

9 March 2017 EMA/108062/2017 European Medicines Agency

Data protection statement for the public consultation on European Medicines Agency policy on access to documents

1. Objective

The objective of this consultation is to receive the views of stakeholder and/or concerned individuals on the revised European Medicines Agency policy on access to documents, the output table on corporate documents and the output table for documents related to medicines for human and veterinary use.

As the public consultation collect comments whereby personal data is further processed, it is subject to data protection rules as established by Regulations (EC) 45/2001.

2. What personal information do we collect and through which technical means?

2.1. Identification data

The personal data collected and further processed are only those data which are necessary for the management and review of the contributions such as the professional contact details of the contributors, including e-mail address, affiliation, work address, and their views on the topic concerned.

2.2. Legal basis

The legal basis for the processing of personal data in this specific context is consistent with the functional needs of the service. In accordance with Article 5(a) of Regulation (EC) No 45/2001, the present processing activity is necessary for the performance of a task carried out by EMA in the public interest on the basis of the TFEU. Moreover, in accordance with Article 5(d) of Regulation (EC) No 45/2001, the data subject has unambiguously given his or her consent to the processing of personal data.



2.3. Technical information

Your contribution will be collected, together with our personal data, through e-mail. EMA's local storage will save a copy of the inputs of participants to the public consultation.

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

3.1. Personal data WILL be published on a publicly available website

Received contributions together with the identity of the contributor, e.g. the name of the organisation making the contribution, will be published on a publicly available website. If you do not agree with this publication of your personal data, you should inform us providing the grounds that such publication would harm your legitimate interests. In this case, subject to a valid justification, the contribution will be published in an anonymous form. Otherwise, in the absence of a legitimate interest to oppose the publication of personal data, the contribution will be published.

If a person sends a contribution on behalf on an organisation, his/her name will not be published.

Any objection concerning publication of personal data should be included on your response to the public consultation.

4. How do we protect and safeguard your information?

Received contributions are recorded in a secured and protected database hosted by the EMA, the operations of which abide by the EMA security policy. The database is not accessible from outside the EMA. Inside the EMA the database can only be accessed using a user ID and password.

5. How can you verify, modify or delete your information?

Participants to the public consultation have a right to access their data at any time. If you wish to verify which personal data is stored, have it modified, corrected or deleted, please contact the data controller by using the contact information at the end of this statement and by explicitly specifying your request.

6. How long do we keep your data?

6.1. We will store your personal data for more than one year

Your personal data and your contribution is stored as part of the record of the public consultation. Two years following the end of the public consultation the contact details of the person making the contribution will be deleted from our internal records.

6.2. Contact information

In case you wish to verify which personal data is stored on your behalf by the responsible data controller, have it modified, corrected, or deleted, or if you have questions regarding the information processed in the context of the public consultation, or on your rights, you are invited to contact the support team, operating under the responsibility of the data controller, using the following contact information:

EMA/108062/2017 Page 2/3 European Medicines Agency
Office of the Deputy Executive Director (Data Controller)
30 Churchill Place
London E14 5EU
UK

Email: ATDPolicy@ema.europa.eu

7. Recourse

Complaints, in case of conflict, can be addressed to:

- The EMA Data Protection Officer: <u>dataprotection@ema.europa.eu</u>; or
- The European Data Protection Supervisor

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