Information from e-VIS 18 September 2020

Ending of the stabilisation period for e-verification in Sweden

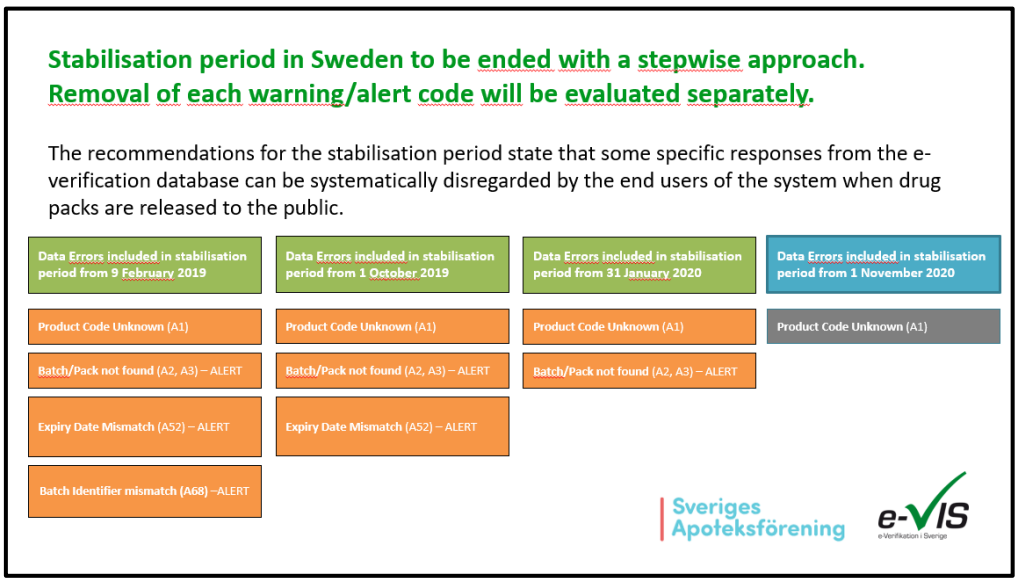
The stabilisation period for the error "serial number/batch is unknown" (A2, A3) ends on 1st November 2020.
As a consequence, packs with these alert categories cannot be disregarded at end-user level.

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 a 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 on 1st October 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 on 31st January 2020.
- **Step 3**
  The stabilisation period for the error "serial number/batch is unknown" (A2, A3) ends on 1st November 2020.



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Step 3: "serial number/batch is unknown" (A2, A3)

The decision to end step 3 of the stabilisation period is based on the fact that the level of incorrect alerts, so-called "technical alerts" is now reaching an acceptable low level that enables handling and investigation of individual packs. The e-verification system has been in operational mode for one and a half year and guidelines for alert handling is fully implemented. All stakeholders in the Swedish market should have had the full opportunity to implement processes around the regulation and the handling of safety features and the processes should now be thoroughly tested during the "use and learn" period.

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.

Continue the work of preventing errors and correcting errors that occur

e-VIS recommends continued measures to further reduce the technical alerts that occur from time to time:

- 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.
- Pharmacies scan packs routinely and in the event of an alert, the pharmacist should first investigate the alerts and after excluded handling error, in accordance with the Swedish guidelines for communication about alerts, report errors through the existing complaint channels.
- The few remaining errors that is triggered by incorrectly set scanners and incorrect interpretation of data from scanners should be corrected as soon as possible by the respective end user and their IT-supplier.
  e-VIS contacts the end users with confirmed scanner errors.
  From September 2020, in addition to initial certification, a re-certification of IT systems in connection to the e-verification system is to be introduced. The re-certification is intended to prevent new errors from occurring when SMVS is updated. The same procedure can be used as a quality-enhancing measure when the end users upgrades their own system

- 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.

Information on alert handling and preventive measures to avoid problems

At e-VIS website, all documentation regarding handling of alerts is to be found.

For example:

- Swedish process for handling and communication of alerts
- Common responses from SMVS (Vanliga svar från e-verifikationsystemet only in Swedish)
- Measures to eliminate and prevent alerts

Incorrect batches that cannot be corrected

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.

* when there is a risk for shortage situation and when the need cannot be met by any other medicine. See also the Medical Products Agency's Questions and answers about safety details (in Swedish)

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