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Revision History

Version	*Date*	*Reason for changes*	*Description of changes made*
1.0	19-Nov-2023	Initial document	In scope of this working instruction are users connected to the medicines verification system via the temporary SOAP API.

Table of Contents

1. Purpose

The purpose of this document is to describe the processes and procedures for handling alerts caused by the medicines verification system from the perspective of different user groups. The document can be used to further develop users' IT systems so that the user can quickly and easily see the content of the verification inquiry, the response from the FiMVS system, and can also distinguish whether it is an error message or an alert.

In scope of this working instruction are users connected to the medicines verification system via the temporary SOAP API. This temporary SOAP API will be maintained until 31-Oct-2024 by when all users must start using the REST API.

The medicines verification system is based on the requirements of EU legislation (Falsified Medicines Directive (2011/62/EU) and the Commission Delegated Regulation (EU) 2016/161). The aim is to prevent falsified medicines entering the legal supply chain for medicinal products and to improve safety.

The medicines verification system applies to almost all prescription medicines. They are equipped with 2D codes that include the unique identifiers for the packs. When dispensing a serialized medicine, the information on the pack is compared to the data in the medicines verification system database. If the information is consistent, we can be assured this is not a falsification. In some cases, however, the pack may cause an alert.

2. Scope

The scope of this document includes the activities in the medicines verification system and the processes and procedures for handling alerts caused by the medicines verification system. However, each user of the verification system will have to resolve the final process for their part.

Medicines verification system alerts must **always** be investigated before the pack is dispensed. If the alert is caused by a false alert and/or if falsification is not suspected, the pack can be dispensed to the customer. N.B. The pack should not be returned to the wholesaler before the cause of the alert is resolved and/or return has been agreed with the marketing authorization holder.

This document has been drafted in co-operation with stakeholders in the pharmaceutical supply chain. The document will be updated as necessary, possible suggestions can be sent to FiMVO at nmvs@fimvo.fi

3. Definitions

Term/Acronym	Definition
EMVO	European Medicines Verification Organisation
EMVS	European Medicines Verification System
EU Hub	European Hub
Fimea	Finnish Medicines Agency
FiMVO	Finnish Medicines Verification Organisation
FiMVS	Finnish Medicines Verification System
GTIN	Global Trade Item Number
IMT	Inter Market Transaction
MAH	Marketing Authorisation Holder
NMVS	National Medicines Verification System
OBP	On-Boarding Partner
PC	Product Code
SN	Serial Number

4. Alerts caused by the Medicines Verification System

Depending on the malfunction / error situation, different levels of deviations can occur in the FiMVS system. The distribution of deviations in these different levels L1 to L5 (described in more detail below) is based on a general definition of the architecture of the EU medicines verification system. From a technical point of view, the FiMVS system always reverts the actual return / alert code in deviations, not the level. NOTE! The description provided by the end user software may differ from the description provided by FiMVS. Users are advised to consult their IT-supplier with regards to this aspect.

- L1: A deviation that the system repairs itself. This deviation is not visible to the user in any way.
- L2: The user receives notice of the deviation.
- L3: In addition to the user the System Administrator (EMVO or FiMVO) receives notice of the deviation.
- L4: In addition to the user more than one system administrator (EMVO or FiMVO) receives notice of deviation.
- **L5: In addition to the user and system administrators, the OBP is also notified of the deviation. This may be a falsified pack. L5 deviations are alerts and each and every alert must be investigated before the pack is dispensed to the patient. If the alert is caused by a false alert and/or if falsification is not suspected, the pack can be dispensed to the customer. N.B. The pack should not be returned to the wholesaler before the reason for the alert is resolved and/or return has been agreed with the marketing authorization holder. All L5 alerts are described in more detail in the table below and following paragraphs.**

All L5 level alerts are described in more detail in the following table:

Alert message	Explanation	Alert code (FiMVS)	Alert code (EU Hub)	Guidelines for investigating the alert
Failed to find a batch for the given data	The batch ID used for the transaction does not exist in the system for this product number. The product code used for the transaction exists in the system.	NMVS_FE_LOT_03	#A2	First check if reading the 2D code was successful. Firstly, contact the MAH, see chapter 6.2
Expiry date does not match the date held in the NMVS	The expiry date used for the transaction does not match the expiry date uploaded to the NMVS. The product code, expiry date and serial number can be found in the NMVS, but the expiry date differs.	NMVS_FE_LOT_12	#A52	First check if reading the 2D code was successful. Firstly, contact the MAH, see chapter 6.3
The batch ID does not match the serial number in the NMVS	The serial number used for the transaction was found for the product code, but it does not match with the batch ID uploaded to the NMVS.	NMVS_FE_LOT_13	#A68	First check if reading the 2D code was successful. Firstly, contact the MAH, see chapter 6.4
Unknown serial number	The serial number used for the transaction does not exist in the system for this product code. Product code and batch ID exist in the system but the serial number is incorrect.	NMVS_NC_PC_02	#A3	First check if reading the 2D code was successful. Firstly, contact the MAH, see chapter 6.5
Property is already set on pack	The pack has already been decommissioned with the same transaction.	NMVS_NC_PCK_19	#A7	Firstly, contact FiMVO, see chapter 6.6
Pack is already inactive	The pack has already been decommissioned with a different transaction.	NMVS_NC_PCK_22	#A24	Firstly, contact FiMVO, see chapter 6.7
Defined timeframe between setting this property and the undo was exceeded	Maximum delay (10 days) between decommissioning and undo was exceeded and undo cannot be performed.	NMVS_NC_PCK_20	#A4	Firstly, contact FiMVO, see chapter 6.8
Undo can only be executed by the same user who previously set the attribute	Undo can only be executed at the same location (i.e. the same end user) where the original transaction occurred.	NMVS_NC_PCK_21	#A5	Firstly, contact FiMVO, see chapter 6.9

5. Exceptions caused by the Medicines Verification System

The following table shows the most common exceptions returned by FiMVS. NOTE! The description provided by the end user software may differ from the description provided by FiMVS. Users are advised to consult their IT-supplier with regards to this aspect.

Exception message	Explanation	Return code (FiMVS)	Return code (EU Hub)	Guidelines for investigating the exception
Unknown product code.	The used product code is not available in the national system (or in the whole EU market if an intermarket transaction is triggered).	NMVS_NC_PC_01	#A1	If not known, the reason for the pack not being in scope of the medicines verification system should be clarified. This can be done after dispensing. If in doubt as to whether the pack is in scope, check with the MAH or with the wholesaler if the pack is a special license product.
The associated product or batch of the entered serial number was recalled.	The user attempted to decommission a pack belonging to a recalled batch.	NMVS_FE_LOT_08	#A9	The pack should be put aside for investigations. If needed, contact the MAH or the wholesaler if the pack is a special license product.
Property is already set on pack (no alert).	The user attempted to reactivate a pack which is already active.	NMVS_NC_PCK_28	#A7	The exception was caused by a human error or a technical issue. The pack is active in the medicines verification system and can be decommissioned as usual.
Pack is already inactive (no alert).	The user attempted to decommission a pack belonging to an expired batch or a withdrawn product.	NMVS_NC_PCK_30	#A8 / #A69	The pack should be put aside for investigations. If needed, contact the MAH or the wholesaler if the pack is a special license product.
Status change could not be performed (no alert).	The user attempted to reactivate a pack which has been marked as stolen or destroyed.	NMVS_NC_PCK_31	#A24	The pack should be put aside for investigations. If needed, FiMVO can be asked to review the pack audit trail (nmvs@fimvo.fi).

6. Processes for handling and investigating alerts

Almost all prescription medicines are within scope of the medicines verification system. All their batches released after February 9, 2019 must be labeled in accordance with the requirements of Delegated Regulation (EU) 2016/161 and any system alerts related to them must be considered suspected falsified medicinal products and resolved in accordance with regulatory guidelines and the users' own approved procedures. See also Roles & Responsibilities in chapter 7.

The Finnish Medicines Agency Fimea has published information on the safety features of medicines on their website.

The following paragraphs describe alerts, their possible root causes, and procedures for handling alerts. The measures are grouped according to the different actors in the distribution chain. Note that the root cause of the alert is not necessarily connected to the actor that triggers the alert (for example, the root cause of an alert in the pharmacy might be the fact that the batch data has not been uploaded to the system by the pharmaceutical company).

Alert processing and investigations proceed according to a three-tiered classification:

- possible suspected falsification: an alert to be investigated with the MAH and / or FiMVO
- suspected falsification: an alert for which any technical or process-related reason has been ruled out indicating a suspected falsification or product defect, which is to be handled and reported by the MAH in accordance with the Fimea regulation on reporting of product defects and suspected falsifications
- confirmed falsification, whereby the MAH acts in accordance with a class 1 product defect process.

This guideline is based on the knowledge and experience gathered by FiMVO as well as similar experiences and insights gained through European cooperation.

6.1 Support and contact details

Support and clarification requests for both FiMVO and MAHs must include the following unique identifiers associated with the product and / or pack to which the request for clarification applies and other necessary information:

1. Product Code (PC / GTIN)
2. Batch number (LOT / Batch)
3. Serial number (SN)
4. Expiry date (EXP)
5. Information regarding what alert is in question (clear alert description) and what support is required
6. It is helpful to include a photo of the 2D code and the human readable data on the pack with the support request N.B. The pack should not be returned to the wholesaler before the cause of the alert is resolved and/or return has been agreed with the marketing authorization holder.

NOTE. The Nordic product number (Vnr) is not maintained in the medicines verification system. The Vnr number does not identify the pack causing the alert. A product code is always a 14-digit GTIN format product code (PC).

Support and clarification requests to FiMVO should be sent to the email address: nmvs@fimvo.fi. Email is the preferred way of communication. Our hotline should only be used if the supply of the medicine to the patient is at risk of being delayed or prevented (hotline: +358 9 6150 4949).

6.2 Failed to find a batch for the given data (NMVS_FE_LOT_03)

Possible root causes of the alert:

- Batch data has not been uploaded to the EMVS system.
- The data used for the transaction (batch ID AND serial number) differs from the data printed on the pack.
  - Scanner reading error or erroneously changed scanned data
  - Manual data entry error

Actor	**Alert handling procedures**
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	1. Check the transaction data in the pharmacy system (if possible). 2. Compare the data of the transaction (especially batch ID and serial number) to the human readable data on the pack. If the data (both batch ID and serial number) are the same as the human readable data on the pack, the most probable cause is that the batch data has not been uploaded to EMVS. In this case, move directly to point 5. 3. If the transaction data (batch ID and serial number) does not match the human readable data, scan the 2D code again. If this is successful and does not generate an alert, the pack can be dispensed. 4. If this still fails, try using another scanner or enter the data manually. If the 2D code scanning or manual entry is successful and no alert is generated, the pack can be dispensed. NOTE. If the 2D code cannot be scanned and the human readable data is also illegible, the pack must not be dispensed. The pack must be reported to the MAH as a product defect. 5. If the pack cannot be dispensed, it should be put aside, and investigations should continue with the MAH. Alerts should be notified to the MAH through the wholesaler's product defect system or directly via email or phone. Notifications must include the pack's human readable data, i.e. product code, serial number, batch ID and expiry date. It is helpful to send a photograph of the pack as an attachment. The photo should include the 2D code and the human readable data on the pack.

Actor	Alert handling procedures
MAH / OBP	Check the alert message: Is this the correct batch number for this product? **a) If no:** it could be a scanning error by the end user or incorrect manual data entry by the end user. If you have received a photograph of the pack, ensure that the 2D code data on the pack is correct. Also, make sure that the 2D code data is identical to the data uploaded to EMVS. If the end user has not made contact, FiMVO (nmvs@fimvo.fi) can check the audit trail in the FiMVS system. Often the alerting pack has been successfully verified after the alert due to a data entry error. If needed FiMVO can also contact the end user. **NOTE!** If incorrect batch data has been printed on the pack, this is a product defect or a possible suspected falsification. The responsible MAH should request the wholesaler, if necessary, to place a sales ban on the batch for the duration of the investigation and perform the investigation together with the OBP. The MAH should pay particular attention to informing pharmacies, wholesalers and Fimea in order to keep them up to date with the situation and to ensure uninterrupted treatment and patient safety. If the investigations confirm that this is a falsified medicine, the product defect process should be followed (Class 1 product defect). The MAH is responsible for the planning and implementation of the required actions. Fimea oversees that the measures are adequate and appropriate. (https://www.fimea.fi/web/en/supervision/pharmacovigilance/product_defects). b) **If yes**: it is likely that the data for this batch has not been uploaded to the EMVS. The MAH should, if appropriate, ask the distributor to place a sales ban on the batch for the period of the investigation. If the reason for the alert is that the OBP has not uploaded the batch data to FiMVS or if the data upload has been unsuccessful, the data should be uploaded without delay, and the MAH should inform all actors in the supply chain and FiMVO of the situation, and when the data has been uploaded successfully. If needed, FiMVO will respond to inquiries as to whether the batch data has been uploaded to the FiMVS system: (nmvs@fimvo.fi).

6.3 Expiry date does not match the date held in the NMVS (NMVS_FE_LOT_12)

Possible root causes of the alert:

- The information printed on the pack differs from the data uploaded to EMVS.
- The transaction data differs from the information on the pack.
  - The manually entered expiry date is in the wrong format (DDMMYY) and should be in the correct format YYMMDD.
  - A typing error made whilst manually entering the expiry date.

Actor	**Alert handling procedures**
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	1. Check the data from the transaction in the pharmacy system (if possible). 2. Compare the data from the transaction (especially expiry date) to the human readable data on the pack. If the data are the same, the most probable cause is that the expiry date in the system differs from the one printed on the pack. In this case, move directly to point 5. 3. If the transaction data (expiry date) does not match the data on the pack, scan the 2D code again. If this is successful and does not generate an alert, the pack can be dispensed. 4. If this still fails, enter the information manually in the correct format, YYMMDD. If the manual entry is successful and no alert is generated, the pack can be dispensed. NOTE. If the 2D code cannot be scanned and the human readable data is also illegible, the pack must not be dispensed. The pack must be reported to the MAH as a product defect. 5. If the transaction is not successful, the pack should be put aside, and investigations should continue with the MAH. Alerts should be notified to the MAH through the wholesaler's product defect system or directly via email or phone. Notifications must include the pack's human readable data, i.e. product code, serial number, batch ID and expiry date. It is helpful to send a photograph of the pack as an attachment. The photo should include the 2D code and the human readable data on the pack. If needed, FiMVO will respond to inquiries as to what expiry date has been uploaded to the FiMVS system: (nmvs@fimvo.fi)

Actor	Alert handling procedures
MAH / OBP	1. Check the alert message: Is this the same expiry date as in the system? 2. If the data is different, the expiry date printed on the pack may differ from the expiry date uploaded to the system, or there is an error with the scanner or an error in manual data entry. 3. If the end user is in contact and has provided a photograph of the pack, check that the 2D code on the pack has the correct information. Check that the 2D code data is the same as data uploaded to EMVS. 4. If the data on the pack differs from the data uploaded, the MAH should, if necessary, request the distributor to place a sales ban on the batch for the duration of the investigation and work with the OBP to solve the situation. The MAH should pay particular attention to informing pharmacies, wholesalers and Fimea in order to keep them up to date with the situation and to ensure uninterrupted treatment and patient safety. 5. If the investigation confirms that this is a genuine falsified medicine, the product default process should be followed (Class 1 product defect). The MAH is responsible for the planning and implementation of the required actions. Fimea oversees that the measures are adequate and appropriate. (https://www.fimea.fi/web/en/supervision/pharmacovigilance/product_defects). 6. If the end user does not contact the MAH, FiMVO (nmvs@fimvo.fi) can help check the pack's audit trail. Often the alerting pack has been successfully verified and/or decommissioned after the alert. FiMVO can also contact the end user in question if necessary.

6.4 The batch ID does not match the serial number in the NMVS (NMVS_FE_LOT_13)

Possible root causes of the alert:

- The information printed on the pack differs from the data uploaded to EMVS.
- The data of the transaction differs from the information printed on the pack.
  - Scanner configuration error (batch ID contains capital and small letters which interchange or special characters change).
  - Scanning errors or erroneous data change after the barcode has been scanned (batch ID is missing one or more characters, or extra characters have appeared after the batch ID, often the EAN code or the beginning of it).
  - Manual data entry error.

Actor	**Alert handling procedures**
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	1. Check the data of the transaction in the pharmacy system (if possible). 2. Compare the data of the transaction (especially the batch data) to the human readable data on the pack. If the data matches the most probable cause is that the batch data differs from what has been uploaded to the EMVS. In this case, move directly to point 6. 3. If the transaction data (batch data) does not match the data on the pack, scan the 2D code again. If this is successful and does not generate an alert, the pack can be dispensed. 4. If this still fails, try using another scanner or enter the information manually. If the 2D code scanning or manual entry is successful and no alert is generated, the pack can be dispensed. NOTE. If the 2D code cannot be scanned and the human readable data is also illegible, the pack must not be dispensed. The pack must be reported to the MAH as a product defect. 5. If scanning is successful with one scanner but not another, the problem could stem from the scanner's configuration. Check that the scanner has been correctly configured. Contact your IT supplier to solve this. The scanner should read and transact data without changing it in any way. 6. If the pack cannot be dispensed, it should be put aside, and investigations should continue with the MAH. Alerts should be notified to the MAH through the wholesaler's product defect system or directly via email or phone. Notifications must include the pack's human readable data, i.e. product code, serial number, batch ID and expiry date. It is helpful to send a photograph of the pack as an attachment. The photo should include the 2D code and the human readable data on the pack.

Actor	Alert handling procedures
MAH / OBP	1. Check the batch ID and serial number in the alert message, is the serial number linked to the batch and does the data match the data uploaded to EMVS? 2. If the data differs, the batch data printed on the pack may differ from the batch data uploaded to the system, or there is an error with the scanner or an error in manual data entry. 3. If the end user does not contact the MAH/OBP, FiMVO (nmvs@fimvo.fi) may be asked to check the pack's audit trail. Often the alerting pack has been successfully verified and/or decommissioned after the alert. In this case the end user does not usually contact the MAH/OBP. FiMVO can also contact the end user in question if necessary. 4. If the end user requests clarification with an attached photograph of the pack, check that the 2D code on the pack has the correct information. In addition, check also that the 2D code data is the same as data uploaded to EMVS. 5. If the data on the pack differs from the data uploaded to FiMVS, the MAH should, if necessary, request the distributor to place a sales ban on the batch for the duration of the investigation and work with the OBP to solve the situation. The MAH should pay particular attention to informing pharmacies, wholesalers and Fimea in order to keep them up to date of the situation and to ensure uninterrupted treatment and patient safety. 6. If the investigations confirm that this is a genuine falsified medicine, the product defect process should be followed (Class 1 product defect). The MAH is responsible for the planning and implementation of the required actions. Fimea oversees that the measures are adequate and appropriate. (https://www.fimea.fi/web/en/supervision/pharmacovigilance/product_defects).

6.5 Unknown serial number (NMVS_NC_PC_02)

Possible root causes of the alert:

- Not all serial numbers in the batch have been uploaded to EMVS.
- The data in the transaction differs from the data printed on the pack.
  - Scanner configuration error (serial number contains capital and small letters which interchange).
  - Scanning errors or erroneous data change after the barcode has been scanned (serial number is missing one or more characters, or extra characters have appeared after the batch ID, often the beginning of the EAN code).
  - Manual data entry error.

Actor	**Alert handling procedures**
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	1. Check the data of the transaction in the pharmacy system (if possible). 2. Compare the data of the transaction (especially the serial number) to the human readable data on the pack. If the data is the same as the human readable data on the pack, the most probable cause is that not all serial numbers in the batch have been uploaded to EMVS, even though the product's master and batch data can be found N.B. The pack does not need to be verified numerous times/on consecutive days. Investigations should begin as soon as it has been confirmed, that the 2D code reading has been successful. In this case, move directly to point 6. 3. If the data of the transaction (serial number) does not match the human readable data, scan the 2D code again. If this is successful and does not generate an alert, the pack can be dispensed. 4. If this still fails, try using another scanner or enter the information manually. If the 2D code scanning or manual entry is successful and no alert is generated, the pack can be dispensed. NOTE. If the 2D code cannot be scanned and the human readable data is also illegible, the pack must not be dispensed. The pack must be reported to the MAH as a product defect. 5. If scanning is successful with one scanner but not another, the problem could stem from the scanner's configuration. Check that the scanner has been correctly configured. Contact your IT supplier to solve this. The scanner should read and transact data without changing it in any way. 6. If the pack cannot be dispensed, it should be put aside, and investigations should continue with the MAH. It may be a falsified pack. Alerts should be notified to the MAH through the wholesaler's product default system or directly via email or phone. The notification must include the pack's human readable data, i.e. product code, serial number, batch ID and expiry date. It is helpful to send a photograph of the pack as an attachment. The photo should include the 2D code and the human readable data on the pack.

Actor	Alert handling procedures
MAH / OBP	Check the serial number in the alert message, does it match the data uploaded to EMVS? **a) If no:** it could be a scanning error by the end user or incorrect manual data entry by the end user, or a genuine falsification. If you have received a photograph of the pack from the end user, ensure that the data in the 2D code on the pack is correct. Also, make sure that the 2D code data is identical to the data uploaded to EMVS. If the end user has not made contact, FiMVO (nmvs@fimvo.fi) can check the audit trail of the pack in the FiMVS system if the MAH/OBP can find in the batch data the serial number that differs only to a small extent from the erroneous serial number. Often the alerting pack has been successfully verified after the alert due to a data entry error. If needed FiMVO can contact the user. **NOTE!** If the investigations confirm that this is a genuine falsified medicine, the product defect process should be followed (Class 1 product defect). The MAH should pay particular attention to informing pharmacies, wholesalers and Fimea in order to keep them up to date of the situation and to ensure uninterrupted treatment and patient safety. The MAH is responsible for the planning and implementation the required actions. Fimea oversees that the measures are adequate and appropriate. (https://www.fimea.fi/web/en/supervision/pharmacovigilance/product_defects). b) **If yes**: it is likely that not all serial numbers in this batch have been uploaded to the EMVS. The MAH should, if appropriate, ask the distributor to place a sales ban on the batch for the duration of the investigation. The MAH together with the OBP investigates the case and performs the required corrective actions including the informing of distribution chain actors and FiMVO of the situation. If needed, FiMVO will respond to inquiries as to whether the batch data has been uploaded to the FiMVS system: (nmvs@fimvo.fi).

6.6 Property is already set on pack (NMVS_NC_PCK_19)

Possible root causes of the alert:

- The same end user has already decommissioned the pack with the same transaction. (NOTE. Before the alert is generated the end user will receive the error message "*NMVS_NC_PCK_23 Re-setting of the property via double scan is registered*" three times).
- Another end user has already decommissioned the pack with the same transaction.
- In some rare cases it is possible that two packs with identical identifiers have been released on the market by the MAH/OBP.

Actor	**Alert handling procedures**
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	1. Undo the previous action on the pack, i.e. reactivate the pack. 2. If the undo is successful, the original transaction was performed by the same end user not more than 10 days ago, which suggests that the original transaction was cancelled but the user forgot to return the pack to the system. The pack state is now active, and the pack can be dispensed/decommissioned from the system. The user must investigate and record the error (e.g. a shared pack which has been opened earlier and decommissioned, or a pack which was not returned to the system after not being dispensed) and take preventive action not to repeat the error. 3. If undo is not possible, and the system returns the exception *Defined timeframe between setting this property and the undo was exceeded (NMVS_NC_PCK_20)*, the original transaction was performed more than 10 days ago by the same user and the pack cannot be reactivated anymore, see chapter 6.8. If the system returns the exception *Undo can only be executed by the same user who previously set the attribute (NMVS_NC_PCK_21)*, the original transaction was performed by a different user. This may be a falsified pack. In this case the pack must not be dispensed until the reason behind the alert has been clarified. The pack should be set aside and clearly marked that it cannot be dispensed. See also chapter 6.9. 4. If the cause of the alert cannot be solved by the user, FiMVO can be asked to review the pack audit trail (nmvs@fimvo.fi). This alert may also be raised when the pack data is not found in FiMVS and in those cases, the MAH / supplier should be contacted to check the audit trail from the EU country where the data is found. Support requests must include the human readable data of the pack, i.e. product code, serial number, batch ID and expiry date. It is helpful to send a photograph of the pack as an attachment. If the audit trail implies a product defect or falsification, this must be notified to the MAH either through the wholesaler's product defect system or via email or phone. N.B. The pack should not be returned to the wholesaler before the cause of the alert has been resolved and / or before the return has been agreed with the MAH.

Actor	Alert handling procedures
MAH / OBP	If the pharmacy / wholesaler contacts the MAH/OBP, FiMVO can be asked to review the pack audit trail (nmvs@fimvo.fi). In cases where the pack data has not been uploaded to FiMVS, FiMVO cannot review the complete audit trail of the pack. FiMVO can check the transactions which were performed in Finland. If necessary, the MAH / OBP can check the audit trail in another EU country by contacting the support of the medicines verification organisation of that particular country.

6.7 Pack is already inactive (NMVS_NC_PCK_22)

Possible root causes of the alert:

- The same user has already decommissioned the pack from the system with a different transaction.
- Another user has already decommissioned the pack from the system with a different transaction.
- In some rare cases it is possible that two packs with identical identifiers have been released on the market by the MAH/OBP.

Actor	**Alert handling procedures**
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	1. Check the pack state in FiMVS (Verify). 2. Undo the previous action on the pack, i.e. reactivate the pack. 3. If the undo is successful, the original transaction was performed by the same user not more than 10 days ago, which suggests that the original transaction was cancelled but the end user forgot to return the pack to the system. The pack state is now active, and the pack can be dispensed/decommissioned. The user must investigate the reason for the error and take preventive action not to repeat the error. 4. If undo is not possible, and the system returns the exception *Defined timeframe between setting this property and the undo was exceeded (NMVS_NC_PCK_20)*, the original transaction was performed more than 10 days ago by the same user and the pack cannot be reactivated anymore, see chapter 6.8. If the system returns the exception *Undo can only be executed by the same user who previously set the attribute (NMVS_NC_PCK_21)*, the original transaction was performed by a different user. This may be a falsified pack. In this case the pack must not be dispensed until the reason behind the alert has been clarified. The pack should be set aside and clearly marked that it cannot be dispensed. See also chapter 6.9. 5. If it is not possible to review the pack audit trail within the user's own system, the user should contact FiMVO for the audit trail of the pack (nmvs@fimvo.fi) 6. If the audit trail implies a product defect or falsification, this must be notified to the MAH either through the wholesaler's product defect system or directly via email or phone. Notifications must include the human readable data of the pack, i.e. product code, serial number, batch ID and expiry date. It is helpful to send a photograph of the pack as an attachment. The photo should include the 2D code and the human readable data on the pack. N.B. The pack should not be returned to the wholesaler before the cause of the alert has been resolved and / or before the return has been agreed with the MAH.
MAH / OBP	If the pharmacy / wholesaler contacts the MAH/OBP, FiMVO can be asked to review the pack audit trail (nmvs@fimvo.fi).

6.8 Defined timeframe between setting this property and the undo was exceeded (NMVS_NC_PCK_20)

Root cause of the error:

- The pack was decommissioned by the same user more than 10 days ago and the action cannot be undone anymore.

Actor	**Error handling procedures**
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	This exception means that the pack was decommissioned by the same user more than 10 days ago and the action cannot be undone anymore. FiMVO can check the pack audit trail (nmvs@fimvo.fi), if needed.
MAH / OBP	If the pharmacy / wholesaler contacts the MAH/OBP, FiMVO can be asked to review the pack audit trail (nmvs@fimvo.fi).

6.9 Undo can only be executed by the same user who previously set the attribute (NMVS_NC_PCK_21)

Root cause of the error:

- Another user has performed the original transaction (e.g. another pharmacy).

Actor	**Error handling procedures**
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	This exception means that another user has performed the original transaction (e.g. another pharmacy). FiMVO can check the pack audit trail (nmvs@fimvo.fi), if needed. The root cause for this error must always be investigated before the pack is dispensed. If falsification is not suspected, the pack can be dispensed to the patient.
MAH / OBP	If the pharmacy / wholesaler contacts the MAH/OBP, FiMVO can be asked to review the pack audit trail (nmvs@fimvo.fi).

7. Roles & Responsibilities

All persons authorised or entitled to supply medicinal products to the public are obliged to verify the safety features of the medicines packs they are dispensing according to the Delegated Regulation (EU) 2016/161 and to decommission the unique identifiers from the medicines verification system. If the verification of the unique identifier indicates that the medicine pack may not be genuine, it must not be distributed or dispensed. Investigations should be initiated without delay.

The marketing authorisation holder bears primary responsibility for addressing suspected or actual falsification. All entities operating in the pharmaceuticals sector are responsible for taking the appropriate measures to address any cases of suspected or actual falsification in products they manufacture, import, distribute or release for consumption.

FiMVO maintains the Finnish Medicines Verification System and monitors its operation and alerts generated in the system. When necessary FiMVO assists system users in resolving alerts. Upon request, FiMVO is obliged to provide Fimea with information stored in the system in order to investigate possible cases of falsification and to inspect, whether individual marketing authorisation holders, manufacturers, wholesalers and pharmacies / hospital pharmacies / dispensaries comply with the Delegated Regulation (EU) 2016/161.

FiMVO is occasionally contacted by end users requesting the permission to dispense a pack which has generated an alert in the system. FIMVO is not the national competent authority, but a non-profit company responsible for the setting up and managing the Medicines Verification System in Finland as required by the EU legislation. FiMVO offers support to distribution chain actors in questions regarding medicines verification, but the responsibility for the assessment and decisions regarding the required actions lies on the actors themselves.

8. Reference documents

Document Identification	Title
Falsified Medicines Directive (2011/62/EU)	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0062&qid=1665402084073&from=EN
Commission Delegated Regulation (EU) 2016/161	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02016R0161-20220101&qid=1665401681977&from=EN
Commission Questions & Answers – document	https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_en.pdf

SIGNATURES **ALLEKIRJOITUKSET** **UNDERSKRIFTER** **SIGNATURER** **UNDERSKRIFTER**

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Maija Maria Gohlke
8282d7dc-9a6a-48a8-b0d1-3652efeb1cbf - 2023-11-06 11:35:29 UTC +02:00
BankID / MobileID - a8aa1366-f8cb-4dcf-9ddf-3bda52fd4d04 - FI

Stanley Jörgen Eklund
7f6995df-2b20-432a-ba8e-0a8494ecb78f - 2023-11-06 11:44:52 UTC +02:00
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Teijo Juhani Yrjönen
0f17729a-c764-419a-b30c-ef17c5c33e7f - 2023-11-06 11:53:49 UTC +02:00
BankID / MobileID - 2149d634-f278-4fb3-b410-96f1ca1c301f - FI

authority to sign	asemavaltuutus	ställningsfullmakt	autoritet til å signere	myndighed til at underskrive
representative	nimenkirjoitusoikeus	firmateckningsrätt	representant	repræsentant
custodial	huoltaja/edunvalvoja	förvaltare	foresatte/verge	frihedsberøvende