ISSUE 1- SUMMER 2021

Newsletter

Welcome

Welcome to our Summer newsletter. 2021 has been another difficult year with the ongoing challenges of Covid. A huge thank you to our manufacturing, wholesaling, pharmacy and hospital colleagues for ensuring that patients continue to receive their medicines and everyone involved in researching, manufacturing, distributing and administering Covid vaccines.

IMVO's key priority for 2021 is to work with pharmacies, hospitals, wholesalers and marketing authorisation holders (MAHs) to prepare for the end of the 'use and learn' phase of FMD rollout in Ireland, now scheduled for Q1 2022. Our focus to date has been on eliminating avoidable alerts in the alert rate this year. The next step is to provide clear guidance on managing alerts, so that alerts are promptly investigated, minimising any impact on supply and that ensuring any fake medicines are quickly identified.

We work closely with colleagues in other national medicines verification organisations (NMVOs) and the European Medicines Verification Organisation (EMVO) to share knowledge and to ensure that the European Medicines Verification System operates as an integrated system across Europe. I am delighted that Mitja Pirman from the Slovenian NMVO has contributed an article (see page 4) on how Slovenia has become one of the leading countries in Europe in terms of FMD implementation.

Leonie Clarke
IMVO General Manager

Use and learn to end in Q1 2022

FMD has been in a ‘use and learn’ phase for pharmacies, hospitals and wholesalers in this country since February 2019 due, in part, to the impact of Covid-19 and Brexit. The Safety Features Oversight Group, following consultation with all relevant stakeholders, has now agreed to end use and learn on a phased basis **concluding at the end of Q1 2022**. Click here to see the full plan, including all the phases and dates. The Safety Features Oversight Group will monitor progress over the coming months to ensure that everything is in place to move to the next phase of the plan, including targeted communications with each group on details of what is involved for them.

Tips for pharmacies and hospitals

Only scan bulk packs once

Make sure your FMD software is connected

More on page 2

Events

We recently hosted webinars for pharmacies, hospitals, wholesalers and marketing authorisation holders (MAHs)

Pharmacies and hospitals

How to... get to grips with scanning & explore other uses of barcodes - April 2021

Click to watch recording

Wholesalers

Update webinar for wholesalers - June 2021

Click to watch recording

MAHs

Update webinar for MAHs - June 2021

Click to watch recording

Want to be notified of upcoming events?

Sign up to our mailing list here. All events are posted on our website here.

Tips for pharmacies and hospitals to avoid alerts

Only scan bulk packs once on the first dispensing

Over 2,400 alerts in June were raised by pharmacy end-users repeatedly scanning the same packs, resulting in 'double decommission' alerts. If you are dispensing from a bulk pack, the pack must only be scanned (decommissioned) once, when it is first opened, and should not be scanned on subsequent dispensings. Many pharmacies have implemented creative solutions to identify which packs have been scanned. We recommend marking scanned packs with an X to remind you to not scan that pack again and to ensure all staff are trained on the agreed process and using it so these 'double decommission' alerts do not arise.

Make sure your FMD software remains connected to IMVS after any IT changes

If there are any updates or changes to your IT hardware or software, for example, updates to your general IT systems, updates to your dispensing software system or antiviral software, always make sure that your FMD software is still working and connected to the Irish Medicines Verification System (IMVS) after the change. You can check this by contacting us to make sure that your scans are being transmitted to the IMVS – Contact Us.

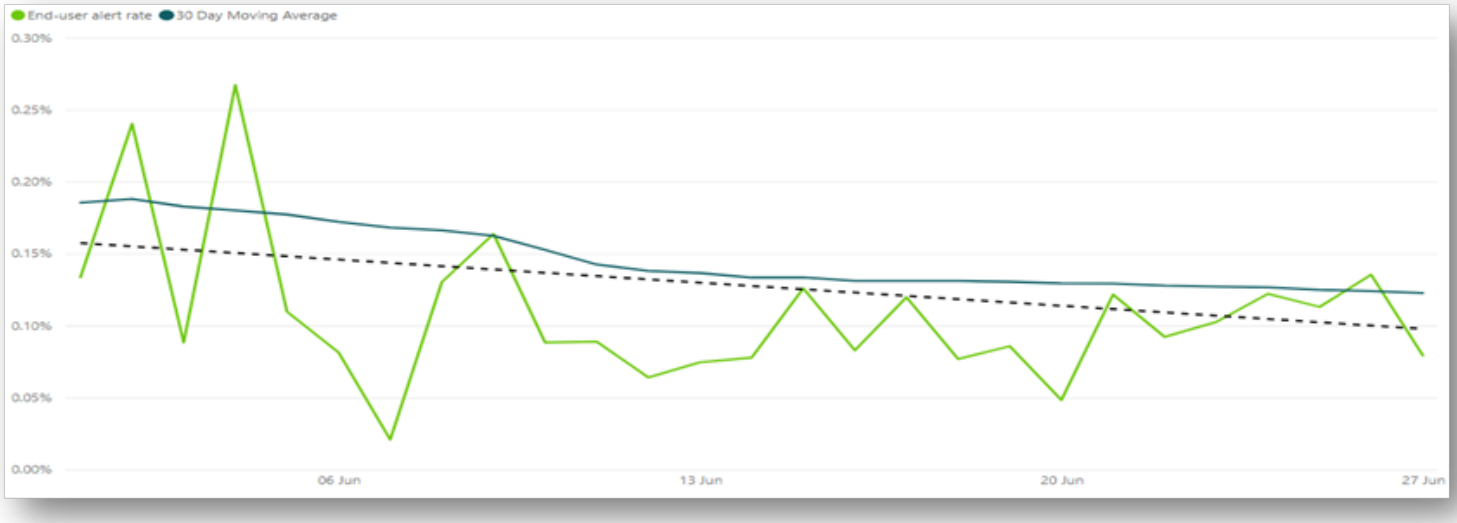
New website launched in 2021

In March this year, we launched a new website. Designed and developed with all our system users in mind. We have streamlined content and there is improved navigation of the site.

Alert rate falling in Ireland

We have made immense progress to date in driving down the alert rate (alerts as a ratio of scans) in Ireland this year and the rate was down to 0.12% in the last week in June. This could not have been achieved without the assistance of MAHs, wholesalers, pharmacies and hospitals who work with IMVO to correct system and process errors on their part that cause alerts. Thank you also to HSE FMD Project Team and FMD software providers who are other key partners in the effort to reduce avoidable alerts in Ireland. Our short-term target is to get the alert rate to 0.05% but we want to push this even lower over the coming months so that alert numbers will be manageable for everyone after use and learn ends.

Analysis of alerts generated by end-users in Ireland, June 2021



EMVO best practice on alert handling

EMVO has published new 'best practice on alert handling' which aims to ensure that all alerts generated in the EMVS are promptly resolved to minimise disruption to supply of medicines to patients – click here to download it. Leonie Clarke from IMVO chaired the group of EMVO and NMVO stakeholders that developed the best practice document. The document sets out decision trees for investigation of alerts, defines the role of end-users (pharmacies, hospitals and wholesalers), MAHs, NMVOs and EMVO, and describes communication channels between them. Our plan now is to use the EMVO document as the starting point for discussions with stakeholders in Ireland on national alert handling guidance over the coming weeks.

New IMVO corporate strategy

Our first corporate strategy has been signed off by the IMVO Board. Between now and 2023, we are aiming for operational excellence in everything we do and to consistently deliver value to our member organisations, employees, and the pharmacies, hospitals, wholesalers and MAHs who use the IMVS. The full strategy is available to read here.

Mitja Pirman, Managing Director, ZAPAZ

ZAPAZ, the Slovenia NMVO, has been a proactive member of the EU FMD community from the early stages of the EMVS project. Like Ireland, Solidsoft Reply (SSR) is our national system provider. After teaming up successfully with colleagues from other SSR countries for the initial User Acceptance Testing, the Slovenian system was the first national system to connect the EU Hub in April 2018. This first joint activity was a great lesson that has proven the obvious advantages of cooperation and knowledge sharing between NMVOs. I no longer see ZAPAZ as merely a national organisation, since I have the opportunity to work closely with my colleagues from various places from Iceland to Cyprus, including the IMVO team.

There are 342 pharmacies, 21 wholesalers and 28 healthcare institutions connected to the Slovenian NMVS which has data from over 220 MAHs. National legislation prescribes sanctions for non-compliance with FMD, with fines ranging from €8,000 to €120,000. When the FMD directive became legally effective, a stabilisation period was introduced in Slovenia which ended in November 2019. During that time we worked closely with end-users and their software providers to reduce unnecessary alerts. We invested a lot of energy in educating and supporting our national stakeholders, verifying and testing interfaces of connected pharmacy systems, helping their IT providers fix bugs and consequently achieved a relatively low percentage of alerts.

The position now is that no pack can be dispensed if there is an alert, until stakeholders have completed their investigation activities, allowing the alert to be marked as resolved. The most essential tool that makes this possible is our alert management system, ‘NMVS Alerts’, a central collaboration platform which enables our end-users and MAHs to interact anonymously and exchange information in real time and enables ZAPAZ to monitor and support alert investigation, and if needed, to escalate individual cases to the national competent authority (NCA) responsible for FMD.

Another big reason for Slovenia becoming a frontrunner in FMD is our close cooperation with the NCA, who provides valuable support in communication, education, alert investigation and particularly in defining national alert handling guidance for stakeholders.