



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 March 2024
EMA/116897/2024
European Medicines Agency

European Medicines Agency's Data Protection Notice For the handling of data subjects' requests

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 exercise of data subject's rights in accordance with Chapter III of Regulation (EU) 2018/1725 (hereinafter "EUDPR").

1. Who is responsible for processing 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, depending on the subject matter and nature of the request, the applicable Head of Division, Advisory Function or Task Force is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation.

You may contact the Data Protection Officer via the following email address:

dataprotection@ema.europa.eu

2. Purpose of this data processing activity

The purpose of this data processing activity is to handle and respond to the requests of data subjects looking to exercise the rights conferred upon them by Regulation (EU) 2018/1725 in the context of performing of the Agency tasks, including:

- Performing the required checks as foreseen by law
- Performing the relevant administrative tasks required to respond to the data subject

2.1. Personal data concerned

We may process personal data directly collected from you when you submit your data subject request and when communicating with us. We may also request an official identification document from you in order to ensure the security of processing and minimize the risk of unauthorised disclosure of personal

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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

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data. As data controller, we must be able to identify which data refer to the data subject and confirm the identity of the person in case of doubts.

We may collect the following personal data from you:

- First and last name
- Email address
- Copy of identification document (driver's license, passport, or any other official document that verifies your identity). For this purpose, EMA will only require certain information (e.g., issuing authority, first and last name, date of issue or expiry date). Other information on the identification document should be redacted where possible. Any other personal data that you, as a data subject, communicate to us (e.g. phone number, postal address)

If the request is done by an individual on behalf of the data subject, we may also process the abovementioned personal data of him/her.

Article 12 EUDPR recognises that EMA may be able to demonstrate that it is not in a position to identify the data subject, including in pseudonymised data it holds. This may be the case if EMA does not have (or no longer has) access to additional information allowing attribution, is demonstrably unable to lawfully obtain such information and is demonstrably unable to reverse the pseudonymisation with the assistance of another controller. Consequently, except where the data subject (for exercising his or her rights) provides additional information enabling his or her identification, the rights of data subjects enumerated in Article 12(2) or 14(2) EUDPR, respectively, shall not apply in this case.

For instance, if you can provide the pseudonym or pseudonyms under which data relating to you is stored, and proof that those pseudonyms pertain to you, EMA will try to identify you. In consequence, your data subject rights will apply in this case. Therefore, in order to give full effect to your rights, EMA will indicate how you can obtain the pseudonyms relating to you, and how they can be used to demonstrate your identity. In this case, EMA may need to provide the identity and the contact details of the source of the pseudonymised data or of the pseudonymising controller.

2.2. Legal basis of the processing

The processing of your personal data in accordance with this Data Protection Notice is necessary for the compliance with a legal obligation to which the controller is subject, namely Article 5(1)(b) of the EUDPR. Article 14 EUDPR sets out the obligations of EMA as data controller when handling data subjects' requests for exercising the rights set out in Chapter III of the EUDPR.

3. How long do we keep your data?

The copy of the identification document will be kept until your identity or the identity of the person making the request on your behalf has been verified.

The remaining personal data will be handled until the request has been concluded. Thereafter, it will be stored for a period of 5 years for audit and compliance purposes, after which all personal data will be deleted.

4. 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(s), advisory function(s) and task force(s) responsible for addressing the request, in addition to the Data Protection Officer and the Legal Department when applicable.

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 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.

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** 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