IRISH MEDICINES VERIFICATION ORGANISATION

Update webinar for Pharmacies & Hospitals

13 OCT 2022

Outline

- Housekeeping – Q&A
- Progress since ‘Use and Learn’ ended on 30 May 2022
- Alert causes in pharmacies and hospitals
- Alert investigation
- ‘Alert help' pages
- *NMVS Alerts*
- Other issues
- Conclusion
- Q&A

Backup slides

- Glossary
- Level 1-5 classification of alerts and exceptions
- Accessing information with Op code
- Summary of IMVO Alert Management Guidance

Progress since ‘Use and Learn’ ended on 30 May 2022

Progress update

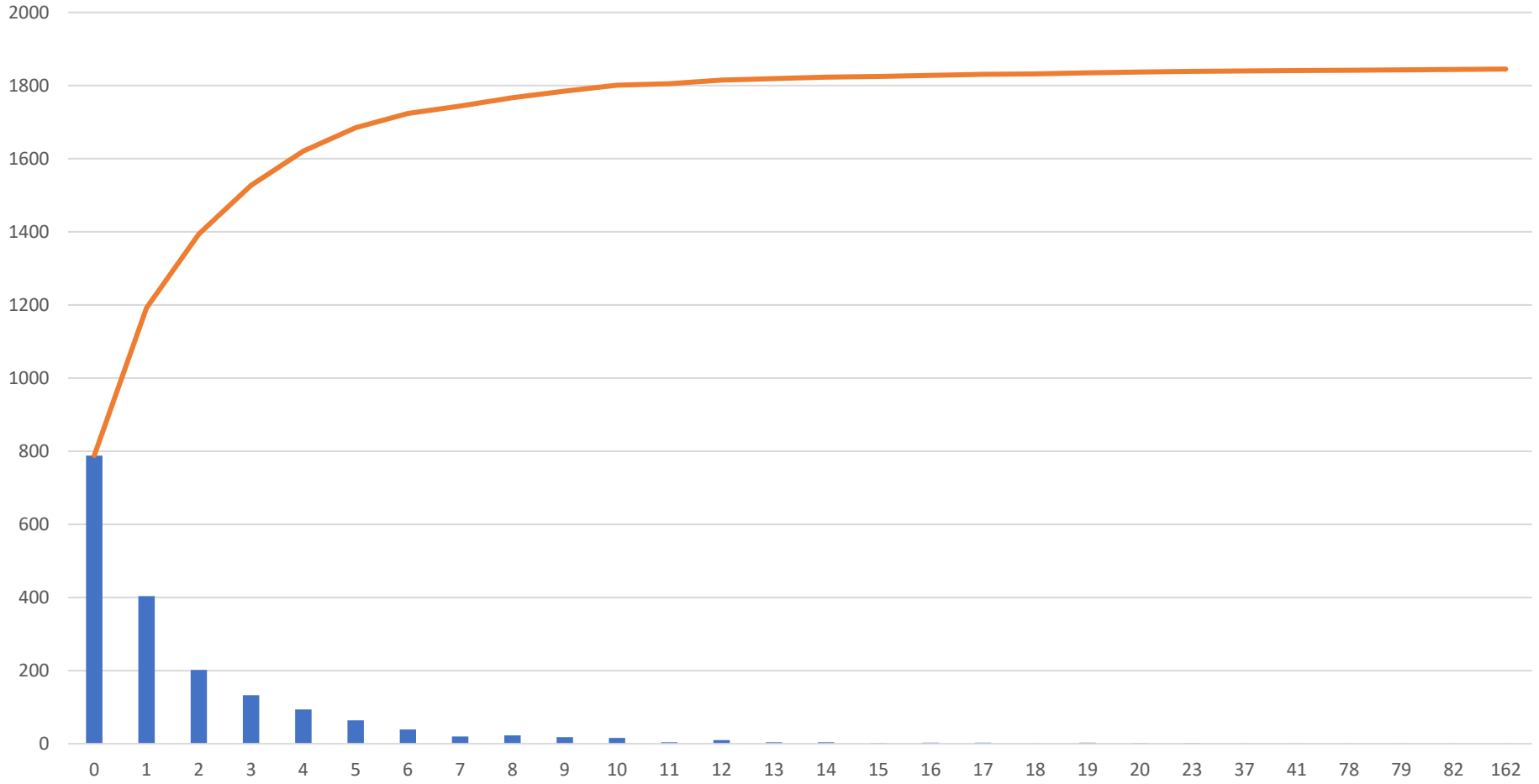
- Pharmacy and hospital engagement with IMVO has increased significantly
- Scanning rate increased – 1.7 million transactions per week
- Alert rate reduced – end-user rate is at approx. 0.05% of total transactions

Scan rates Jan – Sep 2022

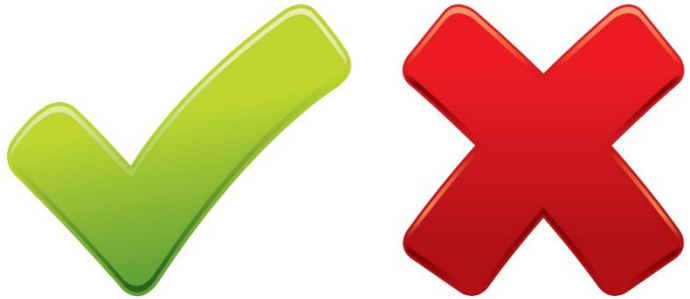
How often did pharmacies get alerts during September 2022?

Percentiles	No. of alerts	What does this mean?
90th percentile	**5**	90% of pharmacies had this amount or fewer alerts during this time period
80th percentile	**3**	80% of pharmacies had this amount or fewer alerts during this time period
70th percentile	**2**	70% of pharmacies had this amount or fewer alerts during this time period
60th percentile	**1**	60% of pharmacies had this amount or fewer alerts during this time period
50th percentile	**1**	50% of pharmacies had this amount or fewer alerts during this time period
40th percentile	**0**	40% of pharmacies had this amount or fewer alerts during this time period

How often did pharmacies get alerts during September 2022?



Alert causes in pharmacies and hospitals



‘Product code not known’ exceptions

- If you get a 'Product code not known’ exceptions, this means that the product is not recognised by the IMVS
- Typical root causes include:
  - The pack is a non-FMD pack e.g. medical device or OTC
  - Linear barcode or QR code was scanned
  - The pack scanned was a ULM with a 2D barcode sourced outside the EU

- Avoid scanning 2D barcodes on medical devices and OTC packs as they will always generate ‘product code not known’ exceptions, as will scanning linear barcodes and QR codes
  - NB – these ‘exceptions’ are not notified to IMVO as alerts and will not appear in *NMVS Alerts*

Exempt medicinal products / ULMs with 2D barcodes on the pack

- **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 as 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

Double decommissioning

- Same pack scanned multiple times
  - Update dispensary procedure to prevent this
- Bulk/Split packs
  - Should only be scanned when opened for the first time

Decommissioned at different location

- Borrowings
  - If borrowing a pack from another pharmacy/hospital remember that they may have already decommissioned the pack
  - If a pack is decommissioned in more than one location, it will generate an alert in the second location that will require you to take action
  - If lending a pack to another pharmacy or hospital and you know it has been decommissioned, include a note to indicate this
  - If you receive a pack from a pharmacy or hospital, and don't know if it has been decommissioned, carry out a verification scan in your FMD software to confirm the status of the pack

Decommissioned at different location (cont)

- Wholesaler procedures
  - Alerts can be caused by errors made by wholesalers
  - IMVO will work to assist in identifying the root cause

- Vaccines
  - National Cold Chain Service vaccines will usually be decommissioned prior to delivery
  - Look for sticker stating they are decommissioned

Other alerts

- Decommission as Destroyed
  - Bulk/split packs reaching expiry date
  - Only decommission to destroy a pack that is in an ‘active’ state and has not expired
- Decommission as Sample
  - Only use this when sample requested by PSI or HPRA
  - Check FMD software setting

Software/Scanner/Data

- Scanner and software issues are largely under control
  - Keep FMD software updated
  - If you update your computer software or firewall or install a new scanner this can cause problems sometimes leading to alerts – contact your software provider
- MAH data uploads
  - Primary wholesaler scanning a sample of incoming batches reduces alerts further down supply chain by identifying missing data (NB wholesalers are not required to scan every pack)
  - IMVO contact MAHs when data issues identified at pharmacy level - MAHs very responsive to upload data

Alert Investigation

How are alerts investigated?

- Pharmacies, hospitals ('end-users') and MAHs* initiate simultaneous investigation of alerts generated in the pharmacy or hospital
- The pharmacy or hospital should look for:
  - Procedural errors, e.g. pack decommissioned twice. The error is documented and pack may be supplied so long as there is no reason to suspect it is falsified
  - Technical issues (scanners / software) where alert relates to data mismatch and procedural error has been ruled out. Once fixed, verify pack again and, if successful, supply pack
- The MAH looks for data issues (e.g. missing data) and system issues

** Marketing Authorisation Holders (MAH) are not required to investigate certain alert types, e.g. double-decommission, as root cause is generally at end-user side*

How will you know what the issue is?

- The exception/alert message in your FMD software will:
  - give you a high level summary of what has happened
  - provide a link to an 'Alert help' page on the IMVO website to assist you in identifying a root cause for the alert and providing guidance on how to fix it (if is something under your control such as 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 take action to prevent further alerts
  - Objective is to ensure that issues leading to large numbers of alerts in given end-user location (e.g. faulty scanner, software issue) or with a particular batch (e.g. missing data) are quickly identified and resolved with support from IMVO

Next steps

- IMVO steps in if there is no feedback from the end-user or MAH within 2 working days and ensures the alert is investigated if not already done
  - If end-user or MAH does not provide required assistance/information to enable investigation to be completed, IMVO is required to escalate this to PSI or HPRA as appropriate

Example of Alert Help

‘Pack has already been marked as supplied’

Pack marked as supplied

Alert Help

The instructions below will guide you through identifying what caused this alert. You are not required to follow these steps until use and learn ends, but you may wish to do so to become familiar with the process for following up on alerts. Finding out the root cause of this alert will also help you to take steps to prevent similar alerts in future.

Pack has already been marked as Supplied

Has this pack been decommissioned on your behalf by the wholesaler or pharmacy you received it from?

YES

NO

Have you previously decommissioned this pack at your location?

YES

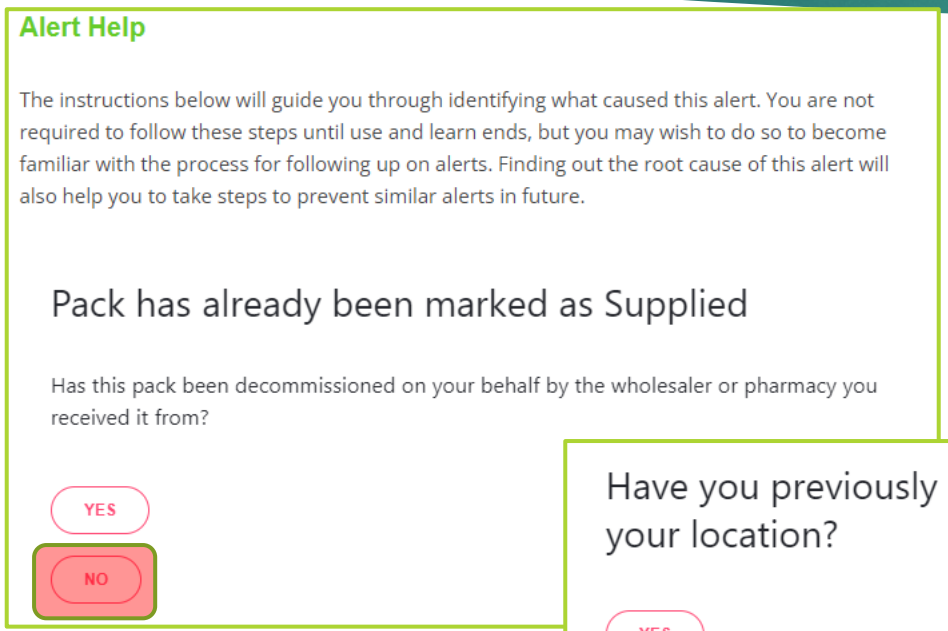
NO

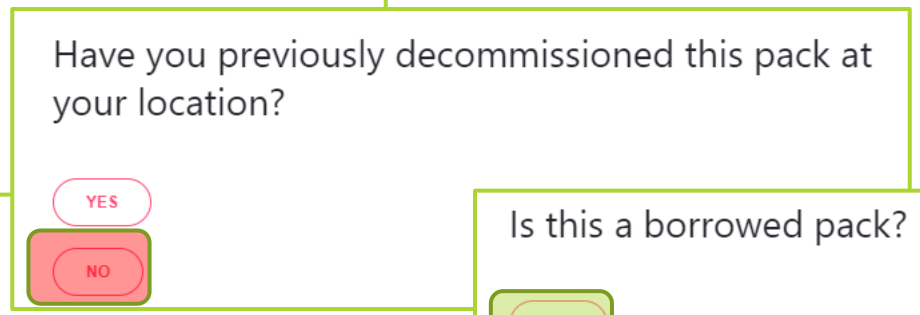
Double Dispense

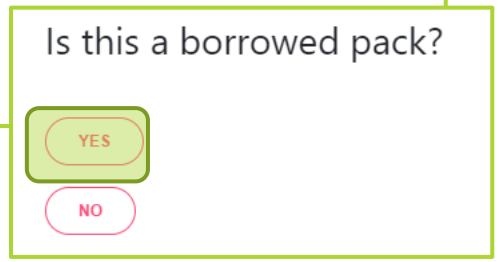
Each pack must only be decommissioned once, including bulk/split packs (these should only be decommissioned when first opened). If you are certain that you made a procedural error the investigation is complete. You should document the root cause of the alert in NMVS Alerts and you may return the pack to saleable stock.

←

Pack marked as supplied







Borrowed pack

If you know the pack was decommissioned at the location you borrowed it from, you must document the root cause of the alert in NMVS Alerts. Once the root cause is documented the investigation is complete and you may return the pack to saleable stock.

Contact IMVO for support with this alert if you do not know if the pack was previously decommissioned at the location you borrowed it from.

Pack marked as supplied

Alert Help

The instructions below will guide you through identifying what caused this alert. You are not required to follow these steps until use and learn ends, but you may wish to do so to become familiar with the process for following up on alerts. Finding out the root cause of this alert will also help you to take steps to prevent similar alerts in future.

Pack has already been marked as Supplied

Has this pack been decommissioned on your behalf by the wholesaler or pharmacy you received it from?

YES

NO

Have you previously decommissioned this pack at your location?

YES

NO

Is this a borrowed pack?

YES

NO

Withhold pack from saleable stock.

- Set the pack aside and contact IMVO for support with this alert.
- The pack may not be placed back into saleable stock until the alert investigation is complete and falsification has been ruled out.
- Please document the source of this pack in NMVS Alerts.

[Link to IMVO guide to using NMVS Alerts]

NMVS Alerts

- Facilitates efficient handling of alerts by allowing end-users, MAHs and IMVO to:
  - Quickly communicate with other parties about an alert, while preserving end-user anonymity vis-à-vis the MAH, which is a core principle of the EMVS
  - Maintain a record of their own actions/findings for each alert (useful back-up when you decide to supply the pack)
- You can easily upload a pack photo to *NMVS Alerts* (if MAH has asked for one)

How to access *NMVS Alerts* – 2 options

1. Set up account – email alert.support@imvo.ie to register

- End-users and MAHs have option to create an account in *NMVS Alerts* free of charge which allows them to:
  - log in to see a list of all their own Level 5 alerts
  - report any information they have to add about the alert
- Over 200 end-users now registered for full accounts

2. Access it via email link

- When a Level 5 alert is generated in your FMD software, automated email will be issued to end-user with a link to alert record in *NMVS Alerts*
- Not necessary to have an account in *NMVS Alerts* to receive/access link
- Link may be used to report information about alert, send photo etc

IMVO Alert status change IE-KH4-32Q-4A5-S9C-29U - FMD alert management Dear Colleague, Alert IE-KH4-32Q-4A5-S9C-29U was raised at your location. Please investigate the alert and docu...

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!

Please note: by clicking the temporary link you accept the *Terms & Conditions*. Temporary links are valid for 7 days or sooner if you save a change to the alert in *NMVS Alerts*.

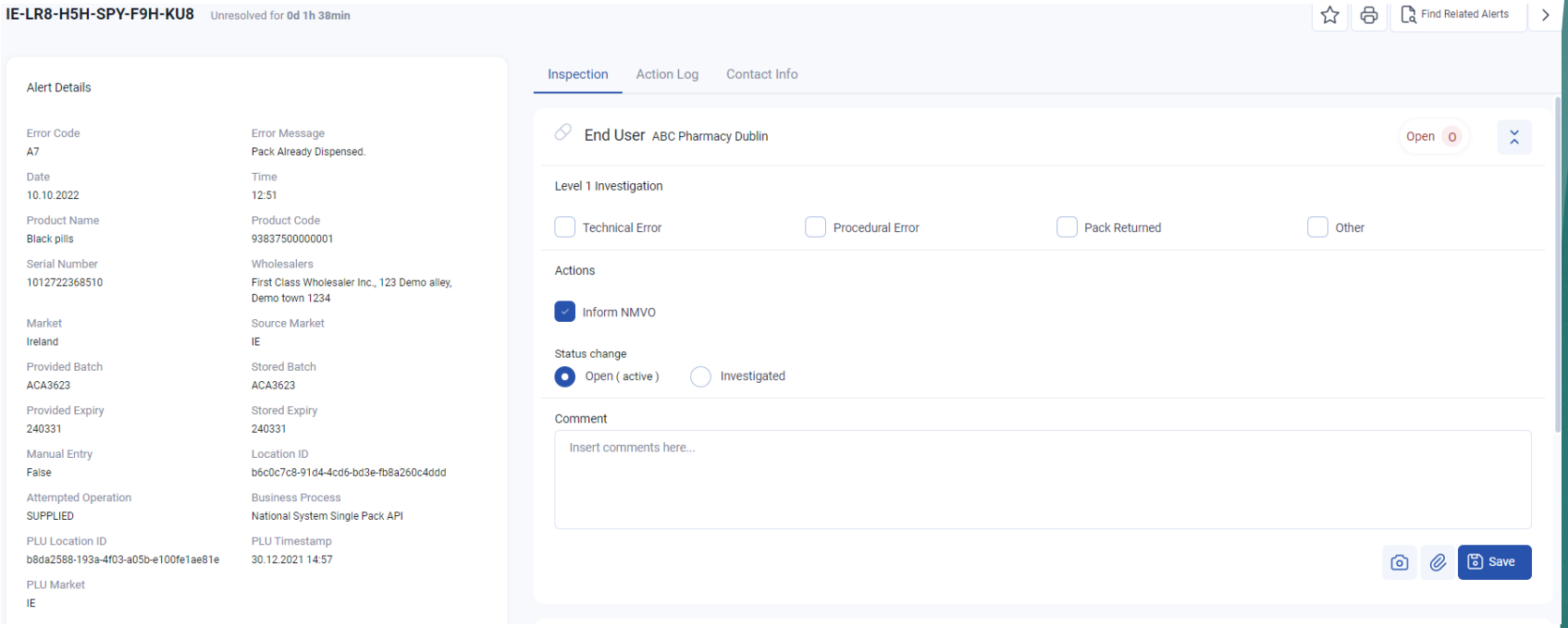
If you have an NMVS Alerts account, you can log on to the *NMVS Alerts system* to view all FMD alerts in ABC Pharmacy Dublin.

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

Email notification received after an alert is generated



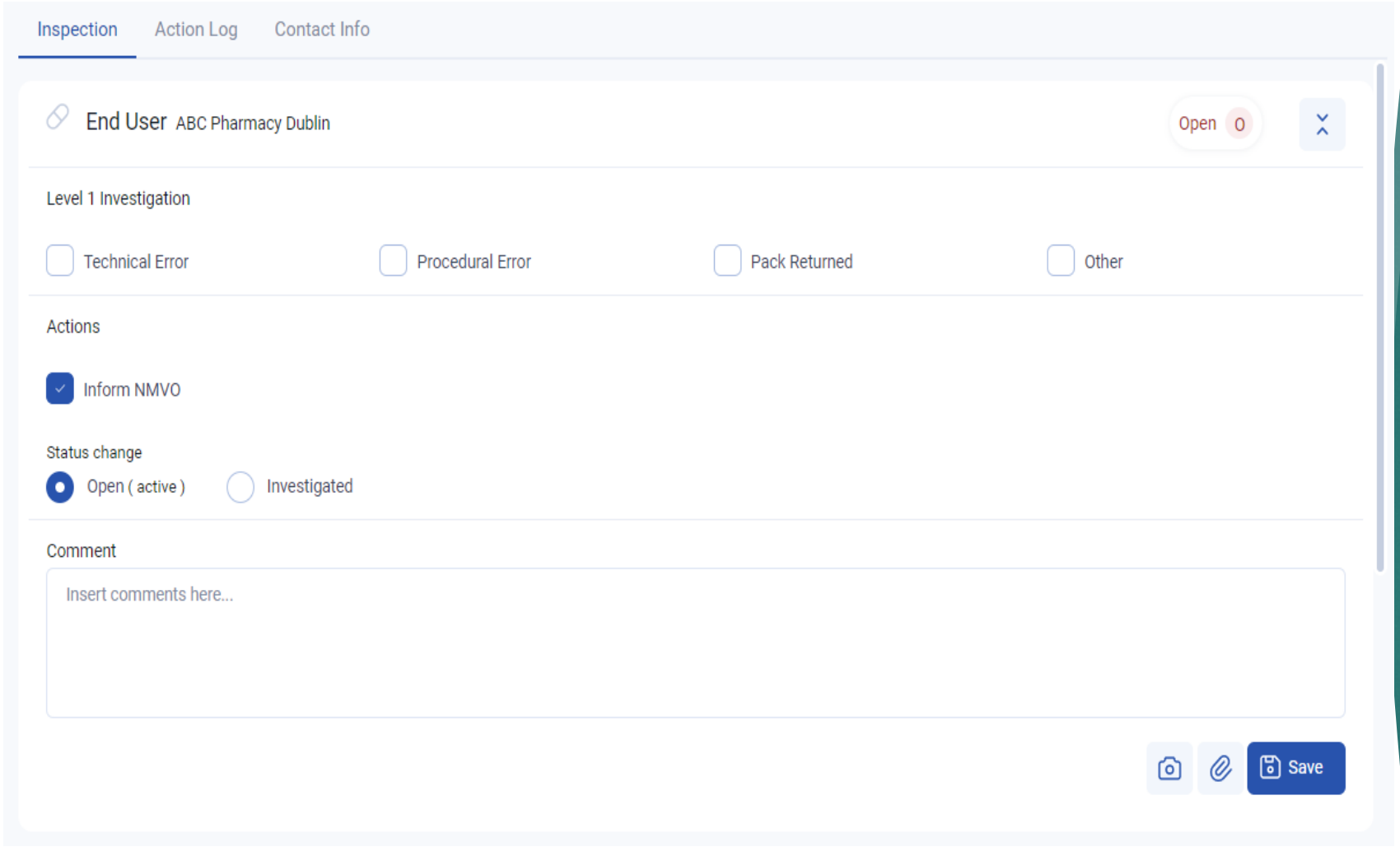
End-user section in NMVS Alerts

IE-LR8-H5H-SPY-F9H-KU8 Unresolved for **0d 1h 38min**

Alert Details

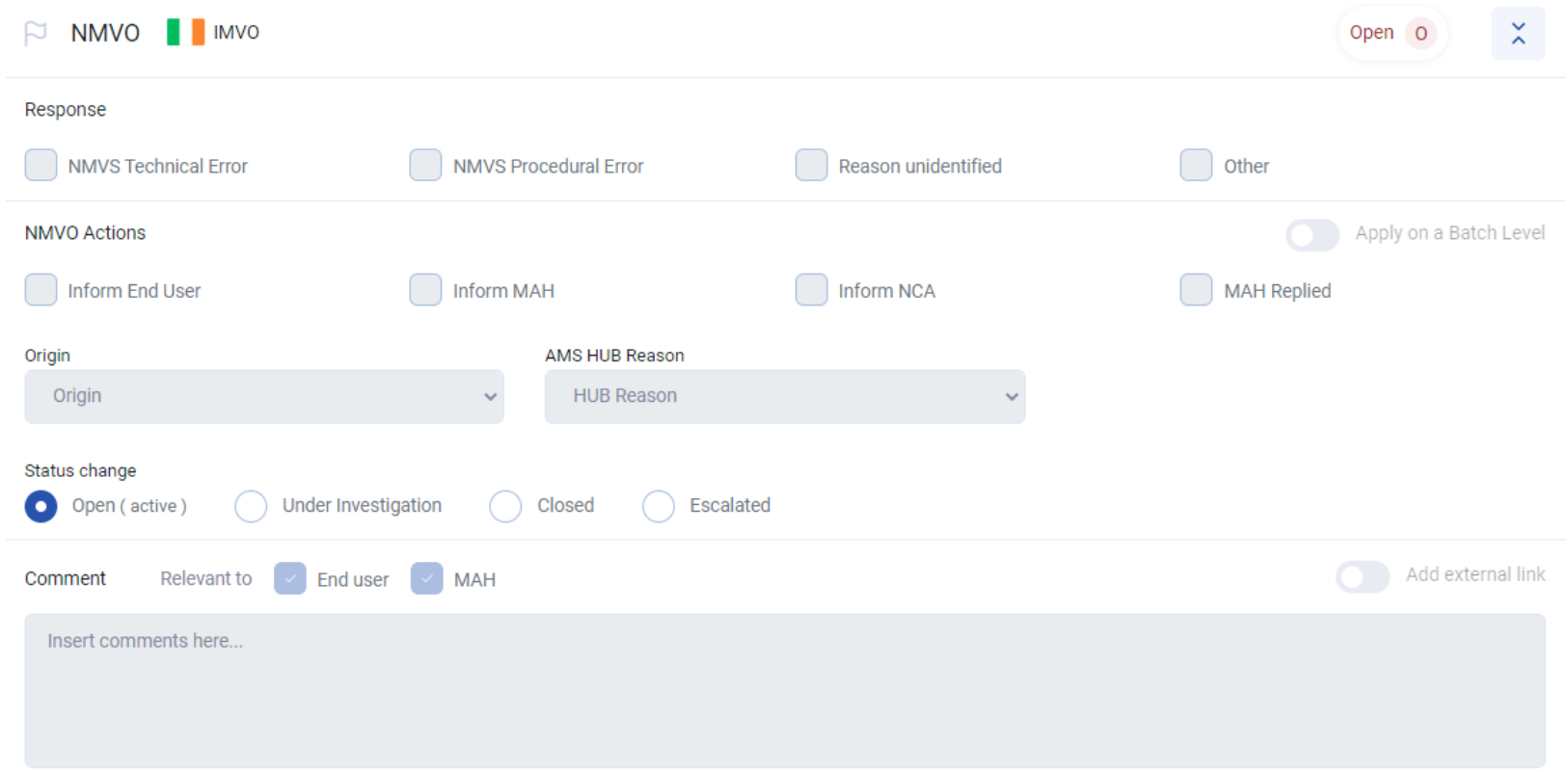
Error Code A7	Error Message Pack Already Dispensed.
Date 10.10.2022	Time 12:51
Product Name Black pills	Product Code 93837500000001
Serial Number 1012722368510	Wholesalers First Class Wholesaler Inc., 123 Demo alley, Demo town 1234
Market Ireland	Source Market IE
Provided Batch ACA3623	Stored Batch ACA3623
Provided Expiry 240331	Stored Expiry 240331
Manual Entry False	Location ID b6c0c7c8-91d4-4cd6-bd3e-fb8a260c4ddd
Attempted Operation SUPPLIED	Business Process National System Single Pack API
PLU Location ID b8da2588-193a-4f03-a05b-e100fe1ae81e	PLU Timestamp 30.12.2021 14:57
PLU Market IE	

End-user section in NMVS Alerts



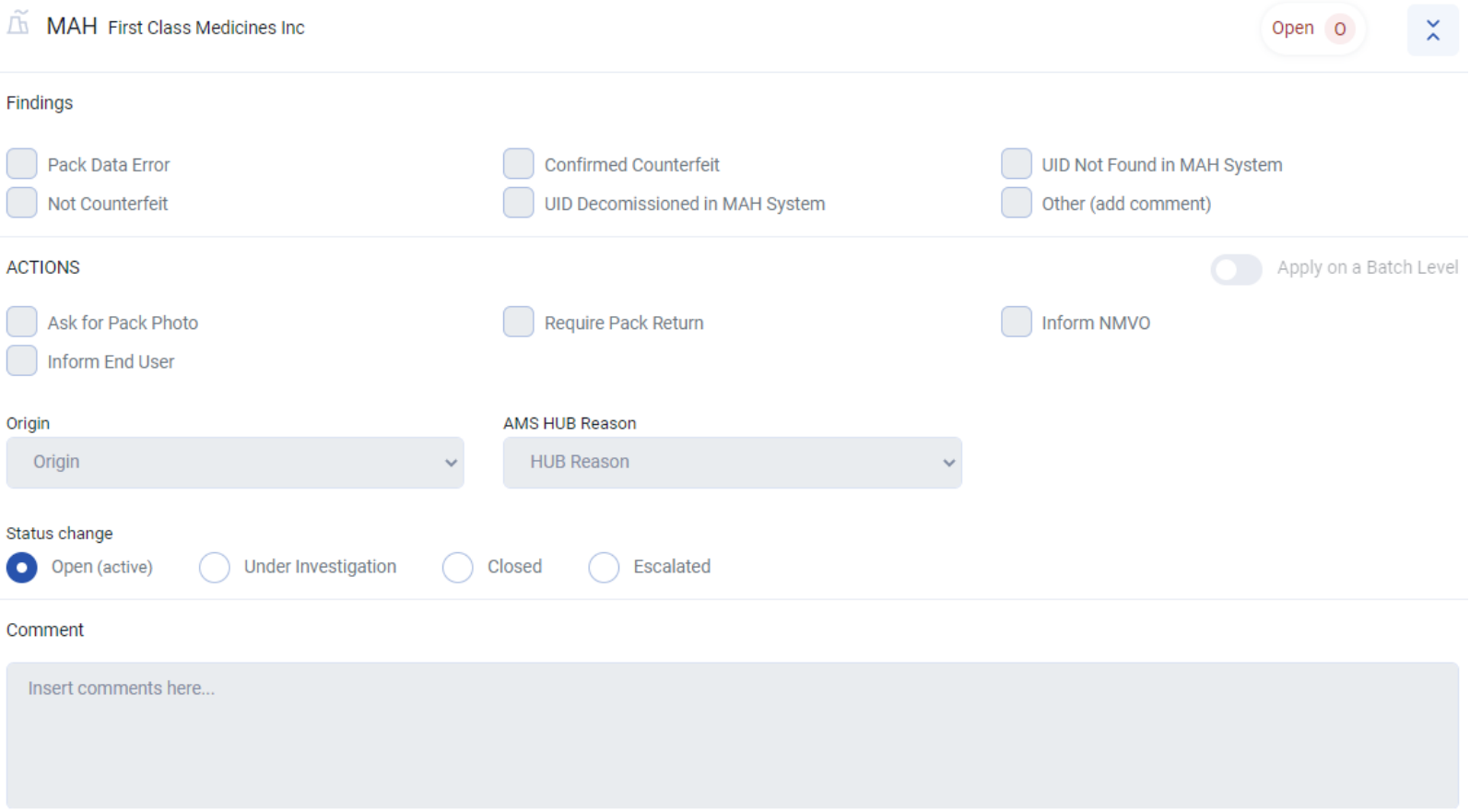
End-user section in NMVS Alerts

Info. from NMVO and MAH available to end-user in NMVS Alerts



IMVO or MAH will mark alerts as 'Closed' in *NMVS Alerts* when we know the root cause

Info. from NMVO and MAH available to end-user in NMVS Alerts



IMVO or MAH will mark alerts as 'Closed' in *NMVS Alerts* when we know the root cause

Where was a pack last decommissioned?

Using *NMVS Alerts to assist alert investigation*

IE-LR8-H5H-SPY-F9H-KU8 Unresolved for **0d 1h 14min**

Alert Details

Error Code A7	Error Message Pack Already Dispensed.
Date 10.10.2022	Time 12:51
Product Name Black pills	Product Code 93837500000001
Serial Number 1012722368510	Wholesalers First Class Wholesaler Inc., 123 Demo alley, Demo town 1234
Market Ireland	Source Market IE
Provided Batch ACA3623	Stored Batch ACA3623
Provided Expiry 240331	Stored Expiry 240331
Manual Entry False	Location ID b6c0c7c8-91d4-4cd6-bd3e-fb8a260c4ddd
Attempted Operation SUPPLIED	Business Process National System Single Pack API
PLU Location ID b8da2588-193a-4f03-a05b-e100fe1ae81e	PLU Timestamp 30.12.2021 14:57
PLU Market IE	

Your location

Location where pack was previously decommissioned

Other issues

Internet Explorer

- Several pharmacies and hospitals have experienced issues accessing the IMVO ‘Alert help’ pages (linked from their FMD software) where Internet Explorer is the web browser used

- If you have this problem, using a different browser such as Chrome, Microsoft Edge or Firefox should resolve the matter for you

Can I return packs with alerts to the wholesaler?

- HPRA has confirmed that packs that have generated alerts must not be returned by pharmacies or hospitals to wholesalers while an alert investigation is ongoing, as such packs could be falsified and should not be put back into the supply chain. This applies even if you have ruled out a technical or procedural error on your part
- If your investigation and that of the MAH have ruled out all obvious root causes for the alert, the MAH may request that the pack be returned to them for further investigation:
  - MAH will provide details of the process for sending back the pack
  - If the MAH requests the pack to be sent back via a wholesaler, the pack should not be sent as a standard business return, as it must be processed as a product quality complaint by the wholesaler, which is a separate process to their normal returns process

Should I report alerts to the HPRA?

- Alerts should **not** be reported by pharmacies or hospitals as suspected quality defects to the HPRA
- If a pack is found to be a confirmed falsification after the alert investigation is complete, the MAH is responsible for notifying the HPRA
- **Anti-tampering device (ATD)**
  - Even if the barcode scan has been successful, if you have reason to believe that the packaging has been interfered with, based on your examination of the ATD, you must report your concern to the HPRA (as a suspected quality defect via the usual reporting mechanisms) and not supply the pack
  - Reports of packs being tampered with are to be submitted as suspected product quality defect via HPRA's online reporting system

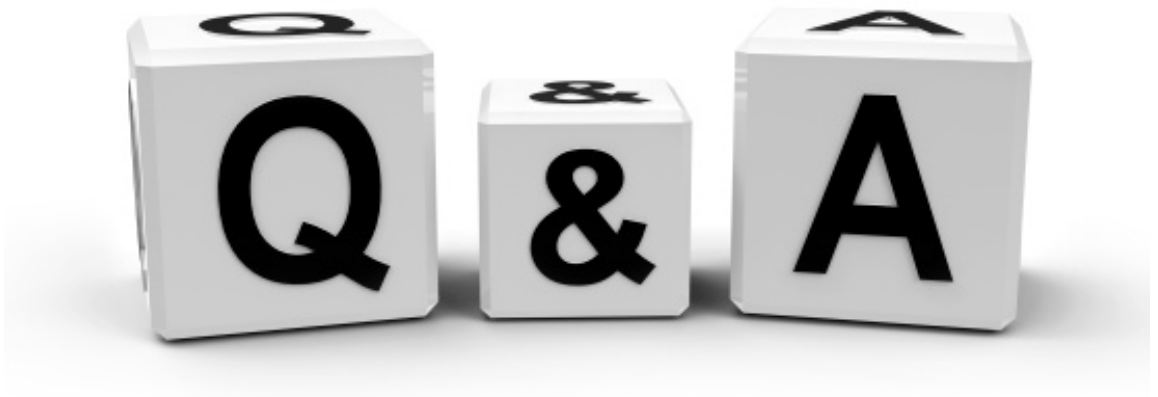
To conclude …

Summary

- If your scanner and software are working as they should and care is taken to avoid double-decommissioning and other procedural errors, you will get very few alerts
- If you do get a Level 5 alert, a few quick steps will quickly reveal if there is a root cause at your end
  - If you find an issue with your scanner and software and fix it, the pack may be supplied once you have verified it
  - If you find a procedural error, e.g. double-decommissioning, the pack may be supplied – strongly recommend you document your rationale for supplying the pack in *NMVS Alerts*
- If the alert is due to a data error, the MAH or IMVO will quickly pick this up and ensure that the correct data is uploaded and will tell you, so you can scan the pack again and go ahead and supply
- Contact IMVO if you need support at any time:
  - Extended support hours available – 08.00-20.00 weekdays, 09.00-18.00 Sat, 11.00-18.00 Sun/public holidays)

For more information …

- **IMVO** www.imvo.ie
  - All alert/***NMVS Alerts* account** related queries: alert.support@imvo.ie
  - All other queries: info@imvo.ie
  - Tel: +353-1-5715320
  - Twitter: @imvo_Ireland
  - LinkedIn: IMVO | Irish Medicines Verification Organisation
- **PSI**
  - https://www.thepsi.ie/gns/Pharmacy_Practice/FalsifiedMedicinesDirective.aspx
  - Queries: info@psi.ie
  - Tel: +353(0)1 218 4000
- **HPRA**
  - FMD: http://www.hpra.ie/homepage/medicines/special-topics/falsified-medicines-legislation
  - Queries: compliance@hpra.ie
  - Tel: +353-1-6764971
- **HSE FMD Project Team email**: HSE.Support@ezfmd.com
- **European Commission Q&A on Safety Features** – available on IMVO website



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BACKUP SLIDES

Glossary

Term/acronym	Definition
Alert	A Level 5 exception that is raised in the IMVS that indicates a pack is a potential falsification
Batch ID	This is the batch/lot number on a medicinal product pack
Decommission	Decommission' under FMD means changing the status of a pack from active in the supply chain. The term decommission is often used to describe the action of marking a pack as supplied. Some FMD systems use different terminology to describe the action of decommissioning a pack as supplied (e.g. dispense, supply, dispense now).
EMVS	European Medicines Verification System (which comprised the EU Hub and all the connected national medicines verification systems)
End-User	Wholesaler or person authorised or entitled to supply medicines to the public (e.g., pharmacy, healthcare institution) that wishes to create an account in the IMVS in order to establish connections to the IMVS from software system(s) on specific terminals in specific location(s) in their organisation
Exempt medicinal products (EMP)	Also known as unlicensed medicines (ULMs) or unauthorised medicines. An exempt medicinal product is a medicinal product that has not been authorised for sale or supply in Ireland either by the HPRA or by the European Commission and which is sourced from outside Ireland
FMD	Falsified Medicines Directive. FMD is a general term used to refer to EU and Irish legislation relating to falsified medicines and safety features – Directive 2011/62/EU, Commission Delegated Regulation on Safety Features (EU) 2016/161 (as amended) and the Medicinal Products (Safety Features on Packaging) Regulations 2019 (S.I. No. 36 of 2019)
FMD software	The software used by end-users to verify/decommission packs under FMD
HPRA	Health Products Regulatory Authority
IMT	Intermarket transaction

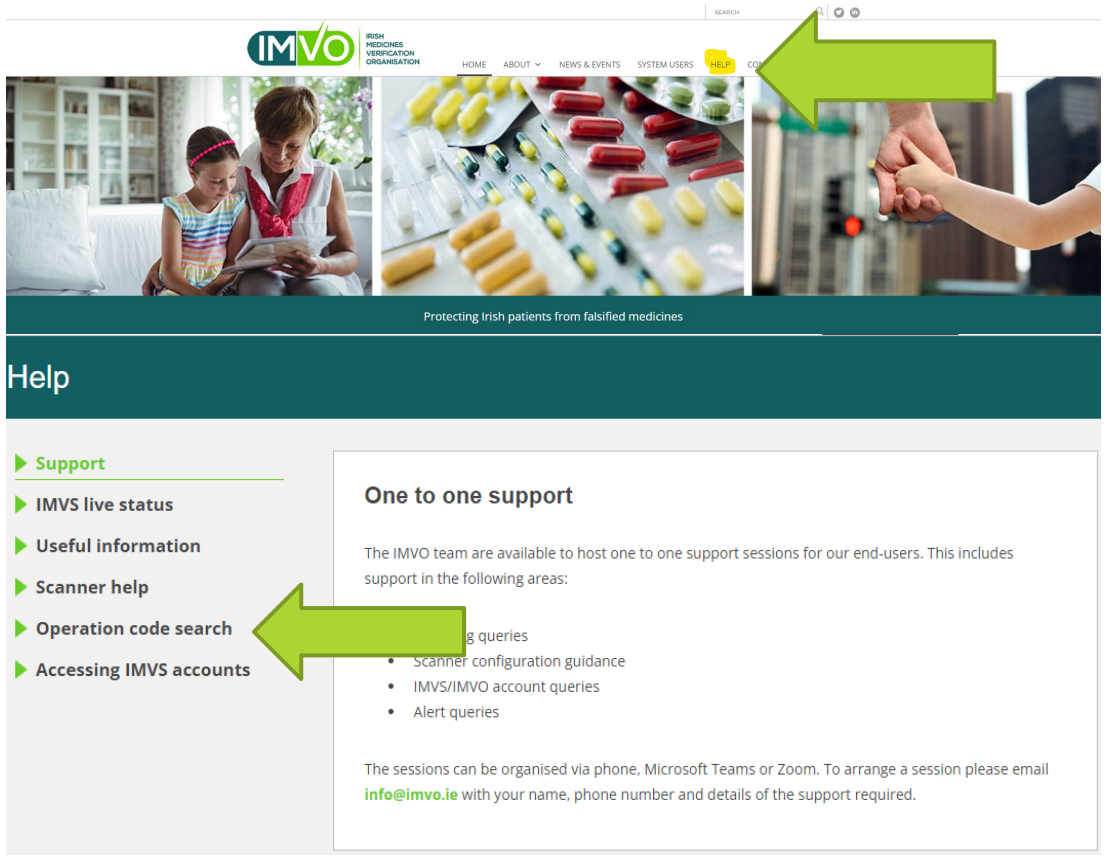
Glossary

Term/acronym	Definition
IMVS	Irish Medicines Verification System (The IMVS is part of the EMVS)
MAH	Marketing Authorisation Holder
NMVS	National Medicines Verification System
NMVS Alerts	Name of the alert management system currently in use by IMVO
Operation code (Op code)	The code corresponding to the response from the IMVS for any given transaction/operation
Product code (PC)	The 14-digit code on a medicinal product pack that uniquely identifies the product (also known as a GTIN 'Global Trade Item Number')
PSI	Pharmaceutical Society of Ireland
Serial number	An alphanumeric code used for uniquely identifying a pack within a specified batch

Level 1-5 classification of alerts and exceptions

- Different levels of exceptions or deviations arise in IMVS depending on the situation that has occurred
- Exceptions are classified as Level 1 to 5 :
  - **L1:** System repairs deviation itself; end-user is not notified
  - **L2**: ***End-user alone*** is notified of the exception
  - **L3**: The system administrator (**IMVO**) is also notified
  - **L4**: More than one system administrator are also notified (**IMVO + EMVO**)
  - **L5**: System administrators, OBP(MAH) and HPRA are all informed as well as end-user. This exception is referred to as an **'alert'** (i.e. unique Alert ID generated) and represents a potential falsified medicine

Accessing information with Operation code:



1 – Visit IMVO.ie

2 – Select Help from the main menu

3 – Select Operation code search from the side menu

Accessing information with Op code (ctd)

4 – Enter the Op code provided by the FMD Software on screen

5 - Interact with the options on screen

Summary of IMVO Alert Management Guidance

IMVO Alert Management Guidance

- Defines high level alert handling process for pharmacies, hospitals, wholesalers (end-users), MAHs and IMVO
  - Drawn up following consultation with stakeholders and HPRA and PSI and is aligned with EMVO best practice on alert handling
  - Key principle underpinning guidance is that alert does not mean that a pack is definitely falsified as alerts can arise due to technical, procedural or system issues
  - Objective is to ensure alerts are quickly investigated and closed out if a root cause is found, enabling pack to be supplied/returned to saleable stock as soon as possible
  - Summary of guidance is included in the back-up slides
- 'Alert help' pages on IMVO website, linked from your FMD software, are based on guidance and should be first point of reference when investigating alert as information provided is tailored to relevant alert type

Summary of alert management process

- The following slides summarise the alert management process set out in the guidance (see section 5 of guidance for details)

What's in/out of scope of the guidance?

- Guidance describes process for managing 'Level 5' alerts
- Following activities are out of scope of the guidance:
  - Investigation of alerts other than Level 5 alerts, e.g. 'Product not found'
  - HPRA processes
  - Alert prevention activities
  - Arrangements relating to credit/refund/replacement of packs that cannot be supplied to patients due to an unresolved alert – these matters are outside remit of IMVO, HPRA and PSI

Summary of how alerts are investigated

Type of alert	Example of error message on screen	Pharmacy or hospital	MAH
Pack data mismatch *There is a mismatch between the data scanned from the pack barcode and what is held in the IMVS database for that pack*	• Pack not found • Batch not found • Batch ID mismatch • Expiry data mismatch	Check for procedural error	Check for missing/incorrect data in IMVS
		Check if there is any information about the alert from IMVO or the MAH	Check for issue with IMVS/EMVS
		Check for scanner or software issue	Request photo of pack if no data or system issue or error on end-user side
		Seek external technical support from IT department/FMD software provider	Request pack for examination if no root cause if found by MAH or end-users
Pack state mismatch *The pack is not in the expected state (active/decommissioned etc.) and therefore a request to change its status cannot be completed*	• Pack is already in the requested state • Pack was already decommissioned in another location	Check for procedural error, e.g. double scan or borrowed pack already decommissioned	MAHs are not required to proactively investigate these alerts as they are typically due to issue on end-user side
		Check if there is any information about the alert from IMVO or the MAH *in NMVS Alerts*	

What happens if alert is not due to end-user scanner/software/procedural issue?

- You must withhold pack from saleable stock (i.e. quarantine it) until:
  - MAH confirms they have identified root cause (e.g. data issue, system issue) & if possible fixed root cause (e.g. by uploading data) **or**
  - MAH requests pack to be returned for examination on basis that end-user error, data and system issues have been ruled out and they now need to analyse the pack. MAH will advise on how pack is to be returned
- HPRA has confirmed packs with alerts must be retained in location where they were scanned and not returned to the wholesaler as part of standard business returns