



IRISH
MEDICINES
VERIFICATION
ORGANISATION

Webinar for pharmacies and hospitals

NOVEMBER 2023

Agenda

- ▶ Scanning and Alerts
- ▶ Managing alerts
 - ▶ Ozempic example
- ▶ NMVS Alerts
- ▶ Current issues
- ▶ Support available from IMVO



A person in a white lab coat is using a handheld scanner on a patient's hand. The background is a teal gradient with a blurred image of the person and patient. A bright green vertical bar is in the top right corner.

Scanning & Alerts

When must pharmacy or hospital decommission a pack?

- ▶ When pack is being dispensed/supplied:
 - ▶ **Community pharmacies** – at ‘time of supplying it to the public’
 - ▶ **Hospitals** – at any time after pack arrives in hospital (anti-tamper device check must be done at time of supply)
- ▶ In case of bulk/split pack, decommission pack **once only**, when it is opened for first time
- ▶ Pack intended for destruction **that has not expired**
- ▶ Pack being supplied as sample to competent authority, e.g. PSI, HPRA
- ▶ Packs supplied to GPs/nursing homes/schools etc
- ▶ Authorised medicine being supplied for use in a clinical trial



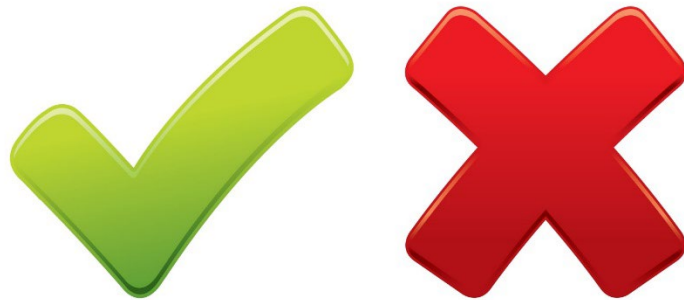
Alerts

- ▶ 'Alert' is generated when:
 - ▶ Data scanned from barcode does not match data in IMVS or
 - ▶ Status of pack (active or decommissioned) does not match what is in IMVS
- ▶ End-user and MAHs do initial investigation to look for root causes on their side
- ▶ If no obvious root cause for alert, pack is deemed to be 'suspected falsification' and is assessed further by MAH
- ▶ If pack is confirmed to be falsified, HPRA is informed
- ▶ Approximately 0.05% of scans generate alerts

How often did pharmacies get alerts during October 2023?

Percentiles	No. of alerts	What does this mean?
90th percentile	3	90% of pharmacies had this amount or fewer alerts during this time period
80th percentile	2	80% of pharmacies had this amount or fewer alerts during this time period
70th percentile	1	70% of pharmacies had this amount or fewer alerts during this time period
60th percentile	0	60% of pharmacies had this amount or fewer alerts during this time period
50th percentile	0	50% of pharmacies had this amount or fewer alerts during this time period

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

Recent Ozempic example

European Medicines Agency (EMA) 18 October

- ▶ Falsified packs of Ozempic (semaglutide, 1 mg, solution for injection) have been identified at wholesalers in the EU and the UK.
- ▶ In the EU, each medicine pack has a unique 2D barcode and serial number so that it can be tracked in an EU-wide electronic system. When the packs of the falsified Ozempic were scanned, the serial numbers were shown to be inactive, thereby alerting operators to a potential falsification.

ema.europa.eu

Federal Institute for Drugs and Medical Devices (BfArM)

- ▶ Initial investigations by the manufacturer Novo Nordisk A/S have shown that there is no semaglutide in the counterfeit drug Ozempic®
- ▶ According to the results of the German official testing laboratory Chemical and Veterinary Investigation Office (CVUA) Karlsruhe, the affected pens contain insulin.

Original:



Fälschung:



Bfarm.de

Decommissioned at another location alerts

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

- ▶ You will not have 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



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.



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.

A screenshot of a web page titled 'Sign in'. It features two input fields: 'User ID' and 'Password'. The 'User ID' field has a small icon of three dots on the right. The 'Password' field is masked with asterisks and has a 'Reset password' link to its right. Below the fields is a blue 'Sign in' button. At the bottom of the page, there is a small copyright notice: '© NMVS Alerts 2020 v0.1.20210.0'. The entire sign-in form is enclosed in a light green border.



ALERT ID

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

Resolved for 27d 1h 25min



Find Related Alerts

ALERT DETAILS

Error Code	Error Message
A24	Pack Already Decommissioned.
Date	Time
12.10.2023	16:15
Product Name	Product Code
-	10169817467653
Serial Number	Wholesalers
11oLMnDonXfRoaJgRgM	
Market	
Ireland	
Provided Batch	
000000	
Provided Expiry	
230912	
Manual Entry	
False	
Attempted Operation	
SUPPLIED	
PLU Location ID	
7afd9227-ae0-4ae9-a4	
97036fcc7c	

Inspection Action Log Contact Info

INVESTIGATION FIELD

End User TestSite-Development

Open

Level 1 Investigation

Technical Error

Procedural Error

Pack Returned

Other

Actions

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

MAH FinClassMedicines Inc.

Open

IMVO

Open

Open

This indicates that the alert is open and hasn't been investigated by IMVO and/or MAH.

Under Investigation

This alert is being investigated by IMVO and/or MAH.

Closed

This shows that the alert was closed by IMVO and/or MAH.

MAH Investigated

This shows that the alert has been investigated by the MAH and the root cause was not identified on their side.

MAH (MANUFACTURER) AND IMVO ALERT INVESTIGATION STATUS

MAH

Open

IMVO

Open

CLICK TO EXPAND



TYPE OF ERROR

Technical Error

Procedural Error

Pack Returned

Other

'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

Investigation Status

Investigation pending
Root Cause on My Side
Root Cause Not on My Side

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.



STATUS CHANGE

Status change



Open (active)



Investigated

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



COMMENTS

Comment

Insert comments here...

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

Actions



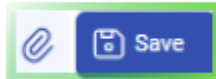
Inform NMVO

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

Save



SAVE BUTTON



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

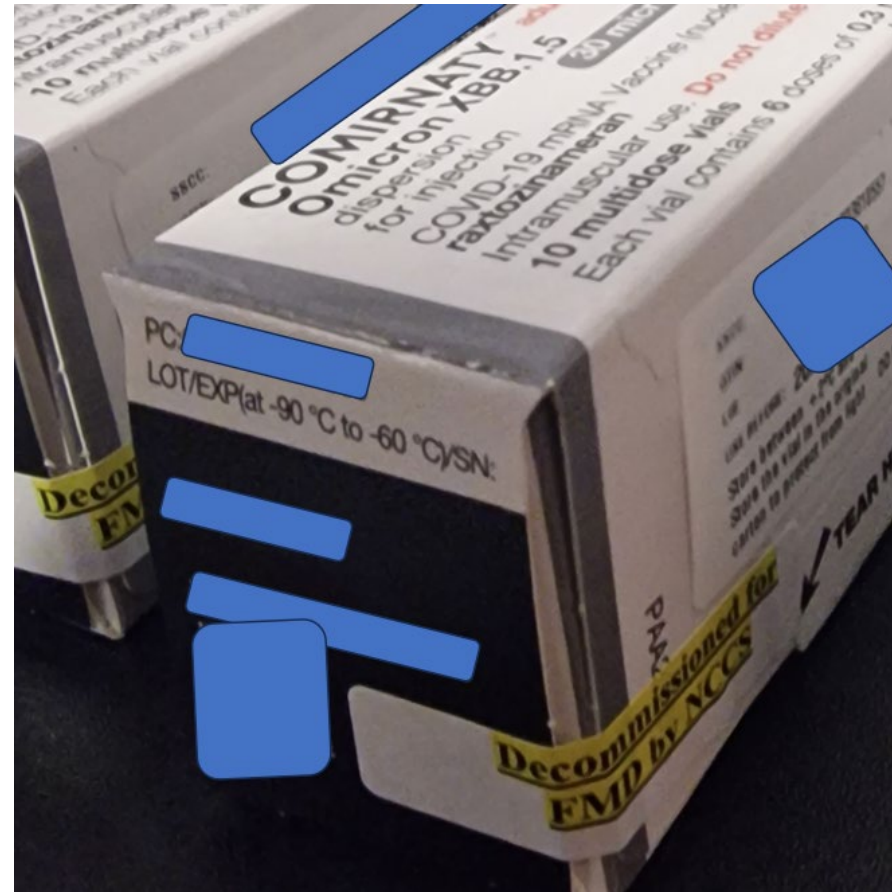


Current Issues

Current issues – Covid Vaccines

Double decommissioning

Decommissioned for
FMD by NCCS



Current issues - 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



Current issues – Scanning mode

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.





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](#)
- ▶ Twitter: [@imvo_Ireland](#)

▶ PSI

- ▶ FMD: https://www.thepsi.ie/gns/Pharmacy_Practice/FalsifiedMedicinesDirective.aspx
- ▶ Queries: info@psi.ie

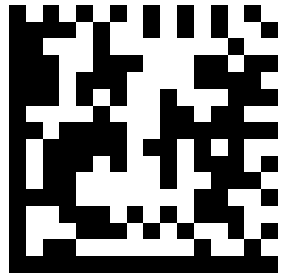
▶ HPRA

- ▶ 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>
- ▶ Queries: compliance@hpra.ie

▶ European Commission Q&A on Safety Features – available on [IMVO website](#)







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