

EMVO NEWSLETTER

European Medicines Verification Organisation

What's new at EMVO:

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NMVO Update - Romania



Implementing the Falsified Medicines Directive in Romania has proved to be a complex and challenging endeavor. Key factors in reaching the milestones set out so far, have been the team's dedication and the constant communication with the other NMVOs and with EMVO. The collaboration between these entities has led to the project being managed effectively, the efforts of the group having been focused on a common goal: ensuring patient safety by preventing falsified medicines from entering the legal supply chain.

After nine months the NMVS overview in Romania is as follows:

- 7,744 pharmacies registered in NMVS, out of 9,551;
- 502 hospitals registered in NMVS, out of 520;
- 284 wholesalers registered in NMVS, out of 311;
- 285 MAH registered in OSMR, out of 609.

A stabilization period has not been officially communicated in Romania. The NCAs conveyed the message that all End Users must register in the NMVS, and since August 2019 there are fines in place for non-compliance with the Delegated Regulation (EU) 2016/161 for MAHs, End Users and NMVO.

The scanning activity has increased while alerts decreased: in week 45 there were 0.58 % alerts out of 4.716.539 transactions.

OSMR uses an alert management software which provides an automated solution for alert handling, which is designed to optimize the procedure along with response times. Through this application we constantly analyze alert data in order to increase the accuracy of the automated alert resolution process. The experience of working with alerts allowed specialists to implement ways to automatically identify known issues and formulate relevant assumptions as first resolutions.

As a final step, the software sends automated reports to End Users, enabling them to quickly understand and fix the identified technical issues.

Another essential element of the software is the status overview it provides on all existing L5 alerts, enabling OSMR to offer rapid answers to queries coming from the NCAs.

The result can already be seen in the decreasing number of alerts from the last weeks.



The onboarding process of MAHs to OMSR has benefited from the collaboration with EMVO which involved sharing information from both sides, ensuring thus full transparency of the process for both EMVO and OSMR. For more information on the enrollment process, please visit our website: <https://osmr.ro/>

The uniqueness of the project remains a constant challenge and an opportunity for the network of actors involved to set the basis of a knowledge sharing platform, tailored to efficiently meet the needs of a successful medicines verification system implementation.



Letters of Announcement

On 4th November, EMVO issued confirmation that, on 2nd November, Release 1.6.02 of the EU Hub had been successfully deployed to the Production Environment (PRD). We had previously announced the functionalities of this release.

For the full announcement, please follow this link: <https://bit.ly/34nrLIY>

On 21st November, EMVO issued guidance to OBPs on the alert message category “manualentryflag” as it has been noted that a number of end user systems are misconfigured and not correctly announcing whether data has been entered manually.

For further information: <https://bit.ly/37JI4mo>

On 22nd November, EMVO announced that the finalised deployment date for Release 6.3 of the OBP Portal was 23rd November. This release was successfully deployed as per the schedule announced.

To see the full announcement, please follow this link:

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

EMVO Helpdesk and Support

As part of EMVO's goal of constantly improving our efficiency and strengthening the support we provide to OBPs, we recently announced that we are enhancing our Helpdesk and support capabilities. Our support team will be fully brought in-house by the end of 2019, in order that they can work hand-in-hand with our Operations department. This in-housing will allow for a full transfer of knowledge between departments.

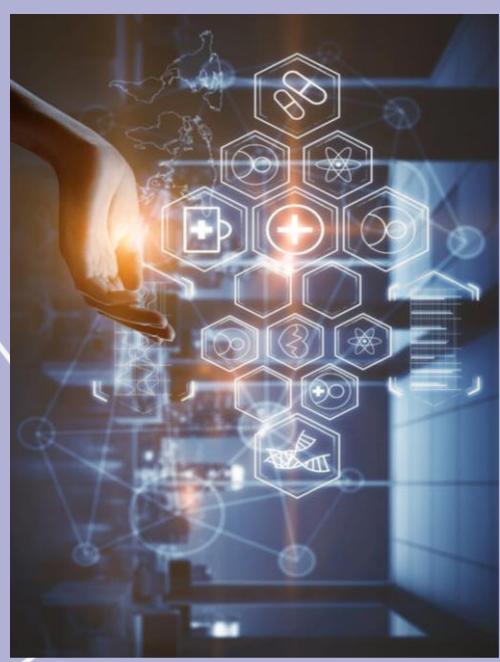
In addition, from **2nd January** we will have new contact information for the EMVO Helpdesk. A new number will be activated: **+32 2 657 00 08**. In order to ensure that this change is not missed, we will be issuing an additional announcement nearer the time. See the full announcement here: <https://bit.ly/2QZloGP>

Published documents

On 12th November, updated versions of the OBP On-boarding Presentation (v12.0) and OBP On-boarding Guideline (v11.0) were published on the Knowledge Database of EMVO's website.

EMVO regularly updates the information and documentation available on the Knowledge Database. During the past months, this section of our website has been re-designed.

EMVO recommends that all OBPs regularly check this section of our website.



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.

European Medicines Verification System Information (EVI)

EMVO strongly recommends subscribing to the EVI as the best means to receive immediate updates on all Information, Known Issues and Downtimes in the EMVS.

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