## Putting MPs manufactured in the Russian Federation into circulation

Members of the chain: Manufacturer.

Preconditions:

- MPs are produced and marked on the side of the manufacturer.

Operations should be executed in sequence to complete the chain. The date/time in each loaded xml should exceed those of the previous one.

- 1. MP packaging (311).
- 2. Sampling (312).
- 3. Manufacturing of finished products (313).

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### 1. Operation: MP packaging (311)

Scheme: 311. Contains a list of SGTINs of packed MPs.

Steps	Expected reaction of PA	Expected reaction of USO
Manufacturer: upload and send xml 311 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 311 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Accepted</operation_result> .
Manufacturer: check the CIL (control identification label) status in the Participant's PA (Personal Account).	CIL with a "Labelled" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

### 2. Operation: Sampling (312)

Steps	Expected reaction of PA	Expected reaction of USO
Manufacturer: upload and send xml 312 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 312 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Manufacturer: check the CIL status in the Participant's PA (Sampling)	CIL with a "Sample taken" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation). CIL uploaded in xml 312 should be used in the filter.	Check of CIL status in the Participant's PA
<u>Manufacturer</u> : check that other CIL have not changed their status	CIL from Step 1 should be used in the filter, except for the CIL withdrawn from circulation in Step 2. The CIL have a "Labelled" status.	Check of CIL status in the Participant's PA

Scheme: 312. Contains a part of CIL from Step1 (MP packaging).

### 3. Operation: Manufacturing of finished products (313)

Scheme: 313. Contains SGTINs from step 1, except for the ones selected as samples in Step 2.

Steps	Expected reaction of PA	Expected reaction of USO
Manufacturer: upload and send xml 313 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully".	A message generated according to scheme 313 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message.
	The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a

		reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Manufacturer: check the CIL status in the Participant's PA (putting into circulation)	CIL with an "In circulation" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

## Putting MPs into circulation by a representative office of a foreign marketing authorization holder

Members of the chain: representative office of a foreign MA holder. Preconditions: - MPs are produced and marked on the side of the manufacturer.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### 1. Operation: Transfer of information on the issuing of MPs by a representative office of a foreign MA holder (321)

Scheme: 321. Contains a list of SGTINs of produced MPs.

Steps	Expected reaction of PA	Expected reaction of USO
Representative office of a foreign <u>MA holder</u> : upload and send xml 321 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 321 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
<u>Representative</u> office of a foreign <u>MA holder</u> : check the CIL status in the Participant's PA	CIL with a "Labelled" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

## Importation of a marketing authorization to the Russian Federation by a foreign holder

Members of the chain: Foreign MA holder, Importer. Preconditions:

- MPs are produced and marked on the side of the manufacturer.

The following operations should be executed in sequence to complete the chain:

1. Transfer of information on the shipment of MPs to the Russian Federation (331) – Foreign MA holder.

2. Transfer of information on the importation of MPs to the Russian Federation (332) – Importer.

- 3. Sampling (312) Importer.
- 4. Transfer of information on the results of customs clearance (335) Importer.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### 1. Operation: Transfer of information on the shipment of MPs to the Russian Federation (331)

Scheme: 331. Contains a list of SGTINs of MPs shipped to the Russian Federation.

Steps	Expected reaction of PA	Expected reaction of USO
Foreign MA holder: upload and send xml 331 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 331 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Accepted</operation_result> .
Foreign MA holder: check the CIL status in the Participant's PA	CIL with a "Shipped to RF" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

### 2. Operation: Transfer of information on the importation of MPs into the RF (332)

Scheme: 332. Contains a list of SGTINs imported into the Russian Federation.

Steps	Expected reaction of PA	Expected reaction of USO
Importer: upload and send xml 332 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 332 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Importer: verify the CIL status in the Participant's PA	CIL with an "Import to the RF" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

### 3. Operation: Sampling (312)

Scheme: 312. Contains a portion of SGTINs from Step 2.

Steps	Expected reaction of PA	Expected reaction of USO
Importer: upload and send xml 312 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document	A message generated according to scheme 312 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message.
	contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>

Importer: check the CIL status in the Participant's PA (Sampling)	CIL with a "Sample taken" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation). CIL uploaded in xml 312 should be used in the filter.	Check of CIL status in the Participant's PA
Importer: check that other CIL have not changed their status	CIL from Step 2 should be used in the filter, except for the CIL withdrawn from circulation in Step 3.	Check of CIL status in the Participant's PA

### 4. Operation: Submission of information on customs clearance results (335)

Scheme: 335. Contains SGTINs subject to customs clearance

Steps	Expected reaction of PA	Expected reaction of USO
Importer: upload and send xml 335 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 335 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Importer: check the CIL status in the Participant's PA	CIL with an "In circulation" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation). CIL uploaded in xml 335 should be used in the filter.	Check of CIL status in the Participant's PA

Acceptance of the MPs at the warehouse by the

### Importer after release from the customs area

Members of the chain: Importer. Preconditions:

- MPs have been produced and labelled by the Manufacturer.
- MPs have passed customs control.
- Information on MPs is identical to information in the customs declaration.
- 1. MPs accepted at the Importer's warehouse (341).

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### 1. Operation: Acceptance of MPs at the Importer's warehouse (341)

Scheme: 341. Contains a list of SGTINs received from the custom control area.

Steps	Expected reaction of PA	Expected reaction of USO
Importer: upload and send xml 341 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 341 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Importer: verify the CIL status in the Participant's PA	CIL with an "In circulation" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

## Transfer of MPs to the Owner (production of MPs under a contract)

Members of the chain: Manufacturer, Owner.

Preconditions:

- The Manufacturer should have CIL produced under a contract
- The owner of CIL should be Manufacturer.

Operations should be executed in sequence to complete the chain. The date/time in each loaded xml should exceed those of the previous one.

- 1. Manufacturer: Transfer of MPs to the Owner (381).
- 2. Owner: Acceptance of MPs by the owner (701).

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

#### 1. Operation: Transfer of MPs to the owner (381)

Scheme: 381. Contains SSCC and/or SGTIN of MPs to be transferred to the Owner.

Steps	Expected reaction of PA	Expected reaction of USO
Manufacturer: upload and send xml 381 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 381 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Accepted</operation_result> .
Manufacturer: check the CIL status in the Participant's PA (transfer to the owner)	CIL with a "Transferred to the Owner" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation). Check the "CIL owner" column - Manufacturer should be specified.	Check of CIL status in the Participant's PA
Owner: check for notification in incoming documents	A document is displayed in the "Document register" - "Incoming" section of the Participant's PA according to notification scheme 603. Sender - Manufacturer. Document contents feature SSCC/SGTIN from 381.	A document is displayed in the incoming documents in the USO according to notification scheme 603. Document contents feature SSCC/SGTIN from 381.

### 2. Operation: Acceptance of MPs by the Owner (701)

Scheme: 701. Contains SSCC/SGTIN of accepted MPs from Step 1.

Steps	Expected reaction of PA	Expected reaction of USO
<u>Owner</u> : upload and send xml 701 by manual operations in the Participant's PA	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 701 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
<u>Owner:</u> check the CIL status in the Participant's PA. (Acceptance by the Owner)	CIL with an "In circulation" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation). The owner of CIL has changed.	Check of CIL status in the Participant's PA
Manufacturer: check notification in incoming documents	A document is displayed in the "Document register" - "Incoming" section of the Participant's PA according to notification scheme 607. Manufacturer - Owner. Document contents feature SSCC/SGTIN from 701.	A document is displayed in the incoming documents in the USO according to notification scheme 607. Document contents feature SSCC/SGTIN from 701.

# Shipment/acceptance of MPs with a direct acceptance procedure (accounting as per SSCC/SGTIN)

Members of the chain: Seller, Buyer. Preconditions:

- The Seller should have CIL.
- The Seller should be Seller.

The following operations should be executed in sequence to complete the chain:

- 1. Seller: uploading of shipment information (415 xml)
- 2. Buyer: acceptance (701 xml)

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### 1. Operation: Uploading of shipment information

Scheme: 411. Contains information on SSCC and/or SGTIN of shipped MPs. Type of acceptance: regular order

Steps	Expected reaction of PA	Expected reaction of USO
Seller: upload and send xml 415 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The Participant has generated a message in the XML format in his information system according to scheme 415. A generated message was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
<u>Seller</u> : check the CIL status in the Participant's PA	CIL with "In circulation" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation). The owner of CIL has not changed, "Seller" is specified.	Check of CIL status in the Participant's PA
Buyer: check notification in incoming documents	A document is displayed in the "Document register" - "Incoming" section of the Participant's PA according to notification scheme 602. Sender – "Seller". Document contents feature a list of SSCC/SGTIN shipped from 415.	A document is displayed in the incoming documents in the USO according to notification scheme 602. Document contents feature SSCC/SGTIN from 415.

### 2. Operation: Acceptance

Scheme: 701. Contains information on SSCC and/or SGTIN from scheme 415 (Step 1). Type of acceptance: regular order

Steps	Expected reaction of PA	Expected reaction of USO
Buyer: upload and send xml 701 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The Participant has generated a message in the XML format in his information system according to scheme 701. A generated message was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Buyer: check the CIL status in the Participant's PA	CIL with an "In distribution" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation). The CIL owner has changed, "Buyer" is specified.	Check of CIL status in the Participant's PA.
Seller: check notification in incoming documents	Document 607 is displayed in the "Document register" – "Incoming" section of the Participant's PA. Document contents feature a list of SSCC/SGTIN shipped from 701.	A document is displayed in the incoming documents in the USO according to notification scheme 607. Document contents feature SSCC/SGTIN from 701.

## Shipment/acceptance of MPs with a reverse acceptance order (accounting by SSCC/SGTIN)

Members of the chain: Seller, Buyer. Preconditions:

- The Seller should have CIL.
- The Seller should be Seller.

The following operations should be executed in sequence to complete the chain:

- 1. Buyer: acceptance (416 xml).
- 2. Seller: confirmation of shipment information (701 xml).

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### 1. Operation: Acceptance

Scheme: 416. Contains SSCC/SGTIN information. Type of acceptance: reverse order.

Steps	Expected reaction of PA	Expected reaction of USO
Buver: upload and send xml 416 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The Participant has generated a message in the XML format in his information system according to scheme 416. A generated message was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Seller: check the CIL status in the Participant's PA	CIL with "In circulation" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation). The owner of CIL has not changed, "Seller" is specified.	Check of CIL status in the Participant's PA
Seller: check notification in incoming documents	Document 602 is displayed in the "Document register" – "Incoming" section of the Participant's PA. Sender – "Seller". Document contents feature a list of SSCC/SGTIN received from 416.	A document is displayed in the incoming documents in the USO according to notification scheme 602. Document contents feature SSCC/SGTIN from 416.

### 3. Operation: Confirmation of shipment information

Scheme: 411. Contains information on SSCC/SGTIN of shipped MPs from scheme 416 (Step 1).

Type of acceptance: regular order

Steps	Expected reaction of PA	Expected reaction of USO
<u>Seller</u> : upload and send xml 701 using a	The document is successfully signed and sent.	The Participant has generated a message in the XML format in his information system according to

selected method (USO/PA)	The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	scheme 701. A generated message was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Accepted</operation_result> .
Seller: check the CIL status in the Participant's PA	CIL with "In circulation" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation). The owner of CIL has not changed, "Seller" is specified.	Check of CIL status in the Participant's PA
Buyer: check notification in incoming documents	Document 607 is displayed in the "Document register" – "Incoming" section of the Participant's PA. Sender – "Seller". Document contents feature a list of SSCC/SGTIN shipped from 701.	A document is displayed in the incoming documents in the USO according to notification scheme 607. Document contents feature SSCC/SGTIN from 701.

### Internal displacement of MPs

Chain members: any Participant.

Preconditions:

- The owner of CIL should be Participant.
- The Participant has 2 or more registered places of business and/or consignment warehouses.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### 1. Operation: Internal displacement (431)

Scheme: 431. SSCC/SGTIN to be displaced are specified. receiver\_id attribute = receiver id.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 431 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 431 was sent using the USO web service (POST /farm/in/), and a reply message has been received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Participant: check the location of CIL	Select the filter by "place of business" in the "CIL register" section. Specify a place of business from scheme 431. A list of SSCC/SGTIN specified in scheme 431 is displayed in the results.	Check of the location of CIL in the Participant's PA

## Shipment of MPs to a Participant not registered in the IS

Chain members: any Participant. Preconditions:

- The Participant has CIL with an "In circulation" status.
- The registered Participant is the owner of CIL.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### Operation: Shipment of MPs to a Circulation Participant not registered in Labelling IS

Scheme: 441. Contains a list of SGTIN and/or SSCC of MPs to be shipped to an unregistered Participant.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 441 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully".	A message generated according to scheme 441 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique

	The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Participant: verify the CIL status in the Participant's PA.	CIL with a "Shipped to an nonregistered Participant" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

### Repackaging/relabelling of MPa

Chain members: any Participant.

Preconditions:

- The Participant should have CIL.
- The owner of CIL should be Participant.

The following operations should be executed in sequence to complete the chain: Transfer of information on repackaging and re-labelling of medicinal products (811).

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

#### Operation: repackaging/relabelling of MPs (811)

Scheme: 811. Contains data on the SGTIN of new consumer packaging and the SGTIN of old consumer packaging.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 811 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully".	A message generated according to scheme 811 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message.
	The reply receipt for the document contains a processing result: <operation_result>Accepted<td>The participant addressed the USO web service (GET /farm/out/) using</td></operation_result>	The participant addressed the USO web service (GET /farm/out/) using

	on_result>.	the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Participant: check the composition of consumer packaging. Complete filtering by using a new SGTIN from 811 in the "CIL register" section of the Participant's PA	Displays a list of CIL. The old SGTIN should be used when applying a filter in the "CIL register" section – the CIL list should be left blank.	Check of the packaging composition in the Participant's PA

### Aggregation up to transport packaging

Members of the chain: any Participant

Preconditions:

- The Participant should have CIL.
- The owner of CIL should be Participant.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

Aggregation up to transport packaging can be achieved by the following operations:

- Creation and packaging for a single transport container scheme 911
- Creation and packaging in multiple transport containers scheme 915

### Operation: Aggregation up to transport packaging (911)

Scheme: 911. The number of transport packaging is indicated in the SSCC attribute. Indicate all CIL to be included in transport packaging in the SGTIN list.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 911 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully".	A message generated according to scheme 911 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message.
	The reply receipt for the document	

	contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Participant: check the composition of transport packaging. Complete filtering by "Identification code of tertiary packaging" (SSCC) in the "CIL register" section of the Participant's PA. Use SSCC from 911.	Displays a list of CIL. The list matches the one specified in the uploaded scheme 911, and the "Identification code of tertiary packaging" column matches SSCC.	Check of CIL status in the participant's PA

### Operation: Aggregation up to transport packaging – multiple transport containers (915)

Scheme: 915. The SSCC numbers of all transport containers should be indicated in the scheme. All CIL to be included in each transport container should be indicated in the SGTIN list.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 915 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 915 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Participant: check the composition of	Displays a list of CIL. The list matches the one specified in the uploaded scheme 915 for the	Check of CIL status in the participant's PA

transport	particular SSCC, and the value in	
packaging.	the "Identification code of tertiary	
Complete	packaging" column matches SSCC.	
filtering by		
"Identification		
code of tertiary		
packaging"		
(SSCC) in the		
"CIL register"		
section of the		
Participant's PA.		
Use SSCC from		
915.		

### Inclusion of MPs into packaging

Members of the chain: any Participant

Preconditions:

- The Participant should have CIL outside of transport packaging.
- The Participant should have CIL aggregated up to transport packaging.
- The owner of CIL should be Participant.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

#### Operation: Inclusion of MPs into packaging (914)

Scheme: 914. Box number is indicated in the SSCC attribute. All CIL to be included into packaging should be indicated in the SGTIN list.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 914 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 914 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Participant:	Displays a list of CIL. The list should	Check of CIL status in the

check the	contain CIL from 914 xml and CIL	participant's PA
composition of	previously located in the transport	
transport	packaging of MPs.	
packaging.		
Complete		
filtering by		
"Identification		
code of tertiary		
packaging"		
(SSCC) in the		
"CIL register"		
section of the		
Participant's PA.		
Use SSCC from		
914 xml.		

### Removal of MPs from packaging

Chain members: any Participant.

Preconditions:

- The Participant should have CIL aggregated up to transport packaging.
- The owner of CIL should be Participant.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### Operation: Removal from packaging (913)

Scheme: 913. Specify a portion of SGTIN to be removed from group packaging.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 913 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document	A message generated according to scheme 913 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message.
	contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Participant: verify that the CIL have	CIL information is displayed. The "Identification code of tertiary	Check of CIL status in the participant's PA

been removed from the box. Complete filtration by SGTIN in the Register section of the Participant's PA.	packaging" column is blank.	
Use SGTIN of removed MPs (specified in 913 xml).		
Participant: check the composition of the box, execute filtering by "Identification code of tertiary packaging" (SSCC) in the "CIL register" section of the Participant's PA.	Displays a list of CIL. The list matches the previous one, except for the CIL specified in 913.	Check of CIL status in the participant's PA

### Deconsolidation of transport packaging

Members of the chain: any Participant

Preconditions:

- The Participant should have CIL aggregated up to transport packaging.
- The owner of CIL should be Participant.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### Operation: Deconsolidation of transport packaging (912)

Scheme: 912. The SSCC of transport packaging to be deconsolidated is specified.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 912 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully".	A message generated according to scheme 912 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message.

	The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Participant: verify that the CIL have been removed from transport packaging. Complete filtration by SGTIN in the Register section of the Participant's PA. Use any SGTIN from the transport packaging.	CIL information is displayed. The "Identification code of tertiary packaging" column is blank.	Check of CIL in Participant's PA

### Retail sale of MPs

Members of the chain: Pharmacy (retail point of sale)

Preconditions:

- The Pharmacy should have CIL.
- The owner of CIL should be Pharmacy.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### Operation: Retail sale (511)

Scheme: 511. Contains sgtin sold in the Pharmacy.

Steps	Expected reaction of PA	Expected reaction of USO
Pharmacy: upload and send xml 511 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is	A message generated according to scheme 511 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state
	set to "File processed successfully".	code and a registered unique identifier of the sent message.

	The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Pharmacy: check the CIL status in the Participant's PA (retail sale).	CIL with a "Retail sale" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

### Supply of MPs on prescription

Members of the chain: Pharmacy. Preconditions:

- The Pharmacy should have CIL.
- The owner of CIL should be Pharmacy.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### 1. Operation: Selling on prescription

Scheme: 521. Contains information on SGTIN sold on prescription.

Steps	Expected reaction of PA	Expected reaction of USO
<u>Pharmacy</u> : upload and send xml 521 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The Participant has generated a message in the XML format in his information system according to scheme 521. A generated message was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message.
		The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Accepted</operation_result>

		on_result>.
<u>Pharmacy</u> : check the CIL status in the Participant's PA.	CIL with a "Selling of MPs on preferential prescription" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied.	Check of CIL status in the Participant's PA

### Distribution of MPs in a medical institution

Members of the chain: Medical institution. Preconditions:

- The Medical institution should have CIL.
- The owner of CIL should be Medical institution.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### Operation: Distribution in a medical institution

Scheme: 531. Contains information on SGTIN distributed to a medical institution department.

Steps	Expected reaction of PA	Expected reaction of USO
<u>Medical</u> <u>institution</u> : upload and send xml 531 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The Participant has generated a message in the XML format in his information system according to scheme 531. A generated message was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Medical institution: check the CIL status in the Participant's PA.	CIL with a "Used for the delivery of healthcare" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied.	Check of CIL status in the Participant's PA

## Transfer of MPs for destruction and Destruction of MPs

Chain members: any Participant. Preconditions:

- The Participant has CIL with an "In circulation" status.
- The Participant is the owner of CIL.
- The CIL should be destroyed.

Operations should be executed in sequence to complete the chain. The date/time in each loaded xml should exceed those of the previous one.

- 1. Transfer of MPs for disposal (541).
- 2. Destruction of MPs (542).

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### 1. Operation: Transfer of MPs for disposal (541)

Scheme: 541. Contains a list of SGTIN and/or SSCC of MPs to be transferred for destruction.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 541 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 541 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Accepted</operation_result> .
Participant: check the CIL status in the Participant's PA.	CIL with a "Transferred for destruction" status is displayed in the table of search results in the "CIL register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

2. Operation: destruction of MPs (542)

Scheme: 542. Contains a list of SGTIN and/or SSCC of MPs from Step 1 for which an "Act on the destruction of MPs" has been received.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 542 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 542 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Accepted</operation_result> .
Participant: check the CIL status in the Participant's PA.	CIL with an "Destroyed" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

## Withdrawal of MPs from circulation due to various reasons

Chain members: any Participant. Preconditions:

- The Participant has CIL with an "In circulation" status.
- The Participant is the owner of CIL.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### Operation: Withdrawal of MPs from circulation due to various reasons (552)

Scheme: 552. Contains a list of SGTIN and/or SSCC of MPs to be withdrawn from circulation.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 552 using a selected		A message generated according to scheme 552 was sent using the USO web service (POST /farm/in/), and a

-		
	the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Accepted</operation_result>
		on_result>.
Participant: verify the CIL status in the Participant's PA.	CIL with a "withdrawn from circulation" status is displayed in the table of search results in the "CIL Register" section with the corresponding CIL filter applied (indicating the date and time of operation).	Check of CIL status in the Participant's PA

## Cancellation of a previously registered personal operation

Chain members: any Participant.

Preconditions:

- The owner of CIL should be Participant.
- The Participant cancels his operation.
- The cancelled operation is the last registered operation with CIL data.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### Operation: Cancellation of a previously registered operation (250)

Scheme: 250. Contains the type and identifier on the operation to be cancelled.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 250 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully".	A message generated according to scheme 250 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message.
	The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	The participant addressed the USO web service (GET /farm/out/) using the unique identification number of

		the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Participant: verify the cancellation of operation	The operation has been cancelled, which is confirmed by a change of status/consition of CIL from the cancelled operation.	Check in Participant's PA

## Recall by the seller of a portion of goods transferred to the Buyer

Members of the chain: Buyer, Seller. Preconditions:

availability of previously registered information on the shipment of medicinal products from the warehouse of a medicinal product circulation subject registering the recall;
in relation to medicinal products awaiting confirmation.

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

### Operation: Recall of a portion of transferred goods (251)

Steps Expected reaction of PA Expected reaction of USO Seller: upload The document is successfully signed A message generated according to and send xml and sent. scheme 251 was sent using the 251 using a USO web service (POST /farm/in/), The status of the sent document in and a reply message was received selected method (USO/PA) the "Document Register" section is from the USO with a Success state set to "File processed successfully". code and a registered unique identifier of the sent message. The reply receipt for the document contains a processing result: The participant addressed the USO <operation result>Accepted</operati</pre> web service (GET /farm/out/) using on result>. the unique identification number of the sent message and received a reply document with a positive processing result containing <operation result>Accepted</operati</pre> on\_result>. Buyer: verify the Notification of MP circulation subject Check of CIL status in the recall of MPs on the recall of a portion of goods (or Participant's PA notification on operation refusal). A list of CIL is displayed in the "CIL register" section with a filter by CIL from 251 xml applied. CIL status -

Scheme: 251. Contains SGTIN and/or SSCC of recalled MPs.

### Refusal to accept a portion of goods

Members of the chain: Recipient

Preconditions:

- availability of previously registered information on the shipment of medicinal products to the Recipient and in relation to medicinal products awaiting confirmation of acceptance by the Recipient (with a regular acceptance order);

- detection of errors by the Recipient in the previously send proprietary information on the acceptance of medicinal products at the warehouse and in relation to medicinal products awaiting confirmation of shipment by the Sender (with a reverse acceptance scheme).

Uploading can be completed either from the participant's personal account, or using the Participant's information system integrated with USO (Universal Exchange and Guaranteed Delivery System).

#### Operation: Refusal to accept a portion of goods (252)

Steps	Expected reaction of PA	Expected reaction of USO
Recipient: upload and send xml 252 using a selected method (USO/PA)	The document is successfully signed and sent. The status of the sent document in the "Document Register" section is set to "File processed successfully". The reply receipt for the document contains a processing result: <operation_result>Acceptedon_result&gt;.</operation_result>	A message generated according to scheme 252 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Recipient: verify the rejection of MP acceptance.	Notification of the rejection of a portion of goods for the medicinal product circulation subject – Sender – is received from Labelling IS. A list of CIL is displayed in the "CIL register" section with a filter by CIL from 252 xml applied. The CIL list is blank (as the owner of CIL is Seller).	Check of CIL status in the Participant's PA

Scheme: 252. Contains SGTIN and/or SSCC of the MP the acceptance of which is rejected.

## Change of the list of trusted contractors for reverse acceptance

Members of the chain: any Participant

Preconditions:

- The Participant uses a shipment scheme with a reverse acceptance order
- The list of trusted contractors should be supplemented with an organization OR
- An organization should be removed from the list of trusted contractors

A scheme has been implemented for uploading using the Participant's information system integrated in USO, as the function of adding contractors is implemented in the PA interface, and the uploading of a scheme is not required in this case.

### Operation: Change of the list of trusted contractors (212)

Scheme: 212. Contains SGTIN and/or SSCC of the MP the acceptance of which is rejected.

Steps	Expected reaction of PA	Expected reaction of USO
Participant: upload and send xml 212 using USO		A message generated according to scheme 212 was sent using the USO web service (POST /farm/in/), and a reply message was received from the USO with a Success state code and a registered unique identifier of the sent message. The participant addressed the USO web service (GET /farm/out/) using the unique identification number of the sent message and received a reply document with a positive processing result containing <operation_result>Acceptedon_result&gt;.</operation_result>
Participant: verify changes in the list of trusted contractors.	The list in the "Permitted contractors for reverse acceptance" tab in the Participant's profile of the PA has been changed according to the uploaded scheme 212	-