EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

November 03, 2016. **No 73** Astana city

on the Procedure for Qualification of Qualified Persons of Medicinal Product Manufacturers

Pursuant to Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014, Article 9 of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, paragraph 98 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 adopt the attached Procedure for Qualification of Qualified Persons of Medicinal Product Manufacturers.

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, except paragraph 6 of the Procedure adopted by this Decision.

Paragraph 6 of the Procedure adopted by this Decision shall enter into force on 1 January 2019.

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**

ADOPTED
by the Decision of Council of
the Eurasian Economic Commission No. 73
of 3 November 2016

the P R O C E D U R E
for Procedure for Qualification of Qualified Persons of Medicinal Product Manufacturers

1. This Procedure lays down requirements for education, training, and practical experience of the Qualified Persons of medicinal product manufacturers in the Member States of the Eurasian Economic Union (hereinafter to as Qualified Persons, Member States, and the Union, respectively) and for the procedure of their qualification.

2. The to be Qualified Person shall have acquired practical experience over at least three years in manufacturing or quality assurance activities, or quality control activities of medicinal products, and evidence of formal qualifications awarded on completion of a university course of study in one of the following scientific disciplines:

a) Chemistry;

b) Chemical technology;

c) Chemical pharmacy;

d) Biology;

e) Biotechnology;

f) Microbiology;

g) Pharmacy;

h) Medicine;

i) Veterinary medicine.

3. Certification to carry out functions of the Qualified Person at the enterprises that manufacture medicinal gases is also allowed for persons having evidence of formal qualifications awarded on completion of a university course of study in physicotechnical sciences.

4. Qualified Person functions at the undertakings manufacturing radiopharmaceuticals are also may be carried out by persons with completed higher education in the field of nuclear physics and radio-physics.

5. Compliance of national training programs with scientific disciplines referred to in paragraphs 2 to 4 of this Procedure is to be verified by a competent authority of the Member State in the area of pharmaceuticals which qualifies Qualified Persons (hereinafter referred to as the competent authority).

6. When receiving higher or additional education, the to be a Qualified Person, except persons referred to in paragraphs 3 and 4 of this Procedure, shall be trained in the following subjects (disciplines, modules):

a) applied (medical and biological) physics;

b) general and inorganic chemistry;

c) organic chemistry;

d) analytical chemistry;

e) pharmaceutical chemistry, including analysis of medicinal products;

f) biological chemistry;

g) physiology;

h) microbiology;

i) pharmacology;

j) pharmaceutical engineering;

k) toxicology/toxicological chemistry;

l) pharmacognosy.

7. The procedure of qualification shall include verification of education, training and practical experience of a to be Qualified Person with the requirements laid down in this Procedure and the Rules of Good Manufacturing Practice of the Union. Based on the results of such verification, the competent authority shall decide whether to qualify the Qualified Person (specifying the types of activities for the manufacturing of medicinal products which the Qualified Person is qualified for, in accordance with the Rules of Good Manufacturing Practice of the Union) or not.

The list and format of the documents submitted by a to be Qualified Person, procedure and decision-making rules shall be established by the competent authority.

8. A decision of the competent authority to qualify a Qualified Person shall confirm that the Qualified Person meets the requirements laid down in this Procedure.

9. Information on Qualified Persons shall be entered in the Register of Qualified Persons of the Union and made publicly available on the official website of the competent authority and official website of the Union on the Internet and in compliance with personal data protection legislation.

10. A decision on qualification of a Qualified Person may be revoked by the competent authority where:

a) it identifies that the to be Qualified Person has submitted false information or documents;

b) the Qualified Person furnishes the competent authority with an application for revocation of qualification; or

c) in other cases as laid down in the legislation of the Member States.

11. Information on revocation of a decision on qualification of a Qualified Person shall be entered in the Register of Qualified Persons of the Union and made publicly available on the official website of the competent authority and official website of the Union on the Internet and in compliance with personal data protection legislation.