

ADOPTED
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at its forty-third (30th ordinary)
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REGULATIONS ON EURASIAN PHARMACEUTICAL REGISTER

CHAPTER 1 GENERAL PROVISIONS

1. This Regulations establish the purpose and general principles of the formation and maintenance of the Eurasian Pharmaceutical Register (hereinafter referred to as "Pharmaceutical Register"), set the legal and organizational basis for the formation and maintenance of the Pharmaceutical Register, determine the information content included in the Pharmaceutical Register, its legal status, grounds for its inclusion in the Pharmaceutical Register, amendments, and exclusions of the specified information from the Pharmaceutical Register.

2. For the purposes of the present Regulations the following definitions shall mean:

"Convention" – the Eurasian Patent Convention signed in Moscow on September 9, 1994;

"Patent Regulations" – the Patent Regulations under the Eurasian Patent Convention referred to in Articles 3(3)(vii), 14 and 19 of the Convention;

"Contracting State" – a State party to the Convention;

"Organization" – the Eurasian Patent Organization according to Article 2(1) of the Convention;

"Eurasian Office" – the Eurasian Patent Office according to Articles 2(3) and 4 of the Convention;

"national Office" – the national Patent Office of a Contracting State;

"Eurasian patent" – a patent for invention granted by the Eurasian Office as referred to in Article 15 of the Convention;

"national patent" – a patent for invention granted by a national Office under the national legislation of a Contracting State;

"patent owner" – a person having the exclusive right to the patented invention according to Article 9 of the Convention or to the national legislation of a Contracting State.

3. The Pharmaceutical Register constitutes a set of credible and systematized data on Eurasian and national patents for inventions related to active pharmaceutical ingredients (hereinafter referred to as "API") having international nonproprietary names (hereinafter referred to as "INN"), which is created to ensure the enforcement and realization of exclusive rights to the aforementioned inventions on the territory of Contracting States.

4. The Pharmaceutical Register shall be formed and maintained by the Eurasian Office.

CHAPTER 2

PURPOSE AND PRINCIPLES OF THE FORMATION AND MAINTENANCE OF THE PHARMACEUTICAL REGISTER

5. The purpose of the formation and maintenance of the Pharmaceutical Register is to provide any interested persons, judicial and other competent authorities of the Contracting States with reliable and comprehensive information confirming the protection of API-related inventions by Eurasian and/or national patents, as well as the legal status of such protection.

6. The formation and maintenance of the Pharmaceutical Register shall be based on the following principles:

- credibility and relevance of the information included in the Pharmaceutical Register and its subsequent updating;

- compliance of the information in the Pharmaceutical Register with the information in the Register of Eurasian patents and/or state registers of inventions of the Contracting States;

- transparency and accessibility of the information contained in the Pharmaceutical Register;

- free access to the information in the Pharmaceutical Register;

- continuity and uninterrupted functioning of the Pharmaceutical Register.

CHAPTER 3

GENERAL REQUIREMENTS FOR THE FORMATION AND MAINTENANCE OF THE PHARMACEUTICAL REGISTER

7. The Pharmaceutical Register shall be formed and maintained in Russian. INN, names of patent owners, and titles of inventions shall be also included in the Pharmaceutical Register in English.

8. The Pharmaceutical Register shall be formed and maintained in electronic form on the Organization's website and made available to all interested parties.

9. The Pharmaceutical Register shall ensure:

- collection, storage, processing and analysis of the information of the Pharmaceutical Register;

- access to the information contained in the Pharmaceutical Register;

- interaction of the Pharmaceutical Register with other web resources of the Organization, containing information on Eurasian patents, as well as with information resources of national offices containing information on national

patents in the Pharmaceutical Register, with due regard to agreements concluded between the Organization and national offices;

obtaining and maintaining credible and up-to-date information;

monitoring the accuracy and relevance of the data in the Pharmaceutical Register.

CHAPTER 4

INFORMATION INCLUDED IN THE PHARMACEUTICAL REGISTER

10. The Pharmaceutical Register shall include the following information:

10.1. data on Eurasian and national patents which protect:

API (chemical compounds, including those described by a general structural formula, biotechnological products);

compositions and combinations containing API;

processes of production of API;

medical uses of API ;

10.2. data on the legal status of Eurasian and national patents that protect API-related inventions;

10.3. data on licenses and other agreements concluded in respect of API-related inventions protected by Eurasian and/or national patents, as well as provided limitations of the exclusive rights to such inventions.

11. The Pharmaceutical Register consists of two parts: the part related to Eurasian patents and the part related to national patents. The information on Eurasian and national patents for API-related inventions included in the Pharmaceutical Register shall be grouped according to the INN to which they pertain.

12. The part of the Pharmaceutical Register related to Eurasian patents shall include the following data:

INN or combination of INN;

number of the Eurasian patent;

number and date of filing of the Eurasian patent application;

title of the invention;

claim (claims) related to API;

name of the patent owner, the country code of his or her residence (information on all patent owners, if there are several);

date of expiration of the term of the Eurasian patent under Article 11 of the Convention;

information on the validity of the Eurasian patent on the territory of each Contracting State;

information on the extension of the term of the Eurasian patent on the territory of Contracting States (if available);

information on certificates for medicinal product's marketing authorization issued by the competent authorities of Contracting States (if available);

information on licenses and other agreements registered on the territory of Contracting States (if available);

information on compulsory licenses granted on the territory of Contracting States and other limitations of the exclusive right to the invention imposed on their territories (if available);

links to web resources of the Organization containing comprehensive information on the Eurasian patent.

13. The part of the Pharmaceutical Register related to national patents shall include the following data:

INN or combination of INN;

code of the Contracting State;

number of the national patent;

number and date of filing of the national patent application;

title of the invention;

claim (claims) related to API;

name of the patent owner, the country code of his or her residence (information on all patent owners, if there are several);

date of expiration of the term of the national patent;

information on the validity of the national patent on the territory of the Contracting State;

information on the extension of the term of the national patent on the territory of the Contracting State (if available);

information on certificates for medicinal product's marketing authorization issued by the competent authority of the Contracting State (if available);

information on licenses and other agreements registered on the territory of the Contracting State (if available);

information on compulsory licenses granted on the territory of the Contracting State and other limitations of the exclusive right to the invention imposed on their territory (if available);

links to web resources of the national office containing comprehensive information on the national patent.

CHAPTER 5

INCLUSION OF INFORMATION IN THE PHARMACEUTICAL REGISTER

14. Information indicated in paragraphs 12 and 13 of this Regulation shall be included in the Pharmaceutical Register at the request of patent owners.

The Eurasian Office may establish a fee for the examination of patent owners' requests for inclusion of information in the Pharmaceutical Register.

15. Information indicated in paragraph 12 of these Regulations may also be included in the Pharmaceutical Register by the Eurasian Office on the basis of data obtained from patent owners' request for extension of the term of Eurasian patents filed in accordance with Rule 16(5) of the Patent Regulations.

16. Information indicated in paragraph 13 of these Regulations may also be included in the Pharmaceutical Register by the Eurasian Office on the basis of data obtained pursuant the implementation of agreements concluded between the Organization and national offices.

17. Information on Eurasian and national patents indicated in paragraphs 12 and 13 of these Regulations shall be included in the Pharmaceutical Register based on the results of the examination conducted by the Eurasian Office on the concordance of the INN and the API protected by the Eurasian or national patent.

18. The Eurasian Office shall establish the procedure for the inclusion of information in the Pharmaceutical Register.

CHAPTER 6

AMENDMENTS TO THE INFORMATION CONTAINED IN THE PHARMACEUTICAL REGISTER

19. The Eurasian Office shall amend the information in the Pharmaceutical Register at the request of patent owner, marketing authorization holder, observations of a third party, as well as upon its own initiative, subject to the provisions of paragraphs 20–25 of these Regulations.

20. At the request of patent owner any amendments may be entered to the information contained in the Pharmaceutical Register that are not contrary to these Regulations.

21. At the request of marketing authorization holder the information in the Pharmaceutical Register may be amended only to supplement it with information on the registered medicinal product, which contains API protected by a Eurasian or national patent.

22. Any amendments that are not contrary to these Regulations may be entered to the information in the Pharmaceutical Register upon observations of third parties that may be submitted in respect of the non-conformity of the INN with the subject matter protected by the Eurasian or national patent, the information on which is included in the Pharmaceutical Register, or in respect of any other record contained in the Pharmaceutical Register.

23. The Eurasian Office shall enter amendments to the information in the Pharmaceutical Register upon the request of patent owner, marketing authorization holder or observations of a third party, after verification of the information contained in said request or observations, respectively.

24. The Eurasian Office is entitled to correct technical and other obvious mistakes made in data in the Pharmaceutical Register on its own initiative.

25. When any data on a Eurasian patent is amended in the Register of Eurasian Patents, the relevant amendments shall be immediately entered by the Eurasian Office to the Pharmaceutical Register.

The Eurasian Office enters amendments to data on a national patent in the Pharmaceutical Register on the basis of information received by the Eurasian Office from the relevant national office within the data exchange on the legal status of national patents included in the Pharmaceutical Register.

26. The Eurasian Office shall establish the procedure for amending the information contained in the Pharmaceutical Register, including the procedure for submitting and examining of requests from patent owners, marketing authorization holders and third parties observations.

CHAPTER 7

EXCLUSION OF INFORMATION FROM THE PHARMACEUTICAL REGISTER

27. Information on the Eurasian patent shall be excluded from the Pharmaceutical Register in the following cases:

- upon termination of the Eurasian patent validity on the territory of all Contracting States pursuant to Rule 56 of the Patent Regulations;
- upon expiration of the Eurasian patent's term stipulated in Article 11 of the Convention, provided that the period of validity of the Eurasian patent is not extended in accordance with Rule 16(5) of the Patent Regulations.

28. Information on the national patent shall be excluded from the Pharmaceutical Register in the following cases:

- upon lapse of a national patent due to non-payment of fees for maintaining the national patent;
- in case of surrender of the national patent by patent owner;
- in case of revocation of the national patent;
- upon expiration of the national patent's term established by the national legislation of the Contracting State.

29. The information on Eurasian or, respectively, national patent may be excluded from the Pharmaceutical Register at any time during the period of validity of the relevant Eurasian or national patent at the request of the patent owner.

30. The Eurasian Office shall establish the procedure for the exclusion of information from the Pharmaceutical Register.

CHAPTER 8

LEGAL STATUS OF INFORMATION IN THE PHARMACEUTICAL REGISTER. GRANTING EXTRACTS FROM THE PHARMACEUTICAL REGISTER

31. Information contained in the Pharmaceutical Register is publicly available and open and may be used by any person to inform the public about the existence of exclusive rights to API-related inventions protected by Eurasian and/or national patents, as well as the current legal status of such Eurasian and national patents.

32. Information included in the Pharmaceutical Register may be recognized as official for use in the Contracting State to certify the protection of API, processes of their production and their medical uses by Eurasian and/or national patents on the territory of a Contracting State.

Information in the Pharmaceutical Register may be recognized as official on the territory of a Contracting State under an agreement concluded between the Contracting State and/or an international intergovernmental organization to which the Contracting State is a member, and the Organization, or on other grounds provided for in the national legislation of the Contracting State.

Information included in the Pharmaceutical Register and recognized as official in a Contracting State can be used on its territory to enforce and protect the

exclusive rights to API-related inventions, including through provisional measures under the national law of the Contracting State.

33. The Eurasian Office provides extracts from the Pharmaceutical Register.

Extracts from the Pharmaceutical Register shall be provided to any person upon their request and subject to payment of a fee established by the Eurasian Office. No fee is payable in case of providing extracts from the Pharmaceutical Register at the request of judicial and other competent authorities of Contracting States.

An extract from the Pharmaceutical Register contains information on the compliance of the patented subject matter with a specific INN or a combination of INN, indicating the claims under the Eurasian or, respectively, national patent protecting the API.

Extracts from the Pharmaceutical Register in respect of the information recognized as official in accordance with part two of paragraph 32 of these Regulations shall certify the protection of API-related inventions indicated in the extract by Eurasian and (or) national patents on the territory of the respective Contracting States.

Extracts from the Pharmaceutical Register shall be provided in Russian.