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.

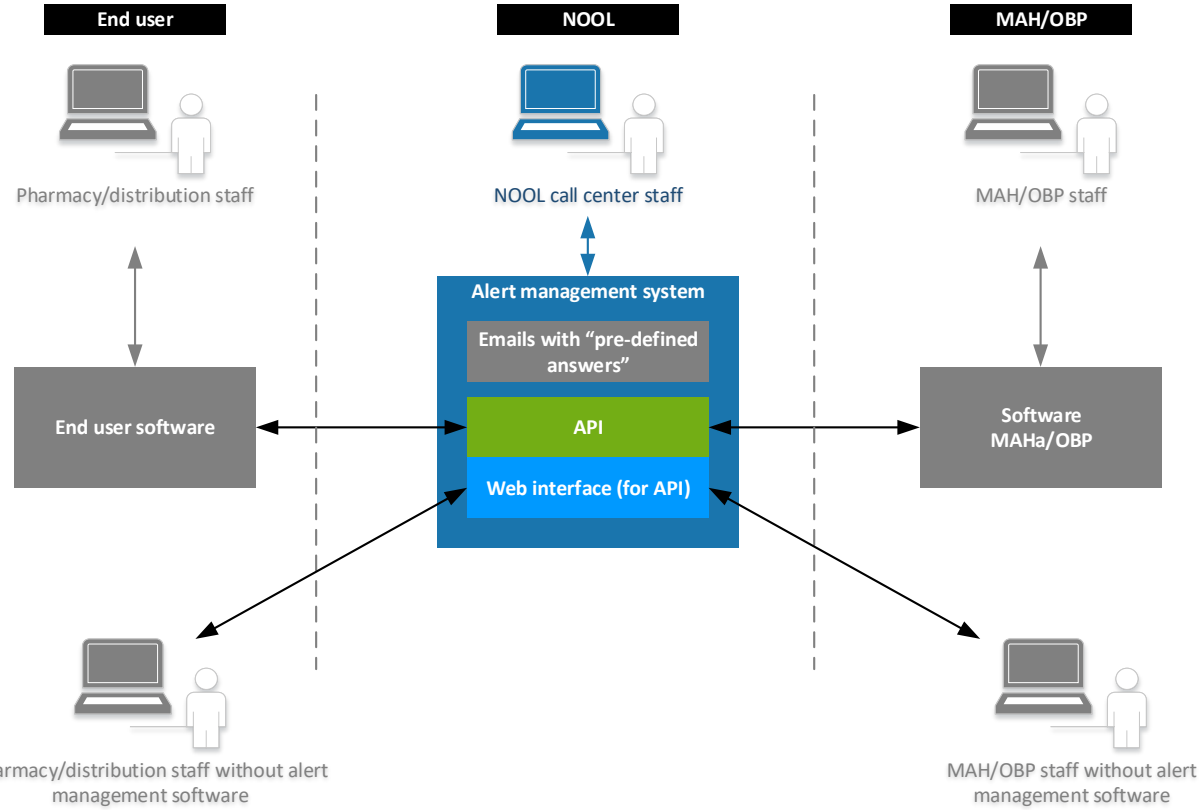
ALERT MANAGEMENT SYSTEM

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

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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.**

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..

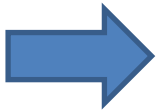
REGISTRATION FOR ACCESS CREDENTIALS

Contact

For all requests related to the registration email registrace@czmvo.cz should be used.

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

Example of registration e-mail



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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 >

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/

Produkcní prostredí/Production enviroment:
Webove rozhrani/Web interface: https://portal.czmvo.cz/
Rozhrani API/API interface: https://api.czmvo.cz/

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

NOOL team

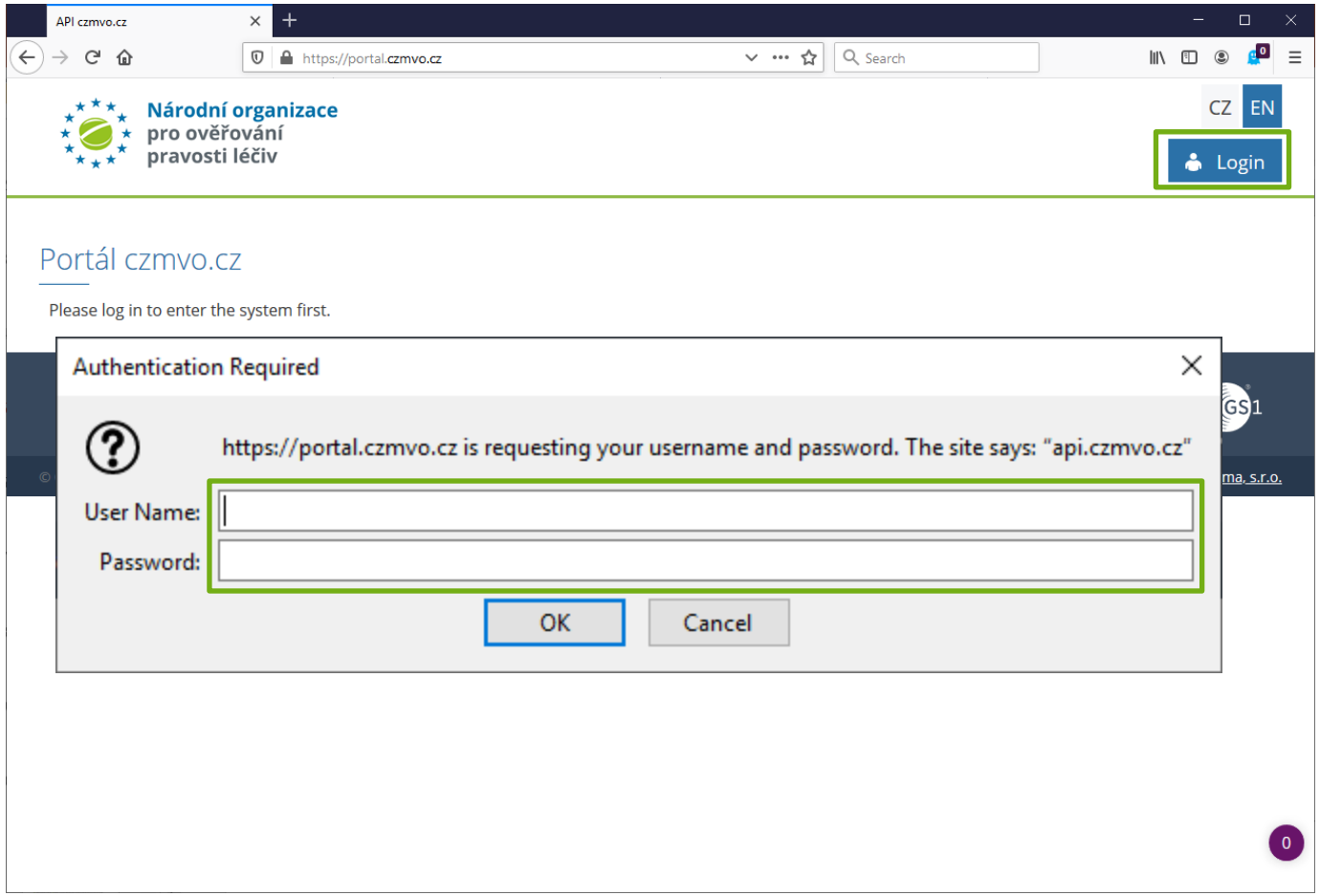
LOGIN TO NOOL ALERT MANAGEMENT SYSTEM

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).



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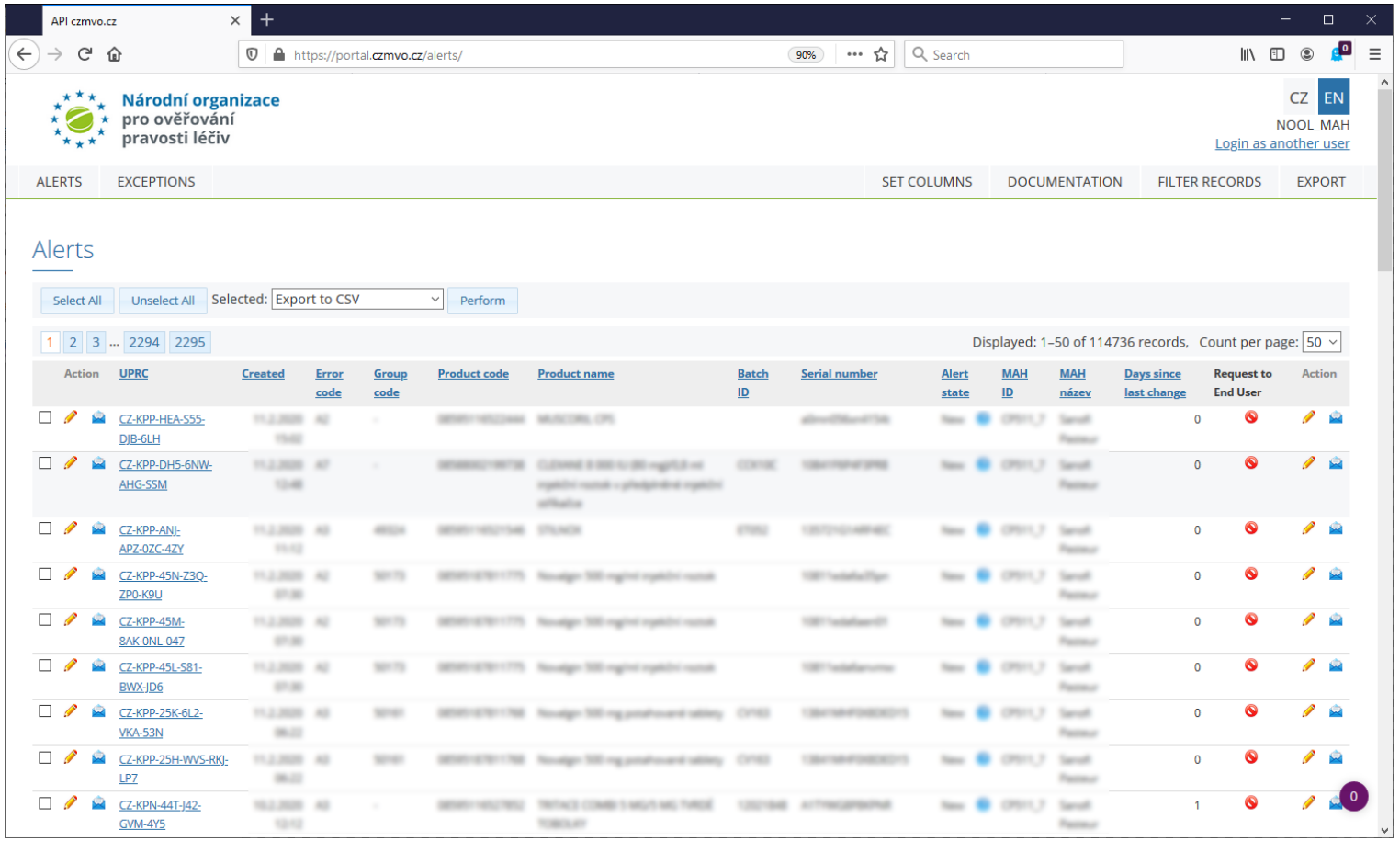
MAIN PAGE

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.



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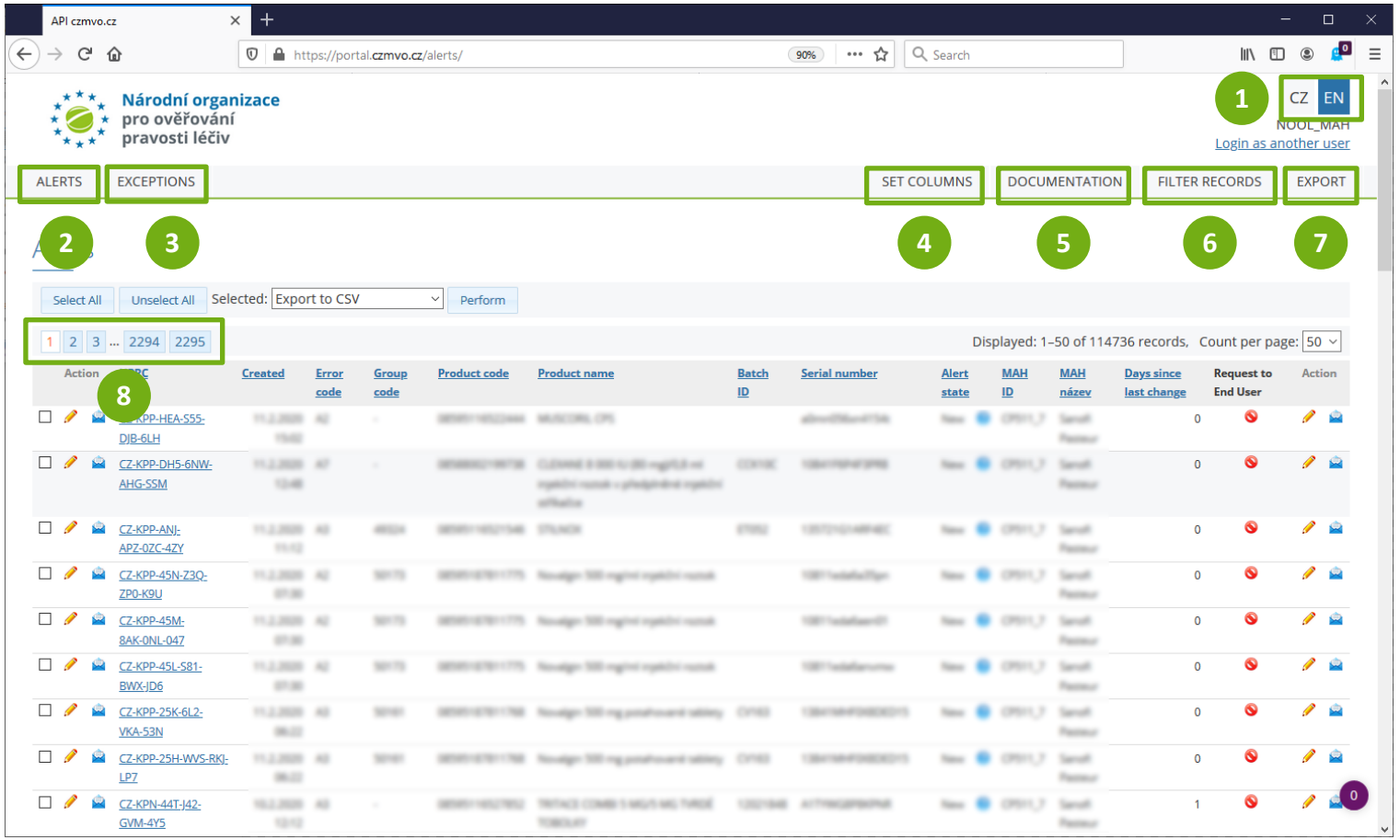
MAIN PAGE - CONTROLS

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.



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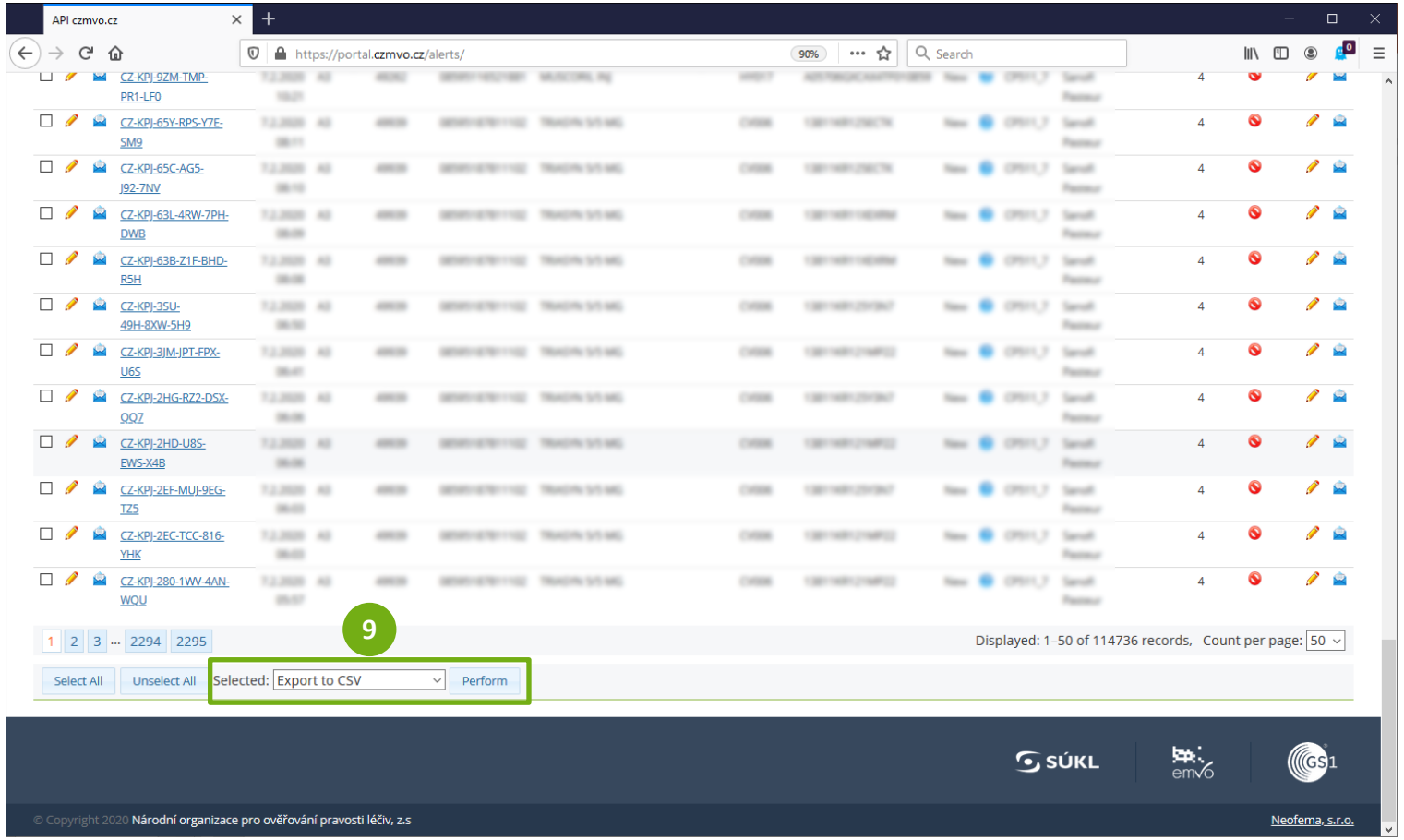
MAIN PAGE - CONTROLS

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.



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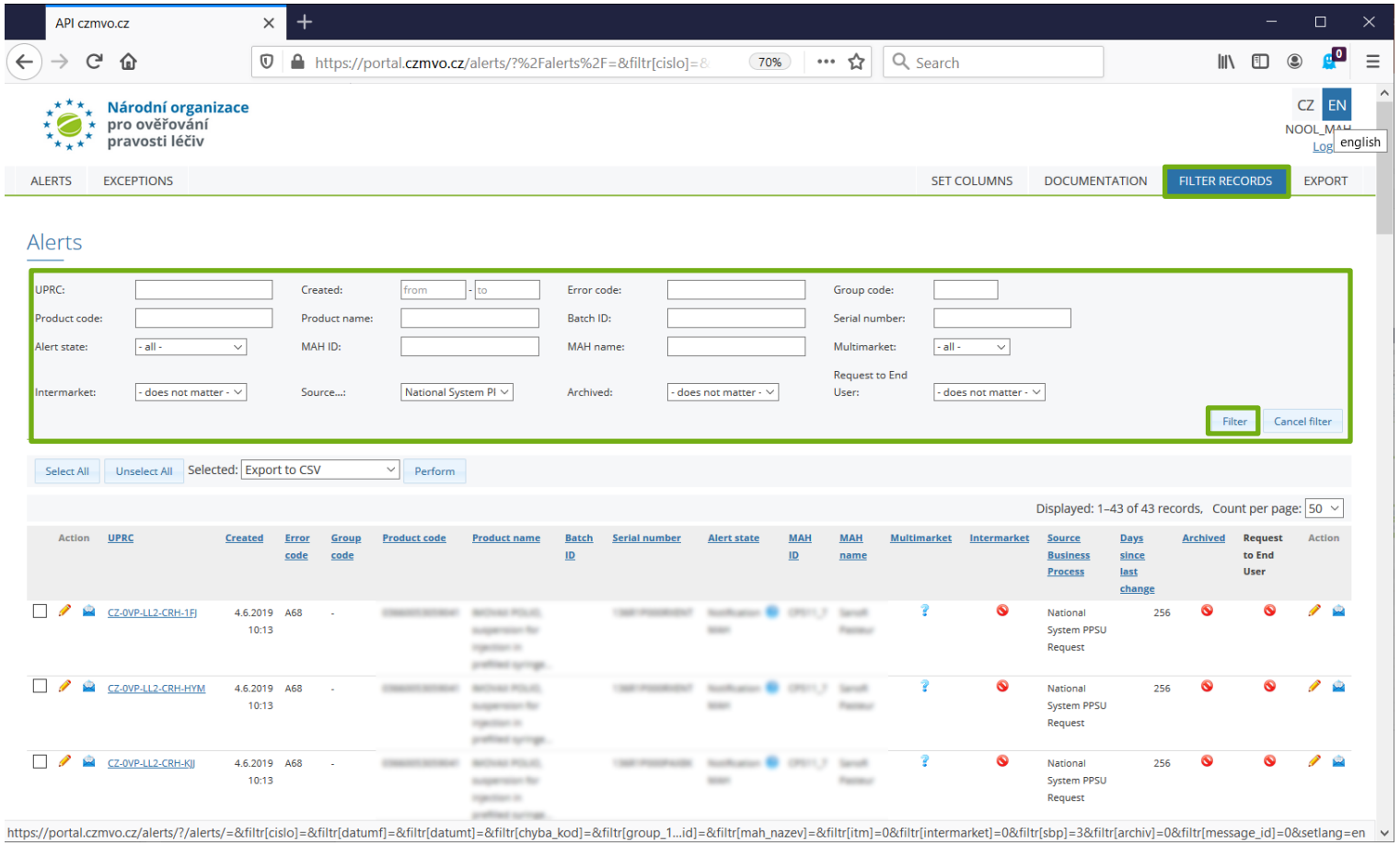
ALERTS FILTERS

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*".



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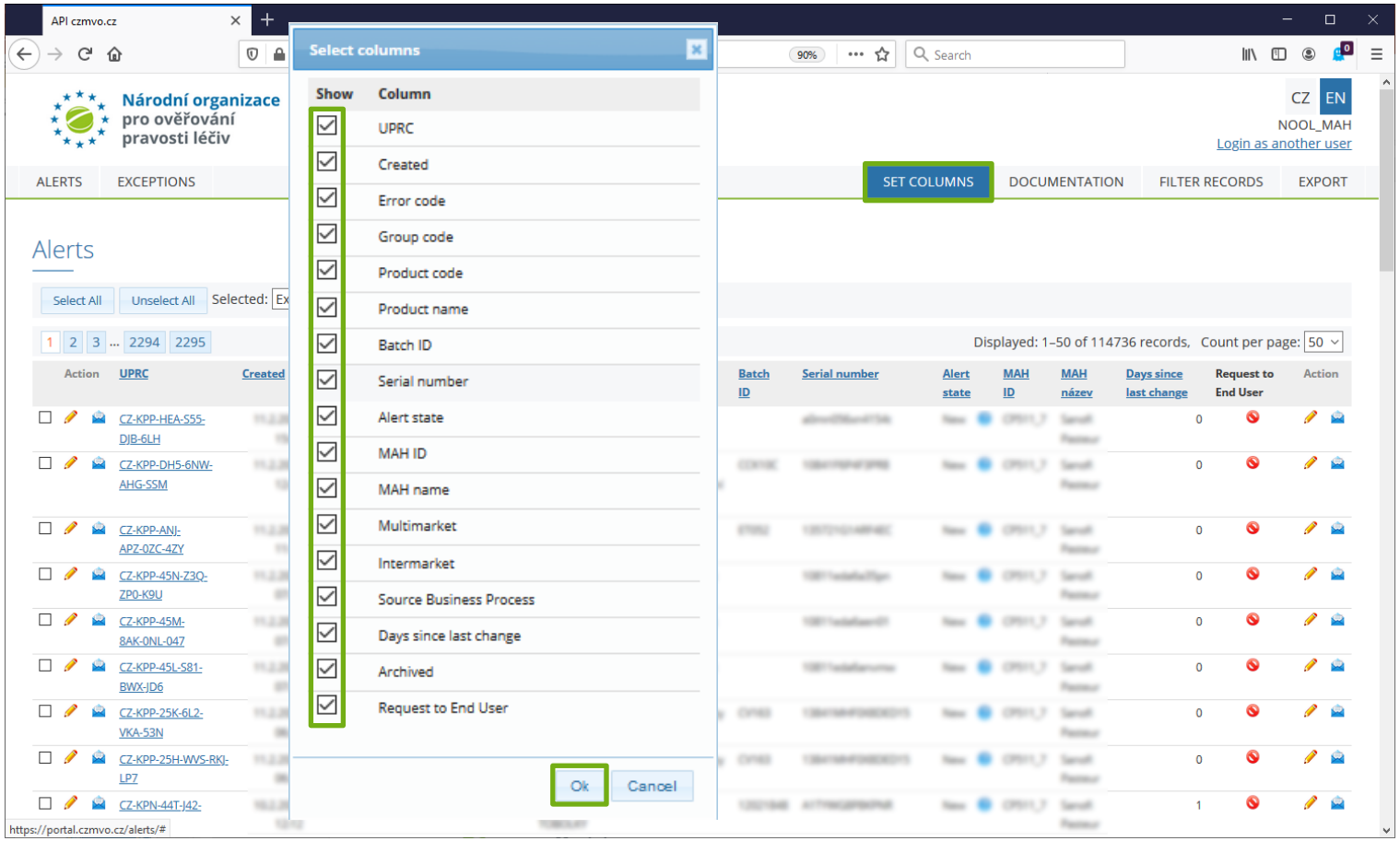
VIEW CHANGE

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*".



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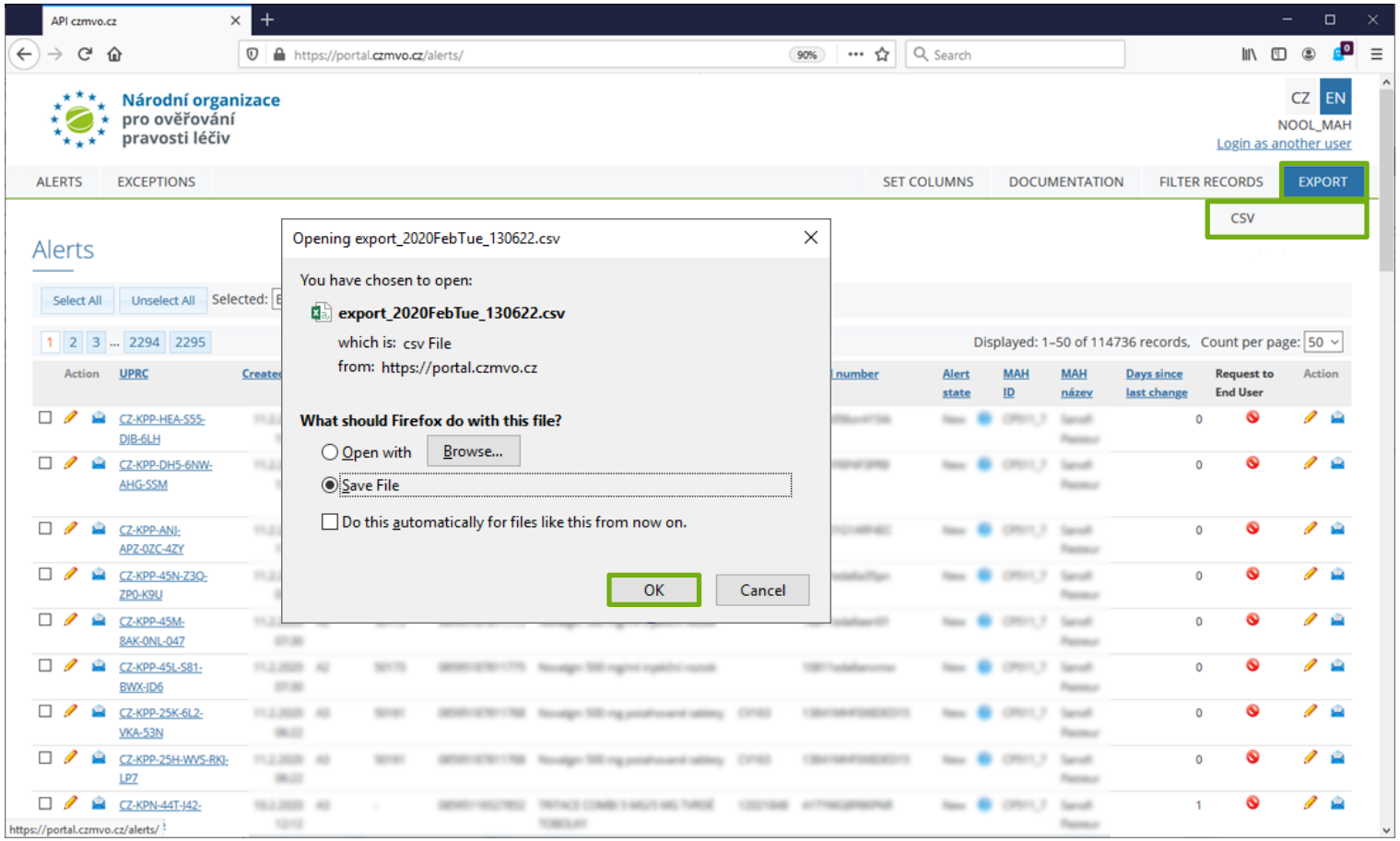
EXPORT ALL ALERTS ACCORDING FILTER

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*".



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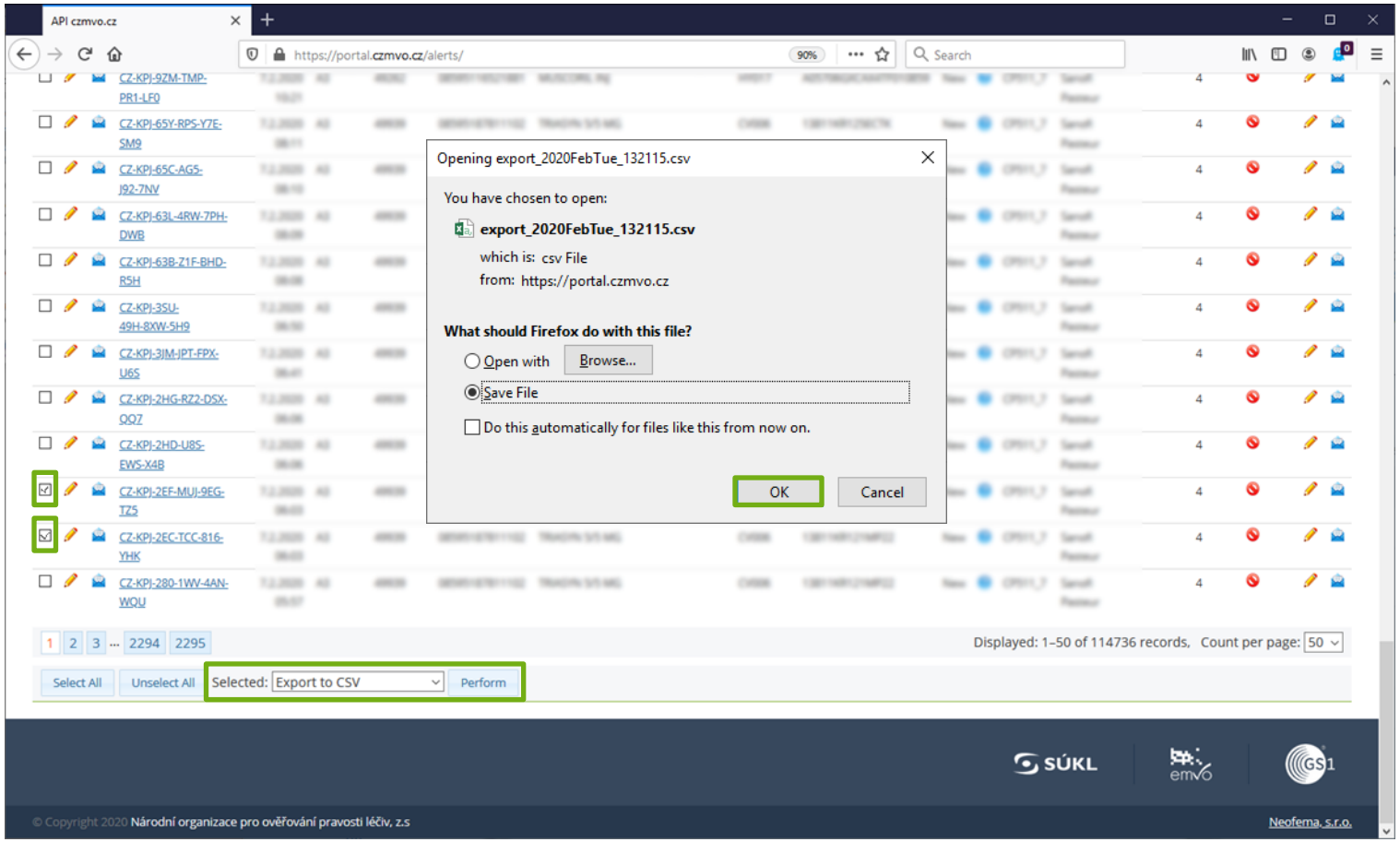
EXPORT SELECTED ALERTS

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*".



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VIEW GROUP OF ALERTS

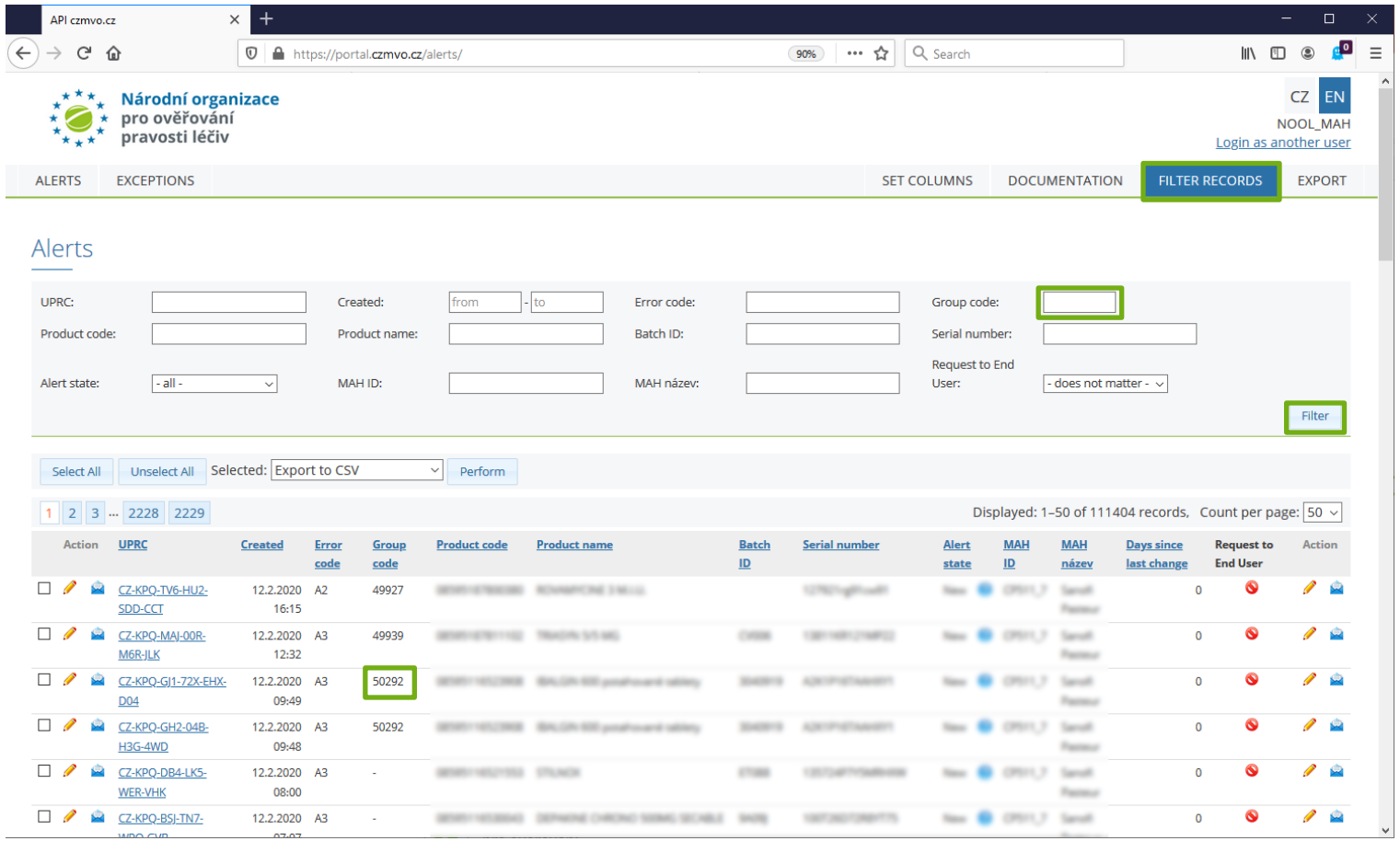
Use filter function. Put the group ID to the filter and click "*Filter*". List of all alerts belonging to the group be listed.

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.



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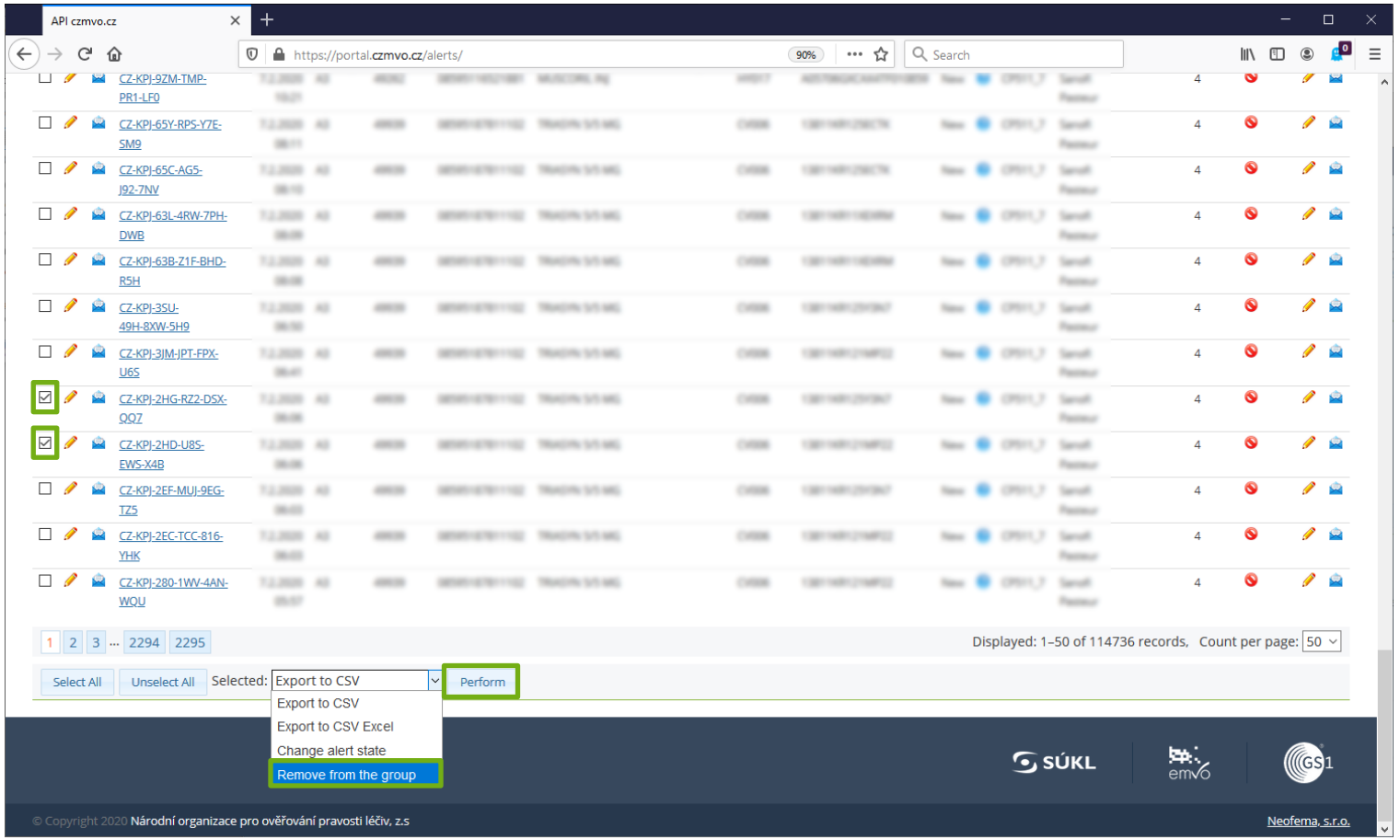
REMOVE ALERTS FROM GROUP

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*".



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VIEW ALERT DETAIL

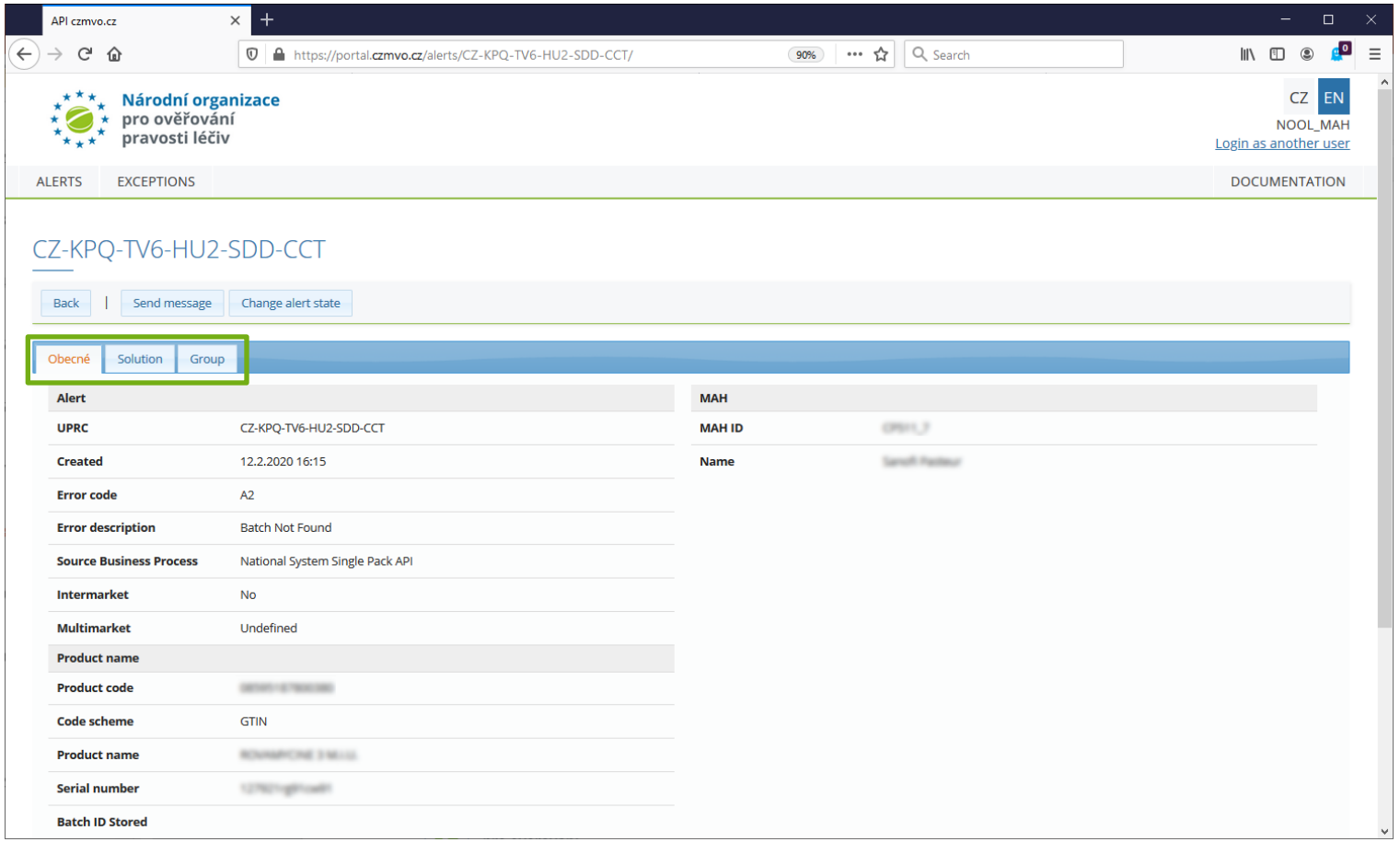
Click on the UPRC code of alert and **page with alert detail appear**. There are several lists in the alert detail.

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 od 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.



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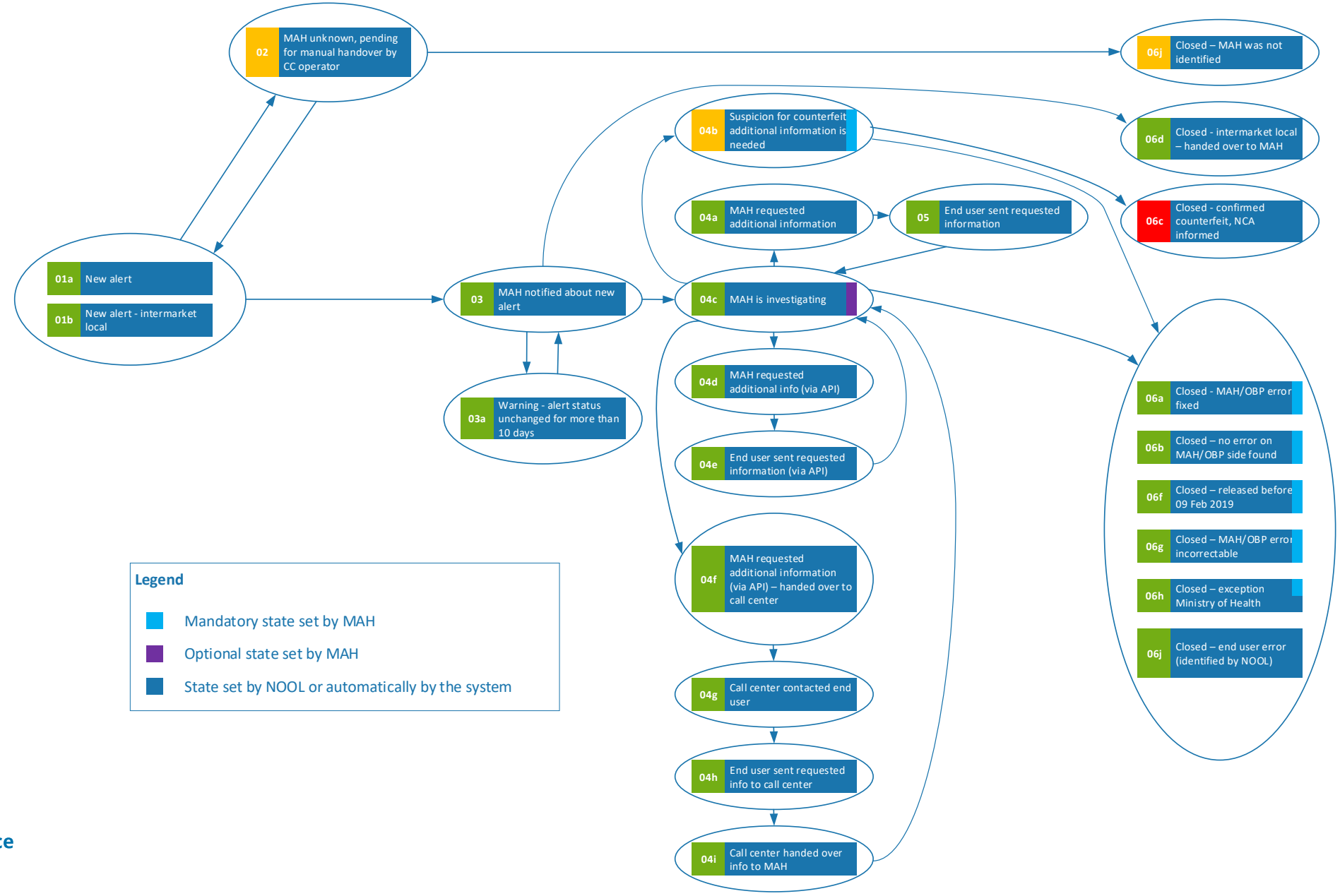
ALERT FLOW

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.



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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 incorrectable	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

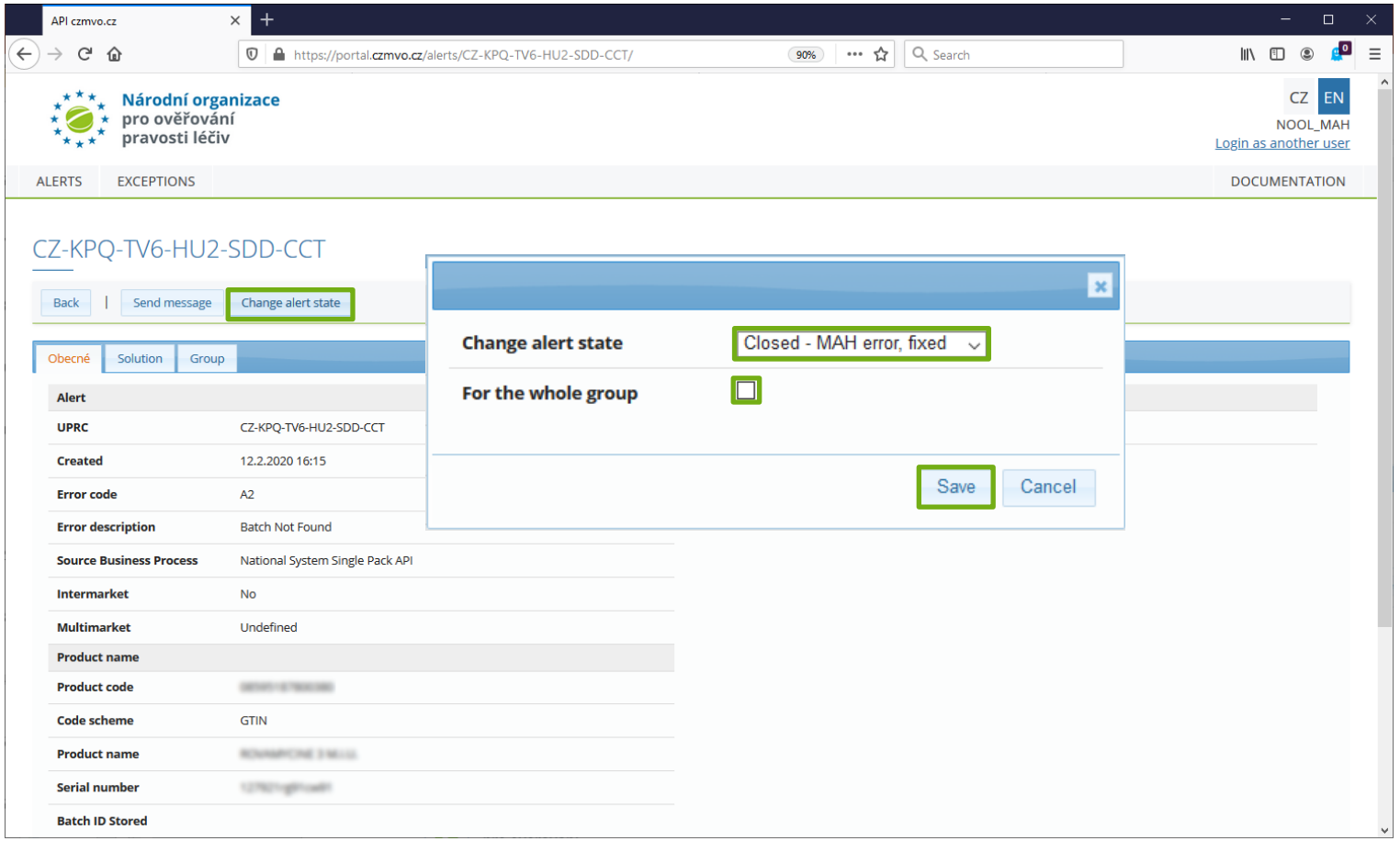
CHANGE ALERT STATE

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*".



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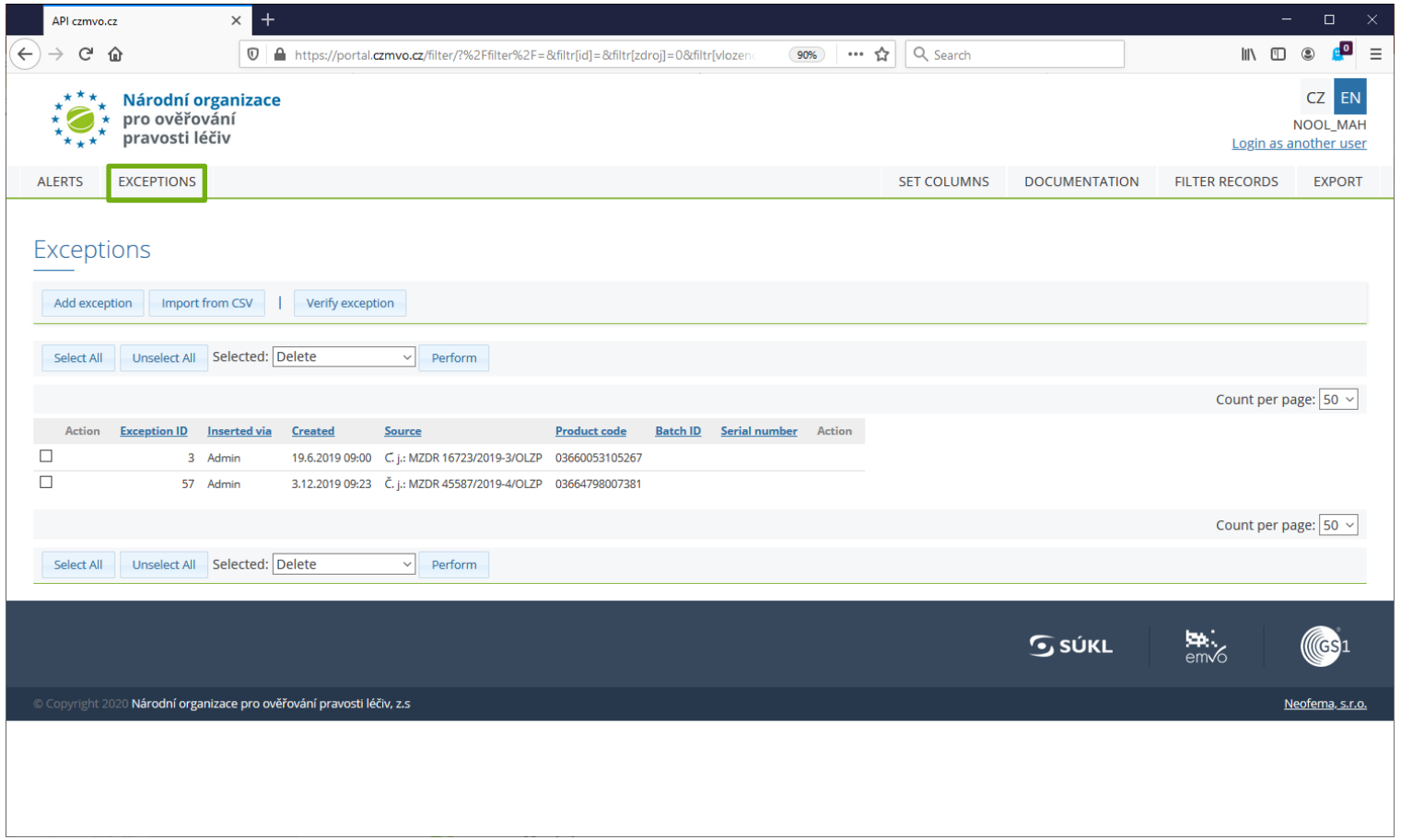
EXCEPTIONS

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.

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.



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ADD EXCEPTION

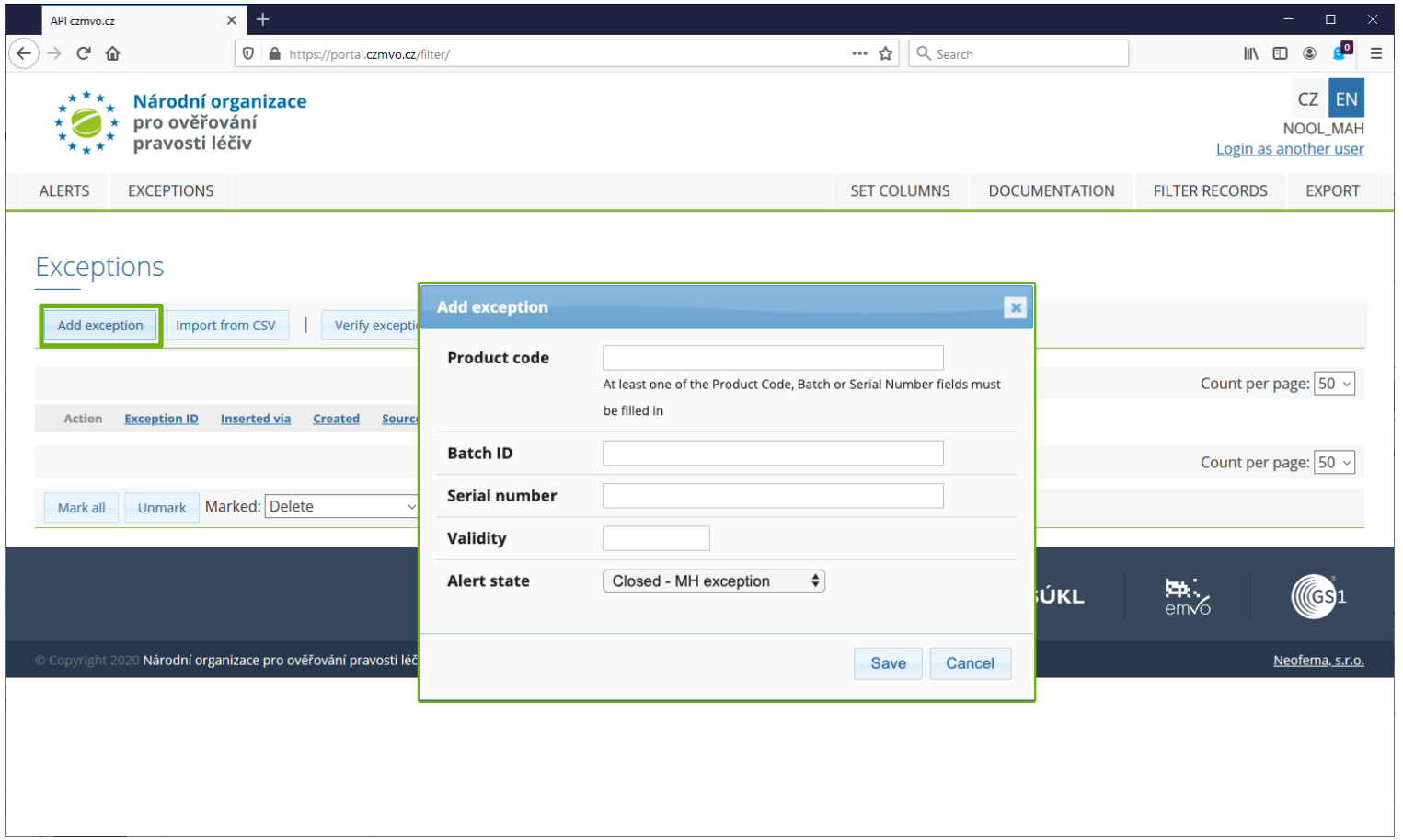
New exception can be added clicking button "*Add exception*".

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.



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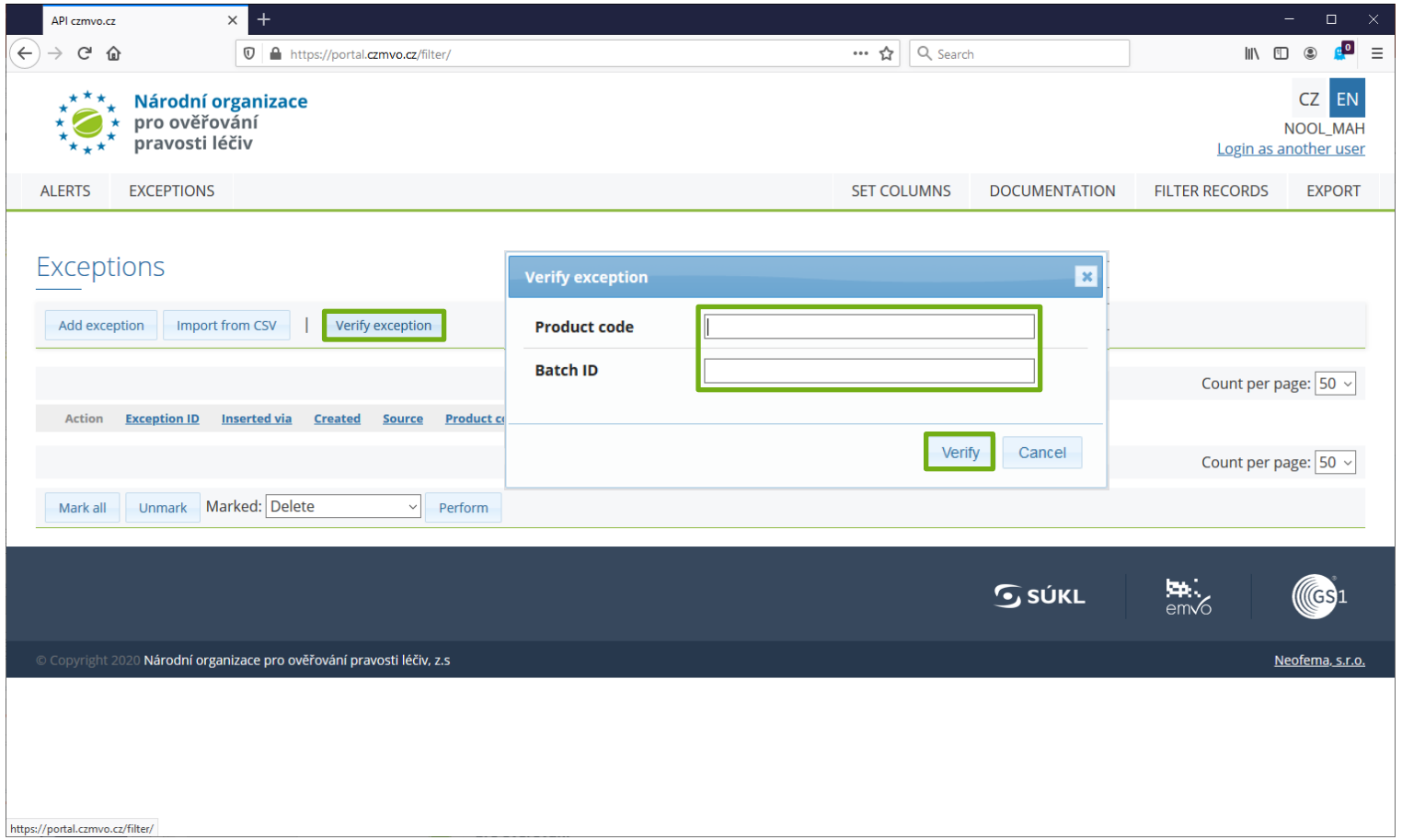
VERIFY PRODUCT FOR THE EXCEPTION

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".



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ANONYMOUS COMMUNICATION BETWEEN MAH AND END USER

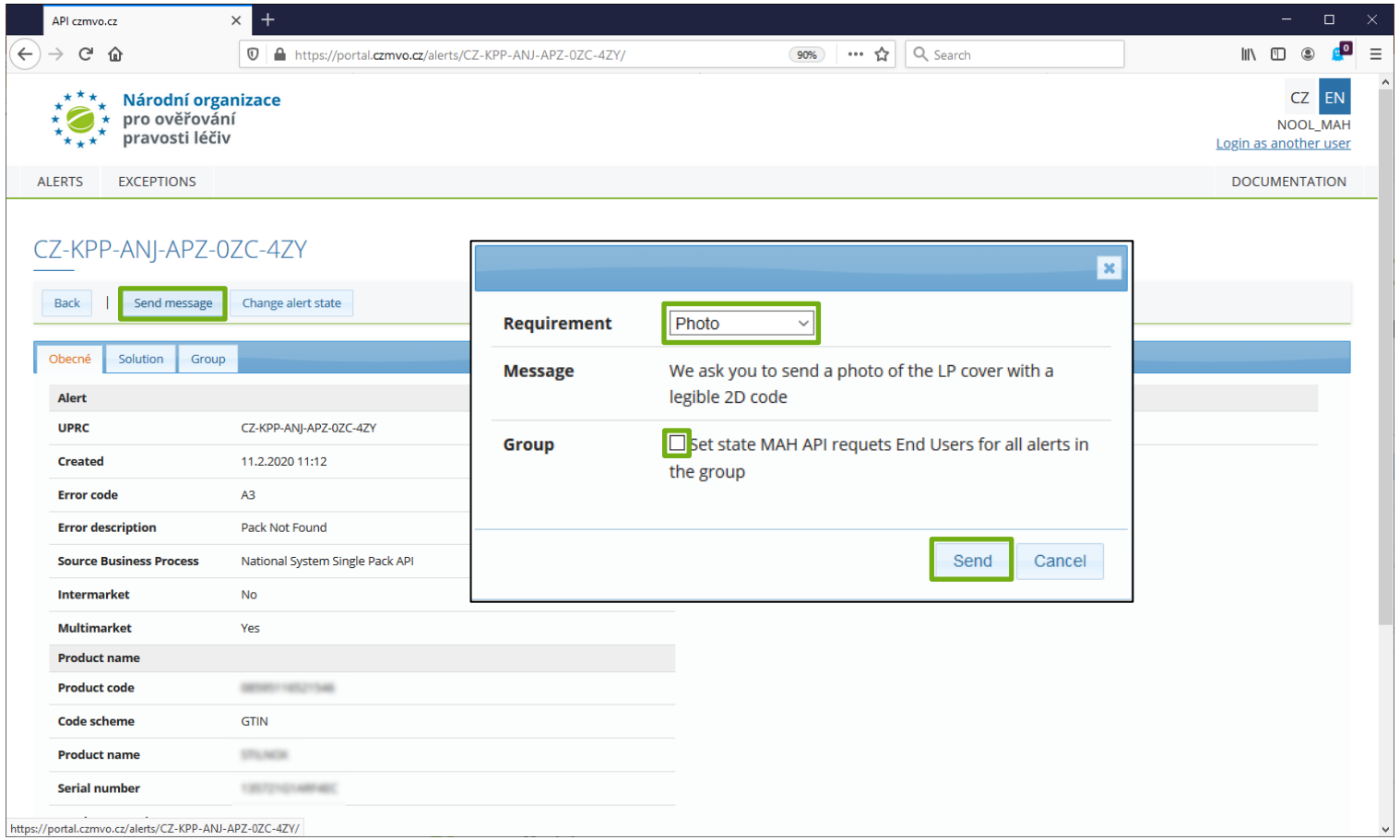
Alert management system supports **anonymous exchange** of "predefined" messages between MAH and end user.

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.



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COMMUNICATION – PREDEFINED MESSAGES

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

Note:

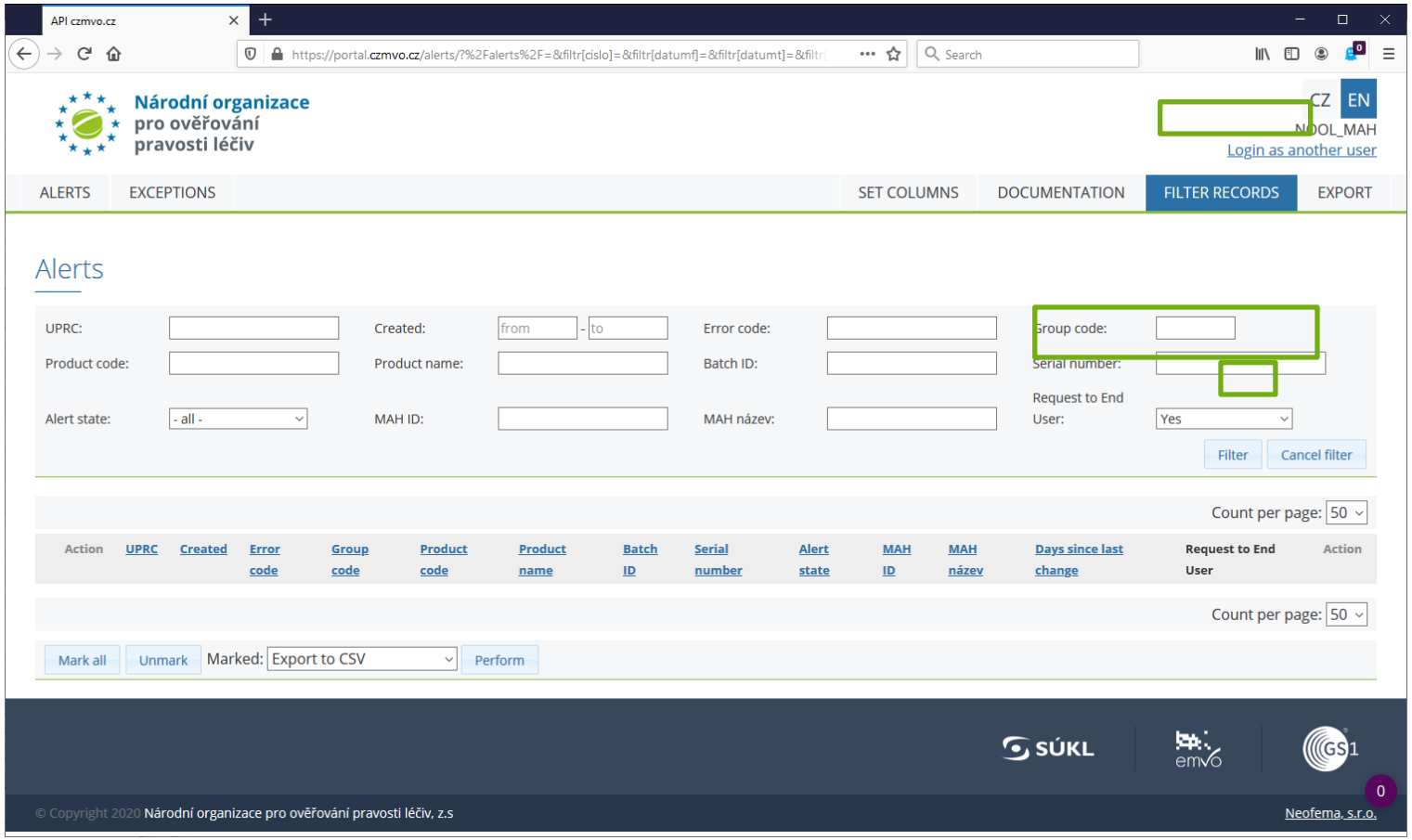
List of messages **may change based on feedback** from the users of the system.

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 witch request for additional information can be displayed via filter.

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



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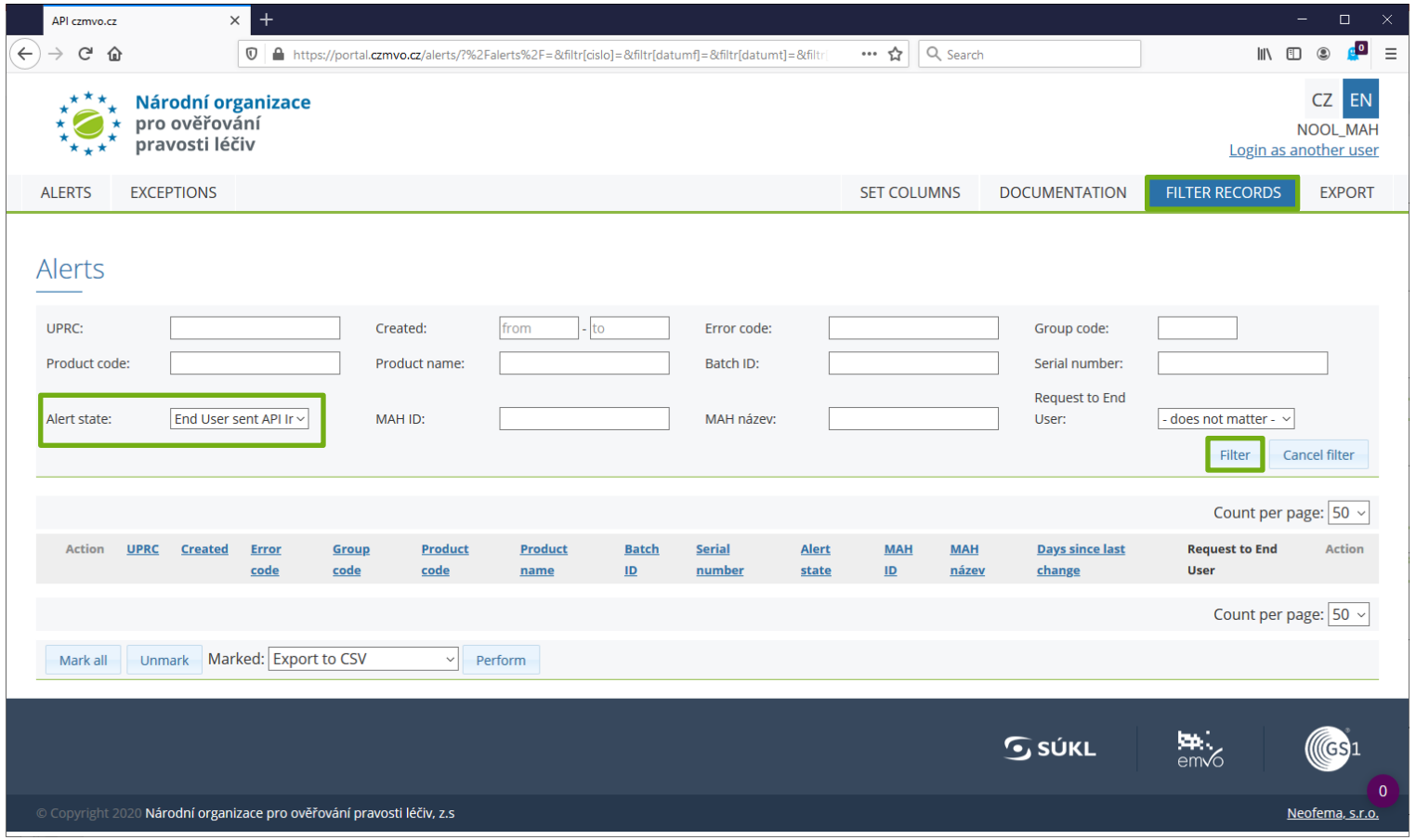
COMMUNICATION – SHOW LIST OF END USERS ANSWERS

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)*”.



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