EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Policy and administrative support
Finance, budget and controls

PUBLIC CALL FOR EXPRESSION OF INTEREST

AS COMMISSION APPOINTEES
TO THE EUROPEAN MEDICINES AGENCY
PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE

AS INDEPENDENT SCIENTIFIC EXPERTS (PRAC/23/EXP)

This Commission call for expression of interest relates to Commission appointments to the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA). With this call the Commission is looking for independent scientific experts.
Those experts are appointed as members of the PRAC for a period of three years, which may be prolonged once and thereafter renewed. This call is intended to select candidates to replace the current independent experts as of 2 July 2024. Current members may reapply.

What is the Pharmacovigilance Risk Assessment Committee?

Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines. The EU Pharmacovigilance system has been subject to a comprehensive review leading to a more robust legislation[1] that ensures the EU has now one of the world's most advanced pharmacovigilance systems.

One of the key features of the legislation which is in force since July 2012 is the creation of the Pharmacovigilance Risk Assessment Committee (PRAC) as a scientific committee of the European Medicines Agency. PRAC ensures the availability of the necessary expertise and resources for pharmacovigilance assessment at Union level and has a key function in the evaluation of the safety of medicines and risk minimisation measures at EU level, with the ultimate goal of reducing adverse drug reactions.[2]

Composition and role of the Pharmacovigilance Risk Assessment Committee

The Pharmacovigilance Risk Assessment Committee is composed of one member and one alternate appointed by each Member State, six scientific expert members appointed by the Commission, one member and alternate representing healthcare professionals appointed by the Commission and one member and alternate representing patient organisations appointed by the Commission. The six scientific experts are meant to

[1] Regulation (EC) No 726/2004 (OJ L 136, 30.4.2004, p.1) as amended by Regulation (EU) No 1235/2010, OJ L 348, 31.12.2010, p. 1.

[2] For ease of reference the provisions of the Regulation directly relating to the Pharmacovigilance Risk Assessment Committee are reproduced in the Annex to this document.

complement and strengthen the expertise provided by the Member States' appointees and the patient organisations' and healthcare professionals' representatives.

This call relates only to the appointment of the six scientific expert members. Article 61a of Regulation (EC) No 726/2004 stipulates that the Commission shall appoint to the PRAC six independent scientific expert members "with a view to ensuring that the relevant expertise is available within the Committee, including clinical pharmacology and pharmacoepidemiology" (Article 61a (1)(b)).

The mandate of the PRAC covers all aspects of the risk management of the use of medicinal products for humans including the detection, assessment, minimisation and communication relating to the risk of adverse reactions. More specifically, the Committee gives recommendations as part of any Union-wide post-authorisation assessment based on pharmacovigilance data relating to medicinal products for human use and is responsible for making recommendations on risk management systems and monitoring their effectiveness.

Key expertise needed by the Committee for performing its tasks consists of risk identification, risk assessment (including clinical pharmacology and pharmaco-epidemiology), risk management, risk minimisation, risk communication as well as knowledge on pharmacovigilance systems.

Workload and allowances

Appointees will be expected to attend the meetings of the Pharmacovigilance Risk Assessment Committee that will meet each month for a maximum of four consecutive days at the EMA premises.[3] They should be prepared to actively contribute to scientific discussions, to examine documents and to make comments during meetings of the Committee. Appointees will be involved in the Committee's procedures in the same way as any other members.

The independent scientific experts appointed by the Commission are expected to contribute to high level discussions in the Committee and to provide the necessary expertise for fulfilling its tasks.

Applicants should take into account that meetings in general involve preparatory work. They should also be willing to work with electronic methods for the management and exchange of documents. The working documents are in English and the meetings are also conducted in English. A very good command of English is therefore essential.

Travel, accommodation and subsistence costs for members of the PRAC will be met by the EMA according to its reimbursement rules for committee members.[4]

Independence – Conflict of interest

Members of the PRAC shall not have financial or other interests in the pharmaceutical industry and in the medical devices industry which could affect their impartiality. They

[3] Virtual meeting might replace the physical meetings. The arrangements are dealt with exclusively by the European Medicines Agency without the European Commission involvement.

[4] Cf. https://www.ema.europa.eu/en/documents/other/rules-reimbursement-expenses-delegates-attending-meetings-effect-16-june-2022_en.pdf

shall undertake to act in the public interest and in an independent manner and shall make an annual declaration of their financial and other interests and as soon as their interests change. Members are asked to provide declarations at each meeting of any specific interests which might be considered prejudicial to their independence in relation to the items on the agenda.

For this purpose it is essential that applicants submit, together with their application, a declaration of interests form, as explained below, which is fully completed. All applicants will be subject to a pre-screening of any potential conflict of interest in line with the rules of the EMA[5].

Any detected current direct interest will lead to the exclusion from the appointment process.

Assessment criteria:

According to the provisions of the Regulation (EC) No 726/2004, in particular Articles 61a (1) and (3), the members of PRAC shall be appointed on the basis of their relevant expertise in pharmacovigilance matters and risk assessment of medicinal products for human use, in order to guarantee the highest levels of specialist qualifications and a broad spectrum of relevant expertise. Moreover, the members shall be appointed with a view to ensuring that the relevant expertise is available within the Committee, including clinical pharmacology and pharmacoepidemiology.

Please note that based on Article 61a (1., point b) and (3) the Commission will take into account the expertise provided by the members already appointed to the PRAC.

Taking into account the above provisions and the provisions on the independence of members, the assessment of expressions will be based on:

- General scientific/medical expertise (including clinical and general practice, medical statistics) (scored out of 10)

- Specific scientific expertise in pharmacoepidemiology/ drug regulatory science/ biostatistics/ population data/ biologicals (such as vaccines)/ specific population (such as paediatric, elderly)/ therapeutic areas (such as hepatology, hematology, dermatology, nephrology, pharmacogenomics, ATMP, neurodevelopment disorders, oncology) / medicines used in pregnancy and breastfeeding/ big data in pharmacoepidemiology(scored out of 20)

- Specific pharmacovigilance expertise I, in the field of the risk management of the use of medicinal products for human use including the detection, assessment, minimisation and communication relating to the risk of adverse reactions and monitoring of effectiveness of risk management systems (scored out of 30)
- Specific pharmacovigilance expertise II, in the field of the design and the evaluation of post-authorisation safety studies and pharmacovigilance audit (scored out of 20)

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[5] Cf. European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts, available online under the following link: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&mid=WC0b01ac0580029338 and in particular https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en.pdf

- Regulatory expertise/experience in the area of medicinal products, including pharmacovigilance (scored out of 10)

Application procedure and closing date

Interested persons must complete both the application form and the form on declaration of interests below, which can both also be downloaded for on-screen completion from the Health and Food Safety Directorate-General's web-site at:

https://health.ec.europa.eu/medicinal-products/call-ema-committees-and-board-members_en#open-call

After completion, both the application form and the form on declaration of interests should be printed, signed and dated.

The application must include (a) a letter of motivation (signed), (b) the completed application form (signed), (c) the completed form on declaration of interests (signed), and (d) a CV. If appropriate, supporting documents may be annexed. The Commission reserves the right to ask for further supporting documents at a later stage, if deemed necessary.

Applications must be completed in one of the official languages of the European Union including the necessary documentation. It would, however, be appreciated, without it being a requirement, if at least a summary of experience and other pertinent information could be provided in English in order to facilitate the selection procedure.

In submitting an application, applicants accept the procedures and conditions as described in this Call and in the documents to which it refers. In compiling their application, applicants may under no circumstances refer to any documents submitted in prior applications (example: photocopies of previous applications will not be accepted). Any misrepresentation in supplying the required information may lead to exclusion from the present Call.

The **deadline** for submission of applications is **12:00 noon, Brussels time, 7 December 2023.**

Applications should be delivered:

By electronic means not later than 12:00 noon, Brussels time, 7 December 2023 to the following address:

SANTE-CALL-AGENCIES@ec.europa.eu

The subject of the email should contain the reference number of the call for expression of interest (PRAC/23/EXP).

For any further inquiry on this call, please contact SANTE-CALL-AGENCIES@ec.europa.eu by referring in the subject of the email to the reference number of the call: (PRAC/23/EXP).

Appointment process

All candidates applying to this call for expressions of interest will be informed of the outcome of the selection process.

Candidates who are not appointed may be invited to constitute a reserve list to be used in the event of the need to replace experts who are unable to complete their mandate.

Protection of personal data

The Commission will ensure that candidates' personal data are processed as required by Regulation (EU) No 2018/1725 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1). This applies in particular to the confidentiality and security of such data. For more detailed information on the scope, purposes and means of the processing of their personal data in the context of this Call, candidates are invited to consult the specific privacy statement published on the Call webpage at the following address: https://health.ec.europa.eu/medicinal-products/call-ema-committees-and-board-members_en

Brussels, October 2023

ANNEX

Provisions directly relating to the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 as amended by Regulation (EU) No 1235/2010, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

Article 56

1. The Agency shall comprise:

a) the Committee for Medicinal Products for Human Use, which shall be responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for human use;

aa) the Pharmacovigilance Risk Assessment Committee, which shall be responsible for providing recommendations to the Committee for Medicinal Products for Human Use and the coordination group on any question relating to pharmacovigilance activities in respect of medicinal products for human use and on risk management systems and it shall be responsible for monitoring the effectiveness of those risk management systems;

b) the Committee for Medicinal Products for Veterinary Use, which shall be responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for veterinary use;

c) the Committee on Orphan Medicinal Products;

d) the Committee on Herbal Medicinal Products;

da) the Committee for Advanced Therapies;

e) the Paediatric Committee

f) a Secretariat, which shall provide technical, scientific and administrative support for the committees and ensure appropriate coordination between them, and which shall provide technical and administrative support for the coordination group and ensure appropriate coordination between it and the Committees;

g) an Executive Director, who shall exercise the responsibilities set out in Article 64;

h) a Management Board, which shall exercise the responsibilities set out in Articles 65, 66 and 67.

2. The committees referred to in paragraph 1(a) to (da) may each establish standing and temporary working parties. The committees referred to in paragraph 1(a) and (b) may establish scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which the committee concerned may delegate certain tasks associated with drawing up the scientific opinions referred to in Articles 5 and 30.

   When establishing working parties and scientific advisory groups, the committees shall in their rules of procedures referred to in Article 61(8) provide for:

   a) the appointment of members of these working parties and scientific advisory groups on the basis of the lists of experts referred to in the second subparagraph of Article 62(2); and
   b) consultation of these working parties and scientific advisory groups.

3. The Executive Director, in close consultation with the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use, shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in Article 57(1)(n), particularly regarding the development of new therapies.

   Each committee shall establish a standing working party with the sole remit of providing scientific advice to undertakings.

4. The Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use may, if they consider it appropriate, seek guidance on important questions of a general scientific or ethical nature.

Article 61a

1. The Pharmacovigilance Risk Assessment Committee shall be composed of the following:

   a) one member and one alternate member appointed by each Member State, in accordance with paragraph 3 of this Article;
   b) six members appointed by the Commission, with a view to ensuring that the relevant expertise is available within the Committee, including clinical pharmacology and pharmacoepidemiology, on the basis of a public call for expressions of interest;

c) one member and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent healthcare professionals;

d) one member and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations.

The alternate members shall represent and vote for the members in their absence. The alternate members referred to in point (a) may be appointed to act as rapporteurs in accordance with Article 62.

2. A Member State may delegate its tasks in the Pharmacovigilance Risk Assessment Committee to another Member State. Each Member State may represent no more than one other Member State.

3. The members and alternate members of the Pharmacovigilance Risk Assessment Committee shall be appointed on the basis of their relevant expertise in pharmacovigilance matters and risk assessment of medicinal products for human use, in order to guarantee the highest levels of specialist qualifications and a broad spectrum of relevant expertise. For this purpose, Member States shall liaise with the Management Board and the Commission in order to ensure that the final composition of the Committee covers the scientific areas relevant to its tasks.

4. The members and alternate members of the Pharmacovigilance Risk Assessment Committee shall be appointed for a term of 3 years, which may be prolonged once and thereafter renewed following the procedures referred to in paragraph 1. The Committee shall elect its Chairman from among its members for a term of 3 years, which may be prolonged once.

5. Paragraphs 3, 4, 6, 7 and 8 of Article 61 shall apply to the Pharmacovigilance Risk Assessment Committee.

6. The mandate of the Pharmacovigilance Risk Assessment Committee shall cover all aspects of the risk management of the use of medicinal products for human use including the detection, assessment, minimisation and communication relating to the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product for human use, the design and evaluation of post-authorisation safety studies and pharmacovigilance audit.