

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 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Batch expired, batch recalled or product withdrawn.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

**Step 3 – target to end
stabilisation March 2020**

**Step 2 – not covered by
stabilisation 31 Jan 2020**

**Step 1 – not covered by
stabilisation 1 Oct 2019**

Not included in Soft Launch

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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.