EURASIAN ECONOMIC COMMISSION
BOARD

DECISION

September 22, 2015. **No 121** City of Moscow

on the Rules of Procedure of the Eurasian Economic Union Pharmacopoeial Committee

(As amended by the Decision 170 of the Board of the EEC of 27 December 2016)

Pursuant to Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014, Article 5 of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, paragraph 29 of Appendix No 2 to the Regulations of the Eurasian Economic Commission as approved by Decision No 98 of the Supreme Eurasian Economic Council of 23 December 2014, and by Decision No. 108 of the Supreme Eurasian Economic Council of 23 December 2014 on the Implementation of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union, the Board of the Eurasian Economic Commission has decided:

1. To approve the Rules of Procedure of the Eurasian Economic Union Pharmacopoeial Committee.

2. This Decision shall enter into force on the day of entry into force of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014.

Chairperson of the Board of the Eurasian Economic Commission

V. Khristenko

APPROVED
by Decision No. 121 of the Board of
the Eurasian Economic Commission of
3 November 2016

the RULES
of Procedure of the Eurasian Economic Union Pharmacopoeial Committee

I. GENERAL PROVISIONS

1. These Rules of procedure have been developed in accordance with Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014, Article 5 of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014 and Decision 108 of the Supreme Eurasian Economic Council of 23 December 2014 and lay down authority, rules of operation and composition of the Eurasian Economic Union Pharmacopoeial Committee (hereinafter referred to as the Pharmacopoeial Committee).

2. The Union Pharmacopoeial Committee shall be established with the view of consideration and approval of general chapters and monographs of the Eurasian Economic Union Pharmacopoeia (hereinafter referred to as the Union Pharmacopoeia), including monographs for veterinary medicinal products, to be included in the Union Pharmacopoeia (hereinafter referred to as monographs).

3. The operation of the Committee shall be governed by the Treaty on the Eurasian Economic Union dated 29 May 2014, the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, legal acts constituting law of the Eurasian Economic Union (hereinafter referred to as the Union) and these Rules of procedure.

4. The Union Pharmacopoeial Committee shall operate in cooperation with competent authorities of the Union Member States (hereinafter referred to as the Member States), international and regional organisations, public enterprises, and other organisations.

5. The core principles of the Union Pharmacopoeial Committee's operation are the principles of legitimacy, free will, openness, equality, cooperative decision-making, and taking into account the perspectives of the parties to the pharmaceutical market.

II. AUTHORITY OF THE UNION PHARMACOPOEIAL COMMITTEE

6. The Union Pharmacopoeial Committee shall have the following authority:

a) Development of the framework for harmonisation of pharmacopoeias of the Member States and methods of harmonisation of pharmacopoeial texts and the development of the procedure of harmonisation of pharmacopoeias of the Member States

b) Establishing common approaches to the development of pharmacopoeial texts for different types of pharmaceutical products (substances for pharmaceutical use, herbal substances, finished products, etc.)

c) Establishing of guidance for the development and harmonisation of pharmacopoeial texts

d) Establishing application forms for the development, update, or amendment of pharmacopoeial texts

e) Establishing a list of documents which shall accompany draft pharmacopoeial texts

f) Making decisions on the development, update, or amendment of pharmacopoeial texts

g) Drafting an annual business plan for the Union Pharmacopoeial Committee

h) Selecting Member States' test laboratories for the verification of draft pharmacopoeial texts upon proposals made by the competent authorities of the Member States

i) Scientific assessment of draft pharmacopoeial texts, draft pharmaceutical quality guidelines and documents or materials accompanying thereof

j) Scrutinising draft pharmacopoeial texts, draft pharmaceutical quality guidelines and documents or materials accompanying thereof and making decision on approval or rejection providing the reasons for decisions made

k) Development and approval of the draft Union Pharmacopoeia to submit it to the Eurasian Economic Commission (hereinafter referred to as the Commission);

l) Establishing the list of Union Pharmacopoeia reference standards

m) International scientific and technical co-operation in the area of pharmaceutical quality.

III. OPERATION MANAGEMENT

7. The Pharmacopoeial Committee shall consist of representatives of the Member States.

The number of Union Pharmacopoeial Committee members from each Member State shall be limited to 7 individuals.

To provide organizational and technical support for Pharmacopoeial Committee activities, the Head of Department responsible for regulation of medicinal products within the Union shall establish a secretariat of the Pharmacopoeial Committee, consisting of officers and servants of the Commission which shall not be members of the Pharmacopoeial Committee and shall not vote.

8. Changes of Union Pharmacopoeial Committee members shall be proposed by the competent authorities of the Member States.

9. Meetings of the Union Pharmacopoeial Committee may be attended by the assessors of the Member States, qualified representatives of the non-Union countries, international or reginal organisations, including a drug developer, manufacturer or marketing authorisation holder as proposed by competent authorities of the Member States or the Commission. These individuals shall not become members of the Pharmacopoeial Committee and shall not vote.

Proposals on the Union Pharmacopoeial Committee meeting addenda shall be submitted to the Union Pharmacopoeial Committee secretariat in writing before the meeting takes place.

10. The Union Pharmacopoeial Committee shall consist of a chair of the, deputy chairs, members of the Union Pharmacopoeial Committee.

11. The chair of the Union Pharmacopoeial Committee shall be elected during the first meeting of the Union Pharmacopoeial Committee by ballot voting of a qualified majority of at least two third of participating Union Pharmacopoeial Committee members from the candidates proposed by the competent authorities of the Member States.

The term of a Union Pharmacopoeial Committee chair shall be limited to 3 years.

Election of a new Union Pharmacopoeial Committee chair shall take place within the last scheduled before the current chair's term lapses. Where the Union Pharmacopoeial Committee chair steps down on his/her motion or cannot fulfil their tasks, the election of a new chair shall take place on unscheduled meeting of the Union Pharmacopoeial Committee.

12. The Union Pharmacopoeial Committee chair shall:

a) be responsible for general management of the Union Pharmacopoeial Committee activities and work;

b) chair the meetings of the Union Pharmacopoeial Committee, approve the meeting agenda of the Union Pharmacopoeial Committee, sign the meeting minutes of the Union Pharmacopoeial Committee;

c) based on discussion at the meeting of the Union Pharmacopoeial Committee and the meeting minutes, approve:

The model of harmonisation of Member States pharmacopoeias, types and mechanisms of harmonisation of pharmacopoeial texts requirements, and the procedure for harmonisation of the Member States pharmacopoeias in accordance with the Conception of Harmonization of Pharmacopeias of the Member States of Eurasian Economic Union subject to approval by the Commission;

general approaches to establishment of pharmacopoeial texts for different types of medicinal products (substances for pharmaceutical use, herbal substances, finished products, etc.);

the guideline on the development and harmonisation of pharmacopoeial texts;

application forms for the development of the pharmacopoeial texts, updates, or amendments to pharmacopoeial texts;

a list of documents and materials accompanying a draft pharmacopoeial text;

a list of documents and materials accompanying a draft pharmaceutical quality guideline;

pharmacopoeial textx, updates, or amendments to pharmacopoeial texts outlining the date of taking effect of these pharmacopoeial texts, updates, or amendments to pharmacopoeial texts;

documents on Union Phamacopoeial Committee activities, including the working plan of the Union Phamacopoeial Committee, outlining the Member States developing the draft pharmacopoeial texts, updates, or amendments to the pharmacopoeial texts;

a list of quality testing laboratories of the Member States to verify draft pharmacopoeial texts bases on proposals of the competent authorities of the Member States;

a list of reference standards of the Union Pharmacopoeia;

d) appoint a head of the Union Phamacopoeial Committee secretariat;

e) approve heads and members of designated expert groups, the procedure and scope of the designated expert groups.

13. In the absence of the Union Phamacopoeial Committee chair, their tasks shall be delegated to any of the deputy chairs of the Union Phamacopoeial Committee.

14. Union Phamacopoeial Committee deputy chairs shall be elected from the candidates proposed by the competent authorities of the Member States for the position of a Union Phamacopoeial Committee deputy chair in accordance with procedure for electing a Union Phamacopoeial Committee chair.

Election of Union Pharmacopoeial Committee deputy chairs shall be carried out together with election of the Union Pharmacopoeial Committee chair.

The number of Union Pharmacopoeial Committee deputy chairs shall be limited to 5 people.

15. The Union Pharmacopoeial Committee secretariat (hereinafter referred to as the secretariat) shall be established by the Commission from the officials and employees of the Commission as proposed by the Commission department responsible for pharmaceuticals in the Union.

16. The Executive Secretary of the Committee shall be appointed by the head of the Commission department responsible for pharmaceuticals in the Union.

17. The Secretariat shall:

a) manage and provide operational support to the Union Pharmacopoeial Committee;

b) receive applications from the competent authorities of the Member States on development of pharmacopoeial texts, updates, or amendments to the pharmacopoeial texts together with their reasons;

c) receive draft pharmacopoeial texts, draft pharmaceutical quality guidelines, as well as the documents or materials accompanying thereof;

d) prepare of Union Pharmacopoeial Committee minutes abstract on approval or rejection of the pharmacopoeial texts, updates, or amendments to the pharmacopoeial texts or draft pharmaceutical quality guidelines

e) prepare and lay before the Commission of the draft Union Pharmacopoeia as approved by the Union Pharmacopoeial Committee;

f) prepare and lay before the Commission of the draft pharmaceutical quality guidelines;

g) maintain the list of reference standards of the Union Pharmacopoeia;

h) publish of the draft pharmacopoeial texts and draft pharmaceutical quality guidelines as recommended by the designated expert groups for the adoption by the Union Pharmacopoeial Committee, on the official web site of the Union;

i) highlight the activities of the Union Pharmacopoeial Committee on the official web site of the Union;

j) prepare draft agenda for the meeting of Union Pharmacopoeial Committee or draft agenda for meetings of designated expert groups;

k) minute meetings of the Union Pharmacopoeial Committee and designated expert groups;

l) prepare and provide materials for meetings of the Union Pharmacopoeial Committee and designated expert groups.

18. The head of the secretariat shall:

a) be responsible for general management of the secretarial;

b) assign responsibilities between secretariat members.

19. Within the Union Pharmacopoeial Committee, designated expert groups shall be established to discuss and assess draft pharmacopoeial texts, draft pharmaceutical quality guidelines and to present them to approval by the Union Pharmacopoeial Committee.

20. The designated expert groups shall be composed in accordance with the proposals of competent authorities of the Member States or the Commission from the members of the Union Pharmacopoeial Committee and assessors working at scientific institutions, educational institutions for higher education, representatives of the competent authorities of the Member States not included in the Union Pharmacopoeial Committee, pharmaceutical manufacturers, quality test laboratories staff.

21. The head of a designated expert group of the Union Pharmacopoeial Committee shall be responsible for general management of the designated expert group and chair meetings of the designated expert group.

22. Decisions of the designated expert group shall be taken based on discussion of the topics included in the designated expert group meeting agenda and recorded in the meeting minutes which shall be signed by the head of the designated expert group. Designated expert group members which do not agree with the majority opinion may write their disagreeing opinion. The disagreeing opinion of designated expert group members shall be appended to the minutes and is recognized as its part.

23. Members of the Union Pharmacopoeial Committee and designated expert group shall work bona fide.

24. Meetings of the Union Pharmacopoeial Committee shall be carried out in accordance with its schedule (scheduled meetings).

Scheduled meetings shall take place at least 4 times per year.

Unscheduled meetings of the Union Pharmacopoeial Committee may take place upon decision of the Union Pharmacopoeial Committee chair.

25. Union Pharmacopoeial Committee members shall take part at the meetings personally, and delegation of the authority is not allowed.

26. Before a Union Pharmacopoeial Committee meeting, the secretariat shall prepare a draft agenda taking into account any decisions made at the designated expert group meetings, as the case may be.

The draft agenda of the scheduled Union Pharmacopoeial Committee meeting shall be sent to the Union Pharmacopoeial Committee members at least 10 calendar days before the meeting day.

27. The meeting agenda of the Union Pharmacopoeial Committee shall be approved by its chair at the beginning of the meeting based on the draft provided by the secretariat.

Union Pharmacopoeial Committee meetings shall take place where at least two third of the Union Pharmacopoeial Committee take part in the meeting.

The Union Pharmacopoeial Committee chair shall check the quorum immediately before the meeting.

Where the quorum has not been reached, the Union Pharmacopoeial Committee chair shall make a decision to postpone the meeting which shall be reflected in the meeting minutes.

28. The designated expert group head shall report decisions made by the designated group at the Union Pharmacopoeial Committee meeting.

29. Based on discussion by the Union Pharmacopoeial Committee of a draft pharmacopoeial text or draft pharmaceutical quality guideline, a decision shall be made on approval or rejection of the proposed draft together with the reasons in case of rejection.

30. Where the Union Pharmacopoeial Committee rejects the draft pharmacopoeial text, it shall be referred to its developer which shall elaborate it taking into account recommendations made at the designated expert group meetings. The elaboration shall be completed within 40 calendar days.

Where the Union Pharmacopoeial Committee rejects the draft pharmaceutical quality guideline, it shall be referred to its developer which shall elaborate it taking into account recommendations made at the designated expert group meetings. The elaboration shall be completed within 40 calendar days.

31. The decision on approval or rejection of the draft pharmacopoeial text or draft pharmaceutical quality guideline shall be made openly by the simple majority of the members taking part at the Union Pharmacopoeial Committee.

32. The decision of the Union Pharmacopoeial Committee shall be reflected in the minutes which shall be signed by the Union Pharmacopoeial Committee chair. The minutes shall be signed by the members taking part in the Union Pharmacopoeial Committee Union.

33. Approval by the Union Pharmacopoeial Committee of the pharmacopoeial text shall constitute a basis for the approval by the Union Pharmacopoeial Committee chair of the pharmacopoeial text, updates or amendments to the pharmacopoeial text and determining periods of taking into effect of that pharmacopoeial text, updates or amendments to the pharmacopoeial text.

Approval of the pharmacopoeial text, updates or amendments to the pharmacopoeial text shall constitute a basis for consideration by the Commission for including of that pharmacopoeial text, updates or amendments to the pharmacopoeial text in the Union Pharmacopoeia.