

THE GOVERNMENT OF THE RUSSIAN FEDERATION

DECREE

dd. December 14, 2018 No. 1556

MOSCOW

On Approval of the Regulations on the System for Monitoring of Flow of Medicinal Products for Human Use

In accordance with Clauses 5-7 of Article 67 of Federal Law "On Circulation of Medicines", the Government of the Russian Federation **hereby decrees:**

1. To approve the enclosed Regulations on the System for Monitoring of Flow of Medicinal Products for Human Use.

2. This Decree shall be executed by the competent federal executive authorities within the maximum number of their employees established by the Government of the Russian Federation, and the federal budget allocations provided for management and administration in the field of established functions.

3. This Decree shall come into effect as from the day of its official publication, with the exception of provisions of Clause 4 hereof.

4. The Regulations on the System for Monitoring of Flow of Medicinal Products for Human Use approved by this Decree with respect to the medicines manufacturers as regards the application of the means of identification on primary package (for the medicinal products for human use with no secondary package provided) and on secondary (consumer) package of medicinal products for human use, as well as with respect to legal entities and individual entrepreneurs manufacturing, storing, importing to the Russian Federation, dispensing, selling, transferring, administering and destructing medicinal products for human use as regards the entry of information about medicinal products for human use to the System for Monitoring of Flow of Medicinal Products for Human Use shall come into effect from the effective date of paragraphs Two and Five of Subclause "b" of Clause 7 of Article 1 of Federal Law dated December 28, 2017 No. 425-FZ "On Amending the Federal Law "On Circulation of Medicines".

Chairman of the Government of the
Russian Federation

Seal:
EXECUTIVE OFFICE OF THE
GOVERNMENT OF THE RUSSIAN
FEDERATION
RECORD MANAGEMENT AND
ARCHIVING DEPARTMENT
OF THE GOVERNMENT OF THE
RUSSIAN FEDERATION
NO. 1

D. Medvedev

REGULATIONS

On the System for Monitoring of Flow of Medicinal Products for Human Use

I. General Provisions

1. These Regulations shall establish:

a) The procedure for application of the Identification Means of a Medicinal Product for human use (hereinafter referred to as the Medicinal Products), requirements as to its structure and format of information contained in the Identification Means of a Medicinal Product, and its characteristics;

b) The procedure for establishment, development, putting into operation, operation and withdrawal from operation of the system for monitoring of flow of Medicinal Products (hereinafter referred to as the Monitoring System);

c) The procedure for interaction of the Monitoring System with other state information systems and information systems of legal entities and individual entrepreneurs specified in Clauses 7 and 10 of Article 67 of Federal Law "On Circulation of Medicines";

d) The procedure for entry of information about Medicinal Products into the Monitoring System by legal entities and individual entrepreneurs manufacturing, storing, importing to the Russian Federation, dispensing, selling, transferring, administering and destructing Medicinal Products, and contents thereof;

e) The procedure for providing information contained in the Monitoring System.

2. The terms used herein shall have the following meanings:

"Aggregation" means a process of combining Medicinal Products into Group Package by a Subject of Medicines Circulation at any stage of Medicinal Products circulation with application of the corresponding Group Code of Tertiary (Shipping) Package of a Medicinal Products, and with saving in the Monitoring System of the information regarding interrelation of the identification means of each Medicinal Product inserted into the Group Package with Group Code of Tertiary (Shipping) Package of Medicinal Products within the formed Group Package;

"Putting of Medicinal Products into Circulation" means:

in case of Russian manufacture, operations performed with Medicinal Products starting from the production stage of Medicinal Products filling (packing) into primary package (for Medicinal Products for which no Secondary (Consumer) Package of a Medicinal Product is provided), and into secondary (consumer) package to completion of the production stage of release quality control;

in case of manufacture outside the Russian Federation (except for the Medicinal Products imported from the Eurasian Economic Union member states), operations performed with Medicinal Products starting from the production stage of release control to completion of the customs procedure for release for domestic consumption upon import of Medicinal Products to the Russian Federation;

in case of manufacture outside the Russian Federation, with regard to Medicinal Products imported from the Eurasian Economic Union member states, operations performed with Medicinal Products starting from the production stage of release control to placement of Medicinal Products at a pharmaceutical warehouse and completion of the procedures for Medicinal Products

conformity certification;

"Secondary (Consumer) Package of a Medicinal Product" means a package delivered to the customer and designed for accommodation of a single Primary Package of a Medicinal Product or combining several primary packages of Medicinal Products;

"Withdrawal of Medicinal Products from Circulation" means distribution, sale and dispensing (including on prescription) of Medicinal Products to consumer, administration, transfer for destruction, loss and disposal of Medicinal Products, sampling, export of Medicinal Products previously imported to the Russian Federation (re-export), as well as withdrawal from circulation for other reasons;

"Global Trade Item Number" means a unique code assigned to a commodity group upon description thereof on the information resource which ensures accounting and storage of reliable data on the goods according to the corresponding nomenclature of goods;

"Group Package" means grouped packages (primary, secondary (consumer), tertiary (shipping) packages of a Medicinal Product);

"Group Code" means identification means of a Group Package of Medicinal Products, a combination of symbols unique for each individual Tertiary (Shipping) Package of a Medicinal Product represented in the form of a linear bar code formed by the Group Code Issuer;

"Application Identifier" means a prefix representing a set of 2 or more symbols at the beginning of element string and uniquely identifying the value and format of data field following the prefix;

"Individual Serial Trade Item Number" means a numerical or alpha-numerical sequence;

"Verification Code" means a sequence of symbols provided by the Monitoring System operator to the Medicinal Product Identification Means Issuers which consists of a verification key and an electronic signature;

"Medicinal Products Labeled with Identification Means" mean Medicinal Products marked with the identification means, reliable information about which has been duly transferred to the Monitoring System;

"Labeling of Medicinal Product Packages with Identification Means" means application of identification means on Secondary (Consumer) Package of a Medicinal Product (or, in the absence thereof, on Primary Package of a Medicinal Product);

"Description of a Medicinal Product" means a list of characteristics placed by the Subject of Medicines Circulation on the relevant information resource which ensures accounting and storage of reliable data on the goods according to the corresponding nomenclature of goods;

"Primary Package of a Medicinal Product" means a facility or a set of facilities ensuring protection of Medicinal Products from damage and loss, environment, contamination, and having direct contact with Medicinal Products;

"Withdrawal Recorder" means a software and hardware cryptographic system which ensures generation and recording of legally relevant data on Withdrawal of Medicinal Products from Circulation;

"Serialized Global Trade Item Number" means a unique identifier of Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, of Primary Package of a Medicinal Product) formed by addition of the Individual Serial Trade Item Number to the Global Trade Item Number;

"Identification Means" mean a unique sequence of symbols presented in a machine-readable form or using another means (technology) of automatic identification which is applied on the Medicinal Products package by printing or labeling;

"Subjects of Medicines Circulation" mean legal entities and individual entrepreneurs manufacturing, storing, importing to the Russian Federation, dispensing, selling, transferring, administering and destructing Medicinal Products;

"Tertiary (Shipping) Package of a Medicinal Product" means a Group Package used for storage, transportation and movement of a Medicinal Product between Subjects of Medicines Circulation;

"Issue Recorder" means a software and hardware cryptographic system (cryptographic safety controller) which ensures provision of the Identification Means Issuers with Verification Codes, generation and recording of legally relevant data on labeling of Medicinal Product packages with Identification Means in the Monitoring System;

"Filling (Packaging) of a Medicinal Product" means a production stage at which a Medicinal Product is contained into Primary Package of a Medicinal Product or into Secondary (Consumer) Package of a Medicinal Product;

"Group Code Issuer" means a Subject of Medicines Circulation generating and applying a Group Code on a Tertiary (Shipping) Package of Medicinal Products;

"Identification Means Issuer" means a medicines manufacturer performing the production stage of Filling (Packaging) of a Medicinal Product with application of Identification Means on Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, on Primary Package of a Medicinal Product) in case the Medicinal Product is manufactured in the Russian Federation, or the holder or owner of Marketing Authorization of the Medicinal Product (hereinafter referred to as the Marketing Authorization) in case the Medicinal Product is manufactured outside the Russian Federation, or the Russian representative office of a foreign organization holding or owning the Marketing Authorization in case the Medicinal Product is manufactured outside the Russian Federation.

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

3. When applied on Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, on Primary Package of a Medicinal Product), the Identification Means shall have the following characteristics:

a) a 2D bar code shall be applied using dot symbols in line with the requirements of the National Standard of the Russian Federation (GOST R ISO/IEC 16022-2008 "Automatic Identification. Bar Coding. Data Matrix Symbols Specification") approved by Order of the Federal Agency for Technical Regulation and Metrology;

b) a 2D bar code shall be applied with a quality class C or higher in line with the requirements of the National Standard of the Russian Federation (GOST R ISO/IEC 15415-2012 "Information Technology. Automatic Identification and Data Capture Techniques. Bar Code Symbol Test Specification for Print Quality Assessment. Two-Dimensional Symbols") approved by Order of the Federal Agency for Technical Regulation and Metrology;

c) a 2D bar code shall be applied by printing using ECC-200 Error Correction method in line with the requirements of the National Standard of the Russian Federation (GOST R ISO/IEC 16022-2008 "Automatic Identification. Bar Coding. Data Matrix Symbols Specification") approved by order of the Federal Agency for Technical Regulation and Metrology;

d) when applying the Identification Means of a Medicinal Product, ASCII coding shall be used based on the National Standard of the Russian Federation (GOST R ISO/IEC 16022-2008 "Automatic Identification. Bar Coding. Data Matrix Symbols Specification") approved by Order

of the Federal Agency for Technical Regulation and Metrology.

4. Information contained in the Identification Means shall be applied as a 2D bar code on the production line by printing or labeling with a sticker inseparable from the package.

5. Information contained in the Identification Means shall have the following structure:

Feature of Data Matrix symbols means a symbol having code 232 in ASCII symbols table;

First data group means Global Trade Item Number consisting of 14 numerical symbols preceded by Application Identifier (01);

Second data group means Individual Serial Trade Item Number consisting of 13 symbols of numeric or alphanumeric sequence (Latin alphabet) preceded by Application Identifier (21). A special separator symbol having code 29 in ASCII symbols table shall be used as an ending symbol for this data group;

Third data group means verification key provided by the Monitoring System operator to the Identification Means Issuers as part of a Verification Code in accordance with these Regulations, which consists of 4 symbols (numbers, lower and upper case letters of the Latin alphabet) preceded by Application Identifier (91). A special separator symbol having code 29 in ASCII symbols table shall be used as an ending symbol for this data group;

Fourth data group means electronic signature provided by the Monitoring System operator to the Identification Means Issuers as part of a Verification Code in accordance with these Regulations which consists of 88 symbols (numbers, lower and upper case letters of the Latin alphabet, as well as special symbols) preceded by Application Identifier (92).

Additionally, at the discretion of the Identification Means Issuer, the following can be included in 2D bar code before the third and fourth data groups:

Fifth data group means Medicinal Product batch number containing up to 20 symbols of numeric or alphanumeric sequence (Latin alphabet) preceded by Application Identifier (10). A special separator symbol having code 29 in ASCII symbols table shall be used as an ending symbol for this data group;

Sixth data group means expiry date preceded by Application Identifier (17). Medicinal Product expiry date shall be recorded as 6 numeric symbols in "year - month - day" ("YYMMDD") format.

In cases when the precise expiry date value is not specified in days ("DD") as of the date of product release, the Identification Means Issuer shall specify the date value as of the first or the last day of the month in accordance with the shelf life approved by the Medicinal Product normative documentation.

Requirements as to the sequence of data groups in the Identification Means structure shall be set out for the first data group that must always be located at the beginning of the Identification Means sequence, as well as to the third and fourth data groups that must be located at the end of the Identification Means sequence.

Individual Serial Trade Item Number shall be generated so as to ensure its uniqueness for each Global Trade Item Number during the entire operation life of the Monitoring System.

Global Trade Item Number and Individual Serial Trade Item Number shall be duplicated in the form of a legible printed text.

III. Procedure for Obtaining Verification Codes and Group Code

6. The Identification Means Issuers shall obtain Verification Codes from the Monitoring System operator using Issue Recorders.

7. The Identification Means Issuer registered with the Monitoring System shall file an application for Verification Codes to the Monitoring System operator. The application shall be filed using Issue Recorders. In this case, interactions between the Issue Recorders and information systems of the Identification Means Issuer shall be performed using the data formats published by the Monitoring System operator on its official website. The application for Verification Codes shall contain:

a) Serialized Global Trade Item Number, in case the Individual Serial Trade Item Number is generated by the Identification Means Issuer;

b) Global Trade Item Number and quantity of Individual Serial Trade Item Numbers, in case the Individual Serial Trade Item Number is generated by the Monitoring System operator.

8. Verification Codes shall be assigned by the Monitoring System operator for each Serialized Global Trade Item Number.

The Monitoring System operator shall, within 2 hours after receiving an application for Verification Codes, send to the Identification Means Issuer a list of data (Serialized Global Trade Item Numbers and Verification Codes) for the labeling of Medicinal Product packages with Identification Means, and record the same in the Monitoring System using Issue Recorders.

9. The Monitoring System operator shall ensure the receipt of Verification Codes by the Identification Means Issuers by providing them with Issue Recorders. Issue Recorders shall be provided by transferring them to the Identification Means Issuers or by granting remote access to such recorders to the Identification Means Issuer's information system. A decision to choose the method of provision shall be made by the Identification Means Issuer.

The Monitoring System operator shall provide Identification Means Issuers with the Issue Recorders free of charge. For the purpose of such provision, the Identification Means Issuer shall sign agreements with the Monitoring System operator including, inter alia, the terms of provision with such equipment and its routine maintenance on a free-of-charge basis. Standard form agreements shall be approved by the Ministry of Industry and Trade of the Russian Federation.

The Issue Recorder provided to the Identification Means Issuer shall be registered by the Monitoring System operator.

10. Group Code shall be generated based on the National Standard of the Russian Federation (GOST ISO/IEC 15417-2013 "Information Technology. Automatic Identification and Data Capture Techniques. Code 128 Bar Code Symbol Specification") approved by Order of the Federal Agency for Technical Regulation and Metrology, and shall contain the following data structure:

Application Identifier (00);

Group Code extension symbol;

Registration number of the Subject of Medicines Circulation obtained in the information resource which ensures the accounting and storage of reliable data on the goods according to the corresponding nomenclature of goods;

Individual Serial Trade Item Number;

Check sum (amount calculated based on the preceding figures using a special algorithm, which is meant to guarantee the data integrity).

The information included in the Group Code can be duplicated in the form of a readable printed text.

Group Code shall be generated and applied on Tertiary (Shipping) Package of a Medicinal Product by the Group Code Issuers by printing or labeling.

IV. Rules for Establishment, Putting into Operation, Operation and Withdrawal from Operation of the Monitoring System

11. The Monitoring System shall be established, developed, put into operation, operated and withdrawn from operation by the Monitoring System operator as agreed with the Ministry of Health of the Russian Federation and with the Federal Service for Surveillance in Healthcare in accordance with the requirements to the procedure for establishment, development, putting into operation, operation and withdrawal from operation of the state information systems and further storage of information contained in their databases as approved by Decree of the Government of the Russian Federation dd. July 6, 2015 No. 676 "On Requirements to the Procedure for Establishment, Development, Putting into Operation, Operation and Withdrawal from Operation of the State Information Systems and Further Storage of Information Contained in Their Databases", and in accordance with these Regulations.

12. The Monitoring System shall be established, developed and operated on the basis of:

a) Ensuring completeness, reliability, preservation of the information received and transferred using the Monitoring System, as well as the timeliness of its provision;

b) Gratuitousness of providing medicines manufacturers with information on the batches and lots of Medicinal Products manufactured by them and being in the civil circulation in the Russian Federation which is contained in the Monitoring System;

c) Unity of the organizational and methodological support of the Monitoring System;

d) Ensuring the use of unified registers, classifiers and directories of the Monitoring System, including those that must be used in the information systems of legal entities or individual entrepreneurs specified in Clauses 7 and 10 of Article 67 of Federal Law "On Circulation of Medicines";

e) Granting of regulated access to the Monitoring System;

f) Uninterrupted operation of the Monitoring System.

13. The Monitoring System shall be put into operation by a task force appointed by the Monitoring System operator with the participation of representatives of the concerned federal executive authorities.

14. The Monitoring System shall ensure:

a) Validation of the Identification Means;

b) Traceability of Medicinal Products flow from the medicines manufacturer to the end user;

c) Blocking of acceptance of information supplied to the Monitoring System in accordance with these Regulations.

15. The Monitoring System shall contain the following information:

a) Information about Subjects of Medicines Circulation;

b) Information about Medicinal Products and their circulation.

16. The main sources of information contained in the Monitoring System shall include:

a) Subjects of Medicines Circulation;

b) Federal executive authorities at the exercise of their functions using the state information

systems.

17. Coefficient of the Monitoring System accessibility shall be no less than 99.5 percent without taking into account the planned maintenance periods.

Maintenance of the Monitoring System shall be conducted not more than 4 times a year, maintenance period being not more than 24 hours.

V. Interaction of the Monitoring System with Other State Information Systems and Information Systems of Subjects of Medicines Circulation

18. The Monitoring System shall interact with the following information systems:

- a) The Unified Register of Medicine Manufacturing License;
- b) The unified register of licenses, including licenses issued by the state authorities of the constituent entities of the Russian Federation in accordance with the delegated authority to license certain types of activities in the field of health protection;
- c) The unified state information system in the field of 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) Automated information system of the Federal Service for Surveillance in Healthcare;
- h) The unified automated information system of customs authorities;
- i) Information systems of Subjects of Medicines Circulation.

19. Information supplied to the Monitoring System by the state information systems of the federal executive authorities, and information transferred from the Monitoring System is specified in Annex No. 1.

20. Within information interaction, the Monitoring System shall exchange information with the state information systems of the concerned federal executive authorities and executive authorities of the constituent entities of the Russian Federation, including via the infrastructure which ensures information and technological interaction of information systems used for the provision of state and municipal services, and for the performance of state and municipal functions in electronic form.

The Monitoring System shall be connected to the unified system of interagency electronic interaction in accordance with Decree of the Government of the Russian Federation dated September 8, 2010 No. 697 "On the Unified System for Interagency Electronic Interaction" free of charge.

21. The Monitoring System shall interact with information systems of Subjects of Medicines Circulation by means of electronic information services using standard electronic interaction protocols and interfaces.

22. Engineering standards and requirements to the technological compatibility between the Monitoring System and the information systems specified in Clause 18 hereof shall be set by the Monitoring System operator in line with the requirements of the Russian laws on information technology in coordination with the Ministry of Digital Development, Communications and Mass Media of the Russian Federation and with the operator of the interacting information system.

VI. Procedure for Entering Information about Medicinal Products into the Monitoring System by Subjects of Medicines Circulation, and Contents Thereof

23. Information about Medicinal Products shall be entered into the Monitoring System by Subjects of Medicines Circulation after they are registered with the Monitoring System and provided with a user account of a Subject of Medicines Circulation.

Registration of Subjects of Medicines Circulation in the Monitoring System and provision with a user account shall be performed based on reliable data supplied by Subjects of Medicines Circulation to the Monitoring System in electronic format, and on the documents submitted to the Federal Service for Surveillance in Healthcare.

24. For the purpose of registration with the Monitoring System, Subjects of Medicines Circulation recognized as tax residents of the Russian Federation, individual entrepreneurs and Russian representative offices of foreign organizations holding or owning the Marketing Authorization shall enter the following data in electronic format signed using enhanced qualified electronic signature of the head of the organization (Russian representative office of the foreign organization) or individual entrepreneur into the registration form of the Monitoring System on the Monitoring System operator's official site:

Taxpayer identification number;

Information on the presence or absence of a medicine manufacturing license, license for pharmaceutical activities (including wholesale and retail trade of medicines) and license for medical activities;

Contact person's surname, name, patronymic (if any) and phone number;

E-mail.

Subjects of Medicines Circulation being organizations recognized as tax residents of the Russian Federation, individual entrepreneurs having no medicine manufacturing license, license for pharmaceutical activities (including wholesale and retail trade of medicines) or license for medical activities, as well as Russian representative offices of foreign organizations holding or owning the Marketing Authorization which have no medicine manufacturing license, license for pharmaceutical activities (including wholesale and retail trade of medicines) or license for medical activities, shall, within 10 calendar days after the entry of data specified in paragraphs two - five of this clause, file a paper-based application to the Federal Service for Surveillance in Healthcare for registration with the Monitoring System (hereinafter referred to as the application) as per the form approved by the Ministry of Health of the Russian Federation.

25. For the purpose of registration with the Monitoring System, Subjects of Medicines Circulation being foreign organizations holding or owning the Marketing Authorization which are not recognized as tax residents of the Russian Federation and have no Russian representative offices, shall enter the following data in electronic format into the registration form of the Monitoring System on the Monitoring System operator's official site:

Name of the Marketing Authorization holder or owner;

Taxpayer number in the country of incorporation;

Code of the country of incorporation;

Contact person's surname, name, patronymic (if any) and phone number;

E-mail.

Authorized representatives of Subjects of Medicines Circulation being foreign organizations

holding or owning the Marketing Authorization which are not recognized as tax residents of the Russian Federation and have no Russian representative offices, shall, within 10 calendar days after the entry of data specified in paragraphs two - six of this clause, submit to the Federal Service for Surveillance in Healthcare the original documents confirming the right to represent the said Subjects of Medicines Circulation, and a paper-based application as per the form approved by the Ministry of Health of the Russian Federation.

26. Processing and check of information supplied to the Monitoring System for registration shall be performed automatically, including by means of interaction with other state information systems, using the unified system of interagency electronic interaction, within 14 working days after Subjects of Medicines Circulation supply information to the Monitoring System.

The Federal Service for Surveillance in Healthcare shall consider the applications filed under paragraph six of clause 24 hereof, as well as the applications and original documents submitted under paragraph seven of clause 25 hereof within 5 working days and report the results of applications and original documents consideration to the Monitoring System within 1 working day after making the relevant decision.

The decision to register (or refuse to register) a Subject of Medicines Circulation with the Monitoring System shall be made by the Federal Service for Surveillance in Healthcare using the Monitoring System functions.

A decision to register a Subject of Medicines Circulation with the Monitoring System shall be made, provided that there are no discrepancies between the information specified in the application and the information entered in the Monitoring System (if the applications are filed under paragraphs six of clause 24 and seven of clause 25 hereof), and that the reliability of information entered in the Monitoring System is confirmed.

27. Registration with the Monitoring System shall be refused to Subjects of Medicines Circulation due to the following reasons:

a) Regarding the Russian manufactures of medicines performing the production stages of Medicinal Products filling (packaging) into secondary (consumer) package and (or) tertiary (shipping) package (or, in the absence thereof, into primary package) of Medicinal Products:

Nonconformity of data of the owner of a qualified certificate of the digital signature verification key (hereinafter referred to as the Qualified Certificate) with data of the head of organization, as well as the lack of information regarding a Qualified Certificate issued to the head of organization;

Lack of information regarding any entries in the Unified State Register of Legal Entities;

Lack of information regarding a valid license in the Unified Register of Medicine Manufacturing License;

b) Regarding the Marketing Authorization holders or owners (if a Medicinal Product is manufactured outside the Russian Federation) being organizations recognized as tax residents of the Russian Federation or individual entrepreneurs and having no medicine manufacturing license, license for pharmaceutical activities (including wholesale and retail trade of medicines) or license for medical activities:

Nonconformity of data of the owner of a Qualified Certificate with data of the head of organization or individual entrepreneur; lack of information regarding a Qualified Certificate issued to the head of organization or individual entrepreneur;

Lack of information regarding any entries in the Unified State Register of Legal Entities or in the Unified State Register of Individual Entrepreneurs;

Any discrepancies between the information specified in the application filed under paragraph six of clause 24 hereof, and the information supplied to the Monitoring System;

c) Regarding any foreign organizations holding or owning the Marketing Authorization which are not recognized as tax residents of the Russian Federation and have no Russian representative offices, any discrepancies between the information specified in the application filed under paragraph seven of clause 25 hereof, and the information supplied to the Monitoring System;

d) Regarding the Russian representative offices of foreign organizations holding or owning a Marketing Authorization:

Nonconformity of data of the owner of a Qualified Certificate with data of the head of representative office; lack of information regarding a Qualified Certificate issued to the head of representative office;

Lack of information regarding any entries in the State Register of Accredited Branches and Representative Offices of Foreign Legal Entities;

Any discrepancies between the information specified in the application filed under paragraph six of clause 24 hereof, and the information supplied to the Monitoring System (for the Russian representative offices of foreign organizations holding or owning a Marketing Authorization which have no medicine manufacturing license, license for pharmaceutical activities (including wholesale and retail trade of medicines) or license for medical activities);

e) Regarding wholesalers of Medicinal Products, retailers of Medicinal Products, healthcare organizations and individual entrepreneurs:

Nonconformity of data of the owner of a Qualified Certificate with data of the head of organization; lack of information regarding a Qualified Certificate issued to the head of organization;

Lack of information regarding any entries in the Unified State Register of Legal Entities or in the Unified State Register of Individual Entrepreneurs;

Lack of information regarding a valid license in the Unified Register of Medical and Pharmaceutical Licenses.

28. After the Subject of Medicines Circulation is registered with the Monitoring System and provided with a user account, the corresponding notice shall be sent to its e-mail address specified at information submission by the Monitoring System operator using the Monitoring System functions. In this regard, the repeated use of the same e-mail address for the registration of user accounts of different Subjects of Medicines Circulation shall be prohibited.

29. The Subject of Medicines Circulation which has received a notice of registration with the Monitoring System, shall, at the user account function activation, enter into the Monitoring System a list of addresses of the places of economic activity by selecting such address from the addresses specified in medicine manufacturing licenses, licenses for pharmaceutical activities (including wholesale and retail trade of medicines) and licenses for medical activities, as well as a list of addresses of the pharmaceutical warehouses (if any).

The Subject of Medicines Circulation being the holder or owner of the Marketing Authorization of a Medicinal Product manufactured outside the Russian Federation, and (or) its Russian representative office that have received a notice of registration with the Monitoring System, shall enter into the Monitoring System the information regarding the manufacturing sites performing the production stage of Medicinal Products filling (packaging) into Secondary (Consumer) Package of a Medicinal Product (or, in the absence thereof, into Primary Package of a Medicinal Product) and the production stage of release quality control.

30. The submission of information to the Monitoring System by Subjects of Medicines Circulation shall be performed by the Monitoring System operator via the developed electronic information services using standard electronic interaction protocols and interfaces.

Subjects of Medicines Circulation being organizations recognized as tax residents of the Russian Federation, individual entrepreneurs and Russian representative offices of foreign organizations holding or owning the Marketing Authorization shall be authorized in the Monitoring System using the Qualified Certificate.

Subjects of Medicines Circulation being foreign organizations holding or owning the Marketing Authorization which are not recognized as tax residents of the Russian Federation and have no Russian representative offices shall be authorized in the Monitoring System using a basic electronic signature.

31. Information to be transferred to the Monitoring System shall be generated and submitted in the form of electronic documents signed using enhanced qualified electronic signature, except as provided in paragraphs two-six of this clause.

The following information shall not be signed using enhanced qualified electronic signature:

Information regarding retail trade of Medicinal Products transferred by Subjects of Medicines Circulation in electronic form as part of fiscal documents in accordance with the Russian laws on the use of cash-register equipment;

Information regarding Withdrawal of Medicinal Products from Circulation transferred by Subjects of Medicines Circulation in electronic form using the Withdrawal Recorders or cash-register equipment (in case of dispensing Medicinal Products on prescription free of charge or at a discount);

Information transferred by Subjects of Medicines Circulation in electronic form using the Issue Recorders;

Information transferred hereunder by the organizations being Subjects of Medicines Circulation which are not recognized as tax residents of the Russian Federation.

32. Information shall be transferred to the Monitoring System by sending files in the format agreed upon with the Ministry of Health of the Russian Federation and published by the Monitoring System operator on its official website.

The date of supplying information to the Monitoring System shall be the date specified in the certificate of information receipt generated in the form of an electronic document when the information is recorded in the Monitoring System.

Information shall be supplied to the Monitoring System by Subject of Medicines Circulation at the performance of operations with Medicinal Products in a sequential order, except as provided for in these Regulations. In this regard, information on the next operation with a Medicinal Product shall be transferred after Subjects of Medicines Circulation receive confirmation of the successful processing of information about the previous operation with the Medicinal Product by the Monitoring System.

33. Upon description of Medicinal Products, information shall be entered into the information resource which ensures accounting and storage of reliable data on the goods according to the corresponding nomenclature of goods, and the Monitoring System by the following Subjects of Medicines Circulation:

In case of Medicinal Products manufacture in the Russian Federation, by the medicines manufacturers completing the production stage of Medicinal Products filling (packaging) into Secondary (Consumer) Package of a Medicinal Product (or, in the absence thereof, into Primary Package of a Medicinal Product);

In case of Medicinal Products manufacture outside the Russian Federation (foreign manufacture), by the Marketing Authorization holders or owners and (or) by their Russian representative offices or authorized representatives.

The list of information to be supplied by Subjects of Medicines Circulation upon description of Medicinal Products to the information resource which ensures accounting and storage of reliable data on the goods according to the corresponding nomenclature of goods is specified in Annex No. 2.

Subjects of Medicines Circulation specified in paragraphs two and three of this clause shall record Medicinal Products in the Monitoring System based on an electronic application containing:

Global Trade Item Number;

Marketing Authorization number and date of Medicinal Product registration in the State Register of Medicines.

Received information shall be processed automatically by generating a request for obtaining information about a Medicinal Product from the unified state information system in the field of healthcare and from the information resource which ensures accounting and storage of reliable data on the goods according to the corresponding nomenclature of goods.

34. Information to be supplied by Subjects of Medicines Circulation to the Monitoring System when putting Medicinal Products into circulation is specified in Annex No. 3.

Information to be supplied by Subjects of Medicines Circulation to the Monitoring System when withdrawing Medicinal Products from circulation is specified in Annex No. 4.

35. As part of putting Medicinal Products manufactured in the Russian Federation into circulation in the Russian Federation, the Subject of Medicines Circulation which fills (packages) Medicinal Products into Secondary (Consumer) Package of a Medicinal Product (or, in the absence thereof, into Primary Package of a Medicinal Product), shall, within 5 working days after completing the production stage of Medicinal Products filling (packaging), but before supply of information about any further operations with such Medicinal Products, supply to the Monitoring System the information provided for in clause 1 of Annex No. 3 hereto.

Upon sampling of a Medicinal Product for the purpose of quality control of the manufactured Medicinal Product, the Subject of Medicines Circulation which takes samples of the Medicinal Product shall supply to the Monitoring System the information provided for in clause 2 of Annex No. 4 hereto.

The Subject of Medicines Circulation which performs the production stage of Medicinal Products filling (packaging) into Secondary (Consumer) Package of a Medicinal Product (or, in the absence thereof, into Primary Package of a Medicinal Product), shall, within 5 working days after completing the production stage of release quality control, but before provision of information about any further operations with the Medicinal Products put into operation, supply to the Monitoring System the information provided for in clause 2 of Annex No. 3 hereto.

36. As part of putting Medicinal Products manufactured outside the Russian Federation into circulation in the Russian Federation, the Subject of Medicines Circulation being the Marketing Authorization holder or owner, or the Russian representative office of the foreign organization being the Marketing Authorization holder or owner, shall, within 20 working days after completing the production stage of release quality control, but before provision of information about any further operations with such Medicinal Products, supply to the Monitoring System the information provided for in clause 3 of Annex No. 3 hereto.

37. As part of importing Medicinal Products to the Russian Federation, the Subject of Medicines Circulation being the Marketing Authorization holder or owner, or the Russian representative office of the foreign organization being the Marketing Authorization holder or owner, shall, within 45 working days after the shipment of Medicinal Products to the Russian Federation, but before delivery of Medicinal Products to the destination in the Russian Federation and before provision of information about any further operations with such Medicinal Products,

supply to the Monitoring System the information provided for in clause 4 of Annex No. 3 hereto.

The Subject of Medicines Circulation importing Medicinal Products to the Russian Federation shall, within 5 working days after the delivery of Medicinal Products to the destination in the Russian Federation, and before provision of information on the customs authorities' decision to release Medicinal Products for domestic consumption, supply to the Monitoring System the information provided for in clause 5 of Annex No. 3 hereto.

When performing customs operations in the course of customs declaration and placement of Medicinal Products under the customs procedure for release for domestic consumption, the customs authority shall:

Request from the Monitoring System the information on Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (in case the whole Group Package is imported) for comparison with the data specified in the Medicinal Product declaration;

Transfer data on the Medicinal Products release for domestic consumption to the Monitoring System.

If any amendments are made to the information specified in the Medicinal Product declaration, the customs authority shall, within 5 working days after releasing the Medicinal Product for domestic consumption, transfer amended data on the Medicinal Product to the Monitoring System.

When sampling Medicinal Products in the customs control zone for the purpose of Medicinal Products compliance certification, the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation shall supply to the Monitoring System the information provided for in clause 2 of Annex No. 4 hereto.

When transferring the title to Medicinal Products placed under the customs procedure in the customs control zone of the customs warehouse, the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation shall, within 5 working days after executing the relevant documents on transfer of title to Medicinal Products, and before provision of information about any further operations with Medicinal Products, supply to the Monitoring System the information provided for in clause 6 of Annex No. 3 hereto.

In this regard, the Subject of Medicines Circulation to which the title to Medicinal Products placed under the customs procedure of the customs warehouse has been transferred, shall, within 5 working days after execution of the relevant documents on the transfer of title to Medicinal Product and recording of information regarding the transferred Medicinal Products in the Monitoring System, and before provision of information on any further operations with Medicinal Products, confirm the reliability of the information contained in the Monitoring System regarding the accepted Medicinal Products by supplying to the Monitoring System the information provided for in clause 7 of Annex No. 3 hereto.

When moving Medicinal Products between the customs control zones, the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation, or the Subject of Medicines Circulation to which the title to the Medicinal Product placed under the customs procedure of the customs warehouse has been transferred, shall, within 5 working days after such movement, and before provision of information on any further operations with Medicinal Product, supply to the Monitoring System the information provided for in clause 8 of Annex No. 3 hereto.

The Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation, shall, within 5 working days after the date of decision to release Medicinal Products for domestic consumption made by the customs authorities, and before provision of information on any further operations with Medicinal Products, supply to the Monitoring System the information provided for in clause 9 of Annex No. 3 hereto.

When moving Medicinal Products from the customs control zone, the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation, or the Subject of Medicines Circulation to which the title to the Medicinal Products has been transferred, which has placed Medicinal Products under the customs procedure of the customs warehouse, shall, within 5 working days after the acceptance of Medicinal Products at the pharmaceutical warehouse and completion of the customs procedure for goods release for domestic consumption (or from the date of decision to release Medicinal Products for domestic consumption made by the customs authorities, if the procedure for conventional goods release is applied), and before provision of information on any further operations with Medicinal Products, supply to the Monitoring System the information provided for in clause 10 of Annex No. 3 hereto.

38. As part of importing Medicinal Products to the Russian Federation from the Eurasian Economic Union member states, the Subject of Medicines Circulation being the Marketing Authorization holder or owner, or the Russian representative office of the foreign organization being the Marketing Authorization holder or owner, shall, within 5 working days after the shipment of Medicinal Products to the Russian Federation, and before provision of information about any further operations with such Medicinal Products, supply to the Monitoring System the information provided for in clause 11 of Annex No. 3 hereto.

The Subject of Medicines Circulation which accepts Medicinal Products at the pharmaceutical warehouse as part of their import to the Russian Federation from the Eurasian Economic Union member states, shall, within 5 working days after the acceptance of Medicinal Products, and before provision of information about any further operations with such Medicinal Products, supply to the Monitoring System the information provided for in clause 12 of Annex No. 3 hereto.

When putting Medicinal Products into circulation in the Russian Federation as part of their import to the Russian Federation from the Eurasian Economic Union member states, the Subject of Medicines Circulation which accepts Medicinal Products at the pharmaceutical warehouse of Medicinal Products, shall, within 5 working days after the receipt of documents on product conformity, and before provision of information about any further operations with such Medicinal Products, supply to the Monitoring System the information provided for in clause 13 of Annex No. 3 hereto.

39. Information to be supplied by Subjects of Medicines Circulation to the Monitoring System when performing any operations with a Group Package is specified in Annex No. 5.

40. Upon Aggregation, the Subject of Medicines Circulation shall apply a Group Code to Tertiary (Shipping) Package of a Medicinal Product, and supply to the Monitoring System the information provided for in clause 1 of Annex No. 5 hereto, before provision of information about any further operations with such Medicinal Product.

41. Upon deconsolidation of Tertiary (Shipping) Package of a Medicinal Product, removal of Medicinal Products from Tertiary (Shipping) Package of a Medicinal Product, or addition of Medicinal Products to Tertiary (Shipping) Package of a Medicinal Product, the Subject of Medicines Circulation shall, for the Medicinal Products located in the Russian Federation within 5 working days, or for the Medicinal Products located outside the Russian Federation within 20 working days after the date of the relevant operation with Medicinal Products or with Tertiary (Shipping) Package of a Medicinal Product, and before provision of information about any further operations with such Medicinal Products or with Tertiary (Shipping) Package of a Medicinal Product, supply to the Monitoring System the information provided for in clauses 2-4 of Annex No. 5 hereto.

42. Information to be supplied by Subjects of Medicines Circulation to the Monitoring System at circulation and domestic movement of Medicinal Products is specified in Annex No. 6.

43. The Subject of Medicines Circulation moving Medicinal Products between addresses of

the places of economic activity under the license (with due regard to such activities as medicines manufacturing and pharmaceutical activities) and (or) pharmaceutical warehouses, shall, within 5 working days after the actual date of Medicinal Products movement, and before provision of information about any further operations with such Medicinal Products, supply to the Monitoring System the information provided for in clause 1 of Annex No. 6 hereto.

44. Upon transfer of Medicinal Products between Subjects of Medicines Circulation, information may be supplied to the Monitoring System by the Subject of Medicines Circulation which transfers Medicinal Products (hereinafter referred to as the Direct Information Supply Procedure), or by the Subject of Medicines Circulation which accepts Medicinal Products (hereinafter referred to as the Reverse Information Supply Procedure).

The decision to select Direct Information Supply Procedure or Reverse Information Supply Procedure shall be made independently by Subjects of Medicines Circulation supplying such information.

If the Direct Information Supply Procedure is selected, the Subject of Medicines Circulation which transfers Medicinal Products to another Subject of Medicines Circulation as part of civil-law relations, shall, within 5 working days after the actual date of Medicinal Products shipment, supply to the Monitoring System the information provided for in clause 2 of Annex No. 6 hereto.

In this regard, the Subject of Medicines Circulation, which accepts Medicinal Products from another Subject of Medicines Circulation as part of civil-law relations, shall, within 5 working days after the acceptance of Medicinal Products and recoding of information about the shipped Medicinal Products in the Monitoring System, but before provision of information about any further operations with such Medicinal Products, confirm reliability of the information contained in the Monitoring System by supplying to the Monitoring System the information provided for in clause 4 of Annex No. 6 hereto.

If the Reverse Information Supply Procedure is selected, the Subject of Medicines Circulation which accepts Medicinal Products from another Subject of Medicines Circulation as part of civil-law relations, shall, within 5 working days after the date of Medicinal Products acceptance, supply to the Monitoring System the information regarding the accepted Medicinal Products provided for in clause 3 of Annex No. 6 hereto.

In this regard, the Subject of Medicines Circulation which transferred Medicinal Products to another Subject of Medicines Circulation as part of civil-law relations, shall, within 5 working days after the recoding of information about the accepted Medicinal Products in the Monitoring System, but before provision of information about any further operations with such Medicinal Products, confirm reliability of the information about the transferred Medicinal Products contained in the Monitoring System by supplying to the Monitoring System the information provided for in clause 4 of Annex No. 6 hereto.

45. The Subject of Medicines Circulation performing contract manufacturing of Medicinal Products in the Russian Federation, upon transfer of Medicinal Products (finished products) to the Subject of Medicines Circulation being the customer of such contract manufacturing, shall, within 5 working days after the transfer of Medicinal Products, supply to the Monitoring System the information provided for in clause 5 of Annex No. 6 hereto.

In this regard, the Subject of Medicines Circulation being the customer of contract manufacturing of Medicinal Products, shall, within 5 working days after the acceptance of Medicinal Products and the recoding of information about the transferred Medicinal Products in the Monitoring System, but before provision of information about any further operations with such Medicinal Products, confirm reliability of the information about the transferred Medicinal Products contained in the Monitoring System by supplying to the Monitoring System the information provided for in clause 4 of Annex No. 6 hereto.

46. The Subject of Medicines Circulation which withdraws Medicinal Products from circulation (except for the withdrawal of Medicinal Products by sampling, exporting the Medicinal Products previously imported to the Russian Federation, or transferring for destruction), shall, within 5 working days after the date of corresponding operation, supply to the Monitoring System the information provided for in clause 1 of Annex No. 4 hereto.

47. The Subject of Medicines Circulation which withdraws Medicinal Products from circulation by sampling upon import of a batch of Medicinal Products to the Russian Federation, shall supply to the Monitoring System the information provided for in clause 2 of Annex No. 4 hereto, within 5 working days after the date of supplying to the Monitoring System information about the acceptance of Medicinal Products at the pharmaceutical warehouse, but before supply of information about any further operations with Medicinal Products of the said batch from which samples have been taken.

48. The Subject of Medicines Circulation which withdraws Medicinal Products from circulation by transferring Medicinal Products for destruction, shall, within 5 working days after the date of transferring Medicinal Products for destruction, but before supply of information about the fact of Medicinal Products destruction, supply to the Monitoring System the information provided for in clause 3 of Annex No. 4 hereto.

Following the destruction of Medicinal Products, the Subject of Medicines Circulation that has transferred Medicinal Products for destruction shall, within 5 working days after the date of receiving a certificate of destruction, supply to the Monitoring System the information provided for in clause 4 of Annex No. 4 hereto.

49. The Subject of Medicines Circulation which withdraws Medicinal Products from circulation by means of re-export, shall, within 5 working days after the date of decision on re-export made by the customs authorities, supply to the Monitoring System the information provided for in clause 9 of Annex No. 3 hereto.

50. Upon repeated Putting of Medicinal Products into Circulation, the Subject of Medicines Circulation which has previously withdrawn Medicinal Products from circulation or released such Medicinal Products outside the Russian Federation (in case of export of the Medicinal Products previously imported to the Russian Federation), shall, within 5 working days after the date of corresponding operation, supply to the Monitoring System the information provided for in clause 14 of Annex No. 3 hereto.

51. Subjects of Medicines Circulation carrying on retail trade of Medicinal Products and dispensing Medicinal Products labeled with the Identification Means shall record information about the withdrawal of Medicinal Products using cash-register equipment.

Upon Withdrawal of Medicinal Products from Circulation by dispensing Medicinal Products on prescription free of charge or at a discount, or by dispensing Medicinal Products, Subjects of Medicines Circulation which do not carry on retail trade of Medicinal Products shall supply information about the Withdrawal of Medicinal Products from Circulation to the Monitoring System using the Withdrawal Recorders provided by the Monitoring System operator.

Subjects of Medicines Circulation withdrawing Medicinal Products from circulation by dispensing Medicinal Products on prescription free of charge or at a discount, or by dispensing Medicinal Products shall be provided with the recorders of Medicinal Products withdrawal by the Monitoring System operator free of charge. For the purpose of such provision, Subjects of Medicines Circulation shall sign agreements with the Monitoring System operator to include, inter alia, the terms of provision with such equipment and its routine maintenance on a free-of-charge basis.

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

After providing any Subject of Medicines Circulation with a Withdrawal Recorder, the Monitoring System operator shall register the said provided recorder with the Monitoring System within 5 working days.

52. Subjects of Medicines Circulation shall, upon detection of any errors in information (false information) supplied by them to the Monitoring System upon putting of Medicinal Product into circulation and in the course of circulation of Medicinal Products, supply to the Monitoring System any information needed to correct the specified errors in information (false information) (hereinafter referred to as the Error Correction).

Subjects of Medicines Circulation shall be entitled to correct errors until they are notified of an inspection to be duly conducted by the Federal Service for Surveillance in Healthcare in response to the supply of erroneous (false) information by Subjects of Medicines Circulation.

If any other Subjects of Medicines Circulation participated in supply of erroneous (false) information, the Error Correction shall be deemed accepted after all participants of supply of erroneous (false) information confirm reliability of the performed Error Correction in the Monitoring System.

The following Error Correction shall be made in the Monitoring System with regard to the in-house operations:

Cancellation of a previously recorded operation by the Subject of Medicines Circulation (provided that no actions involving the transfer of title to Medicinal Products have been performed after the operation);

Withdrawal of the notice of Medicinal Products shipment by the Subject of Medicines Circulation that had sent such notice to the recipient of Medicinal Products. Such correction shall be possible before submission of information regarding the confirmation of Medicinal Product transfer by another Subject of Medicines Circulation;

Refusal to accept Medicinal Products by the Subject of Medicines Circulation being the recipient of Medicinal Products. Such correction shall be possible before submission of information regarding the confirmation of Medicinal Product transfer by another Subject of Medicines Circulation.

53. Blocking of acceptance of information about Putting of Medicinal Products into Circulation and (or) Withdrawal of Medicinal Products from Circulation by the Monitoring System (hereinafter referred to as the Blocking) shall be performed automatically according to the rules established by the Federal Service for Surveillance in Healthcare.

The list of reasons for Blocking is given in Annex No. 7.

Blocking shall be cancelled automatically when the Subject of Medicines Circulation eliminates the reasons for Blocking.

In certain cases determined by the Federal Service for Surveillance in Healthcare, Blocking allows for the supply of information about Medicinal Products return to the supplier, Medicinal Products transfer for destruction and (or) another type of Medicinal Products withdrawal from circulation.

Blocking and unblocking may be applied for any item of Medicinal Product, lot of Medicinal Products or batch of Medicinal Products.

VII. Procedure for Providing Information Contained in the Monitoring System

54. Access to the individuals and legal entities, federal executive authorities, authorities of

the constituent entities of the Russian Federation and local administration bodies interested in obtaining information from the Monitoring System shall be granted by the Monitoring System operator upon agreement with the Ministry of Health of the Russian Federation and the Federal Service for Surveillance in Healthcare.

55. Access to information contained in the Monitoring System shall be granted by the Monitoring System operator with due regard to the following provisions:

a) Federal executive authorities, authorities of the constituent entities of the Russian Federation and local administration bodies shall access information contained in the Monitoring System, inter alia, via the infrastructure ensuring information and technological interaction of the information systems used for provision of state and municipal services, and for performance of state and municipal functions in electronic form;

b) Subjects of Medicines Circulation supplying information for entry in the Monitoring System shall access the information supplied by them and any reference information contained in the Monitoring System via the user account of the Subject of Medicines Circulation or via the electronic information services using standard electronic interaction protocols and interfaces;

c) Citizens shall access any information contained in the Monitoring System upon verification of the Identification Means, inter alia, via the official website of the Monitoring System's operator or via a mobile application.

56. Upon verification of the Identification Means, the mobile application shall provide the following capabilities of the Monitoring System:

a) Read-out of the Identification Means from Secondary (Consumer) Package of a Medicinal Product (or, in the absence thereof, from Primary Package of a Medicinal Product);

b) Display of the results of the Identification Means verification in the Monitoring System;

c) Possibility to supply information about any violations of the procedure for labeling of Medicinal Products to the Monitoring System.

57. The Subject of Medicines Circulation may access all electronic documents supplied by it to the Monitoring System, as well as any electronic documents generated by the Monitoring System following the processing of any documents received from the Subject of Medicines Circulation.

VIII. Monitoring System Operator

58. Upon agreement with the Ministry of Health of the Russian Federation and the Federal Service for Surveillance in Healthcare, the Monitoring System operator shall ensure:

a) Establishment, development, putting into operation, operation and withdrawal from operation of the Monitoring System, provision of information contained in the Monitoring System, and interaction of the Monitoring System with other information systems;

b) Implementation of the public control mechanisms, including the receipt of information about the results of the Identification Means verification and complaints of individuals, legal entities and individual entrepreneurs, storage, processing and transfer of such information to the competent federal executive authorities.

59. In accordance with the Russian law, the Monitoring System operator shall be liable for:

a) Storage of all data and database records of transactions which are recorded in the Monitoring System;

- b) Integrity, safety and consistency of information in the Monitoring System;
 - c) Maintenance and storage of unified registers, reference information, classifiers and data exchange formats;
 - d) Uninterrupted and fail-safe operation of the Monitoring System;
 - e) Recovery of the Monitoring System and its components after the failure handling subject to complete elimination of the causes of such failure, as well as for preserving the integrity of any software and hardware facilities and databases installed on the servers;
 - f) Structural redundancy, automated detection of the server node failure, and task switching to another server node, as well as the availability of a redundant network access diversified in terms of connection to providers;
 - g) Information security and data protection against unauthorized access or information leakage;
 - h) Consulting and technical support to Subjects of Medicines Circulation regarding the Monitoring System, and to individuals regarding the mobile application;
 - i) Collection and analysis of any reports from legal entities, individuals and individual entrepreneurs for the purpose of assigning the tasks to improve and upgrade databases.
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ANNEX No. 1
to the Regulations on the System for
Monitoring of Flow of Medicinal Products for
Human Use

INFORMATION

**Supplied by the State Information Systems of the Federal Executive Authorities to the
System for Monitoring of Flow of Medicinal Products for Human Use, as Well as
Information Transferred from the System for Monitoring of Flow of Medicinal Products for
Human Use**

1. The following information shall be supplied from the Unified Register of Medicine Manufacturing License to the system for monitoring of flow of Medicinal Products for human use (hereinafter referred to as the Monitoring System, Medicinal Products) for the purpose of transferring information about any medicine manufacturing licenses held by a medicines manufacturer being an organization recognized as a tax resident of the Russian Federation:

- a) Taxpayer identification number of the medicine's manufacturer;
- b) Primary state registration number of the medicine's manufacturer;
- c) Name of the medicine's manufacturer;
- d) License number;
- e) Date of license issue;
- f) License validity status;
- g) License validity status change date;

h) Address of the place of activities under the license (global unique identifier of the address object in the Federal Information Address System and description thereof);

- i) List of works and services according to the license;
- j) List of dosage forms according to the license;
- k) Additional description of works (services).

2. The following information shall be supplied from the Unified Register of Licenses, including licenses issued by the state authorities of the constituent entities of the Russian Federation by virtue of the delegated authority to license certain types of healthcare activities, to the Monitoring System for the purpose of transferring information about any licenses held by Subjects of Medicines Circulation being the organizations recognized as tax residents of the Russian Federation or individual entrepreneurs:

- a) Taxpayer identification number of the Subject of Medicines Circulation;
- b) License number;
- c) Effective date of the license;

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

- e) License status (identifier and description);
- f) License validity status change date;
- g) List of works and services according to the license (identifiers and description).

3. The following information shall be supplied from the unified state information system in the field of healthcare to the Monitoring System for the purpose of Medicinal Products description:

- a) Unique identifier of record in the unified structured reference catalogue of Medicinal Products;
- b) Number of the Marketing Authorization;
- c) Date of state registration of a Medicinal Product;
- d) Status of the Marketing Authorization;
- e) International nonproprietary, generic or chemical name of a Medicinal Product;
- f) Name of the Marketing Authorization holder or owner;
- g) Country of incorporation of the Marketing Authorization holder or owner;
- h) Taxpayer code of the Marketing Authorization holder or owner in the country of incorporation;
- i) Evidence of the Medicinal Product inclusion into the List of Vital and Essential Drugs;
- j) Medicinal Product trade name;
- k) Primary Package of a Medicinal Product;
- l) Amount of dosage form in primary package;
- m) Secondary (Consumer) Package of a Medicinal Product (if any);
- n) Quantity of Primary Package of a Medicinal Product in Secondary (Consumer) Package of a Medicinal Product (if any);
- o) Dosage form;
- p) Quantity of dosage measuring units of Medicinal Product;
- q) Name of the Subject of Medicines Circulation which fills (packs) Medicinal Products into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product);
- r) Taxpayer code of the Subject of Medicines Circulation which fills (packs) Medicinal Products into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product) in the country of incorporation;
- s) Country of incorporation of the Subject of Medicines Circulation which fills (packs) Medicinal Products into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product);
- t) Address of the place of activities of the Subject of Medicines Circulation which fills (packs) Medicinal Products into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product) specified in the medicine manufacturing license, if any (global unique identifier of the address object in the Federal Information Address System and description);
- u) Name of the Subject of Medicines Circulation performing the stage of release quality control;
- v) Taxpayer code of the Subject of Medicines Circulation performing the stage of release quality control in the country of incorporation;
- w) Country of incorporation of the Subject of Medicines Circulation performing the stage of release quality control;
- x) Address of the place of activities of the Subject of Medicines Circulation performing the production stage of release quality control which is specified in the medicine manufacturing license, if any (global unique identifier of the address object in the Federal Information Address

System and description);

y) Date of registration of the maximum price for Medicinal Product;

z) Maximum registered price in rubles.

4. The following information shall be supplied from the Unified State Register of Legal Entities and the Unified State Register of Individual Entrepreneurs, respectively, to the Monitoring System for the purpose of confirming reliability of the information about state registration of Subjects of Medicines Circulation being the organizations recognized as tax residents of the Russian Federation or individual entrepreneurs:

a) Taxpayer identification number of the Subject of Medicines Circulation;

b) Code of tax authority;

c) Status code of a legal entity or an individual entrepreneur;

d) Name of the Subject of Medicines Circulation;

e) Status of the entry regarding registration of the legal entity or individual entrepreneur;

f) Information about the head of the Subject of Medicines Circulation or information about the individual entrepreneur.

5. The following information shall be supplied from the State Register of Accredited Branches and Representative Offices of Foreign Legal Entities to the Monitoring System for the purpose of confirming reliability of the information about state registration of the Russian representative offices of foreign organizations holding or owning the Marketing Authorization:

a) Taxpayer identification number of the representative office;

b) Tax authority code of the representative office;

c) Name of the representative office;

d) Number of the accreditation record;

e) Information about the foreign organization;

f) Accreditation status code;

g) Information about the head of representative office.

6. The following information about temporary withdrawal (about cancellation of temporary withdrawal) of Medicinal Products from circulation at the initiative of the competent federal executive authority shall be supplied from the subsystem "Monitoring of the Medicines Quality" of the automated information system of the Federal Service for Surveillance in Healthcare to the Monitoring System for the purpose of security assurance:

a) Date from which it is necessary to perform temporary withdrawal (cancellation of temporary withdrawal) of a Medicinal Product from circulation;

b) Number of the Marketing Authorization;

c) Date of state registration of Medicinal Product;

d) Ground for temporary withdrawal (cancellation of temporary withdrawal) of a Medicinal Product from circulation;

e) Details of the document regarding temporary withdrawal (cancellation of temporary withdrawal) of a Medicinal Product from circulation;

f) Global Trade Item Number;

g) Production batch number;

h) Taxpayer identification number of the Subject of Medicines Circulation (if withdrawal is made only from one Subject of Medicines Circulation, rather than withdrawal of the entire batch (lot)).

7. The following information about the Medicinal Products imported to the Russian Federation and placed under specific customs procedures, which is specified in the goods customs declaration, shall be supplied from the Unified Automated Information System of the customs authorities to the Monitoring System for the purpose of preventing and suppressing crimes and administrative offences attributed to the competence of the Russian customs authorities:

- a) Customs authority code;
- b) Date of registration of the customs declaration of a Medicinal Product;
- c) Registration number of the customs declaration of a Medicinal Product;
- d) Serialized Global Trade Item Number;
- e) Customs value, statistical value and invoice value of a Medicinal Product;
- f) Code of the country of origin of a Medicinal Product;
- g) Taxpayer identification number of the Subject of Medicines Circulation that imports and declares Medicinal Product;
- h) Code of the declared customs procedure in accordance with the classifier of the types of customs procedures;
- i) Data on the release of a Medicinal Product for domestic consumption.

8. On request, the Monitoring System shall transfer to the Unified Automated Information System of the customs authorities the following information about the Medicinal Products imported to the Russian Federation for the purpose of preventing and suppressing crimes and administrative offences reserved to the competence of the Russian customs authorities:

- a) Taxpayer identification number of the Subject of Medicines Circulation that imports Medicinal Products to the Russian Federation and declares Medicinal Products;
 - b) Code of the country of origin of a Medicinal Product;
 - c) Global Trade Item Number;
 - d) Serialized Global Trade Item Number and Group Code of the Group Package in which the Medicinal Product put into circulation is contained;
 - e) Medicinal Product status in the Monitoring System;
 - f) List of Serialized Global Trade Item Numbers in the Group Package.
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ANNEX No. 2
to the Regulations on the System for
Monitoring of Flow of Medicinal Products
for Human Use

LIST

of Information to be Supplied by Subjects of Medicines Circulation upon Description of Medicinal Products for Human Use to the Information Resource Which Ensures Accounting and Storage of Reliable Data on the Goods According to the Corresponding Nomenclature of Goods

1. Trade name of the Medicinal Product for human use (hereinafter referred to as the Medicinal Product).
 2. Brand (trademark).
 3. Number of the Marketing Authorization.
 4. Date of state registration of a Medicinal Product.
 5. Name of the Marketing Authorization holder or owner.
 6. Address of the Marketing Authorization holder or owner.
 7. International non-proprietary name of a Medicinal Product.
 8. Dosage form.
 9. Quantity of dosage measuring units of a Medicinal Product.
 10. Type of Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, Primary Package of a Medicinal Product).
 11. Material of Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, Primary Package of a Medicinal Product).
 12. Quantity (measure) of Medicinal Product in Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, in Primary Package of a Medicinal Product).
 13. Existence of an unlabeled Primary Package of a Medicinal Product inside Secondary (Consumer) Package of a Medicinal Product (in case of Secondary (Consumer) Package of a Medicinal Product).
 14. Description of unlabeled Primary Package of a Medicinal Product inside Secondary (Consumer) Package of a Medicinal Product.
 15. Name of filler (packer) (to be specified if filling (packaging) takes place in the Russian Federation).
 16. Address of filler (packer) into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product) (to be specified if filling (packaging) takes place in the Russian Federation).
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INFORMATION

to be Supplied by Subjects of Medicines Circulation to the System for Monitoring of Flow of Medicinal Products for Human Use When Putting Medicinal Products for Human Use into Circulation

I. Information on the Medicinal Products for human use manufactured in the Russian Federation which is to be supplied by Subjects of Medicines Circulation to the System for Monitoring of Flow of Medicinal Products for Human Use

1. Upon completion of the stage of filling (packaging) Medicinal Products for human use (hereinafter referred to as the Medicinal Products) into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product), Subjects of Medicines Circulation shall submit to the System for Monitoring of Flow of Medicinal Products for Human Use (hereinafter referred to as the Monitoring System) the following information with regard to each trade item of Medicinal Product:

- a) Date of operation;
- b) Taxpayer identification number of the Subject of Medicines Circulation which fills (packs) Medicinal Products into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product);
- c) Address of the place of activities where the stage of filling (packaging) Medicinal Products into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product) has been completed;
- d) Type of production order (contract or own manufacture);
- e) Taxpayer identification number of the Subject of Medicines Circulation being the customer of contract manufacture (in case of information submission by the Subject of Medicines Circulation engaged in contract manufacture);
- f) Medicinal Product Global Trade Item Number;
- g) Medicinal Product production batch number;
- h) Medicinal Product expiry date;
- i) Serialized Global Trade Item Number assigned to Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, to Primary Package of a Medicinal Product).

2. Upon completion of the stage of release quality control, Subjects of Medicines Circulation shall supply to the Monitoring System the following information about the release of finished products with regard to each trade item of a Medicinal Product manufactured in the Russian Federation:

- a) Date of operation;
- b) Taxpayer identification number of the Subject of Medicines Circulation which records information about the release of finished products;
- c) Place of activities of the Subject of Medicines Circulation which records information

about the release of finished products;

d) Type of conformity document – certificate of conformity or declaration of conformity;

e) Conformity document details (date and number);

f) Serialized Global Trade Item Number or Group Code of the package in which the Medicinal Product is released into circulation (if the Group Package is released as a whole).

II. Information about Medicinal Products manufactured outside the Russian Federation which is to be supplied by Subjects of Medicines Circulation to the Monitoring System

3. Upon completion of the production stage of release quality control, Subjects of Medicines Circulation shall supply to the Monitoring System the following information with regard to each Medicinal Product item manufactured outside the Russian Federation:

a) Date of operation;

b) Taxpayer code of the Marketing Authorization holder or owner in the country of incorporation, or taxpayer identification number (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation);

c) Code of the country of incorporation of the Marketing Authorization holder or owner (for the Subject of Medicines Circulation being a foreign organization not recognized as a tax resident of the Russian Federation and having no Russian representative offices);

d) Taxpayer code of the Subject of Medicines Circulation which fills (packs) Medicinal Products into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product) in the country of incorporation;

e) Code of the country of incorporation of the Subject of Medicines Circulation which fills (packs) Medicinal Products into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product);

f) Name of the Subject of Medicines Circulation which fills (packs) Medicinal Products into Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, into Primary Package of a Medicinal Product);

g) Taxpayer code of the Subject of Medicines Circulation performing the production stage of release quality control in the country of incorporation;

h) Code of the country of incorporation of the Subject of Medicines Circulation which performs the production stage of release quality control;

i) Name of the Subject of Medicines Circulation which performs the release quality control;

j) Global Trade Item Number;

k) Medicinal Product production batch number;

l) Medicinal Product expiry date;

m) Serialized Global Trade Item Number assigned to Secondary (Consumer) Package of a Medicinal Product (in the absence thereof, to Primary Package of a Medicinal Product).

III. Information about the Medicinal Products imported to the Russian Federation which is to be supplied by Subjects of Medicines Circulation to the Monitoring System

4. Upon completion of the shipment of Medicinal Products to the Russian Federation, Subjects of Medicines Circulation shall supply to the Monitoring System the following information with regard to each Medicinal Product item:

a) Date of operation;

b) Taxpayer code of the Marketing Authorization holder or owner in the country of incorporation, or taxpayer identification number (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation);

c) Code of the country of incorporation of the Marketing Authorization holder or owner (for the Subject of Medicines Circulation being a foreign organization not recognized as a tax resident of the Russian Federation and having no Russian representative offices);

d) Code of the taxpayer being the Medicinal Products seller in the country of incorporation;

e) Code of the country of incorporation of the Medicinal Products seller;

f) Taxpayer identification number of the Subject of Medicines Circulation being the Medicinal Products buyer in the Russian Federation;

g) Details of the source document which is the basis for Medicinal Product shipment to the Russian Federation;

h) Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is shipped as a whole).

5. Upon importing and placing Medicinal Products at the temporary storage warehouse or in the customs control zone, Subjects of Medicines Circulation shall supply to the Monitoring System the following information with regard to each Medicinal Product item:

a) Date of operation;

b) Taxpayer code in the country of incorporation or taxpayer identification number of the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation);

c) Code of the country of incorporation of the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation (for the Subject of Medicines Circulation being a foreign organization not recognized as a tax resident of the Russian Federation and having no Russian representative offices);

d) Code of the customs authority and registration number of the warehouse (address of the goods location in accordance with the goods declaration);

e) Code of the taxpayer being the Medicinal Products seller in the country of incorporation;

f) Code of the country of incorporation of the Medicinal Products seller;

g) Type of contract;

h) Details of the source document which is the basis for Medicinal Product import to the Russian Federation (date and number);

i) Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is imported as a whole).

6. Subjects of Medicines Circulation which transfer the Medicinal Products placed under the customs procedure of the customs warehouse to another owner (change of owner) shall supply to

the Monitoring System the following information with regard to each Medicinal Product item:

- a) Date of operation;
- b) Taxpayer code in the country of incorporation or taxpayer identification number of the Subject of Medicines Circulation which transfers Medicinal Products (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation);
- c) Code of the country of incorporation of the Subject of Medicines Circulation which transfers Medicinal Products (for the Subject of Medicines Circulation being a foreign organization not recognized as a tax resident of the Russian Federation and having no Russian representative offices);
- d) Taxpayer identification number of the Subject of Medicines Circulation which accepts Medicinal Products;
- e) Details of the source document which is the basis for Medicinal Product transfer (date and number);
- f) Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is transferred as a whole).

7. Upon confirmation of the information about transferred Medicinal Products contained in the Monitoring System, Subjects of Medicines Circulation to which the title to a Medicinal Product placed under the customs procedure of the customs warehouse has been transferred shall supply to the Monitoring System the following information with regard to each Medicinal Product item:

- a) Date of operation;
- b) Taxpayer identification number of the Subject of Medicines Circulation which accepts Medicinal Products;
- c) Taxpayer code in the country of incorporation or taxpayer identification number of the Subject of Medicines Circulation which transfers Medicinal Products (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation);
- d) Code of the country of incorporation of the Subject of Medicines Circulation which transfers Medicinal Products (for the Subject of Medicines Circulation being a foreign organization not recognized as a tax resident of the Russian Federation and having no Russian representative offices);
- e) Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is transferred as a whole).

8. Upon movement of Medicinal Products for human use between the customs control zones, Subjects of Medicines Circulation shall supply to the Monitoring System the following information with regard to each Medicinal Product item:

- a) Date of operation;
- b) Taxpayer code in the country of incorporation or taxpayer identification number of the Subject of Medicines Circulation which moves Medicinal Products (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation);

c) Code of the country of incorporation of the Subject of Medicines Circulation which moves Medicinal Products (for the Subject of Medicines Circulation being a foreign organization not recognized as a tax resident of the Russian Federation and having no Russian representative offices);

d) Code of the customs authority and the registration number of the dispatch warehouse (address of the declared goods location from which the goods are moved);

e) Code of the customs authority and the registration number of the acceptance warehouse (address of the goods location to which they are moved);

f) Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is moved as a whole).

9. When the customs authorities make a decision to release Medicinal Products for domestic consumption, Subjects of Medicines Circulation shall supply to the Monitoring System the following information with regard to each Medicinal Product trade item:

a) Date of operation;

b) Taxpayer identification number of the Subject of Medicines Circulation which declares Medicinal Products in the Russian Federation;

c) Customs procedure code;

d) Customs authority code;

e) Details of the customs declaration of the Medicinal Product;

f) Customs value of the Medicinal Product according to the customs declaration of the Medicinal Product;

g) Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is placed under the customs procedure as a whole);

h) Type of conformity document – certificate of conformity or declaration of conformity;

i) Conformity document details (date and number).

10. Upon movement of Medicinal Products from the customs control zone to the pharmaceutical warehouse, Subjects of Medicines Circulation shall supply to the Monitoring System the following information with regard to each Medicinal Product item:

a) Date of operation;

b) Taxpayer identification number of the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation;

c) Address of the place of activities of the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation;

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

e) Details of the source document which is the basis for Medicinal Product acceptance at the pharmaceutical warehouse (date and number);

f) Price indicated in the accompanying documentation for the goods on the basis of which a customs declaration is drawn up, taking into account customs duties and customs clearance fees;

g) Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is accepted at the pharmaceutical warehouse as a whole).

11. Upon importing Medicinal Products to the Russian Federation from the Eurasian

Eurasian Economic Union member states, Subjects of Medicines Circulation shall supply to the Monitoring System the following information with regard to each Medicinal Product trade item:

- a) Date of operation;
- b) Taxpayer code of the Marketing Authorization holder or owner in the country of incorporation, or taxpayer identification number (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation);
- c) Code of the country of incorporation of the Marketing Authorization holder or owner (for the Subject of Medicines Circulation being a foreign organization not recognized as a tax resident of the Russian Federation and having no Russian representative offices);
- d) Code of the taxpayer being the Medicinal Products seller in the country of incorporation;
- e) Code of the country of incorporation of the Medicinal Products seller;
- f) Taxpayer identification number of the Subject of Medicines Circulation being the Medicinal Products buyer in the Russian Federation;
- g) Address of the place of activities of the Subject of Medicines Circulation being the Medicinal Products buyer in the Russian Federation;
- h) Details of the source document which is the basis for Medicinal Product shipment to the Russian Federation (date and number);
- i) Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is shipped as a whole).

12. Upon importing Medicinal Products to the Russian Federation from the Eurasian Economic Union member states, and placement thereof at the pharmaceutical warehouse, Subjects of Medicines Circulation shall supply to the Monitoring System the following information with regard to each Medicinal Product trade item:

- a) Date of operation;
- b) Taxpayer identification number of the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation;
- c) Address of the place of activities of the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation;
- d) Code of the taxpayer being the Medicinal Products seller in the country of incorporation;
- e) Code of the country of incorporation of the Medicinal Products seller;
- f) Details of the source document which is the basis for Medicinal Product import to the Russian Federation (date and number);
- g) Price of the Medicinal Product (including VAT) according to the source documents;
- h) Amount of the value added tax (if the transaction is subject to such tax);
- i) Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is imported as a whole).

13. Upon putting Medicinal Products into circulation as part of their import to the Russian Federation from the Eurasian Economic Union member states, Subjects of Medicines Circulation shall supply to the Monitoring System the following information with regard to each Medicinal Product item:

- a) Date of operation;
- b) Taxpayer identification number of the Subject of Medicines Circulation which imports

Medicinal Products to the Russian Federation;

c) Address of the place of activities of the Subject of Medicines Circulation which imports Medicinal Products to the Russian Federation;

d) Type of conformity document – certificate of conformity or declaration of conformity;

e) Conformity document details (date and number);

f) Serialized Global Trade Item Number or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is imported as a whole).

14. Upon repeated putting into circulation of the Medicinal Products previously withdrawn from circulation due to re-export, sampling or disposal, Subjects of Medicines Circulation shall supply to the Monitoring System the following information with regard to each Medicinal Product item:

a) Date of operation;

b) Taxpayer code in the country of incorporation or taxpayer identification number of the Subject of Medicines Circulation which has withdrawn such Medicinal Products from circulation previously (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation);

c) Address of the place of activities of the Subject of Medicines Circulation (for the organizations recognized as tax residents of the Russian Federation, and for individual entrepreneurs);

d) Code of the country of incorporation (for the Subject of Medicines Circulation being a foreign organization not recognized as a tax resident of the Russian Federation and having no Russian representative offices);

e) Causes of the previous withdrawal of the Medicinal Product from circulation;

f) Serialized Global Trade Item Number of the Medicinal Product repeatedly put into circulation.

INFORMATION

to be Supplied by Subjects of Medicines Circulation to the System for Monitoring of Flow of Medicinal Products for Human Use When Withdrawing Medicinal Products for Human Use from Circulation

1. Upon withdrawal of Medicinal Products for human use (hereinafter referred to as the Medicinal Products) from circulation by distribution (selling) Medicinal Products to consumers, or by dispensing Medicinal Products on prescription free of charge or at a discount, or by dispensing Medicinal Products, or by withdrawing Medicinal Products for other reasons, the Subject of Medicines Circulation shall supply to the System for Monitoring of Flow of Medicinal Products (hereinafter referred to as the Monitoring System) the following information about the Medicinal Products withdrawn from circulation:

a) Date of operation;

b) Taxpayer code in the country of incorporation or taxpayer identification number of the Subject of Medicines Circulation which withdraws Medicinal Products from circulation (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation);

c) Address of the place of activities from which Medicinal Products are withdrawn from circulation;

d) Type of Medicinal Products withdrawal from circulation;

e) Type of document confirming Withdrawal of Medicinal Products from Circulation (sales check, limited-issue form, contract, etc.);

f) Details of the document confirming the Withdrawal of Medicinal Products from Circulation;

g) Serialized Global Trade Item Number of Medicinal Products being withdrawn from circulation;

h) Price of Medicinal Products (including VAT) (in case of selling Medicinal Products to consumers);

i) Amount of the value added tax (in case of selling Medicinal Products to consumers, if the sale of Medicinal Products is subject to value added tax).

2. Upon Withdrawal of Medicinal Products from Circulation by sampling for various purposes, the Subject of Medicines Circulation shall supply to the Monitoring System the following information about the Medicinal Products withdrawn from circulation:

a) Date of operation or date of recording of information in the Monitoring System (for the Medicinal Products withdrawn from circulation by sampling upon import of Medicinal Products to the Russian Federation);

b) Taxpayer identification number of the Subject of Medicines Circulation which withdraws Medicinal Products from circulation;

c) Address of the place of activities from which Medicinal Products are withdrawn from circulation, or the customs control zone (in case of operation being performed in the customs control zone);

d) Type of sampling;

e) Serialized Global Trade Item Number of the Medicinal Product being withdrawn from circulation.

3. Upon Withdrawal of Medicinal Products from Circulation by transferring Medicinal Products for destruction, the Subject of Medicines Circulation shall supply to the Monitoring System the following information about the Medicinal Products withdrawn from circulation:

a) Date of operation;

b) Taxpayer identification number of the Subject of Medicines Circulation which withdraws Medicinal Products from circulation;

c) Address of the place of activities from which Medicinal Products are withdrawn from circulation;

d) Reason (ground) for the Medicinal Product transfer for destruction;

e) Details of the decision of the competent federal executive authority to withdraw Medicinal Products from circulation (if available);

f) Details of the document confirming the transfer of Medicinal Products for destruction;

g) Serialized Global Trade Item Number or Group Code of the package in which such Medicinal Product is contained (if the Group Package is withdrawn from circulation as a whole);

h) Identification number of the taxpayer performing the destruction of Medicinal Products.

4. Upon destruction of Medicinal Products that had been transferred for destruction previously, the Subject of Medicines Circulation shall supply to the Monitoring System the following information about the fact of Medicinal Products destruction:

a) Date of operation;

b) Taxpayer identification number of the Subject of Medicines Circulation which had withdrawn Medicinal Products from circulation;

c) Medicinal Products destruction method;

d) Details of the document confirming the destruction of Medicinal Products (Medicinal Products destruction certificate);

e) Serialized Global Trade Item Number or Group Code of the package in which such Medicinal Product is contained (if the Group Package is withdrawn from circulation as a whole);

f) Identification number of the taxpayer that performed the destruction of Medicinal Products.

ANNEX No. 5
to the Regulations on the System for
Monitoring of Flow of Medicinal
Products for Human Use

INFORMATION

to be Supplied by Subjects of Medicines Circulation to the System for Monitoring of Flow of Medicinal Products for Human Use When Performing Operations with Group Package

1. Upon Aggregation, the Subject of Medicines Circulation shall supply to the system for monitoring of flow of Medicinal Products for human use (hereinafter referred to as the Monitoring System) the following information:

a) Date of operation (for the Medicinal Products for human use (hereinafter referred to as the Medicinal Products) located outside the Russian Federation, in cases when Aggregation is performed before completion of the release quality control stage, any date between the date of completion of the release quality control stage and the date of Medicinal Products shipping to the Russian Federation may be indicated);

b) Taxpayer code in the country of incorporation or taxpayer identification number (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or the Russian representative office of the Subject of Medicines Circulation) of the Subject of Medicines Circulation which performs Aggregation;

c) Address of the place of economic activity (in case of manufacture in the Russian Federation) or the code of the country (in case of manufacture outside the Russian Federation) where the Aggregation has been performed, or the customs control zone (in case of Aggregation being performed in the customs control zone);

d) Group Codes of the Group Packages being created;

e) List of Serialized Global Trade Item Numbers or Group Codes of packages of a lower inclusion level making part of each Group Package being created.

2. Upon removal of Medicinal Products from the Group Package, Subjects of Medicines Circulation shall supply the following information to the Monitoring System:

a) Date of operation;

b) Taxpayer code in the country of incorporation or taxpayer identification number (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation) of the Subject of Medicines Circulation which performs the operation;

c) Address of the place of economic activity (in case of operation being performed in the Russian Federation) or the code of the country (in case of operation being performed outside the Russian Federation) where the operation is performed, or the customs control zone (in case of operation being performed in the customs control zone);

d) Serialized Global Number of a Trade Item removed from the Group Package or Group Code of the package of a lower inclusion level being removed from the Group Package.

3. Upon addition of Medicinal Products to the Group Package, Subjects of Medicines Circulation shall supply the following information to the Monitoring System:

a) Date of operation;

b) Taxpayer code in the country of incorporation or taxpayer identification number (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, and an individual entrepreneur, or for the Russian representative office of the Subject of Medicines Circulation) of the Subject of Medicines Circulation which performs the operation;

c) Address of the place of economic activity (in case of operation being performed in the Russian Federation) or the code of the country (in case of operation being performed outside the Russian Federation) where the operation is performed, or the customs control zone (in case of operation being performed in the customs control zone);

d) Serialized Global Trade Item Number or Group Code of package of a lower inclusion level with which the addition operation is being performed;

e) Group Code of the package with which the operation is being performed.

4. Upon deconsolidation of the Group Package, Subjects of Medicines Circulation shall supply the following information to the Monitoring System:

a) Date of operation;

b) Taxpayer code in the country of incorporation or taxpayer identification number (for the Subject of Medicines Circulation being an organization recognized as a tax resident of the Russian Federation, individual entrepreneur, or the Russian representative office of the Subject of Medicines Circulation) of the Subject of Medicines Circulation which performs the operation;

c) Address of the place of economic activity (in case of operation being performed in the Russian Federation) or the code of the country (in case of operation being performed outside the Russian Federation) where the operation is performed, or the customs control zone (in case of operation being performed in the customs control zone);

d) Type of the package transformation operation (deconsolidation);

e) Group Code of the package being deconsolidated.

ANNEX No. 6
to the Regulations on the System for
Monitoring of Flow of Medicinal Products for
Human Use

INFORMATION

to be Supplied by Subjects of Medicines Circulation to the System for Monitoring of Flow of Medicinal Products for Human Use at Circulation and Domestic Movement of Medicinal Products for Human Use

1. Upon movement of Medicinal Products for human use (hereinafter referred to as the Medicinal Products) between the addresses of the places of activities and (or) pharmaceutical warehouses, the Subject of Medicines Circulation shall supply to the System for Monitoring of Flow of Medicinal Products for Human Use (hereinafter referred to as the Monitoring System) the following information about the Medicinal Products being moved with regard to each trade item of the Medicinal Product:

a) Date of operation (acceptance at the warehouse to which Medicinal Products have been moved);

b) Taxpayer identification number of the Subject of Medicines Circulation which moves the Medicinal Product;

c) Address of the place of economic activity or consignment warehouse from which the Medicinal Product is moved;

d) Address of the place of economic activity or consignment warehouse to which the Medicinal Product is moved;

e) Details of the source document which is the basis for Medicinal Product movement (date and number);

f) Serialized Global Trade Item Number of the Medicinal Product or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is moved as a whole).

2. Upon transfer of Medicinal Products to another Subject of Medicines Circulation as part of civil-law relations (if a Direct Information Supply Procedure is selected), the Subject of Medicines Circulation shall supply to the Monitoring System the following information about the shipped Medicinal Products with regard to each trade item of the Medicinal Product:

a) Date of operation;

b) Taxpayer identification number of the Subject of Medicines Circulation which ships the Medicinal Product;

c) Address of the place of activities from which the Medicinal Product is shipped;

d) Taxpayer identification number of the Subject of Medicines Circulation which accepts the Medicinal Product;

e) Address of the place of activities to which the Medicinal Product is shipped (in case of shipment to a Subject of Medicines Circulation which is not registered with the Monitoring System, such information shall not be specified);

f) Taxpayer identification number of the state authority (in case the Medicinal Product is transferred as part of the state provision of medicines);

g) Details of the state contract (in case the Medicinal Product is transferred as part of the state provision of medicines);

h) Source of funding;

i) Type of civil-law relations between Subjects of Medicines Circulation;

j) Serialized Global Trade Item Number of the Medicinal Product or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is transferred as a whole);

k) Details of the source document which is the basis for Medicinal Product transfer (date and number);

l) Price of the Medicinal Product (including VAT) according to the source documents;

m) Amount of the value added tax (if the Medicinal Product transfer is subject to such tax).

3. Upon acceptance of Medicinal Products from another Subject of Medicines Circulation as part of civil-law relations (if a Reverse Information Supply Procedure is selected), the Subject of Medicines Circulation shall supply to the Monitoring System the following information about the accepted Medicinal Products with regard to each item of Medicinal Product:

a) Date of operation;

b) Taxpayer identification number of the Subject of Medicines Circulation which accepts the Medicinal Product;

c) Address of the place of activities at which the Medicinal Product is accepted;

d) Taxpayer identification number of the Subject of Medicines Circulation which has shipped the Medicinal Product;

e) Address of the place of activities from which the Medicinal Product has been shipped;

f) Taxpayer identification number of the state authority (in case Medicinal Products are transferred as part of the state provision of medicines);

g) Details of the state contract (in case Medicinal Products are transferred as part of the state provision of medicines);

h) Source of funding;

i) Type of civil-law relations of Subjects of Medicines Circulation;

j) Serialized Global Trade Item Number of Medicinal Product or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is transferred as a whole);

k) Details of the source document which is the basis for Medicinal Product transfer (date and number);

l) Price of the Medicinal Product (including VAT) according to the source documents;

m) Amount of the value added tax (if the Medicinal Product transfer is subject to such tax).

4. Upon confirmation of the reliability of information about the transferred or accepted Medicinal Products contained in the Monitoring System, the Subject of Medicines Circulation shall supply to the Monitoring System the following information with regard to each trade item of Medicinal Product:

a) Date of operation;

b) Taxpayer identification number of the Subject of Medicines Circulation which transfers the Medicinal Product;

c) Taxpayer identification number of the Subject of Medicines Circulation which accepts the Medicinal Product;

d) Serialized Global Trade Item Number of a Medicinal Product or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is transferred as a whole).

5. Upon transfer of Medicinal Products (finished products) to the Subject of Medicines Circulation being the customer of such contract manufacturing, the Subject of Medicines Circulation performing contract manufacturing of Medicinal Products in the Russian Federation shall supply to the Monitoring System the following information about the transferred Medicinal Products with regard to each trade item of Medicinal Product:

a) Date of operation;

b) Taxpayer identification number of the Subject of Medicines Circulation which transfers the Medicinal Product;

c) Address of the place of activities from which the Medicinal Product is transferred;

d) Taxpayer identification number of the Subject of Medicines Circulation which accepts the Medicinal Product;

e) Address of the place of activities to which the Medicinal Product is transferred;

f) Serialized Global Trade Item Number of the Medicinal Product or Group Code of the Group Package in which such Medicinal Product is contained (if the Group Package is transferred as a whole);

g) Details of the source document which is the basis for Medicinal Product transfer (date and number).

ANNEX No. 7
to the Regulations on the System for
Monitoring of Flow of Medicinal
Products for Human Use

LIST

of Reasons for Blocking of Acceptance of Information about Putting of Medicinal Products for Human Use into Circulation and (or) Withdrawal of Medicinal Products for Human Use from Circulation by the System for Monitoring of Flow of Medicinal Products for Human Use

1. Revealed non-compliance with any quality requirements in the course of random quality control of medicines and federal surveillance in the field of medicines circulation exercised by the Federal Service for Surveillance in Healthcare and its local agencies.

2. Adoption of a decision by the Federal Service for Surveillance in Healthcare based on the results of consideration of a report received from a Subject of Medicines Circulation containing information on the discovery of non-compliance of the Medicinal Products for human use (hereinafter referred to as the Medicinal Products) put into circulation with the requirements set by the Ministry of Health of the Russian Federation upon registration of the said Medicinal Products.

3. Adoption of a decision by the Ministry of Health of the Russian Federation to cancel state registration of a Medicinal Product as prescribed by Clause 6 of Article 32 of the Federal Law "On Circulation of Medicines".

4. Absence of information in the System for Monitoring of Flow of Medicinal Products (hereinafter referred to as the Monitoring System) about the fact that the Subject of Medicines Circulation which supplies information on the Medicinal Product circulation actually has such Medicinal Product available.

5. Expiry of the Medicinal Product shelf life in accordance with the information recorded in the Monitoring System.

6. Discrepancy between the information about the Medicinal Product supplied by the Subject of Medicines Circulation upon description of the Medicinal Product to the information resource which ensures accounting and storage of reliable data on the goods according to the corresponding nomenclature of goods, and the information received by the Monitoring System from the unified state information system in the field of healthcare.

7. Supply to the Monitoring System of information about the sale of a Medicinal Product from the pharmaceutical warehouse during secure storage.

8. Supply to the Monitoring System of information about shipment (sale) of a Medicinal Product before recording of information about Putting of Medicinal Products into Circulation in the said system.

9. Supply of information to the Monitoring System in violation of the requirements of the Regulations on the System for Monitoring of Flow of Medicinal Products for Human Use approved by Decree of the Government of the Russian Federation dated December 14, 2018 No. 1556 "On Approval of the Regulations on the System for Monitoring of Flow of Medicinal Products for Human Use".

10. Absence of any information in the Monitoring System about possession by the Subject of Medicines Circulation of any licenses entitling the Subject of Medicines Circulation to perform the corresponding operations.

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

12. Presence of an entry in respect of the applicant in the Unified State Register of Legal Entities regarding the unreliability of information entered in accordance with Clauses 5 and (or) 6 of Article 11 of the Federal Law "On State Registration of Legal Entities and Individual Entrepreneurs".
