

EMVS Community 2021 Holiday Bulletin

(2021/12/16)



Welcome to the “EMVS Community Holiday Bulletin 2021”, a collaboration between the European Medicines Verification Organisation (EMVO) and the National Medicines Verification Organisations (NMVOs). With this bulletin, we, the European Medicines Verification System (EMVS) Community, aim to sum up and offer a retrospective of EMVO and the NMVOs' main achievements for 2021 and highlight the importance of this continuous and strong cooperation.

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The EMVS: A success story with many actors involved

The EMVS is a world-first for its stakeholder model, its scale and technology and it represents an unprecedented step towards preventing falsified medicines from entering the legal supply chain. The EMVS provides an additional safety layer to more than 460 million people across Europe.

Since 9th February 2019, the EMVS is live and interconnecting around 2.500 pharmaceutical companies, 4.000 wholesale distribution authorisation holders, 100.000 pharmacies, 6.000 hospital pharmacies and 500 dispensing doctors in 29 countries.

Throughout this network, millions of prescription medicines are dispensed to patients every day. This is translated into the EMVS as more than 30 million transactions done daily in real-time by wholesalers, pharmacies and hospitals.

Reaching these landmarks can only be accomplished thanks to the active and continuous collaboration between EMVO and the NMVOs as well as with the stakeholders, the regulators and the EMVS users. The EMVS Community ensures that the system remains technically stable, secure and that any issues are ironed out without any disruption for patients or the pharmaceutical supply chain, in addition to further deterring falsifiers from attempting to enter the legal supply chain.

Performance Report: Change Control Management of the EMVS

The governance of such a system is complex and requires a continuous improvement process. No project of comparable scale has ever been done.

The EU Change Control Board (EU CCB) was established in April 2020 with the mission to govern the EMVS interoperability and change management, to ensure smooth operation and ultimately contribute to patient safety.

Since its establishment, more than 300 changes were processed and implemented through 17 releases (on average, almost one per month). The high number of changes shows that the EMVS is maturing into a stable system, proving that the change management model is working as intended. This ensures that the system is finetuned for the connected MAHs and end-users.

The EMVS also proves stable by looking at the low number of incidents occurring in production environment after deployments thanks to the prior execution of the interoperability tests which show a low number of findings. The stability is mainly achieved through a robust process to evaluate changes and thanks to an early alignment between all system owners.

Therefore, an objective for the EU CCB is to create predictability for all involved systems and their users. One way to provide predictability is to jointly plan the coming year's releases. The approved release plan for 2022 is the following (releases are presented on the months planned for deployment in production):

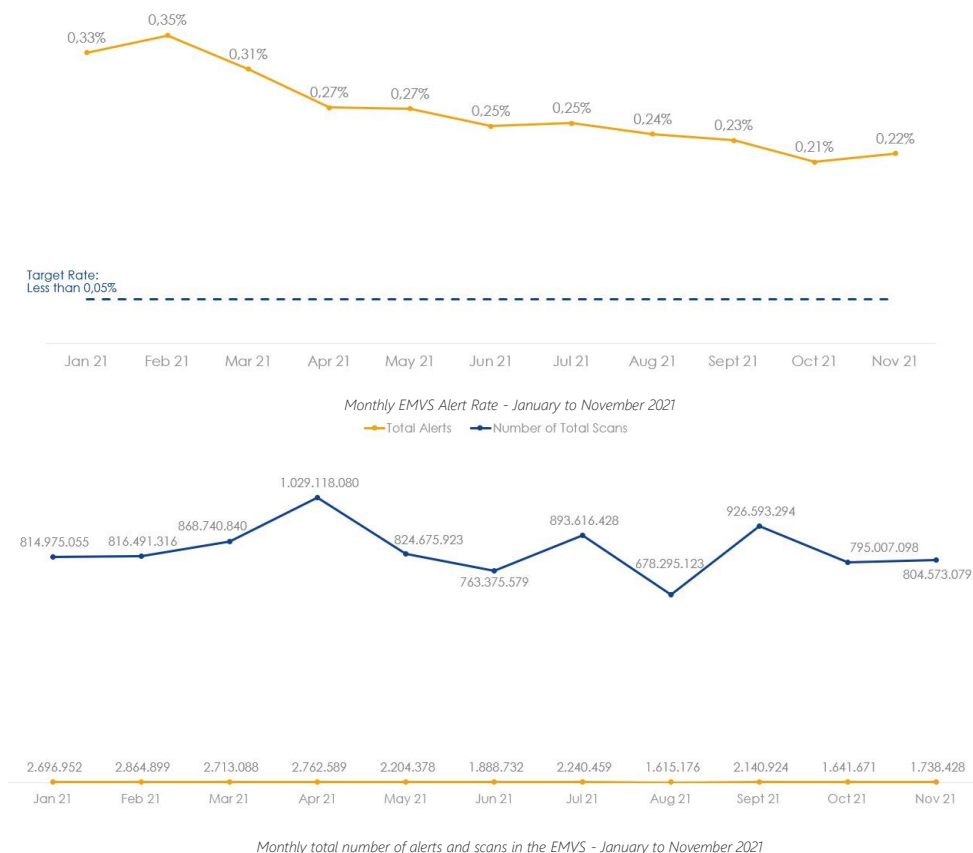
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
			SSR NS 10	ARV NS 1.10	EU Hub 1.11			ARV NS 1.11 + Rep 1.07	SSR NS 11		EU Hub 1.12

Looking ahead, the EU CCB will strive to create a longer-term outlook for the EMVS by aiming to apply a standardised release cycle plan where efficient testing and smooth roll-out of changes can be made and also by creating an outlook for the changes that the EMVS will need to have in a mid- and long-term perspective. Both are valuable in continuing the protection of all people across EU from falsified medicines.

EMVS achievements in 2021

Alert Rate

The alert rate in the EMVS steadily decreased in 2021, starting with a monthly alert rate of 0,33% in January, dropping to 0,22% in November. The absolute number of alerts decreased by one million, from 2,7M alerts in January to 1,7M alerts in November.

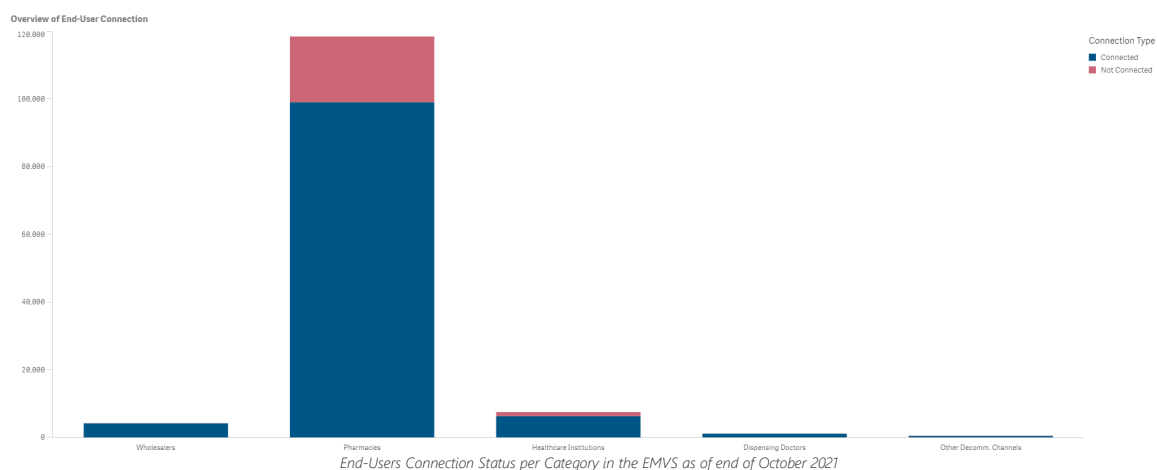


Most of the alerts raised by national transactions in 2021 were A68 (Batch ID Mismatch) alerts, as well as A24 & A7 (Attempt to decommission an already decommissioned pack) alerts generally caused by a single or a few end-users, even though these numbers are decreasing. These cases are being addressed by the NMVOs with the concerned user directly, involving EMVO when necessary.

The EMVS Community will continue its hard work in addressing, resolving and decreasing alerts. Nevertheless, the NCAs' assistance in shedding light on this topic is highly valuable as it will help us to produce new material and spark other ideas, helping the EMVS Community to pursue its mission and manage the reduction of alerts.

End-Users Connection

3.000 additional end-users have been connected in 2021, including 1.647 pharmacies in France, and 5 countries increased their percentage of end-users connected to 99% or more.



As previously demonstrated in our "EMVS Community Newsletter" released in April, the rate of connected End-Users would increase if the NCAs engage further and enforce the regulation more tightly.

System Releases

- EU Hub
 - SR 1.9 was deployed in Production in June
 - SR 1.10 was deployed in Production in December
 - Arvato National Systems
 - UKNI Core 1.08 and Reporting 1.04 were deployed in Production in February
 - Core R1.08.007 patch release and Reporting R1.05.008 patch release were deployed in Production in May
 - Core 1.09.007 was deployed in Production in November
 - Solidsoft National Systems
 - R8.0 was deployed in Production in April
 - R9.0 was deployed in Production in October
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Working together in 2022

Despite the complexity of the EMVS landscape and the number of parties involved in the EMVS-ecosystem/Supply Chain, 2021 was marked with many significant achievements thanks to the hard and continuous work of the Community!

We will continue to pursue our mission by working diligently and will provide you with regular updates in the form of "EMVS Community Newsletter" on a quarterly basis throughout 2022.

As demonstrated multiple times, the success story "EMVS" can only thrive with the assistance of all involved actors. Therefore, your continuous support and cooperation are of vital importance and highly appreciated.

Patient health and safety can only be protected when we work together!

We wish you a warm and happy holiday season!

[Any feedback?](#)



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

Kind Regards,

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