Frequently asked questions

Login to the National Medicines Verification System (NMVS) [Národní systém pro ověřování pravosti léčiv (CZMVS)] and the Alert Management System (AMS)

How should I log in to or register in the Alert Management System (AMS), the National Medicines Verification System (CZMVS)?

Use the main page of the CZMVO's website: http://www.czmvo.cz/ to register in or log in to the National Medicines Verification System (CZMVS) or to the EVA portal (Emergency Verification Application), which can be used in the case of the pharmacy application's failure or a problem with the CZMVS. You can also simply register in or log in to the Alert Management System (AMS).

What should I do if I need to log in to the CZMVS portal and to change my organization's information/to add another location?

Use the link to the CZMVS portal: https://portal-cz.nmvo.eu/ and enter the login name (the superuser's email address) and password. After you click on "Log in," you will be asked to enter the authorization code sent to your e-mail address. If you forgot your password, click on "Change Password" on the login screen.

What should I do if the CZMVS is not available?

Medicinal products subject to anti-counterfeiting legislation must continue to be verified upon dispensation. If you are authorized to dispense them, you need to scan the 2D code of each pack; the unique identifier will be saved in pharmacy/distribution software (SW). As soon as the CZMVS is available again, pharmacy SW will send all of the 2D codes scanned while the CZMVS was unavailable for verification. The availability of the CZMVS can be checked on the CZMVO website - CZMVS status tab (https://www.czmvo.cz/cs/stav-nsol/). It shows the traffic light and the system status. Green means that the system is available without any limitation. If the verification problems persist, there may be a local problem with SW or the Internet.

How to find out whether the CZMVS is unavailable or there is an error in the connection or availability of the end user's SW Internet connection?

The CZMVS status tab (https://www.czmvo.cz/cs/stav-nsol/) on the CZMVO website shows the traffic light and the system status; green means that the system is available

without limitation. If the problems still persist, there may be a local problem with SW or the Internet.

What should I do if the medicinal product cannot be verified and yet the CZMVS is working?

We recommend verifying the end user's (pharmacy's) Internet connection and/or contacting your IT SW provider or IT support.

How do I contact the National Medicines Verification Organization?

- Operational support and questions about handling and closing alerts: support@czmvo-alert.cz
- Support concerning registration in the CZMVS and AMS: registrace@czmvo.cz
- General information: info@czmvo.cz
- By phone (the first or second option at) +420 224 834 153, +420 224 834 154, +420 224 834 155

Alerts and technical problems

What should I do if the pharmacy scans the 2D code of a medicinal product subject to anti-counterfeiting legislation and an alert is generated?

The medicinal product (MP) with alert information should be quarantined. The MP is marked with a unique alert code (alert identifier = alert ID in the format CZ-XXX-XXX-XXX-XXX-XXX), or the alert ID should be saved in the end users' SW together with the records about the pack, which can then be used when the pack is returned to the distributor. The alert status and any potential requests for additional information for an alert investigation are available in the Alert Management System (AMS). For more information, go to the CZMVO website https://www.czmvo.cz/cs/sprava-alertu/ You should check within 14 days or as soon as possible after the alert whether it was an error on the part of the end user (whether the scanner was properly set up, Y/Z was switched because the keyboard setting was changed or lower case letters were used instead of upper case letters and vice versa by turning on CapsLock). The proper setting of the scanner can be checked by a test scan. The medicinal product that cannot be dispensed can be returned to the distributor after the 14-day quarantine.

What should I do if the scanner incorrectly scans the 2D code (switched Y/Z or lower case/upper case letters), an alert is generated and I (pharmacist) notice it, change the keyboard setting or turn off "CapsLock?" Can I rescan the 2D

code without waiting for the marketing authorization holder (MAH) to resolve the alert?

Yes, as soon as the pharmacist eliminates the error, successfully re-verifies the medicinal product and decommissions the unique identifier subject to anti-counterfeiting legislation, he can dispense the medicinal product to the patient, even if the medicinal product has already been verified once and an alert has been generated due to his error. The end user's error is resolved once the medicinal product has been successfully re-verifed and the unique identifier decommissioned. The alert will then be closed in the CZMVS (this will be implemented starting in January 2022).

What should I do if a medicinal product cannot be repeatedly verified (an alert is generated) and then is successfully verified? Can I dispense this medicinal product?

If you discover and fix an error on your part as the end user, see above (e.g. you turn off CapsLock or switch to the correct keyboard setting), you can dispense the medicinal product to the patient after the scanned 2D code was successfully verified and the unique identifier (UI) decommissioned.

Is it possible to dispense a medicinal product permitted by the Ministry of Health in compliance with Section 11(r) of the Pharmaceuticals Act in spite of a generated alert?

IT SW of end users should record this information based in data provided by the NCA, and therefore such a medicinal product can be dispensed in spite of the generated alert. At the same time, the Alert Management System (operated by the CZMVS) closes these alerts based on the above-mentioned paragraph. Therefore, it is also possible to see the change in the alert status in the pharmacy via API and then to dispense the medicinal product (provided that the information is not available directly in the pharmacy IT SW upon verification).

How to proceed in case of a suspected counterfeit?

If a marketing authorization holder (MAH) identifies a medicinal product as "Suspected Counterfeit" based on an alert investigation, the CZMVO is required to complete the audit trail by determining where the alert was generated, to find out from the end user the specific device and person who generated the alert and to inform the NCA, the European Commission and the European Medicines Agency about the suspected counterfeit. A standard counterfeit investigation will then take place.

How to proceed if a medicinal product that is being received or has already been received shows "the medicinal product has already been dispensed" upon its dispensing?

Find out whether it was dispensed in another pharmacy or in your pharmacy. You can find this out from your information system, provided that it uses the latest version of API 2.2 and displays notifications for individual operation codes. Your software provider will advise you about the correct procedure. A medicinal product dispensed in your pharmacy can be reactivated within 10 days of the original (even though erroneous) dispensing and can be dispensed once it has been verified and the unique identifier decommissioned. Medicinal products dispensed earlier or in another pharmacy cannot be properly dispensed.

How to proceed if an alert was generated during prescription corrections or retaxation?

Check with your SW provider whether you make corrections and retaxation correctly – if you do it correctly, no alerts should be generated due to "accounting" corrections once the medicinal product was dispensed. You can also ask your SW provider to modify the settings of your information software to avoid alerts generated due to corrections or retaxation.

What should I do about an alert generated for a medicinal product prepared in our pharmacy?

Check with your SW provider whether you process the preparation of such a medicinal product in the right way - every pack of the medicinal product can be "dispensed" and the unique code decommissioned only once. It is not allowed to repeat the dispensing request for additional uses of an already opened pack.

What should I do about an alert generated during the decommissioning of a COVID vaccine identifier?

Every identifier can be decommissioned only once - if you receive vaccines from different sources (a regional hospital, distribution company, etc.), verify the unique identifier of the pack of the medicinal product before decommissioning, or ask your supplier whether it has already been done.

How to return a medicinal product to the distributor (in terms of the FMD)?

Find out from the pharmacy system (or in any other way, depending on the process set up at your pharmacy) which pack should be returned (i.e. the medicinal product has been quarantined for at least 14 days, the MAH has not yet resolved the alert and it is

not an error of the part of the pharmacy - the end user). After that issue a product return to the distributor that delivered the medicinal product to the pharmacy. Make sure that the product return is done correctly in line with your SW - your SW supplier will provide you with more information. Upon receipt, the distributor will check whether the medicinal product generates an alert; if so, the distributor will place the medicinal product in quarantine and will handle the alert with the MAH. However, you must first check the status of the medicinal product before returning it. If the pharmacy decommissioned the unique identifier, the complaint/product return will not be accepted.

What should I do if I find out that the ATD of the pack of the medicinal product, which has been successfully verified and is being dispensed, has been tampered with?

The medicinal product with a compromised ATD should not be dispensed to the patient. Return it to the distributor and use the pharmacy system to report it to the NCA. However, if the situation requires it (e.g. as part of patient education), you, as a pharmacist, can break the ATD in front of the patient and then dispense the medicinal product.

What should I do if the pharmacy dispenses the medicinal product, the customer does not pick it up, the re-activation deadline (10 days at the same place) expires and the distributor refuses to take the medicinal product back?

In compliance with the Regulation, it is recommended to verify medicinal products when they are being dispensed, not in advance. The distributor is not required to take back from pharmacy medicinal products that can no longer be verified in the CZMVS for this reason.

How to proceed if the 2D code is unreadable?

Verify the following in eye-readable data: product code (PC), serial number (SN), batch number (LOT) and expiration date (EXP). All four data must be entered correctly into the system. If even these eye-readable data are not legible, the medicinal product should be returned. It can be returned based on the standard procedures.

What if the pack shows only month and year and I need to enter the expiration date when doing manual verification?

As of November 2020, under Release 7.0 CZMVS, the expiration day is no longer important for generating an alert; only the month and year are compared, i.e. when entering data manually, you can enter any date as the "day" for the expiration date.

Is it possible to take back from a patient an already dispensed medicinal product?

This is not possible according to the legislation of the Czech Republic. According to the Regulation, a medicinal product can re-enter the "Active" status only if it has not yet been dispensed to the patient (the medicinal product has not yet left the pharmacy). In the case the patient changes his mind during the dispensing of the medicinal product, make sure that the dispensing is correctly canceled and the medicinal product properly reactivated. Your SW provider will advise you about the correct procedure - if you do not do it correctly, it may not be possible to dispense the medicinal product later on and an alert will be generated.

What should I do with a pack without safety features?

First check whether the pack was released from production before 9 February 2019 or whether it falls under the FMD – prescription-only medicinal products, unless they are included in the list in Annex I of the Delegated Regulation (EU) 2016/161, or medicinal products not requiring prescription and included in the list in Annex II to this Regulation.

How to verify foreign medicinal products that were individually imported?

Foreign medicinal products, which are subject to anti-counterfeiting legislation and are furnished with safety features, must be verified in the same way as those intended for the Czech market. Through the so-called "Intermarket transaction," the medicinal product will be verified in the repository of another EU Member State for whose market the medicinal product was originally intended.

How are medicinal products under the Specific Treatment Program verified?

More detailed information about the handling of medicinal products in the Specific Treatment Program is provided in the statement of the approval of the Specific Treatment Program.

What should I do with a pack with an FMD identifier and a sticker showing e.g. "FMD not working, use EAN"?

Check whether it is a medicinal product under the Specific Treatment Program - more detailed information about how to handle these medicinal products is provided in the statement of the approval of the Specific Treatment Program. If in doubt, do not hesitate to ask your supplier for more information about these medicinal products.

How can I transfer a medicinal product to another warehouse/storage location (in terms of the FMD)?

Do not decommission the unique identifier - UI, i.e. do not use "Supplied" or "Decommissioned." This method of decommissioning the UI should only be used when dispensing a medicinal product to a patient or a healthcare facility. This is not a standard procedure that can be used. According to the Pharmaceuticals Act, this procedure cannot be used between a pharmacy and distribution, even if they have the same IN. A transfer between warehouses in other locations of the same distributor should mean a physical transfer and the UI should not be decommissioned – do not use the "Decommissioned" or "Supplied" status. Ask your software provider about the correct procedure - every pharmacy software requires different steps.

Is there a prescribed order of information in simple text?

The order of data elements is not specified, although it is recommended that Product code (PC) be placed first. On the packaging, look for the labels (PC / GTIN, LOT / BATCH, EXP, SN - attention, the labels are not part of the value of the items). Ask your SW supplier about how to correctly enter them in your SW.

Alert Management System (AMS)

How to find out the alert status of the medicinal products quarantined in our pharmacy quarantine?

Your pharmacy's IT SW can find out the status of a generated alert by an inquiry sent to the Alert Management System (AMS) operated by CZMVO https://www.czmvo.cz/cs/sprava-alertu/ via API or by logging in to the AMS web interface. If the end user 's IT SW does not offer this functionality, you can ask your pharmacy/distribution IT SW provider to find out the alert status or request access to the AMS (registrace@czmvo.cz) and access the AMS via the web interface, using the username and password.

An alert was generated in our pharmacy/warehouse, but the medicinal product was later on successfully verified. Can I remove it from quarantine and dispense it to the patient? I can see in the AMS that the MAH has not yet closed the alert.

Yes, if the medicinal product was successfully verified, you can dispense it to the patient, even though the MAH has not yet closed the alert in the Alert Management System. The alert will then be closed by the CZMVO based on the successful verification and decommissioning of the UI (it will be implemented starting in January 2022).

The NCA's statement/confirmation regarding the CZMVO's questions

Is it necessary to close alerts generated in 2020?

All alerts in the Alert Management System (AMS) must be closed. However, some types of alerts from 2020 can be closed by so-called shortened investigation, without the cooperation of end users. It concerns 3 types of alerts:

A7 – "Pack already in the requested state"

A3 – "Pack not found"

A52 – "Expiry date mismatch"

These types of alerts from 2020 can be closed if the MAH eliminates the error on its part and provides maximum available information.

These types of alerts generated in 2020 can be closed in the AMS after the MAH provides maximum information and with a flag indicating a non-standard investigation.

Can the end user close an alert generated by the end user's error?

Alerts that are generated by CZMVS end users and identified as a technical error, i.e. an incorrect scanner or keyboard setting (CapsLock, switched keyboard), a software error or an incorrect manual entry, can be closed in the Alert Management System with the status "Closed - EU - Technical Error" once their cause has been removed. The medicinal product can be dispensed once it has been successfully verified and the unique identifier decommissioned.

In the case that marketing authorization holders (MAHs) and CZMVS end users do not cooperate or investigate, the CZMVO will proceed as follows:

Once a month, the CZMVO will provide the State Institute of Drug Control with a list of marketing authorization holders (MAHs) who do not investigate alerts as well as with a list of end users who do not respond to MAHs' repeated requests for additional information about alerts.

Who closes alerts generated for medicinal products that were granted an exemption in Section 11 (r) of the Pharmaceuticals Act?

The CZMVO will continue to close alerts in the AMS that concern a batch or medicinal product exempted in Section 11 (r)) of the Pharmaceuticals Act.

How are alerts clearly caused by MAHs/OBPs closed?

Alerts generated by marketing authorization holders may be closed by marketing authorization holders without any detailed investigation. Marketing authorization holders must state the cause of the alert and use the appropriate option to close the alert in the Alert Management System.

Can medicinal products dispensed by a hospital pharmacy to the hospital ward be returned to the hospital pharmacy?

Requested medicinal products dispensed by a hospital pharmacy cannot be returned to the pharmacy. If a hospital pharmacy dispensed a medicinal product requested by a healthcare provider and the unique identifier was decommissioned, the medicinal product would be considered to be dispensed to the public, even though it was dispensed to the healthcare facility and not to a patient.

When does the quarantine of medicinal products start?

The quarantine starts as soon as the first alert for a given medicinal product and serial number is generated, even if several consecutive alerts are generated for one pack of the medicinal product, i.e. the same serial number.