



EUROPEAN COMMISSION

PROTECTION OF YOUR PERSONAL DATA

This privacy statement provides information about the processing and the protection of your personal data.

Processing operation:

Targeted consultation activities (including surveys, interviews and workshops) to support the revision of the general pharmaceutical legislation

Data Controller: *Directorate General for Health and Food Safety (DG SANTE)/Directorate B/Unit B.5 – Medicines: policy, authorisation and monitoring*

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.

This privacy statement concerns the processing operation 'Targeted consultation activities', namely several types of data collection activities, including web-based targeted surveys, interviews and workshops, involving the main stakeholders affected by the general pharmaceutical legislation (Directive 2001/83/EC and Regulation (EC) No 726/2004) and conducted for an external study performed by a contractor to support the revision of this legislation undertaken by DG SANTE, Unit B.5 as presented below.

Technopolis Consulting Group Belgium (the data processor) established in Belgium is *the data processor*.

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

Purpose of the processing operation:

The purpose of the targeted consultation activities is to obtain the views of as well as facts, figures and evidence from stakeholders and individuals concerned by the subject matter of the targeted consultation activity at hand (hereafter, 'targeted consultation'). For the design, evaluation and revision of initiatives it is indispensable for the Commission to receive input and views from those who will be concerned by the policy or initiative.

Your views and contributions will not be published on a website directly as received; they will be published in the form of a summary report, or included in a wider policy document. Your identity will not be published but is your responsibility if you opt for confidentiality of your personal data to avoid any reference in your submission or contribution that would reveal your identity.

To avoid misuse, anonymous contributions to the targeted survey may not be accepted.

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) processing is necessary for compliance with a legal obligation to which the controller is subject.

The Union law which is the basis for the processing based on Articles 5(1)(a) and (b) of Regulation (EU) 2018/1725 is the Treaty of the European Union, and more specifically its Articles 1 and 11, 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 DG SANTE, Unit B.5 collects the following categories of personal data:

- *name and surname,*
- *profession,*
- *country of residence,*
- *e-mail address of the respondent,*
- *the name, size, type and transparency number of the organisation on whose behalf the respondent is contributing.*

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

5. How long do we keep your personal data?

DG SANTE, Unit B.5 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 retention period is without prejudice to an earlier elimination of personal data not part of the file or cases of administrative elimination.

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 European 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 notifications [DPO-1530.4 ARES-NOMCOM. ARES \(Advanced Records System\) et NOMCOM \(Nomenclature Commune\)](#), [DPO-3871-3 Notification for the digital archival repository and ARCHISscanning](#) and [DPO-2806-5 Gestion des dossiers papier structurés par nom de personnes et transférés aux Archives Historiques](#)).).

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 either on the servers of the European Commission or of its contractor Technopolis Consulting Group Belgium. All processing operations are carried out pursuant to the [Commission Decision \(EU, Euratom\) 2017/46](#) of 10 January 2017 on the security of communication and information systems in the European Commission.

The Commission's contractors are bound by a specific contractual clause for any processing operations of your data on behalf of the Commission, and by the confidentiality obligations deriving from the General Data Protection Regulation in the EU Member States ('GDPR' [Regulation \(EU\) 2016/679](#)).

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.

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 the revision of the general pharmaceutical legislation supported which these targeted consultation activities support 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.

The Commission as controller has contracted Technopolis Consulting Group Belgium to collect data on its behalf for the purpose of the targeted consultation activities as part of the external study described in section 1.

Technopolis Consulting Group Belgium uses the following subprocessors:

- Technopolis SARL (France)
- Technopolis BV (Netherlands)
- Technopolis Limited (UK)
- Milieu Law & Policy Consulting (Belgium)
- Utrecht University (Netherlands)

The contractor's server containing the personal data is located in the European Union.

Web-based third-party IT tools and other applications may be used to process your personal data: Microsoft 365 products and services (i.e. Outlook, Teams, Office and SharePoint), SurveyMonkey online survey tool, Trint transcription software, and Zoom video conferencing facility. Providers of these tools are committed to compliance with the EU GDPR data processing requirements.

These web-based tools use cookie technology for the technical functioning of the website (functional cookies) or for gathering statistics (analytical cookies). These may also link to other communication channels, including social media. The cookie-related information is however not used to identify data subjects personally. When you visit the website, there will be specific privacy statements and cookie policies that will indicate how long the browser history of your visit will be kept. We recommend that users read the relevant privacy policies carefully before using them. Enabling cookies is not strictly necessary for a website to work but it will provide you with a better browsing experience. If you prefer, you can configure your browser to reject all cookies, or to

notify you when a cookie is set. Each browser is different, so check the "Help" menu of your browser to learn how to change your cookie and privacy preferences. For more information about HTTP cookies and how to disable them, or restrict the categories of cookies you wish to accept, you can consult the information at www.allaboutcookies.org/manage-cookies/.

The use of a third-party IT tool does not in any way imply that the European Commission endorses them or their privacy policies. In the event that one or more third party IT tools are occasionally unavailable, we accept no responsibility for lack of service due to their downtime.

Transfer of personal data to the United Kingdom can be carried out based on an adequacy decision in line with Article 47 of Regulation (EU) 2018/1725.

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 DG SANTE, Unit B.5 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.

Any request for access to personal data will be handled within one month. Any other request mentioned above will be addressed within 15 working days.

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, DG SANTE, Unit B.5, EU-PHARMACEUTICAL-STRATEGY@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-11467**.