Information from e-VIS December 10, 2019

The stabilisation period for e-verification in Sweden ends – step 2

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

- 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 next step in ending stabilisation period will apply 31st January 2020 by removing the error "Expiry date on pack does not match the expiry date stated by the product owner in the database." (A52)

- Step 3
  Errors regarding "serial number/batch is unknown" (A2, A3) will be evaluated in January 2020 and the target is to remove these codes from stabilisation period in March 2020.

Step 2:

The error "Expiry date mismatch" is now considered to be under control and is only triggered to a limited extent. Reporting packs that cause this alert when properly scanned can be considered to increase the quality and safety of the drug supply.
From 31 January, 2020 and onwards packs with "expiry date mismatch" will be reported as suspected falsifications according to e-VIS alert handling guidelines.

By removing one alert category, 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. A step-by-step approach minimises the risk of impact on the patient and shortages. Removing "Expiry date mismatch" from the stabilisation period is not considered to cause risks for shortages.

For a summary in English: https://e-vis.se/wp-content/uploads/2019/12/Summary-end-of-stabilisation-period-in-Sweden-January-2020-FINAL.pdf

Full information in Swedish: https://e-vis.se/wp-content/uploads/2019/12/Avslut-av-stabiliseringsperiod-januari-2020-FINAL.pdf

e-VIS recalls that the possibility to ignore data errors from the e-verification system applies to end-users who verify and deactivate packaging 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.

Preventive actions to reduce the alerts in the e-verification system in Sweden

Find below some examples of preventive actions to reduce the alerts.

Pharmaceutical companies

- Investigate alerts with end-users and e-VIS. It is important that all possible problems are identified and corrected.
- Analyse the alerts that come to your OBP and give feedback to e-VIS for alerts that are suspected of being caused by end-users' handling.
- To reduce the risk with packs on the market where data is not uploaded or has data errors. Verify packs in each batch before they are shipped or ensure that verification is done by the wholesaler.
- **Expiry date mismatch**
  Investigate root cause within your company and with any subcontractor and correct identified root causes. If your internal serialisation communication system cannot process DD=”00” but your printing system can handle DD=”00” resulting in you sending data to the EMVS that is not identical to that printed within the Data Matrix Code, you should take immediate corrective action, for example by correcting the data via the help of EMVO Gateway.
  As further preventive action you may consider to always print the last day of the month in the Data Matrix Code, which would avoid any data mismatch in the future.
- **Indian packs** with Indian 2D codes. Do not reuse GTIN from Indian 2D codes – see also guidelines on e-VIS web (in Swedish).

Wholesalers

- Sample checks on incoming goods prevent packs with deviations from being sent to pharmacies.
- Notify pharmaceutical companies of alerts that are discovered. The message should be that the deviations must be corrected.

Pharmacies

- Document identified discrepancies in own systems.
- Follow up and investigate end-user errors.
- Ensure that the scanner and scanner software are correctly configured via the IT system providers. e-VIS will also notify any problems with scanners via alerts and will also send out information for help to work preventively on these problems.

We request all stakeholder to take responsibility for ensuring that packs with data errors is not passed on further in the distribution chain closer to the patient.

Warnings and alerts from the e-verification system will stop packs from being supplied to the patient. Investigation and management at the pharmacy are very time and resource consuming.

Pharmaceutical companies investigate all alerts, including errors due to errors caused by end-users, for example from incorrectly configured scanners. These investigations takes time and resources that otherwise could be used for faster investigations and preventative work.

Regarding packs with exemptions from FMD

Packs with safety details that is not in line with FMD but that have been given exemptions from the Swedish Medicines Agency to be placed on the market for medical reasons/risk for shortages also causes questions and investigations at the pharmacy level.

For packs with exemptions pharmacies wish to receive information about the approved exemption upon delivery of the pack to the pharmacy.

Please also note that e-VIS needs to be informed about exemptions to be able to close alerts.

If there should be any uncertainties, questions etc contact us at info@e-vis.se