



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 November 2025
EMA/903983/2019

Records of data processing activity (public)

Name and reference number of processing operation: Early Notification System (ENS), EMA-TDT-014

1.	Last update of this record, version number:	1.0
2.	Reference number:	EMA-TDT-014
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of the Digital Business Transformation Task Force 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)	Not applicable
6.	Name and contact details of processor (where applicable)	• Microsoft Ireland Operations Limited, South County Business Park, One Microsoft Place, Carmanhall and Leopardstown, Dublin, D18 P521, Ireland • Capgemini, Reykjavikplein 1, 3543 AK Utrecht, The Netherlands
7.	Purpose of the processing	The Early Notification System (ENS) is a critical activity, used on a weekly basis and critical during crises to fulfil a legislative requirement for EMA to coordinate the sharing of key (safety) information around medicines. It operates 24/7, ensuring continuous communication with key stakeholders in the EU Regulatory Network (Heads of Agencies, senior European Commission officials, EMA committee members, national heads of communications (WGCP), and international partners). It ensures coordination, consistent messaging, and alignment of responses within the EU and supports EMA's reputational

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		goals, reinforcing alignment and collaboration within the regulatory network and internationally.
8.	Description of categories of persons whose data EMA processes and list of data categories	Documentation created, displayed and shared via the Early Notification System does not contain personal data. The only personal data shared is EMA's Head of Public and Stakeholder Engagement Department signature, as communications are sent on his behalf. ENS will only process the contact details (name and email and the name of their organisation) of users (employees of EMA and National Competent Authorities) to ensure access to ENS via IAM¹.
9.	Time limit for keeping the data	In case 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 their right to object, the personal data stored at application level and access to the information will be automatically removed.
10.	Recipients of the data	EMA employees and contractors who provide access to the system to the ENS users. The processors listed in section 6 may have access to the personal data for the purpose of fulfilling their tasks.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Agency's processor (see section 1.2) and their sub-processor(s)² may transfer certain user data³ 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 Commission⁴ determining whether a country outside the EU offers an adequate level of data protection or Standard Contractual Clauses of the European Commission⁵, 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 EMA's Account Management system and propagated to Microsoft Entra ID, which abides by the security provisions established in the Agency's security policies. Access by EMA internal users is protected by modern authentication including multi factor authentication.

¹ For more information on how EMA processes personal data in IAM, please see the dedicated Data Protection Notice available here: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-use-ema-authentication-services-microsoft-entra-id_en.pdf

² A list can be provided upon request

³ 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-agency-privacy-statement-ms-suite_en.pdf

⁴ [Adequacy decisions | European Commission \(europa.eu\)](https://ec.europa.eu/commission/presscorner/detail/en/ip_18_1111)

⁵ [Standard Contractual Clauses \(SCC\) | European Commission \(europa.eu\)](https://ec.europa.eu/commission/presscorner/detail/en/ip_18_1111)

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/data-protection-privacy-ema https://www.ema.europa.eu/en/documents/other/european-medicine-agencys-data-protection-notice-interactive-regulatory-information-system-iris_en.pdf Here you may find the data protection notice regarding this specific data processing operation as well.
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