



EUROPEAN COMMISSION

## **DATA PRIVACY STATEMENT FOR INTERVIEWS**

### **PROTECTION OF YOUR PERSONAL DATA**

**Processing operation:** *Interviews for the study supporting Analyses on markets of medical devices and medicinal products (MedPro II) under specific contract No. HADEA/2025/SC/0038 [under the FRAMEWORK CONTRACT FOR THE IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION AND DATA-DRIVEN POLICY FOR MEDICAL PRODUCTS \(HADEA/2024/OP/0029\)](#)*

**Controller:** *European Commission/ DG 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 targeted consultation activities to obtain your views on a specific initiative, policy or intervention.

The processing activities under this Data Protection Notice for the targeted interviews include:

- Invitations to stakeholders to participate in online interviews in the framework of the study’s targeted consultation activities;
- Management of stakeholders’ participation and their inclusion in participant lists; and
- Management of follow-up actions, such as the collection of feedback, the distribution of reports and other publications or information, and other consultation activities within this study.

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.

Personal data (first name, last name, contact information) is collected through: i) desk research, ii) referral by peers and/or iii) publicly accessible sources such as websites of the European Commission, Member State governments, companies, other organisations, as well as through Google and LinkedIn searches.

For reasons of transparency and openness your views will, in principle, be published on a Europa website, in the form of a summary report. The Commission only publishes your identity if you consent to the publication.

- In the context of the targeted consultation activity, you will be recorded (audio / video). We will ask for your consent to be recorded at the start of the interviews. In case you do not consent to be recorded, we will take written notes of your contribution. The recording is for note taking purposes only and will not be publicly available.

- The subject matter of the consultation activity require you to provide personal data in your response that may identify or make you identifiable. These personal data will only be published subject to your explicit consent.
- 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.
- 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;
- (b) 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,*
- *profession,*
- *country of residence,*
- *e-mail address of the respondent,*
- *the name of a self-employed individual (natural persons) on whose behalf the respondent is contributing,*
- *personal data related to the physical, economic, cultural, or social identity of the respondent, insofar as they are not falling under Article 10 of the Regulation,*
- *personal data included in the response or contribution to the targeted consultation activity, including (personal) opinions (if the targeted consultation at hand requires so),*
- *audio/video recording.*

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 (*or of its contractors (processors) if contractors are engaged to assist the controller*). 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?**

The following entities process your personal data on our behalf:

- Austrian National Public Health Institute (Gesundheit Österreich Beratungs GmbH/GÖ B), Stubenring 6, 1010 Wien, Austria
- RAND Europe (Eastbrook, Shaftesbury Road, Cambridge, CB2 8BF, United Kingdom)
- Milieu Consulting SRL (Chaussée de Charleroi 112, 1060 Brussels, Belgium)

Access to your personal data is provided to the Commission staff responsible for carrying out this *processing operation* (specifically, HaDEA and DG SANTE staff) and Commission contractors in charge of executing the study, namely **GÖ B** (Gesundheit Österreich Beratungs GmbH, Stubenring 6, 1010 Wien, Austria), **RAND Europe** (Eastbrook, Shaftesbury Road, Cambridge, CB2 8BF, United Kingdom) and **Milieu Consulting SRL** (Chaussée de Charleroi 112, 1060 Brussels, Belgium) 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.

Certain personal data may be made public on the Europa website, namely:

- any personal data on which you consented to their publication;
- personal data spontaneously provided by you in your contribution (without it being required by the targeted consultation activity).

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.

Transfers of personal data outside of the EU or the EEA (specifically to the UK) may occur in the context of the processing operation, for the Commission to carry out its tasks and to comply with its obligations under the applicable legislation and to the financing agreements with the partner/beneficiary countries.

Potential transfers of personal data to the partner/beneficiary countries take place on the basis of derogations set out in Regulation (EU) 2018/1725, namely for important reason of public interest (Article 50(1)(d)). Such public interest is outlined in articles 1 and 11 of the Treaty on European Union as well as in Article 298 of the Treaty on the Functioning of the European Union.

Processing of personal data by the processor may qualify as international transfer when the contractor is a non EU/EEA entity, use a local office located in the country where the project/programme is implemented or a non EU/EEA subcontractor.

Access to your personal data is provided to the Commission’s contractor responsible for carrying out the evaluation 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 at 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](mailto: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](mailto: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.