

Version 2.0
17.12.2018

Finnish Medicines Verification System

Process Descriptions

Introduction

The medicines verification system is based on the requirements of EU legislation. The aim is to prevent the use of falsified medicines in the legal supply chain for medicinal products.

This document describes the processes for using the medicines verification system. The aim is that the activities related to medicines verification would be merged as far as possible with existing practices.

The supply chain stakeholders have their own internal policies that need to be updated in regards to medicines verification. The purpose of this document is to describe the activities in the verification system and to present solutions to problems. However, each user of the verification system will have to resolve the final process for their part.

This document has been drafted in co-operation with stakeholders in the pharmaceutical supply chain. The document will be updated as necessary.

Legislation

Falsified Medicines Directive (2011/62/EU)

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf (EN)

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_fi.pdf (FI)

Commission Delegated Regulation (EU) 2016/161

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf (EN)

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_fi.pdf (FI)

Commission Questions & Answers - document

https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_en.pdf

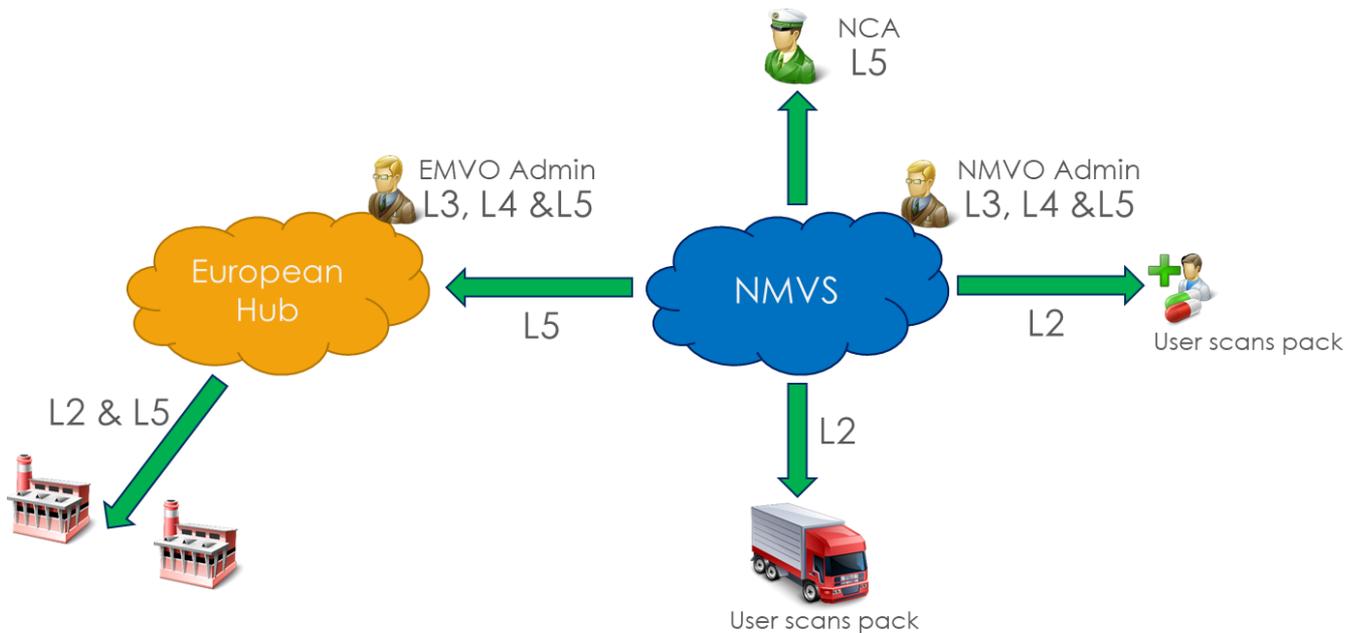
Abbreviations

EMVO	European Medicines Verification Organisation
EMVS	European Medicines Verification System
EU Hub	European central database
Fimea	Finnish Medicines Agency
FiMVO	Finnish Medicines Verification Organisation
FiMVS	Finnish Medicines Verification System
MAH	Marketing Authorisation Holder
OBP	On-boarding partner; the body representing the pharmaceutical company in the European central database, the Hub
PC	Product Code
SN	Serial Number

Basic principles for handling system deviations

Different levels of deviations may occur in the FiMVS system depending on the disruption/error situation.

- L1: A deviation that the system repairs itself. This deviation does not appear to the user in any way.
- L2: The user receives notice of the deviation.
- L3: The System Administrator (EMVO or FiMVO) receives notice of the deviation.
- L4: More than one system administrator receives notice of deviation.
- L5: In addition to the user and system administrators, the OBP and the local competent authority are also notified of the deviation. This may be a falsified pack. L5 level deviations are referred to below as alerts.



Level 5 (L5) alert

L5 alerts contain the following information:

- Time stamp
- Alert ID
- Product Code
- Serial Number
- Return code NMVS
- Return code Description NMVS
- Return code Hub
- Client ID
- User ID

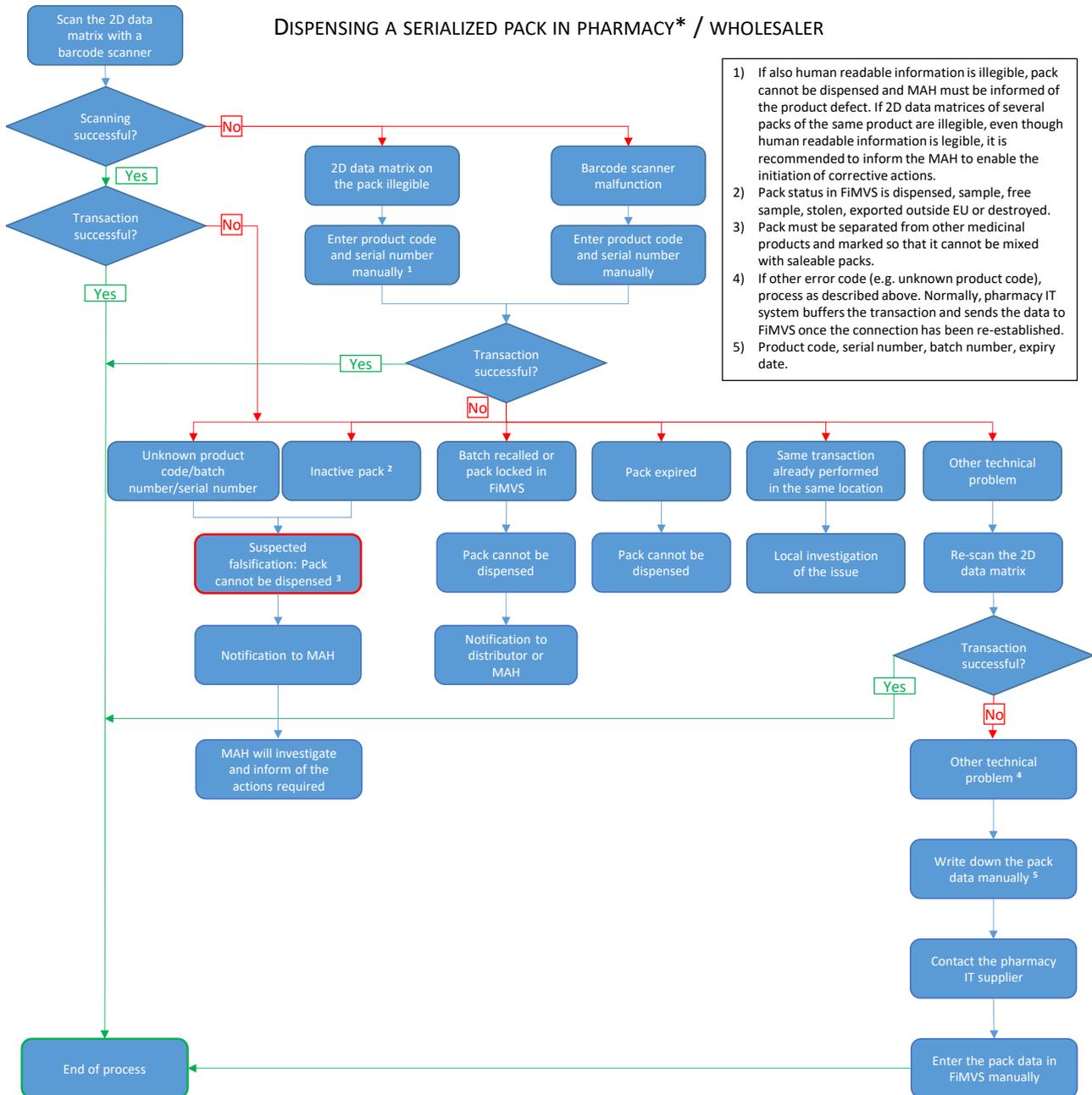
When FiMVO/EMVO/OBP receives an L5 alert, it can download a pack disclosure report, with which it is possible to begin investigating the alert without the pack being in the physical possession of FiMVO/EMVO/OBP.

N.B. If the product code is unknown, the system cannot alert the OBP. In these cases, the alert is sent only to FiMVO, EMVO and Fimea.

The reason for an L5 alert may be a potential falsified medicine.

On the other hand, an L5 alert may arise because the information on the product, batch, or individual pack has not been entered into the FiMVS system. Such alerts in pharmacies can be prevented, for example, by the wholesaler verifying one pack from each batch upon receipt.

1. Dispensing a serialized pack in pharmacy* / wholesaler



* Pharmacy/ hospital pharmacy/ dispensary

- The integrity of the anti-tampering device (ATD) must always be checked before dispensing a pack.
- If the ATD is damaged, this is a product defect. This triggers a normal product defect process.
- N.B. It is possible that there will be serialized packs without ATDs which have been released for sale or distribution before 9.2.2019. In these cases, the pack can be dispensed to the patient despite not having an ATD.
- The status of a pack before dispensing and/or after the execution of a transaction may be verified by using the *G110 Verify single pack* function.

Exceptions in the dispense process

1.1. The scanner is unable to read the 2D data matrix

- a. If the scanner does not work (technical fault), the pack can be dispensed by entering its product code (PC) and serial number (SN) manually using the *G122 Dispense single pack manual entry* function.
- b. In the same way, if the 2D data matrix is unreadable the pack can be dispensed by entering its product code (PC) and serial number (SN) manually using the *G122 Dispense single pack manual entry* function. N.B. If 2D data matrices on multiple packs from the same batch are found to be unreadable it is recommended to inform the Marketing Authorisation Holder (MAH) to enable the initiation of corrective actions.
- c. If the human readable information is illegible the pack cannot be dispensed and the MAH must be informed of the product defect.

1.2. Unknown product code, batch number or serial number

- a. If the FiMVS system notifies that the product code, batch number or serial number is unknown the pack cannot be dispensed to the patient. N.B. The system also alerts if the expiry date encoded in the 2D data matrix differs from the expiry date uploaded into the system or if the serial number does not match the batch number. In both cases the pack cannot be dispensed to the patient.
- b. In the case of an alert, information is sent automatically from FiMVS to FiMVO and Fimea, and from the EU Hub to the OBP. N.B. If the product code is unknown, the system cannot alert the OBP. The OBP is only notified if the product code is found in the system.
- c. Packs which are not found in the FiMVS system must be separated from other medicinal products and clearly marked that they cannot be dispensed. Suspected falsified medicines should be reported to the MAH either through the wholesaler's product defect notification system or directly by email or phone. Fimea receives information directly from FiMVS.
- d. The MAH of the product requests the distributor, if necessary, to place a sales ban on the batch during the investigation. Together with the OBP, the MAH will investigate the suspected falsification. The MAH should pay particular attention to keeping pharmacies, wholesalers and Fimea up to date with the situation so they are always as fully aware of the situation as possible and can, where necessary, inform their customers and ensure the continuity of the medical treatment and

patient safety. The MAH should plan the information measures and channels in advance.

- e. If the reason for an unknown product code or serial number is that the OBP has not uploaded pack or batch information to the FiMVS via the EU Hub or the uploading of the data failed, the information must be submitted to the system without delay and the MAH should inform the supply chain operators about the situation and when the information is available on the system. N.B. Batch data must be uploaded even if the batch has been released for sale before 9.2.2019!
- f. If the investigation confirms that this is a genuine falsification, the process for class 1 product defects should be followed. The MAH holds responsibility for the planning and implementation of the measures. Fimea will supervise and ensure that the measures are adequate and appropriate.

1.3. Inactive pack

- a. If the FiMVS system notifies that the pack is inactive, i.e. marked as dispensed, a medicinal sample, a free medicinal sample, stolen, exported from the EU or destroyed, the pack may not be dispensed to the customer.
- b. Information of the alert is sent automatically from FiMVS to FiMVO, Fimea and from the EU Hub to the OBP.
- c. Packs which are marked inactive in FiMVS must be separated from other medicinal products and clearly marked that they cannot be dispensed. Suspected falsified medicines should be reported to the MAH either through the wholesaler's product defect notification system or directly by email or phone. Fimea receives information directly from FiMVS.
- d. The MAH of the product requests the distributor, if necessary, to place a sales ban on the batch during the investigation. Together with the OBP, the MAH will investigate the suspected falsification. The MAH should pay particular attention to keeping pharmacies, wholesalers and Fimea up to date with the situation so they are always as fully aware of the situation as possible and can, where necessary, inform their customers and ensure the continuity of the medical treatment and patient safety. The MAH should plan the information measures and channels in advance.
- e. If the investigation confirms that this is a genuine falsification, the process for class 1 product defects should be followed . The MAH holds responsibility for the planning and implementation of the measures. Fimea will supervise and ensure that the measures are adequate and appropriate.

1.4. Batch recalled or pack locked in FiMVS

- a. If the FiMVS system notifies that a batch has been recalled from the supply chain or the pack is locked, the pack cannot be dispensed.
- b. A pack which is marked as recalled or locked must be separated from other medicinal products and clearly marked that it cannot be dispensed. The supplier or MAH must be contacted for additional information and instructions.
- c. If the MAH has duly informed the supply chain operators of the withdrawal, this is a deviation from the pharmacy/wholesaler processes, which must be investigated in accordance with the pharmacy/wholesaler standard operating procedures.

1.5. Pack has been expired

- a. If the FiMVS system notifies that the expiry date of the pack has been exceeded, the pack cannot be dispensed to the patient.

- b. The expired pack must be disposed of appropriately, and deviations handled according to pharmacy/wholesaler standard operating procedures.

1.6. The same transaction already performed earlier in the same location

- a. If a pharmacy/wholesaler tries to dispense a pack which has already been dispensed in the same location, the FiMVS system will notify this, but will not create an alert.
- b. The pharmacy/wholesaler must investigate the cause of this error, (e.g. the pack has been opened and part of the contents dispensed earlier) and try to develop their process to avoid facing a similar situation in the future.

1.7. Other technical problem

- a. If the FiMVS system returns a technical error (e.g. *General exception occurred*), the pack status in the system may be confirmed by using the *G110 Verify single pack* transaction.
- b. If the pack status in the system has not changed and it is still active, the transaction can be performed again.
- c. If the system continues to return an error code, the pharmacy can dispense the pack, but they must write down the pack information (product code, serial number, batch number, expiry date).
- d. The pharmacy must contact their IT supplier to determine the reason for the error.
- e. Once the error has been fixed, the pack must be registered as dispensed in the FiMVS system by using the *G122 Dispense single pack manual entry* transaction and entering the product code and serial code.

2. Decommissioning a serialized pack as a medicinal sample

- If a pack is provided as a medicinal sample, for example to Fimea or to the MAH, it should be decommissioned from the FiMVS system using *G150 Sample single pack* or *G155 Bulk sample packs* transaction.
- N.B. *G155 Bulk sample packs* transaction can only be performed by a wholesaler.
- The process and possible exceptions are the same as in section 1 **Dispensing a serialized pack in pharmacy / wholesaler**

3. Decommissioning a serialized pack as a free medicinal sample

- If a pack is distributed from a wholesaler as a free medicinal sample for further distribution to a healthcare professional authorized to supply or prescribe medicinal products, it must be decommissioned from the FiMVS system using *G160 Free sample single pack* or *G165 Bulk free sample packs* transaction.
- N.B. This transaction can only be performed by a wholesaler.
- The process and possible exceptions are the same as in section 1 **Dispensing a serialized pack in pharmacy / wholesaler**

4. Decommissioning a serialized pack to be exported to outside the EU

- If a pack is exported from a wholesaler to outside the EU, it must be decommissioned from the FiMVS system using *G140 Export single pack* or *G145 Bulk export packs* transaction.
- N.B. This transaction can only be performed by a wholesaler or an OBP via the EU Hub.
- The process and possible exceptions are the same as in section 1 **Dispensing a serialized pack in pharmacy / wholesaler**

5. Locking a serialized pack

- Packs can be locked in the FiMVS system by using *G170 Lock single pack* or *G175 Bulk lock packs* transaction.
- N.B. Locking prevents any changes in the status of the pack in the FiMVS system and should only be used when it is justified to ensure patient safety. Locking is generally performed by the OBP through the EU Hub. This action must be notified to the supply chain operators and Fimea without delay, preferably before the locking is performed. It should also be noted that locking a pack does not replace, for example, putting a batch on a sales ban by the distributor, nor does it remove the responsibility to inform the appropriate stakeholders. Locking can be considered as a supplementary backup measure mainly for class 1 product defects.
- N.B. This transaction can only be performed by a wholesaler or an OBP via the EU Hub.
- The process and possible exceptions are the same as in section 1 **Dispensing a serialized pack in pharmacy / wholesaler**.

6. Destroying a serialized pack

- If a pack which is active in the FiMVS system is destroyed, it must be decommissioned from the FiMVS system using *G130 Destroy single pack* or *G135 Bulk destroy packs* transaction.
- N.B. *G135 Bulk destroy packs* transaction can only be performed by a wholesaler.
- The process and possible exceptions are the same as in section 1 **Dispensing a serialized pack in pharmacy / wholesaler**.
- If the pack is damaged in such a way that the 2D data matrix and human readable information is unreadable, and is otherwise unavailable, the pack will remain active in the FiMVS system and will only be decommissioned when the expiry date of the batch is reached.

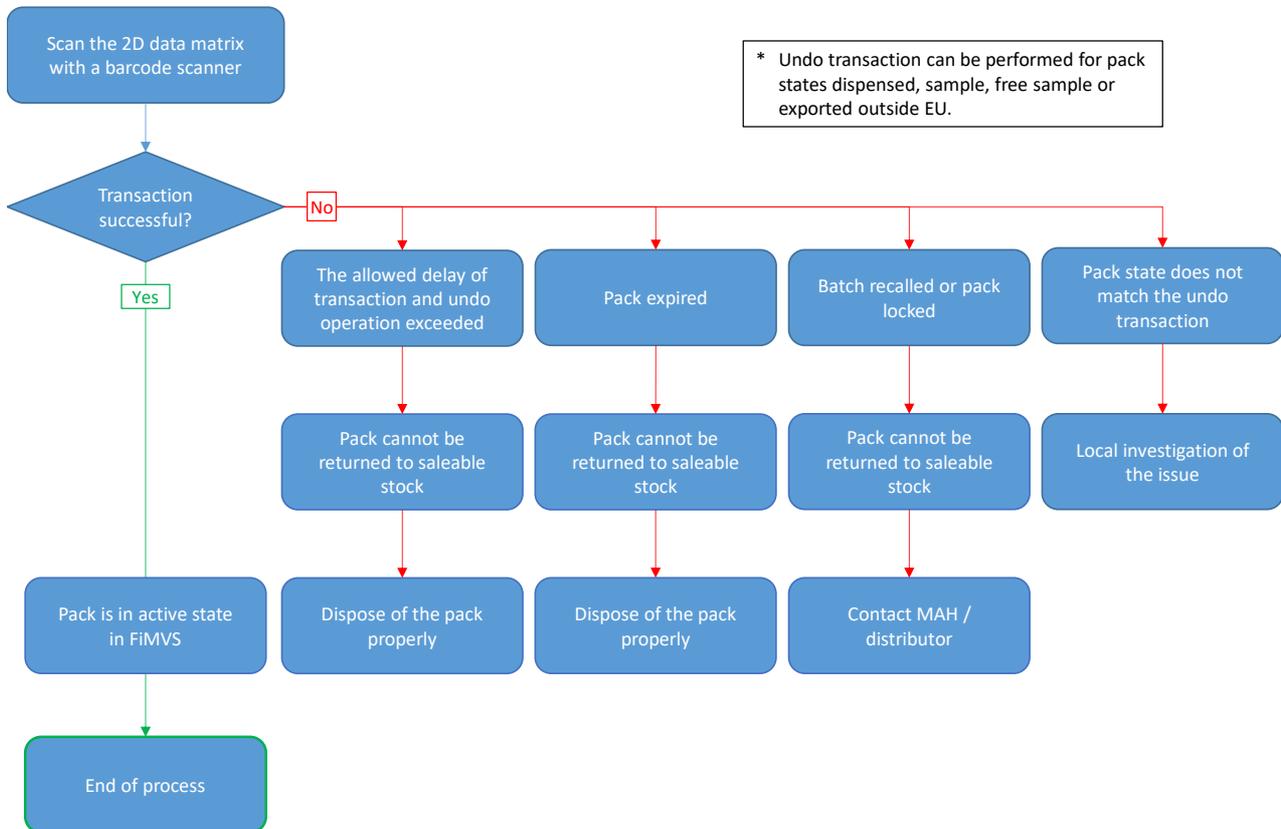
- N.B. If the pack is already inactive in the FiMVS system or has expired, it no longer can or needs to be decommissioned.

7. Recording a serialised pack as stolen

- If the pack is stolen and its unique identifier is available, it must be removed from the FiMVS system using *G180 Stolen single pack* or *G185 Bulk stolen packs* transaction.
- The process and possible exceptions are the same as in section **1 Dispensing a serialized pack in pharmacy / wholesaler**.
- If the unique identifier information of the stolen pack is unavailable, it will remain active in the FiMVS system and will only be decommissioned when the expiry date of the batch is reached.
- N.B. This transaction can only be performed by a wholesaler or an OBP via the EU Hub.

8. Undo transactions in FiMVS

UNDO TRANSACTIONS IN FiMVS*



- If a pack is registered in the FiMVS system as dispensed, a medicinal sample, a free medicinal sample or exported outside the EU, but has always been in possession of the pharmacy/hospital pharmacy/dispensary/wholesaler which performed the original transaction, the same actor may undo the transaction within 10 days.
- In this case the pack can be returned to the sales stock.

Exceptions in the undo transaction processes

8.1 The allowed delay of the transaction and undo operation has been exceeded

- If more than 10 days (240 hours) has passed since the original transaction (dispense, medicinal sample, free medicinal sample, export outside the EU) was performed, the pack can no longer be returned to the active state in the FiMVS system. The only exception is locking the pack which has no time limit for undo transaction.
- N.B. Packs registered as stolen or destroyed cannot be returned to the active state in the FiMVS system.

8.2 Pack has been expired

- If the shelf life of the pack has expired after the original transaction was performed but before the undo transaction, the pack can no longer be returned to the active state in the FiMVS system. The pack should be disposed of properly.

8.3 The pack state does not match the undo transaction

- a. If a pack is active in the FiMVS system or the undo transaction does not match the inactive state of the pack, the system indicates that the pack status does not match the undo transaction. In this case it is necessary to locally investigate and identify the reason for the error message (mix-up of packs, use of an incorrect undo transaction).

8.4 Undo successful: Batch recalled or pack locked

- a. N.B. Even if the batch has been recalled or the pack has been locked after performing the original transaction, the transaction can be undone. However, in these cases the pack cannot be dispensed because the batch has been recalled or the pack has been locked. The pharmacy/hospital pharmacy/dispensary/wholesaler must contact the distributor or the MAH to clarify the situation and receive instructions.

9. Other possible exceptions

- 9.1. The connection between the pharmacy IT system and the FiMVS system is lost, but the pharmacy/hospital pharmacy/dispensary/wholesaler IT system works**
- a. If the connection to the FiMVS system is lost, the pharmacy/hospital pharmacy/dispensary/wholesaler IT system buffers the decommission transaction. A short connection interruption will thus not prevent the dispensing of a pack.
 - b. When the connection is re-established the pharmacy/hospital pharmacy/dispensary/wholesaler IT system retrospectively sends the data from the buffer to the FiMVS system.
 - c. The process and possible exceptions are the same as in section **1 Dispensing a serialized pack in pharmacy / wholesaler**.
 - d. As the pack that has possibly caused the alert has already been dispensed to the patient, the situation must be assessed to consider if the contact details of the customer should be sought for and if the customer should be contacted. Fimea should be informed before the customer is contacted.
 - e. If the connection interruption is long and/or repetitive, the pharmacy/hospital pharmacy/dispensary/wholesaler should contact their own IT supplier to clarify if the reason could be a software error, hardware failure or a technical failure in the connection.
- 9.2. Other technical fault, the pharmacy IT system is not able to connect to the FiMVS system**
- a. If the pharmacy/hospital pharmacy/dispensary/wholesaler IT system is not able to connect to the FiMVS system, the pharmacy/hospital pharmacy/dispensary/wholesaler IT system buffers the decommission transaction.
 - b. The pharmacy/hospital pharmacy/dispensary/wholesaler must contact their IT supplier who will identify the reason for the problem together with IT supplier of FiMVS.
 - c. When the error has been fixed, the pharmacy/hospital pharmacy/dispensary/wholesaler IT system sends the data in the buffer to the FiMVS system.
 - d. The process and possible exceptions are the same as in section **1 Dispensing a serialized pack in pharmacy / wholesaler** .
 - e. As the pack that has possibly caused the alert has already been dispensed to the patient, the situation must be assessed to consider if the contact details of the customer should be sought for and if the customer should be contacted. Fimea should be informed before the customer is contacted.

9.3. Use of the web-based graphical user interface (Web GUI)

- a. In some exceptional situations, the pharmacy/hospital pharmacy/dispensary/wholesaler may perform transactions in FiMVS using a web-based GUI.
- b. Use of Web GUI requires a working network connection, a valid certificate installed in the browser, as well as a user ID and password for logging in.
- c. All the same transactions that can be executed using the pharmacy/hospital pharmacy/dispensary/wholesaler IT system are available. N.B. Bulk functions (wholesalers) cannot be performed with a web-based user interface.
- d. A scanner cannot be used with the web-based system, all information must be entered manually.
- e. N.B. In situations where neither the pharmacy IT system nor the web based user interface can be used and the patient needs the serialized medicinal product to ensure an uninterrupted medical treatment, the human readable information (product code, serial number, batch number, expiry date) must be recorded manually.
- f. When the FiMVS system is again operational the pack must be registered as dispensed in the FiMVS system by using *G122 Dispense single pack manual entry* transaction and entering the product code and serial number.

9.4. General or wide-ranging and/or long-lasting EMVS or FiMVS system malfunctions

- a. The processes for any general or wide-ranging and/or long-term EMVS or FiMVS system disturbances are described in a separate document.