EMA/335709/2023
24/07/2023

European Medicines Agency's Data Protection Notice

For the user test of the Critical Medical Device Shortages (CMDS) system

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of the submission of data to the Critical Medical Device Shortages (CMDS) system as required according to Regulation (EU) 2022/123[1].

Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 foresees the coordination and management of shortages of critical medical devices during public health emergencies in the EU/EEA. Article 25 of the Regulation requires the Agency to develop IT monitoring and reporting systems to collect information regarding the supply and availability of critical medical devices. The CMDS has therefore been developed to enable the submission of the required information to the Agency by the relevant stakeholders.

The Agency conducts a specific user test of the **National Competent Authorities** (**NCA)-webform of EMA's CMDS system**.

Who is responsible for processing your data?

1.1. Who is the data controller?

EMA is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Regulatory Science and Innovation Task Force is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation. You may contact the Internal Controller via the following email address:

Datacontroller.Horizonscanning@ema.europa.eu

[1] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1.2. Who is the data processor?

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

- To provide the software tools enabling users to carry out their tasks for the purposes listed below.

  The contact details of the data processor(s) are the following: European Commission, Directorate-General for Health and Food Safety (DG SANTE), Unit R4 – Information Systems, 1049 Bruxelles/Brussel, Belgium.

- To process personal data on behalf of the Agency in the course of performing this user test and providing secretariat support.

  The contact details of the data processor(s) are the following: PwC EU Services EESV, Woluwedal 18, 1932 Zaventem, Belgium and Intellera Consulting S.p.A., via Gaetano de Castillia n. 23, 20124, Milan, Italy.

2. Purpose of this data processing

The purpose of this data processing activity is to perform the user test of the webform applicable to National Competent Agencies of EMA's CMDS. The Agency asks participants of the test to provide feedback on the usability of the webform and for specific feedback on the data fields. The testing does not require the submission of any operational data for the purpose of this user test. Entering random and fictive test information is sufficient.

2.1. Personal data concerned

In this processing operation we process data that you will send via email to our functional mailbox. In addition, when you enter the NCA-webform, personal data will be processed and stored by the system. This data includes the following:

- Your name
- Your email address associated to your EU-login account
- "Unique Identifier at the Commission" (UID)

  The UID is associated with the EU Login is the European Commission's user authentication service. It allows authorised users to access a wide range of the Commission's web services, using a single email address and password.

- The name of your organisation

In addition, the name of your organisation and the UID will be submitted to DG SANTE for the purpose of granting access to the NCA-webform.

2.2. Legal basis of the processing

When you provide your data for the purpose of the user testing, you consent to the processing of that data in accordance with this Data Protection Notice and in line with Article 5(1)(d) of Regulation (EU) 2018/1725. You may opt-out from the processing in a response to the functional mailbox mentioned in Section 1.1. In your response, please state what is the personal data that you want to exclude and what is the actual processing activity that you do not want EMA to carry out on your data. You also have the right to withdraw your consent later at any time. Please note that such withdrawal does not affect the lawfulness of processing carried out by EMA before the withdrawal of your consent.

In addition, the operation of the CMDS is necessary for the performance of the Agency's tasks carried out in the public interest in line with Article 5(1)(a) of Regulation (EU) 2018/1725. In particular, the processing of data is necessary for the performance of tasks carried out in the public interest as provided for under Article 25 and Article 27 of Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

In this regard, please note that you have the **right to object** against the processing as explained in Section 5 below.

3. How long do we keep your data?

Participants' personal data will remain available until the results of the user test have been fully analysed (no later than **3 months after the user test is completed**). Should the user test prove unsuccessful, or elements have been identified that make it necessary to perform another user test, participants might be contacted again at a later stage for a re-run. As stated in section 2.2 you have the right to withdraw consent at any time. Please note that such withdrawal does not affect the lawfulness of processing carried out by EMA before the withdrawal of your consent.

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

The data collected will be processed by the data processors and internally by the Agency. It is accessible by authorised EMA personnel within the EMA Task Force responsible for the specific procedure.

DG-SANTE as the host of the data collection system will process the personal information for the purpose stated in section 2 of this document. The Agency processes the data for the purposes of this user test.

5. 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 Data Protection Notice provides information on how EMA collects and uses your personal data. Requests for other information regarding the processing may also be directed to the Internal Controller.
- **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.
- **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 provide certain services to you. 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. If you do so, EMA may only continue processing your personal data if it demonstrates overriding legitimate grounds to do so or if this is necessary for the establishment, exercise or defence of legal claims.
- **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 Data Protection Notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

6. 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 Data Protection Notice or the general EMA

Privacy Statement, please contact the **Internal Controller** at Datacontroller.Horizonscanning@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