



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 May 2020
EMA/415481/2019 Rev. 2

European Medicines Agency's Privacy Statement concerning requests for information or access to documents

This Privacy Statement explains how the European Medicines Agency (hereinafter "EMA" or "Agency") collects and uses your personal data for the purpose of handling your request, namely:

- **Requests for access to documents:** when handling formal requests for access to EMA documents submitted on the AskEMA online form;
- **Requests for information:** when handling a request for information from EMA submitted in writing (e.g. on the AskEMA form) or by phone call.

1. Who is the data controller?

EMA is ultimately responsible to comply with data protection rules for EU institutions. On behalf of EMA, the Head of Stakeholders and Communication Division is appointed as an 'Internal Controller' to ensure correct processing of personal data.

The contact details of the Internal Controller are the following: S-DataController@ema.europa.eu

2. Purpose of this data processing

The purpose of this data processing activity is the handling of requests for access to EMA documents or information from EMA and providing the requested information or documents to the requester.

3. What personal data do we process and how?

For the purpose of handling AskEMA requests, we process data directly collected from you when you submit your request via phone or via the AskEMA online form available here:

<https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency>

In the AskEMA online form and/or when submitting a request over the phone you might be asked to provide personal details such as your name (title, first name and surname), your affiliation, i.e. the name of employer or organisation (if applicable, e.g. when you submit the request on behalf of them), your email address, your location (country) and the subject matter of your request. You may provide additional contact details for the purpose of contacting you in relation to your request. For requests

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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



submitted over the phone, this privacy statement should be read in conjunction with the Privacy Statement concerning operation of the EMA Switchboard.

In the course of handling your request, your personal data is processed for the purpose of contacting you and answering your request for documents or information. In the case of access to document requests, the data (your name, affiliation, time of submission, content and subject matter of the request) may be used for the purpose of applying the queuing system as explained in Q14 of the 'Guide on access to unpublished documents'.¹

Please note that - as explained in the referenced section Q14 of the 'Guide on access to unpublished documents' –in the context of applying the queuing mechanism your abovementioned data may be processed for the purpose of detecting possible circumvention of the system. When requesters are informed that their request have been placed in the same queue due to a detected possible circumvention, they have the opportunity to explain seemingly suspicious patterns. In case you submit such explanation, any personal data included will be processed only for the purpose of verifying your statements.

4. Legal Basis

When you provide the data in writing (e.g. on the AskEMA online form) or via phone call, you consent to the processing of that data in accordance with this Privacy Statement. Please refer to Section 7 below concerning your rights regarding the processing of your data, including the right to withdraw your consent.

In addition, the processing of the data provided by you is necessary for the performance of EMA's tasks carried out in the public interest as required under European citizens' rights to access to documents and request for information – based on the following:

Access to documents

The processing of your personal data in the context of handling access to documents requests is necessary for performing the task attributed to EMA by Article 73 of Regulation (EC) No 726/2004 and Regulation (EC) No 1049/2001.

In addition, in order to develop good administrative practices facilitating the exercise of the right to access to documents, EMA has adopted 'The European Medicines Agency policy on access to documents' (Policy/0043), as well as the 'Guide on access to unpublished documents'.² Accordingly, besides Regulation (EC) No 1049/2001, requests for access to documents are processed in accordance with the referenced Policy and Guide as well.

Request for information

The processing of your personal data in the context of handling requests for information is necessary for performing the task attributed to EMA by Article 41(4) of the Charter of Fundamental Rights of the European Union stating that every person may write to the institutions of the Union in one of the languages of the Treaties and must have an answer in the same language.

In addition, in order to develop good administrative practices facilitating the exercise of the right to request information from EMA, the Agency has adopted 'The European Medicines Agency Code of Good

¹ Available here: https://www.ema.europa.eu/en/documents/other/guide-access-unpublished-documents_en.pdf

² Available here: https://www.ema.europa.eu/en/documents/other/guide-access-unpublished-documents_en.pdf

Administrative Behaviour'.³ In particular, requests for information are processed in accordance with Article 18 of the Code.

5. How long do we keep your data?

Your file (including the request, the response, any related correspondence and all supporting documentation) will be stored by EMA for a maximum of ten years after the closure of the case, or as long as EMA is under a legal obligation to do so.

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

The data collected will be processed internally by EMA staff responsible for handling your request, including Documents Access and Publication (DAP) service members.

In addition, requests for information may be allocated to EMA staff within the concerned department/office. Requests are allocated to the responsible EMA department/office based on the subject matter of the request.

7. What are your rights in relation this processing?

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. Requests for other information, such as information on recipients can be directed to the Data Controller on the contact details stated in this Privacy Statement.
- **Right to withdraw consent** – You have the right to withdraw your consent to the processing of your personal data which you gave in writing (e.g. by submitting the AskEMA online form) or via submitting request over the phone.

Please note that if you withdraw your consent regarding data that is necessary to process your request, the Agency will not be able to provide you the requested document or information. EMA will advise you if this is the case at the time you withdraw your consent.

Please note that the withdrawal of your consent does not affect the lawfulness of processing carried out by EMA before the withdrawal.

- **Right to rectification** – You have the right to obtain - without undue delay - the rectification or completion of your personal data if it is incorrect or incomplete.
- **Right to erasure** – You have the right to request 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, 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.

³ Available here: https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-good-administrative-behaviour_en.pdf

- **Right to object** – If the Agency processes your data for the performance of a task in the public interest (without your consent or due to the requirement of another lawful basis) you have the right to object to this processing on grounds related to your particular situation.
- **Right to portability** - Where the processing is carried out by automated means you have the right to receive your personal data (which was provided to the EMA 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.

You have the right to lodge a complaint with the European Data Protection Supervisor (EDPS) at any time at the following address: edps@edps.europa.eu.

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

8. Recourse

In case you have any questions regarding the processing of your personal data, or if you think that the processing is unlawful or it is not in compliance with this Privacy Statement you may contact the Internal Controller directly on the following email address: S-DataController@ema.europa.eu

In addition, you may submit a question or complaint to the **EMA Data Protection Officer** (dataprotection@ema.europa.eu) or you may lodge a complaint with the **European Data Protection Supervisor** via the following contact details:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en