Decree of the Government of the Russian Federation of 12/14/2018 No. 1556 (as amended on 6/30/2021) "On Approval of the Regulation on the Track and Trace System of Medicines for Medical Use"

Publication source

The document release has not been previously published.
Original document was published in publications of
Official web-portal of legal information http://www.pravo.gov.ru, 12/24/2018,
"Collection of Legislation of the Russian Federation", 12/31/2018, No. 53 (part I), article 8641.
For information on the publication of the documents creating this revision, see the Reference to these documents.

Note to the document

The beginning of the revision - 07/01/2021.

The amendments are introduced by Decree of the Government of the Russian Federation of 06/30/2021 No. 1069, and shall become effective from July 1, 2021.

This documents is included into the list of laws and statutory instruments that are exempt from abolition requirement from 01/01/2021, established by the Federal Law of 07/31/2020 No. 247-FZ. Compliance with the mandatory requirements contained in this document is being accessed by carrying out of state control (surveillance), and non-compliance with the requirements may be a ground for instituting administrative action (Decree of the Government of the Russian Federation of 12/31/2020 No. 2467).

Document title
Decree of the Government of the Russian Federation of 12/14/2018 No. 1556 (as amended on 6/30/2021)
"On Approval of the Regulation on the Track and Trace System of Medicines for Medical Use"

GOVERNMENT OF THE RUSSIAN FEDERATION

DECREE
of December 14, 2018 No. 1556

ON APPROVAL OF THE REGULATION ON THE TRACK AND TRACE SYSTEM OF MEDICINES FOR MEDICAL USE

List of modifying documents
(as amended by Decrees of the Government of the Russian Federation of 8/30/2019 No. 1118, of 12/31/2019 No. 1954, of 03/02/2020 No. 219, of 03/20/2020 No. 311, of 7/21/2020 No. 1079, of 11/2/2020 No. 1779, of 12/18/2020 No. 2166, of 1/28/2021 No. 60, of 6/30/2021 No. 1069)

The Government of the Russian Federation decrees:
(as amended by Decree of the Government of the Russian Federation of 12/31/2019 No. 1954)

1. To approve the attached Regulation on Track and Trace System of Medicines for Medical Use.

1^1. To establish that, according to the Regulation approved by this Decree, legal entities and entrepreneurs, which are pharmaceutical entities (the "pharmaceutical entities") shall:

register in the Track and Trace System of Medicines for Medical Use (the "Track and Trace System") from January 1, 2020 until February 29, 2020 (inclusive) or after February 29, 2020 within 7 calendar days from the day when these pharmaceutical entities have a need to perform any activities related to circulation of medicines provided that they have the right to perform such activities;

no later than 21 calendar days from the day of registering in the Track and Trace System ensure that their information systems are ready for information interaction with the Track and Trace System and send an application to the Track and Trace System operator for information interaction testing, specifying the manufacturers of software and hardware of the information systems;

take an information interaction test of their information systems and the Track and Trace System according to the procedure, which is available at the official website of the Track and Trace System operator in the information and telecommunications network Internet, for medicine marking, medicine introduction into circulation, medicine circulation and withdrawal from circulation according to the Regulation approved by this Decree, within 2 calendar months from the day when their information systems are ready for information interaction with the Track and Trace System;

starting from July 1, 2020 enter the information about all operations that concern medicines to the Track and Trace System, according to the Regulation approved by this Decree.
(Cl. 1^1 is introduced by Decree of the Government of the Russian Federation of 12/31/2019 No. 1954)

1^2. Registration of legal entities and individuals registered as individual entrepreneurs, which are pharmaceutical entities as of January 1, 2020, in the information system, which provided information support for the experiment according to Decree of the Government of the Russian Federation of January 24, 2017 No. 62 "On the Experiment on Marking with Control (Identification) Marks and Monitoring of the Circulation of Certain Types of Medicines for Medical Use", shall be treated as registration in the Track and Trace System.

If during the experiment the data submitted by the pharmaceutical entities to the information system, which provided information support for the experiment, and the documents submitted by them to the Federal Service for Surveillance in Healthcare do not comply with the requirements to data and documents stipulated in the Regulation, which is approved by this Decree, then starting from January 1, 2020 such pharmaceutical entities shall add the outstanding and/or up-to-date data to the Track and Trace System and submit the outstanding and/or up-to-date documents to the Federal Service for Surveillance in Healthcare before July 1, 2020 (inclusive).
(Cl. 1^2 is introduced by Decree of the Government of the Russian Federation of 12/31/2019 No. 1954)

1^3. Those pharmaceutical entities that are manufacturers of the medicine, for which they perform the technological operations that correspond to production stages of medicine prepacking (packing) (in case of medicine manufacturing in the Russian Federation), or that are medicine marketing authorization holders or representative offices of foreign marketing authorization holders in the Russian Federation (in case of medicine manufacturing outside the Russian Federation) shall proceed as follows prior to the medicine introduction into circulation:

enter the medicine data into the Track and Trace System according to the Regulation approved by this Decree, no later than 30 calendar days from the day of their registration in the Track and Trace System;

via the Track and Trace System send the System operator an (electronic) application to obtain marking code emission registrars or remote access to them no later than May 1, 2020 or within 7 calendar days from the day of registration in the Track and Trace System if these pharmaceutical entities need to perform any activities related to circulation of medicines provided that they have the right to perform such activities;

starting from July 1, 2020 provide for application of identification means on primary package of medicine (if secondary package is not available) and on secondary (consumer) package of medicine;

starting from January 1, 2020 have the right to apply medicine identification means on primary package of medicine (if secondary package is not available) and on secondary (consumer) package of medicine.

Therewith, if starting from January 1, 2020 any pharmaceutical entities apply medicine identification means on primary package of the medicine (if secondary package is not available) and on secondary (consumer) package of medicine, then they shall submit data about application of identification means to the Track and Trace System.
(Cl. 1^3 is introduced by Decree of the Government of the Russian Federation of 12/31/2019 No. 1954)

1^4. Those pharmaceutical entities, which perform medical activities and withdraw medicines from circulation when providing medical care, and those pharmaceutical entities, which issue medicine free of charge on prescription, shall via the Track and Trace System send the Track and Trace System operator an (electronic) application to obtain disposal registrars no later than

February 15, 2020 or within 7 calendar days from the day of registration in the Track and Trace System if those pharmaceutical entities need to perform any activities related to circulation of medicines provided that they have the right to perform such activities.
(Cl. 1^4 is introduced by Decree of the Government of the Russian Federation of 12/31/2019 No. 1954 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

1^5. To establish that the Track and Trace System operator shall provide:

that pharmaceutical entities, which are described in Clause 1^3 hereof, are equipped with marking code emission registrars or provided with remote access to such emission registrar devices, which are located in the infrastructure of the Track and Trace System operator, on the conditions stipulated in the Regulation approved by this Decree, no later than 45 calendar days from the day when an application is received from pharmaceutical entities to obtain these devices or remote access thereto;

that pharmaceutical entities, which perform medical activities and withdraw medicines from circulation when providing medical care, and pharmaceutical entities, which issue medicines free of charge on prescription, are equipped with disposal registrars on conditions stipulated in the Regulation approved by this Decree, no later than 45 calendar days from the day when an application is received from pharmaceutical entities to obtain these devices or remote access thereto;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

that information interaction testing for the information systems of pharmaceutical entities and the Track and Trace System is arranged no later than 30 calendar days from the day when an application is received from pharmaceutical entities for information interaction testing.
(Cl. 1^5 is introduced by Decree of the Government of the Russian Federation of 12/31/2019 No. 1954)

1^6. To establish that the Track and Trace System operator shall provide marking codes starting from January 1, 2020 (Cl. 1^6 is introduced by Decree of the Government of the Russian Federation of 12/31/2019 No. 1954)

1^7. To establish that payment for the services on provision of marking codes by the Track and Trace System operator shall be charged starting from July 1, 2020 (Cl. 1^7 is introduced by Decree of the Government of the Russian Federation of 12/31/2019 No. 1954)

2. This Decree shall be implemented by the appropriate federal executive authorities within the maximum number of their employees, which is determined by the Government of the Russian Federation, and budgetary allocations, which are provided for them in the federal budget for supervision and management with regard to the established functions.

3. This Decree shall become effective from the day of its official publishing, except for those provisions given in Clause 4 hereof.

4. Regulation on the Track and Trace System of Medicines for Medical Use, approved by this Decree, concerning medicine manufacturers with regard to identification means application on primary package (concerning medicines for medical use that do not have secondary package) and secondary (consumer) package of medicines for medical use, as well as concerning legal entities and individual entrepreneurs that manufacture, store, import into the Russian Federation, issue, sell, transfer, use, and dispose of medicines for medical use, with regard to adding information about medicines for medical use into the Track and

Trace System of Medicines for Medical Use, shall become effective on the day when the second and the fifth paragraph of Subclause “b”, Clause 7, Article 1 of the Federal Law No. 425-FZ “On Amending the Federal Law “On Medicine Circulation” dated December 28, 2017 enter into force.

Chairman of the Government of
the Russian Federation
D. MEDVEDEV

Approved by
Decree of the Government of the
Russian Federation
of December 14, 2018 No. 1556

REGULATION
ON THE TRACK AND TRACE SYSTEM OF MEDICINES FOR MEDICAL USE

List of modifying documents
(as amended by Decrees of the Government of the Russian Federation of 8/30/2019 No. 1118, of 3/2/2020 No. 219, of 3/20/2020 No. 311, of 7/21/2020 No. 1079, of 11/2/2020 No. 1779, of 12/18/2020 No. 2166, of 1/28/2021 No. 60, of 06/30/2021 No. 1069)

I. General Provisions

1. This Regulation defines:

a) the procedure used to apply identification means on any medicine for medical use (the "medicines"), requirements to their structure and format of the information contained in medicine identification means, their parameters;

b) the procedure used to create, develop, commission, operate, and decommission the Track and Trace System of Medicines (the "Track and Trace System");

c) the procedure for interaction of the Track and Trace System with other state information systems and information systems of legal entities and individual entrepreneurs, which are specified in Part 7 and 10 of Article 67 of the Federal Law "On Medicine Circulation";

d) the procedure used by legal entities and individual entrepreneurs, which manufacture, store, import into the Russian Federation, issue, sell, transfer, use and dispose of medicines, to enter information about medicines and its content;

e) the procedure used to provide information contained in the Track and Trace System.

2. Following are the terms and definitions used in this Regulation:

"aggregation" means a process of bundling medicines into a tertiary (shipping) medicine package at any stage of medicine circulation by a pharmaceutical entity, with application of a corresponding identification code of tertiary (shipping) medicine package and with recording in the Track and Trace System how identification means or identification codes of each medicine in this package correlate with identification code of tertiary (shipping) medicine package;
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

"medicine introduction into circulation":

for manufacturing in the Russian Federation — shall mean operations with medicines from the production stage of medicine prepacking (packing) into primary medicine packages (for medicines without secondary (consumer) medicine package) and secondary (consumer) medicine packages to completing the production stage of release quality control and submitting the documents and data, which are stipulated in Part 1, Article 52^1 of the Federal Law "On Medicine Circulation", to the Federal Service for Surveillance in Healthcare or obtaining a permit described in Part 7, Article 52^1 of the Federal Law "On Medicine Circulation" (in case of manufacturing of immunobiological medicines);
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

for manufacturing outside the Russian Federation — shall mean operations with medicines from the production stage of medicine prepacking (packing) into primary medicine packages (for medicines without secondary (consumer) medicine package) and secondary (consumer) medicine packages to medicine placing at a pharmaceutical warehouse and submitting the documents and data, which are stipulated in Part 2, Article 52^1 of the Federal Law "On Medicine Circulation", to the Federal Service for Surveillance in Healthcare or obtaining a permit described in Part 7, Article 52^1 of the Federal Law "On Medicine Circulation" (in case of manufacturing of immunobiological medicines);
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

this paragraph is no longer effective. - Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

"secondary (consumer) package" shall mean a package received by a consumer and designed to contain a single primary package of medicine or several primary packages of medicine;

"medicine withdrawal from circulation" shall mean medicine sale and issue (including on a prescription) to a consumer, use, transfer for destruction, loss and retirement of medicines, sampling, export of the medicines previously imported to the Russian Federation (re-export), as well as withdrawal from circulation for other reasons;

"global trade item number" shall mean a unique code assigned to a group of goods when they are described in an information resource that enables accounting and storage of reliable data on the goods of the corresponding goods nomenclature;

paragraph ten and eleven are no longer effective — Decree of the Government of the Russian Federation of 3/20/2020 No. 311;

"application identifier" shall mean a set of 2 or more digits, which is located at the beginning of the element string and unambiguously identifies the application and format of the data field following the prefix;
(as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

"pharmaceutical entity identifier" shall mean a unique code assigned by the Track and Trace System to a pharmaceutical entity as a result of its registration in the Track and Trace System based on the data submitted by the pharmaceutical entity on taxpayer identification number for each business place according to the license for medicine manufacturing, license for pharmaceutical activities, license for circulation of narcotics, psychotropic substances, and their precursors, and cultivation of drug-yielding plants (if such

license is available) or on taxpayer code in the country of registration and on code of the country of registration (for pharmaceutical entities that are not recognized as tax residents of the Russian Federation);
(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

"individual serial number of trade item" shall mean a numeric or alphanumeric sequence;

"identification code" shall mean a serial global trade item number, which is a unique identifier of secondary (consumer) medicine package (or, if not applicable, of a primary medicine package), generated by adding an individual serial number of trade item to the global trade item number;
(paragraph is introduced by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

"tertiary (shipping) medicine package identification code" shall mean a sequence of symbols generated according to the requirements of Section III hereof;
(paragraph is introduced by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

"marking code" shall mean a unique sequence of symbols, which consists of an identification code and a verification code, generated to identify the primary package (concerning medicines for medical use without secondary package) and secondary (consumer) package of medicines for medical use;
(paragraph is introduced by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118 as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

"verification code" shall mean a sequence of symbols, which is generated by cryptographic conversion of identification code, allowing to detect fake identification codes when codes are checked using a fiscal memory device and/or technical means intended to check the verification code;
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

"medicines marked with identification means" shall mean medicines with identification means applied on them and with reliable data (including the data about the applied identification means and/or material media that contain identification means) about them submitted to the Track and Trace System according to the established procedure;
(as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

"marking of medicine packages with identification means" shall mean applying the identification means on a secondary (consumer) medicine package (if unavailable, on a primary medicine package);

"medicine description" shall mean a list of characteristics posted by a pharmaceutical entity at the appropriate information resource that enables accounting and storage of reliable data about the goods of the corresponding goods nomenclature;

"primary medicine package" shall mean a facility or a set of facilities which protect medicines against damage and loss, environmental effect, contamination and which are in direct contact with medicines;

"disposal registrar" shall mean the information exchange hardware, which is designed to transfer to the Track and Trace System the information on medicine withdrawal from circulation, that includes hardware and software encryption (cryptographic) technical means with functions of verification code

checking, for which the Federal Security Service of the Russian Federation issued a document on its compliance with the established requirements to encryption (cryptographic) means of data protection applicable to encryption (cryptographic) means for marking code verification;
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

paragraph is no longer effective — Decree of the Government of the Russian Federation of 3/20/2020 No. 311;

"identification means" shall mean a marking code, which is presented in machine-readable form or using other automatic identification tools (technology) and which is generated for application on secondary (consumer) medicine package (if unavailable, on primary medicine package) using methods that prevent separation of the identification means and/or material media containing the identification means from medicine package without damaging it;
(as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

"pharmaceutical entities" shall mean legal entities and individual entrepreneurs that manufacture, store, import into the Russian Federation, issue, sell, transfer, use medicines and hand them over for destruction;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

"tertiary (shipping) medicine package" shall mean a package used to store, transport and transfer a medicine between pharmaceutical entities;
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

"emission registrar" shall mean the information exchange hardware, which is designed to obtain marking codes and transfer to the Track and Trace System the information on marking of medicine packages with identification means, that functions as technical means for verification code checking, for which the Federal Security Service of the Russian Federation issued a document on its compliance with the established requirements to encryption (cryptographic) means of data protection applicable to encryption (cryptographic) means for marking code verification, or that includes technical means for verification code checking, for which the Federal Security Service of the Russian Federation issued a document on its compliance with the established requirements to encryption (cryptographic) means of data protection applicable to encryption (cryptographic) means for marking code verification;
(as amended by Decree of the Government of the Russian Federation of 3/2/2020 No. 219)

"prepacking (packing) of medicine" shall mean a production stage when a medicine is placed into its primary package or secondary (consumer) package;

this paragraph is no longer effective. - Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

"issuer of tertiary (shipping) package identification code" shall mean a pharmaceutical entity that generates and applies the identification code of tertiary (shipping) medicine package on a tertiary (shipping) package of medicines;
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

"issuer of identification means" shall mean the medicine manufacturer that is engaged in the production stage of medicine prepacking (packing) with application of identification means on secondary (consumer) medicine package (if unavailable, on primary medicine package) when the medicine is manufactured in the Russian Federation; or the holder of medicine marketing authorization (the "marketing authorization") when the medicine is manufactured outside the Russian Federation; or a representative office of the foreign holder of marketing authorization in the Russian Federation when the medicine is manufactured outside the Russian Federation.
(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

II. Identification Means Characteristics, Procedure of Application, and Requirements to Structure and Format of the Information Contained in Identification Means

3. Identification means applied on secondary (consumer) medicine package (if unavailable, on primary medicine package) has the following characteristics:

a) two-dimensional bar code is applied with dot characters according to the requirements of the National Standard of the Russian Federation (GOST R ISO/IEC 16022-2008 "Automatic Identification. Bar Coding. Data Matrix Symbology Specification") that is approved by an Order of the Federal Agency for Technical Regulation and Metrology;

b) two-dimensional bar code is applied with the quality class level C or higher according to the requirements of the National Standard of the Russian Federation (GOST R ISO/IEC 15415-2012 "Automatic Identification and Data Capture Techniques. Bar code Symbol Test Specification for Print Quality Assessment. Two-Dimensional Symbols") that is approved by an Order of the Federal Agency for Technical Regulation and Metrology;

c) two-dimensional bar code is printed using the ECC-200 error correction method according to the requirements of the National Standard of the Russian Federation (GOST R ISO/IEC 16022-2008 "Automatic Identification. Bar Coding. Data Matrix Symbology Specification") that is approved by an Order of the Federal Agency for Technical Regulation and Metrology;

d) when medicine identification means are applied, ASCII encoding is used based on the National Standard of the Russian Federation (GOST R ISO/IEC 16022-2008 "Automatic Identification. Bar Coding. Data Matrix Symbology Specification") that is approved by an Order of the Federal Agency for Technical Regulation and Metrology.

4. The data, which are contained in identification means, are applied by manufacturer as two-dimensional bar code on secondary (consumer) medicine package (if unavailable, on primary medicine package) or on material media (label) by means of printing, which prevents separation of the material medium containing the identification means from medicine package without damaging it.

In case of import into the Russian Federation when the medicine batch is manufactured outside the Russian Federation (excluding medicines imported from member states of the Eurasian Economic Union), the two-dimensional bar code may be printed on a material medium (label) that prevents separation of the material medium (label), which contains the identification means, from medicine package without damaging it, with subsequent application of the material medium (label) on secondary (consumer) medicine packages (if unavailable, on primary medicine packages) at the customs warehouse, which address is specified as business place in the license for pharmaceutical activities of the medicine wholesaler.

(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)(Cl. 4 as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

5. Following is the structure of information contained in identification means:

data Matrix symbology attribute — a sign with code 232 in the table of ASCII symbols;

first data group — global trade item number, which consists of 14 numeric symbols, preceded by application identifier (01);

second data group — individual serial number of trade item, which consists of 13 symbols of numeric or alphanumeric sequence (Latin letters), preceded by application identifier (21). The end symbol for this data group is a special divider with code 29 in the table of ASCII symbols, or FUNCTION 1 symbol (FNC1);
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

third data group — verification key identifier (individual sequence number) provided to identification means issuers by the Track and Trace System operator as part of verification code according to this Regulation, which consists of 4 symbols (numbers, lowercase and uppercase Latin letters) and which is preceded by application identifier (91). The end symbol for this data group is a special divider with code 29 in the table of ASCII symbols, or FUNCTION 1 symbol (FNC1);
(as amended by Decrees of the Government of the Russian Federation of 8/30/2019 No. 1118, of 3/20/2020 No. 311)

fourth data group — verification code value provided to identification means issuers by the Track and Trace System operator as part of verification code according to this Regulation, which is preceded by application identifier (92) and which consists of 44 symbols (numbers, lowercase and uppercase Latin letters, and special symbols).
(as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

Paragraphs seven through ten are no longer effective — Decree of the Government of the Russian Federation of 8/30/2019 No. 1118.

Data groups shall be placed in their order — from the first group to the forth group.
(as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

Individual serial number of trade item is generated so that it is unique for each global trade item number for the entire period of operation of the Track and Trace System.

Global trade item number and individual serial number of trade item are repeated as legible printed text.

III. Procedure to Obtain Marking Codes, Generate Identification Codes for Tertiary (Shipping) Medicine Package, and Register Them in the Track and Trace System

(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

6. Issuers of identification means can obtain marking codes from the Track and Trace System operator using emission registrars.
(as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

7. An issuer of identification means that is registered in the Track and Trace System shall submit an application to obtain marking codes to the Track and Trace System operator. The application shall be sent by means of an emission registrar. Emission registrars interact with information systems of the issuer of identification means using those data formats, which are posted by the Track and Trace System operator on the official website of the Track and Trace System in the information and telecommunications network Internet. An application to obtain marking codes contains the following information:
(as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

a) identification code if the issuer of identification means generates the individual serial number of trade item;
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

b) global trade item number and the quantity of individual serial numbers of trade item if the Track and Trace System operator generates the individual serial number of trade item.

8. Marking code is generated by the Track and Trace System operator by assigning a verification code to each identification code and is included in the identification means register of the Track and Trace System operator.
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

The Track and Trace System operator shall, no later than 2 hours after receiving an application to obtain marking codes, send a list of generated marking codes to the issuer of identification means.
(Cl.8 as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

8^1. Issuers of identification means shall be denied any marking codes for the following reasons:

a) there are no data, which are stipulated in Clause 7 hereof, in the application to obtain marking codes;

b) there are no data that the issuer of identification means is registered in the Track and Trace System;

c) the Track and Trace System operator does not have any data on the emission registrar which was used to send the application to obtain marking codes;

d) the Track and Trace System has any previously registered data on any identification code provided according to Subclause "a", Clause 7 hereof;
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

e) the Track and Trace System does not have any data on global trade item number provided according to Subclause "b", Clause 7 hereof.

(Cl. 8^1 is introduced by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

9. The Track and Trace System operator ensures that issuers of identification means receive marking codes by equipping the issuers of identification means with emission registrars.

The Track and Trace System operator shall equip issuers of identification means with emission registrars, which includes providing remote access to an emission registrar located in the infrastructure of Track and Trace System operator, free of charge. For the purposes of such equipping the issuer of identification means shall enter into contracts with the Track and Trace System operator, which include conditions of providing an emission registrar and its routine maintenance free of charge or conditions of rendering a service of providing an emission registrar, which is located in the infrastructure of the Track and Trace System operator, by providing remote access to it free of charge. The decision on the choice of equipment shall be made by the issuer of identification means. Standard form of these contracts shall be approved by the Ministry of Industry and Trade of the Russian Federation.

Those issuers of identification means, which are not recognized as tax residents of the Russian Federation and which do not have any representative offices in the Russian Federation, may be equipped and the contracts with the Track and Trace System operator, which are stipulated in paragraph two of this Clause, may be concluded through an authorized representative.
(Cl. 9 as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

9^1. After receiving any marking code the issuer of identification means shall ensure that the code is converted into identification means, that the identification means are applied on secondary (consumer) medicine package (if unavailable, on primary medicine package) or on material medium (label) and shall submit data about application of the identification means into the Track and Trace System according to paragraph one of Clause 35 or Clause 36 hereof no later than one of the following dates:

medicine introduction into circulation if any identification means, which have been converted from the corresponding marking code, are applied on the package (label) of this medicine, when the medicine is manufactured in the Russian Federation;

medicine delivery to the place of arrival in the Russian Federation and of filing a goods customs declaration according to the procedure of release for domestic consumption or of filing a goods customs declaration according to the procedure of release for domestic consumption of a medicine marked at the customs warehouse as described in paragraph two of Clause 4 hereof, when the medicine is manufactured outside the Russian Federation (excluding medicines that are imported from member states of the Eurasian Economic Union);

medicine import into the Russian Federation to a pharmaceutical warehouse, when the medicine is manufactured outside the Russian Federation — for medicines that are imported from member states of the Eurasian Economic Union.

Payment to the Track and Trace System operator for the service of marking code provision, as stipulated in Decree of the Government of the Russian Federation of May 8, 2019 No. 577 "On Approval of the Amount of Payment for the Services on Provision of Marking Codes Required to Generate Identification Means and Monitor the Turnover of Goods That Are Subject to Mandatory Marking with Identification Means, and On the Payment Procedure" is made by the issuer of identification means before the marking code is received or within 180 calendar days from the date when the marking code is received, but no later than one of the following dates:

medicine introduction into circulation if any identification means, which have been converted from the corresponding marking code, are applied on the package (label) of this medicine, when the medicine is manufactured in the Russian Federation;

medicine delivery to the place of arrival in the Russian Federation and of filing a goods customs declaration according to the procedure of release for domestic consumption or of filing a goods customs declaration according to the procedure of release for domestic consumption of a medicine marked at the customs warehouse as described in paragraph two of Clause 4 hereof, when the medicine is manufactured outside the Russian Federation (excluding medicines that are imported from member states of the Eurasian Economic Union);

medicine import into the Russian Federation to a pharmaceutical warehouse, when the medicine is manufactured outside the Russian Federation — for medicines that are imported from member states of the Eurasian Economic Union.

In this case the Track and Trace System operator registers (enters) information about application of identification means, which is specified by the issuer of identification means in the data on application of identification means, in (to) the Track and Trace System once the payment is received for the services on provision of the marking code converted into the corresponding identification means.

The decision on the choice of payment option for the service of marking code provision shall be made by the issuer of identification means.

If the issuer of identification means pays for the service of marking code provision before submitting the data on application of identification means, which are converted from the corresponding marking code, such a service shall be recognized as rendered by the Track and Trace System operator at the moment when the issuer of identification means receives the paid marking codes.

If the issuer of identification means pays for the service of marking code provision after submitting the data on application of identification means, which are converted from the corresponding marking code, such a service shall be recognized as rendered by the Track and Trace System operator at the moment when the Track and Trace System operator registers (enters) information from the data on application of identification means, which are converted from the corresponding marking code, in (to) the Track and Trace System.

If, according to Decree of the Government of the Russian Federation of May 8, 2019 No. 577 "On Approval of the Amount of Payment for the Services on Provision of Marking Codes Required to Generate Identification Means and Monitor the Turnover of Goods That Are Subject to Mandatory Marking with Identification Means, and On the Payment Procedure", the service of marking code provision is not payable, then after receiving any marking code the issuer of identification means shall ensure that it is converted into identification means, the identification means are applied on secondary (consumer) medicine package (if unavailable, on primary medicine package) or on a material medium (label) and shall within 180 calendar days submit the data on identification means application to the Track and Trace System pursuant to paragraph on of Clause 35 or to Clause 36 hereof, but no later than one of the following dates:

medicine introduction into circulation if any identification means, which have been converted from the corresponding marking code, are applied on the package (label) of this medicine, when the medicine is manufactured in the Russian Federation;

medicine delivery to the place of arrival in the Russian Federation and of filing a goods customs declaration according to the procedure of release for domestic consumption or of filing a goods customs declaration according to the procedure of release for domestic consumption of a medicine marked at the customs warehouse as described in paragraph two of Clause 4 hereof, when the medicine is manufactured outside the Russian Federation (excluding medicines that are imported from member states of the Eurasian Economic Union);

medicine import into the Russian Federation to a pharmaceutical warehouse, when the medicine is manufactured outside the Russian Federation — for medicines that are imported from member states of the Eurasian Economic Union.
(Cl. 9^1 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

9^2. Marking codes shall be canceled in the following cases:

a) violation of the due date, which is stipulated in paragraph five through eight of Clause 9^1 hereof, for payment for the services of marking code provision;

b) violation of the due date, which is stipulated in paragraph one through four and/or thirteen through sixteen of Clause 9^1 hereof, for submitting the data on application of identification means to the Track and Trace System.
(Cl. 9^2 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

9^3. Registration of data on application of identification means in the Track and Trace System may be rejected for the following reasons:

a) the identification codes, which are specified in the data on application of identification means, are not available in the register of identification means of the Track and Trace System operator;

b) data on application of identification means are provided by the issuer of identification means after the due date, which is stipulated in paragraph one through four and/or thirteen through sixteen of Clause 9^1 hereof;

c) the Track and Trace System operator does not have any data on the emission registrar which was used to send data to the Track and Trace System;

d) there is no confirmation of payment for marking codes converted into identification means, the data on which application, as stipulated in paragraph one of Clause 35 or Clause 36 hereof, should be submitted to the Track and Trace System by the issuer of identification means.
(Cl. 9^3 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

10. Identification code of tertiary (shipping) medicine package shall be generated based on the regional standard (GOST ISO/IEC 15417-2013 "Information Technology. Automatic Identification and Data Capture Techniques. Code 128 Bar Code Symbology Specification"), which is approved by an Order of the Federal Agency for Technical Regulation and Metrology, consists of 18 numeric symbols and has the following data structure:
(as amended by Decrees of the Government of the Russian Federation of 3/20/2020 No. 311, of 7/21/2020 No.1079)

application identifier (00);

extension character for identification code of tertiary (shipping) medicine package;
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

registration number of pharmaceutical entity that is obtained in the appropriate information resource, which enables accounting and storage of reliable data about the goods of the corresponding goods nomenclature;

serial number of tertiary (shipping) medicine package;
(as amended by Decrees of the Government of the Russian Federation of 8/30/2019 No. 1118, of 3/20/2020 No. 311)

control number (a number that is calculated according to a special algorithm from the previous digits and is used to guarantee data integrity).

The data included in the identification code of tertiary (shipping) medicine package may be repeated as legible printed text.
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

Identification code of tertiary (shipping) medicine package is generated and applied on tertiary (shipping) medicine package by the issuers of identification codes of tertiary (shipping) medicine package by means of printing or labeling.
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

IV. Rules for Creating, Commissioning, Operating, and Decommissioning of the Track and Trace System

11. The Track and Trace System shall be created, developed, commissioned, operated, decommissioned by the Track and Trace System operator as agreed with the Ministry of Health of the Russian Federation and the Federal Service for Surveillance in Healthcare in accordance with the requirements to the procedure of creating, developing, commissioning, operating, and decommissioning of state information systems and further storage of information contained in their databases that are approved by Decree of the Government of the Russian Federation of July 6, 2015 No. 676 "On Requirements to the Procedure of Creating, Developing, Commissioning, Operating, and Decommissioning of State Information Systems and Further Storage of Information Contained in Their Databases" and with this Regulation.

12. The Track and Trace System shall be created, developed, and operated on the following basis.

a) it shall be ensured that the information, which is received and sent using the Track and Trace System, is complete, reliable, safe, and timely provided;

b) medicine manufacturers shall be provided with information from the Track and Trace System that concerns medicine series and batches, which are produced by them and are in civil circulation in the Russian Federation, free of charge;

c) organizational and methodological support of the Track and Trace System shall be unified;

d) unified registers, classifiers, and catalogs of the Track and Trace System shall be used, including the mandatory ones for information systems of legal entities and individual entrepreneurs, which are

specified in Part 7 and 10 of Article 67 of the Federal Law “On Medicine Circulation”;

e) regulated access to the Track and Trace System shall be provided;

f) the Track and Trace System operation shall be uninterrupted.

13. The Track and Trace System shall be commissioned by a workgroup formed by the Track and Trace System operator, involving representatives of the federal executive authorities concerned.

14. The Track and Trace System shall ensure:

a) validity check of identification means;

b) tracking and tracing of medicines from the medicine manufacturer to the end consumer;

c) blocking of acceptance of the information provided to the Track and Trace System according to this Regulation.

15. The Track and Trace System contains the following information:

a) data on pharmaceutical entities;

b) data on medicines and their circulation.

16. Following are the main sources of information contained in the Track and Trace System:

a) pharmaceutical entities;

b) federal executive authorities when they perform their functions using any state information systems.

17. Availability factor of the Track and Trace System is at least 99.5 percent, excluding planned maintenance periods.

Maintenance of the Track and Trace System shall take place no more than 4 times a year, maintenance period shall be no more than 24 hours.

V. Procedure for Interaction of the Track and Trace System with Other State Information Systems and Information Systems of Pharmaceutical Entities

18. The Track and Trace System interacts with the following information systems:

a) the unified register of licenses for medicine manufacturing;

b) the unified register of licenses, including the licenses issued by state bodies of constituent entities of the Russian Federation according to the delegated authority to license certain types of healthcare activities;

c) the unified state information system in healthcare;

d) the unified state register of legal entities;

e) the unified state register of individual entrepreneurs;

f) the state register of accredited branches and representative offices of foreign legal entities;

g) the automated information system of the Federal Service for Surveillance in Healthcare;

h) the unified automated customs information system;

i) information systems of pharmaceutical entities.

19. Appendix 1 describes the data, which should be submitted by state information systems of the federal executive authorities to the Track and Trace System, and the data, which should be transferred from the Track and Trace System.

20. During information interaction the Track and Trace System exchanges data with state information systems of the concerned federal executive authorities and executive authorities of constituent entities of the Russian Federation, including by means of the infrastructure that provides for information and technology interaction of information systems used to render state and municipal services and to perform state and municipal functions electronically.

The Track and Trace System shall be connected to the Unified Interagency Electronic Interaction System according to Decree of the Government of the Russian Federation of September 8, 2010 No. 697 "On the Unified Interagency Electronic Interaction System" free of charge.

21. The Track and Trace System and information systems of pharmaceutical entities interact by means of electronic information services, using standard protocols and interfaces of electronic interaction.

22. Specifications and requirements for technological compatibility of the Track and Trace System and the information systems specified in Clause 18 hereof shall be established by the Track and Trace System operator according to the legal requirements of the Russian Federation in information technology, as agreed with the Ministry of Digital Development, Communication and Mass Media of the Russian Federation and with operator of the information system with which interaction takes place.

VI. Procedure for Entering the Medicine Information into the Track and Trace System by Pharmaceutical Entities, and Its Content

23. Medicine information shall be entered into the Track and Trace System by pharmaceutical entities after they are registered in the Track and Trace System and provided with a user account of pharmaceutical entity.

A pharmaceutical entity can be registered in the Track and Trace System and provided with a user account based on reliable data, which should be submitted by the pharmaceutical entities to the Track and Trace System electronically, and documents, which should be submitted to the Federal Service for Surveillance in Healthcare.

24. In order to be registered in the Track and Trace System those pharmaceutical entities, which are recognized as tax residents of the Russian Federation, individual entrepreneurs, and representative offices

of foreign marketing authorization holders in the Russian Federation, shall electronically enter the following data, signed with enhanced qualified electronic signature of the head of organization (representative office of foreign organization in the Russian Federation) or individual entrepreneur, into the registration form of the Track and Trace System available at the official website of the Track and Trace System operator in the information and telecommunications network Internet:

taxpayer identification number;

data on availability or lack of license for medicine manufacturing, license for pharmaceutical activities (including wholesale and retail sale of medicines), license for circulation of narcotics, psychotropic substances, and their precursors, and cultivation of drug-yielding plants, and license for medical care;
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

last name, first name, patronymic name (if any), and telephone number of the contact person;

e-mail.

Those pharmaceutical entities, which are recognized as tax residents of the Russian Federation, individual entrepreneurs that do not have a license for medicine manufacturing, a license for pharmaceutical activities (including wholesale and retail sale of medicines), a license for circulation of narcotics, psychotropic substances, and their precursors, and cultivation of drug-yielding plants, and a license for medical care, as well as representative offices of foreign marketing authorization holders in the Russian Federation, which do not have a license for medicine manufacturing, a license for pharmaceutical activities (including wholesale and retail sale of medicines), a license for circulation of narcotics, psychotropic substances, and their precursors, and cultivation of drug-yielding plants, and a license for medical care, shall also, no later than 10 calendar days from the date of entering the data stipulated in paragraph two through five of this Clause, submit an application to register in the Track and Trace System (the "application") to the Federal Service for Surveillance in Healthcare on paper as per the form approved by the Ministry of Health of the Russian Federation.
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

Pharmaceutical entities recognized as tax residents of the Russian Federation and individual entrepreneurs, which have licenses for medicine manufacturing, licenses for pharmaceutical activities (including wholesale and retail sale of medicines), licenses for circulation of narcotics, psychotropic substances, and their precursors, and cultivation of drug-yielding plants, and licenses for medical care, may be registered in the Track and Trace System using the federal state information system "Unified Identification and Authentication System in the Infrastructure That Provides for Information and Technology Interaction of Information Systems, Which Are Used to Render State and Municipal Services Electronically".
(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

25. In order to be registered in the Track and Trace System those pharmaceutical entities, which are foreign marketing authorization holders that are not recognized as tax residents of the Russian Federation and do not have any representative offices in the Russian Federation, shall electronically enter the following data in the registration form of the Track and Trace System available at the official website of the Track and Trace System operator in the information and telecommunications network Internet:

name of the marketing authorization holder;

taxpayer number in the country of registration;

code of the country of registration;

last name, first name, patronymic name (if any), and telephone number of the contact person;

e-mail.

Authorized representatives of those pharmaceutical entities, which are foreign marketing authorization holders that are not recognized as tax residents of the Russian Federation and do not have any representative offices in the Russian Federation, shall also, no later than 10 calendar days from the date of entering the data stipulated in paragraph two through six of this Clause, submit original documents, which confirm the right to represent these pharmaceutical entities, and an application to the Federal Service for Surveillance in Healthcare on paper as per the form approved by the Ministry of Health of the Russian Federation.

26. Data submitted to the Track and Trace System for registration are processed and checked automatically, including by means of interacting with other state information systems using the Unified Interagency Electronic Interaction System, within 14 business days from the date when pharmaceutical entities submit the data to the Track and Trace System.

The Federal Service for Surveillance in Healthcare shall review the applications, which are provided according to paragraph six of Clause 24 hereof, and the applications and original documents, which are provided according to paragraph seven of Clause 25 hereof, within no more than 5 business days and shall send the information on the results of review of applications and original documents to the Track and Trace System within 1 business day from the day when the corresponding decision is made.

The Federal Service for Surveillance in Healthcare shall make a decision whether to register (or refuse to register) any pharmaceutical entity in the Track and Trace System, using the Track and Trace System functions.

It shall be decided to register a pharmaceutical entity in the Track and Trace System if there are no discrepancies between the information in the application and the data entered in the Track and Trace System (when applications were submitted according to paragraph six of Clause 24 and seven of Clause 25 hereof) and if validity of the data entered in the Track and Trace System is confirmed.

27. A pharmaceutical entity shall be denied registration in the Track and Trace System for the following reasons:

a) for medicine manufacturers in the Russian Federation that are engaged in the production stages of medicine prepacking (packing) into secondary (consumer) packages and/or tertiary (shipping) packages (if unavailable, into primary medicine packages) of medicines:

the data on the owner of qualified certificate of electronic signature verification key (the “qualified certificate”) does not match the data on the head of organization, and there are no data on the qualified certificate issued to the head of organization;

there are no data concerning any records in the Unified State Register of Legal Entities;

there are no data concerning a valid license in the Unified Register of Licenses for Medicine Manufacturing;

b) for marketing authorization holders (when the medicine is manufactured outside the Russian Federation) that are organizations recognized as tax residents of the Russian Federation or individual entrepreneurs and that do not have a license for medicine manufacturing, a license for pharmaceutical activities (including wholesale and retail sale of medicines), a license for circulation of narcotics, psychotropic substances, and their precursors, and cultivation of drug-yielding plants, and a license for medical care:
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

the data on the owner of qualified certificate does not match the data on the head of organization or individual entrepreneur, there are no data on qualified certificate issued to the head of organization or to individual entrepreneur;

there are no data on any records in the Unified State Register of Legal Entities or the Unified State Register of Individual Entrepreneurs;

there are any discrepancies between the information in the application, which is provided according to paragraph six of Clause 24 hereof, and the data, which is submitted to the Track and Trace System;

c) for foreign marketing authorization holders that are not recognized as tax residents of the Russian Federation and that do not have representative offices in the Russian Federation — there are any discrepancies between the information in the application, which is provided according to paragraph seven of Clause 25 hereof, and the data, which is submitted to the Track and Trace System;

d) for representative offices of foreign marketing authorization holders in the Russian Federation:

the data on the owner of qualified certificate does not match the data on the head of representative office, and there are no data on qualified certificate issued to the head of representative office;

there are no data on any records in the State Register of Accredited Branches and Representative Offices of foreign legal entities;

there are any discrepancies between the information in the application, which is provided according to paragraph six of Clause 24 hereof, and the data, which is submitted to the Track and Trace System (for representative offices of foreign marketing authorization holders in the Russian Federation that do not have a license for medicine manufacturing, license for pharmaceutical activities (including wholesale and retail sale of medicines), license for circulation of narcotics, psychotropic substances, and their precursors, and cultivation of drug-yielding plants, and license for medical care);
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

e) for medicine wholesalers (including those which perform outsourcing functions), medicine retailers, medical organizations, and individual entrepreneurs:
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

the data on the owner of qualified certificate does not match the data on the head of organization, and there are no data on qualified certificate issued to the head of organization;

there are no data on any records in the Unified State Register of Legal Entities or the Unified State Register of Individual Entrepreneurs;

there are no data on any valid license in the unified register of licenses, including the licenses issued by state bodies of constituent entities of the Russian Federation according to the delegated authority to license certain types of activities.
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

28. Using the functions of the Track and Trace System, the Track and Trace System operator shall send a corresponding notification to the e-mail, which is specified with the data, as a result of registration of a pharmaceutical entity in the Track and Trace System and its provision with a user account. The same e-mail address may not be used multiple times to register user accounts of different pharmaceutical entities.

29. When activating the user account functions, a pharmaceutical entity that received a notification on registration in the Track and Trace System shall submit a list of business place addresses to the Track and Trace System by selecting an address from those specified in licenses for medicine manufacturing, licenses for pharmaceutical activities (including wholesale and retail sale of medicines), license for circulation of narcotics, psychotropic substances, and their precursors, and cultivation of drug-yielding plants, and licenses for medical care, as well as a list of pharmaceutical warehouses (of these licenses are available).
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

A pharmaceutical entity, which is a holder of marketing authorization for a medicine manufactured outside the Russian Federation, and/or its representative office in the Russian Federation that received a notification on registration in the Track and Trace System shall submit to the Track and Trace System the information about those production sites, which are engaged in the production stage of medicine prepacking (packing) into secondary (consumer) medicine packages (if unavailable, into primary medicine packages) and the production stage of release quality control.

30. Pharmaceutical entities shall submit data to the Track and Trace System on the basis of electronic services developed by the Track and Trace System operator, using standard protocols and interfaces of electronic interaction.

Pharmaceutical entities, which are recognized as tax residents of the Russian Federation, are individual entrepreneurs, and are representative offices of foreign organizations in the Russian Federation being marketing authorization holders, shall log in to the Track and Trace System by means of a qualified certificate.

Pharmaceutical entities, which are marketing authorization holders that are not recognized as tax residents of the Russian Federation and do not have any representative offices in the Russian Federation, shall log in to the Track and Trace System by means of a basic electronic signature.

Pharmaceutical entities, which are recognized as tax residents of the Russian Federation, and individual entrepreneurs may log in to the Track and Trace System by using the federal state information system “Unified Identification and Authentication System in the Infrastructure That Provides for Information and Technology Interaction of Information Systems, Which Are Used to Render State and Municipal Services Electronically”.
(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

31. The data, which are submitted to the Track and Trace System, shall be generated and presented as electronic documents signed with an enhanced qualified electronic signature, except for the cases stipulated in paragraph two to six of this Clause.

The following shall not be signed with an enhanced qualified electronic signature:

data on retail sale of medicines that are electronically submitted by pharmaceutical entities as part of fiscal documents according the laws of the Russian Federation regarding the use of control and cash register equipment;

data on medicine withdrawal from circulation that are electronically submitted by pharmaceutical entities using disposal registrars or control and cash register equipment (in case of prescription medicines issued free of charge or at a discount);

data that are electronically submitted by pharmaceutical entities using emission registrars;

data that is submitted according to this Regulation by pharmaceutical entities, which are not recognized as tax residents of the Russian Federation.

32. Data shall be submitted to the Track and Trace System by sending files in the format and as per the instructions, which describe how data should be provided by pharmaceutical entities, approved by the Ministry of Health of the Russian Federation and posted by the Track and Trace System operator on its official website in the information and telecommunications network Internet.
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

The date of provision of information to the track and trace system shall be considered a date, recorded in the receipt of acceptance of information, produced during its successful processing and recording in the track and trace system in the form of electronic document, except for provision of the information as per clause 44 hereof by the pharmacy organization, engaged in retail trading of medicines, marked with identification means, and in issue of prescription medicines, marked with identification means, at a discount, by the pharmaceutical entity, performing medical activity and withdrawal from circulation of medicines, marked with identification means, during medical care, and by pharmaceutical entity engaged in release of medicines marked with identification means free-of-charge on medicine prescription. The date of provision of information to the track and trace system in the stated cases shall be considered a date of sending of the information to the track and trace system by the indicated pharmaceutical entities.
(as amended by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

Before February 1, 2021, if the pharmaceutical entity fails to receive the receipt on acceptance of the information as per the second paragraph hereof, when providing the information to the track and trace system as per the paragraph three of clause 35, clauses 37 - 38(1), 40, 41, 43, 44, 44(2) and 45 hereof within 15 minutes from the moment of provision, the pharmaceutical entity shall be entitled to perform further operations with the medicines, without waiting for the receipt on acceptance of the information to be received.
(paragraph is introduced by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

In case of medicines, the details of which have been submitted in accordance with sections 1 and 2 of article 52.1 of the Federal Law "On Medicine Circulation" to the Federal Service for Surveillance in Healthcare before February 2021, or for which permits for introduction into civil circulation of immunobiologicals stipulated in Part 7 of Article 52.1 of the Federal Law "On Medicine Circulation" have

been issued before February 1, 2021, pharmaceutical entity shall be entitled to perform further operations with the medicines in accordance with the procedure provided for in paragraph three hereof until the medicines are expired. (paragraph is introduced by Decree of the Government of the Russian Federation of 1/28/2021 No. 60)

When handling any medicine, a pharmaceutical entity shall submit data to the Track and Trace System in due sequence, except for the cases stipulated herein. Data on another operation with a medicine shall be submitted after the pharmaceutical entity receives confirmation that the data on the previous operation with the medicine have been successfully processed by the Track and Trace System.

The format of interaction of information systems of pharmaceutical entities with the Track and Trace System will be changed no more than once in 180 days, except when this format needs to be changed in the cases stipulated in the laws of the Russian Federation.
(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

33. The following pharmaceutical entities shall enter data to the information resource, which enables accounting and storage of reliable data on the goods by the corresponding goods nomenclature, and the Track and Trace System when describing any medicines:

for medicines produced in the Russian Federation — medicine manufacturers that finish the production stage of prepacking (packing) of medicines into secondary (consumer) medicine packages (if unavailable, into primary medicine packages);

for medicines manufactured outside the Russian Federation (in case of foreign manufacturing) — marketing authorization holders and/or their representative offices in the Russian Federation or authorized representatives with regard to data entering into the information resource that enables accounting and storage of reliable data on the goods by the corresponding goods nomenclature.
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

Appendix 2 contains a list of data for medicine description to be submitted by pharmaceutical entities to the information resource that enables accounting and storage of reliable data on the goods by the corresponding goods nomenclature.

Those pharmaceutical entities, which are specified in paragraph two and three of this Clause, shall register medicines in the Track and Trace System based on an electronic application with the following content:

global trade item number;

number of marketing authorization and date of medicine registration in the state register of medicines.

The received data shall be processed automatically by generating a request to obtain medicine data from the unified state information system in healthcare and from the information resource that enables accounting and storage of reliable data on the goods by the corresponding goods nomenclature.

34. Appendix 3 describes the data to be submitted by pharmaceutical entities to the Track and Trace System during medicine introduction into circulation.

Appendix 4 describes the data to be submitted by pharmaceutical entities to the Track and Trace

System during medicine withdrawal from circulation.

35. As part of medicine introduction into circulation in the Russian Federation for medicines manufactured in the Russian Federation, the pharmaceutical entity, which prepacks (packs) medicines into secondary (consumer) packages (if unavailable, into primary packages), shall use an emission registrar to submit the data, which are stipulated in Clause 1 of Appendix 3 hereto, to the Track and Trace System before providing data on further handling of such medicines.

(as amended by Decree of the Government of the Russian Federation of 8/30/2019 No.1118)

In case of medicine sampling as part of quality control of the manufactured medicine, the pharmaceutical entity that takes medicine samples shall submit the data, which are stipulated in Clause 1 of Appendix 4 hereto, to the Track and Trace System.

(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No.1079)

The pharmaceutical entity, which is engaged in the production stage of medicine release quality control, shall submit the data, which are stipulated in Clause 2 of Appendix 3 hereto, to the Track and Trace System before providing data on further handling of medicines introduced into civil circulation, within 5 business days from the date when the production stage of release quality control is finished and the documents and data, which are stipulated in Part 1 of Article 52^1 of the Federal Law "On Medicine Circulation", are submitted to the Federal Service for Surveillance in Healthcare or the permit is received as stipulated in Part 7 of Article 52^1 of the Federal Law "On Medicine Circulation" (for manufacturing of immunobiological medicines).

(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

36. As part of medicine introduction into circulation in the Russian Federation for medicines manufactured outside the Russian Federation, the pharmaceutical entity, which is a marketing authorization holder or a representative office of a foreign marketing authorization holder in the Russian Federation, shall use an emission registrar to submit the data, which are stipulated in Clause 3 of Appendix 3 hereto, to the Track and Trace System when finishing the production stage of medicine packing (if secondary package is unavailable, prepacking) or marking of medicine packages with identification means at the customs warehouse according to paragraph two of Clause 4 hereof, before providing any data on further handling of such medicines.

(as amended by Decrees of the Government of the Russian Federation of 8/30/2019 No.1118, of 7/21/2020 No.1079)

In case of marking of medicine packages with identification means at the customs warehouse according to paragraph two of Clause 4 hereof, the pharmaceutical entity, which is a marketing authorization holder or a representative office of a foreign marketing authorization holder in the Russian Federation, shall submit the data, which are stipulated in Clause 3^1 of Appendix 3 hereto, to the Track and Trace System before providing any data, which are stipulated in paragraph one of this Clause.

(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No.1079)

37. For medicine import into the Russian Federation, data may be submitted to the Track and Trace System by the pharmaceutical entity, which ships the medicines to the Russian Federation (the "direct order of data submission for medicine import into the Russian Federation"), or by the pharmaceutical entity, which imports the medicines into the Russian Federation (the "reverse order of data submission for medicine import into the Russian Federation"), except for the case when medicine packages are marked with identification means at the customs warehouse according to paragraph two of Clause 4 hereof.

Direct or reverse order of data submission for medicine import into the Russian Federation shall be selected by pharmaceutical entities, which submit these data, on their own.

If the direct order of data submission for medicine import into the Russian Federation is selected, the pharmaceutical entity, which is a marketing authorization holder or a representative office of a foreign marketing authorization holder in the Russian Federation, shall submit the data, which are stipulated in Clause 4 of Appendix 3 hereto, to the Track and Trace System within 45 business days from the date of medicine shipment to the Russian Federation, before the medicines are delivered to the place of arrival in the Russian Federation and the data on further handling of such medicines are submitted.

Before providing any data on further handling of these medicines the pharmaceutical entity, which imports the medicines into the Russian Federation, shall also confirm reliability of the data in the Track and Trace System by submitting the data, which are stipulated in Clause 7 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when the medicines are delivered to the place of arrival in the Russian Federation and when the data on medicine shipment to the Russian Federation are registered in the Track and Trace System.

If the reverse order of data submission for medicine import into the Russian Federation is selected, the pharmaceutical entity, which imports the medicines into the Russian Federation, shall submit the data, which are stipulated in Clause 5 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date of medicine delivery to the place of arrival in the Russian Federation or the date of aggregation completion (if medicines are aggregated after they are delivered to the place of arrival in the Russian Federation), before providing any data on the decision of the customs authorities to release the medicines for domestic consumption.

Before providing any data on further handling of these medicines the pharmaceutical entity, which is a marketing authorization holder or a representative office of a foreign marketing authorization holder in the Russian Federation, shall also confirm reliability of the data in the Track and Trace System by submitting the data, which are stipulated in Clause 7 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when the data on medicine import into the Russian Federation are registered in the Track and Trace System.

Before July 1, 2021, confirmation of reliability of the information provided in the track and trace system during import of the medicines into the Russian Federation, can be carried out by the pharmaceutical entity who is a marketing authorization holder or owner, or a representative office of a foreign organization in the Russian Federation who is the marketing authorization holder or owner, as per paragraph six hereof, or by the operator of the track and trace system by means of checking the track and trace system for the registered identifier of the pharmaceutical entity who is a marketing authorization holder or owner, or a representative office of a foreign organization in the Russian Federation who is the marketing authorization holder or owner, and for the registered identification code or an identification code of tertiary (shipping) package containing the medicine (in case of transfer of the entire tertiary (shipping) medicine package). As a result of this check the operator of the track and trace system, using the functionality of the Track and Trace System, shall send to the pharmaceutical entity who has provided previously the information on the previous operation with the medicine to the Track and Trace System, the notification on provision of information as per paragraph five hereof, with indication of the information checked by the operator of the Track and Trace System.

(paragraph is introduced by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

In case of marking of medicine packages with identification means at the customs warehouse according to paragraph two of Clause 4 hereof, the pharmaceutical entity, which is a marketing authorization holder or a representative office of a foreign marketing authorization holder in the Russian Federation, shall submit the data, which are stipulated in Clause 4 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when marking of medicine packages with identification means at the customs warehouse is finished, before providing any data on further handling of these medicines.

Before providing any data on further handling of these medicines the pharmaceutical entity, which imported the medicines into the Russian Federation, shall also confirm reliability of the data in the Track and Trace System by submitting the data, which are stipulated in Clause 7 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when the data, which are stipulated in paragraph seven of this Clause, are registered in the Track and Trace System.
(as amended by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

Before July 1, 2021, during marking of the medicine packages with identification means at the customs warehouse as per paragraph two of clause 4 hereof, the provision of the information as per paragraph eight hereof to the Track and Trace System can be carried out by the pharmaceutical entity who imported the medicines into the Russian Federation and reliability of the information can be confirmed by operator of the track and trace system by means of checking the track and trace system for the registered identifier of the pharmaceutical entity who is a marketing authorization holder or owner, or a representative office of a foreign organization in the Russian Federation who is the marketing authorization holder or owner, and for the registered identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transfer of the entire tertiary (shipping) medicine package). As a result of this check the operator of the track and trace system, using the functionality of the Track and Trace System, shall send to the pharmaceutical entity who has provided previously the information on the previous operation with the medicine to the Track and Trace System, the notification on provision of information, with indication of the information checked by the operator of the Track and Trace System.
(paragraph is introduced by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

Provisions of the paragraph seven and ten hereof do not apply to the medicines intended for the persons sick with haemophilia, mucoviscidosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic, and associated tissues, multiple sclerosis, hemolytic-uremic syndrome, systemic onset juvenile arthritis, mucopolysaccharidosis types I, II, and VI, unspecified atrophic anemia, inherited deficiency of factors II (fibrinogen), VII (labile factor), X (Stuart-Prower), persons after transplantation of organs and/or tissues.

(paragraph is introduced by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

When conducting any customs operations during customs declaration and subjecting any medicines to the customs procedure of release for domestic consumption, the customs authority shall:

request data from the Track and Trace System concerning the identification code or the identification code of tertiary (shipping) medicine package, which contains such a medicine (in case of importing an entire tertiary (shipping) medicine package), in order to check them against the data specified in the customs declaration for the medicine;

before February 1, 2021, in case of non-receipt to the Unified Automated Information System of Customs Authorities of the information requested in the Track and Trace System on identification code or the identification code of tertiary (shipping) medicine package, which contains such a medicine (in case of importing an entire tertiary (shipping) medicine package), within 2 business hours of the customs authority from the moment of sending of the respective request, the check of the data against the data specified in the customs declaration for the medicine is not carried out. The absence of such a check shall not be considered an obstacle to prevent the release of the medicines for domestic consumption;

(paragraph is introduced by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

submit data on medicine release for domestic consumption to the Track and Trace System.

If there are any changes in the data specified in the customs declaration for any medicine, the customs authority shall submit corrected medicine data to the Track and Trace System within 5 business days after the changes are made.

If the ownership of medicines, which are subjected to the customs procedure of customs warehouse, is transferred in the customs control area, the pharmaceutical entity, which imports the medicines into the Russian Federation, shall submit the data, which are stipulated in Clause 6 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when the corresponding documents on the transfer of medicine ownership are prepared.

Before providing any data on further handling of these medicines the pharmaceutical entity, to which the ownership of the medicine subjected to the customs procedure of customs warehouse is transferred, shall also confirm reliability of the data in the Track and Trace System by submitting the data, which are stipulated in Clause 7 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when the corresponding documents on the medicine ownership transfer are prepared and when the data on the transferred medicines are registered in the Track and Trace System.

In case of medicine transportation between customs control areas after the medicines arrive to the place of delivery, which is defined in international goods shipping documents by the pharmaceutical entity that imports the medicines into the Russian Federation, the pharmaceutical entity, which imports the medicines into the Russian Federation, or the pharmaceutical entity, to which the ownership of the medicine subjected to the customs procedure of customs warehouse is transferred, shall submit those data, which are stipulated in Clause 8 of Appendix 3 hereto, within 5 business days from the date of such transportation, before providing any data on further handling of the medicine.

Before providing any data on further handling of these medicines the pharmaceutical entity, which imports medicines into the Russian Federation, or the pharmaceutical entity, to which the ownership of the medicines subjected to the customs procedure of customs warehouse is transferred, shall submit those data, which are stipulated in Clause 9 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date of decision made by the customs authorities to release the medicines for domestic consumption.

In case of medicine transportation from the customs control area, the pharmaceutical entity, which imports medicines into the Russian Federation, or the pharmaceutical entity, to which the ownership of the medicines subjected to the customs procedure of customs warehouse is transferred, shall submit those data, which are stipulated in Clause 10 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when the medicines are accepted at a pharmaceutical warehouse and when the customs

procedure of goods release for domestic consumption is completed (or from the date when the decision is made by the customs authorities to release the medicines for domestic consumption if the procedure of conditional goods release is used), before providing any data on further handling of these medicines.
(Cl. 37 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

37[1]. In case of introduction into civil circulation of medicines, which are imported into the Russian Federation (excluding the medicines that are imported from member states of the Eurasian Economic Union), the pharmaceutical entity, which imports medicines into the Russian Federation, shall submit those data, which are stipulated in Clause 13 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when the medicines are accepted at the customs warehouse and when the documents and data, which are stipulated in Part 2 of Article 52[1] of the Federal Law "On Medicine Circulation", concerning the medicines to be introduced into civil circulation are submitted to the Federal Service for Surveillance in Healthcare, or when the permit is obtained according to Part 7 of Article 52[1] of the Federal Law "On Medicine Circulation" (in case of import of immunobiological medicines into the Russian Federation), before providing any data on further handling of these medicines.
(Cl. 371 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

38. For medicine import into the Russian Federation from member states of the Eurasian Economic Union, data may be submitted to the Track and Trace System by the pharmaceutical entity, which ships the medicines to the Russian Federation (the "direct order of data submission for medicine import into the Russian Federation from member states of the Eurasian Economic Union"), or by the pharmaceutical entity, which accepts the medicines at a pharmaceutical warehouse in the Russian Federation (the "reverse order of data submission for medicine import into the Russian Federation from member states of the Eurasian Economic Union").

Direct or reverse order of data submission for medicine import into the Russian Federation from member states of the Eurasian Economic Union shall be selected by pharmaceutical entities, which submit these data, on their own.

If the direct order of data submission for medicine import into the Russian Federation from member states of the Eurasian Economic Union is selected, the pharmaceutical entity, which is a marketing authorization holder or a representative office of a foreign marketing authorization holder in the Russian Federation, shall submit the data, which are stipulated in Clause 11 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date of medicine shipment to the Russian Federation from member states of the Eurasian Economic Union, before submitting any data on further handling of such medicines.

Before providing any data on further handling of these medicines the pharmaceutical entity, which accepts the medicines at a pharmaceutical warehouse in the Russian Federation, shall also confirm reliability of the data in the Track and Trace System by submitting the data, which are stipulated in Clause 7 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when the medicines are accepted and the data on medicine shipment to the Russian Federation from member states of the Eurasian Economic Union are registered in the Track and Trace System.

If the reverse order of data submission for medicine import into the Russian Federation from member states of the Eurasian Economic Union is selected, the pharmaceutical entity, which accepts the medicines at a pharmaceutical warehouse in the Russian Federation in case of import into the Russian Federation from member states of the Eurasian Economic Union, shall submit the data, which are stipulated in Clause 12 of

Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when these medicines are accepted, before submitting any data on further handling of such medicines.

Before providing any data on further handling of these medicines the pharmaceutical entity, which is a marketing authorization holder, or a representative office of a foreign marketing authorization holder in the Russian Federation, shall also confirm reliability of the data in the Track and Trace System by submitting the data, which are stipulated in Clause 7 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when the data on medicine acceptance at a pharmaceutical warehouse in the Russian Federation are registered in the Track and Trace System.

Before July 1, 2021, the confirmation of reliability of the information provided in the track and trace system during import of the medicines into the Russian Federation from member states of the Eurasian Economic Union, can be carried out by the pharmaceutical entity who is a marketing authorization holder or owner, or a representative office of a foreign organization in the Russian Federation who is the marketing authorization holder or owner, as per paragraph six hereof, or by the operator of the track and trace system by means of checking the track and trace system for the registered identifier of the pharmaceutical entity who is a marketing authorization holder or owner, or a representative office of a foreign organization in the Russian Federation who is the marketing authorization holder or owner, and for the registered identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transfer of the entire tertiary (shipping) medicine package). As a result of this check the operator of the track and trace system, using the functionality of the Track and Trace System, shall send to the pharmaceutical entity who has provided previously the information on the previous operation with the medicine to the Track and Trace System, the notification on provision of information as per paragraph five hereof, with indication of the information checked by the operator of the Track and Trace System.

(paragraph is introduced by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

Provisions of the paragraph seven hereof do not apply to the medicines intended for the persons sick with haemophilia, mucoviscidosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic, and associated tissues, multiple sclerosis, hemolytic-uremic syndrome, systemic onset juvenile arthritis, mucopolysaccharidosis types I, II, and VI, unspecified atrophic anemia, inherited deficiency of factors II (fibrinogen), VII (labile factor), X (Stuart-Prower), persons after transplantation of organs and/or tissues.

(paragraph is introduced by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)(Cl. 38 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

38^1. In case of introduction into civil circulation of medicines, which are imported into the Russian Federation from member states of the Eurasian Economic Union, the pharmaceutical entity, which accepts the medicines at a pharmaceutical warehouse in the Russian Federation, shall submit those data, which are stipulated in Clause 13 of Appendix 3 hereto, to the Track and Trace System within 5 business days from the date when the documents and data, which are stipulated in Part 2 of Article 52^1 of the Federal Law "On Medicine Circulation", concerning the medicines to be introduced into civil circulation are submitted to the Federal Service for Surveillance in Healthcare, or when the permit is obtained according to Part 7 of Article 52^1 of the Federal Law "On Medicine Circulation" (in case of import of immunobiological medicines into the Russian Federation), before providing any data on further handling of these medicines.
(Cl. 38^1 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

39. Appendix 5 describes the data to be submitted by pharmaceutical entities to the Track and Trace System in case of handling of tertiary (shipping) medicine packages.

(Cl. 39 as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

40. When aggregating those medicines, which have the same global trade item number, the pharmaceutical entity shall apply the identification code of tertiary (shipping) medicine package on the tertiary (shipping) medicine package and shall submit those data, which are stipulated in Clause 1 of Appendix 5 hereto, to the Track and Trace System before providing any data on further handling of such medicine.
(as amended by Decrees of the Government of the Russian Federation of 3/20/2020 No. 311, of 7/21/2020 No. 1079)

41. When disaggregating any tertiary (shipping) medicine package, removing any medicines from tertiary (shipping) medicine package, adding any medicines into tertiary (shipping) medicine package, the pharmaceutical entity shall submit those data to the Track and Trace System, which are stipulated in Clause 2 - 4 of Appendix 5 hereto, before submitting any data on further handling of such medicines or tertiary (shipping) medicine packages.
(Cl.41 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

42. Appendix 6 describes the data to be submitted by pharmaceutical entities to the Track and Trace System during circulation and internal transportation of medicines.

43. The pharmaceutical entity, which transports medicines between business places according to the license (considering activities such as medicine manufacturing, pharmaceutical activities, and circulation of narcotics, psychotropic substances, and their precursors, cultivation of drug-yielding plants) and/or between pharmaceutical warehouses, shall submit those data, which are stipulated in Clause 1 of Appendix 6 hereto, to the Track and Trace System within 5 business days from the actual date of medicine transportation, before submitting any data on further handling of such medicines.
(Cl. 43 as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

44. For medicine transfer between pharmaceutical entities, data may be submitted to the Track and Trace System by the pharmaceutical entity, which transfers the medicines (the "direct order of data submission for medicine circulation"), or by the pharmaceutical entity, which accepts the medicines (the "reverse order of data submission for medicine circulation").
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

Direct or reverse order of data submission for medicine circulation shall be selected by pharmaceutical entities, which submit these data, on their own.
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No.1079)

If the direct order of data submission for medicine circulation is selected, the pharmaceutical entity, which transfers the medicines to another pharmaceutical entity within civil law relations, shall submit the data, which are stipulated in Clause 2 of Appendix 6 hereto, to the Track and Trace System in 1 business day from the actual date of medicine shipment.
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

The pharmaceutical entity (except for separate subdivisions of the medical organizations (outpatient clinics, feldsher and feldsher-midwife stations), which accepts the medicines from another pharmaceutical entity within civil law relations, shall also confirm reliability of the data in the Track and Trace System by submitting the data, which are stipulated in Clause 4 of Appendix 6 hereto, to the Track and Trace System within 1 business day from the date when the medicines are accepted and when the data on shipped

medicines are registered in the Track and Trace System, before providing any data on further handling of these medicines.

(as amended by Decrees of the Government of the Russian Federation of 7/21/2020 No. 1079, of 12/18/2020 No. 2166)

If the reverse order of data submission for medicine circulation is selected, the pharmaceutical entity (except for separate subdivisions of the medical organizations (outpatient clinics, feldsher and feldsher-midwife stations), which accepts the medicines from another pharmaceutical entity within civil law relations, shall submit the data on accepted medicines, which are stipulated in Clause 3 of Appendix 6 hereto, to the Track and Trace System in 1 business day from the date of medicine acceptance.

(as amended by Decrees of the Government of the Russian Federation of 7/21/2020 No. 1079, of 12/18/2020 No. 2166)

Separate subdivisions of the medical organizations (outpatient clinics, feldsher and feldsher-midwife stations) shall confirm reliability of the data contained in the Track and Trace System and shall submit the data on accepted medicines to the Track and Trace System as per paragraphs four and five hereof, within 30 business days from the date when the medicines are accepted.

(paragraph is introduced by Decree of the Government of the Russian Federation of 12/18/2020 No. 2166)

The pharmaceutical entity, which transferred the medicines to another pharmaceutical entity within civil law relations, shall also confirm reliability of the data in the Track and Trace System by submitting the data, which are stipulated in Clause 4 of Appendix 6 hereto, to the Track and Trace System within 1 business day from the date when the data on accepted medicines are registered in the Track and Trace System, but before providing any data on further handling of these medicines.

(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

Before February 1, 2022, the confirmation of reliability of the information provided in the track and trace system during circulation of the medicines can be carried out by the pharmaceutical entity who has transferred the medicines to another pharmaceutical entity under civil law relations, as per paragraph seven hereof, or by the operator of the track and trace system by means of checking the track and trace system for the taxpayer identification number of the pharmaceutical entity who has transferred the medicines to another pharmaceutical entity under civil law relations, and for the registered identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transfer of the entire tertiary (shipping) medicine package). As a result of this check the operator of the track and trace system, using the functionality of the Track and Trace System, shall send to the pharmaceutical entity who has provided previously the information on the previous operation with the medicine to the Track and Trace System, the notification on provision of information as per paragraph five hereof, with indication of the information checked by the operator of the Track and Trace System. (paragraph is introduced by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779 as amended by Decree of the Government of the Russian Federation of 6/30/2021 No. 1069)

Provisions of the paragraph eight hereof do not apply to the medicines intended for the persons sick with haemophilia, mucoviscidosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic, and associated tissues, multiple sclerosis, hemolytic-uremic syndrome, systemic onset juvenile arthritis, mucopolysaccharidosis types I, II, and VI, unspecified atrophic anemia, inherited deficiency of factors II (fibrinogen), VII (labile factor), X (Stuart-Prower), persons after transplantation of organs and/or tissues.

(paragraph is introduced by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779 as amended by Decree of the Government of the Russian Federation of 6/30/2021 No. 1069)

44[1]. In order to avoid potential disclosure of information classified as state secret in case of transfer of medicines, which are purchased for the purposes of state defense and security, humanitarian aid, mitigation of emergencies, large-scale accidents, and natural and man-made incidents, to federal executive authorities, state bodies of constituent entities of the Russian Federation, and organization authorized by them, the pharmaceutical entity, which transfers these medicines, shall submit the data on medicine withdrawal from circulation, excluding the data stipulated in Subclause "d", "e", "g" — "i" of Clause 1 of Appendix 4 hereto, to the Track and Trace System within 5 business days from the actual date of medicine shipment.
(as amended by Decrees of the Government of the Russian Federation of 3/20/2020 No. 311, of 7/21/2020 No. 1079)

The Ministry of Health of the Russian Federation shall approve the procedure of providing the data on withdrawal from circulation for medicines that are specified in paragraph one of this Clause.
(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

44[2]. The pharmaceutical entity, which performs outsourcing functions in case of transfer of medicines to pharmaceutical entities that issue medicines free of charge or at a discount on prescription for medicines purchased for provision of citizens from the federal budget resources and/or budget resources of constituent entities of the Russian Federation, shall submit the data, which are stipulated in Clause 6 of Appendix 6 hereto, to the Track and Trace System within 1 business day from the actual date of medicine shipment.

Before providing any data on further handling of these medicines the pharmaceutical entity (except for separate subdivisions of the medical organizations (outpatient clinics, feldsher and feldsher-midwife stations), which accepts the medicines into the Russian Federation, shall also confirm reliability of the data in the Track and Trace System by submitting the data, which are stipulated in Clause 4 of Appendix 6 hereto, to the Track and Trace System within 1 business days from the date when the medicines are accepted and when the data on shipped medicines are registered in the Track and Trace System.
(as amended by Decree of the Government of the Russian Federation of 12/18/2020 No. 2166)

Separate subdivisions of the medical organizations (outpatient clinics, feldsher and feldsher-midwife stations) shall confirm reliability of the data contained in the Track and Trace System as per paragraph two hereof within 30 business days from the date when the medicines are accepted.
(paragraph is introduced by Decree of the Government of the Russian Federation of 12/18/2020 No. 2166)(Cl. 44[2] is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

45. When transferring medicines (finished products) to the pharmaceutical entity that is the customer of contract manufacturing, the pharmaceutical entity, which is the contract manufacturer of medicines in the Russian Federation, shall submit the data, which is provided in Clause 5 of Appendix 6 hereto, to the Track and Trace System within 5 business days from the date of medicine transfer.

Before providing any data on further handling of these medicines the pharmaceutical entity, which is the customer of contract manufacturing of medicines, shall also confirm reliability of the data on transferred medicines in the Track and Trace System by submitting the data, which are stipulated in Clause 4 of Appendix 6 hereto, to the Track and Trace System within 5 business days from the date when the medicines are accepted and when the data on transferred medicines are registered in the Track and Trace System.

46. The pharmaceutical entity (except for separate subdivisions of the medical organizations (outpatient clinics, feldsher and feldsher-midwife stations), which withdraws medicines from circulation (excluding medicine withdrawal from circulation by exporting the medicines previously imported into the Russian Federation, by destroying the medicines subjected to the customs procedure of destruction, by exporting outside the customs area of the Eurasian Economic Union for medicines marked with identification means, subjected to the customs procedure of export, or by transferring for destruction of medicines previously introduced into civil circulation in the Russian Federation) shall submit the data, which are stipulated in Clause 1 of Appendix 4 hereto, to the Track and Trace System within 5 business days from the date of the corresponding operation or the date of medicine acceptance at a pharmaceutical warehouse (in case of medicine circulation in the customs control area).
(as amended by Decree of the Government of the Russian Federation of 12/18/2020 No. 2166)

Separate subdivisions of the medical organizations (outpatient clinics, feldsher and feldsher-midwife stations) shall submit the data, which are stipulated in Clause 1 of Appendix 4 hereto, to the Track and Trace System within 30 business days from the date of the corresponding operation.
(paragraph is introduced by Decree of the Government of the Russian Federation of 12/18/2020 No. 2166)(Cl. 46 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

47. The pharmaceutical entity, which withdraws medicines from circulation by destroying the medicines subjected to the customs procedure of destruction, by exporting outside the customs area of the Eurasian Economic Union for medicines marked with identification means, subjected to the customs procedure of export, shall submit the data, which are stipulated in Clause 2 to Appendix 4 hereto, to the Track and Trace System within 5 business days from the date of the corresponding operation.
(Cl.47 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

48. The pharmaceutical entity, which withdraws medicines from circulation by transferring the medicines for destruction, shall submit the data, which are stipulated in Clause 3 of Appendix 4 hereto, to the Track and Trace System within 5 business days from the date when the medicines are transferred for destruction before submitting the information about destruction of the medicines.

As a result of medicine destruction, the pharmaceutical entity, which transferred the medicines for destruction, shall submit the data, which are stipulated in Clause 4 of Appendix 4 hereto, to the Track and Trace System within 5 business days from the date when the destruction certificate is received.

49. The pharmaceutical entity, which withdraws medicines from circulation by means of re-export, shall submit the data, which are stipulated in Clause 2 of Appendix 4 hereto, to the Track and Trace System within 5 business days from the date when the customs authorities decide on re-export.
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

50. In case of medicine re-introduction into circulation (excluding those medicines the data on which withdrawal from circulation are submitted to the Track and Trace System according to Clause 44^1 hereof), the pharmaceutical entity, which previously withdrew the medicines from circulation or released these medicines outside the Russian Federation (in case of exporting the medicines that had been previously imported into the Russian Federation), shall submit the data, which are stipulated in Clause 14 of Appendix 3 hereto, within 5 business days from the date of the corresponding operation.

The Ministry of Health of the Russian Federation shall approve the procedure of providing the data on re-introduction into circulation for medicines that are specified in paragraph two of Clause 44^1 hereof.
(Cl. 50 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

51. Those pharmaceutical entities, which sell medicines by retail and issue prescription medicines at a discount, with the medicines marked with identification means, shall submit data on medicine withdrawal from circulation using control and cash register equipment.

Information on medicines, which are withdrawn from circulation by pharmaceutical entities that do not use any control and cash register equipment or use the control and cash register equipment in the mode, which does not provide for mandatory sending of fiscal documents to the tax authorities via the fiscal data operator, in cases determined by the Federal Law “On the Use of Control and Cash Register Equipment in the Russian Federation”, shall be submitted to the Track and Trace System by such pharmaceutical entities using the functions of the Track and Trace System.

Those pharmaceutical entities, which are engaged in medical activities and medicine withdrawal from circulation during medical care, and those pharmaceutical entities, which issue medicines free or charge on prescription, shall use disposal registrars provided by the Track and Trace System operator to submit information to the Track and Trace System concerning medicine withdrawal from circulation by issuing free of charge on prescription or by issuing during medical care.

The Track and Trace System operator shall equip those pharmaceutical entities, which withdraw medicines from circulation when providing medical care or when releasing prescription medicines free of charge, with disposal registrars free of charge. In order to be equipped, pharmaceutical entities shall enter into contracts with the Track and Trace System operator, including those, which conditions include provision and routine maintenance of such equipment free of charge.

Standard form of such contracts shall be approved by the Ministry of Industry and Trade of the Russian Federation.

In case of disposal registrar inoperability, which is confirmed with a notification to be sent by the pharmaceutical entity to the Track and Trace System operator, then, while the disposal registrar operability is being restored or the disposal registrar is being replaced, the pharmaceutical entity shall use the functions of the Track and Trace System to submit data on medicine withdrawal from circulation by releasing free of charge or by releasing for medical care.
(Cl. 51 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

52. If any errors (unreliable data) are found in the data, which are submitted by them to the Track and Trace System during medicine introduction into circulation and medicine circulation, the pharmaceutical entities shall submit information, which is required to correct these errors (unreliable data) in the data (the “error correction”) to the Track and Trace System.

Pharmaceutical entities have the right to correct any errors before they are notified that an inspection is ordered concerning them, which is to be conducted by the Federal Service for Surveillance in Healthcare as per the established procedure, as the pharmaceutical entities submitted erroneous (unreliable) data.

If other pharmaceutical entities have contributed to submitting of data where any errors (unreliable data) are discovered, then error corrections shall be considered accepted after all pharmaceutical entities, which have contributed to submitting of data where the errors (unreliable data) are discovered, confirm reliability of the error corrections in the Track and Trace System.

Provisions of the paragraph three hereof do not apply to the correction of errors in the information submitted to the Track and Trace System by the pharmaceutical entities in accordance with the procedure

provided for in paragraph five, Clause 44, hereof. In this case, the accuracy of the corrections submitted to the Track and Trace System shall be confirmed in accordance with paragraph eight, Clause 44 hereof.
(as amended by Decree of the Government of the Russian Federation of 6/30/2021 No. 1069)

The following error corrections shall be made in the Track and Trace System for own operations:

canceling of a previously registered operation by the pharmaceutical entity (if no operations with transfer of medicine ownership were performed after this operation);

recalling of a message on medicine shipment by the pharmaceutical entity, which sent this message to the medicine receiver. This correction is possible before any data are submitted on confirmation of medicine transfer by another pharmaceutical entity;

refusal of a pharmaceutical entity, which receives medicines, to accept the medicines. This correction is possible before any data are submitted on confirmation of medicine transfer by another pharmaceutical entity;

correction by a pharmaceutical entity of data previously sent to the Track and Trace System by this pharmaceutical entity concerning medicine transfer to another pharmaceutical entity, with confirmation of such correction by the pharmaceutical entity, to which these medicines are transferred.
(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

53. The Track and Trace System shall automatically block the acceptance of data on medicine introduction into circulation, on medicine circulation and/or withdrawal from circulation (the "blocking") according to the regulations defined by the Track and Trace System operator and agree with the Federal Service for Surveillance in Healthcare.
(as amended by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

Appendix 7 contains a list of reasons for blocking.

Blocking will be canceled automatically when the pharmaceutical entity eliminates the reasons for blocking.

In certain cases, which are listed by the Federal Service for Surveillance in Healthcare, the data on medicine return to supplier, on medicine transfer for destruction and/or on other type of medicine withdrawal from circulation can be submitted with active blocking.

Blocking may be activated and canceled for a medicine item, medicine batch, or medicine series.

VII. Procedure for Providing the Information Contained in the Track and Trace System

54. The Track and Trace System operator shall provide access of those individuals and legal entities, federal executive authorities, state authorities of constituent entities of the Russian Federation, and local government authorities, which are interested in obtaining any information from the Track and Trace System, as agreed with the Ministry of Health of the Russian Federation.
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

The Russian Federation shall be the owner of information contained in the Track and Trace System.

The Ministry of Health of the Russian Federation shall exercise the powers of the owner of information contained in the Track and Trace System on behalf of the Russian Federation. The owner of information contained in the Track and Trace System shall ensure that this information is confidential, excluding the information classified by the Government of the Russian Federation as public information.
(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

The Track and Trace System operator shall handle the information contained in the Track and Trace System or authorize such handling within the power established by federal laws and accepted according to them by other laws and regulations of the Russian Federation, including this Regulation.
(paragraph is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

55. The Track and Trace System operator provides access to the information contained in the Track and Trace System considering the following provisions:

a) access of federal executive authorities, state authorities of constituent entities of the Russian Federation, and local government authorities to the information contained in the Track and Trace System is provided, in particular, by the infrastructure that enables information and technology interaction of information systems, which are used to provide state and municipal services and perform state and municipal functions electronically;

b) access of pharmaceutical entities, which provide information to be submitted to the Track and Trace System, to the information submitted by them and reference data contained in the Track and Trace System shall be provided via the user account of pharmaceutical entity or via electronic information services using standard protocols and interfaces of electronic interaction;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) access of citizens to the information contained in the Track and Trace System when they check any identification means shall be provided, in particular, using the website of the Track and Trace System operator in the information and telecommunications network Internet and the mobile application.

56. The mobile application provides the following features of the Track and Trace System for checking of identification means:

a) reading of identification means from secondary (consumer) medicine package (if unavailable, from primary medicine package);

b) displaying of the results of identification means check in the Track and Trace System;

c) an option to send data on violation of the medicine marking procedure to the Track and Trace System.

57. A pharmaceutical entity can access all electronic documents sent by it to the Track and Trace System, as well as the electronic documents that are created by the Track and Trace System based on the results of processing of documents, which are received from the pharmaceutical entity, and the information, which is classified by the Government of the Russian Federation as public information.
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

VIII. Operator of the Track and Trace System

57[1]. The issuer of identification means that is registered in the Track and Trace System and that submitted data to the Track and Trace System concerning application of identification means on medicine packages, apart from the data specified in Clause 57 hereof, shall be provided with access to information on series and batches of these medicines with regard to information on the medicine owners and their number throughout the entire supply or shipment chain.
(Cl. 57[1] is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

57[2]. Medicine consumers shall be provided with access to the information, which is classified by the Government of the Russian Federation as public information.
(Cl. 57[2] is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

57[3]. Federal executive authorities shall be provided with access to the following data for the purposes defined herein:

a) information on pharmaceutical entities, on medicines and their circulation that is required to perform the tasks and functions assigned to federal executive authorities for the purposes defined herein;

b) statistical information on medicines and their circulation;

c) information classified by the Government of the Russian Federation as public information.
(Cl. 57[3] is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

57[4]. The content of information in the Track and Trace System, which federal executive authorities can access, shall be defined in information interaction agreements concluded by the Track and Trace System operator with federal executive authorities and the Ministry of Health of the Russian Federation.
(Cl. 57[4] is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

57[5]. The Federal Service for Surveillance in Healthcare shall be provided with access to the information from the Track and Trace System for the following purposes:

a) monitoring of compliance of healthcare professionals, heads of medical organizations, pharmaceutical professionals, and heads of pharmacies with the restrictions applied to them during their professional practice according to the laws of the Russian Federation;

b) state supervision (surveillance) in medicine circulation;

c) monitoring of the range and prices of vital and essential medicines;

d) inspection of the activities of medical organizations and pharmacies, medicine wholesalers, other organizations and individual entrepreneurs that work in healthcare, according to the established procedure.
(Cl. 57[5] is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

57[6]. The Federal Tax Service shall be provided with access to the information from the Track and Trace System for the following purposes:

a) monitoring and supervision of the correct calculation, complete and timely payment of taxes and

duties to the corresponding budget of the budgetary system of the Russian Federation, and in cases stipulated in the laws of the Russian Federation — of correct calculation, complete and timely payment of other mandatory charges;

b) monitoring of compliance with the requirements to control and cash register equipment and with the conditions of its registration and use;

c) monitoring of revenue accounting for legal entities and individual entrepreneurs;

d) inspection activities, including office and field inspections. (Cl. 57^6 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

57^7. The Federal Customs Service shall be provided with access to the information, which is contained in the Track and Trace System, for the purposes of being provided, as stipulated by the laws of the Russian Federation, with the powers of customs control over the goods imported into the Russian Federation, including customs control after goods release, and monitoring of correct calculation and timely payment of customs duties, taxes, special, anti-dumping, countervailing duties, and other charges to be collected by the customs authorities.
(Cl. 57^7 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

57^8. The Federal State Statistics Service shall be provided with access to the information, which is contained in the Track and Trace System, in order to be provided with functions of generation of official statistical information on social, economic, demographic, environmental, and other public processes in the Russian Federation.
(Cl. 57^8 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

57^9. The Federal Antimonopoly Service shall be provided with access to the information, which is contained in the Track and Trace System, for the purposes of state monitoring of compliance with antimonopoly laws of the Russian Federation.
(Cl. 57^9 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

58. The Track and Trace System operator shall provide for the following as agreed with the Ministry of Health of the Russian Federation and the Federal Service for Surveillance in Healthcare:

a) creation, development, commissioning, operation, and decommissioning of the Track and Trace System, provision of information contained in the Track and trace System, and interaction of the Track and Trace System with other information systems;

b) implementation of public control mechanisms, including reception of information on the results of identification means checking and complaints of individuals and legal entities, individual entrepreneurs, storage, processing, and transfer of this information to the authorized federal executive bodies.

59. The Track and Trace System operator shall be responsible for the following according to the laws of the Russian Federation:

a) for database storage of all data and records of transactions to be registered in the Track and Trace System;

b) for integrity, safety, and consistency of information in the Track and Trace System;

c) for maintenance and storage of the unified registers, reference data, classifiers, and formats of data exchange;

d) for uninterrupted and failsafe operation of the Track and Trace System;

e) for restoration of operability of the Track and Trace System and its components after fault management, provided that fault causes are completely eliminated, and for maintenance of integrity of the software, hardware, and databases installed on the servers;

f) for structural redundancy, automatic detection of any server node failure, and task switching to another server node, as well as for availability of a network access, which is redundant and diversified by connection to providers;

g) for information security and data protection against unauthorized access and information leak;

h) for advice and technical support in the Track and Trace System for pharmaceutical entities and in the mobile application for individuals;

i) for collection and analysis of requests made by legal entities, individuals, and individual entrepreneurs for formulation of tasks on improvement and upgrading of databases.

60. In case of a fault in the Track and Trace System, which resulted in rejected acceptance of data on any performed operations from pharmaceutical entities, the Track and Trace System operator shall post the following data on the official website of the Track and Trace System operator in the information and telecommunications network Internet:

a) information about the fault no later than 4 hours after it occurs;

b) information on elimination of the fault causes and complete restoration of the Track and Trace System operability no later than 4 hours after the complete restoration of the Track and Trace System operability, with the duration of limited operation.
(Cl. 60 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

Appendix 1
To the Regulation on the Track and Trace
System of Medicines for Medical Use

DATA TO BE PROVIDED BY STATE INFORMATION SYSTEMS OF FEDERAL EXECUTIVE AUTHORITIES TO THE TRACK AND TRACE SYSTEM OF MEDICINES FOR MEDICAL USE AND DATA TO BE SUBMITTED FROM THE TRACK AND TRACE SYSTEM OF MEDICINES FOR MEDICAL USE

List of modifying documents
(as amended by Decrees of the Government of the Russian Federation of
03/20/2020 No. 311, of 7/21/2020 No. 1079)

1. The following data shall be provided from the unified register of manufacturing licenses in order to submit information on medicine manufacturing licenses of medicine manufacturers, which are organizations recognized as tax residents of the Russian Federation, to the Track and Trace System of Medicines for Medical Use (the "Track and Trace System", "medicines"):

a) taxpayer identification number of medicine manufacturer;

b) main state registration number of medicine manufacturer;

c) name of medicine manufacturer;

d) license number;

e) date of license issue;

f) license validity status;

g) date of validity status change of license;

h) business place address as per the license (global unique identifier of the address object in the Federal Information Address System and description of the address object);

i) list of works and services provided by license;

j) list of dosage forms provided by license;

k) additional description for works (services).

2. The following data shall be submitted to the Track and Trace System from the unified register of licenses, including the licenses issued by state bodies of constituent entities of the Russian Federation according to the delegated authority to license certain types of healthcare activities for the purposes of submitting of information on licenses of pharmaceutical entities, which are organizations recognized as tax residents of the Russian Federation or individual entrepreneurs:

a) taxpayer identification number of pharmaceutical entity;

b) license number;

c) license effective date;

d) business place address as per the license (global unique identifier of the address object in the Federal Information Address System and description);

e) license validity status (identifier and description);

f) date of validity status change of license;

g) list of works and services provided by license (identifiers and description).

3. The following data shall be submitted to the Track and Trace System from the unified state information system in healthcare for the purposes of medicine description:

a) unique identifier of a record in the unified structured catalog of medicines;

b) number of medicine marketing authorization;

c) date of state registration of medicine;

d) validity status of medicine marketing authorization;

e) international non-proprietary, or unified, or chemical name of medicine;

f) name of the holder of medicine marketing authorization;

g) country of registration of the holder of medicine marketing authorization;

h) taxpayer code of the holder of medicine marketing authorization in the country of registration;

i) attribute of medicine availability in the list of vital and essential medicines;

j) trade name of medicine;

k) primary package of medicine;

l) quantity of dosage forms in primary package;

m) secondary (consumer) package of medicine (if any);

n) quantity of primary medicine packages in secondary (consumer) medicine package (if any);

o) dosage form;

p) quantity of medicine dosage units;

q) name of the pharmaceutical entity, which prepacks (packs) medicines into secondary (consumer) medicine packages (if unavailable, into primary medicine packages);

r) taxpayer code of the pharmaceutical entity, which prepacks (packs) medicines into secondary (consumer) medicine packages (if unavailable, into primary medicine packages) in the country of registration;

s) country of registration of the pharmaceutical entity, which prepacks (packs) medicines into secondary (consumer) medicine packages (if unavailable, into primary medicine packages);

t) business place address of the pharmaceutical entity, which prepacks (packs) medicines into secondary (consumer) medicine packages (if unavailable, into primary medicine packages), that is specified in the license for medicine manufacturing if such license is available (global unique identifier of the address object in the Federal Information Address System and description);

u) name of the pharmaceutical entity, which is engaged in the stage of release quality control;

v) taxpayer code of the pharmaceutical entity, which is engaged in the stage of release quality control in the country of registration;

w) country of registration of the pharmaceutical entity, which is engaged in the stage of release quality control;

x) business place address of the pharmaceutical entity, which is engaged in the production stage of release quality control, that is specified in the license for medicine manufacturing if such license is available (global unique identifier of the address object in the Federal Information Address System and description);

y) date of registration of marginal price of medicine;

z) marginal registered price in RUB;

aa) name of the pharmaceutical entity, which is engaged in the stage of manufacturing of finished dosage form;
(Subclause "aa" is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

bb) taxpayer code of the pharmaceutical entity, which is engaged in the stage of manufacturing of finished dosage form in the country of registration;
(Subclause "bb" is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

cc) country of registration of the pharmaceutical entity, which is engaged in the stage of manufacturing of finished dosage form.
(Subclause "cc" is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

4. The following data shall be submitted to the Track and Trace System from the Unified State Register of Legal Entities and the Unified State Register of Individual Entrepreneurs respectively for confirmation of reliability of data on state registration of pharmaceutical entities, which are organizations recognized as tax residents of the Russian Federation:

a) taxpayer identification number of pharmaceutical entity;

b) code of tax authority;

c) code of legal entity or individual entrepreneur status;

d) name of pharmaceutical entity;

e) status of record on registration of legal entity or individual entrepreneur;

f) data on the head of pharmaceutical entity or on individual entrepreneur.

5. The following data shall be submitted to the Track and Trace System from the state register of accredited branches and representative offices of foreign legal entities for confirmation of reliability of data on registration of representative offices of foreign medicine authorization holders in the Russian Federation:

a) taxpayer identification number of representative office;

b) code of registration tax authority of representative office;

c) name of representative office;

d) accreditation record number;

e) data on foreign organization;

f) accreditation status code;

g) data on the head of representative office.

6. The following data on withdrawal (canceling of withdrawal) from circulation of medicines, which is initiated by an authorized executive body, shall be submitted to the Track and Trace System from the automated information system of the Federal Service for Surveillance in Healthcare for safety purposes:
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

a) start date for withdrawal (canceling of withdrawal) of medicine from circulation;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

b) number of medicine marketing authorization;

c) date of state registration of medicine;

d) grounds for withdrawal (canceling of withdrawal) of medicine from circulation;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

e) details of document on withdrawal (canceling of withdrawal) of medicine from circulation;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

f) global trade item number;

g) production series number;

h) taxpayer identification number of pharmaceutical entity (in case of medicine removal from only one pharmaceutical entity, not removal of the entire series (batch).

6^1. The following medicine data shall be submitted to the automated information system of the Federal Service for Surveillance in Healthcare from the Track and Trace System for confirmation of reliability of data provided by pharmaceutical entities to the Federal Service for Surveillance in Healthcare when medicines are introduced into civil circulation:

a) taxpayer identification number of the pharmaceutical entity, which prepacked (packed) medicines into secondary (consumer) medicine packages (if unavailable, into primary medicine packages) in case of medicine production in the Russian Federation, or imported medicines into the Russian Federation and provided customs declaration in case of introduction into circulation of medicine manufactured outside the Russian Federation;

b) name of the pharmaceutical entity, which prepacked (packed) medicines into secondary (consumer) medicine packages (if unavailable, into primary medicine packages) in case of medicine production in the Russian Federation, or imported medicines into the Russian Federation and provided customs declaration (in case of introduction into circulation of medicine manufactured outside the Russian Federation);

c) medicine data obtained as part of medicine description in the Track and Trace System according to Clause 33 of the Regulation on the Track and Trace System of Medicines for Medical Use, which is approved by Decree of the Government of the Russian Federation of December 14, 2018 No. 1556 “On Approval of the Regulation on the Track and Trace System of Medicines for Medical Use”;

d) production series number;

e) production series size;

f) date of medicine prepacking (packing) into secondary (consumer) medicine packages (if unavailable, into primary medicine packages) in case of medicine production in the Russian Federation;

g) taxpayer identification number of the medicine owner in case of contract manufacturing of medicine in the Russian Federation;

h) name of the medicine owner in case of contract manufacturing of medicine in the Russian Federation;

i) registration date of customs declaration for medicine (in case of introduction into civil circulation of medicine manufactured outside the Russian Federation);

j) registration number of customs declaration for medicine (in case of introduction into civil circulation of medicine manufactured outside the Russian Federation);

k) data on medicine release for domestic consumption (in case of introduction into circulation of medicine manufactured outside the Russian Federation).
(Cl. 6^1 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

6^2. The following data shall be submitted to the Track and Trace System from the automated

information system of the Federal Service for Surveillance in Healthcare for confirmation of reliability of data on medicine introduction into civil circulation:

a) date of data registration in the automated information system of the Federal Service for Surveillance in Healthcare;

b) details of a record made in the automated information system of the Federal Service for Surveillance in Healthcare about the medicine to be introduced into civil circulation;

c) global trade item number of the medicine to be introduced into civil circulation;

d) number of production series of the medicine to be introduced into civil circulation;

e) number of secondary (consumer) packages (if unavailable, of primary packages) of the medicine to be introduced into civil circulation;

f) number of permit to introduce into civil circulation that is provided by the Federal Service for Surveillance in Healthcare (in case of introduction into civil circulation of immunobiological medicines);

g) taxpayer identification number of the pharmaceutical entity, which introduces medicine into civil circulation.
(Cl. 6^2 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

6^3. The following data on medicine destruction shall be submitted to the automated information system of the Federal Service for Surveillance in Healthcare from the Track and Trace System for the purposes of federal state supervision in circulation of medicines for medical use by the Federal Service for Surveillance in Healthcare:

a) date when data on medicine destruction is entered into the Track and Trace System;

b) taxpayer identification number of the pharmaceutical entity, which transferred the medicine for destruction;

c) name of the pharmaceutical entity, which transferred the medicine for destruction;

d) taxpayer identification number of the organization, which destroyed the medicine;

e) name of the organization, which destroyed the medicine;

f) address of the organization, which destroyed the medicine;

g) details of the medicine destruction certificate (date and number);

h) medicine data obtained as part of medicine description in the Track and Trace System according to Clause 33 of the Regulation on the Track and Trace System of Medicines for Medical Use, which is approved by Decree of the Government of the Russian Federation of December 14, 2018 No. 1556 “On Approval of the Regulation on the Track and Trace System of Medicines for Medical Use”;

i) method of destruction;

j) date of destruction;

k) reason and grounds of medicine transfer for destruction.
(Cl. 6^3 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

7. The following data on medicines imported into the Russian Federation and subjected to certain customs procedures as per goods customs declaration shall be submitted to the Track and Trace System from the Unified Automated Information System of Customs Authorities for the purposes of prevention and suppression of crimes and administrative infractions within the jurisdiction of the customs authorities of the Russian Federation:

a) customs authority code;

b) date of registration of the medicine customs declaration;

c) registration number of the medicine customs declaration;

d) identification code;
(Subclause "d" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

e) customs value, statistical value, and invoice value of the medicine;

f) code of the country of origin of the medicine;

g) taxpayer identification number of the pharmaceutical entity, which imports and declares the medicine;

h) code of the reported customs procedure as per the classifier of customs procedures;

i) data on medicine release for domestic consumption.

8. The Track and Trace System shall submit the following data on medicines, which are imported into the Russian Federation, to the Unified Automated Information System of Customs Authorities upon request for the purposes of prevention and suppression of crimes and administrative infractions within the jurisdiction of the customs authorities of the Russian Federation:

a) taxpayer identification number of the pharmaceutical entity, which imports medicines into the Russian Federation and declares them;

b) code of the country of origin of the medicine;

c) global trade item number;

d) identification code and identification code of tertiary (shipping) medicine package, which contains the medicine introduced into circulation;
(Subclause "d" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

e) medicine status in the Track and Trace System;

f) list of identification codes contained in tertiary (shipping) medicine package.

(Item “f” as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

Appendix 2
To the Regulation on the Track and
Trace System of Medicines for
Medical Use

LIST OF DATA FOR MEDICINE DESCRIPTION TO BE SUBMITTED BY PHARMACEUTICAL ENTITIES TO THE INFORMATION RESOURCE THAT ENABLES ACCOUNTING AND STORAGE OF RELIABLE DATA ON THE GOODS BY THE CORRESPONDING GOODS NOMENCLATURE

1. Trade name of the medicine for medical use (the “medicine”).

2. Brand (trade mark).

3. Number of medicine registration certificate.

4. Date of state registration of the medicine.

5. Name of the holder of medicine marketing authorization.

6. Address of the holder of medicine marketing authorization.

7. International non-proprietary name of the medicine.

8. Dosage form.

9. Number of medicine dosage units.

10. Type of secondary (consumer) medicine package (if unavailable, of primary medicine package).

11. Material of secondary (consumer) medicine package (if unavailable, of primary medicine package).

12. Medicine quantity (measure) in secondary (consumer) medicine package (if unavailable, in primary medicine package).

13. Presence of any unmarked primary medicine package inside secondary (consumer) medicine package (if secondary (consumer) medicine package is available).

14. Description of unmarked primary medicine package inside secondary (consumer) medicine package.

15. Name of prepacker (packer) (to be specified in case of prepacking (packing) in the Russian Federation).

16. Address of prepacker (packer) of secondary (consumer) medicine packages (if unavailable, primary medicine packages) (to be specified in case of prepacking (packing) in the Russian Federation).

Appendix 3
To the Regulation on the Track and
Trace System of Medicines for
Medical Use

DATA TO BE SUBMITTED TO THE TRACK AND TRACE SYSTEM OF MEDICINES FOR MEDICAL USE BY PHARMACEUTICAL ENTITIES IN CASE OF INTRODUCTION INTO CIRCULATION OF MEDICINES FOR MEDICAL USE

List of modifying documents
(as amended by Decrees of the Government of the Russian Federation of 8/30/2019 No. 1118, of 03/20/2020 No. 311, of 7/21/2020 No. 1079, of 11/2/2020 No. 1779)

I. Date on Medicines for Medical Use Manufactured in the Russian Federation to be Submitted by Pharmaceutical Entities to the Track and Trace System of Medicines for Medical Use

1. When finishing the stage of prepacking (packing) of medicines for medical use (the "medicines") into secondary (consumer) medicine packages (if unavailable, into primary medicine packages), the pharmaceutical entities shall submit the following information on each medicine trade item to the Track and Trace System of Medicines (the "Track and Trace System"):

a) operation date;

b) identifier of the pharmaceutical entity, which prepacks (packs) medicines into secondary (consumer) medicine packages (if unavailable, into primary medicine packages);
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

d) type of production order (contract or own manufacturing);

e) identifier of the pharmaceutical entity, which is the customer of contract manufacturing (if the information is provided by the pharmaceutical entity, which the contract manufacturer);
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

f) global trade item number of medicine trade item;

g) number of medicine production series;

h) date of medicine shelf life expiration;

i) identification code assigned to secondary (consumer) medicine package (if unavailable, to primary medicine package);
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

j) information on the used emission registrar.
(Subclause "j" is introduced by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

2. After finishing the stage of release quality control and submitting the documents and data to the Federal Service for Surveillance in Healthcare, pharmaceutical entities shall submit the following information to the Track and Trace System concerning release of finished products for each trade item of medicine manufactured in the Russian Federation:

a) operation date;

b) identifier of the pharmaceutical entity, which registers the data on release of finished products;

c) details of a record made in the automated information system of the Federal Service for Surveillance in Healthcare about the medicine to be introduced into civil circulation (date and internal identifier);

d) number of permit to introduce into civil circulation that is provided by the Federal Service for Surveillance in Healthcare (in case of introduction into civil circulation of immunobiological medicines);

e) identification code of tertiary (shipping) medicine package, which contains the medicine released into circulation (in case of release of the entire tertiary (shipping) medicine package).
(Cl. 2 as amended by Decree of the Government of the Russian Federation of 07/21/2020 No. 1079)

II. Data to be Provided by Pharmaceutical Entities to the Track and Trace System Concerning Medicines Manufactured Outside the Russian Federation

3. When finishing the production stage of medicine prepacking (packing) or finishing the marking of medicine packages with identification means at a customs warehouse according to paragraph two of Clause 4 of the Regulation on the Track and Trace System of Medicines for Medical Use, which is approved by Decree of the Government of the Russian Federation of December 14, 2018 No. 1556 "On Approval of the Regulation on the Track and Trace System of Medicines for Medical Use" (the "Regulation"), pharmaceutical entities shall submit the following information to the Track and Trace System concerning each medicine trade item manufactured outside the Russian Federation:

a) operation date;

b) identifier of the pharmaceutical entity, which is the marketing authorization holder, or of a representative office of the pharmaceutical entity in the Russian Federation;

c) identifier of the pharmaceutical entity, which prepacks (packs) medicines into secondary (consumer) medicine packages (if unavailable, into primary medicine packages);

d) identifier of the pharmaceutical entity, which is engaged in the production stage of release quality control;

e) global trade item number;

f) number of medicine production series;

g) date of medicine shelf life expiration;

h) code of the customs authority and registration number of the customs warehouse (if medicine packages are marked with identification means at the customs warehouse);

i) identification code assigned to secondary (consumer) medicine package (if unavailable, to primary medicine package);

j) information on the used emission registrar.
(Cl. 3 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

3^1. In case of marking of medicine packages with identification means at a customs warehouse according to paragraph two of Clause 4 of the Regulation, pharmaceutical entities shall submit the following data to the Track and Trace System:

a) identifier of the pharmaceutical entity, which is the marketing authorization holder, or of a representative office of the pharmaceutical entity in the Russian Federation;

b) operation date;

c) global trade item number;

d) code of the customs authority and registration number of the customs warehouse where medicine packages marked with identification means according to paragraph two of Clause 4 of the Regulation;

e) identification codes.
(Cl. 3^1 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

III. Data to be Provided by Pharmaceutical Entities to the Track and Trace System Concerning Medicines Imported into the Russian Federation

4. When finishing the medicine shipment to the Russian Federation or after submitting the data on marking of medicine packages with identification means at a customs warehouse according to paragraph two of Clause 4 of the Regulation, pharmaceutical entities shall submit the following information for each medicine item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which is the marketing authorization holder, or of a representative office of the pharmaceutical entity in the Russian Federation (not required if information is provided as per the paragraphs seven and ten of clause 37 and paragraph seven of clause 38 of the Provision);
(as amended by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779);

c) identifier of the pharmaceutical entity, which is the medicine seller (not required if information is provided as per the paragraphs seven and ten of clause 37 and paragraph seven of clause 38 of the Provision);

(as amended by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

d) identifier of the pharmaceutical entity, which is the medicine buyer in the Russian Federation;

e) contract type;

f) details of the primary document, which is the grounds for medicine shipment to the Russian Federation;

g) code of the customs authority and registration number of the customs warehouse (goods location address as per goods customs declaration, unless medicine packages are marked with identification means at the customs warehouse according to paragraph two of Clause 4 of the Regulation);

h) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of shipment of the entire tertiary (shipping) medicine package).
(Cl. 4 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

5. In case of import, pharmaceutical entities shall submit the following information for each medicine item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which imports medicines into the Russian Federation;

c) code of the customs authority and registration number of the customs warehouse (goods location address as per goods customs declaration);

d) identifier of the pharmaceutical entity, which is the medicine seller (not required if information is provided as per the paragraphs seven and ten of clause 37 and paragraph seven of clause 38 of the Provision);
(as amended by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

e) contract type;

f) details of the primary document, which is the grounds for medicine import into the Russian Federation (date and number);

g) identifier of the pharmaceutical entity, which is the marketing authorization holder, or of a representative office of the pharmaceutical entity in the Russian Federation (in case of medicine import into the Russian Federation by a pharmaceutical entity, which is not the marketing authorization holder.) (not required if information is provided as per the paragraphs seven and ten of clause 37 and paragraph seven of clause 38 of the Provision);
(as amended by Decree of the Government of the Russian Federation of 11/2/2020 No. 1779)

h) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of import of the entire tertiary (shipping) medicine package).
(Cl. 5 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

6. Those pharmaceutical entities, which transfer medicines subjected to the customs procedure of

customs warehouse to another owner (change of ownership), shall submit the following information for each medicine item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which transfers the medicines;

c) identifier of the pharmaceutical entity, which accepts the medicines;

d) details of the primary document, which is the grounds for medicine transfer (date and number);

e) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transfer of the entire tertiary (shipping) medicine package).
(Cl. 6 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

7. When confirming the data on medicine shipment or import into the Russian Federation, or on medicine acceptance at a pharmaceutical warehouse in the Russian Federation, or on transfer of ownership of medicine subjected to the customs procedure of a customs warehouse, when confirming the data in the Track and Trace System, pharmaceutical entities shall submit the following information for each medicine item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which confirms the data;

c) identifier of the pharmaceutical entity, which previously registered the information on medicine shipment or import into the Russian Federation, or on medicine acceptance at a pharmaceutical warehouse in the Russian Federation, or on transfer of ownership of medicine subjected to the customs procedure of a customs warehouse;

d) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transfer of the entire tertiary (shipping) medicine package).
(Cl. 7 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

8. In case of medicine transportation between customs control areas, pharmaceutical entities shall submit the following information for each medicine item to the Track and Trace System:
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

a) operation date;

b) identifier of the pharmaceutical entity, which transports the medicines;
(Subclause “b” as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

d) code of the customs authority and registration number of the customs shipping warehouse (goods location address as per goods customs declaration from where the goods are transported);
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

e) code of the customs authority and registration number of the customs warehouse (goods location address to where the goods are transported);

f) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transportation of the entire tertiary (shipping) medicine package).
(Subclause "f" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

9. When a decision is made on medicine release for domestic consumption, as decided by the customs authorities, pharmaceutical entities shall submit the following information for each medicine trade item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which declares the medicines in the Russian Federation;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) customs procedure code;

d) customs authority code;

e) details of the medicine customs declaration;

f) customs value of the medicine according to the medicine customs declaration;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

g) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of subjecting the entire tertiary (shipping) medicine package to the customs procedure);
(Subclause "g" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

h) – i) are no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079.

10. In case of medicine transportation from the customs control area to a pharmaceutical warehouse, pharmaceutical entities shall submit the following information for each medicine item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which imports medicines into the Russian Federation;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079.

d) code of the customs authority and registration number of the customs shipping warehouse;

e) details of the primary document, which is the grounds for medicine acceptance at the pharmaceutical warehouse (date and number);

f) value, which is specified in the goods shipping documents and based on which the customs declaration is prepared, including customs duties and customs clearance fees;

g) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of acceptance of the entire tertiary (shipping) medicine package at the pharmaceutical warehouse).
(Subclause "g" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

11. When finishing the medicine shipment to the Russian Federation from member states of the Eurasian Economic Union, pharmaceutical entities shall submit the following information for each medicine trade item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which is the marketing authorization holder, or of a representative office of the pharmaceutical entity in the Russian Federation;

c) identifier of the pharmaceutical entity, which is the medicine seller;

d) identifier of the pharmaceutical entity, which is the medicine buyer in the Russian Federation;

e) details of the primary document, which is the grounds for medicine shipment to the Russian Federation (date and number);

f) contract type;

g) medicine value (including value added tax) according to primary documents;

h) value added tax amount;

i) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of shipment of the entire tertiary (shipping) medicine package).
(Cl. 11 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

12. In case of medicine import into the Russian Federation from member states of the Eurasian Economic Union and placement at a pharmaceutical warehouse, pharmaceutical entities shall submit the following information for each medicine trade item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which imports medicines into the Russian Federation;

c) identifier of the pharmaceutical entity, which is the medicine seller (not required if information is provided as per the paragraphs seven and ten of clause 37 and paragraph seven of clause 38 of the Provision);
(as amended by Decree of the Government of the Russian Federation of 11/02/2020 No. 1779)

d) contract type;

e) details of the primary document, which is the grounds for medicine import into the Russian

Federation (date and number);

f) medicine value (including value added tax) according to primary documents;

g) value added tax amount;

h) identifier of the pharmaceutical entity, which is the marketing authorization holder, or of a representative office of the pharmaceutical entity in the Russian Federation (in case of medicine import into the Russian Federation by a pharmaceutical entity, which is not the marketing authorization holder) (not required if information is provided as per the paragraphs seven and ten of clause 37 and paragraph seven of clause 38 of the Provision);
(as amended by Decree of the Government of the Russian Federation of 11/02/2020 No. 1779)

i) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of import of the entire tertiary (shipping) medicine package).
(Cl. 12 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

13. After submitting the documents and data to the Federal Service for Surveillance in Healthcare, pharmaceutical entities shall submit the following information for each medicine item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which imports medicines into the Russian Federation;

c) details of a record made in the automated information system of the Federal Service for Surveillance in Healthcare about the medicine to be introduced into civil circulation (date and internal identifier);

d) number of permit to introduce into civil circulation that is provided by the Federal Service for Surveillance in Healthcare (in case of introduction into civil circulation of immunobiological medicines);

e) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of import of the entire tertiary (shipping) medicine package).
(Cl. 13 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

14. In case of medicine re-introduction into circulation, pharmaceutical entities shall submit the following information for each medicine item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which previously withdrew these medicine from circulation;

c) reasons of the previous withdrawal of medicine from circulation;

d) identification code of the medicine to be re-introduced into civil circulation;

e) reasons of medicine re-introduction into circulation.
(Cl. 14 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

Appendix 4
To the Regulation on the Track and
Trace System of Medicines for
Medical Use

DATA TO BE SUBMITTED TO THE TRACK AND TRACE SYSTEM OF MEDICINES FOR MEDICAL USE BY PHARMACEUTICAL ENTITIES IN CASE OF WITHDRAWAL FROM CIRCULATION OF MEDICINES FOR MEDICAL USE

List of modifying documents
(as amended by Decrees of the Government of the Russian Federation of
03/20/2020 No. 311, of 7/21/2020 No. 1079)

1. In case of withdrawal from circulation of medicines for medical use (the "medicines") by selling medicines to customers, or issuing medicines free of charge or at a discount on prescription or issuing medicines during medical care, sampling or withdrawal from circulation for other reasons, the pharmaceutical entity shall submit the following information for the medicines withdrawn from circulation to the Track and Trace System of Medicines (the "Track and Trace System"):

a) operation date;

b) identifier of the pharmaceutical entity, which withdraws the medicines from circulation;

c) type of medicine withdrawal from circulation;

d) type of the document, which confirms medicine withdrawal from circulation (receipt, accountable form, contract, other);

e) details of the document, which confirms medicine withdrawal from circulation;

f) identification codes of medicines withdrawn from circulation or identification codes of tertiary (shipping) medicine package, which contains this medicine (in case of withdrawal of the entire tertiary (shipping) medicine package from circulation for other reasons);

g) medicine value (including value added tax) (if the medicine is sold to a customer);

h) value added tax amount (if the medicine is sold to a customer;

i) number of primary medicine packages to be withdrawn from circulation and total number of primary medicine packages in secondary (consumer) medicine package (in case of withdrawal from circulation of a disaggregated secondary (consumer) package).
(Cl. 1 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

2. In case of medicine withdrawal from circulation by destroying the medicines subjected to the customs procedure of destruction, by exporting outside the customs area of the Eurasian Economic Union for medicines subjected to the customs procedure of export (re-export), the pharmaceutical entity shall

submit the following information to the Track and Trace System concerning the medicines withdrawn from circulation:

a) operation date;

b) identifier of the pharmaceutical entity, which withdraws the medicines from circulation;

c) customs authority code;

d) customs procedure code;

e) identification code of the medicine to be withdrawn from circulation or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of withdrawal from circulation of the entire tertiary (shipping) medicine package);

f) details of the medicine customs declaration.
(Cl. 2 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

3. In case of medicine withdrawal from circulation by transferring medicines for destruction, the pharmaceutical entity shall submit the following information to the Track and Trace System concerning the medicines withdrawn from circulation:

a) operation date;

b) identifier of the pharmaceutical entity, which withdraws the medicines from circulation;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079.

d) grounds and reason of medicine transfer for destruction;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

e) details of the decision on medicine withdrawal from circulation made by the authorized federal executive body (if any);

f) details of the document, which confirms medicine transfer for destruction;

g) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of withdrawal from circulation of the entire tertiary (shipping) medicine package);
(Subclause “g” as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

h) identification number and address of the taxpayer, which destroys the medicines.
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

4. When destroying the medicines previously transferred for destruction, the pharmaceutical entity shall submit the following information on medicine destruction to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which withdrew the medicines from circulation;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) method of medicine destruction;

d) details of the document, which confirms medicine destruction (medicine destruction certificate);

e) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of withdrawal from circulation of the entire tertiary (shipping) medicine package);
(Subclause “e” as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

f) identification number of the taxpayer, which destroyed the medicines.

Appendix 5
To the Regulation on the Track and Trace
System of Medicines for Medical Use

DATA TO BE SUBMITTED TO THE TRACK AND TRACE SYSTEM OF MEDICINES FOR MEDICAL USE BY PHARMACEUTICAL ENTITIES WHEN HANDLING TERTIARY (SHIPPING) MEDICINE PACKAGES

List of modifying documents
(as amended by Decrees of the Government of the Russian Federation of
03/20/2020 No. 311, of 7/21/2020 No. 1079)

1. When aggregating those medicines for medical use (the "medicines"), which have the same global trade item number, pharmaceutical entities shall submit the following information to the Track and Trace System of Medicines for Medical Use (the "Track and Trace System"):
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

a) operation date (for medicines for medical use (the "medicines"), which are located outside the Russian Federation, when aggregation is performed before the stage of release quality control, any date may be specified between the date when the stage of release quality control is completed and the date when the medicines are shipped to the Russian Federation);

b) identifier of the pharmaceutical entity, which aggregates;
(Subclause "b" as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079.

d) identification codes of tertiary (shipping) medicine packages, tertiary (shipping) medicine packages being created;
(Subclause "d" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

e) list of identification codes or identification codes of medicine packages of lower nesting level that are included in each tertiary (shipping) medicine package created.
(Subclause "e" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

2. When removing any medicines from tertiary (shipping) medicine packages, pharmaceutical entities shall submit the following information to the Track and Trace System:
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

a) operation date;

b) identifier of the pharmaceutical entity, which performs the operation;
(Subclause "b" as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079.

d) identification code of the trade item removed from tertiary (shipping) medicine package, or identification code of medicine package of a lower nesting level that is removed from tertiary (shipping) medicine package.
(Subclause "d" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

3. When adding any medicines into tertiary (shipping) medicine packages, pharmaceutical entities shall submit the following information to the Track and Trace System:
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

a) operation date;

b) identifier of the pharmaceutical entity, which performs the operation; (Subclause "b" as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

d) identification code or identification code of medicine package of a lower nesting level, with which the adding operation is performed;
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

e) identification code of tertiary (shipping) medicine package for which the operation is performed.
(as amended by Decrees of the Government of the Russian Federation of 3/20/2020 No. 311, 7/21/2020 No.1079)

4. When disaggregating any tertiary (shipping) medicine packages, pharmaceutical entities shall submit the following information to the Track and Trace System:
(as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

a) operation date;

b) identifier of the pharmaceutical entity, which performs the operation;
(Subclause "b" as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

d) type of the operation of disaggregation of tertiary (shipping) medicine package;
(Subclause "d", as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

e) identification code of tertiary (shipping) medicine package, tertiary (shipping) medicine package being disaggregated.
(Subclause "e", as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

Appendix 6
To the Regulation on the Track and Trace
System of Medicines for Medical Use

DATA TO BE SUBMITTED TO THE TRACK AND TRACE SYSTEM OF MEDICINES FOR MEDICAL USE BY PHARMACEUTICAL ENTITIES IN CASE OF CIRCULATION AND INTERNAL TRANSPORTATION OF MEDICINES FOR MEDICAL USE

List of modifying documents
(as amended by Decrees of the Government of the Russian Federation of
03/20/2020 No. 311, of 7/21/2020 No. 1079), of 11/2/2020 No. 1779)

1. When transporting any medicines for medical use (the "medicines") between business place addresses and/or pharmaceutical warehouses, the pharmaceutical entity shall submit the following information on the transported medicines for each medicine trade item to the Track and Trace System of Medicines (the "Track and Trace System"):

a) date of operation (acceptance at the warehouse to which the medicine is transported);

b) identifier of the pharmaceutical entity, which transports the medicines, with the address of business place or secure storage warehouse from which the medicine is transported;
(Subclause "b" as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

d) identifier of the pharmaceutical entity with the address of business place or secure storage warehouse to which the medicine is transported;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

e) details of the primary document, which is the grounds for medicine transportation (date and number);

f) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transportation of the entire tertiary (shipping) medicine package);
(Subclause "f" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

g) details of the state or municipal contract (in case of medicine transportation for provision of citizens from the federal budget resources and/or budget resources of constituent entities of the Russian Federation);
(Subclause "g" is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

h) financing source (in case of medicine transportation for provision of citizens from the federal

budget resources and/or budget resources of constituent entities of the Russian Federation);
(Subclause "h" is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

i) medicine value (including value added tax) according to primary documents (in case of medicine transportation for provision of citizens from the federal budget resources and/or budget resources of constituent entities of the Russian Federation);
(Subclause "i" is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

j) value added tax amount (in case of medicine transportation for provision of citizens from the federal budget resources and/or budget resources of constituent entities of the Russian Federation).
(Subclause "j" is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

2. When transferring any medicines to another pharmaceutical entity within civil law relations in case of direct order of data submission according to Clause 44 of the Regulation on the Track and Trace System of Medicines for Medical Use, which is approved by Decree of the Government of the Russian Federation of December 14, 2018 No. 1556 "On Approval of the Regulation on the Track and Trace System of Medicines for Medical Use", the pharmaceutical entity shall submit the following information on shipped medicines for each medicine trade item to the Track and Trace System:
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

a) operation date;

b) identifier of the pharmaceutical entity, which ships the medicines;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

d) identifier of the pharmaceutical entity, which accepts the medicine;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

e) – f) are no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

g) details of the state or municipal contract (in case of medicine transfer for provision of citizens from the federal budget resources and/or budget resources of constituent entities of the Russian Federation);
(Subclause "g" as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

h) financing source;

i) type of civil law relations between pharmaceutical entities;

j) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transfer of the entire tertiary (shipping) medicine package);
(Subclause "j" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

k) details of the primary document, which is the grounds for medicine transfer (date and number);

l) medicine value (including value added tax) according to primary documents;

m) value added tax amount.
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

3. When accepting any medicines from another pharmaceutical entity within civil law relations in case of reverse order of data submission according to Clause 44 of the Regulation on the Track and Trace System of Medicines for Medical Use, which is approved by Decree of the Government of the Russian Federation of December 14, 2018 No. 1556 "On Approval of the Regulation on the Track and Trace System of Medicines for Medical Use", the pharmaceutical entity shall submit the following information on accepted medicines for each medicine item to the Track and Trace System:
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

a) operation date;

b) identifier of the pharmaceutical entity, which accepts the medicines (or its tax identification number if information is provided as per paragraph seven of clause 44 of the Provision on the Track and Trace System of Medicines for Medical Use approved by Decree of the Government of the Russian Federation of December 14, 2018 No. 1556 "On Approval of the Regulation on the Track and Trace System of Medicines for Medical Use");
(as amended by Decrees of the Government of the Russian Federation of 7/21/2020 No. 1079, of 11/02/2020 No.1779)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

d) identifier of the pharmaceutical entity, which shipped the medicine;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

e) – f) are no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

g) details of the state or municipal contract (in case of medicine transfer for provision of citizens from the federal budget resources and/or budget resources of constituent entities of the Russian Federation);
(Subclause "g" as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

h) financing source;

i) type of civil law relations between pharmaceutical entities;

j) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transfer of the entire tertiary (shipping) medicine package);
(Subclause "j" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

k) details of the primary document, which is the grounds for medicine transfer (date and number);

l) medicine value (including value added tax) according to primary documents;

m) value added tax amount.
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

4. When confirming reliability of the data on the Track and Trace System concerning the transferred or accepted medicines, the pharmaceutical entity shall submit the following information for each medicine trade item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which confirms the data;
(Subclause "b" as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) identifier of the pharmaceutical entity, which previously submitted the data on medicine shipment or acceptance;
(Subclause "c" as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

d) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transfer of the entire tertiary (shipping) medicine package);
(Subclause "d" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

e) attribute confirming that medicine, which is temporarily withdrawn from circulation as initiated by the authorized federal executive body, may (may not) be accepted.
(Subclause "e" is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

5. When transferring any medicines (finished products) to the pharmaceutical entity, which is the customer of contract manufacturing, the pharmaceutical entity, which is the contract manufacturer of medicines in the Russian Federation, shall submit the following information on transferred medicines for each medicine trade item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which transfers the medicines;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

c) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

d) identifier of the pharmaceutical entity, which accepts the medicine;
(as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

e) is no longer effective — Decree of the Government of the Russian Federation of 7/21/2020 No. 1079;

f) identification code or identification code of tertiary (shipping) medicine package, which contains this medicine (in case of transfer of the entire tertiary (shipping) medicine package);
(Subclause "f" as amended by Decree of the Government of the Russian Federation of 3/20/2020 No. 311)

g) details of the primary document, which is the grounds for medicine transfer (date and number).

6. When transferring any medicines purchased for provision of citizens from the federal budget resources and/or budget resources of constituent entities of the Russian Federation, the pharmaceutical entity, which performs outsourcing functions, shall submit the following information on transferred medicines for each medicine trade item to the Track and Trace System:

a) operation date;

b) identifier of the pharmaceutical entity, which transfers the medicines;

c) identifier of the pharmaceutical entity, which accepts the medicine;

d) details of the primary document, which is the grounds for medicine transfer (date and number);

e) identification code or identification code of tertiary (shipping) package, which contains the medicine (in case of transfer of the entire tertiary (shipping) medicine package).
(Cl. 6 is introduced by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

Appendix 7
To the Regulation on the Track and Trace
System of Medicines for Medical Use

LIST OF REASONS FOR THE TRACK AND TRACE SYSTEM OF MEDICINES FOR MEFICAL USE TO BLOCK THE ACCEPTANCE OF DATA ON INTRODUCTION INTO CIRCULATION OF MEDICINES FOR MEDICAL USE, ON CIRCULATION AND/OR WITHDRAWAL FROM CIRCULATION OF MEDICINES FOR MEDICAL USE

List of modifying documents
(as amended by Decrees of the Government of the Russian Federation of 8/30/2019 No. 1118, of 7/21/2020 No. 1079)

1. Detection of non-compliance with quality requirements in the course of random quality control of medicines and of federal supervision in medicine circulation, which are provided by the Federal Service for Surveillance in Healthcare and its local offices.

2. Decision made by the Federal Service for Surveillance in Healthcare that follows the review of a request filed by a pharmaceutical entity and that contains data on detection of non-compliance of medicines for medical use, which are released into circulation (the "medicines"), with the requirements established by the Ministry of Health of the Russian Federation upon registration of these medicines.

3. Decision made by the Ministry of Health of the Russian Federation to cancel the state registration of medicine as per the procedure stipulated in Clause 6 of Article 32 of the Federal Law "On Medicine Circulation".

4. There are no data in the Track and Trace System of Medicines (the "Track and Trace System") that the pharmaceutical entity, which submits data on medicine circulation, is in possession of this medicine.

5. Expiration of medicine shelf life according to the data registered in the Track and Trace System.

6. Data on global trade item number, marketing authorization number of medicine, and date of medicine registration in the state register of medicines that are provided for medicine description by a pharmaceutical entity to the information resource, which enables accounting and storage of reliable data on the goods by the corresponding goods nomenclature, do not match the data that are received by the Track and Trace System from the unified state information system in healthcare.
(Clause 6 as amended by Decree of the Government of the Russian Federation of 7/21/2020 No. 1079)

7. Submitting of data to the Track and Trace System concerning medicine sale from a pharmaceutical warehouse in case of secure storage.

8. Submitting of data concerning medicine shipment (sale) before registering any data on medicine introduction into circulation in the Track and Trace System.

9. Submitting of data to the Track and Trace System with violation of requirements of the Regulation

on the Track and Trace System of Medicines for Medical Use, which is approved by Decree of the Government of the Russian Federation of December 14, 2018 No. 1556 “On Approval of the Regulation on the Track and Trace System of Medicines for Medical Use”.

10. There are no data in the Track and Trace System that the pharmaceutical entity has a license that grants the pharmaceutical entity a right to perform respective operations.

11. There are no data on the informant being a valid legal entity in the Unified State Register of Legal Entities, or a valid individual entrepreneur in the Unified State Register of Individual Entrepreneurs, or a valid branch or representative office of a foreign legal entity in the Russian Federation in the state register of accredited branches and representative offices of foreign legal entities.

12. The Unified State Register of Legal Entities contains a record, which is entered according to Clause 5 and/or 6 of Article 11 of the Federal Law “On State Registration of Legal Entities and Individual Entrepreneurs”, about unreliable data concerning the informant.

13. There are grounds to reject registration of data on application of identification means as stipulated in Clause 9(3) of the Regulation on the Track and Trace System of Medicines for Medical Use, which is approved by Decree of the Government of the Russian Federation of December 14, 2018 No. 1556 “On Approval of the Regulation on the Track and Trace System of Medicines for Medical Use”.
(Cl. 13 is introduced by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)

14. Decision made by the Ministry of Health of the Russian Federation to suspend the medicine use according to Part 7 of Article 64 and Article 65 of the Federal Law “On Medicine Circulation”.
(Cl. 14 is introduced by Decree of the Government of the Russian Federation of 8/30/2019 No. 1118)