

PROTECTION OF YOUR PERSONAL DATA

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1. Introduction

This privacy statement explains the reason for the processing, the way we collect, handle and ensure protection of all personal data provided, how that information is used and what rights you may exercise in relation to your data (the right to access, rectify, block etc.).

The European institutions are committed to protecting and respecting your privacy. As this service/application collects and further processes personal data, 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 data¹, is applicable.

This privacy statement concerns a consultation undertaken by DG SANTE, hereinafter referred as the operating DG.

2. Why do we process your data?

Purpose of the processing operation: *Unit SANTE B5* (referred to hereafter as Data Controller) collects contributions on a specific topic and, eventually, publishes them through different means (the Internet, Commission's publications, meetings etc.).

¹ [Regulation \(EU\) 2018/1725](#)

Personal data collected in this context may become part of a database with the purpose of facilitating the interaction between the EC and its stakeholders in their areas of interest. A specific record should cover this processing.

If data subjects do not wish to be included in this database, they can address themselves to **the operating DG**.

Lawfulness of the processing operation:

The processing operations of personal data in the context of consultations are necessary and lawful under article 5 (a) of Regulation (EU) 2018/1725.

The current revision of the Guideline on the format and content of applications for designation as orphan medicinal products and on the transfer of designations from one sponsor to another addresses the European Medicines Agency new online platform to submit applications for designations as orphan medicinal products.

This guideline is intended to provide supplementary advice on how to compile the information that should be provided by sponsors in an application for orphan medicinal product designation.

The comments received will be taken into account by the European Commission in the finalisation of the Guideline on the format and content of applications for designation as orphan medicinal products and on the transfer of designations from one sponsor to another.

3. Which data do we collect and process?

Only data necessary for the participation to the Consultation can be collected and processed, namely: title, first name, family name, organisation, department/service, organisation's geographic area of activity, country, city, phone, e-mail address, data subject's categories they represent, language, and contribution.

The data are given by data subjects on a voluntary basis. No data fields fall under article 10.

4. How long do we keep your data?

Unit SANTE B5 only keeps the data for as long as follow-up actions to **the Consultation** are necessary with regard to the purpose(s) of the processing of personal data.

All personal data will be deleted from databases **1 year** after the last action in relation **to the Consultation**.

Reports containing personal data will be archived according to the Commission's legal framework

5. How do we protect your data?

All data in electronic format (e-mails, documents, uploaded batches of data etc.) are stored either on the servers of the European Commission or of its contractor the operations of which abide by the

European Commission's security decision of 16 August 2006 [C(2006) 3602] concerning the security of information systems used by the European Commission;

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

The staff of the operating DG has access to your data on a need to know basis.

7. What are your rights and how can you exercise them?

According to Regulation (EU) 2018/1725, you are entitled to access your personal data and rectify, block, restrict processing or delete it. You can exercise your rights by contacting the data controller, or in case of conflict the Data Protection Officer and if necessary the European Data Protection Supervisor using the contact information given at point 7 below.

8. Contact information

If you have comments or questions, any concerns or a complaint regarding the collection and use of your personal data, please feel free to contact the Data Controller using the following contact information:

The Data Controller:

- Unit B5 - Medicines: policy, authorisation and monitoring
- Functional mailbox: sante-pharmaceuticals-B5@ec.europa

The Data Protection Officer (DPO) of the Commission: DATA-PROTECTION-OFFICER@ec.europa.eu

The European Data Protection Supervisor (EDPS): edps@edps.europa.eu.

9. Where to find more detailed information?

The Commission Data Protection Officer publishes the register of all operations processing personal data. You can access the register on the following link: <http://ec.europa.eu/dpo-register>