Call for expressions of interest as Commission appointees to the European Medicines Agency Paediatric Committee

Background

1. This Commission call for expressions of interest relates to Commission appointees to the European Medicines Agency (EMEA) Paediatric Committee to represent health professionals and patient associations.

2. Regulation (EC) No 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use[1] 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 established as part of the EMEA.

3. For ease of reference the provisions of the paediatric regulation directly relating to the Paediatric Committee are reproduced in the Annex to this document. Of particular note, Article 4 of the paediatric regulation provides for the composition of the Paediatric Committee.

4. Paragraph (c) of Article 4 states that the Paediatric Committee shall include "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".

5. Paragraph (d) of Article 4 states that the Paediatric Committee shall include "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".

6. In addition to work to prepare for meetings, appointees will be expected to attend the Paediatric Committee which meets three consecutive days each month at the EMEA in London, UK. Travel and subsistence costs for members of the Paediatric Committee will be met by the EMEA. The working language of the Paediatric Committee is English.

7. Appointment to the Paediatric Committee shall be for a renewable period of three-years.

Call for expressions of interest - how and by when

8. Expressions of interest in being Commission appointees to represent either health professionals or patient associations should be notified to Dr Peter Arlett at the European Commission by e-mail to peter.arlett@ec.europa.eu. The deadline for receipt of such notifications is 18.00 p.m. on 31 August 2007.

9. Expressions of interest should provide the following information in the order indicated:

I. Category: health professional representative or patient associations representative
II. Name, job title and qualifications of proposed member
III. Name, job title and qualifications of proposed alternate

[1] OJ L 378, 27.12.2006, p. 1 as amended by Regulation (EC) No1902/2006 OJ L 378, 27.12.2006, p. 20

IV. Representatives of which organisation.
V. 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.
VI. Experience of the individuals including that relevant to the competencies listed in Article 4(1) third subparagraph, of the paediatric regulation (see the Annex).
VII. Experience of the individuals relevant to the tasks of the Paediatric Committee listed in Article 6(1) of the paediatric regulation (see the Annex).
VIII. Motivation as to why the 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.
IX. Curriculum Vitae for the proposed member and alternate should be attached.

Assessment criteria

10. Assessment of expressions will be based on:
I. Whether individuals represent either health professional or patient associations at a European level.
II. Whether individuals have competencies and experience relevant to the tasks of the Paediatric Committee listed in Article 6(1) of the paediatric regulation
III. Whether individuals have experience relevant to the competencies of the Paediatric Committee listed in Article 4(1) third subparagraph of the paediatric regulation
IV. 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[2].
V. Ability and experience in representing organisations, and the characteristics of the organisation represented.

Appointment process

11. Based on the assessment criteria listed at point 10 above, the European Commission will draw up two lists of appointees, one for health professionals and one for patient associations. The European Parliament will be consulted on the Commission proposals for appointments to the Paediatric Committee prior to the appointments being made.

Pharmaceuticals Unit
DG Enterprise and Industry
European Commission
June 2007

[2] Potential applicants may wish to note that at the time the call was made public the Paediatric Committee lacked specific expertise in paediatric pharmacy (formulations), paediatric research (methodology) and ethics.

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 and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

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. 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.

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 paragraphs 5 and 7 of Article 25.

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 concerned agreed paediatric investigation plan 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.