



REPUBLIC OF TURKEY
MINISTRY OF HEALTH
Medicines & Medical Devices Agency

PTS XML STANDARD GUIDELINE

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REVISION INDEX

VERSION	DATE	NOTES
1.0	14.02.2012	First version
1.1	06.09.2012	The "version" field has been added. The 'billTo' field has been changed with the 'shipTo' field.
1.2	29.11.2011	The containerType field has been added to the carrierType complex type to be able to indicate the type of the product list or carrier. The XML scheme has been updated.

1.3	05.12.2011	New definitions have been added to the containerType field.
1.4	02.03.2012	The actionType field and the carrierLabel fields have been identified with the new XSD. Some topics have been identified as Appendixes and the values which can be inserted into the actionType field have been added as Appendixes.
2.0	17.09.2012	XSD has been revised with the new type definitions and name.
2.0	17.09.2012	The explanations of new added types have been added and related information has been updated.
2.0	17.09.2012	New document format has been added.

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1. INTRODUCTION

1.1. Abstract

After ITS was put into use the problem of managing transfers of products occurred in the sector especially between manufacturers and pharmaceutical wholesalers. ITS operating with notifications on the basis of drug units made it obligatory to establish a relationship between transportation units (bundles, cases, pallets etc.) and the products within these units in the management of the supply chain among system stakeholders. While the standardization studies on this issue within the sector continued, the demand that this transfer operation is to be provided by a central structure which every stakeholder could rely on and accept jointly occurred. With the conveyance of these demands to the Turkish Medicines and Medical Devices Agency (TITCK, former General Directorate of Pharmaceutical and Pharmacy) a workshop on 13.12.2010 was made by Nart Bilişim Hizmetleri (TechN'arts) with the participation of the related stakeholders. At the end of the workshop it was shared with the stakeholders that this central structure is to be provided by TechN'arts; and the XML data format planned to be used in this structure was determined with the participation of the stakeholders.

The needs of our stakeholders have become clear with the development of the Turkish Pharmaceutical Track and Trace System and it inevitable that PTS has developed due to these needs. Therefore the PTS XML standard is being updated taking the needs of our stakeholders into consideration.

1.2. General Information

The Package Transfer System (abbreviated as PTS) has been prepared with the aim of transferring the information of the physical transfers between the stakeholders in the virtual environment in order to meet the needs of the sector by TechN'arts. The usage of PTS is obligatory in case the receiving stakeholders demands. The information of physical

transfers are shared in the in the format determined in this Guideline apart from the bilateral agreements among stakeholders.

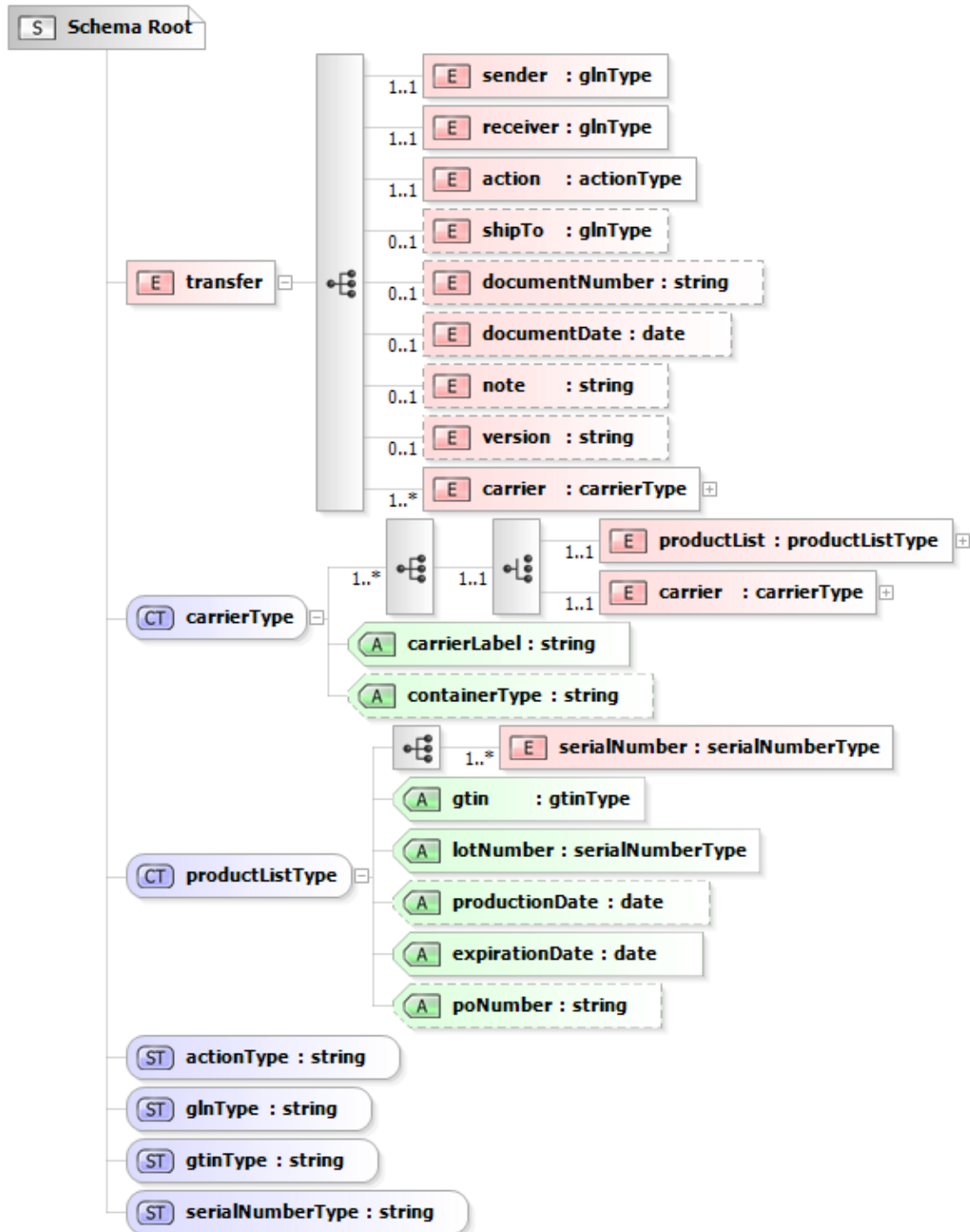
This guideline has been prepared to identify the file standard to be used in PTS.

1.3. Target Audience & Samples

This guideline appeals to the software developing units of the stakeholders.

Sample XMLs will be shared on site called github : <https://github.com/ilactakipsistemi>

2. SCHEMATIC VIEW OF XSD



3. XSD EXPLANATIONS

3.1. XSD Location and its Usage

The XML standards to be used for PTS are defined in the XSD document given in **Appendix II** and XSD should be used in generating XML and its validation. Not using XSD while generating XML causes problems in the validation by the recipient.

The XSD document can be obtained from the below given URL:

http://its.saglik.gov.tr/pts_xml_schema_v_2_0.xsd

3.2. Simple Types

3.2.1. actionType

This type defines an enumeration of characters referring action types. It may only contain the characters given in **Appendix I** and are given with the action types which the characters represent. Examples are also given so that some actions are better understood. However the usage of these actions are not limited to the given examples. As the objective of the actions is to define the action that the stakeholder should take, examples can vary.

The elements with this type contains one value from the mentioned enumeration.

3.2.2. glnType

Detailed information related to the GLN can be found in the “Regulation Regarding the Packaging and Labeling of Medicinal Products for Human Use”. GLN is 13 characters long and constituted of only digits.

This type is used for GLN containing elements. Contains exactly 13 numeric characters.

3.2.3. **gtinType**

Detailed information related to the GTIN can be found in the “Regulation Regarding the Packaging and Labeling of Medicinal Products for Human Use”. GTIN is 14 characters long and constituted of only digits.

This type is based on “string” type. Could contain exactly 14 numeric characters.

3.2.4. **serialNumberType**

Detailed information related to the Serial Number and Batch Number can be found in the “Regulation Regarding the Packaging and Labeling of Medicinal Products for Human Use”. Both numbers are one to 20 characters long and constituted of digits and capital letters.

This type is based on “string” type. Could contain one to 13 alfa-numeric characters.

3.3. **Complex Types**

3.3.1. **carrierType**

- ▲ **carrierLabel** - Is the barcode number determined for transport units as it has been stated in the “Regulation Regarding the Packaging and Labeling of Medicinal Products for Human Use”. Is an alphanumerical field of maximum 20 characters. It should not contain any fill characters. It is a mandatory field. This field should consist of 20 zeros (0) for carriers which do not have a SSCC in product tranfers of small quantities.
- ▲ **containerType** - It is a field used to indicate the type of the product list or carrier. Consists of a single character: “P”: Pallet, “C”: Case, “S”: Shrink or Bundle, “B”: Box in a Case, “E”: Small shrink or bundle; these are characters to denote the specified container types. It is an optional field.
- ▲ **productList** - Is in the type of productListType and is a list of products.
- ▲ **carrier** - Is in the carrierType type. Contains the labels of the products and carrier.

3.3.2. productListType

- ▲ **gtin** - This attribute is in the `gtinType` type. Contains *Global Trade Item Number (Barcode Number)* of related drug. It is a mandatory field.
- ▲ **serialNumber** - This element is in the `serialNumberType` type. Contains the *Serial Number* of related drug unit. In a product list at least one Serial Number should be given. It is a mandatory field.
- ▲ **lotNumber** - This attribute is in the `serialNumberType` type. Contains the *Batch Number (Lot Number)* of related drug. It is a mandatory field.
- ▲ **expirationDate** - This attribute contains the expiration date of the related drug unit in the XML Date type. It is a mandatory field.
- ▲ **productionDate** - Contains the production date of the related drug in the XML Date type. Its usage is optional.
- ▲ **poNumber** - Is an alphanumeric field. Its usage is optional.

3.4. Elements

- ▲ **sender** - Is in the `glnType` type. Contains the GLN code of the stakeholder sending the package.
- ▲ **receiver** - Contains the target GLN code of the transfer. This field is 13 characters long and is a mandatory field constituted of only digits.
- ▲ **action** - Expresses the action which the stakeholder receiving the package has to take. It may only contain the characters given in **Appendix I** and are given with the action types which the characters represent. Examples are also given so that some actions are better understood. However the usage of these actions are not limited to the given examples. As the main objective of the actions is to define the action that the stakeholder should take as already stated above, examples can vary.
- ▲ **shipTo** - Is an alphanumeric field of maximum 20 characters. It can be used to identify where the product will be shipped to. It should not contain any fill characters. Its usage is optional.

- ▲ **documentNumber** - Contains the Document Number of the Transfer. Is an alphanumerical field of maximum 20 characters. It should not contain any fill characters. Its usage is optional.
- ▲ **documentDate** - Contains the date information related to the document. It is in the XML-Date type. Its usage is optional. Date information which is not in the XML-Date type will cause errors in the validation of the XML information.
- ▲ **Note** - Is a notes field of maximum 50 characters. Its usage is optional.
- ▲ **Verison** - Contains the version of the Package Transfer System XML Standard. Its usage is optional. Its value is 2.0 for this document.
- ▲ **Carrier** - Is in the carrierType type. Contains the labels of the products and carrier.

4. APPENDIX

4.1. Appendix 1 - Action Types of the ActionType

- ▲ **“P” - product Purchase:** Expresses that the stakeholder receiving the package should purchase the products with a product purchase notification. For example it indicates that the stakeholder should make a product purchase notification using this action type when a manufacturer dispatches products to a pharmaceutical wholesaler with a ITS dispatch notification.
- ▲ **“S” - diSpatch:** Expresses that the stakeholder receiving the package should make a dispatch notification. This action type can be used so that products which are processed by a third party logistic company can be dispatched.
- ▲ **“C” - dispatch Cancellation:** Expresses that the stakeholder receiving the package should obtain the products with a dispatch cancellation notification. For example if a hospital returns the products in its own stock to a pharmaceutical wholesaler using the ITS product return service, this action type indicates that the pharmaceutical wholesaler needs to take the returned products by invoking the dispatch cancellation service.
- ▲ **“R”- Return:** Expresses that the stakeholder receiving the package should return the products using the product return notification. For example let’s say that a pharmaceutical wholesaler sent the product information of another pallet rather than the product information of the pallet of products he has actually dispatched to a hospital and the hospital has made a notification with this wrong pallet. For these products to be returned through ITS the pharmaceutical wholesaler can send this package with this action type.
- ▲ **“D” - Deactivation:** Expresses that the stakeholder receiving the package needs to deactivate the products with the deactivation notification.
- ▲ **“M” - production/Manufacture:** Expresses that the stakeholder receiving the package needs to manufacture the products with a production notification. For example a company making contracted manufacturing uses this action type so that the licensee company can make a production notification for the products.

- ▲ **“I” - Importation:** Expresses that the stakeholder receiving the package needs to notify that the imported products are manufactured with the production notification. For example a manufacturer manufacturing products outside of Turkey sends packages with this action type so that the importer company in Turkey can make a production notification.
- ▲ **“X” - eXportation:** Expresses that the stakeholder receiving the package needs to export the products with an exportation notification.
- ▲ **“O” - cOnsume:** Expresses that the stakeholder (hospital) receiving the package need to consume the products with a consumption notification.
- ▲ **“N” - iNformation:** Expresses that the stakeholder receiving the package is wanted to be informed about the products.
- ▲ **“T” -Turnover:** Expresses that the products need to be turned over by the stakeholder receiving the package with a product turnover notification.
- ▲ **“L” - turnover cancellatiOn:** Expresses that the products need to be obtained by the stakeholder receiving the package with a product turnover notification.
- ▲ **“F” - transFer:** Expresses that a transfer of products which do not need an ITS notification has been made. It is an action type for the use of companies (like logistic companies) which are not ITS stakeholders however play a role in the supply chain.
- ▲ **“K” - Transfer Cancellation:** Expresses that the transfer of products which do not need an ITS notification is cancelled. It is an action type for the use of companies (like logistic companies) which are not ITS stakeholders however play a role in the supply chain.

4.2. Appendix 2 - XSD Scheme

```
<?xml version="1.0" encoding="utf-8"?>
<xs:schema attributeFormDefault="unqualified" elementFormDefault="qualified"
xmlns:xs="http://www.w3.org/2001/XMLSchema">
  <xs:element name="transfer">
    <xs:complexType>
      <xs:sequence>
        <xs:element name="sender" type="glnType" minOccurs="1" maxOccurs="1" />
        <xs:element name="receiver" type="glnType" minOccurs="1" maxOccurs="1" />
        <xs:element name="action" type="actionType" minOccurs="1" maxOccurs="1" />
        <xs:element name="shipTo" type="glnType" minOccurs="0" maxOccurs="1" />
        <xs:element name="documentNumber" type="xs:string" minOccurs="0" maxOccurs="1" />
        <xs:element name="documentDate" type="xs:date" minOccurs="0" maxOccurs="1" />
        <xs:element name="note" type="xs:string" minOccurs="0" maxOccurs="1" />
        <xs:element name="version" type="xs:string" minOccurs="0" maxOccurs="1" />
        <xs:element name="carrier" type="carrierType" minOccurs="1" maxOccurs="unbounded" />
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:complexType name="carrierType">
    <xs:sequence minOccurs="1" maxOccurs="unbounded">
      <xs:choice minOccurs="1" maxOccurs="1">
        <xs:element name="productList" type="productListType" minOccurs="1" maxOccurs="1" />
        <xs:element name="carrier" type="carrierType" minOccurs="1" maxOccurs="1" />
      </xs:choice>
    </xs:sequence>
    <xs:attribute name="carrierLabel" use="required">
      <xs:simpleType>
        <xs:restriction base="xs:string">
          <xs:length value="20" />
        </xs:restriction>
      </xs:simpleType>
    </xs:attribute>
    <xs:attribute name="containerType" type="xs:string" use="optional" />
  </xs:complexType>
  <xs:complexType name="productListType">
    <xs:sequence>
      <xs:element name="serialNumber" type="serialNumberType" minOccurs="1" maxOccurs="unbounded" />
    </xs:sequence>
    <xs:attribute name="gtin" type="gtinType" use="required" />
    <xs:attribute name="lotNumber" type="serialNumberType" use="required" />
    <xs:attribute name="productionDate" type="xs:date" use="optional" />
    <xs:attribute name="expirationDate" type="xs:date" use="required" />
    <xs:attribute name="poNumber" type="xs:string" use="optional" />
  </xs:complexType>
  <xs:simpleType name="actionType">
    <xs:restriction base="xs:string">
```

```
<xs:enumeration value="P" /><!-- Mal Alim (product Purchase) -->
<xs:enumeration value="S" /><!-- Satis (diSpatch) -->
<xs:enumeration value="C" /><!-- Cancel Sale (dispatch Cancellation) -->
<xs:enumeration value="R" /><!-- Iade (Return) -->
<xs:enumeration value="D" /><!-- Deaktivasyon (Deactivation) -->
<xs:enumeration value="M" /><!-- Uretim (production/Manufacture) -->
<xs:enumeration value="I" /><!-- Ithalat (Importation) -->
<xs:enumeration value="X" /><!-- Ihrac (eXportation) -->
<xs:enumeration value="O" /><!-- Sarf (cOnsume) -->
<xs:enumeration value="N" /><!-- Bilgi (iNformation) -->
<xs:enumeration value="T" /><!-- Devir (Turnover) -->
<xs:enumeration value="L" /><!-- Devir Iptal (turnover cancelLlation) -->
<xs:enumeration value="F" /><!-- Aktarim (non-its transFer) -->
<xs:enumeration value="K" /><!-- Aktarim Iptal (non-its cancel transfer) -->
</xs:restriction>
</xs:simpleType>
<xs:simpleType name="glnType">
  <xs:restriction base="xs:string">
    <xs:pattern value="[0-9]{13}"/>
  </xs:restriction>
</xs:simpleType>
<xs:simpleType name="gtinType">
  <xs:restriction base="xs:string">
    <xs:pattern value="[0-9]{14}"/>
  </xs:restriction>
</xs:simpleType>
<xs:simpleType name="serialNumberType">
  <xs:restriction base="xs:string">
    <xs:pattern value="[0-9A-Z]{1,20}"/>
  </xs:restriction>
</xs:simpleType>
</xs:schema>
```