EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, European Medicines Agency

PUBLIC CALL FOR EXPRESSION OF INTEREST

AS COMMISSION APPOINTEES
TO THE EUROPEAN MEDICINES AGENCY PAEDIATRIC COMMITTEE
TO REPRESENT PATIENT ASSOCIATIONS (PDCO/13/PO) OR
HEALTH PROFESSIONALS (PDCO/13/HP)

This Commission call for expression of interest relates to Commission appointments to the Paediatric Committee (PDCO) of the European Medicines Agency (EMA). With this call the Commission is looking for:

- Representatives of patient associations (reference: PDCO/13/PO)
- Representatives of health professionals (reference: PDCO/13/HP).

Those representatives are appointed as members of the PDCO for a renewable period of three years. The three-year term of the current members started on 1 August 2011 and ends on 31 July 2014. This call is intended to select candidates to replace the current civil society representatives as of 1 August 2014. Current members may reapply.

What is the Paediatric Committee?

The Paediatric Regulation (Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use) aims to facilitate the development and accessibility of medicinal products for use in the paediatric population, to ensure that medicinal products used to treat children are subject to research of high quality and are appropriately authorised for its use, and to improve the information available on the use of medicinal products in the various paediatric populations.

To meet these objectives, the Regulation establishes a system of obligations, rewards and incentives for the pharmaceutical industry for when medicinal products are developed.

The Regulation gives the EMA and its Paediatric Committee primary responsibility for handling the operational aspects of the legislation and for discussing individual development projects with companies. The Paediatric Committee (PDCO) is therefore central to the operation of the Regulation.

Like other Committees of the EMA it consists of representatives of Member States competent authorities, but foresees additionally the participation of representatives of civil society. Those members represent patient associations and health professionals. They are involved in the committee's procedures in the same way as other members.

Composition and remit of the Paediatric Committee

The Paediatric Committee is composed of five members of the Committee for Medicinal Products for Human Use (CHMP) with their alternates, appointed by the CHMP itself; one member and one alternate appointed by each Member State (except Member States already represented through the members appointed by the CHMP); three members and alternates representing health professionals and three members and alternates representing patients' associations.

The main responsibility of PDCO is to assess the content of submitted paediatric investigation plans and adopt opinions on them in accordance with the Paediatric Regulation. This includes the assessment of applications for a full or partial waiver and assessment of applications for deferrals.

Other tasks of the Paediatric Committee include:

- assessing data generated in accordance with agreed paediatric investigation plans and adopting opinions on the quality, safety or efficacy of any medicine for use in the paediatric population (at the request of the CHMP or a competent authority);
- advising and supporting the EMA on the creation of a European network of persons and bodies with specific expertise in the performance of studies in the paediatric population;
- providing advice on any question relating to paediatric medicines;
- establishing and regularly updating an inventory of paediatric medicinal product needs;
- advising the EMA and the European Commission on the communication of arrangements available for conducting research into paediatric medicines.

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

Patient organisation representative: One main task is patient advocacy so to ensure that children's (and parents') 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.

Health professional representative: This member should ensure that the needs of practitioners, clinicians, pharmacists or other health professionals on the ground and real-life implications are taken into account, when addressing paediatric research projects. The candidate should be a member of a health professional organisation and have a good understanding of paediatric related matters. Proven experience in liaison and communication with health professionals will be an advantage.

Workload and allowances

Appointees will be expected to attend the Paediatric Committee which meets three consecutive days each month at the EMA in London, UK.[1] They should be prepared to actively contribute to scientific discussions, to examine documents and to make comments during meetings of the Committee having a specific focus on the target group they represent (patients or health professionals). They should respect the procedural and legal timelines provided by the Paediatric Regulation.

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

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.

Travel, accommodation and subsistence costs for members of the Paediatric Committee will be met by the EMA according to its reimbursement rules for committee members.

Independence – Conflict of interest

Members of the PDCO 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 interests as well as 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.[2] Any detected direct interest will lead to the exclusion from the appointment process.

Assessment criteria

For representatives of patient associations assessment of expression of interest will be based on:

- Whether individuals represent patient associations at a European level;
- Whether individuals have competencies and experience relevant to the tasks of the Paediatric Committee listed in Articles 6(1) and 4(1) third subparagraph of the Paediatric Regulation;

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[1] Meeting dates are published here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000265.jsp&mid=WC0b01ac0580028e9d.

[2] Cf. European Medicines Agency policy on the handling of conflict of interests of scientific committee members and experts, available online under the following link http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf.

- Ability and experience in representing organisations, and the characteristics of the organisations represented;
- Good knowledge of the English language.

For representatives of health professionals assessment of expression of interest will be based on:

- Whether individuals represent health professionals at a European level;
- Whether individuals have competencies and experience relevant to the tasks of the Paediatric Committee listed in Article 6(1) and 4(1) third subparagraph of the Paediatric Regulation;
- Ability and experience in representing organisations, and the characteristics of the organisations represented;
- Good knowledge of the English language.

Please note that in accordance with Article 4(1) last subparagraph of the Paediatric Regulation, the Commission will take into account the expertise provided by the members already appointed to the PDCO.[3]

Application procedure and closing date

Interested persons must complete 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 Consumers Directorate-General's web-site at:

http://ec.europa.eu/health/human-use/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 health professionals and patient associations be submitted by the organisations they represent. The organisation may suggest a pair consisting of a member and an alternate.

The **deadline** for submission of applications is **8 November 2013**.

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[3] In view of the current composition of the PDCO, expertise in the following areas would be considered as an advantage: clinical trial methodology / medical statistics, child and adolescent psychiatry, paediatric pharmacology, and toxicology / preclinical studies, but also in the disciplines of paediatric oncology, vaccines (for prevention of infectious diseases), medical ethics, pharmacovigilance and public health.

Applications should be submitted:

(a) either by electronic means not later than 8 November 2013 to the following address: Sanco-pharmaceuticals-D5@ec.europa.eu

> The subject of the email should contain the reference number of the call for expression of interest. For representatives of health professionals the reference number is PDCO/13/HP, for representatives of patient associations the reference number is PDCO/13/PO.

(b) or by post or by courier service not later than 8 November 2013 (date as postmarked or the date of the deposit slip) to the following address:

> European Commission
> Health and Consumers Directorate-General
> Unit D5 "Medicinal products – authorisations, European Medicines Agency"
> - Call for interest PDCO/13/HP (use this reference for health professional organisations)
> - Call for interest PDCO/13/PO (use this reference for patient associations)
> DM24 02/133
> BE-1049 Brussels

For any further inquiry on this call, please contact Sanco-pharmaceuticals-D5@ec.europa.eu by referring in the subject of the email to the reference number of the call: PDCO/13/HP or PDCO/13/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.

In accordance with the legal requirements, the European Parliament will be consulted prior to the appointment. Subsequently, the Commission will appoint the most suitable candidates as members to the Committee, and the second-best as alternates.

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/human-use/index_en.htm

Brussels, September 2013

ANNEX

Provisions directly relating to the Paediatric Committee of Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use[4]

Article 3

1. By 26 July 2007, a Paediatric Committee shall be established within the European Medicines Agency set up under Regulation (EC) No 726/2004, hereinafter 'the Agency'. The Paediatric Committee shall be considered as established once the members referred to in Article 4 (1)(a) and (b) have been appointed.

The Agency shall fulfil the secretariat functions for the Paediatric Committee and shall provide it with technical and scientific support.

2. Save where otherwise provided for in this Regulation, Regulation (EC) No 726/2004 shall apply to the Paediatric Committee, including the provisions on the independence and impartiality of its members.

3. The Executive Director of the Agency shall ensure appropriate coordination between the Paediatric Committee and the Committee for Medicinal Products for Human Use, the Committee for Orphan Medicinal Products, their working parties and any other scientific advisory groups.

The Agency shall draw up specific procedures for possible consultations between them.

Article 4

1. The Paediatric Committee shall be composed of the following members:

(a) five members, with their alternates, of the Committee for Medicinal Products for Human Use, having been appointed to that Committee in accordance with Article 61(1) of Regulation (EC) No 726/2004.

These five members with their alternates shall be appointed to the Paediatric Committee by the Committee for Medicinal Products for Human Use;

(b) one member and one alternate appointed by each Member State whose national competent authority is not represented through the members appointed by the Committee for Medicinal Products for Human Use;

(c) three members and three alternates appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent health professionals;

(d) three members and three alternates 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 associations.

The alternates shall represent and vote for the members in their absence.

For the purposes of points (a) and (b), Member States shall cooperate, under the coordination of the Executive Director of the Agency, in order to ensure that the final composition of the Paediatric Committee, including members and alternates, covers the scientific areas relevant to paediatric medicinal products, and including at least: pharmaceutical development, paediatric medicine, general practitioners, paediatric pharmacy, paediatric pharmacology, paediatric research, pharmacovigilance, ethics and public health.

For the purposes of points (c) and (d), the Commission shall take into account the expertise provided by the members appointed under points (a) and (b).

2. The members of the Paediatric Committee shall be appointed for a renewable period of three years. At meetings of the Paediatric Committee, they may be accompanied by experts.

3. The Paediatric Committee shall elect its Chairman from among its members for a term of three years, renewable once.

4. The names and qualifications of the members shall be made public by the Agency.

[4] Official Journal of the European Union, L 378, 27.12.2006, p.1.

Article 5

1. When preparing its opinions, the Paediatric Committee shall use its best endeavours to reach a scientific consensus. If such a consensus cannot be reached, the Paediatric Committee shall adopt an opinion consisting of the position of the majority of the members. The opinion shall mention the divergent positions, with the grounds on which they are based. This opinion shall be made accessible to the public pursuant to Article 25(5) and (7).

2. The Paediatric Committee shall draw up its rules of procedure for the implementation of its tasks. The rules of procedure shall enter into force after receiving a favourable opinion from the Management Board of the Agency and, subsequently, from the Commission.

3. All meetings of the Paediatric Committee may be attended by representatives of the Commission, the Executive Director of the Agency or his representatives.

Article 6

1. The tasks of the Paediatric Committee shall include the following:

(a) to assess the content of any paediatric investigation plan for a medicinal product submitted to it in accordance with this Regulation and formulate an opinion thereon;

(b) to assess waivers and deferrals and formulate an opinion thereon;

(c) at the request of the Committee for Medicinal Products for Human Use, a competent authority or the applicant, to assess compliance of the application for a Marketing Authorisation with the agreed paediatric investigation plan concerned and formulate an opinion thereon;

(d) at the request of the Committee for Medicinal Products for Human Use or a competent authority, to assess any data generated in accordance with an agreed paediatric investigation plan and formulate an opinion on the quality, safety or efficacy of the medicinal product for use in the paediatric population;

(e) to advise on the content and format of data to be collected for the survey referred to in Article 42;

(f) to support and advise the Agency on establishing the European network referred to in Article 44;

(g) to assist scientifically in the elaboration of any documents related to the fulfilment of the objectives of this Regulation;

(h) to provide advice on any question related to medicinal products for use in the paediatric population, at the request of the Executive Director of the Agency or the Commission;

(i) to establish a specific inventory of paediatric medicinal product needs and update it on a regular basis, as referred to in Article 43;

(j) to advise the Agency and the Commission regarding the communication of arrangements available for conducting research into medicinal products for use in the paediatric population;

(k) to make a recommendation to the Commission on the symbol referred to in Article 32(2).

2. When carrying out its tasks, the Paediatric Committee shall consider whether or not any proposed studies can be expected to be of significant therapeutic benefit to and/or fulfil a therapeutic need of the paediatric population. The Paediatric Committee shall take into account any information available to it, including any opinions, decisions or advice given by the competent authorities of third countries.