1 July 2021
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:	1 July 2021, version 2
2.	Reference number:	TRS5
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Regulatory Science and Innovation Task Force, 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)	Insight, Strawinskylaan 4117, Office 5-111, Atrium Building North Tower, 1077 XY Amsterdam Contact details: SIDEII.EU@insight.com.
7.	Purpose of the processing	The i-SPOC system has been established, temporarily and solely, in the context of the EU Regulatory Authorities Industry Single Point of Contact on shortages of medicines caused by major events in the context of the COVID-19 pandemic. The purpose of the processing is to report on current or anticipated shortages of medicinal products, authorised and marketed in the EEA/EU, used in COVID-19 patients for centrally and nationally authorised products for human use. The processing has two phases: • Phase 1 focusses exclusively on the subset of medicines used in a hospital intensive care unit setting, selected in consultation with national competent authorities. • Phase 2, which has not yet commenced and will start only depending on public health needs, would focus on reporting shortages for a broader range of medicines used in the treatment of COVID-19 patients. An external company has been engaged to design and test a robotic process automation to collect and compile i-SPOC shortage data submitted by Marketing Authorisation

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		Authorities in the scope of the reporting requirement. Access to this data is limited to the design and testing phase. The company is exposed to a limited portion of data for the sole purpose of design and testing.
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: • List of SPOC persons identified in the National Competent Authorities in EU-27/EEA, including their names, email addresses and country code. • List of Industry SPOC persons identified by the Marketing Authorisation Holders/Industry Trade Associations subject to the scope of the i-SPOC system, including their names and email address, telephone number, job title, location.
9.	Time limit for keeping the data	The personal data collected is retained for no longer than the reporting requirement of COVID-19 related medicine shortage notifications to EMA is longer deemed necessary by the EU Executive Steering Group.
10.	Recipients of the data	The data on the medicinal products and the personal data is processed by EMA staff within the Division responsible for the management of the i-SPOC system. The list of NCA SPOC and Industry SPOC persons will not be published on the EMA corporate website. Contact details of NCA SPOC and Industry SPOC persons may be shared with the European Commission (who chairs the EU Executive Steering Group) on a need to know basis.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Not applicable
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 privacy statements on specific data processing operations.