



EUROPEAN COMMISSION

PROTECTION OF YOUR PERSONAL DATA

Processing operation: *Targeted consultation activities: targeted surveys (study supporting the monitoring of availability of medical devices on the EU market)*

Controller: *European Commission/SANTE/D3*

Record reference: *DPR-EC-01011*

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1. Introduction

The European Commission (hereafter 'the Commission') is committed to protect your personal data and to respect your privacy. The Commission collects and further processes personal data pursuant to [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 (repealing Regulation (EC) No 45/2001).

This privacy statement explains the reason for the processing of your personal data, the way we collect, handle and ensure protection of all personal data provided, how that information is used and what rights you have in relation to your personal data. It also specifies the contact details of the responsible Data Controller with whom you may exercise your rights, the Data Protection Officer and the European Data Protection Supervisor.

The information in relation to the processing of personal data linked to targeted consultation activities organised by the services of the Commission is presented below.

2. Why and how do we process your personal data?

Purpose of the processing operation: The Commission collects and uses your personal information within the framework of the *study supporting the monitoring of availability of medical devices on the EU market (targeted surveys)*.

You are being contacted by the service of the Commission since it has concluded that your views are relevant and necessary to inform the specific initiative, policy or intervention concerned by the targeted consultation.

The contact details of the prospective respondent are already in the possession of/processed by the controller/processor and their further processing for the targeted consultation activity is lawful;

For reasons of transparency and openness your views will, in principle, be published on a Europa website, in the form of a dashboard. Data collected from the questions relating to the targeted revision of the MDR/IVDR will in principle only be made publicly available in an aggregated and anonymised way.

To avoid misuse, anonymous contributions to the Commission may not be accepted, regardless whether you consent to the publication of your identity together with your contribution.

The Commission service responsible may decide to:

- require respondents to provide personal data in their response given the subject matter of the consultation;
- use EUSurvey and/or EULogin or Alchemer;
- store personal data in a document management system such as ARES.
- It is your responsibility if you opt for confidentiality of your personal data to avoid any reference in your submission or contribution itself that would reveal your identity.
- The consultation activity uses the Commission's online questionnaire tool EUSurvey that requires you to login via your 'EU Login' or 'social media account'. 'EU Login' requires certain personal data such as the name, surname and e-mail address of the registrant. For further information, please refer to the privacy statements of 'EU Login' and 'EU Survey' as well as the processing operations 'Identity & Access Management Service (IAMS)' (reference number in the public DPO register: [DPR-EC-03187](#)) and 'EUSurvey'

- (reference number: [DPR-EC-01488](#)). Should you choose to log in through your social media account, please refer to the pertinent social media platform's privacy statement.
- Your contribution to the targeted consultation is stored in the Commission's document management system (for further information on the Commission's document management system please refer to the processing operation 'Management and (short- and medium-term) preservation of Commission documents', reference number: [DPR-EC-00536](#)).

The personal data processed may be reused for the purpose of procedures before the EU Courts, national courts, the European Ombudsman or the European Court of Auditor.

Your personal data will not be used for an automated decision-making including profiling.

3. On what legal ground(s) do we process your personal data

We process your personal data, because:

- (a) processing is necessary for the performance of a task carried out in the public interest;
- (c) it is based on your consent, for one or more specified purposes:
 - If the subject matter of a targeted consultation requires respondents to provide personal data in their response that make the data subject identifiable, their publication;

The Union law which is the basis for the processing based on Article 5(1)(a) of Regulation (EU) 2018/1725 is the Treaty of the European Union, and more specifically its Articles 1 and 11, Article 298 of the Treaty on the Functioning of the European Union, read in conjunction with Recital 22 of Regulation (EU) 2018/1725), as well as the Protocol 2 on the application of the principles of subsidiarity and proportionality.

4. Which personal data do we collect and further process?

In order to carry out this processing operation the following categories of personal data may be processed:

- *name and surname,*
- *organisation and job title,*
- *country of work,*
- *e-mail address and phone number of the respondent,*

Furthermore, you may spontaneously provide other, non-requested personal data in the context of your reply to the targeted consultation.

Please note that the Data Controller does not request nor expect that data subjects provide any special categories of data under Article 10(1) of Regulation 2018/1725 (that is "personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation") related to themselves or to third persons in their contributions to the targeted consultation activity. Any spontaneous inclusion of these types of personal data is the responsibility of the data subject and by including any of these types of data

the data subject is considered to provide his/her explicit consent to the processing, in accordance with Article 10(2)(a) of Regulation 2018/1725.

5. How long do we keep your personal data?

The Data Controller only keeps your personal data for the time necessary to fulfil the purpose of collection or further processing, namely for a maximum of five years after the closure of the file to which the present targeted consultation belongs. A file is closed at the latest once there has been a final outcome in relation to the initiative to which the targeted consultation contributed.

This administrative retention period of five years is based on the retention policy of European Commission documents and files (and the personal data contained in them), governed by the common Commission-level retention list for European Commission files [SEC\(2019\)900](#). It is a regulatory document in the form of a retention schedule that establishes the retention periods for different types of European Commission files. That list has been notified to the European Data Protection Supervisor.

The administrative retention period is the period during which the Commission departments are required to keep a file depending on its usefulness for administrative purposes and the relevant statutory and legal obligations. This period begins to run from the time when the file is closed.

In accordance with the common Commission-level retention list, after the 'administrative retention period', files including (the outcome of) targeted consultations (and the personal data contained in them) can be transferred to the Historical Archives of the European Commission for historical purposes (for the processing operations concerning the Historical Archives, please see record of processing 'Management and long-term preservation of the European Commission's Archives', registered under reference number [DPR-EC-00837](#)).

6. How do we protect and safeguard your personal data?

All personal data in electronic format (e-mails, documents, databases, uploaded batches of data, etc.) are stored on the servers of the Commission *and of its contractors (processors)*. All processing operations are carried out pursuant to [Commission Decision \(EU, Euratom\) 2017/46](#) of 10 January 2017 on the security of communication and information systems in the Commission.

In order to protect your personal data, the Commission has put in place a number of technical and organisational measures. Technical measures include appropriate actions to address online security, risk of data loss, alteration of data or unauthorised access, taking into consideration the risk presented by the processing and the nature of the personal data being processed. Organisational measures include restricting access to the personal data solely to authorised persons with a legitimate need to know for the purposes of this processing operation.

The Commission's processors (contractors) are bound by a specific contractual clause for any processing operations of your personal data on behalf of the Commission. The processors have to put in place appropriate technical and organisational measures to ensure the level of security, required by the Commission.

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

Access to your personal data is provided to the Commission staff responsible for carrying out this *study supporting the monitoring of availability of medical devices on the EU market* and to authorised staff according to the "need to know" principle, in particular to follow-up on the targeted consultation. Such staff abide by statutory, and when required, additional confidentiality agreements.

Please note that pursuant to Article 3(13) of Regulation (EU) 2018/1725 public authorities (e.g. Court of Auditors, EU Court of Justice) which may receive personal data in the framework of a particular inquiry in accordance with Union or Member State law shall not be regarded as recipients; the processing of those data by those public authorities shall be in compliance with the applicable data protection rules according to the purposes of the processing.

Access to your personal data is also provided to the Commission's contractor the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG) responsible for carrying out the study and to authorised staff according to the "need to know" principle.

The information we collect will not be given to any third party, except to the extent and for the purpose we may be required to do so by law.

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

You have specific rights as a 'data subject' under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access your personal data and to rectify them in case your personal data are inaccurate or incomplete. Under certain conditions, you have the right to erase your personal data, to restrict the processing of your personal data, to object to the processing and the right to data portability.

You have the right to object to the processing of your personal data, which is lawfully carried out pursuant to Article 5(1)(a), on grounds relating to your particular situation.

Insofar you have consented to the certain processing of your personal data to the Data Controller for the present processing operation, you can withdraw your consent at any time by notifying the Data Controller. The withdrawal will not affect the lawfulness of the processing carried out before you have withdrawn the consent.

You can exercise your rights by contacting the Data Controller, or in case of conflict the Data Protection Officer. If necessary, you can also address the European Data Protection Supervisor. Their contact information is given under Heading 9 below.

Where you wish to exercise your rights in the context of one or several specific processing operations, please provide their description (i.e. their Record reference(s) as specified under Heading 10 below) in your request.

In accordance with Article 14(3) of Regulation (EU) 2018/1725, your request as a data subject will be handled within one month of receipt of the request. That period may be extended by two further months where necessary, taking into account the complexity and number of the requests. In such case you will be informed of the extension of the time limit, together with the reasons for the delay.

9. Contact information

- The Data Controller

If you would like to exercise your rights under Regulation (EU) 2018/1725, or if you have comments, questions or concerns, or if you would like to submit a complaint regarding the collection and use of your personal data, please feel free to contact the Data Controller (SANTE-MED-DEV@ec.europa.eu).

- **The Data Protection Officer (DPO) of the Commission**

You may contact the Data Protection Officer (DATA-PROTECTION-OFFICER@ec.europa.eu) with regard to issues related to the processing of your personal data under Regulation (EU) 2018/1725.

- **The European Data Protection Supervisor (EDPS)**

You have the right to have recourse (i.e. you can lodge a complaint) to the European Data Protection Supervisor (edps@edps.europa.eu) if you consider that your rights under Regulation (EU) 2018/1725 have been infringed as a result of the processing of your personal data by the Data Controller.

10. Where to find more detailed information?

The Commission Data Protection Officer (DPO) publishes the register of all processing operations on personal data by the Commission, which have been documented and notified to him. You may access the register via the following link: <http://ec.europa.eu/dpo-register>.

This specific processing operation has been included in the DPO's public register with the following Record reference: DPR-EC-01011.