الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Integration Guide for Drug Track & Trace System

Version 2.1

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بالأهــــم نهتــــم

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Version 2.1

Saudi Food & Drug Authority

Drug Sector

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Please visit SFDA's website at

https://www.sfda.gov.sa/en/regulations?tags=2

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Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

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Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

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DOCUMENT CONTROL

Version	Author	Date	Comments
1.0	Drug Availability & Tracking Center	22 April 2018	Draft for comments
2.0	Drug Availability & Tracking Center	24 October 2018	Final
2.1	Drug Availability & Tracking Center	05 August 2024	Update (Next page shows the updated details

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WHAT'S NEW IN VERSION NO. 2.1?

Section	Description of Change
References	**Addition:** The guideline adds number of service names.
Stakeholders -Manufacturers	**Addition:** The guideline adds number of Operation names.
Stakeholders - Warehouses	**Addition:** The guideline adds number of Operation names.
Stakeholders - Consumption Centers	**Addition:** The guideline adds number of Operation names.
Stakeholders - Pharmacies	**Addition:** The guideline adds number of Operation names.
Notifications - Main Operations	**Addition:** The guideline adds number of web service names.
	Modification: The guideline modifies certain usage purposes.

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Table of Content:

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1. Introduction

1.1. Purpose

The purpose of this document is to present a brief description of the Drug Track & Trace System. It will explain the purpose and features of the system, the interfaces of the system, what the system will do, the constraints under which it must operate and how the system will react to external stimuli. This document is intended for the developers of the stakeholder's software system that will integrate with DTTS.

1.2. Scope

SFDA implemented a web-based solution for tracking of pharmaceutical products in order to improve the integrity of the supply chain.

The supply chains of these products are:
- Manufacturers
- Warehouses
- Pharmacies
- Medical and Dispense Centers

Track & Trace System is a system that track and control all processes of the products starting from the manufacturing/importing until the patient usage. The system provides a full tracking model, enabling sharing of information between industry regulators and payers and also across the supply chain and a greater transparency of the movements on a box or a batch level as opposed to the principle of monitoring only the first and last stakeholder.

1.3. Datamatrix

All drug units tracked in the supply chain will include a datamatrix printed on itself. This datamatrix is based on GS1 Standards. It will include GTIN+SN+XD and BN.
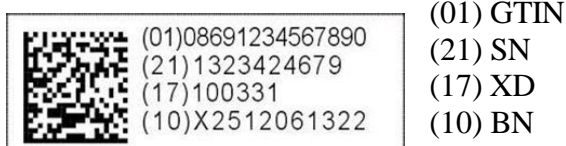
For more information about datamatrix please refer;
https://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf

For information about Application Identifiers please refer;
https://www.gs1.org/sites/default/files/docs/barcodes/GS1%20Application%20Identifiers.pdf

A sample Datamatrix printed on a drug unit;

(01) GTIN
(21) SN
(17) XD
(10) BN

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2. Definitions

Shortcuts	Definition
BN	Batch or Lot Number
DTTS	Drug Track & Trace System
GLN	Global Location Number
GTIN	Global Trade Item Number
GS1	Global Standards One
ID	Identification Number
ISD	Interface Specification Document
MD	Manufacturing Date
PTS	Package Transfer Service
SFDA	Saudi Food and Drug Authority
SN	Serial Number
WSDL	Web Services Description Language
XD	Expiration Date

3. References

Service Name	ISD Filename
Accept Service	DTTS-ISD.ACCEPTSERVICE -nnn
Accept by Batch Number Service	DTTS-ISD.ACCEPTBYBATCH-nnn
Accept Cancel Service	DTTS-ISD.ACCEPTSERVICE -nnn
Accept Cancel by Batch Number Service	DTTS-ISD.ACCEPTBYBATCH-nnn
Check Status Service	DTTS-ISD.CHECKSTATUS-nnn
City List Service	DTTS-ISD.CITYLIST-nnn
Consume Product	DTTS-ISD.CONSUME-nnn
Consume Cancel Product	DTTS-ISD.CONSUME-nnn
Country List Service	DTTS-ISD.COUNTRYLIST-nnn
Deactivate Product	DTTS-ISD.DEACTIVATE-nnn
Deactivate Cancel Product	DTTS-ISD.DEACTIVATE-nnn
Dispatch Service	DTTS-ISD.DISPATCH-nnn
Dispatch by Batch Number Service	DTTS-ISD.DISPATCHBYBATCH-nnn
Dispatch Cancel Service	DTTS-ISD.DISPATCH-nnn
Dispatch Cancel by Batch Number Service	DTTS-ISD.DISPATCHBYBATCH-nnn
Drug List Service	DTTS-ISD.DRUGLIST-nnn
Error Code List Service	DTTS-ISD.ERRORCODELIST-nnn
Export Product	DTTS-ISD.EXPORT-nnn
Export Cancel Product	DTTS-ISD.EXPORT-nnn
Import Product	DTTS-ISD.IMPORT-nnn
Import Cancel Product	DTTS-ISD.IMPORT-nnn
Pharmacy Sale Product	DTTS-ISD.PHARMACYSALE-nnn
Pharmacy Sale Cancel Product	DTTS-ISD.PHARMACYSALE-nnn
PTS Download	DTTS-ISD. PACKAGETRANSFER-nnn
PTS Query	DTTS-ISD. PACKAGETRANSFER-nnn
PTS Upload	DTTS-ISD. PACKAGETRANSFER-nnn
Return Service	DTTS-ISD.RETURN-nnn
Return by Batch Number Service	DTTS-ISD.RETURNBYBATCH-nnn
Stakeholder List Service	DTTS-ISD.STAKEHOLDERLIST-nnn
Supply Product	DTTS-ISD.SUPPLY-nnn
Supply Cancel Product	DTTS-ISD.SUPPLY-nnn
Transfer Service	DTTS-ISD.TRANSFER-nnn
Transfer Cancel Service	DTTS-ISD.TRANSFER-nnn
Transfer by Batch Number Service	DTTS-ISD.TRANSFERBYBATCH-nnn
Transfer by Batch Number Cancel Service	DTTS-ISD.TRANSFERBYBATCHNUMBER-nnn

− All ISD files are available in the system portals.

4. How System Operates

DTTS works on SOAP-XML Web Services. Every service is authenticated by username & password. Every stakeholder need to get a username & password from SFDA. All web services based on Request & Response messaging. Every Request will get response representing the status of the request (either successful or error). All operations between stakeholders are two way, means if a stakeholder sends a products to other, receiver stakeholder also needs to send accept notification to DTTS for starting operations on the product. Without accept or cancel notification, Product will stay between stakeholders and none of the stakeholder can do any operation on it.

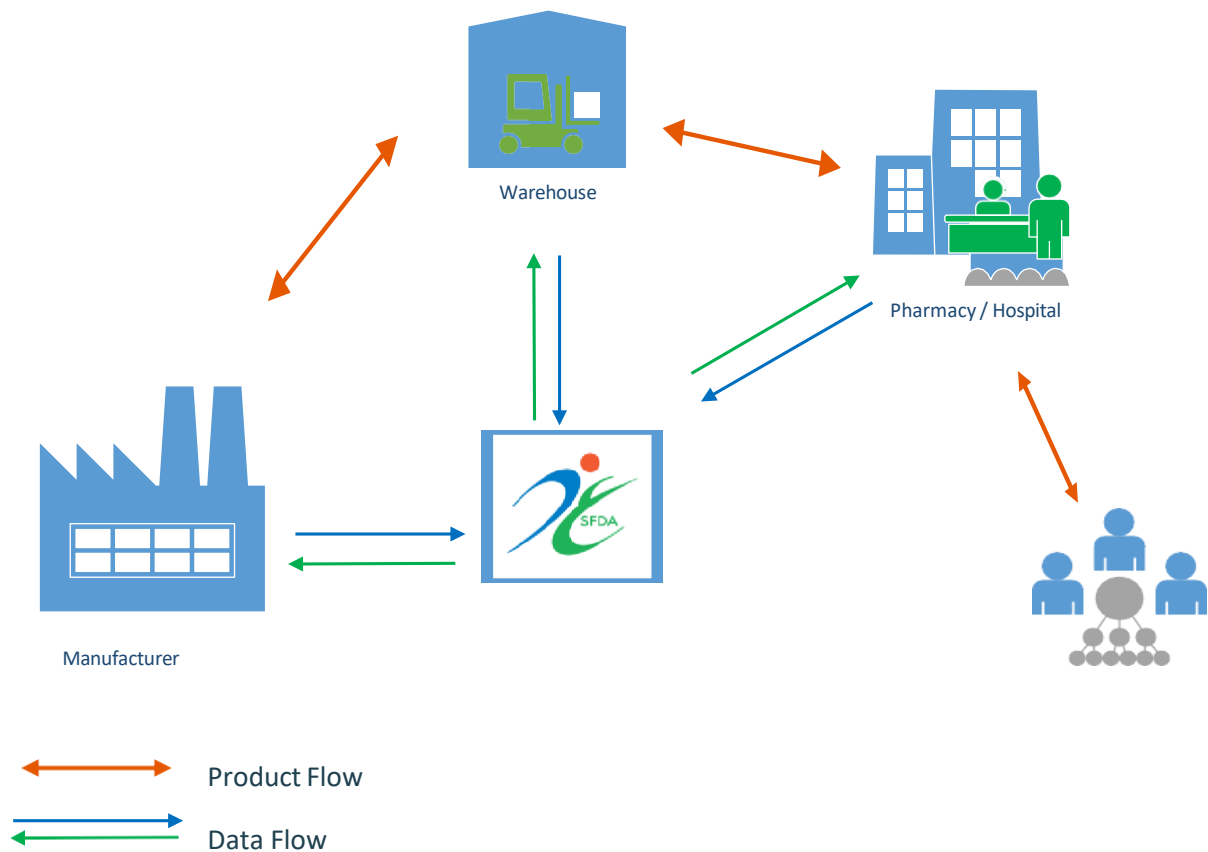All operations are GTIN and SN or Batch Number based.

FIGURE 1 DTTS WORK FLOW

5. Stakeholders

All stakeholders in the system must have a unique GLN ID. After getting GLN ID, SFDA will register the stakeholder into the DTTS. For getting GLN ID please refer to SFDA/GS1.

5.1. Manufacturers

A manufacturer is the first entry point of a product to the DTTS. After the manufacturing process, product supply information must be sent to the DTTS. Starting with this supply notification product can start moving between stakeholders.

When does a drug unit need to be registered on the DTTS?

Manufacturer can register a drug unit after all production phases (or import phases) complete. To avoid unnecessary Supply Cancel operation, you must be sure that all production phases (or import phases) must be finished. Moreover, it must be kept in mind that marketing of that unit is forbidden without registration.

Manufacturer cannot add a product (supply or import) with the same GTIN and SN.

The operation that manufacturers can perform are as follows and SFDA may restrict them;

Operation Name
Supply Product
Supply Cancel Product
Import Product
Import Cancel Product
Dispatch Product
Dispatch Cancel Product
Dispatch by Batch Number Product
Dispatch Cancel by Batch Number Product
Accept Product
Accept by Batch Number Product
Accept Dispatch Service
Deactivate Product
Deactivate Cancel Product
Export Product
Export Cancel Product
Return Product
Return by Batch Number Product
PTS Upload
PTS Download
PTS Query

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5.2. Warehouses

A warehouse is the collection and transmission point of the products between manufacturers and Pharmacies/Hospitals/Consumption Centers. Warehouses accept from manufacturers and dispatch the products.

In addition, if a warehouse has privilege to import, Import Product service can be used by that warehouse. Moreover, import phases must completed before sending Import Product message to the DTTS. And registration of drug units must be done before marketing.

The operation that warehouses can perform are as follows and SFDA may restrict them;

Operation Name
Dispatch Product
Dispatch Cancel Product
Dispatch by Batch Number Product
Dispatch Cancel by Batch Number Product
Accept Product
Accept by Batch Number Product
Accept Dispatch Service
Deactivate Product
Deactivate Cancel Product
Import Product
Import Cancel Product
Export Product
Export Cancel Product
Return Product
Return by Batch Number Product
PTS Upload
PTS Download
PTS Query

5.3. Consumption Centers

Consumption Center is the place where drugs are consumed for patients. These places include Hospitals, physical therapy centers, and dialysis center. Consumption Centers accept from warehouses and consume for the patients. Consumption Centers send notification for each Sellable Unit.

The operation that consumption centers can perform are as follows and SFDA may restrict them;

Operation Name
Accept Product
Accept by Batch Number Product
Accept Dispatch Service
Deactivate Product
Deactivate Cancel Product
Consume Product
Consume Cancel Product
Return Product
Return by Batch Number Product
Transfer Product
Transfer Cancel Product
Transfer by Batch Number Product
Transfer Cancel by Batch Number Product
PTS Upload
PTS Download
PTS Query

5.4. Pharmacies

Pharmacy is the place where drugs are sold to patients. Pharmacies accept from warehouses and sell drug to the patients.

The operation that pharmacies can perform are as follows and SFDA may restrict them;

Operation Name
Accept Product
Accept by Batch Number Product
Accept Dispatch Service
Deactivate Product
Deactivate Cancel Product
Pharmacy Sale Product
Pharmacy Sale Cancel Product
Return Product
Return by Batch Number Product
Transfer Product
Transfer Cancel Product
Transfer by Batch Number Product
Transfer Cancel by Batch Number Product
PTS Upload
PTS Download
PTS Query

6. Notifications

DTTS works on SOAP-XML Based Web services. DTTS Web Services use SOAP Version 1.2.

All stakeholders need to register itself to SFDA and need to get a username/password for using DTTS Web services. Web Services WSDLs and ISD files will be shared after completing registration process with SFDA. Stakeholders need to modify their own computer systems for sending notifications to DTTS and receiving notifications from DTTS.

6.1. Main Operations

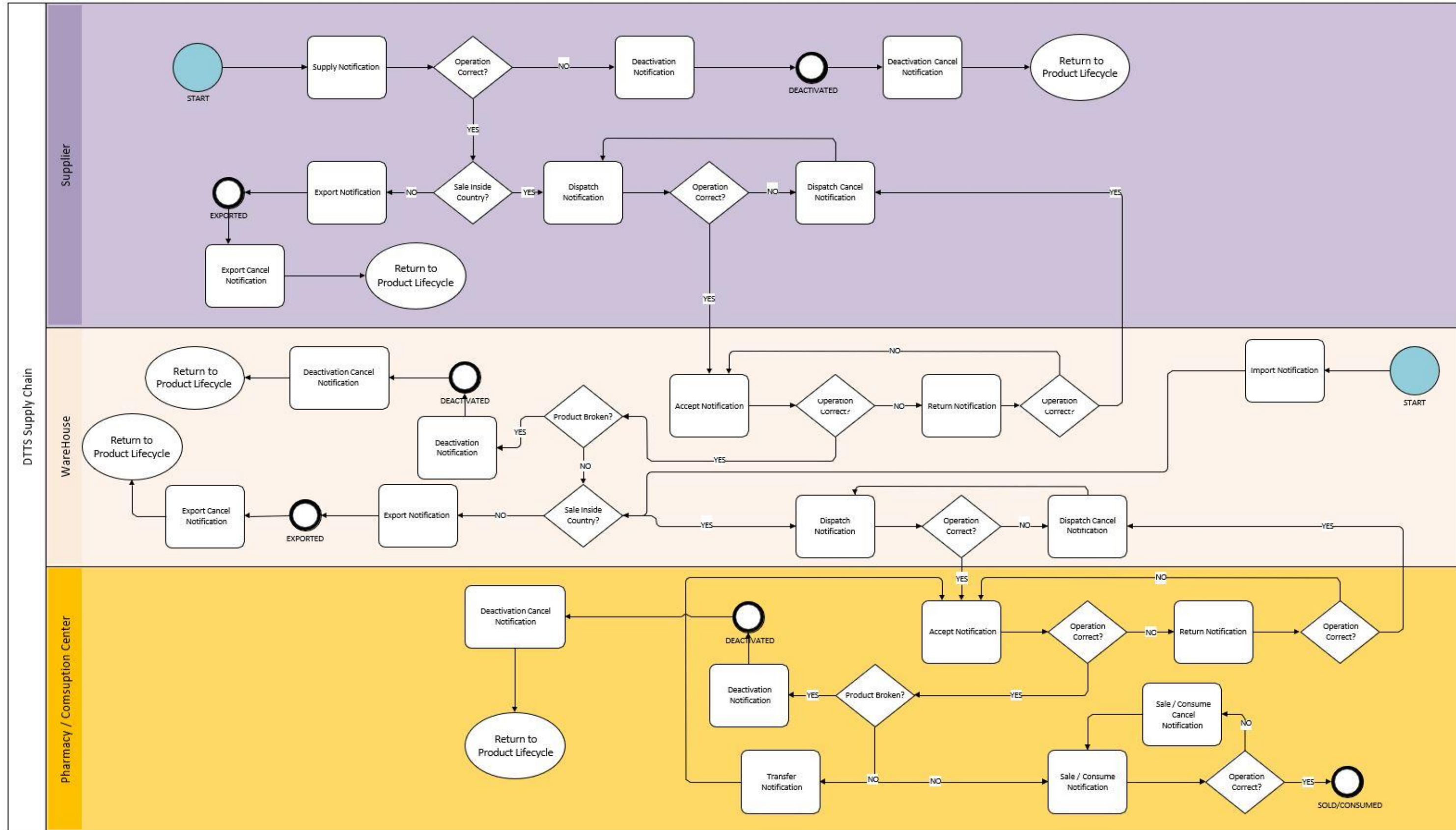| Web Service Name	Usage Purpose
Accept Service	is used by receiver stakeholder to accept the sent product on a Serial Number level.
Accept by Batch Number Product	is used by receiver stakeholder to accept the sent product on a Batch Number level.
Accept Dispatch Service	is used to accept all units in a Dispatch Notification. A Dispatch Notification can represent a package. By this operation, all units in a package can be accepted at once.
Consume Service	is used by Consumption Centers when a drug is used in a treatment/cure of a patient.
Consume Cancel Service	is used to cancel a consume operation by the stakeholder that initially consume that product.
Deactivation Service	is used to make a product put out of the system with the reasons (Broken Product, Expired Product, Recalled Product…).
Deactivation Cancel Service	is used to cancel a deactivation operation by the stakeholder that initially deactivate that product.
Dispatch Service	is used to send a product to another stakeholder on a Serial Number level. After dispatch receiver stakeholder need to send Accept notification.
Dispatch Cancel Service	is used to cancel a dispatch operation on a Serial Number level. Sender stakeholder could use this, if receiver selected wrong, or product information was wrong or receiver Returns a product to Sender.
Dispatch by Batch Number Product	is used to send a product to another stakeholder on a Batch Number level. After dispatch receiver stakeholder need to send Accept notification.
Dispatch Cancel by Batch Number Product	is used to cancel a dispatch operation on a Batch Number level. Sender stakeholder could use this, if receiver selected wrong, or product information was wrong or receiver Returns a product to
Export Service	is used to export a product out of the country, exported products cannot be used inside the country.
Export Cancel Service	is used to cancel an export operation by the stakeholder that initially export that product.
Import Service	is used to register a product in the system by importing outside the country. This operation is the initial step for a product lifecycle

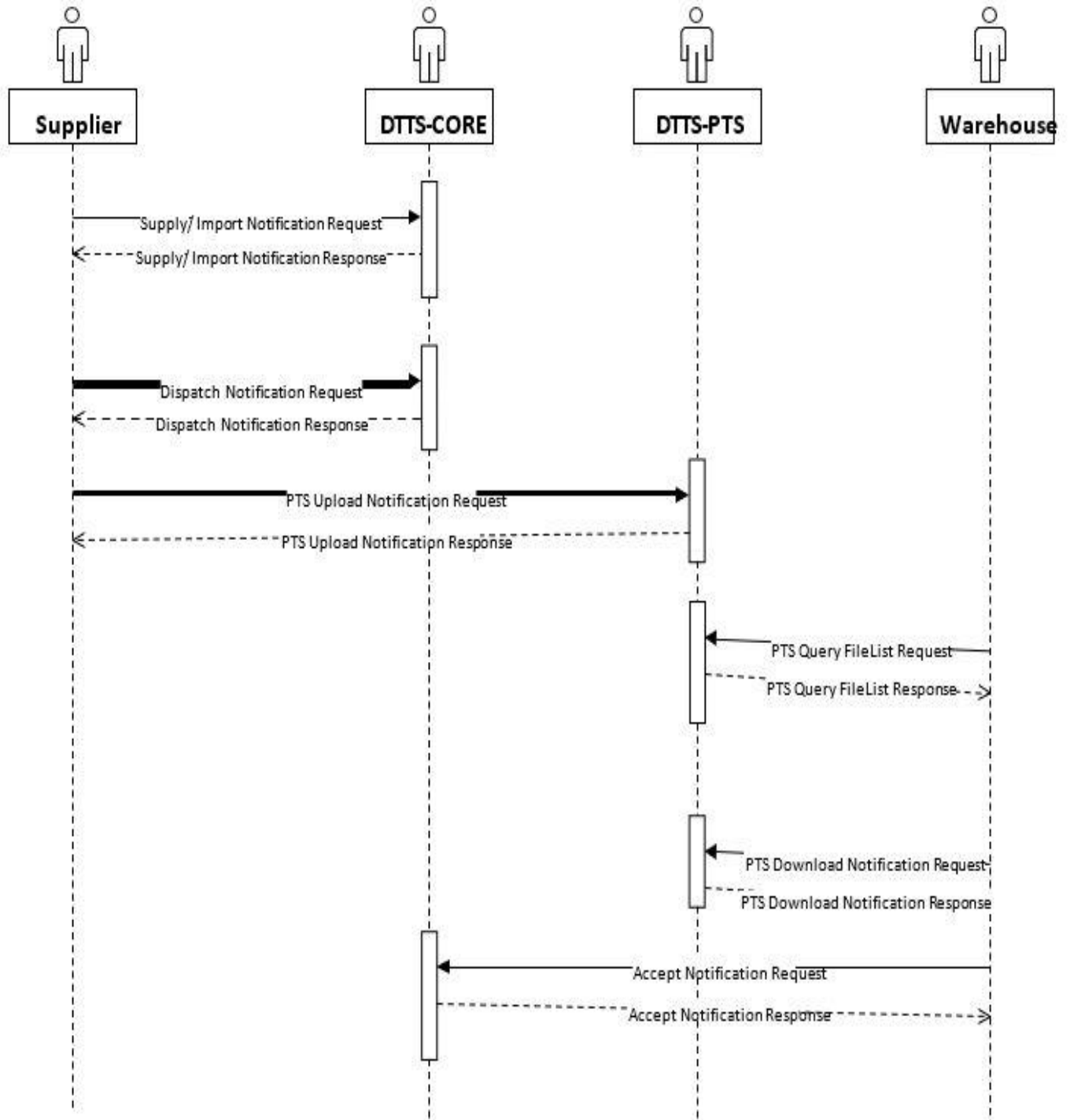| Web Service Name	Usage Purpose
	same as Supply operation.
Import Cancel Service	is used to cancel import operation.
Pharmacy Sale Service	is used by Pharmacy to sell a product to a patient.
Pharmacy Sale Cancel Service	is used to cancel a pharmacy sale operation.
Return Service	is used to send back a product to the sender stakeholder on a Serial Number level. Return reason can be recall, expiry date, wrong receiver, etc.
Return by Batch Number Product	is used to send back a product to the sender stakeholder on a Batch Number level. Return reason can be recall, expiry date, wrong receiver, etc.
Supply Service	is used to register a product in the system, which are manufactured in the country. This operation is the initial step for a product lifecycle same as Import operation.
Supply Cancel Service	is used to cancel Supply Service.
PTS Upload	is used to make easier of exchanging of huge amounts of product. This is an Aggregation Operation. From manufacturer to warehouses or vice-versa, too many product are dispatching. When Manufacturer wants to dispatch products, the files should be prepared including all GTIN-SN-BN-XD sent to warehouse and uploads this file to DTTS with this service
PTS Download	is used to download the file including Product GTIN-SN-BN-XD information sent by manufacturer from PTS. This is an Aggregation Operation. When clients download this file they can extract product information send accept notification for these products to DTTS.
PTS Check Package	is used to check if there is a file sent to stakeholder itself. By this way, it can be controlled if there is any undownloaded package for their owned products.
Transfer Service	is used by Consumption Centers or Pharmacies to transfer products between each same type of stakeholders on a Serial Number level. Pharmacies can transfer product between only pharmacies and Consumption Centers can transfer product between only Consumption Centers.
Transfer Cancel Service	is used to cancel a transfer operation on a Serial Number level.
Transfer by Batch Number Product	is used by Consumption Centers or Pharmacies to transfer products between each same type of stakeholders on a Batch Number level. Pharmacies can transfer product between only pharmacies and Consumption Centers can transfer product between only Consumption Centers.
Transfer Cancel by Batch Number Product	is used to cancel a transfer operation on a Batch Number level.

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6.2. Query Operations

Below Web Services will be used to retrieve reference data to be used or got in the notifications.

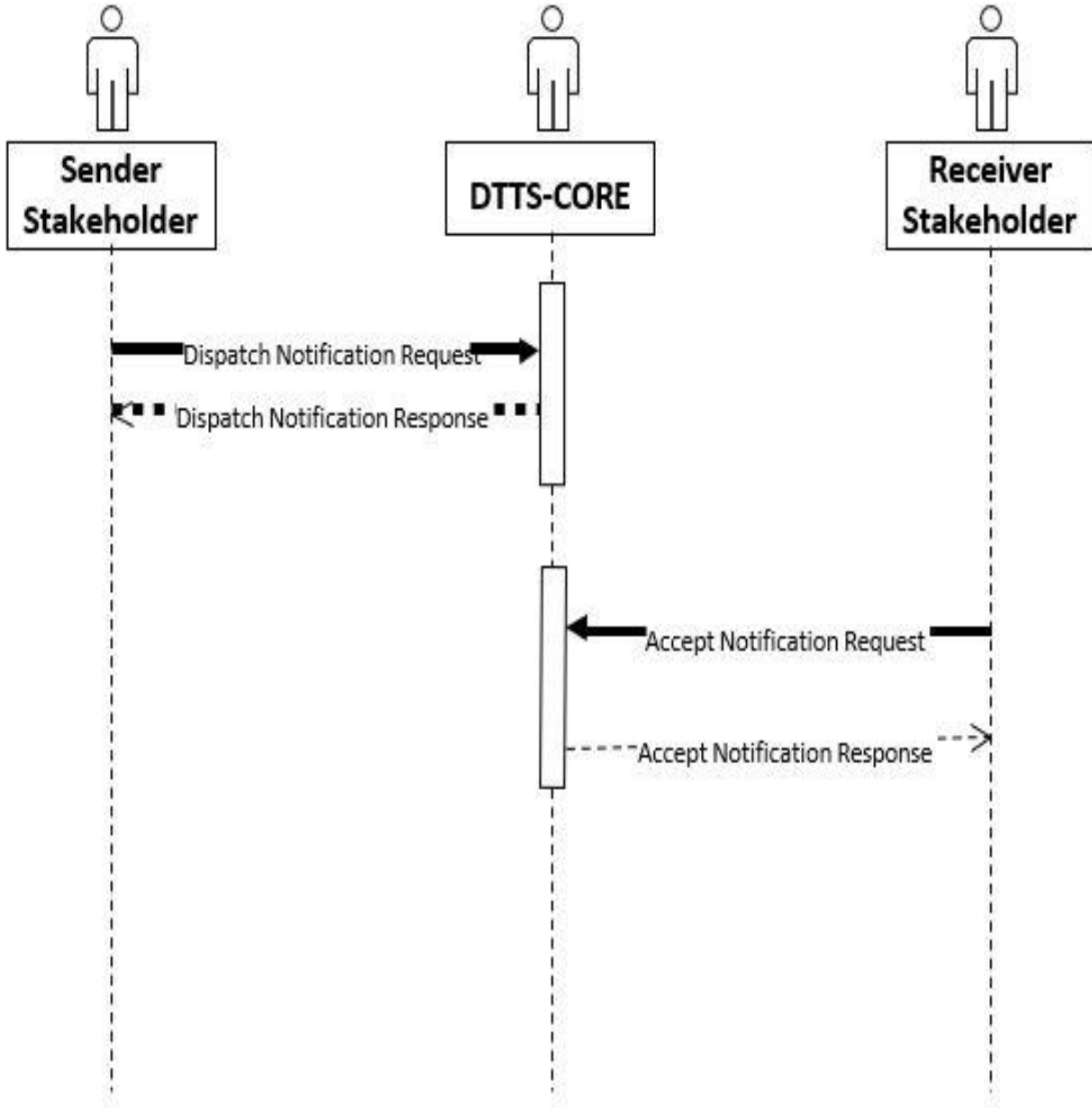| Web Service Name	Usage Purpose
Check Status Service	This service can be used for query a drug status and ownership. Sometimes a drug can be in shipment status so receiver stakeholder cannot do any operation on that drug. With this service, he can check the status of the drug.
City List Service	This service returns all the City and Region information registered in the system.
Country List Service	For Export Notification, Country code returned from this service must be used. Otherwise, system will give error about the country.
Dispatch Detail Service	is used to query the content of a dispatch operation.
Drug List Service	This service returns all the Drugs registered in the system.
Error Code List Service	This service returns all or specified error code and its description. Error codes returned for a notification can be queried for its description. And then stakeholder take action for the notified products.

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6.3. DTTS Web Services Workflow

6.4. DTTS Bulk (Aggregation) Operations Workflow

6.5. DTTS Dispatch & Accept Operations Workflow

7. Integration Testing:

All stakeholders must perform an integration testing with test server before they send any notification to the DTTS production server.

To perform integration testing, the establishment or company with one of their stakeholders must register in DTTS, and then send the testing request to Tracking.drug@sfda.gov.sa