EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

November 03, 2016. **No 75** Astana city

on the Approval of the Rules of Procedure of the Expert Committee for Medicinal Products

Pursuant to Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014, Article 7(8) of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, paragraph 90 of Appendix No 1 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 Council of the Eurasian Economic Commission has decided:

1. To approve the Rules of Procedure of the Expert Committee for Medicinal Products.

2. This Decision shall enter into force on the 10th day following that of entry into force of the Protocol of 2 December 2015 on the Accession of the Republic of Armenia to the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, but not earlier than on the 10th day following that the official publication of this Decision.

Members of the Board of the Eurasian Economic Commission:

From the Republic of Armenia	From the Republic of Belarus	From the Republic of Kazakhstan	From the Republic of Kyrgyzstan	From the Russian Federation
V. Gabrielyan	**V. Matyuschevsky**	**A. Mamin**	**O. Pankratov**	**I. Shuvalov**

APPROVED
by Decision No. 83 of the Council
of the Eurasian Economic Commission
of 3 November 2016

R U L E S
OF PROCEDURE OF THE EXPERT COMMITTEE FOR MEDICINAL PRODUCTS

I. GENERAL PROVISIONS

1. The Expert Committee for Medicinal Products (hereinafter referred to as the Committee) is hereby established within the Eurasian Economic Commission (hereinafter referred to as the Commission) in accordance with Article 7(8) of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014 and Decision No 108 of the Supreme Eurasian Economic Council of 23 December 2014.

2. 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.

3. The core principles of the Committee's operation are the principles of legitimacy, free will, openness, equality, competency and expertise of the members, cooperative decision-making, and taking into account the global scientific and technical progress.

4. Based on requests from competent authorities of the Union Member States (hereinafter referred to as the Member States), members of the Commission Board, and members of the Committee, the Committee shall develop proposals on the following issues:

a) harmonisation and alignment of legislation of the Member States in the area of pharmaceuticals;

b) harmonisation of legislation of the Member States in the area of supervision of pharmaceuticals and cooperation between pharmaceutical competent authorities;

c) ensuring uniformity of mandatory requirements for the safety, efficacy, and quality of medicinal products within the Member States and enforcement thereof;

d) enacting common rules and requirements for the governing of medicinal products within the Union;

e) ensuring common approaches to creating a quality assurance system for medicinal products.

5. To ensure the implementation of the Common Principles and Rules of Medicinal Products Circulation within the Union, the Committee, based on requests from the pharmaceutical competent authorities of the Member States (hereinafter referred to as the competent authorities), shall settle irregularities in the governing medicinal products by issuing recommendations, including the following issues:

a) dispute resolution between competent authorities regarding granting a marketing authorisation and assessment of the safety, quality, and efficacy of medicinal products, recognition of the nonclinical, clinical, and other test data on medicinal products, the conclusions of inspections of manufacturing, nonclinical and clinical tests/studies of medicinal products, and pharmacovigilance systems for compliance with the rules of good pharmaceutical practice and the requirements approved by the Commission;

b) considering divergent opinions made by the competent authorities on the assessment of the risk/benefit balance of the medicinal products marketed in the Member States;

c) deciding whether it is necessary to conduct a joint pharmaceutical inspection of a pharmaceutical undertaking for compliance with the requirements of good pharmaceutical practices and selecting the Member State's pharmaceutical inspectorate responsible for the inspection;

d) selecting the reference product for nonclinical or clinical tests/studies where so provided by the Rules for Conducting Bioequivalence Studies of Medicinal Products in the Eurasian Economic Union and Rules for investigation of biological medicinal products of the Eurasian Economic Union, the term for a new pharmaceutical dose form of a medicinal product being developed where no appropriate term exists in the Pharmaceutical Dose Form Nomenclature;

e) other issues within the scope of the Committee as laid down in legal acts constituting law of the Union.

6. To ensure the implementation of the Common Principles and Rules of Medicinal Products Circulation within the Union, the Committee, in response to applications submitted by pharmaceutical undertakings, shall consider the issues that are not regulated by the Commission's acts and related to nonclinical or clinical tests/studies, quality assurance of medicinal products or the activities of pharmaceutical inspectors, and adopt appropriate recommendations.

7. The Committee shall consider the issues provided in paragraphs 5 and 6 of these Rules within 60 calendar days of receipt of the request/application.

II. COMPOSITION AND PROCEDURE OF FORMATION OF THE COMMITTEE

8. The members of the Committee shall be appointed by the Commission Board for three years from the representatives of the Member States proposed to the Commission by the competent authorities limited to three individuals from each Member State.

At the request of the respective competent authority, a representative of a Member State may be recalled from the Committee, and the competent authority shall nominate another member for replacement. The new representative of the Member State to the Committee shall be approved by the Commission Board.

9. The Board member responsible for the governing medicinal products shall chair the Committee meetings and have overall governance of the Committee (hereinafter referred to as the Chairperson of the Committee).

10. A Standing Secretariat of the Committee consisting of the officials and employees of the Commission (hereinafter referred to as the Secretariat) shall be established.

11. Where necessary, advisory and working groups shall be established within the Committee to consider and draw up recommendations or proposals on certain issues.

III. CHAIRPERSON OF THE COMMITTEE AND THE SECRETARIAT

12. The Chairperson of the Committee shall:

a) govern the activities of the Committee and arrange the work to accomplish the tasks assigned to the Committee in accordance with these Rules;

b) approve the Rules of procedure of the Committee meetings;

c) coordinate the draft agenda, dates, time, and venue of a Committee meeting;

d) conduct the Committee meeting;

e) sign the minutes of the Committee meeting endorsed by the Committee members that were attending at the meeting;

f) communicate recommendations and proposals drawn up by the Committee to the Commission Board and the competent authorities;

g) approve the Rules of procedure and composition of the advisory and working groups proposed by the competent authorities and established within the Committee;

h) represent the Committee at the meetings of the Commission Board and in relations with other bodies of the Union;

i) appoint the Executive Secretary of the Committee.

13. The Secretariat shall provide administrative support to the Committee, participate in preparing documents for the Chairperson of the Committee, members of the Committee, advisory and working groups.

14. The Executive Secretary of the Committee shall govern Secretariat activities.

15. The Executive Secretary of the Committee shall be appointed by the Chairperson of the Committee from the officials and employees of the Commission.

16. The Executive Secretary of the Committee shall:

a) prepare and communicate the draft agenda and materials of the Committee meeting to the Committee members;

b) take minutes of the Committee meeting and submit it to the Chairperson of the Committee for signing;

c) monitor the fulfilment of the orders set out in the minutes of the Committee meetings;

d) notify the members of the Committee of the date, time, and venue of the upcoming meeting of the Committee;

e) create the Committee's draft work plans and distribute them to the members of the Committee;

f) control the preparation and distribution of working materials for the meetings of the Committee;

g) organise the preparation and communication of final documents of the Committee to the Committee members.

IV. Procedure of the Committee

17. The proposals for the draft agenda of the Committee meeting and any supplemental materials, including electronical format, shall be forwarded to the Chairperson of the Committee by the competent authorities, the members of the Commission Board and the members of the Committee at least 15 calendar days prior to the day of the meeting of the Committee, except for the advisory group reports which shall be forwarded to the Committee for consideration on the day they are approved by the chair of the group.

Where urgent consideration is needed, the representatives of the competent authorities may propose additional items to the agenda directly at the Committee meeting.

18. Any requests submitted to the Committee for consideration shall include materials necessary for making appropriate decisions. Proposals to the Committee meeting agenda shall be explained in a statement included in the accompanying materials.

19. If the submitted materials are insufficient, the Executive Secretary of the Committee may request additional materials from the competent authorities or the persons who proposed their issues to the Committee for consideration, or other competent authority.

20. The Secretariat shall prepare a draft agenda for the Committee meeting based on the materials received from the competent authorities, members of the Board of the Commission, and members of the Committee.

21. The agenda of the Committee meeting and the materials on the issues included in the agenda shall be forwarded (or emailed) to the members of the Committee at least 5 calendar days prior to the day of the Committee meeting.

22. The meetings of the Committee shall be held on a regular basis, not less often than once in three months.

23. The representative of a competent authority that applied to the Committee for resolving any disagreements which had arisen during the granting a marketing authorisation for medicinal products shall be invited to the Committee meeting to make representations on the issue.

24. The Committee shall take appropriate steps to ensure confidentiality of the information submitted in accordance with legal acts constituting law of the Union and applicable legislation of the Member States.

25. The quorum shall be reached when two thirds of the total members of the Committee, including at least one representative of each Member State, are present.

The meeting of the Committee may be held in any Member State subject by approval by the Chairperson of the Committee based on proposals from the members of the Committee. The Chairperson of the Committee may decide to hold the meetings in the form of a video and/or online conference.

Where the representative of a Member State cannot participate in the Committee meeting, the competent authority of the Member State shall forward information in writing describing its opinions on the meeting agenda items to the Committee.

26. The meetings of the Committee shall be opened and closed by the Chairperson of the Committee.

27. The draft recommendations and proposals of the Committee to be considered at the Committee meeting shall be prepared by the Secretariat.

28. To prepare recommendations pursuant to paragraphs 5 and 6 of these Rules, the Committee may establish advisory groups, and for the issues set out in paragraph 4, working groups.

29. The decision on establishing an advisory or working group shall be made at a Committee meeting within scrutiny of the respective issue of the Committee meeting agenda.

In the event of any requests in accordance with paragraph 5 of the Rules, the decision to establish an advisory group may also be made by the Chairperson of the Committee.

30. The term of advisory or working groups shall be established within the decision on establishment thereof by the Committee or its Chairperson, based on the tasks and time needed to prepare a recommendation or proposal and a report.

31. Based on requests/applications submitted in accordance with paragraphs 4, 5, or 6 of these Rules, the Secretariat shall, within 5 calendar days following the receipt of the request/application, electronically notify the Committee members of establishing an advisory or working group.

Within 5 calendar days following the receipt of the above notice, the Committee members shall electronically send their proposals of nominees for the advisory or working group to the Secretariat.

Within 3 calendar days following the receipt of all proposals of nominees to the advisory or working group, the Secretariat shall prepare and forward a proposal on establishing the advisory or working group to the Chairperson of the Committee.

32. The advisory or working group shall consist of the Committee members and independent experts from the Member States who have the training, expertise and practical experience required to tackle the issues raised and who submitted a declaration of interest stating no conflict of interest in the issues raised.

33. Where a conflict of interest in any issues is identified for a member of the advisory or working group, the Chairperson of the Committee shall, within two calendar days, make a decision to remove such a member from discussion in which the conflict of interest was identified, and the respective competent authority, members of the Committee, and advisory or working group shall be immediately notified thereof.

34. If necessary, the Committee shall set tasks for the advisory or working groups in order to develop recommendations and proposals for the requests/applications received.

35. The meetings of the advisory or working groups and the meetings of the Committee may be attended by the representatives of the pharmaceutical undertakings, scientific and medical staff, experts of the expert organisation, including those who participated in the assessment of the medicinal product and independent experts proposed by the competent authorities or the Commission.

36. The chairs of the advisory or working groups shall be selected from the Committee members, other representatives of the competent authorities or assessment organisations of the Member States.

37. The chars shall plan the work of the advisory or working groups and govern their current activities.

38. Following the recommendations of chairs of the advisory or working groups to obtain the information necessary to prepare recommendations or proposals, the Chairperson of the Committee shall forward (including electronically) the respective requests to the competent authorities and organisations. The response to the requests shall be given electronically within 20 calendar days following the day they were served.

The Secretariat shall forward the materials received along with the request/application to the members of the respective advisory or working group in accordance with paragraphs 5 and 6 of these Rules.

39. Upon completion of the work or when a recommendation/proposal has been developed, the advisory or working group shall prepare a report subject to approval by the group chair and submitted to the Committee for consideration.

Based on the consideration of the report by the advisory or working group, the Committee shall adopt respective recommendations or proposals.

40. The agenda at the meeting of the Committee shall be reported by the Chairperson of the Committee, a member of the Committee or a representative of the competent authority.

When drafting an agenda, the issues related to the resolution of disputes arising in the course of granting a marketing authorisation for medicinal products shall be of the first priority.

41. The Committee shall pass recommendations and proposals:

a) by consensus: for the issues set out in paragraphs 5(a), (b) and (e) and 6 of these Rules;

b) by a majority vote in open voting (each Member State has one vote): for the issues set out in paragraph 5(c) and (d). The members of the Committee may issue a special opinion on the resolution passed and attach it to the minutes.

The Committee members representing the Member States shall participate in the voting.

42. At the end of the Committee meeting, the minutes shall be prepared, signed by the Chairperson of the Committee and sent to the competent authorities within 5 calendar days.

The recommendations and proposals of the Committee adopted as a result of considering the request/application shall be sent by the Executive Secretary of the Committee to the applicant’s address within 5 calendar days from the adoption thereof.

43. The competent authorities shall inform the Chairperson of the Committee of the steps taken to implement the recommendations and proposals of the Committee.

44. The Committee may decide to make recommendations and proposals publicly available on the official website of the Union.