

Approved by
Deputy Minister of Health
of the Russian Federation
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GUIDELINES FOR PARTICIPANTS OF THE EXPERIMENT ON MARKING WITH IDENTIFICATION TOOLS AND MONITORING THE CIRCULATION OF CERTAIN TYPES OF PHARMACEUTICAL PRODUCTS FOR MEDICAL USE

These guidelines have been developed to replace the guidelines for conducting the experiment on marking with control (identification) marks and monitoring of the circulation of certain types of pharmaceutical products for medical use in civil circulation in the Russian Federation, approved by the Ministry of Health of the Russian Federation on 28 February 2017.

1. General provisions

1.1. These guidelines are developed in accordance with Federal Law of 28 December 2017 No. 425-FZ On amendments to the Federal Law "On the circulation of pharmaceutical products", data sheet of the priority project for the "Introduction of the automated system for monitoring the circulation of pharmaceutical products from the manufacturer to the end consumer to protect the public from counterfeit pharmaceutical products and the prompt removal of counterfeit and low quality pharmaceutical product from circulation", approved by the Presidium of the Presidential Council of the Russian Federation for Strategic Development and Priority Projects, as well as resolutions of the Government of the Russian Federation of 24 January 2017 No. 62 "On the experiment on marking with control (identification) marks and monitoring the circulation of certain types of pharmaceutical products for medical use" and of 30 December 2017 No. 1715 "On the amendment of the resolution of the Government of the Russian Federation of 24 January 2017 No. 62" ("Resolution," "Experiment").

1.2. Guidelines on conducting the Experiment ("Guidelines") regulate the relations associated with the implementation of the Experiment conducted in accordance with the Resolution.

1.3. Goals and objectives defined in the Resolution should be taken into account during the Experiment.

1.4. For the purpose of these Guidelines, key terms shall be used with the following definitions:

1.4.1. Pharmaceutical products means substances or their combinations that come into contact with the human or animal body, penetrate into organs or tissues of the human or animal body, are used for prophylaxis, diagnostics (except for substances or their combinations that do not come into contact with the human or animal body), disease treatment, rehabilitation, or for the preservation, prevention or termination of pregnancy and minerals obtained from the blood, blood plasma, organs, tissues of the human or animal body, or plants by synthesis or using biological technologies.

1.4.2. Pharmaceutical products ("Medicines") are medicines that are formulated products used to prevent, diagnose and treat diseases, and rehabilitate, preserve, prevent or terminate pregnancy.

1.4.3. Formulated product means the state of the medicine corresponding to the methods of its administration and use, and ensuring the achievement of the desired therapeutic effect.

1.4.4. Medicine identification tool means the unique sequence of characters in machine-readable form or presented using other means (technology) of automatic identification, compiled in accordance with Appendix 1 hereto.

1.4.5. The system for monitoring of pharmaceutical products circulation ("FSIS MPPC") is the federal state information system for monitoring the circulation of pharmaceutical products for medical use from the manufacturer to the end consumer using identification tools for pharmaceutical products for medical use.

1.4.6. The components of FSIS MPPC are the functional subsystems of FSIS MPPC.

1.4.7. The subjects of circulation of the medicine are individual entrepreneurs and legal entities carrying out activities during the circulation of the medicine, as well as holders of registration certificates ("RC") and/or their representative offices in the Russian Federation.

1.4.8. Medicine production series are the amount of medicine produced as a result of one technological cycle by its manufacturer.

1.4.9. Medicine primary package is a means or set of means that ensure the protection of a medicine from damage and loss, environmental exposure, contamination and direct contact with the medicine.

1.4.10. The recycled (retail) package of a medicine is the package it is delivered to the consumer in and serves to accommodate one primary package of the medicine, or combines several primary packages of the medicine.

1.4.11. The tertiary (factory, shipping) package of a medicine is a group package used for storing, shipping and moving the medicine among the subjects of circulation and combining arbitrary sets of recycled (retail) packages of the medicine or tertiary (factory, shipping) packages of the medicine.

1.4.12. The global ID of the trade unit ("Global Trade Item Number"/"GTIN") is a unique code used to identify at least the manufacturer, the trade name of the medicine, the formulated product, the dosage of the pharmaceutical product, and the completeness of the medicine package.

1.4.13. The individual serial number of the recycled (retail) package (in its absence, the primary package) is the numeric or alphanumeric sequence compiled in accordance with Appendix 1 hereto.

1.4.14. The Serialised Global Identification Number of the trade unit ("sGTIN") is a unique serial number of the recycled (retail) package of the medicine formed by adding the individual serial number of the recycled (retail) package to the global ID of the trade unit, and in its absence, the primary package.

1.4.15. The group code is the identification tool of the group package of the medicine, or a combination of symbols unique for each individual tertiary (factory, shipping) package of the medicine, in the form of a linear barcode generated by the issuer of group codes in accordance with the characteristics, rules, structure and format presented in Appendix 1 to these guidelines, which is applied to the group packaging of the medicine by printing or labeling during aggregation.

1.4.16. The group code issuer is the subject of medicine circulation, which forms and applies the group code.

1.4.17. The medicine identification tools issuer is the manufacturer of the medicine that carries out the stage of "filling/packaging of the medicine in recycled (retail) package", and the application of identification tools to the recycled (retail) package of pharmaceutical products (in its absence, to the

primary package).

1.4.18. The marking of packages of pharmaceutical products is the application of identification tools to the recycled (retail) package of the medicine (in its absence, to the primary package) by the issuer of identification tools, as well as group codes on the tertiary (factory, shipping) package by the issuer of group codes.

1.4.19. Medicines marked with identification tools are medicines marked with suitable identification tools, the reliable information of which is transferred to FSIS MPPC in accordance with the established procedure established in these Guidelines.

1.4.20. Serialisation is the process of data generation for the tools of identification and marking of the recycled (retail) package of a medicine carried out in the framework of the production cycle stage of "filling/packaging of the medicine in a recycled package" (in its absence, in the primary package).

1.4.21. Aggregation is the process of combining medicines in a group package with the preservation of information about the relationship of identification tools of each integrated medicine with the group code of the created group package and the corresponding group code applied to the group package.

1.4.22. Completion of the finished product release stage is the confirmation by an authorised person of the manufacturer of the pharmaceutical products of the compliance of the series of the medicines with the requirements established during their state registration.

1.4.23. The owner of the medicine is the subject of circulation of the medicines holding the rights of possession, use and disposal of the medicines.

1.4.24. Putting a pharmaceutical product into circulation in the Russian Federation ("putting a medicine into circulation"), as concerns medicines of Russian production, means operations with the medicines from the completion of the production stage of filling (packaging) the medicine in the primary package (for pharmaceutical products for medical use, for which there is no secondary package) and the recycled (retail) package of the pharmaceutical products for medical use until the completion of the outgoing control stage and confirmation by an authorised person of the manufacturer of pharmaceutical products that the medicines comply with the requirements established upon their state registration, and in the event of foreign production, the operations performed with the medicine from the completion of the stage of outgoing control and confirmation by an authorised person of the manufacturer of pharmaceutical products of the compliance of the medicine with the requirements established upon their state registration until the completion of the customs procedure of release for domestic consumption during the import of the medicines in the Russian Federation.

1.4.25. The withdrawal of medicines from circulation is the sale of a medicine to the consumer, the use of a medicine for the manufacture of other medicines, transfer for the destruction, loss, damage and other retirement of the medicines, sampling for various purposes, export of previously imported medicines to the Russian Federation, and sale of medicines outside the Russian Federation previously in circulation in the Russian Federation, and the release of medicines for medical use.

1.4.26. The circulation of pharmaceutical products means the production, receipt, storage, movement and transfer of medicines between the subjects of circulation of the medicines and transfer for destruction (in the framework of these Guidelines).

1.4.27. The description of a medicine is the list of characteristics specified in Appendix 2 to these guidelines, published (formed) by the participants of circulation of the medicine in the relevant

information resource, ensuring the accounting and storage of reliable medicine-related data in compliance with correspondent classification.

1.4.28. The release of a pharmaceutical product for medical use is the transfer of the medicine by the medical organisation to the medical department.

1.5. Experiment participants are the following:

a) authorised Federal executive authorities comprised of:

- Ministry of Health of the Russian Federation ("Russian Ministry of Health")
- Ministry of Industry and Trade of the Russian Federation ("MIT RF")
- Ministry of Finance of the Russian Federation ("MF RF")
- Federal Service for Supervision of Healthcare ("Roszdravnadzor"), local offices of Roszdravnadzor
- Federal Customs Service ("FCS RF")
- Federal Tax Service ("FTS RF"), the operator of FSIS MPPC ensuring the design, development and operation of the system, and providing information support for the Experiment
- health management authorities of constituent entities of the Russian Federation

b) subjects of medicine circulation:

- Russian manufacturers of medicines that carry out the stages of "filling/packaging of medicines in the recycled (and in its absence, in the primary package) and/or tertiary package"
- Russian manufacturers of medicines that carry out the stages of "outgoing quality control"
- Russian and foreign holders of registration certificates of the medicines
- representative offices of foreign holders of registration certificates of medicines ("medicine RC"), registered in accordance with the established procedure in the state register of accredited branches, representative offices of foreign legal entities of FTS RF ("representative offices of foreign holders of medicine RC")
- medicine wholesale trade organisations
- medicine retail trade organisations
- medical organisations

1. Experiment participants from among the subjects of circulation of the medicines are determined voluntarily.

2. The monitoring and evaluation of the implementation of the Experiment is carried out in accordance with the measures of the datasheet and consolidated plan of the priority "Introduction of the automated system for monitoring the circulation of pharmaceutical products from the manufacturer to the end consumer to protect the public from counterfeit pharmaceutical products and the prompt withdrawal

of counterfeit and low-quality pharmaceutical product from circulation" project.

2. Characteristics of identification tools, structure and format requirements

2.1. The structure of the code, the method of formation and the format of the code for the coding of identification tools of the recycled (retail) (and in its absence, the primary package) and tertiary (factory, shipping) package of medicines for marking in the framework of the Experiment must meet the requirements described in Appendix 1 hereof.

3. Requirements for equipment used in the application and reading of identification tools

3.1. Within the framework of the Experiment, it is permissible to apply identification tools using printing or labelling methods without restrictions on the type of equipment used.

3.2. The requirements for the quality of application of identification tools to the recycled (retail) package of medicines (and in its absence, to the primary package) are described in Appendix 1 hereof.

4. FSIS MPPC requirements

4.1. For the purpose of the Experiment, FSIS MPPC shall be used to track the movement of medicines from the manufacturer to the final consumer and support state control and supervision in the field of medicines circulation and pharmaceutical activity, created on a phased basis to implement Federal Law of 28 December 2017 No. 425-FZ "On amendments to the Federal Law on the circulation of medicines".

4.2. Information support for the monitoring of the movement of medicines from the manufacturer to the final consumer is implemented as part of FSIS MPPC and described in Appendix 3 hereof.

4.3. Principles of operation of FSIS MPPC:

- medicines are identified in FSIS MPPC on the basis of the serial global ID of the trade unit

- full traceability of the movement of a medicine package from the manufacturer to the final consumer is ensured by entering the relevant information into FSIS MPPC as electronic documents signed with simple e-signatures (applicable for the registration of foreign holders) or enhanced qualified e-signatures transmitted by the subjects of medicine circulation due to changes in the state and/or location of the medicine throughout the entire life cycle of the medicine

- information about the movement of a medicine from one subject of circulation to another shall only be accepted in the prescribed manner

4.4. FSIS MPPC components shall be created taking into account the use of a centralised architecture representing a single information resource. The main values of key classifiers in FSIS MPPC are described in Appendix 4 hereof. In the creation of FSIS MPPC, the necessary mechanisms for information interaction shall be implemented to allow access to information for all participants of the Experiment, with the option for their subsequent expansion. FSIS MPPC shall ensure the scalability of its solutions.

4.5. FSIS MPPC shall ensure the fulfilment of the following requirements: the storage of all

transaction records in the database registered in FSIS MPPC in the framework of the Experiment for 5 (five) years.

4.6. The system-wide server components of FSIS MPPC shall support structural redundancy, automatic detection of server node failure and task (load) switching to another server node, and also have a network access hub for clients that is redundant and diversified in terms of connection to providers.

4.7. As part of FSIS MPPC, the following functions of its components shall be automated during the development process:

- automation of user registration in FSIS MPPC, creation of personal accounts and registering information about a medicine
- automation of obtaining and registering information about actions performed as part of the process of putting a medicine into circulation
- automation of obtaining and registering information about actions performed as part of a medicine's circulation in the Russian Federation
- automation of registration of information about the withdrawal of medicines from circulation
- automation of public control over the circulation of medicines
- automation of the automatic blocking of information on the sale of medicines with an expired shelf life
- automatic blocking of information about the circulation of falsified, counterfeit and low-quality medicines
- automation of the control and prompt detection of possible irregularities during the registration of information in FSIS MPPC by the subjects of medicines circulation
- automation of providing information and analytical support for the activities of federal executive authorities in the field of medicine circulation and monitoring of the movement of medicines (according to Appendix 3 hereto).

5. The procedure for information exchange

5.1. The relevance in law of all transactions registered by the subjects of medicine circulation in FSIS MPPC shall be ensured by the signing of relevant documents with an enhanced qualified e-signature.

5.2. Information electronic services shall ensure the performance of the following functions:

- creation and signing of documents submitted to FSIS MPPC by enhanced qualified e-signature
- receipt of the response to previously sent documents
- saving of the contents of the documents sent and responses received to them, as well as information about the facts of document sending (document number, date and time of sending, information about the authorised person who signed and sent the document, date and time of receipt of the answer).

5.3. As part of the Experiment, information on the performance of the relevant operations shall be registered in FSIS MPPC by the subjects of medicine circulation in accordance with Section 8 hereof.

The authorisation of the subjects of medicine circulation, which are residents of the Russian Federation, and representative offices of foreign organisations that are holders of medicine RC in the Russian Federation, is performed in FSIS MPPC via enhanced qualified e-signature.

The authorisation of the subjects of medicine circulation, which are foreign entities and holders of medicine RC, and are not residents of the Russian Federation and have no representative offices in the Russian Federation, in FSIS MPPC is performed by means of login and password.

The transfer of information to FSIS MPPC is carried out by the submission of files in the format presented by the operator of FSIS MPPC (data composition and formats may vary).

The date of submission of information to FSIS MPPC is the date recorded on the receipt of information, which is formed when it is entered in FSIS MPPC as an electronic document.

When sequential operations are carried out by the subjects of medicine circulation, information is provided to FSIS MPPC sequentially (except for cases provided for in these Guidelines). Information about the next operation with the medicine is submitted after the subject of medicine circulations receives confirmation of the successful processing in FSIS MPPC of information about the previous operation with the medicine.

Subjects of medicine circulation provide information to FSIS MPPC independently, including with the involvement of other legal entities or individual entrepreneurs authorised by the subjects of medicine circulation and acting on behalf of the subjects of medicine circulation in accordance with the legislation of the Russian Federation.

6. The procedure for the interaction of FSIS MPPC with state information systems

6.1. These Guidelines set out the requirements for FSIS MPPC and the procedure for its interaction with other state information systems.

6.2. The Operator develops FSIS MPPC, provides information contained in FSIS MPPC by providing access to FSIS MPPC, including by making the relevant information service available on the Operator's official website online, or using the Unified System of Interdepartmental Electronic Interaction, according to the rules established by Appendix 5 hereto.

6.3. The services to ensure interdepartmental electronic interaction of the FSIS MPPC should meet the requirements of the order of the Ministry of Communications and Mass Media of the Russian Federation of 27 December 2010 No. 190 "On approval of the technical requirements for the interaction of information systems in a single interdepartmental electronic interaction system". A description of services is provided in the relevant technological maps of interdepartmental interaction.

6.4. The registers and reference information are kept in FSIS MPPC in accordance with the principles of consistency, continuity and integrity of information. In order to ensure traceability, reference data from external information systems and resources can be downloaded and updated from the available resources of federal executive authorities, among others.

7. The procedure for participation in the Experiment and registration of subjects

of medicine circulation in FSIS MPPC

7.1. The application for participation in the Experiment is voluntarily filed with FSIS MPPC electronically. The subjects of medicine circulation, which are residents of the Russian Federation, sign the application with the enhanced qualified e-signature issued to the head of the organisation in one of the certification centres accredited by the Ministry of Communications and Mass Media of Russia <1>. Certificates of e-signature verification keys and the software module ensuring the operation of the e-signature must be installed on the computer from which FSIS MPPC is entered.

<1> <http://minsvyaz.ru/ru/activity/govservices/2/>.

7.2. Registration of the subjects of medicine circulation in the FSIS MPPC and the provision of a personal account are carried out on the basis of reliable information provided by the subjects of medicine circulation in the FSIS MPPC electronically and/or documents submitted to Roszdravnadzor in accordance with paragraph 30 of these Guidelines.

To register with FSIS MPPC, the subjects of medicine circulation, which are residents of the Russian Federation or representative offices of foreign organisations in the Russian Federation, who are holders of medicine RC, send the following information signed by the enhanced qualified e-signature of the head of the organisation (representative office of a foreign organisation in the territory of the Russian Federation) or individual entrepreneur:

- a) INN/KPP
- b) information on the availability of a license for at least one of the activities
- c) name and phone number of the contact person (in the event of an absence of a license)
- d) email

Subjects of medicine circulation, which are holders of registration certificates for medicines without licenses to manufacture medicines or licenses for medical and pharmaceutical activities, shall submit to Roszdravnadzor a statement in the form approved by the Ministry of Health of Russia within ten calendar days from the date of submission of information <2>.

<2> <https://www.rosminzdrav.ru/poleznye-resursy/sistema-markirovki-lekarstvennyh-preparatov/metodicheskie-materialy>.

7.3. To register with FSIS MPPC, the subjects of medicine circulation, which are foreign organisations and holders of medicine registration certificates which do not have representative offices in the Russian Federation, send the following information to FSIS MPPC electronically:

- a) name of the holder of medicine RC
- b) taxpayer registration number in the country of registration
- c) code of the country of registration

d) full name and telephone number of the contact person

e) email

7.4. Roszdravnadzor considers applications for voluntary participation in the Experiment from foreign holders of registration certificates.

7.5. Original documents confirming the right to represent the interests of a foreign holder of medicine RC, and the application for voluntary participation in the Experiment in the form of Appendix 4 hereof ("application") must be submitted within ten calendar days from the date of filing the electronic application to Roszdravnadzor at the following address: 4 Slavyanskaya Square, Bldg. 1, 109074 Moscow.

7.6. The basis for the commencement of the procedure for the consideration of information submitted for the registration of foreign organisations which are holders of medicine RC and do not have representative offices in the Russian Federation is the receipt of the set of documents by Roszdravnadzor.

7.7. Roszdravnadzor reviews the set of documents within five business days and reports (transmits) information about the results of its consideration to FSIS MPPC within one business day from the date of the adoption of the relevant decision.

The processing and verification of information submitted for registration, including the result of the review by Roszdravnadzor of the set of documents, is carried out by FSIS MPPC, including through the use of the Unified System of Interdepartmental Electronic Interaction with the external information resources of federal executive authorities within 14 business days from the date of submission of the information to FSIS MPPC by the subjects of medicine circulation.

7.8. Grounds for refusing registration as an Experiment participant:

a) Russian manufacturers of pharmaceutical products carrying out the “filling/packaging of pharmaceutical products in recycled and/or tertiary package” stage (and in their absence, the primary package), can be refused registration in FSIS MPPC on the basis of their completed application for participation in the Experiment for the following reasons:

- absence of an enhanced qualified e-signature of the head of the organisation, which is a subject of medicines circulation and resident of the Russian Federation; or non-compliance of the data of the owner of the qualified certificate with the data of the head of the organisation, which is a subject of medicine circulation; absence of information about the valid certificate of enhanced qualified e-signature issued to the head of the organisation, which is a subject of medicine circulation and a resident of the Russian Federation

- absence of information about valid records in the Unified State Register of Legal Entities/Unified State Register of Individual Entrepreneurs of FTS RF or the absence of information about valid records in the State Register of accredited branches or representative offices of foreign legal entities of FTS RF

- absence of information about a valid license in the Unified Register of Licenses for the Production of Medicines of MIT RF, the absence of information about a valid license in the Unified Register of Licenses for Medical and Pharmaceutical Activities of Roszdravnadzor, the absence of information about the registration certificate of the medicine in the State Register of Medicines of the Ministry of Health of Russia specified in the information

- absence of information about a positive decision from Roszdravnadzor

b) holders of medicine registration certificates, the medicine of which is manufactured outside the Russian Federation, and which are residents of the Russian Federation, can be refused registration in FSIS MPPC on the basis of the completed application for participation in the Experiment for the following reasons:

- absence of an enhanced qualified e-signature of the head of the organisation, which is a subject of medicines circulation and resident of the Russian Federation; or non-compliance of the data of the owner of the qualified certificate with the data of the head of the organisation, which is a subject of medicine circulation; absence of information about the valid certificate of enhanced qualified e-signature issued to the head of the organisation, which is a subject of medicine circulation and a resident of the Russian Federation

- absence of information about valid records in the Unified State Register of Legal Entities/Unified State Register of Individual Entrepreneurs of FTS RF or the absence of information about valid records in the State Register of accredited branches or representative offices of foreign legal entities of FTS RF

- absence of information about the specified medicine RC in the State Register of Medicines of the Ministry of Health of Russia

- absence of information about a positive decision from Roszdravnadzor

c) foreign holders of registration certificates of medicines can be refused registration in FSIS MPPC on the basis of their completed application for participation in the Experiment for the following reasons:

- absence of information about the specified medicine RC in the State Register of Medicines of the Ministry of Health of Russia

- absence of information about a positive decision from Roszdravnadzor

Consultant Plus: note.

Subparagraphs are numbered in accordance with the official text of the document.

e) foreign holders of registration certificates of medicines can be refused registration in FSIS MPPC on the basis of their completed application for participation in the Experiment for the following reasons:

- absence of an enhanced qualified e-signature of the head of the applicant, or non-compliance of the data of the owner of the qualified certificate with the data of the head of the applicant

- absence of information on valid entries in the State Register of Accredited Branches and Representative Offices of Foreign Legal Entities of FTS RF

- absence of information about a positive decision from Roszdravnadzor

d) medicine wholesale trade, retail trade and medical organisations can be refused registration in FSIS MPPC on the basis of their completed application for participation in the Experiment for the following reasons:

- absence of information about a valid certificate of an enhanced qualified signature issued to the head of the applicant organisation

- absence of information about valid entries in the Unified State Register of Legal Entities/Unified

State Register of Individual Entrepreneurs of FTS RF

- absence of information about the current license in the Unified Register of Licenses for the Medical and Pharmaceutical Activities of Roszdravnadzor

- absence of information about a positive decision from Roszdravnadzor

Based on the results of the processing and verification of information provided by the subject of medicine circulation for registration in FSIS MPPC and the provision of a personal account, the relevant notification is sent to the email address provided when submitting the information. The use of the same email address for the registration of personal accounts of various subjects of medicine circulation is prohibited.

7.9. The subject of medicine circulation receiving a notification about the positive review of the submitted information, when activating their Personal Account functions, shall when necessary enter the list of trading addresses by choosing from the addresses indicated in the licenses, and also enter the list of consignment warehouses. In the event of foreign production RC holders and/or their representative offices in the Russian Federation, they must enter the list of names of production sites that carry out the “filling/packaging of medicines in the recycled package” (in its absence, in the primary package) and the “outgoing control quality” stages of the production cycle.

7.10. The registration of medicines in FSIS MPPC is carried out by the following subjects of medicine circulation:

- in the event of the production of medicines in the Russian Federation, by medicine manufacturers performing the completion of the production stage of “filling (packaging) medicines in the recycled (retail) package” (and in its absence, in the primary package)

- in the event of the manufacture of medicines outside the Russian Federation (foreign production), by the holders of medicine RC and/or their representative offices in the Russian Federation or authorised representatives

The registration of medicines in FSIS MPPC is carried out on the basis of the electronic application containing:

a) the global ID of the trade unit

b) RC number and the date of the registration of the medicine in the State Register of Medicines of the Russian Ministry of Health.

Received information is processed automatically by creating a request to obtain information about medicines from the State Register of Medicines of the Russian Ministry of Health, the State Register of Limit Sale Prices for the Manufacturers of Medicines included in the list of vital and essential medicines, the Russian Ministry of Health and the information resource ensuring the storage of reliable data about medicines, in accordance with Appendix 2 to these Guidelines.

According to the results of the automatic analysis and successful processing of the received data by FSIS MPPC, a medicine card containing its description is generated.

Information about the creation (refusal to create) the medicine card with its description is automatically sent to the personal account of the subject of medicine circulation that registered the medicine.

7.11. The subject of medicine circulation can supplement, edit and delete Personal Account users when necessary using FSIS MPPC.

8. The procedure for the interaction of Experiment participants and rules for the entry of information in FSIS MPPC

8.1. The procedure for the interaction of participants of the Experiment, including the list and procedure for entering information in FSIS MPPC when putting medicines in civilian circulation packed in the Russian Federation.

8.1.1. In the framework of putting medicines manufactured in the Russian Federation into circulation, the manufacturer of the medicines that carries out the filling (packaging) of medicines in the recycled (retail) package, within five business days from the date of completion of the production stage of filling (packaging) the medicine, but before providing information about further operations with such medicines, provides the information to FSIS MPPC provided for in paragraph 1 of Appendix 7 to these Guidelines.

8.1.2. Samples of medicines (to verify compliance in terms of quality, to declare compliance, to control and archive samples, etc.) taken by the Russian manufacturer of medicines are documented by the Russian manufacturer of medicines within five business days from the date of completion of the sampling stage, but before providing information about subsequent operations with such medicines to FSIS MPPC in accordance with paragraph 2 of Appendix 10 to these Guidelines.

8.1.3. As part of putting medicines produced in the Russian Federation into circulation, the manufacturer of medicines, within five business days from the date of completion of the outgoing control stage, but before providing information about subsequent operations with the medicine put into circulation, provides the information to FSIS MPPC about putting the medicine into circulation provided for in paragraph 2 of Appendix 7 to these guidelines.

8.2. The procedure for the interaction of the Experiment participants, including the list and procedure for entering information into FSIS MPPC, in the event of the production of the medicines abroad and their import in the Russian Federation.

8.2.1. As part of putting medicines produced outside the Russian Federation into circulation, the subject of medicine circulation, which is the holder of medicine RC, the representative office of the foreign holder of RC or the foreign holder of RC without a representative office in the Russian Federation, before providing information about subsequent operations with such medicine, provides the information to FSIS MPPC about the production of finished products provided for in paragraph 3 of Appendix 7 to these Guidelines.

In the framework of import of medicines into the Russian Federation, the subject of medicine circulation, which is the holder of medicine RC, the representative office of the foreign holder of the RC or the foreign holder of the RC, which does not have a representative office in the Russian Federation, submits the information to FSIS MPPC about the shipment of medicines to the Russian Federation provided for in paragraph 4 of Appendix 7 to these guidelines, prior to the submission to FSIS MPPC of the information by the participant of medicine circulation that imports pharmaceutical products into the Russian Federation about the import and placement of medicines in the customs zone of the Russian Federation.

In the event of importing a medicine into the Russian Federation in the framework of a consignment agreement, the subject of medicine circulation, which is the holder of medicine RC, is not required to

submit the information provided for in paragraph 4 of Appendix 7 to these Guidelines.

The subject of medicine circulation importing the medicine into the Russian Federation, within five business days from the date of import and placement of the medicine in the customs zone of the Russian Federation, but before providing information about the placement of the medicine under the relevant customs procedures, submits the information to FSIS MPPC provided for in paragraph 5 of Appendix 7 to these Guidelines.

Within five business days from the date of issuance of the declaration for the medicines confirming the release of the medicines into free circulation, but before submitting information about the subsequent operations with the medicines, the subject of medicine circulation that imports the medicines into the Russian Federation, provides to FSIS MPPC the information provided for in paragraph 6 of Appendix 7 to these Guidelines.

When transferring medicines between different customs control zones, the subject of medicine circulation importing medicines into the Russian Federation submits the information to FSIS MPPC provided for in Clause 7 of Appendix 7 to these Guidelines.

8.2.2. When performing customs operations in the process of customs declaration and the placing of medicines under the customs procedure for release for domestic consumption, the customs authority:

- requests information in FSIS MPPC about the serial global ID of the trade unit or group code for reconciliation with the data specified in the medicine declaration;
- submits data to FSIS MPPC about the release of the medicine for domestic consumption.

When making changes and/or additions to the information specified in the declaration for medicines after the release of medicines for domestic consumption, the customs authority submits the corrected information to FSIS MPPC.

When a medicine is transferred from the customs control zone, the subject of medicine circulation, which imports the medicine into the Russian Federation, or the subject of medicine circulation to whom the ownership rights for medicines placed under the customs procedure of the customs warehouse are transferred, within five business days from the date of acceptance of the medicine to the pharmaceutical warehouse, but before submitting information about subsequent operations with the medicine, submits the information to FSIS MPPC provided for in paragraph 8 of Appendix 7 to these Guidelines.

8.2.3. When placing medicines under the customs procedure of a customs warehouse, ownership rights to the medicines in the customs control zone can be transferred. When ownership rights for the medicine are transferred by the subject of medicine circulation importing the medicine into the Russian Federation, within five business days from the date of creating the relevant documents about the transfer of ownership, but before submitting information to FSIS MPPC about subsequent operations, the subject of circulation submits the information to FSIS MPPC provided for in paragraph 9 of Appendix 7 to these Guidelines.

The subject of medicine circulation, to whom the ownership rights to the medicines placed under the customs procedure of a customs warehouse were transferred, also confirms the accuracy of the information contained in FSIS MPPC about the accepted medicines, submitting the information to FSIS MPPC provided for in paragraph 10 of Appendix 7 to these Guidelines, within five business days from the date of creating the relevant documents on the transfer of ownership and registration in FSIS MPPC of the information about the transferred medicines, but before submitting information about subsequent

operations with the medicine.

When the medicine is placed under the customs procedure for release for domestic consumption, the subject of medicine circulation, to whom the ownership of the medicine is transferred, within five days from the date of the decision of the customs authority to complete clearance in accordance with the declared customs procedure, submits the information to FSIS MPPC about customs clearance provided for in paragraph 6 of Appendix 7 to these Guidelines.

8.2.4. In the framework of the import of medicines to the Russian Federation from EEU Member States, the subject of medicine circulation, which is the holder of the medicine RC, submits the information to FSIS MPPC about the shipment of the medicines to the Russian Federation provided for by paragraph 11 of Appendix 7 to these Guidelines before providing information about subsequent operations with these medicines.

The subject of medicine circulation accepting the medicines in a warehouse in the framework of import into the Russian Federation from EEU Member states, submits the information to FSIS MPPC provided for by paragraph 12 of Appendix 7 to these Guidelines, within five business days from the date of acceptance of the medicine, but before any subsequent operations with this medicine.

In the framework of putting the medicine into circulation, the subject of medicine circulation accepting the medicine at the warehouse in the framework of importing in the Russian Federation from the EEU Member States submits the information to FSIS MPPC provided for by paragraph 13 of Appendix 7 to these Guidelines.

8.3. The procedure for the interaction of Experiment participants, including the list and procedure for entering information into FSIS MPPC when carrying out operations with group packages.

8.3.1. In the aggregation process, the subject of medicine circulation applies the group code to the group package and submits the information to FSIS MPPC provided for in paragraph 1 of Appendix 8 to these Guidelines before submitting information about subsequent operations with the medicine.

Medicines manufactured in the Russian Federation can also be aggregated to at least one nesting level, and the information about the aggregation can be communicated to FSIS MPPC by the subjects of medicine circulation putting the medicines into circulation before transferring these medicines to the following participants of medicine circulation.

For medicines produced outside the Russian Federation, the implementation of aggregation of at least one level of nesting and the transfer of information about aggregation to FSIS MPPC by the subjects of medicine circulation holding registration certificates for the medicines or importing the medicines in the Russian Federation, can be performed before the placement of the medicines under the customs procedure of release for domestic consumption.

8.3.2. When a group package is broken up, a medicine is withdrawn from the group package and a different medicine is inserted into the group package; the subjects of medicine circulation submit the information to FSIS MPPC provided for by paragraphs 2 and 3 of Appendix 8 to these Guidelines within five business days from the date of such operations with medicines located in the Russian Federation, or within 20 business days from the date of such movement for medicines located outside the the Russian Federation, but prior to the submission of information about subsequent operations with the medicine or group package.

8.3.3. The cancellation of the group code of the tertiary (factory, shipping) package of the medicines

upon the withdrawal of the recycled (retail) package (and, when absent, the primary package) is made only when, as a result of the completion of the operation, there are no other packages of medicines in the tertiary (factory, shipping) package, which is confirmed by FSIS MPPC data. In all other cases, a note is made in FSIS MPPC about changes to the composition of the tertiary (factory, shipping) package of the medicine.

8.3.4. In the event of breaking up the tertiary (factory, shipping) package of medicines, the corresponding group code of the tertiary (group, shipping) package of medicines shall be indicated. The group code of the broken up tertiary (factory, shipping) package is also cancelled in FSIS MPPC, but the serial global identification numbers of trade units remain in circulation.

8.3.5. When conducting operations with medicine aggregated into a group package, in the cases provided for in these guidelines, it is permitted to transmit information about the code of the group package without indicating the serial global identification number of the trade unit.

The transfer of information about the group package code is also considered to be equivalent to the transfer of information about the serial global identification numbers of the trade units of the medicines contained in this group package according to FSIS MPPC data.

8.4. The procedure for the interaction of Experiment participants, including the list and procedure for entering information in FSIS MPPC, in the circulation and internal movement of medicines.

8.4.1. The subject of medicine circulation moving medicines between trading addresses according to its own license (taking into account the types of activity: production of medicines, pharmaceutical activity) ("trading address") and/or consignment warehouses, within five business days from the actual date of movement, but before providing information about subsequent operations with these medicines, submits information to FSIS MPPC provided for in paragraph 4 of Appendix 9 to these guidelines.

8.4.2. When transferring medicines between subjects of medicine circulation, information can be submitted to FSIS MPPC in direct or reverse order of information submission.

The decision about the choice of the type of procedure for the submission of information is made independently by the subjects of medicine circulation providing this information.

In the event of the selection of the direct procedure for the submission of information, the subject of medicine circulation transferring the medicine to another subject of medicine circulation within the framework of civil law relations, providing for the transfer of ownership of the given medicines, or within the framework of intermediary relations (agency or commission agreement), submits the relevant information to FSIS MPPC provided for by paragraph 1 of Appendix 9 to these Guidelines within five business days from the date of shipment of the medicine.

In this event, the subject of medicine circulation accepting the medicines from another subject of medicine circulation in the framework of civil law relations, providing for the transfer of ownership for these medicines, or in the framework of intermediary relations (agency or commission agreement), within five business days from the date of medicine acceptance and registration of the information about the shipped medicines with FSIS MPPC, but before submitting information about further operations with these medicines, confirms the accuracy of the information contained in FSIS MPPC about the received medicines, providing the relevant information to FSIS MPPC provided for by paragraph 3 of Appendix 9 to these Guidelines.

In the event of the selection of the reverse procedure for the submission of information, the subject

of medicine circulation accepting the medicine from another subject of medicine circulation within the framework of civil law relations, providing for the transfer of ownership of the given medicines, or within the framework of intermediary relations (agency or commission agreement), submits the information to FSIS MPPC about the accepted medicines provided for by paragraph 2 of Appendix 9 to these Guidelines within five business days from the date of acceptance of the medicine.

In this event, the subject of medicine circulation transferring the medicines to another subject of medicine circulation in the framework of civil law relations, providing for the transfer of ownership for these medicines, or in the framework of intermediary relations (agency or commission agreement), within five business days from the date of registration with the FSIS MPPC of information about the accepted medicines but before submitting information about further operations with these medicines, confirms the accuracy of the information contained in FSIS MPPC about the accepted medicines, providing the relevant information to FSIS MPPC provided for in paragraph 3 of Appendix 9 to these Guidelines.

8.4.3. The subject of medicine circulation carrying out the contract production of medicines in the Russian Federation, upon the transfer of the medicines to the subject of medicine circulation, which is the customer of this contract production, within five business days from the date of transfer of the medicines to the owner, submits the information to FSIS MPPC about the transferred medicines provided for by paragraph 5 of Appendix 9 to these Guidelines.

The subject of medicine circulation, which is the customer of this contract production, also within five business days from the date of acceptance of the medicines and registration in FSIS MPPC of the information about the transferred medicines, but before submitting information about subsequent operations with these medicines, confirms the accuracy of the information contained in FSIS MPPC about the transferred medicines, providing the relevant information to FSIS MPPC provided for by paragraph 3 of Appendix 9 to these Guidelines.

8.5. The procedure for the interaction of Experiment participants, including the list and procedure for entering information in FSIS MPPC, in the withdrawal of medicines from circulation.

8.5.1. The subject of medicine circulation withdrawing a medicine from circulation (except for the withdrawal of a medicine from circulation by sampling, re-export or transfer for destruction), within five business days from the date of the relevant operation submits the information to FSIS MPPC about the withdrawn medicine provided for by paragraph 1 of Appendix 10 to these Guidelines.

8.5.2. The subject of medicine circulation carrying out the withdrawal of a medicine from circulation by sampling, within five business days from the date of the relevant operation submits the information to FSIS MPPC about the withdrawn medicine provided for by paragraph 2 of Appendix 10 to these Guidelines.

When sampling is carried out to confirm compliance when a medicine is imported in the Russian Federation, information about the relevant operation shall be provided by the subject of medicine circulation accepting the medicine at the pharmaceutical warehouse within five business days from the date of acceptance of the medicine at the pharmaceutical warehouse, but before submitting information about subsequent operations with the medicines.

8.5.3. The subject of medicine circulation withdrawing a medicine from circulation by transferring the medicine for destruction provides the information to FSIS MPPC about the destruction of the medicine provided for by paragraph 4 of Appendix 10 to these Guidelines within five business days from the date of destruction of the medicine, but not until the registration in FSIS MPPC of the information about the withdrawal of the medicine from circulation by its transfer for destruction, in addition to the

information about the medicine withdrawn from circulation provided for in paragraph 3 of Appendix 10 to these Guidelines.

The subject of medicine circulation withdrawing a medicine from circulation by re-export, within five business days from the date of documentation of the relevant customs procedure submits the information to FSIS MPPC provided for by paragraph 6 of Appendix 7 to these Guidelines.

8.5.4. When necessary, the subject of medicine circulation can repeatedly put into circulation a medicine previously withdrawn from circulation as a result of re-export, sampling or retirement.

A medicine can be repeatedly put into circulation only by the subject of medicine circulation that previously withdrew these medicines from circulation or previously released them outside the Russian Federation in the event of re-export.

The subject of medicine circulation putting a medicine into circulation again, within five business days from the date of the relevant operation submits the information to FSIS MPPC provided for by paragraph 15 of Appendix 7 to these Guidelines.

8.5.5. In the event of damage or opening the recycled (retail) package (in its absence, the primary package), the subject of medicine circulation must register the relevant operation about the withdrawal of the pharmaceutical product from circulation. Identification tools withdrawn in this manner cannot be reused.

8.6. The procedure for the interaction of Experiment participants, including the list and procedure for entering information in FSIS MPPC, in the process of remarking of medicines.

Medicine remarking operations are performed by the Russian manufacturer carrying out the "filling/packaging of medicines in the recycled (and in its absence, the primary package) and/or tertiary package", and/or the representative office of the foreign holder of the registration certificate for medicines produced outside the Russian Federation, in FSIS MPPC by submitting the information described in paragraph 14 of Appendix 7 of these Guidelines

9. The procedure for the interaction of Experiment participants upon the correction of information

9.1. Subjects of medicine circulation, in the event of the detection of errors in information (inaccurate information) provided by them to FSIS MPPC when putting medicines into circulation, the circulation of medicines and withdrawal of medicines from circulation, can submit the necessary corrections to FSIS MPPC.

The following adjustments and changes can be made to FSIS MPPC:

- cancellation by the subject of medicine circulation of its previously registered operation (operations cannot be cancelled if other actions were undertaken subsequently with the transfer of ownership of the medicine)

- recall by the subject of medicine circulation or the sender of medicines transferred to the recipient (this operation is used in the event when the sent identification tools are waiting for acceptance by the second party). In this scheme, there is no mandatory attribute that defines the relationship with the specific operation previously sent to FSIS MPPC. This means that the participant can specify any set of identification tools from various source documents

- refusal by the subject of medicine circulation or the receiver to accept the medicines (this operation is used in the event when the sent identification tools are waiting for acceptance by the second party).

Subjects of medicine circulation discovering an error (inaccurate information) in submitted information can make corrections until they learn about an inaccurate reflection of information (errors) in FSIS MPPC, or about the scheduling of an audit of their operations, from the controlling authorities.

If other subjects of medicine circulation participated in the procedure of the provision of information, in which errors (inaccurate information) were found, the corrections are considered accepted after all participants confirm the validity of the corrections submitted to FSIS MPPC.

10. The procedure for the interaction of Experiment participants upon the blocking of information transfer

10.1. Roszdravnadzor blocks the adoption by FSIS MPPC of information about putting into circulation and the circulation and/or withdrawal of medicines from circulation using FSIS MPPC, including automatically, in the cases specified in Appendix 11 to these Guidelines, as well as removes such block using FSIS MPPC, including automatically, when the subject of medicine circulation resolves the issues giving rise to the block.

Blocking the receipt of information in FSIS MPPC about putting into circulation and the circulation and/or withdrawal of medicines from circulation, as well as the removal of this block, can be introduced with respect to a unit or batch of medicines, or with respect to a production batch.

In some cases, when the acceptance of information in FSIS MPPC about putting into circulation and the circulation and/or withdrawal of a medicine from circulation is blocked, information about the return of the medicine to the supplier and/or transfer of the medicine for destruction and/or other withdrawal of the medicine from circulation can be submitted.

Appendix 1
to the Guidelines
on the procedure for the implementation of the Experiment

CHARACTERISTICS OF IDENTIFICATION TOOLS, AND STRUCTURE AND FORMAT REQUIREMENTS

1. Characteristics of identification tools.

The information contained in identification tools is applied as a two-dimensional barcode, at the discretion of the manufacturer is duplicated in the form of readable printed text, and the global identification number of the trade unit and the individual serial number of the recycled (retail) package must be duplicated.

It is permitted to apply the identification tool as a two-dimensional barcode in any empty space of the recycled package (in its absence, the primary package).

The recognition and error correction function must be equivalent to or higher than Data Matrix ECC200 ("DataMatrix"). The two-dimensional barcode is applied in accordance with the requirements of GOST R ISO/IEC 16022-2008 with dot symbols with dimensions within 0.255 mm - 0.615 mm.

Requirements for the quality of the application of identification tools to the recycled (retail) package of pharmaceutical products:

- application with quality level C or higher according to ISO 15415 (GOST R ISO/IEC 15415-2012)
- application by printing, using the ECC-200 error correction method
- using ASCII encoding based on ISO 16022 (GOST R ISO/IEC 16022-2008)

2. Rules of formation and requirements for the structure and format of information contained in the identification tools:

a) the first group of data is the global identification number of the trade unit consisting of 14 digital symbols preceded by an application ID (01)

b) the second group of data is the individual serial number of the recycled (retail) package, consisting of 13 characters in a numeric or alphanumeric sequence (Latin alphabet) preceded by an application ID (21). The final character for this data group is a special delimiting character with code 29 in the ASCII character table

c) the third group of data is the TN VED code, preceded by an application ID (240). There are 4 digital symbols in the TN VED code (the first 4 characters of the 10-digit TN VED code are indicated). In the event the TN VED code is not placed at the end of the encoded sequence as part of the two-dimensional code, you must use a terminating delimiting character with code 29 in the ASCII character table.

Additionally, at the discretion of the issuer of identification tools, the following two groups of data may be included in the two-dimensional barcode:

d) the fourth group of data is the number of the production batch of the medicine, consisting of not more than 20 characters in a numeric or alphanumeric sequence (Latin alphabet), preceded by an application ID (10). The final character for this data group is a delimiting character with code 29 in the ASCII character table

e) the fifth data group is the expiration date, preceded by an application ID (17) and formed by the issuer using identification tools. The format for recording the numeric characters of the expiration date of a medicine is YYMMDD (6 characters).

When the value of the expiration date in days "DC" is not established on the production line at the time of production, the issuer of identification tools may indicate the value of the date at its discretion.

There are no requirements for the sequence of groups of data in the structure of identification tools, with the exception of the first group of data.

If the fields "series" or "individual serial number of the recycled (retail) package" are in the last place, the delimiting symbol is not required.

The individual serial number of the recycled (retail) package is generated with due regard to the

following requirements:

- the uniqueness of the individual serial number of the recycled (retail) package of the medicine for each product code (GTIN) must be ensured during all operations with FSIS MPPC

- all necessary data for the coding of the identification tools of the recycled (retail) package are generated (formed) by the issuer of identification tools in the process of carrying out production operations and applied to the recycled (retail) package by the issuer of identification tools independently, taking into account the requirements for ensuring the uniqueness of the combination of values contained in the first group (global identification number of the trading unit (GTIN)) and the second group (individual serial number of the recycled (retail) package of the medicine).

Any other additional methods and means of protection of medicine packages from falsification and counterfeit are not mandatory within the framework of the Experiment and remain at the discretion of the issuer of identification tools.

3. Composition and format of information included in the group code.

The group code is formed in accordance with GOST ISO/IEC 15417-2013 and contains the following data structure:

a) Application ID (00)

b) Extension symbol

c) the registration No. of the issuer of the group code acquired from the information resource for the accounting and storage of reliable medicine-related data in compliance with the correspondent classification

d) individual serial number of the tertiary (factory, shipping) package, created by a group code issuer according to a random assignment sequence

e) check sum

Data included in the group code may be duplicated as readable printed text.

All the necessary data for the coding of identification tools of the tertiary (factory, shipping) packaging are generated and applied to the tertiary (factory, shipping) package of medicine by the issuers of identification tools via printing or labelling.

Appendix 2
to the Guidelines
on the procedure for the implementation of the Experiment

LIST OF INFORMATION SUBMITTED BY THE SUBJECTS OF MEDICINE CIRCULATION TO THE INFORMATION RESOURCE FOR THE ACCOUNTING AND STORAGE OF RELIABLE MEDICINE-RELATED DATA IN COMPLIANCE WITH THE CORRESPONDENT

CLASSIFICATION

When describing the medicine in the information resource for the accounting and storage of reliable medicine-related data in compliance with the correspondent classification, the subjects of medicine circulation submit the following information:

- a) trade name of the medicine
- b) brand (trademark)
- c) number of medicine registration certificate
- d) date of state registration of the medicine
- e) name of the holder of the medicine registration certificate
- f) address of the holder of the medicine registration certificate
- g) 4-digit TNVED code

Consultant Plus: note.

Paragraphs are numbered in accordance with the official text of the document.

- h) International non-proprietary name (INN)
- i) formulated product
- j) number of units of measurement of medicine dosage
- k) type of recycled (retail) package
- l) material of recycled (retail) package
- m) quantity (measure) of medicine in the recycled (retail) package
- n) inclusion inside the recycled (retail) package of the non-marked (primary) package
- o) description of the inserted non-marked (primary) package
- p) name of the packer (filler); completed if packing (filling) is carried out in the Russian Federation
- q) address of the packer (filler) in the recycled (retail) package; completed if packing (filling) is carried out in the Russian Federation

The description of the medicine in the information resource for the accounting and storage of reliable medicine-related data in compliance with the correspondent classification is carried out by the subjects of medicine circulation, which are residents of the Russian Federation.

Appendix 3
to the Guidelines
on the procedure for the implementation of the Experiment

LIST OF THE MEDICINE MOVEMENT MONITORING FUNCTIONS IN FSIS MPPC

N o.	Description	Russia n Ministr y of Health	Roszd ravna dzor	MIT RF	FCS RF	FTS RF
1	Monitoring of the amount of medicines put into civil circulation	+	+	+	-	+
2	Monitoring if maximum sale prices for medicines included in the list of vital and essential medicines are exceeded	+	+	-	-	+
3	Monitoring of the quantity and cost of the medicines imported in the Russian Federation	+	+		+	+
4	Monitoring the location of the medicine in accordance with the sample inspection tasks	-	+	-	-	+
5	Monitoring the movement of medicines acquired at the expense of state budgets of all levels	+	+	-	-	-
6	Monitoring violations identified during the attempt by subjects of circulation of the repeated withdrawal of medicines from circulation	+	+	-	-	+
7	Monitoring of violations identified during the attempt of subjects of circulation to register operations of the sale and release of medicines with an expired shelf life	+	+	-	-	+
8	Monitoring of violations identified in the timeliness of entering information by the subjects of medicine circulation	-	+	-	-	+
9	Monitoring of information about the quantity of medicines transferred for destruction	+	+	-	-	+
10	Monitoring of the number of inquiries and reports about violations identified when checking the legitimacy of medicines by external users	-	+	-	-	+

DESCRIPTION OF THE VALUES OF THE KEY CLASSIFIERS IN FSIS MPPC

1. The classifier of the types of medicine packages ensures storage of the following values:

- primary package
- recycled (retail) package
- tertiary (factory, shipping) package

2. The classifier of the types of operations of breaking up (transformation) of medicine package ensures the storage of the following values:

- withdrawal of samples from the tertiary (factory, shipping) package
- the breaking up of tertiary package (factory, shipping) of a lower level from the tertiary (factory, shipping) package of a higher level
- full breaking up from the tertiary (factory, shipping) package to the recycled (retail) package
- insertion of additional packages of medicines to the tertiary (shipping) package

3. The classifier of the types of acceptance of the medicines to the warehouse ensures the storage of the following values:

- receipt of the medicine from the supplier
- return of the medicine from the buyer
- posting of excess medicines

4. The classifier of the types of production orders for medicines ensures storage of the following values:

- own production of medicines
- contracted production of medicines

5. The classifier of the types of putting medicines into circulation ensures storage of the following values:

- medicines produced in the Russian Federation
- medicines produced abroad

6. The classifier of the types of withdrawal of medicines from circulation ensures storage of the following values:

- sampling to verify quality compliance
- selection and transfer for the storage of control and archive samples
- sampling by customs authorities
- sampling for declaration of compliance
- sampling in the framework of mandatory certification
- sampling in the framework of sample inspection
- sampling in the framework of federal health surveillance
- sampling for clinical studies <1>

<1> To assess the quality of reproducible pharmaceutical products in relation to the original.

- sampling for pharmaceutical expertise
- sampling for quality expertise in the implementation of registration processes <2>

<2> In the event it is necessary to make changes to the registration file and regulatory documents for the pharmaceutical product.

- transfer of display samples
- sale of medicines in retail trade
- sale of medicines by reduced-price prescription
- use of medicines in the framework of the production of formulated products
- use of medicines in the delivery of healthcare services
- re-export
- transfer of medicines for destruction
- shortage (damage, loss) of medicines
- embezzlement, theft of medicines
- retirement of medicines without transfer for destruction
- withdrawal from circulation of identification tools accumulated within the framework of the Experiment
- miscellaneous

**RULES
OF THE CREATION, DEVELOPMENT AND OPERATION OF FSIS MPPC
AND INTERACTION WITH OTHER STATE
INFORMATION SYSTEMS**

1. Rules of the creation, development and operation of FSIS MPPC.

1.1. The creation, development and operation of FSIS MPPC is based on the following principles:

- a) ensuring the completeness, reliability and security of information received and transmitted using FSIS MPPC, and the timeliness of its provision
- b) gratuitousness of the provision of information in FSIS MPPC
- c) unified organisational and methodological support of FSIS MPPC
- d) ensuring regulated access to FSIS MPPC
- e) uninterrupted operation of FSIS MPPC

1.2. FSIS MPPC ensures:

- a) identification of medicines on the basis of the serial global identification number of the trade unit
- b) complete traceability of the movement of medicine from the manufacturer to the final consumer through the entry of the relevant information transmitted by FSIS MPPC users due to changes in the state and (or) location of the medicine throughout the life cycle of the medicine
- c) blocking the adoption of information by FSIS MPPC about putting into circulation, the circulation and/or withdrawal of medicines from circulation on behalf of authorized federal executive authorities in the cases specified in these Guidelines.

1.3. FSIS MPPC contains the following information:

- a) information about the participants of medicine circulation
- b) information about pharmaceutical products and their circulation
- c) information about the status of medicines

1.4. The main sources of information contained in FSIS MPPC are:

- a) information transmitted by the subjects of medicine circulation

b) information transmitted by federal executive authorities in the exercise of their functions using state information systems specified in section II of this Appendix.

1.5. The availability ratio of FSIS MPPC is of at least 99.5%, excluding scheduled maintenance periods.

Maintenance of FSIS MPPC shall be carried out not more than 4 times a year; the maintenance period shall not be more than 24 hours.

1.6. In the framework of development of FSIS MPPC, the FSIS MPPC Operator can make changes to the formats of information interaction with FSIS MPPC.

Subjects of medicine circulation are notified about changes to the formats of information interaction with FSIS MPPC by publishing the latest version of the formats of information interaction on the Operator's official website on the Internet at least seven business days before the release of the new version of FSIS MPPC.

2. Rules for the interaction of FSIS MPPC with other state information systems

2.1. During its operation, FSIS MPPC is involved in information interaction with the following state information systems of the federal executive authorities, in terms of obtaining information:

a) unified register of licenses for the production of medicines of the Ministry of Industry and Trade of Russia

b) unified register of licenses, including licenses issued by the executive authorities of constituent territories of the Russian Federation in accordance with delegated authority for the licensing of specific healthcare activities, by Roszdravnadzor

c) state register of medicines of the Ministry of Health of Russia

d) state register of the maximum sale prices of medicine producers included in the list of vital and essential medicines, by the Ministry of Health of Russia

e) unified state register of legal entities/unified state register of individual entrepreneurs of FTS RF

f) state register of accredited branches, representative offices of foreign legal entities of FTS RF

g) the "Monitoring the quality of medicines" subsystem of the Automated Information System of Roszdravnadzor

h) unified automated information system of the customs authorities of FCS RF.

2.2. The unified register of licenses for the production of medicines of the Ministry of Industry and Trade of Russia transfers the following information about licenses for the production of medicines of the manufacturer of medicines, which is a resident of the Russian Federation:

a) INN of the medicine manufacturer

b) OGRN of the medicine manufacturer

c) name of the medicine manufacturer

- d) license number
- e) date of issue of the license
- f) status of the license
- g) date of modification of the status of the license
- h) trading address according to the license (global unique ID of the address facility in the Federal Information Address System ("FIAS") and description)
- i) list of works and services according to the license
- j) list of formulated products according to the license
- k) additional description of works/services

2.3. Information about the licenses of the subjects of medicine circulation, who are residents of the Russian Federation, is transferred from the Unified Register of Licenses to the FSIS MPPC of Roszdravnadzor, including licenses issued by state authorities of the constituent entities of the Russian Federation in accordance with the delegated authority for licensing certain types of activities in the area of healthcare; in particular, the following information is collected:

- a) INN/KPP of the subject of medicine circulation
- b) license number
- c) date of commencement of the license
- d) trading address according to the license (global unique ID of the address facility in FIAS and description)
- e) status of the license (ID and description)
- f) date of modification of the status of the license
- g) list of works and services according to the license (IDs and description)

2.4. The Russian Ministry of Health transfers the following information about medicines to FSIS MPPC from the State Register of Medicines and the State Register of the Maximum Sale Prices for Manufacturers included in the List of Vital and Essential Medicines:

- a) number of the medicine registration certificate
- b) date of state registration of the medicine
- c) status of medicine registration certificate
- d) international non-proprietary name, or grouping, or chemical name
- e) name of the holder of the medicine registration certificate
- f) country of registration of the holder of medicine registration certificate

- g) the taxpayer code of the holder of medicine registration certificate in the country of registration
- h) the presence of the medicine in the List of Vital and Essential Pharmaceutical Products for Medical Use
- i) trade name of the medicine
- j) primary package of the medicine
- k) quantity of formulated product in the primary package
- l) recycled (retail) package of the medicine
- m) quantity of the primary package in the recycled (retail) package
- n) formulated product
- o) number of units of measurement of medicine dosage
- p) name of the subject of medicine circulation carrying out the filling (packaging) of the medicine in the recycled (retail) package
- q) taxpayer code of the subject of medicine circulation carrying out the filling (packaging) of the medicine in the recycled (retail) package in the country of registration
- r) country of registration of the subject of medicine circulation carrying out the filling (packaging) of the medicine in the recycled (retail) package
- s) trading address of the subject of medicine circulation carrying out the filling (packaging) of the medicine in the recycled (retail) package under the license (global unique ID of the address in FIAS and description)
- t) name of the subject of medicine circulation carrying out outgoing control
- u) taxpayer code of the subject of medicine circulation carrying out outgoing control in the country of registration
- v) country of registration of the subject of medicine circulation carrying out outgoing control
- w) trading address of the subject of medicine circulation carrying out outgoing control under the license (global unique ID of the address in FIAS and description)
- x) date of registration of the maximum price of the pharmaceutical product
- y) maximum registered price, in RUB

2.5. The FTS RF transfers the following information about the state registration of the subjects of medicine circulation, which are residents of the Russian Federation, to FSIS MPPC from the Unified State Register of Legal Entities/Unified State Register of Individual Entrepreneurs:

- a) INN/KPP of the subject of medicine circulation (KPP is provided only for legal entities)
- b) tax authority code

Consultant Plus: note.

Subparagraphs are numbered in accordance with the official text of the document.

d) status code of the legal entity or individual entrepreneur

c) name of the participant of circulation

d) status of the record on the registration of the legal entity or individual entrepreneur

e) information about the head of the subject of medicine circulation or information about the individual entrepreneur

2.6. The FTS RF transmits the following information about the registration of representative offices of foreign organisations, which are subjects of medicine circulation in the Russian Federation, to FSIS MPPC from the State Register of Accredited Branches and Representative Offices of Foreign Legal Entities:

a) INN/KPP of the representative office

b) code of the tax authority of the representative office

c) name of the representative office

d) number of accreditation record

e) information about the foreign entity

f) status code of accreditation

g) information about the head of the representative office

2.7. The Automated Information System of Roszdravnadzor transmits the following information about the temporary withdrawal/cancellation of the temporary withdrawal of medicines from circulation on the initiative of the authorised federal executive authority to FSIS MPPC from the "Monitoring of the quality of medicines" subsystem:

a) date from which it is necessary to ensure the temporary withdrawal/cancellation of the temporary withdrawal from circulation

b) number of medicine registration certificate

c) date of state registration of the medicine

d) basis of temporary withdrawal from circulation/cancellation of temporary withdrawal from circulation

e) details of the document about the temporary withdrawal/cancellation of the temporary withdrawal from circulation

f) global ID of the trade unit

g) number of production batch

h) INN/KPP of the subject of medicine circulation (if the withdrawal concerns only one of the subjects of medicine circulation and not the entire series/batch);

2.8. The FCS RF transfers the following information about the medicines imported in the Russian Federation and placed under certain customs procedures containing the declaration for the medicines to FSIS MPPC from the unified automated information system of the customs authorities:

a) code of the customs authority

b) registration date of the declaration of the medicine

c) registration No. of the declaration of the medicine

d) code of the medicine in accordance with the classification of foreign economic activity of the Eurasian Economic Union

e) serial global ID of the trade unit or the group code of the package, in which the medicine is released into circulation (in the event of a release of the entire group package)

f) customs value, statistic value and invoiced cost of the medicine

g) code of the country of origin of the medicine

h) tax identification number of the subject of medicine circulation importing and declaring the medicine

i) code of the declared customs procedure in accordance with the classification of types of customs procedures

2.9. FSIS MPPC transmits the following information about the medicines imported in the Russian Federation to the Unified Automated Information System of the customs authorities of FCS RF on request:

a) tax identification number of the subject of medicine circulation importing and declaring the medicine

b) code of the medicine in accordance with the classification of the foreign economic activity of the Eurasian Economic Union

c) global ID of the trade unit

d) group code of the package of the medicine, which contains the medicine released into circulation (in the event of the release of the entire group package)

e) status of the medicine in FSIS MPPC

f) list of serial global IDs of the trade item contained in the group package

2.10. The detailed list of information provided by the state information systems of the federal executive authorities to FSIS MPPC is determined by the agreed technological maps of interdepartmental interaction.

2.11. Within the framework of information interaction, the FSIS MPPC provides information to the state information systems of stakeholding federal executive authorities in accordance with the agreed technological maps of interdepartmental interaction.

Appendix 6
to the Guidelines
on the procedure for the implementation of the Experiment

Application form
for the voluntary participation in the Experiment
of foreign holders of registration certificates
without representative offices in
the Russian Federation

General information about the foreign holder of RC			
Name of the foreign legal entity			
Information about the registration of the foreign legal entity in the country of registration (name of the registering authority, registration No., taxpayer code or its equivalent)			
Name and digital code of the country of registration in accordance with the General Classifier of Countries of the World		Address of the foreign legal entity in the country of registration	
Last name and first name of the responsible person for participation in the Experiment, position, contact information, email			
Information about the medicines proposed for participation in the marking Experiment			
Number of the registration certificate	INN	Trade name	Trade name Packaging, filling, dosage, release form
Information about the production sites where finished products participating in the Experiment are manufactured			

Trading address	Information about the manufacturer: name, tax registration code	Information about the production line (type and brand of equipment, marking method)	
Information on the import in the Russian Federation of medicines participating in the Experiment			
Name of the seller	Name of the importer	Number of the registration certificate	Packaging, filling, dosage, release form

Date of application for the state registration of the pharmaceutical product for medical use

_____ __, 201_

Application for the state registration of the pharmaceutical product for medical use submitted by:

Company seal
(title)

(full name)

(signature)

Appendix 7
to the Guidelines
on the procedure for the implementation of the Experiment

**LIST
OF INFORMATION SUBMITTED BY THE SUBJECTS OF MEDICINE CIRCULATION TO
FSIS MPPC
UPON PUTTING MEDICINES INTO CIRCULATION**

Information transmitted by the subjects of medicine circulation to FSIS MPPC about medicines produced in the Russian Federation:

1. Upon the completion of the stage of filling (packaging) medicines in the recycled (retail) package, subjects of medicine circulation submit the following information for each unit of medicine:

a) transaction date

b) tax identification number of the subject of medicine circulation carrying out the filling (packaging) of the medicine in the recycled (retail) package

c) trading address of where the stage of filling (packaging) of the medicine in the recycled (retail) package is completed

d) type of production order (contracted or own production)

e) tax identification number of the subject of medicine circulation, which is the customer of contract production (in the event of the submission of information by the subject of medicine circulation performing the contract production)

f) global ID of the trade unit

g) number of the medicine production batch

h) expiration date of the medicine

i) code of the medicine in accordance with the classification of foreign economic activity of the Eurasian Economic Union (TN VED code)

h) serial global identification number of the trade unit assigned to the recycled (retail) package of the medicine

2. At the end of the outgoing control stage, subjects of medicine circulation submit the following information about the release of finished products for each unit of medicine manufactured in the Russian Federation:

a) transaction date

b) tax identification number of the subject of medicine circulation registering information about the release of finished products

c) the trading address of the subject of medicine circulation registering information about the release of finished products

d) the type of document confirming compliance according to the confirmation form of compliance of products with the requirements of technical regulations (certificate, declaration)

e) details of the document confirming compliance (date and number)

Consultant Plus: note.

Subparagraphs are numbered in accordance with the official text of the document.

f) serial global ID of the trade unit or the group code of the package, in which a medicine is released into circulation (in the event of the release of the entire group package).

Information transmitted by the subjects of medicine circulation to FSIS MPPC about medicines produced outside the Russian Federation:

3. At the end of the outgoing control stage, subjects of medicine circulation submit the following information in relation to each unit of medicine manufactured outside the Russian Federation:

a) transaction date

b) taxpayer registration number of the holder of the registration certificate for the medicine in the country of registration or the tax identification number (for subjects of medicine circulation, which are

residents of the Russian Federation or with a representative office, which is a subject of medicine circulation in the Russian Federation);

c) code of the country of registration of the holder of the medicine registration certificate (for subjects of medicine circulation, which are not residents of the Russian Federation)

d) taxpayer registration number of the subject of medicine circulation carrying out the filling (packaging) of the medicine in the recycled (retail) package in the country of registration

e) code of the country of registration of the subject of medicine circulation carrying out the filling (packaging) of the medicine in the recycled (retail) package

f) name of the subject of medicine circulation carrying out the filling (packaging) of the medicine in the recycled (retail) package

g) taxpayer registration number of the subject of medicine circulation carrying out outgoing control in the country of registration

h) code of the country of registration of the subject of medicine circulation carrying out outgoing control

i) name of the subject of circulation carrying out outgoing control

j) global ID of the trade unit

k) number of the production batch of the medicine

l) expiration date of the medicine

m) code of the medicine in accordance with the classification of foreign economic activity of the Eurasian Economic Union (TN VED code)

n) serial global identification number of the trade unit assigned to the recycled (retail) package of the medicine

Information transmitted by the subjects of medicine circulation to FSIS MPPC about medicines imported into the Russian Federation:

4. Subjects of medicine circulation provide the following information in respect of each unit of medicine upon the completion of the shipment of medicines to the Russian Federation:

a) transaction date

b) taxpayer registration number of the holder of the registration certificate for the medicine in the country of registration or the tax identification number (for subjects of medicine circulation, which are residents of the Russian Federation or with a representative office, which is a subject of medicine circulation in the Russian Federation);

c) code of the country of registration of the holder of the medicine registration certificate (for subjects of medicine circulation, which are not residents of the Russian Federation)

d) registration number of the seller of the medicine (taxpayer) in the country of registration

e) code of the country of registration of the seller of the medicine

f) tax identification number of the subject of medicine circulation purchasing the medicine in the Russian Federation

g) details of the primary document, which is the basis for the shipment of the medicine to the Russian Federation

h) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the shipment of the entire group package).

5. Subjects of medicine circulation provide the following information in relation to each unit of medicine during the import and placing of medicines in temporary storage or a customs control area:

a) transaction date

b) taxpayer registration number in the country of registration or tax identification number (for subjects of medicine circulation, which are a resident of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine circulation importing the medicine into the Russian Federation

c) code of the country of registration of the subject of medicine circulation importing the medicine into the Russian Federation (for subjects of medicine circulation, which are not residents of the Russian Federation)

d) code of the customs authority and registration No. of the warehouse (address of the location of the goods according to the declaration)

e) registration number of the seller of the medicine (taxpayer) in the country of registration

Consultant Plus: note.

Subparagraphs are numbered in accordance with the official text of the document.

f) code of the country of registration of the medicine seller

g) contract type

h) details of the source document, which is the basis for the import of the medicine into the Russian Federation (date and number)

i) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the import of the entire group package)

6. Subjects of medicine circulation provide the following information in respect of each unit of the medicine when placing medicines under the relevant customs procedure (changing the customs procedure):

a) transaction date

b) tax identification number of the subject of medicine circulation, which declares the medicine in the Russian Federation

c) type of document confirming compliance according to the confirmation form of compliance of products with the requirements of technical regulations (certificate, declaration)

d) details of the document confirming compliance (date and number)

e) code of the customs procedure

f) code of the customs authority

g) details of the customs declaration for the medicines

h) the customs value of the medicines according to the declaration for medicines

i) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the placement under the customs procedure of the entire group package)

7. Subjects of medicine circulation provide the following information in relation to each trade unit when moving medicines between customs control zones:

a) transaction date

b) taxpayer registration number in the country of registration or tax identification number (for subjects of medicine circulation, which are a resident of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine circulation moving the medicine

c) code of the country of registration of the subject of medicine circulation carrying out the movement of medicines (for subjects of medicine circulation, which are not residents of the Russian Federation)

Consultant Plus: note.

Subparagraphs are numbered in accordance with the official text of the document.

c) code of the customs authority and registration No. of the shipping warehouse (the address of the location of the goods according to the declaration, from which the goods are moved)

d) code of the customs authority and registration No. of the destination warehouse (the address of the location of the goods, to which the goods are moved)

e) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the movement of the entire group package)

8. Subjects of medicine circulation provide the following information in relation to each unit of medicine when moving medicines from the customs control zone to the pharmaceutical warehouse:

a) transaction date

b) tax identification number of the subject of medicine circulation, which imports the medicine into the Russian Federation

c) trading address of the subject of medicine circulation importing the medicine to the Russian

Federation

d) code of the customs authority and registration No. of the shipping warehouse (address of the location of the goods, from which the goods are shipped)

e) details of the source document, which is the basis for the acceptance of the medicine at the warehouse (date and number);

e) the value on the shipping documentation for the goods, on the basis of which the customs declaration is issued, taking into account customs duties and fees for customs clearance

f) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the acceptance at the warehouse of the entire group package)

9. Subjects of medicine circulation provide the following information in relation to each unit of medicine when transferring the medicines placed under the customs procedure of a customs warehouse to another owner (change of ownership):

a) transaction date

b) taxpayer registration number in the country of registration or tax identification number (for subjects of medicine circulation, which are residents of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine circulation transferring the medicine

c) code of the country of registration of the subject of medicine circulation transferring the medicines (for subjects of medicine circulation, which are not residents of the Russian Federation)

d) tax identification number of the subject of medicine circulation transferring the medicine

e) tax identification number of the subject of medicine circulation accepting the medicine

f) details of the source document, which are the basis for the transfer of the medicine (date and number)

Consultant Plus: note.

Subparagraphs are numbered in accordance with the official text of the document.

h) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the transfer of the entire group package)

10. Subjects of medicine circulation accepting the medicines placed under the customs procedure of a customs warehouse provide the following information in relation to each unit of the medicine when confirming the information contained in FSIS MPPC about the transferred medicines:

a) transaction date

b) tax identification number of the subject of medicine circulation accepting the medicine

c) tax identification number of the subject of medicine circulation accepting the medicine

d) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the transfer of the entire group package)

11. Subjects of medicine circulation provide the following information in respect of each unit of medicine upon the shipment of medicines to the Russian Federation from EEU Member States:

a) transaction date

b) taxpayer registration number of the holder of the registration certificate for the medicine in the country of registration or the tax identification number (for subjects of medicine circulation, which are residents of the Russian Federation or with a representative office, which is a subject of medicine circulation in the Russian Federation);

c) code of the country of registration of the holder of the medicine registration certificate (for subjects of medicine circulation, which are not residents of the Russian Federation)

d) registration number of the seller of the medicine (taxpayer) in the country of registration

e) code of the country of registration of the seller of the medicine

f) tax identification number of the subject of medicine circulation purchasing the medicine in the Russian Federation

g) trading address of the subject of medicine circulation purchasing the medicine in the Russian Federation

Consultant Plus: note.

Subparagraphs are numbered in accordance with the official text of the document.

h) details of the primary document, which is the basis for the shipment of the medicine to the Russian Federation (date and number)

h) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the shipment of the entire group package).

12. Subjects of medicine circulation provide the following information in respect of each unit of medicine upon the import of medicines into the Russian Federation from EEU Member States and placement at the warehouse:

a) transaction date

b) tax identification number of the subject of medicine circulation, which imports the medicine into the Russian Federation

c) trading address of the subject of medicine circulation importing the medicine to the Russian Federation

d) registration number of the seller of the medicine (taxpayer) in the country of registration

e) code of the country of registration of the seller of the medicine

f) details of the source document, which is the basis for the import of medicine into the Russian Federation (date and number)

g) the cost of the medicine (including value added tax) according to source documents

h) the amount of value added tax (if such tax is imposed on the transaction)

i) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the import of the entire group package)

13. Subjects of medicine circulation provide the following information in respect of each unit of medicine upon putting medicines into circulation in the framework of import to the Russian Federation from EEU Member States:

a) transaction date

b) tax identification number of the subject of medicine circulation, which imports the medicine into the Russian Federation

c) trading address of the subject of medicine circulation importing the medicine to the Russian Federation

d) the type of document confirming compliance according to the confirmation form of compliance of products with the requirements of technical regulations (certificate, declaration)

e) details of the document confirming compliance (date and number)

f) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the import of the entire group package).

14. The operations of remarking medicines are documented in FSIS MPPC by the Russian manufacturer carrying out the stage of “filling/packaging of the medicine in the recycled and/or tertiary packaging”, and/or the representative office of the foreign holder of medicine RC, and/or the holder of medicine RC manufactured outside the Russian Federation, by submitting the following information:

a) transaction date

b) taxpayer registration number of the holder of the registration certificate for the medicine in the country of registration or the tax identification number (for subjects of medicine circulation, which are residents of the Russian Federation or with a representative office, which is a subject of medicine circulation in the Russian Federation);

c) code of the country of registration of the holder of the medicine registration certificate (for subjects of medicine circulation, which are not residents of the Russian Federation)

d) serial global identification number of the trade unit of the new recycled (retail) package of the medicine

e) serial global identification number of the trade unit of the old recycled (retail) package of the medicine

15. Subjects of medicine circulation provide the following information to FSIS MPPC when

repeatedly putting into circulation medicines previously withdrawn from circulation as a result of re-export, sampling and retirement:

a) transaction date

b) taxpayer registration number in the country of registration or tax identification number (for subjects of medicine circulation, which are residents of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine, which previously withdrew the medicine from circulation

c) trading address of the subject of medicine circulation (for residents of the Russian Federation)

d) code of the country of registration (for subjects of medicine circulation, which are not residents of the Russian Federation)

e) reasons for the withdrawal of the medicine from circulation

f) serial global identification number of the trade unit repeatedly put into circulation

Appendix 8
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**LIST
OF INFORMATION SUBMITTED BY THE SUBJECTS OF MEDICINE CIRCULATION TO
FSIS MPPC
WHEN PERFORMING OPERATIONS WITH A GROUP PACKAGE**

1. Subjects of medicine circulation provide the following information in the course of aggregation:

a) transaction date (for medicines located outside the Russian Federation, in the event when aggregation takes place before the completion of the outgoing control stage, any date can be indicated between the end date of the outgoing control stage and the date of shipment of the medicines to the Russian Federation)

b) taxpayer registration number in the country of registration or tax identification number (for the subjects of medicine circulation, which are residents of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine circulation carrying out aggregation

c) trading address (in the event of Russian production) or the name of the country (in the event of foreign production), where aggregation took place, or the customs control zone (in the event of aggregation in the customs control zone)

d) group codes of created group packages

e) list of serial global identification numbers of the trade unit or group codes of lower level nesting packages included in each created group package

2. Subjects of medicine circulation provide the following information in the course of withdrawing medicines from the group package:

a) transaction date

b) taxpayer registration number in the country of registration or tax identification number (for subjects of medicine circulation, which are residents of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine circulation performing the operation

c) trading address (in the event of the performance of the operation in the Russian Federation) or the name of the country (in the event of the performance of the operation outside the Russian Federation), where the operation took place, or the customs control zone (in the event of the performance of the operation in the customs control zone)

d) serial global identification number of the trade unit or group package code of the lower nesting level, for which the withdrawal operation is performed.

3. Subjects of medicine circulation provide the following information in the event of the additional insertion of medicines in the group package:

a) transaction date

b) taxpayer registration number in the country of registration or tax identification number (for subjects of medicine circulation, which are residents of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine circulation performing the operation

c) trading address (in the event of the performance of the operation in the Russian Federation) or the name of the country (in the event of the performance of the operation outside the Russian Federation), where the operation took place, or the customs control zone (in the event of the performance of the operation in the customs control zone)

d) serial global identification number of the trade unit or group package code of the lower nesting level, for which the additional insertion operation is performed

e) group package code, in relation to which the operation is performed

4. Subjects of medicine circulation provide the following information in the event of breaking up the group package:

a) transaction date

b) taxpayer registration number in the country of registration or tax identification number (for subjects of medicine circulation, which are residents of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine circulation performing the operation

c) trading address (in the event of the performance of the operation in the Russian Federation) or the name of the country (in the event of the performance of the operation outside the Russian Federation), where the operation took place, or the customs control zone (in the event of the performance of the operation in the customs control zone)

- d) type of packaging transformation operation (breaking up)
- e) group code of the broken up package

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**LIST
OF INFORMATION SUBMITTED BY THE SUBJECTS OF MEDICINE CIRCULATION TO
FSIS MPPC
IN THE CIRCULATION AND INTERNAL MOVEMENT OF THE MEDICINES**

1. The subject of medicine circulation when transferring medicines to another participant of medicine circulation in civil law relations, providing for the transfer of ownership to the medicines, or in the framework of intermediary relations (agency or commission agreement), provides the following information about shipped medicines for each unit of medicine in the event of the selection of the direct procedure for the submission of information:

- a) transaction date
- b) tax identification number of the subject of medicine circulation shipping the medicine
- c) trading address, from which the medicines are shipped
- d) tax identification number of the subject of medicine circulation transferring the medicine
- e) trading address, to which medicines are shipped (this information is not indicated in the event of shipment to an unregistered participant of medicine circulation)
- f) source of funding
- g) type of civil legal relations of the subjects of medicine circulation
- h) serial global ID of the trade unit or group code of the package, which contains the given medicine (in the event of the transfer of the entire group package)
- i) details of the source document, which is the basis for the transfer of the medicine (date and number)
- j) the price of the medicine (taking into account the value added tax) in accordance with the source documents (except in the event of the transfer of medicines in the framework of intermediary relations)
- k) the amount of value added tax (if such tax is imposed on the transfer of the medicine)

2. When accepting medicines from another subject of medicine circulation in civil law, the subject of medicine circulation, providing for the transfer of ownership to the medicines or in the framework of intermediary relations (agency or commission agreement), provides the following information about

accepted medicines for each unit of the medicine in the event of the selection of the opposite procedure for the submission of information:

- a) transaction date
- b) tax identification number of the subject of medicine circulation accepting the medicine
- c) trading address, at which medicines are accepted
- d) tax identification number of the subject of medicine circulation shipping the medicine
- e) trading address, from which the medicines are shipped
- f) source of funding
- g) type of civil legal relations of the subjects of medicine circulation

h) serial global ID of the trade unit or group code of the package, which contains the given medicine (in the event of the transfer of the entire group package)

i) details of the source document, which is the basis for the transfer of the medicine (date and number)

j) the price of the medicine (taking into account the value added tax) in accordance with the source documents (except in the event of the transfer of medicines in the framework of intermediary relations)

k) the amount of value added tax (if such tax is imposed on the transfer of the medicine)

3. The subject of medicine circulation provides the following information in relation to each unit of the medicine when confirming the accuracy of the information contained in FSIS MPPC about transferred or accepted medicines:

a) transaction date

b) taxpayer registration number in the country of registration or tax identification number (for subjects of medicines circulation, which are residents of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine circulation transferring the medicine

c) taxpayer registration number in the country of registration or tax identification number (for subjects of medicine circulation, which are residents of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine circulation accepting the medicine

d) serial global ID of the trade unit or the group code of the package containing the given medicine (in the event of the transfer of the entire group package).

4. The subject of medicine circulation provides the following information about transferred medicines in relation to each unit of the medicine when moving the medicines between its trading addresses and/or consignment warehouses:

a) transaction date (date of acceptance at the warehouse, to which the goods were moved)

- b) tax identification number of the subject of medicine circulation moving the medicine
- c) trading address or consignment warehouse, from which medicines are moved

Consultant Plus: note.

Subparagraphs are numbered in accordance with the official text of the document.

- e) trading address or the address of the consignment warehouse, to which the medicines are moved
- f) serial global ID of the trade unit or the group code of the package containing the given medicine (in the event of the movement of the entire group package)
- g) details of the source document, which is the basis for the movement of the medicine (date and number)

5. The subject of medicine circulation that carries out contract production of medicines in the Russian Federation, when transferring the medicines (finished products) to a participant of medicine circulation, which is the customer of such contracted production, provides the following information about the transferred medicines in relation to each unit of the medicine:

- a) transaction date
- b) tax identification number of the subject of medicine circulation transferring the medicine
- c) trading address, from which the medicines are transferred
- d) tax identification number of the subject of medicine circulation transferring the medicine
- e) trading address, to which the medicines are transferred
- f) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the transfer of the entire group package)
- g) details of the source document, which is the basis for the transfer of the medicine (date and number)

Appendix 10
to the Guidelines
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**LIST
OF INFORMATION SUBMITTED BY THE SUBJECTS OF MEDICINE CIRCULATION TO
FSIS MPPC
IN THE EVENT OF THE WITHDRAWAL OF MEDICINES FROM CIRCULATION**

1. In the event of the withdrawal of medicines from circulation via the sale of medicines to consumers or sale of medicines by reduced-price prescription or the release of medicines for medical use,

or otherwise not specified herein, the subject of medicine circulation provides the following information about the medicine withdrawn from circulation:

a) transaction date

b) taxpayer registration number in the country of registration or tax identification number (for subjects of medicine circulation, which are residents of the Russian Federation, or the representative office of the subject of medicine circulation in the Russian Federation) of the subject of medicine circulation withdrawing the medicine from circulation

c) trading address, from which the medicines are withdrawn from circulation

d) type of withdrawal of medicine from circulation

e) the type of document confirming the withdrawal of the medicine from circulation (check, limited-issue form, contract, reduced-price prescription, etc.)

f) details of the document confirming the withdrawal of the medicine from circulation

g) serial global identification number of the trade unit being withdrawn from circulation

h) the price of the medicine (including value added tax) (in the event of the sale of the medicine to consumers)

i) the amount of value added tax (in the event of the sale of the medicine to consumers if value added tax is charged on the sale of the medicine).

2. The subject of medicine circulation provides the following information about the medicine withdrawn from circulation in the event of the withdrawal of the medicine from circulation by sampling for various purposes:

a) transaction date or the date of registration of information in FSIS MPPC (in relation to medicines withdrawn from circulation by sampling when imported into the Russian Federation)

b) tax identification number of the subject of medicine circulation withdrawing the medicine from circulation

c) trading address, from which the medicine is withdrawn from circulation, or the customs control zone (when the operation is performed in the customs control zone)

d) type of withdrawal of medicines from circulation or type of sampling (in the event of control, archive samples and samples to confirm compliance in the framework of technical regulation)

e) details of the document confirming the withdrawal of medicines from circulation (with the exception of control, archive samples and samples to confirm compliance in the framework of technical regulation)

f) serial global identification number of the trade unit of the medicine being withdrawn from circulation

3. The subject of medicine circulation provides the following information about the medicine withdrawn from circulation in the event of the withdrawal of the medicine from circulation via the

transfer of the medicine for destruction:

- a) transaction date
- b) tax identification number of the subject of medicine circulation withdrawing the medicine from circulation
- c) trading address, from which the medicines are withdrawn from circulation
- d) the basis of the transfer for destruction
- e) details of the decision of the competent federal executive authority about the withdrawal of the medicine from circulation (if any)
- f) details of the document confirming the transfer of the medicine for destruction
- g) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the withdrawal from circulation of the entire group package)
- h) tax identification number of the taxpayer destroying the medicines
- i) trading address, to which the medicine is transferred for destruction

4. The subject of medicine circulation provides the following information about the fact of destruction of the medicine upon the destruction of the medicine previously transferred for destruction:

- a) transaction date
- b) tax identification number of the subject of medicine circulation withdrawing the medicine from circulation
- c) method of destruction of the medicine
- d) details of the document confirming the destruction of the medicine (the certificate of destruction of the medicine)
- e) serial global ID of the trade unit or the group code of the package, which contains the given medicine (in the event of the withdrawal from circulation of the entire group package)
- f) tax identification number of the taxpayer performing the destruction of the medicine

Appendix 11
to the Guidelines
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**LIST
OF REASONS FOR BLOCKING BY THE FEDERAL EXECUTIVE
AUTHORITIES OF THE POSSIBILITY OF SUBMITTING INFORMATION TO FSIS MPPC**

ABOUT PUTTING INTO CIRCULATION, CIRCULATION AND/OR WITHDRAWAL FROM CIRCULATION OF MEDICINES

1. The Federal Service for Supervision of Healthcare (Roszdravnadzor) blocks the acceptance of information by FSIS MPPC about putting into circulation, circulation and/or withdrawal from circulation of medicines in the following cases:

a) identification of non-compliance with quality requirements in the framework of selective quality control of the medicines and federal supervision in the area of circulation of medicines carried out by Roszdravnadzor and its territorial agencies

b) the expiration date of the medicine in accordance with the information registered in FSIS MPPC

c) inconsistency of information about a medicine supplied by the subject of medicine circulation when describing a medicine in the information resource for the accounting and storage of reliable medicine-related data in compliance with the correspondent classification and information obtained by FSIS MPPC from the State Register of Medicines of the Russian Ministry of Health

d) attempt to submit information to FSIS MPPC about the shipment (sale) of medicines from the consignment warehouse

e) attempt to submit information to FSIS MPPC about the shipment (sale) of the medicines before the registration of information about putting medicine into circulation

f) attempt to provide information to FSIS MPPC in violation of the requirements of these Rules

g) absence of information in FSIS MPPC about the availability of licenses of the subject of medicine circulation, which give the participant of medicine circulation the right to carry out the relevant operations

h) adoption of the decision by Roszdravnadzor in accordance with the results of consideration of the message from the subject of medicine circulation containing information about the discovery of non-compliance of medicines released into circulation with the requirements of technical regulations

i) absence of information in FSIS MPPC about the availability of the medicine with the subject of medicine circulation, which provides information about the circulation of the given medicine.

2. FTS RF blocks the acceptance of information by FSIS FSIS at the stage of personal account registration in FSIS MPPC in the following cases:

a) absence of information about the applicant in the Unified State Register of Legal Entities as a valid legal entity, or in the Unified State Register of Individual Entrepreneurs as a valid individual entrepreneur, or in the State Register of Accredited Branches and Representative Offices of Foreign Legal Entities as an operating branch or representative office of a foreign legal entity in the Russian Federation

b) existence with respect to the applicant of entry in the Unified State Register of Legal Entities about the inaccuracy of information entered in accordance with paragraph 5 and/or 6 of article 11 of the Federal Law On the State Registration of Legal Entities and Individual Entrepreneurs.

3. FCS RF 3 blocks the acceptance of information by FSIS MPPC about putting into circulation, circulation and/or withdrawal of a medicine from circulation in the event of the absence of information in

FSIS MPPC about the completion of customs procedures for the release for domestic consumption in relation to medicines imported into the Russian Federation.