EURASIAN ECONOMIC COMMISSION COUNCIL

DECISION

November 03, 2016.	**No 84**	Astana city

on the Procedures for Establishing and Operating the Eurasian Economic Union Common Register of Authorised Medicinal Products and Pharmaceutical Information Databases

Pursuant to Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014, Article 14 of the Agreement on the Common Principles and Rules of Medicinal Products Circulation within the Eurasian Economic Union of 23 December 2014, paragraph 102 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 Common Register of Authorised Medicinal Products;

Procedure for Establishing and Operating the Common Information Database of Substandard, Falsified and/or Counterfeit Medicinal Products Seized in the Eurasian Economic Union Member States;

Procedure for Establishing and Operating the Common Information Database of the Adverse Drug Reactions/Effects, including Reports on Lack of Efficacy in the Eurasian Economic Union Member States;

Procedure for Establishing and Operating the Common Information Database of Suspended, Recalled, or Prohibited Medicinal Products in the Eurasian Economic Union Member States.

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. 84 of the Council of the
Eurasian Economic Commission
of 3 November 2016

the PROCEDURE for Establishing and Operating the Eurasian Economic Union Common Register of Authorised 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 14 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 establishing and operating the Eurasian Economic Union Common Register of Authorised Medicinal Products (hereinafter referred to as the Common Register).

This Procedure has been developed to ensure the unified record-keeping of medicinal products authorised for marketing in accordance with the rules established by the Eurasian Economic Commission (hereinafter referred to as the Commission) and to provide the public information on medicinal products released for marketing within the Eurasian Economic Union (hereinafter referred to as the Union) Single Market.

For the purposes of this Procedure, the terms used in the Rules for granting a marketing authorisation and assessment of medicinal products for human use subject to approval by the Commission (hereinafter referred to as the Rules for granting a marketing authorisation and assessment of medicinal products) are also used herein.

2. The Common Register is a common information resource containing information on medicinal products authorised in accordance with the Rules for granting a marketing authorisation and assessment of medicinal products and established within the Integrated Information System of the Union (hereinafter referred to as the Integrated System) based on communications between the pharmaceutical competent authorities/assessment organisations of the Member States of the Union (hereinafter referred to as the competent authorities/assessment organisations, Member States, respectively) or between the competent authorities/assessment organisations and the Commission.

3. The Common Register shall be established and operated by the Commission based on the information submitted electronically by the competent authorities/assessment organisations in accordance with the Rules for granting a marketing authorisation and assessment of medicinal products.

4. Communications between competent authorities/assessment organisations or between competent authorities/assessment organisations and the Commission when establishing, operating, or using the Common Register shall be carried out by implementing the respective common process within the Union via the Integrated System.

5. Establishing and operating the Common Register includes:

1) receipt relevant information on medicinal products authorised in accordance with the Rules for granting a marketing authorisation and assessment of medicinal products submitted by the competent authorities/assessment organisations by the Commission;

2) entry of the information submitted by the competent authorities/assessment organisations into the Common Register by the Commission;

3) making publicly available the Common Register information by the Commission on the Union web portal;

4) the update of Common Register information by the Commission;

5) storage of the information available in the Common Register;

6) granting access to the information in the Common Register.

6. The competent authorities/assessment organisations shall be responsible for accuracy of the information submitted for entry into, or update of, the Common Register.

7. The Common Register shall contain the following information:

1) 6-digit marketing authorisation number for a medicinal product generated via the Integrated System at the request of the competent authority/assessment organisation of the reference Member State and assigned by it;

2) the names of the reference Member State and, where applicable, Member States concerned;

3) the date the marketing authorisation for medicinal product was issued by the reference Member State and, where applicable, the dates the marketing authorisation for the medicinal product was issued by the Member States concerned;

4) the expiration date of the marketing authorisation for a medicinal product (the word 'unlimited' shall appear for marketing authorisations of unlimited validity);

5) the date of renewal of the marketing authorisation;

6) the date of varying (reissuing of) the marketing authorisation for a medicinal product;

7) the brand name of a medicinal product in the reference Member State and, where applicable, the brand names of the medicinal product in the Member States concerned;

8) the international non-proprietary name or, if one does not exist, common or generic name, or chemical name of the active substance of the medicinal product (for combination medicinal products, the names of active substances shall be stated separated using '+' (if a product contains three or fewer active substances); where a product contains more than three active substances, the names thereof shall be omitted);

9) the pharmaceutical form of a medicinal product;

10) the strength or concentration of a medicinal product;

11) the presentation of a medicinal product;

12) information on the medicinal product manufacturer (the names and addresses of the manufacturing sites involved in the manufacture of the medicinal product);

13) the name and address of the holder of the marketing authorisation for a medicinal product;

14) the Anatomical Therapeutic Chemical (ATC) classification system code;

15) the expiry date (shelf life) of a medicinal product;

16) the supply category of a medicinal product;

17) the Summary of Product Characteristics in the reference Member State and, where applicable, Member States concerned;

18) the Medication Guide (Patient Leaflet) in the reference Member State and, where applicable, Member States concerned;

19) the final assessment report on safety, efficacy, and quality, after confidential data is deleted;

20) the normative document on the quality of the medicinal product;

21) the medicinal product packaging mock-ups;

22) the name of the active substance used in the manufacture of a medicinal product;

23) the name and address of the manufacturer of the active substance used in the manufacture of a medicinal product;

24) any special conditions of granting authorisation for a medicinal product and the deadlines for fulfilment thereof, where applicable;

25) the Risk Management Plan as approved by the competent authority/assessment organisation, where applicable;

26) other special characteristics of a medicinal product:

A new, generic, hybrid, biosimilar, or well-established use medicinal product;

A herbal, homeopathic, radiopharmaceutical, advanced therapy, immunological, plasma-derived, or biotechnological product;

A controlled substance medicinal product stating the Member State where the product is under control);

An orphan designation stating the Member State where the medicinal product has orphan designation.

8. Where the marketing authorisation for a medicinal product is revoked, the respective information, including the date of revocation, shall be reported by the competent authorities/assessment organisations to the Commission for entering into the Common Register within three business days beginning with the day of revocation.

9. The competent authorities/assessment organisations shall notify each other of the revocation of the marketing authorisation for a medicinal product via the Integrated System within three business days beginning with the day of revocation.

10. The Common Register information shall be publicly available, except for the information specified in sub-paragraphs 20 and 21 of paragraph 7 of this Procedure.

11. The Common Register information shall be provided by the competent authorities/assessment organisations at the request of interested parties.

12. Within granting a marketing authorisation for medicinal products or processing other procedures related to marketing authorisation in accordance with the Rules for granting a marketing authorisation and assessment of medicinal products, the competent authorities/assessment organisations shall exchange the following information and documents via the Integrated System:

1) the marketing authorisation/renewal/variation application number or the number of an application for bringing a marketing authorisation dossier of a medicinal product authorised in the Member States of the Union before the Agreement on Common Principles and Rules Governing Medicinal Products within the Union of 23 December 2014 came into effect and up until 31 December 2020, into compliance with these Rules for granting a marketing authorisation and assessment of medicinal products, generated by the Integrated System at the request of an competent authority/assessment organisation of the reference Member State and assigned by the reference Member State;

2) the marketing authorisation application dossier for a medicinal product or variation application dossier;

3) the normative document on the quality of the medicinal product;

4) the medicinal product packaging mock-ups for the reference Member State and, where applicable, Member States concerned;

5) assessment reports of competent authorities/assessment organisations drawn up in accordance with the Rules for granting a marketing authorisation and assessment of medicinal products, including the laboratory test reports;

6) requests of competent authorities/assessment organisations to provide additional information sent to the applicant in the course of granting a marketing authorisation or processing other procedures related to authorisation and respective responses;

7) requests of competent authorities/assessment organisations of the Member States concerned sent to the competent authority/assessment organisation of the reference Member State and respective responses;

8) documents, including reports, on the pharmaceutical inspections related to the medicinal product and conducted by pharmaceutical inspectorates of the Member States;

9) information on the time-table of consideration of a marketing authorisation application dossier or variation application dossier in the Common Technical Document format, assessment reports and test reports referred to in sub-paragraph 5 of this paragraph, requests and respective responses in accordance with sub-paragraphs 6 and 7 of this Paragraph.

13. The competent authorities/assessment organisations shall submit the information referred to in sub-paragraphs 1 and 9 of paragraph 12 of this Procedure using the Integrated System to the Commission.

When considering disputes within the Expert Committee for medicinal products, the competent authorities/assessment organisations shall submit all the information set out in paragraph 12 of this Procedure using the Integrated System upon a request of the Commission.

The Commission shall protect the information accessed under this paragraph from unauthorised access.

14. The information set out in sub-paragraphs 20 and 21 of paragraph 7 and sub-paragraphs 2 to 8 of paragraph 12 of this Procedure shall not be publicly available and shall be accessible by the competent authorities/assessment organisations or Commission only.

15. For at least 20 years beginning with the date of applying for granting a authorisation for a medicinal product, the competent authorities shall keep and provide (upon request of the competent authorities/assessment organisations of the other Member States or Commission) the following information via the Integrated System:

1) marketing authorisation application dossiers, including current, initial and intermediate versions of the documents included therein;

2) assessment reports of competent authorities/assessment organisations drawn up in accordance with the Rules for granting a marketing authorisation and assessment of medicinal products.

ADOPTED
by Decision No. 84 of the Council of the
Eurasian Economic Commission
of 3 November 2016

the PROCEDURE for Establishing and Operating the Common Information Database of Substandard, Falsified and/or Counterfeit Medicinal Products Seized in the Eurasian Economic Union Member States

1. This Procedure has been developed to implement Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014 and Article 14 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 Establishing and Operating the Common Information Database of Substandard, Falsified and/or Counterfeit Medicinal Products Seized in the Eurasian Economic Union Member States (hereinafter referred to as the Common Database, Union, Member States, respectively).

2. The Common Database is a common information resource containing information on medicinal products which have been withdrawn from the Union market by a decision of healthcare competent authorities of the Member States (hereinafter referred to as the competent authorities) due to Out-of-Specification issues or being falsified and/or counterfeit.

The Common Database shall be established using the Union Integrated Information System (hereinafter referred to as the Integrated System) based on communications between the competent authorities or between the competent authorities and the Eurasian Economic Commission (hereinafter referred to as the Commission).

3. The Common Database shall be established and operated by the Commission based on the information submitted electronically by the competent authorities/assessment organisations in accordance with the Procedure for Cooperation Between the Member States in Detecting Falsified, Counterfeit and/or Substandard Medicinal Products subject to approval by the Commission.

4. Communications between competent authorities/assessment organisations or between competent authorities/assessment organisations and the Commission when establishing, operating, or using the Common Database shall be carried out by implementing the respective common process within the Union via the Integrated System.

5. Establishing and operating the Common Database includes:

a) receipt current information on medicinal products which have been withdrawn from the Union market by a decision of competent authorities due to Out-of-Specification issues or being falsified and/or counterfeit by the Commission;

b) entry of the information submitted by the competent authorities into the Common Database by the Commission;

c) making publicly available the Common Database information by the Commission on the Union web portal;

d) the update of Common Database information by the Commission;

e) storage of the information available in the Common Database;

f) granting access to the information in the Common Database to interested parties.

6. The competent authorities shall be responsible for accuracy of the information submitted for entry into the Common Database.

7. The information on medicinal products which have been withdrawn from the Union market by a decision of competent authorities due to Out-of-Specification issues or being falsified and/or counterfeit shall submitted by the competent authority to the Commission for entry into the Common Database, based on a competent authority's decision to withdraw the medicinal product from the market.

8. The Common Database shall contain the following information:

a) for a substandard medicinal product (including an active substance), i.e. a defective medicinal product:

the Member State name where the batch/lot of the defective medicinal product has been seized;

the brand name of the medicinal product, if available;

the international non-proprietary name or, if one does not exist, common or generic name, or chemical name of the active substance of the medicinal product (for combination medicinal products, the names of active substances shall be stated separated using '+' (if a product contains three or fewer active substances); where a product contains more than three active substances, the names thereof shall be omitted);

the pharmaceutical form of the medicinal product;

the strength or concentration of the medicinal product;

the presentation of the medicinal product;

the batch number of the medicinal product;

the date of manufacture of the medicinal product, if available;

the expiry date (month) of the medicinal product, if available;

the medicinal product batch size stated in the quality standard, if available;

the medicinal product manufacturer's name;

the country where the manufacturer of the medicinal product is established;

the marketing authorisation holder name according to the Eurasian Economic Union Common Register of Medicinal Products;

the amount of the substandard medicinal products seized;

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

the supplier's name, if known;

the supplier's country of origin, if known.

a list of the out of specification attributes of the medicinal product;

the steps taken by the pharmaceutical competent authority;

b) for a falsified and/or counterfeit medicinal product (including active substances):

the Member State name where the batch/lot of the falsified and/or counterfeit medicinal product has been seized;

the brand name accompanying the seized the falsified and/or counterfeit medicinal product;

the pharmaceutical form of the falsified and/or counterfeit medicinal product;

the strength of the falsified and/or counterfeit medicinal product;

the presentation of the falsified and/or counterfeit medicinal product;

the international non-proprietary name or, if one does not exist, common or generic name, or chemical name of the active substance of the medicinal product (for combination medicinal products, the names of active substances shall be stated separated using '+' (if a product contains three or fewer active substances); where a product contains more than three active substances, the names thereof shall be omitted);

the manufacturer's name stated on the outer package of the falsified and/or counterfeit medicinal product;

the country where the manufacturer stated on the outer package of the falsified and/or counterfeit medicinal product is established;

the batch number stated on the falsified and/or counterfeit medicinal product package;

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

the expiry date (month) stated on the falsified and/or counterfeit medicinal product package, if known;

a photographic picture of the package of the falsified and/or counterfeit medicinal product;

the amount of the falsified and/or counterfeit medicinal product seized;

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

the supplier's name, if known;

the supplier's country of origin, if known.

a brief description of the attributes falsification and/or counterfeit nature of the medicinal product;

the steps taken by the pharmaceutical competent authority.

9. The above information shall submitted by the competent authorities to the Commission within three business days beginning with the date when the competent authority made its decision on substandard, falsified, or counterfeit nature of the medicinal product.

Where so provided by the Procedure for Cooperation Between the Member States in Detecting Falsified, Counterfeit and/or Substandard Medicinal Products subject to approval by the Commission, the competent authorities shall immediately send appropriate notification to each other via the Integrated System.

10. The information on a medicinal product shall be removed from the Common Database within three business days beginning with the day the Commission receives the following information from the competent authorities:

the competent authority has overturned its decision to withdraw the medicinal product from the market;

the competent authority's decision that the medicinal product is substandard, falsified and/or counterfeit has been overturned by a court of the Member State.

The competent authorities shall submit information on medicinal products subject to removal from the Common Database to the Commission within three business days beginning with the day such a decision is made.

11. The Common Database information shall be publicly accessible.

12. The competent authority shall provide the Common Database information to interested parties upon their request, including electronically.

ADOPTED
by Decision No. 84 of the Council
of the Eurasian Economic Commission
of 3 November 2016

PROCEDURE
for Establishing and Operating the Common Information Database of the Adverse Drug Reactions/Effects, including Reports on Lack of Efficacy in the Eurasian Economic Union Member States

1. This Procedure has been developed to implement Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014 and Article 14 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 Establishing and Operating the Common Information Database of the Adverse Drug Reactions/Effects, including Reports on Lack of Efficacy in the Eurasian Economic Union Member States (hereinafter referred to as the Common Database, Union, Member States, respectively).

2. The Common Database is a common information resource established within the Integrated Information System of the Union (hereinafter referred to as the Integrated System) based on communications between the pharmaceutical competent authorities of the Member States (hereinafter referred to as the competent authorities) or between the competent authorities and the Eurasian Economic Commission (hereinafter referred to as the Commission) and shall contain the following information.

a) information on any serious adverse drug reactions/effects detected in the Member States and recognised as valid;

b) reports on lack of efficacy of medicinal products.

3. The Common Database shall be established and operated by the Commission based on the information submitted electronically by the competent authorities in accordance with the Rules of Good Pharmacovigilance Practice subject to approval by the Commission.

The competent authorities shall submit this information within three business days beginning the day of receipt.

Where so provided by the Rules of Good Pharmacovigilance Practice, the competent authorities shall immediately send appropriate notification to each other via the Integrated System.

4. In case of serious unexpected adverse drug reactions/effects or life-threatening cases of lack of efficacy, communications between the competent authorities or between the competent authorities and the Commission when establishing, operating, or using the Common Register shall be carried out by implementing the respective common process within the Union via the Integrated System.

5. Establishing and operating the Common Database includes:

a) receipt current information on any detected adverse drug reactions/effects, including reports on lack of efficacy and entry this information into the Common Database by the Commission;

b) making publicly available the Common Database information by the Commission on the Union web portal;

c) the update of Common Database information by the Commission;

d) storage of the information available in the Common Database;

e) protection the Common Database information from an unauthorised access;

f) granting access to the Common Database information.

6. All information on serious adverse drug reactions and reports on life-threatening cases of lack of efficacy detected in the Member States shall be submitted by the competent authorities to the Common Database.

7. The Common Database shall contain the following information:

a) the brand name of the medicinal product;

b) the pharmaceutical form of the medicinal product;

c) the strength of the medicinal product;

d) the presentation of the medicinal product;

e) the batch number stated on the medicinal product package;

f) the medicinal product manufacturer' name which responsible for batch release;

g) information on any detected adverse drug reactions, including reports on lack of efficacy;

h) individual case safety reports;

i) information in the electronic format complying with the International Conference on Harmonisation of Technical Requirements for Authorisation of Pharmaceuticals for Human Use Guideline E2B on Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports.

ADOPTED
by Decision No. 84 of the Council
of the Eurasian Economic Commission
of 3 November 2016

PROCEDURE
for Establishing and Operating the Common Information Database of Suspended, Recalled, or Prohibited Medicinal Products in the Eurasian Economic Union Member States

1. This Procedure has been developed to implement Article 30 of the Treaty on the Eurasian Economic Union of 29 May 2014 and Article 14 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 Establishing and Operating the Common Information Database of Suspended, Recalled, or Prohibited Medicinal Products in the Eurasian Economic Union Member States (hereinafter referred to as the Common Database, Union, Member States, respectively).

2. The Common Database is a common information resource containing information on medicinal products suspended, withdrawn, or prohibited by pharmaceutical competent authorities of the Member States (hereinafter referred to as the competent authorities) and shall be established using the Union Integrated Information System (hereinafter referred to as the Integrated System) based on communications between the competent authorities or between the competent authorities and the Eurasian Economic Commission (hereinafter referred to as the Commission).

3. The Common Database shall be established and operated by the Commission based on the information submitted electronically by the competent authorities on suspended, withdrawn, or prohibited medicinal products.

The competent authority shall submit the above information within three business days after the day it made an appropriate decision or received information on the recall of a medicinal product by the manufacturer or marketing authorisation holder, or from the day court decision referred in paragraph 8(b) of this Procedure came into effect.

The competent authorities shall notify each other via the Integrated System of this decision within three business days beginning with the day it was made.

4. Communications between competent authorities or between competent authorities and the Commission when establishing, operating, or using the Common Database and when withdrawing or prohibiting use of medicinal products due to safety issues shall be carried out by implementing the respective common process within the Union via the Integrated System.

5. Establishing and operating the Common Database includes:

a) receipt current information on any suspended, withdrawn, or prohibited medicinal products by the Commission;

b) making publicly available the Common Database information by the Commission on the Union web portal;

c) storage of the information on any suspended, withdrawn, or prohibited medicinal products available in the Common Database;

a) granting access to the information on any suspended, withdrawn, or prohibited medicinal products available in the Common Database.

6. Based on the decision of the competent authority, the information on suspended, withdrawn, or prohibited medicinal products shall be sent by the competent authorities to the Commission for entry into the Common Database.

7. The Common Database shall contain the following information:

a) the authorisation number in the Union Common Register of Authorised Medicinal Products, where available;

b) the date of granting an authorisation for the suspended, withdrawn, or prohibited medicinal product and marketing authorisation number, where available;

c) the brand name of the medicinal product with suspended marketing authorisation, withdrawn from the market or prohibited for medical use in the Member States;

d) the pharmaceutical form of the suspended, withdrawn, or prohibited medicinal product;

e) the strength of the suspended, withdrawn, or prohibited medicinal product;

f) the presentation of the suspended, withdrawn, or prohibited medicinal product;

g) the suspended, withdrawn, or prohibited medicinal product manufacturer' name which responsible for batch release;

h) the country where the suspended, withdrawn, or prohibited medicinal product has been manufactured;

i) the authorisation number of the competent authority's decision and the date of making this decision;

j) the reason for suspension, withdrawal, or prohibition of the medicinal product;

k) the amount of the suspended, withdrawn, or prohibited medicinal product which is a subject to competent authority's decision (batch, lot, full withdrawal from the market, etc.);

l) the batch/lots numbers of the suspended, withdrawn, or prohibited medicinal product which is a subject to competent authority's decision where the decision is limited to certain batches/lots);

m) an electronic image of the competent authority's decision;

n) the marketing authorisation holder's name.

8. The information on suspended, withdrawn, or prohibited medicinal products shall be removed from the Common Database in the following cases:

a) the competent authority has overturned its decision;

b) the competent authority's decision has been overturned by a court of the Member State.

9. When the competent authority makes a decision to remove information on a suspended, withdrawn, or prohibited medicinal product, this information shall be transferred from the Common Database to the Commission to be entered into the Common Database, within three business days beginning with the day such a decision is made or day of the entry into force of the court decision referred to in paragraph 8(b) of this Procedure.

10. The Common Database information shall be publicly accessible.

11. The competent authority shall provide the Common Database information to interested parties upon their request, including electronically.