

PRIVACY STATEMENT

For processing of personal data related to EXPERT SELECTION PROCEDURES

Processing operation: Processing of personal data related to the call for expression of interest for the expert panels on medical devices and *in vitro* diagnostic medical devices

Data Controller responsible: European Commission - Directorate-General for Health and Food Safety, Directorate B - Health systems, medical products and innovation, Unit B.6 - Medical devices, Health Technology Assessment (hereinafter "DG SANTE B.6")

Record reference: DPR-EC-01066.1

1. Context and Controller

As the European Commission (hereinafter "Commission") and the European Medicines Agency (hereinafter "EMA") services collect and further process personal data, they are subject 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 and agencies and on the free movement of such data.

Personal data processing operations are under the responsibility of the Head of Unit, acting as Controller, of the Unit of the Commission publishing the particular Call for expression of interest for expert panels for medical devices and *in vitro* diagnostic medical devices.

2. What personal information do we collect, for what purpose, under which legal bases and through which technical means?

Types of personal data

Personal data collected and further processed concern the expert applicant as a natural person. Information can relate to all or some of the following data:

- Name (first name, family name, previous family name);
- Place and date of birth;
- Gender, nationality, title, function;
- Contact details (e-mail address, business telephone number, mobile telephone number, fax number, postal address, company and department, country of residence, internet address);
- Bank account reference (IBAN and BIC codes), VAT number, national insurance number, passport number, ID number will also be required from the selected candidates;
- Other personal data contained in the application forms or CVs (expertise, technical skills and languages, professional experience including details on current and past employment).

Purpose

Upon reception of your expression of interest by the Commission and EMA services, your personal data is collected and further processed for the purpose of the management and administration of selection of experts by Commission and EMA services under the responsibility of the Controller, either for appointment as panel members or for inclusion on a central list of available experts, as per Article 106 (5) and (6) of Regulation (EU) 2017/745.

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

Legal bases

The establishment of expert panels and the central list of available experts is stipulated by Regulation (EU) 2017/745 on medical devices (OJ L 117 5.5.2017 p.1-175), hereinafter the "Medical Device Regulation". These expert panels are also referred to by Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (OJ L 117 5.5.2017 p.176-332).

The legal bases for the processing operations on personal data is Council Regulation (EC, Euratom) N° 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union (hereinafter the "Financial Regulation") (OJ L193 of 30/07/2018), in particular Articles 237-238 for selection of experts as well as 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 and agencies and on the free movement of such data. We process your personal data, because processing is necessary for the performance of a task carried out in the public interest (Article 5(1)(a) of Regulation (EU) 2018/1725), since it allows for the selection of members of expert panels (individuals appointed as members in a personal capacity) and also increases the transparency on expert panels. Processing is also necessary to comply with a legal obligation to which the controller is subject (Article 5(1)(b) of Regulation (EU) 2018/1725).

As regards, in particular, the declarations of interests filled in by candidate members the processing of personal data serves the public interest of enabling the Commission to verify in the process of selection the experts' independence in performing their tasks. Furthermore, the public disclosure of declarations of interests of those experts once appointed allows for public scrutiny of the interests declared by these experts, which is necessary in order to ensure public confidence in the independence of these experts. The public disclosure of declarations of interests also ensures a high degree of transparency with respect to the membership of expert panels groups and aims at contributing to fostering the integrity of the experts in question.

Technical means

Your personal data is provided by submission of your expression of interest. The information is collected and stored in an isolated secure system until the selection

procedure is closed. Upon that closure, the information is processed by Commission and EMA personnel and transferred to Commission and/or EMA systems (as described in point 4.), under the responsibility of the Controller mentioned in point 1.

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

For the purpose detailed above, access to your personal data is given to the following persons, without prejudice to a possible transmission to the bodies in charge of a monitoring or inspection task in accordance with Community law:

- Commission and EMA staff responsible for carrying out this processing operation and to other authorised Commission and EMA staff according to the “need to know” principle. Such staff abide by statutory, and when required, additional confidentiality agreements;
- Members of the public: In case you are selected, your personal data will be made public, in accordance with the Commission's obligation to publish information on the outcome of the selection procedures and on the beneficiaries of funds deriving from the budget of the European Community (Articles 38 and 163 of the Financial Regulation, respectively), as well as legal obligations in Article 106(3) and (6) of the Medical Device Regulation and the implementing act making provisions for expert panels to be designated as per Article 106(1) of the Medical Device Regulation. The information will concern in particular your name and affiliation, CV and the declaration of interest form. It will be published on the website of the Commission dedicated to the operation of expert panels on medical devices and *in vitro* diagnostic devices.

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

The collected personal data and all related information are stored after closure of the call for expression of interest on the premises of the Commission and/or the EMA and on the Commission and/or the EMA servers of a computer data centre. The Commission premises and operations of all computer centres abide by the Commission's security decisions and provisions established by the Directorate of Security of the Commission. In particular, 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.

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.

5. 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 is 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 on grounds relating to your particular situation in accordance with Article 23(1) of Regulation (EU) 2018/1725.

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 7 below. 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.

6. How long do we keep your personal data?

For selection of experts, your personal data are kept for the duration of your involvement in the expert panels or as long as you are included in the central list of available experts in the service in charge of the procedure, and in the archives for a period of 5 years following the end of your involvement in the expert panels or removal of your name from the central list.

In case of reimbursement of expenses and payment of allowances, your personal data will be used for communication purposes until the end of the financial commitment and discharge.

Your personal data are also kept until the end of a possible audit, if one started before the end of the above period.

After the period mentioned above has elapsed, files containing personal data of experts are sampled to be sent to the historical archives of the Commission for further conservation. The non-sampled files are destroyed.

7. Contact information

- The Data Controller

Regarding the personal data collected in the course of the process of selection of the members of the expert panels, 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, please contact: SANTE-CONSULT-B6@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.