

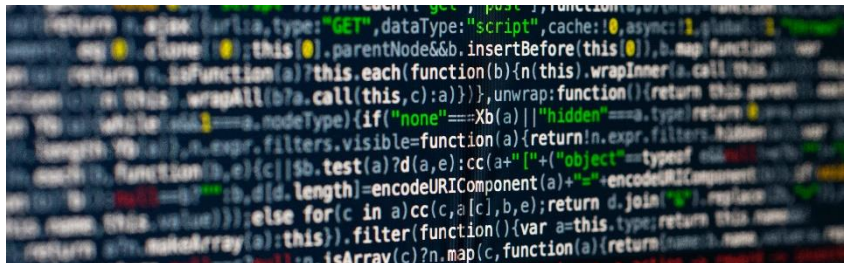
EMVO NEWSLETTER

European Medicines Verification Organisation

What's new at EMVO:

- I. NMVO Update
- II. Letter of Announcement
- III. Technical Updates

NMVO Update



MaMVO was registered as a legal entity in November 2018 and went live in January 2019. Despite the limited time available to the coming into effect of the Delegated Regulation, with great commitment and team effort from the stakeholders, in just over 2 weeks more than 80% of pharmacies were on-boarded onto the system. The repository was also rapidly populated with data, over 23 million packs being uploaded in the same timeframe. Notwithstanding the success of the ramp-up phase, Malta found it necessary to follow the lead of other countries and adopt a soft launch of the implementation of the FMD, with a stabilisation period of 6 months to ensure an uninterrupted supply of medicines.

Malta, being a small member state, is characterised by a pharmaceutical supply chain that is heavily dependent on supply by overseas authorisation holders. This has led to a number of challenges in the implementation of the Delegated Regulation typical of such markets, namely difficulty in obtaining payment from MAHs, an exceedingly high proportion of multi-market packs in the repository, and a high degree of reliance on intermarket transactions. This has, in turn, led to an atypical profile of alerts; around 70% of alerts generated by local end-users are A2 (Batch not found) alerts. Moreover, alerts generated by local end-users are typically only a low fraction of the total number of alerts generated in the system. In an average week, local end-users generate around 600 alerts, representing approximately 2% of all local scans.



This figure increases into the thousands if one takes into consideration alerts generated by incoming intermarket transactions, failed multi-market pack synchronisations and alerts generated directly by Onboarding Partners (OBPs) through the EU Hub.

MaMVO's outlook for the coming months is that proactiveness is required to decrease the number of false positive alert-causing packs entering the supply chain. It is with this in mind that MaMVO will not be extending the stabilisation period for wholesale dealers in August 2019. More information on MaMVO is available from our web portal www.mamvo.org or by contacting us on mail to: info@mamvo.org.



Nadine Borg & Claude Farrugia



Letter of Announcement

On Thursday 19th June, EMVO released a communication dedicated to providing clear guidance to Parallel Distributors on the completion of Product Master Data.

More specifically, this was related to the MAH details within the Product Master Data.

EMVO released this communication as errors in the Product Master Data of some Parallel Distributors have been uncovered. We stressed the need to update Product Master Data which has been incorrectly uploaded, to avoid any future use of incorrect MAH details.

Forthcoming communication

EMVO will shortly reach out to OBPs to provide further guidance on alerts which are being caused by not uploading Product Master and Pack Data for all countries of a Multi-Market Pack.

If Product Master and Pack Data are not loaded for all markets, alerts will be caused in the national systems.





Technical Updates

EU Hub

On 11th June, EMVO reported on a Known Issue related to missing callbacks for Parallel Distributors.

This issue is affecting Pack Status Update processes with OBPs not receiving a confirmation that this process has been successful.

For further information: <https://bit.ly/31K5298>

On 14th June, EMVO communicated via the EVI on a Known Issue related to missing callbacks from the EU Hub.

EMVO originally reported that a Known issue was affecting the uploading of data for some OBPs. The root cause of this issue was subsequently identified, and the issue was resolved. The impact of this issue was first felt on Friday 7th June, with it being resolved on Wednesday 12th June.

For further information: <https://bit.ly/31H2KYf>

On 19th June, EMVO reported on two Known Issues affecting Inter-Market Transactions (IMTs).

The first of these is the slow response of the systems to IMTs. Presently, some IMTs are failing due to a timeout, as the EU Hub requires a response to an IMT query within 800 milliseconds. If this response is not received within this time, the IMT will not be successful. EMVO and the NMVOs are currently performing a full root cause analysis on this issue.

Furthermore, there is an issue related to the instances when an IMT should be raised. The EMVO URS defines that an IMT is only raised if a Product Code is unknown locally. Currently, IMTs are being raised at national level if the Product Code is known but the Batch and Serial Number are not known. IMTs are therefore being raised when they should not be. A change request is to be raised with the EU CAB to resolve this issue.

For further information: <https://bit.ly/2WSIEaW>

National system updates

Via the EVI, several NMVOs have also released communications related to Known Issues in their systems.

On 6th June, *KOWAL*, the Polish Medicines Verification Organisation released a communication on alerts that could raise concerns as to the authenticity of packs of medicines in circulation.

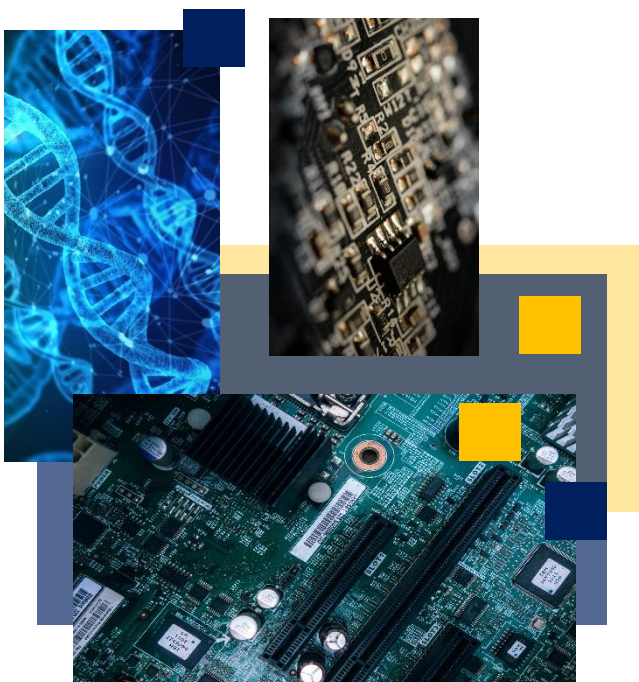
For further information: <https://bit.ly/2Fk3Klj>

On 11th June, *securPharm*, the German Medicines Verification Organisation and its partner ACS release on the EVI that they identified the root cause for approximately 150.000 micro uploads per week.

For further information: <https://bit.ly/2XUgMn6>

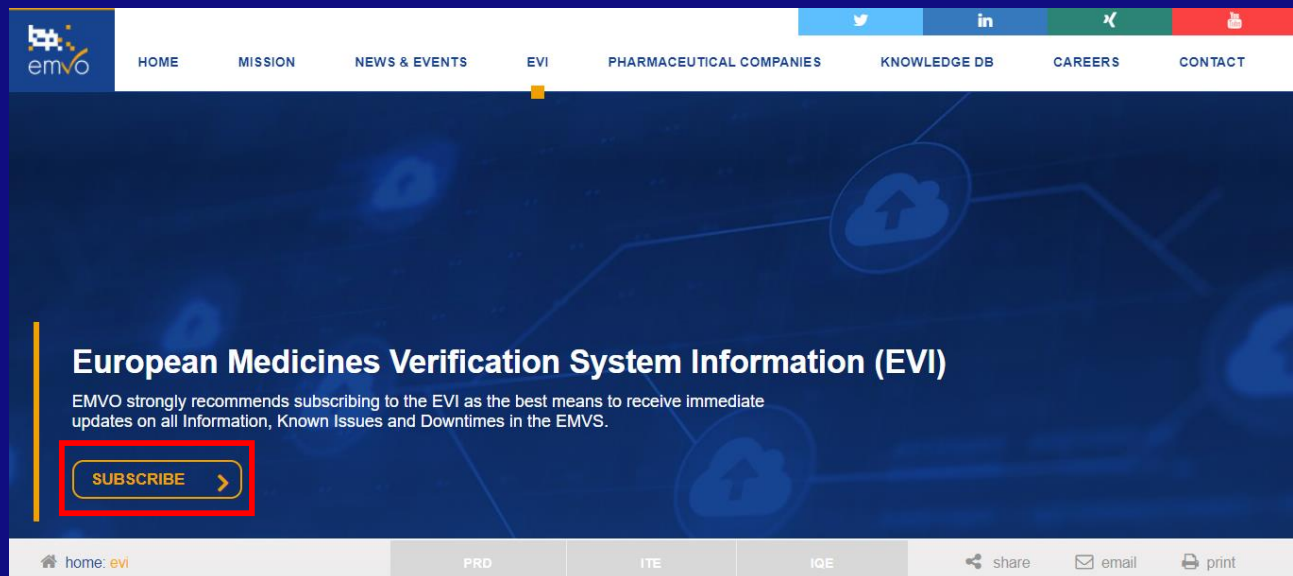
On the same day, *securPharm* and its partner ACS release another communication about the identification of the root cause for approximately 100.000 Intermarket Transactions per day from the German NMVS to the EU HUB.

For further information: <https://bit.ly/2RrNI3F>



European Medicines Verification System Information (EVI)

We strongly encourage all interested parties to subscribe to notifications from the EVI tool on our website. This is the best way to receive technical updates related to the systems of the EMVS, with general information also being posted here alongside Known Issues and Downtimes.



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