EMA/712947/2022

European Medicines Agency's Data Protection Notice

Interactive Regulatory Information System (IRIS)

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") as part of IRIS, the Agency's regulatory and scientific information-management platform for handling medicinal product-related regulatory procedures.

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 the Digital Business Transformation Task Force (TDT) is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation.

The contact details of the Data Controller are the following: datacontrollertdt@ema.europa.eu

1.2. Who is the data processor?

The Agency engages a third party to process data on behalf of the Agency 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:

Microsoft Ireland Operations Limited

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 management of marketing authorisation applications received in the context of the performance of the Agency's tasks, including:

- Management and completion of all procedures summarised below including interactions with marketing authorisation applicants (MAAs)/ marketing authorisation holders (MAHs) and the scientific committee members and experts involved in the assessment;
- Communications with the European Commission pertaining to the activities above;

- Publication of information of relevance to stakeholders including patient organisations, healthcare professionals and academic structures pertaining to the activities above.

More specifically, IRIS currently supports the following procedures:

Procedure	Description
Orphan designation	Applications for orphan designation for a medicine and management of related pre- and post- orphan designation activities (e.g., maintenance, transfers, amendments, withdrawals, annual reports).
Parallel distribution	Submission of notifications of parallel distributions and management of related activities (e.g., annual reports, safety updates).
Scientific advice – human and veterinary	Requesting scientific advice (including protocol assistance) on the best methods and study designs to generate robust data on how well a medicine works and how safe it is.
Innovation Task Force's consultation	Applications for a briefing meeting with EMA's Innovation Task Force.
Inspections	Increasing efficiency on reporting inspections data and creating a better overview of scientific/regulatory data by managing your inspections for Good Manufacturing Practices (GMP) via IRIS.
Marketing status	Report changes in the marketing status of a single product, or multiple products at the same time, for each presentation and EU Member State. You can also submit declarations of permanent cessation of marketing, and the decision not to apply for renewal or request to withdraw a central marketing authorisation.
Veterinary Signal Management	Submitting annual statements and signal management reports on veterinary signal management and management-related activities.
Medicines shortages	Registration of MAH Industry – Single Point of Contact (i-SPOC) on supply and availability issues according to Regulation (EU) 2022/123.[1] For further information, please also refer to the data protection notice for the Industry Single Point of Contact (i-SPOC) system.
General	Request for a Research Product Identifier or change of name and address of an applicant on regulatory entitlements.

[1] EMA Privacy Statement and the record for the central register for MAHs' reporting obligations according to Regulation (EU) 2022/123 Art. 9(3) are published on the EMA website in the following links.

- https://www.ema.europa.eu/en/documents/other/records-data-processing-activity-public-industry-single-point-contact-i-spoc-reporting-system_en.pdf
- https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-industry-single-point-contact-i-spoc-system_en.pdf

2.1. Personal Data concerned

When you submit applications as part of the regulatory procedures for the purpose described above, personal data of the following individuals may be included:

- Any person creating, editing, submitting or withdrawing an application;
- Any contact person associated in the application, or of an additional Industry Manager or Industry Contributor to the submission as defined in the IRIS guide to registration and Research Product Identifier (RPIs);
- The contact person at the sponsor's premises, for delivery of the European Commission decision, if applicable[2];
- The single point of contact person for a MAA/MAH.

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

- Full name
- Email address
- Job title
- Business phone and/or fax number
- Address (street, City, ZIP/Postal Code, Country/Region)
- Department
- Alternative email address
- Alternative contact number
- Address (State/Province)

2.2. Legal Basis

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) 1725/2018 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 (EC) No. 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
- Regulation (EC) No. 141/2000 on orphan medicinal products;
- Regulation (EC) No. 1901/2006 on medicinal products for paediatric use;
- Regulation (EC) No. 1394/2007 on advanced therapy medicinal products;
- Directive 2001/83/EC on the Community code relating to medicinal products for human use;
- Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices;
- and other applicable European Union legislation.

Please note that you have the **right to object** against the processing as explained in Section 4 below.

[2] Please note that validation of proof of establishment may be needed when natural persons apply for orphan designation or a transfer of an orphan designation, which is performed outside of IRIS. Please see the related data protection notice.

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)[3] may transfer certain user data[4] 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[5] determining whether a country outside the EU offers an adequate level of data protection or
- Standard Contractual Clauses of the European Commission[6], for the countries where no adequacy decision is in place.

3. How long do we keep your data?

Each application that is submitted (whether the application is validated or withdrawn) will be kept while the medicinal product is on the market and for 30 years following its withdrawal. Data included in draft submissions that are deleted or never submitted by the applicant will be kept for a maximum of 7 months.

IRIS will scan all the submissions to identify those that have been inactive (no change in data) for more than 7 months and send an email to the submission contact (a.k.a. portal contact) to inform of the upcoming deletion of the submission unless a change is made to the submission in the following 2 weeks. If no change is made to the submission during that time, it will be deleted and definitively removed from IRIS, including any documents uploaded to IRIS. A final email will be sent to the submission contact, to notify the permanent removal of the submission from the system.

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 by authorised EMA staff within the EMA Division responsible for the evaluation of medicines or of the specific procedure and the EMA Scientific Committee Secretariats (Human/Veterinary divisions as applicable).

A subset of the data is accessible in the IRIS Network Portal 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.

The access is controlled through the Identity and Access Management (IAM) by authorised admin users. Each Competent Authority has an admin user who ensures the correct assignment of Coordinator, Manager and Contributor roles. Admin users ensure that the role of the users who have left their Competent Authority is removed from IAM. Users' accounts are automatically deactivated after 6 months of inactivity.

The contact email, telephone number and/or fax, and address of sponsors (e.g., for orphan designations) are published on the EMA corporate website.

[3] A list can be provided upon request
[4] Please refer to the European Medicines Agency's Data Protection Notice for Microsoft 365 (M365) Services
[5] Adequacy decisions | European Commission (europa.eu)
[6] Standard Contractual Clauses (SCC) | European Commission (europa.eu)

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.
- **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