



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 September 2026
EMA/247394/2020

Records of data processing activity (public)

Industry Single Point of Contact (i-SPOC) reporting system

1.	Last update of this record, version number:	22 September 2026, Version 3.0
2.	Reference number:	TRS5
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Regulatory Science and Innovation Task Force (TRS) Contact: datacontroller.horizonscanning@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 Address: South County Business Park, One Microsoft Place, Carmanhall and Leopardstown, Dublin, D18 P521, Ireland
7.	Purpose of the processing	The purpose of this data processing activity is the monitoring of the supply and demand of medicines considered to be critical to address a particular crisis such as a public health emergency (PHE) or a major event (ME) and preparedness for such circumstances in the context of performing of the Agency tasks defined under Regulation (EU) 2022/123, including: • Gathering information on potential and actual shortages, including available stocks and forecasts of supply and demand, while assessing the merits of each indication of information as being of a commercially confidential nature and protecting such information against unjustified disclosure. • Channelling aggregated information on supply and demand to the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) which will coordinate urgent actions within the Union in relation to the management of

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		issues relating to the supply of medicinal products. National reporting requirements should still be met independently. Further, communicating reporting requirements in the context of the European Shortages Monitoring Platform (ESMP¹) for crisis preparedness and management, and any related follow-up notifications and communications.
8.	Description of categories of persons whose data EMA processes and list of data categories	The following categories of data subject and data elements are subject to this processing operation: • The list of i-SPOC persons identified by the marketing authorisation holder subject to reporting obligations for medicinal products (for human use) for which it holds a marketing authorisation valid in any EU/EEA country included in a list of critical medicines for a public health emergency (PHE) or major event (ME) and preparedness of such according to Article 6 of Regulation (EU) 2022/123, published on EMA's website. EMA processes the following data on the i-SPOCs identified: • Names • Email addresses • Telephone numbers • Job titles • Business addresses
9.	Time limit for keeping the data	EMA keeps the personal data for as long as the individual is the i-SPOC for the MAH, and until a replacement has been registered via IRIS ² .
10.	Recipients of the data	The data collected is being processed internally by the Agency and is accessible to authorised EMA staff within the EMA division(s) responsible for the management of the i-SPOC system. A subset of the data is accessible in the IRIS Network Portal to some EMA Scientific Committee members, and through a shared platform for operational and analytical purposes to staff members of national competent authorities with relevant access security roles for the management of medicine shortages in the EEA, and the European Commission. In the context of preparedness activities i-SPOC contact information may be made available to the Regulatory Network, i.e. members of the Medicine Shortages Single Point of Contact (SPOC) Working Party.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to	Not applicable

¹ Accessible at: <https://esmp.ema.europa.eu/> and for more information, please see: https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-data-protection-notice-european-shortages-monitoring-platform-esmp_en.pdf

² Accessible at: <https://iris.ema.europa.eu/> and for more information, please see: https://www.ema.europa.eu/en/documents/other/european-medicine-agencys-data-protection-notice-interactive-regulatory-information-system-iris_en.pdf

	which ones and with which safeguards?	
12.	General description of security measures, where possible.	The Agency has appropriate technical and organisational measures in place, including organisational policies, to safeguard the security of personal data and ensure the confidentiality, integrity and availability of the relevant systems, services and the personal data processed within them. In particular, • The servers storing the data are located within secure premises on a secure network and protected by additional physical security measures; • Network firewalls to protect the logical perimeter of the IT infrastructure; • Administrative measures include the obligation of all Agency and non-Agency personnel having access to the system (including those maintaining the equipment and the systems to sign non-disclosure agreements; • Access rights to users are granted only to the system areas which are strictly necessary to carry out their roles. The access to those areas is protected with personal password; • Only the system administrator can grant, alter or annul any access rights of any persons
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 EMA General Privacy Statement as well as the data protection notices on specific data processing operations, such as the i-SPOC Data Protection Notice: European Medicines Agency's Data Protection Notice for the Industry Single Point of Contact (i-SPOC) system