



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/472380/2019  
European Medicines Agency

## European Medicines Agency's privacy statement

### Public and targeted consultation

The European Medicines Agency (hereinafter 'EMA' or 'Agency') is committed to respecting the right to data protection of 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 (hereinafter 'Regulation').

This privacy statement explains how the Agency collects and uses personal data for purposes related to public and targeted consultations in accordance with the Agency's data-protection obligations under the Regulation. The launching and management of public consultations by the Agency involves the collection and processing of the personal data of stakeholders, interested parties and individuals who submit their contributions to these consultations. If you fall into one of these categories, it is important that you read and retain this statement, together with any other privacy statements EMA may provide on specific occasions when it is collecting or using personal data about you, so that you are aware of how and why EMA is using such data, and what your rights are under the Regulation.

### 1. Who is the data controller?

EMA is ultimately responsible for complying with Regulation (EU) 2018/1725. Internally, the Head of Division in charge of a particular consultation is appointed to act as the data controller.

Should you wish to send a question or request to the data controller, please contact:

[S-DataController@ema.europa.eu](mailto:S-DataController@ema.europa.eu).

### 2. Purpose of this data processing

EMA uses the personal information of contributors to launch and manage public consultations, and to receive and assess the feedback and suggestions from contributors. This processing may also include the publication of received contributions on EMA's corporate website ([www.ema.europa.eu](http://www.ema.europa.eu)) for the purposes of transparency.

The Agency may contact contributors to request clarification or to disseminate the results of consultations. The Agency may also contact contributors to let them know about other public consultations and invite them to participate, unless the contributors do not agree to this processing.

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**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](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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## **3. What personal data does EMA collect, and how?**

### ***3.1. Personal data concerned***

EMA collects and processes basic personal information about contributors, i.e. the full names of the individuals or organisations, and their email addresses.

Contributions received, together with the identity of the contributors, may be published on EMA's corporate website. The contribution may be published in an anonymous form if the contributor objects to the publication of his or her personal data on the grounds that such publication would harm his or her legitimate interests. Otherwise, objections in the absence of a legitimate interest to oppose publication of personal data will neither be published nor, in principle, its content be taken into account. Any objections concerning publication of personal data should be sent to the contact details of the Data Controller as mentioned in Section 1 above.

The Agency discourages contributors from including other personal data concerning themselves or personal data concerning third parties in their responses and contributions. If contributors record personal data concerning other individuals, then they should declare that they are acting in accordance with the applicable data protection legislation.

### ***3.2. Legal basis for data processing***

The Agency processes personal data of contributors to public consultations on the basis of their consent provided directly when submitting the report on the form for submission of comments.<sup>1</sup> Participating in public consultations is voluntary and contributors can withdraw their consent any time.

In addition, the consultations registered in the EMA's database (see below) are necessary for the management and functioning of the Agency in the course of performing of its tasks carried out in the public interest as mandated in Regulation (EC) 726/2004. Therefore, the processing is lawful under Article 5(a) of Regulation (EU) 2018/1725 and is justified on the grounds of public interest.

### ***3.3. Recipients of the data***

Contributions will be published on the Agency's corporate website. In cases where contributions are submitted by individuals on behalf of a legal person or organisation, the identity of the latter will be published.

Contributions received, together with the personal data of contributors, will be recorded in the Agency's document management system, which is not accessible from outside the Agency.

## **4. Data security**

The Agency has put appropriate technical and organisational measures (security policies and procedures) in place to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access. The Agency takes all necessary measures to ensure the maximum safety and security of personal data held both offline and online, in hardcopy and digital forms.

Contributions, together with the personal data of contributors, are normally collected through EMA's email system, which abides by the security provisions established in the Agency's security policies. Access by EMA internal users is password-protected.

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<sup>1</sup> [https://www.ema.europa.eu/documents/template-form/form-submission-comments-scientific-guidelines\\_en.doc](https://www.ema.europa.eu/documents/template-form/form-submission-comments-scientific-guidelines_en.doc)

## 5. Your data protection rights

As a 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.
- **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.
- **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, found at [www.ema.europa.eu/en/about-us/legal/privacy-statement](http://www.ema.europa.eu/en/about-us/legal/privacy-statement).
- **Right to object** – If the Agency processes your data for the performance of a task in the public interest (without your consent or 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 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](http://www.ema.europa.eu/en/about-us/legal/privacy-statement).

## 6. How long does EMA keep personal data?

EMA deletes all personal data of contributors five years after publication of final documentation in relation to the consultation.

The contributions are published on EMA's corporate website and archived internally.

## 7. 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 in the contact details indicated in Section 1 above.

Data subjects may lodge a complaint with the **EMA Data Protection Officer**:  
[dataprotection@ema.europa.eu](mailto: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 addresses:

- Email: [edps@edps.europa.eu](mailto:edps@edps.europa.eu)
- Website: [www.edps.europa.eu](http://www.edps.europa.eu)
- Further contact information: [www.edps.europa.eu/about-edps/contact\\_en](http://www.edps.europa.eu/about-edps/contact_en)