Medicines verification processes and the launch of SMVS. e-VIS recommends a 'soft launch approach' for Sweden.

e-VIS and the Swedish Pharmacy Association have published a recommendation (in Swedish together with an English translation) of how to handle and communicate around alerts from the Swedish Medicines Verification System. This recommendation is a result from a working group with representatives from all stakeholders.

In order to ensure an uninterrupted medicines supply throughout the whole supply chain e-VIS, together with the representatives of the supply chain, have agreed on certain operating procedures which are not according to the above-mentioned process description document. e-VIS recommends a 'soft launch approach' for the e-verification in Sweden. These extraordinary procedures will be implemented from 9 Feb 2019 and 8 weeks onward giving all stakeholders the possibility to gain more experience on the functioning of SMVS and the extent of system alerts. During this so-called soft launch all 2D-codes will be scanned but certain system alerts caused by missing or incorrectly uploaded data will not be considered as indicative of a potential falsification by pharmacies, hospital pharmacies and other end-users that supplies medicines to the general public. The same applies also to wholesalers with regards to returns from pharmacies, hospital pharmacies and other wholesalers according to Art. 20 (a) of the DR. Soft launch also applies for wholesalers when they supply according to Art. 23 of the Delegated Regulation (EU) 2016/161 or when wholesalers in Sweden function as 'hospital pharmacy'. Please note that soft launch does not applies for wholesalers receiving new incoming batches.

The soft launch approach is justified by the unlikeliness that medicines already in the supply chain in Sweden from 9 February 2019 and 8 weeks onwards have been released after the 9 February 2019. If distributors in Sweden verify at least one pack from each new serialized batch they receive as part of their incoming inspection, batches with data errors can be detected and thereby corrected as a prevention of false alarms.

The soft launch does not mean that pharma companies are exempt from uploading data to the EU Hub. In order to ensure a working supply chain all serialized data must be loaded retrospectively.

All other system alerts (except data errors) must be investigated as potential falsifications. Alerts caused by the end-user should as well be investigated and processes updated with preventive actions.

During the soft launch, all stakeholders in the supply chain should monitor their processes. e-VIS will monitor the performance of SMVS and system alerts, and perform corrective actions, if required.

After 8 weeks the soft launch will be discontinued and from that point on, all system alerts will be treated as potential falsifications.

The detailed recommendation for a soft launch (in Swedish) is published on the e-VIS webpage.