EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

November 03, 2016. **No 90** Astana city

On the Adoption of the Procedure for Establishing and Operating of the Eurasian Economic Union Pharmaceutical Inspectors Register

Pursuant to Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014, Article 10(4) of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, paragraph 101 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 of the of the Eurasian Economic Union Pharmaceutical Inspectors Register.

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**

ADOPTED
by the Decision of the Council of the
Eurasian Economic Commission No. 90
of 3 November 2016

the P R O C E D U R E
for Establishing and Operating
of the Eurasian Economic Union Pharmaceutical Inspectors Register

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 10(4) 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 Establishing and Operating of the of the Eurasian Economic Union Pharmaceutical Inspectors Register.

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;

'Pharmaceutical Inspector' means a person authorised to carry out pharmaceutical inspections and named in the Register of Pharmaceutical Inspectors of the Eurasian Economic Union.

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

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/pharmaceutical inspectorates of the Eurasian Economic Union Member States (hereinafter referred to as Member States, the Union, competent authorities/pharmaceutical inspectorates, respectively).

5. When establishing and operating the Register, communication between the competent authorities/pharmaceutical inspectorates 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 / pharmaceutical inspectorates shall send current information on their pharmaceutical inspectors 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 / pharmaceutical inspectorates to the Register data via the Integrated System.

7. The competent authorities/pharmaceutical inspectorates shall be responsible for the reliability of information on the pharmaceutical inspectors 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 pharmaceutical inspectors:

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;

position title;

h) the start date of pharmaceutical inspection activities;

i) the end date of pharmaceutical inspection activities.

10. The Register shall contain the following information on pharmaceutical inspectors that shall not be publicly accessible and may be accessed by the competent authorities/pharmaceutical inspectorates 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.) statement of Good Pharmaceutical Practices which are authorised to be verified by the pharmaceutical inspector;

g) details of professional experience in the latest position:

date of employment;

date of dismissal;

h) practical experience in assessment of pharmaceutical undertakings, including healthcare facilities, to verify their compliance with the requirements of Good Pharmaceutical Practices.

III. Procedure for operating the Register

11. Once the decision is made by a competent authority/pharmaceutical inspectorate on appointment of a pharmaceutical inspector, the competent authority/pharmaceutical inspectorate 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 pharmaceutical inspector to be entered into the Register occur, the competent authority/pharmaceutical inspector that made the decision to enter the pharmaceutical inspector into the Register 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/pharmaceutical inspectorates.

13. The competent authority/pharmaceutical inspectorate shall send the information on cessation of pharmaceutical inspector's duties 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/pharmaceutical inspectorates for 10 years.

IV. Access to the Register information

14. 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.

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

16. In the course of establishing and operating the Register, the Commission shall ensure protection of the non-public information on pharmaceutical inspectors from unauthorised access.