EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Pharmaceuticals

PUBLIC CALL FOR EXPRESSION OF INTEREST

AS COMMISSION APPOINTEES
TO THE EUROPEAN MEDICINES AGENCY PAEDIATRIC COMMITTEE
TO REPRESENT PATIENT ASSOCIATIONS OR HEALTH PROFESSIONALS (PDCO/10/PH/1)

This Commission call for expression of interest relates to Commission appointees to the European Medicines Agency (EMA) Paediatric Committee to represent health professionals and patient associations (reference: PDCO/10/PH/1).

Background

Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use lays down rules concerning the development of medicinal products for human use in order to meet the specific therapeutic needs of the paediatric population. Central to the operation of the regulation is the Paediatric Committee (PDCO) established as part of the EMA.

The Paediatric Committee is the second scientific committee within the Agency in which representatives of civil society participate as full members. Those members represent patient associations and health professionals. They are involved in the committee's procedures in the same way as any other members.

According to Article 4 of the Regulation PDCO shall include "three members and three alternates appointed by the Commission, on the basis of a public call for expression of interest, after consulting the European Parliament, in order to represent health professionals" as well as three members and three alternates in order to represent patient associations.

Those members are appointed for a renewable period of three years. The first appointment after the creation of the Paediatric Committee took effect on 1 August 2008. Hence, the term of the current members ends on 31 July 2011.

This call is intended to select candidates to replace the members that were appointed for the period starting on 1 August 2008. Current members may reapply.

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

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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 Regulation (EC) No 1901/2006 as amended. 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 Agency 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 (at the request of the Agency's Executive Director or the European Commission);
- establishing and regularly updating an inventory of paediatric medicinal product needs;
- advising the Agency and the European Commission on the communication of arrangements available for conducting research into paediatric medicines.

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.

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.

Independence

Members of the Paediatric Committee should not have financial or other interests in the pharmaceutical industry which could affect their impartiality, should undertake to act in

[1] Meeting dates are published here: http://www.ema.europa.eu/htms/human/paediatrics/pdco.htm.

the public interest and in an independent manner and should make an annual declaration of their financial interest.[2]

Selection criteria

Assessment of expressions will be based on:

- Whether individuals represent either health professional or patient associations at a European level;
- Whether individuals have competencies and experience relevant to the tasks of the Paediatric Committee listed in Article 6(1) of the paediatric regulation;
- Whether individuals have experience relevant to the competencies of the Paediatric Committee listed in Article 4(1) third subparagraph of the paediatric regulation;
- Based on Article 4(1) last subparagraph, the Commission shall take into account the expertise provided by the members already appointed to the Paediatric Committee[3];
- Ability and experience in representing organisations, and the characteristics of the organisations represented;
- Good knowledge of the English language.

Selection procedure

The selection procedure will consist of four stages:

- Verification of the admissibility of the applications;
- Comparative evaluation and establishment of a list of most suitable applicants;
- Consultation of the European Parliament;
- Appointment as members of the Committee.

How to apply

Expression of interest in being Commission appointees to represent either health professionals or patient associations should be submitted by 6 September 2010 at the latest preferably by electronic means to the following address:

Sanco-pharmaceuticals@ec.europa.eu

The subject of the email should contain the reference number of the call for expression of interest: PDCO/10/PH/1.

Supporting documents to the application may alternatively be provided by letter by 6 September 2010 at the latest (date as postmarked) to the following address:

European Commission
DG Health and Consumers

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[2] For details see: http://www.ema.europa.eu/pdfs/general/direct/conflicts/3165303en.pdf.

[3] At the time of publication of the call for expression of interest PDCO lacked specific expertise especially in methodology and pneumology, but also in psychiatry, paediatric pharmacy, paediatric pharmacology, paediatric medicines development, pharmacovigilance, and toxicology.

Unit SANCO C8
- Call for interest PDCO/10/PH/1 -
B-1049 Brussels

Applications must be completed in one of the official languages of the European Union including the necessary documentation. They should be preferably submitted by the organisation, which the individual will represent. The following information should be provided in the order indicated:

(1) Category: health professional representative or patient association representative

(2) Name, job title, qualifications and contact address of proposed member

(3) Name, job title, qualifications and contact address of proposed alternate

(4) Curriculum Vitae for the proposed member and alternate should be attached

(5) Representatives of which organisation

(6) Presentation of the organisation(s) represented including the organisation's legitimacy (i.e. statutes registered in an EEA Member State); mission and objectives, paediatric focus, capability to represent patients or health professionals, whether the governing body is elected, how accountability and transparency of funding and activities are ensured

(7) Experience of the individuals including that relevant to the competencies listed in Article 4(1) third subparagraph, of the paediatric regulation (see the Annex)

(8) Experience of the individuals relevant to the tasks of the Paediatric Committee listed in Article 6(1) of the paediatric regulation (see the Annex).

(9) Motivation as to why individuals (member and alternate) consider that they should be chosen as members of the Paediatric Committee to represent either health professionals or patient associations in Europe, in the best interest of children.

Current Commission appointees, who reapply, may refer as regards points 7 and 8 to documents provided for their initial appointment.

For any further information on this call, please contact Mr. Florian Schmidt via florian.schmidt@ec.europa.eu or Sanco-pharmaceuticals@ec.europa.eu by referring in the subject of the email to the reference number of the call: PDCO/10/PH/1.

Brussels, 18 June 2010

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.