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Registration guide for UI and API users

Union product database for veterinary medicinal products



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1. Purpose and context

This guide serves to help web-UI (User Interface) and API (Application Programming Interface) 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)), pharmaceutical industry and general public.

2. UPD registration overview

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

For NCA, pharmaceutical industry and general public users

1. You must have an active EMA account

As a representative of NCA, pharmaceutical industry or general public users, 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 below section 3. EMA Account Management (EAM) and environment access).

For NCA and pharmaceutical industry users

2. The organisation 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.

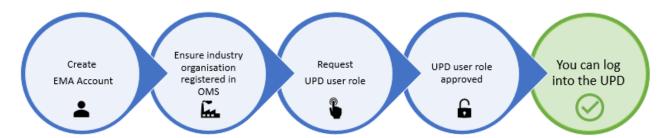
If marketing authorisation holder (MAH) that you represent does not appear in the OMS list, it will need to be included. Otherwise, you will not be able to affiliate yourself to this organisation when you submit a request for UPD access role in EAM (see below section 4. OMS: Pharmaceutical industry organisation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

<u>EMA Account Management (EAM)</u> is the online gateway for managing access to EMA applications. Through EAM, you can create an account and request the roles you need to use various EMA services.

Like other EMA systems, the EMA Account Management platform has two environments:

- <u>Test</u>: used to request access for EMA testing environments.
- Production: used to request access for live EMA systems.

Competent Authorities must **request access to each environment separately** because access rights in **UPD** are environment-specific. Other users (pharmaceutical industry and general public) can request access only to the production environment:

- To access the UPD UAT environment (UI Portal and API), you must request access through the <u>EAM test environment</u>.
- To access **the UPD production environment (UI Portal and API),** you must request access through the <u>EAM production environment</u>.

All the sections in this document apply to both environments. The EAM test and UPD UAT environments are full replicas of the production setup, designed to help users learn and practice using EMA platforms without impacting live access or regulatory data.

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 <u>Organisation Management Service (OMS)</u>. This is needed for you to be able to request a UPD access role via EAM.

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

- Look up your MAH organisation in <u>OMS</u> (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 above section *3. EMA Account Management (EAM) and environment access*).

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.

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 above section 3. EMA Account Management (EAM) and environment access). 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.

The overview of the UPD user roles and permissions is detailed in the table below:

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 General Public |
|--|----------------------|----------------------------|-----------------------|----------------------------|----------------------------------|-----------------------------|--------------------------|
| Manage users in EAM | ✓ | | | ✓ | | | |
| Create/submit data | ✓ | ✓ | | √ 1,3 | √ _{1,3} | | |
| Update data | ✓ | ✓ | | √ 1,2 | √ _{1,2} | | |
| Nullify data | ✓ | ✓ | | | | | |
| Search/View/ Export data | ✓ | ✓ | ✓ | √ 1 | √ i | √ 1 | |
| Record variations not requiring assessment | | | | √ 1 | √ i | | |
| Approve/Reject variations not requiring assessment | ✓ | ✓ | | | | | |
| Obtain report on dataset changes* | ✓ | ✓ | ✓ | √ 1 | √ i | ✓ | |
| Connect to UPD API | ✓ | | | ✓ | | | ✓ |
| Email Configuration | ✓ | | | ✓ | | | |

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 the 'Super User' 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.

¹ Own products only
2 For marketing authorisation status and availability status only
3 For workens of sales, date of placing on the market and provision of 3rd country names only
3 For volumes of sales, date of placing on the market and provision of 3rd country names only
4 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.

5.1.1. Competent authorities (CA)

The following roles and accesses are implemented in both the UAT and the Production environment (see above section 3. EMA Account Management (EAM) and environment access). The roles and accesses (including API credentials) are independent per environment. Rights are granted per environment and API credentials are generated per environment as well. The instructions to request and assign the roles apply equally to both environments. We recommend performing exploratory work in UAT, avoiding potential unwanted changes on the Production data.

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 <u>User Administrator Guide</u> 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.

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.

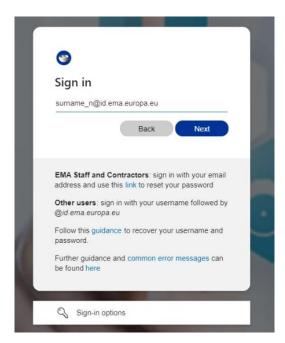
4. **UPD - API**

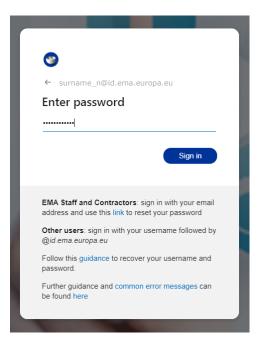
For Competent authorities there are three different APIs and each provides access to different type of data:

- 1) API for UPD Products/Procedures;
- 2) API for UPD VNRA (variations not requiring assessment);
- 3) API for VoS (volume of sales).

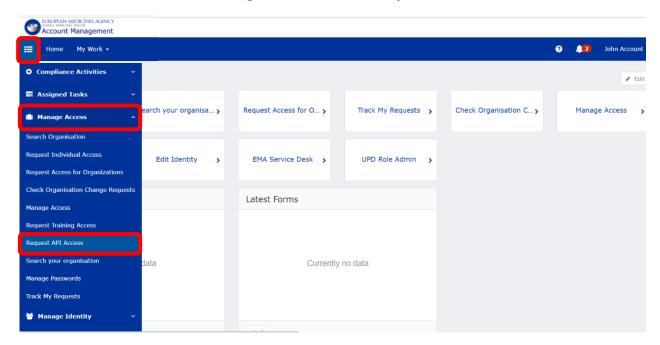
All three APIs require authentication and authorisation via a valid Bearer Token to use each endpoint. You should request the API role if you intend to use the UPD API services. **This role must be requested by the 'Super user' of your organisation and will be approved by EMA.**

> Go to <u>EAM test environment</u> **or** <u>EAM production environment</u> and log-in with your username and password or with your email address

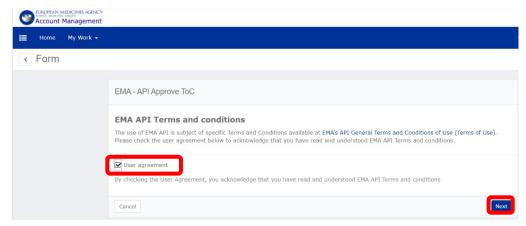




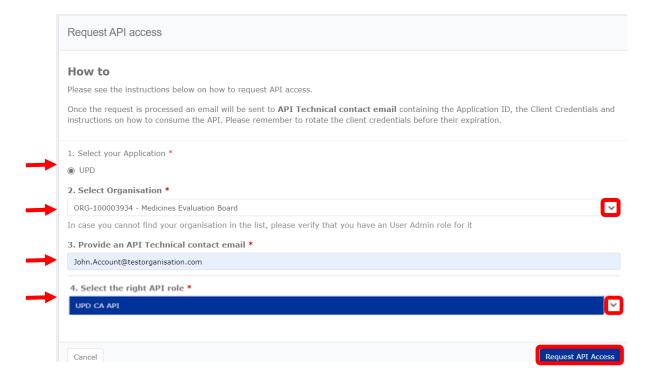
> In the menu bar, select Manage Access and then Request API Access



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



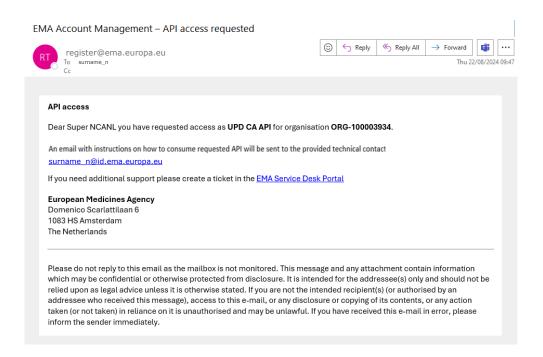
- Select Application: UPD
- > Select your Organisation using the drop-down menu
- > Provide API technical contact email address (this email address will be used to send notifications about the API account including the initial notification with Client ID and 'secret'). The API technical contact email address can be the same email address associated with your EMA account.
- > Select the right API role using the drop-down menu:
 - For competent authorities1: UPD CA API
- Click Request API Access



If you received a request summary, click OK to continue.

¹ If EMA systems need an API, a direct connection will be set up by EMA IM.

> You will receive an email with a notification of your request for API access when the request has been approved.



- > When the access is granted and processed you receive a second email UPD App Registration Request Processed containing the following information necessary to access UPD API:
 - Client ID
 - Client Secret
 - OAuth2 Token Endpoint
 - Scope

Users shall take into consideration the following aspects:

- The protocol supported is OAuth2 Client Credentials flow.
- Registered users upon accessing UPD API can connect their internal system and access product data based on the need.
- The API Client Credentials are generated only upon request by the Super Users. If non-Super Users from the same Organisation wish to access UPD API should either:
 - o use the same set of credentials, OR
 - o should set up the access into their internal system to meet their needs.
- Only one set of credentials is generated per Super User. The credentials will only be sent by email once after the request has taken place. Please store the credentials in a secure place. If the organisation needs more than one set of credentials, it will be necessary to onboard another 'Super User' that will have to follow the same steps and will receive a newly generated, independent, set of credentials.
- After any undesirable event regarding the credentials (lose, leak, non-delivery, etc.) please contact us via the <u>Agency's Service Desk portal</u>.

• The <u>UPD Access Policy</u> – Annex A provides clarification on the level of accessibility per stakeholder group and UPD data element.

See an example below on the content included in the email generated by the system upon completion of the registration in EAM:

SUBJECT: UPD API Registration Details

Dear Sir/Madam,

Please find below the details of your registration with the UPD API.

OAuth2 Properties

| Property | Value |
|-----------------|---|
| Token URL | POST https://login.microsoftonline.com/4efbf65c-4a81-4f2d-835a-e8630de67663/oauth2/v2.0/token |
| Client Id | e1e68a03-6b1f-47d1-a158 |
| Client Secret | pKZ8O |
| Scope | api://euema |
| Expiration date | 09/03/2027 08:01:55 |

 $\textbf{IMPORTANT}. \ Please \ take \ note \ of \ the \ expiration \ date \ and \ raise \ an \ \underline{\text{EMA Service Desk}} \ request \ to \ renew \ the \ credentials \ before \ expiration.$

Reference Information

| Property | Value | | |
|---|--------------------------------------|--|--|
| User | your.user.id@id.ema.europa.eu | | |
| Object Id | 8e379c2a-1385-409a-a22c-a467c79e643a | | |
| Display Name | spor-apim-s2s-client | | |
| Key Id | 39ece8a8-7c7a-41a0-b63c-3220410926ff | | |
| For any issues please open an EMA Service Desk request and quote the Reference Information. | | | |
| Kind regards, | | | |
| SPOR / UPD Team | | | |

5.1.2. Pharmaceutical industry

MAHs shall nominate the users that may acquire the following roles and accesses **only for the Production environment** (see above section *3. EMA Account Management (EAM) and environment access*), for both the UPD UI Portal and API service.

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 <u>User Administrator Guide</u> 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 <u>User Administrator Guide</u> 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.

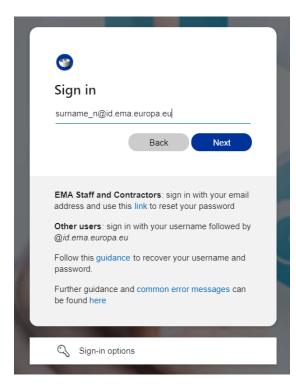
3. UPD - Industry Search/View

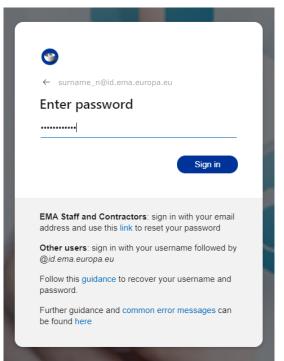
You should request this role if you intend to use UPD to only read and export data on veterinary medicinal products of the organisation you represent. This role will be approved by the 'Industry Super User' of the organisation you represent.

4. **UPD - API**

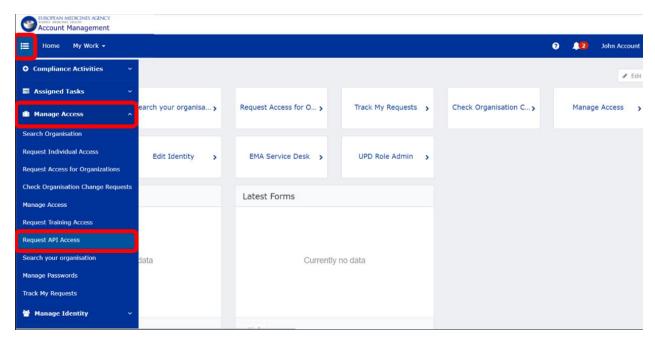
You should request the API role if you intend to use the UPD API services. This role must be requested by the 'Industry Super user' of your organisation and will be approved by EMA.

Go to <u>EAM production environment</u> and log-in with your username and password or with your email address

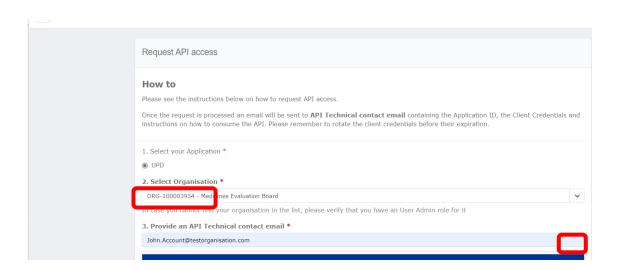




In the menu bar, select Manage Access and then Request API Access

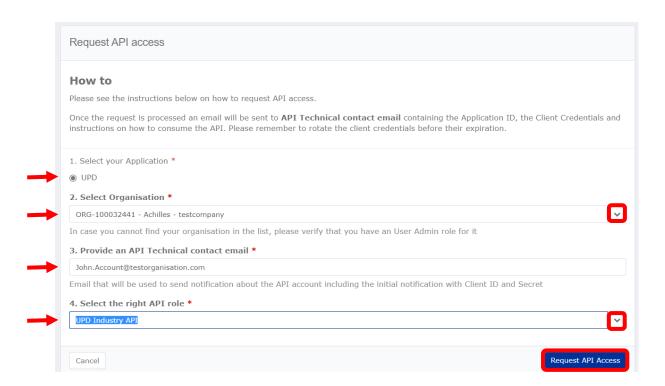


Read the EMA API Terms and conditions and Accept them by ticking the box of user agreement and click Next

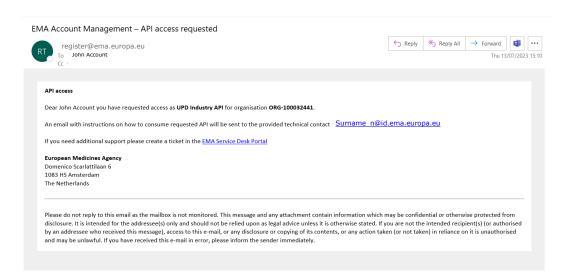


- Select Application: UPD
- > Select your Organisation using the drop-down menu
- Provide API technical contact email address (this email address will be used to send notifications about the API account including the initial notification with Client ID and 'secret'). The API technical contact email address can be the same email address associated with your EMA account.
- > Select the right API role using the drop-down menu
- For industry: UPD industry API

Click Request API Access



- > If you received a request summary, click OK to continue.
- > You will receive an email with a notification of your request for API access when the request has been approved.



- > When the access is granted and processed you receive a second email UPD App Registration Request Processed containing the following information necessary to access UPD API:
 - Client ID
 - Client Secret
 - OAuth2 Token Endpoint
 - Scope

Users shall take into consideration the following aspects:

- The protocol supported is OAuth2 Client Credentials flow.
- Registered users upon accessing UPD API can connect their internal system and access product data based on the need.
- The API Client Credentials are generated only upon request by the Super Users. If non-Super Users from the same Organisation wish to access UPD API should either:
 - o use the same set of credentials, OR
 - o should set up the access into their internal system to meet their needs.
- After any undesirable event regarding the credentials (lose, leak, non-delivery, etc.) please contact us via the <u>Agency's Service Desk portal</u>.
- The <u>UPD Access Policy</u> Annex A provides clarification on the level of accessibility per stakeholder group and UPD data element.

See an example below on the content included in the email generated by the system upon completion of the registration in EAM:

SUBJECT: UPD API Registration Details

Dear Sir/Madam

Please find below the details of your registration with the UPD API.

OAuth2 Properties

| Property | Value |
|-----------------|---|
| Token URL | POST https://login.microsoftonline.com/4efbf65c-4a81-4f2d-835a-e8630de67663/oauth2/v2.0/token |
| Client Id | e1e68a03-6b1f-47d1-a158 |
| Client Secret | pKZ8O |
| Scope | api://euema |
| Expiration date | 09/03/2027 08:01:55 |

IMPORTANT: Please take note of the expiration date and raise an EMA Service Desk request to renew the credentials before expiration.

Property Value User your_user.id@id_ema_europa.eu Object Id 8e379c2a-1385-409a-a22c-a467c79e643a Display Name spor-apim-s2s-client... Key Id 39ece8a8-7c7a-41a0-b63c-3220410926ff For any issues please open an EMA Service Desk request and quote the Reference Information. Kind regards, SPOR / UPD Team

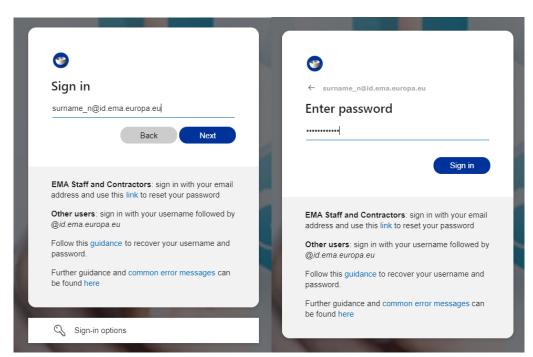
5.1.3. General Public

1. **UPD - API**

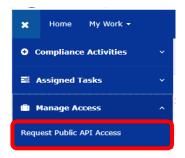
Firstly, you must register for an EMA user account in the EMA Account Management (EAM) portal, if you do not already have one (see above section 3. EMA Account Management (EAM) and environment access).

Secondly, you should request the API role if you intend to use the UPD API services.

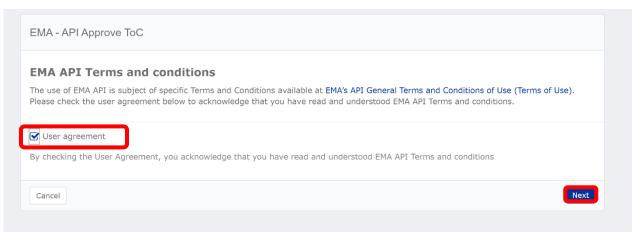
> Go to <u>EAM production environment</u> and log-in with your username and password or with your email address



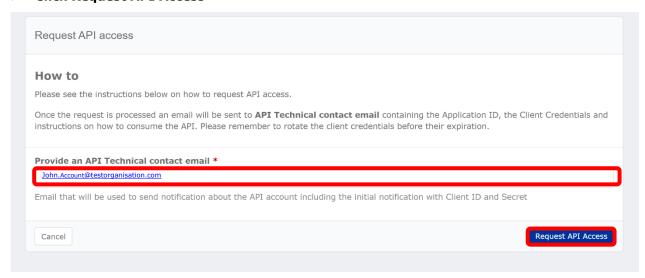
In the menu bar, select Manage Access and then Request Public API Access



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



- > Provide an 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'). The API technical contact email address can be the same email address associated with your EMA account.
- > Click Request API Access



- > If you received a request summary, click OK to continue.
- > You will receive an email with a notification of your request for API access when the request has been approved.

| API access | | |
|--|--|--|
| Dear Surname_n you have requested public api access. | | |
| An email with instructions on how to consume requested API will be sent to the provided technical contact <u>John.Account@testorganisation.com</u> | | |
| If you need additional support please create a ticket in the EMA Service Desk Portal | | |
| European Medicines Agency Domenico Searlattilian 6 1088 145 Amsterdam The Netherlands | | |
| Please do not reply to this email as the mailbox is not monitored. This message and any attachment contain information which may be confidential or otherwise protected from disclosure. It is intended for the addressee(s) only and should not be relied upon as legal advice unless it in otherwise stated. If you are not the intended recipient[a] (or authorised by an addressee who received this message), access to this e-mail, or any disclosure or copying of its contents, or any action taken (or not taken) in reliance on it is unauthorised and may be unlawful. If you have received this e-mail in error, please inform the sender immediately. | | |

- When the access is granted and processed you receive a second email UPD App Registration Request Processed containing the following information necessary to access UPD API:
 - Client ID
 - Client Secret
 - OAuth2 Token Endpoint
 - Scope

Users shall take into consideration the following aspects:

- The protocol supported is OAuth2 Client Credentials flow.
- Registered users upon accessing UPD API can connect their internal system and access product data based on the need.
- The <u>UPD Access Policy</u> Annex A provides clarification on the level of accessibility per stakeholder group and UPD data element.

See an example below on the content included in the email generated by the system upon completion of the registration in EAM:

SUBJECT: UPD API Registration Details

Dear Sir/Madam,

Please find below the details of your registration with the UPD API.

OAuth2 Properties

| Property | Value |
|-----------------|---|
| Token URL | POST https://login.microsoftonline.com/4efbf65c-4a81-4f2d-835a-e8630de67663/oauth2/v2_0/token |
| Client Id | e1e68a03-6b1f-47d1-a158 |
| Client Secret | pKZ8O |
| Scope | api://euema |
| Expiration date | 09/03/2027 08:01:55 |

IMPORTANT: Please take note of the expiration date and raise an EMA Service Desk request to renew the credentials before expiration.

Reference Information

| Property | Value | |
|---|--------------------------------------|--|
| User | your.user.id@id.ema.europa.eu | |
| Object Id | 8e379c2a-1385-409a-a22c-a467c79e643a | |
| Display Name | spor-apim-s2s-client | |
| Key ld | 39ece8a8-7c7a-41a0-b63c-3220410926ff | |
| For any issues please open an EMA Service Desk request and quote the Reference Information. | | |

5.2. Request UPD user role for Competent authorities and Pharmaceutical industry

As explained above in section 2. 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 above section 3. EMA Account Management (EAM) and environment access).
- 2. The organisation on whose behalf you will be carrying out UPD activities must be registered in OMS
- 3. The affiliation to a given Industry organisation 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 variations not requiring assessment or maintain availability information).

For example, you could be employed by a consultancy company A, but requesting access as 'UPD Industry Edit/Search/View user' to submit a variation on behalf of MAH B. In this case, you would need to request affiliation to MAH B.

A single UPD user can request affiliation to more than one organisation. For example, a user who works for a consultancy company 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 for Competent authorities and Pharmaceutical industry

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.

Kind regards, SPOR / UPD Team

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 (<u>upd-portal-prod.azurewebsites.net</u>);
- 3. Click "Sign In" and follow the steps on the screen;
- 4. If you encounter any issue with your access to UPD please refer to the guidance documentation in the <u>EAM production environment</u>.