March 2023

EMVS Community Newsletter

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Introduction : Welcome to the first edition of the year!

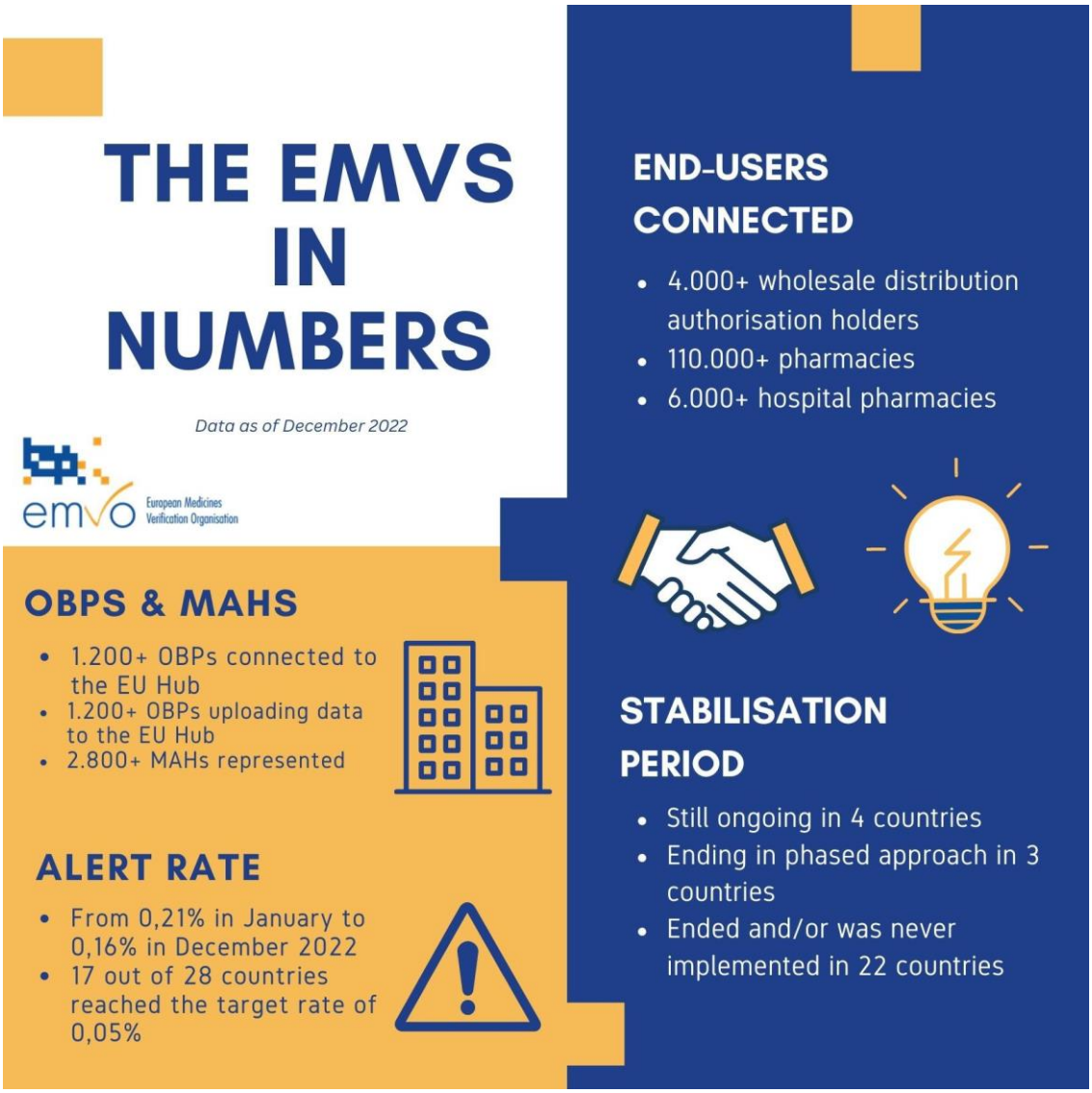
Welcome to this new edition of the EMVS (European Medicines Verification System) Community Newsletter! In this issue, we celebrate and

look back at what the EMVS has achieved in the past 4 years since the "Go-live" of the system. We are happy to confirm the successful "go-live" of the European Alert Management System (EAMS) and the connection of numerous OBPs and NMVOs already. Additionally, we will be sharing some moments and reflections from the 4th Anniversary Reception and 1st Annual EMVS Forum which took place on February 9th and 10th, respectively. We hope you will enjoy reading our newsletter! If you have any comments or feedback which you would like to share, do not hesitate to reach out to us on communications@emvo-medicines.eu.

EMVS 4 years in the making

The European Medicines Verification Organisation (EMVO) and the National Medicines Verification Organisations (NMVOs) are celebrating their anniversary this year, marking four years of ensuring authenticity of medicines across Europe. EMVO was established in 2015 as a non-profit organization to oversee the implementation of the European Hub as part of the EMVS, which was mandated by the Falsified Medicines Directive (FMD) to prevent the entry of falsified medicines into the legal supply chain. EMVS is a unique IT implementation as for the first-time pharma supply chain stakeholders were mandated to enact and complete a piece of European legislation, and it has successfully managed to do this quickly and efficiently.

Since its launch, the EMVS has been implemented in all EU countries as well as Norway, Iceland and Liechtenstein. In total it covers over 2,500 pharmaceutical manufacturers, over 4,000 wholesalers, and over 106,000 pharmacies and hospitals.



In a joint effort, EMVO and the NMVO's mission is to ensure the effective and efficient implementation and operation of the EMVS, to guarantee the security of the medicines supply chain, and to protect public health. Over the past four years, EMVO and the NMVOs have been working tirelessly to achieve this goal, working in close collaboration with European and National Stakeholders and many other parties involved.

Looking ahead, EMVO and the NMVOs will continue to work to enhance the EMVS, improve collaboration between all parties and ensure the system remains fit for purpose in the face of evolving threats to the medical supply chain.

In conclusion, EMVS's fourth anniversary is a significant milestone that shows how collaboration has created a unique IT project which successfully protects public health in Europe in a timely and secure manner. As we face ongoing challenges in the global healthcare landscape, such as medical shortages and global pandemics, EMVO and the NMVOs will continue to lead the way by promoting digitisation for the safety and quality of medicines for patients across Europe.

Official "go-live" of the European Alert Management System (EAMS)

On 9 February 2023, the European Alert Management System (EAMS) Hub went officially live and is welcoming onboard all interested OBPs and NMVOs. EMVO wishes to remind you that the use of the system is free of charge and does not include any additional fees.

Benefits of using the system

Leonie Clarke, the Chief Executive of the Irish Medicines Verification Organisation (IMVO) and the Chair of the EAMS Steering Committee, shares some of the main benefits and functionalities of the system:

"The EAMS is an important new collaborative tool that supports more efficient management of alerts by everyone involved - end-users, MAHs/OBPs and NMVOs. It offers users the capability to:

- Manage, track and document their own alerts. It provides real-time updates, available 24/7, on the status of alerts based on information entered by the end-user, MAH/OBP and/or the NMVO;
- Quickly communicate with other parties about an alert, while preserving end-user anonymity vis-à-vis the MAH/OBP, a core principle of the EMVS. This removes the need for rounds of emails or phone calls;
- Request (MAHs/OBPs) and upload (end-users) pack photos when needed for the MAH/OBP's investigation.

- Maintain a record of their own actions in relation to any given alert, suitable for internal auditing and NCA queries and inspections.
- From an MAH/OBP perspective, the new AMS Portal provides the additional benefit of being able to manage alerts across multiple markets via a single platform."

The EAMS is a project which required the involved and dedication of many partners to achieve its full potential. Therefore, we truly hope you can support us in further promoting the system and all the advantages it brings when using the system.

4th Anniversary Reception recap

On 9 February, the EMVS celebrated the 4-year anniversary with a reception at the Royal Library of Belgium. EMVS' partners and supporters across Europe were invited to come together to mark this special anniversary.

During the reception, EMVO's President, Kasper Ernest (Secretary General of Affordable Medicines Europe), shared his overall takeaways for this 4th-year anniversary with the enthusiastic crowd.

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Overall, Kasper shared that the EMVS was successfully launched, which was a milestone considering the scale of the system and the seamless interoperability of 28 national systems connecting in such a short amount of time. While there were some difficulties in the first few years, development progressed steadfastly thanks to the dedicated experts and personnel from the NMVOs and EMVO.

The President further highlighted the birth of a new "sibling" for the EMVS, the European Alerts Management System (EAMS) which on February 9, 2023, has officially gone live. The EAMS has been in the making for more than 9 months, and although there were some obstacles during its development, it is now fully operational. EMVO hopes that the EAMS and the whole EMVS grow together to handle alerts effectively.

EMVO's President then concluded his speech by thanking the whole Community, including EMVO Stakeholders, national Stakeholders, NCAs, NMVOs and the EMVO team for their hard work during these 4 past years.

If you are curious about how the reception looked, check out some pictures below and make sure to head over to EMVO's LinkedIn page for a further glimpse of this special night!

1st Annual EMVS Forum: Overview of the event

The 1st Annual EMVS Forum took place on 10th February at the European Parliament. We had the honour to be hosted by the Member of the European Parliament (MEP) Marisa Matias. During the meeting, EMVO Stakeholders and guests came together to discuss the EMVS' main purpose – keeping patients safe by ensuring a protected medicines supply chain in Europe, while exploring potential future collaboration opportunities. It was a unique event filled with valuable exchange of knowledge and points of view from prominent organisations such as the European Commission, OECD, FDA, GS1, FAMHP (Belgian NCA) UNICEF and BfArM & WGEO.

The event was a great opportunity to also touch upon some of the main areas which require the dedication and support from the NCAs. It was highlighted that the end of the stabilisation period and handling of alerts go somewhat hand in hand. Mainly, it was noted that the stabilisation period should end in all countries and the handling of packs raising alerts should be handled uniformly which has not been the case in some countries.

The harmonisation of alert handling requires perseverance and resilience from the NCAs. Harmonisation of alerts handling is not only vital for the timely handling and reduction of alerts, but it will also ensure that no patients are left without their medicine due to a raised alert – a challenge recognised and faced by the end-users.

To support all the users in this task, EMVO together with the support of the NMVOs, prepared a "Best Practice on Alert Handling" guide which aims to minimise alerts due to technical, data or procedural errors generated in the EMVS. Notwithstanding that national variations currently exist, the aspiration is that this document will provide a basis for progressing dialogue with NCAs and stakeholders in each country towards harmonisation of requirements across Europe. It is also hoped that it will be useful for countries that have not yet defined national procedures for alert handling. If you are interested, please consult the guideline here.

The EAMS was also mentioned as a solution to the timely handling of alerts as it is a new collaborative tool that supports more efficient management of alerts by everyone involved - end-users, MAHs/OBPs and NMVOs.

Nevertheless, alert harmonisation and the end of the stabilisation period can only be achieved with the strong support and efforts not only from EMVO and the NMVOs but also from the NCAs and the European Commission. EMVO is strongly encouraging the authorities to be active and demanding while providing the needed support.

Please consult here the June 2022 issue of the EMVS Community Newsletter to read more about the stabilisation period & alerts overview where Leonie Clarke, IMVO Chief Executive, share their experience with the end of the "FMD 'use and learn'".

If you are interested in finding more about the Authorities' perspective in fighting fake medicines or exploring the presented global trends to tackle falsified medicines, check out the recording of the meeting here as well as the slide deck here used during the meeting.

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

Kind Regards,

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