


EMVO Newsletter 10th May 2019




I. NMVO contribution



Beginning from this week, one NMVO will be publishing an article in this newsletter in order to share their current experience and give an insight into their work.

This week, *Kristina von Sydow*, General Manager of e-VIS, provides an update on FMD implementation in Sweden.

A successful implementation in Sweden



First of all, we would like to conclude that the implementation of FMD in Sweden has been successful because of a true collaboration with all different stakeholders from the supply chain. Working all together with the same goal the start of e-verification in Sweden went well. The Swedish system has been functional during the first months and pharmacies and wholesalers use the system routinely since February 9. All pharmacies and wholesalers in Sweden are connected to the system. From the hospital side, one healthcare region is not yet onboarded.

Evolution of the situation

We see daily that transactions in the system are increasing, which indicates that the number of packs with 2D-codes on the market is increasing and that pharmacies and wholesalers are increasing their scanning. Pharmacists in Sweden have been scanning packs as a part of their pack control for two decades – with FMD coming into force the scanning is shifted from one-dimensional to two-dimensional codes.

With an increase of transactions comes an increase of alerts. In Sweden we see alerts caused by data not being uploaded or uploaded but with a mismatch in expiry date. Retrospective upload is still sometimes a debate. Alerts caused by so called ‘Indian packs’ are common – from dialogue with the Swedish MPA end-users are scanning all packs with 2D-codes (even those without ATD) and the Indian packs are therefore included in the alerts statistics. Alerts caused by end-user handling were quite frequent from the start, but pharmacy chains experiencing these problems quickly changed their processes. To some extent we see alerts caused by scanner misconfigurations. End-users with scanner misconfigurations are being approached by e-VIS to make sure to decrease “false alerts”.

Since 9th February

A soft launch of eight weeks starting 9th February has recently been extended into a stabilisation period that lasts until the end of September 2019. These precautions were recommended by e-VIS together with the Swedish Pharmacy Association in order to ensure an uninterrupted medicines supply throughout the whole supply chain. Alerts caused by data missing or mismatches should not be seen as potential falsifications during the stabilisation period. However, this 'soft launch' applies only to end-users when dispensing packs to patients. All other obligations are in force – pharmaceutical companies that are aware of data missing or mismatches in Sweden should take corrective actions immediately. There is really nothing 'soft' with this soft launch.

How do we improve our procedures?

To make sure that Sweden will be ready for full implementation of FMD after summer e-VIS are working together with the pharmacies, wholesalers and local representatives/MAH/OBPs to find the packs that causes the alerts and to find the root causes for the errors. In dialogue with the stakeholders in Sweden e-VIS are

- Communicating with MAHs/OBPs and giving them the possibility to cross-check alerts. At the same time we ask MAHs/OBPs to confirm if alerts caused by scanner issues.
- Communicating with end-users with scanner misconfigurations.
- Compiling a list with all Indian packs in Sweden.
- Having workshops with representatives from whole supply chain.
- Together with the Swedish NCA closely monitoring the progress of the FMD implementation.

Kristina Von Sydow, CEO, 

II. Technical updates

A. Pack Disclosure Report

We had previously announced that a fix was to be implemented and rolled out to Production Environment (PRD) on Tuesday 23rd April. This planned fix was indeed implemented; however, we have subsequently identified a further issue, which we are currently investigating. As such, it remains the case that the Pack Disclosure Report is not working for the time being.

EMVO will, of course, keep you fully informed on this topic and will provide an update as soon as possible. Please note that this issue does not prevent an OBP from uploading data to the EU Hub.

B. Alert Handling data

Since our last newsletter, we have continued in our work on monitoring the development of alerts and working on preventative actions to mitigate (false) alerts.

We can report that EMVO is collecting alert data on an ongoing basis, in order to spot trends and identify corrective actions which can take place. As a result of this, we can report, that for every category of alerts the rate of alerts being generated is significantly down since the start of the Operational Phase.

We have developed preventative actions specific to each alert category and will continue to adapt these to the developing challenge.

III. General news update

A. New European Commission Q&A

On Friday 4th May, the European Commission released a new version (V.14) of its “Q&A Safety Features for Medicinal products for human use document”.

This document sets out frequently-asked 'questions and answers' regarding the implementation of the rules on the safety features for medicinal products for human use.

These rules are officially enshrined in Articles 47a, 54(o) and 54a of Directive 2001/83/EC, and in Commission Delegated Regulation (EU) 2016/1612.

The main changes are found in sections 1.6; 5.9; 7.15 and 8.9.

You will find the complete document on the EMVO website: <https://bit.ly/2V2LLel>.



B. Website upgrade

In order to better reflect the requirements of the Operational Phase of the EMVS we are currently beginning an upgrade of the EMVO website. In recent months we have been responsive to the needs of OBPs in developing the EVI tool, and we believe that the development of the website will have a similarly positive effect.

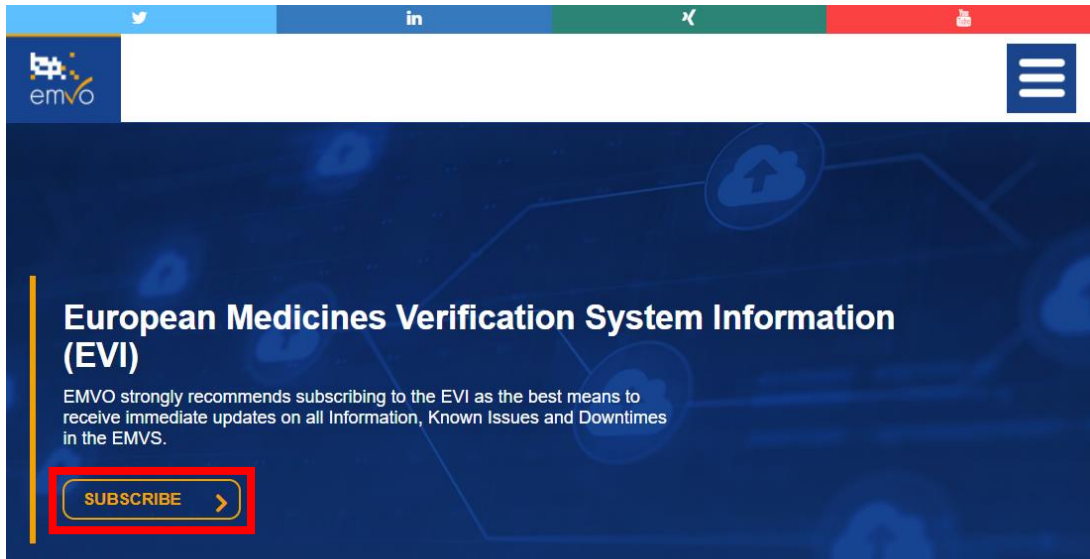
As a result, some changes will soon take place on the EMVO website,

- A new page of the site will be dedicated to the newsletter for easier access. We will also reorganise and simplify our database to help with browsing the available documents in our Knowledge Database.

We will keep you informed of the evolution of each of these changes and hope that they will allow you to better understand and use our website.

C. European Medicines Verification System Information (EVI)

We strongly encourage all interested parties to subscribe to notifications from the EVI tool on our website (see next page). 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.



European Medicines Verification System Information (EVI)

EMVO strongly recommends subscribing to the EVI as the best means to receive immediate updates on all Information, Known Issues and Downtimes in the EMVS.

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European Medicines Verification Organisation

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