PROCEDURE FOR HANDLING ALERTS FOR END USERS, MARKETING AUTHORIZATION HOLDERS AND PARALLEL IMPORTERS

(pursuant to Directive 2001/83/EC of the European Parliament and of the Council, Directive 2011/62/EU and Commission Delegated Regulation (EU) 2016/161)

ver. 2.1

(translation of the Czech document, v2.1, published on October 21st, 2025;
replaces version 2.0 – changes: Original chapters 6 and 7 merged into one – now chapter 6, subchapter layout changed, information clarified)

» Answers to frequently asked questions related to FMD/CZMVO/CZMVS/CZAMS are recorded in the document FREQUENTLY ASKED QUESTIONS IN REGARD TO FMD AND ALERTS located on the CZMVO website in the 'Important Information/Q&A' section.

» General information about FMD is described in the document FMD Principles (Falsified Medicines Directive)', located on the CZMVO website in the individual sections of the 'System Users' part.

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List of abbreviations and terms

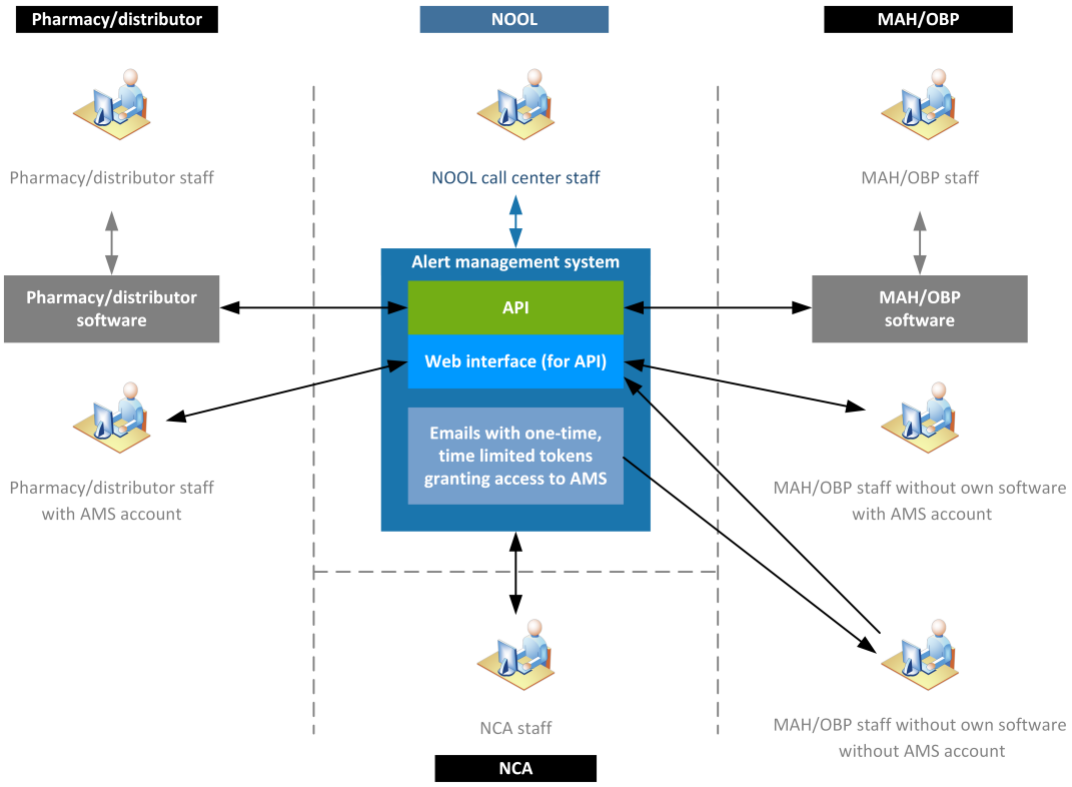
Abbreviations	Description
CZMVO = NOOL	Czech Medicines Verification Organization - Národní organizace pro ověřování pravosti léčiv, z.s.
NMVS = CZMVS	National/Czech Medicines Verification System
CZAMS	Czech Alert Management System
EMVS	European Medicines Verfication System (NMVSs + EU Hub)
OBP	On-Boarding Partner – An entity uploading data to EU HUB on behalf of an MAH
MAH	Marketing Authorization Holder
FMD	Falsified Medicines Directive - EU 2011/62/EU
Alert	An exception generated in CZMVS indicating a potential counterfeit suspect
UPRC	Unique Pack Return Code – alert level 5 identifier
UI	An identifier that provides for authenticity verification and identification of a single pack of a medicinal product
ATD	Anti-tampering device – a means to prevent tampering with the outer packaging of a medicinal pack
2D code	Two-dimensional data matrix code (as per GS1)
Parallel importer (PD)	Distribution licence holder for medicinal products providing for a resale between countries
FAQ	Frequently Asked Questions
IMT	Intermarket transaction
MP	Medicinal Product

1 Czech Alert Management System (CZAMS)

The Czech Alert Management System, created and operated by CZMVO, is a module of the CZMVO Information System that supports CZMVS. The purpose of this system is to streamline the administration of alert investigations, automate the entire investigation process, and share information about the results.

Alerts management can be done in several ways:

- Integration of the user's own alert management system with the Alert Management System operated by CZMVO via **API**.
- Users that do not have their own alert management system, or are not allowed by their organization's policy to integrate their own system with another system, can directly access CZAMS via a **web interface**.
- One-time, time-limited access to the CZAMS web interface for a single alert only. A link including a token is sent automatically with a gererated e-mail.



Picture 1 – Alert management

More information is provided in the following documents:
CZMVO web interface for alert management – **user manual for MAHs/OBPs**
https://www.czmvo.cz/en/alert-management/producers-mah-parallel-distributors/
CZMVO web interface for alert management – **user manual for end users**
https://www.czmvo.cz/en/alert-management/distributors-pharmacies/
API for alert management - **documentation for developers**
https://www.czmvo.cz/en/alert-management/it-companies/

2 The alert handling process

The picture below shows the process of alert handling, including the activity of all parties involved in the process, i.e. end users (pharmacies and distributors), MAHs/OBPs and marketing authorization holders in the role of parallel distributors. Activities of CZMVO are specified in chapter 3.

For the sake of clarity, the process has been divided into three separate pictures for end users, MAHs/OBPs, marketing authorization holders in the role of parallel distributors and CZMVO, depending on their role in the process, but together they form one entirety (picture 3, page 11; picture 5, page 32; picture 6, page 33).

2.1 End users

The main responsibility of the end user is to verify the safety features of medicinal products upon dispensation to public or any other transaction (export, destruction, etc.) Subsequently a UI is decommissioned in CZMVS, or more precisely in EMVS. In other cases if a distributor is a designated wholesaler or purchases packs of medicinal products from the designated wholesaler, the verification is carried out on a random basis.

The end user should primarily check the ATD and subsequently scan the 2D code of the pack of a medicinal product. In case the safety features are successfully verified, the pack can be supplied (or other required transaction be performed).
In case CZMVS fails to respond in the process of verification due to either unavailability of CZMVS or any issue on the part of the end user (e.g. no Internet connection), it is possible to use the "postponed verification" function. However, this function must be implemented in the end user's software.

In case an alert is generated during the end user's transaction (i.e. verification of the safety features was unsuccessful) the pack cannot be supplied or distributed at that point in time. If the root cause cannot be fixed, the pack must be quarantined and an investigation carried out immediately so as to rule out an error on the part of the end user. The investigation status must be regularly monitored in CZAMS, i.e. the result of investigaton determined by the MAH or CZMVO. It is assumed that the end user's application software will handle most situations automatically. It is also possible to view the alert status by navigating to the web interface of CZAMS.

The end user will commence investigation of the alert if it is clear that the error was caused on their own part. In such cases the end user does not need to wait for the MAH to begin investigation. After that, the end user will close the alert accordingly as either a procedural or a technical error depending on the identified root cause. Upon request, the end user should cooperate and provide additional information related to alert investigation to MAH or CZMVO.

Provided the error that caused the alert has been fixed, e.g. scanner or keyboard settings adjusted (technical error) or the MAH has confirmed correction of data in the repository, the end user will re-perform verification of the UI of the pack and will eventually decommission the pack.

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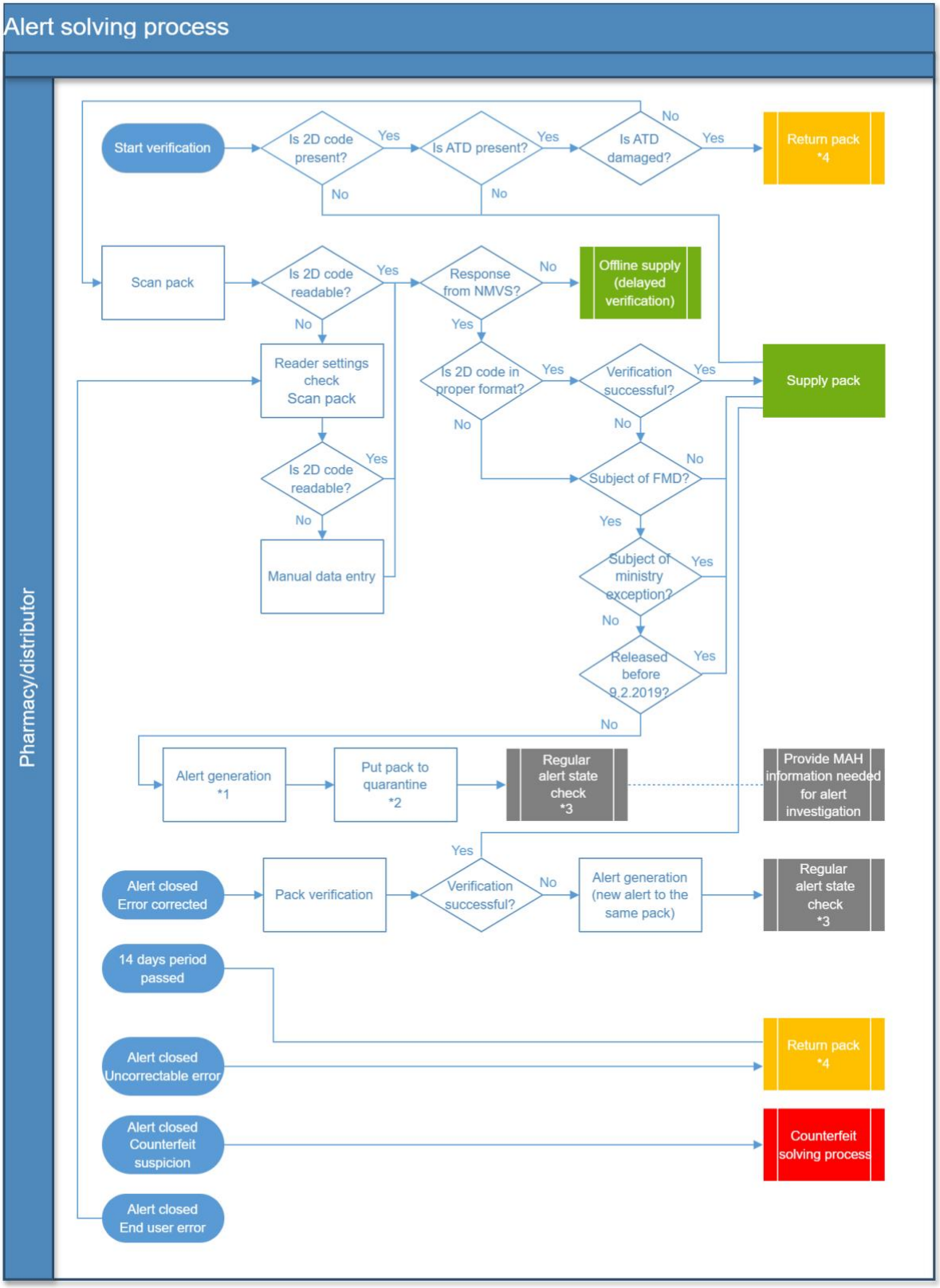
The corresponding alert should however be closed in CZAMS. If raised due to an error on the part of the end user, the end user may close it see Chapter 5.1, or it can be closed by the MAH. Re-performing the verification process should not be executed if the medicinal product is approved by the Ministry of Health as per Act No. 378/2007 Coll., on Pharmaceuticals, article 11r or it has been confirmed, based on investigation, that the pack was released from production prior to February 9th 2019. This does not apply to packs returned to the wholesaler.

In the course of alert investigation, the end user, MAH and CZMVO can communicate directly in CZAMS using pre-defined bilingual messages in Czech and English. CZAMS also enables sending files or additional information.

A closed alert can be re-opened in case the end user disputes the result of investigation selected by MAH. This is not applicable if the pack has already been released from quarantine and dispensed (or destroyed, exported, etc.)

In case a counterfeit suspect is confirmed, investigation will commence in compliance with the standard procedure of the State Institute for Drug Control (SIDC), and the end user will be prompted to cooperate.



Picture 1 - Process of resolving alerts for the end user

*1) An alert is generated by the system and not by the user.
*2) Every company will decide about placing a medicinal product in quarantine and about how it will be handled, based on its own policy and rules.
*3) End users' software will typically check the alert status on a regular basis. Users whose software does not include this feature can access the CZAMS web interface..
*4) Medicinal products will be returned in accordance with the processes outlined in the contract between the end user, distributor, and manufacturer. Any compromised ATD must be reported to the SIDC.

Note: Off-line supply = CZMVS is unavailable. In this case, actions should be taken in accordance with Regulation 161/2016, Article 29 – Obligations in the event of an inability to verify the authenticity and decommission the unique identifier. Notwithstanding Article 25(1), if technical issues prevent authorized or entitled persons from verifying the authenticity of, and decommissioning, a unique identifier at the time the medicinal product is supplied to the public, these individuals must record the unique identifier and verify its authenticity and decommission it as soon as the technical issues are resolved.

Chapter 2 The alert handling process (outlined above) describes scenarios that may arise during the verification of medicinal products and the corresponding response in CZMVS. It does not cover non-standard situations that may occur when medicinal products are returned from hospital wards to hospital pharmacies (e.g., returns to another workplace, expiration of the 10-day deadline, etc.). Such situations are treated in CZMVS as alerts and are handled according to standard processes.

The end user will receive an error message and, if configured in their software, may also see an error code (referred to as the operation code), which is primarily intended for IT support personnel. These error codes, or operation codes, are documented in the software provider's documentation (National Medicines Verification System Developer Portal (ITE)).

End users will be presented with instructions as part of the error message, explaining the necessary steps to proceed. These instructions depend on the specific implementation in the pharmacy's or distributor's software.

Recommendation: If a pack of a medicinal product is to be returned, it should be labeled with the data generated by the system based on the alert.
Our recommendation is to print the data generated by CZMVS (at least **Alert ID**):

Alert date and time
Alert unique identifier (referred to as Alert ID)
Product code
Product name
Lot number
Pack serial number

The SW provider should ensure this information is printed and displayed.

Recommendation: The end user's software should provide information about whether the medicinal product is subject to the FMD or not.

Recommendation: In case of returned packs, the alert data (see the Recommendation above) should also be electronically transmitted between the pharmacy and the relevant distributor, provided that the systems allow it.

Recommendation: Distributors should verify at least one pack from each batch in order to minimize the situations where the distributor sends to the pharmacy packs that are not in compliance with the Regulation.

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2.2 MAH

The main responsibility of MAH is to thoroughly investigate alerts. In case the alert is raised due to their own error, e.g. incorrect data upload, the alert should be closed by the MAH on their end. In all other scenarios the alert should be closed by the end user for either a technical or a procedural error. The MAH can intervene in the alert investigation at any time and close it on their end, except in the case of a procedural error, where the alert investigation is reserved for the end user for the first 2 days from the date the alert was raised. Every alert should thus end up in the "Closed" status indicating the investigation result (correctable/non-correctable data error, the end user's error, MAH error, etc.).

Using CZAMS, the MAH can request additional information from the end user or reach out to the CZMVO Support Team (in complicated cases).

MAHs also investigate whether the error was due to a data discrepancy—meaning the data on the pack does not match the data in the system—or if it was caused by the end user's error. Additionally, they check if the medicinal product is not permitted by the Ministry of Health according to Section 11 (r) of the Pharmaceuticals Act. Based on their findings, MAHs will provide the results of their investigation.

In the case that a suspected counterfeit is confirmed, the standard procedure in compliance with the SIDC will proceed.
In the case that the MAH detects an error on the part of the end user, there are two options the MAH can apply:

- The MAH will close the alert concluding it is the end user's error;
- The MAH will inform the end user that the error was probably caused by them, and will proceed to close the alert.

Note: If the end user fixes a technical error on their part and the following pack verification is successful, the pack can be released from quarantine and dispensed to public. In such a case, the end user may also close the alert. If not, the alert will be closed automatically by CZAMS based on the pack audit trail.

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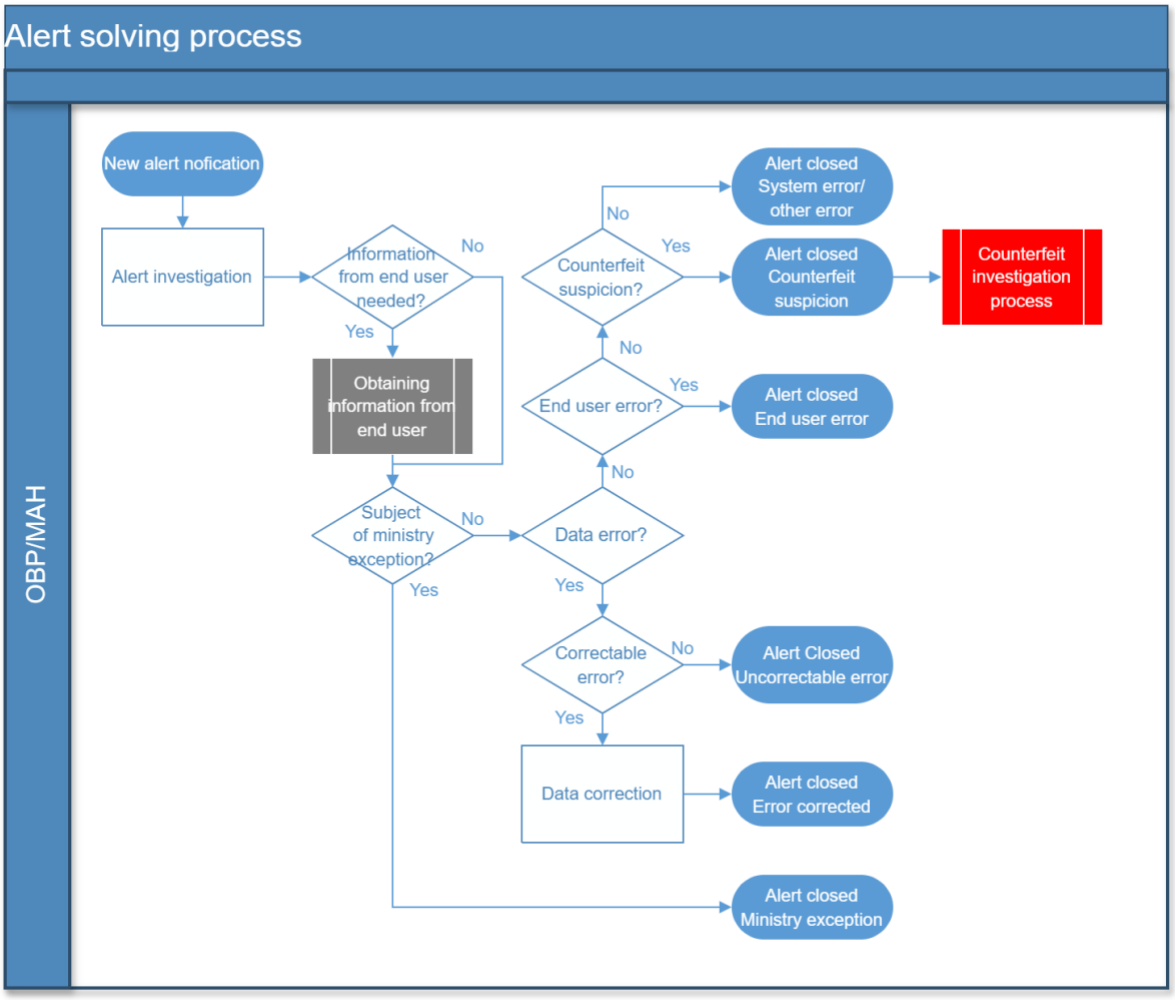


Picture 3 – The process of handling alerts for MAHs/OBPs

2.3 Parallel Importer

2.3.1 Parallel import into the Czech Republic

Parallel import refers to the distribution of a medicinal product from another member state to the Czech Republic, provided that this medicinal product has obtained registration in the Czech Republic, is registered in the member state from which it is distributed, and the distribution is not carried out by the holder of the marketing authorization in the Czech Republic or in cooperation with them. From the perspective of CZMVO, in such a situation, the parallel importer acts as the MAH (Marketing Authorization Holder), meaning they upload data about the medicinal products to the repository and handle alerts that arise in CZMVS in relation to these products. Details regarding the handling of MAH alerts are provided in Chapter 2.2 MAH.

2.3.1 Parallel import outside of the Czech Republic

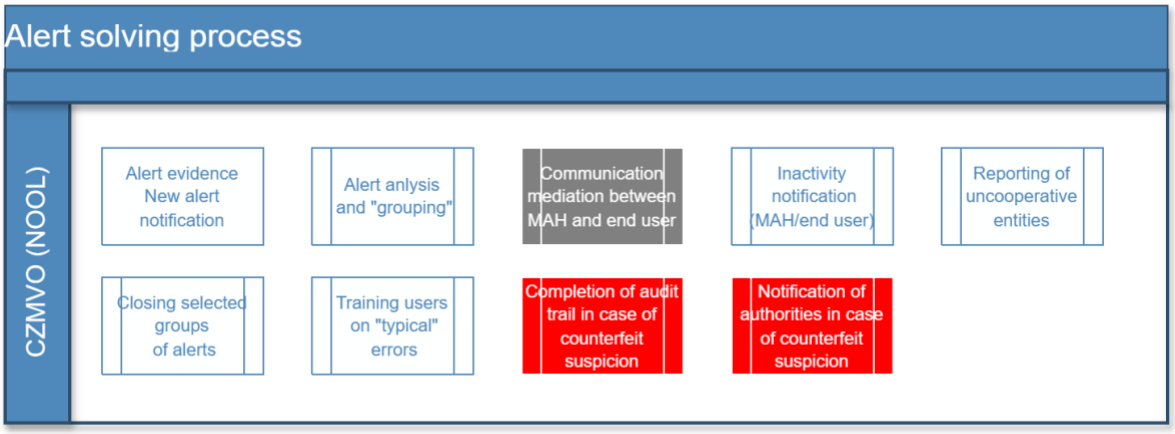
In cases where a parallel importer from another member state distributes medicinal products from the Czech Republic to another member state, the parallel importer must first deregister the pack of the medicinal product from the Czech national repository, meaning they must decommission the unique identifier of the pack. The status of the deregistered identifier will be Checked - Out. From the perspective of the MAH, in this situation, the parallel importer is considered the end user, as the transaction relates to a medicinal product that the MAH has registered in the Czech Republic. Subsequently, the pack will be repacked, and the serialized new data for the original pack will be uploaded by the parallel importer through the EU HUB into the CZMVO system.

3 The Activity of CZMVO

3.1 Alert investigation

The main responsibility of CZMVO is to ensure that alerts are properly investigated and closed. Its role is primarily to ensure the recording of alerts and the progress of investigations, as well as to provide assistance to individual participants during the investigation of alerts. This also includes sending notifications about inactivity.

In the case of a suspected counterfeit, CZMVO supports communication, ensures the completion of the audit trail, and informs and cooperates with the SIDC.



Picture 4 – The process of handling alerts for CZMVO

The following steps arise from Directive 2001/83/EC, Regulation 2016/161/EU and EMVO's instructions and recommendations. These steps are taken after the CZMVO generates an alert.

To provide for the resolution of alerts, the CZAMS has been created. The alert management system allows for the processing of alerts and provides access for MAH/OBP and end users in various ways:

- Via a **direct API communication - the user** connects their alert management system with CZAMS
- Via **the web portal** – authorized users may access alerts via a web portal
- One-time limited access to CZAMS. If MAH/OBP does not have full access to CZAMS, they will receive an e-mail once an alert is raised (limited to administration of the single alert only)

3.1.1 Alert generation

a. CZMVO receives an alert e-mail (notification) – alert level 5 generated in CZMVS.
b. Alerts in the notification are transformed into data format.
c. CZMVO checks completeness and correctness of the data message (CZMVS, EU-HUB).
d. Additional information from CZAMS is added to the data (e.g. data about the MAH/OBP, the end user, etc.).
e. The data are stored in CZAMS.

3.1.2 Alert investigation

a) Alerts are first divided into groups by MAH and alert type.
b) CZAMS performs a pre-analysis of alerts and adds the information to the individual alert, such as whether it is:
    - An MAH/OBP's transaction;
    - A parallel distributor's transaction;
    - An end user's intermarket transaction;
    - An end user's technical or procedural error;
    - A medicinal product exempted pursuant to Section 11 (r) of the Pharmaceuticals Act.
c) The result of pre-analysis is made accessible to the CZAMS user
d) CZMVO monitors the amount of alerts by end user location and contacts the end users raising a higher number of alerts. After the request for a scan check to verify whether the scanner is correctly set up, CZMVO Support team may inform the end users about the potential cause of their errors. MAHs/OBPs handle alerts directly with end users via API or the web interface and predefined messages.
e) In the case that the MAH/OBP does not respond or resolve the problem by the required deadline, the Alert Management System will inform the MAH/OBP by e-mail (after 5 and 10 days of inactivity following the day the alert was generated) or will request again the investigation result. In the case that the MAH does not cooperate for a long period (30 days and more), CZMVO will inform the SIDC about the MAH's inactivity see chapter 4.1.

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f) The MAH may request CZMVO for cooperation or send an anonymous message to the end user via API or the web interface; both the MAH and CZMVO may be prompted to cooperate during alert investigations.
g) The end user tries to identify the cause of the alert as quickly as possible and also close it if it was caused by a technical or procedural error (see Chapter 5.2). If the MAH requests additional information, such as pack photos, the end user will provide cooperation. If the end user is unsure about the correct investigation procedure or needs assistance, they can contact CZMVO.
h) CZMVO regularly monitors the status of individual alerts and proactively supports their investigation and closing.

3.1.3 Alert closing

a. Alerts are primarily investigated and closed by the end user. The MAH can intervene in the investigation of any alert and close it on their side. If the issue is on the MAH's side, for example, missing data, the alert should be closed by the MAH.

b. In case the end user intends to change the status of an alert that has been closed already, they will be asked to provide the rationale for reopening. It is possible to reopen alerts in a certain statuses only, provided that the pack has not yet been dispensed to a patient (or destroyed, exported from the EU, etc.).
It is possible to reopen the following alert statuses:
   - 06c - Closed - MAH error- Not fixed.
   - 06j - Closed - MAH transaction error - Not fixed.
   - 06k - Closed - PD error - Not fixed.

c) In the case that the MAH/OBP suspects that the investigated alert may represent a counterfeit, CZMVO will secure completion of the audit trail and identify the end user's employee and facility where the alert was generated, and inform the SIDC, the European Medicines Agency (EMA) and the European Commission (EC). CZMVO may fulfill this information duty directly or through a third party.

   CZMVO must ensure that authorities will be notified as soon as it is clear that the alert triggered in compliance with Article 36 (b) of Commission Delegated Regulation (EU) 2016/161 was not caused by technical problems in the repositories system, data uploading, verifying person, or similar technical matters (see QUESTIONS and ANSWERS of the EC to the interpretation of Commission Delegated Regulation (EU) 2016/161 – ver. 18b – question 7.17).

3.2 Supervision of CZMVO over CZMVS

CZMVO is required to establish and ensure the operation of the system for verifying the authenticity of medicinal products (CZMVS) and, among other things, to implement security procedures that ensure that only users whose identity, role, and legitimacy have been verified can access the repository (CZMVS) and upload data into it.

CZMVS is continuously monitored. Monitoring of CZMVS is accessible on the CZMVO website: https://www.czmvo.cz/en/czmvs-status/ At the same time, CZMVO must regularly conduct audits of CZMVS to verify compliance with the requirements of the FMD legislation.

In the event of critical incident indicators (e.g., an unusually large number of alert notifications from a single workplace, disproportionately high query frequency from one workplace, etc.) that could jeopardize the stability of the entire CZMVS system, CZMVO may request that the end user resolve the issue.

Note: The contract between CZMVO and end users sets forth the rights and obligations of both parties when using CZMVS. Chapter 5 of the Agreement also explicitly states the obligation to use only certified (approved by CZMVO) software solutions for communication with CZMVS. The end user bears full responsibility for any incorrect or risky functioning of the software solution with respect to CZMVS.

4 The Role of SIDC in alert investigation

The State Institute for Drug Control (SIDC) acts as the regulatory authority in the context of FMD. In this role, it supervises the compliance of individual entities and has access to the CZAMS system as an observer (viewer). This allows it to monitor all alerts throughout their lifecycle. In some cases, it may request cooperation from CZMVO in investigating alerts. In the event of confirmed counterfeit suspicion, CZMVO provides SIDC with assistance and supplies all relevant information.

SIDC also has access to CZMVO where it can generate various reports, such as audit trails, summaries of pack/batch movements and statuses, track the activities of individual entities, etc.

SIDC conducts regular inspections and local investigations at end-user sites, MAHs and CZMVO to ensure compliance with the obligations arising from FMD legislation. For end-users, SIDC checks connections to CZMVO and actively supports the use of the Alert Management System (CZAMS) and alert resolution; approach to alert resolution is also monitored during inspections at MAHs.

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4.1 Reporting of Non-Cooperating Entities to SIDC

CZMVO provides SIDC with an overview of non-cooperating entities in the alert investigation process on a monthly basis. This process encourages active involvement of the parties involved and increases the overall number of closed alerts. The report includes:

4.1.1 Reporting of Non-Cooperating MAHs

a) MAHs with a total share of closed alerts less than 50%, if at least 50 alerts have been generated for their medicinal products in the given year.
b) MAHs with a total share of closed alerts of 0%.

4.1.2 Reporting of Non-Cooperating End-Users

An end-user who, after repeated requests, has failed to provide the MAH with supplementary information necessary for investigating the alert, i.e., when the alert status is "03d - EU - MAH request - inactivity for 5 days" for more than 30 days.

5 Overview of potential scenarios during verification

a) The pack can be dispensed

The request has been successfully processed, the data in CZMVS correspond to the information in the UI on the pack, and the status of the unique identifier is Active. The authenticity of the pack is verified, and therefore it can be dispensed to the patient (‘green response’).

b) The pack cannot be dispensed, further verification is required

After scanning the 2D code, the end user will receive more detailed information about the alert, and further action will be required on their part, their software, or CZMVS. IT service providers are advised to ensure that the description explaining the cause of the alert is clear and understandable to the end user.

Examples:

- Messages notifying the end user that the medicinal product has been withdrawn or the batch has expired.
- Messages notifying the end user of issues with their software or scanner. The messages may also warn that the end user has scanned a code that is not a 2D code or that the information in the 2D code is incorrectly encoded.
- Messages notifying that the end user is about to make too many attempts to decommission (5 attempts are allowed from the same location), and that another attempt will trigger an alert.

c) The pack cannot be dispensed, counterfeit suspect.

The operator authorized to dispense the pack should not dispense it. The generated operational codes in the SW, or the error message text and possibly the error code (the so-

called operational code) displayed to the end user, inform that the pack cannot be further distributed or dispensed due to suspicion of counterfeit medicinal product.
For messages of this type, the end user will receive an alert, which will also be sent to the CZMVO and the relevant MAH/OBP.
Information about the alert is stored in the CZMVS logging system, including details about the involved users, MAH, and all information related to the medicinal product/pack.

5.1 End user technical and procedural errors

End user alerts are divided into two main groups: Technical and procedural.

5.1.1 Technical error

A technical error indicates a problem with the identification of a pack, where there is no match between the data entered into the system (via scanner or manually) and the data uploaded to the repository. The system cannot recognize the pack because at least one value of the unique identifier (PC, SN, LOT, EXP) does not match.

This may be caused by, for example, incorrect keyboard settings, low scanner quality, or an error in manual entry. A typical consequence of such an error is reading a string of characters that is too short or too long, lowercase letters, character mismatch (e.g., O/0, 3/E, l/I), or mismatch between Y/Z.

Alerts caused by technical errors:
A2 - Batch not found (Serial number is unknown. Batch was not found. An alert was triggered.)
A3 - Pack not found (Serial number is unknown. An alert was triggered.)
A68 - Batch number mismatch (The batch identifier does not match the recorded batch identifier. An alert was triggered.)
A52 - Expiry date mismatch (The expiration date does not match the recorded expiration date. An alert was triggered.)

Fixing a technical fault is relatively easy. If, upon further verification at the same location, no alert occurs and the packaging is successfully dispensed/decommissioned, the technical error has most likely been resolved in this particular case, and the original alert can be closed.

Example:
The serial number of the pack is loaded into the system with lowercase letters 'abcdefghijklmnop,' and an alert is triggered. The pharmacist or warehouse worker notices that the Caps Lock key is on. They correct the error (by turning off Caps Lock), and subsequent verification of the pack with the serial number 'ABCDEFGHIJKLMNOP' decommissions the unique identifier, and the pack is successfully decommissioned/dispensed in the system. The pharmacist can dispense the pack to the public, a wholesaler can send it further along the distribution channel, and also close the corresponding alert triggered by the Caps Lock key being pressed. The technical error has been resolved. The alert can be closed in CZAMS with the

status 06b - Closed - End User - Technical error. This status will be automatically set in CZAMS if there is a record of a successful dispense in the audit trail of the pack – see chapter 5.1.6

A technical error caused by the MAH can only be resolved by correcting the uploaded data in the repository. Until the MAH performs such a correction (i.e. the alert status changes to 06a - Closed - MAH error - Fixed, or the end user receives a message confirming that the data has been corrected), the end user should not attempt to re-verify the pack. Otherwise, another alert may be generated, as the data in the repository likely has not yet been corrected.
If the data is not corrected within 14 days from the date the original alert occurred, the end user may return the pack to the supplier according to their internal procedures.

List of End User technical errors:

- Fast scanning causes the batch number to be incorrectly merged with the GTIN or SN, or the batch number is scanned twice.
- Mismatch between Y/Z or letter case mismatch – caused by toggled Caps Lock before scanning (or pressing Shift while scanning). The Y/Z mismatch is caused by switching to a keyboard layout different from the one set for the scanner – typically between English and Czech keyboards, or sometimes between QWERTZ and QWERTY layouts.
- Scanning medicinal products with incorrectly configured scanners can result in the wrong batch number being sent (mostly due to incorrect sensor settings).
- Incorrect manual entry (e.g., 1 vs. l, O vs. 0).
- Failure to use separators causes part of the number or other characters to shift into the batch number (end-user software error).
- End-user systems convert the expiration date (e.g., 210600) to the date 210531 or 2510631 (this no longer occurs in the Czech Republic).
- Manual entry – incorrect repeated manual input of data or manual entry of the expiration date from the pack in the MM/YY format.

List of technical errors on the part of the MAH:

- Incorrectly printed code on the pack
- OBP using "Indian codes" reused a GTIN that was later used for FMD, resulting in an alert
- The manufacturer printed incorrect pack identification data in the 2D code
- The manufacturer printed incorrect pack identification data in the human-readable format
- Product pack data is missing from the repository

Regardless of whether the technical error was caused by the MAH or the end user, if the pack cannot be successfully verified, it should be placed in quarantine.

5.1.2 Procedural error

In case of a **procedural error,** the pack data has been correctly found in the repository, however, the status of the unique identifier is not active, meaning the requested transaction cannot be performed. The main cause of such errors is the execution of a repeated or unauthorized transaction. Someone is attempting to change the status of a pack that has already been dispensed or decommissioned in the system.

Alerts caused by procedural errors:

A7 – Pack already in the requested state (The message informs the user that the pack cannot be dispensed/decommissioned, or that it has already been dipsensed/decommissioned).

A24 – Status change could not be performed (The message informs the user that the pack cannot be dispensed/decommissioned, or that it has already been dispensed/decommissioned).

However, the procedural error cannot be fixed. Once the unique identifier of the pack has been decommissioned/dispensed in the system (i.e., not active), it cannot be reactivated*, and any transaction with this pack will generate an alert. In such cases, no correction can be made.

Example: A pack of a medicinal product (MP) is dispensed in CZMVS upon arrival at the facility. When the pack is dispensed to the patient, the pharmacist mistakenly tries to dispense it again in CZMVS, which triggers an alert (pack has already been dispensed).

CZAMS allows dispensation of the pack even after a procedural error by the end user (pharmacy, wholesaler), provided the investigation has been concluded and the conditions stipulated by the State Institute for Drug Control (SIDC) have been met. This solution is available in CZAMS only for the "End-User" role, only for End-User transactions, and only for unresolved alerts "A7" and "A24", where the alert is in a workflow state in which the end user can change the status or send a predefined message. The result of this solution of the process error using this tool might allow the pharmacy/wholesaler to dispense the pack immediately (without verification in CZMVS).

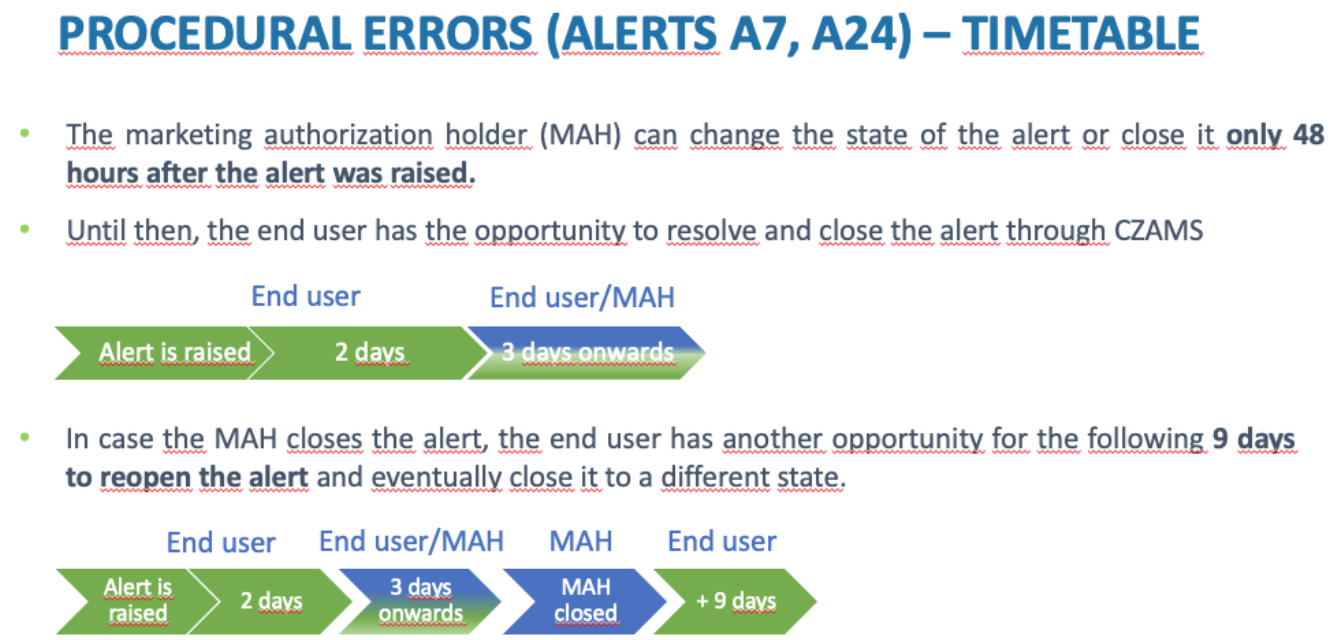
The MAH/OBP can close end-user procedural errors with the status "06f - Closed - End User process error - cannot be dispensed" after 2 days from the date the alert was raised (if the alert has not been resolved by the end user by that time). For the first 2 days after the alert is generated, the end user has time to investigate, document the cause, and provide an affidavit via CZAMS or their pharmacy/warehouse application. All necessary steps can be easily performed with just a few clicks. CZAMS will guide the end user through the process and give direction on how to handle the pack.

However, if the end user, for some reason, has not closed the alert within 2 days, the MAH/OBP can close it on their side to the status 06f - Closed - End User process error - cannot be dispensed". Once closed, the end user may reopen the alert within the next 9 days and change

the status to “06m - Closed - End User process error – the pack can be supplied” but again, only if the conditions stipulated by SIDC are met (CZAMS will give direction during the resolution of the procedural error stating that the pack can be dispensed).

If two different locations are involved in the case (the location where the alert was raised and the location where the pack was successfully decommissioned are different), CZMVO will interfere in the investigation and may also close the alert.

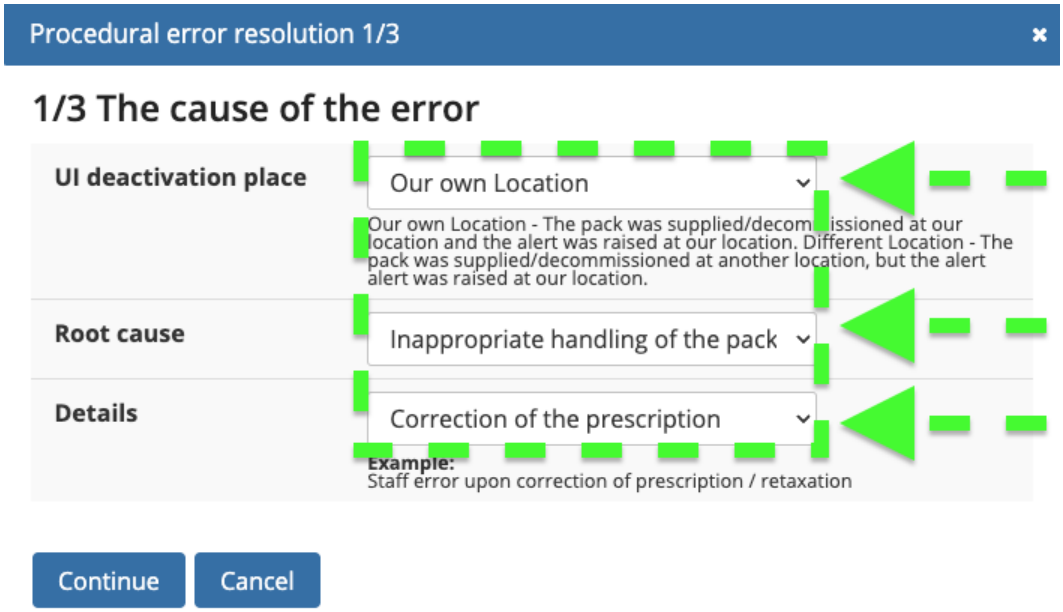
A procedural error is rarely caused by the MAH. After the product data is uploaded to the repository, each pack identifier is in the Active status and its status can be changed.



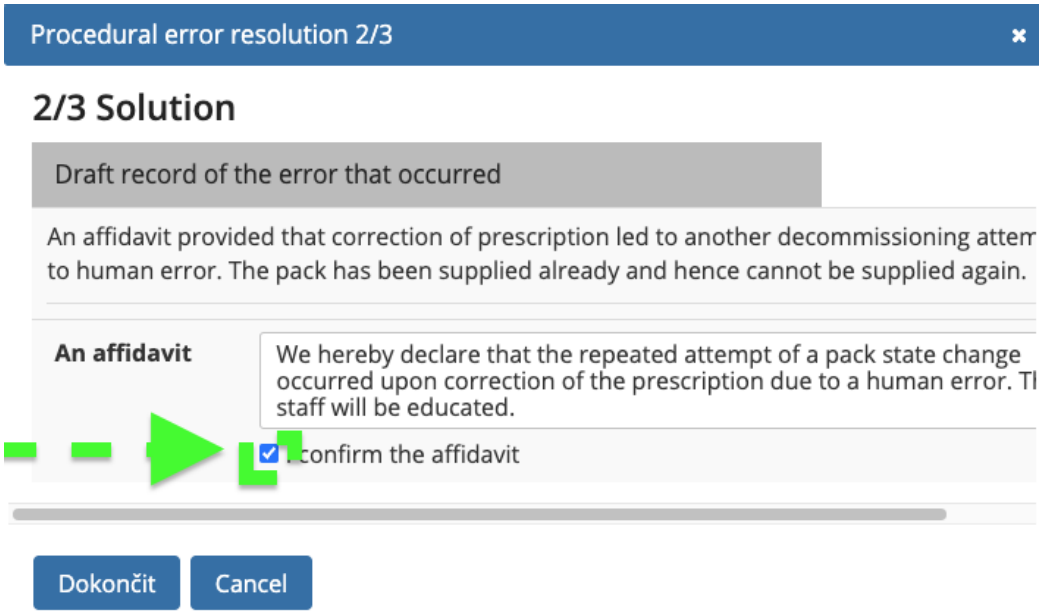
Procedural errors resolution in CZAMS

Inside an A7 or A24 alert click on „Procedural alert resolution“ button.

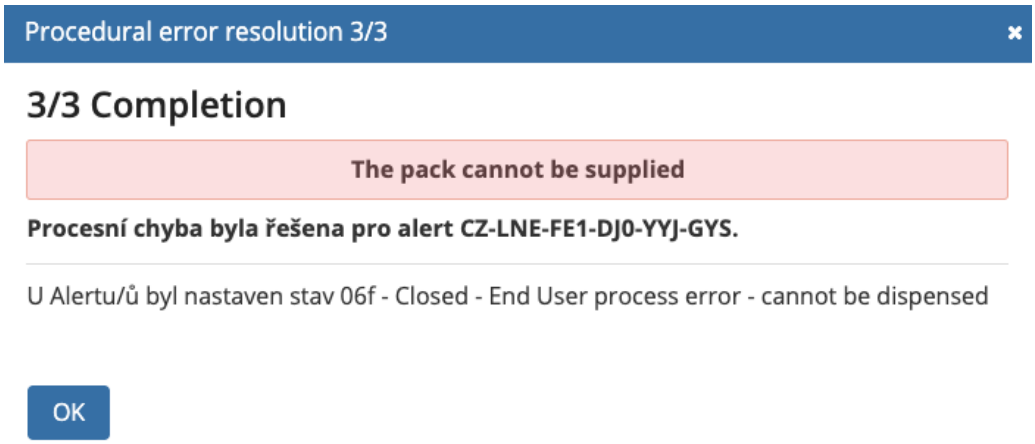
1/ In the pop-up window, the user selects from the available options “UI deactivation place”*, Root cause, and Details. (The example below displays a situation when a pharmacist mistakenly performed a repeated pack dispensation). If the field “UI deactivation place” is filled out automatically, the system was able to retrieve this information from the pack audit trail.



2/ Confirmation of the affidavit:



3/ Completion of the resolution



The alert is now closed and no action is required from either of the parties (End user, MAH, CZMVO). This procedure is the correct solution for end user in case of a procedural error. Since the exact root cause on the part of the end user cannot be determined by the MAH, the MAH is not permitted to interfere with the alert during the first 2 days from when the alert was raised.

A list of end user procedural errors.

- A repeated attempt to Supply the pack (the pack remained at the same location and was not re-activated).
- A repeated attempt of a pack state change (e.g. Supplied, Active) due to a delayed response from CZMVS.
- A repeated attempt to decommission the pack in other state than Supplied e.g. Destroyed, Stolen.
- Preparation of a compound or dispensation of a drug in parts - the pack is Supplied repeatedly.
- An attempt to Supply a pack intended for disposal(the current state of the pack is Destroyed).
- Resale between pharmacies where the selling pharmacy incorrectly marks the pack as Supplied, and the second pharmacy generates an alert when attempting to dispense it to the patient.
- Warehousing transfer between locations – the original pharmacy decommissions the pack during invoicing.
- Hospital – decommissioning upon receipt, then a request to transfer the pack to another location (within the same organization), where decommissioning occurs again.
- SW (PIS) error occurs upon correction of the prescription / retaxation / stocktaking - SW (PIS) re-executes the Supplied transaction.
- Staff error upon correction of prescription / retaxation.

- Mixing of active packs (available for dispensation) with reserved packs (set as Supplied already).
- A pack returned by the patient was erroneously mixed with active drugs in stock and anattempt to Supply the pack occurred.

A detailed table of the causes of procedural errors can be found in table on page 48.

5.1.3 Alerts raised by MAH transactions

Some alerts may also be triggered by transactions from the MAH, who communicate with CZMVO through the EU HUB. Such an alert will not appear for the Czech end user. The MAH transaction can be performed either by the MAH or by a parallel distributor, who checks out packs from the Czech warehouse for repackaging purposes.
A MAH transaction can be recognized in CZAMS by one of the following values in the Source Business Process field:

- **MAH PPD** – Uploading of the packa to the national repository (product pack data)
- **MAH PPV** – Verification of uploaded data (product pack verification)
- **MAH PPSU Request** – Request for a pack status change (product pack status update) – This source process occurs when a parallel distributor or MAH wants to change the pack status in the repository. Since neither the MAH nor the parallel distributor have access to the national repositories, the status change must be initiated by the EU Hub. The EU Hub selects one of the national repositories, where it knows the batch exists. However, if the pack status in the selected repository cannot be changed to the requested status or if the pack is not found in the repository at all, an alert will be generated.

The MAH is solely responsible for the alerts created by the MAH. The MAH should close the alert in CZAMS after identifying the cause. If there is no action taken, CZAMS will send several reminders, as described in Chapter 7.1.3.
Each new alert has the status " 01b - MAH - New - MAH/OBP/PD transaction". After completing the investigation, the MAH closes the alert with the status " 06i - Closed - MAH transaction error - Fixed." or "06j - Closed - MAH - Transaction Error - Not Fixed".
If the MAH requires assistance from CZMVO to investigate the alert, they can request it in CZAMS by using the “Send message” button within the alert.

5.1.4 Alerts raised by parallel importers

The parallel distributor mostly generates alerts A7, A24, or A3. Currently, all alerts are closed by the MAH, as the parallel distributor does not have access to CZMVO or CZAMS. If an entity generates a large number of alerts in a single day (>20), CZMVO will investigate the case, examines the audit trail of the pack, initiate communication with the parallel distributor, and inform the MAH. CZMVO will then forward the feedback from the parallel distributor to the MAH in anonymized form and prompt the MAH to close the alerts.

The MAH closes the parallel distributor's alerts with the status "06k - Closed - PD - Error - Not Fixed." This process has not yet been finalized.

5.1.5 High priority alerts

Alerts for certain medicinal products may require immediate investigation, such as products with a higher risk of counterfeiting or in the case of an acute shortage of a medicinal product on the market. CZMVO will mark the product code of such a product as a priority in CZAMS and immediately sends an e-mail to both the MAH and the end user calling for prompt action. In CZAMS, the alert will be marked in red. CZMVO will contact the end user and, after determining the root cause, will inform the MAH. Currently, CZMVO manages the list of high-priority products, but the MAH or the State Institute for Drug Control (SIDC) can also request inclusion of a product as a priority.

5.1.6 Alerts closed automatically

CZAMS automatically closes alerts in the following cases:

Exception by the Ministry of Health (MZ)

The pack of a medicinal product is part of a batch for which an exception has been granted by the Ministry of Health according to § 11 (r) of the Medicines Act. If an alert is triggered when verifying the unique identifier of such a pack, CZAMS will automatically close it with the status " 06d - Closed - MAH error - MH exception." The pack can be dispensed to the public.

Closure based on the pack audit trail

When an alert is triggered, CZAMS automatically retrieves the audit trail of the pack to check whether the pack was subsequently dispensed successfully. This action is repeated until the alert is closed by one of the involved parties or until an audit record confirming successful dispensation is generated. In such cases, CZAMS will close the alert. This procedure is applied for alerts A2, A52, and A68.

Transaction initiated by a foreign national system

If an alert is generated during such a transaction in CZMVS, CZMVO will not conduct the investigation because the affected pack is not physically located within the Czech Republic. These alerts do not require special attention.

Pack status synchronization – National System PPSU Request

In a situation where the pack status is successfully changed in a foreign national system, and the Czech Republic is one of the target markets for that batch (a so-called multimarket batch), CZMVS will synchronize the pack status. During this operation, an alert may be triggered due to communication delays between systems of different markets (alerts A7, A24) or due to MAH/OBP errors when uploading data into the repository (alert A3).

Transaction from a foreign market - National System Intermarket

If an end user from another country performs a transaction that requires communication with the Czech national repository, a regular alert may be generated in CZMVS, just as with alerts from Czech pharmacies and distributors. However, the responsibility for investigating such an alert lies with the market that holds the pack in physical form. CZMVO has access to the complete audit trail of the pack and can, if necessary, provide assistance to the market that triggered the alert. CZAMS will close the alert automatically.

The product is not subject to FMD

If CZMVO receives information (e.g. from SIDC) that a certain batch of a medicinal product, which is normally verified in accordance with the FMD, is in fact not subject to FMD and alerts are being generated, CZMVO will close each alert for the given batch with the status " 06l - Closed - Non FMD"

5.2 Level 3 alerts

In addition to the standard level 5 alerts, which indicate a potential suspicion of counterfeiting, various other warnings (alerts) are generated in CZMVS in situations where the normal process flow is disrupted. These warnings are categorized by severity into levels 1 through 5. Alerts of level 3 can also be monitored in CZAMS.

For level 3 alerts, no UPRC in the format CZ-XXX-XXX-XXX-XXX-XXX are created. The level 3 alert identifier was defined in agreement with SIDC as follows: a string of characters consisting of the prefix "CZ," the location ID, and the sequence number (e.g., CZ-ff760bfd-7704-4ddf-b77e-9db0aa2a80a6-000001).

The process for investigating level 3 alerts has not yet been finalized. Currently, all such alerts are for informational purposes only, and no investigation is required. All such alerts are therefore currently displayed only to CZMVO and SIDC users.

5.2.1 A1 alerts

These represent a warning where the product code (GTIN) of a medicinal product cannot be found in any European national repository. The MAH is not known.

5.2.2 A4 alerts

When attempting to reactivate a pack that was decommissioned more than 10 days ago, an A4 alert is generated. The pack can no longer be reactivated and is permanently decommissioned.

5.2.3 A5 alerts

If the reactivation attempt is made at a different location than the one that performed the dispense/decommission, an A5 alert is generated.

5.2.4 A8 alerts

If the pack's expiry date has passed, an A8 alert is generated. The entire batch has expired and the pack cannot be dispensed or decommissioned.

5.2.5 A9 alerts

If the entire batch of a product has been recalled for any reason, packs from this batch cannot be dispensed or decommissioned. Attempting to do so will result in an A9 alert.

5.2.6 A10 alerts

If the pack has already been decommissioned as dispensed by the same entity, it cannot be dispensed again. An A10 alert will be generated upon attempt. However, the pack can still be reactivated within 10 days of the original dispense.

5.2.7 A22 alerts

If the market performing the operation is disconnected from the EMVS, the operation cannot be completed and an A22 alert is generated. This alert has been active in CZMVS since January 1, 2025, due to the disconnection of the UK system from the EMVS.

More information on the CZMVO website: https://www.czmvo.cz/en/news/disconnecting-the-british-system-from-emvs-update/

5.2.8 A70 alerts

If an inter-market operation fails due to a foreign national repository not responding to the EU-HUB within the specified time limit, an A70 alert is generated.

6 CZAMS automatic notifications

CZAMS sends automatic notifications to MAHs end users by e-mail informing about inactivity in the following situations:

6.1 An alert has been raised

- Everytime a new alert is raised - does not concern alerts closed within the same day by 24:00

  (In case of a procedural error see 7.2.2 below, the MAH only receives 1 notification, 48 hours from the time the alert was raised.)

6.2 Alert has not been closed within the set time limit

6.2.1 Techninal errors

- In case of inactivity– Alert remains unclosed for a period of 5 days – **The alert state *„03a - MAH - unclosed alert older than 5 days“***
- In case of inactivity– Alert remains unclosed for a period of 10 days - **The alert state „03b - MAH - unclosed alert older than 10 days“**

6.2.2 Procedural errors

- In case of inactivity– Alert remains unclosed for a period of 5 days – **„03f - End User- process error - not closed 5 day“**
- In case of inactivity– Alert remains unclosed for a period of 10 days - **The alert state „03g - End User- process error - not closed 10 days“**

(The MAH only receives 1 notification, 48 hours from the time the alert was raised)

6.2.3 Alerts raised by MAH (PD) transactions

- In case of inactivity– Alert remains unclosed for a period of 5 days – **„03m MAH - MAH transaction - not closed for 5 days“**
- In case of inactivity– Alert remains unclosed for a period of 10 days - **The alert state „03n MAH - MAH transaction - not closed for 10 days“**

6.2.4 Suspension of Notifications Upon Request for Assistance

- If the end user requires assistance from CZMVO to investigate an alert (when the alert is in the state " 04b - MAH/End User - Info from CZMVO"), sending of notifications will be suspended.
- Once the end user/CZVMVO sends feedback (when the alert is in the state " 05d - CZMVO - Info to MAH"), the notification countdown will resume, and all days since the day the alert was raised will be counted.

Example:

- 10th November 2023 – An A2 alert is raised (batch not found) → Notification.
- 13th November 2023 - MAH asks the end user to provide additional information (The alert state ***„04a - MAH - info from End user "***) – *notifications to MAH paused.*
- 15th November 2023 – The end user is not responding (The alert state ***„03c - End user - MAH request - Inactivity 48 hours"***) – *notifications to MAH remain paused.*
- *17th November 2023* – The end user has provided a response (The alert state ***„05a - End user - Info to MAH"***) – *Notifications to MAH have been resumed. 7 days have passed since the alert was raised (10.11)* → *The MAH receives a notification about inactivity.*

6.3 End user fails to provide additional information to MAH

The alert states applicable for MAH if additional information is needed:

- „04b - MAH/End User - Info from CZMVO"
- „03c - End user - MAH request - Inactivity 48 hours"
- „03d - End user - Inactivity 5 days"

When investigating an alert, the MAH may require additional information, such as a photo of the pack or other clues to correctly determine the root cause. In such cases, the MAH will send a message to the end user via CZAMS, and the alert status will change to "04b - MAH/End User - Info from CZMVO". "This status means that the end user is required to provide the requested information to the MAH. All of this can be easily done in CZAMS, where photos or other documents can also be uploaded to the alert.

However, if the end user does not provide the information, CZAMS will automatically change the alert status to ESCALATION STATES "03c" and then "03d." For all three statuses, the system will send a notification to the end user.

NOTE: **All alerts that remain in the "03d" status for over 30 days are reported to SIDC.**

6.4 Unknown MAH

If an alert is generated for a medicinal product that does not have a record in the Czech national repository (CZMVS), CZAMS may not always have information about the marketing authorization holder (MAH) for that product. **As a result, the alert cannot be properly assigned to a specific MAH, investigated, or closed.**

The end user will receive an email, automatically sent from CZAMS, requesting the immediate provision of information about the MAH. The status of such an alert is "01c - Unknown MAH." The information about the MAH for the product can be entered directly into CZAMS or the CZMVO Support team can be contacted at tel.: +420 224 834 153-5, email: support@czmvo.cz.

If the end user does not respond, CZMVO will send a reminder. The status of the alert will change to "04d - CZMVO - Info from end user - MAH unknown".

WARNING: For the correct identification of the MAH, **the name of the marketing authorization holder (MAH) is required, not the name of the manufacturer or distributor.**

7 Appendices

7.1 States of the 2D code

For the verification of the medicinal product, all three data elements (PC, SN, batch) must be in the "Active" status simultaneously; otherwise, the medicinal product will always be in the "Decommissioned" status, meaning the packa cannot be verified or dispensed. The verification of individual data elements is being carried out gradually.

Table P.1 – States of a medicinal product

Product state	Description
Active	The medicinal product with the given product code is active
Withdrawn (Inactive)	The medicinal product with the given product code has been withdrawn from the market.

Table P.2 – States of a batch of a medicinal product

Batch state	Description
Active	The batch for the given medicinal product is active.
Recalled (Inactive)	The batch for the given medicinal product has been recalled.
Expired (Inactive)	The batch for the given medicinal product has expired.

Table P.3 – States of a pack of a medicinal product

Pack state	Authotized party to perform a pack state change				Description
	Pharmacy	Wholesaler	Parallel importer	MAH/OBP	
Active	YES	YES	YES	YES	The medicinal product with the given serial number can be supplied/decommissioned.
Supplied/Dispensed	YES	YES	YES	YES	The medicinal product with the given serial number has been decommissioned as Supplied. The serial number **can be re-activated within 10 days at the same location** (no limit applies for the number of re-activations).
Exported	NO	YES	YES	YES	The medicinal product with the given serial number has been decommissioned as Exported. The serial number **can be re-activated within 10 days at the same location.**
Sample	YES	YES	YES	YES	The medicinal product with the given serial number has been provided as sample to the relevant authorities. The serial number has been decommissioned but **can be re-activated within 10 days at the same location.**
Free Sample	NO	YES	YES	YES	The medicinal product with the given serial number has been provided as a free sample. The serial number has been decommissioned but **can be re-activated within 10 days at the same location.**
Locked	NO	YES	YES	YES	The medicinal product with the given serial number has been temporarily locked for further investigation or other action. The serial number **can be re-activated without any time limit** at the same location.
Destroyed	YES	YES	YES	YES	The medicinal product with the given serial number has been decommissioned as Destroyed. The serial number is **decommissioned permanently.**
Stolen	NO	YES	YES	YES	The medicinal product with the given serial number has been decommissioned as Stolen. The serial number is **decommissioned permanently.**
Checked-out	NO	NO	YES	NO	The medicinal product with the given serial number has been repacked by a parallel importer. The serial number is **decommissioned permanently.**
Re-introduction/Re-activation	YES	YES	YES	NO	The medicinal product with the given serial number has been decommissioned/supplied.. The serial number is decommissioned permanently but can be **re-activated without any time limit at the same location.**

Based on this diagram, the following responses generated in the CZMVS are available after the medicinal product verification request was sent:

Potential medicinal product statuses: GTIN return status/ Product code (PC)

- Active
- Withdrawn
- PC Not Found

Potential batch statuses: Lot return status (LOT) and expiry date (EXP)

- Active
- Batch Recalled
- Batch Code Not Found (for the concerned PC)
- Expiry Date Passed (EXP)
- The expiry date in the system differs from the expiry date when querying a specific PC/batch number

Potential pack statuses: SN return status (SN) of each pack

- Active
- Decommissioned (for any reason) or Locked = Not Active
- SN Not Found

The data elements are checked in the system in the following order: product code, serial number, batch number, expiry date. In the case that the PC is not found, the system cannot continue to check SN, LOT and EXP. In the case that a medicinal product is permitted in compliance with Section 11 (r) of the Pharmaceuticals Act, CZMVS will send the end user information that the PC was not found, but will not generate an alert and thus no investigation by CZMVO or the MAH/OBP will commence. Once the 2D code has been read and potentially compared with the data in the repository, the statutes summarized in the following two tables can occur.

Table P.4 – Statuses that do not allow to supply a medicinal product regardless of the FMD

Product code (PC)	Serial number (SN)	Batch (LOT)	Expiry date (EXP)	Action
Found	Found Active	Found	Expired	The batch is expired. Procedure according to the existing procedure.
Found	Recalled	x	x	The batch is recalled. Procedure according to the existing procedure.
Withdrawn	x	x	x	The product (all batches of the PC) is withdrawn. Procedure according to the existing procedure.
Found	Destroyed	x	x	The pack is destroyed.*
Found	Stolen	x	x	The pack is stolen.*

x – it makes no sense to verify

Active - the pack can be verified and supplied once it has been successfully verified

* A medicinal product that actually exists but is shown in the system as "Destroyed" or "Stolen" is considered a suspected counterfeit and it is necessary to initiate the investigation of the medicinal product.

Statuses in Table P.4 probably **do not indicate a counterfeit**, but the medicinal product pack **cannot be supplied** for some other reason. These statuses can be handled by using existing procedures (complaints, quality defects).

Note:

- *Recalled – a batch of a medicinal product is recalled*
- *Withdrawn – a medicinal product and all its batches are withdrawn*

Table P.5 – The status that allows to supply a pack of a medicinal product

Product code (PC)	Serial number (SN)	Batch (LOT)	Expiry date (EXP)	Action
Active	Active	Active	Active	The given transaction can be performed.

Once PC has been verified, SN, LOT and EXP are compared. In the case that SN is not found in CZMVS, it is necessary to use LOT to find SN in other national systems. In the case that LOT is not found, the system can check neither SN nor EXP, etc. (see Table P.6).

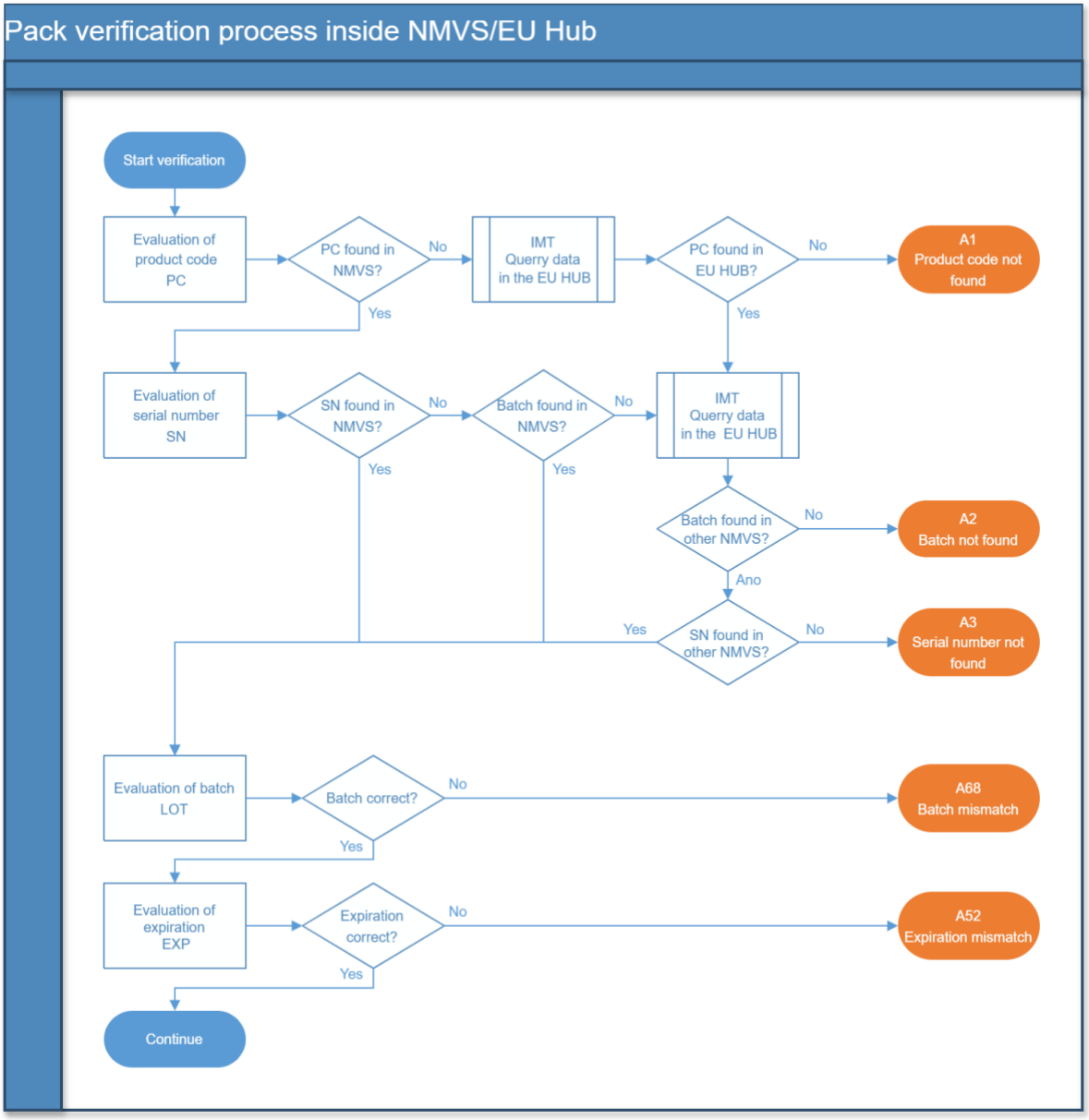
The order of verification of the individual data elements corresponds to the order of columns in Table P.6 (for illustration). In the case that a data element is not found, differs or is inactive, the data elements in the columns to the right from this data element are not verified, and the system generates an alert due to the reason specified in the description.

Table P.6 describes the statuses, based on which the system generates an alert, and thus these statuses may indicate a suspected counterfeit. In such a case, the pack of a medicinal product must be examined.

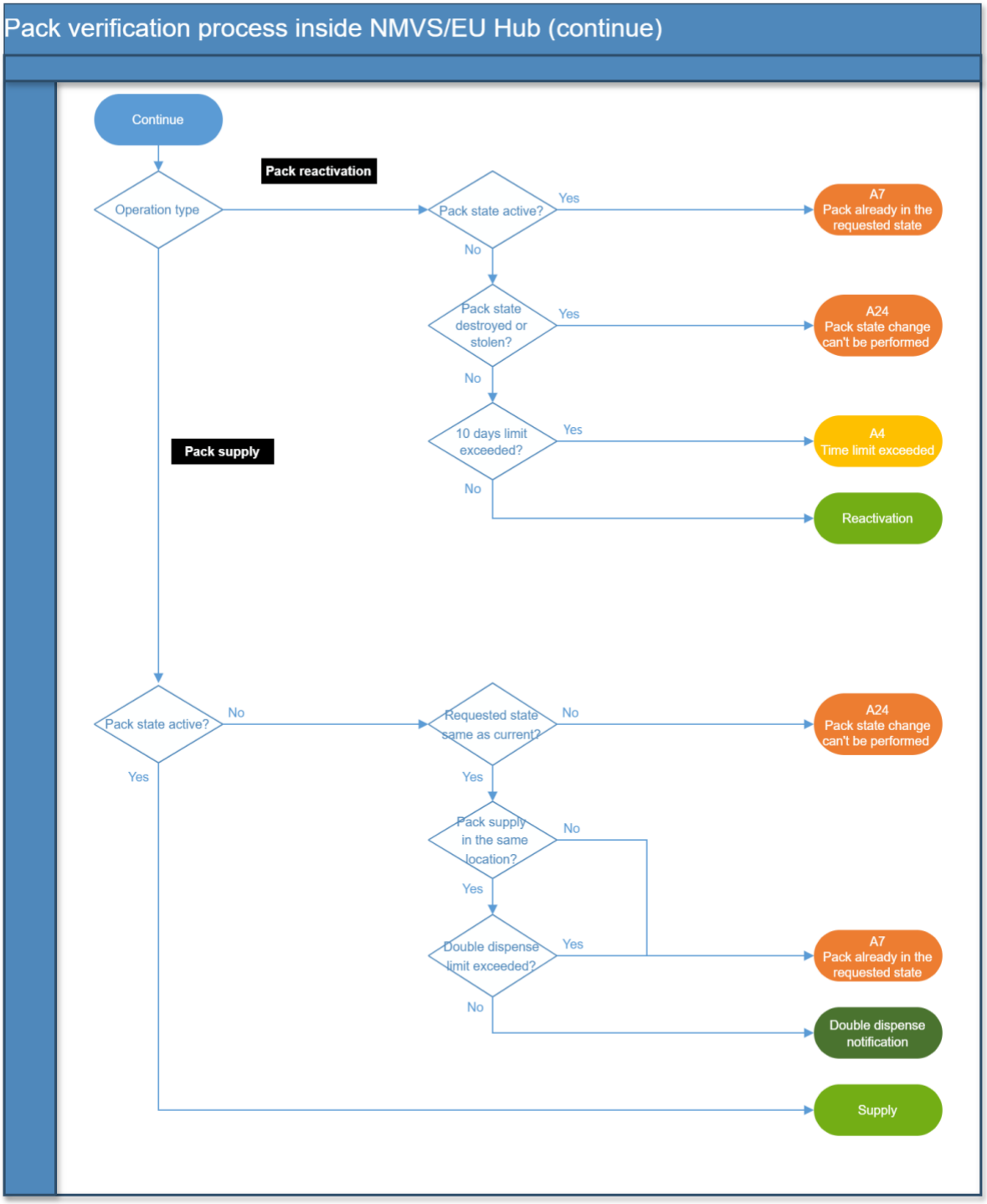
Note:

In the case that no SN is found during the second step of an intermarket transaction (IMT), the system will use LOT to search for SN in the system of another Member State. In the case that it is

still not found, CZMVS will indicate that SN was not found.



Picture 5 – The process of medicinal product verification



Picture 6 – The process of medicinal product verification (continued)

*Table P.6 – Statuses that may **indicate** "Suspected Counterfeit" and generate an alert*

Product code (PC)		Serial number (SN)		Batch (LOT)	Expiry date (EXP)	Description	Alert Code
CZMVS	EU-HUB*	CZMVS	NMVS of other country*	CZMVO NMVS**	CZMVO NMVS		
Not found	Not found	x	x	x	x	Product code not found.	A1
Found + match	x	Not found	x	Not found[1)]	x	Batch not found.	A2
Found + match	x	Not found	Not found	Found + match[3)]	x	Serial number not found.	A3
Found + match	x	Found + match	x	Different	x	Batch ID mismatch.	A68
Found + match	x	Found+ match	x	Found+ match	Different	Date expiry mismatch.	A52
Found + match	x	Found x Duplicate in bulk	x	x	x	Duplicate in bulk operation.	A32
Intermarket operation - searching for data in EU HUB and other national systems							
Not found	Found + match	x	Not found	x	x	Serial number not found.	A3
Not found	Found + match	x	x	Not found[2)]	x	Batch not found.	A2
Not found	Found + match	x	Found + match	Found+ match	Different	Date expiry mismatch.	A52
Alerts caused by an erroneous operation - upon reactivation							
Found + match	x	Found Inactive[4)]	x	Found+ match	Found+ match	Serial number is not in the Active state (see Tab 2).	A5
Found + match	x	Found Active[6)]	x	Found+ match	Found+ match	The pack is already active.	A7
Found + match	x	Found Inactive[7)]	x	Found+ match	Found+ match	Re-activation period has passed.	A4
Found + match	x	Found Inactive[8)]	x	Found+ match	Found+ match	Status change could not be performed.	A24
Alerts caused by an erroneous operation - upon Supply/Decommissioning - applicable also for IMT opearations. The verificaion would occur in a differ							
Found + match	x	Found Inactive[4)]	x	Found+ match	Found+ match	Serial number is not in the Active state (see Tab 2).	A5
Found + match	x	Found Inactive[5)]	x	Found+ match	Found+ match	Serial number is not in the Active state (see Tab 2).	A7
Found + match	x	Found Inactive	x	Found+ match	Found+ match	Status change could not be performed.	A24

x - it makes no sense to verify

[1)] SN not found in CZMVS results in identifying LOT in order to search for SN in another NMVS.

[2)] Use of an intermarket transaction, a query to EU HUB or NMVS of another Member State.

[3)] It is verified in CZMVS or NMVS of another Member State, depending on where LOT was found.

[4)] Attempt to reactivate at another location.

[5)] Supply attempt in the "Inactive" status.

[6)] Cancellation attempt (pack reactivation), but the pack has already been active.

[7)] The 10-day reactivation deadline expired.

[8)] The national system refused one or several changes in the status of a pack indicated as stolen or destroyed – these are statuses that cannot be reversed.

7.2 ALERTS – Types and causes

Table P.7 – Alert types and their causes

OC Operation code	Alert type	Identified alert causes
41020002	A2 – Batch Not Found	• Data not uploaded – the batch is missing or was incorrectly uploaded. • IMT failure (if the batch number was incorrectly entered or the batch was not found in another Member State's repository). • Incorrectly printed code on the pack. • Quick scanning causes conjunction of batch number with GTIN or SN, or the batch number is read twice. • Switched Y/Z or lower case and upper case letters – due to CAPS LOCK on before scanning (or – SHIFT on during scanning). Y/Z are switched when keyboard setting is different than that required for the scanner – in case of keyboard emulators of scanners (usually English x Czech, sometimes QWERTZ x QWERTY). • OBP with "Indian codes" uses GTIN that is later on used for the FMD, i.e. an alert is generated. • Some numbers or other characters appear in the batch number because separators were not used. • Scanning of medicinal products with incorrectly set-up scanners will send a wrong batch number (at least during scanner setting). • Incorrect manual entry (1 x l, O x 0). • System time out (the batch not found because no response was received within the required time limit). • Scanning test codes in the CZMVS production environment.
41020005	A52 – Expiry Data Mismatch	• Some numbers or other characters appear in the batch number because separators were not used. • End users' systems convert expiry dates e.g. 210600 to 210531 or 2510631 (it no longer occurs in the CR). • Manual entry – incorrect repeated manual entry of data or manual entry of expiry date from packaging in MM/RR format. • System time out (the date not verified because no response was received within the required time limit). • Manufacturer uploaded incorrect product pack data to EU Hub. • Manufacturer printed incorrect pack identification data

OC Operation code	Alert type	Identified alert causes
		into the 2D code. • Manufacturer printed incorrect pack identification data into human-readable format. • Batch number was entered instead of expiry date.
41020001 41020002 41020011 41020012	A3 – Pack Not Found	• Data not uploaded – serial numbers are missing or were incorrectly uploaded. • Some numbers or other characters appear in the serial number because separators were not used. • Switched Y/Z or lower case and upper case letters – (see comment to A2 type). • Incorrect manual entry. • Incorrectly printed code. • Quick scanning of several packs at the same time. • Part of another SN, GTIN or the batch is scanned into SN. • SN is too short (cut-off) or too long (includes some other data) or includes disallowed characters. • Unfinished/incorrect scanning – an incomplete number or the EAN code is attached to the batch number. • System time out (pack not found because no response was received within the required time limit).
41020003 41020007 41020008 41020009	A68 – Batch ID Mismatch	• Incorrectly uploaded batch number. • Some numbers or other characters appear in the batch number because separators were not used. • Quick scanning causes conjunction of several data. • Batch number was scanned twice. • Unfinished/incorrect scanning – an incomplete number or the EAN code is attached to the batch number. • Switched Y/Z or lower case and upper case letters – due to CAPS LOCK on before scanning (or – SHIFT on during scanning). Y/Z are switched when keyboard setting is different than that required for scanner – in case of keyboard emulators of scanners (usually English x Czech, sometimes QWERTZ x QWERTY). • Incorrect manual entry (1 x l, O x 0).
	A7 – Pack Already in Requested State	• Data re-upload of already distributed packs by the MAH. • Double transaction or incorrect pack decommissioning to incorrect status by mistake. • Incorrect internal marking and classification of a pack due

OC Operation code	Alert type	Identified alert causes
51220200 51220201 51220202 51420100 51420101 51421000 51421100 51421200 51320300 51320301 51320400 51320401 51320500 51320501 51320600 51320601 51320700 51320701 51320800 51320801		to misunderstanding. • Resale between pharmacies where the selling pharmacy incorrectly decommissions a pack to the "Supplied" status and the other pharmacy generates an alert when dispensing the pack to a patient. • OBP tries to change the pack status of an already decommissioned unique identifier ("sample to sample"). • Errors that lead to a re-sending request. • System time out.
51220000 51220300 51220301 51220400 51220401 51220500 51220501 51220600 51220601 51220700 51220701 51220800 51220801 51220900 51320000 51320200 51320201 51320900 51420000 51420300 51420301 51420400 51420401 51320300	A24 – Status Change Could Not Be Performed	• OBP tries to decommission an already decommissioned 2D code. • Attempt to double decommission by the end user – already decommissioned pack. • Attempt to decommission an already inactive or expired pack. • Incorrect internal marking and classification of a pack due to misunderstanding.

OC Operation code	Alert type	Identified alert causes
51320301 51320400 51320401 51320500 51320501 51320600 51320601 51320700 51320701 51320800 51320801		
61020015	A32 – Duplicite Pack Identifiers	• Bulk query – duplicite SN in a batch.
Level 3 alerts		
41020000	A1 – Product code unknown,	• Product code not uploaded into the EMVS. • Product Master Data (PMD) not uploaded or transmitted to CZMVS. • Product codes are not in compliance with national coding requirements (NTIN instead of GTIN). • Scanned medicinal products do not fall under the FMD ("Indian codes," "medical devices"). • Incorrect manual entry. • Scanning of the 2D code on a box or pallet.
51420200 51420002	A4 – Time limit exceeded	• 10-day re-activation period has passed
51420201 51420500	A5 – Attempted undo by a different party	• A different entity than the one that originally decommissioned the pack attempts to reactivate it.
51221000 51321000	A8 – Pack Expired	• The pack expiry date has passed.
51321100	A9 – Pack on recall	• The batch has been recalled
11220200 11220201 11320400	A10 – Pack already dispensed	• The pack has been already decommissioned supplied by the same location

OC Operation code	Alert type	Identified alert causes
11320500 11320800		
B1020001	A22 – Market not found	• The national repository responsible for verifying or decommissioning the pack has been disconnected from the EMVS
B1020000	A70 – System unavailable	• The national repository responsible for verifying or decommissioning the pack is unavailable. Intermarket operation error

7.3 Alert pre-analysis

During the alert pre-analysis phase, CZMVO will provide information about the alert for further investigation and offer potential causes in CZAMS.

Table P.8 – Alert pre-analysis – a list of potential findings and additional information about alerts

Name	Description of situation evaluated during pre-analysis	Alert handling options – MAH
EUT - Date	Presumably an incorrect expiration dat value provided.	MAH/OBP proceeds to investigate and resolve the alert in cooperation with the end user (either confirms the root cause or identifies a different one) or the alert can be closed directly by the end user using the state 06b - Closed - End User - Technical error. The pack must be verified prior to dispensation.
EUT - Long string in Serial number	Presumably an incorrect scanner settir / long character string in Serial number.	MAH/OBP proceeds to investigate and resolve the alert in cooperation with the end user (either confirms the root cause or identifies a different one) or the alert can be closed directly by the end user using the state 06b - Closed - End User - Technical error. The pack must be verified prior to dispensation.
EUT - Caps Lock	Presumably a keyboard setup error (CapsLock).	MAH/OBP proceeds to investigate and resolve the alert in cooperation with the end user (either confirms the root cause or identifies a different one) or the alert can be closed directly by the end user using the state 06b - Closed -

Name	Description of situation evaluated during pre-analysis	Alert handling options – MAH
		End User - Technical error. The pack must be verified prior to dispensation.
EUT - EN/CZ	Presumably an incorrect keyboard language setting (EN/CZ).	MAH/OBP proceeds to investigate and resolve the alert in cooperation with the end user (either confirms the root cause or identifies a different one) or the alert can be closed directly by the end user using the state 06b - Closed - End User - Technical error. The pack must be verified prior to dispensation.
EUT - Short character string in Serial number	Presumably an incorrect scanner setting / short character string in Serial number).	MAH/OBP proceeds to investigate and resolve the alert in cooperation with the end user (either confirms the root cause or identifies a different one) or the alert can be closed directly by the end user using the state 06b - Closed - End User - Technical error. The pack must be verified prior to dispensation.
EUT – Incorrect length and SN format	Presumably an incorrect scanner setting.	MAH/OBP proceeds to investigate and resolve the alert in cooperation with the end user (either confirms the root cause or identifies a different one) or the alert can be closed directly by the end user using the state 06b - Closed - End User - Technical error. The pack must be verified prior to dispensation.
EUT - Character mismatch	End user error - technical. Presumably a character mismatch (O/0,E/3,I/L,...) due to a lower quality scanner.	MAH/OBP proceeds to investigate and resolve the alert in cooperation with the end user (either confirms the root cause or identifies a different one) or the alert can be closed directly by the end user using the state 06b - Closed - End User - Technical error. The pack must be verified prior to dispensation.
EUT - Fixed, supplied	According to the audit trail, the pac was subsequently successfully verified and supplied.	The alert was closed automatically based on the pack audit trail. No further action required to be taken by MAH/OBP.
EUT - Duplication in bulk operation	Presumably a duplicate Serial number in bulk transaction.	The MAH/OBP can close the alert using the state 06b - Closed - End User - Technical error
EUP - Repeated	A repeated pack state change request that occurred on the same location	The end user will provide explanation of the alert root cause selecting the appropriate options

Name	Description of situation evaluated during pre-analysis	Alert handling options – MAH
	where the pack state was previously changed successfully.	from the drop-down list in the CZAMS. The end user will document the case and confirm the affidavit. If the end user does not close the alert within 48 hours from the alert date, it will be opened for MAH/OBP to close it on their side.
EUP - Repeated- This location	A repeated pack state change request that occurred on the same location where the pack state was previously changed successfully.	The end user will provide explanation of the alert root cause selecting the appropriate options from the drop-down list in the CZAMS. The end user will document the case and confirm the affidavit. If the end user does not close the alert within 48 hours from the alert date, it will be opened for MAH/OBP to close it on their side.
EUP – Repeated– Other location	A repeated pack state change request that did not occur at the same location, i.e. the pack state was previously changed successfully at a different location.	The end user will provide explanation of the alert root cause selecting the appropriate options from the drop-down list in the CZAMS. The end user will document the case and confirm the affidavit. If the end user does not close the alert within 48 hours from the alert date, it will be opened for MAH/OBP to close it on their side.
EUP - Unauthorized	An unauthorized pack state change request. The system cannot determine whether the successful pack state change occurred at the same location, or a different location.	The end user will provide explanation of the alert root cause selecting the appropriate options from the drop-down list in the CZAMS. The end user will document the case and confirm the affidavit. If the end user does not close the alert within 48 hours from the alert date, it will be opened for MAH/OBP to close it on their side.
EUP - Unauthorized - This location	An unauthorized pack state change request that occurred on the same location where the pack state was previously changed successfully.	The end user will provide explanation of the alert root cause selecting the appropriate options from the drop-down list in the CZAMS. The end user will document the case and confirm the affidavit. If the end user does not close the alert within 48 hours from the alert date, it will be opened for MAH/OBP to close it on their side.
EUP - Unauthorized - Other location	An unauthorized pack state change request that did not occur at the same location, i.e. the pack state was previously changed successfully at a different location.	The end user will provide explanation of the alert root cause selecting the appropriate options from the drop-down list in the CZAMS. The end user will document the case and confirm the affidavit. If the end user does not close the alert within 48 hours from the alert date, it will be opened for MAH/OBP to close it on their side.
MAH - Batch is not uploaded in CZMVS	MAH/OBP error. Presumably the batch number does not exist in CZMVS (data is missing because the batch is not uploaded).	MAH will check the uploaded data and eventually perform a corrective action. If the error is indeed caused by MAH/OBP, the alert can be closed using the state 06a - Closed - MAH error – Fixed

Name	Description of situation evaluated during pre-analysis	Alert handling options – MAH
		or 06c - Closed - MAH error- Not fixed.
PSUN - MAH	MAH error - PSUN transaction - unrecorded data or uploaded in a wrong version	Alert will be closed automatically in CZAMS.
EU – N/A	End user transaction, pre-analysis did not determine the cause - suspected MAH error (incorrect or unloaded data, 2D printing error) or counterfeit.	MAH/OBP to check the uploaded data. A possible 2D printing error or a counterfeit.
MAH – Randomization	The serial number does not meet the required randomization criteria.	A54 alert (insufficient randomization of the serial number) has been closed automatically. MAH/OBP should revise the data upload process.
MAH - exception 11r	MAH error - Exception granted by the Ministry of Health as per Act No. 378/2007 Coll., on Pharmaceuticals, article 11r.	MAH/OBP can close the alert using the state „06d - Closed - MAH error - MH exception ". The alert can also be closed by CZMVO in CZAMS.
NMVS Error - Synchronization issue	NMVS Error - Synchronization issue (PSUN transaction, alert raised outside of CZ).	Alert will be closed automatically in CZAMS
EU – Not subject to FMD	Although the pack bears a 2D matrix code, it does not fall within the scope of the FMD.	Alert will be closed automatically in CZAMS.

7.4 Alert statuses in the Alert Management System (CZAMS)

In the Alert Management System, individual statuses are defined as part of the resolution process for alerts generated in CZMVO. The alert status code list describes the various parts of the alert resolution process from the perspective of all users of the Alert Management System (CZAMS), as well as the automated steps defined within the process.
Each status has a specific designation, consisting of a **status number** (e.g. 01d, 04a, 06m…) and a **status name** (e.g. Unknown MAH, MAH requested additional information from the end user, Closed – End user process error…). The status name is shortened as much as possible to allow it to be displayed when using filters in CZAMS.

A full description of each alert status is available in CZAMS under the **Resolution** tab.

Alert statuses in CZAMS are grouped according to the phase of the alert resolution process:

- New alert statuses
- Ongoing alert statuses
- Escalation alert statuses
- Closing alert statuses

7.4.1 New alert statuses

Alert status	Alert status visible to		Recommended solution	
	End user	MAH	End user	MAH
• 01a - New - End User transaction • 01aa - New - End User transaction - One time	YES	YES	If the verification of a medicinal product pack fails and an alert is generated, the end user should keep the pack in quarantine until the investigation is completed. The probable cause is displayed in the field "Pre-analysis – automatic". **Technical error:** If the error is clear and has been corrected, you may attempt to verify the pack again. If the verification is successful, the pack can be dispensed, and the alert can be closed with the status 06b - Closed - End User - Technical error, see the table *Closing alert statuses below*. **More details in chapter *5.1.1.*** **Procedural error:** If the cause is known, the alert can be closed by selecting the appropriate option in CZAMS. **More details in chapter *5.1.2.*** If the end user does not identify a technical or procedural error, the pack should remain in quarantine, and the end user should wait for the alert to be closed by the MAH. If the cause is not identified within 14 days from when the alert was generated, the end user may return the pack to the supplier in accordance with internal procedures.	As soon as the MAH/OBP receives information about the generation of an alert, they should immediately begin investigating the possible cause of the alert. **If the error is on the side of the MAH (e.g. missing uploaded data), corrective action should be taken as quickly as possible.** If the error is clearly on the part of the end user, the alert can be closed with the status 06b – Closed – End User Technical error. **See chapter *5.1.1.* for more details.** If the alert was caused by a technical or process error on the part of the end user (**see chapter 5.1**), the end user can close the alert themselves. If the end user does not identify such an error, the pack should remain in quarantine and the end user should wait for the alert to be closed by the MAH. The MAH may request additional information from the end user, such as a photo of the pack or a scan – see status 04a in the table *Ongoing alert statuses* below. **If the root cause is not identified within 14 days of the alert being generated, the end user may return the pack to the supplier.**
•01b - MAH - New - MAH/OBP/PD transaction	NO	YES	MAH transaction	The alert was triggered by a MAH or PD transaction. As soon as the MAH/OBP receives information about the alert, they should immediately begin investigating the possible cause of the alert. MAH may also request assistance from CZMVO (see status 04f in the table *Ongoing alert statuses* below).
•01c - Unknown MAH	YES	NO	Product information is not available in CZMVS. The MAH is unknown. The alert cannot currently be closed in CZAMS. Please provide CZMVO with information about the MAH as soon as possible. You can, for example, send a photo of the pack using the "Send message to CZMVO" option in CZAMS. If the error was technical and you have fixed it, you may try verifying the pack again. **However, until the MAH is allocated, the alert cannot be closed.**	At this moment, the alert is not assigned to any MAH.
•01d - Exception Level 3	NO	NO	Level 3 alerts are currently not displayed to end users or MAHs. See Chapter 5.2 for more details.	Level 3 alerts are currently not displayed to end users or MAHs. See Chapter 5.2

7.4.2 Ongoing alert statuses

Alert status	Alert status visible to		Recommended solution	
	End user	MAH	End user	MAH
•02a - Investigation - End user transaction	YES	YES	The alert is being handled by the MAH. **Keep the medicinal product pack in quarantine until the investigation is completed**. For next steps, see statuses 01a and 01aa in the New Alert Statuses table above.	By setting this status, the MAH informs the CZAMS system that it is handling the alert. This means that in the case of a longer resolution time, the MAH will not receive escalation emails (after 5 or 10 days of inactivity) – see the Alert Escalation Alert Statuses table below. For next steps, see statuses 01a and 01aa in the New Alert Statuses table above.
•02b - MAH - Investigation - MAH/OBP/PD transaction	NO	YES	MAH transaction.	The alert was triggered by a MAH or PD transaction. By setting this status, the MAH informs CZAMS that it is handling the alert, and will not receive escalation emails (after 5 or 10 days of inactivity) – see the Escalation Alert Statuses table below. For next steps, see status 01b in the New Alert Statuses table above.
•04a - MAH - info from End user	YES	YES	MAH is requesting additional information. Details can be found in the text message or in the message attachment. Please respond promptly. **The end user should keep the pack in quarantine until the investigation is completed.** If a technical error was fixed or the root cause of a procedural error is known, the alert can be closed – see statuses 01a and 01aa in the the New Alert Statuses table above.	The end user has received a request for additional information. In case of inactivity, the alert will be escalated – see the Alert Escalation Statuses table below. If the issue was caused by a technical or procedural error on the part of the end user (**see chapter 5.1**), the end user may close the alert on their own.
•04b - MAH/End User - Info from CZMVO	YES	YES	MAH or end user is requesting additional information from CZMVO, or mediation of anonymized information to the other party. If a technical error was fixed or the root cause of a procedural error is known, the alert can be closed – see statuses 01a and 01aa in the New Alert Statuses table above.	MAH or end user is requesting additional information from CZMVO, or mediation of anonymized information to the other party. MAH has already reviewed the data uploaded to CZMVS and possible causes of the alert. If the issue was caused by a technical or procedural error on the part of the end user (**see chapter 5.1**), the end user may close the alert on their own.
•04d - CZMVO - Info from end user - MAH unknown	YES	NO	CZMVO repeatedly requests the end user to provide information about the MAH. For next steps, see status 01c in the New Alert Statuses table above.	At this time, the alert is not assigned to any MAH.
•04f - MAH information from CZMVO - PD transaction	NO	YES	MAH transaction	The alert was triggered by a MAH or PD transaction. MAH is requesting additional information from CZMVO, or anonymized information from the PD. MAH has already reviewed the data uploaded to CZMVS and the possible causes of the alert.

•05a - End user - Info to MAH	YES	YES	The end user has forwarded information to the MAH and is waiting for a response. If a technical error was fixed or the root cause of a procedural error is known, the alert can be closed – see statuses 01a and 01aa in the New Alert Statuses table above.	The end user has forwarded information to the MAH and is waiting for a response. If the issue was caused by a technical or procedural error on the part of the end user (**see chapter 5.1**), the end user may close the alert on their own.
•05c - CZMVO - Info End user to MAH •05d - CZMVO - Info to MAH/End User	YES	YES	CZMVO has forwarded information to the end user or MAH. If a technical error was fixed or the root cause of a procedural error is known, the alert can be closed – see statuses 01a and 01aa in the New Alert Statuses table above.	CZMVO has forwarded the information to the end user or MAH. If the issue was caused by a technical or procedural error on the part of the end user (**see chapter 5.1**), the end user may close the alert on their own.
•05f - CZMVO - infromation to MAH - PD transaction •05g - CZMVO - infromation to MAH - MAH/OBP transaction	NO	YES	MAH transaction.	The alert was triggered by a MAH or PD transaction. CZMVO has provided additional information or mediated anonymized information from the PD. MAH has already reviewed the data uploaded to CZMVS and the possible causes of the alert.

7.4.3 Escalation alert statuses

Alert status	Alert status visible to		Recommended solution	
	End user	MAH	End user	MAH
•03a - MAH/End User - unclosed alert older than 5 days •03b - MAH/End User - unclosed alert older than 10 days	YES	YES	The alert was not investigated within the specified time frame (remained in status 01a or 01aa), and therefore a notification was sent to both the end user and the MAH. For further steps see status 01a and 01aa in the New Alert Statuses table above. If the root cause is not identified within 14 days of the alert's creation, the end user may return the pack to the distributor according to its internal procedures.	The alert was not investigated within the specified time frame (remained in status 01a or 01aa), and therefore a notification was sent to both the end user and the MAH. For further steps see status 01a and 01aa in the New Alert Statuses table above. If the root cause is not identified within 14 days of the alert's creation, the end user may return the pack to the supplier.
•03c - End user - MAH request - Inactivity 48 hours •03d - End user - Inactivity 5 days	YES	YES	The MAH requested additional information, but the end user did not provide any within the specified time frame. A notification was sent to the end user. Further steps: see status 04a in the *Ongoing alert statuses* table above. **Note:** After more than 14 days of inactivity, the MAH may close the alert as status 06o (see the *Closing alert statuses* table below). **In such case, the end user will be reported to the State Institute for Drug Control (SÚKL).**	The end user received a request for additional information and was notified of inactivity. After more than 14 days of inactivity, you may close the alert as status 06o (see the *Closing alert statuses* table below). In such case, the end user will be reported to the State Institute for Drug Control (SÚKL). If the error was due to a technical or procedural error of the end user (**see Chapter 5.1**), the end user may close the alert on their own.
•03f - End User- process error - not closed 5 day •03g - End User- process error - not closed 10 days	YES	YES	The alert, which originated due to a procedural error, was not closed within the specified time frame. If the cause is known, the alert can be closed in CZAMS by selecting the appropriate option (**see Chapter 5.1.2**).	The alert, which originated due to a process error (**see Chapter 5.1.2**), was not closed within the specified time frame. Further steps: see status 01a and 01aa in the New Alert Statuses table above.

•03m MAH - MAH transaction - not closed for 5 days •03n - MAH - MAH transaction - not closed for 10 days	NO	YES	MAH transaction.	The alert was generated by an MAH or PD transaction and was not closed within the specified time frame. A notification was sent to the MAH. Further steps: see status 01b in the New Alert Statuses table above.

7.4.4 Closing alert statuses

Alert status	Alert visible to		Recommended solution	
	End user	MAH	End user	MAH
•06a - Closed - MAH error - Fixed	YES	YES	The alert was caused by an error on the part of the MAH, and the error has been corrected. After successful verification, the pack may be dispensed. **If verification fails again:** a) If less than 14 days have passed since the original alert, place the pack back into quarantine with a new UPRC alert. b) If more than 14 days have passed, return the pack to the supplier.	The MAH identified and corrected one of the following issues: -Missing or incorrectly uploaded Product Pack Data (serial number, batch number, expiration date). Once the MAH ensures the data correction, the end user may verify the pack again and dispense it upon successful transaction. **If verification still fails after correction, the end user may return the pack to the supplier after 14 days from the alert's creation.**
•06b - Closed - End User - Technical error	YES	YES	The alert was closed by the end user or MAH due to a technical error on the part of the end user (see status 01a and 01aa in the New Alert Statuses table above). The alert could also have been closed automatically based on a successful dispensing record in the pack audit trail (**see Chapter 5.1.6**).	The alert was closed by the end user or MAH due to a technical error on the part of the end user (see status 01a and 01aa in the New Alert Statuses table above). The alert could also have been closed automatically based on a successful dispensing record in the pack audit trail (**see Chapter 5.1.6**).
•06c - Closed - MAH error- Not fixed.	YES	YES	The alert was caused by an MAH error that cannot be corrected. **See Chapter *5.1.1.*** for more information. The pack cannot be re-verified (a new alert would be generated) and **must not be dispensed to the public**. Return the pack to the supplier with the alert ID attached.	The MAH identified one of the following uncorrectable causes: -Missing or incorrectly uploaded Product Pack Data (serial number, batch number, expiration date). **See Chapter *5.1.1.* The pack must not be dispensed to the public**. The end user may return the pack to the supplier.
•06d - Closed - MAH error - MH exception	YES	YES	An exemption was granted by the Ministry of Health (MH) for the affected batch of the medicinal product in accordance with § 11 letter r) of the Medicines Act. The alert is automatically closed (**see Chapter 5.1.6**). **The pack may be dispensed to the public.**	An exemption was granted by the Ministry of Health (MH) for the affected batch of the medicinal product in accordance with § 11 letter r) of the Medicines Act. The alert is automatically closed (**see Chapter 5.1.6**). **The pack may be dispensed to the public.**
•06f - Closed - End User process error - cannot be dispensed	YES	YES	The alert was close by the end user or MAH and originated from the end user procedural error. **More information in 5.1.2. The pack must not be dispensed to the public.**	The alert was closed by the end user or MAH and originated from the end user procedural error. **See Chapter 5.1.2.**The pack must not be dispensed to the public.
•06g - Closed - NMVS error	YES	YES	The alert originated due to a CZMVO error, e.g. as a result of a slow response.	The alert was caused by synchronization issues between pack statuses across national markets (**see Chapter 5.1.6**).

•06h - Suspected Counterfeit!	YES	YES	The alert was marked by the end user or MAH as a suspected falsification. All possible technical or procedural errors have been ruled out. Keep the pack in quarantine. CZMVO will contact both the MAH and end user. If falsification is confirmed, SIDC, EMVO, EMA, and the European Commission will be informed (see status 07a below).	The alert was marked by the end user or MAH as a suspected falsification. All possible technical or procedural errors have been ruled out. Keep the pack in quarantine.CZMVO will contact both the MAH and end user. If falsification is confirmed, SIDC, EMVO, EMA, and the European Commission will be informed (see status 07a below).
•06i - Closed - MAH transaction error - Fixed.	NO	YES	MAH transaction.	The alert originated from an MAH or PD transaction. Missing or incorrectly uploaded Product Pack Data (serial number, batch number, expiration date). The error was corrected.
•06j - Closed - MAH transaction error - Not fixed.	NO	YES	MAH transaction	The alert originated from an MAH or PD transaction. Missing or incorrectly uploaded Product Pack Data (serial number, batch number, expiration date). The error cannot be corrected.
•06k - Closed - PD error - Not fixed.	NO	YES	MAH transaction	The MAH closed the alert as an error on the part of the PD.
•06l - Closed - Non FMD	YES	YES	The medicinal product is not subject to FMD. **The pack may be dispensed to the public.** If the end user or MAH determines that the batch of the medicinal product is not subject to FMD, the alert may be closed under this status. This status may also be set automatically (CZMVO has information that the batch is not subject to FMD) – **see Chapter 5.1.6**	The medicinal product is not subject to FMD. **The pack may be dispensed to the public.** If the end user or MAH determines that the batch of the medicinal product is not subject to FMD, the alert may be closed under this status. This status may also be set automatically (CZMVO has information that the batch is not subject to FMD) **– see Chapter 5.1.6.**
•06m - Closed - End User process error – the pack can be supplied	YES	YES	The end user selected the cause of the procedural error (**see chapter 5.1.2.**) from the options provided in CZAMS and confirmed an affidavit. **The pack may be dispensed to the public.**	The end user selected the cause of the procedural error (**see chapter 5.1.2.**) from the options provided in CZAMS and confirmed an affidavit. **The pack may be dispensed to the public.** The confirmed cause can be found in the alert details.
•06n - IMT Fullfilling	NO	YES	Transaction by end user on another market (outside the Czech Republic).	The alert was triggered by an intermarket transaction. The end user on another market (outside CZ) attempted to verify or change the status of a pack for which data is not available in that market. The alert is closed automatically – **see Chapter 5.1.6.**
•06o - Closed - End User does not cooperate - cannot be supplied	YES	YES	The alert was closed by the MAH due to non-cooperation by the end user (see status 03d in the Escalation Alert Statuses table above). **The pack must not be dispensed to the public. The end user will be reported to SIDC.**	The alert was closed by the MAH due to non-cooperation by the end user (see status 03d in the Escalation Alert Statuses table above). The pack must not be dispensed to the public. The end user will be reported to SIDC.
•06z - Closed - Unclosed level 5 alert created before year	YES	YES	The alert was created more than 365 days ago and was not closed by either the end user or MAH. CZMVO closed the alert automatically based on an agreement between SIDC and CZMVO.	The alert was created more than 365 days ago and was not closed by either the end user or MAH. CZMVO closed the alert automatically based on an agreement between SIDC and CZMVO
•07a - Closed - Counterfeit! Info passed	YES	YES	The counterfeit was confirmed. CZMVO forwarded the information to SIDC, EMVO, EMA, and the European Commission.	The counterfeit was confirmed. CZMVO forwarded the information to SIDC, EMVO, EMA, and the European Commission.

7.5 List of end user procedural errors

Root cause	Details	Examples	Dispensation of the pack to the public
Delayed system response	**Your own text (optional)**	A repeated attempt of a pack state	can be supplied
Pharmacy information system (PIS) error	**Correction of the prescription**	SW (PIS) error occurs upon correction of the prescription / retaxation / stocktaking - SW (PIS) re-executes the Supplied transaction.	cannot be supplied!
	Your own text (mandatory)	Other error caused by pharmacy information system (PIS)	can be supplied
Inappropriate handling of the pack	**Pack state not verified prior to the transaction**	A repeated attempt to Supply the pack (the pack remained at the same location and was not re-activated)	can be supplied
		A repeated attempt to reactivate the pack as a result of a human error	can be supplied
		A repeated attempt to decommission the pack in other state than Supplied e.g. Destroyed, Stolen.	cannot be supplied!
		Preparation of a compound or dispensation of a drug in parts - the pack is Supplied repeatedly.	can be supplied
	Correction of the prescription	Staff error upon correction of prescription / retaxation	cannot be supplied!
	Stocking error	Mixing of active packs (available for dispensation) with reserved packs (set as Supplied already)	can be supplied
		An attempt to Supply a pack intended for disposal(the current state of the pack is Destroyed)	cannot be supplied!
		An attempt to Supply a pack set to Destroyed state accidentally. The pack is NOT intended for disposal and the Destroyed state was set by error. Any attempt to supply the pack will hence raise an alert	can be supplied
	Returned pack	An attempt to set a pack returned by the patient to Destroyed (the current state is Supplied)	cannot be supplied!
		A pack returned by the patient was erroneously mixed with active drugs in stock and an attempt to Supply the pack occurred. (Illegal activity!)	cannot be supplied!
	Pack transferred outside of the current location	The pack was transferred between locations of the same organization and decommissioned by the originating location.	
		The pack brought in by the patient was mistakenly decommisioned during the prescription correction/retaxation.	
		The pack of the medicinal product was incorrectly decommissioned as "Dispensed" by the distributor, in violation of Article 23 of Regulation (EU) 2016/161. A repeated attempt to dispense the product by the hospital/pharmacy triggered an alert.	
		Emergency alert raised in a district hospital - the pack was already set to Supplied by the regional hospital and the district hospital re-attempts to Supply the pack.	
		The pack was transferred between locations of a different organization and decommissioned by the originating location.	cannot be supplied!