FMD making a difference?
- Windsor Framework
- Support available from IMVO
- Q&A
- Back-up slides
  - Overview of alert management
  - Common causes of alerts

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 – register operated in Ireland by PSI
  - Tougher controls on & 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

European Medicines Verification System (EMVS)



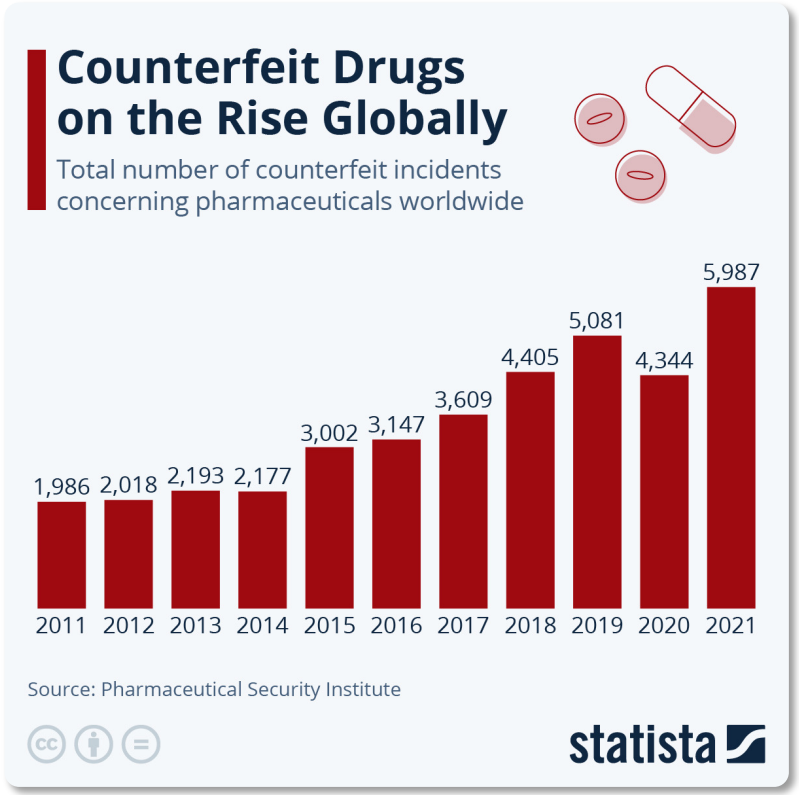
Covers 29 countries:

- 25 EU (GR & IT due to join in 2025)
- 3 EEA
- Northern Ireland (until 31 Dec 2024)

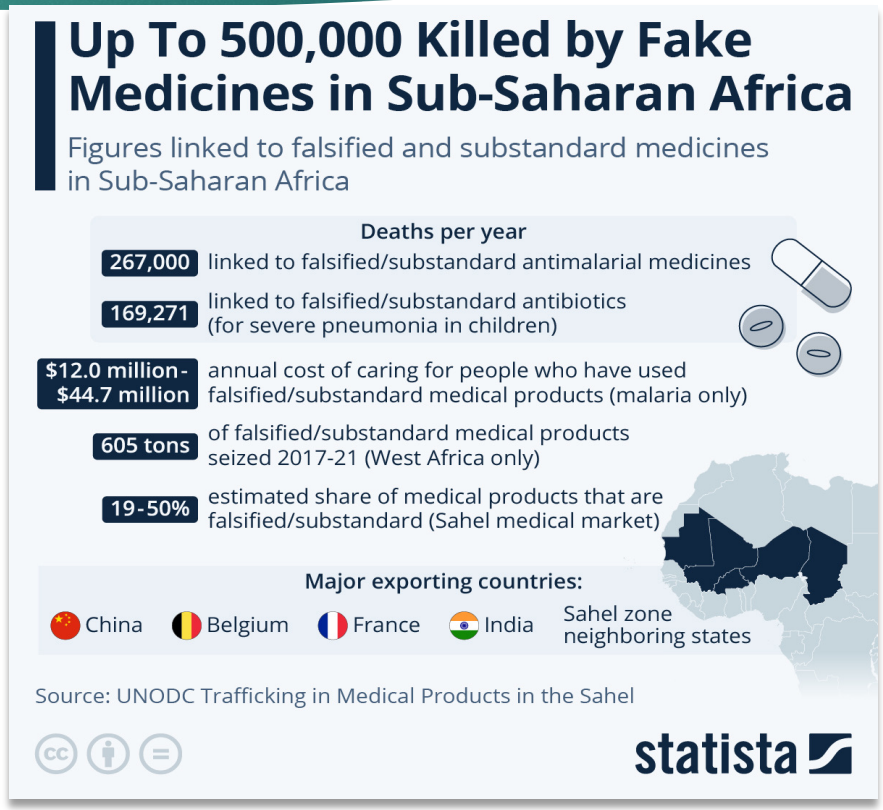
Why was Falsified Medicines Directive necessary?

- Significant problem with illegal medicines worldwide:
  - WHO estimates that 10% of medicines in low- and middle-income countries are substandard or falsified
  - HPRA seized almost 900,000 dosage units of falsified and other illegal medicines in 2023
  - HPRA has detained 1,401 units of illegal GLP-1 products (e.g. Ozempic®, Wegovy®, Saxenda®, Victoza®, etc.) in 2024 to date
- Very little hard data on number of falsified medicines in the legitimate supply chain in Europe but realisation that action was needed to strengthen and harmonise controls to prevent introduction of falsified medicines
- Serialisation has been mandated in approximately 80% of countries across the globe to minimise the risks of fraudulent drugs entering the market

Counterfeit medicines are a global problem



https://www.statista.com/chart/30067/worldwide-counterfeit-pharmaceuticals-incidents/



https://www.statista.com/chart/30068/falsified-medicines-in-sub-saharan-africa/

WHO Alerts on Falsified and Sub-Standard Medicines

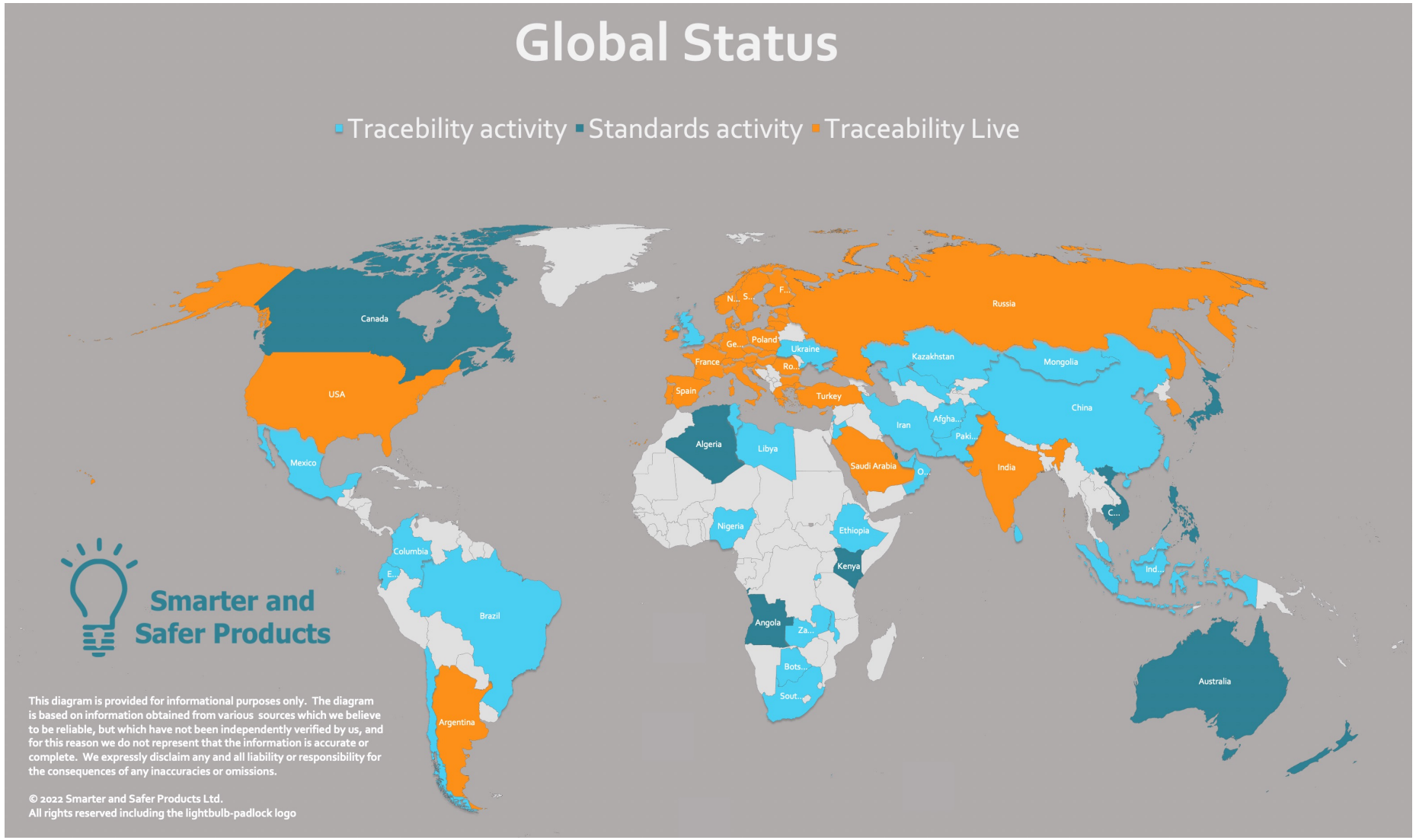
Source: [Full List of WHO Medical Product Alerts]

Barcoding and traceability – *a global view*

This diagram illustrates the level of activity across the world in adoption of GS1 standards* and traceability

- **Traceability live** means that legislation is in place and active.
- **Traceability and Standards activity** means everything from early governmental strategy through to legislation being established.
- **Standards activity** relates to any use of the GS1 standards which are not specifically serialisation and traceability related

**GS1 is a non-profit organisation that publishes and promotes use of barcoding standards in supply chains*

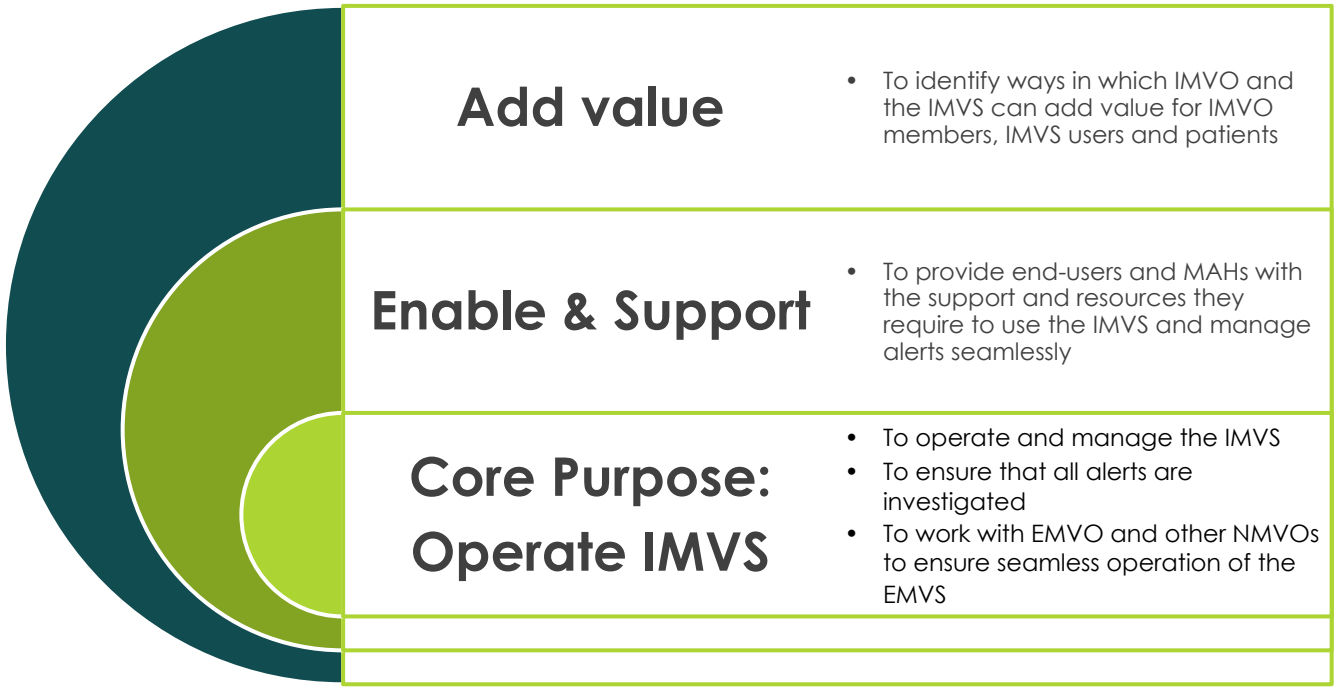


May 2022

Roles and responsibilities

IMVO

- Set up and manage the Irish Medicines Verification System (IMVS)
- Ensure IMVS operates effectively as part of EMVS by collaborating with EU counterparts
- Assist pharmacies, hospitals and wholesalers ('end-users') in connecting to the IMVS and offering help with issues that may arise
- Work with end-users and marketing authorisation holders (MAHs) to minimise avoidable alerts
- Provide for the immediate investigation of alerts represent potential incidents of falsification and ensure the HPRA, European Medicines Agency and EU Commission are notified should the falsification be confirmed – this involves liaising with end-users and MAHs



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)** – responsibility for supervising the IMVS and ensuring that all parties – end-users, manufacturers/MAHs and IMVO – comply with their obligations
  - ***HPRA:*** oversees manufacturers, MAHs, wholesalers and IMVO and leads investigation if falsified medicines are identified
  - ***PSI:*** oversees retail pharmacy businesses and pharmacists

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 product is marketed
- Involved in investigation of alerts on their products

Roles and responsibilities (ctd)

Wholesalers

- Not required to verify all packs that pass through their warehouses, only the following:
  - Returns from customers – can't return decommissioned packs to stock
  - Packs received from any source 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

Where are we now?

European Medicines Verification System five years on …

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)*

Progress in Ireland over the last 5 years

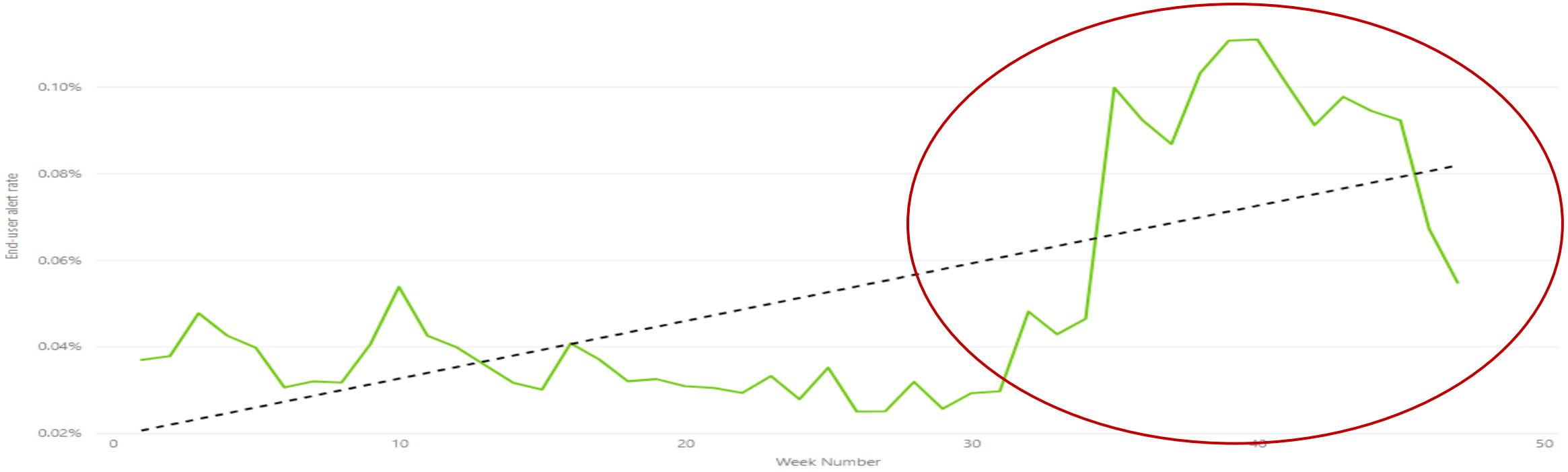
- End-user alert rates in Ireland are consistently in region of **0.05% of total scans,** due to efforts of end-users and MAHs to minimise avoidable alerts
- **Continuous communication** by IMVO to pharmacies, hospitals, wholesalers and MAHs on most common issues seen by us in order to help prevent further alerts
- Pharmacy and hospital **engagement with IMVO has increased** significantly
- ***NMVS Alerts*** usage by pharmacies and hospitals is steadily increasing
- **Continuous improvement** of EMVS (including IMVS) to the enhance user experience, performance and eliminate system-related alerts – system is very stable, with very few delays or downtime
- Decommissioning rates are improving but **still not close to full scanning**

What are most common causes of alerts?

- Exempt medicinal products / unlicensed medicines (ULMs)
- Borrowed packs that were already decommissioned by the lending location
- Alerts due to wholesaler errors e.g. hospital aggregation, repeated scanning
- Some MAH procedural errors, e.g. delays in data upload, repeating bulk transactions in error
- More information about common causes of alerts is included in back-up slides

Analysis of alerts – Jan to Nov 2024

Alert to Scan Ratio for end-users



Products causing extra alerts in recent week

- **Estramon** Transdermales Pflaster 37.5, 50, 75, 100
  - Four batches decommissioned as 'Sample' in error by the manufacturer
    - NK1274, NL7876, NL3207, NL1901
- **Utrogestan** 200 mg capsule molle orale ou vaginale
  - Supplied in a decommissioned state ('exported') as it was originally exported outside EU before being brought back into Ireland

IMVO/HPRA guidance on scanning unlicensed medicines

Developed by IMVO and HPRA in 2022 to prevent scanning issues with ULMs (which are out of scope of FMD)

- 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]*

Other issues to look out for

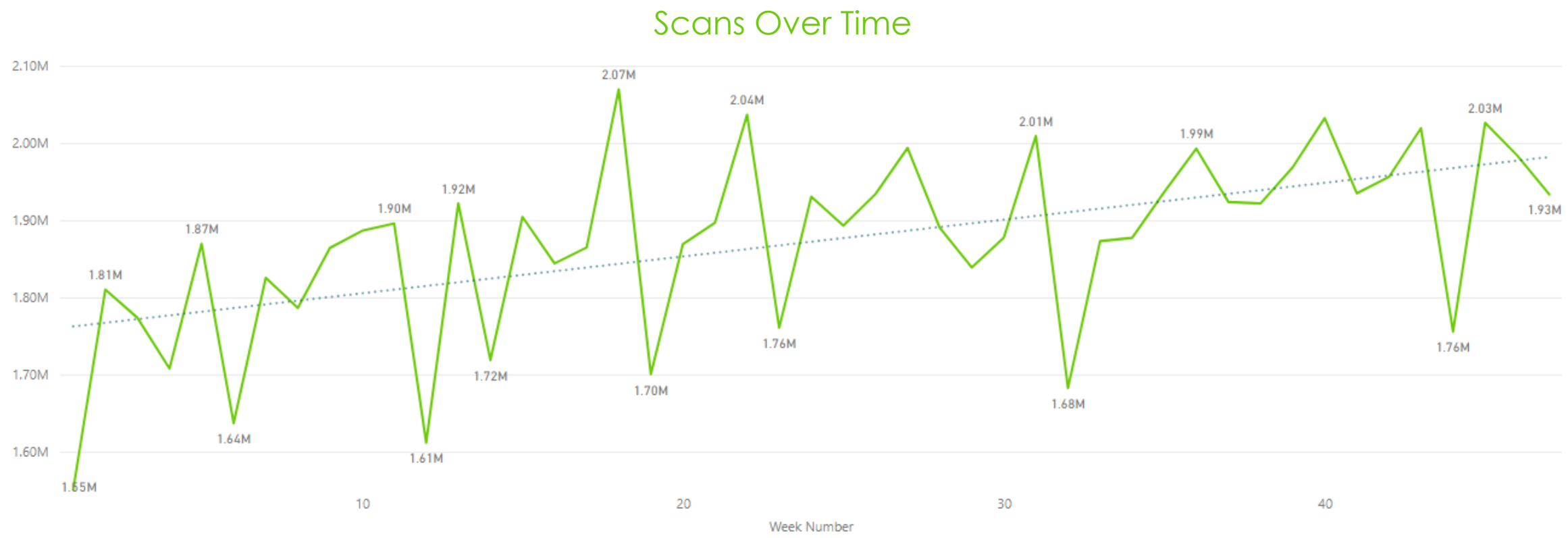
Vaccines

- Before scanning any vaccines, check if they have already been decommissioned by the NCCS (look for sticker)

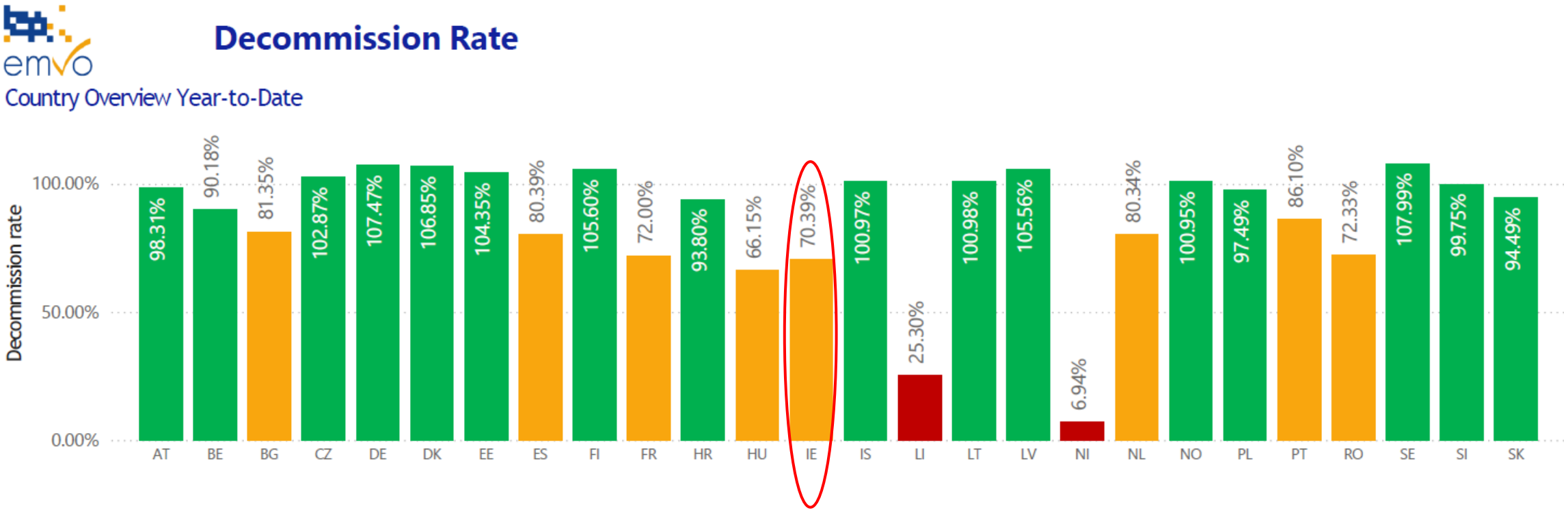
Correct scanning mode?

- Verify or Decommission/Supply

Scanning activity Jan 2024 – Nov 2024



EU decommissioning rates as at 31 Oct



Is FMD making a difference?

EU Commission Report on FMD

- As mandated by the Falsified Medicines Directive, the Commission published a report on FMD in July following extensive consultation with national authorities, national medicines verification organisations and EMVS users across Europe
- Points of note in the report:
  1. It is critical that the measures in the FMD/DR are fully implemented to reach their full potential
  2. The FMD/DR have had two main positive results:
     - Make it more difficult to introduce illegal products into the legal supply chain by increasing the hurdles and the cost of falsification for criminals, so illegal products stay in the illegal circuit
     - They generate data for investigators that make it possible to detect suspicious packages and track falsifying activities

EU Commission Report on FMD (ctd)

- Points of note from the report (ctd):

3. It is not yet possible to draw final conclusions as to the effects of the FMD/DR and the actual ability of the EMVS to effectively detect all falsified medicinal products because:
   - Some end-users are still not connected
   - 26% of medicines with safety features in Europe are not decommissioned
   - Some IT systems at national level still trigger too many false alerts
   - Lack of standard procedures to qualify cases as confirmed cases of falsification and lack of centralised reporting across the EU/EEA make comparisons and trend analysis particularly difficult
   - Greece and Italy are only due to join the EU system in 2025

EU Commission Report on FMD (ctd)

- Points of note from the report (ctd):

4. Falsifications

   - Substantial and steady progress in detecting falsified medicines since the FMD/DR came into application. The current scope, with its flexibility [relating to reimbursement, pharmacovigilance and pharmacoepidemiology] …. appropriately balances the risks posed by falsified medicines with the administrative burden involved in preventing these risks
   - Most cases of falsification have been detected in the illegal supply chain (often via unauthorised sales on the internet); categories of medicinal products most likely to be falsified are expensive medicines such as anti-cancer injections and 'lifestyle drugs'
   - Medicinal products purchased in official channels, i.e. physical or online authorised pharmacies, can be assumed to be safe

EU Commission Report on FMD (ctd)

- Areas the Commission is actively working on include:
  - Decommissioning rates
  - Technical issues triggering large numbers of false alerts that discourage stakeholders from using the system
  - Lack of guidance on anti-tampering devices

Have any falsified medicines been detected by the EMVS?

- No counterfeit or falsified medicines have been detected in Ireland since FMD implementation in 2019, but not all packs are being scanned
- EMVS is designed primarily as a deterrent - very low incidence of falsified medicines being detected is to be expected
  - Approx. 14 billion transactions take place each year across Europe (1.9 million per week in Ireland)
- That said, EMVS has also proven its value in finding fakes:
  - Falsified medicines were identified at wholesaler level by Czech and Slovakian NMVSs in 2022
  - Falsified Ozempic® packs were identified in **legal** supply chains in Austria, Germany and UK in 2023 – reinforces importance of scanning as last line of defence in preventing fake medicines reaching patients

Ozempic® example

EMA alerts EU patients and healthcare professionals to reports of falsified Ozempic pens

18 October 2023

News | Human | Medicines

The European Medicines Agency has been notified by relevant national competent authorities that pre-filled pens falsely labelled as the diabetes medicine Ozempic (semaglutide, 1 mg, solution for injection) have been identified at wholesalers in the EU and the UK.

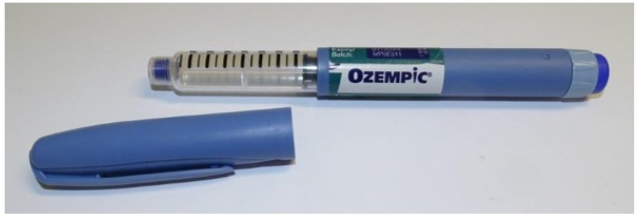
The pens, with labels in German, originated from wholesalers in Austria and Germany.

Federal Institute for Drugs and Medical Devices (BfArM, Germany)

"Initial investigations by the manufacturer Novo Nordisk A/S have shown that there is no semaglutide in the counterfeit pack Ozempic® … According to the results of the German official testing laboratory … the affected pens contain insulin"

Original:

Fälschung:



Images of original and counterfeit drug Ozempic® (Copyright Original Novo Nordisk; Copyright Forgery CVUA Karlsruhe)

‘Decommissioned at another location’ alerts

- The following type of alert was seen with the Ozempic falsifications:

  “Pack already decommissioned/supplied/dispensed at another location”

- 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
  - Packaging of legitimate decommissioned packs is stolen, filled with fake medicines and reintroduced into the supply change
- 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

Windsor Framework

What is the Windsor Framework (WF)?

- Windsor Framework ('WF') is a post-Brexit legal agreement between EU and UK, adopted in March 2023, which adjusts operation of Northern Ireland Protocol in several areas, including medicines, to ensure that people in NI have access to all medicines at same time and under same conditions as rest of the UK
- WF is due to take effect on 1 Jan 2025
- As a result of the WF:
  - FMD no longer applies in Northern Ireland from 1 Jan 2025 – the UKNI national medicines verification system ('UKNI NMVS') will be disconnected from EMVS and all data in that system will be permanently erased
  - UK packs may still carry 2D barcodes so long as they cannot be recognised by the EMVS
  - UK packs must be labelled with 'UK only' from 1 Jan 2025

Will a new UK falsified medicines system be introduced?

- UK Medicines and Medical Devices Act 2021 provides legal basis for setting up a UK falsified medicines system post Brexit
- MHRA WF Q&A states that *"The UK is considering all options for a national falsified medicines system, including a do nothing option …"*
- Notwithstanding lack of clarity on a future UK falsified medicines scheme, it appears that many manufacturers plan to avail of option to continue to apply 2D barcodes and anti-tampering devices to packs released to market in UK after 1 Jan 2025

Why is the Windsor Framework (WF) of interest here?

- WF is relevant to Ireland due to our traditional links to the UK in terms of joint IE/UK packs and UK-only packs sourced as exempt medicinal products (EMPs)/ unlicensed medicines/ULMs to address shortages
- Despite current advice not to scan ULMs, in practice many ULMs are scanned and these scans are successful for EU and UK packs as they can be verified and decommissioned via intermarket transactions against the relevant NMVS
- From 1 Jan 2025, FMD issues will arise if UK packs carrying 2D barcodes are scanned here
  - Option of verifying /decommissioning these packs via intermarket transactions against UKNI NMVS is gone
  - **From 1 January 2025, every UK pack with 2D barcode that is scanned in Ireland will generate an exception/alert** (same will apply across the EU)

‘UK only’ labels

- Will the ‘UK only’ label help to pick out UK packs in a busy dispensary?
- Limited value at least initially because:
  - ‘UK only’ label requirement will not apply to packs already in circulation prior to 1 Jan 2025
  - ‘UK Only’ may be printed anywhere on pack – some companies plan to add it to ‘human readable’ barcode data panel
  - The text must be ‘conspicuous and clearly legible’, at least 7-point font per current MHRA guidance

UK Only

Preparing for the Windsor Framework (WF)

- IMVO has worked closely with the Department of Health, HPRA, PSI and colleagues in other NMVOs and EMVO over the last 18 months to assess and mitigate the FMD impacts of the WF
  - Some of the issues identified have been resolved via changes to the EMVS, however, it is not technically possible to prevent UK packs from generating alerts when scanned from 1 Jan 2025 onwards
  - Not possible to change effective date of WF from 1 Jan to a 'better' time of year - this date was agreed by UK Government and EU 18 months ago
- Communications underway to explain the FMD impacts of the WF to pharmacies, hospitals, wholesalers, manufacturers and marketing authorisation holders (MAHs) in Ireland and what to do to minimise problems
- HPRA has published Q&A on Windsor Framework to assist manufacturers, MAHs and wholesalers
- Planning for extra support calls and emails to IMVO service desk at beginning of January

FMD in Ireland post Windsor Framework

- FMD still applies across the EU
- FMD obligations for pharmacies, hospitals and wholesalers in Ireland are unchanged

Advice to pharmacies and hospitals on how to avoid FMD issues with UK packs from 1 Jan 2025

- After 1 Jan 2025 the only way to avoid an alert/exception with **UK packs** is **not to scan them**
- If you inadvertently do scan a UK pack, you will get an **amber** or **red** alert/exception message on your FMD software (as per previous slide). Notwithstanding this, 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 has expired. Your FMD software may not be able to flag that the pack is expired because of the UK system having been disconnected
- Always check the anti-tampering device on the pack (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. Email qualitydefects@hpra.ie to report this

**Advice has been agreed with HPRA, PSI and Department of Health*

Windsor Framework: useful resources and support

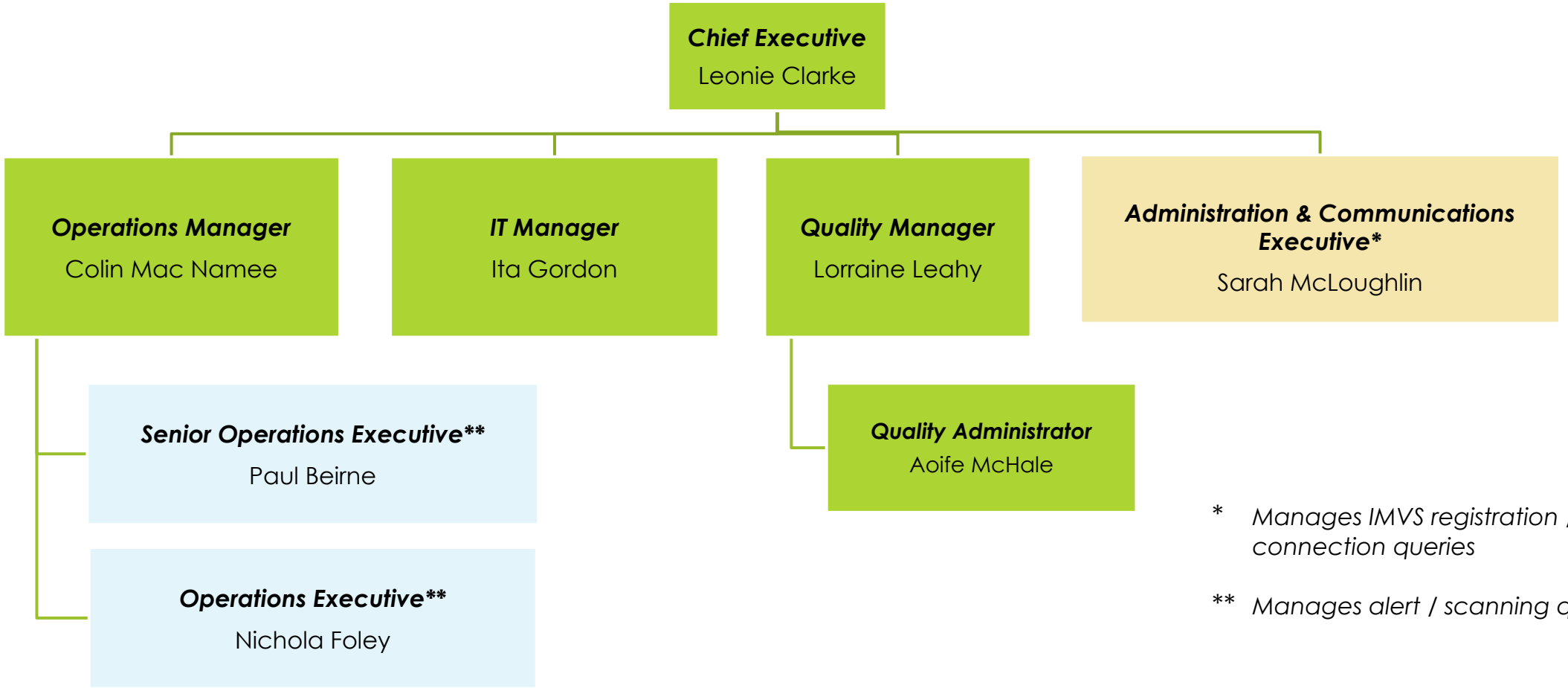
- IMVO service desk is open every day except Christmas Day – contact details are provided at end of the presentation
- Dedicated page on IMVO website (including FAQs): Windsor Framework – IMVO
- Webinars for pharmacies and hospitals held throughout Oct and Nov
  - Slides and the recording are available here on our website.
  - Mop-up webinar will be held in December if there is demand
- Articles in November editions of IPU Review and Irish Pharmacist
- Printed A5 cards will be posted to every pharmacy and hospital within next 2 weeks
- HPRA Q&A on Windsor Framework

What can you do to minimise the impact of the Windsor Framework in your practice?

- Ensure your teams are aware of what will happen from 1 Jan 2025, i.e. all UK packs will generate alerts if scanned
  - Encourage everyone involved in FMD scanning to watch the IMVO Windsor Framework webinar recording/read the slides
  - Have the printed A5 cards to hand in the dispensary so information is to hand
- Stress to your team that the only way to prevent lots of alerts/exceptions is not to scan UK packs
- Contact our service desk if you have any queries
- Keep scanning Irish packs and following up on any alerts that arise so we can optimise the value of FMD in protecting patients in Ireland from falsified medicines

Support available from IMVO

Meet the team



* *Manages IMVS registration / connection queries*

** *Manages alert / scanning queries*

What support is available?

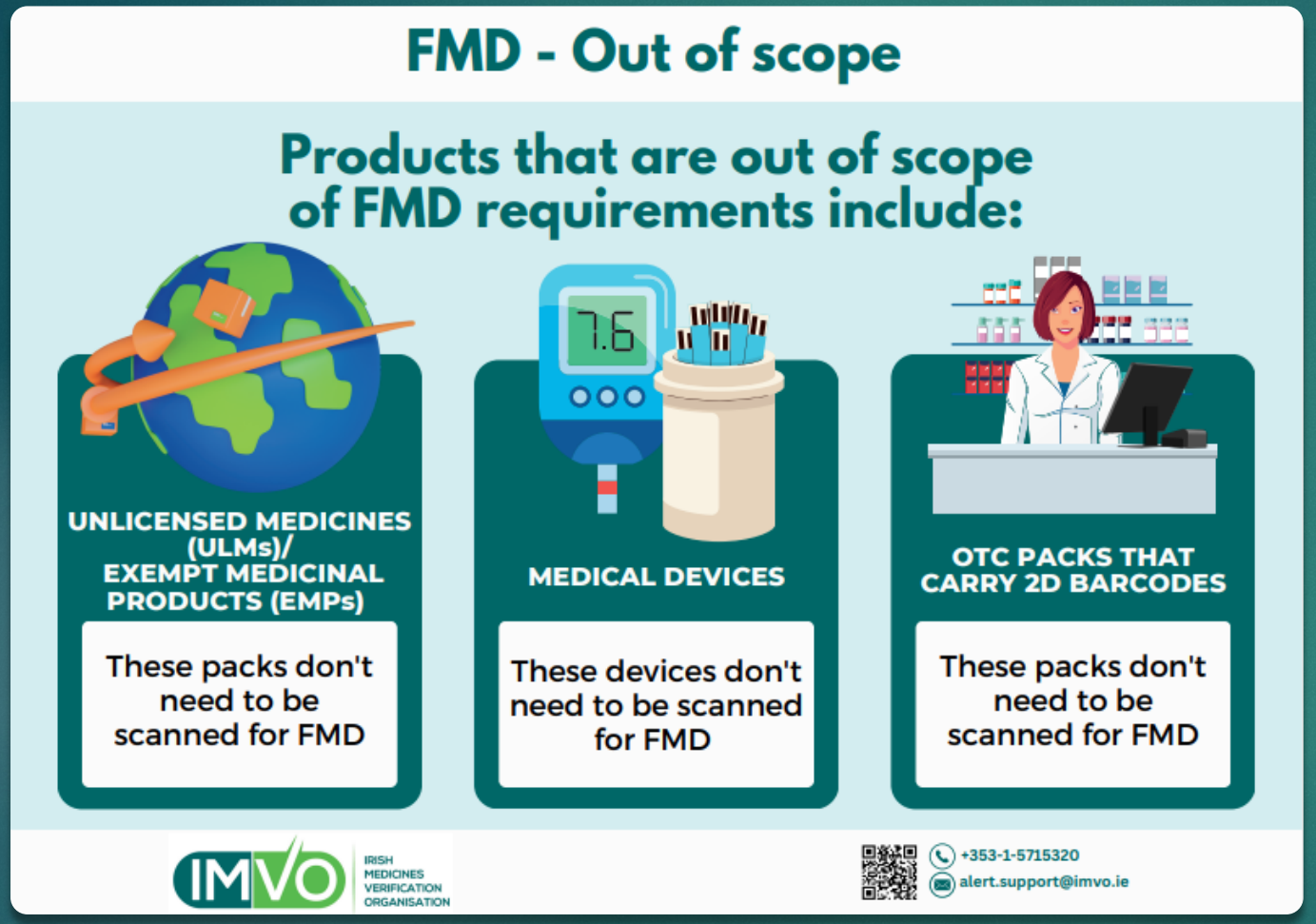
- Contact **our service desk**
  - Tel: +353-1-5715320
  - Email: info@imvo.ie
  - Opening hours:

    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
- Note: If you are having problems with your FMD software, please contact your FMD software provider first

What support is available? (ctd)

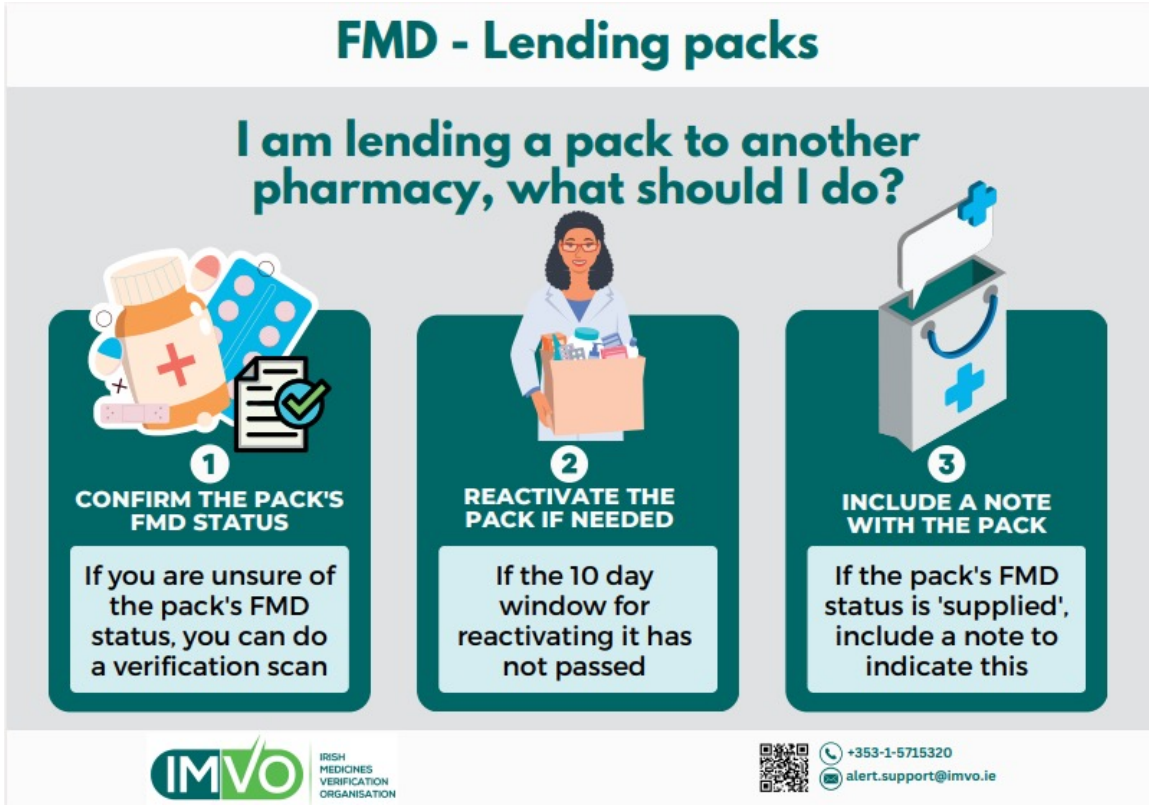
- **Visit our website** www.imvo.ie
  - **FAQs:** https://www.imvo.ie/support/faqs/
- Guidance videos on a range of topics, including *NMVS Alerts* are available on IMVO's **YouTube channel:** https://www.youtube.com/@irishmedicinesverification5361
- **Live IMVS status** is available at: https://status.nmvo.eu/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



FMD reference cards

FMD reference cards

FMD reference cards



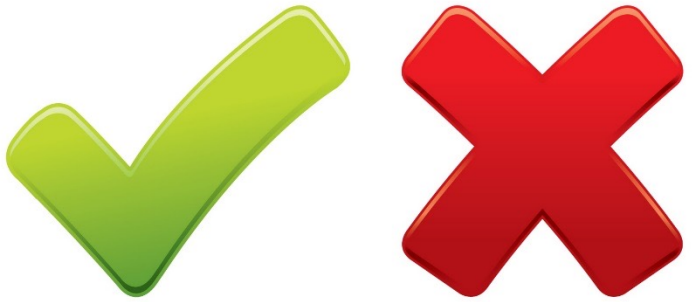
For more information …

- **Follow us on social media**
  - LinkedIn: IMVO | Irish Medicines Verification Organisation
  - X (formerly Twitter): @imvo_Ireland
- **PSI**
  - FMD: https://www.thepsi.ie/gns/Pharmacy_Practice/FalsifiedMedicinesDirective.aspx
  - Queries: info@psi.ie
- **HPRA**
  - FMD: http://www.hpra.ie/homepage/medicines/special-topics/falsified-medicines-legislation
  - Brexit: http://www.hpra.ie/homepage/about-us/stakeholders/brexit/brexit---latest-information

IRISH
MEDICINES
VERIFICATION
ORGANISATION


BACKUP SLIDES

Overview of Alert management



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)**
  - Those **red** or **amber** responses which represent potential falsifications are **'alerts'** and can be recognised as follows:
    - The message 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 and falsification ruled out before the pack can be supplied
- All other scan responses are known as **'exceptions'**

Examples of alerts (i.e. potential falsifications)

Alert message	Likely root cause	What to do next?

Batch not found	• Scanner or software issue
	• Data not uploaded by MAH
		• Follow advice in IMVO 'help' page (linked from your FMD software)
		• If you identify a root cause in the pharmacy, notify IMVO
		• 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	

Examples of 'exceptions'

Scan message	Likely root cause	What to do next?
Product code not known	Barcode on non-FMD pack was scanned, e.g. medical device, OTC, 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	
Pack cannot be reactivated as it was decommissioned in another location	The pack was decommissioned before you received it	
'The product code or batch is unknown locally. Inter-market communication error. Do not retry' **New message from 1 Jan 2025**	This is a new exception message linked with the Windsor Framework - you have scanned a UK pack and the UKNI system cannot found	Supply the pack unless you have overriding concerns that it may be falsified or has been tampered with or it has expired

How will you know what the issue is and what to do next?

- The exception/alert message in your FMD software will:
  - give you a **high-level summary** of what has happened, e.g. 'batch ID mismatch'
  - provide a **link to a 'help' page on the IMVO** website to assist you in identifying a root cause for the alert/exception. The help page also provides guidance on how to fix the issue if it relates to a scanner or software issue
- IMVO also monitors the IMVS for large numbers of alerts, unusual patterns of alerts by product (by batch or by end-user location) and will contact you or the MAH or FMD software provider (as appropriate) to advise on how to prevent further alerts

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* 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

nmvsalerts

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

- **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
- **Scanning unlicensed medicines** (ULMs) may also cause alerts on occasion

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