



**Národní organizace  
pro ověřování  
pravosti léčiv**



# **NOOL ALERT MANAGEMENT SYSTEM WEB INTERFACE**

System demonstration  
User Manual for MAH/OBP – version 2.8

*17. 2. 2020*

# INTRODUCTION

## Audience

This manual is intended mainly for MAH, but it can provide information also to the other users of NOOL's alert management system via web interface, i.e. don't use own alert management system integrated with NOOL alert management system via API.

Examples showed in the manual can be specific for MAH. Set of functions for MAH is different from the functions available for distributors and pharmacies.

## Prerequisites for using the system

- ✓ MAH has signed contract with NOOL
- ✓ Valid access credentials to NOOL alert management were issued to MAH/OBP by NOOL organization.

Notice: **One MAH can have more the one user account if desired.**

## Terminology

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

Non-profit organization to ensure developing and managing National medicines verification system (CZMVS) in the Czech Republic.

### **NOOL alert management system**

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

# ALERT MANAGEMENT SYSTEM

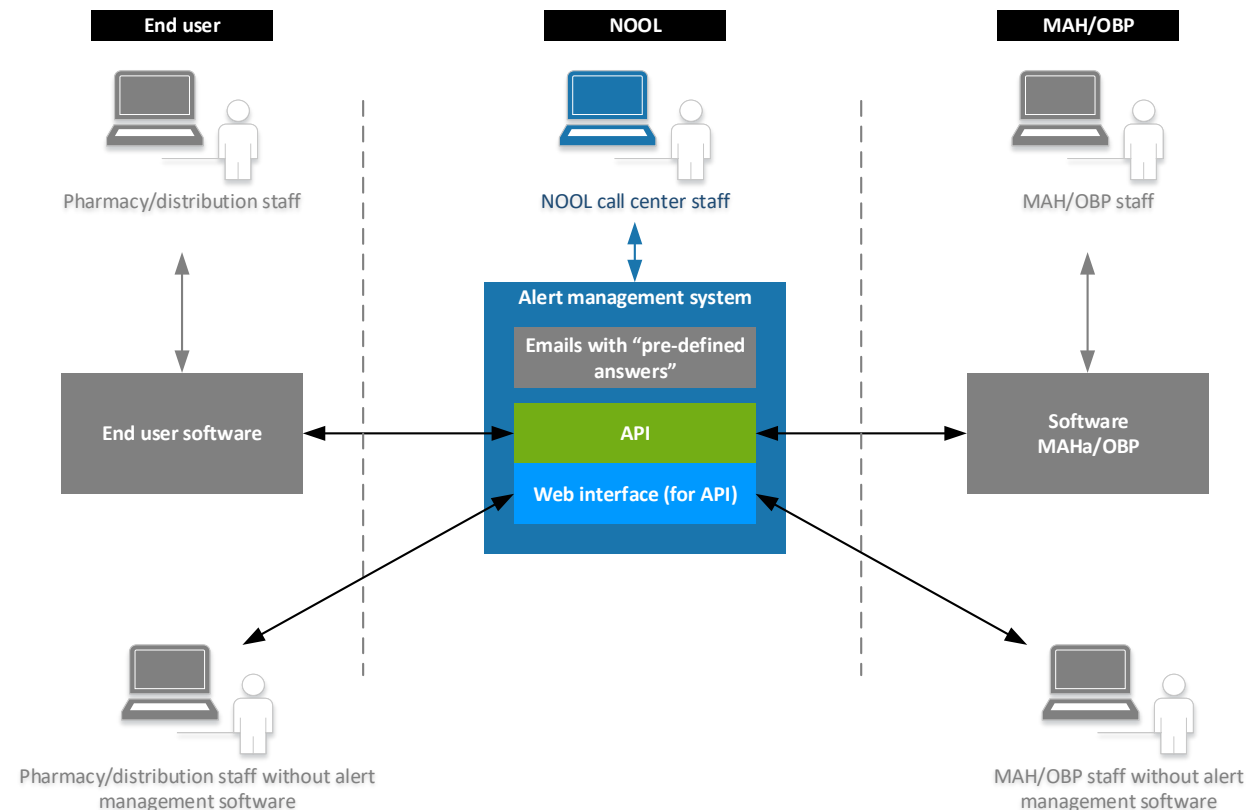
**Alert management system** operated by NOOL is supplementary system to the Czech national medicines verification system (CZMVS). Purpose of the system is to make alert investigation easier and support automation of the investigation process.

**Alert management in Czech Republic can be done by different ways:**

- ✓ One way is to integrate MAH(OBP)'s software with NOOL alert management system via **API** and manage alerts in own system.
- ✓ Users without own alert management system or users where corporate policies do not allow integration can use **web interface** of NOOL alert management system. **Usage of the web interface is subject of this manual.**
- ✓ Existing e-mails with pre-defined answers "on click" can still be used.

Note: The **API for IT development** is described in detail in "*Alerts Management API\_Documentation\_2.2.docx*"

[www.czmvo.cz/en/system-users/producers-mah-parallel-distributors](http://www.czmvo.cz/en/system-users/producers-mah-parallel-distributors)



# MOVEMENT FROM “CLICK” E-MAIL TO ACTIVE ALERTS MANAGEMENT

## Existing e-mails with pre-defined answers “on click”

**Existing system** which sends **e-mail notification** about alerts with links to pre- defined answers (solutions) will be kept.

Description of the email system and work with alert groups is described on [www.czmvo.cz/en/system-users/producers-mah-parallel-distributors](http://www.czmvo.cz/en/system-users/producers-mah-parallel-distributors).

**NOOL recommends to all MAH’s to switch to the new alert management system through web interface or API.**

## Benefits of alert management system via web interface or API

- ✓ **Easier processing, better overview and filtering options**
- ✓ **Support for automation of investigation process**
- ✓ **Support for anonymous communication between MAH and end user during investigation process.**

## Switch to the alert management system via web interface or API

MAH needs to contact NOOL first to get access credentials to the NOOL alert management system via web interface or API.

Credentials allow access to the both test and production environment, but **production system is by default inactive.**

**Once MAH is ready to use the alert management system, it has to be explicitly requested from NOOL to activate production alert management system.** Since that time MAH is switched to the new alert management system via web interface and API and will no longer receive e-mail notifications with pre-defined answers “on-click”.

**Note:** It is **not possible to have active to both ways at the same time** i.e. e-mail notification with links and access via web interface and API!

# PROCESSING TIME & ESCALATION

## New alert notification

NOOL alert management system sends notification about new alerts once a day. Notification doesn't contain any details; it is just notice that new alerts have been delivered to the MAH.

## Investigation time

Alert should be investigated and closed within **14\***days, which is set period during which the product generating alert will be kept in the pharmacy. After this period the product will be returned back to the distributor (except the alerts caused by an error of 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 **10 days**. Notification is sent to the FMD contact provided during registration process.

Note: This function will not be activated before Q2/2020.

## Archiving

**Closed alert** is marked as “**for archiving**” after **90 days**. Since that status of the alert cannot be changed. After another **365 days** is alert archived and it is no longer visible in the system for alerts management..

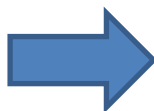
# REGISTRATION FOR ACCESS CREDENTIALS

## Contact

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

Once NOOL registers MAH in the alert management system MAH 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 2020 12:27  
To whom: <info@czmvo.cz>  
Subject: < CZMVS - registrace - sprava Alertu/CZMVS - registration - Alert administration >

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Vazeny pane/pani, zasilame Vam pristupy do NSOL systemu Spravy alertu.

Dear Sir/ Madam, We send you access to the CZMVS Alert Management System.

Prístupove udaje /Access credentials:

Login: nooltest  
Heslo/Password: bb5e7dbe8f

Testovací prostredi/Sandbox:

Webove rozhrani/Web interface: <https://sandbox.czmvo.cz/>  
Rozhrani API/API interface: <https://api.czmvo.cz/t/>

Produkcni prostredi/Production enviroment:

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

Dulezite upozorneni: Produkcni prostredi bude zpřístupneno az na vyzadani MAHem!  
Important notice: Production environment will be activated after MAH confirmation!

NOOL team



**Národní organizace  
pro ověřování  
pravosti léčiv**

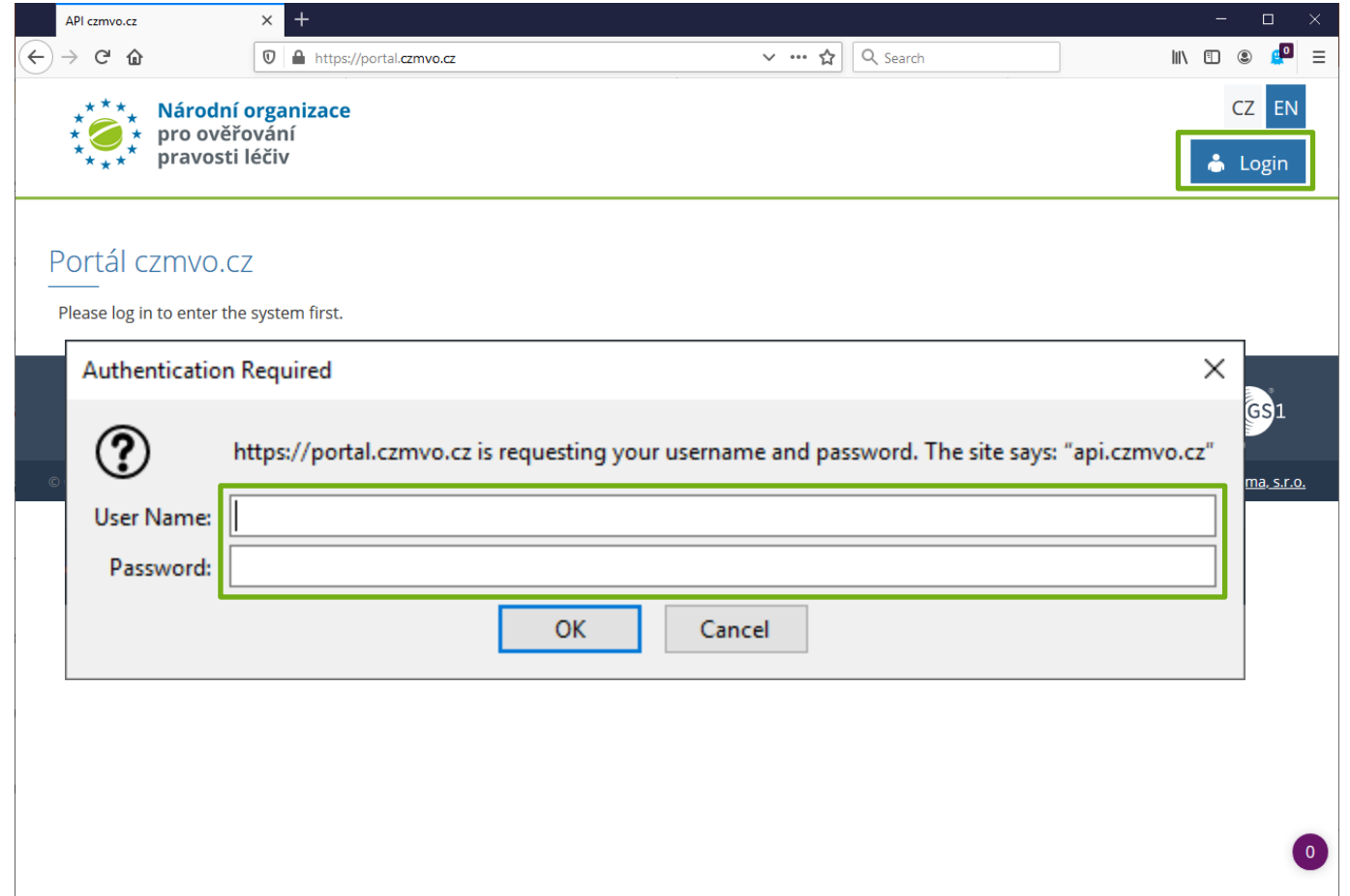
# LOGIN TO NOOL ALERT MANAGEMENT SYSTEM

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

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

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

**Note:** If you don't have credentials or you forget your password please contact NOOL ([registrace@czmvo.cz](mailto:registrace@czmvo.cz)).



The screenshot shows a web browser window with the URL <https://portal.czmvo.cz>. The page header features the logo of the National Organization for Medication Safety (Národní organizace pro ověřování pravosti léčiv) and a language selector (CZ/EN). A blue "Login" button is highlighted with a green box. Below the header, the text "Portál czmvo.cz" and "Please log in to enter the system first." is visible. An "Authentication Required" dialog box is overlaid on the page, containing a question mark icon, the message "https://portal.czmvo.cz is requesting your username and password. The site says: 'api.czmvo.cz'", and two input fields for "User Name:" and "Password:". The "User Name:" field is highlighted with a green box. At the bottom of the dialog are "OK" and "Cancel" buttons.

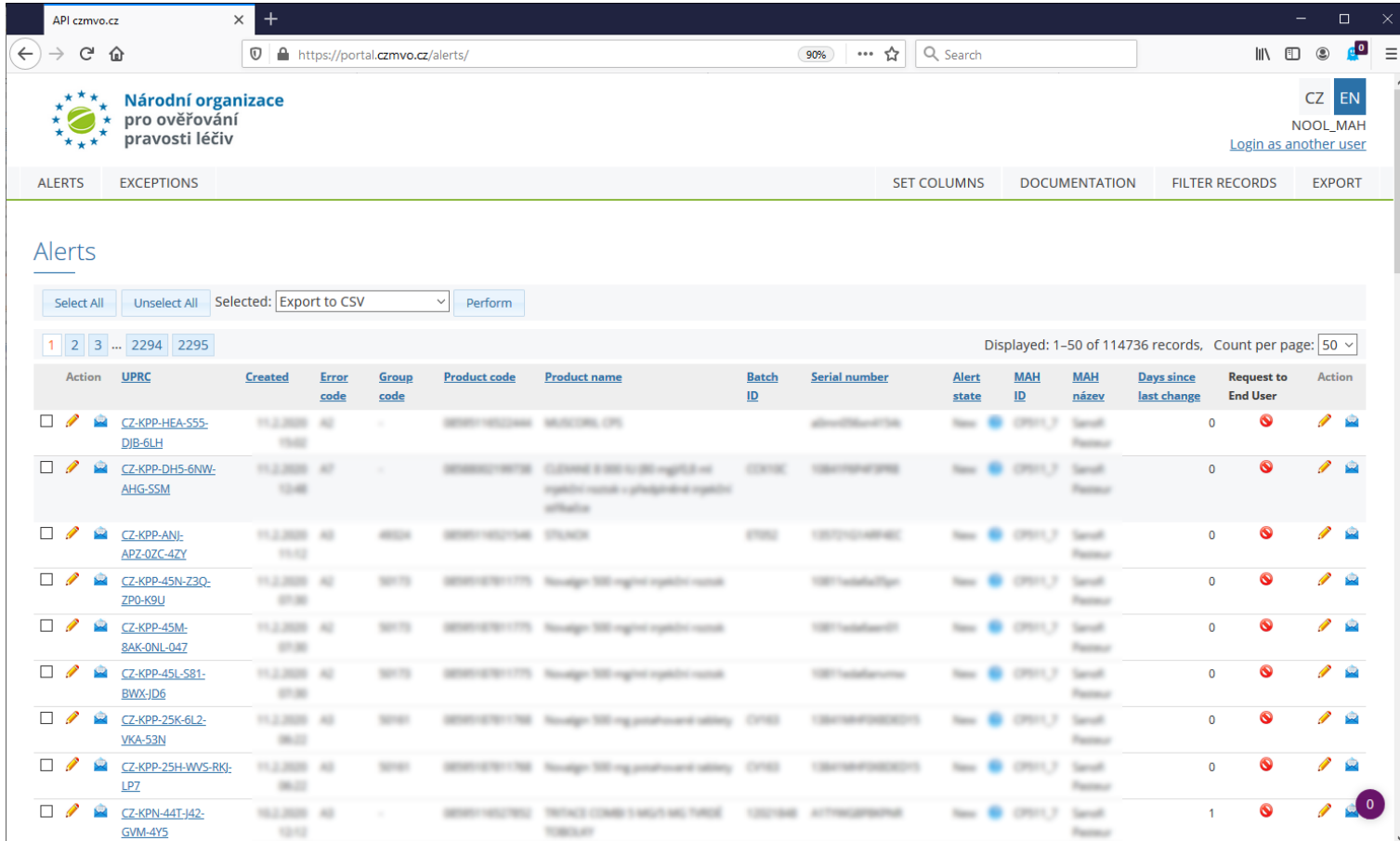
# MAIN PAGE

Once MAH/OBP successfully logs in, main page is showed.

List contains all alerts belonging to the MAH.

Note: System works on MAH level, i.e. it works with alerts relevant to the MAH only.

If organization has more than one MAH, credentials for each MAH will be generated.



The screenshot shows a web browser window with the URL <https://portal.czmvvo.cz/alerts/>. The page header includes the logo of the National Organization for Medication Safety (Národní organizace pro ověřování pravosti léčiv) and the user information: CZ EN, NOOL\_MAH, and a link to [Login as another user](#). The main content area is titled "Alerts" and features a table with the following columns: Action, UPRC, Created, Error code, Group code, Product code, Product name, Batch ID, Serial number, Alert state, MAH ID, MAH název, Days since last change, Request to End User, and Action. The table displays 10 rows of alert data, including details such as UPRC codes (e.g., CZ-KPP-HEA-555-DIB-6LH), creation dates (11.2.2020), error codes (42), and product names (e.g., 8625296, 020488 0.000 10.000 mg/0.2 ml roztok v injekční stříkačce s upravenou vzdušnou atmosférou). The page also includes navigation buttons like "Select All", "Unselect All", and "Export to CSV", along with a pagination control showing "Displayed: 1-50 of 114736 records, Count per page: 50".

Action	UPRC	Created	Error code	Group code	Product code	Product name	Batch ID	Serial number	Alert state	MAH ID	MAH název	Days since last change	Request to End User	Action
<input type="checkbox"/>	<a href="#">CZ-KPP-HEA-555-DIB-6LH</a>	11.2.2020 15:52	42	-	8625296	8625296, 020		4848028401796	New	02011_7	Sevali Prestor	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPP-DHS-6NW-AHG-SSM</a>	11.2.2020 13:48	47	-	020488	0.000 10.000 mg/0.2 ml roztok v injekční stříkačce s upravenou vzdušnou atmosférou	020192	108168470296	New	02011_7	Sevali Prestor	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPP-ANI-APZ-0ZC-4ZY</a>	11.2.2020 15:12	42	4924	020488	020488	020192	108168470296	New	02011_7	Sevali Prestor	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPP-45N-Z3Q-ZPO-K9U</a>	11.2.2020 07:30	42	50175	020101701175	Novogin 100 mg/ml roztok v injekční stříkačce		108168470296	New	02011_7	Sevali Prestor	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPP-45M-8AK-ONL-047</a>	11.2.2020 07:30	42	50175	020101701175	Novogin 100 mg/ml roztok v injekční stříkačce		108168470296	New	02011_7	Sevali Prestor	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPP-45L-S81-BWX-JD6</a>	11.2.2020 07:30	42	50175	020101701175	Novogin 100 mg/ml roztok v injekční stříkačce		108168470296	New	02011_7	Sevali Prestor	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPP-25K-6L2-VKA-53N</a>	11.2.2020 06:22	42	50161	020101701170	Novogin 100 mg, prodloužená uvolňovací forma	020192	108168470296	New	02011_7	Sevali Prestor	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPP-25H-WWS-RKI-LP7</a>	11.2.2020 06:22	42	50161	020101701170	Novogin 100 mg, prodloužená uvolňovací forma	020192	108168470296	New	02011_7	Sevali Prestor	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPN-44T-42-GVM-4Y5</a>	10.2.2020 13:12	42	-	020101702192	TRIFACE 0.250 mg/ml roztok v injekční stříkačce	1021948	417764268048	New	02011_7	Sevali Prestor	1	<input type="checkbox"/>	<input type="checkbox"/>



# MAIN PAGE - CONTROLS

1. Language selector
2. Switch to the **alert** list
3. Switch to the **exception** list
4. Customization of showed **columns**
5. Link to the **documentation** on the NOOL website
6. Show/hide **filter**
7. **Export** data (all displayed items in the list)
8. **Page** selector

## Note:

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

The screenshot shows the main page of the API.czmo.cz portal. The page is titled "Národní organizace pro ověřování pravosti léčiv" (National organization for verification of drug authenticity). The page is divided into two main sections: "ALERTS" and "EXCEPTIONS". The "ALERTS" section is currently active. The page includes a language selector (1) in the top right corner, which is set to "CZ". Below the language selector, there are buttons for "SET COLUMNS" (4), "DOCUMENTATION" (5), "FILTER RECORDS" (6), and "EXPORT" (7). The "ALERTS" section has a "Select All" button, an "Unselect All" button, and a "Selected:" dropdown menu set to "Export to CSV". Below these buttons is a "Perform" button. The table below shows a list of alerts with columns for Action, Created, Error code, Group code, Product code, Product name, Batch ID, Serial number, Alert state, MAH ID, MAH název, Days since last change, Request to End User, and Action. The table is currently displaying 1-50 of 114736 records, with a count per page of 50. The page selector (8) shows the current page is 1 of 2294 pages. The table contains several rows of alert data, including details for products like CZ-KPP-HEA-555-DIB-6LH, CZ-KPP-DHS-6NW-AHG-SSM, CZ-KPP-AN-APZ-0ZC-4ZY, CZ-KPP-45N-Z3Q-ZPO-K9U, CZ-KPP-45M-BAK-0NL-04Z, CZ-KPP-45L-S81-BWX-ID6, CZ-KPP-25K-6L2-VKA-53N, CZ-KPP-25H-W5S-RKJ-LPZ, and CZ-KPN-44T-J4Z-GVM-4Y5.

# MAIN PAGE - CONTROLS

9. Perform operation Export/Change alert state/Remove from group with selected (marked) items only.

**Tip:** Some controls are doubled. Placed at the top and bottom of the page.

The screenshot displays a web application interface for managing alerts. The main area contains a table of alert records, each with a checkbox, a pencil icon, and a trash icon. The table columns include alert ID, status, priority, and other details. At the bottom of the page, there is a control bar with the following elements:

- Page navigation: 1, 2, 3, ..., 2294, 2295
- Buttons: Select All, Unselect All, Perform
- Dropdown menu: Selected: Export to CSV
- Text: Displayed: 1-50 of 114736 records. Count per page: 50

A green circle with the number '9' is overlaid on the page navigation area, and a green box highlights the 'Selected: Export to CSV' dropdown and the 'Perform' button.

# ALERTS FILTERS

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

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

Filter will show once you click the button “Filter records”. Select criteria and confirm selection by clicking button “Filter”.

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

API.czmvvo.cz

https://portal.czmvvo.cz/alerts/?%2Falerts%2F=&filtr[cislo]=8

Národní organizace pro ověřování pravosti léčiv

ALERTS EXCEPTIONS SET COLUMNS DOCUMENTATION FILTER RECORDS EXPORT

Alerts

UPRC:  Created: from  to  Error code:  Group code:

Product code:  Product name:  Batch ID:  Serial number:

Alert state:  MAH ID:  MAH name:  Multimarket:

Intermarket:  Source...:  Archived:  Request to End User:

Select All Unselect All Selected:

Displayed: 1-43 of 43 records. Count per page:

Action	UPRC	Created	Error code	Group code	Product code	Product name	Batch ID	Serial number	Alert state	MAH ID	MAH name	Multimarket	Intermarket	Source Business Process	Days since last change	Archived	Request to End User	Action
<input type="checkbox"/>	<a href="#">CZ-0VP-1L2-CRH-1FJ</a>	4.6.2019 10:13	A68	-		Service PPSU, suspension for injection in pre-filled syringe...								National System PPSU Request	256			<input type="button" value="edit"/> <input type="button" value="delete"/>
<input type="checkbox"/>	<a href="#">CZ-0VP-1L2-CRH-HYM</a>	4.6.2019 10:13	A68	-		Service PPSU, suspension for injection in pre-filled syringe...								National System PPSU Request	256			<input type="button" value="edit"/> <input type="button" value="delete"/>
<input type="checkbox"/>	<a href="#">CZ-0VP-1L2-CRH-KJ</a>	4.6.2019 10:13	A68	-		Service PPSU, suspension for injection in pre-filled syringe...								National System PPSU Request	256			<input type="button" value="edit"/> <input type="button" value="delete"/>

https://portal.czmvvo.cz/alerts/?alerts/?=&filtr[cislo]=&filtr[datumf]=&filtr[datumt]=&filtr[chyba\_kod]=&filtr[group\_1...id]=&filtr[mah\_nazev]=&filtr[itm]=0&filtr[intermarket]=0&filtr[spb]=3&filtr[archiv]=0&filtr[message\_id]=0&setlang=en

# VIEW CHANGE

All columns are viewed by default.

User can change the view by clicking button “*Set columns*”. Window with list of all available columns will appear. User can select which columns be showed and selection confirm clicking “*Ok*”.

The screenshot shows a web application interface for the National Organization for Medication Safety (Národní organizace pro ověřování pravosti léčiv). A modal dialog box titled "Select columns" is open, allowing the user to choose which columns to display in the table. The dialog has two columns: "Show" (checkboxes) and "Column". The columns listed are: UPRC, Created, Error code, Group code, Product code, Product name, Batch ID, Serial number, Alert state, MAH ID, MAH name, Multimarket, Intermarket, Source Business Process, Days since last change, Archived, and Request to End User. The "Show" column for all items is checked. The "Set columns" button is highlighted in green. The background shows a table of alerts with columns: Action, UPRC, Created, Batch ID, Serial number, Alert state, MAH ID, MAH název, Days since last change, Request to End User, and Action. The "Set columns" button is also highlighted in green in the background.

# EXPORT ALL ALERTS ACCORDING FILTER

All alerts in the list (according filter set) can be exported to file.

Click button “*Export*” on the right side and click to the select format, csv or excel. Save dialog will appear. Select “*Save file*” and Click “*Ok*”.

The screenshot shows the 'Alerts' page on the portal.czmvvo.cz website. The page header includes the logo of the 'Národní organizace pro ověřování pravosti léčiv' and the user 'NOOL\_MAH'. The main content area displays a list of alerts with columns for 'number', 'Alert state', 'MAH ID', 'MAH název', 'Days since last change', 'Request to End User', and 'Action'. A modal dialog box is open in the center, titled 'Opening export\_2020FebTue\_130622.csv'. The dialog contains the following text: 'You have chosen to open: export\_2020FebTue\_130622.csv which is: csv File from: https://portal.czmvvo.cz'. Below this, it asks 'What should Firefox do with this file?' and provides three options: 'Open with Browse...', 'Save File' (which is selected), and 'Do this automatically for files like this from now on.'. The 'OK' button is highlighted with a green box.

# EXPORT SELECTED ALERTS

If **only selected alerts need to be exported**, it is possible to use **export button** at the top or at the bottom of the page.

First select alerts you want to export, by filter or clicking checkboxes beside UPRC. Next step is to select operation “**Export to CSV**” in the drop-box and click button “**Perform**”. Save dialog will appear. Select “**Save file**” and Click “**OK**”.

The screenshot displays a web browser window with the URL <https://portal.czmvo.cz/alerts/>. The main content is a table of alerts with columns for ID, status, and actions. Two rows are selected, indicated by green checkboxes. At the bottom of the table, there are buttons for 'Select All', 'Unselect All', a dropdown menu set to 'Export to CSV', and a 'Perform' button. A dialog box titled 'Opening export\_2020FebTue\_132115.csv' is open, showing the file name and type (csv File) and asking 'What should Firefox do with this file?'. The 'Save File' option is selected, and the 'OK' button is highlighted.



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SÚKL

emvó

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Neofarma, s.r.o.

# VIEW GROUP OF ALERTS

Use filter function. Put the group ID to the filter and click “Filter”. List of all alerts belonging to the group be listed.

If you don't know the group ID, you can get it by searching for the alert belonging to the group. Group ID than can be showed in the alert detail.

If there is no Group ID showed in the alert detail, the alert doesn't belong to any group.

## Alert groups

- ✓ It is built-in function of alert management system to group alerts with **probably** the same characteristic during the time period.
- ✓ Grouping is based on Product code, Error code, Batch ID, etc.
- ✓ Group is always created by the packs with the same MAH and Product code, it never mixes different products in one group.
- ✓ The grouping allows change of the status in bulk which speed up the process.

API czmvo.cz

https://portal.czmvo.cz/alerts/

Národní organizace pro ověřování pravosti léčiv

ALERTS EXCEPTIONS SET COLUMNS DOCUMENTATION FILTER RECORDS EXPORT

Alerts

UPRC: [ ] Created: [from] - [to] Error code: [ ] Group code: [50292]

Product code: [ ] Product name: [ ] Batch ID: [ ] Serial number: [ ]

Alert state: [- all -] MAH ID: [ ] MAH název: [ ] Request to End User: [- does not matter -]

Filter

Select All Unselect All Selected: Export to CSV Perform

1 2 3 ... 2228 2229

Displayed: 1-50 of 111404 records, Count per page: 50

Action	UPRC	Created	Error code	Group code	Product code	Product name	Batch ID	Serial number	Alert state	MAH ID	MAH název	Days since last change	Request to End User	Action
<input type="checkbox"/>	<a href="#">CZ-KPO-TV6-HU2-SDD-CCT</a>	12.2.2020 16:15	A2	49927	00001420000	TRAVICIN 0,5% SLS		10701970401	New	0001_7	Sund	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPO-MAH-00R-M6R-JLK</a>	12.2.2020 12:32	A3	49939	00001420110	TRAVICIN 0,5% SLS	1000	10701970402	New	0001_7	Sund	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPO-GI1-72X-EHX-D04</a>	12.2.2020 09:49	A3	50292	00001420000	WALZIN 0,05% gelová emulze	0000	10701970401	New	0001_7	Sund	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPO-GH2-04B-H3G-4WD</a>	12.2.2020 09:48	A3	50292	00001420000	WALZIN 0,05% gelová emulze	0000	10701970401	New	0001_7	Sund	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPO-DB4-LK5-WER-VHK</a>	12.2.2020 08:00	A3	-	00001420110	TRAVICIN 0,5% SLS	0700	10701970400	New	0001_7	Sund	0	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<a href="#">CZ-KPO-BSJ-TN7-WPO-CVW</a>	12.2.2020 07:07	A3	-	00001420000	WALZIN 0,05% gelová emulze	0000	10701970401	New	0001_7	Sund	0	<input type="checkbox"/>	<input type="checkbox"/>

# REMOVE ALERTS FROM GROUP

If you recognize during the investigation that some alerts have different cause and such alerts need to be solved separately **you can remove them from the group.**

Mark alerts you need to remove by clicking checkbox on the left or right side of the windows. Next step is to select function *“Remove from the group”* drop box and click button *“Perform”*.

The screenshot displays the 'API czmvo.cz' interface for managing alerts. The browser address bar shows 'https://portal.czmvo.cz/alerts/'. The main content area is a table of alerts, each with a checkbox for selection. Two alerts are selected, indicated by green boxes around their checkboxes. At the bottom of the table, there are buttons for 'Select All', 'Unselect All', and a 'Selected:' dropdown menu. The dropdown menu is open, showing options: 'Export to CSV', 'Export to CSV Excel', 'Change alert state', and 'Remove from the group'. The 'Remove from the group' option is highlighted with a green box. To the right of the dropdown is a 'Perform' button, also highlighted with a green box. The footer of the page includes logos for SÚKL, emvo, and GS1, along with the text '© Copyright 2020 Národní organizace pro ověřování pravosti léčiv, z.s.' and 'Neofema, s.r.o.'.



# VIEW ALERT DETAIL

Click on the UPRC code of alert and **page with alert detail appear**. There are several lists in the alert detail.

List **“General”** shows details about alert like date of creation, error code, by user provided or in EU-HUB stored information, etc.

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

List **“Group”** shows list of the all alerts belonging to the same group.

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

The screenshot shows a web browser window with the URL <https://portal.czmvvo.cz/alerts/CZ-KPQ-TV6-HU2-SDD-CCT/>. The page header includes the logo of the National Organization for Medication Safety (Národní organizace pro ověřování pravosti léčiv) and navigation tabs for ALERTS, EXCEPTIONS, and DOCUMENTATION. The main content area displays the alert ID CZ-KPQ-TV6-HU2-SDD-CCT and a navigation bar with buttons for Back, Send message, and Change alert state. Below this, there are three tabs: Obecné (highlighted), Solution, and Group. The alert details are presented in two columns:

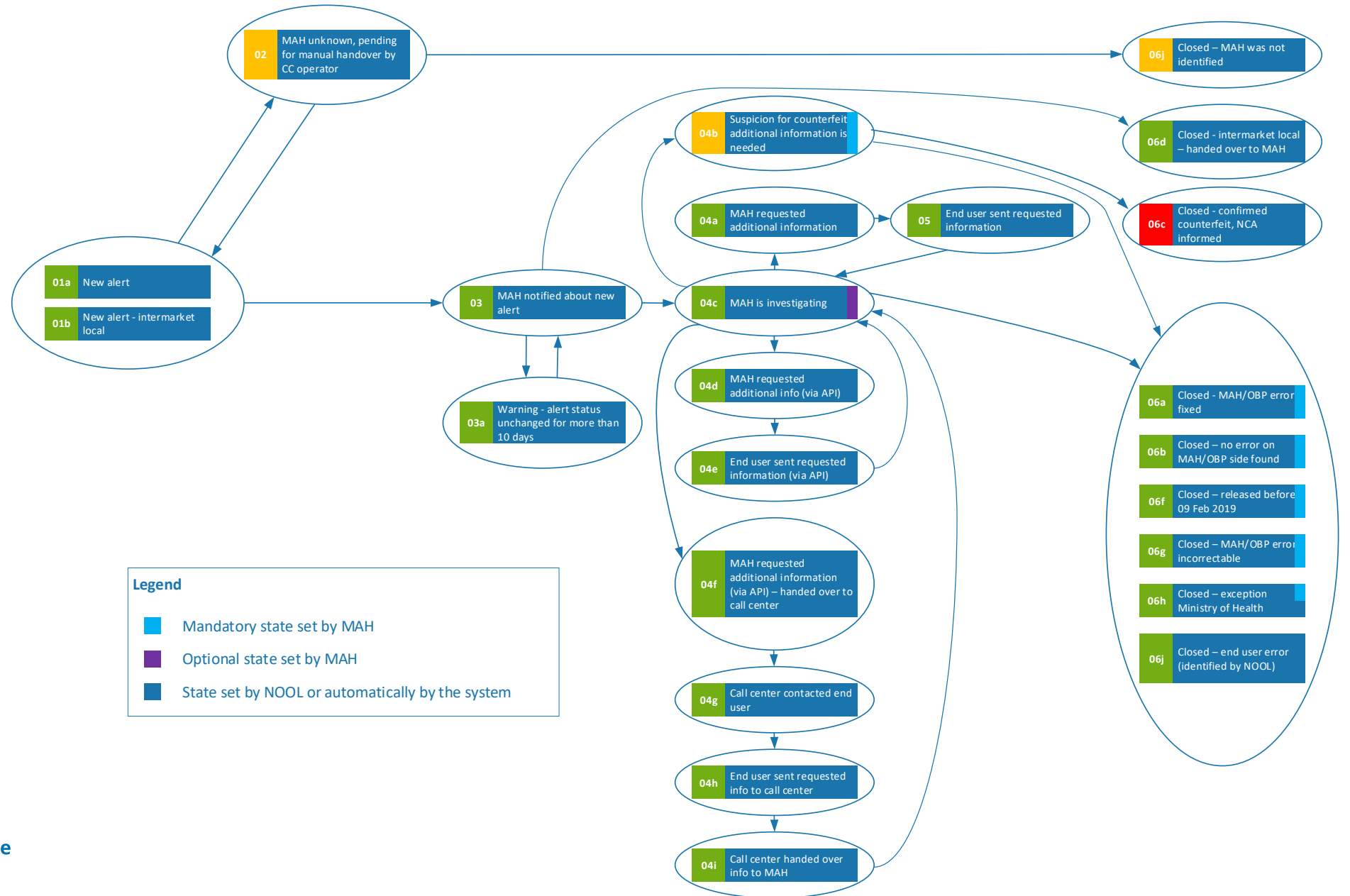
Alert		MAH	
UPRC	CZ-KPQ-TV6-HU2-SDD-CCT	MAH ID	0001_2
Created	12.2.2020 16:15	Name	Sanofi Pasteur
Error code	A2		
Error description	Batch Not Found		
Source Business Process	National System Single Pack API		
Intermarket	No		
Multimarket	Undefined		
Product name			
Product code	0001_2/0001_2		
Code scheme	GTIN		
Product name	KLONOPIN 2 MG/12		
Serial number	1270191040		
Batch ID Stored			

# ALERT FLOW

Alert flow is on the picture.

Some states are intended for internal use.

Alerts relevant for MAH's are marked by light blue and purple colors at the end. Please see the legend.



# ALERT STATES

Alert state is changing through the whole lifecycle from the opening to final close. **Some states are set by the system, another have to be set by MAH.**

There is a list of alert **states which can be set by MAH** in the table.

## Note:

In case of **potential counterfeit state 04b** has to be set by MAH. **NOOL sets final state 06c when investigation is completed and NCA informed.**

State	Description	Set by	Detail
04b	Suspicion for counterfeit, additional information is needed	MAH	Serious suspicion for counterfeit
04c	MAH is investigating	MAH (optionally)	Alert is being actively investigated
06a	Closed - MAH/OBP error fixed	MAH	Alert cause identified and corrected
06b	Closed – no error on MAH/OBP side found	MAH	Probably caused by a problem on the end user side
06c	Closed – suspicion for counterfeit, NCA informed	NOOL	Serious suspicion for counterfeit. NCA informed.
06f	Closed – released before 09 Feb 2019	MAH/system	Pack released before FMD came into effect
06g	Closed – MAH/OBP error incorrecable	MAH	Alert cause identified but can not be corrected.
06h	Closed – exception Ministry of Health	MAH/system	The pack is under exception of the Ministry of Health



# CHANGE ALERT STATE

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

There is also checkbox to change the state of the all alerts which belong to the same group.

## Important:

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

The screenshot shows a web browser window with the URL <https://portal.czmvvo.cz/alerts/CZ-KPQ-TV6-HU2-SDD-CCT/>. The page header includes the logo of the National Organization for Medication Safety (Národní organizace pro ověřování pravosti léčiv) and navigation tabs for ALERTS and EXCEPTIONS. The main content area displays the alert group details for CZ-KPQ-TV6-HU2-SDD-CCT, including a table with the following information:

Alert	
UPRC	CZ-KPQ-TV6-HU2-SDD-CCT
Created	12.2.2020 16:15
Error code	A2
Error description	Batch Not Found
Source Business Process	National System Single Pack API
Intermarket	No
Multimarket	Undefined
Product name	
Product code	
Code scheme	GTIN
Product name	
Serial number	
Batch ID Stored	

Overlaid on this page is a modal dialog box titled "Change alert state". It features a dropdown menu currently set to "Closed - MAH error, fixed" and a checkbox labeled "For the whole group" which is currently unchecked. The dialog includes "Save" and "Cancel" buttons at the bottom right.

# EXCEPTIONS

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

List of exceptions are primarily maintained and checked by NOOL, however MAH may also modify exception list.

All performed changes have to be compliant with approved exceptions by Ministry of Health and related legislation.

Click button “*Exception*” to view list of exception.

The screenshot displays the 'EXCEPTIONS' page in the portal.czmvo.cz system. The page features a navigation bar with tabs for 'ALERTS' and 'EXCEPTIONS' (highlighted). Below the navigation bar, there are buttons for 'Add exception', 'Import from CSV', and 'Verify exception'. A table of exceptions is shown with columns: Action, Exception ID, Inserted via, Created, Source, Product code, Batch ID, Serial number, and Action. Two rows are visible, each with a checkbox in the Action column. The page also includes a 'Count per page' dropdown set to 50 and a 'Perform' button. The footer contains logos for SÚKL, emvO, and GS1, along with the text '© Copyright 2020 Národní organizace pro ověřování pravosti léčiv, z.s.' and 'Neofema s.r.o.'.

Action	Exception ID	Inserted via	Created	Source	Product code	Batch ID	Serial number	Action
<input type="checkbox"/>	3	Admin	19.6.2019 09:00	C, j.: MZDR 16723/2019-3/OLZP	03660053105267			
<input type="checkbox"/>	57	Admin	3.12.2019 09:23	Č, j.: MZDR 45587/2019-4/OLZP	03664798007381			

# 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 exception is added all new alerts meeting set parameters will be automatically closed (state changed to “*Closed – MH exception*”).

## Note:

Automatic closing will be applied to the new alerts only. Old alerts have to be closed manually.

The screenshot displays the 'Add exception' dialog box overlaid on the 'Exceptions' management page of the 'portal.czmvvo.cz' application. The dialog box contains the following fields and options:

- Product code:** A text input field with a note below it: "At least one of the Product Code, Batch or Serial Number fields must be filled in".
- Batch ID:** A text input field.
- Serial number:** A text input field.
- Validity:** A text input field.
- Alert state:** A dropdown menu currently set to "Closed - MH exception".

At the bottom of the dialog are "Save" and "Cancel" buttons. The background interface shows a table with columns for "Action", "Exception ID", "Inserted via", "Created", and "Source". The "Add exception" button in the top left of the dialog is highlighted with a green box.

# 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 the web interface of the National Organization for Medication Verification (NOOL\_MAH). The main page is titled "Exceptions" and features a navigation menu with "ALERTS" and "EXCEPTIONS" selected. A "Verify exception" button is highlighted with a green box. A modal dialog box is open, titled "Verify exception", with two input fields for "Product code" and "Batch ID", both also highlighted with green boxes. The dialog includes "Verify" and "Cancel" buttons. The footer of the page contains logos for SÚKL, emv6, and GS1, along with the text "© Copyright 2020 Národní organizace pro ověřování pravosti léčiv, z.s." and "Neofema\_s.r.o.".

# ANONYMOUS COMMUNICATION BETWEEN MAH AND END USER

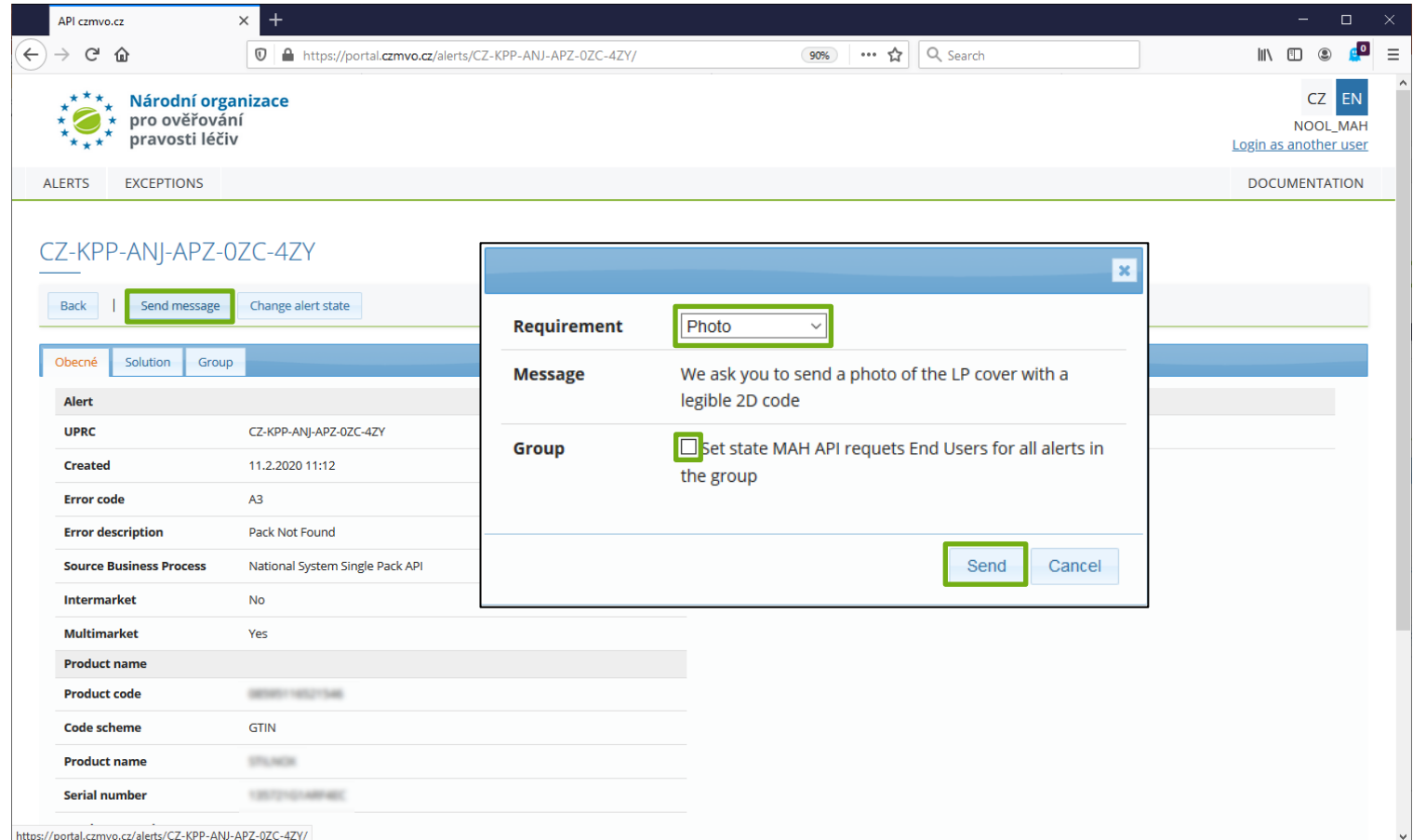
Alert management system supports **anonymous exchange** of “predefined” messages between MAH and end user.

The communication is intended to support MAH investigation for example in case MAH needs a pack photo.

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. Optionally you can assign request to the all alerts in the group by clicking checkbox “*Group*”.

## Note:

Communication requires that both MAH and end user use either Alert management API or web interface which is not mandatory. If answer to the request does not arrive in reasonable time (**24 hours**) “standard” communication via NOOL call center need to be used.



The screenshot shows a web browser window with the URL <https://portal.czmvvo.cz/alerts/CZ-KPP-ANJ-APZ-0ZC-4ZY/>. The page header includes the logo of the National Organization for Medication Safety (Národní organizace pro ověřování pravosti léčiv) and navigation tabs for ALERTS, EXCEPTIONS, and DOCUMENTATION. The main content area displays an alert for CZ-KPP-ANJ-APZ-0ZC-4ZY with details such as UPRC, Created date, Error code, and Product information. A dialog box is open over the alert, allowing the user to send a message. The dialog box has a 'Requirement' dropdown menu set to 'Photo', a 'Message' field containing the text 'We ask you to send a photo of the LP cover with a legible 2D code', and a 'Group' checkbox that is checked. The 'Send' button is highlighted with a green box.

Alert	
UPRC	CZ-KPP-ANJ-APZ-0ZC-4ZY
Created	11.2.2020 11:12
Error code	A3
Error description	Pack Not Found
Source Business Process	National System Single Pack API
Intermarket	No
Multimarket	Yes
Product name	
Product code	
Code scheme	GTIN
Product name	
Serial number	



# COMMUNICATION – PREDEFINED MESSAGES

List of available requests for additional information is in the table.

**Note:**

List of messages **may change based on feedback** from the users of the system.

Requirement	Description
Photo	We ask you to send a photo of the pack cover with a legible 2D code.
Photo, more info	We ask you to send a photo of the pack cover with a legible 2D code. Please take visually readable data (EAN, batch, SN, expiration date, etc.).
Distributor	We ask for the supplier name of the pack.
Error End-user	End-user error. Check the sensor settings. In case of disagreement please provide a justification.



# COMMUNICATION – SHOW LIST OF REQUESTS TO END USER

List of alert with request for additional information can be displayed via filter.

Turn on filter followed by setting the field “*Request to end user*” to “*Yes*”.

The screenshot shows the 'Alerts' section of the website. The 'Request to End User' dropdown is highlighted with a green box. The table below shows the columns for the alerts list.

Action	UPRC	Created	Error code	Group code	Product code	Product name	Batch ID	Serial number	Alert state	MAH ID	MAH název	Days since last change	Request to End User	Action
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Count per page: 50

Mark all Unmark Marked: Export to CSV Perform

Count per page: 50

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# COMMUNICATION – SHOW LIST OF END USERS ANSWERS

List of alerts with answers to requests for additional information can be displayed via filter.

Turn on filter. In the next step set field “Alert state” to state “End user sent requested information (via API)”.

The screenshot shows the 'Alerts' management interface in the API portal. The 'Alert state' dropdown menu is highlighted with a green box and set to 'End User sent API Ir'. The 'Filter' button is also highlighted with a green box. The table below shows columns for UPRC, Created, Error code, Group code, Product code, Product name, Batch ID, Serial number, Alert state, MAH ID, MAH název, Days since last change, and Request to End User.

Action	UPRC	Created	Error code	Group code	Product code	Product name	Batch ID	Serial number	Alert state	MAH ID	MAH název	Days since last change	Request to End User	Action
--------	------	---------	------------	------------	--------------	--------------	----------	---------------	-------------	--------	-----------	------------------------	---------------------	--------