RULES OF PROCEDURE OF THE EUROPEAN PHARMACOPOEIA COMMISSION

These *Rules of Procedure* are issued and maintained 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 proceeds in accordance with the provisions of the *Convention on the Elaboration of a European Pharmacopoeia* as amended by the Protocol that entered into force on 1 November 1992.

The European Pharmacopoeia Commission has drawn up the following documents, which are related to and complement these Rules of Procedure:

- *Guide for the Work of the European Pharmacopoeia,*
- *Code of Practice for the work of the European Pharmacopoeia,*
- *Guide on the declassification of documents pertaining to the work of the European Pharmacopoeia.*

Hereinafter, European Pharmacopoeia shall be written 'Ph. Eur.', European Pharmacopoeia Commission shall be written 'EPC', the *Convention on the Elaboration of a European Pharmacopoeia* shall be written 'the Convention', National Pharmacopoeia Authorities shall be written 'NPA' and 'groups' shall be used indifferently to refer Ph. Eur. groups of experts and working parties or both. The term 'text' covers monographs, general chapters and other texts to be published in the Ph. Eur.

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

INDEX

1. MEMBERSHIP OF THE EPC

1.1 The EPC shall be composed of delegations appointed in pursuance of Article 5 of the Convention. The members of the EPC are the members of these delegations.

1.2 The alternates referred to in Article 5 of the Convention shall participate in the EPC only when the members of delegations are prevented from doing so, and for that purpose become members of the EPC.

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 EPC

2.1 In pursuance of subparagraphs a), c) and d) of Article 6 of the Convention, the EPC:

- decides on the work programme for the elaboration of the Ph. Eur. and on the best approach to achieve it,
- adopts the texts for their publication in the Ph. Eur.,
- recommends their date of entry into force,
- decides on the general principles to be applied in the work.

To this end, the EPC prepares a public mission statement defining the role and purpose of the Ph. Eur. and draws up its own Rules of Procedure.

2.2 The EPC may appoint groups.

2.3 The EPC 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*, the *Code of Practice of the European Pharmacopoeia* and the *Guide on the declassification of documents pertaining to the work of the European Pharmacopoeia* are respected.

2.4 The EPC assigns priority for the work programme in line with the approved set of priorities for the coming three years (see section 7.2).

2.5 The EPC evaluates proposals for introduction, revision, suspension or suppression of texts.

2.6 The EPC allocates agreed work items to a group and makes a regular review of overall progress with the work programme, including revision work.

2.7 The EPC approves the terms of reference of groups, defines criteria to be applied in the selection of experts and *ad hoc* specialists and approves the composition of groups, based on the proposals made by the Presidium.

3. CHAIR OF THE EPC

3.1 The Chair of the EPC 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. In the case of non-electronic voting, two tellers appointed by the EPC shall count the votes cast.

Applications for the Chair shall be submitted in writing to the Secretariat (i.e. the EDQM's European Pharmacopoeia Department) 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 applications received.

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

Applications shall be accompanied by a *curriculum vitae*, a declaration of interests and a statement of motivation.

3.2 The term of office of the Chair is three years. This person shall not immediately be eligible thereafter for re-election. The Chair's successor shall be elected at the last EPC session of the aforementioned period of three years but will not take over as Chair until this period has expired. Only exceptionally, in the event that no applications or no suitable applications have been received, can the term of the office of the Chair be prolonged by the EPC.

3.3 Upon taking up his duties, the Chair shall immediately cease to be a member of his delegation; the latter may then be completed in accordance with Paragraph 1 of Article 5 of the Convention.

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 EPC. 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 EPC 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 Rule 3.1 of these Rules of Procedure shall apply *mutatis mutandis* to the election of the Vice-Chairs.

4.3 The term of office of the Vice-Chairs is three years. Immediate re-election to the same position is not permitted (i.e. a first or second Vice-Chair shall not be eligible for re-election to the same position immediately thereafter, whereas a second Vice-Chair would be eligible for re-election as first Vice-Chair and vice versa).

4.4 In order to provide for a reasonable rotation of responsibilities, ideally a person should not be appointed to a Vice-Chair position for more than two successive terms and only exceptionally, where no other suitable candidate is available, to additional terms.

4.5 The next Vice-Chairs shall be elected at the last EPC session of the three-year term; however, they shall not take up their duties until this period has expired.

4.6 When a Vice-Chair is requested to take over the Chair of a session, he ceases to be a member of his delegation.

5. PRESIDIUM

5.1 The Presidium consists of the Chair and the two Vice-Chairs; they are assisted by the Secretary to the EPC. The Director of the European Directorate for the Quality of Medicines & HealthCare (EDQM) may also assist the Presidium on an *ad hoc* basis.

6. DUTIES OF THE CHAIR OF THE EPC

6.1 In consultation with the Secretary to the EPC and, where necessary, the Vice-Chairs, the Chair of the EPC decides on the draft agenda for a session.

6.2 During sessions of the EPC, the Chair 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 these Rules.

6.3 Between sessions, the Chair shall oversee the work of the EPC and, where necessary, act in consultation with the other members of the Presidium on behalf of the EPC.

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 EPC 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 Upon its appointment, the Presidium prepares for consideration by the EPC a set of proposals concerning the general principles and role of the Ph. Eur., criteria for prioritisation of work and a set of priorities for the coming three years. After each session of the EPC, the Presidium may review the work programme for reconsideration by the EPC.

7.3 The Presidium prepares for consideration by the EPC a set of proposals concerning the Terms of Reference of groups, together with the appropriate selection criteria for the nomination of experts and *ad hoc* specialists to each group.

7.4 In accordance with Rule 7.3, the Presidium, based on the applications received from Contracting Parties and from the Secretariat, prepares for consideration by the EPC a proposal for the composition of groups.

8. CONTRACTING PARTIES TO THE CONVENTION

8.1 Each Contracting Party shall notify the Secretariat of the national authority responsible for implementing the decisions of the EPC as foreseen under Article 1 of the Convention (NPA), the responsible person at the NPA and the relevant contact details.

9. EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE

9.1 The Secretariat shall prepare the sessions of the EPC and the meetings of the groups 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 EPC or the groups in accordance with the provisions of the *Code of Practice for the work of the European Pharmacopoeia* and the *Guide on the declassification of documents pertaining to the work of the European Pharmacopoeia*. Such documents shall be provided to the Presidium of the EPC, to the address of the responsible contact person(s) named by each Contracting Party (i.e. the NPA), and, as appropriate, to members of each delegation or group.

9.2 The Secretariat shall be responsible for the publication of drafts (once approved by the group) in Pharmeuropa and of texts adopted by the EPC; each publication shall be issued in the official languages of the Council of Europe.

9.3 Immediately after the adoption by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) (previously the Public Health Committee referred to in subparagraph a) of Article 2 of the Convention) 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 EPC has decided to entrust certain parts of the work. The Secretariat shall contribute to the work on elaboration of texts.

9.5 The EDQM shall organise the preparation, establishment, maintenance and replacement of batches of reference standards.

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

10. GROUPS

10.1 The EPC appoints groups for a period of three years unless otherwise defined by the EPC. Groups of experts cover the main scientific disciplines involved in the quality control of medicinal products and their constituents. Working parties deal with a specific aspect of the work or with a specific topic and may be appointed for a defined period, i.e. until their activities are considered as completed.

10.2 Each group has Terms of Reference. These Terms of Reference are proposed by the Presidium and approved by the EPC.

10.3 Each group has a work programme defined by the EPC. Progress on the work programme is reviewed regularly by the EPC.

10.4 Groups of experts report directly to the EPC. Working parties report directly to the EPC unless otherwise decided.

10.5 Groups 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 Chairs of groups

10.6.1 Each Contracting Party may propose one candidate for appointment as Chair of a group, taking account of his competence for the work involved and of his past contribution. It is considered an advantage if the candidate is also a member of the EPC.

10.6.2 If more than one suitable application is received, the Chair of a group shall be elected by the EPC by a majority of the delegations casting a vote.

10.6.3 Following the election of the Chair and the Vice-Chairs of the EPC, the EPC appoints the Chairs of groups for a period of three years unless otherwise defined by the EPC. In order to ensure that the Chairs are fairly distributed amongst the delegations and to provide for a reasonable rotation of responsibilities, ideally a person should not be appointed for more than two successive terms of office as Chair of a given group and only exceptionally, where no other suitable candidate is available, to additional terms.

10.7 Experts, *ad hoc* specialists and substitutes

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

10.7.2 Experts from Ph. Eur. member states (wherever they are working and irrespective of their nationality) are proposed by a Contracting Party, unless otherwise authorised by the EPC. Experts from non-Ph. Eur. member states are proposed by the Secretariat.

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

10.7.4 When an expert or *ad hoc* specialist proposed by a Contracting 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 group accordingly.

10.7.5 Unless otherwise decided by the EPC or, in urgent cases, by its Chair, substitutes for experts proposed by the Secretariat are not allowed.

11. CONSULTATIONS

11.1 Drafts of new texts and of texts having undergone a technical revision are submitted for public consultation on the *Pharmeuropa* website, after approval by the Group. The decision whether or not to publish for public consultation a draft text that has undergone a rapid revision or a text that is to be suspended (in part or in its entirety) will be taken on a case-by-case basis by the EPC. Further information can be found in the *Guide for the Work of the European Pharmacopoeia*.

11.2 The EPC may decide to hear the representatives of associations or scientific institutions.

11.3 The EPC may also decide to seek the advice of consultants.

12. OBSERVERS

12.1 The CD-P-PH may appoint an observer to attend meetings the sessions of the EPC; these observers shall have the right to speak and to make proposals.

12.2 The EPC 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 or agencies 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 nor may they take decisions.

13. SESSIONS AND AGENDA OF THE EPC

13.1 The sessions of the EPC can be in-person, hybrid or virtual. In-person sessions shall be held in Strasbourg, the seat of the Council of Europe.

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

13.3 Once a session has been convened in accordance with Rule 13.2, any requests for postponement must reach the Secretariat at least 21 days before the first day of the session. The session shall be postponed if three-quarters of the delegations have informed the Secretariat of their agreement 14 days before the date originally set. A decision to bring forward the date of the Session shall be taken only when all the delegations have informed the Secretariat of their agreement at least 14 days before the new date proposed.

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

13.5 A delegation to the EPC may request to confirm its decision on an item by the confirmation date. The confirmation date is proposed by the Chair of the EPC at the beginning of a session, for approval by the EPC.

13.6 Sessions of the EPC shall be held in private.

14. MEETINGS OF THE GROUPS

14.1 Group meetings can be in-person, hybrid or virtual. In-person meetings shall be held in Strasbourg, unless otherwise justified. If it is proposed to hold a meeting elsewhere, the Chair of the group should make a request in writing to the Director of the EDQM providing justification for this in terms of the contribution it will make to the advancement of the work of the group. The Secretariat will consult the NPAs before taking a decision.

14.2 Meetings of the groups shall be held in private.

15. REPORTS OF THE EPC

15.1 After each session of the EPC, the Secretariat shall issue a summary of decisions promptly and prepare a report.

15.2 The report shall give the text of and, where appropriate, the grounds for all decisions taken by the EPC, particularly those relating to:

(a) the general principles to be applied in elaborating the Ph. Eur.;
(b) the texts provided for in Article 6 of the Convention intended to be included in the Ph. Eur.

15.3 The report shall include, where necessary the name of each text adopted and the reference number of the document in which the text appears, together with the text of any adopted amendments to that document.

15.4 Each report shall be submitted for approval to the EPC at the session following that to which it refers. Once approved, the report shall then be transmitted to the CD-P-PH in accordance with Article 4 of the Convention.

16. LANGUAGES

16.1 The working languages of the EPC 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 that person arranges for interpretation into one of the official languages.

17. QUORUM

17.1 The decisions of the EPC 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 cases, 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 EPC and the tellers (in case of non-electronic voting) if any delegation has chosen to be represented in this way.

18. INTRODUCTION, REVISION, SUSPENSION OR SUPPRESSION OF TEXTS IN/OF THE PH. EUR.

18.1 Proposals concerning the introduction, revision, suspension or suppression of texts in/of the Ph. Eur. may be made by:

- the Chair of the EPC;
- a delegation;
- an NPA;
- a group through the intermediary of its Chair;
- the Secretariat;
- manufacturers and other interested parties from member states through the intermediary of their NPA;
- manufacturers and other interested parties from Observers through the intermediary of the Secretariat;
- manufacturers and other interested parties from non-member states or non-observers through the intermediary of the Secretariat;
- etc.

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

19. REVISION OF THE RULES OF PROCEDURE

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

19.2 Amendments thereto shall require a three-quarters majority of the votes cast 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 specify one or more items):