e-VIS
e-Verifikation i Sverige

Information from e-VIS: March 29th 2019
E-verification in Sweden - experience from first 7 weeks and next step

First of all we would like to conclude that the start of e-verification in Sweden has gone well. The Swedish system has been functional during the first few weeks. Pharmacy and wholesalers use the system routinely since February 9 - we see daily that the transactions in the system are increasing, which indicates that the number of packs with 2D codes on the market are increasing and that pharmacies and wholesalers increase their scanning.

Soft launch approach

Prior to the 9th of February, e-VIS recommended a so-called soft launch approach of e-verification to ensure uninterrupted medicines supply throughout the whole supply chain. The reason for this decision was that pack data was not uploaded to a desired level and the quality of the data that was uploaded was not secured. The e-verification system in its entirety, including all users' processes and systems, lacked desirable maturity on February 9, where all parts of the supply chain functions, in order to guarantee a patient-safe 'go-live'.

The soft launch approach that was recommended by e-VIS was intended for packs released to market before February 9, and to a large extent already circulated in the supply chain. The soft launch applied to pharmacies, but also wholesalers for reversed logistics or when deactivating packs on behalf of a healthcare provider.

An important part of the soft start was that all end-users (pharmacies, wholesalers, regions) were to scan all 2D codes, starting no later than February 9. Alerts that were triggered in the system because of that data was not uploaded or that the information that was uploaded was not correct, could be overlooked and the packs dispensed to patients. Because all the 2D codes are scanned and error signals are triggered, e-VIS and all users of the system have been able to gain experience about the system and its processes over the last few weeks.

Based on the experience we now have of the e-verification system and the processes of e-verification, we can conclude that the soft launch approach was a wise decision. On average, we see in Sweden about 3700 alerts per day.

However, we have not seen any alerts caused by potential falsifications. The alerts we see are caused by data not being uploaded, data not having the correct format and to some extent handling errors from end users.

Next step - continued stabilisation period

The number of alerts triggered from the end users could still risk interruptions to the medicines supply with a result that packs being withheld from the patients.

e-VIS together with the Swedish Pharmacy Association see that the soft launch cannot end yet as planned and now instead plan for an extension of the stabilisation period.

Dialogue with all stakeholders is ongoing and the Medical Products Agency has been informed.

e-VIS and the Swedish Pharmacy Association strive for a continued stabilisation period to be designed in a clear and predictable way - but also that during the extension it should be clear that packs with alerts from the e-verification system should not be further distributed in the medicines supply chain. e-VIS also strives to report the status of alerts and products to the Medical Products Agency on a regular basis.

No timeframes for the stabilisation period have yet been established. The e-VIS will return with this shortly.

Description of continued stabilisation period

A continued stabilisation period means that the pharmacy can dispense packs to the patient even if the e-verification system alerts that the pack is not uploaded or is uploaded but has some data error. These errors should not be seen as potential falsifications during the stabilisation period:

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

Alerts should, however, be investigated and the root cause should be addressed, it is important that the pharmaceutical companies investigate the alarms together with the end users and e-VIS.

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. Using the stabilisation period as an opportunity to continue selling products without correcting data errors does not contribute to the constructive and forward-looking efforts that is needed so that we together can realise the value from the large investments made regarding e-

verification. 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.