IRISH MEDICINES VERIFICATION ORGANISATION

Webinar for wholesalers

19 NOVEMBER 2025

Outline

- Windsor Framework update
- General update on FMD in Ireland
- Issues affecting wholesaler
- Support available from IMVO

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Recalled / withdrawn / expired UK packs	• No pack state info. available – scan may not indicate if pack is recalled / withdrawn / expired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:**

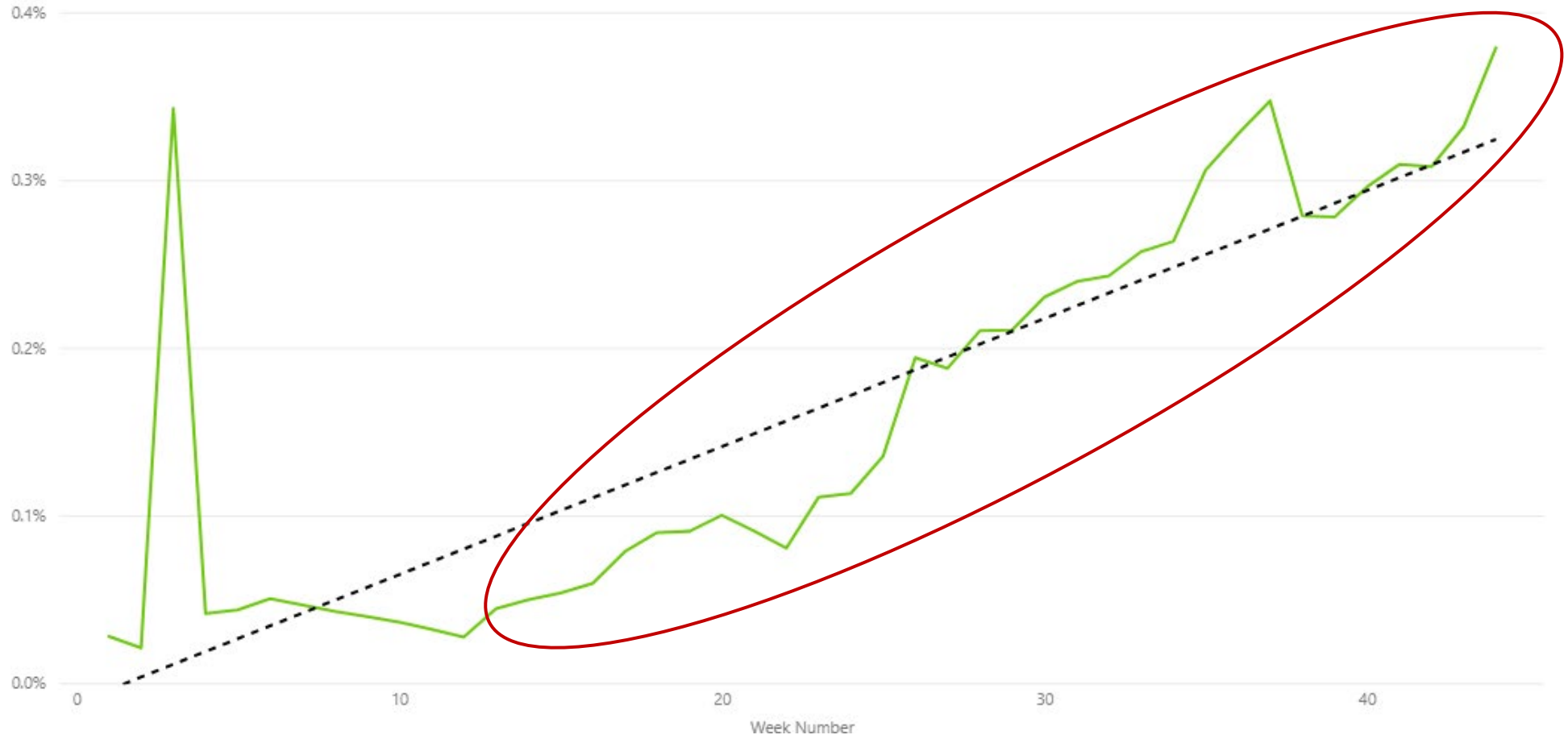
  Week 42 alert to scan ratio: 0.32% (0.31% end-user alert rate, 0.02% adjusted*)
  Week 43 alert to scan ratio: 0.58% (0.30% end-user alert rate, 0.02% adjusted)
  Week 44 alert to scan ratio: 0.35% (0.34% end-user alert rate, 0.02% adjusted)
  Week 45 alert to scan ratio: 0.93% (0.40% end-user alert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

Issues affecting wholesalers

Issues affecting wholesalers

- Aggregation
- Article 23 decommissioning
- Returns
  - Alerts on decommissioned returns need feedback via NMVS Alerts
- EMPs/ULMs
  - Community pharmacy awareness

Queries from wholesalers

Queries from wholesalers (1 of 2)

- **Out of date/expired medicine**
  - **Question:** Do packs that have passed the expiry date need to be decommissioned as 'destroyed' within FMD software?
  - **Answer**: Packs that have expired **do not** need to be decommissioned as 'destroyed' within FMD software, as the IMVS automatically changes its status to 'expired' when the expiry date is reached.
- There is more information on the FAQs page of our website **here** about expired/damaged medicines

Queries from wholesalers (2 of 2)

- **Wholesale Distribution Authorisation (WDA)**
- We've had some queries from wholesalers about whether they need to register with IMVO and connect to the Irish Medicines Verification System (IMVS)
  - The HPRA notifies IMVO when a WDA has been issued to a wholesaler
  - If '**holding**' of prescription only medicinal products is specified in the wholesale classifications, IMVO will send a letter to the wholesaler about registering with IMVO
  - The wholesaler will be required to register if they're 'holding' packs in scope of FMD
  - If they are not 'holding' packs within scope of FMD, there is no requirement for them to register
  - For any regulatory queries, please contact the HPRA directly

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*

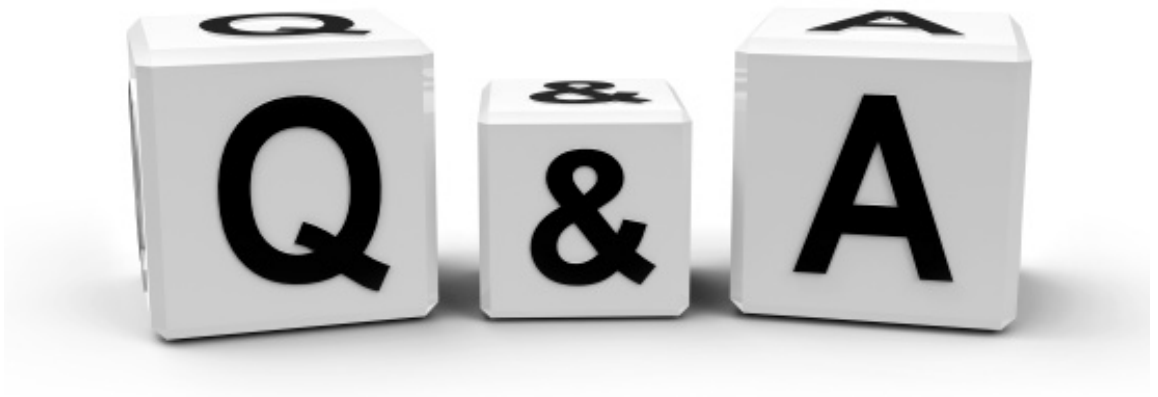
** Monitored during business hours only – for urgent out of hours issues, please phone or email service desk*

What support is available? (2/2)

- **Visit our website** www.imvo.ie
  - **FAQs:** https://www.imvo.ie/support/faqs/
- 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
- **HPRA**
  - Queries: compliance@hpra.ie
- **European Commission Q&A on Safety Features** – available on IMVO website



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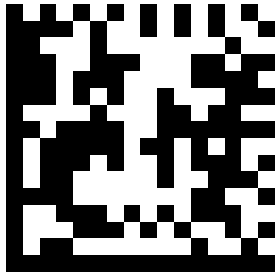

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