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Version 3

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 ("EMA" or "Agency") as part of IRIS,[1] the Agency's regulatory and scientific information-management platform for handling medicinal product-related scientific and 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 are the data processors?

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, South County Business Park, One Microsoft Place, Carmanhall and Leopardstown, Dublin, D18 P521, Ireland[2]
- Experlogix, Newtonstraat 2, 3902 HP Veenendaal, The Netherlands[3]
- Capegemini, Reykjavikplein 1, 3543 AK Utrecht, The Netherlands

2. Purpose of this data processing

The purpose of this data processing activity is the management of marketing authorisation applications (MAAs) and other related medicines regulatory procedures. Applications for marketing authorisations for

[1] Accessible at: https://iris.ema.europa.eu/
[2] Microsofts general Privacy Policy is available at: https://privacy.microsoft.com/en-gb/privacystatement
[3] Experlogix's general Privacy Policy is available at: https://www.experlogix.com/privacy-policy/

medicines are created by applicants/marketing authorisation holders (MAH) and submitted to the Agency. MAAs are received in the context of the performance of the Agency's tasks, including:

- Management and completion of all regulatory procedures summarised below including interactions with applicants for marketing authorisations (hereafter referred to as "applicants")/MAHs and the scientific committee members and experts involved in the assessment of the quality, safety and efficacy of medicines;
- Communication with the European Commission pertaining to the activities above;
- Communication by email with users pertaining to changes to the interfaces, services and infrastructure of the IRIS and PLM[4] portals (e.g. major updates, incidents, availability disruption);
- Publication of information of relevance to stakeholders including patient organisations, healthcare professionals and academic structures pertaining to the activities above.
- Communication with the European Medicines Regulatory Network (EMRN) within the context of the Early Notification System (ENS).

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 (SA) – 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 (ITF) 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 inspections for Good Manufacturing Practices (GMP), Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP) 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. This includes the submission of declarations of permanent cessation of marketing, the decision not to apply for renewal or a request to withdraw a central marketing authorisation.
Veterinary Signal Management	Submitting annual statements and signal management reports on veterinary signal management and other management-related activities.

[4] PLM portal stands for "Procedures Life-Cycle Management" portal.

Procedure	Description
Medicines shortages	Registration of MAH's Industry – Single Point of Contact (i-SPOC) on supply and availability issues according to Regulation (EU) 2022/123. For further information, please also refer to the data protection notice for the Industry Single Point of Contact (i-SPOC) system.
PRIME	Or Priority Medicines, is an initiative aimed at enhancing support for the development of medicines that target unmet medical needs. The program provides early and proactive support to developers of promising medicines, helping them to optimise their development plans and accelerate the evaluation process.
Paediatrics	It refers to the development and regulation of medicines specifically for children. The EMA has a dedicated framework to ensure that medicines for children are safe, effective, and appropriately researched.
Post-authorisation processes	They are essential procedures that take place after a medicinal product has been authorised for use. These processes ensure that the product remains safe, effective, and of high quality throughout its lifecycle. Here are some key post-authorization processes: Variations, PSUSA. PASS, PAM, Transfers, Annual Reassessments, Referrals, Line extensions and Art 61.3 (changing the labelling and package leaflet).
General	Request for a Research Product Identifier or change of name and address of an applicant on regulatory entitlements.

To support above procedures, IRIS comprises the following sites and components:

IRIS | Regulatory & Scientific Information Management Platform			
3 sites	**Components**	**Access**	**Benefits**
CRM[5]	Evaluation/ Validation Platform ("CRM Interface")	Accessed by EMA staff	• Customer Data Management • Case Management • Manage Interactions
IRIS Portal	Data Submission Platform ("Industry Portal")	Accessed by pharmaceutical industry[6]users in the context of their MAAs	• Used by applicants and MAH to provide data and documents • Online web form replaces PDFs • Pre-populated administrative data
	Collaboration tool ("Network Portal")	Accessed by EU Medicines Regulatory Network (EMRN)[7] and EMA staff	• Search, access, and display data on ongoing and past procedures (cases)

[5] CRM stands for "Customer Relationship Management"
[6] For more information on the pharmaceutical industry, please see: Pharmaceutical industry | European Medicines Agency (europa.eu)
[7] For more information on the EMRN please see: European medicines regulatory network | European Medicines Agency (europa.eu)

IRIS | Regulatory & Scientific Information Management Platform			
			• Includes cases created for the processes included in the previous table
PLM Portal	electronic Application Forms (eAF)	Accessed by industry users, EMRN and EMA staff	• Used by applicants and MAH to create new application forms
	electronic Product Information (ePI)	Accessed by industry users, EMRN and EMA staff	• Used by applicants and MAH to create new electronic Product Information documents. • Used by EMRN and EMA staff for approving and publishing of the ePIs
	Product User Interface	Accessed by industry users and EMRN.	• Access to and enrichment and correction of product data
	PLM Forum	Accessed by industry users, EMRN and EMA staff	• Used by applicants and MAH to stay up to date on the latest PLM news (e.g. new features, release information)
Document repository	Cloud-based file storage	Accessed by EMRN and EMA staff	• Single secure platform for document sharing and viewing, editing • Simultaneous editing of documents
ENS Portal (Early Notification System)	Online portal	Accessed by EMRN and EMA staff	• Critical during crises to fulfil a legislative requirement for EMA to coordinate the sharing of key (safety) information around medicines. • Used by EMRN and EMA staff to retrieve communication materials and to set up notifications based on topic of interest. • Used by EMA staff to post communication materials

2.1. Personal Data concerned

Personal data of IRIS users

When you submit an application as part of one of the regulatory procedures described above, personal data of the following individuals may be included:

- Any person creating, editing, submitting or withdrawing a MAA;

- Any contact of a person associated with the submission or of an additional Industry Manager or Industry Contributor for the submission as defined in the IRIS guide to registration and Research Product Identifier (RPIs)[8];
- The contact person at the sponsor's premises, for delivery of the European Commission decision, if applicable[9];
- The industry - Single Point of Contact (i-SPOC) person for an applicant/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, State)
- Department
- Alternative email address
- Alternative contact number

2.2. Legal Basis

The processing of personal data for the purpose 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 tasks carried out in the public interest as set out in Union pharmaceutical and medical device legislation governing the scientific and regulatory procedures managed through IRIS, namely:

- 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;
- Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the Transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93
- Commission Regulation (EC) No 1234/2008 ('the Variations Regulation')
- Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures.
- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

[8] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration-rpis_en.pdf
[9] 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.

- Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council.
- Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.
- Commission Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities.
- Regulation EU No 536/2014 on clinical trials on medicinal products for human use.
- Notice to Applicants, volume 2A, Procedures for marketing authorisation, Chapter 3 Union Referral Procedures.
- Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010, amending, as regards pharmacovigilance, Directive 2001/83/EC.

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

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)[10] may transfer certain user data[11] 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[12] determining whether a country outside the EU offers an adequate level of data protection or
- Standard Contractual Clauses of the European Commission[13], 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.

Regarding the EMA and NCA contact details for ENS, if a staff member is leaving the EMA or NCA service, e.g., due to end of contract, resignation or retirement, or if the staff member has exercised

[10] A list can be provided upon request
[11] Please refer to the European Medicines Agency's Data Protection Notice for Microsoft 365 (M365) Services, available at: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-ms-suite_en.pdf
[12] Adequacy decisions | European Commission (europa.eu)
[13] Standard Contractual Clauses (SCC) | European Commission (europa.eu)

their right to object, the personal data stored at application level and access to the information will be automatically removed.

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 each 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 with the exception of CCMO, where the admin user will be allocated within the EMA. 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.

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