16 April 2019 Stockholm

E-verification in Sweden – instructions for an extended stabilisation period

As communicated on March 29, 2019, the stabilisation period for e-verification in Sweden will be extended from the original eight weeks. Find below instructions and clarification regarding the continued stabilisation period.

Time Frames:
The stabilisation period for e-verification in Sweden is extended until 30 September 2019.

Affected Stakeholders:

e-VIS wants to clarify that the stabilisation period applies only to end-users who verify and deactivate packs, for example pharmacies, healthcare facilities and in some cases when wholesalers deactivate packs or handle packs in return logistics.

There is no stabilisation period for other stakeholders.

Detailed information of a continued end-user stabilisation period

A continued stabilisation period means that pharmacies and healthcare facilities have the opportunity to hand out packs to the patient even if the e-verification system signals that the pack is not uploaded or has certain specific data errors. See also previous guidelines on e-VIS web (in Swedish). Guidelines in English can be found here.

These warnings should not be considered as possible falsifications during the stabilization period:

- Batch identifier mismatch
- Serial number or product code not found
- Expiry date mismatch

During the extended stabilisation period there are signals from the e-verification system that end-users must react to from start, see previous guidelines on the e-VIS web (in Swedish).

All end-users should respond to and investigate alerts that are due to end-user error management.

Investigation of alerts during the stabilisation period

Alerts triggered in the e-verification system during the stabilisation period must be investigated and the root cause must be addressed as soon as possible. It is important that the pharmaceutical companies investigate the alerts together with the end-users and e-VIS. e-VIS therefore urges pharmacies and healthcare facilities to use the form on

Reklameläkemedel.se (or internal corresponding form) already during the stabilisation period and report packs with alerts, so that the routine developed for managing alerts can be evaluated during the stabilisation period.

Some pharmaceutical companies regularly provide feedback to e-VIS with measures taken in the event of an alerts, or with information to forward to the end users, since errors can be due to the end-users' handling. Since end-user handling errors are very difficult to detect during the stabilisation period, it is important that as a pharmaceutical company via e-VIS provide information to end-users, for example when errors in scanners/software are possible root cause for alerts so that these alerts can be investigated.

To what extent possible, e-VIS compiles lists of alerts that have been triggered in the Swedish e-verification system and sends to the relevant pharmaceutical companies. The purpose of these lists is to give the companies an opportunity to cross-check with the alerts received directly via the EMVS system but also to provide e-VIS with the root cause for these alerts (at a general level) and the time frames for when these problems are planned to be solved (if they are not already are solved).

Actions for pharmaceutical companies regarding packs with alerts/deviations during the stabilisation period

A pack for which the data elements in the printed 2D code do not match with the information in the e-verification database, or a pack which have an erroneous status should be seen as a pack with a deviation. For the responsible pharmaceutical company, this means that the deviation must be taken care of as soon as possible.

For pharmaceutical companies that have packages that cause alerts in the e-verification system, the following possibilities are available:

- **Correct the error as soon as possible**
  If the error is noticed by an end user: give feedback to the end user about the timeframes for when the error can be corrected.

  We are aware that currently some companies experience technical problems that prevent a quick handle and correction of packs. However, packs with alerts must be corrected to be considered fully salable.

  Provide feedback to wholesaler or pharmacy when the error can be corrected even if the time frame is longer than the three days that the recommendations from e-VIS and the Swedish Pharmacy Association specify.

- **If medically justified**
  Seek exemption from the Medical Products Agency to (temporary) continue to provide packs with the deviation.

Alert caused by a so-called Indian pack

These alerts are currently not possible to correct. Ensure that the product is included in the list e-VIS compiles around Indian packs. e-VIS recommends that GTIN from Indian 2D codes is not used for packages that are serialised according to FMD.

See also the information on Indian 2D codes on the e-VIS web (in Swedish).

Monitoring of alerts during the stabilisation period

e-VIS will continue to monitor the signals from the e-verification system and will, to the extent possible, notify MAH/local representatives of products/batches that cause alerts. e-VIS will also notify end-users of deviations that they may need to take action on.

Please note that pharmaceutical companies have access to all their alerts in the system via their OBP and that is the primary way of knowing that alerts have been generated in the e-verification system.

e-VIS has regular reconciliations with the Medical Products Agency during the stabilisation period around the alerts in the e-verification system.

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

Find below some examples of how each stakeholder can contribute to effective alert management during the stabilisation period through preventive actions:

Pharmaceutical companies

- Investigate alerts with end-users and e-VIS. It is important, during the stabilisation period, all possible problems are identified and corrected.

- 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 is to always print the last day of the month in the Data Matrix Code, which would avoid any data mismatch in the future. Read more in the information from EMVO.

- Indian packs with Indian 2D codes. Do not reuse GTIN from Indian 2D codes – see also guidelines on e-VIS web (in Swedish).

- 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

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 or, if medically justified, seek exemption from the MPA.

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. When the stabilisation period is to be discontinued, packs causing alerts will not be possible to dispense.

When erroneous packs are moved along the supply chain and closer to the patient, the problems are passed on to colleagues in pharmacies and in the worst case to patients.