EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 July 2023
EMA/338096/2023

Records of data processing activity (public)

Interactive Regulatory Information System (IRIS) – EMA-TDT-003

1.	Last update of this record, version number:	New
2.	Reference number:	EMA-TDT-003
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of the Digital Business Transformation Task Contact: datacontrollertdt@ema.europa.eu
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	N/A
6.	Name and contact details of processors (where applicable)	• Microsoft Ireland Operations Limited, South County Business Park, One Microsoft Place, Carmanhall and Leopardstown, Dublin, D18 P521, Ireland • Experlogix, Newtonstraat 2, 3902 HP Veenendaal, The Netherlands • Capegemini, Reykjavikplein 1, 3543 AK Utrecht, The Netherlands
7.	Purpose of the 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 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 [1] 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.
8.	Description of categories of persons whose data EMA processes and list of data categories	**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)[2]; • The contact person at the sponsor's premises, for delivery of the European Commission decision, if applicable[3]; • The industry - Single Point of Contact (i-SPOC) person for an applicant/MAH.

[1] PLM portal stands for "Procedures Life-Cycle Management" portal.
[2] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration-rpis_en.pdf
[3] 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.

		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
9.	Time limit for keeping the 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.
10.	Recipients of the data	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.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	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)[4] may transfer certain user data[5] to third countries. As part of the transfer of such personal data, the Agency's processor is relying on the following transfer mechanisms:

[4] A list can be provided upon request
[5] 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

		• Adequacy decision of the European Commission[6] determining whether a country outside the EU offers an adequate level of data protection or • Standard Contractual Clauses of the European Commission[7], for the countries where no adequacy decision is in place.
12.	General description of security measures, where possible.	The Agency has put appropriate technical and organisational measures (security policies and procedures) in place to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access. The Agency takes all necessary measures to ensure the maximum safety and security of personal data held both offline and online, in hardcopy and digital forms. The personal data of users, are normally collected through the IRIS Industry Portal and the EMA Account Management System, which abide by the security provisions established in the Agency's security policies.
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	Details concerning the processing of your personal data are available on the Agency's website at: https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement Here you may find the data protection notice regarding this specific data processing operation as well: https://www.ema.europa.eu/en/documents/other/european-medicine-agencys-data-protection-notice-interactive-regulatory-information-system-iris_en.pdf

[6] Adequacy decisions | European Commission (europa.eu)
[7] Standard Contractual Clauses (SCC) | European Commission (europa.eu)