Dear participants,

After installing an IS MDLP update, it will not support loading older versions of the schemes!

We recommend you to review these changes and prepare your accounting systems in advance for a planned migration to the new schemes.

The following changes will be made available as part of the update:

In order to develop the IS MDLP, the current business processes (hereinafter - BP) were optimized, as well as the new ones were finalized which were implemented in the IS MDLP (including taking into account the proposals of subjects of medicines circulation).

MDLP IS does not support loading older schemes versions.

The following changes were made in Release 1.34:

1. For marketing authorisation holders/manufacturers of the Russian Federation, the rules of introduction into circulation were changed, in accordance with the entry into force of 449 FL. In accordance with 449 FL, BP of introduction into circulation was improved in the MDLP IS (section 3).

Changes were made to the BP for the introduction of drugs produced outside the Russian Federation (BP Section 3.4)

1.1 MD importation into the Russian Federation from the countries, EEU non-members

1.1.1 Customs authorities have provided the possibility of issuing MD for internal consumption until the subject of the application to AIS Roszdravnadzor or obtaining permission to put into circulation immunobiological MD.

Changes were made to the BP for acceptance of MD to the warehouse by the importer after the release from the customs zone when imported into the territory of the Russian Federation (section 3.4):

- The sequence of reporting the input of MD in circulation was changed.
    - A new scheme **342-release_in_circulation** "Registration of information about the introduction of MD into the circulation in the territory of the Russian Federation in IS MDLP" was developed
    - Scheme **312-register_control_samples.xsd** "Registration in MDLP System of information about medicinal drugs sample selection" was excluded

1.1.2 Changes were made to the BP for MD importation into the Russian Federation from the countries, EEU non-members (section 3.3.1/3.3.2)

Changes to scheme **335-fts_data.xsd** were made (Registration in MDLP System of information about results of medicinal drugs customs clearance). There is no need to transfer the details of the compliance confirmation document (the element **confnum_info** was changed to optional).

1.1.3 Changes were made to the BP for special features of MD importation without acceptance (without importer) by the MD owner (section 3.3.3)

Changes to scheme **333-foreign_import_consignment.xsd** were made (Registration in MDLP System of information about medicinal drugs importation into the Russian Federation without acceptance):

- optional **contract_type** element changed to mandatory.

1.2 Changes were made to the BP for the introduction of MD into the circulation produced in the territory of the countries, member states of the EEU

1.2.1 Changes were made to the BP for MD importation into the Russian Federation from the countries, EEU non-members, without acceptance (BP section 3.6.1/3.6.2)

There is no more need to transfer the details of the compliance confirmation document from the information.
Changes to scheme **363-eeu_release.xsd** were made (Registration in MDLP System of information about medicinal drugs introduction into circulation in the territory of the Russian Federation):

- the element **confnum_info** was replaced with a simple element **release_info** with the format of the reference release_info_type

1.2.2 A new BP was developed for the importation of MD into the Russian Federation from the member states of the EEU and the MD introduction into circulation by the MAH - a resident of the Russian Federation (section 3.6.3)
It is possible to register the information on the import of medicines without acceptance by one owner. New schema was created:

- **360-eeu_owner.xsd** (Registration of information on import of own medicines into the Russian Federation from the countries of EEU);

1.3 Changes were made to the BP for the MD introduction into circulation in the territory of the Russian Federation (section 3.1)
Changes to scheme **313-register_product_emission.xsd** were made (Registration in MDLP System of information about medicinal drugs release):

- deleted elements **confirm_doc** (type of document confirming compliance), **doc_num** (Registration number of document confirming compliance), **doc_date** (Registration date of document confirming compliance);
- added a simple element **release_info** (details of the introduction into the circulation) with the format of the reference release_info_type.

1.4 Changes were made to the BP for the MD withdrawal from circulation (section 5.5)

- Additional sample types were included in a scheme **552-withdrawal.xsd** (Registration in MDLP System of information about medicinal drugs withdrawal from circulation for a variety of reasons).

1.5. Changes were made to the scheme **base_types.xsd:**

- For type **withdrawal_type_enum** new values were added (19-control samples within the quality control process and 20-archival samples);
- deleted type **control_samples_type_enum** - Types of sample selection of medicinal drugs;

1.6 Changes were made to the scheme **base_ref.xsd**:

- New reference was added **realease_info_type** - details of the introduction into the circulation

2. Changes were made to the BP «MD circulation» (section 4)
2.1 A new BP was developed «transfer of MD between its own activity locations within the framework of the state drug supply» (section 4.7.3). New schema was created:

- **470-move_state_dispatch.xsd** (Registration in MDLP System of information about transfering of medicinal drugs between different activity locations within the framework of the state drug supply).

3. Changes were made to the BP «MD withdrawal from circulation» (section 5)
3.1 Changes were made to the details in operation **541-move_destruction.xsd** (Registration in MDLP System of information about medicinal drugs transfer for destruction)
3.4. The structure of the scheme **511-retail_sale.xsd** (Registration in MDLP System of information about retail sale of medicinal drugs) was finalized
3.5. The ability to fix operation **531-health_care.xsd/10531-skzkm_health_care.xsd** (Registration in MDLP System of information about medicinal drugs dispenning for medical use) for any type of financing, under the state contract, was added.
3.6. Changes were made to the scheme limits **552- withdrawal.xsd** (Registration in MDLP System of information about medicinal drugs withdrawal from circulation for a variety of reasons). Details of

documents (**doc_num** and **doc_date**) are optional if you specify the type of withdrawal from circulation (**withrawal_type**) 6 is withdrawn from circulation as a result of shipment to an unregistered participant.

4. Common changes

4.1. Changes were made to **vat_value**. In case the transaction is not subject to VAT it is necessary to transfer 0. The **vat_value** (VAT sum) optional element was changed to mandatory in the following diagrams:

- 341-receive_importer.xsd
- 361-eeu_shipment.xsd;
- 362-eeu_import.xsd;
- 415-move_order.xsd;
- 416-receive_order.xsd;
- 441-move_unregistered_order.xsd;
- 461-move_eeu.xsd;
- 511-retail_sale.xsd;
- 601-move_order_notification.xsd;
- 602-receive_order_notification.xsd;
- 615-eeu_shipment_notification.xsd;
- 10511-retail_sell_kkt.xsd.

4.2. The ability to transfer information about the details of the base document in the scheme **417-move_return.xsd** (Registration in MDLP System of information about return of suspended medicinal drugs) was added. **Doc_num** (base document details: document number) and **doc_date** (base document details: document Date) were added to details.

4.3. Changes were made to the scheme limits **915- multi_pack.xsd** (Registration in MDLP System of information about medicinal drugs packing in set of tertiary (shipping) packages). At the scheme level **915-multi_pack.xsd**, the limitations on the number of SGTIN are excluded and changes are made to the established system restrictions, in the MDLP IS. The limit for the number of simultaneous SSCC bulk packs has been increased to 20,000 and the number of SGTIN within a single pack has been reduced to 350.

4.4. Changes were made to the reference **base_ref.xsd**:

- reference **fias_addr_type** was deleted;
- changes were made to the reference **org_address_type**. Element "**address**" was deleted.