IRISH MEDICINES VERIFICATION ORGANISATION

Webinar for Wholesalers

12 OCTOBER 2022

Outline

- Housekeeping – Q&A, recording
- Progress since end of ‘use and learn’
- Alert causes in wholesalers
- Management of alerts
- *NMVS Alerts*
- Brexit/small market issues
- IMVS updates
- The ‘ask of wholesalers’
- Q&A

Backup slides

- Glossary
- Level 1-5 classification of alerts and exceptions
- Accessing information with ‘Op code’

Progress since ‘Use and Learn’ ended

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

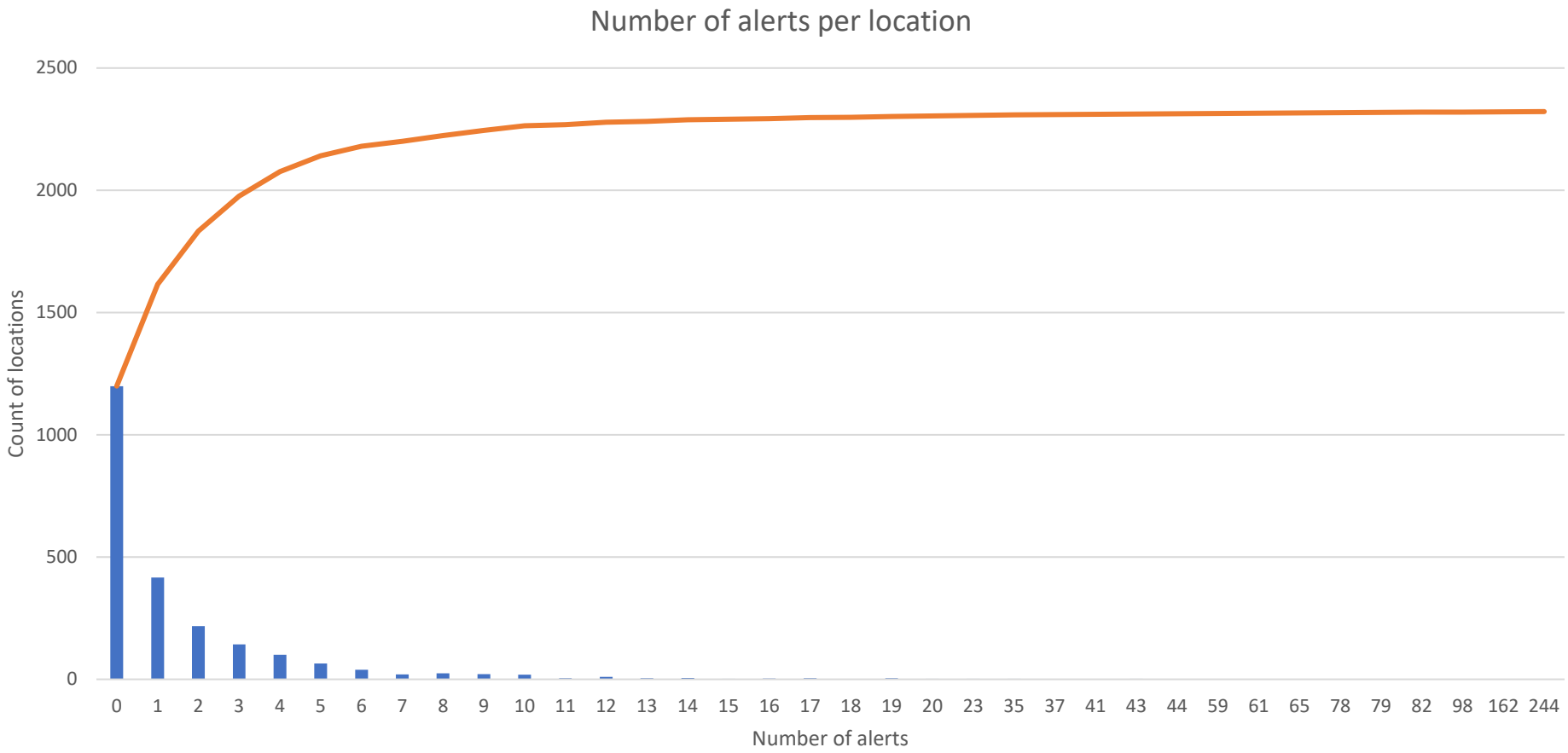
** Pharmacies, hospitals and wholesalers*

Scan rates Jan – Sep 2022

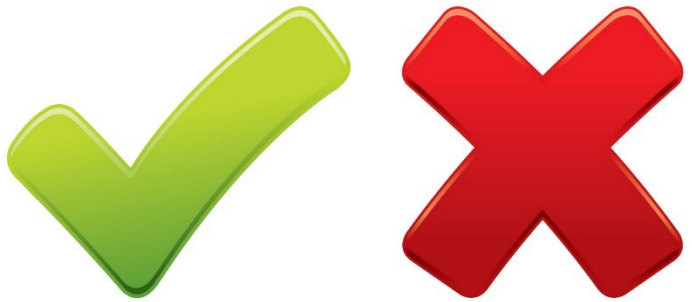
How often did end-users get alerts during September 2022?

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

How often did end-users get alerts in during September 2022?



Alert causes in wholesalers



Alerts generated by wholesalers

Alert description	Most common cause of alert at wholesaler level
Batch not found	Batch not yet released by MAH (shipped under quarantine) and as such data not yet uploaded to IMVS. Data was not uploaded to IMVS by MAH in error
Pack/serial no. not found	Data upload error (relatively uncommon alert at wholesaler level)
Pack already in requested state	Procedural error
Status change could not be performed	Procedural error
Expiry date mismatch	Scanner/software issue
Batch mismatch	Scanner issue

Wholesaler-generated alerts in pharmacies and hospitals

Aggregation service offered by wholesalers to hospitals

- Aggregation barcode must match delivered packs
- Deviations cause alerts in other locations who receive physical packs

Returns

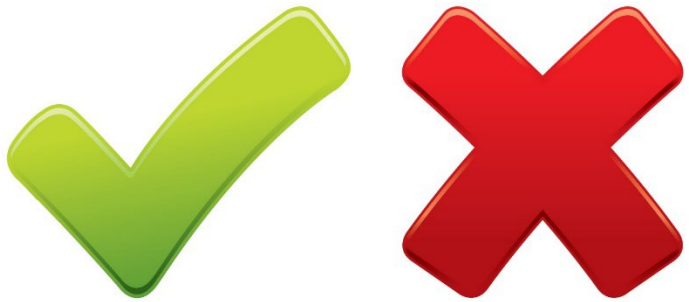
- Packs returned to a wholesaler in a decommissioned state must not be returned to saleable stock, otherwise causes alerts when scanned and complex alert investigation

Wholesaler-generated alerts in pharmacies and hospitals (ctd)

Article 23 decommissioning (as supplied/dispensed)

- You must ensure that the customer meets the Article 23 criteria and does not intend to scan packs themselves
  - Hospitals and community pharmacies cannot be designated as Article 23 locations
- The HSE maintains a list of HSE Article 23 locations – contact the HSE FMD project team if you have any doubt whether a HSE site is to be treated as an Article 23 location

Management of alerts



How are alerts investigated by end-users?

- End-users and MAH* initiate simultaneous investigation of alerts generated in the pharmacy, hospital or wholesaler site
- The end-user 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

Extra steps for wholesalers

- Alerts generated by wholesalers should be managed as part of your quality management system
- In addition to using *NMVS Alerts* to communicate the outcome of your alert investigation to all relevant parties, follow any alert notification procedures in technical agreements that you may have with MAHs
- You may be contacted by a pharmacy, hospital or other party about a pack you supplied to them which generated an alert when scanned. The action to be taken varies depending on what type of alert is involved:
  - If the alert is due to the fact that the pack was already decommissioned, you should investigate if the alert has arisen because of an error on your part while the pack was in your possession, e.g., pack decommissioned as supplied or destroyed in error
  - For all other alerts, refer the person contacting you to IMVO for further assistance

Verifying packs at goods inwards

- Scanning of sample of packs received by primary distributors at goods inwards is extremely helpful
- Advice given to **MAHs** by IMVO relating to this scanning:
  - *Check that data has been uploaded correctly and on time, by scanning one pack per batch before releasing batches to supply chain (or ask your primary wholesaler to do this for you)*
  - *If you send packs to your primary wholesaler prior to batch release and data upload, please inform them data is not uploaded*
  - *If receiving large numbers of alerts on batches that you have uploaded to IMVS, ask us to check if the batch is visible to us - sometimes data does not get to IMVS from EU Hub and needs to be re-uploaded*


nmvsalerts

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

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*.

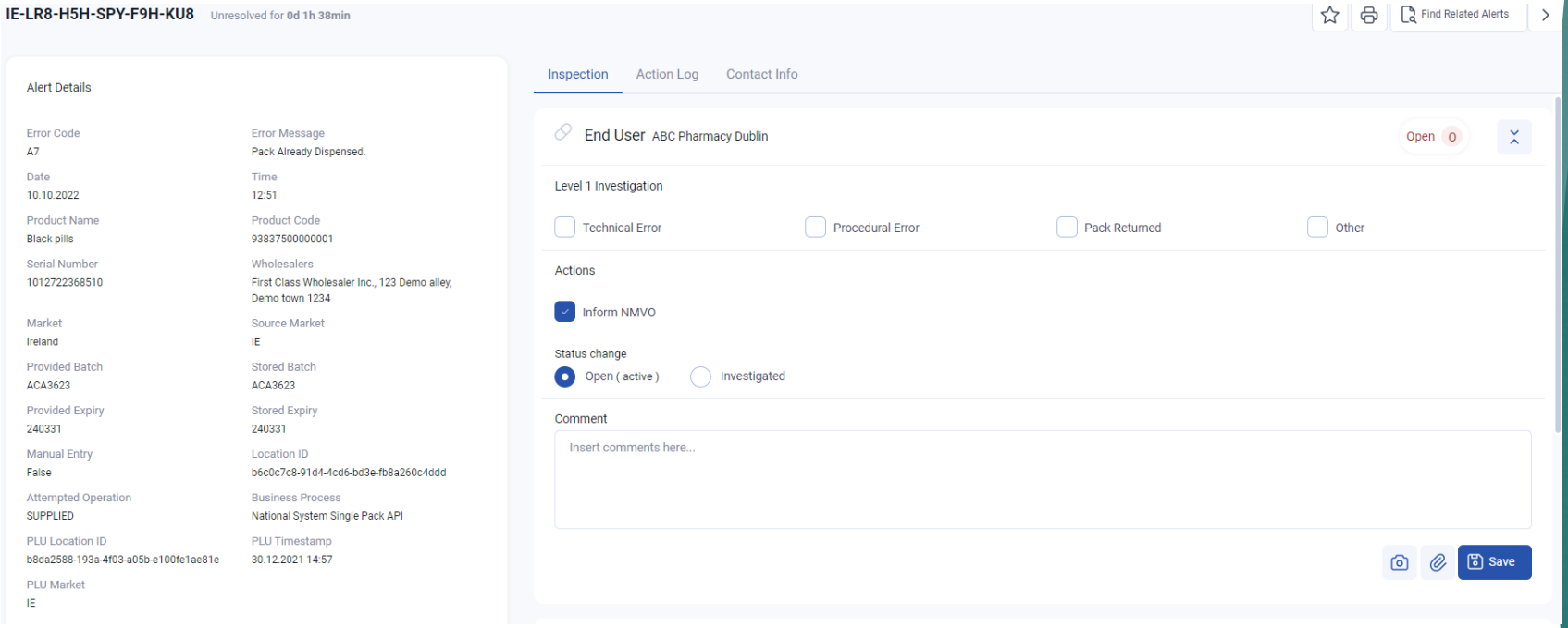
If you have an NMVS Alerts account, you can log on to the *NMVS Alerts system* to view all FMD alerts in ABC Pharmacy Dublin.

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 sent to you after alert is generated



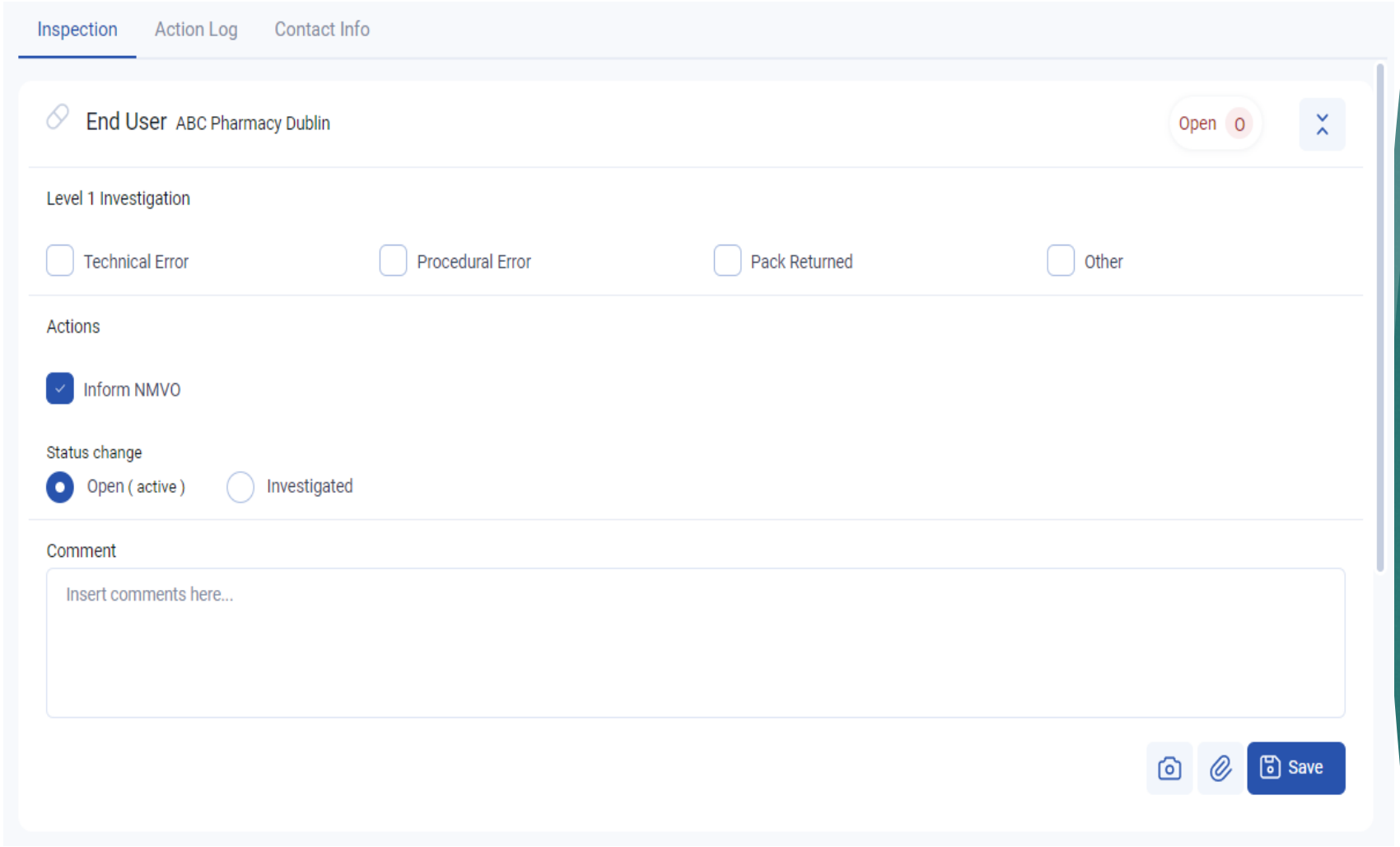
End-user section in NMVS Alerts

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

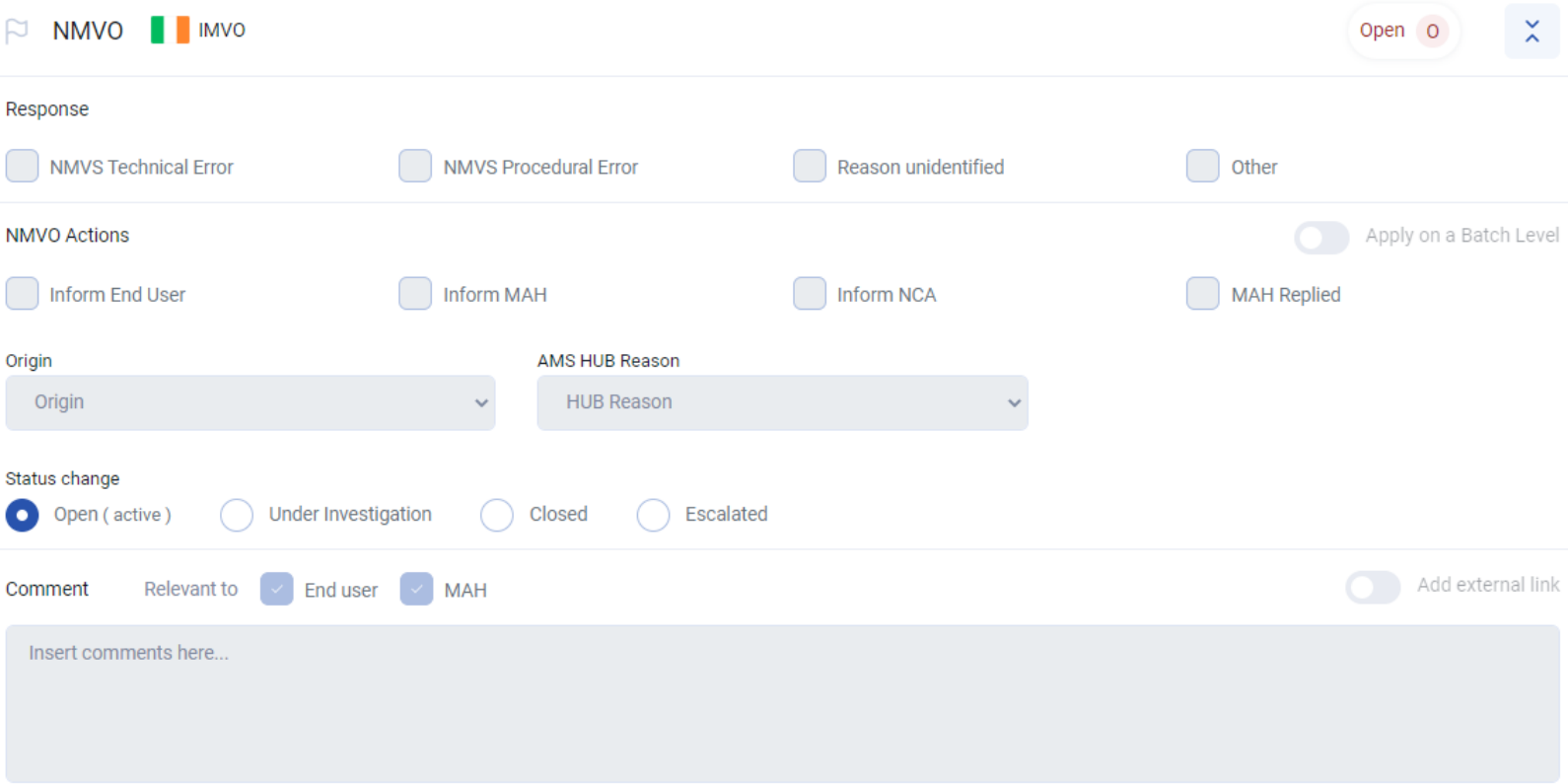
Alert Details

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	

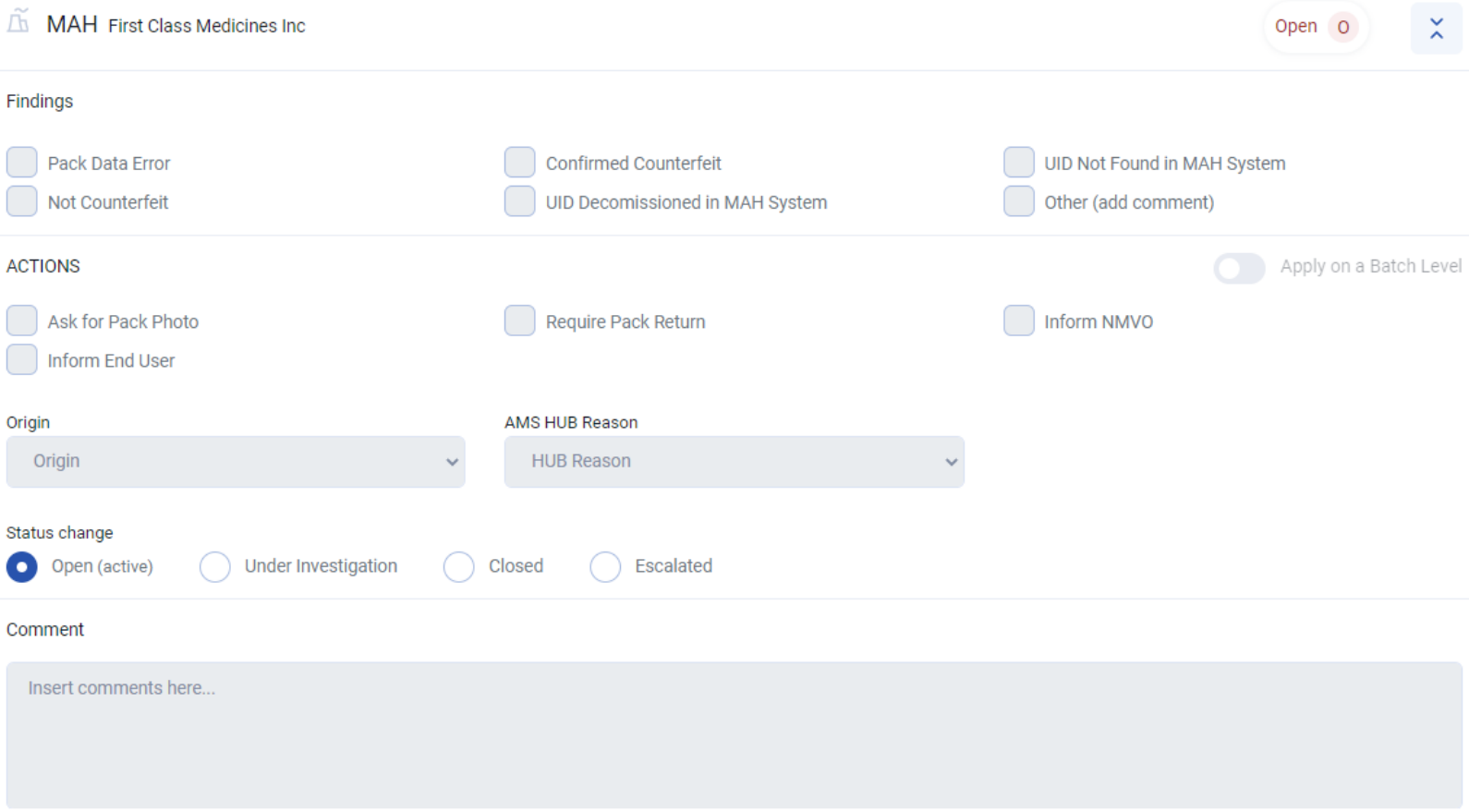
End-user section in NMVS Alerts



End-user section in NMVS Alerts



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



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

Brexit / small market issues

Small market issues

- Ireland as a small market **proportionally more medicine shortages and sourcing of packs from other markets** - significant impact from FMD perspective:
  - More intermarket transactions (IMTs) – problems arise if EU Hub or fulfilling national market is temporarily unavailable
  - Flexible regulatory arrangements may be in place to ensure availability of medicines, e.g.
    - Packs sourced as exempt medicinal products ('unlicensed medicines'/'ULMs')
    - Batch specific requests (BSRs) granted by HPRA to MAH to bring in packs from other markets
- **Higher risk of alerts** with these packs, leading to 'noise'/ confusion for end-users

Brexit

- **Monitoring impact of Brexit** from FMD perspective ongoing priority for IMVO
- **High reliance on packs sourced from UK** to address medicines shortage issue now more challenging due to Brexit, esp. when they are serialised and data hasn't been uploaded

IMVS updates

Information on IMVS live status

- Real-time status of Solidsoft national systems, including IMVS, available at: https://status.nmvo.eu/
- We will also notify you of downtime during new release deployments

IMVS Release 11

- The IMVS will be upgraded on Sunday 16th October to Release 11
- The deployment is planned to start at 21.00 Irish time
- This will require a system outage of between 3 and 6 hours

The ‘ask’ of wholesalers

What you can do?

- **Ensure that returned packs that are already decommissioned are <u>not</u> returned to saleable stock**, to prevent avoidable alerts for the next customer who receives them
- **Keep working on minimising alerts** due to software, scanners, procedural errors
  - Make sure faulty scanners are dealt with quickly
  - Watch out for software issues, especially after any software/hardware upgrade
  - Analyse transactions that lead to multiple alerts, e.g. duplicate decommissioning, and implement CAPAs to prevent recurrence
- Give us **feedback on your alert investigations as quickly as possible**, via *NMVS Alerts*
- Let us know if you become aware of **particular exempt medicinal products or BSR packs causing many alerts / unexpected alerts**

What you can do? (ctd)

- **Contact us if you need help** with anything or have any questions – our service desk is open at the following times:

  Monday-Friday: 08.00-20.00

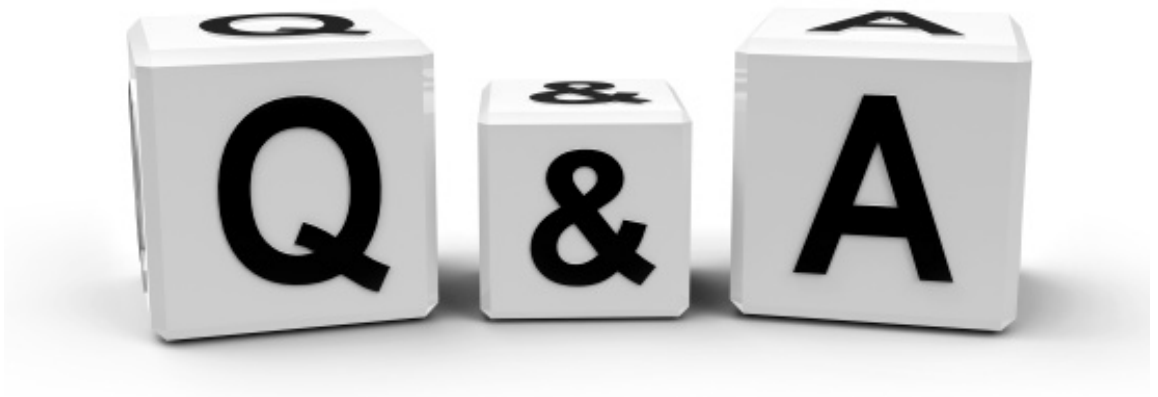
  Saturday: 09.00-18.00

  Sunday/public holidays: 11.00-18.00

- All **feedback** on how we can improve our service to you is very welcome!

For more information …

- **IMVO** www.imvo.ie
  - All alert 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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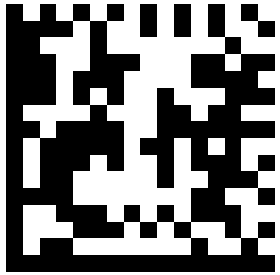

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BACKUP SLIDES

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

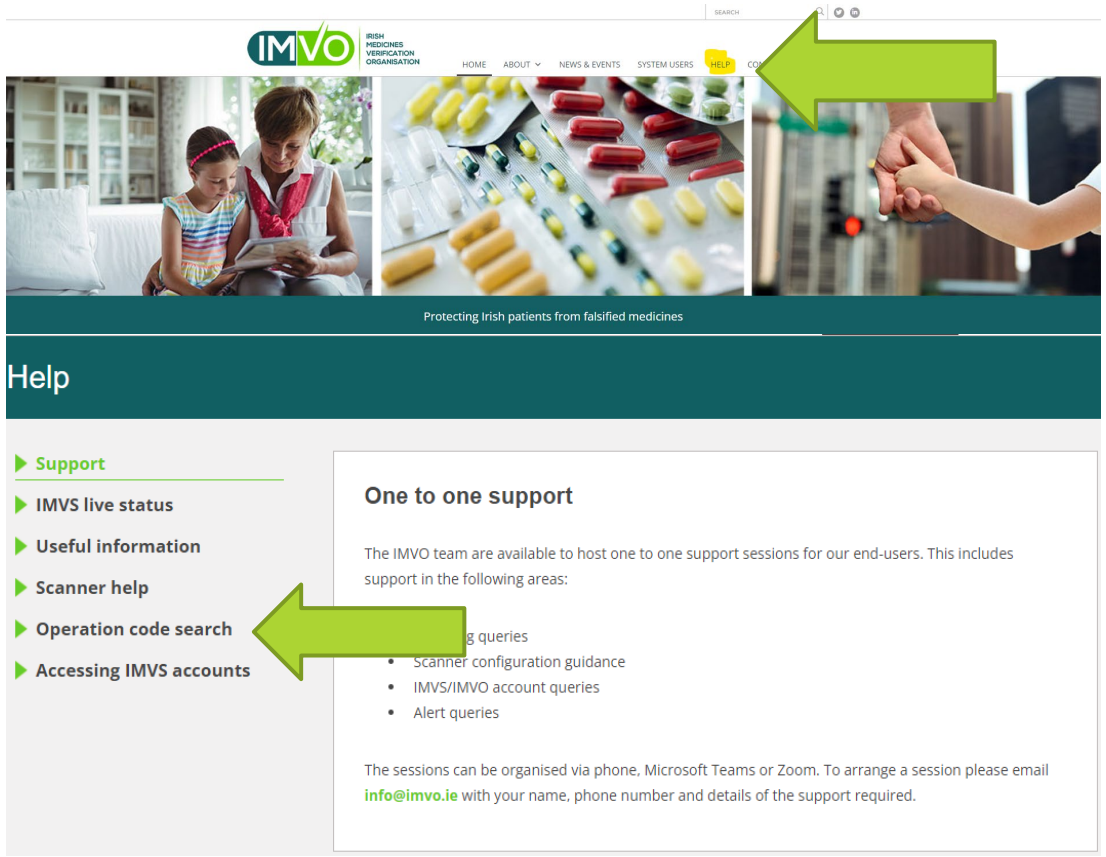
Level 1-5 classification of alerts and exceptions

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 ‘Alert help’ pages on www.imvo.ie with Op code

Accessing information with Op 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