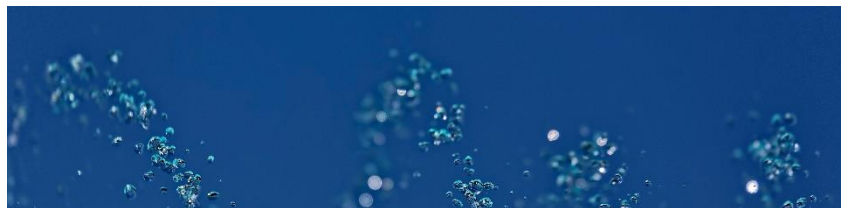


EMVO NEWSLETTER

European Medicines Verification Organisation

NMVO Update



A new medicines safety verification system has been successfully implemented in Latvia. It is operational already for 7 months with the aim to prevent the risk of patients receiving falsified medicines. Since 9th February 2019 end-users in Latvia have decommissioned from the system more than 4.6 million medicine packages.

There are already 1,188 end-users connected to the Latvian system. All pharmacies (822) and hospitals (30), most healthcare institutions (205) and wholesalers (57) have connected to the system. Dispensing doctors (dental institutions/ practices and general practitioners) have been less active. They started onboarding mainly after 9th February. They have alternative to buy medicine in pharmacy where the package is decommissioned.

There are almost 40 million active packs in the Latvian repository. Every week there are in average 0.5 million transactions done. Dispensing activity is steadily increasing. 245 Marketing Authorization Holders (MAH) have uploaded more than 3,900 products into the repository.

In Latvia the average number of L5 alerts generated in the system are 1,200 per week. All current alerts are related to technical and procedural issues. Around 40% of alerts are coming from MAHs (including Parallel Distributors) through EU HUB. The number of alerts created by end-users are only 0.1% of the total number of verified medicine packages.

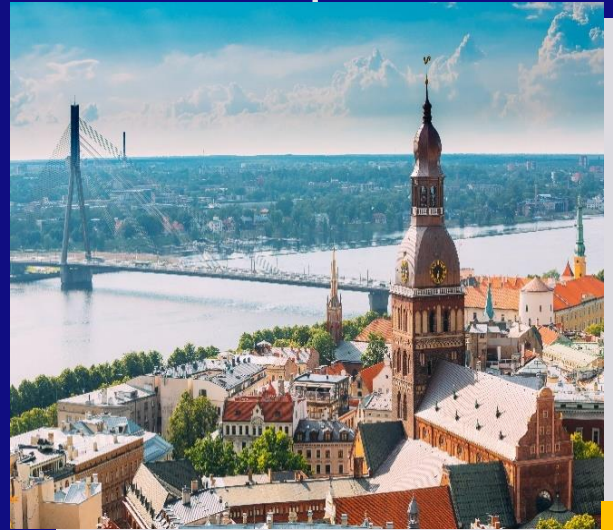
What's new at EMVO:

- I. NMVO Update
- II. Technical Update
- III. Letters of Announcement



Main reasons for L5 alerts in August 2019:

- Upload of incorrect products and its batches in EU HUB by MAHs;
- Verify packages that are not fully equipped with safety features;
- Attempt to decommission an already decommissioned pack;
- Scanner and IT system configuration issues;
- Indian packages.



In case of an alert, LZVO contacts both end-users and producer's representatives to check the causes of the alert message, their actions and outcome. In majority of cases the reason is identified within 2-3 days. In more than 10 cases also national competent authorities (NCA) are involved to clarify the situation.

There is no stabilization or grace period in Latvia. All involved stakeholders must comply with Delegated Regulation and fulfil their tasks. Transitional period does not apply for products which were released before 9th February 2019 with a unique identifier. The unique identifiers for such products must be uploaded to the European system before distribution to the market.

LZVO regularly reports to its NCA – Department of Pharmaceuticals of Ministry of Health, Health Inspectorate and State Agency of Medicines. The Health Inspectorate undertake regular inspections to pharmacies, healthcare institutions and wholesalers and control distribution of medicines and decommissioning is a part of the control. LZVO provide the necessary information to authorities to fulfil their tasks. The current focus is to those end-users who have not connected to national system and who do not use the system.

Inese Erdmane
Chair of the Board





Technical Update

On the 10th September, EMVO announced Release 1.6 of the EU Hub, which is planned to 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 of the bulk management of sample packs.

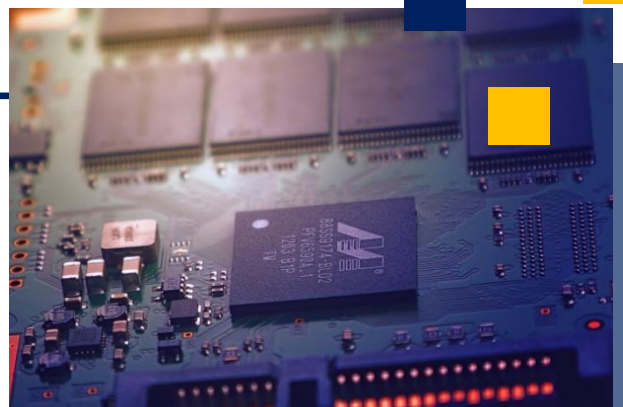
Release 1.6 will also make the provision of a 'National Code' in the Product Master Data mandatory for countries who have this requirement in place. Currently this is only relevant to Portugal, Austria, Germany and Spain. Moreover, with this Release, EMVO will provide for more distinctive descriptions for the O1 error and the time stamp format in alerts will now be in Zulu-time (aka Z-Time).

Finally, please note that the OBP Interface Schema 2016 will remain available after the Release.

EMVO will communicate on the latest status of the deployment of Release 1.6 and provide more concrete delivery dates in good time.

For the full list of functionalities, please follow this link:

<https://bit.ly/2ISfISj>



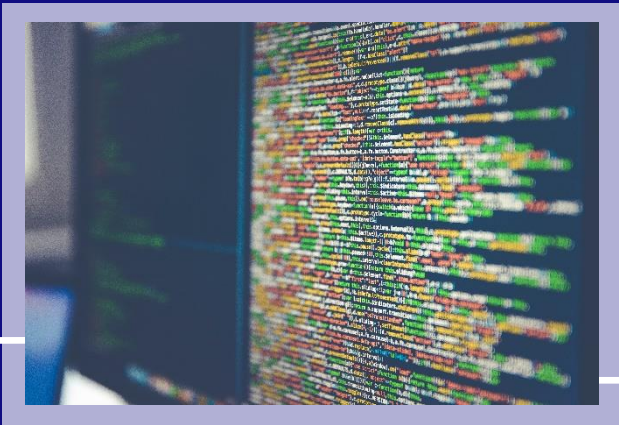
Letters of Announcement

On the 21st August, EMVO released a new format for alert messages in a number of national systems.

For the full list of formats, please follow this link: <https://bit.ly/2Hh0fmX>

On the 5th September, EMVO issued further guidance on how to prevent the generation of alerts by leaving sufficient lead time between data upload and verification/decommissioning.

For further information: <https://bit.ly/2kPv0ap>



On the 10th September, following several recent and malicious attempts to gain financial and other sensitive information, EMVO reminded OBPs to be cautious with invoices and requests for financial and any other information linked to the EMVS.

For further information: <https://bit.ly/2lqYX0Z>

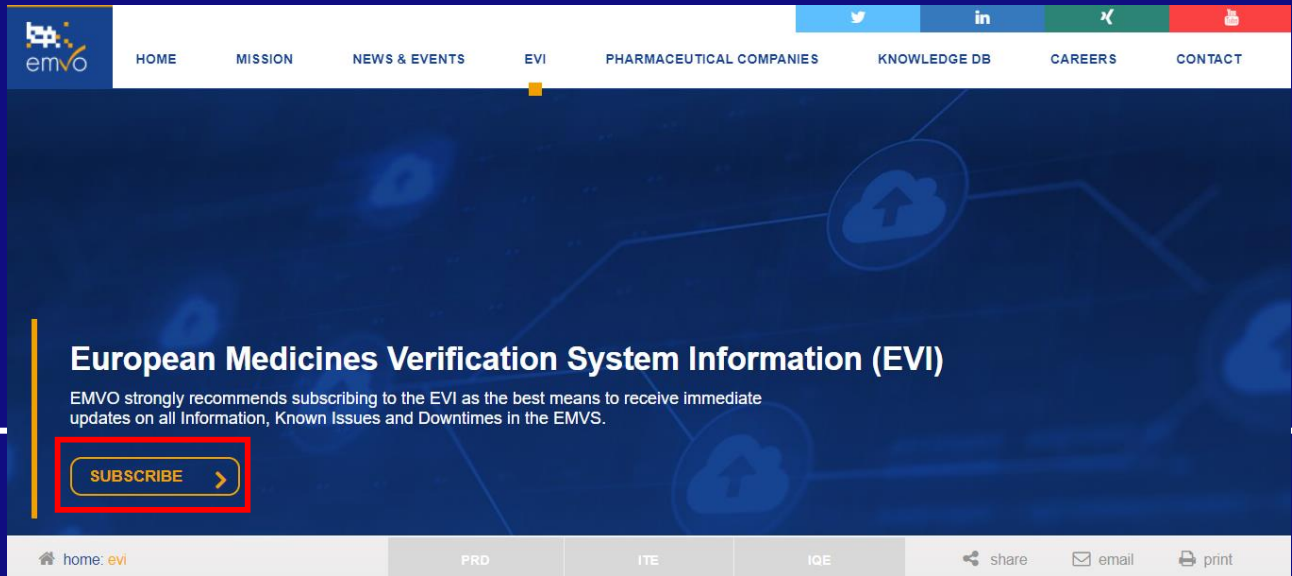
On the 24th September, EMVO published the latest version of the NMVO Fee Models overview on our website.

For further information: <https://bit.ly/2kPvqgZ>



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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