



Národní organizace  
pro ověřování  
pravosti léčiv

# CZMVO ALERT MANAGEMENT SYSTEM WEB INTERFACE

User Manual for marketing authorization holders MAH/On-boarding partners OBP  
**Release 7.0**

*19th October 2023*

# INTRODUCTION

## Audience

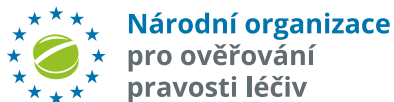
This manual is intended mainly for MAH/OBP, but it can provide information also to other users of CZMVO alert management system via the web interface.

The examples depicted in this manual are specific for MAH/OBP. The set of functions available for MAH/OBP may differ from the functions available for distributors and pharmacies.

## Prerequisites for using the system

- ✓ MAH/OBP has signed a contract with CZMVO
- ✓ The MAH / OBP has received the primary administrator access data to the Alert Management System. NOOL will send it to you on request.

**Notice:** The administrator subsequently manages all other users and their rights (including sending notifications) himself.



## Terminology\*

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

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

### Alert management system (AMS) NOOL

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).

\* Remaining terminology on the page 52 - “Alert states and their solutions”

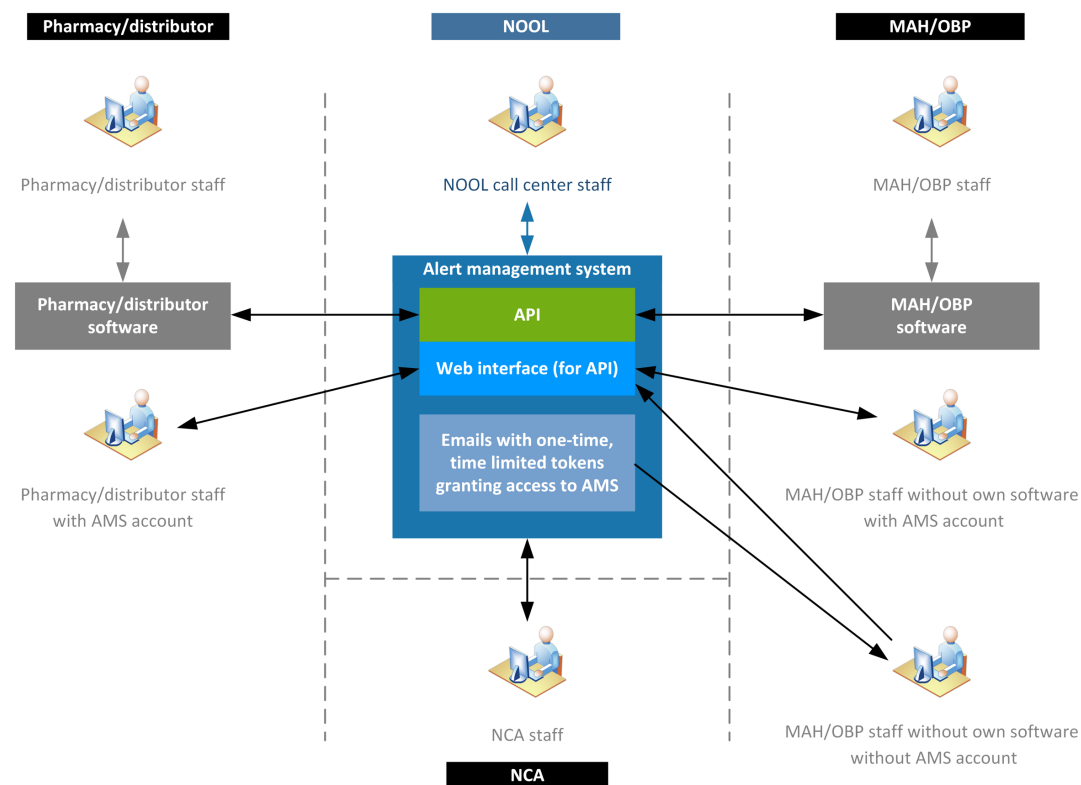
# ALERT MANAGEMENT SYSTEM

**Alert Management System (AMS)** operated by NOOL is a supplementary system to the Czech Medicines Verification System (CZMVS). The purpose of this system is to facilitate the administration associated with investigation of alerts and thus help simplify and speed up the entire investigation process.

**Alert management in the Czech Republic can be done in three options:**

- ✓ By **integrating the user's own alert management system** with the Alert-operated Alert Management System using API communication.
- ✓ **Full access to the web interface** of the NOOL **Alert Management System**. The description of this option is the main content of this manual.
- ✓ **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.

See: NOOL Alert Management System - one-time\_access\_MAH\_7.0.pdf  
- <https://www.czmvo.cz/file.php?id=802>



# 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 then, 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**.



# 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.

# 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.

## Two-factor authentication for the web interface

To access the web interface, a two-step authentication will be implemented. As the second step, e-mail address or Google/Microsoft authenticator may be used (or others).

Selection of the second step will be adjustable by the administrator, eventually by the user administering users of the concerned organization.

The users should transfer to the higher version of secured access to AMS at any time in the following 5 months.

## Time limit for web login

After a non-activity longer than a set time (currently 4 hours), the user will be logged out automatically.

## IT SECURITY

### Account lock after several unsuccessful attempts

If a user enters an incorrect password several times, the corresponding account will be locked for a defined period.. (Currently 3 unsuccessful attempts = account lock for 60 minutes).

### Login page attributes settings

The parametr autocomplete="off" is set for the account login page to prevent certain types of attacks.

### Error messages unification upon login

The aim is to unify error messages in order to block guessing of valid login accounts.

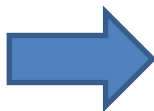
# REGISTRATION FOR ACCESS CREDENTIALS

## Contact

For all requests related to the registration email [registrace@czmvo.cz](mailto:registrace@czmvo.cz) should be used.

Once NOOL registers MAH/OBP in the alert management system MAH/OBP will obtain registration e-mail.

Example of registration e-mail



## Example of Registration e-mail from NOOL

From: NOOL <no-reply@czmvo.cz>  
Date: Wednesday 12th February 2021 12:27  
To whom: <info@czmvo.cz>  
Subject: < CZMVS - registrace - sprava Alertu/CZMVS - registration - Alert administration >

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Vazeny pane/pani, zasilame Vam pristupy do NOOL Systemu pro spravu alertu (AMS):

Dear Sir/ Madam, We send you access to the CZMVS Alert Management System (AMS):

Pristupove udaje/Access credentials:

Login: TEST  
Heslo/Password: 92ec2350cf

Ostre prostredi/Production enviroment:  
Webove rozhrani/Web interface: <https://portal.czmvo.cz/>  
Rozhrani API/API interface: <https://api.czmvo.cz/>

Doporucujeme si **pristupove udaje po zalogovani zmenit.**

We recommend that **you change the access data after logging in.**

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Na tento e-mail neodpovidejte - je automaticky generovan systemem!  
Do not reply to this e-mail - it is automatically generated by the system!  
NOOL, z.s.

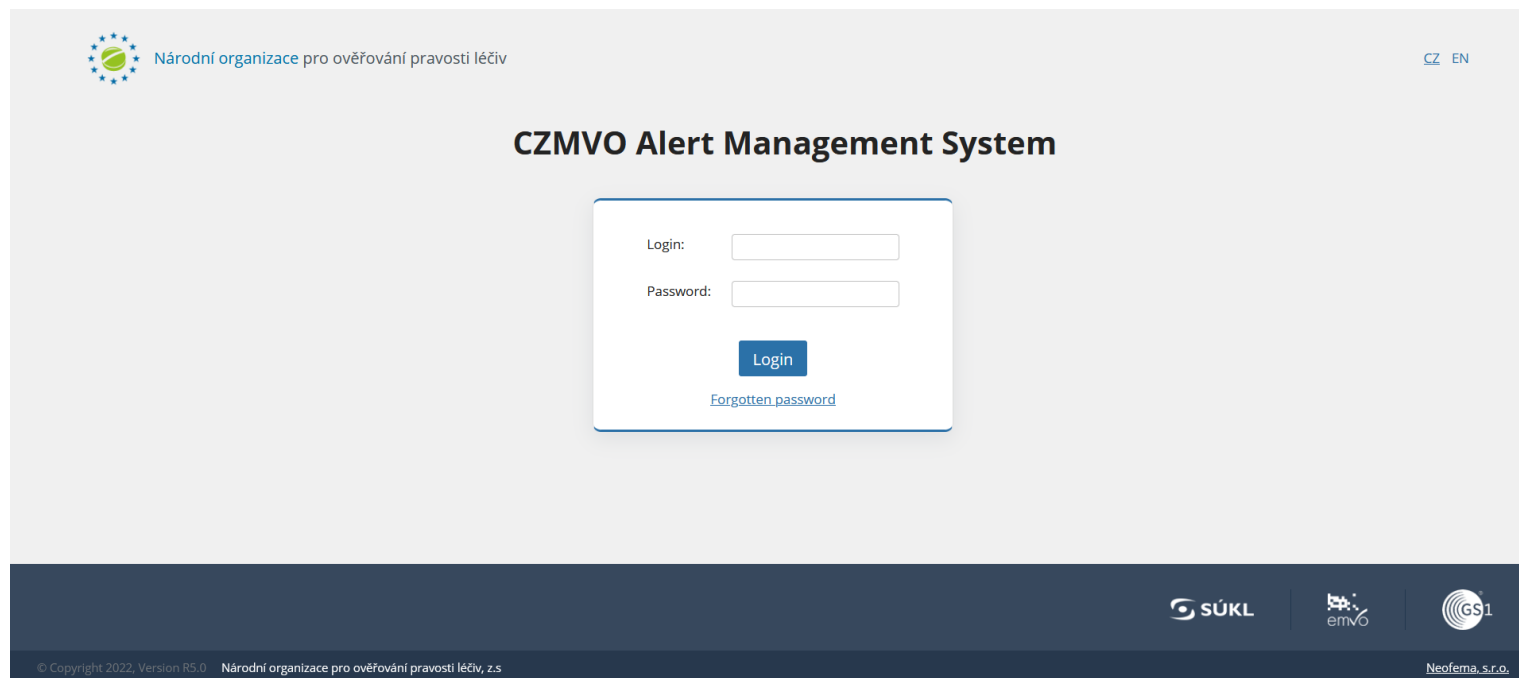
# LOGIN TO NOOL ALERT MANAGEMENT SYSTEM

Web interface of NOOL **PRODUCTION** alert management system is available on the link: <https://portal.czmvo.cz>

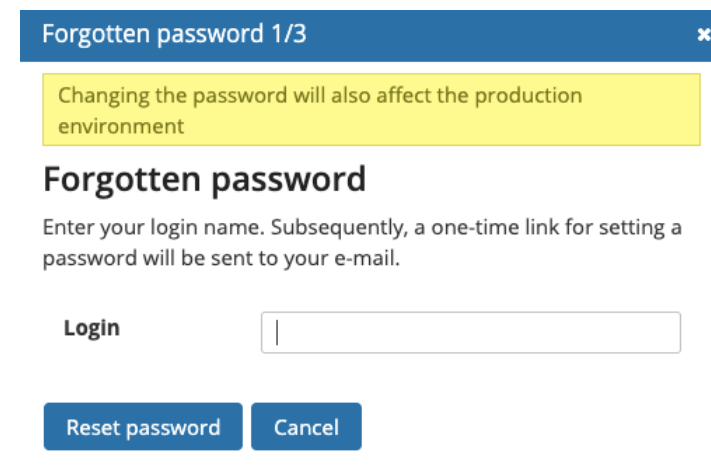
1. k „*Login*“. Authentication dialog will appear.
2. Enter *Login name* and *Password* provided by the NOOL into login page.

Web interface of NOOL **TEST** alert management system is available on the link: <https://sandbox.czmvo.cz> It is designed to testing and development of functionalities for current production environment (i.e. test and production environment are identical – same functionalities). Test env. Is updated every night with a copy of current production data, therefore testing can be done on real production data. The following night, all data will be overwritten with new current data and any changes made will be ignored. Changes in the test env. hence do not influence data in the production environment at all.

**DEVELOPMENT environment** was made available. It is used to testing and development of IT SWs **for future version/release of AMS, that is to be implemented** into production environment in the near future. Web interface **DEVELOPMENT** of AMS NOOL is available on the link: <https://beta.czmvo.cz>



**Note:** If you forget your password, it is possible to generate a new password by clicking on "*Forgotten password*". If you do not know your login, send a request for a password reset to [registration@czmvo.cz](mailto:registration@czmvo.cz). ([registrace@czmvo.cz](mailto:registrace@czmvo.cz)).



# TWO-FACTOR AUTHENTICATION SETUP

After a successful login to the web portal, you will be prompted to set up a two-factor authentication. As a second factor, you may select an e-mail address or Google Authenticator.

## Instructions to set up authentication via an e-mail address:

1. Select the authentication method "E-mail". Click on "Continue".
2. Insert an e-mail address in the field "E-mail". A verification code will be sent to this address.
3. Copy the authorization code from the body of the e-mail sent to your e-mail address.
4. Enter the code in the "Verification code" field and click "Finish".
5. Click "OK". The setup has been completed.

Toto je automaticky generovaný e-mail. Na tuto zprávu neodpovídejte.

This is an automatically generated email. Do not reply to this message.

Vážený uživatelé CZ AMS/Dear users of CZ AMS,

vas autorizacni kod pro vstup je / your authorization code for entry is:

**784835**

Platnost kodu je 10 minut. / The code is valid for 10 minutes.

S pozdravem/Regards  
NOOL, z.s.

The screenshot shows four sequential steps of the authentication setup process, each in a separate browser window:

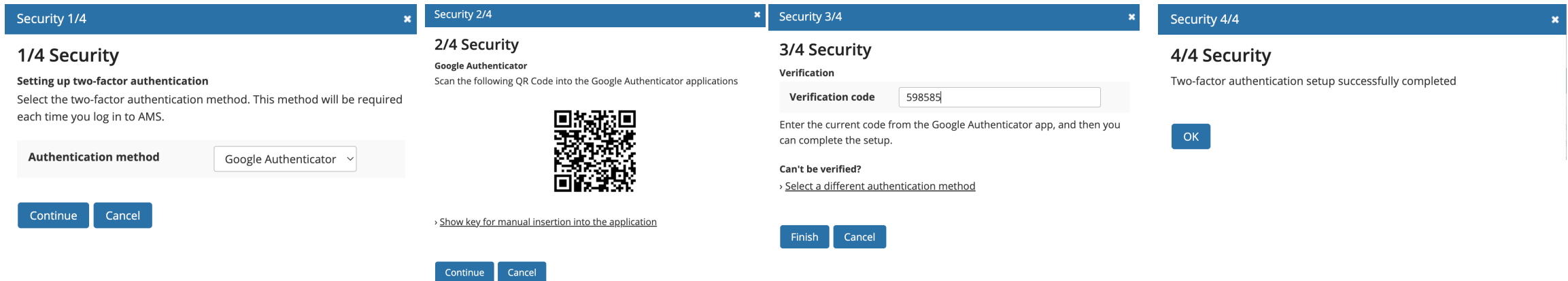
- Security 1/4:** "1/4 Security" - "Setting up two-factor authentication". The user selects "E-mail" as the authentication method. Buttons: "Continue", "Cancel".
- Security 2/4:** "2/4 Security" - "E-mail". The user enters the email address "lukas.le@mvo.cz". Buttons: "Continue", "Cancel".
- Security 3/4:** "3/4 Security" - "Verification". A verification code "784835" has been sent to the email. The user enters "784835" in the "Verification code" field. Buttons: "Finish", "Cancel".
- Security 4/4:** "4/4 Security" - "Two-factor authentication setup successfully completed". Button: "OK".

At the bottom left of the screenshot is the logo of the National Organization for the Verification of Medicines (Národní organizace pro ověřování pravosti léčiv).

# TWO-FACTOR AUTHENTICATION SETUP

## Instructions to set up authentication via the application Google Authenticator:

1. Select the authentication option "Google Authenticator". Click on "Continue".
2. With your device, scan the QR code into the application Google Authenticator. Click on "Continue".
3. In the field "Verification code" enter the current code displayed in your application. Click "Finish".
4. Click "OK". The setup has been completed.



The image displays four sequential screenshots of the Google Authenticator setup process:

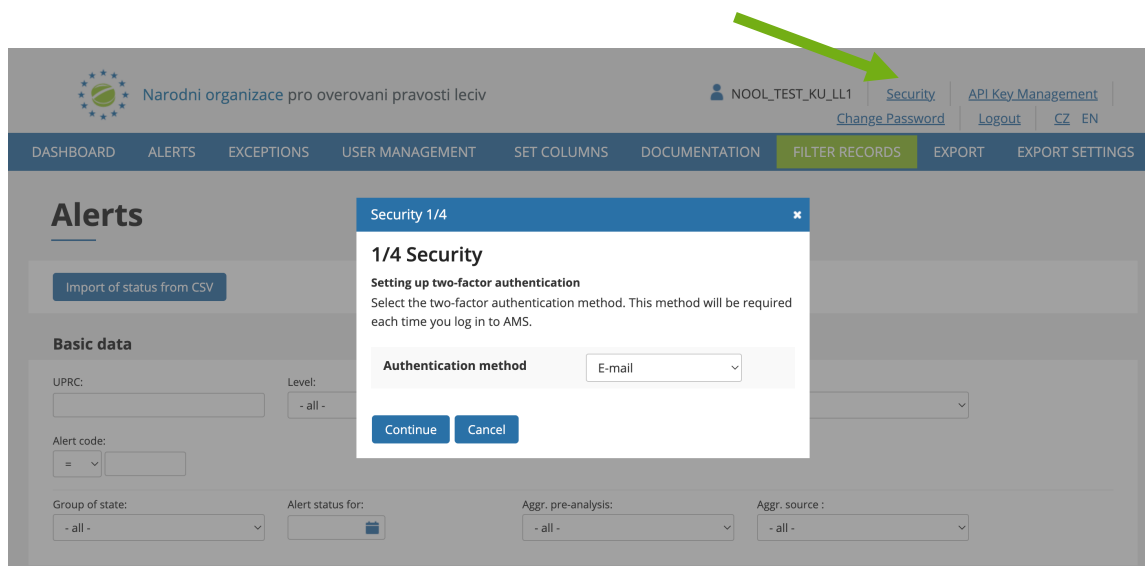
- Security 1/4:** Titled "1/4 Security", it shows the "Setting up two-factor authentication" screen. A dropdown menu for "Authentication method" is set to "Google Authenticator". "Continue" and "Cancel" buttons are at the bottom.
- Security 2/4:** Titled "2/4 Security", it shows the "Google Authenticator" screen with a QR code for scanning. A link for "Show key for manual insertion into the application" is visible. "Continue" and "Cancel" buttons are at the bottom.
- Security 3/4:** Titled "3/4 Security", it shows the "Verification" screen. A text input field contains the code "598585". Below it, instructions and a "Can't be verified?" link are present. "Finish" and "Cancel" buttons are at the bottom.
- Security 4/4:** Titled "4/4 Security", it shows the completion screen with the message "Two-factor authentication setup successfully completed" and an "OK" button.

# TWO-FACTOR AUTHENTICATION SETUP

Depending on your selected option, upon each login you will be prompted to enter the verification code, either via e-mail or the Google Authentication application.

**The two-factor authentication option can be changed anytime.**

1. On the top right click on the “Security” link and select the required option. Further steps as per pages 9 and 10.



The screenshot displays the user interface of the National Organization for Drug Verification (Národní organizace pro ověřování pravosti léčiv). The top navigation bar includes links for 'Security', 'API Key Management', 'Change Password', 'Logout', 'CZ', and 'EN'. A green arrow points to the 'Security' link. Below the navigation bar, the 'Alerts' section is visible, featuring a modal dialog box titled 'Security 1/4'. The dialog box contains the following text: '1/4 Security', 'Setting up two-factor authentication', and 'Select the two-factor authentication method. This method will be required each time you log in to AMS.' Below this text is a dropdown menu labeled 'Authentication method' with 'E-mail' selected. At the bottom of the dialog are 'Continue' and 'Cancel' buttons. The background shows the 'Alerts' page with various filters and a 'Basic data' section.



# 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.

Národní organizace pro overování pravosti léčiv

NOOL\_TEST\_KU\_LL1 | Change Password | Logout | CZ EN

DASHBOARD | ALERTS | EXCEPTIONS | USER MANAGEMENT | DOCUMENTATION

## T&C

### LICENCE TERMS AND CONDITIONS FOR THE USE OF THE ALERT MANAGEMENT SYSTEM (hereinafter referred to as the "Licence")

**Provider of the license:**

Národní organizace pro ověřování pravosti léčiv, z.s.,  
with its registered seat at Pobežnění 620/3, Karlín, Postal Code 186 00, Prague 8,  
ID No.: 058 51 742,  
registered in the Associations Register maintained by the Municipal Court in Prague, File No. L 67982  
(hereinafter referred to as "NOOL").

This Licence regulates the terms and conditions of the connection and access to the Alert Management System (hereinafter referred to as the "AMS") and use of the AMS, which is operated by NOOL.  
NOOL allows use of the AMS to the User (as defined in Art. 1 of this Licence) subject to the contents of this Licence. NOOL does not sell the AMS to the User (as defined in Art. 1 of this Licence) and NOOL remains the non-profit legal entity that establishes and manages the AMS.

#### 1. DEFINITION

As used in this Licence, the following terms shall have the following meanings:

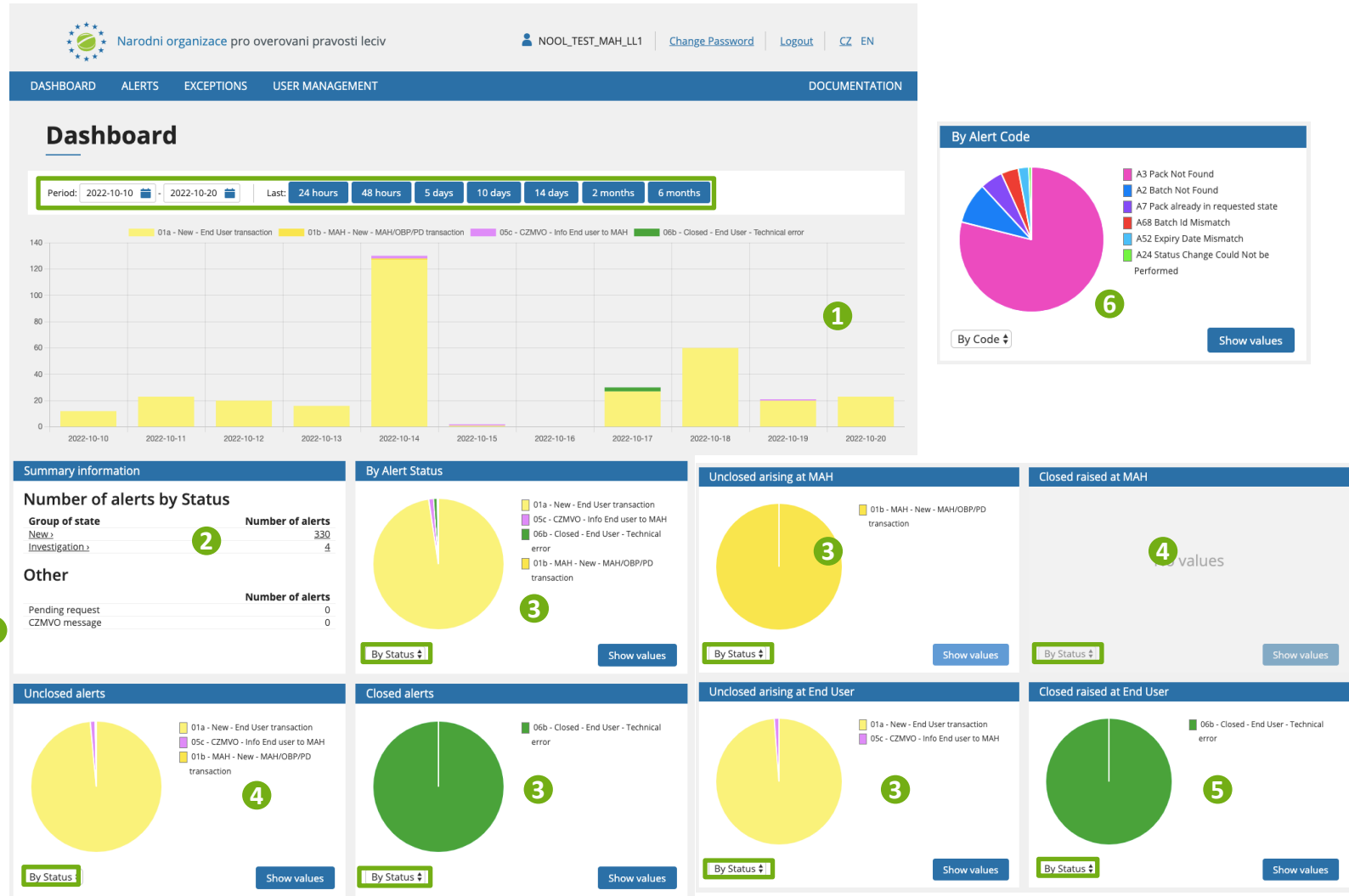
- » **Access** is a set of login data that allows to log into AMS and manage Alerts in AMS.
- » **Alerts** are alerts which arise in the process of authentication of medicinal products as a result of the detection of a potential counterfeit medicinal product or as a result of a procedural or technical error and which are managed in the AMS.
- » **AMS** means Alert Management System, which is operated by NOOL. Alerts are operated (i.e. inserted, modified and solved) in the AMS.
- » **Confidential Information** is
  1. all Data;
  2. all information and software for or relating to the AMS (including the AMS interface); and
- » any information which, unless otherwise described above, is designated by the disclosing party as confidential or is of such a nature that a reasonable person would believe it to be confidential.
  - » **Data** means any information uploaded to the AMS, processed by the AMS, transferred to the AMS, generated or stored by or through AMS, whether or not such data contains Personal Data.
  - » **Delegated Regulation** means Commission Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules on the safety features appearing on the packaging of medicinal products for human use.
  - » **Effective Date** means the date on which this Licence is executed.
  - » **End User** is a distributor or a person authorised or entitled to dispense medicinal products to the public.
  - » **EU Falsified Medicines Directive** means Directive 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use as regards the prevention of the entry of falsified medicinal products into the legal supply chain and, where applicable, the relevant implementing laws of the relevant EEA Member States.
  - » **European Central Repository** refers to the part of the EMVS under the responsibility of EMVO which serves as the central information and data router as referred to in Article 32(1)(a) of the Delegated Regulation for the transfer of data to and from the National Systems; it is set up and managed by EMVO.
  - » **European Medicines Verification Organisation** or "EMVO" means a non-profit legal entity established to set up and manage the European Central Repository in accordance with the EU Falsified Medicines Directive and the Delegated Regulation.
  - » **European Medicines Verification System** or "EMVS" means the European Medicines Verification System established and administered in accordance with Chapter VII of the Delegated Regulation; it consists of the European Central Repository and the National Systems and enables End Users to verify the authenticity of medicinal products in accordance with the provisions of the EU Falsified Medicines Directive and the Delegated Regulation.
  - » **Intellectual Property Rights** are any or all patents, rights to inventions, utility models, registered designs, design rights, trademarks, service marks, copyrights, ancillary and related rights, database rights, trade names and business names, domain rights,<sup>[1]</sup> knowledge and experience, computer software rights, proprietary promotional materials, trade secrets and any and all other intellectual or industrial property rights in all their inherent and moral aspects, as well as any application thereof anywhere in the world (whether or not registered).
  - » **Marketing Authorisation Holder** or "MAH" is a company, as well as any other holder of a marketing authorisation for a medicinal product with effects in the Czech Republic, to which the EU Falsified Medicinal Products Directive and the Delegated Regulation apply. Marketing Authorisation holders are also parallel importers of medicinal products in the Czech Republic.
  - » **National Medicines Verification Organisation** or "NMVO" means a non-profit legal entity established in the European Union that is responsible for the establishment and management of a national and/or transnational repository in accordance with the provisions of the EU Falsified Medicines Directive and the Delegated Regulation.

# MAIN SCREEN - DASHBOARD

After a successful login, the main screen **Dashboard** will appear.

The dashboard comprises:

- a) **A bar chart** – the current states of alerts raised in a selected date range 1
- b) **A summary overview** of count of alerts and requests in a selected date range. 2
- c) **Pie charts** – with a detailed analysis of alerts raised in a selected date range
  - By states of alerts (unclosed/closed) 3
  - Raised by MAH 4
  - Raised by end users 5
  - By alert codes



Changing By status/By code in tiles „Closed“ and „Unclosed you can switch between the selected display

# MAIN SCREEN – DATE RANGE SELECTION

## Dashboard

Period: 2022-10-10 - 2022-10-20 | Last: 24 hours 48 hours 5 days 10 days 14 days 2 months 6 months

October 2022						
Su	Mo	Tu	We	Th	Fr	Sa
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

Clicking in the little frame you can select the displayed date range either in the calendar or on the bar. The last selected date range will be set for the following login.

# MAIN SCREEN – SUMMARY OVERVIEW

## Summary information

### Number of alerts by Status

Group of state	Number of alerts
<a href="#">New &gt;</a>	330
<a href="#">Investigation &gt;</a>	4

### Other
















	Number of alerts
Pending request	0
CZMVO message	0

In the **summary overview** table the user can display a summary of alerts in a requested state.

After clicking on the alert state (or the number) a screen displaying the corresponding list of alerts will appear within the date range selected in the previous step (the system jumps to “Alerts” tab).

Listing is limited by filters: Group of state: New ✕

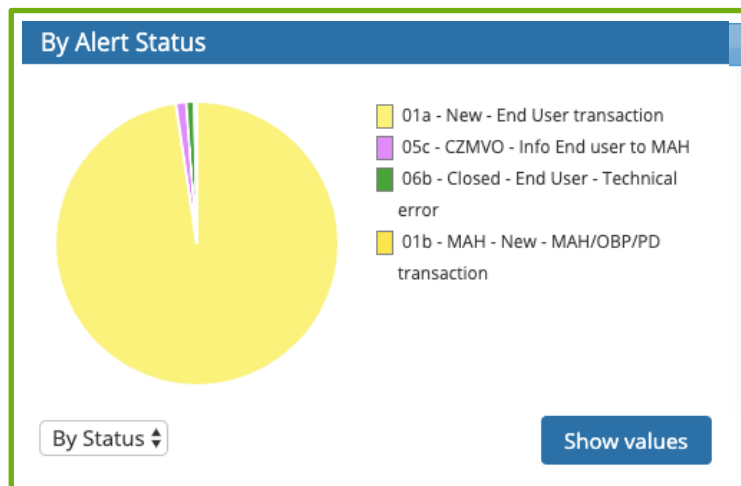
Displayed: 1–50 of 330 records 1 2 3 ... 6 7 Count per page:

Action	UPRC	Level	Created	Number of days since last alert status change (from-to)	Alert code	Priority	Group code	Anonymous group	Group of state	Product code	National Code	Catalogue Market	P
<input type="checkbox"/>   	<a href="#">CZ-LRL-Z1E-ASX-40V-0J0</a>	5	2022-10-20 12:22	0	A7	Standard	-	88651	New	08594739214323	8594739214323	CZ	C ta
<input type="checkbox"/>   	<a href="#">CZ-LRL-YZJ-53E-5H0-PCB</a>	5	2022-10-20 12:20	0	A7	Standard	-	88651	New	08594739214323	8594739214323	CZ	C ta
<input type="checkbox"/>   	<a href="#">CZ-LRL-YXF-DVP-1JV-3KY</a>	5	2022-10-20 12:18	0	A7	Standard	-	88651	New	08594739214323	8594739214323	CZ	C ta
<input type="checkbox"/>   	<a href="#">CZ-LRL-YX3-FG1-WZ1-DR5</a>	5	2022-10-20 12:18	0	A3	Standard	-	-	New	08594739024403	8594739024403	CZ	G m
<input type="checkbox"/>   	<a href="#">CZ-LRL-YX0-3E2-K97-D98</a>	5	2022-10-20 12:18	0	A3	Standard	-	-	New	08594739038899	8594739038899	CZ	O H Lé

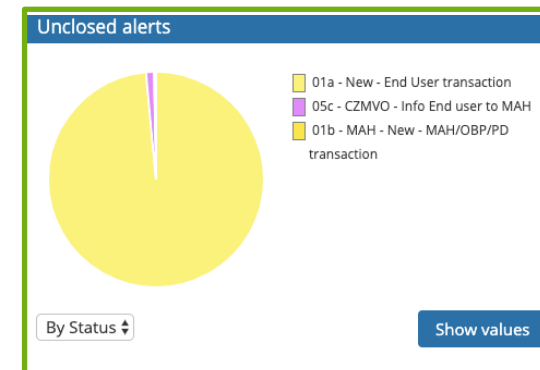
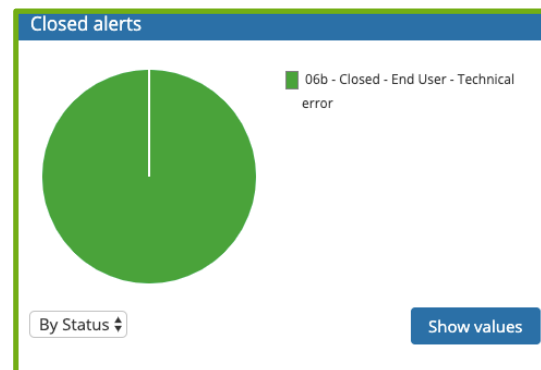


Národní organizace  
pro ověřování  
pravosti léčiv

# MAIN SCREEN – DISPLAY ALERT VALUES



In the tiles **By alert state**, **Closed alerts**, **Unclosed alerts** and **By alert code** the user can view the count of alerts and the percentage ratio by clicking „Show values“.



**By Alert Status (By Status)** ✕

	Number	Procent
01a - New - End User transaction	329	97,6%
05c - CZMVO - Info End user to MAH	4	1,2%
06b - Closed - End User - Technical error	3	0,9%
01b - MAH - New - MAH/OBP/PD transaction	1	0,3%
<b>Total</b>	<b>337</b>	

Ok

**Closed alerts (By Status)** ✕

	Number	Procent
06b - Closed - End User - Technical error	3	100%
<b>Total</b>	<b>3</b>	

Ok

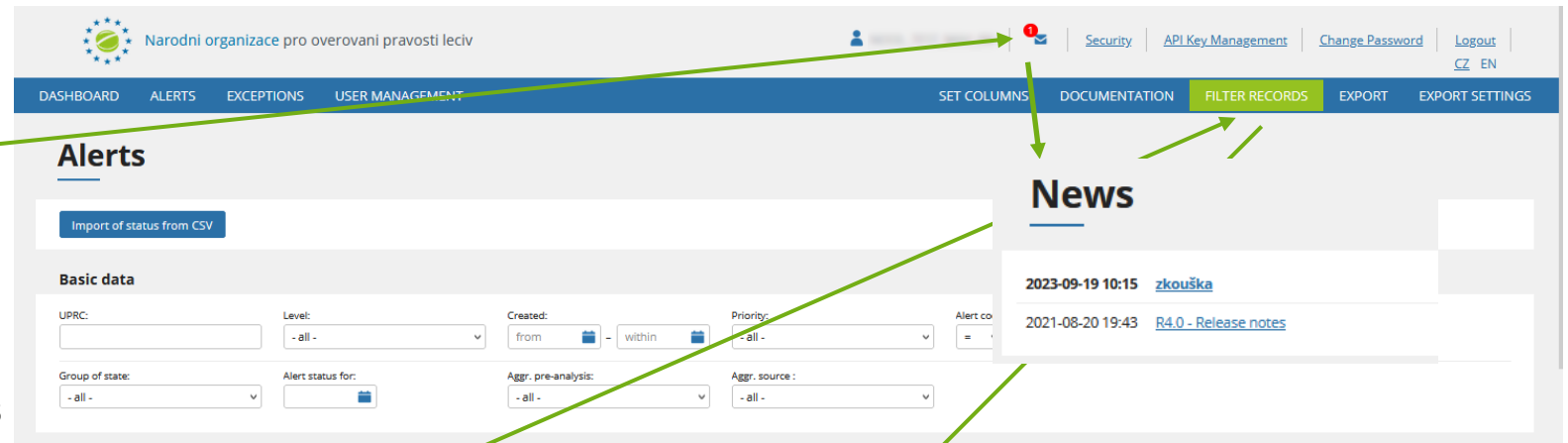
**Unclosed alerts (By Status)** ✕

	Number	Procent
01a - New - End User transaction	329	98,5%
05c - CZMVO - Info End user to MAH	4	1,2%
01b - MAH - New - MAH/OBP/PD transaction	1	0,3%
<b>Total</b>	<b>334</b>	

Ok

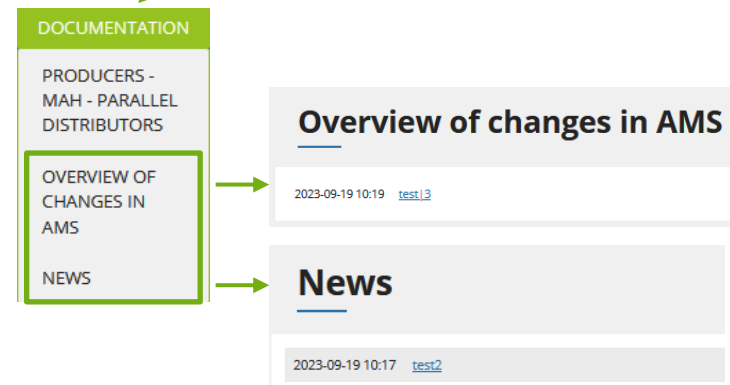
# INFORMATION ABOUT CHANGES, UPDATES, NOTIFICATIONS

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 will appear in this menu containing a link to the related release notes.

A new line "News" was added containing links to the selected news from the NOOL's website (e.g. Did you know, that )



# USER ADMINISTRATION

The user with admin rights can see the “Users Administration” button, which enables to enter the subsection for administration of users.

## User roles:

**Administrator** - Administration of users, complete administration of alerts

**User** – complete administration of alerts

**Viewer** – alerts browsing, generating exports

The screenshot shows the 'User Management' page of a web application. At the top, there is a navigation bar with the logo of the National Organization for Drug Safety Verification (Národní organizace pro ověřování pravosti léčiv) and the text 'Národní organizace pro ověřování pravosti léčiv'. The navigation bar includes links for 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', 'USER MANAGEMENT' (highlighted), 'SET COLUMNS', 'DOCUMENTATION', 'FILTER RECORDS', and 'EXPORT'. A user profile dropdown is visible in the top right corner with options for 'Change Password', 'Logout', and language selection 'CZ EN'. Below the navigation bar, the page title is 'User Management'. A yellow warning banner states: 'User management can only be performed in a production environment.' Below this, there is an 'Add User' button. The main content area displays a table of users with the following columns: Action, Active, Login, Name, E-mail, Environment, Role, Notification, and Action. The table shows 7 records, all with 'Active' status and 'Production and testing environment' as the environment. The roles are 'Admin' and 'User'. The 'Notification' column shows a bell icon for Admins and a checkmark for Users. The 'Action' column contains edit icons. The page footer shows the URL 'https://beta.czmo.cz/users/irds' and a 'Count per page: 50' dropdown menu.

Action	Active	Login	Name	E-mail	Environment	Role	Notification	Action
	✓	[redacted]	[redacted]	[redacted]	Test only	Admin		
	✓	[redacted]	[redacted]	[redacted]	Test only	Admin		
	✓	[redacted]	[redacted]	[redacted]	Production and testing environment	Admin	✓	
	✓	[redacted]	[redacted]	[redacted]	Production and testing environment	Admin	✓	
	✓	[redacted]	[redacted]	[redacted]	Production and testing environment	User	✓	
	✓	[redacted]	[redacted]	[redacted]	Production and testing environment	User	✓	
	✓	[redacted]	[redacted]	[redacted]	Production and testing environment	Admin	✓	

# USER ADMINISTRATION

In the **User administration** section a user with the „**admin**“ role may create, edit or deactivate new users

After clicking on "**Add user**" a screen with fields for a new user will appear.

Note: once entered, the user can only be deactivated, it cannot be cancelled (due to log consistency).

The screenshot shows the 'User Management' section of a web application. At the top, there is a navigation bar with 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', and 'USER MANAGEMENT' (highlighted). The page title is 'User Management'. A yellow banner states: 'User management can only be performed in a production environment.' Below this is an 'Add User' button. The main content area displays a table of users with the following columns: Action, Active, Login, Name, E-mail, Environment, Role, Notification, and Action. The table contains 7 records. The first two records are in a 'Test only' environment with an 'Admin' role. The remaining five records are in a 'Production and testing environment' with 'Admin' or 'User' roles. Each record has a pencil icon for editing and a checkmark for the 'Active' status. The page footer shows the URL 'https://beta.czmvvo.cz/users/ 1rds' and a 'Count per page: 50' dropdown menu.

Action	Active	Login	Name	E-mail	Environment	Role	Notification	Action
	✓	[blurred]	[blurred]	[blurred]	Test only	Admin	✓	
	✓	[blurred]	[blurred]	[blurred]	Test only	Admin	✓	
	✓	[blurred]	[blurred]	[blurred]	Production and testing environment	Admin	✓	
	✓	[blurred]	[blurred]	[blurred]	Production and testing environment	Admin	✓	
	✓	[blurred]	[blurred]	[blurred]	Production and testing environment	User	✓	
	✓	[blurred]	[blurred]	[blurred]	Production and testing environment	User	✓	
	✓	[blurred]	[blurred]	[blurred]	Production and testing environment	Admin	✓	



# USER ADMINISTRATION

In the section “Users administration”, a user with admin rights may **edit their own details, add, activate or deactivate users.**

The screenshot displays a web-based user administration interface. At the top, there are navigation buttons: "Back", "Save", and "Apply". The interface is divided into several sections:

- General:** Includes fields for "Active" (checked), "Name", "Login", and "E-mail". A note below the E-mail field states "E-mail for delivery of access data".
- Authorization:** Includes a dropdown for "Environment" (set to "Test only"), a dropdown for "Role" (set to "User"), and a section for "MAH" with a checkbox "All" checked and a note: "If checked, then the user has access to the alerts of the MAH."
- Notification:** Includes an "Allowed" checkbox (unchecked) with a note: "Sending notification e-mails from the system is allowed. You must complete at least one e-mail below." Below this is a text area for "E-mails" with a note: "Each e-mail on its own line".
- Notification settings:** A list of checkboxes, all of which are checked:
  - Information on the entry of high-priority alerts (vaccines,...)
  - Information on closing the alert by CZMVO or End User
  - Escalation - MAH inactivity 5 days
  - Escalation - MAH inactivity 10 days
  - Information on sending a message to NOOL (messenger)
  - Information about the new alert
  - Information on reopening an already closed alert by MAH or End User
  - Obdržena nová zpráva od KU/NOOL (předvolené)
  - Information on sending a message to End User (default)A note at the bottom states: "At least one MAH must have Information on the entry of high-priority alerts (vaccines,...), Escalation - MAH inactivity 5 days, Escalation - MAH inactivity 10 days notifications turned on."

# ADD USER

1. Tick or untick this box to **activate / block** a user.
2. **Identifier** (Name, Title).
3. **Login** (login name).
4. **E-mail** where you wish to receive your credentials.
5. Tick or untick this box to **receive notification e-mails**. These e-mails notify you about new alerts raised or your own inactivity (e.g. no action taken for more than 10 days from the alert date).
6. If the box is checked in step 5, please **insert e-mail accounts** where you wish to receive notification e-mails. You may enter an unlimited number of e-mail addresses.

The screenshot shows the 'ADD USER' form with the following sections and fields:

- General**
  - Active:**  (1)
  - Name:** [Text input field] (2)
  - Login:** [Text input field] (3)
  - E-mail:** [Text input field] (4)  
E-mail for delivery of access data
- Authorization**
  - Environment:** Test only
  - Role:** User
  - MAH:** (8)
    - All
    - [Other MAH]
- Notification**
  - Allowed:**  (5)  
Sending notification e-mails from the system is allowed. You must complete at least one e-mail below.
  - E-mails:** [Text area] (6)  
Each e-mail on its own line
  - Notification settings:** (7)
    - Information on the entry of high-priority alerts (vaccines,...)
    - Information on closing the alert by CZMVO or End User
    - Escalation - MAH inactivity 5 days
    - Escalation - MAH inactivity 10 days
    - Information on sending a message to NOOL (messenger)
    - Information about the new alert
    - Information on reopening an already closed alert by MAH or End User
    - Obdržena nová zpráva od KU/NOOL (předvolené)
    - Information on sending a message to End User (default)

7. Selecting notifications the user wishes to receive

8. Selecting MAH(s) whose alerts you wish to manage.

# ADD USER

Back | Save | Apply

<b>General</b>	<b>Authorization</b>
<b>Active</b> <input checked="" type="checkbox"/>	<b>Environment</b> <input type="text" value="Test only"/>
<b>Name</b> <input type="text"/>	<b>Role</b> <input type="text" value="Test only"/>
<b>Login</b> <input type="text"/>	<b>MAH</b> <input type="text" value="Production and testing environment"/>
<b>E-mail</b> <input type="text"/>	<small>If checked, then the user has access to the alerts of the MAH.</small>
<small>E-mail for delivery of access data</small>	<input checked="" type="checkbox"/> All
<b>Notification</b>	<input type="checkbox"/> <small>Information on sending a message to End User</small>
<b>Allowed</b> <input type="checkbox"/>	
<small>Sending notification e-mails from the system is allowed. You must complete at least one e-mail below.</small>	
<b>E-mails</b> <input type="text"/>	
<small>Each e-mail on its own line</small>	
<b>Notification settings</b>	
<input checked="" type="checkbox"/> Information on the entry of high-priority alerts (vaccines,...)	
<input checked="" type="checkbox"/> Information on closing the alert by CZMVO or End User	
<input checked="" type="checkbox"/> Escalation - MAH inactivity 5 days	
<input checked="" type="checkbox"/> Escalation - MAH inactivity 10 days	
<input checked="" type="checkbox"/> Information on sending a message to NOOL (messenger)	
<input checked="" type="checkbox"/> Information about the new alert	
<input checked="" type="checkbox"/> Information on reopening an already closed alert by MAH or End User	
<input checked="" type="checkbox"/> Obdržena nová zpráva od KU/NOOL (předvolené)	
<input checked="" type="checkbox"/> Information on sending a message to End User (default)	
<small>At least one MAH must have information on the entry of high-priority alerts (vaccines,...), Escalation - MAH inactivity 5 days, Escalation - MAH inactivity 10 days notifications turned on.</small>	

9. Selecting the environment, the user has access to (testing, testing and production).

**Note:** The credentials (login and password) are identical for both environments.

# ADD USER

Back | Save | Apply

**General**

Active

Name

Login

E-mail   
E-mail for delivery of access data

**Authorization**

Environment

Role  Viewer  
User  
Admin  
All

MAH

**Notification**

Allowed   
Sending notification e-mails from the system is allowed. You must complete at least one e-mail below.

E-mails   
Each e-mail on its own line

**Notification settings**

- Information on the entry of high-priority alerts (vaccines,...)
- Information on closing the alert by CZMVO or End User
- Escalation - MAH inactivity 5 days
- Escalation - MAH inactivity 10 days
- Information on sending a message to NOOL (messenger)
- Information about the new alert
- Information on reopening an already closed alert by MAH or End User
- Obdržena nová zpráva od KU/NOOL (předvolené)
- Information on sending a message to End User (default)

At least one MAH must have Information on the entry of high-priority alerts (vaccines,...), Escalation - MAH inactivity 5 days, Escalation - MAH inactivity 10 days notifications turned on.

## 10. Select user role (Administrator, User, Viewer)

**Admin** - Complete administration of alerts and users.

**User** - Complete administration of alerts.

**Viewer** – alerts browsing , exports

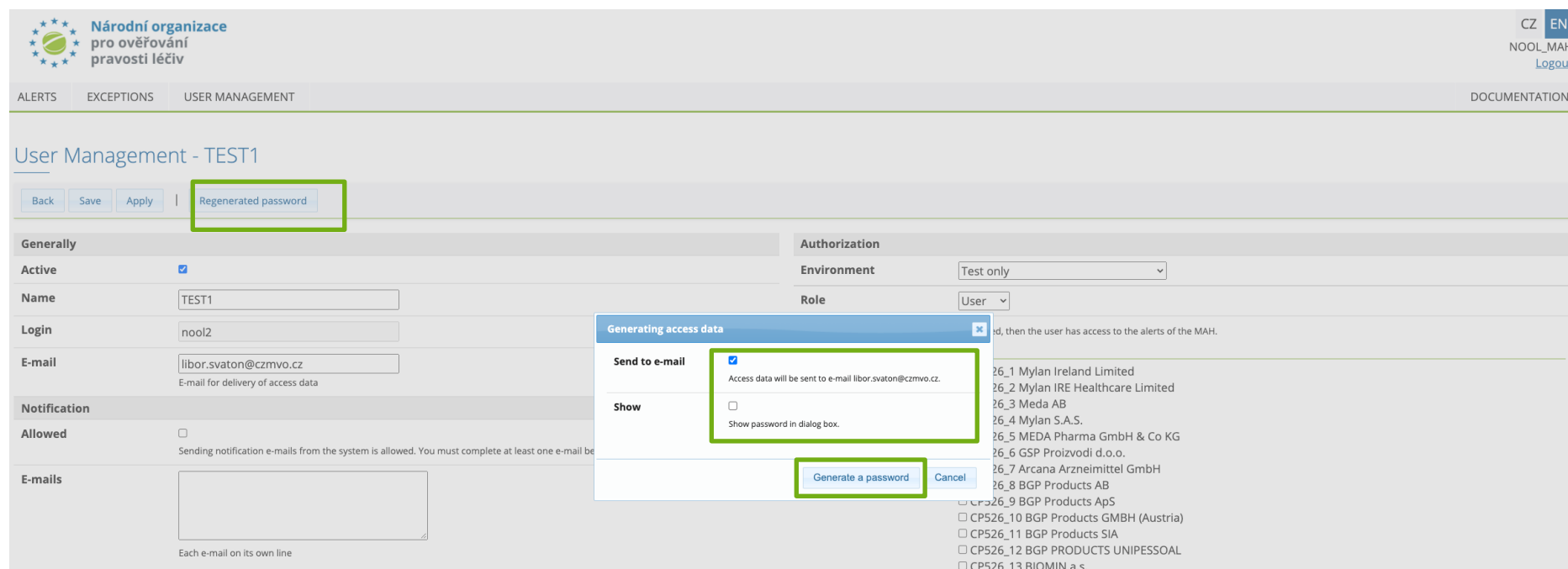
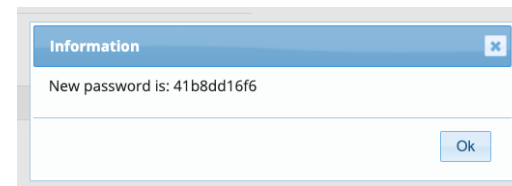
Clicking „Save“ will save your data.

# ADD USER

After saving the new user's data, you have an option to **send the credentials** to a selected e-mail address. You may also **display** them by clicking "Generate Password".

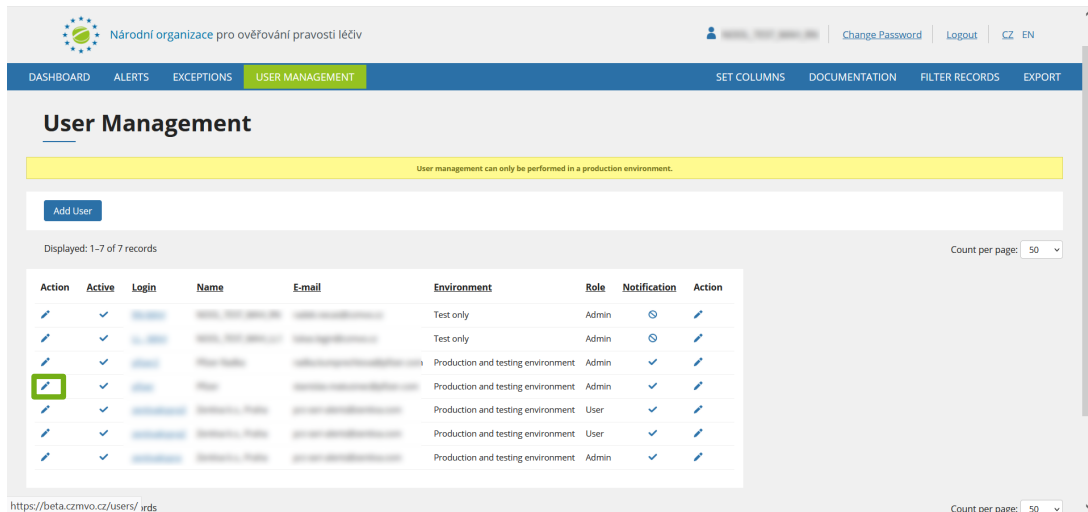
Click „OK“ to confirm.

Note: Please write down your password unless you have chosen to receive it by e-mail.

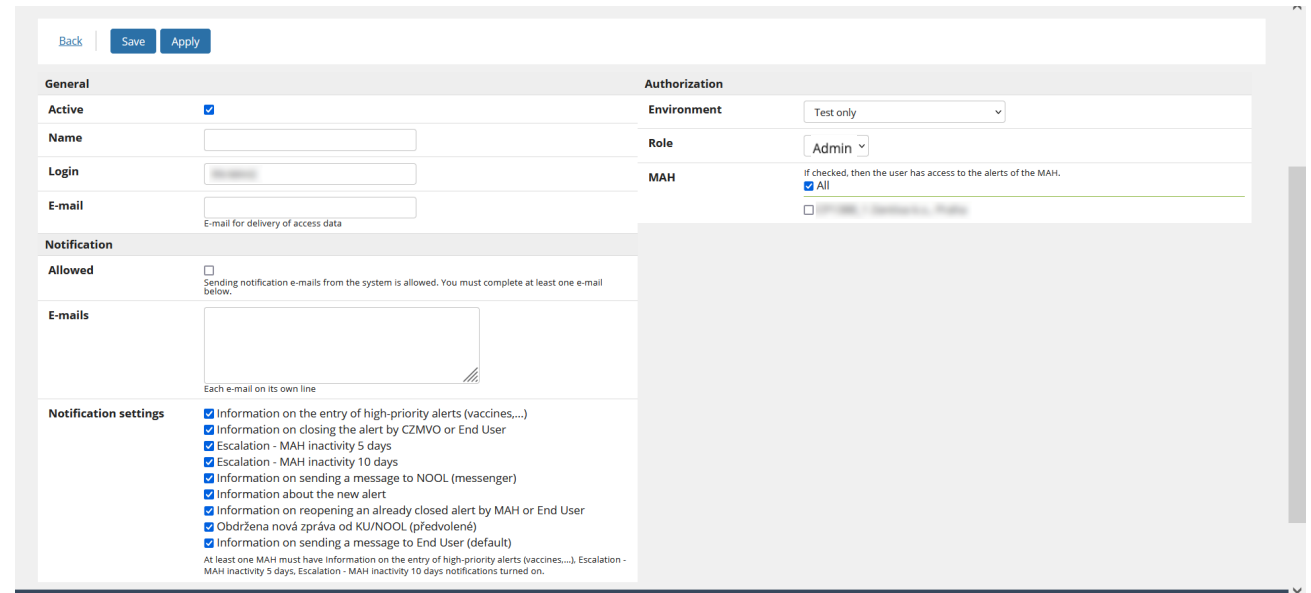
A screenshot of a web application interface for user management. The page title is "User Management - TEST1". There are buttons for "Back", "Save", "Apply", and "Regenerated password" (highlighted with a green box). The interface is divided into sections: "Generally" (Active, Name: TEST1, Login: nool2, E-mail: libor.svaton@czmvo.cz), "Notification" (Allowed), and "E-mails". On the right, there is an "Authorization" section with "Environment" set to "Test only" and "Role" set to "User". A "Generating access data" dialog box is open, showing "Send to e-mail" (checked) and "Show" (unchecked) options. A "Generate a password" button (highlighted with a green box) is visible at the bottom of the dialog. The background shows a list of pharmaceutical companies with checkboxes.

# USER UPDATE

Clicking on the “*pencil*” icon generates a pop-up window displaying details of users. If you have admin rights, you will be able to edit or deactivate current users.



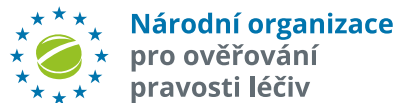
The screenshot shows the 'User Management' page in a web application. At the top, there is a navigation bar with 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', and 'USER MANAGEMENT' (highlighted). Below the navigation bar, there is a yellow warning banner that reads 'User management can only be performed in a production environment.' Below the banner, there is an 'Add User' button. The main content area displays a table of users with columns for 'Action', 'Active', 'Login', 'Name', 'E-mail', 'Environment', 'Role', 'Notification', and 'Action'. The first row is highlighted, and a green box highlights the pencil icon in the 'Action' column of the first row. The table shows 7 records, and the page is displaying 1-7 of 7 records. The URL at the bottom is 'https://beta.czmvo.cz/users/irids'.



The screenshot shows the user update form. At the top, there are 'Back', 'Save', and 'Apply' buttons. The form is divided into several sections: 'General', 'Authorization', 'Notification', and 'Notification settings'. The 'General' section includes fields for 'Active' (checked), 'Name', 'Login', and 'E-mail'. The 'Authorization' section includes a dropdown for 'Environment' (set to 'Test only'), a dropdown for 'Role' (set to 'Admin'), and a checkbox for 'MAH' (checked). The 'Notification' section includes a checkbox for 'Allowed' (unchecked) and a text area for 'E-mails'. The 'Notification settings' section includes a list of checkboxes for various notification types, all of which are checked. The URL at the bottom is 'https://beta.czmvo.cz/users/irids'.

It is possible to deactivate any number of users on the condition that at least **1 user with the Admin role** will remain active.

**Each type of notification must have at least 1 receiver!**



# CHANGING A PASSWORD

A user can change the password at any time. In the main window click on „Change password“

Follow the instructions in the pop-up window

The screenshot shows a web application interface for the National Organization for Drug Safety (Národní organizace pro ověřování pravosti léčiv). The user is logged in as NOOL\_TEST\_KU\_LL3. The interface includes a navigation bar with 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', and 'DOCUMENTATION'. The main content area displays a 'Dashboard' with a bar chart showing data from 2023-09-26 to 2023-10-17. A modal window titled 'Changing the password 1/2' is open, prompting the user to enter their old password, a new password (with a note: 'The password must be at least 8 characters long and have at least one number and one letter'), and a password confirmation. A yellow warning box states 'Changing the password will also affect the production environment'. A 'Change Password' button is highlighted. A second modal window titled 'Changing the password 2/2' is partially visible, showing a confirmation message 'The password has been changed' and an 'OK' button.

# MAIN PAGE –ALERTS - CONTROLS

1. **Language** selector
2. Password change
3. Switch to Dashboard
4. Switch to the **exception** list
5. Switch to the **user management**
6. Customization of displayed **columns**
7. Link to the **documentation** on the NOOL website
8. Show/hide **filter**
9. **Export** data (all displayed items in the list)
10. **Export settings**

The screenshot shows the 'Alerts' page of the NOOL system. At the top, there is a header with the organization's name 'Národní organizace pro ověřování pravosti léčiv' and a user profile 'NOOL\_TEST\_MAH\_LL1'. A language selector 'CZ EN' is highlighted with callout 1. Below the header is a navigation bar with tabs: 'DASHBOARD' (callout 3), 'ALERTS', 'EXCEPTIONS' (callout 4), 'USER MANAGEMENT' (callout 5), 'SET COLUMNS' (callout 6), 'DOCUMENTATION' (callout 7), 'FILTER RECORDS' (callout 8), 'EXPORT' (callout 9), and 'EXPORT SETTINGS' (callout 10). A 'Change Password' link is highlighted with callout 2. The main content area is titled 'Alerts' and features an 'Import of status from CSV' button (callout 11). Below this, there is a pagination control showing 'Displayed: 1-50 of 26140 records' and a 'Count per page' dropdown set to 50. A table of alerts is displayed with columns: Action, UPRC, Level, Created, Number of days since last alert status change (from-to), Alert code, Priority, Group code, Anonymous group, Group of state, Product code, National Code, Trh katalogu, Product, Batch ID Stored, Batch ID Provided, and Serial number. The table contains four rows of alert data.

11. Import of statuses via a CSV file

12. Delivered messages

## Note:

Clicking on column's name sort items according the selected column.



# MAIN PAGE - CONTROLS

12. Export/change state/remove from group/add to group marked (selected) alerts.

13. Action detail/send message/group with one alert.

The screenshot displays a table of alerts with the following columns: checkboxes, icons (edit, message, gift), a blue circle with '5', a date and time (2022-10-14 08:37), a status '0', a priority 'A3', a severity 'Standard', two dashes, and a state 'New'. A context menu is open over the sixth row, listing actions: '- choose -', 'Export to CSV', 'Export to CSV Excel', 'Export to XLSX Excel', 'Send message', 'Send message to CZMVO', 'Change alert state', 'Remove from the group', 'Remove from the anonymous group', and 'Add to group'. A 'Perform' button is located at the bottom right of the table. At the bottom left, there are links for 'Select All', 'Unselect All', and a 'Selected:' dropdown menu currently showing '- choose -'. A blue button labeled 'Perform' is positioned to the right of the 'Selected:' dropdown.

Checkbox	Icons	5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input type="checkbox"/>		5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input type="checkbox"/>		5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input type="checkbox"/>		5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input checked="" type="checkbox"/>		5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input checked="" type="checkbox"/>		5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input type="checkbox"/>		5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input type="checkbox"/>		5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input type="checkbox"/>		5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input type="checkbox"/>		5	2022-10-14 08:37	0	A3	Standard	-	-	New

# COLUMN SETTINGS

By default all columns are displayed.

This setting can be changed by clicking „*Set Columns*“. A pop-up with a list of columns will appear and the user can select the columns they wish to display. The selection will be confirmed by clicking „*OK*“.

The screenshot shows the 'Alerts' page of the National Organization for Medication Verification system. A 'Set Columns' dialog box is open, allowing users to select which columns to display in the table. The dialog lists the following columns with checkboxes:

- UPRC
- Level
- Created
- Number of days since last alert status change (from-to)
- Alert code
- Priority
- Group code
- Anonymous group
- Group of state
- Product code
- National Code
- Trh katalogu
- Product
- Batch ID Stored
- Batch ID Provided
- Serial number
- Date of expiration
- Alert state
- MAH ID
- MAH name
- EMVS MAH ID
- OBP ID
- OBP Název
- Source Market
- Preanalysis - automatic
- Source Business Process
- Manual Entry
- Archived
- Closed
- Pending request

The 'OK' button is highlighted with a green box. The background shows the 'Alerts' table with columns: Action, UPRC, Level, Created, Number of days since last alert status change (from-to), Alert code, and Priority. The table displays several rows of alert data.

# ALERT FILTERS

Button “*Alerts*” shows all alerts assigned to the MAH. In case of pharmacy or distributor, a list of all alerts generated by the organization is displayed.

Alerts can be filtered by various criteria or conditions: **UPRC**, **Group ID**, **Batch ID**, **Period**, **Product code**, **Serial number**, **Axx Error code**, **Product name**, **State**, **Intermarket**, **Business process**, **result of Pre-analysis**, **Requested information** from the end user, etc.

Filter will appear once you click the button “*Filter records*”. Select criteria and confirm selection by clicking button “*Filter*” or “*Enter*”.

Removing the filter settings – click on button “*Cancel Filter*”.

Národní organizace pro ověřování pravosti léčiv

Change Password Logout CZ EN

DASHBOARD ALERTS EXCEPTIONS USER MANAGEMENT SET COLUMNS DOCUMENTATION **FILTER RECORDS** EXPORT EXPORT SETTINGS

## Alerts

Import of status from CSV

### Basic data

UPRC:  Level:  Created: from  - within  Priority:  Alert code:

Group of state:  Alert status for:  Aggr. pre-analysis:  Aggr. source:

### Details

Product code:  National Code:  Product:  Batch ID Stored:  Batch ID Provided:

Serial number:  Date of expiration:  Source Business Process:  Manual Entry:  Source Market:

Trh katalogu:

### Investigation

Alert state:  Group code:  Anonymous group:  Number of days since last alert status cha...: from  - within  Archived:

Closed:  Preanalysis - automatic:

CZMVO message:  Number of days since CZMVO message: from  - within  Pending request:  MAH ID:  MAH name:

EMVS MAH ID:  OBP ID:  OBP Název:

**Filter**

Displayed: 1-50 of 26140 records    ...   Count per page: 50

Action	UPRC	Level	Created	Number of days since last alert status change (from: to)	Alert code	Priority	Group code	Anonymous group	Group of state	Product code	National Code	Trh katalogu	Product	Batch ID Stored	Batch ID Provided	Serial number
<input type="checkbox"/>																
<input type="checkbox"/>																



Národní organizace  
pro ověřování  
pravosti léčiv

# VIEW ALERT DETAIL

Click on the UPRC code of an alert or the pencil icon to view a **page with alert details**. There are several tabs in the alert detail.

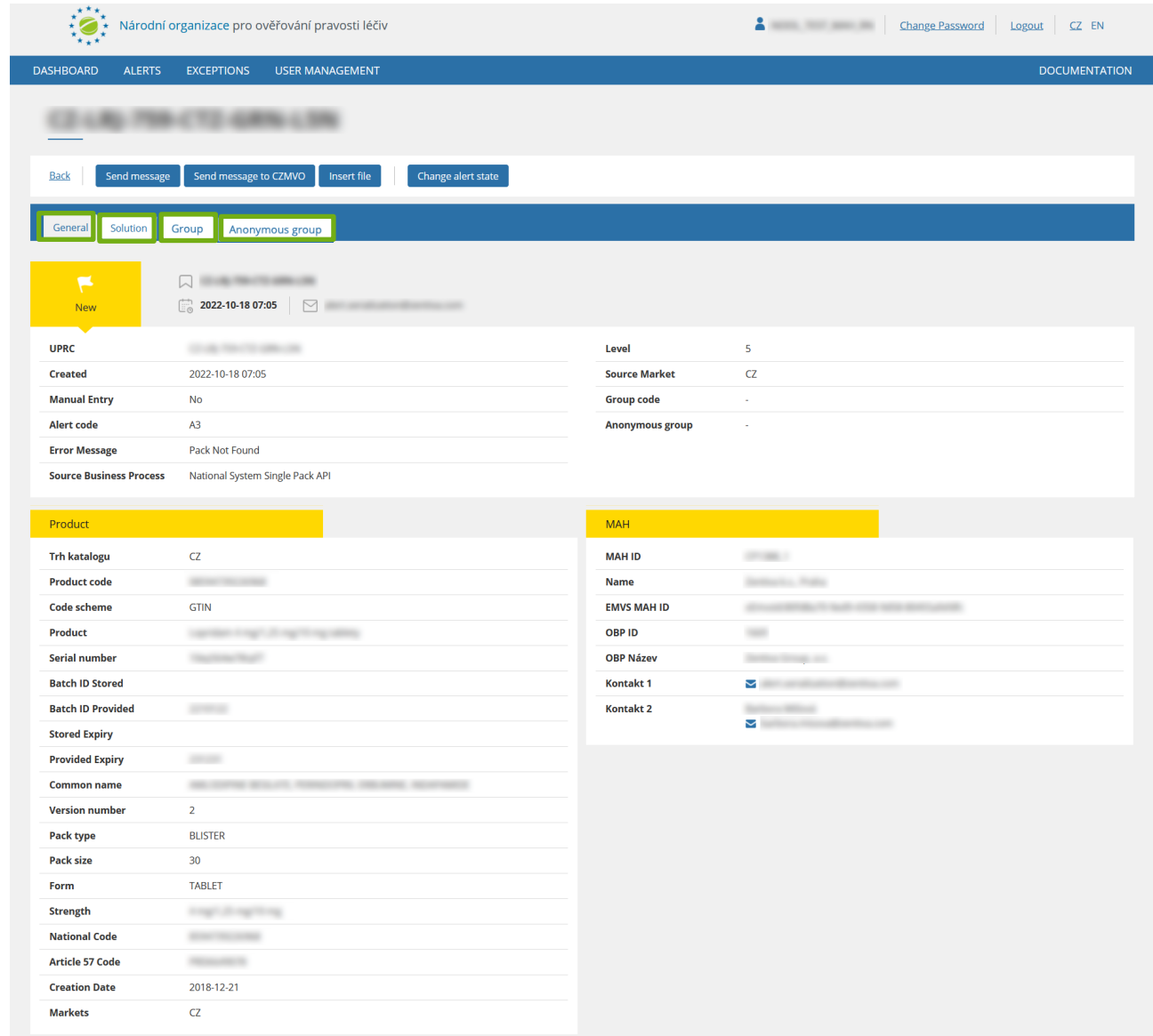
Tab *“General”* shows details about alert such as date of alert, error code, batch ID provided by the user provided or stored in EU-HUB, etc.

Tab *“Solution”* shows alert State, history of State changes, communication log between end-user and MAH (text, files), date of the last update, etc.

Tab *“Group”* shows list of the all alerts that belong to the same group.

Tab *„Anonymous group“* shows list of the alerts which belong to the same group of alerts within one organisation.

Click button *„Back“* to return to the list of alerts.



The screenshot displays the 'VIEW ALERT DETAIL' page in a web application. At the top, there is a header with the logo of the National Organization for the Verification of the Authenticity of Medicines (Národní organizace pro ověřování pravosti léčiv) and navigation links for 'Change Password', 'Logout', and language options 'CZ' and 'EN'. Below the header is a navigation bar with tabs for 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', 'USER MANAGEMENT', and 'DOCUMENTATION'. The main content area features a breadcrumb trail and a set of action buttons: 'Back', 'Send message', 'Send message to CZMVO', 'Insert file', and 'Change alert state'. A tabbed interface is visible with 'General', 'Solution', 'Group', and 'Anonymous group' tabs. The 'General' tab is active, showing a 'New' alert with a timestamp of '2022-10-18 07:05'. The alert details are presented in two columns:

UPRC		Level	5
Created	2022-10-18 07:05	Source Market	CZ
Manual Entry	No	Group code	-
Alert code	A3	Anonymous group	-
Error Message	Pack Not Found		
Source Business Process	National System Single Pack API		

Below the alert details, there are two sections: 'Product' and 'MAH'.

Product	
Trh katalogu	CZ
Product code	
Code scheme	GTIN
Product	
Serial number	
Batch ID Stored	
Batch ID Provided	
Stored Expiry	
Provided Expiry	
Common name	
Version number	2
Pack type	BLISTER
Pack size	30
Form	TABLET
Strength	
National Code	
Article 57 Code	
Creation Date	2018-12-21
Markets	CZ

MAH	
MAH ID	
Name	
EMVS MAH ID	
OBP ID	
OBP Název	
Kontakt 1	
Kontakt 2	

# CHANGE ALERT STATE \*

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

Checking “*For the whole group*” option will set the requested state to all alerts in the same group of alerts.

Checking “*For the entire anonymous group*” will set the requested state to all alerts in the same anonymous group

## Important:

Before you change the state of the group, please verify that all alerts in the group have the same reason and solution. Grouping is an automated function and it may happen that alerts with different root cause are grouped. In such case, you need to remove some alerts from the group use function “*Remove from group*”.

The screenshot displays the AMS system interface. At the top, there is a navigation menu with 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', and 'USER MANAGEMENT'. A 'Change alert state' button is highlighted in the background. A dialog box is open, showing the 'Change alert state' configuration. The dialog box includes a dropdown menu for 'Change alert state' (02a - MAH - Investigatio), a 'State description' field (Investigation - end-user transaction), and two checkboxes: 'For the whole group' and 'For the entire anonymous group', both of which are checked. The 'Save' button is highlighted in the dialog box. The background interface shows a list of alerts with columns for 'Created', 'Manual Entry', 'Alert code', 'Error Message', and 'Source Business Process'.

**Note:** It is not possible to change alert states in bulk if the current state of an alert pertaining to the bulk does not enable the change of state as per the workflow (this applies even for a single alert in the bulk that is in a different state. The change of state will not happen). If you also want to send messages to the End User for alerts in the group, use the “*Send message*” button, which can also change the status of the alert (depending on the type of message used) within the entire selected alert group.

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

# BULK CHANGE OF ALERT STATUSES

For a bulk change of alert statuses, you may import a CSV file with a list of alerts and ID of the status you wish to set for those alerts. The required status change must however conform to the process workflow, otherwise the system will dismiss the request.

First click on „*Import of status from CSV*“ button in Filter Records.

Select the file from a directory. In the Allowed states table you can see an overview of all IDs, codes and names of statuses. Each row of the inserted file must contain the UPRC of the alert and the required ID you wish to set. These two values must be separated by a comma. An example is displayed below. Click „*Continue*“



Národní organizace  
pro ověřování  
pravosti léčiv

Národní organizace pro ověřování pravosti léčiv

DASHBOARD ALERTS EXCEPTIONS USER MANAGEMENT SET COLUMNS DOCUMENTATION FILTER RECORDS EXPORT EXPORT SETTINGS

### Alerts

Import of status from CSV

**Basic data**

UPRC:  Level:  Created:   Priority:  Alert code:

Group of state:  Alert status for:  Aggr. pre-analysis:  Aggr. source:

**Details**

Product code:  National Code:  Product:  Batch ID Stored:  Batch ID Provided:

Serial number:  Date of expiration:  Source Business Process:  Manual Entry:  Source Market:

Trh katalogu:

Import of status from CSV 1/3

## 1/3 Insert a file

File

Soubor nevybrán

CSV file, first row ignored, first UPRC column, second alert status (ID, name or CZV code)

Allowed states

ID	Code	Name
1	01a	01a - New - End User transaction
2	01aa	01aa - New - End User transaction - Notification
3	01b	01b - MAH - New - MAH/OBP/PD transaction
7	02a	02a - MAH - Investigation - End user transaction
10	02b	02b - MAH - Investigation - MAH/OBP/PD transaction
11	02c	02c - CZMVO - Investigation MAH
13	03a	03a - MAH - Inactivity 5 days
14	03b	03b - MAH - Inactivity 10 days

Continue

Cancel

# BULK CHANGE OF ALERT STATUSES

If the file is correct, alerts where the status change will occur are displayed in a table. The status that will be allocated to the alerts can be seen in the right column. Click „*Continue*“.

If the request for alert status change was compliant with the process workflow, the status has been changed. Click „*Finished*“.

Import of status from CSV 2/3

### 2/3 Checking data before importing

Report

Line	UPRC	New alert state	Error
2	CZ-LRL-Z1E-ASX-40V-0J0	06b - Closed - End User - Technical error	
3	CZ-LRL-YZJ-53E-5H0-PCB	06b - Closed - End User - Technical error	
4	CZ-LRL-YXF-DVP-1JV-3KY	06b - Closed - End User - Technical error	
5	CZ-LRL-YX3-FG1-WZ1-DR5	06b - Closed - End User - Technical error	
6	CZ-LRL-YX0-3E2-K97-D98	06b - Closed - End User - Technical error	
7	CZ-LRL-YV6-SPN-UL2-2SB	06b - Closed - End User - Technical error	
8	CZ-LRL-YPC-C8G-YD3-SR5	06b - Closed - End User - Technical error	
9	CZ-LRL-YNQ-8U4-VB1-EYF	06b - Closed - End User - Technical error	
10	CZ-LRL-XRH-FM1-YHP-239	06b - Closed - End User - Technical error	

Export

Clicking Continue will make changes to the alert status according to the list above for which no error has been detected. The operation may take a long time, wait for it to complete.

Continue Cancel

Import of status from CSV 3/3

### 3/3 Import finished

Import of alerts status was finished.

10 alerts has been changed.

Finished

**Note:** The inserted file must be in CSV format and must contain values separated by comma (without a space).

In the example below, we want to set the alerts to the status 06b - Closed - End User - Technical error. The ID of this status is 34. The first row of the column A will be ignored by the system and may hence contain any value. It is critical that the UPRC and Status ID values are inserted on the second row or lower in column A. All other columns must be left empty, otherwise the system will disregard the file.

	A	B
1	UPRC,ID	
2	CZ-LRL-Z1E-ASX-40V-0J0,34	
3	CZ-LRL-YZJ-53E-5H0-PCB,34	
4	CZ-LRL-YXF-DVP-1JV-3KY,34	
5	CZ-LRL-YX3-FG1-WZ1-DR5,34	
6	CZ-LRL-YX0-3E2-K97-D98,34	
7	CZ-LRL-YV6-SPN-UL2-2SB,34	
8	CZ-LRL-YPC-C8G-YD3-SR5,34	
9	CZ-LRL-YNQ-8U4-VB1-EYF,34	
10	CZ-LRL-XRH-FM1-YHP-239,34	
11	CZ-LRL-WYQ-9V2-R1S-Q6C,34	

# 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).

The screenshot shows the user interface of the National Organization for Drug Verification. The header includes the organization's logo and name, the user's name (NOOL\_TEST\_MAH\_LL2), and navigation links. The main content area features a navigation bar with 'DASHBOARD', 'ALERTS', and 'EXCEPTIONS'. Below this, the alert details for 'CZ-M' are displayed, including a yellow warning box with the text: 'The alert must be closed within 13 days and 23:25 hours, otherwise the pack cannot be supplied or returned.' and 'You'll be able to close the alert in 1 day and 23:24 hours.' Below the warning box, there are buttons for 'Back', 'Send message', 'Send message to CZMVO', 'Insert file', and 'Change alert state'. A table at the bottom provides details about the alert:

UPRC	CZ-M	Level	5
Created	2023-10-30 14:15	Source Market	CZ



# LEVEL 3 ALERTS

In case a situation emerges disrupting the normal process flow, CZMVS will generate an exception (alert). The alerts are divided into levels (1-5) according to the gravity of the situation. AMS covers all level 5 alerts, which indicate a potential counterfeit and also a couple of level 2 alerts.

A1 – product code not found

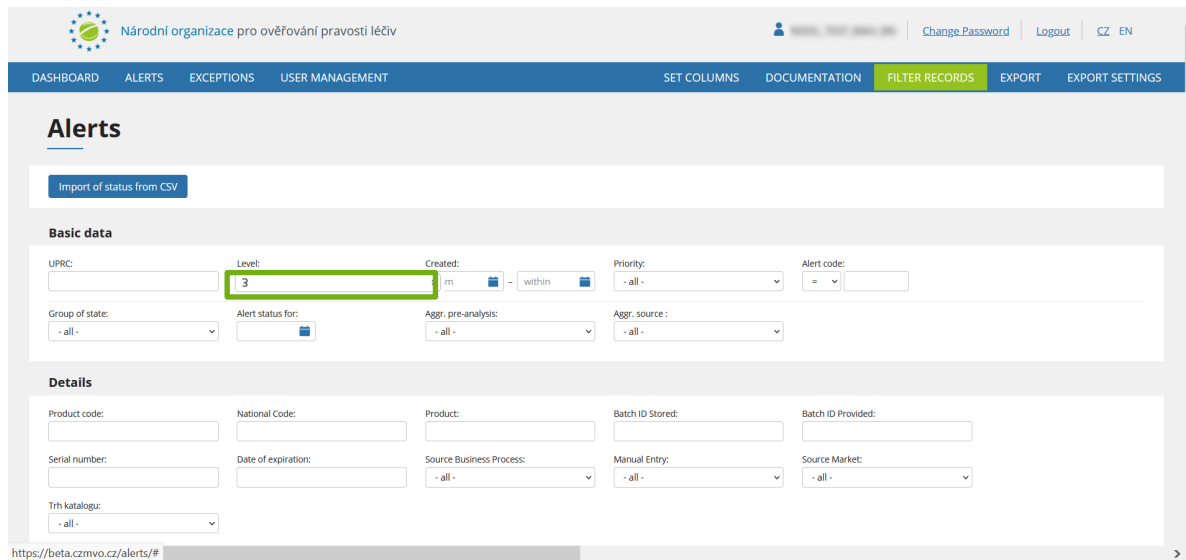
A5 – reactivation attempt was carried out at a different location

- A1 alerts represent an exception where the product code (GTIN) cannot be found in any of the national repositories. The marketing authorization holder is unknown. CZMVS will contact the end user for identification of the MAH and gather alert details. If a technical error is ruled out on the end user's side, the MAH is contacted to confirm the authorization and clarify the cause of missing data in the repository. If the error is fixed and the following verification is successful, the pack can be supplied to public.
- In order for CZMVO to provide for immediate investigation, we kindly ask end users to contact us, as soon as an A1 alert is raised, with MAH details. You can send your information to [alerts@czmvo.cz](mailto:alerts@czmvo.cz)

Note: For level 3 alerts no UPRC in the form of CZ-XXX-XXX-XXX-XXX-XXX is generated. The exception identifier is a chain of characters composed of the prefix CZ, location ID, and a serial number in an ascending order.  
(CZ-ff760bfd-7704-4ddf-b77e-9db0aa2a80a6-000001).

# LEVEL 3 ALERTS

To display level 3 alerts, go to „Filter Records“, select the value „3“ in the „Level“ field and click „Filter“.



Národní organizace pro ověřování pravosti léčiv

DASHBOARD ALERTS EXCEPTIONS USER MANAGEMENT SET COLUMNS DOCUMENTATION FILTER RECORDS EXPORT EXPORT SETTINGS

## Alerts

Import of status from CSV

**Basic data**

UPRC:  Level:  Created:  -  within  Priority:  Alert code:

Group of state:  Alert status for:  Aggr. pre-analysis:  Aggr. source:

**Details**

Product code:  National Code:  Product:  Batch ID Stored:  Batch ID Provided:

Serial number:  Date of expiration:  Source Business Process:  Manual Entry:  Source Market:

Trh katalogu:

<https://beta.czmvv.cz/alerts/#>

Listing is limited by filters: Level: 3

Displayed: 1-50 of 326 records 1 2 3 ... 6 7 Count per page: 50

Action	UPRC	Level	Created	Number of days since last alert status change (from-to)	Alert code	Priority	Group code	Anonymous group	Group of state	Product code	National Code	Catalogu Market
<input type="checkbox"/>	<a href="#">CZ-9c400249-a9ca-4505-b59a-ba9ac1ac74bf-000004</a>	3	2022-10-20 12:16	0	A5	Standard	-	-	New	08594065340109	8594065340109	CZ
<input type="checkbox"/>	<a href="#">CZ-9c400249-a9ca-4505-b59a-ba9ac1ac74bf-000003</a>	3	2022-10-20 12:16	0	A5	Standard	-	-	New	08594065340109	8594065340109	CZ
<input type="checkbox"/>	<a href="#">CZ-6ee52925-357b-42f3-a1e9-085c1595654f-000002</a>	3	2022-10-20 12:11	0	A1	Standard	-	-	New	04015630066797		CZ
<input type="checkbox"/>	<a href="#">CZ-9c400249-a9ca-4505-b59a-ba9ac1ac74bf-000002</a>	3	2022-10-20 12:03	0	A5	Standard	-	-	New	08594065340109	8594065340109	CZ
<input type="checkbox"/>	<a href="#">CZ-9c400249-a9ca-4505-b59a-ba9ac1ac74bf-000001</a>	3	2022-10-20 12:03	0	A5	Standard	-	-	New	08594065340109	8594065340109	CZ



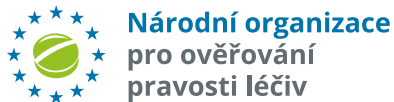
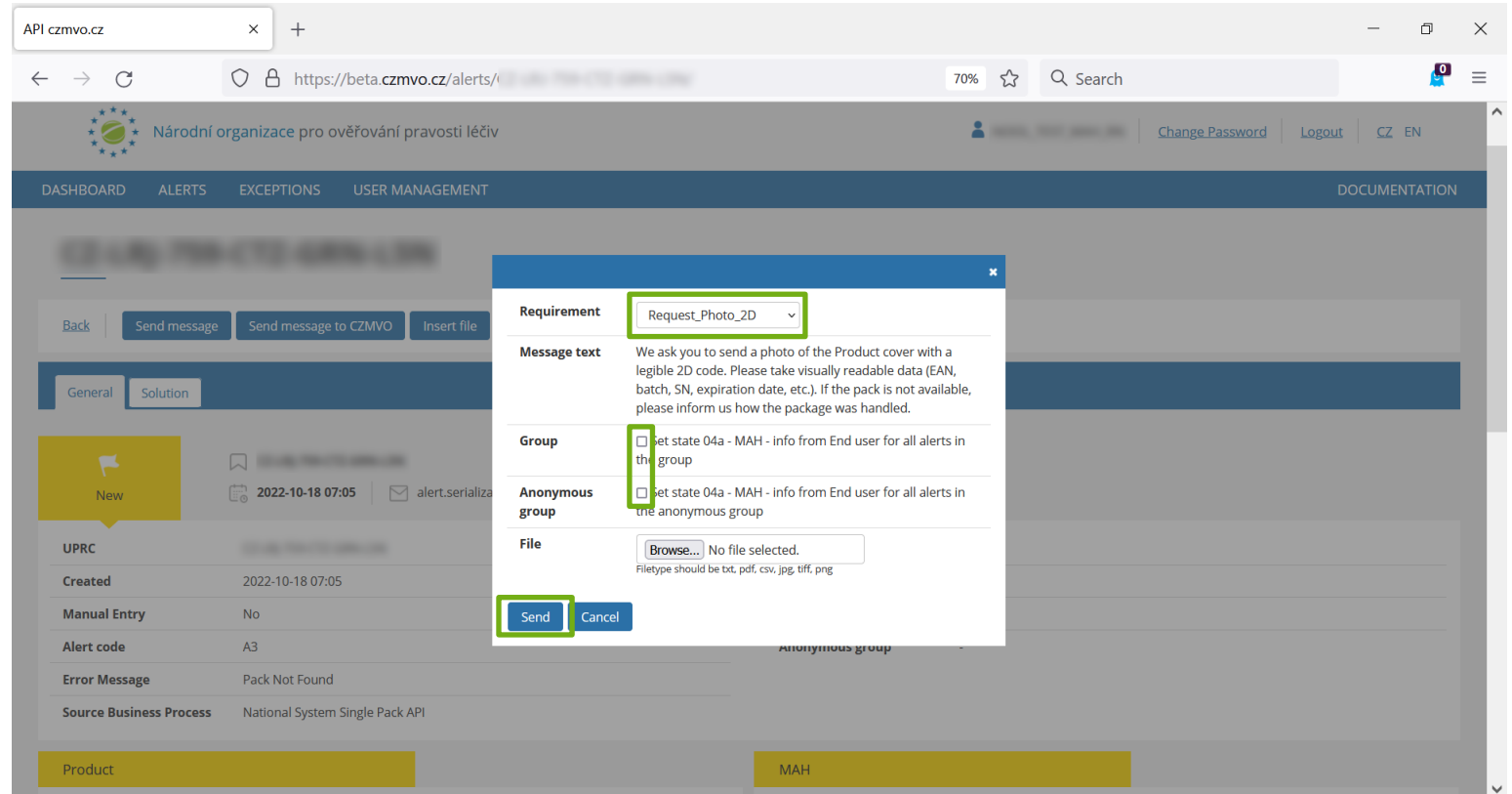
Národní organizace  
pro ověřování  
pravosti léčiv

# 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. Optionally you can assign the request to all alerts in the group by clicking checkbox “*Group*” or „*Anonymous group*“. You can also add an attachment. Clicking „*Send* „will send the message. **Note:** For this type of communication, it is required that both MAH and end user use either Alert management API or web interface. If the answer to the request is not delivered within reasonable time (**48 hours**) “standard” communication via NOOL call centre need to be used.



**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 MAH/End user, information about inactivity is passed to NCA (SUKL).**

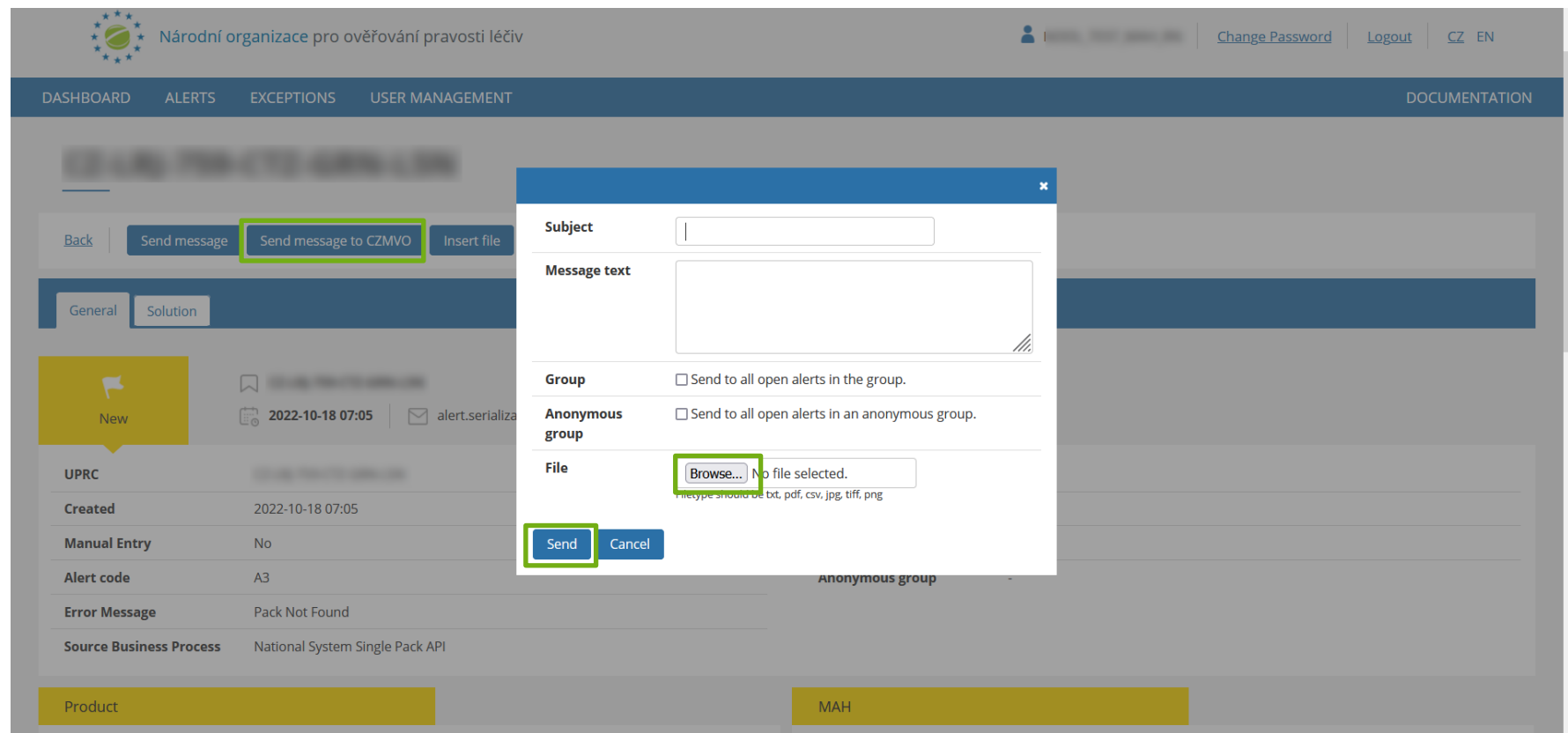
# COMMUNICATION BETWEEN CZMVO AND USERS

The AMS supports **anonymous exchange** of messages between NOOL 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*”

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

Note.: The text could possibly be in any language, however; we recommend that English or Czech language be used.



# COMMUNICATION – PREDEFINED MESSAGES

## List of predefined MAH/OBP messages:

### Notice:

The list and message texts are continually updated based on feedback from system users.

ID	Název_CZ	Název_AJ	Text_CZ	Text_AJ	Stav po odeslání zprávy	Pro
2	Fotka_2D	Photo_2D	Žádáme o zaslání foto obalu LP, s čitelným 2D kódem. Nafotoťte prosím i vizuálně čitelné údaje (EAN, šarže, SN, datum expirace, apod.). V případě, že balení již není k dispozici, informujte nás, jak bylo s balením naloženo.	We ask you to send a photo of the Product cover with a legible 2D code. Please take visually readable data (EAN, batch, SN, expiration date, etc.). If the pack is not available, please inform us how the package was handled.	04a - MAH - Info od KU	MAH
4	Chyba_End-User	Error_End_User	Chyba na straně koncového uživatele. Zkontrolujte nastavení snímače či kontaktujte Všeho dodavatele SW. V případě nesouhlasu zašlete zdůvodnění.	End-user error. Check the sensor settings. In case of disagreement please provide a justification.	06b - Uzavřeno - KU - Technická chyba	MAH
22	Vrátit distributorovi	Return to distributor	Žádáme o vrácení LP zpět distributorovi. LP nelze vydat!	We request that the pack be returned to the distributor. Pack cannot be supplied!	06c - Uzavřeno - MAH chyba - Neopraveno	MAH
24	Požadavek - NOOL	CZMVO - request	Požadujeme investigaci NOOL.	We require a CZMVO investigation.	04b - MAH - Info od NOOL	MAH
30	Ověření balení	Pack verify	Prosíme o opakovaní ověření balení. Chyba na straně MAH byla opravena.	Please re-verify the packaging. An error on the MAH side has been fixed.	04a - MAH - Info od KU	MAH

## List of predefined end user messages:

ID	Název_CZ	Název_AJ	Text_CZ	Text_AJ	Stav po odeslání zprávy	Pro
5	2020_Alert	2020_Alert	Alert z roku 2020. Balení jsme vydali – nelze již doložit.	Alert from 2020. Pack we supplied - it can no longer be documented.	05a - KU - Info na MAH	Koncový uživatel
6	Není chyba koncového uživatele	Is not End User error	Chyba není na naší straně. Snímač i SW jsou nastaveny korektně. Balení je blokováno v karanténě, nelze korektně ověřit!	The mistake is not on our side. Both the scanner and the SW were set correctly. The packaging is blocked in the quarantine, it cannot be verified correctly!	05a - KU - Info na MAH	Koncový uživatel
7	Opravená technická chyba	Fixed technical error	Potvrzujeme technickou chybu na naší straně (chyba v nastavení snímače, SW, apod.). Opraveno/vydáno.	We confirm an technical error on our side (error in the settings of the sensor, SW, etc.). Fixed/supplied.	05a - KU - Info na MAH	Koncový uživatel
25	Opravená chyba ručního zadání	Fixed error_manual entry	Potvrzujeme jako příčinu vzniku alertu chybu při ručním zadávání dat. Opraveno/vydáno.	We confirm an technical error on our side (error in the settings of the sensor, SW, etc.). Fixed/supplied.	05a - KU - Info na MAH	Koncový uživatel
27	Opravená technická chyba_End User	Fixed technical_End User error	Potvrzujeme technickou chybu na naší straně. Opraveno/vydáno.	We confirm an technical error on our side (error in the settings of the sensor, SW, etc.). Fixed/supplied.	06b - Uzavřeno - KU - Technická chyba	Koncový uživatel
31	Opravená chyba ručního vstupu nečitelný 2D kód	Fixed error_manual entry_unreadable 2D code	Potvrzujeme chybu na naší straně (chyba při ručním zadávání špatně čitelného 2D kódu). Opraveno/vydáno.	We confirm an error on our side (error when manually entering illegible 2D code). Fixed/supplied.	05a - KU - Info na MAH	Koncový uživatel
32	Opravená chyba umístění 2D kódu	Fixed error_incorrect loading due to 2D code placement	Z důvodu umístění 2D kódu vedle EAN kódu došlo k chybnému načtení kódu snímačem. Vzápětí bylo SN ověřeno úspěšně.	Due to the placement of the 2D code next to the EAN code, the scanner read the code incorrectly. Immediately, the SN was verified successfully.	05a - KU - Info na MAH	Koncový uživatel



Národní ústav  
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# COMMUNICATION – VIEW A LIST OF ALERTS WITH A REQUEST TO PROVIDE ADDITIONAL INFORMATION

A list of alerts for which the MAH/OBP has requested additional information can be viewed with help of a filter.

Click „Filter Records“. Set one of the options in the field „Pending request“ and push the button „Filter“ or „Enter“.

**MAH by End User** – A request from MAH to the End user (e.g. to provide a picture of the pack) - the alert is in the state “04a”, “03c”, “03d”.

**MAH by CZMVO** – A request from MAH to CZMVO) - the alert is in the state “04b”

**CZMVO by End User** – A request from CZMVO to the End user - the alert is in state “04d”



**DASHBOARD   ALERTS   EXCEPTIONS   USER MANAGEMENT   SET COLUMNS   DOCUMENTATION   FILTER RECORDS   EXPORT   EXPORT SETTINGS**

Serial number:    Date of expiration:    Source Business Process:    Manual Entry:    Source Market:

Trh katalogu:

**Investigation**

Alert state:    Group code:    Anonymous group:    Number of days since last alert status cha...:  -    Archived:

Closed:    Preanalysis - automatic:

CZMVO message:    Number of days since CZMVO message:  -    Pending request:    MAH ID:    MAH name:

EMVS MAH ID:    OBP ID:

Displayed: 1-50 of 26153 records      ...     Count per page:

Action	UPRC	Level	Created	Number of days since last alert status change (from-	Alert code	Priority	Group code	Anonymous group	Group of state	Product code	National Code	Trh katalogu	Product	Batch ID Stored	Batch ID Provided	Serial number
--------	------	-------	---------	--	------------	----------	------------	-----------------	----------------	--------------	---------------	--------------	---------	-----------------	-------------------	---------------

# COMMUNICATION – VIEW A LIST OF ALERTS WITH AN ANSWER FROM THE END USER

A list of alerts where the answer has been provided by the end user can be viewed with help of a filter.

Click „*Filter Records*“. Set the field „*Alert state*“ to „*05a - End user - Info to MAH*“ and push the button „*Set*“ or „*Enter*“.

### Alerts

Import of status from CSV

#### Basic data

UPRC:  Level:  Created:  -  Priority:  Alert code:

Group of state:  Alert status for:  Aggr. pre-analysis:  Aggr. source:

#### Details

Product code:  National Code:  Product:  Batch ID Stored:  Batch ID Provided:

Serial number:  Date of expiration:  Source Business Process:  Manual Entry:  Source Market:

Trh katalogu:

#### Investigation

Alert state:  Group code:  Anonymous group:  Number of days since last alert status cha...:  -  Archived:

Closed:  Preanalysis - automatic:

CZMVO message:  Number of days since CZMVO message:  -  Pending request:  MAH ID:  MAH name:

EMVS MAH ID:  OBP ID:  OBP Název:

Displayed: 1-50 of 26140 records 1 2 3 ... 522 523 Count per page: 50

Action	UPRC	Level	Created	Number of days since last alert status change (from-to)	Alert code	Priority	Group code	Anonymous group	Group of state	Product code	National Code	Trh katalogu	Product	Batch ID Stored	Batch ID Provided	Serial number
<input type="checkbox"/>																
		5	2022-10-18 07:05	0	A3	Standard	-	-	New							
<input type="checkbox"/>																
		5	2022-10-18 06:49	0	A3	Standard	-	-	New							



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# VIEW GROUP OF ALERTS

## Grouping alerts

- ✓ Grouping of alerts is an automatic function of the system where alerts of presumably the identical root cause raised within a specific time range (currently 14 days is set) are grouped together.

There are two types of groups in the system:

## GROUP

- ✓ The grouping is done based on MAH, product code, alert type, batch id and eventually date of expiry
- ✓ The group always contains medicinal packs with the same product code

## ANONYMOUS GROUP

- ✓ The grouping is done based on the alert type and location.
- ✓ The group always represents a single location

The screenshot shows the 'Investigation' filter interface with the following fields:

- Alert state: - all -
- Group code: [highlighted]
- Anonymous group: [highlighted]
- Number of days since last alert status cha...: from - within
- Archived: - all -
- Closed: - all -
- Preanalysis - automatic: - all -
- CZMVO message: - all -
- Number of days since CZMVO message: from - within
- Pending request: - all -
- MAH ID: [ ]
- MAH name: [ ]
- EMVS MAH ID: [ ]
- OBP ID: [ ]
- OBP Název: [ ]

A 'Filter' button is located below the filter fields.

Below the filter is a pagination bar: 'Displayed: 1-50 of 26140 records' with page numbers 1, 2, 3, ..., 522, 523. 'Count per page: 50' is also visible.

The table below has the following columns: Action, UPRC, Level, Created, Number of days since last alert status change (from-to), Alert code, Priority, Group code, Anonymous group, Group of state, Product code, National Code, Trh katalogu, Product, Batch ID Stored, Batch ID Provided, Serial number.

Two rows are highlighted in yellow:

Action	UPRC	Level	Created	Number of days since last alert status change (from-to)	Alert code	Priority	Group code	Anonymous group	Group of state	Product code	National Code	Trh katalogu	Product	Batch ID Stored	Batch ID Provided	Serial number
[icon]	[icon]	[icon]	2022-10-18 07:05	0	A3	Standard	88659	89234	New	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
[icon]	[icon]	[icon]	2022-10-18 06:49	0	A3	Standard	-	-	New	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

Use a filter to view a group or an anonymous group. Insert the group code in the „Group code“ field and press „Filter“

If you do not know the number of the group/anonymous group, you can get it from the list of alerts. Search for alerts pertaining to the group. The number is displayed in the „Group code“ column

If there is no number in the „group code“ field, it means the alert is individual and does not belong to any group.



# REMOVE ALERTS FROM GROUP

If you figure out, in course of the investigation process, that some alerts have a different root cause and they need to be solved separately, **you can remove them from the group**.

Mark alerts you wish to remove by clicking checkbox on the left or right side of the window. Next step is to select *“Remove from the group”* in the drop-down list and click the button *“Perform”*.

Similarly, by selecting *“Add to group”*, any alert can be added to the required group at the user's discretion.

## Groups/anonymous groups allow:

- ✓ **Collective closing of alerts** that were raised for the same root cause.
- ✓ **Collective communication** (MAH → end-user), i.e. sending the same message or documents to marked alerts at the same time (collectively).

The screenshot displays a table of alerts with the following columns: checkboxes, icons, ID, date, time, priority, severity, status, and type. A context menu is open over the fifth row, which has its checkboxes checked. The menu options are: '- choose -', 'Export to CSV', 'Export to CSV Excel', 'Export to XLSX Excel', 'Send message', 'Send message to CZMVO', 'Change alert state', 'Remove from the group', 'Remove from the anonymous group', and 'Add to group'. The 'Remove from the group' option is highlighted with a green box. At the bottom right, a 'Perform' button is also highlighted with a green box.

Checkbox	Icons	ID	Date	Time	Priority	Severity	Status	Type			
<input type="checkbox"/>				5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input type="checkbox"/>				5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input type="checkbox"/>				5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input checked="" type="checkbox"/>				5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input checked="" type="checkbox"/>				5	2022-10-14 08:37	0	A3	Standard	-	-	New
<input type="checkbox"/>				-	-	-	A3	Standard	-	-	New
<input type="checkbox"/>				-	-	-	A3	Standard	-	-	New
<input type="checkbox"/>				-	-	-	A3	Standard	-	-	New

# ALERT GROUPS ALLOCATION PERIOD

For each ordinary and anonymous group, the MAH can define a period within which the alerts will be allocated to the specific group. By default, 1 day is set, however; the MAH can set the period to any duration up to 90 days.

In the „Group“ tab or „Anonymous group“ tab, click the „Modify validity“ button.

In the pop-up window enter a value indicating the number of days within which the alerts will be allocated to the specific group. Click the „Save“ button.



The alert must be closed within 13 days and 22:50 hours, otherwise the pack cannot be supplied or returned.

[Back](#) | [Send message](#) | [Send message to CZMVO](#) | [Insert file](#) | [Change alert state](#)

[General](#) | [Solution](#) | [Group](#) | [Anonymous group](#)

Anonymous group 90280

<b>Group code</b>	90280
<b>Created</b>	2023-10-30 15:00
<b>Group validity</b>	2023-10-31 15:00 <a href="#">Modify validity</a>
<b>Alert code</b>	A3

Alerts

UPRC	Created	Product code	Batch ID	Serial number	Alert status
<a href="#">CZ-M5B-KJ5-ORR-04J-VEL</a>	2023-10-30 14:26	08594739266643		10x5t3h36r09t9	01a - New - End User transaction
<a href="#">CZ-M5B-KJN-5SP-ZM4-ZBA</a>	2023-10-30 14:26	08594739266643		10x1wyctht4047	01a - New - End User transaction
<a href="#">CZ-M5B-KK3-9BE-MZW-KTD</a>	2023-10-30 14:27	08594739266643		10x5t3h36r09t9	01a - New - End User transaction

**New validity**  days  
Number of days from the creation of the group (max 90), the period of time during which alerts will be added to the group

[Save](#) [Cancel](#)

# REPORTS - SUMMARY EXPORT

„Summary export“ generates an overview of alerts for a set period.

The report can be generated for a certain period only or for the date of the last change.

Available formats are CSV, CSV Excel and XLSX Excel.

Generation of the report can be confirmed by clicking on the „Report“ button.

Example of the summary report for the desired period:

Report,"for the period"	
Generated,"2022-10-20 16:12"	
Period,"2022-10-19 16:12-"	
Alert state,Number	
01a - New - End User transaction,14	
06b - Closed - End User - Technical error,10	
Total,24	
In the solution,14	
Closed,10	
From that mistake MAH,0	

The screenshot shows the web interface for the National Organization for Medication Safety. The main navigation bar includes 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', 'USER MANAGEMENT', 'SET COLUMNS', 'DOCUMENTATION', 'FILTER RECORDS', 'EXPORT', and 'EXPORT SETTINGS'. The 'Alerts' section is active, displaying a table of records with columns: Action, UPRC, Level, Created, Number of days since last alert status change (from-to), Alert code, Priority, Group code, Anonymous group, Group of state, Product code, National Code, Trh katalogu, Product, Batch ID Stored, Batch ID Provided, and Serial number. A 'Summary report' dialog box is open, allowing users to generate a report for a specific period (e.g., 'for the period'), within a 24-hour window, in CSV format. The 'Report' button is highlighted in green.

# EXPORT ALL ALERTS IN THE SET FILTER

Press the "Export" button on the right and select the desired format (CSV, CSV EXCEL, XSLX).

Select the required export type from the list and press the "Export" button. The file is saved in your default file storage directory.

The more entries you export the longer it will take to generate the report. The maximum count of entries is 65000

The screenshot shows the web interface of the National Organization for Medication Verification. The top navigation bar includes 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', 'USER MANAGEMENT', 'SET COLUMNS', 'DOCUMENTATION', 'FILTER RECORDS', 'EXPORT', and 'EXPORT SETTINGS'. The 'EXPORT' menu is open, showing options: 'CSV', 'CSV EXCEL', 'XLSX EXCEL', 'SUMMARY REPORT', and 'REPORT'. A 'Confirmation' dialog box is displayed, stating: 'A maximum of 65,000 records are exported. The export may take tens of seconds depending on the number of records exported.' Below the dialog, there are 'Export' and 'Cancel' buttons. The main content area shows a table of alerts with columns: Action, UPRC, Level, Created, Number of days since last alert status change (from-to), and a table with columns: ilogu, Product, Batch ID Stored, Batch ID Provided, and Serial number. The table displays several rows of alert data.

# EXPORT SELECTED ALERTS

If you wish to export **only a few selected alerts**, select "**Export to CSV**, to CSV Excel, Export to XLSX Excel" available in the operations panel, which is located above and below the list of alerts.

Select the required alerts by **clicking on the checkbox on the left**. In the list of operations, select the desired export type and click the "**Perform**" button. The file is saved in your default file storage directory.

The screenshot displays a table of alerts with columns for selection, actions, ID, date, time, priority, severity, status, and other details. A context menu is open over one of the rows, showing the following options:

- choose -
- Export to CSV
- Export to CSV Excel
- Export to XLSX Excel
- Send message
- Send message to CZMVO
- Change alert state
- Remove from the group
- Remove from the anonymous group
- Add to group

At the bottom of the interface, there are buttons for "Select All", "Unselect All", a "Selected:" dropdown menu, and a highlighted "Perform" button.

# EXCEPTIONS

**Exceptions granted by Ministry of Health** allow for dispensation of defined products even if the verification process fails.

The list of exceptions is created and edited by CZMVO, **however the MAH/OBP is responsible for correctness and completeness of the data.**

The MAH/OBP may edit the the list continually.

**All performed changes have to be compliant with approved exceptions by Ministry of Health and related legislation (Act No. 378/2007 Coll., on Pharmaceuticals, article 11r.).**

Press the button **“Exceptions”** to view the list of exceptions.

Action	Exception ID	Inserted via	Valid from	Valid to	Source	Product code	Batch ID	Action
<input type="checkbox"/>	316	API	2021-07-19 09:09		-	05099151009456	KK251	
<input type="checkbox"/>	315	API	2021-07-15 06:28		-	08594158891129	8078983	
<input type="checkbox"/>	313	Admin	2021-05-10 10:05		https://pristupy.sukl.cz/mah11overview.html	08590335500358	AHABB416AO	
<input type="checkbox"/>	312	Admin	2021-04-15 07:42	2023-05-31 00:00	https://pristupy.sukl.cz/mah11overview.html	05415062328286	DY6727	
<input type="checkbox"/>	311	Admin	2021-04-15 07:41	2023-06-30 00:00	https://pristupy.sukl.cz/mah11overview.html	05415062328286	EF2496	
<input type="checkbox"/>	310	Admin	2021-04-15 07:40	2023-08-31 00:00	https://pristupy.sukl.cz/mah11overview.html	05415062328286	EM9854	
<input type="checkbox"/>	309	Admin	2021-04-15 07:38	2023-07-31 00:00	https://pristupy.sukl.cz/mah11overview.html	05415062328286	EM9853	
<input type="checkbox"/>	305	API	2021-03-03 14:07		-	05099151009647	KK392	
<input type="checkbox"/>	304	API	2021-03-03 13:54		-	05099151009456	KK275	

# ADD AN EXCEPTION

New exception can be added clicking button “*Add exception*”.

New dialog will appear. Fill in Product code, Batch ID, Serial ID and Expiration and click “*Save*”.

Once an exception is added all new alerts that meet the set parameters will be automatically closed (state changed to “*Closed – ZOL par11r exception*”).

## Note:

Automatic closing will be applied to new alerts only. Old alerts raised before the exception was added must be closed manually.

The screenshot shows the 'Exceptions' management interface. At the top, there are three buttons: 'Add exception' (highlighted with a green box), 'Import from CSV', and 'Verify exception'. Below the buttons, a table displays a list of exceptions with columns for 'Action', 'Exception ID', 'Inserted via', and 'Valid from'. A modal dialog titled 'Add exception' is open, showing the following fields:

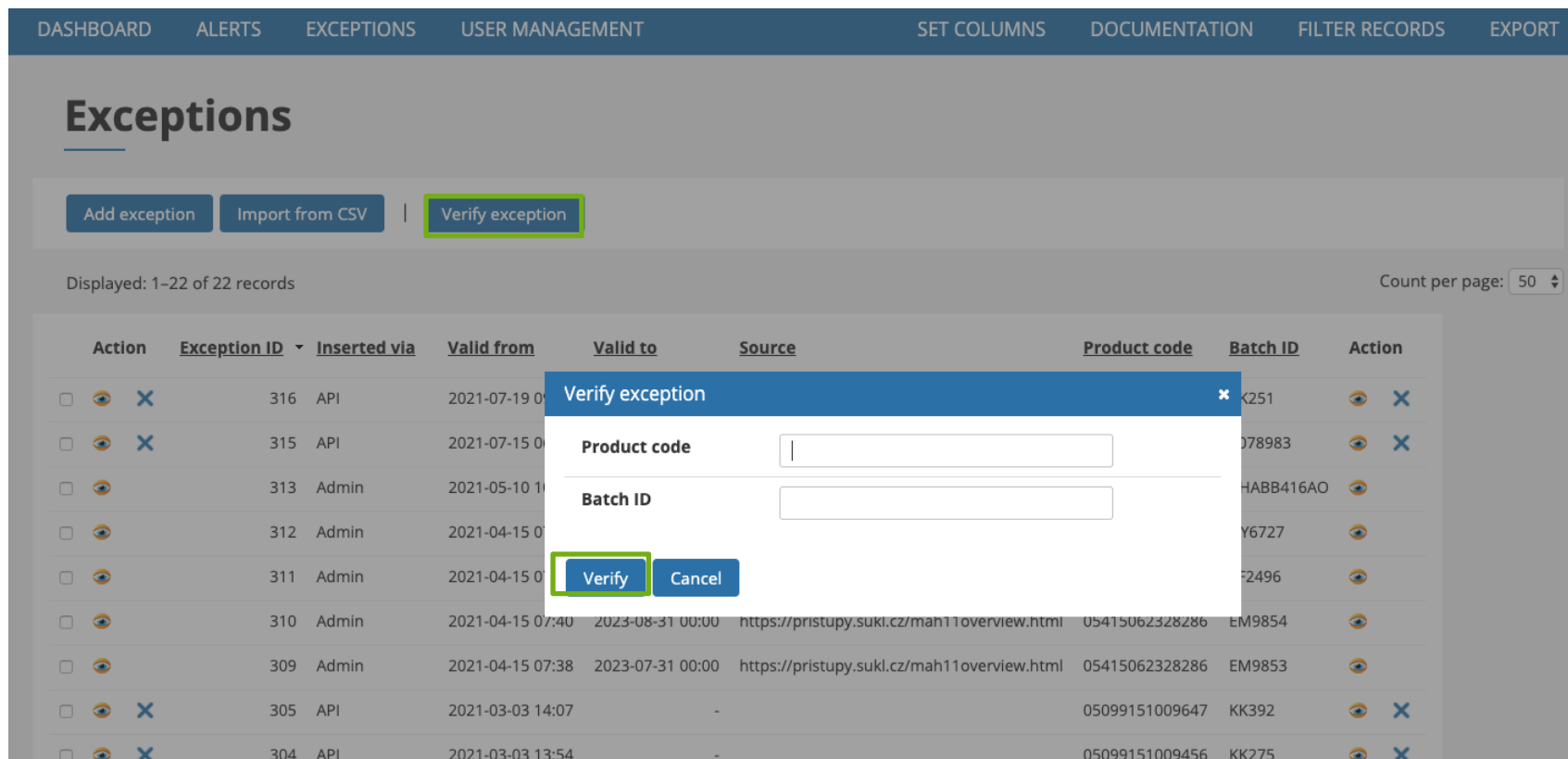
- Source:** A text input field with the placeholder text 'insert no. of decision of the Ministry of Health'.
- Note:** A text area with the placeholder text 'eg links to the website of the Ministry of Health, etc.'.
- File:** A file selection field with a 'Vybrat soubor' button and the text 'Soubor nevybrán'. Below it, it says 'Filetype should be txt, pdf, csv, jpg, tiff, png'.
- Product code:** A text input field with the note 'At least one of the Product Code, Batch fields must be filled in'.
- Batch ID:** A text input field.
- Validity:** A text input field.
- Alert state:** A dropdown menu with the selected option '06d - Closed - MAH error'.

At the bottom of the modal, there are two buttons: 'Save' (highlighted with a green box) and 'Cancel'.

# VERIFY IF AN EXCEPTION APPLIES FOR A SPECIFIC PRODUCT

Products can be verified if there is an exception applicable.

Click the button “*Verify exception*”. Dialog will appear. Fill in Product code and batch and click “*Verify*”.



The screenshot shows a web application interface for managing exceptions. At the top, there is a navigation bar with links: DASHBOARD, ALERTS, EXCEPTIONS, USER MANAGEMENT, SET COLUMNS, DOCUMENTATION, FILTER RECORDS, and EXPORT. Below this, the main heading is "Exceptions". There are three buttons: "Add exception", "Import from CSV", and "Verify exception" (highlighted with a green box). Below the buttons, it says "Displayed: 1-22 of 22 records" and "Count per page: 50". A table of exceptions is visible, with columns: Action, Exception ID, Inserted via, Valid from, Valid to, Source, Product code, Batch ID, and Action. A dialog box titled "Verify exception" is open, containing two input fields: "Product code" and "Batch ID", and two buttons: "Verify" (highlighted with a green box) and "Cancel".

Action	Exception ID	Inserted via	Valid from	Valid to	Source	Product code	Batch ID	Action
<input type="checkbox"/>	316	API	2021-07-19 0				K251	<input type="checkbox"/>
<input type="checkbox"/>	315	API	2021-07-15 0				078983	<input type="checkbox"/>
<input type="checkbox"/>	313	Admin	2021-05-10 1				HABB416AO	<input type="checkbox"/>
<input type="checkbox"/>	312	Admin	2021-04-15 0				Y6727	<input type="checkbox"/>
<input type="checkbox"/>	311	Admin	2021-04-15 0				F2496	<input type="checkbox"/>
<input type="checkbox"/>	310	Admin	2021-04-15 07:40	2023-08-31 00:00	https://pristupy.suki.cz/man11overview.html	05415062328286	EM9854	<input type="checkbox"/>
<input type="checkbox"/>	309	Admin	2021-04-15 07:38	2023-07-31 00:00	https://pristupy.sukl.cz/mah11overview.html	05415062328286	EM9853	<input type="checkbox"/>
<input type="checkbox"/>	305	API	2021-03-03 14:07		-	05099151009647	KK392	<input type="checkbox"/>
<input type="checkbox"/>	304	API	2021-03-03 13:54		-	05099151009456	KK275	<input type="checkbox"/>



# END USERS' PROCEDURAL ERRORS

- The 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: As a new feature the **MAH/OBP** can close the end user’s procedural error with the alert state „06f - Closed - End User process error - cannot be dispensed“ only after **2 days** have passed from the date the alert was raised.
- If the end user is aware of a procedural error that **can be fixed** and an affidavit is submitted as per **conditions stipulated by SÚKL** (NCA), the end user 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 is applicable for the period of **9 days** from the pack state change to “06f”

# END USERS' PROCEDURAL ERRORS

- A pack transaction in CZMVS can only be performed if the status of the unique identifier is Active. If a pack is incorrectly supplied or decommissioned, its unique identifier is permanently deactivated and any further attempt for a pack state change will generate an alert\*
- In such cases the end user may close the alert if caused as a result of a procedural error that the end user is aware of and eventually they may dispense the pack to public on the condition that the root cause is well-documented and details are communicated via AMS\*\*

\*with the exception of reactivation as per article 13 of COMMISSION DELEGATED REGULATION (EU) 2016/161

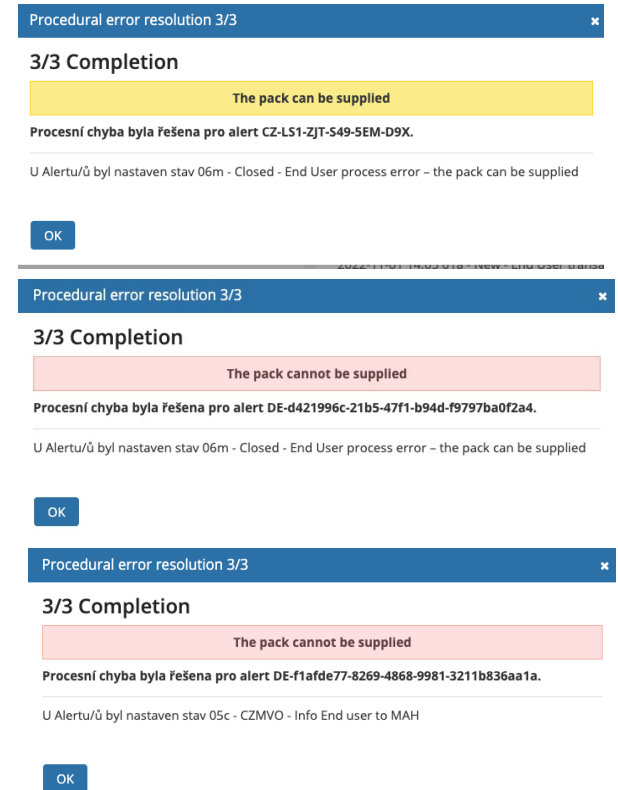
\*\*This direction has been approved by SÚKL (NCA)



Resolution of end users' procedural errors via AMS can result in the following outcomes"

1. „The pack can be supplied - The alert will be closed to 06m - Closed - End User process error - can be verified, End user has documented the cause. Alert is closed and the pack can be supplied to public.
2. „The pack cannot be supplied“ – The alert will be closed to 06f - Closed - End User process error - cannot be dispensed. The alert is closed and the pack cannot be supplied to public.
3. „The pack cannot be supplied. The alert will be closed to 05c - CZMVO - Info End user to MAH. The alert is escalated to CZMVO for further investigation. (This situation occurs whenever the incorrect decommissioning of the unique identifier was carried out at a different location).

Note: The complete overview of procedural errors is available at the end of this document.



The screenshots show three instances of 'Procedural error resolution 3/3' messages. Each message has a blue header with a close button (x) and a '3/3 Completion' status. The first message has a yellow background and states 'The pack can be supplied' with the alert ID 'CZ-LS1-ZJT-549-5EM-D9X'. The second message has a pink background and states 'The pack cannot be supplied' with the alert ID 'DE-d421996c-21b5-47f1-b94d-f9797ba0f2a4'. The third message has a pink background and states 'The pack cannot be supplied' with the alert ID 'DE-f1afde77-8269-4868-9981-3211b836aa1a'. Each message includes a detailed description of the error and an 'OK' button.

# END USERS' 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

**The pack cannot be supplied**

Back | Send message | Send message to CZMVO | Insert file | Change alert state

General | **Solution**

**Alert status**

Archived	No
Priority	Standard
Alert status	06m - Closed - End User process error - the pack can be supplied
State description	Closed - End User process error - the pack can be supplied. The end user has documented the cause
Last state change	2023-09-13 15:21
Last alert change	2023-09-13 15:21
Preanalysis - automatic	EUP - Double supply End user error - procedural. Presumably a double supply.
Investigation result	Closed - End User Error

**Process error resolution**

Created	2023-09-13 15:21
Group	No
Anonymous group	No
UI deactivation place	Our own Location
Root cause	Inappropriate handling of the pack
Details	Correction of the prescription
Error	Staff error upon correction of prescription / retaxation
An affidavit	Čestně prohlašujeme, že při opravě receptu došlo vlivem lidské chyby k pokusu o znovuzneplatnění LP. Personál bude řádně proškolen. Balení nelze vydat veřejnosti.

**Note**

MAH note *No note has been entered yet* [Add note](#)

**Processing by API**

- 2023-09-13 15:21 PCH Request submitted, ID: aa4665d910901168
- 2022-10-03 13:30 Preprocess, EUP - Double supply

**Alert status changes**

- 2023-09-13 15:21 06m - Closed - End User process error - the pack can be supplied
- 2022-10-03 13:30 01a - New - End User transaction



## 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)



Národní organizace  
pro ověřování  
pravosti léčiv

# 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 solutions



# 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
<b>EUT - Date</b>	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.
<b>EUT - Long string in Serial number</b>	Presumably an incorrect scanner setting / long character string in Serial number).	
<b>EUT - Caps Lock</b>	Presumably a keyboard setup error (CapsLock).	
<b>EUT - EN/CZ</b>	Presumably an incorrect keyboard language setting (EN/CZ).	
<b>EUT - Short character string in Serial number</b>	Presumably an incorrect scanner setting / short character string in Serial number).	
<b>EUT - Character mismatch</b>	End user error - technical. Presumably a character mismatch (O/0,E/3,I/L,...) due to a lower quality scanner.	The alert was closed automatically based on the pack audit trail. No further action required to be taken by MAH/OBP.
<b>EUT - Fixed, supplied</b>	According to the audit trail, the pack was subsequently successfully verified and supplied.	
<b>EUT - Duplication in bulk operation</b>	Presumably a duplicate Serial number in bulk transaction.	
		The MAH/OBP can close the alert using the state 06b - Closed - End User - Technical 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
<b>EUP - Repeated</b>	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.
<b>EUP - Repeated- This location</b>	A repeated pack state change request that occurred on the same location where the pack state was previously changed successfully.	
<b>EUP – Repeated– Other location</b>	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.	
<b>EUP - Unauthorized</b>	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.	
<b>EUP - Unauthorized - This location</b>	An unauthorized pack state change request that occurred on the same location where the pack state was previously changed successfully.	
<b>EUP - Unauthorized - Other location</b>	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
<b>MAH - Batch is not uploaded in CZMVS</b>	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.
<b>PSUN - MAH</b>	MAH error - PSUN transaction - unrecorded data or uploaded in a wrong version	Alert will be closed automatically in AMS.
<b>EU – N/A</b>	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.
<b>MAH – Randomization</b>	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.
<b>MAH - exception 11r</b>	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.
<b>NMVS Error - Synchronization issue</b>	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
<b>01a</b> <b>New – end user transaction</b>	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.
<b>01b</b> <b>MAH – New - MAH/OBP transaction</b>	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.
<b>02a</b> <b>MAH - Investigation - End user</b>	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).
<b>02b</b> <b>MAH - Investigation - MAH/OBP transaction</b>	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).
<b>03a</b> <b>MAH – Inactivity 7 days</b>	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“.
<b>03b</b> <b>MAH – Inactivity 10 days</b>	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
<b>04a</b> <b>MAH – Info from end user</b>	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)
<b>04b, 04f</b> <b>MAH - Info from CZMVO</b>	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)
<b>05a</b> <b>End user - Info to MAH</b> <b>05b</b> <b>CZMVO - Contacts end User</b> <b>05c</b> <b>NOCZMVO - Info end user to MAH</b> <b>05d,05f</b> <b>NOOL – Info MAH</b>	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

# 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
<b>03f - EU – process error - inactivity 5 days</b> <b>03g – process error 10 days</b>	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.
<b>03i – technical error 5 days</b> <b>03j – technical error 10 days</b>	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
<b>03m – MAH alert not closed 5 days</b>	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.
<b>03n – MAH alert not closed 10 days</b>	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.

# 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
<b>06a MAH error - Corrected</b>	<ul style="list-style-type: none"> <li>• Data not uploaded – batch missing or not uploaded correctly, Product Pack Data missing.</li> <li>• IMT did not run (if not correctly entered batch number, batch is not found in system of other country).</li> <li>• System Time out (batch is not found due to not received answer to request in required time limit).</li> <li>• Batch data not uploaded correctly.</li> <li>• Data missing – SN missing or not properly uploaded.</li> <li>• System Time out (date not verified due to not received answer to request in required time limit).</li> <li>• One element of the Data Matrix Code appears in the batch field, because group separators have not been set properly.</li> <li>• Retrospective upload capability not implemented in the OBP software.</li> </ul>	<p>Keep medicinal pack in quarantine until the end of alert investigation. Once alert is closed, provided info from AMS: <b>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).</b></p>	<p>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.</p>

# 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
<b>06b</b> <b>Closed - Technical error - End user</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• SN is too short (chopped off) or too long (part of other data) or not allowed characters included.</li> <li>• Not finished/wrong scanning – incomplete number or product code connected to batch number.</li> <li>• 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).</li> <li>• Scanning with not properly set up scanner cause wrong batch number compare to set data CZMVS.</li> <li>• Wrong manual entry (1 x l, O x 0) or wrong repeated manual entry of expiration date from pack MM/RR.</li> <li>• One element of the Data Matrix Code appears in the Serial Number field, because group separators have not been set properly.</li> </ul>	<p><b>End–user should correct the cause of alert according to what caused it:</b></p> <ul style="list-style-type: none"> <li>• Repeated scan after previous scanning with short break</li> <li>• Caps lock off prior to scanning followed by scanning of the pack again.</li> <li>• Switch to Czech keyboard or QWERTZ x QWERTY keyboard followed by scanning of the pack again.</li> <li>• To modify end-user IT SW (after agreement with IT SW provider) so not proper using of group separators are corrected.</li> <li>• To modify end-user IT SW (after agreement with IT SW provider) to correct expiration data.</li> <li>• Scan UI again or carefully input all relevant data for verification.</li> </ul> <p>Use “control scan”, if possible, to verify proper scanner set up and after that go back to medicinal pack with alert.</p> <p><b>End-user can than again verify pack and if decommission is successful pack can be release from quarantine and provided to patient.</b></p>	<p>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.</p>

# 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
<b>06c</b> <b>Closed - MAH error - Not corrected</b>	<ul style="list-style-type: none"> <li>• Wrong print of FMD code on the pack.</li> <li>• OBP with „Indian codes “ uses GTIN, that is later on used for FMD, i.e. alert is generated.</li> <li>• Group separators have not been used properly so some element of the Data Matrix Code appears in batch number.</li> <li>• Producer printed not correct data on the medicines pack into 2D code.</li> <li>• Producer printed not correct data into eye readable format.</li> <li>• Re-upload of the data by MAH/OBP to already distributed packs.</li> <li>• OBP tries to change pack status to already decommissioned pack (i.e. „sample to sample“).</li> </ul>	<p>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.</p> <p>Once alert is closed, provided info from AMS:  <b>MAH / OBP error. Unable to correct - cannot be re-verified. Return the packaging to the supplier with alert ID identification.</b></p> <p>End user should return pack back to distribution (wholesaler) according to return process set up in end-user organisation.</p>	<p>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.</p>

# 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
<b>06d Closed - ZOL 11r exception</b>	<ul style="list-style-type: none"> <li>• Wrong print of FMD code on the pack.</li> <li>• OBP with „Indian codes “ uses GTIN, that is later on used for FMD, i.e. alert is generated.</li> <li>• Group separators have not been used properly so some element of the Data Matrix Code appears in batch number.</li> <li>• Producer printed not correct data on the medicines pack into 2D code.</li> <li>• Producer printed not correct data into eye readable format.</li> <li>• Re-upload of the data by MAH/OBP to already distributed packs.</li> <li>• OBP tries to change pack status to already decommissioned pack (i.e. „sample to sample“).</li> </ul>	<p>Keep medicinal pack in quarantine until the end of alert investigation. Wait for closing the alert by MAH/OBP or CZMVS.</p> <p>Once alert is closed, provided info from AMS: <b>Exception ZOL - 11r - DO NOT VERIFY. Can be supplied to patient. Remove from quarantine.</b></p>	<p>During alert investigation <b>MAH/OBP</b> 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.</p>

# 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
<b>06e</b> <b>Closed - Before</b> <b>02/09/2019</b>	<ul style="list-style-type: none"> <li>Partially serialised product (without SN or other production data from the Data Matrix Code), release from production prior 9.2.2019.</li> </ul>	<p>Keep medicinal pack in quarantine until the end of alert investigation and closing by MAH/OBP.</p> <p>Once alert is closed, provided info from AMS:</p> <p><b>Release from production before 09/02/2019 - not subject to FMD - DO NOT VERIFY! The pack can be supplied to patient. Remove from quarantine.</b></p>	<p>During alert investigation <b>MAH/OBP</b> 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.</p>

# 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
<b>06f</b> <b>Closed - Process error KU - cannot be issued</b>	<ul style="list-style-type: none"> <li>• Attempt to double decommission by end-user – already decommissioned pack.</li> <li>• Attempt to decommission already non-active or expired pack.</li> <li>• Not proper internal marking of pack due to misunderstanding.</li> <li>• Double operation or wrong decommissioning to wrong alert status by mistake.</li> <li>• Resale between pharmacies; pharmacy that resale not pack does not properly decommission pack to alert status “Supplied” and 2<sup>nd</sup> pharmacy during decommission to patient generates alert..</li> <li>• Errors that lead to repeated request to decommission.</li> </ul>	<p>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.</p> <p>Once alert is closed, provided info from AMS: <b>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.</b></p>	<p>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.</p>

## 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
<b>06m</b> <b>Closed – End user process error – can be supplied after documenting the cause</b>	<ul style="list-style-type: none"> <li>• Attempt to double decommission by end-user – already decommissioned pack.</li> <li>• Attempt to decommission already non-active or expired pack.</li> <li>• Not proper internal marking of pack due to misunderstanding.</li> <li>• Double operation or wrong decommissioning to wrong alert status by mistake.</li> <li>• Incorrect internal labeling and packaging due to misunderstanding.</li> <li>• Resale between pharmacies; pharmacy that resale not pack does not properly decommission pack to alert status “Supplied” and 2<sup>nd</sup> pharmacy during decommission to patient generates alert.</li> <li>• Errors that lead to repeated request to decommission.</li> <li>• Attempted double dispense by end user - pack already dispensed.</li> <li>• An attempt to dispense an already inactive or expired pack.</li> <li>• Incorrect internal labeling and packaging due to misunderstanding.</li> </ul>	<p>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.</p> <p><b>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.</b></p> <p>After the investigation is completed and the alert is closed, a message in AMS:  <b>Not a MAH/OBP error. end user documented the cause - LP can be supplied.</b></p>	<p>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.</p>



## CLOSING ALERT STATUSES

- Type of alerts: **All**. 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 (2<sup>nd</sup> column), we recommend that you follow the directions for end users (3<sup>rd</sup> column) or for the MAH (4<sup>th</sup> column).

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
<b>06g</b> <b>Closed - CZMVS error</b>	Relevant to pack that, <ul style="list-style-type: none"> <li>• Were already successfully supplied in CZ, but data synchronization for multimarket packs was not correct.</li> <li>• Were not decommissioned due to long response time of the system; status change was not done correctly.</li> </ul>	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): <b>CZMVS Error - The pack can be verified again! Remove from quarantine.</b> <b>CZMVS Error - The pack cannot be verified again! Return back.</b>	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: All. 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 (2<sup>nd</sup> column), we recommend that you follow the directions for end users (3<sup>rd</sup> column) or for the MAH (4<sup>th</sup> column).

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
<b>06o - Closed - End User does not cooperate - cannot be supplied</b>	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. <b>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)</b>	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 inform 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
<b>06h</b> – Suspected Counterfeit!	<ul style="list-style-type: none"> <li>all the potential causes on MAH, end-user side and CZMVO are excluded</li> </ul>	<p>Keep medicinal pack in quarantine until the end of alert investigation</p> <p>Once alert is closed, provided info from AMS:</p> <p><b>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.</b></p>	<p>During alert investigation by all relevant parties all potential causes of alert on MAH, end-user side and CZMVO were excluded</p> <p>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).</p>

# 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
<b>06i</b> - Closed - MAH transaction error - Fixed	<ul style="list-style-type: none"> <li>Transaction between MAH system and EU HUB (i.e. PSUM transaction)</li> </ul>	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.
<b>06j</b> - Closed - MAH transaction error - Not corrected	<ul style="list-style-type: none"> <li>Transaction between MAH system and EU HUB (i.e. PSUM transaction)</li> </ul>	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?
<b>06k</b> - Closed - PD error - Not fixed	<ul style="list-style-type: none"> <li>Wrong operation by parallel distributor</li> </ul>	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?
<b>06n</b> - Closed - IMT fulfilling - Alert originated outside CZ, MAH is investigating in another market	<ul style="list-style-type: none"> <li>All potential causes of alerts, but alert occurred on the pack decommissioned in other country, while data in CZMVS.</li> </ul>	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
<b>06I</b> - Non FMD	<ul style="list-style-type: none"> <li>• Scan products which are out of scope of the FMD (OTC, 'Indian Product Codes', medical device, etc.)</li> <li>• Product Code not uploaded into the EMVS.</li> <li>• Product Master Data not uploaded into the EMVS (or failure to transmit to CZMVS)</li> <li>• Product codes not compliant with national coding requirements (NTIN instead of GTIN)</li> <li>• Incomplete 2D matrix code</li> <li>• Manual entry error</li> <li>• Scan of test codes in Production Environment (PRD) Scanning of 2D data matrix code on shipper box or pallet</li> </ul>	<p>Keep medicinal pack in quarantine until the end of alert investigation and closing by MAH/OBP or CZMVO.</p> <p>Once alert is closed, provided info from AMS:</p> <p><b>Medicinal product is not subject to FMD. Can be issued without verifying. Remove from quarantine.</b></p>	MAH or end-user found out during alert investigation that verified pack or device is not subject to FMD.
<b>06z</b> - Closed - 2019 alert	<ul style="list-style-type: none"> <li>• All potential causes of alerts</li> </ul>		Alerts from 2019 were automatically closed based on agreement with NCA. During 2019 it was enabled to supply over the alert.



The list of end users' procedural errors



# THE LIST OF PROCEDURAL ERRORS

Root cause	Details	Examples	Dispensation of the pack to the public
<b>Delayed system response</b>	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
<b>Pharmacy information system (PIS) error</b>	Correction of the prescription	SW (PIS) error occurs upon correction of the prescription / relaxation / 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
<b>Inappropriate handling of the pack</b>	<b>Pack state not verified prior to the transaction</b>	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
	<b>Correction of the prescription</b>	Staff error upon correction of prescription / relaxation	cannot be supplied!
	<b>Stocking error</b>	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
	<b>Returned pack</b>	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!
	<b>Pack transferred outside of the current location</b>	The pack was transferred between locations of the same organization and decommissioned by the originating location.	cannot be supplied!
		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.			