e-VIS recommendations for handling exceptions and alerts from SMVS

Translation for information purposes only, the Swedish version prevails

Content

Dokumenthistorik

1.0	2022-12-20	Första version av dokumentet
2.0	2023-05-23	Uppdatering med anledning av att slutanvändare förväntas dokumentera i NMVS Alerts när orsaken till alerten beror på slutanvändarens egen hantering
3.0	N/A	Version skipped to align with the Swedish original recommendations.
4.0	2024-01-13	Update due to new response codes. The new response codes provide information about whether the serial number format follows the pharmaceutical company's standard. Update on recommendations if a package lacks a 2D code. All batches for products covered by the regulations must be uploaded to EMVS from February 2024. Clarification that the end-user can see which values were entered when calling the alert in NMVS Alerts. Definitions and description of the e-verification system moved to the end of the document. Responses in presented in the English translation.

1 Target audience and purpose

This document is an English translation from the Swedish NMVS (*e-VIS rekommendationer för hantering av varningar och alerts från SMVS)*. The recommendations cover guidance for how end-users should handle and investigate packs that have caused alerts or other warnings from the Swedish NMVS (National Medicines Verification System). For MAH the recommendations complement EMVO Best Practice on Alert Handling.

The recommendations have been developed by e-VIS, the Swedish National Medicines Verification Organisation, in collaboration with Swedish stakeholder organisations for pharmacies, wholesalers and pharmaceutical companies.

1.1 Target audience

The recommendations are intended for end-users of the system (pharmacies, hospital pharmacies, wholesalers, and healthcare) as well as for MAH / MAH representatives so that each organisation in the supply chain can base their SOPs, instructions, and training materials on these recommendations.

1.2 Purpose of the recommendations

The recommendations are a basis for each organisation in the supply chain to use as a foundation in its processes and SOPs, instructions, and training materials.

The recommendations are designed to:

- Ensure that possible counterfeits are investigated as quickly as possible so that falsified medicines cannot enter the legal supply chain or reach patients.
- Pharmacies and distributors should handle and communicate an alert in the same way.
- Pharmaceutical companies should quickly become aware of problems with packs, act and give feedback on why an alert has arisen.
- Avoid different interpretations that lead to ambiguities, extra administration, and long lead times.
- Reduce the risk of medicine shortage.
- Patients should not suffer from long waiting times as pharmacies cannot live up to their supply requirements.

1.3 Prerequisites for the recommendations

- Packs with a full 2D-code must be uploaded to SMVS in order to be supplied.
- It is the responsibility of all stakeholders to assess the risk of shortages and patient risks against their own interests and priorities.
- If an MAH delays communication and uploading, pharmacies may be left without medicines that can be supplied and this can eventually lead to entire batches being returned, which can lead to shortages.
- MAH should work preventively to ensure that pack is uploaded to the EU hub.
- Warnings and alerts due to handling errors of end-users should be prevented and corrected by the end-user.
- Even if a medicine is not a falsification, the pack is still substandard if the information in the 2D-code, the information printed on the pack and the information in SMVS do not match. If a pack has quality deficiencies that generate alerts in SMVS, the pack can only be distributed further, if there is an approved exemption from the Medical Products Agency regarding the quality defect and that pharmacies and other concerned parties are informed about the exemption.

- The joint work with SMVS is based on openness and understanding between the stakeholders. If deviations occur in a stakeholder's process, we all understand the importance of informing other parties in the supply chain of our deviations to prevent errors and deviations from repeating.

1.3.1 Scanning and checking the 2D-code must be done correctly

For the recommendations to work, the end-user must ensure that the 2D-code is read correctly and that requests against SMVS are made according to current specifications and requirements. This means, for example, that:

- Scanner and IT-system correctly can separate the four (or more) elements of the 2D-code.
- Scanner and IT-system reads and sends information in the 2D-code exactly as it is specified without changing special characters and correctly reporting lowercase and uppercase letters.
- The IT-system indicates, in the request to SMVS, if the printed 2D-code on the pack has been scanned or information entered manually.

e-VIS provides control codes that can be used to verify that the end-user's scanner equipment can read the 2D-code correctly.

2 Basic process for handling pack that provides alerts and exceptions from SMVS

When an exception or alert which may suggest a possible falsification has been triggered in the Swedish NMVS by the end-user.

2.1 Put the pack in quarantine and store safely together with alert-ID or other information about the case

Packs which have caused alerts or has the incorrect status cannot be supplied to the public. The pack shall be considered substandard until the error has been corrected.

2.1.1 Pack causing exceptions or alerts in the Swedish NMVS can only be supplied or distributed further when:

- Scanner errors have been identified and corrected. If scanner error has caused the error, the pack can be decommissioned by entering the serial number and the product code manually when the scanner error cannot be corrected directly.
- Data errors have been corrected by MAH or an exception from the regulations has been approved by the Swedish Medical Products Agency.
- End-user has reassured that incorrect status is due to end-users own handling of the pack and that the pack has been reactivated after the end-user has reassured that the medicines otherwise has been handled according to quality standards.

Packs that do not fulfil the demands in the delegated regulation on safety features must not remain in supply chain.

2.2 Check whether the error is due to the end-user's own handling of the pack

Warnings in SMVS can occur due to the end-user's own handling. Such warnings or alerts do not need to be reported to MAH but need to be documented by the end-user.

If an alert has been created and the error is due to the end-user's own handling, it is important that the end-user can present information about the cause of the alert in cases where MAH, e-VIS or the Swedish Medical Products Agency investigates the alert.

2.2.1 If the exception or alert is due to the end-users own handling of the packs

1. Document the cause of the event in the e-VIS Alertportal, NMVS Alerts.
    - e-VIS will close the alert when information about the cause has been received from the end-user.
2. Handle the pack according to existing SOPs
3. When asked by the MAH/Swedish Medical Products Agency/e-VIS, the end-user reports back the root cause of the alert.

2.3 Report the warning or alert to MAH or MAH local representative

Reporting is performed according to an agreed process through existing complaint reporting channels. Most pharmacies use the complaint platform **reklameraläkemedel.se**. The platform is governed by Lif (the Swedish Trade Association for the Research-Based Pharmaceutical Industry)

Add alerts@e-vis.se as a copy - if a channel other than the "complaints form" is used. e-VIS needs to be informed that the warning does not concern a possible falsification.

MAH must reply to the reporting end-user within 2 working days.

2.3.1 Report to MAH should contain at least the following information:

- Product code and which medicine the report applies to.
- Alert-ID - must always be specified when reporting if such has been generated.
- Serial number in cases where the Alert-ID is missing or when no alert has been generated. If both the Alert-ID and the serial number are missing, the investigation cannot be carried out.
- Which warning was generated from the e-verification database and other relevant description of the incident. Please also describe whether the patient's needs could be met with other packs.

2.3.2 MAH investigates together with the end-user

- MAH may ask the end-user to send an image of the 2D code to investigate data errors.
- In the case of feedback and communication between end-users and MAH regarding reports for e-verification warnings and alerts, e-VIS wishes alerts@e-vis.se to be copied. e-VIS needs to be informed that the reported e-verification warning does not concern a possible falsification.
- When responding to end-users, language and expressions should be comprehensible to the end-user.

Please note that the process differs from the process for complaint reporting.

3 Expected responses from SMVS

Below are the responses from SMVS that should be expected when verifying, decommissioning, and reactivating a pack.

3.1 Expected responses when supplying and decommissioning pack in SMVS

3.1.1 When pack is verified prior to supply, destruction, or other decommissioning or prior to further distribution.

ID	Operation	Status	Alert?	Response
11110100	Verify	Active	NO	The pack is available to be dispensed.

Packs available in a pharmacy and in the supply chain should be active in SMVS.

Packs have to be active in SMVS to be supplied or decommissioned.

3.1.2 When a pack is supplied to the public or to be used in health care.

ID	Operation	Status	Response
11210200	Supply	Supplied	The pack has been supplied.

The response states that the pack has been supplied by the end-user. No other supply of the pack or decommissioning should be able to be done.

3.1.3 When decommissioning a pack as destroyed

ID	Operation	Status	Response
11310400	Decommission	Destroyed	The pack has been marked as destroyed.

The response indicates that the pack has been decommissioned as destroyed. No other supply of the pack or decommissioning should be able to be done.

3.1.4 When decommissioning the pack of other reasons

ID	Operation	Status	Response
11310500	Decommission	Sample	The pack has been marked as a sample.
11310800	Decommission	Exported	The pack has been marked as exported from the EU.
11310600	Decommission	Free Sample	The pack has been marked as a free sample.
11310300	Decommission	Stolen	The pack has been decommissioned as stolen.
11310700	Decommission	Locked	The pack has been marked as locked.

The response indicates that the pack has been decommissioned depending on reason and the pack should not be available to be dispensed. No other supply of the pack or decommissioning should be able to be done except for packs decommissioned as locked where the pack can be decommissioned as destroyed or stolen.

3.2 When reactivating the pack

3.2.1 When verifying the pack prior to reactivation of the pack

ID	Operation	Status	Response
11110201	Verify	Supplied	The pack was decommissioned as supplied at this location.

The pack must have been decommissioned as supplied at the same location for it to be reactivated. Note that the pack also must fulfil accurate quality standards to be reactivated.

3.2.2 When reactivating the pack to active status

ID	Operation	Status	Response
11410100	Reactivation	Active	The pack has been reactivated.

The pack has been reactivated to active status and can be put back in available stock.

4 Warnings that the 2D-datamatrix does not contain mandatory information or if the pack does not contain a 2D-datamatrix

Pack subject to the delegated regulation on security features shall be marked with a 2D-code containing a unique identifier. The 2D-code must include the elements product code, serial number, batch number, and expiration date. The information in the 2D-code must also follow the GS1 standard.

Since February 2024, e-VIS assesses that all batches of products covered by the regulations should be marked with safety features and uploaded to SMVS. Batches released before February 9, 2019 should have passed their expiration date and should no longer be on the market.

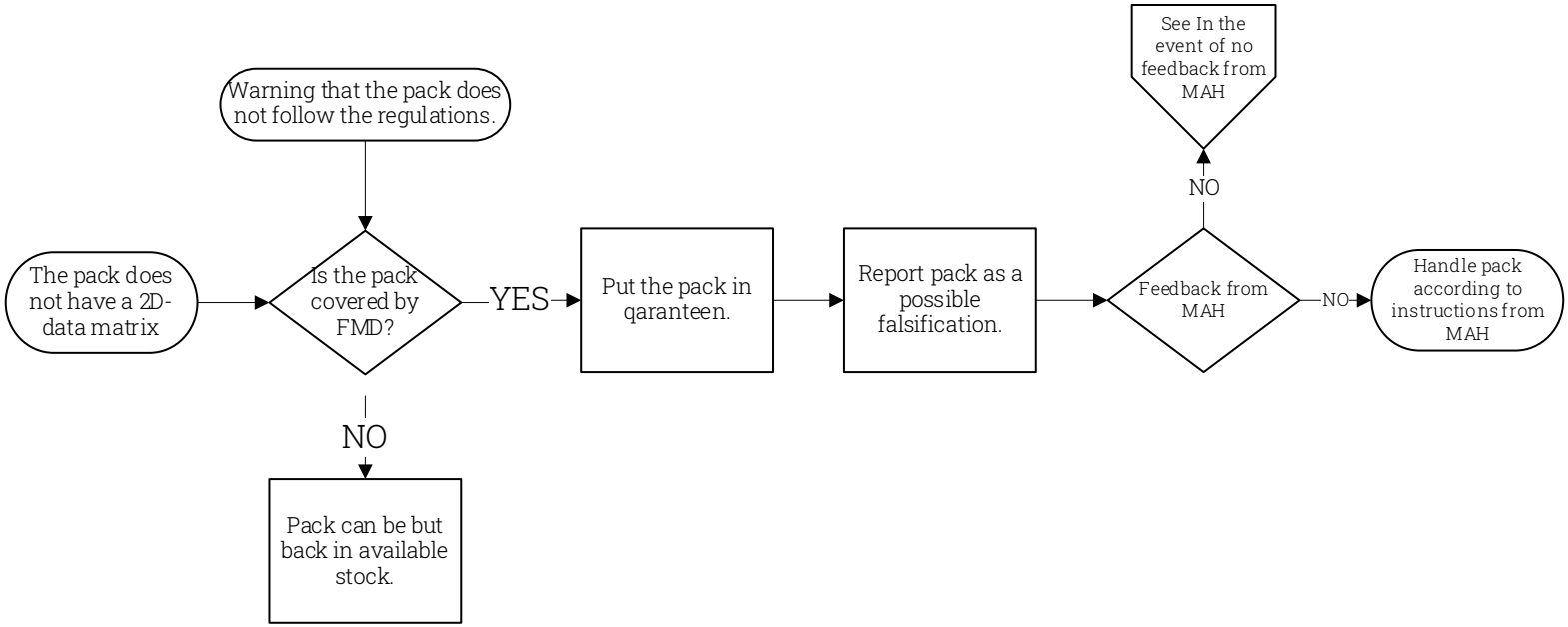
4.1 Warnings regarding the pack doesn't follow the requirement on safety features

ID	Operation	Status	Alert?	Response	Comment
61020000	All operations	N/A	NO	A batch identifier is required.	In the request information on a batch number is missing. If the 2D-code is scanned a batch number always has to be part of the request.
61020001			NO	A product code is required.	In the request information on a product code is missing. A product code must always be part of the request to SMVS
61020004			NO	An expiry date is required.	In the request information on a expiry date is missing. If the 2D-code is scanned an expiry date always has to be part of the request.
61020003			NO	A serial number is required.	In the request information on a serial number is missing. A serial number must always be part of the request to SMVS

4.2 Possible reasons for the warning

- Information in the 2D-datamatrix has not been read correctly by the scanner or data fields are missing when adding data manually.
- The medicine is a veterinary medicine and is therefore not subject to the regulations on safety features.
- The medicine is an over-the-counter medicine that is not subject to the regulations on safety features or another medicine that is not subject to the regulations.
- The medicine is a licensed medicine approved for the market outside the EU/EEA. The regulations on safety features only applies to medicines from the EU/EEA. For example, medicines from the USA, Switzerland or the UK do not need to have safety features.
- Incorrect information has been encoded in the 2D-datamatrix
- The medicine is a counterfeit or has serious quality deficiencies.

4.3 Handling the warnings



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Pharmacy, hospital pharmacy, medical unit, wholesale	**1. Check if the medicine is covered by FMD** In VARA /LiiV there is information from the Medical Products Agency whether a product / medicine is subject to the regulations on safety features. This information may also be available directly in the end-user's IT-system. Examples of medicines that are not subject to the regulations on safety features are veterinary medicinal products, over-the-counter medicines other than omeprazole 20 mg in hard capsules and some prescription medicinal products for human use. **2. Licensed medicinal products and medicinal products sourced with a foreign labelling exemption** • Human medicinal products that are approved and supplied within the EU/EEA must have a 2D code and safety seal just like medicinal products approved in Sweden. These medicinal products must be verifiable and deactivated. o If such pack cannot be found or is already decommissioned, the pack must be handled in the same way as Swedish packaging. Note that Greece and Italy has not yet fully implemented the regulations. It is usually stated in the exemption decisions if the medicinal product lacks safety features. • Medicinal products that are approved outside the EU/EEA are not covered by the regulations at all and can never be uploaded to the EMVS o Note that the packs still may have a 2D-datamatrix. However, this 2D data matrix has no connection to the European e-verification system. **3. Quarantine the pack (along with alert-ID)** Set the pack in quarantine according to regular storage conditions (e.g. quarantine in the refrigerator when a refrigerated product) as the pack should be able to be returned to saleable stock after investigation. Keep the pack together with the alert-ID created so that the event can be linked to the current pack. If no alert-ID has been created, other information (e.g. short description) about the event should be saved with the pack. • In a protected way: if a possible counterfeit, the pack can be evidence in a criminal investigation. For example, put the pack in a plastic bag and label the bag with the alert-ID. **4. Report the pack as a possible counterfeit to MAH** The pack must be reported to MAH if the pack does not comply with the regulations.

5 Warnings that the pack cannot be found in or matches SMVS

Pack data errors, i.e. warnings that the pack cannot be found in SMVS, are errors that in many cases can be corrected by MAH by uploading or correcting data in the SMVS.

These errors can also be due to scanner errors or incorrect scanner readings by the end-user. In these cases, the errors must be investigated and corrected by the end-user. The end-user can check the pack by manually entering the product code and serial number from the information on the pack if a scanner error cannot be corrected directly.

When decommissioning or reactivating, the SMVS always controls if the pack is in the database and therefore warnings below can be displayed during all operations against SMVS.

5.1 Warnings that the pack cannot be found in or matches SMVS

ID	Operation	Status	Alert?	Response	Comment
41020002 (#A2)	All operations	N/A	YES	The serial number is unknown. The batch has not been found. An alert has been raised.	Product code can be found in SMVS. Serial number cannot be found in SMVS. Batch number cannot be found in SMVS.
41020001 (#A3)	All operations	N/A	YES	The serial number is unknown. An alert has been raised.	Product code and batch number can be found in SMVS. Serial number cannot be found in SMVS.
41020010 (#A3) **41020011 (#A3)** **41020012 (#A3)**	All operations	N/A	YES	The serial number is unknown. The length or format does not match what has been uploaded. Possible scanner or software malfunction. An alert has been raised.	Same as above, but that the SMVS recognize that the format of the serial number does not match the format of the serial numbers uploaded for the batch.
41020003 (#68)	All operations	N/A	YES	The batch identifier mismatches the recorded batch identifier. An alert has been raised.	Product code and serial number can be found in SMVS. Batch number does not match the batch number in SMVS.
41020007 (#68) **41020008 (#68)** **41020009 (#A68)**	All operations	N/A	YES	The batch identifier mismatches the recorded batch identifier. The length or format does not match what has been uploaded. Possible scanner or software malfunction. An alert has been raised.	Same as above, but that the SMVS recognize that the format of the batch number does not match the format of the batch number uploaded for the product code.
41020005 (#52)	All operations	N/A	YES	The expiry date mismatches the recorded expiry date. An alert has been raised.	Product code and serial number can be found in SMVS. Expiry date does not match the expiry date in SMVS.

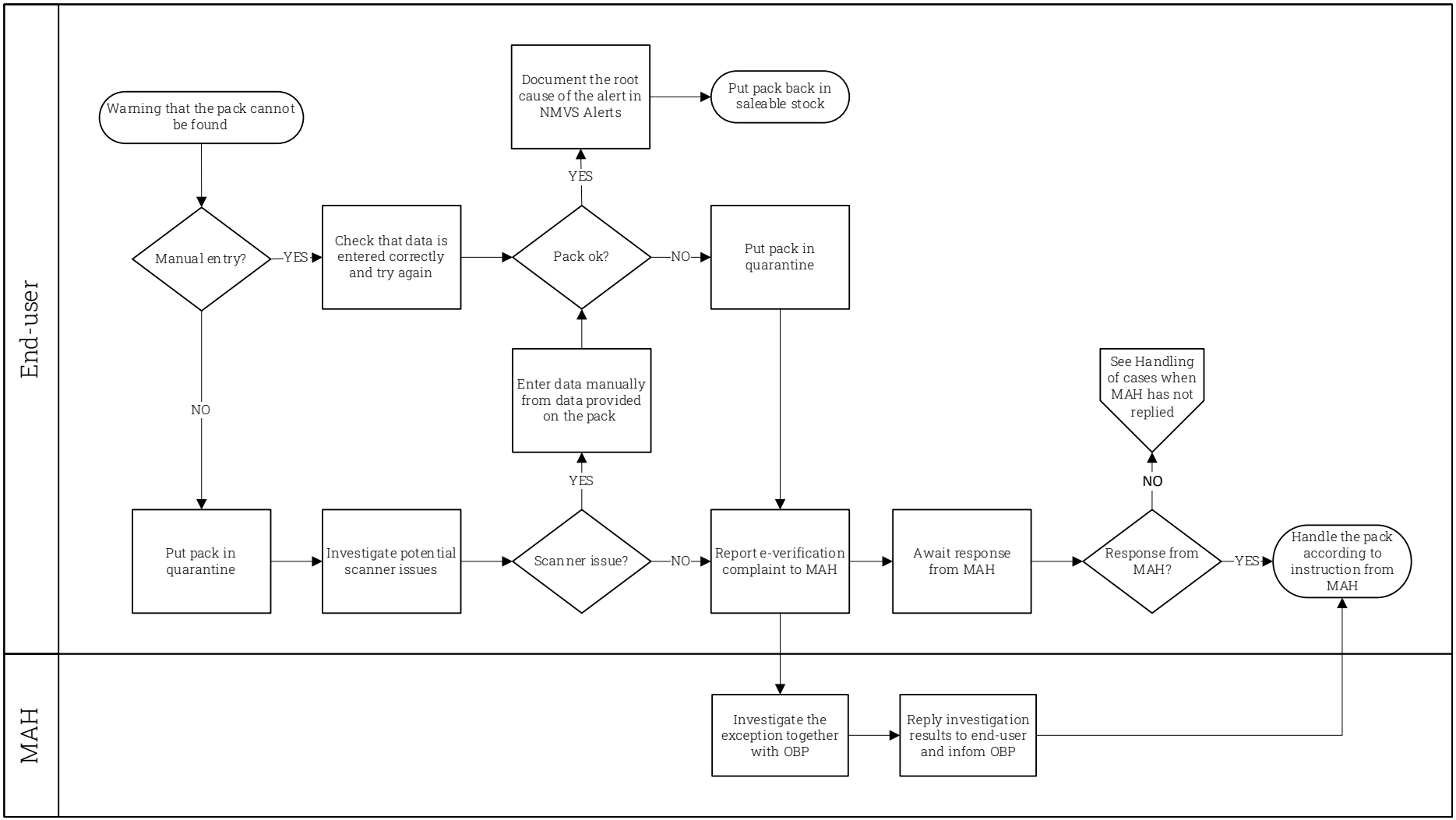
5.2 Warning that the product code, serial number, batch and expiration date do not follow the GS1 standard – (the format is invalid).

ID	Operation	Status	Alert?	Response	Comment
61020008	All operations	N/A	NO	The product code is invalid.	The product code does not follow the established GS1 standard for product codes. A product code should always contain 14 digits.
61020006				The batch identifier is invalid.	The batch does not follow the established GS1 standard for batch numbers.
61020007				The expiry date is invalid.	The expiry date does not follow the established GS1 standard for expiration dates.
61020011				The serial number is invalid.	The serial number does not follow the established GS1 standard for expiration dates.

5.3 Possible reasons for the warning:

- The batch or some packs in the batch have not been uploaded to the database by the MAH.
- The data/information printed on the pack (data readable to the human eye or data in the 2D-code) does not match the data uploaded to the database. For example, spaces occur in the 2D-code.
- Incorrect information has been entered when checking the pack:
    - The scanner equipment has replaced uppercase and lowercase letters with each other or replaced special characters such as "/" and "-"
    - The scanner equipment has not correctly separated the four or more elements of the 2D-code.
    - Incorrect information has been read or entered when manually entering information printed on the pack.
- Information on the pack (human-readable or 2D-code data) does not match the information in the database.
- An initial 0 has not been included in the operation to SMVS, which means that the product code does not contain 14 digits.
- The pack of the medicine is a counterfeit or has other serious quality deficiencies.

5.4 Handling the warning



Pharmacy, hospital pharmacy, medical unit, wholesale	1. Has data from the 2D-code been entered manually? (I.e. not by scanning) • It is possible to enter information from the pack manually if scanning of the pack is not possible. If incorrect information is entered by mistake, this causes an alert when verifying the pack since the pack will not be found in SMVS. • In these cases, try entering the data again. • If the alert was caused solely due to incorrectly entered data, reporting to MAH does not need to be done. • If the correct information has been entered (and double check created another warning), the pack should be reported to MAH. 2. Investigate possible scanner errors • Scanner errors sometimes causes alert. These errors prevent dispensing of medicines and should be investigated as far as possible if alert occurs. If the end-user can check which information the scanner has read, the following checks may be made by the end-user: • Make sure that the serial number on the pack corresponds to the scanner read serial number. • Make sure that the batch number on the pack corresponds to the scanner read batch number. • The end-user can check whether the scanner may have read the data incorrectly by checking the information in the alert in NMVS Alerts. When an alert has been generated, you can see in the alert in NMVS Alerts what data was sent in the call to SMVS and can then check this against the data on the pack to see that it matches. • Check that there is no difference between uppercase and lowercase letters or that special characters are incorrectly read. (The best way to avoid these errors is to ensure the correct settings in the scanner already during installation) 3. Document the reasons for the alert • If the end-user has caused a warning or alert, this needs to be documented by the end-user in NMVS Alerts. This is important so e-VIS or MAH can be informed about the root cause of the alert. 4. Quarantine the pack (along with alert-ID) • Set the pack in quarantine according to regular storage conditions (e.g. quarantine in the refrigerator when a refrigerated product) as the pack should be able to be returned to saleable stock after investigation. • Keep the pack together with the alert-ID created so that the event can be linked to the current pack. If no alert-ID has been created, other information (e.g. short description) about the event should be saved with the pack. • In a protected way: if a possible counterfeit, the pack can be evidence in a criminal investigation. For example, put the pack in a plastic bag and label the bag with alert-ID. 5. Report the e-verification warning to MAH • The pack should be reported to MAH if the pack cannot be found in SMVS. Always enter the alert-ID if it has been created. 6. Await feedback from MAH within 2 working days

	• Feedback from MAH should take place within two working days. If MAH cannot reach a conclusion on the error within three working days, the end-user should be informed about the delay. **7. Handle the pack according to instructions from MAH** • MAH can confirm the error and notify that the error is fixed. In these cases, the end-user can re-verify the pack to ensure that the error is fixed. • MAH's investigation is facilitated if the end-user can send an image of the pack's 2D-code. MAH can then often investigate without physically requesting the pack. • MAH may ask the end-user to return the pack. Returns are made according to MAH's instructions. • MAH can confirm incorrect handling on the end-user side such as scanner errors. These errors shall then be further investigated by the end-user.
MAH	**8. Investigate the alert together with MAH's OBP function.** MAH needs to investigate the alert together with its OBP function. • Note that the alert notification from EMVS is sent to the OBP function and the investigation may need to be coordinated. • Note that an end-user does not need to report warnings where later verification of the pack has been successful. **Coordinate end-user report with alert message:** • Identify alert message sent from EMVS. Note that the end-user may have scanned the same pack several times and therefore a report can cover several alert messages. **If scanner error is not excluded** **9. To further rule out scanner errors, MAH may ask for an image of the 2D-code.** If the information in the 2D-code does not match the information in the alert, it may be due to scanner errors, incorrect manual entry of data, quality deficiencies in manufacturing or a counterfeit. Ask the end-user to send an image of the pack where the 2D-code and the printed information is visible. **At A2 (batch and serial number not found)** Verify that the batch is properly uploaded in EMVS. • It is likely that the batch is not uploaded in EMVS. • MAH should ensure that further distribution of the batch is stopped until the batch is uploaded and that the pack can be verified against the system. • Pharmacies, wholesalers and hospital pharmacies as well as e-VIS must be informed of the incident.

At A3 (serial number missing)
Check that the batch is correctly uploaded in the system and that the packs are uploaded to the Swedish market.
Check for signs that individual serial numbers have not been uploaded to the database.

- It is likely that individual serial numbers have not been uploaded to the database.
- MAH should ensure that further distribution of the batch is stopped until all packs are uploaded.
- Pharmacies, wholesalers and hospital pharmacies as well as e-VIS must be informed of the incident.

At A68 (batch number does not match)

- Batch numbers in the 2D-code do not match the information that is uploaded. Keep in mind that spaces are actual characters. Note that incorrect spaces in batch numbers cannot be uploaded and corrected in EMVS as spaces are not a valid character.

10. Inform the end-user about the investigation
The end-user shall be informed of the investigation result. Sent the investigations result as soon as the investigation shows that it is not a possible counterfeit.
e-VIS should always be added as a copy of feedback via alerts@e-vis.se

If the error has been corrected
Inform the end-user that the error has been fixed and ask the end-user to verify the pack again.

If the error cannot be corrected
Inform the end-user about how to handle the obsolete pack. If the error concerns several packs on the market or an entire batch, other end-users should also be informed about the error and how the pack should be handled.

If the error is assumed to be on the end-user's side
Inform the end-user of the results of the investigation and that the error is believed to be due to handling or scanner errors.

6 Warning that the product code is unknown

If a pack that is not subject to the requirements for safety features is verified against SMVS, a warning that product code cannot be found will be generated.

Since SMVS does not know which MAH owns the product, no alert is created in these cases.

If this warning is generated, check that the pack is subject to the requirements on safety features. In VARA/LiiV, there is marking from the Medical Products Agency at the pack level that indicates whether the medicine should have safety features or not.

Please note that products released before 9 February 2019 are not subject to the regulations for safety features.

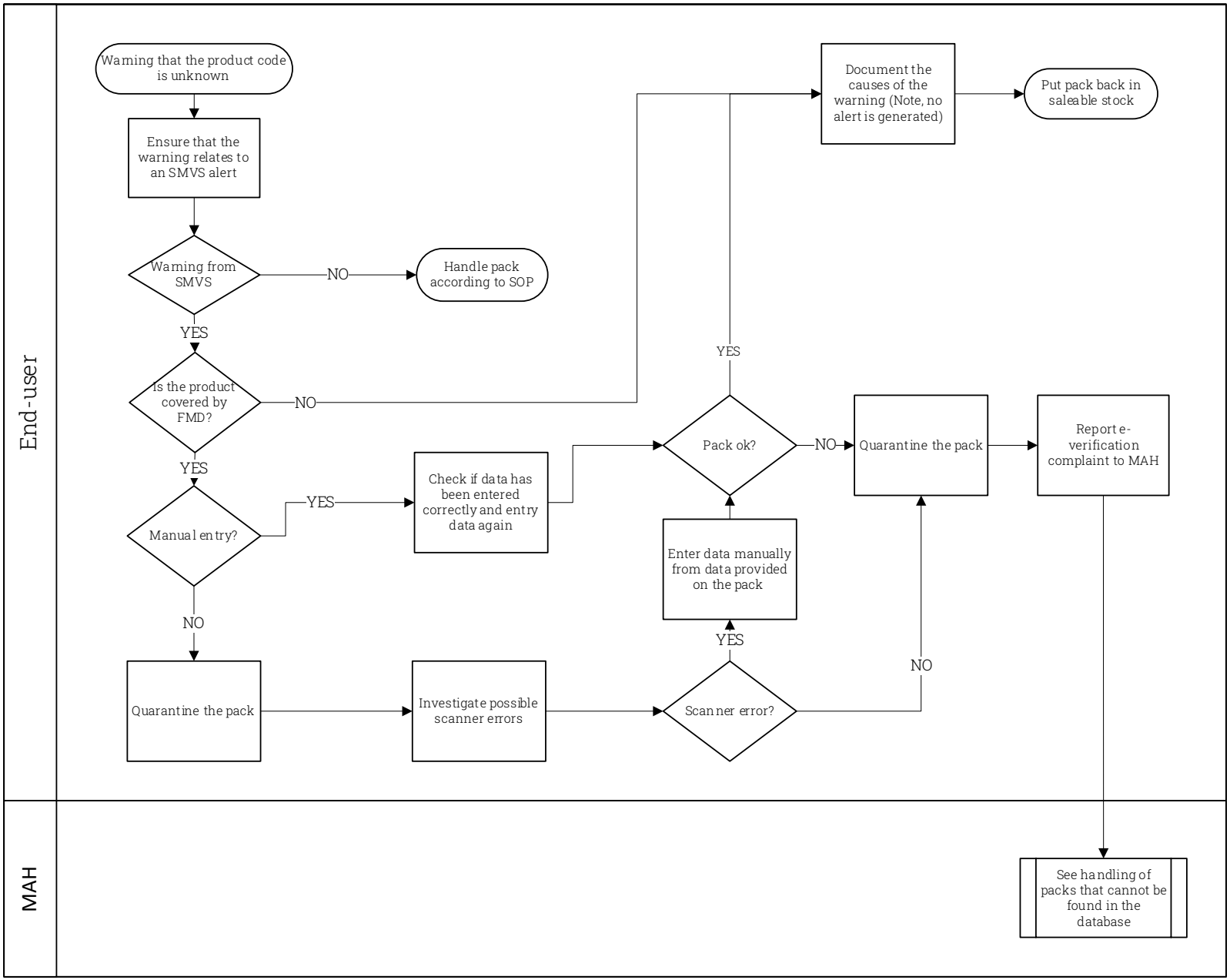
6.1 Warning that the product code is unknown

ID	Operation	Status	Alert?	Response	Comment
41020000 (#A1)	All operations	N/A	NO	Product code unknown	Product code can't be found in SMVS. No further search or control of pack data is performed in SMVS.

6.2 Possible reasons for the warning

- The product is not uploaded to the database.
- The medicine is a veterinary medicine and is not covered by the regulatory framework for safety features.
- The medicine is a licensed medicine from outside the EU/EEA. These medicines are not covered by the regulatory framework for safety features.
- The medicine is an over-the-counter medicine that is not subject to the requirements on safety features or another medicine that is not covered by the requirements. Information on the pack (data readable to the human eye or data in the 2D-code) does not match the data in the database.
- Incorrect information has been entered when checking the pack:
    - The scanner equipment has not separated the four or more elements of the 2D-code correctly.
    - Incorrect information has been read or entered when manually entering information printed on the pack.
- The pack of the medicine is a counterfeit or has other serious quality deficiencies.

6.3 Handling the warning



Pharmacy, hospital pharmacy, medical unit, wholesale	1. Ensure that the warning relates to an SMVS alert • Many pharmacies and other end-users use the product code in the 2D-code to do picking checks or to identify the medicine in other processes. These checks are made against the pharmacy's goods register, which often receives its information from VARA / LiiV. If the product code is incorrectly entered in the pharmacy's own stock management system, the product code on the pack cannot identify an item in the system. However, these warnings are not linked to the e-verification database (SMVS). For example, it may be the case that the medicine cannot be identified in the end-user's stock management system, but the product code is uploaded in SMVS. Problems with stock management systems shall be handled according to the end-user's own procedures for this type of error and shall not be reported as a possible counterfeit. • Verify that the warning concerns SMVS. 2. Is the product covered by FMD? • If the medicine is not covered by FMD, the product code should not be uploaded to the database. In VARA there is information about whether the medicine is subject to the regulations on safety features. Only medicines released after 9 February 2019 must have safety features. 3. Has data from the 2D-code been entered manually? (I.e. not by scanning) • It is possible to enter information from the pack manually if scanning of the pack is not possible. If incorrect information is entered by mistake, this causes an alert when verifying the pack since the pack will not be found in SMVS. • In these cases, try entering the data again. • If the alert was caused solely due to incorrectly entered data, reporting to MAH does not need to be done. • If the correct information has been entered (and double check created another warning), the pack should be reported to MAH. 4. Investigate possible scanner errors • Scanner errors sometimes cause alert. These errors prevent dispensing of medicines and should be investigated as far as possible if alert occurs. If the end-user can check which information the scanner has read, the following checks may be made by the end-user: • Check that the product code on the pack corresponds to the product code read. 5. Document the reasons for the warning • If the warning is due to the end-user's own handling, there is no need to report to the MAH. However, the end-user may need to document deviations in their own QMS. Note that this warning does not generate an alert, which is why no documentation is made in NMVS Alerts. 6. Quarantine the pack (along with alert-ID) • Set the pack in quarantine according to regular storage conditions (e.g. quarantine in the refrigerator when a refrigerated product) as the pack should be able to be returned to saleable stock after investigation. • Keep the pack together with the alert-ID created so that the event can be linked to the current pack. If no alert-ID has been created, other information (e.g. short description) about the event should be saved with the pack. In a protected way: if a possible counterfeit, the pack can be evidence in a criminal investigation. Put the pack in a plastic bag and label the bag with alert-ID.

MAH	7. **Investigate the warning together with OBP function.** • MAH needs to investigate the error along with its OBP function. Check if the pack is covered by the regulations for safety features and if the current product should be uploaded in SMVS. **If scanner error is not excluded** • To further rule out scanner errors, MAH may ask for an image of the 2D-code. • If the information in the 2D-code does not match the information in the alert, it may be due to scanner errors, incorrect manual entry of data, quality deficiencies in manufacturing or a counterfeit. • Ask the end-user to send an image of the pack where the 2D-code and the printed information is visible. **If the error has been corrected** • Inform the end-user that the error has been fixed and ask the end-user to verify the pack again. **If the error cannot be corrected** • Inform the end-user about how to handle the obsolete pack. If the error concerns several packs on the market or an entire batch, other end-users should also be informed about the error and how the pack should be handled. **If the error is assumed to be on the end-user's side** • Inform the end-user of the results of the investigation and that the error is believed to be due to handling or scanner errors.

7 Warnings that the pack is not active or has an incorrect status

7.1 Warnings that the pack is marked as supplied or decommissioned in the same location

The pack has previously been dispensed or decommissioned at the same pharmacy, hospital pharmacy or wholesaler. The end-user should primarily investigate handling errors in their own handling.

Below are responses sent to the end-user system when the pack has already been marked as supplied or decommissioned as destroyed. Note that there are more possible replies if the pack has previously been decommissioned as Exported, Sample, Free Sample, Checked out, Locked or Stolen.

7.1.1 Pack already marked as supplied in the same location

If pack is decommissioned or marked as supplied again, a warning will be displayed to the end-user. Alerts will be created if further attempts at decommissioning are made.

ID	Operation	Status	Alert?	Response
11110201	Verify	Supplied	NO	The pack was decommissioned as supplied at this location.
11220201	Supply	Supplied	NO	The pack was previously supplied at this location. The next attempt will be rejected.
51220201 (#A7)		Supplied	YES	The pack was previously supplied at this location. Too many repeated attempts. An alert has been raised.
51320201 (#A24)	Decommission	Supplied	YES	The pack is already decommissioned as supplied at this location. An alert has been raised.

7.1.2 Pack already decommissioned as destroyed at the same location

ID	Operation	Status	Alert?	Response
11110401	Verify	Destroyed	NO	The pack was decommissioned as destroyed at this location.
51220401 (#A24)	Supply	Destroyed	YES	The pack cannot be supplied because it is already decommissioned as destroyed at this location. An alert has been raised.
51320401 (#A7/#A24)	Decommission	Destroyed	YES	The pack is already decommissioned as destroyed at this location. An alert has been raised.

7.2 Warnings that the pack is marked as supplied or decommissioned in another location

7.2.1 Pack already marked as supplied in another location

If the pack has previously been marked as supplied in another location, an alert will be generated immediately if end-users try to mark the pack as decommissioned again.

ID	Operation	Status	Alert?	Response
11110200	Verify	Supplied	NO	The pack was decommissioned as supplied at another location.
51220200 (#A7)	Supply	Supplied	YES	The pack cannot be supplied. An alert has been raised.
51320200 (#A24)	Decommission	Supplied	YES	The pack is already decommissioned as supplied at another location. An alert has been raised.

7.2.2 Pack already decommissioned as destroyed elsewhere

ID	Operation	Status	Alert?	Response
11110400	Verify	Destroyed	NO	The pack was decommissioned as destroyed at another location.

51220400 (#A24)	Supply	Destroyed	YES	The pack cannot be supplied because it is already decommissioned as destroyed at another location. An alert has been raised.
51320400 (#A7/#A24)	Decommission	Destroyed	YES	The pack cannot be decommissioned. An alert has been raised.

7.3 Warning that pack is not active to be handed over to the customer or to be distributed further in the supply chain

Medicinal products available for delivery to the customer and released to the public shall be active in the database. If the pack is no longer active, this means that the pack will no longer be available on the market for further distribution or delivery to the customers and patients.

The following section describes the handling of medicines that are to be forwarded to the customer or distributed further. Pack to be distributed further must be active in the database so that they can be decommissioned as supplied then dispensed.

When decommissioning in the same location

If decommissioning has previously taken place at the same pharmacy or wholesaler, it is likely that the warning has arisen due to the pharmacy's or wholesaler's own handling of the pack, for example a pack to be destroyed is marked as destroyed twice or if the end-user discovers a pack in the dispensing order that is already decommissioned as supplied at the same pharmacy. If the warning is due to the end-user's own handling, the case should be handled in the end-user's own quality system so that any questions can be answered in the event of any questions from MAH, e-VIS or the Medical Products Agency. If an alert has been generated, the end-user must inform e-VIS of the root cause in NMVS Alerts.

In case of decommissioning at another location

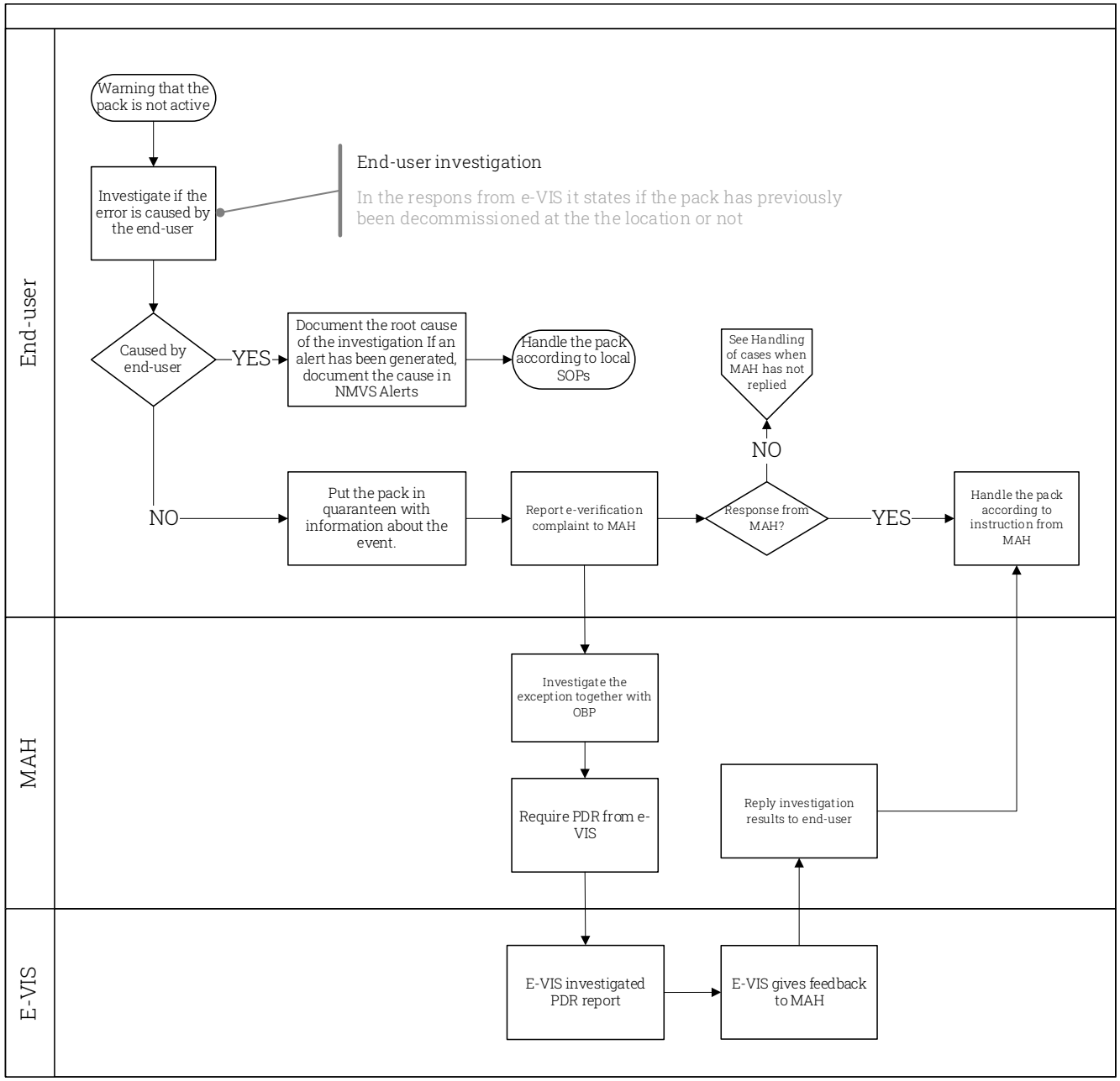
If the pack has been decommissioned elsewhere, the pack shall be reported as the pack shall not be in the possession of the current end-user. The pack should be reported as a possible falsification to MAH.

Exceptions to the above apply if the pharmacy knows that the pack came to the pharmacy from another business, for example if a complaint is accidentally decommissioned during destruction. When the pharmacy knows the reason, the pack does not need to be reported.

7.4 Possible reasons for the warnings:

- Pack has been decommissioned in connection with dispensing and delivery at a pharmacy or wholesaler but has never been dispensed to patient/customer. Reactivation has not taken place when pack has been put back in saleable stock.
- Pack has been decommissioned as destroyed by mistake and has subsequently been returned to saleable stock.
- Pack to be distributed within the EU has been accidentally decommissioned as exported outside the EU.
- Wholesalers have returned already decommissioned pack upon return to saleable stock.
- The same 2D-code has been printed on two or more packs.
- Quality deficiencies in the end-user's handling of pharmaceutical pack or falsification of the origin of the medicine such as:
    - Medicines that are to be destroyed, exported or for some other reason are not available on the market have again ended up in saleable stock.
    - Medicines that are already handed over to customers have again ended up in saleable stock.
- The pack of the medicine is a counterfeit or has other serious quality deficiencies.

7.5 Handling the warning



Pharmacy, hospital pharmacy, medical unit, wholesale	**8. Check if the reason is due to the pharmacy/wholesaler's own handling of the pack** The end-user needs to investigate whether previous decommissioning is due to the end-user's own handling or not before further reporting takes place. • In particular, the end-user needs to investigate whether decommissioning took place at the same pharmacy or not! • In case of uncertainty, e-VIS can be contacted to investigate further, e-VIS can see where previous decommissioning has taken place if it is considered to be of benefit to the investigation. **9. Document the reasons for the warning/alert** If the end-user has caused a warning or alert, this needs to be documented by the end-user. If the warning has generated an alert the cause should be documented by the end-user in NMVS Alerts. **10. Quarantine the pack (along with alert-ID)** • Set the pack in quarantine according to regular storage conditions (e.g. quarantine in the refrigerator when a refrigerated product) as the pack should be able to be returned to saleable stock after investigation. • Keep the pack together with the alert-ID created so that the event can be linked to the current pack. If no alert-ID has been created, other information (e.g. short description) about the event should be saved with the pack. • In a protected way: if a possible counterfeit, the pack can be evidence in a criminal investigation. For example, put the pack in a plastic bag and label the bag with alert-ID. **11. Report the e-verification warning to MAH** Normally, incorrect status of a pack is detected in connection with verification of the pack. In these cases, SMVS does not initiate an alert. It is therefore important that reporting takes place through regular reporting channels. **12. Handle the pack according to MAH's instructions and document** MAH may ask the end-user to send the pack to MAH for further investigation or request a photo of the pack for investigation of the defect.

MAH	**13. MAH conducts investigation of the warning** Investigate if there is a known reason why pack is decommissioned in the supply chain. Note that alerts are not always generated for warnings regarding the status of the pack. For this reason, an alert-ID or alert message is not always available at the OBP function. **14. MAH asks e-VIS to investigate audit trail for a specific pack** MAH can ask e-VIS to make further investigation of the case by requesting the history of the pack. When inquiring to e-VIS: • Include original report from reporting pharmacy. If e-VIS does not have evidence that the end-user has requested an investigation of the warning, e-VIS will not be able to disclose information about which pharmacy has made previous transactions. • If the pack is not uploaded in the Swedish system, a check will be made against another European system where the pack is uploaded. In these cases, this country will be contacted for support in the investigation. • e-VIS is not able to disclose information about which locations a pack has previously been decommissioned unless consent has been obtained from the end-user. • e-VIS will provide feedback that decommissioning has taken place elsewhere and that e-VIS is investigating the incident together with the end-users. • If the pack is verified by a wholesaler between decommissioning's, the wholesaler will be informed of this. MAH receives information that the pack should be returned to wholesaler by the end-user. • e-VIS will contact the other end-user regarding reasons for the decommissioning. • If double serial numbers are suspected, MAH will be informed of this. **15. Inform the end-user about the investigation** If previous decommissioning has taken place at the end-user who reported the pack or if handling errors have been confirmed by e-VIS • Inform the end-user of the results of the investigation and that the error is believed to be due to handling errors. **If previous decommissioning has occurred at another end-user** Inform the end-user to save the pack in quarantine as investigation may take a long time.

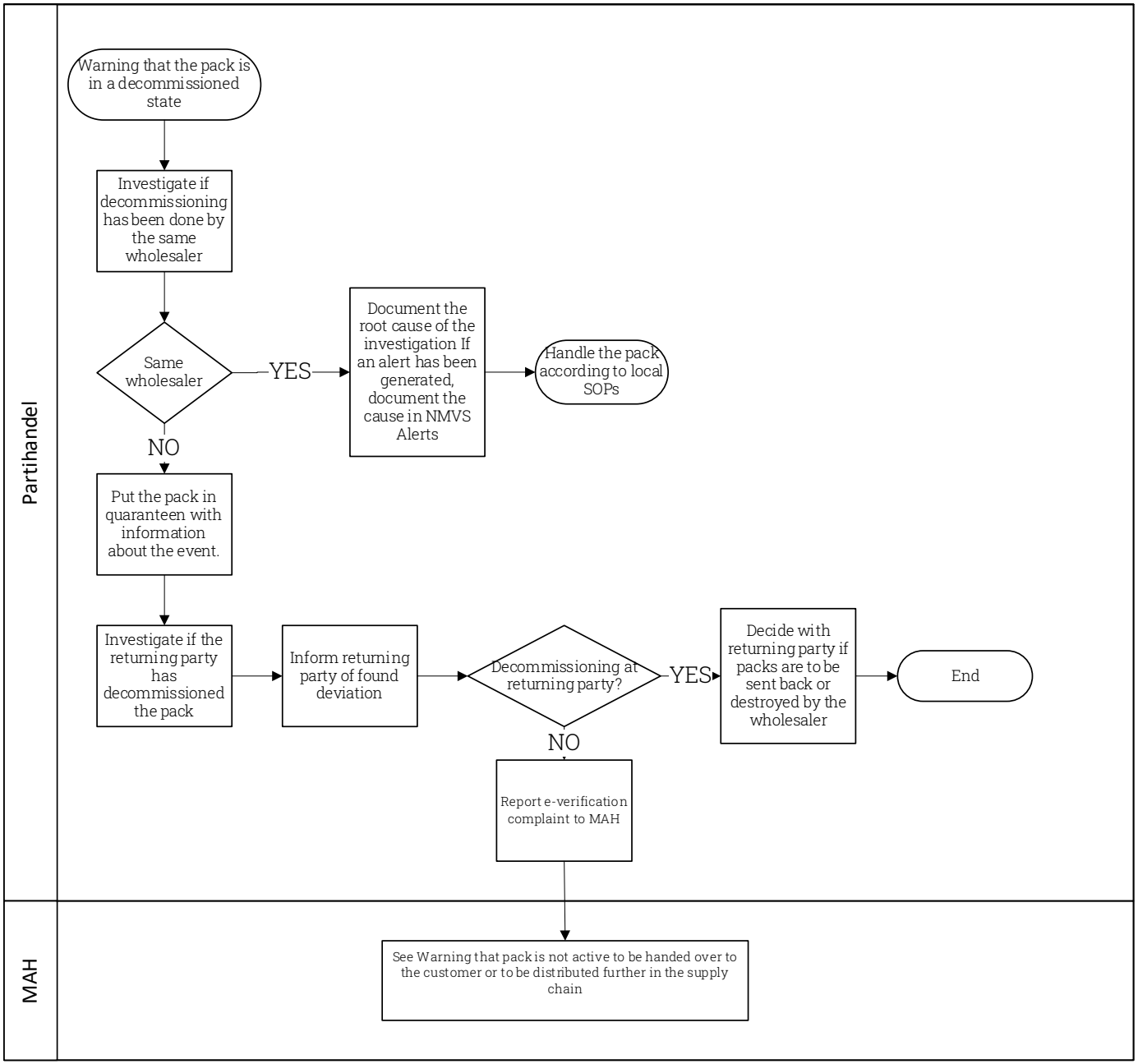
7.6 Handling of warnings indicating that pack has incorrect status when checking return to wholesale

Medicinal products returned to wholesale distribution shall not be decommissioned by the end-user returning the pack. For example, if a pack is to be returned for disposal at the wholesaler, the pack must be returned in active status. A pack that has the status of destroyed should already be destroyed and therefore should not be subject to a return. Likewise, a pack that has the status of supplied must be handed over to the customer and therefore should not be subject to a return.

7.7 Possible reasons for the warnings

- Pack has been decommissioned as destroyed by pharmacies or other wholesalers before return to wholesale
- Pack has been marked as supplied without leaving the pharmacy or other end-user and no reactivation has taken place before pack is put back in saleable stock. The pack was later returned to wholesale.
- Quality deficiencies in the handling of pharmaceutical pack or falsification of the origin of the medicine such as:
    - The pack has been delivered to the pharmacy in already decommissioned status.
    - Medicines that are to be destroyed, exported or for any other reason are not available on the market have again been put into saleable stock.
    - Medicines that are already handed over to customers have again ended up in saleable stock.
- The pack of the medicine is a counterfeit or has other serious quality deficiencies.

7.8 Handling the warning



Wholesaler	**1. Investigate whether decommissioning has previously taken place at the same wholesale** If the decommissioning has previously taken place at the same wholesaler, the pack shall be handled in the same way as in section 6 above. **2. Document the reasons for the warning/alert** If the end-user has caused a warning or alert, this needs to be documented by the end-user. If the warning has generated an alert the cause should be documented by the end-user in NMVS Alerts. **3. Quarantine the pack (along with alert-ID)** • Set the pack in quarantine according to regular storage conditions (e.g. quarantine in the refrigerator when a refrigerated product) as the pack should be able to be returned to saleable stock after investigation. • Keep the pack together with the alert-ID created so that the event can be linked to the current pack. If no alert-ID has been created, other information (e.g. short description) about the event should be saved with the pack. • In a protected way: if a possible counterfeit, the pack can be evidence in a criminal investigation. For example, put the pack in a plastic bag and label the bag with alert-ID. **4. Check if the pharmacy/wholesaler who made the return has decommissioned the pack** If the pack has status exported, free sample, locked or stolen, decommissioning cannot have been done by pharmacies as they cannot deactivate a pack to these statuses. If verification responses show that the pack has been decommissioned elsewhere (i.e. a location other than the wholesaler), the decommissioning may have taken place at the pharmacy/wholesaler that returned the pack. This does not have to be the case as the pack may have arrived at the end-user already decommissioned. If the pharmacy/wholesaler who has made the return does not know if decommissioning has taken place at their location, e-VIS can be contacted. **5. Notify deviation to the pharmacy/wholesaler who reported the return** Deviations that decommissioned pack has been returned must always be sent to the person who made the return. If feedback is required from the person who carried out the return, this must be stated in the deviation message. **6. Decide in consultation if pack is to be destroyed or returned to the pharmacy/wholesaler** Decide in consultation with the returnee whether pack can be destroyed at the wholesaler or whether the pack should be returned to the pharmacy/wholesaler who made the return. If the returned pack is to be destroyed, the pack does not need to be sent back to the pharmacy/wholesaler who made the return. If the returned pack can be put back in saleable stock, the pharmacy/wholesaler who made the return can request that the pack should be sent back. **7. Report the e-verification warning to MAH** Normally, incorrect status of a pack is detected in connection with verification of the pack. In these cases, SMVS does not create any alert. It is therefore important that reporting takes place through existing reporting channels. **8. Handle the pack according to MAH's instructions and document** MAH may ask the end-user to send the pack to MAH for further investigation or request a photo of the pack for investigation of the defect.
MAH	**9. See handling at 7.5.**

8 Warnings that the pack is recalled, withdrawn or expired in date

In SMVS, MAH can set a product code to withdrawn and a batch to recalled. When the batch expiration date in the database has passed, the pack will be set to the expired status.

Below indicates the handling of medicines to available stock and medicines intended for supply and further distribution.

Note that a pack may be subject to withdrawal or deregistration even if the pack still has a status ACTIVE in the database.

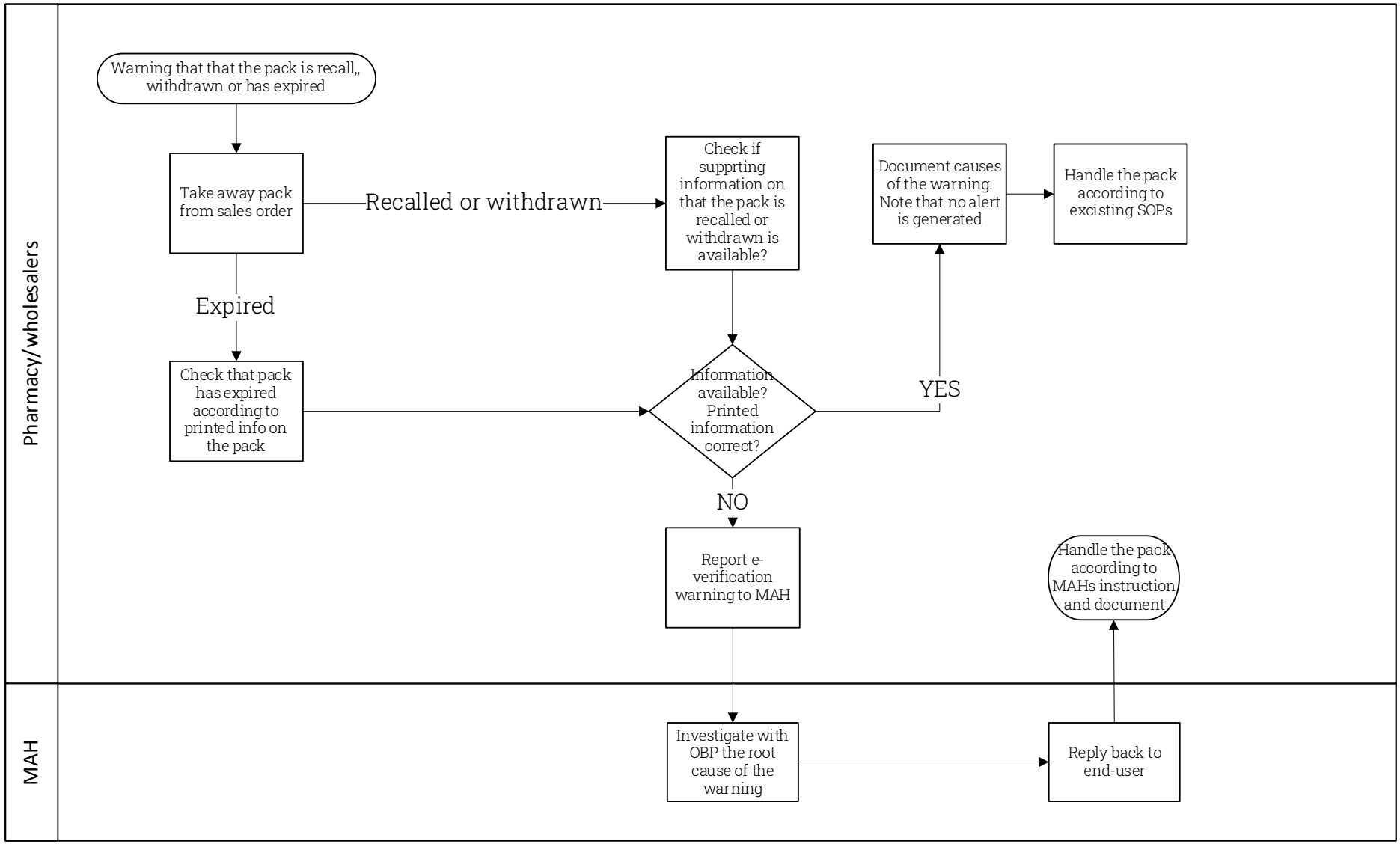
8.1 Warnings that the pack is recalled, withdrawn, or expired in date

ID	Operation	Status	Alert?	Response
11111100	Verify	Recalled	NO	The batch has been recalled.
11111200		Withdrawn	NO	The product has been withdrawn.
11111000		Expired	NO	The batch has expired.
51221100	Supply	Recalled	NO	The pack cannot be supplied. The batch has been recalled.
51221200		Withdrawn	NO	The pack cannot be supplied. The product has been withdrawn.
51221000		Expired	NO	The pack cannot be supplied. The batch has expired.
51321100	Decommission	Recalled	NO	The pack cannot be decommissioned. The batch has been recalled.
51321200		Withdrawn	NO	The pack cannot be decommissioned. The product has been withdrawn.
51321000		Expired	NO	The pack cannot be decommissioned. The batch has expired.

8.2 Possible reasons for the warnings:

- The withdrawn, recalled or expired medicine has not been removed from the end-user's available stock in a timely manner.
- Information that the medicine is withdrawn or recalled has not reached the end-user when the medicine is verified or that information on withdrawal/deregistration has not been sent out.
- The medicine has been incorrectly marked as recalled or withdrawn in SMVS by MAH.
- Quality deficiencies in pharmacies or wholesalers' handling of pharmaceutical pack or falsification of the origin of the medicine such as:
    - Recalled, withdrawn or expired medicines has returned to available stock at the end-user.

8.3 Handling the warning



Pharmacy, hospital pharmacy, medical unit, wholesale	**1. Check that information is available to support pack withdrawn or recalled** **If withdrawn** Check if the medicine is withdrawn in VARA or has information about the withdrawal been sent in another way to the end-user. **If recalled** Check if the recall letter has been sent to the end-user or if there is information about the recall on the Medical Products Agency's website. **2. Check that the date has actually passed according to information on the pack** Check that the expiration date on the pack has de facto passed. **3. Document the reasons for the warning** If the warning is due to the end-user's own handling, there is no need to report to the MAH. However, the end-user may need to document deviations in their own QMS. Note that this warning does not generate an alert, which is why no documentation is made in NMVS Alerts. **4. Handle the pack correctly according to the current SOPs** When the pack is subject to recall or withdrawal, the pack shall be handled in accordance with the end-user's procedures for recalled and withdrawn packs. **5. Report the e-verification alert to MAH** Since no alert is created it is important that reporting takes place via existing reporting channels. **6. Quarantine the pack (along with alert-ID)** • Set the pack in quarantine according to regular storage conditions (e.g. quarantine in the refrigerator when a refrigerated product) as the pack should be able to be returned to saleable stock after investigation. • Keep the pack together with the alert-ID created so that the event can be linked to the current pack. If no alert-ID has been created, other information (e.g. short description) about the event should be saved with the pack. • In a protected way: if a possible counterfeit, the pack can be evidence in a criminal investigation. For example, put the pack in a plastic bag and label the bag with alert-ID. **7. Handle the pack according to MAH's instructions and document** MAH may ask the end-user to send the pack to MAH for further investigation or request a photo of the pack for investigation of the defect.
MAH	**8. Investigate together with OBP function the reason for the warning** **If expired date** Check that the date in SMVS matches what is stated on the pack. • If date 2512 or 2025 12 is written, this corresponds to December 31, 2025. If 251201 is specified in SMVS, the expiration date is incorrectly specified in SMVS. **If recall and withdrawal** • Check that information about recall and withdrawal has been sent to pharmacies and wholesalers according to current SOPs. • Together with the OBP function, investigate why the pack has been marked as recall and withdrawal in the system. Please note that if a batch is marked as recalled or withdrawn in EMVS, this will affect all pack on the market. If a pack is to be withdrawn solely from wholesale distribution, the pack shall remain in active status.

9 Warnings when reactivating pack

A pack can be reactivated under certain conditions. Reactivation can only take place in the same location and must take place within 10 days. It is also only pack that has the status supplied, exported out of the EU, sample, free sample and locked that can be reactivated. A pack decommissioned to the status of destroyed cannot be reactivated.

9.1 Warnings that the pack cannot be reactivated

ID	Status	Alert?	Svar	Comment
9.1.1 Warnings that the pack cannot be reactivated when the pack is already active As the pack is already active, the pack cannot be reactivated. Make sure that the medicine is curative before the medicine is put back in available stock.				
51420101	Active	NO	The pack has already been reactivated to active at this location.	Appears when the end-user tries to reactivate a pack that has never been decommissioned and is therefore active. Also appears when the end-user tries to reactivate a pack that is in active status when it has already been reactivated.
51420100	Active	NO	The pack cannot be reactivated. The status is already active.	
9.1.2 Reactivation warnings that the time limit has been exceeded For handling the warning, see 7 Warnings that the pack is not active or has an incorrect status				
51420200	Supplied	NO	The pack cannot be reactivated. Time limit exceeded.	Displayed when end-users try to reactivate a status in the same location where pack was previously decommissioned, but the 10-day time limit has been exceeded.
51420501	Sample	NO	The pack cannot be reactivated. Time limit exceeded.	
51420801	Exported	NO	The pack cannot be reactivated. Time limit exceeded.	
51420601	Free Sample	NO	The pack cannot be reactivated. Time limit exceeded.	
51420002	N/A	NO	The pack cannot be reactivated. Time limit exceeded.	The warning is the same as above, but the decommissioning has taken place in another national system and the status of the pack has not been returned to the end-user.
9.1.3 Warnings that pack cannot be reactivated when the pack has a status that cannot be reactivated For handling the warning, see 7 Warnings that the pack is not active or has an incorrect status				
51420401	Destroyed	NO	The pack cannot be reactivated because it was decommissioned as destroyed at this location.	Warning to the end-user that a pack that has been decommissioned in the same location cannot be reactivated. A pack that has been set to destroyed status can never be reactivated.
51420301	Stolen	NO	The pack cannot be reactivated because it was decommissioned as stolen at this location.	
9.1.4 Reactivation warnings that the pack has been decommissioned elsewhere For handling the warning, see 7 Warnings that the pack is not active or has an incorrect status				
51420201	Supplied	NO	The pack cannot be reintroduced. It was supplied at another location.	The pack cannot be reactivated since the pack was supplied at another location.
51420400	Destroyed	NO	The pack cannot be reactivated because it was decommissioned as destroyed at another location.	The pack cannot be reactivated as decommissioning has taken place at another location.
51420500	Sample	NO	The pack cannot be reactivated. It was decommissioned at another location.	

51420800	Exported	NO	The pack cannot be reactivated. It was decommissioned at another location.	When verifying these packs, the end-user receives information that the pack has previously been decommissioned elsewhere. The pack shall be handled in accordance with section 7 above
51420600	Free Sample	NO	The pack cannot be reactivated. It was decommissioned at another location.	
51420300	Stolen	NO	The pack cannot be reactivated because it was decommissioned as stolen at another location.	
51420900	Checked-Out	NO	The pack cannot be reactivated. It was decommissioned at another location.	
51420700	Locked	NO	The pack cannot be reactivated. It was decommissioned at another location.	
51420001	N/A	NO	The pack cannot be reactivated. It was decommissioned at another location.	The warning is the same as above, but the decommissioning has taken place in another national system and the status of the pack has not been returned to the end-user.
9.1.5 Warnings that the pack cannot be reactivated when the batch or product code is already recalled, withdrawn, or expired in date **For handling the warnings, see section 8 Warnings that the pack is recalled, withdrawn or expired in date**				
11411100	Recalled	NO	The pack is recalled on this market due to its batch state.	The warning is displayed if the pack cannot be reactivated when the batch or product has been withdrawn, expired in date or recalled from the market. The pack cannot be reactivated as the packs are not to be returned to saleable stock.
11411200	Withdrawn	NO	The pack is withdrawn on this market due to its product state.	
11411000	Expired	NO	The pack is expired due to batch state.	
51421100	Recalled	NO	The pack cannot be reactivated. The batch has been recalled.	The packs are already active AND the batch or product has been withdrawn, expired in date or recalled from the market. The pack should not be returned to saleable stock.
51421200	Withdrawn	NO	The pack cannot be reactivated. The product has been withdrawn.	
51421000	Expired	NO	The pack cannot be reactivated. The batch has expired.	

10 In the event of no feedback from MAH

Pharmacy, hospital pharmacy, medical unit, wholesale	1. **Verify pack again** The end-user can verify the pack again to check if errors have been corrected. 2. **Send reminder to MAH** If MAH has not provided feedback, MAH should be reminded of the investigation. The end-user can also try to reach MAH by phone. 3. **Critical medicines where feedback does not come from MAH** If MAH does not provide feedback on the submitted complaint report, e-VIS can be contacted, which in turn tries to reach MAH if it concerns a critical medicine where the incident needs to be investigated quickly. 4. **Escalate the incident to the Medical Products Agency** If no feedback is received from MAH, the incident can be escalated to the Medical Products Agency by the end-user.

11 Background and definitions

11.1 Content of the 2D-code

A **complete** 2D-code contains:

- Product code
- Serial number
- Batch number
- Expiry date
- Possible cost reimbursement number. This number is found in 2D-codes for some European pack as it is a requirement in some European countries. In Sweden, this number is not a requirement.

11.2 When should the control of the pack take place

The Commission's delegated regulation sets requirements for when a pack is to be verified and decommissioned. The Swedish Medical Products Agency is responsible for supervising that pharmacies and wholesalers comply with the regulations. Below are some examples of occasions where control and decommissioning of medicines against SMVS should take place.

11.2.1 When should medicines be decommissioned as dispensed

When a medicine is released to the public, the pack shall be marked as supplied in the system.

When dispensing medicines the pack must be marked as supplied as close as possible to delivery to the patient.

Medicinal products used in hospitals and healthcare centres shall be marked as supplied when the medicine is in the possession of the health care unit. No further sale of the medicine may take place after the medicine has been decommissioned.

The health care facility may use an outpatient pharmacy, hospital pharmacy or wholesaler to carry out the decommissioning on behalf of the health care facility in connection with the dispensing of the on requisition. The medicine is decommissioned in connection with the handover of the medicines to the hospital or health care unit. Details of the healthcare providers possibility to contract decommissioning to outpatient pharmacies, hospital pharmacies or wholesalers are described in the Swedish Medical Products Agency's *Vägledning om tillämpning av EU-förordning 2016/161 om säkerhetsdetaljer på läkemedelsförpackningar*.

11.2.2 When should medicines be decommissioned as destroyed

Medicinal products shall be decommissioned as destroyed in SMVS when medicinal products from available stock are sent for destruction under the responsibility of the end-user or are to be treated as medicinal waste.

Note that a pack which already is decommissioned (e.g. as supplied) cannot be decommissioned again for any other reason (e.g. for destruction). If the medicine is for example, returned from a patient in the event of a complaint, the medicine cannot be decommissioned as destroyed since the medicine already is decommissioned as supplied.

11.2.3 Regarding return to wholesale

When pharmacies return medicines to wholesalers, the pharmacy should not decommission the pack. The packs should normally be active in SMVS. If medicinal products are returned to the wholesaler, they shall be active when they arrive at the wholesaler. An exception is if the pack is marked as withdrawn, recalled or expired or if another agreement exists in the event of, for example, a complaint.

e-VIS recommends that end-users verify pack before returning it to ensure that the pack is not in an incorrect status.

11.2.4 Distribution of medicines within the EU

When released medicines are distributed within the EU, pack must be active. Medicines should only be decommissioned as exported outside the EU when medicines are distributed outside the EU/EEA. Licensed medicines or exempted foreign packs originating in the EU/ESS must be active in EMVS so that end-users can verify and decommission the pack.

11.3 Response and alert from SMVS

SMVS sends a response to the end-user after each transaction.

- The responses are classified by SMVS as Information or Warnings
- Warnings are sent if the operation the end-user tried to perform failed
- Some warnings also generate an alert in the system
- The end-user is responsible for how the responses are displayed in their system and that there are SOPs for how the responses should be handled.

Upon verification and status change of the unique identifier in SMVS, responses will be sent to the end-user's IT system. Different responses will be sent depending on the request made to SMVS, the status of the pack and the status change that the user wants to make.

The end-user shall assess, after the information or warning, whether the pack is accurate and can be supplied or whether the pack may be a possible counterfeit or substandard.

11.3.1 Information

SMVS sends responses in the form of information when the operation that the end-user wanted to carry out was successful, for example when:

- The end-user has marked a pack as supplied or decommissioned a pack successfully.
- The end-user has verified a pack, the pack has been found in SMVS, and information about the status of the pack has been sent to the end-user. The end-user will also receive information on whether the pack has previously been decommissioned in the same location or not.

11.3.2 Warnings

If the pack cannot be found in SMVS or if a status change cannot be performed, a warning will be sent to the end-user.

11.3.3 Alert

Some of the warnings also initiate an alert in the system. Each alert receives a unique alert-ID.

If an alert is generated, then:

4. An alert-ID is sent to the end-user's system
5. An alert message is sent to e-VIS

6. An alert message is sent to MAH's OBP function via the EU hub
7. The Medical Products Agency gets access to the alert information through a reporting function in SMVS (government reports)

11.3.4 e-VIS Alert Management System NMVS Alerts

e-VIS investigates and documents the cause of alerts in the e-VIS Alert Management System, NMVS Alerts. Pharmacies and wholesalers have access to the alerts that have been generated by their own locations. All alerts generated by end-users in Sweden are saved in the alert portal.

End-users document in the alert portal the reason for alerts in cases where the reason is known to the end-user. For example, if the alert was caused by mishandling, technical error or mistake at the pharmacy/wholesaler.

11.3.5 Non-e-verification warnings

The end-user's IT-system can display many different types of warnings in the processes when a 2D-code is scanned, for example warnings about the wrong item in the pharmacy's picking control or if the medicine cannot be identified in the end-user's own stock management system. These warnings do not apply to e-verification or e-VIS activities and are therefore not covered by these recommendations.

When developing IT-system and processes, it should be clear to the user that a warning originates from SMVS so that these can be easily distinguished from other warnings.

11.4 Definitions

SMVS	Swedish Medicines Verification System – the Swedish part of the European database for safety features on medicinal products for human use
EMVS	European Medicines Verification System. Covers the entire European e-verification system with all national databases and the EU central hub.
FMD	Falsified Medicines Directive – EU directive on safety features on medicinal products for human use that is partly implemented via the EU Regulation (2016/161) on safety features on medicinal products for human use.
e-VIS	e-Verification in Sweden develops and is responsible for the Swedish part (SMVS) of the European system that prevents falsified medicines from reaching patients via pharmacies or healthcare.
NMVS Alerts	e-VIS Alert management system for documentation and investigation of alerts from SMVS.
End-user	End-users of SMVS are pharmacies, hospital pharmacies, healthcare, and wholesalers. End-users are those who use SMVS to check the authenticity of the pack. The definition includes both local pharmacies and wholesalers, as well as central support functions within the end-user organisation.
Location	A pharmacy or wholesale business at its physical address where the control of pack is carried out against SMVS. If the same pharmacy license or wholesale license conducts business at different addresses, these should be treated as different locations in SMVS.
MAH	Marketing Authorisation Holder – the pharmaceutical company responsible for the product. In this document, the term MAH also includes the representative of the MAH. Parallel importers are also covered.
OBP function	On-Boarding Partner (OBP) the entity/organisation that, under MAH's responsibility, handles the upload of data in the European e-verification system (EMVS)
Unique identifier	The sequence of numbers consisting of the product code, serial number, batch number, and expiration date used to identify an individual pack. The unique identifier shall be printed on the pack in the form of a 2D-code.
2D-code	2D-codes are a two-dimensional symbol on the pharmaceutical pack in the GS1 Data Matrix format. The 2D-code contains of the unique identifier and means that the unique identifier can be machine read with a scanner. Please note that the unique identifier is never printed in a QR code.
Operation	A request or type of use of SMVS. In SMVS, the following operations on a pack can be done by an end-user: Verify pack Check if the pack is in the system and check the status of the pack. A pack can be verified any number of times.

	Supply pack Deactivate/mark a pack as delivered to the public, e.g. dispensed to a patient or prescribed to the patient in a hospital / healthcare facility. Verification always takes place at the same time. An already supplied or decommissioned pack cannot be supplied or decommissioned again. **Decommission pack** Deactivate the pack for a reason other than the above. For pharmacies in case of destruction or mark the pack as a sample. Wholesalers can decommission pack for several reasons. Verification always takes place at the same time. An already supplied or decommissioned pack cannot be supplied or decommissioned again. **Reactivate pack** To reactivate a pack, already decommissioned / supplied, back in active status.
Response	The message that is sent to the end-user after an operation is performed. A response is always sent when an operation is performed against SMVS to the end-user.
Alert	For some responses, SMVS also generates an alert. The alert is sent to the MAH via MAH's OBP function and to e-VIS. Each alert also has its own unique alert-ID.
Operation code (ID)	Is a number that identifies a specific response from SMVS.
Status	Specifies the status of a pack. An active pack is available to be decommissioned or supplied. See list of possible statuses for a pack below.

Status

Aktiv	Active	The pack is active in the system and can be decommissioned in EMVS.
Expedierad	Supplied	The pack has been handed out to the patient or for use in healthcare. Pack that has been decommissioned can be reactivated within 10 days in the same location. If a pack is opened and part of the pack is dispensed, for example during dose dispensing, the pack must be decommissioned when the first supply takes place from the pack.
Destruerad	Destroyed	The pack has been marked as destroyed and should not be available to be handed out to the patient. The pack cannot be reactivated.
Läkemedelsprov för myndighet	Sample	The pack is decommissioned as a sample for an authority and should not be available to be handed out to patients. Pack that has been decommissioned can be reactivated within 10 days in the same location.
Exporterad ut ur EU	Exported	The pack has been marked as exported outside the EU and cannot be handed over to patients within the EU/ESS. Pack that has been decommissioned can be reactivated within 10 days in the same location.
Läkemedelsprov	Free sample	The pack has been marked as a free sample for marketing purposes and should not be available to be handed out to patients. Pack that has been decommissioned can be reactivated within 10 days in the same location.
Låst	Locked	The pack has been locked in the system to prevent further distribution or delivery during the ongoing investigation. A locked pack can be reactivated at any time from the same location and can be permanently decommissioned as destroyed or stolen from any location.
Stulen	Stolen	The pack has been marked as stolen. The pack cannot be reactivated.

Utcheckad	Checked-out	The pack is used for parallel distribution or parallel import and should not be available to be handed out to the patient. Pack that has been decommissioned can be reactivated within 10 days in the same location.
Utgången i datum	Expired	The batch has passed its expiration date. Decommissioning occurs automatically when the expiration date in SMVS has passed.
Indragen	Recalled	The batch has been marked as recalled by MAH. The packs in the batch cannot be reactivated.
Återkallad	Withdrawn	The pharmaceutical product has been withdrawn, for example, when the medical authorisation of the medicine has been withdrawn. The pack of the product cannot be reactivated.