IRISH MEDICINES VERIFICATION ORGANISATION

# Webinar for MAHs

26 SEPTEMBER 2022

# Outline

- Housekeeping – 'Mute', Q&A, recording
- IMVS/EMVS updates
- Scanning & Alert rates
- Progress since end of use and learn
- Alert management in Ireland
- *NMVS Alerts*
- Brexit/small market issues
- MAH fees
- The 'ask' of MAHs
- Q&A

# Backup slides

- EMVS planning/EMVS priorities 2023
- Information on IMVS live status
- Guidance issued to pharmacies on exempt medicinal products
- MAH registration
- How to access *NMVS Alerts*

# IMVS/EMVS updates


# IMVS/EMVS

- **Next release of IMVS (R11)** will go live in mid-October – mostly changes to improve end-user experience and fix defects
- **Overall EMVS (including IMVS) is performing well**
  - IMVS system performance was impacted by Microsoft issue on 7th September - lead to issues for a short period due to transactions timing out
- Discussions are continuing at national and European level on introducing **non-FMD functionality in EMVS** to generate tailored exemption messages for alerts on packs that are out of scope of FMD or have received an NCA exemption related to an FMD issue

# IMVS/EMVS (ctd)

- NMVOs and EMVO now put in place **robust planning tools for EMVS** to ensure better co-ordination and alignment of changes across national systems and EU Hub (see back-up slides for details)
- Planning underway for **Greece and Italy** to join the EMVS (they are obliged to join by latest Feb 2025) – Greece likely to join in 2023, no date unknown yet for Italy
- See back-up slides for details of how to find out IMVS 'live' status

# European Alert Management System (EAMS)

- EMVO and NMVOs are working towards objective of pan-European network of national AMSs connected via AMS Hub which is managed by EMVO (the 'EAMS')
- Each OBP via one point of access to AMS Hub giving access to all connected national AMSs
- E2E pilot is underway and will continue until end of 2022
  - 3 countries using *NMVS Alerts* are taking part in pilot – Cyprus, France and Slovenia
  - Ireland eventually plans to connect our AMS to AMS Hub

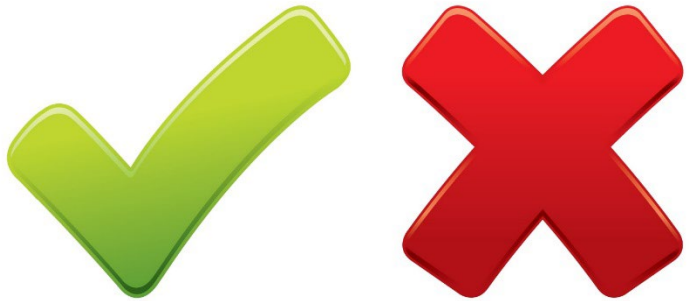
# Scanning

# Scanning rate 1 Jan – 18 Sep 2022

# Activity to increase scanning

- Scanning now on upward trajectory
- PSI is responsible for ensuring that pharmacies meet their scanning obligations and they are actively pursuing non/low scanning pharmacies
- IMVO providing reports on scanning activity to PSI and supporting pharmacies to resolve any issues relating to scanning

# Alert rates



# Alert rates

- **Trends from the past 4 weeks:**

  Week 34 alert to scan ratio: 0.11% (0.11% end-user alert rate)
  Week 35 alert to scan ratio: 0.09% (0.06% end-user alert rate)
  Week 36 alert to scan ratio: 0.10% (0.06% end-user alert rate)
  Week 37 alert to scan ratio: 0.10% (0.06% end-user alert rate)

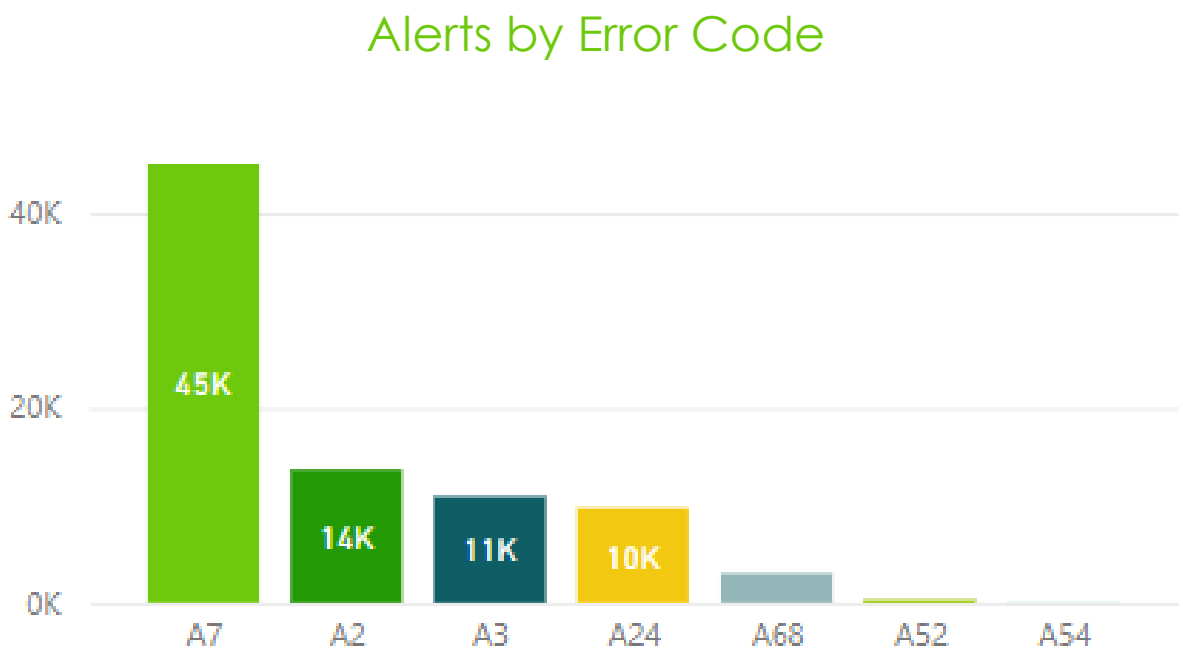
- **Analysis from latest EMVO monitoring report (week 34 – w/c 22 Aug 2022)**

  Overall alert to scan ratio across Europe: 0.18%
  Minimum alert to scan ratio: 0.01% (Austria)
  Maximum alert to scan ratio: 1.69% (Liechtenstein – 15 alerts)

# Analysis of alerts – 1 Jan to 18 Sep 2022

Alert to Scan Ratio

# Analysis of alerts – 1 Jan to 18 Sep 2022




**A7** – Pack already in requested state

**A2** – Batch not found

**A3** – Pack not found (unknown serial number)

**A24** – Status change could not be performed

**A68** – Batch ID mismatch

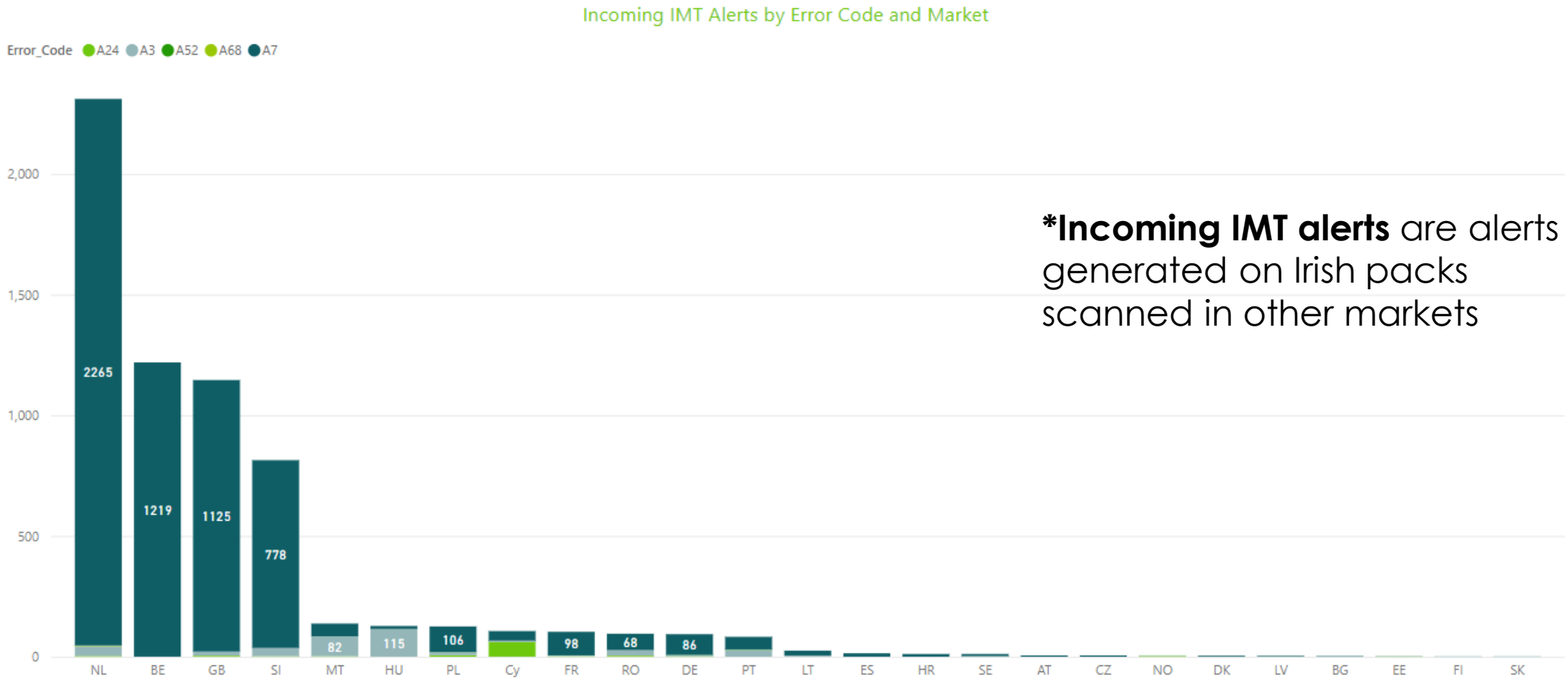
**A52** – Expiry date mismatch

**A54** – Insufficient randomisation of serial numbers

# Sources of alerts

| Source of alerts | Week 31 (w/c 1 Aug) | | Week 34 (w/c 22 Aug) | | Week 36 (w/c 22 Aug) | |
|---|---|---|---|---|---|---|
| | No. of alerts | % of total alerts | No. of alerts | % of total alerts | No. of alerts | % of total alerts |
| Intermarket transactions – IE end user | 947 | 50% | 958 | 49% | 311 | 18% |
| Decommissioned at multiple locations | 227 | 12% | 215 | 11% | 196 | 11% |
| Repeated decommissioning at same location | 286 | 15% | 136 | 7% | 92 | 5% |
| Software | 109 | 6% | 28 | 1% | 25 | 1% |
| Scanner | 52 | 3% | 54 | 3% | 28 | 1% |
| Other | 74 | 4% | 316 | 16% | 400 | 22% |
| MAH transactions | 0 | 0% | 5 | 0% | 497 | 29% |
| MAH data issues | 84 | 4% | 120 | 6% | 25 | 6% |
| Intermarket transactions – non-IE end user | 122 | 6% | 118 | 6% | 131 | 7% |
| Total | 1,901 | 100% | 1,950 | 100% | 1,705 | 100% |

# Analysis of incoming IMT alerts* – 1 Jan to 18 Sep 2022




***Incoming IMT alerts** are alerts generated on Irish packs scanned in other markets

# Summary of alerts – end-users

- End-user alert rate increased during Jul/Aug
- Issues in recent weeks:
  - Exempt medicinal products / unlicensed medicines (ULMs) – ongoing challenge
  - Packs brought in from UK where data has not been uploaded to EMVS (not mandatory for data to be uploaded for serialised UK packs)
  - Alerts due to wholesaler error e.g. hospital aggregation

# Key causes of MAH alerts

- Data upload issues:
  - Late / incomplete uploads – redoing partial uploads can cause alerts
  - Errors in data – wrong product code, batch number, incomplete data
- MAH attempts to decommission already decommissioned pack (e.g. 'exported' to 'exported' or repeating 'destroy' operations)
- Manner in which 2D barcode is printed on pack can cause alerts, e.g. too close to linear barcode, not enough 'white space' around barcode
- If multi-market product not licensed here and IE set up as market in EU Hub but no data uploaded to IE, this is likely to cause alerts in other markets

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

# Progress update

- Pharmacy and hospital engagement with IMVO has increased significantly, although mainly during normal working day and not in evenings or at weekends
- IMVO now has a call centre providing 1st line support, with extended opening hours
  - Mon-Fri – 08.00-20.00
  - Sat – 09.00-18.00
  - Sun/public holidays – 11.00-18.00
- Webinars and regular email updates for pharmacies and hospitals to brief them on most common issues seen since 30 May and how to avoid them
- Discussions underway with HPRA and PSI on when they will intervene with end-users and MAHs who do not provide essential information or support to IMVO to enable alerts to be investigated – IMVO will make several attempts to engage with end-user or MAH before escalating to relevant NCA

# Alert management in Ireland

# Overview of '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
- The guidance was drawn up following consultation with stakeholders and HPRA and PSI (pharmacy regulator)
- For alerts generated by end-users – pharmacies, hospitals, wholesalers –the end-user and MAH are expected to launch simultaneous investigations
- Priority is to ensure packs may be supplied once falsification is ruled out
- See back-up slides for details of roles and responsibilities of MAHs, end-users and IMVO re alert management

# A7, A24 and A68 alerts

- NB: MAHs **should not proactively investigate** following categories of end-user alerts, unless asked to do so by IMVO or HPRA:
  - ***A7/A24 (double decommission)*** as the root cause is generally end-user procedural error
  - ***A68 (batch ID mismatch)*** as the root cause is generally an end-user software issue

# What you can do to reduce alerts

- 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
- Analyse your own transactions that lead to multiple alerts, e.g. duplicate decommissioning, and implement CAPAs to prevent recurrence

# How to resolve alerts quickly

- Correct any data errors (e.g. missing/incorrect data) as soon as you become aware of them
- Use *NMVS Alerts* to inform IMVO and end-user(s) if you have identified the root cause of an alert or series of alerts on batch


nmvsalerts

# *NMVS Alerts*

- Collaborative tool which facilitates efficient handling of alerts by allowing all the relevant parties to:
  - manage, track and document alerts. It provides real-time information on the status of alerts based on information entered by the end-user, MAH and/or IMVO
  - 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 an audit trail of their own actions for inspection purposes

# Engagement by end-users re alerts

- *NMVS Alerts* usage by end-users is increasing steadily
  - More and more pharmacies are using the *NMVS Alerts link* sent to them when alert is generated to provide feedback / check what MAH has reported
  - 193 end-users have signed up for accounts which gives them access to all their alert information
  - Pharmacies are also engaging with IMVO about alerts via phone and email

# Closing bulk alerts in NMVS Alerts

- Currently MAHs with basic free account in *NMVS Alerts* cannot 'resolve' bulk alerts (i.e. related alerts on the same batch)
- IMVO can 'resolve' bulk alerts for you, to request this, please email alert.support@imvo.ie with the root cause and alert IDs of the relevant alerts (or batch ID for alerts which are raised on an entire batch)

# Communicating within *NMVS Alerts*

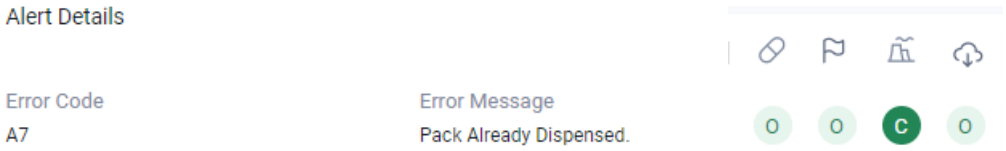
- Messaging within *NMVS Alerts* can go directly to the end-user as well as the NMVO
  - Ensure the language is clear
  - Ensure the guidance/advice is definite

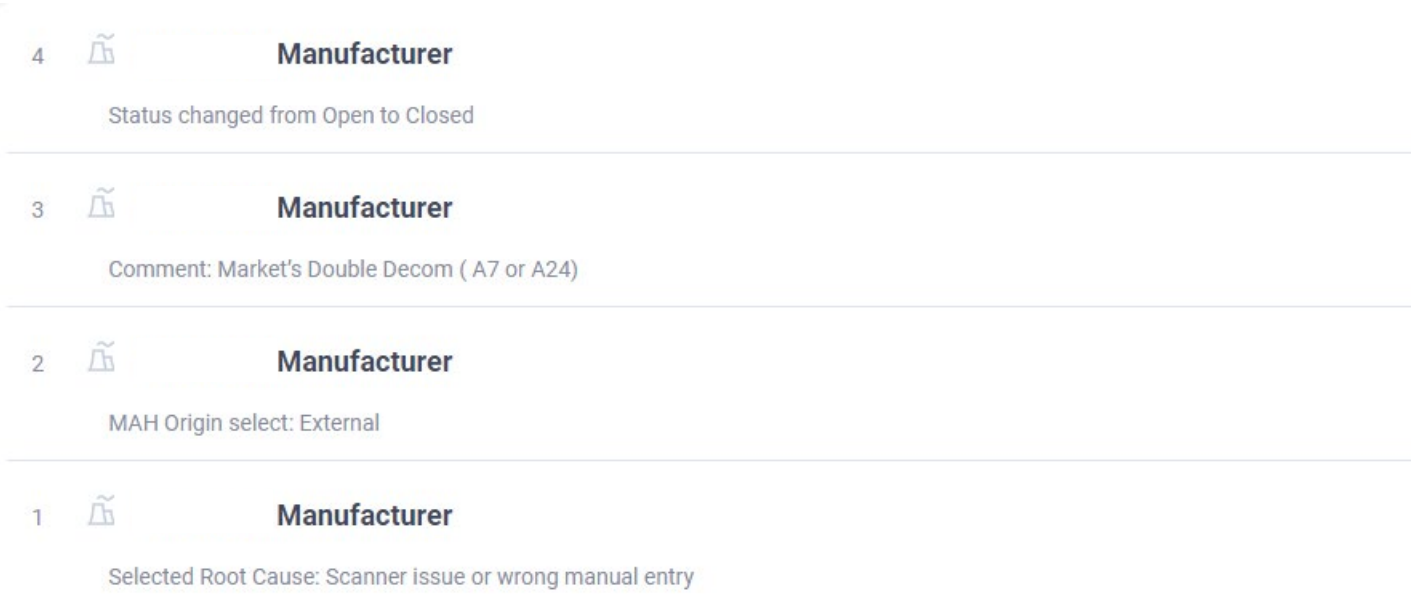
# Automated closure of alerts within *NMVS Alerts*

***IMVO step 1a – IMVO notified of alert root cause by MAH***

If the MAH informs IMVO and the end-user via *NMVS Alerts* that the alert was due to an MAH data or procedural error, the MAH should close the alert in *NMVS Alerts*. No further action is required by IMVO or the end-user. If the notification comes from the MAH by email to IMVO, IMVO will inform the end-user and close the alert in *NMVS Alerts* (if not already done by the MAH).

IMVO Alert Management Guidance
7.2 Communication of alert investigation results




**Impact**

- End user does not get alert notification
- Preventing alert investigation
- Automation rules incorrect
  - Should not apply to an A7 alert

# Brexit / small market issues

# Small market issues

- Small markets such as Ireland have **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.
    - Supply of packs under national arrangements per Article 5(1) of Directive 2021/83/EC, including exempt medicinal products in Ireland
    - Batch specific requests (BSRs) granted by HPRA to batches 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
- Implementation / operational aspects of **Brexit changes** to EMVS required by **Commission Delegated Regulation (EU) 2022/315** will be challenging for all markets

# MAH Fees

# MAH fees 2023-2025

- Annual **MAH User Fee** will be €6,000 for 2023, 2024 and 2025 (reduced from 2022 fee of €8,000)
  - Discount of €3000 will be given on MAH user fee in 2023
  - We will email you in Nov to check your invoicing details, including if PO no. is required
  - Invoices will be issued by IMVO in early Jan 2023, due for payment by 9th February 2023
- MAH **registration fee** will be **€1,000** from 2023 (reduced from €4,000)
- If you have any queries about MAH fees & rebates, please email mah@imvo.ie

# MAH fees 2023-2025 (ctd)

**Why will a discount be given in 2023?**

- IMVO Board decided in 2021 that one year's operational expenditure is the appropriate level of reserves for IMVO
- Credit notes were issued in 2021 to reduce our reserves but a further adjustment is required to reach the agreed target
- IMVO finances are now in steady state and no further discounts or credit notes are foreseen after 2023

# MAH fees - rebates

- 60% rebates will continue to be available on annual MAH fees for MAHs with prior year income in the Irish market less than €100K
- If you wish to apply for a rebate in 2023, please request an application form by email from mah@imvo.ie

# The ‘ask’ of MAHs

# Help us to reduce alerts

- Ensure data for all your products is uploaded correctly and on time (before entering supply chain)
  - Primary wholesalers are scanning sample numbers of packs at goods inwards to check that data has been uploaded
  - If you're sending packs to your primary wholesaler before QP release and data upload, tell them, otherwise their scans will generate alerts
- Correct any errors identified after data is uploaded
- Ensure procedures are designed to reduce risk of double decommissioning
- If receiving large number 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 Hub and needs to be re-uploaded
- Notify us if HPRA:
  - Approves BSR where there is likely to be an FMD impact
  - Grants exemption to continue selling packs, notwithstanding error in data in barcode or in EMVS data

# Managing your data

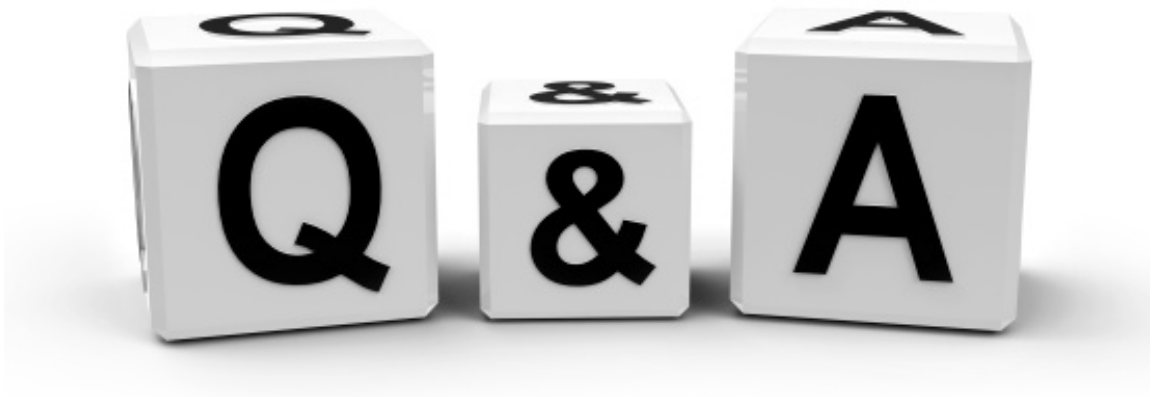
- Make sure that product name in IMVS matches what's printed on pack – mismatch in name/form/strength causes confusion for end-users
- Only mark a batch as 'recalled' in the IMVS if the batch is being recalled to pharmacy level – do not mark as 'recalled' if recall is only to wholesaler level as this will lead to 'pack recalled' warnings in pharmacies and hospitals
- Refer queries re data upload and EU Hub issues to EMVO

# Keep your contact details up to date

- Please send all alert queries to alert.support@imvo.ie
- IMVO sends queries about your alerts to:
  - Your nominated Single Point of Contact (SPOC) for alerts and back-up SPOC
  - If SPOC not notified to IMVO, emails are sent to:
    - Person in regular contact with IMVO or main MAH contact person on file
    - OBP SPOC (from list provided by EMVO)
- Please ensure our communications are going to right person
- If not already done, tell us who is your Single Point of Contact (SPOC) for alerts and back-up SPOC (email alert.support@imvo.ie)
- Notify of any changes in your contact details (including Finance)

# 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
- **European Commission Q&A on Safety Features** – available on IMVO website

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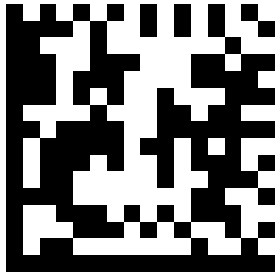

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BACKUP SLIDES

# EMVS planning

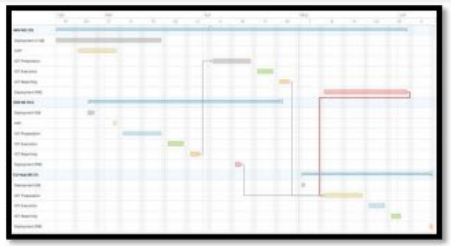
## TOOLS FOR EMVS PLANNING – SHORT, MID AND LONG-TERM

**Long-term – outlook on the way ahead and reflect the EMVS priorities**

**Mid-term – where do we need to align to make short term happen**

**Short-term – what we will do next year**


| Big ticket item | High-level rationale |
|---|---|
| FMD and non-FMD Lists | • Further reduce alerts<br>• Activation of the non-FMD functionality depending on EU COM approval |
| Greece onboarding (BPS - placeholder) | • To be included into 2023 priorities if one of the current BPS is selected and onboarding takes place in 2023 (need to accommodate GR for UAT and IOT). To be communicated to Greek NMVO accordingly |
| Small markets (Brexit) | • Legal requirement. To be implemented in the EU Hub still in 2022<br>• Breaks the end-user interface |
| EMVS Data Retention Time & data storage growth | • Legal requirement<br>• Data storage growth to be taken together with the EMVS Data Retention Time<br>• In progress under the Working Group – the output will be a data retention policy |
| Divestures and Acquisitions | • Improve process and data quality<br>• Part 1 to be implemented in the EU Hub still in 2022 |
| NCA Reports | • Implement full audit trail (depends on a written statement by the EU COM, not received yet)<br>• Implement other minor changes to improve reports |
| NHRN uploaded with a specific format | • Increase quality of the data loaded by OBPs – chance in the EU Hub |



### EMVS Long-Term Roadmap

- Tool for **continuous planning** process – live document
- **Guides thinking** and objectives, and **provides wider visibility** over the future
- **Enables alignment** and good **decision-making**
- **Enables financial planning**
- Reviewed annually

### Pipeline management

- Log the **changes that require alignment and further work before submission to governance**
- **Enables decision on the content of the releases in the coming year**
- Reviewed quarterly

### Standard release plan

- Calendar for the **releases in the coming years**
- Reviewed bi-monthly

# EMVS priorities 2023

| Big ticket item | High-level rationale |
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| **FMD and non-FMD Lists** | • Further reduce alerts<br>• Activation of the non-FMD functionality depending on EU COM approval |
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| **NHRN uploaded with a specific format** | • Increase quality of the data loaded by OBPs – chance in the EU Hub |

# Summary of IMVO Alert Management Guidance

# End-user investigation of alerts

- 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, they may verify pack again and, if successful, supply pack
- End-users are asked to provide feedback via *NMVS Alerts*

# MAH investigation of alerts

- For end-user alerts other than A7, A24 and A68 alerts , MAH must look for **data issues** (e.g. missing data), then **issues with EMVS**, e.g. EU Hub issue
- MAHs must also investigate all alerts generated from their own transactions on packs under their control (note – end-users don't see these alerts)
- MAHs are expected to provide feedback within 2 working days of alert being generated (or update on progress with investigation if root cause is not yet known)
- MAH may request a photo of the pack from end-user if there is no obvious root cause from initial investigation, and follow up with request to return the pack if necessary

# IMVO's role

- IMVO monitors IMVS for large numbers / unusual patterns of alerts by product/batch/end-user, and immediately contacts end-user or MAH or FMD software provider to take action to prevent further alerts
- For other alerts, IMVO steps in if there is no feedback from the end-user or MAH within 2 working days of the alert being generated and ensures the alert is investigated if not already done
- If end-user or MAH does not provide assistance/information required to enable alert to be investigated, matter is escalated to relevant NCA
  - MAHs, wholesalers - HPRA
  - Pharmacies - PSI

# What happens if end-user cannot identify a root cause on their side?

- End-user must withhold the pack from saleable stock (i.e. quarantine it at their premises) until either:
  - MAH confirms they have identified root cause (e.g. data issue, system issue) and 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 must advise end-user on how pack is to be returned

# Guidance issued to pharmacies on exempt medicinal products

- IMVO has worked with HPRA and PSI to develop guidance for pharmacies and hospitals on how to handle exempt medicinal products (also known as unlicensed medicines or ULMs) from an FMD perspective
- **Summary of guidance:**
  - If you know the pack is a ULM, do not 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

# Information on system status

- Real-time status of Solidsoft national systems, including IMVS, available at: https://status.nmvo.eu/
- EMVO's **EVI** service provides information on disruption/ downtime / changes to Hub & national systems
  - Subscribe for notifications at https://emvo-medicines.eu/evi/

# MAH registration

- If you need to transfer your registration to a new MAH or register a new MAH at any time, contact mah@imvo.ie for guidance on process and fees payable
- Registration only takes a few days
- IMVO's preference is for MAH agreements to be signed electronically
- NB - registration with EMVO to create a connection to the EU Hub to upload data is a completely separate process & takes several weeks as many steps involved

# How to access *NMVS Alerts*

***Set up account***

- 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 in the country to which the account relates
  - report any information they have to add about the alert (e.g. 'data not uploaded')
  - 'resolve' alerts where the investigation is complete and the root caused is known
- Premium OBP/MAH license allows access to extra features: batch level action and multi level selection and the ability to see its alerts in all countries where it is a MAH (as opposed to only in the national market with free license)

***Email link***

- When a Level 5 alert is generated, automated email can 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