NEWSLETTER

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BEST PRACTICE - REDUCING THE NUMBER OF ALERTS IN THE EMVS

The OSMR Team shared with the European Medicines Verification System (EMVS) Community the most important elements of the process of reducing the number of alerts generated by the National Medicines Verification System (NMVS), that we would also like to outline in our Newsletter.
The alerts' percentage generated by the NMVS has been significantly reduced during the previous year:

Behind these numbers lies incredible effort and commitment showed not only by the OSMR team, but also by all the parties involved in the project: manufacturers of medicinal products, wholesalers, pharmacists from community pharmacies, hospitals and other medical centers, software providers, the National Competent Authorities, EMVO & Arvato, without whose excellent cooperation the positive outcomes would have been in vain.

OSMR emphasizes the importance of teamwork and cross-functional collaboration and in the case of

the reduction of the alerts generated by the NMVS, promoting a collaborative and idea-sharing environment has been an impactful approach.
Thus, the basis for an active communication with the stakeholders has been set, 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.

An important element of the stakeholders' communication is represented by the ***Software Providers' Virtual Gatherings***. The main goal that has been achieved was the consolidation of a working community that has managed to provide valuable input towards lowering the number of alerts.

Furthermore, ***a workflow has been established, whilst being constantly updated and improved, with the purpose of analysing the alerts and identifying their root cause***. Every step of the alert`s investigation, be it manual or automated, is checked in terms of QA procedures and legally to observe the Delegated Regulation`s provisions. This incredible amount of work made it possible to minimize the large number of L5 alerts that are caused by technical and operational issues.

Moreover, an application has been developed – ***The Alert Manager Application*** – which has significantly improved the process of managing & minimizing the alerts raised by the NMVS.
The actions presented above have proven to be successful undertakings, however one crucial element fosters the workflow, consisting ***of the development and implementation of a procedural framework, constantly updated for improvement and followed by all the involved parties.***

All the relentless effort that the OSMR Team has put in minimizing the number of alerts raised by the system succeeded in placing ***Romania among the countries in Europe that have managed to achieve the objective set for reaching an alert rate of less than 0,05%.***

COUNTRIES PREPARING TO JOIN THE EMVS - ITALY AND GREECE

Two more countries are preparing to join the European Medicines Verification System (EMVS): ***Italy and Greece.***

At the time of entry into force of the Falsified Medicines Directive, the two countries had their own systems in place for the verification of the authenticity of medicinal products. Thus, a transitional period has been granted.

According to the Delegated Regulation 2016/161, Art. 50, the latest date for implementing the FMD in the respective countries is ***February 9th, 2025***.

Romania has offered its support throughout the on-boarding process as best practice sharing is a value-added element that is promoted throughout the EMVS Community.