

CZMVO Alert management system

Release: 7.A

CZMVO (Alert Management System - AMS) release R7.A responds mainly to changes related to the implementation of the R12 release of the National System for the Verification of Medicines (CZMVS) and contains the following main modifications:

1. CHANGES BASED ON CZMVS RELEASE - VERSION R12

1.1. New fields in the alert e-mail

The loading script has been updated. The "*Client ID*" and "*Transaction Code*" fields are now taken directly from the alert email into the alert record. In addition, new fields *User-Agent*, *API Version*, *Manual Entry*, *Operation Code*, *Event Message*, *Is Intermarket* have been added to the email.

Alert record is extended by fields "*Operation Code*", "*Event Message*". These fields are added to the alert detail (section "*General*" - "*Alert header*"). The "*Client ID*" is displayed above the "*Device*" field. "*API version*", "*User-Agent*" are also displayed in this section.

The "*Intermarket*" data is displayed in the "*Product*" section.

1.2. Using API 2.5 to call reports from CZMVS

1.2.1. For working with reports it is necessary to switch to API 2.5 from R12.

1.3. Modifications in the Daily Snapshot automatic report processing

1.3.1. Modification of the batch codebook

The "Batches" sheet contains three new columns:

"Min SN Length" - displays the minimum SN length in a given batch.

"Max SN Length" - shows the maximum length of SN in a given batch

"SN Format" - shows whether the SN contains numbers (N), uppercase letters (U), lowercase letters (L) and/or special characters (S)

This information is now mandatory for MAHs when uploading product data.

1.4. Adjustment of the pre-investment

1.4.1. Use of Daily Snapshot data for pre-investment in alert processing.

The values of the loaded SN are automatically compared with the data in the Daily Snapshot:

a) IF the length of the "**SN**" is **shorter** than the value in the "**Min SN Length**" field, then the value of **ID 10** from the "Result of the NOOL investigation" codebook ("*KUT - Short String in SN*") is inserted into the "*Result of the NOOL investigation*" field.

b) IF the length of the "**SN**" is **longer** than the value in the "**Max SN Length**" field, then the value of **ID 9** from the "NOOL Result" codebook ("*KUT - Long String in SN*") shall be entered in the "*NOOL Result*" field.

c) It shall be checked whether the characters of the retrieved string "SN" meet the conditions in the field "SN Format". If not, then the value of **ID 2** from the code list "Result of NOOL investigation" ("*KUT - Character substitution*") shall be inserted in the field "Result of NOOL investigation".

Note: This pre-investment refines the existing SN analysis.

2. OTHER CHANGES in AMS

2.1. Pending alerts with a creation date longer than 1 year are automatically closed.

If the date of occurrence of the **pending alert** (in any state) is higher than the value of the parameter in the setting (currently 365 days):

- a) The alert is automatically closed with the status "*06z - Closed - Alert originated before 2022*".
- b) The value AMS ID=15 ("*Closed - Alert occurred before 2022*") is entered in the "Alert investigation result" field.
- c) Enter the following text in the "Note" field:

"Date Time - Alert was closed by CZMVO after agreement from NCA. MAH did not initiate or complete the alert investment. CZMVO cannot guarantee that it was not a counterfeit."

2.2. Correction of possible misclassification of technical errors as procedural and vice versa.

The user cannot close **A7** and **A24** errors as **technical errors** (i.e. the possibility to use the status "*06b - Closed KU - technical error*") is cancelled. On the other hand, if **A7** and **A24** are **not errors**, the states "*06f - Closed - KU - Process error - cannot be issued*" or "*06m - Closed - KU - Process error - can be issued*" cannot be used for closure.