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*.

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. In the context of this document, "*expert from Ph. Eur. Member State*" means a person nominated by a Contracting Party wherever he/she is working and irrespective of his/her nationality, and "*expert from non-Ph. Eur. Member State*" means any other expert showing interest in participating in the work of the Ph. Eur.

The *Rules of procedure of the European pharmacopoeia* are complemented by the *Guide for work of the European pharmacopoeia* and the *Code of Practice for the work of the European Pharmacopoeia.*

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

INDEX

37
38

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.

1.3 A *curriculum vitae* and a declaration of interests shall accompany all appointments of members and of alternates referred to in Article 5 of the Convention.

2. FUNCTIONS OF THE COMMISSION

2.1 In pursuance of subparagraphs a) and c) 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 and draws up its own Rules of Procedure.

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, the *Guide for the Work* and the *Code of Practice 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 *ad hoc* 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 the rest of the term and can be re-elected for another full term.

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 Vice-Chairs are elected in order of their precedence.

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 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 the nomination of Experts and *ad hoc* Specialists to each Group of Experts and Working Party.

7.4 In accordance with rule 7.3 the Presidium, based on candidatures sent by each Contracting Party, by Observers or by the Secretariat, 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 authority for the implementation of the decisions of the Commission in its respective country as foreseen under Article 1 of the Convention (National Pharmacopoeia Authority, NPA), the responsible person at the NPA and the relevant contact details.

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 the *Guide for the Work of the European Pharmacopoeia*. 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 contact 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 AND WORKING PARTIES

10.1 The Commission appoints Groups of Experts and Working Parties, 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. Working Parties deal with a specific aspect of the work or with a specific topic and are normally appointed for a defined period.

10.2 Each Group of Experts or Working Party has Terms of Reference. These Terms of Reference are proposed by the Presidium and approved by the Commission.

10.3 Each Group of Experts or Working Party has a work programme defined by the Commission. Progress on the work programme is reviewed annually by the Commission.

10.4 Groups of Experts report directly to the Commission. Working Parties report directly to the Commission unless otherwise decided.

10.5 Groups of Experts and Working Parties are comprised of experts and if applicable, *ad hoc* specialists having current scientific and/or technical knowledge to cover the duties described in the Terms of Reference.

10.6 <u>Chairs of Groups of Experts and Working Parties</u>

10.6.1 Each Contracting Party may propose one candidate for appointment as Chair of a Group of Experts or Working Party, taking account of his competence for the work involved and of his past contribution. The candidate shall preferably be a member of the Commission.

10.6.2 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.

10.6.3 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.

10.6.4 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.

10.7 **Experts, *ad hoc* specialists and substitutes**

10.7.1 Experts or *ad hoc* specialists are proposed for appointment to Groups of Experts or Working Parties, taking account of their competence for the work involved.

10.7.2 Experts from Ph. Eur. Member States are proposed by a Contracting Party. Applications of experts from non-Ph. Eur. Member States are directly addressed to the Secretariat.

10.7.3 *Ad hoc* specialists are proposed by a Contracting Party, by the Secretariat or by a member of the Group of Experts or Working Party.

10.7.4 When an appointed expert or *ad hoc* specialist from a Ph. Eur. Member State 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 or Working Party accordingly.

10.7.5 Substitutes from non-Ph. Eur. Member States are not allowed unless decided so by the Commission or, in urgent cases, by its Chair.

11. CONSULTATIONS

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

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

12. OBSERVERS

12.1 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.

12.2 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.

12.3 The observers referred to in Rule 12.2 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.

13. SESSIONS AND AGENDA OF THE COMMISSION

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

13.2 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.

13.3 Once a Session has been convened in accordance with this Rule 13.2, 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.

13.4 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.

13.5 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.

13.6 Sessions of the Commission shall be held in private.

14. MEETINGS OF THE GROUPS OF EXPERTS AND WORKING PARTIES

14.1 Groups of Experts and Working Parties shall hold their meetings in Strasbourg, unless otherwise justified. If it is proposed to hold a meeting elsewhere, the Chair should make a request in writing to the Director of EDQM providing justification for this in terms of the contribution to the advancement of the work of the group. The Director of the EDQM will consult National Pharmacopoeia Authorities before taking a decision.

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

15. REPORTS OF THE COMMISSION

15.1 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.

15.2 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 subparagraph d of Article 6 of the Convention.

15.3 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.

16. LANGUAGES

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

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

17. QUORUM

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

17.2 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.

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

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

— the Chair of the Commission,

— a delegation,

— a National Pharmacopoeia Authority,

— 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 Pharmacopoeia Authority,

— manufacturers and other interested parties from Observer States through the intermediary of a National Pharmacopoeia Authority or the Secretariat,

— manufacturers and other interested parties from non-Member or non-Observer States through the intermediary of the Secretariat.

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

19. REVISION OF THE RULES OF PROCEDURE

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

19.2 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 17.2: 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:

Representative of the delegation (name, date and signature):

The above delegation will be represented by the following delegation as provided for in the Rule of Procedure 17.2:

Representing delegation:

Representative of the representing delegation (name, date and signature):

Valid for:

Session (number):

Date(s) on which the delegation is to be represented:

Agenda items (please indicate “all agenda items” or specific one or more items):