Tuesday, 29th October 2019

emvo NEWSLETTER

European Medicines Verification Organisation

What's new at EMVO:

NMVO Update

After one and the half years of preparation the Hungarian Medicines Verification System (HUMVS) is up and running since 9th February 2019. In the last 8 months more than 200 million packs, 16,500 batches and about 5,000 product codes were successfully uploaded.

The number of the end users connected to the HUMVS is 3.250, the biggest group is the community pharmacies (2.936), hospital pharmacies and community pharmacies in hospitals (184), wholesalers (111) and dispensing doctors, other users (19). These partners are served by 38 IT service providers. The connection rate of the end uses is above 99%. Hungarian Medicines Verification Organization (HUMVO) has about 300 Marketing Authorization Holders (MAH) partners.

After the go live the Hungarian National Competent Authority (NCA) announced Grace period which is still valid, and the end of it is not defined yet. The key messages of this period are that the regulation should be followed by everybody, but in some alert cases the product can still be dispensed to the patients. This is a very important period for every stakeholder affected by serialization to use the systems, to learn and correct mistakes before the regulation will be strictly applicable, and the grace period will end.

The number of the weekly transactions in HUMVS is more than 5,5 million, and the rate of the successful transactions is above 99% in the last 16 weeks. In week 41 is was 99,55%, which is a new record since the go live.

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In the first weeks after 9th February the daily number of alerts were around 12.000, and the key reasons behind were scanner related issues in ca. 70-80%, and the missing uploads in ca. 20-30%. Most of the scanner issues came from exchange of the Y and the Z, or Uppercase and Lowercase letters.

The Hungarian team is working very closely together with the IT service providers of the end users (meetings, list of the end users with the highest number of alerts). The seven different IT systems in community pharmacies were checked and the experiences and recommendation for further development were shared with the providers.

On the other hand, the list of all alerts generated in the system are shared with the MAHs to support them to correct the uploading mistakes, missing uploads.

The result is, that the number of alerts decreased to 4.000-4.500 per day (99,4% success rate). Nowadays the higher number of false alerts came from uploading mistakes and missing uploads, most of the end user related issues were eliminated.

HUMVO has close working relationship with the NCA, sharing weekly statistics, and providing the necessary data upon request for them to fulfil their role. The focus of the NCA now are the end users who don't use the system at all, and the MAHs don't upload anything into HUMVS via the EU Hub, but have products marketed in Hungary. Targeted inspections and warnings are coming, in serious cases penalty will be applied.

Ágnes Pap-Tóth

General Manager

Letters of Announcement

On the 4th October, EMVO released a Letter of Announcement which provided clarification and updated guidance to wholesalers on the verification of one pack per batch (released after 9th February) upon receipt.

For the full letter, please follow this link: https://bit.ly/2qBAUhS

On the 15th October, EMVO issued a Letter of Announcement on Multi-Market Packs, which restated the importance of uploading the master, batch and pack data for all markets to which the MMP can be distributed.

For further information: https://bit.ly/2VOHFZh

EU Hub Release 1.6

On the 10th September, EMVO officially announced Release 1.6 of the EU Hub, and stated that the Release would be available in IQE in mid-October, and in PRD in mid-November. Some of the improved functionalities which the release will bring to OBPs are an enhanced Product Master Data Report, a simpler serial number randomisation test, and the enabling the bulk management of sample packs.

The OBP Interface Schema 2016 will remain available with this release.

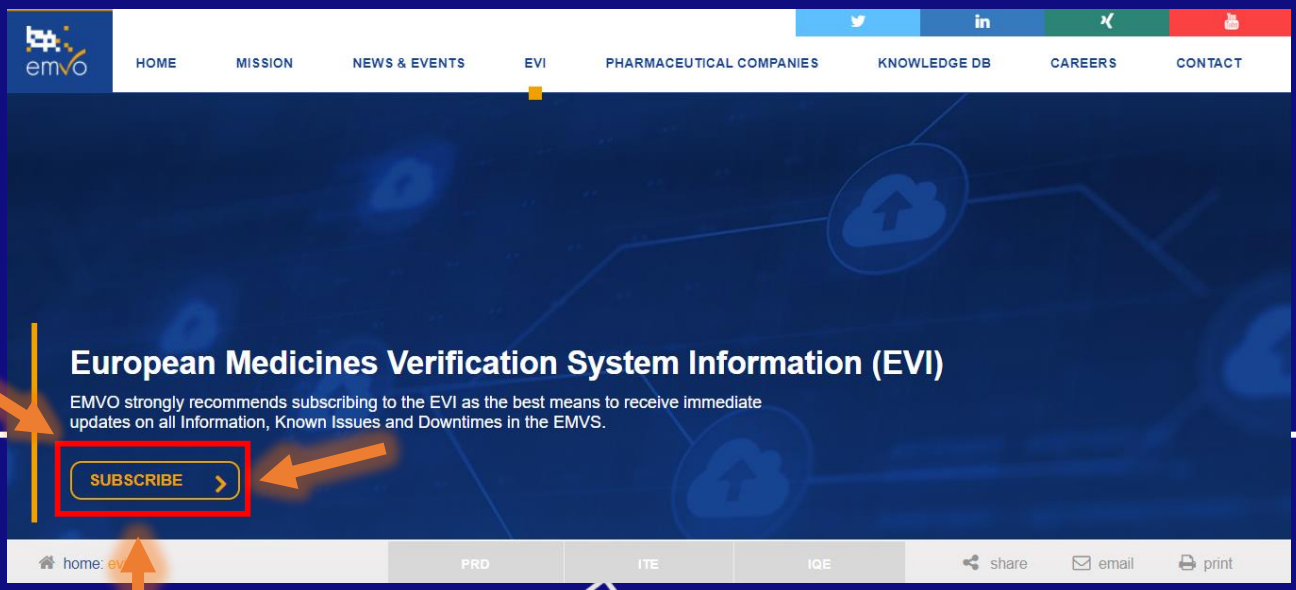
For the full list of functionalities, please follow this link: https://bit.ly/2lSfISj

Since then, on 18th October EMVO communicated on the successful deployment of Release 1.6 to the Integrated Quality Environment (IQE). Please see Letter of Announcement here: https://bit.ly/2JinKwD

On Friday 25th October, we announced that Release 1.6 will be available for use in the Production Environment (PRD) on Saturday 2nd November. Please see the Letter of Announcement here: https://bit.ly/2Wj3Tmm

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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