What's new at EMVO:

I. NMVO Update
II. New On-boarding Guideline
III. EU HUB Release 1.5
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.
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 Divestures & 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. Divestitures and Acquisitions / Mergers and Acquisitions activities
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.

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**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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