October 2022

EMVS Community Newsletter

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Introduction:

Welcome to a new edition of the EMVS Community Newsletter!

In this new issue we will present you a variety of topics which will helpyou understand better how our EMVS system functions. We will start with a perspective on Serialisation by the Romanian NCA, a deep dive into critical countries, a status update on the EAMS pilot experience, and finally a thorough introduction to intermarket transactions.

If you have any comments or feedback which you would like to share, **reach out to us on communications@emvo-medicines.eu.**

Serialisation: Perspective from the National Agency for Medicines and Medical Devices of Romania

From Mr. Razvan Mihai Prisada, President of ANMDMR (Romanian NCA)

The great threat which falsified medicines pose to the patients' health is the primary reason why the Falsified Medicines Directive has been developed and implemented.

All European countries understood the magnitude and uniqueness of such a project being implemented, along with all the challenges it would bring and decided to continue in this endeavor, placing the patients' safety above anything else.

Since the beginning of the preparation phase in 2017, as part of the

overall planning of the national implementation of the European Medicines Verification System (EMVS), Working Groups coordinated by the National Agency for Medicines and Medical Devices of Romania (ANMDMR) and, at that time, the newly incorporated Romanian Medicines Serialisation Organisation (OSMR) were established, covering the sensitive areas impacted by the serialisation project. Communication, transparency, dedication and hard work of all the stakeholders have been essential to achieving the deadline, leading thus to what I consider to be a successful project implementation.

The communication channel between ANMDMR, OSMR, medicines manufacturers, marketing authorization holders – MAHs, community and hospital pharmacies, healthcare institutions, wholesalers, parallel importers and software suppliers has been strengthened and has led to an efficient collaboration between stakeholders.

Currently, ANMDMR is actively involved in the process of managing the alerts generated by the National Medicines Verification System (NMVS) – after the technical issues have been eliminated by OSMR – by verifying the traceability of medicinal product batches in the reports made by distributors, communicating with MAHs and End-Users involved, with the purpose of investigating suspicions of counterfeit and confirmation/refutation of counterfeiting.

ANMDMR is also a constant presence in the Software Providers' Virtual Gatherings - online gatherings initiated by OSMR, which managed to consolidate a working community that has provided valuable input towards lowering the number of falsified alerts.

Our organization will continue to monitor the compliance with the Commission Delegated Regulation (EU) 2016/161, placing resources, time and effort to preventing falsified medicines from entering the legal supply chain and guaranteeing patients' access to authentic medicines.

Critical Countries

From Tracy Slosse, EMVO Partner and Project Expert

EMVO has identified which countries could be qualified as "critical", based on three parameters:
The **Alert rate:** a percentage of the total number of scans (total number of alerts divided by the total number of scans). This figure includes alert categories A2, A3, A52, A68, A24, A7. (Note: only alerts and scans raised by national transactions).

- The percentage of **connected End-Users** (pharmacies, healthcare institutions, wholesalers, dispensing doctors and other decommissioning channels).
- The **decommissioning rate**: the number of successful decommissioning for dispense transactions divided by the market size (provided by IQVIA and confirmed by the NMVOs).

The applied rationale is that a country is identified as "critical" if it has at least one "critical" parameter or 2 "challenging" parameters within the last three months.

EMVO is regularly updating the list and following up the CAPAs put in place. Thanks to the efforts undertaken in the countries, two have recently gone off the list. EMVO encourages strong collaboration between the NMVOs and the NCAs to work towards achieving the target rates.

Parameter	Challenging	Critical
Alert rate	Between 0,01% and 1%	Above 1%
Decommissioning for dispense rate	Between 60% and 90%	Below 60%
End-Users Connection rate	Between 95% and 99%	Below 95%

Status update on the EAMS Pilot Experience

From Matisse Jubb, EMVO EAMS Project Manager

Following the release of the EAMS Qualification Process and the Pilot countries' engagement in connecting their systems to the AMS Hub, the EAMS End-to-End Pilot was kicked off in June 2022. The EAMS End-to-End Pilot took place from June to mid-September 2022, and was closed with the release of AMS Lilith (P 2.0.0 H 1.3.0) on September 13th, 2022. This End-to-End Pilot allowed Pilot OBPs and countries to test the AMS Hub's connection to different national system blueprints. We organized weekly sessions to gather feedback from both Pilot OBPs and Piloting countries.

The following countries are connected: Germany, Slovenia, Romania, Poland, and Cyprus. France is currently going through the Qualification process to finalize their connection.

The EAMS Handbook is under the review of the EAMS Steering Committee. EMVO plans to kick off the second Pilot once this has been finalized. The EAMS Handbook is a document based on the Best Practices on Alert Handling Guidelines. It is the result of a collaborative effort from EMVO, Pilot OBPs and Customer Group representatives.

Close collaboration with national authorities is extremely important for a successful implementation. Therefore, EMVO strongly encourages the NCAs to be involved in the EAMS project to help promote its use throughout the community.

Introduction to Intermarket Transactions

From Claude Farrugia, MAMVO and Ita Gordon, IMVO

Intermarket tra**nsactions** (IMTs) are a core part of the EMVS but present their own unique challenges.

This type of transaction is triggered when a pack is scanned in a local market, while the pack's unique identifiers are not stored in that local market's NMVS, but in another, 'fulfilling', market's NMVS. There are various reasons why this might be the case, including the onboarding partner being unaware the pack will be shipped to that particular local market, a pharmacy/hospital that is located near a country border having physical medicines supplied by either country, and COVID-19 vaccines uploaded to only larger markets, but distributed to all markets.

In an IMT, the pack's 2D barcode data is sent via the EU Hub to the other market for verification or decommissioning and the response is then sent back to the local market. Thus technically, many more steps are involved in an IMT compared to a local transaction.

Investigating alerts raised via an intermarket transaction is more complex because of the limited information available to the local NMVO. The local NMVO can only see the events that happened locally but not events that happened in other markets, such as the pack creation details or a change of pack status (for example, 'active' to 'exported'). For these alerts, collaboration with the NMVO of the fulfilling market is essential to understand the full history of the pack and resolve the alert. However, it should be noted that only the NMVO of the local market can see the name and address of the end user who scanned the pack; this information is not visible to other NMVOs or stakeholders.

NMVOs will continue this close collaboration and cooperation on IMTs to ensure that alerts are investigated and the possibility of a falsified medicine is ruled out as quickly as possible.

Stay up to date with the EMVS!

We are always issuing interesting and insightful EMVS Community newsletters, so make sure to stay **tuned for our next Holiday edition in December and for our NCA workshop taking place on November 30th!**

We'd love your feedback!

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

Kind Regards,

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