Národní organizace
pro ověřování
pravosti léčiv

CZMVO ALERT MANAGEMENT SYSTEM
ONE-TIME ACCESS GUIDE

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

Release 5.0

26th October 2022

INTRODUCTION

Audience

This manual is intended exclusively for MAH/OBP that are not connected to the PROD environment of the Czech Alert Management system) AMS and can only access alerts via one-time tokens.

The examples depicted are primarily targeted at MAH/OBP .

Terminology*

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

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

Alert management system (AMS) NOOL

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).

* Remaining terminology on the page 17 - “Alert states and their solutions”

ALERT MANAGEMENT SYSTEM

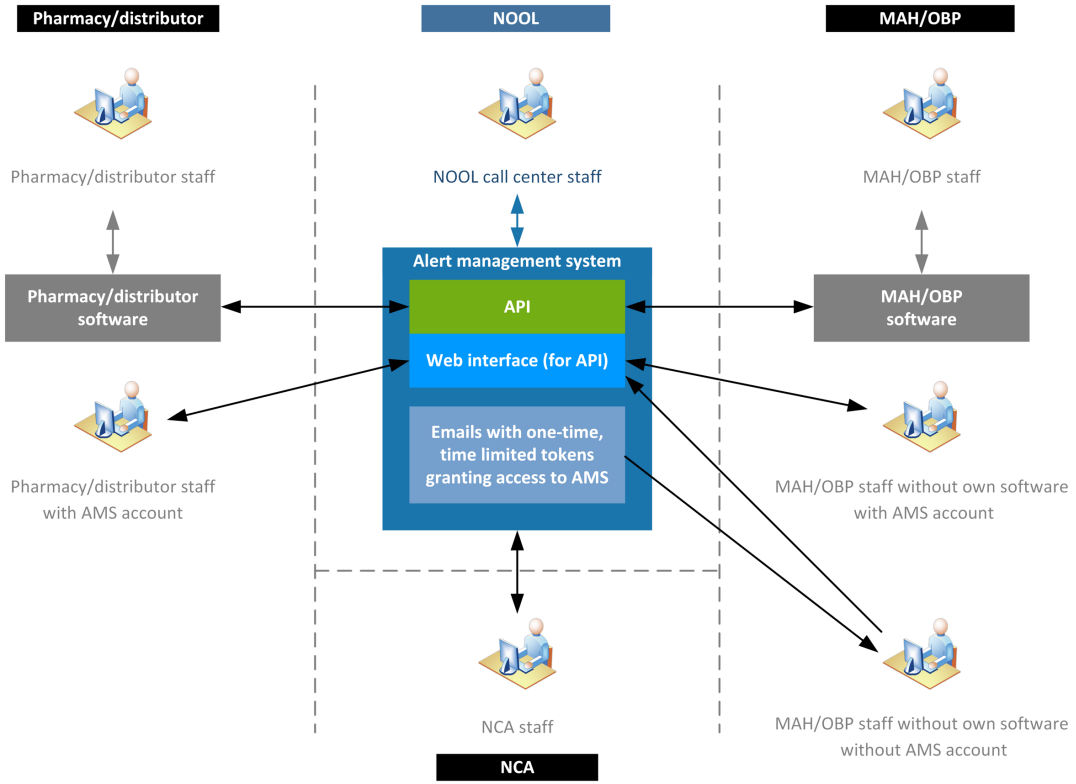
Alert Management System (AMS) operated by NOOL is a supplementary system to the Czech national medicines verification system (CZMVS). The purpose of this system is to facilitate the administration associated with the investigation of alerts, thus helping to simplify and speed up the entire investigation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

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

- ✓ **Direct access** to the alert management system **web interface**. **The description of this interface is the main purpose of this manual.**
- ✓ By **integrating the user's own alert management system** with the Alert-operated Alert Management System using API communication.
- ✓ **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.

Note: The **API for IT development** is described in detail in *"Alerts Management API_ Documentation_2.4.pdf"* on

www.czmvo.cz/en/system-users/producers-mah-parallel-distributors



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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 alert management system 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.**

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Switch to the alert management system 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/file.php?id=688

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.

Note. This is only available in the PROD environment.

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

System sends notifications in case that MAH is not acting, i.e. status of the alert has not changed in the past **5 days**.

System sends **2nd notice - warning**, in case MAH/OBP is not acting, i.e. status of the alert has not changed in the past **10 days**.

Warning: After **30 days**, if the alert has still not been investigated, SÚKL (NCA) is informed in a monthly report of „non active MAHs".

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

Vazeni/Dear,

v Systemu pro overovani leciv 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=ud05iz8zqvsdefaurlxdkuvtniss6gosoyqtey26b769i9k5qgwqprjnbm21

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., letni cas = UTC + 2hod).

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

Pro spravu alertu, vzniklych na uzemí Ceské republiky, velmi doporucujeme pouzivat nas system pro spravu alertu (NOOL - AMS).Pokud nejste jeste registrovani, pozadejte 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.

AGREEMENT WITH THE TERMS AND CONDITIONS

Prior to accesing 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.

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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 Pobřežní 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 License, 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 License 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, 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.

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This Licence shall be governed by the laws of the Czech Republic.
Any dispute between the Parties arising out of this Licence shall be submitted to and finally decided by the courts of the Czech Republic.

[1] Including *sui generis* rights to databases under Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases.

I agree with the Terms and Conditions

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.

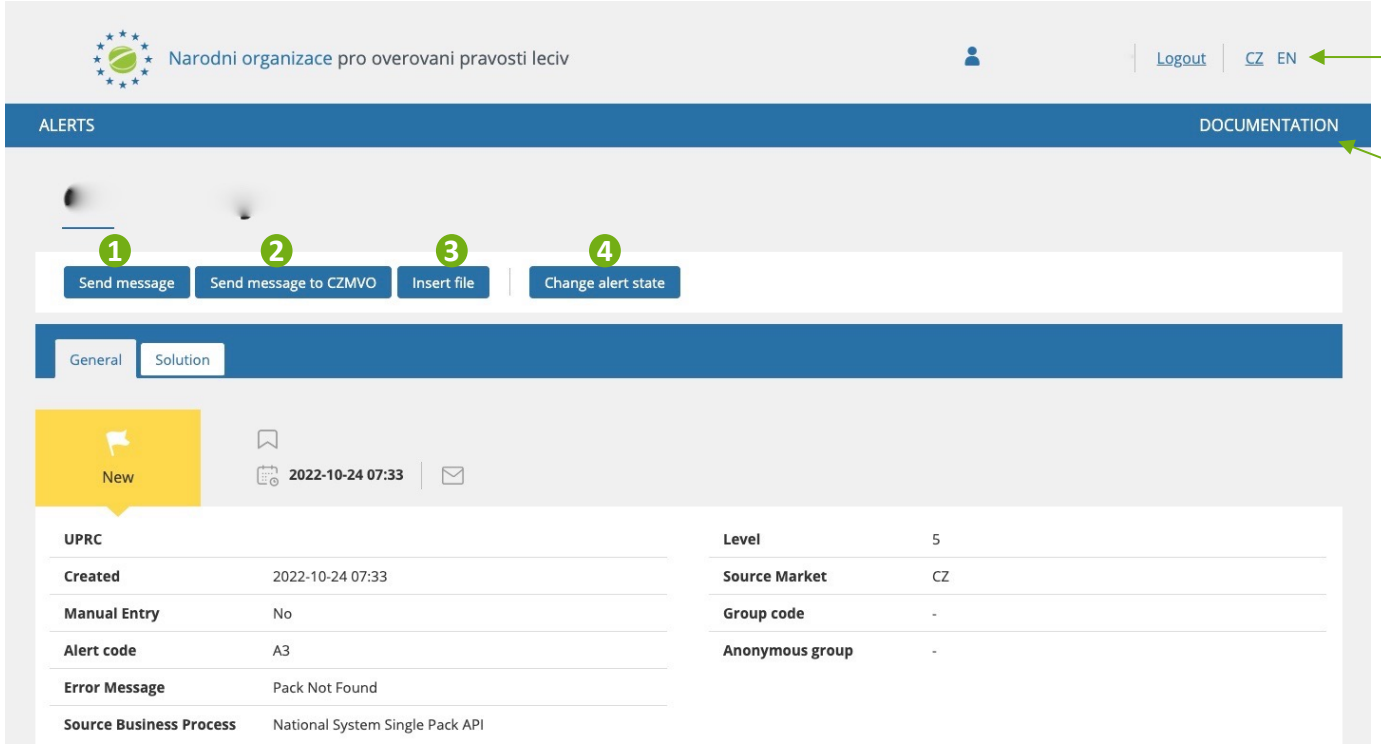
There are 4 action buttons:

➢Send message 1
Send a pre-defined message to CZMVO or end user and chnage the aelrt 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.



Selection of language

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

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AMS – TAB GENERAL

Tab General contains 3 parts:

1. Alert

UPRC – Unique pack return code (alert identification number)

Created – Date when the alert was raised.

Manual Entry – Indication of whether the unique identifier was entered to the system by scanner or by hand.

Alert code – Alert code.

Error message – Description of the alert.

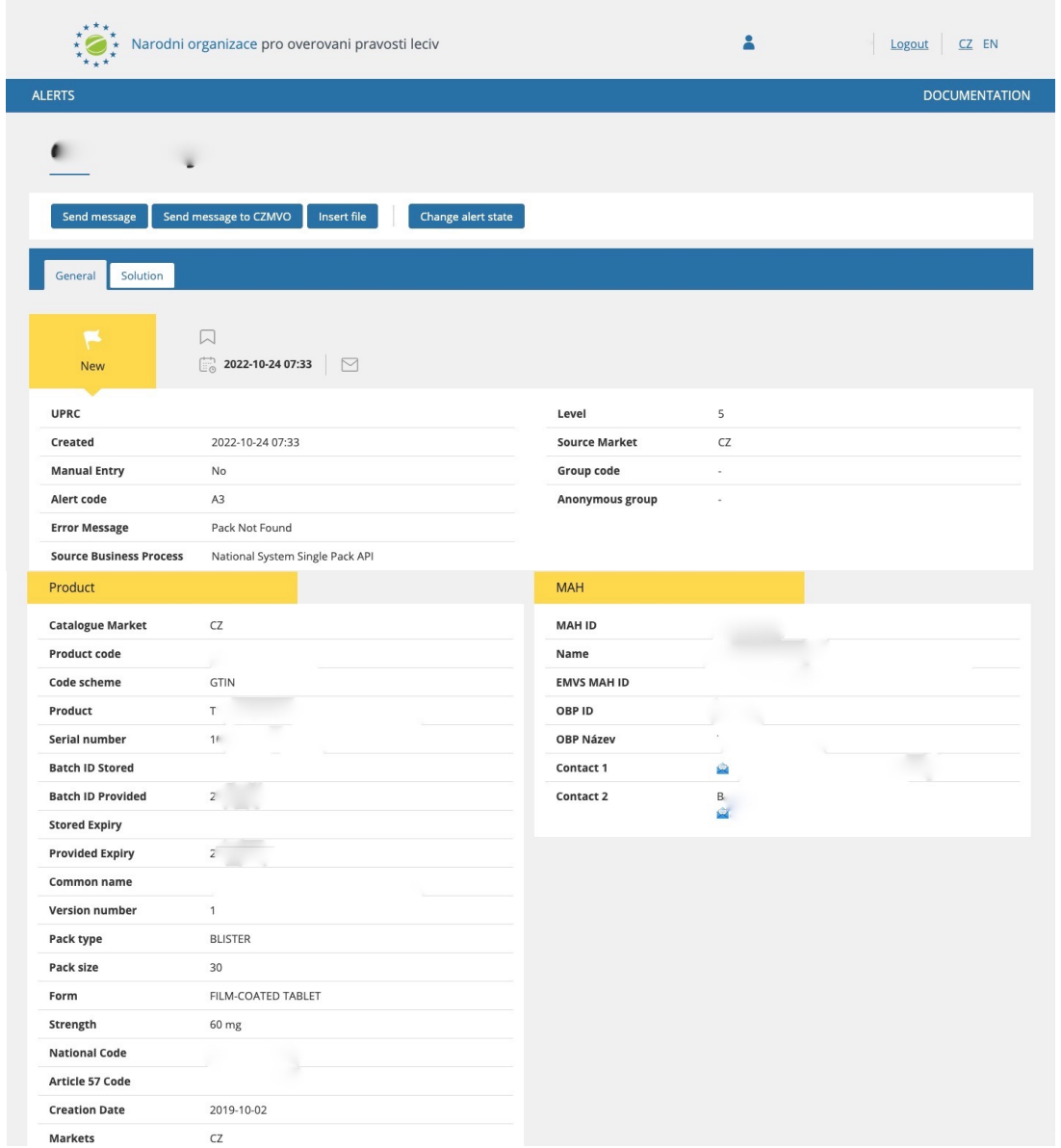
Source Business Process – Initiator of the transaction (National system = End User, MAH = MAH/OBP/Parallel importer).

Level – Alert level

Source Market – Market that initiated the transaction.

Group code – A group of alerts of the same MAH (you can only work with groups in the full AMS environment).

Anonymous Group– A group of alerts of the same end user (Pharmacy, Distributor) (you can only work with groups in the full AMS environment).



2. Product

Details related to the medical product

3. MAH

MAH-related details

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AMS – TAB SOLUTION

Priority – Alert priority (standard/high)

Alert state – Current alert status.

State description – Alert status description.

Last state change– Date when the last state change occurred.

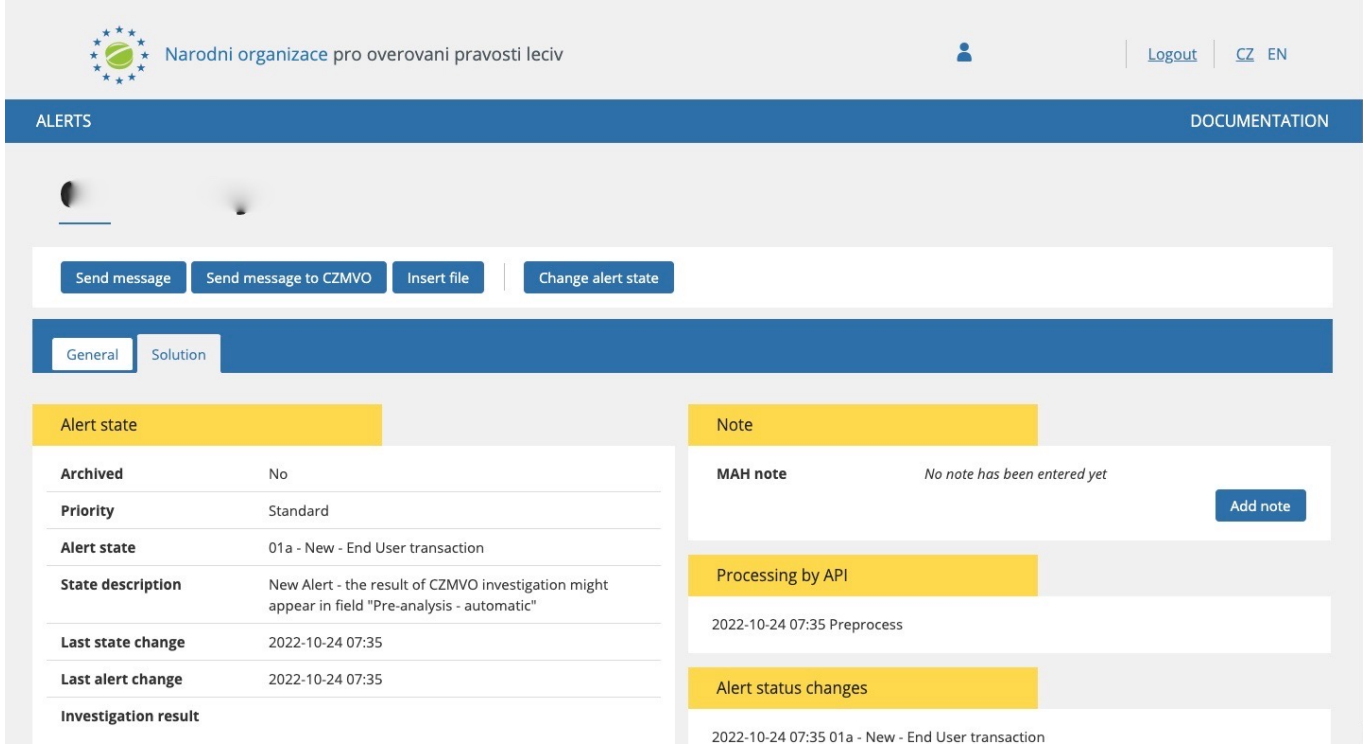
Last alert change – Date of the last change to the alert

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.



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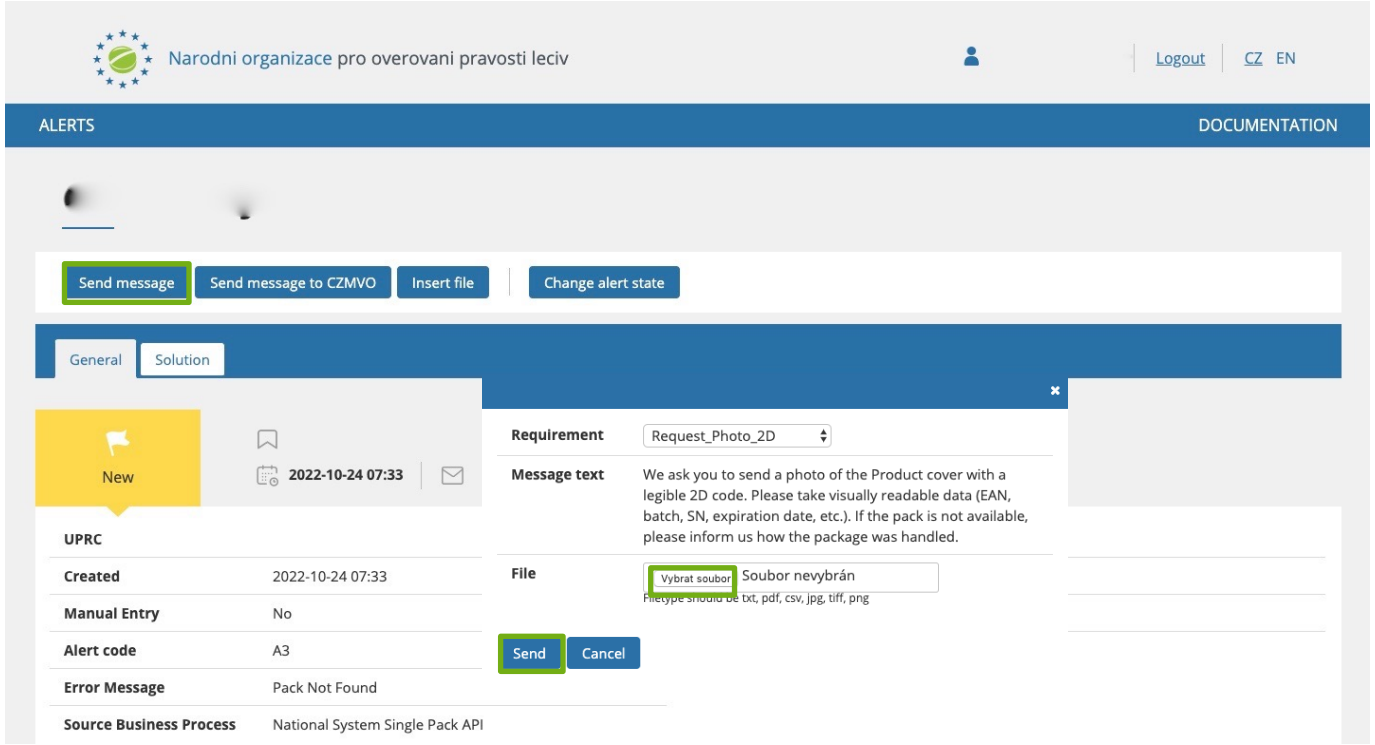
ANONYMOUS COMMUNICATION BETWEEN MAH/OBP AND END USER

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).



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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).**

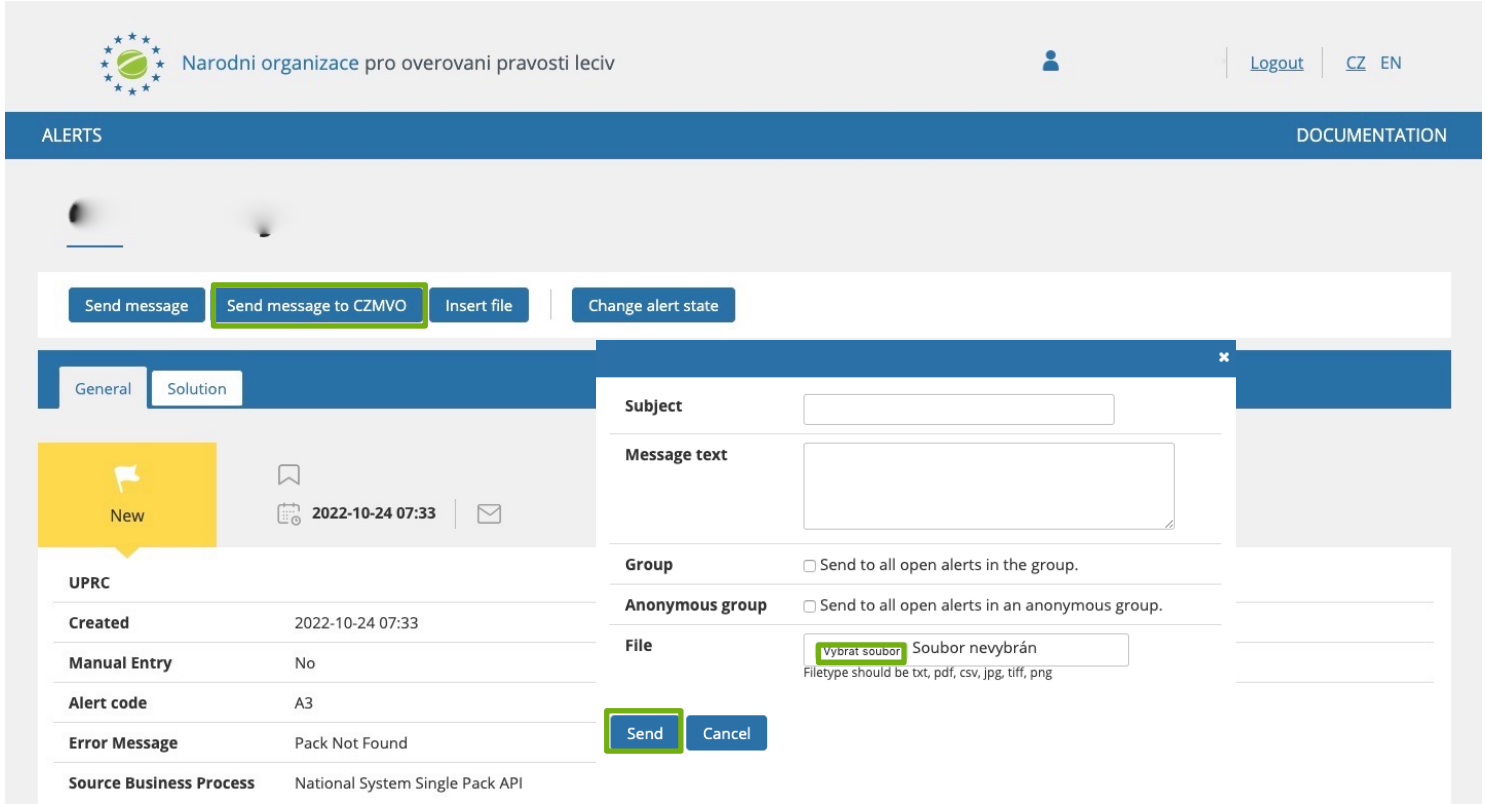
COMMUNICATION BETWEEN CZMVO AND USERS

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"*

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

Note.: The text could possibly be in any language, however; we recommend that English or Czech language be used.



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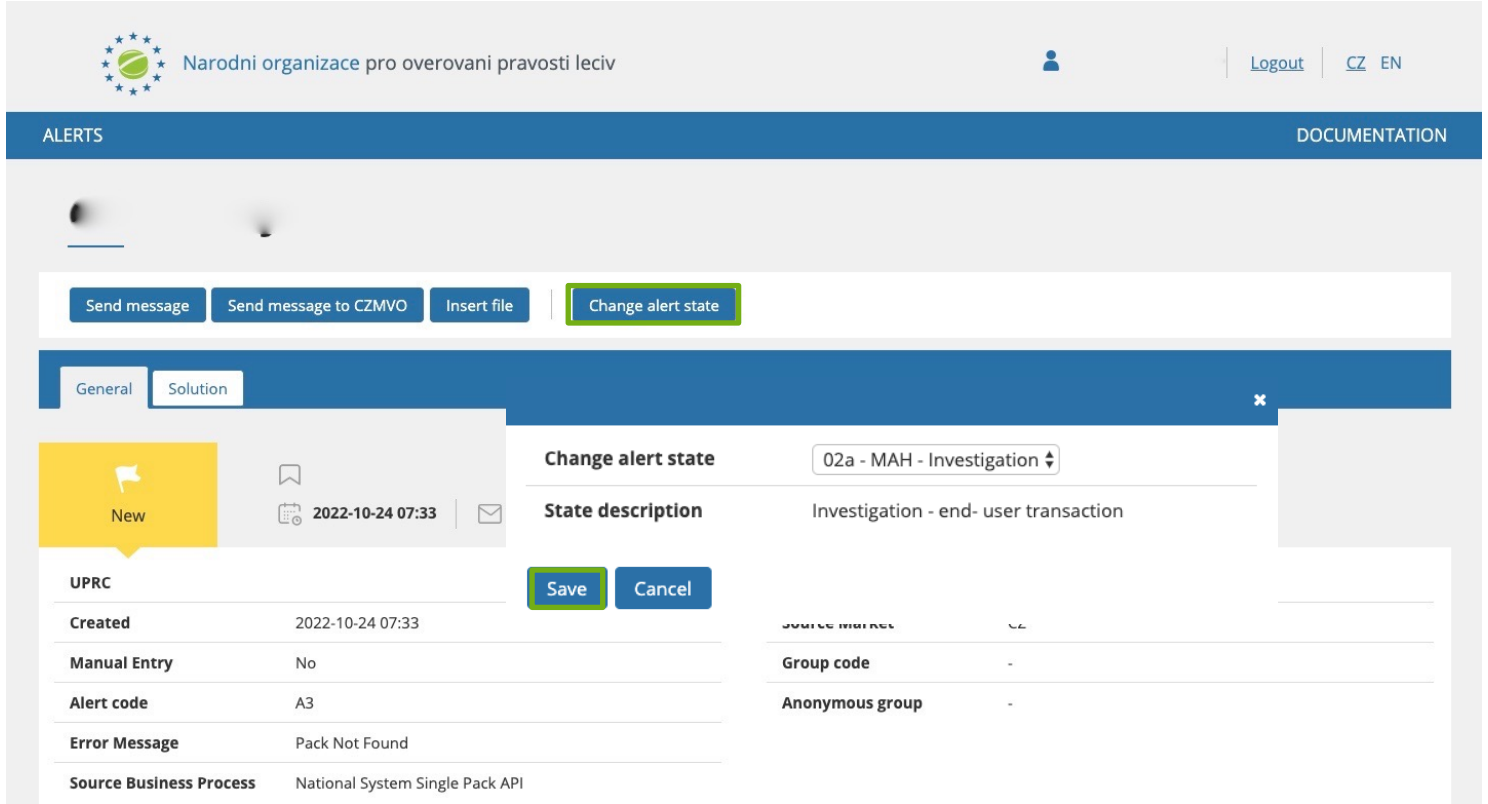
Note: If you require additional information from the end user /CZMVO it is necessary to monitor the alert regularly via the link in e-mail. The requested information will be available directly in tab Solution, in the AMS.

CHANGE ALERT STATE

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



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

END USERS‘ PROCEDURAL ERRORS

- The new version of 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.:As a new feature the **MAH/OBP** can close the end user‘s procedural error with the alert state *„06f - Closed - End User process error - cannot be dispensed“* only after **9 days** have passed from the date the alert was raised.

- 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“.*

COMMUNICATION – PREDEFINED MESSAGES

List of predefined MAH/OBP messages:

Notice:

The list and message texts are continually updated based on feedback from system users.

ID	Název_CZ	Název_AJ	Text_CZ	Text_AJ	Stav po odeslání zprávy	Pro
2	**Fotka_2D**	Photo_2D	Žádáme o zaslání fota obalu LP, s čitelným 2D kódem. Nafoťte prosím i vizuálně čitelné údaje (EAN, šarže, SN, datum exspirace, apod.). V případě, že balení již není k dispozici, informujte nás, jak bylo s balením naloženo.	We ask you to send a photo of the Product cover with a legible 2D code. Please take visually readable data (EAN, batch, SN, expiration date, etc.). If the pack is not available, please inform us how the package was handled.	04a - MAH - Info od KU	MAH
4	**Chyba_End-User**	Error_End_User	Chyba na straně koncového uživatele. Zkontrolujte nastavení snímače či kontaktujte Všeho dodavatele SW. V případě nesouhlasu zašlete zdůvodnění.	End-user error. Check the sensor settings. In case of disagreement please provide a justification.	06b - Uzavřeno - KU - Technická chyba	MAH
22	**Vrátit distributorovi**	Return to distributor	Žádáme o vrácení LP zpět distributorovi. LP nelze vydat!	We request that the pack be returned to the distributor. Pack cannot be supplied!	06c - Uzavřeno - MAH chyba - Neopraveno	MAH
24	**Požadavek - NOOL**	CZMVO - request	Požadujeme investigaci NOOL.	We require a CZMVO investigation.	04b - MAH - Info od NOOL	MAH
30	**Ověření balení**	Pack verify	Prosíme o opakovaní ověření balení. Chyba na straně MAH byla opravena.	Please re-verify the packaging. An error on the MAH side has been fixed.	04a - MAH - Info od KU	MAH

List of predefined end user messages:

ID	Název_CZ	Název_AJ	Text_CZ	Text_AJ	Stav po odeslání zprávy	Pro
5	**2020_Alert**	**2020_Alert**	Alert z roku 2020. Balení jsme vydali – nelze již doložit.	Alert from 2020. Pack we supplied - it can no longer be documented.	05a - KU - Info na MAH	Koncový uživatel
6	**Není chyba koncového uživatele**	Is not End User error	Chyba není na naší straně. Snímač i SW jsou nastaveny korektně.Balení je blokováno v karanténě, nelze korektně ověřit!	The mistake is not on our side. Both the scaner and the SW were set correctly.The packaging is blocked in the quarantine, it cannot be verified correctly!	05a - KU - Info na MAH	Koncový uživatel
7	**Opravená technická chyba**	Fixed technical error	Potvrzujeme technickou chybu na naší straně (chyba v nastavení snímače, SW, apod.). Opraveno/vydáno.	We confirm an technical error on our side (error in the settings of the sensor, SW, etc.). Fixed/supplied.	05a - KU - Info na MAH	Koncový uživatel
25	**Opravená chyba_ruční zadání**	Fixed error_manual entry	Potvrzujeme jako příčinu vzniku alertu chybu při ručním zadávání dat. Opraveno/vydáno.	We confirm an technical error on our side (error in the settings of the sensor, SW, etc.). Ffixed/supplied.	05a - KU - Info na MAH	Koncový uživatel
27	**Opravená technická chyba_End User**	Fixed technical_End User error	Potvrzujeme technickou chybu na naší straně. Opraveno/vydáno.	We confirm an technical error on our side (error in the settings of the sensor, SW, etc.). Fixed/supplied.	06b - Uzavřeno - KU - Technická chyba	Koncový uživatel
31	**Opravená chyba_ruční vstup_nečitelný 2D**	Fixed error_manual entry_unreadable 2D code	Potvrzujeme chybu na naší straně (chyba při ručním zadávání špatně čitelného 2D kódu). Opraveno/vydáno.	We confirm an error on our side (error when manually entering illegible 2D code). Fixed/supplied.	05a - KU - Info na MAH	Koncový uživatel
32	**Opravená chyba_ chybné načtení kvůli umístění 2D kódu**	Fixed error_ incorrect loading due to 2D code placement	Z důvodu umístění 2D kódu vedle EAN kódu došlo k chybnému načtení kódu snímačem. Vzápětí bylo SN ověřeno úspěšně.	Due to the placement of the 2D code next to the EAN code, the scanner read the code incorrectly. Immediately, the SN was verified successfully.	05a - KU - Info na MAH	Koncový uživatel

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Alert states and their solutions

TERMS

All alerts must be investigated and closed

int the shortest time possible

- **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.

PRE-ANALYSES NOOL – INFORMATION TO NEW ALERTS

After alerts pre-analyses NOOL provides information to alert supporting further investigation and offers probable causes of alerts in AMS

- Type of alert: **all**

Name	Situation description to pre-analysed alerts	Next steps in alerts investigation – MAH
Operation MAH/OBP	Indication based on system transaction - origin of the alert by MAH, before medicines pack was distributed to end-user.	MAH/OBP continues investigation and closing the alert without need to involve end-user.
IMT operation	Alert occurred on a different market (data in the NMVS system) than where pack was verified. Indicated if CZ is „initiating“ or „fulfilling“ market.	MAH/OBP continues investigation of alerts marked as „initiating market“ according to common processes. Alerts „fulfilling market“ are in AMS NOOL closed automatically (these should be investigated and closed in the system of “initiating market”.
MAH - Exception ZOL 11r	MAH issue with data or print that cannot be corrected – covered by exception ZOL 11r	MAH/OBP can close alert as “06d - Closed - Exception ZOL par 11r “, alerts with exception can be closed by AMS NOOL
EUT - Caps Lock	Probable cause of alert analysed - end-user error – technical. Suspicion of untreated mistake of keyboard (Caps Lock).	MAH/OBP continues investigation and closing the alert in cooperation with end-user (confirmation of alert cause or identification of different alert cause); alert can also be investigated and closed directly by End-user as "6b - Closed – End-user technical error” and verify UI of the pack again before pack is released from quarantine and supplied to patient.
EUT – long string in SN	Probable cause of alert analysed - end-user error – technical . Suspicion of inaccurate set up of scanner (long string in SN).	
EUT - EN/CZ	Probable cause of alert analysed - end-user error – technical . Suspicion of untreated mistake of keyboard (EN/CZ).	

Notice: EU = end-user
EUT = end-user technical error

PRE-ANALYSES NOOL – INFORMATION TO NEW ALERTS - II

After alerts pre-analyses NOOL provides information to alert supporting further investigation and offers probable causes of alerts in AMS

- Type of alert: **all**

Name	Situation description to pre-analysed alerts	Next steps in alerts investigation – MAH
EUT – short string in SN	Probable cause of alert analysed - end-user error – technical. Suspicion of inaccurate set up o of scanner (short string in SN).	MAH/OBP continues investigation and closing the alert in cooperation with end-user (confirmation of alert cause or identification of different alert cause); alert can also be investigated and closed directly by End-user as "6b - Closed – End-user technical error" and verify UI of the pack again before pack is released from quarantine and supplied to patient.
EUT – commutation of characters	Probable cause of alert analysed - end-user error – technical. Suspicion of low quality of scanner (characters commutation O/0,E/3,I/L,...)	
EUP – repeated supply	Probable cause of alert analysed - end-user error – procedural. Probable repeated (double) supply	MAH/OBP continues investigation and closing the alert in cooperation with end-user (confirmation of alert cause or identification of different alert cause) 06f – Closed - Procedural error EU – supply not alllowed.
MAH – batch not uploaded	MAH – data not uploaded	MAH/OBP continues investigation and closing the alert.
CZMVS - alerts from 2020	Alerts z roku 2020 + A3 nebo A7 nebo A52 - lze řešit MAHem zrychleně bez zapojení koncového uživatele.	MAH/OBP investigates and closes the alert without need to involve end-user (agreed with NCA). Alert is marked in AMS NOOL for easy identification of these alert with specific investigation and closing.
CZMVS - PSUN	CZMVS NSOL – error in synchronization between markets (PSUN transaction, alert occurred outside of CZ).	Alert is automatically closed in AMS NOOL.

Notice: EUP = end-user procedural error

CONTINUOUS ALERT STATUSES

Alerts investigation by MAH and next steps of the solution including relevant AMS statuses

- Type of alert: **all**

Alert code and name in AMS	End-user - procedure during alerts investigation	MAH – steps during alert investigation
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“.

Incidents A1 and A5 should be investigated in near future

Other statuses 01x, 02x relate to CZMVO investigation

After 30 days report to NCA

CONTINUOUS ALERT STATUSES - II

- Type of alert: **all**

Alert code and name in AMS	End-user - procedure during alerts investigation	MAH – steps during alert investigation
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 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** **NOCZMVO - Info end user to MAH** **05d,05f** **NOOL – Info MAH** **05e** **KU – End user - Info - A1, A5**	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.

Other statuses 04x relate to CZMVO investigation

CLOSING ALERT STATUSES

Alerts closing and next steps of the solution including relevant AMS statuses

- Type of alerts: **A2, A3, A52 and 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 in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06a **MAH error - Corrected**	• 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). • One element of the Data Matrix Code appears in the batch field, because group separators have not been set properly. • Retrospective upload capability not implemented in the OBP software.	Keep medicinal pack in quarantine until the end of alert investigation. Once alert is closed, provided info from AMS: **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).**	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.

Notice: IMT = intermarket transaction

CLOSING ALERT STATUSES

- Type of alerts: **A2, A3, A52 and 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 in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06b Closed - Technical error - End user	• 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.	**End–user should correct the cause of alert according to what caused it**: • 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. Use “control scan”, if possible, to verify proper scanner set up and after that go back to medicinal pack with alert. **End-user can than again verify pack and if decommision is successful pack can be release from quarantine and provided to patient.**	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 error es well, if MAH/OBP can prove based on info identified, technical error was caused by end-user.

CLOSING ALERT STATUSES

- Type of alerts: **A2, A3, a52 and 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 in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06c Closed - MAH error - Not corrected	• 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").	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: **MAH / OBP error. Unable to correct - cannot be re-verified. Return the packaging to the supplier with alert ID identification.** End user should return pack back to distribution (wholesaler) according to return process set up in end-user organisation.	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.

CLOSING ALERT STATUSES

- Type of alerts: **A2, A3, 52 and 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 in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06d **Closed - ZOL 11r exception**	• 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").	Keep medicinal pack in quarantine until the end of alert investigation. Wait for closing the alert by MAH/OBP or CZMVS. Once alert is closed, provided info from AMS: **Exception ZOL - 11r - DO NOT VERIFY. Can be supplied to patient. Remove from quarantine.**	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.

CLOSING ALERT STATUSES

- Type of alerts: **all**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once the cause (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 in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06e **Closed - Before 02/09/2019**	• Partially serialised product (without SN or other production data from the Data Matrix Code), release from production prior 9.2.2019.	Keep medicinal pack in quarantine until the end of alert investigation and closing by MAH/OBP. Once alert is closed, provided info from AMS: **Release from production before 09/02/2019 - not subject to FMD - DO NOT VERIFY! The pack can be supplied to patient. Remove from quarantine.**	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.

CLOSING ALERT STATUSES

- Type of alerts**: 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 in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06f **Closed - Process error KU - cannot be issued**	• 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. • 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.	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 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.**	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. **End-user should in the future document process error in AMS – chose from predefined options according to instructions relevant to process errors. Start of using such process to be agreed and confirmed with NCA. After that pack could be released from quarantined and supplied to patient.**.

CLOSING ALERT STATUSES

- Type of alerts: **All**. Under the terms of alert investigation, the end user ought to examine possible technical causes of the alert on their side – most frequently caused by wrong procedures, human error or inappropriate software settings. If you are certain that the alert was caused by one of the following examples (2nd column), we recommend that you follow the directions for end users (3rd column) or for the MAH (4th column).

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06g **Closed - CZMVS error**	Relevant to pack that, • 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.	During alert investigation that was created on Czech market keep medicinal pack in quarantine until the end of alert investigation and closing alert NOOL. Once alert is closed, provided info from AMS (based on cause of CZMVS): **CZMVS Error - The pack can be verified again! Remove from quarantine.** **CZMVS Error - The pack cannot be verified again! Return back.**	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. 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). AMS system closes alert on behalf of CZMVO. No impact on packs in CZ.

CLOSING ALERT STATUSES

- Type of alerts: A**ll**. Under the terms of alert investigation, the end user ought to examine possible technical causes of the alert on their side – most frequently caused by wrong procedures, human error or inappropriate software settings. If you are certain that the alert was caused by one of the following examples (2nd column), we recommend that you follow the directions for end users (3rd column) or for the MAH (4th column).

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06o - Closed - End User does not cooperate - cannot be supplied	The MAH has concluded the investigation and repeatedly requested the end user for additional information. The end user is not cooperating. The pack cannot be supplied. CZMVO will inform SÚKL. **Note.: This state is only applicable if more than 9 days have passed since the alert was set to state 03d (End user Inactivity – 5 days)**	The alert has been closed by the MAH. The pack cannot be supplied. The end user did not cooperate despite receiving multiple notifications and warnings. CZMVO will inform SÚKL. Immediately contact CZMVO or respond to requests of the MAH/CZMVO.	Closed. The end user is not cooperating despite receiving multiple warnings. The pack cannot be supplied. CZMVO will inform SÚKL.

CLOSING ALERT STATUSES

- Type of alerts: **all**. During investigation of alert should MAH/OBP check data uploaded into EMVS/CZMVS, end-user to check potential technical or process error, CZMVO checks potential system errors. Once all potential causes on MAH, end-user side and CZMVO are excluded, next steps should follow recommended process for end-user (column 3) or MAH (column 4):

Alert code and name in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06h – Suspected Counterfeit!	• 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

- Type of alerts: **A7, A24**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once the cause (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 in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06i - Closed - MAH transaction error - Fixed	• 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	• 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	• 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	• 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 - X

- Type of alerts: **A1**. During investigation of alert MAH/OBP should check data uploaded into EMVS/CZMVS. Once the cause (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 in AMS	Most common alert causes	End-user - procedure during alerts investigation	MAH – steps during alert closing
06l **- Non FMD**	• 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	Keep medicinal pack in quarantine until the end of alert investigation and closing by MAH/OBP or CZMVO. Once alert is closed, provided info from AMS: **Medicinal product is not subject to FMD. Can be issued without verifying. Remove from quarantine.**	MAH or end-user found out during alert investigation that verified pack or device is not subject to FMD.
06z **- Closed – 2019,202,2021 alert**	• All potential causes of alerts		Alerts from 2019-2021 were automatically closed based on agreement with NCA.

Complete list of alerts statuses and proces maps AMS

ALERTS STATUS COMPLETE LIST

Aktivní	Stav EMVO AMS	ID	Status Code	Zkratka stavu pro AMS	Short name Alert status AMS	Zpráva pro MAH	Message for MAH
A	Active	1	01a	Nový - transakce KU	New - end user transaction	**Nová výstraha - výsledek investigace NOOL případně v poznámce.**	New Alert - the result of CZMVO investigation might appear in Note
A	Active	2	01aa	Nový - Notifikace	New - Notification	**Nová výstraha - výsledek investigace NOOL případně v poznámce.**	New Alert - the result of CZMVO investigation might appear in Note
	Active	3	01b	MAH - Nový - transakce MAH/OBP/PD	MAH - New - MAH/OBP/PD transaction	**Nová výstraha - operace MAH/OBP/PD**	New Alert - MAH/OBP/PD transaction
A	Under Investigation	7	02a	MAH - Investigace - KU	MAH - Investigation - End user	**Zahájili jste Investigaci - operace koncového uživatele**	You have initiated investigation - end- user transaction
A	Under Investigation	10	02b	MAH - investigace - operace MAH/OBP/PD	MAH - Investigation - MAH/OBP/PD transaction	**Investigace - operace MAH/OBP/PD**	Investigation - MAH/OBP/PD transaction
A	Under Investigation	13	03a	MAH - Nečinnost 5 dní	MAH - Inactivity 5 days	**Upozornění, výstraha ve stavu "Nový" více než 5 dní**	Warning, the alert has remained in "New" status for over 5 days
A	Under Investigation	14	03b	MAH - Nečinnost 10 dní	MAH - Inactivity 10 days	**Varování - výstraha ve stavu "Nový" více než 10 dní**	Warning, the alert has remained in "New" status for over 10 days
A	Under Investigation	15	03c	KU - Nečinnost 48 hodin	End user - Inactivity 48 hours	**Koncový uživatel obdržel upozornění, že MAH požaduje doplňující informace a po více než 24 hodinách mu je nedodal.**	The end user failed to provide additional information requested by MAH within 24 hours
A	Under Investigation	146	03d	KU - Nečinnost 5 dní	End user - Inactivity 5 days	**Koncový uživatel obdržel upozornění, že MAH požaduje doplňující informace a po více než 5 dnech mu je nedodal.**	The end user failed to provide additional information requested by MAH within 5 days
A	Under Investigation	17	04a	MAH - Info od KU	MAH - info from end user	**Vyžádány doplňující informace od koncového uživatele**	Additional information requested from the end user
A	Under Investigation	19	04b	MAH - Info od NOOL	MAH - Info from CZMVO	**Vyžádány doplňující informace od NOOL**	Additional information requested from the CZMVO
A	Under Investigation	24	04f	MAH - Info od NOOL - transakce PD	MAH - Info from CZMVO - PD transaction	**Vyžádány doplňující informace od NOOL**	Additional information requested from the CZMVO
A	Under Investigation	25	05a	KU - Info na MAH	End user - Info to MAH	**Koncový uživatel zaslal požadované doplňující informace**	The end user has sent the required additional information
A	Under Investigation	26	05b	NOOL- kontakt KU	CZMVO - Contacts end User	**NOOL kontaktuje koncového uživatele**	CZMVO contacts end-user
A	Under Investigation	27	05c	NOOL - Info od KU na MAH	CZMVO - Info end user to MAH	**Požadované informace od koncového uživatele předány**	The end user has provided the required information
A	Under Investigation	29	05d	NOOL - Info na MAH	CZMVO - Info to MAH	**Požadované informace od NOOL předány**	The required information is passed from CZMVO
A	Under Investigation	29	05f	NOOL - Info na MAH - transakce PD	CZMVO - Info to MAH - PD transaction	**Požadované informace od NOOL předány**	The required information is passed from CZMVO
A	Closed	33	06a	Uzavřeno - Chyba MAH - Opraveno	Closed - MAH error - Corrected	**Uzavřeno - chyba MAH/OBP, opraveno**	Closed - MAH/OBP error, corrected
A	Closed	34	06b	Uzavřeno - Technická chyba KU	Closed - Technical error - End user	**Uzavřeno - MAH/OBP vyloučil chybu na své straně. KU potvrdil, že se jedná o technickou chybu KU.**	Closed - MAH/OBP ruled out a mistake on his side. End user confirmed technical error on his side.
A	Closed	35	06c	Uzavřeno - Chyba MAH - Neopraveno	Closed - MAH error- Not corrected.	**Uzavřeno - Chyba MAH/OBP - nelze opravit**	Closed - MAH/OBP error - cannot be corrected
A	Closed	36	06d	Uzavřeno - Výjimka ZOL 11r	Closed - ZOL 11r exception	**Uzavřeno - výjimka ZOL 11r**	Closed - ZOL - 11r
A	Closed	37	06e	Uzavřeno - Před 9.2.2019	Closed - Before 02/09/2019	**Uzavřeno - Propuštěno z výroby před 9.2.2019**	Closed - Released from production before 02/09/2019
A	Closed	38	06f	Uzavřeno - Procesní chyba KU - nelze vydat	Closed - Process error KU - cannot be dispensed	**Uzavřeno - procesní chyba KU- nelze vydat**	Closed - process error EU- cannot be issued
N	Closed	145	06m	Uzavřeno - Procesní chyba KU - lze vydat	Closed - Process error KU - can be issued	**Uzavřeno - procesní chyba KU- lze vydat po zdokumentování příčiny KU**	Closed – End User process error - (can be dispensed after his documentation of the cause)
A	Closed	39	06g	Uzavřeno - Chyba NSOL	Closed - CZMVS error	**Uzavřeno - chyba NSOL**	Closed - CZMVS Error
A	Escalated	40	06h	Podezření na padělek!	Suspected Counterfeit!	**Vyšetřování ze strany MAH i NOOL potvrdilo možný padělek, informace bude předána na SÚKL, EMVO, EMA, EK**	Investigation by MAH and CZMVO confirmed a possible forgery, information will be passed to NCA, EMVO, EMA, EK
A	Closed	41	06i	Uzavřeno - Chyba MAH transakce - Opraveno	Closed - MAH transaction error - Fixed.	**Uzavřeno - chyba MAH/OBP, opraveno. MAH/OBP transakce.**	Closed - MAH/OBP error, corrected.MAH / OBP transactions.
A	Closed	42	06j	Uzavřeno - Chyba MAH transakce - Neopraveno	Closed - MAH transaction error - Not corrected.	**Uzavřeno - Chyba MAH/OBP - nelze opravit. MAH/OBP transakce.**	Closed - MAH/OBP error - cannot be corrected.MAH / OBP transactions.
A	Closed	43	06k	Uzavřeno - chyba PD - Neopraveno	Closed - PD error - Not fixed.	**Uzavřeno - chyba paralelního distributora. Nelze opravit. MAH/OBP transakce**	Closed - parallel distributor error. Cannot be corrected, cannot be suplied. MAH/OBP transactions.
A	Closed	8	06n	Uzavřeno – IMT fulfilling – Alert vznikl mimo CZ, MAH vyšetřuje na jiném trhu	Closed - IMT fulfilling - Alert originated outside CZ, MAH is investigating in another market	**Uzavřeno – IMT fulfilling – Alert vznikl mimo CZ, MAH vyšetřuje na jiném trhu**	Closed - IMT fulfilling - Alert originated outside CZ, MAH is investigating in another market
A	Closed	147	06o	Uzavřeno - KU nesppolupracuje - nelze vydat	Closed - End User does not cooperate - cannot be supply	**Uzavřeno, koncový uživatel ani přes urgence nespolupracuje - nelze vydat. NOOL informuje SÚKL**	Closed, end user does not cooperate despite urgency - does not supply. CZMVO inform NCA.
A	Closed	45	06z	Uzavřeno – Alert 2019	Closed - 2019 alert	**Uzavřeno – alert z roku 2019**	Closed - 2019 alert
A	Closed	46	07a	Podezření na padělek! Info předáno	Counterfeit! Info passed	**Vyšetřování ze strany MAH i NOOL potvrdilo možný padělek, informace byla předána na SÚKL, EMVO,**	Investigation by MAH and CZMVO confirmed a possible counterfeit. Information was passed to NCA, EMVO, EMA, EK

Národní organizace pro ověřování pravosti léčiv

WORK FLOW

AMS

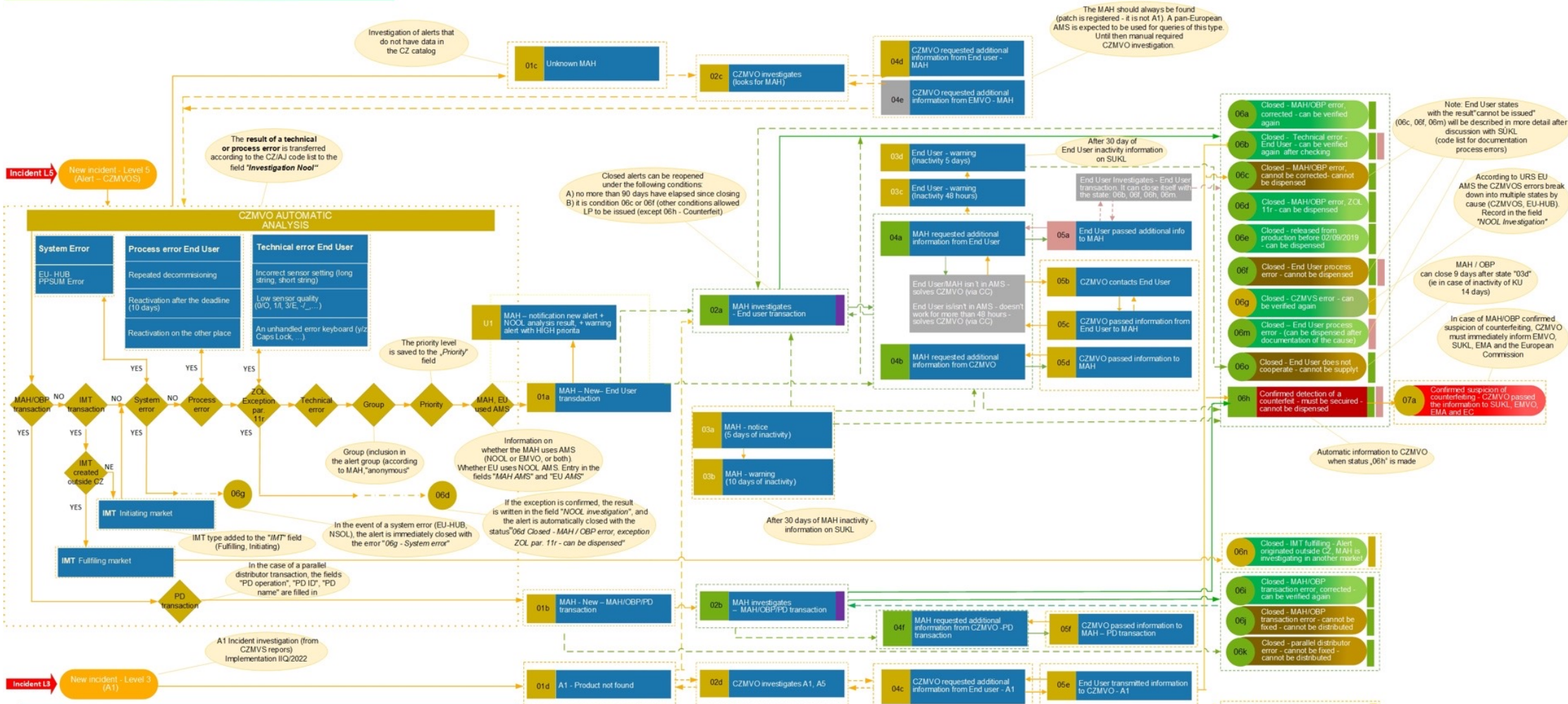
MAH/ OBP

Stav alertu	Alert state	Možné změny stavu alertu	Alert state change options	Možné změny stavu volbou "Zaslat zprávu"	Alert state change option via "Send message" button	Možné zprávy	Send Message options
01a - Nový - transakce KU 01aa - Nový - Notifikace	01a - New - End User transaction 01aa - New - Notification	02a - MAH - Investigace - KU	02a - MAH - Investigation - End user	04a - MAH - Info od KU	04a - MAH - info from end user	2 - Fotka_2D	2 - Photo_2D
		06a - Uzavřeno - Chyba MAH - Opraveno	06a - Closed - MAH error - Fixed			30 - Ověření balení	30 - Pack verify
		06b - Uzavřeno - Technická chyba KU	06b - Closed - End user - Technical error	04b - MAH - Info od NOOL	04b - MAH - Info from CZMVO	24 - Požadavek - NOOL	24 - CZMVO - request
		06c - Uzavřeno - Chyba MAH - Neopraveno	06c - Closed - MAH error - Not fixed.	06a - Uzavřeno - Chyba MAH - Opraveno	06a - Closed - MAH error - Fixed	4 - Chyba_End-User	4 - Error_End_User
		06d - Uzavřeno - Výjimka ZOL 11r	06d - Closed - MAH error - MH exception	06c - Uzavřeno - Chyba MAH - Neopraveno	06c - Closed - MAH error - Not fixed.	22 - Vrátit distributorovi	22 - Return to distributor
		06e - Uzavřeno - Před 9.2.2019	06e - Closed - Before 02/09/2019				
		06f - Procesní chyba KU - nelze vydat	06f - Closed - End User - Process error				
		06h - Podezření na padělek!	06h - Suspected Counterfeit!				
01b - MAH - Nový - transakce MAH/OBP/PD	01b - MAH - New - MAH/OBP/PD transaction	02b - MAH - investigace - operace MAH/OBP/PD	02b - MAH - Investigation - MAH/OBP/PD transaction	04f -MAH - Info od NOOL - transakce PD	04f - MAH - Info from CZMVO - PD transaction		
		06i - Uzavřeno - Chyba MAH transakce - Opraveno	06i - Closed - MAH transaction error - Fixed.				
		06j - Chyba MAH transakce - Neopraveno	06j - Closed - MAH transaction error - Not fixed.				
		06k - Uzavřeno - chyba PD - Neopraveno	06k - Closed - PD error - Not fixed.				
02a - MAH - Investigace - KU	02a - MAH - Investigation - End user	06a - Uzavřeno - Chyba MAH - Opraveno	06a - Closed - MAH error - Fixed	04a - MAH - Info od KU	04a - MAH - info from end user	2 - Fotka_2D	2 - Photo_2D
		06b - Uzavřeno - Technická chyba KU	06b - Closed - End user - Technical error			30 - Ověření balení	30 - Pack verify
		06c - Uzavřeno - Chyba MAH - Neopraveno	06c - Closed - MAH error - Not fixed.	04b - MAH - Info od NOOL	04b - MAH - Info from CZMVO	24 - Požadavek - NOOL	24 - CZMVO - request
		06d - Uzavřeno - Výjimka ZOL 11r	06d - Closed - MAH error - MH exception	06a - Uzavřeno - Chyba MAH - Opraveno	06a - Closed - MAH error - Fixed	4 - Chyba_End-User	4 - Error_End_User
		06e - Uzavřeno - Před 9.2.2019	06e - Closed - Before 02/09/2019	06c - Uzavřeno - Chyba MAH - Neopraveno	06c - Closed - MAH error - Not fixed.	22 - Vrátit distributorovi	22 - Return to distributor
		06f - Procesní chyba KU - nelze vydat	06f - Closed - End User - Process error				
		06h - Podezření na padělek!	06h - Closed - Counterfeit!				
02b -MAH - investigace - operace MAH/OBP/PD	02b - MAH - Investigation - MAH/OBP/PD transaction	06i - Uzavřeno - Chyba MAH transakce - Opraveno	06i - Closed - MAH transaction error - Fixed.	04f -MAH - Info od NOOL - transakce PD	04f - MAH - Info from CZMVO - PD transaction		
		06j - Chyba MAH transakce - Neopraveno	06j - Closed - MAH transaction error - Not fixed.				
		06k - Uzavřeno - chyba PD - Neopraveno	06k - Closed - PD error - Not fixed.				
03a - MAH - Nečinnost 5 dní 03b - MAH - Nečinnost 10 dní	03a - MAH - Inactivity 5 days 03b - MAH - Inactivity 10 days	02a - MAH - Investigace - KU	02a - MAH - Investigation - End user				
		06a - Uzavřeno - Chyba MAH - Opraveno	06a - Closed - MAH error - Fixed				
		06b - Uzavřeno - Technická chyba KU	06b - Closed - End user - Technical error				
		06c - Uzavřeno - Chyba MAH - Neopraveno	06c - Closed - MAH error - Not fixed.				
		06d - Uzavřeno - Výjimka ZOL 11r	06d - Closed - MAH error - MH exception				
		06e - Uzavřeno - Před 9.2.2019	06e - Closed - Before 02/09/2019				
		06f - Procesní chyba KU - nelze vydat	06f - Closed - End User - Process error				
		06h - Podezření na padělek!	06h - Closed - Counterfeit!				
03c - KU - Nečinnost 48 hodin	03c - End user - Inactivity 48 hours	06a - Uzavřeno - Chyba MAH - Opraveno	06a - Closed - MAH error - Fixed				
		06b - Uzavřeno - Technická chyba KU	06b - Closed - End user - Technical error				
		06c - Uzavřeno - Chyba MAH - Neopraveno	06c - Closed - MAH error - Not fixed.				
		06e - Uzavřeno - Před 9.2.2019	06e - Closed - Before 02/09/2019				
		06f - Procesní chyba KU - nelze vydat	06f - Closed - End User - Process error				
		06h - Podezření na padělek!	06h - Closed - Counterfeit!				
03d - KU - Nečinnost 5 dní	03d - End user - Inactivity 5 days	06a - Uzavřeno - Chyba MAH - Opraveno	06a - Closed - MAH error - Fixed				
		06b - Uzavřeno - Technická chyba KU	06b - Closed - End user - Technical error				
		06c - Uzavřeno - Chyba MAH - Neopraveno	06c - Closed - MAH error - Not fixed.				
		06e - Uzavřeno - Před 9.2.2019	06e - Closed - Before 02/09/2019				
		06f - Procesní chyba KU - nelze vydat	06f - Closed - End User - Process error				
		06o -Uzavřeno - KU nespolupracuje - nelze vydat	06o - Closed - End User does not cooperate - cannot be supply				
		06h - Podezření na padělek!	06h - Closed - Counterfeit!				
04a - MAH - Info od KU	04a - MAH - Info from end user	02a - MAH - Investigace - KU	02a - MAH - Investigation - End user				
05a - KU - Info na MAH	05a - End user - Info to MAH	02a - MAH - Investigace - KU	02a - MAH - Investigation - End user				
05b - NOOL- kontakt KU 05c - NOOL - Info od KU na MAH 05d - NOOL - Info na MAH	05b - CZMVO - Contacts end User - CC 05c - CZMVO - Info end user to MAH 05d - CZMVO - Info to MAH	06a - Uzavřeno - Chyba MAH - Opraveno	06a - Closed - MAH error - Fixed				
		06b - Uzavřeno - Technická chyba KU	06b - Closed - End user - Technical error				
		06c - Uzavřeno - Chyba MAH - Neopraveno	06c - Closed - MAH error - Not fixed.				
		06d - Uzavřeno - Výjimka ZOL 11r	06d - Closed - MAH error - MH exception				
		06e - Uzavřeno - Před 9.2.2019	06e - Closed - Before 02/09/2019				
		06f - Procesní chyba KU - nelze vydat	06f - Closed - End User - Process error				
		06h - Podezření na padělek!	06h - Closed - Counterfeit!				
06c - Uzavřeno - Chyba MAH - Neopraveno	06c - Closed - MAH error - Not fixed.	02a - MAH - Investigace - KU	02a - MAH - Investigation - End user	Důvod znovuotevření	Why reopened	1 - Chybně uzavřeno	1 - Incorrectly closed
		06a - Uzavřeno - Chyba MAH - Opraveno	06a - Closed - MAH error - Fixed				
		06b - Uzavřeno - Technická chyba KU	06b - Closed - End user - Technical error				
		06d - Uzavřeno - Výjimka ZOL 11r	06d - Closed - MAH error - MH exception				
		06e - Uzavřeno - Před 9.2.2019	06e - Closed - Before 02/09/2019				
		06f - Procesní chyba KU - nelze vydat	06f - Closed - End User - Process error				
		06h - Podezření na padělek!	06h - Closed - Counterfeit!				
06j - Uzavřeno - Chyba MAH transakce - Neopraveno	06j - Closed - MAH transaction error - Not fixed.	02b - MAH - Investigation - MAH/OBP/PD transaction	02b - MAH - Investigation - MAH/OBP/PD transaction	Důvod znovuotevření	Why reopened	1 - Chybně uzavřeno	1 - Incorrectly closed
06k - Uzavřeno - chyba PD - Neopraveno	06k - Closed - PD error - Not fixed.		06i - Closed - MAH transaction error - Fixed.				

NOOL Alert Management System

Map of alert processes and statuses

Version 4.2 12/2021



CAPTION

- Final states of the alert, manually set MAH
- Continuous states of the alert, manually set MAH
- The final states of the alert are set automatically or manually by NOOL
- Final states of the alert, manually set by the End User (EU)
- Final state of the alert. Can be re-verified.
- Final state of the alert. Cannot verify again.
- Confirmed suspected counterfeit. Packing in quarantine.

MAH activities: Obligatory / Optional

CZMVO activities: Obligatory / Optional

End User activities: Obligatory / Optional

States outside the CZMVO AMS workflow

CC - NOOL call-centrum
EU - End User

API - Application Programming Interface (all AMS functionalities are available via WEB GUI and API)
EMVO - European Medicines Verification Organisation
EMA - European Medicines Agency
EC - European Commission
SUKL - Státní ústav pro kontrolu léčiv – Czech NCA

EMVO AMS alert status	NOOL AMS alert status
New	--
Active	01
Escalated	07
Under Investigation	02, 03, 04, 05
Closed	06

Overview of warning and alert notifications

U1 Notifications: MAH - New alert + result of "NOOL analysis" +/- High Priority Alert (info MAH, possibly CZMVO)

03a Warning: MAH - status "New" for more than 7 days

03b Warning: MAH - status "New" for more than 10 days

03c Warning: End User did not respond to the MAH request for 48 hours

03d Warning: End User did not respond to the MAH request for 5 days

Overview of information notifications

04a MAH requested additional information from End User - info MAH and End User, in case End User does not use AMS info also CZMVO

04b,04f MAH requested additional information from CZMVO - info MAH and CZMVO

05a End User submitted additional INFO to MAH - info MAH and End User

05c CZMVO passed information from KU to MAH - info MAH and CZMVO

05d,05f CZMVO passed information to MAH - info MAH and CZMVO

06a, 06b, 06c, 06d, 06e, 06f, 06m, 06o Closed - info MAH and End User

06g Closed – CZMVOS error - can be verified again - info MAH, NOOL, End User

06h Confirmed forgery suspected - info MAH, CZMVO, End User

02a MAH investigates – End User operations - Info MAH and End User (only in case of reopening of already closed state)