

Text of the Russian Pharma Serialization and Tracing Pilot Guidelines as translated by Google Translate

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APPROVED
Minister of Health of the
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GUIDELINES

For conducting a pilot on marking with control (identification) marks and monitoring the turnover of certain types of medicinal products for medical use that are in civil circulation on the territory of the Russian Federation

I. General Provisions

1. These Methodological Recommendations were developed in accordance with item 5 of the list of instructions of the President of the Russian Federation following the meeting with the members of the Government of the Russian Federation No. Pr-285 of February 4, 2015, on the development and phased implementation of an automated system for monitoring the movement of medicinal products for medical use (hereinafter - medicinal product) from the manufacturer to the end user, using the marking and identification of medicinal product packages, in order to ensure effective quality control of medicinal products in circulation and combat their falsification, as well as Russian Government Resolution No. 62 of January 24, 2017, "Conducting Pilot on marking with control (identification) signs and monitoring the turnover of certain types of medicinal products for medical use" (hence, respectively, PP, Pilot).

2. Methodological recommendations on the procedure for conducting a pilot on marking with control (identification) signs (hereinafter referred to as barcode) and monitoring the movement of medicinal products (hereinafter referred to as the Methodological Recommendations) regulate the relations connected with the implementation in 2017 of the Pilot on Labeling of barcode and Monitoring of medicinal product Movement in Accordance with the PP.

3. In carrying out the Pilot, the goals and objectives defined in 1111 should be taken into account.

4. For the purposes of these Guidelines, the notions contained in Article 4 of Federal Law No. 61-FZ of April 12, 2010 "On the circulation of medicines" are used, as well as the following terminological definitions:

A) **Marking** is a state information system created for the purpose of informing the marking of goods of the barcode.

B) **Component of MDLP** - a functional subsystem of the IP "Marking", created for the purpose of information support for marking medicinal product barcode.

C) **Monitoring the movement of medicinal product** - conducting an analysis of the movement of medicinal product in the Component of MDLP on the basis of information registered by the subjects of circulation of medicinal product in accordance with these Methodological Recommendations.

D) **Production series of medicinal product** - the amount of medicinal product produced as a result of one technological cycle by its manufacturer.

E) **Primary packaging of a medicinal product** is a means or a set of means to protect medicinal products from damage and losses, the environment, from contaminants that have direct contact with the medicinal product.

F) **Secondary (consumer) packaging** - packaging that arrives at the customer and serves to house a single primary package or combine several primary packages.

G) **Tertiary (factory, transport) packaging** is a package combining arbitrary sets of medicines packaged in secondary (consumer) packaging or packed in tertiary (factory, transport) packaging used for storing, transporting and moving medicinal products between subjects of treatment.

H) **Control (identification) sign (barcode)** - Information carrier formed in the framework of the pilot in accordance with paragraph 9 of these guidelines for application to secondary (consumer) packaging of medicinal product or in accordance with paragraph 10 of these guidelines for application to tertiary (factory, transport) packaging of medicinal product.

I) **medicinal product Identification Number** is a unique code that allows to identify at least the manufacturer, the trade name of medicinal product, the dosage form, the dosage of the drug and the completeness of the medicinal product package. As part of the Pilot, the Global Trade Item Number (GTIN, Global Trade Item Number) is used as the medicinal product identification number.

J) **Individual serial number** is a digital or alphanumeric sequence that for the purposes of identification of secondary (consumer) medicinal product packages is made in accordance with

paragraph 9 of these guidelines, and for the purposes of identification of tertiary (factory, transport) packages in accordance with paragraph 10 of these guidelines .

L) The unique identifier of the secondary (consumer) packaging of medicinal product (hereinafter referred to as sGTIN, Serialized Global Trade Item Number) - A combination of the product code (GTIN) and the individual serial number unique for each individual secondary (consumer) package of medicinal product.

M) The unique identifier of the tertiary (factory, transport) packaging of medicinal product is a combination of symbols unique for each individual tertiary (factory, transport) package of medicinal product, compiled in accordance with the requirements specified in paragraph 10 of these guidelines.

N) Issuers of barcode are subjects of medicinal product circulation that enter medicinal product into circulation and label medicinal product packages.

O) Labeling of medicinal product packages - application by the issuer of the barcode to the secondary (consumer) packaging of the medicinal product (and in its absence - to the primary packaging), as well as to the tertiary (factory, transport) packaging of the barcode.

P) Serialization - the process of "*packing / packaging of medicinal product in the secondary packaging*" performed during the production cycle, the process of generation of individual serial numbers of secondary (consumer) medicinal product packages and their coding together with other data in the barcode with subsequent application in order to ensure the identification of secondary (consumer) Packings medicinal product.

Q) Aggregation - the process of combining medicinal product packages into tertiary (factory and / or transport) packaging, preserving information on the relationship of the unique identifiers of each enclosed medicinal product packaging with the unique identifier of the tertiary (factory, transport) package being created and applying the corresponding barcode to the tertiary (factory,) Packing in order to ensure the traceability of the medicinal product movement along the commodity distribution chain without the need to open the tertiary (factory, transport) package.

Aggregation implies the possibility of having any level of nesting:

- aggregation of the first level - the combination of secondary (consumer) packages in tertiary (factory, transport) packaging, for example, in a parcel post or in a box of corrugated cardboard;
- second-level aggregation - the association of tertiary (factory, transport) packages in another tertiary (factory, transport) packaging of a higher level of nesting, for example, in a pallet or container.

R) **Completion of the stage of output of finished products** - confirmation by the authorized person of the manufacturer of medicinal products of the conformity of the lot (lot) of medicinal product to the requirements established with their state Registration.

S) **Completion of the stage of the issuing quality control of medicinal product** - Execution of a document confirming the conformity of the quality of a series (lot) of medicinal product to the requirements established during their state registration.

T) **The owner of the medicinal product** is the subject of circulation of medicinal products, which owns the rights to own, use and dispose of these medicinal products.

5. Pilot owners are:

A) authorized federal bodies of state power

Consisting of:

- Ministry of Health of the Russian Federation (Ministry of Health of Russia);
- Ministry of Industry and Trade of the Russian Federation (hereinafter referred to as the Ministry of Industry and Trade of Russia);
- Ministry of Finance of the Russian Federation (Ministry of Finance of Russia);
- Federal Service for Supervision in Health Care (Roszdravnadzor), the territorial bodies of Roszdravnadzor;
- Federal Customs Service (FCS of Russia);
- Federal Tax Service (FTS of Russia) – operator IS Marking, providing design, development, development and operation of the system, providing information support for the pilot;

B) subjects of treatment of medicinal product:

- Russian medicinal product producers that carry out the stages "*Packing / packaging of medicinal product in secondary and / or tertiary packaging*";
- Russian medicinal product producers that carry out the stages "*Issuing quality control*";
- foreign holders of medicinal product registration certificates;
- Representative offices of foreign holders of medicinal product registration certificates registered in accordance with the established procedure in the state register of accredited branches, representations of foreign legal entities of the Federal Tax Service of Russia (hereinafter referred to as Representative offices of foreign holders of RU);
- wholesale trade organizations;

- the organization of retail trade of medicinal product;
- Medical organizations.

6. Participants of the Pilot on the part of the subjects of circulation of medicinal product are determined on a voluntary basis on the basis of their applications. At the same time, priority subjects for participating in the pilot are the subjects engaged in trafficking in PL for the provision of patients with hemophilia, cystic fibrosis, pituitary nazism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissues, multiple sclerosis, Transplantation of organs and (or) tissues, as well as medicines of wide application for achieving maximum social effect. The possibility of joining new subjects of medicinal product circulation to the Pilot during its implementation is allowed.

7. Monitoring of the implementation of the Pilot is carried out in accordance with the activities of the consolidated plan for the priority project "Implementation of an automated system for monitoring the movement of medicinal products from the manufacturer to the end user to protect the public from counterfeit medicines and promptly remove counterfeit and inferior drugs from circulation." The evaluation of the results is carried out on the basis of the passport of the priority project "Introduction of an automated system for monitoring the movement of medicinal products from the manufacturer to the end user to protect the public from counterfeit medicines and the prompt removal of counterfeit and inferior drugs from circulation" (approved by protocol No. 9 of the Presidium of the Council, dated October 25, President of the Russian Federation for Strategic Development and Priority Projects).

8. In the course of the pilot and solely for its purposes, the list of functions for monitoring the movement of medicinal products, enshrined in relevant regulatory legal acts, is supplemented by the following functions:

- Monitoring of the turnover in the territory of the Russian Federation of medicinal product, experimentally marked by the barcode symbol;
- monitoring the timeliness of the submission of information transferred by the entity of the medicinal product in the Component of MDLP as part of IS Marking.

II. The composition of information included in the barcode, and the rules for its application

9. The structure of the code, the method of formation and the format of the code for encoding the barcode of secondary (consumer) medicinal product packages for labeling within the framework of the Pilot must comply with the requirements below:

- A) The secondary (consumer) packaging is applied with a barcode in the form of a two-dimensional bar code, suitable for machine reading, and its recognition and error correction function must be equivalent to or higher than the Data Matrix ECC200 (hereinafter referred to as DataMatrix). Bar codes compiled in accordance with ISO / IEC 16022-2008 will be deemed to

meet the requirements of this paragraph. The recommended location of the two-dimensional bar code is the secondary (consumer) packing valve of the medicinal product (if available).

B) Composition of 2D bar code data for application to secondary (consumer) packaging of medicinal product:

- *the first data group* is the GTIN, which is preceded by the application identifier (01). The number of numeric characters is 14.

In order to participate in the Pilot in order to obtain GTIN on medicinal product, the relevant subjects of medicinal product circulation need to join the Automated Identification Association "UNISCAN / GS1 RUS" (hereinafter - GS1 RUS);

- *the second data group* is the individual serial number of the secondary (consumer) packaging of medicinal product, preceded by the application indicator (21) and generated by the issuer of the barcode symbol. The number of characters in the digital or alphanumeric sequence (Latin alphabet) is 13 (thirteen). The final character for this data group is the Function 1 Symbol Character (FNC1) separator (which uses the character <GS>, code 29 in the ASCII character table).

When generating the individual serial number of the secondary (Consumer) packaging, the issuer of a barcode symbol must use a random number generator in such a way that the probability of guessing the individual serial number of the secondary (consumer) package of medicinal products was negligible and in any case less than one in ten thousand. The uniqueness of the individual serial number of the secondary (consumer) packaging of medicinal product for each product code (GTIN) should be provided either within 5 years from the date of medicinal product entry into circulation or within 1 year from the expiration date of the medicinal product, whichever comes later;

- *the third data group* - the TH code of the foreign economic activity, which is preceded by the application identifier (240). The number of digital symbols in the TN VED code is 4 (the first 4 characters of the 10-digit TN VED code are indicated). In cases where the TN VED code is not located at the end of the encoded sequence in the two-dimensional code, it is necessary to use the trailing symbol Function 1 Symbol Character (FNC1) (using <GS>, code 29 in the ASCII character table).

The following groups of data are not mandatory for inclusion in the barcode, their inclusion remains at the discretion of the issuer barcode

- *the fourth group of data* is the number of the production medicinal product series, which is preceded by the application identifier (10) and which is generated by the issuer of the barcode.

The number of characters in the alphanumeric or alphanumeric sequence (Latin alphabet) in the medicinal product series is established by the issuer of the barcode, but

cannot exceed 20 characters. The final character for this data group must be the Function 1 Symbol Character separator (FNC1) (which uses the character <GS>, code 29 in the ASCII character table);

- *The fifth group of data* is the expiration date, preceded by the application identifier (17) and which is generated by the issuer of the barcode. The format for recording numeric characters for the expiration date of the medicinal product - YYMMDD (6 characters).

In those cases when the value of the expiration date in days "DD" is not established on the production line at the time of production, the issuer of the barcode shall indicate "01" instead of "DD", which corresponds to the first number of the given month;

C) Requirements for the sequence of data groups in the structure of the barcode code, provided that the application identifiers mentioned above are not used, except for the first group of data.

D) All necessary data for encoding in the barcode are generated by the issuer of the barcode during its production operations and are applied to the secondary (consumer) packaging by the issuer of the barcode independently, taking into account the abovementioned requirements for ensuring the uniqueness of the combination of values contained in the first group (ID number medicinal product (GTIN)) and the second group (the individual serial number of the secondary (consumer) packing of medicinal product) data. Any other additional methods and methods for protecting medicinal product packages from counterfeiting and counterfeiting are not mandatory within the Pilot and remain at the discretion of the issuer of the barcode symbol.

E) Within the framework of the Pilot, the barcode symbol is placed by issuers for secondary (consumer) packaging of medicinal product by printing or labeling methods at the issuer's discretion without any restrictions.

10. The structure of the code, the method of forming and the format of the code for encoding the barcode symbol of the tertiary (factory, transport) package of medicinal product for marking within the framework of the Pilot must meet the requirements below:

A) On the tertiary (factory, transport) packaging, a barcode symbol shall be applied in the form of a linear bar code in the Code 128 format in accordance with GOST ISO / IEC 15417-2013 (hereinafter Code 128) containing the unique identifier of the tertiary (factory, transport) Formed in the framework of the Pilot in accordance with one of three types:

- *the first type* is designed for encoding in the barcode symbol and applying to the tertiary packaging when performing the aggregation operation by the issuers of the barcode symbol and is a unique identifier of the tertiary (factory, transport) package in the form of the Serial Shipping Container Code (hereinafter referred to as SSCC), which consists of 18 (eighteen) Symbols in accordance with the data structure provided by the international non-profit association GS1, namely: the package expansion indicator, the

issuer's registration number issued by the entry into the national association GS1¹, and the individual serial number of the tertiary (factory, transport) package compiled by the issuer of the barcode symbol for an arbitrary (As a rule, sequential) order of assignment. The SSCC code is preceded by the application identifier (00);

- *the second type* is intended for encoding in the barcode and applying to the factory packaging when the barcode issuers fulfill the first level aggregation operation with one product code (GTIN) and contains 3 (three) groups of data, namely the GTIN (preceded by the identifier (01) consists of 14 numeric symbols), the HS code (which is preceded by the application identifier (240), consists of 4 numeric characters) and the individual serial number of the tertiary (factory, transport) package (preceded by the application identifier (21), is compiled by the issuers of the barcode in accordance with the requirements reflected in paragraph 9 of these guidelines in terms of generating an individual serial number of secondary (consumer) packaging). In the absence of the necessary free space on the packaging of the medicinal product of the "parcel" type with one product code (GTIN), it is allowed to compile and encode the barcode in the form of a two-dimensional bar code.

- *the third type* is intended for use in the implementation of the aggregation operation by the wholesale trade organizations of medicinal products that have not entered into GS1 ENG, and is a unique identifier of the tertiary (factory, transport) package, which, by analogy with the SSCC code, consists of 18 (eighteen) characters and contains 3 (Three) groups of data, namely: a package expansion indicator (1 digit in length), an identifier of the wholesale trade organization of the medicinal product in the Marking Lab, and an individual serial number of the tertiary (factory, transport) package, compiled by the issuer of the barcode in any order of assignment. The third type of data is preceded by the application identifier (999). The ID of the wholesale trade organization medicinal product is assigned automatically when registered in the IS "Marking".

11. All necessary data for encoding in the barcode are generated and applied to the tertiary (factory, transport) packaging of medicinal products by the issuers of barcode by printing or labeling methods. In order to conduct the Pilot and ensure traceability, the barcode issuers participating in the Pilot ensure that the serialization and aggregation requirements are met.

12. Within the framework of the Pilot, it is allowed at the discretion of the issuer of the barcode to duplicate the information contained in the barcode on the secondary (consumer) packaging and / or on the tertiary (factory, transport) packaging in the form of a readable printed text. For readable printed text on the secondary (consumer) packaging it is recommended to use the following data format:

- KP (01): The identification number of the GTIN;
- SI (21): Individual serial number of secondary (consumer) packaging of medicinal product;

¹ For example, legal entities that are residents of the Russian Federation may be members of the GS1 RUS.

- NA (10): Number of the production series medicinal product;
- SG (17): Expiration date in the format "DD.MM.YYYY".

III. Requirements for the equipment used for the application and reading of codes

13. Within the framework of the Pilot conducted by the issuer, the barcode is

Secondary (consumer) packing of medicinal product and tertiary (factory, transport) packing of medicinal product by printing or labeling methods at the discretion of the issuer of barcode without restrictions using any equipment.

At the opening of the secondary (consumer) packaging, the subject of circulation of the medicinal product must register the corresponding operation for the withdrawal of medicinal product from the turnover (paragraph 65 of these Guidelines). The withdrawn from the turnover of barcode is not reusable.

If the Pilot is successful, these methods of applying the barcode to the medicinal product package are planned to be maintained.

14. As a recommended range of sizes of individual dot characters constituting a two-dimensional bar code applied to the secondary (consumer) packing of medicinal product, it is recommended to use dot symbols with dimensions in the range 0.255 mm to 0.615 mm.

15. Recommended quality requirements for the application of barcode to secondary (consumer) packaging medicinal product:

- application with a level of quality class C or higher in accordance with the standard ISO 15415 (GOST R ISO / IEC 15415-2012);
- printing by using the ECC-200 error correction method;
- use of ASCII coding based on the ISO 16022 standard (GOST R ISO / IEC 16022-2008).

16. The reading equipment shall allow reading codes generated in accordance with ISO 15415 (ISO / IEC 15151: 2012) and the parameters given in paragraph 14 of these Methodological Recommendations.

IV. Information system requirements

17. For the purpose of the Pilot, and in the future, for tracking the movement

medicinal product from the manufacturer to the end user with the support of the functions of state control and supervision in the sphere of circulation of medicinal product and pharmaceutical activities will be used a phased information system for the marking of goods of the barcode, created by the Federal Tax Service of Russia.

18. Functions of information support for marking and

Monitoring of the medicinal product movement from the producer to the end user is realized as part of the IS "Marking" component of MDLP.

19. The following principles should be ensured in the Component of MDLP as part of the "Marking" IP:

- Identification of medicinal product in the "Marking" IS is made on the basis of unique identifiers of the secondary (consumer) packaging;
- full traceability of the medicinal product series from manufacturer to

The end user is provided at the expense of entering in the IS "Marking"

Corresponding information in the form of electronic documents signed by a strengthened qualified electronic signature transmitted by the participants of information interaction in connection with changes in the state and / or location of medicinal products throughout the lifetime of the medicinal product;

- Information on each transfer of medicinal product from one subject to another must be accepted by each participant in the interaction.

20. The component of MDLP as part of IS Marking should be created taking into account the application of a centralized architecture, which is a single information resource. The software products used in the implementation of the component architecture must meet the requirements of the priority of using free software.

21. When creating the components of MDLP, the necessary information interactions should be implemented within the Marking IC, allowing access to information for all participants with the possibility of expansion. In the part of system-wide software, scalability of solutions must be ensured.

22. The component of MDLP as part of the "Marking" IS shall ensure that the following requirements are met for the purpose indicators:

- storage of all transaction records in the database registered in the MDLP Component within the framework of the pilot, for 5 (five) years;
- Server subsystems should ensure the level of availability of information services 99.9% (maximum number of hours of idle time per year is not more than 9) in 24 hours 7 days a week;
- the time to restore the functionality of the components of MDB in the label "Labeling" after the elimination of the failure is no more than 45 minutes, provided that the cause of the failure

is completely eliminated and the integrity of the software and databases installed on the server (workstation) is maintained;

23. System-wide server components of the Marking IC should support the ability to structure redundancy, automatically detect the failure of the server node and switch tasks (load) to another server node, and also have a client access concentrator that is redundant and diversified to connect to the providers.

24. With regard to the creation of the MD component of the LI within the "Marking" IS, when developing a special software component, the following functions are automatically enforced:

- Automation of functions of registration of users in the System, creation of personal cabinets and input of extended information about medicinal product;
- Automation of functions for obtaining and registering information about the actions performed within the process of entering into the turnover of medicinal product;
- Automation of functions for obtaining and registering information about actions carried out within the framework of the medicinal product process in the territory of the Russian Federation;
- Automation of the registration function in the System of information on the withdrawal of medicinal product from the turnover;
- automation of the functions of exercising public control over the circulation of medicinal product;
- Automation of functions of automatic blocking of medicinal product realization with expired shelf life;
- Automation of functions of withdrawal from circulation of falsified, counterfeit and poor quality medicinal product;
- Automation of control functions and prompt detection of possible violations when registering information in the Component of MDLP as part of IS "Marking" by medicinal product entities;
- automation of the functions of providing information and analytical support to the activities of federal executive bodies in the sphere of medicinal products circulation and monitoring of medicinal product movement (according to Appendix No. 2 to these methodological recommendations).

25. The creation of the MDLP component of the Marking is carried out in accordance with the Consolidated Plan of the Priority Project "Implementation of an automated system for monitoring the movement of medicinal products from the manufacturer to the end consumer to protect the public from counterfeit medicines and prompt removal of counterfeit and inferior drugs from circulation."

V. Procedure for the transfer and exchange of information

26. The legal significance of all transactions recorded

Subjects of circulation in the Component of MDLP as part of IS Marking, should be ensured by the signing of the relevant documents with a strengthened qualified electronic signature.

27. Information exchange of participants with Labeling is carried out on the basis of the developed information electronic services using standard protocols and electronic interaction interfaces that support the guaranteed delivery of data packets.

Authentication in the IS "Marking" of the subjects of circulation of medicinal product is carried out by means of a certificate of qualified electronic signature.

28. Developed information electronic services,

Perform an automated exchange must provide the following functions:

- formation and signing of electronic documents into the system;
- Receiving a response to a previously submitted document;
- preservation of the contents of the sent documents and the responses received to them, as well as information on the facts of the documents (document number, date and time of dispatch, information about the authorized person who signed and sent the document, date and time of receiving the response).

29. Within the framework of the Pilot, the information on the relevant transactions must be registered in the Component of MDLP as part of the IP Marking by the entities of the medicinal product's circulation no later than 5 working days from the date of their commission, but certainly until the transfer of ownership of the medicinal product.

VI. The order of interaction of the information system with available resources

30. For the purposes of the Pilot, Labeling shall provide for interaction through the Unified Inter-Agency Electronic Interaction System (hereinafter referred to as SMEV) with the following information systems of federal executive bodies:

- State register of medicinal products for medical use, posted on the official website of the Ministry of Health of Russia in the information and telecommunication network "Internet";
- A single register of licenses for the production of medicines of the Ministry of Industry and Trade of Russia;

- A single register of licenses, including licenses issued by state authorities of the constituent entities of the Russian Federation in accordance with the transferred authority to license certain types of activities, posted on the official website of Roszdravnadzor in the information and communication network "Internet";
- Unified State Register of Legal Entities / Unified State Register of Individual Entrepreneurs;
- Subsystem "Selective control" of the automated information system of Roszdravnadzor;
- Subsystem "Quality control of medicines" of the automated information system of Roszdravnadzor;
- State Register of Accredited Branches, Representative Offices of Foreign Legal Entities of the Federal Tax Service of Russia.

31. Services for the provision of inter-agency electronic interaction with IS Marking must comply with the requirements of the Order of the Ministry of Communications and Mass Media of the Russian Federation of December 27, 2010, No. 190 "On Approving Technical Requirements for the Interaction of Information Systems in a Unified System of Interagency Electronic Interaction." The description of the services is provided in the respective technological maps of interdepartmental interaction.

32. The storage of registers and the maintenance of normative and reference information in the Component of MDLP as part of IS Marking is carried out 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, including those downloaded and updated from the available resources of federal executive bodies through the use of SMEE.

VII. The procedure for submitting an application for participation in the pilot and registration of participants in the pilot in the IP Marking

33. The application for participation in the Pilot on a voluntary basis is made out in the IS "Marking" in electronic form. medicinal product entities who are residents of the Russian Federation sign the application with an enhanced qualified electronic signature issued to the head of the organization in one of the certifying centers accredited by the Ministry of Communications of Russia².

On the computer from which the "Labeling" IS is logged, the certificates of the electronic signature verification keys and the program module providing the work with the electronic signature must be installed.

34. When registering an application for participation in the Pilot, the subject of treatment of the medicinal product, who is a resident of the Russian Federation, indicates the following information:

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

- *type of the subject of conversion of medicinal product;*
- *the e-mail address to which automatic notification of the completion of the application review process should be sent.*

Data on the TIN and CAT of the subject of the medicinal product treatment who is a resident of the Russian Federation will be obtained on the basis of the data of the electronic signature key certificate that was used when signing the application.

35. Foreign holders of medicinal product registration certificates in the electronic application for participation in the Pilot indicate the following information:

- name of the foreign holder of the registration certificate of the medicinal product (in Russian);
- number of the registration certificate and the date of registration of the medicinal product, the marking of which will be carried out in accordance with the requirements of these guidelines;
- the last name, first name, patronymic of the applicant (in Russian);
- applicant's contact phone number;
- the e-mail address to which automatic notification of the completion of the application review process should be sent.

36. Roszdravnadzor participates in the examination of the application for participation on a voluntary basis in a pilot executed by foreign holders of registration certificates.

37. Original documents confirming the right to provide

Interests of the foreign holder of the registration certificate of the medicinal product,

And an application for participation on a voluntary basis in the Pilot in the form according to Appendix No. 1 of these guidelines (hereinafter referred to as the application) must be submitted to Roszdravnadzor at the address: 109074, Moscow, Slavyanskaya Ploshchad, 10, 10, 4, building 1.

38. The basis for initiating the procedure for considering the application of the foreign holder of the medicinal product registration certificate is the receipt in Roszdravnadzor of a set of documents specified in paragraph 37 of these Methodological Recommendations. The period for consideration of the application by Roszdravnadzor does not exceed 5 working days.

39. Information on the results of consideration of the decision on registration of the foreign holder of the registration certificate as a participant in the Pilot shall be transferred by Roszdravnadzor to the Component of MDLP as part of the Labeling Company within one working day from the date of the relevant decision.

40. Grounds for refusing to register as a participant of the pilot:

A) in the registration in the IS "Marking" on the basis of a formal application for participation in the Pilot to Russian medicinal product producers,

Carrying out the stages of "packing / packing of medicinal product into secondary and / or tertiary packaging", and Russian medicinal product manufacturers performing the stages "issuing quality control" are refused for the following reasons:

- Lack of enhanced qualified electronic signature of the head of the applicant organization or inconsistency of the data of the owner of the qualified certificate to the head of the applicant organization;
- lack of information about the current records in the Unified State Register of Legal Entities / Unified State Register of Individual Entrepreneurs of the Federal Tax Service of Russia;
- the lack of information on the current license in the Unified Register of Licenses for the Manufacture of Medicines of the Ministry of Industry and Trade of Russia;

B) in the registration in the IS "Marking" on the basis of a formal application for participation in the Pilot, foreign holders of registration certificates are refused for the following reasons:

- Lack of information about the registration certificate of the medicinal product in the State Register of medicinal products for medical use indicated in the application;
- the lack of information on the positive decision taken, described in paragraph 3 of these guidelines.

C) in the registration in the IS "Marking" on the basis of a formal application for participation in the Pilot of Representative Offices of foreign holders, the RU is refused for the following reasons:

- Lack of enhanced qualified electronic signature of the head of the applicant organization or inconsistency of the data of the owner of the qualified certificate to the head of the applicant organization;
- lack of information about the current records in the State Register of Accredited Branches, Representative Offices of Foreign Legal Entities of the Federal Tax Service of Russia;

D) in the registration in the IS "Marking" on the basis of a registered application for participation in the Pilot, wholesale organizations of the PL, retail organizations, medical organizations are refused for the following reasons:

- lack of information about the current certificate of the enhanced qualified signature issued to the head of the applicant's organization;

- lack of information about the current records in the Unified State Register of Legal Entities / Unified State Register of Individual Entrepreneurs of the Federal Tax Service of Russia;

- lack of information about the current license in the Unified Register of licenses for medical and pharmaceutical activities of Roszdravnadzor.

41. The applicant's e-mail address specified in the application for participation on a voluntary basis in the Pilot is sent the result of consideration of the application with indication of the automatically assigned identifier of the participant in the IS "Marking".

42. To activate the "Personal Cabinet" and complete the registration in the IS "Marking" it is necessary to enter the list of users from the side of the subject of the frustration of the medicinal product.

At the same time, medicinal product entities that are residents of the Russian Federation must provide information on issued enhanced qualified electronic signatures to users authorized to transmit the necessary information to the Labeling Company on behalf of the medicinal product entity.

VIII. The order of interaction of the pilot participants, including the list and procedure for entering information into the system

VIII. 1. The order of description of medicinal product in the IS "Marking"

43. The description of the medicinal product in the Component of MDLP as part of the Marking is carried out by the Russian medicinal product manufacturer that performs the stage of "*packaging / packaging of medicinal product into secondary and / or tertiary packaging*" and / or the representation of the foreign holder of RU and / or the importer of medicines to the territory of the Russian Federation Federation, on the basis of an electronic application, which states:

- identification number of medicinal product (GTIN);
- the number of the medicinal product registration certificate and the date of the state registration of the medicinal product.

44. The generation procedure and the method of applying a barcode symbol on the medicinal product are carried out in accordance with the requirements of paragraphs 9 and 10 of these Methodological Recommendations.

VIII.2. The order of interaction between the participants of the pilot, including the list and procedure for entering information into the IS "Marking", when entering into civil circulation of medicinal product packaged in the territory of the Russian Federation

45. The final stage of the final packaging is completed by the Russian manufacturer of medicinal product, which performs the stage of "*packaging / packaging of medicinal product in secondary and / or tertiary packaging*", in the Component of MDLP as part of IS "Marking" by sending the following information:

- transaction date;
- TIN / CAT of the Russian manufacturer that has carried out the packaging / packing in the secondary / tertiary packaging;
- the address of the production site that carried out the packaging / packing in the secondary / tertiary packaging;
- type of production order (own production of medicinal product, production of medicinal product under the contract);
- TIN / PPC of the owner of the medicinal product (in the case of production of medicinal product under the contract);
- number of the production series;
- the expiration date;
- list of unique identifiers of secondary (consumer) packaging of medicinal product.

46. The result of the aggregation operation is formalized by the Russian medicinal product manufacturer that performs the "*packing / packing of medicinal product in secondary and / or tertiary packaging*" phase in the Component of MDLP as part of the "Marking" IS by sending the following information:

- transaction date;
- TIN / CAT of the Russian manufacturer that has carried out the packaging / packing in the secondary / tertiary packaging;
- address of the place where the activity is carried out, where the aggregation is performed;
- a list of unique identifiers of the tertiary (factory, transport) packaging of higher level medicinal products, for each of which, in case of aggregation of the first level, the list of unique identifiers of the secondary (consumer) packing of medicinal product is additionally indicated; in case of aggregation of the second level, the list of unique identifiers of the tertiary (factory, transport), United in this group.

47. The operation of sampling medicinal product (to verify compliance with quality, to declare compliance, control and archival samples, etc.) is made by the Russian medicinal product manufacturer who is performing the "*issuing quality control*" stage in the Component of MDLP as part of the "Marking" IS by sending the following information :

- TIN / CAT of the Russian manufacturer that issues quality control;
- type of medicinal product output from turnover;
- transaction date;
- list of unique identifiers of secondary (consumer) packaging of medicinal product.

48. Completion of the stage of finished products is made by the Russian medicinal product manufacturer who is performing the stage of "*issuing quality control*" in the Component of MDLP as part of IS "Marking" by sending the following information:

- transaction date;
- TIN / CAT of the Russian manufacturer that issues quality control;
- address of the production site, which issues quality control;
- type of the document confirming compliance (declaration of conformity, certificate of conformity);
- registration number of the document of confirmation of conformity;
- date of registration of the document of confirmation of conformity;
- list of unique secondary identifiers (Consumer) packaging of medicinal product and / or a list of unique identifiers of the tertiary (factory, transport) packaging of medicinal product (in case of aggregation of consumer medicinal product packages).

49. The transfer to the owner of medicinal product produced as part of the production services is made by the Russian medicinal product manufacturer performing the "*packing / packing of medicinal product into secondary and / or tertiary packaging*" stage in the component of MDLP as part of the "Marking" IS by sending the following information:

- transaction date;
- TIN / CAT of the Russian manufacturer;
- Taxpayer identification number;
- address of the place where the owner of the medicinal product operates (if the medicinal product is moved to the owner's warehouse);
- requisites of the primary document confirming the transfer of medicinal product and invoices (except for persons applying special tax regimes);
- a list of unique identifiers of the secondary (consumer) packaging of medicinal product and / or unique identifiers of the tertiary (factory, transport) packaging of medicinal product.

50. Acceptance to the medicinal product warehouse issued as part of the provision of production services shall be formalized by the medicinal product owner in the Component of MDLP as part of the Labeling Company by sending the following information:

- transaction date;
- Taxpayer identification number;
- requisites of the primary document confirming the movement of the medicinal product;
- address of the place of realization of the activity of the recipient;
- a list of unique identifiers of the secondary (consumer) packaging of medicinal product and / or unique identifiers of the tertiary (factory, transport) packaging of medicinal product.

In case of discrepancies in the information provided on the performance of the transfer of medicinal product to the owner, issued as part of the provision of production services, information from the component of the MDLP is sent to the authorized body to decide on further movement of the medicinal product, in which the discrepancies are revealed.

VIII.3. The order of interaction of the pilot participants, including the list and procedure for entering information into the IS "Marking", in the production of medicinal products abroad and their importation into the territory of the Russian Federation

51. Completion of the stage of the issuing quality control of medicinal product (finished goods) is executed by a representative office of a foreign holder of the RU or by a foreign holder of a registration certificate that does not have a representative office on the territory of the Russian Federation in the Component of MDLP as part of the Labeling Company by sending the following information:

- transaction date;
- Taxpayer Identification Number of the representative office of the foreign holder of the RU or the identifier of the foreign holder of the registration certificate in the IS "Marking";
- the name of the manufacturer that carried out the issuing quality control;
- address of the production site that carried out the issuing quality control;
- number of the production series;
- the expiration date;
- list of unique identifiers of secondary (consumer) packaging of medicinal product.

52. The result of the aggregation operation is drawn up by a representative office of a foreign holder of the RU or by a foreign holder of a registration certificate that does not have a representative office in the territory of the Russian Federation in the Component of MDLP as part of the Marking Company by sending the following information:

- transaction date;
- Taxpayer Identification Number of the representative office of the foreign holder of the RU or the identifier of the foreign holder of the registration certificate in the IS "Marking";
- address of the place where the activity is carried out, where the aggregation is performed;
- a list of unique identifiers of the tertiary (factory, transport) packaging of higher level medicinal products, for each of which, in case of aggregation of the first level, the list of unique identifiers of the secondary (consumer) packing of medicinal product is additionally indicated; in case of aggregation of the second level, the list of unique identifiers of the tertiary (factory, transport), United in this group.

53. The registration of information on the intention to import medicinal product into the Russian Federation shall be made by a representative office of a foreign holder of the RU or by a foreign holder of a registration certificate that does not have a representative office in the territory of the Russian Federation in the Component of MDLP as part of the Labeling Company by sending the following information:

- transaction date;
- INN / K111 of the representative office of the foreign holder of RU or the identifier of the foreign holder of the registration certificate in the IS "Marking";
- the seller of medicines;
- the buyer of medicines;
- the address of the consignor;
- the selling price of the manufacturer;
- list of unique identifiers of the secondary (consumer) packaging of medicinal product and / or unique identifiers of the tertiary (factory, transport) packaging of medicinal product.

54. Registration of information on the importation of medicinal product into the customs territory of the Russian Federation and placement in the customs control zone, as well as in case of transfer of medicinal products between temporary storage warehouses (bonded warehouses), is registered in the Component of MDL as part of IS Marking by the importer (wholesale organization) By sending the following information:

- transaction date;

- INN / CIT of the importer;
- the seller of medicinal products;
- address of the consignor;
- address of the warehouse of temporary storage (bonded warehouse);
- manufacturer's selling price;
- a list of unique identifiers of the secondary (consumer) packaging of medicinal product and / or unique identifiers of the tertiary (factory, transport) packaging of medicinal product.

55. The operations for the selection of medicinal product samples that have been confirmed by compliance are formulated in the Component of MDL as part of the Labeling Company by the importer (wholesale trade organization) after the release of medicinal product for domestic consumption in the territory of the Russian Federation by sending the following information:

- transaction date;
- INN / CIT of the importer;
- type of withdrawal from turnover;
- type of the document confirming compliance (declaration of conformity, certificate of conformity);
- registration number of the document of confirmation of conformity;
- date of registration of the document of confirmation of conformity;
- number of the document confirming the release of medicinal product for domestic consumption;
- list of unique identifiers of secondary (consumer) packaging of medicinal product.

56. In the absence of information provided for in paragraph 55 of these Guidelines, a system operator within the monitoring framework is entitled to verify the specified information in external information systems and resources available to the operator of the system in the framework of information interaction. In the absence and / or inconsistency of the information being checked, the operator of the system has the right to block further movements of the medicinal product, which is reported to the importer and the relevant supervisory authorities.

VIII.4. The procedure for interaction between the participants of the pilot, including the list and procedure for entering information into the Labeling

Company, when carrying out operations to seize, disband and / or rearrange the tertiary packaging

57. The list of information provided by the subject of the medicinal product circulation, registered during the registration of the aggregation operation in the Component of MDLP as part of the Labeling Company by the subject of medicinal product circulation, is reflected in paragraphs 46, 52 and 61 of these guidelines.

58. Operations for the removal, disbanding and / or re-packing of medicinal product packages from tertiary (factory, transport) packaging should be formalized through registration in the Component of MDLP as part of the Labeling Company of independent operations directed by the subjects of circulation.

59. The result of the operation specified in paragraph 58 of these recommendations shall be formalized by the subject of the medicinal product in the Component of MDLP as part of the Labeling Company by sending the following information:

- transaction date;
- TIN / CAT of the subject of medicinal product treatment;
- type of operation of transformation of the packaging of medicinal product (withdrawal, disbanding, re-laying);
- a list of unique identifiers for medicinal product packages, depending on the type of operation performed:
 - In the case of withdrawal of secondary (consumer) packages from the tertiary (factory, transport) package, a list of unique identifiers of the secondary (consumer) packaging of medicinal product, seized packages of medicinal product;

Repayment of the unique identifier of the tertiary (factory, transport) packaging of medicinal product with the withdrawal of secondary (consumer) packages from it is carried out only if the results of the transaction in the tertiary (factory, transport) package do not leave other medicinal product packages according to the IS "Marking". In all other cases, the Component of MDLP makes a note on making changes to the composition of the tertiary (factory, transport) packaging.

- In case of disbanding (destruction) of the tertiary (factory, transport) packing of medicinal product, the corresponding unique identifier of the tertiary (factory, transport) package is indicated. At the same time, a unique identifier of a tertiary (factory, transport) package is being repaired in the component of the MDLP as part of the Labeling Company, but the unique identifiers of the medicinal product packs contained in it remain in circulation;

- In the case of transfer of medicinal product packages from one tertiary (factory, transport) package to another, a list of corresponding unique identifiers of the medicinal product packings to be transferred is indicated, as well as a unique identifier of the tertiary (factory, transport) packaging of the medicinal product in which the re-packing takes place.

If the results of the relocation operation in the original tertiary (factory, transport) package do not leave other medicinal product packings according to Labeling, then the unique identifier of this tertiary package is repaid in the MDLP Component.

VIII.5. The order of interaction of the pilot participants, including the list and procedure for entering information into the IS "Marking", with the turnover of medicinal product

60. The operation of dispatching the medicinal product from the warehouse is made out by the entity of circulation in the Component of MDLP as part of the Labeling Company by sending the following information:

- transaction date;
- the type of operation of the medicinal product shipment from the warehouse (sale, return to the supplier);
- Taxpayer identification number;
- address of the place of activity of the sender;
- TIN / CIT of the recipient;
- address of the place of realization of the activity of the recipient;
- source of financing (budgetary, extra-budgetary);
- requisites of the primary document confirming the transfer of ownership of medicinal products and invoices (except for persons applying special tax regimes);
- the selling price of the medicinal product, rubles;
- a list of unique identifiers of the secondary (consumer) packaging of medicinal product and / or unique identifiers of the tertiary (factory, transport) packaging of medicinal product.

In the framework of the conducted pilot when carrying out the shipment of the medicinal product by the wholesale trade organization in accordance with the order of the retail trade organization and in the absence of the technological capability to equip the picking places with the appropriate equipment for

reading the individual serial numbers of consumer packages, it is allowed to register the shipment of medicinal product in the component of the MDLP as part of the Labeling "Within 1 working day from the moment of receiving information about the acceptance of the medicinal product in the warehouse by the retail organization³.

61. The operation of acceptance of medicinal product is formalized by the subject of medicinal product circulation in the Component of MDLP as part of IS "Marking" by sending the following information:

- transaction date;
- INN / K1111 of the seller;
- INN / K111 of the buyer;
- type of acceptance transaction to the warehouse (receipt, return from the supplier);
- address of the place of business of the buyer;
- requisites of the primary document confirming the transfer of ownership of medicinal products and invoices (except for persons applying special tax regimes);
- the purchase price of the medicinal product, rubles;
- a list of unique identifiers of the secondary (consumer) packaging of medicinal product and / or unique identifiers of the tertiary (factory, transport) packaging of medicinal product.

62. In case of finding discrepancies in information provided by the subjects of the medicinal product referring to the transfer of ownership of the medicinal product, information from the MDLP component is sent to the authorized body to make a decision on the further movement of medicinal products for which discrepancies have been identified.

63. The result of the aggregation operation performed by the issuer of the barcode symbol as part of the order picking and preparation of the medicinal product for shipment is processed in the Component of MDLP as part of the Marking Company by sending the following information:

- transaction date;
- TIN / CAT of the subject of medicinal product treatment;
- address of the place where the activity is carried out, where the aggregation is performed;
- a list of unique identifiers of the tertiary (factory, transport) medicinal product packing of higher level, for each of which, in case of aggregation of the first level, the list of unique identifiers of the secondary (consumer) packaging of medicinal product is additionally indicated.

³ In this case, the principle of the reverse order of acceptance by the parties to the transaction is used.

In case of aggregation of the second level, the list of unique identifiers of the tertiary (factory, transport), united in this group, is indicated.

64. The operations of transferring medicinal products between the addresses of the activities (according to the license) without the transfer of ownership rights are formalized by the entity of circulation in the Component of MDLP as part of IS "Marking" by sending the following information:

- transaction date;
- TIN / CAT of the subject of circulation;
- address of the place of activity of the sender;
- address of the place of realization of the activity of the recipient;
- requisites of the primary document confirming the internal movement of the medicinal product;
- a list of unique identifiers of the secondary (consumer) packaging of medicinal product and / or unique identifiers of the tertiary (factory, transport) packaging of medicinal product.

VIII.6. The order of interaction of the pilot participants, including the list and procedure for entering information into the "Marking" IS, when withdrawing from the medicinal product

65. The registration of information on withdrawal from the medicinal product turnover shall be formalized by the entity of circulation in the Component of MDLP as part of the Labeling Company by sending the following information:

- transaction date;
- TIN / CAT of the subject of circulation;
- address of the place of business;
- type of medicinal product output from turnover;
- requisites of the primary document depending on the type of medicinal product output from the turnover:
 - or the number of the cashier's check, if the sale of medicinal product in the retail trade is carried out;
 - or the number and date of registration of the prescription, if the medicinal product is on a discounted prescription;

- or the details of the waybill for the transfer of medicinal product to the offices, if the use of medicinal products is provided in the provision of medical assistance;
 - either the requisites of the contract and the act of transfer for destruction, if the transfer of the medicinal product to the organization carrying out the destruction is being effected;
- list of unique identifiers of secondary (consumer) packaging of medicinal product and / or unique identifiers of tertiary (factory, transport) packaging of medicinal product;
 - cost;
 - TIN / K1TP of the organization carrying out destruction (in case of transfer of PL for destruction);
 - the address of the place of carrying out the activities for the destruction of medicinal product (in case of transfer of PL for destruction).

66. In the event of the expiration of the medicinal product shelf life, their implementation is automatically blocked in the Component of MDLP as part of the Labeling Company.

VIII.7. The order of interaction of the pilot participants, including the list and procedure for entering information into the IS "Marking", when re-marking medicinal product

67. The medicinal product re-labeling operations are executed by the Russian manufacturer performing the "*packing / packing of medicinal product in secondary and / or tertiary packaging*" stage and / or the representation of the foreign holder of RU and / or the foreign holder of the registration certificate that does not have a representative office in the territory of the Russian Federation in Component of MDLP as part of IS "Marking" by sending the following information:

- transaction date;
- TIN / CIT of the subject of circulation or the identifier of the foreign holder of the registration certificate in the IS "Marking";
- unique identifier of new secondary (consumer) packaging of medicinal product;
- unique identifier of the old secondary (consumer) packaging of medicinal product.

Appendix №1

To the Methodological recommendations for carrying out the pilot on marking with control (identification) signs and monitoring the turnover of certain types of medicinal products for medical use that are in civil circulation on the territory of the Russian Federation

Application form

For participation on a voluntary basis in the Pilot of foreign holders of registration certificates that do not have representation in the territory of the Russian Federation

General information on the foreign holder of Uzbekistan			
Name of foreign legal entity:			
Information on the registration of a foreign legal entity in the country of registration (name of the registration authority, registration number, taxpayer's code or equivalent)			
Name and digital code of the country of registration in accordance with the Common Classifier of Countries of the World		Address of a foreign legal entity in the country of registration	
Surname, name, patronymic of the person responsible for participating in the Pilot, position, contact information, e-mail			
Information on medicinal products proposed for participation in the Labeling Pilot			
Registration certificate number	Mn	Tradename	Trade name Packaging, packaging, dosage, form of release
Information about the production sites where the finished product is being produced, participating in the Pilot			
Address of place of business	Information about the manufacturer: Name, Code of registration with the tax authorities	Information about the production line (type and brand of equipment, method of marking)	

Information on the importation into the RUSSIAN FEDERATION of those participating in the LI pilot			

Date of application for state registration of medicinal product for medical use: _____

The application for state registration of a medicinal product for medical use, presented:

_____ M.P.
 (position) (FULL NAME.) (signature)

Appendix No. 2

To the Methodological recommendations
for carrying out the pilot on marking
with control (identification) signs and
monitoring the turnover of certain types of
medicinal products for medical use that are
in civil circulation on the territory of the
Russian Federation

List of functions for monitoring medicinal product traffic using the Component of MDLP as part of IS Marking

#	Name	Ministry of Health of Russia	Roszdraznadzor	Ministry of Industry and Trade of Russia	FCS of Russia	The Federal Tax Service of Russia
1	Monitoring of the number of medicinal products released into civil circulation	+	+	+	-	+
2	Monitoring of exceeding the maximum selling prices for medicinal product, included in the list of VED	+	+	-	-	+
3	Monitoring of the quantity and value of medicinal product imported to the territory of the Russian Federation	+	+	+	+	+
4	Monitoring of identified violations in terms of inconsistencies in the addresses of locations where activities are carried out (according to the relevant license)	-	+	+	-	-
5	Monitoring of identified violations when attempting to transmit information about medicinal products for which there is no information on commissioning or the previous phase of medicinal product turnover	-	+	-	-	+
6	Monitoring of medicinal product location in accordance with tasks for spot monitoring	-	+	-	-	+
7	Monitoring of the movement of medicinal product acquired from the state budgets of all levels	+	+	-	-	-
8	Monitoring of identified violations when attempting to register subjects of circulation of medicinal product operations for the sale and dispensing of medicines for which a decision was made to temporarily withdraw from circulation	-	+	-	-	+

9	Monitoring of detected violations when attempting to register entities for the re-withdrawal from circulation of PL	+	+	-	-	+
10	Monitoring of revealed violations when attempting to register by the entities of circulation transactions for the sale and release of medicinal products with expired shelf life	+	+	-	-	+
11	Monitoring of revealed violations in terms of timeliness of entering information by subjects of treatment of PL	-	+	-	-	+
12	Monitoring of information on the number transferred to the destruction of PL	+	+	-	-	+
13	Monitoring of the total number of registered transactions	+	+	+	-	+
14	Monitoring of external users' requests to the medicinal product legitimacy verification service	-	+	-	-	+
15	Monitoring of the number of complaints and reports of violations detected while verifying the legitimacy of medicinal products by external users	-	+	-	-	+

Appendix No. 3

To the Methodological recommendations
for carrying out the pilot on
marking with control (identification) signs
and monitoring the turnover of certain
types of medicinal products for medical
use that are in civil circulation on the
territory of the Russian Federation

**Description of the values of key classifiers in the Component of MDLP as part of
IS Marking**

1. The classifier of medicinal product package types provides storage of the following values:
 - A) primary packaging;
 - B) secondary (consumer) packaging;
 - C) Tertiary (factory, transport) packaging.
2. The classifier of types of operations for the dismantling (transformation) of the packing P provides storage of the following values:
 - A) taking samples from tertiary (factory, transport) packaging;
 - B) the transfer of samples from one tertiary (factory, transport) packaging to another;
 - C) the dismantling of the tertiary packaging (factory, transport) of a lower level from the tertiary (factory, transport) package of a higher level;
 - D) complete disbandment from tertiary (factory, transport) packaging to secondary (consumer) packaging.
3. Classifier of types of acceptance of medicinal product into the warehouse provides storage of the following values:
 - A) receipt of medicinal product from the supplier;
 - B) return of the medicinal product from the buyer;
 - C) capitalization of surplus medicines.
4. Classifier type of production orders medicinal product provides storage of the following values:
 - A) own production of medicinal product;

B) Contract production of medicinal product.

5. The classifier of input medicinal product types into turnover ensures the storage of the following values:

A) medicinal products produced in the territory of the Russian Federation;

B) medicinal product produced abroad.

6. The classifier of medicinal product output types from the turnover provides storage of the following values:

A) sampling for quality assurance;

B) selection and transfer for storage of control and archival samples;

C) sampling by customs authorities;

D) sampling for declaration of compliance;

E) Sampling in the framework of mandatory certification;

(E) Sampling in the framework of sampling;

G) selection of samples within the framework of federal supervision in the field of health care;

H) sampling for clinical trials⁴;

I) sampling for pharmaceutical examination;

J) selection of samples for quality examination in the implementation of registration processes⁵;

K) transfer of demonstration samples;

M) sale of medicinal product in the retail trade;

N) leave of PL for a prescription;

O) use of medicinal product in the production of dosage forms;

P) use of medicinal product in the provision of medical care;

Q) re-export;

R) transfer to destruction of medicinal product;

⁴ To assess the quality of reproducible drugs in relation to the original.

⁵ In those cases when it is required to make changes to the registration dossier and regulatory documents for the medicinal product.

S) shortage (damage, loss) of the medicinal product;

T) theft, embezzlement of medicinal product;

U) other.