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**RULES OF PROCEDURE FOR THE STANDING COMMITTEE ON MEDICINAL
PRODUCTS FOR HUMAN USE**

(adopted by the Committee on 13 September 2011)

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THE STANDING COMMITTEE ON MEDICINAL PRODUCTS FOR HUMAN USE,

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 use¹ and in particular Article 121 thereof,

Having regard to Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers², and in particular Article 9(1) thereof,

Having regard to the standard rules of procedure published by the Commission³,

HAS ADOPTED THE FOLLOWING RULES OF PROCEDURE:

Article 1

Convening a meeting

1. A meeting of the committee shall be convened by the chair, either on his/her own initiative, or at the request of a simple majority of members of the committee.
2. In the case referred to in the second subparagraph of Article 3(5) of Regulation (EU) No 182/2011, where the written procedure is terminated without result, the chair shall convene a committee meeting within a reasonable time.
3. Joint meetings of the committee with other committees may be convened to discuss issues coming within their respective areas of responsibility.

Article 2

Agenda

1. The chair shall draw up the agenda and submit it to the committee.
2. The agenda shall make a distinction between:

¹ OJ L 311, 28.11.2001, p. 67.

² OJ L 55, 28.2.2011, p. 13.

³ OJ C 206, 12.07.2011, p. 11.

- (a) draft implementing acts to be adopted by the Commission on which the committee is asked to give an opinion, in accordance with the examination procedure provided for in:
- Article 121(2) and (3) of Directive 2001/83/EC;
 - Article 87(2) and (3) of Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency^{4,5};
 - Article 26(2) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004;⁶
 - Article 10a(2) of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products;⁷
 - Article 21(2) of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;⁸
- (b) other issues put to the committee for information or a simple exchange of views, either on the chair's initiative, or at the written request of a member of the committee.

Article 3

Documentation to be submitted to members of the committee

1. For the purpose of the second subparagraph of Article 3(3) of Regulation (EU) No 182/2011, the chair shall submit the invitation, the draft agenda and the draft implementing act on which the committee is asked to give an opinion to the members of the committee well in advance of the meeting, taking into account the urgency and the complexity of the matter, and no later than 14 calendar days before the date of the meeting. Other documents related to the meeting, in particular documents accompanying the draft implementing act, shall, as far as possible, be submitted within the same time-limit.

All documents shall be submitted in accordance with Article 12(2).

⁴ OJ L 136, 30.4.2004, p. 1.

⁵ Where applicable, in conjunction with Article 12, second paragraph of Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

⁶ OJ L 324, 10.12.2007, p. 121.

⁷ OJ L 18, 22.1.2000, p. 1.

⁸ OJ L 121, 1.5.2001, p. 34.

2. In duly justified cases, the chair may, on his/her own initiative or at the request of a member of the committee, shorten the time-limit for submission of documents referred to in paragraph 1. Except in cases of extreme urgency, the time-limit shall not be shorter than 5 calendar days.

Article 4

Opinion of the committee

1. The committee shall deliver its opinion on a draft implementing act within the time-limit laid down by the chair in accordance with the second subparagraph of Article 3(3) of Regulation (EU) No 182/2011.
2. Where the advisory procedure leads to a vote, the outcome of the vote shall be decided by a simple majority of the component members of the committee, in accordance with Article 4(1) of Regulation (EU) No 182/2011.

Where the committee's opinion is required under the examination procedure, the outcome of the vote shall be decided by a qualified majority, in accordance with Article 5(1) of Regulation (EU) No 182/2011.

3. Unless a member of the committee objects, the chair may, without proceeding to a formal vote, establish that the committee has delivered a positive opinion, by consensus, on the draft implementing act.
4. The chair, in consultation with the members of the committee, may, on his/her own initiative or at the request of a member of the committee, postpone a vote until the end of the meeting or to a later meeting.
5. In accordance with the second subparagraph of Article 3(4) of Regulation (EU) No 182/2011, the chair shall endeavour to find solutions which command the widest possible support within the committee. Before the vote, the chair shall inform the committee of the manner in which the discussions and suggestions for amendments have been taken into account, in particular as regards those suggestions which have been largely supported within the committee.

Article 5

Representation

1. Each Member State shall be considered to be one member of the committee. Each member of the committee shall decide on the composition of its delegation and inform the chair. With the chair's permission, the delegations may be accompanied by experts who are not part of the delegation.
2. Within a reasonable time and no later than 5 calendar days before the date of a committee meeting, the following information shall be communicated to the chair:
 - (a) the composition of each delegation, except where such composition is already known to the chair;

- (b) the names and functions of any experts accompanying the delegations and the reasons for which their presence is required.

If the chair does not object to the participation of an expert in advance of the committee meeting, the permission referred to in paragraph 1 is considered to be granted.

3. The reimbursement of travel expenses by the Commission shall be paid in accordance with the applicable rules, subject to budgetary funds provided for this purpose.
4. A Member State delegation may represent a maximum of one other Member State. The Member State that is being represented shall inform the chair of this before the meeting, or, at the latest, before the vote.

Article 6 **Working groups**

1. The committee may create working groups to examine particular issues. The working groups shall be chaired by a representative of the Commission.
2. The working groups shall report back to the committee under the responsibility of their chair.

Article 7 **Third parties and experts**

1. The representatives of the Republic of Iceland, the Principality of Liechtenstein and the Kingdom of Norway may attend the committee meetings, in accordance with Article 100 of the Agreement on the European Economic Area⁹.
2. Representatives of acceding countries shall be invited to attend the meetings of the committee as from the date of signature of the Treaty of accession.
3. The chair may decide to invite representatives of other third parties or other experts to talk on particular matters, on his/her own initiative or at the request of a member of the committee. However, a simple majority of the component members of the committee may oppose their participation in the meeting.
4. Representatives of third parties and experts referred to in paragraphs 1, 2 and 3 shall not be present at and shall not participate in voting of the committee.

Article 8 **Written procedure**

1. The chair may obtain the committee's opinion by written procedure in accordance with Article 3(5) of Regulation (EU) No 182/2011. In particular, the chair may use

⁹ OJ L 1, 3.1.1994, p. 3.

the written procedure to obtain the committee's opinion in cases where the draft implementing act has already been discussed during a committee meeting.

2. The chair shall inform the members of the committee of the outcome of a written procedure without delay, and no later than 14 calendar days after the expiry of the time-limit.
3. When the committee's opinion is required for the adoption of a Commission decision under Articles 10, 20(3) second subparagraph or 22¹⁰ of Regulation (EC) No 726/2004, or Articles 34 or 107(2) fourth subparagraph¹¹ of Directive 2001/83/EC, the opinion is to be given by written procedure, in accordance with the following rules:
 - (a) Notwithstanding Article 12(2) of these Rules of Procedure, the chair shall send the draft decision either in written or electronic form to the competent national authorities or bodies designated by each Member State.
 - (b) Member States shall have 22 calendar days to forward their written observations on the draft decision to the Commission. However, if a decision has to be taken urgently, a shorter time-limit may be set by the chair according to the degree of urgency involved. This time-limit shall not, otherwise than in exceptional circumstances, be shorter than 5 calendar days.
 - (c) Any Member State which does not express its opposition or intention to abstain from voting on the draft decision within the time-limit laid down in indent (b) shall be considered to have given its tacit agreement to the draft decision.
 - (d) Member States may, within the time-limit of indent (b), forward written observations and stating their reasons in detail, request in writing that the draft decision be discussed by a plenary meeting of the Committee. In that case, the written procedure shall terminate and the chair shall convene the Committee as soon as possible.
 - (e) Where, in the opinion of the Commission, written comments put forward by a Member State raise important new questions of a scientific or technical nature which have not been dealt with in the opinion delivered by the European Medicines Agency, the chair shall suspend the procedure and the Commission shall refer the matter to the Agency for further examination. The chair shall inform the members of the Committee thereof.
4. This Article shall not apply where the draft decision prepared by the Commission is not in accordance with the opinion of the European Medicines Agency as referred to in the third paragraph of Article 33 of Directive 2001/83/EC.

¹⁰ This provision shall be read in conjunction with the provisions of Regulation (EU) No 1235/2010.

¹¹ This provision shall be read in conjunction with the provisions of Directive 2010/84/EU.

Article 9
Secretarial support

The Commission shall provide secretarial support for the committee and, if necessary, the working groups created pursuant to Article 6(1).

Article 10
Minutes and summary record of meetings

1. For the purpose of Article 3(6) of Regulation (EU) No 182/2011, the minutes of each meeting shall be drawn up under the responsibility of the chair. Committee members shall have the right to ask for their position to be recorded in the minutes. The chair shall send the minutes to the committee members without delay and no later than one month after the meeting.

The members of the committee shall send any comments they may have on the draft minutes to the chair in writing. If there is any disagreement, the matter shall be discussed by the committee. If the disagreement persists, the relevant comments shall be annexed to the final minutes.

2. For the purpose of Article 10 of Regulation (EU) No 182/2011, the chair shall be responsible for drawing up a summary record briefly describing each item on the agenda and the results of the vote on any draft implementing act submitted to the committee. The summary record shall not mention the individual position of the members in the committee's discussions.

Article 11
Attendance list and conflicts of interest

1. At each meeting, the chair shall draw up an attendance list specifying the authorities and organisations to which the persons designated by the Member States to represent them belong.
2. At the beginning of each meeting, any person designated by the Member States, as well as experts who have been authorised by the chair to participate in the meeting in accordance with Article 5(1) and Article 7(3), and representatives of third parties who have been invited to attend the meeting in accordance with Article 7 shall inform the chair of any conflict of interest with regard to a particular item on the agenda.

In the event of such a conflict of interest, the person concerned shall, at the request of the chair, withdraw from the meeting whilst the relevant items of the agenda are being dealt with.

Article 12
Correspondence

1. Correspondence relating to the committee shall be submitted to the Commission, for the attention of the chair of the committee.

2. Correspondence for members of the committee shall be submitted to the Permanent Representations of the Member States, preferably by electronic means. Where a Permanent Representation indicates to the Commission a specific central electronic address for correspondence related to work of the committees, that address shall be used for correspondence. In addition, correspondence may be submitted directly to the persons designated by the Member States to represent them in the committee.

Article 13

Access to documents and confidentiality

1. Requests for access to committee documents shall be handled in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council¹². It is for the Commission to take a decision on requests for access to those documents pursuant to its Rules of Procedure as amended by Decision 2001/937/EC, ECSC, Euratom¹³. If the request is addressed to a Member State that Member State shall apply Article 5 of Regulation (EC) No 1049/2001.
2. The committee's discussions shall be confidential.
3. Documents submitted to members of the committee, experts and representatives of third parties shall be confidential¹⁴, unless access is granted to those documents pursuant to paragraph 1 or they are otherwise made public by the Commission.
4. The members of the committee, as well as experts and representatives of third parties, shall be required to respect the confidentiality obligations set out in this Article. The chair shall ensure that experts and representatives of third parties are made aware of the confidentiality requirements imposed upon them.

Article 14

Protection of personal data

The processing of personal data by the committee and its working groups shall be in conformity with Regulation (EC) No 45/2001 of the European Parliament and of the Council¹⁵, under the responsibility of the chair acting as the controller, within the meaning of point (d) of Article 2 of that Regulation.

¹² OJ L 145, 31.5.2001 p. 43.

¹³ OJ L 345, 29.12.2001, p. 94.

¹⁴ In accordance with Article 339 TFEU, "[t]he members of the institutions of the Union, the members of committees, and the officials and other servants of the Union shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components".

¹⁵ OJ L 8, 12.1.2001, p. 1.