EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Resource management and better regulation
Finance, budget and controls

PUBLIC CALL FOR EXPRESSION OF INTEREST

AS COMMISSION APPOINTEE TO THE PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE

A) AS REPRESENTATIVE OF PATIENT ORGANISATIONS (PRAC/24/PO) OR

B) AS REPRESENTATIVE OF HEALTHCARE PROFESSIONALS (PRAC/24/HP)

Corrigendum 1 dated 12/09/2024 – Deadline extension (see point 10 below)

1. Background

This Commission call for expressions of interest relates to the Commission appointments to the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA). With this call the Commission is looking for:

- Representatives of patient organisations (**PRAC/24/PO**);
- Representatives of healthcare professionals (**PRAC/24/HP**).

2. 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 is based on a 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 is the Pharmacovigilance Risk Assessment Committee as a scientific committee of the European Medicines Agency. The 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]

3. 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 and one member and alternate representing patient organisations.**

This call relates only to the appointment of the highlighted category of members.

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[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.

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 will give recommendations as part of Union-wide post-authorisation assessments based on pharmacovigilance data relating to medicinal products for human use and will be responsible for making recommendations on risk management systems and monitoring their effectiveness.

Key expertise needed by the Committee for performing its tasks includes risk identification, risk assessment, risk management, risk minimisation, risk communication as well as knowledge on pharmacovigilance systems.

The members of the PRAC are appointed for a period of three years, which may be prolonged once and thereafter renewed. The three-year term of the current members will end on 01 May 2025.

4. What is the specific role of patient organisation and healthcare professional representatives in the Committee?

- Patient organisation representative: One main task is patient advocacy to ensure that patient needs as a whole are taken into account in the deliberations of the Committee. Public safety communication on individual medicinal products should for example consider specific patient requirements. The candidate should be a member of a patient organisation. Although a medical background is not a requirement, a broad knowledge of medical and legislative issues related to the approval and use of medicines is recommended and will be needed to effectively contribute to the scientific discussions of the Committee. A broad understanding of pharmaceutical safety issues in specific disease areas and beyond and related regulatory aspects would be an advantage.

- Healthcare professional representative: This member should ensure that the needs of practitioners, clinicians, pharmacists or other healthcare professionals on the ground and real-life implications are taken into account, when addressing safety issues, particularly in consideration of the fact that some of the outcome documents produced by the Committee will be addressing the healthcare professional directly. The candidate should be a member of a healthcare professional organisation and have a good understanding of pharmacovigilance related matters. Proven experience in liaison and communication with healthcare professionals will be an advantage.

5. Workload and allowances

Active and regular participation of the appointees in EMA Committee meetings is essential for the functioning of the Committee. Appointees will be expected to attend and actively participate in the meetings of the Pharmacovigilance Risk Assessment Committee, for the duration of their mandate.

The Committee holds its meetings either physically at the EMA premises in Amsterdam, The Netherlands or in a fully remote setting, where all participants connect to the meeting remotely. In-person attendance for physical meetings is expected for the

appointee in order to contribute to quorum and to voting on Committee opinions. The Committee meets each month for a maximum of four consecutive days [3]

Appointees should be prepared to contribute to scientific discussions, to examine documents and to make comments during meetings of the Committee, with a specific focus on the target group they represent (patients or healthcare professionals). Appointees will be involved in the Committee's procedures in the same way as other members, as relevant. They should respect the procedural and legal timelines.

Applicants should take into account that meetings 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. Therefore, a good command of English is essential.

More information about the role of patients and healthcare professionals in EMA scientific committees is available at: https://www.ema.europa.eu/en/documents/other/role-members-representing-patients-and-healthcare-professionals-organisations-ema-scientific-committees_en.pdf

For physical meetings travel, accommodation and subsistence costs for the members of the Committee will be met by the EMA according to its reimbursement rules for delegates.[4]

6. Transparency

The activities of the committees shall be carried by observing principles of transparency. EMA shall publish all relevant documents on a dedicated website. In particular, it shall make available to the public, without undue delay: — the names of the members of the committee; — the members' curriculum vitae and declarations of interests; — the committee rules of procedure; — certain opinions adopted by the committee in accordance with the relevant legislation; - the agenda and minutes of committee meetings, including a list of participants.

7. Duty of confidentiality

Article 76 of Regulation (EC) No 726/2004 sets out a duty of confidentiality for members of scientific Committees. They must treat information on EMA's work with the utmost discretion and confidentiality and must not disclose information of the kind covered by the obligation of professional secrecy, even after their duties have ceased.

8. Independence – Conflict of interest

Members of the PRAC shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They 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 or as soon as their interests change. Members are required to provide declarations of any specific interests at each meeting, which might be considered prejudicial to their independence in relation to the items on the agenda.

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[3] Meetings dates are published at this link.

[4] Cf. Rules for reimbursement of expenses for delegates and experts attending meetings.

For this purpose, it is essential that applicants submit, together with their application, a duly completed declaration of interest form (as explained below). All applicants will be subject to a pre-screening of any potential competing interests in line with the rules of EMA[5]. **Any detected current direct interest will lead to the exclusion from the appointment process**.

9. Assessment criteria

For representatives of patient organisations (PRAC/24/PO) assessment of expressions of interest will be based on:

- Whether individuals represent patient organisations. Ability and experience in representing organisations, and the characteristics of the organisations represented will be assessed (i.e. representing the interests and perspectives of those directly affected by regulatory decisions). Representing organisations active at European level would be an asset.
- Whether individuals have competencies and experience relevant to the tasks of the Pharmacovigilance Risk Assessment Committee according to Article 56(1)(aa) and Article 61a(6) of Regulation No (EC) 726/2004[6].

For representatives of healthcare professionals (PRAC/21/HP) assessment of expressions of interest will be based on:

- Whether individuals represent healthcare professionals. Ability and experience in representing organisations, and the characteristics of the organisations represented will be assessed (i.e. representing the interests and perspectives of those directly affected by regulatory decisions). Representing organisations active at European level would be an asset.
- Whether individuals have competencies and experience relevant to the tasks of the Pharmacovigilance Risk Assessment Committee according to Article 56(1)(aa) and Article 61a(6) of Regulation No (EC) 726/2004[7].

The documents adopted by EMA on the criteria to be fulfilled by patients' and healthcare professionals' organisations will be considered in the assessment process.[8]

10. Application procedure and closing date

Interested persons must comply with the requirements below, otherwise their applications will not be taken into consideration.

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[5] Cf. European Medicines Agency policy on the handling of competing interests, available online under the following link: https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees-members-and-experts_en.pdf

[6] See Annex for details of these Articles.

[7] See Annex for details of these Articles.

[8] Criteria to be fulfilled by patients' and consumers' organisations or by healthcare professionals' organisations involved in European Medicines Agency (EMA) activities.
And: Assessment of patient, consumer and healthcare professional organisations' compliance with EMA eligibility criteria.

Interested persons must complete, print, sign and date the application and the declaration of interests forms, which are available on the Health and Food Safety Directorate-General's website:

https://ec.europa.eu/health/documents/public_call/call_index_en

The application must include:

(a) the completed **application form** (signed),
(b) the completed **declaration of interests form** (signed),
(c) a **CV**,
(d) a **recommendation letter** from the organisation that the applicant wishes to represent.

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

The appointment is nominal for individual natural persons. However, these individuals are appointed with the purpose of representing interested parties via organisations at the European level. Therefore, applications to this Call need to be submitted in agreement with the organisation that the applicant intends to represent. This agreement should be demonstrated in the recommendation letter – as an attachment (d) for the application.

Organisations can put forward (i.e. support by a recommendation letter) more than one candidate.

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 the supplied information may lead to exclusion from the present Call.

The **deadline** for submission of applications is **30.09.2024** 11:59 pm, Brussels time.

The completed application must be sent by electronic means not later than **30.09.2024**, 11:59 pm, Brussels time, to the following electronic address: SANTE-CALL-AGENCIES@ec.europa.eu

The subject of the email should contain the reference number of the call for expression of interest. For representatives of healthcare professionals the reference number is PRAC/24/HP, for representatives of patient organisations the reference number is PRAC/24/PO.

For any further information 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/24/HP or PRAC/24/PO, as appropriate.

11. 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.

The European Parliament will be consulted prior to the appointment. Subsequently, the Commission will appoint the most suitable candidate as a member to the Committee, and the second-best as alternate.

12. Protection of personal data

The Commission will ensure that candidates' personal data are processed as required by 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 6 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 (OJ L 295, 21.11.2018, p. 39). 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://ec.europa.eu/health/documents/public_call/call_index_en

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.