

# INFORMATION FROM E-VIS



18 JUNE 2020

## CONTACT DURING SUMMER 2020

### CONTACT

The best way to get in touch with e-VIS during summer is to send an email.

#### Alert Related Questions

Email: [alerts@e-vis.se](mailto:alerts@e-vis.se)

#### General and Technical Questions

Email: [info@e-vis.se](mailto:info@e-vis.se)

#### Contracts and Fees (MAH)

Email: [administration@e-vis.se](mailto:administration@e-vis.se)

Website: [e-vis.se](http://e-vis.se)

Q & A: [e-vis.se/qa-2/](http://e-vis.se/qa-2/)

**Telephone (Switch)** +46 (0)8 462 37 00

Business Hours 08.00-17.00

Closed for lunch 12.00-13.00

### ONBOARDING OF END USERS

Requests will be handled with regards to e-VIS personnel availability during summer. We will make our best to manage requests as soon as possible but if urgent, please send an email to [info@e-vis.se](mailto:info@e-vis.se)

### WITH REGARDS TO COVID-19

Since March, the e-VIS team, have been working from home. This time has been challenging for all of us, but at the same time we have gained an extra multi-tasking superpower which will help us in our day-to-day responsibilities.

### EMVO HELPDESK

Email: [helpdesk@emvo-medicines.eu](mailto:helpdesk@emvo-medicines.eu)

## ENDING OF THE STABILISATION PERIOD IN SWEDEN – STEP 3

Step 3 in ending of the stabilisation period for e-verification in Sweden have been temporarily on hold due to the Covid-19 pandemic.

The target is to end the stabilisation period, step 3, as soon as the situation in the supply chain allows.

The categories still in stabilisation are:

**#A2** - Batch not found and **#A3** - Pack not found

Please read more in the [Letter Update Step 3](#)

At [e-VIS webb Q & A](#) you will find further information

## NEW TARGET DATE FOR ENDING STABILISATION PERIOD STEP 3

The target date for ending the stabilisation period for the last two alert categories is now set to after summer:

**30 September 2020.**

## SAVE THE DATE – WEBINAR (ONLY IN SWEDISH)

Save the date **22 September, at 9-12 am** when e-VIS will be hosting a Live streamed webinar (in Swedish) for MAH's and end users to give an update on implementation of FMD.

Further information will be announced in August.

## THE SWEDISH PHARMACY ASSOCIATION – BECOMES A MEMBER OF E-VIS

The Swedish Pharmacy Association, the industry organization for Sweden's pharmacy, now becomes a member of e-VIS. The Swedish Pharmacy Association represents ten members who account for almost 100 percent of the pharmacy market in Sweden. The fact that the Swedish Pharmacy Association becomes a member of e-VIS also means that their CEO, Johan Wallér, takes a seat on the e-VIS Board. [Press release to be found here.](#)

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## HIGH DEMAND AND PRESSURE ON THE MEDICINES SUPPLY CHAIN – INCREASED RISK FOR FALSIFICATIONS

The decision to pause the last step of the stabilisation period is based on not further burdening the supply chain under the prevailing circumstances. It is important to point out that a supply chain under high pressure in combination with increased global demand for medicines makes us more vulnerable to getting falsifications in the legal chain.

e-VIS recalls that the possibility to ignore data errors from the e-verification system applies to end users who verify and deactivate packs when they are to be dispensed to the public, for example pharmacies, healthcare facilities and in some cases when wholesalers deactivate packs or handle packs in return logistics. Other stakeholders have never been included in the stabilisation period.

It is particularly important to emphasize that a great responsibility rests with MAHs and wholesalers that packs with errors in uploaded data in the e-verification system or in the 2D codes are not to be sent to pharmacies.

### In the light of the above, e-VIS recommends that:

- Wholesalers continue with batch sample verifications at delivery and emphasise that packs with errors must not be forwarded to pharmacies.
- The MAHs use the possibility of order sample verifications at the wholesalers if it is not included in the core service from the wholesaler.
- MAHs continue their efforts to correct and prevent errors to occur.
- The pharmacies routinely scan packs so that alerts are created even if the soft launch continues. This may be obvious but important to emphasise. By scanning all packs, signals can be picked up even if the end-users still apply soft launch.
- The 2D code is scanned at the pharmacy's pack control. The pack control itself (not connected to the SMVS) will fail if the product code is not found in the Swedish article register and is also a signal to react on.
- Communication about the risk of falsification is made to everyone who handles medicines in the distribution chain.

## MEASURES TO ELIMINATE AND PREVENT ALERTS

The volume of alerts, as well as the alerts/transactions ratio have been declining since the EMVS go-live on February 9<sup>th</sup>, 2019. However, a significant number of alerts remain and must be eliminated from the system.

Likewise, alerts must be prevented from being raised when new organisations connect to SMVS or e.g. when new scanners or software are adopted by existing end-users.

[Guideline](#) to describe the measures to be taken by each type of entity in the supply chain that is connected to the Swedish Medicines Verification System (SMVS) in order to eliminate and prevent alerts from being raised by the SMVS is published at our website <https://e-vis.se/qa-2/#ett> Q&A 1.7

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## EMVO – NEW TECHNICAL DOCUMENT ON ALERT AND NOTIFICATIONS

A new document, **EMVO\_0402\_EMVS Alerts & Notifications**, is now available to OBPs. It can be found in the Technical Info Pack on the OBP Portal.

The document describes alerts and notifications emanating from the European Medicines Verification System (EMVS). It can be used to help identify the triggers that cause the EMVS to issue alerts for Potential Suspect Falsification packs and may assist with the design of processes and procedures for investigation and handling of potential suspect falsification packs and other scenarios where suspicious activity is detected.

Link to [Letter of Announcement](#)

