European Medicines Verification Organisation

EMVO NEWSLETTER

Friday, June 07th 2019

What's new at EMVO:

I. NMVO Update
II. New On-boarding Guideline
III. EU HUB Release 1.5

NMVO Update

Last time, Ricardo Valente gave an insight to the situation in Portugal.

This week, Leonie Clarke, the General Manager of the Irish Medicines Verification Organisation (IMVO) tells about her experience and the situation in Ireland.

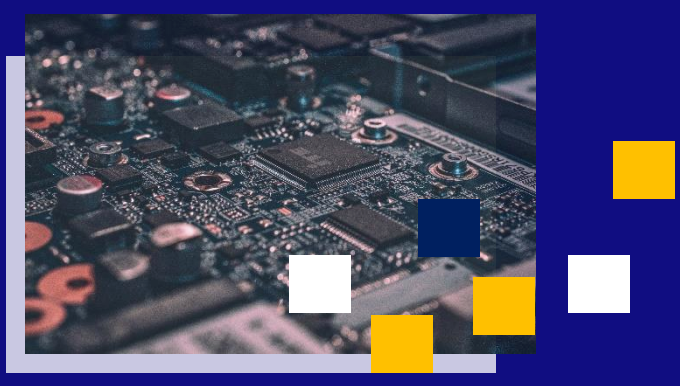
It has been a rollercoaster ride since industry, pharmacy and wholesaler stakeholders first met in 2015 to start planning the implementation of the Irish Medicines Verification System. This led to the setting up of IMVO in April 2017 and the go live of our national system a year later.

Onboarding over 2000 pharmacies, hospitals and wholesalers was a key task for IMVO before 9th February. We continue to work closely with our NCAs – the Health Products Regulatory Authority (HPRA) and the Pharmaceutical Society of Ireland (PSI) - to ensure that everyone who needs to register has done so and is connected to the system and actively scanning. All pharmacies and hospitals are now registered and the vast majority of them are connected, as are most wholesalers.

There are now almost 130 million active packs in the Irish repository and scanning activity is increasing week by week.

The 'use and learn' period in Ireland has been extended until 9th September 2019. During this period, pharmacies, hospitals, wholesalers and manufacturers/MAHs are expected to intensify efforts to eliminate avoidable errors.

Over 900,000 alerts have been generated in Ireland since 9th February. The alert rate remains relatively high, although it is falling steadily. The vast majority of alerts are due to manufacturer issues. We are providing analyses of alerts per batch to the MAHs causing most of the alerts so they can take action to address the root causes. From early June, the HPRA will also be provided with these reports and will monitor trends and follow up with MAHs as required. Relatively few alerts are being caused by end-users and they arise due to incorrectly configured scanners, software changing expiry dates, etc. IMVO has worked with the Irish Pharmacy Union, the Irish Health Service Executive and the PSI to prevent and reduce end-user errors, as well as communicating with IT software providers whose systems are causing problems.



Planning for Brexit is another priority for IMVO due to the large number of multimarket packs with the UK. We are liaising with colleagues in the UK, EMVO and other affected NMVOs regarding the measures needed to minimise problems with joint UK packs when the UK is no longer part of the EMVS. Preparing for Brexit is obviously also a priority for the relevant MAHs. Many MAs for products marketed in Ireland have already been transferred from UK MAHs to affiliates elsewhere in the EU.

IMVO has greatly enjoyed sharing the rollercoaster ride that is FMD with our stakeholders, EMVO and other NMVOs so far and we look forward to continuing this very productive collaboration over the months and years ahead.

IMVO IRISH MEDICINES VERIFICATION ORGANISATION

New versions of the On-boarding Guideline and On-boarding presentation

This week, new versions of the On-boarding Guideline and On-boarding presentation have been released and are now available on EMVO's website.

These updated documents include:

- Detailed process descriptions
- An updated abbreviation list
- Advice for Divesture &Acquisitions / Mergers & Acquisitions

For instance, on page 30 of the On-boarding Guideline document, it is detailed that the entered/appointed SPOC, SPOC Assistant (or new people assigned to the same role), should not share the same e-mail address.

The successful user creation, user permission and access of the SPOC and SPOC assistant is based on the uniqueness of the email address.

In case an OBP would like to increase the number of recipients receiving communication from EMVO besides the SPOC & SPOC Assistant (if applicable), EMVO recommends using a dedicated mailing list/inbox e.g. "serialisation@emvo.eu", as the e-mail address of the SPOC Assistant account. However please note that the e-mail address needs to be linked to a registration of a contact person (forename & last name).

The Technical Info Pack has also been updated (some documents having been added) at page 46.

Moreover, if you select the EMVO Gateway, the following information that you have sent to the EMVO Helpdesk has been updated:

- Environment (IQE/PRD)
- Company Name
- SPOC Name
- SPOC Email

You will also find further information in the updated Guideline concerning the information an OBP, Company or MAH(s) must provide in face of one of the following scenarios (page 56):

1. MA transfers
2. MAH transfers
3. Divestiture and Acquisitions / Mergers and Acquisitions activities

EU HUB Release 1.5 & upcoming included changes

This week, EMVO communicated that the timeline of the EU Hub Release 1.5 has changed. The documentation for Release 1.5 did not meet EMVO Quality expectations and in consequence the release has been postponed.

In addition, it was necessary to align release planning in the EMVS ecosystem. As such, and following further consultation with our supplier, Release 1.5 will now be available in IQE in the first half of July, and in PRD in the first half of August.

The new release of the EU Hub will include several functionality changes for OBPs:

- The Product Master Data Report is enhanced and will report the data as uploaded by the OBP.
- The serial number randomisation test will be simplified. From Release 1.5 only the random guess chance test will be performed.
- Bulk activity for sample packs will be enabled. After Release 1.5, OBPs will be able change the pack status of 'free sample' and 'sample' packs in bulk, whereas it is currently only possible to do so for individual packs.
- In countries which require a national code to be included in Product Master Data, it will now be mandatory to do so from Release 1.5. This change is relevant to: Portugal, Austria, Germany, and Spain.
- Release 1.5 will provide more distinctive descriptions of the 'O1 System Not Available' messages.

We will of course be providing updates about Release 1.5, and when it will be deployed in ITE, IQE, and PRD environments.
Please note that the OBP interface will not change with Release 1.5.

Technical Update

Technical issue

Since Thursday 6th June, the EU Hub may be reporting a small number of O1 errors.
We are performing a regular re-deployment of the Retry Service with a restart of the affected node.

Root cause

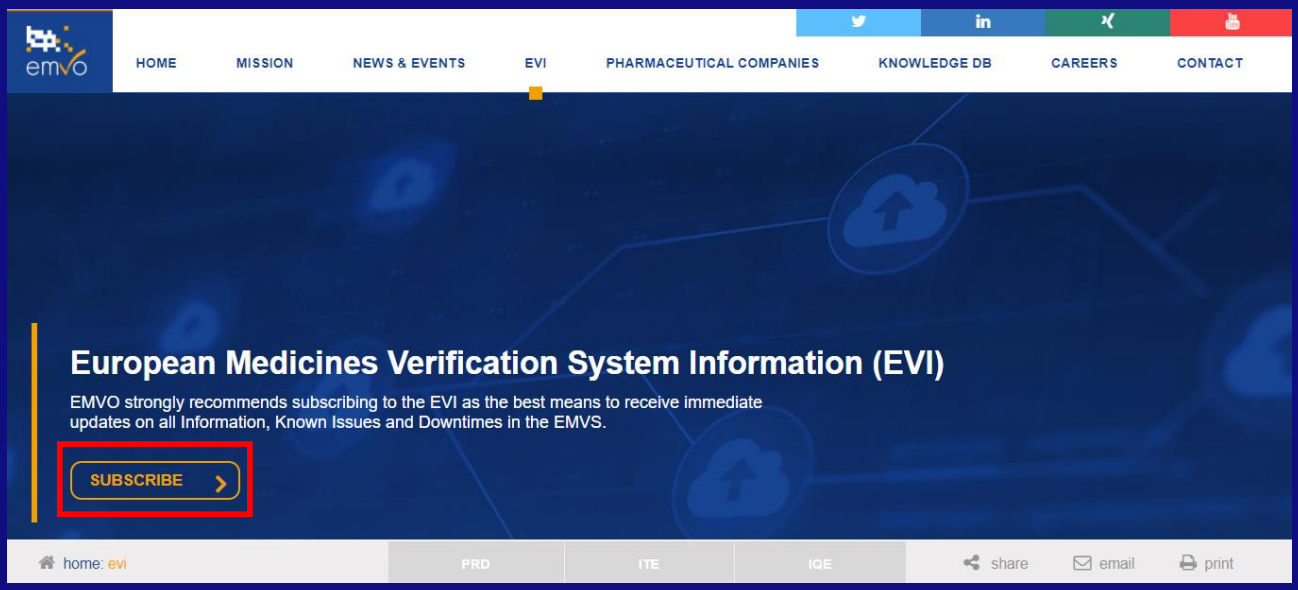
The root cause of the issue is still under analysis and no impact has been noticed except in alert queuing.
The impact of this issue is not high, except on the speed of alert delivery.

What next?

EMVO will provide an update on this issue as soon as possible. If you have any further questions, please be assured that EMVO's Helpdesk (helpdesk@emvomedicines.eu) remains at your disposal.
You will find the full EVI document here: https://bit.ly/2I2wzLb

European Medicines Verification System Information (EVI)

We strongly encourage all interested parties to subscribe to notifications from the EVI tool on our website. This is the best way to receive technical updates related to the systems of the EMVS, with general information also being posted here alongside Known Issues and Downtimes.



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European Medicines Verification Organisation

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