IRISH MEDICINES VERIFICATION ORGANISATION

End of ‘use and learn’: Webinar for wholesalers

28 APRIL 2022

Outline

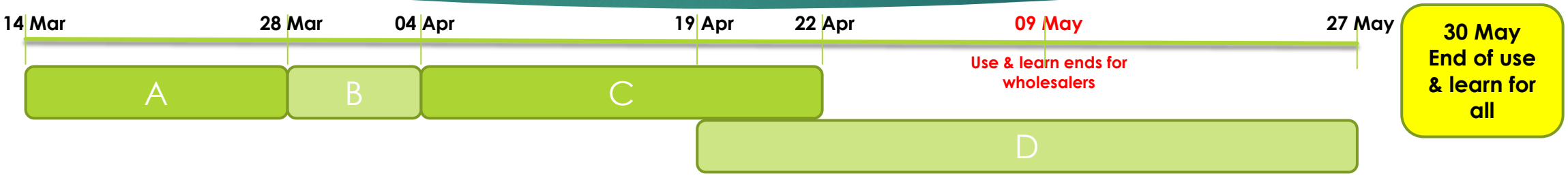
- Housekeeping – 'Mute', Q&A, recording
- End of 'use and learn' for wholesalers
- Summary of IMVO Alert Management Guidance
- Scanning & alerts
- *NMVS Alerts*
- Miscellaneous
- The 'ask of wholesalers'
- Brexit
- Q&A

Backup slides

- 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

End of ‘use and learn’

End of ‘use and learn’ timeline



Date	Phase	Details
14 Mar – 27 Mar	Phase 5/A **‘Prepare’**	• Recruit initial small pool of pilot participants • Finalise Alert Management Guidance

28 Mar – 03 Apr	Phase 5/B
	‘Inform’
		• Prepare and support pilot participants
		  • Alert Management Guidance
		  • NMVS Alerts Training

04 Apr – 22 Apr	Phase 5/C **‘Go Live’**	• Initial pilot with small pool of participants from MAHs, wholesalers, hospitals and pharmacies
19 Apr – 27 May	Phase 5/D **‘Expand’**	• All MAHs, hospitals and pharmacies invited to join pilot • Pre pilot Information & support to all participants in the full pilot • Full pilot participation and live support offered to all MAHs, hospitals and pharmacies
09 May	**‘Use and learn’ ends for wholesalers**	• ‘Use and learn’ phase for FMD in Ireland will end for wholesalers for all remaining activities

Summary of IMVO Alert Management Guidance

What is the 'IMVO Alert Management Guidance'?

- IMVO Alert Management Guidance ('the guidance') describes overall framework for alert investigation, covering all types of Level 5 alerts whether generated by end-user or MAH transactions
  - Includes step-by-step process flows for end-users (pharmacies, hospitals, wholesalers), MAHs and IMVO
  - Provides basis for the on-screen 'Alert help' available from a link in the alert message in your FMD software. This should be your first point of reference when investigating an alert as the information provided is tailored to the relevant alert type
- The guidance was drawn up following consultation with stakeholders and HPRA and PSI
- Draft prepared for pilot will be refined as required based on experience gained during the pilot

Objectives of the guidance

- Define role of all parties in investigating alerts
- Ensure that alerts can be quickly investigated and closed out when a root cause is found, enabling the pack to be returned to saleable stock as soon as possible
- Describe process for escalation to HPRA as ‘confirmed falsification’ if no root cause can be found for the alert

What's out of scope of the guidance?

- Following activities are out of scope of the guidance:
  - Investigation of alerts other than Level 5 alerts, e.g. e.g. 'Product code unknown'
  - 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

How are alerts investigated?

- End-users (pharmacies, hospitals or wholesalers) and MAHs initiate simultaneous investigation of alerts generated at end-user locations
- End-users 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

How are alerts investigated? (ctd)

- **NB - MAHs not required to proactively investigate certain categories of alerts that are typically due to end-user error (A7/A24 – double decommission) or software problem (A68 – batch ID mismatch), unless asked to do so by IMVO or HPRA**
- For other alerts, MAHs look for data issues (e.g. missing data) and issues with EMVS
- MAHs must also investigate alerts generated from their own transactions (note – end-users never see these alerts)
- 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 alert to be investigated, matter is escalated to relevant NCA

How will you know what issue is?

- Depending on which FMD software you are using, it may be programmed to provide links from alert message to 'alert help' page on IMVO website to assist end-users in identifying a root cause for an alert, if they can fix it and how to do this, e.g. scanner check and re-configuration
  - Advice is linked with operation codes ('Op codes') returned for different types of responses generated when a pack is scanned. The advice for each Op code can also be looked up directly on the IMVO website – see back-up slides for details of how to do this
- IMVO monitors IMVS for large numbers of alerts, unusual patterns of alerts by product, batch or end-user, and contacts end-user or MAH or FMD software provider 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

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

- End-user 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

  - 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 the location where they were scanned, and in the case of pharmacies and hospitals, not returned to the wholesaler as part of standard business returns

MAH investigation

- If the alert is generated during an MAH transaction via EU Hub (e.g. packs accidently decommissioned as 'locked' twice), MAH investigates and advises IMVO of outcome
- In case of alert generated on a pack in end-user location, MAH checks if the alert is due to a data issue and if so, corrects it
- MAH may request a photo of the pack from end-user if there is no obvious root cause – often photo is enough to confirm pack is genuine or alternatively that packaging is falsified.
- If there is no data issue, MAH checks if there is a problem with the EU Hub that may have caused the alert
- MAH is required to provide feedback on their investigation to NMVO within 2 working days (and they will inform end-user)
  - In practice, issues such as missing data are identified and fixed straightaway by uploading the data
  - More complex problems may take longer to resolve but MAH must provide regular updates

MAH investigation (ctd)

- If data, procedural and technical issues have been ruled out, the pack is considered a **suspected falsification**
- MAH requests pack to be returned for examination and advises end-user how this is to be done
- If MAH cannot confirm that the pack is genuine from their examination of the pack, it is considered a **confirmed falsification** and HPRA, IMVO etc. are informed
- **Note:** MAH may also be able to identify the pack as a confirmed falsification when they review photo of the pack. In this case, the MAH should also request that the pack be returned to them

Communications during alert investigations

Alert management system

- *NMVS Alerts* is the name of the alert management system being rolled out by IMVO – guidance describes in section 3 how it supports alert investigations and communications
- 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

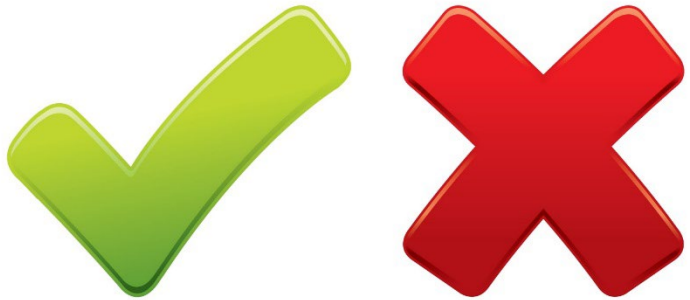
Email/phone

- In the event that an organisation 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

Extra steps in guidance 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 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

Scanning & alerts



Scan responses and alerts

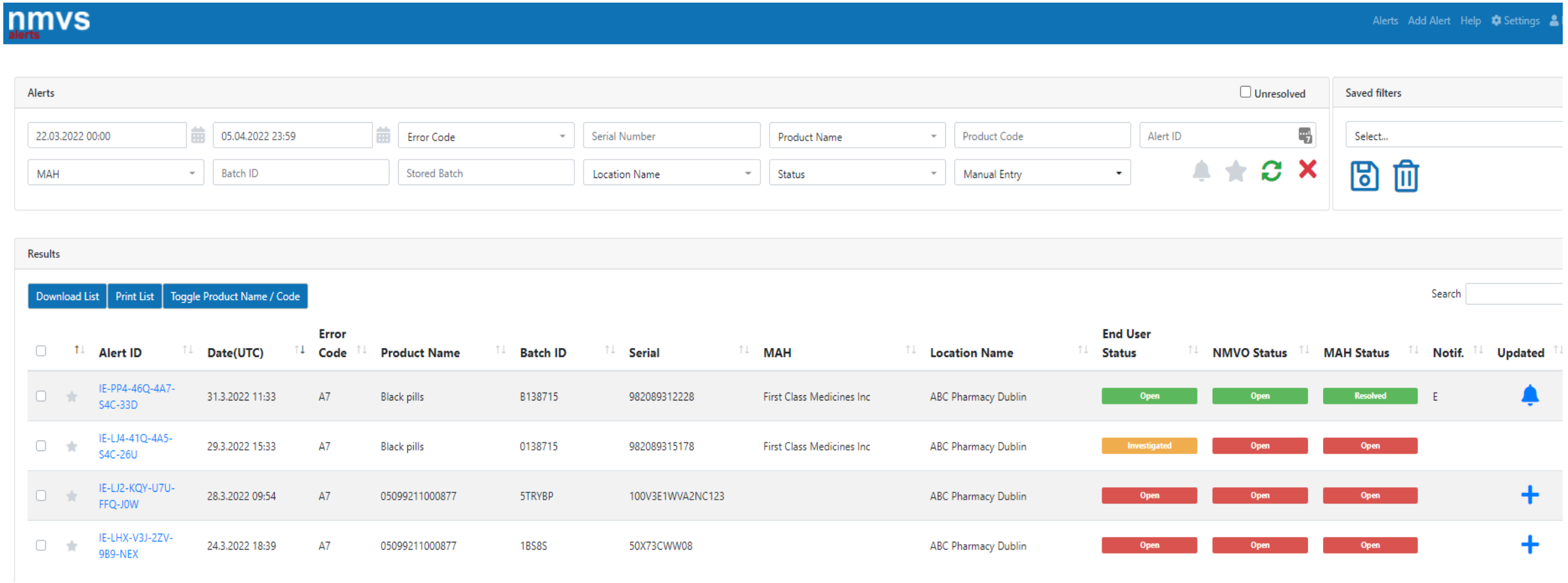
- See ‘IMVO Wholesaler Update February 2022’ for refresher on ‘Level 5’ alerts (potential falsifications) and non-Level 5 exceptions generated by IMVS
- When you verify or decommission a pack, your FMD software displays a response which contains text and which may be colour coded (red/amber/green) depending on the outcome of the scan (if you have chosen to implement IMVO’s RAG recommendations)
- Level 5 alerts are flagged as red, have a unique alert, are accompanied by an ‘alert has been raised’ message, are sent to the MAH and are recorded in *NMVS Alerts*
- Keep in mind non-Level 5 exceptions also need to be followed up on


nmvs
alerts

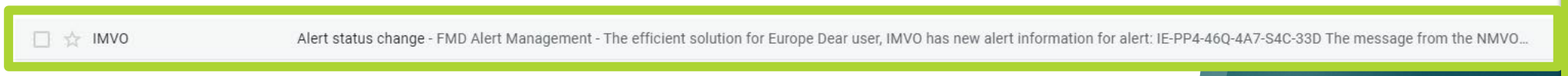
NMVS Alerts

- Please revisit slides and video recording from 'IMVO Wholesaler Webinar February 2022' for refresher on how to set up an account and use *NMVS Alerts*

NMVS Alerts



	Alert ID	Date(UTC)	Error Code	Product Name	Batch ID	Serial	MAH	Location Name	End User Status	NMVO Status	MAH Status	Notif.	Updated
☐ ☆	IE-PP4-46Q-4A7-S4C-33D	31.3.2022 11:33	A7	Black pills	B138715	982089312228	First Class Medicines Inc	ABC Pharmacy Dublin	Open	Open	Resolved	E	
☐ ☆	IE-LJ4-41Q-4A5-S4C-26U	29.3.2022 15:33	A7	Black pills	0138715	982089315178	First Class Medicines Inc	ABC Pharmacy Dublin	Investigated	Open	Open		
☐ ☆	IE-LJ2-KQY-U7U-FFQ-J0W	28.3.2022 09:54	A7	05099211000877	5TRYBP	100V3E1WVA2NC123		ABC Pharmacy Dublin	Open	Open	Open		
☐ ☆	IE-LHX-V3J-2ZV-9B9-NEX	24.3.2022 18:39	A7	05099211000877	1BS8S	50X73CWW08		ABC Pharmacy Dublin	Open	Open	Open		



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

TCK GmbH Frankfurter Str. 720-726, 51145 Köln, Germany support@nmvs-alerts.com www.nmvs-alerts.com

End-user documentation of root cause

← Back to List View

Next alert →

Alert Details ☆

7D 23H 59MIN

Alert ID	IE-LJ2-KQY-U7U-FFQ-J0W	**Error Code**	A7	**Market**	Ireland
Date/Time	28. 03. 2022 09:54	**Error Message**		**Source Market**	
Product Code	05099211000877	**Provided Batch**	5TRYBP	**Provided Expiry**	241031
Serial Number	100V3E1WVA2NC123	**Stored Batch**		**Stored Expiry**	
Manual Entry		**Location ID**	b6c0c7c8-91d4-4cd6-bd3e-fb8a260c4ddd		
Attempted Operation		**Business Process**			
Product Name					

Open

End User Inspection

28. 03. 2022 09:54

ABC Pharmacy Dublin

7 Clanwilliam Terrace, Dublin 2

IT Vendor:

01 5715320

imvo.test01@gmail.com

NMVS Response

The user is not connected via API

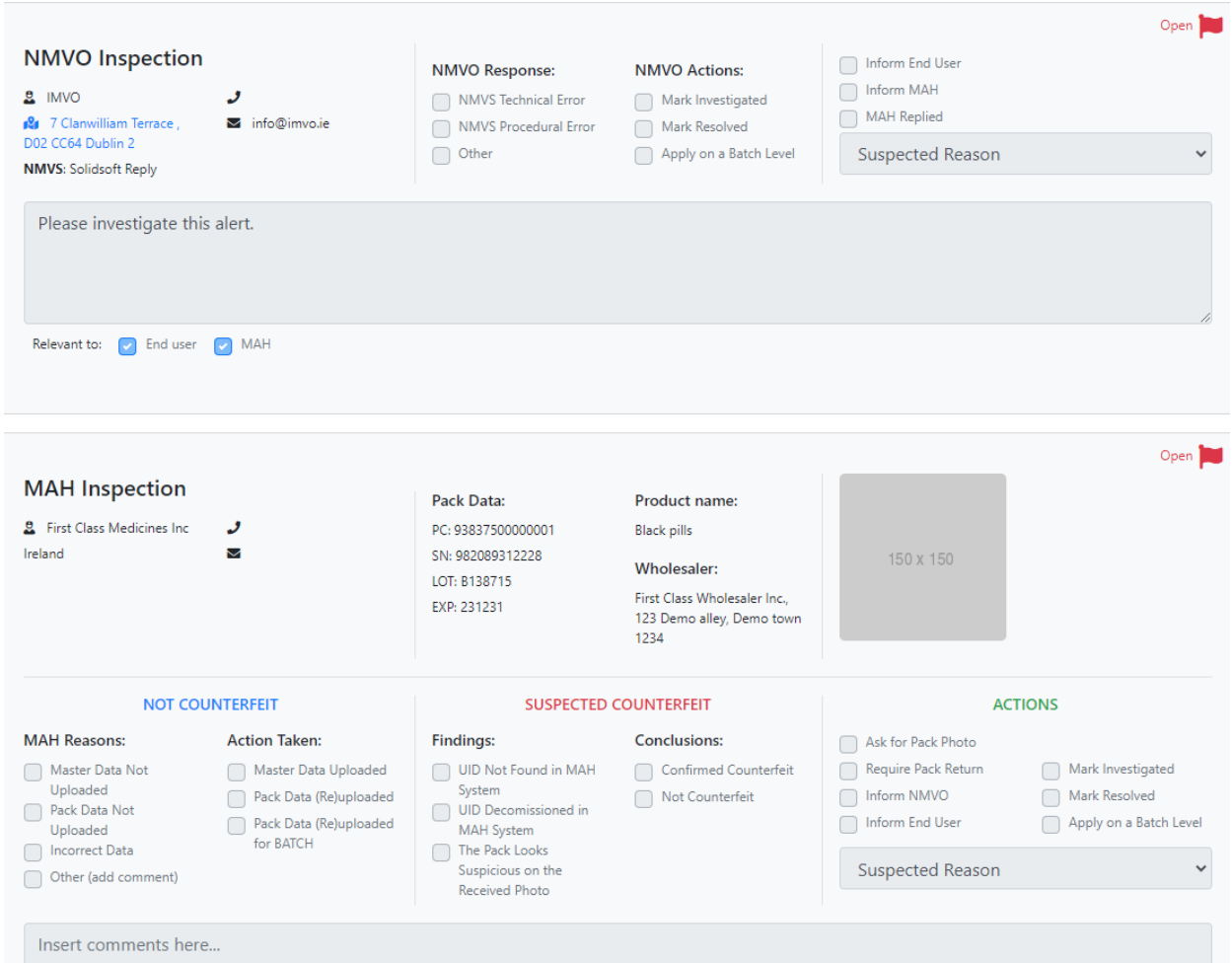
Level 1 Investigation

- [ ] Technical Error
- [ ] Procedural Error
- [ ] Pack Returned
- [ ] Other
- [ ] Mark Investigated
- [x] Inform NMVO

Insert comments here...

Save

End-user documentation of root cause



End-user documentation of root cause

Miscellaneous

Minimising alerts due to data upload issues

- Voluntary scanning by primary distributors at goods inwards of sample of packs received is extremely helpful – please inform MAHs if alerts are generated indicative of a data issue
- Advice given to **MAHs** by IMVO:
  - 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

Exempt medicinal products / ULMs

- Exempt medicinal products/unlicensed medicines (ULMs) with 2D barcodes that originate from other markets are challenging from FMD perspective as the data may not be found when they are scanned, leading to alerts
- The table on the next slide outlines how to deal with these packs depending on where they originated from

Exempt medicinal products / ULMs (ctd)

Country of origin	Recommend to scan?	Remarks
EEA (EU country + IS, LI, NO)	Yes	The EMVS will locate the data for the pack in whatever market it comes from (via an 'intermarket transaction' or 'IMT'). • **NB:** FMD software will not display the name of these products as the IMVS only has this information for packs intended for sale in Ireland. • IMT alert can be recognised from the 2 letter country code in the Alert ID, Not 'IE', e.g. alert with the 'MT' suffix relates to a pack originating from Malta • ***If no root cause of an alert is identified - please contact IMVO for assistance as we may need to follow up with the NMVO in the other market on matters such as data upload issues***
Outside the EEA (other than UK)	No	• These packs will generate a 'product code unknown' exception if scanned • They may be identified by a non-EU manufacturer name and address on the pack and sometimes they will not have an ATD
UK-only packs	No	Because of Brexit, UK-only packs which are serialised may not have data uploaded in the EMVS • If the data has been uploaded, the pack should scan correctly, unless there is a procedural, scanner or software issue in the pharmacy • If the data has not been uploaded, an alert may be generated

The ‘ask’ of wholesalers

What you can do?

- **Ensure that returned packs that are already decommissioned are not returned to saleable stock**, to prevent avoidable alerts for the next customer who receives them
- **Make sure your teams are aware of your FMD procedures** and are trained on what is involved ahead of end of use and learn for all your alerts on 9th May
- **Intensify efforts to prevent alerts** due to software, scanners, procedural errors
  - Make sure scanners are working
  - Watch out for software issues and tell us about them
  - 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**, ideally via NMVS Alerts
- **Contact us if you need help** with anything or have any questions
- All feedback on how we can improve the process is very welcome!

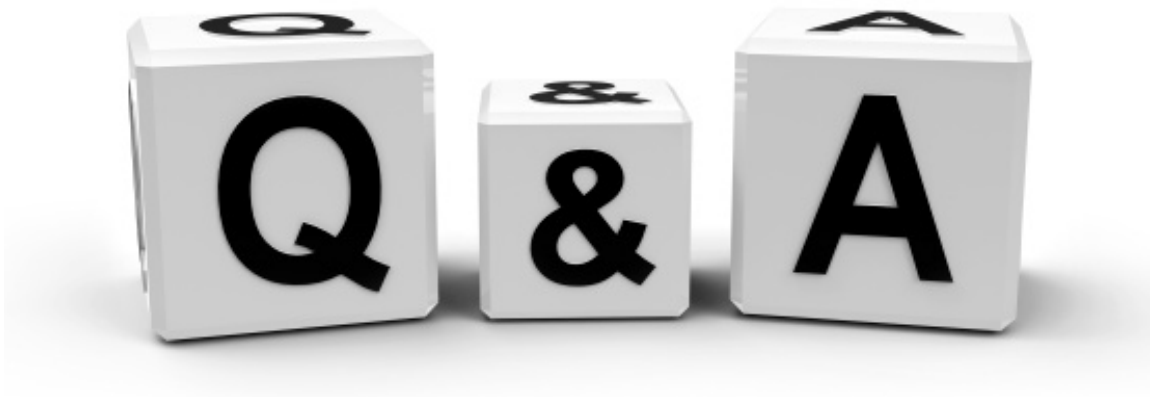
Brexit

Brexit

- Commission Delegated Regulation (EU) 2022/315 which amends original Delegated Regulation (EU) 2016/161 to deal with Brexit-related matters now finalised
  - Extends until end 2024, derogation from requirement to 'decommission as exported' packs distributed to UK, provided they are manufactured and labelled for UK market or UK market and Ireland, Cyprus and/or Malta markets
  - Changes required to EMVS so that UK-only or UK joint packs will generate 'non-Union pack' alerts if verified outside NI, Ireland, Malta or Cyprus (designed to ensure continuity of supply in these small markets)
    - EMVO currently reviewing what this will mean in practice and timing of changes

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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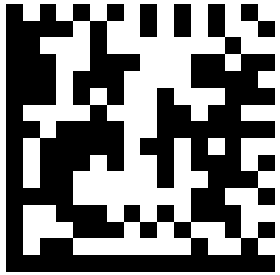

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BACKUP SLIDES

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

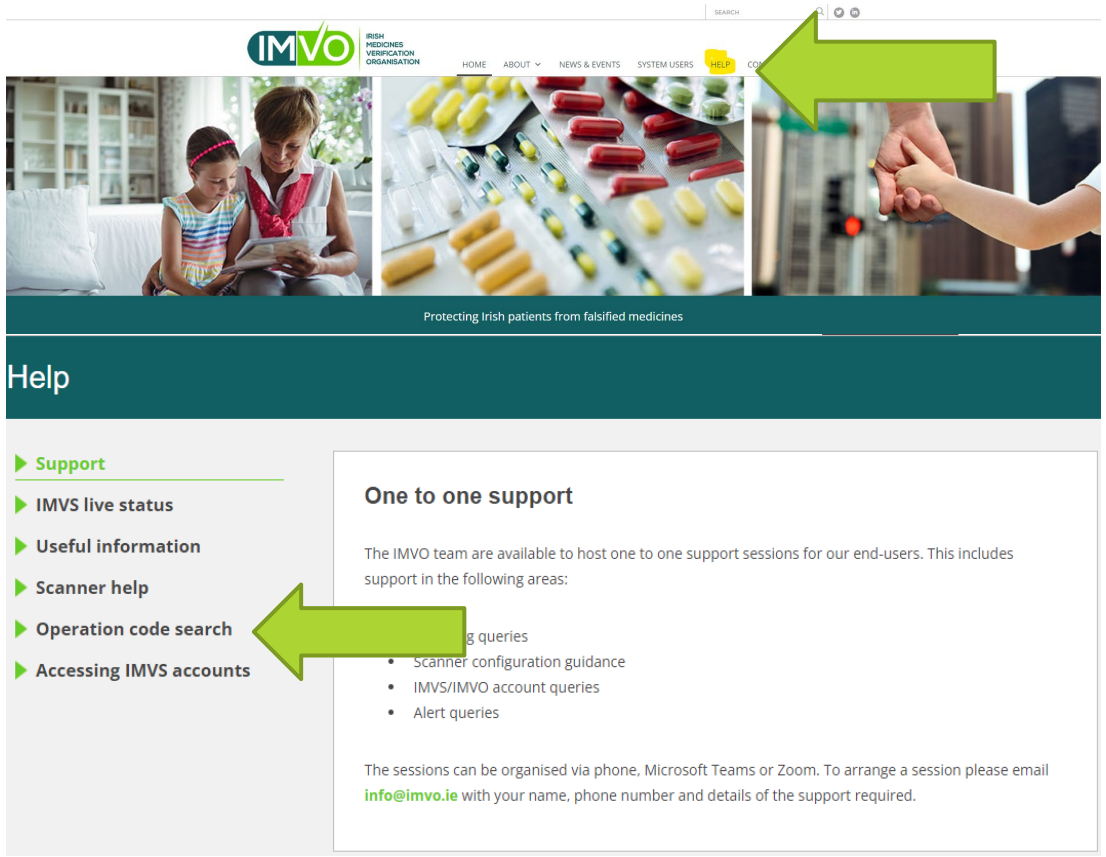
Level 1-5 classification of alerts and exceptions

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 help pages 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