Erfarenhet från e-VIS Mock Exercise 2025

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e-VIS is the National Medicines Verification Organisation in Sweden in the scope of the Commission Delegated Regulation (EU) 2016/161. e-VIS is a non-profit organisation established in 2016 by the key stakeholders in the medicines supply chain in Sweden to manage the national medicines verification system for Sweden.

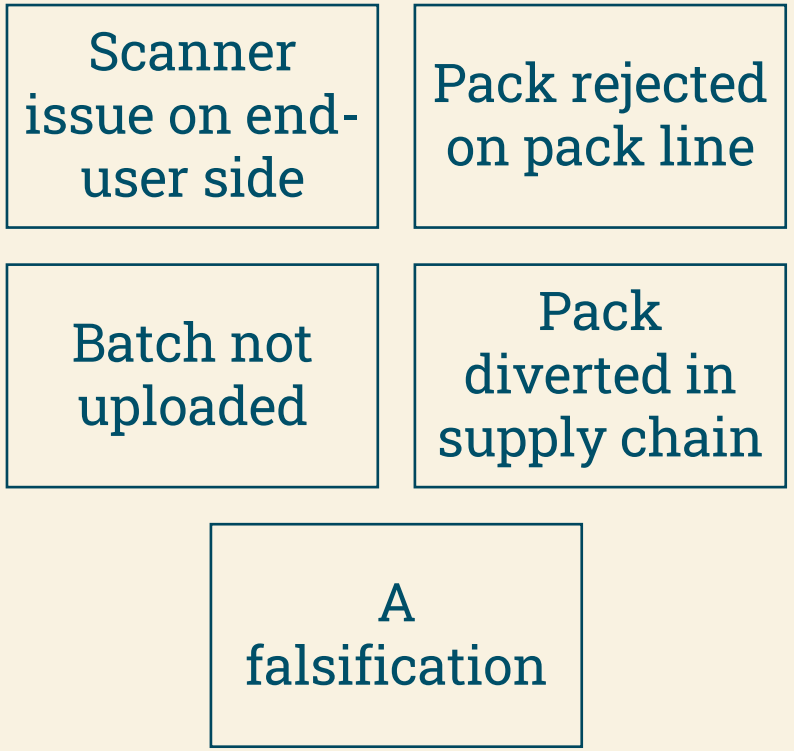
Purpose

To improve and clarify the **alert management process** for medicinal products in Sweden.

The purpose of this mock exercise was to improve and clarify the alert management process in Sweden, from the **creation of an alert** in the system to the **identification of possible falsification**. The focus was on **process**, **responsibility**, and **communication**.

Method

- Stakeholders from **across the Swedish medicines supply chain** participated in five scenario-based exercises to test:
  - If a root cause for the alerts can be found at MAH, pharmacies or wholesalers in cases where the pack is not a counterfeit
  - If an actual falsification can be identified when the pack triggers warnings and alerts.
- These scenarios simulated **real-life situations** involving alerts and warnings, requiring participants to investigate, communicate, and resolve issues collaboratively.
- Media awareness training
- Neither **SMVS nor other real-life data** was used during the exercise.



Participants

- e-VIS
- Pharmacies – Sveriges Apoteksförening
- Wholesalers - LDF
- Marketing authorization holders: Lif, FGL & LH
- Swedish National Competent Authority - Läkemedelsverket

Main conclusions 1/2

- **Strong Competence:** Participants demonstrated robust knowledge and capability in managing alerts and potential falsifications.
- **Communication Improvements:** Recommendations include better sharing of alert handling guidelines with all stakeholders and ensuring pharmacies know when and how to report issues, including copying in e-VIS on relevant correspondence.
- **Technical and Procedural Issues:**
  - The 10-day rule for reactivating decommissioned packs may be too short, sometimes leading to unnecessary destruction of medicines.
  - Guidelines for uploading packs in the EMVS (European Medicines Verification System)
  - Improve access to information about exemptions
  - Possibility to lock batches in the EMVS.

Main conclusions 2/2

- **Reporting Channels:** There is a need to clarify how Marketing Authorisation Holders (MAHs) should report falsifications to the NCA, and whether a 24-hour contact point is needed, similar to product recall procedures.

- **Need to clarify Processes:** The exercise highlighted the necessity to further clarify processes and responsibilities for reporting and managing confirmed falsifications. This includes defining the actions e-VIS should take and establishing clear guidelines for cooperation with the Swedish Medicines Agency (NCA).

- **Collaboration and Information Sharing:** The exercise underscored the importance of coordinated investigation and communication, especially in cases of confirmed falsification, and the need for clear protocols for information sharing with the NCA, law enforcement, and the public.

Questions?