Friday, 5th July 2019

EMVO NEWSLETTER

European Medicines Verification Organisation

What's new at EMVO:

I. NMVO Contribution

II. General updates

III. Divestitures & Acquisitions guidance

NMVO Contribution

This week's NMVO contribution comes from Mitja Pirman, managing director at **ZAPAZ, the Slovenian medicines verification organisation** who gives an insight on the situation in Slovenia.

ZAPAZ, Medicines Verification Institute Slovenia, is an engaged and active member of WeMVO and SSR customer community from the early stages of the EU FMD project. In the NBS Pilot phase we on-boarded all Slovenian pharmacies, hospitals and wholesalers. We signed contract with 210 MAHs, who uploaded over 35 million serial numbers into the national system so far. After 9th February we actively supported End-user software providers to identify and mitigate reasons for fake alerts. Our cooperation and contribution proved to be successful, as also last week one of the IT providers started applying suggested fixes in some of the largest pharmacy chains. This gives us optimism that we will not encounter many End-user side technical reasons of generated alerts anymore.

Transition to the operation phase is, of course, challenging for all of us. Our prime goal within the transition phase is to establish the necessary processes and platforms that ensure easy identification of the root causes of suspicious events, information exchange and logging of activities within individual investigation cases. Process-wise, we classified communication and information forwarding rules and prioritisation for different types of alerts. In the recent weeks we started On-boarding the first voluntary pilot users to the alert management portal for shortening potential cause identification and simplifying information exchange. For example, if summarized details indicate that the reason likely lies on the End-user side (small letters, suspicious UID format), a link to the alert information form is propagated to the End User for marking inspection actions and leaving feedback.
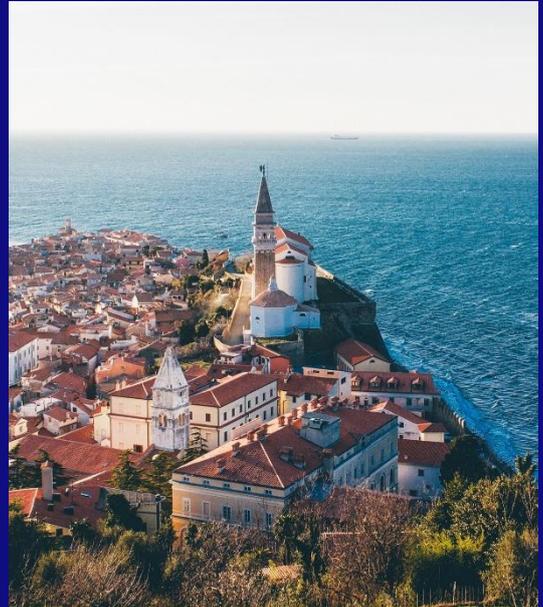
On the other hand, if we identify missing (A2, A3) or inconsistent (A52) data in the NMVS, the MAH is the first one who receives details and investigation form. Onboarded MAHs can close and resolve alerts on batch level or require photos of the pack for easier investigation. In the less obvious or even suspicious cases, for example, where PDR indicates different locations amid multiple dispensing attempts (A7), the NCA will be informed by default. Every investigation activity and all information are stored in the history log, so we can track response times for individual alerts. Stakeholders in Slovenia suggested that we should aim towards 24h resolution time for majority of the alerts.

I am optimistic; that we will manage transition to daily operations, perform our legal obligations and remain actively supportive towards all national and European stakeholders after the stabilization period ends.

Mitja Pirman
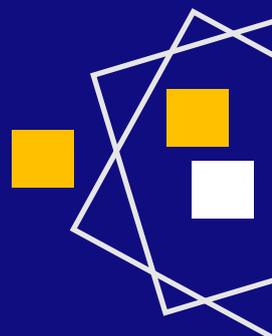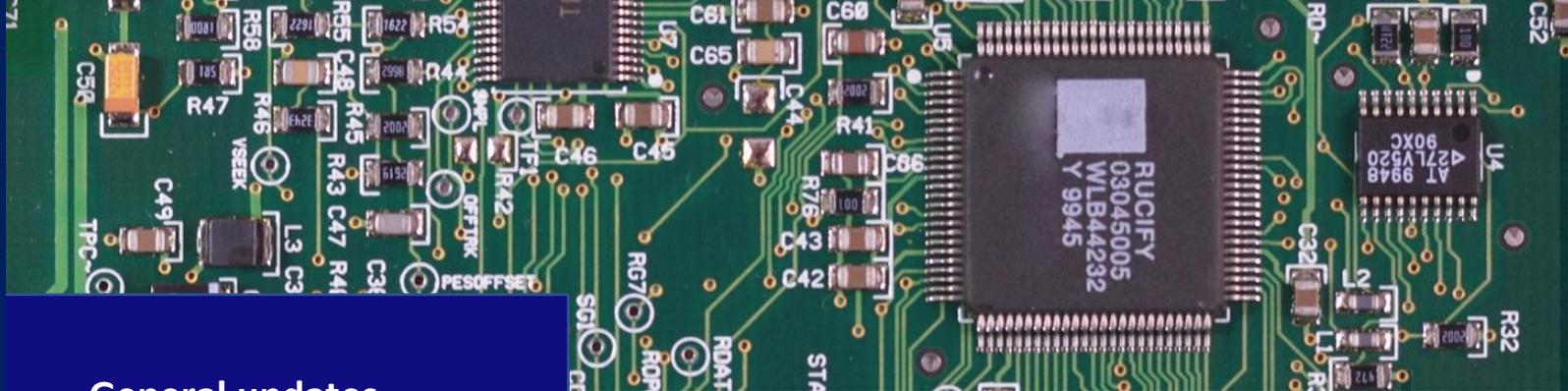
General updates

New EMVS Functionality Matrix

On 25th June, the new version of the EMVS Functionality Matrix was made available on the EMVO website.

To access the new version: **https://bit.ly/31Xky1w**

Technical documentation for EU Hub Release 1.5

On 1st July, EMVO made available the draft technical documentation for EU Hub Release 1.5 via the OBP Portal. The Technical Information Pack includes all draft documentation and code samples.

For further information, please follow this link: **https://bit.ly/2J0sQhy**
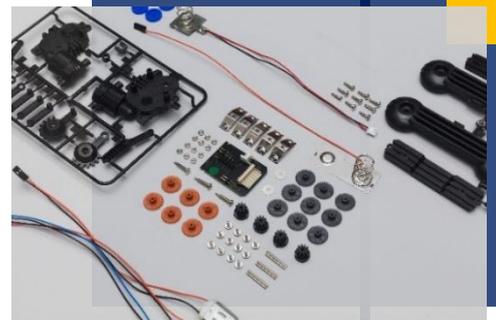
EVI entries

On 20th June, a planned downtime was announced for the French national system.
For further information, follow this link: **https://bit.ly/2Xr1aLp**

On 25th June, an incident related to the Lithuanian national system was communicated on the EVI.

Divestitures & Acquisitions guidance

Once OBPs are fully on-boarded to the EU Hub EMVO continues to provide a range of assistance through our Helpdesk. One subject we assist with is aspects of the EMVS which might be impacted in Divestiture & Acquisition (D&A) activities of marketing authorisation holders.

EMVO has published a series of documents related to D&A activities on our website in the OBP section of our Knowledge Database.

In the OBP Divestitures and Acquisitions Guide, we provided guidance on D&A scenarios such as:

- Acquisition/divestiture of a part of the business affecting a set of products for a set of markets (i.e. affecting a set of SKUs)

- Merger of two companies

- Acquisition of a company by another company

- Scenarios where a new legal entity is created by a Transferor prior to divestiture in order to carve out the divested business

We have provided information on the following areas which should be considered in a D&A scenario when interacting with the EMVS:

- Establishing/updating contract with EMVO/NMVOs

- The uploading of data (product master data, product pack data) to the European Hub

- Production-related topics

- Receipt and processing of alerts e.g. suspicious pack alerts

- Access to product history in the EU Hub and NMVSs

In addition to this guide, we have also provided template letters related to Data Upload and Wholesale Transactions. These templates can be used by marketing authorisation holders to notify EMVO of D&A activities.

If you have further questions related to D&A activities after having consulted these documents, we ask that you contact our Helpdesk directly at the beginning of the D&A process, in order that we are able to provide full advice and assistance.
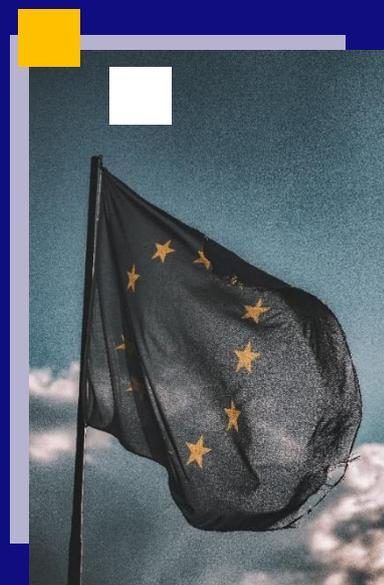
European Medicines Verification System Information (EVI)

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.
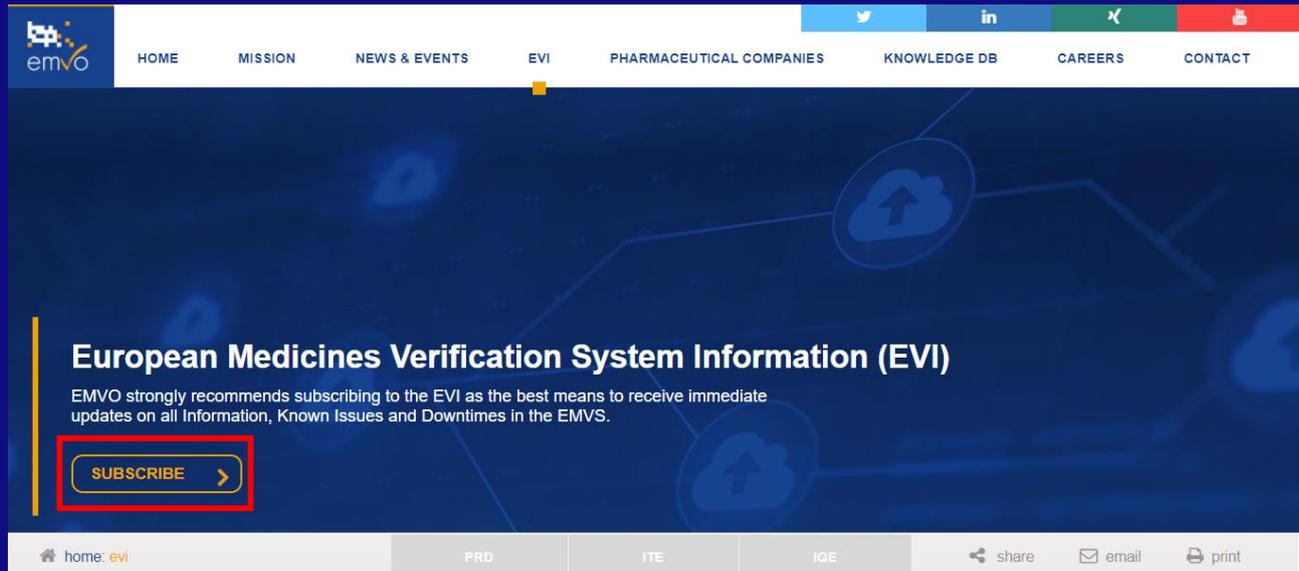
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