

SPECIFIC PRIVACY STATEMENT

Call for expressions of interest for the position of member of the Pharmacovigilance Risk Assessment Committee as representatives of healthcare professionals and patient organisations (PRAC/21/PH and PRAC/21/PO)

1. Objectives of the Call

The objective of the present Call is to invite applications for the positions of Commission appointed members to the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency ("EMA") established by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency¹, as amended by Regulation (EU) No 1235/2010².

Since management of the selection procedure involves the collection and further processing of some of your 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 data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC is applicable.

The processing of personal data in the context of the Call is under the responsibility of the Head of Unit A3 "Finances, budget and controls" of the European Commission's Directorate-General for Health and Food Safety, acting as the Controller.

2. What personal information do we collect and for what purpose?

Processing is based on Article 61a(1) of Regulation (EC) No 726/2004, according to which members of the Pharmacovigilance Risk Assessment Committee are appointed by the Commission on the basis of a public call for expression of interest and in case of healthcare professionals and patient organisation representatives after consulting the European Parliament.

Processing is lawful in accordance with Article 5(1)(a) and (b) of Regulation (EU) 2018/1725, since it is necessary for the performance of a task carried out in the public interest and for compliance with a legal obligation to which the Controller is subject under Article 61a(1) of Regulation (EC) No 726/2004.

For the purposes of appointing members and consulting the European Parliament, the following personal data are processed under the responsibility of the Controller at the Commission.

¹ OJ L 136, 30.4.2004, p. 1.

² OJ L 348, 31.12.2010, p.1.

2.1 Application form

The application form mainly collects identification data and contact information of applicants in the Call, together with data on the applicants' language knowledge, current employer, qualifications and professional experience.

This information is necessary to select the most suitable candidates to fill the position of members of the Pharmacovigilance Risk Assessment Committee and to ensure that they have the competence and collective expertise needed to guide EMA on matters relating to the fulfilment of its mission.

Your contact details will also be used by the Commission for the purposes of contacting you to inform you of the outcome of the selection procedure and if appropriate, for consulting the European Parliament. If you are appointed as a member, your contact details and a copy of your CV will be sent to EMA.

2.2 Declaration of interests form

The declaration of interests form collects data concerning the applicant's professional career (participation in scientific bodies, etc.), private interests (ownership or other investments, membership or affiliation, etc.) and interests of close family members.

This data needs to be collected to safeguard the independence of EMA, in line with the aim of Article 63(2) of Regulation (EC) No 726/2004 according to which members of EMA committees are to act in the public interest and in an independent manner.

In the context of the evaluation of candidates' applications prior to the adoption of the Commission's list, declaration of interest forms are submitted to EMA for screening purposes.

2.3 Other documents included in the application

The application must include a reference letter from organisation represented and Curriculum Vitae. Applicants may be requested to provide supporting documents at a later stage.

2.4 Evaluation data

Evaluation grids and other data relating to applicants are generated as a result of the assessment activities carried out by the selection committee with regard to the matching of applications against the evaluation criteria set out in the Call.

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

Access to your personal data is given, on a need-to-know basis, to the following actors involved in the selection procedure: staff members in the unit responsible for managing the Call, members of the selection committees and members of the Commission adopting the final decision on the list.

The applications are submitted to EMA for screening purposes of the potential competing interests.

In accordance with Article 61a(1) of Regulation (EC) No 726/2004, the list of candidates to represent healthcare professionals and patient organisations drawn up by the Commission is forwarded, together with the relevant background documentation, to the European Parliament. As soon as possible the European Parliament may submit its view for consideration to the Commission, which will then appoint the members of the Pharmacovigilance Risk Assessment Committee.

No personal data is transmitted to parties which are outside the recipients and the legal framework mentioned. This is without prejudice to the possible transmission of data to the bodies in charge of a monitoring or inspection task in conformity with EU law, including the European Court of Auditors, the Internal Audit Service, OLAF, the European Ombudsman and the European Data Protection Supervisor.

Applicants are also informed that the names of appointed members will be published on the webpage of the Directorate-General for Health and Food Safety for transparency reasons³. If you wish to object to such publication of your personal data on the grounds that it would harm your compelling and legitimate interests, you should contact the responsible Controller by using the "Contact Information" provided under Section 7 below and by explicitly stating your request.

4. How do we protect and safeguard your information?

Access to your data is only granted to a well-defined population of authorised users (staff members of the Commission involved in the management of the Call) and to staff in the IT service of the Directorate-General for Health and Food Safety for technical purposes.

Your personal data are stored in computers of the Directorate-General for Health and Food Safety, the operations of which underlie the Commission's security decisions and provisions established by the Security Directorate.

Appropriate measures are in place in accordance with Article 33 of Regulation (EU) 2018/1725, in particular to protect the data provided by applicants against possible misuse by internal or external persons. Specific protection mechanisms are used while transmitting the information to the recipients indicated under Section 3 above.

5. How can you verify, modify or delete your information?

In case you want to have access to your personal data or to have them rectified, erased or the processing of your personal data restricted in the cases referred to under Articles 17, 18, 19, 20 and 23 of Regulation (EU) 2018/1725, you should contact the responsible Controller by using the "Contact information" provided under Section 7 below and by explicitly stating your request. Legitimate requests will be replied by the Controller within 15 working days as from receipt of the request.

In particular, applicants have the right to request the rectification of their identification data at any time. In order to ensure fair and equal conditions for the selection process, data demonstrating compliance with the evaluation criteria set out in the Call may not be rectified or updated after the closing date for the Call.

Applicants may request access to their evaluation results once the decision on appointment for this position has been taken. However, where necessary to protect the confidentiality and independence of the deliberations of the (pre-selection and) selection committee(s), and the rights and freedoms of other persons in accordance with Article 81(1)(e) of Regulation (EU)

³ The list will be published at the following address: [Calls for expression of interest | Public Health \(europa.eu\)](#) .

2018/1725, access may be denied to (1) the comparative data concerning other applicants; (2) the individual opinions of the evaluators involved in the selection procedure.

6. How long do we keep your data?

Your data will be kept for 3 years after the end of the selection procedure. However, if you are among the candidates who have been appointed as members of the Pharmacovigilance Risk Assessment Committee, your data will be kept for a period corresponding to the entire duration of your mandate, if longer than the abovementioned period of 3 years.

7. Contact Information

In case you have questions concerning the processing of your personal data in the context of the Call, or would like to exercise your rights as data subject (see Section 5 above), you should contact the responsible Controller by using the following contact information and by explicitly stating your request and by referring in the subject to the reference number PRAC/21/PH or PRAC/21/PO, as appropriate:

DG SANTE Unit A3 "Finances, budget and controls"
European Commission
Directorate-General for Health and Food Safety
B -1049 Brussels
Belgium
SANTE-CALL-AGENCIES@ec.europa.eu

You may contact the European Commission's Data Protection Officer with regard to all issues related to the processing of your personal data and the exercise of your rights under Regulation (EU) 2018/1725 by using the following contact information:

Data Protection Officer
European Commission
1049 Bruxelles/Brussel
Belgium
data-protection-officer@ec.europa.eu

8. Recourse

Complaints against any data processing act executed under the Commission's responsibility can be addressed to the European Data Protection Supervisor at the following address:

European Data Protection Supervisor (EDPS)
Rue Wiertz 60
B-1047 Brussels
Belgium
Phone: +32 2 283 19 00
Fax: +32 2 283 19 50
edps@edps.europa.eu