



EUROPEAN COMMISSION  
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Policy and Administrative Support  
Finance, budget and controls

**PUBLIC CALL FOR EXPRESSION OF INTEREST**  
**AS COMMISSION APPOINTEES**  
**TO THE EUROPEAN MEDICINES AGENCY PAEDIATRIC COMMITTEE**  
**TO REPRESENT PATIENT ASSOCIATIONS (PDCO/22/PO) OR**  
**HEALTH PROFESSIONALS (PDCO/22/HP)**

***Background***

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/22/PO)<sup>1</sup>;
- Representatives of health professionals (reference: PDCO/22/HP)<sup>2</sup>.

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 2020 and ends on 31 July 2023. This call is intended to select candidates to replace the current civil society representatives as of 1 August 2023. 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 designed for children use 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

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<sup>1</sup> Three members and three alternates.

<sup>2</sup> Three members and three alternates.

development projects with companies. The Paediatric Committee is therefore central to the operation of the Regulation.

### ***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 patient 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.

The tasks of the Paediatric Committee are detailed in article 6 of the Paediatric Regulation and include:

- assessing data generated in accordance with agreed paediatric investigation plans and adopting opinions on compliance;
- providing advice on any question relating to paediatric medicines;
- establishing and regularly updating an inventory of paediatric medicinal product needs;
- assisting scientifically in the elaboration of documents related to the fulfilment of the objectives of the Paediatric Regulation.

### ***What is the specific role of patient association and health professional representatives in the Committee?***

**Patient association representative:** The 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 association. The representatives will bring their unique real-life perspective as end-users of medicines and to ensure that this is delivered throughout the committee's activities and outcome. 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 facilitate effective contribution 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 member will bring input from day-to-day clinical practice; including at the level of prescribing, dispensing and/or administering medicines and provide valuable insight on the potential impact of regulatory decisions. The candidate should have a good understanding of paediatric related matters. Proven experience in representing health professionals, e.g. as a member of a professional association, is expected.

### ***Workload and allowances***

Active and regular participation of the appointees is essential for the functioning of the Committee. Appointees will be expected to actively participate in all meetings and the entire meeting of the Paediatric Committee, which meets three consecutive days each month. The Committee holds a meeting either physically at the EMA in Amsterdam, the Netherlands with the possibility to participate remotely if the member is unable to participate in person, or in a fully remote setting where all participants connect to the meeting remotely. 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). Appointees will be involved in the committee's procedures in the same way as other members. 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. Therefore a good command of English is essential.

Travel, accommodation and subsistence costs for members of the Paediatric Committee will be met by the EMA according to its reimbursement rules for delegates.<sup>3</sup>

### ***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 and other interests or as soon as their interests change. Members are required to provide declarations of any specific interests at each meeting, 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 rules of the EMA.<sup>4</sup> Any detected current direct interest will lead to the exclusion from the appointment process.

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

<sup>4</sup> Cf. European Medicines Agency policy on the handling of competing 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\\_00\\_0178.jsp&mid=WC0b01ac0580029338](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_00_0178.jsp&mid=WC0b01ac0580029338)

### *Assessment criteria*

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

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

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

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

Please note that based on 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.<sup>5</sup>

The documents adopted by the European Medicines Agency on the criteria to be fulfilled by patients' and health professionals' organisations and the role of members representing patients' and healthcare professionals' organisations on EMA Scientific Committees will be considered in the assessment process<sup>6</sup>.

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<sup>5</sup> At the time of the publication of the call for expression of interest the PDCO defined its areas of expertise as required by legislation, and the areas of expertise that could be reinforced, as follows:

- Scientific areas relevant to paediatric medicinal products (as per the legal requirement):
  - pharmaceutical development, paediatric medicine, general practitioners, paediatric pharmacy, paediatric pharmacology, paediatric research, pharmacovigilance, ethics, public health.
- Preferred areas of expertise identified by the PDCO:
  - infectious diseases (e.g. COVID-19)
  - paediatric oncology/haematology
  - psychiatry
  - cardiology
  - neonatology
  - biostatistics

<sup>6</sup>[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/Regulatory_and_procedural_guideline/2009/12/WC500018099.pdf)

### ***Application procedure and closing date***

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

[https://health.ec.europa.eu/medicinal-products/call-ema-committees-and-board-members\\_en](https://health.ec.europa.eu/medicinal-products/call-ema-committees-and-board-members_en)

After completion, the application form and the form on declaration of interests should be printed, signed and dated.

The application must include:

- (a) the completed application form (signed),
- (b) the completed form on declaration of interests (signed),
- (c) a CV,
- (d) a recommendation letter from the association that the applicant wishes to represent.

If 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.

The appointment is nominal for individual natural persons. However, these individuals are appointed with the purpose of representing interested parties via associations at the European level. Therefore, applications to this call need to be submitted in agreement with the association that the applicant intends to represent. This agreement should be demonstrated in the recommendation letter – as an attachment (d) for the application. Associations can put forward (i.e. support by a recommendation letter) more than one candidate.

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 the supplied information may lead to exclusion from the present call.

**Applications must be submitted: by electronic means not later than 3 November 2022 11:59 pm, Brussels time.**

The completed application must be sent:

by electronic means not later than 3 November 2022, 11:59 pm, Brussels time, to the following address: [SANTE-CALL-AGENCIES@ec.europa.eu](mailto:SANTE-CALL-AGENCIES@ec.europa.eu)

The subject of the email should contain the reference number of the call for expression of interest: PDCO/22/HP or PDCO/22/PO, as appropriate.

For any further inquiry on this call, please contact [SANTE-CALL-AGENCIES@ec.europa.eu](mailto:SANTE-CALL-AGENCIES@ec.europa.eu) by referring in the subject of the email to the reference number of the call: PDCO/22/HP or PDCO/22/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 legislative requirements, 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.

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 or alternates 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 (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39). 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://health.ec.europa.eu/medicinal-products/call-ema-committees-and-board-members\\_en](https://health.ec.europa.eu/medicinal-products/call-ema-committees-and-board-members_en)

Brussels, October 2022

## 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<sup>7</sup>**

#### *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.

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<sup>7</sup> Official Journal of the European Union, L 378, 27.12.2006, p.1.

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 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.