

RULES OF PROCEDURE OF THE EUROPEAN PHARMACOPOEIA COMMISSION

These Rules of Procedure have been revised by the European Pharmacopoeia Commission in accordance with Article 5, Paragraph 2 of the Convention on the Elaboration of a European Pharmacopoeia. They replace the Rules of Procedure adopted on 20 March 2007.

The "European Pharmacopoeia Commission", hereinafter called "the Commission", shall proceed in accordance with the provisions of the "Convention on the Elaboration of a European Pharmacopoeia" hereinafter called "the Convention" as amended by the Protocol that entered into force on 1 November 1992.

All references in these Rules of Procedure to functions, titles or positions shall be construed as applying equally to men and women.

1. MEMBERSHIP OF THE COMMISSION

- 1.1 The Commission shall be composed of delegations appointed in pursuance of Article 5 of the Convention. The members of the Commission are the members of these delegations.
- 1.2 The alternates referred to in Article 5 of the Convention shall sit on the Commission only when the members of delegations are prevented from doing so and for that purpose become members of the Commission.

2. FUNCTIONS OF THE COMMISSION

- 2.1 In pursuance of paragraph a) of Article 6 of the Convention, the Commission decides on the work programme for the elaboration of the European Pharmacopoeia and decides the general policies to be applied in the work. To this end, the Commission prepares a public mission statement defining the role and purpose of the European Pharmacopoeia.
- 2.2 The Commission may appoint Groups of Experts and Working Parties.
- 2.3 The Commission has the ultimate responsibility for the progress of the work that has been decided upon and for ensuring that these Rules and that the Guide for the Work of the European Pharmacopoeia are followed.
- 2.4 The Commission evaluates proposals for inclusion, revision or suppression of monographs and general chapters. The Commission defines criteria for setting priorities for the work programme.
- 2.5 The Commission allocates agreed work items to a Group of Experts or Working Party and makes an annual review of overall progress with the work programme, including revision work.
- 2.6 The Commission approves the terms of reference of Groups of Experts and Working Parties, defines criteria to be applied in the selection of experts and specialists and approves the composition of Groups of Experts and Working Parties, based on the proposals made by the Presidium.

3. CHAIR OF THE COMMISSION

- 3.1 The Chair of the Commission shall be elected by a two-thirds majority of the votes cast by the delegations in a secret ballot in accordance with paragraph 3 of Article 5 of the Convention; two tellers appointed by acclamation shall count the votes cast.

Candidatures for the Chair shall be submitted in writing to the Secretariat not later than 28 days before the beginning of the Session at which an election is to take place. Not later than 21 days before the beginning of the Session, the Secretariat shall notify the delegations in writing of candidatures received.

Votes cast for persons whose candidature has not been declared in accordance with the preceding paragraph shall be considered void.

Candidatures shall be accompanied by a curriculum vitae and a statement of motivation.

- 3.2 The term of office of the Chair shall be three years. He shall not immediately be eligible thereafter for re-election. His successor shall be elected at the last meeting of the Commission in the aforementioned period of three years; he shall not, however, take up his duties until this period has expired.
- 3.3 Upon taking up his duties, the Chair shall at once cease to be a member of his delegation; the latter may then be completed in accordance with Rule 1.2 of these Rules of Procedure.
- 3.4 If, during his term of office, the Chair becomes permanently unable to continue his duties, the first or, if he is not available, the second Vice-Chair shall act in his place until a new Chair is elected at the next Session of the Commission. The Chair so elected shall hold office for three years from the time of his election.

4. VICE-CHAIRS

- 4.1 The Commission shall elect two Vice-Chairs who shall fulfil the duties of the Chair when he is absent or temporarily unable to discharge his duties. The order of precedence of the Vice-Chairs shall be determined by the Commission before their election.
- 4.2 The provisions of Rules 3.1 and 3.2 of these Rules of Procedure shall apply *mutatis mutandis* to the election and term of office of the Vice-Chairs.
- 4.3 When a Vice-Chair is requested to take over the chair of a Session, the Vice-Chair ceases to be a member of his delegation; the latter may then be completed in accordance with the provisions of Rule 1.2 of these Rules of Procedure.

5. PRESIDIUM

- 5.1 The Presidium consists of the Chair and the two Vice-chairs; they are assisted by the Director of the European Directorate for the Quality of Medicines and HealthCare (EDQM) and the Secretary to the Commission.

6. DUTIES OF THE CHAIR OF THE COMMISSION

- 6.1 The Chair of the Commission decides, in consultation with the Director of the EDQM and the Secretary to the Commission and, where necessary the Vice-Chairs, the draft agenda for a session.
- 6.2 The Chair, at Sessions of the Commission, shall direct the proceedings and announce decisions. He shall call to order any speaker whose observations are not relevant to the subject under discussion or not within the terms of reference of the Commission.
- 6.3 During the period between sessions, the Chair shall oversee the work of the Commission and, where necessary, act in consultation with the other members of the Presidium on behalf of the Commission.

7. DUTIES OF THE PRESIDIUM

- 7.1 The Presidium participates in the preparatory work between sessions. It shall collectively endeavour to prepare the items to be discussed by the Commission to facilitate the decision-making process. The Presidium may hold meetings between sessions for this purpose. A report of such meetings shall be prepared by the Secretariat.
- 7.2 The Presidium upon appointment prepares for consideration by the Commission a set of proposals concerning the general policy and role of the European Pharmacopoeia, criteria for prioritisation of work and a set of priorities for the coming three years. After each Session of the Commission the Presidium may review the work programme for reconsideration by the Commission.
- 7.3 The Presidium upon appointment prepares for consideration by the Commission a set of proposals concerning the terms of reference of Groups of Experts and Working Parties and the appropriate selection criteria for nomination of Experts and Specialists to each Group of Expert and Working Party.
- 7.4 In accordance with rule 7.3 the Presidium, based on candidatures sent by each Contracting Party, prepares for consideration by the Commission a proposal for the composition of Groups of Experts and Working Parties.

8. CONTRACTING PARTIES TO THE CONVENTION

- 8.1 Each Contracting Party shall notify the Secretariat of the responsible contact person(s) for implementation of the decisions of the Commission in its respective country as foreseen under Article 1 of the Convention.

9. SECRETARIAT

- 9.1 The Secretariat shall prepare the Sessions of the Commission and the meetings of the Groups of Experts and Working Parties in consultation with the respective Chairs and shall draft the summaries and reports of them in accordance with the provisions of Rules 10.13, 11.12 and 17. It shall be responsible for the preparation and distribution of all documents and other written communications intended to be studied by the Commission, the Groups of Experts or the Working Parties. All documents issued by the Secretariat shall be sent to the Presidium of the Commission, to the address of the responsible contact person(s) named by each Contracting Party, and, as appropriate, to members of each delegation, Group of Experts or Working Party.
- 9.2 The Secretariat shall be responsible for the publication of monographs, general chapters and other official texts adopted by the Commission; each publication shall be issued in the two official languages.
- 9.3 Immediately after the adoption by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) of a Resolution giving effect to the date of implementation or suppression of texts, the Secretariat shall notify the Contracting Parties.
- 9.4 The Secretariat shall be responsible for establishing and maintaining appropriate contacts with the laboratories to which the Commission has decided to entrust certain work. The Secretariat shall contribute to the work on elaboration of monographs and general chapters. The Secretariat shall organise the preparation, the establishment, the maintenance and the replacement of batches of reference standards.

- 9.5 The Secretary General of the Council of Europe or his representative, the Director of the EDQM and the Secretary to the Commission may, at any time, make a statement on any subject under discussion.

10. GROUPS OF EXPERTS

- 10.1 Following the election of the Chair and the Vice Chairs of the Commission, the Commission appoints Groups of Experts, for a period of three years unless otherwise defined by the Commission. Groups of Experts cover the main scientific disciplines of quality control of medicinal products and their constituents.
- 10.2 Groups of Experts are constituted by experts having current scientific and/or technical knowledge in these disciplines.
- 10.3 Each Group of Experts has Terms of Reference. These Terms of Reference are proposed by the Presidium and approved by the Commission.
- 10.4 Each Group of Experts has a work programme defined by the Commission. Progress on the work programme is reviewed annually by the Commission.
- 10.5 Groups of Experts report directly to the Commission.
- 10.6 Each Contracting Party may propose one expert for appointment to each Group of Experts, taking account of the competence of the person proposed for the work involved. For re-appointment of a Group of Experts at the end of its term of office, proposals shall be submitted not later than 56 days before the beginning of the Session at which the appointment is to be made. For other appointments, proposals shall be submitted not later than 28 days before the beginning of the Session at which the appointment is to be made.
- 10.7 Where required to provide the necessary supplementary expertise, each Contracting Party may propose one or more specialists, having a current scientific and/or technical knowledge in a specific aspect of the work or a specific topic, for appointment to a Group of Experts. A specialist so appointed attends a meeting when the relevant topic is on the agenda. Proposals for appointment of specialists shall be made according to the schedule described under 10.6.
- 10.8 A curriculum vitae and a declaration of interests shall accompany all proposals for appointment.
- 10.9 The experts and specialists shall be appointed by the Commission for their personal competence. They shall be allocated to Groups of Experts on the proposal of the Presidium according to the selection criteria approved by the Commission in virtue of Rule 2.6.
- 10.10 In accordance with Rule 10.1, each Group of Experts shall be appointed for a period of three years. At the end of this period the term of office of each expert or specialist expires, but may be renewed. Where an expert or a specialist is appointed during the three-year period, his term of office shall end at the same time as that of other members of the group. At a time sufficiently before the end of the term of office, the Secretariat of the Commission shall ask each Contracting Party for its proposals, in writing, for the designation of experts or specialists.
- 10.11 When an appointed member of a Group of Experts is unable to attend a meeting, the Contracting Party may send a substitute and, in this case, shall inform the Secretariat and the Chair of the Group of Experts accordingly. The substitute should have a similar knowledge and expertise to the appointed member and his CV should be sent to the Secretariat.

- 10.12 Subject to approval by the Commission or, in urgent cases, by its Chair, and the prior approval of the Chair of the Group of Experts and of the Contracting Party, ad hoc specialists may assist the appointed member when supplementary technical advice is needed.
- 10.13 A member of the Commission's Secretariat shall attend each meeting of the Groups of Experts. The Secretariat shall issue a summary of decisions promptly after the meeting and prepare a report which shall be submitted for approval by correspondence or at the following meeting and distributed to the members of the Commission. The member of the Secretariat in attendance may at any time contribute to the work of the Group of Experts.

11. WORKING PARTIES

- 11.1 To deal with a specific aspect of the work or with a specific topic the Commission appoints Working Parties for a defined period.
- 11.2 Working Parties are constituted by specialists having a current scientific and/or technical knowledge in a specific aspect of the work or a specific topic.
- 11.3 Each Working Party has Terms of Reference. These terms of reference are proposed by the Presidium and approved by the Commission.
- 11.4 Each Working Party has a work programme defined by the Commission. Progress on the work programme is reviewed annually by the Commission.
- 11.5 Unless otherwise decided, Working Parties report directly to the Commission.
- 11.6 Each Contracting Party may propose more than one specialist for appointment to a Working Party, taking account of the competence of the person proposed for the work involved. For re-appointment of a Working Party at the end of its term of office, proposals shall be submitted not later than 56 days before the beginning of the Session at which the appointment is to be made. For other appointments, proposals shall be submitted not later than 28 days before the beginning of the Session at which the appointment is to be made.
- 11.7 A curriculum vitae and a declaration of interests shall accompany all proposals for appointment.
- 11.8 The specialists shall be appointed by the Commission for their personal competence. They shall be allocated to the respective Working Party on the proposal of the Presidium according to the selection criteria approved by the Commission in virtue of Rule 2.6.
- 11.9 In accordance with Rule 11.1, the term of office of Working Parties shall be limited to the period defined by the Commission and shall in any case be reviewed following the election of the Chair and the Vice-Chairs. At the end of this period the term of office of members of working parties may be renewed. In this case, at a time sufficiently before the end of the term of office, the Secretariat of the Commission shall ask each Contracting Party for its proposals, in writing, for the designation of specialists.
- 11.10 When an appointed member of a Working Party is unable to attend a meeting, the Contracting Party may send a substitute and, in this case, shall inform the Secretariat and the Chair of the Working Party accordingly. The substitute should have a similar knowledge and expertise to the appointed member and his CV should be sent to the Secretariat.

11.11 Subject to approval by the Commission or, in urgent cases, by its Chair, and the prior approval of the Chair of the Working Party and of the Contracting Party, ad hoc specialists may assist the appointed member when supplementary technical advice is needed.

11.12 A member of the Commission's Secretariat shall attend each meeting of the Working Parties. The Secretariat shall issue a summary of decisions promptly after the meeting and prepare a report which shall be submitted for approval by correspondence or at the following meeting and distributed to the members of the Commission. The member of the Secretariat in attendance may at any time contribute to the work of the Working Parties.

12. CHAIRS OF GROUPS OF EXPERTS AND WORKING PARTIES

12.1 Each Group of Experts or Working Party shall have as its Chair a member of the Commission, unless otherwise approved by the Commission. The Chair of a Group of Experts or Working Party shall be elected by the Commission by a majority of the delegations casting a vote.

Candidatures shall be submitted in writing to the Secretariat not later than 28 days before the beginning of the Session at which an appointment is to take place. Not later than 21 days before the beginning of the Session, the Secretariat shall notify the delegations in writing of candidatures received.

12.2 Following the election of the Chair and the Vice Chairs of the Commission, the Commission appoints the Chairs of Groups of Experts and Working Parties for a period of three years unless otherwise defined by the Commission. In order to make a fair distribution of Chairs between the delegations and to provide for a reasonable rotation in the responsibilities, a person may be appointed to not more than two successive terms of office as Chair of a given Group of Experts and only exceptionally, where no other candidate is available, to a third successive term.

12.3 The term of office of the Chair of a Working Party is the defined period of its activities, and shall in any case be reviewed following the election of the Chair and the Vice-Chairs of the Commission.

12.4 In the absence of the Chair, the Group of Experts or Working Party shall elect an acting Chair from among its members.

12.5 The Chairs of Groups of Experts and Working Parties may be convened to special meetings subject to the approval of the Commission, which shall also determine the date and agenda of such meetings.

12.6 The Chair, with the support of the Secretariat, is responsible for the progress of the work allocated to the Group of Experts or Working Party and to this end establishes a plan for carrying out the work, distributes the work in consultation with the members and ensures that time limits set for assignments are respected.

13. CONSULTATIONS

13.1 The Commission may decide to hear the representatives of associations or scientific institutions.

13.2 It may also decide to seek the advice of consultants.

14. OBSERVERS

14.1 The European Committee on Pharmaceuticals and Pharmaceutical Care (previously the Public Health Committee referred to in sub-paragraph a of Article 2 of the Convention)

may arrange to be represented at the sessions of the Commission by an observer; the latter shall have the right to speak and to make proposals.

14.2 The Commission may also, by a unanimous vote of the delegations casting a vote admit to some of its sessions technically qualified observers, such as:

(a) observers from Member States of the Council of Europe that are not parties to the Convention;

(b) observers from States that are not Members of the Council of Europe;

(c) observers from international governmental organisations;

(d) observers from international non-governmental organisations.

14.3 The observers referred to in Rule 14.2 shall have the right to speak; they may not, however, make proposals unless these are put forward by one of the delegations referred to in Rule 1 of these Rules of Procedure.

14.4 The Commission may, by a unanimous vote of the delegations casting a vote, admit as observers in Groups of Experts or Working Parties, technically qualified persons from States or organisations admitted to the Commission as observers.

15. SESSIONS AND AGENDA OF THE COMMISSION

15.1 The Commission shall hold its Sessions in Strasbourg, the seat of the Council of Europe.

15.2 The Commission shall sit whenever necessary but at least twice a year; it shall be convened on behalf of and at the request of the Chair of the Commission by the Secretariat at least 21 days before the opening of each Session. The Chair of the Commission must convene the Commission if three-quarters of the delegations so request.

15.3 Once a Session has been convened in accordance with this Rule 15.2, any request for postponement must reach the Secretariat at least 21 days before the date set for the opening of the Session. A decision to postpone the Session shall be deemed to have been taken if three-quarters of the delegations shall have informed the Secretariat of their agreement 14 days before the date originally set. A decision to advance the date of the Session shall be deemed to have been taken only when all the delegations have informed the Secretariat of their agreement, at least 14 days before the new date proposed.

15.4 The agenda shall be adopted at the beginning of each Session on the basis of a draft which the Secretariat of the Commission shall prepare in consultation with the Commission's Chair and send to the delegations at least 21 days before the opening of the Session. An addendum to the agenda may be provided to delegations prior to the beginning of the Session and adopted by the Commission as part of the final agenda.

15.5 A delegation to the Commission may request that discussion of a document be postponed if it has not been distributed by the Secretariat sufficiently in advance of the Session.

15.6 Sessions of the Commission shall be held in private.

16. MEETINGS OF THE GROUPS OF EXPERTS AND WORKING PARTIES

16.1 Groups of Experts and Working Parties shall hold their meetings in Strasbourg, unless otherwise justified.

16.2 Meetings of the Groups of Experts and Working Parties shall be held in private.

17. REPORTS OF THE COMMISSION

17.1 After each Session of the Commission, the Secretariat shall issue a summary of decisions promptly and prepare a report. It shall give the text of and, where appropriate, the grounds for all decisions taken by the Commission, particularly those relating to:

- (a) the general principles to be applied in elaborating the European Pharmacopoeia;
- (b) the relevant methods of analysis;
- (c) the monographs provided for in Article 6 of the Convention and intended to be included in the European Pharmacopoeia.

17.2 The report shall include, where necessary:

- (a) the name of each monograph adopted and the reference number of the document in which the text appears, together with the text of any adopted amendments to that document;
- (b) the dates of entry into force recommended in accordance with sub-paragraph *d* of Article 6 of the Convention.

17.3 The draft report shall be transmitted to the delegations within 28 days of the end of the Session. The delegations shall inform the Secretariat not later than 42 days before the beginning of the next Session of any amendments and textual corrections, with their origin, that they wish to be included in the final report.

17.4 Each final report shall be submitted for approval by the Commission at the Session following that to which it refers and shall then be transmitted to the European Committee on Pharmaceuticals and Pharmaceutical Care in accordance with Article 4 of the Convention.

18. LANGUAGES

18.1 The working languages of the Commission shall be the official languages of the Council of Europe.

18.2 Any delegate may speak in a language other than the official languages, provided he himself arranges for interpretation into one of the official languages.

19. QUORUM

19.1 The decisions of the Commission shall be valid only if a majority of the delegations is present.

19.2 Each delegation may at its request be represented by another delegation. In such a case the delegation represented shall be considered as present for the purposes of quorum and voting. A delegation wishing to be so represented shall inform the Secretariat in writing before the vote (see form in Annex). The Secretariat shall inform the tellers if any delegation has chosen to be so represented.

20. INTRODUCTION, REVISION OR SUPPRESSION OF TEXTS IN/OF THE EUROPEAN PHARMACOPOEIA

20.1 Proposals concerning the introduction, revision or suppression of monographs, general chapters and other texts in/of the European Pharmacopoeia may be made by:

- the Chair of the Commission,
- a delegation,
- a Group of Experts or Working Party through the intermediary of its Chair,
- the Secretariat,
- manufacturers and other interested parties from Member States through the intermediary of their national delegation,
- manufacturers and other interested parties from Observer States through the intermediary of a delegation or the Secretariat,
- manufacturers and other interested parties from non-Member or non-Observer States through the intermediary of the Secretariat.

20.2 The procedures to be followed for the elaboration and revision of texts for the European Pharmacopoeia are laid down in the Guide for the Work of the European Pharmacopoeia.

21. ROUTINE REVISION OF THE TEXTS OF THE EUROPEAN PHARMACOPOEIA

21.1 Routine revision of the texts of the Pharmacopoeia shall be effected as follows:

- (a) a delegation or the Chair of the Commission or of a Group of Experts or Working Party or the Secretariat shall present a reasoned request for the revision of a text;
- (b) when the Commission has decided on the priority to be accorded to the proposed revision, the Group of Experts or Working Party concerned shall be informed;
- (c) the usual working procedure shall then be followed and the revised text shall be published after adoption by the Commission.
- (d) the revision of texts for the purpose of correcting inconsequential typographical errors shall be done by the Secretariat without a discussion by the Commission. However, Contracting Parties shall be informed promptly of the correction made and its effective date, which shall be the date of publication.

22. RAPID REVISION OF THE TEXTS OF THE EUROPEAN PHARMACOPOEIA

22.1 When it is necessary to make a rapid revision of a text of the Pharmacopoeia the following procedure shall be followed:

- (a) a delegation or the Chair of the Commission or of a Group of Experts or Working Party or the Secretariat, having noted the need for rapid revision or for the suspension of the whole or part of a text, shall present a proposal for the revised text and, where appropriate, data supporting the proposed revision.
- (b) the Secretariat shall inform the Commission and the Group of Experts or Working Party concerned. The Group or Working Party shall be consulted promptly by a written procedure and, if necessary, be convened as soon as possible and shall take

the necessary action concerning the problem. The Secretariat shall prepare all necessary documents and send them to the delegations;

- (c) the Commission shall take a decision at its next Session or by correspondence;
- (d) if the Commission decides that the revised text shall be published and implemented rapidly, outside the normal publication cycle of the European Pharmacopoeia, this text is published in the form of a Resolution of the European Committee on Pharmaceuticals and Pharmaceutical Care with a view to its rapid implementation.

23. SUPPRESSION OF THE TEXTS OF THE EUROPEAN PHARMACOPOEIA

23.1 When it is necessary to suppress a text of the Pharmacopoeia, the following procedure shall be followed:

- (a) a delegation or the Chair of the Commission or of a Group of Experts or Working Party or the Secretariat, having formed the opinion that a monograph should be suppressed, shall present a reasoned proposal;
- (b) the Secretariat shall transmit the proposal to all the delegations;
- (c) the Commission shall decide whether the monograph shall be suppressed;
- (d) if the Commission decides that the monograph shall be suppressed it shall recommend to the European Committee on Pharmaceuticals and Pharmaceutical Care in accordance with paragraph 3 of Article 4 of the Convention the date at which the suppression shall take effect.

24. REVISION OF THE RULES OF PROCEDURE

24.1 These Rules of Procedure may be amended at any time.

24.2 Amendments thereto shall require a three-quarters majority in accordance with paragraph 3 of Article 7 of the Convention.

Annex

EUROPEAN PHARMACOPOEIA COMMISSION

Rule of Procedure 19.2: representation of one delegation by another

Form to be submitted to the Secretariat by a delegation wishing to be represented by another for the purposes of voting

Delegation (name and signature of the delegate):

The above delegation will be represented by the following delegation as provided for in the Rule of Procedure 19.2:

Representing delegation(name and signature of the delegate):

Valid for:

Session:

Date on which the delegation is to be represented: