



**Národní organizace
pro ověřování
pravosti léčiv**



NOOL ALERT MANAGEMENT SYSTEM ONE-TIME ACCESS GUIDE

User manual for marketing authorization holders MAH/On-boarding partners OBP

Release 7.0

19th October 2023

INTRODUCTION

Audience

This manual is intended for MAH's/OBP's which **are not provisioned** in the alert Management System (AMS) and can access alerts via one-time tokens only.

Terminology*

Národní organizace pro ověřování pravosti léčiv, z.s. (NOOL)

A non-profit organization designed to administer, develop and manage the National medicines verification system (CZMVS) in the Czech Republic.

AMS – NOOL Alert Management System

Supporting system to the national medicines verification system operated by NOOL.

Alert Level 5

At this level of incident, an alert is triggered by the system. The alert is sent to the party that raised it (i.e., end user, MAH / OBP, parallel distributor), as well as to NOOL and SÚKL (Czech NCA).

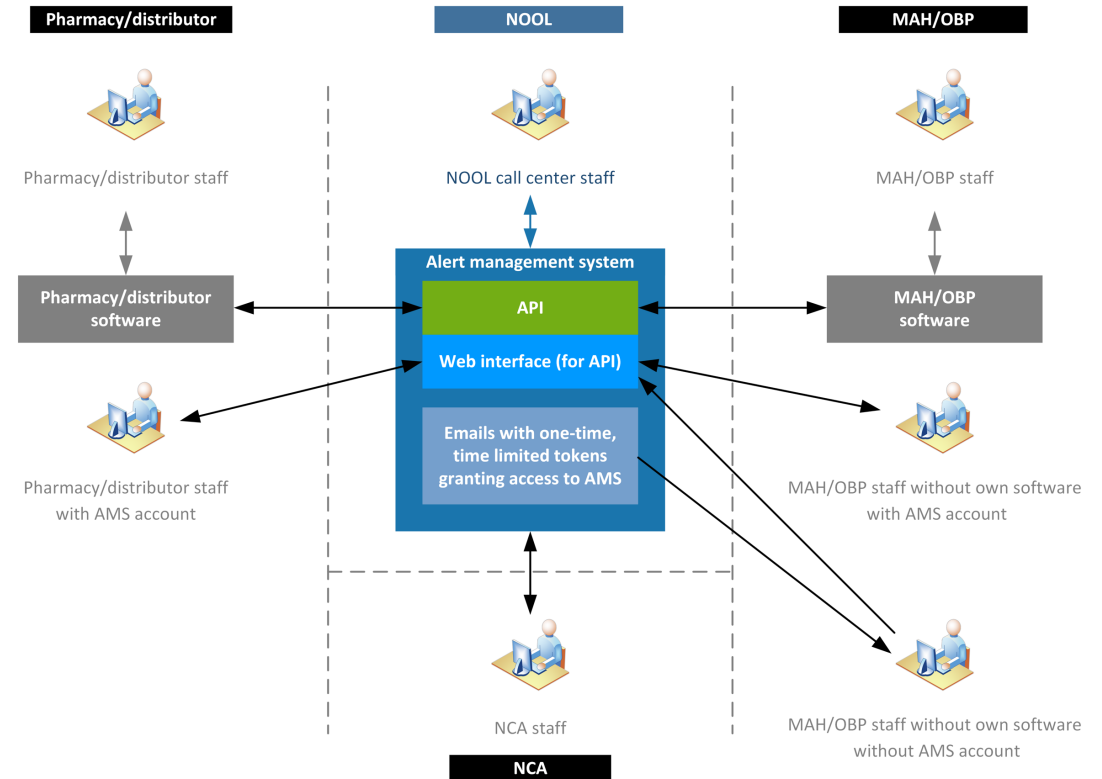
*Other definitions are on the page - “Alert states and their resolution”

ALERT MANAGEMENT SYSTEM

Alert Management System (AMS) operated by NOOL is a supplementary system to the Czech national medicines verification system (CZMVS). The purpose of this system is to facilitate the administration associated with the investigation of alerts, thus helping to simplify and speed up the entire investigation process.

Alert management in Czech Republic can be done by three ways:

- ✓ By integrating the user's own alert management system with the Alert-operated Alert Management System using API communication.
- ✓ Direct access to the alert management system web interface
- ✓ **One-time time-limited access** to the NOOL AMS web interface **only for the given alert**. The access link including a token is sent with an automatically generated e-mail. **This variant is main subject of this manual.**



TRANSITION FROM ONE-TIME ACCESS TO PROD ENVIRONMENT

Existing system of one-time tokens to access AMS

As soon as an alert is raised in AMS, the system will generate a link containing a token for an **MAH/OBP that is not registered in NOOL AMS**. The token will provide a limited access to AMS and enable administration of the concerned alert. **The token is valid for 90 days from the day the alert is raised**. Any change to the alert status will generate a new token valid for **90 days**.

NOOL recommends that all MAH/OBP whose products generate or may generate alerts in the CZ market switch to the alert management system through web interface or API.

Benefits of access via web interface or API

- ✓ Easier and clear work with alerts, filtering options, management of multiple MAHs by a single user.
- ✓ Support of automation of the investigation process
- ✓ Support of anonymous communication between MAH/OBP and end users during investigation process.

Switch to access via web interface or API

MAH/OBP needs to contact NOOL first to get access credentials to the NOOL Alert management system via web interface or API. registrace@czmvo.cz

Credentials allow access to both test and production environment. Other system users will be administered by the MAH/OBP.

Once an MAH/OBP is switched to the PROD environment, they will no longer receive e-mails with one-time tokens.

A detailed handbook for the PROD environment of the AMS is available on the websites of CZMVO:

<https://www.czmvo.cz/en/alert-management/producers-mah-parallel-distributors/>

PROCESSING TIME & ESCALATION

System notification

System notifications (notifications) are sent to the users who set them active in their settings in User Management. Individual types of notifications can be toggled according to the user's needs. There has to be at least one recipient of a given type of notification within the organization.

New alerts notification

END USER TRANSACTIONS

a) **End user technical error** (A2,A3,A68,A52) – MAH/OBP gets notification about new alert **immediately**.

b) **End user process error** (A7,A24) – gets notification about new alert **after 48 hours**.

MAH/OBP TRANSACTIONS

MAH/OBP gets notification about alerts, raised by MAH/OBP transactions, collectively for all alerts for the previous day.

Investigation time

Alert should be investigated and closed ASAP within **14***days, which is a defined period during which the product generating alert will be kept in the pharmacy. After this period, the product will be returned to the distributor.

***14 days is under the Czech Law: No. 44/2019 Sb., § 89, subsection 4,**

“Not acting” notification

END USER TRANSACTIONS

a) **End user technical error** (A2,A3,A68,A52)

In case of inactivity involved parties, i.e. alert status is not changed, MAH/OBP gets first notification after **5 days**, second notification after **10 days**.

b) **End user process error** (A7,A24)

MAH/OBP gets notification after **48 hours**, and can start investigation immediately. Until then, the end user has deadline for investigation. Inactivity during the time is reported to the end user only, MAH/OBP doesn't receive notifications.

MAH/OBP TRANSACTION

In case of inactivity MAH/OBP gets first notification after **5 days**, second notification after **10 days**.

NOTIFICATIONS, PROCESSING TIME & ESCALATION

If MAH requests **additional information for the alert from the end user and the latter does not respond**, the deadlines for **inactivity notification are**: the first notification of inactivity will be received by the end user **48 hours** after the request, the second after **5 days** after the request.

ARCHIVING

A **Closed alert** is marked as “**for archiving**” after **90 days**. The state of the alert cannot be changed once archived.

Notice: Within 90 days, a closed alert can be re-opened, and the investigation can continue under certain conditions. However, it is only applicable to alerts whose closing state disallows dispensation of the pack to public. If the MP has already been dispensed, the alert can no longer be re-opened.

After **5 years** the alert is archived and is no longer visible in the alert management system.

E-MAIL NOTIFYING ABOUT A NEW ALERT RAISED

If the MAH is not connected to the PROD environment of the AMS, once an alert is generated, they will receive an e-mail containing a link to a token to AMS. The message gives information about UPRC as well as the access expiration date.

Sample e-mail:

Předmět: NSOL Upozorneni - novy alert ! / CZMVS Notification - new alert ! CZ-LM7-LCC-W3Y-0J4-PLV

Na tento e-mail neodpovídejte - je automaticky generovan systemem! / Do not reply to this e-mail - it is automatically generated by the system!

Vazeni/Dear,

v Systemu pro overovani leziv dle FMD (NSOL) vznikl nový alert.
In the **Czech Medicines Verification system (CZMVS)** there is a **new alert**.

UPRC: CZ-LM7-LCC-W3Y-0J4-PLV

Casove omezeny pristup do Systemu pro spravu alertu / Time limited access into Alert Management System

<https://beta.czmvo.cz/alerts/CZ-LM7-LCC-W3Y-0J4-PLV/?mt=ud05iz8zqvsdefaurfxdkuvtniss6gosoyqtey26b769i9k5ggwqprjnbnm21>

Platnost do/Validity to: {platnost} / 2022-09-20 10:35

Pozn. / Notice:

Cas vzniku alertu a zmeny stavu je uveden v **UTC**. (Zimní cas = UTC +1 hod., letní cas = UTC + 2hod).

The time of origin of the alert is given in **UTC**.

Pro spravu alertu, vzniklych na uzemi Ceské republiky, velmi doporučujeme používat náš system pro spravu alertu (NOOL - AMS). Pokud nejste ještě registrovani, požadejte o pristupové udaje na tel.: +420 224 834 153-5, nebo e-mailem: registrace@czmvo.cz.

We strongly recommend using our alert management system (CZMVO - AMS) to manage alerts generated in the Czech Republic. If you are not registered yet, request access data on phone.: +420 224 834 153-5, or by e-mail: registrace@czmvo.cz.

NOOL, z.s.



**Národní organizace
pro ověřování
pravosti léčiv**

AGREEMENT WITH THE TERMS AND CONDITIONS

Prior to accessing the AMS for the first time within an organization, it is necessary to read and agree with the terms and conditions of using the Alert management system.

Národní organizace pro overování pravosti léčiv

NOOL_TEST_KU_LL1 | Change Password | Logout | CZ EN

DASHBOARD | ALERTS | EXCEPTIONS | USER MANAGEMENT | DOCUMENTATION

T&C

LICENCE TERMS AND CONDITIONS FOR THE USE OF THE ALERT MANAGEMENT SYSTEM (hereinafter referred to as the "Licence")

Provider of the license:

Národní organizace pro ověřování pravosti léčiv, z.s.,
with its registered seat at Pobežnění 620/3, Karlín, Postal Code 186 00, Prague 8,
ID No.: 058 51 742,
registered in the Associations Register maintained by the Municipal Court in Prague, File No. L 67982
(hereinafter referred to as "NOOL").

This Licence regulates the terms and conditions of the connection and access to the Alert Management System (hereinafter referred to as the "AMS") and use of the AMS, which is operated by NOOL.
NOOL allows use of the AMS to the User (as defined in Art. 1 of this Licence) subject to the contents of this Licence. NOOL does not sell the AMS to the User (as defined in Art. 1 of this Licence) and NOOL remains the non-profit legal entity that establishes and manages the AMS.

1. DEFINITION

As used in this Licence, the following terms shall have the following meanings:

- » **Access** is a set of login data that allows to log into AMS and manage Alerts in AMS.
- » **Alerts** are alerts which arise in the process of authentication of medicinal products as a result of the detection of a potential counterfeit medicinal product or as a result of a procedural or technical error and which are managed in the AMS.
- » **AMS** means Alert Management System, which is operated by NOOL. Alerts are operated (i.e. inserted, modified and solved) in the AMS.
- » **Confidential Information** is
 1. all Data;
 2. all information and software for or relating to the AMS (including the AMS interface); and
- » any information which, unless otherwise described above, is designated by the disclosing party as confidential or is of such a nature that a reasonable person would believe it to be confidential.
 - » **Data** means any information uploaded to the AMS, processed by the AMS, transferred to the AMS, generated or stored by or through AMS, whether or not such data contains Personal Data.
 - » **Delegated Regulation** means Commission Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules on the safety features appearing on the packaging of medicinal products for human use.
 - » **Effective Date** means the date on which this Licence is executed.
 - » **End User** is a distributor or a person authorised or entitled to dispense medicinal products to the public.
 - » **EU Falsified Medicines Directive** means Directive 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use as regards the prevention of the entry of falsified medicinal products into the legal supply chain and, where applicable, the relevant implementing laws of the relevant EEA Member States.
 - » **European Central Repository** refers to the part of the EMVS under the responsibility of EMVO which serves as the central information and data router as referred to in Article 32(1)(a) of the Delegated Regulation for the transfer of data to and from the National Systems; it is set up and managed by EMVO.
 - » **European Medicines Verification Organisation** or "EMVO" means a non-profit legal entity established to set up and manage the European Central Repository in accordance with the EU Falsified Medicines Directive and the Delegated Regulation.
 - » **European Medicines Verification System** or "EMVS" means the European Medicines Verification System established and administered in accordance with Chapter VII of the Delegated Regulation; it consists of the European Central Repository and the National Systems and enables End Users to verify the authenticity of medicinal products in accordance with the provisions of the EU Falsified Medicines Directive and the Delegated Regulation.
 - » **Intellectual Property Rights** are any or all patents, rights to inventions, utility models, registered designs, design rights, trademarks, service marks, copyrights, ancillary and related rights, database rights, trade names and business names, domain rights,^[1] knowledge and experience, computer software rights, proprietary promotional materials, trade secrets and any and all other intellectual or industrial property rights in all their inherent and moral aspects, as well as any application thereof anywhere in the world (whether or not registered).
 - » **Marketing Authorisation Holder** or "MAH" is a company, as well as any other holder of a marketing authorisation for a medicinal product with effects in the Czech Republic, to which the EU Falsified Medicinal Products Directive and the Delegated Regulation apply. Marketing Authorisation holders are also parallel importers of medicinal products in the Czech Republic.
 - » **National Medicines Verification Organisation** or "NMVO" means a non-profit legal entity established in the European Union that is responsible for the establishment and management of a national and/or transnational repository in accordance with the provisions of the EU Falsified Medicines Directive and the Delegated Regulation.

AMS – MAIN SCREEN

Once the terms and conditions are read and agreed to, the main screen of the AMS web interface will appear. This is where the MAH can perform administration of the alert

The page contains two tabs:

Tab „*General*“ displays alert information such as alert creation day, values entered by the user, values stored in the repository, etc.

Tab „*Solution*“ displays the current **Alert status**, alert status change log or communication log with the end user (messages, files), date of the last alert state change, etc.

There are 4 action buttons:

➤ Send message ①

Send a pre-defined message to CZMVO or end user and change the alert state

➤ Send message to CZMVO ②

Send a message directly to CZMVO. Sending the message will not change the alert status

➤ Insert file ③

Insert a file to the alert (txt, pdf, csv, jpg, tiff, png)

➤ Change alert state ④

Change the alert state according to the process workflow.



UPRC		Level	5
Created	2022-10-24 07:33	Source Market	CZ
Manual Entry	No	Group code	-
Alert code	A3	Anonymous group	-
Error Message	Pack Not Found		
Source Business Process	National System Single Pack API		

Selection of language

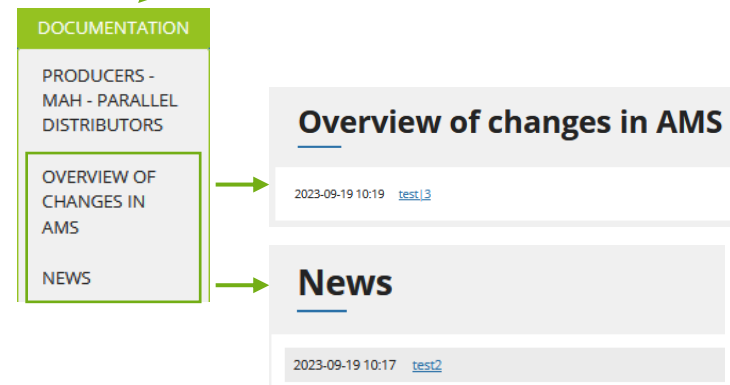
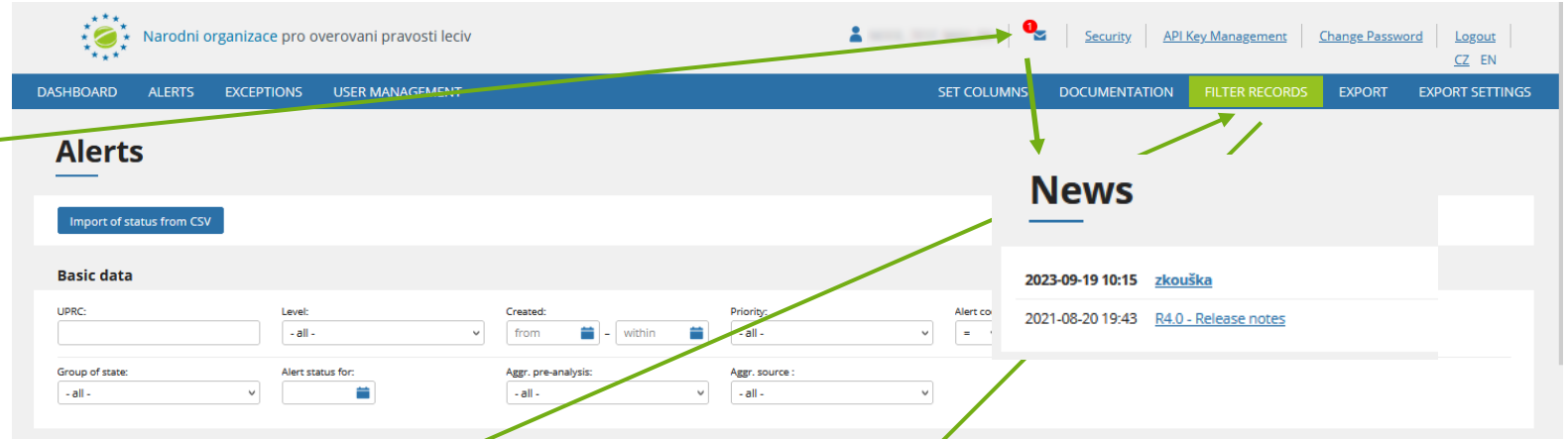
Important information for MAH/OBP (via web sites of CZMVO).

AMS – MAIN SCREEN

Envelope icon is visible in the top bar with an indication of the number of unread messages. After clicking on "envelope" a list of all messages will appear. Unread ones are indicated in bold, read ones are in normal font. After reading, information about user/login who has read the message is recorded.

A new line "Overview of changes in AMS" has been added to the main menu in the "Documentation" column. With each new release of AMS, a new line appears in this menu. It will contain link to related release notes.

A new line "News" was added. There are lines which are links to selected news from the NOOL's website.



AMS – TAB GENERAL

Tab General contains three parts:

1. Alert

Alert details:

UPRC – Unified identifier of an alert.

Created – Alert creation date.

Manual entry – Indication of whether the unique identifier was inserted into the system by a reader or manually.

Alert code – It specifies code of an alert.

Error message – Description of alert cause.

Source Business Process – Transaction initiator (National system = End user, MAH = MAH/OBP/Paralel distributor).

Level – Alert level

Source Market – market where transaction was initiated

Group code – identifier of alert group created according MAH (usage allowed in production only)

Anonymous group – identifier of alert group created according end user i.e. pharmacy, distributor (usage allowed in production only)



General		Solution	
UPRC	2022-01-13 11:05	Level	5
Created	2022-01-13 11:05	Source Market	CZ
Manual Entry	Yes	Group code	-
Alert code	A3	Anonymous group	-
Error Message	Pack Not Found		
Source Business Process	National System Single Pack API		
Operation Code			
Event Message			
Category			
Name of event			
Event description			
Product		MAH	
Catalogue Market	No	MAH ID	00000000000000000000000000000000
Intermarket	No	Name	00000000000000000000000000000000
Product code	00000000000000000000000000000000	EMVS MAH ID	00000000000000000000000000000000
Code scheme	GTIN	OBP ID	00000000000000000000000000000000
Product	00000000000000000000000000000000	OBP Name	00000000000000000000000000000000
Serial number	00000000000000000000000000000000	Contact 1	<input checked="" type="checkbox"/> 00000000000000000000000000000000
Batch ID Stored		Contact 2	<input checked="" type="checkbox"/> 00000000000000000000000000000000
Batch ID Provided	00000000000000000000000000000000	Contact 3	<input checked="" type="checkbox"/> 00000000000000000000000000000000
Stored Expiry			
Provided Expiry	00000000000000000000000000000000		
Pack type	BLISTER		
Pack size	10		
Form	TABLET		
Strength	500 MG		
Markets	CZ		

2. Product

Details related to a medical product

3. MAH

MAH related details

AMS – TAB SOLUTION

Archived – Indication whether alert is archived

Priority – Alert priority (standard/high)

Alert status – Current alert status

State description – Alert status description

Last state change– Date when the last state change occurred

Last alert change – Date of the last change to the alert

Investigation result – Result of alert investigation (filled out automatically once the alert is closed with the corresponding status)

MAH note – This is where the MAH can attach a message to the alert. The message can be set invisible to other parties

Processing by API – API communication log

Alert status changes – Status change log

The screenshot displays the 'AMS – TAB SOLUTION' web interface. At the top, there is a header with the logo of the National Organization for the Verification of Medicines (Národní organizace pro ověřování pravosti léčiv) and the text 'Národní organizace pro overovani pravosti leciv'. On the right, there are links for 'Logout', 'CZ', and 'EN'. Below the header, there is a navigation bar with 'ALERTS' and 'DOCUMENTATION'. The main content area shows an alert detail view with two tabs: 'General' and 'Solution'. The 'General' tab is active, displaying a table of alert information. The 'Solution' tab is also visible. Below the table, there are sections for 'Alert state', 'Note', 'Processing by API', and 'Alert status changes'. The 'Alert state' section includes fields for 'Archived', 'Priority', 'Alert state', 'State description', 'Last state change', and 'Last alert change'. The 'Note' section includes a 'MAH note' field with an 'Add note' button. The 'Processing by API' section shows a log entry for '2022-10-24 07:35 Preprocess'. The 'Alert status changes' section shows a log entry for '2022-10-24 07:35 01a - New - End User transaction'.

ALERTS DOCUMENTATION

Send message Send message to CZMVO Insert file Change alert state

General Solution

Alert state	
Archived	No
Priority	Standard
Alert state	01a - New - End User transaction
State description	New Alert - the result of CZMVO investigation might appear in field "Pre-analysis - automatic"
Last state change	2022-10-24 07:35
Last alert change	2022-10-24 07:35
Investigation result	

Note

MAH note *No note has been entered yet* Add note

Processing by API

2022-10-24 07:35 Preprocess

Alert status changes

2022-10-24 07:35 01a - New - End User transaction

ANONYMOUS COMMUNICATION BETWEEN MAH/OBP 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 in such cases when MAH needs for instance a picture of the pack to see the printed 2D Matrix code

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. By “*Select file*” you can add an attachment. You can also add an attachment. Clicking „*Send* „will send the message.

If the end user does not provide answer within an adequate time frame (**48 hours**), it is prudent to use CZMVS call centre service. (e.g., by using NOOL Messenger).

The screenshot displays the user interface of the National Organization for the Verification of the Safety of Medicines (Národní organizace pro ověřování pravosti léčiv). The main navigation bar includes 'DASHBOARD', 'ALERTS', 'EXCEPTIONS', and 'USER MANAGEMENT'. A 'Send message' button is highlighted in the top action bar. A modal dialog box is open, titled 'Requirement', with a dropdown menu set to 'Request_Photo_2D'. The 'Message text' field contains a request for a photo of the product cover with legible 2D code data. The 'Group' section has two radio button options for setting state 04a. The 'File' section has a 'Browse...' button and a note that the filetype should be txt, pdf, csv, jpg, tiff, png. 'Send' and 'Cancel' buttons are at the bottom of the dialog. The background shows an alert detail view with fields like 'Alert status', 'Priority', 'Alert status', 'State description', 'Last state change', 'Last alert change', and 'Investigation result'.



Národní organizace
pro ověřování
pravosti léčiv

Notice: If the MAH / OBP enters a request to the end user (status "04a"), then if the end user is inactive, the end user is notified of the MAH / OBP request by e-mail after **48 hours**. If the KU still does not respond for another **5 days**, a warning is sent to the KU that the KU must start cooperating immediately. **After 30 days of inactivity of the end user, information about inactivity is passed to NCA (SUKL).**

COMMUNICATION BETWEEN CZMVO AND USERS

The AMS supports **anonymous exchange** of messages between CZMVS and users (MAH/OBP, end user)

To send a message to CZMVO, push the button *“Send message to CZMVO”*. A dialog box will open. To attach a file push *“Browse”*. To send the message click *“Send”*

Note: the text can theoretically be in any language, however, English (or Czech) will facilitate NOOL's work the most.

This communication provides for support and facilitation of the alert resolution process and **does not affect the alert state.**

The screenshot shows the AMS interface for 'Narodni organizace pro overovani pravosti leziv'. The main menu includes 'ALERTS' and 'DOCUMENTATION'. A toolbar contains buttons for 'Send message', 'Send message to CZMVO', 'Insert file', and 'Change alert state'. A dialog box is open with tabs for 'General' and 'Solution'. The dialog contains a 'Subject' field, a 'Message text' area, and options for 'Group' and 'Anonymous group'. A 'File' field is present with a 'Vybrat soubor' button and a note: 'Filetype should be txt, pdf, csv, jpg, tiff, png'. 'Send' and 'Cancel' buttons are at the bottom of the dialog.

UPRC	
Created	2022-10-24 07:33
Manual Entry	No
Alert code	A3
Error Message	Pack Not Found
Source Business Process	National System Single Pack API

Note: when requesting additional information from end user or NOOL, it is necessary to continuously check the alert (via the link in the email). The required information will be available directly in AMS in the Solution tab for the given alert

CHANGE ALERT STATE

Button “*Alert state change*” allows change the state of specific alert. Additional window appears with selector of desired state.

The screenshot shows the AMS interface for changing an alert state. The main page has a header with the logo of the National Organization for the Verification of Drug Safety and a navigation bar with 'ALERTY' and 'DOKUMENTACE'. Below the header, there are buttons for 'Zaslat zprávu', 'Zaslat zprávu NOOL', 'Vložit soubor', and 'Změnit stav alertu'. A modal dialog box is open, titled 'Změnit stav alertu'. It contains a dropdown menu for 'Změnit stav alertu' with the selected value '02a - MAH - Investigace'. Below this is a text field for 'Popis stavu' with the value 'Zahájili jste Investigaci - operace koncového uživatele'. There are buttons for 'Uložit', 'Zrušit', and 'Přidat poznámku'. The background shows a table of alert details with columns for 'Stav alertu', 'Archivováno', 'Priorita', 'Stav alertu', 'Popis stavu', 'Poslední změna stavu alertu', and 'Poslední změna alertu'.

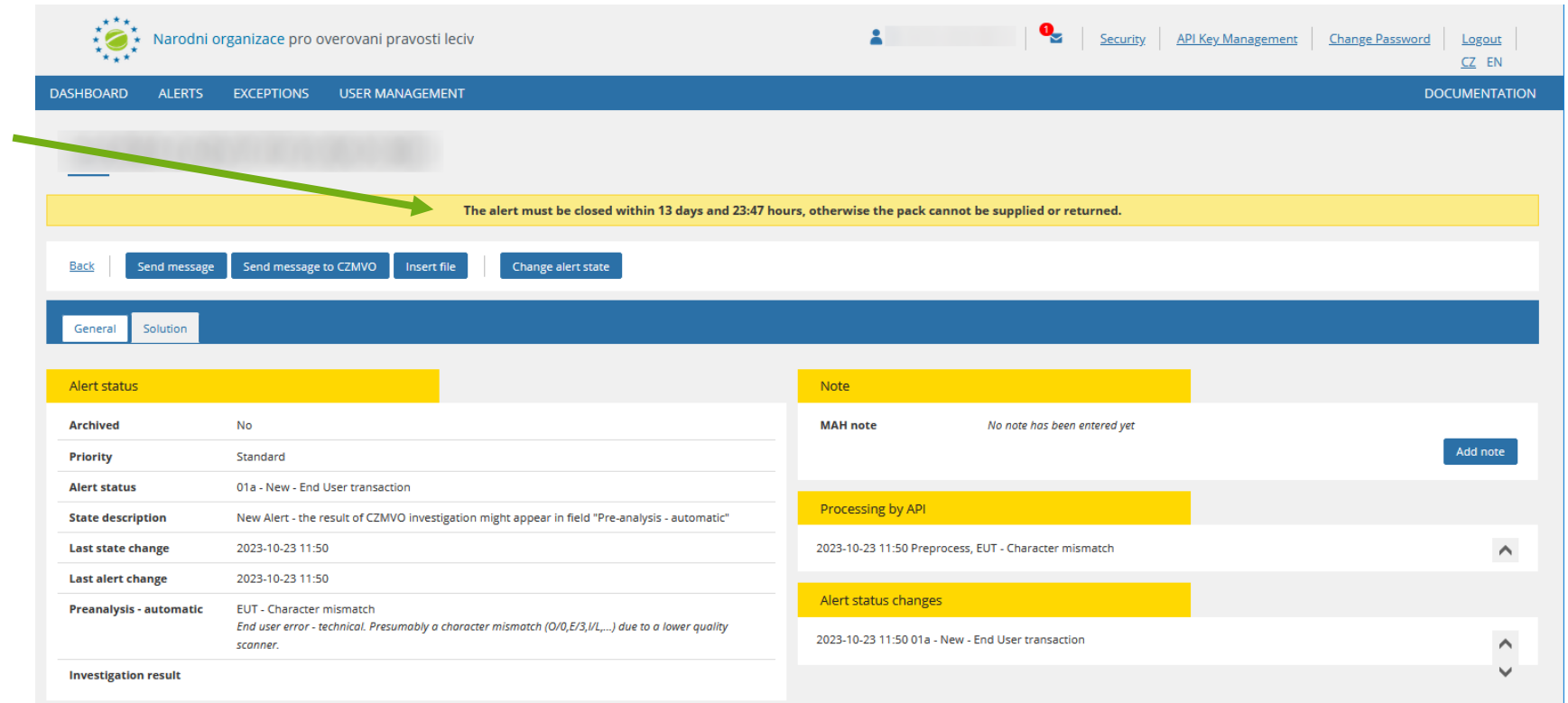
Stav alertu	Archivováno	Priorita	Stav alertu	Popis stavu	Poslední změna stavu alertu	Poslední změna alertu
	Ne	Standardní	01a - Nový - transakce KU	Nová výstraha - výsledek investigace NOOL případně v poli "Předanalýza - automatická"	24.10.2022 07:35	24.10.2022 07:35

Note: A complete list of alert states in AMS and common practice in alert solution can be found at the end of this manual.

ALERT TIME LIMIT INDICATION – NUMBER OF DAYS/HOURS TO TO ENABLE/PREVENT ALERT CHANGE STATE

In the detail of each unclosed alert, an indication of how much time is left to close it is now displayed in the upper part. After this time, the legal period for keeping a potential suspicion pack in quarantine will expire and the pack can't be supplied.

In case of an A7 or A24 alert, the period after which the alert is opened to MAH for closure is also displayed (end user has the first 48 hours period to investigate and close the alert).



Národní organizace pro overování pravosti léčiv

DASHBOARD ALERTS EXCEPTIONS USER MANAGEMENT DOCUMENTATION

The alert must be closed within 13 days and 23:47 hours, otherwise the pack cannot be supplied or returned.

Back Send message Send message to CZMVO Insert file Change alert state

General Solution

Alert status	
Archived	No
Priority	Standard
Alert status	01a - New - End User transaction
State description	New Alert - the result of CZMVO investigation might appear in field "Pre-analysis - automatic"
Last state change	2023-10-23 11:50
Last alert change	2023-10-23 11:50
Preanalysis - automatic	EUT - Character mismatch End user error - technical. Presumably a character mismatch (O/O,E/3,I/L,...) due to a lower quality scanner.
Investigation result	

Note	
MAH note	No note has been entered yet

Add note

Processing by API	
2023-10-23 11:50	Preprocess, EUT - Character mismatch

Alert status changes	
2023-10-23 11:50	01a - New - End User transaction

END USER PROCEDURAL ERRORS

- AMS enables end users to dispense packs to the public despite an alert raised as a result of a procedural error provided conditions stipulated by SÚKL (NCA) are met. This feature is only available to **end users (pharmacy, wholesaler)** and only for **End user transactions** ("Source Business Process = National System...") and for **A7 or A24 alerts** that are open and their state can be changed or a message sent according to the **process workflow**. **The resolution** and closing of a procedural error using this tool may enable the end user to **immediately dispense the medical pack to public** without verification of the pack in CZMVS.
- Note: **MAH/OBP** can close process errors of the end user with the status "06f - Closed - KU - Process error - cannot be dispensed" only after **2 days** have passed since the alert was created (if the alert has not been resolved by the end user by then).
- If the end user is aware of a procedural error that **can be fixed** and a declaration submitted as per **conditions stipulated by SÚKL (NCA)**, they may close the corresponding alert even if already closed as „06f - Closed - End User process error - cannot be dispensed“, and subsequently set the alert to the state „06m - Closed - End User process error - can be supplied“. This change can be made within **9 days** after the alert status has changed to "06f".

END USER PROCEDURAL ERRORS

- Transactions can only be made if the unique pack identifier is active. In case of incorrect release/rejection of the pack, the unique identifier is permanently invalidated and any further attempt to change the pack status will generate an alert*
- **KU can close such an alert in AMS if it itself caused it as a result of a so-called procedural error and possibly release the package to the public. The condition is to properly document the cause and provide detailed information about the alert via AMS****

* With the exception of reactivation according to Article 13. "COMMISSION DELEGATED REGULATION (EU) 2016/161"

** This procedure was approved by SUKL (NCA)

Solving end user process errors in AMS can be completed with the following results:

1. **"Pack can be supplied"** - The alert will be closed to the state *"06m - Closed - end user - process error - can be issued"*. The alert is closed and the package can be released to the public.
2. **"Pack cannot be supplied"** - Alert closes to *"06f - Closed - end user - Process error - cannot be supplied"*. The alert is closed, but the package cannot be supplied to the public.
3. **"Pack cannot be supplied"** - Alert closes to *"05C - NOOL - Info from end user to MAH"*. Alert is forwarded to NOOL for further investigation. (This situation occurs if the invalidation of the unique identifier was done from a different place).

Note: A complete overview of end user process errors is available at the end of the document.

Procedural error resolution 3/3

3/3 Completion

The pack can be supplied

Procesní chyba byla řešena pro alert CZ-LS1-ZJT-S49-5EM-D9X.

U Alertu/ů byl nastaven stav 06m - Closed - End User process error - the pack can be supplied

OK

Procedural error resolution 3/3

3/3 Completion

The pack cannot be supplied

Procesní chyba byla řešena pro alert DE-d421996c-21b5-47f1-b94d-f9797ba0f2a4.

U Alertu/ů byl nastaven stav 06m - Closed - End User process error - the pack can be supplied

OK

Procedural error resolution 3/3

3/3 Completion

The pack cannot be supplied

Procesní chyba byla řešena pro alert DE-f1afde77-8269-4868-9981-3211b836aa1a.

U Alertu/ů byl nastaven stav 05c - CZMVO - Info End user to MAH

OK



Národní organizace
pro ověřování
pravosti léčiv

END USERS' PROCEDURAL ERRORS

- The result of the end user investigation can be viewed in the "Solution" tab in the "Process error resolution" section
- Based on the selected options, end user will also receive information on whether or not the package can be supplied

Back | Send message | Send message to CZMVO | Insert file | Change alert state

General | Solution

Alert status

Archived	No
Priority	Standard
Alert status	06m - Closed - End User process error – the pack can be supplied
State description	Closed - End User process error – the pack can be supplied.The end user has documented the cause
Last state change	2023-09-13 15:21
Last alert change	2023-09-13 15:21
Preanalysis - automatic	EUP - Double supply End user error - procedural. Presumably a double supply.
Investigation result	Closed - End User Error

Note

MAH note *No note has been entered yet* [Add note](#)

Processing by API

- 2023-09-13 15:21 PCH Request submitted, ID: aa4665d910901168
- 2022-10-03 13:30 Preprocess, EUP - Double supply

Alert status changes

- 2023-09-13 15:21 06m - Closed - End User process error – the pack can be supplied
- 2022-10-03 13:30 01a - New - End User transaction

Process error resolution

Created	2023-09-13 15:21
Group	No
Anonymous group	No
UI deactivation place	Our own Location
Root cause	Inappropriate handling of the pack
Details	Correction of the prescription
Error	Staff error upon correction of prescription / retaxation
An affidavit	Čestně prohlašujeme, že při opravě receptu došlo vlivem lidské chyby k pokusu o znovuzneplatnění LP. Personál bude řádně proškolen. Balení nelze vydat veřejnosti.



News in AMS Release 7.0

ALERT MANAGEMENT SYSTEM

AMS – release 7.0 contains following features:

1. **List of all alerts – information about premise was corrected.**
2. **Type of premise was added to the alert detail**
3. **There were new information added to the alert detail****Doplňeny další pomocné informace v detailu alertu.**
New items:
„*Category*“ (e.g.: „Process“)
„*Name of event*“ (e.g.: „PackVerificationFailedUnknownBatchId“)
„*Event description*“ (e.g.: „Pack Verification through intermarket failed because the batch is unknown to the HUB“)
„*IsBadData*“ (e.g.: „False“) (Note: = Check for formal character admissibility (eg a dollar sign in a string - then an error „IsBadData“=true).
„*IsBulk*“ (e.g.: „False/True“).
4. **Anonymous group – display and the possibility to work also for the role "End User"**
 - a) Anonymous group – is shown in the alert list for the "End User" role as well.
 - b) Added the ability to bulk activity over anonymous groups for the "End User" role.
5. **Groups (standard and anonymous) were reworked**
 - a) The period for creating both types of groups has been reduced to 24 hours by default.
 - b) Added the possibility to modify this period for a specific user group ("MAH" role, "End User" role). Interval: 1-90 days.

ALERT MANAGEMENT SYSTEM

AMS – release 7.0 contains following features:

c) All available information about the group is displayed in the overview of standard and anonymous groups, (what it consists of, creation date, termination date of group creation), as well as information about each alert in the group (Status, Alert code, MAH ID, PC, SN, Batch, Expiry Date, etc.).

6. Refinement for sending generic and preset messages during API communication

If the MAH/End User sends a message to the End User/MAH using API communication, this is only possible by selecting from the preconfigured bilingual messages. If the MAH/End User sends a message to NOOL using API communication, both preconfigured messages and free text can be used.

7. Automatic closing of "A54" alerts

All "A54" alerts are automatically closed immediately with the status "06j - Closed - MAH - Transaction error - Uncorrected". Field "Investigation Result NOOL" = "19 - MAH - Randomization".

8. Pre-investigation of end-user technical errors

End user technical error pre-analysis for alert code = [A2, A3, A68] should always give a result. But if the algorithm does not find anything, the value "20 - MAH - NO" will be entered in the field "Investigation result NOOL" ("*End user transaction, pre-analysis did not determine the cause - suspected MAH error (incorrect or unrecorded data, error in printing 2D code) or counterfeit*").

9. Pre-analysis of error A52:

If the string "YYMMDD" in the field "Expiration date provided" is empty, or "MM" is greater than 12, or "RR" is less than 15, or "DD" is greater than 31, then the value "21-EUT - Date" ("*Suspect of wrongly loaded expiration date value*").

ALERT MANAGEMENT SYSTEM

AMS – release 7.0 contains following features:

10. Pre-analysis of end-user process errors:

If the alert is **A7**, then the field "Investigation result NOOL" = "22 - PURCHASE - repeated" (*Incorrect request to repeat an already executed end-user transaction*).

If the alert is **A24**, then the field "Investigation result NOOL" = "23 - PURCHASE - Unauthorized" (*Bad request for unauthorized end-user transaction*).

From the NSOL report data, the location of the alert is compared ("Location ID") with the location of **the last successful transaction before the alert was generated**. After loading the data, it is determined whether the alert originated at the **same/own** premise or **another/foreign** one, and the corresponding data is entered in the "Pre-investigation" field (overwriting the original value), and the process for investigating procedural errors is further adjusted by pre-filling step 1. The user **will be shown** this value "Own"/"Foreign premise" **when the process error closure** is initiated. The user will then **continue from step 2**. If this value is **not filled** in, the user will start from step 1.

11. Alert indication - number of days/hours until status change is enabled/prevented

For each alert is indicated in the header, for the given role and status, how many days are left until the given condition (if such a condition exists for the given alert, status and role).

12. Following charts have been added to the Dashboard for the End User role:

- a) Alerts by premises (Location ID – distribution),
- b) Alerts by premises (Closed, Not closed)
- c) Alerts by device (Client ID) per organization (ORG ID)
- d) Alerts by device (Client ID) per Location ID (premise)

ALERT MANAGEMENT SYSTEM

AMS – release 7.0 contains following features:

13. Improvement of information about changes, news, notifications

- a) Added a new line "Overview of changes in AMS" in the main menu in the "Documentation" column
With each new release of AMS, a new line appears in this menu. It will contain the name of the release with a link to the relevant change document.
- b) A new line "News" has been added in the "Documentation" column.
Here are lines of text with a click on selected News from the NOOL website (eg on "Did you know that").
- c) Improving the use of the already used **Pop Up** window.
After logging into AMS, an "envelope" with an indication of the number of unread messages is visible on the top bar. After clicking on the "envelope" a menu (list) of all messages that are in the record for the pop up window will appear - unread are indicated /bold font x read - normal font. After reading, the information that the message was read by particular login/user is recorded.

14. Alert list change

A "*Source Transaction*" column + "*Source Transaction*" filter has been added to the alert list for the "End User" role as well.

15. Showing options used when handling process errors

It is being displayed what options were chosen by the End User when solving the given process error. Valid for all roles.

16. AMS - NOTIFICATION AND ESCALATION

Reworked automatic notification system (notification and escalation)

See page 5 of this manual.



Alert states and their solution

TERMS

- **Initial analyses in AMS** = alerts are sorted based on the relevant operation, where alerts occurred (MAH/OBP, end-user, parallel distributor); IMT alerts identified, probable cause of alert identified and offered to further investigation (End-user technical or procedural error), exception according to **(Act No. 378/2007 Coll., on Pharmaceuticals, article 11r.**
- **Intermarket alerts** = The market where the alert is raised is different from the market where the pack is physically located, i.e. the pack is verified in one country, however the data are stored in a different country. The initiating market is the market where the pack is physically present and where the verification attempt was performed. The initiating market is responsible for alert investigation. The fulfilling market is the market where the data related to the pack are stored and where eventually an alert is raised. Alerts where the Czech system (CZMS) serves as the fulfilling market are closed automatically.
- **Emergency alerts** = require immediate investigation; marked with index in AMS NOOL. The MAH, the end user and CZMVO are notified by warning immediately after an alert is created. The decision to classify a product as “high-priority product” must be consulted with SÚKL (NCA) in advance (i.e vaccines' against Covid-19).
- **End-user procedural error** = often caused by wrong process in the end-user organisation, human mistake or end-user IT SW process is not integrated in line with FMD.
- **End-user technical error** = often caused by scanner setup, low quality of scanner, end-user IT software or speed of scanning.

NOOL PRE-ANALYSIS - INFORMATION ON NEW ALERTS

As part of the pre-analysis, NOOL provides information about the alert for further investigation and offers a possible cause of the alert

Name	Situation description to pre-analysed alerts	Possible next steps– MAH/OBP
EUT – Date	Suspicion of wrongly loaded expiration date value.	MAH/OBP continues to investigate and close the alert in cooperation with the end user (they confirm the cause of the alert or identify another) or they can investigate the alert directly with end user and close the alert with status 06b - Closed - Technical error end user and re-verify the pack before dispensing.
EUT – SN long string	This is probably an end user error - technical. Suspicion of incorrect reader settings (long string in SN).	
EUT - Caps Lock	This is probably an end-user error - technical. Suspect an untreated keyboard setting (Caps Lock).	
EUT - EN/CZ	This is probably an end user error - technical. Suspect an untreated keyboard setting (EN/CZ).	
EUT – SN short string	This is probably an end user error - technical. Suspicion of faulty reader setting (short string in SN).	
EUT – Characters swap	This is probably an end user error - technical. Suspicion of low quality reader (swapping characters O/0,E/3,I/L,...).	

NOOL PRE-ANALYSIS - INFORMATION ON NEW ALERTS

As part of the pre-analysis, NOOL provides information about the alert for further investigation and offers a possible cause of the alert

Name	Situation description to pre-analysed alerts	Possible next steps– MAH/OBP
EUT – Corrected, Supplied	End user error - technical. Subsequently successfully verified and issued according to the audit trail.	Alert was automatically closed based on audit trail review. No further action is required by MAH/OBP.
EUT – Bulk operation duplicity	Two identical serial numbers retrieved during a bulk operation	MAH/OBP can close the alert with status 06b - Closed - EU - Technical error.
EUP – Repeated	Repeated transaction of pack status change (it is not clear whether the original, successful change was carried out by our own or a foreign premise).	End user will provide an explanation of the cause through AMS, by choosing from the pre-defined options. The case will be properly documented and confirmed by a declaration. If end user doesn't close the alert within 48 hours of its creation, MAH will get possibility to do it at its own.
EUP – Repeated – Own	Repeated transaction of pack status change at the same premise. The pack was previously successfully dispensed at the same premise.	
EUP – Repeated - Foreign	Repeated transaction of pack status change. The pack was previously successfully dispensed at the foreign premise.	
EUP – Not allowed	Unauthorized transaction of pack status change (it is not clear whether the original, successful change was carried out by our own or a foreign premise).	
EUP – Not allowed – Own	Unauthorized transaction of pack status change at the same premise. The pack was previously successfully dispensed at the same premise.	
EUP – Not allowed –Foreign	Unauthorized transaction of pack status change. The pack was previously successfully dispensed at foreign premise.	

NOOL PRE-ANALYSIS - INFORMATION ON NEW ALERTS

As part of the pre-analysis, NOOL provides information about the alert for further investigation and offers a possible cause of the alert

Name	Situation description to pre-analysed alerts	Possible next steps– MAH/OBP
MAH – batch not loaded	Suspect of not loaded data	MAH/OBP checks if data was properly loaded and make correction actions, if necessary. If it is indeed an error on the MAH/OBP side, the alert can be closed with a status of 06a - Closed - MAH Error - Corrected or 06c - Closed - MAH Error - Not Corrected
MAH - PSUM	MAH error – error in inter market synchronization due to missing data in the Czech national system.	Alert will be automatically closed by NOOL.
MAH - BEZ	End user transaction, pre-analysis did not determine cause - suspected MAH error.	MAH/OBP checks uploaded data, possible error in printing 2D code) or counterfeit.
MAH – Randomization	The pack SN does not meet the randomization requirements and therefore can be easily guessed by counterfeiters.	Alert A54 (insufficient serial number randomization) was automatically closed. The MAH/OBP should review the process of data uploading to the repository.
MAH – Exception according 11r	MAH error - treated with an exception according Act No. 378/2007 Coll., on Pharmaceuticals, article 11r	MAH/OBP can close the alert itself with the status "06d Closed - Exception according paragraph 11r". It can be also closed by NOOL.
NSOL - PSUN	NSOL error - intermarket synchronization error (PSUN transaction, alert originated outside the CZ).	Alert will be automatically closed by NOOL.

CONTINUOUS ALERT STATUSES

Alert statuses and further resolution process by users

➤ Alert codes: all

Alert code and name in AMS	Investigation procedures – end user	Investigation procedures – MAH/OBP
01a New – end user transaction	Keep medicinal pack in quarantine until the end of alert investigation.	Once MAH/OBP receive information about alert, the investigation what caused the alert should start immediately.
01b MAH – New - MAH/OBP transaction	End-user does not know about alert, pack is not in end-user location.	Automated pre-analyses identified alert was caused by MAH operation before pack was supplied to end-user location.
02a MAH - Investigation - End user	Keep medicinal pack in quarantine until the end of alert investigation.	MAH can (does not have to) use this alert status. Once the status is used CZMVO is informed in AMS NOOL investigation of alert started, i.e. if longer time for alert investigation is needed no escalation e-amil on inactivity should be sent to MAH (after 7 or 10 days).
02b MAH - Investigation - MAH/OBP transaction	End-user does not know about alert, pack is not in end-user location.	MAH can (does not have to) use this alert status. Once the status is used CZMVO is informed in AMS NOOL investigation of alert started, i.e. if longer time for alert investigation is needed no escalation e-amil on inactivity should be sent to MAH (after 7 or 10 days).
03a MAH – Inactivity 7 days	Keep medicinal pack in quarantine until the end of alert investigation.	MAH received escalation e-mail from AMS that alert status has not changed during last 7 days from status „MAH – New“.
03b MAH – Inactivity 10 days	Keep medicinal pack in quarantine until the end of alert investigation.	MAH received escalation/warning e-mail from AMS that alert status has not changed during last 10 days from status „MAH – New“.

CONTINUOUS ALERT STATUSES

Alert statuses and further resolution process by users

➤ Alert codes: all

Alert code and name	Investigation procedures – end user	Investigation procedures – MAH/OBP
04a MAH – Info from end user	Keep medicinal pack in quarantine until the end of alert investigation. In the meantime request from MAH to provide additional info is received.	MAH requested additional information from end-user via message in AMS (choice from few predefined messages)
04b, 04f MAH - Info from CZMVO	Keep medicinal pack in quarantine until the end of alert investigation.	MAH requested additional information from CZMVO z AMS via message in AMS (empty field to write a comment)
05a End user – Info to MAH 05b CZMVO contacts end user 05c CZMVO – Info end user to MAH 05d, 05f CZMVO – Info MAH	Keep medicinal pack in quarantine until the end of alert investigation. In the meantime provide information requested by MAH or CZMVO during alert investigation, it is also possible to communicate with CZMVO support team.	MAH receive requested information from end-user or in AMS od CZMVO.

ESCALATION ALERT STATUSES – END USER TRANSACTIONS

Alert statuses and further resolution process by users

➤ Alert codes: A7, A24 (03e, 03f, 03g) A2, A3, A52, A68 (03h, 03i, 03j)

Alert code and name	Investigation procedures – end user	Investigation procedures – MAH/OBP
03f - EU – process error - inactivity 5 days 03g – process error 10 days	End user is notified about inactivity. End user finds out the cause, documents the event, selects from the options offered by AMS and confirms the declaration. The pack is being quarantined until the alert investigation is complete.	MAH can change the pack state after 48 hours since it was created. Alert can close with status 06f - Closed - End user process error - cannot be supplied.
03i – technical error 5 days 03j – technical error 10 days	End user is notified about inactivity. End user will try to fix a technical error on its side (checks keyboard language, sensor settings, makes sure CAPS LOCK is not on, etc.). The pack is being quarantined until the alert investigation is complete.	MAH is notified 48 hours after the alert is created due to a technical error. If is not obviously end user error, the MAH verifies uploaded pack data (batch, serial numbers).

ESCALATION ALERT STATUSES – MAH TRANSACTIONS

Alert statuses and further resolution process by MAH's

Alert code and name	Investigation procedures – end user	Investigation procedures – MAH/OBP
03m – MAH alert not closed 5 days	N/A	MAH is notified about alert created by a MAH or a parallel distributor transaction. MAH investigates the cause and closes the alert in AMS.
03n – MAH alert not closed 10 days	N/A	MAH is notified about alert created by a MAH or a parallel distributor transaction. MAH investigates the cause and closes the alert in AMS.

CLOSING ALERT STATUSES

Closed alert statuses and further resolution by NSOL users

- Alert codes: **A2, A3, A52, A68**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended procedure for end-user (column 3) or MAH (column 4).

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06a Closed - MAH error –Corrected	<ul style="list-style-type: none"> Data not uploaded – batch missing or not uploaded correctly, Product Pack Data missing. IMT did not run (if not correctly entered batch number, batch is not found in system of other country). System Time out (batch is not found due to not received answer to request in required time limit). Batch data not uploaded correctly. Data missing – SN missing or not properly uploaded. System Time out (date not verified due to not received answer to request in required time limit). Product pack data no properly loaded The batch number is read instead of the expiration date. 	<p>Keep medicinal pack in quarantine until the end of alert investigation. Once alert is closed, provided info from AMS:</p> <p>Corrected - the pack can be verified again! If the verification is successful, please remove the pack from quarantine and supply to the patient. Otherwise, please return to quarantine with the new alert ID (if no more than 14 days have passed from the first quarantine), or return to distribution with alert ID identification for returned pack (if more than 14 days have passed from the first quarantine).</p>	<p>Once MAH/OBP uploaded and/or corrected data (batch etc.) into EMVS/CZMVS and closed alert with relevant status, end-user can verify and decommission pack again and release from quarantine to patient.</p>

CLOSING ALERT STATUSES

- Alert codes: **A2, A3, A52, A68**. During investigation of alert end-user should (according to options) check possible technical errors /cause of alert on end-user side – usually caused by scanner set up, end-user IT software or scanner speed. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4).

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06b Closed – End user technical error	<ul style="list-style-type: none"> • Too quick scanning cause conjunction of batch number with GTIN or SN, or se batch number is read twice or conjunction of data from more packs to one. • SN is too short (chopped off) or too long (part of other data) or not allowed characters included. • Not finished/wrong scanning – incomplete number or product code connected to batch number. • Commutation Y/Z or capital/small letters – due to caps lock on or SHIFT on during scanning (keyboard is switched to different than required settings. (i.e. English x Czech, QWERTZ x QWERTY). • Scanning with not properly set up scanner cause wrong batch number compare to set data CZMVS. • Wrong manual entry (1 x l, O x 0) or wrong repeated manual entry of expiration date from pack MM/RR. • One element of the Data Matrix Code appears in the Serial Number field, because group separators have not been set properly. 	<p>End-user should correct the cause of alert according to what caused it:</p> <ul style="list-style-type: none"> • Repeated scan after previous scanning with short break • Caps lock off prior to scanning followed by scanning of the pack again. • Switch to Czech keyboard or QWERTZ x QWERTY keyboard followed by scanning of the pack again. • To modify end-user IT SW (after agreement with IT SW provider) so not proper using of group separators are corrected. • To modify end-user IT SW (after agreement with IT SW provider) to correct expiration data. • Scan UI again or carefully input all relevant data for verification. <p>Use “control scan”, if possible, to verify proper scanner set up and after that go back to medicinal pack with alert.</p> <p>End-user can than again verify pack and if decommision is successful pack can be release from quarantine and provided to patient.</p>	<p>MAH/OBP started investigation immediately, in parallel with end-user. Once the cause of end-user is identified, it can be corrected by end-user only. MAH/OBP can, however close alert as end-user errors well, if MAH/OBP can prove based on info identified, technical error was caused by end-user.</p>

CLOSING ALERT STATUSES

- Alert codes: **A2, A3, A52, A68**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4).

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06c Closed - MAH error - Not corrected	<ul style="list-style-type: none"> • Wrong print of FMD code on the pack. • OBP with „Indian codes “ uses GTIN, that is later on used for FMD, i.e. alert is generated. • Group separators have not been used properly so some element of the Data Matrix Code appears in batch number. • Producer printed not correct data on the medicines pack into 2D code. • Producer printed not correct data into eye readable format. • Re-upload of the data by MAH/OBP to already distributed packs. • OBP tries to change pack status to already decommissioned pack (i.e. „sample to sample“). 	<p>Keep medicinal pack in quarantine until the end of alert investigation. Wait for closing the alert by MAH/OBP or provide additional information based on request. Once alert is closed, provided info from AMS:</p> <p>MAH / OBP error. Unable to correct - cannot be re-verified. Return the packaging to the supplier with alert ID identification.</p> <p>End user should return pack back to distribution (wholesaler) according to return process set up in end-user organisation.</p>	<p>After investigation with OBP – data correction or correct upload of the data or correction of wrong print on the pack is not possible. Data (batch) cannot be corrected via EU HUB to EMVS/CZMVS. Pack cannot be supplied to patient.</p>

CLOSING ALERT STATUSES

- Alert codes: **A2, A3, A52, A68**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4).

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06d Closed - ZOL 11r exception	<ul style="list-style-type: none"> • Wrong print of FMD code on the pack. • OBP with „Indian codes “ uses GTIN, that is later on used for FMD, i.e. alert is generated. • Group separators have not been used properly so some element of the Data Matrix Code appears in batch number. • Producer printed not correct data on the medicines pack into 2D code. • Producer printed not correct data into eye readable format. • Re-upload of the data by MAH/OBP to already distributed packs. • OBP tries to change pack status to already decommissioned pack (i.e. „sample to sample“). 	<p>Keep medicinal pack in quarantine until the end of alert investigation. Wait for closing the alert by MAH/OBP or CZMVS.</p> <p>Once alert is closed, provided info from AMS:</p> <p>Exception ZOL - 11r - DO NOT VERIFY. Can be supplied to patient. Remove from quarantine.</p>	<p>During alert investigation MAH/OBP should check if batch of medicine pack has approved exception by Ministry of Health according to Act on Medicines par 11r. If the exception is approved for product of relevant batch, relevant status of alert AMS is set. End-user can release pack from quarantine and supply pack to patient.</p>

CLOSING ALERT STATUSES

- Alert codes: **all**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4).

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06e Closed - Before 02/09/2019	<ul style="list-style-type: none"> Partially serialised product (without SN or other production data from the Data Matrix Code), release from production prior 9.2.2019. 	<p>Keep medicinal pack in quarantine until the end of alert investigation and closing by MAH/OBP.</p> <p>Once alert is closed, provided info from AMS:</p> <p>Release from production before 09/02/2019 - not subject to FMD - DO NOT VERIFY! The pack can be supplied to patient. Remove from quarantine.</p>	<p>During alert investigation MAH/OBP should check, if pack was released prior 9th February 2019, so FMD rules do not apply. If this is confirmed, MAH/OBP should set relevant alert status in AMS. End-user can without further verification/recommission release pack from quarantine and supply to patient.</p>

CLOSING ALERT STATUSES

- Alert codes: **A7, A24**. During investigation of alert end-user should (according to options) check possible procedural errors /cause of alert on end-user side – usually caused by wrong processes on the organisation, human mistake or end-user IT SW set with wrong processes from FMD point of view. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4).

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06f Closed - Process error KU - cannot be issued	<ul style="list-style-type: none"> • Attempt to double decommission by end-user – already decommissioned pack. • Attempt to decommission already non-active or expired pack. • Not proper internal marking of pack due to misunderstanding. • Double operation or wrong decommissioning to wrong alert status by mistake. • Incorrect internal labeling and packaging due to misunderstanding. • Resale between pharmacies; pharmacy that resale not pack does not properly decommission pack to alert status “Supplied” and 2nd pharmacy during decommission to patient generates alert. • Errors that lead to repeated request to decommission. • Attempted double dispense by end user - pack already dispensed. • An attempt to dispense an already inactive or expired pack. • Incorrect internal labeling and packaging due to misunderstanding. 	<p>Keep medicinal pack in quarantine until the end of alert investigation. Once alert occurs, potential process/procedural causes of alert should be investigated by end-user. Investigation by MAH and NOOL ruled out errors caused by MAH/OBP, at the same time process/procedural error caused b end-user was identified.</p> <p>Once alert is closed, provided info from AMS: End user process error. Cannot be corrected, re-verified or supplied. Further course of action depends upon the individual internal procedures of the respective organization.</p>	<p>During alert investigation end-user or MAH identified process error by end-user. These alerts must be closed with proper explanation – documentation of the cause. Potential falsification was ruled out. Another decommission would cause alert. At the same time, it is confirmed that it is not a counterfeit.</p>

CLOSING ALERT STATUSES

- Alert codes: **A7, A24**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4).

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06m Closed – End user process error – can be supplied after documenting the cause	<ul style="list-style-type: none"> • Attempt to double decommission by end-user – already decommissioned pack. • Attempt to decommission already non-active or expired pack. • Not proper internal marking of pack due to misunderstanding. • Double operation or wrong decommissioning to wrong alert status by mistake. • Incorrect internal labeling and packaging due to misunderstanding. • Resale between pharmacies; pharmacy that resale not pack does not properly decommission pack to alert status “Supplied” and 2nd pharmacy during decommission to patient generates alert. • Errors that lead to repeated request to decommission. • Attempted double dispense by end user - pack already dispensed. • An attempt to dispense an already inactive or expired pack. • Incorrect internal labeling and packaging due to misunderstanding. 	<p>Keep medicinal pack in quarantine until the end of alert investigation. Once alert occurs, potential process/procedural causes of alert should be investigated by end-user. Investigation by MAH and NOOL ruled out errors caused by MAH/OBP, at the same time process/procedural error caused by end-user was identified.</p> <p>The end user must document the cause of the process error in accordance with SÚKL (NCA) requirements. By choosing from the prepared options and according to the instructions for solving individual process errors, the medicinal product can be released from quarantine and dispensed without further verification.</p> <p>After the investigation is completed and the alert is closed, a message in AMS: Not a MAH/OBP error. end user documented the cause - LP can be supplied.</p>	<p>The end user or MAH identified a end user process error during investigation. An explanation is required for these alerts - documentation of the cause (preferably in AMS), the cause cannot be fixed in NMVS, i.e. the next attempt to decommission would result in an alert again. At the same time, it is confirmed that it is not a counterfeit.</p>

CLOSING ALERT STATUSES

- Alert codes: **all**. During investigation of alert end-user should (according to options) check possible procedural errors /cause of alert on end-user side – usually caused by wrong processes on the organisation, human mistake or end-user IT SW set with wrong processes from FMD point of view. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4).

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06g Closed - CZMVS error	<p>Relevant to pack that,</p> <ul style="list-style-type: none"> • Were already successfully supplied in CZ, but data synchronization for multimarket packs was not correct. • Were not decommissioned due to long response time of the system; status change was not done correctly. 	<p>During alert investigation that was created on Czech market keep medicinal pack in quarantine until the end of alert investigation and closing alert NOOL.</p> <p>Once alert is closed, provided info from AMS (based on cause of CZMVS):</p> <p>CZMVS Error - The pack can be verified again! Remove from quarantine.</p> <p>CZMVS Error - The pack cannot be verified again! Return back.</p>	<p>MAH does not use this alert status for closing, but previous investigation by MAH should be done. In case no error is identified by MAH, CZMVO starts investigation of alert.</p> <p>During alert investigation CZMVO confirmed error during data synchronisation (pack not in the quarantine because it was successfully decommissioned and supplied before alert was created). No impact on pack distributed in CZ.</p> <p>In the case of a long system response (time out - the pack data is not found due to not receiving a response to the query within the required time limit).</p>

CLOSING ALERT STATUSES

- Alert codes: **all**. During investigation of alert end-user should (according to options) check possible procedural errors /cause of alert on end-user side – usually caused by wrong processes on the organisation, human mistake or end-user IT SW set with wrong processes from FMD point of view. Once one of the causes (mentioned in column 2) is identified, next steps should follow recommended process for end-user (column 3) or MAH (column 4).

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06o - Closed – Lack of end user cooperation – can not be supplied	MAH finished the investigation and repeatedly asked the end user for additional data. The end user is not cooperating. Pack cannot be supplied. CZMVO informs SÚKL (NCA). Note: It can only be used after 9 days in status 03d (End user escalation - 5 days).	The end user was uncooperative even after escalation. NOOL informs SÚKL (NCA). Immediately contact NOOL or respond to MAH or NOOL requests.	Closed, the end user does not cooperate even after escalations - cannot be supplied. NOOL informs SÚKL (NCA).

CLOSING ALERT STATUSES

- Alert codes: **all**. As part of the alert investigation, the MAH/OBP should review the data uploaded to the EMVS/NSOL, the end user should review whether it is a technical or process error on their end, and then NOOL review possible errors in the NSOL system. If it is found that all the listed causes of the alert (2nd column) can be excluded, it is necessary to follow the procedure for the end user (3rd column) or for the MAH (4th column):

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06h – Suspected Counterfeit!	<ul style="list-style-type: none"> all the potential causes on MAH, end-user side and CZMVO are excluded 	Keep medicinal pack in quarantine until the end of alert investigation Once alert is closed, provided info from AMS: Investigation by MAH and CZMVO confirmed a possible COUNTERFEIT! information will be forwarded to NCA, EMVO, EMA, EK. SAVE THE PACKAGE carefully! You will be contacted for further action.	During alert investigation by all relevant parties all potential causes of alert on MAH, end-user side and CZMVO were excluded MAH/OBP marked alert as potential counterfeit, NCA will be informed. Alert will be further investigated with MAH, NCA and end-user according to set up processes. Information should be provided to EMVO, EMA, EK* (in certain cases).

CLOSING ALERT STATUSES

- Alert codes: **A7, A24**. As part of the alert investigation, the MAH/OBP should review the data uploaded to EMVS/NSOL. After detecting any of the following causes (column "Most common causes of the alert"), we recommend following the procedure for MAH (column "Options for solving alerts - MAH"). The table also shows the recommended procedure for

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06i - Closed - MAH transaction error – Fixed	<ul style="list-style-type: none"> Transaction between MAH system and EU HUB (i.e. PSUM transaction) 	End-user does not know about alert, pack is not in end-user location.	MAH during alert investigation found error related to data upload or correction between MAH SW and EU HUB; error corrected. Medicinal packs can be further distributed and decommissioned on the market.
06j - Closed - MAH transaction error - Not corrected	<ul style="list-style-type: none"> Transaction between MAH system and EU HUB (i.e. PSUM transaction) 	End-user does not know about alert, pack is not in end-user location.	MAH during alert investigation found error related to data upload or correction between MAH SW and EU HUB; error corrected; error cannot be corrected. Medicinal packs cannot further distributed and decommissioned on the market – withdrawal?
06k - Closed - PD error - Not fixed	<ul style="list-style-type: none"> Wrong operation by parallel distributor 	End-user does not know about alert, pack is not in end-user location.	CZMVO provides info to MAH about result of investigation with parallel distributor (anonymous). ; error cannot be corrected. Medicinal packs cannot further distributed and decommissioned on the market – withdrawal?
06n - Closed - IMT fulfilling - Alert originated outside CZ, MAH is investigating in another market	<ul style="list-style-type: none"> All potential causes of alerts, but alert occurred on the pack decommissioned in other country, while data in CZMVS. 	End-user in CZ does not know about alert, pack is not in end-user location. Investigation done by country, where pack was decommissioned.	MAH investigates on other market. Additional info can be provided by CZMVO from CZMVS upon request.

CLOSING ALERT STATUSES

- Alert code: **A1**. As part of the L3 exception investigation, the MAH/OBP should review the data uploaded to EMVS/NSOL. After detecting any of the following causes (column "Most common causes of the alert"), we recommend following the procedure for MAH (column "Options for solving alerts - MAH"). The table also shows the recommended

Alert code and name	Most common alert causes	Investigation procedures – end user	Investigation procedures – MAH/OBP
06I - Non FMD	<ul style="list-style-type: none"> • Scan products which are out of scope of the FMD (OTC, 'Indian Product Codes', medical device, etc.) • Product Code not uploaded into the EMVS. • Product Master Data not uploaded into the EMVS (or failure to transmit to CZMVS) • Product codes not compliant with national coding requirements (NTIN instead of GTIN) • Incomplete 2D matrix code • Manual entry error • Scan of test codes in Production Environment (PRD) Scanning of 2D data matrix code on shipper box or pallet 	<p>Keep medicinal pack in quarantine until the end of alert investigation and closing by MAH/OBP or CZMVO.</p> <p>Once alert is closed, provided info from AMS:</p> <p>Medicinal product is not subject to FMD. Can be issued without verifying. Remove from quarantine.</p>	MAH or end-user found out during alert investigation that verified pack or device is not subject to FMD.
06z - Closed - an unclosed alert created more than a year ago	<ul style="list-style-type: none"> • All potential causes of alerts 		Alerts not closed and older than 365 days are automatically closed (after agreement with SÚKL).



End User Process Error Resolution List

TH LIST OF PROCEDURAL ERRORS

Root cause	Details	Examples	Dispensation of the pack to the public
Delayed system response	Your own text (optional)	A repeated attempt of a pack state change (e.g. Supplied, Active) due to a delayed response from CZMVS.	can be supplied
Pharmacy information system (PIS) error	Correction of the prescription	SW (PIS) error occurs upon correction of the prescription / relaxation / stocktaking - SW (PIS) re-executes the Supplied transaction.	cannot be supplied!
	Your own text (mandatory)	Other error caused by pharmacy information system (PIS)	can be supplied
Inappropriate handling of the pack	Pack state not verified prior to the transaction	A repeated attempt to Supply the pack (the pack remained at the same location and was not re-activated)	can be supplied
		A repeated attempt to reactivate the pack as a result of a human error	can be supplied
		A repeated attempt to decommission the pack in other state than Supplied e.g. Destroyed, Stolen.	cannot be supplied!
		Preparation of a compound or dispensation of a drug in parts - the pack is Supplied repeatedly.	can be supplied
	Correction of the prescription	Staff error upon correction of prescription / relaxation	cannot be supplied!
	Stocking error	Mixing of active packs (available for dispensation) with reserved packs (set as Supplied already)	can be supplied
		An attempt to Supply a pack intended for disposal(the current state of the pack is Destroyed)	cannot be supplied!
		An attempt to Supply a pack set to Destroyed state accidentally. The pack is NOT intended for disposal and the Destroyed state was set by error. Any attempt to supply the pack will hence raise an alert	can be supplied
	Returned pack	An attempt to set a pack returned by the patient to Destroyed (the current state is Supplied)	cannot be supplied!
		A pack returned by the patient was erroneously mixed with active drugs in stock and an attempt to Supply the pack occurred. (Illegal activity!)	cannot be supplied!
	Pack transferred outside of the current location	The pack was transferred between locations of the same organization and decommissioned by the originating location.	cannot be supplied!
		Emergency alert raised in a district hospital - the pack was already set to Supplied by the regional hospital and the district hospital re-attempts to Supply the pack.	
The pack was transferred between locations of a different organization and decommissioned by the originating location.			

