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Version 2.0

# 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 the ESMP[1], the Agency's platform for prevention, identification, and management of shortages to ensure medicines are available for patients in the European Union (EU) and European Economic Area (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://esmp.ema.europa.eu/
[2] Microsoft Privacy Statement is available at: https://privacy.microsoft.com/en-gb/privacystatement



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## 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 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
- Preparedness – Critical national shortage notification: reporting process for reporting of a critical shortage in a Member State for centralised shortage assessment and coordination
- Preparedness – Voluntary Solidarity Mechanism (VSM[3]) requests and responses

ESMP collects data from various sources, including:

- Direct submissions from MAHs and NCAs through ESMP interfaces
- Marketing status for centrally authorised products (CAPs) from IRIS
- Substance information from Substance Management Services (SMS)

[3] More information on the MSSG Voluntary Solidarity Mechanism (VSM): https://www.ema.europa.eu/en/documents/other/mssg-voluntary-solidarity-mechanism_en.pdf

- Product information from the Product Management Service (PMS)
- Organisation details from the Organisation Management Services (OMS)
- Referentials data from Referentials Management Services (RMS)

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, and preventing and mitigating medicine shortages.
- 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, VSM requests, critical shortage notifications, and medicines included in the lists 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 the ESMP;
- Any contact person belonging to MAHs or acting on behalf of MAHs, including the Industry Single Point of Contact (i-SPOC), and which interacts with the ESMP, affiliated with an organisation or group of organisations with the ESMP Industry User role[4];
- Any contact of a person belonging to NCAs or acting on behalf of NCAs and which interacts with the ESMP, affiliated with an organisation or group of organisations affiliated with the ESMP NCA User role[5].

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)

[4] As defined in the ESMP User guide for MAHs, available at: https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-user-guide-marketing-authorisation-holders_en.pdf . See section "Accessing the ESMP".
[5] As defined in the ESMP User guide for NCAs, available at: https://www.ema.europa.eu/en/documents/other/european-shortages-monitoring-platform-esmp-user-guide-national-competent-authorities_en.pdf . See section "Accessing the ESMP".

**Account data**

The access is controlled through the EMA Identity and Access Management (IAM)[6]. ESMP only stores necessary references to IAM accounts and does not duplicate personal account information.

### *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)[7] 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[8] determining whether a country outside the EU offers an adequate level of data protection and
- Standard Contractual Clauses of the European Commission[9], 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 the ESMP
- For product contact points: as long as the medicinal product is still in the market

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

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

# 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, and through a shared platform for operational and analytical purposes to staff members of national competent authorities with relevant access security roles for the evaluation and supervision of medicine shortages 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)[10] 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

[10] EMA Account Management Privacy statement

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.

- **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:

**Internal Controller** at datacontroller.horizonscanning@ema.europa.eu

**EMA Data Protection Officer** at dataprotection@ema.europa.eu.

| Address | Postal Address | EMA Switch Board |
|---|---|---|
| European Medicines Agency<br>Domenico Scarlattilaan 6<br>1083 HS Amsterdam<br>The Netherlands | European Medicines Agency<br>PO Box 71010<br>1008 BA Amsterdam<br>The Netherlands | +31 (0)88 781 6000 |

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