FREQUENTLY ASKED QUESTIONS IN REGARD TO FMD AND ALERTS WHEN USING CZMVS AND CZAMS

ver. 5.0

(Changes compared to superseded version 4.0:
- *a link to related documents on the intro page*
- *Chapt. 9 - changes in the registration of MAHs and the method of concluding Cooperation Agreements with MAHs)*

» The alert resolution procedure is described in more detail in the document „ALERT RESOLUTION PROCEDURE FOR END USERS, MARKETING AUTHORIZATION HOLDERS AND PARALLEL IMPORTERS“, published on the CZMVO website in the individual sections of “System users” part (currently available only in Czech).

» General information about FMD is described in the document „FMD Principles (Falsified Medicines Directive) “, published on the CZMVO website in the individual sections of “System users” part.

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Shortcuts and abbreviations

CZMVO	Czech medicines verification organisation
NMVS = CZMVS	National medicines verification system = Czech medicines verification system
CZAMS	Czech alert management system
OBP	On-boarding partner – An entity uploading data into NMVS on behalf of an MAH
MAH	Marketing authorisation holder
FMD	Falsified Medicines Directive - EU 2011/62/EU
Alert	An exception generated in CZMVS indicating a potential counterfeit suspect
UI	Unique identifier – an identifier that provides for authenticity verification and identification of a single pack of a medicinal product
ATD	Anti-tampering device – a means to prevent tampering with the outer packaging of a medicinal pack
2D code	Two-dimensional data matrix code (as per GS1)
Parallel importer	Distribution licence holder for medicinal products providing for a resale between countries
FAQ	Frequently Asked Questions
IMT	Intermarket transaction
SW	Pharmacy/wholesaler information system
Location ID	Identification of a location in CZMVS (alpha-numeric chain of characters)
EVA	Emergency Verification Application – EVA portal for an emergency authenticity verification of a medicinal pack
SIDC	State Institute for Drug Control
PC/GTIN	Product code/Global Trade Item Number – Product code/a unique and internationally recognized product identifier
LOT/BATCH	Batch number
EXP	Expiry date
SN	Serial number
End user	User of NMVS = pharmacy/wholesaler (distributor)

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1 Logging into the National Medicines Verification System (NMVS/CZMVS)

» **How should I log in to or register to the National Medicines Verification System (CZMVS)?**

The credentials to CZMVS will be provided to end users immediately upon upload of a signed contract into the CZMVO database and a successful verification. Using the link https://portal-cz.nmvo.eu, enter your login (the superuser's email address) and password. After you click on "Log in," you will be prompted to enter the authorization code sent to your e-mail address. If you forgot your password, click on "Change Password" on the login screen. To obtain your contract or credentials, please contact CZMVO at registrace@czmvo.cz.

» **What should I do to add a location?**

Log in to CZMVS via https://portal-cz.nmvo.eu. The credentials were sent to you upon signing the contract with CZMVO. To initiate the process of creating a new location, go to „Locations" tab and click „Add a location". The user creating a new location will fill in the mandatory information. CZMVO will automatically receive a notification and will check and verify the entered information. Once an approval is granted, the location will be set to „Active" status (until then the location will remain in the „Pending" state).

» **How do I edit the information about my location?**

Log in to CZMVS via https://portal-cz.nmvo.eu. The credentials were sent to you upon signing the contract with CZMVO. Entries related to a particular location can be edited, e.g. SIDC location code, address, city, postal code. To edit the information go to „Locations" tab and click the pencil icon next to the row of the concerned location. Confirm any change using the „Update" button. Please also inform us about any change at registrace@czmvo.cz.

» **What should I do if CZMVS is unavailable?**

Medicinal products subject to the Falsified medicines directive must continue to be verified upon dispensation. If you are authorized to dispense such packs, scan the 2D code of each pack and the unique identifier will be stored in the pharmacy/wholesaler information system. Once CZMVS is up and running again, your SW will send all the codes scanned while CZMVS was unavailable for an additional verification.

» **How to find out whether 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/en/czmvs-status/) on the CZMVO website shows the traffic light and the system status; the green light indicates 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 pack of a medicinal product cannot be verified yet CZMVS is working?**

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

» **When attempting to verify a pack on a newly created client equipment, the following error message pops up: „You are not authorized to perform the requested transaction". How should I proceed?**

Log in to CZMVS as the location holding the equipment that failed the transaction and check the „Client roles". In order to utilize all the available functions, „Full access" must be selected.

» **Where can I find a list of designated wholesalers for specific products?**

The end users have the option to log in to CZMVS and generate a report Contracted Wholesalers Stakeholder report. This report will return a list of all the contracted wholesalers for the given product.

2 Alerts and technical problems of end users

» **What should I do if the pharmacy scans the 2D code of a medicinal product subject to Falsified medicines legislation/directive and an alert is generated?**

In the first place, you should rule out an error on the side of the end user (correctly set-up scanner, Y/Z mismatch, letter case mismatch due to CapsLock). A test scan might be appropriate to check the correct scanner settings. If the error cannot be fixed and the pack cannot be successfully verified, it should be quarantined along with the information related to the alert which is represented by a unique identifier in the form of CZ-XXX-XXX-XXX-XXX-XXX. This information together with the pack details should be preserved for a future use, for instance upon return to the wholesaler. If the pack cannot be verified successfully even after 14 days of quarantine have elapsed, it may be returned to the wholesaler. The alert state or requests for additional information can be viewed in the Alert management system (CZAMS). More information can be found on the websites of CZMVO in the Alert management section.

» **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 (as a pharmacy/wholesaler) notice it, change the keyboard settings 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 verifies the pack of a medicinal product and decommissions the unique identifier, the pack can be dispensed to the patient, even though the previous attempt to verify the pack failed, and an alert was generated. The error is resolved once the pack is successfully verifed and the unique identifier decommissioned. The alert can be closed in CZAMS directly by the end user as a technical error on their side.

» **What should I do if a pack of medicinal product cannot be repeatedly verified (alerts are generated), but after a while it is verified successfully? Can I dispense this pack?**

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

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

End users' SW should register this type of information based on the data provided by the State institute for Drug Control (SIDC), because such a pack is allowed to be dispensed despite the generated alert. The Alert management system (operated by CZMVO) will close the alert automatically based on the above-mentioned paragraph. The pharmacy can view a change in the alert status via API and eventually dispense the pack (should this information not be available directly in the end user's SW upon verification).

» **How to proceed in case of a suspected counterfeit?**

If a marketing authorization holder (MAH) identifies a pack of a medicinal product as a "Suspected Counterfeit" based on the alert investigation, CZMVO is obliged to secure the audit trail and obtain further information about the location that generated the alert; the specific client equipment and also the person that performed the transaction. CZMVO will also inform the State institute for Drug Control (SIDC), the European Commission and the European Medicines Agency about the suspected counterfeit. A standard counterfeit investigation will then occur.

» **How to proceed if a pack reads "the pack has already been dispensed" upon dispensation, even though it was earlier verified successfully (e. g. upon delivery)?**

Find out if the pack was dispensed at your location or at another location. Your pharmacy/wholesaler information system can give you this information, provided it uses the latest version of API and displays notifications for individual operation codes. Your software provider will advise you about the correct procedure. A pack of a medicinal product dispensed at your pharmacy can be reactivated within 10 days from the original (albeit erroneous) dispensation, and can be dispensed again, once the unique identifier has been verified and decommissioned. Even If the time for reactivation has passed (10 days) and a repeated attempt to supply a pack

raises an alert, the pack can still be dispensed, if conditions stipulated by SIDC are met. If the end user is aware of an error that can be documented as per these conditions, we recommend that the state of the alert be changed or a pre-defined message be sent using a tool directly in CZAMS. The outcome of closing a procedural error using this tool might allow the end user to dispense the pack to patient immediately. Packs originally dispensed at another pharmacy cannot be duly dispensed.

» **How to proceed if an alert was generated during a correction of the prerscription or retaxation?**

Check with your SW provider whether you perform corrections and retaxation correctly – if you do it correctly, no alerts should be generated due to "accounting" corrections once the pack of a medicinal product has been 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 appropriate way - each pack of the medicinal product can be "dispensed" and the unique code decommissioned only once. It is not allowed to repeat the dispensation request for additional uses of a pack that has once been opened already.

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

In your pharmacy information system, find out (or in any other way, depending on the process set up at your pharmacy) which pack should be returned (i.e. the pack has been quarantined for at least 14 days, the MAH has not yet resolved the alert and it is not an error on the side of the pharmacy - the end user). After that, issue a Return of goods form to the wholesaler that provided the pack to the pharmacy. Make sure the return is done correctly, in line with your SW. Your SW supplier will provide you more information. Upon receipt, the wholesaler will check whether the pack generates an alert; if yes, the wholesaler will place the medicinal product into quarantine and will handle the alert with the MAH.

» **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?**

A pack with compromised ATD should not be dispensed to the patient. Return it to the wholesaler and use the pharmacy information system to report it to the SIDC. However, if the situation requires it (e.g. as a part of patient education), you as a pharmacist can break the ATD in front of the patient and subsequently dispense the pack.

» **What should I do if the pharmacy dispenses a pack of a medicinal product, the customer does not pick it up, the re-activation deadline (10 days at the same place) passes and the wholesaler refuses to take the pack back?**

In compliance with the Falsified medicines legislation/directive, it is recommended to verify the packs of medicinal products when they are being dispensed only, not in advance. A wholesaler is not obliged to accept such a return of pack from a pharmacy, if it can no longer be verified in CZMVS for this reason.

» **How to proceed if the 2D code is illegible?**

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

» **What if the pack shows only the month and year of expiration, but I need to enter the full expiration date when performing a manual verification?**

As of November 2020, the release 7.0 CZMVS, the expiration day is no longer evaluated in terms of a pack verification. The system only assesses the month value and the year value, i.e. when entering the data manually, you can enter any date as the "day" for the expiration date.

» **Is it possible to reactivate and subsequently dispense a pack that has been already dispensed earlier to a different patient?**

This is not possible according to the legislation of the Czech Republic. According to the Falsified medicines legislation/directive, a pack of a medicinal product can be reset to the "Active" status only if it has not yet been

dispensed to the patient (the pack has not yet left the premises of the pharmacy). In case the patient changes mind during the dispensation of the pack, make sure that the the transaction is correctly cancelled and the pack duly 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 pack later, and an alert will be raised.

» **What should I do with a pack without security features?**

First, check whether the pack was released from production prior to February 9th 2019. Then, find out if it comes 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 are imported individually?**

Foreign medicinal products subject to Falsified medicines legislation and furnished with security features must be verified in the same way as those intended for the Czech market. The medicinal product will be verified in the repository of another EU Member State for which it was originally intended via a so-called "Intermarket transaction." Aswer from another market will be received back standard way via CZMVS and end-user system.

» **How are medicinal products under the Specific Treatment Program verified?**

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

» **What should I do with a pack containing an FMD identifier and a sticker showing. "FMD not working, use EAN" upon verification?**

Check whether it is a medicinal product under the Specific Treatment Program - more detailed information about handling these medicinal products is provided in the statement of 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 applied. According to the Pharmaceuticals Act, this procedure cannot be used between a pharmacy and a wholesaler, even if they have the same Identification number. A transfer between warehouses to other locations of the same wholesaler should represent 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 – each 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 pack, 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 how to correctly enter them in your SW.

» **What is the recommended direction for packs whose expiry date is due or about to be due?**

Verification in CZMVS always occurs at 3 levels. Product level, batch level and pack level. Only If the status is active at all 3 levels, can the pack be verified/dispensed successfully. For instance, if the system detects that at the product level the product is not active (the product has been withdrawn), the following levels (batch and pack) will not be evaluated, and it will not be possible to dispense/decommission the pack. Equally, if the product is active, but the batch is not (the batch has been recalled or expired), the pack level will not be evaluated. Hence, if the product is withdrawn or the batch has been recalled or expired, the status of each individual pack is irrelevant. In case of an expired batch we recommend that the related packs not be decommissioned as Destroyed, since the pack level will not be evaluated when a transaction is performed on any pack of such a batch

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3 Alert management system (CZAMS) – end users

» **How can I log in to the Alert management system (CZAMS)?**

If you do not have access to CZAMS, we recommend that you send a request for credentials to registrace@czmvo.cz. As soon as CZMVO completes your registration, the system will send out an automatic e-mail message with credentials to log in to the system, including a link to the portal https://portal.czmvo.cz/.

» **How to determine the alert status of the medicinal products held in our pharmacy quarantine?**

The alert status can be obtained by a request to the Alert managemet system (CZAMS) operated by CZMVO via either API or logging to the web interface of CZAMS – more information can be found on the websites of CZMVO in the Alert management section. If the end user's software does not feature this option, you may approach your pharmacy/wholesaler information system provider to secure the alert status for you, or you may request access to CZAMS (registrace@czmvo.cz) via web interface using a login and a password.

» **An alert was raised in our location, but we managed to verify the pack successfully afterwards. Can I take the pack out of the quarantine and dispense it to the patient? In CZAMS, I can see that the MAH has not yet closed the alert.**

Yes, if the pack has been 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 can be closed by the end user as a technical error on their side. If CZAMS detects from the pack autit trail that the pack has been supplied successfully, the alert will be closed automatically.

» **How to close A7 and A24 alerts raised as a result of a procedural error on the side of the end user?**

If conditions stipulated by SIDC are met, A7 and A24 alerts can be closed and in some cases the concerned packs can even be supplied. When the alert is raised, the first 2 days are reserved for the end user to close it on their side. In CZAMS, the root cause can be submitted by clicking the button „Procedural error resolution" and selecting the applicable scenario. If the alert state is changed to „06m - Closed - End User process error – the pack can be supplied", it is possible to supply the pack to public. In case the alert state is changed to „06f - Closed - End User process error - cannot be dispensed", it is not possible to supply the pack, however; the alert is closed in CZAMS. If the alert state is changed to „05c - CZMVO - Info End user to MAH", the alert will be investigated and closed on the side of CZMVO.

The MAH can only close the alerts after the 2 days have passed, as per above. The alert state will be changed to „06f - Closed - End User process error - cannot be dispensed". The end user can however re-open such alert and eventually set it to „06m" if the selected root cause allows it.

4 Alert management system (CZAMS) – MAH

» **How can I log in to the Alert management system (CZAMS)?**

If you do not have access to CZAMS, we recommend that you send a request for credentials to registrace@czmvo.cz. As soon as CZMVO completes your registration, the system will send out an automatic e-mail message with credentials to log in to the system, including a link to the portal https://portal.czmvo.cz/.

» **As a part of the alert investigation process, we need to confirm the name of the end user that raised the alert.**

The Alert management system is fully anonymous and CZMVO is not authorized to give out contact details without a previous consent of the pharmacy/wholesaler. To communicate during the investigation process, we recommend the use of pre-set messages available directly in CZAMS for the specific alert

» **We have requested additional information related to an alert, but the end user is not responding. What should we do now?**

If you request for additional information related to an alert or a picture of the concerned pack, but the end user does not respond within 48 hours, the system will send an automatic escalation to the end user for inactivity. Another notification is sent out after 5 days of inactivity. If the end user is still failing to provide a response, the MAH may opt to close the alert on their side as „06o - Closed - End User does not cooperate - cannot be supplied".

» **How to close A7 and A24 alerts raised as a result of a procedural error on the side of the end user?**

When the alert is raised, the first 2 days are reserved for the end user to close it on their side. The MAH can only close the alerts after the 2 days have passed. The alert state will be changed to „06f - Closed - End User process error - cannot be dispensed". The end user can however re-open such alert and eventually set it to „06m" if the selected root cause allows it.

» **In the Alert managemet system we register alerts raised as an „MAH Request", but we are unaware of any error on our side. What should we do?**

All transactions performed on the MAH or parallel importer side are marked as MAH transactions. That is because parallel importers communicate with the verification system through the EU Hub only, just as MAHs, and their requests are hence marked as „MAH Requests". If the alert originator is a parallel importer, we recommend that you send a request to CZMVO for assistance. CZMVO will investigate the alert directly with the parallel importer.

» **A change of MAH occurs for a medicinal product. Who wil investigate the alerts when the transfer is completed?**

When medicinal products are transferred from one MAH to another Marketing authorization holder (MAH), different situations can occur. To investigate and close alerts is requested by:

- New Marketing authorization holder that should investigate all alerts for transferred medicines (new alerts as well as still not closed alerts by original MAH).
- The original MAH investigates alerts until the medicinal product are transferred to the new MAH. Alerts arising after that date are handled by the MAH to which the medicinal product was transferred.
- Both Marketing authorization holders will investigate alerts during transitional period, that is needed for medicines transfer and is agreed between both MAHs. During this period original MAH investigates open existing alerts, as well as new alerts created over its original medicinal products that were uploaded by original MAH to the repository, until they are sold or expired. That is, any alerts on batches that were uploaded under the original MAH will still be handled by the original MAH. Alerts for batches newly uploaded under the new MAH will be handled by the new holder.

Marketing authorization holder should inform CZMVO about agreement between both MAHs, who will investigate alerts raised before transfer of medicines. Data transfer in EMVS from original MAH to new MAH should also be ensured.

» **I would like to change the contact e-mail for receiving information related to alerts. What should I do?**

If you have access to CZAMS, all contact details can be edited by a user with the Administrator role. If you do not use CZAMS, we recommend that you register and start resolving your alerts in this system (completely free of charge). You may also contact CZMVO at registrace@czmvo.cz.

» **I need to change the e-mail address for receiving the authorization code in order to log in to CZAMS. What should I do?**

The two-factor authentication method can be changed at any time by a CZAMS user after logging to the portal. On the top right, click on the link „Security", select the desired method for verification and insert a new e-mail address.

5 Alert classification

» **What are the most common types of alerts?**

CZMVS can distinguish a variety of so-called Exceptions. These exceptions are classified into 5 levels according to the degree of severity evaluated based on a potential threat of falsification. The level 5 exceptions are referred to as Alerts and must be investigated. The alerts are further categorized based on the type of the originator of the transaction (MAH, End user) or the root cause (technical, procedural). Procedural errors are marked as A7 and A24 alerts, technical alerts are marked as A2, A3, A68, A52. The full scale of alert codes is relatively large, however; the ones mentioned in this paragraph are the most common.

» **What other types of alerts exist?**

The necessity to resolve level 3 alerts is subject to consideration. Currently, they are informative only. Level 3 alerts are raised when the product code of the medicinal product is unknown to all of the european repositories (A1), or when a reactivation attempt is made by a location that did not decommission the pack (A5).

6 FMD Software

» **Where can I find an overview of SW providers?**

The list of SW providers whose software is certified for FMD can be found on the websites of CZMVO in the tab System users/ IT companies.

» **How to prevent software problems related to verification of FMD codes?**

For a full functionality of your equipment, we recommend regular updates of your software, certified SWs only can be used for FMD verification.

» **How to ensure my equipment is connected to CZMVS and the verification is working correctly?**

The options to check connectivity towards CZMVS vary according to the software used at the specific location. A number of SW providers offer some sort of check functions. In case of uncertainties we recommend reaching out to the SW provider.

7 The statement/confirmation of State Institute for Drug Control (SIDC) related to questions raised by CZMVO

» **Can an end user close an alert generated by their own error?**

Alerts generated by CZMVS end users, identified as technical errors, i.e. incorrect scanner or keyboard setting (CapsLock, switched keyboard), software error or incorrect manual entry, can be closed in the Alert management system with the status "06f Closed - EU - Technical Error" once the error has been fixed. The pack of a medicinal product can be dispensed on the condition that the unique identifier has been successfully verified and decommissioned.

» **Is it possible to dispense a pack after a procedural error on the side of the end user (pharmacy, wholesaler)?**

The current version of the Alert management system (CZAMS) enables end users to dispense a pack despite a procedural error as long as the conditions stipulated by SIDC are met. If the end user is aware of a procedural

error (applicable to A7 and A24 alerts), that can be documented as per SIDC conditions and the pack dispensed, we recommend that the alert state be changed or the root cause selected via the „Procedural error resolution“ button directly in CZAMS. The result of this solution and closing the alert using the tool might be that the end user will be able to dispense the pack.

- **How will CZMVO proceed in case of end user/ MAH inactivity or uncooperation in the course of the alert investigation process?**

On a monthly basis, CZMVO will send out a list of MAHs and end users who do not cooperate or fail to provide additional information to SIDC.

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

CZMVO will continue to close alerts in the CZAMS that concern a batch or medicinal product exempted in Section 11 (Paragraph 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 using 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?**

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 is considered dispensed to the public, even though it was dispensed to the healthcare facility and not to a patient.

- **When does quarantine of a pack 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.

8 Recommendations for companies delegating verification of medicinal packs to a third party

- **Our packs of medicinal products are verified by a third party. Do we still need to register to CZMVS?**

Yes, any entity possessing an authorization to distribute packs of medicinal products subject to FMD must be registered to CZMVS. There is however an option where no additional SW is required. More information can be found in the document *Guide – Third Party Verification,* which can be found on the websites of CZMVO in the *System users* section*,* tab *Distributors.*

9 Agreements between marketing authorization holders (MAH) and CZMVO

» **We are a new marketing authorization holder (MAH) in the Czech Republic and we would like to conclude an agreement with CZMVO. What should we do?**

At first you need to fill in the registration details in CZMVO IS. Registration serves to enter the identification data of the Marketing Authorization Holder (MAH) and leads to the conclusion of the Cooperation Agreement.

To register you need the access to CZMVO IS. Please send a request to registrace@czmvo.cz and provide your name and e-mail address to which an invitation with access data will be sent.

» **Who can sign the agreement?**

Only a person (persons) authorized to act and conclude agreements on behalf of the company stated in the Company register.

» **How should we sign the agreement?**

The authorised person signs the contract either manually or electronically using DocuSign. You can choose the method of signing the contract in the NOOL IS registration form (see above).

If you sign manually, send 2 originals of the contract by post to the CZMVO address. After signing on our side, we will send one original back to you. If you are signing via DocuSign, the contract will be sent electronically from CZMVO directly to the persons authorized to sign. The electronically signed contract will then be uploaded by CZMVO to CZMVO IS for download.

» **Should I enclose a copy of the Company register statement?**

Yes.

» **What happens after the agreement is concluded?**

When the agreement is concluded, CZMVO will send you credentials to log in to the Alert management system (CZAMS), where you will resolve and close your alerts. 2 invoices will also be sent to you electronically.

» **What kind of fees will we pay?**

After the Cooperation angreement is concluded, the MAH will pay a one-time Registration fee in the amount of EUR 4.856.

Once a year, the MAH will also pay the **Annual user fee. The amount may change every year.** Actual fee for upcoming year is announced latest by September on CZMVO web page and via e-mail communictaion to MAHs. The fee is invoiced after an agreement is signed for the related calendar year and then every November for the upcoming calendar year.

» **Can the invoice receiver for the user fee be a different entity than an MAH?**

The invoice for a user fee can be issued to a company which the MAH defines as the payer, more precisely the invocie receiver. Hence, it does not need to be issued directly to the marketing authorization holder to whom the fee relates. The MAH may announce a change of the invoicing details in written form or by e-mail

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IČ: 05851742, www.czmvo.cz

(info@czmvo.cz). We kindly request the MAH for a timely information regarding any change related to either the invoicing party or address.

» **We are MAH and also possess a wholesale licence. Do we need to have an agreement with CZMVO as a wholesaler as well?**

Yes. You need to conclude an agreement with CZMVO as a CZMVS end user. Based on this contract, you will be granted access to CZMVS.

10 CZMVO support and contacts

» **How can I contact CZMVO?**

- Operating support and queries related to alerts resolution a closing: support@czmvo.cz
- CZMVO and CZAMS registration support: registrace@czmvo.cz
- General information: info@czmvo.cz
- Telephone contact: +420 224 834 153, +420 224 834 154, +420 224 834 155