

CZMVO Alert Management System

Release: R9.0

The CZMVS Alert Management System (Czech Alert Management System – CZAMS) Release R9.0 introduces the following enhancements:

1. Security

1.1 Expiration of CZMVO IS Invitation According to Configured Time Limit

A configurable expiration period for invitations to the CZMVO Information System has been introduced. **The invitation is currently valid for 96 hours (4 days).**

2. Data Integration

2.1 NCA (SÚKL)

- a) Manual downloading of data from NCA's publicly available communication lists has been replaced by API-based data retrieval, wherever possible.
- b) Data for „Specific Treatment Programs“ (SLP) are now also processed. These medicinal products are added to the product catalog with an indication that they belong to an „SLP“. This information is also displayed in the alert details where applicable.
- c) Processing of exceptions under Section 13r.

Exceptions under Section 13r are now downloaded and handled in the same way as existing exceptions (under Section 11).

Note:

- A new item has been added to the „Investigation Results“ list:
 - „Closed – MAH/OBP Error – MH Exception 13r“
- A new item has been added to the „Preanalysis Results“ list:
 - „MAH – Exception Under 13r“

3. Notifications

3.1 Registration Email confirmation

The system now displays a confirmation that the registration email has been sent to the recipient. It also indicates if the outgoing registration email is returned as undeliverable.

4. Pre-Analysis

4.1 Display of All Alerts for a Given Serial Number (if known)

For all alerts where the **Serial Number (SN)** is known (i.e., the alert code is not „A3“), the system displays **all alerts associated with that serial number**.

The display is similar to the existing Groups and Anonymous Groups functionality and is available in a new submenu within the Alert Detail screen.

The alert table includes:

UPRC, Alert creation date, Product code, Batch ID, Alert status, MAH (MAH ID and Name), Group ID, Anonymous Group ID, Organization (Organization ID and Name), Location Name

Restrictions:

- a) For the MAH role, the following fields are not displayed: Anonymous Group ID, Organization, Location name.
- b) If a location does not belong to the relevant organization, users with the End User role cannot view: Location ID, Location name, Anonymous Group ID

Functions:

- a) Clicking the UPRC opens the corresponding alert, provided the user's role and organization permissions allow access (similar to Groups).
- b) The table can be exported to xlsx or csv.

4.2 MAH Notification for Pre-analysis Result = "N/A" and Alert Code = "A3"

If the pre-analysis result = „N/A“ and the alert code = „A3“ and neither the Serial Number (SN) nor the Batch contains lowercase letters, then **the most likely cause is missing data uploaded by the MAH/OBP**. -> **an automatic notification is sent to the MAH/OBP**: "Please verify that your data has been uploaded to the OBP/MAH Portal."

If the SN or Batch contains lowercase letters for alert code „A3“, the **pre-analysis result** is automatically set to: **„11 – End User error - technical. Presumably a keyboard setup error (CapsLock).**

5. Reports

5.1 Generation of SIDC Reports Directly from CZAMS

Available only for users with the SIDC role

CZAMS provides SIDC users with a total of **33 reports**, accessible through the standard reporting API. These reports can be generated **directly from the Alert Detail** screen with the required parameters preconfigured.

5.2 Processing of the IN1 Report (Pack Not Found Alert Management Report)

- a) For alerts generated by an End User transaction with alert code „A3“, findings from the IN1 report are automatically imported. The Alert Detail may then display a suggestion for the most likely correct Serial Number (SN).
- b) If the Serial Number is automatically populated in this way, an audit trail request is generated for that SN. If the pack has been **successfully verified or dispensed, the alert is automatically closed**.

Note:

As described in point a), the IN1 Processing section of the Alert Detail displays the Location ID and Location Name. **If this Location ID differs from the Location ID where the alert originated**, the process described in point b) is still executed. However, **if successful verification or dispensing occurred at a different site, the alert is not automatically closed** (its status remains unchanged). Instead, **a notification is sent to CZMVO**: Warning – Suspicious activity detected at location "Location ID", "Location Name": Alert (Alert UPRC).

If the process described in point b) is completed, the „Investigation Result“ field is updated. For the final status 06b, the investigation result is set to: **„Closed – End User Error“**.

5.3 Additional Report Data Included in Alerts

Additional information is automatically retrieved from the current Daily Snapshot and attached to the alert immediately after its creation.

Product:

The following field is added below Product:

- *Product Withdrawn*

If Product Withdrawn = „Yes“, the following fields are also displayed:

- *Product Withdraw Date*
- *Product Withdraw Reason*

If the Serial Number exists, the following fields are added below Serial Number:

- *Minimum SN Length*
- *Maximum SN Length*
- *SN Format*

If the Batch exists, the following fields are added below Provided Batch ID:

- *Batch Length*
- *Batch Format*
- *Batch Recalled*

If Batch Recalled = Yes, the following fields are also displayed:

- *Batch Recall Date*
- *Batch Recall Reason*

Below Creation Date, the following information is displayed:

- *Number of Batches*
- *Number of Packs*

Organization:

The following fields are added below Organization Name:

- *Organization Status*
- *Rate limiting plan*

Locations:

The following fields are added below Location Name:

- *Location Status*
- *Number of equipment*

Note: All newly added fields are visible to users according to the existing access rights. For example, users with the MAH role cannot view Organization or Location information.

5.4 Enhanced Export from the Alert List.

Additional columns have been added when using the "All" export option.

New export options are available for related tables, including logs, communications, alerts for the same serial number, groups, etc.

The export user interface has been redesigned and improved for better usability.

6. WORKFLOW

6.1 Parallel Distributor (PD) Transactions

If an alert is generated as a result of a Parallel Distributor (PD) transaction:

- a) The alert is assigned the status „01ba – New – PD Transaction“
- b) The „ORG_ID“ field is **automatically populated**.
- c) Based on the ORG_ID, the system retrieves the following information from the MAH List in the CZMVO Information System: „OBP Name“, **A list of all MAHs associated with the same ORG_ID**, including: MAH ID, MAH Name, FMD Contact Email, Alert Contact Email.
- d) If exactly **one MAH** (one MAH_ID) is found for the specified ORG_ID **and exactly one email contact is available**, the system **automatically generates a one-time alert email**, in the same manner as for standard alerts with status „01aa - New - End User transaction - One time“.
- e) **If the condition described in point d) is not met**, the alert is assigned the new status „01ca – Unknown MAH/Parallel Distributor“
- f) Whenever this status is assigned, the system sends a **notification to CZMVO - Warning – Unknown MAH / Parallel Distributor detected in the CZAMS module“**.
- g) **In this situation, a CZMVO operator manually** selects one or more email contacts from the list of available MAHs and email addresses. Optionally, as with standard alerts, the operator may specify whether the selected recipients apply only to the current alert or to the entire Group (if one is created).
- h) After **saving**, the alert (or Group) with the selected email recipients is automatically changed to the status „01ba – New – PD Transaction“ and **a one-time alert email is then generated automatically**.

After this point, the alert investigation and closure follow the standard workflow, including the existing workflow configuration, predefined message catalog, and email notification mechanisms.

7. DASHBOARD

7.1 General

- a) The Summary Information table is no longer displayed in the Alert Status Flow Chart view.
- b) A new Dashboard option, **Summary Information**, has been added (see Section 7.2).

7.2 Summary Information – Redesigned

a) A new **Outstanding Requests Trend** chart is available, displaying the trend of *Outstanding Requests* over time.

The chart provides the same filtering options as the existing **Alert Status Flow Chart**, including:

- **Last ...** (rolling time period)
 - **Period (From–To)**
 - Color-coded status indicators corresponding to alert status colors
- b) A new **pie chart** displays the **Number of Outstanding Requests by Alert Status**, providing an overview of pending requests grouped by their current workflow status.

8. User interface

8.1 Dynamic User-Defined Filters

Filter management:

- a) Users can save their current filter configuration as a personal filter set.
- b) Saved filter sets can be recalled at any time from the filter list.
- c) Creating custom filter sets is available to all user roles across all modules.

8.2 Communication history

a) All communication (Messages and Messenger messages) has been consolidated into the existing „**History of communication**“ section, which has been renamed to „**Communication**“. This section now contains both predefined messages and Messenger conversations.

b) The „*Process Workflow*“ section has been moved to a new „**Processing**“ section, which now includes: „Processing by API“, „Alert Status Changes“, „Procedural Workflow“

8.3 Group Change Logging

If a Group has been created, users with the **MAH or End User role** may modify its parameters. All changes are recorded in a dedicated log table. The Group header displays the modification history, including: Date and time of the change, User who made the change, Modified parameter, Previous value, New value.

8.4 User-Defined Predefined Messages for Messenger

Users can maintain their own catalog of predefined Messenger messages. Each message can be designated as either Private – available only to the current user, or Shared – available to all users within the same Organization, Location, MAH, or CZMVO.

8.5 New Message Indicator in CZAMS (All Roles)

The system displays an indicator for unread or pending messages in both the Alert List and the Alert Detail.

The indicator is cleared when:

- a) a reply is sent to the message, or
- b) the user clicks the message (envelope) icon in the Alert Detail.

8.6. Note extended to Groups

The Note function has been extended with a new option: Apply note to all alerts in the Group (Yes/No). This option is available when the alert belongs to a Group or Anonymous Group.

8.7. API Key Generation Enhancement

A new Copy to Clipboard button has been added to simplify copying generated API keys.

8.8 Messenger Enhancement

When replying to a message:

the subject of the original message is automatically reused, and the prefix "RE:" is added, consistent with standard email behavior.

8.9 Support for XLS/XLSX Attachments

Messenger attachments may now include files in .xls and .xlsx formats.

8.10 Process Errors – Printable Resolution Report

A new user option has been added for printing a Process Error Resolution Report, available to both CZMVO and End Users.

The report presents the individual resolution steps, with descriptions retrieved from the corresponding reference tables (code lists).