NEWSLE

DECEMBER 2022 ISSUE 4

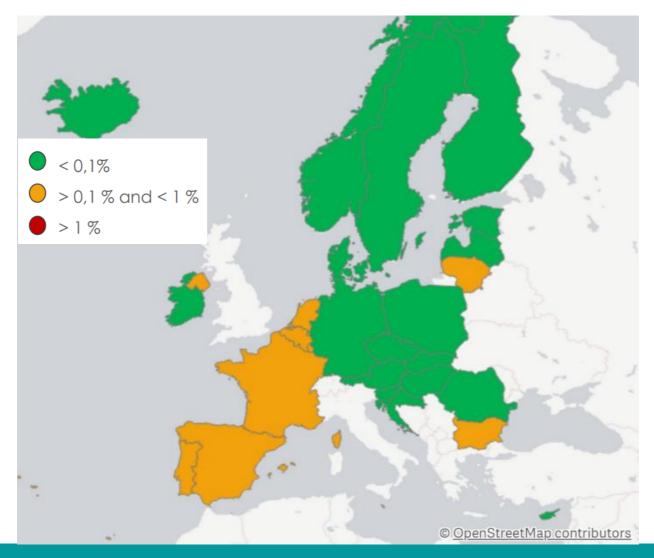
ALERT RATE IN THE EMVS

The importance of a functional and robust European Medicines Verification System (EMVS) is a high priority for all the actors on the legal distribution chain.

All the efforts are now concentrated towards minimizing the number of alerts generated by the system.

At European level, it has been decided that the *alert rate* objective that needs to be reached be *less than* 0,05%.

Since 2020, through consistent hard work, Romania has successfully managed to keep the alert under the established threshold.

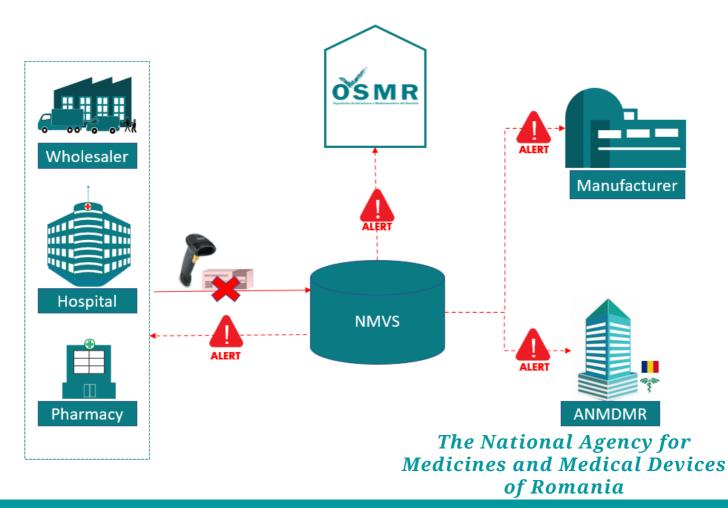


The EMVS is designed as such that when a medicine pack is scanned at the point of dispense, it will be checked and verified for authenticity against a national repository.

If the Unique Identifier (UI) – which is encoded in a 2D Data Matrix code holding information related to the pack - *matches the UI in the repository, the pack is dispensed to the patient.*

On the other hand, should the information taken from the UI differ from the information held in the system, *the medicines pack's authenticity cannot be verified, and an alert will be raised.*

In the image below, the flow of the alerts in the National Medicines Verification System (NMVS) can be visualized:



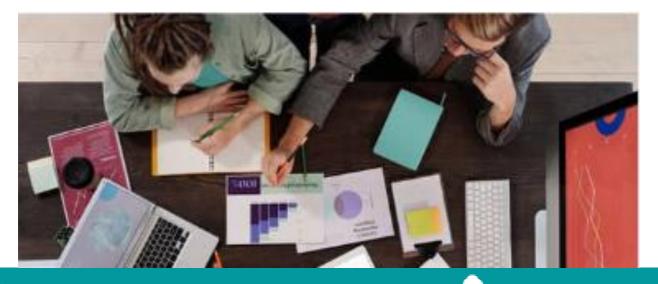
ALERTS' GUIDE

Thus, the alerts generated in the NMVS are sent to the End-User, OSMR, the Medicines' Manufacturer (via the EU Hub), the National Agency for Medicines and Medical Devices and EMVO.

The OSMR Team has set the basis for an active communication with the stakeholders, emphasizing the importance of the correct scanner and software configuration, as well as the accuracy and quality of the data uploaded to the European Hub.

Owing to its continuous improvement principle and its willingness to share information in the most comprehensive manner possible, OSMR has developed an *Alerts' Guide* which can be found on the OSMR website: <u>NMVS Alerts</u>

The Guide aims at providing further information about the processes in the NMVS, the status of the medicines' packs as a result of a transaction undergone, the most frequent types of alerts and their possible causes and most importantly, *some recommendations for the End-Users in their process of alert handling*.



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