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Revision History

Version	Date	Reason for changes	Description of changes made
1.0	04-Dec-2020	Initial document	SOP included in the Quality Management System and the structure has been aligned with the SOP template. Changes introduced by EU Hub R1.8 have been addressed. The most significant change is that all alerts are now propagated to the OBP.

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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.

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.

- 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.**

NOTE! An unknown product number (NMVS_NC_PC_01) does not cause an alert but a level L3 deviation. Although this is not an alert, it is advisable to investigate why this pack is not in the medicines verification scope. This can be done after dispensing. If in doubt as to whether the pack is in scope, check with the MAH. From a technical point of view, the medicines verification system uses the same return code as before (NMVS_NC_PC_01).

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 5.2
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 5.3
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 5.4
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 5.5
Property is already set on pack	Pack is already in requested state. This generates an L5 alert, if pack details have not been uploaded to FiMVS and the system performs an IMT enquiry to the NMVS system of another EU country (e.g. products subject to a special permit).	NMVS_NC_PCK_19	#A7	Firstly, contact FiMVO, see chapter 5.6
Pack is already inactive	The pack has already been decommissioned.	NMVS_NC_PCK_22	#A24	Firstly, contact FiMVO, see chapter 5.7

Alert message	Explanation	Alert code (FiMVS)	Alert code (EU Hub)	Guidelines for investigating the alert
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. This generates an L5 alert, if pack details have not been uploaded to FiMVS and the system performs an IMT enquiry to the NMVS system of another EU country (e.g. products subject to a special permit).	NMVS_NC_PCK_20	#A4	Firstly, contact FiMVO, see chapter 5.8
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. This generates an L5 alert, if pack details have not been uploaded to FiMVS and the system performs an IMT enquiry to the NMVS system of another EU country (e.g. products subject to a special permit).	NMVS_NC_PCK_21	#A5	Firstly, contact FiMVO, see chapter 5.9
Actual pack status doesn't match the undo transaction (set and undo status must be equivalent).	Undo transaction does not match pack status (e.g. *Undo Dispense* attempted for a pack in the status *Sample. Undo Sample* should be used).	NMVS_NC_PCK_06	#A24	Firstly, contact FiMVO, see chapter 5.10
Status change could not be performed	The pack is already inactive, but its status is different to the used transaction (e.g. pack is marked as Sample and the user performs a Dispense transaction. Undo transaction does not match pack status (e.g. *Undo Dispense* attempted for a pack in the status *Sample*). This generates an L5 alert, if pack details have not been uploaded to FiMVS and the system performs an IMT enquiry to the NMVS system of another EU country (e.g. products subject to a special permit).	NMVS_NC_PCK_27	#A24	Firstly, contact the MAH, see chapter 5.11

5. Processes for handling and investigating alerts

Almost all prescription medicines are within scope of the medicines verification system. All batches concerned 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 practices.

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

5.1 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 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 primarily via email, nmvs@fimvo.fi. Our hotline should only be used in urgent matters: +358 9 6150 4949.

5.2 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 information used for the transaction (batch ID AND serial number) is different to the data printed on the pack.
  - Scanner reading error or erroneously changed scanned data
  - Data was incorrectly entered manually

End User	Alert handling procedures
Pharmacy / Hospital pharmacy/ Dispensary / Wholesaler	1. Check the transaction data in the pharmacy system (if possible). 2. Compare the data from 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 details have not been uploaded to EMVS. In this case, move directly to point 5. 3. If the transaction data 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 to the MAH 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.

End User	Alert handling procedures
MAH / OBP	Check the transaction data in 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 is 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 will request the wholesaler, if necessary, to place a sales ban on the batch during investigation and work with the OBP to solve the investigation. 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 design and implementation of this process. 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 uploaded was 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).

5.3 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 to 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.
  - The expiry date in the 2D code is an exact date which is not the last day of the month, and on the human readable data on the pack the date is YYMM → if the end user can't scan the 2D code and manually enters the last day of the month (i.e. different to the data uploaded), this will generate an alert.
  - A typing error made whilst manually entering.
  - The end users IT system changes the expiry date, which is coded in the format YYMM00 (meaning the last day of the month) to YYMMDD → this only generates an alert if the data has not been uploaded into FiMVS and the system performs an IMT enquiry to other EU counties NMVS systems (e.g. special permit products).

End user	**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 data 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 to the MAH 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. If needed, FiMVO will respond to inquiries as to what expiry date had been uploaded to the FiMVS system: (nmvs@fimvo.fi)

End user	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, it could be that the expiry date printed on the pack differs to 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 to the data uploaded, the MAH should, if necessary, request the distributor to place a sales ban on the batch during an investigation and work with the OBP to solve the investigation. 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 design and implementation of this process. Fimea oversees that the measures are adequate and appropriate. (https://www.fimea.fi/web/en/supervision/pharmacovigilance/product_defects). 6. If the end user is not in contact with the MAH, FiMVO (nmvs@fimvo.fi) can help check the pack's audit trail. Often after an alert the end user is able to successfully verify the pack. FiMVO can also contact the end user in question if necessary.

5.4 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.

End user	**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 is different 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 to the MAH 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.

End user	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 one uploaded on EMVS? 2. If the data differs, it could be that the batch data printed on the pack differs to 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 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 to the data uploaded to FiMVS, the MAH should, if necessary, request the distributor to place a sales ban on the batch during an 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 design and implementation of the process. Fimea oversees that the measures are adequate and appropriate. (https://www.fimea.fi/web/en/supervision/pharmacovigilance/product_defects).

5.5 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.

End user	**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 to the MAH 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.

End user	Alert handling procedures
MAH / OBP	Check the serial number in the alert message, does it match the data uploaded on 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 is 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 design and implementation this process. 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 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 serial numbers to FiMVS or if the data uploaded was 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).

5.6 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.
- Another end user has already decommissioned the pack.
- In some rare cases it is possible that two packs with identical identifiers have been released on the market by the MAH/OBP.

NOTE. This only generates an alert if the pack data is not found in FiMVS and an IMT is performed (e.g. a special license product brought to Finland from another EU country) and FiMVS performs a transaction to another EU country's medicine verification system, which generates the alert.

End user	Alert handling procedures
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	1. Check the pack status in FiMVS (Verify). 2. Undo the previous action on the pack (e.g. if the pack has been Dispensed, perform Undo dispense). 3. If the undo is successful, the original transaction was done by the same end user less 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 from the system. The end 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. 4. If undo is not possible, and the system alerts, *Defined timeframe between setting this property and the undo was exceeded (NMVS_NC_PCK_20)* or *Undo can only be executed by the same user who previously set the attribute (NMVS_NC_PCK_21)* the original transaction was performed over 10 days ago or by a different end user. This may be a falsified pack. In this case the pack cannot be dispensed until the reason behind the alert is investigated. The pack should be set aside and clearly marked that it cannot be dispensed. 5. If the cause of the alert cannot be solved at the location of the alert, FiMVO can check the transactions which have been performed in Finland (nmvs@fimvo.fi). If necessary, the MAH / supplier should be contacted to check the audit trail from the EU country from which the data is found. Support requests 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.
MAH / OBP	In this case as the pack data was not uploaded to FiMVS, FiMVO cannot review the complete audit trail of the pack. FiMVO can check the transactions which were performed in Finland (nmvs@fimvo.fi). 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.

5.7 Pack is already inactive (NMVS_NC_PCK_22)

Possible root causes of the alert:

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

End user	**Alert handling procedures**
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	1. Check the pack state in FiMVS (Verify). 2. Undo the previous action on the pack (e.g. if the pack has been D*ispensed*, perform *Undo dispense*). 3. If the undo is successful, the original transaction was done by the same end user under 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 from the system. The end 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. 4. If undo is not possible, and the system alerts, *Defined timeframe between setting this property and the undo was exceeded (NMVS_NC_PCK_20)* or *Undo can only be executed by the same user who previously set the attribute (NMVS_NC_PCK_21)* the original transaction was performed over 10 days ago or by a different end user. This may be a falsified pack. In this case the pack cannot be dispensed until the reason behind the alert is investigated. The pack should be set aside and clearly marked that it cannot be dispensed. 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 to the MAH 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. N.B. The pack should not be returned to the wholesaler before the cause of the alert is 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 provide the pack audit trail (nmvs@fimvo.fi).

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

Root cause of the alert:

- The pack was decommissioned over 10 days ago so the action cannot be undone.

NOTE. This only generates an L5 alert if the pack data is not found in FiMVS and an IMT is performed (e.g. a special license product brought to Finland from another EU country) and FiMVS performs a transaction to another EU country's medicine verification system, which generates the alert.

End user	Alert handling procedures
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	If the end user cannot see when and by whom the original transction took place, they should be in contact with the MAH who can check the audit trail in the national verification system in which this. FiMVO can check the transactions which were performed in Finland (nmvs@fimvo.fi). If necessary, the MAH / OBP should be contacted to check the audit trail in another EU country by contacting the support of the medicines verification organisation of that particular country. This notification can also arise in a situation where the product and pack data have been uploaded to the FiMVS system, but it is not an actual alert. FiMVO can check the pack audit trail (nmvs@fimvo.fi). 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 patient.
MAH / OBP	In this case as the pack data was not uploaded to FiMVS, FiMVO cannot review the complete audit trail of the pack. FiMVO can check the transactions which were performed in Finland (nmvs@fimvo.fi). 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. This notification can also arise in a situation where the product and pack data have been uploaded to the FiMVS system, but it is not an actual alert.

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

Root cause of the alert:

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

NOTE. This only generates an alert if the pack data is not found in FiMVS and an IMT is performed (e.g. a special license product brought to Finland from another EU country).

End user	Alert handling procedures
Pharmacy / Hospital pharmacy/ Dispensary / Wholesaler	If the end user cannot see when and by whom the original transaction took place, FiMVO can check the transactions which were performed in Finland (nmvs@fimvo.fi). If necessary, the end user should be in contact with the MAH who can check the audit trail in the EU country where the pack data has been uploaded. This notification can also arise in a situation where the product and pack data have been uploaded to the FiMVS system, but it is not an actual alert. FiMVO can check the pack audit trail (nmvs@fimvo.fi). 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 patient.
MAH / OBP	In this case as the pack data was not uploaded to FiMVS, FiMVO cannot review the complete audit trail of the pack. FiMVO can check the transactions which were performed in Finland (nmvs@fimvo.fi). 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. This notification can also arise in a situation where the product and pack data have been uploaded to the FiMVS system, but it is not an actual alert.

5.10 Actual pack status doesn't match the undo transaction (NMVS_NC_PCK_06)

Root cause of the alert:

- The undo transaction does not correspond with the pack's active state (e.g. *Undo dispense* is performed on a pack which has the active status *Sample*. *Undo Sample* should be used in this case).

End user	**Alert handling procedures**
Pharmacy / Hospital pharmacy/ Dispensary / Wholesaler	1. Check the pack state in FiMVS (Verify). 2. Undo the previous transaction on the pack (e.g. if the pack has been dispensed, perform undo dispense). 3. The end user should investigate why the original incorrect undo transaction was performed and work to take corrective action so as not to repeat the mistake. 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 patient. If needed, FiMVO can provide answers regarding the pack audit trail (nmvs@fimvo.fi).
MAH / OBP	If the end user contacts you, FiMVO can help you by checking the pack audit trail (nmvs@fimvo.fi).

5.11 Status change could not be performed (NMVS_NC_PCK_27)

Possible root causes of this alert:

- The pack is already inactive in the system, but its state is different to the transaction process (e.g. pack is marked as *Sample* and the end user uses the *Dispense* transaction)
- The undo transaction does not correspond with the pack's active state (e.g. *Undo dispense* is performed on a pack which has active status *Sample*. *Undo Sample* should be used in this case)

NOTE. This only generates an alert if the pack data is not found in FiMVS and an IMT is performed (e.g. a special license product is brought to Finland from another EU country).

End user	Alert handling procedures
Pharmacy / Hospital pharmacy / Dispensary / Wholesaler	1. Check the pack state in FiMVS (Verify). 2. Undo the previous action on the pack (e.g. if the pack has been dispensed, perform Undo Dispense). 3. The end user should investigate why the original incorrect undo transaction was performed and work to take corrective action so as not to repeat the mistake. 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 patient. **NOTE!** Since in this case the pack data was not uploaded to FiMVS, FiMVO is incapable of following the audit trail. FiMVO can check the transactions which were performed in Finland (nmvs@fimvo.fi). If necessary, the MAH should investigate the audit trail with the NMVO from the country the data alerted in.
MAH / OBP	In this case as the pack data was not uploaded to FiMVS, FiMVO is incapable of following the audit trail. FiMVO can check the actions which were performed in Finland (nmvs@fimvo.fi). 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. 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.

7. Reference documents

Document Identification	Title
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

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

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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