IRISH MEDICINES VERIFICATION ORGANISATION

Update webinar for Pharmacies & Hospitals

09 JUN 2022

Outline

- Housekeeping – ‘Mute’, Q&A
- Key updates
- Scanning & alerts
- Alert investigation
- Reminders
- Conclusion
- Q&A

Backup slides

- Lifecycle of a scan and ‘Alert help' pages
- *NMVS Alerts*
- Glossary
- Plan for ending ‘use and learn’ period of FMD in Ireland
- Level 1-5 classification of alerts and exceptions
- Accessing information with Op code
- Summary of IMVO Alert Management Guidance

Key updates

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  - the pack as flagged as expired, recalled, withdrawn, stolen or destroyed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

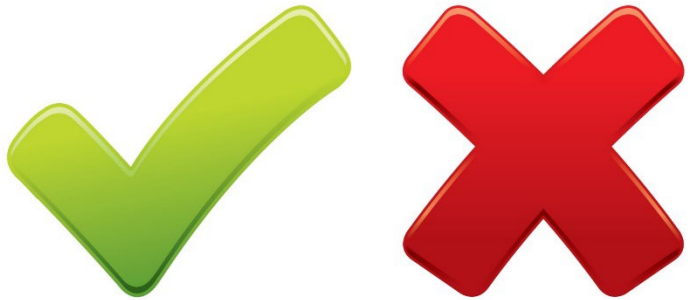
Utrogestan 100mg and 200mg Capsules

- Utrogestan 200mg Capsules molle orale ou vaginale (Batch Numbers 200261 and 202225)
- Utrogestan 100mg Capsules molle orale ou vaginale (Batch Numbers 214679 and 220486)

If pharmacies scan and receive alerts for these four Utrogestan batches, they may supply the packs to patients under their existing procedures, unless they have overriding concerns that a falsified medicine is involved.

If a pharmacist has reason to believe that the packaging has been interfered with, based on their examination of the anti-tamper device on the pack, they must report their concern to the HPRA (as a suspected quality defect via the usual reporting mechanisms) and not supply the pack.

Scanning & alerts



Scan responses and alerts

- When you verify or decommission a pack, your FMD software displays a response which contains text and is colour coded (**green**/**amber**/**red**) depending on the outcome of the scan
- **Amber** and **red** responses indicate there is some mismatch between the information from the scan and what is in the IMVS
- **Potential falsifications:**
  - Not all of the **red** or **amber** responses represent potential falsifications – only **Level 5 alerts** (see back-up slides for more details of level 1-5 classification system)
  - These alerts include the words 'An alert has been raised' and have a unique Alert ID e.g. IE-LJB-AGR-34G-R3A-VG3
  - Level 5 alerts are automatically notified to IMVO, MAH for the product and HPRA
  - Level 5 alerts must be investigated to rule out falsification

Examples of Level 5 alerts

Alert message	Likely root cause*	What to do next?

Batch not found	• Scanner or software issue
	• Data not uploaded by MAH
		• Follow advice in IMVO 'Alert help' (linked from your FMD software)
		• If you can't identify a root cause:
		  • Set pack aside until you are informed of outcome of MAH's investigation
		  • Keep pack in pharmacy/ hospital until the MAH or HPRA advises you what to do next with it
		• Contact IMVO if you need any further assistance

Pack not found / serial number is unknown	• Scanner or software issue • Data not uploaded by MAH (least likely)	
Pack already decommissioned in another location	• Procedural error - decommissioned pack received from another pharmacy or wholesaler	
Pack already decommissioned (bulk/split pack)	• Procedural error (most likely) • Scanner or software issue	
Batch ID mismatch	• Scanner or software issue	

Examples of non-Level 5 exceptions

Alert message	Likely root cause	What to do next?
Product code not known	Barcode on non-FMD pack was scanned, e.g. medical device, OTC, ULM from outside EU	• Follow advice in IMVO 'Alert help' (linked from your FMD software) • Contact IMVO if you need any further assistance
Batch is recalled	Pack has been recalled	
Pack cannot be reactivated – time limit exceeded	More than 10 days have elapsed since pack was decommissioned in your pharmacy	
Pack cannot be reactivated as it was decommissioned in another location	The pack was decommissioned before you received it	

‘Product code not known’ alerts

- If you get a 'Product code not known' alert, 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

- Scanning 2D barcodes on medical devices and OTC packs will always generate ‘product code not known’ alerts, as will scanning linear barcodes and QR codes, so your FMD procedures should include steps to avoid such problems.

Alert Investigation

How are alerts investigated?

- 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

** MAHs 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

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.

Reminders

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 …

Operating after end of use and learn

- **Make sure your pharmacy team (including locums) are aware** of the end of use and learn and are trained on what is involved
- **Intensify efforts to prevent alerts** due to software, scanners, procedural errors
  - Make sure your scanner is working (guidance is available on IMVO website)
  - Watch out for software issues or upgrades
  - Look for patterns of double-decommission alerts – are these occurring due to repeated scanning by your own team or from packs borrowed from other pharmacies/ hospitals?

Operating after end of use and learn (ctd)

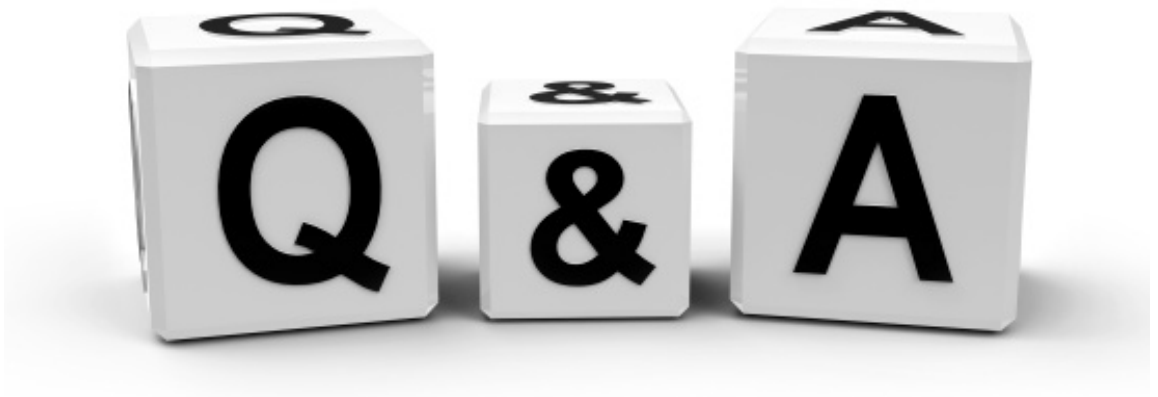
- Become familiar with ***NMVS Alerts*** and give us feedback on your alert investigations
- **Contact us if you need help** with anything or have any questions
- Please provide us with your **preferred email address** for alert communications – ideally a generic one
- All **feedback** on how we can improve the process is very welcome!

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
- 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
- **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
  - 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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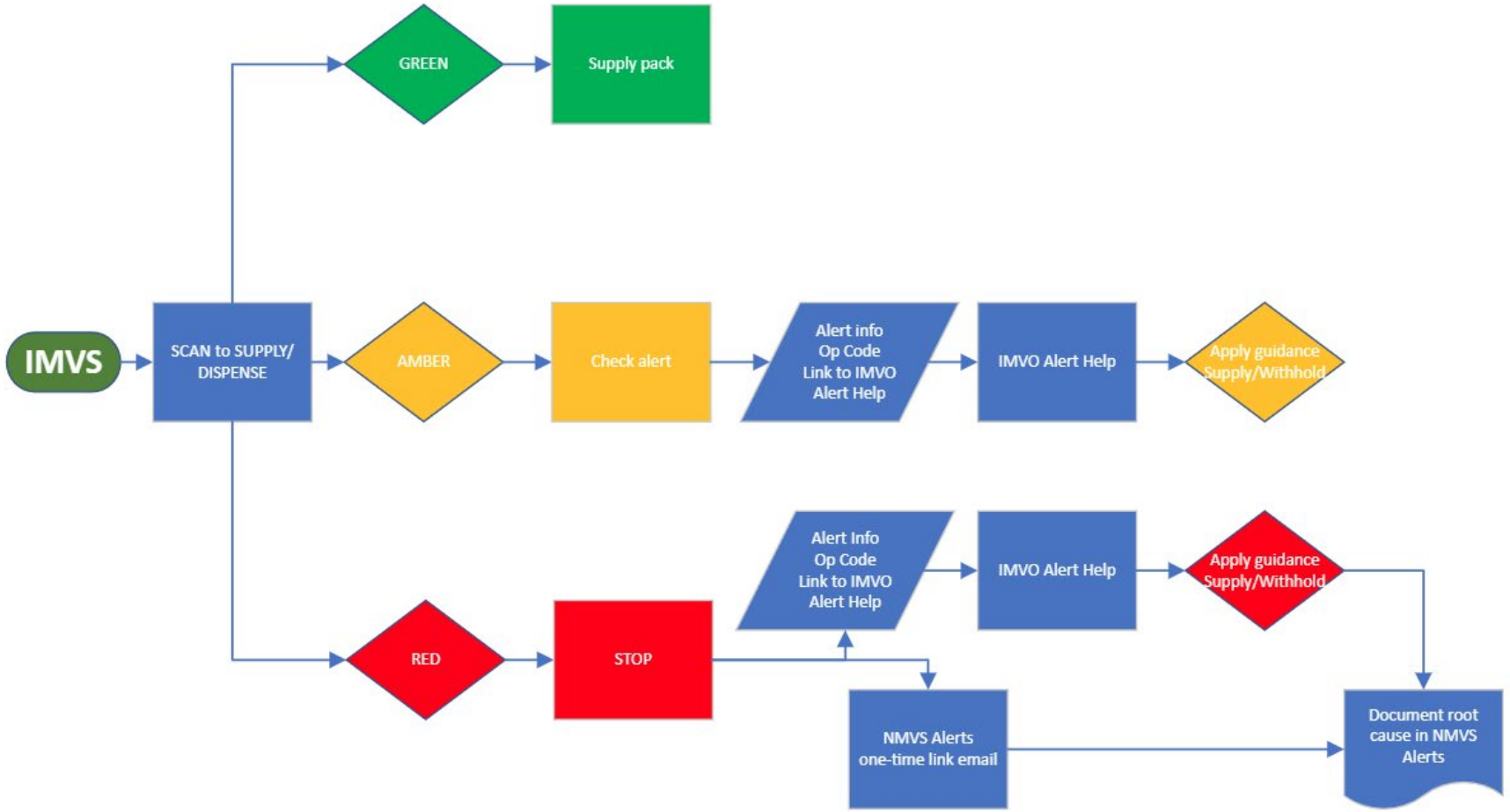
BACKUP SLIDES

Lifecycle of a scan



Walk through of alert:

‘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

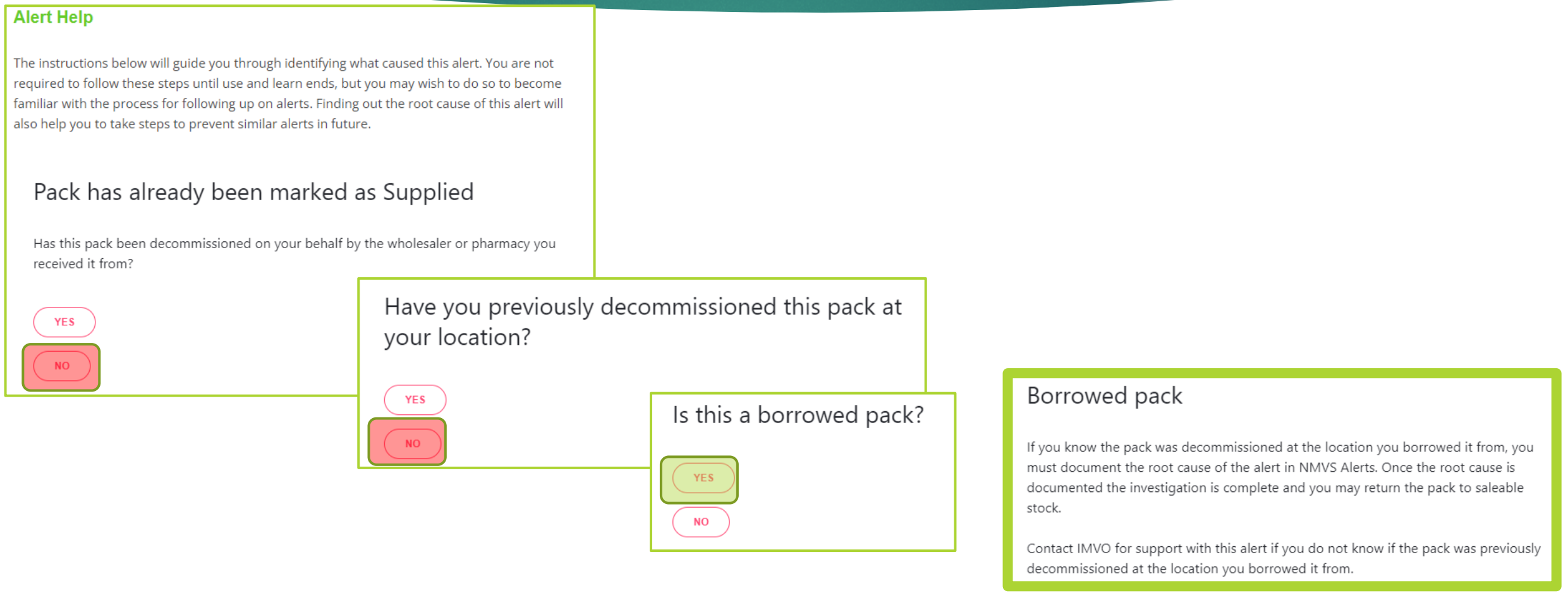
NO

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



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.

Communications during alert investigations

- After use and learn ends on 30 May, you will not be able to supply a pack with a Level 5 alert unless it has been fully investigated and a root cause has been found and falsification ruled out
  - If you find a root cause, the MAH needs to be made aware of this so they can stop looking for a data or IMVS issue
  - If you can't find a root cause in the pharmacy or hospital, you will need to know what the outcome of the MAH's investigation is
- If your investigation and that of MAH do not reveal a root cause for the alert, the MAH may want to request a photo of the pack from you and will give you feedback on their findings
- If the photo of the pack is not sufficient to confirm the pack is genuine, the MAH will ask for the pack to be returned for examination and needs to tell you how to do this

Communications during alert investigations (ctd)

NMVS Alerts

- *NMVS Alerts* is name of alert management system being rolled out by IMVO
- IMVO Alert Management Guidance strongly recommends use of *NMVS Alerts* by all parties involved in an alert – end-user, MAH, IMVO – as this will greatly simplify handling of alerts for all parties and speed up resolution, minimising impact on patient supply

Email/phone

- In the event that a pharmacy chooses not to use *NMVS Alerts*, communications will have to take place with other parties by email or phone. This is not recommended, as it will significantly slow the speed of investigation in those cases
- In this situation, IMVO will act as 'postman' between MAH and end-user for email communications to maintain end-user anonymity


nmvsalerts

NMVS Alerts

- Collaborative web-based tool available 24/7 which provides overview of status of alerts based on information entered by the end-user, MAH and/or IMVO
- 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 (e.g. 'our scanner wasn't working'; 'we accidentally decommissioned the pack several times')

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

Alert status change Inbox ×

IMVO info@imvo.ie via sendgrid.net
to me

nmvs alerts

FMD Alert Management -
The efficient solution for Europe

Dear user,

IMVO has new alert information for alert:
IE-PP4-46Q-4A7-S4C-33D

The message from the NMVO is:
Please investigate this alert.

You can see alert details and mark appropriate actions by clicking the following temporary link:

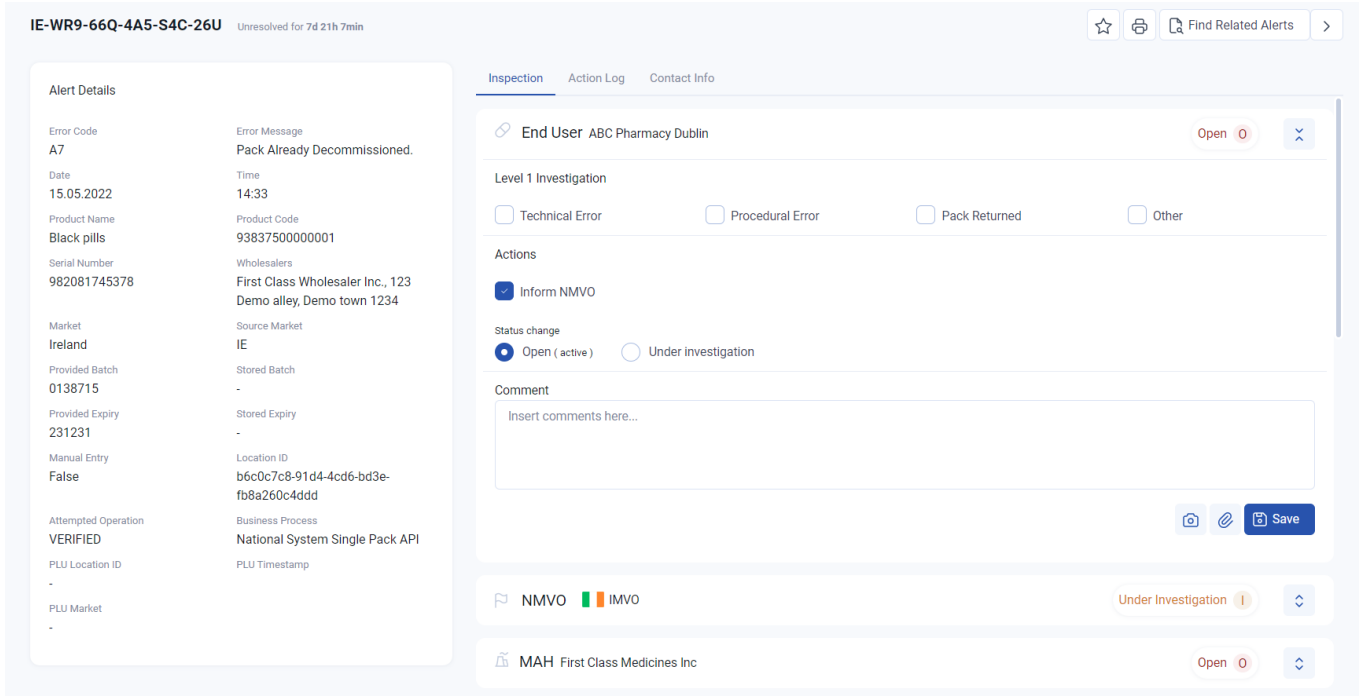
Click here!

Please note: by clicking the temporary link you accept the Terms & Conditions.

For reviewing other alerts in ABC Pharmacy Dublin you can login to the NMVS Alerts portal.

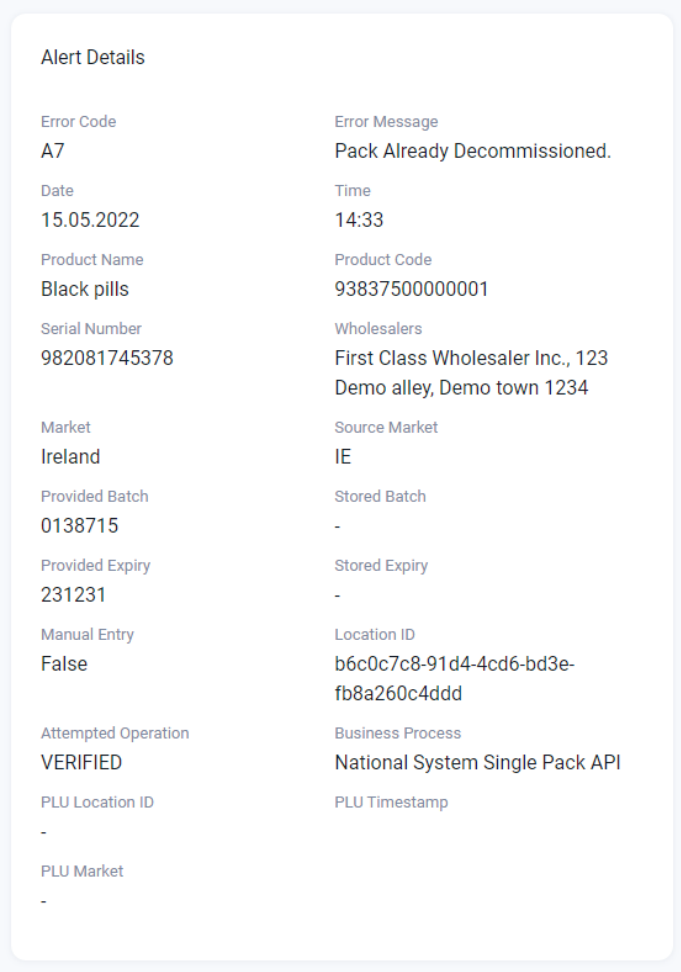
In case of questions or problems please contact our support at support@nmvs-alerts.com.

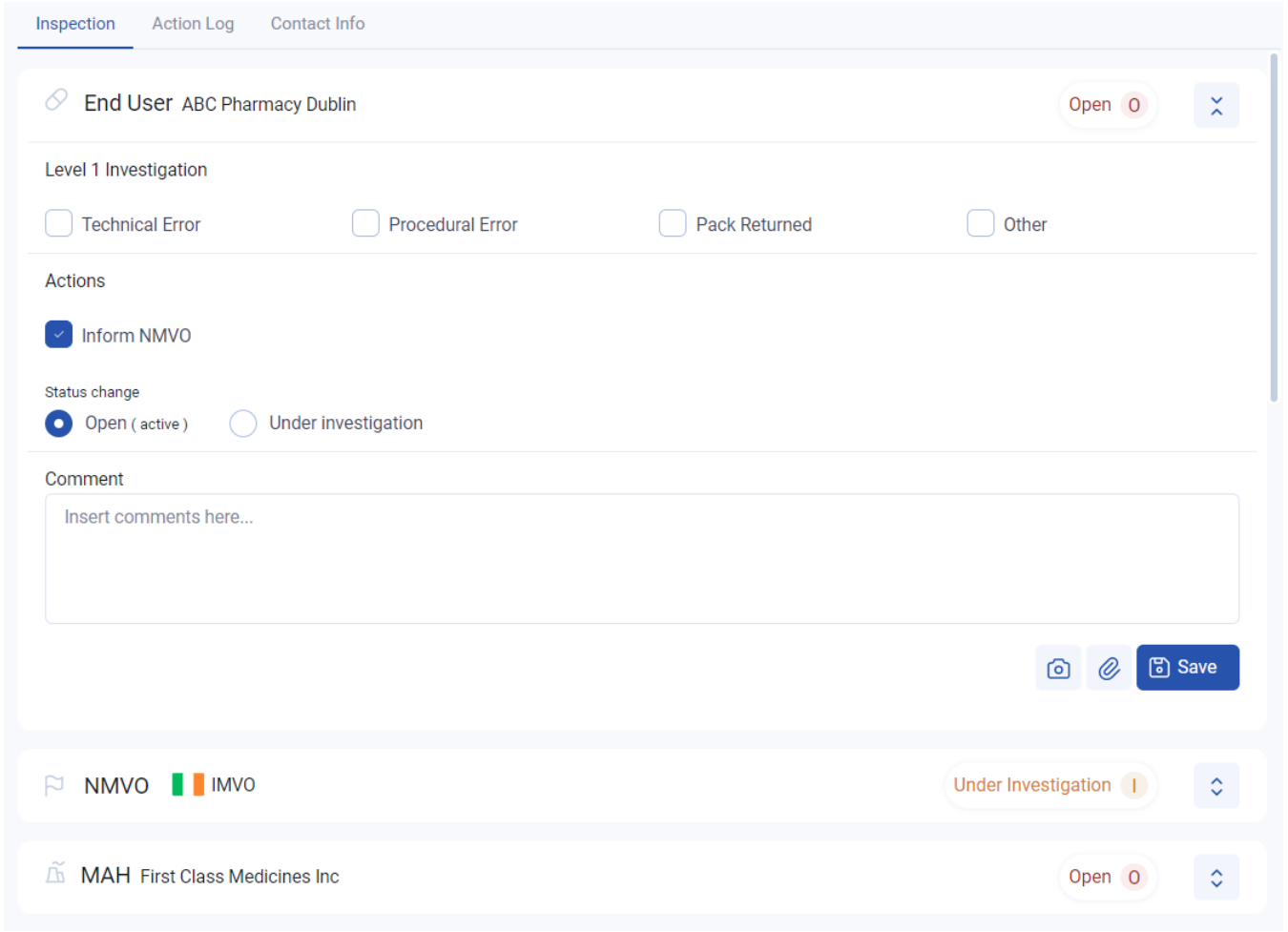
Your IMVO Team



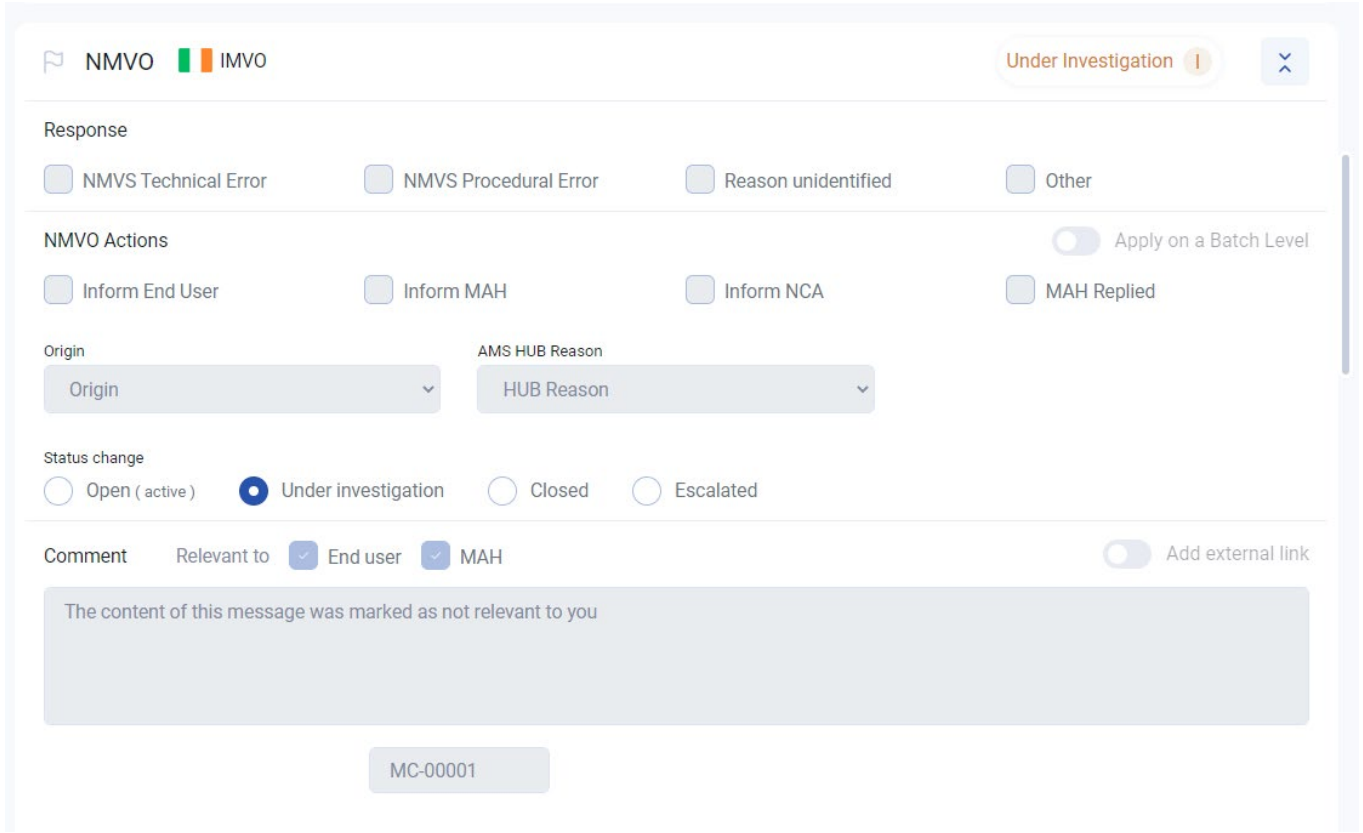
End-user section in NMVS Alerts

End-user section in NMVS Alerts

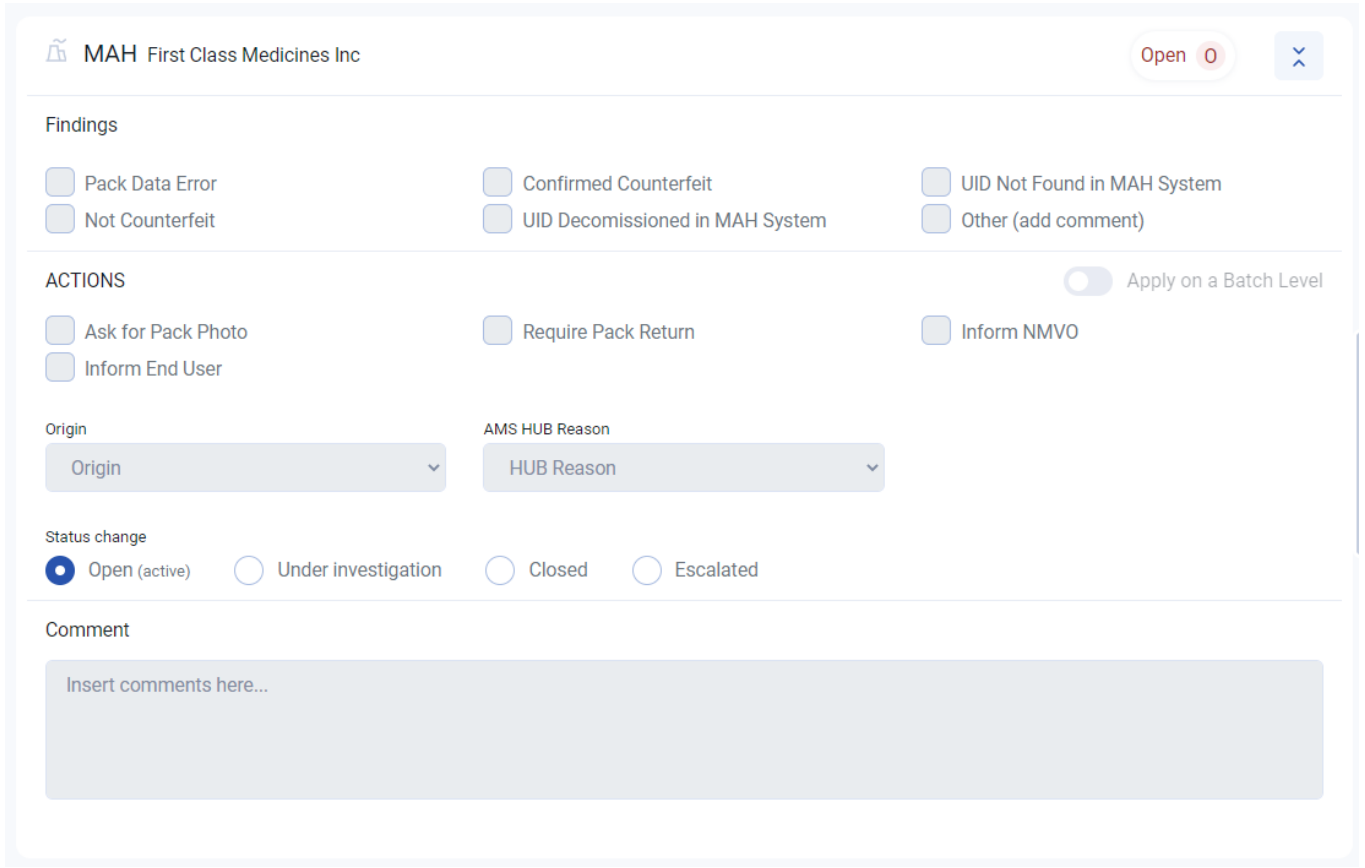




End-user section in NMVS Alerts



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



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

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

Plan for ending ‘use and learn’ period of FMD in Ireland

Plan for ending use and learn

Timing	Phase	Details	Impacted Stakeholders			Notes
			Primary wholesalers	All wholesalers	Pharmacies & hospitals	
Q3 2021	**Phase 1** *Primary wholesalers scan packs at goods inwards*	Primary wholesalers to scan sample of packs at goods inwards and quarantine them if there are alerts due to data issues, until these issues have been resolved by MAHs	✓			• Complete • Many primary wholesalers continuing this on voluntary basis • Packs received <u>prior</u> to batch release and upload of data to IMVS, generate alerts if scanned at goods inwards – ask MAHs to advise you if they are sending packs for which data is not yet uploaded

Plan for ending use and learn (ctd)

Timing	Phase	Details	Impacted Stakeholders			Notes
			Primary wholesalers	All wholesalers	Pharmacies & hospitals	
1st Sep 2021	**Phase 2** *RAG changes for wholesalers*	Wholesaler FMD software to display red/amber/green (RAG) colour coded responses (depending on outcome when pack is scanned) most systems are showing green responses for all scans, regardless of whether there is an alert		✓		• Completed

Plan for ending use and learn (ctd)

Timing	Phase	Details	Impacted Stakeholders			Notes
			Primary wholesalers	All wholesalers	Pharmacies & hospitals	
28th Feb 2022	**Phase 3** *Use & learn ends for returns to wholesalers*	All alerts generated when scanning returned packs must be investigated, and suspected falsification ruled out		✓	✓	• Completed

Plan for ending use and learn (ctd)

Timing	Phase	Details	Impacted Stakeholders			Notes
			Primary wholesalers	All wholesalers	Pharmacies & hospitals	
28th Feb 2022	**Phase 4** *RAG changes for pharmacies & hospitals*	Pharmacy and hospital FMD software to display red/amber/green (RAG) colour coded responses, depending on outcome when pack is scanned – currently most systems are showing green responses for all scans, regardless of whether there is an alert.			✓	• Completed

Plan for ending use and learn (ctd)

Timing	Phase	Details	Impacted Stakeholders			Notes
			Primary wholesalers	All wholesalers	Pharmacies & hospitals	
14th Mar 2022	**Phase 5** *Pilot of alert handling procedures with pharmacies, hospitals and wholesalers*	Pilot of alert handling process. All alerts generated as a result of scanning activity to be investigated but it is not necessary to withhold packs from supply until the alert is resolved.		✓	✓	• The pilot will be managed by IMVO and start with a small number of participants and build from there

Plan for ending use and learn (ctd)

Timing	Phase	Details	Impacted Stakeholders			Notes
			Primary wholesalers	All wholesalers	Pharmacies & hospitals	
9th May 2022	**Phase 6** *Use & learn ends for wholesalers for all remaining activities*	All alerts generated by wholesalers must be investigated, and suspected falsification ruled out, before the relevant packs may be returned to saleable stock or supplied		✓		

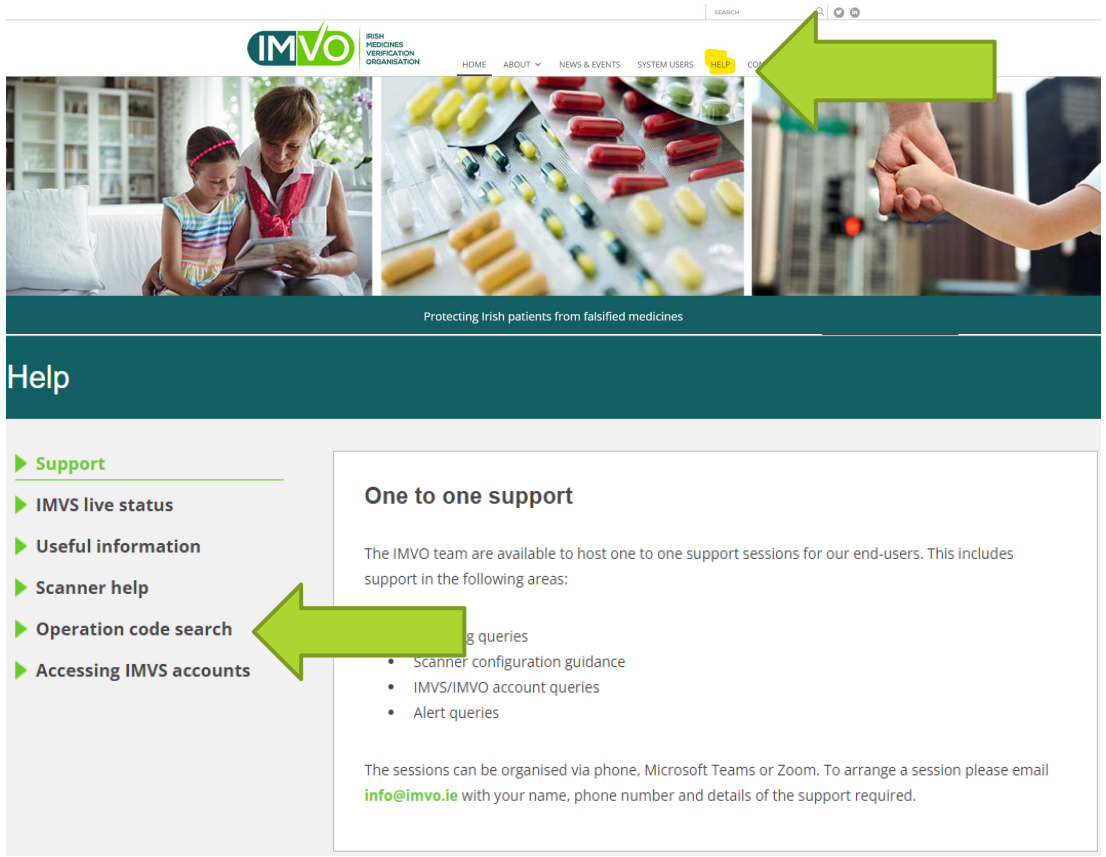
Plan for ending use and learn (ctd)

Timing	Phase	Details	Impacted Stakeholders			Notes
			Primary wholesalers	All wholesalers	Pharmacies & hospitals	
30th May 2022	**Phase 7** *End of use & learn for pharmacies and hospitals*	All alerts generated by pharmacies and hospitals must be investigated, and suspected falsification ruled out, before the relevant packs may be supplied			✓	

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