



NEWSLETTER

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MAHs INVOICING PROCESS FOR 2023

By now most of our affiliate members know that *the month of September marks the beginning of the invoicing process for the following year, process which this year is scheduled to be finalized by December 19th, 2022.*

The novelty element for 2023 is the amount of the operational fee for the National Medicines Verification System (NMVS), which, following the OSMR General Assembly's decision on 13.04.2022, has been set for **10,000 EUR/MAH**.

The difference in the amounts set during the previous years comes from the positive dynamics of the affiliated members.



Each year the budget is carefully analysed and planned based on an accurate overview of Marketing Authorisation Holders (MAHs) expressing their interest to continue or begin marketing their medicinal products on the Romanian market, abiding thus the Falsified Medicines Directive's provisions.

Therefore, the amount of the operational fee can differ from one year to the other.

ALERT MANAGEMENT SYSTEM – AMS ROMANIA CONNECTED

As most of you are aware from EMVO's communications on the subject, the Alert Management System (AMS) project has as goal ***to maximise the efficiency of alert management in the European Medicines Verification System (EMVS).***

The structure of the AMS is the following: an AMS Hub where the OBPs are directly connected to and the various National AMSs, which will allow the end-to-end communication between all stakeholders to investigate alerts.

EMVO has also planned to deliver the AMS Portal, a graphical user interface that can be used by the OBPs to interact with the AMS Hub.

The Pilot Phase of the AMS started on October 4th, 2021, and the countries which volunteered to be part of it are Germany, Slovenia, Romania, Poland, France and Cyprus.

EMVO has organized information sessions dedicated to the AMS Portal for the OBPs and they have also created the AMS Portal User manual – which was made available on the Technical Info Pack section of the OBP Portal.

A lot of effort has been placed into this project, both by EMVO and the pilot countries.



The first country to connect to the production environment of the EU AMS Hub was Slovenia, soon followed by Romania in August 2022.

The established communication flow at national level between the OSMR team and the stakeholders, in particular the End-Users, has not and will not be impacted in any way by the connection to the EU AMS Hub.

