Národní organizace
pro ověřování
pravosti léčiv

NOOL ALERT MANAGEMENT SYSTEM
ONE-TIME ACCESS GUIDE

User manual for marketing authorization holders MAH/On-boarding partners OBP

Release 7.0

19th October 2023

INTRODUCTION

Audience

This manual is intended for MAH's/OBP's which **are not provisioned** in the alert Management System (AMS) and can access alerts via one-time tokens only.

Terminology*

Národní organizace pro ověřování pravosti léčiv, z.s. (NOOL)

A non-profit organization designed to administer, develop and manage the National medicines verification system (CZMVS) in the Czech Republic.

AMS – NOOL Alert Management System

Supporting system to the national medicines verification system operated by NOOL.

Alert Level 5

At this level of incident, an alert is triggered by the system. The alert is sent to the party that raised it (i.e., end user, MAH / OBP, parallel distributor), as well as to NOOL and SÚKL (Czech NCA).

*Other definitions are on the page - "Alert states and their resolution"

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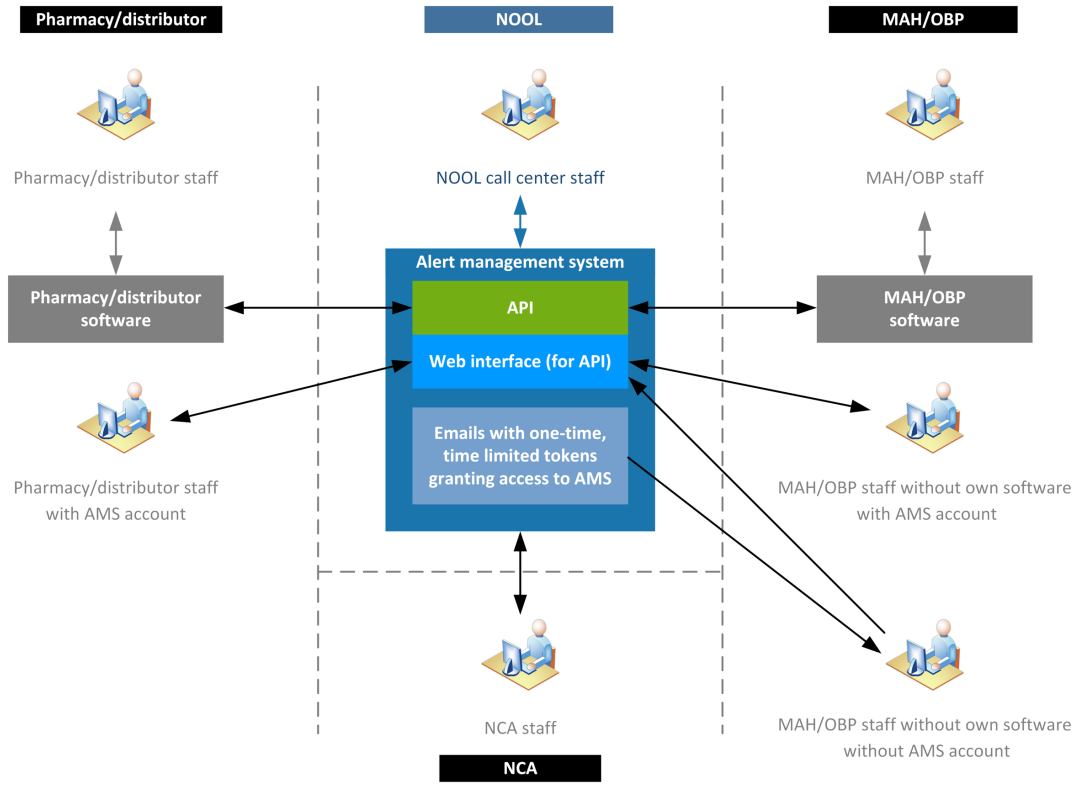
ALERT MANAGEMENT SYSTEM

Alert Management System (AMS) operated by NOOL is a supplementary system to the Czech national medicines verification system (CZMVS). The purpose of this system is to facilitate the administration associated with the investigation of alerts, thus helping to simplify and speed up the entire investigation process.

Alert management in Czech Republic can be done by three ways:

- ✓ By integrating the user's own alert management system with the Alert-operated Alert Management System using API communication.
- ✓ Direct access to the alert management system web interface
- ✓ **One-time time-limited access** to the NOOL AMS web interface **only for the given alert**. The access link including a token is sent with an automatically generated e-mail. **This variant is main subject of this manual.**



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TRANSITION FROM ONE-TIME ACCESS TO PROD ENVIRONMENT

Existing system of one-time tokens to access AMS

As soon as an alert is raised in AMS**,** the system will generate a link containing a token for an **MAH/OBP that is not registered in NOOL AMS**. The token will provide a limited access to AMS and enable administration of the concerned alert. **The token is valid for 90 days from the day the alert is raised**. Any change to the alert status will generate a new token valid for **90 days.**

NOOL recommends that all MAH/OBP whose products generate or may generate alerts in the CZ market switch to the alert management system through web interface or API.

Benefits of access via web interface or API

- ✓ **Easier and clear work with alerts, filtering options, management of multiple MAHs by a single user.**
- ✓ **Support of automation of the investigation process**
- ✓ **Support of anonymous communication between MAH/OBP and end users during investigation process.**

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Switch to access via web interface or API

MAH/OBP needs to contact NOOL first to get access credentials to the NOOL Alert management system via web interface or API. **registrace@czmvo.cz**

Credentials allow access to both test and production environment. Other system users will be administered by the MAH/OBP.

Once an MAH/OBP is switched to the PROD environment, they will no longer receive e-mails with one-time tokens.

A detailed handbook for the PROD environment of the AMS is available on the websites of CZMVO:

https://www.czmvo.cz/en/alert-management/producers-mah-parallel-distributors/

PROCESSING TIME & ESCALATION

System notification

System notifications (notifications) are sent to the users who set them active in their settings in User Management. Individual types of notifications can be toggled according to the user's needs. There has to be at least one recipient of a given type of notification within the organization.

New alerts notification

END USER TRANSACTIONS

a) End user technical error (A2,A3,A68,A52) – MAH/OBP gets notification about new alert **immediately**.

b) End user process error (A7,A24) – gets notification about new alert **after 48 hours**.

MAH/OBP TRANSACTIONS

MAH/OBP gets notification about alerts, raised by MAH/OBP transactions, collectively for all alerts for the previous day.

Investigation time

Alert should be investigated and closed ASAP within **14***days, which is a defined period during which the product generating alert will be kept in the pharmacy. After this period, the product will be returned to the distributor.

***14 days is under the Czech Law: No. 44/2019 Sb., § 89, subsection 4,**

“Not acting” notification

END USER TRANSACTIONS

a) **End user technical error** (A2,A3,A68,A52)

In case of inactivity involved parties, i.e. alert status is not changed, MAH/OBP gets first notification after **5 days**, second notification after **10 days**.

b) **End user process error** (A7,A24)

MAH/OBP gets notification after **48 hours,** and can start investigation immediately. Until than, the end user has deadline for investigation. Inactivity during the time is reported to the end user only, MAH/OBP doesn’t receive notifications.

MAH/OBP TRANSACTION

In case of inactivity MAH/OBP gets first notification after **5 days**, second notification after **10 days**.

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NOTIFICATIONS, PROCESSING TIME & ESCALATION

If MAH requests **additional information for the alert from the end user and the latter does not respond**, the deadlines for **inactivity notification are:** the first notification of inactivity will be received by the end user **48 hours** after the request, the second after **5 days** after the request.

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ARCHIVING

A Closed alert is marked as "**for archiving**" after **90 days**. The state of the alert cannot be changed once archived.

Notice: Within 90 days, a closed alert can be re-opened, and the investigation can continue under certain conditions. However, it is only applicable to alerts whose closing state disallows dispensation of the pack to public. If the MP has already been dispensed, the alert can no longer be re-opened.

After **5 years** the alert is archived and is no longer visible in the alert management system.

E-MAIL NOTIFYING ABOUT A NEW ALERT RAISED

If the MAH is not connected to the PROD environment of the AMS, once and alert is generated, they will receive an e-mail containing a link to a token to AMS. The message gives information about UPRC as well as the access expiration date.

Sample e-mail:

Předmět: NSOL Upozorneni - novy alert ! / CZMVS Notification - new alert ! CZ-LM7-LCC-W3Y-0J4-PLV

Na tento e-mail neodpovidejte - je automaticky generovan systemem! / Do not reply to this e-mail - it is automatically generated by the system!

Vazeni/Dear,

v Systemu pro overovani leciv dle FMD (NSOL) vznikl **nový alert**.
In the **Czech Medicines Verification system** (CZMVS) there is a **new alert**.

UPRC: CZ-LM7-LCC-W3Y-0J4-PLV

Casove omezeny pristup do Systemu pro spravu alertu / Time limited access into Alert Management System

https://beta.czmvo.cz/alerts/CZ-LM7-LCC-W3Y-0J4-PLV/?mt=ud05iz8zqvsdefaurlxdkuvtniss6gosoyqtey26b769i9k5qgwqprjnbm21

Platnost do/Validity to: {platnost}} / 2022-09-20 10:35

Pozn. / Notice:

Cas vzniku alertu a zmeny stavu je uveden v **UTC.** (Zimní cas = UTC +1 hod., letni cas = UTC + 2hod).

The time of origin of the alert is given in **UTC**.

Pro spravu alertu, vzniklych na uzemí Ceské republiky, velmi doporucujeme pouzivat nas system pro spravu alertu (NOOL - AMS).Pokud nejste jeste registrovani, pozadejte o pristupové udaje na tel.: +420 224 834 153-5, nebo e-mailem: registrace@czmvo.cz.

We strongly recommend using our alert management system (CZMVO - AMS) to manage alerts generated in the Czech Republic. If you are not registered yet, request access data on phone.: +420 224 834 153-5, or by e-mail: registrace@czmvo.cz.

NOOL, z.s.

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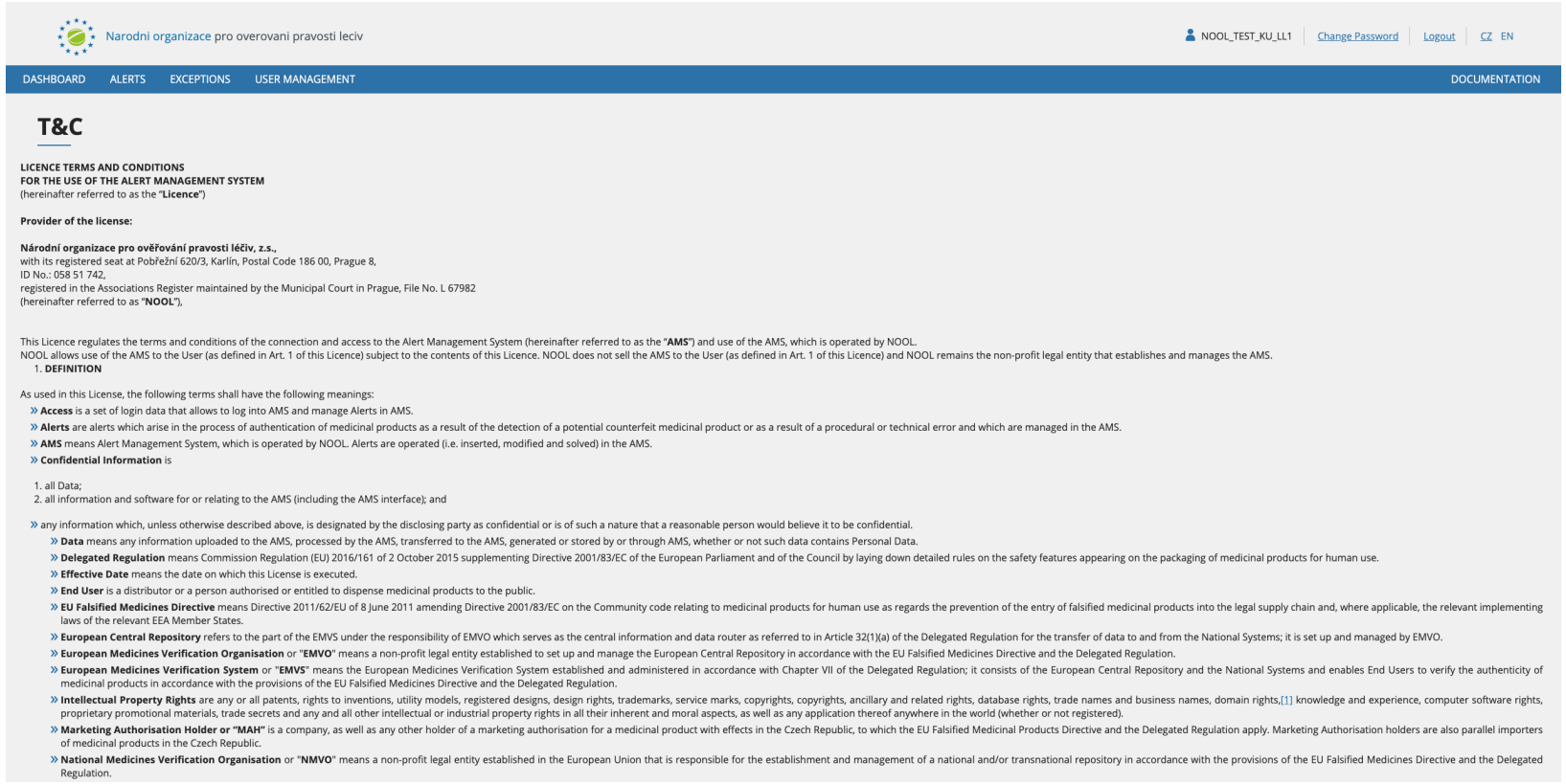
AGREEMENT WITH THE TERMS AND CONDITIONS

Prior to accessing the AMS for the first time within an organization, it is necessary to read and agree with the terms and conditions of using the Alert management system.



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AMS – MAIN SCREEN

Once the terms and conditions are read and agreed to, the main screen of the AMS web interface will appear. This is where the MAH can perform administration of the alert

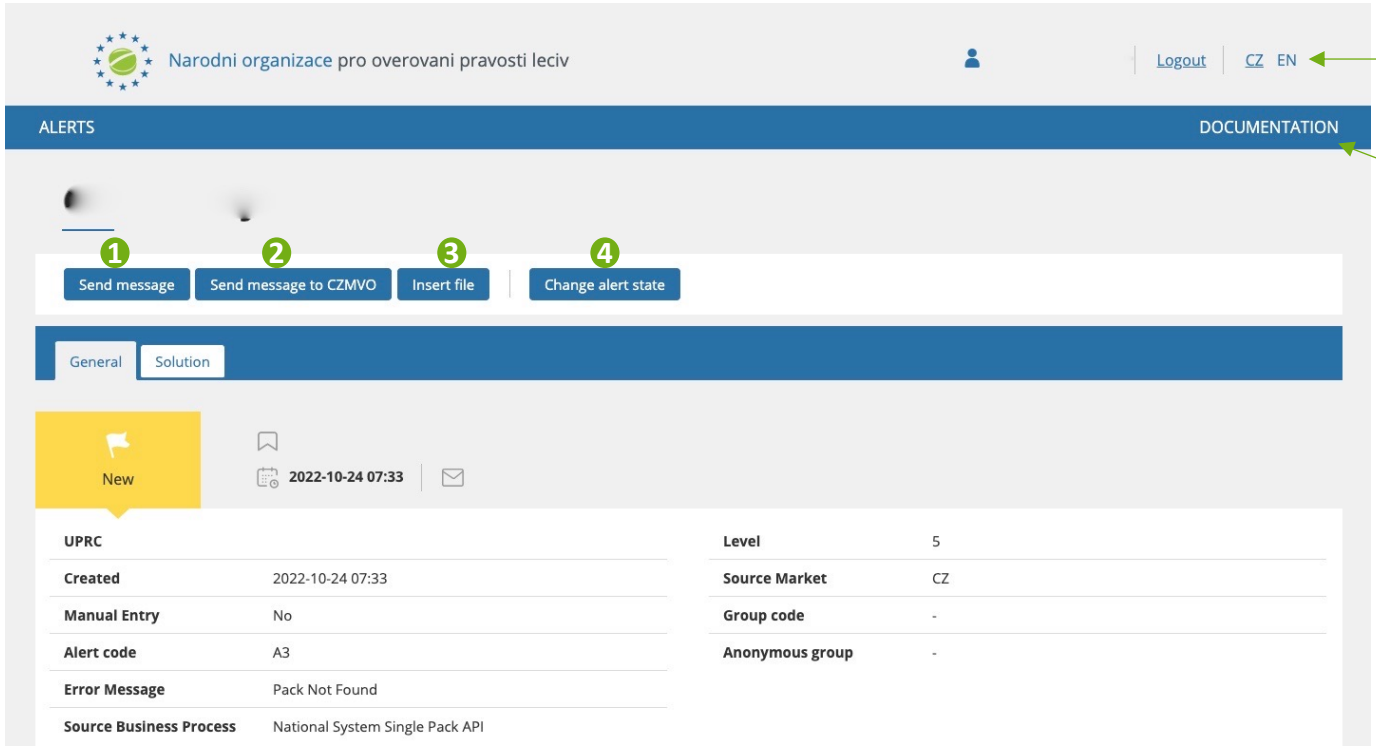
The page contains two tabs:

Tab „*General*“ displays alert information such as alert creation day, values entered by the user, values stored in the repository, etc.

Tab „*Solution*“ displays the current ***Alert status***, alert status change log or communication log with the end user (messages, files), date of the last alert state change, etc.

There are 4 action buttons:

- Send message ❶
  Send a pre-defined message to CZMVO or end user and chnage the aelrt state
- Send message to CZMVO ❷
  Send a message directly to CZMVO. Sending the message will not change the alert status
- Insert file ❸
  Insert a file to the alert (txt, pdf, csv, jpg, tiff, png)
- Change alert state ❹
  Change the alert state according to the process workflow.



Selection of language

Important information for MAH/OBP (via web sites of CZMVO).

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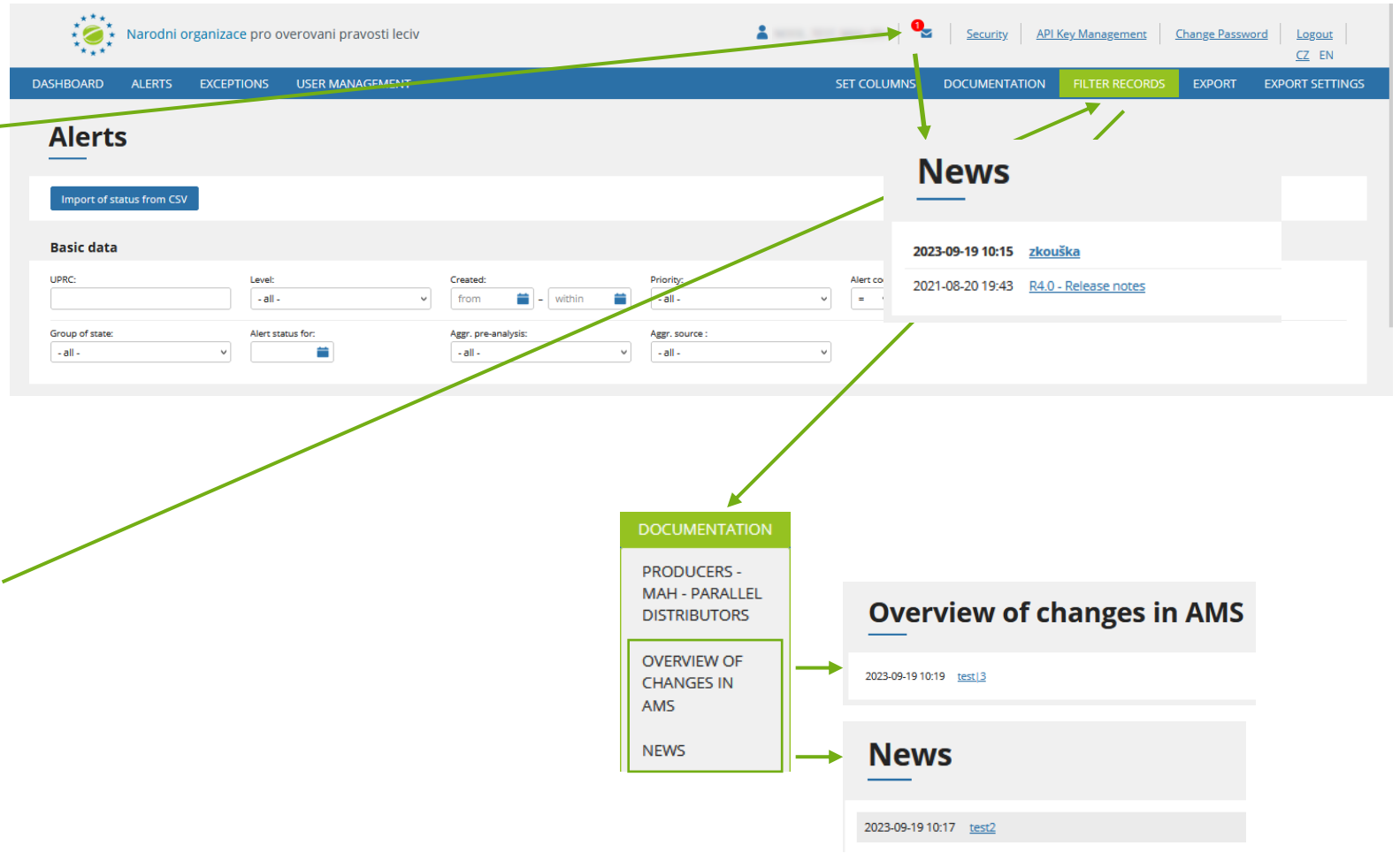
AMS – MAIN SCREEN

Envelope icon is visible in the top bar with an indication of the number of unread messages. After clicking on "envelope" a list of all messages will appear. Unread ones are indicated in bold, read ones are in normal font. After reading, information about user/login who has read the message is recorded.

A new line "Overview of changes in AMS" has been added to the main menu in the "Documentation" column. With each new release of AMS, a new line appears in this menu. It will contain link to related release notes.

A new line “News” was added. There are lines which are links to selected news from the NOOL’s website.



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AMS – TAB GENERAL

Tab General contains three parts:

1. Alert

Alert details:

UPRC – Unified identifier of an alert.

Created– Alert creation date.

Manual entry – Indication of whether the unique identifier was inserted into the system by a reader or manually.

Alert code – It specifies code of an alert.

Error message – Description of alert cause.

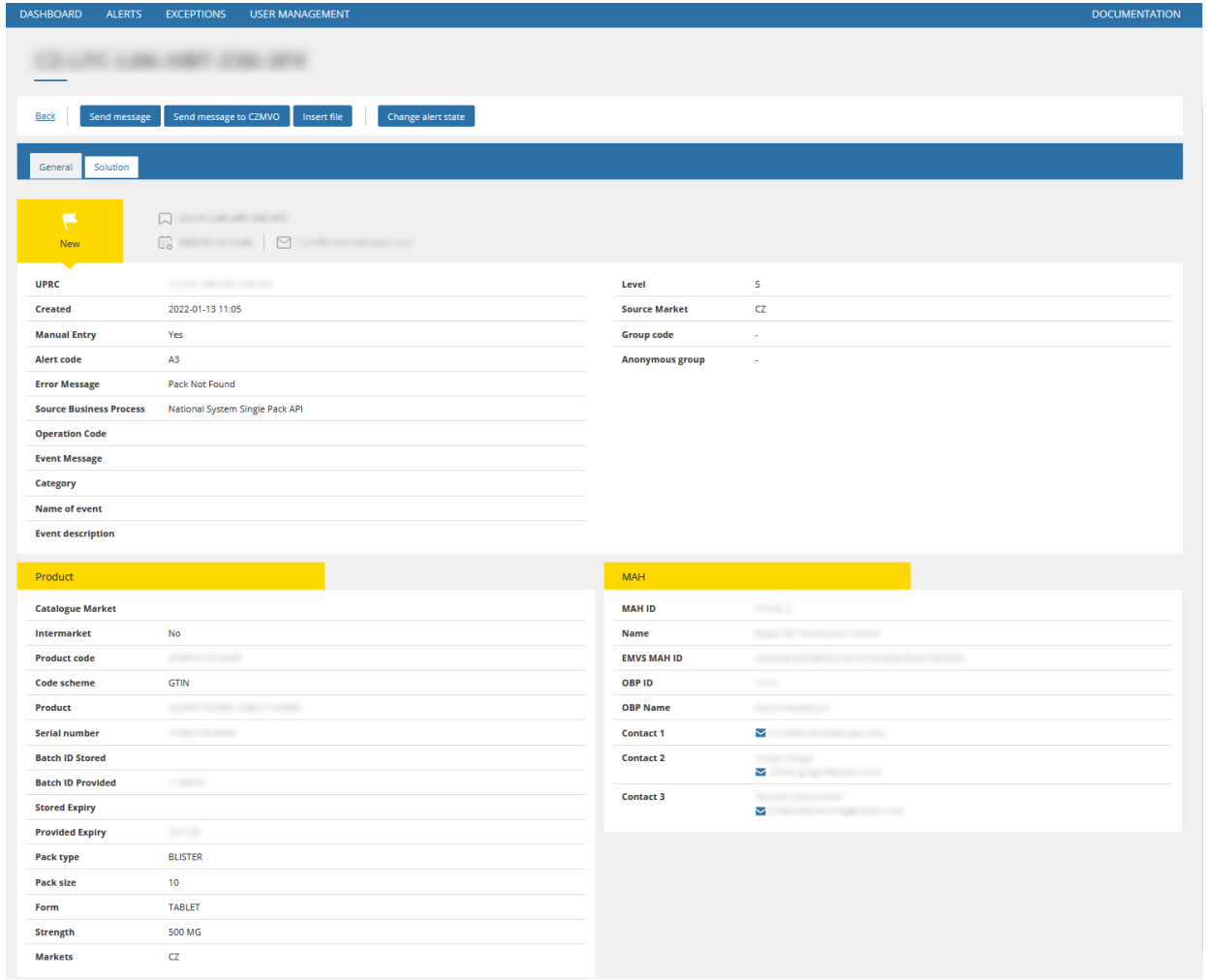
Source Business Process – Transaction initiator (National system = End user, MAH = MAH/OBP/Paralel distributor).

Level – Alert level

Source Market – market where transaction was initiated

Group code – identifier of alert group created according MAH (usage allowed in production only)

Anonymous group– identifier of alert group created according end user i.e. pharmacy, distributor (usage allowed in production only)



2. Product

Details related to a medical product

3. MAH

MAH related details

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AMS – TAB SOLUTION

Archived – *Indication whether alert is archived*

Priority – Alert priority (standard/high)

Alert status – Current alert status

State description – Alert status description

Last state change– Date when the last state change occurred

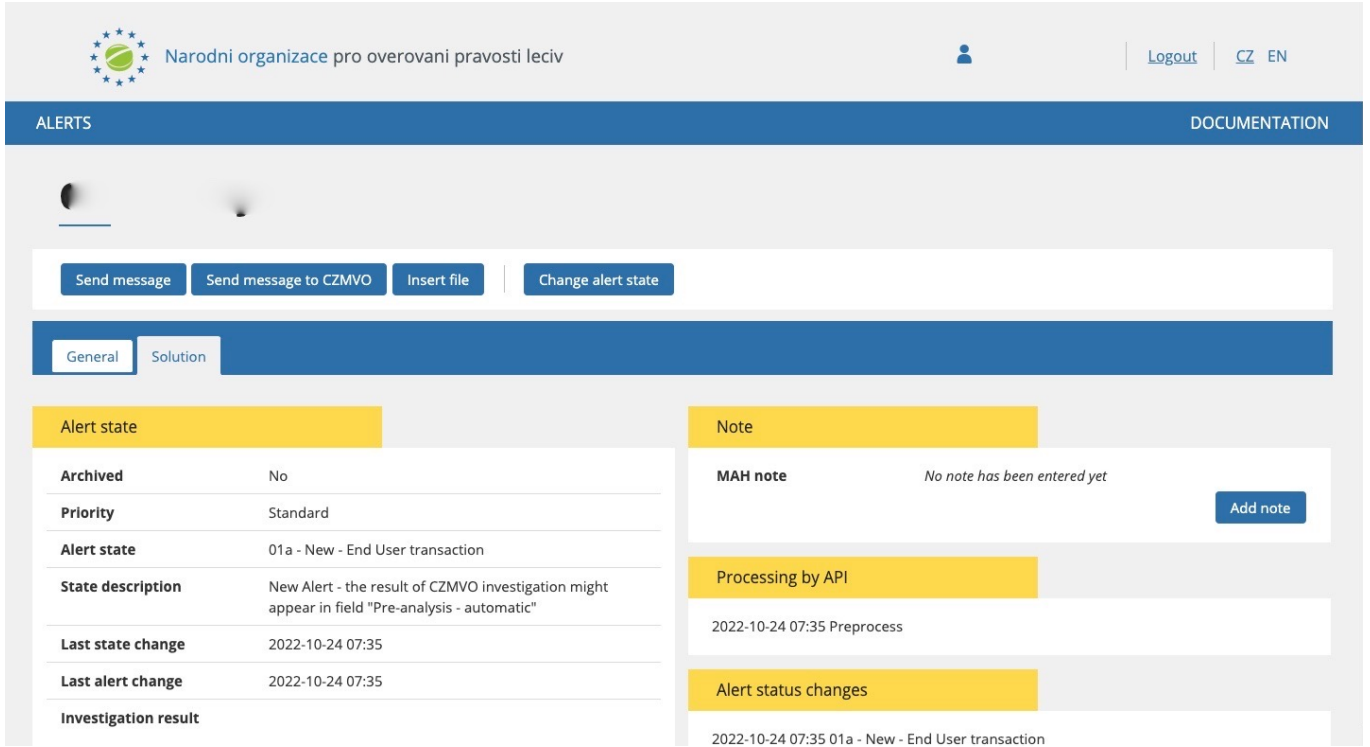
Last alert change – Date of the last change to the alert

Investigation result – Result of alert investigation (filled out automatically once the alert is closed with the corresponding status)

MAH note – This is where the MAH can attach a message to the alert. The message can be set invisible to other parties

Processing by API – API communication log

Alert status changes – Status change log



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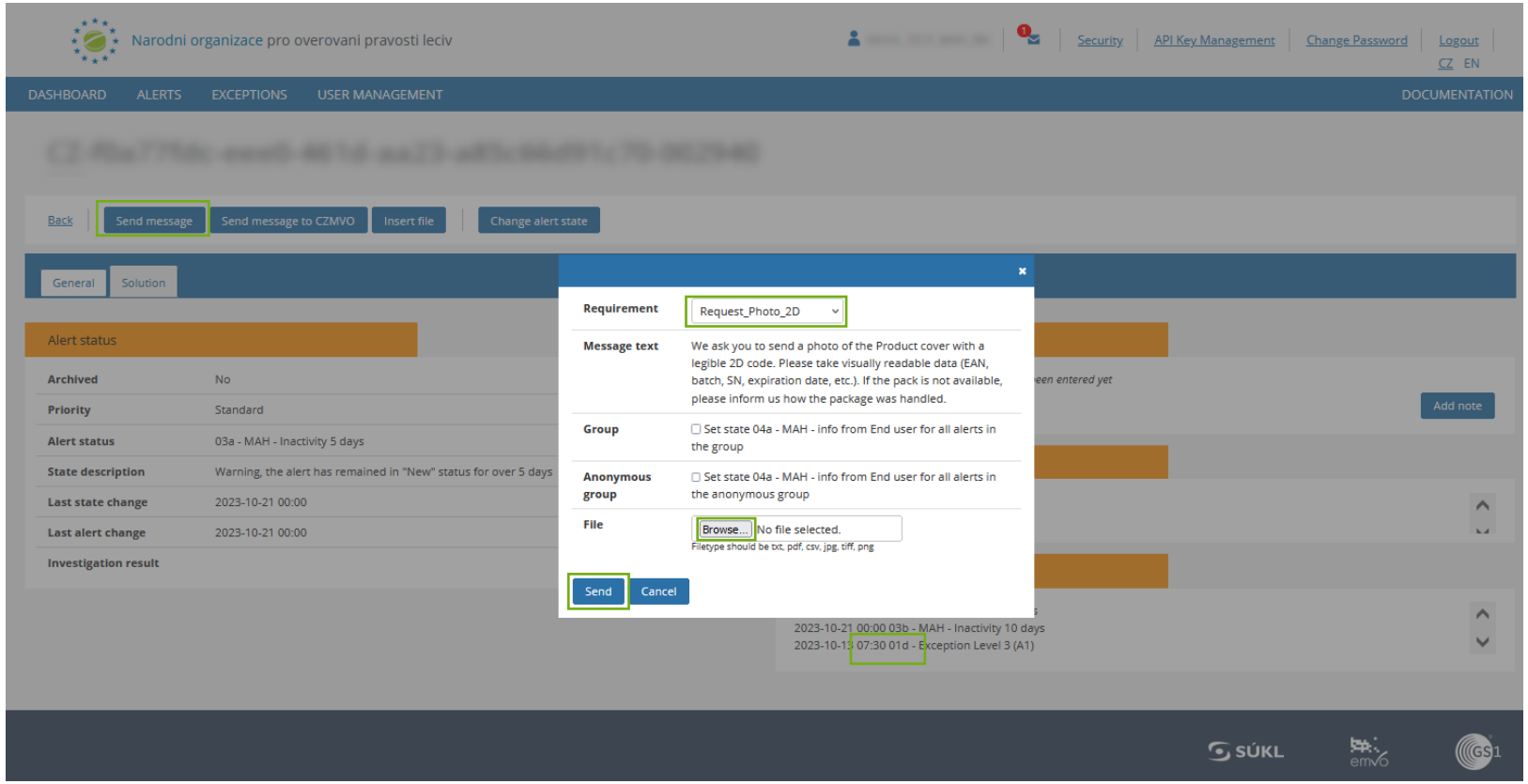
ANONYMOUS COMMUNICATION BETWEEN MAH/OBP AND END USER

Alert management system supports **anonymous exchange** of "predefined" messages between MAH and end user.

The communication is intended to support MAH investigation in such cases when MAH needs for instance a picture of the pack to see the printed 2D Matrix code

To send a message to the end user click button "*Send message*". Dialog box will appear. Select type of requirement from the drop-down menu. By "*Select file*" you can add an attachment. You can also add an attachment. Clicking „*Send „*will send the message.

If the end user does not provide answer within an adequate time frame (**48 hours**), it is prudent to use CZMVS call centre service. (e.g., by using NOOL Messenger).



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Notice: If the MAH / OBP enters a request to the end user (status "04a"), then if the end user is inactive, the end user is notified of the MAH / OBP request by e-mail after **48 hours**. If the KU still does not respond for another **5 days**, a warning is sent to the KU that the KU must start cooperating immediately. **After 30 days of inactivity of the end user, information about inactivity is passed to NCA (SUKL).**

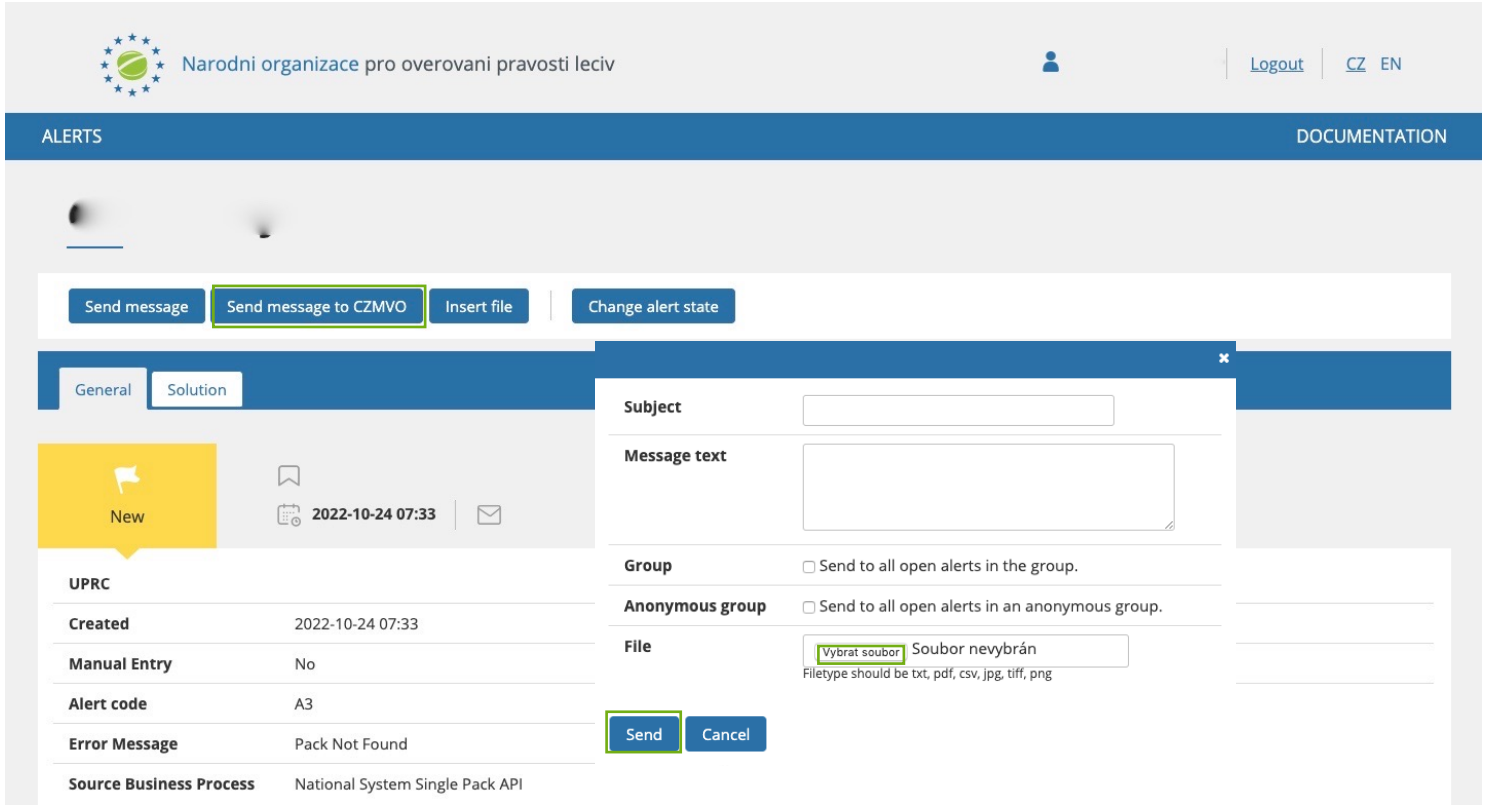
COMMUNICATION BETWEEN CZMVO AND USERS

The AMS supports **anonymous exchange** of messages between CZMVS and users (MAH/OBP, end user)

To send a message to CZMVO, push the button *"Send message to CZMVO".* A dialog box will open. To attach a file push *"Browse".* To send the message click *"Send"*

Note: the text can theoretically be in any language, however, English (or Czech) will facilitate NOOL's work the most.

This communication provides for support and facilitation of the alert resolution process and **does not affect the alert state.**



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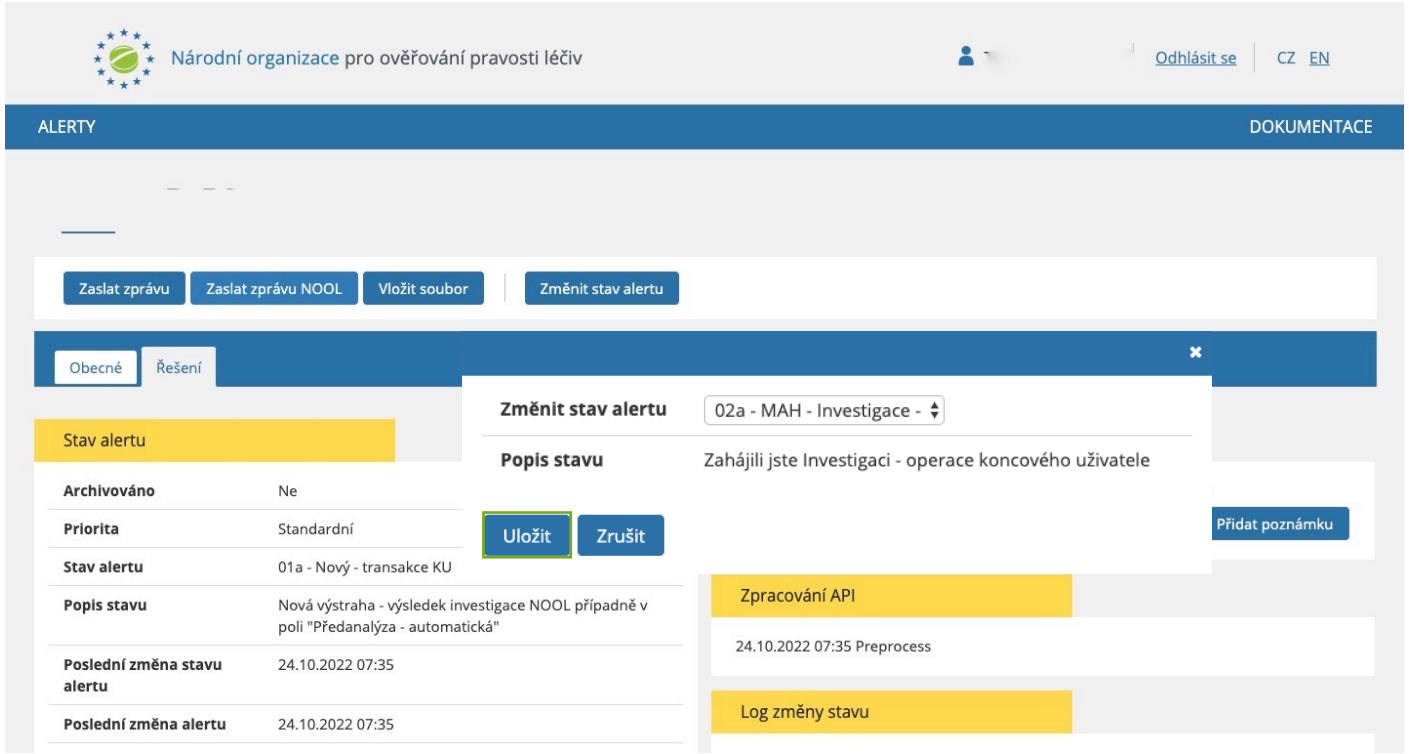
Note: when requesting additional information from end user or NOOL, it is necessary to continuously check the alert (via the link in the email). The required information will be available directly in AMS in the Solution tab for the given alert

CHANGE ALERT STATE

Button "*Alert state change*" allows change the state of specific alert. Additional window appears with selector of desired state.



Note: **A complete list of alert states in AMS and common practice in alert solution can be found at the end of this manual.**

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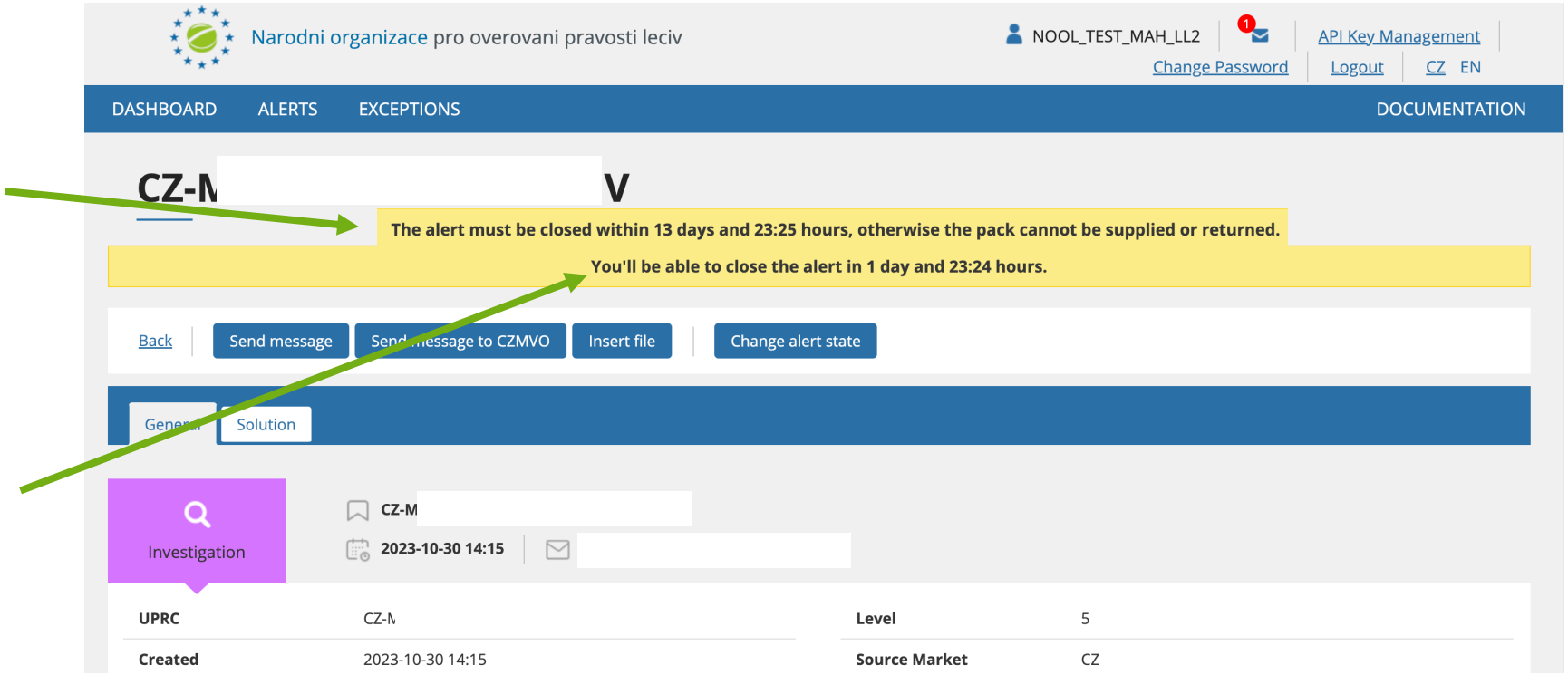
TIME INDICATION– THE NUMBER OF DAYS/HOURS LEFT TO ENABLE/ENFORCE ALERT STATE CHANGE

The time left to close an alert is displayed in the upper part of the alert details. When this time is up, the legal term to preserve a potential counterfeit pack in quarantine expires, and the pack can no longer be supplied to public.

In case of an A7 or A24 alert, an indication displays the time left until the alert will be opened for the MAH to intervene and eventually close the alert (the first 48 hours are reserved for the end user to investigate and resolve the alert).



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END USER PROCEDURAL ERRORS

- AMS enables end users to dispense packs to the public despite an alert raised as a result of a procedural error provided conditions stipulated by SÚKL (NCA) are met. This feature is only available to **end users (pharmacy, wholesaler)** and only for **End user transactions** (“Source Business Process = National System…”) and for **A7 or A24 alerts** that are open and their state can be changed or a message sent according to the **process workflow**. **The resolution** and closing of a procedural error using this tool may enable the end user to **immediately dispense the medical pack to public** without verification of the pack in CZMVS.

- Note: **MAH/OBP** can close process errors of the end user with the status "06f - Closed - KU - Process error - cannot be dispensed" only after **2 days** have passed since the alert was created (if the alert has not been resolved by the end user by then).

- If the end user is aware of a procedural error that **can be fixed** and a declaration submitted as per **conditions stipulated by SÚKL** (NCA), they may close the corresponding alert even if already closed as *„06f - Closed - End User process error - cannot be dispensed“,* and subsequently set the alert to the state *„06m - Closed - End User process error - can be supplied“.* This change can be made within **9 days** after the alert status has changed to "06f".

END USER PROCEDURAL ERRORS

- Transactions can only be made if the unique pack identifier is active. In case of incorrect release/rejection of the pack, the unique identifier is permanently invalidated and any further attempt to change the pack status will generate an alert*

- **KU can close such an alert in AMS if it itself caused it as a result of a so-called procedural error and possibly release the package to the public. The condition is to properly document the cause and provide detailed information about the alert via AMS****

* With the exception of reactivation according to Article 13. " COMMISSION DELEGATED REGULATION (EU) 2016/161"

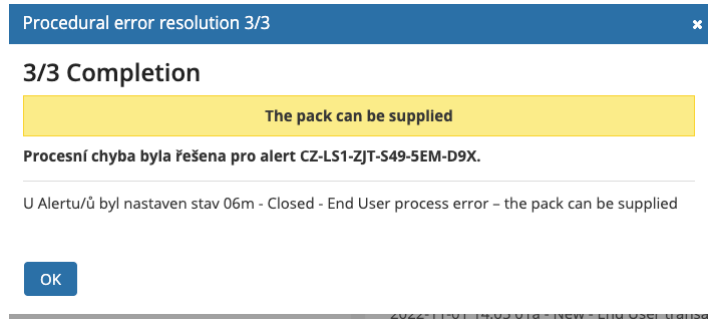
** This procedure was approved by SUKL (NCA)

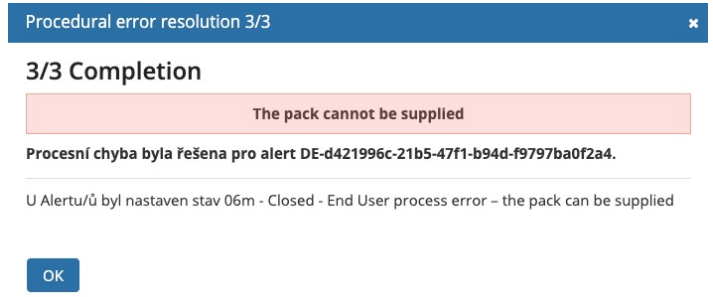
Solving end user process errors in AMS can be completed with the following results:

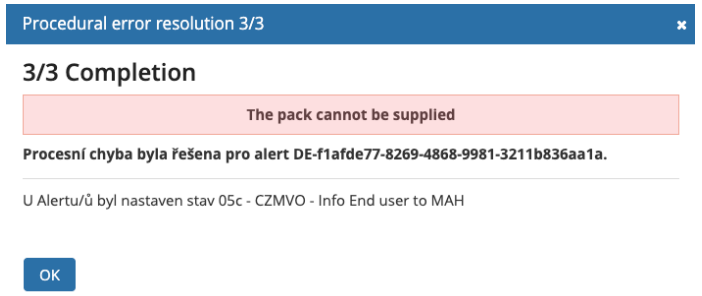
1. "**Pack can be supplied**" - The alert will be closed to the state "*06m - Closed - end user - process error - can be issued*". The alert is closed and the package can be released to the public.

2. "**Pack cannot be supplied**" - Alert closes to "*06f - Closed - end user - Process error - cannot be supplied*". The alert is closed, but the package cannot be supplied to the public.

3. "**Pack cannot be supplied**" - Alert closes to "*05C - NOOL - Info from end user to MAH*". Alert is forwarded to NOOL for further investigation. (This situation occurs if the invalidation of the unique identifier was done from a different place).







Note: A complete overview of end user process errors is available at the end of the document.

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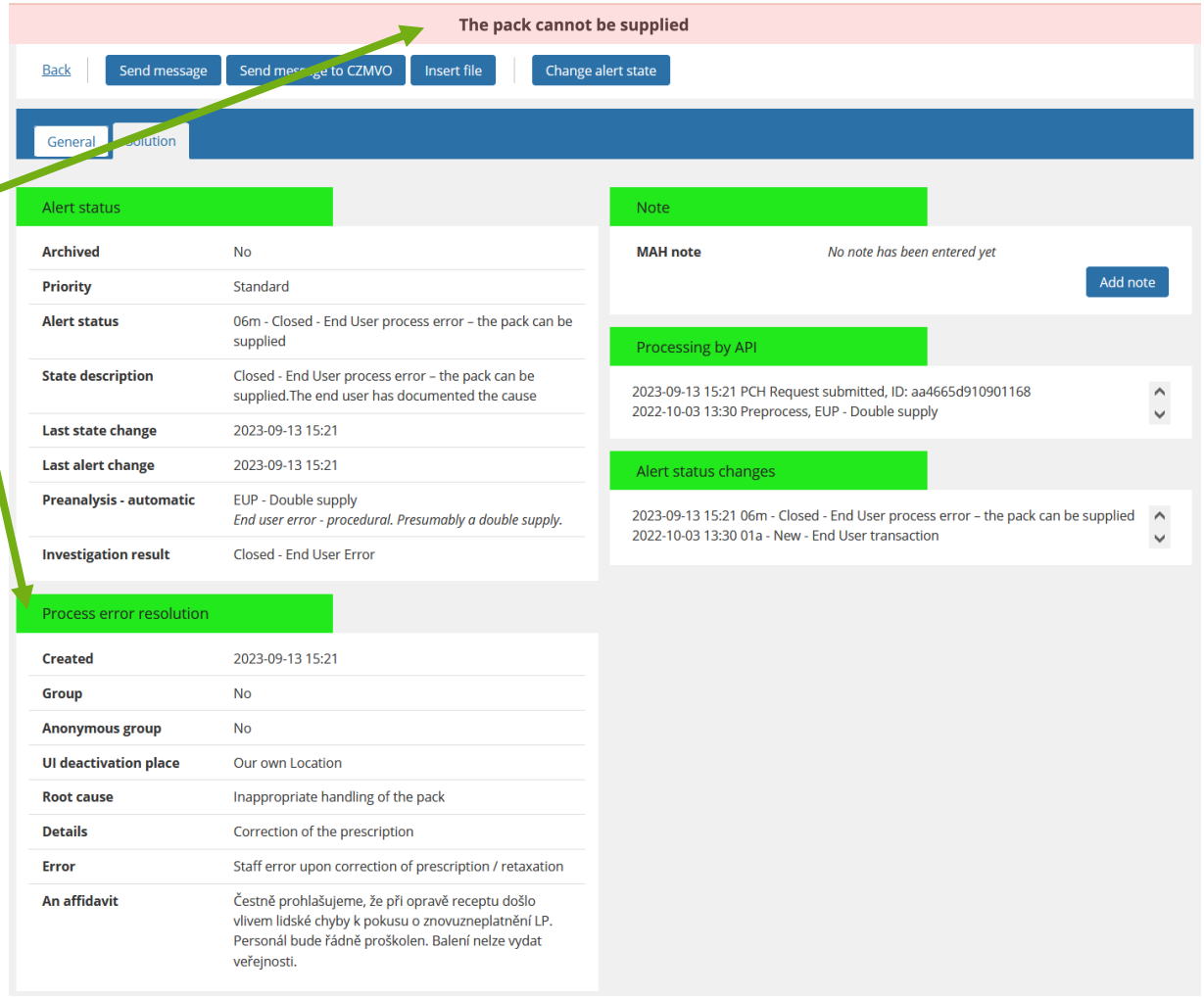
END USER PROCEDURAL ERRORS

- The result of the end user investigation can be viewed in the "Solution" tab in the "Process error resolution" section
- Based on the selected options, end user will also receive information on whether or not the package can be supplied



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News in AMS Release 7.0

ALERT MANAGEMENT SYSTEM

AMS – release 7.0 contains following features:

1. **List of all alerts – information about premise was corrected.**
2. **Type of premise was added to the alert detail**
3. **There were new information added to the alert detailDoplněny další pomocné informace v detailu alertu.**
   New items:
   „*Category*“ (e.g.: „Process“)
   „*Name of event*“ (e.g.: „PackVerificationFailedUnknownBatchId“)
   „*Event description*“ (e.g.: „Pack Verification through intermarket failed because the batch is unknown to the HUB“)
   „*IsBadData*“ (e.g.: „False“) (Note: = Check for formal character admissibility (eg a dollar sign in a string - then an error „IsBadData“=true).
   „*IsBulk*“ (e.g..: „False/True).
4. **Anonymous group – display and the possibility to work also for the role "End User“**
   a) Anonymous group – is shown in the alert list for the "End User" role as well.
   b) Added the ability to bulk activity over anonymous groups for the "End User" role.
5. **Groups (standard and anonymous) were reworked**
   a) The period for creating both types of groups has been reduced to 24 hours by default.
   b) Added the possibility to modify this period for a specific user group ("MAH" role, "End User" role). Interval: 1-90 days.

ALERT MANAGEMENT SYSTEM

AMS – release 7.0 contains following features:

c) All available information about the group is displayed in the overview of standard and anonymous groups, (what it consists of, creation date, termination date of group creation), as well as information about each alert in the group (Status, Alert code, MAH ID, PC, SN, Batch, Expiry Date, etc.).

6. Refinement for sending generic and preset messages during API communication

If the MAH/End User sends a message to the End User/MAH using API communication, this is only possible by selecting from the preconfigured bilingual messages. If the MAH/End User sends a message to NOOL using API communication, both preconfigured messages and free text can be used.

7. Automatic closing of "A54" alerts

All "**A54**" alerts are automatically closed immediately with the status "06j - Closed - MAH - Transaction error - Uncorrected". Field "**Investigation Result NOOL**" = "*19 - MAH - Randomization*".

8. Pre-investigation of end-user technical errors

End user technical error pre-analysis for alert code = [A2, A3, A68] should always give a result. But if the algorithm does not find anything, the value "20 - MAH - NO" will be entered in the field "Investigation result NOOL" ("*End user transaction, pre-analysis did not determine the cause - suspected MAH error (incorrect or unrecorded data, error in printing 2D code) or counterfeit*").

9. Pre-analysis of error A52:

If the string "YYMMDD" in the field "**Expiration date provided**" is empty, or "MM" is greater than 12, or "RR" is less than 15, or "DD" is greater than 31, then the value " 21-EUT - Date" ("*Suspect of wrongly loaded expiration date value*").

ALERT MANAGEMENT SYSTEM

AMS – release 7.0 contains following features:

10. Pre-analysis of end-user process errors:

If the alert is **A7**, then the field "**Investigation result NOOL**" = "*22 - PURCHASE - repeated" (Incorrect request to repeat an already executed end-user transaction) .*

If the alert is **A24**, then the field "**Investigation result NOOL**" = "*23 - PURCHASE - Unauthorized" (Bad request for unauthorized end-user transaction)*.

From the NSOL report data, the location of the alert is compared ("Location ID") with the location of **the last successful transaction before the alert was generated**. After loading the data, it is determined whether the alert originated at the **same/own** premise or **another/foreign** one, and the corresponding data is entered in the "Pre-investigation" field (overwriting the original value), and the process for investigating procedural errors is further adjusted by pre-filling step 1 . The user **will be shown** this value "Own"/"Foreign premise" **when the process error closure** is initiated. The user will then **continue from step 2**. If this value is **not filled** in, the user will start from step 1.

11. Alert indication - number of days/hours until status change is enabled/prevented

For each alert is indicated in the header, for the given role and status, how many days are left until the given condition (if such a condition exists for the given alert, status and role).

12. Following charts have been added to the Dashboard for the End User role:

a) Alerts by premises (Location ID – distribution),
b) Alerts by premises (Closed, Not closed)
c) Alerts by device (Client ID) per organization (ORG ID)
d) Alerts by device (Client ID) per Location ID (premise)

ALERT MANAGEMENT SYSTEM

AMS – release 7.0 contains following features:

13. Improvement of information about changes, news, notifications

a) Added a new line "Overview of changes in AMS" in the main menu in the "Documentation" column
With each new release of AMS, a new line appears in this menu. It will contain the name of the release with a link to the relevant change document.

b) A new line "News" has been added in the "Documentation" column.
Here are lines of text with a click on selected News from the NOOL website (eg on "Did you know that").

c) Improving the use of the already used **Pop Up** window.
After logging into AMS, an "envelope" with an indication of the number of unread messages is visible on the top bar. After clicking on the "envelope" a menu (list) of all messages that are in the record for the pop up window will appear - unread are indicated /bold font x read - normal font. After reading, the information that the message was read by particular login/user is recorded.

14. Alert list change

A "*Source Transaction*" column + "*Source Transaction*" filter has been added to the alert list for the "End User" role as well.

15. Showing options used when handling process errors

It is being displayed what options were chosen by the End User when solving the given process error. Valid for all roles.

16. AMS - NOTIFICATION AND ESCALATION

Reworked automatic notification system (notification and escalation)

See page 5 of this manual.

Alert states and their solution

TERMS

All alerts must be investigated and closed

during the shortest possible time

- **Initial analyses in AMS** = alerts are sorted based on the relevant operation, where alerts occurred (MAH/OBP, end-user, parallel distributor); IMT alerts identified, probable cause of alert identified and offered to further investigation (End-user technical or procedural error), exception according to **(Act No. 378/2007 Coll., on Pharmaceuticals, article 11r.**

- **Intermarket alerts** = The market where the alert is raised is different from the market where the pack is physically located, i.e. the pack is verified in one country, however the data are stored in a different country. The initiating market is the market where the pack is physically present and where the verification attempt was performed. The initiating market is responsible for alert investigation. The fulfilling market is the market where the data related to the pack are stored and where eventually an alert is raised. Alerts where the Czech system (CZMS) serves as the fulfilling market are closed automatically.

- **Emergency alerts** = require immediate investigation; marked with index in AMS NOOL. The MAH, the end user and CZMVO are notified by warning immediately after an alert is created. The decision to classify a product as “high-priority product” must be consulted with SÚKL (NCA) in advance (i.e vaccines' against Covid-19).

- **End-user procedural error** = often caused by wrong process in the end-user organisation, human mistake or end-user IT SW process is not integrated in line with FMD.

- **End-user technical error** = often caused by scanner setup, low quality of scanner, end-user IT software or speed of scanning.

CZMVO PRE-ANALYSIS – THE LIKELY ROOT CAUSE OF THE ALERT

The AMS provides information about the likely root cause of the alert using an automatic pre-analysis. This feature significantly facilitates alert investigation.

Title	Situation description	Solutions possible – MAH/OBP
EUT - Date	Presumably an incorrect expiration date 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 setting / long character string in Serial number).	
EUT - Caps Lock	Presumably a keyboard setup error (CapsLock).	
EUT - EN/CZ	Presumably an incorrect keyboard language setting (EN/CZ).	
EUT - Short character string in Serial number	Presumably an incorrect scanner setting / short character string in Serial number).	
EUT - Character mismatch	End user error - technical. Presumably a character mismatch (O/0,E/3,I/L,...) due to a lower quality scanner.	
EUT - Fixed, supplied	According to the audit trail, the pack 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

Notice: EU = end-user, EUT = end-user technical error, EUP = end-user procedural error

CZMVO PRE-ANALYSIS – THE LIKELY ROOT CAUSE OF THE ALERT

The AMS provides information about the likely root cause of the alert using an automatic pre-analysis. This feature significantly facilitates alert investigation.

Title	Situation description	Solutions possible– MAH/OBP
EUP - Repeated	A repeated 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 AMS. 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.	
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.	
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.	
EUP - Unauthorized - This location	An unauthorized pack state change request that occurred on the same location where the pack state was previously changed successfully.	
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.	

CZMVO PRE-ANALYSIS – THE LIKELY ROOT CAUSE OF THE ALERT

The AMS provides information about the likely root cause of the alert using an automatic pre-analysis. This feature significantly facilitates alert investigation.

Title	Situation description	Solutions possible– MAH/OBP
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 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 AMS.
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 AMS.
NMVS Error - Synchronization issue	NMVS Error - Synchronization issue (PSUN transaction, alert raised outside of CZ).	Alert will be closed automatically in AMS

CONTINUOUS ALERT STATUSES

Alerts investigation by MAH and next steps of the solution including relevant AMS statuses

- Type of alert: **all**

Alert code and name in AMS	End-user - procedure during alerts investigation	MAH – steps during alert investigation
01a **New – end user transaction**	Keep medicinal pack in quarantine until the end of alert investigation.	Once MAH/OBP receive information about alert, the investigation what caused the alert should start immediately.
01b **MAH – New - MAH/OBP transaction**	End-user does not know about alert, pack is not in end-user location.	Automated pre-analyses identified alert was caused by MAH operation before pack was supplied to end-user location.
02a **MAH - Investigation - End user**	Keep medicinal pack in quarantine until the end of alert investigation.	MAH can (does not have to) use this alert status. Once the status is used CZMVO is informed in AMS NOOL investigation of alert started, i.e. if longer time for alert investigation is needed no escalation e-amil on inactivity should be sent to MAH (after 7 or 10 days).
02b **MAH - Investigation - MAH/OBP transaction**	End-user does not know about alert, pack is not in end-user location.	MAH can (does not have to) use this alert status. Once the status is used CZMVO is informed in AMS NOOL investigation of alert started, i.e. if longer time for alert investigation is needed no escalation e-amil on inactivity should be sent to MAH (after 7 or 10 days).
03a **MAH – Inactivity 7 days**	Keep medicinal pack in quarantine until the end of alert investigation.	MAH received escalation e-mail from AMS that alert status has not changed during last 7 days from status „MAH – New“.
03b **MAH – Inactivity 10 days**	Keep medicinal pack in quarantine until the end of alert investigation.	MAH received escalation/warning e-mail from AMS that alert status has not changed during last 10 days from status „MAH – New“.

Incidents A1 and A5 should be investigated in near future

Other statuses 01x, 02x relate to CZMVO investigation

After 30 days report to NCA

CONTINUOUS ALERT STATUSES - II

- Type of alert: **all**

Alert code and name in AMS	End-user - procedure during alerts investigation	MAH – steps during alert investigation
04a **MAH – Info from end user**	Keep medicinal pack in quarantine until the end of alert investigation. In the meantime request from MAH to provide additional info is received.	MAH requested additional information from end-user via message in AMS (choice from few predefined messages)
04b, 04f **MAH - Info from CZMVO**	Keep medicinal pack in quarantine until the end of alert investigation.	MAH requested additional information from from CZMVO z AMS via message in AMS (empty field to write a comment)
05a **End user - Info to MAH** **05b** **CZMVO - Contacts end User** **05c** **NOCZMVO - Info end user to MAH** **05d,05f** **NOOL – Info MAH**	Keep medicinal pack in quarantine until the end of alert investigation. In the meantime provide information requested by MAH or CZMVO during alert investigation, it is also possible to communicate with CZMVO support team.	MAH receive requested information from end-user or in AMS od CZMVO.

Other statuses 04x relate to CZMVO investigation

Národní organizace pro ověřování pravosti léčiv

ESCALATION ALERT STATUSES – END USER TRANSACTIONS

Alert statuses and further resolution process by users

- Alert code: A7, A24 (03e, 03f, 03g) A2, A3, A52, A68 (03h, 03i, 03j)

Kódy stavů a název	Postup při řešení alertu - koncový uživatel	Možnosti řešení alertů – MAH/OBP
03f - EU – process error - inactivity 5 days **03g – process error 10 days**	End user is notified about inactivity. End user finds out the cause, documents the event, selects from the options offered by AMS and confirms the declaration. The pack is being quarantined until the alert investigation is complete.	MAH can change the pack state after 48 hours since it was created. Alert can close with status 06f - Closed - End user process error - cannot be supplied.
03i – technical error 5 days **03j – technical error 10 days**	End user is notified about inactivity. End user will try to fix a technical error on its side (checks keyboard language, sensor settings, makes sure CAPS LOCK is not on, etc.). The pack is being quarantined until the alert investigation is complete.	MAH is notified 48 hours after the alert is created due to a technical error. If is not obviously end user error, the MAH verifies uploaded pack data (batch, serial numbers).

ESCALATION ALERT STATUSES – MAH TRANSACTIONS

Alert statuses and further resolution process by MAH's

- Type of alert: all

Kódy stavů a název	Postup při řešení alertu - koncový uživatel	Možnosti řešení alertů – MAH/OBP
03m – MAH alert not closed 5 days	N/A	MAH is notified about alert created by a MAH or a parallel distributor transaction. MAH investigates the cause and closes the alert in AMS.
03n – MAH alert not closed 10 days	N/A	MAH is notified about alert created by a MAH or a parallel distributor transaction. MAH investigates the cause and closes the alert in AMS.

Národní organizace pro ověřování pravosti léčiv

CLOSING ALERT STATUSES

Alerts closing and next steps of the solution including relevant AMS statuses

- Type of alerts: **A2, A3, A52 and A68**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4):

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06a MAH error - Corrected	• Data not uploaded – batch missing or not uploaded correctly, Product Pack Data missing. • IMT did not run (if not correctly entered batch number, batch is not found in system of other country). • System Time out (batch is not found due to not received answer to request in required time limit). • Batch data not uploaded correctly. • Data missing – SN missing or not properly uploaded. • System Time out (date not verified due to not received answer to request in required time limit). • One element of the Data Matrix Code appears in the batch field, because group separators have not been set properly. • Retrospective upload capability not implemented in the OBP software.	Keep medicinal pack in quarantine until the end of alert investigation. Once alert is closed, provided info from AMS: **Corrected - the pack can be verified again! If the verification is successful, please remove the pack from quarantine and supply to the patient. Otherwise, please return to quarantine with the new alert ID (if no more than 14 days have passed from the first quarantine), or return to distribution with alert ID identification for returned pack (if more than 14 days have passed from the first quarantine).**	Once MAH/OBP uploaded and/or corrected data (batch etc.) into EMVS/CZMVS and closed alert with relevant status, end-user can verify and decommission pack again and release from quarantine to patient.

Notice: IMT = intermarket transaction

CLOSING ALERT STATUSES

- Type of alerts: **A2, A3, A52 and A68**. During investigation of alert end-user should (according to options) check possible technical errors /cause of alert on end-user side – usually caused by scanner set up, end-user IT software or scanner speed. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4):

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06b Closed - Technical error - End user	• Too quick scanning cause conjunction of batch number with GTIN or SN, or se batch number is read twice or conjunction of data from more packs to one. • SN is too short (chopped off) or too long (part of other data) or not allowed characters included. • Not finished/wrong scanning – incomplete number or product code connected to batch number. • Commutation Y/Z or capital/small letters – due to caps lock on or SHIFT on during scanning (keyboard is switched to different than required settings. (i.e. English x Czech, QWERTZ x QWERTY). • Scanning with not properly set up scanner cause wrong batch number compare to set data CZMVS. • Wrong manual entry (1 x l, O x 0) or wrong repeated manual entry of expiration date from pack MM/RR. • One element of the Data Matrix Code appears in the Serial Number field, because group separators have not been set properly.	**End–user should correct the cause of alert according to what caused it**: • Repeated scan after previous scanning with short break • Caps lock off prior to scanning followed by scanning of the pack again. • Switch to Czech keyboard or QWERTZ x QWERTY keyboard followed by scanning of the pack again. • To modify end-user IT SW (after agreement with IT SW provider) so not proper using of group separators are corrected. • To modify end-user IT SW (after agreement with IT SW provider) to correct expiration data. • Scan UI again or carefully input all relevant data for verification. Use “control scan”, if possible, to verify proper scanner set up and after that go back to medicinal pack with alert. **End-user can than again verify pack and if decommision is successful pack can be release from quarantine and provided to patient.**	MAH/OBP started investigation immediately, in parallel with end-user. Once the cause of end-user is identified, it can be corrected by end-user only. MAH/OBP can, however close alert as end-user error es well, if MAH/OBP can prove based on info identified, technical error was caused by end-user.

CLOSING ALERT STATUSES

- Type of alerts: **A2, A3, a52 and A68**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4):

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06c Closed - MAH error - Not corrected	• Wrong print of FMD code on the pack. • OBP with „Indian codes " uses GTIN, that is later on used for FMD, i.e. alert is generated. • Group separators have not been used properly so some element of the Data Matrix Code appears in batch number. • Producer printed not correct data on the medicines pack into 2D code. • Producer printed not correct data into eye readable format. • Re-upload of the data by MAH/OBP to already distributed packs. • OBP tries to change pack status to already decommissioned pack (i.e. „sample to sample").	Keep medicinal pack in quarantine until the end of alert investigation. Wait for closing the alert by MAH/OBP or provide additional information based on request. Once alert is closed, provided info from AMS: **MAH / OBP error. Unable to correct - cannot be re-verified. Return the packaging to the supplier with alert ID identification.** End user should return pack back to distribution (wholesaler) according to return process set up in end-user organisation.	After investigation with OBP – data correction or correct upload of the data or correction of wrong print on the pack is not possible. Data (batch) cannot be corrected via EU HUB to EMVS/CZMVS. Pack cannot be supplied to patient.

Národní organizace pro ověřování pravosti léčiv

CLOSING ALERT STATUSES

- Type of alerts: **A2, A3, 52 and A68**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4):

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06d Closed - ZOL 11r exception	• Wrong print of FMD code on the pack. • OBP with „Indian codes " uses GTIN, that is later on used for FMD, i.e. alert is generated. • Group separators have not been used properly so some element of the Data Matrix Code appears in batch number. • Producer printed not correct data on the medicines pack into 2D code. • Producer printed not correct data into eye readable format. • Re-upload of the data by MAH/OBP to already distributed packs. • OBP tries to change pack status to already decommissioned pack (i.e. „sample to sample").	Keep medicinal pack in quarantine until the end of alert investigation. Wait for closing the alert by MAH/OBP or CZMVS. Once alert is closed, provided info from AMS: **Exception ZOL - 11r - DO NOT VERIFY. Can be supplied to patient. Remove from quarantine.**	During alert investigation **MAH/OBP** should check if batch of medicine pack has approved exception by Ministry of Health according to Act on Medicines par 11r. If the exception is approved for product of relevant batch, relevant status of alert AMS is set. End-user can release pack from quarantine and supply pack to patient.

CLOSING ALERT STATUSES

- Type of alerts: **all**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once the cause (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4):

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06e Closed - Before 02/09/2019	• Partially serialised product (without SN or other production data from the Data Matrix Code), release from production prior 9.2.2019.	Keep medicinal pack in quarantine until the end of alert investigation and closing by MAH/OBP. Once alert is closed, provided info from AMS: **Release from production before 09/02/2019 - not subject to FMD - DO NOT VERIFY! The pack can be supplied to patient. Remove from quarantine.**	During alert investigation **MAH/OBP** should check, if pack was released prior 9th February 2019, so FMD rules do not apply. If this is confirmed, MAH/OBP should set relevant alert status in AMS. End-user can without further verification/recommission release pack from quarantine and supply to patient.

CLOSING ALERT STATUSES

- Type of alerts**: A7, A24**. During investigation of alert end-user should (according to options) check possible procedural errors /cause of alert on end-user side – usually caused by wrong processes on the organisation, human mistake or end-user IT SW set with wrong processes from FMD point of view. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4):

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06f Closed - Process error KU - cannot be issued	• Attempt to double decommission by end-user – already decommissioned pack. • Attempt to decommission already non-active or expired pack. • Not proper internal marking of pack due to misunderstanding. • Double operation or wrong decommissioning to wrong alert status by mistake. • Resale between pharmacies; pharmacy that resale not pack does not properly decommission pack to alert status "Supplied" and 2nd pharmacy during decommission to patient generates alert.. • Errors that lead to repeated request to decommission.	Keep medicinal pack in quarantine until the end of alert investigation. Once alert occurs, potential process/procedural causes of alert should be investigated by end-user. Investigation by MAH and NOOL ruled out errors caused by MAH/OBP, at the same time process/procedural error caused by end-user was identified. Once alert is closed, provided info from AMS: **End user process error. Cannot be corrected, re-verified or supplied. Further course of action depends upon the individual internal procedures of the respective organization.**	During alert investigation end-user or MAH identified process error by end-user. These alerts must be closed with proper explanation – documentation of the cause. Potential falsification was ruled out. Another decommission would cause alert.

CLOSING ALERT STATUSES

- Alert codes: **A7, A24**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4).

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06m Closed – End user process error – can be supplied after documenting the cause	• Attempt to double decommission by end-user – already decommissioned pack. • Attempt to decommission already non-active or expired pack. • Not proper internal marking of pack due to misunderstanding. • Double operation or wrong decommissioning to wrong alert status by mistake. • Incorrect internal labeling and packaging due to misunderstanding. • Resale between pharmacies; pharmacy that resale not pack does not properly decommission pack to alert status "Supplied" and 2nd pharmacy during decommission to patient generates alert. • Errors that lead to repeated request to decommission. • Attempted double dispense by end user - pack already dispensed. • An attempt to dispense an already inactive or expired pack. • Incorrect internal labeling and packaging due to misunderstanding.	Keep medicinal pack in quarantine until the end of alert investigation. Once alert occurs, potential process/procedural causes of alert should be investigated by end-user. Investigation by MAH and NOOL ruled out errors caused by MAH/OBP, at the same time process/procedural error caused b end-user was identified. **The end user must document the cause of the process error in accordance with SÚKL (NCA) requirements. By choosing from the prepared options and according to the instructions for solving individual process errors, the medicinal product can be released from quarantine and dispensed without further verification.** After the investigation is completed and the alert is closed, a message in AMS: **Not a MAH/OBP error. end user documented the cause - LP can be supplied.**	The end user or MAH identified an end user process error during investigation. An explanation is required for these alerts - documentation of the cause (preferably in AMS), the cause cannot be fixed in NMVS, i.e. the next attempt to decommission would result in an alert again. At the same time, it is confirmed that it is not a counterfeit.

CLOSING ALERT STATUSES

- Type of alerts: A**ll**. Under the terms of alert investigation, the end user ought to examine possible technical causes of the alert on their side – most frequently caused by wrong procedures, human error or inappropriate software settings. If you are certain that the alert was caused by one of the following examples (2nd column), we recommend that you follow the directions for end users (3rd column) or for the MAH (4th column).

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06g Closed - CZMVS error	Relevant to pack that, • Were already successfully supplied in CZ, but data synchronization for multimarket packs was not correct. • Were not decommissioned due to long response time of the system; status change was not done correctly.	During alert investigation that was created on Czech market keep medicinal pack in quarantine until the end of alert investigation and closing alert NOOL. Once alert is closed, provided info from AMS (based on cause of CZMVS): **CZMVS Error - The pack can be verified again! Remove from quarantine.** **CZMVS Error - The pack cannot be verified again! Return back.**	MAH does not use this alert status for closing, but previous investigation by MAH should be done. In case no error is identified by MAH, CZMVO starts investigation of alert. During alert investigation CZMVO confirmed error during data synchronisation (pack not in the quarantine because it was successfully decommissioned and supplied before alert was created). AMS system closes alert on behalf of CZMVO. No impact on packs in CZ.

CLOSING ALERT STATUSES

- Type of alerts: A**ll**. Under the terms of alert investigation, the end user ought to examine possible technical causes of the alert on their side – most frequently caused by wrong procedures, human error or inappropriate software settings. If you are certain that the alert was caused by one of the following examples (2nd column), we recommend that you follow the directions for end users (3rd column) or for the MAH (4th column).

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06o - Closed - End User does not cooperate - cannot be supplied	The MAH has concluded the investigation and repeatedly requested the end user for additional information. The end user is not cooperating. The pack cannot be supplied. CZMVO will inform SÚKL. **Note.: This state is only applicable if more than 9 days have passed since the alert was set to state 03d (End user Inactivity – 5 days)**	The alert has been closed by the MAH. The pack cannot be supplied. The end user did not cooperate despite receiving multiple notifications and warnings. CZMVO will inform SÚKL. Immediately contact CZMVO or respond to requests of the MAH/CZMVO.	Closed. The end user is not cooperating despite receiving multiple warnings. The pack cannot be supplied. CZMVO will infrom SÚKL.

CLOSING ALERT STATUSES

- Type of alerts: **all**. During investigation of alert should MAH/OBP check data uploaded into EMVS/CZMVS, end-user to check potential technical or process error, CZMVO checks potential system errors. Once all potential causes on MAH, end-user side and CZMVO are excluded, next steps should follow recommended process for end-user (column 3) or MAH (column 4):

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06h – Suspected Counterfeit!	• all the potential causes on MAH, end-user side and CZMVO are excluded	Keep medicinal pack in quarantine until the end of alert investigation Once alert is closed, provided info from AMS: **Investigation by MAH and CZMVO confirmed a possible COUNTERFEIT! information will be forwarded to NCA, EMVO, EMA, EK. SAVE THE PACKAGE carefully! You will be contacted for further action.**	During alert investigation by all relevant parties all potential causes of alert on MAH, end-user side and CZMVO were excluded MAH/OBP marked alert as potential counterfeit, NCA will be informed. Alert will be further investigated with MAH, NCA and end-user according to set up processes. Information should be provided to EMVO, EMA, EK* (in certain cases).

CLOSING ALERT STATUSES

- Type of alerts: **A7, A24**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once the cause (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4):

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06i - Closed - MAH transaction error - Fixed	• Transaction between MAH system and EU HUB (i.e. PSUM transaction)	End-user does not know about alert, pack is not in end-user location.	MAH during alert investigation found error related to data upload or correction between MAH SW and EU HUB; error corrected. Medicinal packs can be further distributed and decommissioned on the market.
06j - Closed - MAH transaction error - Not corrected	• Transaction between MAH system and EU HUB (i.e. PSUM transaction)	End-user does not know about alert, pack is not in end-user location.	MAH during alert investigation found error related to data upload or correction between MAH SW and EU HUB; error corrected; error cannot be corrected. Medicinal packs cannot further distributed and decommissioned on the market – withdrawal?
06k - Closed - PD error - Not fixed	• Wrong operation by parallel distributor	End-user does not know about alert, pack is not in end-user location.	CZMVO provides info to MAH about result of investigation with parallel distributor (anonymous). ; error cannot be corrected. Medicinal packs cannot further distributed and decommissioned on the market – withdrawal?
06n - Closed - IMT fulfilling - Alert originated outside CZ, MAH is investigating in another market	• All potential causes of alerts, but alert occurred on the pack decommissioned in other country, while data in CZMVS.	End-user in CZ does not know about alert, pack is not in end-user location. Investigation done by country, where pack was decommissioned.	MAH investigates on other market. Additional info can be provided by CZMVO from CZMVS upon request.

CLOSING ALERT STATUSES - X

- Type of alerts: **A1**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once the cause (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4):

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06l **- Non FMD**	• Scan products which are out of scope of the FMD (OTC, 'Indian Product Codes', medical device, etc.) • Product Code not uploaded into the EMVS. • Product Master Data not uploaded into the EMVS (or failure to transmit to CZMVS) • Product codes not compliant with national coding requirements (NTIN instead of GTIN) • Incomplete 2D matrix code • Manual entry error • Scan of test codes in Production Environment (PRD) Scanning of 2D data matrix code on shipper box or pallet	Keep medicinal pack in quarantine until the end of alert investigation and closing by MAH/OBP or CZMVO. Once alert is closed, provided info from AMS: **Medicinal product is not subject to FMD. Can be issued without verifying. Remove from quarantine.**	MAH or end-user found out during alert investigation that verified pack or device is not subject to FMD.
06z **- Closed - 2019 alert**	• All potential causes of alerts		Alerts from 2019 were automatically closed based on agreement with NCA. During 2019 it was enabled to supply over the alert.

Národní organizace pro ověřování pravosti léčiv

The list of end users‘ procedural errors

THE LIST OF 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 change (e.g. Supplied, Active) due to a delayed response from CZMVS.	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.	
		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!