(2022/12/16)

Welcome to the holiday bulletin edition of our EMVS Community newsletter!

In this special holiday edition, we want to wish you all a great holiday season by showcasing some of the accomplishments of the past year, in the hopes of having an even stronger collaboration for 2023. Please read below to see what the EMVS Community has been delivering throughout 2022.

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

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Focus on safety features in national inspections – Perspective from the Swedish NCA

By: Emil Schwan, Gustav Sjöstrand, and Birgitta Sahlin Johansson from Medical Products Agency (MPA; Läkemedelsverket)

Since the Delegated Regulation (EU) 2016/161 came into force, the Swedish MPA has performed themed inspections of safety features and compliance to the regulation of several types of actors in Sweden. In 2019-2020, these included themed inspections with single focus of safety features of selected manufacturers, MAHs, full-line wholesalers and community pharmacies. The Swedish NMVO was also inspected during 2020.

The early themed inspections showed that actors on the Swedish market were generally well prepared, with only a few deficiencies found at each location. We believe that the focus on themed inspections helped the actors understand the agency's interpretation of the regulations, as well as help the agency understand the problems actors faced in the early days of the regulation.

Safety features are also a focus area in general inspections of all actors where safety features are handled as part of the regular inspection programme.

During 2022, the handling of safety features in community pharmacies has been one

of the focus areas in the Swedish MPA's on-site inspections. A majority of Swedish pharmacies belong to five large pharmacy chains. Pharmacies belonging to these chains have been inspected using a standardised set of questions and deficiencies relating to safety features were found. Generally, pharmacy staff was well informed on the purpose and decommissioning of the unique identifier, including alerts. The most common deficiency was pharmacists lacking knowledge of the purpose of the anti-tampering device and what to do when encountering a package with a broken or missing anti-tampering device. In some cases, the pharmacies' instructions regarding safety features were not updated, unclear, or lacking information. The supervision has led to pharmacy chains updating their instructions. The MPA has also repeatedly informed the pharmacies regarding the regulation and the MPA plans to keep safety features as a part of pharmacy inspections in the next years.

2022 Overview from the EU CCB

By: Tina Hou Marer, Director, Danish Medicines Verification Organisation, EU Change Control Board (EU CCB) co-chair

2022 is reaching to its end. Again, this year the EU CCB has accomplished what it was set to achieve through joint effort from customer groups and stakeholders. A sincere thank you to everyone who contributed. Compared to 2021 the number of governance cycles have been reduced from monthly to every other month, and the agreement to set up extraordinary meetings, when something urgent came up, has proven to work well. During 1H22 90 Change Requests (CR) and Fix Requests (FR) were submitted for governance, and hereof 72 CRs and FRs were approved. Early 2022 higher priority CRs were identified, and the EU CCB members agreed to priorities these for 2023. Working groups and task forces have worked hard, to ensure, those changes could be successfully implemented in 2023. Throughout 2022 many members of the EU CCB have been replaced with new representatives and the transition has been successful without any disruption nor delays in the governance cycles.

The EU CCB always strive for the best way possible to accomplish the task of aligning the CRs and FRs within the pan European system, without jeopardizing the interoperability and stability to ensure operational excellence. Therefore, the EU CCB will kick-off the new year by evaluating processes and joint efforts to ensure that the customer groups continue to work smartly together. The governance cycles every other month will continue and new priorities for 2024 will be set to ensure that more complex and higher priority changes can be incorporated into the ecosystem in the future.

CyMVO Achievements in 2022

By: Arthur Isseyegh, Director, Cyprus Medicines Verification Organisation (CyMVO)

2022 was a successful year for the CyMVO as it has sufficiently met its primary goals. These were to **further improve communication** with stakeholders and to **provide them with the best available tools to investigate alerts** in an effective and timely manner. In this respect, efforts were intensified so as to increase the number of end-users connected to the National Alert Management System (NAMS), which provides for seamless communication and exchange of information. Therefore, promoting and facilitating the overall alert investigation process. Currently, **almost all alert communication regarding investigation procedures is performed through NAMS which now has more than 90% of end-users connected**. To further enhance our communication with end-users we have also established an **SMS text communication system** which can also be used to inform end-users on urgent matters, most notably on unexpected downtimes.

The implementation/fine-tuning of the above procedures has led to a **steady decrease in our alert rate** from 0,11% in October 2021 to 0,058 % in November 2022. Despite the increasing number of end-users and the variety of software systems at end-user level, CyMVO provides them with constant support, helping them to perform their alert investigations and fixing errors resulting in false alerts.

Furthermore, the CyMVO has been part of the EAMS Pilot phase since July 2022. The CyMVO is **connected to the AMS Hub through NAMS** - NMVS Alerts, with the main goal to support OBP's and Manufacturers to follow-up on alert investigations facilitating the process both on NAMS and EMVS level. It is expected that the successful implementation of the AMS will further contribute to the reduction of the alert rate. **As CyMVO we are strongly in favor of having a harmonized Alert Management System across all stakeholders and the EAMS is most definitely a move in the right direction**.

Experience and achievements in Latvia

By: Inese Erdmane, Chairwoman of the Board at the Latvian Medicines Verification Organisation (LZVO)

The Latvian Medicines Verification System (LZVS) was introduced without a transition period. The System has been fully operational since the 9th of February, 2019, and has been providing safe medicines through the legal supply chain to 2 million Latvian inhabitants.

We are proud that within almost 4 years, the LZVS has been operating without interruptions, is stable, secure, and available for end-users. The year 2022 was no exception either. Still, there is space for technical improvements and corrections. Together with IT Supplier Arvato and the Arvato Customer Group, the System is being further improved and refined. LZVO provides local expertise to the international team framework.

The basis of any system's successful operation is its people and their interest in the development of the system's operation. The LZVO team is actively participating in the overall activities of the EMVS, particularly within the change control board (CAB) representing Quality Assurance, the Tech Council of IT managers, as well as representing the Arvato Customer Group in the CCB. The LZVO team consists of five employees who work closely with and take care of our clients and partners in Latvia – they support daily activities, consult in case of questions and provide various types of informative and educational activities for MAHs and end-users (seminars, newsletters, reminders). The LZVO keeps regular contact also with local public media and provides information via social networks. For the successful operation of the verification system in Latvia, we say the biggest thanks to our stakeholders, partners, end-users and the Latvian NCA.

The main challenge of the coming years will be the implementation of the AMS. Currently, the level of alerts in Latvia is significantly lower than the target indicator set by the EMVO. The proportion of alerts affecting end-users is constantly decreasing. We expect that the AMS will improve the speed of communication, facilitating a faster investigation of alerts, offering a more secure exchange of information in one platform among all involved parties, as well as keeping all investigation records in one place.

We would like to thank everyone for a successful, open, highly professional, and positive cooperation – the EMVO, NMVOs, MAHs, end-users, and the NCA. May we all have new, interesting challenges and opportunities to deal with in the year ahead!

2022 in review: Insight from the Operations department in EMVO

Looking back at the past year and the many accomplishments of the Operations Department from EMVO, one can only anticipate what will come next for 2023.

EAMS (European Alerts Management System): going live

The EAMS (European Alerts Management System) has been in the works since January 2021, and we're excited to see all the hard work paying off. **The EAMS is planned to go live on 9th February 2023**! Close collaboration with national authorities is extremely important for the successful implementation of this project.

Successful deployment of EU Hub Release 1.11

One of the main achievements of 2022 for the Operations department is without a doubt the **successful deployment of Release 1.11 in the EU Hub**. The Release 1.11 has led to the improvement of the EU Hub by removing redundant code, undergoing general infrastructure maintenance and closing defects associated with PMD version number and missing callbacks related to batch recall reports. Make sure to keep up to date for **January 2023, when Release 1.12 will be deployed in PRD**!

What else to expect for 2023? The department is working on more projects and releases but most important of all the cybersecurity of the system will be enhanced in order to meet the standards of the **NIS2 Directive**.

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 editions in 2023. Until then, we wish you and your families a joyful holiday season and a happy new year!

Any feedback?

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

Kind Regards,

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