

**EURASIAN ECONOMIC COMMISSION
COUNCIL**

**DECISION
No 74**

November 03, 2016.

Astana city

**on the Adoption of the Procedure for Establishing
and Operating the Eurasian Economic Union Register
of Qualified Persons of Pharmaceutical Manufacturers**

Pursuant to Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014, Article 9(2) of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, paragraph 89 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 Establishing and Operating the Eurasian Economic Union Register of Qualified Persons of Pharmaceutical 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.

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. Matyushevsky	A. Mamin	O. Pankratov	I. Shuvalov

ADOPTED
by Decision No. 74 of the Council of
the Eurasian Economic Commission
of 3 November 2016

the PROCEDURE for Establishing and Operating the Eurasian Economic Union Register of Qualified Persons of Pharmaceutical Manufacturers

I. General provisions

1. This Procedure has been developed to implement Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014 and Article 9(2) of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014 and lays down the Establishing and Operating the Eurasian Economic Union Register of Qualified Persons of Pharmaceutical Manufacturers.

2. The terms used in this Procedure shall bear the following meanings:

‘Register’ means a common information resource containing data on the qualified persons of pharmaceutical manufacturers of Eurasian Economic Union Member States and established within the Integrated Information System of the Eurasian Economic Union based on communications between Eurasian Economic Union Member States and the Eurasian Economic Commission;

‘Qualified person’ means a Eurasian Economic Union Member State pharmaceutical manufacturer qualified person whose qualifications and practical experience meets the requirements in force and who is certified to perform the duties of a pharmaceutical manufacturer qualified person in accordance with international treaties and acts consisting of law of the Eurasian Economic Union.

3. The purpose of establishing and operating of the Register is to record and process information on qualified persons.

4. The Register shall established and operated by the Eurasian Economic Commission (hereinafter referred to as the Commission) based of the information submitted electronically to the Commission by pharmaceutical competent authorities of the Eurasian Economic Union Member States (hereinafter referred to as competent authorities, Member States, the Union, respectively).

5. When establishing and operating the Register, communication between the competent authorities and the Commission shall be carried out by implementing the common process within the Union using the Integrated Information System of the Union (hereinafter referred to as the ‘Integrated System’).

6. To establish and operate the register, the competent authorities shall send current information on their qualified persons to the Commission. The latter shall store and publish the Register information on the Union information website as well as provide access of any interested competent authorities to the Register data via the Integrated System.

7. The competent authorities shall be responsible for the reliability of information on the qualified persons sent for the Register.

8. The Register shall be operated in Russian.

II. Register Information

9. The Register shall contain following publicly available information on qualified persons:

a) the Member State that entered the information into the Register;

- b) the surname, first name, and patronymic (if available);
- c) contact details: the telephone and fax numbers, email address (if available);
- d) education;
- e) specialisation in accordance with the certificate on education;
- f) scientific degree (if any);
- g) position/employer:

the full and short name of the legal entity according to the articles of incorporation, the structural and legal form and the unique ID number of the legal entity in the Register of legal entities of the Member State;

legal address of the legal entity;

contact information: the telephone and fax numbers, email address (if available) of the legal entity;

h) qualified person certificate: the number, name of the document, date of issuance, issuing authority;

i) the date when the qualified person started to carry out their duties;

j) the certified manufacturing activity(ies);

k) date of ceasing qualified person certification or the certification revocation date.

10. The Register shall contain the following information on qualified persons that shall not be publicly accessible and may be accessed by the competent authorities only:

a) date of birth;

b) citizenship;

c) place of residence;

d) information on education: the educational institution name, dates of enrolment and graduation, qualification (degree), education document type and code number;

e) information on further education: information on education: the educational institution name, dates of enrolment and graduation, qualification (degree), additional education document type and code number;

f) information on previous employment:

the full and short name of the legal entity according to the articles of incorporation, the structural and legal form and the unique ID number of the legal entity in the Register of legal entities of the Member State;

legal address of the legal entity;

contact information: the telephone and fax numbers, email address (if available) of the legal entity;

position title;

date of employment;

date of dismissal;

g) information on the current employment:

position title;

date of employment;

h) practical experience in manufacturing, quality assurance, or quality control of medicinal products.

III. Procedure for operating the Register

11. Once the decision is made by a competent authority on qualification of a qualified person, the competent authority shall submit the information on that person to the Commission to enter it into the Register.

12. Should any changes in the information on a qualified person to be entered into the Register occur, the competent authority that made the decision to qualify the qualified person shall be submit that information to the Commission via the Integrated System in order to update the data. In this case, the old information shall be retained for ten years and accessible by competent authorities.

13. Where a decision to revoke the certification of a qualified person is made, the competent authorities shall submit this information to the Commission which shall exclude the data from the Register and then send archive it. The archived data shall be accessible by competent authorities for 10 years.

14. Where a qualified person changes the employer from one Member State to another Member State, the competent authority of the previous employer Member State shall send respective information on the change, together with a written request from the qualified person, to the Commission.

IV. Access to the Register information

15. Interested parties shall have Internet access to the public information on qualified persons via the Union Information Portal.

Such an access shall be provided for free 24/7 excluding interruptions due to business continuity maintenance.

16. The access to the non-public information on a qualified person shall be granted to interested parties by the competent authority subject to applicable legislation of the Member State, including personal data protection and confidentiality provisions.

17. In the course of establishing and operating the Register, the Commission shall ensure protection of the non-public information on qualified persons from unauthorised access.