



Národní organizace
pro ověřování
pravosti léčiv



NOOL ALERT MANAGEMENT SYSTEM WEB INTERFACE

User manual for end users – version 2.2

27. 2. 2020

INTRODUCTION

Audience

This manual is intended mainly for end users, 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 end users. Set of functions for end users is different from the functions available for MAH's.

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

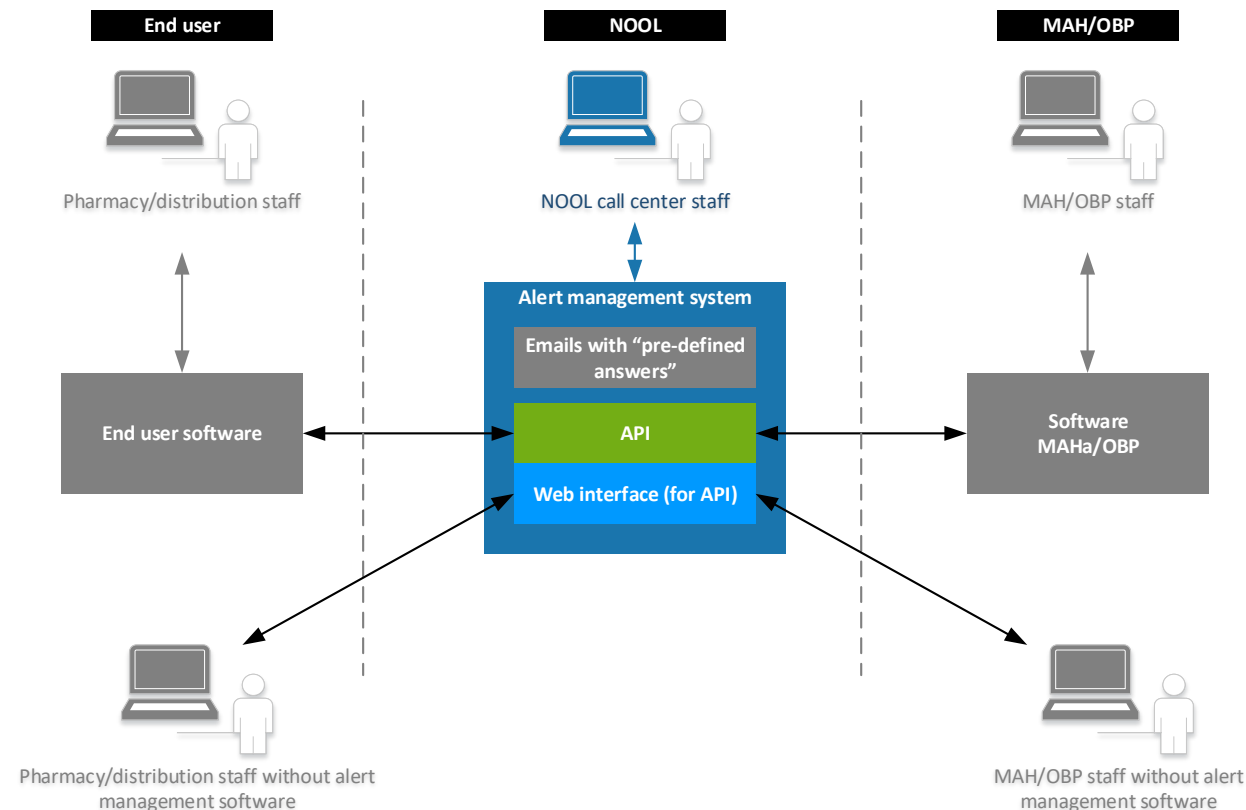
Alert management system operated by NOOL is supplementary system to the Czech national medicines verification system (CZMVS). Purpose of the system is to make alert investigation easier and support automation of the investigation process.

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-Technical documentation.docx*"

<https://www.czmvo.cz/file.php?id=451>



ALERT MANAGEMENT VIA API OR WEB INTERFACE

End user authentication

Standard authentication:

- ✓ Login name and password, generated by the system upon request at registrace@czmvo.cz

Simplified authentication:

- ✓ Alert ID (UPRC) as login a Location ID (premise) as password for the alert state check and work with attached messages.
- ✓ Location ID (premise) as login a the same location ID (premise) as password to check if product number or batch fall under exception Ministry of health.

Functions available after standard authentication

- ✓ Check state one or more alerts according given criteria (period, alert state, location ID etc.).
- ✓ Export list of alerts csv/xls file.
- ✓ Fetching/sending messages attached to an alert.
- ✓ Verification if alert or batch falls under exception Ministry of health.

Functions available after simplified authentication

- ✓ Check alert state and presence of attached messages.
- ✓ Fetching/sending messages attached to an alert.
- ✓ Verification if alert or batch falls under exception Ministry of health.

ALERT MANAGEMENT VIA API OR WEB INTERFACE

Advantages of alert management system:

- ✓ Simplified work with alerts, filters
- ✓ Support for automation of alert management process
- ✓ Support for anonymous communication between MAH and end user during alert investigation.

End user has to contact NOOL to get access credentials for using web interface of alert management system.

*Note: Access credentials allow access to the both **test** and **production** environments. Test environment contains copy of production data, data are copied nightly.*

PROCESSING TIME & ESCALATION

New alert notification (MAH's only)

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 (MAH's only)

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..

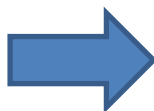
REGISTRATION FOR ACCESS CREDENTIALS

Contact

For all requests related to the registration email registrace@czmvo.cz 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 <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 >

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

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

Prístupové údaje /Access credentials:

Login: nooltest
Heslo/Password: XXX

Testovací prostředí/Sandbox:

Webové rozhraní/Web interface: <https://sandbox.czmvo.cz/>

Rozhraní API/API interface: <https://api.czmvo.cz/t/>

Produkční prostředí/Production environment:

Webové rozhraní/Web interface: <https://portal.czmvo.cz/>

Rozhraní API/API interface: <https://api.czmvo.cz/>

Důležité upozornění: Produkční prostředí bude zpřístupněno až na vyzvání MAHem!

Important notice: Production environment will be activated after MAH confirmation!

NOOL team



Národní organizace
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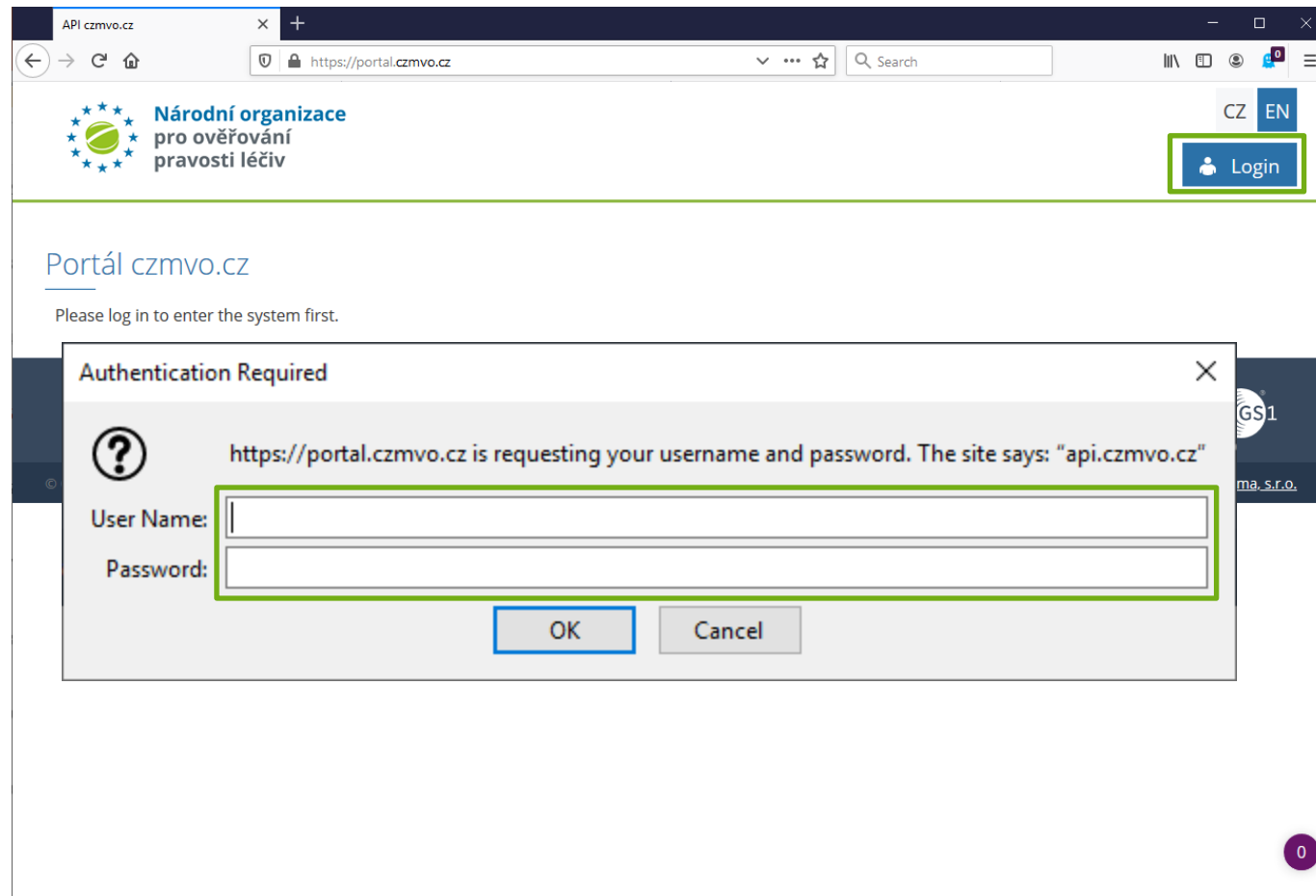
LOGIN TO NOOL ALERT MANAGEMENT SYSTEM

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.



MAIN PAGE

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

List contains all alerts belonging to the end user.

API czmvo.cz

https://portal.czmvo.cz/alerts/90%

Národní organizace pro ověřování pravosti léčiv

CZ EN NOOL_MAH Login as another user

ALERTS EXCEPTIONS SET COLUMNS DOCUMENTATION FILTER RECORDS EXPORT

Alerts

Select All Unselect All Selected: Export to CSV Perform

1 2 3 ... 2294 2295

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"/> | CZ-KPP-HEA-555-DIB-6LH | 11.2.2020 15:02 | 42 | - | 00000110022444 | HEA 555, CPM | | 4064000404754 | New | CPM11_7 | Sanofi Pasteur | 0 | | |
| <input type="checkbox"/> | CZ-KPP-DH5-6NW-AHG-SSM | 11.2.2020 13:48 | 47 | - | 00000002190738 | CLONIDIN 0.0001% roztok v roztoku roztok v glycerolové roztoku | CLONID | 10001000000000 | New | CPM11_7 | Sanofi Pasteur | 0 | | |
| <input type="checkbox"/> | CZ-KPP-ANI-APZ-0ZC-4ZY | 11.2.2020 15:12 | 42 | 40024 | 00000110021748 | STYLANOL | 07002 | 10071010000000 | New | CPM11_7 | Sanofi Pasteur | 0 | | |
| <input type="checkbox"/> | CZ-KPP-45N-Z3Q-ZPO-K9U | 11.2.2020 07:00 | 42 | 50175 | 00000107011775 | Novartis 100 mg roztok roztok roztok | | 10071000000000 | New | CPM11_7 | Sanofi Pasteur | 0 | | |
| <input type="checkbox"/> | CZ-KPP-45M-8AK-ONL-047 | 11.2.2020 07:00 | 42 | 50175 | 00000107011775 | Novartis 100 mg roztok roztok roztok | | 10071000000000 | New | CPM11_7 | Sanofi Pasteur | 0 | | |
| <input type="checkbox"/> | CZ-KPP-45L-S81-BWX-ID6 | 11.2.2020 07:00 | 42 | 50175 | 00000107011775 | Novartis 100 mg roztok roztok roztok | | 10071000000000 | New | CPM11_7 | Sanofi Pasteur | 0 | | |
| <input type="checkbox"/> | CZ-KPP-25K-6L2-VKA-53N | 11.2.2020 06:22 | 42 | 50141 | 00000107011768 | Novartis 100 mg prášek prášek prášek | CL142 | 10001000000000 | New | CPM11_7 | Sanofi Pasteur | 0 | | |
| <input type="checkbox"/> | CZ-KPP-25H-WVS-RKI-LP7 | 11.2.2020 06:22 | 42 | 50141 | 00000107011768 | Novartis 100 mg prášek prášek prášek | CL142 | 10001000000000 | New | CPM11_7 | Sanofi Pasteur | 0 | | |
| <input type="checkbox"/> | CZ-KPN-44T-J42-GVM-4Y5 | 10.2.2020 13:12 | 42 | - | 00000110021762 | TRIFACE COMB 5 mg/5 mg/5 mg/5 mg | 10021000 | 10071000000000 | New | CPM11_7 | Sanofi Pasteur | 1 | | |

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.

API czmvo.cz

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

Národní organizace pro ověřování pravosti léčiv

ALERTS EXCEPTIONS SET COLUMNS DOCUMENTATION FILTER RECORDS EXPORT

Select All Unselect All Selected: Export to CSV Perform

1 2 3 ... 760 761

| Action | MPRC | Created | Error code | Group code | Product code | Product name | Batch ID | Serial number | Alert state | Organization ID | Location code | Location name | Days since last change | Arch |
|--------------------------|--|-----------------|------------|------------|----------------|---|----------|----------------|-------------|-----------------|----------------|--------------------|------------------------|------|
| <input type="checkbox"/> | CZ-KPW-ZLO-GYS-QM2-A51 | 17.2.2020 15:15 | A3 | 50645 | 00000011000017 | PROSTEDK na pľigovnu hapti pľibek pro hapti novok | 1010017 | 00000011000017 | New | 02 | 17000011000017 | Novok hapti 000017 | 0 | |
| <input type="checkbox"/> | CZ-KPW-ZIS-MZD-X4G-R62 | 17.2.2020 15:14 | A3 | 50645 | 00000011000017 | PROSTEDK na pľigovnu hapti pľibek pro hapti novok | 1010017 | 00000011000017 | New | 02 | 17000011000017 | Novok hapti 000017 | 0 | |
| <input type="checkbox"/> | CZ-KPW-ZIP-G11-3P2-P87 | 17.2.2020 14:57 | A2 | 50420 | 00000011000017 | PROSTEDK na pľigovnu hapti pľibek pro hapti novok | 1010017 | 00000011000017 | New | 02 | 17000011000017 | Novok hapti 000017 | 0 | |
| <input type="checkbox"/> | CZ-KPW-YHA-SHH-V7D-0HA | 17.2.2020 14:38 | A3 | 50645 | 00000011000017 | PROSTEDK na pľigovnu hapti pľibek pro hapti novok | 1010017 | 00000011000017 | New | 02 | 17000011000017 | Novok hapti 000017 | 0 | |
| <input type="checkbox"/> | CZ-KPW-YGD-ZSU-9F5-775 | 17.2.2020 14:37 | A52 | 49694 | 00000011000017 | PROSTEDK na pľigovnu hapti pľibek pro hapti novok | 1010017 | 00000011000017 | New | 02 | 17000011000017 | Novok hapti 000017 | 0 | |
| <input type="checkbox"/> | CZ-KPW-WCS-FDV-79L-N8G | 17.2.2020 13:25 | A2 | 50017 | 00000011000017 | PROSTEDK na pľigovnu hapti pľibek pro hapti novok | 1010017 | 00000011000017 | New | 02 | 17000011000017 | Novok hapti 000017 | 0 | |
| <input type="checkbox"/> | CZ-KPW-W2C-SXG-R41-CM7 | 17.2.2020 13:15 | A2 | 49901 | 00000011000017 | PROSTEDK na pľigovnu hapti pľibek pro hapti novok | 1010017 | 00000011000017 | New | 02 | 17000011000017 | Novok hapti 000017 | 0 | |

https://portal.czmvo.cz/alerts/?setlang=en

MAIN PAGE - CONTROLS

9. Export selected (marked) items only.

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

The screenshot displays the 'API czmvo.cz' portal interface. The main content area is a table listing various controls, each with a checkbox, a link to the control details, and several data fields including dates, times, and status indicators. At the bottom of the table, there is a pagination bar showing '1', '2', '3', '760', and '761'. Below the pagination bar, there are buttons for 'Select All', 'Unselect All', and a 'Selected:' dropdown menu. The 'Export to CSV' button is highlighted with a green circle and the number 9. To the right of the 'Export to CSV' button is a 'Perform' button. The bottom of the page features a dark blue footer with logos for 'SÚKL', 'emvO', and 'GS1', along with copyright information for 'Národní organizace pro ověřování pravosti léčiv, z.s.' and 'Neofema s.r.o.'.

| Control ID | Date | Time | Status | Details |
|------------------------|-----------|-------|--------|---------|
| CZ-KPT-927-CSJ-AMT-B7X | 14.2.2020 | 15:27 | A52 | - |
| CZ-KPT-870-LEK-N55-YD8 | 14.2.2020 | 15:19 | A2 | 49743 |
| CZ-KPT-8HZ-MKL-RPX-GTS | 14.2.2020 | 15:09 | A2 | 50420 |
| CZ-KPT-7TH-M7C-KK0-2KU | 14.2.2020 | 14:45 | A52 | 50542 |
| CZ-KPT-7RC-YDH-3JZ-NQK | 14.2.2020 | 14:42 | A52 | 50542 |
| CZ-KPT-5BE-SU1-2PA-XSY | 14.2.2020 | 13:20 | A2 | - |
| CZ-KPT-5BC-D40-R9M-8GU | 14.2.2020 | 13:20 | A2 | - |
| CZ-KPT-5B9-SNU-N8P-XY8 | 14.2.2020 | 13:20 | A2 | - |
| CZ-KPT-5B9-W3S-SNG-MRW | 14.2.2020 | 13:17 | A2 | - |

Displayed: 1-50 of 38005 records, Count per page: 50

Select All Unselect All Selected: Export to CSV Perform

ALERTS FILTERS

Button “*Alerts*” shows all alerts assigned to the end user. 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**, **period**, **Error code**, **Group code**, **Product code**, **Product name**, **Batch ID**, **Serial number**, **Alert state**, **MAH ID**, **MAH name**, **Archiving attribute**, **Request for additional information**.

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*”.

The screenshot shows the 'Alerts' page of the API czmvo.cz. The page has a header with the logo of the 'Národní organizace pro ověřování pravosti léčiv' and a navigation bar with tabs: ALERTS, EXCEPTIONS, SET COLUMNS, DOCUMENTATION, FILTER RECORDS (highlighted), and EXPORT. Below the navigation bar, there is a section titled 'Alerts' with a filter form. The filter form contains the following fields:

- UPRC:
- Created: from to
- Error code:
- Group code:
- Product code:
- Product name:
- Batch ID:
- Serial number:
- Alert state:
- MAH ID:
- MAH name:
- Archived:
- Request to End User:

A green box highlights the filter form, and a green button labeled 'Filter' is located at the bottom right of the form. Below the filter form, there is a table of alerts. The table has the following columns: Action, UPRC, Created, Error code, Group code, Product code, Product name, Batch ID, Serial number, Alert state, Organization ID, Location code, Location name, Days since last change, and Arch. The table displays 4 records, with the first three being highlighted in green. The first record is for UPRC CZ-KPW-ZL0-GYS-QM2-A51, created on 17.2.2020 at 15:15, with error code A3 and group code 50645. The second record is for UPRC CZ-KPW-ZIS-MZD-X4G-R62, created on 17.2.2020 at 15:14, with error code A3 and group code 50645. The third record is for UPRC CZ-KPW-Z1P-G11-3P2-PB7, created on 17.2.2020 at 14:57, with error code A2 and group code 50420. The fourth record is for UPRC CZ-KPW-YHA-5HH-V7D-QHA, created on 17.2.2020 at 14:38, with error code A3 and group code 50645. The table also shows a pagination bar at the bottom with '1 2 3 ... 760 761' and a 'Display: 1-50 of 38005 records, Count per page: 50' indicator.

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 the API czmvo.cz interface. A 'Select columns' dialog box is open, allowing users to choose which columns to display. The dialog has a table with 'Show' and 'Column' headers. The 'Show' column contains checkboxes, and the 'Column' column lists the available columns. The 'Ok' button is highlighted with a green box.

| Show | Column |
|-------------------------------------|-------------------------|
| <input checked="" type="checkbox"/> | UPRC |
| <input checked="" type="checkbox"/> | Created |
| <input checked="" type="checkbox"/> | Error code |
| <input checked="" type="checkbox"/> | Group code |
| <input checked="" type="checkbox"/> | Product code |
| <input checked="" type="checkbox"/> | Product name |
| <input checked="" type="checkbox"/> | Batch ID |
| <input checked="" type="checkbox"/> | Serial number |
| <input checked="" type="checkbox"/> | Alert state |
| <input checked="" type="checkbox"/> | MAH ID |
| <input checked="" type="checkbox"/> | MAH name |
| <input checked="" type="checkbox"/> | Multimarket |
| <input checked="" type="checkbox"/> | Intermarket |
| <input checked="" type="checkbox"/> | Source Business Process |
| <input checked="" type="checkbox"/> | Days since last change |
| <input checked="" type="checkbox"/> | Archived |
| <input checked="" type="checkbox"/> | Request to End User |

The background interface shows the 'Alerts' section with a list of alerts. The 'SET COLUMNS' button is highlighted with a green box. The 'Ok' button in the dialog is also highlighted with a green box.

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 displays the web application interface for the National Organization for the Verification of Drug Safety (Národní organizace pro ověřování pravosti léčiv). The main content area shows a list of alerts under the 'Alerts' tab. A modal dialog is open, prompting the user to choose how to handle the downloaded file 'export_2020FebTue_130622.csv'. The 'Save File' option is selected. The background table lists various alerts with their unique identifiers, states, and associated MAH (Marketing Authorization Holder) information.

| number | Alert state | MAH ID | MAH název | Days since last change | Request to End User | Action |
|--------|-------------|---------|-----------|------------------------|---------------------|-----------------|
| 130622 | New | CZ011_7 | Savit | 0 | 0 | [Edit] [Delete] |
| 130622 | New | CZ011_7 | Savit | 0 | 0 | [Edit] [Delete] |
| 130622 | New | CZ011_7 | Savit | 0 | 0 | [Edit] [Delete] |
| 130622 | New | CZ011_7 | Savit | 0 | 0 | [Edit] [Delete] |
| 130622 | New | CZ011_7 | Savit | 0 | 0 | [Edit] [Delete] |
| 130622 | New | CZ011_7 | Savit | 0 | 0 | [Edit] [Delete] |
| 130622 | New | CZ011_7 | Savit | 0 | 0 | [Edit] [Delete] |
| 130622 | New | CZ011_7 | Savit | 0 | 0 | [Edit] [Delete] |
| 130622 | New | CZ011_7 | Savit | 0 | 0 | [Edit] [Delete] |
| 130622 | New | CZ011_7 | Savit | 0 | 0 | [Edit] [Delete] |

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 the 'portal.czmvo.cz/alerts/' web interface. A table of alerts is visible, with several rows highlighted. At the bottom of the table, there are buttons for 'Select All', 'Unselect All', and a dropdown menu currently set to 'Export to CSV', followed by a 'Perform' button. A Firefox download dialog is open in the center, titled 'Opening export_2020FebTue_132115.csv'. It informs the user that they have chosen to open a CSV file from the portal. The dialog asks 'What should Firefox do with this file?' and offers three options: 'Open with Browse...', 'Save File' (which is selected), and 'Do this automatically for files like this from now on.'. 'OK' and 'Cancel' buttons are at the bottom right of the dialog. The footer of the page includes logos for SÚKL, emvó, and GS1, along with copyright information for Národní organizace pro ověřování pravosti léčiv, z.s. and Neofema s.r.o.

VIEW GROUP OF ALERTS

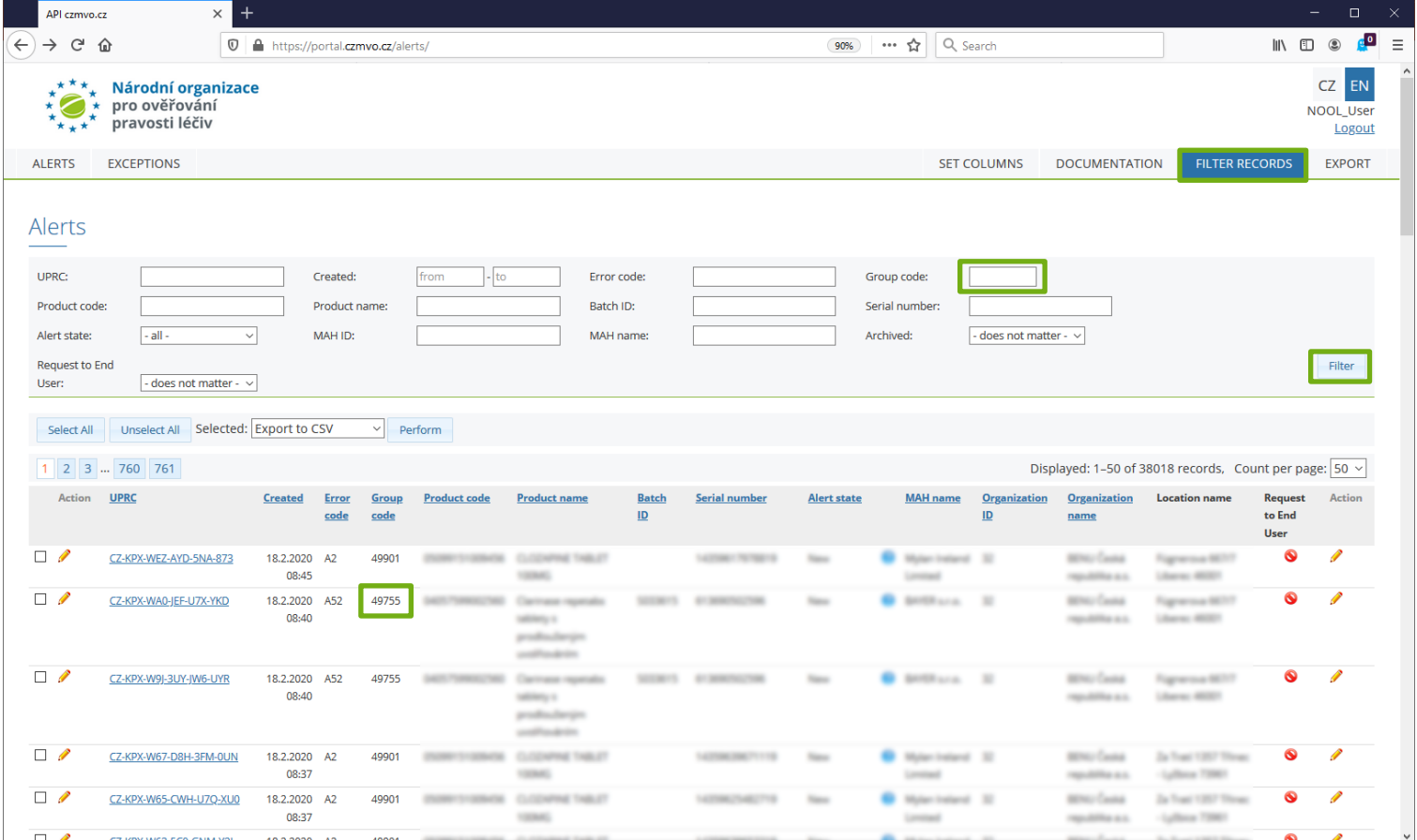
Use filter function. Put the group ID to the filter and click “*Filter*”. List of all alerts belonging to the group be listed.

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 grouping

- ✓ 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.



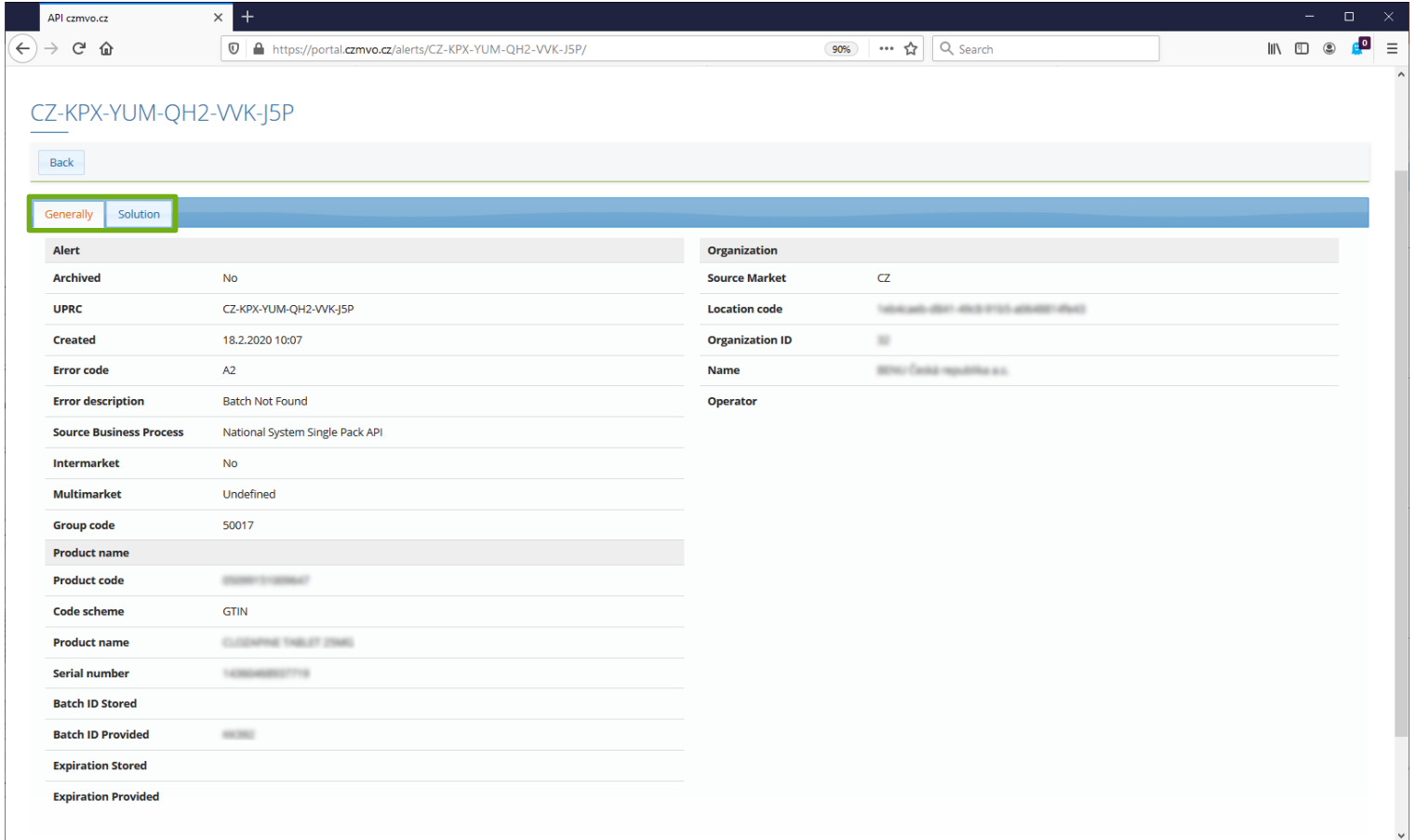
VIEW ALERT DETAIL

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.

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

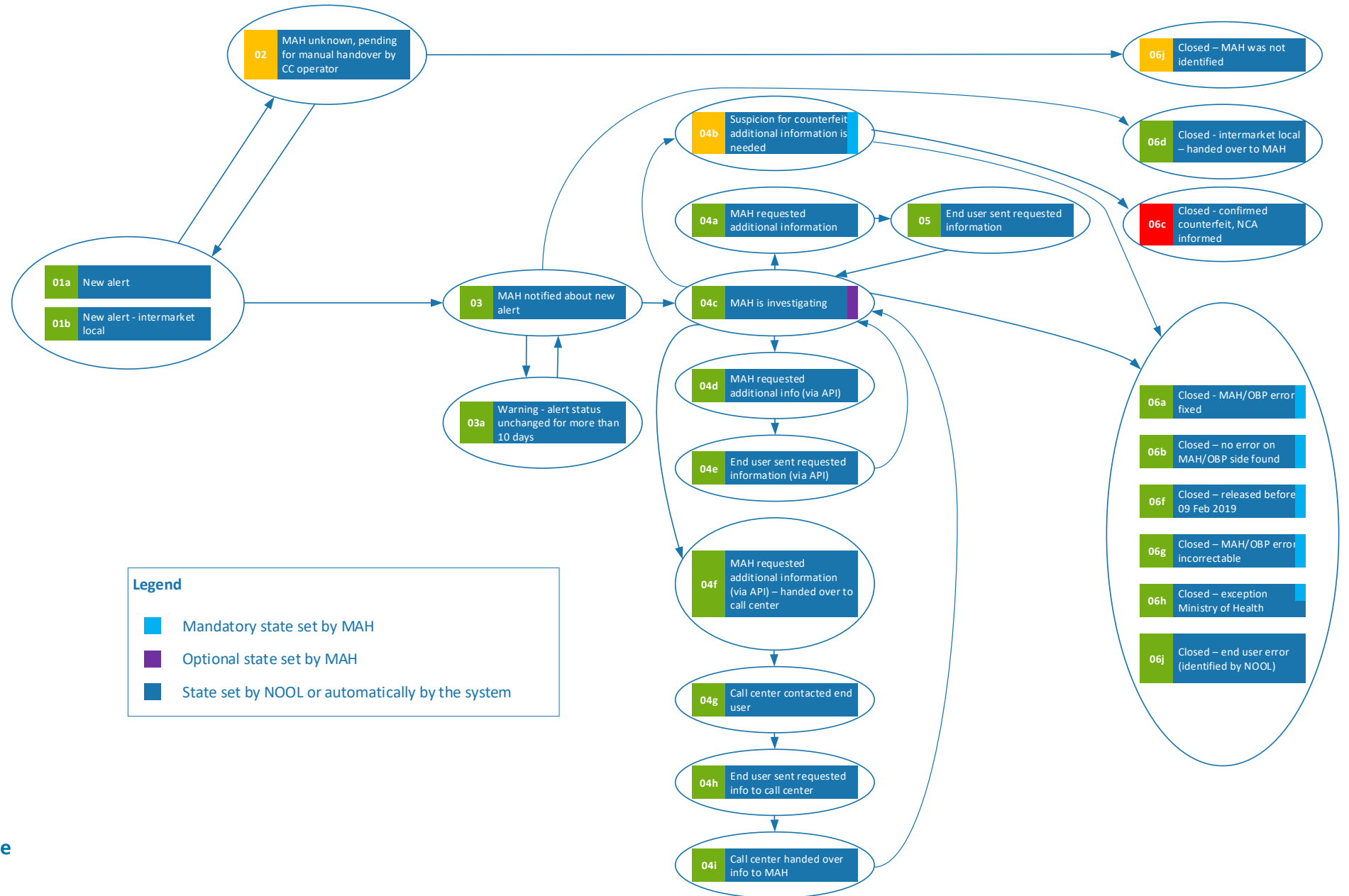


ALERT FLOW

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.**

Closed alert states are most interesting for **end users**, to decide whether repeat verify operation (in case of correctable error) or return pack back to distributor. (incorrectable error).

Important are also states when MAH is asking for additional information.

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 |
|-------|--|------------|-------------------------------|
| 06a | Closed - MAH/OBP error fixed | MAH | Verify pack again |
| 06b | Closed – no error on MAH/OBP side found | MAH | Verify pack again |
| 06c | Closed – suspicion for counterfeit, NCA informed | NOOL | |
| 06d | Closed – Intermarket Local Handed over to MAH | NOOL | |
| 06f | Closed – released before 09 Feb 2019 | MAH/system | |
| 06g | Closed – MAH/OBP error incorrectable | MAH | Return pack to distributor |
| 06h | Closed – exception Ministry of Health | MAH/system | |
| 06j | Closed – end user error (identified by NOOL) | | Verify pack again |
| 04d | MAH requested additional information (via API) | System | Provide requested information |

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.

Communication is showed in alert detail in sheet “**Solution**” in section Messages at the bottom of the page.

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 displays the web interface for API czmvo.cz. The browser address bar shows the URL: https://sandbox.czmvo.cz/alerts/CZ-KNY-9TW-0V0-M3E-MN1/. The interface has two tabs: 'Generally' and 'Solution', with 'Solution' being the active tab. Below the tabs, there is a table with the following data:

| Priority | Low |
|-------------------|---|
| Alert state | Closed - end user error |
| State description | MAH has ruled out a mistake on its side - check scanner settings - can be verified again! |
| Last state change | 10.2.2020 16:32 |
| Last alert change | 10.2.2020 16:32 |

Below the table, there is a section titled 'Investigation result'.

On the right side of the interface, there is a section titled 'Processing by Call centrum' and 'Processing by API'. The 'Processing by API' section shows a list of messages:

- 10.2.2020 15:13 Zaslání zprávy ID: 117
- 10.2.2020 15:13 nastaven stav ID: 12 (Uzavřeno - chyba KU)
- 10.2.2020 15:16 nastaven stav ID: 21 (MAH - Investigace)
- 10.2.2020 15:18 Zaslání zprávy ID: 120
- 10.2.2020 16:32 Zaslání zprávy ID: 121
- 10.2.2020 16:32 nastaven stav ID: 12 (Uzavřeno - chyba KU)

Below the messages, there is a section titled 'Messages' which contains a list of messages:

- Chyba_End-User** 10.2.2020 16:32
Chyba na straně koncového uživatele. Zkontrolujte nastavení snímače. V případě nesouhlasu zašlete zdůvodnění.
- Chyba_End-User** 10.2.2020 15:13
Chyba na straně koncového uživatele. Zkontrolujte nastavení snímače. V případě nesouhlasu zašlete zdůvodnění.
- Re: Chyba_End-User** 10.2.2020 15:15
Nesouhlasíme - viz foto OBALU - je chybně tisk na obalu.
- Re: Re: Chyba_End-User** 10.2.2020 15:18
File: [Screenshot \(4\).png](#) (367 KB)


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*”.

API czmvo.cz

https://sandbox.czmvo.cz/alerts/?%2Falerts%2F=&filtr[cislo]=8&f 90%

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NOOL_User
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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: Archived:
Request to End User:

Select All Unselect All Selected: Export to CSV

Displayed: 1-2 of 2 records, Count per page: 50

| Action | UPRC | Created | Error code | Group code | Product code | Product name | Batch ID | Serial number | Alert state | Request to End User | Action |
|--|--|--------------------|------------|------------|------------------|--|------------------|------------------|----------------------------|---|---|
| <input type="checkbox"/>  | CZ-KNZ-X0Z-KN4-F5Y-R8F | 23.1.2020 15:43 | A7 | - | 0000000000000000 | Citronová a pomerančová kyselina v kombinaci s hydrogenným fosforem a hydrogenným kyslíkem | 0000000000000000 | 0000000000000000 | MAH API requests End Users |   |  |
| <input type="checkbox"/>  | CZ-KNY-9TW-0V0-M3E-MN1 | 22.1.2020 08:24 | A2 | 48756 | 0000000000000000 | Tragopanax flavescens extractum in a pro-lyophilized form | 0000000000000000 | 0000000000000000 | Closed - end user error |   |  |

Displayed: 1-2 of 2 records, Count per page: 50

COMMUNICATION – SEND ANSWER TO MAH

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

In alert detail click switch to sheet “*Solution*”. You can see request in the section Messages. Click on button “*Answer*”. New dialog will appear. Attachment can be added via button “*Browse*” and optionally message or text can be inserted in array “*Note*”. Message will be sent by clicking button “*Answer*”.

The screenshot shows a web browser window with the URL <https://sandbox.czmvo.cz/alerts/CZ-KNZ-X0Z-KN4-F5Y-R8F/>. The page displays an alert detail for the ID CZ-KNZ-X0Z-KN4-F5Y-R8F. The 'Solution' tab is selected, showing a table with alert details and a 'Messages' section. A dialog box is open for sending an answer, with fields for 'File' (containing a 'Browse...' button and a file type hint), 'Note' (a text area), and 'Answer' (a button). The 'Answer' button is highlighted with a green box. The footer of the page includes logos for SÚKL, emvO, and GS1, and the text 'pravosti léčiv, z.s.' and 'Neofema, s.r.o.'.

| Priority | Low |
|----------------------|-----------|
| Alert state | MAH API r |
| State description | MAH requ |
| Last state change | 10.2.2020 |
| Last alert change | 10.2.2020 |
| Investigation result | |

Messages

Fotka_EAN 10.2.2020 15:08

Žádáme o zaslání fota obalu LP, s čitelným 2D kódem. Nafotťte prosím i vizuálně čitelné údaje (EAN, šarže, SN, datum expirace, apod.)

File **Browse...** No file selected.
Filetype should be txt, pdf, csv, jpg, tiff, png

Note

Answer **Cancel**

Answer

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. |



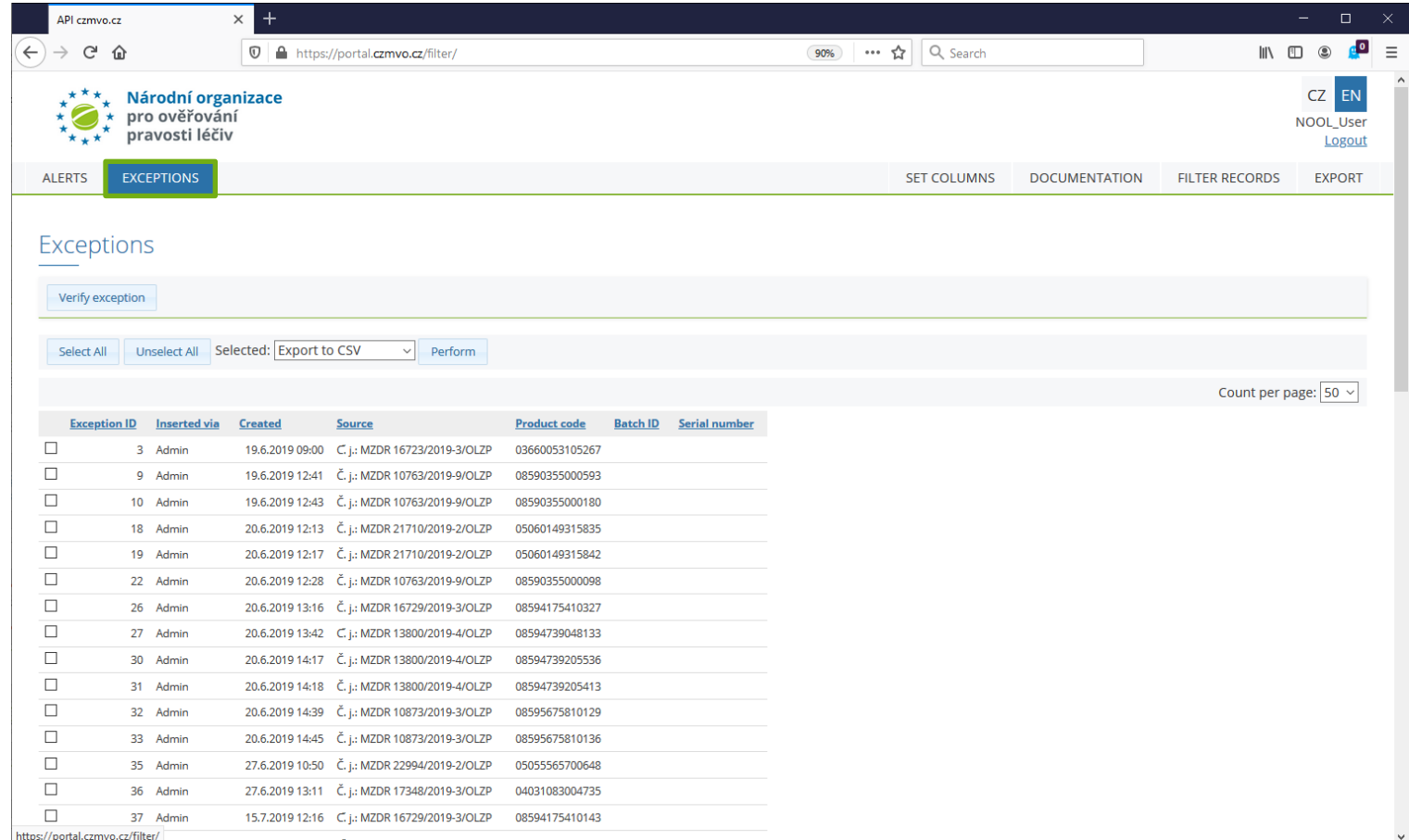
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EXCEPTIONS

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.

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



| Exception ID | Inserted via | Created | Source | Product code | Batch ID | Serial number |
|--------------------------|--------------|-----------------|-------------------------------|----------------|----------|---------------|
| <input type="checkbox"/> | 3 Admin | 19.6.2019 09:00 | C, j.: MZDR 16723/2019-3/OLZP | 03660053105267 | | |
| <input type="checkbox"/> | 9 Admin | 19.6.2019 12:41 | Č, j.: MZDR 10763/2019-9/OLZP | 08590355000593 | | |
| <input type="checkbox"/> | 10 Admin | 19.6.2019 12:43 | Č, j.: MZDR 10763/2019-9/OLZP | 08590355000180 | | |
| <input type="checkbox"/> | 18 Admin | 20.6.2019 12:13 | Č, j.: MZDR 21710/2019-2/OLZP | 05060149315835 | | |
| <input type="checkbox"/> | 19 Admin | 20.6.2019 12:17 | Č, j.: MZDR 21710/2019-2/OLZP | 05060149315842 | | |
| <input type="checkbox"/> | 22 Admin | 20.6.2019 12:28 | Č, j.: MZDR 10763/2019-9/OLZP | 08590355000098 | | |
| <input type="checkbox"/> | 26 Admin | 20.6.2019 13:16 | Č, j.: MZDR 16729/2019-3/OLZP | 08594175410327 | | |
| <input type="checkbox"/> | 27 Admin | 20.6.2019 13:42 | C, j.: MZDR 13800/2019-4/OLZP | 08594739048133 | | |
| <input type="checkbox"/> | 30 Admin | 20.6.2019 14:17 | Č, j.: MZDR 13800/2019-4/OLZP | 08594739205536 | | |
| <input type="checkbox"/> | 31 Admin | 20.6.2019 14:18 | Č, j.: MZDR 13800/2019-4/OLZP | 08594739205413 | | |
| <input type="checkbox"/> | 32 Admin | 20.6.2019 14:39 | Č, j.: MZDR 10873/2019-3/OLZP | 08595675810129 | | |
| <input type="checkbox"/> | 33 Admin | 20.6.2019 14:45 | Č, j.: MZDR 10873/2019-3/OLZP | 08595675810136 | | |
| <input type="checkbox"/> | 35 Admin | 27.6.2019 10:50 | Č, j.: MZDR 22994/2019-2/OLZP | 05055565700648 | | |
| <input type="checkbox"/> | 36 Admin | 27.6.2019 13:11 | Č, j.: MZDR 17348/2019-3/OLZP | 04031083004735 | | |
| <input type="checkbox"/> | 37 Admin | 15.7.2019 12:16 | C, j.: MZDR 16729/2019-3/OLZP | 08594175410143 | | |

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 NOOL portal interface. The main content area is titled 'Exceptions' and features a table of exception records. A dialog box titled 'Verify exception' is open, prompting the user to enter a 'Product code' and a 'Batch ID'. The 'Verify' button in the dialog is highlighted with a green box. The table below contains the following data:

| Exception ID | Inserted via | Created | Source |
|--------------|--------------|-----------------|-------------------------------|
| 3 | Admin | 19.6.2019 09:00 | C. j.: MZDR 16723/2019-3/OLZP |
| 9 | Admin | 19.6.2019 12:41 | Č. j.: MZDR 10763/2019-9/OLZP |
| 10 | Admin | 19.6.2019 12:43 | Č. j.: MZDR 10763/2019-9/OLZP |
| 18 | Admin | 20.6.2019 12:13 | Č. j.: MZDR 21710/2019-2/OLZP |
| 19 | Admin | 20.6.2019 12:17 | Č. j.: MZDR 21710/2019-2/OLZP |
| 22 | Admin | 20.6.2019 12:28 | Č. j.: MZDR 10763/2019-9/OLZP |
| 26 | Admin | 20.6.2019 13:16 | Č. j.: MZDR 16729/2019-3/OLZP |
| 27 | Admin | 20.6.2019 13:42 | C. j.: MZDR 13800/2019-4/OLZP |
| 30 | Admin | 20.6.2019 14:17 | Č. j.: MZDR 13800/2019-4/OLZP |
| 31 | Admin | 20.6.2019 14:18 | Č. j.: MZDR 13800/2019-4/OLZP |
| 32 | Admin | 20.6.2019 14:39 | Č. j.: MZDR 10873/2019-3/OLZP |
| 33 | Admin | 20.6.2019 14:45 | Č. j.: MZDR 10873/2019-3/OLZP |
| 35 | Admin | 27.6.2019 10:50 | Č. j.: MZDR 22994/2019-2/OLZP |
| 36 | Admin | 27.6.2019 13:11 | Č. j.: MZDR 17348/2019-3/OLZP |
| 37 | Admin | 15.7.2019 12:16 | C. j.: MZDR 16729/2019-3/OLZP |