8 June 2020
EMA/222043/2020

European Medicines Agency's Privacy Statement

For the Industry Single Point of Contact (i-SPOC) system

The European Medicines Agency (hereinafter "EMA" or "Agency") is committed to respect the right to data protection of its staff members and the public. The Agency collects and uses personal data in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data. It aims to ensure that your personal information is collected lawfully, stored safely, and used responsibly.

This Privacy Statement explains the most essential details of the processing of personal data by the EMA in the context of the EU Regulatory Authorities-Industry Single Point of Contact (i-SPOC) system, which has been set up by the EU Executive Steering Group on shortages of medicines caused by major events[1] (hereinafter referred to as the "EU Executive Steering Group") on 26 March 2020 in context of the COVID-19 pandemic.[2]

The i-SPOC system has been established, temporarily and solely in the context of the COVID-19 pandemic - for Industry at company (corporate) level - to report on current or anticipated shortages of medicinal products, authorised and marketed in the EEA/EU, used in COVID-19 patients to the European Medicines Agency (EMA), for centrally and nationally authorised products for human use.

The i-SPOC system is established in agreement with the EU Industry Trade Associations following their proposal for its implementation and is a two-way communication channel between the European medicines regulatory network (via EMA) and MAHs.

The i-SPOC system is being launched in two phases:

- In the first phase, starting on **Friday 17 April 2020**, the scope of reporting will focus exclusively on current or anticipated shortages of a subset of medicines used in the hospital intensive care unit (ICU) setting, selected in consultation with national competent authorities (31 active substances, in total).
- A second phase, for which its start date is yet to be determined and depending on the public health needs, will focus on reporting of shortages for a broader range of medicines used in the treatment of COVID-19 patients.

[1] The EU Executive Steering Group is chaired by the European Commission. Its membership is made up of representatives from the European Commission, the Heads of Medicines Agencies (HMA), EMA, the chairs of the Coordination groups for Mutual-recognition and Decentralised Procedures for both human and veterinary medicines (CMDh and CMDv), as well as risk communication specialists.

[2] https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/availability-medicines-during-covid-19-pandemic#enhanced-monitoring-system-for-medicines-used-for-treating-covid-19-section

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Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1. Who is responsible for your data?

1.1. Who is the data controller?

The European Medicines Agency ("EMA") is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Deputy Executive Director is appointed as a 'Data Controller' to ensure the lawful conduct of this processing operation.

The contact details of the Data Controller are the following: DEDdataprotection@ema.europa.eu

1.2. Who is the data processor?

The Agency engages a third party to process data on behalf of the Agency and, in particular, to carry out the following activities:

- Design and test a robotic process automation to collect and compile i-SPOC shortage data submitted by the MAHs in scope of the reporting requirement. Access of said data will be limited to the design and testing phase, therefore the third party will be exposed to a small portion of data.

The contact details of the data processor are the following:

Address: Insight, Strawinskylaan 4117, Office 5-111, Atrium Building North Tower, 1077 XY Amsterdam;

Email: SIDEII.EU@insight.com

1.3 Purpose of this data processing

The purpose of this data processing activity is the management of COVID-19 related medicine shortage notifications submitted by MAHs to EMA, or any additional follow-up notifications, if applicable in the context of performing of the Agency tasks, including:

- EMA to gather information on medicinal product(s) used for the treatment of COVID-19 patients, which can be (potentially) at risk of supply disruptions, in the context of the COVID-19 pandemic. When shortages are anticipated, the i-SPOC system should aim at preventing shortages from occurring.
- EMA to channel aggregated information on supply shortages to the EU Executive Steering Group, which will decide on the EU-level coordinated actions necessary to address these supply shortages in the best way (irrespective of their licensing route). National reporting requirements should still be met independently.

1.4 Personal Data concerned

In this processing operation we process personal data of both industry and NCA SPOC persons in the context of COVID-19 related medicine shortage notifications to EMA, or any additional follow-up notifications, if applicable. Such data may include the following:

- 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.

1.5 Legal Basis

The processing described in this Privacy Statement is carried out by the Agency in accordance with its public mandate under Article 168 of the Treaty on the Functioning of the European Union, on which the decision of the EU Executive Steering Group on shortages of medicines caused by major events of 26 March 2020 is based. Article 81 of Directive 2001/83/EC states that MAHs, and their distributors, within the limits of their responsibilities, should ensure appropriate and continued supplies to pharmacies and persons authorised or entitled to supply medicinal products so that the needs of patients in the Member State in question are met. In this regard, EMA and HMA published guidance for marketing authorisation holders on detecting and reporting medicine shortages.[3] Therefore, the processing of personal data in the context of the i-SPOC system is also related to the performance of EMA's tasks in the public interest, based on Article 5(1)(a) of Regulation (EU) 2018/1725.

In addition, when you provide your data, you consent to the processing of that data in accordance with this Privacy Statement. You have the right to withdraw your consent later at any time by contacting the data controller (see email address in Section 1.1 above). Please note that such withdrawal does not affect the lawfulness of processing carried out by EMA before the withdrawal of your consent.

2. How long do we keep your data?

EMA keeps the personal data for no longer than the reporting requirement of COVID-19 related medicine shortage notifications to EMA is necessary by the EU Executive Steering Group. Accordingly, the Agency will delete or (where possible) anonymise all personal data collected and processed in relation to this processing activity, within 3 months from the date when the requirement of COVID-19 related medicine shortage notifications will be terminated by the EU Executive Steering Group.

3. Who has access to your information and to whom is it disclosed?

The data collected will be processed internally by staff within the EMA 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.

4. 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 Privacy Statement 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 if it is incorrect or incomplete.

[3] Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA), available: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf

- **Right to withdraw consent –** You have the right to withdraw your consent to the processing of your personal data. However, this will not affect the lawfulness of any processing carried out before consent is withdrawn.
  - Please note that if you withdraw your consent, the Agency may not be able to carry out certain activities in relation to the i-SPOC system. EMA will advise you if this is the case at the time you withdraw your consent.
- **Right to erasure** – You have the right to require EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing. In certain cases, your data may be kept to the extent it is necessary, for example, to comply with a legal obligation of the Agency or if it is necessary for reasons of public interest in the area of public health.
- **Right to restrict processing** – In a few, codified cases, you have the right to obtain the restriction of the processing, 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 General Privacy Statement, hosted at www.ema.europa.eu/en/about-us/legal/privacy-statement.
- **Right to object** – You have the right to object at any time to this processing on grounds related to your particular situation.
- **Right to portability** - Where the processing is carried out based on your consent and in automated means you have the right to receive your personal data (which was provided to the EMA directly by you) in a machine-readable format. You may also ask the EMA to directly transfer such data to another controller.

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 privacy notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

5. 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 Privacy Statement or the general EMA Privacy Statement, please contact the **Data Controller** at DEDdataprotection@ema.europa.eu 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