INSTRUCTION
on Submission of Information by Pharmaceutical Entities to Track and Trace System of Medicines for Medical Use (PASSPORTS OF PROCESSES)

Version 1.38.2

Moscow
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Introduction

This Instruction on Submission of Information by Pharmaceutical Entities to Track and Trace System of Medicines for Medical Use (the Passports of Processes) is developed according to para. 32 of Regulation on the Track and Trace System of Medicines for Medical Use approved by Resolution of the Government of the Russian Federation No. 1556 dated December 14, 2018 (the Regulation on the Track and Trace System).

These Passports of Processes establish the following:

procedures for registration of pharmaceutical entities and medicines produced by them in the Track and Trace System of Medicines for medical use (the Track and Trace System, MDLP System);

procedures for submission of information to the track and trace system by pharmaceutical entities, including the list of submitted information.

Information is provided by pharmaceutical entities to the Track and Trace System with consideration of:

- status model of the Track and Trace System given in Appendix No. 1 to these Passports of Processes;

- restrictions for use of the operations given in Appendix No. 2 to these Passports of Processes.

Terms and Abbreviations

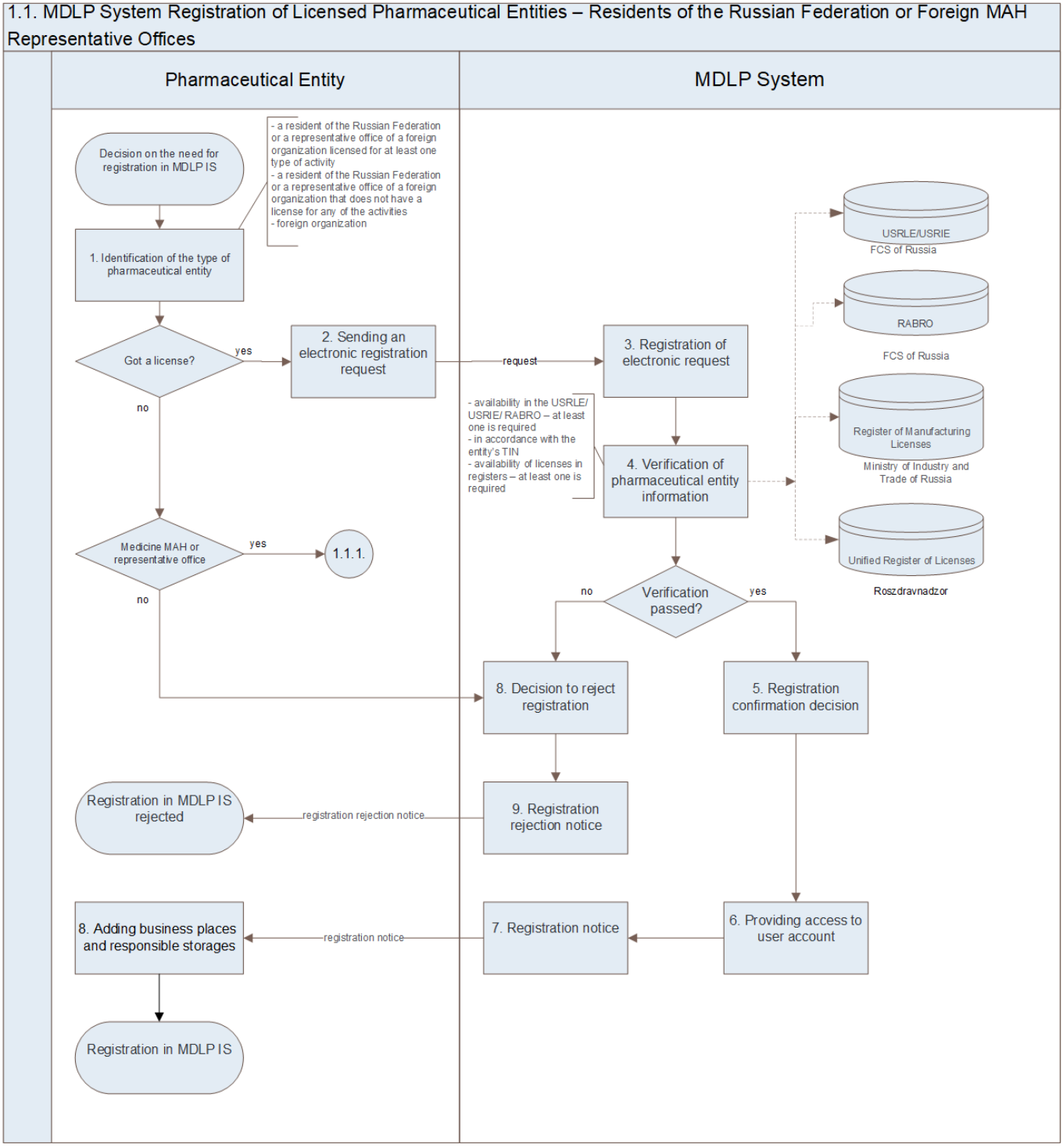
Term / Abbreviation	Description
CRE	Cash register equipment
DR	Disposal registrar shall mean the information exchange hardware designed to transfer to the Track and Trace System the information on medicine withdrawal from circulation, that includes hardware and software encryption (cryptographic) technical means with functions of verification code checking, for which the Federal Security Service of the Russian Federation issued a document on its compliance with the established requirements to encryption (cryptographic) means of information protection applicable to encryption (cryptographic) means for marking code verification
EAEU	Eurasian Economic Union
EQES	Enhanced qualified electronic signature
ER	Emission registrar shall mean the information exchange hardware designed to obtain marking codes and transfer to the Track and Trace System the information on marking of medicine packages with identification means, that functions as technical means for verification code checking, for which the Federal Security Service of the Russian Federation issued a document on its compliance with the established requirements to encryption (cryptographic) means of information protection applicable to encryption (cryptographic) means for marking code verification, or that includes technical means for verification code checking, for which the Federal Security Service of the Russian Federation issued a document on its compliance with the established requirements to encryption (cryptographic) means of data protection applicable to encryption (cryptographic) means for marking code verification;
ESKLP	Unified Register of Medicines of the Unified Government Information System in the Healthcare of Ministry of Health of the Russian Federation
FD	Fiscal document
FDF	Fiscal document format
FDO	Fiscal data operator
FEA	Federal Executive Authority
Foreign counterparty	36-digit identifier, assigned to a foreign counterparty when it is registered in MDLP System by MAH for medicine

Term / Abbreviation	Description
identifier	manufactured outside the territory of the Russian Federation (or by its official representative office)
GS1 RUS	An information resource that provides accounting and storage of reliable data on goods according to the corresponding commodity nomenclature, Association of automatic identification "UNISCAN/GS1 RUS", using GS1 standards
GTIN	Global trade item number shall mean a unique code assigned to a group of goods when they are described at an information resource that enables accounting and storage of reliable data on the goods of the corresponding goods nomenclature
Identifier of the goods location in the customs-controlled area	36-digit identifier, assigned to the location area of goods in the customs-controlled area according to the register of the owners of secure storage warehouses, the register of the owners of customs warehouses and the register of the Authorized Economic Operators of the Federal Customs Service (FCS) of Russia
Identifier of the pharmaceutical entity's business place	14-digit identifier of the business place of the pharmaceutical entity (resident of the Russian Federation) according to license (manufacturing license, license for pharmaceutical and medical activities, license for narcotics circulation), assigned following the results of registration of business place in MDLP System by the pharmaceutical entity, based on pharmaceutical entity's TIN and the address of the business place (according to FIAS – Federal Information Address System)
IEIS	Interagency Electronic Interaction System
IM	Identification means shall mean a marking code presented in machine-readable form or using other automatic identification tools (technology) and generated for application on secondary (consumer) medicine package (if unavailable—on primary medicine package) using methods that prevent separation of the identification means and/or material media containing the identification means from medicine package without damaging it
License	License for medicine manufacturing, license for pharmaceutical activities, license for circulation of narcotic substances, psychotropic substances, and their precursors, and cultivation of drug-yielding plants, and license for medical care

Term / Abbreviation	Description
MAH	Marketing authorization holder for a medicine manufactured outside the territory of the Russian Federation
MAH office, representative office	Official representative office in the territory of the Russian Federation of the foreign organization which is a MAH for medicine manufactured outside the territory of the Russian Federation
MDLP System, Track and Trace System	Federal State Track and Trace Information System of Medicines for medical use
Medicines	Medicines for medical use
Pharmaceutical entity	A pharmaceutical entity engaged in production, storage, importation into the Russian Federation, dispensing, sales, transfer, use and transfer for destruction of medicines
RABRO	Register of Accredited Branches and Representative offices of the Federal Tax Service (FTS) of Russia
Registration number of the pharmaceutical entity in MDLP System	36-digit number assigned to the pharmaceutical entity when it is registered in MDLP System based on information about taxpayer code in the country of registration (or TIN for residents of the Russian Federation) and code of country of pharmaceutical entity's registration (for foreign organizations)
SGTIN	Serialized Global Trade Item Number, identification code shall mean a serial global trade item number, which is a unique identifier of a secondary (consumer) medicine package (or, if not applicable, of a primary medicine package), generated by adding an individual serial number of trade item to the global trade item number
SSCC	Serial Shipping Container Code, identification means of medicine tertiary (shipping) packing, a unique combination of characters provided in the form of linear bar code for each individual tertiary (shipping) packing of the medicine
TIN	Taxpayer Identification Number
USRLE/USRIE	Unified State Register of Legal Entities / Unified State Register of Individual Entrepreneurs of the Federal Tax Service (FTS) of Russia
VEM	Vital and essential medicines

1. Section “Registration of Pharmaceutical Entities in MDLP System”

1.1. MDLP System Registration of Licensed Pharmaceutical Entities – Residents of the Russian Federation or Foreign MAH Representative Offices



Picture 1

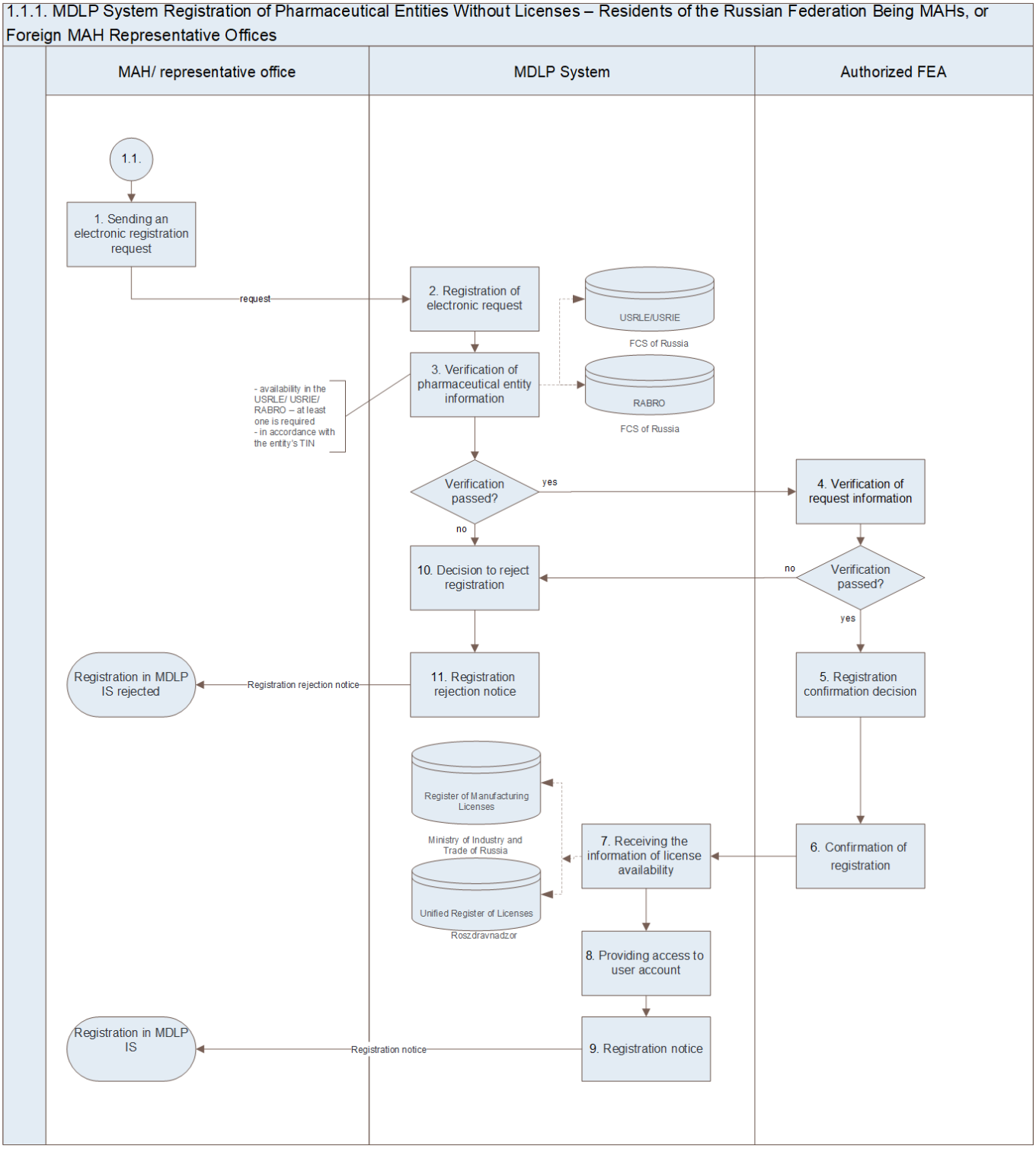
Annotation	Pharmaceutical entities can be registered in MDLP System based on electronic request. The electronic request, sent by a resident of the Russian Federation or a representative office of foreign MAH, shall be signed using EQES. The data in the electronic request for registration is processed and verified by MDLP System software, also using IEIS with external information resources of FEA. When a request is sent, the type of pharmaceutical entity is automatically identified based on the submitted TIN: TIN of foreign MAH representative offices begins with 9909, otherwise the organization is recognized as a resident of the Russian Federation. Registration of pharmaceutical entities – residents of the Russian Federation being MAHs, or foreign MAH representative offices without a license for at least one of the activities (manufacturing license, license for pharmaceutical, medical activities, or narcotics circulation) shall be in accordance with section 1.1.1 of these Passports of Processes. Following the results of the request check: – if there is no reason for rejection, the registration of the organization in MDLP System is completed, a user account is created, and the pharmaceutical entity receives its MDLP System registration number; – if there is reason for rejection, a message is sent that the request for registration in the MDLP System is rejected and user account is denied. User account functions available to the pharmaceutical entity are formed by the MDLP System software in accordance with the license and activity type: medicine manufacturing; pharmaceutical and medical activities; circulation of narcotic, psychotropic substances and their precursors; cultivation of drug-yielding plants Upon registration in MDLP System, pharmaceutical entity adds business places under license to the user account of the MDLP System. If necessary, the pharmaceutical entity is entitled to block and activate the business places in the user account of the MDLP System. Details about the availability of the operations for blocked business places can be found in Appendix No.2 herein

<table>
<tr><td>Interaction participants</td><td>– resident of the Russian Federation that has a license for at least one type of the activities;
– foreign MAH representative office which has a license for at least one type of the activities</td></tr>
<tr><td colspan="2">Description of the actions performed</td></tr>
<tr><td colspan="2">1. Identification of the type of pharmaceutical entity</td></tr>
<tr><td colspan="2">2. – 3. Sending and registration of electronic request for registration of the pharmaceutical entity in MDLP System</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>The pharmaceutical entity specifies the following information in the registration request:
– TIN of the pharmaceutical entity (to be filled automatically from the qualified certificate);
– type of the pharmaceutical entity (resident of the Russian Federation or foreign resident representative office, foreign resident);
– license availability (yes/no, at least one type of activities);
– surname, name, patronymic (if any) (to be filled automatically from the qualified certificate);
– contact phone number;
– e-mail address</td></tr>
<tr><td colspan="2">4. Identification of the pharmaceutical entity’s type and automatic verification of information about the pharmaceutical entity using integrative interaction with external information resources</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>Obtaining information about the registration of legal entity or individual entrepreneur in the USRLE/USRIE of the FTS of Russia (in case of registration as a resident of the Russian Federation):
– TIN of the pharmaceutical entity;
– name of the pharmaceutical entity or surname, name, patronymic (if any) for individual entrepreneur;
– surname, name, patronymic (if any) of the head (for legal entities);
– status of registration record of legal entity and/or individual entrepreneur.
Obtaining information about legal entity accreditation in the RABRO of the FTS of Russia (registration as a representative office):</td></tr>
</table>

	– TIN of the pharmaceutical entity; – name of the pharmaceutical entity or surname, name, patronymic (if any) for individual entrepreneur); – surname, name, patronymic (if any) of the head (for legal entities); – status of registration record of the foreign MAH representative office. Obtaining information about availability of manufacturing license in **Register of Medicine Manufacturing Licenses of the Ministry of Industry and Trade of Russia**: – TIN of the pharmaceutical entity; – license number; – addresses of business places; – list of the works and services; – license status. Obtaining information about availability of a relevant license in the **Unified Register of Licenses, including licenses issued by governmental bodies of constituent entities of the Russian Federation according to the delegated authority to license individual types of health care activities, Roszdravnadzor**: – TIN of the pharmaceutical entity; – license number; – addresses of business places; – list of the works and services; – license status.
5. Automatic decision on registration (if there is no reason for rejection)	
6. Creating the user account in MDLP System and providing access to the user account for the pharmaceutical entity (if there is no reason for rejection)	
7. Notice to the pharmaceutical entity about registration in MDLP System (if there are no reasons for rejection)	
8. Adding the business places (in accordance with the licenses) and responsible storages by the pharmaceutical entity	
9. Automatic decision to deny registration of the pharmaceutical entity in MDLP System (if there are reasons for rejection)	
List of	– there is no information about the registration of the

reasons for rejection to register	pharmaceutical entity in the USRLE/USRIE/RABRO of the FTS of Russia; – there is no information about the license for at least one of the activities (medicine manufacturing, pharmaceutical, medical activity, narcotics circulation) in the registers (Ministry of Industry and Trade of Russia, Federal Service for Surveillance in Healthcare of Russian Federation) – information on the owner of qualified certificate of electronic signature verification key (the "qualified certificate") does not match the data on the head of organization or individual entrepreneur, there are no data on the qualified certificate issued to the head of organization or individual entrepreneur, and the enhanced qualified electronic signature is invalid
10. Notice to the pharmaceutical entity of rejection to register in MDLP System with indication of reasons (if there are reasons for rejection)	
Special conditions	The registration of more than one business place (using one INN) for one pharmaceutical entity with the same address and FIAS code is not permitted. If there is a need to introduce individual records for business places located at the same address, the address should be detailed to the level of the room and each business place should be assigned unique FIAS code

1.1.1. MDLP System Registration of Pharmaceutical Entities Without Licenses – Residents of the Russian Federation Being MAHs, or Foreign MAH Representative Offices



Picture 2

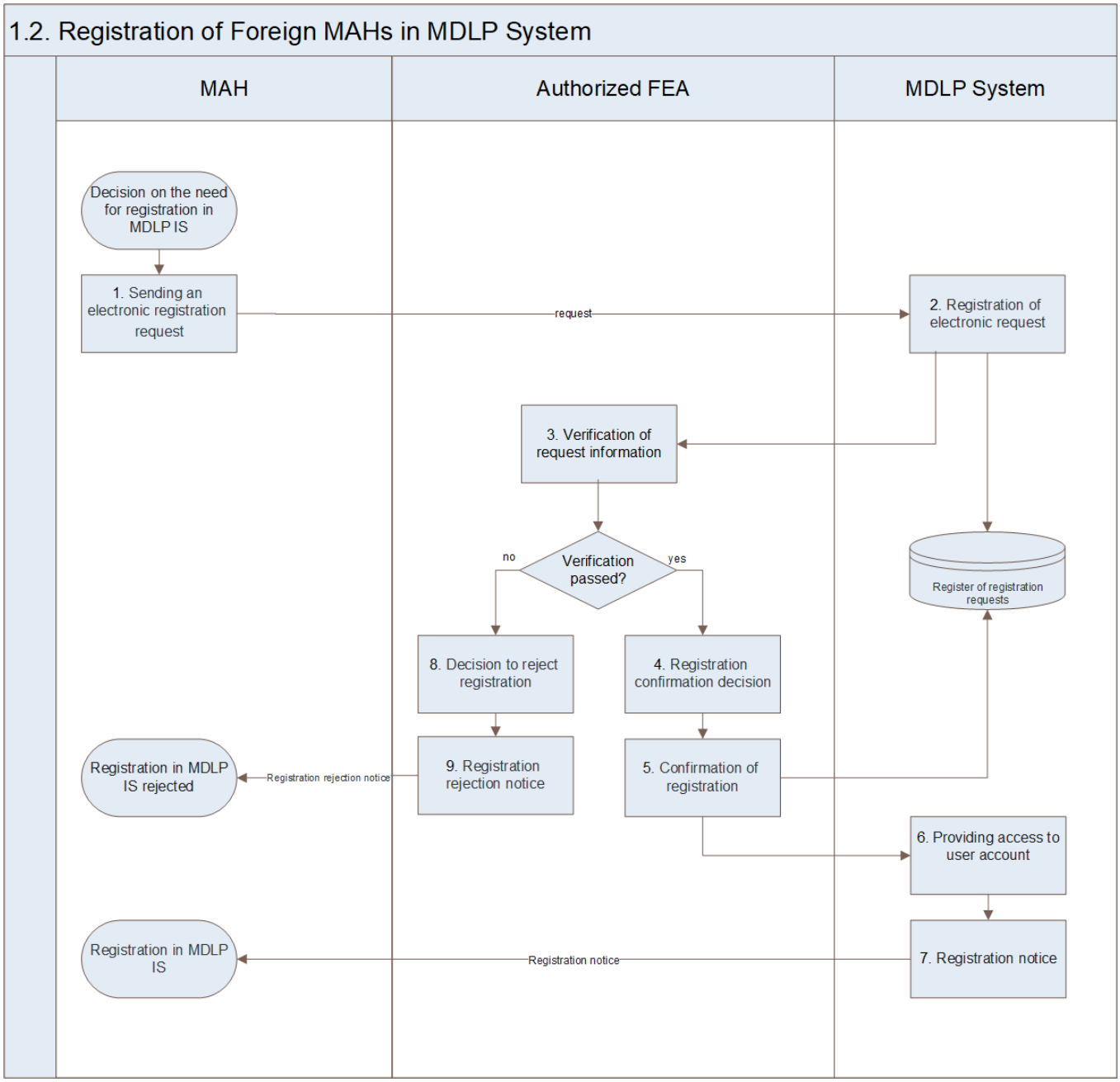
Annotation	Registration of the pharmaceutical entity in MDLP System is performed on the basis of electronic request signed with EQES. When a request is sent, a type of the pharmaceutical entity is automatically identified based on the submitted TIN: TIN of foreign MAH representative offices begins with 9909, otherwise the organization is recognized as a resident of the Russian Federation. Data in the electronic request for registration is processed and verified by MDLP System software, also using IEIS with external information resources of FEA. An authorized FEA shall review (by using MDLP System functions) data submitted by a pharmaceutical entity to the MDLP System for registration, as well as shall make a decision whether to register (or refuse to register). Following the results of the request check: – if there is no reason for rejection, the registration of the organization in MDLP System is completed, a user account is created, and the pharmaceutical entity receives its MDLP System registration number; – if there is reason for rejection, a message is sent that the request for registration in the MDLP System is rejected and user account is denied
Interaction participant	– resident of the Russian Federation being MAH, without a license for at least one of the activities; – foreign MAH representative office without a license for at least one of the activities; – authorized FEA
Description of the actions performed	
1. – 2. Sending and registration of electronic request for registration of the pharmaceutical entity in MDLP System	
List of information to be transferred	The pharmaceutical entity specifies the following information in the registration request: – TIN of the pharmaceutical entity (to be filled automatically from the qualified certificate); – type of the pharmaceutical entity (resident of the Russian Federation or foreign resident representative office, foreign resident);

	– license availability (yes/no, at least one type of activities); – surname, name, patronymic (if any) (to be filled automatically from the qualified certificate); – contact phone number; – e-mail address
3. Identification of the pharmaceutical entity's type and automatic verification of information about the pharmaceutical entity using integrative interaction with external information resources	
List of information to be transferred, and the owner of information resource	Obtaining information about the registration of legal entity or individual entrepreneur in the **USRLE/USRIE of the FTS of Russia** (in case of registration as a resident of the Russian Federation): – TIN of the pharmaceutical entity; – name of the pharmaceutical entity or surname, name, patronymic (if any) for individual entrepreneur; – status of registration record of legal entity and/or individual entrepreneur. Obtaining information about legal entity accreditation in the **RABRO of the FTS of Russia** (in case of registration of representative offices of foreign MAHs): – TIN of the pharmaceutical entity; – name of the pharmaceutical entity or surname, name, patronymic (if any) for individual entrepreneur; – status of registration record of the foreign MAH representative office
4. Check by the authorized FEA of the data provided in the electronic request	
5. Making a decision on registration of the pharmaceutical entity in MDLP System and on providing user account access (if there is no reason for rejection)	
6. Confirmation by the authorized FEA of the electronic request of the pharmaceutical entity in MDLP System (if there is no reason for rejection)	
7. Creating the user account in MDLP System and receiving additional information on the pharmaceutical entity (if there is no reason for rejection)	
List of information to be transferred, and the owner of	Obtaining information about availability of manufacturing license in **Register of Medicine Manufacturing Licenses of the**

information resource	**Ministry of Industry and Trade of Russia**: – TIN of the pharmaceutical entity; – license number; – addresses of business places; – list of the works and services; – license status. Obtaining information about availability of the relevant license in **the Unified Register of Licenses, including licenses issued by governmental bodies of constituent entities of the Russian Federation according to the delegated authority to license individual types of health care activities:** – TIN of the pharmaceutical entity; – license number; – addresses of business places; – list of the works and services; – license status
8. Providing access to the MDLP System user account for the pharmaceutical entity (if there is no reason for rejection)	
9. Notice to the pharmaceutical entity of registration in MDLP System (if there are no reasons for rejection)	
10. Making a decision to deny the pharmaceutical entity registration in MDLP System (if there are reasons for rejection)	
List of reasons for rejection to register	– there is no information about the registration of the pharmaceutical entity in the USRLE/USRIE/RABRO of the FTS of Russia; – there is no information about the pharmaceutical entity registered as a MAH in the State Register of Medicines of the Ministry of Health of the Russian Federation; – information on the owner of qualified certificate of electronic signature verification key (the "qualified certificate") does not match the data on the head of organization or individual entrepreneur, there are no data on the qualified certificate issued to the head of organization or individual entrepreneur, and the enhanced qualified electronic signature is invalid

11.Notice to the pharmaceutical entity about rejection of registration in MDLP System with indication of reasons (if there are reasons for rejection)

1.2. MDLP System Registration of MAHs Being Foreign Organizations

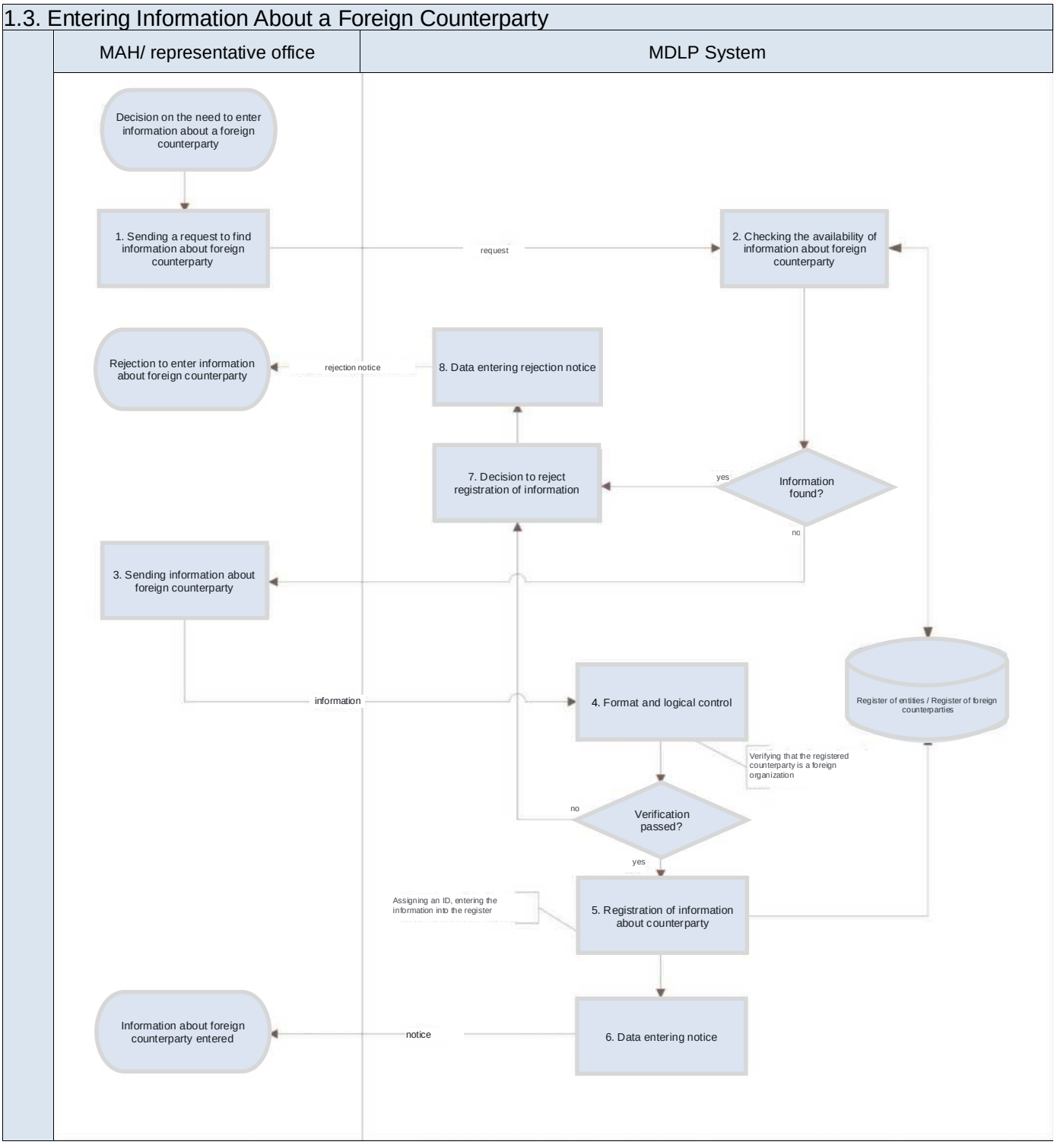


Picture 3

Annotation	Foreign MAH without representation in the territory of the Russian Federation or which has made a decision on individual interaction with MDLP System without engaging a representative office in the Russian Federation can be registered in MDLP System on the basis of electronic request. An authorized FEA shall review (by means of MDLP System functions) data submitted by a pharmaceutical entity to the MDLP System for registration, as well as shall make a decision whether to register (or refuse to register). Following the results of check of the request: – if there is no reason for rejection, the registration of the organization in MDLP System is completed, a user account is created and the pharmaceutical entity receives its registration number in MDLP System; – if there is reason for rejection, a message is sent that the request for registration in the MDLP System is rejected and user account is denied
Interaction participants	– foreign MAH; – authorized FEA
Description of the actions performed	
1. – 2. Sending and registration of electronic request for registration of the pharmaceutical entity in MDLP System	
List of information to be transferred, and the owner of information resource	The foreign MAH shall specify the following information in the MDLP System registration request: – name of MAH; – type of the pharmaceutical entity (resident of the Russian Federation or foreign resident representative office, foreign resident); – taxpayer code of foreign MAH in the country of registration (TIN analogue); – code of the country of foreign MAH's registration; – zip code; – surname, name, patronymic (if any); – contact phone number; – e-mail address

3. Check by the authorized FEA of the data provided in the electronic request	
4. Making a decision on registration of the pharmaceutical entity in MDLP System and on providing user account access (if there is no reason for rejection)	
5. Confirmation by the authorized FEA of the electronic request of the pharmaceutical entity in MDLP System (if there is no reason for rejection)	
6. Creating a user account in MDLP System and providing access to the user account for the pharmaceutical entity (if there is no reason for rejection)	
7. Notice to the pharmaceutical entity about registration in MDLP System (if there are no reasons for rejection)	
List of reasons for rejection to register	– there is no information about the foreign MAH in the medicine marketing authorization of the State Register of Medicines of Ministry of Health of the Russian Federation
8. Making a decision to reject registration in MDLP System (if there are reasons for rejection)	
9. Notice to the pharmaceutical entity about rejection of registration in MDLP System with indication of reasons (if there are reasons for rejection)	
Special conditions	A name of the MA holder shall be specified in the request for registration in the MDLP System strictly in line with a name that is registered in the MA in the State Register of Medicines of the Ministry of Health of the Russian Federation

1.3. Entering Information in MDLP System About a Foreign Counterparty

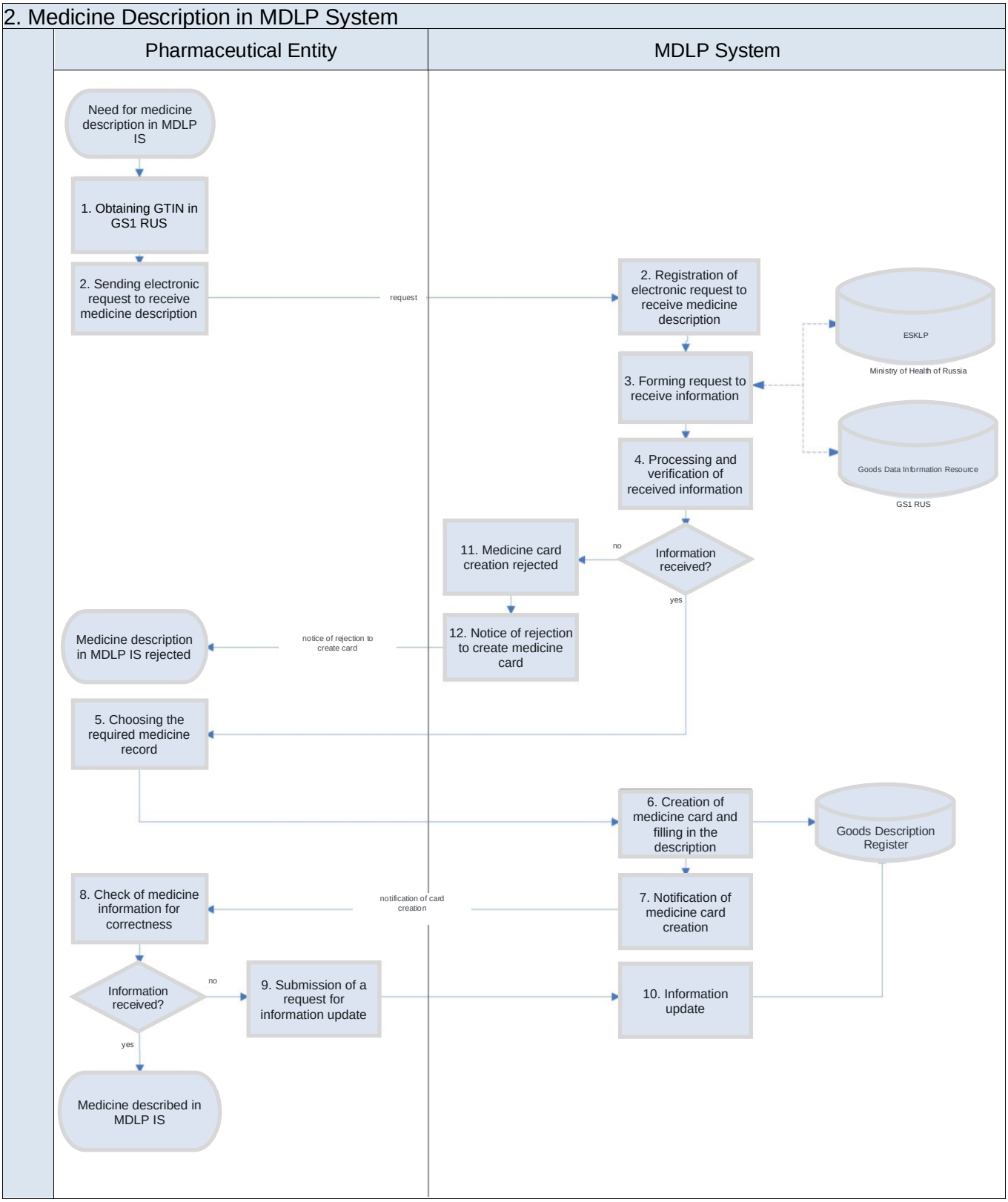


Picture 4

Annotation	The MAH (its representative office) enters data on foreign counterparties to register foreign medicine manufacturers, which complete the production stage of prepacking/packing into secondary (consumer) package and release quality control, and on foreign medicine sellers
Interaction participants	– MAH, or representative office of foreign MAH
Description of the actions performed	
1. – 2. Checking the availability of information on registered foreign counterparty in MDLP System	
List of information to be transferred, and the owner of information resource	You can search for information by using the following criteria: – taxpayer code of foreign counterparty in the country of registration; – code of the country of foreign counterparty's registration
3. Sending information about a foreign counterparty to be registered in MDLP System (if there is no previous record in MDLP System)	
List of information to be transferred, and the owner of information resource	MAH specifies the following information when registering information about a foreign counterparty in MDLP System: – name of foreign counterparty; – taxpayer code of foreign counterparty in the country of registration (TIN analogue); – code of the country of foreign counterparty's registration; – zip code
4. Format and logical control and automatic decision-making on the possibility of entering information about a foreign counterparty into MDLP System	
5. Entry of information about a foreign counterparty into the Register of Foreign Counterparties in MDLP System (if there is no reason for rejection) and assignment of the identifier of a foreign counterparty	
6. Notice to the pharmaceutical entity on entering information about a foreign counterparty in MDLP System	
7. Decision to reject registration of information about a foreign counterparty (if there are reasons for rejection)	
List of reasons	– there is already registered information about this foreign

for rejection to register	counterparty in the Register of Foreign Counterparties
8. Notice to the pharmaceutical entity on rejection of entering information about the foreign counterparty in MDLP System with indication of the reason (if there are reasons for rejection)	

2. Section “Medicine Description in MDLP System”



Picture 5

Annotation	Medicines are described in MDLP System on the basis of the pharmaceutical entity's electronic request. First, the pharmaceutical entity must register the medicine in GS1 RUS to receive GTIN. The request for medicine description is sent by the Russian manufacturer of the medicine (when the medicine is produced in the territory of the Russian Federation), or by the MAH or its representative office (when the medicine is produced outside the territory of the Russian Federation) If any discrepancies are found between the information about a medicine registered in MDLP System and the information specified in the marketing authorization, a pharmaceutical entity may submit an electronic request for the information update. The electronic request for update of the information on medicines is approved by the Operator of MDLP System based on the confirming documents submitted by the pharmaceutical entity
Interaction participants	– Russian manufacturer of the medicine; – MAH, or representative office of foreign MAH
Description of the actions performed	
1. Registration of the medicine in GS1 RUS and GTIN obtaining	
List of information to be transferred, and the owner of information resource	When describing a medicine in GS1 RUS, a pharmaceutical entity shall provide the following information: – trade name of the medicine; – brand (trade mark); – number of the medicine marketing authorization; – medicine registration date; – name of the marketing authorization holder; – address of the marketing authorization holder; – international non-proprietary name; – dosage form; – number of the medicine dosage units; – type of secondary (consumer) medicine package (if

	unavailable, of primary medicine package); – material of secondary (consumer) medicine package (if unavailable, of primary medicine package); – quantity (measure) of medicine in secondary (consumer) medicine package (if unavailable, in primary medicine package); – presence of any unmarked primary medicine package inside a secondary (consumer) medicine package (if secondary (consumer) medicine package is available); – description of unmarked primary medicine package inside a secondary (consumer) medicine package; – name of prepacker (packer) (to be specified in case of medicine prepacking (packing) in the Russian Federation); – address of prepacker (packer) of secondary (consumer) medicine packages (if unavailable, primary medicine packages) (to be specified in case of prepacking (packing) in the Russian Federation) – GTIN
2. – 3. Sending and registration of electronic request to receive medicine description in MDLP System	
List of information to be transferred, and the owner of information resource	The following key parameters are indicated in the electronic request in MDLP System: – number of medicine marketing authorization; – medicine registration date. – GTIN
4. Forming requests to receive information about the medicine in ESKLP and in GS1 RUS	
List of information to be transferred, and the owner of information resource	List of information received from **ESKLP of the Ministry of Health of the Russian Federation**: – international non-proprietary name; – indication of availability on the VEM list; – dosage form; – dosage (value); – dosage (unit of measurement);

	– trade name; – number of dosage form in primary packing; – number of primary packages in the consumer packing; – packing completeness; – number of medicine marketing authorization; – medicine registration date; – expiration date of the medicine marketing authorization; – marginal registered price (for VEM) in RUB List of information received from **GS1 RUS**: – GTIN; – name on packing;
5. Processing, registration and verification of information received from the external information resources	
6. Selection of the required medicine record by the pharmaceutical entity (if there are no reasons for rejection)	
7. Creation of the medicine card and filling in the description in the MDLP System (if there are no reasons for rejection)	
8. Notice to the pharmaceutical entity on creating the medicine card in MDLP System (if there are no reasons for rejection	
9. Check of the medicine card data in MDLP System for correctness	
10. Submission of a request for medicine data update in MDLP System	
List of information to be transferred, and the owner of information resource	When submitting a request, a pharmaceutical entity shall select the data to be updated, specify a correct value and enclose confirming documents. The request may contain the following data to be updated: - manufacturer's maximum sale price; - dosage form; - dosage; - primary packing; - secondary (consumer) packing
11.Correction of information in MDLP System according to the request data	
12. Rejection to create the medicine card in MDLP System (if there are reasons for	

rejection)	
List of reasons for rejection to register	- there is no information about the medicine in ESKLP; - there is no information about the medicine in GS1 RUS; - mismatching of information (date and number of the marketing authorization, trade name) in ESKLP and GS1 RUS
13.Notice to the pharmaceutical entity on rejection to create the medicine card in MDLP System with indication of the reason (if there are reasons for rejection)	
Special conditions	A pharmaceutical entity selects the required record when describing the medicine from the list of records on goods items generated by the Unified Register of Medicines (ESKLP) within the same medicine marketing authorization. When submitting a request for the data update, a pharmaceutical entity shall attach scanned copies of confirming documents: – when changing the manufacturer's maximum sale price – a scanned copy of the medicine marketing authorization and a scanned copy of an order for manufacturer's maximum sale price setting; – when changing the dosage form/dosage/primary packing/secondary (consumer) packing – a scanned copy of the medicine marketing authorization

2.1 Adding instruction and medicine package images

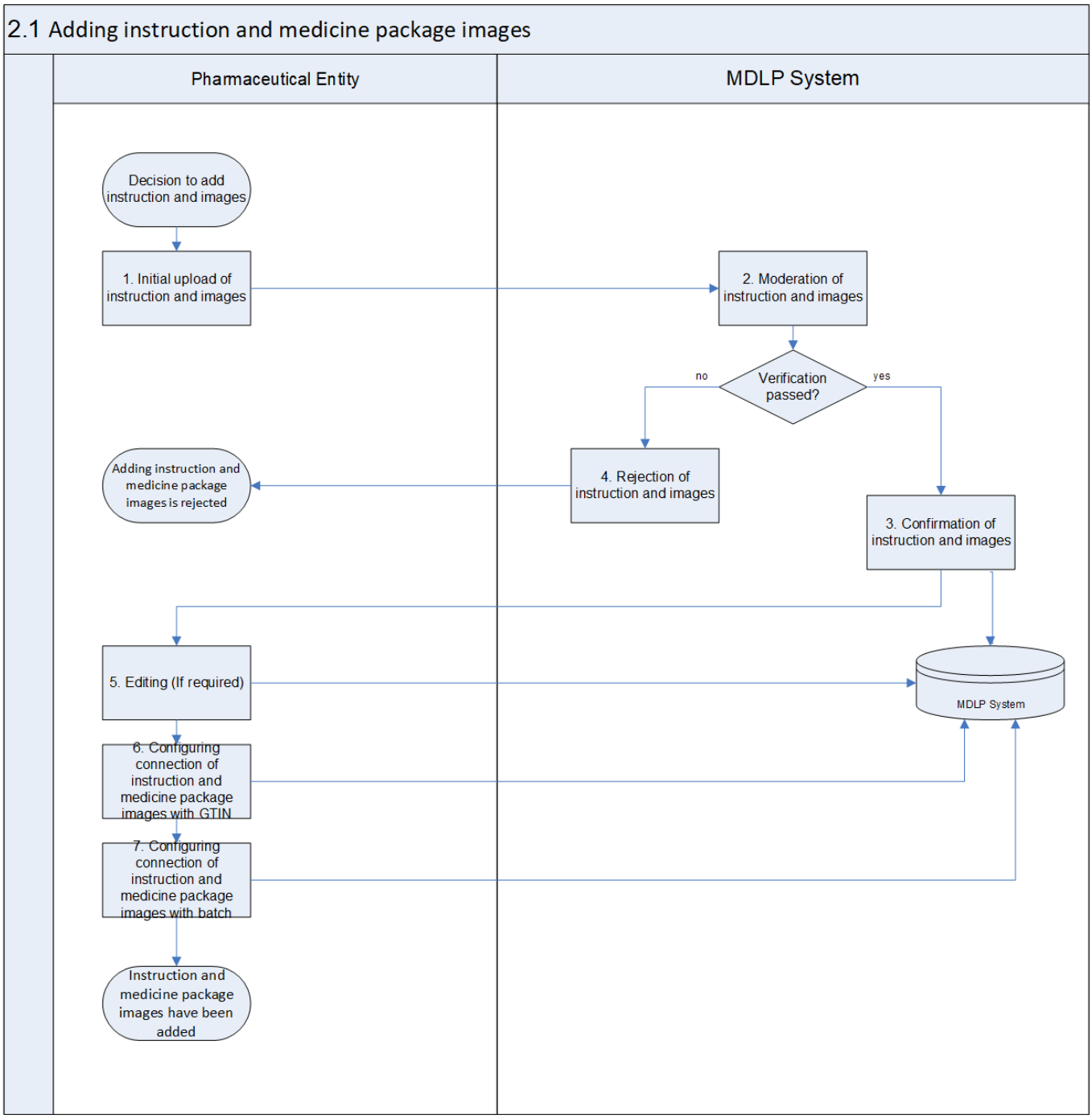


Figure 1

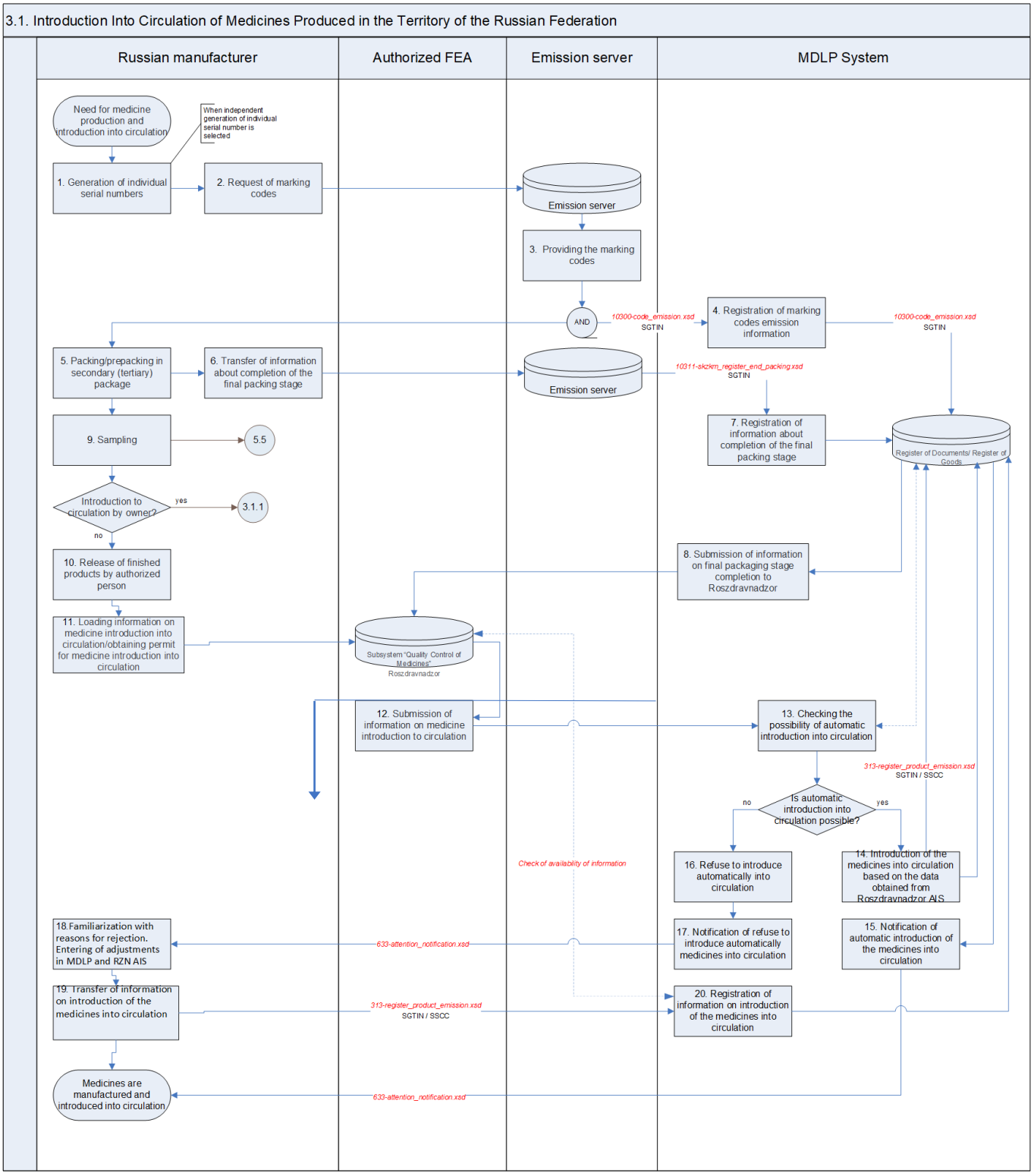
Annotation	Pharmaceutical entities – IM issuers (Russian medicine manufacturers, MA holders or representative offices of foreign MAHs) shall voluntarily provide an instruction on medical use of the medicine (current as of the date of introduction of the medicine into civil circulation) to the MDLP System from September 1, 2023 till June 30, 2024
Interaction participants	– Russian manufacturer of the medicines; – MA holder or representative office of foreign MAH
Description of the actions performed	
1. Initial upload of the instruction and medicine package images	
List of information to be transferred, and the owner of information resource	As part of provision of the instruction and medicine package images, a pharmaceutical entity shall upload the following data to the MDLP System by using the features in the MDLP System user account, or by using API methods: – JSON instruction; – PDF instruction; – medicine package images. JSON instruction shall contain the following fields: – MA number; – date of medicine state registration; – MA holder; – trade name; – dosage form; – active substance; – composition; – description of the medicine appearance; – pharmacotherapeutic group; – indications for use; – contra indications; – with caution; – use during pregnancy and lactation; – dosage and administration;

	– side effects; – overdose; – interaction with other medicines; – release form; – effects of the medicine on ability to drive and use machines; – expiration date; – storage conditions; – indication to store medicines out of reach of children; – conditions of sale in pharmacies; – manufacturer; – support service. PDF instruction content should correspond with JSON instruction content. Requirements to medicine package images: – medicine package image format – PNG; – aspect ratio — square; – resolutions 854x854 or 1280x1280; – a size of one file — no larger than 2 MB; – number of files of the medicine package images - maximum 5. The instruction and medicine package images will be saved in the following registries: – registry of instructions and images; – registry of medicines. When a pharmaceutical entity creates the instruction and medicine package images, they have the “Draft” status
2. Sending a container for moderation by a pharmaceutical entity and moderation of the provided data	
3. After moderation the instruction and medicine package images have the “Confirmed” status.	
4. If there are grounds for refusal, after moderation the instruction and medicine package images have the “Rejected” status	

A list of the grounds for refusal to register information	– provision of incorrect information when uploading the instruction and medicine package images
5. Editing the instruction and medicine package images	
6. Configuring connection of instruction and medicine package images with GTIN	
List of information to be transferred, and the owner of information resource	To configure connection of instructions and medicine package images with GTIN, a pharmaceutical entity shall submit the following information to the MDLP System: – GTIN; – identifier of the created instruction and images; – attribute of indication of the default container for those batches that do not have explicitly specified identifier of the instruction and medicine package images
7. Configuring connection of instruction and medicine package images with a production series number	
List of information to be transferred, and the owner of information resource	To configure connection of instruction and medicine package images with a production series number, a pharmaceutical entity shall submit the following information to the MDLP System: – GTIN; – production series number; – identifier of the created instruction and medicine package images
Special conditions	When uploading the instruction and medicine package images, upload of JSON instruction is mandatory. As a result of upload of instruction and medicine package images, the instructions and images will be displayed in Chestny ZNAK app when scanning the identification means applied to the medicine package

3. Medicine Introduction into Circulation

3.1. Introduction Into Circulation of Medicines Produced in the Territory of the Russian Federation



Picture 7

Annotation	Individual serial numbers for coding of secondary (consumer) packing of medicine (in its absence – the primary packing of the medicine) can be generated independently by Russian manufacturers of the medicine or by MDLP System Operator by request. As a result, a unique combination of GTIN and individual serial number of secondary (consumer) medicine packing (in its absence – the primary packing of the medicine) is called SGTIN and determines the unique identification code of secondary (consumer) medicine packing (in its absence – the primary packing of the medicine) for traceability in MDLP System. DataMatrix is applied on each secondary (consumer) medicine package (in its absence – the primary packing of the medicine), containing the following fields: – SGTIN (mandatory); – verification code (provided by Operator of MDLP System). Russian medicine manufacturer can obtain the marking codes from the Operator of MDLP System using emission registrar provided by the Operator of MDLP System by means of transfer or provision of remote access (by the decision of the Russian manufacturer of the medicine). The code in the form of Code128, containing the individual serial number of the group packing – SSCC, is applied on each tertiary (shipping) medicine packing. When aggregating medicine packages, the relevant information is recorded according to Section 9.1 of these Passports of Processes. As part of introduction of the medicines into circulation, the data are automatically transferred from Roszdravnadzor AIS to MDLP System after documents and data, which are stipulated in Part 1, Article 52^1 of the Federal Law "On Medicine Circulation", are transferred by a Russian manufacturer of the medicines to Roszdravnadzor or the permission is received as stipulated in Part 7 of Article 52^1 of the Federal Law "On Medicine Circulation" (for manufacturing of immunobiological medicines). In case of successful registration in the MDLP System of the data which have been received from Roszdravnadzor AIS, participants of interaction in the MDLP System are allowed to continue to carry out trading operations with the medicines

	(medicine circulation) and to continue to reflect the actions. In case of MDLP System refusal to introduce automatically medicines into circulation (if there are grounds for refusal), a Russian manufacturer of the medicines shall perform the required checks and amend the data which are contained in Roszdravnadzor AIS and (or) MDLP System, and shall send data on introduction of the medicines into circulation to the MDLP System without assistance. When registering with the MDLP System of information on the end of the stage of final packing and on further operations with the medicines, a Russian manufacturer of the medicine is entitled to use one identifier of the business place (which is registered for one of the list of the business place addresses in line with a license for medicine manufacturing) in the operations specified, in the event that the actual addresses of the operations are within the boundaries of one separate territory of the production site. In case withdrawal of medicine samples from circulation is required, the relevant information shall be registered according to section 5.5 of these Passports of Processes. If the medicine is introduced into circulation by its owner in case of contract production, the corresponding transactions are registered in MDLP System according to section 3.1.1 of these Passports of Processes. The information on medicine packing completion in secondary (consumer) packing shall be transferred by the Russian manufacturer of the medicines to MDLP System using the emission registrar Operations of registration of information about completion of final medicine packing and medicine introduction into circulation according to this section are available for the pharmaceutical entity that has a medicine manufacturing license. After registration of information about completion of final medicine packing in MDLP System, the emission type is assigned for SGTIN: “Emitted by owner” in case of in-house production or “Emitted within contract manufacturing” in case of contract manufacturing.
Interaction participants	– Russian manufacturer of the medicine
Description of the actions performed	

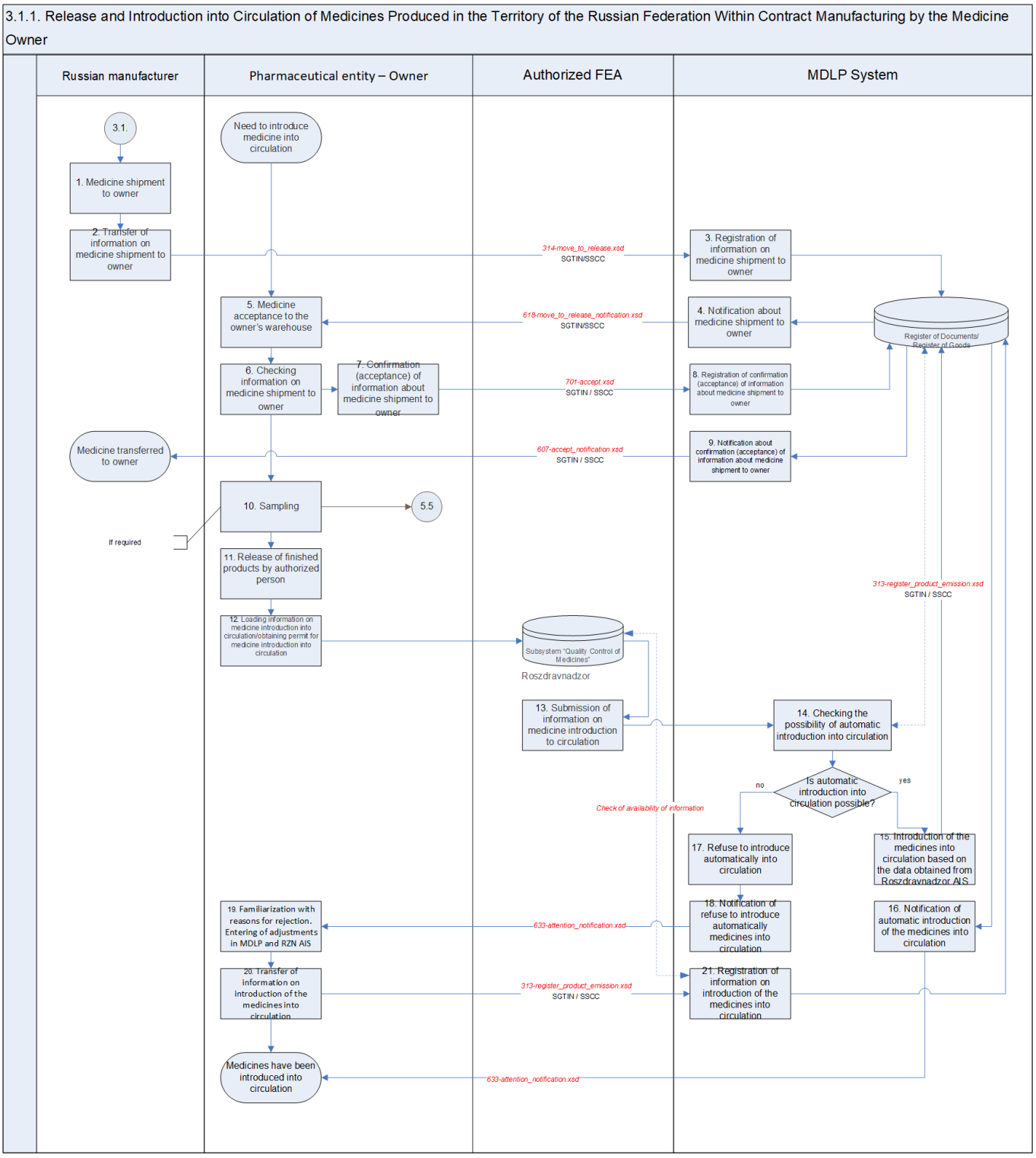
<table>
<tr><td colspan="2">1. Generation of individual serial numbers of secondary (consumer) medicine packing (in its absence – the primary packing of the medicine)</td></tr>
<tr><td colspan="2">2. Request for marking codes to the Operator of MDLP System using ER and according to the relevant API specification version of the Order Management Station as of the date of order available on the official website of MDLP System operator</td></tr>
<tr><td colspan="2">3. MDLP System operator shall provide a Russian manufacturer of the medicines with the marking codes</td></tr>
<tr><td colspan="2">4. Registration of marking codes emission information in MDLP System by means of scheme 10300-code_emission.xsd</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>When registering information on the emission of marking codes in MDLP System, the following information is recorded:
– emission date;
– registration number of the Russian manufacturer of medicine in MDLP System;
– identifier of order management station (OMS) provided by MDLP System Operator;
– OMS marking codes order identifier;
– GTIN;
– SGTIN list</td></tr>
<tr><td colspan="2">5. Medicine packing/prepacking in secondary (consumer) (in its absence – the primary packing of the medicine) and tertiary (shipping) packing</td></tr>
<tr><td colspan="2">6. – 7. Registration of information about completion of the final packing stage in MDLP System by means of scheme 10311-skzkm_register_end_packing.xsd</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>When registering the operations of final packing completion in MDLP System, the Russian manufacturer of the medicine sends the following information (for each unit of goods) using ER and according to the relevant API specification version of the Orders management station as of the date of data submission available on the official website of MDLP System operator:
– operation date;
– identifier of the Russian medicine manufacturer’s business place;</td></tr>
</table>

	– production order type (own production, contract production); – registration number of the medicine owner in MDLP System (in case of contract manufacturing); – production series number; – expiration date; – GTIN; – SGTIN; – information about the emission registrar used for registration of information (unique ER identifier, unique identifier of the system that generated the message, identifier of the report in marking codes status change)
8. Transfer of the information on final packing completion for further medicine introduction into civil circulation from MDLP System to Medicine Quality Control Subsystem of Roszdravnadzor AIS	
List of information to be transferred, and the owner of information resource	Through IEIS, MDLP System sends the information on final packing completion to the automated information system of Roszdravnadzor according to the information interaction format
9. Selection of control and archive samples	
10. Release of the finished products by the authorized person of the Russian manufacturer of the medicine	
11. Submitting the information necessary for introduction of medicine into circulation to the Subsystem “Quality Control of Medicines” of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation and obtaining the permit to introduce immunobiological medicines into circulation	
12. Transfer of the data, which have been provided by a Russian manufacturer of the medicines before introduction into civil circulation, or of the permission to introduce immunobiological medicines into civil circulation from the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS to the MDLP System	
13. Automated checking the possibility of automatic introduction of the medicines into circulation based on the data obtained from the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS	
14. Automatic introduction of the medicine into circulation and automatic	

<table>
<tr><td colspan="2">generation of scheme 313-register_product_emission.xsd (if there are no grounds for refusal)</td></tr>
<tr><td colspan="2">15. Notification (to a Russian manufacturer of the medicines) of automatic introduction of the medicine into circulation by means of scheme 633-attention_notification.xsd</td></tr>
<tr><td colspan="2">16. MDLP System refusal to introduce automatically medicines into circulation (if there are grounds for refusal)</td></tr>
<tr><td>A list of the grounds for refusal to register information</td><td>– lack in the MDLP System of GTIN and batch of the medicines introduced into circulation, that have been received from Roszdravnadzor AIS;
– SGTINs have a status which is different from the “Awaiting release” status;
– information on preparation of test samples/test specimens is not entered into the MDLP System;
– number of SGTINs that are introduced into circulation, exceeds number of medicine packages that are introduced into circulation, in line with the data from Roszdravnadzor AIS;
– SGTINs are not on the balance of the pharmaceutical entity, information about which has been received from Roszdravnadzor AIS;
– a business place where SGTINs are at the time of automatic introduction into circulation, has been blocked due to the absence of the valid license</td></tr>
<tr><td colspan="2">17. Notification (to a Russian manufacturer of the medicines) of refuse to introduce automatically medicine into circulation by means of scheme 633-attention_notification.xsd</td></tr>
<tr><td colspan="2">18. A Russian manufacturer of the medicines shall familiarize itself with the</td></tr>
</table>

reasons of refuse to introduce automatically medicines into circulation, check the data and introduce necessary amendments in the Subsystem "Quality Control of Medicines" of Roszdravnadzor AIS and (or) in the MDLP System	
19.– 20. Registration of information in MDLP System about medicine introduction into circulation by means of scheme 313-register_product_emission.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about operations of medicine introduction into circulation, the Russian medicine manufacturer sends the following information: – operation date; – business place identifier of the Russian medicine manufacturer that registers the information on completion of release quality control; – date of publication of information in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation; – number of permit by the Federal Service for Surveillance in Healthcare to introduce the medicine into civil circulation (for immunobiological medicines only); – internal identifier of the record on medicine introduction into civil circulation in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation); – SGTIN and/or SSCC
Special conditions	According to the Regulations of the Track and Trace System, marking codes are ordered, identification means are applied and data are submitted to MDLP System by the issuer of identification means, thus the business place identifier of a Russian medicine manufacturer specified for operation 10311 shall be registered in the User account of a pharmaceutical entity which has ordered the marking codes, and correspond to the Russian medicine manufacturer registration number in MDLP System specified for operation 10300. The number of medicine packages for which the information on introduction into circulation is registered shall not exceed the batch size for which the information is registered in Roszdravnadzor AIS.

3.1.1. Release and Introduction into Circulation of Medicines Produced in the Territory of the Russian Federation Within Contract Manufacturing by the Medicine Owner



Picture 8

Annotation	If the medicine is introduced into circulation by medicine owner, other than the Russian medicine manufacturer engaged in medicine packing (prepacking) in a secondary (consumer) packing, (in its absence – the primary packing of the medicine), medicine transfer to the medicine owner must be registered in MDLP System. Information on the medicine transfer to the owner is submitted to MDLP System by the Russian medicine manufacturer within 5 business days after the date of medicine transfer In this case the owner confirms the information registered by the Russian medicine manufacturer within 5 business days after the date of medicine acceptance and registration in MDLP System of the information about such transferred medicines In case withdrawal of medicine samples from circulation is required, the relevant information shall be registered according to section 5.5 of these Passports of Processes. Registration of further operations on medicine introduction into circulation is carried out by the medicine owner. As part of introduction of the medicines into circulation, data are automatically transferred from Roszdravnadzor AIS to MDLP System after documents and data, which are stipulated in Part 1, Article 52^1 of the Federal Law "On Medicine Circulation", are transferred by a medicine owner to Roszdravnadzor or the permission is received as stipulated in Part 7 of Article 52^1 of the Federal Law "On Medicine Circulation" (for manufacturing of immunobiological medicines). In case of successful registration in the MDLP System of the data which have been received from Roszdravnadzor AIS, participants of interaction in the MDLP System are allowed to continue to carry out trading operations with the medicines (medicine circulation) and to continue to reflect the actions. In case of MDLP System refusal to introduce automatically medicines into circulation (if there are grounds for refusal), a medicine owner shall perform the required checks and amend the data which are contained in Roszdravnadzor AIS and (or) MDLP System, and shall send the data on introduction of the medicines into circulation to the MDLP System without assistance. If necessary, the owner of the medicine can return the medicines shipped by the contract manufacturer. Information about the medicine return by owner to the manufacturer, which was in

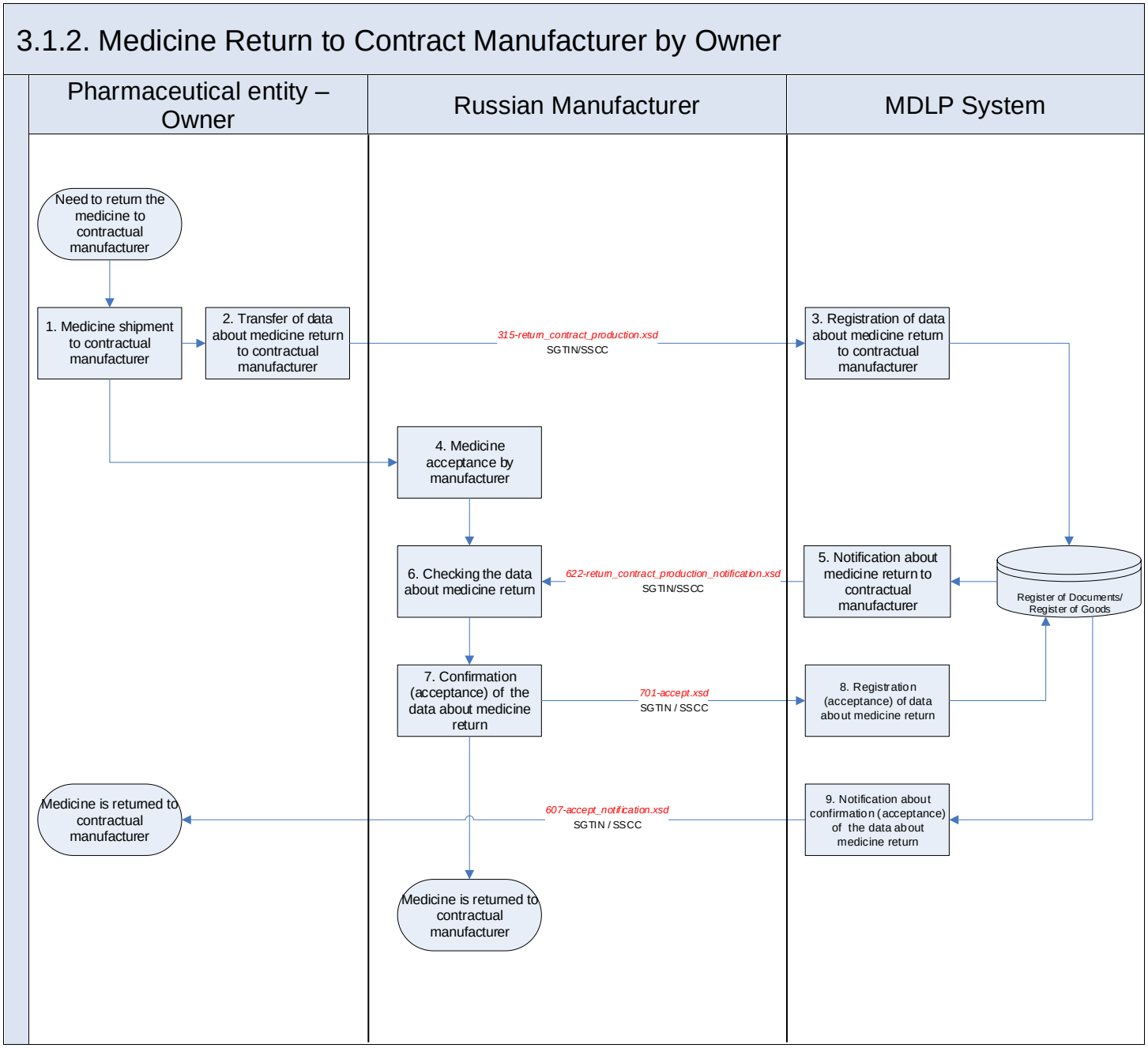
	charge of the production stage of medicine packing (prepacking) in consumer packing, shall be registered in MDLP System in accordance with section 3.1.2 of these Passports of Processes. Operations of information registration about medicine introduction into circulation according to this section are available for the pharmaceutical entity that has a medicine manufacturing license
Interaction participants	– Russian manufacturer of the medicine – medicine owner
Description of the actions performed	
1. Medicine shipment to the medicine owner	
2. – 3. Registration of information in MDLP System about the medicine shipment for release of finished products by means of scheme 314-move_to_release.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about the medicine shipment for release of finished products, the Russian medicine manufacturer sends the following information: – operation date; – identifier of the Russian medicine manufacturer's business place where the medicine is shipped from; – identifier of the medicine owner's business place where the medicine is accepted; – date of confirming primary document; – number of confirming primary document; – SGTIN and/or SSCC
4. Notice to the owner about the medicine shipment for release of finished products by means of scheme 618-move_to_release_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the medicine owner about the medicine shipment for release of finished products is formed on the basis of the operation, which was earlier registered by the Russian medicine manufacturer, and contains the following data: – operation date; – identifier of the Russian medicine manufacturer's business place where the medicine is shipped from; – identifier of the medicine owner's business place where the

	medicine is accepted; – date of confirming primary document; – number of confirming primary document; – SGTIN and/or SSCC
5. Medicine acceptance by the owner	
6. Checking by the medicine owner of the information previously registered by the Russian manufacturer about the medicine shipment to the owner	
7. – 8.Confirmation (acceptance) by the medicine owner of the information about medicine shipment for release of finished products by means of scheme 701-accept.xsd	
List of information to be transferred	For confirmation (acceptance) of the information, previously registered by the Russian medicine manufacturer, about medicine shipment for release of finished products, the medicine owner ensures that the following data is sent to MDLP System: – identifier of the medicine owner's business place where the medicine is accepted; – identifier of the Russian medicine manufacturer's business place where the medicine is shipped from; – operation date; – SGTIN and/or SSCC
9. Notice to the Russian medicine manufacturer about confirmation (acceptance) of medicine shipment information by the medicine owner by means of scheme 607-accept_notification.xsd	
List of information to be transferred	The notice to the Russian medicine manufacturer about confirmation (acceptance) of medicine shipment information by the medicine owner is formed on the basis of the previously registered operation and contains the following information: – identifier of the medicine owner's business place where the medicine is accepted; – identifier of the Russian medicine manufacturer's business place where the medicine is shipped from; – operation date; – SGTIN and/or SSCC
10. Selection of samples (if required)	

11. Release of the finished products by the authorized person of medicine owner	
12. Provision of the information necessary for introduction of medicine into circulation to the Subsystem “Quality Control of Medicines” of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation and obtaining the permit to introduce immunobiological medicines into circulation	
13. Transfer of the data, which have been transferred by a medicine owner before introduction into civil circulation, or of the permission to introduce immunobiological medicines into civil circulation from the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS to the MDLP System	
14. Automated checking the possibility of automatic introduction of the medicines into circulation based on the data obtained from the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS	
15. Automatic introduction of the medicine into circulation and automatic generation of scheme 313-register_product_emission.xsd (if there are no grounds for refusal)	
16. Notification (to a medicine owner) of automatic introduction of the medicine into circulation by means of scheme 633-attention_notification.xsd	
17. MDLP System refusal to introduce automatically medicines into circulation (if there are grounds for refusal)	
A list of the grounds for refusal to register information	– lack in the MDLP System of GTIN and batch of the medicines introduced into circulation, that have been received from Roszdravnadzor AIS; – SGTINs have a status that is different from the “Awaiting introduction into circulation by owner” status; – information on preparation of test samples/test specimens is not entered into the MDLP System; – number of SGTINs that are introduced into circulation, exceeds number of medicine packages that are introduced into circulation, in line with the data from Roszdravnadzor AIS; – SGTINs are not on the balance of the pharmaceutical entity, information about which has been received from

	Roszdravnadzor AIS; – a business place where SGTINs are at the time of automatic introduction into circulation, has been blocked due to the absence of the valid license
18. Notification (to a medicine owner) of refuse to introduce automatically medicine into circulation by means of scheme 633-attention_notification.xsd	
19. The medicine owner shall familiarize itself with the reasons of refuse to introduce automatically medicines into circulation, check the data and introduce necessary amendments in the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS and (or) in the MDLP System	
20. – 21. Registration of information in MDLP System about medicine introduction into circulation by means of scheme 313-register_product_emission.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about operations of medicine introduction into circulation, the medicine owner sends the following information: – operation date; – business place identifier of the medicine owner that registers the information on completion of release quality control; – date of publication of information in the Subsystem “Quality Control of Medicines” of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation; – number of decision made by the Federal Service for Surveillance in Healthcare to introduce the medicine into civil circulation (for immunobiological medicines only); – internal identifier of the record on medicine introduction into civil circulation in the Subsystem “Quality Control of Medicines” of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation; – SGTIN and/or SSCC
Special conditions	The number of medicine packages for which the information on introduction into circulation is registered shall not exceed the batch size for which the information is registered in Roszdravnadzor AIS

3.1.2. Return of Medicines Produced in the Territory of the Russian Federation within Contract Manufacturing, by the Medicine Owner to the Contract Manufacturer



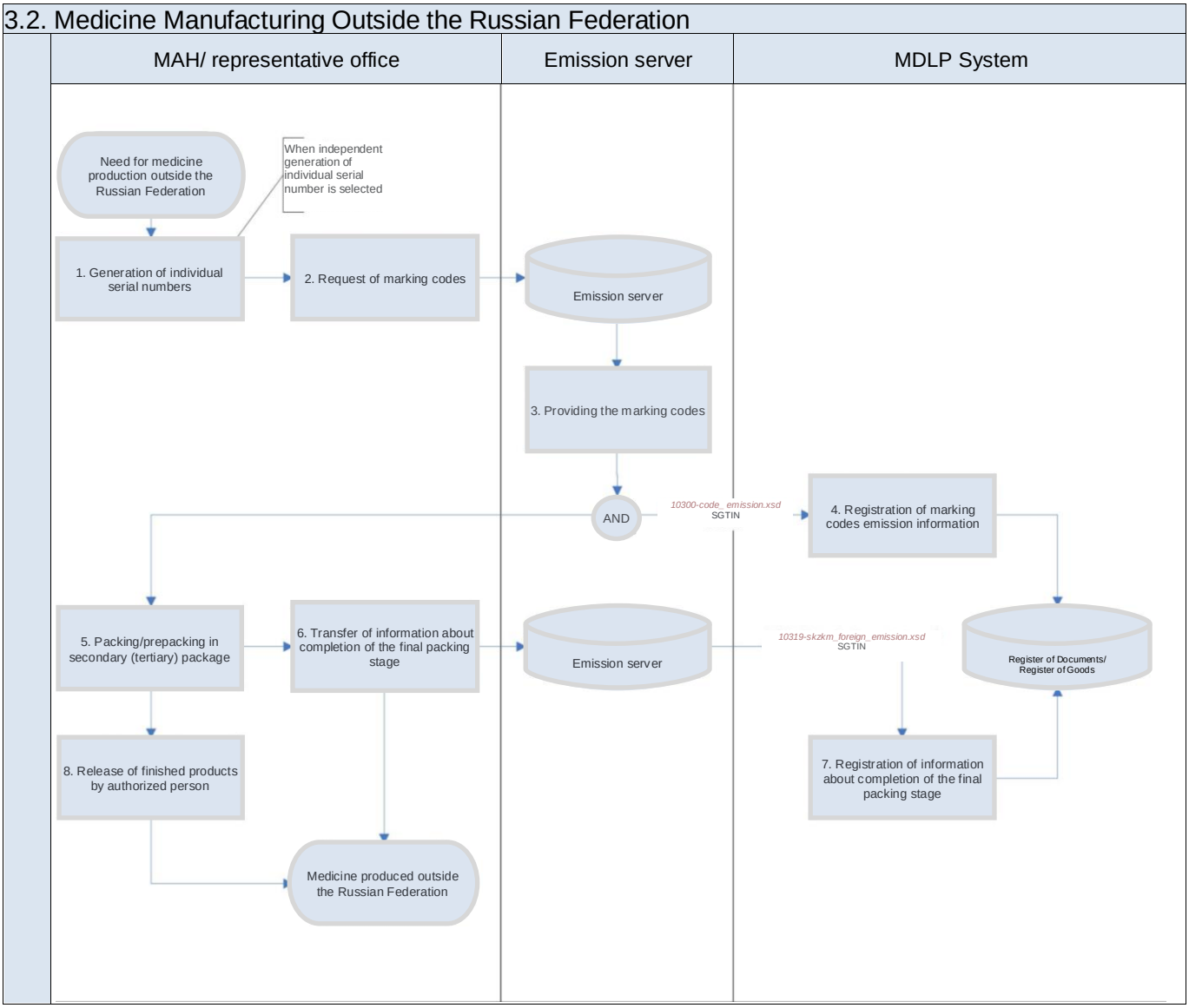
Picture 9

Annotation	If necessary, the owner of the medicine can return the medicines shipped by the contract manufacturer. The information shall be registered in MDLP System by the medicine owner to which the medicines produced within contract manufacturing have been previously transferred Information on the medicine return to the contract manufacturer is submitted to MDLP System by the medicine owner within 5 business days after the date of medicine shipment. In this case the Russian manufacturer of the medicines confirms the information registered by the owner within 5 business days after the date of medicine acceptance and registration in MDLP System of the information about the medicine return
Interaction participant	– pharmaceutical entity that is the owner of the medicine; – contract manufacturer (a Russian manufacturer of the medicines)
Description of the actions performed	
1. Medicine shipment to the contract manufacturer within the return procedure	
2. – 3. Registration of the information about the medicine return to the contract manufacturer in MDLP System by means of scheme 315-return_contract_production.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the operation of medicine return to the contract manufacturer, the pharmaceutical entity, which returns the medicine, shall send the following information: – operation date; – identifier of the business place of the medicine owner returning the medicine; – identifier of the Russian medicine manufacturer's business place; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
4. Medicine acceptance by the contract manufacturer	

5. Notification of the contract manufacturer about the medicine return by the owner by means of scheme 622-return_contract_production_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the contract manufacturer about registration of medicine return data is formed on the basis of the operation, previously registered by the pharmaceutical entity that performs the return, and contains the following information: – operation date; – identifier of the business place of the owner returning the medicine; – identifier of the Russian medicine manufacturer's business place; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
6. Checking by the contract manufacturer of the previously registered information about the medicine return by the owner	
7. – 8. Registration of confirmation (acceptance) of the information about the medicine return by the contract manufacturer by means of scheme 701-accept.xsd	
List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information about the medicine return by the owner, the contract manufacturer sends the following information to MDLP System: – operation date; – identifier of the Russian medicine manufacturer's business place; – identifier of the business place of the owner returning the medicine; – SGTIN and/or SSCC
9. Notification of the owner returning the medicine about confirmation (acceptance) of the medicine return information by the contract manufacturer by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the owner returning the medicine about confirmation (acceptance) by the contract manufacturer of the information about the medicine return is formed on the basis of the operation previously registered by the contract manufacturer and contains the following information:

	– operation date; – identifier of the Russian medicine manufacturer's business place; – identifier of the business place of the owner returning the medicine; – SGTIN and/or SSCC
Special conditions	It is allowed to return the medicine to the Russian pharmaceutical manufacturer's business place, which is different from the one used to ship the medicine

3.2. Medicine Manufacturing Outside the Russian Federation



Picture 10

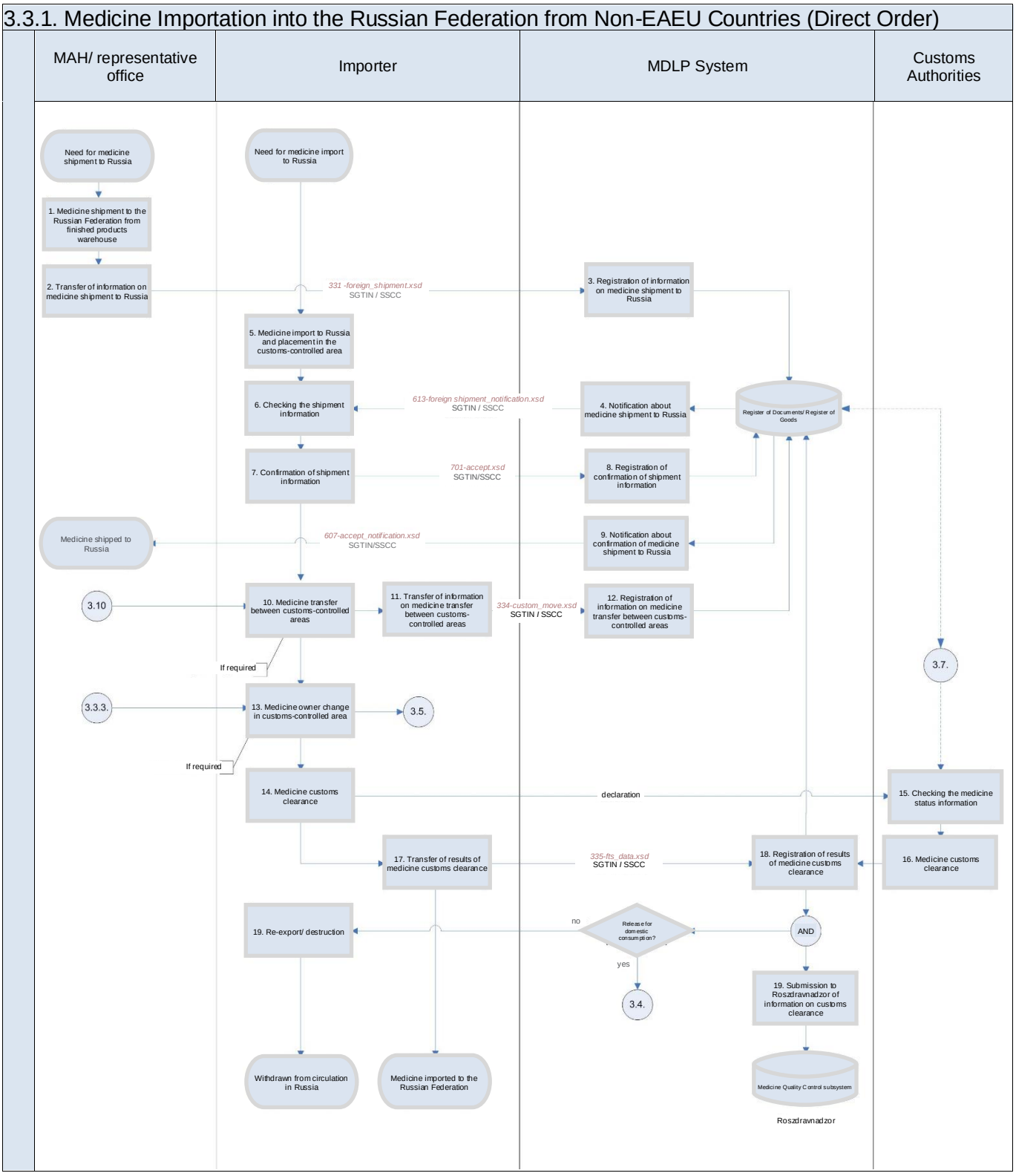
Annotation	Individual serial numbers for coding of secondary (consumer) packing of medicine (in its absence – the primary packing of the medicine) can be generated by MAH or by MDLP System Operator by request. As a result, a unique combination of GTIN and individual serial number of secondary (consumer) medicine packing (in its absence – the primary packing of the medicine) is called SGTIN and determines the unique identification code of secondary (consumer) medicine packing for traceability in MDLP System. DataMatrix is applied on each secondary (consumer) medicine package (in its absence – the primary packing of the medicine), containing the following fields: – SGTIN (mandatory); – verification code (provided by Operator of MDLP System Verification codes can be obtained by MAH (or representative office of foreign MAH) from the MDLP System Operator using emission registrar. Emission registrar is provided by transferring it to MAH (or representative office of foreign MAH), or by providing remote access to it via the information system of MAH (or representative office of foreign MAH). The decision on the choice of equipment is made by MAH independently. The information on completion of the final medicine packing stage outside the Russian Federation can be registered in MDLP System by MAH (or its representative office) using emission registrar. Each tertiary (shipping) package of medicines is marked with identification means in the form of linear bar code Code128 containing individual serial number of group packing – SSCC. When aggregating medicine packages, the relevant information is recorded according to Section 9.1 of these Passports of Processes. If it is required to register information on medicine withdrawal from circulation for various reasons, the MAH (or its representative office) can register the corresponding operation in accordance with section 5.5. of these Passports of Processes. After registration of the above information in MDLP System, “Emitted by foreign manufacturer” emission type is assigned to SGTIN.
Interaction participants	– MAH (or representative office of foreign MAH)

<table>
<tr><td colspan="2">Description of the actions performed</td></tr>
<tr><td colspan="2">1. Generation of individual serial numbers of secondary (consumer) medicine packing (in its absence – the primary packing of the medicine)</td></tr>
<tr><td colspan="2">2. Request for marking codes from the Operator of MDLP System using ER and according to the relevant API specification version of the Orders management station as of the date of order available on the official website of MDLP System operator</td></tr>
<tr><td colspan="2">3. Provision of marking codes to the pharmaceutical entity by the Operator of MDLP System</td></tr>
<tr><td colspan="2">4. Registration of marking codes emission information in MDLP System by means of scheme 10300-code_emission.xsd</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>When registering information on the emission of marking codes in MDLP System, the following information is recorded:
– emission date;
– registration number of the MAH (or its representative office) in MDLP System;
– identifier of order management station (OMS) provided by MDLP System Operator;
– OMS marking codes order identifier;
– GTIN;
– SGTIN list</td></tr>
<tr><td colspan="2">5. Medicine packing/prepacking in secondary (consumer) (in its absence – the primary packing) and tertiary (shipping) packing</td></tr>
<tr><td colspan="2">6. – 7. Registration of information about the completion of the final medicine packing stage outside the Russian Federation in MDLP System by means of scheme 10319-skzkm_foreign_emission.xsd</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>When registering in MDLP System the operations of completion of the final medicine packing stage outside the Russian Federation, the MAH (or its representative office) sends the following information using ER and according to the relevant API specification version of the Orders management station as of the date of data submission available on the official website of MDLP System operator:
– operation date;</td></tr>
</table>

	– registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—foreign medicine manufacturer that packs/prepacks the medicine in secondary (tertiary) packing; – identifier of foreign counterparty—foreign medicine manufacturer that performs release quality control (if any); – GTIN; – production series number; – expiration date; – SGTIN; – information about the emission registrar used for registration of information (unique identifier of emission registrar, unique identifier of the system which formed the message, identifier of marking code status change report)
8. Confirmation of compliance of finished products with the established requirements and series release by the manufacturer's authorized person	
Special conditions	According to the Regulations of the Track and Trace System, marking codes are ordered, identification means are applied and data are submitted to MDLP System by the issuer of identification means, thus the Marketing Authorization Holder (or its representative office) registration number in MDLP System specified for operation 10319 shall correspond to the Marketing Authorization Holder (or its representative office) registration number in MDLP System specified for operation 10300

3.3. Import of marked medicine to the Russian Federation and customs clearance

3.3.1. Medicine Importation into the Russian Federation from Non-EAEU Countries (Direct Order)



Picture 11

Annotation	Registration in MDLP System of the information about medicine importation into the Russian Federation suggests the possibility of using direct or reverse data transfer order. If the direct data transfer and confirmation order is selected, the MAH (or its representative office) registers information about medicine shipment to the Russian Federation, and the Importer confirms the information registered by the MAH (or its representative office). Information about medicine shipping to the Russian Federation is submitted to MDLP System by the Marketing Authorization Holder (or its representative office) within 45 business days from the date of the medicine shipping to the Russian Federation before the medicine delivery to its destination in the Russian Federation In this case the importer confirms the information registered by the Marketing Authorization Holder (or its representative office) within 5 business days from the date of the medicine delivery to its destination in the Russian Federation and registration in MDLP System of the information about the medicine shipping to the Russian Federation. If the Importer is not determined at the time of medicine shipment to the Russian Federation (when importing under a consignment contract), the MAH (or its representative office) instead of actions 1–9 of this section, shall register the information in accordance with section 3.3.3. of these Passports of Processes. If necessary, the medicine can be transferred between different customs-controlled areas after the goods arrive to the delivery destination, which is defined by the importer in the international goods transport documents, and/or if internal customs transit is arranged from the places of entry to the Russian Federation. The relevant information shall be transferred by the Importer to MDLP System within 5 business days from the date of such transfer. If medicines are placed under the customs procedure of a customs warehouse, transactions may be made that provide for the transfer of ownership, use and (or) disposal of these medicines. When transferring the medicine property right, the pharmaceutical entity shall register the operations in MDLP System according to section 3.5 of these Passports of Processes. Registration of information regarding future operations with the transferred medicines in MDLP System should be carried out by

	the new owner. To check the possibility of the medicine release for domestic use, the Federal Customs Service of Russia sends to MDLP System a request for obtaining the information about the imported medicines according to Section 3.7 of these Passports of Processes. If the customs authorities decide to release the medicine for domestic consumption, the pharmaceutical entity that imports the medicine to the Russian Federation shall register the relevant information in MDLP System. Information about the medicine customs clearance result is submitted to MDLP System by the importer within 5 business days from the date of decision on the medicine release for domestic use made by the customs authorities. The customs cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine acceptance in tertiary (shipping) packages.
Interaction participants	– MAH, or representative office of foreign MAH; – importer; – FCS of Russia
Description of the actions performed	
1. Medicine shipment to the Russian Federation from the finished products warehouse	
2. – 3. Registration of information about medicine shipment to the Russian Federation in MDLP System by means of scheme 331-foreign_shipment.xsd	
List of information to be transferred, and the owner of information resource	When registering the information about medicine shipment to the Russian Federation, the MAH (or its representative office) sends the following information: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – registration number of the importer in MDLP System; – identifier of the goods location in the customs-controlled area (according to the goods declaration);

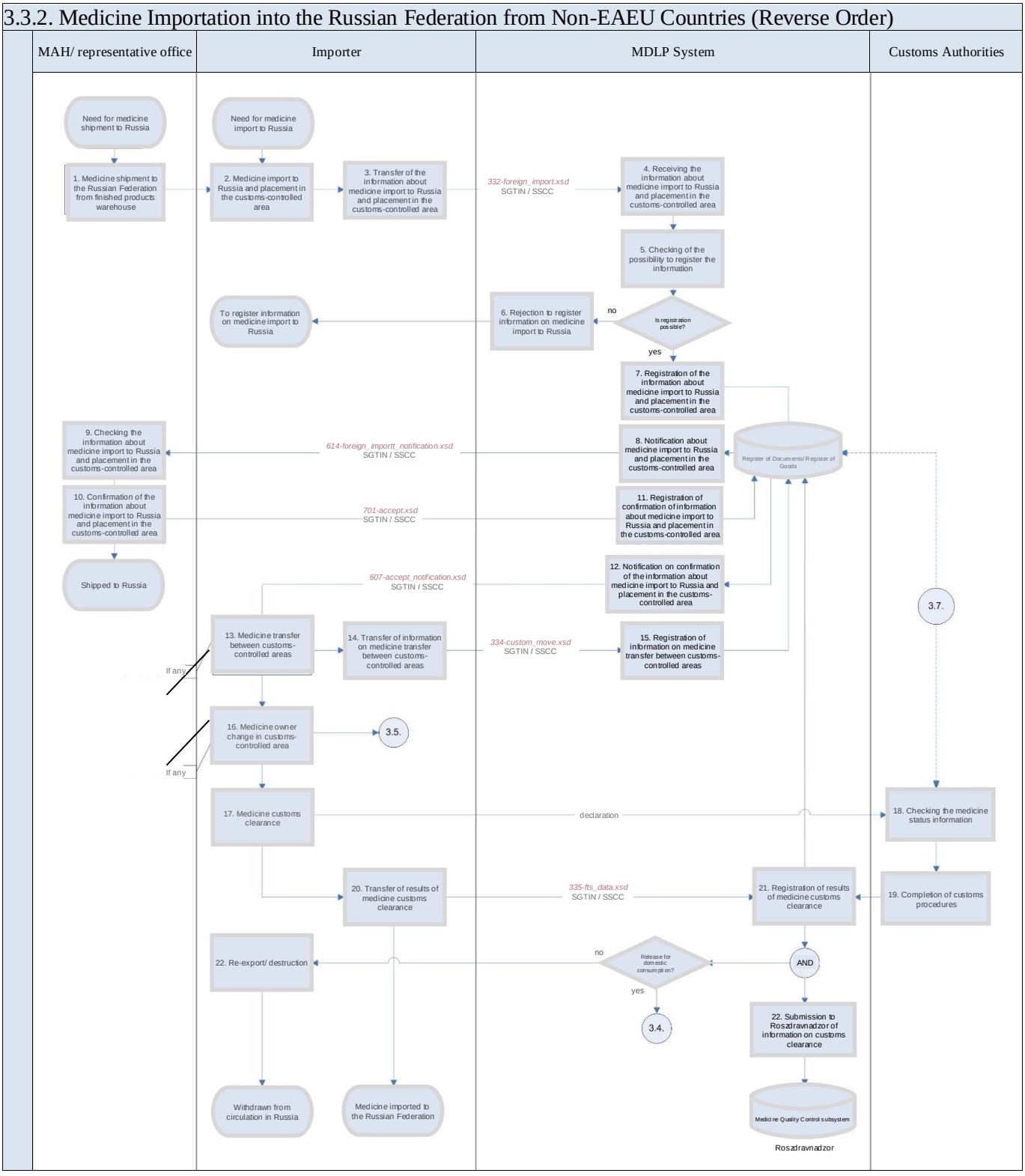
	– contract type; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
4. Notice to the importer about medicine shipment to the Russian Federation by means of scheme 613-foreign_shipment_notification.xsd	
List of information to be transferred, and the owner of information resource	The notice to the importer about medicine shipment to the Russian Federation is formed on the basis of the operation, which was previously registered by the MAH (or its representative office), and contains the following data: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – registration number of the importer in MDLP System; – identifier of the goods location in the customs-controlled area (according to the goods declaration); – contract type; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
5. Medicine importation into the Russian Federation and placement in the customs-controlled area	
6. Checking by importer of the information, previously registered by the MAH (or its representative office), about medicine shipment to the Russian Federation	
7. – 8. Confirmation (acceptance) by the importer of information about medicine shipment to the Russian Federation by means of scheme 701-accept.xsd	
List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information about medicine shipment to the Russian Federation, the importer sends the following data to MDLP System: – registration number of the importer in MDLP System; – registration number of the MAH (or its representative office) in MDLP System;

	– operation date; – SGTIN and/or SSCC
9. Notice to MAH (or its representative office) about confirmation (acceptance) by the importer of the information about medicine shipment to the Russian Federation by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	The notice to the MAH (or its representative office) about confirmation (acceptance) by the importer of the information on medicine shipment to the Russian Federation is formed on the basis of the operation previously registered by the importer, and contains the following information: – registration number of the importer in MDLP System; – registration number of the MAH (or its representative office) in MDLP System; – operation date; – SGTIN and/or SSCC
10.Medicine transfer between the customs-controlled areas (if required)	
11.– 12. Registration of information about medicine transfer between the customs-controlled areas in MDLP System (if required) by means of scheme 334-custom_move.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about medicine transfer between the customs-controlled areas, the pharmaceutical entity sends the following information: – operation date; – registration number of the pharmaceutical entity in MDLP System; – identifier of the goods location in the customs-controlled area (from where it is transferred); – identifier of the goods location in the customs-controlled area (where it is transferred to); – date of the transfer supporting document; – number of the transfer supporting document; – SGTIN and/or SSCC
13.Transfer of ownership right for the medicines placed in customs warehouse (if required)	

<table>
<tr><td colspan="2">14. Medicine customs clearance (filing of the declaration for goods to the customs authorities)</td></tr>
<tr><td colspan="2">15. Checking of the imported medicine information by the FCS of Russia</td></tr>
<tr><td colspan="2">16. Registration of the declaration for goods and decision-making by the customs authorities (refusal to declare the goods if there are any reasons)</td></tr>
<tr><td colspan="2">17.– 18. Registration of information about the results of medicine customs clearance in MDLP System by means of scheme 335-fts_data.xsd</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>If there is no reason to refuse to register the declaration for goods, the importer sends the following information to MDLP System:
– operation date;
– registration number of the importer in MDLP System;
– customs procedure code (release for domestic consumption, destruction, re-export, customs transit);
– customs authority code;
– date and time of the decision made;
– number of the declaration for goods;
– customs cost of the goods according to the goods declaration;
– SGTIN and/or SSCC.
If it is required to indicate different customs cost inside of a group packing, the importer shall send the following additional data for SSCC:
– GTIN;
– production series number;
– customs cost of the medicine (for the indicated GTIN and series number).</td></tr>
<tr><td colspan="2">19. Transfer of the information about the customs clearance for further medicine introduction into civil circulation from MDLP System to Medicine Quality Control Subsystem of Roszdravnadzor AIS</td></tr>
<tr><td>List of information to be transferred, and the owner of information</td><td>Through IEIS, MDLP System sends the information about the customs clearance to the automated information system of Roszdravnadzor according to the information interaction format</td></tr>
</table>

resource	
20.Re-export, customs transit or destruction (if the customs procedure specified is other than release for internal use) when transferring information on the customs clearance results	
Special conditions	Prior to submission of the declaration for goods, it is necessary to ensure that SGTIN or SSCC are registered in MDLP System and have correct status, i.e. all required information is submitted to MDLP System (see Section 3.7 of these Passports of Processes). It shall be considered that the date and time of the information submission to MDLP System are deemed to be the date and time recorded in the receipt generated upon their registration in MDLP System. When declaring the goods, the pharmaceutical entity specifies the marking level code designation and the list of SGTIN or SSCC in the declaration for goods. When importing a medicine in tertiary (shipping) package, a higher level SSCC (level code=2) shall be submitted. If no aggregation is made, SGTIN shall be specified (level code=0). As required, on request to the MDLP System technical support service, an option may be given for the importer to register the logical operation of return upon the medicine import to the Russian Federation (337-return_import.xsd) in order to return the medicine to the balance sheet of the Marketing Authorization Holder to ensure the possibility of further sending the correct information about the medicine shipping to the Russian Federation. The operation is registered after an incorrect acceptance by the importer of the information about the medicine shipping to the Russian Federation and shall be confirmed by the Marketing Authorization Holder

3.3.2. Medicine Importation into the Russian Federation from Non-EAEU Countries (Reverse Order)



Picture 12

Annotation	Registration in MDLP System of the information about medicine importation into the Russian Federation suggests the possibility of using direct or reverse data transfer order. If the reverse data transfer and confirmation order is selected, the importer registers information about the medicine importation into the Russian Federation and placement in the customs-controlled area, while the MAH (or its representative office) confirms the information registered by the importer. The reverse data confirmation order requires registration of a list of trusted counterparties—importers in the user account of MAH (or its representative office). Information about the medicine import to the Russian Federation is submitted to MDLP System by the importer within 5 business days from the date of the medicine delivery to the destination in the Russian Federation or the date of aggregation completion (if the medicines are aggregated after their delivery to the destination in the Russian Federation). In this case the Marketing Authorization Holder (or its representative office) confirms the information registered by the importer within 5 business days from the date of registration in MDLP System of the information about the medicine import to the Russian Federation. If necessary, the medicine can be transferred between different customs-controlled areas after the goods arrive to the delivery destination, which is defined by the importer in the international goods transport documents, and/or if internal customs transit is arranged from the places of entry to the Russian Federation. The relevant information shall be transferred by the Importer to MDLP System within 5 business days from such transfer. If medicines are placed under the customs procedure of a customs warehouse, transactions may be made that provide for the transfer of ownership, use and (or) disposal of these medicines. When transferring the medicine property right, the pharmaceutical entity shall register this operation in MDLP System according to section 3.5 of these Passports of Processes. Registration of information regarding future operations with the transferred medicines in MDLP System should be carried out by the new owner. For the purpose of checking the possibility of medicine release for internal consumption, the FCS of Russia may send a request to MDLP System to obtain information on the status of the imported medicine according to section 3.7. of these Passports

	of Processes. If the customs authorities decide to release the medicine for domestic consumption, the pharmaceutical entity that imports the medicine to the Russian Federation shall register the relevant information in MDLP System. Information about the medicine customs clearance result is submitted to MDLP System by the importer within 5 business days from the date of decision on the medicine release for domestic use made by the customs authorities. The customs cost of the medicine shall always be given in the registered operation per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine acceptance in tertiary (shipping) packages.
Interaction participants	– MAH, or representative office of foreign MAH; – importer; – FCS of Russia
Description of the actions performed	
1. Medicine shipment to the Russian Federation from the finished products warehouse	
2. Medicine importation into the Russian Federation	
3. – 4. Submission of information to MDLP System about medicine importation into the Russian Federation by means of scheme 332-foreign_import.xsd	
List of information to be transferred, and the owner of information resource	When registering the information about medicine import to the Russian Federation, the importer sends the following information: – operation date; – registration number of the importer in MDLP System; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – identifier of the goods location in the customs-controlled area (according to the goods declaration); – contract type; – date of the primary document;

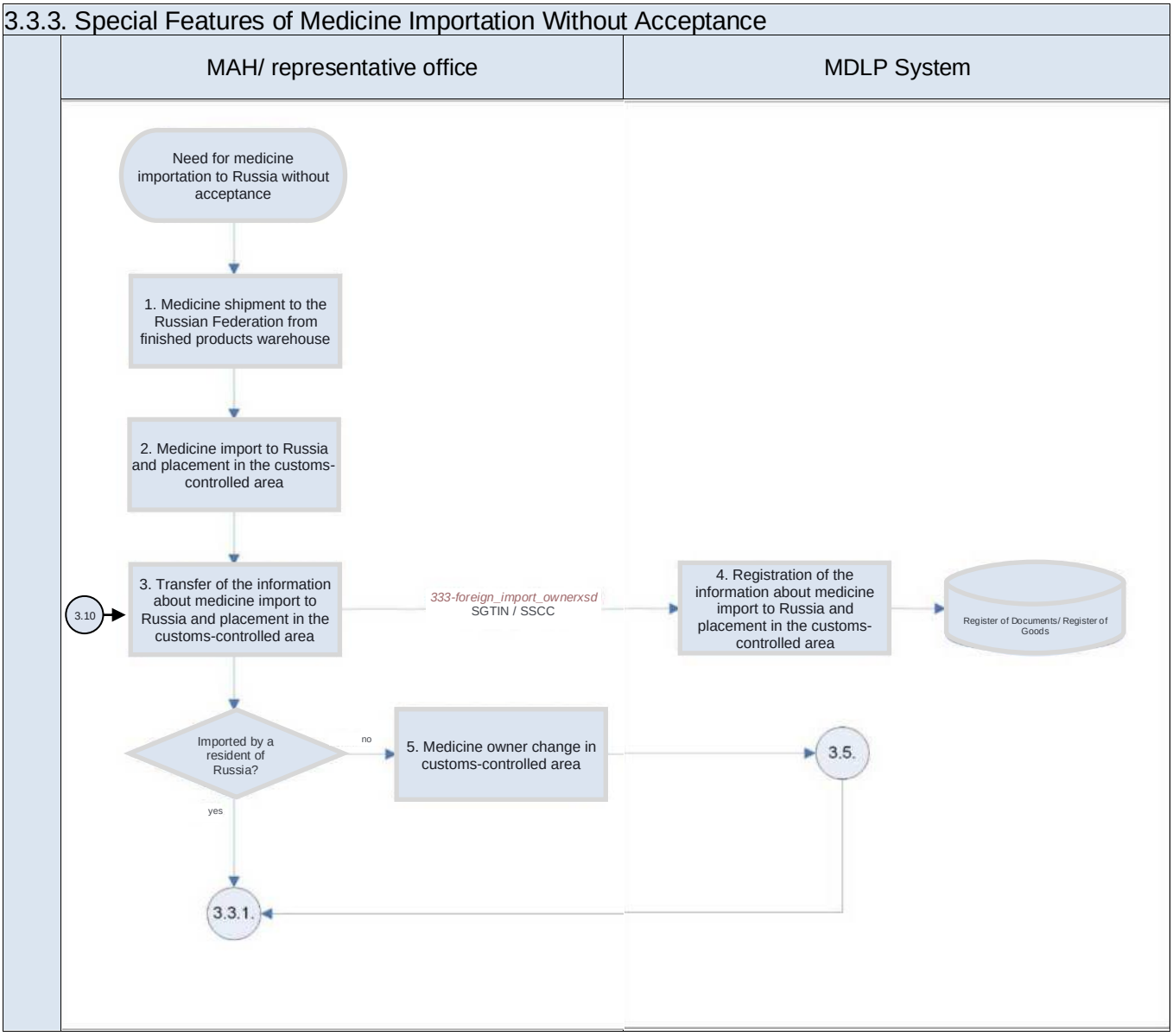
	– number of the primary document; – SGTIN and/or SSCC
5. Checking of the possibility to register the information about medicine importation into the Russian Federation (availability of the pharmaceutical entities on the list of trusted counterparties)	
6. Rejection of registration of the data about medicine import into the Russian Federation if the importer is not on the list of trusted counterparties of MAH (or its representative office)	
7. Registration of information about medicine importation into the Russian Federation in MDLP System (if there are no reasons to reject)	
8. Notice to MAH (or its representative office) about medicine importation to the Russian Federation by means of scheme 614-foreign_import_notification.xsd	
List of information to be transferred, and the owner of information resource	The notice to the MAH (or its representative office) about medicine import to the Russian Federation is formed on the basis of the operation previously registered by the importer, and contains the following information: – operation date; – registration number of the importer in MDLP System; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – identifier of the goods location in the customs-controlled area (according to the goods declaration); – contract type; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
9. Checking by MAH (or its representative office) of the information, previously registered by the importer, about medicine import to the Russian Federation	
10.– 11. Confirmation (acceptance) by the MAH (or its representative office) of the information about medicine importation into the Russian Federation by means of scheme 701-accept.xsd	
List of information	For confirmation (acceptance) of the information, registered by

to be transferred, and the owner of information resource	the importer, about medicine import to the Russian Federation, the MAH (or its representative office) sends the following data to MDLP System: – registration number of the MAH (or its representative office) in MDLP System; – registration number of the importer in MDLP System; – operation date; – SGTIN and/or SSCC
12.Notice to the importer about confirmation (acceptance) by the MAH (or its representative office) of the information about medicine importation into the Russian Federation by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	The notice to the importer about confirmation (acceptance) by MAH (or its representative office) of information about medicine import to the Russian Federation is formed on the basis of the operation previously registered by the by MAH (or its representative office), and contains the following information: – registration number of the MAH (or its representative office) in MDLP System; – registration number of the importer in MDLP System; – operation date; – SGTIN and/or SSCC
13.Medicine transfer between the customs-controlled areas (if required)	
14.– 15. Registration of information about medicine transfer between the customs-controlled areas in MDLP System (if required) by means of scheme 334-custom_move.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about medicine transfer between the customs-controlled areas, the pharmaceutical entity sends the following information: – operation date; – registration number of the pharmaceutical entity in MDLP System; – identifier of the goods location in the customs-controlled area (from where it is transferred); – identifier of the goods location in the customs-controlled area (where it is transferred to);

	– date of the transfer supporting document; – number of the transfer supporting document; – SGTIN and/or SSCC
16.Transfer of ownership right for the medicines placed in customs warehouse (if required)	
17.Medicine customs clearance (filing of the declaration for goods to the customs authorities)	
18.Checking of the imported medicine status information by the FCS of Russia	
19.Registration of the declaration for goods and decision-making by the customs authorities (refusal to declare the goods if there are any reasons)	
20.– 21. Registration of information about the results of medicine customs clearance in MDLP System by means of scheme 335-fts_data.xsd	
List of information to be transferred, and the owner of information resource	If there is no reason to refuse to register the declaration for goods, the importer sends the following information to MDLP System: – operation date; – registration number of the importer in MDLP System; – customs procedure code (release for domestic consumption, destruction, re-export, customs transit); – customs authority code; – date and time of the decision made; – number of the declaration for goods; – customs cost of the medicine according to the goods declaration; – SGTIN and/or SSCC. If it is required to indicate different customs cost inside of a group packing, the importer shall send the following additional data for SSCC: – GTIN; – production series number; – customs cost of the medicine (for the indicated GTIN and series number).
22.Transfer of the information about the customs clearance for further medicine	

introduction into civil circulation from MDLP System to Medicine Quality Control Subsystem of Roszdravnadzor AIS	
List of information to be transferred, and the owner of information resource	Through IEIS, MDLP System sends the information about the customs clearance to the automated information system of Roszdravnadzor according to the information interaction format
22. Re-export, customs transit or destruction (if the customs procedure specified is other than release for domestic consumption) when transferring information on the customs clearance results	
Special conditions	Prior to submission of the declaration for goods, it is necessary to ensure that SGTIN or SSCC are registered in MDLP System and have correct status, i.e. all required information is submitted to MDLP System (see Section 3.7 of these Passports of Processes). It shall be considered that the date and time of the information submission to MDLP System are deemed to be the date and time recorded in the receipt generated upon their registration in MDLP System. When declaring the goods, the pharmaceutical entity specifies the marking level code designation and the list of SGTIN or SSCC in the declaration for goods. When importing a medicine in tertiary (shipping) package, a higher level SSCC (level code=2) shall be submitted. If no aggregation is made, SGTIN shall be specified (level code=0). As required, on request to the MDLP System technical support service, an option may be given for the importer to register in MDLP System the logical operation of return upon the medicine import to the Russian Federation (337-return_import.xsd) in order to return the medicine to the balance sheet of the Marketing Authorization Holder to ensure the possibility of further sending the correct information about the medicine import to the Russian Federation. The operation is registered after an incorrect acceptance by the Marketing Authorization Holder of the information about the medicine import to the Russian Federation and shall be confirmed by the Marketing Authorization Holder

3.3.3. Special Features of Medicine Importation Without Acceptance (Without Importer) by One Owner

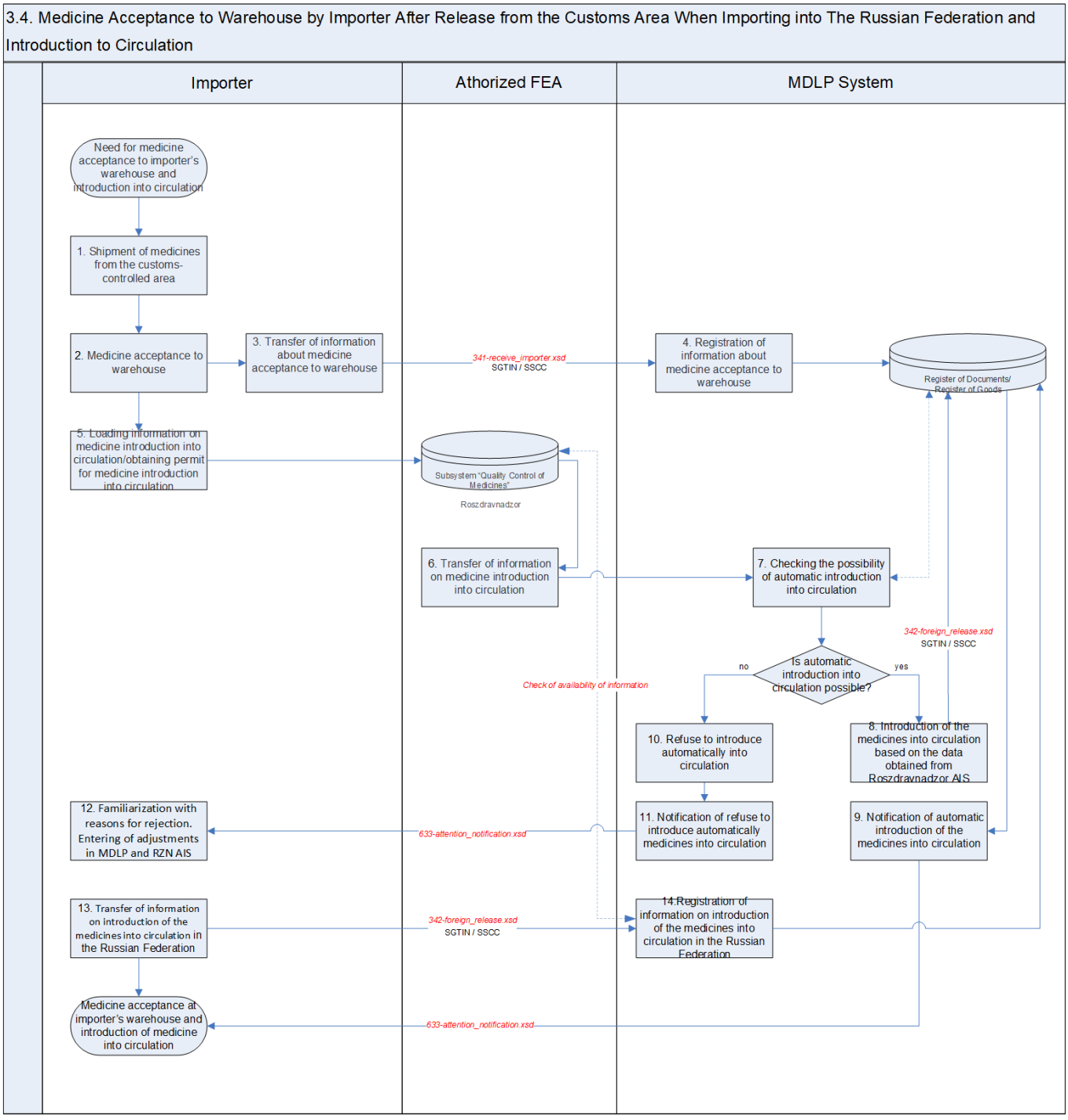


Picture 13

Annotation	MAH (or its representative office), instead of actions 1–9 of section 3.3.1. of these Passports of Processes, registers the information according to this section if: – importer is not specified at the moment of medicine shipment to the Russian Federation (when transported according to a contract of consignment); – the importer is an MAH being a resident of the Russian Federation, or representative office of a foreign organization in the territory of the Russian Federation. Information about the medicine import to the Russian Federation is submitted to MDLP System by the Marketing Authorization Holder (or its representative office) within 5 business days from the date of the medicine delivery to the destination in the Russian Federation or the date of aggregation completion (if the medicines are aggregated after their delivery to the destination in the Russian Federation). When registering the information, the foreign MAH shall further register the information on the medicine owner change in the customs-controlled area according to section 3.5. of these Passports of Processes. Registration of information regarding future operations with the transferred medicines in MDLP System shall be carried out by the new owner This process is also used for transfer of data about export by MAH (or its representative office) of medicines marked in the customs-controlled area (at the customs warehouse).
Interaction participant	– MAH, or representative office of foreign MAH
Description of the actions performed	
1. Medicine shipment to the Russian Federation from the finished products warehouse	
2. Medicine importation into the Russian Federation and placement in the customs-controlled area	
3. – 4. Registration of information about medicine import to the Russian Federation without importer in MDLP System by means of scheme 333-foreign_import_owner.xsd	
List of information to be transferred, and the owner of	When registering the information about medicine import to the Russian Federation without importer, the MAH (or its representative office) sends the following information to

information resource	MDLP System: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – identifier of the goods location in the customs-controlled area (according to the goods declaration); – contract type; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
5. Transfer of ownership right for the medicines placed in the customs warehouse in the customs-controlled area (if required)	

3.4. Medicine Acceptance to Warehouse by Importer After Release from the Customs Area When Importing into The Russian Federation



Picture 14

Annotation	After custom clearance and release for domestic consumption, the medicines shall be placed in the pharmaceutical warehouses of the importer (or logistics operator). Placement of goods conditionally released under customs control in the pharmaceutical importer's warehouse is allowed. In case of sample selection in the customs-controlled area and the need to withdraw the selected medicine samples from circulation, the relevant information shall be registered according to section 5.5 of these Passports of Processes. Medicines may be shipped from the customs-controlled area to the logistics operator's warehouse. Information about the medicine shipping from the customs control area to the pharmaceutical warehouse is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the medicine acceptance to the pharmaceutical warehouse and the completion of the customs procedure of goods release for domestic use (or from the date of decision on the medicine release for domestic use issued by the customs authorities through the procedure of conditional goods release). The cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine acceptance in tertiary (shipping) packages. As part of introduction of the medicines into circulation, data are automatically transferred from Roszdravnadzor AIS to MDLP System after documents and data, which are stipulated in Part 2, Article 52^1 of the Federal Law "On Medicine Circulation", are transferred by importer to Roszdravnadzor or the permission is received as stipulated in Part 7 of Article 52^1 of the Federal Law "On Medicine Circulation" (for manufacturing of immunobiological medicines). In case of successful registration in the MDLP System of the data which have been received from Roszdravnadzor AIS, participants of interaction in the MDLP System are allowed to continue to carry out trading operations with the medicines (medicine circulation) and to continue to reflect the actions. In case of MDLP System refusal to introduce automatically medicines into circulation (if there are grounds for refusal), importer shall perform the required checks and amend the data

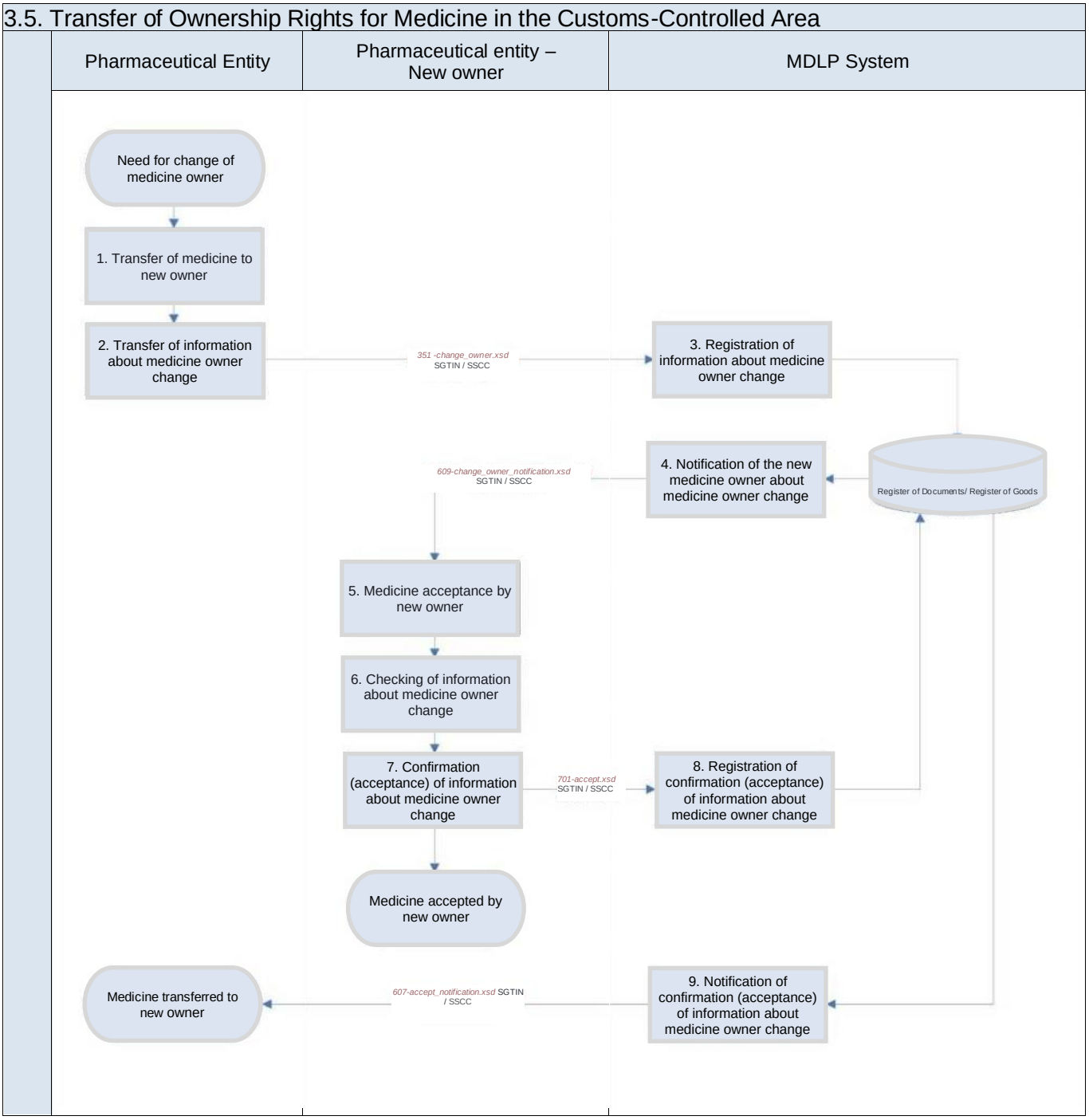
	which are contained in Roszdravnadzor AIS and (or) MDLP System, and shall send the data on introduction of the medicines into circulation to the MDLP System without assistance.
Interaction participants	– importer
Description of the actions performed	
1. Shipment of medicines from the customs-controlled area	
2. Medicine acceptance to warehouse by the importer	
3. – 4. Registration of information about medicine acceptance to the importer's warehouse in MDLP System by means of scheme 341-receive_importer.xsd	
List of information to be transferred, and the owner of information resource	When registering the results of medicine acceptance to the warehouse in MDLP System, the importer sends the following information: – operation date; – identifier of the importer's business place where the medicine is accepted; – identifier of the goods location in the customs-controlled area (from where it is shipped); – date of the primary document; – number of the primary document; – medicine cost in RUB (including customs fees, duties and taxes, VAT); – VAT amount in RUB (if no VAT is applicable, specify zero); – SGTIN and/or SSCC. If it is required to indicate different prices inside of a group packing, the importer shall send the following additional data for SSCC: – GTIN; – production series number; – medicine cost, RUB (for the specified GTIN and series numbers, including customs fees, duties and taxes, VAT included); – VAT amount, RUB (if applicable)

5. Submitting the information necessary for introduction of medicine into circulation to the Subsystem “Quality Control of Medicines” of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation and obtaining the permit to introduce immunobiological medicines into circulation	
6. Transfer of the data, which have been transferred by importer before introduction into civil circulation, or of the permission to introduce into civil circulation of immunobiological medicines from the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS to the MDLP System	
7. Automated checking the possibility of automatic introduction of the medicines into circulation based on the data obtained from the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS	
8. Automatic introduction of the medicine into circulation and automatic generation of scheme 342-release_in_circulation.xsd (if there are no grounds for refusal)	
9. Notification to importer of automatic introduction of the medicine into circulation by means of scheme 633-attention_notification.xsd	
10. MDLP System refusal to introduce automatically medicines into circulation (if there are grounds for refusal)	
A list of the grounds for refusal to register information	– lack in the MDLP System of GTIN, batch and goods declaration number for the medicines introduced into circulation, that have been received from Roszdravnadzor AIS; – mismatch between number of the goods declaration which has been specified by a pharmaceutical entity in scheme 335-fts_data.xsd and number of the goods declaration which has been received from the FCS of Russia; – mismatch between quantity of the medicines which has been received from the FCS of Russia as part of information on release of goods for domestic consumption and quantity of the SGTINs which has been specified by a pharmaceutical entity in scheme 335-fts_data.xsd; – number of SGTINs that are introduced into circulation, exceeds number of medicine packages that are introduced into circulation, in line with the data from Roszdravnadzor AIS; – when for the SGTINs during the period from the receipt of information about introduction into circulation from Roszdravnadzor AIS till a notification is sent to a pharmaceutical entity by means of scheme 633-attention_notification.xsd, the pharmaceutical entity has submitted other documents contained information about these SGTINs to the MDLP IS

	– SGTINs are not on the balance of the pharmaceutical entity, information about which has been received from Roszdravnadzor AIS; – a business place where SGTINs are at the time of automatic introduction into circulation, has been blocked due to the absence of the valid license; – SGTINs have a status which is different from the "Admitted to the warehouse from the customs-controlled area" status; – SGTIN nesting is more than 2 levels
11. Notification to importer of refuse to introduce automatically medicine into circulation by means of scheme 633-attention_notification.xsd	
12. Importer shall familiarize itself with the reasons of refuse to introduce automatically medicines into circulation, check the data and introduce necessary amendments in the Subsystem "Quality Control of Medicines" of Roszdravnadzor AIS and (or) in the MDLP System	
13. – 14. Registration of information about medicine introduction into circulation in the Russian Federation in MDLP System by means of scheme 342-release_in_circulation.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about medicine introduction into circulation in the Russian Federation, the importer shall send the following information: – operation date; – identifier of the importer's business place where the medicine is accepted; – date of publication of information in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation; – number of decision made by the Federal Service for Surveillance in Healthcare to introduce the medicine into civil circulation (for immunobiological medicines only); – internal identifier of the record on medicine introduction into civil circulation in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation – SGTIN and/or SSCC
Special conditions	The number of medicine packages for which the information on introduction into circulation in the Russian Federation is

	registered shall not exceed the imported medicine batch size for which the information is registered in Roszdravnadzor AIS

3.5. Transfer of Ownership Rights for Medicine in the Customs-Controlled Area



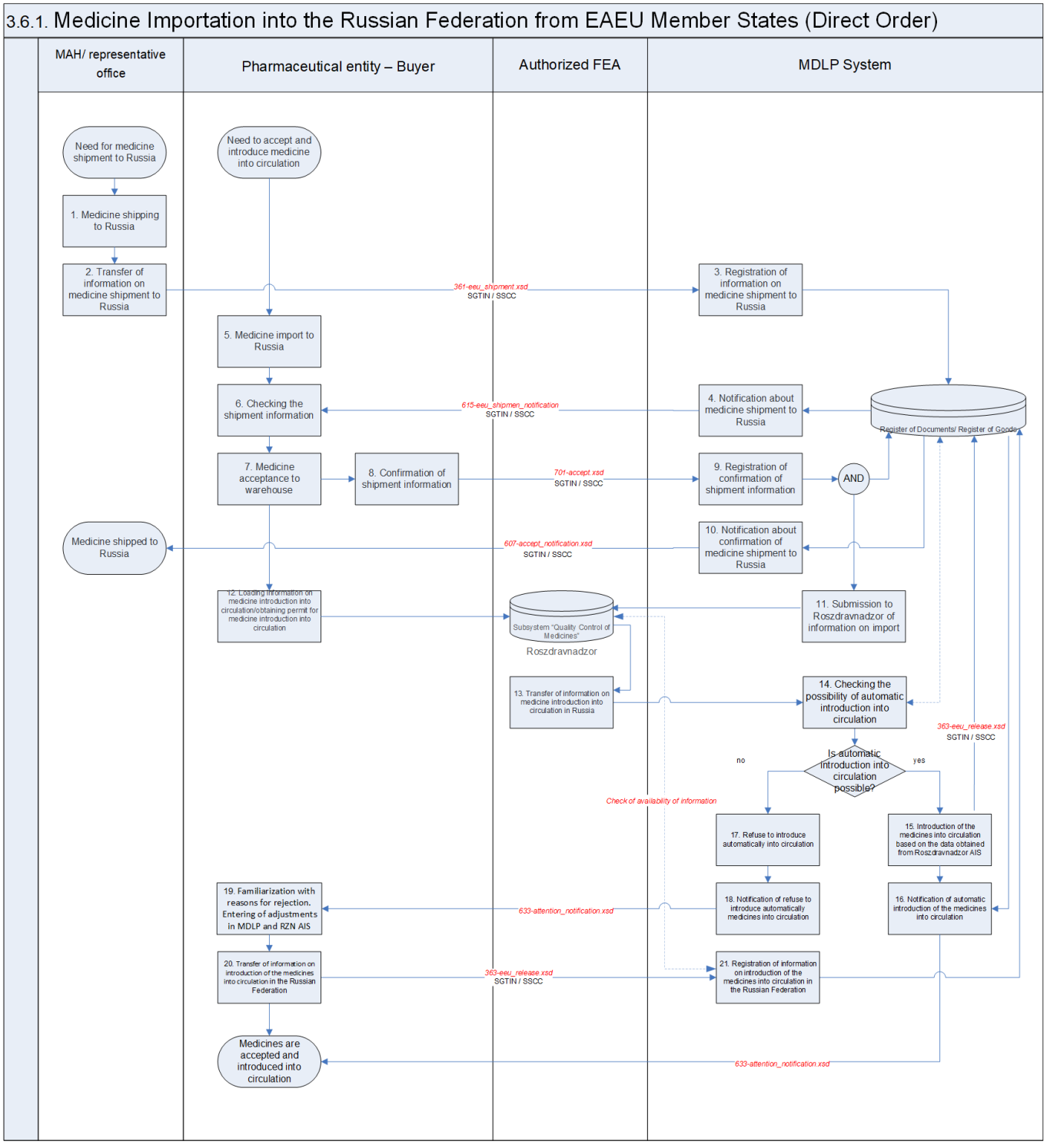
Picture 15

Annotation	If medicines are placed under the customs procedure of a customs warehouse, transactions may be made that provide for the transfer of ownership, use and (or) disposal of these medicines. When medicine owner is changed in the customs-controlled area, the pharmaceutical entity that transfers the medicine ownership right shall register the corresponding operation in MDLP System. Information about the medicine owner change in the customs control area is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of execution of the relevant documents on the medicine ownership transfer. In this case the pharmaceutical entity to whom the medicine ownership is transferred, confirms the registered information within 5 business days from the date of execution of relevant documents on medicine ownership transfer and registration in MDLP System of the information about transferred medicines Registration of information regarding future operations with the transferred medicines in MDLP System shall be carried out by the new owner. If it is required to return the medicine previously transferred to the new owner, the medicine return information shall be registered by the new owner pursuant to this section hereof. The pharmaceutical entity which previously transferred the medicine shall be specified as the receiver
Interaction participant	– pharmaceutical entity that transfers the medicine ownership right; – pharmaceutical entity that is the new owner of the medicine
Description of the actions performed	
1. Transfer of ownership right for the medicines placed in the customs warehouse in the customs-controlled area	
2. – 3. Registration of information about medicine owner change in MDLP System by means of scheme 351-change_owner.xsd	
List of information to be transferred, and the owner of information	When registering in MDLP System the information about medicine owner change, the pharmaceutical entity that transfers the medicine ownership right shall send the following information:

resource	– operation date; – registration number of the pharmaceutical entity that transfers the medicine ownership right in MDLP System; – registration number of the new medicine owner in MDLP System; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
4. Notification of the new medicine owner about medicine owner change by means of scheme 609-change_owner_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the new medicine owner about medicine owner change is formed on the basis of the operation, previously registered by the pharmaceutical entity that transfers the medicine ownership right, and contains the following data: – operation date; – registration number of the pharmaceutical entity that transfers the medicine ownership right in MDLP System; – registration number of the new medicine owner in MDLP System; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
5. Acceptance of the medicine by the new owner	
6. Checking by the new medicine owner of the previously registered information about transfer of medicine ownership rights	
7. – 8. Registration of confirmation (acceptance) of the information about transfer of medicine ownership rights in MDLP System by the new owner by means of scheme 701-accept.xsd	
List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information about transfer of medicine ownership rights, the new owner sends the following data to MDLP System: – operation date; – registration number of the new medicine owner in MDLP System;

	– registration number of the pharmaceutical entity that transfers the ownership right in MDLP System; – SGTIN and/or SSCC
9. Notification of the pharmaceutical entity that transfers the medicine ownership right about confirmation (acceptance) of information about the transfer of medicine ownership right by the new medicine owner by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the pharmaceutical entity that transfers the medicine ownership right about confirmation (acceptance) of the owner change information by the new medicine owner is formed on the basis of the operation, previously registered by the new owner, and contains the following information: – operation date; – registration number of the new medicine owner in MDLP System; – registration number of the pharmaceutical entity that transfers the ownership right in MDLP System; – SGTIN and/or SSCC

3.6.1. Medicine Importation into the Russian Federation from EAEU Member States (Direct Order)



Picture 16

Annotation	Registration in MDLP System of the information about medicine importation into the Russian Federation from EAEU member states suggests the possibility of using direct or reverse data transfer order. If the direct data transfer and confirmation order is selected, the MAH (or its representative office) registers information about medicine shipment to the Russian Federation, and the medicine buyer in the Russian Federation confirms the registered shipping information. Information about the medicine shipping to the Russian Federation from EAEU countries is submitted to MDLP System by the Marketing Authorization Holder (or its representative office) within 5 business days from the date of the medicine shipping to the Russian Federation from EAEU countries. In this case the importer confirms the information registered by the Marketing Authorization Holder (or its representative office) within 5 business days after the date of medicine acceptance and registration in MDLP System of the information about the medicine shipping to the Russian Federation from EAEU countries. In case of sampling or the need to withdraw the medicine samples from circulation, the relevant information shall be registered according to section 5.5 of these Passports of Processes. The cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine delivery in tertiary (shipping) packages. As part of introduction of the medicines into circulation, the data are automatically transferred from Roszdravnadzor AIS to MDLP System after documents and data, which are stipulated in Part 2, Article 52^1 of the Federal Law "On Medicine Circulation", are transferred by importer to Roszdravnadzor or the permission is received as stipulated in Part 7 of Article 52^1 of the Federal Law 'On Medicine Circulation' (for manufacturing of immunobiological medicines). In case of successful registration in the MDLP System of the data which have been received from Roszdravnadzor AIS, participants of interaction in the MDLP System are allowed to continue to carry out trading operations with the medicines (medicine circulation) and to continue to reflect the actions. In case of MDLP System refusal to introduce automatically

	medicines into circulation (if there are grounds for refusal), importer shall perform the required checks and amend the data which are contained in Roszdravnadzor AIS and (or) MDLP System, and shall send the data on introduction of the medicines into circulation to the MDLP System without assistance.
Interaction participants	– MAH, or representative office of foreign MAH; – pharmaceutical entity that buys the medicine (Buyer)
Description of the actions performed	
1. Medicine shipment to the Russian Federation from EAEU member state	
2. – 3. Registration of information in MDLP System about medicine shipment to the Russian Federation from EAEU member states by means of scheme 361-eeu_shipment.xsd	
List of information to be transferred, and the owner of information resource	When registering the information about medicine shipment to the Russian Federation from a EAEU member state, the MAH (or its representative office) sends the following information to MDLP System: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – identifier of the buyer's business place where the medicine is accepted; – contract type; – date of the primary document; – number of the primary document; – medicine selling price (VAT included) in RUB; – VAT amount, RUB (if no VAT is applicable, specify zero) in RUB – SGTIN and/or SSCC If it is required to indicate different prices inside of a group packing, the MAH (or its representative office) shall send the following additional data for SSCC: – GTIN; – production series number;

	– medicine selling price, RUB (for the specified GTIN and series numbers, VAT included); – VAT amount, RUB (if no VAT is applicable, specify zero)
4. Notification of the Buyer about medicine shipment to the Russian Federation from EAEU member state by means of scheme 615-eeu_shipment_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the Buyer about medicine shipment to the Russian Federation from EAEU member state is formed on the basis of the operation, previously registered by MAH (or its representative office), and contains the following data: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – identifier of the buyer's business place where the medicine is accepted; – contract type; – date of the primary document; – number of the primary document; – medicine selling price (VAT included), RUB; – VAT amount, RUB (if no VAT is applicable, specify zero) – SGTIN and/or SSCC If different prices have been specified within a group package, the notification additionally contains the following information for SSCC: – GTIN; – production series number; – medicine selling price, RUB (for the specified GTIN and series numbers, VAT included); – VAT amount, RUB (if no VAT is applicable, specify zero)
5. Medicine importation into the Russian Federation from EAEU member state	
6. Checking by the buyer of the information, previously registered by the MAH (or its representative office), about medicine shipment to the Russian Federation	

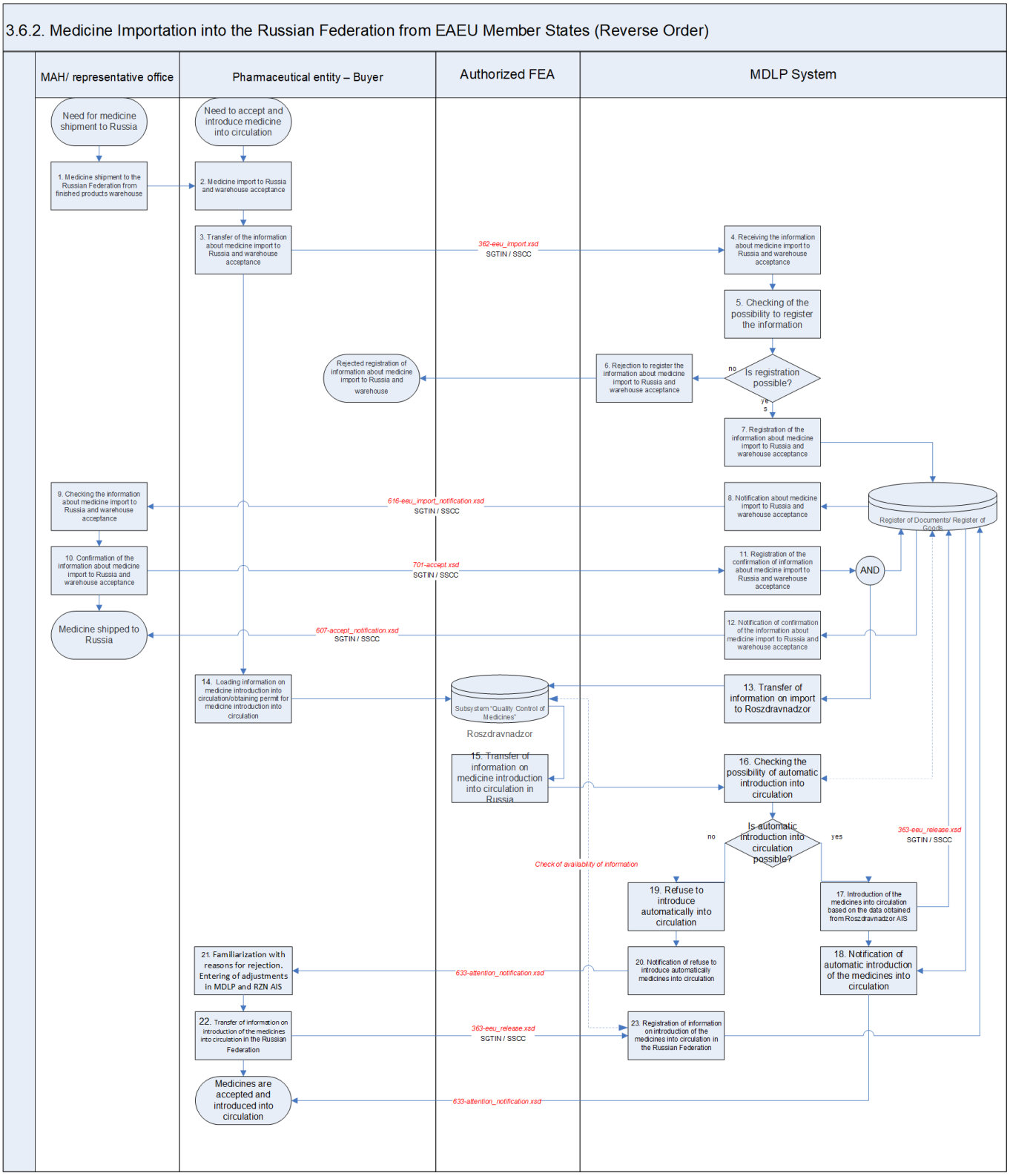
<table>
<tr><td colspan="2">7. Medicine acceptance to buyer’s warehouse</td></tr>
<tr><td colspan="2">8. – 9. Confirmation (acceptance) by the buyer of the information in MDLP System about medicine shipment to the Russian Federation from EAEU member state by means of scheme 701-accept.xsd</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>For confirmation (acceptance) of the information, previously registered by the MAH (or its representative office), about medicine shipment to the Russian Federation from EAEU member state, the buyer sends the following data to MDLP System:
– operation date;
– identifier of the buyer’s business place where the medicine is accepted;
– registration number of the MAH (or its representative office) in MDLP System;
– SGTIN and/or SSCC;</td></tr>
<tr><td colspan="2">10. Notice to MAH (or its representative office) about confirmation (acceptance) by the buyer of the information about medicine shipment to the Russian Federation from EAEU member state by means of scheme 607-accept_notification.xsd</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>The notice to the MAH (or its representative office) about confirmation (acceptance) by the buyer of the information on medicine shipment to the Russian Federation from EAEU member state is formed on the basis of the operation, previously registered by the buyer, and contains the following information:
– operation date;
– identifier of the buyer’s business place where the medicine is accepted;
– registration number of the MAH (or its representative office) in MDLP System;
– SGTIN and/or SSCC;</td></tr>
<tr><td colspan="2">11. Transfer of the information about the medicine import to the Russian Federation for further medicine introduction into civil circulation from MDLP System to Medicine Quality Control Subsystem of Roszdravnadzor AIS</td></tr>
<tr><td>List of information to be transferred, and the owner of information</td><td>Through IEIS, MDLP System sends the information about the medicine import to the Russian Federation to the automated information system of Roszdravnadzor according to the information interaction format</td></tr>
</table>

resource	
12. Provision of the information necessary for introduction of medicine into circulation to the Subsystem “Quality Control of Medicines” of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation and obtaining the permit to introduce immunobiological medicines into circulation	
13. Transfer of the data, which are transferred by importer before introduction into civil circulation, or of the permission to introduce into civil circulation of immunobiological medicines from the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS to the MDLP System	
14. Automated checking the possibility of automatic introduction of the medicines into circulation based on the data obtained from the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS	
15. Automatic introduction of the medicine into circulation and automatic generation of scheme 363-eeu_release.xsd (if there are no grounds for refusal)	
16. Notification to importer of automatic introduction of the medicine into circulation by means of scheme 633-attention_notification.xsd	
17. MDLP System refusal to introduce automatically medicines into circulation (if there are grounds for refusal)	
A list of the grounds for refusal to register information	– lack in the MDLP System of GTIN, batch, number and date of the shipment of the medicines introduced into circulation, that have been received from Roszdravnadzor AIS; – number of SGTINs that are introduced into circulation, exceeds number of medicine packages that are introduced into circulation in line with the data from Roszdravnadzor AIS; – when for the SGTINs during the period from the receipt of information about introduction into circulation from Roszdravnadzor AIS till a notification is sent to a pharmaceutical entity by means of scheme 633-attention_notification.xsd, the pharmaceutical entity has submitted other documents contained information about these SGTINs to the

	MDLP System – SGTINs are not on the balance of the pharmaceutical entity, information about which has been received from Roszdravnadzor AIS; – a business place where SGTINs are at the time of automatic introduction into circulation, has been blocked due to the absence of the valid license; – SGTINs have a status which is different from the "Imported to the Russian Federation" status; – SGTIN nesting is more than 2 levels
18. Notification to importer of refuse to introduce automatically medicine into circulation by means of scheme 633-attention_notification.xsd	
19. Importer shall familiarize itself with the reasons of refuse to introduce automatically medicines into circulation, check the data and introduce necessary amendments in the Subsystem "Quality Control of Medicines" of Roszdravnadzor AIS and (or) in the MDLP System	
20.–21. Registration of information about medicine introduction into circulation in the Russian Federation in MDLP System by means of scheme 363-eeu_release.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about medicine introduction into circulation in the Russian Federation, the buyer shall send the following information: – operation date; – identifier of the buyer's business place where the medicine is accepted; – date of publication of information in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation; – number of decision made by the Federal Service for Surveillance in Healthcare to introduce the medicine into civil circulation (for immunobiological medicines only); – internal identifier of the record on medicine introduction into civil circulation in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for

	Surveillance in Healthcare of the Russian Federation – SGTIN and/or SSCC. If it is required to submit several details to the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation, the buyer provides additional information: – GTIN; – production series number; – date of publication of information for the specified GTIN in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation; – number of decision made by the Federal Service for Surveillance in Healthcare to introduce the medicine into civil circulation (for immunobiological medicines only) for the specified GTIN; – internal identifier of the record on medicine introduction into civil circulation in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation for the specified GTIN;
Special conditions	The number of medicine packages for which the information on introduction into circulation in the Russian Federation is registered shall not exceed the imported medicine batch size for which the information is registered in Roszdravnadzor AIS. As required, on request to the MDLP System technical support service, an option may be given for the buyer to register in MDLP System the logical operation of return upon the medicine import to the Russian Federation (337-return_import.xsd) in order to return the medicine to the balance sheet of the Marketing Authorization Holder to ensure the possibility of further sending the correct information about the medicine shipping to the Russian Federation. The operation is registered after an incorrect acceptance by the buyer of the information about the medicine shipping to the Russian Federation and shall be confirmed by the Marketing Authorization Holder

3.6.2. Medicine Importation into the Russian Federation from EAEU Member States (Reverse Order)



Picture 17

Annotation	Registration in MDLP System of the information about medicine importation into the Russian Federation from EAEU member states suggests the possibility of using direct or reverse data transfer order. If the reverse data transfer and confirmation order is selected, the medicine buyer registers information about the medicine importation into the Russian Federation, while the MAH (or its representative office) confirms the registered import information. The reverse data confirmation order requires registration of a list of trusted counterparties—buyers in the user account of MAH (or its representative office). Information about the medicine import to the Russian Federation from EAEU countries is submitted to MDLP System by the importer within 5 business days from the date of the medicine shipping to the Russian Federation from EAEU countries. In this case the Marketing Authorization Holder (or its representative office) confirms the information registered by the importer within 5 business days from the date of the medicine acceptance and registration in MDLP System of the information about the medicine shipping to the Russian Federation from EAEU countries. In case of sampling or the need to withdraw the medicine samples from circulation, the relevant information shall be registered according to section 5.5 of these Passports of Processes. The cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine acceptance in tertiary (shipping) packages. As part of introduction of the medicines into circulation, the data are automatically transferred from Roszdravnadzor AIS to MDLP System after documents and data, which are stipulated in Part 2, Article 52^1 of the Federal Law "On Medicine Circulation", are transferred by importer to Roszdravnadzor or the permission is received as stipulated in Part 7 of Article 52^1 of the Federal Law "On Medicine Circulation" (for manufacturing of immunobiological medicines). In case of successful registration in the MDLP System of the data which have been received from Roszdravnadzor AIS, participants of interaction in the MDLP System are allowed to continue to carry out trading operations with the medicines

	(medicine circulation) and to continue to reflect the actions. In case of MDLP System refusal to introduce automatically medicines into circulation (if there are grounds for refusal), importer shall perform the required checks and amend the data which are contained in Roszdravnadzor AIS and (or) MDLP System, and shall send the data on introduction of the medicines into circulation to the MDLP System without assistance.
Interaction participants	– MAH, or representative office of foreign MAH – pharmaceutical entity that buys the medicine (Buyer)
Description of the actions performed	
1. Medicine shipment to the Russian Federation from EAEU member state	
2. Medicine importation into the Russian Federation from EAEU member state and acceptance to warehouse	
3. – 4. Submission of information to MDLP System about medicine importation into the Russian Federation from EAEU member state and warehouse acceptance by means of scheme 362-eeu_import.xsd	
List of information to be transferred, and the owner of information resource	When registering the information about medicine importation into the Russian Federation from a EAEU member state and warehouse acceptance, the buyer submits the following information: – operation date; – identifier of the buyer's business place where the medicine is accepted; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – contract type; – date of the primary document; – number of the primary document; – medicine purchasing price (VAT included), RUB; – VAT amount, RUB (if no VAT is applicable, specify zero) – SGTIN and/or SSCC If it is required to indicate different prices inside of a group packing, the buyer shall send the following additional data for

	SSCC: – GTIN; – production series number; – medicine purchasing price, RUB (for the specified GTIN and series numbers, VAT included); – VAT amount, RUB (if no VAT is applicable, specify zero)
5. Checking of the possibility to register the information about medicine importation into the Russian Federation and warehouse acceptance (availability of the pharmaceutical entities on the list of trusted counterparties)	
6. Rejection of registration of the data about medicine import into the Russian Federation and warehouse acceptance if the receiver is not on the list of trusted counterparties of MAH (or its representative office)	
7. Registration of information about medicine importation into the Russian Federation from EAEU member state and warehouse acceptance in MDLP System (if there are no reasons to reject)	
8. Notification of the MAH (or its representative office) about medicine importation into the Russian Federation from EAEU member state and warehouse acceptance by means of scheme 616-eeu_import_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the MAH (or its representative office) about medicine import to the Russian Federation from EAEU member state and warehouse acceptance is formed on the basis of the operation, previously registered by the buyer, and contains the following information: – operation date; – identifier of the buyer's business place where the medicine is accepted; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – contract type; – date of the primary document; – number of the primary document; – medicine purchasing price (VAT included), RUB; – VAT amount, RUB (if no VAT is applicable, specify zero)

	– SGTIN and/or SSCC. If different prices have been specified within a group package, the notification additionally contains the following information for SSCC: – GTIN; – production series number; – medicine purchasing price, RUB (for the specified GTIN and series numbers, VAT included); – VAT amount, RUB (if no VAT is applicable, specify zero)
9. Checking by the MAH (or its representative office) of the information, previously registered by the buyer, about medicine importation into the Russian Federation from EAEU member state and warehouse acceptance	
10.– 11. Confirmation (acceptance) in MDLP System of the information about medicine importation into the Russian Federation from EAEU member state and warehouse acceptance by MAH (or its representative office) by means of scheme 701-accept.xsd	
List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information, previously registered by the buyer, about medicine import to the Russian Federation from EAEU member state and warehouse acceptance, the MAH (or its representative office) sends the following data to MDLP System: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – identifier of the buyer's business place where the medicine is accepted; – SGTIN and/or SSCC;
12.Notification of the buyer about confirmation (acceptance) by MAH (or its representative office) of the information about medicine importation into the Russian Federation from EAEU member state and warehouse acceptance by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the buyer about confirmation (acceptance) by MAH (or its representative office) of the information about medicine importation into the Russian Federation from EAEU member state and warehouse acceptance is formed on the basis of the previously registered operation and contains the following

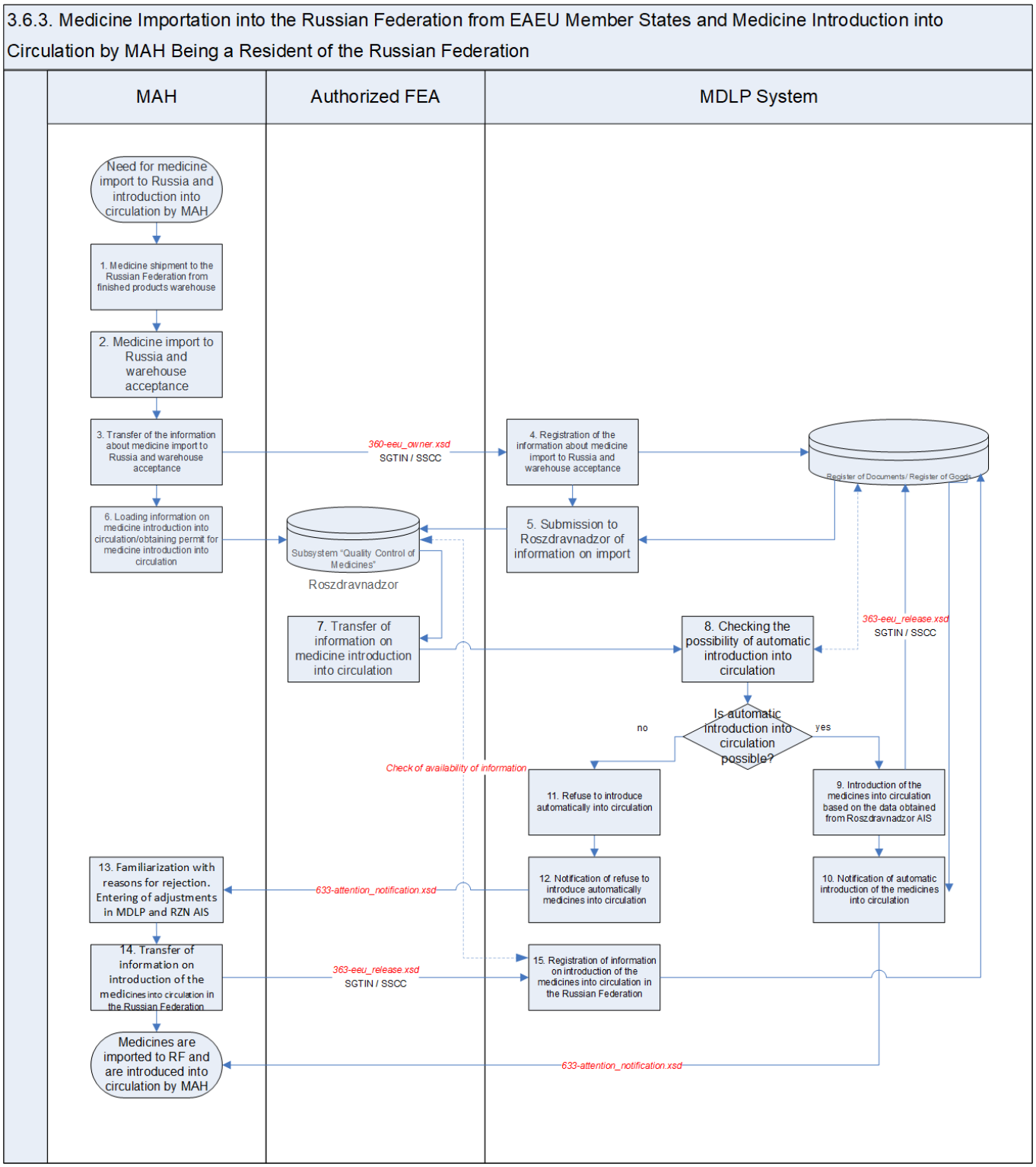
	information: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – identifier of the buyer's business place where the medicine is accepted; – SGTIN and/or SSCC; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on temporary medicine withdrawal from circulation according to section 7.1 of these Passports of Processes)
13. Transfer of the information about the medicine import to the Russian Federation for further medicine introduction into civil circulation from MDLP System to Medicine Quality Control Subsystem of Roszdravnadzor AIS	
List of information to be transferred, and the owner of information resource	Through IEIS, MDLP System sends the information about the medicine import to the Russian Federation to the automated information system of Roszdravnadzor according to the information interaction format
14. Provision of data that are required to introduce medicines into circulation, to the Subsystem "Quality Control of Medicines" of Roszdravnadzor AIS and obtainment a permission to introduce into circulation for immunobiological medicines	
15. Transfer of the data, which are transferred by importer before introduction into civil circulation, or of the permission to introduce into civil circulation of immunobiological medicines from the Subsystem "Quality Control of Medicines" of Roszdravnadzor AIS to the MDLP System	
16. Automated checking the possibility of automatic introduction of the medicines into circulation based on the data obtained from the Subsystem "Quality Control of Medicines" of Roszdravnadzor AIS	
17. Automatic introduction of the medicine into circulation and automatic generation of scheme 363-eeu_release.xsd (if there are no grounds for refusal)	
18. Notification to importer of automatic introduction of the medicine into circulation by means of scheme 633-attention_notification.xsd	
19. MDLP System refusal to introduce automatically medicines into circulation (if	

there are grounds for refusal)	
A list of the grounds for refusal to register information	– lack in the MDLP System of GTIN, batch, number and date of the shipment of medicines introduced into circulation, that have been received from Roszdravnadzor AIS; – number of SGTINs that are introduced into circulation, exceeds number of medicine packages that are introduced into circulation in line with the data from Roszdravnadzor AIS; – when for the SGTINs during the period from the receipt of information about introduction into circulation from Roszdravnadzor AIS till a notification is sent to a pharmaceutical entity by means of scheme 633-attention_notification.xsd, the pharmaceutical entity has submitted other documents contained information about these SGTINs to the MDLP System – SGTINs are not on the balance of the pharmaceutical entity, information about which has been received from Roszdravnadzor AIS; – a business place where SGTINs are at the time of automatic introduction into circulation, has been blocked due to the absence of the valid license; – SGTINs have a status which is different from the "Imported to the Russian Federation" status; – SGTIN nesting is more than 2 levels
20. Notification to importer of refuse to introduce automatically medicine into circulation by means of scheme 633-attention_notification.xsd	
21. Importer shall familiarize itself with the reasons of refuse to introduce automatically medicines into circulation, check the data and introduce necessary amendments in the Subsystem "Quality Control of Medicines" of Roszdravnadzor AIS and (or) in the MDLP System	
22.– 23. Registration of information about medicine introduction into circulation in the Russian Federation in MDLP System by means of scheme 363-eeu_release.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about medicine introduction into circulation in the Russian Federation, the buyer shall send the following information: – operation date; – identifier of the buyer's business place where the medicine

	is accepted; – date of publication of information in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation; – number of decision made by the Federal Service for Surveillance in Healthcare to introduce the medicine into civil circulation (for immunobiological medicines only); – internal identifier of the record on medicine introduction into civil circulation in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation – SGTIN and/or SSCC If it is required to submit several details to the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation, the buyer provides additional information: – GTIN; – production series number; – date of publication of information for the specified GTINs in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation; – number of decision made by the Federal Service for Surveillance in Healthcare to introduce the medicine into civil circulation (for immunobiological medicines only) for the specified GTINs; – internal identifier of the record on medicine introduction into civil circulation in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation)for the specified GTINs;
Special conditions	The number of medicine packages for which the information on introduction into circulation in the Russian Federation is registered shall not exceed the imported medicine batch size for which the information is registered in Roszdravnadzor AIS. As required, on request to the MDLP System technical support service, an option may be given for the buyer to register in MDLP System the logical operation of return upon the medicine import to the Russian Federation (337-return_import.xsd) in

	order to return the medicine to the balance sheet of the Marketing Authorization Holder to ensure the possibility of further sending the correct information about the medicine import to the Russian Federation. The operation is registered after an incorrect acceptance by the Marketing Authorization Holder of the information about the medicine import to the Russian Federation and shall be confirmed by the Marketing Authorization Holder

3.6.3. Medicine Importation into the Russian Federation from EAEU Member States and Medicine Introduction into Circulation by MAH Being a Resident of the Russian Federation



Picture 18

Annotation	In case the MAH for medicine produced in EAEU is a resident of the Russian Federation and imports its own medicine to the Russian Federation, information on medicine importation from EAEU member state and medicine introduction into circulation in the Russian Federation shall be registered pursuant to this section hereof. Information about the medicine import to the Russian Federation from EAEU countries is submitted to MDLP System by the Marketing Authorization Holder (or its representative office) within 5 business days from the date of the medicine acceptance to pharmaceutical warehouse in Russian Federation. In case of sampling or the need to withdraw the medicine samples from circulation, the relevant information shall be registered according to section 5.5 of these Passports of Processes As part of introduction of the medicines into circulation, the data are automatically transferred from Roszdravnadzor AIS to MDLP System after documents and data, which are stipulated in Part 2, Article 52^1 of the Federal Law "On Medicine Circulation", are transferred by MAH to Roszdravnadzor or the permission is received as stipulated in Part 7 of Article 52^1 of the Federal Law "On Medicine Circulation" (for manufacturing of immunobiological medicines). In case of successful registration in the MDLP System of the data which have been received from Roszdravnadzor AIS, participants of interaction in the MDLP System are allowed to continue to carry out trading operations with the medicines (medicine circulation) and to continue to reflect the actions. In case of MDLP System refusal to introduce automatically medicines into circulation (if there are grounds for refusal), MAH shall perform the required checks and amend the data which are contained in Roszdravnadzor AIS and (or) MDLP System, and shall send the data on introduction of the medicines into circulation to the MDLP System without assistance
Interaction participant	– MAH
Description of the actions performed	
1. Medicine shipment to the Russian Federation from the finished products warehouse	
2. Medicine importation into the Russian Federation and acceptance to warehouse	

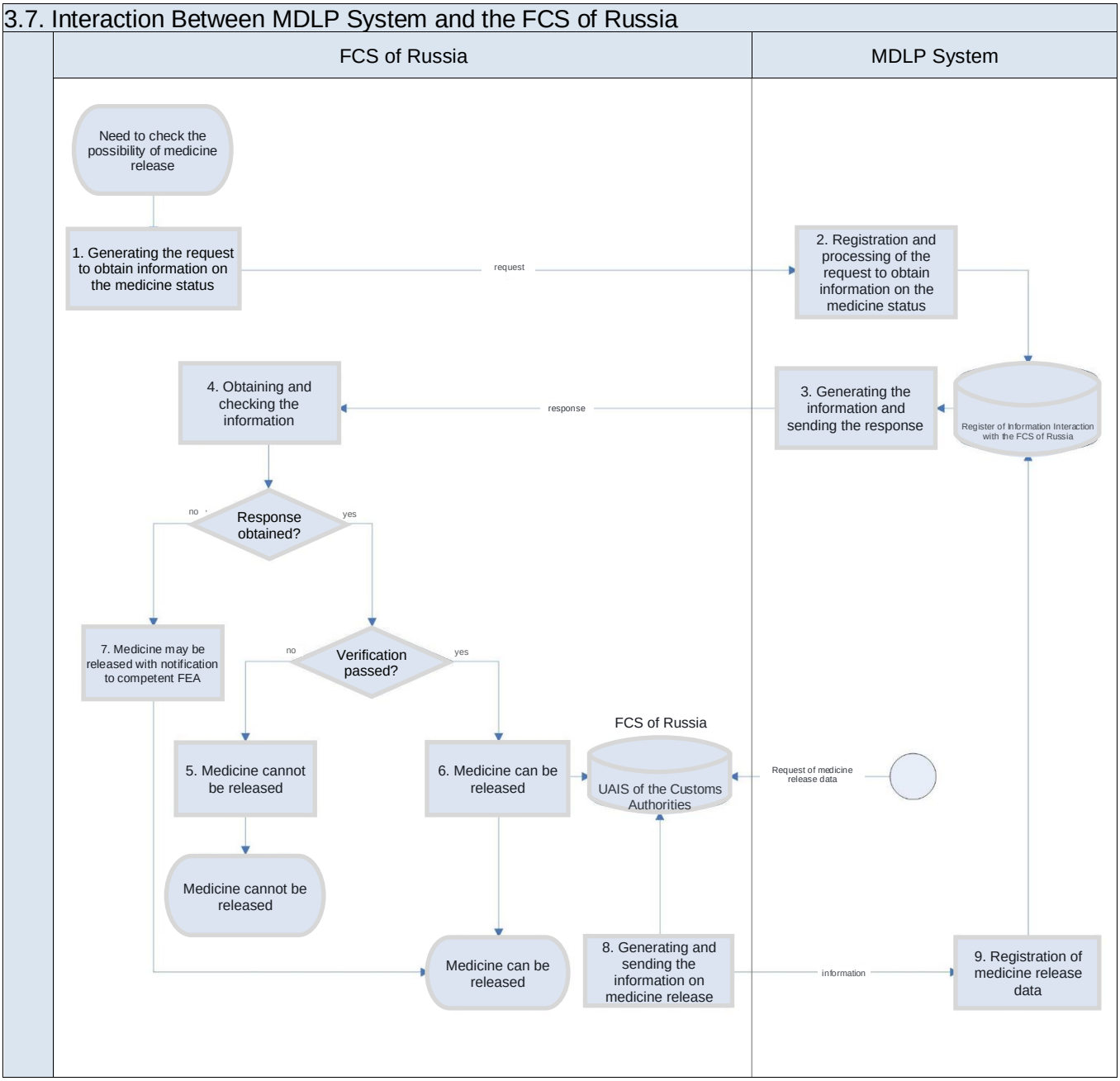
<table>
<tr><td colspan="2">3. – 4. Registration of information in MDLP System about medicine importation into the Russian Federation from EAEU member states by means of scheme 360-eeu_owner.xsd</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>When registering the information about own medicine importation into the Russian Federation from a EAEU member state and warehouse acceptance, the MAH submits the following information to MDLP System:
– operation date;
– identifier of the MAH’s business place where the medicine is accepted;
– contract type (own funds);
– date of the supporting document;
– number of the supporting document;
– SGTIN and/or SSCC</td></tr>
<tr><td colspan="2">5. Transfer of the information about the medicine import to the Russian Federation for further medicine introduction into civil circulation from MDLP System to Medicine Quality Control Subsystem of Roszdravnadzor AIS</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>Through IEIS, MDLP System sends the information about the medicine import to the Russian Federation to the automated information system of Roszdravnadzor according to the information interaction format</td></tr>
<tr><td colspan="2">6. Submitting the information necessary for introduction of medicine into circulation to the Subsystem “Quality Control of Medicines” of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation and obtaining the permit to introduce immunobiological medicines into circulation</td></tr>
<tr><td colspan="2">7. Transfer of the data, which are transferred by MA holder before introduction into civil circulation, or of the permission to introduce into civil circulation of immunobiological medicines from the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS to the MDLP System</td></tr>
<tr><td colspan="2">8. Automated checking the possibility of automatic introduction of the medicines into circulation based on the data obtained from the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS</td></tr>
<tr><td colspan="2">9. Automatic introduction of the medicine into circulation and automatic generation of scheme 363-eeu_release.xsd (if there are no grounds for refusal)</td></tr>
</table>

10. Notification to MAH of automatic introduction of the medicine into circulation by means of scheme 633-attention_notification.xsd	
11. MDLP System refusal to introduce automatically medicines into circulation (if there are grounds for refusal)	
A list of the grounds for refusal to register information	– lack in the MDLP System of GTIN, batch, number and date of the shipment of medicines introduced into circulation, that have been received from Roszdravnadzor AIS; – number of SGTINs that are introduced into circulation, exceeds number of medicine packages that are introduced into circulation in line with the data from Roszdravnadzor AIS; – when for the SGTINs during the period from the receipt of information about introduction into circulation from Roszdravnadzor AIS till a notification is sent to a pharmaceutical entity by means of scheme 633-attention_notification.xsd, the pharmaceutical entity has submitted other documents contained information about these SGTINs to the MDLP System – SGTINs are not on the balance of the pharmaceutical entity, information about which has been received from Roszdravnadzor AIS; – a business place where SGTINs are at the time of automatic introduction into circulation, has been blocked due to the absence of the valid license; – SGTINs have a status which is different from the “Imported to the Russian Federation” status; – SGTIN nesting is more than 2 levels
12.Notification to MAH of refuse to introduce automatically medicine into circulation by means of scheme 633-attention_notification.xsd	
13. MAH shall familiarize itself with the reasons of refuse to introduce automatically medicines into circulation, check the data and introduce necessary amendments in the Subsystem “Quality Control of Medicines” of Roszdravnadzor AIS and (or) in the MDLP System	
14.– 15. Registration of information about medicine introduction into circulation in the Russian Federation in MDLP System by means of scheme 363-eeu_release.xsd	
List of information	When registering in MDLP System the information about

to be transferred, and the owner of information resource	medicine introduction into circulation in the Russian Federation, the MAH shall send the following information: – operation date; – identifier of the MAH's business place where the medicine has been accepted; – date of publication of information in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation; – number of decision made by the Federal Service for Surveillance in Healthcare to introduce the medicine into civil circulation (for immunobiological medicines only); – internal identifier of the record on medicine introduction into civil circulation in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation) – SGTIN and/or SSCC If it is required to submit several details to the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation, the MAH provides additional information: – GTIN; – production series number; – date of publication of information for the specified GTINs in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation; – number of decision made by the Federal Service for Surveillance in Healthcare to introduce the medicine into civil circulation (for immunobiological medicines only) for the specified GTINs; – internal identifier of the record on medicine introduction into civil circulation in the Subsystem "Quality Control of Medicines" of the AIS of the Federal Service for Surveillance in Healthcare of the Russian Federation)for the specified GTINs;
Special conditions	The number of medicine packages for which the information on introduction into circulation in the Russian Federation is registered shall not exceed the imported medicine batch size for

	which the information is registered in Roszdravnadzor AIS

3.7. Interaction Between MDLP System and the FCS of Russia



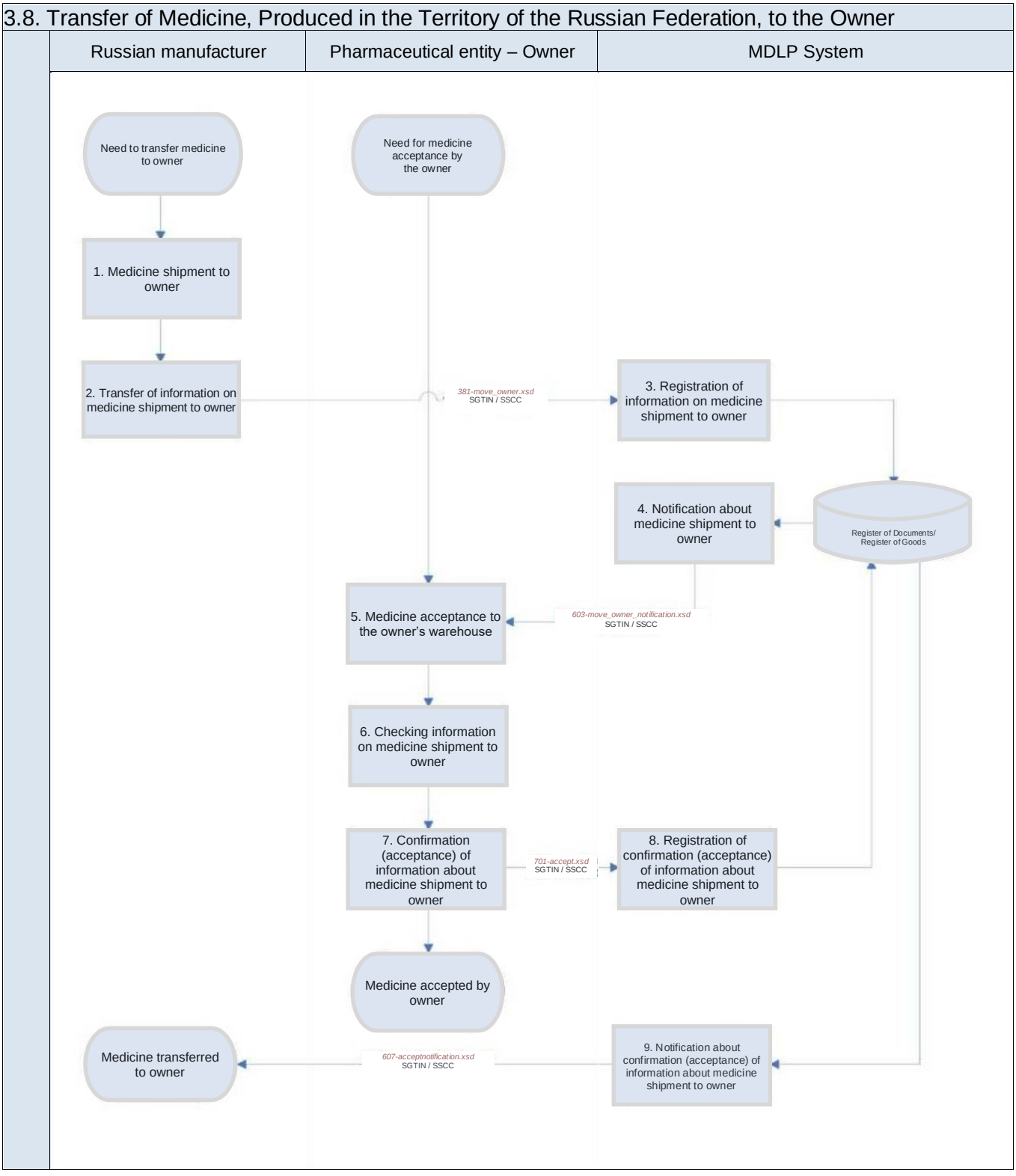
Picture 19

Annotation	For the purpose of checking the possibility of medicine release for domestic consumption, the FCS of Russia sends a request to MDLP System to obtain information on the status of the declared medicine When performing customs formalities during the medicine customs declaring procedure and placing the medicines under the customs procedure for release for domestic use, the customs authority shall request the information about SGTIN or SSCC from MDLP System, to verify the information specified in the goods declaration. Upon successful data verification, if the information stated in the goods declaration corresponds with the data specified in MDLP System, and if other release conditions are observed, the customs authorities release the goods for domestic use. Customs authorities send to MDLP System the information about the medicine release for domestic use. If SGTIN or SSCC stated in the goods declaration are missing in the MDLP System, or if such SGTIN or SSCC are specified with unacceptable status, the customs authorities refuse the medicine release for domestic use. If the release conditions are observed, but no response is received from MDLP System within the established time, the customs authorities release the medicines for domestic use and inform the authorized Federal Executive Authorities (Rospotrebnadzor, Russian Ministry of Internal Affairs) about the actual release of such medicines. If a response is received from MDLP System after such medicine release, according to which SGTIN or SSCC stated in the goods declaration are missing, the customs authorities make a decision to carry out customs control
Interaction participants	– FCS of Russia
Description of the actions performed	
1. Generating and sending the request to obtain information on the medicine status	
List of information to be transferred, and the owner of information resource	UAIS of the customs authorities, through IEIS, transfers the request to MDLP System according to the information interaction format.

2. Registration and processing of the request to obtain information on the medicine status	
3. Generating and sending the response to the request to obtain information on the medicine status	
List of information to be transferred, and the owner of information resource	MDLP System, through IEIS, transfers the response to the request of medicine status information to the customs authorities UAIS according to the information interaction format.
4. Obtaining and checking of information, making a decision on the possibility of medicine release for domestic consumption	
5. Refusal of the customs authorities to release the medicines for domestic use (with reasonable grounds for rejection)	
6. Medicine release for domestic use by the customs authorities (without reasonable grounds for rejection)	
7. Medicine release for domestic use by the customs authorities with notification to authorized FEA (if no response to the request of customs authority UAIS is received from MDLP System)	
8. Generating and sending the information to MDLP System from the customs authorities UAIS on medicine release for domestic consumption	
List of information to be transferred, and the owner of information resource	UAIS of the customs authorities, through IEIS, transfers the information on medicine release for domestic consumption to MDLP System according to the information interaction format.
Special conditions	The customs authority UAIS sends a request for the medicine availability and status in MDLP System by its SGTIN or SSCC, depending on the type of packing specified in the goods declaration. For successful medicine release for domestic use, the requested SGTIN or SSCC status in MDLP System shall show the result of operations registered in MDLP System: - final packing completion outside the Russian Federation; - medicine shipping to the Russian Federation/medicine import to the Russian Federation (with acceptance); - medicine package marking in the customs control area (if

	marking is carried out at the customs warehouse); - ownership transfer for the medicine placed under the customs procedure of the customs warehouse (as required)

3.8. Transfer of Medicine, Produced in the Territory of the Russian Federation, to the Medicine Owner



Picture 20

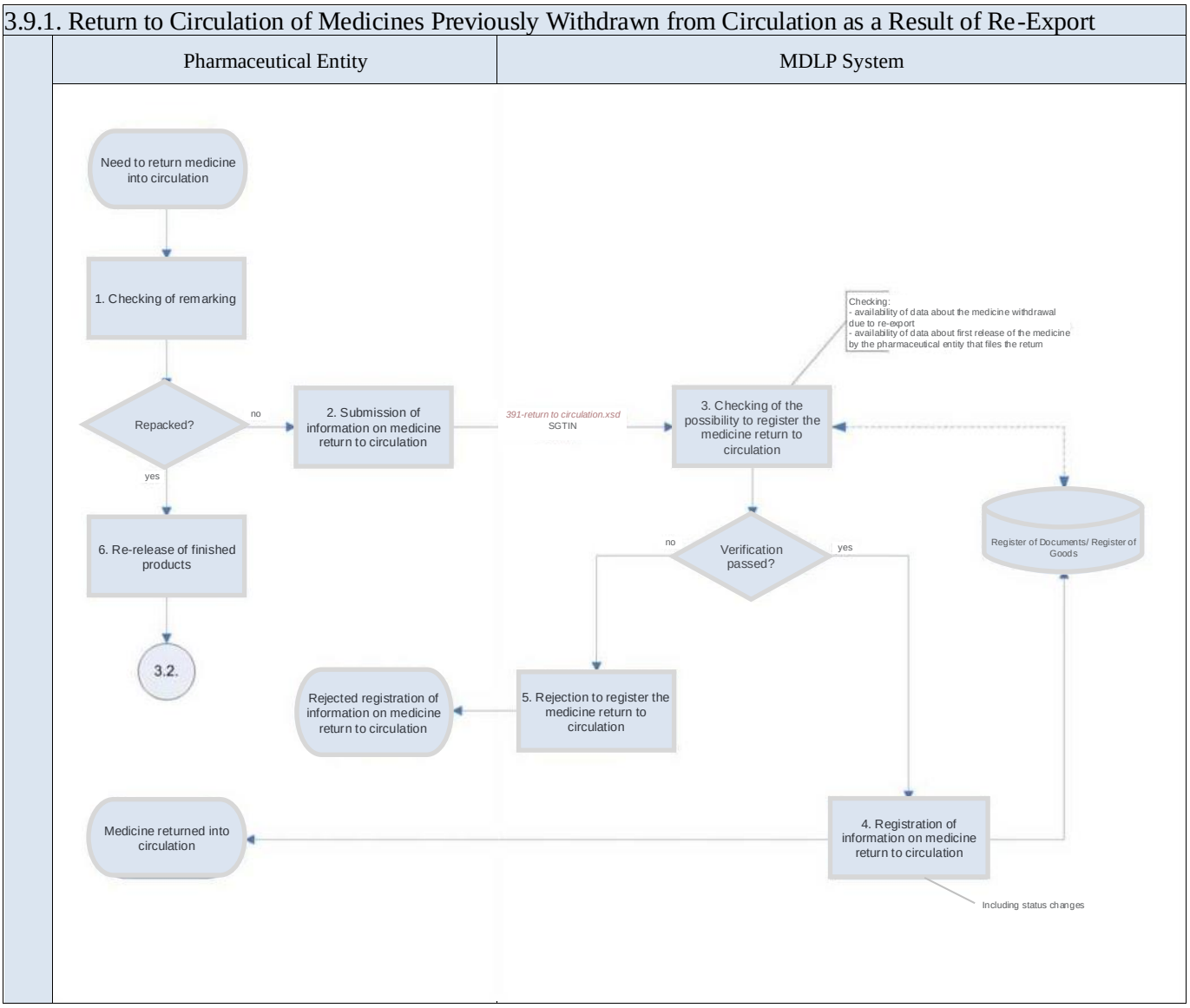
Annotation	If the owner of the produced medicine is an organization that is different from the medicine MAH and/or manufacturer specified in the production stages of the medicine marketing authorization, then the operation of medicine transfer to the medicine owner shall be registered in MDLP System Information on the medicine transfer to the owner is submitted to MDLP System by the pharmaceutical entity within 5 business days after the date of medicine transfer. In this case the owner confirms the information registered by the Russian manufacturer of the medicines within 5 business days after the date of medicine acceptance and registration in MDLP System of the information about such transferred medicines. If necessary, the owner can return the medicines shipped by the contract manufacturer. Information about the medicine return by owner to the manufacturer, which was in charge of the production stage of medicine packing (prepacking) in consumer packing, shall be registered in MDLP System in accordance with section 3.1.2 of these Passports of Processes.
Interaction participants	– contract manufacturer (Russian manufacturer of the medicine); – medicine owner
Description of the actions performed	
1. Medicine shipment to the medicine owner	
2. – 3. Registration of information on medicine shipment to the owner in the MDLP System by means of scheme 381-move_owner.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about the medicine shipment to the owner, the Russian medicine manufacturer sends the following information: – operation date; – identifier of the Russian medicine manufacturer's business place where the medicine is shipped from; – identifier of the medicine owner's business place where the medicine is accepted; – date of confirming primary document; – number of confirming primary document; – SGTIN and/or SSCC

<table>
<tr><td colspan="2">4. Notification of the owner about medicine shipment by means of scheme 603-move_owner_notification.xsd</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>Notification of the medicine owner about the medicine shipment is formed on the basis of the operation, which was earlier registered by the Russian medicine manufacturer, and contains the following data:
– operation date;
– identifier of the Russian medicine manufacturer’s business place where the medicine is shipped from;
– identifier of the medicine owner’s business place where the medicine is accepted;
– date of confirming primary document;
– number of confirming primary document;
– SGTIN and/or SSCC</td></tr>
<tr><td colspan="2">5. Medicine acceptance by the owner</td></tr>
<tr><td colspan="2">6. Checking by the medicine owner of the information previously registered by the Russian manufacturer about the medicine shipment to the owner</td></tr>
<tr><td colspan="2">7. – 8. Confirmation (acceptance) by the medicine owner of the information about medicine shipment by means of scheme 701-accept.xsd</td></tr>
<tr><td>List of information to be transferred</td><td>For confirmation (acceptance) of the information, previously registered by the Russian medicine manufacturer, about medicine shipment, the medicine owner ensures that the following data is sent to MDLP System:
– identifier of the medicine owner’s business place where the medicine is accepted;
– identifier of the Russian medicine manufacturer’s business place where the medicine is shipped from;
– operation date;
– SGTIN and/or SSCC
– confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes)</td></tr>
<tr><td colspan="2">9. Notice to the Russian medicine manufacturer about confirmation (acceptance) of</td></tr>
</table>

	medicine shipment information by the medicine owner by means of scheme 607-accept_notification.xsd
List of information to be transferred	The notice to the Russian medicine manufacturer about confirmation (acceptance) of medicine shipment information by the medicine owner is formed on the basis of the previously registered operation and contains the following information: – identifier of the medicine owner’s business place where the medicine is accepted; – identifier of the Russian medicine manufacturer’s business place where the medicine is shipped from; – operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC

3.9. Medicine Return to Circulation

3.9.1. Return to Circulation of Medicines Previously Withdrawn from Circulation as a Result of Re-Export

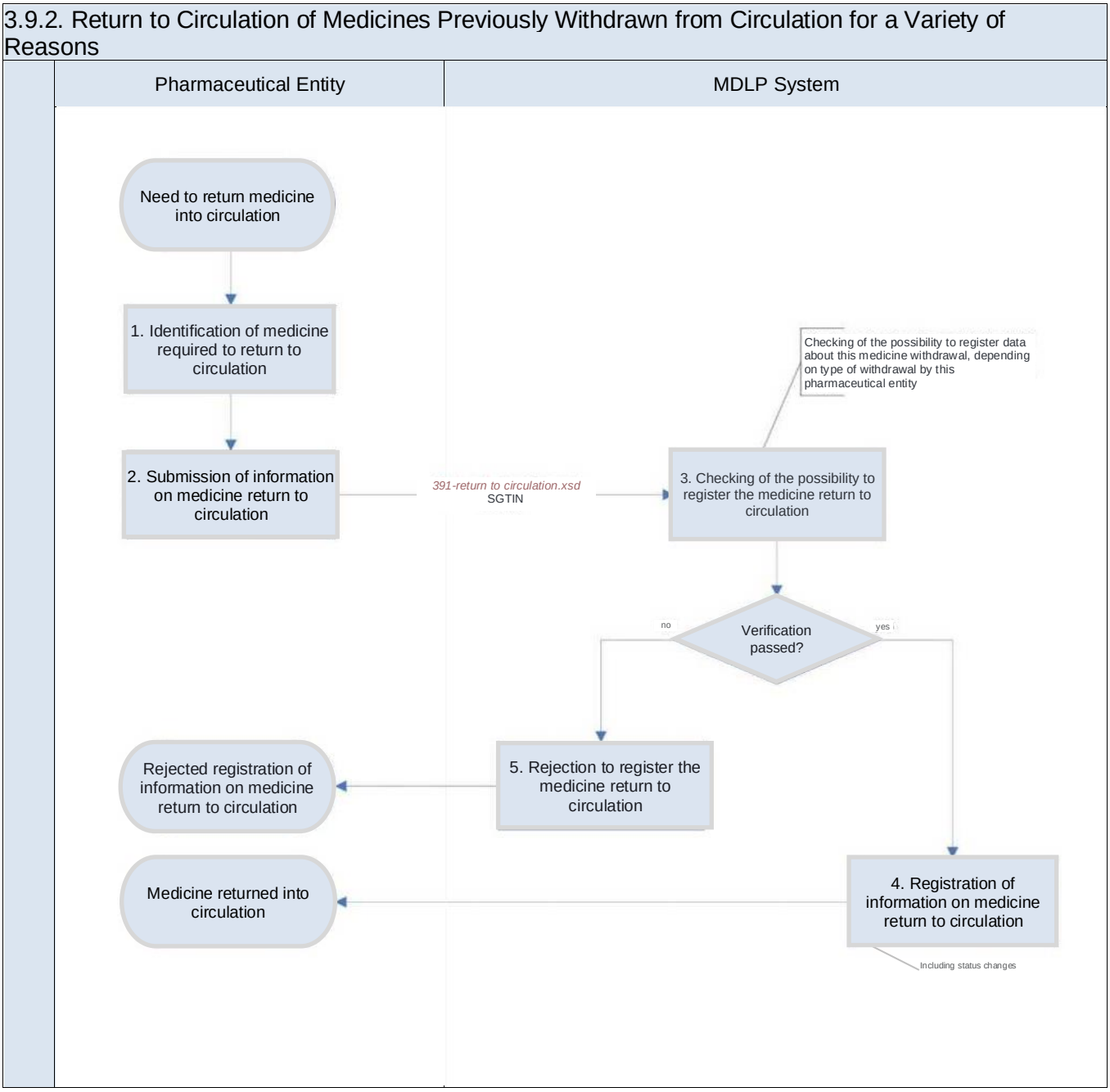


Picture 21

Annotation	If necessary, the pharmaceutical entity can return to circulation the medicine earlier withdrawn from circulation as a result of re-export. Operation of re-introduction into circulation is used for changing the status for allowing to perform further operations in MDLP System with medicines previously not introduced into civil circulation. Information on medicine return to circulation can be reported only by the pharmaceutical entity, which previously registered the information on medicine release outside the territory of the Russian Federation – MAH (or its representative office). Information on the medicine re-introduction into circulation is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the relevant operation. In case of repacking of the previously withdrawn medicine and applying new SGTINs, the pharmaceutical entity will register the operation in MDLP System in accordance with section 3.2 of these Passports of Processes.
Interaction participants	– MAH, or representative office of foreign MAH
Description of the actions performed	
1. Checking of remarking of the medicine previously withdrawn from circulation	
2. Submitting of information in MDLP System about medicine return into circulation (if the medicine was not remarked) by means of scheme 391-return_to_circulation.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about medicine return to circulation, the MAH (or its representative office) sends the following information to MDLP System: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – reason for medicine withdrawal from circulation; – SGTIN
3. Automatic checking of the possibility to register the operation of medicine return to circulation	
4. Registration of information about medicine return to circulation in MDLP	

System (if there are no reasons to reject)	
5. Rejection to register the information about medicine return to circulation (if there are any reasons to reject)	
List of reasons for rejection to register	– there is no information on medicine withdrawal from circulation as a result of re-export; – there is no information on medicine release by this pharmaceutical entity
6. Re-release of medicine with medicine repacking and remarking	

3.9.2. Return to Circulation of Medicines Previously Withdrawn from Circulation for a Variety of Reasons



Picture 22

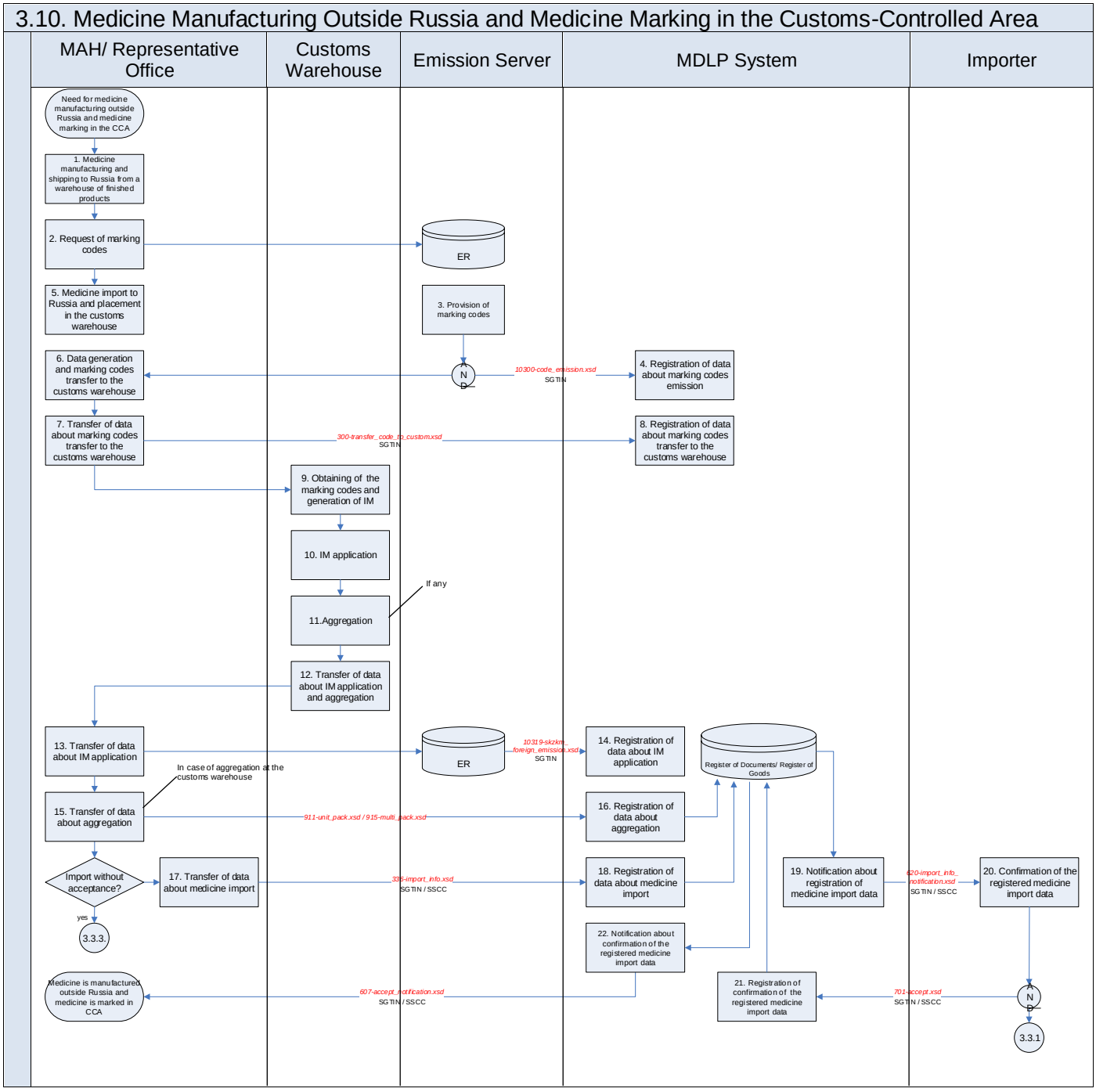
Annotation	If necessary, the pharmaceutical entity can return to circulation the medicine which was earlier withdrawn from circulation for a variety of reasons. Operation of re-introduction into circulation is used both for return into circulation of the medicines previously withdrawn from civil circulation, and for changing the status for that allowing to perform further operations in MDLP System with the medicines previously not introduced into civil circulation, as well as the medicines which are not for sale. The medicine may be returned to circulation only by the pharmaceutical entity that previously withdrew this medicine from circulation, except in the case of re-introduction into circulation of the medicine previously withdrawn from circulation as a result of write-off of the medicines during shipment within the closed contracts (agreements). In this case, data on re-introduction into circulation shall be registered by a pharmaceutical entity being a receiver of such medicines. Information on the medicine re-introduction into circulation is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the relevant operation. Medicine return to circulation in accordance with this section of the Passports of Processes can be applied to the medicines that were: – earlier selected as samples (deprecated operation 312) (type 3); – earlier selected as part of federal state supervision (surveillance) executed by Roszdravnadzor (type 7); – earlier withdrawn from circulation due to discarding (type 1); – earlier withdrawn from circulation as a result of retail sale (only for substandard medicine) (type 9); – earlier withdrawn as part of release by subsidized prescription (only for substandard medicine) (type 4); – earlier issued for health care delivery (only for substandard medicine) (type 5); – earlier withdrawn from circulation due to export (type 10); – earlier withdrawn from circulation due to the medicine export to the territory of EAEU member state (type 8); – earlier withdrawn from circulation due to shipment to unregistered participant (return from unregistered

	participant) (type 6); – earlier withdrawn from circulation for clinical studies (type 11); – earlier withdrawn from circulation as a result of release of the medicine in a pharmacy based on the documents (only for substandard medicine) (type 12); – earlier withdrawn from circulation within export of the medicine outside the territory of the Russian Federation (type 13); – earlier withdrawn from circulation with "sold at retail" withdrawal type within test purchase (type 9)
Interaction participants	– pharmaceutical entity that earlier withdrew the medicine from circulation; – pharmaceutical entity - a receiver of the medicines earlier withdrawn from circulation within the closed contracts (agreements)
Description of the actions performed	
1. Identification of the medicine required to return to circulation	
2. Submission to the MDLP System of information on medicine return to circulation by means of scheme 391-return_to_circulation.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the operation of medicine return to circulation, the pharmaceutical entity sends the following information to MDLP System: – date of operation; – registration number in MDLP System or identifier of the business place of the pharmaceutical entity that re-introduces into circulation; – reason for withdrawal from circulation; – reason for the return (adequate/inadequate quality); – date of the primary document (if any) or a date of the state contract on State defense order (in case of withdrawal from circulation within the closed contracts (agreements)); – number of the primary document (if any) or identifier of the state contract on State defense order (in case of withdrawal from circulation within the closed contracts (agreements));

	– SGTIN
3. Automatic checking of the possibility to register the operation of medicine return to circulation	
4. Registration of information about medicine return to circulation in MDLP System (if there are no reasons to reject)	
5. Rejection to register in MDLP System the information about medicine return to circulation (if there are any reasons to reject)	
List of reasons for rejection to register	– there is no information on the corresponding previously registered operation of medicine withdrawal from circulation; – there is no information on medicine withdrawal from circulation by the pharmaceutical entity that registers information on medicine return to circulation, except in the case of re-introduction into circulation of the medicines previously withdrawn from circulation as a result of write-off of the medicines during shipment within the closed contracts (agreements); – mismatch between an identifier of the state contract on State defense order and identifier that is specified in the operation of withdrawal from circulation within closed contracts (agreements)
Special conditions	For the medicines previously withdrawn from circulation as a result of sale, issue of the medicine in a pharmacy based on the documents, release on a preferential medicine prescription or release for medical treatment, re-introduction into circulation is allowed only for substandard medicines with indication of a relevant reason for return in operation 391. In case of re-introduction into circulation of the medicines previously withdrawn from circulation during shipment of the medicines within the closed contracts (agreements), a pharmaceutical entity being the medicine receiver must fill in the number of the primary document in the operation of re-introduction into circulation. The number shall correspond to the number of the supporting document which contains in accordance with Section 5.5 hereof an identifier of the state contract on State defense order assigned pursuant to article 6.1 of the Federal Law “On State Defense Order”. Conditions of the operation of medicine return to circulation with indication of the return reason (reason_return_type_enum)

	can be found in Appendix 2 herein. Re-introduction into circulation of the medicines previously sold at retail within test purchase will be available after an additional notification from the MDLP System operator to pharmaceutical entities

3.10. Medicine Manufacturing Outside the Russian Federation and Marking in the Customs-Controlled Area



Picture 2

Annotation	IM can be applied to each secondary (consumer) packing of a medicine (in its absence – the primary packing of a medicine) in the customs-controlled area for the medicines placed under the customs procedure of a customs warehouse, whose owner has a license for pharmaceutical activity at the warehouse address. IMs shall be applied in accordance with the requirements established by the law for the use of methods preventing separation of the IMs and / or the physical media having the IMs from the medicine packing without damaging it. MAH (or its representative office) shall order marking codes from the Operator of MDLP System, using an emission registrar before the medicine is placed under the customs procedure of a customs warehouse. Emission registrar is provided by transferring it to MAH (or representative office of foreign MAH), or by providing remote access to it via the information system of MAH (or representative office of foreign MAH). The decision on the choice of equipment is made by MAH independently. Marking codes shall be paid by the pharmaceutical entity not later than upon sending the report on identification means application in the customs-controlled area to MDLP System. Upon receiving the marking codes the MAH (or its representative office) shall transfer them to the customs warehouse for IM generation and application without using MDLP System. At the same time, the MAH (or its representative office) shall submit information that documents the marking code transfer to the customs warehouse in MDLP System. Submission of information about the marking codes transfer to the customs warehouse locks further operations with the marking codes until the IMs are applied at the customs warehouse and the MAH (or its representative office) transfers the corresponding information to MDLP System. By order of the MAH (or its representative office), the customs warehouse generates and applies IMs, aggregates the medicines (if necessary), transfers the information about IM application to the medicine packings and about aggregation to the MAH (or its representative office). The information is transferred without using MDLP System. Following the completion of IM application at the customs warehouse, the MAH (or its representative office) shall ensure the transfer of the information about IM application, using

	an emission registrar. After registration of the above information in MDLP System, “Marked in the customs-controlled area” emission type is assigned to SGTIN. In case of aggregation at customs warehouse the corresponding information shall be transferred in MDLP System by the MAH (or its representative office) upon transferring the information about IM application. Upon sending the report on identification means application or the information about aggregation, the MAH (or its representative office) shall register the information about importation terms and conditions for the medicines marked with IMs in customs-controlled area, and the importer shall confirm the information registered by the MAH (or its representative office). Information on the conditions of medicine import to the Russian Federation is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the medicine marking at the customs warehouse. In this case the importer confirms the registered information within 5 business days from the date of registration in MDLP System of the information about the conditions of medicine import to the Russian Federation. In case the MAH (or its representative office) is the importer, it shall register the information about importation terms and conditions in accordance with section 3.3.3. of these Passports of Processes. Registration of further information about the customs clearance in MDLP System shall be performed by the importer in accordance with section 3.3.1 of these Passports of Processes
Interaction participants	– MAH (or representative office of foreign MAH) – importer – customs warehouse
Description of the actions performed	
1. Medicine manufacturing and shipment to the Russian Federation without IM application	
2. Request for marking codes from the Operator of MDLP System using ER and according to the relevant API specification version of the Orders management station as of the date of order available on the official website of MDLP System	

operator (can be made in advance)	
3. Provision of marking codes to the pharmaceutical entity by the Operator of MDLP System	
4. Registration of marking codes emission information in MDLP System by means of scheme 10300-code_emission.xsd	
List of information to be transferred, and the owner of information resource	When registering information about the emission of marking codes in MDLP System, the following information is recorded: – emission date; – registration number of the MAH (or its representative office) in MDLP System; – identifier of order management station (OMS) provided by MDLP System Operator; – OMS marking codes order identifier; – GTIN; – SGTIN list
5. Medicine importation into the Russian Federation and placement in the customs-controlled area (customs warehouse) for IM application	
6. Generation of the required information and transfer of the marking codes to the customs warehouse for IM application, without using MDLP System	
List of information to be transferred, and the owner of information resource	The electronic document sent to customs warehouse for IM generation and application shall include the following information: – registration number of the MAH (or its representative office) in MDLP System; – GTIN; – production series number; – expiration date; – number of marking codes (maximum 10,000); – list of marking codes
7. – 8. Registration of information about the marking codes transfer to the customs warehouse by the MAH (or its representative office) in MDLP System by means of scheme 300-transfer_code_to_custom.xsd	
List of information	When registering in MDLP System the operations of marking

to be transferred, and the owner of information resource	code transfer to the customs warehouse, the MAH (or its representative office) sends the following information to MDLP System: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – GTIN; – identifier of the goods location in the customs-controlled area (customs warehouse); – SGTIN
9. Receiving marking codes at the customs warehouse and generating IMs for application to the medicine packings	
10. IM application to the secondary (consumer) packing of the medicine (and in absence of the medicine secondary packing – to the medicine primary packings) in the customs warehouse	
11. Medicine aggregation to the tertiary (shipping) packing in the customs warehouse (if necessary)	
12. Customs warehouse transferring the information about completion of IM application to the secondary (consumer) packing of the medicine (and in its absence – to the medicine primary packings), as well as the information about aggregation (if aggregation is performed at the customs warehouse) to the MAH (or its representative office), without using MDLP System	
13.– 14. Registration of information about IM application at the customs warehouse by the MAH (or its representative office) in MDLP System by means of scheme 10319-skzkm_foreign_emission.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the operations of IM application at customs warehouse, the MAH (or its representative office) sends the following information, using emission registrar and according to the relevant API specification version of the Orders management station as of the date of data submission available on the official website of MDLP System operator: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—foreign medicine manufacturer that packed / prepacked the medicine in

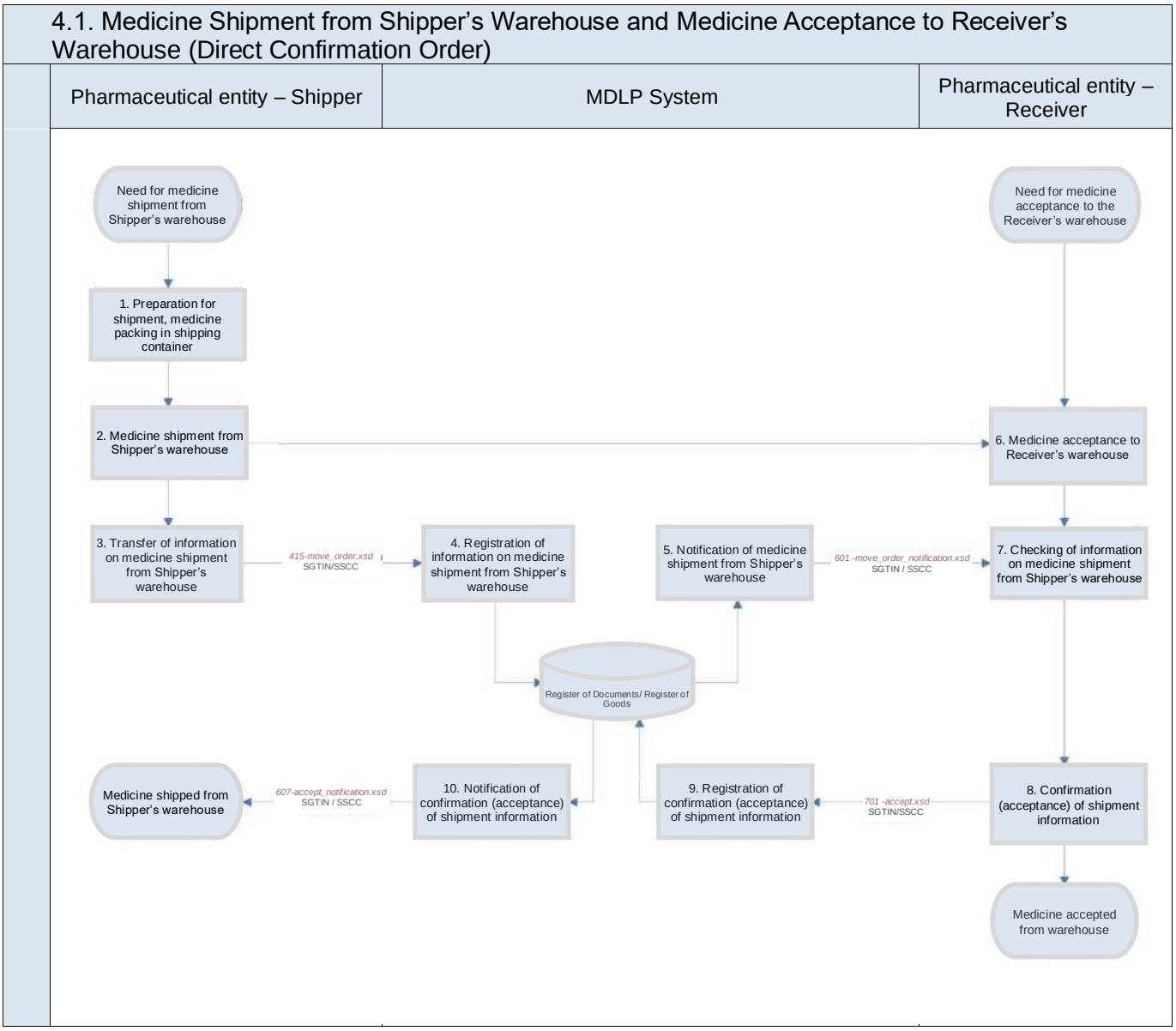
	secondary (tertiary) packing; – identifier of foreign counterparty—foreign medicine manufacturer that performed release quality control; – GTIN; – production series number; – expiration date; – indicator of IM application in the customs-controlled area; – identifier of the goods location in the customs-controlled area (customs warehouse); – SGTIN; – information about the emission registrar used for registration of information (unique identifier of emission registrar, unique identifier of the system which formed the message, identifier of marking code status change report)
15.– 16. Registration of information about aggregation by the MAH (or its representative office) in MDLP System (the list of information is given in section 9.1 of these Passports of Processes) by means of schemes 911-unit_pack.xsd / 915-multi_pack.xsd	
17.– 18. Registration of information about importation terms and conditions for the medicines marked in the customs warehouse and imported to the Russian Federation by the MAH (or its representative office) in MDLP System by means of scheme 336-import_info.xsd	
List of information to be transferred, and the owner of information resource	When registering the information about importation terms and conditions for the medicines marked in the customs warehouse and imported to the Russian Federation, the MAH (or its representative office) sends the following information: – date of transferring the importation terms and conditions information; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – registration number of the importer in MDLP System; – contract type; – date of the primary document; – number of the primary document;

	– SGTIN and/or SSCC
19. Notification of the importer about registration of the information about medicine importation terms and conditions in MDLP System by the MAH (or its representative office) by means of scheme 620-import_info_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the importer about registration of the information about the terms and conditions of the medicine importation to the Russian Federation is formed on the basis of the operation previously registered by the by MAH (or its representative office), and contains the following information: – operation date; – registration number of the MAH (or its representative office) in MDLP System; – identifier of foreign counterparty—medicine seller (if any); – registration number of the importer in MDLP System; – contract type; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
20.– 21. Confirmation (acceptance) by the importer of the information about the terms and conditions of the medicine importation to the Russian Federation registered by the MAH (or its representative office) by means of scheme 701-accept.xsd	
List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information about the terms and conditions of the medicine importation to the Russian Federation, the importer sends the following information to MDLP System: – registration number of the importer in MDLP System; – registration number of the MAH (or its representative office) in MDLP System; – operation date; – SGTIN and/or SSCC

22. Notification of the MAH (or its representative office) about confirmation (acceptance) by the importer of the information about the terms and conditions of the medicine importation to the Russian Federation by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the MAH (or its representative office) about confirmation (acceptance) by the importer of the information about the terms and conditions of the medicine importation to the Russian Federation is formed on the basis of the operation previously registered by the importer, and contains the following information: – registration number of the importer in MDLP System; – registration number of the MAH (or its representative office) in MDLP System; – operation date; – SGTIN and/or SSCC
Special conditions	According to the Regulations of the Track and Trace System, marking codes are ordered, identification means are applied and data are submitted to MDLP System by the issuer of identification means, thus the Marketing Authorization Holder (or its representative office) registration number in MDLP System specified for operation 10319 shall correspond to the Marketing Authorization Holder (or its representative office) registration number in MDLP System specified for operation 10300

4. Section “Medicine Circulation”

4.1. Medicine Shipment from Shipper’s Warehouse and Medicine Acceptance to Receiver’s Warehouse (Direct Confirmation Order)



Picture 24

Annotation	Registration of information on medicine circulation in MDLP System involves confirmation of operation information by both parties. If the direct data transfer and confirmation order is selected, the seller registers the information on medicine shipping to the buyer, and the buyer confirms the information on medicine shipment registered by the seller. Information on the medicine shipment to the receiver is submitted to MDLP System by the medicine shipper within 1 business day from the actual date of the medicine shipment. In this case the receiver confirms the information registered by the shipper within 1 business day from the date of the medicine acceptance and registration in MDLP System of the information about such shipped medicines The cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine delivery in tertiary (shipping) packages. If it is necessary to return the medicine, the buyer and the seller register the operations according to this section: the buyer acts as the shipper, and the seller acts as the receiver. The shipper registers the information in MDLP System on shipment with the appropriate type “Return to Supplier”. Information on return of the medicine from the buyer shall be submitted by the medicine shipper to MDLP System within 1 business day from the actual date of the medicine shipment. And a receiver of the returned medicines shall confirm data registered by the shipper, within 30 business days from the date when the medicines are accepted. In case of medicine shipping within state medicine provision, the information on medicine movement will be available in the user account of the relevant state authority for which the medicine is procured at the expense of the federal or regional budget. The information in MDLP System about medicine shipment within state medicine provision is registered by the shipper according to this section of the Passport of Processes in case of “direct” delivery to the medicine issue places (without using intermediate warehouse of the logistics service provider), or in case of medicine shipment to the warehouse of the logistics service provider for further medicine transfer to places of issue
Interaction	– pharmaceutical entity that sells the medicine (shipper);

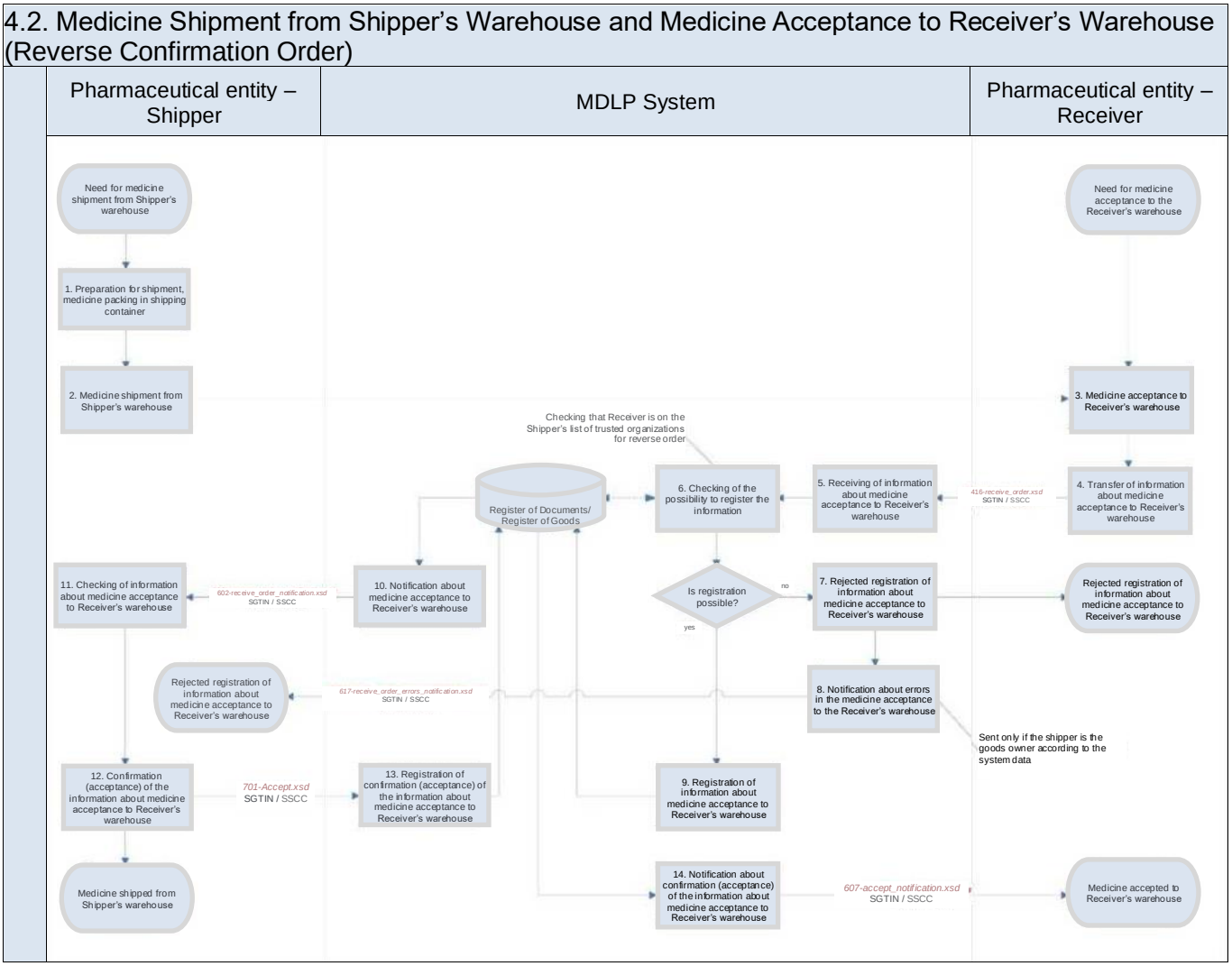
participants	– pharmaceutical entity that buys the medicine (receiver)
Description of the actions performed	
1. Preparation for shipment, medicine packing in shipping container	
2. Medicine shipment from shipper's warehouse	
3. – 4. Registration of information on medicine shipment from shipper's warehouse in the MDLP System by means of scheme 415-move_order.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the operation of medicine shipment, the shipper sends the following information to MDLP System: – operation date; – identifier of the shipper's business place where the medicine has been shipped from; – identifier of the receiver's business place where the medicine is accepted; – type of operation of shipping from warehouse (sale, return to supplier); – source of finance; – contract type; – register contract number (in case of medicine shipment within state medicine provision); – date of the shipping document; – number of the shipping document; – medicine selling price, RUB (VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero); – SGTIN and/or SSCC. If it is required to indicate different prices inside of a group packing, the shipper shall send the following additional data for SSCC: – GTIN; – production series number; – medicine selling price, RUB (for the specified GTIN and series numbers, VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero);
5. Notification of the receiver about medicine shipment from shipper's warehouse	

by means of scheme 601-move_order_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the receiver about the medicine shipment is formed on the basis of the operation, which was earlier registered by the shipper, and contains the following data: – operation date; – identifier of the shipper's business place where the medicine has been shipped from; – identifier of the receiver's business place where the medicine is accepted; – type of operation of shipping from warehouse (sale, return to supplier); – source of finance; – contract type; – register contract number (in case of medicine shipment within state medicine provision); – shipping document details (number and date); – medicine selling price, RUB (VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero); – SGTIN and/or SSCC. If different prices have been specified within the group package: – GTIN; – production series number; – medicine selling price, RUB (for the specified GTIN and series numbers, VAT included); VAT amount, RUB (if no VAT is applicable; specify zero);
6. Medicine acceptance to the receiver's warehouse	
7. Checking by the receiver of the information on medicine shipment from shipper's warehouse	
8. – 9. Confirmation (acceptance) by the receiver of the information on medicine shipment from shipper's warehouse by means of scheme 701-accept.xsd	
List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information, previously registered by the shipper, about medicine shipment, the receiver ensures that the following data is sent to MDLP System: – identifier of the receiver's business place where the

	medicine is accepted; – identifier of the shipper's business place where the medicine is shipped from; – operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC
10.Notification of the shipper about confirmation (acceptance) by the receiver of the information on medicine shipment from shipper's warehouse by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the shipper about confirmation (acceptance) by the receiver of the information on medicine shipment is formed on the basis of the previously registered operation and contains the following information: – identifier of the receiver's business place where the medicine is accepted; – identifier of the shipper's business place where the medicine is shipped from; – operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes) – SGTIN and/or SSCC
Special conditions	MDLP System records the actual value of the medicine consumer packing unit, which shall correspond to the value of the medicine consumer packing unit reflected in the accompanying documents. At the same time, the unit value is calculated according to the formula "Total value of the batch with VAT / quantity" with rounding to the whole kopek according to the rule "to the nearest whole". Under this approach, the inverse calculation results (consumer packing unit value*quantity) will cause a difference between the total value of the batch and the total amount of VAT provided by the supplier in the accompanying documents for minor mathematical error occurred due to rounding. It is also allowed when the actual values of the consumer packing units are specified in MDLP FGIS in accordance with the

	consignment note, but the indicated sum of all consumer packing values is lower than the state contract value by less than one consumer packing value. These discrepancies do not constitute grounds for the consignee's refusal to recognize the medicine on the basis of the data contained in the accompanying documents. When entering information on the financing source, it is necessary to take into account the contract (agreement) requirements and follow the following rules: – source type "1 - own funds" is used for delivery of the medicine with payment from own funds; – source type "2 - federal funds" is used for delivery of the medicine with payment only from the federal budget resources; – source type "3 - regional funds" is used for delivery of the medicine with payment only from the regional funds; – source type "4 - budget funds of non-budgetary foundations" is used for delivery of the medicine with payment only from the budgets of compulsory medical insurance funds, social insurance fund; – source type "5 - mixed budget funds" is used for delivery of the medicine with combined payment from the different sources specified in types 1 - 4. If at the time of the data registration there is no registry number, procurement notice number may be specified instead of the contract registry number. When specifying value 2 (federal funds) as the financing source, it is recommended to specify the following contract type value: 6 (state medicine provision)

4.2. Medicine Shipment from Shipper's Warehouse and Medicine Acceptance to Receiver's Warehouse (Reverse Confirmation Order)



Picture 25

Annotation	Registration of information on medicine circulation in MDLP System involves confirmation of operation information by both parties. Wholesale trade organizations, within preparation for medicine sale, can provide order picking using specialized equipment. Automated order picking makes the identification of each medicine secondary (consumer) packing a quite time-consuming procedure, and therefore, in order to ensure traceability of each secondary (consumer) packing, it is assumed that packages can be identified at the time of goods acceptance by the buyer. If the reverse data transfer and confirmation order is selected, the receiver shall register the information on medicine acceptance to warehouse, and the shipper shall confirm the information on medicine acceptance to the buyer's warehouse. The reverse data confirmation order requires registration of a list of authorized counterparties—receivers in the shipper's user account. Information on the medicine acceptance is submitted to MDLP System by the medicine receiver within 1 business day from the date of the medicine acceptance. In this case the shipper confirms the information registered by the receiver within 1 business day from the date of registration in MDLP System of the information about such accepted medicines. The cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine acceptance in tertiary (shipping) packages. If it is necessary to return the medicine, seller and buyer shall register operations in accordance with this section - a buyer acts as a shipper, and a seller acts as a receiver. A receiver shall register information about acceptance in the MDLP System with the "Return from buyer" type. Information on return of the medicine from the buyer shall be submitted by the medicine receiver to the MDLP System within 30 business day from the date of the medicine acceptance. And the shipper shall confirm the data registered by the receiver, within 1 business day from the date when data on accepted medicines are registered in the MDLP System. In case of medicine acceptance within state medicine provision,

	the information on medicine movement will be available in the user account of the relevant state authority for which the medicine is procured at the expense of the federal or regional budget. The information about medicine acceptance within state medicine provision is registered in MDLP System according to this section of the Passports of Processes by the receiver that acts as the place of medicine issue, or the logistic services supplier for further medicine transfer to places of issue
Interaction participants	– pharmaceutical entity that sells the medicine (shipper); – pharmaceutical entity that buys the medicine (receiver)
Description of the actions performed	
1. Preparation for shipment, medicine packing in shipping container	
2. Medicine shipment from shipper's warehouse	
3. Medicine acceptance to the receiver's warehouse	
4. – 5. Submission of information about medicine acceptance to the receiver's warehouse in MDLP System by means of scheme 416-receive_order.xsd	
List of information to be transferred, and the owner of information resource	When registering the results of medicine acceptance to the warehouse in MDLP System, the receiver sends the following information: – operation date; – identifier of the receiver's business place where the medicine has been accepted; – identifier of the shipper's business place where the medicine has been shipped from; – type of warehouse acceptance operation (arrival, return from buyer); – source of finance; – contract type; – register contract number (in case of medicine acceptance within state medicine provision); – date of the shipping document; – number of the shipping document; – medicine purchasing price, RUB (VAT included);

	– VAT amount, RUB (if no VAT is applicable; specify zero); – SGTIN and/or SSCC. If it is required to indicate different prices inside of a group packing, the receiver shall send the following additional data for SSCC: – GTIN; – production series number; – medicine purchasing price, RUB (for the specified GTIN and series number, VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero);
6. Checking of the possibility to register the operation of medicine acceptance to the receiver's warehouse (availability of the pharmaceutical entities on the list of trusted counterparties)	
7. Rejection to register the information about medicine acceptance to the receiver's warehouse (if the receiver is not on the list of trusted counterparties of the shipper)	
8. Notification of the shipper about errors in the medicine acceptance to the receiver's warehouse by means of scheme 617-receive_order_errors_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the shipper about errors in the medicine acceptance to the receiver's warehouse contains the following information: – operation date; – identifier of the receiver's business place where the medicine is accepted; – identifier of the shipper's business place where the medicine has been shipped from; – error code; – error description; – SGTIN and/or SSCC with failed acceptance registration
9. Registration of information about medicine acceptance to the receiver's warehouse in MDLP System (if there are no reasons to reject)	
10. Notification of the shipper about medicine acceptance to the receiver's warehouse by means of scheme 602-receive_order_notification.xsd	

List of information to be transferred, and the owner of information resource	Notification of the shipper about medicine acceptance to the receiver's warehouse is formed on the basis of the operation, which was previously registered by the receiver, and contains the following information: – operation date; – identifier of the receiver's business place where the medicine has been accepted; – identifier of the shipper's business place where the medicine has been shipped from; – type of warehouse acceptance operation (arrival, return from buyer); – source of finance; – contract type; – register contract number (in case of medicine acceptance within state medicine provision); – date of the shipping document; – number of the shipping document; – medicine purchasing price, RUB (VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero); – SGTIN and/or SSCC. If different prices have been specified within a group package, the notification will additionally contain the following information: – GTIN; – production series number; – medicine purchasing price, RUB (for the specified GTIN and series number, VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero);
11.Checking by the shipper of the information about medicine acceptance to the receiver's warehouse	
12.– 13. Confirmation (acceptance) by the shipper of the information about medicine acceptance to the receiver's warehouse by means of scheme 701-accept.xsd	
List of information to be transferred,	For confirmation (acceptance) of the information, registered by the receiver, about medicine warehouse acceptance, the receiver

and the owner of information resource	sends the following data to MDLP System: – identifier of the shipper's business place where the medicine has been shipped from; – identifier of the receiver's business place where the medicine has been accepted; – operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC
14. Notification of the receiver about confirmation (acceptance) by the shipper of the information on medicine acceptance to the receiver's warehouse by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the receiver about confirmation (acceptance) by the shipper of the information on medicine acceptance to the receiver's warehouse is formed on the basis of the previously registered operation and contains the following information: – identifier of the shipper's business place where the medicine has been shipped from; – identifier of the receiver's business place where the medicine has been accepted; – operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes) – SGTIN and/or SSCC
Special conditions	MDLP System records the actual value of the medicine consumer packing unit, which shall correspond to the value of the medicine consumer packing unit reflected in the accompanying documents. At the same time, the unit value is calculated according to the formula "Total value of the batch with VAT / quantity" with rounding to the whole kopek according to the rule "to the nearest whole". Under this approach, the inverse calculation results (consumer packing unit value*quantity) will cause a difference

	between the total value of the batch and the total amount of VAT provided by the supplier in the accompanying documents for minor mathematical error occurred due to rounding. It is also allowed when the actual values of consumer packing units are specified in MDLP FGIS in accordance with the consignment note, but the indicated sum of all consumer packing values is lower than the state contract value by less than one consumer packing value. These discrepancies do not constitute grounds for the consignee's refusal to recognize the medicine on the basis of the data contained in the accompanying documents. When entering information on the financing source, it is necessary to take into account the contract (agreement) requirements and follow the following rules: – source type "1 - own funds" is used for delivery of the medicine with payment from own funds; – source type "2 - federal funds" is used for delivery of the medicine with payment only from the federal budget resources; – source type "3 - regional funds" is used for delivery of the medicine with payment only from the regional funds; – source type "4 - budget funds of non-budgetary foundations" is used for delivery of the medicine with payment only from the budgets of compulsory medical insurance funds, social insurance fund; – source type "5 - mixed budget funds" is used for delivery of the medicine with combined payment from the different sources specified in types 1 - 4. If at the time of the data registration there is no registry number, procurement notice number may be specified instead of the contract registry number. When specifying value 2 (federal funds) as the financing source, it is recommended to specify the following contract type value: 6 (state medicine provision) It is not allowed to submit information in line with this section with regard to the medicines with international non-proprietary name "Ethanol" and medicines which contain narcotics, psychotropic substances, and their precursors and which are included into Section I of the list of the medicines for medical use which are medicines containing controlled substances, approved by authorized federal executive authority in accordance with Article 581 of the Federal Law "On Medicine

	Circulation" (before August 31, 2024 - the Order of the Ministry of Health of the Russian Federation of April 22, 2014 No. 183n, from September 1, 2024 - the Order of the Ministry of Health of the Russian Federation of September 1, 2023 No. 459n)

4.2.1 Medicine Shipment from Shipper's Warehouse and Medicine Acceptance to Receiver's Warehouse by means of posting operation without confirmation (acceptance)

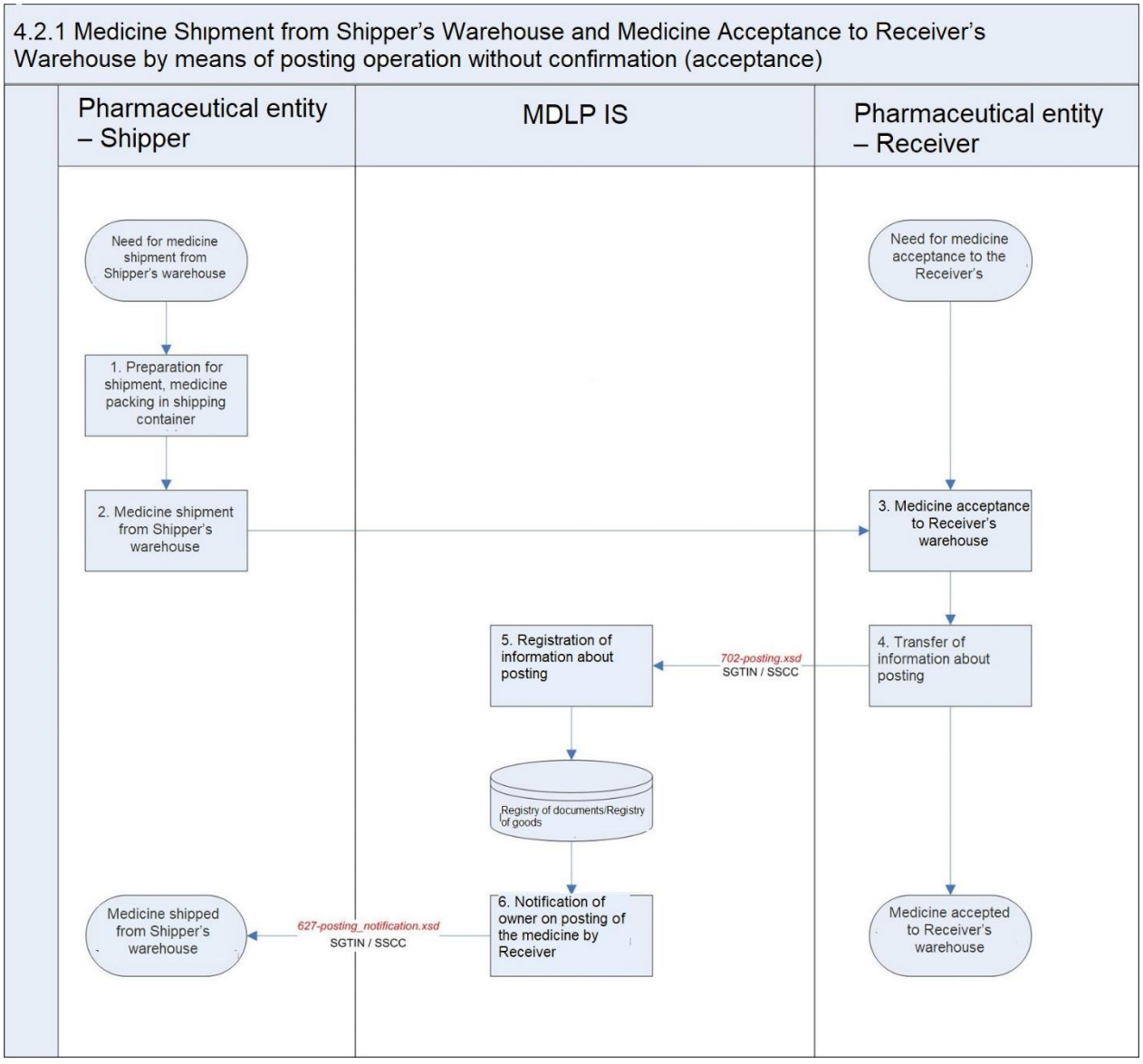


Figure 3

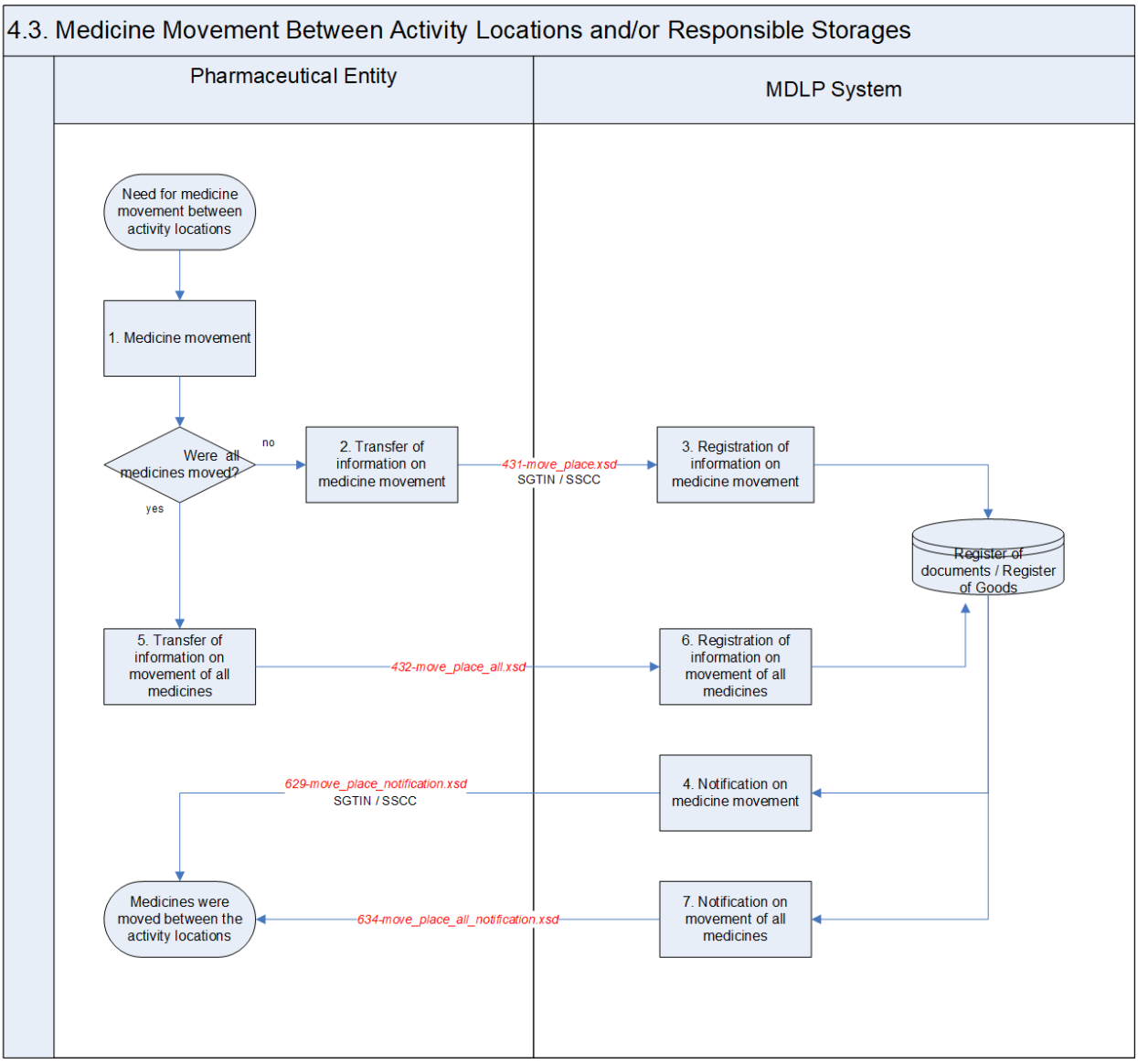
Annotation	Information on the medicine acceptance can be registered by the Receiver without Shipper's confirmation (acceptance) (if mutually agreed by the parties (Shipper and Receiver)). The veracity of the information on the medicine acceptance submitted to MDLP System by the Receiver by means of the posting operation is confirmed by MDLP System Operator. Information on the medicine posting shall be submitted by the medicine Receiver to MDLP System within 1 business day from the date of the medicine acceptance. In the registered information on medicine acceptance, including as part of return, medicine consignor shall coincide with the current medicine owner according to MDLP System. In the registered operation the medicine cost shall always be given per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – as well as upon the medicine acceptance in tertiary (shipping) packings. If there is a need to return the medicines for which a posting operation was previously registered, during return the supplier shall record the information in accordance with the current section of the Process Passports
Interaction participants	– pharmaceutical entity that sells the medicine (shipper); – pharmaceutical entity that buys the medicine (receiver)
Description of the actions performed	
1. Preparation for shipment, medicine packing in shipping container	
2. Medicine shipment from shipper's warehouse	
3. Medicine acceptance to the receiver's warehouse	
4. – 5. Registration in MDLP System of information on posting of the medicine at the receiver's warehouse by means of scheme 702-posting.xsd	
List of information to be transferred, and the owner of information resource	When registering the results of medicine acceptance to the warehouse by means of the posting operation in MDLP System, the receiver sends the following information: – operation date; – identifier of the receiver's business place where the medicine has been accepted; – identifier of the shipper's business place from which the medicines

	have been shipped or TIN/KPP of shipper (it is allowed when data are registered with indication of the “misgrading” operation type); – type of the posting operation (arrival, return from buyer, misgrading); – source of finance; – contract type; – register contract number (in case of medicine posting within state medicine provision); – date of the shipping document; – number of the shipping document; – medicine purchasing price, RUB (VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero); – SGTIN and/or SSCC. If it is required to indicate different prices inside of a group packing, the receiver shall send the following additional data for SSCC: – GTIN; – production series number; – medicine selling price, RUB (for the specified GTIN and series numbers, VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero)
6. Notification of the medicine owner in accordance with MDLP System data about medicine posting by means of scheme 627-posting_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the medicine owner in accordance with MDLP System data about medicine posting contains the following data: – operation date; – identifier of the receiver’s business place where the medicine has been accepted; – TIN of provider specified in the posting operation; – name of provider specified in the posting operation; – identifier of the medicine owner in MDLP System; – list of posted SGTIN and/or SSCC
Special conditions	MDLP System records the actual value of the medicine consumer packing unit, which shall correspond to the value of the medicine consumer

	packing unit reflected in the accompanying documents. At the same time, the unit value is calculated according to the formula “Total value of batch with VAT / quantity” with rounding to the whole kopek according to the rule “to the nearest whole”. Under this approach, the inverse calculation results (consumer packing unit value*quantity) will cause a difference between the total value of the batch and the total amount of VAT provided by the supplier in the accompanying documents for minor mathematical error occurred due to rounding. It is also allowed when the actual values of consumer packing units are specified in MDLP FGIS in accordance with the consignment note, but the indicated sum of all consumer packing values is lower than the state contract value by less than one consumer packing value. These discrepancies do not constitute grounds for the consignee’s refusal to recognize the medicine on the basis of the data contained in the accompanying documents. When entering information on the financing source, it is necessary to take into account the contract (agreement) requirements and follow the following rules: – source type “1 - own funds” is used for delivery of the medicine with payment from own funds; – source type “2 - federal funds” is used for delivery of the medicine with payment only from the federal budget resources; – source type “3 - regional funds” is used for delivery of the medicine with payment only from the regional funds; – source type “4 - budget funds of non-budgetary foundations” is used for delivery of the medicine with payment only from the budgets of compulsory medical insurance funds, social insurance fund; – source type “5 - mixed budget funds” is used for delivery of the medicine with combined payment from different sources specified in types 1 - 4. If at the time of the data registration there is no registry number, procurement notice number may be specified instead of the contract registry number. When specifying value 2 (federal funds) as the financing source, it is recommended to specify the following contract type value: 6 (state medicine provision). Posting operation is only used for the medicines introduced into civil circulation. When using “arrival” and “return from the buyer” posting operation types, consignor shall coincide with the current medicine owner according to

	MDLP System. Use of “regrading” posting operation type is allowed in case of the need to register information on acceptance of the medicines in respect of which regrading has been allowed by the pharmaceutical entities, which are not counterparties for this operation, in case of violation of registration of information on transfer of medicines on the supply chain and impossibility of correction of information on operation by the counterparty, as well as in case of updating the balance in case of absence of relevant information on the medicine consignor (in this case, a pharmaceutical entity, which registers acceptance information, shall be specified as the consignor). It is not allowed to submit information in line with this section with regard to the medicines being part of the list of high-cost nosologies, the medicines with international non-proprietary name “Ethanol” and medicines which contain narcotics, psychotropic substances, and their precursors and which are included into Section I of the list of the medicines for medical use which are medicines containing controlled substances, approved by authorized federal executive authority in accordance with Article 58^1 of the Federal Law “On Medicine Circulation” (before August 31, 2024 - the Order of the Ministry of Health of the Russian Federation of April 22, 2014 No. 183n, from September 1, 2024 - the Order of the Ministry of Health of the Russian Federation of September 1, 2023 No. 459n). It is allowed to submit information in line with this section about return of the medicines with international non-proprietary name “Ethanol” and medicines which contain narcotics, psychotropic substances, and their precursors in case if information on posting of the medicine at the receiver’s warehouse by means of scheme 702-posting.xsd is registered for the medicines mentioned until September 1, 2023.

4.3. Medicine Movement Between Activity Locations and/or Responsible Storages



Picture 27

Annotation	MDLP System provides the possibility to register the medicine movements between different business places (according to license) inside a pharmaceutical entity and/or responsible medicine storages. Information on the medicine transfer is submitted to MDLP System by the pharmaceutical entity within 5 business days from the actual date of the medicine transfer. In case of medicine movement within state medicine provision, the information on medicine movement will be available in the user account of the relevant state authority for which the medicine is procured at the expense of the federal or regional budget. The information on medicine movement within state medicine provision is registered in MDLP System according to this section of the Passports of Processes by the logistic services supplier if its subdivision is the place of medicine issue. If it is necessary to move all medicines located at the business place to another business place, a pharmaceutical entity shall transmit the information in accordance with paras 5 - 6 of this section
Interaction participant	– pharmaceutical entity that moves the medicine
Description of the actions performed	
1. Medicine movement between different business places and/or responsible storages by the pharmaceutical entity	
2. – 3. Registration of information about medicine movement between different business places and/or responsible storages in MDLP System by means of scheme 431-move_place.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about medicine movement between different business places and/or responsible storages, the pharmaceutical entity sends the following information: – operation date; – identifier of the pharmaceutical entity's business place/ responsible storage where the medicine has been shipped from; – identifier of the pharmaceutical entity's business place/ responsible storage where the medicine has been accepted;

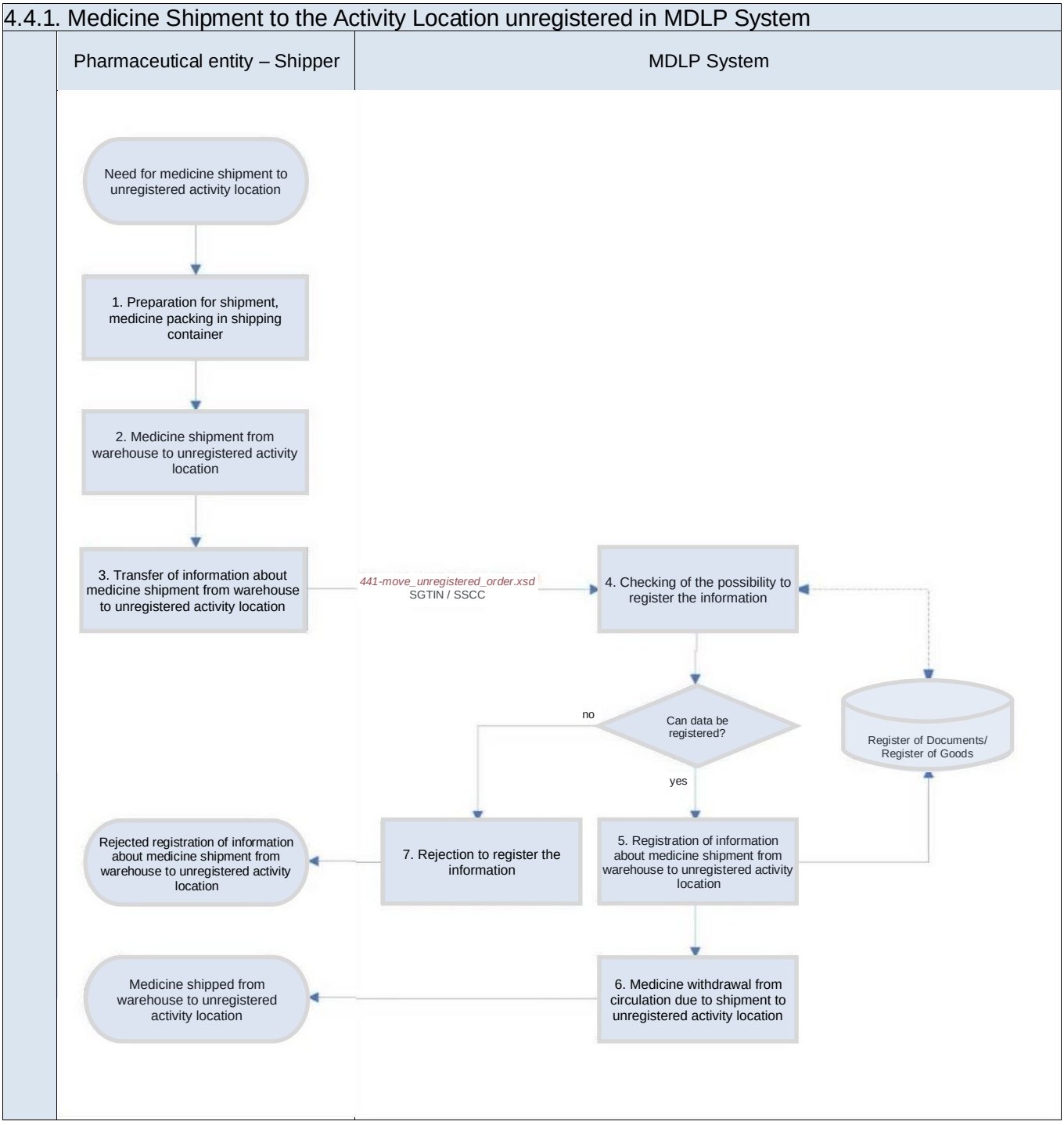
	– date of the movement document; – number of the movement document; – SGTIN and/or SSCC

4. Notification to receiver on movement of the medicines between different business places and / or responsible storages using scheme 629-move_place_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification to receiver of the medicine on movement of the medicines between different business places contains the following information: – operation date; – identifier of the pharmaceutical entity's business place/responsible storage where the medicine has been shipped; – identifier of the pharmaceutical entity's business place/responsible storage where the medicine has been accepted; – date of the movement document; – number of the movement document; – SGTIN and/or SSCC
5. – 6. Registration in MDLP System of information on movement of all medicines between different business places and / or responsible storages 432-move_place_all.xsd	
List of information to be transferred, and the owner of information resource	To register results of movement of all medicines between different business places and / or responsible storages with the MDLP System, the pharmaceutical entity sends the following information: – operation date; – identifier of the pharmaceutical entity's business place/responsible storage where the medicine has been shipped; – identifier of the pharmaceutical entity's business place/responsible storage where the medicine has been accepted; – date of the movement document; – number of the movement document

7. Notification to receiver on movement of all medicines between different business places and / or responsible storages using scheme 634-move_place_all_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification to receiver of the medicine on movement of all medicines between different business places and / or responsible storages contains the following information: – operation date; – identifier of the pharmaceutical entity's business place/responsible storage where the medicine has been shipped; – identifier of the pharmaceutical entity's business place/responsible storage where the medicine has been accepted; – date of the movement document; – number of the movement document; – identifier of operation (on movement of all medicines) previously registered in the MDLP System

4.4. Medicine Circulation If the Pharmaceutical Entity Is Not Registered in MDLP System, or the Activity Location Is Not Registered in MDLP System According to the License of the Pharmaceutical Entity That Is Registered in MDLP System

4.4.1. Medicine Shipment to an Activity Location Unregistered in MDLP System (Including to a Pharmaceutical Entity Unregistered in MDLP System)



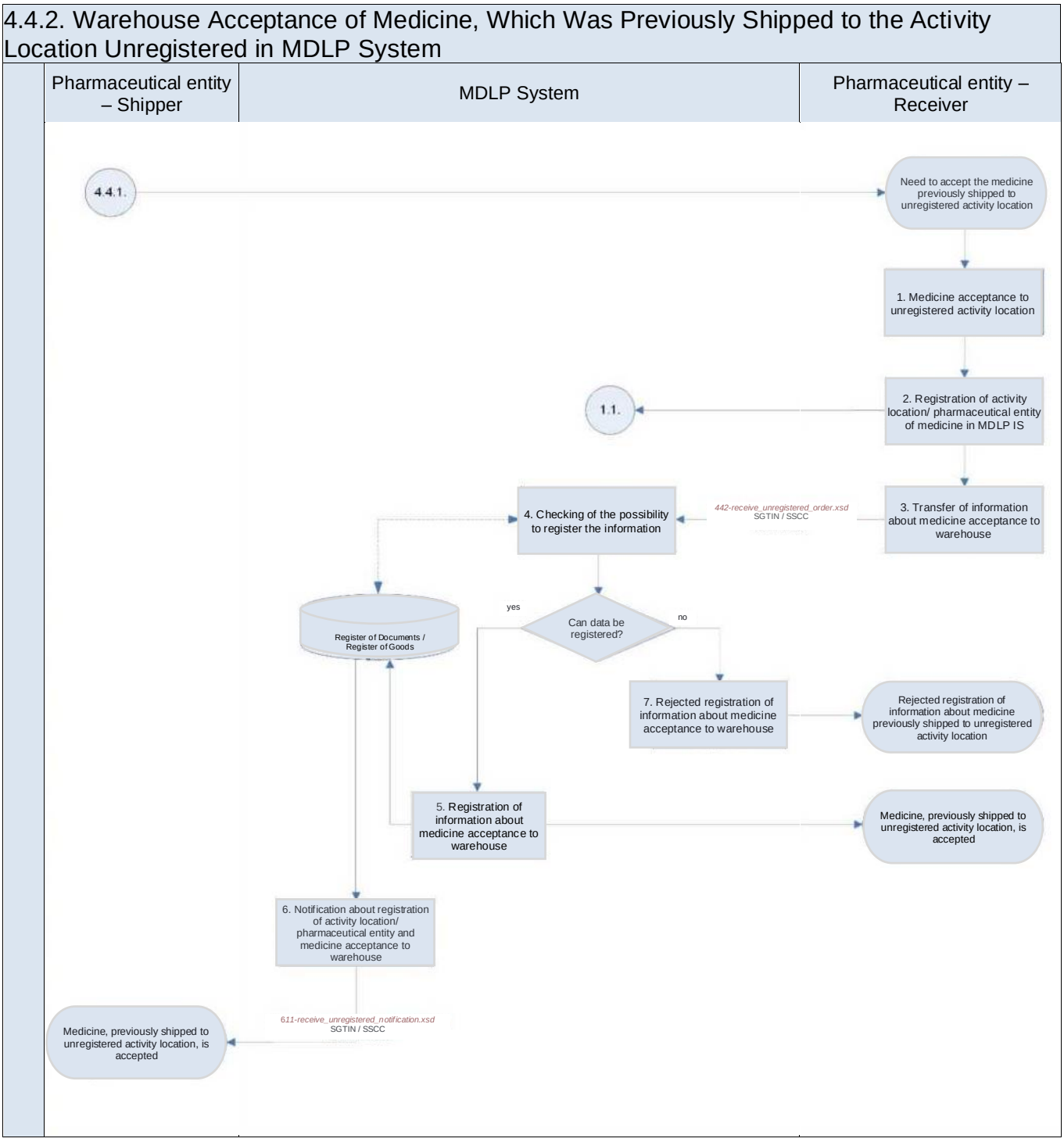
Picture 28

Annotation	The shipper can ship the medicine to the business place unregistered in MDLP System according to license in the following cases: – the receiver is not registered in MDLP System; – the business place is not registered in MDLP System according to the license of the receiver that is registered in MDLP System; Information on the medicine shipment is submitted to MDLP System by the pharmaceutical entity within 5 business days from the actual date of the medicine transfer The cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine delivery in tertiary (shipping) packages. In this case the shipped medicine shall be withdrawn from circulation. It is not allowed to register information in accordance with this section herein with regard to the medicines shipped within state activities on medicine provision, except for shipment of the medicines to newly annexed territories (Donetsk People's Republic, Luhansk People's Republic, Zaporizhzhia oblast and Kherson oblast). The territories specified can have any financing source
Interaction participants	– pharmaceutical entity that ships the medicine (shipper)
Description of the actions performed	
1. Preparation for shipment, medicine packing in shipping container	
2. Medicine shipment from the shipper’s warehouse to unregistered business place	
3. Submission to MDLP System of the information about medicine shipment to an business place unregistered in MDLP System (including to a pharmaceutical entity unregistered in MDLP System) by means of scheme 441-move_unregistered_order.xsd	
List of information to be transferred, and the owner of	When registering in MDLP System the operation of medicine shipment to an business place unregistered in MDLP System (including to a pharmaceutical entity unregistered in MDLP System), the shipper sends the following information:

information resource	– operation date; – identifier of the shipper's business place where the medicine is shipped from; – TIN of the receiver (if the receiver is not registered in MDLP System) or registration number of the receiver in MDLP System (if the business place in not registered in MDLP System); – contract type; – date of the shipping document; – number of the shipping document; – medicine selling price, RUB (VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero); – SGTIN and/or SSCC. If it is required to indicate different prices inside of a group packing, the shipper shall send the following additional data for SSCC: – GTIN; – production series number; – medicine selling price, RUB (for the specified GTIN and series numbers, VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero);
4. Checking of the possibility to register the information about medicine shipment to an business place unregistered in MDLP System	
5. Registration of information about medicine shipment from warehouse to an business place unregistered in MDLP System (if there are no reasons to reject)	
6. Medicine withdrawal from circulation due to medicine shipment to an business place unregistered in MDLP System	
7. Rejection to register the information about medicine shipment to an business place unregistered in MDLP System (if there are any reasons to reject)	
List of reasons for rejection to register the	– the receiver is registered in MDLP System (if the medicine is shipped to a pharmaceutical entity unregistered in MDLP System, and TIN of the receiver is specified);

information	– the receiver is not registered in MDLP System (if the medicine is shipped to an business place unregistered in MDLP System, and the MDLP System registration number of the receiver is specified); – the receiver is not a resident of the Russian Federation
Special conditions	It is not allowed to use this operation if the medicine is transferred to the pharmaceutical entities which are subject to registration in MDLP System according to the Regulation on the Track and Trace System. It is also used to register information in the MDLP System on shipment of the medicines to receivers on the annexed territories (Donetsk People's Republic, Luhansk People's Republic, Zaporizhzhia oblast and Kherson oblast)

4.4.2. Warehouse Acceptance of the Medicine Previously Shipped to an Activity Location Unregistered in MDLP System (Including to a Pharmaceutical Entity Unregistered in MDLP System)



Picture 29

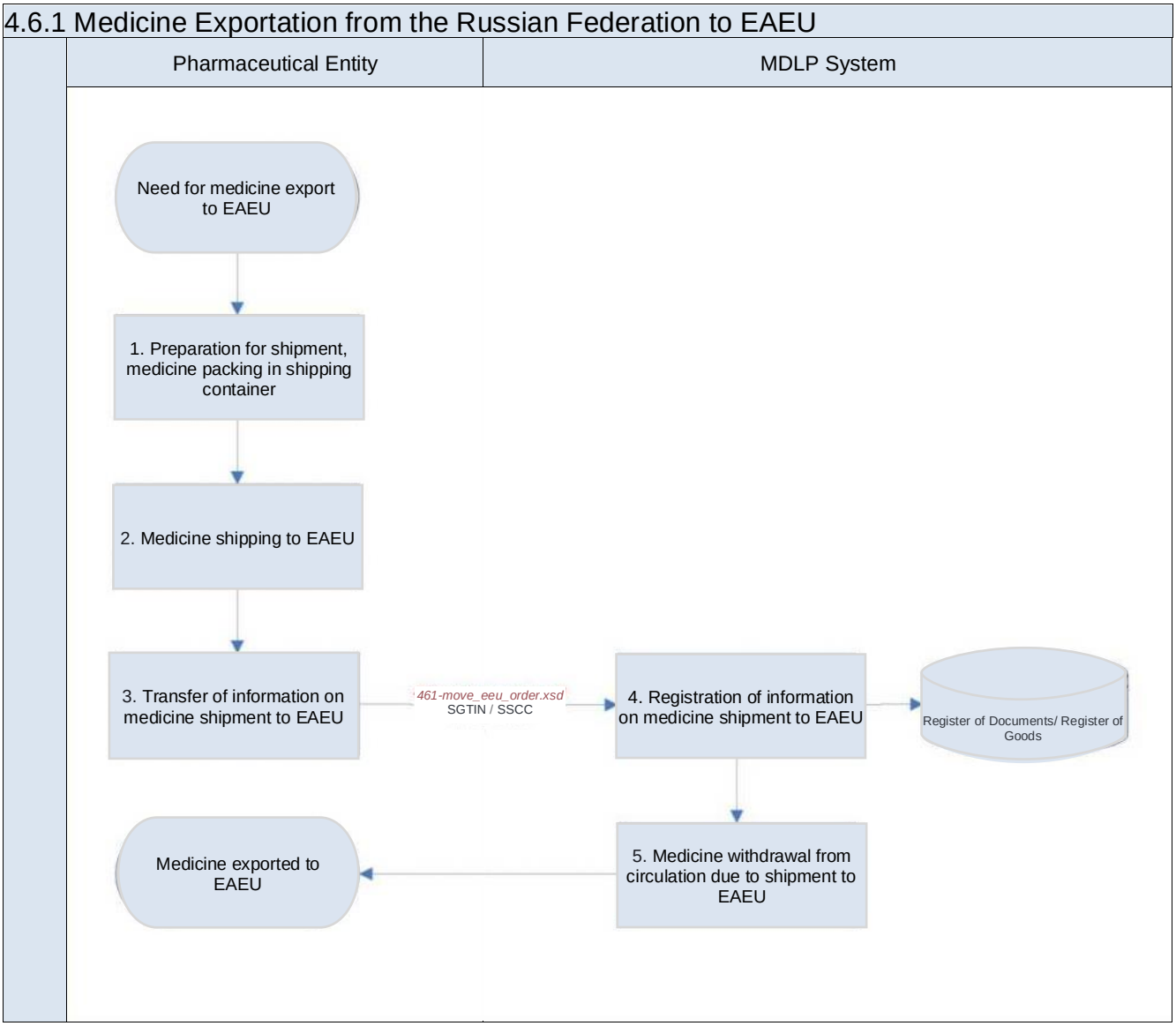
Annotation	In order to enable the possibility to register in MDLP System the information about further operations concerning the medicine for which it was previously registered that it was shipped to an business place unregistered in MDLP System (according to section 4.4.1. of these Passports of Processes), the medicine receiver shall: – register in MDLP System according to section 1.1. of these Passports of Processes (if the receiver in not registered in MDLP System); – register the business place, where the medicine has been accepted, in MDLP System according to the license (if the receiver is registered in MDLP System, and the business place where the medicine has been accepted is not registered in MDLP System); – register in MDLP System the information about warehouse acceptance of the medicine, which was previously shipped to the business place unregistered in MDLP System Information on the medicine acceptance is submitted to MDLP System by the pharmaceutical entity within 5 business days from the actual date of the medicine acceptance and registration in MDLP System of the pharmaceutical entity
Interaction participants	– pharmaceutical entity that ships the medicine (shipper); – pharmaceutical entity that accepts the medicine (receiver)
Description of the actions performed	
1. Medicine acceptance to the receiver's business place unregistered in MDLP System	
2. Registration of the receiver in MDLP System or registration of the business place, where the medicine was accepted, in MDLP System (if the receiver is registered in MDLP System)	
3. Submission to MDLP System of the information about warehouse acceptance of the medicine which was previously shipped to unregistered business place by means of scheme 442-receive_unregistered_order.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about warehouse acceptance of the medicine which was previously shipped to unregistered business place, the receiver sends the following information: – operation date;

	– identifier of the receiver's business place where the medicine has been accepted; – identifier of the shipper's business place where the medicine has been shipped from; – date of the shipping document; – number of the shipping document; – SGTIN and/or SSCC
4. Checking of the possibility to register the information about warehouse acceptance of the medicine which was previously shipped to unregistered business place	
5. Registration in MDLP System of the information about warehouse acceptance of the medicine which was previously shipped to unregistered business place (if there are no reasons to reject)	
6. Notification of the shipper about registration of the receiver (receiver's business place) in MDLP System and about registration by the receiver of the information on warehouse acceptance of the medicine which was previously shipped to unregistered business place by means of scheme 611-receive_unregistered_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the shipper about the receiver's registration and about medicine acceptance to the receiver's warehouse is formed on the basis of the operation, which was previously registered by the receiver, and contains the following information: – operation date; – identifier of the receiver's business place where the medicine has been accepted; – identifier of the shipper's business place where the medicine has been shipped from; – date of the shipping document; – number of the shipping document; – SGTIN and/or SSCC
7. Rejection to register in MDLP System the information about the receiver's warehouse acceptance of the medicine which was previously shipped to unregistered business place (if there are any reasons to reject)	
List of reasons for rejection to register	– there is no previously registered operation of medicine shipment to an business place unregistered in MDLP

the information	System; – the receiver, which is indicated in the previously registered operation of medicine shipment to unregistered business place, does not match the business place identifier of the receiver specified in the medicine warehouse acceptance operation being registered
Special conditions	Operation is intended for the medicines produced before July 1, 2020 and shipped previously to unregistered business place, as well as shipped previously to receivers to the annexed territories (Donetsk People's Republic, Luhansk People's Republic, Zaporizhzhia oblast and Kherson oblast)

4.6. Medicine Exportation from the Russian Federation

4.6.1. Medicine Exportation from the Russian Federation to the Territory of EAEU Member State

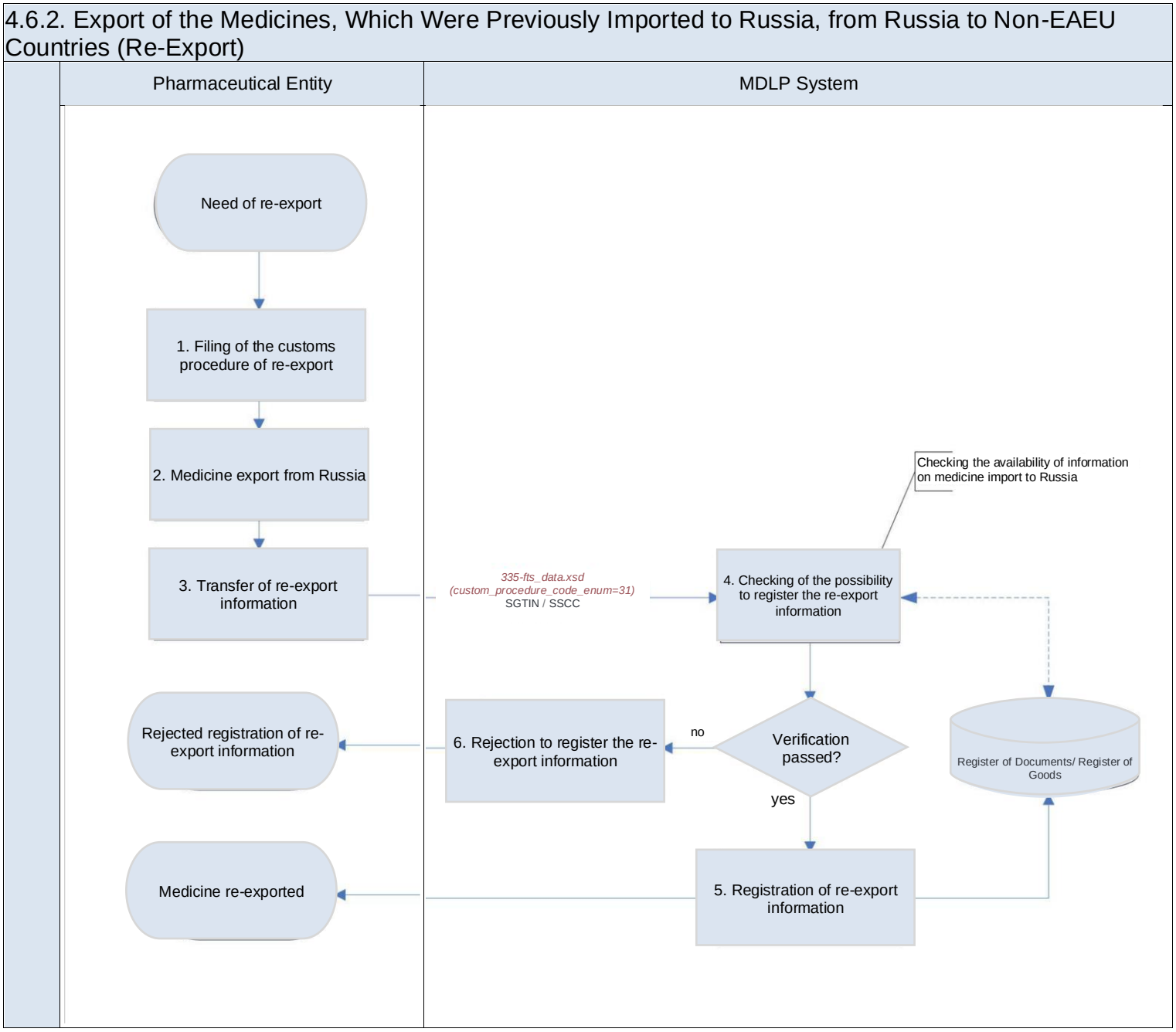


Picture 30

Annotation	In case of medicine exportation from the territory of the Russian Federation to the territory of EAEU member state, the exporting pharmaceutical entity shall register the corresponding operation in MDLP System. Information on the medicine export is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the relevant operation. The cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine delivery in tertiary (shipping) packages. In this case the shipped medicines are withdrawn from circulation, further circulation of such medicines is not allowed.
Interaction participants	– pharmaceutical entity that ships the medicine (shipper)
Description of the actions performed	
1. Preparation for shipment, medicine packing in shipping container	
2. Medicine shipment to the territory of EAEU member state from shipper's warehouse	
3. – 4. Registration of information in MDLP System about medicine export to the territory of EAEU member state by means of scheme 461-move_eeu.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about medicine export from the Russian Federation to the territory of EAEU member state, the shipper sends the following information: – operation date; – identifier of the shipper's business place where the medicine is shipped from – taxpayer code of the medicine receiver in the country of registration; – code of the country of medicine receiver's registration; – date of the shipping document; – number of the shipping document; – contract type; – medicine selling price, RUB (VAT included); – VAT amount, RUB (if no VAT is applicable, specify zero);

	– SGTIN and/or SSCC. If it is required to indicate different prices inside of a group packing, the shipper shall send the following additional data for SSCC: – GTIN; – production series number; – medicine selling price, RUB (for the specified GTIN and series numbers, VAT included); – VAT amount, RUB (if no VAT is applicable, specify zero)
5. Medicine withdrawal from circulation due to shipment to the territory of EAEU member state	

4.6.2. Export of the Medicines, Which Were Previously Imported to Russia, from Russia to Non-EAEU Countries (Re-Export)

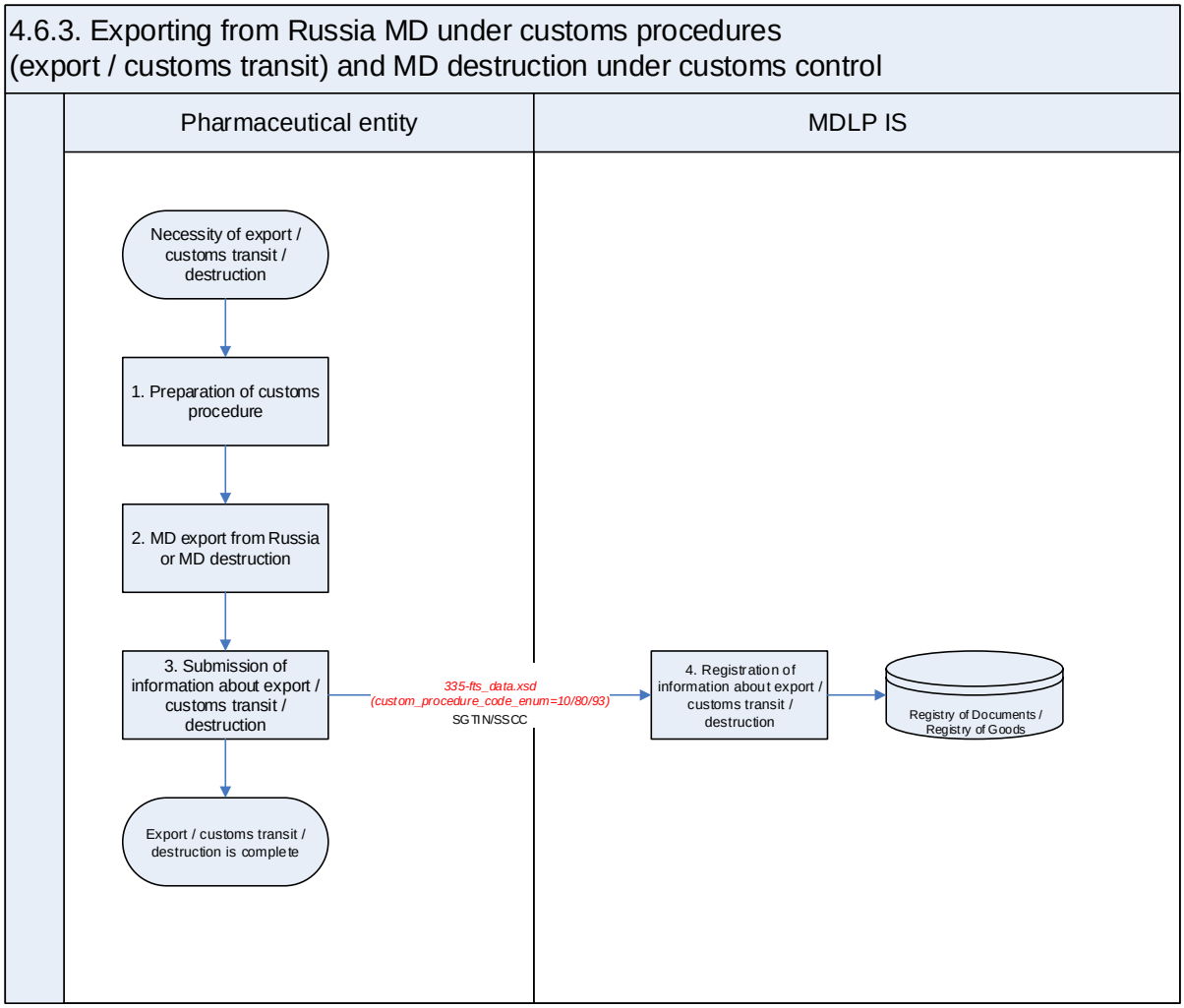


Picture 31

Annotation	If it is required to re-export the medicine from the territory of the Russian Federation, the exporting pharmaceutical entity shall register the corresponding operation in MDLP System. Re-export procedure is allowed for medicines that are placed in the customs-controlled area or were previously introduced into circulation in Russia. Information on re-export of the medicines for which Roszdravnadzor has decided to suspend the circulation, is registered in accordance with this section of the Passports of Processes. Information on the medicine export is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the relevant operation. The customs cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine delivery in tertiary (shipping) packages. In this case the shipped medicines are withdrawn from circulation, further circulation of such medicines is not allowed.
Interaction participants	– re-exporting pharmaceutical entity
Description of the actions performed	
1. Filing of the customs procedure of re-export	
2. Medicine shipping from Russia within the re-export procedure	
3. Submission to MDLP System of the information on filing the customs procedure of re-export and on medicine export from the Russian Federation by means of scheme 335-fts_data.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information on filing the customs procedure of re-export, the pharmaceutical entity sends the following data: – operation date; – registration number of the pharmaceutical entity in MDLP System; – customs procedure code (re-export); – customs authority code;

	– date and time of the decision made; – number of the declaration for goods; – customs cost of the medicine according to the goods declaration; – SGTIN and/or SSCC. If it is required to indicate different customs cost inside of a group packing, the pharmaceutical entity shall send the following additional data for SSCC: – GTIN; – production series number; – customs cost of the medicine (for the indicated GTIN and series number).
4. Checking of the possibility to register the information on medicine re-export	
5. Registration of information about medicine re-export in MDLP System (if there are no reasons to reject)	
6. Rejection to register in MDLP System the information about medicine re-export (if there are any reasons to reject)	
List of reasons for rejection to register the information	– there is no information previously registered in MDLP System about medicine importation into the Russian Federation

4.6.3. Importation of Medicines under Customs Procedures (Export, Customs Transit) from Russia, Destruction of Medicines under Customs Control



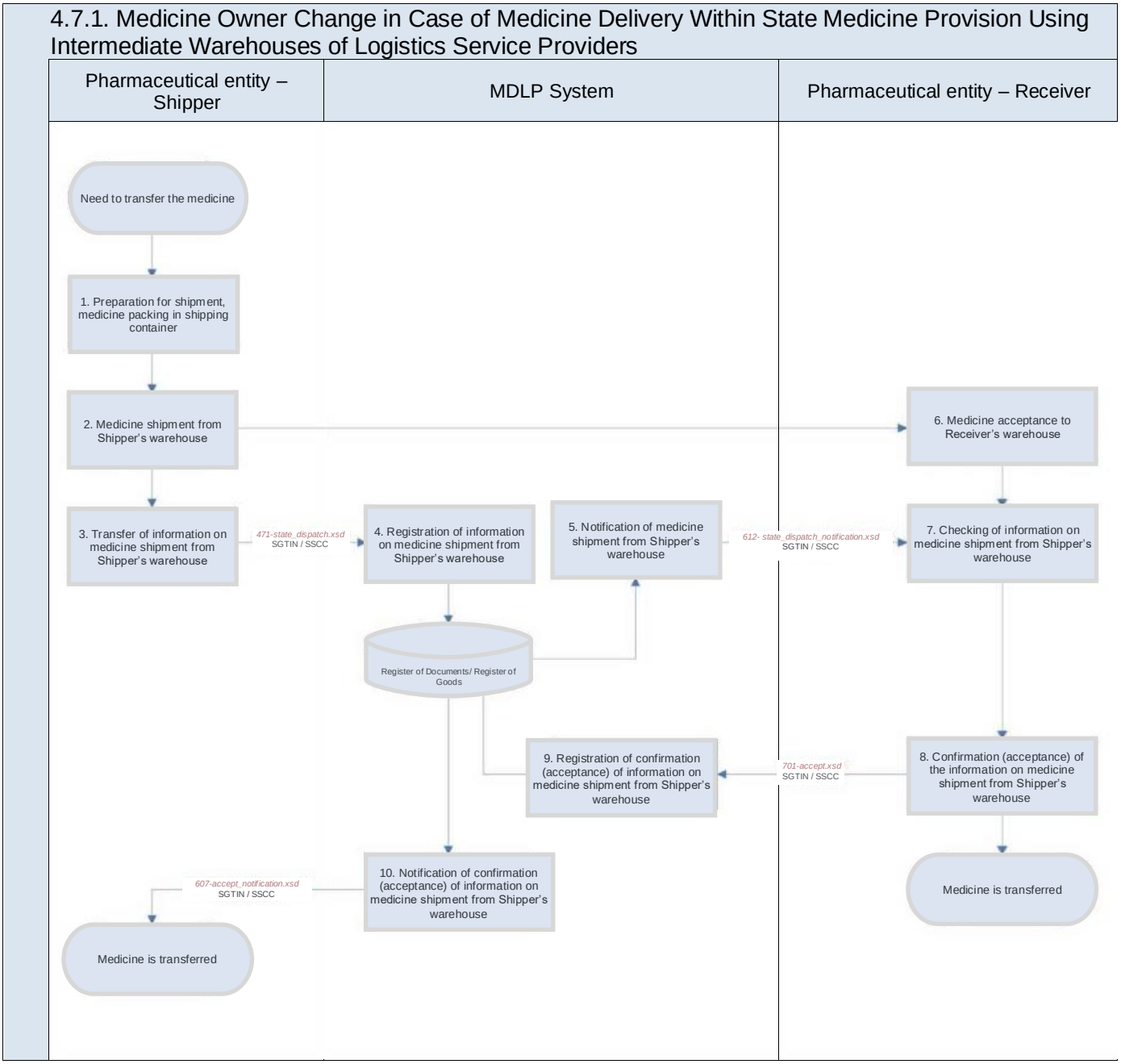
Picture 32

Annotation	If it is required to export the marked medicine from the territory of the Russian Federation within the procedure of medicine export or customs transit, as well as destruction under customs control, the pharmaceutical entity performing the operation shall register the corresponding operation in MDLP System. Information on the medicine export is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the relevant operation. The export procedure is allowed for both medicines that are placed in the customs-controlled area, and medicines that were previously introduced into circulation in Russia. The procedures of customs transit and destruction under customs control are registered for the medicines that are in the customs-controlled area. The customs cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine delivery in tertiary (shipping) packages. In this case the shipped or destroyed medicines are withdrawn from circulation, further circulation of such medicines is not allowed.
Interaction participants	– the pharmaceutical entity that conducts the operation
Description of the actions performed	
1. Filing of the customs procedure	
2. Medicine shipping from Russia within the export procedure of export or customs transit, or medicine destruction under customs control	
3. – 4. Submission to MDLP System of the information on filing the customs procedure of export or customs transit, or medicine destruction under customs control by means of scheme 335-fts_data.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information on filing the customs procedure, the pharmaceutical entity sends the following data: – operation date; – registration number of the pharmaceutical entity in MDLP System; – customs procedure code (export, customs transit, destruction

	under customs control); – code of export country (for customs procedure for export); – customs authority code; – date and time of the decision made; – number of the declaration for goods; – customs cost of the medicine according to the goods declaration; – SGTIN and/or SSCC. If it is required to indicate different customs cost inside of a group packing, the pharmaceutical entity shall send the following additional data for SSCC: – GTIN; – production series number; – customs cost of the medicine (for the indicated GTIN and series number).
Special conditions	If goods are exported to the Republic of Uzbekistan, it is necessary to fill in a “Code of export country” detail

4.7. Special Processes in Medicine Circulation

4.7.1. Medicine “Owner” Change in Case of Medicine Delivery at the Expense of the Federal Budget or the Budgets of Constituent Entities of the Russian Federation, Using Intermediate Warehouses of Logistics Service Providers



Picture 33

Annotation	In case of medicine delivery within state medicine provision, intermediate warehouses of logistics service providers (pharmaceutical entities operating as outsourcers) may be used. For further medicine transfer to a medicine issue place, which is not a division of logistics service provider (i.e. medicine transfer to another "owner"), the logistics service provider shall be a registered MDLP System user and shall register the corresponding operation in MDLP System. Registration of the information on medicine transfer to a new owner involves confirmation of the operation information by both parties. The shipper shall register the information on medicine transfer to the receiver, and the receiver shall confirm the medicine transfer information registered by the shipper. Information on the medicine transfer is submitted to MDLP System by the medicine shipper within 1 business day from the actual date of the medicine shipment. In this case the receiver confirms the information registered by the shipper within 1 business day from the date of the medicine acceptance and registration in MDLP System of the information about such shipped medicines. In case of medicine movement within state medicine provision, the information on medicine movement will be available in the user account of the relevant state authority for which the medicine is procured at the expense of the federal or regional budget
Interaction participant	– pharmaceutical entity that ships the medicine (shipper); – pharmaceutical entity that accepts the medicine (receiver)
Description of the actions performed	
1. Preparation for shipment, medicine packing in shipping container	
2. Medicine shipment from the shipper's warehouse	
3. – 4. Registration of information in MDLP System about medicine owner change within state medicine provision by means of scheme 471-state_dispatch.xsd	
List of information to be transferred, and the owner of	In order to register the information in MDLP System about medicine owner change within state medicine provision, the shipper sends the following data: – operation date;

information resource	– identifier of the shipper's business place where the medicine is shipped from; – identifier of the receiver's business place where the medicine is accepted; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
5. Notification of the receiver about medicine shipment from shipper's warehouse within medicine owner change by means of scheme 612-state_dispatch_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the receiver about the medicine shipment from shipper's warehouse is formed on the basis of the operation, which was earlier registered by the shipper, and contains the following data: – operation date; – identifier of the shipper's business place where the medicine is shipped from; – identifier of the receiver's business place where the medicine is accepted; – date of the primary document; – number of the primary document; – SGTIN and/or SSCC
6. Medicine acceptance to the receiver's warehouse	
7. Checking by the receiver of the information, previously registered by the shipper, on medicine shipment from warehouse	
8. – 9. Confirmation (acceptance) by the receiver of the information on medicine shipment from shipper's warehouse by means of scheme 701-accept.xsd	
List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information, previously registered by the shipper, about medicine shipment from warehouse, the receiver ensures that the following data is sent to MDLP System: – identifier of the receiver's business place where the medicine is accepted; – identifier of the shipper's business place where the medicine is shipped from;

	– operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC
10. Notification of the shipper about confirmation (acceptance) by the receiver of the information on medicine shipment from shipper's warehouse by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the shipper about confirmation (acceptance) by the receiver of the information on medicine shipment from warehouse is formed on the basis of the operation, previously registered by the receiver, and contains the following information: – identifier of the receiver's business place where the medicine is accepted; – identifier of the shipper's business place where the medicine is shipped from; – operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC

4.7.2. Medicine Transfer for Further Selling in the Interests and at the Expense of the Owner (Agency Agreement, Commission Agreement) (Direct Confirmation Order)

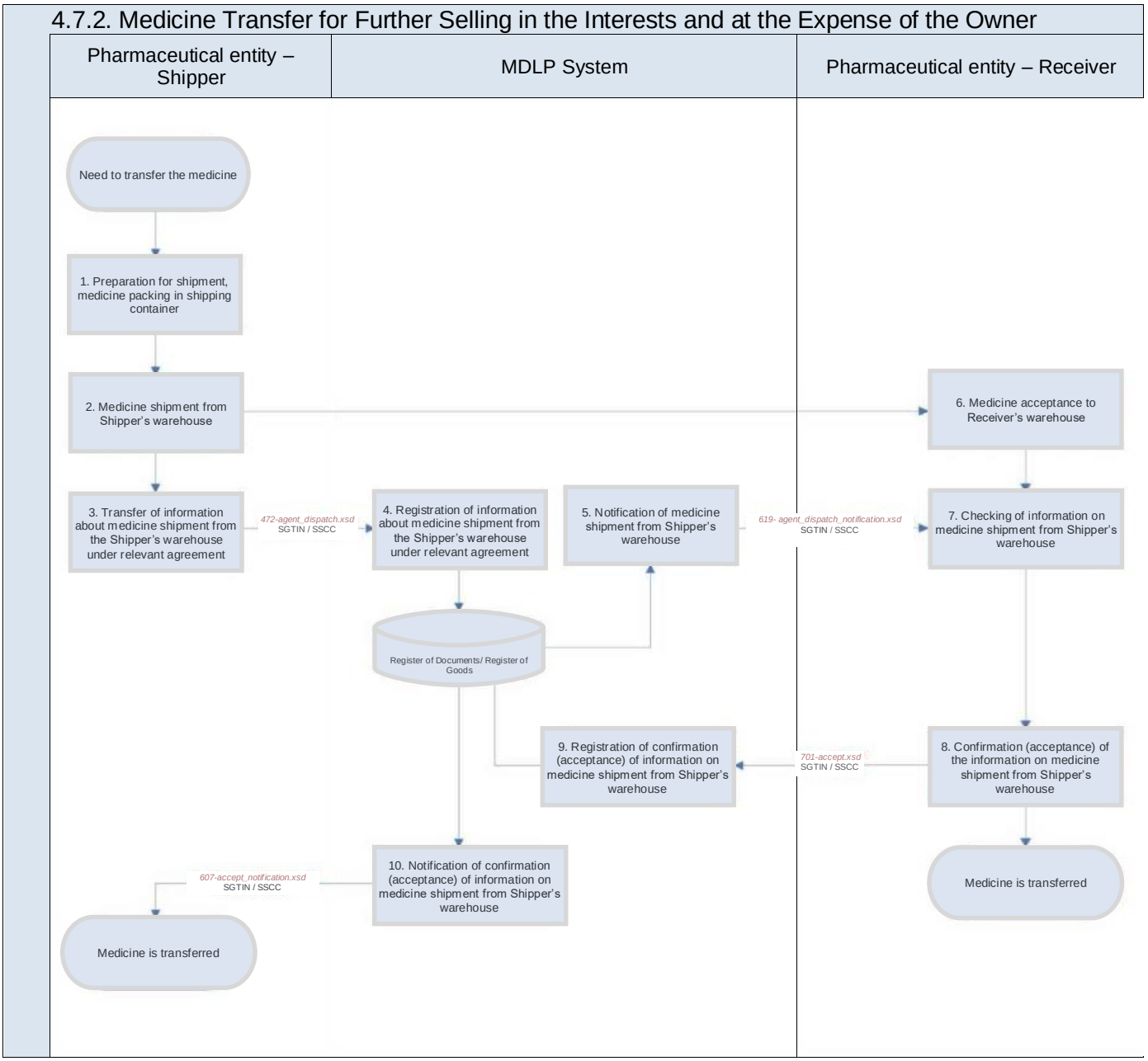


Figure 34

Annotation	When selling medicine under agency agreements and commission agreements in the interests of the customer, the information about medicine transfer for selling shall be registered in the MDLP System. Registration of the information in the MDLP System on medicine transfer for selling involves confirmation of the operation information by both parties. In case of direct order, the customer under the agreement (the shipper) shall register the information on medicine transfer to the contractor (the receiver), and the receiver shall confirm the medicine transfer information registered by the shipper. Information on the medicine shipment is submitted to MDLP System by the shipper within 1 business day from the actual date of the medicine shipment. In this case the receiver confirms the information registered by the shipper within 1 business day from the date of registration in MDLP System of the information about such shipped medicines. When returning the medicines that have been previously transferred to the receiver under an agency agreement or a commission agreement, the pharmaceutical entity returning the medicine shall register the return information in MDLP System pursuant to this section hereof, indicating the “Return” shipment type. Information on return of the medicine shall be submitted by a pharmaceutical entity that returns the medicine, to MDLP System within 1 business day from the actual date of the medicine shipment. And a receiver of the returned medicines shall confirm the data registered by the medicine shipper, within 30 business days from the date when the medicines are accepted. In order to register the confirmation and further operations with the medicine in MDLP System, the receiver (commission agent, agent) must be a registered user of MDLP System.
Interaction participant	– pharmaceutical entity that ships the medicine (shipper); – pharmaceutical entity that accepts the medicine (receiver)
Description of the actions performed	
1. Preparation for shipment, medicine packing in shipping container	
2. Medicine shipment from the shipper’s warehouse	
3. – 4. Registration of information in MDLP System about medicine shipment from	

the shipper’s warehouse under the agreement by means of scheme 472-agent_dispatch.xsd	
List of information to be transferred, and the owner of information resource	In order to register the information in MDLP System about medicine shipment from the shipper’s warehouse under the agreement, the shipper sends the following information: – operation date; – identifier of the shipper’s business place where the medicine is shipped from; – identifier of the receiver’s business place where the medicine is accepted; – type of shipment operation (sale, return); – date of the supporting document; – number of the supporting document; – SGTIN and/or SSCC
5. Notification of the receiver about medicine shipment from shipper’s warehouse under the agreement by means of scheme 619-agent_dispatch_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the receiver about the medicine shipment from shipper’s warehouse is formed on the basis of the operation, which was earlier registered by the shipper, and contains the following data: – operation date; – identifier of the shipper’s business place where the medicine is shipped from; – identifier of the receiver’s business place where the medicine is accepted; – type of shipment operation (sale, return); – date of the supporting document; – number of the supporting document; – SGTIN and/or SSCC
6. Medicine acceptance to the receiver’s warehouse	
7. Checking by the receiver of the information, previously registered by the shipper, on medicine shipment from warehouse	
8. – 9. Confirmation (acceptance) by the receiver of the information on medicine shipment from shipper’s warehouse by means of scheme 701-accept.xsd	

List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information, previously registered by the shipper, about medicine shipment from warehouse, the receiver ensures that the following data is sent to MDLP System: – identifier of the receiver's business place where the medicine is accepted; – identifier of the shipper's business place where the medicine is shipped from; – operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC
10. Notification of the shipper about confirmation (acceptance) by the receiver of the information on medicine shipment from shipper's warehouse by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the shipper about confirmation (acceptance) by the receiver of the information on medicine shipment from warehouse is formed on the basis of the operation, previously registered by the receiver, and contains the following information: – identifier of the receiver's business place where the medicine is accepted; – identifier of the shipper's business place where the medicine is shipped from; – operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC

4.7.3. Transfer of Medicines for Further Sale in the Interests and at the Expense of the Owner (agent contract, commission contract) (reverse confirmation procedure)

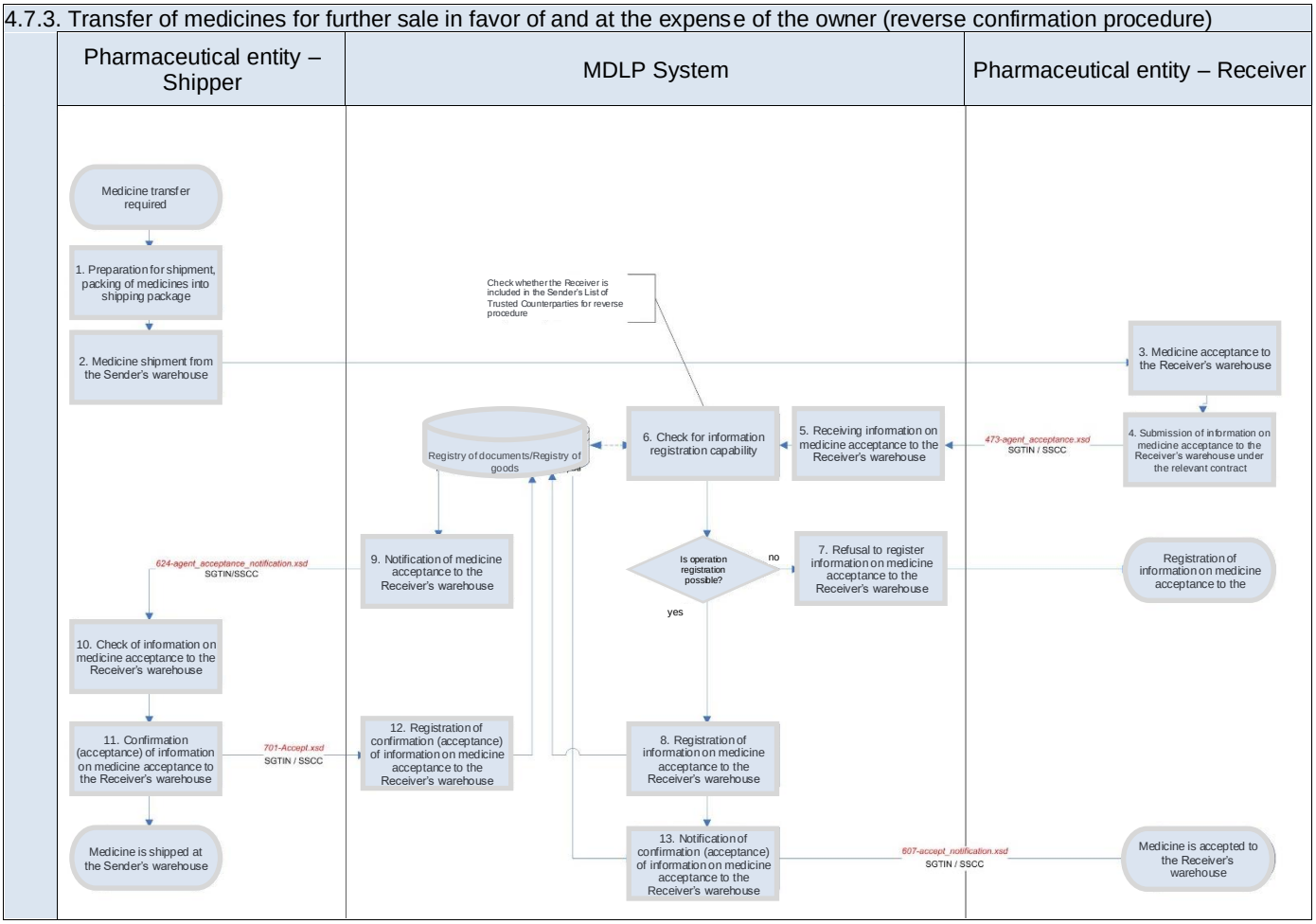


Figure 35

Annotation	When selling the medicines under agency agreements and commission sales agreements in the interests and at the expense of the customer, the information on the medicine transfer for sale shall be registered in MDLP System. Registration in MDLP System of the information about the medicine transfer for sale includes the confirmation of information about the operation performance by both parties. In case of reverse confirmation order, the contractor under the contract (receiver) registers the information about the medicine acceptance, and the Customer under the contract (shipper) confirms the information registered by the receiver. A list of relevant approved counterparties (receivers) shall be registered in the shipper's user account for reverse confirmation order. Information on the medicine acceptance is submitted to MDLP System by the receiver within 1 business day from the actual date of the medicine acceptance. In this case the shipper confirms the information registered by the receiver within 1 business day from the date of registration in MDLP System of the information about such accepted medicines. If it is necessary to return the medicine, the contractor and the customer shall register operations in accordance with this section - the contractor acts as a shipper, and the customer acts as a receiver. A receiver shall register information about acceptance in the MDLP System with the "Return from buyer" type. Information on return of the medicine from the contractor shall be submitted by the customer to the MDLP System within 30 business days from the date of the medicine acceptance. And the contractor shall confirm the data registered by the receiver, within 1 business day from the date when data on accepted medicines are registered in the MDLP System
Interaction participant	– pharmaceutical entity shipping the medicines (shipper); – pharmaceutical entity accepting the medicines (receiver)
Description of the actions performed	
1. Preparation for shipment, medicine packing in shipping container	
2. Medicine shipment from the shipper's warehouse	

3. Medicine acceptance to the receiver’s warehouse	
4. – 5. Transfer to MDLP System of the information on acceptance of medicines by agent under agency contract by means of scheme 473-agent_acceptance.xsd	
List of information to be transferred, and the owner of information resource	For registration in MDLP System of the information on medicine acceptance to warehouse by an agent under the contract, the receiver shall ensure submission of the following information: – operation date; – identifier of the receiver’s business place where the medicine is accepted; – identifier of the shipper’s business place where the medicine is shipped from; – type of acceptance operation (receiving, return from counterparty); – date of the supporting document; – number of the supporting document; – SGTIN and/or SSCC
6. Check of possibility to register the operation of medicine acceptance to the receiver’s warehouse (the pharmaceutical entities should be on the list of trusted counterparties)	
7. Refusal to register the information on medicine acceptance to the receiver’s warehouse (if the receiver is not on the list of the shipper’s trusted counterparties)	
8. Registration in MDLP System of the information on medicine acceptance to the receiver’s warehouse (if there is no reason for rejection)	
9. Notification to the shipper of medicine acceptance to the receiver’s warehouse under the contract by means of scheme 624-agent_acceptance_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification to the shipper of medicine acceptance to the receiver’s warehouse is generated based on the operation previously registered by the receiver, and contains the following information: – operation date; – identifier of the receiver’s business place where the medicine is accepted; – identifier of the shipper’s business place where the

	medicine is shipped from; – type of acceptance operation (receiving, return from counterparty); – date of the supporting document; – number of the supporting document; – SGTIN and/or SSCC
10.Check by the receiver of the information on medicine shipment from warehouse previously registered by the shipper	
11.– 12. Confirmation (acceptance) by the shipper of the information on medicine acceptance to the receiver's warehouse by means of scheme 701-accept.xsd	
List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information on medicine acceptance to warehouse registered by the receiver, the shipper submits the following information to MDLP System: – identifier of the shipper's business place where the medicine is shipped from; – identifier of the receiver's business place where the medicine is accepted; – operation date; – confirmation of the suspended goods acceptance (to be indicated if Roszdravnadzor made a decision on suspension of the medicine circulation according to para. 7.1 of the Passports of Processes); – SGTIN and/or SSCC
13.Notification to the receiver of confirmation (acceptance) by the shipper of the information on medicine acceptance to the receiver's warehouse by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification to the receiver of confirmation (acceptance) by the shipper of information on medicine acceptance to warehouse is generated based on the operation previously registered by the shipper, and contains the following information: – identifier of the shipper's business place where the medicine is shipped from; – identifier of the receiver's business place where the medicine is accepted; – operation date; – confirmation of the suspended goods acceptance (to be

	indicated if Roszdravnadzor made a decision on suspension of the medicine circulation according to para. 7.1 of the Passports of Processes); – SGTIN and/or SSCC
Special conditions	It is not allowed to submit information in line with this section with regard to the medicines being part of the list of high-cost nosologies, the medicines with international non-proprietary name “Ethanol” and medicines which contain narcotics, psychotropic substances, and their precursors and which are included into Section I of the list of the medicines for medical use which are medicines containing controlled substances, approved by authorized federal executive authority in accordance with Article 58^1 of the Federal Law “On Medicine Circulation” (before August 31, 2024 - the Order of the Ministry of Health of the Russian Federation of April 22, 2014 No. 183n, from September 1, 2024 - the Order of the Ministry of Health of the Russian Federation of September 1, 2023 No. 459n)

4.7.4. Medicine Movement Between Own Activity Locations In Case of Medicine Procurement at the Expense of the Federal Budget or the Budgets of Constituent Entities of the Russian Federation

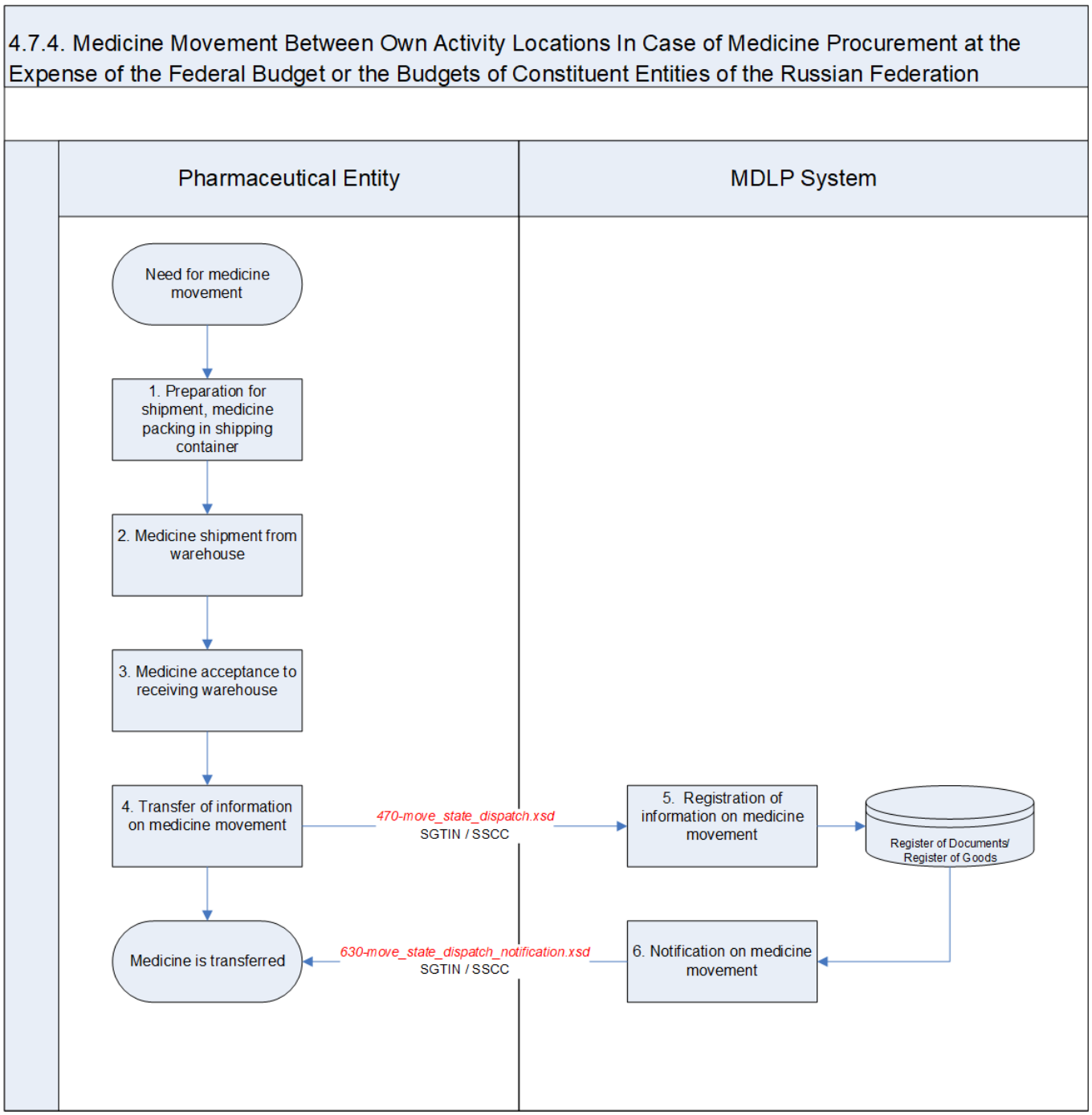


Figure 36

Annotation	In case of medicine delivery by contractor under a contract within state medicine provision to medicine issue places, which are business places pursuant to the license of the pharmaceutical entity, the relevant information shall be registered in MDLP System following the medicine acceptance to warehouse at the issue location. Information on the medicine transfer is submitted to MDLP System by the pharmaceutical entity within 5 business days from the actual date of the medicine transfer. The cost of the medicine shall always be given in the registered operations per unit of goods – the secondary (consumer) packing of the medicine (in its absence – the primary packing of the medicine) – including the cases of medicine delivery in tertiary (shipping) packages. In case of medicine delivery within state medicine provision, the information on medicine movement will be available in the user account of the relevant state authority for which the medicine is procured at the expense of the federal or regional budget
Interaction participant	– pharmaceutical entity which is the supplier under the contract
Description of the actions performed	
1. Preparation for shipment, medicine packing in shipping container	
2. Medicine shipment from shipper's warehouse to the issue location	
3. Medicine acceptance at the issue location	
4. – 5. Registration in MDLP System of the information about medicine movement between own business places within state medicine provision by means of scheme 470-move_state_dispatch.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about medicine movement between own business places within state medicine provision, the supplier sends the following data: – operation date; – identifier of the pharmaceutical entity's business place where the medicine is shipped from; – identifier of the pharmaceutical entity's business place where the medicine is accepted; – date of the primary document;

	– number of the primary document; – source of finance (federal and regional budget); – register number of the contract; – medicine cost in RUB (VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero); – SGTIN and/or SSCC. If it is required to indicate different prices inside of a group packing, the pharmaceutical entity shall send the following additional data for SSCC: – GTIN; – production series number; – medicine cost, RUB (for the specified GTIN and series number, VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero); – SGTIN and/or SSCC
6. Notification to receiver on medicines movement between different business places within state activities on medicine provision using scheme 630-move_state_dispatch_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification to receiver on medicines movement between different business places within state activities on medicine provision is formed on the basis of the movement operation registered previously and contains the following information: – operation date; – identifier of the pharmaceutical entity's business place where the medicine is shipped; – identifier of the pharmaceutical entity's business place where the medicine is accepted; – date of the primary document; – source document number; – financing source (federal and regional budget); – register contract number; – medicine value, rub. (VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero); – SGTIN and/or SSCC. If different prices are specified inside a group packing, the

	following additional data for SSCC shall be provided: – GTIN; – production series number; – medicine value, RUB (for the specified GTIN and series numbers, VAT included); – VAT amount, RUB (if no VAT is applicable; specify zero); – SGTIN and/or SSCC
Special conditions	This operation is also used when the contractor is the medicine receiver, and the medicine transfer under the contract is not provided. If at the time of the data registration there is no a registry number, procurement notice number may be specified instead of the contract registry number

4.7.5. Arbitration Procedure

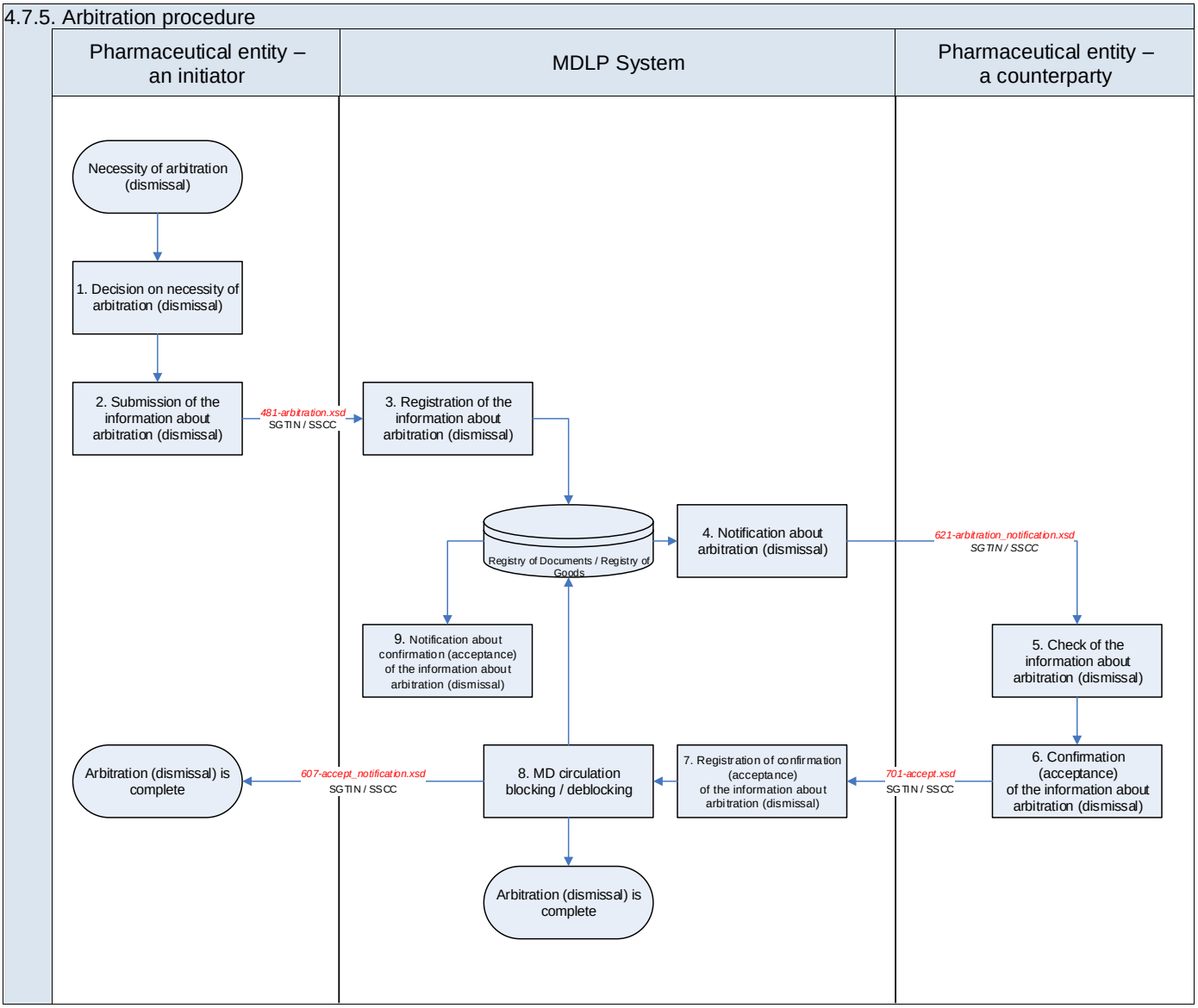


Figure 37

Annotation	In case of any disagreements arising between the medicine shipper and the medicine receiver and if an additional time is required to resolve the disagreements, for the purposes of elongation of the allotted registration period for the information about medicine shipment / acceptance, as well as for the purposes of the information acceptance, the pharmaceutical entities shall register information about arbitration in MDLP System. The information can be registered both by the shipper and by the receiver of the medicine. At the same time the counterparty shall confirm the information about arbitration. Registration of information about arbitration is allowed if any previously registered information about the medicine shipment to the receiver or information about the medicine acceptance by the receiver is available for the medicines awaiting confirmation (acceptance) by the counterparty. Both the whole batch and its part can be referred to arbitration. If SGTIN is in a group packing, the whole group packing shall be referred to arbitration. Upon referring to arbitration, the function of the medicine movement registration is temporarily locked in MDLP System until the information about the arbitration dismissal is registered in MDLP System. The information about the arbitration dismissal can be registered in MDLP System by any of the parties pursuant to this section hereof. After registration of the information about the arbitration dismissal in MDLP System the pharmaceutical entities can register the following operations, depending on the agreements reached: – confirmation (acceptance) by the receiver of the information about medicine shipment from the shipper's warehouse according to Section 4.1 of these Passports of Processes; – confirmation (acceptance) by the shipper of the information about medicine acceptance to the receiver's warehouse according to Section 4.2 of these Passports of Processes; – confirmation (acceptance) by the receiver of the information about medicine shipment from the shipper's warehouse within state medicine provision according to Section 4.7.1 of these Passports of Processes; – confirmation (acceptance) by the receiver of the information about medicine shipment from the shipper's warehouse under

	an agency agreement (direct confirmation order) according to Section 4.7.2 of these Passports of Processes; – confirmation (acceptance) by the shipper of the information on medicine acceptance to the receiver's warehouse for a delivery made under an agency agreement (reverse confirmation procedure) according to Section 4.7.3 of these Passports of Processes; – confirmation (acceptance) by the receiver of the information about the suspended medicine return according to Section 7.2 of these Passports of Processes; – recalling by the shipper of the information about medicine transferred to receiver according to Section 10.2 of these Passports of Processes; – receiver's refusal to accept the medicine according to Section 10.3 of these Passports of Processes
Interaction participant	– pharmaceutical entity that is an arbitration (dismissal) initiator; – pharmaceutical entity that is a counterparty of the pharmaceutical entity filing a request for arbitration (initiating arbitration dismissal)
Description of the actions performed	
1. Pharmaceutical entities making a decision on filing a request for arbitration (arbitration dismissal)	
2. – 3. Registration of the information about the arbitration (dismissal) in MDLP System by means of scheme 481-arbitration.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about the arbitration (dismissal), the initiating pharmaceutical entity sends the following information: – operation date; – identifier of the initiator's business place; – identifier of the counterparty's business place; – date of the supporting document; – number of the supporting document; – type of operation (filing a request for arbitration, initiating arbitration dismissal);

	– SGTIN and/or SSCC
4. Notification of the counterparty about filing a request for arbitration (initiating arbitration dismissal) by the initiator by means of scheme 621-arbitration_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the counterparty about filing a request for arbitration (initiating arbitration dismissal) is formed on the basis of the operation previously registered by the initiator, and contains the following information: – operation date; – identifier of the initiator's business place; – identifier of the counterparty's business place; – date of the supporting document; – number of the supporting document; – type of operation (filing a request for arbitration, initiating arbitration dismissal); – SGTIN and/or SSCC
5. Checking by the counterparty of the information about filing a request for arbitration (initiating arbitration dismissal) previously registered by the initiator	
6. – 7. Confirmation (acceptance) by the counterparty of the information about filing a request for arbitration (initiating arbitration dismissal) by means of scheme 701-accept.xsd	
List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information, registered by the initiator, about filing a request for arbitration (initiating arbitration dismissal), the counterparty sends the following information to MDLP System: – identifier of the counterparty's business place; – identifier of the initiator's business place; – operation date; – confirmation of the information about suspended goods (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC

8. Automatic locking of the function of the medicine movement registration (under arbitration) or unlocking of the function of the medicine movement registration (upon arbitration dismissal) in MDLP System	
9. Notification of the initiator about confirmation (acceptance) by the counterparty of the information about filing a request for arbitration (initiating arbitration dismissal) by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the initiator about confirmation (acceptance) of the information about filing a request for arbitration (initiating arbitration dismissal) is formed on the basis of the operation previously registered by the counterparty, and contains the following information: – identifier of the counterparty's business place; – identifier of the initiator's business place; – operation date; – confirmation of the information about suspended goods (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC

4.7.6. Movement of Medicine under Reorganization of the Pharmaceutical Entities - Residents of the Russian Federation

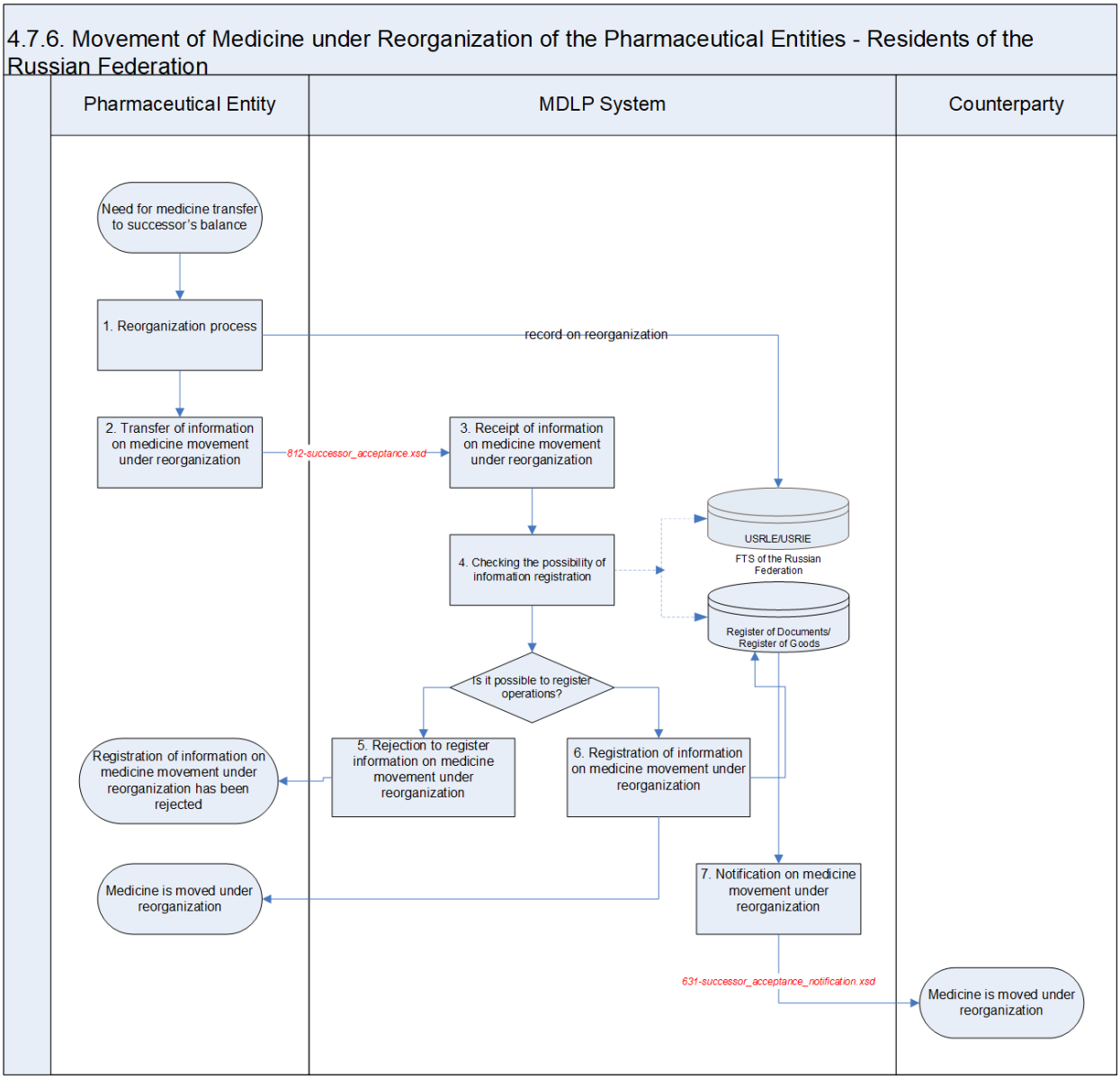

4.7.6. Movement of Medicine under Reorganization of the Pharmaceutical Entities - Residents of the Russian Federation
Pharmaceutical Entity
MDLP System
Counterparty
Need for medicine transfer to successor's balance
1. Reorganization process
record on reorganization
2. Transfer of information on medicine movement under reorganization
812-successor_acceptance.xsd
3. Receipt of information on medicine movement under reorganization
USRLE/USRIE
FTS of the Russian Federation
4. Checking the possibility of information registration
Register of Documents/ Register of Goods
Is it possible to register operations?
Registration of information on medicine movement under reorganization has been rejected
5. Rejection to register information on medicine movement under reorganization
6. Registration of information on medicine movement under reorganization
Medicine is moved under reorganization
7. Notification on medicine movement under reorganization
631-successor_acceptance_notification.xsd
Medicine is moved under reorganization

Figure 4

Annotation	In implementing the reorganization procedures, the pharmaceutical entity being the resident of the Russian Federation may need to transfer the medicines from his/her balance to the balance of the successor organization. Information on transfer of the medicine to the successor's balance can be registered both by sender (predecessor) and by the receiver (successor) of the medicine. In doing so, the counterparty will be notified of the transfer of the medicine to the successor's balance. To transfer the medicine in accordance with this section of the Passports of Processes, the relevant information on reorganization, including information on successors of the pharmaceutical entity reorganized must be entered in USRLE/USRIE of the FTS of the Russian Federation. When registering information, all medicines, which are on the predecessor's balance with permissible statuses listed in Appendix No.1 of the Passports of Processes, shall be transferred. It is also allowed to transfer the medicines in respect of which a part of the secondary (consumer packing) has been withdrawn
Interaction participants	– pharmaceutical entity who registers information on transfer of the medicine to successor; – counterparty
Description of the actions performed	
1. Completion of the reorganization procedure with submission of the relevant information to USRLE of the FTS of the Russian Federation	
2. – 3. Transfer of the information to MDLP System on movement of the medicine at the successor's warehouse under reorganization using scheme 812-successor_acceptance.xsd	
List of information to be transferred, and the owner of information resource	To register information in the MDLP System on transfer of the medicine to the successor's warehouse under reorganization, the pharmaceutical entity shall transmit the following information: – operation date; – registration number of the pharmaceutical entity who registers information in the MDLP System; – identifier of the pharmaceutical entity's business place who transfers the medicine (predecessor); – identifier of the pharmaceutical entity's business place who accepts the medicine (successor); – date of the supporting document; – number of the supporting document
4. The possibility to register operations of the medicine transfer to successor's warehouse under reorganization (availability of information in USRLE of the FTS of the Russian Federation and medicine statuses) is tested	

5. Rejection to register information on transfer of the medicine to successor's warehouse under reorganization (if there are grounds for rejection)	
6. Recording of information on transfer of the medicine to successor's warehouse under reorganization (if there are no grounds for rejection)	
7. Notification to counterparty on movement of the medicines from predecessor's business place to successor's business place under reorganization using scheme (631-successor_acceptance_notification.xsd)	
List of information to be transferred, and the owner of information resource	Notification to counterparty on movement of the medicines from predecessor's business place to successor's business place under reorganization contains the following information: – registration number of the pharmaceutical entity who registers information in the MDLP System; – name of the pharmaceutical entity - sender – identifier of the pharmaceutical entity's business place who transfers the medicine (predecessor); – identifier of the pharmaceutical entity's business place who accepts the medicine (successor); – operation date; – identifier of the medicine movement operation previously registered in the MDLP System
Special conditions	Medicines, which are awaiting confirmation (acceptance) of the operation by the counterparty, expired medicines, as well as medicines, which are in statuses not provided for in Appendix No.1 herein, are not transferred. It is recommended not to move the medicines for which the MDLP System has received information on withdrawal of the medicines being in the awaiting registry. Movement under reorganization is available only for the medicines, which according to MDLP System are located at a registered business place, and is unavailable for the medicines, which are outside the territory of the Russian Federation and are pending acceptance at the warehouse from the customs control area when importing the medicines into the territory of the Russian Federation.

4.7.7. Notification from pharmaceutical entity to the MDLP System on absence of the medicines on balance

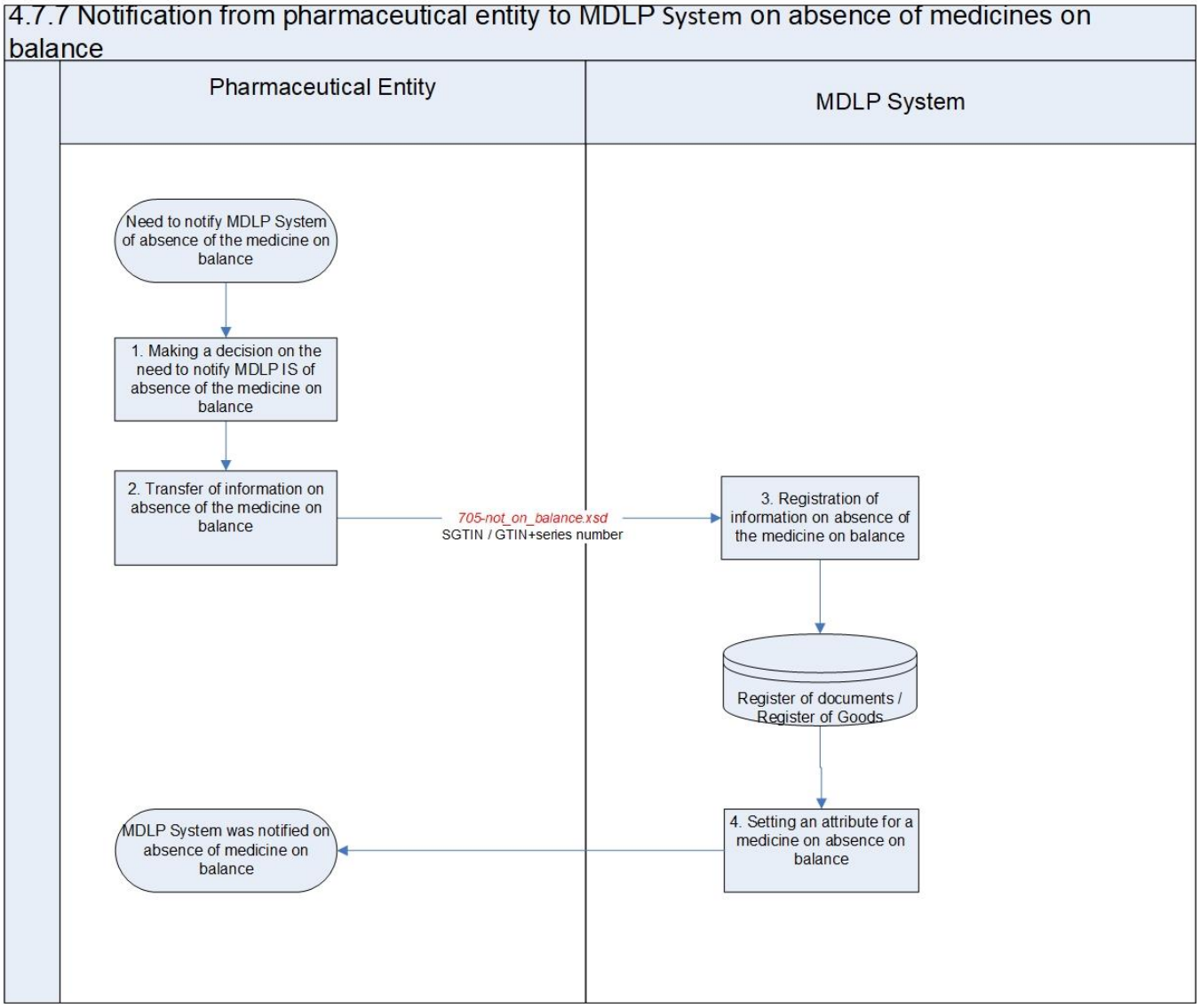

4.7.7 Notification from pharmaceutical entity to MDLP System on absence of medicines on balance
Pharmaceutical Entity
MDLP System
Need to notify MDLP System of absence of the medicine on balance
1. Making a decision on the need to notify MDLP IS of absence of the medicine on balance
2. Transfer of information on absence of the medicine on balance
705-not_on_balance.xsd
SGTIN / GTIN+series number
3. Registration of information on absence of the medicine on balance
Register of documents / Register of Goods
4. Setting an attribute for a medicine on absence on balance
MDLP System was notified on absence of medicine on balance

Figure 5

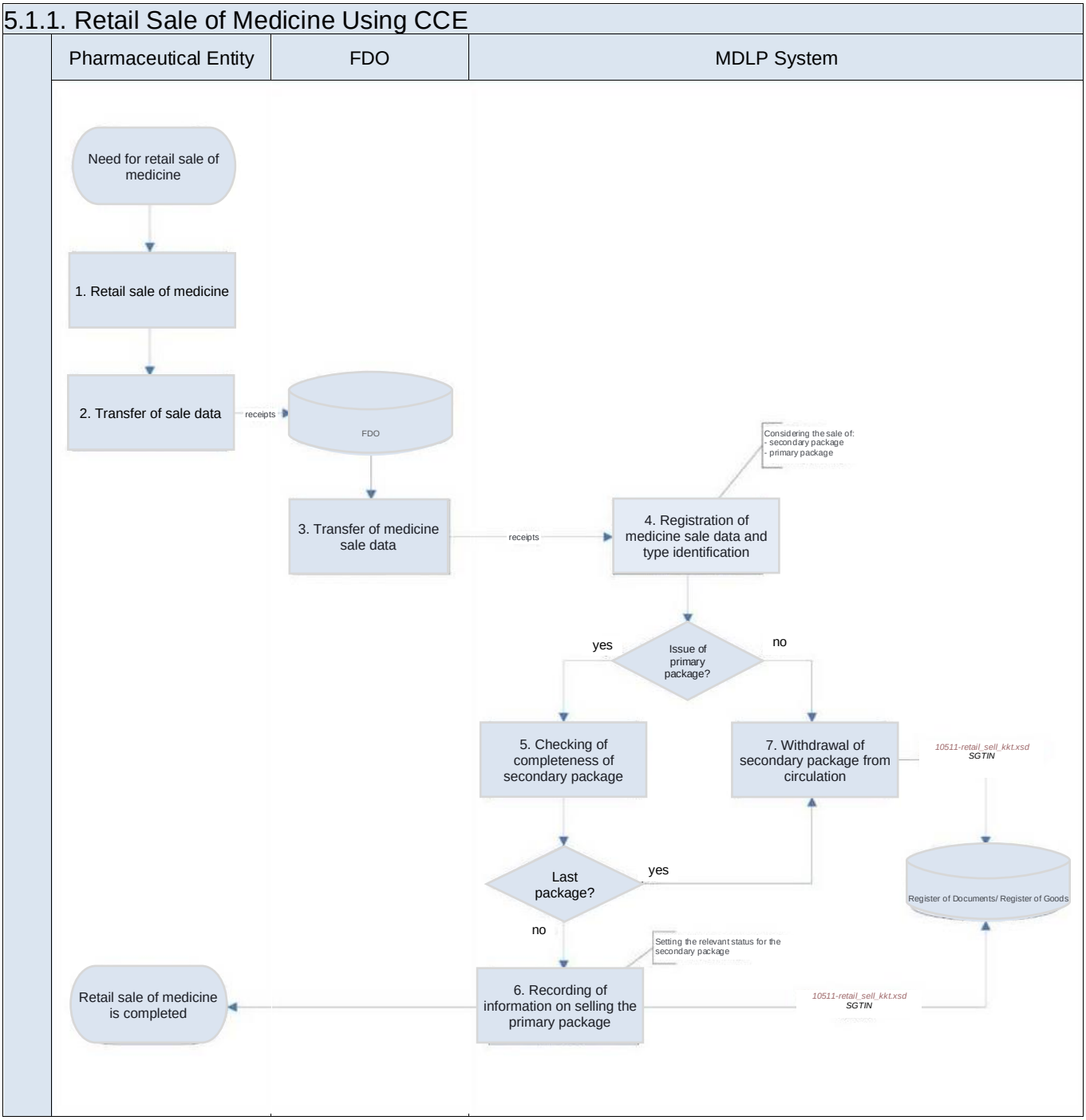
Annotation	In order to update information in the MDLP System about the actual presence of the medicines in a balance sheet, when transferring the medicines belonging to one production batch to another pharmaceutical entity within civil law relations, a pharmaceutical entity that has a license for wholesale trade of medicines, shall send a notification to the MDLP System about absence of the medicines on balance. Information about absence of the medicines on balance shall be submitted by a pharmaceutical entity to MDLP System within 10 business days from the actual date of the shipment of: – the entire production batch of the medicines within one shipment; – remaining medicines which belong to a certain production batch, if the medicines of one production batch are shipped in several batches at different times. Information about absence of the medicines on balance is not transferred by a pharmaceutical entity for the medicines for which an operation of shipment by direct order of data submission has been registered and which are awaiting acceptance by the second party. In this case, an appropriate attribute of absence of the medicine in the warehouse of the pharmaceutical entity (on the balance of which such medicines are recorded according to the MDLP System) will be set for such medicines. A notification can be sent both for a specific SGTIN and for a whole batch of the medicines (that is in the shipper's inventory). If further operations for such medicines are registered by another pharmaceutical entity, these medicines will be recorded on the balance sheet of such pharmaceutical entity and the set attribute will be removed
Interaction participants	– pharmaceutical entity who sends a notification on absence of the medicine on the balance sheet
Description of the actions performed	
1. Making a decision on the need to send a notification to the MDLP System of absence of the medicine on the balance sheet	
2. – 3. Registration in the MDLP System of information on absence of the medicine on the balance sheet by means of scheme 705-not_on_balance.xsd	

List of information to be transferred, and the owner of information resource	To register information in the MDLP System on absence of the medicine on the balance sheet, the pharmaceutical entity shall transmit the following information: – operation date; – identifier of the pharmaceutical entity's business place; – SGTIN or GTIN and medicine production batch number
Special conditions	The notification is not used for the expired medicines. When the attribute is set, the medicine is not cleared from the balance of the pharmaceutical entity who has sent the notification. Medicines should not be withdrawn from circulation. In case of purchase of a new shipment of the medicines within one production batch, or return of previously shipped production batch of the medicines within the time limit for submission of information to the MDLP System, there is no need to submit information about the earlier completed shipment of the last shipment of the medicines which relate to the same production batch (on condition that information about return or new acceptance of the medicine production batch is submitted to MDLP System)

5. Section “Medicine Withdrawal from Circulation”

5.1. Retail Sale of Medicine

5.1.1. Retail Sale of Medicine Using CRE (Including Medicine Sale on Preferential Prescription with Partial Payment)



Picture 40

Annotation	In case of medicine-selling settlement with a citizen, the pharmacy shall issue a receipt and send the corresponding data to MDLP System. If the pharmacy uses CRE, the information on retail sale of medicine can be transmitted through FDO in accordance with Federal Law No.54-FZ of May 22, 2003. The information about retail sale of medicine is transferred to MDLP System by interaction with the information systems of FDO. Information is sent according to the rules of information sending within CRE exchange formats for medicine disposal registration in MDLP System specified in Appendix 3 to these Passports of Processes. In accordance with the current legislation of the Russian Federation, medicine issue is allowed in primary (hereinafter referred to as partial sale) and secondary (consumer) packages. In case of partial sale, the cash receipt contains the number of primary packages sold and the total number of primary packages in the secondary (consumer) packing according to completeness. The information about the received cash receipts is recorded in MDLP System from FDO in aggregated form once a day for each business place of the pharmaceutical entity (if available in the receipt)
Interaction participants	– pharmacy; – FDO
Description of the actions performed	
1. Retail sale of medicine	
2. Transfer of cash receipts to FDO	
3. – 4. Loading of the information on retail sale of medicine to MDLP System from FDO's information systems	
5. Checking of completeness of secondary (consumer) package in case of partial selling (integrity control by aggregated parts)	
6. Recording of the information on selling of primary medicine package (if the partially sold primary package is not the last one)	
7. Withdrawal of secondary (consumer) medicine package from circulation (if	

selling a secondary (consumer) package or selling the last primary package) by means of scheme 10511-retail_sell_kkt.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about retail sale of medicine, the following information is recorded on the basis of cash receipts received from FDO's information systems: – type of withdrawal from circulation (formed automatically by MDLP System); – identifier of the pharmaceutical entity's business place or registration number of the pharmaceutical entity in MDLP System; – TIN of the seller; – number of fiscal cash receipt (tag 1040); – type of fiscal cash receipt (sales receipt, correction receipt); – version of the fiscal data format (tag 1209); – operation date; – date of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – number of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – series of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – cost of the purchased item (retail price) including discount and markup (tag 1079), RUB; – VAT amount, RUB (tag 1200; specify zero if no VAT is applicable); – discount amount (when releasing on preferential prescription with partial payment); – number of primary packages sold and total number of primary packages in secondary (consumer) packing (in case of partial sale); – identifier of the resulting receipt according to the cash receipt (generated automatically by MDLP System)

	– SGTIN
Special conditions	Due to the established period of information submission to MDLP System, the required information on medicine shipment/acceptance confirmed (accepted) by the counterparty, and the information on domestic medicine transfer (as required) may be unavailable in MDLP System as of the date of receiving of the information on medicine retail sale from FDO. In this case SGTIN is registered in the expectation register until all the required information on medicine circulation is received by MDLP System for a period of 7 business days (total established period for submission of missing information to MDLP System). Data about particulars of the prescriptions for medicines are transferred with regard to prescription forms that have number, series and date, provided by the applicable law of the Russian Federation

5.1.2. Retail Sale of Medicine Without CRE (Including Medicine Sale on Preferential Prescription with Partial Payment)

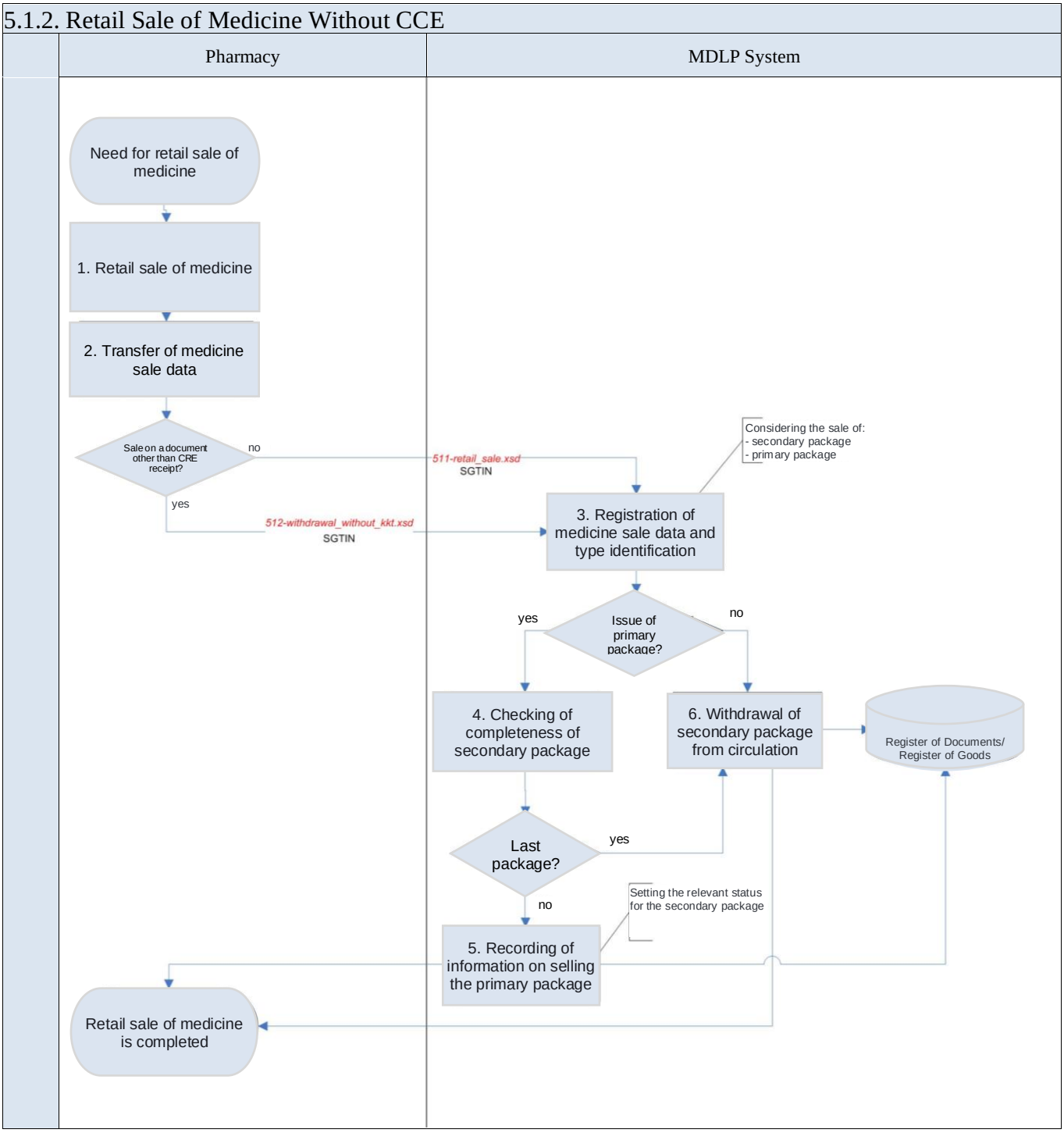


Figure 41

Annotation	In case of medicine-selling settlement with a citizen, the pharmacy may avoid using CRE as provided by the law, but shall issue the sale-confirming document and send the corresponding data to MDLP System. Information on the medicine sale and release on a preferential prescription with partial payment is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the relevant operation. When medicines are released in a pharmacy on documents other than cash register receipt (release on birth certificates, under voluntary health insurance, etc.) a pharmaceutical entity registers the relevant operation. In accordance with the current legislation of the Russian Federation, medicine issue is allowed in primary (hereinafter referred to as partial sale) and secondary (consumer) packages. In case of partial sale of medicine, the pharmaceutical entity shall submit the information to the MDLP System, including the number of primary packages sold and the total number of primary packages in the secondary (consumer) packing according to completeness.
Interaction participants	– pharmacy
Description of the actions performed	
1. Retail sale of medicine	
2. – 3. Registration in the MDLP System of the information on retail sale of medicine by means of scheme 511-retail_sale.xsd / 512-withdrawal_without_kkt.xsd	
List of information to be transferred, and the owner of information resource	In order to register the results of retail sale of medicine in MDLP System, the pharmacy sends the following information: – operation date; – identifier of the pharmacy's business place; – type of the document (receipt, strict security form, agreement etc.); – name of the document (if required); – date of the document; – number of the document; – date of prescription (when selling prescription medicines

	with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – number of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – series of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – retail price, RUB; – VAT amount, RUB (if no VAT is applicable; specify zero); – discount amount (when releasing on preferential prescription with partial payment); – number of primary packages sold and total number of primary packages in secondary (consumer) packing (in case of partial sale); – SGTIN To register in MDLP System the result of medicine release in a pharmacy on documents other than cash register receipt (release on birth certificates, under voluntary health insurance, etc.), a pharmacy sends the following information: – operation date; – identifier of the pharmacy's business place; – document date; – document number; – date of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – number of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – series of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial

	payment); – value, RUB; – VAT amount, RUB (if the transaction is not subject to VAT, 0 is specified); – quantity of sold primary packages and total quantity of primary packages in a secondary (consumer) package (in case of partial release); – SGTIN
4. Checking of completeness of secondary (consumer) package in case of partial selling (integrity control by aggregated parts)	
5. Recording of the information on selling of primary medicine package (if the partially sold primary package is not the last one)	
6. Withdrawal of secondary (consumer) medicine package from circulation (if selling a secondary (consumer) package or selling the last primary package)	
Special conditions	Data about particulars of the prescriptions for medicines are transferred with regard to prescription forms that have number, series and date, provided by the applicable law of the Russian Federation

5.1.3. Retail Sale of Medicine by Means of Distance Selling

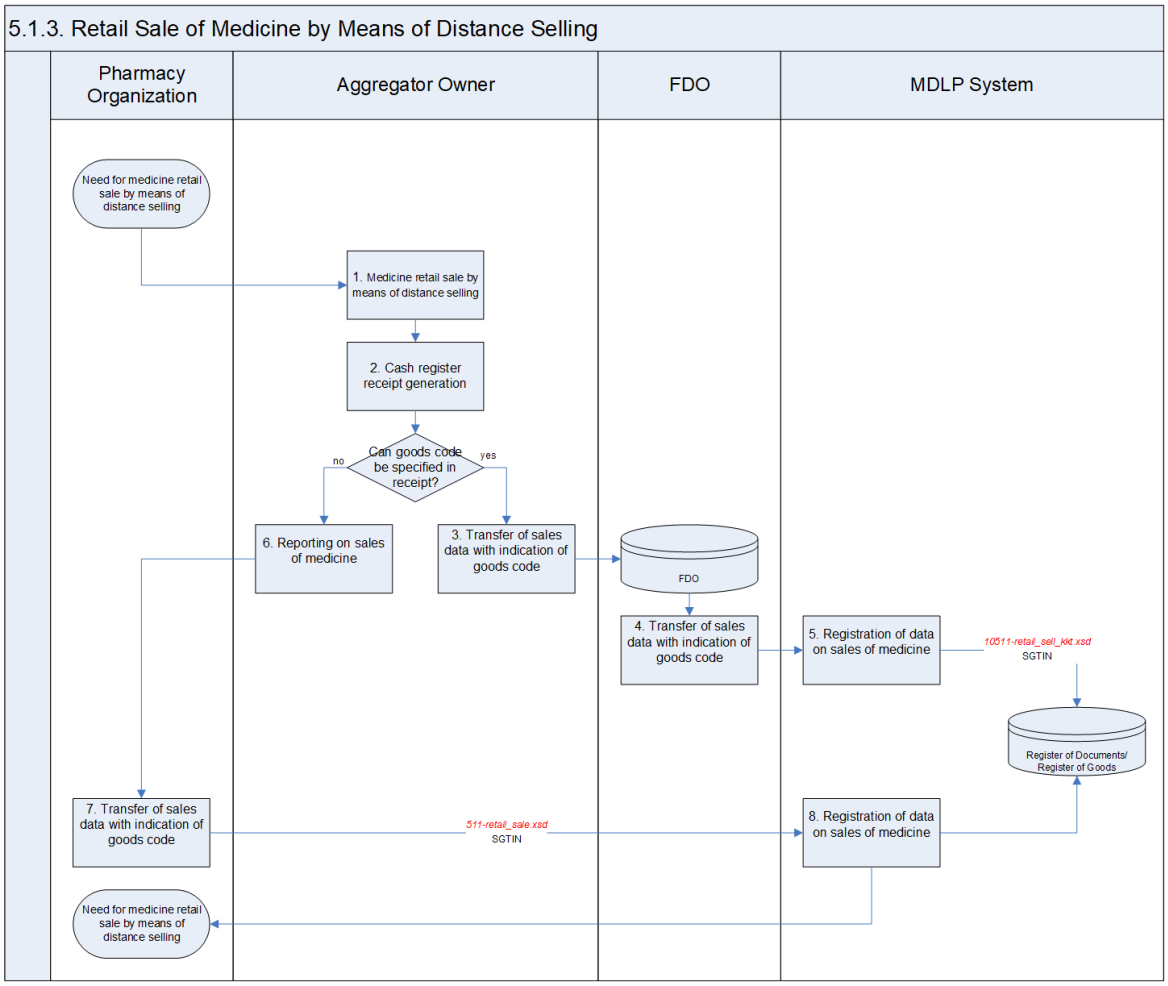


Figure 42

Annotation	Retail sale of medicinal products (except for prescription medicinal products for a medicinal product, narcotic drugs and psychotropic drugs, as well as alcohol-containing medicinal products with a volume fraction of ethyl alcohol exceeding 25 per cent) can be carried out by remote means. Payment for medicines and delivery services can be done at the buyer's choice in cash or non-cash settlements, by prepayment for the order or its payment on the place of receipt. In case of non-cash payment, cash register receipt will be issued with the list of SGTINs being in the bundle of the order. In the fiscal document, it is necessary to fill in tag 1226 (INN of supplier) for each item to monitor sales by distance selling of the medicines. In case of payment in arrears after the medicine is delivered, cash register receipt will be issued by courier after receiving funds from the customer. Information on goods code can be transferred in the fiscal document by interacting with FDO information systems (by filling tag 1226 - INN of the supplier) for each item or information on retail sale of the medicine can be also transferred through scheme 511. Method for transferring information to MDLP System either through FDO with indication of the goods code, or by transferring information by means of MDLP System by scheme 511, is chosen by agreement of the pharmacy organization and aggregator owner. If medicine is sold by an organization that performs the functions of the aggregator and is not registered participant of the MDLP System: – If it is possible to fill in the goods code in the cash register receipt, at the moment of receipt of the order in the FD, aggregator fills in the goods code in the cash register receipt on the basis of the SGTINs received from the drugstore. Tag 1226 (INN of the supplier - medicine owner in the MDLP System) shall be additionally filled in the FD for each goods item. Upon receipt and processing of the FD in the MDLP System, the medicine will be withdrawn from circulation by INN of the pharmacy organization. – If aggregator cannot fill in the goods code in the cash register receipt, medicine is withdrawn from circulation within distance selling by the pharmacy organization by sending the information to the MDLP System by means of scheme 511. In case of partial sale, cash register receipt will contain the number of primary packings sold and the total number of primary packings in secondary (consumer) packing according to completeness. Recording of information on the receipts received from FDO is carried out in the MDLP System once a day in aggregated form for each business place of the pharmaceutical entity (if available in the receipt)
Interaction participants	– pharmacy organizations; – owner of the aggregator (aggregator); – FDO
Description of the actions performed	

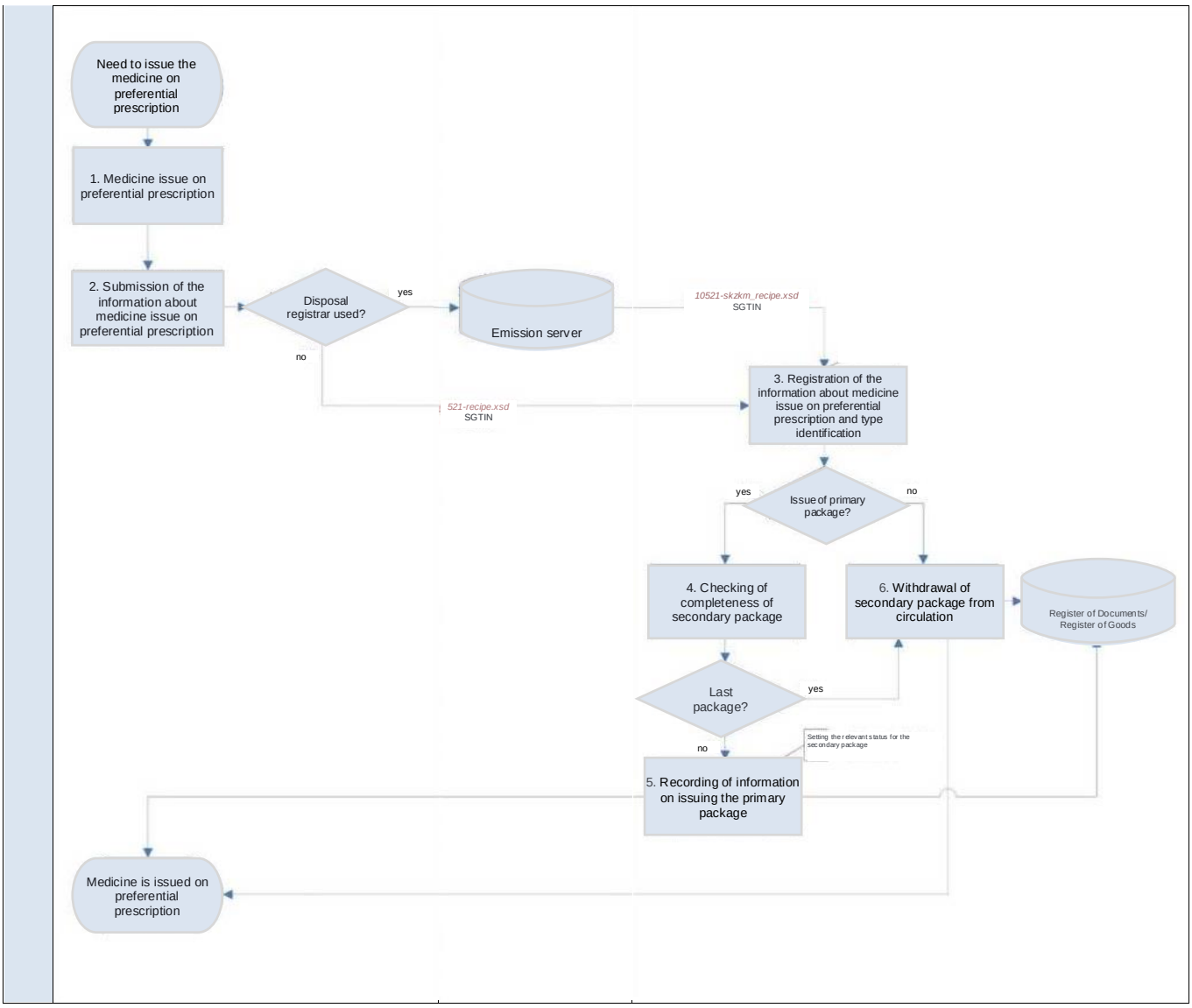
1. Retail sale of medicine by means of distance selling	
2. Cash register receipt generation	
3. Transfer of receipt with the goods code to the FDO (if aggregator can specify goods code and pharmacy organization’s business place in the cash register receipt)	
4. – 5. Uploading of information on medicine retail sale into the MDLP System from the FDO information systems (when aggregator indicates the goods code and the pharmacy organization’s business place in the cash register receipt)	
List of information to be transferred, and the owner of information resource	When registering the results of the medicine retail sale by means of distance selling in the MDLP System, the following information must be recorded on the basis of the receipts received from the FDO information systems: – type of withdrawal from circulation (it is automatically generated by MDLP System); – INN of the seller; – number of fiscal receipt (tag 1040); – type of fiscal receipt (sales receipt, correction receipt); – format version of fiscal data (tag 1209); – operation date; – Supplier’s INN (tag 1226); – settlement subject cost (retail sale price) considering discounts and extra charges (tag 1079), rub; – VAT amount, RUB (tag 1200, if no VAT is applicable, zero will be specified); – discount amount (in case of sale on preferential prescription with partial payment); – date of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – number of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – series of prescription (when selling prescription medicines with regard to prescription forms that have number, series and date, including selling on prescriptions with partial payment); – attribute of distance selling of the medicines (tag 1265); – number of primary packings sold and the total number of primary packings in secondary (consumer) packing (in case of partial sale); – identifier of the result certificate for receipt (it is automatically generated by MDLP System);

	– SGTIN (tag 1162\1163)
6. Aggregator informs the pharmacy organization of the medicine sale by means of distance selling (if it is not possible to indicate the goods code in the cash register receipt)	
7. – 8. Registration in MDLP System of information on medicine retail sale by means of distance selling by using scheme 511-retail_sale.xsd (if aggregator cannot indicate the goods code)	
List of information to be transferred, and the owner of information resource	To register the results of the medicine retail sale by means of distance selling in the MDLP System, the pharmaceutical entity shall transmit the following information: – operation date; – identifier of the pharmacy organization's business place; – document type (receipt); – document name (if required); – document date; – document number; – INN of the organization that conducted the distance selling (aggregator's); – retail sale price, rub.; – VAT amount, RUB (if no VAT is applicable; specify zero); – discount amount (in case of sale on preferential prescription with partial payment); – number of primary packings sold and the total number of primary packings in secondary (consumer) packing (in case of partial sale); – SGTIN
Special conditions	In accordance with Part 2 of Article 551 of the Federal Law "On Medicine Circulation", the pharmaceutical entities that are participants of the experiment on distance retail trade of the prescription medicines are entitled to carry out distance retail trade of the prescription medicines and to submit information to the MDLP System in accordance with this section. Data about particulars of the prescriptions for medicines are transferred with regard to prescription forms that have number, series and date, provided by the applicable law of the Russian Federation

5.2. Medicine Issue on Preferential Prescription

5.2.1. Medicine Issue on Preferential Prescription Without CRE

5.2.1. Medicine Issue on Preferential Prescription Without CRE			
	Pharmacy/ Medical organizations	Emission server	MDLP System


Need to issue the medicine on preferential prescription
1. Medicine issue on preferential prescription
2. Submission of the information about medicine issue on preferential prescription
Disposal registrar used?
yes
no
Emission server
10521-skzkm_recipe.xsd
SGTIN
521-recipe.xsd
SGTIN
3. Registration of the information about medicine issue on preferential prescription and type identification
Issue of primary package?
yes
no
4. Checking of completeness of secondary package
6. Withdrawal of secondary package from circulation
Register of Documents/ Register of Goods
Last package?
yes
no
Setting the relevant status for the secondary package
5. Recording of information on issuing the primary package
Medicine is issued on preferential prescription

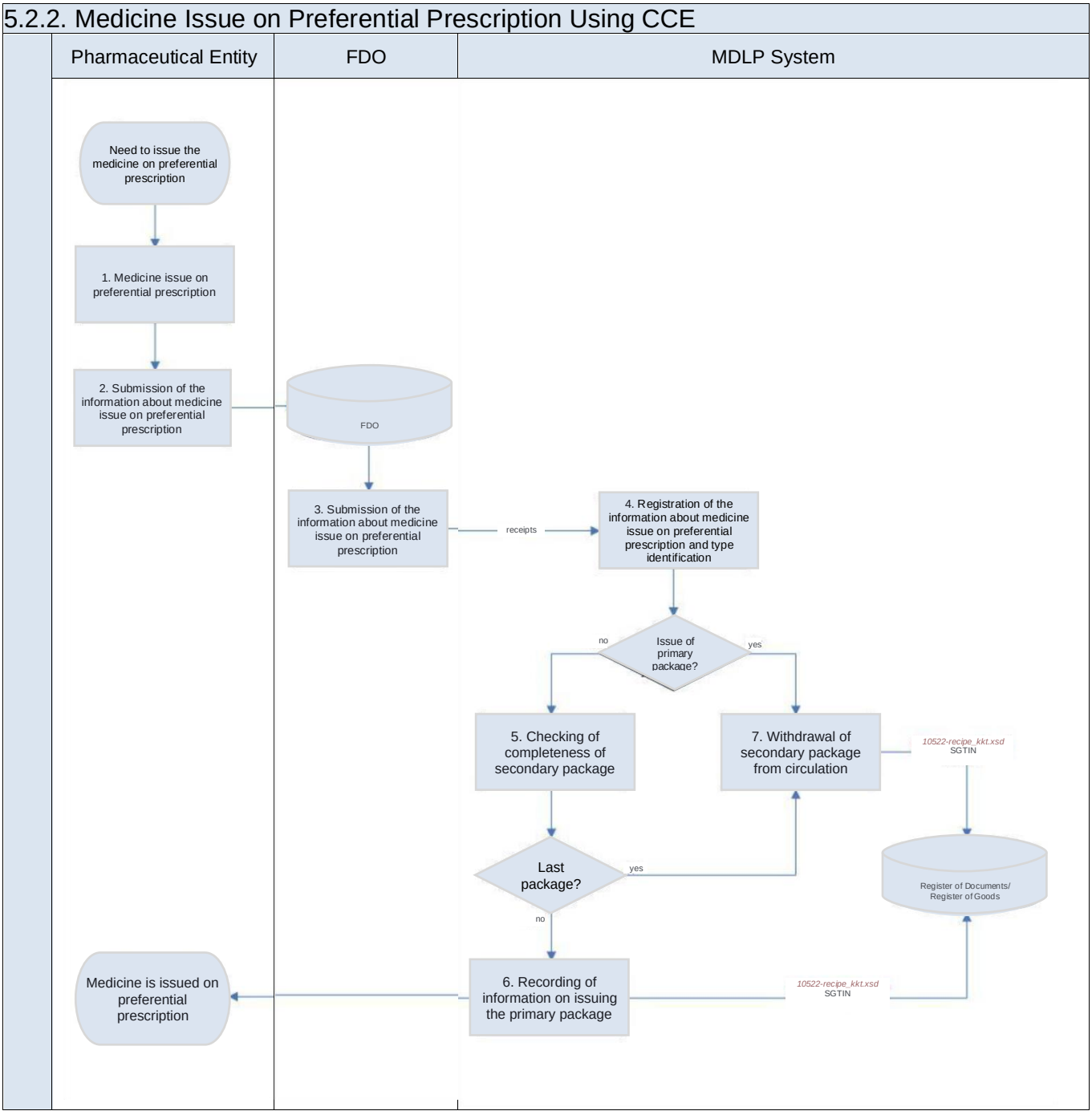
Picture 43

Annotation	When releasing medicine on a preferential prescription, the pharmacy employee makes a note on the prescription (name or number of the pharmacy, name and dosage of the medicine, issued amount, signature of the person who issued the medicine, and date of issuing). When releasing the medicine on preferential prescriptions, which are valid within one year, the preferential prescription shall be returned to the patient, indicating the name or number of the pharmacy, signature of the pharmacy employee, issued amount and the date of issuing on the back side. The notes on prior issuing of the medicine are taken into consideration when the patient comes to the pharmacy again. Medicine is issued to the citizens entitled to receive medicine free of charge (without payment) or to receive medicine with discount (with partial payment). Information on the medicine release on a subsidized prescription is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the relevant operation. In case of medicine issue with partial payment, the pharmaceutical entity shall register the corresponding operation in MDLP System according to section 5.1.1 or section 5.1.2 of these Passports of Processes. In accordance with the current legislation of the Russian Federation, medicine issue is allowed in primary (hereinafter referred to as partial issue) and secondary (consumer) packages. In case of partial issue of medicine, the pharmaceutical entity shall submit the information to the MDLP System, including the number of primary packages issued and the total number of primary packages in the secondary (consumer) packing according to completeness. If the disposal registrar provided by MDLP System Operator is available, the pharmaceutical entity may transfer the information about medicine issuing on preferential prescription to MDLP System using the disposal registrar in automated mode. The information on medicine issue within high cost nosologies program shall be registered only using disposal registrar.
Interaction participants	– pharmacy/ medical organization
Description of the actions performed	

<table>
<tr><td colspan="2">1. Medicine issue on preferential prescription</td></tr>
<tr><td colspan="2">2. – 3. Registration of information on medicine issue on preferential prescription in the MDLP System by means of schemes 10521-skzkm_recipe.xsd / 521-recipe.xsd</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>In order to register the information about medicine issue on preferential prescription without payment in MDLP System, the issuing organization sends the following information:
– operation date;
– business place identifier of the organization that issues the medicine on preferential prescription;
– date of preferential prescription;
– number of preferential prescription;
– serial number of the preferential prescription (if required);
– number of primary packages issued and total number of primary packages in secondary (consumer) packing (in case of partial issue);
– SGTIN;
– information about the device used for registration of information (in case of data transmission using a disposal registrar)</td></tr>
<tr><td colspan="2">4. Checking of completeness of secondary (consumer) package in case of partial issue (integrity control by aggregated parts)</td></tr>
<tr><td colspan="2">5. Recording of the information on issue of primary medicine package (if the partially issued primary package is not the last one)</td></tr>
<tr><td colspan="2">6. Withdrawal of secondary (consumer) medicine package from circulation (if issuing a secondary (consumer) package or the last primary package)</td></tr>
<tr><td>Special conditions</td><td>Due to the established period of information submission to MDLP System when using DR, the required information on medicine shipment/acceptance confirmed (accepted) by the counterparty, and the information on domestic medicine transfer (as required) may be unavailable in MDLP System as of the date of sending the information on medicine release on a subsidized prescription. In this case SGTIN is registered in the expectation register before all the required information on medicine circulation is received by MDLP System for a period of 7 business days (total established period for submission of</td></tr>
</table>

	missing information to MDLP System) In case if identification means applied to the medicines do not pass verification of the cryptopart during disposal by means of the DR, scheme 10523-skzkm_code_error_recipe.xsd will be automatically formed for such medicines instead of scheme 10521-skzkm_recipe.xsd

5.2.2. Medicine Issue on Preferential Prescription Using CRE



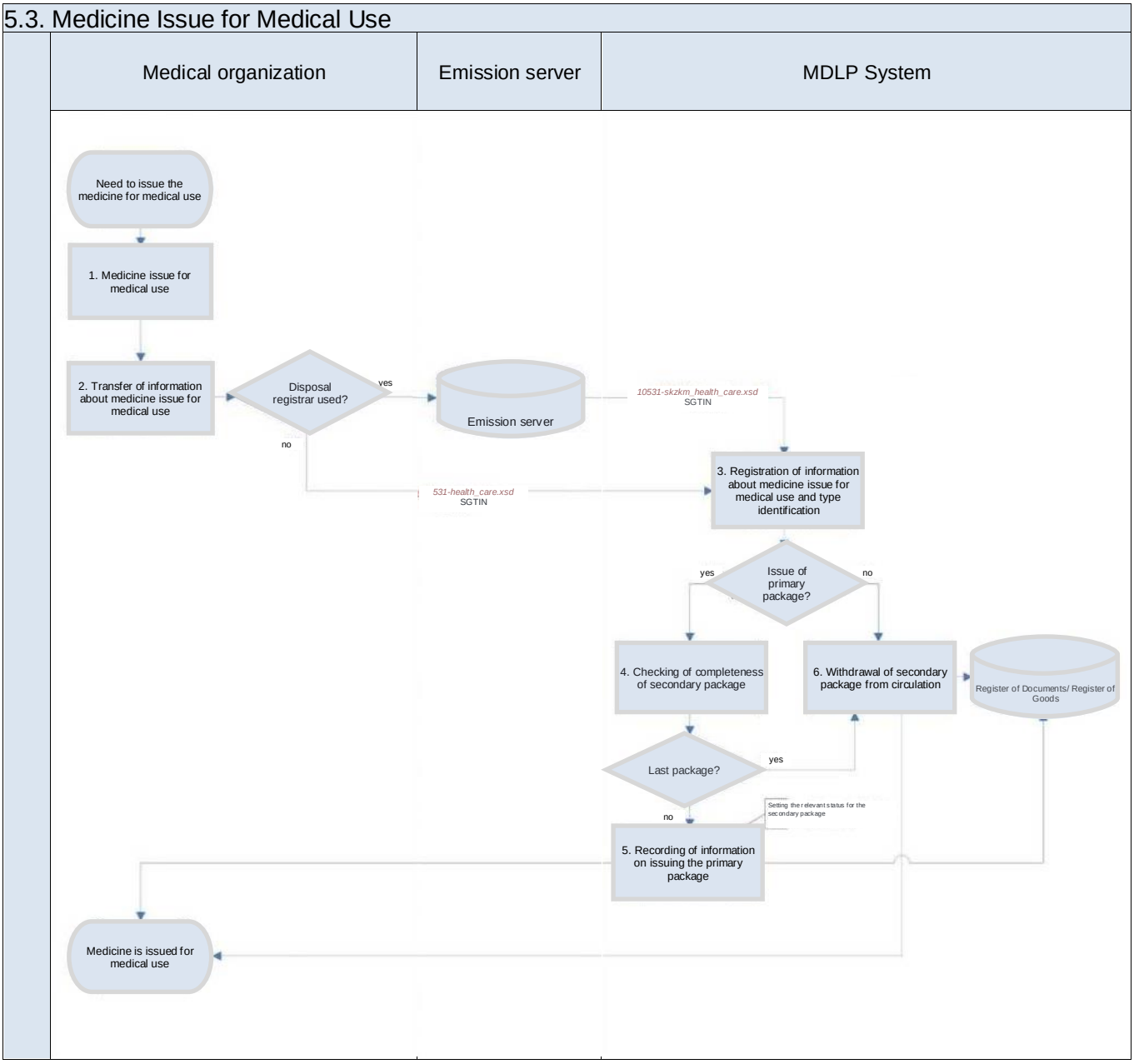
Picture 44

Annotation	When releasing medicine on a preferential prescription, the pharmacy employee makes a note on the prescription (name or number of the pharmacy, name and dosage of the medicine, issued amount, signature of the person who issued the medicine, and date of issuing). When releasing the medicine on preferential prescriptions, which are valid within one year, the preferential prescription shall be returned to the patient, indicating the name or number of the pharmacy, signature of the pharmacy employee, issued amount and the date of issuing on the back side. The notes on prior issuing of the medicine are taken into consideration when the patient comes to the pharmacy again. Medicine is issued to the citizens entitled to receive medicine free of charge (without payment) or to receive medicine with discount (with partial payment). In case of medicine issue with partial payment, the pharmaceutical entity shall register the corresponding operation in MDLP System according to section 5.1.1 or section 5.1.2 of these Passports of Processes. If the pharmacy uses CRE, the information about medicine issue on preferential prescription may be transmitted through FDO. In this case the information about medicine issue on preferential prescription is transferred to MDLP System by interaction with the information systems of FDO. In accordance with the current legislation of the Russian Federation, medicine issue is allowed in primary (hereinafter referred to as partial issue) and secondary (consumer) packages. In case of partial issue of medicine, the information submitted the to the MDLP System through FDO shall include the number of primary packages issued and the total number of primary packages in the secondary (consumer) packing according to completeness. The information received from FDO is recorded in MDLP System in aggregated form once a day for each business place of the pharmaceutical entity (if available in the receipt)
Interaction participants	– pharmacy; – FDO
Description of the actions performed	

1. Medicine issue on preferential prescription	
2. Submission of the information about medicine issue on preferential prescription to FDO	
3. – 4. Loading of the information about medicine issue on preferential prescription to MDLP System from FDO's information systems	
5. Checking of completeness of secondary (consumer) package in case of partial selling (integrity control by aggregated parts)	
6. Recording of the information on issue of primary medicine package (if the partially issued primary package is not the last one)	
7. Withdrawal of secondary (consumer) medicine package from circulation (if issuing a secondary (consumer) package or issuing the last primary package) by means of schemes 10522-recipe_kkt.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about medicine issue on preferential prescription, the following information is recorded on the basis of data received from FDO's information systems: – type of withdrawal from circulation (formed automatically by MDLP System); – identifier of the pharmaceutical entity's business place or registration number of the pharmaceutical entity in MDLP System; – TIN of the pharmaceutical entity; – number of fiscal cash receipt (tag 1040); – type of fiscal cash receipt (sales receipt, correction receipt); – version of the fiscal data format (tag 1209); – operation date; – date of preferential prescription (when releasing on preferential prescription with partial payment); – number of preferential prescription (when releasing on preferential prescription with partial payment); – serial number of preferential prescription (when releasing on preferential prescription with partial payment, if required); – number of primary packages issued and total number of primary packages in secondary (consumer) packing (in

	case of partial issue); – identifier of the resulting receipt for CRE receipt (generated automatically by MDLP System facilities); – SGTIN
Special conditions	Due to the established period of information submission to MDLP System, the required information on medicine shipment/acceptance confirmed (accepted) by the counterparty, and the information on domestic medicine transfer (as required) may be unavailable in MDLP System as of the date of receipt from FDO of the information on medicine release on a subsidized prescription. In this case SGTIN is registered in the expectation register before all the required information on medicine circulation is received by MDLP System for a period of 7 business days (total established period for submission of missing information to MDLP System)

5.3. Medicine Issue for Medical Use

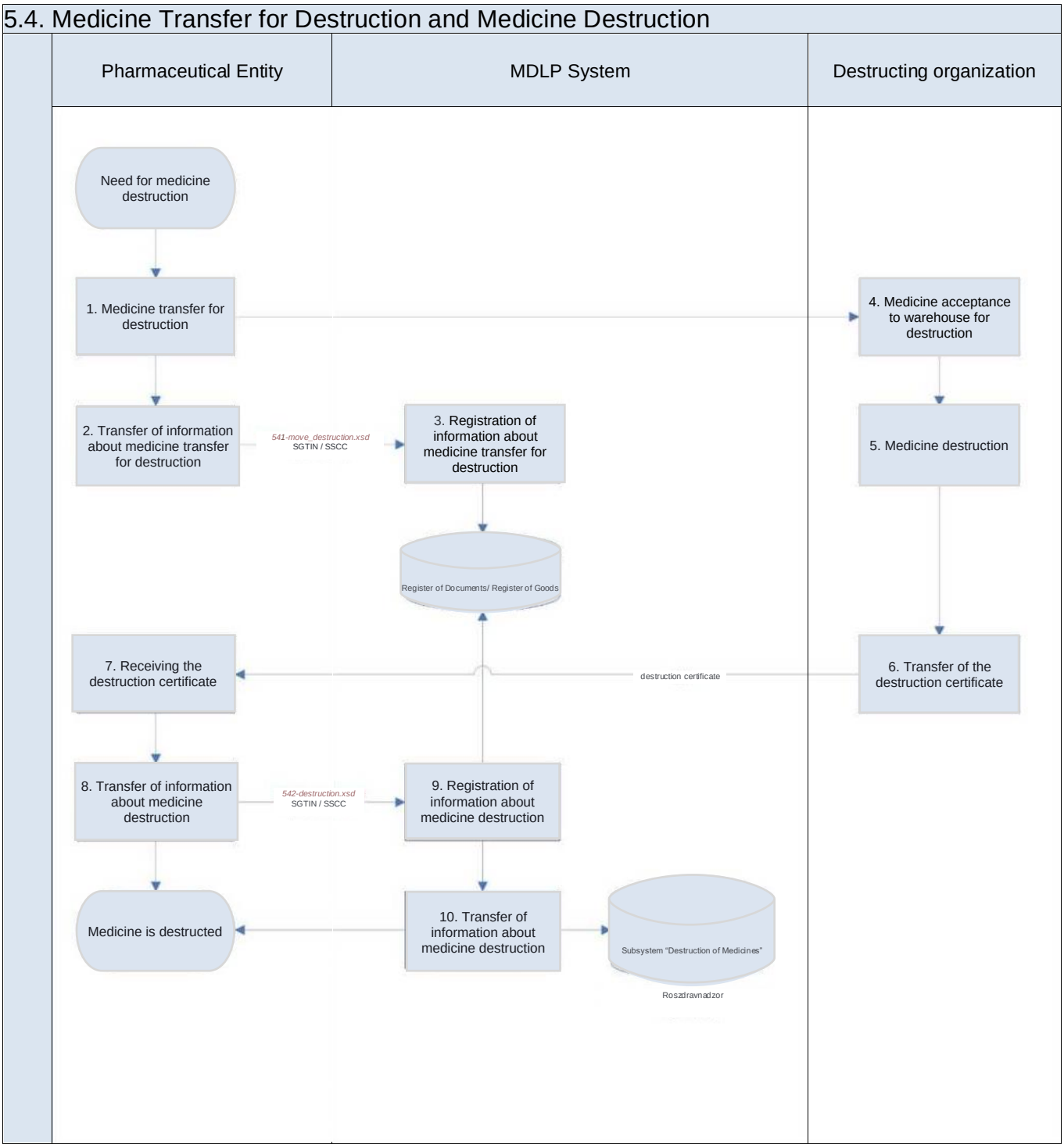


Picture 45

Annotation	Medicine is issued for medical use on the basis of department requirements or according to other documents prescribed by law and/or established by the internal rules of the medical organization, as part of medical care in outpatient or inpatient facilities in medical organizations of any form of ownership and departmental affiliation. Registration of information about medicine issue for medical use according to this section is available for the pharmaceutical entity that has a license for pharmaceutical/medical activity and narcotics circulation. Information on the medicine release for medical use is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the relevant operation. It is allowed to issue medicine for medical use in primary (hereinafter referred to as partial issue) and secondary (consumer) package. In case of partial issue of medicine, the pharmaceutical entity shall submit the information to the MDLP System, including the number of primary packages issued and the total number of primary packages in the secondary (consumer) packing according to completeness. If the disposal registrar provided by MDLP System Operator is available, the pharmaceutical entity may transfer the information about medicine issue for medical use to MDLP System using the disposal registrar in automated mode.
Interaction participants	– medical organization
Description of the actions performed	
1. Partial issue of medicine for medical use	
2. – 3. Registration of information about medicine issue for medical use in MDLP System by means of schemes 10531-skzkm_health_care.xsd / 531-health_care.xsd	
List of information to be transferred, and the owner of information resource	In order to register the operation of medicine issue for medical use in MDLP System, the medical organization sends the following information: – operation date; – identifier of the medical organization’s business place;

	– date of the document acting as the basis for medicine issue; – number of the document acting as the basis for medicine issue; – number of primary packages issued and total number of primary packages in secondary (consumer) packing (in case of partial sale); – SGTIN; – information about the device used for registration of information (in case of data transmission using a disposal registrar)
4. Checking of completeness of secondary (consumer) package in case of partial issue (integrity control by aggregated parts)	
5. Recording of the information on issuing of primary medicine package (if the partially issued primary package is not the last one)	
6. Withdrawal of secondary (consumer) medicine package from circulation (if issuing a secondary (consumer) package or the last primary package)	
Special conditions	Due to the established period of information submission to MDLP System when using DR, the required information on medicine shipment/acceptance confirmed (accepted) by the counterparty, and the information on domestic medicine transfer (as required) may be unavailable in MDLP System as of the date of sending the information on medicine release on a subsidized prescription. In this case SGTIN is registered in the expectation register before all the required information on medicine circulation is received by MDLP System for a period of 7 business days (total established period for submission of missing information to MDLP System). In case if identification means applied to the medicines do not pass verification of the cryptopart during disposal by means of the DR, scheme 10532-skzkm_code_error_healthcare.xsd will be automatically formed for such medicines instead of scheme 10531-skzkm_health_care.xsd Information on sale of the medicines for medical use is submitted to the MDLP System upon the corresponding operation, it is not allowed to withdraw medicines for medical use from circulation upon acceptance of the medicines to the balance of the medical organization.

5.4. Medicine Transfer for Destruction and Medicine Destruction



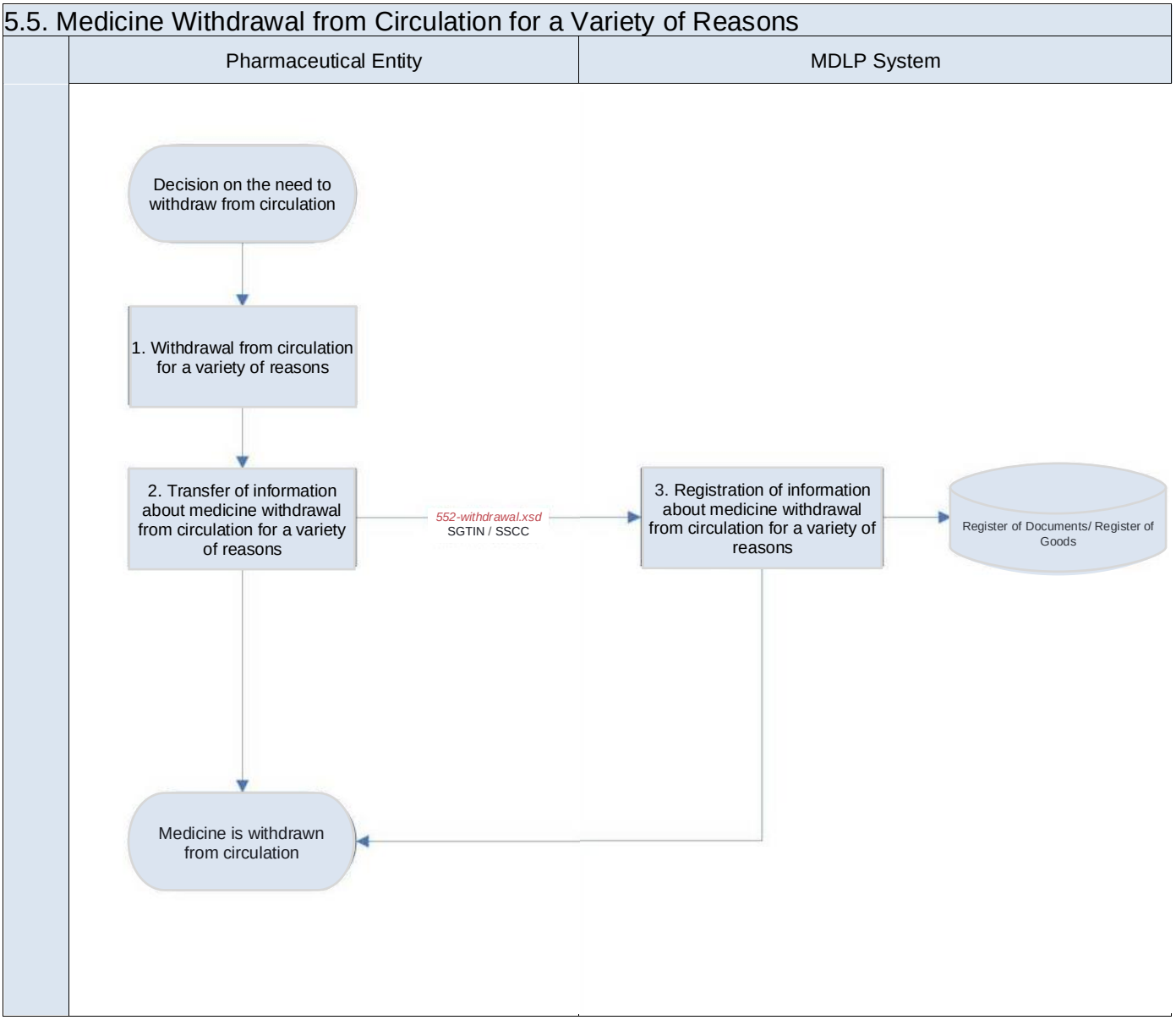
Picture 46

Annotation	Substandard, counterfeit and falsified medicine shall be withdrawn, removed and destructed by the medicine-related decision of their owner, decision of the Federal Service for Surveillance in Healthcare of the Russian Federation. The substandard, counterfeit and falsified medicine owner, who made a decision on their withdrawal, removal and destruction, transfers the medicine to the organization that destructs medicine, on the basis of the relevant contract. The organization that destructs medicine shall prepare a medicine destruction certificate. The pharmaceutical entities, which are owners of the medicine subject to destruction, shall send the medicine destruction certificates to the Federal Service for Surveillance in Healthcare of the Russian Federation. Information on medicine transfer for destruction is submitted to MDLP System by a pharmaceutical entity within 5 business days after the date of medicine transfer for destruction. Following the medicine destruction, a pharmaceutical entity submits to MDLP System the information on the destruction event within 5 business days from the date of receiving the destruction certificate
Interaction participants	– pharmaceutical entity that transfers the medicine for destruction
Description of the actions performed	
1. Medicine transfer for destruction by the pharmaceutical entity	
2. – 3. Registration of the information about medicine transfer for destruction in MDLP System by means of scheme 541-move_destruction.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about operations of medicine transfer for destruction, the pharmaceutical entity sends the following information: – operation date; – identifier of the pharmaceutical entity's business place where the medicine is transferred for destruction from; – TIN/KPP of the destructing organization; – address of the warehouse of the destructing organization (according to FIAS);

	– date of the contract; – number of the contract; – date of the certificate of medicine transfer for destruction; – number of the certificate of medicine transfer for destruction; – reason of medicine transfer for destruction; – basis of medicine transfer for destruction; – details of the decision of the Federal Service for Surveillance in Healthcare of the Russian Federation regarding medicine withdrawal from circulation (if available); – SGTIN and/or SSCC
4. Medicine acceptance to warehouse of the destructing organization, for subsequent destruction	
5. Medicine destruction	
6. Transfer of the medicine destruction certificate to the pharmaceutical entity that transferred the medicine for destruction	
7. Receiving the medicine destruction certificate	
8. – 9. Registration of information about medicine destruction in MDLP System by means of scheme 542-destruction.xsd	
List of information to be transferred, and the owner of information resource	The information about medicine destruction is registered in MDLP System by the pharmaceutical entity that preciously transferred the medicine for destruction. The following information is sent to MDLP System: – operation date; – identifier of the pharmaceutical entity's business place where the medicine is transferred for destruction from; – destruction method; – TIN/KPP of the destructing organization; – date of the medicine destruction certificate; – number of the medicine destruction certificate; – SGTIN and/or SSCC
10. Automatic transfer of information from MDLP System to the Subsystem "Destruction of Medicines" of the automated information system of the Federal	

Service for Surveillance in Healthcare of the Russian Federation	
List of information to be transferred, and the owner of information resource	Through IEIS, MDLP System sends the information on the medicine destruction to the automated information system of Roszdravnadzor according to the information interaction format

5.5. Medicine Withdrawal from Circulation for a Variety of Reasons (Selection for Sampling Control, Shortage, Customs Control, etc.)



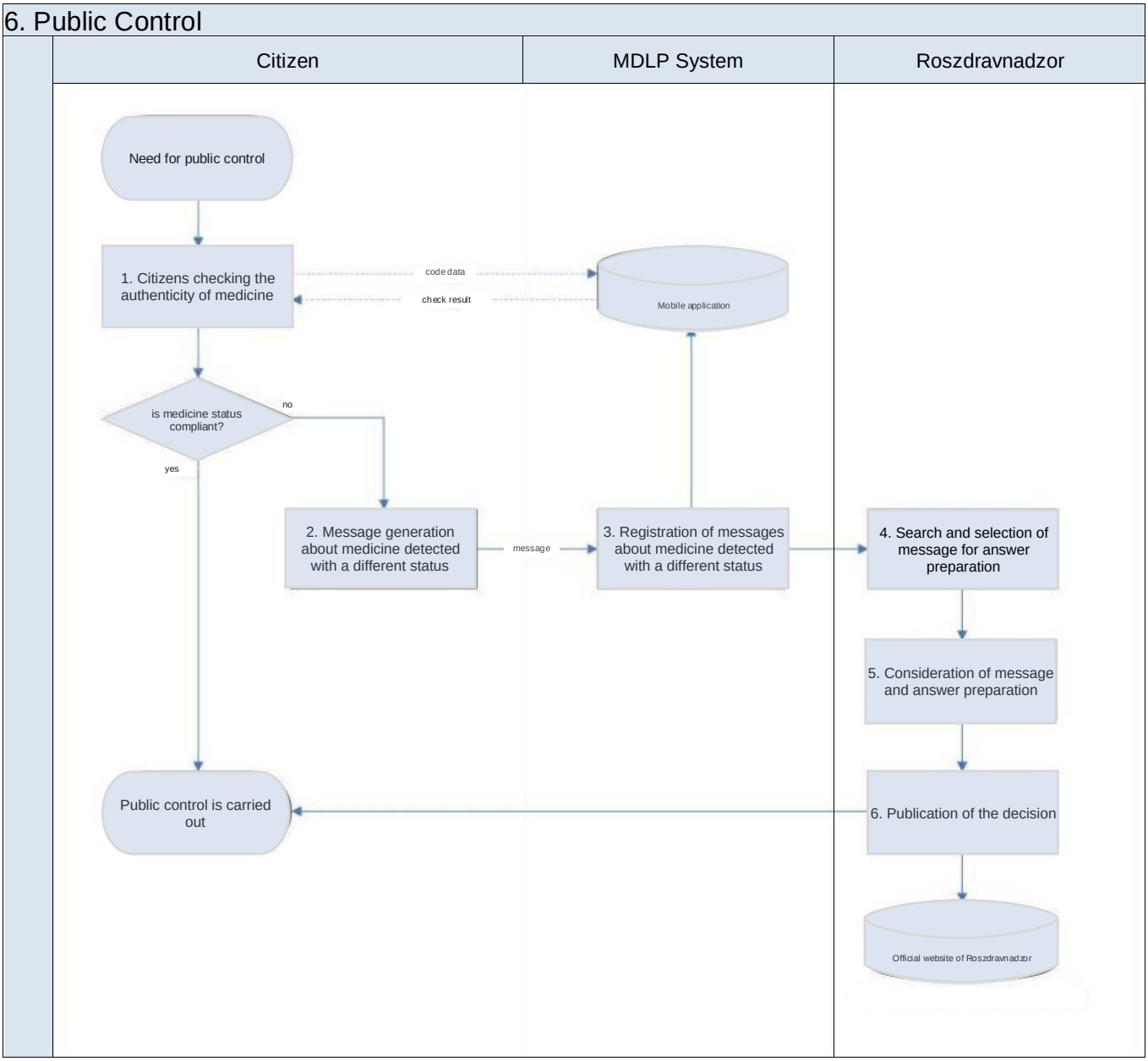
Picture 47

Annotation	Medicine can be withdrawn from circulation by pharmaceutical entities considering different types of the operations performed: – sampling by customs authorities (type 7); – sampling for federal state supervision (surveillance) (type 6); – sampling for clinical studies (type 9); – sampling for pharmaceutical expertise (type 10); – shortage (type 11); – transfer of demonstration samples (type 12); – discarding without transfer for destruction (type 13); – withdrawal from circulation of SSCC/SGTIN accumulated during the experiment period (type 14); – discarding of broken up secondary packing (type 16); – discarding of production rejects (type 15); – production of medical devices (type 17); – medicine production (type 18); – control sampling (type 19); – retain sampling (type 20); – theft (type 21); – write-off of the medicines with no information according to BP (type 23); – export outside the territory of the Russian Federation (type 24); – delivery of humanitarian assistance (type 26). Information on medicine withdrawal from circulation is submitted to MDLP System by the pharmaceutical entity within 5 business days from the date of the relevant operation
Interaction participants	– pharmaceutical entity that withdraws the medicine from circulation
Description of the actions performed	
1. Medicine withdrawal from circulation for a variety of reasons by the	

pharmaceutical entity	
2. – 3. Registration of information about medicine withdrawal from circulation for a variety of reasons in MDLP System by means of schemes 552-withdrawal.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about operations of medicine withdrawal from circulation for a variety of reasons, the pharmaceutical entity sends the following information: – operation date; – registration number of the MAH (or its representative office) or identifier of the pharmaceutical entity's business place; – type of withdrawal from circulation; – code of country of exports (for the following types of withdrawal from circulation: export outside the territory of the Russian Federation and delivery of humanitarian assistance); – date of the supporting document (if necessary) or a date of the state contract on State defense order (in case of withdrawal from circulation within the closed contracts (agreements)); – number of the supporting document (if necessary) or identifier of the state contract on State defense order (in case of withdrawal from circulation within the closed contracts (agreements)); – SGTIN and/or SSCC; – part of the secondary packing
Special conditions	It is not allowed to register the information on withdrawal from circulation with type "Withdrawal of medicines accumulated during the experiment period" for medicines supplied under the high cost nosologies program. It is not allowed to register the information on withdrawal from circulation with type "Withdrawal of medicines accumulated during the experiment period" for medicines produced after 7/1/2020. Writing off the stripped secondary packing is allowed only for the medicines for which the operation of partial disposal (retail sale, release on a subsidized prescription, release for medical use) was previously registered. Registration of information on withdrawal from circulation with "Writing off without transfer for destruction" type is used, among

	other things, to register information on the medicine shipment within the closed contracts (agreements). In case of such shipment, a detail - number of the supporting document shall contain an identifier of the state contract on State defense order assigned pursuant to article 6.1 of the Federal Law “On State Defense Order”. When registering an information on withdrawal of the medicine from circulation within export outside the territory of the Russian Federation or delivery of humanitarian assistance, a code of country of exports shall be specified. Operation with the “federal oversight” type (type 8) is deprecated

6. Section “Public Control”



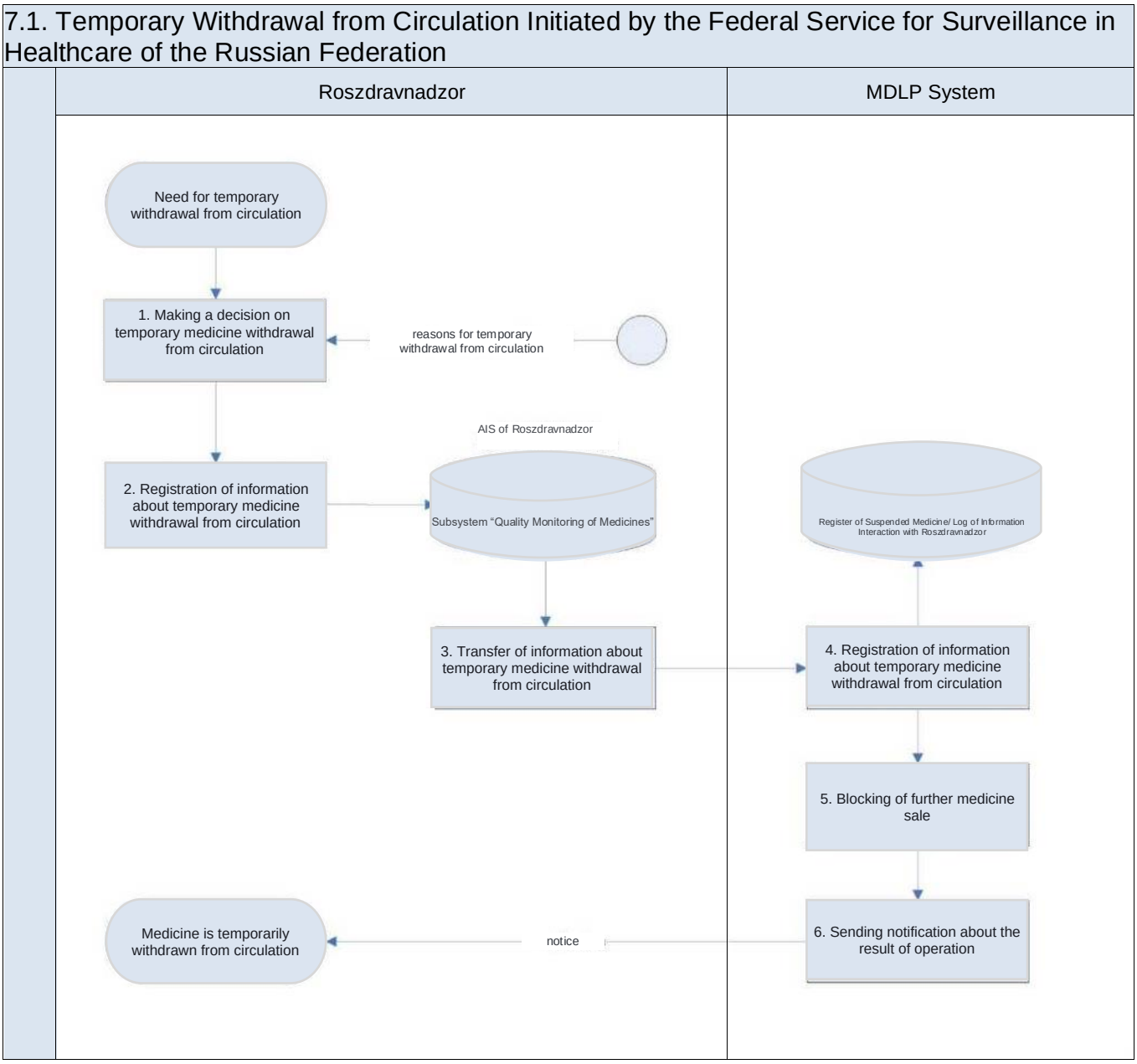
Picture 48

Annotation	Within the public control, citizens of the Russian Federation should be able to verify medicine authenticity when reading the two-dimensional bar code on the secondary (consumer) packing using a mobile device camera. If a medicine is discovered with unknown authenticity or incorrect status according to MDLP System, the citizens may send an appropriate message to MDLP System.
Interaction participants	– citizens of the Russian Federation; – Roszdravnadzor
Description of the actions performed	
1. Checking of the authenticity of goods item by citizens of the Russian Federation using MDLP System	
List of information for a citizen	– trade name; – date of check; – expiration date; – dosage form, dosage; – marking code; – international non-proprietary name; – production series number; – content of secondary (consumer) packing of medicine; – SGTIN status as per MDLP System data
2. – 3. Registration of information on the goods item discovered with incorrect status according to MDLP System	
List of information to be transferred, and the owner of information resource	If the medicine status is incorrect, the citizen shall register a message, specifying the following data: – date of non-conformity detection; – data of medicine location at the moment of authenticity check; – information about the violator; – information about the claimant; – medicine trade name; – SGTIN (if available)

4. Searching of the information in MDLP System registered by external users and selection of messages to prepare the answers
5. Review of the selected messages by the Federal Service for Surveillance in Healthcare of the Russian Federation
6. Reporting on the decision made on the website of the Federal Service for Surveillance in Healthcare of the Russian Federation

7. Section “Suspension of Circulation”

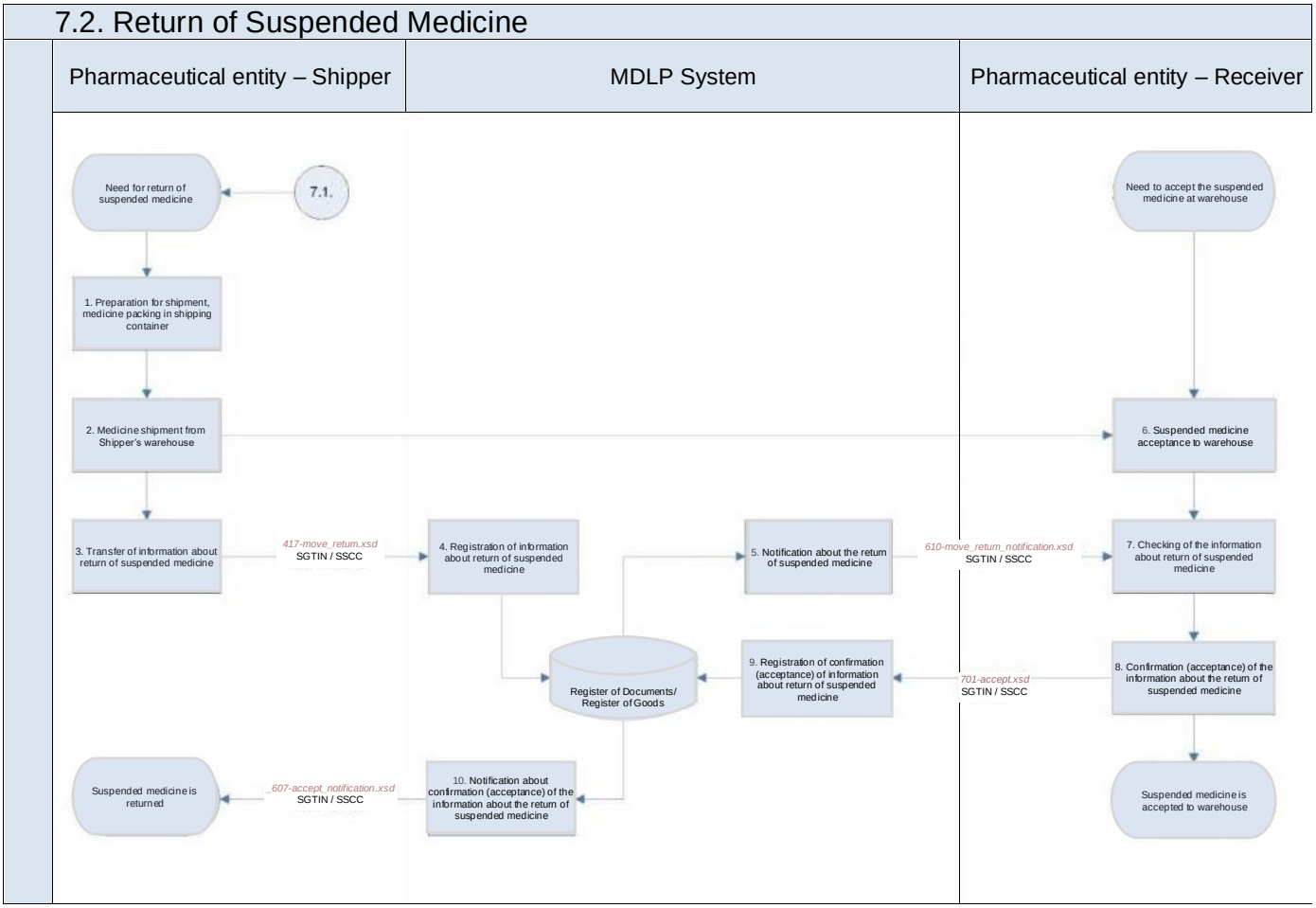
7.1. Suspension of Circulation Initiated by the Federal Service for Surveillance in Healthcare of the Russian Federation



Picture 49

<table>
<tr><td>Annotation</td><td>Suspension of medicine circulation:
– can be carried out following the results of quality non-compliance identification within federal state supervision (surveillance) of medicine circulation by the Federal Service for Surveillance in Healthcare of the Russian Federation and its local offices;
– can be initiated by the medicine MAH.
Suspension of circulation is possible both of the entire series, and of individual medicine batches</td></tr>
<tr><td>Interaction participant</td><td>– Roszdravnadzor</td></tr>
<tr><td colspan="2">Description of the actions performed</td></tr>
<tr><td colspan="2">1. Making a decision by the Federal Service for Surveillance in Healthcare of the Russian Federation on suspension of medicine circulation, including by the results of quality non-compliance identification within federal state supervision (surveillance) of medicine circulation by the Federal Service for Surveillance in Healthcare of the Russian Federation and its local offices, or initiated by the medicine MAH</td></tr>
<tr><td colspan="2">2. Information registration on suspension of medicine circulation in the Subsystem “Quality Monitoring of Medicines” of the automated information system of the Federal Service on Surveillance in Healthcare of the Russian Federation</td></tr>
<tr><td colspan="2">3. – 4. Automatic transfer of information from the Subsystem “Quality Monitoring of Medicines” of the automated information system of the Federal Service for Surveillance in Healthcare of the Russian Federation to MDLP System</td></tr>
<tr><td>List of information to be transferred, and the owner of information resource</td><td>The information is transferred from the Subsystem “Quality Monitoring of Medicines” through IEIS according to the information interaction format</td></tr>
<tr><td colspan="2">5. Blocking of further medicine sale</td></tr>
<tr><td colspan="2">6. Sending the notice to the Federal Service for Surveillance in Healthcare of the Russian Federation regarding the operation completion results</td></tr>
</table>

7.2. Return of Suspended Medicine



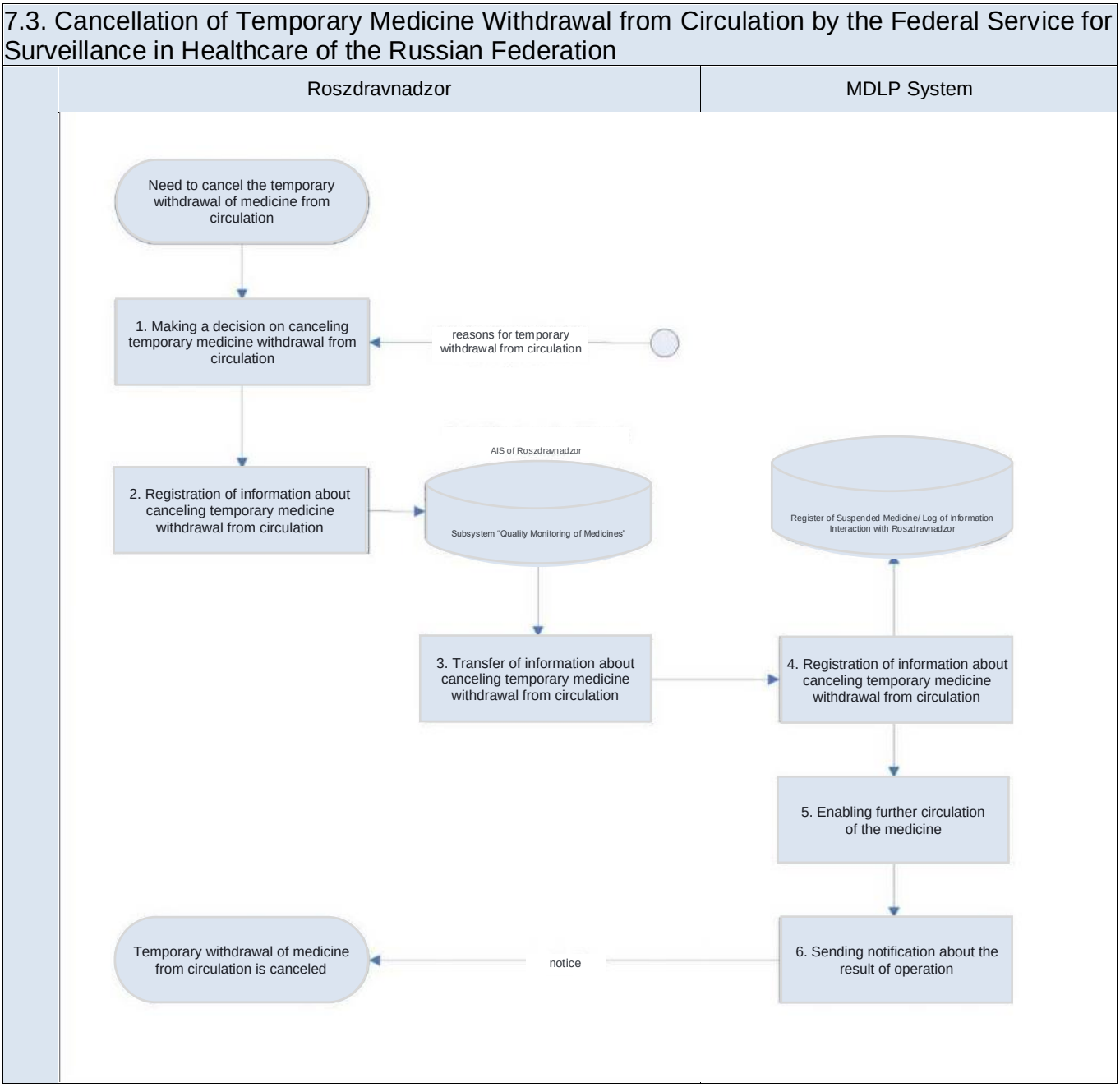
Picture 50

Annotation	The procedure of suspended medicine return in accordance with this section of the Passports of Processes is allowed for those medicines which circulation was suspended by the Federal Service for Surveillance in Healthcare of the Russian Federation, as well as for those medicines in respect of which information has been previously registered in accordance with Section 3.9.2 hereof. Information on the medicine shipment is submitted to MDLP System by the shipper within 1 business day from the actual date of the medicine shipment. In this case the receiver confirms the information registered by the shipper within 30 business days from the date of registration in MDLP System of the information about such shipped medicines
Interaction participant	– pharmaceutical entity that returns the suspended medicine (shipper); – pharmaceutical entity that accepts the suspended medicine (receiver)
Description of the actions performed	
1. Preparation for shipment, medicine packing in shipping container	
2. Medicine shipment from shipper’s warehouse	
3. – 4. Registration of information about the return of suspended medicine in MDLP System by means of scheme 417-move_return.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the operation of suspended medicine return, the shipper sends the following information: – operation date; – identifier of the shipper’s business place where the medicine is shipped from; – identifier of the receiver’s business place where the medicine is accepted; – date of the shipping document; – number of the shipping document; – SGTIN and/or SSCC
5. Notification of the Receiver about the return of suspended medicine by means of scheme 610-move_return_notification.xsd	

List of information to be transferred, and the owner of information resource	Notification of the receiver about the return of suspended medicine is formed on the basis of the operation, which was earlier registered by the shipper, and contains the following data: – operation date; – identifier of the shipper's business place where the medicine is shipped from; – identifier of the receiver's business place where the medicine is accepted; – date of the shipping document; – number of the shipping document; – SGTIN and/or SSCC
6. Suspended medicine acceptance to the receiver's warehouse	
7. Checking by the receiver of the information registered by the shipper in MDLP System about the return of suspended medicine	
8. – 9. Confirmation (acceptance) by the receiver of the information about the return of suspended medicine by means of scheme 701-accept.xsd	
List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information, previously registered by the shipper, about the return of suspended medicine, the receiver ensures that the following data is sent to MDLP System: – identifier of the receiver's business place where the medicine is accepted; – identifier of the receiver's business place where the medicine is accepted; – operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC
10. Notification of the shipper about confirmation (acceptance) by the receiver of the information about the return of suspended medicine by means of scheme 607-accept_notification.xsd	
List of information	Notification of the shipper about confirmation (acceptance) by

to be transferred, and the owner of information resource	the receiver of the information on the return of suspended medicine is formed on the basis of the operation, previously registered by the receiver, and contains the following information: – identifier of the receiver's business place where the medicine is accepted; – identifier of the receiver's business place where the medicine is accepted; – operation date; – confirmation of suspended goods acceptance (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of the Passports of Processes); – SGTIN and/or SSCC
Special conditions	The medicines produced outside the Russian Federation (for which Roszdravnadzor has decided to suspend the circulation) can be returned to the importer's business place. If it is necessary to re-export such medicines, information is transferred to MDLP System in accordance with section 4.6.2 hereof.

7.3. Cancellation of Suspension of Medicine Circulation by the Federal Service for Surveillance in Healthcare of the Russian Federation



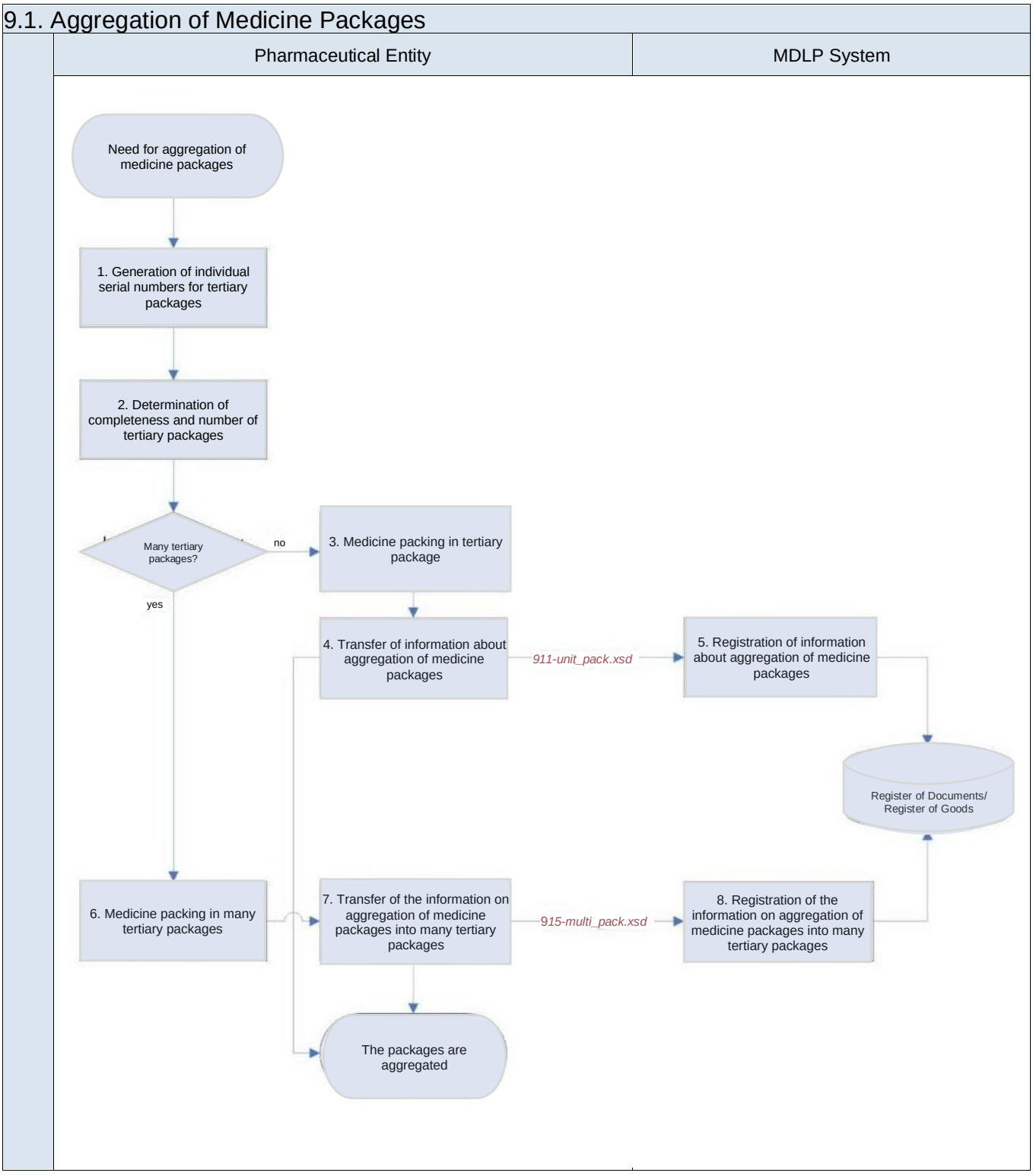
Picture 51

Annotation	In some cases it is possible to cancel the previously registered operation of “Suspension of Medicine Circulation”. Operations of “Cancellation of Suspension of Medicine Circulation” in MDLP System can be registered by the employees of the Federal Service for Surveillance in Healthcare of the Russian Federation, both in case of medicine circulation suspension initiated by the Federal Service for Surveillance in Healthcare of the Russian Federation, and in case of medicine circulation suspension initiated by a pharmaceutical entity. Cancellation of medicine circulation suspension is possible both of the entire series, and of individual medicine batches
Interaction participant	– Roszdravnadzor
Description of the actions performed	
1. Making a decision by the Federal Service for Surveillance in Healthcare of the Russian Federation on cancellation of medicine circulation suspension, including as initiated by the medicine MAH or the pharmaceutical entity	
2. Information registration on cancellation of medicine circulation suspension in the Subsystem “Quality Monitoring of Medicines” of the automated information system of the Federal Service on Surveillance in Healthcare of the Russian Federation	
3. – 4. Automatic transfer of information from the Subsystem “Quality Monitoring of Medicines” of the automated information system of the Federal Service for Surveillance in Healthcare of the Russian Federation to MDLP System	
List of information to be transferred, and the owner of information resource	The information is transferred from the Subsystem “Quality Monitoring of Medicines” through IEIS according to the information interaction format
5. Re-enabling the registration of information on medicine circulation	
6. Sending the notice to the Federal Service for Surveillance in Healthcare of the Russian Federation regarding the operation completion results	

8. Medicine Repacking and Remarking (terminated)

9. Aggregation and Transformation (Extraction, Deconsolidation, Nesting) of Medicine Packages

9.1. Aggregation of Medicine Packages

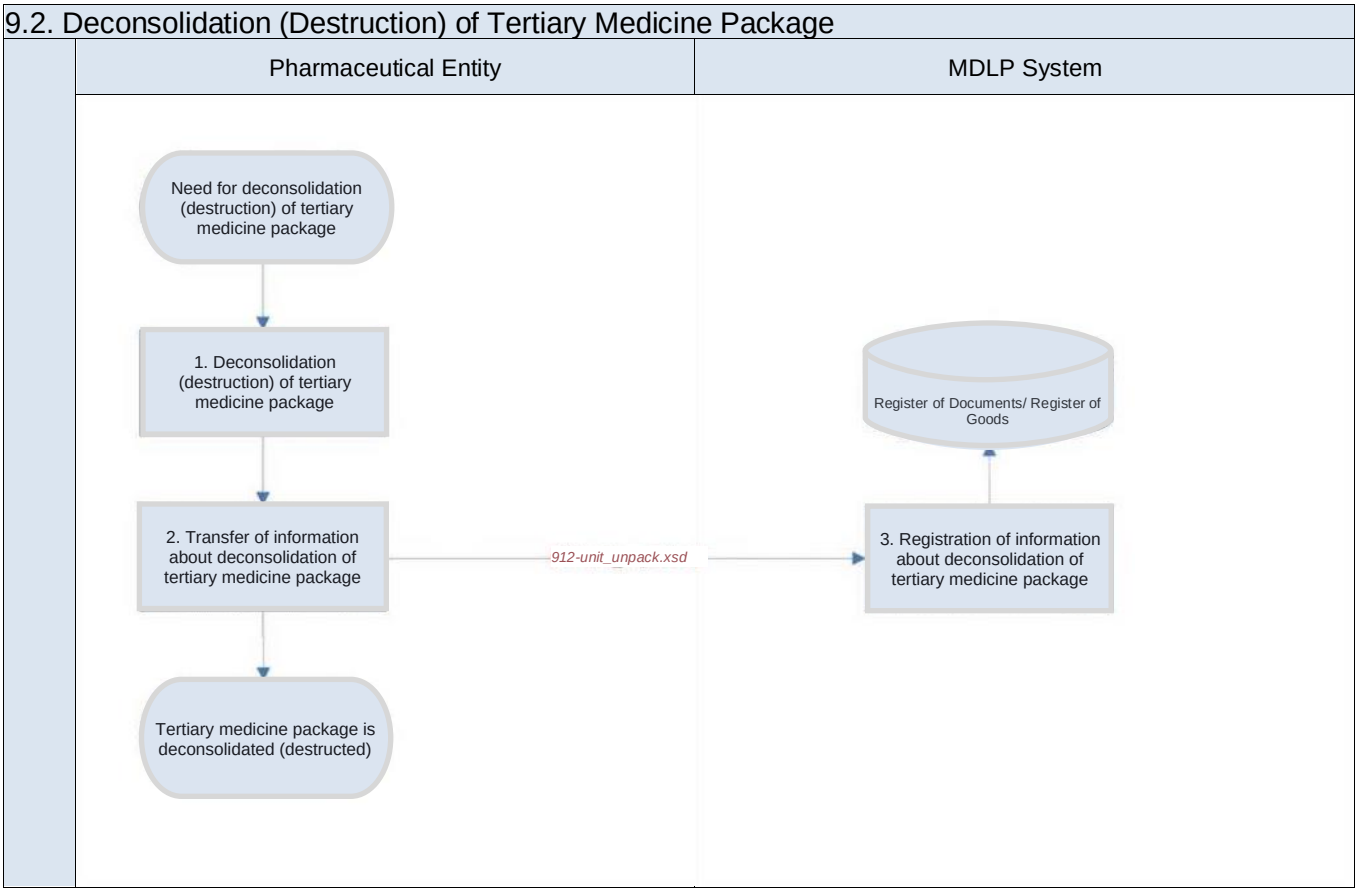


Picture 52

Annotation	Aggregation is the process of combining medicine packages into tertiary (shipping) package, saving the information on interrelation of the unique identifiers of each medicine package nested with the unique identifier of the tertiary (shipping) package created. Aggregation implies the possibility of any level of nesting: – first level of aggregation means consolidation of secondary (consumer) packages in tertiary (shipping) package; – second level of aggregation means consolidation of tertiary (shipping) packages in another tertiary (shipping) package of a higher level of nesting. If necessary, the pharmaceutical entity can submit the information about generation of many tertiary (shipping) packages. Aggregation can be performed by the pharmaceutical entity at various stages of the medicine production cycle and circulation
Interaction participant	– pharmaceutical entity that aggregates the medicine packages
Description of the actions performed	
1. Generation of individual serial numbers of tertiary (shipping) packages	
2. Determination of completeness and number of tertiary (shipping) packages	
3. Medicine packing in tertiary (shipping) package	
4. – 5. Registration of information about the medicine package aggregation in MDLP System by means of scheme 911-unit_pack.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about aggregation operations, the pharmaceutical entity sends the following information: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's business place; – SSCC aggregated into; – SGTIN or SSCC included into a tertiary package
6. Medicine packing in many tertiary (shipping) packages	
7. – 8. Registration of the information in MDLP System on aggregation of medicine packages into many tertiary (shipping) packages by means of scheme 915-multi_pack.xsd	

List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about the operations of aggregation into many tertiary (shipping) packages, the pharmaceutical entity sends the following information: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's business place; – SSCCs aggregated into; – SGTIN or SSCC included into a tertiary (shipping) packages
Special conditions	When sending the information on aggregation of SGTIN to be paid, but not paid as of the date of information sending, the aggregation operation will be received by MDLP System, and the final recording of information on aggregation and unlocking the option to register further information on such medicines will be provided after paying for all marking codes specified in the aggregation operation. Restrictions for medicine packing aggregation (911): - for aggregation of level 1: SSCC may contain only medicines with the same GTIN and production series number; - for aggregation of level 2 and higher levels: SSCC may contain only group packings (SSCC) with medicines with the same GTIN and production series number. Restrictions for aggregation in multiple tertiary (shipping) packages (915): - for aggregation of level 1: SSCC may contain only medicines with the same GTIN and production series number; - for aggregation of level 2 and higher levels: SSCC may contain only group packings (SSCC) with medicines with the same GTIN and production series number; - For one operation only one-time SSCC aggregation is allowed with different GTINs and production series numbers provided compliance with requirement—each SSCC contains goods with the same GTIN and production series number

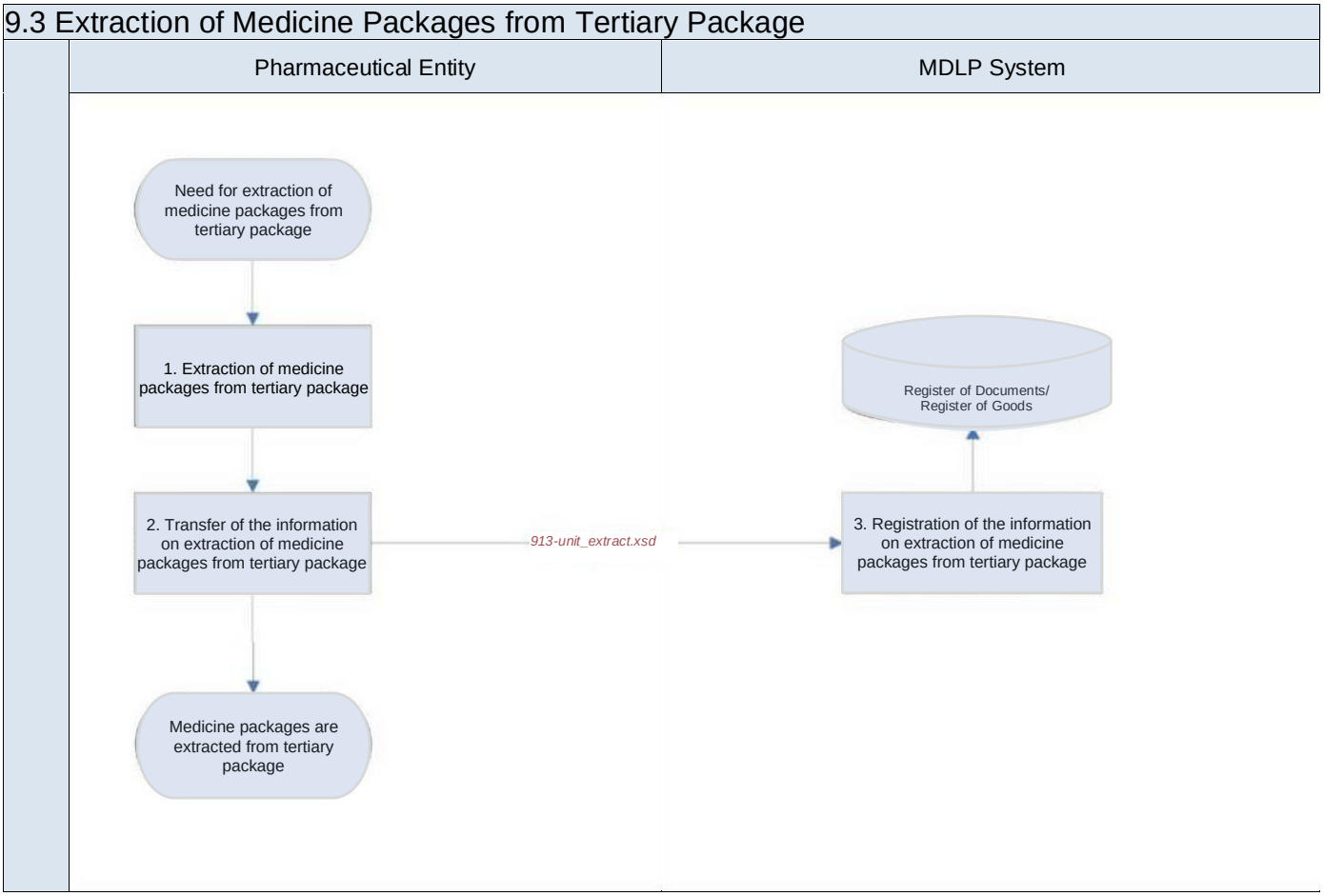
9.2. Deconsolidation (Destruction) of Tertiary Medicine Package



Picture 53

Annotation	The operation of tertiary (shipping) medicine package deconsolidation (destruction) is recorded by means of MDLP System registration of independent operations carried out by pharmaceutical entities. The deconsolidation operation may be used both in case of deconsolidation to one level, and to secondary (consumer) medicine packages. Registration of information about deconsolidation of several medicine tertiary packages within one operation in MDLP System is allowed. Deconsolidation (destruction) of tertiary medicine packages can be performed by the pharmaceutical entity at different stages of medicine circulation
Interaction participant	– pharmaceutical entity that deconsolidates the medicine packages
Description of the actions performed	
1. Deconsolidation (destruction) of tertiary (shipping) medicine package	
2. – 3. Registration of information about deconsolidation of tertiary (shipping) medicine package in MDLP System by means of scheme 912-unit_unpack.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about the operations of medicine tertiary (shipping) package deconsolidation, the pharmaceutical entity sends the following information: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's business place; – type of package deconsolidation operation; – SSCC of deconsolidated medicine packages

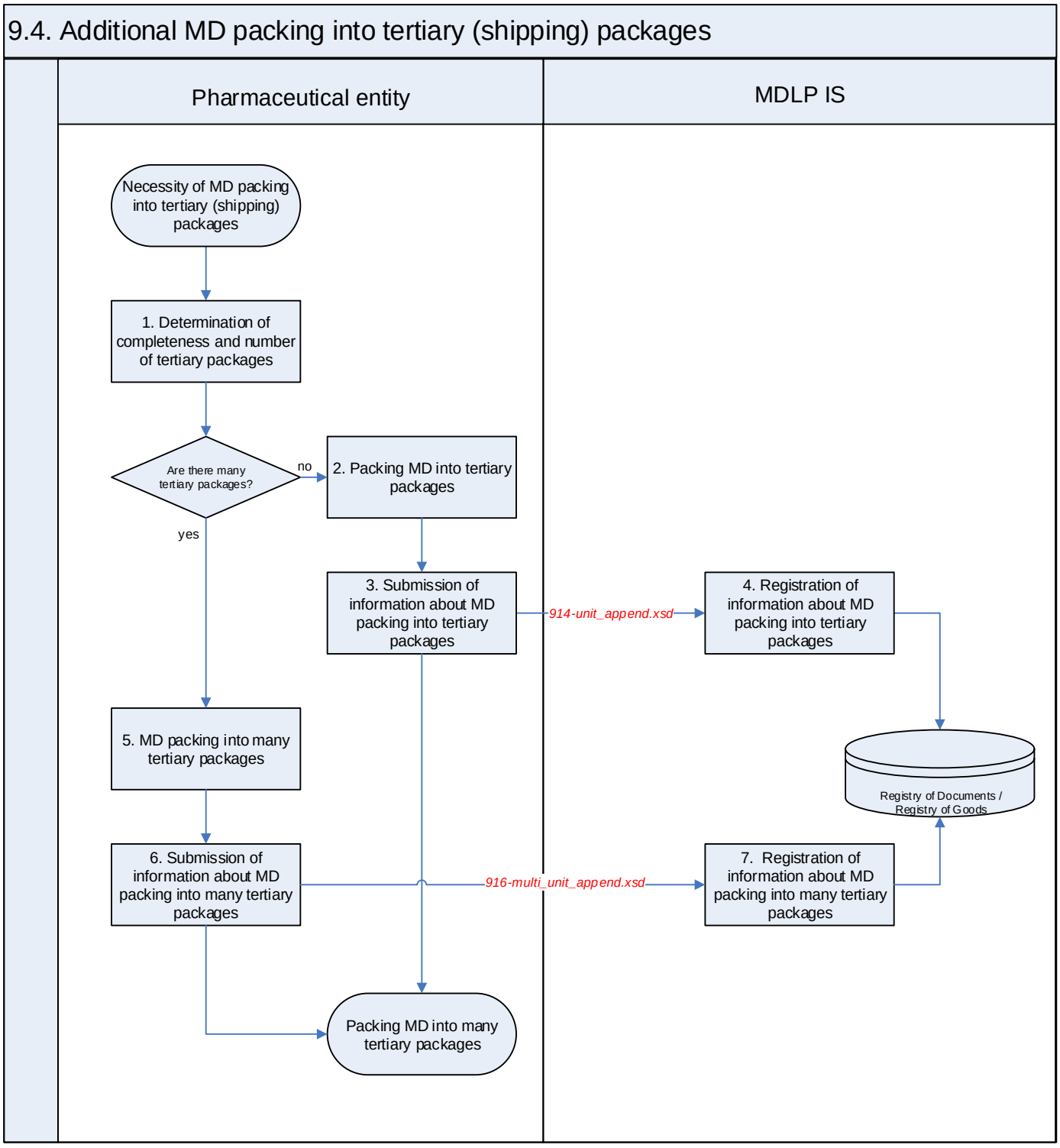
9.3. Extraction of Medicine Packages from Tertiary Package



Picture 54

Annotation	The operation of extraction of medicine packages from tertiary (shipping) package is recorded by means of MDLP System registration of independent operations carried out by pharmaceutical entities. Extraction of medicine packages from tertiary (shipping) package can be performed by the pharmaceutical entity at different stages of medicine circulation
Interaction participant	– pharmaceutical entity that extracts the medicine packages
Description of the actions performed	
1. Extraction of medicine packages from tertiary (shipping) package	
2. – 3. Registration of information about extraction of medicine packages from tertiary (shipping) package in MDLP System by means of scheme 913-unit_extract.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about the operations of extraction of medicine packages from tertiary (shipping) package, the pharmaceutical entity sends the following information: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's business place; – SGTIN or SSCC of the extracted medicine packages
Special conditions	Restrictions for medicine packing removal: – it is not allowed to remove SGTIN from SSCC of higher nesting level without preliminary registration of the operation of removal from SSCC of lower nesting level (only one level removal is allowed); – it is allowed to register the removal from different SSCC within one operation

9.4. Additional Nesting of Medicine Packages into Tertiary (Shipping) Package



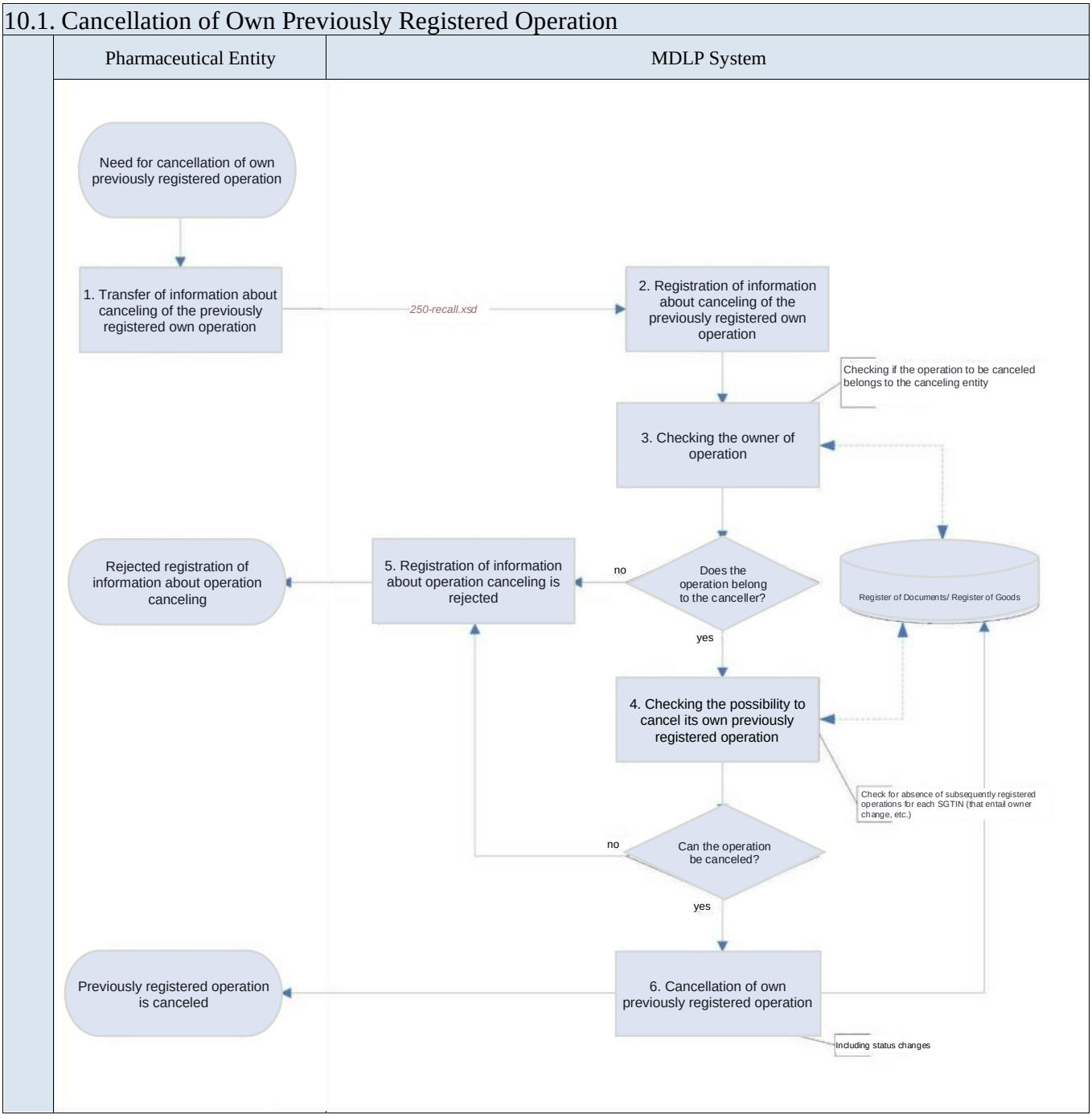
Picture 55

Annotation	The operation of additional nesting of medicine packages into tertiary (shipping) package is recorded by means of MDLP System registration of independent operations carried out by pharmaceutical entities. This operation is used both in case of filling to completeness of tertiary (shipping) package with secondary (consumer) and tertiary (shipping) medicine packages, and in case of re-laying of medicine packages from one tertiary (shipping) package into another. If necessary, the pharmaceutical entity can transfer the information about insertion of medicine packages into many tertiary (shipping) packages. Additional nesting of medicine packages can be performed by the pharmaceutical entity at different stages of medicine circulation
Interaction participant	– pharmaceutical entity that additionally nests the medicine packages
Description of the actions performed	
1. Determination of completeness and number of tertiary (shipping) packages	
2. Additional nesting of medicine packages into tertiary (shipping) package	
3. – 4. Registration of information about additional nesting of medicine packages into tertiary (shipping) package in MDLP System by means of scheme 914-unit_append.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the operations of additional nesting of medicine packages into tertiary (shipping) package, the pharmaceutical entity sends the following information: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's business place; – SSCC of the medicine package where packages are added into; – SGTIN or SSCC of the nested medicine packages
5. Medicine packing in many tertiary (shipping) packages	
6. – 7. Registration of the information in MDLP System about insertion of	

medicine packages into many tertiary (shipping) packages by means of scheme 916-multi_unit_append.xsd	
List of information to be transferred, and the owner of information resource	When registering in MDLP System the information about insertion of medicine packages into many tertiary (shipping) packages, the pharmaceutical entity sends the following information: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's business place; – SSCCs into which the insertion was performed; – SGTINs or SSCCs inserted into tertiary (shipping) packages
Special conditions	It is allowed to add in SSCC only medicines with the same GTIN and production series number as contained therein or only SSCC containing the same GTIN and production series number as the SSCC into which it is added

10. Cancellation of Registered Operations, Recall of Medicine Transfer Data, Medicine Acceptance Rejection, Information Update

10.1. Cancellation of Its Own Previously Registered Operation by the Pharmaceutical Entity

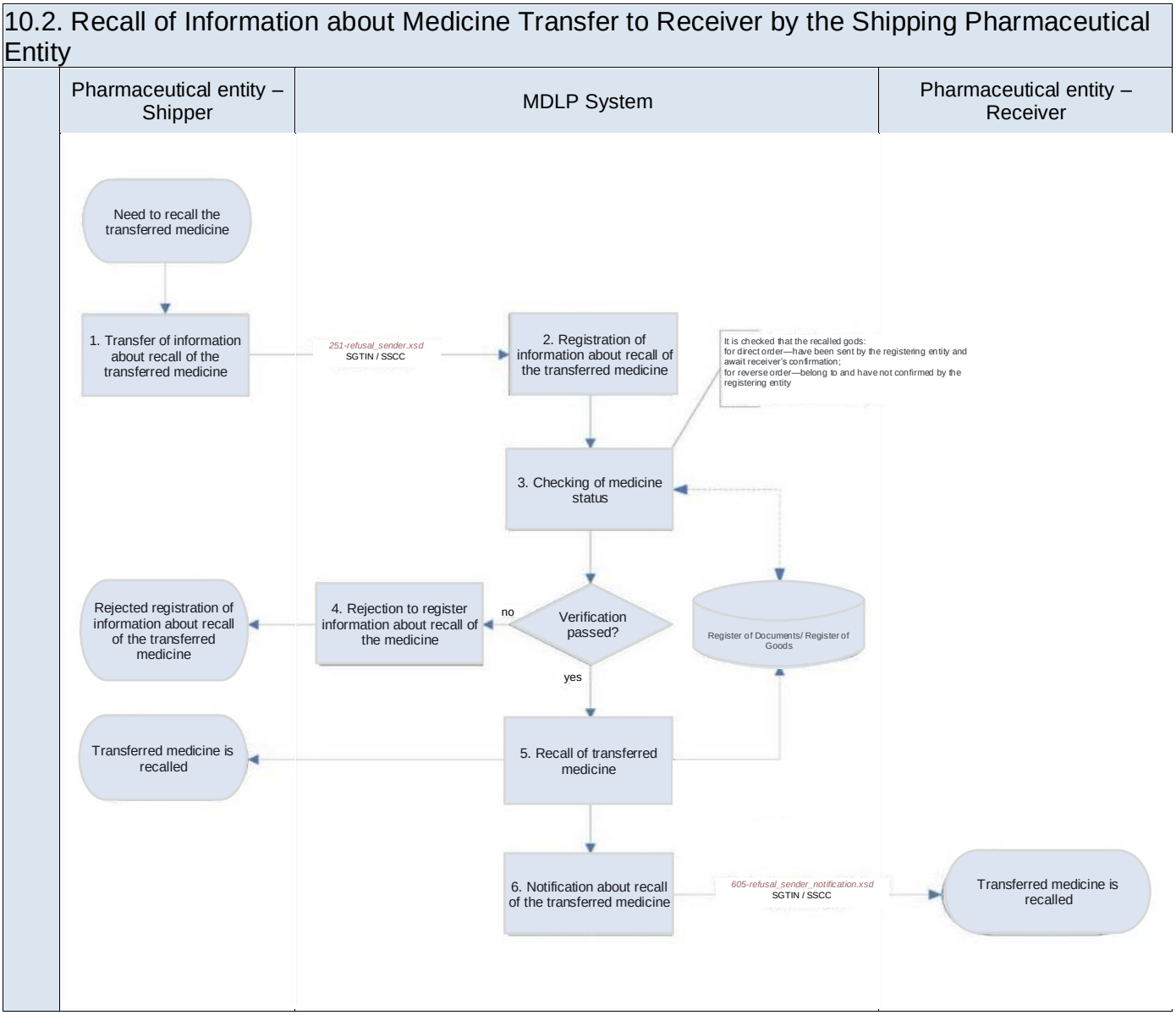


Picture 56

Annotation	If necessary, the pharmaceutical entity may cancel its own previously registered operation about medicine. This operation can be used only if there is no transfer of ownership right for the medicine, which is subject to operation canceling, to other pharmaceutical entity; and cannot be used if there are any subsequently registered operations concerning the medicine. The pharmaceutical entity can cancel only its own previously registered operation.
Interaction participant	– pharmaceutical entity that cancels the operation
Description of the actions performed	
1. – 2. Registration of information about canceling of the previously registered own operation in MDLP System by means of scheme 250-recall.xsd	
List of information to be transferred, and the owner of information resource	In order to cancel its own previously registered operation in MDLP System, the pharmaceutical entity sends the following information: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's business place; – identifier of the operation registered in MDLP System that requires canceling; – type of the original operation (to be canceled); – description of the reason of cancellation (recalling) of the operation (if available)
3. – 4. Automatic checking of the owner of operation to be canceled and of the cancellation possibility	
5. Rejection to register the information operation canceling (if there are reasons for rejection)	
List of reasons for rejection to register the information	– there are some operations subsequently registered for the medicine; – the information about the pharmaceutical entity, which files the operation cancellation, does not match the information about the pharmaceutical entity, which registered the operation to be canceled

6. Cancellation of the operation previously registered in MDLP System by the pharmaceutical entity, including modification of goods statuses (if there are no reasons for rejection)	
Restrictions of the operation application	The cancellation operation can only be applied to the following previously registered operations: - uploading of information about marking codes transfer to the customs warehouse (300); – uploading of information about finished products release by the Russian manufacturer of medicine (313); – uploading of information about medicine import to the Russian Federation without importer (333); – uploading of information about medicine movement between various customs-controlled areas (334); – uploading of information about customs clearance (335) for introduction for domestic consumption only; – uploading of information about medicine acceptance to warehouse by importer after release from the customs area when importing into the Russian Federation (341); – uploading of information about medicine introduction into circulation in the Russian Federation (342); – uploading of information about own medicine import to the Russian Federation from EAEU member states (360); – uploading of information about medicine introduction into circulation in the Russian Federation when importing the medicine from EAEU (363); – uploading of information about medicine movement between various business places (431); – uploading of information about medicine movement between own business places within state medicine provision (470); – uploading of information about medicine transfer for destruction (541)

10.2. Recall of Information about Medicine Transfer to Receiver by the Shipping Pharmaceutical Entity



Picture 57

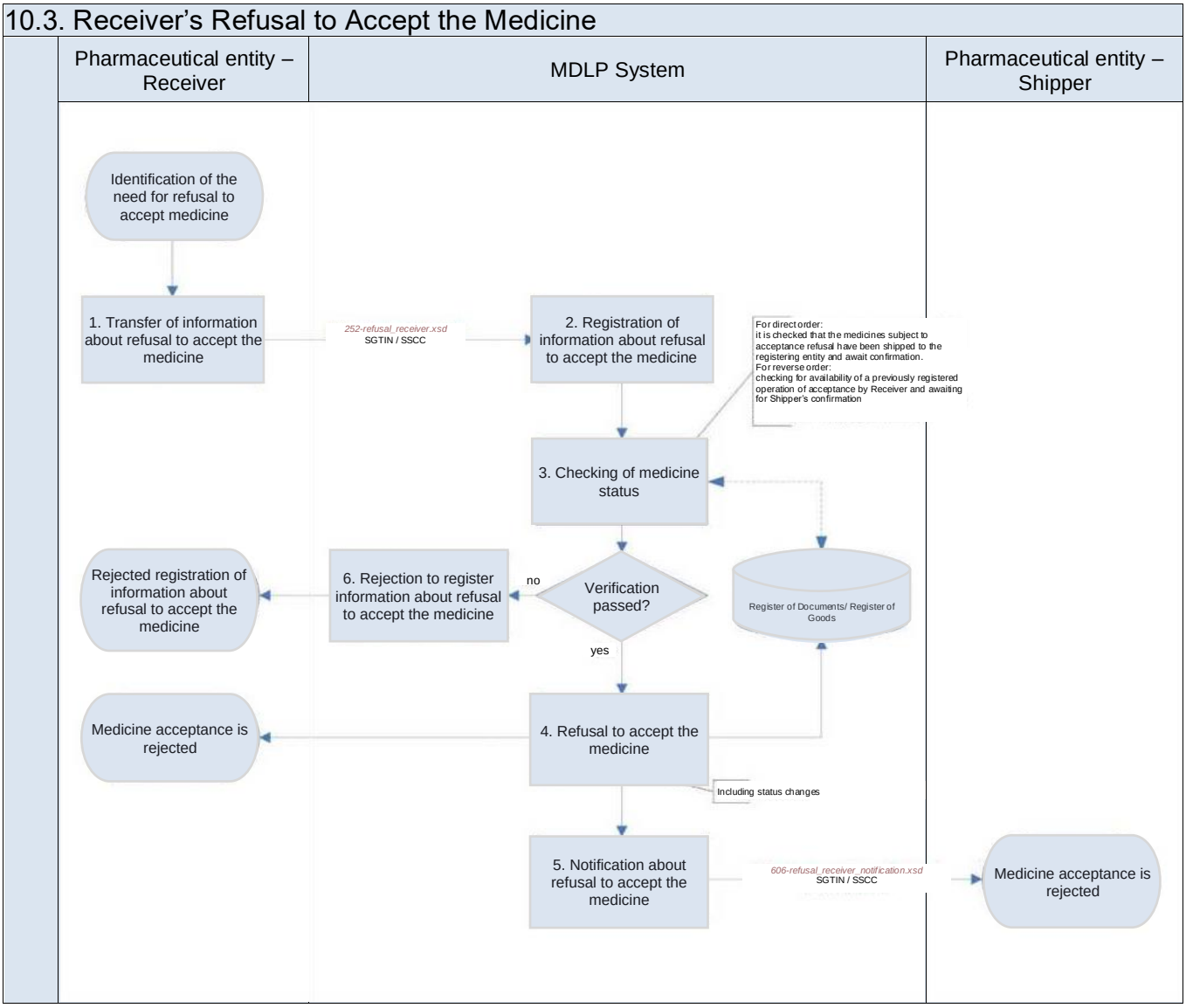
Annotation	The shipper can register the operation of recall of the information about medicine transfer (both if discrepancies were discovered when the shipper analyzed the information about the medicine sent from warehouse and information about the medicine accepted to warehouse by the receiver, and if the shipper discovered any errors in the previously sent information). This operation can be used only under the following circumstances: in case of direct confirmation order: - there is some previously registered information about medicine shipment from warehouse of the shipper that files the recall; - for the medicine awaiting confirmation; in case of reverse confirmation order: - shipper is the owner of the medicine to be recalled; - the medicine transfer to the receiver is not confirmed by the shipper
Interaction participant	– pharmaceutical entity that transfers the medicine (shipper); – pharmaceutical entity that accepts the medicine (receiver)
Description of the actions performed	
1. – 2. Registration of information in MDLP System about shipper recalling the information about the medicine transferred to the receiver by means of scheme 251-refusal_sender.xsd	
List of information to be transferred, and the owner of information resource	In order to recall the information previously sent to the receiver in MDLP System, the pharmaceutical entity sends the following information: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's (shipper) business place; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's (receiver) business place; – description of the reason for medicine recall; – confirmation of suspended goods recall (indicated if the

	Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of these Passports of Processes); – SGTIN and/or SSCC of the recalled medicine
3. Automatic checking of medicine status (availability of the operation previously registered by the shipper about transfer of the medicine to be recalled to the receiver or possession right checking)	
4. Rejection to register the information about recall of the medicine previously transferred to the receiver (if there are any reasons to reject)	
5. Recall of information about the transferred medicine and its return to shipper's balance (if there are no reasons for rejection)	
Restrictions of the operation application	The operation of recalling the medicine transferred to Receiver can be applied by Shipper only to the following previously registered operations: – uploading of information on update when transferring the medicines to another pharmaceutical entity (254); – uploading of information about medicine shipment for release of finished products (314); – uploading of information about medicine return to the contract manufacturer (315); – uploading of information about shipment of medicines to the Russian Federation (331); – uploading of information about medicine import to the Russian Federation (332); – uploading of information about importation terms and conditions for the medicines marked in the customs warehouse and imported to the Russian Federation (336); – uploading of information on logical medicine return for update of the information on medicine import to the Russian Federation (337);uploading of information about transfer of ownership rights for the medicine undergoing the customs procedure of customs warehouse (351); – uploading of information about medicine shipment to the Russian Federation from EAEU member states (361); – uploading of information about medicine import to the

	Russian Federation from EAEU member states (362); – uploading of information about medicine transfer to the owner (381); – uploading of information about medicine shipment from warehouse of the pharmaceutical entity (415); – uploading of information about medicine acceptance to warehouse (416); – uploading of information about return of suspended medicine (417); – uploading of information about medicine owner change within state medicine provision (471); – uploading of information about medicine shipment from the shipper's warehouse under agency agreement (direct confirmation order) (472) – uploading of information on medicine acceptance to receiver's warehouse under an agency contract (reverse confirmation order) (473); – uploading of information about filing a request for arbitration or initiating arbitration dismissal (481)
6. Notification of the receiver about shipper recalling the information about the medicine transferred to the receiver by means of scheme 605-refusal_sender_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification of the receiver about shipper recalling the information about the medicine transferred to the receiver is formed on the basis of the operation, which was previously registered by the shipper, and contains the following data: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's (shipper) business place; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's (receiver) business place; – description of the reason for goods recall; – confirmation of suspended goods recall (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of

	medicine circulation according to section 7.1 of these Passports of Processes); – SGTIN and/or SSCC of the recalled medicine

10.3. Refusal of the Receiving Pharmaceutical Entity to Accept the Medicine



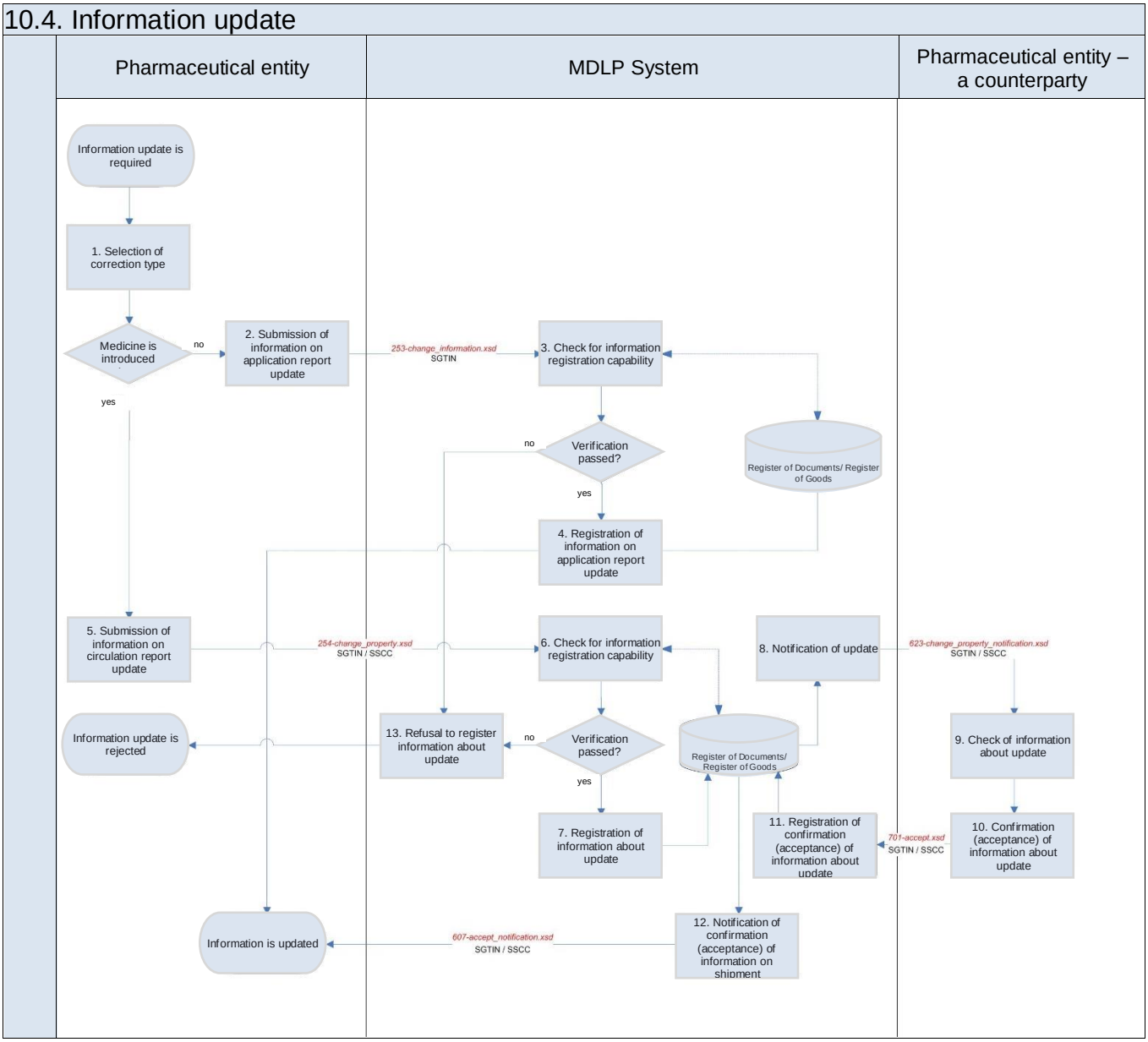
Picture 58

Annotation	The receiver may register the operation of refusal to receive the transferred goods if any discrepancies were discovered during medicine acceptance by the receiver and if refusal to accept the transferred goods is needed. This operation can be used only in the following cases: - if there is some previously registered information about medicine shipment to the receiver and about the medicine awaiting confirmation of acceptance by the receiver (in case of direct acceptance order); - if the receiver discovers any errors in its own previously sent information about medicine acceptance to warehouse and about medicine awaiting confirmation of shipment by the shipper (in case of reverse acceptance order)
Interaction participant	– pharmaceutical entity that accepts the medicine (receiver); – pharmaceutical entity that transfers the medicine (shipper)
Description of the actions performed	
1. – 2. Registration in MDLP System of information about the receiver's refusal to accept the medicine by means of scheme 252-refusal_receiver.xsd	
List of information to be transferred, and the owner of information resource	In order to reject acceptance of the transferred medicine, the receiver sends the following information to MDLP System: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's (receiver) business place; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's (shipper) business place; – description of the reason of refusal to accept medicine; – confirmation of suspended goods acceptance rejection (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of these Passports of Processes); – SGTIN and/or SSCC for which the warehouse acceptance rejection is registered by the receiver
3. Automatic checking of medicine status: availability of a previously registered	

operation of medicine transfer to the receiver (in case of direct acceptance order) or availability of an operation of medicine warehouse acceptance previously registered by the receiver (in case of reverse acceptance order)	
4. Refusal to accept the medicine transferred to the receiver (if there are no reasons for rejection)	
Restrictions of the operation application	The operation of receiver's refusal to accept the goods transferred by the shipper can be applied only to the following previously registered operations: – uploading of information on information update when transferring the medicines to another pharmaceutical entity (254); – uploading of information about medicine shipment for release of finished products (314); – uploading of information about medicine return to the contract manufacturer (315); – uploading of information about shipment of medicines to the Russian Federation (331); – uploading of information about medicine import to the Russian Federation (332); – uploading of information about importation terms and conditions for the medicines marked in the customs warehouse and imported to the Russian Federation (336); – uploading of information on logical medicine return for update of the information on medicine import to the Russian Federation (337); – uploading of information about transfer of ownership rights for the medicine undergoing the customs procedure of customs warehouse (351); – uploading of information about medicine shipment to the Russian Federation from EAEU member states (361); – uploading of information about medicine import to the Russian Federation from EAEU member states (362); – uploading of information about medicine transfer to the owner (381); – uploading of information about medicine shipment from warehouse of the pharmaceutical entity (415); – uploading of information about medicine acceptance to

	warehouse (416); – uploading of information about return of suspended medicine (417); – uploading of information about medicine owner change within state medicine provision (471); – uploading of information about medicine shipment from the shipper's warehouse under agency agreement (direct confirmation order) (472) – uploading of information on medicine acceptance to receiver's warehouse under an agency contract (reverse confirmation order) (473); – uploading of information about filing a request for arbitration or initiating arbitration dismissal (481)
5. Notification of the shipper about receiver's refusal to accept the medicine by means of scheme 606-refusal_receiver_notification.xsd	
List of information to be transferred, and the owner of information resource	– operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's (receiver) business place; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's (shipper) business place; – description of the reason of refusal to accept the goods; – confirmation of suspended goods acceptance rejection (indicated if the Federal Service for Surveillance in Healthcare of the Russian Federation made a decision on suspension of medicine circulation according to section 7.1 of these Passports of Processes); – SGTIN and/or SSCC for which the warehouse acceptance rejection is registered by the receiver
6. Rejection to register the information about receiver's refusal to accept the medicine (if there are any reasons to reject)	

10.4 Information Update



Picture 59

Annotation	As required, a pharmaceutical entity may perform the following updates of previously submitted information: – update of the information on final packing completion (including when producing medicines outside the Russian Federation); – update of the information on medicine transfer to another pharmaceutical entity (the Counterparty) with confirmation of such update by the Counterparty. Update of the information on final packing completion may be used if no further operations are registered for this medicine, or after canceling the registered operation of medicine introduction into circulation and disaggregation. Update of the information on medicine transfer to the Counterparty may be used if discrepancies are identified in the information after the goods acceptance. Information on updates is sent by the pharmaceutical entity which has previously registered the medicine transfer operation (operations 415/416/471/472)
Interaction participant	– the pharmaceutical entity which updates the information; – counterparty
Description of the actions performed	
1. Selecting the required type of update	
2. Submission to MDLP System of the information about update of information on final packaging stage completion by means of scheme 253-change_information.xsd	
List of information to be transferred, and the owner of information resource	To update the information on final packaging stage completion in MDLP System, a pharmaceutical entity submits the following information: – operation date; – registration number of the pharmaceutical entity or identifier of the pharmaceutical entity's (receiver's) business place; – list of information to be updated (to be selected); – SGTIN to be updated. The following previously submitted information is to be updated:

	– medicine expiration date; – production series number; – registration number of medicine owner in MDLP System (for contract manufacturing); – identifier of a foreign counterparty—foreign medicine manufacturer that packs / prepacks medicine in secondary (tertiary) packing; – identifier of a foreign counterparty—foreign medicine manufacturer that performs release quality control; – production order type
3. Automatic check of the option to update the information on final medicine packaging stage completion	
4. Recording of the information about update of information on final medicine packaging stage completion (without reasons for refusal)	
5. Submission to MDLP System of the information about update of information on medicine transfer to counterparty by means of scheme 254-change_property.xsd	
List of information to be transferred, and the owner of information resource	To update the information on final packaging stage completion in MDLP System, a pharmaceutical entity submits the following information: – operation date; – identifier of the pharmaceutical entity's business place; – identifier of the counterparty's business place; – type of initial operation to be updated; – identifier of the operation to be updated; – list of the information to be updated (to be selected); – SGTIN or SSCC. The following previously submitted information is to be updated: – primary document details – number; – primary document details – date; – financing source (only for the first shipment); – contract register No. in Unified Information System for Procurement; – contract type;

	– medicine price (with VAT), RUB; – VAT amount (if the transaction is not subject to VAT, 0 is specified)
6. Automatic check of the option to update the information on medicine transfer to counterparty	
7. Recording of the information about update of information on medicine transfer to counterparty (if there are no reasons for rejection)	
8. Notification to counterparty of information update by the pharmaceutical entity by means of scheme 623-change_property_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification to the counterparty of information update by the pharmaceutical entity is generated based on the operation, previously registered by the pharmaceutical entity, and contains the following information: – operation date; – identifier of the pharmaceutical entity's business place; – identifier of the counterparty's business place; – type of initial operation to be updated; – identifier of the operation to be updated; – list of the information to be updated (to be selected); – SGTIN or SSCC. Information to be corrected: – primary document details – number; – primary document details – date; – financing source (only for the first shipment); – contract register No. in Unified Information System for Procurement; – contract type; – medicine price (with VAT), RUB; – VAT amount (if the transaction is not subject to VAT, 0 is specified)
9. Check of the information about update by the counterparty	
10.– 11. Confirmation (acceptance) of the information about update by the counterparty by means of scheme 701-accept.xsd	

List of information to be transferred, and the owner of information resource	For confirmation (acceptance) of the information about update registered by the pharmaceutical entity, the counterparty sends the following information to MDLP System: – identifier of the counterparty's business place; – identifier of the business place of the pharmaceutical entity that has sent the information about update; – operation date; – SGTIN and/or SSCC
12.Notification to the pharmaceutical entity of confirmation (acceptance) by the counterparty of information about update by means of scheme 607-accept_notification.xsd	
List of information to be transferred, and the owner of information resource	Notification to the pharmaceutical entity of confirmation (acceptance) by the counterparty of information about update is generated based on the previously registered operation, and contains the following information: – identifier of the counterparty's business place; – identifier of the business place of the pharmaceutical entity that has sent the information about update; – operation date; – SGTIN and/or SSCC
13.Refusal to register the information about update (with reasons for refusal)	
List of reasons for refusal to register the information	Update of information on final packaging stage completion: – information about update is sent by a pharmaceutical entity which is different from that which has previously registered the information on final packaging stage completion; – performance of further registered operations with this medicine, or canceling of previously registered operations of the medicine introduction into circulation and disaggregation. Update of the information on medicine transfer to counterparty: – information about update is sent by a pharmaceutical entity which is different from that which has previously registered the information on medicine transfer; – information about update indicates a counterparty which is different from that which has previously accepted the

	information on medicine transfer; – no information about previously sent operation on medicine transfer is available; – no acceptance of previously sent operation on medicine transfer is provided; – information on financing source update is sent for a delivery other than the first delivery
Special conditions	Within one operation 253, according to item 2 of this section, information can be corrected only for SGTINs issued in one production batch

Change History

Version	List of Changes
1.38.2	**Section 1.1:** - invalidity of the enhanced qualified electronic signature was added into the list of reasons for rejection to register; **Section 1.1.1:** - registration process has been corrected due to the lack of the need for provision of the documents to Roszdravnadzor; - changes were made to the List of reasons for rejection; **Section 1.2:** - registration process has been corrected due to the lack of the need for provision of the documents to Roszdravnadzor; - changes were made to the List of reasons for rejection; **Section 2.1** – A new process to add instructions and medicine package images to the MDLP System was implemented; **Sections 3.1, 3.1.1, 3.4, 3.6.1, 3.6.2, 3.6.3:** - changes were made in terms of end-to-end process of introduction of the medicine into circulation; **Section 4.1:** - changes were made to Annotation in terms of deadline for submission of information when returning medicines; **Section 4.2:** - changes were made to Annotation in terms of deadline for submission of information when returning medicines; - additional restrictions on the use of reverse order were added to Special conditions; **Section 4.2.1:** - additional restrictions on the use of posting operation were added; - conditions for indication of TIN/KPP in the posting operation were added; **Section 4.4.1:** - supplemented by the need to use the process when shipment is carried out to annexed territories; **Section 4.7.2:** - changes were made to Annotation in terms of submission of information when returning medicines;

Version	List of Changes
	Section 4.7.3: - changes were made to Annotation in terms of submission of information when returning medicines; - additional restrictions on the use of reverse order were added to Special conditions; **Section 4.7.7:** - Annotation of the process was corrected and supplemented with conditions for operation use; **Sections 5.1.1, 5.1.2:** - clarifications on indication of the prescription particulars when selling medicines were added; **Sections 5.1.3:** - additional conditions on the process use were added; **Sections 5.3:** - additional restrictions were added into the Special conditions; **Sections 9.1, 9.4:** - additional restrictions on production batch were added into the Special conditions; **Appendix 1** and **Appendix 2** were corrected. **Appendix 3:** - changes were made in terms of prescription particulars indication when selling medicines without subsidy
1.38.1	**Appendix No.1:** - it has been supplemented by permitted transitions for registration of information on export of the medicines not introduced into circulation on the territory of the Russian Federation
1.38	**Section 3.1.:** - Annotation has been corrected in the part of possibility to use one identifier of the business place for the operations carried out within one separate territory; **Section 3.9.2:** - Annotation has been corrected in the part of clarification of the pharmaceutical entity who re-introduced a medicine into circulation; - a list of the medicines for which re-introduction into circulation may be applied, has been supplemented;

Version	List of Changes
	- special conditions have been supplemented with the requirements when registering an information on re-introduction into circulation the medicines previously withdrawn from circulation during shipment of the medicines within the closed contracts (agreements). **Section 4.3.:** - a variant of the process of movement of all medicines between business places and / or responsible storages has been developed. **Section 4.6.3:** - composition of the data which are recorded when transmitting the data on customs procedure for export, has been supplemented with a code of country of exports; - special process conditions were added. **Section 4.7.7:** - New process of "Notification from pharmaceutical entity to the MDLP System on absence of the medicines on balance" was implemented. **Section 5.5:** - supplemented with new types of withdrawal from circulation; - composition of the data which are recorded when transmitting the data on withdrawal of the medicine from circulation with a type - export outside the territory of the Russian Federation has been supplemented with a code of country of exports; - special conditions have been supplemented with the requirements when registering an information on withdrawal from circulation during shipment of the medicines within the closed contracts (agreements). **Appendix No.1:** - it is supplemented by permitted transitions for registration of information on movement of all medicines and for notification of absence on the balance. **Appendix No.2:** - description for schemes 432 and 705 was supplemented
1.37.2	**Section 3.9.2:** - Annotation was corrected in the part of the list of the operations, after which medicine can be reintroduced into circulation. **Section 4.2.1:** - modifications were introduced into annotation and special conditions. **Sections 5.2.1 and 5.3:** - information on conditions of formation of schemes (10523-

Version	List of Changes
	skzkm_code_error_recipe.xsd and 10532-skzkm_code_error_healthcare.xsd) during disposal by using DR for the medicine with invalid MC, was added into special conditions. **Appendix No.1:** - status model was supplemented by the "Operations with stripped package" section; - Section 7 was modified in terms of paused_circulation status. **Appendix No.2:** - restrictions for schemes were supplemented in terms of their use for expired medicine; - restrictions for schemes 10523, 10532 were supplemented. **Appendix No.3:** - Section II was modified
1.37	**Section 1.1:** - information on the need to register business places and on the possibility to block/activate business places was added into annotation. **Section 3.9.2:** - information on the possibility to return the medicines (previously withdrawn from circulation for clinical studies) into circulation was added into annotation. **Section 4.2.1:** - information recorded during the posting was supplemented by an identifier of the medicine shipper's business place and posting operation type. **Section 4.3:** - was supplemented by the step to send notification on medicine movement. **Section 4.7.4:** - was supplemented by the step to send notification on medicine movement. **Section 4.7.6.** - new process of movement of the medicine under reorganization of the pharmaceutical entities - residents of the Russian Federation was implemented. **Section 5.1.3** – new process of retail sale of medicine by means of distance selling was implemented. **Section 5.5:** - annotation was supplemented by new type of withdrawal from circulation

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	(theft); - information to be transmitted was supplemented by part of the secondary packing. **Section 10.4:** - special process conditions were added. **Appendix No.1:** - was supplemented by permitted transitions for registration of information on transfer of the medicine under reorganization procedure. **Appendix No.2:** - restrictions for scheme 391 were added; - operations were supplemented by the possibility to be applied to blocked business places; - description of scheme 812 was added
1.36.2	**Section 3.1:** - error in the numbering of the process diagram was fixed. **Section 3.1.2:** - special process conditions were added. **Section 4.6.2:** - annotation was supplemented with the possibility of applying a re-export operation to the medicines for which Roszdravnadzor has decided to suspend the circulation. **Section 7.2:** - special process conditions were added. **Appendix No.2:** - condition of SSCC auto-disaggregation for Scheme 335 and restrictions were changed; - restrictions for scheme 552 were added
1.36.1	Descriptions of registered data are supplemented with the name of the corresponding xsd schemes. **Section 1.1:** - special process conditions were added; - step providing for registration of business place was added. **Section 3.1, Section 3.2:**

Version	List of Changes
	special process conditions were added. **Section 4.1, Section 4.2:** special process conditions were added **Section 4.2.1 –** New medicine posting process was added. **Section 4.7.4, Section 5.5, Section 9.1:** special process conditions were added
1.36	Term "Licenses" is added in **Terms and Abbreviations** section. **Section 1.1, Section 1.1.1, Section:** List of reasons for refusal to register the information is supplemented. **Section 2:** supplemented with the scope of information to be sent by a pharmaceutical entity for medicine registration in GS1 RUS. **Section 3.1, Section 3.1.1, Section 3.1.2:** annotations are supplemented with the information on established period for information submission to MDLP System. **Section 3.3.1, Section 3.3.2:** - annotations are supplemented with the information on established period for information submission to MDLP System; - special conditions of the process are supplemented. **Section 3.3.3, Section 3.4, Section 3.5:** annotations are supplemented with the information on established period for information submission to MDLP System. **Section 3.6.1, Section 3.6.2:** - annotations are supplemented with the information on established period for information submission to MDLP System; - special conditions of the process are supplemented. **Section 3.6.3, Section 3.8, Section 3.10:** annotations are supplemented with the information on established period for information submission to MDLP System. **Section 3.9.1, Section 3.9.2:** annotations are supplemented with details on application of the operation of medicine reintroduction into circulation and information on established period for information submission to MDLP System.

Version	List of Changes
	Section 4.1: - information contained in para. 8-9 and para. 10 is updated; - annotation is supplemented with the information on established period for information submission to MDLP System. **Section 4.2, Section 4.3, Section 4.4.1, Section 4.4.2, Section 4.6.1, Section 4.6.2, Section 4.6.3, Section 4.7.1, Section 4.7.2:** annotations are supplemented with details on application of the operation of medicine reintroduction into circulation and information on established period for information submission to MDLP System. **Section 4.7.3:** A new process of transfer of medicines for further sale in favor of and at the expense of the owner (agent contract, commission contract) as per reverse confirmation procedure is implemented. **Section 4.7.4:** - section numbering is changed from 4.7.3; - annotation is supplemented with the information on established period for information submission to MDLP System. **Section 4.7.5:** - section numbering is changed from 4.7.4; - list of operations available for registration after arbitration dismissal is supplemented. **Section 5.1.1:** - scope of information to be recorded based on the CRE receipts is supplemented with identifier of the resulting receipt for CRE receipt; - supplemented with special conditions of the process. **Section 5.1.2:** Supplemented with information registration procedure for medicine release in a pharmacy on documents other than cash register receipt (release on birth certificates, under voluntary health insurance, etc.); - annotation is supplemented with the information on established period for information submission to MDLP System. **Section 5.2.1:** - annotation is supplemented with the information on established period for information submission to MDLP System; - supplemented with special conditions of the process. **Section 5.2.2:**

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	- scope of information to be recorded based on the CRE receipts is supplemented with identifier of the resulting receipt for CRE receipt; - supplemented with special conditions of the process. **Section 5.3:** - annotation is supplemented with the information on established period for information submission to MDLP System; - supplemented with special conditions of the process. **Section 5.4, Section 5.5, Section 7.2:** annotations are supplemented with the information on established period for information submission to MDLP System. **Section 9.3:** supplemented with special conditions of the process. **Section 10.2, Section 10.3:** extended restrictions for application of the operation in part of permitted operations. **Section 10.4:** - conditions of update of the information on medicine production are clarified; - production order type is included in the scope of updated information on medicine production; - List of reasons for refusal to register the information is updated **Appendix 1** and **Appendix 2** are updated
1.35.1	**Document name** is changed according to the Regulation on the Track and Trace System of Medicines for Medical Use approved by Resolution of the Government of the Russian Federation No. 1556 dated December 14, 2018 (as amended on July 21, 2020). **Introduction** section is added. **Terms and Abbreviations** section is supplemented with new abbreviations. **Section 2:** - diagram, annotation and description of the actions performed are supplemented with a procedure for update of registered information on medicines; - supplemented with special conditions of the process. **Section 3.1, Section 3.2:** - annotation is supplemented with reference to Section 9.1 for aggregation

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	operation; - description of the actions performed is supplemented with the requirement to observe the API Specification of the Orders Management Station when ordering marking codes and sending a report on final packaging stage completion; - diagrams and descriptions of the actions performed are supplemented with an interval for interaction between MDLP System and Roszdravnadzor AIS; - supplemented with special conditions of the process. **Section 3.1.1** is supplemented with special conditions of the process. **Section 3.3.1, Section 3.3.2, Section 3.6.1, Section 3.6.2, Section 3.6.3:** - diagrams and descriptions of the actions performed are supplemented with an interval for interaction between MDLP System and Roszdravnadzor AIS; - supplemented with special conditions of the process. **Section 3.4** is supplemented with special conditions of the process. **Section 3.7:** - annotation is supplemented with the information on interaction with the Federal Customs Service of Russia; - description of the actions performed is detailed according to the results of interaction between MDLP System and the Federal Customs Service of Russia; - supplemented with special conditions of the process. **Section 3.9.2** is supplemented with special conditions of the process. **Section 3.10:** - restriction to medicine batch size to be marked at the customs warehouse is excluded; - annotation is supplemented; - description of the actions performed is supplemented with the requirement to observe the API Specification of the Orders Management Station when ordering marking codes and sending a report on marking at the customs warehouse; - supplemented with special conditions of the process. **Section 4.3**: clarification is added on the process application when transferring the medicine for responsible storage. **Section 4.4.1, Section 4.4.2, Section 4.7.3, Section 5.5** are supplemented with special conditions of processes.

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	Section 6: list of information for individuals is updated. **Section 8** is excluded (terminated). **Section 9.1, Section 9.4** are supplemented with special conditions of the process. **Section 10.4 –** A new process of information update is implemented. The Passports of Processes are supplemented with **Appendix 1** (MDLP System status model) and **Appendix 2** (description of restrictions to application of operations)
1.35	**Section 3.1:** - excluded the possibility of registration of the information about medicine packing completion without using an emission registrar; - introduced clarifications concerning operations for medicine primary package in case of absence of the secondary (consumer) package; - corrected details of the document on medicine introduction into civil circulation. **Section 3.1.1:** - introduced clarifications concerning operations for medicine primary package in case of absence of the secondary (consumer) package; - corrected details of the document on medicine introduction into civil circulation; - supplemented the description with a reference to the new process of medicine return to the contract manufacturer (**Section 3.1.2**). **Section 3.1.2:** Implemented the new process of medicine return to the contract manufacturer. **Section 3.2:** - introduced clarifications concerning operations for medicine primary package in case of absence of the secondary (consumer) package; - the possibility of information registration without using an emission registrar was excluded; - introduced clarifications on optional nature of submission of information about the site that performs release quality control, if medicine packages are marked outside the territory of the Russian Federation. **Section 3.3.1:** - excluded instruction to place medicines in a temporary storage upon import;

Version	List of Changes
	- introduced a clarification on correct specification of customs cost; - excluded suspended goods acceptance attribute (valid only for the medicines introduced into civil circulation) from the information list; - supplemented the diagram with a reference to the new **Section 3.10** (marking at customs warehouse). **Section 3.3.2**: - excluded instruction to place medicines in a temporary storage upon import; - introduced a clarification on correct specification of customs cost; - excluded suspended goods acceptance attribute (valid only for the medicines introduced into civil circulation) from the information list. Supplemented the diagram in **Section 3.3.3** with a reference to the new **Section 3.10** (marking at customs warehouse). **Section 3.4:** - introduced a clarification on correct specification of a medicine cost; - corrected details of the document on medicine introduction into civil circulation. **Section 3.5:** - supplemented with a possibility to use the operation upon returning the medicines that have previously been transferred to the new owner in the customs-controlled area; - excluded suspended goods acceptance attribute (valid only for the medicines introduced into civil circulation) from the information list. **Section 3.6.1** and **Section 3.6.2**: - introduced a clarification on correct specification of a medicine cost; - corrected details of the document on medicine introduction into civil circulation. Corrected details of the document on medicine introduction into civil circulation in **Section 3.6.3**. Supplemented the description in **Section 3.8** with a reference to the new process of medicine return to the contract manufacturer (**Section 3.1.2**). **Section 3.9.2**: - supplemented the list of cases allowing medicine return to circulation; - supplemented the list of information with optional details of supporting document.

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	Section 3.10: Implemented a new process of marking of the medicine packages produced outside the territory of the Russian Federation, at a customs warehouse. **Sections 4.1, 4.2, 4.4.1, 4.6.1, 4.6.2** and **4.7.3**: implemented a clarification on correct specification of medicine cost. **Section 4.6.3:** - introduced a clarification on correct specification of customs cost; - broadened applicability of the process for cases of customs transit and destruction under customs control. **Section 4.7.2:** - supplemented with a possibility to use the return data for registration; - supplemented the information list with a new optional attribute "Type of shipment operation". **Section 4.7.4**: Implemented a new process of arbitration. **Section 5.4**: supplemented the information list with a new optional attribute "Reason of medicine transfer for destruction". **Section 8**: implemented a note on the process duration. **Section 9.2**: supplemented with a possibility of deconsolidation of numerous medicine tertiary packages. **Section 9.4**: supplemented with a possibility of additional insertion to numerous medicine tertiary packages. **Sections 10.1–10.3**: broadened the lists of the operations for which registration of information about cancellation, recall and rejection is allowed
1.34.1	Diagram versions are unchanged. **Section 3.4** was updated with a possibility of medicine shipment from the customs-controlled area to the logistics operator warehouse. Export and re-export processes were prepared **(Section 4.6.2 and Section 4.6.3).** **Section 5.2.1** was updated with information on how to use disposal registrar when submitting data on medicine issue within the high cost nosologies program. **Section 5.5** was updated with restrictions concerning registration of data about withdrawal of medicine, which is supplied within the high cost nosologies program, from circulation
1.34	1. Changes were made to register the information about medicine introduction into circulation as per the requirements of Federal

Version	List of Changes
	Law No.449-FZ dd. 28/11/2018: - registration of information about sampling using scheme 312-register_control_samples.xsd was excluded **(Section 3.1, Section 3.1.1, Section 3.4, Section 3.6.1, Section 3.6.1);** - additional types of withdrawal for various reasons were introduced for sampling **(Section 5.5);** - type and details of the document confirming compliance were excluded from information about medicine introduction into circulation **(Section 3.1, Section 3.1.1)**, information about customs clearance results **(Section 3.3.1, Section 3.3.2)**, information about medicine introduction into circulation in the Russian Federation upon medicine importation from EAEU countries **(Section 3.6.1, Section 3.6.2)** - the following was included into information about medicine introduction into circulation **(Section 3.1, Section 3.1.1)**, information about medicine introduction into circulation in the Russian Federation upon medicine importation from EAEU countries **(Section 3.6.1, Section 3.6.2)**: date of publication of information about introduction into circulation/permit to introduce immunobiological medicines into circulation in AIS of Roszdravnadzor, number of permit of Roszdravnadzor to introduce into circulation (for immunobiological medicines) and number of document confirming medicine compliance with the requirements established upon its state registration. - the requirement to register information about medicine introduction into circulation using 342- foreign_release.xsd **(Section 3.4)** was added to the process of medicine acceptance to warehouse by importer after release from customs area upon medicine importation to the Russian Federation; - the process of medicine importation to the Russian Federation from EAEU member states and medicine introduction into circulation by MAH that is a resident of the Russian Federation was prepared **(Section 3.6.3)**; - changes were introduced to restrictions of operation application **(Section 10.1, Section 10.2,** Section **10.3).** 2. The process of medicine movement between own business places within state medicine provision **(Section 4.7.3)** was prepared. 3. Changes were made in the structure of information submitted in case of return of suspended medicine **(Section 7.2)**. 4. Clarifications were made on the need to specify VAT=0 if the operation is not subject to such tax **(Section 3.4, Section 3.6.1, Section 3.6.2, Section 4.1, Section 4.2, Section 4.4.1, Section 4.6, Section 5.1.1, Section 5.1.2)**

Version	List of Changes
	5. Clarification on possible application of operation of medicine withdrawal from circulation due to various reasons by MAH (if necessary) was added to the medicine production process outside the Russian Federation **(Section 3.2)**
1.33	**Section 1.1, Section 1.1.1:** - the name of the information resource of the Federal Service for Surveillance in Healthcare of Russian Federation was changed (Unified Register of Licenses; **Section 1.3:** - list of reasons for rejection to register information about foreign counterparties was changed; **Section 4.7:** - section number 4.7 changed to 4.7.1; - the process of medicine circulation under agency agreements and commission agreements was created (Section 4.7.2); **Section 5.5:** - the possibility of transferring information about medicine withdrawal from circulation using the emission registrar was excluded
1.32	**Section 3.1:** - the process was supplemented with the steps of obtaining the marking codes and registering the information about issue of codes in MDLP System; **Section 3.1.1:** - scheme number was corrected—Owner notification of medicine shipment (now the number is 618); **Section 3.2:** the process was supplemented with the steps of obtaining the marking codes and registering the information about issue of codes in MDLP System;
1.31	**Section 3.1:** - the process of introduction into circulation was created for medicine produced in the territory of the Russian Federation by contract manufacturer, by medicine owner (Section 3.1.1); - diagram in Section 3.1. was modified due to creation of a new process of introduction into circulation by the medicine owner; **Section 3.3.1, Section3.3.2, Section 3.3.3, Section 3.6.1, Section 3.6.2.:**

Version	List of Changes
	- a clarification was introduced for submission of the identifier of foreign counterparty—medicine seller (if any) as part of the information; **Section 5.1.1., Section 5.2.2.:** - the following was excluded from the data transferred from CRE: fiscal sign of the document and the image of the receipt in base64 format
1.30	**Section 5.1.2, Section 5.2.1 and Section 5.3:** changes were made in the format of information transferred about the share within partial sale/ issue
1.29	**Section 4.2:** - implemented the transfer of notification to the shipper about errors when registering the acceptance of medicine to the warehouse by the receiver; **Section 5.1.1:** - changed the process of registration of information about retail sale of medicine using CRE; **Section 5.2:** - the process of medicine issue on preferential prescription using CRE (Section 5.2.2) was created - changed the number and name of Section 5.2.1. Medicine Issue on Preferential Prescription Without CRE (previously Section 5.2); **Section 5.5:** - introduced additional types of withdrawal from circulation (production of medical devices, production of medicine); - changed the necessity of the supporting document date and number
1.28	**Section 3.2:** - the possibility of transferring the information on completion of medicine packing stage using emission registrar was implemented; **Section 3.3.3:** - process and scheme name was changed; - list of information transferred on medicine importation into the Russian Federation without acceptance was revised; - need to transfer the information about medicine owner change within the customs-controlled area when medicine is imported by a resident of the Russian Federation, which is MAH or representative office of a foreign organization, was excluded; **Section 3.9:**

Version	List of Changes
	- the processes of medicine return to circulation were united (previously 3.9, 3.10, 4.5); - a list was made of the types of medicine withdrawal from circulation after which medicine return to circulation is possible; - list of information transferred about medicine return to circulation was revised; **Section 5.3:** the process was revised in terms of the possibility of registering the information on partial medicine issue for medical use; list of information transferred about medicine issue for medical use was revised; **Section 5.5:** - additional allowable types of withdrawal from circulation were introduced (discarding of broken up package, production rejects); - the possibility of information transfer on discarding of production rejects using emission registrar was implemented
1.27	**Section 3.1:** - the possibility of transferring the information on completion of medicine packing stage using emission registrar was implemented; - list of information transferred on completion of medicine packing stage was revised; **Section 3.2:** - list of information transferred on release of finished products outside the Russian Federation was revised; **Section 3.3:** - the process of medicine importation into the Russian Federation with direct confirmation order (Section 3.3.1) was developed; - list of information transferred about medicine shipping to the Russian Federation was revised; - the process of medicine importation into the Russian Federation with reverse confirmation order (Section 3.3.2) was developed; - list of information transferred about medicine importation to the Russian Federation was revised; - the process of medicine importation under consignment contract (Section 3.3.3) was developed;

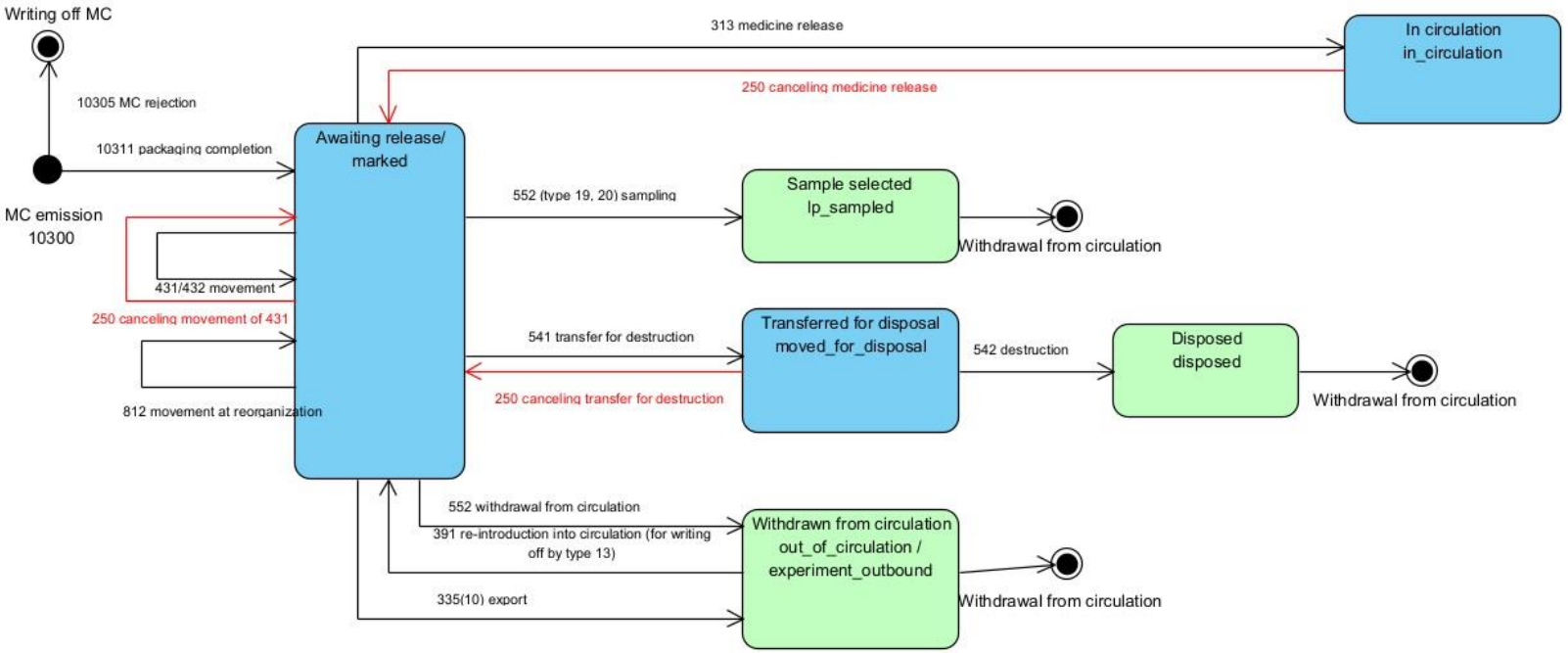
Version	List of Changes
	Section 3.6: - the process of medicine importation into the Russian Federation from the territory of EAEU member state with direct confirmation order (Section 3.6.1) was developed; - list of information transferred about medicine shipping to the Russian Federation from the EAEU member state was revised; - the process of medicine importation into the Russian Federation from the territory of EAEU member state with reverse confirmation order (Section 3.6.2) was developed; - list of information transferred about medicine importation to the Russian Federation from the EAEU member state was revised; **Section 5.1:** revisions to the process in terms of possibility of registering the information about partial medicine selling and preferential medicine selling with partial payment; **Section 5.2:** - revisions to the process in terms of possibility of registering the information about partial medicine issue on preferential prescription; - the possibility of information transfer on medicine issue on preferential prescription using disposal registrar was implemented; **Section 5.3:** - list of information transferred about medicine issue for medical use was revised; - the possibility of information transfer on medicine issue for medical use using disposal registrar was implemented; **Section 10.1:** revisions to the list of operations subject to cancellation **Section 10.2:** revisions to the list of operations subject to recall **Section 10.3:** revisions to the list of operations subject to rejection

Appendix 1
to Instruction on Submission of Information
by Pharmaceutical Entities
to Track and Trace System of Medicines
for Medical Use

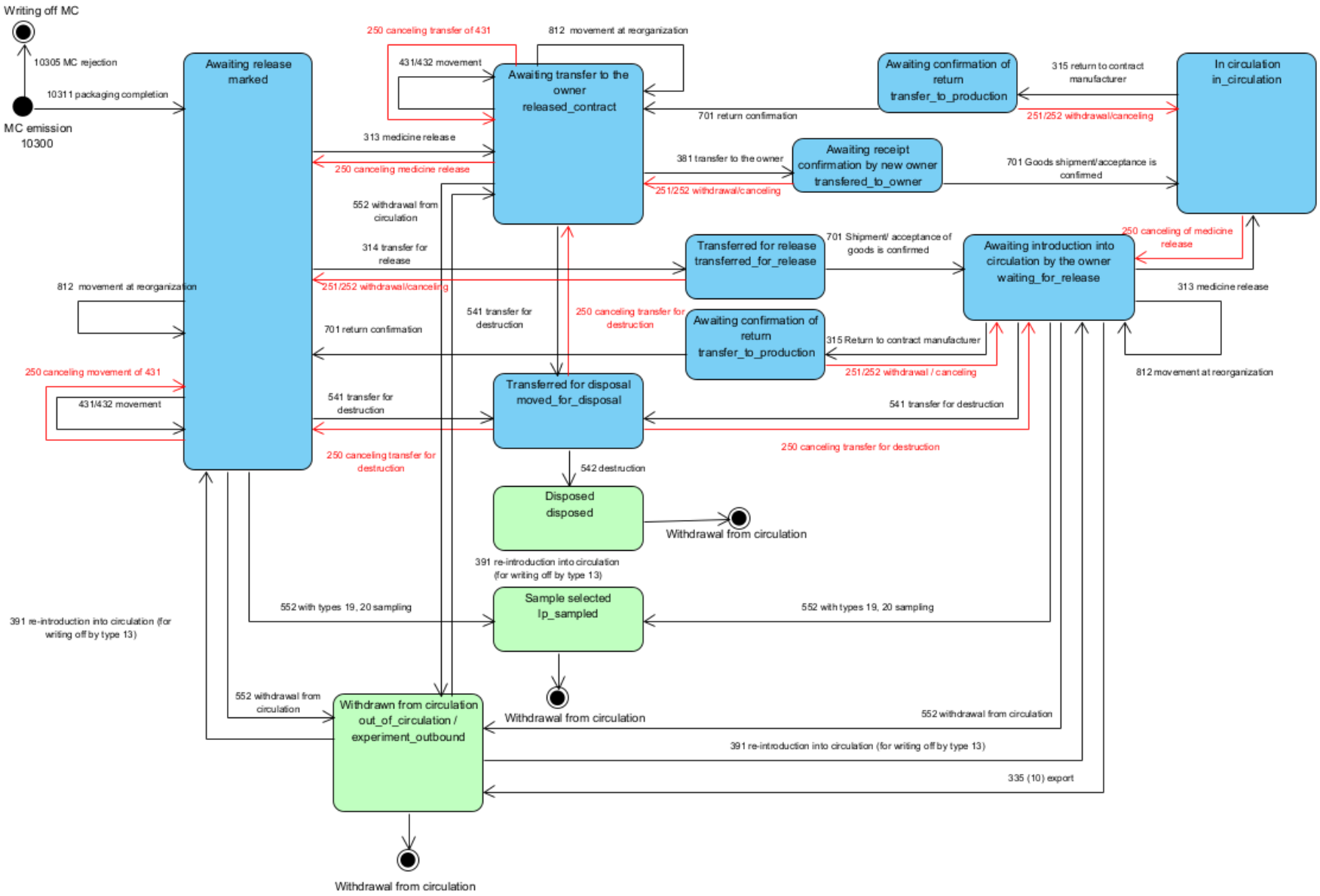
STATUS MODEL
of Track and Trace Information System of Medicines for Medical Use

Table of Contents

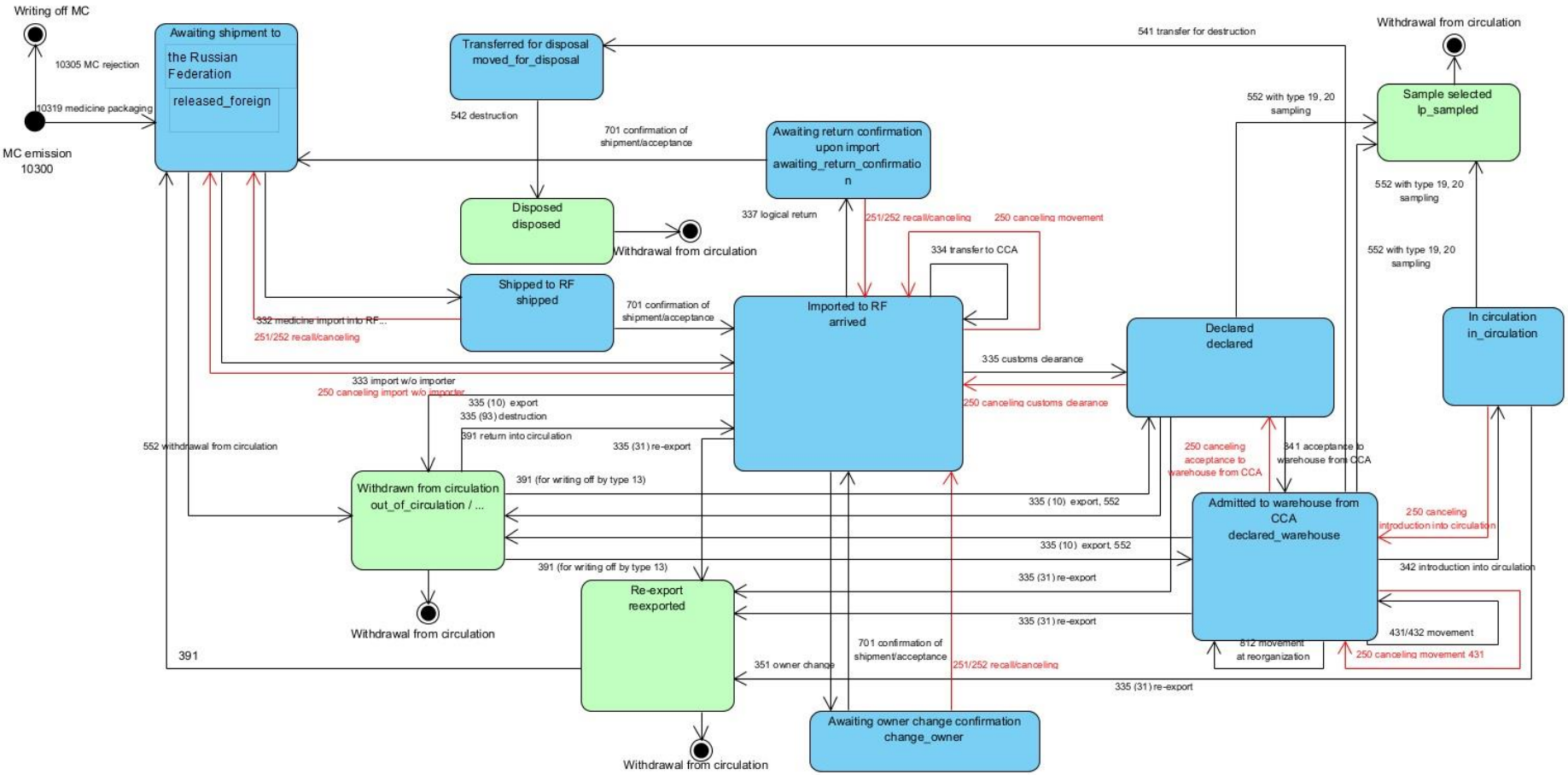
1. Own Manufacture of Medicines in the Russian Federation



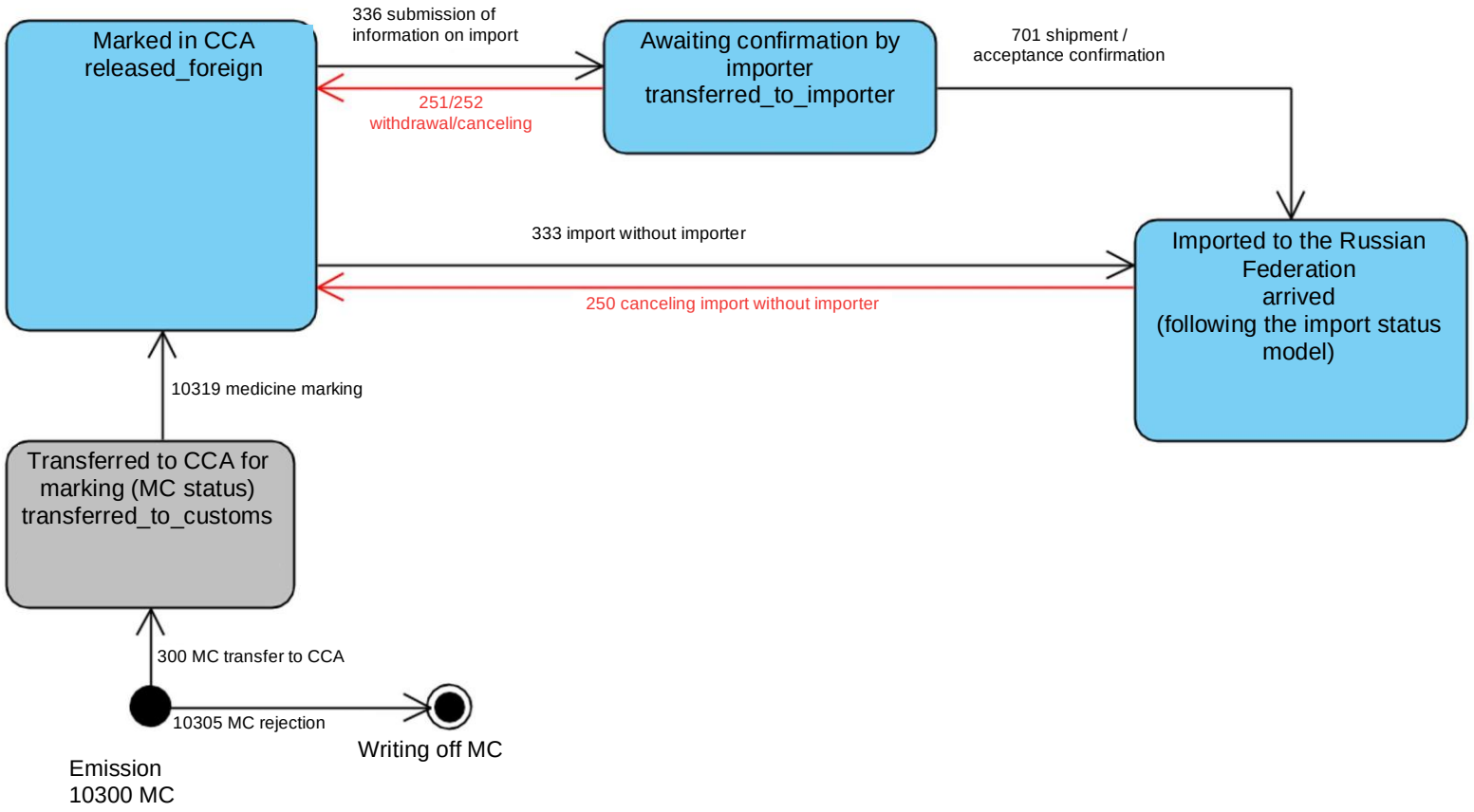
2. Contract Manufacture of Medicines in the Russian Federation



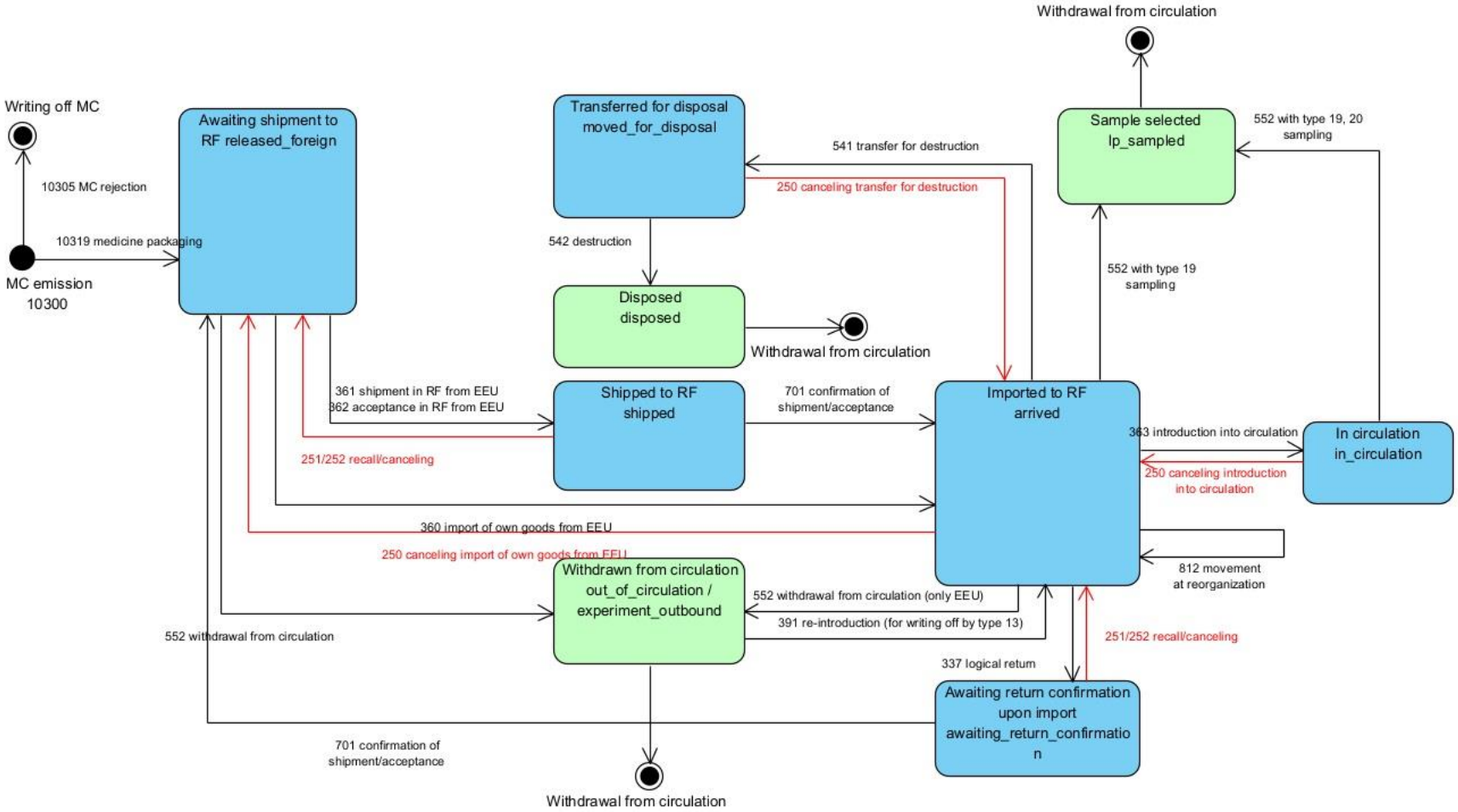
3. Foreign Manufacture of Medicines and Import of Medicines in the Russian Federation



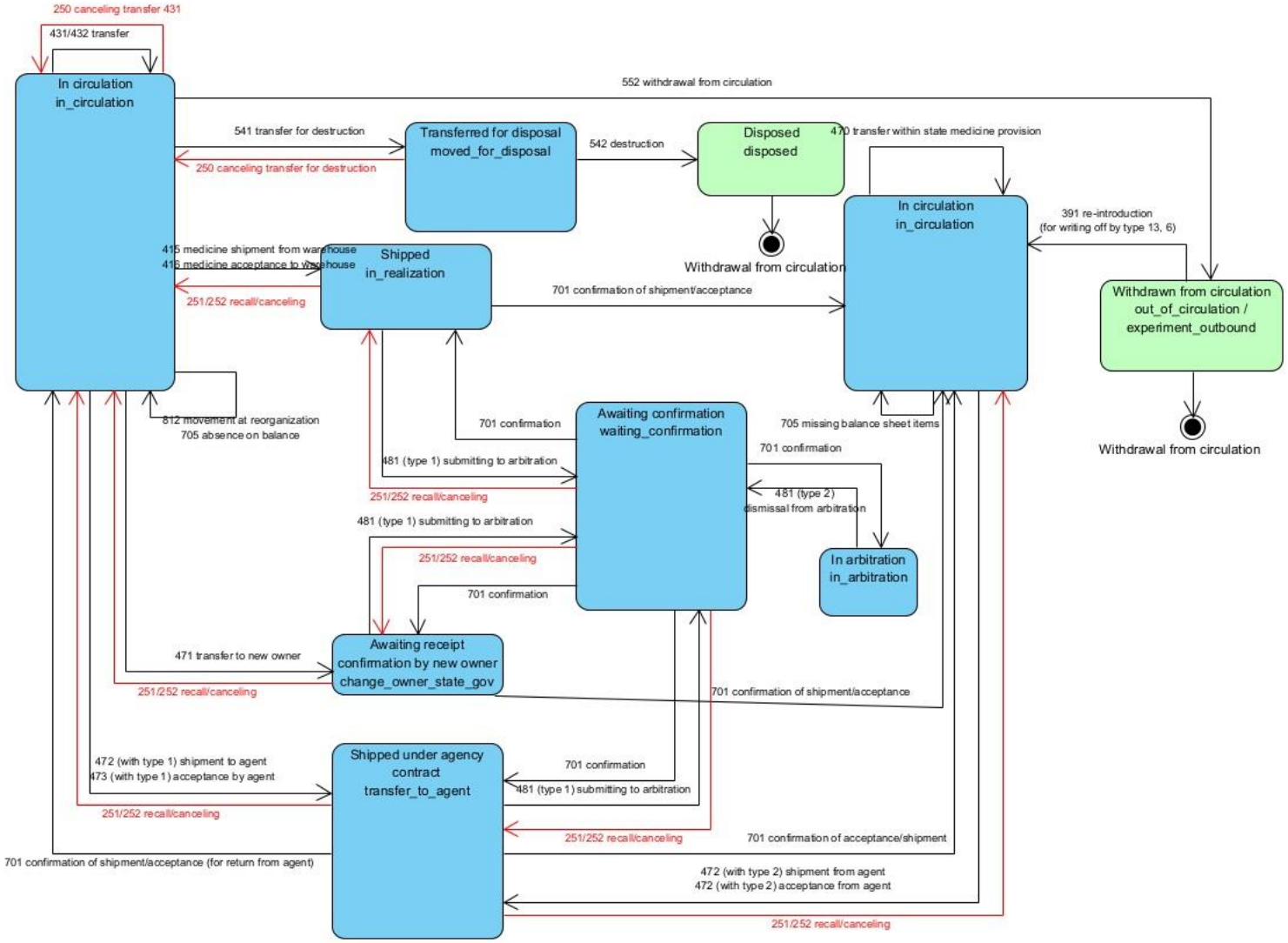
4. Foreign Manufacture of Medicines and Marking of Medicine Packings in the Customs Control Area (at Customs Warehouse)



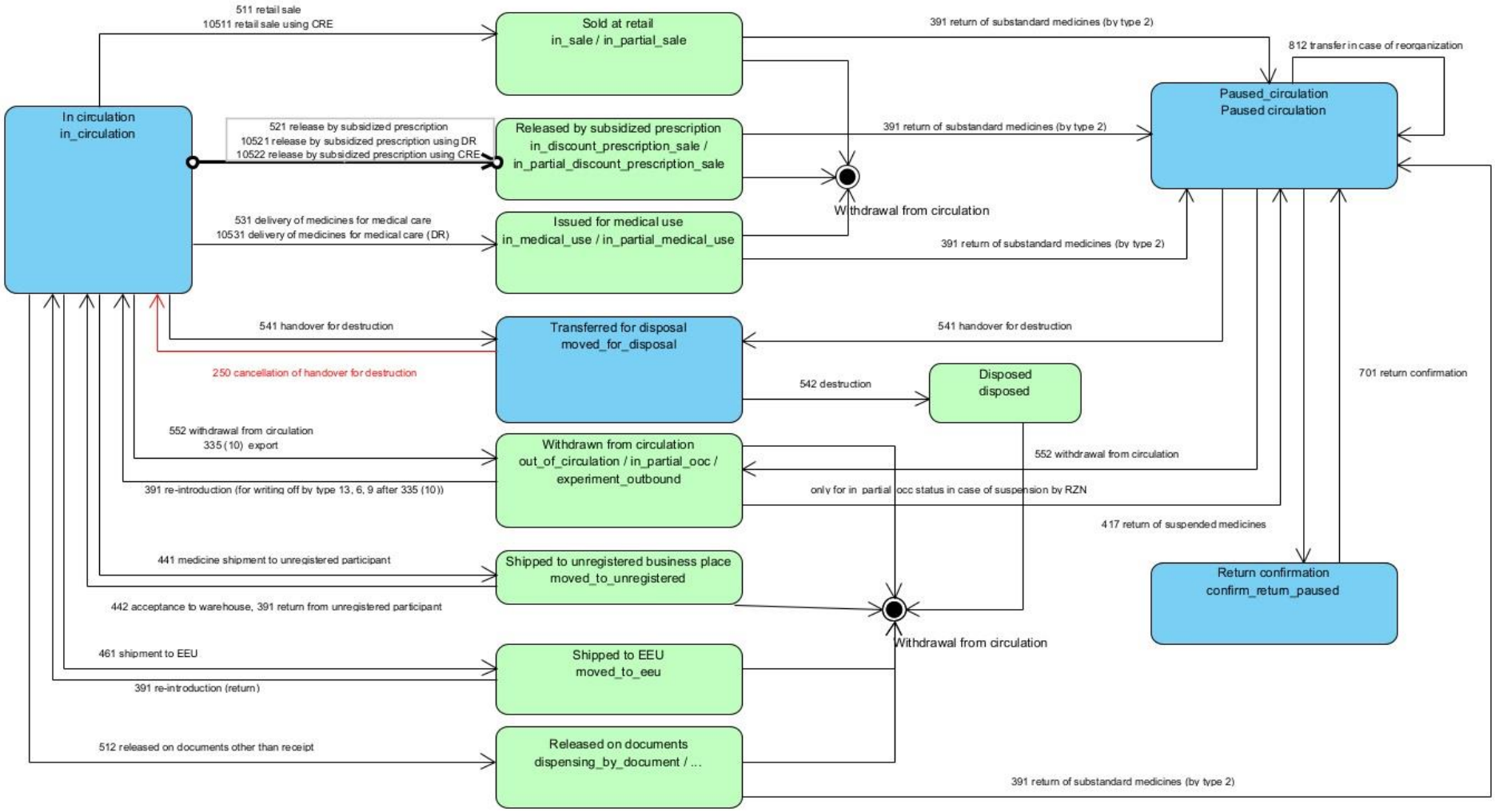
5. Foreign Manufacture of Medicines and Import of Medicines from EAEU Countries



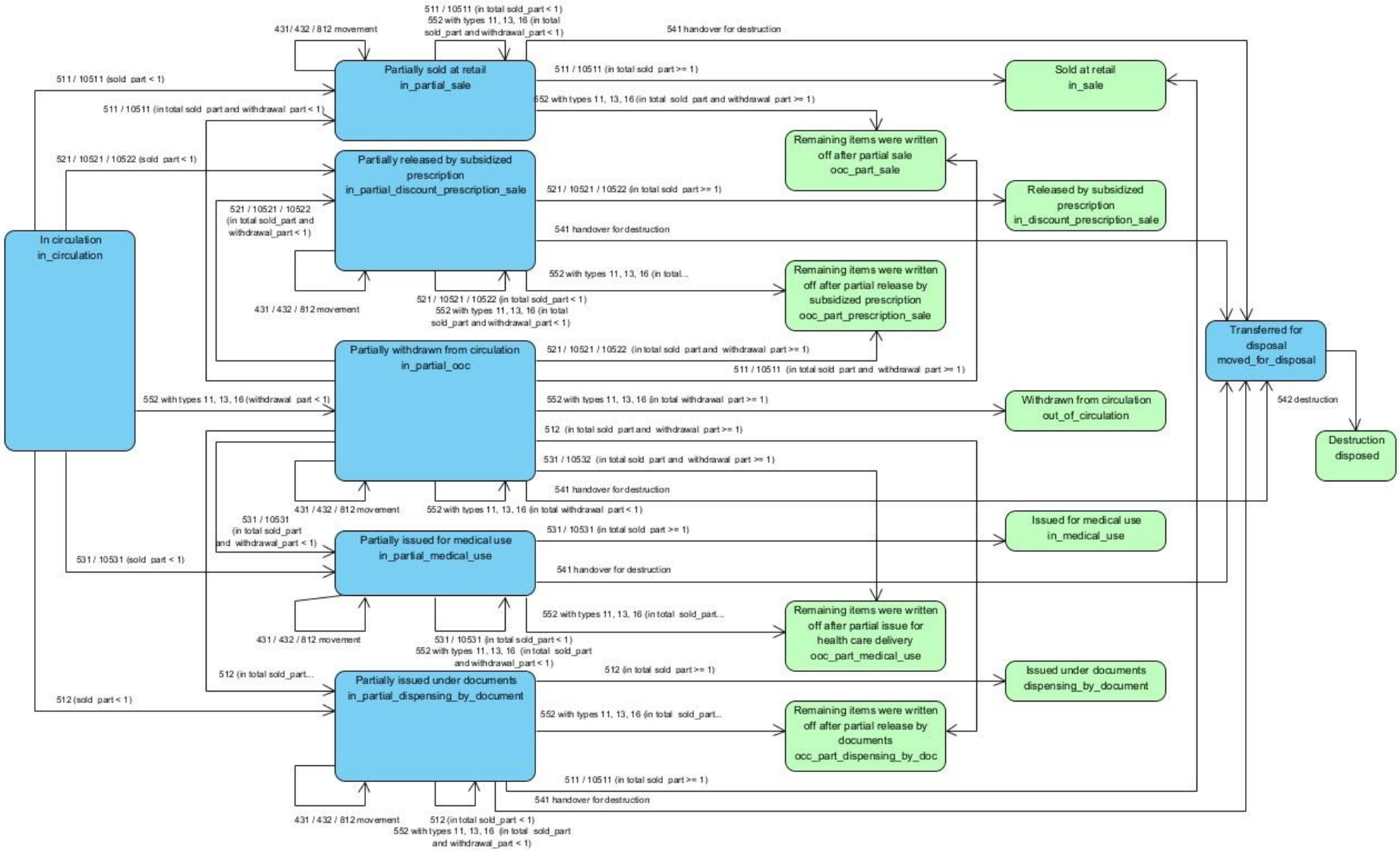
6. Medicine Circulation in the Russian Federation



7. Medicine Withdrawal from Circulation



8. Operations with Stripped Package



Appendix 2
to Instruction on Submission of Information
by Pharmaceutical Entities
to Track and Trace System of Medicines
for Medical Use

Restrictions for Usage of Operations

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
10300	Issue of marking codes	SGTIN	-	-	no	-	Canceling is prohibited	generated automatically via ER
10305	Rejection of Marking Codes	SGTIN	-	-	no	-	Canceling is prohibited	generated automatically via ER
10311	Packing completion (emission registrar)	SGTIN	prohibited	-	no	-	Canceling is prohibited. Update of some attributes before registration of subsequent operations using scheme 253	generated automatically via ER
10319	Medicine release outside the Russian Federation (emission registrar)	SGTIN	-	-	no	-	Canceling is prohibited. Update of some attributes before registration of subsequent operations using scheme 253	generated automatically via ER
10511	Retail sale using CRE	SGTIN	prohibited	-	no	-	Financing source (source_type attribute) of SGTIN shall be 1. In case of retail sale with partial subsidy, financing source may be 1 or 3 Canceling is prohibited	generated automatically based on the data received from FDO
10521	Release on subsidized medicine prescription (disposal registrar)	SGTIN	prohibited	-	no	-	Financing source (source_type attribute) of SGTIN shall be 2 or 3 Canceling is prohibited	generated automatically via DR
10522	Release on subsidized medicine prescription using CRE	SGTIN	prohibited	-	no	-	Financing source (source_type attribute) of SGTIN shall be 2 or 3 Canceling is prohibited	generated automatically based on the data received from FDO

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
10523	Release of medicines with invalid MC on preferential recipes (disposal registrar)	SGTIN	prohibited	-	no	-	Financing source (source_type attribute) of SGTIN must be 2 or 3 Cancellation is prohibited.	it is automatically formed by means of DR
10531	Release for delivery of medical treatment (disposal registrar)	SGTIN	prohibited	-	no	-	Financing source (source_type attribute) of SGTIN shall be 1, 2, 3, 4 or 5 Canceling is prohibited	generated automatically via DR
10532	Delivery of medicines with invalid MC for medical care (disposal registrar)	SGTIN	prohibited	-	no	-	Financing source (source_type attribute) of SGTIN must be 1,2, 3, 4 or 5 Cancellation is prohibited.	it is automatically formed by means of DR
20521	Registration of information on connection of disposal registrar	SGTIN	prohibited	-	no	-	Canceling is prohibited. Service scheme for check of DR connection	generated automatically via DR
213	Booking (booking cancellation) of shipping packing numbers	SSCC	-	-	no	yes	Booking cancellation (operation_type=2) may be performed only by the participant that has booked the specified SSCC	
250	Operation canceling	-	allowed	-	no	-	Used only for canceling of own previously registered operations with SGTIN or SSCC. No other operations shall be between the operation to be canceled and operation 250. Not used for packing operation and withdrawal from circulation operation Permitted for blocked business places It is not used for cancellation of the operation for which a registration has completed with partial information acceptance (Partial)	
251	Recall of part of the goods by Sender	SGTIN, SSCC	allowed	allowed	no	no	Used for operations requiring acceptance in relation to SGTIN/SSCC expecting confirmation by the second party Permitted for blocked business places It is allowed for expired medicines	
252	Rejection of acceptance of part of the goods by Buyer	SGTIN, SSCC	allowed	allowed	no	no	Used for operations requiring acceptance in relation to SGTIN/SSCC expecting confirmation by the second party Permitted for blocked business places It is allowed for expired medicines	

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
253	Update of previously submitted details	SGTIN	prohibited	-	no	-	Performed only after 10311 or 10319; no other operations shall be between the operation to be updated and operation 253, or operation 313 shall be canceled (for Russian manufacture) and disaggregation shall be performed. Canceling is prohibited	
254	Data update	SGTIN, SSCC	allowed	-	yes	no	Not used in relation to SGTIN/SSCC expecting confirmation by the second party. Update of 'source' is available only for the first shipment under a public contract. Update of information is allowed for the information previously sent using schemes 415, 416, 417, 471, 472. Recall (251)/refusal (252) operations are used. Unavailable after group packing reaggregation operations	
300	Transfer of codes to CCA	SGTIN	-	-	no	-	Identifier from the register of places in the customs control area with pharmaceutical license availability attribute shall be indicated in 'customs_receiver_id' field. Canceling is allowed (250)	
313	Medicine release	SGTIN, SSCC	prohibited	-	no	no	Canceling is allowed (250)	
314	Medicine shipment to the owner for finished goods release	SGTIN, SSCC	prohibited	allowed	yes	no	Recall (251)/refusal (252) operations are used	
315	Medicine return to the contract manufacturer	SGTIN, SSCC	allowed	prohibited	yes	no	It is allowed for expired medicines. Recall (251)/refusal (252) operations are used	

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
331	Medicine shipment in the Russian Federation	SGTIN, SSCC	-	-	yes	no	Allowed types Type of contract upon sale (contract_type_enum): • 1 - retail sale • 2 - commission • 3 – agency • 4 - free of charge transfer Prohibited for emission type 4 – marked in the customs control area. Recall (251)/refusal (252) operations are used	
332	Medicine import into the Russian Federation	SGTIN, SSCC	-	-	yes	no	Buyer (sender of message 332) shall be in the list of trusted counterparties of seller Allowed types Type of contract upon sale (contract_type_enum): • 1 - retail sale • 2 - commission • 3 – agency • 4 - free of charge transfer Prohibited for emission type 4 – marked in the customs control area. Recall (251)/refusal (252) operations are used	
333	Medicine import into the Russian Federation on consignment	SGTIN, SSCC	-	-	no	no	Allowed types Type of contract upon sale (contract_type_enum): • 7 – consignment contract • 8 - own funds Canceling is allowed (250)	
334	Transfer within the customs control zone	SGTIN, SSCC	-	-	no	no	Canceling is allowed (250)	
335	Release for domestic use Export clearance Refusal in favor of the state within the customs control zone Re-export clearance Transfer for destruction from the customs control zone Customs clearance	SGTIN, SSCC	-	-	no	yes*	SGTIN status is assigned depending on the value in the ‘custom_procedure_code’ field. Re-export can be also formed for SGTIN with paused_circulation status export_country_code element is mandatory if custom_procedure_code = 10. Canceling is allowed (250) * auto-disaggregation is performed when registering the operations of types 10, 31,80	

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
336	Submission of information on import	SGTIN, SSCC	-	-	yes	no	Only if previously registered information on marking in the customs control area is available (300, 10319 within CCA). Not applicable to the goods import from EAEU. Recall (251)/refusal (252) operations are used	
337	Submission of information on logical return of medicines when importing into the Russian Federation	SGTIN, SSCC	-	-	yes	no	Recall (251)/refusal (252) operations are used. Opens at request to Technical Support Service	
341	Acceptance to warehouse from the customs control area	SGTIN, SSCC	allowed	-	no	no	Canceling is allowed (250)	
342	Medicine introduction into circulation in the Russian Federation	SGTIN, SSCC	allowed	-	no	no	Canceling is allowed (250)	
351	Change of medicine owner	SGTIN, SSCC	-	-	yes	no	Recall (251)/refusal (252) operations are used	
360	Import of own medicines from EAEU	SGTIN, SSCC	prohibited	-	no	no	Allowed types Type of contract upon sale (contract_type_enum): • 8 - own funds Canceling is allowed (250)	
361	Medicine shipment into the Russian Federation from EAEU	SGTIN, SSCC	-	allowed	yes	no	Allowed types Type of contract upon sale (contract_type_enum): • 1 - retail sale • 2 - commission • 3 – agency • 4 - free of charge transfer Recall (251)/refusal (252) operations are used	
362	Medicine import into the Russian Federation from EAEU	SGTIN, SSCC	allowed	-	yes	no	Allowed types Type of contract upon sale (contract_type_enum): • 1 - retail sale • 2 - commission • 3 – agency • 4 - free of charge transfer Recall (251)/refusal (252) operations are used	

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
363	Introduction of medicine from EAEU into circulation in the Russian Federation	SGTIN, SSCC	prohibited	-	no	no	Canceling is allowed (250)	
381	Medicine shipment to owner	SGTIN, SSCC	prohibited	allowed	yes	no	Recall (251)/refusal (252) operations are used	
391	Re-introduction into circulation	SGTIN	prohibited	-	no	-	Only for medicines previously withdrawn from circulation using scheme 552 with type 13, scheme 335 with type 31 and 10, scheme 461, scheme 511, scheme 521, scheme 531, scheme 441, scheme 552 with type 6,9,24 For operation 391 after operations 511, 512, 521, 531, only type 2 is allowed (substandard quality). For operation 391 after operation 335 with type 31, 441, 461, only type 1 is allowed (proper quality). Canceling is prohibited Registration of operations for stripped package is prohibited	
415	Medicine shipment from warehouse	SGTIN, SSCC	prohibited	allowed	yes	no	Allowed types Type of contract upon sale (contract_type_enum): • 1 - retail sale • 2 - commission • 3 - agency • 4 - free of charge transfer • 5 - return to contract manufacturer • 6 - state medicine provision During registration with financing source = 2 or 3, contract type = 6 shall be indicated. Contract_num is mandatory if financing source = 2 or 3 and contract type = 6. Permitted when operation with turnover_type=2 is registered from blocked business place. Operations with turnover_type=2 can be registered for the expired medicines. Recall (251)/refusal (252) operations are used	

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
416	Medicine acceptance to warehouse	SGTIN, SSCC	allowed	prohibited	yes	yes	Buyer (sender of message 416) shall be in the list of trusted counterparties of seller Allowed types Type of contract upon sale (contract_type_enum): • 1 - retail sale • 2 - commission • 3 - agency • 4 - free of charge transfer • 5 - return to contract manufacturer • 6 - state medicine provision During registration with financing source = 2 or 3, contract type = 6 shall be indicated. Contract_num is mandatory if financing source = 2 or 3 and contract type = 6. Permitted when operation with turnover_type=2 is registered from blocked business place. Operation with receive_type=2 can be registered for the expired medicine. Recall (251)/refusal (252) operations are used	
417	Return of suspended medicines	SGTIN, SSCC	allowed	allowed	yes	no	Permitted when information is transferred from blocked business place. Recall (251)/refusal (252) operations are used	
431	Transfer	SGTIN, SSCC	allowed	allowed	no	no	Permitted when information is transferred from blocked business place. It is allowed for expired medicines. Canceling is allowed (250)	
432	Movement of all medicines	-	allowed	allowed	no	no	Canceling is prohibited. It is allowed for expired medicines. It is unavailable for medicines awaiting confirmation	

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
441	Medicine shipment to unregistered business place	SGTIN, SSCC	prohibited	-	no	yes	Financing source (source_type attribute) of SGTIN shall be 1. For shipment to an unregistered participant, INN shall be included in local USRLE, but shall not belong to a registered participant. Allowed types Type of contract upon sale (contract_type_enum): • 1 - retail sale • 2 - commission • 3 - agency • 4 - free of charge transfer Canceling is prohibited	
442	Acceptance to warehouse of medicines previously shipped to an unregistered business place	SGTIN, SSCC	prohibited	-	no	no	Canceling is prohibited	
461	Medicine shipment in EAEU	SGTIN, SSCC	prohibited	-	no	yes	Financing source (source_type attribute) of SGTIN shall be 1. Canceling is prohibited	
470	Medicine transfer within the state medicine provision	SGTIN, SSCC	allowed	allowed	no	no	Financing source (source_type attribute) of SGTIN shall be 1 Canceling is allowed (250)	
471	Transfer to a new owner	SGTIN, SSCC	prohibited	allowed	yes	no	Financing source (source_type attribute) of SGTIN shall be 2 or 3 Operations with turnover_type=2 can be registered for the expired medicines. Recall (251)/refusal (252) operations are used	
472	Medicine shipment under an agency contract	SGTIN, SSCC	prohibited	allowed	yes	no	If the 'turnover_type' is not filled, the default value 1 – shipment is assigned. Operations with turnover_type=2 can be registered for the expired medicines. Recall (251)/refusal (252) operations are used	
473	Medicine acceptance under an agency contract	SGTIN, SSCC	allowed	prohibited	yes	no	Operation with receive_type=2 can be registered for the expired medicine. Recall (251)/refusal (252) operations are used	

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
481	Arbitration	SGTIN, SSCC	allowed	allowed	yes	no	Available only for SGTIN and SSCC expecting acceptance – after operations 415, 416, 417, 471, 472, 473. Identifier 'subject_id' specified in the above operations or identifier of a counterparty (shipper_id, receiver_id) may be used as 'subject_id'. Recall (251)/refusal (252) operations are used	
511	Retail sale	SGTIN	prohibited	-	no	-	Financing source (source_type attribute) of SGTIN shall be 1. In case of retail sale with partial subsidy, financing source (source_type attribute) may be 3. Canceling is prohibited	
512	Medicine sale on documents other than CRE receipt	SGTIN	prohibited	-	no	-	Canceling is prohibited	
521	Release on subsidized medicine prescription	SGTIN	prohibited	-	no	-	Canceling is prohibited. Use of scheme for 7VZN medicines is prohibited	
531	Release for delivery of medical treatment	SGTIN	prohibited	-	no	-	Financing source (source_type attribute) of SGTIN shall be 1, 2, 3 Canceling is prohibited	
541	Transfer for destruction	SGTIN, SSCC	prohibited	-	no	no	If the value of 'reason_for_destruction' attribute is not filled, the default value = 1 - substandard medicine is assigned. Permitted when information is transferred from blocked business place. It is allowed for expired medicines. Canceling is allowed (250)	
542	Destruction	SGTIN, SSCC	prohibited	-	no	yes	Permitted when information is transferred from blocked business place. It is allowed for expired medicines. Canceling is prohibited	

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
552	Withdrawal from circulation	SGTIN, SSCC	prohibited	-	no	yes	The 'doc_num' and 'doc_date' elements are not mandatory for filling if the following types of 'withdrawal_type' are specified: • 6 - sample control • 7 - customs control • 8 - federal supervision • 9 - for clinical studies • 10 - for pharmaceutical expertise • 17 – production of medical products • 18 – production of pharmaceuticals • 19 - control sampling under quality control • 20 - retain sampling export_country_code element is mandatory if withdrawal_type = 24 or 26. Permitted when information is transferred from blocked business place. It is allowed for expired medicines if withdrawal_type = 11, 13, 16 or 21. Canceling is prohibited Registration of operation 552 with type 14 for 7VZN medicines is forbidden	
701	Shipment / acceptance confirmation	SGTIN, SSCC	allowed	allowed	no	no	Permitted when information is transferred from blocked business place. It is allowed for expired medicines. Canceling is prohibited	
702	Posting	SGTIN, SSCC	allowed	-	no	no	Only for the medicines introduced into civil circulation Operation with receive_type=2 can be registered for the expired medicine. The medicines should not have the "Shipped" status for operation 702 of return type. Canceling is prohibited. Use of schemes for VZN medicines is prohibited	

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	SSCC autodisaggregation	Restrictions (except for XSD restrictions)	Note
705	Notification of absence on the balance sheet	- or SGTIN	yes	-	no	no	Canceling is prohibited. It is allowed only for BP with manufacturing or wholesale license. It is not allowed for expired medicines	
812	Transfer of medicines under reorganization	-	prohibited	allowed	no	no	Canceling is prohibited. It is unavailable for the medicine awaiting confirmation	

Aggregation and Reaggregation Operations

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	Canceling, refusal	Restrictions (except for general ones)	Note
911	Aggregation	SGTIN, SSCC	allowed	-	no	prohibited	It is prohibited to aggregate: • SGTIN and SSCC in one group packing; • SGTIN and SSCC with different statuses in one group packing; • SGTIN and SSCC with different financing sources (source_type) in one group packing; • imported SGTIN immediately after registration of operations 342/363 and Russian SGTIN previously received after operations 415/416 Permitted when information is transferred from blocked business place. It is allowed for expired medicines. During registration of operation 911 for unpaid codes, the information will be accepted by the system, the final registration of the information and unlocking of further operations will be after payment of all SGTINs indicated in the aggregation operation	
912	Group packing disaggregation	SGTIN, SSCC	allowed	-	no	prohibited	Permitted when information is transferred from blocked business place.	

XSD-scheme No.	Brief operation description	Packing type	Perform from responsible storage	Perform for responsible storage	Requires acceptance/refusal	Canceling, refusal	Restrictions (except for general ones)	Note
913	Withdrawal from group packing	SGTIN, SSCC	allowed	-	no	prohibited	if packing is multi-layered, it is prohibited to remove SGTINs from lower layers Permitted when information is transferred from blocked business place.	
914	Inclusion in group packing	SGTIN, SSCC	allowed	-	no	prohibited	if packing is multi-layered, it is prohibited to add SGTINs to lower layers It is allowed for expired medicines. Permitted when information is transferred from blocked business place.	
915	Group aggregation	SGTIN, SSCC	allowed	-	no	prohibited	It is prohibited to aggregate: • SGTIN and SSCC in one group packing; • SGTIN and SSCC with different statuses in one group packing; • SGTIN and SSCC with different financing sources (source_type) in one group packing; • imported SGTIN immediately after registration of operations 342/363 and Russian SGTIN previously received after operations 415/416 During registration of operation 915 for unpaid codes, the information will be accepted by the system, the final registration of the information and unlocking of further operations will be after payment of all SGTINs indicated in the aggregation operation Permitted when information is transferred from blocked business place.	
916	Group nesting	SGTIN, SSCC	allowed	-	no	prohibited	simultaneous nesting in different layers of group packings, or simultaneous nesting of SGTIN and SSCC within one operation is prohibited Permitted when information is transferred from blocked business place.	

Appendix 3
to Instruction on Submission of Information
by Pharmaceutical Entities
to Track and Trace System of Medicines
for Medical Use

Section I. Rules of Information Submission within CRE Exchange Formats for Medicine Disposal Registration in MDLP System

1. General Requirements

When registering the medicine withdrawal from circulation through CRE, the information in MDLP System shall be submitted according to FDF approved by FTS for further data conversion into 105XX MDLP System data schemes.

FDF of version 1.05\1.1 does not contain expressly the following information required for registration of the information using data schemes 10511 and 10522 in MDLP System:

1. SGTIN (recommendations for SGTIN recording in tag 1162 are given in Section 5 of this Appendix);
2. prescription date (scheme 10522);
3. prescription number (scheme 10522);
4. prescription series (scheme 10522);
5. identifier of business place (schemes 10511, 10522);
6. identifier of request (schemes 10511, 10522).

Information given in items 2-5 of the list above shall be submitted according to the procedure described below in this Appendix. It shall be noted that 1084 is the tag of a document, and not of a goods item, thus a separate CRE receipt shall be generated for each prescription.

Clarifications for filling of other FDF tags are given in Section 4 of this Appendix.

Forms of primary documents containing the information to be submitted are described below.

1. Forms of subsidized prescriptions are determined by Order of the Ministry of Health of the Russian Federation No. 1093n of November 24, 2021:
    a. Form No. 148-1/y-88. OKUD code 3108805.
    b. Form No. 148-1/y-04 (l). OKUD code 3108805.
    c. Form No. 107-1/y. OKUD code is not defined in Order of the Ministry of Health of the Russian Federation.
    d. Form No. 107/y-НП. OKUD code is not defined in Order of the Ministry of Health of the Russian Federation.

For exchange format unification, when sending data of forms No. 107-1/y and No. 107/y-НП in tag 1085, similar to forms No. 148-1/y, the OKUD code 3108805 shall be specified as an attribute of a subsidized prescription.

FDF is approved by Order of the FTS of Russia No. ЕД-7-20/662@ dated September 14, 2020 (the Order of the FTS of Russia) and described in Appendix 2 to the Order.

2. Format of Recording CRE Receipt Tags 1084 and 1191

CRE receipt tag 1084 is an integrated tag and contains the following tags:

Table 1

Code	Tag name	Format	Size
1085	name of additional user details	String CP-866	64
1086	value of additional user details	String CP-866	256

The following details shall be submitted in tag 1085:

1. Prefix “mdlp” as an attribute indicating that tag 1086 contains the specific information for submission to MDLP System;
2. Optionally 7 characters from the range of “0..9” indicating the type of supporting document which contains the data submitted in tag 1086, according to the National Index of Administrative Documentation (OKUD).
    a. Absence of these characters indicates that the information on medicine retail sale are sent in the receipt.
    b. The value “3108805” indicates that the tag 1086 sends the information on a subsidized receipt with 100% or partial subsidy (tag 1086 shall contain details with prefix “ps”).
    c. Other values of tag 1085 are not allowed.

All details sent in tag 1086 shall be separated with delimiting characters “&”; each detail shall be matched with a unique prefix to simplify machine processing of data:

dn = <number of industry-specific document>, **doc_num**, maximum 200 characters;

dd = <date of industry-specific document> in the format YYMMDD, **doc_date;**

ps = <number of subsidized prescription series>, **prescription_series;**

sid = <identifier of business place of pharmaceutical entity in MDLP System>, **subject_id.**

Identifier of pharmaceutical entity (sid) - 14-digit number (14-byte long string in CP-866, allowed characters are [“0” - “9”]).

When recording a data string, the ending character shall be “&”.

When determining the maximum total length of details **dn** and **ps**, the restrictions for tag 1086 length established by FDF (256 byte as per version 1.05\1.1) shall be taken into consideration.

For inclusion of character “&” in details with prefix **dn** or **ps**, the submitted data shall contain a sub-string “&&” that is not interpreted as a delimiting character or an ending character, and is replaced with character “&” when processing and sending to MDLP System.

Example of tag 1084 generation.

ps = 45102

dn = АБV492&781

dd = 10.11.2018 (181110)

sid = 71752852194630

For the case of medicine disposal registration upon sale without subsidy

Table 2

Tag	Detail name	Value
1085	name of additional user details	mdlp
1086	value of additional user details	sid71752852194630&

For the case of medicine disposal registration upon sale on prescription without subsidy

Table 3

Tag	Detail name	Value
1085	name of additional user details	mdlp
1086	value of additional user details	ps45102&dnАБV492&&781&dd181110&sid71752852194630&

For the case of medicine disposal registration upon sale on a subsidized receipt with partial payment

Table 4

Tag	Detail name	Value
1085	name of additional user details	mdlp
1086	value of additional user details	ps45102&dnАБV492&&781&dd181110&sid71752852194630&

For the case of medicine disposal registration upon release with 100% subsidy

Table 5

Tag	Detail name	Value
1085	name of additional user details	mdlp3108805
1086	value of additional user details	ps45102&dnАБV492&&781&dd181110&sid71752852194630&

The following details are submitted in tag 1191:

“mdlp” means specific information for sending to MDLP System;

sp = <part of consumer (marking) packing to be withdrawn from circulation>, **sold_part;**

ss = <amount of subsidy>, **subsidy_sum** (amount to be compensated from the federal or regional budget when calculating for this settlement subject on a subsidized prescription). It is used for filling of MDLP parameter “discount”.

Detail **sp** is included in tag 1191 directly after the prefix **mdlp**, detail name is not specified as prefix. Consists of: the total number of released primary packings (integer number as a string, leading zeros are prohibited), and then the number of primary packings in a marked packing (integer number as a string, leading zeros are prohibited) separated with character “/” with ending character “&”, i.e. when 4 of 12 blisters are released, the string “4/12&” is specified.

If a fractional part is not specified after prefix “mdlp**”**, the packing is considered to be withdrawn from circulation in full unbroken.

Examples of permitted values of tag 1191: “mdlp”, “mdlp2/12&”.

Detail **ss** for subsidized medicines contains the amount to be compensated from the regional or federal budget. In the receipt details, this value shall be specified as a total for all receipt items as a “consideration amount”. It shall be sent only for subsidized prescriptions with partial subsidy, for prescriptions with 100% subsidy and for prescriptions sold at retail without subsidy, this detail shall not be sent in the fiscal data.

Detail **ss** shall always follow the first delimiting character “&”, the detail name is not specified as prefix. If tag 1191 does not contain any information on partial release (release of entire packing), the delimiting character “&” shall be specified after prefix “mdlp” and before detail **ss**.

Detail **ss** always ends with character “&”. Value of detail “ss” is a string where the permitted characters are only [0..9], which is interpreted as a decimal number with fixed precision of 2 characters after a decimal mark between integer and fractional part.

Examples of permitted values of tag 1191 for a subsidy of 123.00 RUB: “mdlp&12300&”, “mdlp2/12&12300&”.

3. Document Generation with CRE

When generating a document with CRE for a medicine withdrawal from circulation in a pharmacy due to its release on a subsidized prescription with 100% subsidy, the following rules shall be observed:

1. tag 1079 (unit price of settlement subject including discounts and extra charges) shall contain a zero value during data communication.

2. tag 1023 (quantity of settlement subject) for a medical organization shall always be 1 for all marked medicines according to note 12 to table 21 of the Order of the FTS of Russia.

When generating CRE documents, a CRE receipt containing the prescription details in tag 1084 is generated only for one particular subsidized prescription for subsidized medicines. To transmit information on unsubsidized medicines from the same prescription, as well as for other goods, a separate receipt shall be generated.

When selling medicines without prescription or on unsubsidized prescription, medicines may be recorded as separate settlement subjects in one receipt together with other goods and services. In this case, it is not required to specify medicines in a separate receipt.

The “mdlp” string shall be recorded in the “Additional detail of settlement object” (tag 1191) of each such

settlement subject. This record indicates that this settlement subject belongs to the goods group “Medicines” and withdrawal from circulation of SGTIN recorded in tag 1162 of this settlement subject shall be registered in MDLP System. In this case, tag 1085 of such CRE receipt shall contain the “mdlp” detail if at least one medicine is included in the list of CRE receipt settlement subjects, and tag 1086 shall contain the identifier of a business place of a pharmaceutical entity.

Example of generation of tags 1191 and 1084 when selling medicines without prescription or on an unsubsidized prescription (recording in one receipt with settlement subjects of other goods groups and services is allowed)

Table 6

Tag	Detail name	Value
1085	name of additional user details	mdlp
1086	value of additional user details	sid717528521946&
1191	additional detail of settlement subject	mdlp

Algorithm of tag 1084 recording is given in Section 6 of this Appendix.

For a subsidized medicine, VAT rate (tag 1199) and VAT amount (tag 1200) shall be indicated. However, if VAT does not apply to subsidized medicines, the VAT rate shall assume the value 6.

Values for “VAT rate” are as follows:

Table 7

VAT rate name	EF format	PF format
VAT rate is 20%	1	“VAT 20%”
VAT rate is 10%	2	“VAT 10%”
Estimated VAT rate is 20/120	3	“VAT 20/120”
Estimated VAT rate is 10/110	4	“VAT 10/110”
VAT rate is 0%	5	“VAT 0%”
VAT exempt	6	-

If tag 1199 has a value of “VAT rate 0%” and “VAT exempt”, the “VAT amount” in tag 1200 shall have the value of the settlement subject price, and not 0. With these values of tag 1199, the VAT amount specified in tag 1200 in will not be sent to MDLP FGIS (Note: “VAT amount” field in scheme 10511 is not mandatory).

The settlement subject attribute (tag 1212) for medicines in electronic form (EF) shall have value “1”, so in

printed form (PF), according to Table 25 of the Order of the FTS of Russia, is should be “GOODS”, “T” or may be omitted.

If the receiver partially pays for prescribed medicines, the amount to be paid shall be specified in tag 1031 (cash amount as per receipt) and/or tag 1081 (non-cash amount as per receipt), and the subsidy amount – in tag 1217 (consideration amount as per receipt). For example, the total value as per receipt is 1000 RUB, in this case the medicine receiver pays 50% in cash, and the tags will have the following values:

1217 (consideration amount as per receipt) = 500 RUB

1031 (cash amount as per receipt) = 500 RUB

1020 (settlement amount specified in the receipt) = 1000 RUB

4. Details Indicated in CRE Receipt When Selling Marked Goods

Table 8*

Detail name	Tag	Mandatory **	Format	Repeated	Storage	FS	Note No.
document name	1000	1	P	No	-	-	-
FD form code	-	1	E	No	5 years	1, 4	-
FDF version number	1209	1	E	No	30 days	4	-
user name	1048	P-1, E-3	PE	No	30 days	4	10
user INN	1018	P-1, E-3	PE	No	30 days	4	10
buyer (client)	1227	3	PE	No	30 days	4	-
buyer (client) INN	1228	3	PE	No	30 days	4	-
receipt number per shift	1042	1	E	No	30 days	4	-
date, time	1012	1	PE	No	5 years	1, 4	-
shift number	1038	1	E	No	30 days	4	-
settlement attribute	1054	1	PE	No	5 years	1, 4	13
applied taxation system	1055	P-3, E-1	PE	No	30 days	4	-
cashier	1021	2	PE	No	30 days	4	3, 16
cashier INN	1203	3	E	No	30 days	4	16
CRE registration number	1037	1	PE	No	30 days	4	-
automatic machine number	1036	2	PE	No	30 days	4	4, 10

Detail name	Tag	Mandatory **	Format	Repeated	Storage	FS	Note No.
settlement address	1009	P-1, E-2	PE	No	30 days	4	10
settlement place	1187	P-1, E-2	PE	No	30 days	4	10
buyer's phone number or e-mail	1008	P-3, E-2	PE	No	30 days	4	7, 9, 17
settlement subject	1059	1	PE	Yes	30 days	See Table 21	15
settlement amount specified in the receipt (accountable form)	1020	1	PE	No	5 years	1, 4	5
amount as per receipt (accountable form) in cash	1031	P-2, E-1	PE	No	30 days	4	1
amount as per receipt (accountable form) in non-cash	1081	P-2, E-1	PE	No	30 days	4	1
amount as per receipt (accountable form) using prepayment (offsetting advance payment and/or previous payments)	1215	P-2, E-1	PE	No	30 days	4	1
amount as per receipt (accountable form) using postpayment (on credit)	1216	P-2, E-1	PE	No	30 days	4	1
amount as per receipt (accountable form) in consideration	1217	P-2, E-1	PE	No	30 days	4	1
VAT amount as per receipt at the rate of 20%	1102	2	PE	No	30 days	4	6, 18
VAT amount as per receipt at the rate of 10%	1103	2	PE	No	30 days	4	6, 18
settlement amount as per receipt with VAT at the rate of 0%	1104	2	PE	No	30 days	4	6, 18
settlement amount as per receipt without VAT	1105	2	PE	No	30 days	4	6, 18
VAT amount as per receipt at the estimated rate of 20/120	1106	2	PE	No	30 days	4	6, 18
VAT amount as per receipt at the	1107	2	PE	No	30 days	4	6, 18

Detail name	Tag	Mandatory **	Format	Repeated	Storage	FS	Note No.
estimated rate of 10/110							
CRE attribute only for settlements on the Internet	1108	3	E	No	30 days	4	8
e-mail of the receipt sender	1117	2	E	No	30 days	4	7, 9, 10, 17
agent attribute	1057	2	PE	No	30 days	4	2
phone number of the transfer operator	1075	P-2, E-3	PE	Yes	30 days	4	2
bank payment agent operation	1044	2	PE	No	30 days	4	2
phone number of the payment agent	1073	P-2, E-3	PE	Yes	30 days	4	2
phone number of the payment processor	1074	P-2, E-3	PE	Yes	30 days	4	2
transfer operator name	1026	2	PE	No	30 days	4	2
transfer operator address	1005	2	PE	No	30 days	4	2
transfer operator INN	1016	2	PE	No	30 days	4	2
phone number of the provider	1171	P-2, E-3	PE	Yes	30 days	4	2
FTS website	1060	P-3, E-2	PE	No	30 days	4	10
additional receipt detail (accountable form)	1192	3	PE	No	30 days	4	11
additional user detail	1084	3	PE	No	30 days	4	12
FD number	1040	1	PE	No	5 years	1, 4	-
FMD number	1041	1	PE	No	5 years	1, 4	-
DFA (1)	1077	1	PE	No	5 years	4	-
MFA (4)	-	1	E	No	30 days	-	-
QR code	1196	1	P	No	-	-	14

* - according to Table 20 of the Order of the FTS of Russia

** - values of “Mandatory” column are described in Table 10

Notes:

1) Detail “amount as per receipt (accountable form) in non-cash” (tag 1081) is included in the CRE receipt (accountable form) in printed format only if the amount paid via electronic payment facilities is other than zero.

Detail “amount as per receipt (accountable form) in cash” (tag 1031) is included in the CRE receipt (accountable form) in printed format only if the amount paid in cash funds is other than zero.

Detail “amount as per receipt (accountable form) using prepayment (offsetting advance payment and/or previous payments)” (tag 1215) is included in the CRE receipt (accountable form) in printed format only if the amount paid as prepayment is other than zero.

Detail “amount as per receipt (accountable form) using postpayment (on credit)” (tag 1216) is included in the CRE receipt (accountable form) in printed format only if the amount paid on credit is other than zero.

Detail “amount as per receipt (accountable form) in consideration” (tag 1217) is included in the CRE receipt (accountable form) in printed format only if the amount paid in consideration is other than zero.

Total value of details “amount as per receipt (accountable form) in cash” (tag 1031), “amount as per receipt (accountable form) in non-cash” (tag 1081), “amount as per receipt (accountable form) using prepayment (offsetting advance payment)” (tag 1215), “amount as per receipt (accountable form) using postpayment (on credit)” (tag 1216) and “amount as per receipt (accountable form) in consideration” (tag 1217) shall be equal to the value of detail “settlement amount specified in the receipt (accountable form)” (tag 1020).

2) Details “agent attribute” (tag 1057), “phone number of the payment agent” (tag 1073), “phone number of the payment processor” (tag 1074) and “phone number of the provider” (tag 1171) are included in CRE receipt (accountable form) containing the information on the settlements of a user that is a payment agent or a payment subagent.

Details “transfer operator address” (tag 1005), “transfer operator INN” (tag 1016), “transfer operator name” (tag 1026), “bank payment agent operation” (tag 1044), “agent attribute” (tag 1057), “phone number of the payment agent” (tag 1073), “phone number of the transfer operator” (tag 1075) and “phone number of the provider” (tag 1171) are included in CRE receipt (accountable form) containing the information on the settlements of a user that is a bank payment agent or a bank payment subagent.

The detail “agent attribute” (tag 1057) is included in the cash register receipt (accountable form) containing information about settlement of a user who is a commission agent, appointee or other agent.

3) The detail “cashier” (tag 1021) is included in the FD in all cases, except for the use of CRE for settlements carried out using automatic settlement machines.

4) The detail “automatic machine number” (tag 1036) shall be included in CRE receipt (accountable form) when using CRE with automatic settlement machine.

5) The value of the detail “settlement amount specified in the receipt (accountable form)” (tag 1020) shall be calculated as a total of all values of the detail “cost of settlement subject including discounts and extra charges” (tag 1043). If the value of the detail “settlement amount specified in the receipt (accountable form)” (tag 1020) is calculated using the external calculating device and is used for FD generation based on the results of calculations performed by this device, the values of the detail “settlement amount specified in the receipt (accountable form)” (tag 1020) calculated by the external calculating device may not be included in FD if its value in rubles, excluding kopecks, is not equal to the total value of all details “cost of settlement subject including discounts and extra charges” (tag 1043) in rubles, excluding kopecks.

6) A CRE receipt (accountable form) shall include at least one of the following details: “VAT amount as per receipt at the rate of 20%” (tag 1102), “VAT amount as per receipt at the rate of 10%” (tag 1103), “VAT

amount as per receipt at the rate of 0%" (tag 1104), "settlement amount as per receipt without VAT" (tag 1105), "VAT amount as per receipt at the estimated rate of 20/120" (tag 1106), "VAT amount as per receipt at the estimated rate of 10/110" (tag 1107).

7) Details "buyer's phone number or e-mail" (tag 1008) and "e-mail of the receipt sender" (tag 1117) may be included in CRE receipt (accountable form) in electronic format and may be included in FD in printed format if such FD is generated in printed format in the following cases:

- CRE receipt (accountable form) is sent to the buyer (client) in electronic format;

- the buyer (client) is provided with electronic attributes, which identify such CRE receipt (accountable form), and with information on web address of the information resource where such CRE receipt (accountable form) may be obtained.

8) Detail "CRE attribute only for settlements on the Internet" (tag 1108) shall be included in FD when it is generated by CRE used only for settlements carried out using electronic payment facilities in the Internet.

9) Details "buyer's phone number or e-mail" (tag 1008) and "e-mail of the receipt sender" (tag 1117) in CRE receipt (accountable form) are specified for generating FD via CRE used in data transmission mode when sending FD to the buyer in electronic format.

10) Details "user name" (tag 1048), "user INN" (tag 1018), "FTS website" (tag 1060), "e-mail of the receipt sender" (tag 1117), "automatic machine number" (tag 1036) shall be included in CRE receipt (accountable form) when it is sent to FDO in electronic format if the specified details have not been sent previously to FDO in the registration report or report on changes in registration parameters.

Details "settlement address" (tag 1009) and "settlement place" (tag 1187) shall be included in CRE receipt (accountable form) when it is sent to FDO in electronic format if the specified details differ from the details sent previously to FDO in the registration report or report on changes in registration parameters.

11) Detail "additional receipt detail (accountable form)" (tag 1192) is determined by the FTS of Russia and may be included in CRE receipt (accountable form) considering the features of the activity area of settlements.

12) Detail "additional user detail" (tag 1084) may be included in CRE receipt (accountable form) by the user considering the features of the activity area of settlements.

13) The CRE shall exclude the possibility of generating a CRE receipt (accountable form) in electronic form and in printed form containing the information on settlements with more than one detail "settlement attribute" (tag 1054).

14) Detail "QR code" (tag 1196) shall be printed in a CRE receipt (accountable form) in a separate selected part of a CRE receipt (accountable form) as a 2D bar code.

15) A CRE receipt (accountable form) generated by CRE in autonomous mode may contain maximum 10 details "settlement subject" (tag 1059) containing the detail "goods code" (tag 1162).

16) Details "cashier" (tag 1021) and "cashier INN" (tag 1203) may be omitted in FD if CRE is used for settlements carried out using automatic settlement machines.

17) When generating FD via CRE, details "e-mail of the receipt sender" (tag 1117) and "buyer's phone number or e-mail" (tag 1008) shall have the value "none" in case of sending in electronic format, provided that:

- CRE is used on automatic settlement machines and QR code is displayed on the screen of an automatic settlement machine during settlement, according to the law of the Russian Federation on CRE use;

- settlements are carried out as an offset and return of prepayments and/or advance payments previously made by individuals for the rendered services in the area of public cultural events, services on carriage of passengers, luggage, cargo and cargo-luggage, communication services, as well as other services provided by the law of the Russian Federation on CRE use;

- settlements are carried out by a driver or a conductor inside a vehicle when selling travel documents (tickets) and passes for travel by public transport through provision of a buyer (client) with the above documents (tickets) and passes in paper form with indication of the information sufficient for identification and free of charge receipt by a buyer (client) via information resources of the fiscal data operator and/or the tax authority available in the Internet, of a CRE receipt (strict reporting form) in electronic format.

18) Details “VAT amount as per receipt at the rate of 20%” (tag 1102), “VAT amount as per receipt at the rate of 10%” (tag 1103), “VAT amount as per receipt at the rate of 0%” (tag 1104), “settlement amount as per receipt without VAT” (tag 1105), “VAT amount as per receipt at the estimated rate of 20/120” (tag 1106), “VAT amount as per receipt at the estimated rate of 10/110” (tag 1107) are included in the printed form of a CRE receipt (accountable form) for settlements between legal entities and/or individual entrepreneurs, and may be omitted in the printed form of a CRE receipt (accountable form) in other cases.

Table 9* Data structure of “settlement subject” detail

Detail name	Tag	Mandatory **	Format	Storage	Repeated	FS	Note No.
settlement method attribute	1214	2	PE	30 days	No	4	6, 10, 11
settlement item attribute	1212	3	PE	30 days	No	4	7
agent attribute to settlement item	1222	3	PE	30 days	No	4	8
agent data	1223	3	PE	30 days	No	4	8
provider data	1224	3	PE	30 days	No	4	8
provider INN	1226	P-3, E-2	PE	30 days	No	4	8, 9
settlement subject name	1030	2	PE	30 days	No	4	2, 5
settlement subject measurement unit	1197	3	PE	30 days	No	4	-
goods code	1162	2	PE	30 days	No	4	13, 14, 15, 16, 18
excise tax	1229	3	PE	30 days	No	4	-
code of the country of goods origin	1230	3	PE	30 days	No	4	-
goods declaration number	1231	3	PE	30 days	No	4	-
unit price of settlement subject including	1079	2	PE	30 days	No	4	2

Detail name	Tag	Mandatory **	Format	Storage	Repeated	FS	Note No.
discounts and extra charges							
VAT amount for settlement subject unit	1198	3	PE	30 days	No	4	-
quantity of settlement subject	1023	2	PE	30 days	No	4	2, 12
VAT rate	1199	2	PE	30 days	No	4	4, 17
VAT amount for settlement subject	1200	3	PE	30 days	No	4	-
cost of settlement subject including discounts and extra charges	1043	1	PE	30 days	No	4	1
additional detail of settlement subject	1191	3	PE	30 days	No	4	3

* - according to Table 21 of the Order of the FTS of Russia for all details “Format” = “PE”, “Repeated” = “No”

** - values of “Mandatory” column are described in Table 10

Notes:

1) The value of detail “cost of settlement subject including discounts and extra charges” (tag 1043) shall be equal to the value of detail “unit price of settlement subject including discounts and extra charges” (tag 1079) multiplied by the value of detail “quantity of settlement subject” (tag 1023). If the value of detail “cost of settlement subject including discounts and extra charges” (tag 1043) is calculated using the external calculating device and is included in a CRE receipt (accountable form) based on the results of calculations performed by this device, the value of detail “cost of settlement subject including discounts and extra charges” (tag 1043) calculated by the external calculating device shall not differ by more than 1 kopeck from the value of detail “cost of settlement subject including discounts and extra charges” (tag 1043) calculated as the value of detail “unit price of settlement subject including discounts and extra charges” (tag 1079) multiplied by the value of detail “quantity of settlement subject” (tag 1023).

2) For individual entrepreneurs who are tax payers using a patent tax system and a simplified tax system, as well as for individual entrepreneurs using a tax system for agricultural commodity producers, except for individual entrepreneurs selling excised products, the requirement for mandatory inclusion in a CRE receipt (accountable form) of details “settlement subject name” (tag 1030), “quantity of settlement subject” (tag 1023) and “unit price of settlement subject” (tag 1079) is not applicable until February 1, 2021.

For individual entrepreneurs who are tax payers using the tax system based on a unified tax on imputed income for specific activities during the performance of the types of business activities established by clause 2 of article 346.26 of the Tax Code of the Russian Federation, except for individual entrepreneurs selling excised products, the requirement for mandatory inclusion in a CRE receipt (accountable form) of details “settlement subject name” (tag 1030), “quantity of settlement subject” (tag 1023) and “unit price of settlement subject” (tag 1079) is not used until January 1, 2021.

3) Detail “additional detail of settlement subject” (tag 1191) may be included in a CRE receipt (accountable form), a CRE correction receipt (correction accountable form) considering the features of the activity area of settlements.

The value of detail “additional detail of settlement subject” (tag 1191) is determined by the FTS of Russia.

4) If detail “settlement subject” (tag 1059) of a CRE receipt (accountable form) contains the information on

settlement subject that is subject to value added tax, the detail “settlement subject” (tag 1059) of a CRE receipt (accountable form) shall include detail “VAT rate” (tag 1199).

Detail “VAT rate” (tag 1199) is included in detail “settlement subject” (tag 1059), except for the cases when settlements are carried out by users that are not value added tax payers or that are exempt from liability to pay value added tax, as well as to carry out settlements on settlement subject which are not subject to (are exempt from) value added tax.

5) Detail “settlement subject name” (tag 1030) is included in FD, except for the case when detail “settlement method attribute” (tag 1214) has a value of “3”.

6) The values of detail “settlement method attribute” (tag 1214) are specified in Table 24 of the Order of the FTS of Russia.

7) The values of detail “settlement subject attribute” (tag 1212) are specified in Table 25 of the Order of the FTS of Russia.

8) Details “agent attribute by settlement subject” (tag 1222), “provider data” (tag 1224) and detail “provider INN” (tag 1226), if it is included in FD, are included in detail “settlement subject” (tag 1059) if the specified details contain information about settlements carried out by the user acting as a payment agent (subagent), bank payment agent (subagent), commission agent, attorney or another agent.

Detail “agent data” (tag 1223), if it is included in FD, is included in detail “settlement subject” (tag 1059) if the specified detail contains information about settlements carried out by the user acting as a payment agent (subagent) or bank payment agent (subagent).

9) If detail “settlement subject” (tag 1059) or detail “agent attribute” (tag 1057) contain information about settlements carried out by the user acting as a payment agent (subagent), bank payment agent (subagent), commission agent, attorney or another agent, the FD shall contain detail “provider INN” (tag 1226).

10) Detail “settlement method attribute” (tag 1214) is included in detail “settlement subject” (tag 1059) if the settlement method attribute has a value other than “full payment, including advance payment (prepayment) on the date of transmission of settlement subject”.

11) Detail “settlement method attribute” (tag 1214) is included in the printed form of a CRE receipt (accountable form) if the settlement method attribute has a value other than “full payment, including advance payment (prepayment) on the date of transmission of settlement subject” (detail “settlement method attribute” (tag 1214) has a value of 4).

12) If detail “goods code” (tag 1162) contains a code allowing to identify a goods item for which the information is included in detail “settlement subject” (tag 1059), the value of detail “quantity of settlement subject” (tag 1023) shall have a value of one.

13) Detail “goods code” (tag 1162) is included in a CRE receipt (accountable form) for return or sale of goods marked with identification means, and may be omitted in a CRE receipt (accountable form) in other cases.

14) When performing operations with goods marked with identification means, detail “goods code” (tag 1162) included in a CRE receipt (accountable form) in electronic format is generated according to Table 26 of the Order of the FTS of Russia.

When performing other operations, the value of detail “goods code” (tag 1162), if it is included in a CRE receipt (accountable form), is generated according to Table 26 of the Order of the FTS of Russia.

15) In printed format detail “goods code” (tag 1162) shall have a value of “[M]” only if the goods are marked with identification means, and its marking code contains an identification code that is identified according to

Table 26 of the Order of the FTS of Russia.

In other cases, detail “goods code” (tag 1162) is not included in FD in printed format.

16) If 2 initial bytes of the value of detail “goods code” (tag 1162) assume the value “00h 00h”, the specified detail may be omitted in the fiscal document on the CRE used in autonomous mode, and if it is included in the FD, it shall be stored for 30 days.

17) Detail “VAT rate” (tag 1199) is included in printed form of a CRE receipt (accountable form) for settlements between legal entities and/or individual entrepreneurs, and may be included in printed form of a CRE receipt (accountable form) in other cases.

18) If detail “goods code” (tag 1162) is included in the FD in electronic form to be sent to tax authorities, it shall also be included in the FD to be sent to a buyer in electronic form.

Table 10

Values of “Mandatory” attribute	**Conditions of detail use in FD**
1	a detail shall be included in the FD in the format required by these FDF
2	a detail shall be included in the FD in the format required by these FDF in the cases specified in the note to such detail, and may be omitted in the FD in other cases. If a detail is included in the FD in cases which are not specified in the notes, its format shall correspond to the format required by the FDF
3	a detail may be omitted in the FD. If a detail is included in the FD, its format shall correspond to the format required by these FDF

Notes:

If CRE provides for the FD generation according to the FDF with the FDF version number “1.05”, the values of details “CRE FDF version” (tag 1189) and “FDF version number” (tag 1209) shall assume a value of “2”.

If CRE provides for the FD generation according to the FDF with FDF version number “1.1”, and FMD provides for the FDF generation according to the FDF with FDF version number “1.1”, the detail “FDF version number” (tag 1209) shall assume a value of “3”.

The value of detail “FDF version number” (tag 1209) is determined when generating a registration report or a report on re-registration due to fiscal memory device replacement, and may not be redetermined until a new report on re-registration due to fiscal memory device replacement is generated.

Information for determination of the value of detail “CRE FDF version” (tag 1189) is specified by the CRE manufacturer in software tools of the CRE model version which shall be included in the CRE package.

Information for determination of the value of detail “CRE version” (tag 1188) is specified by the CRE manufacturer in software tools of the CRE model version which shall be included in the CRE package.

Information for determination of the value of detail “FMD FDF version” (tag 1190) is specified by the fiscal memory device manufacturer in software tools of the fiscal memory device which shall be included in the fiscal memory device.

The FDF shall correspond to the format with the version number indicated in the detail “FDF version number” (tag 1209).

Operator confirmation shall have the FDF with the same FDF version as the received FD.

The list of FD details is given in Table 4 of the Order of the FTS of Russia.

5. Algorithm of Tag 1162 (Goods Nomenclature Code) Recording When Coding Data on Medicine Marking

1. Type of goods identifier

Bytes [1:2] (2 bytes) – Marking code type

Constant value: 44h 4Dh.

2. Goods code identifier

Bytes [3:8] (6 bytes) – goods code (GTIN)

A 14-digit goods code is used. When recording in CRE, the goods code (GTIN) is generated according to the rules of a number conversion from the decimal numeration system into the sexadecimal numeration system, with filling of leading zeros (left zeros) to 6 bytes.

3. Serial number, identification code of product packing

Bytes [9:21] (13 bytes) – Serial number (Serial)

Serial number includes figures, capital and lower-case Latin letters, delimiting characters:!”%&’()*+-.,_/:;=<>?. It is generated according to the rules of ASCII interpretation in hex.

Example of tag 1162 generation

The following data on the marking code are obtained:

GTIN: (dec) 98765432101234

GTIN is converted into binary format: (hex) 59 D3 9E 7F 19 72

Serial: (chr) ABC1234567890, (hex) 41 42 43 31 32 33 34 35 36 37 38 39 30

Tag 1162 is generated:

The value of marking type code is added: 44h 4Dh

TLV is generated for sending to CRE. As tag 1162 does not have a fixed value, the reserve bytes in CRE are not sent:

(HEX) 8A 04 15 00 44 4D 59 D3 9E 7F 19 72 41 42 43 31 32 33 34 35 36 37 38 39 30,

where:

- 8Ah 04h is a tag number (1162) in HEX, where the least significant byte is the first one, LE format (to convert into DEC, it shall be read as 04 8A);

- 15h 00h is the value length of tag 1162 in HEX, where the least significant byte if the first one, LE format (2+6+13 = 21 bytes).

6. Algorithm of Tag 1084 (Additional User Detail) Recording When Coding Data on a Subsidized Prescription

Tag 1084 is a structure and consists of tag 1085 (name of additional user details) and tag 1086 (value of

additional user details)

1. Name of additional user detail (tag 1085) when selling on a prescription with 50% subsidy: mdlp3108805

It contains a text string in CPP 866 coding.

Bytes [1:11] (11 bytes) – (hex) 6D 64 6C 70 33 31 30 38 38 30 35.

Tag 1085 is generated as TLV for sending to CRE (reserve bytes are not transmitted):

(hex) 3D 04 0A 00 6D 64 6C 70 33 31 30 38 38 30 35

3Dh 04h is the number of tag 1085

0Bh 00h is the value length of tag 1085 (11 bytes)

2. Value of additional detail (tag 1086) when selling on a prescription with 50% subsidy: ps45102&dnAБV492&&781&dd181110&sid71752852194630&

It contains a text string in CPP 866 coding.

Bytes [1:49] (49 bytes) –

(hex) 70 73 34 35 31 30 32 26 64 6E C0 C1 56 34 39 32 26 26 37 38 31 26 64 64 31 38 31 31 31 30 26 73 69 64 37 31 37 35 32 38 35 32 31 39 34 36 33 30 26

Tag 1086 is generated as TLV for sending to CRE (reserve bytes are not transmitted)**:**

(hex) 3E 04 31 00 70 73 34 35 31 30 32 26 64 6E C0 C1 56 34 39 32 26 26 37 38 31 26 64 64 31 38 31 31 31 30 26 73 69 64 37 31 37 35 32 38 35 32 31 39 34 36 33 30 26

3Eh 04h is the number of tag 1086

31h 00h is the value length of tag 1086 (49 bytes)

3. An integrated detail “additional user detail” (tag 1084) is generated as STLV for sending to CRE (reserve bytes are not transmitted)

It consists of tags 1085 and 1086 with a total length.

(hex) 3C 04 44 00 3D 04 0B 00 6D 64 6C 70 33 31 30 38 38 30 35 3E 04 31 00 70 73 34 35 31 30 32 26 64 6E C0 C1 56 34 39 32 26 26 37 38 31 26 64 64 31 38 31 31 31 30 26 73 69 64 37 31 37 35 32 38 35 32 31 39 34 36 33 30 26

3Ch 04h is the number of tag 1084

44h 00h is the length of tag 1084 (TLV length of tag 1085 + TLV length of tag 1086: 4 + 11 + 4 + 49 = 68 bytes)

3Dh 04h is the number of tag 1085

0Bh 00h is the value length of tag 1085 (11 bytes)

3Eh 04h is the number of tag 1086

31h 00h is the value length of tag 1086 (49 bytes)

6. Algorithm of Tag 1084 (Additional User Detail) Recording When Coding Data on a Subsidized Prescription

Receipt for prescription with 100% subsidy:

online cash register
CASH REGISTER RECEIPT
Aspirin
01 0.00 X 1.000 =0.00
VAT 0%=0.00
Good item FULL SETTLEMENT
GC 98765432101234 ABC1234567890
Ibuprofen
02 0.00 X 1.000 =0.00
VAT 0%=0.00
Good item FULL SETTLEMENT
GC 08667432171234 BFA1234567890
TOTAL AMOUNT =0.00

VAT amount 0%
=0.00

ANOTHER PAYMENT FORM
=0.00

User: LLC ABC
Address: Novaya st.1, Moscow
Sender email address: shop@crpt.ru
Settlement place: Yuzhnaya st. 32, Moscow
Cashier: V. A. Sidorov
FDO: FDO No.1
FTS site: www.nalog.ru

CRE factory number: 00106200000010
INN:123456789012
CRE registration number:1234567890123456
Fiscal memory device No.1234567890123456
Fiscal document No. 0000000118
Fiscal attribute: 9876543210
Shift No. 00006
Receipt No. 00003
1/5/2019 2:35 PM
INCOME
Taxation system: GTS
COME AGAIN!

Receipt when the buyer pays 50%:

online cash register
CASH REGISTER RECEIPT
Aspirin
03 100.00 X 1.000 =100.00
VAT 20%=16.67
Good item FULL SETTLEMENT
GC 98765432101234 ABC1234567890
Ibuprofen
04 130.00 X 1.000 =130.00
VAT 10%=11.82
Good item FULL SETTLEMENT
GC 8667432171234 BFA1234567890
TOTAL AMOUNT =230.0

VAT amount 20%
=16.67
VAT amount 10%
=11.82

```
---------------------------------------
IN CASH                        =115.00
ANOTHER PAYMENT FORM
=115.00
---------------------------------------
User:                  LLC ABC
Address:            Novaya st.1, Moscow
Sender email address:      shop@crpt.ru
Settlement place:     Yuzhnaya st. 32,
Moscow
Cashier:                     V. A.
Sidorov
FDO:                               FDO
No.1
FTS site:                   www.nalog.ru
---------------------------------------
CRE factory number:      INN:12345678901
00106200000010           2
CRE registration
number:1234567890123456
Fiscal memory device
No.1234567890123456
Fiscal document No.
0000000118
Fiscal attribute:
9876543210
Shift No.
00006
Receipt No.
00003
1/5/2019 2:35 PM
INCOME
Taxation system: GTS
              COME AGAIN!
---------------------------------------
```

Section II. Changes in the procedure for transmitting the information in the CRE exchange formats for registering the medicine disposal in MDLP System (FDF 1.2)

1. Changes application

The procedure for transmitting information to form json receipts based on the received incoming notification from FDO for FDF 1.2.

2. Value of detail “industrial detail of settlement item” tag 1260

Register receipts are aligned with the MDLP System goods group on the basis of the value in tag 1262. Register receipts are aligned with MDLP System if FEA identifier in tag 1262 equals to “020”.

The details of the “Date of Supporting Document” (tag 1263) and the “Number of Supporting Document” (tag 1264) must contain information about the sectoral regulatory and legislative acts on the basis of which the compound detail “industrial detail of settlement item” was formed (tag 1260).

Date of Supporting Document (tag 1263): 14.12.2018

Number of Supporting Document (tag 1264): 1556

All transferred values in the part of the detail “industrial detail of settlement item” (tag 1260) must be separated by delimiter characters “&”.

The detail "value of industrial detail" (tag 1265) should consist of data elements and be provided with unique prefixes-identifiers, for example:

Id1 = <Value 1>;

Id2 = <Value 2>;

An example of a line of a record of the "value of industrial detail" (tag 1265):

Id1=Value1&Id2=Value2&Id3=Value3

In cases of partial subsidy from the Federal or Regional Budget, the receipt details must state these sums for each receipt item. This only applies to preferential partial subsidy prescriptions, for prescriptions with 100% subsidy, this detail does not need to be transferred in FD.

The value is transferred in tag 1265 as part of tag 1260, which refers to tag 2007 in "**ss**" detail. The detail "**ss**" always ends with the symbol "&". The value of detail **ss** is a string in which only characters [0..9] are valid, which is interpreted as a decimal number with a fixed precision of 2 digits after the decimal separator of the whole and fraction part.

Example of filling in tag 1265 as part of tag 1260:ss=12300&

In case of the medicine disposal registration for the sale without subsidy:

Table 11

Tag	Detail name	Value	Record of json value
1265	value of industrial detail	tm=mdlp&sid=00752852194630&	"properties": { "propertyName": "mdlp", "propertyValue": "sid00752852194630&" },

In case of the medicine disposal registration for the sale on prescription without subsidy:

Table 12

Tag	Detail name	Value	Record of json value
1265	value of industrial detail	tm=mdlp&ps=45102&dn=АБV492&&781&dd=181110&sid=00752852194630&	"properties": { "propertyName": "mdlp", "propertyValue": "ps=45102&dn=АБV492&&781&dd=181110&sid=00752852194630&" },

In case of the medicine disposal registration for the sale with preferential prescription with partial payment:

Table 13

Tag	Detail name	Value	Record of json value
1265	value of industrial detail	tm=mdlp&ps=45102&dn=АБV492&&781&dd=181110&sid=00752852194630&ss=12300&	"properties": { "propertyName": "mdlp", "propertyValue": "ps=45102&dn=АБV492&&781&dd=181110&sid=00752852194630&" },

In case of the medicine disposal registration for the sale with 100% subsidy:

Table 14

Tag	Detail name	Value	Record of json value
1265	value of industrial detail	tm=mdlp&tr=3108805&ps=45102&dn=АБV492&&781&dd=181110&sid=00752852194630&	"properties": { "propertyName": "mdlp3108805", "propertyValue": "ps=45102&dn=АБV492&&781&dd=181110&sid=00752852194630&" },

In case of distance retail sale of the medicine, “ds=1” value is indicated in the “distance trade” attribute in a value of the “value of industrial detail” detail (tag 1265). An example of filling a detail “value of industrial detail” (tag 1265) with the “distance trade” attribute.

Table 15

Tag	Detail name	Value
1265	value of industrial detail	tm=mdlp&sid=00752852194630&ds=1&

3. Value of detail “fractional quantity of marked goods” tag 1291

The detail “fractional part” (tag 1292) is filled automatically on the basis of the values of the details “numerator” (tag 1293), “denominator” (tag 1294).

The value of the detail “numerator” (tag 1293) should be strictly less than the value of the detail “denominator” (tag 1294).

The value of details “numerator” (tag 1293) and “denominator” (tag 1294) cannot be equal to “0”.

The value of the detail “denominator” (tag 1294) is filled in with a value equal to the quantity of goods in the consignment (packaging) having a common marking code for the goods.

When detail “fractional quantity of marked goods” (tag 1291) is included into a part of detail “settlement item” (tag 1059), the detail “quantity of the settlement item” (tag 1023) must take a value equal to “1”.

The detail “fractional quantity of marked goods” (tag 1291) is included into the part of the detail “data on the marked goods” (tag 2007) only if the value of the detail “measure of the quantity of the settlement item” (tag 2108) takes the value equal to “0”.

Record of value 1292 in json is formed with mdlp prefix from tag 1265.

Example: “mdlp2/12&”

Table 16

Tag	**Detail name**	**Value from tag 1292**	**Value from tag 1265**	**Record of json value of the detail “settlement item” 1059**

1292	fractional quantity of marked goods	2/12	tm=mdlp	"items": [
				{
				"productCode": "RE0EMKhAzDYwMDAwMFk0TUNCRUU5",
				"name": "омепразол капс киш/р",
				"price": 5600,
				"quantity": 1,
				"sum": 5600,
				"nds": 2,
				"ndsSum": 509,
				"productType": 1,
				"paymentType": 4,
				"propertiesItem": "mdlp2/12&"
				}

If the detail “fractional part” is missing, formation of "propertiesItem" value of the detail “settlement item” 1059 in json shall be taken equal to “mdlp” from tag 1265 “tm=mdlp”.

Example: "propertiesItem": "mdlp"