



Národní organizace
pro ověřování
pravosti léčiv

CZMVO ALERT MANAGEMENT SYSTEM WEB INTERFACE

User Manual for marketing authorization holders MAH/On-boarding partners OBP
Release 5.0

26th October 2022

INTRODUCTION

Audience

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

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

Prerequisites for using the system

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

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

Terminology*

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

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

Alert management system (AMS) NOOL

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

Alert Level 5

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

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

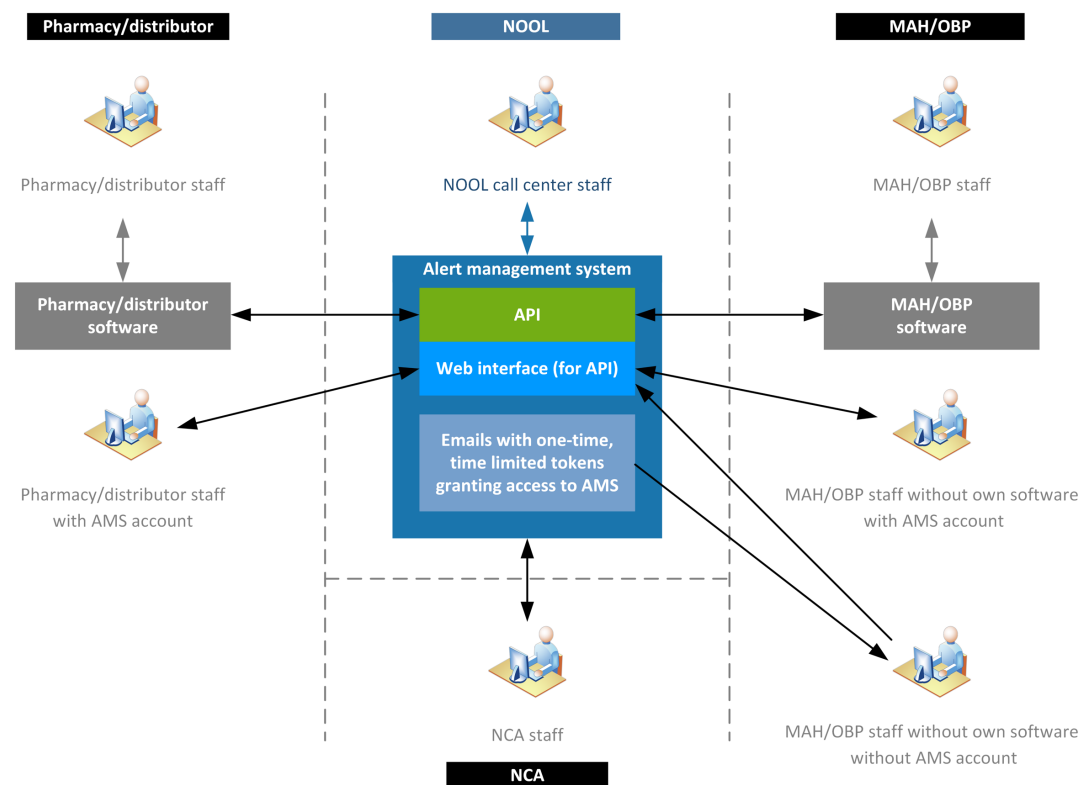
ALERT MANAGEMENT SYSTEM

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

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

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

See: NOOL Alert Management System - one-time_access_MAH_5.0.pdf
- <https://www.czmvo.cz/file.php?id=200>



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PROCESSING TIME & ESCALATION

System notification

System notifications (notifications) are sent to those users who have them set as active in their settings in User Management. Individual types of notifications can be toggled according to the user's needs.

New alert notifications

As soon as an alert occurs, AMS sends a notification to MAH/OBP. The alert contains the basic identification and some other data (e.g., the result of the automatic pre-analysis).

Investigation time

Alert should be investigated and closed **ASAP** within **14***days, which is a set period during which the pack generating the alert will be retained in the pharmacy. After this period, the product will be returned to the distributor (except the alerts caused by an error of an end-user).

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

“Not acting” notification

System sends notification in case that MAH is not acting, i.e. status of the alert has not changed in the past **5 days**.

System sends **2nd notice - warning**, in case MAH/OBP is not acting, i.e. status of the alert has not changed in the past **10 days**.

Warning: After **30 days**, if the alert has still not been investigated, SÚKL (NCA) is informed about „non active MAHs“.

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.

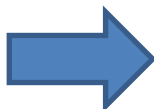
REGISTRATION FOR ACCESS CREDENTIALS

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 env. hence do not influence data in the production environment at all.

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

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

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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NOOL_TEST_KU_LL1 | Change Password | Logout | CZ EN

DASHBOARD | ALERTS | EXCEPTIONS | USER MANAGEMENT | DOCUMENTATION

T&C

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

Provider of the license:

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

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

1. DEFINITION

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

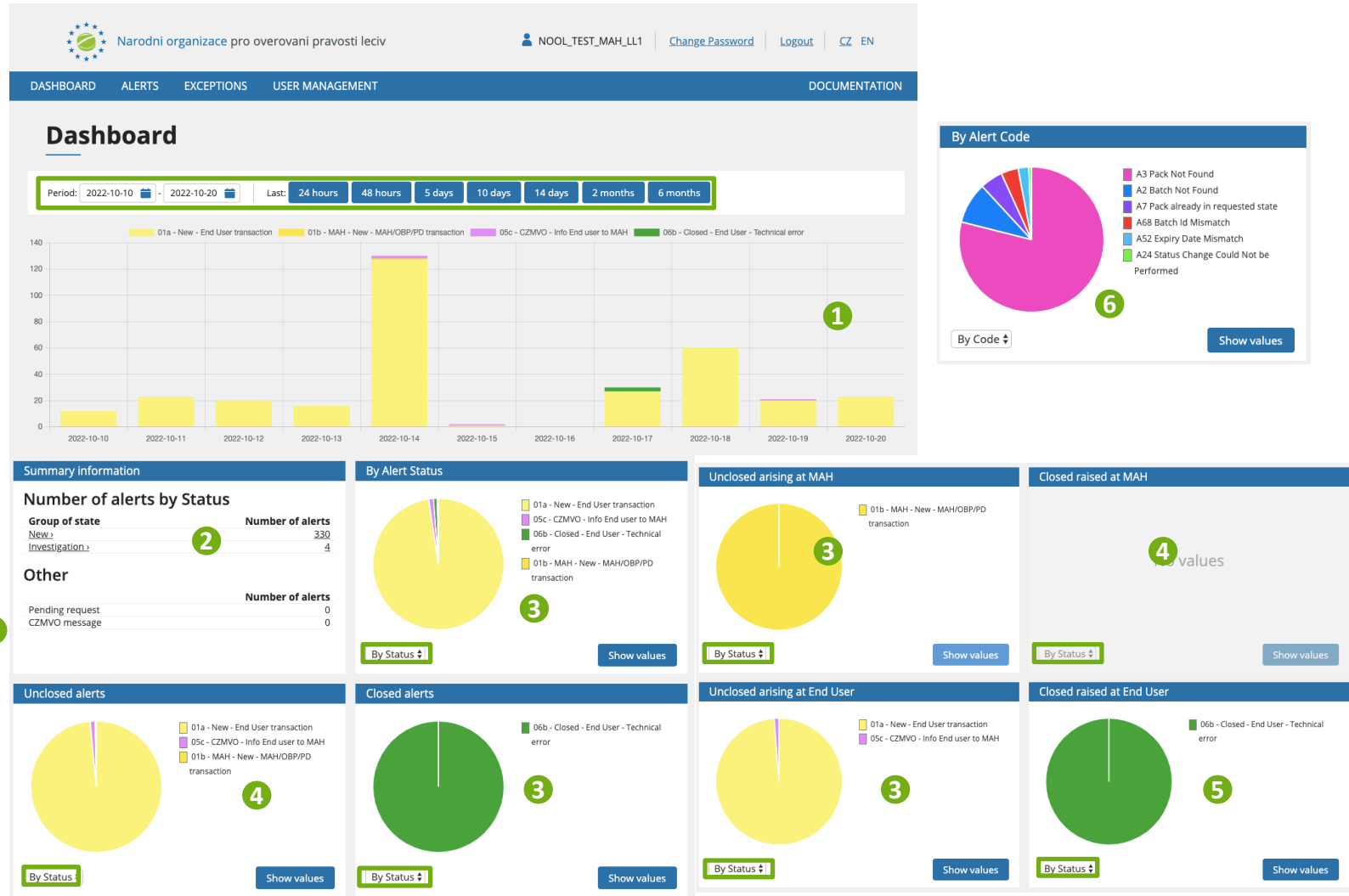
- » **Access** is a set of login data that allows to log into AMS and manage Alerts in AMS.
- » **Alerts** are alerts which arise in the process of authentication of medicinal products as a result of the detection of a potential counterfeit medicinal product or as a result of a procedural or technical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

MAIN SCREEN - DASHBOARD

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

The dashboard comprises:

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



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

MAIN SCREEN – DATE RANGE SELECTION

Dashboard

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

October 2022

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

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

MAIN SCREEN – SUMMARY OVERVIEW

Summary information

Number of alerts by Status

Group of state	Number of alerts
New >	330
Investigation >	4

Other

	Number of alerts
Pending request	0
CZMVO message	0

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
















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

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

Displayed: 1–50 of 330 records

1 2 3 ... 6 7

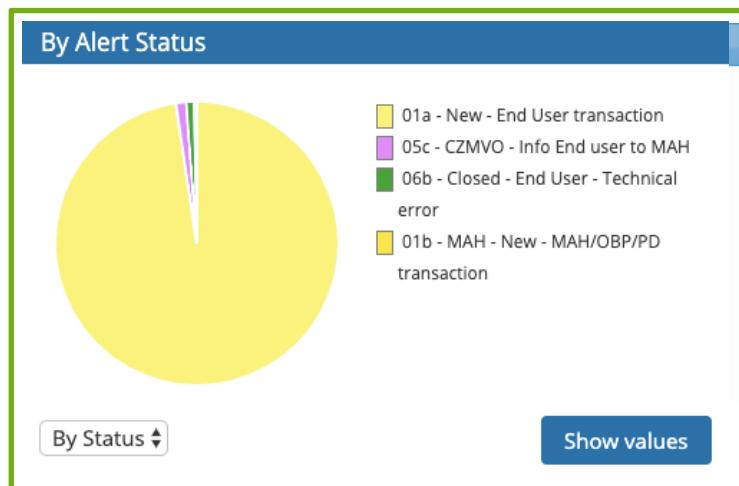
Count per page:

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

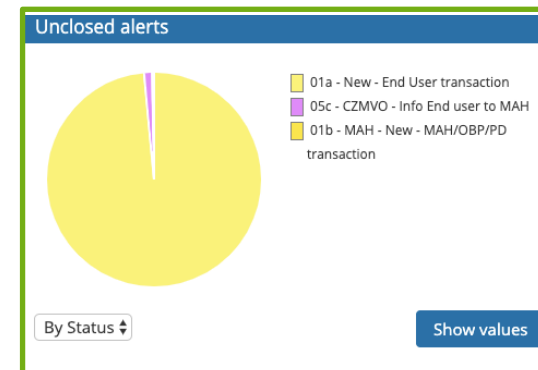
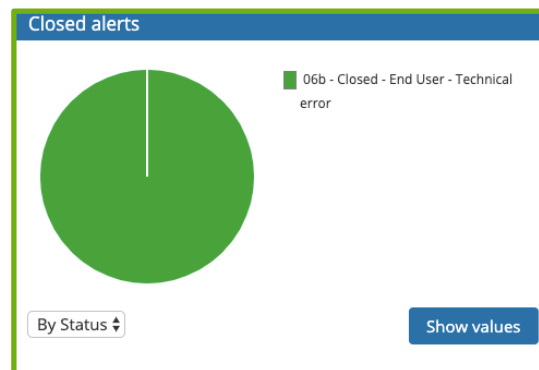


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MAIN SCREEN – DISPLAY ALERT VALUES



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“.



By Alert Status (By Status) ✕

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

Ok

Closed alerts (By Status) ✕

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

Ok

Unclosed alerts (By Status) ✕

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

Ok

USER ADMINISTRATION

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

User roles:

Administrator - Administration of users, complete administration of alerts

User – complete administration of alerts

Viewer – alerts browsing, generating exports

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

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

USER ADMINISTRATION

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

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

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

Národní organizace pro ověřování pravosti léčiv

Change Password | Logout | CZ EN

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

User Management

User management can only be performed in a production environment.

Add User

Displayed: 1-7 of 7 records Count per page: 50

Action	Active	Login	Name	E-mail	Environment	Role	Notification	Action
✎	✓	Test only	Admin	☑	✎
✎	✓	Test only	Admin	☑	✎
✎	✓	Production and testing environment	Admin	☑	✎
✎	✓	Production and testing environment	Admin	☑	✎
✎	✓	Production and testing environment	User	☑	✎
✎	✓	Production and testing environment	User	☑	✎
✎	✓	Production and testing environment	Admin	☑	✎

https://beta.czmvv.cz/users/ vrs Count per page: 50

USER ADMINISTRATION

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

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

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



ADD USER

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

The screenshot shows a web form for adding a user, divided into several sections. The form includes a 'Back' link and 'Save' and 'Apply' buttons at the top. The 'General' section contains fields for 'Active' (checkbox), 'Name', 'Login', and 'E-mail'. The 'Authorization' section includes 'Environment' (dropdown), 'Role' (dropdown), and a 'MAH' section with a checkbox for 'All' and a list of MAHs. The 'Notification' section has an 'Allowed' checkbox, an 'E-mails' text area, and a 'Notification settings' list of checkboxes. Numbered callouts (1-8) are placed over the form to indicate specific steps: 1. Active checkbox; 2. Name field; 3. Login field; 4. E-mail field; 5. Allowed checkbox; 6. E-mails text area; 7. Notification settings list; 8. MAH section.

7. Selecting notifications the user wishes to receive

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

ADD USER

Back | Save | Apply

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

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

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

ADD USER

Back Save Apply

General

Active

Name

Login

E-mail
E-mail for delivery of access data

Authorization

Environment Test only

Role **10** Viewer
User
Admin
All

MAH

Notification

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

E-mails
Each e-mail on its own line

Notification settings

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

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

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

Admin - Complete administration of alerts and users.

User - Complete administration of alerts.

Viewer – alerts browsing , exports

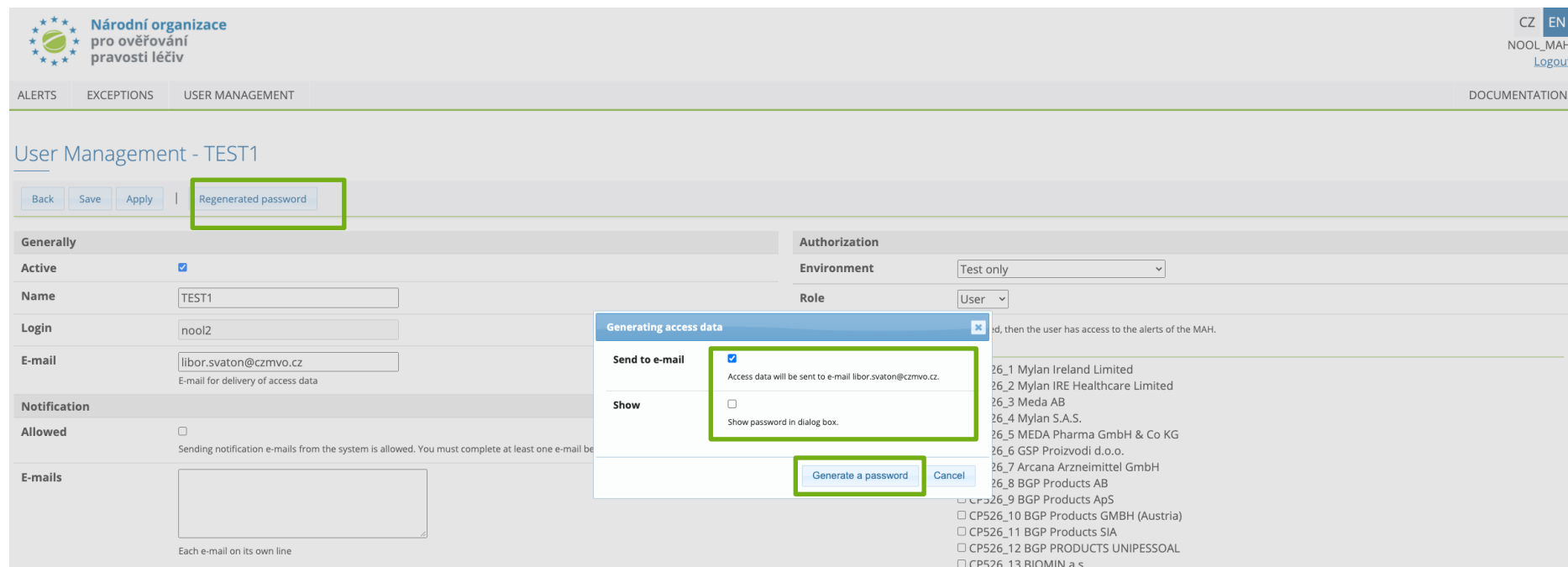
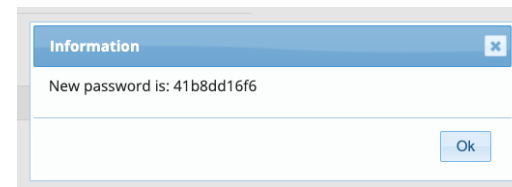
Clicking „Save“ will save your data.

ADD USER

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

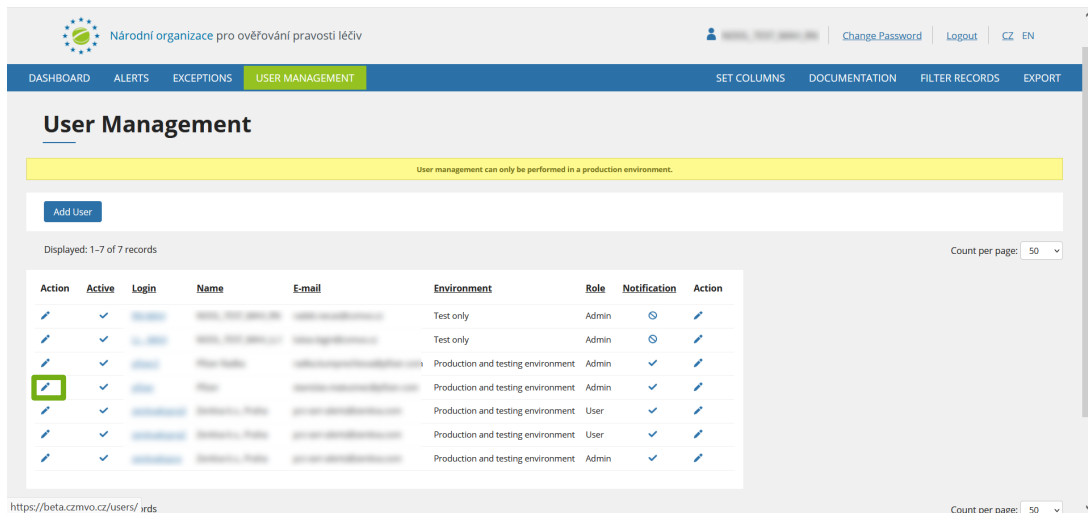
Click „OK“ to confirm.

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

A screenshot of a web application interface for user management. The page title is "User Management - TEST1". There are buttons for "Back", "Save", "Apply", and "Regenerated password" (highlighted with a green box). The "Generally" section shows "Active" checked, "Name" as "TEST1", "Login" as "nool2", and "E-mail" as "libor.svaton@czmvo.cz". The "Authorization" section shows "Environment" as "Test only" and "Role" as "User". A "Generating access data" dialog box is open, with "Send to e-mail" checked and "Show" unchecked. The "Generate a password" button in the dialog is also highlighted with a green box. The background shows a list of pharmaceutical companies with checkboxes.

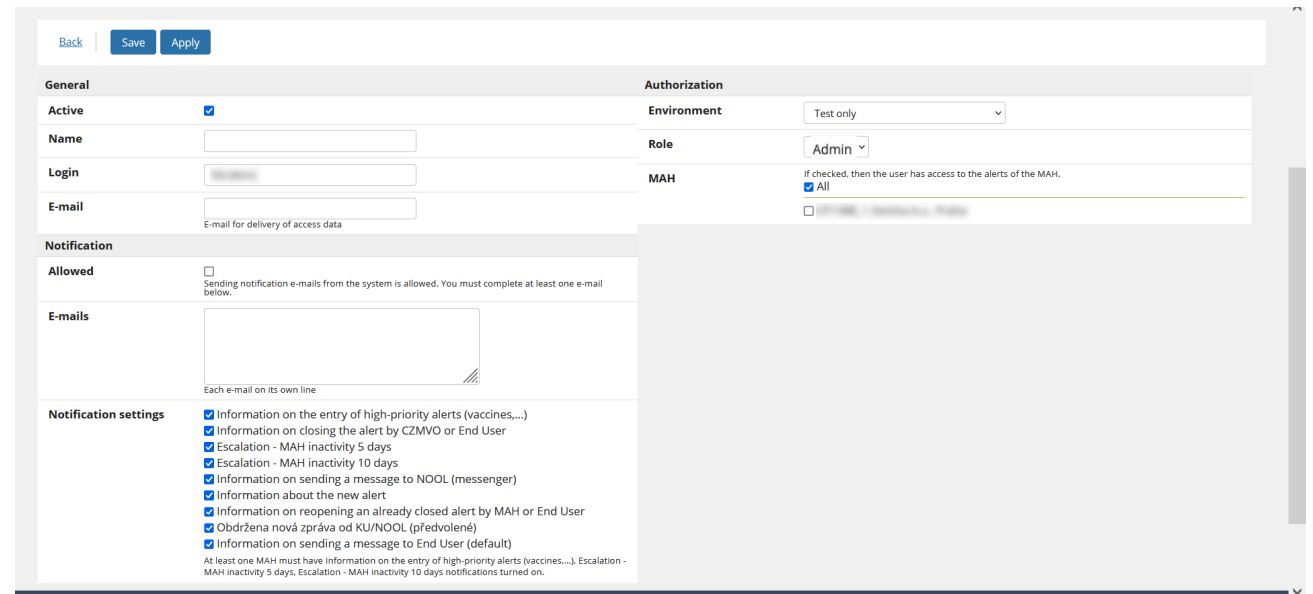
USER UPDATE

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



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

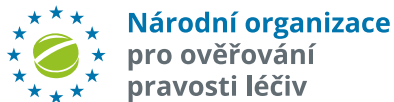
Action	Active	Login	Name	E-mail	Environment	Role	Notification	Action
	<input checked="" type="checkbox"/>	Test only	Admin		
	<input checked="" type="checkbox"/>	Test only	Admin		
	<input checked="" type="checkbox"/>	Production and testing environment	Admin	<input checked="" type="checkbox"/>	
	<input checked="" type="checkbox"/>	Production and testing environment	Admin	<input checked="" type="checkbox"/>	
	<input checked="" type="checkbox"/>	Production and testing environment	User	<input checked="" type="checkbox"/>	
	<input checked="" type="checkbox"/>	Production and testing environment	User	<input checked="" type="checkbox"/>	
	<input checked="" type="checkbox"/>	Production and testing environment	Admin	<input checked="" type="checkbox"/>	



The screenshot shows the user update form. It has a 'Back' button and 'Save' and 'Apply' buttons. The form is divided into several sections: 'General' with fields for 'Active' (checked), 'Name', 'Login', and 'E-mail'; 'Authorization' with fields for 'Environment' (Test only), 'Role' (Admin), and 'MAH' (All); 'Notification' with a checkbox for 'Allowed' and a text area for 'E-mails'; and 'Notification settings' with a list of checkboxes for various notification types. The 'Notification settings' section includes: Information on the entry of high-priority alerts (vaccines,...), Information on closing the alert by CZMVO or End User, Escalation - MAH inactivity 5 days, Escalation - MAH inactivity 10 days, Information on sending a message to NOOL (messenger), Information about the new alert, Information on reopening an already closed alert by MAH or End User, Obdržena nová zpráva od KLU/NOOL (předvolené), and Information on sending a message to End User (default).

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!



MAIN PAGE –ALERTS - CONTROLS

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

The screenshot shows the main interface of the National Organization for Medication Verification (NOOL). At the top, there is a header with the organization's name and logo, a user profile, a 'Change Password' button, a 'Logout' button, and a language selector (CZ/EN). Below the header is a navigation menu with tabs for DASHBOARD, ALERTS, EXCEPTIONS, USER MANAGEMENT, SET COLUMNS, DOCUMENTATION, FILTER RECORDS, EXPORT, and EXPORT SETTINGS. The 'Alerts' section is active, displaying a table of records. A callout '11' points to an 'Import of status from CSV' button. The table has columns for Action, UPRC, Level, Created, Number of days since last alert status change (from-to), Alert code, Priority, Group code, Anonymous group, Group of state, Product code, National Code, Trh katalogu, Product, Batch ID Stored, Batch ID Provided, and Serial number. The table shows four rows of data with yellow background.

11. Import of statuses via a CSV file

Note:

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

MAIN PAGE - CONTROLS

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

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

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

Checkbox	Icons	5	Date/Time	Severity	Priority	Other	Status
<input type="checkbox"/>	[edit, message, gift]	5	2022-10-14 08:37	A3	Standard	-	New
<input type="checkbox"/>	[edit, message, gift]	5	2022-10-14 08:37	A3	Standard	-	New
<input type="checkbox"/>	[edit, message, gift]	5	2022-10-14 08:37	A3	Standard	-	New
<input checked="" type="checkbox"/>	[edit, message, gift]	5	2022-10-14 08:37	A3	Standard	-	New
<input checked="" type="checkbox"/>	[edit, message, gift]	5	2022-10-14 08:37	A3	Standard	-	New
<input type="checkbox"/>	[edit, message, gift]	5	2022-10-14 08:37	A3	Standard	-	New
<input type="checkbox"/>	[edit, message, gift]	5	2022-10-14 08:37	A3	Standard	-	New
<input type="checkbox"/>	[edit, message, gift]	5	2022-10-14 08:37	A3	Standard	-	New

COLUMN SETTINGS

By default all columns are displayed.

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

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

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

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

VIEW ALERT DETAIL

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

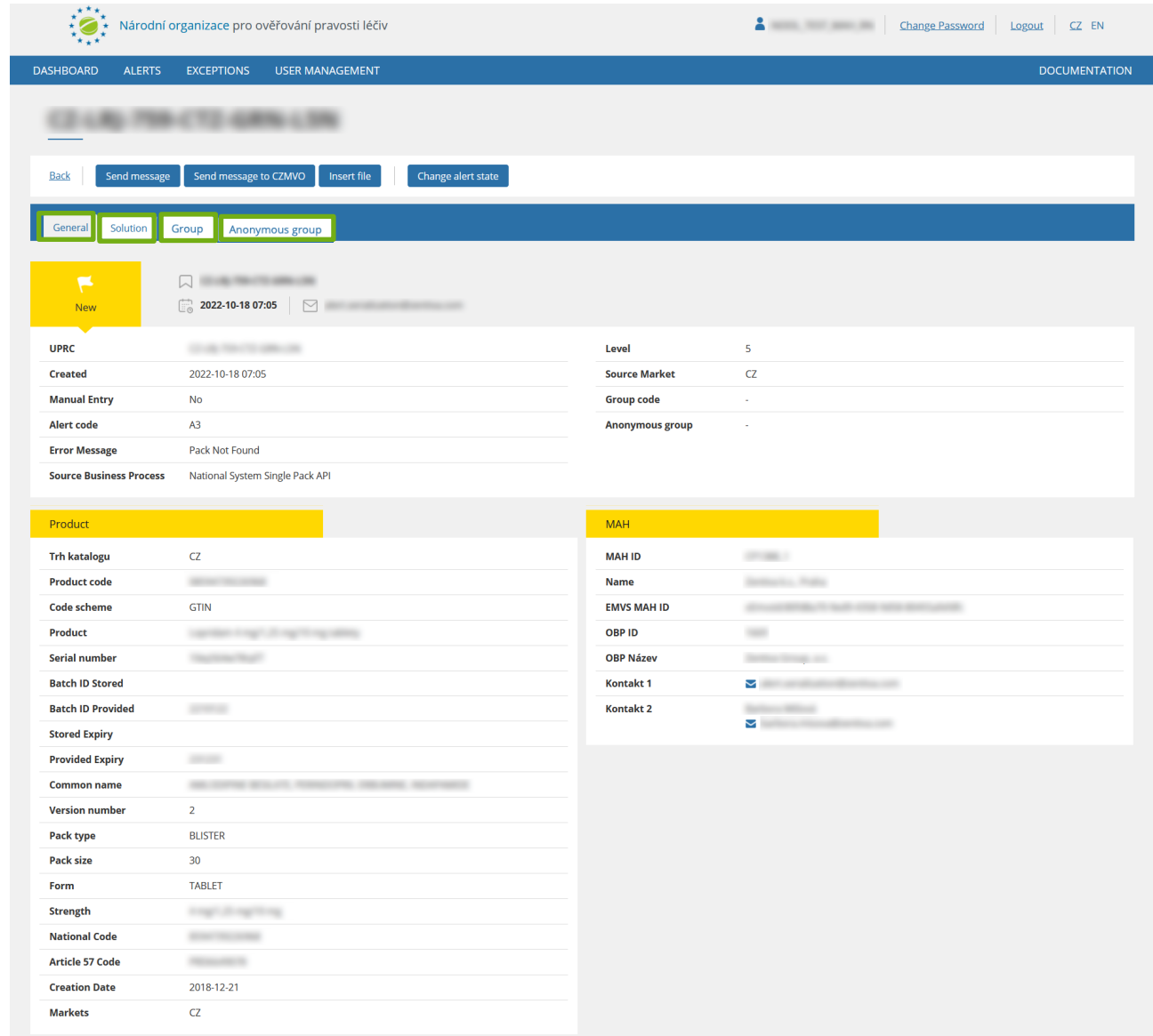
Tab *“General”* shows details about alert such as date of alert, error code, batch ID provided by the user provided or stored in EU-HUB, etc.

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

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

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

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



The screenshot displays the 'VIEW ALERT DETAIL' page of a web application. At the top, there is a header with the logo of the 'Národní organizace pro ověřování pravosti léčiv' and navigation links for 'Change Password', 'Logout', and 'CZ EN'. Below the header is a navigation bar with tabs for 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', 'USER MANAGEMENT', and 'DOCUMENTATION'. The main content area features a breadcrumb trail and a set of action buttons: 'Back', 'Send message', 'Send message to CZMVO', 'Insert file', and 'Change alert state'. A tabbed interface is shown with 'General', 'Solution', 'Group', and 'Anonymous group' tabs. The 'General' tab is active, displaying a 'New' alert card with a date of '2022-10-18 07:05'. Below this, there are two columns of key-value pairs for alert details. The left column includes fields like 'UPRC', 'Created', 'Manual Entry', 'Alert code', 'Error Message', and 'Source Business Process'. The right column includes 'Level', 'Source Market', 'Group code', and 'Anonymous group'. At the bottom, there are two sections: 'Product' and 'MAH', each containing a list of attributes and values.

Product	MAH
Trh katalogu: CZ	MAH ID: [redacted]
Product code: [redacted]	Name: [redacted]
Code scheme: GTIN	EMVS MAH ID: [redacted]
Product: [redacted]	OBP ID: [redacted]
Serial number: [redacted]	OBP Název: [redacted]
Batch ID Stored: [redacted]	Kontakt 1: [redacted]
Batch ID Provided: [redacted]	Kontakt 2: [redacted]
Stored Expiry: [redacted]	
Provided Expiry: [redacted]	
Common name: [redacted]	
Version number: 2	
Pack type: BLISTER	
Pack size: 30	
Form: TABLET	
Strength: [redacted]	
National Code: [redacted]	
Article 57 Code: [redacted]	
Creation Date: 2018-12-21	
Markets: CZ	

CHANGE ALERT STATE *

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

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

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

Important:

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

The screenshot displays the 'Change alert state' dialog box in the AMS application. The dialog is titled 'Change alert state' and features a dropdown menu set to '02a - MAH - Investigatio'. Below the dropdown, there are two checkboxes: 'For the whole group' and 'For the entire anonymous group', both of which are currently unchecked. At the bottom of the dialog are 'Save' and 'Cancel' buttons. The background shows a navigation menu with 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', and 'USER MANAGEMENT'. The main content area shows a table of alerts with columns for 'Created', 'Manual Entry', 'Alert code', 'Error Message', and 'Source Business Process'. A yellow bar at the bottom of the alert list indicates the 'Product' is 'MAH'.

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

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

BULK CHANGE OF ALERT STATUSES

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

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

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



Národní organizace
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Národní organizace pro ověřování pravosti léčiv

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

Alerts

Import of status from CSV

Basic data

UPRC: Level: Created: Priority: Alert code:

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

Details

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

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

Trh katalogu:

Import of status from CSV 1/3

1/3 Insert a file

File

Soubor nevybrán

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

Allowed states

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

Continue

Cancel

BULK CHANGE OF ALERT STATUSES

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

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

Import of status from CSV 2/3

2/3 Checking data before importing

Report

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

Export

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

Continue

Cancel

Import of status from CSV 3/3

3/3 Import finished

Import of alerts status was finished.

10 alerts has been changed.

Finished

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

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

Automatické ukládání

Domů Vložení Kreslení Rozložení

Vložit

Calibri (Základní te...)

B I U

Možná ztráta dat Pokud tento sešit ul...

Aktualizace Office Pokud chcete mít...

A1 UPRC, ID

	A	B
1	UPRC, ID	
2	CZ-LRL-Z1E-ASX-40V-0J0,34	
3	CZ-LRL-YZJ-53E-5H0-PCB,34	
4	CZ-LRL-YXF-DVP-1JV-3KY,34	
5	CZ-LRL-YX3-FG1-WZ1-DR5,34	
6	CZ-LRL-YX0-3E2-K97-D98,34	
7	CZ-LRL-YV6-SPN-UL2-2SB,34	
8	CZ-LRL-YPC-C8G-YD3-SR5,34	
9	CZ-LRL-YNQ-8U4-VB1-EYF,34	
10	CZ-LRL-XRH-FM1-YHP-239,34	
11	CZ-LRL-WYQ-9V2-R15-Q6C,34	



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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 alert@czmvo-alert.cz

Note: For level 3 alerts no UPRC in the form of CZ-XXX-XXX-XXX-XXX-XXX is generated. The exception identifier is a chain of characters composed of the prefix CZ, location ID, and a serial number in an ascending order.

(CZ-ff760bfd-7704-4ddf-b77e-9db0aa2a80a6-000001).

LEVEL 3 ALERTS

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

Národní organizace pro ověřování pravosti léčiv

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

Alerts

Import of status from CSV

Basic data

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

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

Details

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

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

Trh katalogu:

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

Listing is limited by filters: Level: 3

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

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



Národní organizace
pro ověřování
pravosti léčiv

ANONYMOUS COMMUNICATION BETWEEN MAH/OBP AND END USER

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

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

To send a message to the end user click button “*Send message*”. Dialog box will appear. Select type of requirement from the drop-down menu. By “*Select file*” you can add an attachment. Optionally you can assign the request to all alerts in the group by clicking checkbox “*Group*” or „*Anonymous group*“. You can also add an attachment. Clicking „*Send* „will send the message. **Note:** For this type of communication, it is required that both MAH and end user use either Alert management API or web interface. If the answer to the request is not delivered within reasonable time (**48 hours**) “standard” communication via NOOL call center need to be used.



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

The screenshot shows a web browser window with the URL <https://beta.czmvo.cz/alerts/>. The page header includes the logo of the National Organization for Drug Safety (Národní organizace pro ověřování pravosti léčiv) and navigation links for Dashboard, Alerts, Exceptions, User Management, and Documentation. A dialog box is open, allowing the user to send a message. The dialog box contains the following fields:

- Requirement:** A dropdown menu with the selected option "Request_Photo_2D".
- Message text:** A text area containing the message: "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."
- Group:** A checkbox labeled "Get state 04a - MAH - info from End user for all alerts in the group".
- Anonymous group:** A checkbox labeled "Get state 04a - MAH - info from End user for all alerts in the anonymous group".
- File:** A "Browse..." button with the text "No file selected." and a note: "Filetype should be txt, pdf, csv, jpg, tiff, png".
- Buttons:** "Send" and "Cancel" buttons.

The background of the dialog box shows a table with alert details:

UPRC	Created	Manual Entry	Alert code	Error Message	Source Business Process
	2022-10-18 07:05	No	A3	Pack Not Found	National System Single Pack API

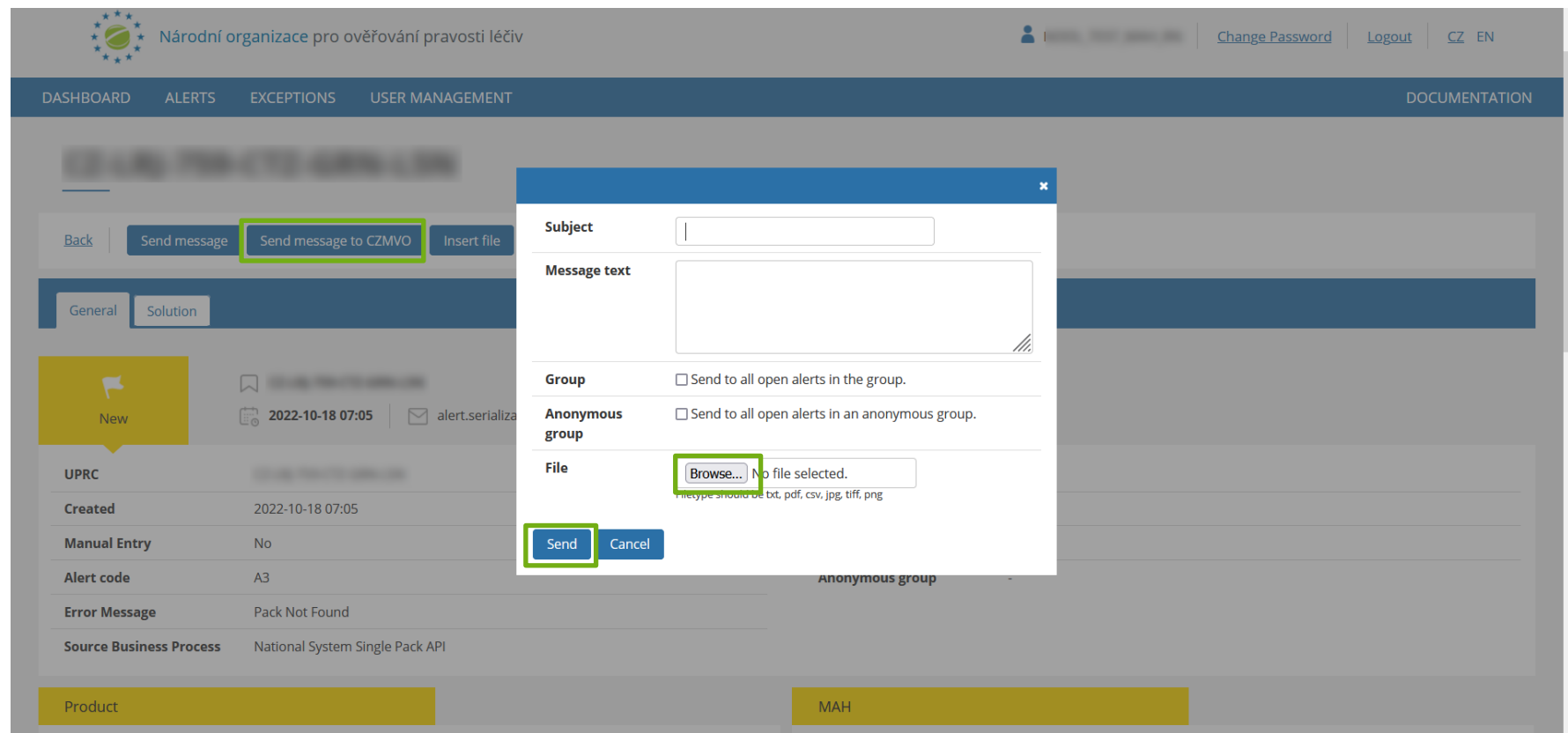
COMMUNICATION BETWEEN CZMVO AND USERS

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.



The screenshot displays the web interface of the National Organization for the Verification of Drug Authenticity (Národní organizace pro ověřování pravosti léčiv). The main navigation bar includes 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', 'USER MANAGEMENT', and 'DOCUMENTATION'. A user profile is visible in the top right corner with options for 'Change Password', 'Logout', and language selection ('CZ', 'EN').

The central area shows an alert resolution process. A 'New' button is present, along with an alert entry for '2022-10-18 07:05' with the message 'alert.serializa'. Below this, a table lists details for the alert:

UPRC	Created
	2022-10-18 07:05
Manual Entry	No
Alert code	A3
Error Message	Pack Not Found
Source Business Process	National System Single Pack API

At the bottom, there are fields for 'Product' and 'MAH'. A dialog box is open over the interface, titled 'Send message to CZMVO'. It contains the following fields and options:

- Subject:** A text input field.
- Message text:** A large text area for the message content.
- Group:** A checkbox labeled 'Send to all open alerts in the group.'
- Anonymous group:** A checkbox labeled 'Send to all open alerts in an anonymous group.'
- File:** A 'Browse...' button next to a text field that says 'No file selected.' Below this, a note specifies 'file type should be: txt, pdf, csv, jpg, tiff, png'.
- Buttons:** 'Send' and 'Cancel' buttons at the bottom of the dialog.

COMMUNICATION – PREDEFINED MESSAGES

List of predefined MAH/OBP messages:

Notice:

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

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

List of predefined end user messages:

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



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

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

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

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

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

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

The screenshot shows a web application interface with a navigation bar at the top containing tabs: DASHBOARD, ALERTS, EXCEPTIONS, USER MANAGEMENT, SET COLUMNS, DOCUMENTATION, FILTER RECORDS (highlighted), EXPORT, and EXPORT SETTINGS. Below the navigation bar is a filter section with several input fields and dropdown menus: Serial number, Date of expiration, Source Business Process (set to - all -), Manual Entry (set to - all -), Source Market (set to - all -), Trh katalogu (set to - all -), Alert state (set to - all -), Group code, Anonymous group, Number of days since last alert status change (with from and within fields), Archived (set to - all -), Closed (set to - all -), Preanalysis - automatic (set to - all -), CZMVO message (set to - all -), Number of days since CZMVO message (with from and within fields), Pending request (dropdown menu open showing options: - all -, Yes, MAH by End User, MAH by CZMVO, CZMVO by End User, No), MAH ID, and MAH name. A blue Filter button is located below the filter section. Below the filter section, it says "Displayed: 1-50 of 26153 records" and "Count per page: 50". At the bottom, there is a table header with columns: Action, UPRC, Level, Created, Number of days since last alert status change (from-), Alert code, Priority, Group code, Anonymous group, Group of state, Product code, National Code, Trh katalogu, Product, Batch ID Stored, Batch ID Provided, and Serial number.

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

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

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

Alerts

Import of status from CSV

Basic data

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

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

Details

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

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

Trh katalogu:

Investigation

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

Closed: Preanalysis - automatic:

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

EMVS MAH ID: OBP ID: OBP Název:

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

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



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VIEW GROUP OF ALERTS

Grouping alerts

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

There are two types of groups in the system:

GROUP

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

ANONYMOUS GROUP

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

Investigation

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

Closed: Preanalysis - automatic:

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

EMVS MAH ID: OBP ID: OBP Název:

Displayed: 1-50 of 26140 records ... 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	Trh katalogu	Product	Batch ID Stored	Batch ID Provided	Serial number
<input type="checkbox"/>					5	2022-10-18 07:05	0	A3	Standard	88659	89234	New				
<input type="checkbox"/>					5	2022-10-18 06:49	0	A3	Standard	-	-	New				

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

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

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

REMOVE ALERTS FROM GROUP

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

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

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

Groups/anonymous groups allow:

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

The screenshot displays a table of alerts with the following columns: checkboxes, icons, ID (5), date (2022-10-14 08:37), severity (A3), priority (Standard), and status (New). A context menu is open over one row, listing actions such as 'Export to CSV', 'Send message', and 'Remove from the group'. The 'Remove from the group' option is highlighted with a green box. Below the table, there are 'Select All', 'Unselect All', and 'Selected:' labels, and a 'Perform' button is highlighted with a green box.



REPORTS - SUMMARY EXPORT

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

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

Available formats are CSV, CSV Excel and XLSX Excel.

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

Example of the summary report for the desired period:

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

The screenshot shows the web interface of the National Organization for Drug Verification (Národní organizace pro ověřování pravosti léčiv). The main navigation bar includes Dashboard, Alerts, Exceptions, User Management, Set Columns, Documentation, Filter Records, Export, and Export Settings. The 'Alerts' page is active, displaying a table of records. A modal window titled 'Summary report' is open, showing the following configuration:

- Report: for the period
- Period: within 24 hours
- Report format: CSV

The modal also features 'Report' and 'Cancel' buttons. The background table shows columns for Action, UPRC, Level, Created, Number of days since last alert status change (from-to), Alert code, Priority, Group code, Anonymous group, Group of state, Product code, National Code, Trh katalogu, Product, Batch ID Stored, Batch ID Provided, and Serial number.

EXPORT ALL ALERTS IN THE SET FILTER

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

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

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

The screenshot shows the web interface of the National Organization for Medication Verification. The top navigation bar includes 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', 'USER MANAGEMENT', 'SET COLUMNS', 'DOCUMENTATION', 'FILTER RECORDS', 'EXPORT', and 'EXPORT SETTINGS'. The 'EXPORT' menu is open, showing options: 'CSV', 'CSV EXCEL', 'XLSX EXCEL', 'SUMMARY REPORT', and 'REPORT'. A 'Confirmation' dialog box is displayed, stating: 'A maximum of 65,000 records are exported. The export may take tens of seconds depending on the number of records exported.' Below the dialog, there are 'Export' and 'Cancel' buttons. The main content area shows a table of alerts with columns: Action, UPRC, Level, Created, Number of days since last alert status change (from-to), Status, Severity, Priority, and Type. The table is currently displaying 1-50 of 26140 records.

Action	UPRC	Level	Created	Number of days since last alert status change (from-to)	Status	Severity	Priority	Type
<input type="checkbox"/>		5	2022-10-18 07:05	0	A3	Standard	-	New
<input type="checkbox"/>		5	2022-10-18 06:49	0	A3	Standard	-	New
<input type="checkbox"/>		5	2022-10-18 06:28	0	A68	Standard	-	New
<input type="checkbox"/>		5	2022-10-18 06:28	0	A3	Standard	-	New

EXPORT SELECTED ALERTS

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

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

The screenshot displays a table of alerts with columns for selection, actions, ID, date, time, priority, severity, status, and type. Two alerts are selected, indicated by blue checkmarks in the first column. A context menu is open over the selected alerts, listing various actions. The 'Export to CSV' option is highlighted with a green box. At the bottom of the interface, there are buttons for 'Select All', 'Unselect All', a 'Selected:' dropdown menu, and a 'Perform' button, which is also highlighted with a green box.

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

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

Select All Unselect All Selected: - choose - Perform

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.

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

Exceptions

Add exception Import from CSV | Verify exception

Displayed: 1–22 of 22 records Count per page: 50

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

ADD EXCEPTION

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

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

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

Note:

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

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

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

At the bottom of the dialog are 'Save' (highlighted with a green box) and 'Cancel' buttons. The background table shows a list of exceptions with columns for 'Action', 'Exception ID', 'Inserted via', and 'Valid from'.

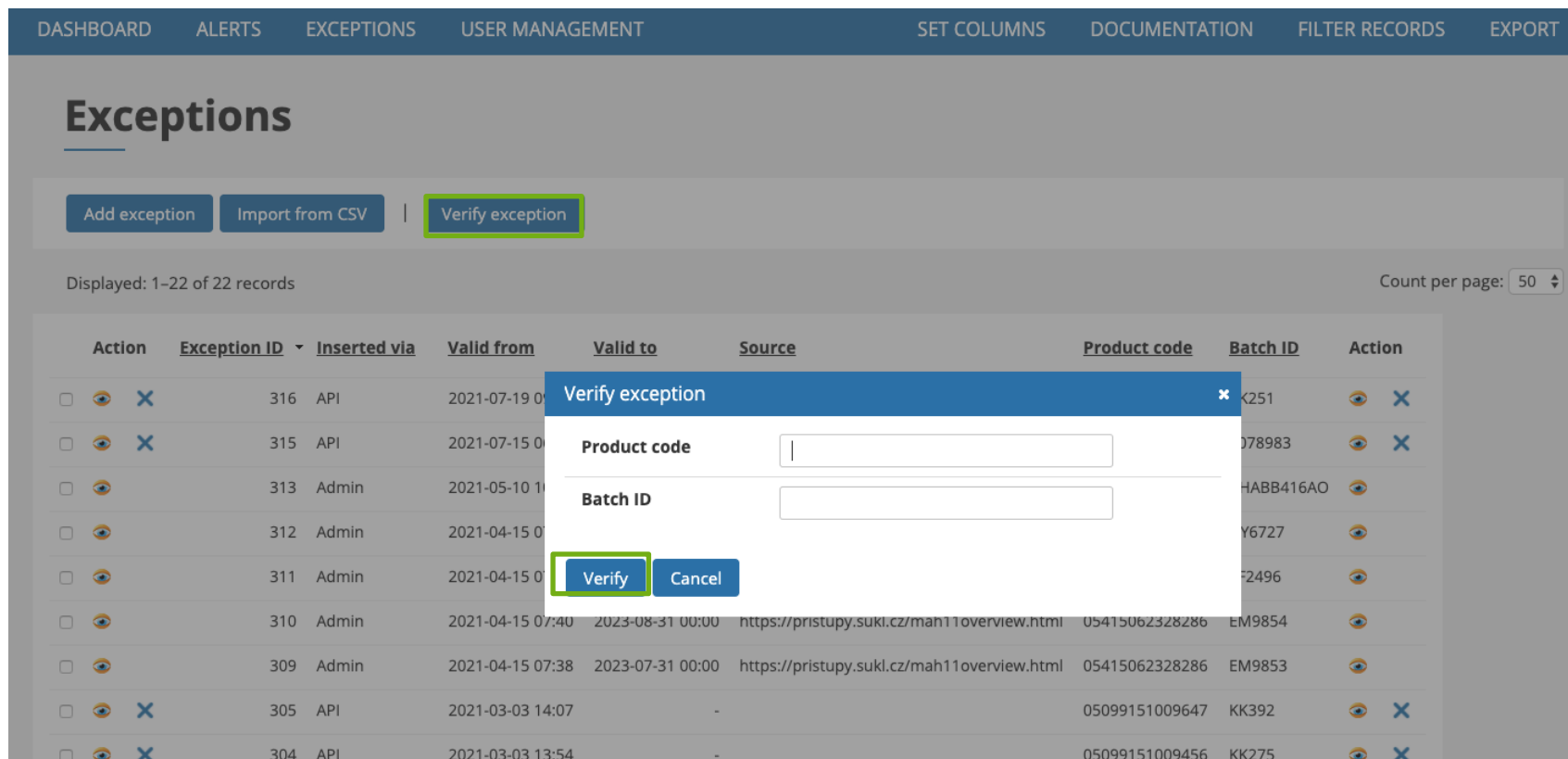


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VERIFY PRODUCT FOR THE EXCEPTION

Products can be verified if there is an exception applicable.

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



The screenshot displays a web application interface for managing exceptions. The top navigation bar includes links for DASHBOARD, ALERTS, EXCEPTIONS, USER MANAGEMENT, SET COLUMNS, DOCUMENTATION, FILTER RECORDS, and EXPORT. The main heading is 'Exceptions'. Below the heading are three buttons: 'Add exception', 'Import from CSV', and 'Verify exception' (highlighted with a green box). The interface shows a table of 22 records, with the first few visible. A modal dialog box titled 'Verify exception' is open, containing two input fields: 'Product code' and 'Batch ID'. Below the input fields are two buttons: 'Verify' (highlighted with a green box) and 'Cancel'. The table columns are: Action, Exception ID, Inserted via, Valid from, Valid to, Source, Product code, Batch ID, and Action.

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



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END USERS' PROCEDURAL ERRORS

- The new version of 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 **9 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 a declaration submitted as per **conditions stipulated by SÚKL (NCA)**, they may close the corresponding alert even if already closed as „06f - Closed - End User process error - cannot be dispensed“, and subsequently set the alert to the state „06m - Closed - End User process error - can be supplied“.

END USERS' PROCEDURAL ERRORS

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

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

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



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

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



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



New functionalities and updates
in AMS Release 5.0



ALERT MANAGEMENT SYSTEM

AMS – release 5.0 new functionalities and updates:

1.EVIDENCE AND INVESTIGATION OF LEVEL 3 EXCEPTIONS

Level 3 alerts are newly loaded from Exceptions report to AMS.

A new field “Level” (number values 1-5) was created. A filter was added for this field.

Note: “Alert Level” =5 has been allocated to all existing alerts (both active and archived).This does not involve alerts that have been removed from the AMS.

CONSENT TO DELEGATE ADMINISTRATION OF ALERTS ON BEHALF OF AN MAH

Upon creation of an account for a new MAH/OBP, a new query related to administration of alerts will appear in the web form. Note: The existing users will not be prompted to give any consent since administration of their alerts is already being carried out based on previous e-mail communication and agreement between CZMVO and MAH/OBP.

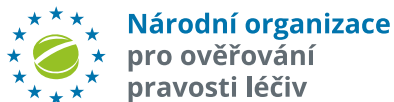
DASHBOARD

A new option in the main menu: „**Dashboard**“, this page also serves as the „Main page“ after logging to AMS. The dashboard comprises:

A flow chart of alerts raised in the selected date range.

Available intervals: 24 hours, 48 hours, 5, 10, 14 days, 2, 6 months, and „from - to“ option

Information window (all roles):



„Count of alerts“ - „New“, „Investigation“, „Escalation“

„Count of alerts“ - „Pending request“

„Count of alerts“ - „CZMVO message“

ALERT MANAGEMENT SYSTEM

2. THE OPTION TO LIMIT END USER'S ACCESS TO AMS FOR INDIVIDUAL LOCATION/S

The objective is to give the option, for pharmacy chains in particular, to limit access to alerts for users of the corresponding location only, or a group of locations.

The Users administration will newly display an overview of all locations that belong to the respective Organization.

By default, all locations will be checked. The user with admin rights may, on creation of or editing a user account, check locations to which he wishes to grant access for the respective user.

3. PROCEDURAL ERRORS

The new version of 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 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 pack to public

ALERT MANAGEMENT SYSTEM

4. WORKFLOW MODIFICATION

Several improvements have been made to the AMS workflow, especially from the perspective of logical connections (eg. alert states applicable for end user transactions cannot be set for MAH transactions and vice versa, etc.)

5. PRE-INVESTIGATION MODIFICATION

Repeated running of the alert „Pre-investigation“.

Any and all pre-investigation is evaluated upon alert creation and the system will not record any change that occurs later. For this reason an automatic refresh was incorporated so as to consider some selected entries -this only involves unresolved alerts at the time of refresh (e.g. Exception, the user is in AMS, successful dispensation of the MP after a repeated verification, etc.) Currently a repeated check of a selected data is set to occur 4x in 24 hours.

CZMVS ERROR INDICATION MODIFICATION.

MAH errors (data not uploaded or uploaded with the wrong version) and transaction NMVS error (the pack state change did not occur in all repositories) are differentiated.

Modification of groups

Source transaction type” added (MAH or end user transaction) as another criteria in creation of Groups. The objective is to improve creation of Groups and thus provide for a convenient work with groups of alerts.

ALERT MANAGEMENT SYSTEM

6. „MINOR“ MODIFICATIONS

The overall appearance of the AMS has been modernized including colorization of aggregated alert states for a better orientation.

Communication logs have been made more transparent (the latest is always on top) the entries are in a single language according to the current language setting

There is also an indication that a filter is applied to the current overview of alerts. There is a new date filter for Alert state (e.g. all alerts that set to 04f state on 1.10.2022, etc.)

„MINOR“ FUNCTIONAL CHANGES

A NEW OPTION TO SEND PRESET MESSAGES OR SEND MESSAGES TO A LIMITED NUMBER OF FILTERED ALERTS

It is now possible to create your own limited (max 100 entries) list of alerts (e.g. with selected fields) and include them in a list for sending preset messages or a bulk state change or send a message via Messenger.

STATE CHANGE AND MESSAGES FOR A GROUP OF ALERTS - INFORMATION THAT A STATE CHANGE OR A MESSAGE FAILED

If a group contains an alert whose state cannot be changed due to the process workflow, an error message will pop up informing that “The request cannot be performed, the group contains an alert or more alerts whose state cannot be changed due to the current state.

ALERT MANAGEMENT SYSTEM

Product name field was added to notification e-mails for MAH an End user. The product name will be displayed if available.

THE LIST OF ALERT STATES MODIFICATION

The list of alerts is expanded based on requests by SW companies. There are new fields “State type” and “state type description” with indication for the end user as to how the pack should be handled.

Example: “Do not take any action”, “Verify 2D code and return to stock” “Remove from communication and return to stock” Additional information from the end user required”, etc.



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.

PRE-ANALYSES NOOL – INFORMATION TO NEW ALERTS

After alerts pre-analyses NOOL provides information to alert supporting further investigation and offers probable causes of alerts in AMS

➤ Type of alert: all

Name	Situation description to pre-analysed alerts	Next steps in alerts investigation – MAH
Operation MAH/OBP	Indication based on system transaction - origin of the alert by MAH, before medicines pack was distributed to end-user.	MAH/OBP continues investigation and closing the alert without need to involve end-user.
IMT operation	Alert occurred on a different market (data in the NMVS system) than where pack was verified. Indicated if CZ is „initiating“ or „fulfilling“ market.	MAH/OBP continues investigation of alerts marked as „initiating market“ according to common processes. Alerts „fulfilling market“ are in AMS NOOL closed automatically (these should be investigated and closed in the system of “initiating market”).
MAH - Exception ZOL 11r	MAH issue with data or print that cannot be corrected – covered by exception ZOL 11r	MAH/OBP can close alert as “06d - Closed - Exception ZOL par 11r “, alerts with exception can be closed by AMS NOOL
EUT - Caps Lock	Probable cause of alert analysed - end-user error – technical. Suspicion of untreated mistake of keyboard (Caps Lock).	MAH/OBP continues investigation and closing the alert in cooperation with end-user (confirmation of alert cause or identification of different alert cause); alert can also be investigated and closed directly by End-user as "6b - Closed – End-user technical error” and verify UI of the pack again before pack is released from quarantine and supplied to patient.
EUT – long string in SN	Probable cause of alert analysed - end-user error – technical . Suspicion of inaccurate set up of scanner (long string in SN).	
EUT - EN/CZ	Probable cause of alert analysed - end-user error – technical . Suspicion of untreated mistake of keyboard (EN/CZ).	

Notice: EU = end-user

EUT = end-user technical error

PRE-ANALYSES NOOL – INFORMATION TO NEW ALERTS - II

After alerts pre-analyses NOOL provides information to alert supporting further investigation and offers probable causes of alerts in AMS

➤ Type of alert: all

Name	Situation description to pre-analysed alerts	Next steps in alerts investigation – MAH
EUT – short string in SN	Probable cause of alert analysed - end-user error – technical. Suspicion of inaccurate set up o of scanner (short string in SN).	MAH/OBP continues investigation and closing the alert in cooperation with end-user (confirmation of alert cause or identification of different alert cause); alert can also be investigated and closed directly by End-user as "6b - Closed – End-user technical error" and verify UI of the pack again before pack is released from quarantine and supplied to patient.
EUT – commutation of characters	Probable cause of alert analysed - end-user error – technical. Suspicion of low quality of scanner (characters commutation O/0,E/3,I/L,...)	
EUP – repeated supply	Probable cause of alert analysed - end-user error – procedural. Probable repeated (double) supply	MAH/OBP continues investigation and closing the alert in cooperation with end-user (confirmation of alert cause or identification of different alert cause) 06f – Closed - Procedural error EU – supply not allowed.
MAH – batch not uploaded	MAH – data not uploaded	MAH/OBP continues investigation and closing the alert.
CZMVS - alerts from 2020	Alerts z roku 2020 + A3 nebo A7 nebo A52 - lze řešit MAHem zrychleně bez zapojení koncového uživatele.	MAH/OBP investigates and closes the alert without need to involve end-user (agreed with NCA). Alert is marked in AMS NOOL for easy identification of these alert with specific investigation and closing.
CZMVS - PSUN	CZMVS NSOL – error in synchronization between markets (PSUN transaction, alert occurred outside of CZ).	Alert is automatically closed in AMS NOOL.

Notice: EUP = end-user procedural error

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-mail 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-mail 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 05e KU – End user - Info - A1, A5	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

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	<ul style="list-style-type: none"> • 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. 	<p>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).</p>	<p>Once MAH/OBP uploaded and/or corrected data (batch etc.) into EMVS/CZMVS and closed alert with relevant status, end-user can verify and decommission pack again and release from quarantine to patient.</p>

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	<ul style="list-style-type: none"> • 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. 	<p>End–user should correct the cause of alert according to what caused it:</p> <ul style="list-style-type: none"> • 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. <p>Use “control scan”, if possible, to verify proper scanner set up and after that go back to medicinal pack with alert.</p> <p>End-user can than again verify pack and if decommission is successful pack can be release from quarantine and provided to patient.</p>	<p>MAH/OBP started investigation immediately, in parallel with end-user. Once the cause of end-user is identified, it can be corrected by end-user only. MAH/OBP can, however close alert as end-user error es well, if MAH/OBP can prove based on info identified, technical error was caused by end-user.</p>

CLOSING ALERT STATUSES

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

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06c Closed - MAH error - Not corrected	<ul style="list-style-type: none"> • 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“). 	<p>Keep medicinal pack in quarantine until the end of alert investigation. Wait for closing the alert by MAH/OBP or provide additional information based on request.</p> <p>Once alert is closed, provided info from AMS: MAH / OBP error. Unable to correct - cannot be re-verified. Return the packaging to the supplier with alert ID identification.</p> <p>End user should return pack back to distribution (wholesaler) according to return process set up in end-user organisation.</p>	<p>After investigation with OBP – data correction or correct upload of the data or correction of wrong print on the pack is not possible. Data (batch) cannot be corrected via EU HUB to EMVS/CZMVS. Pack cannot be supplied to patient.</p>

CLOSING ALERT STATUSES

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

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06d Closed - ZOL 11r exception	<ul style="list-style-type: none"> • 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“). 	<p>Keep medicinal pack in quarantine until the end of alert investigation. Wait for closing the alert by MAH/OBP or CZMVS.</p> <p>Once alert is closed, provided info from AMS:</p> <p>Exception ZOL - 11r - DO NOT VERIFY. Can be supplied to patient. Remove from quarantine.</p>	<p>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.</p>

CLOSING ALERT STATUSES

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

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

CLOSING ALERT STATUSES

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

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
<p>06f Closed - Process error KU - cannot be issued</p> <div style="border: 1px solid black; border-radius: 50%; padding: 10px; width: fit-content; margin-top: 20px;"> <p>After NCA approval new closing alert status 06m – Closed – Process error KU – can be supplied (can be supplied after required documentation) is enabled.</p> </div>	<ul style="list-style-type: none"> 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. 	<p>Keep medicinal pack in quarantine until the end of alert investigation. Once alert occurs, potential process/procedural causes of alert should be investigated by end-user. Investigation by MAH and NOOL ruled out errors caused by MAH/OBP, at the same time process/procedural error caused b end-user was identified Pack canont be supplied to patient even if alert is solved with status closed-process error end-user (possibility to supply pack and requested documentation for relevant process errors are discussed with NCA).</p> <p>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.</p>	<p>During alert investigation end-user or MAH identified process error by end-user. These alerts must be closed with proper explanation – documentation of the cause. Potential falsification was ruled out. Another decommission would cause alert.</p> <p>End-user should in the future document process error in AMS – chose from predefined options according to instructions relevant to process errors. Start of using such process to be agreed and confirmed with NCA. After that pack could be released from quarantined and supplied to patient.. Currently it is necessary to return such packs to distribution/wholesaler.</p>

CLOSING ALERT STATUSES

- Type of alerts: All. Under the terms of alert investigation, the end user ought to examine possible technical causes of the alert on their side – most frequently caused by wrong procedures, human error or inappropriate software settings. If you are certain that the alert was caused by one of the following examples (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	<p>Relevant to pack that,</p> <ul style="list-style-type: none"> • 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. 	<p>During alert investigation that was created on Czech market keep medicinal pack in quarantine until the end of alert investigation and closing alert NOOL.</p> <p>Once alert is closed, provided info from AMS (based on cause of CZMVS):</p> <p>CZMVS Error - The pack can be verified again! Remove from quarantine.</p> <p>CZMVS Error - The pack cannot be verified again! Return back. Currently all packs with CZMVS error are returned back to distribution. Potential release from quarantine and supply to patient is still discussed with NCA.</p>	<p>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.</p> <p>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.</p>



CLOSING ALERT STATUSES

- Type of alerts: All. Under the terms of alert investigation, the end user ought to examine possible technical causes of the alert on their side – most frequently caused by wrong procedures, human error or inappropriate software settings. If you are certain that the alert was caused by one of the following examples (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 inform SÚKL.

CLOSING ALERT STATUSES

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

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06h – Suspected Counterfeit!	<ul style="list-style-type: none"> all the potential causes on MAH, end-user side and CZMVO are excluded 	<p>Keep medicinal pack in quarantine until the end of alert investigation</p> <p>Once alert is closed, provided info from AMS:</p> <p>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.</p>	<p>During alert investigation by all relevant parties all potential causes of alert on MAH, end-user side and CZMVO were excluded</p> <p>MAH/OBP marked alert as potential counterfeit, NCA will be informed. Alert will be further investigated with MAH, NCA and end-user according to set up processes. Information should be provided to EMVO, EMA, EK* (in certain cases).</p>

CLOSING ALERT STATUSES

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

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06i - Closed - MAH transaction error - Fixed	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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
06I - Non FMD	<ul style="list-style-type: none"> • 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 	<p>Keep medicinal pack in quarantine until the end of alert investigation and closing by MAH/OBP or CZMVO.</p> <p>Once alert is closed, provided info from AMS:</p> <p>Medicinal product is not subject to FMD. Can be issued without verifying. Remove from quarantine.</p>	MAH or end-user found out during alert investigation that verified pack or device is not subject to FMD.
06z - Closed - 2019 alert	<ul style="list-style-type: none"> • 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.



The list of end users' procedural errors



TH 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 / relaxation / stocktaking - SW (PIS) re-executes the Supplied transaction.	cannot be supplied!
	Your own text (mandatory)	Other error caused by pharmacy information system (PIS)	can be supplied
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 / relaxation	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.	cannot be supplied!
Emergency alert raised in a district hospital - the pack was already set to Supplied by the regional hospital and the district hospital re-attempts to Supply the pack.			
The pack was transferred between locations of a different organization and decommissioned by the originating location.			





Complete list of alerts statuses
and proces maps AMS



ALERTS STATUS COMPLETE LIST



Národní organizace
pro ověřování
pravosti léčiv

Aktivní	Stav EMVO AMS	ID	Status Code	Zkratka stavu pro AMS	Short name Alert status AMS	Zpráva pro MAH	Message for MAH
A	Active	1	01a	Nový - transakce KU	New - end user transaction	Nová výstraha - výsledek investigace NOOL případně v poznámce.	New Alert - the result of CZMVO investigation might appear in Note
A	Active	2	01aa	Nový - Notifikace	New - Notification	Nová výstraha - výsledek investigace NOOL případně v poznámce.	New Alert - the result of CZMVO investigation might appear in Note
	Active	3	01b	MAH - Nový - transakce MAH/OBP/PD	MAH - New - MAH/OBP/PD transaction	Nová výstraha - operace MAH/OBP/PD	New Alert - MAH/OBP/PD transaction
A	Under Investigation	7	02a	MAH - Investigace - KU	MAH - Investigation - End user	Zahájili jste investigaci - operace koncového uživatele	You have initiated investigation - end-user transaction
A	Under Investigation	10	02b	MAH - investigace - operace MAH/OBP/PD	MAH - Investigation - MAH/OBP/PD transaction	Investigace - operace MAH/OBP/PD	Investigation - MAH/OBP/PD transaction
A	Under Investigation	13	03a	MAH - Nečinnost 5 dní	MAH - Inactivity 5 days	Upozornění, výstraha ve stavu "Nový" více než 5 dní	Warning, the alert has remained in "New" status for over 5 days
A	Under Investigation	14	03b	MAH - Nečinnost 10 dní	MAH - Inactivity 10 days	Varování - výstraha ve stavu "Nový" více než 10 dní	Warning, the alert has remained in "New" status for over 10 days
A	Under Investigation	15	03c	KU - Nečinnost 48 hodin	End user - Inactivity 48 hours	Koncový uživatel obdržel upozornění, že MAH požaduje doplňující informace a po více než 24 hodinách mu je nedodal.	The end user failed to provide additional information requested by MAH within 24 hours
A	Under Investigation	146	03d	KU - Nečinnost 5 dní	End user - Inactivity 5 days	Koncový uživatel obdržel upozornění, že MAH požaduje doplňující informace a po více než 5 dnech mu je nedodal.	The end user failed to provide additional information requested by MAH within 5 days
A	Under Investigation	17	04a	MAH - Info od KU	MAH - info from end user	Vyžádány doplňující informace od koncového uživatele	Additional information requested from the end user
A	Under Investigation	19	04b	MAH - Info od NOOL	MAH - Info from CZMVO	Vyžádány doplňující informace od NOOL	Additional information requested from the CZMVO
A	Under Investigation	24	04f	MAH - Info od NOOL - transakce PD	MAH - Info from CZMVO - PD transaction	Vyžádány doplňující informace od NOOL	Additional information requested from the CZMVO
A	Under Investigation	25	05a	KU - Info na MAH	End user - Info to MAH	Koncový uživatel zaslal požadované doplňující informace	The end user has sent the required additional information
A	Under Investigation	26	05b	NOOL - kontakt KU	CZMVO - Contacts end User	NOOL kontaktuje koncového uživatele	CZMVO contacts end-user
A	Under Investigation	27	05c	NOOL - Info od KU na MAH	CZMVO - Info end user to MAH	Požadované informace od koncového uživatele předány	The end user has provided the required information
A	Under Investigation	29	05d	NOOL - Info na MAH	CZMVO - Info to MAH	Požadované informace od NOOL předány	The required information is passed from CZMVO
A	Under Investigation	29	05f	NOOL - Info na MAH - transakce PD	CZMVO - Info to MAH - PD transaction	Požadované informace od NOOL předány	The required information is passed from CZMVO
A	Closed	33	06a	Uzavřeno - Chyba MAH - Opraveno	Closed - MAH error - Corrected	Uzavřeno - chyba MAH/OBP, opraveno	Closed - MAH/OBP error, corrected
A	Closed	34	06b	Uzavřeno - Technická chyba KU	Closed - Technical error - End user	Uzavřeno - MAH/OBP vyloučil chybu na své straně. KU potvrdil, že se jedná o technickou chybu KU.	Closed - MAH/OBP ruled out a mistake on his side. End user confirmed technical error on his side.
A	Closed	35	06c	Uzavřeno - Chyba MAH - Neopraveno	Closed - MAH error - Not corrected.	Uzavřeno - Chyba MAH/OBP - netze opravit	Closed - MAH/OBP error - cannot be corrected
A	Closed	36	06d	Uzavřeno - Výjimka ZOL 11r	Closed - ZOL 11r exception	Uzavřeno - výjimka ZOL 11r	Closed - ZOL - 11r
A	Closed	37	06e	Uzavřeno - Před 9.2.2019	Closed - Before 02/09/2019	Uzavřeno - Propuštěno z výroby před 9.2.2019	Closed - Released from production before 02/09/2019
A	Closed	38	06f	Uzavřeno - Procesní chyba KU - nelze vydat	Closed - Process error KU - cannot be dispensed	Uzavřeno - procesní chyba KU - nelze vydat	Closed - process error EU - cannot be issued
N	Closed	145	06m	Uzavřeno - Procesní chyba KU - lze vydat	Closed - Process error KU - can be issued	Uzavřeno - procesní chyba KU - lze vydat po zdokumentování příčiny KU	Closed - End User process error - (can be dispensed after his documentation of the cause)
A	Closed	39	06g	Uzavřeno - Chyba NSOL	Closed - CZMVS error	Uzavřeno - chyba NSOL	Closed - CZMVS Error
A	Escalated	40	06h	Podezření na padělek!	Suspected Counterfeit!	Vyšetřování ze strany MAH i NOOL potvrdilo možný padělek, informace bude předána na SÚKL, EMVO, EMA, EK	Investigation by MAH and CZMVO confirmed a possible forgery, information will be passed to NCA, EMVO, EMA, EK
A	Closed	41	06i	Uzavřeno - Chyba MAH transakce - Opraveno	Closed - MAH transaction error - Fixed.	Uzavřeno - chyba MAH/OBP, opraveno. MAH/OBP transakce.	Closed - MAH/OBP error, corrected. MAH / OBP transactions.
A	Closed	42	06j	Uzavřeno - Chyba MAH transakce - Neopraveno	Closed - MAH transaction error - Not corrected.	Uzavřeno - Chyba MAH/OBP - netze opravit. MAH/OBP transakce.	Closed - MAH/OBP error - cannot be corrected. MAH / OBP transactions.
A	Closed	43	06k	Uzavřeno - chyba PD - Neopraveno	Closed - PD error - Not fixed.	Uzavřeno - chyba paralelního distributora. Nelze opravit. MAH/OBP transakce	Closed - parallel distributor error. Cannot be corrected, cannot be supplied. MAH/OBP transactions.
A	Closed	8	06n	Uzavřeno - IMT fulfilling - Alert vznikl mimo CZ, MAH vyšetřuje na jiném trhu	Closed - IMT fulfilling - Alert originated outside CZ, MAH is investigating in another market	Uzavřeno - IMT fulfilling - Alert vznikl mimo CZ, MAH vyšetřuje na jiném trhu	Closed - IMT fulfilling - Alert originated outside CZ, MAH is investigating in another market
A	Closed	147	06o	Uzavřeno - KU nespolupracuje - nelze vydat	Closed - End User does not cooperate - cannot be supply	Uzavřeno, koncový uživatel ani přes urgence nespolupracuje - nelze vydat. NOOL informuje SÚKL	Closed, end user does not cooperate despite urgency - does not supply. CZMVO inform NCA.
A	Closed	45	06z	Uzavřeno - Alert 2019	Closed - 2019 alert	Uzavřeno - alert z roku 2019	Closed - 2019 alert
A	Closed	46	07a	Podezření na padělek! Info předáno	Counterfeit! Info passed	Vyšetřování ze strany MAH i NOOL potvrdilo možný padělek, informace byla předána na SÚKL, EMVO,	Investigation by MAH and CZMVO confirmed a possible counterfeit. Information was passed to NCA, EMVO, EMA, EK

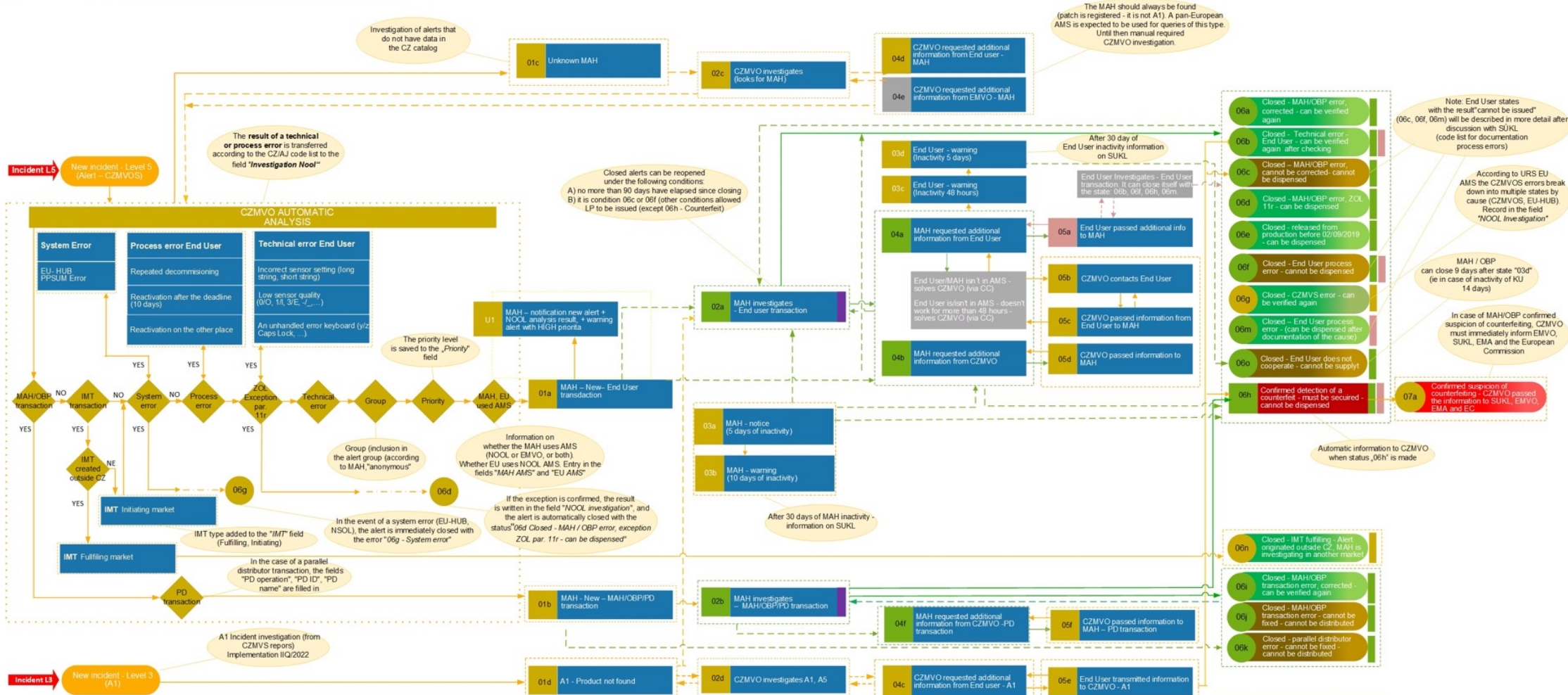
WORK FLOW

AMS

MAH/ OBP

Stav alertu	Alert state	Možné změny stavu alertu	Alert state change options	Možné změny stavu volbou "Zaslat zprávu"	Alert state change option via "Send message" button	Možné zprávy	Send Message options
01a - Nový - transakce KU 01aa - Nový - Notifikace	01a - New - End User transaction 01aa - New - Notification	02a - MAH - Investigace - KU 06a - Uzavřeno - Chyba MAH - Opraveno 06b - Uzavřeno - Technická chyba KU 06c - Uzavřeno - Chyba MAH - Neopraveno 06d - Uzavřeno - Výjimka ZOL 11r 06e - Uzavřeno - Před 9.2.2019 06f - Procesní chyba KU - nelze vydat 06h - Podezření na padělek!	02a - MAH - Investigation - End user 06a - Closed - MAH error - Fixed 06b - Closed - End user - Technical error 06c - Closed - MAH error - Not fixed. 06d - Closed - MAH error - MH exception 06e - Closed - Before 02/09/2019 06f - Closed - End User - Process error 06h - Suspected Counterfeit!	04a - MAH - Info od KU 04b - MAH - Info od NOOL 04c - MAH - Info od NOOL 04d - MAH - Info od NOOL - transakce PD 04e - MAH - Info od KU 04f - MAH - Info od NOOL - transakce PD	04a - MAH - info from end user 04b - MAH - Info from CZMVO 04c - MAH - Info from CZMVO 04d - MAH - Info from CZMVO - PD transaction 04e - MAH - info from end user 04f - MAH - Info from CZMVO - PD transaction	2 - Fotka_2D 30 - Ověření balení 24 - Požadavek - NOOL 4 - Chyba_End-User 22 - Vrátit distributorovi	2 - Photo_2D 30 - Pack verify 24 - CZMVO - request 4 - Error_End_User 22 - Return to distributor
01b - MAH - Nový - transakce MAH/OBP/PD	01b - MAH - New - MAH/OBP/PD transaction	02b - MAH - investigace - operace MAH/OBP/PD 06i - Uzavřeno - Chyba MAH transakce - Opraveno 06j - Chyba MAH transakce - Neopraveno 06k - Uzavřeno - chyba PD - Neopraveno	02b - MAH - Investigation - MAH/OBP/PD transaction 06i - Closed - MAH transaction error - Fixed. 06j - Closed - MAH transaction error - Not fixed. 06k - Closed - PD error - Not fixed.	04f - MAH - Info od NOOL - transakce PD	04f - MAH - Info from CZMVO - PD transaction		
02a - MAH - Investigace - KU	02a - MAH - Investigation - End user	06a - Uzavřeno - Chyba MAH - Opraveno 06b - Uzavřeno - Technická chyba KU 06c - Uzavřeno - Chyba MAH - Neopraveno 06d - Uzavřeno - Výjimka ZOL 11r 06e - Uzavřeno - Před 9.2.2019 06f - Procesní chyba KU - nelze vydat 06h - Podezření na padělek!	06a - Closed - MAH error - Fixed 06b - Closed - End user - Technical error 06c - Closed - MAH error - Not fixed. 06d - Closed - MAH error - MH exception 06e - Closed - Before 02/09/2019 06f - Closed - End User - Process error 06h - Closed - Counterfeit!	04a - MAH - Info od KU 04b - MAH - Info od NOOL 04c - MAH - Info od NOOL 04d - MAH - Info od NOOL - transakce PD 04e - MAH - Info od KU 04f - MAH - Info od NOOL - transakce PD	04a - MAH - info from end user 04b - MAH - Info from CZMVO 04c - MAH - Info from CZMVO 04d - MAH - Info from CZMVO - PD transaction 04e - MAH - info from end user 04f - MAH - Info from CZMVO - PD transaction	2 - Fotka_2D 30 - Ověření balení 24 - Požadavek - NOOL 4 - Chyba_End-User 22 - Vrátit distributorovi	2 - Photo_2D 30 - Pack verify 24 - CZMVO - request 4 - Error_End_User 22 - Return to distributor
02b - MAH - investigace - operace MAH/OBP/PD	02b - MAH - Investigation - MAH/OBP/PD transaction	06i - Uzavřeno - Chyba MAH transakce - Opraveno 06j - Chyba MAH transakce - Neopraveno 06k - Uzavřeno - chyba PD - Neopraveno	06i - Closed - MAH transaction error - Fixed. 06j - Closed - MAH transaction error - Not fixed. 06k - Closed - PD error - Not fixed.	04f - MAH - Info od NOOL - transakce PD	04f - MAH - Info from CZMVO - PD transaction		
03a - MAH - Nečinnost 5 dní 03b - MAH - Nečinnost 10 dní	03a - MAH - Inactivity 5 days 03b - MAH - Inactivity 10 days	02a - MAH - Investigace - KU 06a - Uzavřeno - Chyba MAH - Opraveno 06b - Uzavřeno - Technická chyba KU 06c - Uzavřeno - Chyba MAH - Neopraveno 06d - Uzavřeno - Výjimka ZOL 11r 06e - Uzavřeno - Před 9.2.2019 06f - Procesní chyba KU - nelze vydat 06h - Podezření na padělek!	02a - MAH - Investigation - End user 06a - Closed - MAH error - Fixed 06b - Closed - End user - Technical error 06c - Closed - MAH error - Not fixed. 06d - Closed - MAH error - MH exception 06e - Closed - Before 02/09/2019 06f - Closed - End User - Process error 06h - Closed - Counterfeit!				
03c - KU - Nečinnost 48 hodin	03c - End user - Inactivity 48 hours	06a - Uzavřeno - Chyba MAH - Opraveno 06b - Uzavřeno - Technická chyba KU 06c - Uzavřeno - Chyba MAH - Neopraveno 06e - Uzavřeno - Před 9.2.2019 06f - Procesní chyba KU - nelze vydat 06h - Podezření na padělek!	06a - Closed - MAH error - Fixed 06b - Closed - End user - Technical error 06c - Closed - MAH error - Not fixed. 06e - Closed - Before 02/09/2019 06f - Closed - End User - Process error 06h - Closed - Counterfeit!				
03d - KU - Nečinnost 5 dní	03d - End user - Inactivity 5 days	06a - Uzavřeno - Chyba MAH - Opraveno 06b - Uzavřeno - Technická chyba KU 06c - Uzavřeno - Chyba MAH - Neopraveno 06e - Uzavřeno - Před 9.2.2019 06f - Procesní chyba KU - nelze vydat 06o - Uzavřeno - KU nespoupracuje - nelze vydat 06h - Podezření na padělek!	06a - Closed - MAH error - Fixed 06b - Closed - End user - Technical error 06c - Closed - MAH error - Not fixed. 06e - Closed - Before 02/09/2019 06f - Closed - End User - Process error 06o - Closed - End User does not cooperate - cannot be supply 06h - Closed - Counterfeit!				
04a - MAH - Info od KU 05a - KU - Info na MAH	04a - MAH - Info from end user 05a - End user - Info to MAH	02a - MAH - Investigace - KU 02a - MAH - Investigace - KU	02a - MAH - Investigation - End user 02a - MAH - Investigation - End user				
05b - NOOL - kontakt KU 05c - NOOL - Info od KU na MAH 05d - NOOL - Info na MAH	05b - CZMVO - Contacts end User - CC 05c - CZMVO - Info end user to MAH 05d - CZMVO - Info to MAH	06a - Uzavřeno - Chyba MAH - Opraveno 06b - Uzavřeno - Technická chyba KU 06c - Uzavřeno - Chyba MAH - Neopraveno 06d - Uzavřeno - Výjimka ZOL 11r 06e - Uzavřeno - Před 9.2.2019 06f - Procesní chyba KU - nelze vydat 06h - Podezření na padělek!	06a - Closed - MAH error - Fixed 06b - Closed - End user - Technical error 06c - Closed - MAH error - Not fixed. 06d - Closed - MAH error - MH exception 06e - Closed - Before 02/09/2019 06f - Closed - End User - Process error 06h - Closed - Counterfeit!				
06c - Uzavřeno - Chyba MAH - Neopraveno	06c - Closed - MAH error - Not fixed.	02a - MAH - Investigace - KU 06a - Uzavřeno - Chyba MAH - Opraveno 06b - Uzavřeno - Technická chyba KU 06d - Uzavřeno - Výjimka ZOL 11r 06e - Uzavřeno - Před 9.2.2019 06f - Procesní chyba KU - nelze vydat 06h - Podezření na padělek!	02a - MAH - Investigation - End user 06a - Closed - MAH error - Fixed 06b - Closed - End user - Technical error 06d - Closed - MAH error - MH exception 06e - Closed - Before 02/09/2019 06f - Closed - End User - Process error 06h - Closed - Counterfeit!	Důvod znovuotevření	Why reopened	1 - Chybně uzavřeno	1 - Incorrectly closed
06j - Uzavřeno - Chyba MAH transakce - Neopraveno 06k - Uzavřeno - chyba PD - Neopraveno	06j - Closed - MAH transaction error - Not fixed. 06k - Closed - PD error - Not fixed.	02b - MAH - Investigace - operace MAH/OBP/PD 06i - Uzavřeno - Chyba MAH transakce - Opraveno 06j - Chyba MAH transakce - Neopraveno 06k - Uzavřeno - chyba PD - Neopraveno	02b - MAH - Investigation - MAH/OBP/PD transaction 06i - Closed - MAH transaction error - Fixed. 06j - Closed - MAH transaction error - Not fixed. 06k - Closed - PD error - Not fixed.	Důvod znovuotevření	Why reopened	1 - Chybně uzavřeno	1 - Incorrectly closed





CAPTION

	Final states of the alert, manually set MAH		Final state of the alert. Can be re-verified.
	Continuous states of the alert, manually set MAH		Final state of the alert. Cannot verify again.
	The final states of the alert are set automatically or manually by NOOL		Confirmed suspected counterfeit. Packing in quarantine.
	Final states of the alert, manually set by the End User (EU)		

	MAH activities		CZMVO activities		End User activities		States outside the CZMVO AMS workflow
	Obligatory		Obligatory		Obligatory		Optional
	Optional		Optional		Optional		

CC - NOOL call-centrum
 EU - End User

API - Application Programming Interface (all AMS functionalities are available via WEB GUI and API)
 EMA - European Medicines Verification Organisation
 EMA - European Medicines Agency
 EC - European Commission
 SUKL - Státní ústav pro kontrolu léčiv - Czech NCA

EMVO AMS alert status	NOOL AMS alert status
New	--
Active	01
Escalated	07
Under Investigation	02, 03, 04, 05
Closed	06

Overview of warning and alert notifications

U1 Notifications: MAH - New alert + result of "NOOL analysis" +/- High Priority Alert (info MAH, possibly CZMVO)

03a Warning: MAH - status "New" for more than 7 days

03b Warning: MAH - status "New" for more than 10 days

03c Warning: End User did not respond to the MAH request for 48 hours

03d Warning: End User did not respond to the MAH request for 5 days

Overview of information notifications

04a MAH requested additional information from End User - info MAH and End User, in case End User does not use AMS info also CZMVO

04b,04f MAH requested additional information from CZMVO - info MAH and CZMVO

05a End User submitted additional INFO to MAH - info MAH and End User

05c CZMVO passed information from KU to MAH - info MAH and CZMVO

05d,05f CZMVO passed information to MAH - info MAH and CZMVO

06a, 06b, 06c, 06d, 06e, 06f, 06m, 06n Closed - info MAH and End User

06g Closed - CZMVO error - can be verified again - info MAH, NOOL, End User

06h Confirmed forger suspected - info MAH, CZMVO, End User

02a MAH investigates - End User operations - Info MAH and End User (only in case of reopening of already closed state)