

# Ending the Stabilisation Period in Sweden



## A Stepwise Approach

Summary of guidelines, September 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 is no stabilisation period for other stakeholders.**
- Recommendation from e-VIS and Swedish Pharmacy Association. No official stabilisation period.
- During spring extended until 30 September 2019
- Warnings not 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 in January – 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
- Soft Launch to be ended 30 September with a step wise approach

# Stabilisation period for End-Users in Sweden until 30<sup>th</sup> September

## 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Batch expired, batch recalled or product withdrawn.

# Stepwise approach for ending stabilisation period

## Data Errors Included in soft launch

Product Code Unknown (A1)

Pack not found  
(A2, A3) – ALERT

**Step 3 – to be  
evaluated in Jan 2020**

Expiry Date Mismatch  
(A52) – ALERT

**Step 2 – to be  
evaluated in Nov 2019**

Batch Identifier mismatch  
(A68) – ALERT

**Step 1 – not covered by  
Soft Launch 1 Oct 2019**

## 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 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.