5 March 2025
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Version 1

European Medicines Agency's Data Protection Notice

European Shortages Monitoring Platform (ESMP)

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency ("EMA" or "Agency") as part of ESMP[1], the Agency's platform for prevention, identification, and management of shortages to ensure medicines are available for patients in the EU and EEA.

1. Who is responsible for your data?

1.1 Who is the data controller?

The Agency is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Regulatory Science and Innovation Task Force (TRS) is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation.

The contact detail of the Data Controller is: Datacontroller.Horizonscanning@ema.europa.eu

1.2. Who are the data processors?

The Agency engages a third party to process data on behalf of the Agency and to provide the software tools enabling ESMP users to carry out their tasks for the purpose listed below.The contact details of the data processors are the following:

- Microsoft Ireland Operations Limited, South County Business Park, One Microsoft Place, Carmanhall and Leopardstown, Dublin, D18 P521, Ireland[2]
- Capgemini, Reykjavikplein 1, 3543 AK Utrecht, The Netherlands

[1] Accessible at https://www.esmp.ema.europa.eu/
[2] Microsoft Privacy Statement is available at: https://privacy.microsoft.com/en-gb/privacystatement

Official address **Domenico** Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
An agency of the European Union

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact
Telephone +31 (0)88 781 6000

2. Purpose of this data processing

The purpose of this data processing activity is to prevent, monitor and manage medicines shortages in the EU and European Economic Area (EEA).

The platform (ESMP) aims to gather information on shortages, supply and demand of critical medicines during crisis situations, and potential supply issues that can lead to such crises from pharmaceutical companies and Member States. It operates in normal circumstances and during crisis situations under the lead of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) with a view of helping to manage and prevent medicine shortages. EMA will collect data via the platform from National Competent Authorities (NCAs) and Marketing Authorisation Holders (MAHs) to ensure timely responses and efficient management of medicinal product shortages.

The ESMP is accessible to MAHs users to download, submit and manage data related to:

- Crisis/MSSG-led preparedness - Availability information: data on medicine availability
- Crisis/MSSG-led preparedness - Marketing status for nationally authorised products (NAPs): information on the marketing status of NAPs
- Crisis/MSSG-led preparedness - Manufacturing information: details on manufacturing capacities and plans for centrally and nationally authorised products
- Crisis/MSSG-led preparedness - Alternative therapies: submission of data on alternative therapies available

Preparedness - Routine shortage reporting: regular reporting of shortages to assist in preparedness activities

The ESMP is accessible to NCA users to download, submit and manage data related to:

- Crisis - Stock and supply: information on stock levels and supply forecasts.
- Crisis - Patient estimation: estimations of patient needs.
- Crisis - Medicine usage: data on the usage of medicines.
- MSSG-led preparedness – National demand: estimated 6-month needs when triggered by demand-supply issues or external events

ESMP collects data from various sources, including:

- Product information from the Product Management Service (PMS)
- Marketing status for Centrally Authorised Products (CAPs) from IRIS
- Organisation details from the Organisation Management Services (OMS)
- Direct submissions from MAHs and NCAs through ESMP interfaces

The ESMP is accessible to EMA users for the following purposes:

- Operational purposes: monitoring supply, demand, and availability of medicines, especially during crises and preparedness activities.

Data analytics purposes: analysing trends, identifying potential shortages, and supporting decision-making processes.

2.1. Personal data concerned

Personal data of ESMP users

For this processing operation the personal data of ESMP users is processed in the context of the reporting of information to EMA for medicines in routine shortage reporting, crisis situations, MSSG-led preparedness activities, and medicines included in the list of critical medicines, or any additional follow-up notifications, if applicable.

The categories of data subjects whose personal data will be processed are:

- Any person downloading, submitting and managing shortage-related data through ESMP;
- Any contact person belonging to MAHs or acting on behalf of MAHs and which interacts with ESMP, affiliated with an organisation or group of organisations with the ESMP Industry User role[3];
- Any contact of a person belonging to NCAs or acting on behalf of NCAs and which interacts with ESMP, affiliated with an organisation or group of organisations affiliated with the ESMP NCA User role[4].

The personal data of the individuals listed above may include the following:

- First and last name
- Email address
- Job title
- Organisation name
- Department/Division name
- Business phone and/or fax number

Business/professional address (street, City, ZIP/Postal Code, Country/Region, State)

Account data

The access is controlled through the Identity and Access Management (IAM)[5]. ESMP only stores necessary references to IAM accounts and does not duplicate personal account information.

[3] As defined in the ESMP User guide for MAHs, available at: european-shortages-monitoring-platform-esmp-user-guide-national-competent-authorities_en.pdf. See section "Accessing the ESMP".
[4] As defined in the ESMP User guide for NCAs, available at: european-shortages-monitoring-platform-esmp-user-guide-national-competent-authorities_en.pdf. See section "Accessing the ESMP".
[5] For information about personal data processing in IAM, please see the Identity and Access Management Data Protection Notice, available at: EMA Account Management_Privacy statement

2.2. Legal basis

The processing of personal data for the stated purposes are necessary for the performance of the Agency's tasks carried out in accordance with Article 5(1)(a) of Regulation (EU) 1725/2018 i.e., the processing is necessary for the performance of tasks carried out in the public interest or in the exercise of official authority vested in the Agency based on the tasks set out in:

- Regulation (EU) No. 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices provides for a framework to set up an interoperable information technology platform at Union level to monitor and report on shortages of medicinal products. In accordance with Article 13 of the Regulation, the Agency shall set up, maintain, and manage an IT platform to be known as the European shortages monitoring platform ('ESMP').

ESMP users have the **right to object** against the processing as explained in Section 5 below.

2.3. Transfer of personal data outside of EU

As part of the software tools enabling IRIS users to carry out their tasks as set out in section 2, the Agency's processor (see section 1.2) and their sub-processor(s)[6] may transfer certain data to third countries. As part of the transfer of such personal data, the Agency's processor is relying on the following transfer mechanisms:

- Adequacy decision of the European Commission[7] determining whether a country outside the EU offers an adequate level of data protection and
- Standard Contractual Clauses of the European Commission[8], for the countries where no adequacy decision is in place.

3. How long do we keep your data?

The Agency keeps the personal data:

- For ESMP users: as long as the person is active in the service related to ESMP
- For product contact points: as long as the medicinal product is still in the market

Analytical data may be retained in anonymised form for long periods for trend analysis and forecasting.

[6] A list can be provided upon request
[7] Data protection adequacy for non-EU countries
[8] Standard Contractual Clauses of the European Commission

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

The personal data collected is being processed internally by the Agency and is strictly controlled and limited to authorised individuals:

- Authorised EMA staff within relevant EMA division(s) responsible for prevention, identification, and management of shortages
- Staff members of national Competent Authorities in the EEA
- European Commission representatives

A subset of the data may be accessible in ESMP to EMA Scientific Committee members, staff members of national Competent Authorities for the evaluation and supervision of medicines in the EEA, and the European Commission.

Contact details of persons handling shortage data may be shared on a need-to-know basis with the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) which will coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products. National reporting requirements should still be met independently.

The access is controlled through the Identity and Access Management (IAM)[9] by authorised admin users.
The contact email, telephone number and/or fax, and address of sponsors are published on the EMA corporate website.

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.
- **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 data if it is incorrect or incomplete.
- **Right to restrict processing –** In a few, codified cases, you have the right to obtain the restriction of the processing of your personal data, 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 Data Protection and Privacy, hosted at https://www.ema.europa.eu/en/about-us/data-protection-privacy.

[9] EMA Account Management_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 Data Protection and 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 **Data Controller** at the address reported in section 1.1. above, 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