Information from e-VIS 30 March 2020

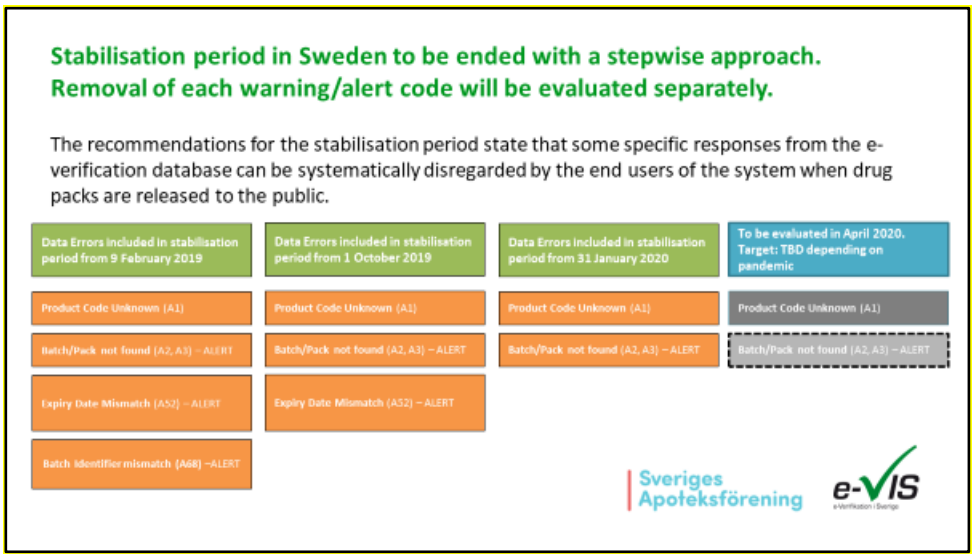
Ending of the stabilisation period for e-verification in Sweden – step 3 on pause

e-VIS and the Swedish Pharmacy Association have recommended a stabilisation period for e-verification in Sweden. The stabilisation period lasted until September 30, 2019 and have since then being phased out with a stepwise approach.

A step-by-step approach minimises the risk of impact on the patient and shortages

By removing **one** alert category at the time, the pharmaceutical industry and end-users will have the opportunity to gain experience and lessons learned before removing more categories of alerts from the stabilisation period

- Step 1
  The stabilisation period in Sweden ended October 1, 2019 by removing the error "The batch identifier does not match the identifier specified by the product owner" (A68) from the stabilisation period.
- Step 2
  The stabilisation period for the error “Expiry date on pack does not match the expiry date stated by the product owner in the database.” (A52) ended at 31st January 2020.
- **Step 3**
  With regards to Covid 19 pandemic, the step 3 in ending the stabilisation period concerning the errors “serial number/batch is unknown” (A2, A3) will be temporarily on hold.



Step 3 will not be evaluated before end of April with regards to ongoing Covid-19 pandemic.

As the whole medicines supply chain is under high pressure due to the ongoing pandemic, and pharmacies and wholesalers are expecting more staffing shortages for some time to come, it is not advisable to evaluate and take a decision in the current situation that the step 3 in the phased out approach of the stabilisation period. Demand for medicines has risen sharply and wholesalers have handled volumes corresponding to a population of about 15 million since the beginning of March - for Sweden with a population of about 10 million. MAHs are also at risk of being in a situation when it comes to shortages in human resources, and the flow of medicines to patients must be ensured.

On the basis of the situation, e-VIS and the Swedish Pharmacy Association have jointly decided not to evaluate step 3 now, but temporarily put the last step in stabilisation period on hold.

There is no indication that step 1 and 2 need to be reversed, the responsible implementation of FMD in Sweden can continue, but right now with a slightly slower pace and strongly linked to the development of the ongoing corona pandemic

More information on step 1 and 2: https://e-vis.se/wp-content/uploads/2019/12/Letter_Ending-stabilisation-period-in-Sweden-step-2-January-2020_FINAL.pdf

Next step:
e-VIS will, together with the Swedish Pharmacy Association, continuously, but not earlier than the end of April, evaluate when there are conditions for ending the stabilisation period.

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 released 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.
- e-VIS will strengthen the monitoring of errors regarding the “serial number is unknown” in order to be able to find anomalous errors and will also monitor any increases that cannot be explained by known problems.
- Communication about the risk of falsification is made to everyone who handles medicines in the distribution chain.

For preventive actions to reduce the alerts in the e-verification system in Sweden, please see: https://e-vis.se/wp-content/uploads/2020/03/Measures-to-eliminate-and-prevent-alerts-v1.0_Final.pdf

For MAHs that have packs, causing alerts in the e-verification system where the error is not possible to correct and if **it is medically justified**: apply for exemption to release and sell packs with deviations from the Swedish Medicines Agency.

Any questions, please contact e-VIS at info@e-vis.se.