IRISH MEDICINES VERIFICATION ORGANISATION

Webinar for MAHs

UPDATE FOR MAHS

12 NOVEMBER 2025

Outline

- Windsor Framework update
- General update on FMD in Ireland
- New IMVO Corporate Strategy 2025-2027
- European updates
- MAH fees 2026

Windsor Framework (WF)

FMD impact of Brexit

- UK left EU on 31st January 2020 and EU law continued to apply in UK during a transition period until 31st December 2020
- FMD was discontinued in Great Britain (England, Scotland, Wales), while FMD remained mandatory in Northern Ireland (to avoid a hard border on island of Ireland)
- FMD no longer applies in Northern Ireland since 1st January 2025
- What does this mean?
  - Packs placed on UK market must be labelled '**UK Only**'
  - Pack data from these UK packs will not be uploaded to the EMVS
  - Every UK single market pack with 2D barcode that is scanned in Ireland **will generate an exception/alert**

Impact of Windsor framework on UK single market packs in circulation in EEA

- i.e. UK single market packs brought into EEA markets (e.g. under Article 5(1) and Article 126a of Directive 2001/83/EC) – often sourced to address shortages and other local supply issues
- FMD issues arise where UK packs carry 2D barcodes
  - Option of verifying /decommissioning these packs via IMTs against UKNI NMVS is gone
  - Since 1 Jan 2025, every UK single market pack with 2D barcode that is scanned in EEA is generating an exception/alert
- See next slide for more details

Responses when UK single market packs are scanned in EEA since 1Jan 2025

Pack type	Outcome when scanned since 1 Jan 2025
If product code/batch ID are known to EMVS (i.e. pack data was uploaded to EMVS before 1 Jan 2025)	• 'Market not available' **exception [new]**
If product code is known but batch ID is unknown (i.e. product was set up in EMVS but batch data was not uploaded)	• 'Batch not found' **A2 alert***
If product is not known to EMVS	• 'Product code unknown' **exception**
2D barcode does not contain 4 data elements, e.g. no serial number	• Response will depend on FMD software and whether the scan is transmitted to the NMVS
Recalled / withdrawn / expired UK packs	• No pack state info. available – scan may not indicate if pack is recalled / withdrawn / expired

Advice provided to Irish end-users

- From 1 January 2025, the only way to avoid an alert/exception with UK packs is **not to scan them**
- If you inadvertently scan a UK pack, you will get an **amber** or **red** alert message on your FMD software. 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

Above advice has been agreed with HPRA, DoH and PSI

General update on FMD in Ireland

IMVS statistics

	No.
End-users connected to IMVS	**2105**
Pharmacies	1904
Hospitals	101
Wholesalers	98
Other dispensing outlets	2
MAHs registered with IMVO	**374**

Figures at 12/11/2025

Scanning activity – YTD

Alert rates

- **Trends from the past 4 weeks:**

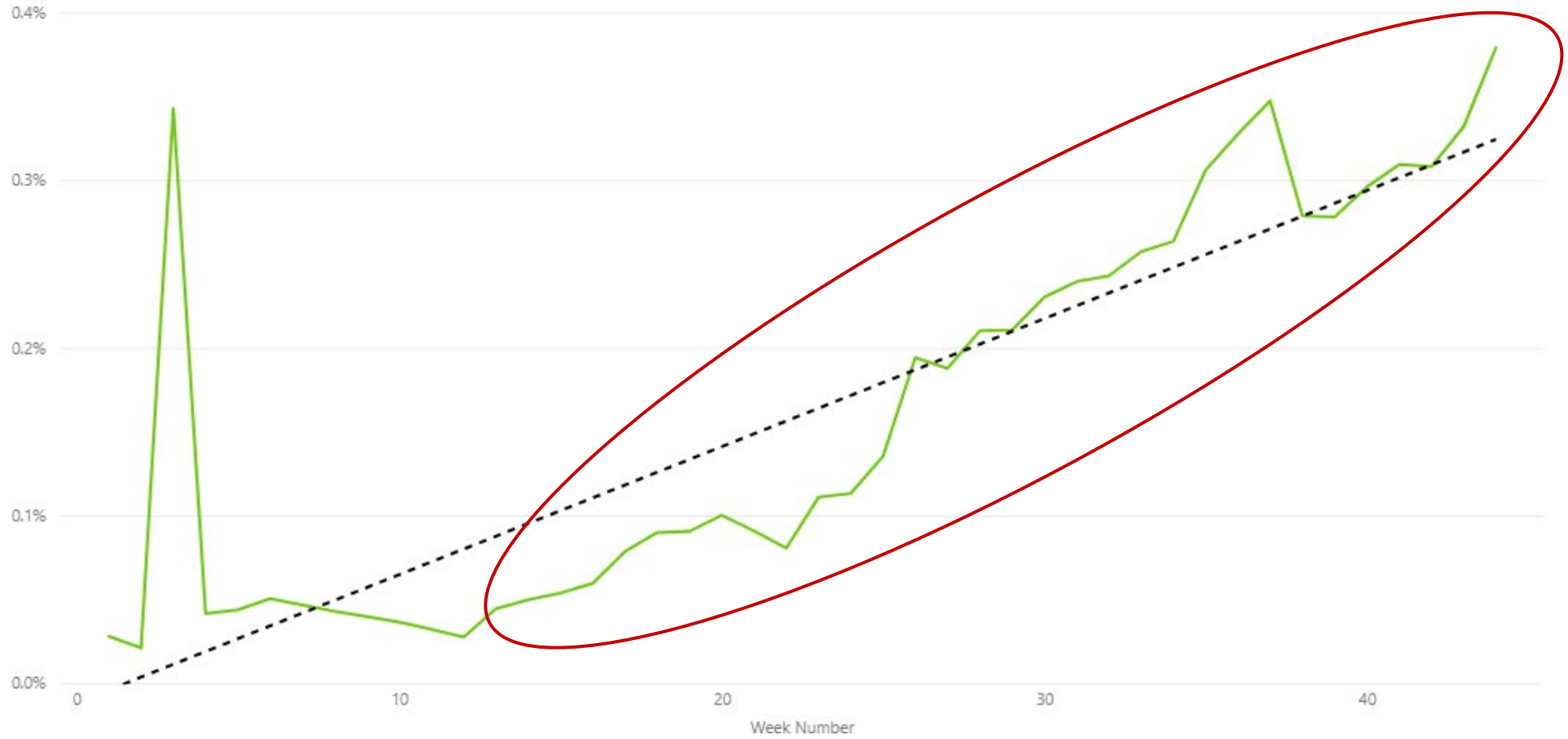
  Week 42 alert to scan ratio: 0.32% (0.31% end-user alert rate, 0.02% adjusted*)
  Week 43 alert to scan ratio: 0.58% (0.30% end-user alert rate, 0.02% adjusted)
  Week 44 alert to scan ratio: 0.35% (0.34% end-user alert rate, 0.02% adjusted)
  Week 45 alert to scan ratio: 0.93% (0.40% end-user alert rate, 0.02% adjusted)

- **Analysis from latest EMVO monitoring report (September 2025)**

  Overall alert to scan ratio across Europe: 0.08%
  Minimum alert to scan ratio: 0.005% (Austria)
  Maximum alert to scan ratio: 3.07% (Malta)

  ** Adjusted rate excludes alerts caused by exempt medicinal products (EMPs) and alerts from non-IE end-users scanning IE packs via IMTs*

Analysis of alerts – YTD



Summary of alerts

- End-user alert rate is now in region of 0.3% due to impact of Windsor Framework.
  - 0.02% excluding spikes and EMPs
- Issues which drive alert rate in Ireland include:
  - Scanning of UK single market packs in IE as exempt medicinal products
  - Alert spikes due to MAH (mostly) procedural errors
- IMVO is taking all steps possible to investigate all alerts
  - But … key gap is failure of some end-users (mostly) & MAHs to provide feedback on their investigations as we cannot definitively ascertain root cause and close alert without this

NMVS Alerts

- IMVO uses the ***NMVS Alerts*** alert management system (AMS)
- Usage of NMVS Alerts by MAHs and end-users to give feedback on their alert investigations is increasing
- We are still considering connecting to the EU AMS Hub

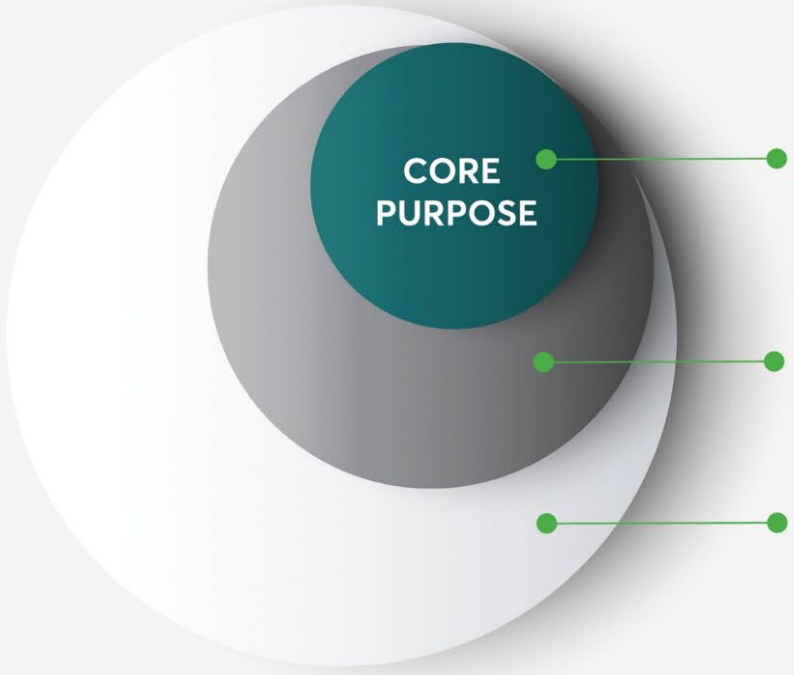
European Medicines Verification System (EMVS)

- EMVS (including IMVS) continues to perform well – no significant incidents or downtime
- IMVS Release 17 was deployed successfully on 2 November. This release included multiple technical and IT security-related updates

New IMVO Corporate Strategy 2025-2027

Our Purpose

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



TO OPERATE THE IMVS

- To operate and manage the IMVS
- To ensure that all alerts are investigated
- To work with the EMVO and other NMVOs to ensure the seamless operation of the EMVS

ENABLE AND SUPPORT OUR STAKEHOLDERS USING THE IMVS

- To provide end-users and MAHs with the support and resources they require to use the IMVS and manage alerts seamlessly

ADD VALUE TO OUR STAKEHOLDERS

- To identify ways in which IMVO and the IMVS can add value for IMVO members, IMVS users, patients and other stakeholders

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

VALUES: Trust | Collaboration | Ambition | Agility | Innovation

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

European matters

Action by EMVO re PMD quality issues

- EMVO has been working for some time to address the problem of inaccurate Product Master Data (PMD) uploaded to the EU Hub, e.g. wrong product name, common name, MAH name, etc.
- EMVO is now proactively screening PMD in the EU Hub and plans to notify relevant OBPs when errors are identified
- PMD errors breach the requirement in the EMVO OBP participation agreement to comply with FMD obligations, in particular obligations imposed on MAHs relating to upload of data to the EMVS under Article 33 of Commission Delegated Regulation (EU) 2016/161
- EMVO also plans to notify the national competent authority of the market(s) where the MAH(s) listed in the PMD of the affected product(s) is/are located

Medicines verification in other countries

- **Greece*:** system live since February and implementation is progressing well – still in 'tolerance' phase - https://hmvo.gr/
- **Italy*:** expected to connect to EU Hub before end of year which will allow data upload to commence and system to go live - https://www.nmvoitalia.it/
- **Ukraine:** plans are progressing rollout of a medicines verification system that follows EU FMD model. Ukrainian NMVO was established in September 2025

** Greece and Italy were not obliged to implement FMD until 9 Feb 2025 (6 years after other countries) as they had pre-existing serialisation schemes. Belgium was in the same position but opted to switch over to the EMVS model in 2019.*

Revision of EU Pharma legislation (1/3)

- 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*"

Revision of EU Pharma legislation (2/3)

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

Revision of EU Pharma legislation (3/3)

3. **Re-dispensing of returned medicines by pharmacies**

   - IMVO and several other NMVOs have made submissions at national level to express concern about FMD aspects of proposed new Article 207a of draft Directive which permits re-dispensing of medicines returned by the public. EMVO has made a submission to EU Commission
   - Implementation of provision (if adopted) will a matter for decision at Member State level

MAH fees 2026

MAH fees

- 2026 Annual User Fee for MAHs has been set at €6,000 (no increase vs 2025)
  - Rebates of 60% are available for MAHs with turnover < €100,000 (prior year data) – new application to be made each year
- Invoices will be issued by IMVO in Jan 2026, due for payment by 9 February 2026
- We will email all MAHs shortly to check contact details and request PO numbers – **please reply to this email**
- If you need to change MAH or register a new MAH during the year, contact mah@imvo.ie for guidance on the process and any fees payable

Support available from IMVO

What support is available? (1/2)

- **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*
- **MAH account/registration/invoice queries** – email mah@imvo.ie*

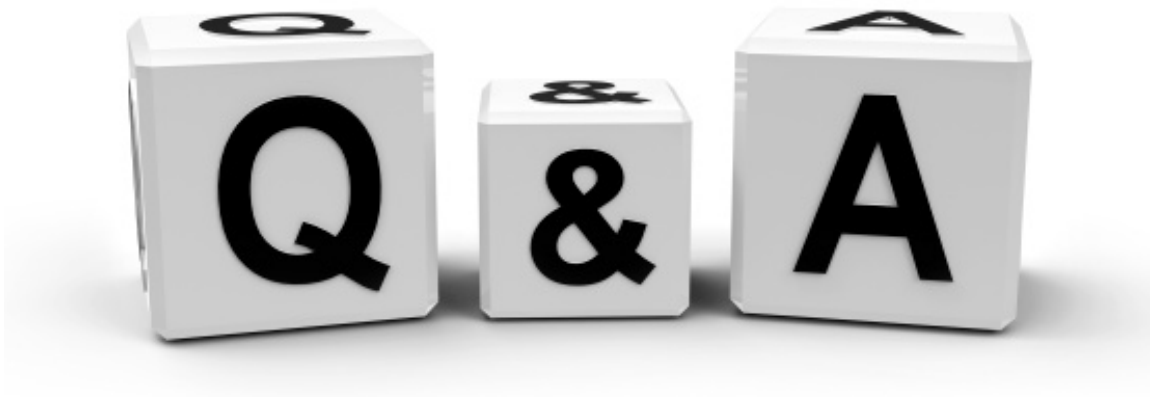
** Monitored during business hours only – for urgent out of hours issues, please phone or email service desk*

What support is available? (2/2)

- **Visit our website** www.imvo.ie
  - **FAQs:** https://www.imvo.ie/support/faqs/
  - **Registering as MAH:** https://www.imvo.ie/system-users/getting-connected-to-the-imvs/
- 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/

General information

- **Follow us on social media**
  - LinkedIn: IMVO | Irish Medicines Verification Organisation
  - X/Twitter: @imvo_Ireland
- **HPRA**
  - Queries: compliance@hpra.ie
- **European Commission Q&A on Safety Features** – available on IMVO website



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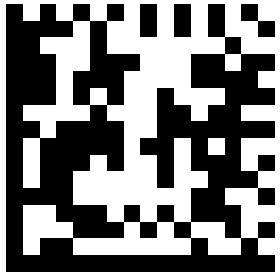

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