March 2022

EMVS Community Newsletter

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Introduction: Celebrating the EMVS third anniversary

To celebrate the EMVS third anniversary on February 9th 2022, Andreas Walter, EMVO's General Manager, thanked all involved parties and reminded once again that patient safety can only be protected when all parties work together – *"The EMVS is a challenging project. It's a complex landscape and there are many parties involved. Yet it has become evident*

that working together towards the same goal is not only feasible but has proven to be successful. EMVO continues to support the EMVS Community by strengthening the key priorities and encouraging mutual collaboration and commitment of all users."

For more information on the EMVS Community's achievements and upcoming projects, please consult EMVO's communication.

Alert Management System (AMS)

The Alert Management System (AMS) is an EMVS project involving representatives from all EMVS stakeholders. The AMS's purpose is to support users at all levels on alert investigations. The AMS will guarantee anonymity in the alert handling process while offering an environment that streamlines communication and alert statuses across the AMS Hub and national alert management systems, connecting MAHs, Wholesalers, Pharmacies and Hospitals together. This will enable a more efficient management of alerts.

The first release of the AMS took place in October 2021, kicking off the first Pilot phase with 10 OBPs testing the AMS. In January this year, 20 more OBPs joined the AMS Pilot. To prepare a progressive roll-out to the community, 100 additional OBPs were invited to join the AMS in the month of February. The AMS Team has been working closely with NMVO's to prepare the End-to-End Pilot that is planned to start in May 2022.

The AMS Team plans to have four AMS Summits (info sessions) in March, as well as an End-to-End Demo of real-life scenarios of the different AMS-users in April (further details to be communicated later).

Last but not least, the qualification process of national alert management systems is planned to be ready in April.

Close collaboration with the national authorities is extremely important for a successful implementation. EMVO strongly encourages the NCAs to

be involved in the AMS -project to help promote its use throughout the community. If you would like to keep updated with the AMS, please click here to subscribe to EMVO's AMS Newsletter.

Best Practice – Reducing the number of alerts in the National Medicines Verification System (NMVS)

From OSMR, the Romanian NMVO

The OSMR Team has ensured that the National Medicines Verification System (NMVS) is fully operational, developing the technical environment for a secured market, preventing the entry of falsified medicinal products into the legal supply chain.

The alerts percentage generated by the NMVS has been significantly reduced during the previous year.

Behind these numbers lies a huge effort and commitment, shown not only by the OSMR team and collaborators, 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 emphasises the importance of teamwork and cross-functional collaboration and in the case of reducing the alerts generated in 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, emphasising the importance of the correct scanner and software configuration, as well as the accuracy and quality of the data uploaded to the European Hub.**

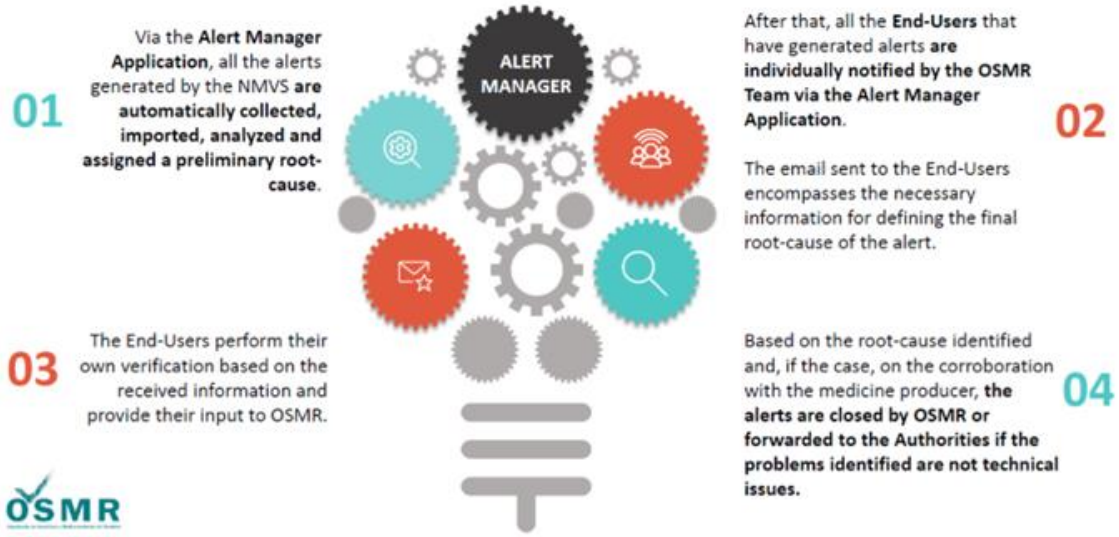
An important element of the stakeholders' communication is represented by the **Software Providers' Virtual Gatherings**. The main goal that has been achieved was the consolidation of a working community that has managed to provide valuable input towards lowering the number of alerts.

Starting in 2019, meetings took place every month to provide a better understanding of the serialisation context and to ensure that the technical requirements were successfully met.

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 alerts' 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 minimise the large number of L5 alerts that were caused by technical and operational issues.

Moreover, an application has been developed – *The Alert Manager Application* – which has significantly improved the process of managing & minimising the alerts raised by the NMVS.

Below you can find the overview of the main steps for managing the alerts and the importance of the Alert Manager Application within the entire process.



The presented actions 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 unrelenting effort that the OSMR Team has put in minimising 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%.**

Perspective of an NCA on the importance of implementing the FMD throughout Europe and at the national level

From JAZMP, the Agency for medicinal products and medical devices of the Republic of Slovenia

In the globalised world with diverse supply chains, the Falsified Medicines Directive enables an additional level of security that benefits patients all over Europe. To implement new requirements on safety features, a stepwise approach was chosen since it was expected that due to the complexity of the system, technical problems and therefore a larger number of false alerts will arise in the beginning. To ensure an unimpeded

supply of medicines, the stabilisation period was introduced from the 9th of February until the end of November 2019.

Short after the Delegated regulation came into force, the document on Alert handling procedure was prepared in cooperation with ZAPAZ, the Slovenian NMVO, and with the agreement of all stakeholders. In accordance with the agreed procedure, the first stage of alert investigation starts at ZAPAZ within 24 hours from the time that alert is triggered. After processing the information from stakeholders, and in case technical or procedural errors are excluded, the alert is escalated to the NCA Inspection as a suspect falsified product.

Investigation of alerts requires close cooperation communication between ZAPAZ, the NCA and relevant stakeholders on a daily basis. The communication was made much easier with the alert management portal that was established by ZAPAZ. The portal is a communication channel, that replaces the conventional communication flow of phones or e-mails. It enables a consolidated view for all stakeholders. Besides communication on alert handling, a constant cooperation with ZAPAZ regarding improvements of the system and processes and providing help to stakeholders is also in place. We are convinced that such cooperation enables us all to handle alerts in a way that each one is fully investigated. Despite that, it is sometimes still not possible to find the cause of the alert, but it is nevertheless ensured that such packs are not supplied to the patients.

It is important for an NCA to be able to closely monitor and analyse alerts. For this purpose, ZAPAZ provides us with a weekly report on alerts. From those reports, we can get useful information on which alerts are common, in which group of stakeholders they occur, in which pharmacy they are often repeated and how much time is needed by a stakeholder to resolve an alert. This helps us to identify some systematic errors, for instance, problems with scanners or irregularities in working procedures in pharmacies, or common errors with certain manufacturers, such as data upload. This information is important for risk assessment and planning of inspections.

Despite a successful implementation of the rules on safety features and a good cooperation with NMVO, several challenges remain. The first challenge relates to responses from the system that the product code is unknown. Such response poses a major risk that a product is falsified and should also be included in a group of level 5 (L5) alerts, therefore, we requested ZAPAZ to treat those responses as L5 alerts. Another challenge relates to NCA reports, particularly to the audit trail report that is, in case of intermarket transactions, still not complete. NCAs can see only operations performed on their territory, which poses an obstacle to swift and efficient investigations.

With an expectation that these challenges will be addressed in near future, we would like to conclude with the advantages of this system, which, in addition to the very main purpose of preventing the entry of falsified medicines into the legal supply chain and protecting health and lives of patients, also gives a detailed insight into the supply chain of medicines and processes on the individual pack level. This gives the work of regulators and supervisors an extra dimension that can be used for reimbursement, pharmacovigilance and pharmacoepidemiology purposes.

Stay up to date with the EMVS

The next EMVS Community Newsletter is planned for June 2022!

Any feedback?

If you have any questions, please do not hesitate to contact our Helpdesk.

Kind Regards,

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