EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Resource management and better regulation
Finance, budget and controls

PUBLIC CALL FOR EXPRESSIONS OF INTEREST
as Commission appointees to the Committee for Orphan Medicinal Products to represent patient organisations (COMP/20/P)

This European Commission call for expressions of interest relates to the appointment by the Commission of members representing patients' organisations to the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA).

Background

Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products[1] ("the Regulation") lays down specific rules concerning the criteria and procedure for the designation of an orphan medicinal product. Central to the operation of this Regulation is the Committee for Orphan Medicinal Products (COMP) established as part of the EMA.

According to Article 4(3) of the Regulation the COMP shall include "three members nominated by the Commission to represent patients' organisations". These members shall be appointed for a term of three years, which shall be renewable.

The mandate of the appointed members will run from 1 July 2021 to 30 June 2024. Current members may reapply.

Composition and role of the COMP

The COMP is composed of one member nominated by each Member State, three members nominated by the Commission to represent patients' organisations and three members nominated by the Commission on the basis of a recommendation from the EMA.

The main task of the COMP is to examine applications for the designation of a medicinal product as an orphan medicinal product which is submitted to it in accordance with the Regulation on Orphan Medicinal Products.

Other tasks of the COMP are:

[1] OJ L 18, 22.1.2000

- to advise the Commission on the establishment and development of a policy on orphan medicinal products for the EU;

- to assist the Commission in liaising internationally on matters relating to orphan medicinal products, and in liaising with patient support groups;

- to assist the Commission in drawing up detailed guidelines.

What is the specific role of patient organisation representatives' in the Committee?

Patient organisation representative: The main task is patient advocacy so to ensure that patients' needs as a whole are taken into account in the deliberations of the Committee. The candidate should be a member of a patient organisation. Although a medical background is not a requirement, a broad knowledge of medical and to a certain extent regulatory issues related to the research, approval and use of medicines is recommended and will be needed to effectively contribute to the scientific discussions of the Committee.

Workload and allowances

Appointees will be expected to attend the meetings of the COMP which meets once a month at the EMA premises.[2]

The members should be prepared to actively contribute to scientific discussions, to examine documents and to make comments having a specific focus on the target group they represent (patients). They should respect the procedural and legal timelines provided by the Regulation on Orphan Medicinal Products.

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. The very good command of English is therefore essential.

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

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[2] Meeting dates are published here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/comp_meetings_landing_page.jsp&mid=WC0b01ac0580028e77

Virtual meeting might replace the physical meetings as long as the sanitary situation requires so. The arrangements are dealt with exclusively by the European Medicines Agency without the European Commission involvement.

[3] Cf. https://www.ema.europa.eu/en/documents/other/rules-reimbursement-expenses-delegates-attending-meetings-effect-14-june-2019_en.pdf

Independence – Conflict of interest

Members of COMP 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 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 interest 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 EMA[4]. Any detected direct interest will lead to the exclusion from the appointment process.

Assessment criteria

Assessment of expressions of interest will be based on:

- Whether individuals represent patient organisations. Representing organisations active at a European level will be considered an asset. Ability and experience in representing organisations, and the characteristics of the organisations represented will be assessed;

- Whether individuals have competencies and experiences relevant to the tasks of the COMP listed in Article 4 (2) of the Regulation on Orphan Medicinal Products (*to consult the list of task of the Committee see annex below);*

The documents adopted by the European Medicines Agency on the criteria to be fulfilled by patients' organisations will be considered in the assessment process[5].

Application procedure and closing date

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

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

After completion, the application form and the form on declaration of interest 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)[6], and (d) a CV. If

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[4] More information on the rules of conflict of interest are available here: https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-competing-interests-scientific-committees_en.pdf

[5] http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/12/WC500018099.pdf

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.

Applications are preferably to be submitted by the represented organisations.

The **deadline** for submission of applications is **18 December 2020.**

The complete application must be sent by electronic means not later than **18 December 2020** to the following address: SANTE-CALL-AGENCIES@ec.europa.eu .

The subject of the e-mail should contain the reference number of the call for expression of interest: COMP/20/P.

For any further information on this call, please contact: SANTE-CALL-AGENCIES@ec.europa.eu by referring in the subject of the e-mail to the reference number of the call: COMP/20/P.

Appointment process

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 members 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 (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:

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

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[6] Due to current sanitary restrictions access to office equipment (like scanner, printers) might be restricted. To accommodate this difficultly the Commission will, on an exceptional basis, accept the application documents without a written signature by the date of the call deadline expiry. The handwritten signature (or an equivalent electronic signature) are however necessary and the applicants are urged to arrange at their earliest convenience the delivery of signed documentation to the email address SANTE-CALL-AGENCIES@ec.europa.eu. **The Commission Services reserves the right to require the signed copy of documentation at the later stage of the selection procedure.**

Brussels, October 2020.

ANNEX

Provisions directly relating to the Committee for Orphan Medicinal Products of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products

Article 4

Committee for Orphan Medicinal Products

1. A Committee for Orphan Medicinal Products, hereinafter referred to as 'the Committee', is hereby set up within the Agency.

2. The task of the Committee shall be:

(a) to examine any application for the designation of a medicinal product as an orphan medicinal product which is submitted to it in accordance with this Regulation;

(b) to advise the Commission on the establishment and development of a policy on orphan medicinal products for the European Union;

(c) to assist the Commission in liaising internationally on matters relating to orphan medicinal products, and in liaising with patient support groups;

(d) to assist the Commission in drawing up detailed guidelines.

3. The Committee shall consist of one member nominated by each Member State, three members nominated by the Commission to represent patients' organisations and three members nominated by the Commission on the basis of a recommendation from the Agency. The members of the Committee shall be appointed for a term of three years, which shall be renewable. They may be accompanied by experts.

4. The Committee shall elect its Chairman for a term of three years, renewable once.

5. The representatives of the Commission and the Executive Director of the Agency or his representative may attend all meetings of the Committee.

6. The Agency shall provide the secretariat of the Committee.

7. Members of the Committee shall be required, even after their duties have ceased, not to disclose any information of the kind covered by the obligation of professional secrecy.