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EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

December 21, 2016 **No. 141** city of Moscow

On Approval of the Procedure for Application of Measures to Suspend or Prohibit Use of Medical Products Posing Threat to Human Life and (or) Health, Poor-Quality, Counterfeit and Falsified Medical Products by Authorized Authorities of Member States of the Eurasian Economic Union and their Withdrawal from Circulation in the Territories of Member States of the Eurasian Economic Union

In accordance with Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014, paragraph 3 of Article 8 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, paragraph 93 of Annex No. 1 to the Rules of Procedure of the Eurasian Economic Commission approved by Decision No. 98 of the Supreme Eurasian Economic Council dated December 23, 2014, and in order to implement Decision No. 109 of the Supreme Eurasian Economic Council dated December 23, 2014 "On Implementation of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union", the Council of the Eurasian Economic Commission **decided:**

1. To approve the attached Procedure for application of measures to suspend or prohibit use of medical products posing threat to human life and (or) health, poor-quality, counterfeit and falsified medical products by authorized authorities of Member States of the Eurasian Economic Union and their withdrawal from circulation in the territories of Member States of the Eurasian Economic Union.

2. This Decision shall enter into force after 10 calendar days have elapsed from the effective date of the Protocol, signed on December 2, 2015, on the accession of the Republic of Armenia to the Agreement on Common Principles and Rules for the circulation of medical products (medical devices and medical equipment) within the Eurasian Economic Union dated December 23, 2014, but not earlier than after 10 calendar days have elapsed from the date of the official publication of this Decision.

Members of the Council of the Eurasian Economic Commission:

For the Republic of Armenia	For the Republic of Belarus	For the Republic of Kazakhstan	For the Kyrgyz Republic	For the Russian Federation
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V. Gabrielyan	**V. Matyushevskiy**	**A. Mamin**	**O. Pankratov**	**I. Shuvalov**

APPROVED
by Decision No. 141 of the Council of
the Eurasian Economic Commission
dated December 21, 2016

PROCEDURE
for Application of Measures to Suspend or Prohibit Use of Medical Products Posing Threat to Human Life and (or) Health, Poor-Quality, Counterfeit and Falsified Medical Products by Authorized Authorities of Member States of the Eurasian Economic Union and their Withdrawal from Circulation in the Territories of Member States of the Eurasian Economic Union

1. This Procedure is developed in order to implement Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014 and paragraph 3 of Article 8 of the Agreement on Common Principles and Rules for Circulation of Medical Products (Medical Devices and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014 (hereinafter referred to as the Agreement) and и establishes rules for adoption of measures to suspend or prohibit use of medical products, posing threat to human life and (or) health, poor-quality, counterfeit and falsified medical products by authorized authorities of Member States of the Eurasian Economic Union as well as their withdrawal from circulation in the territories of Member States.

2. For the purposes of this Procedure the concepts are used having the following meanings:

"counterfeit medical product" – medical product released or circulated with violation of the requirements of the legislation of a Member State of the Eurasian Economic Union in the field of intellectual property;

"poor quality medical product" – a medical product which does not comply with general requirements for safety and efficacy of medical products, requirements for their marking, technical and operational documentation on them and cannot be used in a safe manner according to the purpose determined by the manufacturer;

"falsified medical product" – a medical product, deliberately accompanied with false information on its composition, characteristics and (or) manufacturer.

3. The authorized authority of the Member State decides to suspend or prohibit the use and withdrawal from circulation in the territory of its state of a medical product posing threat to human life and (or) health, poor-quality, counterfeit or falsified medical product based on the results obtained in the course of the state control (supervision) in the sphere of medical products circulation or identified during monitoring of safety, quality and efficacy of medical products, carried out in accordance with the Rules for monitoring of safety, quality and efficacy of medical products approved by Decision No. 174 of the Board of the Eurasian Economic Commission dated December 22, 2015.

4. The term for which the use of a medical product is suspended shall not exceed 180 calendar days from the date of adoption of the relevant decision. This period can be extended by the authorized authority of the Member State, if it is necessary to conduct an additional examination of safety, quality and efficacy of the medical product in connection with the revealed negative consequences of its use for the period of such examination.

5. The use of the medical product can be suspended by the authorized authority of the Member State on the basis of the application submitted by the manufacturer of the medical product or its authorized representative (with justification) for the period indicated in the application.

6. The authorized authority of the Member State within 1 working day from the date of the decision to suspend the use of the medical product or to extend the period of suspension of the use of the medical product places it on its official website in the information and telecommunications network Internet.

The authorized authority of the Member State within 3 working days form the date of adoption of a decision to suspend the use of the medical product or extend the period of suspension of the use of the medical product notifies the manufacturer of the medical product or his authorized representative with a registered mail with a delivery confirmation or in the form of an electronic document with digital signature or in electronic form via telecommunication channels of the decision taken with indication of reasons and period of suspension of use of the medical product, as well as the need to eliminate circumstances that led to the suspension of the use of the medical product by the manufacturer or his authorized representative. The copies of relevant expert opinions are attached to the notice.

7. The authorized authority of the Member State takes a decision to resume the use of the medical product if the facts and circumstances that served as the basis for the decision to suspend the use of this medical product are not confirmed by the results obtained during the research (tests) and notifies manufacturer or his authorized representative of the decision taken.

8. If the manufacturer or his authorized representative fails to eliminate circumstances that served as the basis for the decision to suspend the use of the medical product within the period specified by the authorized authority of the Member State, the authorized authority of the Member State decides to prohibit the use of the medical product and withdraw it from circulation in the territory of the Member State.

9. The authorized authority of the Member State conducts the following activities if a counterfeit or falsified medical product is identified in circulation in the territory of its State:

a) within 5 working days from the date of establishment of this fact, it notifies the owner (supplier and (or) seller) of the medical product of the need to submit to the authorized authority of the Member State the medical product (if possible) and documentation allowing to identify the medical product and (or) to ensure necessary conditions for identification of the medical product by an authorized authority of the Member State;

b) conducts the identification of the medical product in accordance with its marking, package and documentation which allows to identify the medical product, including the following:

name and location of the manufacturer, country of origin, including the address of the place of manufacture of the medical product;

medical product name;

date of manufacture and expiration date (life time);

lot number (batch, series);

storage (operation) conditions;

marking with a special trademark of circulation;

information on registration within the Union (number and date of the registration certificate, name of the authorized authority of the Member State that issued the registration certificate);

information on the document that establishes the requirements for technical characteristics of the medical product (if any);

c) takes a decision to prohibit the use and withdraw a counterfeit or falsified medical product from circulation in the territory of the Member State.

10. Within 5 working days from the date of identification that the medical product posing threat to human life and (or) health, poor-quality, counterfeit or falsified medical product is circulated in the territory of the Member State, the authorized authority using means of an integrated information system of the Union notifies authorized authorities of the Member States and the Eurasian Economic Commission on reasons and time limits for the suspension or prohibition of the use of the medical product and its withdrawal from circulation in the territory of the Member State.

11. The authorized authority of the Member State, if necessary, sends a request using the integrated information system of the Union to the authorized authority of another Member State to obtain additional information related to the identification of the medical product posing threat to human life and (or) health, counterfeit or falsified medical product.

The authorized authority of the Member States submits the data on the basis on the specified request within a period not exceeding 15 calendar days from the date of receipt of the request.

12. Control over the execution of decisions to suspend or prohibit the use of the medical product and withdraw it from circulation in the territory of the Member State is carried out by the authorized authority of the Member State in the manner established by the legislation of the Member State.

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