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Uniform Rules for Registering Medicinal Products in the Eurasian Economic Union

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Abstract

The pharmaceutical component of the regional and integration cooperation within the Eurasian Economic Union is characterized by the formation of the common market of medicinal products.
The unified principles and rules of the medicinal products' circulation are determined by a considerable number of new legislative and regulatory documents that regulate various types of activities on the pharmaceutical market.
Registration is an important stage in the lifecycle of a medicinal product and is one of the measures of non-tariff regulation in the foreign trade system.
The registration is a complex activity associated with various components, for example preclinical, clinical researches, pharmacovigilance, quality control, production, pharmaceutical inspection and information interaction.
The system analysis of the activity performed by the Supreme Eurasian Economic Council, the Council and College of the Eurasian Economic Commission for the period of 2014-2017 made it possible to determine the main regulatory documents on registration issues.

Keywords: Registration of medicinal products, common market of medicinal products, the Eurasian Economic Union.

INTRODUCTION

The history of the regional and integration development within the Eurasian Economic Union began in 1994 (the Eurasian Union). In 2010 the Customs Union of the Republic of Belarus, the Republic of Kazakhstan and the Russian Federation started functioning.
The Eurasian Economic Union is an international organization for the regional economic integration established in 2014 by the Agreement, nowadays with the member states being the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Kyrgyz Republic and the Russian Federation.

The common market of medicinal products within the Eurasian Economic Union has been forming since the early 2016. The common market is an intermediate form of development of regional and integration processes in foreign trade activities between the free trade zone and the customs union on the one hand, and the economic union, monetary union and full integration, on the other hand.

The system analysis of the activities of the Supreme Eurasian Economic Council, the Council and College of the Eurasian Economic Commission for the period of 2014-2017 made it possible to define the main documents and groups of documents on forming the common market of medicinal products [1-4]:

- Treaty on the Eurasian Economic Union dated 29.05.2014 – Chapter VII, Article 30, Article 100 Clause 1,
- Agreement on Common Principles and Rules of Circulation of Medicinal Products within the Eurasian Economic Union dated 23.12.2014,
- Decision of the Supreme Eurasian Economic Council No. 108 "On realisation of Agreement on common principles and regulations of circulation of medicines within the Eurasian Economic Union" dated 23.12.2014,
- Decision of the Supreme Eurasian Economic Council No. 98 "On Regulations of the Eurasian Economic Commission" dated 23.12.2014,
- Decisions of the Council of the Eurasian Economic Commission No. 73-93 et al. dated 03.11.2016,
- Decisions of the College of the Eurasian Economic Commission, and
- National legislations of member states.

The common market of medicinal products must comply with the standards of the good pharmaceutical practices and be based on the principles of harmonization and unification of the requirements of member states' legislation on the circulation of pharmaceutical products, including authorization and control and supervision activity by the relevant bodies.

MAIN PART

Agreement on Common Principles and Rules of Circulation of Medicinal Products within the Eurasian Economic Union dated 23.12.2014 (hereinafter referred to as the Agreement) defines the basic guidelines and the relevant documents to be developed and/or approved by the Commission.

The Common Rules established by the Agreement are the main norms of non-tariff regulation that cover the following processes of circulation of medicinal products on the common market: preclinical and clinical trials, assessment, registration, pharmacovigilance, quality control, manufacturing, storage, transportation, distribution.

Registration of a medicinal product is the process of obtaining of a permission for the medical use of a medicinal product on the territory of one or several states that are members of the Union carried out in accordance with the Rules of marketing authorization and assessment of medicinal products for medical use approved by the Eurasian Economic Commission (Information Guide of the Definitions Applied within the Eurasian Economic Union in the area of Medicinal Products' Circulation).

Registration and expert examination for the circulation on the common market is carried out by the member states in accordance with the Decision of the Council of the Eurasian Economic Commission No. 78 "On Rules of marketing authorization and assessment of medicinal products for medical use" (hereinafter referred to as the Rules for marketing authorization and assessment) dated 03.11.2016. These Rules establish requirements for the structure, mode, content of the registration dossier, the structure and content of the report on the evaluation of the registration dossier, the form of the registration certificate, the procedure for making changes in the registration dossier, and the

grounds for refusing to register, recall, cease or terminate the registration certificate. In this context, it is necessary to pay attention to a new document – Decision of the College of the Eurasian Economic Commission No. 79 dated 30.06.2017 (Requirements to the Electronic Form of Applications and Documents of the Registration Dossier Provided for marketing authorization and assessment of Medicinal Products for Medical Use).

In accordance with the general principles of medicinal products' registration (Chapter III of the Rules of marketing authorization and assessment), registration can be carried out at the applicant's request:

- Consistently in several member states in accordance with the procedure of mutual recognition, or
- Simultaneously in several member states in accordance with the decentralized registration procedure.

The procedure of mutual recognition is carried out

a) By the reference state for the medicinal product to circulate on the market of that state only (the national registration procedure),
b) In the states of recognition – at the applicant's request after the registration of the medicinal product in the reference state according to the procedure of mutual recognition.

The decentralized registration procedure is carried out simultaneously by several member states where a registration application has been submitted with selecting the reference state. The applicant independently chooses the reference state and, if necessary, the state of recognition when applying for the registration.

In all cases only one state can act as a reference. The reference state is the member state of the Union that prepares an expert report on the evaluation of the safety, efficiency and quality of the medicinal product based on the examination of the medicinal product in accordance with the Rules of Marketing authorization and Assessment.

Preclinical and clinical trials, manufacturing, quality control, pharmacovigilance and pharmaceutical inspections are important components for registration and examination procedures and are regulated by many new documents of the Eurasian Economic Union.

The nomenclature of medicinal forms approved by the Decision of the College of the Eurasian Economic Commission No. 172 dated 22.12.2015 is used for the registration and examination. The following norms stipulate the principal ideas of the registration:

- Registration of medicinal products having different qualitative composition of active substances under one trade name is prohibited,
- Member states do not allow the re-registration practice in the national legislation if ~~of~~ medicinal products have been registered on their territory in accordance with the Rules of the Eurasian Economic Union, and
- Pharmaceutical substances, medicines made in pharmacies, exhibition samples, products for preclinical and clinical trials, medicines imported by an individual for personal use, medicinal products not intended for sale on the customs territory of the Union, radiopharmaceuticals manufactured directly in medical organizations, samples for registration and standard samples are not registered in the Union.

The most important aspect is the mutual recognition in the procedure of registering the results of preclinical (nonclinical), clinical and other studies (tests), the results of manufacturing inspection, pharmacovigilance systems for compliance with the rules of good pharmaceutical practices and requirements. At the same time member states create conditions for the medicinal products' studies (tests) in accordance with international standards and ensure the comparability of their results.

Disputes arising during the registration are settled by the Expert Committee on Medicinal Products established under the Commission and consisting of representatives of member states in accordance with the Decision of the Council of the Eurasian Economic Commission No. 75 "On approval of Regulations on the Expert Committee on medicines" dated 03.11.2016.

The information about the registered medicinal products is entered in the Unified Register of Registered Medicinal Products of the Eurasian Economic Union, the formation and maintenance of which are approved by the Decision of the Council of the Eurasian Economic Commission No. 84 dated 03.11.2016. The information databases of instructions on medical use, graphic design (design) of packages and normative documents on quality should be integrated into the Unified Register of Registered Medicinal Products of the Eurasian Economic Union.

The registered medicinal products sold within the Union shall be marked in accordance with the unified marking requirements approved by Decision of the Council of the Eurasian Economic Union No. 76 dated 03.11. 2016, and they must contain instructions for use corresponding to the requirements for the instructions on medical use and general characteristic of medicinal products approved by Decision of the Council of the Eurasian Economic Union No. 88 dated 03.11. 2016.

The Order of the College of the Eurasian Economic Commission No. 43 dated 02.05.2017 provides for the Russia's development of an act on guidance for specifying the content of active substances or extracts from herbal medicines in the labeling of medicinal products and instructions for medical use by 2019.

When registering a medicinal product, it is classified as a prescription or nonprescription one in accordance with the Decision of the College of the Eurasian Economic Commission No. 178 "On Rules for Determining Categories of Prescription and Nonprescription Medicinal Products" dated 29.12.2015. It is possible to change the medicinal product release category by confirming the registration (re-registration) and making changes that require an examination of the expected benefit to the possible risk in the registration dossier of the medicinal product.

In accordance with Article 16 of the Agreement, in the cases provided by the legislation of its state, the authorized body of a member state has the right to take a decision on ceasing, revocation or refusal to extend the validity period of the medicinal product registration certificate issued by it. Within the information interaction, authorized bodies of other member states and the Commission should be immediately informed about this.

In the context of registration aspects, it is reasonable to pay attention to Decision of the Council of the Eurasian Economic Commission No. 92 "On Individual Issues of Medicines Circulation" dated 03.11.2016. It determines the norms for defining the interchangeability within the common market [5].

In particular, it has been established that the decision of the authorized body of the member state to issue a registration

certificate that is valid on the whole territory of the Eurasian Economic Union, is made without taking into account the results of defining the interchangeability that do not affect the further circulation of medicinal products within the Eurasian Economic Union.

The coordinating role of Russia in determining the interchangeability within the formation of the common market is the data obtained from defining the interchangeability of medicinal products in Russia (Federal Law No. 61-FZ "On the Circulation of Medicinal Products", Article 27.1, Government Decree No. 1154 dated 10.10.2015) and to submit a report on the results of applying this procedure to the Eurasian Economic Commission until 31.12. 2018.

The national acts of Russia determine that the interchangeability is defined by the FSBI Expert Commission of the Ministry of Health during the state registration on the basis of comparison with the reference product when assessing a medicinal product in terms of the quality control and (or) examination of the ratio of the expected benefits to the possible risk of use, in accordance with the established procedure. It is important to note that the absence of indications for use in the instructions for medical use specified in the instruction for the medical use of the reference medicinal product and protected by the current patent is not an obstacle for defining the interchangeability.

It is necessary to note that the interchangeability is determined for using it when purchasing medicinal products for state and municipal needs, to implement medicine procurement programs financed by the state, municipal budgets and state off-budget funds.

CONCLUSION

As a result of analyzing the activity of the Council and College of the Eurasian Economic Commission for Technical Regulation, the authors have determined the main documents approved for the period of 2014-2017 that establish the uniform registration rules on the common market of medicinal products.

It is necessary to be aware about various harmonized and unified components on the issues of registering medicinal products on the common market in order to solve tactical tasks in certain transition periods, to define strategic goals for the development of domestic export and imports, and to increase the export potential of the pharmaceutical industry in the world trade system for member states of the Eurasian Economic Union.

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