



**Národní organizace  
pro ověřování  
pravosti léčiv**

# **NOOL IS – MAH MODULE**

## **User manual**

for Marketing Authorisation Holders (MAH) and On-Boarding Partners (OBP)

(Version 1.0)

*5<sup>th</sup> May 2025*

# INTRODUCTION

## Purpose of the document

This guide is intended for **MAHs** or their **designated Representatives** who wish to register with NOOL, Inc.

## Terminology

### **National Medicines Verification Organization - CZMVO (NOOL)**

A non-profit organization that ensures the implementation and operation of the Czech System for the Verifying the authenticity of Medicines (CZMVS) in the Czech Republic.

### **NOOL IS**

NOOL Information System. It includes a set of modules that cover MAH/OBP registration, end users (pharmacies, distributors), SW companies, alert investigation and monitoring and notification processes.

### **CZAMS – Czech Alert Management System**

Complementary system to NSOL, operated by NOOL. It is used for effective investment of causes of non-conformities (alerts) in identification of medicinal products according to FMD.

# REGISTRATION

The Marketing Authorisation Holder (MAH) registration process for CZMVO-NOOL consists of **3 steps**:

## 1. Fill in the registration data in NOOL IS.

The **registration** is used to enter identification data into the **NOOL Information System** (hereinafter NOOL IS) about the MAH (or his/her Representative) and leads to the conclusion of a **Cooperation Agreement**.

The request for access to the NOOL IS should be sent to [registrace@czmvo.cz](mailto:registrace@czmvo.cz). Please provide your name and email address to which an **invitation with access data to NOOL IS** (MAH module) will be sent.

## 2. Conclude and sign the "NOOL-MAH Cooperation Agreement".

There are **five variants of the agreement**:

MAH will conclude a **separate agreement** with NOOL (ver\_1).

MAH **authorizes a third party** to enter into a contract with NOOL on its behalf (ver\_2).

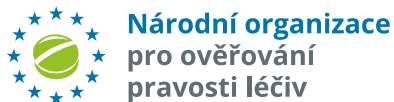
**Several MAHs enter into a contract** with NOOL (ver\_3a).

**Several MAHs instruct one of them** to enter into a contract with NOOL on their behalf (ver\_3b).

**Several MAHs instruct a third party** to enter into a contract (ver\_3c).

According to the role in the contracting process, **select the appropriate version of the contract**. The cooperation agreement is concluded by **signing by the authorized** person(s). If the contract is signed by a representative, it is **necessary to attach a signed power of attorney** (a draft power of attorney can be downloaded below together with the model contracts).

The cooperation agreement can preferably be signed **electronically**, via **DocuSign**, or by **signing the paper version of the agreement**. If signing a hard copy agreement on your end, you will need to mail **two originals** of the agreement to the NOOL office. Once signed on the NOOL side, **one** copy of the contract will be sent back.



# REGISTRATION

In order to prove the authorization of a natural person to act on behalf of the company, we require an **extract from a foreign commercial register** or similar register from which this authorization is evident. If the contract is signed on behalf of the company by a person other than the person named in the extract from the commercial or other register, the signatory must provide a power of **attorney granted** by the person who is authorised to act for the company according to the extract. A specimen power of attorney is available [here](#).

### 3. Pay CZMVO fees

MAH will pay a one-time **Registration Fee + Annual User Fee**.

**Registration Fee** - The purpose of the registration fee is to cover the implementation costs of the Czech system for authentication of medicines (NSOL). It is currently set at EUR 4 856 (excluding VAT).

**Annual User Fee** - The annual user fee is paid by MAH each year during the use of the NSOL system. This fee is used to cover the ongoing costs associated with the operation of NSOL.

The amount of this fee is reviewed each year at the same time as the NOOL budget planning for the next period, and the amount is published at least 4 months before the end of the current year.

For 2025, the annual user fee is set at **EUR 4 250** (excluding VAT) for each MAH.

Further information on the whole registration process and fees can be found on the NOOL website ([www.czmvo.cz](http://www.czmvo.cz)).

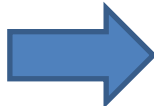
# INVITATION TO NOOL IS - MAH MODULE

## Contact

Please use the contact email for all registration requests: [registrace@czmvo.cz](mailto:registrace@czmvo.cz)

Once CZMVO has registered you in the NOOL IS - MAH management module, the system will send you an email with your access data.

Example of an e-mail with access data



## Example of a registration e-mail

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From: NOOL <no-reply@czmvo.cz>  
Date: Wednesday 12th February 2025 12:27  
To whom: <info@czmvo.cz>  
Subject: < NOOL IS - registrace /NOOL IS - registration >

Vazeny pane/pani, zasilame Vam pristupy do NOOL IS :

Dear Sir/ Madam, We send you access to the NOOL IS:

Pristupove udaje/Access credentials:

Login: TEST  
Heslo/Password: 92ec2350cf

Webove rozhrani/Web interface: <https://portal.czmvo.cz/>

Rozhrani API/API interface: <https://api.czmvo.cz/>

Doporucujeme si **pristupove udaje po zalogovani zmenit.**

We recommend that **you change the access data after logging in.**

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

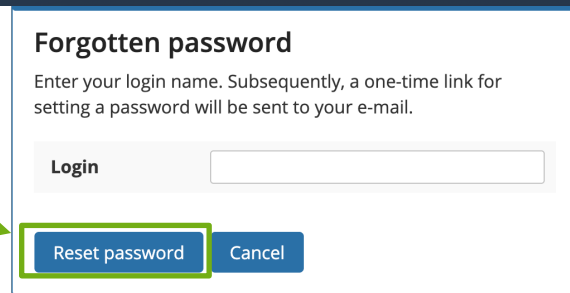
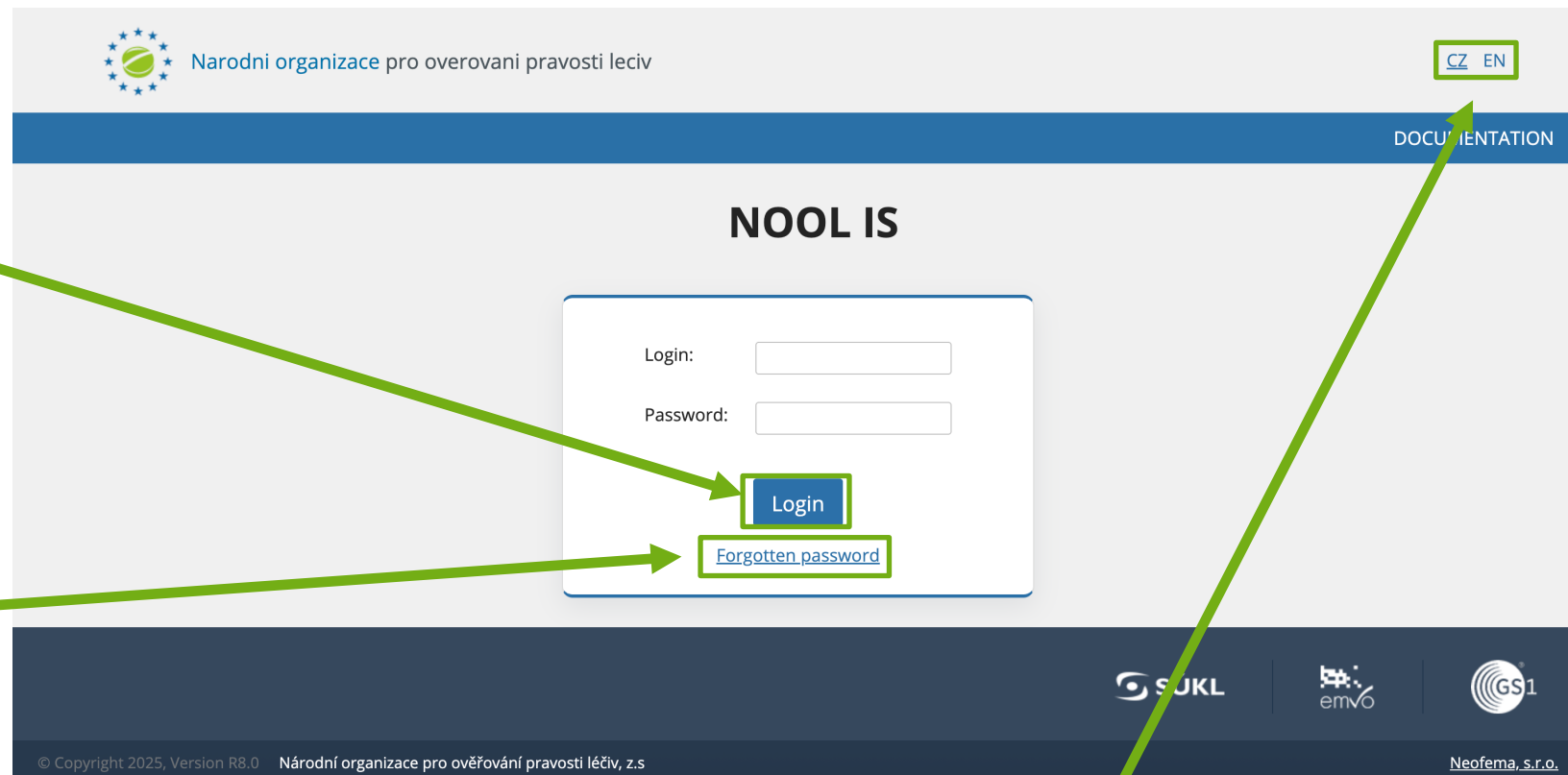
NOOL, z.s.

# LOGIN TO NOOL IS

The web interface of the **PRODUCTION** NOOL IS is at: <https://portal.czmvo.cz>.

Enter your access data provided by NOOL and click on "**Login**".

**Note:** If you forget your password, you can click on "**Forgot Password**" to generate a new password. In case you do not know your login, please ask for a new password to be generated and sent to [registrace@czmvo.cz](mailto:registrace@czmvo.cz). Then enter the sent password in the "Login" field and click on "**Reset Password**".



Selecting the language of the text: by clicking on the appropriate abbreviation, you can select the appropriate language („CZ“, or „EN“).

## Two-factor authentication for the web interface

**Two-factor authentication** is implemented for access to the web interface. Primarily email and/or **Google Authenticator** can be used as the second factor.

The choice of the type of the second factor is configurable by the user in the user management of the organization.

## Time limit for web login

An automatic user logout after a defined period of **inactivity** (currently **4 hours**) is implemented.

# IT SECURITY

## Account lockout after several failed logins

If a user repeatedly enters an incorrect password when accessing the web interface, the account will be locked for a defined period of time (currently **3 failed attempts = 60 minutes of lockout**).

## Attribute for login page

The autocomplete="off" parameter is set for the login page to prevent certain types of attacks.

## Unification of login error messages

The goal is to prevent guessing of valid logins by unifying error messages during login attempts.

# SETTING UP TWO-FACTOR AUTHENTICATION

After successfully logging into the web interface, you will be prompted to set up **two-factor authentication**. Either an **e-mail address** or **Google Authenticator** can be selected as the second level of security.

## Procedure for setting up security using an e-mail address:

1. Select the "*E-mail*" authentication method. Click "*Continue*".
2. Click on the "E-mail" field and enter the email address to which the authentication code will be sent.
3. Copy the **authorization code** from the body of the e-mail that was sent to the e-mail address you selected
4. Paste the code into the "Authentication Code" field and click "*Finish*".
5. Click "*OK*". **The setup is complete.**

Toto je automaticky generovaný e-mail. Na tuto zprávu neodpovídejte.

This is an automatically generated email. Do not reply to this message.

Vážený uživatelé CZ AMS/Dear users of CZ AMS,

vas autorizací kód pro vstup je / your authorization code for entry is:

**784835**

Platnost kódu je 10 minut. / The code is valid for 10 minutes.

S pozdravem/Regards  
NOOL, z.s.

The image shows four sequential screenshots of the security setup interface:

- Security 1/4:** "1/4 Security" - "Setting up two-factor authentication". The user selects "E-mail" as the authentication method. Buttons: "Continue", "Cancel".
- Security 2/4:** "2/4 Security" - "E-mail". The user enters "lukas.legin@czmvo.cz" in the "E-mail" field. Buttons: "Continue", "Cancel".
- Security 3/4:** "3/4 Security" - "Verification". A verification code "784835" has been sent to the user's email. The user enters "784835" in the "Verification code" field. Buttons: "Finish", "Cancel".
- Security 4/4:** "4/4 Security" - "Two-factor authentication setup successfully completed". Button: "OK".

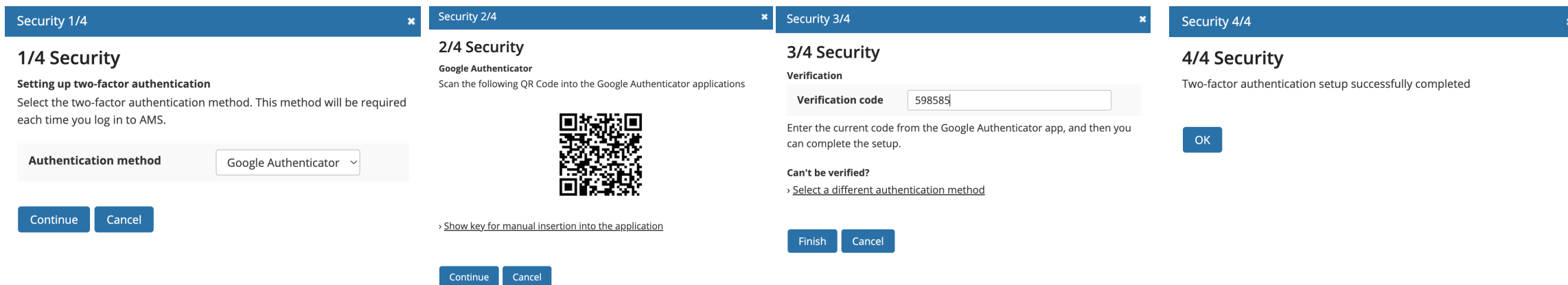
Logo of Národní organizace pro ověřování pravosti léčiv (National Organization for Verification of the Authenticity of Medicines) is visible in the bottom left corner.



# TWO-FACTOR AUTHENTICATION SETUP

## Instructions to set up authentication via the application Google Authenticator:

1. Select the authentication option "Google Authenticator". Click on "Continue".
2. With your device, scan the QR code into the application Google Authenticator. Click on "Continue".
3. In the field "Verification code" enter the current code displayed in your application. Click "Finish".
4. Click "OK". The setup has been completed.



The image displays four sequential screenshots of the Google Authenticator setup process:

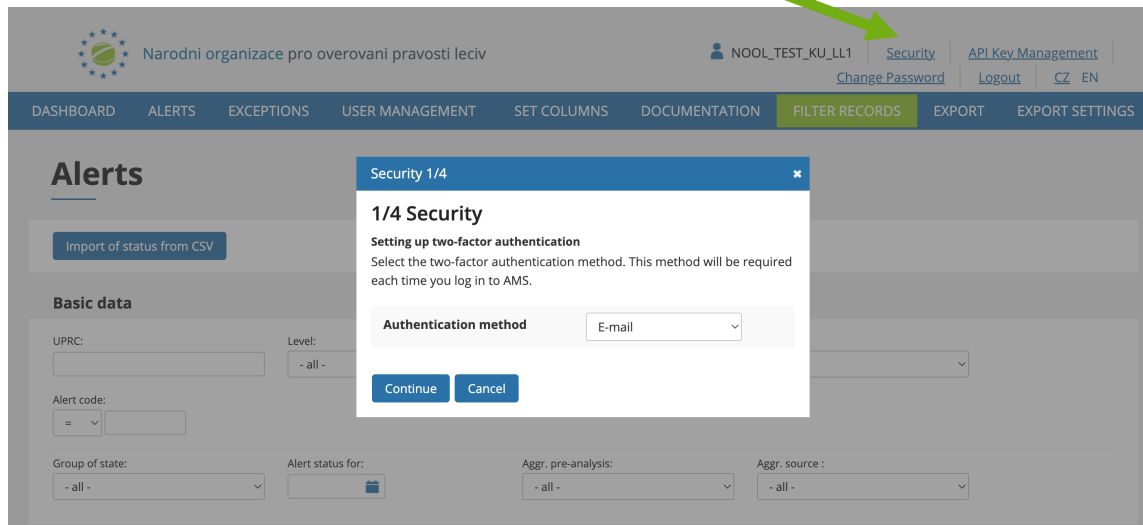
- Security 1/4:** Titled "1/4 Security", it shows the "Setting up two-factor authentication" screen. A dropdown menu for "Authentication method" is set to "Google Authenticator". "Continue" and "Cancel" buttons are at the bottom.
- Security 2/4:** Titled "2/4 Security", it shows the "Google Authenticator" screen with a QR code to scan. A link for "Show key for manual insertion into the application" is visible. "Continue" and "Cancel" buttons are at the bottom.
- Security 3/4:** Titled "3/4 Security", it shows the "Verification" screen. A text input field contains the code "598585". Below it, instructions state to enter the current code from the app. A "Can't be verified?" section offers a link to "Select a different authentication method". "Finish" and "Cancel" buttons are at the bottom.
- Security 4/4:** Titled "4/4 Security", it shows the completion screen with the message "Two-factor authentication setup successfully completed". An "OK" button is at the bottom.

# TWO-FACTOR AUTHENTICATION SETUP

Depending on your selected option, upon each login you will be prompted to enter the verification code, either via e-mail or the Google Authentication application.

**The two-factor authentication option can be changed anytime.**

1. On the top right click on the “Security” link and select the required option. Further steps as per pages 9 and 10.



The screenshot shows the user interface of the AMS system. At the top right, the user is logged in as 'NOOL\_TEST\_KU\_LL1'. A green arrow points to the 'Security' link in the top navigation bar. Below the navigation bar, the 'Alerts' section is visible. A modal dialog box titled 'Security 1/4' is open, displaying the '1/4 Security' configuration screen. The dialog contains the following text: 'Setting up two-factor authentication. Select the two-factor authentication method. This method will be required each time you log in to AMS.' Below this text, there is a dropdown menu for 'Authentication method' currently set to 'E-mail'. At the bottom of the dialog are 'Continue' and 'Cancel' buttons. The background shows the 'Alerts' page with various filters and a 'Basic data' section.

# CHANGE PASSWORD

The user can change their password at any time.

In the main window, click on "*Change Password*" in the top right corner.

Then follow the instructions in the pop-up window.

The screenshot displays the user interface of the National Organization for Drug Verification. The top navigation bar includes the organization's logo, name, and user information (NOOL\_LS). A 'Change Password' link is highlighted in the top right corner. The main content area shows a 'Dashboard' with a bar chart titled 'Development chart of CC proces'. Two pop-up windows are shown: the first is the '1/2 Changing the password' form, and the second is an error message indicating that the old password was entered incorrectly and the new password does not meet the required conditions.

# NEW REGISTRATION

## Input information

Before you start the registration process, please familiarize yourself **thoroughly** with the registration procedure. It is important what **role you have**:

- whether you are an MAH
- you are not an MAH, but an MAH or multiple MAHs have authorised you to enter into a Contract with NOOL (you are an "Representative").

To speed up the registration process, have the necessary documents ready (power of attorney, extract from the foreign commercial register, etc.).



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NOOL\_TEST\_MAH\_LS2 | API Key Management | Change Password | Logout | CZ EN

### MAH MANAGEMENT

## New registration

The registration is used to enter the identification data of the MAH (or its representative) and leads to the conclusion of the **Cooperation Agreement**. The registration process and the mutual communication takes place within CZMVO IS (pre-configured bilingual messages can be used).

- Select (option **"My role in registration - I am:"**) whether you are:
  - **"One MAH"** - a single MAH, contracting on his/her own behalf.
  - **"Multiple MAHs or MAH-Representative"** - multiple MAHs signing a joint contract or an MAH registering himself and other MAHs and entering into a contract under a power of attorney for other MAHs.
  - **"Representative"** - a company registering an MAH (or multiple MAHs) who enters into a contract under a power of attorney.
- Click on **"Start registration"**. Enter all the required data, or attach any additional files necessary to sign the contract (e.g. extract from the Companies House or power of attorney).
- Once you have filled in all the information on the form, click on the **"Save & Go"** button. You can interrupt the input of data at any time, add it gradually, or contact NOOL with a question) - **"Send message"** button.
  - » If you want to register another MAH (within the same contract), click on **"Save & Add next MAH"**.
  - » If you are not a MAH but you are authorized to represent one, you will first fill in the details for the Representing Company in the registration form, then click on **"Save & Add MAH"** to add the MAHs you represent.
  - » If you are representing other entities, it is essential to attach signed powers of attorney (a sample here).
  - » If your company is based outside of the Czech Republic, we require an extract from the foreign Commercial Register or similar document to verify that the contract is signed by an authorized person.
  - » If the contract is signed by someone other than the person listed in the Commercial Register, the signing person must provide a power of attorney granted by the person authorized to act on behalf of the company Attorney granted by the person who, according to the extract, is authorized to act for the company (a sample here).
  - » If you apply for a reduced Annual User Fee you will need to conclude an Amendment to the Cooperation Agreement.
- Submit the completed form using the **"Send for Verification"** button.
- The **data will be verified in CZMVO** and a Agreement will be generated. Notification of the creation of the Agreement will be sent to the e-mail address to which the registration access data was sent. The Agreement will be ready for download in CZMVO IS. Once the Agreement has been printed and signatures have been secured on your side, please send **two** originals of the contract to the CZMVO office. Once signed on the CZMVO side, **one** copy of the Agreement will be sent back. If electronic signing of the Agreement via **DocuSign** is **preferred**, the Agreement will be sent electronically from CZMVO directly to those authorized to sign. The electronically signed Agreement will then available to download in CZMVO IS.

CZMVO office address:

Back | **Start Registration**

Basic data

**My role in the registration - I am:**

- ✓ - Select -
- MAH
- More MAH or MAH-Representative
- Representative

- 1 Select: you are an **MAH** and the contract will be concluded for one MAH or for several MAHs or: you are not an MAH but you have been authorized by the MAH/MAHs to represent them (**you are the Representative**). Select **"My role in the registration - I am:"**.
- 2 Then Click on **"Start Registration"**.

# REGISTRATION - AGREEMENT PREVIEW

To familiarize yourself with the content of the Agreement, you can download it in advance (option „*Specimens of Agreements*“).

There are a total of 5 possible Contract variants, but only those Contract types that are relevant for the selected role are always preloaded.

The contract is downloaded after selecting "Download file".

*Please note: if you select the wrong role before starting the registration, this cannot be corrected and a new registration is required!*

The screenshot displays the 'New MAH' registration form in the MAH Management system. The form is divided into several sections: Registration, Company, ID, Registered at, Correspondence address, The agreement is signed by, DocuSign Acceptance, Signatory 2, Signatory 3, Identification, and Alert management. The 'Registration' section is highlighted in yellow, and the 'Specimens of Agreements' dropdown menu is open, showing three options: 'Ver\_1 - MAH - the separate Agreement with CZMVOO', 'Ver\_3a - Several MAHs enter into the Agreement with CZMVOO', and 'Ver\_3b - Several MAHs appoint one of them to enter into the Agreement with CZMVOO on their behalf'. The 'Ver\_3a' option is selected, and a green box highlights the 'Specimens of Agreements' dropdown. A modal window titled 'Specimens of Agreements' is overlaid on the form, showing the same three options. Each option has a 'Download the file' button next to it, which is highlighted with a green box. An 'Ok' button is also visible at the bottom of the modal. A green arrow points from the text 'To familiarize yourself with the content of the Agreement, you can download it in advance (option „Specimens of Agreements“)' to the 'Specimens of Agreements' dropdown. Another green arrow points from the text 'The contract is downloaded after selecting "Download file"' to the 'Download the file' buttons in the modal.

# NEW REGISTRATION - FILLING IN THE DATA

The registration form contains several sections.

In the section. **1** "Registration" you need to select the correct Contract Type (see page 14).

In the "Company" section, **2** the identifying details of the company i.e. MAH or Representative and then the MAH they represent are to be filled in.

In the „Contract Signatory" section **3** the signatory details are entered + acceptance of electronic signing via DocuSign.

In the „Contacts" section. **4** the basic personal contact details for the FMD and for dealing with alerts are entered.

In the section „Invoicing", **5** contacts for sending invoices and, if applicable, requesting a reduced fee, TIN and currency for payment of invoices for fees are entered.



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**New MAH**

[Back](#) | [Save](#) | [Save & Stay](#) | [Save & Add next MAH](#)

**Registration**

**Agreement type** **1** Ver\_3a - Several MAHs ent Specimens of Agreements

**Company** **2**

Company Name\*  
Address\*  
Street  
Town  
Post Code  
Country  
ID\*  
Registered at registered in the Commercial Register maintained by by the court in ref.  
**Correspondence address** **3**  Different address

The agreement is signed by

**DocuSign Acceptance**  
We accept agreement signing via DocuSign

**Signatory 1\*** Name Functions  
**Signatory 2** Name Functions  
**Signatory 3** Name Functions

**Identification**

MAH ID ( EMVO registration - CP Number)  
Associations in Czech Republic Non member

**Alert management**

**Management of other MAH**  
Our alerts will be managed by someone else

**Contacts**

**FMD contacts\*** **4** Name and Surname E-mail  
**Backup contact for FMD** Name and Surname E-mail  
**Alerts contact\*** Name and Surname E-mail Telephone

**Invoicing** **5**

**Fee** We require a reduced fee  
**Invoice to** Address  
**Invoice contacts\*** Name and Surname E-mail E-mail 2 E-mail 3  
**VAT ID\***  
**Currency** CZK

Note: Fields marked with \* are required..

# NEW REGISTRATION - INVOICING DATA

In the "Invoicing" section, you can specify whether the invoice will be issued to an address other than the company's contractual registered office (Option: „*Invoicing to another address*“).



The screenshot shows the 'Invoicing' section with a yellow header. Below it, there are three rows: 'Fee', 'Invoice to', and 'Invoice contacts\*'. The 'Invoice to' dropdown menu is open, showing two options: 'Address' (selected with a checkmark) and 'Other address'. To the right of the 'Fee' row, there is a checkbox labeled 'We require a reduced fee' which is currently unchecked.

It is also possible to request a reduced annual user fee in the "Invoicing" section (Option: "*Request reduced fee*").



The screenshot shows the 'Invoicing' section with a yellow header. Below it, there are three rows: 'Fee', 'Invoice to', and 'Invoice contacts\*'. The 'Fee' row has a checkbox labeled 'We require a reduced fee' which is checked. Below the 'Fee' row, there is a text field with the label 'I declare that the amount of the company's annual sales for all medicinal products for the previous calendar year on the market in the Czech Republic was:' followed by a text input box containing '0' and the label 'EUR'.

After checking the appropriate box, a "Declaration" will open with the option to enter the amount of the company's total annual sales on the Czech market for medicinal products for the previous calendar year.

Note: the request for a reduced fee is subject to further review by NOOL and additional information **may be requested**.

The screenshot shows the 'Currency' dropdown menu with two options: 'CZK' (selected with a checkmark) and 'EUR'.



In the "Invoicing" section you can set which currency you prefer for invoicing by NOOL (Option: „*CZK*“ or „*EUR*“.)

# NEW REGISTRATION - ADDITIONAL INFORMATION

The „**Identification**“ section is filled in with the MAH\_ID = CP number assigned by EMVO (if known at the time of registration). Furthermore, whether the MAH is a member of any professional association in the Czech Republic (AIFP, CAFF) or not.



Identification	
MAH ID ( EMVO registration - CP Number)	<input type="text"/>
Associations in Czech Republic	<ul style="list-style-type: none"><li><input type="checkbox"/> AIFP</li><li><input type="checkbox"/> ČAFF</li><li><input type="checkbox"/> AIFP/ČAFF</li><li><input checked="" type="checkbox"/> Non member</li></ul>

In the section „**Alert management**“ it can be stated that another MAH, either within his/her OBP or another entity, registered in CZAMS, will deal with any alerts on behalf of the MAH.



Alert management	
Management of other MAH	<input checked="" type="checkbox"/> Our alerts will be managed by someone else
MAH	<input type="text" value="Select the MAH"/>



# NEW REGISTRATION - ATTACHMENTS

**Foreign** entities are **required** to submit a mandatory attachment – an extract from the commercial register of the country concerned or a similar register.

Representatives must attach a power of attorney from the entity or entities they represent.

The attachment can be uploaded by selecting „*Insert file*” in the main menu.

Note: Files with the extensions txt, pdf, csv, jpeg, png, and tiff can be **inserted**. Maximum size is 10 MB.

Note: **File type**: “*Agreement*” or “*General*” (any other document).

The screenshot displays a web application interface for a new registration. The main form is titled "01a - New MAH" and includes sections for "Registration", "Company", "Identification", and "Alert management". A green arrow points to the "Insert file" button in the top navigation bar. A modal dialog box is open in the center, titled "Company name", with a yellow warning banner that reads "Status will be adjusted for all MAHs as part of the registration". The dialog contains a "File type" dropdown menu set to "Agreement", a "File" input field with a "Vybrat soubor" (Choose file) button, and a "Send" button. Below the input field, it specifies "Soubor nevybrán" (File not selected) and "Filetype should be txt, pdf, csv, jpg, tiff, png".

# NEW REGISTRATION - COMMUNICATION WITH CZMVO

During registration, preset messages (in Czech or English) can be sent to CZMVO.

In the main menu the option „*Send message*“. After clicking on it, a list of preset bilingual messages will be expanded.

**Note:** The preset messages are continuously updated and modified according to the most frequent requests of registrants.

The screenshot displays a web application interface for MAH registration. The main form is partially visible, showing fields for 'Registration', 'Company', 'ID\*', 'Registered at', 'Correspondence address', 'The agreement is signed by', 'Identification', and 'Alert management'. A 'Send message' dialog box is open in the foreground, featuring a yellow header with the text 'Status will be adjusted for all MAHs as part of the registration'. The dialog contains a 'Send also for registration' checkbox (checked), a 'Message' section, a 'Message text' section, and a 'File' section. A list of preset messages is expanded, including 'Question - Proof of turnover for fee reduction', 'Question - MAH ID', 'Question - general', 'Question - Agreement type', 'Unknown signatory to the Agreement', and 'Sending for verification'. A note below the list states 'Filetype should be txt, pdf, csv, jpg, tiff, png'. The dialog also has 'Send' and 'Cancel' buttons.

# NEW REGISTRATION - COMMUNICATION WITH CZMVO

Examples of preset messages:

Status will be adjusted for all MAHs as part of the registration

Send also for registration  A message will also be sent with the registration form

Message Question - Agreement

Message text Question: We don't know what type of agreement to choose. We ask for advice.

New status 01a - New MAH

File Vybrat soubor Soubor nevybrán  
Filetype should be txt, pdf, csv, jpg, tiff, png

Send Cancel

Status will be adjusted for all MAHs as part of the registration

Send also for registration  A message will also be sent with the registration form

Message Unknown signatory

Message text I don't know yet who will sign the agreement for our side. Can I add a name later?

New status 01a - New MAH

File Vybrat soubor Soubor nevybrán  
Filetype should be txt, pdf, csv, jpg, tiff, png

Send Cancel

Status will be adjusted for all MAHs as part of the registration

Send also for registration  A message will also be sent with the registration form

Message Question - MAH ID

Message text What is MAH ID, where can I find it?

New status 01a - New MAH

File Vybrat soubor Soubor nevybrán  
Filetype should be txt, pdf, csv, jpg, tiff, png

Send Cancel

Send the selected message to NOOL by clicking on "Send".

Note: you can also attach an attachment to the message (a file of an allowed type and smaller than the maximum size).

Status will be adjusted for all MAHs as part of the registration

Send also for registration  A message will also be sent with the registration form

Message Question - Proof of t

Message text We would like to request a reduced fee. How do we prove it?

New status 01a - New MAH

File Vybrat soubor Soubor nevybrán  
Filetype should be txt, pdf, csv, jpg, tiff, png

Send Cancel

Status will be adjusted for all MAHs as part of the registration

Send also for registration  A message will also be sent with the registration form

Message Question - general

Message text Question:

New status 01a - New MAH

File Vybrat soubor Soubor nevybrán  
Filetype should be txt, pdf, csv, jpg, tiff, png

Send Cancel

You can also send a general query in Czech or English (any text).

# NEW REGISTRATION - SAVING DATA

After filling in all the required data and inserting attachments if necessary, the data will be saved by clicking on the „*Save and stay*” option. If you want to enter data for another MAH, click on „*Save and add MAH*”.

Before saving or sending to verification, you are asked if you have entered all the necessary attachments, or you will be informed that the form is incomplete (contains mandatory data not filled in).

The saving is done by clicking on „*Yes*” and „*OK*”.

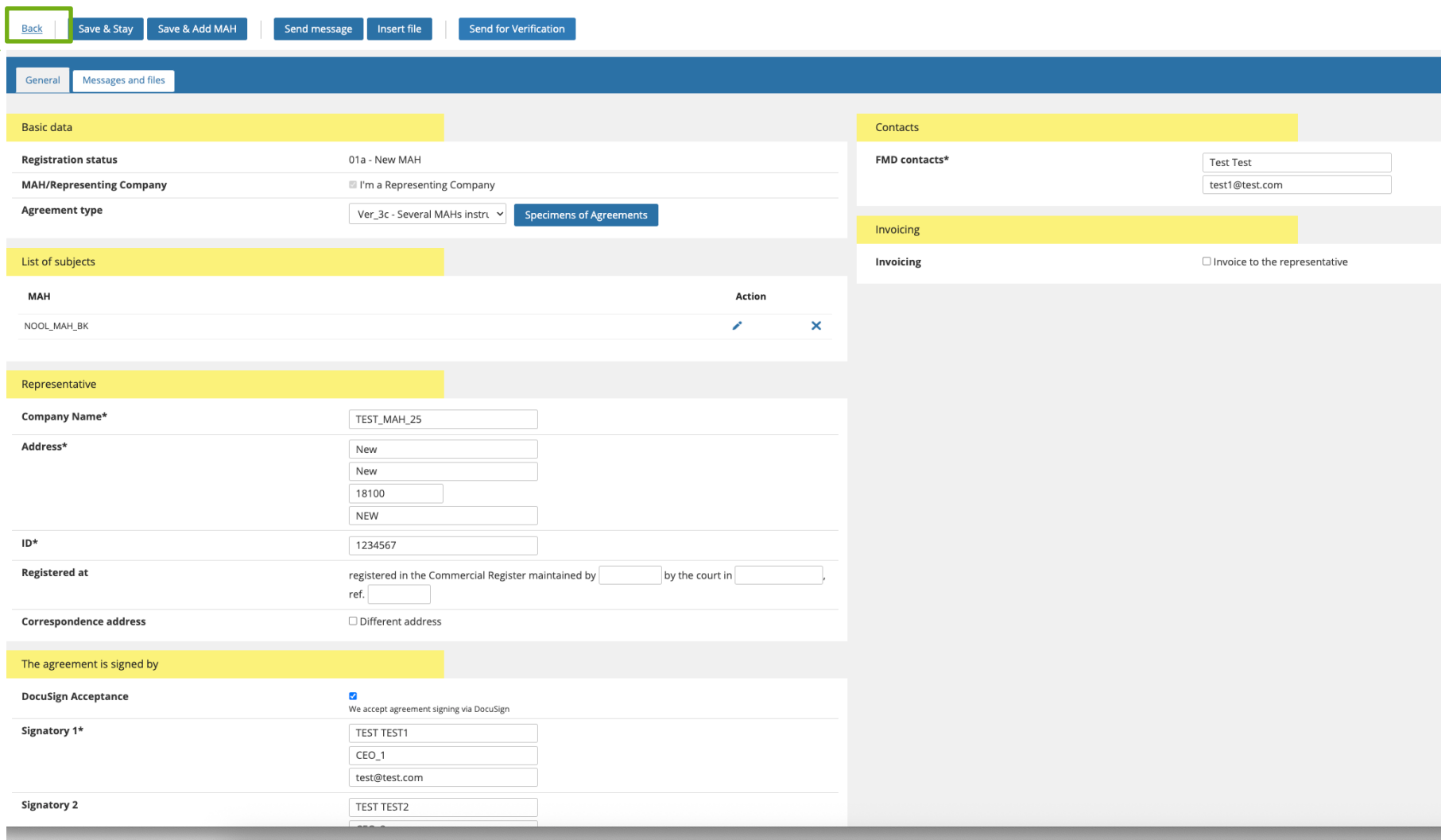
You can return to the editing mode (data entry) by clicking on „*Cancel*” or „*OK*”.

The screenshot shows a web application interface for MAH registration. At the top, there are buttons: "Back", "Save & Stay", "Save & Add MAH", "Send message", "Insert file", and "Send for Verification". The main form is divided into sections: "General", "Public data", "Registration status", "MAH/Representing Company", "Agreement type", "List of subjects", "Representative", "The agreement is signed by", "DocuSign Acceptance", and "Signatory". Two dialog boxes are overlaid on the form. The first is an "Error" dialog with the message "Not all mandatory data are filled in" and an "Ok" button. The second is a "Confirmation" dialog with the message "Have you enclosed all the necessary attachments - a power of attorney or an extract from the commercial register?" and "I agree:" with radio buttons for "Yes" (selected) and "No". Both dialog boxes have "Ok" and "Cancel" buttons at the bottom. Green arrows point from the text blocks to the corresponding buttons and dialog boxes in the screenshot.



# NEW REGISTRATION - SAVING DATA

After saving the data, you can go back to the list of all your MAHs and pending registration contracts by clicking on the „Back” option in the main menu.



Back Save & Stay Save & Add MAH Send message Insert file Send for Verification

General Messages and files

**Basic data**

Registration status 01a - New MAH

MAH/Representing Company  I'm a Representing Company

Agreement type Ver\_3c - Several MAHs instr. Specimens of Agreements

**List of subjects**

MAH	Action
NOOL_MAH_BK	<a href="#">✎</a> <a href="#">✕</a>

**Representative**

Company Name\* TEST\_MAH\_25

Address\*  
New  
New  
18100  
NEW

ID\* 1234567

Registered at registered in the Commercial Register maintained by  by the court in , ref.

Correspondence address  Different address

**The agreement is signed by**

DocuSign Acceptance  We accept agreement signing via DocuSign

Signatory 1\*  
TEST TEST1  
CEO\_1  
test@test.com

Signatory 2  
TEST TEST2

**Contacts**

FMD contacts\*  
Test Test  
test1@test.com

**Invoicing**

Invoicing  Invoice to the representative



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# NEW REGISTRATION - SEND FOR VERIFICATION

For an overview of the communication with NOOL and the attached files, click on "*Messages and files*".

After saving all data in the form, the respective registration will get the status „01a - New MAH". In this state, you can add data or attachments at any time at your discretion or as required by CZMVO.

Edit the data for the MAH - select „*Pencil*" for the respective MAH or Representative.

An incorrectly entered MAH can be cancelled by selecting "x".

The screenshot shows a web interface for a new registration. At the top, there are buttons: [Back](#), [Save & Stay](#), [Send message](#), [Insert file](#), and [Send for Verification](#). Below these are two tabs: [General](#) and [Messages and files](#). The [Messages and files](#) tab is selected. The form is divided into sections: **Basic data**, **Registration status** (01a - New MAH), **MAH/Representing Company** (with a checkbox for "I'm a Representing Company"), **Agreement type** (Ver\_1 - MAH - the separate, with a "Specimens of Agreements" button), and **List of subjects**. The **List of subjects** section contains a table with columns **MAH** and **Action**. The table has one row with the value "TEST TEST\_MAH" and two icons: a pencil and an "x".

If all the information is correct, you can send the form to the CZMVO for checking. Click on the "*Send for Verification*" option or select the "*Send for Verification*" message via "**Send Message**". Both options result in changing the registration status (to „02a-Verification") and sending information to CZMVO that there is a pending registration in the system for verification.

The dialog box has a title bar with a close button. It contains a yellow banner with the text: "Status will be adjusted for all MAHs as part of the registration". Below this, there are three rows of information: **Message** (Sending for verificati), **Message text** (We are sending it for verification), and **New status** (02a Verification). At the bottom, there are two buttons: [Send](#) and [Cancel](#).

# NEW REGISTRATION - VERIFICATION

After you submit your verification request, the Registration Status will change to „02a - Verification“.

**MAH Management**

New registration

Pending registrations

Created	User	E-mail	Registration status	Agreement number	Number of subjects	Action
2025-05-06 09:14	NOOL_TEST_MAH_LS2	libor.svaton@czmvo.cz	02a Verification		1	
2025-04-24 10:14	NOOL_TEST_MAH_LS2	libor.svaton@czmvo.cz	02a Verification		1	

MAH Evidence

Displayed: 1-5 of 5 records Count per page: 50

Action	Registration status	Aggr. registration status	Agreement number	Member	Name	OBP Name	ORG ID	Country	Type	MAH ID	Created	CZAMS	Reduced fee	E-mail - FMD contacts	E-mail - Alerts contact	E-mail - Invoicing	Currency	Notification	Management of other MAH	DocuSign Acceptance	Action
	01a - New MAH	New registration		Non member	TEST_MAH_25			NEW	Representative		2025-05-12 12:30			test1@test.com				Primary e-mail			
	02a Verification	Registration		Non member	TEST_MAH			Česká Republika	MAH	TEST	2025-05-06 09:15			libor.svaton@czmvo.cz	libor.svaton@czmvo.cz	libor.svaton@czmvo.cz	CZK	Primary e-mail			
	02a Verification	Registration		Non member	TEST_MAH			Česko	MAH		2025-04-24 10:18			libor.svaton@czmvo.cz	libor.svaton@czmvo.cz	libor.svaton@czmvo.cz	CZK	Primary e-mail			



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pravosti léčiv

# NEW REGISTRATION - SENT FOR VERIFICATION

In this registration status, the previously entered data can no longer be changed. You can only send a „*Send Message*”<sup>1</sup> message asking for the verification status or insert additional attachments with "*Insert File*".<sup>2</sup>

You can get an overview of received and sent messages and inserted and received files by clicking on "*Messages and files*".<sup>3</sup>

The screenshot shows a registration form with several sections: 'General', 'Messages and files', 'Basic data', 'Registration status', 'MAH/Representing Company', 'Agreement type', and 'List of subjects'. The 'Registration status' is set to '02a Verification'. The 'Agreement type' is 'Ver\_1 - MAH - the separa...'. The 'List of subjects' section contains a table with one row: 'TEST\_MAH'. Annotations 1, 2, and 3 point to the 'Send message' and 'Insert file' buttons, the 'Messages and files' tab, and the 'Messages and files' section respectively.

The screenshot shows the 'Messages MAH/CZMVO' section. It contains a message titled 'Data completion request [NOOL]' dated 2025-04-24 10:24. The message text reads: 'During the verification we found that the following information was incorrectly/completely filled in: Address, iD no error. Please complete.'

The screenshot shows the 'Send message' dialog box. It has a yellow header: 'Status will be adjusted for all MAHs as part of the registration'. The 'Message' field is checked and labeled 'Question - status of Agreement'. The 'Message text' field contains: 'Please let me know the status of our agreement. Thank you.' There are 'Send' and 'Cancel' buttons at the bottom.

The screenshot shows the 'Insert file' dialog box. It has a yellow header: 'Status will be adjusted for all MAHs as part of the registration'. The 'File type' is checked and labeled 'General'. The 'File' field has a 'Vybrat soubor' button and the text 'Soubor nevybrán'. Below the field, it says 'Filetype should be txt, pdf, csv, jpg, tiff, png'. There are 'Send' and 'Cancel' buttons at the bottom.



# NEW REGISTRATION - COMPLETION OF DATA

When checking the data, the CZMVO may find an **inconsistency**, **missing data** or a missing required **attachment**.

In such cases, CZMVO will request completion of the data by automatically sending a **request for completion or correction of the data**. MAH will receive an email notification that completion is required, and the Registration Status will change to "03a - Incomplete Data".

Note: example of a message from CZMVO requesting completion of data.

MAH Evidence

Displayed: 1-5 of 5 records Count per page: 50

Action	Registration status	Aggr. registration status	Agreement number	Member	Name	OBP Name	ORG ID	Country	Type	MAH ID	Created	CZAMS	Reduced fee	E-mail - FMD contacts	E-mail - Alerts contact	E-mail - Invoicing	Currency	Notification	Management of other MAH	DocuSign Acceptance	Action
	01a - New MAH	New registration		Non member	TEST_MAH_25			NEW	Representative		2025-05-12 12:30			test1@test.com				Primary e-mail			
	03a - Incomplete data	Registration - Escalation		Non member	TEST_MAH			Česká Republika	MAH	TEST	2025-05-06 09:15			libor.svaton@czmvo.cz	libor.svaton@czmvo.cz	libor.svaton@czmvo.cz	CZK	Primary e-mail			



### Messages MAH/CZMVO

**Data completion request** [NOOL] | 2025-05-16 10:09

During the verification we found that the following information was incorrectly/completely filled in: Attorney of your MAHs Please complete.



# NEW REGISTRATION - COMPLETION OF DATA

After clicking on the "pencil" **1** in the MAH Register, fill in the required data or insert the missing attachment ("Insert file"). **2** Save the corrected data by clicking on "Save and stay". **3**

Then ask the CZMVO for a new data verification ("Send message") **4** - option "Required data completed, sending for verification".

MAH Evidence

Displayed: 1-5 of 5 records

Action	Registration status	Aggr. registration status	Agreement number	Member	Name	OBP Name	ORG ID	Country	Type	MAH ID	Created	CZAMS	Reduced fee
<b>1</b>	01a - New MAH	New registration		Non member	TEST_MAH_25			NEW	Representative		2025-05-12 12:30	🔄	🔄
	03a - Incomplete data	Registration - Escalation		Non member	TEST_MAH			Česká Republika	MAH	TEST	2025-05-06 09:15	🔄	🔄

TEST\_MAH **3** **4** **2**

Back Save Save & Stay Send message Insert file

General Messages and files

Registration

Registration status 03a - incomplete data

Agreement type Ver.1 - MAH - the separ. Specimens of Agreements

Company

Company Name\* TEST\_MAH

Address\* Pobežní Praha 18100 Česká Republika

ID\* 1234567891123

Registered at registered in the Commercial Register maintained by Krasným by the court in Ostravě ref. 64vd2

Correspondence address  Different address

The agreement is signed by

DocuSign Acceptance  We accept agreement signing via DocuSign

Signatory 1\* TEST TEST1 CEO\_1

Signatory 2 TEST TEST2 CEO\_2

Signatory 3 Name Functions

Identification

MAH ID (EMVO registration - CP Number) TEST

Associations in Czech Republic Non member

Alert management

Management of other MAH  Our alerts will be managed by someone else

Contacts

FMD contacts\* Libor Svatoň\_FMD libor.svaton@czmvo.cz

Backup contact for FMD Libor Svatoň libor.svaton@czmvo.cz

Alerts contact\* Libor Svatoň\_ALERTY libor.svaton@czmvo.cz 111111

Invoicing

Fee  We require a reduced fee

Invoice to TEST\_MAH

Company Name TEST\_MAH

Invoice address\* Pobežní Praha 18100 Česká Republika

Invoice contacts\* Libor Svatoň\_FAKTURA libor.svaton@czmvo.cz E-mail 2 E-mail 3

ID 1234567891123

VAT ID\*

Currency CZK

Status will be adjusted for all MAHs as part of the registration

Send also for registration

Message  Information - other  Completion of incomplete data - send for verification

Message text Required data completed - we are sending for verification.

New status 02a Verification

File  Soubor nevybrán  
Filetype should be txt, pdf, csv, jpg, tiff, png

Send Cancel



# NEW REGISTRATION - SIGNING THE AGREEMENT

After successful verification CZMVO will generate a agreement (in pdf).

Depending on the type of CZMVOL signature:

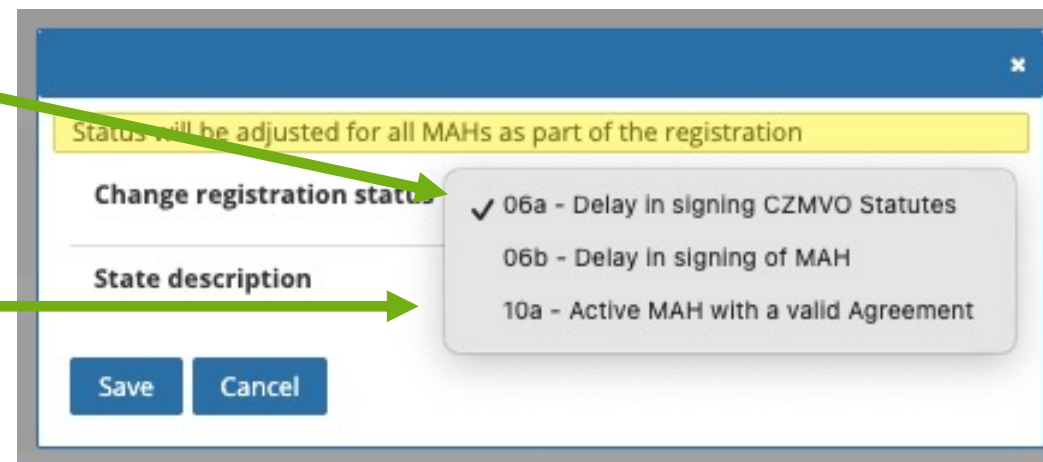
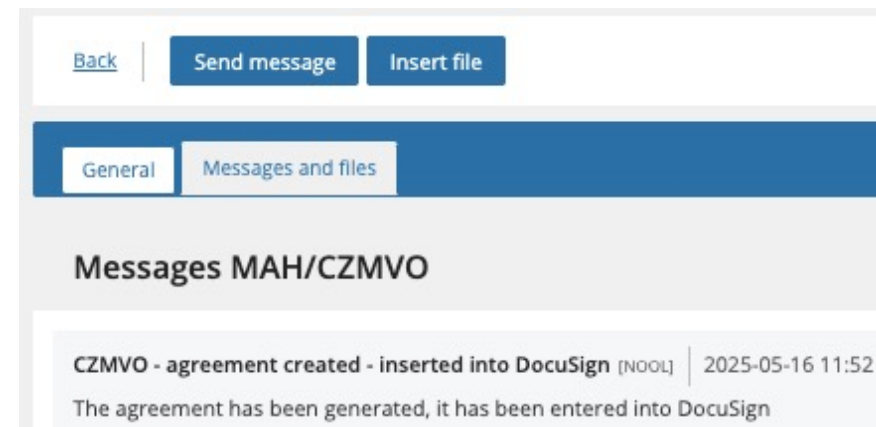
Inserts the generated contract into the **DocuSign** application, within which the agreement is signed by all participants.

or

Changes the registration status to „**04a - Downloadable contract for MAH**“". The MAH/Representative prints the contract from the system in the required number of copies, signs it and sends it by post to the CZMVO. After signing, CZMVO sends the Agreement back by post to the MAH/Representative.

If there is any **delay**, MAH/NOOL is automatically notified.

If everything is in order, all parties **have signed the Agreement**, and the **Agreement** has been received, the Registration Status will change to “**10a - Active MAH with a valid Agreement**” - this **completes Part I of the Registration**.



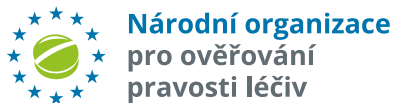
# REGISTRATION - LIST

After the registration is completed, the MAH is in the status „10a - Active MAH with a valid contract“.

The MAH/Representative has the ability to change or add editable information at any time. This includes contact information or a request to change the billing currency.

Editing can be done by clicking on the "pencil".

If the MAH/Representative manages more than one MAH, he can use a number of preset filters (option "Record filter" 1 -), it is possible to set the displayed columns or export 2 the data. (xlsx, csv). 3



**MAH Management**

**Basic data**

Name:  MAH ID:  Aggr. registration status:  Registration status:  Country:  Type:  Created:   Management of other MAH:  Agreement number:

**Details**

Member:  OBP Name:  ORG ID:  E-mail - FMD contacts:  E-mail - Alerts contact:  Notification:  DocuSign Acceptance:  CZAMS:

**Invoicing**

E-mail - Invoicing:  Currency:  Reduced fee:

Listing is limited by filters:

Displayed: 1-2 of 2 records

Action	Registration status	Aggr. registration status	Agreement number	Member	Name	OBP Name	ORG ID	Country	Type	MAH ID	Created	CZAMS	Reduced fee	E-mail - FMD contacts
	10a - Active MAH with a valid Agreement	Active MAH - with Agreement	250005	Non member	AUXpharma s.r.o.			Česká republika	MAH	CP3186	2025-03-12 10:47		<input checked="" type="checkbox"/>	lucie.galnorova@auxpharma...
	10a - Active MAH with a valid Agreement	Active MAH - with Agreement	250004	Non member	GINELADIUS, S.L.	Laboratorios Farmacéuticos ROVI S.A.	1261	Spain	MAH	CP767	2025-03-04 14:18		<input checked="" type="checkbox"/>	mgmolyneux@rovi.es

**Select columns**

Column	Column
<input checked="" type="checkbox"/> Registration status	<input checked="" type="checkbox"/> Aggr. registration status
<input checked="" type="checkbox"/> Agreement number	<input checked="" type="checkbox"/> Member
<input checked="" type="checkbox"/> Name	<input checked="" type="checkbox"/> OBP Name
<input checked="" type="checkbox"/> ORG ID	<input checked="" type="checkbox"/> Country
<input checked="" type="checkbox"/> Type	<input checked="" type="checkbox"/> MAH ID
<input checked="" type="checkbox"/> Created	<input checked="" type="checkbox"/> CZAMS
<input checked="" type="checkbox"/> Reduced fee	<input checked="" type="checkbox"/> E-mail - FMD contacts
<input checked="" type="checkbox"/> E-mail - Alerts contact	<input checked="" type="checkbox"/> E-mail - Invoicing
<input checked="" type="checkbox"/> Currency	<input checked="" type="checkbox"/> Notification
<input checked="" type="checkbox"/> Management of other MAH	<input checked="" type="checkbox"/> DocuSign Acceptance

**FILTER RECORDS** **SET COLUMNS** **EXPORT**

CSV  
CSV EXCEL  
XLSX EXCEL

# REGISTRATION - RECORD DETAIL

MAH MANAGEMENT

ALXpharma s.r.o.

Back Save Save & Stay Send message Insert file

General Messages and files Detailed information

### Registration

Registration status	10a - Active MAH with a valid Agreement
Date of activation	2025-03-12 10:47
Agreement number	250005

### Company

Company Name*	ALXpharma s.r.o.
Address*	D... P... 1... Česká republika
ID*	14034557
Registered at	registered in the Commercial Register maintained by the court in , ref.
Correspondence address	<input type="checkbox"/> Different address Vorklečice 11 Kobyly 46345 Česká republika

### Identification

MAH ID ( EMVO registration - CP Number)	CP3186
Associations in Czech Republic	Non member

### Alert management

Management of other MAH  Our alerts will be managed by someone else

### Contacts

FMD contacts*	<input type="text" value="728339826"/>
Backup contact for FMD	
Alerts contact*	

### Invoicing

Fee  We require a reduced fee

I declare that the amount of the company's annual sales for all medicinal products for the previous calendar year on the market in the Czech Republic was:  EUR

Invoice to	ALXpharma s.r.o.
Company Name	ALXpharma s.r.o.
Invoice address*	D... P... 1... Č... L... I...
Invoice contacts*	L... I...
ID	14034557
VAT ID*	ČZ14034557
Currency	CZK