Translation of the Swedish Recommendations - for information purpose only

Communication and handling of alerts & warnings from the Swedish e-verification system (SMVS)

Recommendation from the Swedish Pharmacy Association and e-VIS

Updated October 2019

Sveriges Apoteksförening

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The recommendations are a basis for each organization in the supply chain to build their routines, instructions and educational materials from.

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Operations in SMVS for end users

Verify pack	Check that the pack can be found in the SMVS and check the status of the pack
Dispense pack	Decommission of a pack when it is dispensed to the public. A verification is made prior to dispense.
Decommission pack	Decommission of a pack for any reason other than ‘dispensing’, as destroyed or mark the package as a sample. A verification is made prior to decommission.
Reactivate pack	Reactive a pack that been decommission. Can only be carried out under certain conditions. A verification is made prior to reactivation.

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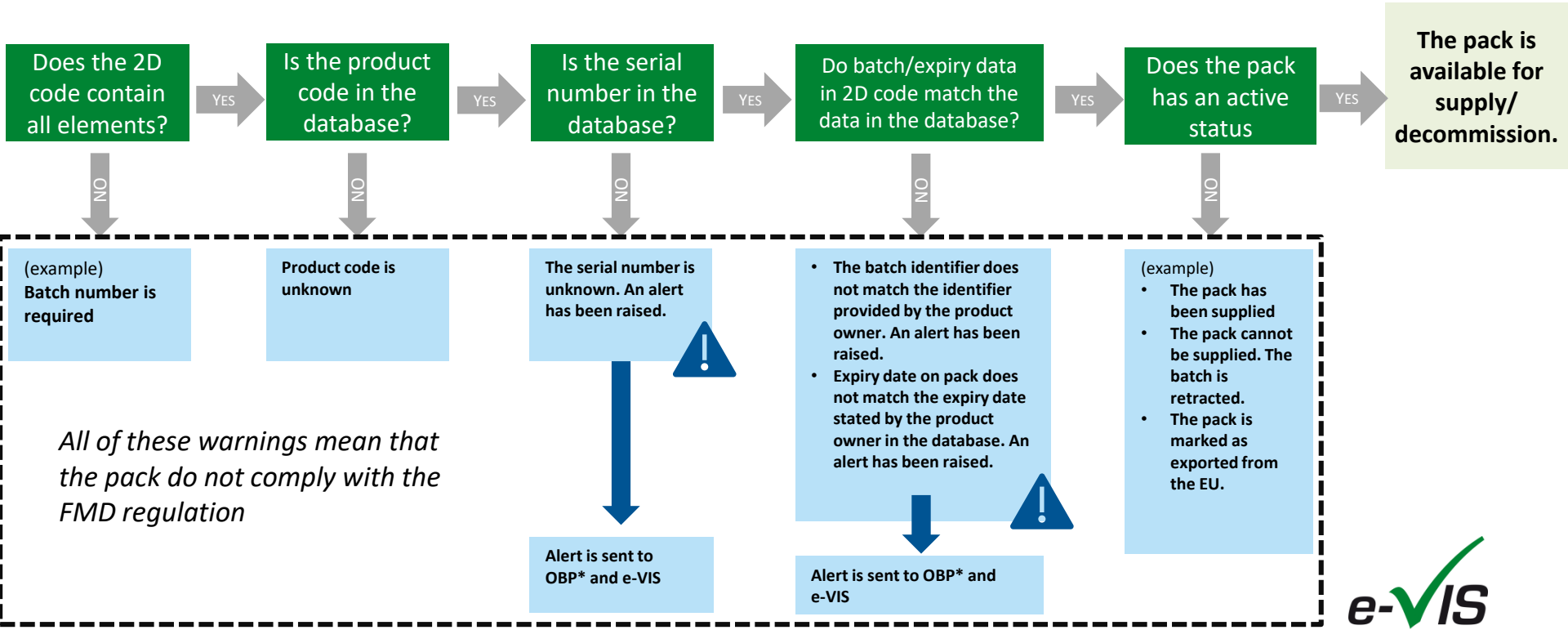
Verify pack in SMVS



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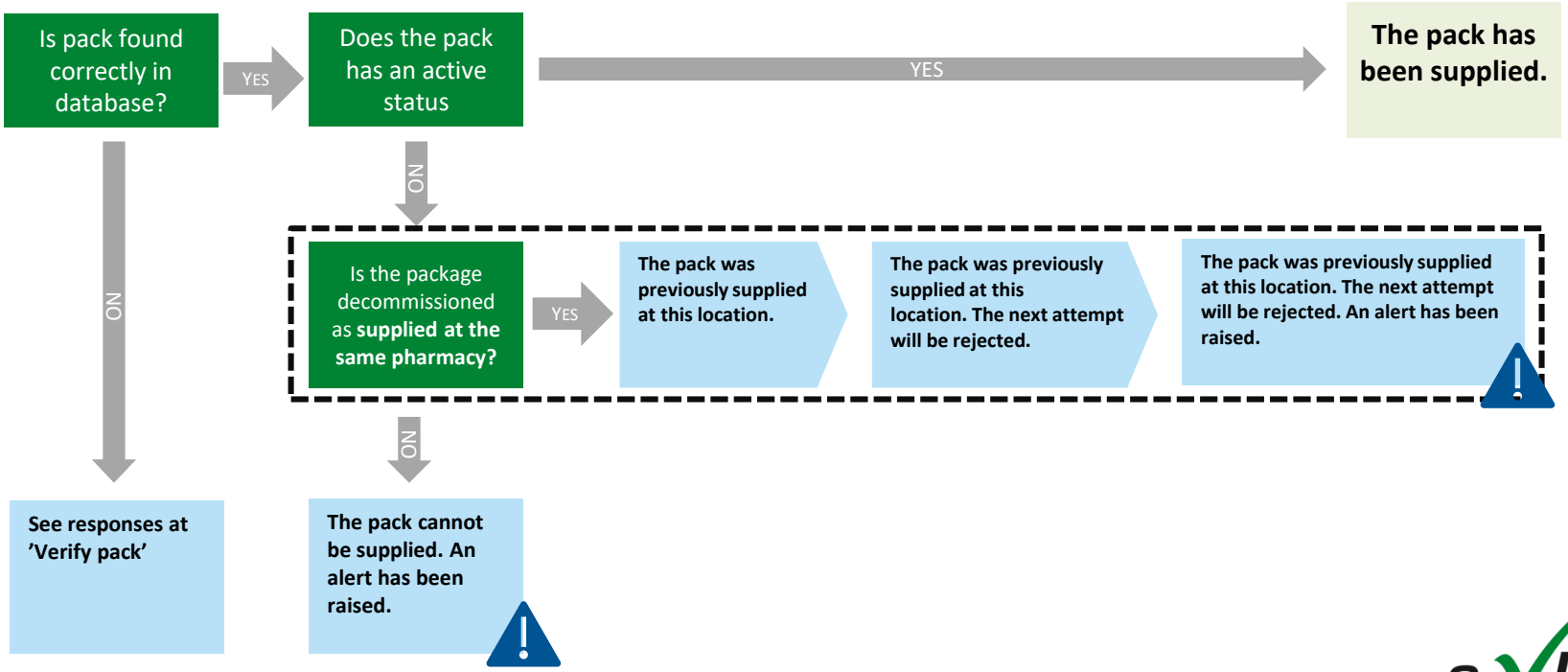
Supply pack in SMVS



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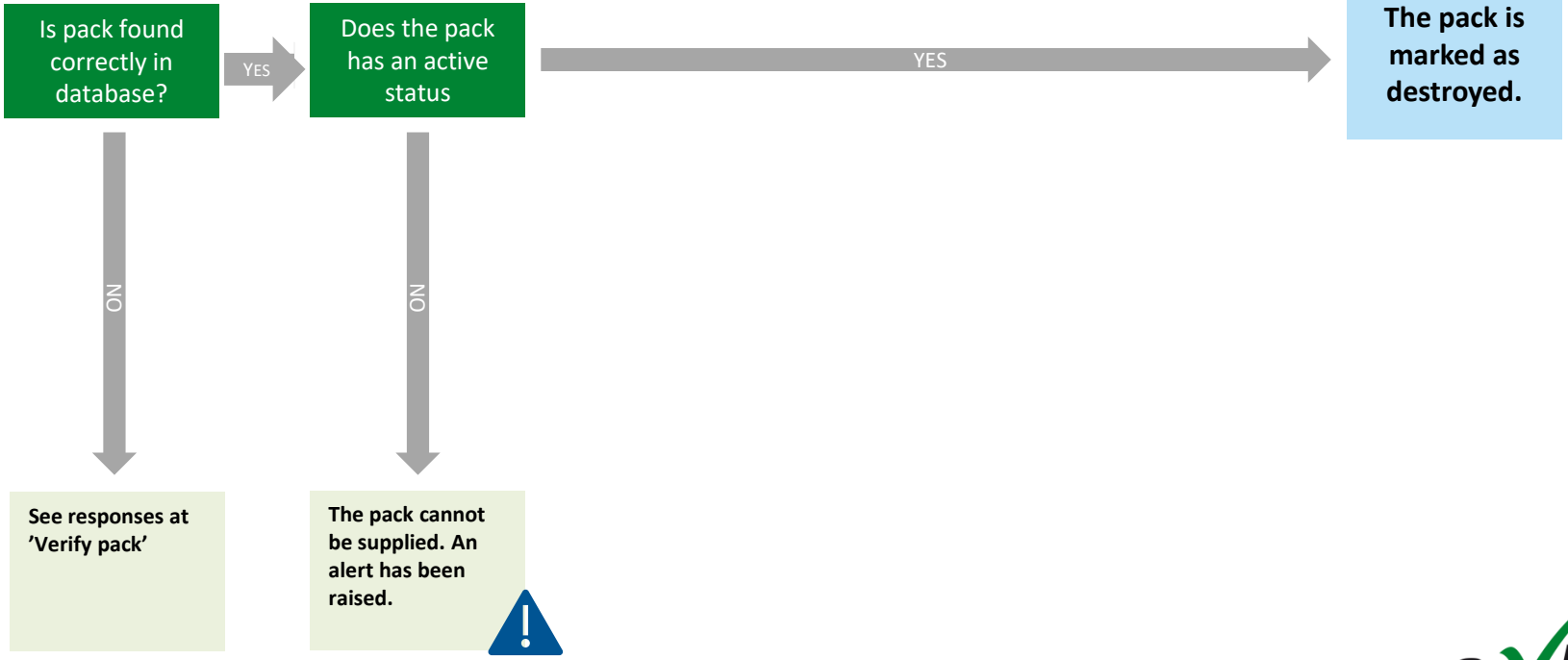
Decommission pack in SMVS



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Warnings and alerts

When verifying and changing status of a unique identity in SMVS, responses will be sent to the end-user's IT system. Different responses will be sent depending on which request is made to SMVS, the status of the pack and what status change the user asking the system to make.

- **Warnings**
  If a pack cannot be found in SMVS or if a status change cannot be made, a warning will be sent as response to the pharmacy.
- **Alerts**
  Some of the warnings also raises a so-called ALERT in the system. Each alert receives a unique alarm ID.

If an alert is raised:

- An ALERT ID is sent to the end user's system
- An alert message in the form of e-mail is sent to e-VIS
- The OBP* can access the alert directly via the system
- The Swedish MPA has access to the alerts via a reporting function in SMVS

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Responses from SMVS

SMVS always sends a response to the end user performing a transaction

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 raises alerts! 

The end user specifies how the response should be displayed and used in the end user's system.

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Responses from SMVS - some examples

Pharmacy verifies a pack	The product code cannot be found in the SMVS	**Warning:** **Product code unknown**
Pharmacy verifies a pack	Product code is found in SMVS, but the serial number cannot be found	**Warning:** **The serial number is unknown. An alert has been raised.**
Pharmacy verifies a pack	The 2D code is not complete, batchnumber not in the code	**Warning:** **A batch identifier is required**
Pharmacy verifies a pack	Pack can be found in the SMVS and the status of the pack is destroyed	Information: The pack is marked as destroyed
Pharmacy is requesting the system to deactivate a pack as supplied.	The pack is found in SMVS and the pack status is active.	Information: The pack has been supplied
Pharmacy is requesting the system to deactivate a pack as supplied.	The pack is found in SMVS and the pack status is destroyed.	**Warning:** **The pack cannot be supplied. An alert has been raised.**

When the pack has been found and its status has been returned, the verification has 'succeeded'. SMVS does not know what the expected answer is.

A pack that is not active will by all likelihood never be deactivated but will be removed from the supply flow directly upon verification

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The recommendations are designed to:

- Ensure that possible falsifications are investigated as quickly as possible so that falsified medicines do not enter the legal supply chain.
- Ensure that all pharmacies and wholesalers handle and communicate alerts in the same way.
- Ensure that local representatives in Sweden (pharmaceutical companies) are noticed rapidly about problems with packs on the Swedish market and so they act and feedback to relevant stakeholders around alerts.
- Avoid different interpretations of alerts that lead to uncertainties, extra administration and long time frames of investigations.
- Secure to avoid the risk of medicines shortages when FMD is implemented.
- Ensure that patients are not affected by long processes if pharmacies cannot meet their supply requirements.

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Content in a 2D code

Packs with a **complete** 2D code has the following elements in the code:

- Product Code
- Serial Number
- Batch Number
- Expiry Date

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Conditions from 9 February 2019 and onwards

- Packs with a complete 2D code must be uploaded in the e-verification system in order to be dispensed. This also applies to packs released to the market before 9 February - retrospective upload must take place.

- Packs with a complete 2D code that are not properly uploaded may be seen as incorrect after 9 February 2019.

- Packs that lack or do not have complete safety features (e.g a non-complete 2D code) will during 2019-2020 be considered as released before 9 February 2019 and therefore not covered by FMD

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Cont. Conditions from 9 February 2019 and onwards

- It is the responsibility of all stakeholders to weigh the risk of shortages and patient risks against their own interests and priorities.
- If a local representative do not communicate and do not take action on uploading of pack data, pharmacies may be in a situation where they don't have any packs to dispense and if there is no response from the local representative/MAH this can lead to the return of entire batches, which can lead to shortages.
- MAH/OBP* (global organizations of pharmaceutical companies) should work preventively to ensure that packages are uploaded in the EU Hub.
- Alerts and warnings due to user errors from the end users should be prevented by adapting procedures and processes to the new situation when the legislation comes into force.

*OBP – Onboarding Partner (manufacturer)

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Three categories of situations from which alert handling guidelines is designed

1. Warnings that generate alerts where the fault is solely due to errors from the end user.

2. Warnings indicating incorrect pack status - defects that cannot be corrected by the OBP.

3. Warnings that generate alerts that indicate data errors on packs - where the error possibly could be corrected by MAH/OBP.

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1. Warnings that generate alerts where the fault is solely due to errors from the end user.

There is no "error" on the packaging or problems with uploaded data.

- Mistakes when manually entering information from the 2D code

- Procedural error - the end user supply a pack that was previously supplied by the same end user or tries to decommission an already deactivated pack by mistake, for example while 'destroying' several packs.

- Potential errors in the end user's IT system, such as scanner errors because of mis-configurations.

2. Warnings indicating incorrect pack status - defects that cannot be corrected by the OBP.

The pack does not have the expected status. For example, in the situation of supplying a pack, the pack is not active and will not be able to be sold. This category contains packs with a high risk of falsifications.

The pack is already in an inactive status when it is to be supplied to the customer, for example:

- exported
- destroyed
- stolen
- supplied by another end users

We expect these cases to be very few.

3. Warnings that generate alerts that indicate data errors on packs - where the error possibly could be corrected by MAH/OBP.

The pack has data errors that may be possible to correct by MAH/OBP and the pack might be sellable after action from OBP by uploading missed/corrected data

- Serial number is missing
- Batch ID is not correct
- Expiration date is not correct
- The package was locked (under investigation).

Risk of many alerts during the first year when the system goes into operational phase. Since these errors could cause shortages that could end up affecting the patient, it is important that this particular category is handled with extra priority by all stakeholders.

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Core process for pharmacies/ wholesalers for handling packs that triggers alerts from the SMVS

Core process for pharmacies/wholesalers:

1. Check if the error is due to the pharmacy's/wholesaler's own handling of the pack.

2. Document the event in own quality system. Always document the alert ID if an ID has been created.

3. If error due to own handling/procedure (1) is excluded. Put pack in quarantine together with any alert ID.

4. Report the pack according to the agreed process through existing complaint reporting channels (eg web based service Reklameraläkemedel.se).
   Alert ID must be reported. If the alert ID is missing or not triggered, the serial number from the pack must be entered to the report. (If both alert ID and serial number are missing, investigation is impossible to complete.)
   Put alerts@e-vis.se on CC if you're not using the 'e-verification form' at Reklameraläkemedel.

   Please note that the process of reporting errors around e-verification differs from the ordinary complaint reporting process.

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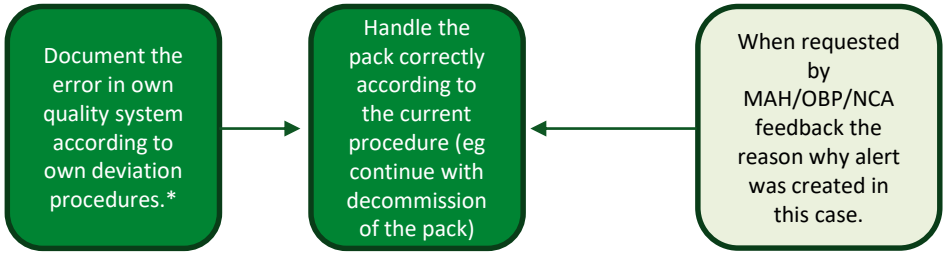
Warnings that generate alerts where the fault is solely due to errors from the end user.

E.g. pharmacy decommission a pack as destroyed twice



* It is important that the end user documents the alert ID in these cases as well. If the alert ID is not automatically stored in the pharmacy IT-system, it needs to be stored together with the deviation documentation.

MAH/OBP, NCA or e-VIS will in their communication refer to the event via alert ID.

In some cases when end users make a procedural error or an incorrect manual input, an alert may be triggered. If the handling error occurs on a pack that was aimed to be handed out to a patient (eg 'double dispense'), this **does not** mean that the package has become 'obsolete'. An alert is not a status but a signal to act on. When this signal is found to be a procedural error the pack can still be supplied to patient.

At the moment, the recommendations are designed in such a way that the end user does not actively communicate to MAH/OBP about alerts due to handling errors. The focus when the system is new should be to investigate the alerts that **do not** depend on the end user. End users still need to do their own investigations on procedural errors. It is important that pharmacies and wholesalers build their routines and set up their systems so that erroneous handling can be avoided and detected before causing alerts.

Please note! Warnings not causing alerts from SMVS due to procedural errors may also need to be documented according to the deviation reporting routine

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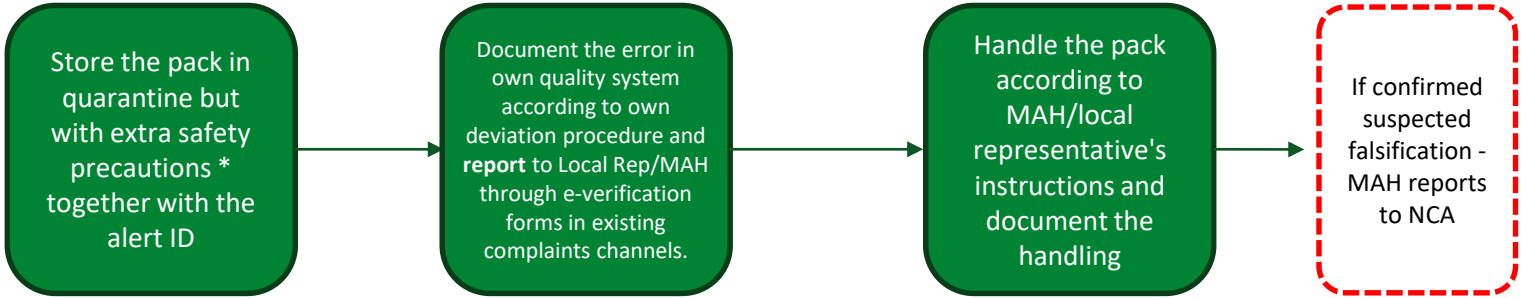
Warnings indicating incorrect pack status - defects that cannot be corrected by the OBP.

E.g:

- pack at a pharmacy that is decommissoned as ’exported out of EU’
- wholesaler receives packs in return logistics that is already decommissioned



* Extra safety precautions: possible falsification and pack could be a proof. For example, put the pack in a plastic bag and mark the bag with alert ID.

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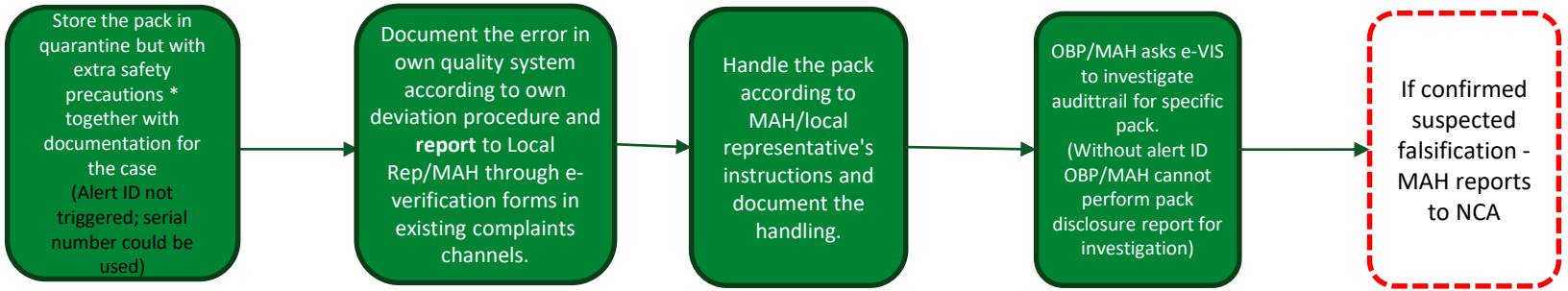
Alternative procedure if Alert ID is not triggered:

Warnings indicating incorrect pack status - defects that cannot be corrected by the OBP.

When performing ordinary pack control at the pharmacy, a verification is made and the pack turns out to be in the status ‘exported out of EU’. No alert is triggered when just verifying.



* Extra safety precautions: possible falsification and pack could be a proof.
For example, put the pack in a plastic bag and mark the bag with documentation.

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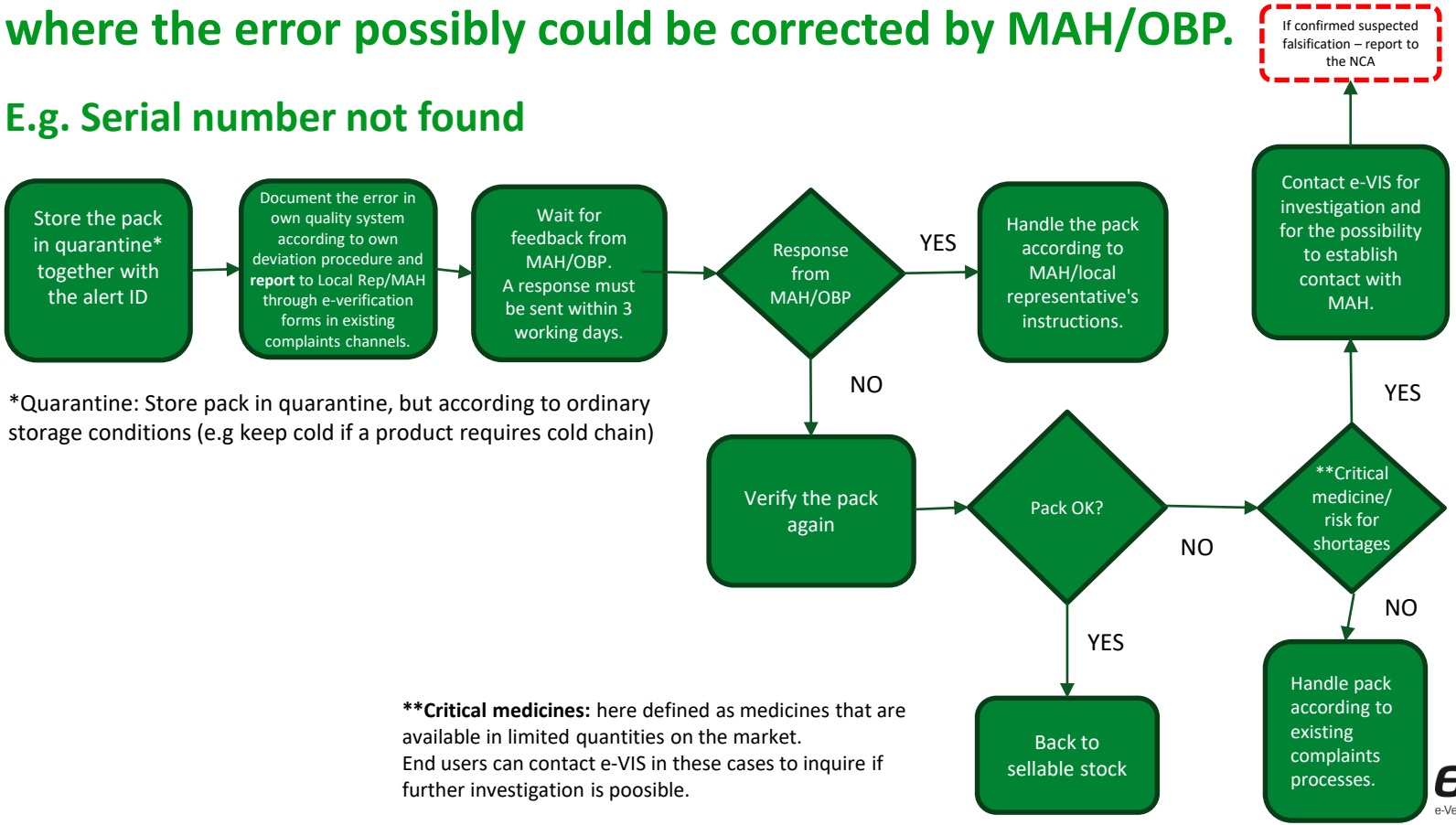
Warnings that generate alerts that indicate data errors on packs – where the error possibly could be corrected by MAH/OBP.

E.g. Serial number not found



*Quarantine: Store pack in quarantine, but according to ordinary storage conditions (e.g keep cold if a product requires cold chain)

****Critical medicines:** here defined as medicines that are available in limited quantities on the market.
End users can contact e-VIS in these cases to inquire if further investigation is poosible.

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Core process for local representative for handling packs that triggers alerts from the SMVS

Core process for local representative/MAH:

1. Local representative receives a report around an alert or a problem for e-verification through the existing complaints channels. (e.g. Reklameraläkemedel)

2. Start investigation

3. Respond as soon as possible but no later than 3 working days to the end user that reported the alert or the problem.
   If answer cannot be given directly, please indicate when answer can be expected.
   Respond with the Alert ID.
   Copy to alerts@e-vis.se

   Please note! An automatic response to the message beeing received is not counted as feedback.

4. If problems with a batch – communicate to wholesaler and further on to the pharmacies.
   Copy to alerts@e-vis.se

5. The error is corrected. Feedback to those affected.
   Copy to alerts@e-vis.se

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Communication: Alerts where the error possibly could be corrected by MAH/OBP

1. When a pharmacy/wholesaler discovers an error that may indicate that one or more packs are not correctly uploaded into the SMVS, the end user must communicate this via the agreed reporting process to the local representative in Sweden as soon as possible.
2. When a local representative in Sweden becomes aware of that one or several packs are not uploaded correctly in the system (via the agreed reporting process or through the OBP), the local representative shall inform the supply chain as soon as possible. The local representative reports to the designated wholesaler and further on to all pharmacies. Copy to alerts@e-vis.se
3. When an end user reported an error a response should be sent from the local representative – this should be made as soon as possible but no later than 3 working days*.
4. The information should, if possible, indicate:
   - which batches are affected by the problem
   - if the error can be corrected and when it is expected to be corrected
   - any other business with regards to the error that end users can benefit from
5. If the error can be corrected, this should be done as soon as possible, but at the latest within one week of the MAH/local representative becoming aware of the error.
6. Pharmacies/wholesalers can do a test verification of the packs they have in stock if possible.
7. Pharmacies/wholesalers should place all packs that are affected by the problem in quarantine while awaiting solution.

*Please note that 3 days for communication is a target number for MAH to be able to provide specific information on when errors can be corrected. However, the local representative should always feedback about timelines and if the target of three days can be met or not.

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Exceptions: other communication routes might be needed to contact local representatives and MAH

- **EU packs**:
  When verifying so called ‘EU packs’ obtained by a wholesaler where the pharmaceutical company has no operations in Sweden and questions occur regarding status in EMVS.
  Contact purchasing wholesaler.
  Please note, wholesalers do not have direct contact with these pharmaceutical companies in many cases so some lead time might be expected.

- **The pharmaceutical company cannot be reached**:
  If an end user cannot reach the MAH through the complaints channels or via information on Fass.se (e.g. if the agent for the pharmaceutical company is not present in Sweden).
  Contact e-VIS for help finding contact information.

- **Emergency situations where Reklameläkemedel is not a suitable communication channel**:
  In cases where a pack alerts or has an incorrect status and it is a **very acute situation** (for example in a hospital situation prior to surgery).
  In this case, it may be necessary to **contact the pharmaceutical company by telephone**.
  Contact information for most pharmaceutical companies can be found on Fass.se

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Handling of miscellaneous errors related to Falsified Medicines Directive

Below are examples of errors where packs should be handled through the **existing complaint reporting process**. These errors are not attributed to the e-verification database itself.

- The Anti Tampering Device (ATD) on the pack is damaged/broken
- The 2D code and the human readable information on the pack is damaged/unreadable
- The quality of the 2D code is too low so scanning is not possible (should probably affect a whole batch)
- The pack has deviations (other than related to FMD) that could indicate that the pack is falsified

Comments:

- If the pack has a 2D code and can be found in the SMVS but lacks ATD. This pack is expected to be released prior to February 9, 2019.
  Please note that this thesis must be revised when the system has been up and running a few years.

- If individual packs has 2D codes that are damaged but the human readable information is OK, the pack can be verified manually and the pack can be handed out to the patient. (Presumed there is no other indications of falsification)

However, feedback to local representatives /MAH on the issues above are valuable for preventing problems in the future.

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Please note that these guidelines for handling of alerts and errors will be updated as the experience of the system increases and as the volume of packs not covered by the legislation decreases.

On the e-VIS website https://e-vis.se/ current version will be published.

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