March 31st 2026
EMA/78505/2026

European Medicines Agency's Data Protection Notice

For the exchange of information during the Critical Medicines Vulnerability Assessment exercise

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 exchange of information between Marketing Authorisation Holders (MAHs) and EMA during the Critical Medicines Vulnerability Assessment exercise.

The Critical Medicines Vulnerability Assessment Exercise has the goal of supporting the implementation of the New EU Pharmaceutical Legislation (Chapter X of the revised Regulation)[1] and the proposed Critical Medicines Act[2] by identifying structural and conditional vulnerabilities in the supply chains of selected medicines, which may benefit from targeted policy actions to improve resilience and ensure secure and continued supply.

1. Who is responsible for processing 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 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.Horizonscanning@ema.europa.eu

[1] https://data.consilium.europa.eu/doc/document/ST-6366-2026-INIT/en/pdf
[2] https://health.ec.europa.eu/medicinal-products/critical-medicines-act_en

1.2. Who is the data processor?

The EMA may engage third parties to process data on their behalf and, in particular, to allow for communication and exchange of information between the Agency and the MAHs. The contact details of the data processor are the following:

Microsoft Ireland Operations Limited[3]
One Microsoft Place, South County Business Park,
Leopardstown, Dublin 18 D18 P521, Ireland
Telephone: +353 (1) 706-3117

2. Purpose of this data processing

The purpose of this data processing activity is the exchange of information needed to conduct the Critical Medicines Vulnerability Assessment Exercise. This information relates to structural and conditional supply chain vulnerabilities for medicinal products containing International Non-proprietary Names (INNs), which have been selected for the exercise.

2.1. Personal data concerned

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

- An individual acting as a contact person for MAHs or acting on behalf of MAHs, which hold a marketing authorisation for one or more of the products selected for the Supply Chain Vulnerability Assessment Exercise.

For the purposes of initiating the exercise, EMA will contact the MAHs either via the industry single point of contact (i-SPOC)[4] or via an alternative contact identified if the MAH has not registered an i-SPOC contact point.

The personal data processed during the exercise may include the following:

- Name and last name
- Job position and organisation
- Professional email address
- Any other personal data (e.g., professional phone number) that may be processed when the Vulnerability Assessment Template is submitted, and/or if further communications are sent to EMA's Vulnerability Assessment mailbox.

[3] For more information on how EMA processes your personal data when using Microsoft 365, please see: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-use-microsoft-applications-onedrive-outlook-365-teams-sharepoint_en.pdf
[4] For more information on how EMA processed your personal data in for the Industry Single Point of Contact (i-SPOC) system, please see: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-industry-single-point-contact-i-spoc-system_en.pdf

2.2. Legal basis of the processing

The processing of personal data in the Critical Medicines Vulnerability Assessment Exercise is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body, as provided for in Article 5(1)(a) of Regulation (EU) 2018/1725 (the EUDPR).

In this regard, Regulation (EU) 2022/123[5] provides a framework for monitoring, preventing, and reporting on shortages of medicinal products and on shortages of medical devices in preparedness and crisis situations.

The work of the Critical Medicines Vulnerability Assessment Exercise focuses on the sharing of information about supply chain vulnerabilities of selected critical medicines, with the aim of informing policy action to prevent future shortages of these medicines. The agreed texts on the New EU Pharmaceutical Legislation, which is foreseen to be adopted later in 2026, stipulates that the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) has an obligation to evaluate the supply chain vulnerability of the medicinal products included in the Union list of critical medicines, as stated in Article 132(1a) of the agreed Regulation text. Furthermore, Marketing Authorisation Holders (MAHs) will be obliged to provide information to EMA and national competent authorities to inform these activities, in accordance with Chapter X of the new Regulation.

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*

The personal data processed in Microsoft is stored within the EU/EEA.

From time to time, Microsoft, acting as a processor of the Agency and together with its subcontractors, may need to transfer personal data to countries outside the EU. This can happen, for example, when they need to prevent or solve security issues. Any such transfers are only made with proper safeguards in place, as required by EU data protection law. This means that Microsoft will only transfer your personal data if the Agency instructs them to do so, or if they must comply with a specific legal obligation, and always in line with the rules set out in Regulation (EU) 2016/679 and the EUDPR.

Microsoft Corporation is certified under the EU-U.S. Data Privacy Framework, so any transfers of your personal data to the U.S. follow the requirements of this framework. If, for any reason, it is not possible to use the Data Privacy Framework, these transfers will then be governed by the 2021 Standard Contractual Clauses agreed between Microsoft Ireland Operations Limited and Microsoft Corporation.

Even when relying on these Clauses, Microsoft limits the number of transfers to countries that have not received an adequacy decision from the European Commission. These limited transfers are made based

[5] 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

on Article 50(1)(d) of Regulation 2018/1725 i.e. the transfer is necessary for reasons of public interest.

3. How long do we keep your data?

This vulnerability assessment exercise is expected to be finalised by the end of 2026. For those registered as an i-SPOC contact point, their contact details will be kept in line with the i-SPOC system retention period, i.e., as long as the individual is the i-SPOC for the MAH, and until a replacement has been named. 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.

For those that are not registered as such, EMA will retain their contact details until they have registered as an i-SPOC for the MAH in IRIS. Registration of an i-SPOC is a two-step process which might take up to 5-10 working days. Once complete, their data will be kept in line with the i-SPOC retention period as explained above.

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

The personal data will be processed by the data processors listed in Section 1.2 and internally by the relevant staff at the Agency within the EMA Task Force responsible for the specific procedure.

The personal email addresses may be shared with the national competent authorities of EU member states, as well as the European Commission, on a need-to-know basis, for the purpose of the exercise.

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:

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 Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands	European Medicines Agency PO Box 71010 1008 BA Amsterdam 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