

CZMVO Alert Management System

Release: 4.1

CZMVO AMS Alert (Management System) R4.1 presents the following features:

1. USER ADMINISTRATION

CZMVO will generate only one account per organization with the administrator role. Administration of other users and roles (*admin, user, viewer*) will be fully managed by users themselves.

Note.: Once a user has been added, their account cannot be deleted but deactivated only (in order to preserve consistency of logs).

2. USER ADMINISTRATION OF NOTIFICATIONS

The user administration will allow each user (*MAH/OBP/End user* role) to select the type of notifications they wish to receive.

Notification:

- a) Information about a new alert raised in the system.
- b) Escalation - MAH - Inactivity 5 days
- c) Escalation - MAH - Inactivity 10 days
- d) Information that a message has been sent to the end user (pre-selected).
- e) Information that a message has been sent to CZMVO (messenger)
- f) Information that an alert has been closed by CZMVO or end user
- g) Information that an alert has been re-opened by MAH or end user
- h) Information about a new high-priority alert raised in the system (Covid-19 vaccines)
- i) Escalation - End user inactivity 48 hours
- j) Escalation - End user inactivity 5 days

This setting affects sending all system notifications or escalations to users registered in the PROD environment of AMS. The setting is allocated to the specific user.

Note: We recommend that Escalation and high priority notifications be allocated to at least 1 user from an organization.

3. USER PASSWORD ADMINISTRATION

User password change due to a) forgotten password b) request for a change.

- a) Forgotten password - The user's name (login) is entered into a form and subsequently a one-time link to the password change page will be sent to the respective e-mail address of the user.
- b) The password can also be changed directly in the user administration.
- c) Any password change is always followed up with an e-mail confirmation that a password change has occurred.

4. PRE-ANALYSIS ADJUSTMENTS

4.1 AUTOMATIC CLOSING OF PPSU ALERTS

IF „Source Business Process“= „National System PPSU Request“ and also „Market“ <> „CZ“ then the field „Preanalysis - automatic “ will be filled out „EMVS Error – PPSU request“, the field „Alert state“ will have the value „06g- Closed – NMVS error“ and the field „Investigation result“ will have the value „Closed - NMVS error“.

4.2 FURTHER ADJUSTMENTS IN PREANALYSIS – minor algorithm changes.

5. BULK IMPORT OF ALERT STATES

We have reactivated the bulk import of alert states. It was necessary to adjust alert state check to ensure the process workflow is met while importing bulk alert states. The bulk import is available for both roles “end user” and “CZMVO”.

6. UNIQUE UTC TIME

Coordinated Universal Time (UTC) will be used in all communication. (logs, e-mails, etc.).

7. PRE-DEFINED MESSAGES

- 7.1 API messages list has been extended with the field “*State for sending messages*” This field determines whether the API message will be applicable for the corresponding alert state. We have therefore adjusted proposing automatic messages in WEB AMS and API.
- 7.2 A filter for this field has been added to the API messages list.

8. FILTER – „NOOL MESSAGES“

8.1 NEW FILTER IN THE LIST OF ALERTS

For all roles we have added a filter to see alerts where “NOOL message” has been sent. (Similarly as pre-defined messages).

8.2 Each “NOOL MESSAGE” can be also sent as notification (e-mail) to the recipient.

The user will also be able to cancel it (see point 2).)

Note: “NOOL message” = communication in AMS between MAH and NOOL or End user and NOOL.

9. Filter – „PENDING REQUEST“

Filter “Request to End User” with options “does not matter”, “YES”, “NO”) previously available for all roles (MAH, End user, CZMVO) has been replaced with “Pending request”

Option “YES” is not applicable, however there are the following options:

“MAH by End user” (alert is in state *04a, 03c, 03d*)

“MAH by CZMVO” (alert is in state *04b*)

“CZMVO by End user” (alert is in neither of the states *04a, 04b, 04d, 03c, 03d*)

Option “NO” is applicable on the condition that alert is in neither of the states *04a, 04b, 04d, 03c, 03d*)

10. BLOCK TO SWITCH AN MAH BACK TO „CLICK E-MAIL ENVIRONMENT“

If a user is the only user of an MAH that is already in PROD environment, it will not be possible to remove their account or switch back to TEST environment. This is to prevent MAHs to accidentally return to TEST environment.

11. OTHER ADJUSTMENTS

11.1 NEW ALERT STATUS - "06o - Closed – End User does not cooperate - cannot be supply".

The MAH now has the option to close an alert in which it requested the cooperation of the end user, but the latter does not respond despite the warning, with the status "06o - Closed - KU does not cooperate - cannot be supply".

Note: It is possible to use it only **after 9 days** in the state "03d (End User escalation - 5 days)".

NOOL can also inform NCA (SÚKL) about these cases.

11.2 The period during which the MAH is notified of inactivity has been **shortened from 7 days to 5 days** (status "03a - MAH - Inactivity 5 days").

