19 May 2025
EMA/565742/2023

European Medicines Agency's Data Protection Notice

For the Organisation Management System (OMS) activities

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of the Organisation Management System (hereinafter "OMS"). OMS supports the management of a single source of validated organisation/location data (OMS Dictionary) that can be used as a reference to support EU regulatory activities and business processes.

More specifically, OMS stores and publishes master data comprising organisation name and location address for organisations such as marketing authorisation holders, sponsors, regulatory authorities and manufacturers and makes the organisation information publicly available.

1. Who is responsible for the processing of your data?

1.1. Who is the data controller?

EMA is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Information Management Division is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation. You may contact the Internal Controller via the following email address: datacontroller.infomanagement@ema.europa.eu

1.2. Who is the data processor?

1.2.1. EMA Data Stewards

The Agency engages third parties to process data on behalf of EMA, to provide and improve the service, enable use of service features and provide customer support. This group of support is dubbed EMA Data Stewards.

The contact details of the data processor(s) are the following:

Syneos Health Netherlands B.V.
De Entrée 99-197
1101 HE Amsterdam
Netherlands

In addition, data processing in OMS is designed to use different supporting software. When you submit changes request in OMS, these changes will be handled by either:

- EMA Data Stewards via OMS portal; or
- EMA Data Stewards via Service Desk/tickets in the ServiceNow portal. For further information about the ServiceNow portal, please consult dedicated Data Protection Notice on European Medicines Agency's privacy statement for ServiceNow (europa.eu)

1.2.2. Service Providers, Business Partners and Others

EMA works with third-party service providers to provide application development, hosting, maintenance, back-up, storage, virtual infrastructure, analysis and other services for us. These third parties may have access to or process your Information on need-to know basis as part of providing those services for us.

2. Purpose of this data processing

The purpose of this data processing activity is to allow stakeholders to support the implementation and management of OMS, a public single source of validated organisation and location data that is used as a reference to support EU regulatory activities and business processes.

The management of OMS Dictionary includes:

Purpose	Actions	Parties involved
To implement OMS and manage change requests through OMS portal	Collect organisation/location information Update organisation/location information	EMA Data Stewards*
To provide organisation reference information in support of EU regulatory activities and business processes	Make organisation/location information publicly available	EMA Data Stewards*
To provide customer support platform (through ServiceDesk tool)	Answer questions, respond to request for information Change requests to fields not included on the OMS portal change request form	EMA Data Stewards*
To implement platform improvements, troubleshoot and/or manage technical issues	Platform development and maintenance through OMS	IT support
To verity the proof of identity of sole traders, entrepreneurs/ individuals who are not publicly registered and who are actively participating in one of the following regulatory procedures: as a Marketing Authorization Holder (MAH) in EudraVigilance (EV), in any role within the EudraDMDP, or	Collect the individual's identity document	Designated EMA staff

Purpose	Actions	Parties involved
as a MAH in the Union Product Database (UPD)		

**EMA Data Steward is responsible for ensuring high-quality data of the organisation's data.*

2.1. Personal data concerned

In this processing operation OMS/EMA processes data directly collected from you when you submit an OMS Change Request through OMS portal. Such data may include the following:

Personal Data Category	Types of Personal Data
1.User Information	• Requester Name • Email Address • Phone Number (optional)

When you submit a Service Desk/tickets through ServiceNow portal. Such data may include the following:

Personal Data Category	Types of Personal Data
1.User Information	• Name • Email Address • Browser • Phone Number (Optional) • Mailing Address (Optional) • User Information if included in EMA's Azure Active Directory[1] • Unique User ID (UUID)
2.Host and Usage Information	• IP Address • User Agent Identifier • Hardware Type • Operating System Type and Version • Client Version • IP Addresses Along the Network Path • MAC Address of Your Client (As Applicable) • Service Version

[1] Azure Active Directory (Azure AD) is a cloud-based identity and access management service. Azure AD enables EMA employees to access external resources, such as Microsoft 365, the Azure portal, and other SaaS applications. Azure Active Directory also helps staff access internal resources like apps on EMA's corporate intranet, and any cloud apps developed for EMA.

Personal Data Category	Types of Personal Data
	• Actions Taken • Geographic Region • Performance, Troubleshooting, and Diagnostics Information
3.User-Generated Information	• Information provided by end user when creating a ticket (e.g., description, attachments)

2.1.1. Personal data concerned – natural person

If you are a sole trader, entrepreneur/individuals who are not publicly registered and who are actively participating in one of the following regulatory procedures—as a Marketing Authorization Holder (MAH) in EudraVigilance (EV), in any role within EudraDMDP, or as a MAH in the Union Product Database (UPD)—the following additional authentication steps are required:

Proof of Identity Submission

Your proof of identity must be securely sent via Eudralink to the following email address: oms@ema.europa.eu.

Description	Details
Accepted forms of ID	• The proof of identity must be an official document issued by the government of a Member State or a third country for identification purposes
Examples of Accepted Documents	• Passport • National Identity Card • Driver's License
Information that can be redacted	• You may redact (hide) information on the ID that is not necessary for confirming your identity
Redactable details	• Size • Eye colour • Photo
Required visible details	The following details must remain visible for the EMA to verify your identity: • Full name (matching the name on your online account) • Date of issue or expiry date of the document • Issuing authority

Description	Details
Additional requirements	• In cases where there is a risk of mistaken identity, additional information such as your birth date may be required. You will be informed if this is necessary
Birth date requirement	• The birth date may be requested when necessary to avoid mistaken identity
Who will authenticate your identity	• Your ID will be verified by a dedicated number of EMA internal staff to ensure confidentiality and proper handling
Data Retention and Deletion	• Once your identity has been successfully authenticated, the copy of your ID document will be securely deleted. This ensures that your personal data is not retained longer than necessary and minimizes the risk of unauthorized access

2.2. Legal basis of the processing

The processing of personal data in OMS is necessary for the performance of the Agency's tasks carried out in the public interest as set out in Article 5(1)(a) of Regulation (EU) 2018/1725 and as required by Regulation (EC) No 726/2004, Directives 2001/83/EC and 2001/82/EC and other applicable Union legislation.

In this regard, please note that you have the **right to object** against the processing as explained in Section 5 below.

2.3. Transfer of personal data outside of EU

Your information may be occasionally shared with service providers located in third countries. Such transfer complies with the provision of Chapter V of the European Union Data Protection Regulation (EUDPR) on transfers of personal data to a country outside the EEA i.e. Article 50(1)(d) of Regulation (EUDPR) 2018/1725.

When personal data is made available in the public domain of OMS and accessed from outside the EU/EEA, it is done in accordance with Article 50(1)(g) of Regulation (EU) 2018/1725. This regulation permits the transfer of data from a register intended by Union law to provide information to the public, which is open for consultation by the general public or by individuals demonstrating a legitimate interest. Such access is allowed only when the specific conditions for consultation outlined in Union law are met in each particular case.

This approach acknowledges that the publicly available information in OMS is essential for supporting the regulatory processes of the European Medicines Regulatory Network, as specified in pharmaceutical legislation. The information is necessary for the operation of key databases, including the database on medicinal products as established in Article 57(l) of Regulation (EU) 726/2004 and the Union product database for veterinary medicinal products as outlined in Article 55 of Regulation (EU) 2019/6, both of which must be accessible to the public.

3. How long do we keep your data?

The personal data processed in OMS portal and EMA's Service Desk is retained for a period of 10 years from the date of the service being requested. This is because there is an operational requirement to retain the data for this period as they are integral part of a regulatory/core business system.

4. Who has access to your information and to whom is it disclosed?

The following groups have access to your information:

- EMA staff involved in the processing;
- EMA Data Stewards contracted by EMA to provide the data management services;
- Very occasionally maintenance teams, auditors, operational security services employed by the EMA;
- Public (organisation name, organisation address, optional e-mail address and telephone number which you provide based on consent).

Within EMA, access rights are restricted on a need-to-know basis. For example, the Information Management Division has access to the data contained within tickets for IT requests and the facilities department has access to the data contained within tickets for requests relating to facilities.

There are administrators that have unrestricted access to the data held in EMA's Service Desk, this access is necessary for the assignment of access rights and the overall management of ServiceDesk.

In addition to this, for individual requests, specific staff can be assigned as a watcher and are therefore also able to track a request (in addition to the requestor). A watcher is assigned by the requester; therefore, the watcher is granted access to the data by the requester.

The vendor of EMA's ServiceDesk and their sub-processors for the general subscription service may have access to your data as is required to provide the service.

5. Your data protection rights

As data subject (i.e. the individual whose personal data is processed), you have a number of rights:

- **Right to be informed** – This Data Protection Notice provides information on how EMA collects and uses your personal data. Requests for other information regarding the processing may also be directed to the Internal Controller.
- **Right to access** – You have the right to access your personal data. You have the right to request and obtain a copy of the personal data processed by EMA.
- **Right to rectification** – You have the right to obtain - without undue delay - the rectification or completion of your personal if it is incorrect or incomplete.
- **Right to erasure** – You have the right to require EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing. In certain cases, your data may be kept to the extent it is necessary, for example, to comply with a legal obligation of the Agency or if it is necessary for reasons of public interest in the area of public health.
- **Right to restrict processing** – In a few, codified cases, you have the right to obtain the restriction of the processing, meaning that your data will only be stored, but not actively processed

for a limited period of time. For more information about this right and its limitations, see the EMA General Privacy Statement, hosted at www.ema.europa.eu/en/about-us/legal/privacy-statement.

- **Right to object** – You have the right to object at any time to this processing on grounds related to your particular situation. If you do so, EMA may only continue processing your personal data if it demonstrates overriding legitimate grounds to do so or if this is necessary for the establishment, exercise or defence of legal claims.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. For anything that is not specifically provided for in this Data Protection Notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

6. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or it is not in compliance with this Data Protection Notice or the general EMA Privacy Statement, please contact the **Internal Controller** at datacontroller.infomanagement@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@ema.europa.eu

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en

ANNEX I

Individual/Natural person registration - ID Handling Instructions and Information for OMS

Purpose: This document provides guidelines for the secure submission and handling of proof of identity (ID) required for verification purposes.

These instructions apply only to sole traders, entrepreneurs/individuals who are not publicly registered and who are actively participating in one of the following regulatory procedures: as a Marketing Authorization Holder (MAH) in EudraVigilance (EV), in any role within the EudraDMDP, or as a MAH in the Union Product Database (UPD).

Please ensure that you follow these instructions carefully to protect your personal data.

Request submission

Please submit a request for information form through ServiceDesk, selecting Service: SPOR and Service Offering: OMS. Attach the template available in the OMS portal, titled 'L - Natural Person Registration Headed Letter Template,' and ensure all required information is included.

Submission of Proof of Identity

Secure Submission
Your proof of identity must be securely sent via Eudralink to the following email address: oms@ema.europa.eu.

Accepted Forms of ID
The proof of identity must be a copy of an official document issued by the government of a Member State or a third country to its citizens for identification purposes. Acceptable documents include:

- Passport
- National Identity Card
- Driver's License

Redaction of Non-Essential Information

- **Redactable Information**
  You may redact (hide) any information on the ID that is not necessary for confirming your identity. This includes:
  - Size
  - Eye colour
  - Photo
- **Essential Information**
  However, the following details must remain visible for the EMA to verify your identity:
  - Full name (matching the name on your online account)
  - Date of issue or expiry date of the document

- Issuing authority

These elements are generally sufficient to verify your identity, as long as the authenticity of the document and its relation to you are assured.

Additional Information

- **Birth Date Requirement**
  In cases where there is a risk of mistaken identity, additional information such as your birth date may be required. You will be informed if this is necessary.

Post-Verification Handling of ID

- **Secure Deletion**
  Once your identity has been successfully authenticated, the copy of your ID document will be deleted securely. This ensures that your personal data is not retained longer than necessary and reduces the risk of unauthorized access. However, please note that your data will be available in the Eudralink package for 30 days. After this period, it will no longer be accessible.

Contact Information

If you have any questions or need further assistance regarding the submission of your proof of identity, please contact the EMA staff through ServiceDesk tool by raising a request for information with Service: SPOR and Service Offering: OMS.