

NEWSLETTER



MAH INVOICING 2019

According to the OSMR General Assembly's decision of 03.07.2019, the annual fee for affiliated members for 2020, meaning the **operational fee for the National Medicines Verification System (NMVS) will be 10.500 EUR/MAH.**

The invoicing process will begin soon, and **the payment deadline is set for December 10th, 2019.**

END USER'S NMVS ONBOARDING

In order to be able to perform all the transactions in the NMVS and thus comply with the Delegated Regulation (EU) 2016/161, **all End Users must complete a complex onboarding process, providing thus proof of their legitimacy.**

As we want to ensure all the steps are followed accordingly and the necessary documents are submitted correctly, a **summary of examples for filling in the Participation Request, Terms and Conditions – Operational Phase, Self-Training Confirmation**, is now available on our website: [Example of Filling In Documents](#)



NATIONAL MEDICINES VERIFICATION SYSTEM – NMVS

An updated version of the NMVS PROD, namely: **NMVS Core Release 1.06 is planned for roll-out in December 2019.** With this Core Release it is planned to introduce a new version of the NMVS interface (v4) and to implement an upgraded version of the NCA (National Competent Authorities) Report as per EMVO User Requirements Specifications.

As interfaces are used by software suppliers to connect the software used by the End Users to the NMVS, it is very important for the **software suppliers to upgrade their software (using the interface version v3) until end of October the latest.**

Meanwhile, a new version for NMVS – 1.04 and for NMVS Reporting Tool – 1.01 have been rolled-out in the Production Environment since August 2019.

IQE TESTING

OSMR would like to remind End Users that IQE Testing is a **mandatory step after each major update of the NMVS PROD**. Thus, starting with 30.07.2019, OSMR started creating ADMIN accounts for each End User on the NMVS integrated quality environment.

All End Users (Clients) must create at least one End User Location account (User) and **perform a number of 8 testing scenarios**, according to the documentation which can be found on the OSMR site – IQE Testing: [IQE Testing Info](#)

Furthermore, the testing has to be done compulsorily using the GLN codes that have already been declared in SIMI (Registering and Incident Management System).

It is of the utmost importance to understand that **undergoing tests in the PROD environment leads to a growing number of false L5 alerts in the system which are being reported also to the National Competent Authorities. Therefore, the tests must be performed exclusively in the testing environment (IQE).**

MANAGING NMVS ALERTS

During the last months, upon close and constant monitoring of the L5 alerts generated by the NMVS, the OSMR technical team has noticed an increase in type 22 Pack Alerts for the same medicines' packs and mostly from Hospital type End Users.

Upon further investigation it has been concluded that the false L5 alerts are generated because the unique identifier is scanned every time medicines are taken out of the same pack.

As this type of false alert needs to be eliminated, the recommendation for **Hospitals**, in this case, is that **the decommissioning be done only once, upon opening the medicine pack**.

In NMVS, once a medicine pack has been decommissioned, its status in the system is changed: from "active" to "inactive". Therefore, decommissioning an inactive pack will always generate a L5 alert in the system.

For information related to **alerts generated by the National Medicines Verification System**, please visit our site where we created this new section dedicated to alerts: [NMVS Alerts](#)

SOFTWARE SUPPLIERS' TELECONFERENCE

Constant communication with the software suppliers is a key action in ensuring the number of false alerts in the system is reduced and that End Users are able to operate the system correctly.

Therefore, OSMR will organize a virtual meeting with the above-mentioned parties to address all current issues and answer pending questions. The **teleconference scheduled for Thursday, September 19th, will take place via Skype, starting with 11:00 until 12:30**. To register, please send us an email at: Felicia.Schiopu@osmr.ro

