e-VIS webinar:
Alert and Exception Handling for MAHs on the Swedish market

2 February 2024

Welcome

For the best possible meeting – mute your microphone when you are not talking

Feel free to ask questions - best done via "Raise you hand" in teams or via chat

Feel free to use the camera when asking questions.

The presentations will be posted on the e-VIS web site after the meeting. We do not record the meeting.

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Agenda

1. **Team e-VIS**
2. **FMD and control of safety features in Sweden**
3. **Investigation of alerts for MAHs on the Swedish market**
4. **Investigation of reported packs via complaint channels from Swedish end-users**
5. **Questions & answers**

Medicines Verification System in numbers

The European system includes and engages close to 2,500 pharmaceutical companies, 4,000 pharmaceutical distributors, 150,000 pharmacies and 6,000 hospital pharmacies in 29 countries

Over 110 million packs per year will be registered in the Swedish part of the system.

A total of 1520 locations are registered in the Swedish system

1 million transactions per day in the Swedish system

Alert rate in Sweden

e-VIS provide for investigation of alerts

0,03 % of all transactions generate alerts

Most pharmacies has a decommissioning rate of 100 %

About 100 complaint reports from end-user regarding packs with FMD-issues per month

FMD and control of safety features

e-VIS webinar on alert handling for MAHs

Responsibilities of end-user

- Verify that the unique identifier is present in the EMVS.
- Control that the unique identifier has not previously been decommissioned.
- Decommission the unique identifier in the EMVS prior to supply to the public or in any other case where the pack leaves the supply chain.
- Check anti-tampering device.

(there are no obligations to “scan a pack”! The most common reason for scanning the 2D-data matrix in a Swedish pharmacy is to use the product code for stock management and to control that the correct medicinal product is dispensed to patient.)

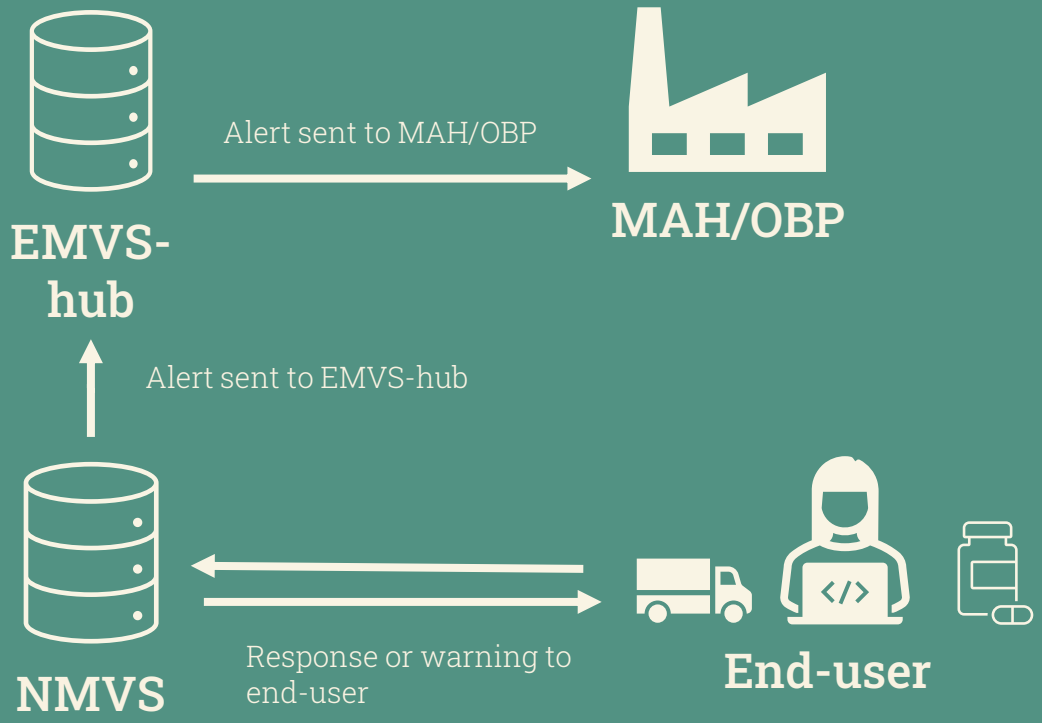
What can be found through the system?

Signal	Falsifications	Quality deficiencies
”Batch or pack not found”	Medicine pack manufactured by other entity than the pharmaceutical company/MAH	Quality deficiencies of MAH’s upload of pack data to the EMVS and control of upload at batch release.
“Pack already supplied”	Medicines that earlier been dispensed or decommissioned have with fraudulent intent been returned to legal supply chain. Falsified packs packed with existing unique identifier	Quality deficiencies in the handling of the packs at pharmacy/wholesaler level, e.g. complaints samples and packs returned through patient complaints. Quality deficiencies in the production/serialisation process/ reconciliation, two or more packs have the same unique id.
"Pack is recalled. Product is withdrawn”	Recalled batches or withdrawn products have with fraudulent intent been returned to legal supply chain.	Quality deficiencies in the handling of packs belonging to recalled batch/withdrawn product. E.g. information regarding the recall has not reached the wholesaler/pharmacy.
“Pack is destroyed”	Packs intended for destruction have been stolen and returned into saleable stock/supply chain.	Quality deficiencies in the handling of packs aimed for destruction at pharmacy/wholesaler level.

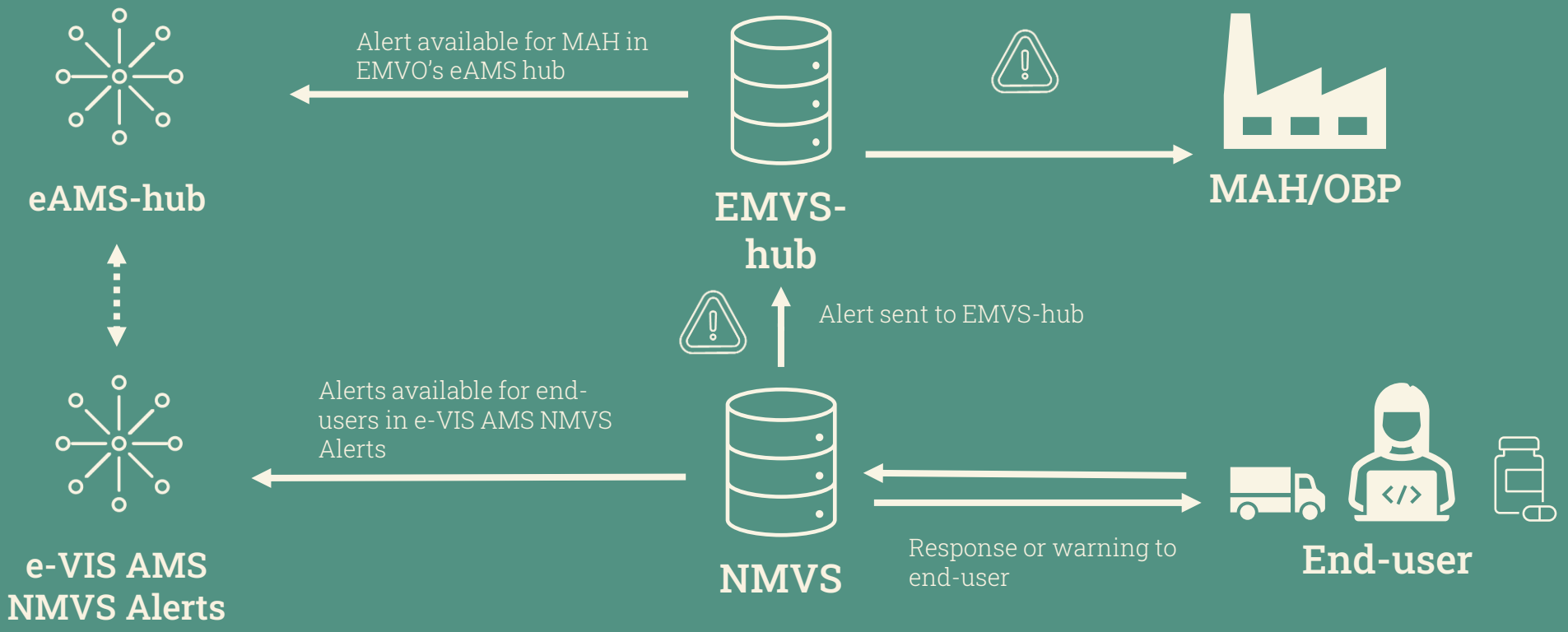
Alerts and exceptions

Alerts generated in the NMVS

- The Swedish NMVS always sends a response to the end-user after a successful or failed verification or status change.
  - End-user systems configuration impacts how responses are shown to end-users
- Some warnings generate alerts. The alerts are sent to the MAH via the EU-hub.
  - The end-users does not receive the alert, but the alert-ID.
  - e-VIS makes the alert available for the end-user via e-VIS AMS (Alert management system) NMVS Alerts.



Alerts generated in NMVS



- The end-users does not receive the alert, but the alert-ID.
- e-VIS makes the alert available for the end-user via e-VIS AMS (Alert management system) NMVS Alerts.
- EMVO also transfer all alerts to the eAMS-HUB where MAHs can access and document their investigation of alerts.

Content of the alert - examples

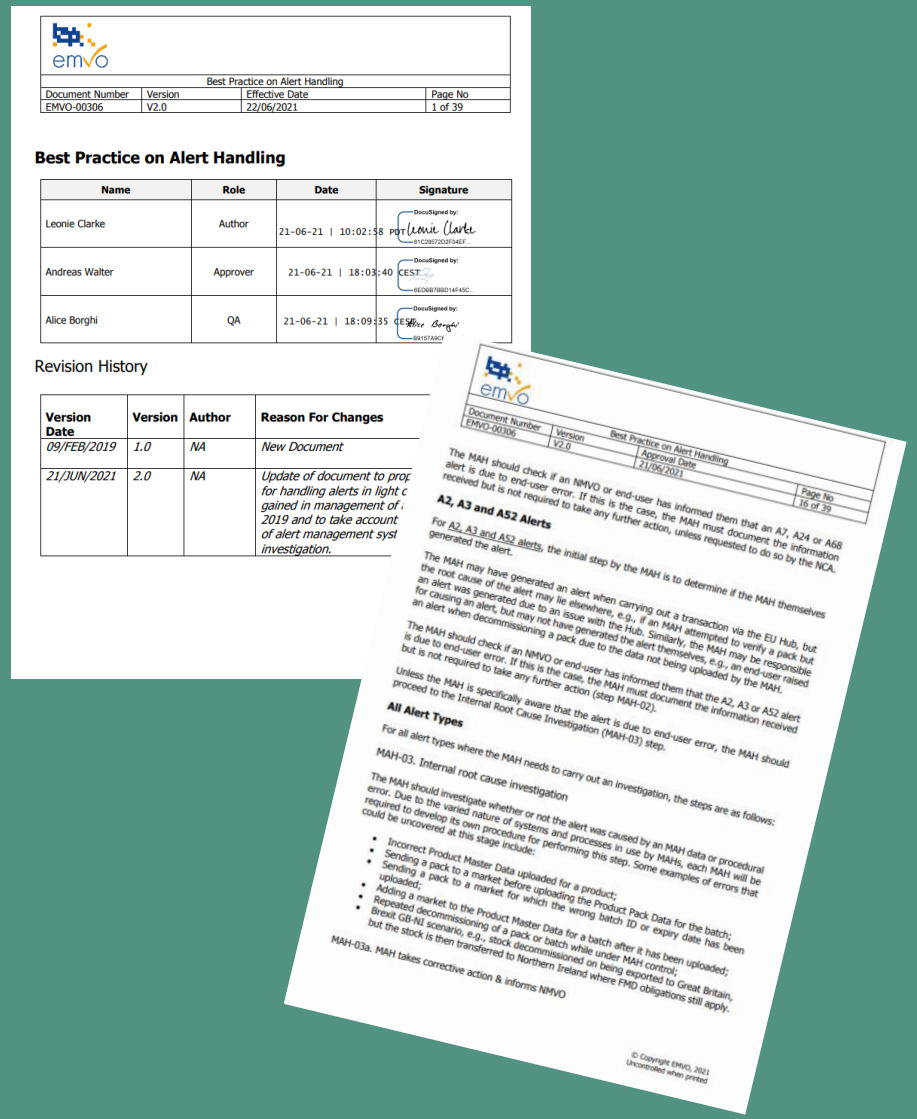
- **Date and time** when the alert was generated
- Alert **code** and alert **message** describing what kind of error that has caused the alert.
- Unique **alert-ID** identifying the alert
- Target or **source market** – the market where the end-user is present
- **Product code** in the request to EMVS generating the alert
- **Serial number** in the request to EMVS generating the alert
- **Batch number** in the request to EMVS generating the alert
- **Expiry date** in the request to EMVS generating the alert
- If unique identifier been added to the request to EMVS by **manual entry** or not
- **Client/Locations ID** of the end-user
- If alert generated during a status change
  - The **target state** requested in the failed status change.
  - **Acctual state** of the pack if known.

Investigation of alerts in Sweden

e-VIS webinar on alert handling for MAHs

EMVO Best Practice on Alert Handling

- Published in June 2021 to harmonize alert investigation within Europe with input from all EMVS stakeholders.
- Describes how alerts should be investigated by MAH and end-users and which alerts that should be investigated.



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Best Practice on Alert Handling			
Document Number	Version	Effective Date	Page No
EMVO-00306	V2.0	22/06/2021	1 of 39

Best Practice on Alert Handling

Name	Role	Date	Signature
Leonie Clarke	Author	21-06-21 | 10:02:58 PDT	DocuSigned by: Leonie Clarke
Andreas Walter	Approver	21-06-21 | 18:03:40 CEST	DocuSigned by:
Alice Borghi	QA	21-06-21 | 18:09:35 CEST	DocuSigned by: Alice Borghi

Revision History

Version Date	Version	Author	Reason For Changes
09/FEB/2019	*1.0*	*NA*	*New Document*
21/JUN/2021	*2.0*	*NA*	*Update of document to prop for handling alerts in light c gained in management of 2019 and to take account of alert management syst investigation.*

emvo

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EMVO-00306	V2.0	Approval Date 21/06/2021	16 of 39

The MAH should check if an NMVO or end-user has informed them that an A7, A24 or A68 alert is due to end-user error. If this is the case, the MAH must document the information received but is not required to take any further action, unless requested to do so by the NCA.

A2, A3 and AS2 Alerts

For A2, A3 and AS2 alerts, the initial step by the MAH is to determine if the MAH themselves generated the alert.

The MAH may have generated an alert when carrying out a transaction via the EU Hub, but the root cause of the alert may lie elsewhere, e.g., if an MAH attempted to verify a pack but an alert was generated due to an issue with the Hub. Similarly, the MAH may be responsible for causing an alert, but may not have generated the alert themselves, e.g., an end-user raised an alert when decommissioning a pack due to the data not being uploaded by the MAH.

The MAH should check if an NMVO or end-user has informed them that the A2, A3 or AS2 alert is due to end-user error. If this is the case, the MAH must document the information received but is not required to take any further action (step MAH-02).

Unless the MAH is specifically aware that the alert is due to end-user error, the MAH should proceed to the Internal Root Cause Investigation (MAH-03) step.

All Alert Types

For all alert types where the MAH needs to carry out an investigation, the steps are as follows:

MAH-03. Internal root cause investigation

The MAH should investigate whether or not the alert was caused by an MAH data or procedural error. Due to the varied nature of systems and processes in use by MAHs, each MAH will be required to develop its own procedure for performing this step. Some examples of errors that could be uncovered at this stage include:

- Incorrect Product Master Data uploaded for a product;
- Sending a pack to a market before uploading the Product Pack Data for the batch;
- Sending a pack to a market for which the wrong batch ID or expiry date has been uploaded;
- Adding a market to the Product Master Data for a batch after it has been uploaded;
- Repeated decommissioning of a pack or batch while under MAH control;
- Brexit GB-NI scenario, e.g., stock decommissioned on being exported to Great Britain, but the stock is then transferred to Northern Ireland where FMD obligations still apply.

MAH-03a. MAH takes corrective action & informs NMVO

End-user Investigation of exceptions generating alerts

- Pharmacies has to decommission the packs as supplied when handed out to the public.
- End-users should investigate all exceptions (regardless if an alert has been generated or not) to check if the exception could be due to end-users own handling of the pack / unique identifier.
  - Remark for Sweden: **If the end-user can't find any root cause on their side**, the pack is reported to MAH / MAH representative with e-VIS on copy.
- End-user inform the NMVO of their investigation if the alert is due to technical or procedural error on their part.
  - Remarks for Sweden: End-users inform e-VIS via e-VIS AMS NMVS Alerts.

MAH investigates alerts

- Alerts are sent to MAH via EMVS Hub.
- Alerts are also available in EMVO eAMS.

MAH investigates alerts

Determine alert type and source

- **MAHs are not required to investigate A7, A24 and A68 alerts except in the following circumstances:**

    a. MAH is aware they have caused the alert(s) due to repeating decommissioning transactions when packs are under their control;

    b. An end-user contacts them about such an alert;

    c. The NMVO contacts them about such alert(s), for example, in the case of an A7, A24 or A68 alert generated by an end-user where no end-user root cause can be identified;

    d. The NCA requests them to investigate such alert(s).

The reason for this approach is that A7 and A24 alerts generated by end-users will rarely be due to errors on the part of the MAH. Similarly, the vast majority of A68 alerts generated by end-users are due to end-user software or scanner issues.

- If Market: EU and Client ID is the one of the MAH the MAH has caused the alerts themselves in the EU-hub.

Alert codes

EMVS Alert code	Error	Definition	MAH requested to investigate
A2	Batch Not Found	The product exists in the EMVS ecosystem, but not the batch or serial number. This error code can only be returned if an intermarket transaction took place and the EU HUB didn't find the batch.	YES
A3	Pack Not Found	The pack has not been found.	YES
A7	Pack Already in Requested State	The pack state change cannot be completed because it is already in the requested state.	NO – unless requested to do so by end-user/NMVO/NCA
A24	Status Change Could Not Be Performed	The pack state change cannot be completed because the requested state conflicts with the current state. E.g. Trying to "Supply" a "Destroyed" pack.	NO – unless requested to do so by end-user/NMVO/NCA
A52	Expiry Date Mismatch	The expiry date supplied for the pack request mismatches the expiry date held within the system for the given batch.	YES
A68	Batch Number Mismatch	The batch number supplied for the pack request mismatches the batch number the pack belongs to.	NO – unless requested to do so by end-user/NMVO/NCA

MAH investigates alerts

MAH documents alert, no further action required

- For A7, A24 or A68 no further action is required unless MAH is aware that the alert is caused by their handling.

If alert documentation in eAMS-hub:

- Set investigation status to Root Cause Not on My Side
- Do not change alert status, or leave as Open
    - A closed alert means that is has been resolved and that a root cause has been found. If MAH cannot find any root cause on their side, it means that further investigation is required by other stakeholders.

MAH investigates alerts

Internal root cause investigation

The MAH should investigate whether or not the alert was caused by an MAH data or procedural error

- Incorrect Product Master Data uploaded for a product;
- Sending a pack to a market before uploading the Product Pack Data for the batch;
- Sending a pack to a market for which the wrong batch ID or expiry date has been uploaded;
- Adding a market to the Product Master Data for a batch after it has been uploaded;
- Repeated decommissioning of a pack or batch while under MAH control;
- Distribution errors in the EU-hub

MAH investigates alerts

Inform or request NMVO support

- If the MAH determines that they were the cause of the alert, the MAH should take corrective action as quickly as possible and inform the NMVO (and end-user if the end-user has contacted them directly about the alert) within 2 working days of the alert being generated.
    - A progress report should be provided after 2 working days if the investigation is not completed at that stage.
- If the MAH has found that the alert was not caused by MAH procedural or data error, or an EU Hub issue, the MAH should contact the relevant NMVO, and ask them to investigate if there is a root cause at national system level or at end-user level.
- **Exception for the Swedish market:**
    - If the end-user has reported the pack to MAH via the national complaint channels, inform the end-user of the results of the investigation. Remember to add alerts@e-vis.se as a copy so e-VIS can close the alert.

MAH investigate alerts

Inform or request NMVO support

If alert documentation in eAMS-hub:

- If root cause is found on MAH side
  - Set investigation status to Root Cause On My Side
  - Change status to Closed
- If root cause not found on MAH side
  - Set investigation status to Root Cause Not On My Side
  - Do not change alert status, or leave as Open

e-VIS is not connected to the eAMS hub – exported data from eAMS can be sent via e-mail.

- Export alert investigation data from eAMS hub for the Swedish market and send to alerts@e-vis.se.
- Specify in the e-mail that MAH require feedback from end-users on A2, A3 and A52 alerts or further investigation is required from the end-user.
- e-VIS will check if investigation has been provided in e-VIS AMS NMVS Alerts and feedback to MAH.

eAMS-HUB and e-VIS eAMS NMVS Alerts

- When e-VIS connects to the eAMS-hub MAHs can share investigations of alerts directly through the eAMS to e-VIS.
- e-VIS can also share end-user investigation and e-VIS's own investigation of alerts directly through the eAMS to the MAH.

eAMS-hub

e-VIS AMS NMVS Alerts

eAMS-HUB and e-VIS eAMS NMVS Alerts

Why hasn't e-VIS yet connected to the eAMS HUB?

- e-VIS priority has been to connect end-users to e-VIS AMS NMVS Alerts.
- Direct access to MAH investigation data in NMVS Alerts must not confuse or create extra workload for end-users.
  - e-VIS want to reassure that MAHs are handling alerts in eAMS hub according to EMVOs Best Practise on Alert handling and according to EMVOs EAMS Handbook
- e-VIS plan is to connect to the eAMS during 2024.

eAMS-hub

e-VIS AMS NMVS Alerts

eAMS-HUB and e-VIS eAMS NMVS Alerts

- Alert can only be closed by MAH when a root cause has been identified.
  - If the MAH does not know the root cause, but suspects that the root cause is on the end-user side, the alert should be left in status Open or Under investigation so that the end-user can continue the investigation.
  - A closed alert will give the impression to the end-user that a root cause has been identified and that no further investigation is required.

- e-VIS goal is to retrieve information about the end-user and MAH investigation of the alerts so that all alerts can be closed.
  - If e-VIS has not received any root cause of an alert e-VIS will contact the respective stakeholders starting where we see the likely root cause.

Investigation of reported packs via complaint channels from end-users

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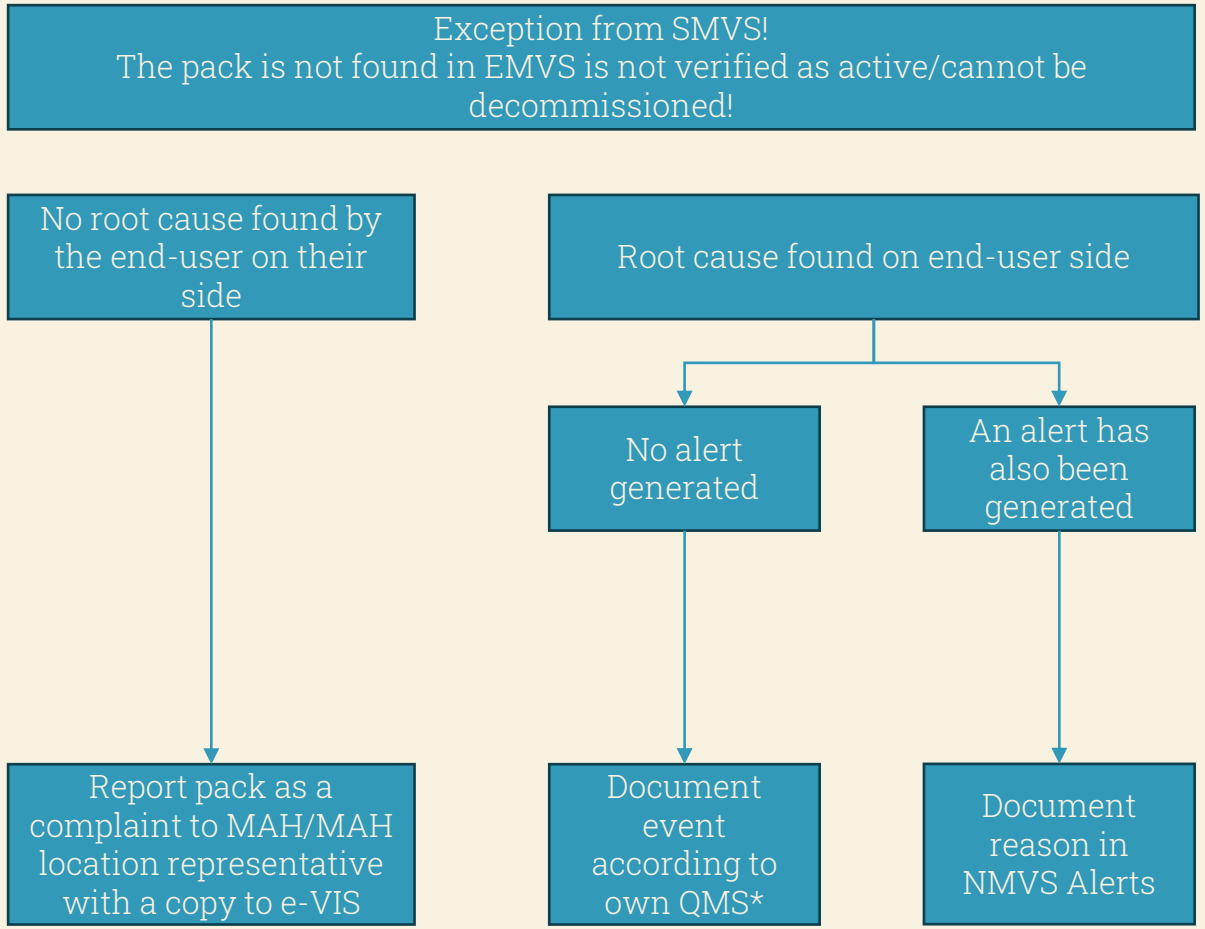
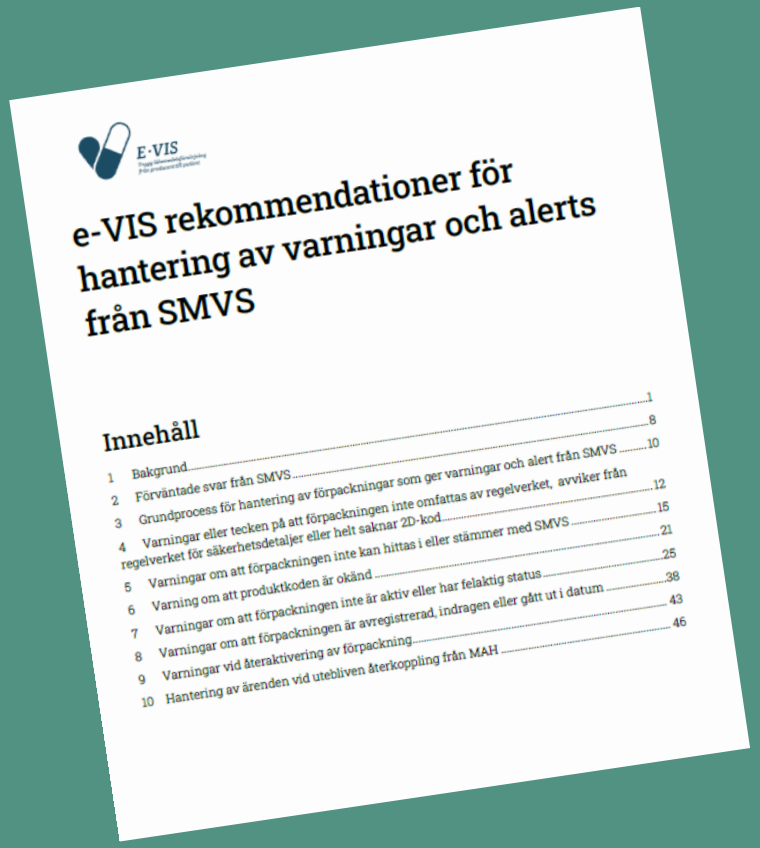
End-users handling of alerts and exceptions

- Pack is not found in EMVS or pack in stock is not verified as active/cannot be decommissioned!
- Investigate! Can the root cause of the exception be found on the end-user's own side?
- Is there a valid exemption from the NCA that grands pharmacies to supply the pack without decommissioning it?



*QMS – Quality Management System

e-VIS recommendations for handling exceptions and alerts



E·VIS

e-VIS rekommendationer för hantering av varningar och alerts från SMVS

Innehåll

Content

- How end-users should handle and report pack generating exceptions.
- Processes for complaint report investigation together with MAH / MAH local representative depending on the type of exception.
- Handling of alerts when root cause is on end-user side.
- Responses and exemptions from EMVS.

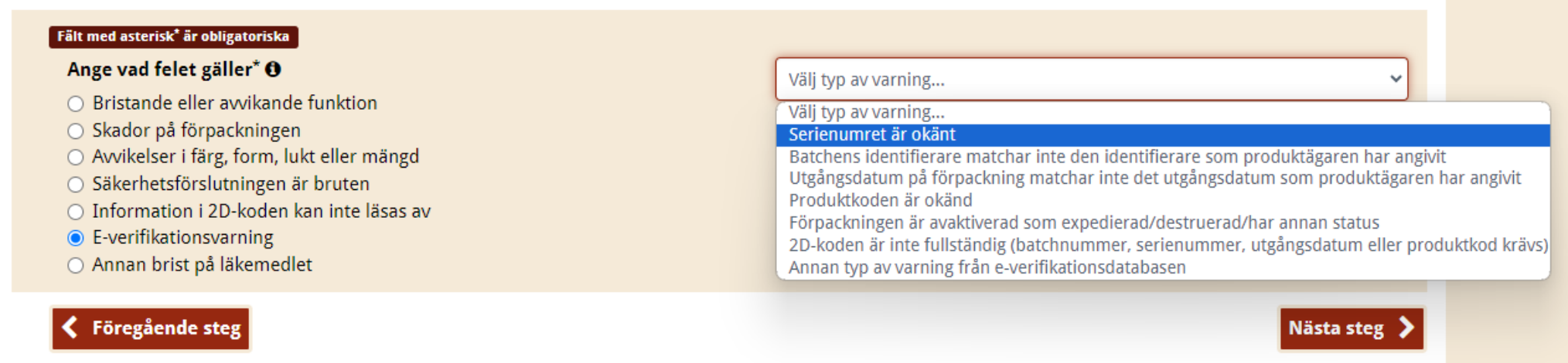
The recommendations have been developed by e-VIS in collaboration with

- Sverige Apoteksförening
- Läkemedelsdistributörs-föreningen
- Läkemedelsindustriföreningen (Lif)
- Föreningen för Generiska Läkemedel och biosimilarer
- Läkemedelshandlarna

Last update in May 2023 with English translation

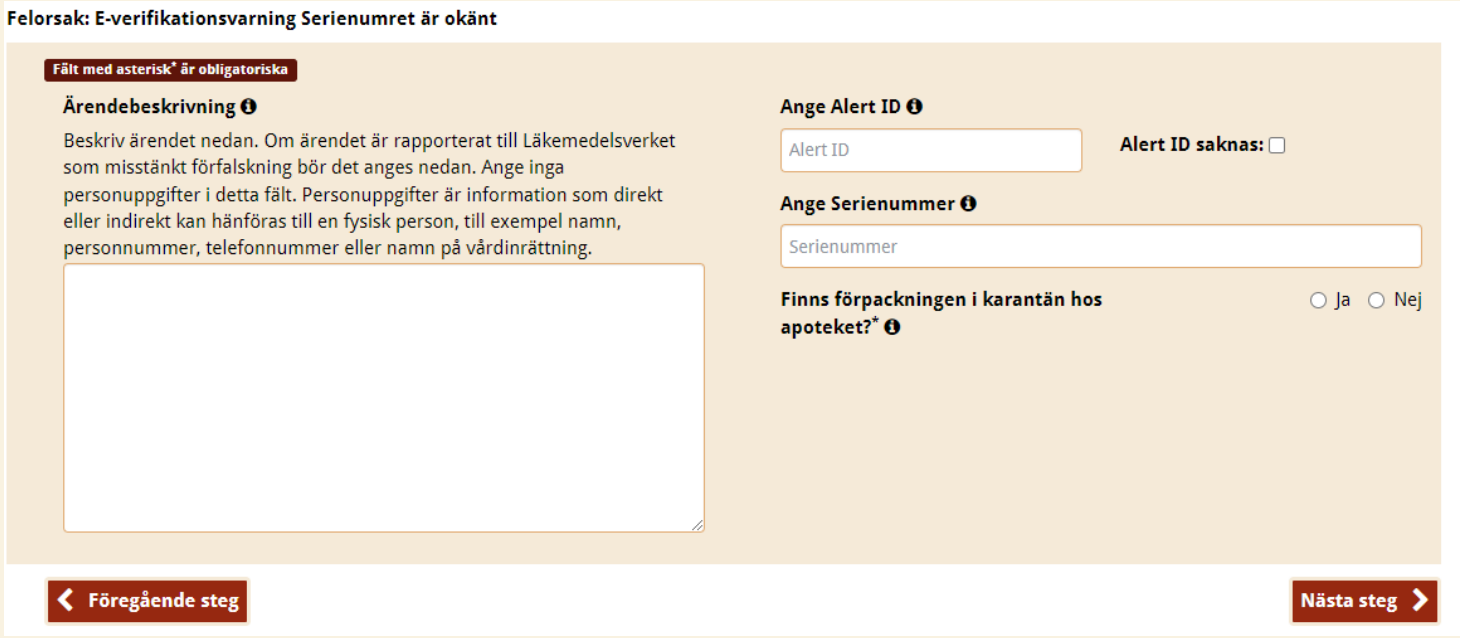
Complaint tool reklameraläkemedel.se

- Quality Complaint web-based form
- End-user selects “E-verifikationsvarning” as an error type
- End-user selects which kind of warning that the end-users has received from the EMVS
- e-VIS recommend all pharmacies and other end-users, when possible, to use reklameraläkemedel.se when requesting investigation from the MAH.
- If other tool is used the end-user should reassure that all information is present in the report / e-mail to the MAH and that alerts@e-vis.se is added as a copy.



Complaint tool reklameraläkemedel.se

- Reporting fields are adapted so serial number and alert-ID is not forgotten.
- E-mail of the complaint is sent to MAH or MAH Local Representative.
- MAH can choose a different e-mail address for complaints regarding FMD exception.
- A copy is sent to alerts@e-vis.se
- A copy is sent to the Swedish NCA and to the reporting end-user.



MAH investigation of complaint reports

Reports when **pack is in unexpected pack status – pack not active**

- If the report concerns a pack already decommissioned at the same location, request the investigation that the end-user has carried out so that they have checked that the root cause is not on their side.

- The pack is always found in EMVS if the report is regarding pack status i EMVS. Check with the data uploaded in EMVS by MAH to check that correct unique identifier is in the report.

- Request information from e-VIS for information of where and when the pack unique identifier has been decommissioned previously.

    - E-VIS checks the pack history in EMVS. Product code and serial number is required.

    - e-VIS needs proof that the end-user has requested investigation of the pack, e.g. a complaint report.

MAH investigation of complaint reports

Report when **pack is not found** in EMVS

- Scanner issues can be hard for a community pharmacy to identify.
  - Compare unique identifier in alert with unique identifier in the complaint report.
  - Request a photo of the pack to compare unique identifier on the pack with unique identifier in the alert.
- Most exceptions generate alerts, request the alert-ID from the end-user
  - It is likely that many alerts has been generated with the same unique identifier. End-users are requested to add one alert-ID per reported pack.
  - If the product code is not found no alert is generated.
- The FMD exception ”product code not found” is many times confused with related to product code information in end-users stock management tool / incorrect product code information i LiiV/VARA.

Respond to end-user

When cause is on the MAH side and cannot be fixed

- Inform end-user that the cause is on the MAH side and that the error cannot be fixed.
- Inform end-user if pack can be destroyed by the end-user or returned.
- If returned to wholesaler, note that the same alert will be generated at the wholesaler when controlled.

If error is not on MAH side

- Inform the end-user that no cause for the error can be found on MAH side.
- Inform the end-user that they have to continue the investigation and that they has to inform e-VIS and the MAH of the result.

When cause is on the MAH side and has been corrected

- Inform the end-user that the error has been fixed and the end-user should be able to verify the pack as active.
- Suggest that end-user contacts MAH again if the error hasn't been resolved.

Reply all on the complaint report – NCA e-mail and reklamationer@lif.se can be removed.

Respond to end-user

For all complaints regarding FMD exceptions

- Always add alerts@e-vis.se as copy
- Refer to “Ärendenummer”/case number in reklameläkemedel.se
- Prioritized information for end-users and e-VIS is:
  - If MAH can confirm that the pack is not a possible falsification.
  - If the cause is on MAH side and a short description of what has happened.
  - How the end-user should handle the pack.
- Offer the end-user to contact MAH if they want information when the full investigation report is ready.

If the complaint report concerns alerts;
alerts are updated in the eAMS hub by the MAH and a response on the complaint report must be sent to the end-user by MAH via e-mail.

E-VIS will close the alerts in the AMS related to the complaint report when e-VIS has received information on a root cause.

Respond to end-user

Use a languange adapted for the end-user

After verification of the inciminated serial number: we can confirm that the units should been rejected by the system, however, they were not rejected.

VS

Due to a mistake on our side, the pack have not been uploaded to the database.

Risk based verification at wholesaler level prevents unnecessary alerts

Q&A

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Why isn’t batch and expiry date always present in the alert?

- The batch number and expiry date is only mandatory if the verification or decommissioning is performed by scanning the 2D-data matrix.
- When entering the unique identifier manually from the data on the pack only the product code and serial number is mandatory.
- e-VIS recommends end-user to not add batch or expiry date when verifying/decommissioning a pack to prevent unnecessary alerts.

Why are there still scanner issues in pharmacies?

- Sweden has a low rate of scanner issues and the issues that are present are located to some end-users.
- Scanner issues can be complicated to replicate and therefore hard to prevent during testing. An issue only occurring 0,001 % of all scans will create a big number of alerts for pharmacies with extensive operations.
- Design of pack can prevent scanner issues by not adding other carriers close to the 2D-data matrix.
- Support and encourage end-users to:
  - Reassure that all packs decomissioned prior to supply.
  - Document in NMVS Alerts or national AMS an alert has been generated due to a scanner issue.

When e-VIS connects NMVS Alerts to the eAMS will we stop use the complaint channels for communications with the end-users?

- No, the complaint channels still has to be used.
- Swedish end-user are required to report packs with quality issues to MAH / MAH representative.
- Not all signals of possible falsifications from the EMVS generates an alerts and these packs has to be reported in an efficient way.
- Most pharmacies never get an alert for months and for that reason the NMVS Alerts is not a widely known system. Reklameraläkemedel.se is used for all kind of complaints and is well known by Swedish pharmacies.

Why does Sweden have national guidelines to complement the EMVO Best Practice On Alert Handling?

- The EMVO Best Practise does only cover handling of exceptions generating alerts.
- According to national legislation all pharmacies has to report all quality issues to MAH / MAH representative. Using the same system for all types of complaits and quality issues facilitates the pharmacy processes.
- Requirements on MAHs are in lager extent harmonized through EU / EES. End-user requirement, especially pharmacy requirements are in a smaller extent harmonized and legislation differ greatly between markets in the EU.
- Complaint reports are usually required for returns to wholesalers.

e-vis.se/en/alerts-and-exceptions/

For more information, recommendations and best practice on handling alerts and exceptions

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Trygg läkemedelsförsörjning
från producent till patient