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# European Medicines Agency's Data Protection Notice

## For the Industry Single Point of Contact (i-SPOC) system for the supply and availability of medicines

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 Industry Single Point of Contact (i-SPOC) system for the supply and availability of medicines for crisis preparedness and management. All marketing authorisation holders (MAHs) in the Union for centrally and nationally authorised medicinal products for human use are required to register an i-SPOC on supply and availability of medicines so that EMA can quickly engage with them if their medicines are included in the lists of critical medicines, and for preparedness activities.

The Agency's IRIS platform[1] will be used to collect details of i-SPOCs for all MAHs and to facilitate future communication with those MAHs of identified critical medicines during public health emergencies or major events and in preparedness for such circumstances. The i-SPOCs should oversee the product supply chain, manufacturing capacity management, and medicine shortages.

## 1. Who is responsible for your data?

### *1.1. Who is the data controller?*

The European Medicines Agency ("EMA") 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 details of the Data Controller are the following:
datacontroller.horizonscanning@ema.europa.eu

### *1.2. Who is the data processor?*

The Agency engages a third party to process data on behalf of the Agency and to provide the software tools enabling IRIS users to carry out their tasks for the purpose listed below.

The contact details of the data processor are the following:

[1] Accessible at: https://iris.ema.europa.eu/ and for more information, please see: https://www.ema.europa.eu/en/documents/other/european-medicine-agencys-data-protection-notice-interactive-regulatory-information-system-iris_en.pdf

Microsoft Ireland Operations Limited[2]

Address: South County Business Park, One Microsoft Place, Carmanhall and Leopardstown, Dublin, D18 P521, Ireland

# 2. Purpose of this data processing

The purpose of this data processing activity is the monitoring of the supply and demand of medicines considered to be critical to address a particular crisis such as a public health emergency (PHE) or a major event (ME) and preparedness for such circumstances in the context of performing of the Agency tasks defined under Regulation (EU) 2022/123[3], including:

- Gathering information on potential and actual shortages, including available stocks and forecasts of supply and demand, while assessing the merits of each indication of information as being of a commercially confidential nature and protecting such information against unjustified disclosure.
- Channelling aggregated information on supply and demand to 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.

Further, communicating reporting requirements in the context of the European Shortages Monitoring Platform (ESMP[4]) for crisis preparedness and management, and any related follow-up notifications and communications.

## *2.1. Personal data concerned*

In this processing operation we process personal data of pharmaceutical industry staff in the context of the reporting of information under Regulation (EU) 2022/123 to EMA for medicines included in the lists of critical medicines and for preparedness activities, or any additional follow-up notifications, if applicable. Such data may include the following:

- The list of i-SPOC persons identified by the marketing authorisation holders subject to the scope of the i-SPOC system subject to reporting obligations for medicinal products (for human use) with a marketing authorisation valid in any EU/EEA country included in a list of critical medicines for a public health emergency (PHE) or major event (ME) and preparedness of such according to Article 6 of Regulation (EU) 2022/123, published on EMA's website.

EMA processes the following data on the i-SPOCs identified: names, email addresses, telephone numbers, job titles, and business addresses.

## *2.2. Legal basis of the processing*

The processing activities of personal data stated above are necessary for the performance of the Agency's tasks carried out in accordance with Article 5(1)(a) of Regulation (EU) 2018/1725[5] ('EUDPR'),

[2] Microsoft Privacy Statement is available at: https://www.microsoft.com/en-gb/privacy/privacystatement
[3] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, available here: https://eur-lex.europa.eu/eli/reg/2022/123/oj/eng
[4] Accessible at: https://esmp.ema.europa.eu/ and for more information, please see: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-european-shortages-monitoring-platform-esmp_en.pdf
[5] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC

i.e. the processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Agency based on the tasks set out in Union law as follows:

- Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. This Regulation provides EMA with a framework to monitor and mitigate potential and actual shortages of centrally and nationally authorised medicinal products for human use considered critical to address a given 'public health emergency' or 'major event'. In addition, Article 9 requires the Agency to establish and maintain a list of Industry Single Points of Contact (i-SPOCs) of MAHs for all medicinal products authorised in the Union. In the event that an authorised product is included in a list of critical medicines identified for a specific public health emergency or major event, this list of contacts is used to enable rapid, two-way communication between EMA and the MAHs of those identified critical medicines to detect, report, and prevent or manage supply and availability issues. Further, this list of contacts is used for crises preparedness activities as needed to enable rapid, two-way communication between EMA and the MAHs.

Please note that you have the **right to object** against the processing as explained in Section 5 below.

## 3. How long do we keep your data?

EMA keeps the personal data for as long as the individual is the i-SPOC for the MAH, and until a replacement has been registered via IRIS[6]. This is necessary to ensure an agile action by the EU Regulatory Network in the context of a major event or a public health emergency.

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

The data collected is being processed internally by the Agency and is accessible to authorised EMA staff within the EMA division(s) responsible for the management of the i-SPOC system.

A subset of the data is accessible in the IRIS Network Portal to some 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 management of medicine shortages in the EEA, and the European Commission.

In the context of preparedness activities i-SPOC contact information may be made available to the Regulatory Network, i.e. members of the Medicine Shortages Single Point of Contact (SPOC) Working Party.

## 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 Privacy Statement 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.

[6] Accessible at: https://iris.ema.europa.eu/ and for more information, please see: https://www.ema.europa.eu/en/documents/other/european-medicine-agencys-data-protection-notice-interactive-regulatory-information-system-iris_en.pdf

- **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 privacy 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:

**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