30 April 2025
EMA/109932/2025

European Medicines Agency's Data Protection Notice

For the Extended EudraVigilance Medicinal Production Dictionary (XEVMPD) processing activities

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter referred to as "EMA" or "Agency") in the context of the eXtended EudraVigilance Medicinal Production Dictionary (hereinafter referred to as "XEVMPD") activities to support the management of a single source of validated product data that can be used as a reference to support EU regulatory activities and business processes.

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 and XEVMPD training support. This group of support is known as 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 XEVMPD is designed to use different supporting software. When you submit product information in the XEVMPD, these changes will be handled by EMA Data Stewards via:

- the XEVMPD user interface (EVWEB); and/or
- XEVMPD Bulk Update tool; and/or
- XEVMPD Data Export tool; and/or
- the Data Management Tracking Tool (DMTT); and/or
- the EMA Service Desk tickets submitted in the ServiceNow portal. For further information about the ServiceNow portal, please consult the dedicated Data Protection Notice.[1] .

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 personal data **on a 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 management of information for authorised medicinal products for human use in the XEVMPD, which is a source of information on medicinal products authorised for human use in the European Economic Area (EEA) that is used as a reference to support EU regulatory activities and business processes.

The management of XEVMPD includes:

Purpose	Actions	Parties involved
To review and assess product data submitted in the XEVMPD by marketing authorisation holders (MAH)	To review and standardise existing information on authorised medicinal products. To update existing medicinal product information so this information is in accordance with the information stated in the supporting documentation (Summary of Product Characteristics, Patient Information leaflet, copy of the document granting or amending the marketing authorisation) and in accordance with the business and technical rules in place.	EMA Data Stewards*
To provide customer support through ServiceNow tool	To answer questions related to the management of medicinal product data in the XEVMPD by external and internal stakeholders (industry, national competent authorities, EMA etc.).	EMA Data Stewards*

[1] https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-ema-help-desk_en.pdf

Purpose	Actions	Parties involved
	To respond to requests for information related to data available in the XEVMPD. To perform amendments to medicinal product data available in the XEVMPD on behalf of MAHs. To assist in resolving incidents related to technical issues with the XEVMPD, its user interface (EVWEB) or any other supporting tool (XEVMPD Bulk Update Tool, XEVMPD Data Export Tool).	
To register participants who wish to undergo the XEVMPD training knowledge evaluation through ServiceNow tool	To perform registration of participants for the XEVMPD e-learning training knowledge evaluation.	EMA Data Stewards*
To implement and/or support the implementation of platform improvements, troubleshoot and/or manage technical issues	To participate in user acceptance testing in development or test environments. To assist users experiencing technical issues by troubleshooting their account or liaising with the users directly outside of the ServiceNow platform (e.g. during a dedicated meeting set up with the user).	IT support

2.1. Personal data concerned

In this processing operation XEVMPD/EMA processes personal data directly collected from you when you submit medicinal product information in the XEVMPD through EVWEB. Such data may include the following:

Personal Data Category	Types of Personal Data
1.User Information	• The username of the registered user that submitted an Extended EudraVigilance Medicinal Product Report Message (XEVPRM) in the XEVMPD via EVWEB. • EudraVigilance ID of the organisation to which the user is affiliated.
2. Qualified Person for Pharmacovigilance (QQPV) Information	• QPPV Code • QPPV name, surname, and contact details (address/phone/email) associated with the QPPV Code.

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 and surname • Email Address • Browser • Phone Number (Optional) • Mailing Address (Optional) • User Information if included in EMA's Azure Active Directory[2] • Unique User ID (UUID)
QPPV/Trusted Deputy information	• QPPV Code • Name and surname • Organisation affiliation • Contact details (address/phone/email)
3.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 • Actions Taken • Geographic Region • Performance, Troubleshooting, and Diagnostics Information
4.User-Generated Information	• Information provided by end user when creating a ticket (e.g., description, attachments, QPPV information etc.)

2.2. Legal basis of the processing

The processing of personal data in XEVMPD is necessary for the performance of the Agency tasks carried out in the public interest as required by Regulation (EC) No 726/2004, Directives 2001/83/EC and 2001/82/EC and other applicable Union legislation. In particular, the processing of data is necessary for the performance of tasks carried out in the public interest as provided for under:

[2] 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.

COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.[3] 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 shared with service providers located in third countries. Any such transfer complies with the provisions of Chapter V of the European Union Data Protection Regulation (EU DPR) on transfers of personal data to a country outside the EEA. In the case of this processing, the Chapter V tool for transfers are the Commission approved Standard Contractual Clauses[4] together with the supplementary measures.

3. How long do we keep your data?

The personal data processed in XEVMPD and ServiceNow 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;
- registered users from national competent authorities.

ServiceNow and the sub-processors that they use 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 several 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.

[3] https://eur-lex.europa.eu/eli/reg_impl/2012/520/oj/eng
[4] https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en;

- **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.