



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 September 2023  
EMA/362250/2023  
Information Management Division

## Registration guide

Union product database for veterinary medicinal products

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



# Table of contents

<b>1. Purpose and context.....</b>	<b>3</b>
<b>2. UPD Registration overview .....</b>	<b>3</b>
<b>3. EMA Account Management.....</b>	<b>4</b>
<b>4. OMS: Pharmaceutical industry organisation registration.....</b>	<b>4</b>
4.1. Create a new organisation .....	4
4.2. Update organisation information.....	4
4.3. OMS change requests supporting documentation.....	5
<b>5. Access to UPD.....</b>	<b>5</b>
5.1. Access roles and permissions .....	5
5.1.1. Competent authorities (CA) .....	5
5.1.2. Pharmaceutical industry .....	9
5.2. Request UPD user role .....	11
<b>6. Log-in into UPD .....</b>	<b>11</b>
6.1. How to set up Additional Security Verification .....	14
6.1.1. Call me method.....	15
6.1.2. Mobile App.....	16

# 1. Purpose and context

This guide serves to help users of the Union Product Database (UPD) to complete the registration steps necessary before accessing the system to carry out relevant data submission activities. The registration steps are independent from the UPD and are similar to those for other European Medicines Agency (EMA) systems, such as EudraVigilance Veterinary and Management Services for Substances, Products, Organisation and Referentials (SPOR) or IRIS.

The document is applicable to the users of the competent authorities (i.e. European Commission (EC), national competent authorities (NCAs)) and pharmaceutical industry.

# 2. UPD registration overview

To use the UPD restricted areas you will need to complete a few registration steps (Figure 1) to ensure that:

## 1. You must have an active EMA account

As a representative of the competent authority or pharmaceutical industry organisation, including persons acting on their behalf, you must register for an EMA user account in the EMA Account Management (EAM) portal, if you do not already have one (see section on the EMA Account Management).

## 2. The organization you represent must be recorded in EMA’s Organisation Management Service (OMS)

All organisations of the competent authorities within the European Economic Area are listed in OMS.

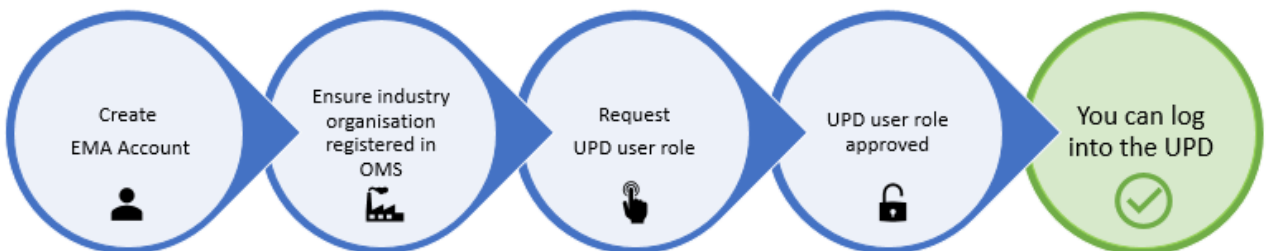
If marketing authorisation holder (MAH) that you represent does not appear in the OMS list, it will need to be included. Otherwise you will not be able to affiliate yourself to this organisation when you submit a request for an UPD access role in EAM (see section 4 on OMS: Pharmaceutical industry organisation registration).

*To register a new organisation in OMS may take up to **ten working days**.*

## 3. You have the appropriate UPD user role and affiliation to an organisation

You will need to submit a request for an UPD access role in EAM. While approval of the UPD user roles is carried out by super users nominated by the competent authorities and pharmaceutical industry organisations, the approval of the first “Super User” is performed by EMA and may take up to **two working days**.

**Figure 1: UPD registration overview**



### 3. EMA Account Management

[EMA Account Management](#) is an online platform where you can request and manage access to EMA applications. Refer to this platform to seek guidance on how to:

- [Find out if you have an EMA account](#)
- [Create an EMA Account](#)
- [Re-activate your account](#)
- [Recover your credentials](#)
- [Request a user access role](#)
- [Manage users' access for your organisation as an "User Admin/Super User"](#)

For further guidance you can also access the [FAQ and EMA Account Management Checklist](#).

### 4. OMS: Pharmaceutical industry organisation registration

As a marketing authorisation holder you will need to ensure that the organisation on whose behalf you will be acting is listed in EMA's [Organisation Management Service \(OMS\)](#). This is needed for you to be able to request a UPD access role via EAM as well as for competent authorities to create new or updated entries in the UPD for products under their responsibility.

There are two ways you can check if your MAH organisation is listed in OMS:

1. Look up your MAH organisation in [OMS](#) (please note this webpage does not work with Internet Explorer and no log-in is required to perform the organisation search). For further information on how to search, please check the OMS Web User Manual available on the SPOR Organisations web page <https://spor.ema.europa.eu/omswi/#/viewDocuments>. We recommend you take note of the organisation ID as it reduces the search results in the EAM when you are requesting a role.
2. Look up your MAH organisation in the EMA Account Management portal while submitting a request for a UPD user role (see section on EMA Account Management).

If the organisation appears in the OMS list, this means that it is already registered and will appear on the drop-down list when requesting your UPD access role in the EMA Account Management portal and in the UPD when creating product records by competent authorities.

#### 4.1. Create a new organisation

If your MAH organisation cannot be found in OMS, you will need to create a new organisation by using the change request functionality in the OMS interface. Please follow the steps on how to register a new organisation that appear in the OMS Web User Manual available on the SPOR Organisations web page <https://spor.ema.europa.eu/omswi/#/viewDocuments>.

To create a new organisation you will need to log in into the SPOR portal with your EMA Account username and password (see section on EMA Account Management). You will not require a specific SPOR user role as the "SPOR unaffiliated user" role is assigned to you by default during the EMA account self-registration process.

#### 4.2. Update organisation information

Users can make changes to their organisation data in OMS using the same **change request** functionality in the OMS interface as to create a new organisation. Please follow the steps on how to

update your MAH organisation data that are listed in the OMS Web User Manual available on the SPOR portal <https://spor.ema.europa.eu/omswi/#/viewDocuments>.

The first step is to search for and view the full details of an organisation and its locations in OMS. If the users:

- find the organisation but not its location, they can ask to add a new location to the organisation;
- find both the organisation and its location, but either of these are not up to date, they can ask to update the organisation and/or location data;
- find the organisation with an active status but the location with an inactive status, they can ask to update the organisation data or add new locations.

In order to request the changes listed above you will need to have the "**SPOR Industry User**" access to the SPOR portal. Prior to that, the "**SPOR Industry Super User**" role which manages access requests for your MAH organisation must be set up. For detailed instructions on the SPOR user registration, refer to the SPOR User Registration Manual available on the SPOR Organisations web page <https://spor.ema.europa.eu/omswi/#/viewDocuments>.

The first "**SPOR Super User**" for each organisation will be approved by EMA. Therefore, consider extra time to submit the request with the required documentation and allow up to **two working days** for EMA to approve it.

### **4.3. OMS change requests supporting documentation**

All change requests must be accompanied by relevant supporting documents or information as described in the OMS Change Requests manual available on the SPOR Organisations web page <https://spor.ema.europa.eu/omswi/#/viewDocuments>.

The standard change request to register a new organisation or update the organisation data can take from **five to ten working days** to be processed.

## **5. Access to UPD**

### **5.1. Access roles and permissions**

To use the UPD, you need to have been granted at least one of the below described **UPD user roles** affiliated to the organisation on whose behalf you will be acting.

**Approval** of the UPD user roles is carried out by **Super Users** nominated by the competent authorities and pharmaceutical industry organisations. Only the approval of the **first "Super User"** request for a competent authority or pharmaceutical organisation is performed by **EMA**. Therefore, before requesting access to the UPD as a subsequent super user or any other user you need to **ensure** that your MAH organisation has a **Super User** in place.

#### **5.1.1. Competent authorities (CA)**

##### **1. UPD - CA Super User**

You should request this role if you work for an organisation acting as a regulatory authority (i.e. EC, NCA) and intend to manage (approve/reject/revoke) access to UPD for users acting on behalf of your organisation.

Only the first request for an “UPD CA Super User” role is evaluated and granted by EMA, and you will need to attach a signed “Nomination Letter”.

This role will give you full access (Edit/Search/View) to UPD and also allow you to access the EAM to administrate (approve/reject) access rights for new and existing users of your organisation.

Please refer to the EMA Account Management [User Administrator Guide](#) to find more information on the responsibilities of a ‘Super User’ and how the EMA Account Management system helps to fulfil them.

Only the super user can request API access if the organisation wishes to use API services.

## 2. UPD - CA Edit/Search/View

You should request this role if you work for an organisation acting as a regulatory authority (i.e. EC, NCA) and intend to use UPD to manage (create/update) data on veterinary medicinal products and approve/reject variations not requiring assessment that fall under your responsibility.

**This role will be approved by the Super User of the organisation you represent.** Please ensure that your organisation has at least one person assigned as Super User before submitting this request otherwise your request will be automatically rejected.

## 3. UPD - CA Search/View

You should request this role if you work for an organisation acting as a regulatory authority (i.e. EC, NCA) and intend to use UPD to only read and export data on veterinary medicinal products.

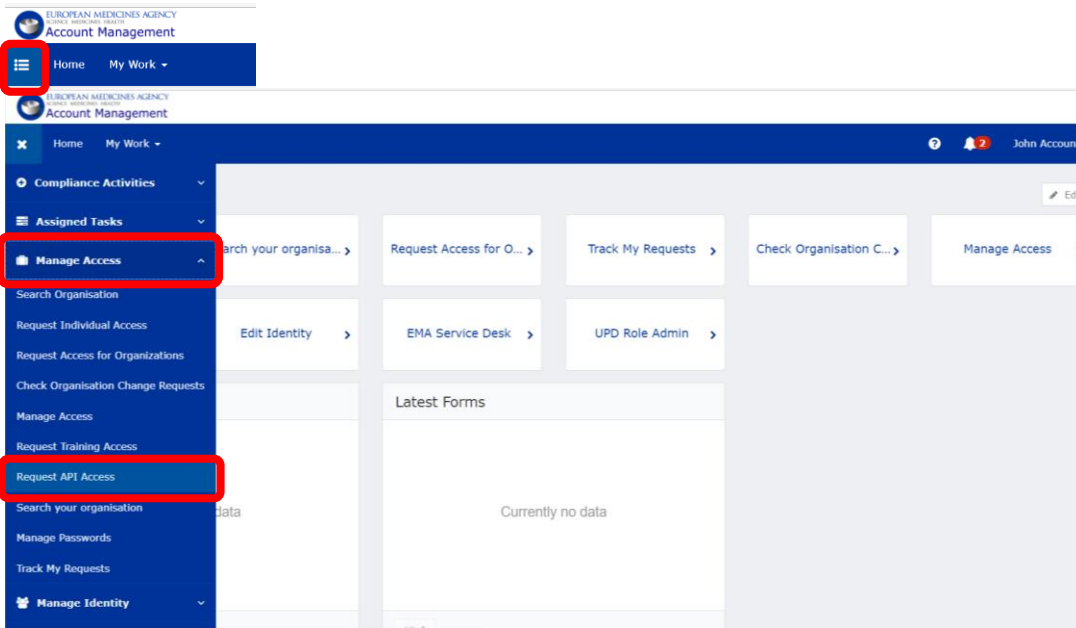
**This role will be approved by the Super User of the organisation you represent.** Please ensure that your organisation has at least one person assigned as Super User before submitting this request otherwise your request will be automatically rejected.

## 4. UPD – API

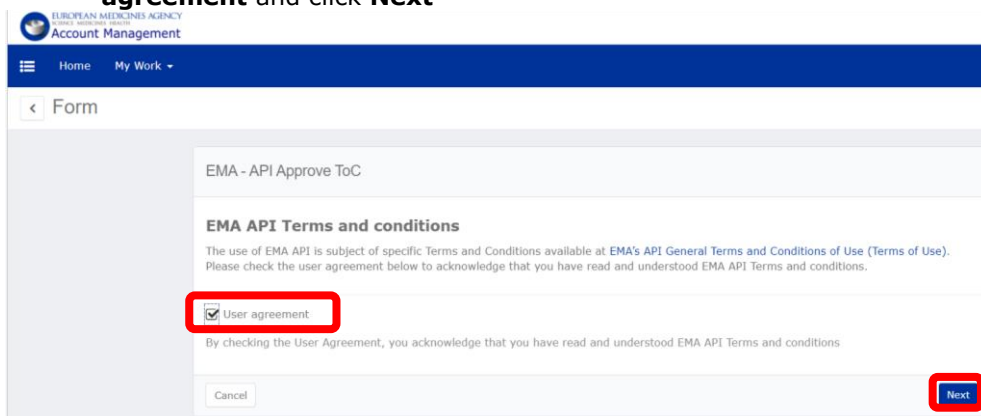
You should request the API role if you intend to use the UPD API services. **This role must be requested by the Super user of your organisation and will be approved by EMA.**

- Go to **EMA Account Management** [Home · EMA Account Management \(europa.eu\)](#) and log-in with your username and password

- In the menu bar, select **Manage Access** and then **Request API Access**



- Read the EMA API Terms and conditions and Accept them by **ticking the box of user agreement** and click **Next**



- **Select Application** (for now only UPD, in future there will be more systems offering API functionality)
- **Select your Organisation** using the drop-down menu
- **Provide API technical contact email address** (this email address will be used to send notifications about the API account including the initial notification with Client ID and 'secret')
- **Select the right API role** using the drop-down menu:
  - For competent authorities: UPD CA API
  - Note: If EMA systems need an API, a direct connection will be set up by EMA IM
- **Click Request API Access**

### Request API access

---

**How to**

Please see the instructions below on how to request API access.

Once the request is processed an email will be sent to **API Technical contact email** containing the Application ID, the Client Credentials and instructions on how to consume the API. Please remember to rotate the client credentials before their expiration.

---

1. Select your Application \*

UPD

2. Select Organisation \*

ORG-100003934 - Medicines Evaluation Board ▼

In case you cannot find your organisation in the list, please verify that you have an User Admin role for it

3. Provide an API Technical contact email \*

John.Account@testorganisation.com

UPD CA API ▼

---

Cancel Request API Access

---

Request provisioning form for: John Account

---

**Please supply initial values for account attributes in the forms below.**

---

**Request Information**

**Requester**  
UPD NCA API Test Account TEST

---

**Target Identity**

First Name	Last Name	Account ID
UPD NCA API Test Account	Account	John Account

**Assigned Roles**  
Azure Birthrights External, UPD CA Super User (ORG-100003934 - Medicines Evaluation Board)

---

**Select your Organisation**

**Requested Roles**

UPD CA API\_Org/ORG-100003934

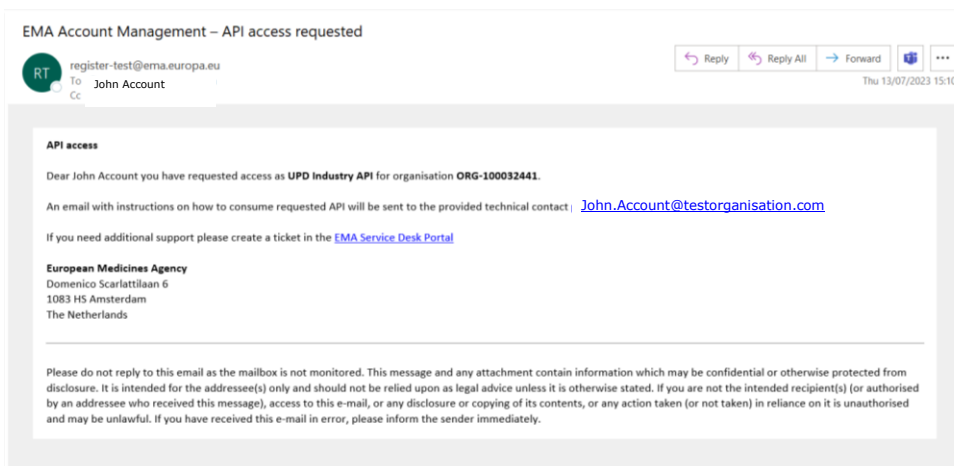
---

Cancel OK

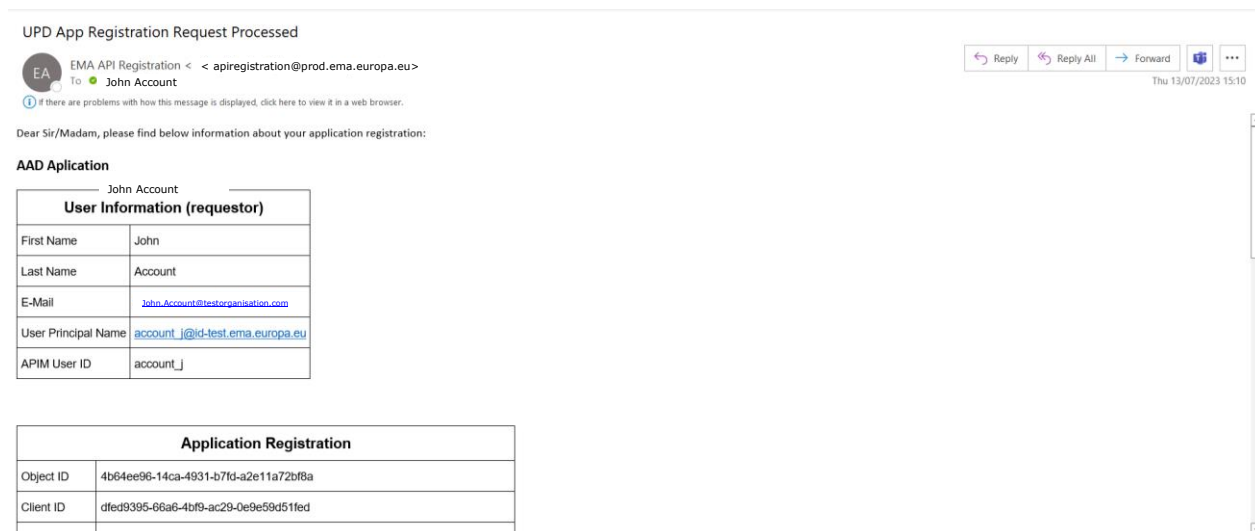
You will receive an email when the request has been approved.



- In your e-mail you receive an email with a notification of your request for API access:



When the access is granted and processed you receive a second **email UPD App Registration Request Processed**. This email provides the user Azure Active Directory (AAD) identification, application registration, the application 'secret' (this is a method used for authentication) and you can start using the API registration.



## 5.1.2. Pharmaceutical industry

### 1. UPD - Industry Super User

You should request this role if you intend to manage (approve/reject/revoke) access to UPD for colleagues of the organisation(s) you are affiliated to. Only the first request for an "UPD Industry Super User" role is evaluated and granted by EMA and you will need to attach a completed and signed copy of the "Affiliation Template Letter", as proof of authority to represent the organisation, available on the [User Administrator Guide](#) web page.

This role will give you full access (Edit/Search/View) to UPD and also allow you to access the EAM to administrate (approve/reject) access rights for new and existing users of your organisation.

Please refer to the EMA Account Management [User Administrator Guide](#) to find more information on how to submit a request for the first 'Super User' role as well as what are the responsibilities of a 'Super User' and how the EMA Account Management system helps to fulfil them.

## 2. UPD - Industry Edit/Search/View

You should request this role if you intend to update your MAH organisation's veterinary medicinal product data and record variations not requiring assessment in UPD.

**This role will be approved by the Industry Super User of the organisation you represent.**

Please ensure the organisation(s) you are affiliated to has at least one person assigned as Industry Super User before submitting this request otherwise your request will be automatically rejected. "

## 3. UPD - Industry Search/View

You should request this role if you intend to use UPD to only read and export data on veterinary medicinal products of the organisation you represent. This role will be approved by the Industry Super User of the organisation you represent. Please ensure the organisation(s) you are affiliated to has at least one person assigned as Industry Super User before submitting this request otherwise your request will be automatically rejected.

The overview of the UPD user roles and permissions is detailed in the figure below (Figure 2):

**Figure 2: Overview of the UPD user roles and permissions**

	UPD CA Super User	UPD CA Edit/Search/View	UPD CA Search/View	UPD Industry Super User	UPD Industry Edit/Search/View	UPD Industry Search/View	UPD API
Manage users in EAM	✓			✓			
Create/submit data	✓	✓		✓ <sup>1,3</sup>	✓ <sup>1,3</sup>		
Update data	✓	✓		✓ <sup>1,2</sup>	✓ <sup>1,2</sup>		
Nullify data	✓	✓					
Search/View/Export data	✓	✓	✓	✓ <sup>1</sup>	✓ <sup>1</sup>	✓ <sup>1</sup>	
Record variations not requiring assessment				✓ <sup>1</sup>	✓ <sup>1</sup>		
Approve/Reject variations not requiring assessment	✓	✓					
Obtain report on dataset changes*	✓	✓	✓	✓ <sup>1</sup>	✓ <sup>1</sup>	✓	
Connect to UPD API							✓
Email Configuration	✓			✓			

<sup>1</sup> Own products only

<sup>2</sup> For marketing authorisation status and availability status only

<sup>3</sup> For volumes of sales, date of placing on the market and provision of 3rd country names only

\*For MVP, requests for 'reports on data set changes' will not be available as a technical service within the UPD Portal or API. Requests for 'reports on data set changes' will be raised through the EMA Service Desk.

Please note the following:

- Only the first request for an "UPD CA Super User" and "UPD Industry Super User" role is evaluated and granted by EMA. All subsequent requests are "**Approved**" or "**Rejected**" by the first "UPD CA Super User" or "UPD Industry Super User" of the organisation, whether for one of the other roles listed above or for another "Super User" role. If nobody has a "Super User" role in your MAH organisation, any requests for the other roles will be automatically rejected by the EMA Account Management system.
- If you have requested either competent authority or industry "**Edit/Search/View**" or "**Search/View**" role/affiliation, the approver will be the "**Super User**" from the organisation you selected in your request, not EMA.
- EMA recommends having at least two contacts per organisation with the "Super User" role, to ensure that user role requests are not delayed in the event of absences or staff mobility.

- When a subsequent request is made for one of the user roles, the “UPD CA Super User” or “UPD Industry Super User” for the organisation to which you are requesting affiliation will be notified automatically by email and (one of them) will carry out the review and approval of your affiliation request.
- It is possible for a single user to be affiliated to multiple organisations, whether the organisations are related or not.
- There are no limitations to the number of “**Super Users**”, nor to the number of users with either “**Edit/Search/View**” or “**Search/View**” role, an organisation may have.

## 5.2. Request UPD user role

As explained in the section on ‘UPD registration overview’ before you can request the necessary role/affiliation to perform relevant activities in the UPD, there are four pre-requisites:

1. You need to have an active EMA user account (see section EMA Account Management);
2. The organisation on whose behalf you will be carrying out UPD activities must be registered in OMS (see section OMS: Pharmaceutical industry organisation registration).
3. The affiliation to a given company gives access to the data of all products for which the company is MAH and allows a user with “Edit/Search/View” rights to perform any type of action in the UPD. UPD access rights cannot be set up on a product basis and also not on an action-type basis (such as submit a variation not requiring assessment or maintain availability information).

For example, you could be employed by a consultancy but requesting access as an “UPD Industry Edit/Search/View user” to submit a variation on behalf of Pfizer Belgium. In this case, you would need to request affiliation to Pfizer Belgium.

A single UPD user can request affiliation to more than one organisation. For example, a user who works for a consultancy may request to be affiliated with one or more pharmaceutical companies.

This will allow the consultant to perform relevant activities on behalf of a pharmaceutical company.

4. At least one “**Super User**” has been set up for this organisation (otherwise, your role request will be automatically rejected).

Once the four prerequisites above are in place, you can request an UPD user role by referring to the dedicated page on how to [request user access](#) in the EMA Account Management portal.

## 6. Log-in into UPD

After you have been notified that your UPD user access role/affiliation has been granted, you may need to wait approximately 30 minutes before accessing the UPD. This is because the EMA Account Management system and the UPD are synchronised about every 20 minutes.

To access the UPD:

1. After having been notified that your UPD user role has been approved, wait for half an hour to allow time for the synchronisation process mentioned above to be completed;
2. Go to the UPD portal ([upd-portal-prod.azurewebsites.net](http://upd-portal-prod.azurewebsites.net));
3. Click “**Sign In**” (top right of your screen);
4. In the next “**Pick an account**” window, EITHER:

- 4.1. Click on “**use another account**” and enter your **EMA username** in the first box **followed by “@id.ema.europa.eu”** – for example, if your EMA username is “surname\_a”, type in “**surname\_a@id.ema.europa.eu**”;

**OR**

- 4.2. If this account name already appears in the “**Pick an account**” list, simply click on it;
5. Make sure that in the first of the sign-in boxes, your EMA Account username followed by the suffix “@id.ema.europa.eu” is shown (Figure 3), and then type your EMA Account password in the box below (Figure 4);
6. Click “Sign In” – this will take you to the UPD portal home page, where you can start to use the system.

**Figure 3**

**Sign in**

EMA: email, other users: userid@id.ema.europa.eu

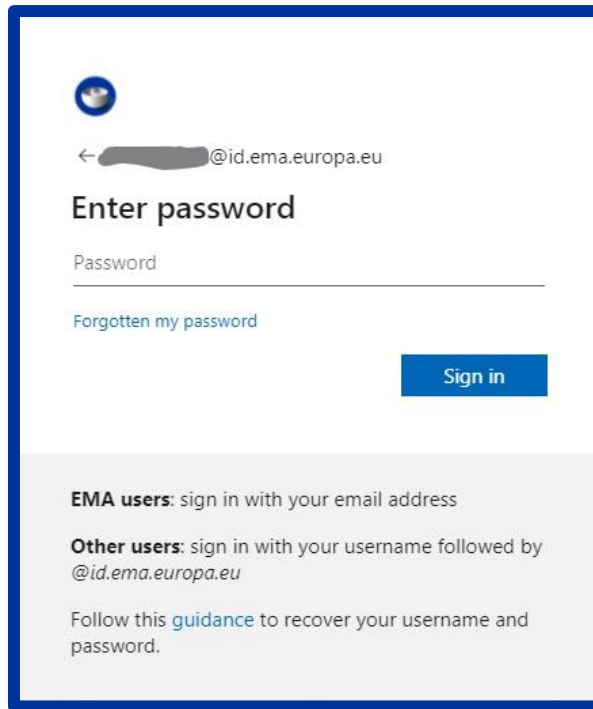
[Can't access your account?](#)

**EMA users:** sign in with your email address

**Other users:** sign in with your username followed by @id.ema.europa.eu

Follow this [guidance](#) to recover your username and password.

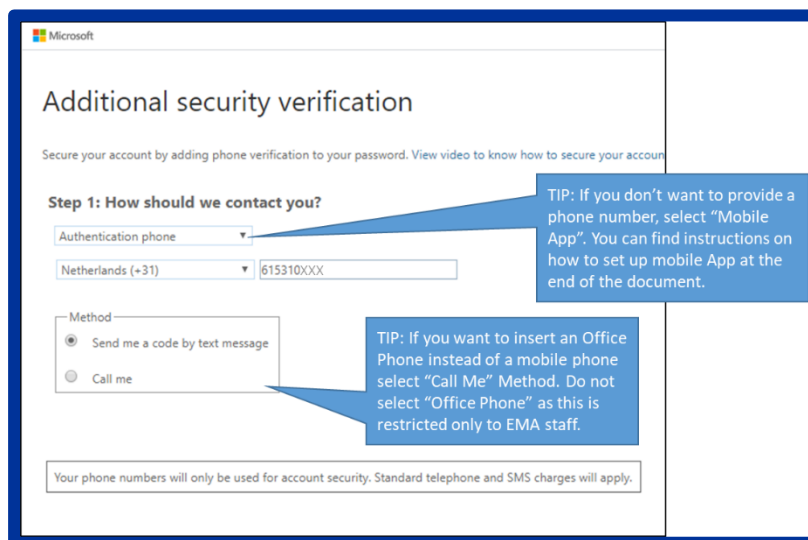
**Figure 4**



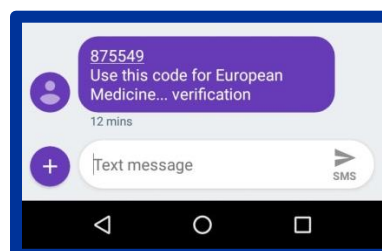
## 6.1. Setting up Multi factor authentication

Follow the prompts to provide more security information:

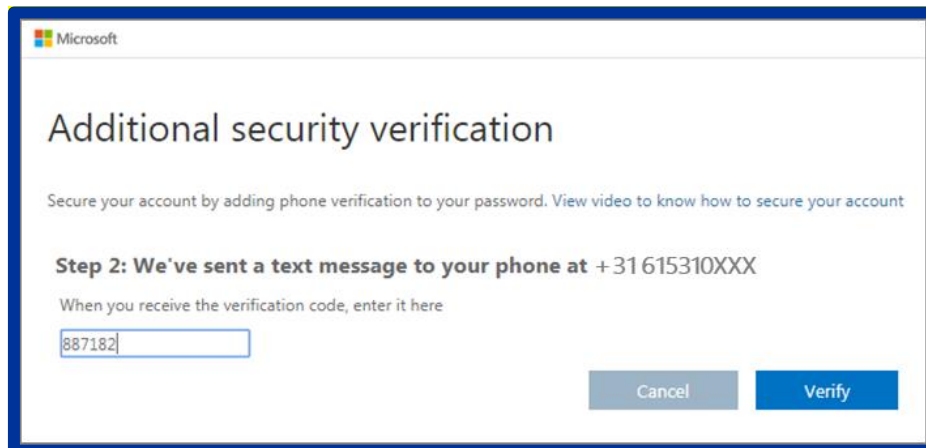
1. Select your country, add your phone number and click Next;



2. Check your phone for an SMS;



3. Enter the 6-digit code and click Verify;



You may need to refresh the page.

After logging in once, the next time you log in you will only need to go as far as step 4 shown above.

**Note:** Should you need to change your phone number or wish to switch authentication methods e.g. from phone to a mobile app you will need to raise a query via the [EMA Service Desk](#).

4. Check your phone for SMS.
5. Enter the 6-digit code and click **"Verify"**. You may need to refresh the page or re-enter into UPD. You will enter into UPD portal (Figure 8).

## **6.2. How to set up Additional Security Verification**

If you prefer to not use a mobile phone number to receive a text message you can select two additional options:

1. "Call me Method"
2. "Mobile App"

### 6.2.1. Call me method

1. Select your country, add your phone number and click "Next"

The screenshot shows the Microsoft 'Additional security verification' page. The title is 'Additional security verification'. Below the title is a subtitle: 'Secure your account by adding phone verification to your password. View video to know how to secure your account'. The main heading is 'Step 1: How should we contact you?'. There are three input fields: 'Authentication phone' (a dropdown menu), 'Country' (a dropdown menu showing 'Netherlands (+31)'), and 'Phone number' (a text box containing '615310XXX'). Below these is a 'Method' section with two radio buttons: 'Send me a code by text message' and 'Call me' (which is selected). A blue callout box points to the 'Call me' option with the text: 'TIP: If you want to insert an Office Phone instead of a mobile phone select "Call Me" Method. Do not select "Office Phone" as this is restricted only to EMA staff.' At the bottom, there is a disclaimer: 'Your phone numbers will only be used for account security. Standard telephone and SMS charges will apply.'

2. You will receive a call, please answer the call and press the hash key # (**Error! Reference source not found.**);

The screenshot shows the Microsoft 'Additional security verification' page, Step 2. The title is 'Additional security verification'. Below the title is a subtitle: 'Secure your account by adding phone verification to your password. View video to know how to secure your account'. The main heading is 'Step 2: We're calling your phone on +31 615310XXX'. Below the heading is a blue icon of a telephone handset and the text 'Answer it to continue...'.

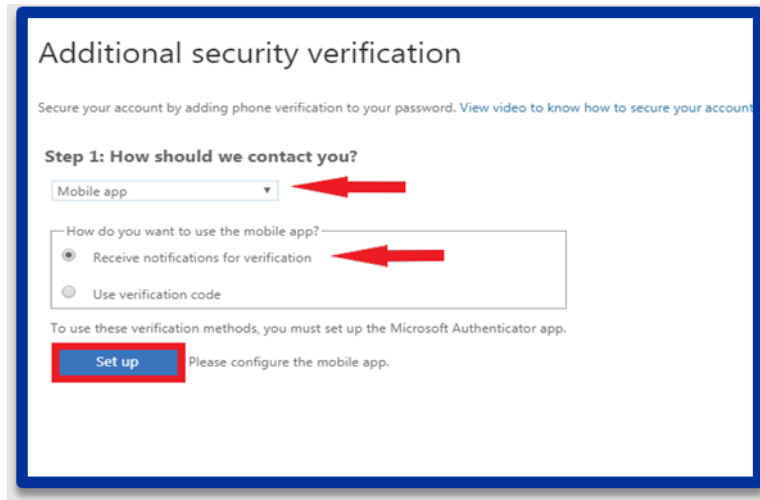
3. Click "Finished" and you will be redirected to the UPD portal.

You may need to refresh the page or re-enter the UPD portal. At your next login you will see the following screen (**Error! Reference source not found.12**).

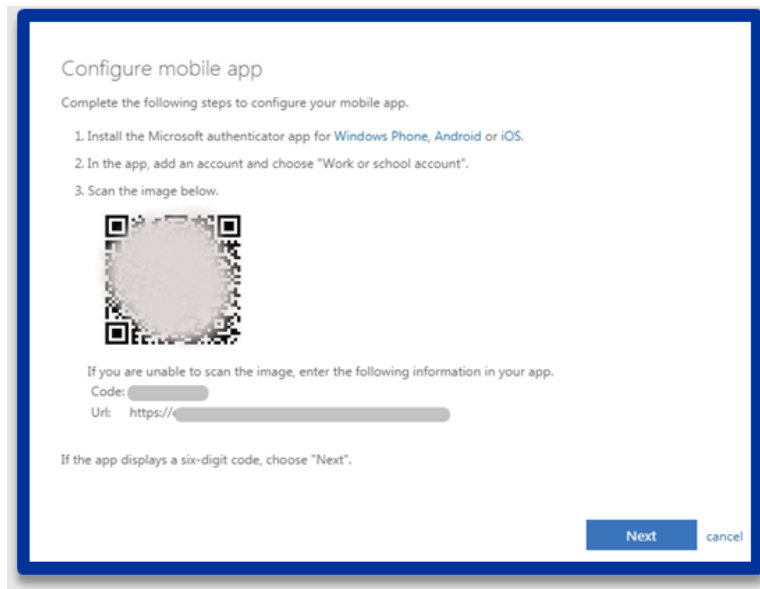
The screenshot shows the Microsoft 'Approve sign-in request' page. The title is 'Approve sign-in request'. Above the title is the Microsoft logo and the email address 'testvittori\_c@id.ema.europa.eu'. Below the title is a blue icon of a telephone handset and the text 'We're calling your phone. Please answer it to continue.'. Below this is the text 'Having trouble? Sign in another way' and a link 'More information'.

## 6.2.2. Mobile App

1. Please select "**Mobile app**" from the drop-down list then tick the first option: "**Receive notifications for verification**" and then select the "**Set up**";

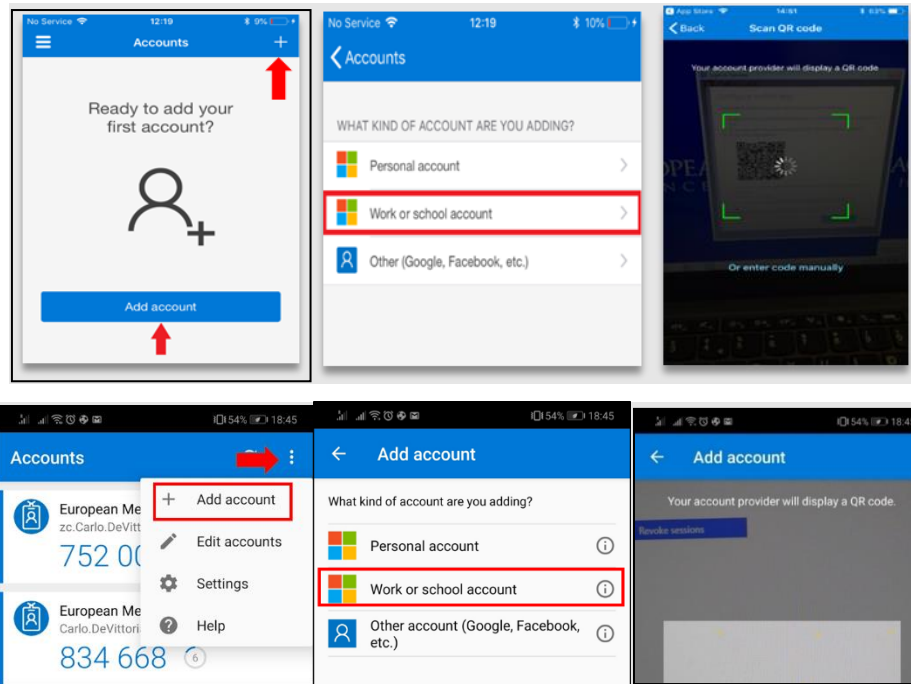


2. The following window will appear with instructions to download the mobile app on your phone;



3. *This step is done on your smartphone:* Download the **Microsoft Authenticator** app from your smartphone. Once installed, select "Add Account" and "Work or school Account" and scan the QR Code;





4. Follow the instructions and you will be prompted on this screen. This step doesn't require any action on your side, it's just a summary of the previous steps, please select "**Cancel**" to finalize the process.

### Additional security verification

When you sign in with your password, you are also required to respond from a registered device. This makes it harder for a hacker to sign in with just a stolen password. [View video to know how to secure your account](#)

what's your preferred option?  
We'll use this verification option by default.

Notify me through app

how would you like to respond?  
Set up one or more of these options. [Learn more](#)

Authentication phone

Office phone   Extension

Alternative authentication phone

Authenticator app

Authenticator app -