

## Questions from MAH's regarding the Swedish Pilot

e-VIS has received a number of questions from MAH's concerning the pilot activities being executed with the Swedish system. Typical questions are:

- What is needed for a MAH to participate in the Pilot?
- How does a MAH apply/register for participation in the Pilot?

The following information is intended to explain the Pilot-situation and to answer those and hopefully other related questions.

e-VIS has been planning for Pilots in several stages, or parts.

Pilot, part 1, was executed in May under strict control and with pre-defined scripts. This was the first use of the system "end-to-end", i.e. pack data uploaded to the Swedish Medicines Verification System (SMVS) via the Eu Hub by a MAH (OBP) and an end-user connected to SMVS Production environment. It was executed with 1 Swedish wholesaler and 1 product from 1 MAH. All use-cases relevant to wholesalers were executed. The scripts were prepared prior to the execution. In addition, alerts from the system were simulated, e.g. a code with an invalid serial number printed on paper was scanned. The Pilot part 1 was successful.

Pilot, part 2, will be performed in August under equally controlled conditions and now 1 pharmacy will execute the use-cases relevant for pharmacies, primarily the "dispense" use-case which, for obvious reasons, cannot be executed by a wholesaler. It will use 2 products from 2 different MAH's.

The participating MAH's in the two first parts of the Pilot are organisations that in an early stage of the Swedish project have volunteered to be active in the Pilot. We regret that it is not possible to expand the Pilot part 2 to more MAHs.

Following these two controlled exercises with pre-defined scripts, the Pilot part 3, is planned to be run during the period September to November. This will include wholesalers and an increasing number of pharmacies from several pharmacy chains

This 3<sup>rd</sup> Pilot will differ from the two previous ones essentially by being "open". This means that the wholesalers and the pharmacies will scan serialized packs as a part of their normal business processes, e.g. when dispensed to patients or returned to the Wholesalers. All use-cases relevant in the daily operations will be executed for the products in scope. There are no simulations planned. For these reasons, there will be no pre-defined scripts and no selection of specific products/packages to be included

During this phase, e-VIS will closely follow the progress and have a continuous communication with the end-user organisations. We will also, importantly, evaluate the business processes we have developed for e-VIS, e.g. on-boarding, and the corresponding SOPs. The end users will also have the opportunity to fine tune any changes to their business processes and corresponding work instructions. Together we will make sure the communication across several organisations work when needed, e.g. when an alert situation occurs. When executing this part of the Pilot, e-VIS will make efforts to provide information about current status of the SMVS and statistics.

MAH actions: There is no need, or possibility, for MAH's to apply or register for participation. Serialised packs from MAH's will automatically be included when they are available on the Swedish market and scanned by end-users connected to the SMVS. e-VIS strongly encourage MAH's to upload

products to the Swedish system, via the EU Hub, thereby making them available for the Pilot as soon as possible.

Please note that there will be a very limited number of products verified/decommissioned in the beginning of the Pilot part 3 period because of the limited number of end users connected. We expect that during the three months period both the number of connected users and the number of serialised packs on the market will grow very quickly. We will assess if there is a need for another scripted pilot where specific features are evaluated but we have not yet decided on this.