June 2023

EMVS Community Newsletter

Contents

Introduction

Welcome to a new edition of the EMVS (European Medicines Verification System) Community Newsletter! In this Spring issue, we will be diving into several topics including: a statement from EMVO's new President, the roles and responsibilities of the NMVO Observers, the experience from the Hungarian NMVO in ending the stabilisation period, the Nordic

recommendations on recalls of batches and withdrawal of products, and finishing with an overview of the EMVS alerts.

We hope you will enjoy this issue and of course, if you have any comments or feedback which you would like to share, do not hesitate to reach out to us at communications@emvo-medicines.eu.

EMVO President statement – GIRP Presidency 2023-2025

"*Dear EMVS Community,*

I hope this letter finds you all in good health and high spirits. As the incoming President of EMVO, it is both an honor and a privilege to address you for the first time in this function through this community newsletter.

In this first letter, I wish to share with you my priorities for the years 2023-2025. Building upon the excellent work done by my predecessors, I aim to drive EMVO forward in achieving our overarching goals and ensuring the success of the European Medicines Verification System (EMVS).

Monika Derecque-Pois

One of our key priorities for the coming years is to connect all end-users within the EMVS. It is crucial to ensure that every stakeholder involved in the supply chain, from manufacturers, and full-service healthcare distributors to pharmacists as well as all healthcare professionals distributing medicines to the public, is seamlessly integrated into the system. By connecting all end-users, we can better enhance the traceability of medicinal products and protect patients in Europe, who obtain their medicinal products from the legal supply chain.

Another important focus area is establishing trust between EMVO and the various EMVO stakeholders and NMVO communities. Trust is the true foundation of successful collaboration, and we will actively work towards fostering strong relationships, open communication based on respect, and mutual understanding. By building trust, we can facilitate cooperation and ensure the smooth functioning of the EMVS eco-system.

What's more, connecting all onboarding partners and end-users to the Alert Management System is also a key objective in order to continue to strengthen and more intensely promote the AMS as a resource to address any alerts quickly and efficiently.

Lastly, we will strive to promote EMVO's achievements and share our success story. We have accomplished significant milestones in securing the supply chain and protecting patients from falsified medicines. It is important to communicate these achievements to raise awareness, inspire confidence, and encourage further collaboration among stakeholders. By showcasing our success, we can inspire others and foster a sense of pride and belonging within the EMVO community.

I am honored to lead EMVO during these exciting times, and I am confident that together, we can achieve our goals and ensure the continued success of the European Medicines Verification System. I look forward to working closely with all stakeholders and leveraging our collective expertise to advance patient safety and protect public health."

Warm regards,

Monika Derecque-Pois
President, European Medicines Verification Organisation (EMVO)
Director General, European Healthcare Distribution Association (GIRP)

New NMVO Observers within the EMVO Board

At EMVO's General Assembly on 11th May 2023, new NMVO Observers within EMVO's Board for 2023 were elected.

Iwona McManus (from KOWAL, Poland) will represent large countries and Inese Erdmane (from LZVO, Latvia) will represent small countries. Kristina von Sydow (from e-VIS, Sweden) was re-elected to represent mid-size countries for another year.

The NMVO Observers represent the views of National Medicines Verification Organisations (NMVOs) in the EMVO Board. The mission of the Observers is to be the voice between NMVOs and the EMVO Board and provide national input in the decision-making of EMVO, on topics that impact the whole ecosystem of the EMVS. Priorities for the Observers are also to provide productive feedback to financial and resource assessments as well as to have a common EMVS strategy established and developed, a strategy that ensures primary objectives for the EMVS and creates possibilities for further development.

We would like to thank former representatives Philippe Gendre (France MVO) and Hjörleifur Thorarinsson (ICEMVO, Iceland) for the knowledge and engagement they brought during their mandates.

Iwona McManus (General Manager, KOWAL), Inese Erdmane (General Manager, LZVO) & Kristina von Sydow (General Manager, e-VIS)

End of Stabilisation in Hungary

Since **9th February 2019** - like all other NMVOs - the Hungarian HUMVS has experienced a high number of false alerts in the system caused by technical and human failures. Fortunately, our Board Members having strong representing ability from medicine supply chain participants and HUMVO has a very close collaboration with the National Competent Authority (OGYÉI). This collaborative effort has ensured that HUMVO was not alone in addressing the rational usage of the serialization system.

Through a series of intensive **working group meetings** held by HUMVO, Stakeholders and Hungarian NCA a stabilization period procedure guide has been concluded: NCA published the first guidance in force from 9th February 2019, where only a few alerts were obligatory to be investigated. Those first bunch of alert types were chosen based on a risk approach; where there was a higher risk to identify potential falsification cases has been included in the task list.

Accession of pharmacies into the system is 100 %; the Chamber of Pharmacists played a pivotal role in supporting and advocating for pharmacists throughout the process.

Currently, we have an average of 2 alerts per end-user per month (naturally that means, a lot of them 0 alerts). There are 7 types of alerts that system users are obliged to investigate, and some of those alerts had not been seen before or were too rare without high number of false alerts in the beginning.

In the last years HUMVO "invented" a mass alerts management program, called "**signal procedure**": a **"signal" is an event per end-user per day where a high number of similar alerts has been detected**. "High" number was defined at the beginning as 100 alerts per day, it has been continuously reduced to 20 and currently we are shifting to the limit of 15 alerts per day. All these "mass-events" are closely investigated, with software providers and NCA included in the process if needed. 40-75% of all the alerts are managed that way and the number of false alerts has decreased by 50% in the first year of implementing this method and is still getting lower.

As false alerts continue to decrease significantly, the discussion on a **phased approach strategy to conclude the stabilization period** has become evident. National Competent Authority continuously requested stricter reporting rules from the system users. It was clear from the beginning that as **users become more familiar with the system** and as HUMVO diligently works towards eliminating mass alert events caused by software or human errors, the focus of the system's usage can be more dedicated to investigating potential falsification cases.

Presently, we observe approximately 8 million monthly scans, generating around 800-1500 alerts per week, resulting in an alert rate of approximately 0.02%. The continuous reduction in false alerts led us to end the stabilization period in February 2023.

Moving forward, HUMVO aims to expedite and enhance alert investigations while further reducing false alerts to below 0.01% or 500 alerts per week by 2024. Achieving this objective necessitates determined and trustworthy end-users who are willing to collaborate and address the root causes of false alerts.

Péter Schneider (General Manager, HUMVO)

Recalls of batches and withdrawal of products within the EMVS – best practices from the Nordic countries – Belgian experience

The Delegated Regulation EU 2016/161 stipulates that medicinal products which are to be recalled or withdrawn from a market should be decommissioned in the national repository in which the recall or the withdrawal is to take place. From a patient safety perspective this means that the EMVS serves as an extra layer of safety, complementing the existing national procedures, ensuring that recalled batches and withdrawn products do not reach patients.

Best Practices Guidance from the Nordic Countries

From a national perspective there has been no clear guidance on how to use the recall and withdrawal functionality in the EMVS. During 2022 the Nordic NMVOs started to receive questions from MAHs and wholesalers on when batches should be recalled through the EMVS and why the functionality is not used consistently between the MAHs. From this point of view, the Nordic NMVOs decided to create a joint recommendation for the recall and withdrawal functionality in the EMVS. The Nordic countries have a high volume of multi-market packs shared between the countries; joint recommendations are therefore of great value for the MAHs.

The Nordic recommendations include the following sections and can be downloaded from any of the Nordic NMVOs' websites:

General recommendations of the functionality in the EMVS, country-specific guidance on when a batch/product should be marked as

recalled/withdrawn, use cases for MAHs, End-user actions and a Q/A section.

It should be noted that the recommendations are published as a **complement to the already existing national recall procedures**.

Improving the recall practice in Belgium by using the National Repository

The Belgium NMVO BeMVO analysed the number of recall warnings on the BeMVS in 2022. Although the Belgian pharmacy association (APB) has an efficient recall system in place, the BeMVS still issued 880 warnings to pharmacists who tried to dispense a recalled product. This analysis proves that the EMVS is in Belgium and Luxemburg already an effective safety net for the recall system of APB. After consultation with all stakeholders, it was decided that BeMVO will continue to monitor the recalls and withdrawals for Belgium and Luxemburg on the BeMVS.

BeMVO has subscribed to the e-alert system of the APB to receive all recalls and withdrawals as soon as they are made public. BeMVO checks if these recalls and withdrawals are also put on the EMVS system and contacts the MAH when this is not the case. To do this correctly BeMVO has used the best practice from the Nordic NMVO's with the addition of the official Belgian and Luxemburg guidelines on recalls and withdrawals.

Consequences of Product Withdrawal & Batch recall

EMVO would like to highlight once again the consequences following Product Withdrawal and Batch recall and remind you that these are **irreversible actions**.

Withdrawal of a product code (SKU) affects all packs of all batches in the transaction specified markets. The status "Withdrawn" prevents the uploading of additional batches to the system for the affected markets. If a product is withdrawn from a market all the batches for that specific product will be decommissioned. Consequently, the end-user(s) of the affected market(s) will not be able to decommission the packs in the EMVS.

When **recalling a batch**, the OBP needs to refer to the Product Code, the Batch ID, the reason for recall and state the list of affected markets.

Be reminded that if the batch level status changes to "recall" all affected product packs will be decommissioned.

EMVO would like to remind once more that the **withdrawal of a product and batch recall within the EMVS are irreversible actions.**

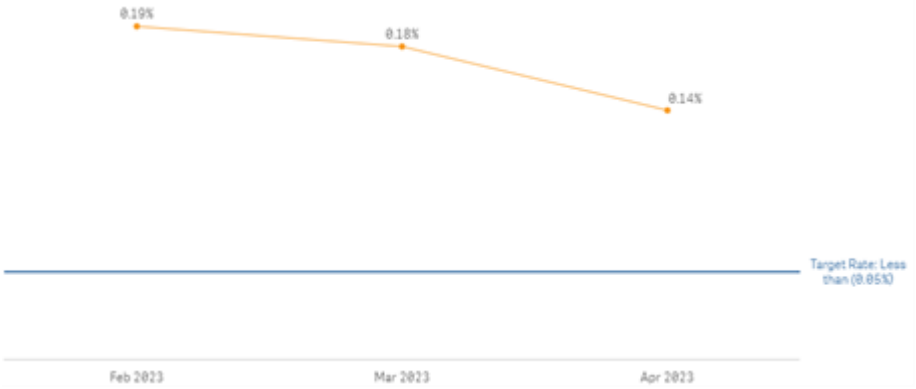
Useful Links:

- Belgium: https://bemvo.be/wp-content/uploads/2023/06/Recall-and-withdrawal- in-NMVS-Belux-recommendations-March-2023-002.pdf
- Denmark: NEWS FROM DMVO
- Finland: https://www.laakevarmennus.fi/en/news/recall-and-withdrawal-emvs-nordic-recommendations
- Iceland: https://lyfjaaudkenni.is/en/news/
- Norway: https://nomvec.no/recall-and-withdrawal-in-nmvs-nordic-recommendations
- Sweden: https://e-vis.se/en/2023/01/10/recall-and-withdrawal-in-emvs-nordic-recommendations/

Kristina von Sydow *(General Manager, e-VIS) &* ***Philippe Coene*** *(General Manager, BeMVO)*

EMVS Alerts Overview

The monthly EMVS alert rate continues to decrease. It reached its lowest point yet in April 2023 with 0,14%, despite a peak at the end of April due to the incidents in Belgium and Poland, which generated over 88.000 alerts in one week. Most of the other alerts were A68 (Batch ID mismatch) alerts and A2 alerts. These cases are being addressed by the NMVOs with the concerned user directly, involving EMVO when necessary.



Stay in touch with the EMVS!

The next issue of our EMVS Community newsletter will be out in Q3 so stay tuned!

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

Kind Regards,

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