

NEWSLETTER



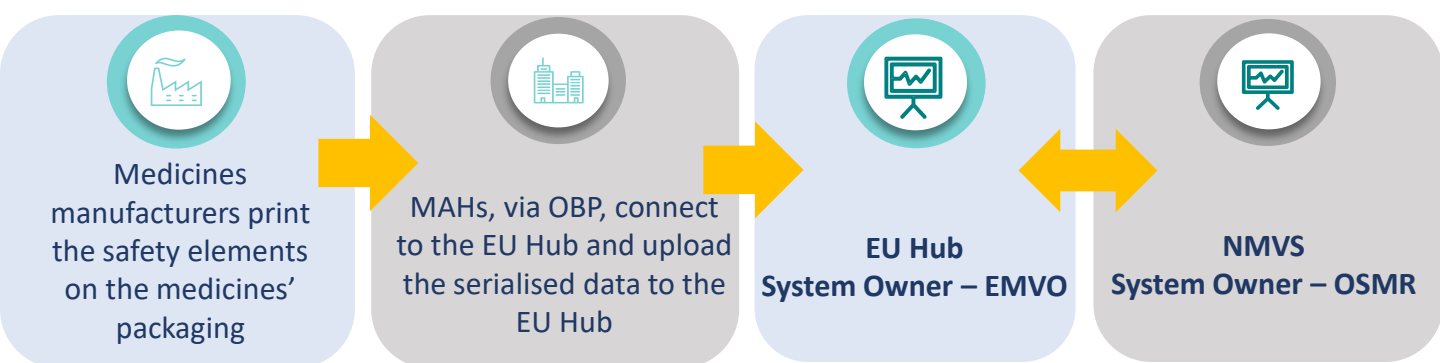
OSMR ONBOARDING PROCESS – STAKEHOLDERS’ EFFECTIVE COLLABORATION

All stakeholders have understood the importance of maintaining an operational European Medicines Verification System, as the main goal of this complex European project, which is preventing falsified medicines from entering the legal supply chain, carries a great responsibility that is equally shared.

A significant amount of effort is done by the pharmaceutical companies, which apart from incorporating the unique identifier (UI) and the anti-tempering device on the outer packaging of all medicines for each individual sales package, also bear the cost of the project implementation.

Effective and dynamic communication between all involved parties has proven essential up to this stage and its value continues to be developed. Therefore, a continuously improving stream of communication between EMVO, OBP companies, NMVO and MAHs has led to an optimal compliance with the procedures for onboarding OSMR and uploading data to the EU Hub.

An aspect which needs to be emphasized is that **EMVO and OSMR are collaborating ever more closely to ensure that the general rule which states that a MAH which is listed as active on the local market and for which the OBP company has uploaded data to the EMVS via the EU Hub has also onboarded the NMVO, is followed.**



MAH INVOICING PROCESS FOR 2021

According to the OSMR General Assembly’s decision of 11.06.2020, the annual fee for OSMR affiliated members for 2021, meaning the **operational fee for the National Medicines Verification System (NMVS) will be the same as this year: 10.500 EUR/MAH.**

The invoicing process and the payment deadline will be announced in due time.

NATIONAL MEDICINES VERIFICATION SYSTEM – NMVS

Starting with April 16th, version 1.06 of the NMVS was made available for End-Users. The newly added functionalities aim at further stabilizing the system as well as towards continually reducing the number of alerts. **On July 29th, the latest version of NMVS Reporting Tool was installed in the production environment, providing thus a larger number of reports to the National Competent Authorities.**

EU HUB

In a Letter of Announcement, EMVO reminded OBP companies that **the 2016 schema of the OBP Interface is no longer supported as of EU Hub release SR1.7.01**, which has been implemented on the 18th of April 2020.

The request from EMVO is that companies which are still using the 2016 schema, to kindly **switch to the 2018 schema** in order to continue to be able to upload data and remain connected to the EU Hub. **As of Q4 2020, the 2016 schema will no longer be operational.**

If OBP companies are not aware of whether they are using the 2016 schema, the recommendation is to consult with the IT provider and take appropriate action accordingly.

NMVS END-USERS

As it can be seen from our bi-weekly report ([bi-weekly report](#)), **a large number of End-Users has onboarded the National Medicines Verification System and are using the system, complying thus with the European and National legislation.**

Our Operational Department is constantly offering support and providing the required information in order to offer the complex onboarding process a smoother understanding.

The latest information made available on our site, targeting the End-Users, is related to the resetting of passwords in NMVS (for both account types: ADMIN & LUF). Furthermore, two other documents have been uploaded – **The Instructions' Manual** related to the on-boarding and use of the NMVS and the **Working Instruction** comprising information about the **on-boarding and access to the NMVS.**

GDPR

We would like to remind you that OSMR processes the data provided by the End-Users and by the Affiliated Members according to the rules and principles of Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR) and the applicable Romanian legislation.

The recipients of the personal data related to the specific purpose of processing may be, as required: the OSMR employees with specific attributions for the purpose of processing, the persons empowered by OSMR, who, under the direct authority of the operator are involved in the supply of goods and services (software providers, consultant, auditors etc.), the Romanian National Agency for Medicines and Medical Devices (ANMDMR) and the European Medicines Verification Organization (EMVO).

OSMR does not transfer personal data outside the European Economic Area.

