EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Relations with agencies and advisory groups

PUBLIC CALL FOR EXPRESSION OF INTEREST

AS COMMISSION APPOINTEE TO THE PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE

A) AS REPRESENTATIVE OF PATIENT ORGANISATIONS (PRAC/15/PO) OR

B) AS REPRESENTATIVE OF HEALTHCARE PROFESSIONALS (PRAC/15/HP)

Background

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

- Representatives of patient organisations (**PRAC/15/PO**);
- Representatives of healthcare professionals (**PRAC/15/HP**).

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 new legislation which is in force since July 2012 is the creation of the Pharmacovigilance Risk Assessment Committee ('PRAC') as a new scientific committee of the European Medicines Agency. PRAC ensures the availability of the necessary expertise and resources for pharmacovigilance assessment at Union level and will have 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

[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.

by the Commission, one member and alternate representing healthcare professionals and one member and alternate representing patient organisations.

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 any Union-wide post-authorisation assessment 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 29 February 2016.

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

- Patient organisation representative: One main task is patient advocacy so 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.

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 in London, UK. 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.

In this regard representatives of healthcare professionals and patient organisations are expected to have a specific focus on the target group they represent (advocacy). They

should provide input based on the real-life experience of those affected by a disease and its current therapeutic environment. They are also expected to contribute by assessing the real-life implications of regulatory decisions.

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 language of the Committee is English.

Travel, accommodation and subsistence costs for the members of the Committee will be met by the EMA according to its reimbursement rules for delegates.[3]

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 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 recently tightened rules of the EMA[4]. Any detected current direct interest will lead to the exclusion from the appointment process.

Assessment criteria

For representatives of patient organisations (PRAC/15/PO) assessment of expressions of interest will be based on:

- Whether individuals represent patient organisations. 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[5];
- Ability and experience in representing organisations, and the characteristics of the organisations represented (i.e. representing the interests and perspectives of those directly affected by regulatory decisions);
- The absence of financial or other interests in the pharmaceutical industry which could affect impartiality of members of the scientific committees' members and experts.

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[3] Cf. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/12/WC500017930.pdf.

[4] 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

[5] See Annex for details of these Articles.

For representatives of healthcare professionals (PRAC/15/HP) assessment of expressions of interest will be based on:

- Whether individuals represent healthcare professionals. 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];
- Ability and experience in representing organisations, and the characteristics of the organisations represented (i.e. representing the interests and perspectives of those directly affected by regulatory decisions);
- The absence of interests in the pharmaceutical industry which could affect impartiality of members of the scientific committees' members and experts.

The documents adopted by the European Medicines Agency on the criteria to be fulfilled by patients' and healthcare professionals' organisations will be considered in the assessment process.

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/12/WC500018099.pdf
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/12/WC500119624.pdf

Application procedure and closing date

Interested persons must comply with the requirements below. Otherwise their applications will not be taken into consideration.
Interested persons must complete the application form and the form on declaration of interests, which can be downloaded for completion from the Health and Food Safety Directorate-General's web-site at:

http://ec.europa.eu/health/documents/public_call/call_index_en.htm

After completion, 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.

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.

It would be preferable that applications for representatives of healthcare professionals and patient organisations be submitted by the organisations they represent.

[6] See Annex for details of these Articles.

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 **30 September 2015**.

The completed application must be sent:

(a) either by electronic means not later than 30 September 2015 to the following address: SANTE-CALL-COMMITTEES-EMA@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/15/HP, for representatives of patient organisations the reference number is PRAC/15/PO.

(b) or by post or by courier service not later than 30 September 2015 (date as postmarked or the date of the deposit slip) to the following address:

European Commission
DG Health and Food Safety
Unit SANTE 03
To the attention of Mr R. Vanhoorde
- Call for interest PRAC/15/HP (use this reference for healthcare professionals)
- Call for interest PRAC/15/PO (use this reference for patient organisations)
Office F101 04/168
B-1049 Brussels
Belgium

For any further information on this call, please contact SANTE-CALL-COMMITTEES-EMA@ec.europa.eu by referring in the subject of the email to the reference number of the call: PRAC/15/HP or PRAC/15/PO, as appropriate.

Appointment process

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

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.

Protection of personal data

The Commission will ensure that candidates' personal data are processed as required by Regulation (EC) No 45/2001 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:

http://ec.europa.eu/health/documents/public_call/call_index_en.htm

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.