E·VIS
Trygg läkemedelsförsörjning
från producent till patient

Report

e-VIS Mock Exercise

31 October 2025

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2. Summary

Purpose:

The e-VIS Mock Exercise, held on 28 August 2025 in Stockholm, was organised to improve and clarify the alert management process in Sweden for medicinal products carrying safety features. The exercise aimed to test and refine the procedures for handling alerts—from their creation in the system to the identification of possible falsification—with a focus on process, responsibility, and communication among all stakeholders.

Approach:

Stakeholders from across the Swedish medicines supply chain (including e-VIS, pharmacies, wholesalers, Marketing Authorisation Holders (MAH), and the Swedish Medical Products Agency [the Swedish National Competent Authority (NCA)] participated in five scenario-based exercises. These scenarios simulated real-life situations involving alerts and warnings, requiring participants to investigate, communicate, and resolve issues collaboratively.

Main Conclusions:

- **Strong Competence:** Participants demonstrated robust knowledge and capability in managing alerts and potential falsifications.
- **Need to clarify Processes:** The exercise highlighted the necessity to further clarify processes and responsibilities for reporting and managing suspected falsifications. This includes defining the actions e-VIS should take and establishing clear guidelines for cooperation with the Swedish NCA.
- **Reporting Channels:** There is a need to clarify how MAHs should report falsifications to the NCA, and whether a 24-hour contact point is needed, similar to product recall procedures.
- **Communication Improvements:** Possibilities for e-VIS to improve the sharing and clarity of alert handling guidelines with all stakeholders and ensuring pharmacies know when and how to report issues, including when to copy 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 that are still under investigation. In some cases, identifying the root cause for decommissioning takes longer than 10 days. There is a need to clarify and possibly update guidelines for uploading packs in the EMVS (European Medicines Verification System) and to improve access to information about exemptions and decommissioning status for pharmacies.
- **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.

Overall:

The mock exercise confirmed that although Sweden's stakeholders are well-prepared, several areas for improvement were identified for alert management, reporting, and inter-organisational cooperation. The recommendations and actions from this exercise will provide a base for updates to national guidelines and processes, strengthening Sweden's ability to detect and respond to falsified medicines in the legal supply chain.

3. Identified areas that need improvements by e-VIS

Area for improvement:	Further investigate:
Further support stakeholders in the alert management processes	• Ensure all stakeholders are aware of the procedures for handling and escalating alerts, including copying in e-VIS on relevant correspondence. • Promote regular training and communication to encourage correct use of NMVS reporting channels by end-users. • Promote use of the end-users reports in the NMVS as a tool for the end-user's internal investigation. • Disseminate clear alert handling guidelines to all stakeholders, particularly pharmacies, to ensure they know when and how to report issues. • Clarify when alerts should be investigated by MAHs and when e-VIS needs to be informed to ensure consistent and timely communication. • Define how MAHs should interpret the information present in alerts and how it can support the investigation of an alert or complaint. • Further for MAHs which information is prioritised for sharing with end-users and e-VIS after the investigation of complaints and alerts.
Decrease number of batches released to market without being uploaded to the EMVS	• Procedures to ensure that all product batches are uploaded to the EMVS prior to market release. • Guidance and oversight for MAHs on EMVS upload requirements to avoid gaps in compliance. • Monitor and address any recurring issues relating to missing batch uploads to maintain supply chain integrity.
Access to information on batches with exemptions for FMD requirements	• Improvement of visibility of exemptions and identification of medicines without exemption.
Processes and responsibilities for reporting and managing falsifications	• Investigate possibilities for clearer collaboration with the Swedish NCA in a case of a falsification. – Define clear guidelines for reporting suspected falsifications, including the roles of e-VIS, the NCA, and MAHs. – Clarify cooperation protocols with the Swedish NCA and law enforcement in cases of confirmed or suspected falsification. – Establish a dedicated 24-hour contact point at the Swedish NCA for urgent reporting, mirroring product recall procedures, if deemed necessary.
Use of NCA reports	• Ensure request to the Swedish NCA to retrieve reports from the NMVS is part of e-VIS instruction for escalation to the NCA.
Lock packs on batch level	• Adress requirement to lock packs on batch level as a future requirement.
10-day rule	• Address possible regulatory changes for the 10-day rule for reactivation of decommissioned packs.

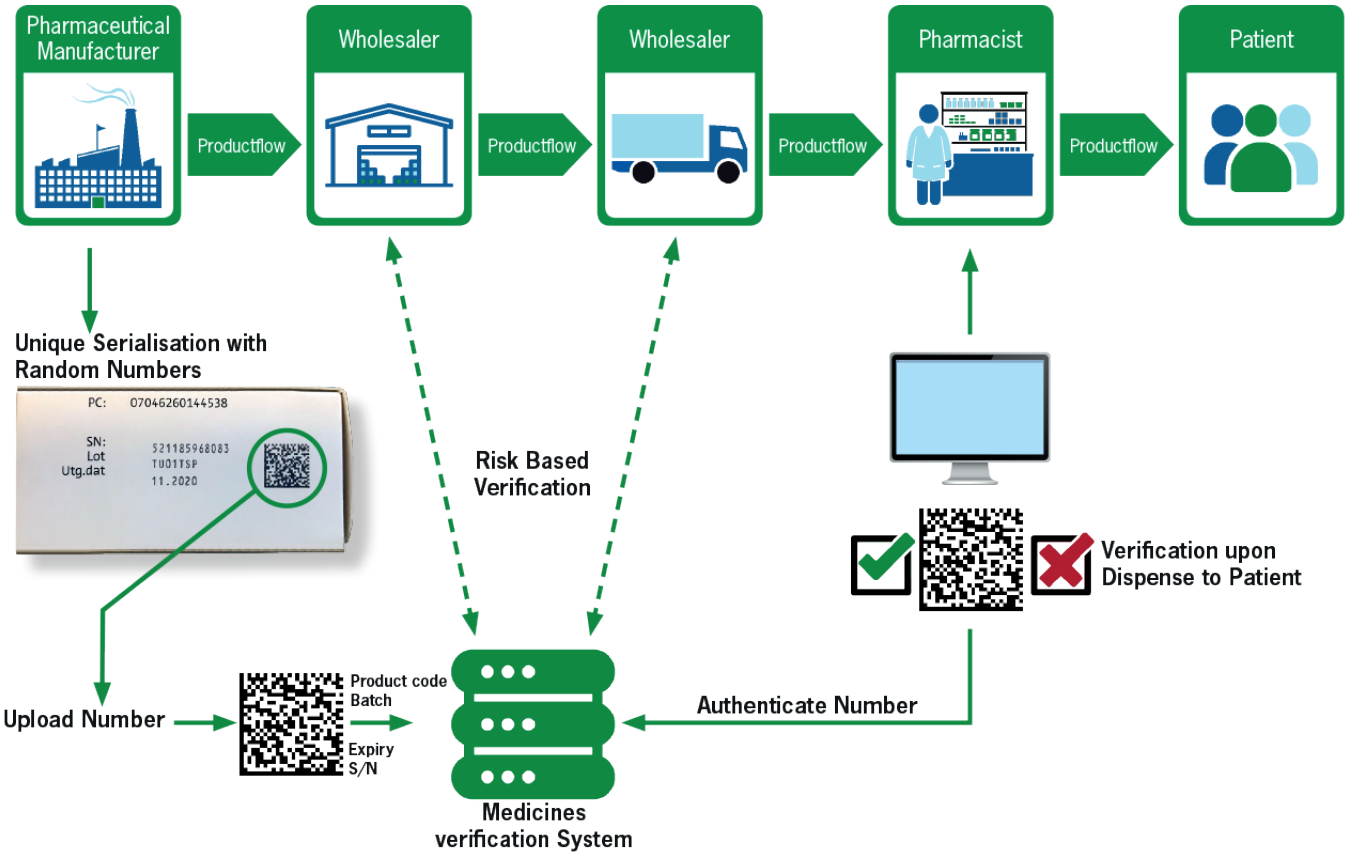
4. Background

This was the second mock exercise arranged by e-VIS. The first mock exercise was done in November 2021. The focus in 2021 was communication, to ensure that pharmacies and end users can contact the MAH in emergency situations. Since 2021, we have gained a greater understanding in handling warnings and alerts. The stabilisation period ended in February 2024, and all European packs are now included in the Falsified Medicines Directive (FMD).

And in 2024, a real falsification entered the European market (but not affecting Sweden).

The value of performing e-verification mock exercises was identified and agreed by e-VIS and the Swedish NCA in 2019 following implementation of the Delegated Regulation (EU) 2016/161 on detailed rules for the safety features appearing on the packaging of medicinal products for human use. Mock exercises are part of e-VIS risk-based alert management process.

e-VIS is the natural coordinator and organiser for this kind of workshop involving all Swedish stakeholders. The aim of a mock exercise should be to prepare nationally for a situation of an identified potential incident of falsification discovered in the legal distribution chain of medicinal products.



Picture 1 – the e-verification distribution flow

4.1 Purpose

The purpose of the mock exercise 2025 was to improve and clarify the alert management process in Sweden, from the creation of an alert in the system to the identification of a possible falsification. The focus was on process, responsibility, and communication.

The aim was to test the processes for packs that cause warnings and alerts to ensure that;

- A root cause for the alerts can be found by an MAH, by pharmacies or by wholesalers in cases where the pack is not a counterfeit product.
- An actual falsification can be found based on when the pack triggers warnings and alerts.

The conclusions from the exercise will be used to clarify the roles and responsibilities of the various actors, identify ambiguities in routines and processes and to complete/improve national alert guidelines.

4.2 Planning phase

Planning of the mock exercise started at e-VIS in May 2025. Via e-VIS Advisory Board, a working group for mock exercise planning was set up. A working group of stakeholders had a meeting in May 2025 to discuss the proposed mock exercise scenarios prepared by e-VIS.

4.3 Participation

The work group during the mock exercise was represented by different stakeholders to gain experience from various sources. The participants represented e-VIS stakeholder organisations and the Swedish Medical Products Agency (NCA).

The participants are listed in **11 Annex – Participants**

5. Performing the mock exercise

5.1 Introduction to the workshop

Following an official welcome, the purpose of the mock exercise and the agenda were presented. The aim and goal of the exercise were explained and experiences from the mock exercise in 2021 were presented. After that, e-VIS held a brief presentation about the handling of alerts and warnings in EMVS.

5.2 Agenda

09.00 Welcome – presentation of the participants and introduction to the Mock Exercise

09.45 Scenario 1 and 2 – including coffee break and discussion

11.00 Scenario 3 and 4

12.00 Lunch break

13.00 Discussion Scenario 3 and 4

13.30 Scenario 5 – including coffee break and discussion

15.00 Media preparedness

15.30 Wrap-up and summary

16.00 End

The participants presented themselves and their background and experiences from e-verification. The participants sat together at stakeholder group tables in the main workshop rooms, i.e. MAH, Distributor, Pharmacy, NCA and e-VIS.

The set-up of the exercise was explained. The work materials, including the scenarios and contact lists that would be used during the exercise were shared. It was highlighted that the invented products used in the scenarios would provide sufficient details to mirror assessment in a real-life situation.

5.3 Workshop workflow

Based on scenarios, the flow of information and communication between stakeholders was explored. Each scenario began with an exemption or alert from the NMVS and concluded with either a supply chain root cause being/having been identified or confirmation that the pack was falsified.

Discussions concerning best-practices today, identified limitations and proposed improvements were encouraged (e.g., in workshop rooms when split into stakeholder groups during scenarios).

Neither SMVS nor other real-life system or data was used during the exercise as the purpose was not to perform tests of systems. Instead, simulated data (in paper) was provided to the participants during the scenarios.

The purpose was to test e-VIS processes. Internal processes at the stakeholders were therefore out of scope.

During the scenario, the Exercise Leader participated in the workshop rooms to provide participants with information regarding the results of actions performed, such as the outcome of internal investigations. This process offered stakeholders direction on subsequent steps within the workflow.

Communication between stakeholder groups and e-VIS was done via e-mail.

5.3.1 Scenarios

- Scenario 1 – Scanner error on end-user side
- Scenario 2 – Pack rejected on pack line
- Scenario 3 – Decommissioned pack returned to supply chain
- Scenario 4 – Batch not uploaded
- Scenario 5 – Duplicate serial numbers, a case of a falsification

5.4 Media preparedness

As a concluding exercise, Kent Björkqvist from Läkemedelsindustriföreningen (Lif) held a presentation about media preparedness. As part of the training, two mock interviews were performed and recorded. Kristina von Sydow from e-VIS and Petra Öström from Apoteket AB, volunteered for the assignment and were interviewed and filmed.

The recordings were shown to the whole group and discussed. Kent gave hands on advice on how to act in a media interviews.

6. Scenario discussions and conclusions

6.1 Scenario 1 – Scanner error on end-user side

Scenario 1 was discussed together with all groups.

6.1.1 Scenario trigger provided

A medicinal product pack is verified during picking control before supply to patient in the pharmacy. The verification response given by SMVS was "The serial number is unknown. The length or format does not match the pharmaceutical company's format. An alert has been initiated in the system"

6.1.2 Information provided during the scenario

Information presented to the pharmacy group:

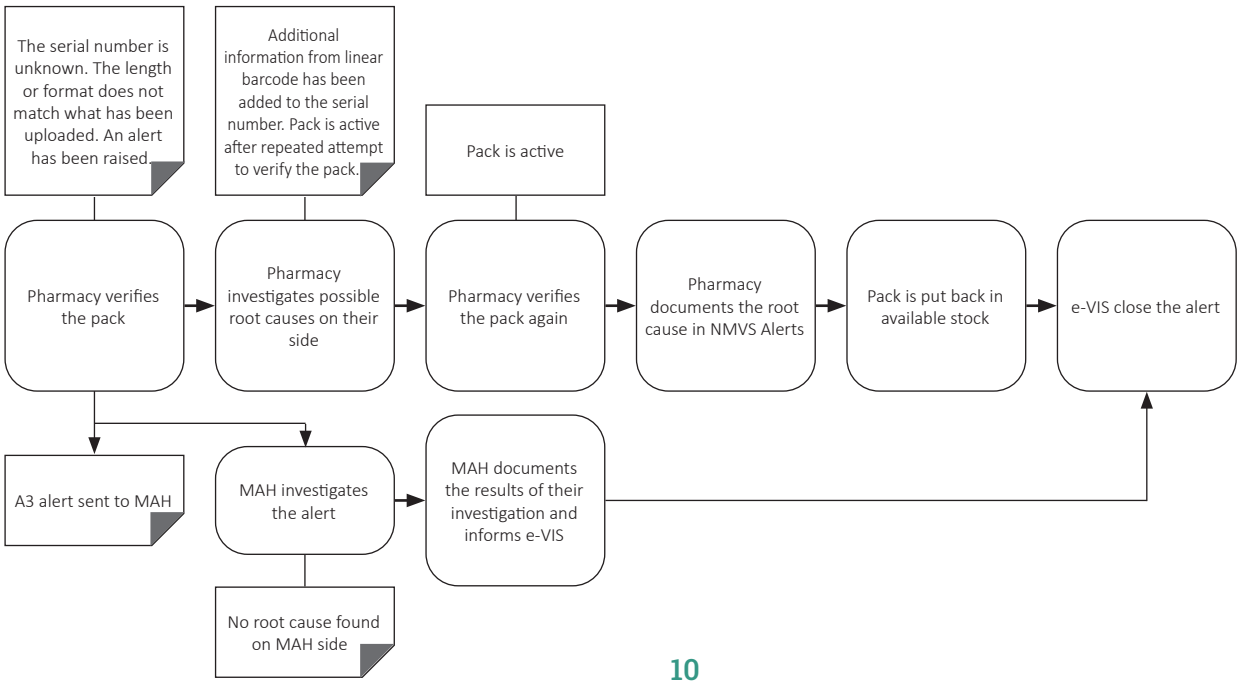
- Medicine controlled during the scenario with information on name, strength, form and size together with API price and MAH name.
- 2D-datamatrix on the affected pack
- Information on the warning generated in SMVS.
- Alerts information on the generated alert that end-user can access via NMVS Alerts together with e-mail notification with the purpose to request investigation.

Additional information presented to the MAH group

- Alert information for the generated alert
- Serialisation data for the batch

6.1.3 e-VIS proposed workflow

The below workflow is solely a proposal and was used during the workshop for discussion. It is not to be seen as a mandatory workflow for real life.



Picture 2 – root cause scenario 1

6.1.4 Root cause identified following investigation:

Scanner error at the end user. The pack is not a falsification.

6.1.5 Discussion scenario 1:

6.1.5.1 End-user investigation

The warning "Serial number not found" indicates that the individual pack is not present in the EMVS and, therefore, should not be in the supply chain. This may suggest that the pack is a potential falsification.

The addition "The length or format does not match what has been uploaded." is shown in the warning when the format of the serial number does not match the standard of the uploaded serial numbers for the batch. This is an indication to the end-user that a root cause of the warning could be incorrect scanning or manual entry of the pack.

Even though a scanner error can be suspected, the pharmacy is expected to investigate all alerts and exceptions from the EMVS.

The pharmacy could, in this case, identify a scanner error on their side by comparing the data string entered in the alert with the unique identifier printed on the pack. The second attempt to verify the pack was successful, hence confirming a scanner error as the root cause.

The pharmacy informed e-VIS of the root cause by documenting in NVMS Alerts that a root cause had been found on their side. The pharmacy clarified in a comment that the scanner had read the 2D-data matrix incorrectly and that the pack had successfully been verified as active in a second attempt.

6.1.5.2 MAH investigation

The MAH group received the alert from the EMVS. There was a discussion regarding when MAHs should investigate alerts and when they should inform e-VIS. An MAH is expected to investigate A2 (serial number and batch not found), A3 (serial number not found) and A52 (batch id mismatch) alerts according to EMVO Best Practice on Alert Handling and always inform e-VIS regardless of the result. However, since e-VIS does not provide any automatic tool for sharing alert investigation results from MAHs, e-VIS request MAHs to prioritise to send information to e-VIS when a root cause has been found on their side.

6.1.5.3 Information included in the alert message

Questions arose around how an MAH can identify whether the alert was generated via manual entry via scanning of the 2D-data matrix and whether the alert is an "intermarket" alert or not.

An alert contains a lot of information on how the alert was triggered. When an alert is triggered the information is sent to the MAH, and which is also available to the end-user via NMVS Alerts. e-VIS has the possibility to further clarify the content of the alert to MAHs and how it can be used to aid the MAH and end-user investigation.

6.2 Scenario 2 – Pack rejected on pack line

Scenario 2 was shared with the MAH and Pharmacy groups, and the groups discussed the scenario in separate rooms.

6.2.1 Scenario trigger provided

A medicinal product pack is verified during picking control before supply to patient in the pharmacy. The verification response given by SMVS is "The serial number is unknown. An alert has been initiated in the system"*

6.2.2 Information provided during the scenario

Information presented to the pharmacy:

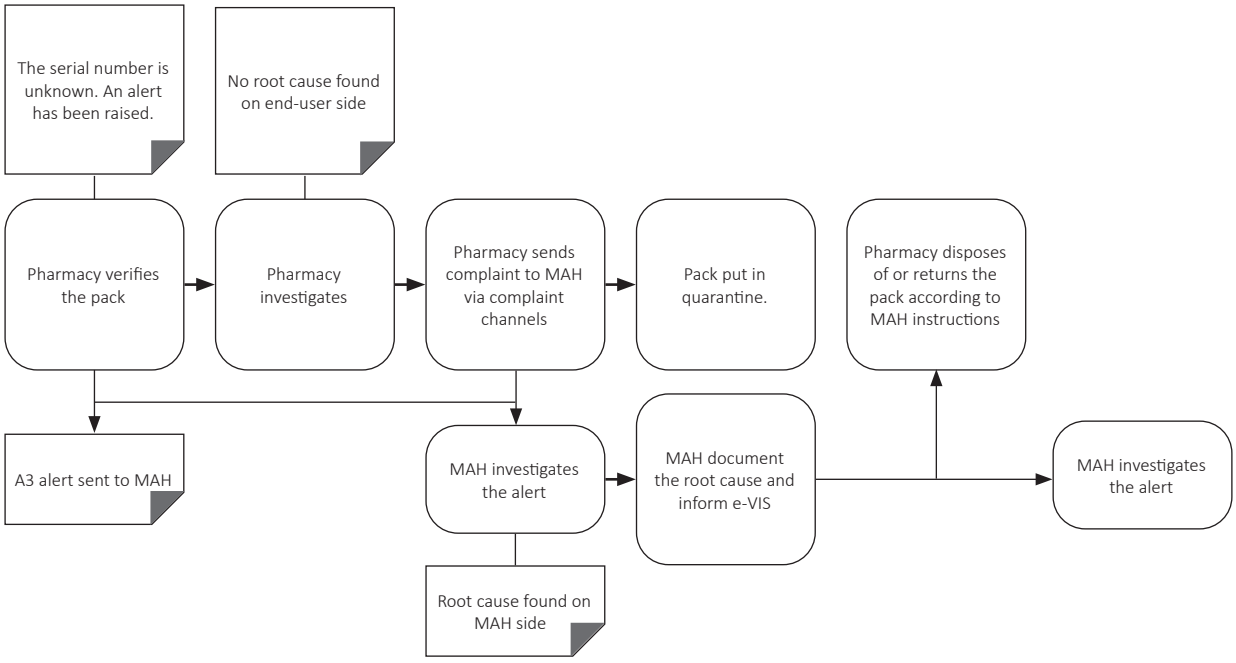
- Medicine controlled during the scenario with information on name, strength, form and size together with API price and MAH name.
- 2D-datamatrix on the affected pack
- Information on the warning generated in SMVS.
- Alerts information on the generated alert that end-user can access via NMVS Alerts together with e-mail notification with the purpose to request investigation.

Additional information presented to the MAH group

- Alert information for the generated alert
- Serialisation data for the batch

6.2.3 e-VIS proposed workflow

The below workflow is solely a proposal and was used during the workshop for discussion. It is not to be seen as a mandatory workflow for real life.



Picture 3 – root cause scenario 2

6.2.4 Root cause identified following investigation:

The pack was rejected/not commissioned at the packing line. The pack is not a falsification.

6.2.5 Discussion scenario 2:

6.2.5.1 End-user investigation

The warning "Serial number not found" indicates that the individual pack is not present in the EMVS and should hence not be in the supply chain, and that the pack can be a falsified product.

The pharmacy investigated if they could see any root cause for the unexpected warning on their side.

The pharmacy controlled if the unique identifier printed on the pack matched the unique identifier in the alert. Since the information was correctly read by the scanner, the conclusion was that no root cause could be found on the end-user side.

The pharmacy submitted a complaint report to the MAH group, with e-VIS copied on the correspondence.

The reported packs were placed in quarantine by the pharmacy group.

There was a discussion in the pharmacy group if they should add any information in NMVS Alerts in these cases. The recommendation from e-VIS is that a pharmacy should only add information to NMVS Alerts when a root cause is known to the pharmacy. In this case, the root cause in unknown and hence the pack should be reported. If the pharmacy identifies a need to document the handling of the alert in NMVS Alerts, they should add the information that the pack has been reported, and clearly state that no root cause has been found on their side.

6.2.5.2 MAH investigation

The MAH group received the complaint and the alert. In the complaint report, the pharmacy had mixed up the letter I with the number 1. Typing errors are quite common in the complaint reports.

The MAH group requested a confirmation of the serial number from the pharmacy. Since the alert-ID was correct in the report, the MAH group could also have found information on the correct serial number via the information in the alert.

The MAH group could identify that the specific serial number for the reported pack was not commissioned when the batch was uploaded to the EMVS. A typical case when this happens is when a single pack is rejected on the pack line for various reasons. The pack should then be removed from the batch, and the serial number assigned marked as not commissioned for the batch. Sometimes, due to human errors, these packs are put back in the batch. This has the effect that the pack is distributed, but the serial number is never uploaded to the EMVS.

In this case, the error could not be corrected. Depending on the error, it can vary if this type of error can be corrected by an MAH or not. If an error cannot be corrected, an MAH must instruct the end-user whether they should return or dispose of the substandard pack.

Which information is prioritised for end-user and e-VIS following an investigation of a complaint or an alert?

It was discussed which level of information requested by the pharmacy and e-VIS so that the complaint and alert can be concluded. The prioritised information is:

1. If a root cause can be found on the MAH's side.
2. If the error can be corrected or not.
3. If the error cannot be corrected, how the pharmacy should handle the substandard pack.

The end-user or e-VIS does not need to know the full root cause or investigation details. While a complete investigation is valuable, unnecessary delays can generate risks for the supply chain. The MAH should notify the end-user within two working days if a root cause is identified on their side. If not, a status update must be sent to the end-user with e-VIS copied after two days.

6.3 Scenario 3 decommissioned pack returned to supply chain

Scenario 3 was shared with the MAH, Pharmacy and Wholesaler groups, and the groups were discussing the scenario in separate rooms

6.3.1 Scenario trigger provided

A medicinal product pack is verified during picking control before supply to patient in the pharmacy. The verification gives the response "The pack has been supplied at another location."*

6.3.2 Information provided during the scenario

Information presented to the pharmacy:

- Medicine controlled during the scenario with information on name, strength, form and size together with API price and MAH name.
- 2D-datamatrix on the affected pack
- Information on the warning generated in SMVS.
  (Note that no alert was generated during the scenario.)

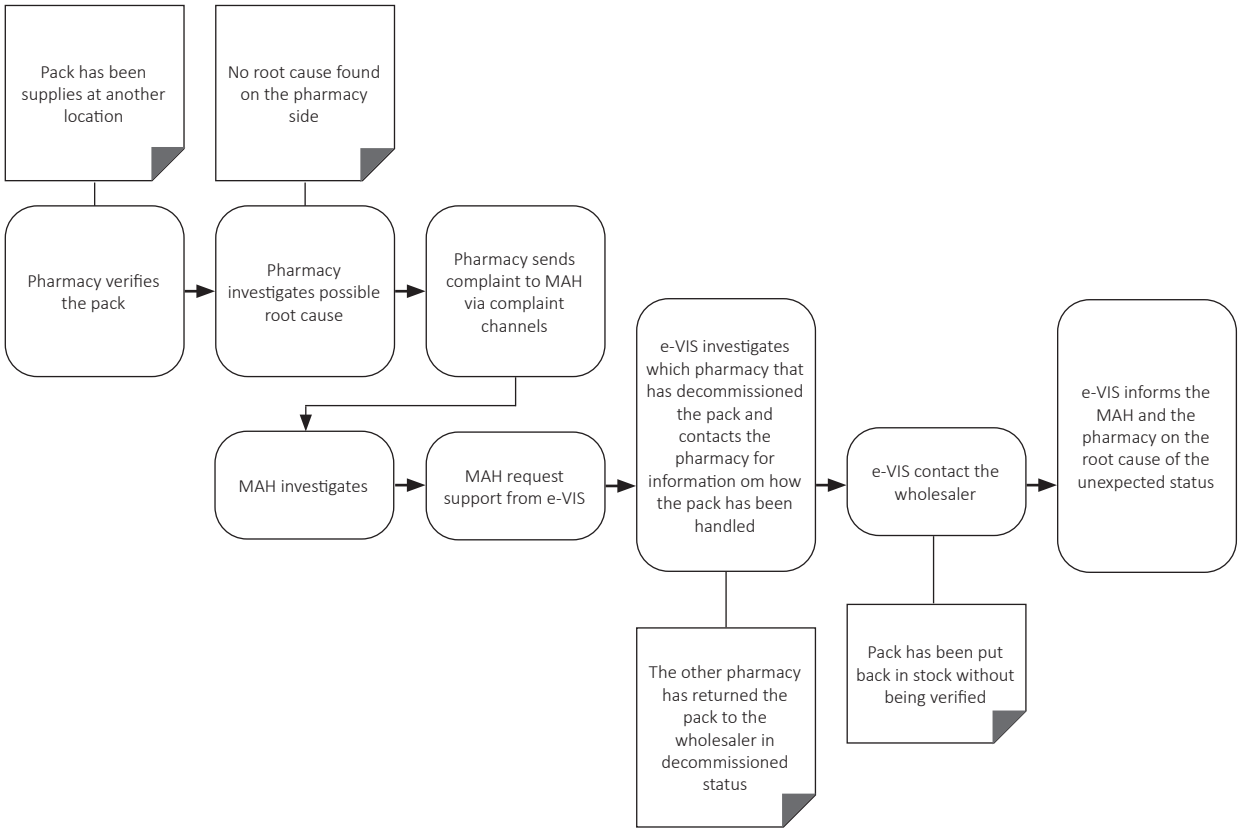
Information presented to the MAH group

- Serialisation data for the batch

Information presented to e-VIS

- Pack audit trail for the pack
- Location data in NMVS

6.3.3 e-VIS proposed workflow:



Picture 4 – root cause scenario 3

6.3.4 Root cause identified following investigation:

The medicine was ordered as a customer reservation and decommissioned when a pharmacist dispensed the pack beforehand of the pick-up. The medicine was not picked up and was therefore returned to the wholesaler in a decommissioned status. The decommissioned pack was put back in available stock by the wholesaler. The pack was then ordered by and delivered to another pharmacy.

6.3.5 Discussion scenario 3:

6.3.5.1 End-user investigation and handling of the scenario

In the scenario, the pharmacy received a response where the pack (the unique identifier) had been decommissioned as supplied at another location.

The response indicates that the pack should have been supplied and no longer should be available in the supply chain, or that the pack is a falsified product.

The pharmacy group investigated if they could see any root cause for the unexpected status on their respective sides.

The pharmacy investigated from where they had received the pack. For the product they could see that the packs in stock had been delivered from a wholesaler. No data was found that indicated any

divergent handling of the pack. Since no root cause could be found the pharmacy sent a complaint to MAH group. e-VIS was added on copy in the complaint. The pack was put in quarantine by the pharmacy.

6.3.5.2 MAH investigation

The MAH group received the complaint and began by verifying whether any errors had occurred during the upload process, specifically by examining the serialisation data for the batch. Typically, this procedure provides an MAH with error information only when the error concerns a pack not found in the EMVS. In cases where the issue pertains to an unexpected status, the unique identifier is almost always consistently uploaded correctly to EMVS.

Since no root cause could be found on their side the MAH group requested support in the investigation from e-VIS. They informed the pharmacy that they had requested support from e-VIS and that the investigation is ongoing.

6.3.5.3 e-VIS investigation of the pack

e-VIS can access pack history for actions taken on the unique identifier in the Swedish repository.

In this case e-VIS could see that the pack had been decommissioned by another Swedish pharmacy (not part of the Scenario). e-VIS contacted the other pharmacy and asked them to investigate their handling of the pack. The other pharmacy concluded that they had returned the pack to a wholesaler and that it was likely that they might have returned the pack in a decommissioned state.

Subsequently, e-VIS contacted the wholesaler group. The wholesaler group identified that they had received a return from the other pharmacy. However, they could not see that they had verified the pack upon return. The wholesaler group made the conclusion that they by mistake had put the already decommissioned pack in available stock and hence distributed it to the reporting pharmacy.

e-VIS informed the pharmacy group and the MAH group of the root cause found and instructed the pharmacy to contact the wholesaler group for instruction on how to handle the substandard pack.

6.3.5.4 General discussion

These cases typically require significant time to resolve for e-VIS, as e-VIS is the sole party within the supply chain with adequate access to the necessary information to conduct a full investigation.

The pharmacy noted that it would be beneficial if the verification response indicated whether previous decommissioning occurred within their organisation (i.e., the same pharmacy chain). This information would enhance their ability to investigate root causes internally.

The information whether the pack has been decommissioned in the same organisation is not available in the verification responses. The end-users can however request an **End-user Pack Audit Trail** from the NMVS with information on all action of the specific unique identifier within their organisation. e-VIS identified that the information on how the end-user reports can be used by end-user organisations can be improved.

6.4 Scenario 4 – batch not uploaded

Scenario 4 was shared with the MAH, Pharmacy and Wholesaler groups, and the groups discussed the scenario in separate rooms

6.4.1 Scenario trigger provided

1. A pharmacist verifies a pack in the picking control* before dispensing.
2. Pack is verified in connection with return control at wholesaler

The verification gives the response "Both the serial number and the batch identifier are unknown. An alert has been initiated in the system." both at the wholesaler and the pharmacy.

6.4.2 Information provided during the scenario

Information presented to the pharmacy group:

- Medicinal product controlled during the scenario with information on name, strength, form and size together with API price and MAH name.
- 2D-datamatrix on the affected pack
- Information on the warning generated in SMVS.
- Alerts information on the generated alert that end-user can access via NMVS Alerts together with e-mail notification with the purpose to request investigation.

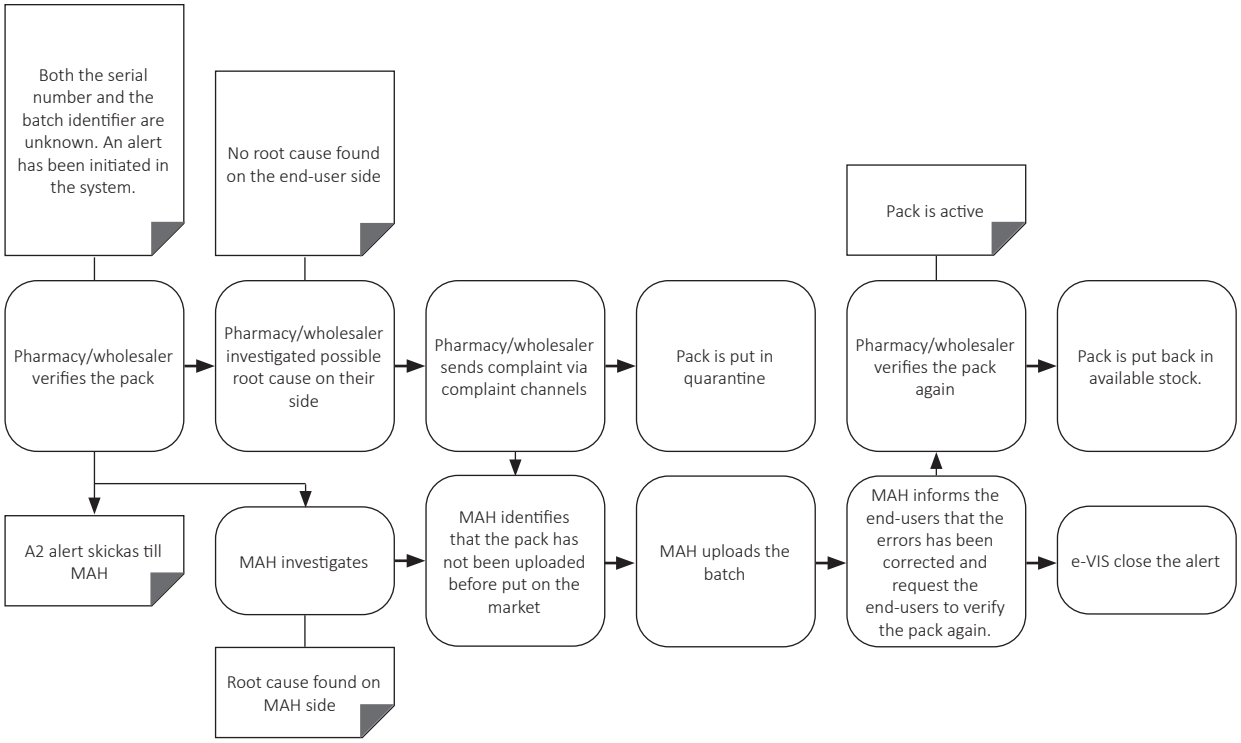
Information presented to the wholesaler group:

- Medicine controlled during the scenario with information on name, strength, form and size together with API price and MAH name.
- 2D-datamatrix on the affected pack
- Information on the warning generated in SMVS.
- Alerts information on the generated alert that end-user can access via NMVS Alerts together with e-mail notification with the purpose to request investigation.
- Information on returns to the wholesaler.

Additional information presented to the MAH group

- Alert information for the two generated alert
- Serialisation data for the batch

6.4.3 e-VIS proposed workflow:



Picture 5 – root cause scenario 4

6.4.4 Discussion scenario 4:

6.4.4.1 End-user investigation

In this case, two packs belonging to the same batch generated a warning and an alert with information that the batch and serial number were not found in EMVS.

The warning generated indicates that the batch has not yet been released to the market or that the batch is a falsification.

Both the pharmacy and the wholesaler group investigated if they could see any root cause for the unexpected status on their respective sides.

The pharmacy and the wholesaler group controlled if the unique identifier printed on the pack matched the unique identifier in the alert. Since the information was correctly read by the scanner, the conclusion was that no root cause could be found on the end-user side.

Subsequently, the pharmacy and the wholesaler group sent a complaint report to MAH. e-VIS was added on copy in the complaints.

Both the pharmacy and the wholesaler group put their respective packs in quarantine.

6.4.4.2 MAH investigation

MAH could identify from the alert and the serialisation data that the batch was not uploaded to EMVS due to a mistake during release of the product. e-VIS was added on copy when the pharmacy and wholesaler groups were informed of the resolution and e-VIS could close the alerts.

The error could be corrected and the pharmacy and wholesaler group were informed to rescan the packs.

The packs were active after rescanning and the packs could be put back in available stock.

6.4.4.3 General discussion regarding batches not being uploaded on released batches

It happens sometimes each year that batches are released to the market without being uploaded to EMVS. In comparison to the total amount of released batches, the error is quite rare, but when it happens is causes extensive problems for the pharmacies.

Although the batches are present in pharmacies, they cannot be dispensed to patients. If no other batches are available, there is a risk that patients may not get their medicines.

e-VIS, the Swedish Medical Product Agency and the European Commission recommend wholesalers to always verify at least one pack per batch when receiving deliveries, with the purpose to identify these errors early in the supply chain.

This process is today implemented by one of the two major wholesalers in Sweden.

A possible explanation to the errors could be uncertainties regarding when a batch should be uploaded to EMVS. A common understanding, also supported by the Swedish NCA, was that the Qualified Person should check that the batch is correctly uploaded in EMVS during release of the batch to market.

6.4.4.4 Uploading of pack in EMVS:

It was suggested to update/clarify the guidelines for a timeframe when the MAH should have uploaded packs in EMVS. Should this be done at release or at arrival of the packs at wholesale/distributor?

The general understanding of the groups was that packs should be uploaded during release as it is part of the quality control.

The pharmacy group emphasised that it would be appreciated if there was a control before batches reach the pharmacies, so that this can be resolved before dispensing. Due to a lot of alerts (especially A2-alerts), there is a risk that a real falsification may pass.

6.4.4.5 Discussion regarding access to information on packs with exemptions from FMD requirements

The pharmacy group brought up the importance of easy access to information on pack and batches that are exempt from FMD requirements. The pharmacies need access to the information at the time of dispensing. Information about approved exemptions is often sent to pharmacies several months before the packs begin to be delivered to the pharmacies. This has the effect that information on the exemption may not be easily accessible when the exempted packs become subject to being supplied.

One suggestion discussed was that the MAH should include information that the packs are covered by an exemption when the packs are delivered to the pharmacies.

The Swedish NCA publishes exemptions for medicines in "Sök läkemedelsfakta" (Läkemedelsfakta is a database for authorised medicinal products in Sweden provided by the Swedish NCA)) on their website under the tab "Dispenser" (exemptions). The tab is only available when there is an approved and still valid exemption for the medicinal product. It was suggested that the Swedish NCA could develop the functionality by:

- Always show the tab "Dispenser" (exemptions) and hereby making it clear that the medicinal products does not have any approved exemptions.
- When the last valid date for an exemption is exceeded, information on exemptions should remain in "Sök läkemedelsfakta" clearly stating that the exemption is no longer valid.

6.4.5 Root cause identified following investigation:

Batch was not uploaded by the MAH. The pack is not a falsification.

6.5 Scenario 5 – duplicate serial numbers, a case of a falsification

Scenario 5 was shared with the MAH, Pharmacy, Wholesaler and NCA groups, and the groups discussed the scenario in separate rooms

6.5.1 Scenario trigger provided

- A pharmacist verifies a pack in the picking control* before dispensing.
- Pack is verified in connection with return control at wholesaler

The verification gives the response "The pack has been supplied at another location."

6.5.2 Information provided during the scenario

Information presented to the pharmacy group:

- Medicine controlled during the scenario with information on name, strength, form and size together with API price and MAH name.
- 2D-datamatrix on the affected pack
- Information on the warning generated in SMVS.
  (Note that no alert was generated during the scenario.)

Information presented to the wholesaler group:

- Medicine controlled during the scenario with information on name, strength, form and size together with API price and MAH name.
- 2D-datamatrix on the affected pack
- Information on the warning generated in SMVS.
  (Note that no alert was generated during the scenario.)

Information presented to the MAH

- Serialisation data for the batch

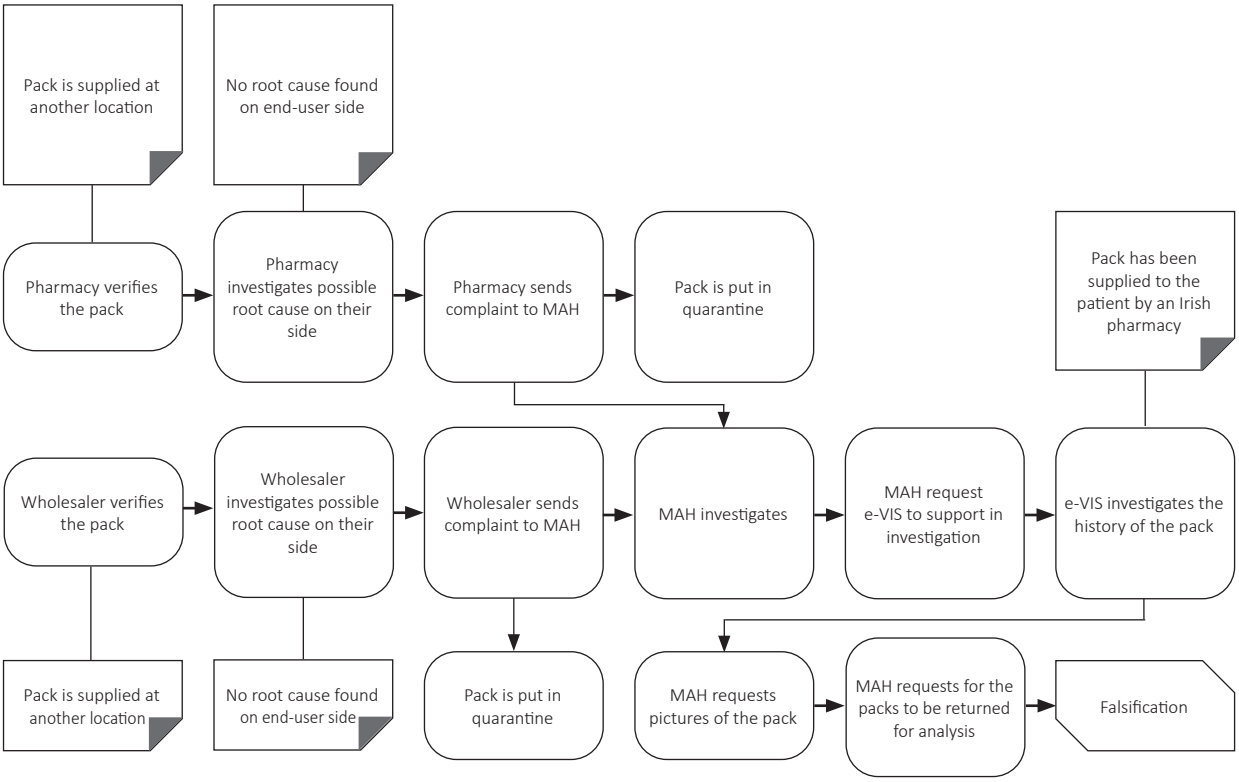
Information presented to e-VIS

- Pack audit trail for the pack from the Swedish NMVS
- Pack audit trail for the pack from the Irish NMVS
- Investigation response from the Irish NMVO
- Location data in NMVS

Information available to the NCA

- I.1 report for the affected pack

6.5.3 e-VIS proposed workflow:



Picture 6 – root cause scenario 5

6.5.4 Root cause identified following investigation:

e-VIS investigated this with the Irish NMVO. The Irish pharmacy had dispensed the pack to a patient. No return has been done to the Swedish wholesaler for this pack.

The MAH group could not see any root cause on their side. Since two pharmacies reported having packs with the same serial number in quarantine, photos of the packs were requested. The MAH group could determine the pack to be a falsified product.

The pack was identified as a falsification where the serial number has been reused by the forger.

6.5.5 Discussion scenario 5:

6.5.5.1 End-user investigation and handling of the scenario

In the scenario, two different packs with the same unique identifier were found in the supply chain. Both the pharmacy and wholesaler groups received a response where the pack (the unique identifier) had been decommissioned as supplied at another location.

The response indicated that the pack should have been supplied and should no longer be available in the supply chain or that the pack is a falsification.

Both the pharmacy and the wholesaler group investigated if they could see any root cause for the unexpected status on their respective side.

The pharmacy group investigated from where they had received the pack. For the product they could see that the packs in stock had been delivered from a wholesaler. No data was found that indicated any divergent handling of the pack. Since no root cause could be found the pharmacy group sent a complaint to MAH, with e-VIS on copy. The pack was placed in quarantine by the pharmacy group.

The wholesaler group investigated with the entity that had returned the pack to them if they might have decommissioned the pack. The entity that had returned the pack had not verified or decommissioned the pack. Since no root cause could be found the wholesaler group sent a complaint to MAH, with e-VIS on copy. The pack was placed in quarantine by the wholesaler group.

6.5.5.2 MAH initial investigation

The MAH group received the two complaints. First MAH checked if there were any errors in the upload by checking the serialisation data for the batch. This step does usually only provide information to a MAH for errors when the pack is not found. When the error concerns an unexpected status, the unique identifier is always correctly uploaded the EMVS.

Since no root cause could be found on their side the MAH group requested support in the investigation from e-VIS.

6.5.5.3 e-VIS investigation of pack history

e-VIS can access pack history for actions taken on the unique identifier in the Swedish repository. In cases where the decommissioning of the pack has occurred in another repository e-VIS cannot

see any information on when the decommissioning has occurred or by whom. e-VIS can however see on which market the last status update of the pack was made. In this case e-VIS could see that the last status update was performed by a user on the Irish market.

e-VIS reached out to the Irish NMVO, who investigated with the Irish end-user how the pack had been handled by them. In this case the unique identifier had been decommissioned by a pharmacy. The pharmacy could confirm that the pack had been supplied to a patient.

e-VIS hence informed the MAH group that no root cause could be found in the handling of the packs. The MAH group should investigate if they might have produced two packs with the same unique identifier.

6.5.5.4 MAH continuous investigation

MAH identified that it was likely that two packs with the same unique identifier was present. There were uncertainties regarding what next steps the MAH group should take, and the MAH group started to discuss if the batch should be recalled, before having requested photos or an analysis of the pack.

After intervention from the exercise leader, the MAH group requested photos of the packs from both the pharmacy and wholesaler groups.

From the photos the MAH group could see that the packs did not represent the standard for the pack. As a last step the MAH group would request the packs from the pharmacy and wholesaler group and in this case the analysis of the packs would show that the packs are falsifications. Due to time limitations the packs were never requested during the exercise.

The MAH group reported the confirmed falsification to the NCA group.

After reporting, the whole group met up for discussion regarding how we together would handle a case of an actual falsification.

6.5.6 Handling of a confirmed falsification on the Swedish market

The group met up to discuss which actions would be taken by the NCA, e-VIS, MAH and end-users in case of a falsifications. In general, it was not fully clear how such a case would be handled and there was not a standardised process other than that the stakeholders were obliged to report falsifications to the NCA.

e-VIS had prepared the discussion around the topics below:

- **Information to NCA:** Who informs the NCA and the EU Commission (Article 37d Commissions Delegated regulation (EU) 2016/161)?
- **Investigating the falsification, gathering information and ensuring security in the supply chain:** Who coordinates the investigation?
- **Information sharing:** Who decides on and produces information for the public and interested parties?

6.5.6.1 Information to NCA: Who informs the NCA and the EU Commission

e-VIS has a responsibility to escalate a case of a falsification to the NCA, EMA and the EU commission. MAHs and wholesalers also has a responsibility to escalate suspected or confirmed cases of a falsification to the authorities.

A case of falsification is most likely confirmed after analysis by the MAH. Therefore, e-VIS recommendation is that the MAH should be the part that escalates the case to the Swedish NCA, EMA and the European Commission when a falsification is found in the legal supply chain.

e-VIS must, however, reassure that the case has been reported. Therefore, e-VIS recommends MAHs to inform e-VIS that a case of falsification has been reported to the authorities. e-VIS would escalate if e-VIS hasn't received any information that the case has been reported.

The approach above was generally accepted by the group. The suggested division of responsibilities regarding reporting is described in e-VIS processes but are not formally approved by the Swedish NCA.

There is no timeframe today for how long e-VIS should wait until a case representing a possible falsification should be reported by e-VIS. However, reporting should be made as soon as the investigation confirms a case of a falsification.

6.5.6.2 Investigating the falsification, gathering information and ensuring security in the supply chain: Who coordinates the investigation?

The MAH and all impacted stakeholders, including e-VIS has a responsibility to investigate a case of falsification. The MAH is the stakeholder who can identify if the pack is an actual falsification. The investigation can however not only be performed by the MAH or a single stakeholder, since information might have to be gathered from e-VIS, impacted pharmacies and healthcare providers, wholesalers and other European NCAs.

e-VIS should also reassure that falsifications that has been identified via the EMVS is investigated, however, e-VIS has no legal mandate to demand information from impacted stakeholders and cannot oblige the MAH to collaborate with e-VIS during the investigation.

Therefore, e-VIS's suggestion is that the NCA coordinates the investigation of a confirmed case of a falsification since they are the only part that has the enforcement to require and gather investigation from the impacted parties.

Recalls and other measures to reassure supply chain is today always decided by the Swedish NCA in close collaboration with the MAH.

Experience from earlier cases of falsifications in other EU-member states has identified that an established collaboration protocol with the NCA and the NMVO is essential for effective information sharing and coordination during an investigation of a confirmed falsification.

6.5.6.3 Recommendation to request the pack analysis

In this case the falsification was identified via analysis of pack photos and the packs were not requested from the wholesaler and the pharmacy for analysis. The group started to discuss if and how the batch could be recalled even before confirming that the packs were actual falsifications.

EMVO's Best Practice on Alert Handling recommends MAHs to request the pack sample if a falsification cannot be ruled out after the initial alert investigation or via analysis of photos of the pack.

e-VIS should further clarify the current recommendation with information to request the pack sample when a falsification cannot be ruled out.

6.5.6.4 Use of NCA reports

e-VIS can, as mentioned above, only find pack history of a unique identifier in its own repository. The NCA however, has access to a report where they can request pack history from the whole EMVS, including all national repositories. For this reason, the NCA is the only party that can identify if other markets have been affected by the falsification and the NCA can also collaborate with other NCAs during the investigation.

In the scenario, a NCA report was prepared. The report contained information on the pack history from the repositories in the EMVS. In addition to Sweden and Ireland, the same serial number had also been verified on the Danish market. This was, however, not discovered during the investigation since the report was not requested.

e-VIS does not have a procedure to recommend the NCA to run certain reports when a case is escalated to the Swedish NCA.

6.5.6.5 Information sharing: Who decides on and produces information for the public and interested parties?

e-VIS's suggestion is that the information sharing is coordinated by the Swedish NCA in collaboration primarily with the MAH but also with e-VIS and impacted stakeholders. This approach was accepted by the group. The information requirements in a case of a falsification can be:

- Press release and other information to the public if deemed necessary.
- Information to impacted stakeholders in the supply chain, such as healthcare, pharmacies other MAHs etc.
- Information to the police and law enforcement agencies.

Access to information is important during an investigation; however, ongoing investigations may restrict access due to confidentiality requirements. To enable e-VIS to provide support, it is necessary for e-VIS to be informed of a suitable NCA contact for the ongoing investigation.

6.5.7 Media contacts in a case of a falsification

A common source of information is important as a reference when talking to the media. A case of a falsification can be of great interest for the media, but experience from cases in other European countries show that sufficient access to information can be hard to obtain during an ongoing investigation if a media handling process has not been established during the investigation.

- A press release from the NCA or the MAH is a good reference for impacted parties when talking to the media.
- Information about if the falsification and the case has been reported to the police.

Has the supply chain been secure and what actions have been taken to reassure safety in the supply chain?

6.5.7.1 To whom at the Swedish Medical Products Agency should the MAH report the identified falsification

The group discussed to whom the MAH should report a case of a falsification at the Swedish NCA. The NCA group informed that suspected falsifications are to be reported to the inspection unit. For recalls there is a 24h contact service available. No such service is available for reporting of falsification at the moment. The group discussed if the same or similar reporting channels as for recalls should be used when reporting a falsification in the supply chain. e-VIS can, in collaboration with the Swedish NCA, aid and further clarify to which department at the Swedish NCA a case of a falsification should be reported by the MAH.

6.5.7.2 Discussions regarding recalls

An identified confirmed falsification must not always require a recall. MAHs are expected to always conduct thorough investigations of the scope and extent of the falsification before contacting the NCA for discussion about initiating recall; this includes identifying the number of affected packs, assessing stock levels, and determining which customers have received the product. As part of the triage process, e-VIS recommends that MAHs request physical samples and photographs.

The functionality to lock packs in EMVS is today not advanced enough to temporarily stop a batch from being further distributed and supplied. Information sharing to impacted stakeholders is key to reassure temporary stop in distribution and supply of packs.

7. Conclusions and general discussions:

The process for managing alerts and exceptions has evolved since the previous mock exercise, resulting in recommendations that are now well-defined and accepted by stakeholders. However, there are possibilities for e-VIS to further inform end-users and MAHs regarding the current recommendations for alert handling.

Further refinement is needed regarding procedures and responsibilities for reporting and handling confirmed cases of falsification. This includes how e-VIS should cooperate with the NCA, use of NCA NMVS report, coordination of the investigation and information to stakeholders and the public, to whom and when an MAH should report a falsification at the NCA.

7.1.1 General discussions regarding functionality in the EMVS and general processes in the supply chain

- Exemptions
- 10-day rule for reactivation of commissioned packs
- Uploading of packs in EMVS
- The function to lock packs in the EMVS

7.1.1.1 10-day rule for reactivation of commissioned packs

The 10-day rule for reactivation of commissioned packs was discussed. The time limit can be a bit short and can cause unnecessary destruction of medicines that are still under investigation. The 10- day rule is however defined in the Delegated regulation for safety features and cannot be changed by e-VIS or the Swedish NCA.

7.1.1.2 Uploading of pack in EMVS:

It was suggested to update/clarify the guidelines for when the MAH should have uploaded packs in EMVS. Should this be done at release or at when the packs are delivered to the wholesaler?

The recommendation from the NCA was that it should be uploaded during release as it is part of the quality control.

The pharmacy group emphasised that it would be appreciated if the wholesalers always made a verification control of one pack per batch before further distribution, so that any errors can be resolved as early in the supply chain as possible. An abundance of alerts (especially A2-alerts), increase the risk that a real falsification may pass.

7.1.1.3 The function to lock packs in the EMVS

Today, there is a function where wholesalers and MAHs can mark an individual pack as locked. The status works as a proxy for quarantine, and the status change should only be performed by the part in possession of the physical pack

In cases when a falsification or quality issues in a batch are suspected, there is a need for a functionality to reversibly mark a batch as locked. This functionality is not available today but has previously been addressed by e-VIS as a requirement for future development.

e-VIS together with the Nordic NMVOs has produced an information document on the Locked function in the EMVS. The document is available on e-VIS webpage.

8. References and links

COMMISSION DELEGATED REGULATION (EU) 2016/161
https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf

DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
https://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:02001L0083-20190726&qid=1597228977235&from=SV

Swedish Alert Guidelines
https://e-vis.se/varningar-larm/

EMVO Best Practice on Alert Handling
https://emvo-medicines.eu/documents/best-practice-on-alert-handling/

Description of functionality – Mark packs as Locked
https://e-vis.se/wp-content/uploads/2025/02/Description-of-functionality-Mark-packs-as-locked-2025-02-07-1.pdf

9. Abbreviations and glossary

e-VIS	e-Verifikation i Sverige
FGL	Föreningen för Generiska Läkemedel och biosimilarer
LDF	Läkemedelsdistributörsföreningen
LH	Läkemedelshandlarna
Lif	De forskande läkemedelsföretagen
MAH	Marketing Authorisations Holder (the definition also includes parallel distributors placing packs on the European market)
OBP	OnBoarding Partner the entity within or contracted by an MAH to upload packs and master data to the EMVS.
SvAF	Sveriges Apoteksförening
NCA	National Competent Authority responsible for reassuring compliance for the regulations a country. The Swedish Medical Product Agency in the Swedish NCA.
NMVO	National Medicines Verification Organisation – e-VIS is the Swedish NMVO
EMVS	European Medicines Verification System – the definition includes all the European National Verification Systems and the EU-hub.
***Picking control:**	Pharmacy process where the pharmacy scans the pack's 2D-data matrix or linear barcode to compare the product code in the pack with the product code in the pharmacy's stock management system with the purpose to reassure that the correct product has been picked. Verification of the pack is commonly integrated together with the picking control.

10. About e-VIS

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.

11. Annex – Participants

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