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.**

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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"

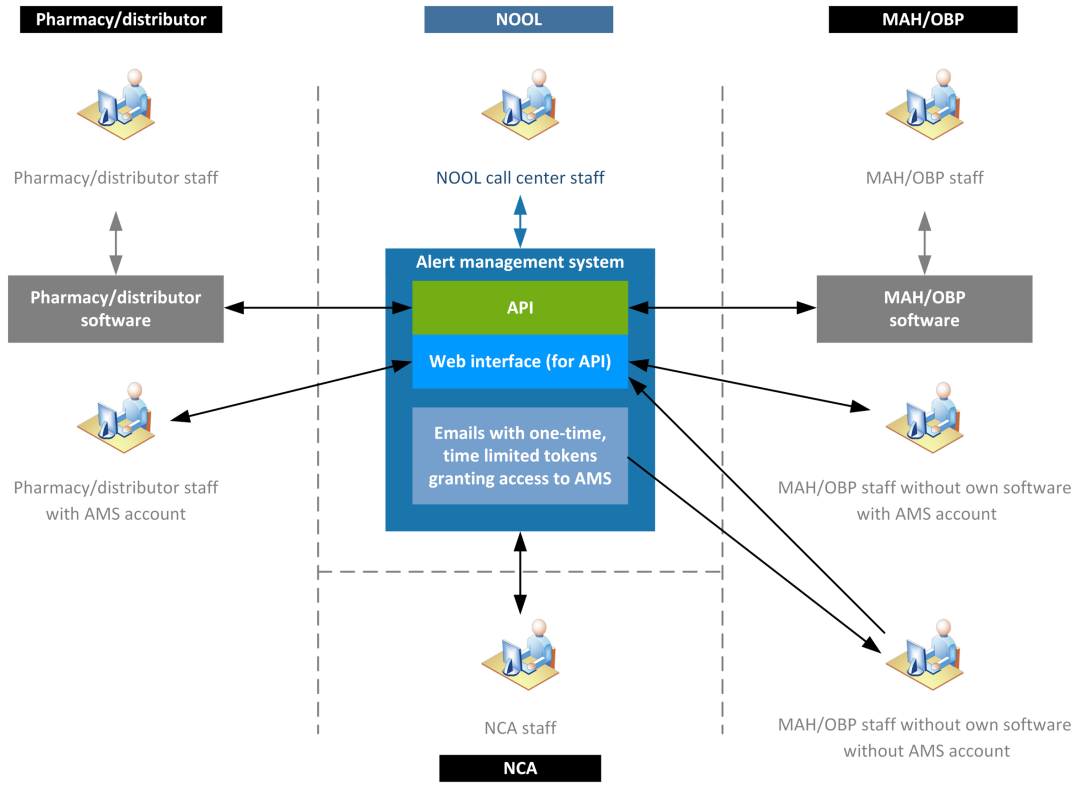
ALERT MANAGEMENT SYSTEM

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_acess_MAH_7.0.pdf - https://www.czmvo.cz/file.php?id=802



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PROCESSING TIME & ESCALATION

System notification

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

New alerts notification

END USER TRANSACTIONS

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

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

MAH/OBP TRANSACTIONS

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

Investigation time

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

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

“Not acting” notification

END USER TRANSACTIONS

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

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

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

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

MAH/OBP TRANSACTION

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

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NOTIFICATIONS, PROCESSING TIME & ESCALATION

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

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ARCHIVING

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

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

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

IT SECURITY

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.

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 unfication upon login

The aim is to unify error messagges 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 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 >

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**.

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.

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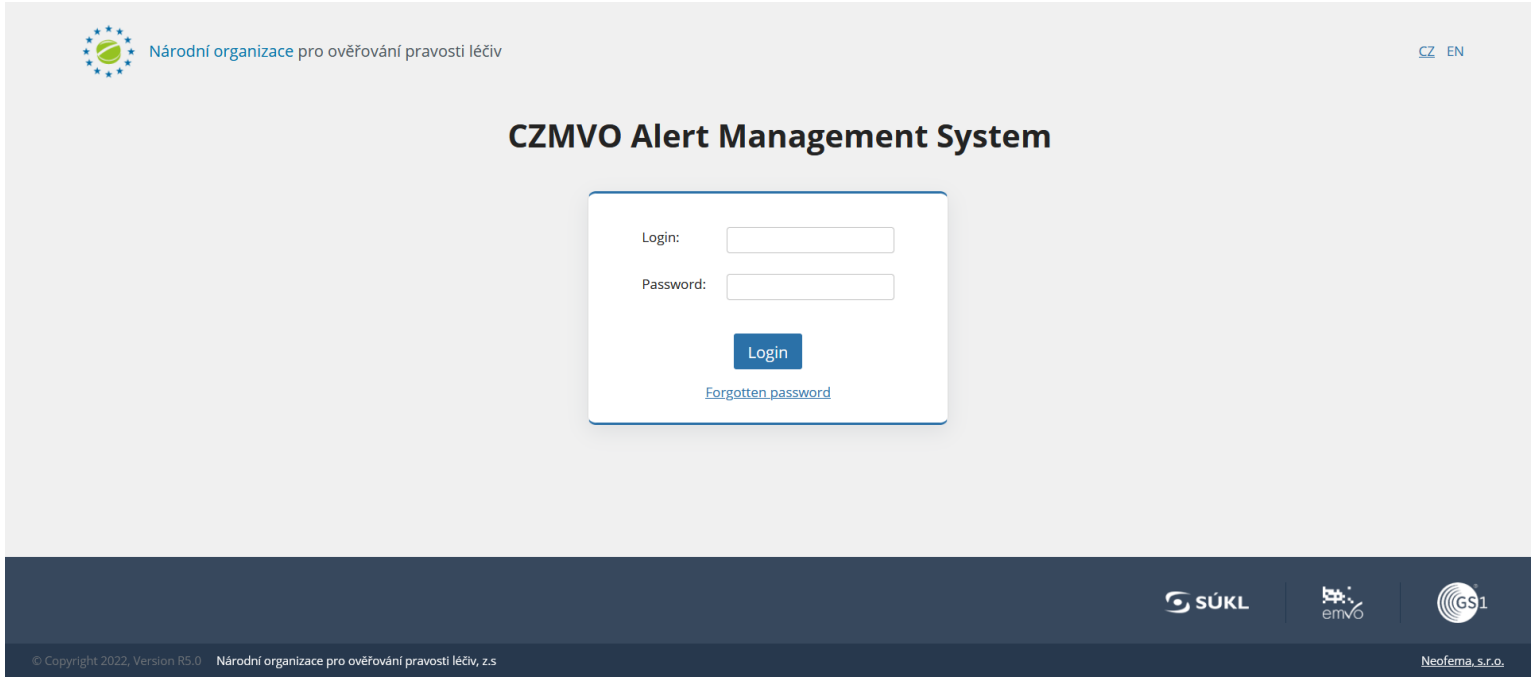
LOGIN TO NOOL ALERT MANAGEMENT SYSTEM

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

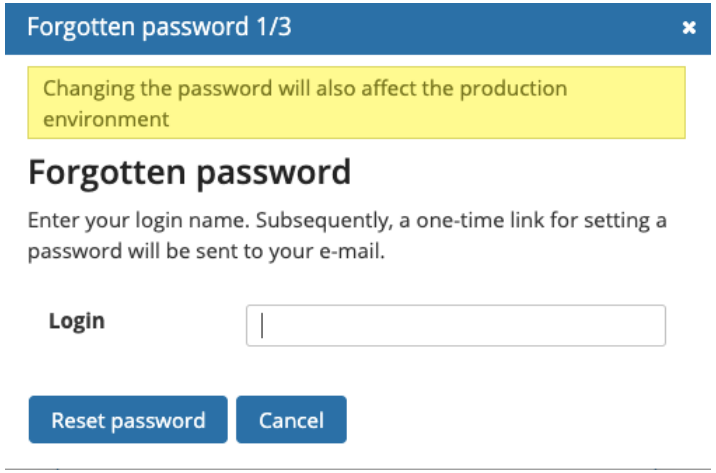
1. k „*Login*“. Authentication dialog will appear.
2. Enter *Login name* and *Password* provided by the NOOL into login page.

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 inv. 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. (registrace@czmvo.cz).

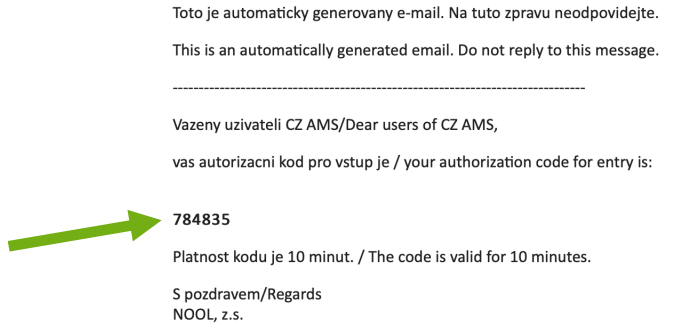


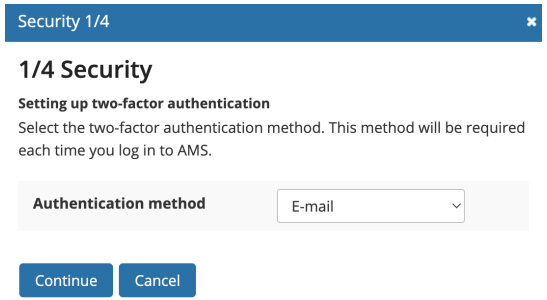
TWO-FACTOR AUTHENTICATION SETUP

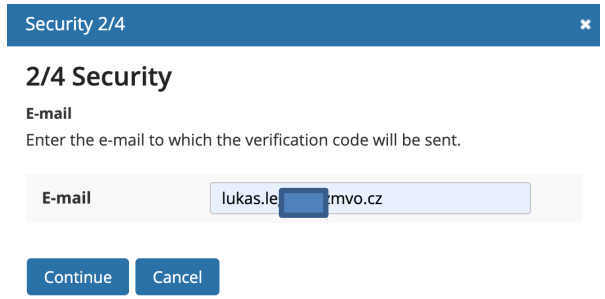
After a successful login to the web portal, you will be prompted to set up a two-factor authentication. As a second factor, you may select an e-mail address or Google Authenticator.

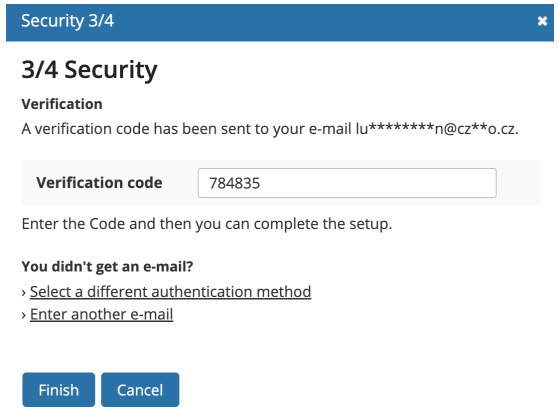
Instructions to set up authentication via an e-mail address:

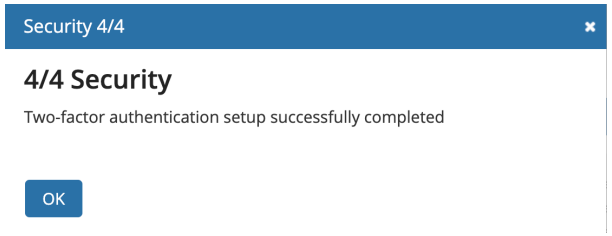
1. Select the authentication method “E-mail”. Click on “Continue”.
2. Insert an e-mail address in the field ”E-mail”. A verification code will be sent to this address.
3. Copy the authorization code from the body of the e-mail sent to your e-mail address.
4. Enter the code in the “Verification code”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











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TWO-FACTOR AUTHENTICATION SETUP

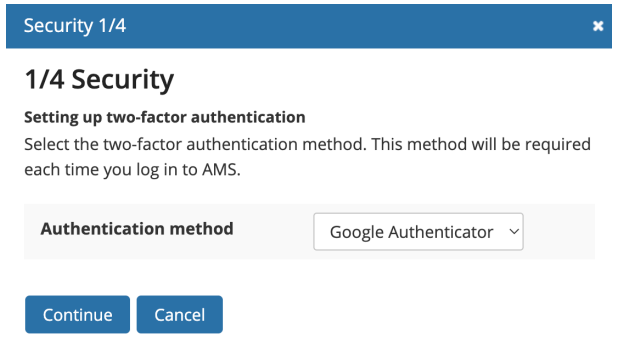
Instructions to set up authentication via the application Google Authenticator:

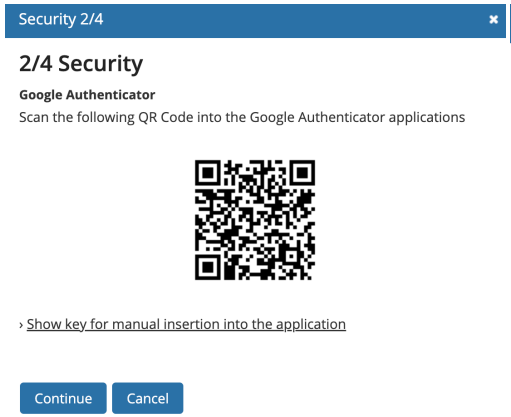
1. Select the authentication option ”Google Authenticator”. Click on “Continue”.

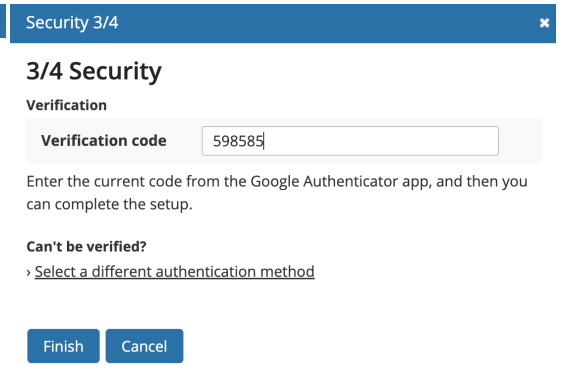
2. With your device, scan the QR code into the application Google Authenticator. Clink on “Continue”.

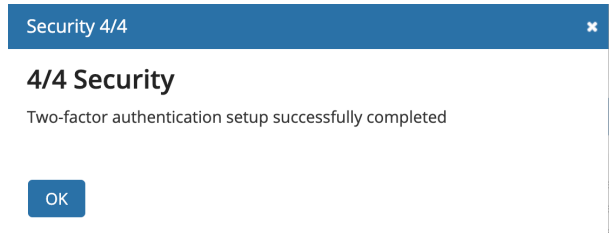
3. In the field “Verification code” enter the current code displayed in your application. Click “Finish”.

4. Click “OK”. The setup has been completed.









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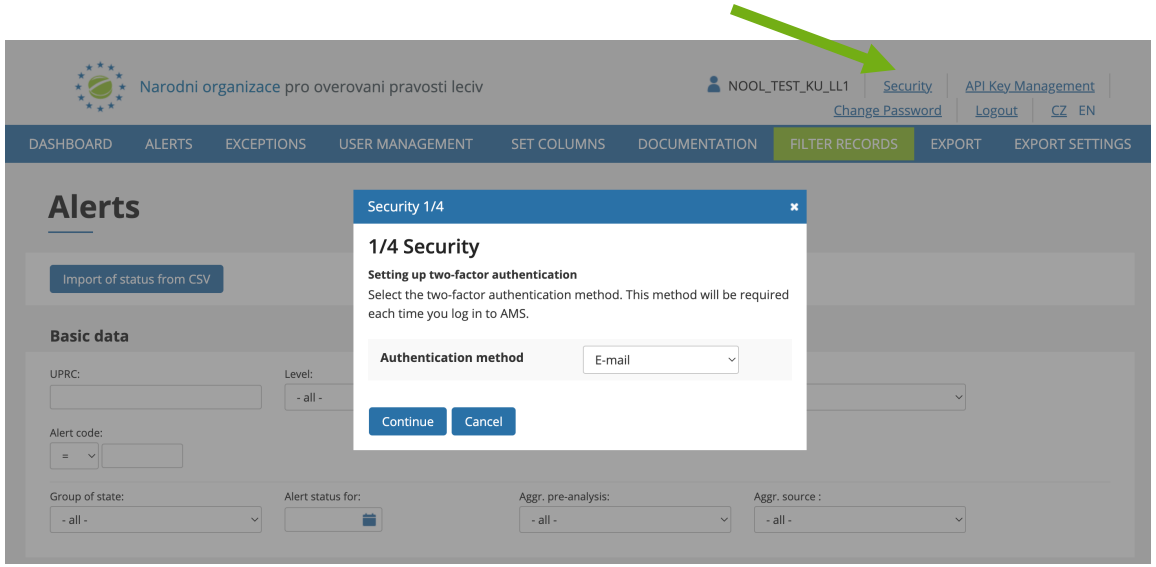
More information on the use of Google Authenticator application can be found on the company websites:
Google Authenticator

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.



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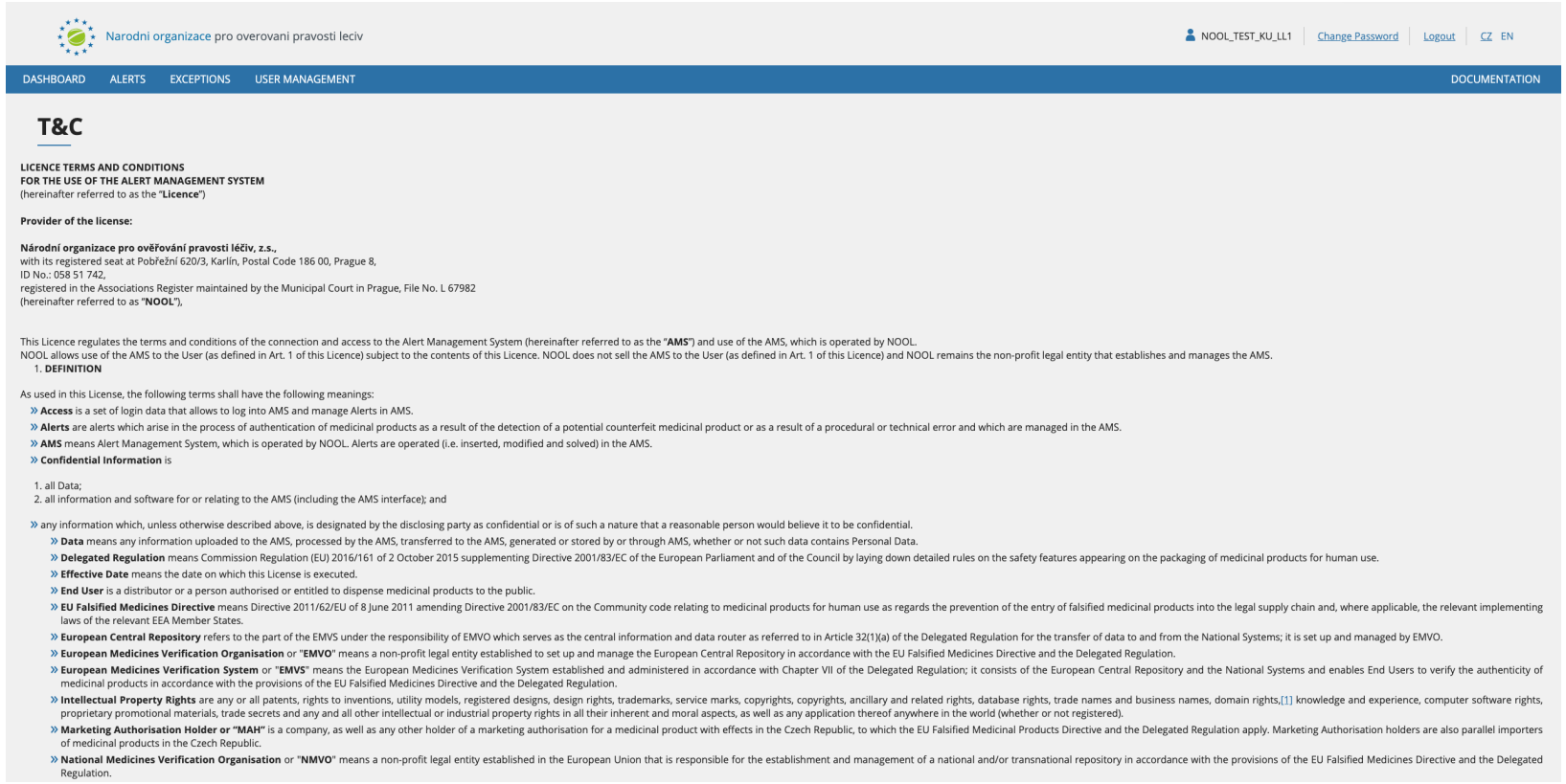
AGREEMENT WITH THE TERMS AND CONDITIONS

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



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MAIN SCREEN - DASHBOARD

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

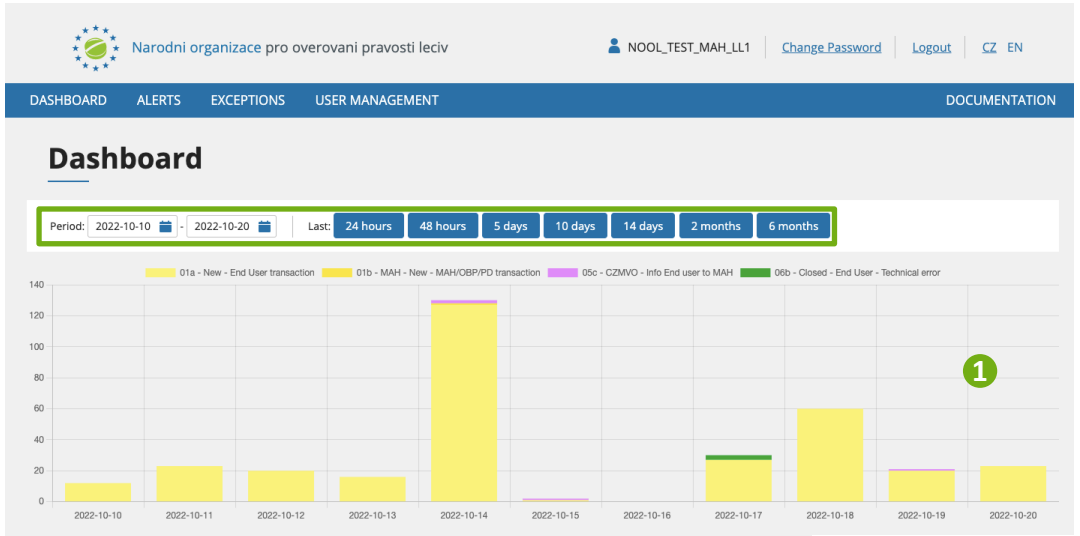
The dashboard comprises:

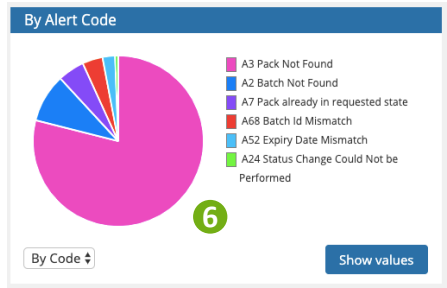
a) **A bar chart** – the current states of alerts raised in a selected date range 1

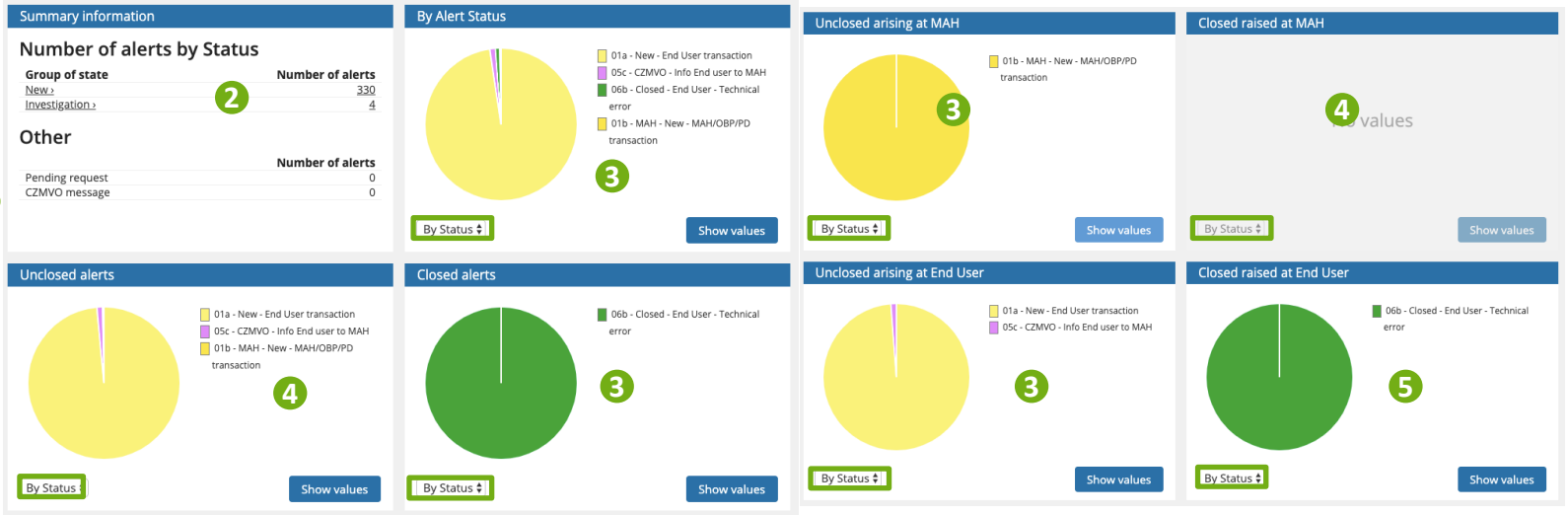
b) **A summary overview** of count of alerts and requests in a selected date range. 2

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 bewteen the selected display

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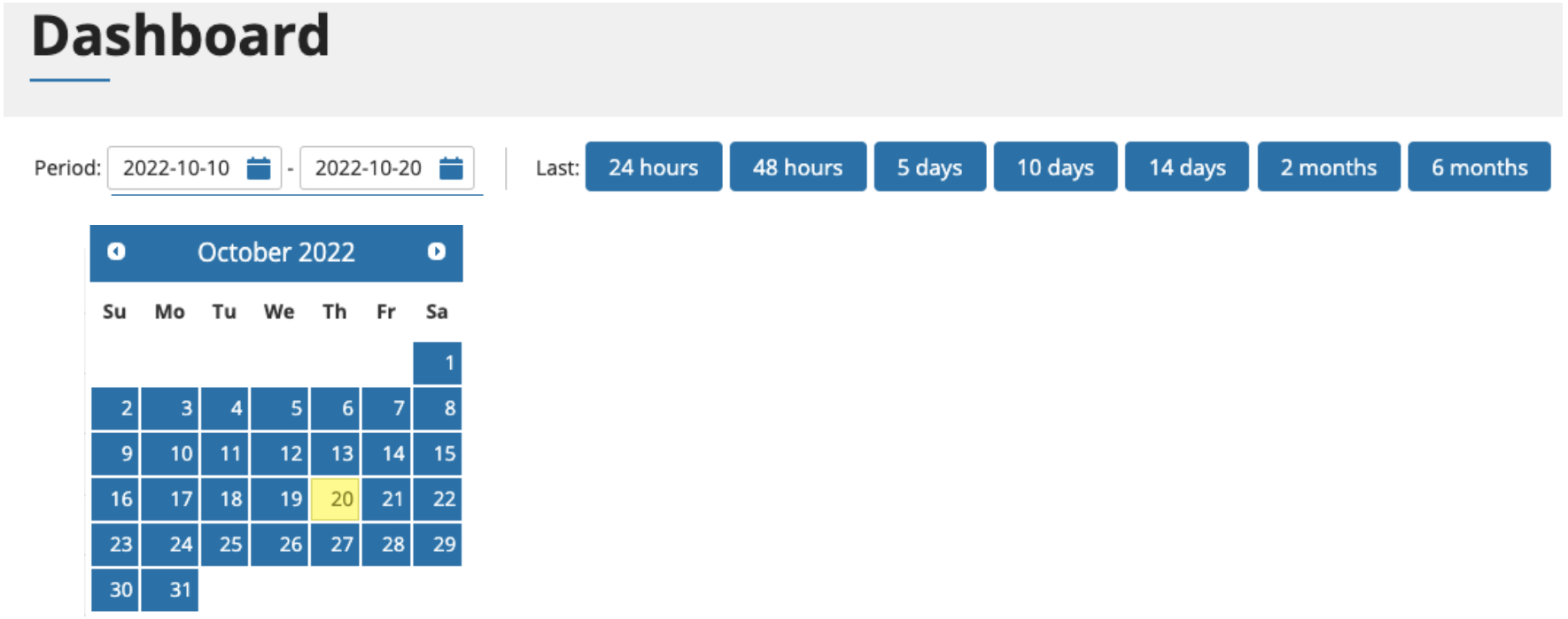
MAIN SCREEN – DATE RANGE SELECTION



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.

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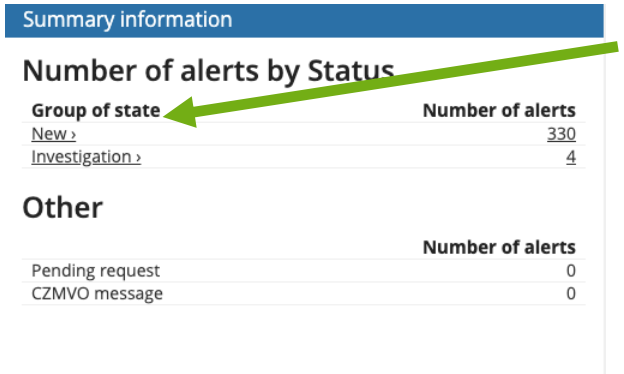
MAIN SCREEN – SUMMARY OVERVIEW



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
	CZ-LRL-Z1E-ASX-40V-0J0	5	2022-10-20 12:22	0	A7	Standard	-	88651	New	08594739214323	8594739214323	CZ	C/ ta
	CZ-LRL-YZJ-53E-5H0-PCB	5	2022-10-20 12:20	0	A7	Standard	-	88651	New	08594739214323	8594739214323	CZ	C/ ta
	CZ-LRL-YXF-DVP-1JV-3KY	5	2022-10-20 12:18	0	A7	Standard	-	88651	New	08594739214323	8594739214323	CZ	C/ ta
	CZ-LRL-YX3-FG1-WZ1-DR5	5	2022-10-20 12:18	0	A3	Standard	-	-	New	08594739024403	8594739024403	CZ	G m
	CZ-LRL-YX0-3E2-K97-D98	5	2022-10-20 12:18	0	A3	Standard	-	-	New	08594739038899	8594739038899	CZ	O H Lé

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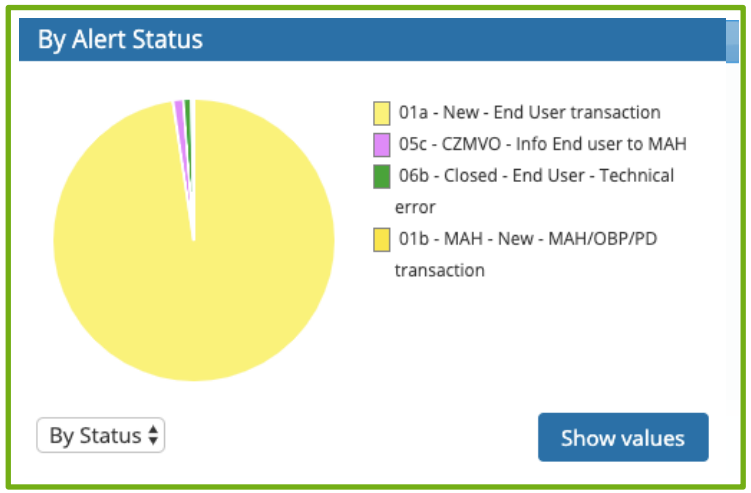
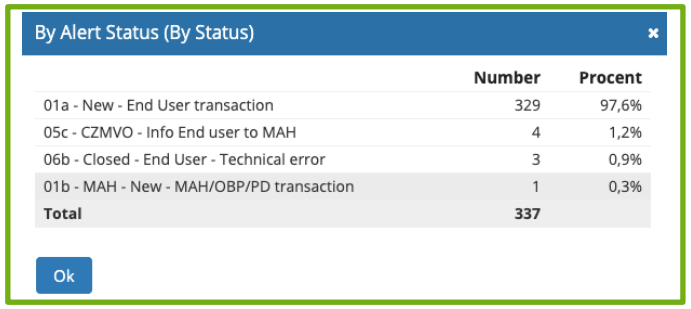
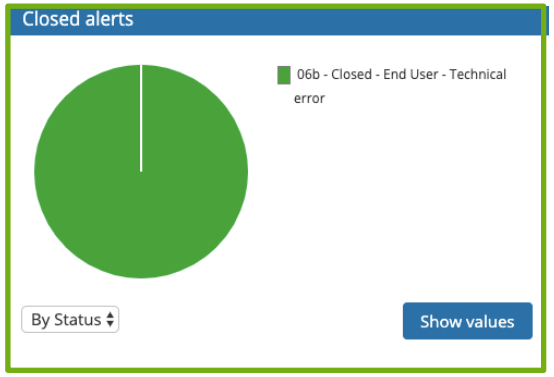
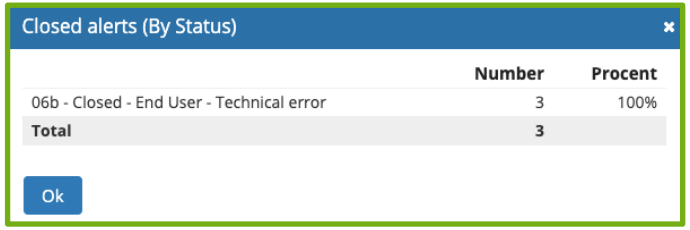
MAIN SCREEN – DISPLAY ALERT VALUES

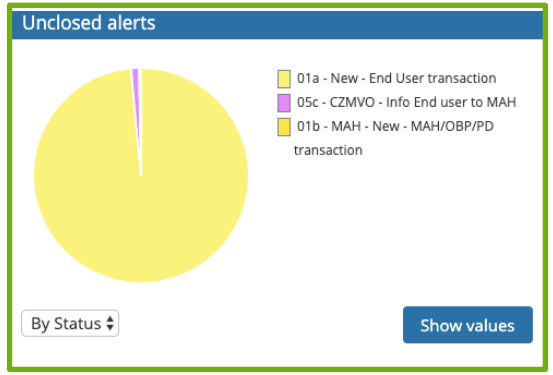


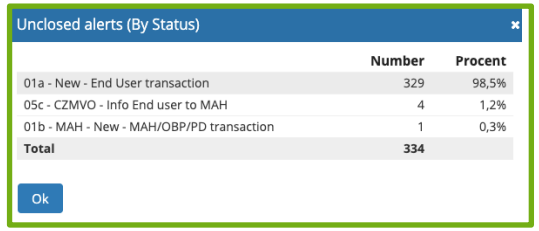
In the tiles **By alert state, Closed alerts, Unclosed alerts and By alert code** the user can view the count of alerts and the percentage ratio by clicking „Show values“.











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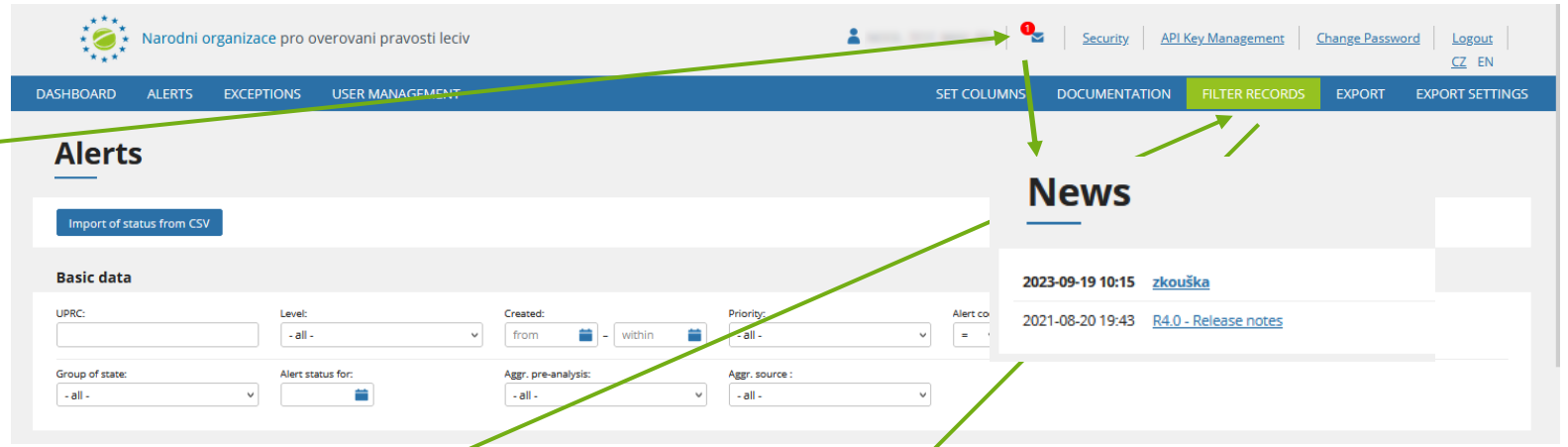
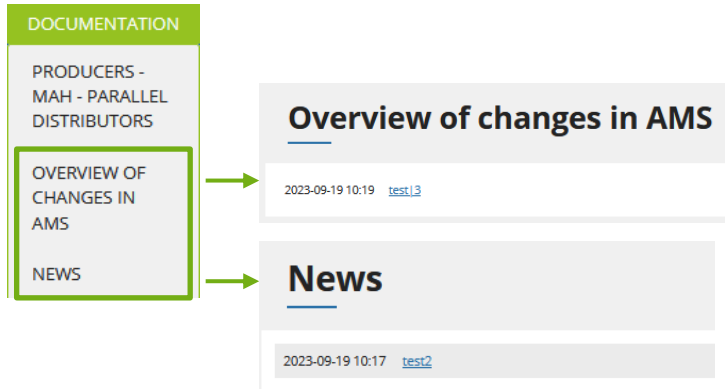
INFORMATION ABOUT CHANGES, UPDATES, NOTIFICATIONS

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)





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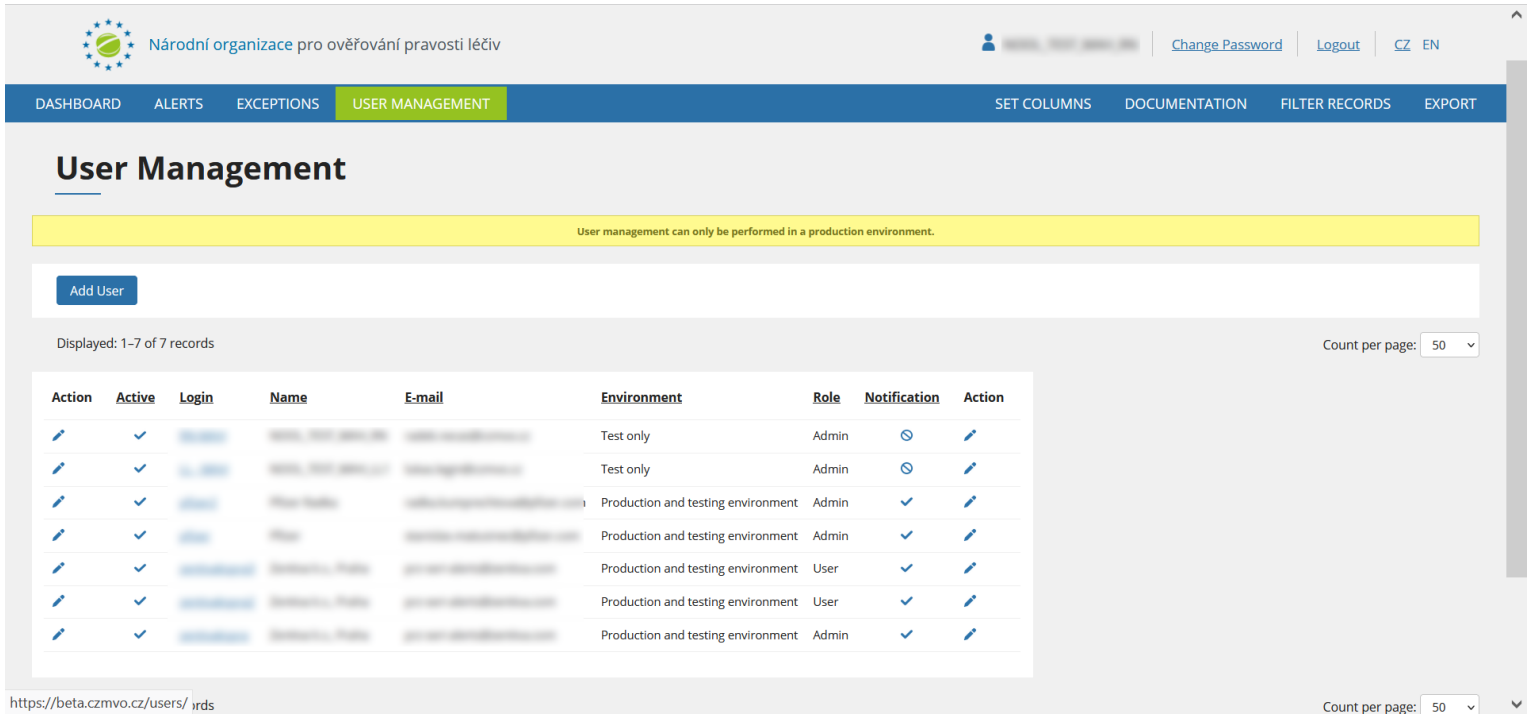
USER ADMINISTRATION

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



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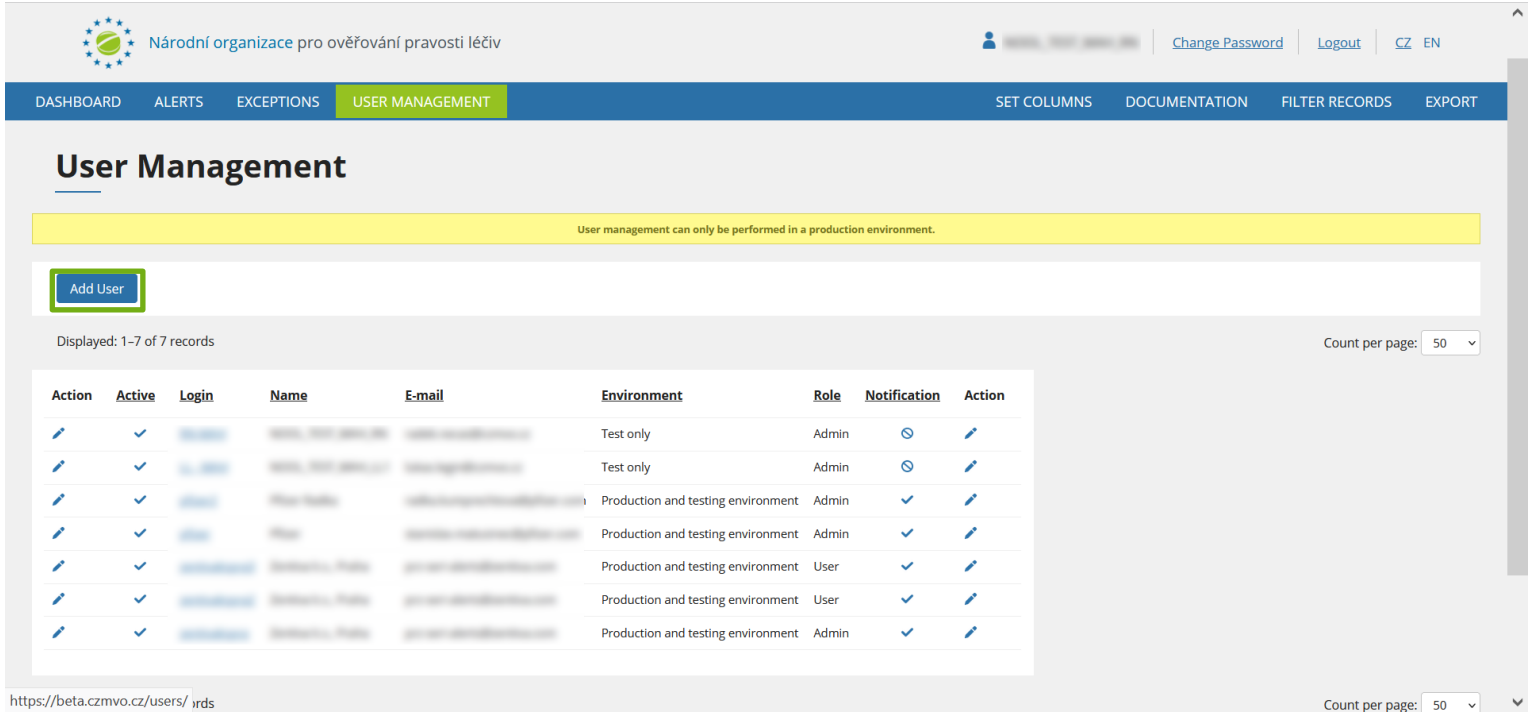
USER ADMINISTRATION

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.

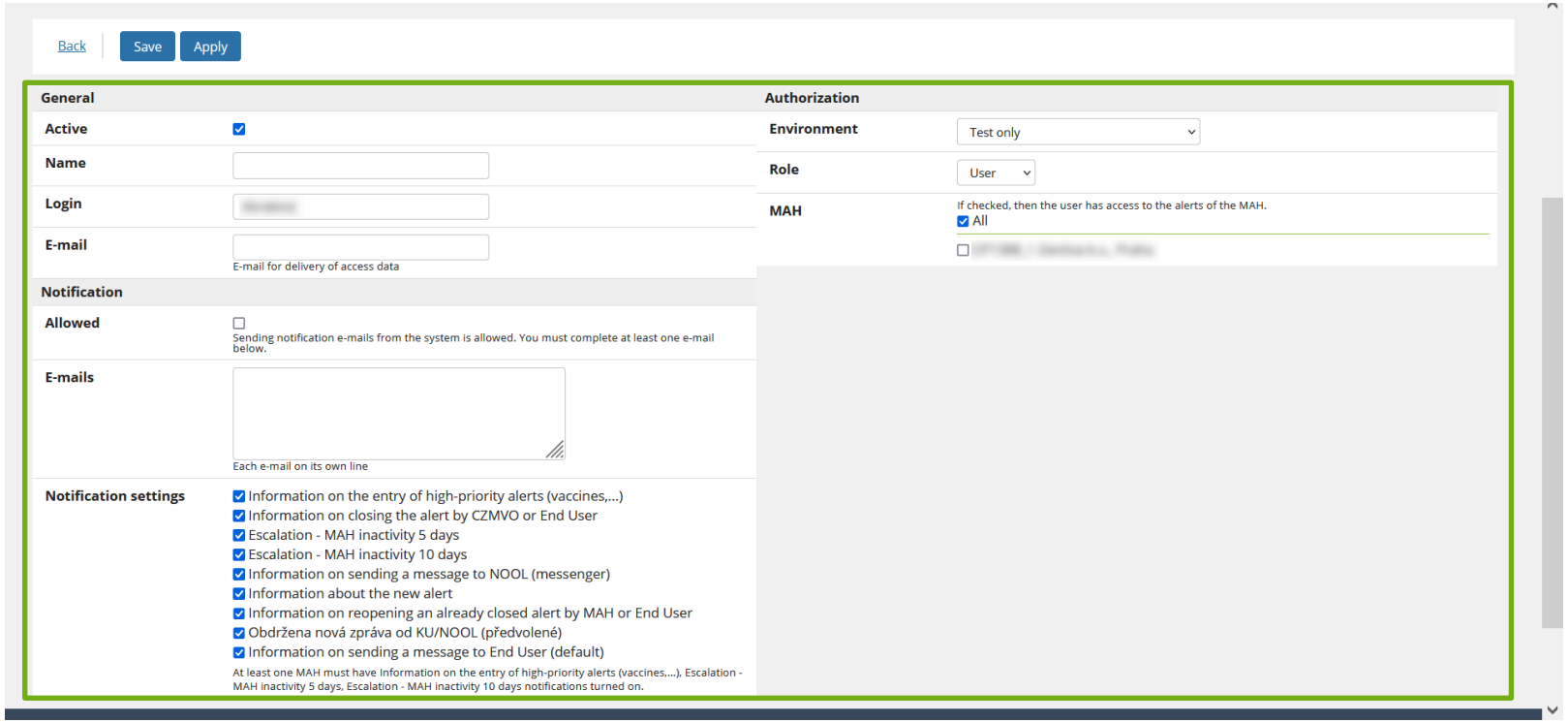
Note: once entered, the user can only be deactivated, it cannot be cancelled (due to log consistency).



Národní organizace pro ověřování pravosti léčiv

USER ADMINISTRATION

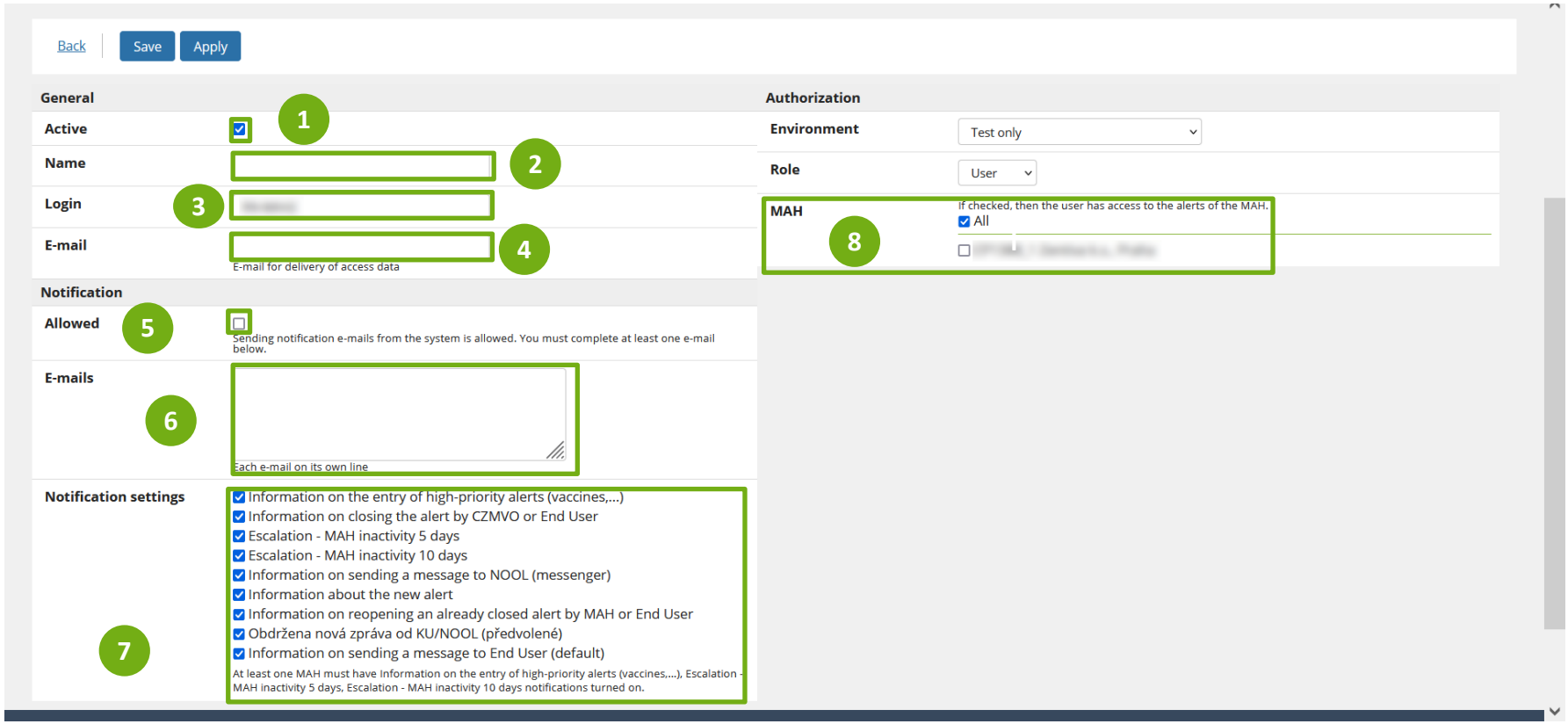
In the section "**Users administration**", a user with admin rights may **edit their own details, add, activate or deactivate users.**



Národní organizace pro ověřování pravosti léčiv

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.

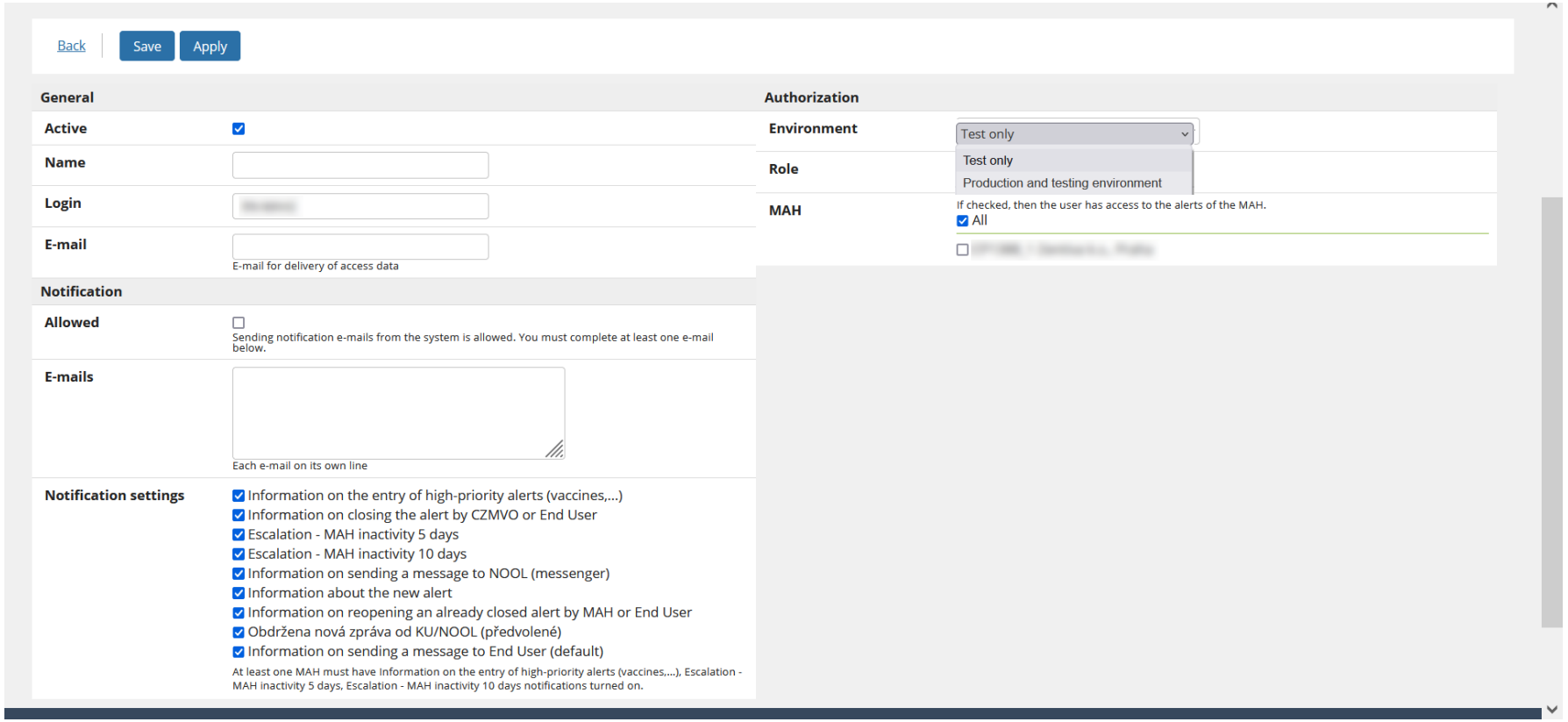


7. **Selecting notifications** the user wishes to receive

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

Národní organizace pro ověřování pravosti léčiv

ADD USER

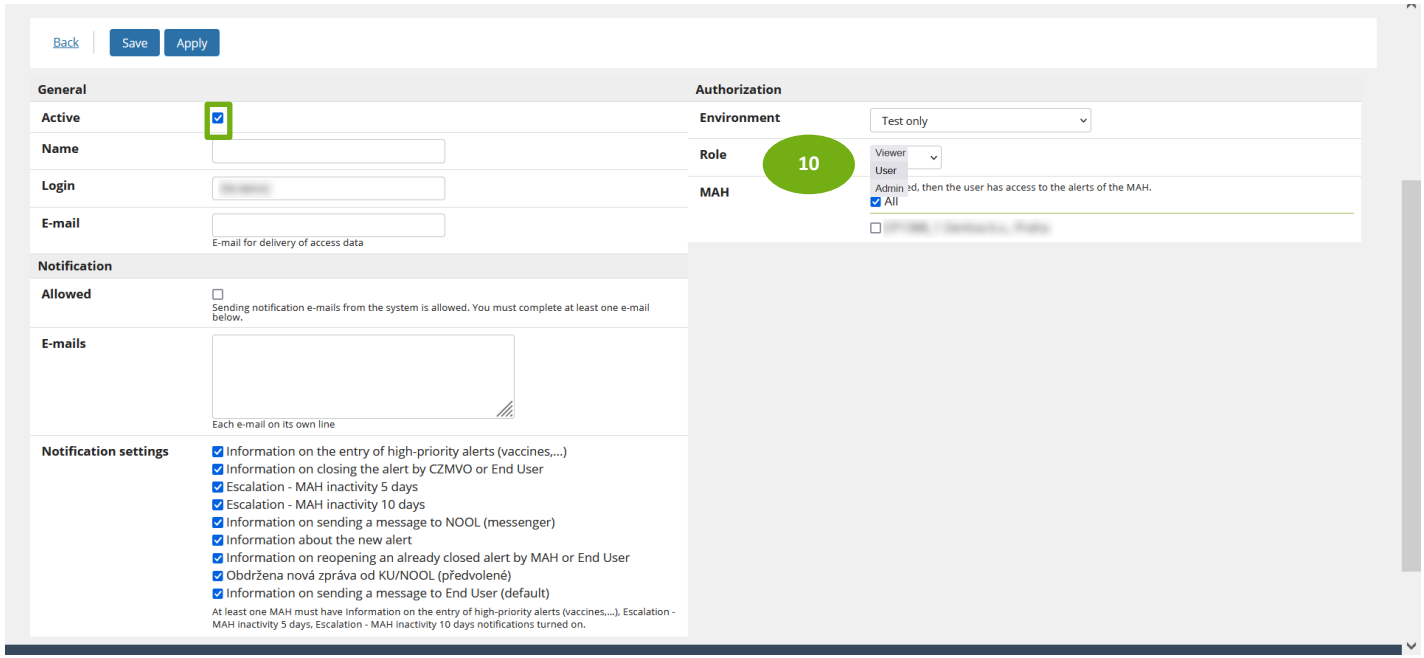


9. **Selecting the environment**, the user has access to (**testing, testing and production**).

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

Národní organizace pro ověřování pravosti léčiv

ADD USER



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

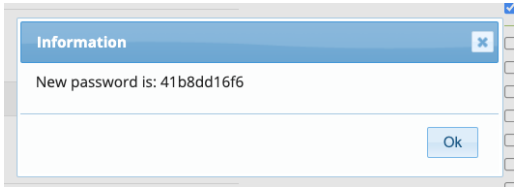
Admin - Complete administration of alerts and users.
User - Complete administration of alerts.
Viewer – alerts browsing , exports

Clicking „*Save*“ will save your data.

Národní organizace pro ověřování pravosti léčiv

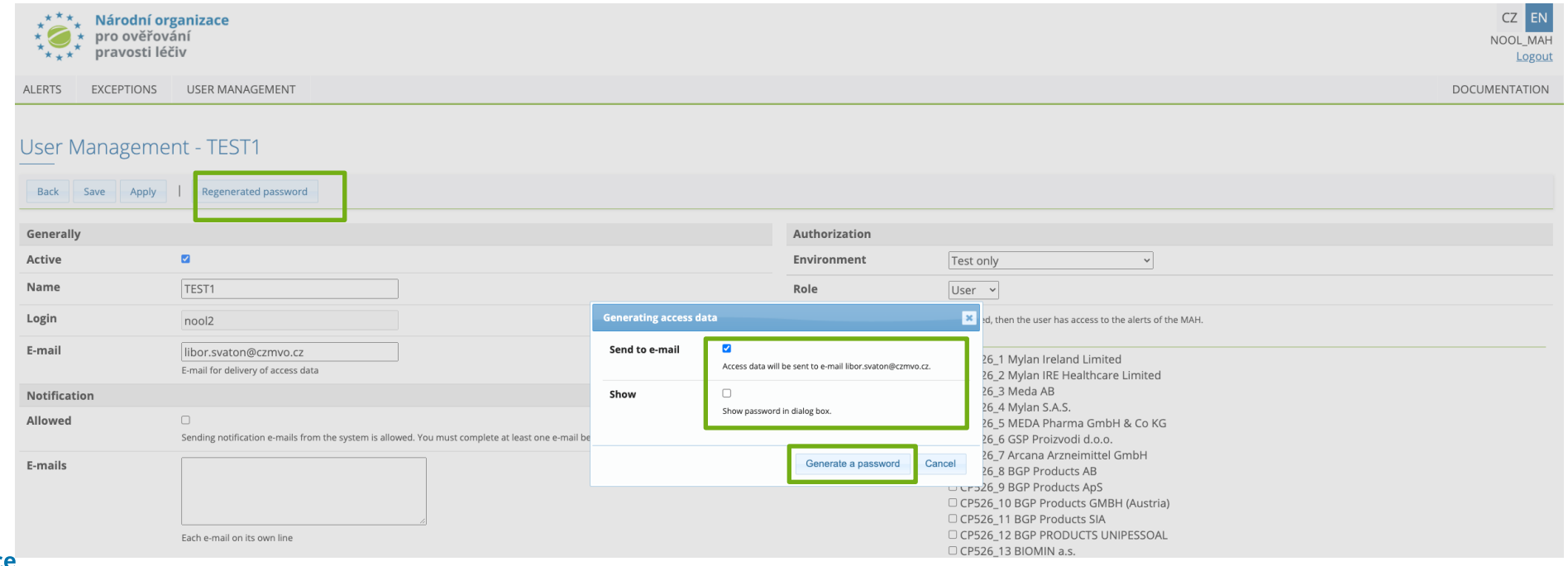
ADD USER

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.

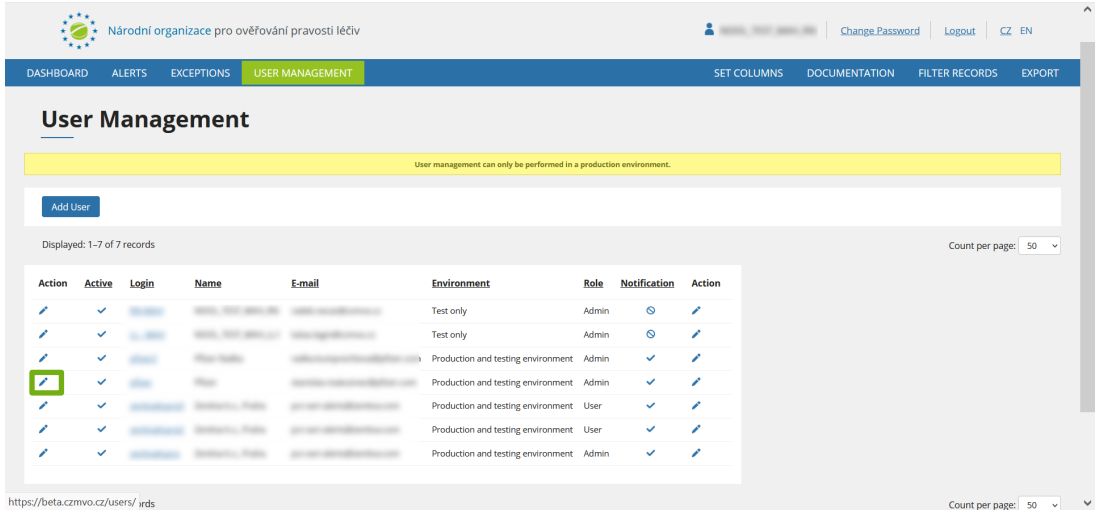
Note: Please write down your password unless you have chosen to receive it by e-mail.

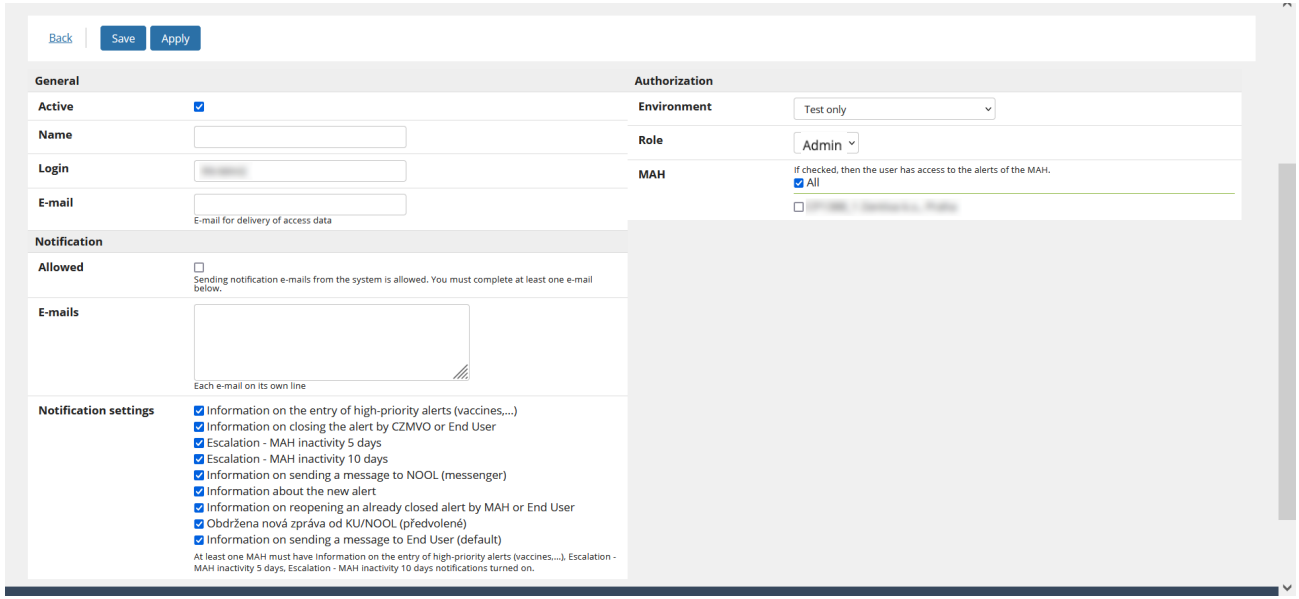


Národní organizace pro ověřování pravosti léčiv

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.





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

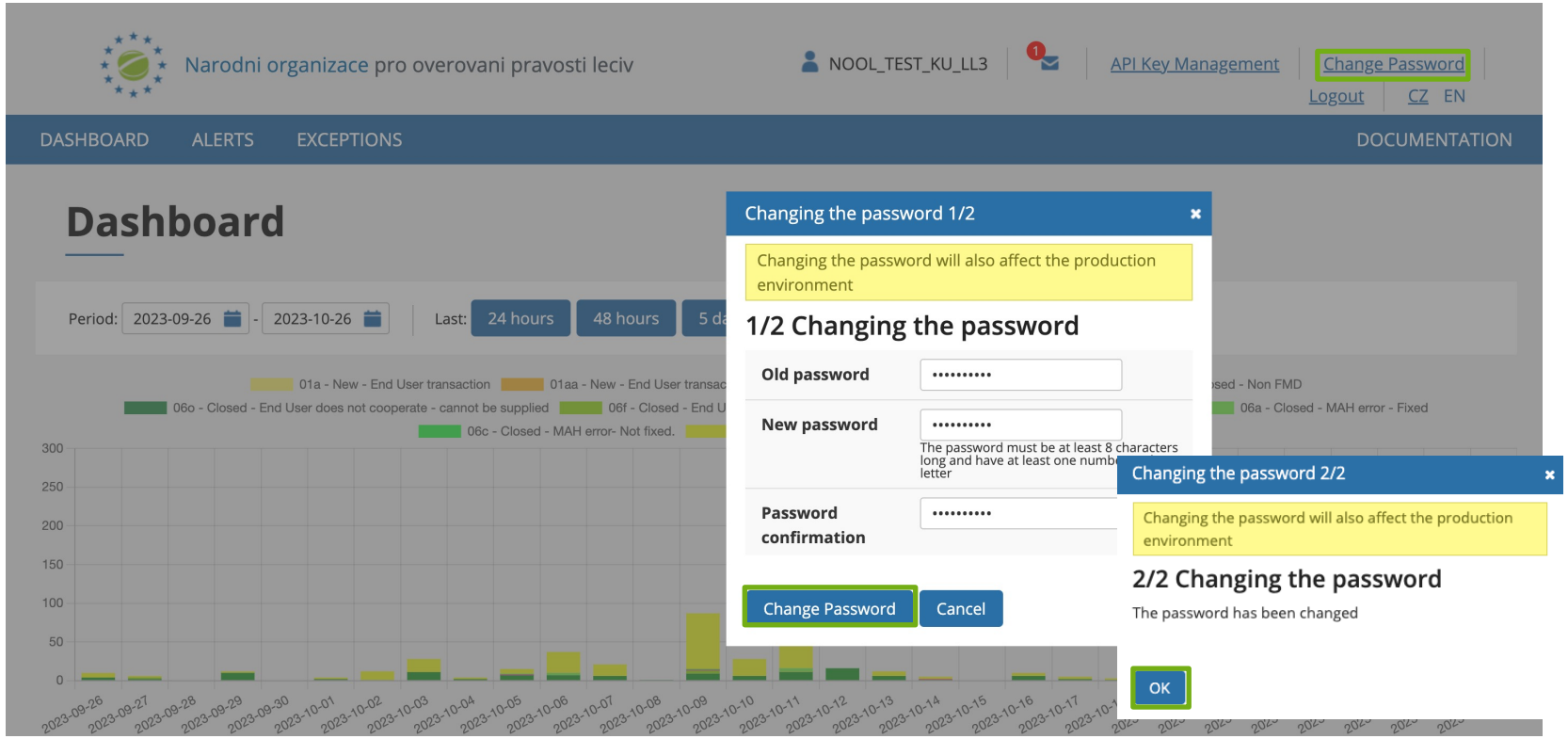
Each type of notification must have at least 1 receiver!

Národní organizace
pro ověřování
pravosti léčiv

CHANGING A PASSWORD

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

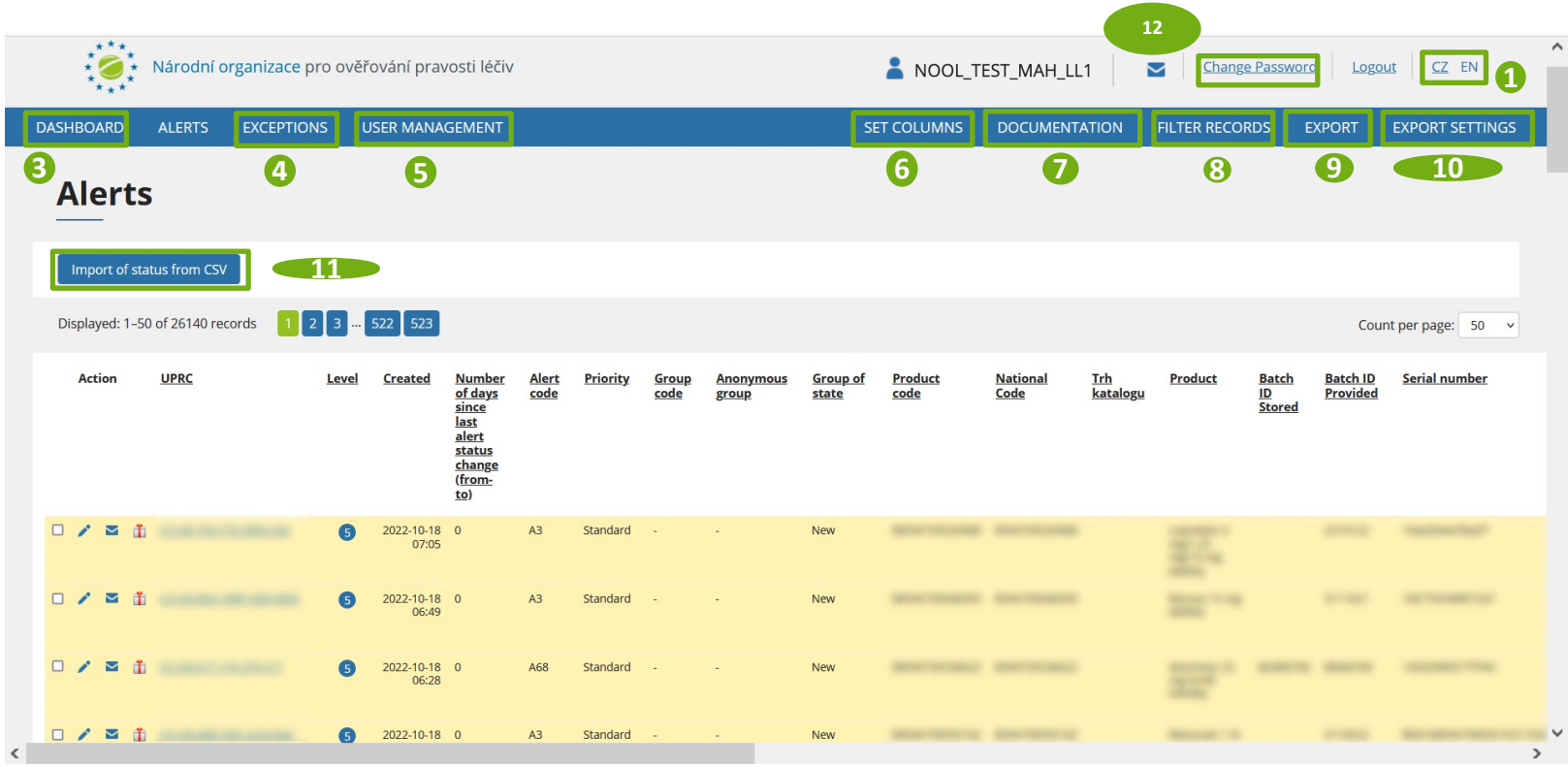
Follow the instructions in the pop-up window



Národní organizace pro ověřování pravosti léčiv

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**



11. Import of statuses via a CSV file

12. Delivered messages

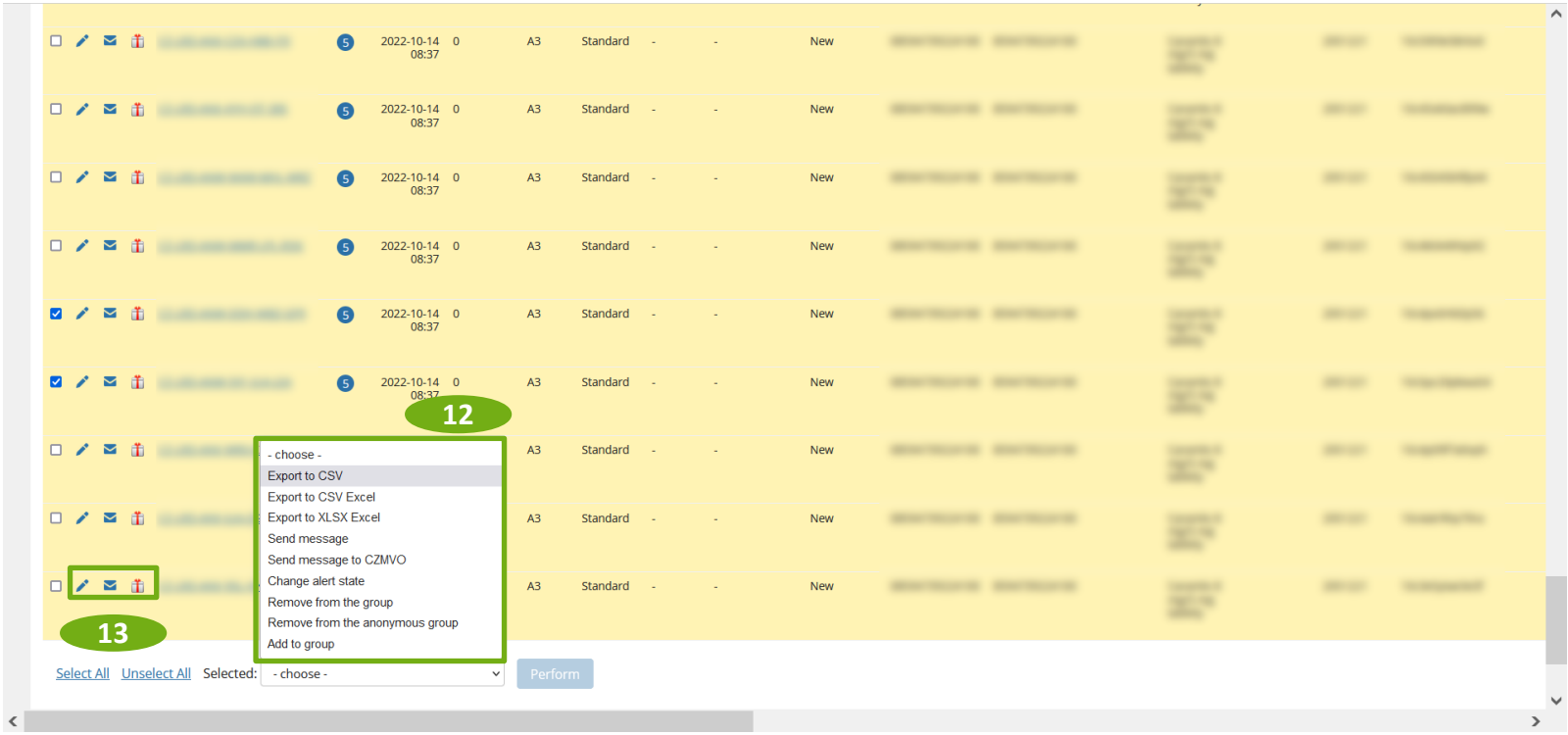
Národní organizace pro ověřování pravosti léčiv

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.

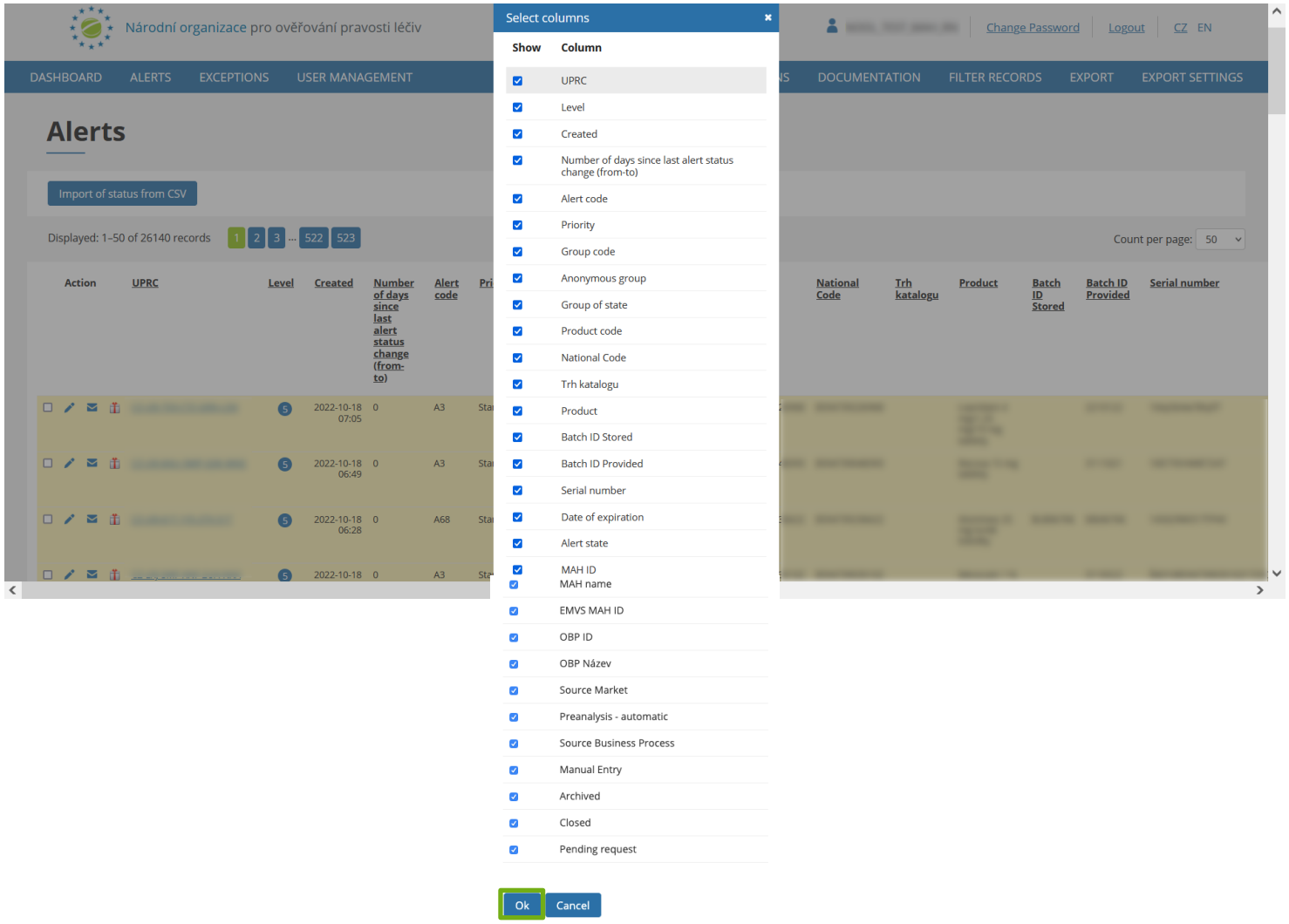


Národní organizace pro ověřování pravosti léčiv

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*“.



Národní organizace pro ověřování pravosti léčiv

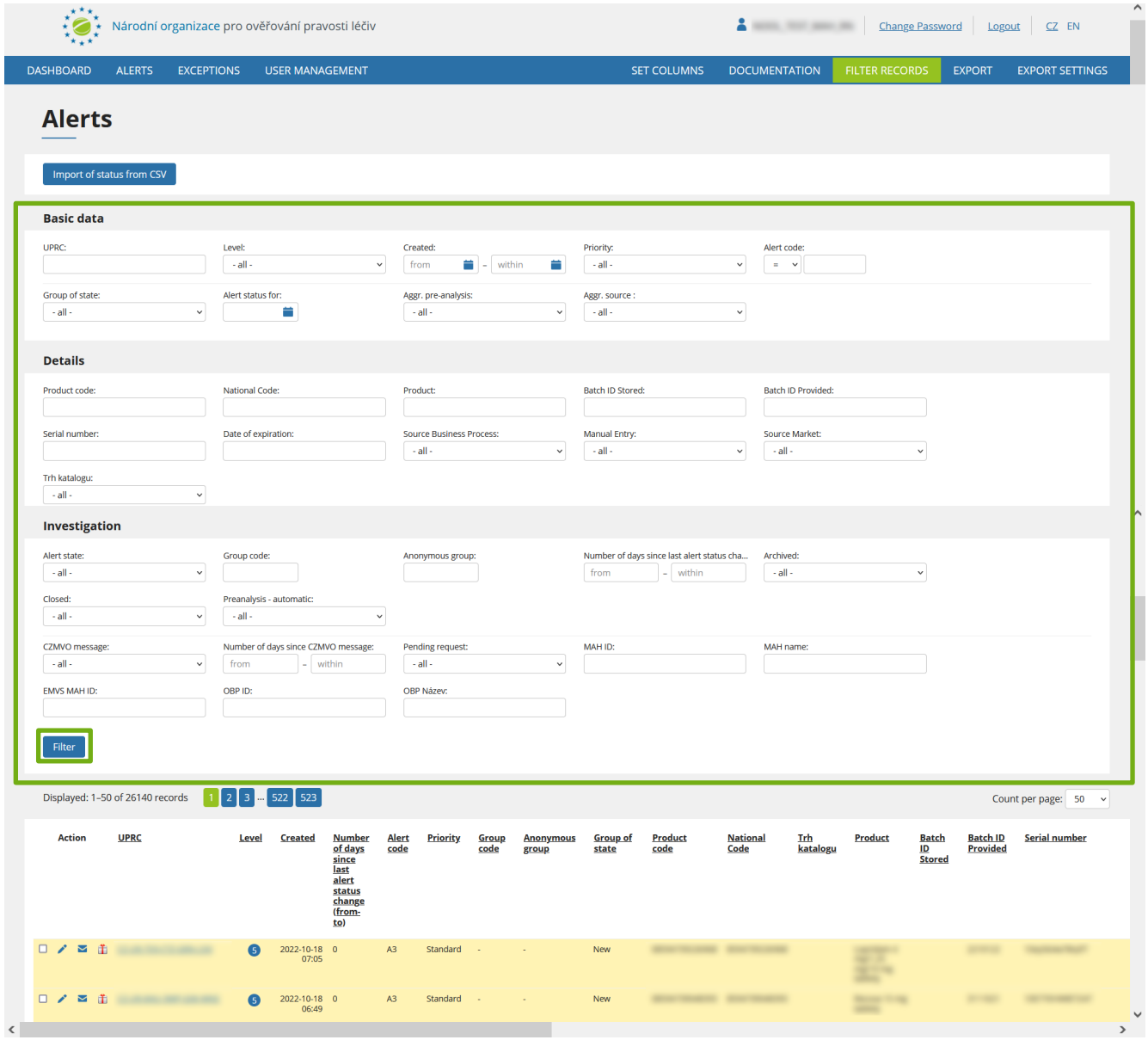
ALERT FILTERS

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

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.

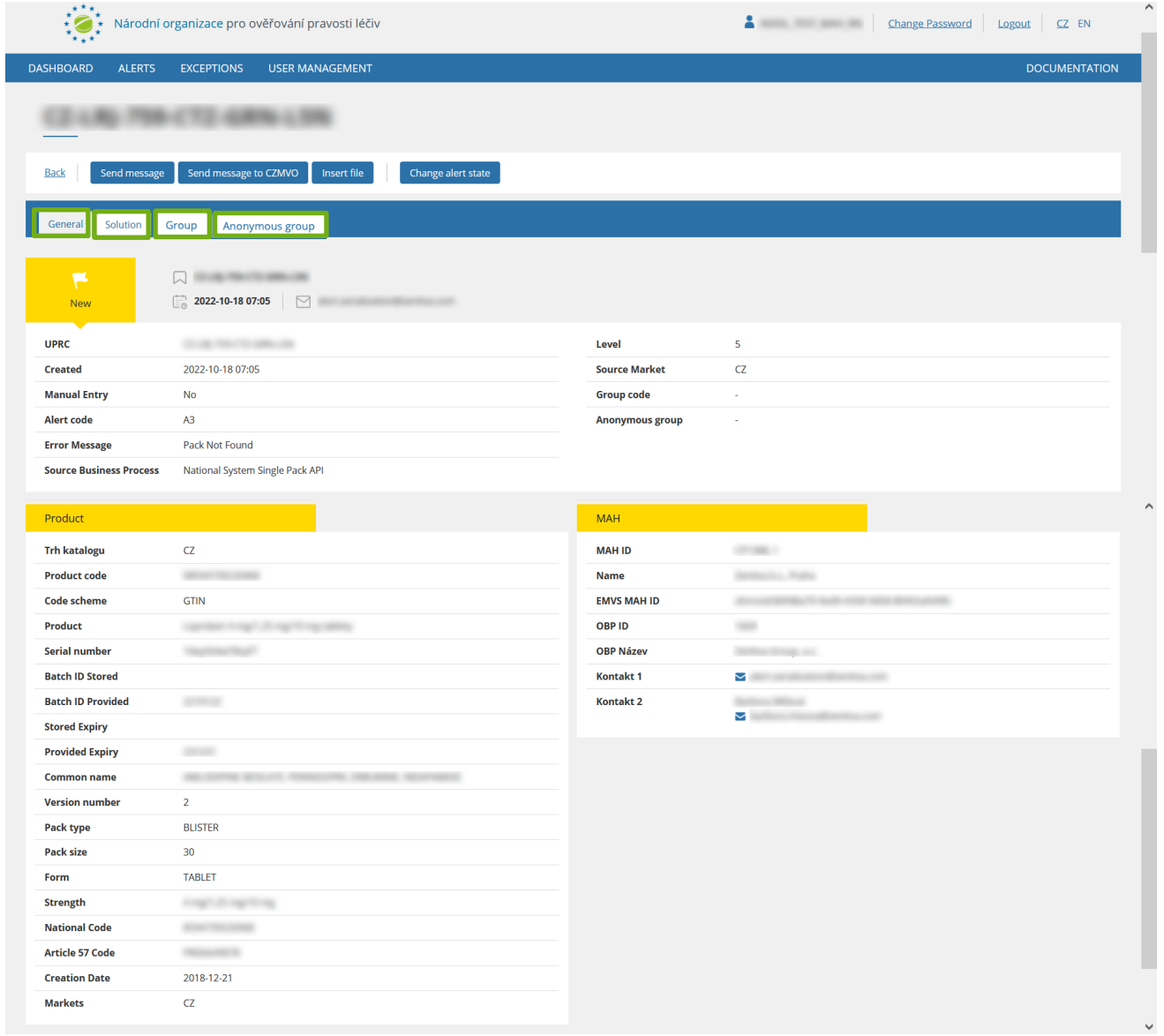
Tab "*General*" shows details about alert such as date of alert, error code, batch ID provided by the user provided or stored in EU-HUB, etc.

Tab "*Solution*" shows alert State, history od 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.



Národní organizace pro ověřování pravosti léčiv

CHANGE ALERT STATE *

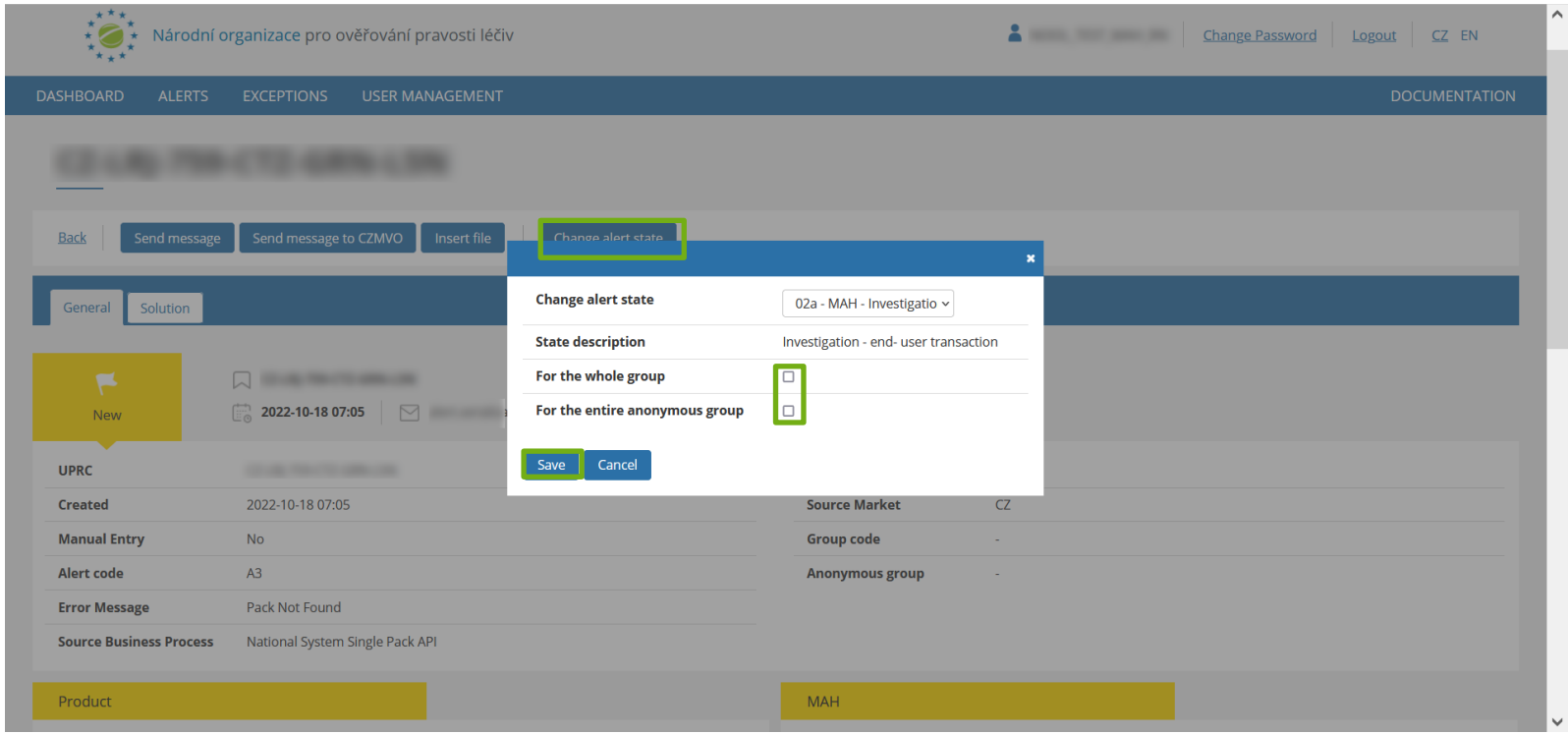
Button "*Alert state change*" allows change the state of specific alert. Additional window appears with selector of desired state.

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 grou*p" 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*".



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.

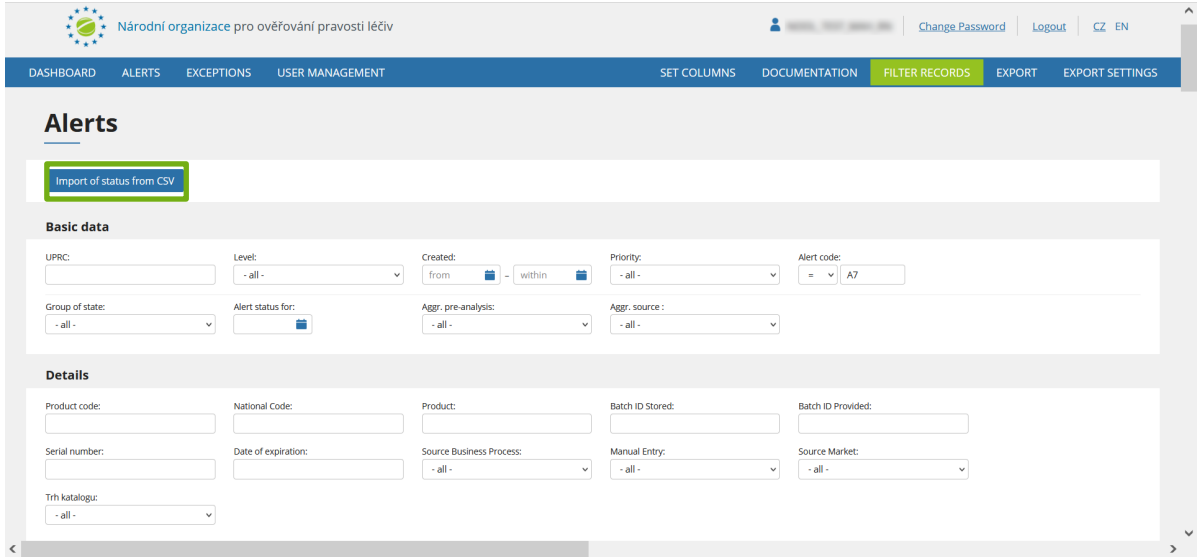
Národní organizace pro ověřování pravosti léčiv

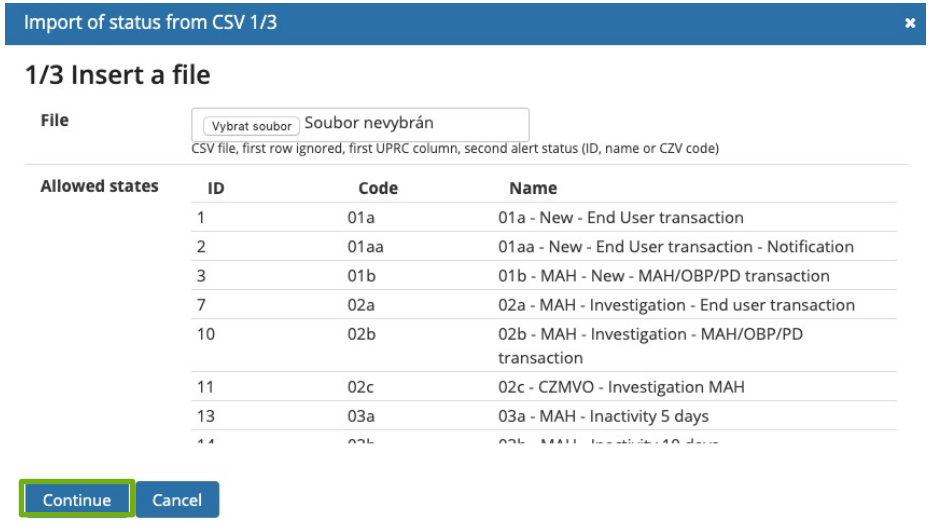
BULK CHANGE OF ALERT STATUSES

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*“



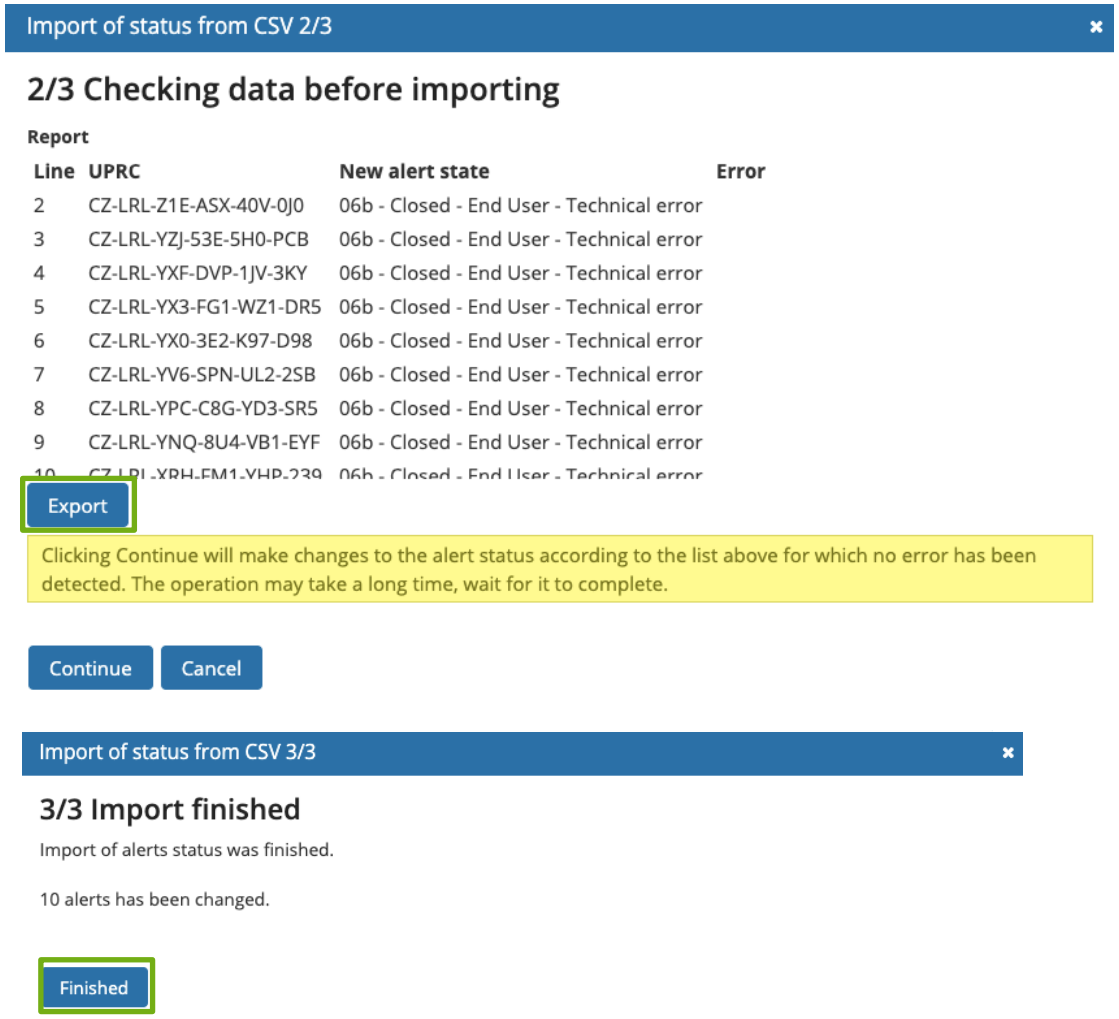


Národní organizace pro ověřování pravosti léčiv

BULK CHANGE OF ALERT STATUSES

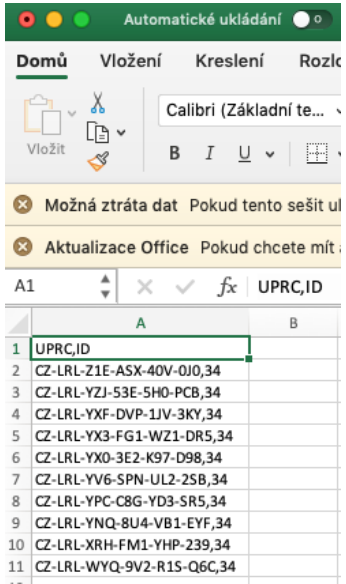
If the file is correct, alerts where the status change will occur are displayed in a table. The status that will be allocated to the alerts can be seen in the right column. Click „*Continue*“.

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



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.

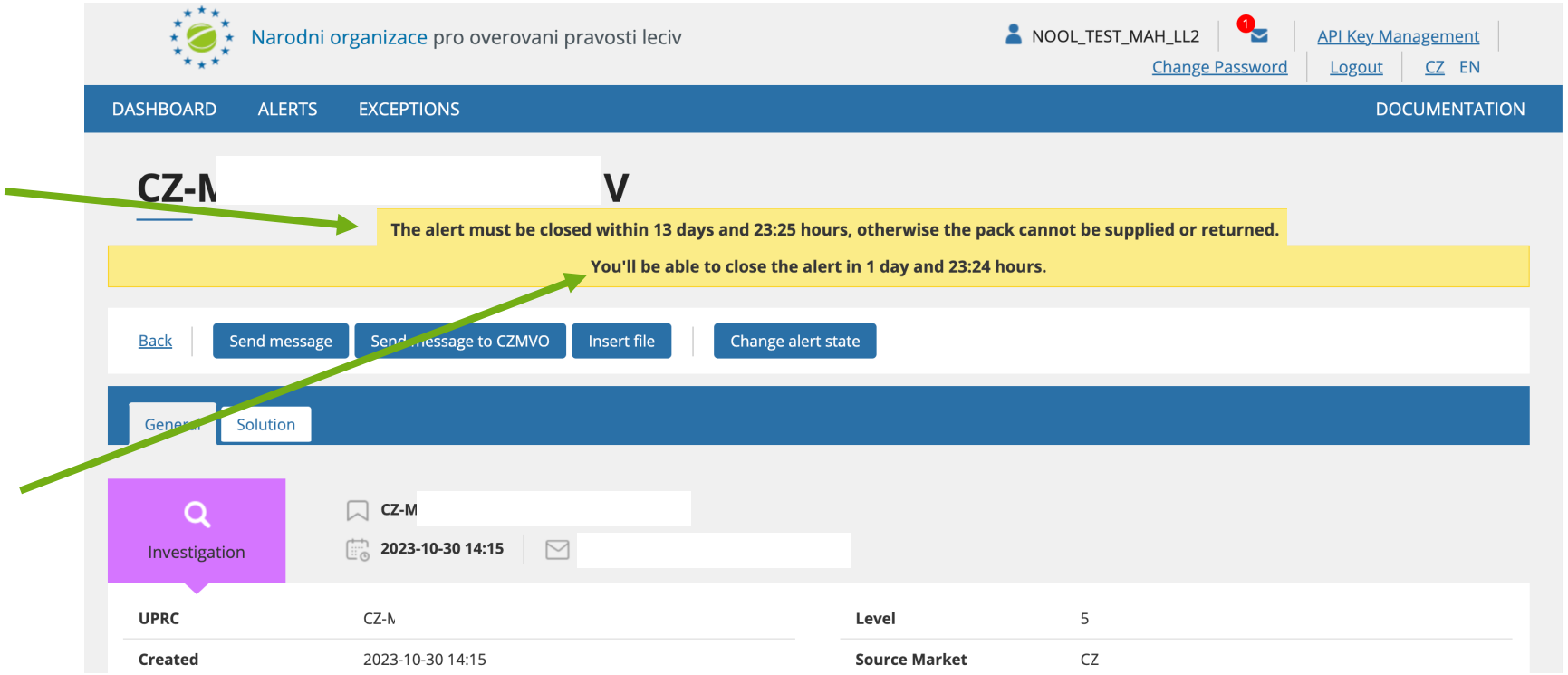


Národní organizace pro ověřování pravosti léčiv

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).



Národní organizace pro ověřování pravosti léčiv

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.

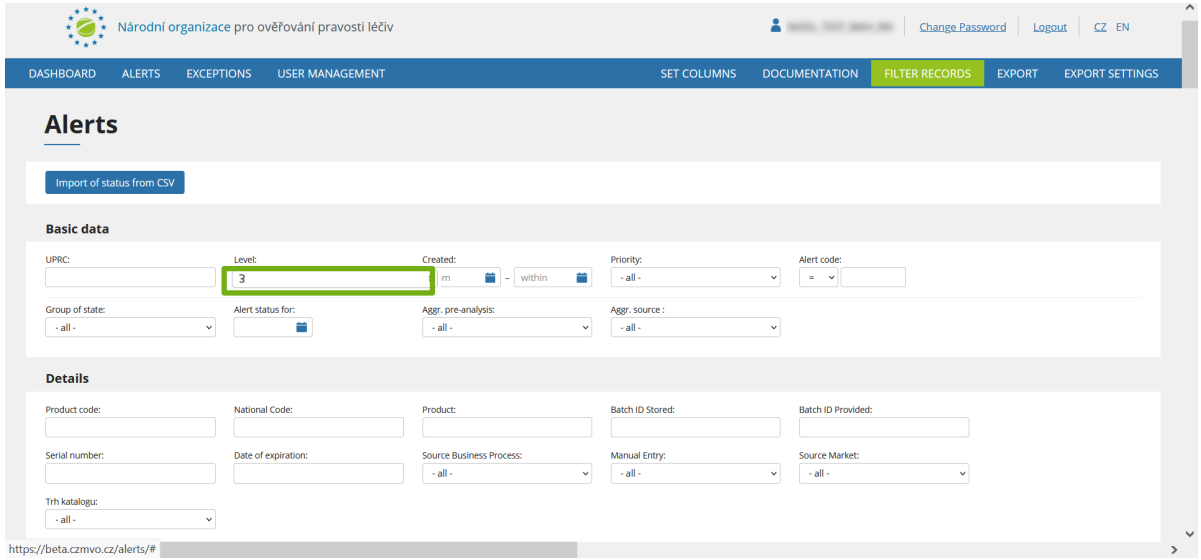
A1 – product code not found
A5 – reactivation attempt was carried out at a different location

- 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

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*“.



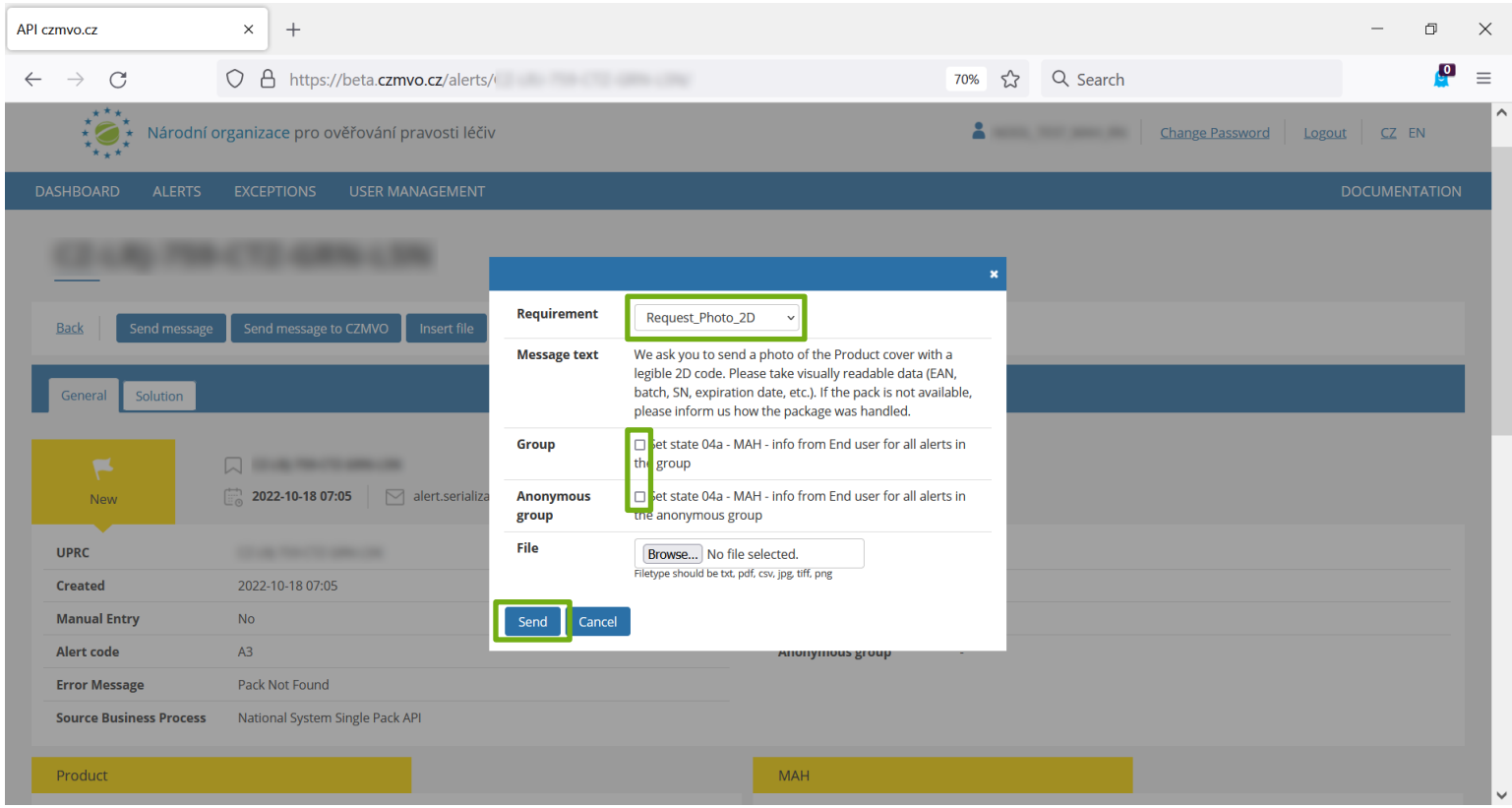
Národní organizace
pro ověřování
pravosti léčiv

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.



Národní organizace pro ověřování pravosti léčiv

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).**

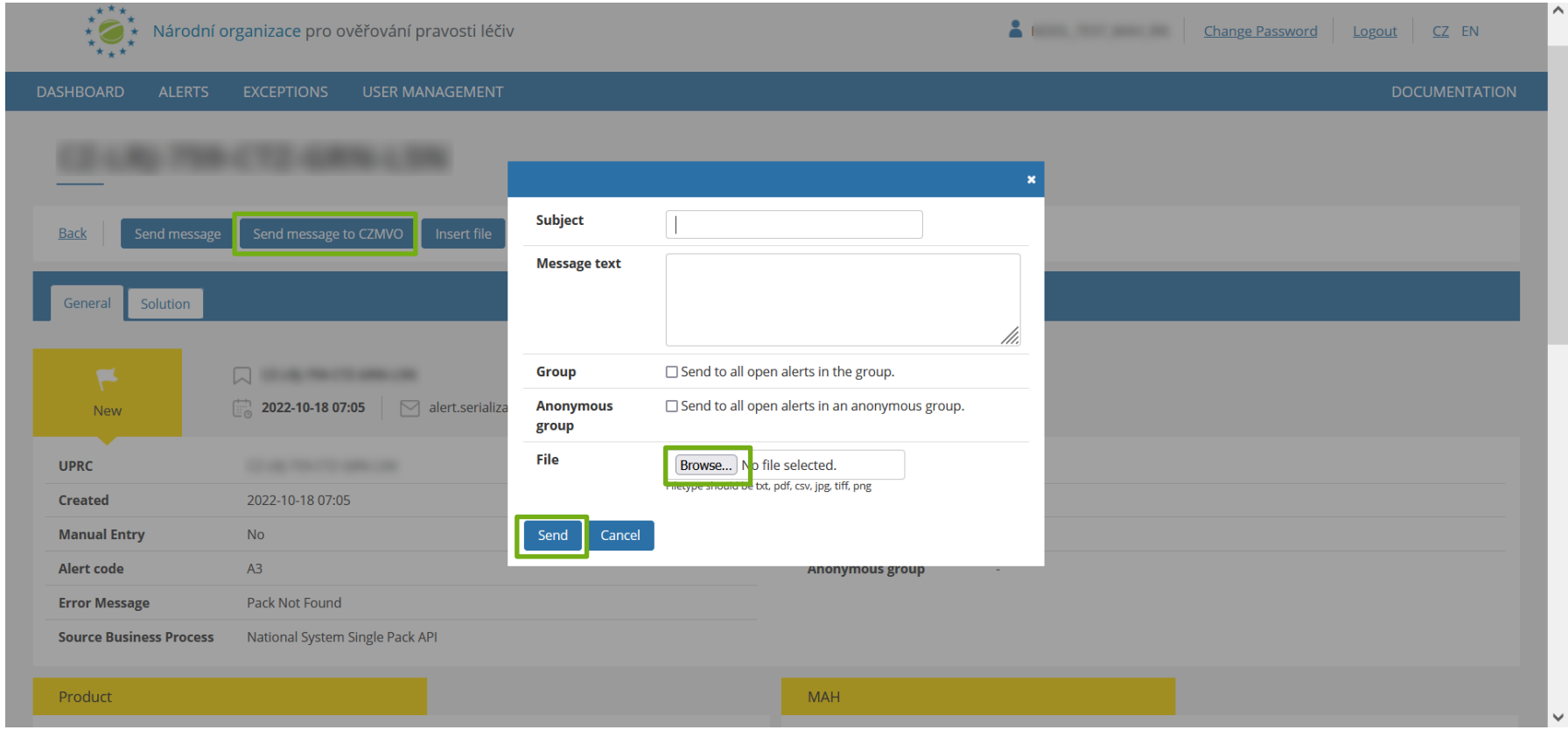
COMMUNICATION BETWEEN CZMVO AND USERS

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.



Národní organizace pro ověřování pravosti léčiv

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 fota obalu LP, s čitelným 2D kódem. Nafoťte prosím i vizuálně čitelné údaje (EAN, šarže, SN, datum exspirace, 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 scaner 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_ruční 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.). Ffixed/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_ruční vstup_nečitelný 2D**	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_ chybné načtení kvůli 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 org ace pro ověřová pravosti léči

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

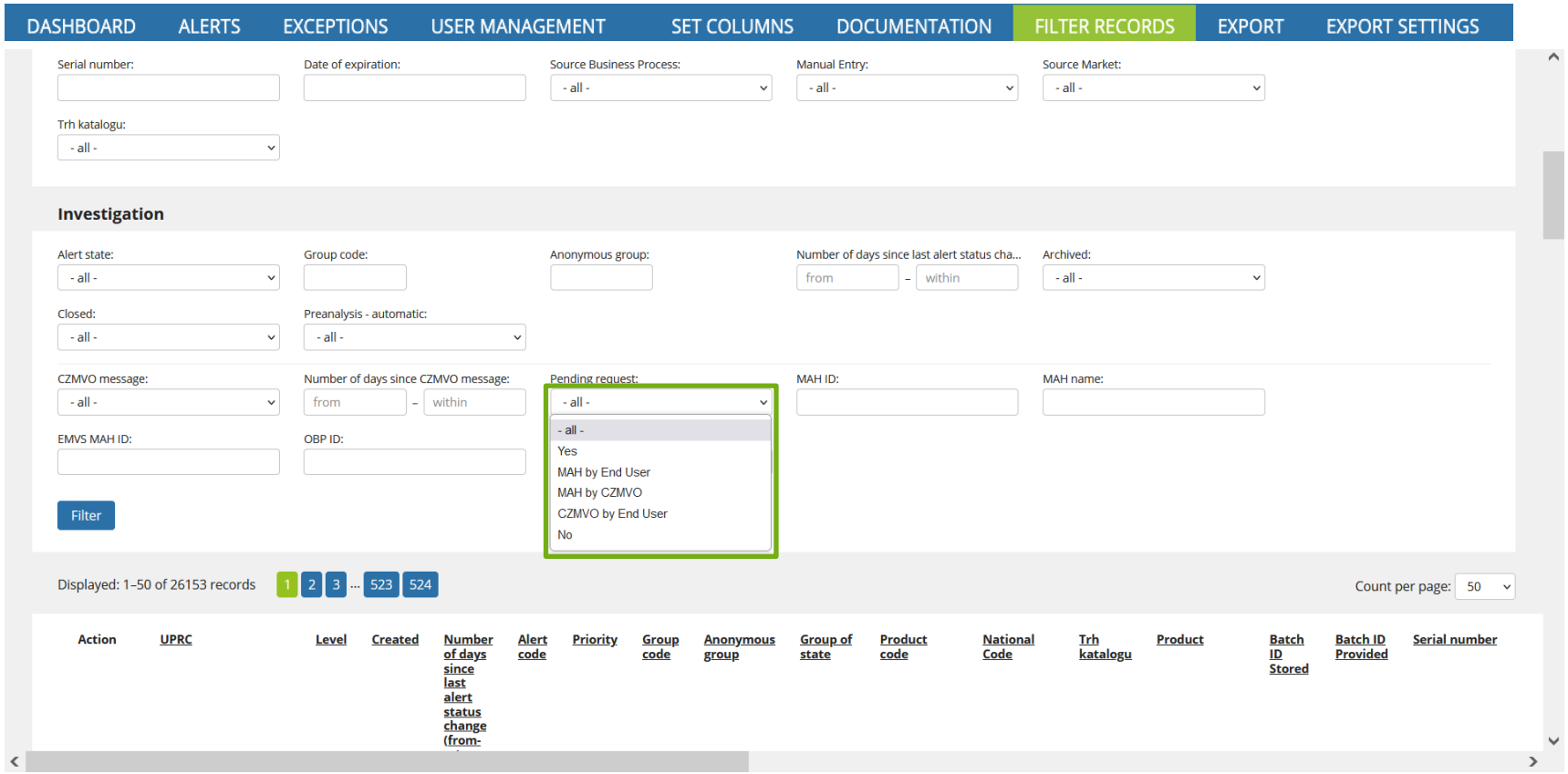
A list of alerts for which the MAH/OBP has requested additional information can be viewed with help of a filter.

Click „Filter Records“. Set one of the options i 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**”

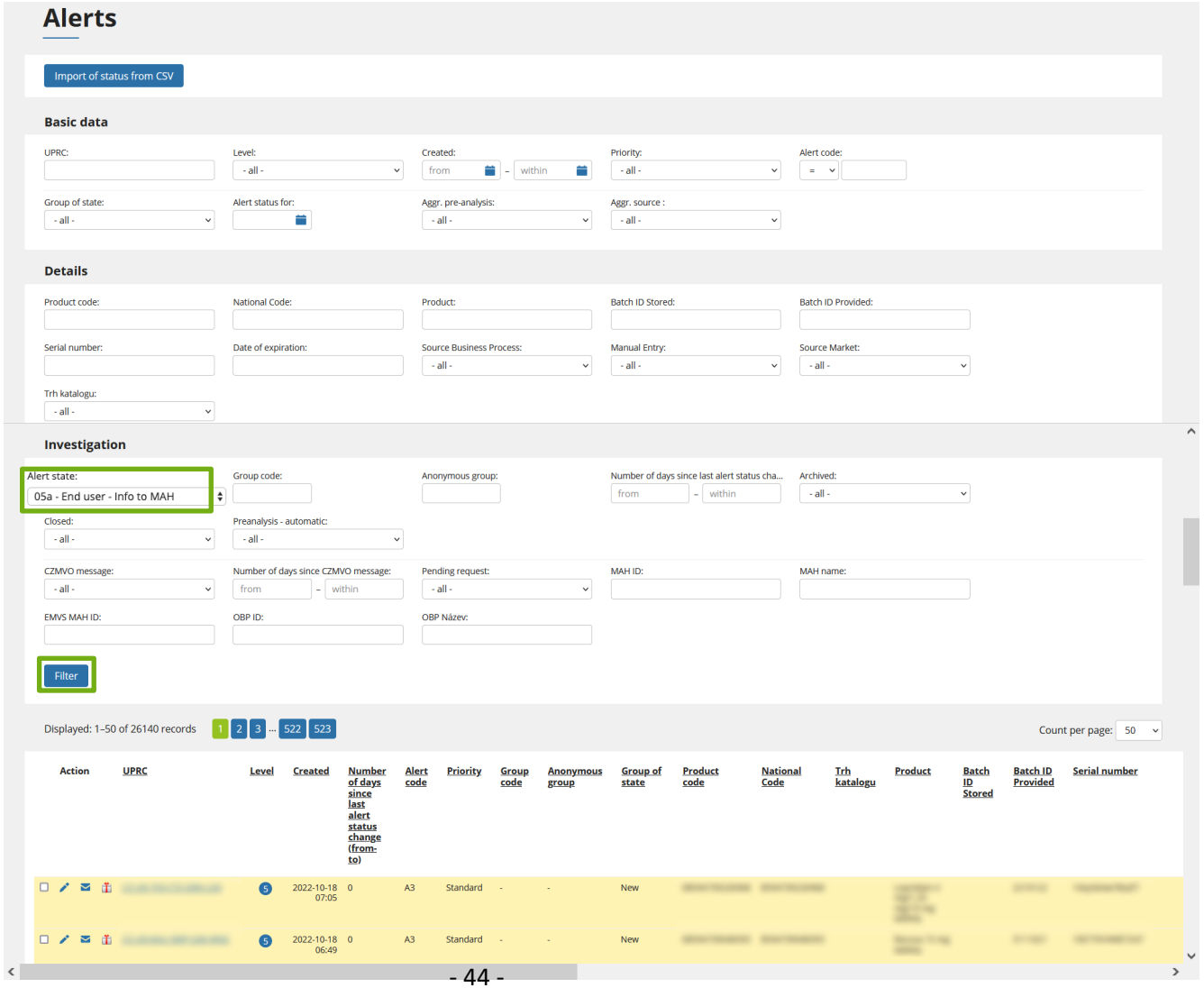


Národní organizace pro ověřování pravosti léčiv

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*“.



Národní organizace pro ověřování pravosti léčiv

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.

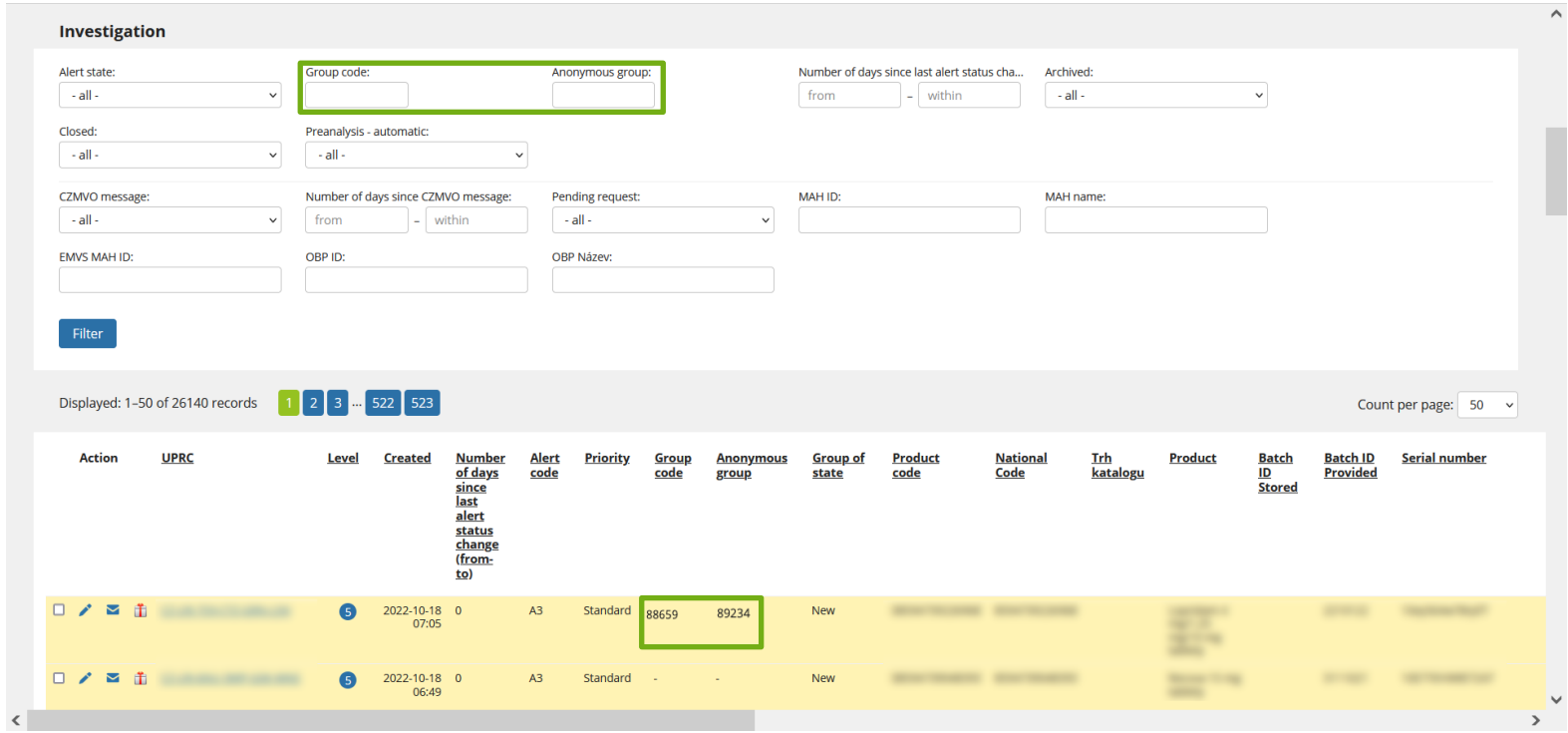
There are two types of groups in the system:

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



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.

Národní organizace pro ověřování pravosti léčiv

REMOVE ALERTS FROM GROUP

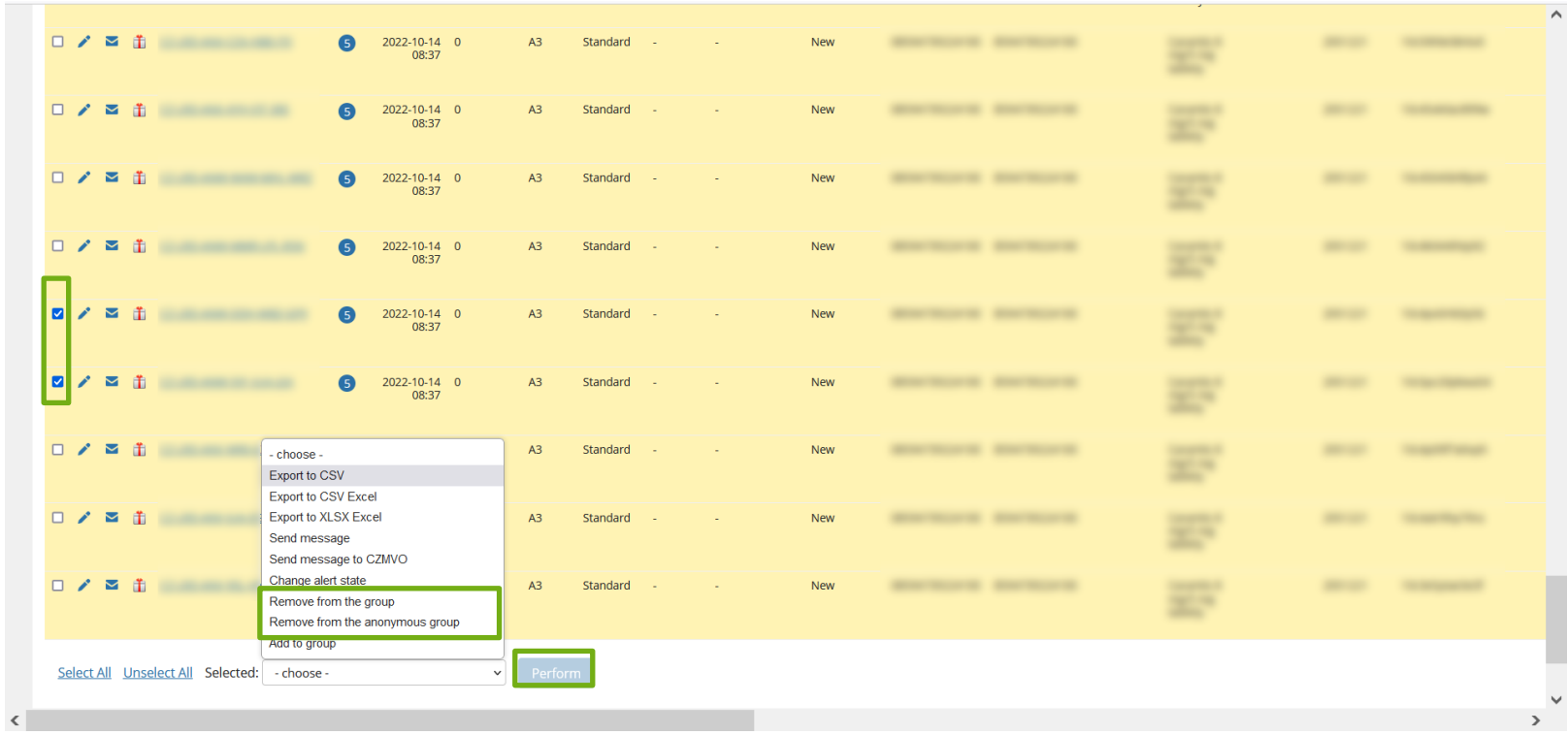
If you figure out, in course of the investigation process, that some alerts have a different root cause and they need to be solved separately, **you can remove them from the group**.

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).



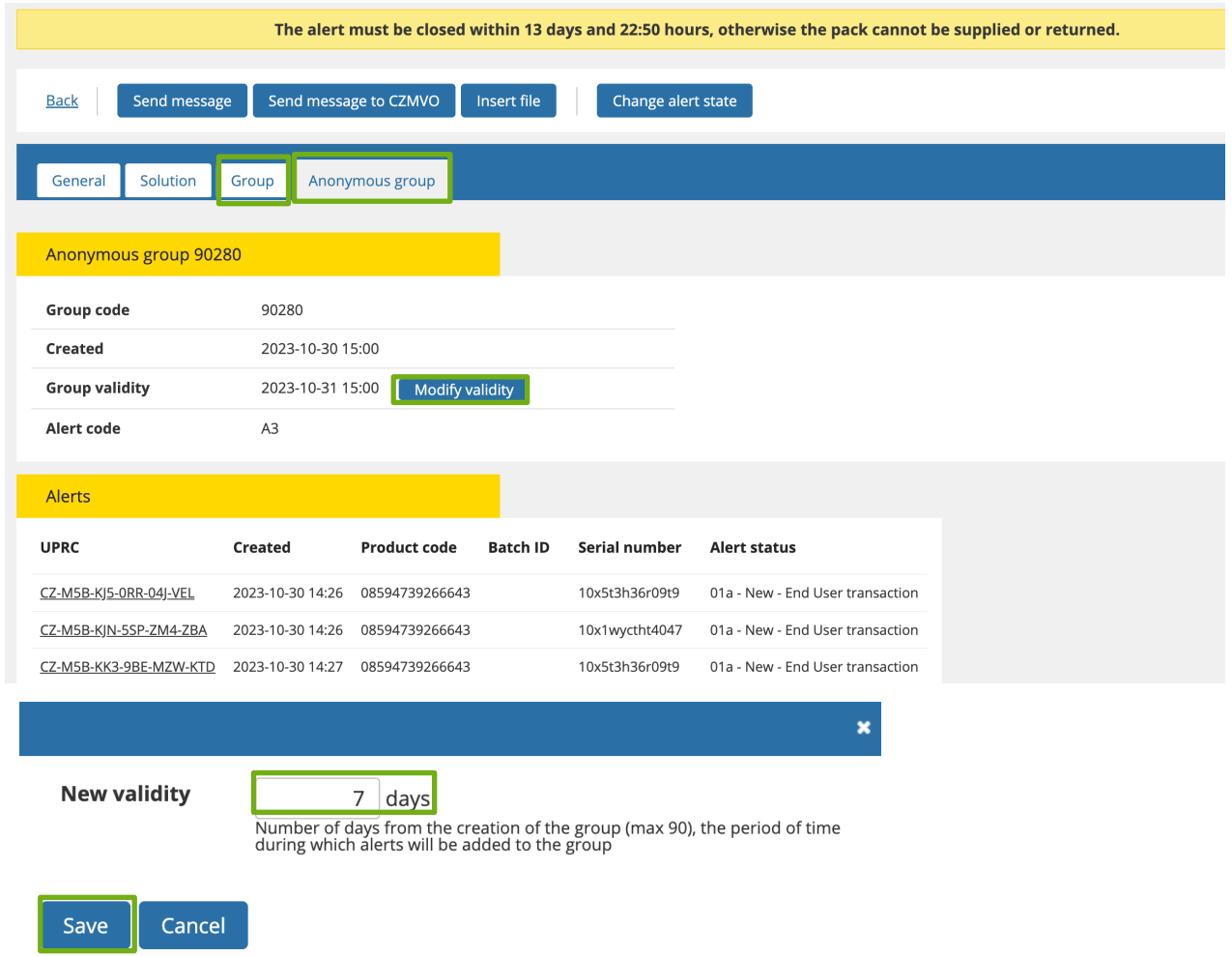
Národní organizace pro ověřování pravosti léčiv

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.



Národní organizace pro ověřování pravosti léčiv

REPORTS - SUMMARY EXPORT

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

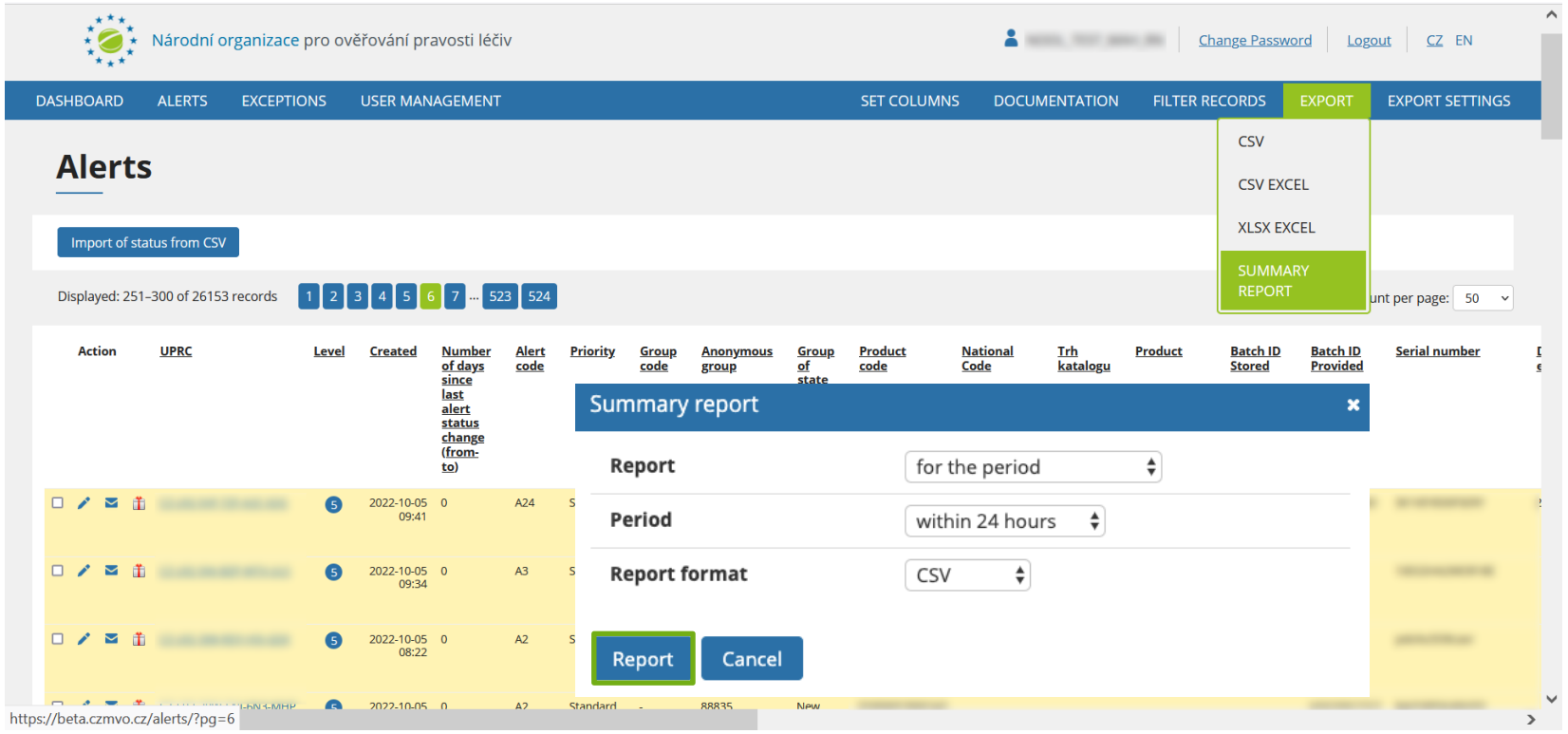
The report can be generated for a certain period only or for the date of the last change.

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 repor 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

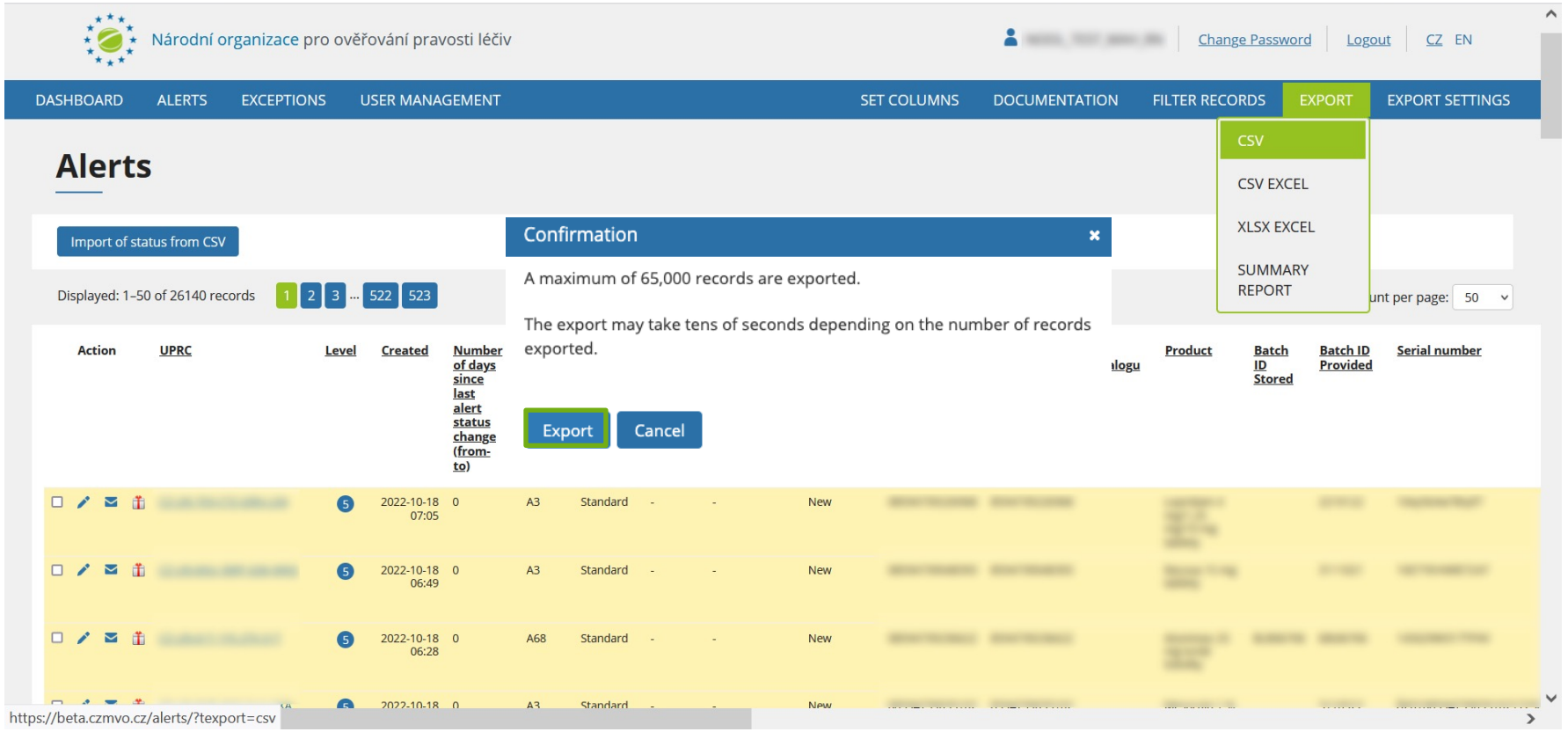


EXPORT ALL ALERTS IN THE SET FILTER

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

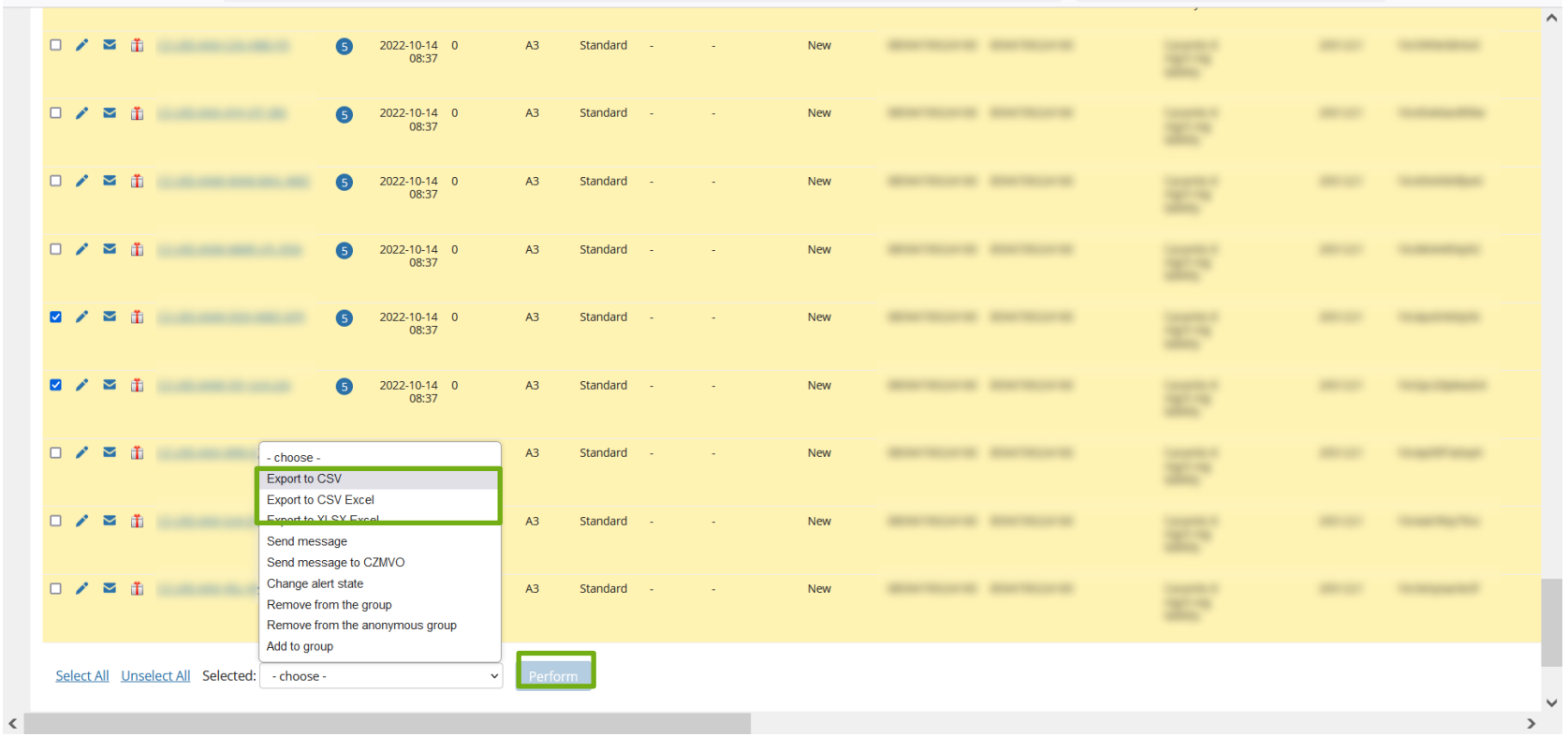


Národní organizace pro ověřování pravosti léčiv

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.



Národní organizace pro ověřování pravosti léčiv

EXCEPTIONS

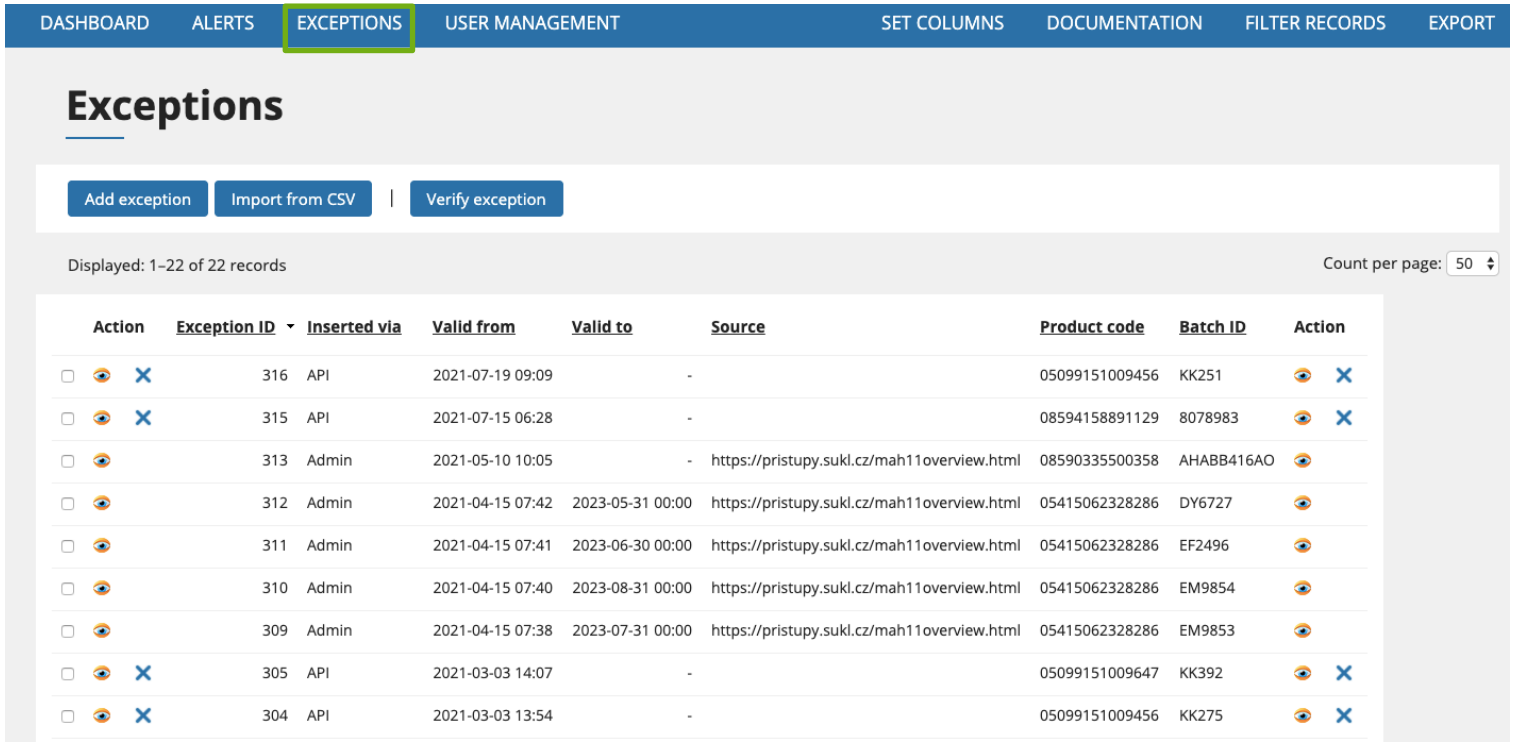
Exceptions granted by Ministry of Health allow for dispensation of defined products even if the verification process fails.

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
	316	API	2021-07-19 09:09	-		05099151009456	KK251	
	315	API	2021-07-15 06:28	-		08594158891129	8078983	
	313	Admin	2021-05-10 10:05	-	https://pristupy.sukl.cz/mah11overview.html	08590335500358	AHABB416AO	
	312	Admin	2021-04-15 07:42	2023-05-31 00:00	https://pristupy.sukl.cz/mah11overview.html	05415062328286	DY6727	
	311	Admin	2021-04-15 07:41	2023-06-30 00:00	https://pristupy.sukl.cz/mah11overview.html	05415062328286	EF2496	
	310	Admin	2021-04-15 07:40	2023-08-31 00:00	https://pristupy.sukl.cz/mah11overview.html	05415062328286	EM9854	
	309	Admin	2021-04-15 07:38	2023-07-31 00:00	https://pristupy.sukl.cz/mah11overview.html	05415062328286	EM9853	
	305	API	2021-03-03 14:07	-		05099151009647	KK392	
	304	API	2021-03-03 13:54	-		05099151009456	KK275	

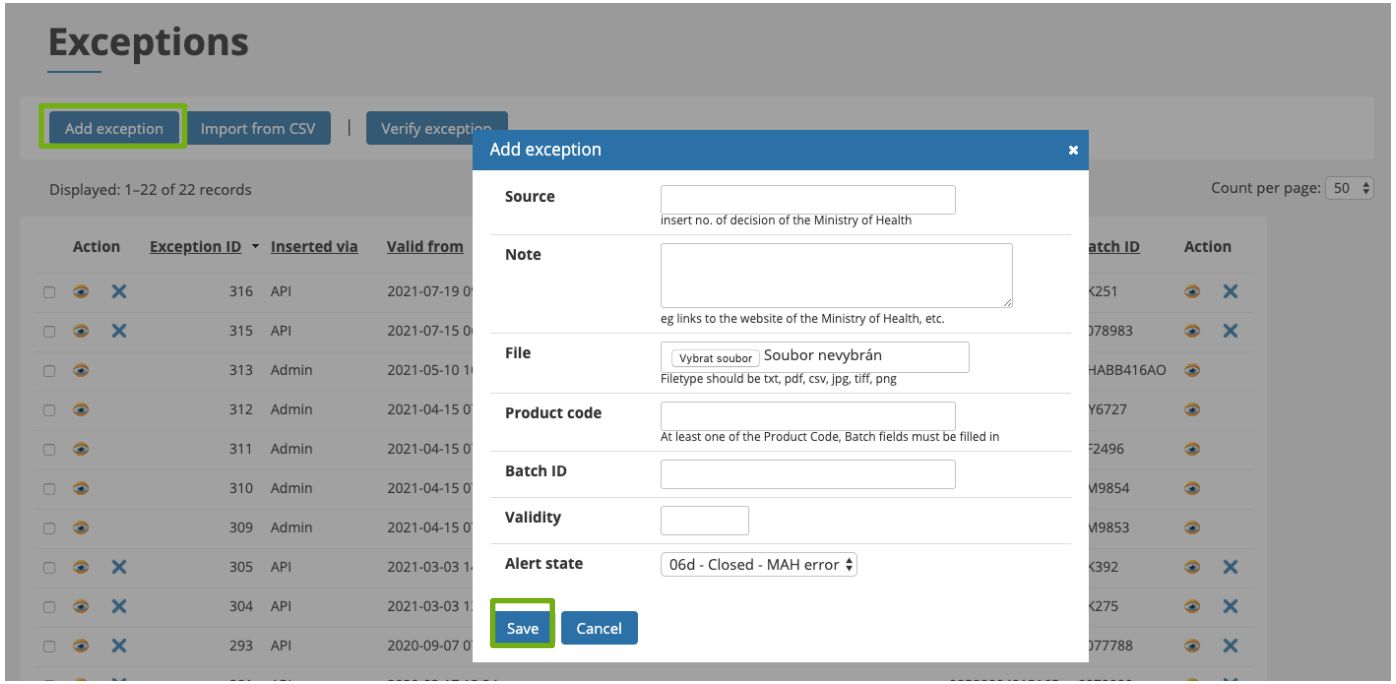
Národní organizace pro ověřování pravosti léčiv

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:

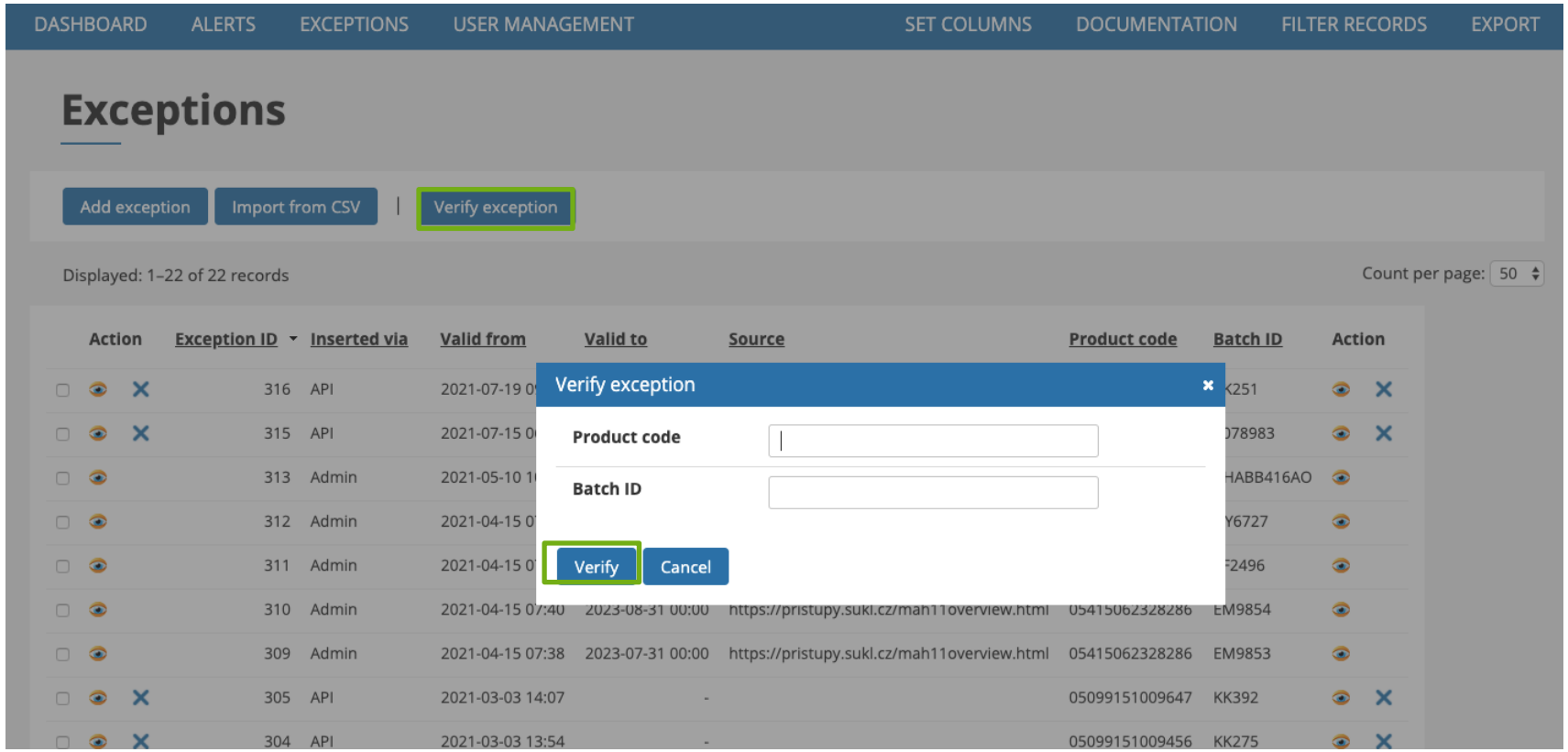
Automatic closing will be applied to new alerts only. Old alerts raised before the exception was added must be closed manually.

Národní organizace pro ověřování pravosti léčiv

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".



Národní organizace pro ověřování pravosti léčiv

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)

Národní organizace pro ověřování pravosti léčiv

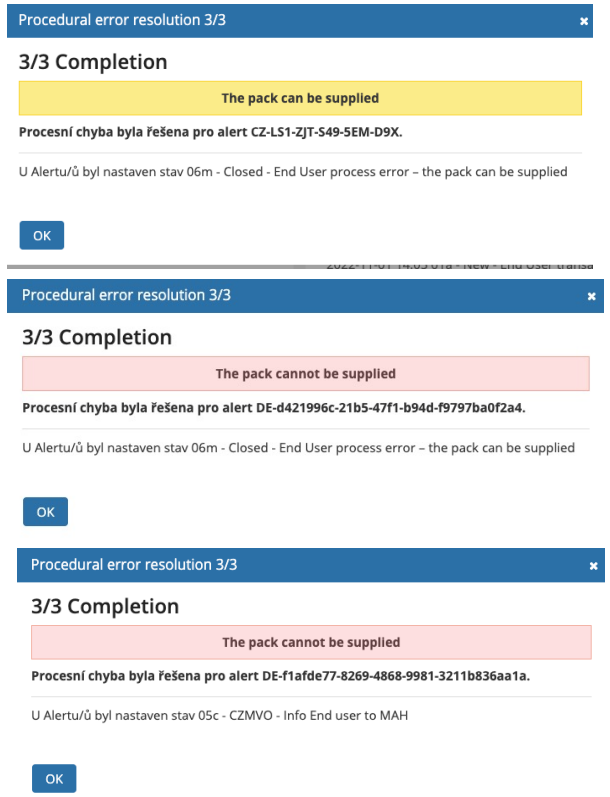
Resolution of end users’ procedural errors via AMS can result in the following outcomes"

1. *„The pack can be supplied* - The alert will be closed to 06m - Closed - End User process error - can be verifiied, 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.

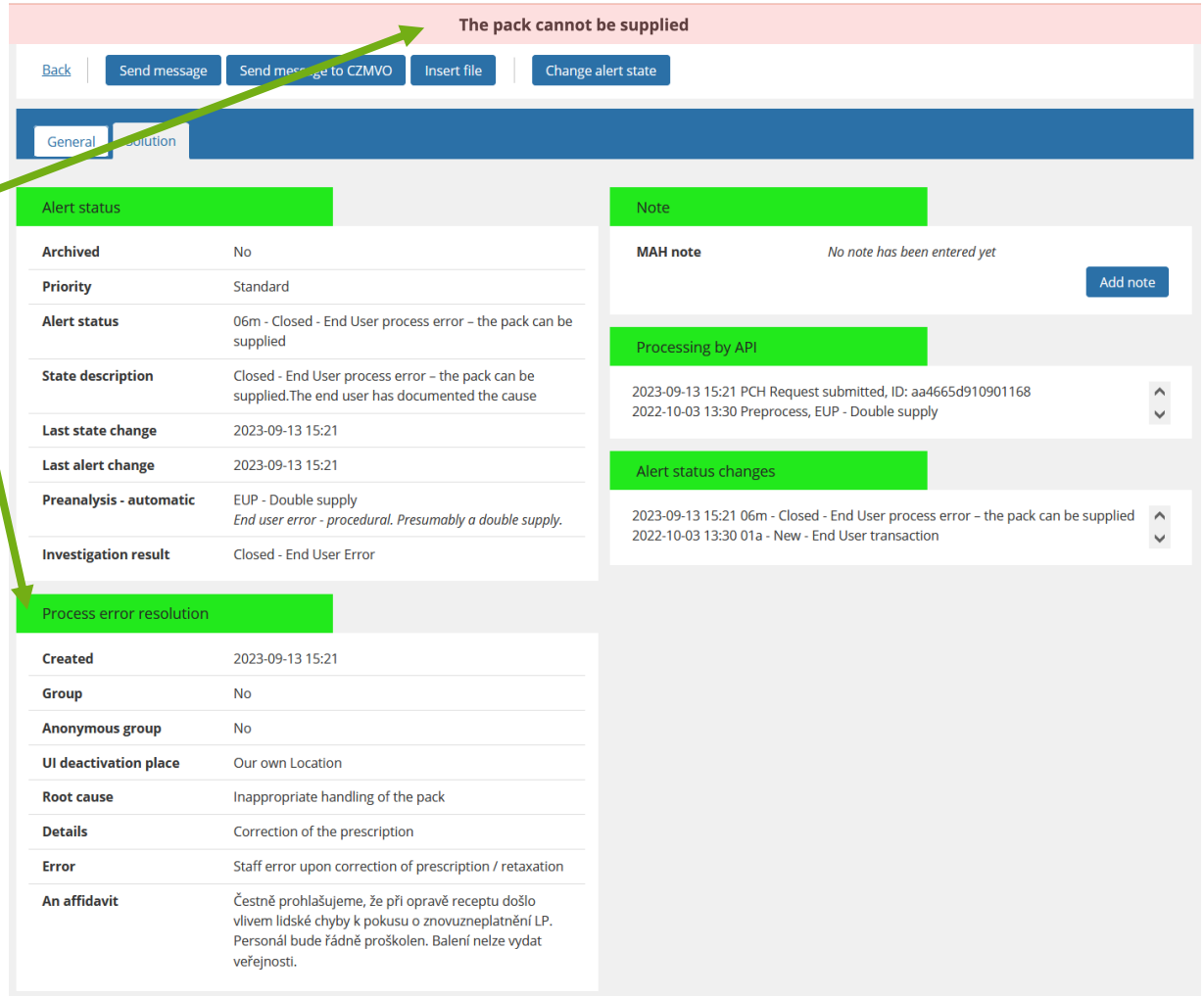
3. *„The pack cnnot be supplied.* The alert will be closed to 05c - CZMVO - Info End user to MAH. The alert is escalated to CZMVO fur further investigation. (This situation occurs whenever the incorrect decommissioning of the unique identifier was carried out at a different location).

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



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



Národní organizace pro ověřování pravosti léčiv

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.

AMS – release 7.0 contains following features:

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

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

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

7. Automatic closing of "A54" alerts

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

8. Pre-investigation of end-user technical errors

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

9. Pre-analysis of error A52:

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

ALERT MANAGEMENT SYSTEM

AMS – release 7.0 contains following features:

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

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

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

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

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

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

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

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

ALERT MANAGEMENT SYSTEM

AMS – release 7.0 contains following features:

13. Improvement of information about changes, news, notifications

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

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

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

14. Alert list change

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

15. Showing options used when handling process errors

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

16. AMS - NOTIFICATION AND ESCALATION

Reworked automatic notification system (notification and escalation)

See page 5 of this manual.

Národní organizace pro ověřování pravosti léčiv

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
EUT - Date	Presumably an incorrect expiration date value provided.	MAH/OBP proceeds to investigate and resolve the alert in cooperation with the end user (either confirms the root cause or identifies a different one) or the alert can be closed directly by the end user using the state 06b - Closed - End User - Technical error. The pack must be verified prior to dispensation.
EUT - Long string in Serial number	Presumably an incorrect scanner setting / long character string in Serial number).	
EUT - Caps Lock	Presumably a keyboard setup error (CapsLock).	
EUT - EN/CZ	Presumably an incorrect keyboard language setting (EN/CZ).	
EUT - Short character string in Serial number	Presumably an incorrect scanner setting / short character string in Serial number).	
EUT - Character mismatch	End user error - technical. Presumably a character mismatch (O/0,E/3,I/L,...) due to a lower quality scanner.	
EUT - Fixed, supplied	According to the audit trail, the pack was subsequently successfully verified and supplied.	The alert was closed automatically based on the pack audit trail. No further action required to be taken by MAH/OBP.
EUT - Duplication in bulk operation	Presumably a duplicate Serial number in bulk transaction.	The MAH/OBP can close the alert using the state 06b - Closed - End User - Technical error

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

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

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

Title	Situation description	Solutions possible– MAH/OBP
EUP - Repeated	A repeated pack state change request. The system cannot determine whether the successful pack state change occurred at the same location, or a different location.	The end user will provide explanation of the alert root cause selecting the appropriate options from the drop-down list in the AMS. The end user will document the case and confirm the affidavit. If the end user does not close the alert within 48 hours from the alert date, it will be opened for MAH/OBP to close it on their side.
EUP - Repeated- This location	A repeated pack state change request that occurred on the same location where the pack state was previously changed successfully.	
EUP – Repeated– Other location	A repeated pack state change request that did not occur at the same location, i.e. the pack state was previously changed successfully at a different location.	
EUP - Unauthorized	An unauthorized pack state change request. The system cannot determine whether the successful pack state change occurred at the same location, or a different location.	
EUP - Unauthorized - This location	An unauthorized pack state change request that occurred on the same location where the pack state was previously changed successfully.	
EUP - Unauthorized - Other location	An unauthorized pack state change request that did not occur at the same location, i.e. the pack state was previously changed successfully at a different location.	

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

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

Title	Situation description	Solutions possible– MAH/OBP
MAH - Batch is not uploaded in CZMVS	MAH/OBP error. Presumably the batch number does not exist in CZMVS (data is missing because the batch is not uploaded).	MAH will check the uploaded data and eventually perform a corrective action. If the error is indeed caused by MAH/OBP, the alert can be closed using the state 06a - Closed - MAH error – Fixed or 06c - Closed - MAH error- Not fixed.
PSUN - MAH	MAH error - PSUN transaction - unrecorded data or uploaded in a wrong version	Alert will be closed automatically in AMS.
EU – N/A	End user transaction, pre-analysis did not determine the cause - suspected MAH error (incorrect or unloaded data, 2D printing error) or counterfeit.	MAH/OBP to check the uploaded data. A possible 2D printing error or a counterfeit.
MAH – Randomization	The serial number does not meet the required randomization criteria.	A54 alert (insufficient randomization of the serial number) has been closed automatically. MAH/OBP should revise the data upload process.
MAH - exception 11r	MAH error - Exception granted by the Ministry of Health as per Act No. 378/2007 Coll., on Pharmaceuticals, article 11r.	MAH/OBP can close the alert using the state „06d - Closed - MAH error - MH exception “. The alert can also be closed by CZMVO in AMS.
NMVS Error - Synchronization issue	NMVS Error - Synchronization issue (PSUN transaction, alert raised outside of CZ).	Alert will be closed automatically in AMS

CONTINUOUS ALERT STATUSES

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

- Type of alert: **all**

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

Incidents A1 and A5 should be investigated in near future

Other statuses 01x, 02x relate to CZMVO investigation

After 30 days report to NCA

CONTINUOUS ALERT STATUSES - II

- Type of alert: **all**

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

Other statuses 04x relate to CZMVO investigation

Národní organizace pro ověřování pravosti léčiv

ESCALATION ALERT STATUSES – END USER TRANSACTIONS

Alert statuses and further resolution process by users

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

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

ESCALATION ALERT STATUSES – MAH TRANSACTIONS

Alert statuses and further resolution process by MAH's

- Type of alert: all

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

Národní organizace pro ověřování pravosti léčiv

CLOSING ALERT STATUSES

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

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

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

Notice: IMT = intermarket transaction

CLOSING ALERT STATUSES

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

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

CLOSING ALERT STATUSES

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

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

Národní organizace pro ověřování pravosti léčiv

CLOSING ALERT STATUSES

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

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

CLOSING ALERT STATUSES

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

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

CLOSING ALERT STATUSES

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

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

CLOSING ALERT STATUSES

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

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

CLOSING ALERT STATUSES

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

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

CLOSING ALERT STATUSES

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

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

CLOSING ALERT STATUSES

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

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

CLOSING ALERT STATUSES

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

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

CLOSING ALERT STATUSES - X

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

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

Národní organizace pro ověřování pravosti léčiv

The list of end users‘ procedural errors

THE LIST OF PROCEDURAL ERRORS

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