EURASIAN ECONOMIC COMMISSION
COUNCIL

DECISION

November 03, 2016. **No 86** Astana city

on the Procedure for Cooperation Between the Eurasian Economic Union Member States in Detecting Falsified, Counterfeit and/or Substandard Medicinal Products

Pursuant to Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014, Article 13 of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, paragraph 91 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 Cooperation Between the Eurasian Economic Union Member States in Detecting Falsified, Counterfeit and/or Substandard Medicinal Products.

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 Decision No. 86 of the Council of the Eurasian Economic Commission of 3 November 2016

the P R O C E D U R E
for Cooperation Between the Eurasian Economic Union Member States in Detecting Falsified, Counterfeit and/or Substandard Medicinal Products

1. This Procedure has been developed to implement Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014 and Article 13 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 procedure for Cooperation Between the Eurasian Economic Union Member States (hereinafter referred to as the Union, Member States, respectively) and the Eurasian Economic Commission (hereinafter referred to as the Commission) in Detecting Falsified, Counterfeit and/or Substandard Medicinal Products.

2. The communication on preventing falsified, counterfeit and/or substandard medicinal products from entering the market shall take place via Contact Points of the Member States competent authorities/competent organisations in the area of supervision over medicinal products (hereinafter referred to as the competent authorities) and the Commission via the Integrated Information System of the Union (hereinafter referred to as the Integrated System).

Email communications between the Contact Points may take place, where necessary.

3. Within the Union Information System in the area of pharmaceuticals, which is part of the Integrated System, following common information resources shall be established:

a) a Single Information Database of medicinal products non-compliant with quality requirements and falsified and/or counterfeit medicinal products seized in the Member States;

b) a Single Information Database of suspended, recalled, or prohibited medicinal products in the Member States;

c) a Single Register of medicinal products authorised in the Union.

4. The Common Information Resources shall be established based on communication between Member States and the Commission.

5. Using the Integrated System, a competent authority shall:

a) communicate with competent authorities of other Member States and the Commission;

b) update the information submitted to it with the view of entering such information into the Common Information Resources.

6. The communication between the competent authorities or between the competent authorities and the Commission when establishing, operating and using the Common Information Resources shall take place by implementation of common processes within the Union using the Integrated System.

7. The information contained in the Common Information Resources shall be made available in accordance with the procedure established by the Commission.

8. The competent authorities may use the Integrated System for communication between each other or the Commission in the following cases:

a) gathering information on cases and circumstances that use of some medicinal products may pose risks for human health or safety;

b) detecting falsified, counterfeit and/or substandard medicinal products in a Member State during supervision of the pharmaceutical market or monitoring the safety, quality, or efficacy of medicinal products;

c) taking steps to suspend marketing authorisations for medicinal products, recall medicinal products, or prohibit use thereof.

9. When communicating information on falsified, counterfeit and/or substandard medicinal products which might be recognised as being classified pursuant to the applicable laws of the Member States, the competent authority of the Member State shall ensure that use and protection of such information is in accordance with the applicable laws of its State.

The competent authorities shall notify each other that the information on falsified, counterfeit and/or substandard medicinal products might be classified.

10. The communication shall take place in the following modes:

a) an immediate notification. An immediate notification shall contain information on a falsified and/or counterfeit medicinal product as laid down in a list of Appendix 1 or on a substandard medicinal product as laid down in a list of Appendix 2;

b) a request for information.

11. Within 72 hours from the confirmation that a medicinal product might be falsified, counterfeit and/or substandard, the competent authority shall send, using the Integrated System, the information to be entered into the Common Information Resources to the Commission. The competent authority shall also notify the competent authorities of other Member States and take measures, within its authority, to immediately withdraw such medicinal products from the market.

12. Having received an immediate notification on a falsified, counterfeit and/or substandard medicinal product, the competent authorities shall confirm the receipt of such a notification.

13. To obtain additional information on the falsified, counterfeit and/or substandard medicinal product, the competent authority of a Member State may send an electronical request to the competent authority of the other Member State.

Subject to Paragraph 10 of this Procedure, the requested information shall be submitted electronically within 15 calendar days beginning with the date of receipt of the aforementioned request.

14. The competent authority of a Member State shall inform the Commission and the competent authorities of other Member States of the Contact Point responsible for revealing and withdrawing the falsified, counterfeit and/or substandard medicinal products, specifying the following information:

a) the details on persons carrying out the communication (surname, first name, patronymic (if any), position, phone number);

b) the emails of the persons carrying out the communication (main and additional);

c) the name and address of the competent authority/organisation.

APPENDIX 1
to the Procedure for Cooperation
Between the Eurasian Economic Union
Member States in Detecting Falsified,
Counterfeit and/or Substandard
Medicinal Products

LIST
of the data included in an immediate notification on a falsified and/or counterfeit medicinal product

1. Information on the Contact Point according to Paragraph 14 of the Procedure for Cooperation Between the Eurasian Economic Union Member States in Detecting Falsified, Counterfeit and/or Substandard Medicinal Products adopted by Decision of the Council of the Eurasian Economic Commission No 86 of 3 November 2016.

2. The state of origin of a falsified and/or counterfeit medicinal product.

3. The brand name accompanying the seized falsified and/or counterfeit medicinal product according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

4. The pharmaceutical form of the medicinal product according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

5. The strength of the medicinal product according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

6. The presentation of the medicinal product according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

7. The international non-proprietary name (if one exists) of the medicinal product.

8. The manufacturer's name stated on the outer package according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

9. The country where the manufacturer stated on the outer package is established, according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

10. The batch number stated on the falsified and/or counterfeit medicinal product package.

11. The date of manufacture (if available) stated on the falsified and/or counterfeit medicinal product package.

12. The package mock-up (if available) of the falsified and/or counterfeit medicinal product.

13. The expiry date stated on the falsified and/or counterfeit medicinal product package.

14. The package size of the seized falsified and/or counterfeit medicinal product.

15. The organisation type where the falsified and/or counterfeit medicinal product was seized, i.e. Customs, a wholesale warehouse, a healthcare institution, pharmacy, etc.

16. The supplier' name, if known.

17. The supplier's country of origin, if known.

18. A description of the attributes showing falsification, i.e. a photo of the falsified package, scanned package of the authentic medicinal product and the falsified one (if available), the assay of the active substance (whether compliant with acceptance criteria), etc.

19. The steps taken by the pharmaceutical competent authority of a Eurasian Economic Union Member State, such as suspension of sales, withdrawal, etc.

ANNEX 2
to the Procedure for Cooperation
Between the Eurasian Economic Union
Member States in Detecting Falsified,
Counterfeit and/or Substandard
Medicinal Products

LIST
of the data included in an immediate notification on a substandard medicinal product

1. Information on the Contact Point according to Paragraph 14 of the Procedure for Cooperation Between the Eurasian Economic Union Member States in Detecting Falsified, Counterfeit and/or Substandard Medicinal Products adopted by Decision of the Council of the Eurasian Economic Commission No 86 of 3 November 2016.

2. The state of origin of a substandard medicinal product.

3. The brand name accompanying the seized substandard medicinal product according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

4. The international non-proprietary name (if one exists) of the medicinal product.

5. The pharmaceutical form of the medicinal product according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

6. The strength of the medicinal product according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

7. The presentation of the medicinal product according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

8. The batch number stated on the substandard medicinal product package.

9. The expiry date stated on the substandard medicinal product package.

10. The medicinal product batch size stated in the quality standard (quality certificate, batch certificate, etc.).

11. The date of manufacture stated on the substandard medicinal product package.

12. The manufacturer’s name stated on the outer package according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

13. The marketing authorisation holder name according to the Eurasian Economic Union Common Register of Medicinal Products.

14. The country where the manufacturer stated on the outer package is established, according to the Register of the Member State of the Eurasian Economic Union or the Eurasian Economic Union Common Register of medicinal products.

15. The amount of the substandard medicinal products seized.

16. The organisation type where the falsified and/or counterfeit medicinal product was seized, i.e. Customs, a wholesale warehouse, a healthcare institution, pharmacy, etc.

17. The supplier’s name, if known.

18. The supplier’s country of origin, if known.

19. A description of the out of specification attributes of the medicinal product, i.e. misbranding, erroneous strength, non-sterility of sterile products, etc.

20. The steps taken by the pharmaceutical competent authority of a Eurasian Economic Union Member State, such as suspension of sales, withdrawal, etc.