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 30th 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  Batch expired, batch recalled or product withdrawn.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

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Step 1 – not covered by Soft Launch 1 Oct 2019

Step 2 – to be evaluated in Nov 2019

Step 3 – to be evaluated in Jan 2020