Ending the Stabilisation Period in Sweden

A Stepwise Approach
Step 1: October 2019
Step 2: January 2020

Summary of guidelines, December 2019
Stabilisation period in Sweden

- 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 are no stabilisation period for other stakeholders.**
- Recommendation from e-VIS and Swedish Pharmacy Association. No official stabilisation period.
- Warnings not to be considered as possible falsifications during the stabilisation period:
  - Product code or pack unknown (A1/A2/A3)
  - Expiry date mismatch (A52)
  - Batch identifier mismatch (A68)
- All end-users should respond to, investigate and take preventive actions for alerts that are due to own handling errors.
- Warnings and alerts due to ‘inactive packs’ have never been included in the soft launch.
  - [Guidelines for alert handling](#) published by e-VIS
  - [New ‘e-verification form’](#) set up in the existing web based ‘quality complaints procedure’.
- Risk Mapping performed in August – high risks ending soft launch for all data errors at one time.
- Stabilisation period to be ended October 2019 with a step wise approach.
Stabilisation period for End-Users in Sweden until 30th September

Data Errors **included** in stabilisation period

- **Product Code Unknown** (A1)
- **Pack not found** (A2, A3) – ALERT
- **Expiry Date Mismatch** (A52) – ALERT
- **Batch Identifier mismatch** (A68) – ALERT

Not **included** in stabilisation period

- **Handling Errors from End-Users.**
  According to guidelines: to be documented in end user quality system. Preventive actions. Example: Tried to commission an already decommissioned pack

- **Warnings and alerts alerts due to ‘inactive packs’.**
  Example: Stolen, Destroyed, Locked, Exported out of EU or Decommissioned in another location.

- **Warnings due to ‘expired packs’**
  Batch expired, batch recalled or product withdrawn.
Stepwise approach for ending stabilisation period

**Data Errors included in soft launch**

- Product Code Unknown (A1)
- Pack not found (A2, A3) – ALERT
- Expiry Date Mismatch (A52) – ALERT
- Batch Identifier mismatch (A68) – ALERT

**Not included in Soft Launch**

- Handling Errors from End-Users. According to guidelines: to be documented in end user quality system. Preventive actions. Example: Tried to commission an already decommissioned pack.
- Warnings and alerts alerts due to ‘inactive packs’. Example: Stolen, Destroyed, Locked, Exported out of EU or Decommissioned in another location.
- Warnings due to ‘expired packs’ Batch expired, batch recalled or product withdrawn.

**Steps**

1. **Step 1** – not covered by stabilisation 1 Oct 2019
2. **Step 2** – not covered by stabilisation 31 Jan 2020
3. **Step 3** – target to end stabilisation March 2020