EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 November 2013
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Paediatric Committee (PDCO)

Rules of procedure of the Paediatric Committee (PDCO)

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 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 (amended by Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006), hereafter the Paediatric Regulation, lays down obligations, rewards and incentives for the development and placing on the market of medicines for use in children, and EU procedures to ensure that medicines used to treat children are subject to ethical research of high quality and are appropriately authorised for use in children, requirements for information to be available on the use of medicines in the various paediatric populations and sets up a Paediatric Committee.

Since the Paediatric Committee is part of the Agency, the Integrated Quality Management System, endorsed by the Agency Management Board on 11 March 2004, applies to this Committee.

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended, on the EU Code relating to medicinal products for human use;

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down EU procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

Having regard to the EEA Joint Committee Decision No 74/1999 of 28 May 1999 regarding the participation of the EEA-EFTA states in the work of the EMA;

Having consulted the European Commission and the Management Board of the Agency on the basis of Article 5(2) of Regulation (EC) No 1901/2006, as amended;

The Committee adopts the following rules of procedure:

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Composition

Article 1

1. The Committee consists of:

    a) five members, with their alternates, of the Committee for Medicinal Products for Human Use (CHMP) appointed by the CHMP;

    b) one member and one alternate appointed by each EU Member State whose national competent authority is not represented through the members appointed by the CHMP;

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

For the purpose of the appointment of the members and alternates by the CHMP and the Member States, the Member States shall cooperate, under the coordination of the Executive Director of the Agency, to ensure that the final composition of the Paediatric Committee will cover 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 purpose of the appointment of the members and alternates appointed by the European Commission, the Commission shall take into account the expertise provided by the members appointed by the CHMP and the Member States.

2. In addition, the Committee shall include one member and one alternate appointed by each of the EEA-EFTA States taken into account the scientific areas above to be covered in the composition of the Committee.

3. Each member of the Paediatric Committee shall be appointed for a renewable period of three years.

Responsibilities of Chair and Vice-Chair

Article 2

1. The Chair, and in his absence the Vice-Chair, is responsible for the efficient conduct of the business of the Committee and shall in particular:

- plan the work of the Committee meetings together with the EMA Secretariat;
- monitor, together with the EMA Secretariat, that the rules of procedure are respected;
- ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed by the Committee;
- decide when a vote is necessary when consensus is not possible;
- ensure, together with the Committee and the Secretariat, the regulatory and scientific consistency of the Committee's opinions and recommendations;

- ensure that scientific grounds are adequately reflected in the Committee opinions;
- co-ordinate together with the EMA secretariat the work of this Committee with that of the other Committees of the Agency.

2. The Vice-Chair will deputise for the Chair when the latter is unable to chair either all or part of the Committee meeting. On such occasions, the Chair will seek the agreement of the Vice-Chair as early as possible, prior to the meeting and the EMA Secretariat shall be informed immediately.
3. If the Vice-Chair takes the chair, his/her place and vote will be assigned to his/her alternate.

Election of Chair and Vice-Chair

Article 3

1. The Chair and Vice-Chair of the Committee shall be elected by and from amongst its members for a term of three years, which may be renewed once.
2. Nominations for Chair and Vice-Chair should be submitted in writing to the EMA secretariat no later than the start of the Committee's meeting at which the election is to take place.
3. Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.
4. The election of the Chair and the Vice-Chair shall be by absolute majority of the members (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one) and by secret ballot. At each round, the candidate(s) with the lowest number of favourable votes shall withdraw. In the case of a tie in the decisive round, another round is organised with two remaining candidates. If, at the decisive round, the candidate with the highest number of votes does not get an absolute majority, a further voting is organised with this candidate only, where he/she needs favourable votes by at least half of the total number of Committee members eligible to vote plus one, to be elected Chair or Vice-Chair, as the case may be.
5. After the election of the Chair, the Member State or, as appropriate, the CHMP or the European Commission who appointed him or her, will designate a new member to replace the Chair as a member of the Committee. From the date of this appointment, the Chair shall lose his/her vote.
6. In the event of resignation of the Chair, the Vice-Chair shall take the chair until a new election is convened.
7. The members and alternates appointed by the EEA-EFTA States may not vote nor be elected Chair or Vice-Chair of the Committee.

Alternates to nominated Committee members

Article 4

1. Each alternate of the Paediatric Committee shall be appointed for a renewable period of three years.
2. Alternates shall represent and vote for the nominated member in the absence of the member, when he/she is not in attendance at the meeting. They may act as Rapporteurs at any time. At the request of the member, the alternate may respond on behalf of the member in case of written procedures or any request for urgent advice from members between meetings.

3. Alternates may not be elected as Chair or Vice-Chair of the Committee but may vote for the election of the Chair or Vice-Chair in the absence of the member.

Rapporteur

Article 5

1. For the evaluation of Paediatric Investigation Plan (PIP), and/or waiver, PIP modification or PIP compliance applications in respect of a procedure, a Rapporteur shall be appointed from amongst the members of the Committee or alternates taking into account their expertise and a fair distribution of the work.
2. The role of the Rapporteur is to contribute to the summary report prepared by the EMA according to the timetable agreed for the evaluation procedure, taking into account the timeframe laid down in the relevant legislation. This role consists of a critical review, providing his/her expertise for the elaboration of the summary report and the drafting of the opinion and identifying issues and proposal for discussion by the Committee.
3. The Rapporteur may propose experts included in the European experts list available at the EMA to help with the assessment. He/she notifies his/her choice to the EMA prior to the start of the procedure or as soon as possible when recognising that further expertise will be needed. Members of the Committee representing their Member States or alternates and experts responsible for the evaluation of applications shall rely on the scientific evaluation and resources made available by national competent authorities and the EMA. The Rapporteur is responsible for coordinating the expertise provided by members and alternates of the Committee as well as other experts where a multidisciplinary expertise for the evaluation of an application is needed.
4. Whenever meetings between Rapporteurs and PIP, waiver or PIP modification applicants take place, the Peer reviewer(s) and EMA secretariat should be involved and the minutes of all contacts shall be made available to all parties. Contacts by other members and alternates with applicants are not considered appropriate and should be avoided during assessment procedures. Should such contacts take place, these shall be reported to the Rapporteur and to the EMA.
5. The Committee may consult the relevant Committees, Working Parties and Scientific Advisory Groups in particular in relation to the evaluation of a PIP, waiver, PIP modification, or compliance application without prejudice of the legal deadlines. In such case the exchange of information shall be forwarded to the group for advice in accordance with the procedure to be agreed by the Committee. If a Working Party, Scientific Advisory Group is consulted for advice, the Relevant Committee should be consulted in advance for prior agreement of involvement.

Other role of the members and alternates of the Committee

Article 6

1. The Committee may also appoint (a) peer reviewer(s) from amongst the members and the alternates in regard to the evaluation of PIP, and/or waiver, PIP modification or compliance.
2. The peer-reviewer should provide additional expertise and contribute to the quality assurance of the summary report and of the scientific issues under discussion.
3. Members or alternates of the Committee may be appointed 'topic' leader to coordinate scientific discussions on particular matters addressed by the Committee.

Other Paediatric Committee activities

Article 7

1. The Committee has other tasks to comply with which are not exhaustively listed in this document, but can be found in Regulation (EC) No 1901/2006, as amended, especially in Article 6.
2. At the request of the CHMP or a competent authority, the Committee may have 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 products for use in the paediatric population.
3. At the request of the Executive Director of the Agency or the European Commission, the Committee may have to provide advice on any question related to medicinal products for use in the paediatric population.
4. The respective practical responsibilities and roles of PDCO members and alternates, rapporteur and peer reviewers, experts and observers and EMA paediatric Co-ordinators are described in a separate document called "Roles and Responsibilities within the Paediatric Committee".

Paediatric Committee's opinions and recommendations

Article 8

1. The quorum required for the adoption of scientific opinions or recommendations by the Committee shall be reached when two thirds of the total members of the Committee eligible to vote are present. The votes shall be positive or negative (unless the provision concerning the conflicts of interest is applied). Pending their nominations, members appointed by the European Commission shall not be taken into account for the purpose of determining the quorum.
2. Whenever possible, scientific opinions or recommendations of the Committee shall be taken by consensus. If such a consensus cannot be reached, the scientific opinion or recommendation will be adopted if supported by a majority of the members of the Committee (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one).
3. If scientific divergences remain, the Chair may ask the members for a "trend vote", on the outcome of a procedure. If a "trend vote" takes place, the applicant may be informed of the trend at Paediatric Committee level at the end of the scientific discussion ahead of any formal vote to conclude the evaluation process.
4. The divergent positions of and the names of the members expressing the divergent positions shall be mentioned in the opinion of the Committee, and where relevant, the minutes of the Committee. Members having divergent positions shall provide them in writing by the end of the meeting, stating clearly the reasons on which they are based. The divergent positions will be appended to the opinion. The reasons for the divergent opinions shall be publicly available together with the documentation made publicly available in relation to the evaluation of applications.
5. The members and alternates from the EEA-EFTA States may not vote but their positions shall be stated separately in the opinion, where relevant, in the minutes of the Committee and in case of divergent opinions appended to the Committee's opinion. Their position is not counted in reaching the Committee's opinion.
6. In the event of no majority position in favour of the concerned opinion, the Committee's opinion is deemed to be negative.

Written procedure

Article 9

1. Draft opinions and recommendations can, after approval of the Chair, be submitted by the EMA Secretariat to the Committee for adoption and respectively for agreement by written procedure. However, such written procedures should be restricted to measures required to be taken between scheduled meetings.
2. Draft opinions or recommendations are addressed to members of the Committee, who may raise objections within a specified time period to be established in agreement with the Chair. The Secretariat shall present a full report on the outcome of the written procedure at the following meeting of the Committee.
3. In the case of serious objections, the Chair decides whether the written procedure should be suspended and the adoption of the draft opinion or recommendation postponed to the next meeting of the Committee.

Re-examination of opinions

Article 10

1. For the implementation of the procedures for the re-examination of opinions as mentioned in Articles 25(2) and 25(3) of Regulation (EC) No 1901/2006, as amended, a different Rapporteur from the one appointed for the initial evaluation will be appointed to assess the grounds for the re-examination of opinions. A different peer reviewer(s) and additional expert(s) may also be appointed if appropriate. This re-examination procedure shall use the best endeavour to ensure a new examination, independent from the first opinion.
2. The re-examination may deal only with the points of the opinion initially identified by the applicant and is based only on the scientific data available when the Committee adopted the initial opinion.
3. The Rapporteur may question the applicant directly and the applicant may also offer to be questioned. The EMA should be involved and the Rapporteur should inform the Committee without delay in writing about details of contacts with the applicant.

Oral Explanations – Meeting(s) with applicant

Article 11

1. The Committee may invite an applicant for a meeting to provide oral explanations in connection with an evaluation procedure on its own initiative, or following a request of the applicant.
2. The Committee may also invite on its own initiative or may consider a request of any other relevant third party for a meeting in connection with an evaluation procedure.
3. Oral explanation/meetings shall be indicated clearly in the draft agenda of the meeting.
4. The Committee shall not make any conclusions during these meetings in the presence of the applicant's representatives or the third parties.

Organisation of meetings

Article 12

1. The Committee shall meet monthly at the Agency, with the possible exception of the month of August. The meeting shall be convened by the Executive Director or his/her representative after consultation with the Chair.
2. The dates of meetings are decided on an annual basis in consultation with the Committee. In exceptional circumstances and on motivated grounds agreed with the Chair an extraordinary meeting may be convened at short notice.
3. The meetings will be held and minuted in English.
4. Upon agreement with the Chair and EMA Secretariat, the PDCO may hold virtual meetings, especially in the event where an extraordinary meeting is deemed necessary.
5. The draft agenda for every meeting shall be circulated, together with the relating documents, by the EMA Secretariat, in consultation with the Chair, at least 14 calendar days before the meeting. This draft agenda shall enable the Committee to perform its duties as defined in Regulation (EC) No 1901/2006, as amended, especially in Article 6.
6. Agendas and minutes of the Committee's meetings shall be made publicly available at pre-defined time points, according to the Agency's policy on transparency.
7. When a member or alternate of the Committee is unable to participate to a meeting, part of meeting, or discussion topic due to conflict of interest, he/she must inform the Secretariat in advance in writing. Such declaration will be recorded in the minutes of the respective meeting.

Coordination with national authorities

Article 13

In addition to their task of providing objective scientific opinions to the applicant, EU and Member States on the questions which are referred to them, the members of the Committee shall ensure that there is appropriate coordination between the tasks of the Agency and the work of national competent authorities including the Coordination Group for Human Medicines (CMD(h)) and the consultative bodies concerned with the marketing authorisation, and the Committee may consult national competent authorities and consultative bodies regarding specific scientific expertise.

Drafting Groups

Article 14

When further consideration is required in order to prepare proposals on specific topics the Committee may convene drafting groups constituted by members or alternates of the Committee, or experts, as appropriate.

Participation of Experts in meetings

Article 15

1. When necessary, the Committee may avail themselves of the services of experts in specific scientific or technical fields. Such experts shall have proven experience in the assessment of medicinal products or in their field of expertise and be included in the European Experts list.
2. In addition members of the Committee may be accompanied by the experts mentioned in paragraph (1). The names of these experts shall be notified to the EMA Secretariat before the meeting which they are due to attend.

Guarantees of independence

Article16

1. The names of the members and alternates of the Committee shall be made public. When each appointment is published, the professional qualifications of each member and alternate shall be specified.
2. The members and alternates of the Committee and experts mentioned in various articles of the present Rules of Procedure shall not have any direct 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. All indirect interests which could relate to the pharmaceutical industry shall be entered in a register held by the Agency which is accessible to the public, on request at the Agency's office. In addition, the Declarations of Interest of the members and alternates of the Committee shall be made available on the Agency's website.
3. Members and alternates of the Committee and experts attending these meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be recorded in the minutes.
4. The specific provisions for handling declaration of interests and confidentiality undertakings as defined in the EMA policy on the handling of conflicts of interests of Scientific Committee are applicable to members of the Committee and experts participating in the scientific activities of the Agency.
5. Any incomplete and/or incorrect DoIs will be handled according to the Agency's breach of trust procedure on conflicts of interests for scientific committee members and experts.
6. The members and alternates of the Committee shall not accept from the Member States any instructions incompatible with the tasks incumbent upon them within the Agency. It is essential for these tasks to remain strictly scientific in nature. Each national competent authority shall monitor the level and independence of the evaluation carried out and facilitate the activities of nominated members and experts. Members States shall refrain from giving Committee members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.

Code of conduct

Article 17

Members and alternates of the Committee and experts participating in EMA's activities shall abide by the principles set out in the European Medicines Agency Code of Conduct.

EMA Secretariat

Article 18

1. Under the authority of the Executive Director, the EMA secretariat shall provide regulatory, legal, technical, scientific and administrative support to the Committee with a view to the performance of its duties as set out in Regulation (EC) No 1901/2006, as amended. This includes but is not limited to the following:

- Organise meetings of the Committee ensuring timely circulation of meeting documents;
- Prepare and co-ordinate the work of the Committee in consultation with the Chair;
- Provide technical and scientific support to Rapporteurs and other members of the Committee;
- Provide legal and regulatory support to the Committee;
- Carry out the validation of the applications submitted to the Agency;
- Prepare the Committee's summary reports and opinions with contribution of the Rapporteur, Peer-reviewer and experts, as appropriate;
- Prepare the EMA opinions and decisions;
- Facilitate the necessary contacts between the Committee, the Rapporteur and the applicant;
- Ensure scientific and regulatory consistency of the opinions / recommendations of the Committee in co-operation with the Chair or Vice-Chair, as appropriate;
- Ensure that the periods laid down by EU legislation for the adoption of the opinions and for the decisions are complied with;
- Prepare and communicate relevant public information related to the activities of the Committee;
- Communicate to applicants the relevant opinions or recommendations of the Committee as well as decisions;
- Ensure adequate co-ordination of the work carried out or exchange of information between this Committee and the CHMP, the COMP, HMPC, CAT, PRAC and CMD(h), where appropriate;
- Prepare the minutes of the meetings of the Committee in consultation with the Chair;
- Communicate to interested parties relevant recommendations of the Committee;
- Communicate the views of the Committee in international fora.

2. The Executive Director of the Agency, members of the EMA secretariat, and representatives of the European Commission, may attend all meetings of the Committee.

Contacts with Interested Parties

Article 19

1. The Committee may establish contacts, on an advisory basis, with parties concerned with the paediatric use of medicinal products, in particular patient organisations and health-care professionals' associations. The Committee may agree to invite representatives of such interested parties to address a plenary meeting.
2. Concept papers, draft guidelines and general regulatory developments will be subject to public consultation of all interested parties (industry, health care professionals, patients/consumers or other).
3. In any case, the Committee shall neither conduct any deliberations nor reach any formal decisions in the presence of members of interested parties.
4. Before any consultation session, interested party representatives and Committee members will communicate to the EMA Secretariat the points they would like to be discussed, so that an agenda of the session can be prepared for agreement by the Committee Chair and circulation by the EMA secretariat.

Observers

Article 20

1. For the purposes of regulatory cooperation, and particularly within the framework of mutual recognition agreements, visiting experts or other representatives from non-EEA regulatory authorities may also participate as observers to the Committee. Participation shall be agreed with the respective Chair in advance of the meeting.
2. At the initiative of the European Commission and in agreement with the Management Board, the Committee may admit representatives of international organisations with interest in the harmonisation of regulations applicable to medicinal products as observers at the Committee or meetings arranged for this purpose to discuss topics of common interest. The conditions for participation shall be determined beforehand by the European Commission.
3. The observers shall be bound by the rules of confidentiality mentioned in Article 16.4.

General Provisions

Article 21

The Committee may if, they consider it appropriate, seek guidance on important questions of a general scientific or ethical nature.

Article 22

The members and alternates of the Committee as well as observers and all experts shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by professional secrecy.

When participating in international or other fora on behalf of the PDCO, members shall ensure that the views expressed are those of the PDCO. They shall follow the EMA policy on scientific publication and representation of EMA scientific committees and their members.

When participating in international or other fora not specifically on behalf of the PDCO, members shall make clear that the views expressed are their own views and not those of the PDCO.

Article 23

The decision to adopt or to amend these rules of procedure shall be taken by a majority of the members of the Committee (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one).

Article 24

The rules of procedure or any amendment to them shall enter into force after receiving a favourable opinion from the EMA Management Board and subsequently, from the European Commission, and will be made publicly available.

Adopted by the Paediatric Committee on 2 August 2007

Agreed by the Management Board on 4 October 2007 (subject to amendment)

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