IRISH MEDICINES VERIFICATION ORGANISATION

Webinar for pharmacies and hospitals

NOVEMBER 2026

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Agenda

- Windsor Framework update
- Current issues
- NMVS Alerts
- Support available from IMVO



Windsor Framework

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**

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

- Since 1st January 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. You may still 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 expired. Your FMD software may not be able to flag that the pack is expired because of the UK system being disconnected from the EMVS
- Always check the ATD (if present on the pack)
- If you have reason to believe the pack has been tampered with, please report this to the HPRA as a product quality defect via the **HPRA's online reporting system**, and do **not** supply the pack.

Alert management for ULM packs

- IMVO maintains a list of ULM batches internally.
- This list is updated when we receive information on a batch through email or via NMVS Alerts. (Either from a pharmacy, wholesaler or manufacturer, however it is mainly from pharmacies in NMVS Alerts)
- Each business day, IMVO closes alerts raised on batches from this list. For example, several batches of Evorel, Duloxetine and Furosemide products are on this list.
- IMVO also closes these alerts based on calls and emails we receive from pharmacists who ask how they should manage such alerts.

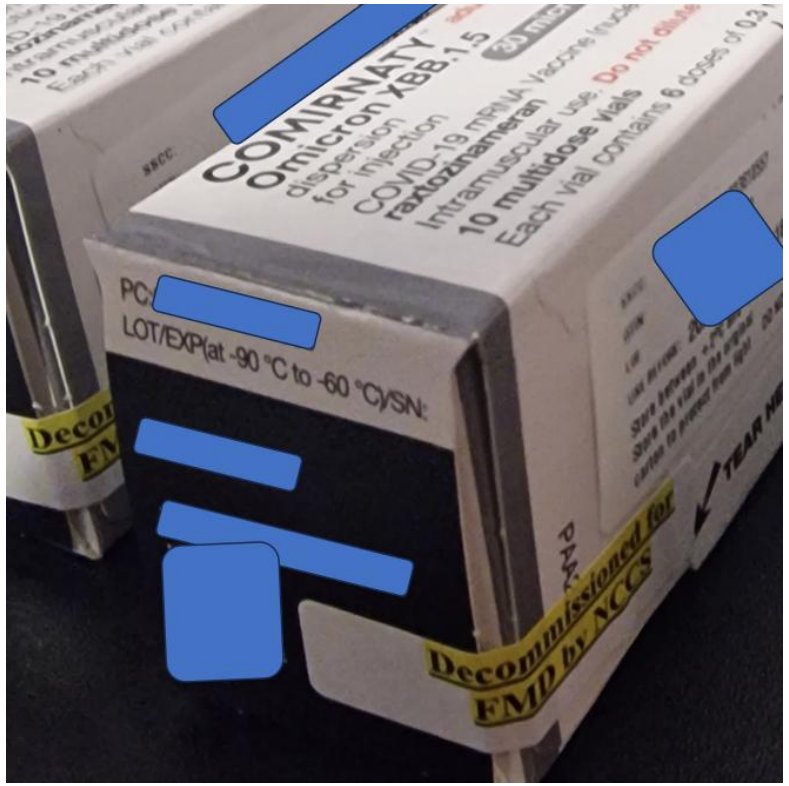
Current Issues

Current issues – Covid and Flu Vaccines

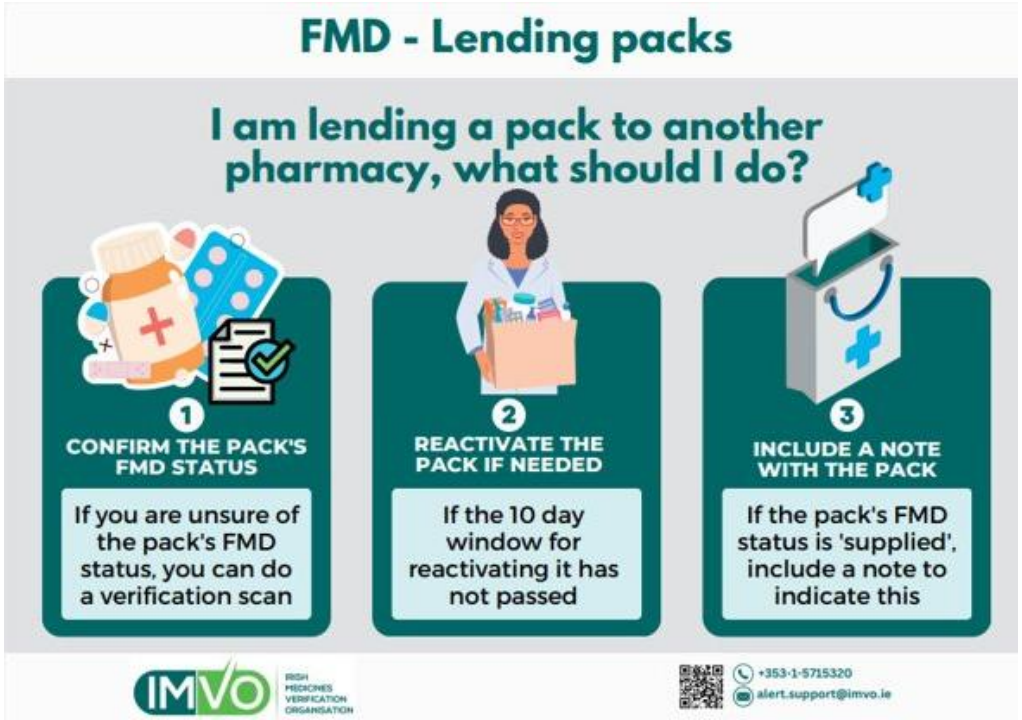
- Alerts raised on Comirnaty vaccine packs
- Packs are being scanned by the NCCS and at pharmacy level, leading to alerts
- If a pack has a sticker like the one in the picture, it does not require any FMD scanning

Decommissioned for FMD by NCCS

- Also seeing alerts raised on flu vaccine packs
- Packs are being scanned by wholesalers on behalf of GP clinics, nursing homes etc. and also at pharmacy level, leading to alerts



Current issues - Borrowings





Current issues – FMD software

Incorrect scanning mode in FMD software

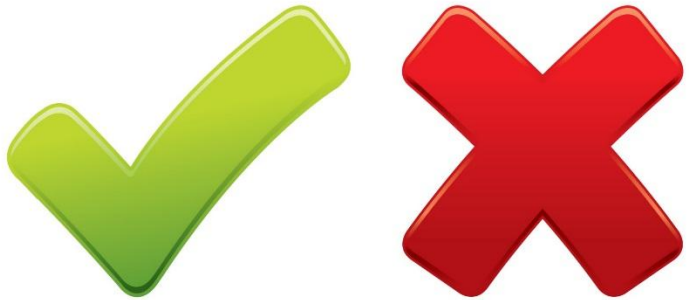
- **Verification:** A medicine may be scanned to verify it is in the IMVS and its status, i.e. is it 'active' or marked as expired or decommissioned as dispensed, recalled, locked, exported, stolen etc.
- **Decommissioning:** 'Decommission' under the FMD directive means changing the status of a pack from active in the supply chain to e.g. supplied, destroyed, sample etc.



FMD software updates

- It is important that your FMD software is on the latest version. Please run any available updates in a timely manner – if in doubt, contact your FMD software provider

Alert Management



How do you know if there is an alert and what to do?

- **Amber** and **red** responses in FMD software indicate an alert/exception that needs to be followed up on:
  - Response includes a high-level description of what has happened (e.g. 'batch ID mismatch', 'pack already decommissioned')
  - Also includes link to 'Alert help' page on IMVO website to assist in identifying a root cause for alert and providing guidance on how to fix it (if it is something under your control such as scanner or software issue) – this guidance is based on IMVO Alert Management Guidance
- Additionally, IMVO monitors IMVS for large numbers of alerts or unusual patterns of alerts, by product, by batch or by end-user location, and contacts end-user or MAH or FMD software provider (as appropriate) to take action to prevent further alerts

nmvsalerts



Access



1 - USING THE NMVS ALERTS ONE-TIME LINK EMAIL FROM ALERT.SUPPORT@IMVO.IE

- The link is valid for 7 days or until such time as the alert is updated.
- The alert link will only work from the email account it was sent to.
- Clicking "Click here" will bring you directly to the alert detail page.


FMD alert management

Dear Colleague,

Alert IE-KH4-32Q-4A5-S9C-29U was raised at your location.

Please investigate the alert and document your findings. If you need assistance on what to do next, please go to the Alert Management page on IMVO's website.

To view the alert, click the temporary link below:

Click here!

NMVS Alerts account, you can log on to the NMVS Alerts system to view all FMD Pharmacy Dublin.

For assistance, email us: alert.support@imvo.ie or phone us: +353-1-5715320

Service hours:

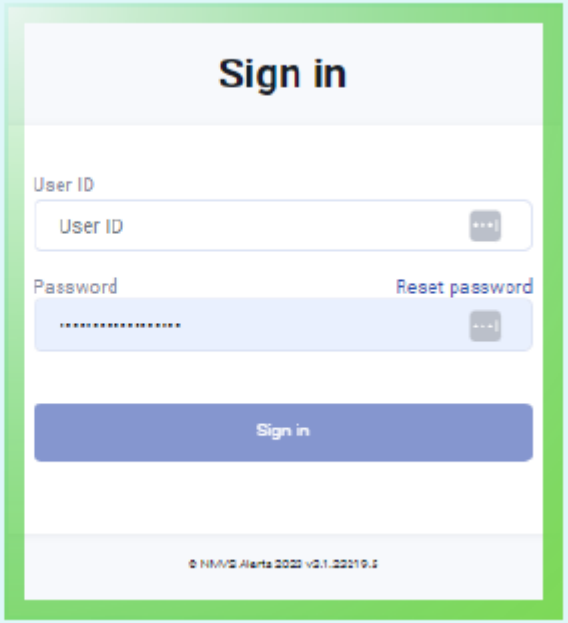
- Monday – Friday 08:00-20:00
- Saturday 09:00-18:00
- Sunday and public holidays 11:00-18:00

Access



2 - LOGGING INTO AN NMVS ALERTS ACCOUNT WITH YOUR USER ID AND PASSWORD

- Click here to login
- If you have an account set up the email address you provided is your User ID
- If you can't remember your password it can be reset using the 'Reset password' link.
- If you don't have an account, or need help to gain access, send an email to alert.support@imvo.ie.





ALERT ID

IE-M4P-7N6-V2J-Q80-9TN

Unresolved for 27d 1h 25min

Find Related Alerts

ALERT DETAILS

Error Code A24	Error Message Pack Already Decommissioned.
Date 12.10.2023	Time 16:15
Product Name -	Product Code 10169817467653
Serial Number 11oLMnDonXRroaJqRghV	Wholesalers -
Market Ireland	Source Market IE
Provided Batch 000000	Stored Batch 000000
Provided Expiry 230912	Stored Expiry 230912
Manual Entry False	Location ID b7590b3d-6537-461c-935a-a97552888a16
Attempted Operation SUPPLIED	Business Process National System Bulk Pack API
PLU Location ID 7afd9227-aec0-4ae8-a488-[illegible]97036fcc7c	PLU Timestamp 12.10.2023 14:13

INVESTIGATION FIELD

Inspection | Action Log | Contact Info

End User TestSite-Development — Open 0

Level 1 Investigation

Technical Error | Procedural Error | Pack Returned | Other

Actions

Inform NMVO

Status change

Open (active) | Investigated

Investigation Status

Comment

Insert comments here...

Save

MAH (MANUFACTURER) AND IMVO ALERT INVESTIGATION STATUS

MAH — Open 0

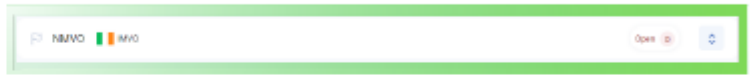
NMVO IMVO — Open 0

CLICK TO EXPAND

Investigation Statuses

There are four different alert status from MAHs (manufacturers) and IMVO:

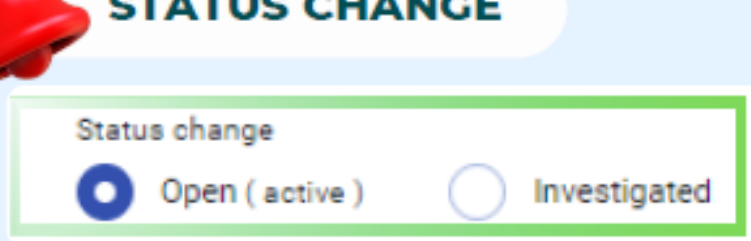




Open O	This indicates that the alert is open and hasn't been investigated by IMVO and/or MAH.
Under Investigation I	This alert is being investigated by IMVO and/or MAH.
Closed C	This shows that the alert was closed by IMVO and/or MAH.
MAH Investigated M	This shows that the alert has been investigated by the MAH and the root cause was not identified on their side.

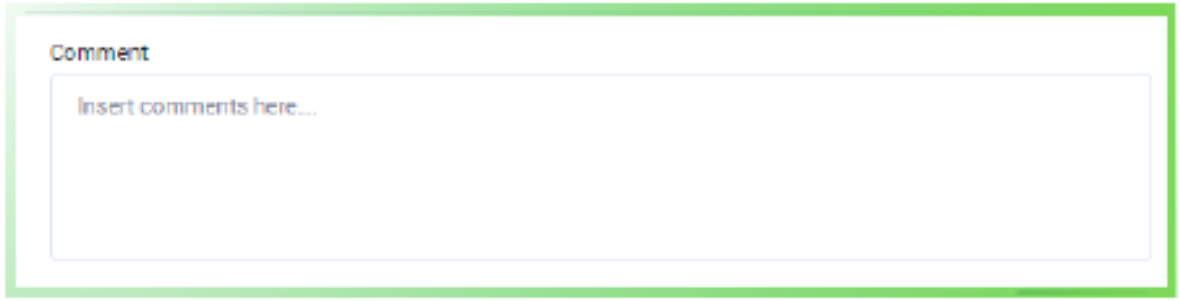


STATUS CHANGE



Once you finish your investigation change the status from 'Open' to 'Investigated'

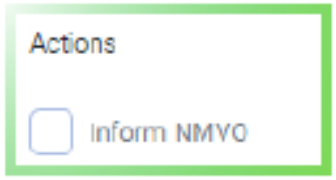
COMMENTS



If you identified the root cause, record your findings here. If not, record the steps you have taken to investigate the alert.

If this is not your first comment, this area may display your previous saved comment. You can erase that to have more space to record your findings.

INFORM NMVO



Always select 'Inform NMVO' before pressing 'Save'. This will send an e-mail notification to IMVO, notifying them about your actions.

TYPE OF ERROR



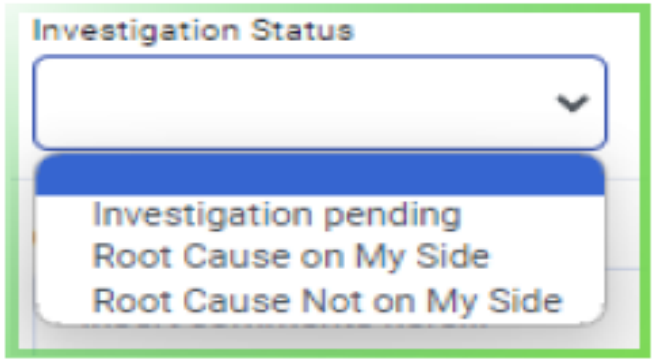
'**Technical error**' is related to either hardware or software issue.

'**Procedural error**' is human error.

'**Pack returned**' indicates if the pack was sent back to either a wholesaler or a manufacturer at their request.

'**Other**' should be used to describe exceptional circumstances only, such as tests, training and scenarios not described above.

INVESTIGATION STATUS



This drop down box allows you to select three options:

'**Investigation pending**' should be used while the investigation is ongoing and no root cause has been identified.

'**Root cause on my side**' should be selected when the outcome of your investigation shows you identified the root cause of the alert as error detected at your location.

'**Root cause not on my side**' should be selected when you concluded the investigation and the root cause of the alert was not at your location.

Save

SAVE BUTTON



You must press the save button to record any changes you make to the alert.

Support available from IMVO

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/
- **Bespoke support sessions for pharmacies by** phone, Zoom or Teams

For more information …

- **Follow us on social media**
  - LinkedIn: IMVO | Irish Medicines Verification Organisation
- **PSI**
  - FMD: https://www.thepsi.ie/gns/Pharmacy_Practice/FalsifiedMedicinesDirective.aspx
  - Queries: info@psi.ie
- **HPRA**
  - Brexit: http://www.hpra.ie/homepage/about-us/stakeholders/brexit/brexit---latest-information
  - Queries: compliance@hpra.ie
- **European Commission Q&A on Safety Features** – available on IMVO website





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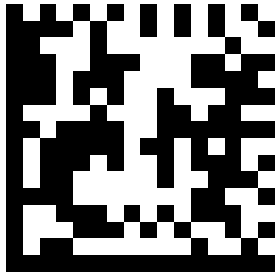

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