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| Guidance Document: Preparation of Regulatory Documents using the Structured Product Labelling (SPL) Standard – Common Guidance for all Document Types |
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Health Products and Food Branch



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| Our mission is to help the people of Canada maintain and improve their health.    Health Canada | The Health Products and Food Branch (HPFB)’s mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by:   * Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, * Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.   Health Products and Food Branch |

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**FOREWORD**

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance’s.

Document Revision History

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# Introduction

This document serves as the technical implementation guide and technical specification for the Health Product and Food Branch’s (HPFB) use of Health Level 7’s (HL7) Structured Product Label (SPL) standard.

This guidance document only includes the technical conformance and validation criteria common to all document types.

Document type specific information will not be included in this guidance. Each document type will have a separate guidance to provide details unique to that document type. Therefore, this guidance is to be read in conjunction with the guidance for the document type being prepared.

## Purpose

To provide guidance on the technical conformance and validation rules needed to prepare regulatory documents using the SPL standard.

## Scope

The following document types are eligible for filing using the SPL standard:

* Product Monograph
* Certified Product Information Document (CPID)

## Policy Objectives

The objective is to use structured data, international standards and controlled vocabularies to achieve the following:

* Manage information as a valuable asset to support the outcomes of programs and services, as well as operational needs and accountabilities.
* Make information more easily discoverable and reusable.
* Encourage the adoption of digital technology to improve access to information, increase efficiency and improve outcomes for patients.

## Background

The HPFB recognized that unstructured document formats, like Portable Document Format (PDF), could not adequately support our information management, digital health and open data objectives. We will therefore need to transition to more advanced technology formats.

Particular attention will be focused on formats that are open source and supported by international standards.

One such format is the Extensible Markup Language (XML). The HPFB’s use of XML will be in compliance with Health Level 7 (HL7) International’s standards.

### XML

XML is a text-based specification used to encode documents in a format that is both human and machine-readable. XML is used as a common format to facilitate the interchange of data over the Internet.

XML is a free open standard developed by the World Wide Web Consortium (W3C).

### HL7 International

Founded in 1987, HL7 is a not-for-profit standards development organization dedicated to providing standards for the exchange of electronic health information that supports clinical practice and the management of health services.

HL7 is supported by more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.

Health Canada is contributing member of HL7.

### SPL

SPL is a HL7 standard that can be used to structure documents using XML and a standard schema. Although SPL was originally designed to structure product labels, its use has since expanded to include other document types.

In the Canadian context, the Product Monograph document type is an example the ‘label’ or ‘the document’ that is being structured.

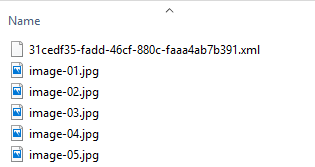
# General Structure and Content of Regulatory Documents in SPL

## Concepts

### XML, images and output folder structure

The SPL document is made up of a single .xml file containing all text based content and metadata. All images and graphics are stored external to the XML file as separate image files that accompany the XML (Refer to **Error! Reference source not found.** for an example).

**Figure 1 Sample of a Structured Product Monograph**



### Style sheet

A style sheet is a file or collection of files that describes how to display an XML document.

Together, a XML document and style sheet can be processed to produce multiple different output documents. These output documents can have different appearances and structures. The original XML source document remains unchanged.

### Schema

An XML schema describes the structure of an XML document.

The purpose of the schema is to define the acceptable building blocks of a given XML document:

* the elements and attributes that can appear in a document
* the number and order of child elements
* data types for elements and attributes
* default and fixed values for elements and attributes

### Validation

Validation is the process of checking a XML document against its schema to confirm that it is both well-formed and valid, as well as checking that the document conforms to various technical aspects such as having content in specific elements and that other elements are omitted.

A XML document is considered well formed if it conforms to XML syntax rules; e.g.,

* XML documents must have a root element
* XML elements must have a closing tag
* XML tags are case sensitive
* XML elements must be properly nested

A XML document is considered valid if it conforms to the XML schema. In this context the HPFB is following HL7’s SPL schema.

### Validation Approach

Validation is a multistep process based on the following phases:

1. Schema Checks: in this phase the document is checked against the associated schema. Should an error be encountered the validation terminates as the results of the validation are questionable.
2. Content checks: in this phase all SPL and doctype checking is performed. N.B. errors that cause a schema error are not included in the content checking.
3. Report Generation: in this phase the various aspects are integrated into a final human readable report.

### Validation Severity Ratings

When a document is validated a report is provided to show the results. Each issue identified in the report will be assigned one of the following three severity ratings:

1. Information: A minor issue has been identified. Information issues should be avoided in future but will not result in a validation failure.
2. Warning: A serious issue has been identified. Warnings can result in a validation failure, especially if they are numerous. Warnings should be corrected before the document is submitted to the HPFB.
3. Error: A critical issue has been identified. An Error results in an immediate validation failure. Errors must be corrected before the document is submitted to the HPFB.

### Rule Categories

The table below details the rule categories; several instances of a category may be used to detail the required validation rules.

**Table 1 SPL validation rule categories and labels**

| **Id** | **Category** | **Label** |
| --- | --- | --- |
| 0 | Debugging | Verification that the rule was invoked. |
| 1 | Schema Issue | The document is either not well formed or valid against the schema. |
| 2 | OID Issue | The codeSystem value is incorrect. |
| 3 | SPL: Omitted Element | An required element is missing. |
| 4 | SPL: Additional Element | An element has been included more than once. |
| 5 | SPL: Attribute Issue | A attribute is missing or included more than once. |
| 6 | SPL: Missing Information | The item (element or attribute) is empty or is missing mandatory aspects. |
| 7 | SPL: Data Inconsistency | The display name does not match the CV for the selected language. |
| 8 | SPL: Attribute Value Issue | The attribute value is set incorrectly or is not in the CV. |
| 9 | SPL: Element Value Issue | The element value is set incorrectly or is not in the CV. |
| 10 | SPL: Notification | There is a notification flag for the content. |
| 11 | SPL: Disallowed Content | Content is not allowed. |
| 12 | SPL: Content Formatting Issue | The content is incorrectly formatted. |
| 13 | SPL: Processing Instruction Issue | The Processing Instruction (PI’s) are either incomplete, incorrect or contextually incorrect. |
| 14 | SPL: Incorrect Context | The value is contextually incorrect. |
| 30 | DT: Omitted Element | An element is missing. |
| 31 | DT: Additional Element | An element has been included more than once. |
| 32 | DT: Attribute Issue | An attribute is missing or included more than once. |
| 33 | DT: Missing Information | The item (element or attribute) is empty or is missing mandatory aspects. |
| 34 | DT: Data Inconsistency | The display name does not match the CV for the selected language. |
| 35 | DT: Attribute Value Issue | The attribute value is set incorrectly or is not in the CV. |
| 36 | DT: Element Value Issue | The element value is set incorrectly or is not in the CV. |
| 37 | DT: Notification | There is a notification flag for the content. |
| 38 | DT: Disallowed Content | Content is not allowed. |
| 39 | DT: Content Formatting Issue | The content is incorrectly formatted. |
| 40 | DT: Processing Instruction Issue | The Processing Instruction (PI’s) are either incomplete, incorrect or contextually incorrect. |
| 41 | DT: Incorrect Context | The value is contextually incorrect. |

## Document Type and Template Type

A Document Type refers to the type of regulatory document. The Template Type refers to the subset(s) or variants within the document type category. E.g., A Product Monograph is one document type and a CPID is another document type. The *2016 Product Monograph – Schedule D* is a Template Type since it is a sub-type of the product monograph. The CPID – Chemical Entity (CPID-CE) is a Template Type since it is a sub-type of the CPID.

## Six Components of an SPL document

The following is a general outline of how SPL documents are structured. Certain aspects of this structure may change depending on the document type. Refer to the guidance for each specific document type for details.

**Table 2 Summary of the six sections that make up every SPM**

| **SPL Component** | | **Description** |
| --- | --- | --- |
| 1. | Prologue | Instructions to software programs; e.g., XML version, links to the style sheet and schema. |
| 2. | Document Information | Identifies the type of document, its unique identifier, its version and its language (French or English). |
| 3. | Author Information | Information about the sponsor; e.g., company name, unique company identifier, address and role. |
| 4. | Product Information | Brand name, dose form, proper/generic name, ingredients information, package type, unit of presentation, marketing status, route of administration |
| 5. | Content | Product monograph content (excluding images); e.g., section headings, paragraphs, formatting, text and tables. |
| 6. | Images | External references to accompanying images; e.g., chemical structure, instructions for use. |

# Controlled Vocabularies

A controlled vocabulary is an established list of standardized, predefined and authorized terms used for indexing and information retrieval. A controlled vocabulary ensures that a subject will be described using the same term each time it is indexed, making it easier to find all information about a specific topic during the search process. They are controlled using a defined governance model, policies, guidance and change control procedures.

All SPL documents rely on controlled vocabularies to a certain extent. Refer to the guidance specific to each document type for details on which controlled vocabularies or terms are applicable and in what context.

Refer to the *Guidance Document: Controlled Vocabulary Governance* [Not yet available] for details on the HPFB’s controlled vocabulary governance framework and change control procedures.

# Technical Requirements for Regulatory Documents in SPL

## Conformance rules for all document types

### Output folder structure, contents and file naming

Each instance of an SPL document shall be stored in a unique folder to avoid filename collisions between SPL documents. Each folder shall contain a .xml file and all accompanying image files. Image files shall be named uniquely to avoid duplication or file name collisions within an SPL document.

### Identifiers

Unless stated otherwise (e.g., Hyperlink ID or Observation Media ID), identifiers shall be Globally Unique Identifiers (GUID). This includes but is not limited to the following:

* Document Root ID
* ID
* SetId
* Section ID

GUID’s should follow the canonical structure, content and formatting rules; e.g., displayed in five groups separated by hyphens, in the form 8-4-4-4-12 for a total of 36 characters (32 alphanumeric characters and four hyphens).

It is the sponsor’s responsibility to ensure that there are no collisions between identifiers.

### Content Changes and Versioning

Any change to content requires an update to the effectiveTime and/or the identifier.

In the case where the content change occurs in an element that does not have an identifier or effectiveTime then the parent element must be versioned. However, the versioning requirement is limited to the closest version-able parent. The versioning does not roll up. Examples of versioning:

1. Changing an image would require the observationMedia@ID to be versioned.
2. Changing the content of a section would require both the section@ID and the effectiveTime@value of the section to be versioned.
3. Changing the content of a section would require both the section@ID and the effectiveTime@value of the section to be versioned.
4. Changing the content of a subsection would require both the section@ID and the effectiveTime@value of the subsection to be versioned, however the parent section would not be versioned as the child contains both an ID and an effectiveTime element.

### File Type

Only file formats detailed in the table below are permitted in the SPL output:

**Table 3 List of acceptable file types**

| **File Format** | **Description** | **Specifications** | **Extension** |
| --- | --- | --- | --- |
| JPEG/JFIF | Joint Photographic Experts Group (JPEG) / JPEG File Interchange Format (JFIF) is a compression standard for encoding and exchanging still digital raster files. | ISO 10918-1 | jpg |
| PDF/A-1 | Portable Document Format Archive version 1, is an archival format designed for long term preservation of digital files based on Adobe PDF v1.4 | ISO 19005-1 | pdf |
| PDF/A-2 | Portable Document Format Archive version 2, is an archival format designed for long term preservation of digital files based on Adobe PDF v1.7 | ISO 19005-2 | pdf |
| XML | Extensible Markup Language (XML) is a markup language that defines document encoding rules. | W3C XML 1.0 | xml |

# Validation Rules: Overall Document

## General Notes

### Elements

When the validation rules are context sensitive (e.g., an element can appear in multiple places within the document) then a dot (.) notation has been used to provide the context. E.g., contactParty (representedOrganization.contactParty and assignedOrganization.contactParty respectively).

Elements that neither contain content nor attributes (E.g., assignedEntity) are not directly validated. Rather, they are validated by the lack of a required child element. Therefore, they are omitted from this document.

Any element not explicitly mentioned in the validation rules can be left empty where permitted by the schema. If the element cannot be left empty it can be removed. N.B. Note this does not mean non-referenced non-validated elements are not permitted. It means they are optional from a business perspective.

Refer to document type guidance for details on what elements are mandatory or option. .

### Visual Aids

The following visual aids are used in the validation rules section to assist the user:

* The element tables identify the rules related to a specific xml element.
* Numbers (1) are used to detail technical conformance requirements; validation rules are detailed directly below the requirements and are organized using letters (a).
* Comments are used to provide further instructions or notes to the reader.

## General Validation Rules

This section will outline general validation rules that apply to the overall document.

### SPL File name

SPL file name is the document id (the value of id@root in the document information section) followed by “.xml”

The SPL content (e.g., xml and images) must always be placed in a single SPL folder (Refer to Section 2.1.1).

The .xml file must be named with GUID from the documentID.

It is the sponsor’s responsibility to ensure there are no content naming collisions between any of the files in the SPL folder.

### SPL Output Folder

The SPL output folder contains only the SPL file and associated files referenced in the .xml.

### External File References

All files associated with the SPL document are referenced in the .xml.

### Well Formed and Valid

The XML is well formed and valid against the schema.

SPL Rule 1 identifies the outcome of the validation for both well formedness and validity of the document.

### Codes

There are no spaces in codes.

*N.B. There is currently no single rule that validates that there are no spaces in a code.*

### Case Sensitivity

The case sensitivity rules for display names are document specific.

All validation is case sensitive, however there is no general case sensitivity rule.

### Display Name

All displayNames are language specific and when derived from a CV they shall be based on the language of the document.

*N.B. there is no general language rule.*

### Id extensions

There are no spaces in id extensions.

N.B. currently there are no validation aspects for spaces in id extensions, however it is planned.

### Processing Instructions

There are no Processing Instructions included in the SPL file.

*N.B. currently there are no validation aspects for Processing Instructions, however it is planned.*

### Schema and Style Sheet

The schema and style sheet are a pure adaptation of the HL7 schema.

*N.B. there is no validation aspect.*

### Images

Images shall be of sufficient quality and size to be legible in the intended context by a user. All images will be displayed as is without transformation or modification.

*N.B. there is no validation aspect.*

### Time

Time values (such as effectiveTime@value, [effectiveTime.low@value](mailto:effectiveTime.low@value) and effectiveTime.high@value) are based on ISO-8601. They use the following format YYYYMMDDHHMMSS+”GMT offset”.

All values other than the + symbol are integers; the time aspect is based on a 24hr notation; and, unless specified otherwise, use the Time Zone offset assumed to be GMT time.

YYYY represents the year and is 4 digits; MM represents the month and is 2 digits; DD represents the day and is 2 digits; HH represents the hour and is 2 digits; MM represents the minutes and is 2 digits; SS represents the seconds and is 2 digits.

The time may be followed by a + (plus) or a - (minus) symbol and a Time Zone offset from GMT expressed as 4 digits. While the ISO standard provides many options the HPFB only allows for the following three permutations on time values:

1. Date Only: in this model the string is limited to YYYYMMDD
2. Date and GMT Time: in this model the string is limited to YYYYMMDDHHMMSS
3. Date and Local Time: in this model the GMT offset is added as an example YYYYMMDDHHMMSS-0500 represents EST. The offset is static and therefore must be manually adjusted for Daylight Saving Time as appropriate.

*N.B. validation is performed at the element level and is doctype specific.*

### Controlled Vocabularies

Controlled vocabulary terms shall only be used as applicable. The sponsor is responsible for ensuring that correct controlled vocabulary terms are used in the appropriate context.

This guidance and the document type guidance will identify when scope constraints are applicable to a term. The majority of the scope constraints are at the document type or template type level. E.g., an NDS cannot use superseded or prohibited terms. Only preferred terms are allowed for use in that context.

SPL Rule 13 and SPL rule 14 are used to validate the context of controlled vocabulary terms (Refer to **Table 1**).

# Validation Rules: Components

This section details the technical and validation aspects for HPFB SPL documents.

## Prolog/Declaration

This section will outline the XML prolog, it must be the first part of the SPL file.

### XML

Outlined below is an example of the prolog/declaration:

<?xml version="1.0" encoding="UTF-8"?>

<?xml-stylesheet type="text/xsl" href="<https://raw.githubusercontent.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Schema/current/SPL.xsd>"?>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| ?xml | N/A | 1:1 |  | XML declaration aspects, this is used to identify the XML version and character encoding. |
| Version | 1:1 |  |  |
| Encoding | 1:1 |  |  |
| Conformance | 1. The version must be 1.0 2. N.B. currently there are no validation aspects for the Prolog/Declaration, however it is planned. 3. The encoding must be UTF-8 4. N.B. currently there are no validation aspects for the Prolog/Declaration, however it is planned. 5. There are no comments or annotations 6. N.B. currently there are no validation aspects for the Prolog/Declaration, however it is planned. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| document | N/A | 1:1 |  | This is the root of the document and details the name space, the schema and the location of the schema.  Additionally, it provides a method to encode document level metadata such as the document type, template type, document language, document version and the document ID |
| xmlns | 1:1 |  |  |
| xmlns:xsi | 1:1 |  |  |
| xsi:schemaLocation | 1:1 |  |  |
| Conformance | 1. There is a document element 2. N.B. currently there are no validation aspects for the document element, however it is planned. 3. There is a name space 4. N.B. currently there are no validation aspects for the name space, however it is planned. 5. The name space is urn:hl7-org:v3 6. N.B. currently there are no validation aspects for the name space, however it is planned. 7. There is a name space for the schema 8. N.B. currently there are no validation aspects for the name space, however it is planned. 9. The name space for the schema is: <http://www.w3.org/2001/XMLSchema-instance> 10. N.B. currently there are no validation aspects for the name space, however it is planned. 11. The schema location is identified 12. N.B. currently there are no validation aspects for the name space, however it is planned. 13. The schemaLocation of the urn:hl7-org:v3 namespace is provided as: <https://raw.githubusercontent.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Schema/current/SPL.xsd> 14. N.B. currently there are no validation aspects for the name space, however it is planned. 15. There are no processing instructions other than the xml and xml-stylesheet declarations 16. N.B. currently there are no validation aspects for the name space, however it is planned. 17. There are no comments 18. N.B. currently there are no validation aspects for the name space, however it is planned. 19. There is a typeId element 20. An instance of Rule Category 3 identifies that the typeId element has not been defined.      1. There is one or more templateId elements 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. There is an id element 4. N.B. there are no validation aspects. 5. There is a code element 6. N.B. there are no validation aspects. 7. There is an effectiveTime element 8. N.B. there are no validation aspects. 9. There is a languageCode element 10. An instance of Rule Category 3 identifies that the element has not been defined. 11. There is a setId element 12. Rule SPL-Rule-3001 (Rule Category 3) identifies that the element has not been defined.      1. There is a versionNumber element 2. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| ?xml-stylesheet | N/A | 1:n | N/A | The formatting related aspects are captured in this Processing Instruction (PI) to ensure consistency. |
| Conformance | 1. There must be both a XSL and CSS stylesheet definition. 2. N.B. validation is doctype specific. | | | |

## Document Information

Outlined in this section are all aspects relating to the Document Information (applicable to the overall document). The Document Information provides the identity of the particular document, its type, template, title, date and versioning as a member of a document set.

### XML

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| templateId | N/A | 1:n |  | Provides an ID for the document template as well as optionally the submission control number and other document metadata. |
| Root | 1:1 |  |  |
|  | Extension | 1:1 |  |  |
| Conformance | 1. templateId elements contain a root attribute and an extension attribute. 2. An instance of Rule Category 5 identifies that the (root) attribute has not been defined. 3. An instance of Rule Category 5 identifies that the (extension) attribute has not been defined. 4. There will be a templateId element where the root attribute value is: 2.16.840.1.113883.2.20.6.9 and the value of the extension attribute derived from the OID. This captures the template that the document is based on. 5. SPL-Rule-2001 (Rule Category 2) identifies that the OID value is incorrect. 6. SPL-Rule-8001 (Rule Category 8) identifies that the extension value is not in the CV. 7. An instance of Rule Category 14 identifies that the extension value is contextually incorrect. 8. An instance of Rule Category 10 identifies that there is a notification flag for the content. 9. There may be additional templateId elements as per the doctype specifications. 10. N.B. validation is doctype specific. | | | |

Outlined below is an example of the document information:

<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 <https://raw.githubusercontent.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Schema/current/SPL.xsd>">

<typeId assigningAuthorityName=”Health Products and Food Branch”/>

<templateId extension="1" root="2.16.840.1.113883.2.20.6.9"/>

<templateId extension="314" root="2.16.840.1.113883.2.20.6.11"/>

<templateId extension="1234A" root="2.16.840.1.113883.2.20.6.49"/>

<id root="a6c469cf-5820-48a8-b140-f8f4d63f5600"/>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.10"/>

<title=”Lipitor”/title>

<effectiveTirme value="20170629235959-0600"/>

<languageCode code="ENG" codeSystem="2.16.840.1.113883.2.20.6.29"/>

<setId root="a30accef-f437-4136-808c-9ed4ada5fcf8"/>

<versionNumber value=“1” description="12"/>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| typeId | N/A | 1:1 |  | Identifies that the document is a HPFB specified document |
| assigningAuthorityName | 1:1 |  |  |
|  |  |  |  |  |
| Conformance | 1. There is a assigningAuthorityName attribute with a value of: Health Products and Food Branch 2. An instance of Rule Category 5 identifies that the (assigningAuthorityName) attribute has not been defined. 3. An instance of Rule Category 8 identifies that the (assigningAuthorityName) attribute value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| code | N/A | 1:1 |  | Details the Document Type (i.e. what is the content of the document).  It is used to document the business document type not the specific template (i.e. PM not the 2004 Standard temple) |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| Conformance | 1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.10. 2. SPL-Rule-2002 (Rule Category 2) identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL-Rule-8002 (Rule Category 8) identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| id | N/A | 1:1 |  | Provides a globally unique ID for the document. |
| Root | 1:1 |  |  |
| Formation Conformance | 1. There is an root attribute 2. SPL-Rule-5001 (Rule Category 5) identifies that the (root) attribute has not been defined. 3. The id@root is a GUID and does not have an extension 4. N.B. as per section 1.4 ID Related there is currently no validation of GUID’s, this will be introduced later. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| title | N/A | 0:1 |  | Provides the title for the document. |
| Conformance | 1. There may be a title element. 2. N.B. validation is doctype specific. 3. The title is free form 4. N.B. there are no validation aspects. 5. There are no figures in the title. 6. N.B. There is currently no validation of titles, this will be introduced later. 7. There are no images in the title. 8. N.B. There is currently no validation of titles, this will be introduced later. 9. Multiple lines may be used in the title with each line separated by a line break <br/> tag. (note: titles can also be as follows: <title mediaType="text/x-hl7-title+xml">). 10. N.B. There is currently no validation of titles, this will be introduced later. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| effectiveTime | N/A | 1:1 |  | Used to capture relevant date information.  Please refer to the Doctype for specific details on the usage. |
| Value | 1:1 |  |  |
| Conformance | 1. There is either a direct or indirect value for the effectiveTime 2. An instance of Rule Category 6 identifies that there is no value defined either directly or via a child element. 3. The effectiveTime@value has as a minimum precision of day and follows the appropriate format. 4. N.B. validation is doctype specific. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| languageCode | N/A | 1:1 |  | Specifies the language of the document |
| Code | 1:1 |  |  |
|  | codeSystem | 1:1 |  |  |
| Conformance | 1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.29. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| setId | N/A | 1:1 |  | Unique identifier for the document that remains constant through all versions/revisions of the document. |
| root | 1:1 |  |  |
| Conformance | 1. There is a root attribute 2. SPL-Rule-5002 (Rule Category 5) identifies that the (root) attribute has not been defined. 3. The setId@root is a GUID and does not have an extension. 4. N.B. as per section 1.4 ID Related there is currently no validation of GUID’s, this will be introduced later. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| versionNumber | N/A | 1:1 |  | The version of the document. |
| value | 1:1 |  |  |
| Conformance | 1. There is a value attribute which is an integer greater than zero that provides a sequence to the versions of the document 2. An instance of Rule Category 5 identifies that the (value) attribute has not been defined. 3. An instance of Rule Category 8 identifies that the versionNumber@value is 0. 4. An instance of Rule Category 8 identifies that the versionNumber@value is not an integer. 5. The value of value must be incremented by 1 for each version of a document with the same setID@root 6. N.B. currently this is not validated, however it is planned to introduce this in the future. 7. There may be description attribute derived from the OID: 2.16.840.1.113883.2.20.6.37. This captures the document status. 8. An instance of Rule Category 8 identifies that the extension value is not in the CV. 9. An instance of Rule Category 10 identifies that there is a notification flag for the content. 10. An instance of Rule Category 14 identifies that the extension value is contextually incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| author | N/A | 1:1 |  | Wrapper element for all organizational aspects. |
| Conformance | Due to the complexity of this element it has been detailed in the Author Information section. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component | N/A | 1:1 |  | Wrapper element for all section related aspects. |
| Conformance | Due to the complexity of this element it has been detailed in several sections primarily the Labeling Content Section Information and the Product Data Informationsections. | | | |

## Author Information

Outlined in this section are all aspects relating to the author aspects for the document

### XML

Outlined below is an overview of the structure for the author information:

<document>

<author>

<assignedEntity>

<representedOrganization> <!— Sponsor -->

<assignedEntity>

<assignedOrganization> <!— Other parties as required-->

The following is a representative example for the author aspect:

<author>

<time/>

<assignedEntity>

<representedOrganization>

<id root="2.16.840.1.113883.2.20.6.31" extension="999999999"/>

<name>Acme Inc.</name>

<contactParty>

<addr>

<streetAddressLine>12 ApplewoodAve</streetAddressLine>

<city>Ottawa</city>

<state>Ontario</state>

<postalCode>K1S 0B5</postalCode>

<country codeSystem="2.16.840.1.113883.2.20.6.17" code="1"/>

</addr>

<telecom value="tel:+1-613-239-9919"/>

<telecom value="mailto:a@b.com"/>

<contactPerson>

<templateId root="2.16.840.1.113883.2.20.6.18" extension="11"/>

<name>

<title>Mr.</title>

<given>John</given>

<family>Doe</family>

</name>

</contactPerson>

</contactParty>

<assignedEntity>

<assignedOrganization>

<assignedEntity>

<assignedOrganization>

<id root="2.16.840.1.113883.2.20.6.31" extension="999999999"/>

<name>Bell Canada</name>

<telecom value="tel:+1-613-239-9009"/>

<telecom value="mailto:c@b.com"/>

<addr>

<streetAddressLine>122 ApplewoodAve</streetAddressLine>

<city>Ottawa</city>

<state>Ontario</state>

<postalCode>K1S 0B3</postalCode>

<country codeSystem="2.16.840.1.113883.2.20.6.17" code="1/>

</addr>

<contactParty>

<contactPerson>

<name>

<family>Last</family>

<given>Fred</given>

</name>

</contactPerson>

</contactParty>

</assignedOrganization>

</assignedEntity>

</assignedOrganization>

<performance>

<actDefinition>

<code code="8" codeSystem="2.16.840.1.113883.2.20.6.33"/>

<product>

<manufacturedProduct classCode="MANU">

<manufacturedMaterialKind>

<templateId root="2.16.840.1.113883.2.20.6.14" extension="A-160621"/>

<code code="123-1234" codeSystem="2.16.840.1.113883.2.20.6.55"/>

</manufacturedMaterialKind>

</manufacturedProduct>

</product>

</actDefinition>

</performance>

</assignedEntity>

</representedOrganization>

</assignedEntity>

</author>

Organizations are identified using HPFB Company IDs. These are identifiers with the root 2.16.840.1.113883.2.20.6.31 and an extension as illustrated below:

<representedOrganization>

<id extension=“Company ID” root="2.16.840.1.113883.2.20.6.31"/>

Outlined below is an example of the contactPerson element:

<contactPerson>

<templateId root="2.16.840.1.113883.2.20.6.18" extension="11"/>

<name>

<title>Mr.</title>

<given>John</given>

<family>Doe</family>

</name>

</contactPerson>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| Author | N/A | 1:1 |  | The root of the organization tree, it details all aspect relating to organizations including locations, roles, relationship to products, and substances. |
| Conformance | 1. There is an author element 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. An instance of Rule Category 4 identifies that more than one element is defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| Time | N/A | 0:1 |  |  |
| Conformance | 1. There may be a time element 2. N.B. currently this is not validated. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedEntity | N/A | 0:1 |  | This is a placeholder element. |
| Conformance | 1. There is an assignedEntity element 2. N.B. currently this is not validated. 3. There is an representedOrganization element 4. N.B. there are no validation aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization | N/A | 1:1 |  | This is the root of the accountable party, they may delegate to other parties via child elements. It captures all information directly relating to the party including: name, ID, location, etc …  Please note that if the accountable party also performs activities there must be a corresponding assignedEntity element. |
| Conformance | 1. The representedOrganization will contain one or more actDefinition elements, one of which must contain [actDefinition.code@code=’1](mailto:actDefinition.code@code='1)’ and [actDefinition.code@codeSystem=’2.16.840.1.113883.2.20.6.33](mailto:actDefinition.code@codeSystem='2.16.840.1.113883.2.20.6.33)’ and include all covered products. 2. An instance of Rule Category 3 identifies that the DIN Owner role is missing. 3. An instance of Rule Category 4 identifies that there is more than one DIN Owner defined. 4. The representedOrganization must contain an id element that has an id@root value of 2.16.840.1.113883.2.20.6.31, and an extension value containing a valid Company ID number or a “Pending” value derived from OID: 2.16.840.1.113883.2.20.6.31. 5. An instance of Rule Category 2 identifies that the OID value is incorrect. 6. An instance of Rule Category 5 identifies that the (root) attribute has not been defined. 7. An instance of Rule Category 5 identifies that the (extension) attribute has not been defined. 8. An instance of Rule Category 8 identifies that more than one company ID has been assigned 9. An instance of Rule Category 8 identifies that the company ID is not in the CV or “Pending”. 10. An instance of Rule Category 10 identifies that there is a notification flag for the content.      1. The representedOrganization will contain a name element. 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. An instance of Rule Category 6 identifies that the name is empty. 4. An instance of Rule Category 8 identifies that the code is not in the CV. 5. An instance of Rule Category 14 identifies that the name does not match the name of the representedOrginization. 6. The representedOrganization will contain a contactParty element. 7. An instance of Rule Category 3 identifies that the element has not been defined. 8. The representedOrganization may contain one or more assignedEntity elements as per the doctype specifics 9. N.B. validation is doctype specific. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.assignedEntity | N/A | 0:1 |  | This is a placeholder element. |
| Conformance | 1. There is an assignedOrganization element 2. N.B. there are no validation aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.assignedEntity.assignedOrganization | N/A | 0:1 |  | This is a placeholder element. |
| Conformance | 1. There is an assignedEntity element 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. An instance of Rule Category 4 identifies that the element has been defined more than once. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.assignedEntity.assignedOrganization.assignedEntity | N/A | 0:1 |  | This is the root for delegated/assigned organizations as well as the role they are assigned with respect to products and substances. |
| Conformance | 1. There is one or more assignedOrganization elements 2. N.B. there are no validation aspects. 3. There is one or more performance elements.   a) N.B. validation is performed at the element level. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.assignedEntity.assignedOrganization.assignedEntity.assignedOrganization | N/A | 0:n |  | This is the root of the assigned party, they may delegate to other parties via child elements.  It captures all information directly relating to the party, including: name, ID, location, etc … |
| Conformance | 1. The assignedOrganization must contain an id element that has an id@root value of 2.16.840.1.113883.2.20.6.31, and an extension value containing a valid Company ID number derived from OID: 2.16.840.1.113883.2.20.6.31 or a value of 999999999 to indicate that the Company ID is Not Available. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (root) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (extension) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the company ID is not in the CV or 999999999. 6. An instance of Rule Category 10 identifies that there is a notification flag for the content. 7. An instance of Rule Category 8 identifies that there is no company ID. 8. An instance of Rule Category 8 identifies that more than one company ID is identified. 9. The assignedOrganization shall contain a name element. 10. An instance of Rule Category 3 identifies that the element has not been defined. 11. The assignedOrganization may contain a telecom element. 12. N.B. there is no validation of optional aspects. 13. The assignedOrganization may contain a contactParty element. 14. N.B. there is no validation of optional aspects. 15. The assignedOrganization may contain one or more assignedEntity elements. 16. N.B. validation is performed at the element level. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| performance | N/A | 0:n |  | The root of identifying the relationship between a party, role product and substance. |
| Conformance | 1. The performance shall contain an actDefinition element. 2. N.B. validation is performed at the element level. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| actDefinition | N/A | 1:1 |  | Identifies a single role and contains one or more products or packages where the party performed the specific role.  Note: to express complex relationships several actDefinition elements may be required. |
| Conformance | 1. The actDefinition shall contain a code element. 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. The actDefinition.code element shall contain code and codeSystem attributes derived from OID 2.16.840.1.113883.2.20.6.33, this captures the specified role. 4. An instance of Rule Category 2 identifies that the OID value is incorrect. 5. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 6. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 7. An instance of Rule Category 8 identifies that the code is not in the CV. 8. An instance of Rule Category 10 identifies that there is a notification flag for the content. 9. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 10. The actDefinition shall contain one or more product elements, these are encapsulated in a manufacturedMaterialKind.code detailing the MPID or PCID of the item. 11. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| product | N/A | 0:1 |  | Root for the Manufactured Product, several product elements may be required. |
| Conformance | 1. There is a manufacturedProduct element, with a classCode attribute value of MANU. 2. An instance of Rule Category 2 identifies that the classCode value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| product.manufacturedProduct | N/A | 1:1 |  | Identifies the specific product, using the MPID or PCID. |
| Conformance | 1. There is a manufacturedMaterialKind element, it is the root of a specific product. 2. An instance of Rule Category 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. If the [manufacturedMaterialKind.code@code](mailto:manufacturedMaterialKind.code@code) value relates to a substance then there will be manufacturedMaterialKind.templateId element. Otherwise the manufacturedMaterialKind.templateId element is optional. 4. N.B. there is no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedMaterialKind.templateId | N/A | 0:1 |  | Captures the specific substance(s) where the role is applicable.  Note: This aspect is only used where the role not applicable at the product or package level but scope constrained to substance(s) in a package or product. |
| Conformance | 1. There maybe one or more manufacturedMaterialKind.templateId element where the root attribute value is: 2.16.840.1.113883.2.20.6.14 and the value of the extension attribute derived from the OID. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (root) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (extension) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the extension is not in the CV. 6. An instance of Rule Category 10 identifies that there is a notification flag for the content. 7. An instance of Rule Category 14 identifies that the extension value is contextually incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedMaterialKind.code | N/A | 0:1 |  | Captures the specific package or product where the role is applicable. |
| Conformance | 1. The manufacturedMaterialKind.code element shall contain code and codeSystem attributes derived from OID 2.16.840.1.113883.2.20.6.55 or 2.16.840.1.113883.2.20.6.56. 2. An instance of Rule Category 4 identifies that the element has been defined more than once. 3. An instance of Rule Category 2 identifies that the OID value is incorrect. 4. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 5. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 6. An instance of Rule Category 10 identifies that there is a notification flag for the content. 7. An instance of Rule Category 14 identifies that the code value is contextually incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedEntity | N/A | 0:1 |  | This is a placeholder element. |
| Conformance | 1. There may be one or more assignedOrganization elements 2. N.B. there is no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| id | N/A | 1:n |  | Captures the organization’s ID and overall role. |
| extension |  |  |  |
| Root |  |  |  |
| Conformance | This is validated as part of the representedOrganization and assignedOrganization elements. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| name | N/A | 1:1 |  | Captures the organization’s name |
| Conformance | 1. The name shall contain the business name that was assigned the id@extension value (sibling id element where root="2.16.840.1.113883.2.20.6.31"). 2. An instance of Rule Category 6 identifies that the name is empty. 3. An instance of Rule Category 8 identifies that name does not match the id@extension value. 4. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asNamedEntity | N/A | 1:1 |  | Used to identify alternative names at the company level. |
| Conformance | N.B. currently this is not validated, however it is planned to introduce this in the future. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.contactParty | N/A | 0:n |  | Captures details on location and communication with the organization as well as the root for the person aspect. |
| Conformance | 1. The contactParty shall contain an addr element 2. N.B. validation is performed at the element level. 3. The contactParty may contain a telecom element 4. N.B. there is no validation of optional aspects. 5. The contactParty may contain a contactPerson element 6. N.B. there is no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedOrganization.contactParty | N/A | 0:n |  | Captures details on location and communication with the organization as well as the root for the person aspect. |
| Conformance | 1. The contactParty may contain an addr element 2. N.B. there are no validation of optional aspects. 3. The contactParty may contain a telecom element 4. N.B. there are no validation of optional aspects. 5. The contactParty may contain a contactPerson element 6. N.B. there are no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.addr | N/A | 0:1 |  | The address for the accountable party |
| Conformance | 1. There shall be an addr element 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. There shall be a complete address 4. An instance of Rule Category 3 identifies that the element has not been defined. 5. An instance of Rule Category 9 identifies that there are not 5 elements in the address, therefore some aspect is missing. 6. The addr shall contain a streetAddressLine. 7. An instance of Rule Category 3 identifies that the element has not been defined. 8. An instance of Rule Category 6 identifies that the element is empty. 9. The addr shall contain a city. 10. An instance of Rule Category 3 identifies that the element has not been defined. 11. An instance of Rule Category 6 identifies that the element is empty. 12. The addr shall contain a state. 13. An instance of Rule Category 3 identifies that the element has not been defined. 14. An instance of Rule Category 6 identifies that the element is empty. 15. The addr shall contain a postalCode. 16. An instance of Rule Category 3 identifies that the element has not been defined. 17. An instance of Rule Category 6 identifies that the element is empty. 18. The addr shall contain a country element 19. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedOrganization .addr | N/A | 0:1 |  | The address for any other party |
| Conformance | 1. There may be an addr element 2. N.B. there is no validation of optional aspects. 3. The addr element may contain a streetAddressLine element. 4. N.B. there is no validation of optional aspects. 5. The addr element may contain a city element. 6. N.B. there is no validation of optional aspects. 7. The addr element may contain a state element. 8. N.B. there is no validation of optional aspects. 9. The addr element may contain a postalCode element. 10. N.B. there is no validation of optional aspects. 11. The addr element may contain a country element. 12. N.B. there is no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| streetAddressLine | N/A | 0:1 |  | Captures the number, apartment, unit, P.O Box as well as the street name or number. |
| Conformance | 1. The element conveys information. 2. An instance of Rule Category 6 identifies that the element is empty. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| city | N/A | 0:1 |  | Captures the city or area information. |
| Conformance | 1. The element conveys information. 2. An instance of Rule Category 6 identifies that the element is empty. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| state | N/A | 0:1 |  | Captures the state, province, region information. |
| Conformance | 1. The element conveys information. 2. An instance of Rule Category 6 identifies that the element is empty. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| postalCode | N/A | 0:1 |  | Captures Postal Code and Zip Code information. |
| Conformance | 1. The element conveys information. 2. An instance of Rule Category 6 identifies that the element is empty. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| country | N/A | 0:1 |  | Captures the country code information. |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| Conformance | 1. The country element shall contain code and codeSystem attributes derived from OID 2.16.840.1.113883.2.20.6.17. 2. An instance of Rule Category 4 identifies that the element has been defined more than once. 3. An instance of Rule Category 2 identifies that the OID value is incorrect. 4. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 5. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 6. An instance of Rule Category 8 identifies that the code is not in the CV. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. 8. An instance of Rule Category 14 identifies that the code value is contextually incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| telecom | N/A | 0:n |  | Captures telco and email contact details, including the device capability and type. |
| value | 1:1 |  |  |
|  | use | 0:1 |  |  |
|  | capability | 0:1 |  |  |
| Conformance | 1. The telecom@value attribute shall have contain a type id followed by : then a string, the type id shall be derived from OID 2.16.840.1.113883.2.20.6.51 2. An instance of Rule Category 5 identifies that the (value) attribute has not been defined. 3. An instance of Rule Category 8 identifies that the type id is not in the CV. 4. An instance of Rule Category 10 identifies that there is a notification flag for the content. 5. An instance of Rule Category 12 identifies that the content is incorrectly formatted. 6. An instance of Rule Category 14 identifies that the type id value is contextually incorrect. 7. The telecom@use attribute shall only contain values from OID: 2.16.840.1.113883.2.20.6.4 8. An instance of Rule Category 8 identifies that the use is not in the CV. 9. An instance of Rule Category 10 identifies that there is a notification flag for the content. 10. An instance of Rule Category 14 identifies that the use value is contextually incorrect. 11. The telecom@capability attribute shall only contain values from OID: 2.16.840.1.113883.2.20.6.19 12. An instance of Rule Category 8 identifies that the capability is not in the CV. 13. An instance of Rule Category 10 identifies that there is a notification flag for the content. 14. An instance of Rule Category 14 identifies that the capability value is contextually incorrect. 15. All telecom attribute values shall use ITU-T E.123 or <username>@<dns-name> notation as an example: +1 613 960 7510 or +1 613 960 7510; ext. 343 or jsmit@i.ca. The number is a global number and therefore must include the country and area code. 16. An instance of Rule Category 12 identifies that the content is incorrectly formatted. 17. The only alpha characters permitted for attribute values are ext, +, @. “ext” shall be used to preface extensions, + to prepend numbers, @ to separate the uid for dns in emails, all other content shall be white space or numeric. White space may be used to delineate numbers or number groups. 18. An instance of Rule Category 12 identifies that the content is incorrectly formatted. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| contactPerson | N/A | 1:1 |  | The root aspect for the persons name information. |
| Conformance | 1. The contactPerson may contain a templateId element. 2. N.B. validation is performed at the element level. 3. The contactPerson shall contain a name element 4. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| name | N/A | 1:1 |  | The first and last name of the person. |
| Conformance | 1. The name element shall as a minimum consist of a name.family and name.given elements 2. An instance of Rule Category 3 identifies that the (name.family) element has not been defined. 3. An instance of Rule Category 4 identifies that the (name.family) element has been defined more than once. 4. An instance of Rule Category 3 identifies that the (name.given) element has not been defined. 5. An instance of Rule Category 4 identifies that the (name.given) element has been defined more than once. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| templateId | N/A | 0:1 |  | Captures the role of the contact in the context of the organization and document. |
| Conformance | 1. There maybe a templateId element where the root attribute value is: 2.16.840.1.113883.2.20.6.18 and the value of the extension attribute derived from the OID. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (root) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (extension) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the extension is not in the CV. 6. An instance of Rule Category 10 identifies that there is a notification flag for the content. 7. An instance of Rule Category 14 identifies that the extension value is contextually incorrect. | | | |

## Core Document Reference

For some SPL documents it is permitted to specify a “core document” reference. A document with a core document reference “inherits” all the sections from the referenced core document and may override certain top-level sections with its own sections. A core document reference is specified as follows:

### XML

Outlined below is an example of a core document reference:

<document> ...

<author .../>

<relatedDocument typeCode="APND">

<relatedDocument>

<setId root="20d9b74e-e3d8-4511-9df9-cec2087372fc"/>

<versionNumber value="1"/>

</relatedDocument>

</relatedDocument>

<component .../>

</document>

The reference contains the setId of the referenced core-document. The document and the core-document can develop independently. The core-document may be updated, but the reference remains to the latest core-document with the same setId. The version number in the reference may be provided to indicate which version of the core-document was used when at the time the referencing document was created or modified.

### Validation

Currently out of scope for the HPFB implementation therefore should not be used. Currently not validated.

## Predecessor Document

Other documents may be merged into this document by providing a reference to the other predecessor documents that are replaced by this document.

### XML

Outlined below is an example of a predecessor document:

<document>

...

<author .../>

<relatedDocument typeCode="RPLC">

<relatedDocument>

<id root="464239de-45c7-4d2f-a89a-45d303f428bd"/>

<setId root=“9ea75e1e-84ef-4605-89ff-dd08a4c94f40”/>

<versionNumber value=“3”/>

</relatedDocument>

</relatedDocument>

<component .../>

</document>

### Validation

Currently out of scope for the HPFB implementation therefore should not be used. Currently not validated.

## Document Body

The body of the document includes the structured text such as Warnings and Precautions (Refer to section *6.7 Labeling Content Section Information*) and specific data elements such as ingredients (Refer to section *6.10 Product Data Information*).

### XML

Outlined below is the structure of the document:

<document>

<author .../>

<component>

<structuredBody>

## Labeling Content Section Information

Outlined in this section are all aspects relating to the SPL documents content.

### XML

Outlined below is an example of a section:

<section ID="62abedf9-6bde-4787-beb0-abd214309427"/> >

<id root="62abedf9-6bde-4787-beb0-abd214307427"/>

<code code="190" codeSystem="2.16.840.1.113883.2.20.6.8"/>

<title>Indications and Clinical Use</title>

<text> Indications and Clinical Use text</text>

<effectiveTime value="20070822"/>

<component/>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| section | N/A | 0:n |  | Element that wraps the sections or subsections, there structure is doctype dependant. |
|  | ID | 1:1 |  | The section ID provides a globally unique ID for a specific section. |
| Conformance | 1. Each section has zero to many section elements (subsections). 2. N.B. there is no validation of optional aspects. 3. Each section shall have an ID attribute. 4. N.B. as per section 1.4 ID Related there is currently no validation of GUID’s, this will be introduced later. 5. Each section has an id element. 6. N.B. validation is performed at the element level. 7. Each section has a code element. 8. N.B. validation is performed at the element level. 9. Each section may have a title element. 10. N.B. validation is performed at the element level. 11. Each section may have a text element. 12. N.B. validation is performed at the element level. 13. Each section has an effectiveTime element. 14. N.B. validation is performed at the element level. 15. Each section may have a confidentialityCode element. 16. N.B. validation is performed at the element level. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| id | N/A | 1:1 |  | Provides a globally unique ID for a specific section.  Note: HPFB uses the Section ID attribute not the ID element as a link and identification mechanism. |
| root | 0:1 |  | Not required but if included must be a GUID. |
| Conformance | 1. There is an id element 2. a) N.B. no validation aspect.      1. There may be a root attribute 2. N.B. there is no validation of optional aspects. 3. The id@root is a GUID and does not have an extension. 4. N.B. as per section 1.4 ID Related there is currently no validation of GUID’s, this will be introduced later. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| code | N/A | 1:1 |  | The section type/label. It is used to identify the content of the section. |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| Conformance | 1. There is a code element 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.8. 4. An instance of Rule Category 2 identifies that the OID value is incorrect. 5. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 6. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 7. An instance of Rule Category 8 identifies that the code is not in the CV. 8. An instance of Rule Category 10 identifies that there is a notification flag for the content. 9. An instance of Rule Category 14 identifies that the code value is contextually incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| title | N/A | 0:1 |  | Provides the title for the section. |
| Conformance | 1. There may be a title element, unless specified otherwise in the document specific validation guidance 2. N.B. there are no validation of optional aspects. 3. The title is free form. 4. N.B. no validation aspect. 5. There are no figures in the title. 6. An instance of Rule Category 12 identifies that the content is incorrectly formatted. 7. There are no images in the title. 8. An instance of Rule Category 12 identifies that the content is incorrectly formatted. 9. Multiple lines may be used in the title with each line separated by a line break <br/> tag. (note: titles can also be as follows: <title mediaType="text/x-hl7-title+xml">). 10. N.B. no validation aspect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| text | N/A | 0:1 |  | Provides the content for the section, including tables, figures, images, formatted and unformatted text. |
| Conformance | 1. There may be text, unless specified otherwise in the document specific validation guidance, if present the text is free form, however the text content may consist of paragraph elements, table elements, and/or list elements. Due to the complexity of this element it has been detailed in section 6.8 Text Information. 2. N.B. no validation aspect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| renderMultiMedia | N/A | 0:n |  | Anchor for image content, it points to the image it does not contain or detail the image. There is one anchor element for each reference. |
|  | referencedObject | 1:1 |  |  |
| Conformance | 1. There may be one or more renderMultiMedia elements. 2. a) N.B. no validation aspect. 3. There is a referencedObject attribute. 4. An instance of Rule Category 6 identifies that the link target can not be found. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| observationMedia | N/A | 0:n |  | Wrapper element for images, it details the type, location, alternative text relating to the image. |
|  | ID | 1:1 |  |  |
| Conformance | 1. There may be one or more observationMedia element 2. N.B. no validation aspect. 3. There is an ID attribute. 4. An instance of Rule Category 5 identifies that the attribute has not been defined. 5. An instance of Rule Category 6 identifies that the attribute is empty. 6. An instance of Rule Category 6 identifies that the link target can not be found. 7. There is a text element 8. An instance of Rule Category 3 identifies that the element has not been defined. 9. An instance of Rule Category 6 identifies that the element is empty. 10. There is a value element 11. An instance of Rule Category 6 identifies that the element is empty. 12. There is a value@mediaType attribute with the xsi:type set to ED, and the mediaType is a string where the first part is “image/” followed by a mediatype derived from OID 2.16.840.1.113883.2.20.6.52. 13. An instance of Rule Category 5 identifies that the (xsi:type) attribute has not been defined. 14. An instance of Rule Category 6 identifies that the (xsi:type) attribute is empty. 15. An instance of Rule Category 8 identifies that the (xsi:type) attribute value is incorrect. 16. An instance of Rule Category 5 identifies that the (mediaType) attribute has not been defined. 17. An instance of Rule Category 6 identifies that the (mediaType) attribute is empty. 18. An instance of Rule Category 8 identifies that the (mediaType) attribute value is incorrect. 19. An instance of Rule Category 8 identifies that the mediatype is not in the CV. 20. An instance of Rule Category 10 identifies that there is a notification flag for the content. 21. An instance of Rule Category 14 identifies that the mediatype value is contextually incorrect. 22. There is a value.reference element 23. An instance of Rule Category 3 identifies that the element has not been defined.      1. There is a value.reference@value attribute, containing the file name, file extension and if required path to the content file. The content shall be all lower case 2. An instance of Rule Category 5 identifies that the attribute has not been defined. 3. An instance of Rule Category 6 identifies that the attribute is empty. 4. An instance of Rule Category 12 identifies that the content is incorrectly formatted (not lowercase). 5. An instance of Rule Category 6 identifies that the link target can not be found. 6. The file name shall not contained in the value.reference@value shall not exceed 59 characters and shall be followed by a 3 character file extension. 7. An instance of Rule Category 8 identifies that the (value) attribute value is incorrect. 8. An instance of Rule Category 14 identifies that the value value is contextually incorrect. 9. The observationMedia element is always contained within a component element. 10. An instance of Rule Category 9 identifies that the element value is incorrect. 11. An instance of Rule Category 14 identifies that the element value is contextually incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| excerpt | N/A | 0:1 |  | Provides a mechanism to tag section specific text excerpts. |
| Conformance | 1. There may be excerpts, unless specified otherwise in the document specific validation guidance. 2. N.B. no validation aspect. 3. The text is free form, however the text content may consist of paragraph elements, table elements, and/or list elements. Due to the complexity of this element it has been detailed in section 6.9 Excerpt Information. 4. N.B. no validation aspect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| effectiveTime | N/A | 1:1 |  | Used to capture relevant date information, such as date of initial creation or date of revision.  Please refer to the Doctype for specific details on the usage. |
| value | 1:1 |  |  |
| Conformance | 1. There is an effectiveTime element 2. An instance of Rule Category 3 identifies that the element has not been defined.      1. There is either a direct or indirect value for the effectiveTime 2. An instance of Rule Category 6 identifies that there is no value defined either directly or via a child element. 3. The effectiveTime@value has as a minimum precision of day and follows the appropriate format.   a) N.B. validation is doctype specific. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| confidentialityCode | N/A | 0:1 |  | Used to capture the relevant disclosure information.  Please refer to the Doctype for specific details on the usage. |
| Conformance | 1. There is a code element 2. N.B. there are no validation of optional aspects. 3. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.21. 4. An instance of Rule Category 2 identifies that the OID value is incorrect. 5. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 6. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 7. An instance of Rule Category 8 identifies that the code is not in the CV. 8. An instance of Rule Category 10 identifies that there is a notification flag for the content. 9. An instance of Rule Category 14 identifies that the code value is contextually incorrect. | | | |

### Labeling Content Section Details

Sections are the basic building blocks of the document and may contain content or nested sections (subsections) and so forth. All sections have the XML structure outlined above (id, title, code, etc…).

Document element contains a single component element, which in turn contains a single <structuredBody> element. The <structuredBody> contains one or more <component> elements, each <component> element in turn contains 0 (Zero) to N (unbounded) <section> elements. Sections are used to aggregate paragraphs into logical groupings. The order in which the sections appear in the document is the order the sections will appear when displayed (rendered) unless otherwise specified in the document specific information.

Sections may also link to other sections rather than including the content directly.

Outlined below is a mock-up of the section structure:

<section>

<!-- this section’s id, codes -->

<text>

<!-- actual text content in “narrative block” markup -->

</text>

</section>

When applicable as per the doctype, sections shall be nested to form sub-sections. The SPL schema requires that the nested <section> element be nested inside a <component> element.

Use nested sections to relate paragraphs. The <section> element applies to all of the nested sections. By nesting sections, computer systems can use the section tags in SPL to display information useful for the care of patients. If information is not associated with the tag, it will not be displayed as illustrated below:

<section>

<!-- this section’s id, codes -->

<text>

<!-- actual text content in “narrative block” markup -->

</text>

<component>

<section>

<!-- subsection content -->

</section>

</component>

<component>

<section>

<!-- subsection content -->

</section>

</component>

</section>

The title (if present) and the order of the sections and subsections are used to render the document. An example showing multilevel nesting is included below:

<component>

<section ID="L16a947eb-e2be-45c0-8b2e-15d0d0eebed8">

<id root="e6bb83b9-2602-4f96-9077-b8b9535c254e"/>

<code code="30" codeSystem="2.16.840.1.113883.2.20.6.8"/>

<title>Part II: Scientific Information</title>

<effectiveTime value="20160802"/>

<component>

<section ID="L32875272-8229-4c12-919e-827854dcd76a">

<id root="0134d52c-f9d4-4698-a082-84b29ee3d95a"/>

<code code="300" codeSystem="2.16.840.1.113883.2.20.6.8"/>

<title>Pharmaceutical Information</title>

<text>some text</text>

<effectiveTime value="20160802"/>

<component>

<section ID="L32875272-8229-4c12-919e-827854ddd76a">

<id root="0134d52c-f9d4-4698-a082-84b29ee3d95a"/>

<code code="300-10" codeSystem="2.16.840.1.113883.2.20.6.8"/>

<title>Drug Substance</title>

<text>some text</text>

<effectiveTime value="20160802"/>

The human readable content is contained within the <text> element in the <section>. Using the following principles for markup of text information improves access to information in labeling:

* Capture the section using the <section> element rather than within a <text> element. This allows computer systems to use and display this information properly.
* Capture the section title using the <title> element rather than placing the text of the title within the <text> element. This allows computer systems to use and display this information properly.
* Link different parts of the labeling using the ID attribute to the <section> element. For example, <section ID="Clin\_Pharm\_Section”> serves as the target of a <linkHtml> element. Linking to the ID attribute of a section allows the link to 'reference' the section entirely, e.g., for retrieval of a whole section in a non-browser interface.
* In general separate content by concept using <paragraph> tags.

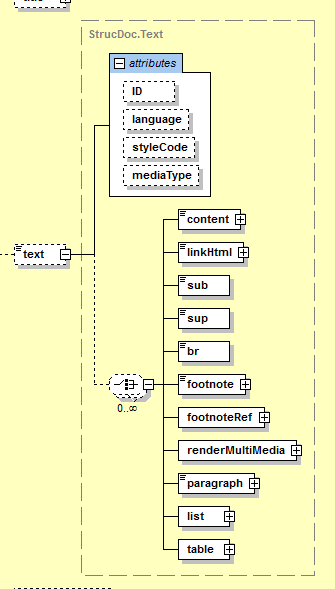
## Text Information

Outlined in this section are all aspects relating to the SPL documents textual content.

### XML

The diagram below shows the structure for the <text> element.

**Figure 2 <text> element**



The outline below shows a sample XML structure containing several paragraphs in the text element.

<section>

<text>

<paragraph>The first paragraph in a section.</paragraph>

<paragraph>The second paragraph in a section.</paragraph>

</text>

</section>

### Text Details

The human readable text content of the document is contained within the <text> element. The actual content is contained within a <paragraph>, <table>, and/or <list>.

* If a section consists only of nested sections, the <text> tag is not included.
* Elements that can be used within the <text> element to capture the human readable content include paragraphs (<paragraph>), lists (<list>), tables (<table>) and images (<renderMultimedia>).
* Elements permitted as children of the <text> element, used as children of the <paragraph> element or within <table> and <list> include superscripts (<sup>), subscripts (<sub>), links (<linkHtml>), line breaks (<br>), footnotes (<footnote>), footnote references (<footnoteRef>).
* Images may be included in the content of labeling using the <renderMultiMedia> tag. This tag may be used as a direct child of <text> for ‘block’ images or as a child of <paragraph> for inline images.

### Formatting Details

There are certain aspects of the content that must be specified in the source to insure that the content of labeling is formatted correctly when rendered, as an example:

<text>

<paragraph>

The next snippet <content styleCode="bold italics">will appear as bold italics</content> in the rendering.

</paragraph>

</text>

Will be rendered as: The next snippet ***will appear as bold italics*** in the rendering.

The <content styleCode=””> can be nested, for example:

<text>

<paragraph>

<content styleCode="bold italics">bold italics</content>

But it can also be represented as:

<text>

<paragraph>

<content styleCode="bold”>

<content styleCode="italics”> bold italics.</content>

</content>

Both of the above will appear as ***bold italics***

The values for <styleCode> for font effect are bold, italics and underline. To assist people who are visually impaired, the <styleCode=”emphasis”> is used to prompt computer screen reader programs to emphasize text such as a box warning. The bold, italics and underline font effects may be used together with each other and the emphasis styleCode. For example:

<content styleCode=”bold”>

<content styleCode=”emphasis”>

</content>

</content>

Will appear as bold and be emphasized by screen reader programs.

#### Symbols and special characters

Special characters can be included in the text. Superscripts and subscripts are accomplished using the <sup> and <sub> tags.

Because the SPL encoding is UTF-8, any Unicode character can be included as is. Unicode references may also be inserted as either &#dddd; where dddd is the Unicode value in decimal notation or &#xdddd; where dddd is the Unicode value in hexadecimal notation. The font used in the standard stylesheet is a Unicode font assuring that most Unicode characters will be rendered correctly if viewed by a browser supporting this font. The only prohibited characters in XML that cannot be directly used are less-than “<” (because SPL XML tags begin with it) and ampersand “&” (because XML entity references begin with it). Use of these two symbols must be replaced by the XML entity references &lt;. and &amp; respectively, as an example: “<paragraph>The mean for group 1 was &lt; 13. </paragraph>” will render as “The mean for group 1 was <13.” and “D&amp;C Yellow #10” will render as “D&C Yellow #10”.

### Footnote Details

The SPL schema includes a specific footnote element <footnote>. Footnotes are rendered automatically by the SPL stylesheet. <footnoteRef> is used to refer to another (usually earlier) footnote. For example, “<footnote ID=”testNote”>This is the footnote content</footnote>” will generate the following footnote at the appropriate end of a section. “6 This is footnote content”

The <footnoteRef> element with the appropriate IDREF attribute, e.g., <footnoteRef IDREF=”testNote”/> will display the footnote reference in the text corresponding to the footnote with the same ID, e.g., in this example footnote 6.

Footnotes are rendered by the default stylesheet using Arabic numbers (e.g., 1,2 3,). Within tables, footnotes are rendered using footnote marks in the series: \* † ‡ § ¶ # ♠ ♥ ♦ ♣, effectively separating numbered footnotes within general text and footnotes within tables. Footnotes within tables are rendered at the bottom of the table.

### List Details

All lists are marked up using the <list> tag, and each item in a list is marked with an <item> tag. The ‘listType’ attribute identifies the list as ordered (numbered) or unordered (bulleted). The default numbering and bulleting are controlled by the stylesheet as illustrated below:

<text>

<paragraph>Fist Para ...</paragraph>

<list listType="ordered" styleCode="BigRoman">

<item>Fist Item</item>

<item>Second Item</item>

</list>

<paragraph>2nd Para ...</paragraph>

</text>

Lists featuring a standard set of specialized markers (standard specialized lists) can be created using the styleCode attribute with the <list> element. Options available for ordered lists are:

* Arabic (List is ordered using Arabic numerals: 1, 2, 3)
* LittleRoman (List is ordered using little Roman numerals: i, ii, iii)
* BigRoman (List is ordered using big Roman numerals: I, II, III)
* LittleAlpha (List is order using little alpha characters: a, b, c)
* BigAlpha (List is ordered using big alpha characters: A, B, C)

For example: <list listType="ordered" styleCode="LittleRoman">

For unordered lists the following options exist:

* Disc (List bullets are simple solid discs: ●)
* Circle (List bullets are hollow discs: ○)
* Square (List bullets are solid squares: ■)

For example: <list listType=”unordered” styleCode=”Disc”>

In addition to the standard specialized lists, user-defined characters are also permitted as markers by nesting <caption> within the <item> tag. Note that any character, XML entity, or Unicode symbol, may be used in the <caption>, and that the <caption> for each <item> are not restricted to the same character. For example: <item><caption>\*</caption> the asterisk is used as item marker here.<item>

### Table Details

Tables can be created with the full structure (header (e.g. for column names), body (e.g. for the rows of the table) and footer e.g. for table footnotes)). The element <tbody> is required for an SPL table while the elements <thead> and <tfoot> are optional in the SPL schema. The structure will display a standard typographical table with rules between the caption (table title) and head, the head and body, and the body and <tfoot>. If a <tfoot> element is included and footnotes are present in a table, then footnotes are rendered after the existing content of the <tfoot> element.

It is recommended to always start with a standard table (i.e. <thead> and <tbody> elements) and test to see whether the rendering is unambiguous and interpretable. It is important that the table communicate labeling content not that it duplicates the presentation in word processed or typeset versions of the package insert. In the unusual situation where additional formatting is needed, the rule styleCode specified or certain attributes may be used to modify the table.

The rule codes are as follows (note that the control names are case sensitive):

* Rule on left side of cell is Lrule
* Rule on right side of cell is Rrule
* Rule on top of cell is Toprule
* Rule on bottom of cell is Botrule

Note: More than one rule control may be used in a cell, e.g., <td styleCode code=”Botrule Lrule”>Cell content</td>

Rule control codes should be used only when necessary for the interpretability of the table. Use of these codes may result in overriding the default rules for tables. Rather than setting the rule for each cell, table rules may also be controlled according to entire rows or columns by use of the styleCode attributes with <col>, <colgroup>, <thead>, <tfoot>, <tbody> and <tr> elements.

To make rowgroups appear with horizontal rules, use the styleCode attribute "Botrule" with the appropriate <tr> element. The Botrule value is rarely needed on the <td> element.

The preferred method for using vertical rules is to define colgroup with styleCode="Lrule” or “Rrule" (or both). Only if this does not yield the desired vertical rule should the Lrule or Rrule code value with styleCode attributes on the <td> or <th> element itself be used. Note: In general, vertical rules should not be used. Good typography for tables means using few vertical rules.

To merge cells vertically and horizontally, the rowspan and colspan attributes should be used on the <td>element.

To determine the width of a table, the width attribute may be used on the <table> element and to determine the width of a table column, the width attribute may be used on the <col> and <colgroup> elements. Note: best practice is to omit the width aspect. This ensures the rendering is done to the width. The only time the width should be specified is when the information is to be smaller than the standard width and in those cases a relative size (%) should be used.

For horizontal alignment, the preferred method for aligning cell content within the margins is to use <col align=”.. ”/> in the <colgroup> element, though this can be used in the <colgroup> element as well. Valid values for align are “left”, “center”, “right”, “justify” (for full justification of contents within the cells), and “char” (for character alignment within the cells). Using the <col align=”.. ”/> markup ensures that the contents for all cells in the column share the same alignment.

For vertical alignment, the valign attribute can be used within cells. For cases in which the cell alignment must be different from other cells in the column, align is also available as an attribute on the other table elements, including <td>.

Markup for table footnote is rendered in the <tfoot> tag. This element does not need to be included in SPL; the standard stylesheet will include a <tfoot> tag if a <footnote> element is present within either the <thead> or <tbody> sections. A <tfoot> section should be included in SPL only if there is additional information other than footnotes that needs to be rendered in this section.

For table text spacing, in some instances, the use of a “tab” or text indentation is desirable in a given table cell. In an SPL document, this effect is achieved by using the nonbreaking space (&#160;) as if it were a “tab” space. As the following snippet of XML shows, two nonbreaking spaces were used to offset the word “Male” from the margin: <td>&#160;&#160;Male</td>. The nonbreaking space can also be used to keep text in a table from breaking inappropriately due to browser resizing.

### Hypertext links

SPL offers hypertext linking capabilities generally similar to those found in the HTML specification.

Links are specified by the <linkHtml> construct, where the value for the href attribute of <linkHtml> (the target of the link) is the ID attribute value of a <section>, <paragraph>, <table>, <list>, <content>,<renderMultimedia> element. The stylesheet does not support the styleCode attribute of the <linkHtml> element; if a styleCode is needed for a link, this should be coded via the <content> element within the link as with other text.

### Recent major changes in labeling text

SPL offers a notation to identify recent major changes in the labeling text including table elements <table> and table data <td>. The recent major text is tagged using the <content styleCode=“xmChange”>, for example:

<text>This is an example of text that is not changed.

<content styleCode=“xmChange”>

This is an example of text that is a recent major change

</content>

This is an example of changed text that is not considered a recent major change

</text>

### Images

The SPL schema uses <observationMedia> elements to identify graphic files to be rendered at the locations where they are referenced by <renderMultiMedia> elements in the <section>. In other words, an image in an SPL will be rendered wherever it is referenced by the renderMultimedia markup, no matter where the observationMedia markup appears. The referencedObject attribute of the renderMultiMedia element identifies the corresponding observationMedia instance by means of its ID identifier such as <renderMultiMedia referencedObject="MM1"/> this is illustrated below:

<section>

<text>

<paragraph>...</paragraph>

<renderMultiMedia referencedObject="MM1"/>

<paragraph>...</paragraph>

</text>

<component>

<observationMedia ID="MM1">

<text>descriptive text</text>

<value xsi:type="ED" mediaType="image/jpeg">

<reference value="drug-01.jpg"/>

</value>

</observationMedia>

</component>

</section>

The <observationMedia> element does not contain the graphics file, but instead points at the file.

For image placement, if an image is a block image (i.e., should appear in its own space), insert the renderMultimedia tag between <paragraph> elements. If an image is inline (i.e., should appear alongside text), insert the renderMultimedia tag in the text of a <paragraph> as appropriate. Inline images are expected to be uncommon and basically represent symbols that cannot be represented by Unicode characters. In addition, <caption> are not applicable for inline images since these are not offset from the surrounding text.

The SPL stylesheet does not perform any resizing graphics or changing the resolution of graphics files. Thus, all images are rendered in the browser as-is, with all characteristics of the actual graphic file itself. To ensure that a graphic will appear as desired, it is very important that the graphic file is edited to a dimension appropriate for its presentation within the browser. If this is not done, the appearance of the graphic may not be consistent with the narrative content reducing the readability of the file. JPEG image file type using appropriate pixels per inch for images for viewing in a browser using the standard style sheet.

Only file formats detailed in **Table 3** are permitted

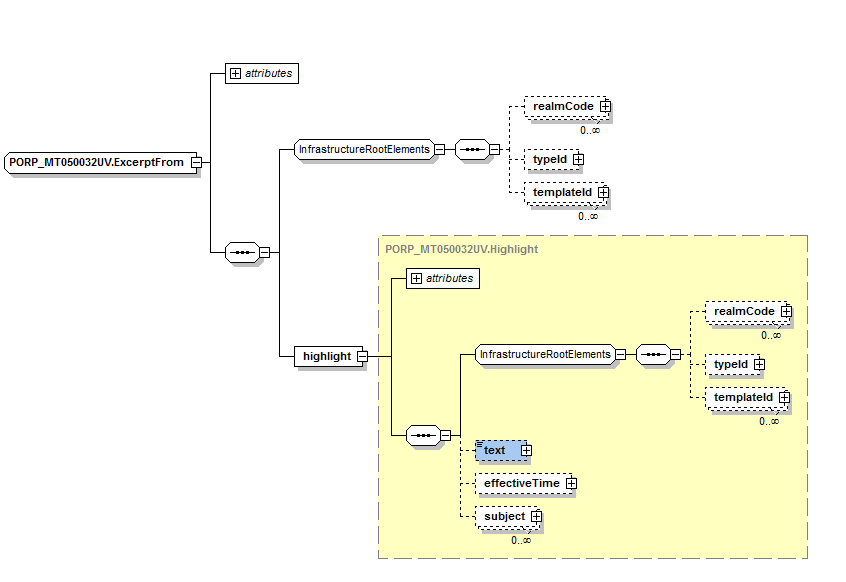
## Excerpt Information

Outlined in this section are all aspects relating to the SPL documents excerpt content.

### XML

The diagram below shows the XML structure for the < excerpt > element.

**Figure 3 <excerpt> element**



The example below shows an example of an excerpt:

<excerpt>

<highlight>

<text>

<list listType="unordered">

<item>Aplastic anemia has been observed in 8% ...(<linkHtml href=”#Section\_5.1”>5.1</linkHtml>)</item>

<item>Monitor for hematological adverse reactions …(<linkHtml href=”#Section\_5.2”>5.2</linkHtml>)</item>

</list>

</text>

</highlight>

</excerpt>

### Excerpt Details

The text blocks for Highlights are coded with the <excerpt> <highlight> elements of the major section of labeling in which they are contained. The structure is outlined below:

<section>

<excerpt>

<highlight>

<text>...</text>

Highlight text is placed under the main section and not under subsections. The following is an example:

<component>

<section>

<id root="47ef84cd-8314-48c3-8ee2-bdff3087f83f"/>

<code code="210" codeSystem="2.16.840.1.113883.2.20.6.8"/>

<title>Warnings and Precautions</title>

<excerpt>

<highlight>

<text>

<list listType="unordered">

<item>Aplastic anemia has been observed in 8% ...(<linkHtmlhref=”#Section\_5.1”>5.1</linkHtml>)

</item>

<item>Monitor for hematological adverse reactions …(<linkHtml href=”#Section\_5.2”>5.2</linkHtml>)

</item>

</list>

</text>

</highlight>

</excerpt>

<component>

<section ID="Section\_5.1">

<id root="a857689e-9563-43c0-a244-8a6d5a25966a"/>

<title>5.1 Aplastic anemia</title>

<text>

<paragraph>Aplastic anemia has been observed in…..</paragraph>

</text>

</section>

</component>

</section>

</component>

This example illustrates the following principles:

1. The <text> block for the Highlights is included as the <excerpt> <highlight> <text> children of the respective section. In the example above, the text block rendered in the highlights section is the child of the “Warnings and Precautions” section.
2. The coding of the highlights text block is not in a subsection.
3. The text block is rendered similar to any other text block, although in a location separate from its actual position in the rendered SPL document.
4. Links to the section or subsection where the primary content exists are explicitly entered in the Highlights text block.

## Product Data Information

Outlined in this section are all general aspects relating to the SPL document’s Product Data aspects.

Products are identified in metadata as children of the SPL product data elements section (section where the code@code="48780-1" and the [code@codeSystem="2.16.840.1.113883.2.20.6.8](mailto:code@codeSystem=%222.16.840.1.113883.2.20.6.8)") this includes items such as the product codes, proprietary and non-proprietary name, dosage form, ingredient and active moiety name, ingredient identifier, ingredient strength, package quantity, type and code, marketing category, marketing status, dosage form appearance, schedule, and route of administration as well as all product characteristics.

### Location in Document

<document>

<component>

<structuredBody>

<component>

<section>

<subject>

<manufacturedProduct>

### XML

Outlined below is the structure for the product data aspects:

<manufacturedProduct>

<manufacturedProduct>

<!-- elements detailed later in this section-->

</manufacturedProduct>

<!-- elements detailed later in this section-->

</manufacturedProduct>

An example of the product data section is outlined below:

<section>

<templateId extension="1" root="2.16.840.1.113883.2.20.6.53"/>

<id root="ae4e1587-e25c-4332-9297-47abd89b4be3"/>

<code code="48780-1" codeSystem="2.16.840.1.113883.2.20.6.8"/>

<title/>

<text/>

<effectiveTime value="20151207"/>

<subject>

<manufacturedProduct>

<manufacturedProduct>

<!-- elements detailed later in this section-->

</manufacturedProduct>

<!-- elements detailed later in this section-->

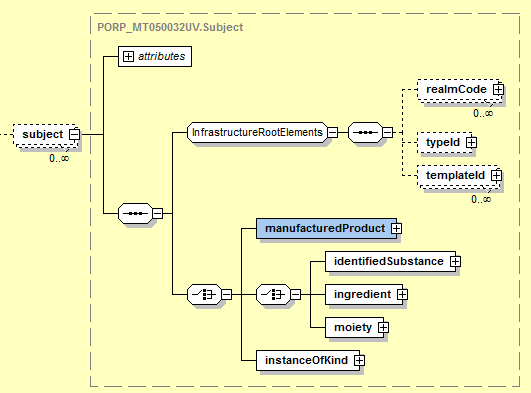
</manufacturedProduct>

</subject>

</section>

The diagram below shows the XML structure for the <subject> element.

**Figure 4 <subject> element**



The following is an example for a drug product:

<manufacturedProduct>

<manufacturedProduct>

<code code="DIN" codeSystem="2.16.840.1.113883.2.20.6.53"/>

<name>proprietary name <suffix>suffix to name</suffix></name>

<formCode code="dose form code" codeSystem="2.16.840.1.113883.2.20.6.3”/>

<asEntityWithGeneric>

<genericMedicine>

<name>non-proprietary name</name>

</genericMedicine>

</asEntityWithGeneric>

</manufacturedProduct>

<subjectOf>

<approval>

<!-- possibly approval number -->

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.11"/>

<!-- possibly other attributes in the marketing category -->

</approval>

</subjectOf>

</manufacturedProduct>

General information relating to the product data elements are provided below:

* Code (Item Code): The unique identification of this product whether or not the (item) code is printed on the product itself. The item code is the DIN assigned by HPFB.
* Name: When specific manufactured or marketed products are described, the name is the proprietary name as it appears on the label divided between <name> and <suffix>. The <name> is the initial portion of the proprietary name describing the ingredients without any other descriptors including trademarks and dosage forms. If necessary, <suffix> is used for descriptors such as “extended release”. When using the <suffix>, a space after the proprietary name is added as necessary. Non-proprietary or generic names of drugs are found in the <genericMedicine><name> element. Device type codes and descriptions use <asSpecializedKind>.
* Description: A brief description is added in the <desc> element that states succinctly the kind of device. This text should be brief to be able to list it in short summary listings. While the text can be up to 512 characters in length, it should normally be much shorter so that it will be useful for listing in tables. A device also has a device-nomenclature code in the <asSpecializedKind> element. This code comes from the Product Classification terminology (OID: 2.16.840.1.113883.2.20.6.27).

The following is an example for a drug product:

<subject>

<manufacturedProduct>

<manufacturedProduct>

<code code="Product Code" codeSystem="2.16.840.1.113883.2.20.6.53"/>

<name>proprietary name <suffix>suffix to name</suffix></name>

<formCode code="dose form code" codeSystem="2.16.840.1.113883.2.20.6.3"/>

<asEntityWithGeneric>

<genericMedicine>

<name>non proprietary name</name>

</genericMedicine>

</asEntityWithGeneric>

</manufacturedProduct>

<subjectOf>

<approval> <!-- possibly approval number -->

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.11" />

<!-- possibly other attributes in the marketing category -->

</approval>

</subjectOf>

</manufacturedProduct>

</subject>

### Equivalence to other Products, Product Source

The following is for referencing information already submitted for a source drug:

<manufacturedProduct>

<manufacturedProduct>

<code code="Product Code" codeSystem=" 2.16.840.1.113883.2.20.6.53"/>

<name>proprietary name <suffix>suffix to name</suffix></name>

<asEquivalentEntity classCode="EQUIV">

<code code="C64637" codeSystem="2.16.840.1.113883.2.20.6.12"/>

<definingMaterialKind>

<code code="source product DIN" codeSystem="2.16.840.1.113883.2.20.6.42"/>

</definingMaterialKind>

</asEquivalentEntity>

</manufacturedProduct>

</manufacturedProduct>

This is a special case of referencing other products for various purposes. Another purpose is for products that are updated with improvement, where it may be useful to indicate a succession to a previous version of the product identified by the item code of the predecessor product. This can be done using the equivalence relationship with <asEquivalentEntity> with a different role code as in outlined in the example below:

<manufacturedProduct>

<manufacturedProduct>

...

<asEquivalentEntity classCode="EQUIV">

<code code="C64637" codeSystem="2.16.840.1.113883.2.20.6.12"/>

<definingMaterialKind>

<code code=”source product DIN” codeSystem=”2.16.840.1.113883.2.20.6.42”/>

The equivalency code would identify if it was a predecessor or same product being referenced.

Product source may be specified under a product as outlined below:

<subject>

<manufacturedProduct>

<manufacturedProduct>

<asEquivalentEntity>

or under parts as outlined below:

<part>

<partProduct>

<asEquivalentEntity>

### Additional Identifiers for this Product

A multitude of other identifiers may be assigned to products by various parties, manufacturers, distributors, wholesalers, regulators. These identifiers are of a varying quality in terms of control for uniqueness and meaning. They may be unique item codes from other ISO 15459 item code systems, or they may be less well defined codes such as “model number” or “catalog number” etc. While those “model numbers” or “catalog numbers” are often not safe for referencing, such identifiers are customer facing and may encode minor product variants, which would be recognized by customers and hence listing such identifier cross references can aid in finding the correct item code, as outlined in the example below:

<manufacturedProduct>

<manufacturedProduct>

...

<asIdentifiedEntity classCode="IDENT">

<id extension="other identifier" root="other identifier root"/>

<code code="other identifier type code" codeSystem="2.16.840.1.113883.2.20.6.13"/>

Non HPFB defined identifications are assigned codes derived from OID: 2.16.840.1.113883.2.20.6.13.

HL7 requires any identifier to be made globally unique, therefore submitters must acquire an OID of their own through any of several sources (e.g. HL7 provides an OID registration service). Submitters must not allow conflicting assignments of model numbers among their own products. Submitters can still create unique identifiers from these model numbers by giving different root OIDs for each kind of identifiers that may be in conflict. Once a company has acquired a root OID this root OID can be freely sub-divided. For example, ACME Fine Devices Inc. may have acquired the OID 2.16.840.1.113883.3.98765 from the HL7 registry. ACME then decided to use a sub-branch .2 under their OID to manage model numbers for the models from models release before 2007 and sub-branch .5 for models released after 2007. There is no specific rule that must be obeyed when sub-dividing OIDs as long as it results in the concatenation of model number code and codeSystem OID to be a unique identifier.

### Code and Name

Outlined below is an example of capturing the code and name aspects:

<section>

<subject>

<manufacturedProduct>

<manufacturedProduct>

<code code="1234-5678" codeSystem=" 2.16.840.1.113883.2.20.6.53"/>

<name>Tazmin<suffix> XR</suffix></name>

<formCode code="C42998" codeSystem="2.16.840.1.113883.2.20.6.3"/>

<asEntityWithGeneric>

<genericMedicine>

<name>tazminate hydrochloride</name>

</genericMedicine>

### Ingredient

Ingredients may be specified for products as outlined below:

<subject>

<manufacturedProduct>

<manufacturedProduct>

<ingredient/>

and parts as outlined below:

<part>

<partProduct>

<ingredient/>

Ingredient information includes the ingredient role, along with the code, name, strength, and possibly the active moiety name(s) and identifier and a reference ingredient name and identifier, as illustrated below

<ingredient classCode="IACT">

<!-- This denotes that the active ingredient is already used in another approved product and is used as a compound product -->

<quantity>

<numerator value="12" unit="mg"/>

<denominator value="100" unit="mL"/>

</quantity>

<ingredientSubstance>

<code code="88888-333" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>Midazolam Hydrochloride</name>

</ingredientSubstance>

</ingredient>

The ingredient role (e.g., active, inactive, etc) is captured using the classCode attribute and is derived from OID: 2.16.840.1.113883.2.20.6.39. The substance is captured in the code element of the ingredientSubstance element, the code is derived from OID 2.16.840.1.113883.2.20.6.14. The numerator unit is derived from OID: 2.16.840.1.113883.2.20.6.15 while the denominator’s unit is derived from OID: 2.16.840.1.113883.2.20.6.38

Detailed below are the Class Code options, definitions and structure.

**Table 4 List of ingredient roles**

| **Level** | **Code** | **Name** | **Description** |
| --- | --- | --- | --- |
| 1 | INGR | ingredient | Relates a component to a mixture. E.g., Glucose and Water are ingredients of D5W, latex may be an ingredient in a tracheal tube.  This code is used to group related items together and is not used directly in the identification of the role. |
| 2 | ACTI | active ingredient | A therapeutically active ingredient in a mixture, where the mixture is typically a manufactured pharmaceutical. It is unknown if the quantity of such an ingredient is expressed precisely in terms of the playing ingredient substance, or, if it is specified in terms of a closely related substance (active moiety or reference substance).  This code is used to group related items together and is not used directly in the identification of the role. |
| 3 | ACTIB | active ingredient - basis of strength | An active ingredient, where the ingredient substance is itself the "basis of strength", i.e., where the role.quantity specifies exactly the quantity of the player substance in the medicine formulation.  Examples: Lopressor 50 mg actually contains 50 mg of metoprolol succinate, even though the active moiety is metoprolol, but also: Tenormin 50 mg contain 50 mg of atenolol, as free base, i.e., where the active ingredient atenolol is also the active moiety. |
| 3 | ACTIM | active ingredient - moiety is basis of strength | An active ingredient, where not the ingredient substance, but the ingredient active moiety is the "basis of strength", i.e., where the role.quantity specifies the quantity of the player substance's active moiety in the medicine formulation. Examples: 1 mL of Betopic 5mg/mL eye drops contains 5.6 mg betaxolol hydrochloride equivalent to betaxolol base 5 mg. |
| 3 | ACTIR | active ingredient - reference substance is basis of strength | An active ingredient, where not the ingredient substance but another reference substance with the same active moiety, is the "basis of strength", i.e., where the role.quantity specifies the quantity of a reference substance, similar but different from the player substance's in the medicine formulation. Examples: Toprol-XL 50 mg contains 47.5 mg of metoprolol succinate equivalent to 50 mg of metoprolol tartrate. |
| 2 | ADJV | adjuvant | A component added to enhance the action of an active ingredient (in the manner of a catalyst) but which has no active effect in and of itself. Such ingredients are significant in defining equivalence of products in a way that inactive ingredients are not. |
| 2 | ADTV | additive | An ingredient that is added to a base, that amounts to a minor part of the overall mixture. |
| 2 | BASE | base | A base ingredient is what comprises the major part of a mixture. E.g., Water in most i.v. solutions or Vaseline in salves. Among all ingredients of a material, there should be only one base. A base substance can, in turn, be a mixture. |
| 2 | CNTM | contaminant ingredient | An ingredient whose presence is not intended but may not be reasonably avoided given the circumstances of the mixture's nature or origin. |
| 2 | IACT | inactive ingredient | An ingredient which is not considered therapeutically active, e.g., colors, flavors, stabilizers, or preservatives, fillers, or structural components added to an active ingredient in order to facilitate administration of the active ingredient but without being considered therapeutically active. An inactive ingredient need not be biologically inert, e.g., might be active as an allergen or might have a pleasant taste, but is not an essential constituent delivering the therapeutic effect. |
| 3 | COLR | color additive | A substance influencing the optical aspect of material. |
| 3 | FLVR | flavor additive | A substance added to a mixture to make it taste a certain way. In food the use is obvious; in pharmaceuticals flavors can hide disgusting taste of the active ingredient (important in pediatric treatments). |
| 3 | PRSV | preservative | A substance added to a mixture to prevent microorganisms (fungi, bacteria) from spoiling the mixture. |
| 3 | STBL | stabilizer | A stabilizer added to a mixture in order to prevent the molecular disintegration of the main substance. |
| 2 | MECH | mechanical ingredient | An ingredient of a medication that is inseparable from the active ingredients, but has no intended chemical or pharmaceutical effect itself, but which may have some systemic effect on the patient.  An example is a collagen matrix used as a base for transplanting skin cells. The collagen matrix can be left permanently in the graft site. Because it is of bovine origin, the patient may exhibit allergies or may have cultural objections to its use. |

If the ingredient is confidential, the element <ingredient> includes a confidentialityCode element as outlined below:

<confidentialityCode code="1" codeSystem="2.16.840.1.113883.2.20.6.21”/>

Outlined below is an example of an active ingredient:

<ingredient classCode=”class code including basis of strength”>

<confidentialityCode code="1" codeSystem="2.16.840.1.113883.2.20.6.21"/>

<quantity>

<numerator value="value" unit="code"/>

<denominator value="value" unit="code"/>

</quantity>

<ingredientSubstance>

<code code="ID" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>active ingredient name</name>

<activeMoiety>

<activeMoiety>

<code code="ID" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>active moiety name</name>

</activeMoiety>

</activeMoiety>

<asEquivalentSubstance>

<definingSubstance>

<code code="ID" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>reference substance name</name>

</definingSubstance>

</asEquivalentSubstance>

</ingredientSubstance>

</ingredient>

Outlined below is an example of an active ingredient, where the basis of strength is the moiety:

<ingredient classCode="ACTIM">

<ingredientSubstance>

<activeMoiety>

<activeMoiety>

<code code="0987654321" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>tazminic acid</name>

Outlined below is an example of an inactive ingredient:

<ingredient classCode="IACT">

<confidentialityCode code="1" codeSystem="2.16.840.1.113883.2.20.6.21"/>

<quantity>

<numerator value="value" unit=“code”/>

<denominator value="value" unit=“code”/>

</quantity>

<ingredientSubstance>

<code code="ID" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>inactive ingredient name</name>

</ingredientSubstance>

</ingredient>

Outlined below is an example of a reference ingredient for the strength:

<ingredient classCode=“ACTIR”>

<ingredientSubstance>

<asEquivalentSubstance>

<definingSubstance>

<code code="A123455678" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>tazemate formate</name>

Source ingredient means using an existing product as one of the ingredient in other compounded drug, as illustrated below:

<ingredient classCode="INGR">

<quantity>

<numerator value="12" unit="mg"/>

<denominator value="1" unit="mL"/>

</quantity>

<ingredientSubstance>

<code code="88888-333" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>MIDAZOLAM HYDROCHLORIDE</name>

</ingredientSubstance>

</ingredient>

As outlined at the beginning of this section the strength for an ingredient is defined in the quantity element and is represented as a numerator and denominator along with a unit of measure and unit of presentation. The numerator unit is derived from OID: 2.16.840.1.113883.2.20.6.15 while the denominator’s unit is derived from OID: 2.16.840.1.113883.2.20.6.38

The Units of Presentation code for a unit that is an “each” is “1”. In most cases, the strength used is that for a single dose following the conventions in the Table below. In the table, an example of “mass” is milligrams, an example of “volume” is milliliter, an example of “time” is hour, and an example of “each” is tablet.

**Table 5 Conventions for expressing strength**

| **Product** | **Numerator unit** | **Denominator unit** |
| --- | --- | --- |
| Oral solid | Mass | Each |
| Oral liquid | Mass | Volume |
| Oral powder for reconstitution with a known volume | Mass | Volume |
| Oral powder for reconstitution with a variable volume | Mass | Each |
| Suppository | Mass | Each |
| Injection liquid | Mass | Volume |
| Injection powder for reconstitution with a known volume | Mass | Volume |
| Injection powder for reconstitution with a variable volume | Mass | Each |
| Inhaler powder | Mass | Each |
| Inhaler liquid | Volume | Each |
| Inhaler blister | Mass | Each |
| Topical cream or ointment | Mass | Mass |
| Topical gel or lotion | Mass | Volume |
| Transdermal patch | Mass | Time |

### Route of administration

Route of administration may be specified for products as outlined below:

<subject>

<manufacturedProduct>

<consumedIn/>

and their parts:

<part>

<consumedIn/>

Route of administration is specified as follows:

<consumedIn>

<substanceAdministration>

<routeCode code="C38288" codeSystem="2.16.840.1.113883.2.20.6.7"/>

</substanceAdministration>

</consumedIn>

Multiple route of administration’s are supported and specified as follows:

<manufacturedProduct>

…

<consumedIn>

<substanceAdministration>

<routeCode code="1" codeSystem="2.16.840.1.113883.2.20.6.7"/>

</substanceAdministration>

</consumedIn>

<consumedIn>

<substanceAdministration>

<routeCode code="22" codeSystem="2.16.840.1.113883.2.20.6.7"/>

</substanceAdministration>

</consumedIn>

</manufacturedProduct>

### Packaging

The packaging includes the quantity of product in the package and the package type, along with all packaging aspect that make up the package (such as inner packages). Packaging may be specified for the product as outlined below:

<manufacturedProduct>

<manufacturedProduct>

<asContent/>

for parts as outlined below:

<part>

<partProduct>

<asContent/>

and for packages as outlined below:

<asContent>

<containerPackagedProduct>

<asContent/>

Packaging is represented as a quantity, a product ID if applicable and a package type. The quantity aspect is represented as a numerator and denominator along with a unit of measure and packaging type. The Units of Presentation code (the numerator) is derived from OID: 2.16.840.1.113883.2.20.6.15, while the Packaging Type code (the denominator) is derived from OID: 2.16.840.1.113883.2.20.6.32.

Products and packages can contain an ID derived from OID: 2.16.840.1.113883.2.20.6.55 and OID: 2.16.840.1.113883.2.20.6.56 respectively.

The product ID aspect has been included in the example below showing 20 mL per Syringe, 100 Syringes per Box for clarity.

<asContent>

<quantity>

<numerator value=“20" unit="mL"/>

<denominator value="1" unit="1"/>

</quantity>

<containerPackagedProduct>

<code code="CAN-12345678-1234-112233" codeSystem="2.16.840.1.113883.2.20.6.56"/>

<formCode code=“121" codeSystem="2.16.840.1.113883.2.20.6.32"/>

<asContent>

<quantity>

<numerator value="100" unit="1"/>

<denominator value="1" unit="1"/>

</quantity>

<containerPackagedProduct>

<code code=" CAN-12345678-1234-445566" codeSystem="2.16.840.1.113883.2.20.6.56"/>

<formCode code=“1" codeSystem="2.16.840.1.113883.2.20.6.32"/>

</containerPackagedProduct>

</asContent>

</containerPackagedProduct>

</asContent>

### Kits, Parts, Components and Accessories

Products may be combined in various ways such as:

* Drug kit with a device part
* Device kit with a drug part
* Device with an embedded drug
* Drug in a delivery device
* Products sold separately but meant to be used together

**Kits and Parts:** When products have more than one part, each part is described under <partProduct>. The total amount of the part in the product is included as follows:

<part>

<partProduct>

<quantity>

<numerator value="total amount of part in product" unit="Ingredient ID"/>

<denominator value="1"/>

</quantity>

<partProduct> <!-- same as above for drug or device. -->

</part>

When a drug product has parts, it is considered a Kit indicated by the formCode for Kit:

<manufacturedProduct>

<manufacturedProduct>

<code code="1123-45600" codeSystem=" 2.16.840.1.113883.2.20.6.53"/>

<name>Easy-Go PreciFuse PorterPump Kit</name>

<formCode code="C47916" codeSystem="2.16.840.1.113883.2.20.6.32"/>

<part>

<!-- ... -->

Note: Medical Devices are currently out of scope for the HPFB’s use of SPL. HPFB will notify industry if there are any plans to expand the use of SPL.

### Drug Kit with a Device Part

The example below illustrates a 2 part kit (drug and device) where the drug is the lead:

<manufacturedProduct>

<manufacturedProduct>

<code code="MPID of kit" codeSystem="2.16.840.1.113883.2.20.6.55"/>

<name>name of kit</name>

<formCode code="C47916" codeSystem="2.16.840.1.113883.2.20.6.32"/>

<asEntityWithGeneric .../>

<part>

<quantity>

<numerator value="amount of this part’s content in one kit" unit="unit for amount"/>

<denominator value="1"/>

</quantity>

<partProduct>

<name>name of drug part</name>

<formCode code="*form code of drug part*" codeSystem="2.16.840.1.113883.2.20.6.32"/>

<ingredient ... />

<asContent>

<quantity>

<numerator value="amount of this part in its package" unit="unit of amount"/>

<denominator value="1"/>

</quantity>

<containerPackagedProduct>

<formCode code="package type" codeSystem="2.16.840.1.113883.2.20.6.38"/>

</containerPackagedProduct>

</asContent>

</partProduct>

</part>

<part>

<quantity>

<numerator value="amount of this device part in one kit"/>

<denominator value="1"/>

</quantity>

<partProduct>

<code code="item code of this device part" codeSystem="item code system OID"/>

<name>name of device part</name>

<desc>description of device part</desc>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="product classification code of device part" codeSystem="2.16.840.1.113883.2.20.6.27"/>

</generalizedMaterialKind>

</asSpecializedKind>

</partProduct>

</part>

### Device Kit with a Drug Part

The example below illustrates a 2 part kit where the device is the lead:

<manufacturedProduct>

<manufacturedProduct>

<code code="item code of device kit" codeSystem="item code system OID"/>

<name>*name of kit*</name>

<desc>brief description of kit</desc>

<formCode code="C47916" codeSystem="2.16.840.1.113883.2.20.6.32"/>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="*product classification code of kit*" codeSystem="2.16.840.1.113883.2.20.6.27"/>

</generalizedMaterialKind>

</asSpecializedKind>

<part> same as device part above </part>

<part> same as drug part above </part>

**Device with an embedded drug:** For example, a drug eluting stent with an embedded active ingredient. Notice that such products do not involve kits and parts as outlined below:

<manufacturedProduct>

<manufacturedProduct>

<code code="device item code" codeSystem="device item code system OID"/>

<name>*device name*</name>

<desc>*brief description*</desc>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="*product classification code of device*" codeSystem="2.16.840.1.113883.2.20.6.27"/>

</generalizedMaterialKind>

</asSpecializedKind>

<ingredient classCode="ACTIB">

<quantity .../>

<ingredientSubstance>

<code code="*ID code of active ingredient*" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>*paclitaxel*</name>

**Drug in a delivery device:** For example, drug in pre-filled syringe. Note that the syringe filled with the drug is a different product than the empty syringe. Hence it would not be correct to put the item code for the empty syringe on the one filled with the drug. In fact, since the pre-filled syringe already has (or should have) an NDC code, there is no need for another item code for it. However, one may want to refer to the item code for the empty syringe as a generalization of the filled syringe as outlined below:

<manufacturedProduct>

<manufacturedProduct>

<code code="*MPID*" codeSystem="2.16.840.1.113883.2.20.6.55"/>

<name>*name of drug*</name>

<formCode code="*form code of drug*" codeSystem="2.16.840.1.113883.2.20.6.32"/>

<ingredient classCode="ACTIB">

<!-- active ingredient -->

</ingredient>

<asContent>

<quantity>

<numerator value="*amount of drug in prefilled device*" unit="*unit of amount*"/> <denominator value="1"/>

</quantity>

<containerPackagedProduct>

<formCode code="form code of prefilled device" codeSystem="2.16.840.1.113883.2.20.6.38"/>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="item code of empty device" codeSystem="item code system of empty device"/>

<desc>brief description of empty device</desc>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="product classification code of device" codeSystem="2.16.840.1.113883.2.20.6.27"/>

</generalizedMaterialKind>

</asSpecializedKind>

</generalizedMaterialKind>

</asSpecializedKind>

</containerPackagedProduct>

Relevance to Canada is TBD pending scope review for products sold separately but meant to be used together. When products are used together but packaged separately, the data element <asPartOfAssembly> is used to identify the other product. The products could be drugs or devices as outlined below:

<manufacturedProduct>

<manufacturedProduct>

<code code="item code of device" codeSystem="code system OID"/>

<name>*name of device*</name>

<desc>brief description of device</desc>

<asSpecializedKind ... product classification for device .../>

<asPartOfAssembly>

<quantity>

<numerator value="1"/>

<denominator value="1"/>

</quantity>

<wholeProduct><!-- this is the assembly, but has no identifier -->

<part>

<quantity>

<numerator value="1"/>

<denominator value="1"/>

</quantity>

<partProduct>

<code code="item code of accessory component" codeSystem="code system OID"/> <name>name of accessory component</name>

<desc>brief description of accessory component</desc>

<asSpecializedKind ... product classification for device .../>

Parts may be specified for the product, as outlined below:

<manufacturedProduct>

<manufacturedProduct>

<part/>

and for part products as outlined below:

<part>

<partProduct>

<part/>

### Marketing Category and Application Number

The approval structure specifies in the <code> the marketing category under which the product is approved for marketing. Products marketed under an approved application have the approved ID in the <id extension> and the Regulatory Transaction OID under <id root>.

<subjectOf>

<approval>

<id extension="application or monograph number" root="2.16.840.1.113883.2.20.6.54"/>

<code code="code for marketing category" codeSystem="2.16.840.1.113883.2.20.6.11"/>

<author>

<territorialAuthority>

<territory>

<country codeSystem="2.16.840.1.113883.2.20.6.17" code="1"/>

</territory>

</territorialAuthority>

</author>

</approval>

</subjectOf>

Marketing category is connected through the <subjectOf> element which may appear on the main product:

<subject>

<manufacturedProduct>

<manufacturedProduct/>

<subjectOf/>

or on parts:

<part>

<partProduct/>

<subjectOf/>

An example is outlined below:

<subjectOf>

<approval>

<id extension="NDS-123456" root="2.16.840.1.113883.2.20.6.54"/>

<code code="C73594" codeSystem="2.16.840.1.113883.2.20.6.11"/>

<author>

<territorialAuthority>

<territory>

<country codeSystem="2.16.840.1.113883.2.20.6.17" code="1"/>

### Marketing status

The marketing status provides information on when the product is on or off the market.

<subject>

<manufacturedProduct>...</manufacturedProduct>

<subjectOf>

<marketingAct>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.37"/>

<effectiveTime>

<high value="20040120"/>

The <code> indicates the activity of “marketing”. The status of the product is described in the <statusCode> as either “active” for being on the market or “completed” when marketing is done the product is no longer going to be available on the market. The date when the product is on or off the market is included in the <effectiveTime>. The date when the product is on the market is characterized by the <low value> while the date the product is off the market such as the expiration date of the last lot released to the market is characterized by the <high value>. At this time HPFB does not track when a product is on the market thus the <low value> is not used. An example of a product that is off the market is outlined below:

<subjectOf>

<marketingAct>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.37"/>

<effectiveTime>

<low value="date when on the market"/>

<high value="date when the product is going to be off the market"/>

</effectiveTime>

</marketingAct>

</subjectOf>

For some types of products, a marketing status may be provided on the package level:

<asContent>

<containerPackagedProduct>...</containerPackagedProduct>

<subjectOf>

<marketingAct>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.37"/>

<effectiveTime>

<high value="20040120"/>

### General Characteristics

Several characteristics may be specified for products. In general, the structure allows specifying properties of the product in a code-value pair, the code saying which property is being specified, the value saying what the property is for the given product. The structure connects to the product through the subjectOf element, the concept is outlined below:

<manufacturedProduct>

<manufacturedProduct> ... </manufacturedProduct>

<subjectOf>

<characteristic>

<code code="*characteristic code*" codeSystem=“2.16.840.1.113883.2.20.6.23”/>

<value xsi:type="*characteristic value type*" ...>

Some characteristics may be specified for packaged products as outlined below:

<manufacturedProduct>

<manufacturedProduct>

...

<asContent>

<containerPackagedProduct> ... </containerPackagedProduct>

<subjectOf>

<characteristic>

<code code="*characteristic code*" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="characteristic value type" ...>

Characteristics use one of a number of different data types. Each data type uses slightly different XML elements and attributes as shown in the templates below:

Characteristic of type physical quantity (PQ):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="PQ" value="quantity value" unit="quantity unit">

Characteristic of type number (REAL):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="REAL" value="quantity value"/>

Characteristic of type integer number (INT):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="INT" value="*quantity value*"/>

Characteristic of coded type (CV):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="CV" code="value code" codeSystem="value code system OID"/>

Characteristic of type character string (ST):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="ST">value string</value>

Characteristic of type interval of physical quantity (IVL\_PQ):

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="IVL\_PQ">

<low value="quantity value low boundary" unit="quantity unit"/>

<high value="quantity value high boundary" unit="quantity unit"/>

</value>

Characteristic of type Boolean (true/false value)

<subjectOf>

<characteristic>

<code code="characteristic code" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="BL" value="true or false"/>

### Product & Device characteristics

Product & Device characteristics include a wide range of items including the scheduling symbol, the therapeutic class, pharmaceutical standard as well as all aspect of the appearance (color, score, shape, size, imprint code and image) as well as aspects such as the flavour, and the production quantity. All of this information is captured under <subjectOf> which is a child of <manufacturedProduct>. The example below illustrated the model:

<subjectOf>

<characteristic classCode="OBS">

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="C48325" codeSystem="2.16.840.1.113883.2.20.6.24"xsi:type="CE">

<originalText>optional original color description text</originalText>

</value>

</characteristic>

</subjectOf>

### Color

The example below provides an illustration for encoding color information:

<subjectOf>

<characteristic>

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="C48333" codeSystem="2.16.840.1.113883.2.20.6.24" xsi:type="CE">

<originalText>LIGHT BLUE</originalText>

#### Image

The example below provides an illustration for encoding image information:

<subjectOf>

<characteristic>

<code code="2" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="ED" mediaType="image/jpeg"> <reference value="8837a946-1912-4c1f-8035-e313fdd11ef2.jpg"/>

#### Shape

The example below provides an illustration for encoding shape information:

<subjectOf>

<characteristic>

<code code="3" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.25" xsi:type="CE">

<originalText>capsule like</originalText>

#### Flavor

The example below provides an illustration for encoding flavour information:

<subjectOf>

<characteristic>

<code code="4" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="C73391" codeSystem="2.16.840.1.113883.2.20.6.26" xsi:type="CE">

<originalText>wild grape</originalText>

#### Scoring

The example below provides an illustration for encoding scoring information:

<subjectOf>

<characteristic>

<code code="5" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value value="1" xsi:type="INT"/>

#### Production Amount

The production amount for a package is specified as:

<manufacturedProduct>

<manufacturedProduct>

...

<asContent>

...

<subjectOf>

<characteristic>

<code code="6" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="INT" value="10000"/>

Unlimited production amounts are specified as: <value xsi:type="INT" nullFlavor="PINF"/>

#### Combination Product Type

To mark products as combination products, the nearest combining package should bear the combination product type characteristic:

<manufacturedProduct>

<manufacturedProduct>

...

<asContent>

...

<subjectOf>

<characteristic>

<code code="7" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="C102835" codeSystem="2.16.840.1.113883.2.20.6.30" xsi:type="CV"/>

#### Reusability

The example below provides an illustration for encoding reusability information:

<subjectOf>

<characteristic>

<code code="8" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value value="1" xsi:type="INT"/>

The value is a positive integer, 1 means single use and any other value meaning reusable up to this many times.

#### Sterile Use

The example below provides an illustration for encoding reusability information:

<subjectOf>

<characteristic>

<code code="9" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type=“BL” value="true"/>

The value is a boolean with allowed values of “true” or “false”.

#### MRI Use

The example below provides an illustration for encoding MRI use information:

<subjectOf>

<characteristic>

<code code="10" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type=“BL” value="true"/>

The value is a boolean with allowed values of “true” or “false”.

#### Size

The example below provides an illustration for encoding size information:

<subjectOf>

<characteristic>

<code code="11" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value unit="mm" value="18" xsi:type="PQ"/>

#### Imprint

The example below provides an illustration for encoding imprint information:

<subjectOf>

<characteristic>

<code code="12" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="ST">05</value>

#### Pharmaceutical Standard

The Pharmaceutical Standard is identified by one or more value elements as illustrated below:

<manufacturedProduct>

<subjectOf>

<characteristic>

<code code="13" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.5" xsi:type="CE">

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="13" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="7" codeSystem="2.16.840.1.113883.2.20.6.5" xsi:type="CE">

</characteristic>

</subjectOf>

#### Scheduling Symbol

The Scheduling Symbol is identified by one or more value elements as illustrated below:

<manufacturedProduct>

<subjectOf>

<characteristic>

<code code="14" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.2" xsi:type="CE"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="14" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="2" codeSystem="2.16.840.1.113883.2.20.6.2" xsi:type="CE"/>

</characteristic>

</subjectOf>

#### Therapeutic Class

The Therapeutic Class is identified by one or more value elements as illustrated below:

<manufacturedProduct>

<subjectOf>

<characteristic>

<code code="15" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="A01AA51" codeSystem="2.16.840.1.113883.2.20.6.6" xsi:type="CE"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="15" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value code="A03CA02" codeSystem="2.16.840.1.113883.2.20.6.6" xsi:type="CE"/>

</characteristic>

</subjectOf>

#### Coating

The example below provides an illustration for encoding coating information:

<subjectOf>

<characteristic>

<code code="16" codeSystem="2.16.840.1.113883.2.20.6.23"/>

<value xsi:type="ST">05</value>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1” section/code/@ codeSystem=”2.16.840.1.113883.2.20.6.8”].section | N/A | 0:1 |  | This is the wrapper for the product data elements section and contains all top-level aspects including ID, type, dates, product subsections. |
|  | ID | 1:1 |  | The section ID provides a globally unique ID for a specific section. |
| Conformance | 1. There may be a section element 2. N.B. validation is doctype specific. 3. Each section shall have an ID attribute. 4. N.B. as per section 1.4 ID Related there is currently no validation of GUID’s, this will be introduced later. 5. There is an id element 6. N.B. currently this is not validated. 7. There is a code element 8. An instance of Rule Category 3 identifies that the element has not been defined.      1. There may be a title element 2. N.B. validation is doctype specific. 3. There may be a text element 4. N.B. validation is doctype specific. 5. There is an effectiveTime element 6. N.B. validation is performed at the element level. 7. There is one or more subject elements 8. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1” section/code/@ codeSystem=”2.16.840.1.113883.2.20.6.8”].section.id | N/A | 1:1 |  | Provides a globally unique ID for a specific section. |
| root | 0:1 |  | Not required but if included must be a GUID. |
| Conformance | 1. There is an id element 2. N.B. currently this is not validated. 3. There may be a root attribute 4. N.B. there is no validation of optional aspects. 5. The id@root is a GUID and does not have an extension. 6. N.B. as per section 1.4 ID Related there is currently no validation of GUID’s, this will be introduced later. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1” section/code/@ codeSystem=”2.16.840.1.113883.2.20.6.8”].section.code | N/A | 1:1 |  | The section type/label. It is used to identify the content of the section. |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| Conformance | 1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.8 and the code value is 48780-1. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1” section/code/@ codeSystem=”2.16.840.1.113883.2.20.6.8”].section.title | N/A | 0:1 |  | Provides the title for the section. |
| Conformance | 1. There is no content in the title element 2. An instance of Rule Category 11 identifies that content is not allowed. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1” section/code/@ codeSystem=”2.16.840.1.113883.2.20.6.8”].section.text | N/A | 0:1 |  | Provides the content for the section. |
| Conformance | 1. There is no content in the text element 2. An instance of Rule Category 11 identifies that content is not allowed. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1” section/code/@ codeSystem=”2.16.840.1.113883.2.20.6.8”].section.subject | N/A | 1:n |  | This is a wrapper element for each discrete product. There is one subject element per product (MPID). |
| Conformance | 1. There is a manufacturedProduct element 2. N.B. currently this is not validated. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1” section/code/@ codeSystem=”2.16.840.1.113883.2.20.6.8”].section.effectiveTime | N/A | 1:1 |  | This is a wrapper for the product related date/time information. |
| value | 1:1 |  |  |
| Conformance | 1. There is an effectiveTime element 2. An instance of Rule Category 3 identifies that the element has not been defined.      1. There is either a direct or indirect value for the effectiveTime 2. An instance of Rule Category 6 identifies that there is no value defined either directly or via a child element. 3. The effectiveTime@value has as a minimum precision of day and follows the appropriate format.   a) N.B. validation is doctype specific. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1” section/code/@ codeSystem=”2.16.840.1.113883.2.20.6.8”].section.effectiveTime.low | N/A | 0:1 |  | Captures the Date of Initial Approval, for the entire product section, i.e. the Date of Initial Approval for the initial (first) product. |
| value | 1:1 |  |  |
| Conformance | 1. There may be a low element 2. N.B. validation is doctype specific. 3. There is an value attribute 4. An instance of Rule Category 5 identifies that the attribute has not been defined. 5. If there is an [effectiveTime.low@value](mailto:effectiveTime.low@value) it is smaller than the effectiveTime.high@value. 6. An instance of Rule Category 8 identifies that the (value) attribute value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1” section/code/@ codeSystem=”2.16.840.1.113883.2.20.6.8”].section.effectiveTime.high | N/A | 0:1 |  | Captures the Date of Revision, for the entire product section. Roles up al contained products. |
| value | 1:1 |  |  |
| Conformance | 1. There may be a high element 2. N.B. validation is doctype specific. 3. There is an value attribute 4. An instance of Rule Category 5 identifies that the attribute has not been defined. 5. If there is an [effectiveTime.high@value](mailto:effectiveTime.high@value) it is greater than the [effectiveTime.low@value](mailto:effectiveTime.low@value).   a) An instance of Rule Category 8 identifies that the (value) attribute value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct | N/A | 1:1 |  | This is a wrapper element that provides a link between the product, product characteristics including approvals, indications and the route of administration. |
| Conformance | 1. There is one manufacturedProduct elements 2. N.B. validation is performed at the element level. 3. There is one or more subjectOf elements 4. N.B. validation is performed at the element level. 5. There is one or more consumedIn element 6. N.B. validation is performed at the element level. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.subjectOf | N/A | 1:1 |  | This is a wrapper for the individual characteristics and marketing aspects. |
| Conformance | 1. There is one or more subjectOf elements 2. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.consumedIn | N/A | 1:1 |  | This is a wrapper for the route of administration aspects |
| Conformance | 1. There is one or more consumedIn element 2. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.manufacturedProduct | N/A | 1:1 |  | This is a wrapper for the product aspect. |
| Conformance | 1. There maybe one or more an templateId elements 2. N.B. validation is performed at the element level. 3. There is an code element 4. N.B. validation is performed at the element level. 5. There may be a name element 6. N.B. validation is performed at the element level. 7. There may be a desc element 8. N.B. currently this is not validated, however it is planned to introduce this in the future. 9. There may be a formCode element 10. N.B. validation is performed at the element level. 11. There may be a asEntityWithGeneric element 12. N.B. validation is performed at the element level. 13. There may be a asEquivalentEntity element 14. N.B. validation is performed at the element level 15. There is an ingredient element 16. N.B. validation is performed at the element level. 17. There may be a part element 18. N.B. validation is performed at the element level. 19. There is an asContent element for all products, however it is optional for parts 20. N.B. validation is performed at the element level. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.manufacturedProduct.templateId | N/A | 1:1 |  | Details product related CV values, identifies the associated OID and value. |
| root | 1:1 |  |  |
|  | extension | 1:1 |  |  |
| Conformance | 1. There maybe one or more templateId elements 2. N.B. there is no validation of optional aspects. 3. There maybe a templateId element where the root attribute value is: 2.16.840.1.113883.2.20.6.53 and the value of the extension attribute derived from the OID. 4. An instance of Rule Category 2 identifies that the OID value is incorrect. 5. An instance of Rule Category 5 identifies that the (root) attribute has not been defined. 6. An instance of Rule Category 5 identifies that the (extension) attribute has not been defined. 7. An instance of Rule Category 8 identifies that the extension value is not in the CV. 8. An instance of Rule Category 14 identifies that the extension value is contextually incorrect. 9. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.manufacturedProduct.code | N/A | 1:1 |  | Identifies the MPID for the product. |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| Conformance | 1. There is an code element 2. An instance of Rule Category 3 identifies that the element has not been defined.      1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.55. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 6. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.manufacturedProduct.name | N/A | 1:1 |  | Details the Brand / Proprietary name of the product. |
| Conformance | 1. There is an name element 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. An instance of Rule Category 4 identifies that more than one element is defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.manufacturedProduct.formCode | N/A | 1:1 |  | Details the Dosage Form of the product. |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| Conformance | 1. There is an formCode element 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.3. If the product has parts, then the code for kits shall be used. 4. An instance of Rule Category 2 identifies that the OID value is incorrect. 5. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 6. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 7. An instance of Rule Category 8 identifies that the code is not in the CV. 8. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 9. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asEntityWithGeneric | N/A | 1:1 |  | Wrapper for the Generic / Non-Proprietary name of the product |
| Conformance | 1. There is an asEntityWithGeneric element 2. An instance of Rule Category 3 identifies that the element has not been defined.      1. There is an asEntityWithGeneric.genericMedicine element 2. An instance of Rule Category 3 identifies that the element has not been defined, this will trigger a schema validation error.      1. There is one or more asEntityWithGeneric.genericMedicine.name elements 2. N.B. validation is performed at the element level. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asEntityWithGeneric.name | N/A | 1:1 |  | Details the Generic / Non-Proprietary name(s) of the product |
| Conformance | 1. There is one or more name element 2. An instance of Rule Category 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. An instance of Rule Category 6 identifies that the (name) element is empty. 4. The name element may not contain a suffix. 5. An instance of Rule Category 12 identifies that the content is incorrectly formatted. 6. The name element may not exceed 512 characters. 7. An instance of Rule Category 12 identifies that the content is incorrectly formatted. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| ingredient | N/A | 1:n |  | Details the ingredients (substances) in the product. This element details the role of the ingredient and child elements provide details on the ingredient. |
|  | classCode | 1:1 |  |  |
| Conformance | 1. There is one or more ingredient element with a classCode attribute derived from OID: 2.16.840.1.113883.2.20.6.39 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. An instance of Rule Category 5 identifies that the (classCode) attribute has not been defined. 4. An instance of Rule Category 8 identifies that the code is not in the CV. 5. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 6. An instance of Rule Category 10 identifies that there is a notification flag for the content. 7. There may be a confidentialityCode element 8. N.B. validation is performed at the element level. 9. There may be a quantity element 10. N.B. validation is performed at the element level. 11. There shall be an ingredientSubstance element 12. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| quantity | N/A | 0:1 |  | This element and its children are used to detail the quantity of the ingredient. |
| Conformance | 1. Numerator and denominator elements may be required to meet the quantity conformance rules. 2. N.B. there is no validation of optional aspects. 3. When there is a unit of measure it is derived from OID: 2.16.840.1.113883.2.20.6.15 4. An instance of Rule Category 8 identifies that the code is not in the CV. 5. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 6. An instance of Rule Category 10 identifies that there is a notification flag for the content. 7. For percentages the numerator unit is not 1, instead use a volume unit for volume fractions and a mass unit for mass fractions. 8. An instance of Rule Category 8 identifies that the (unit) attribute value is incorrect. 9. An instance of Rule Category 14 identifies that the unit value is contextually incorrect. 10. The numerator unit is based on mass (e.g., mg or g) and not volume (e.g. mL or L), except for ingredients such as water, alcohol, and gases. 11. An instance of Rule Category 8 identifies that the (unit) attribute value is incorrect. 12. An instance of Rule Category 14 identifies that the unit value is contextually incorrect. 13. Active ingredients must have both a numerator and denominator value, the values must both be greater than 0 (zero). 14. An instance of Rule Category 5 identifies that the (numerator.value) attribute has not been defined. 15. An instance of Rule Category 8 identifies that the numerator.value is 0. 16. An instance of Rule Category 5 identifies that the (denominator.value) attribute has not been defined. 17. An instance of Rule Category 8 identifies that the denominator.value is 0. 18. In cases that there is no strength, the quantity element is to be omitted. 19. N.B. there is no validation aspect. 20. The denominators values and units for all ingredients in a product are the same. 21. An instance of Rule Category 8 identifies that the (value) attribute value is incorrect. 22. An instance of Rule Category 8 identifies that the (units) attribute value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| numerator | N/A | 0:1 |  | The numerator aspect of the quantity element. |
| Conformance | 1. There may be a numerator element 2. N.B. there is no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| denominator | N/A | 0:1 |  | The denominator aspect of the quantity element. |
| Conformance | 1. There may be a denominator element 2. N.B. there is no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| ingredientSubstance | N/A | 1:1 |  | Details the substance, substance name and the substance that is the basis of strength. |
| Conformance | 1. There is an code element 2. An instance of Rule Category 3 identifies that the element has not been defined.      1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.14. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. 8. There is a name element that shall display the appropriate label. 9. An instance of Rule Category 4 identifies that more than one element is defined. 10. An instance of Rule Category 7 identifies that label does not match the CV. 11. The same ingredient substance code is not used more than once per product. 12. An instance of Rule Category 8 identifies that the (code) attribute value is not unique. 13. An instance of Rule Category 14 identifies that value is contextually incorrect. 14. If the product has no parts and is not a part, then there are one or more active ingredients directly under the product. 15. An instance of Rule Category 8 identifies that the (classCode) attribute value is incorrect (ie the product has no direct ingredient where the classCode is equal to ACTI or a child of ACTI). 16. If the product has parts or is a part then the active ingredients are under parts. 17. An instance of Rule Category 8 identifies that the (classCode) attribute value is incorrect (ie the product has either a direct ingredient where the classCode is equal to ACTI or a child of ACTI, or lacks an ingredient where the classCode is equal to ACTI or a child of ACTI as part of a contained part) 18. There is an activeMoiety element for all active ingredients, non-active ingredients may not have activeMoiety element 19. SPL-Rule-3002 (Rule Category 3) identifies that a required element is missing. 20. SPL-Rule-11001 (Rule Category 11) identifies that a disallowed element has been included. 21. If the strength is based on a reference then, then there is an asEquivalentSubstance element, otherwise the asEquivalentSubstance is not present 22. An instance of Rule Category 3 identifies that the (asEquivalentSubstance) element has not been defined. 23. An instance of Rule Category 11 identifies that a disallowed element has been included. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| activeMoiety | N/A | 0:1 |  | Details the active moiety aspect. |
| Conformance | 1. There is an activeMoiety element 2. N.B. there is no validation aspect. 3. There is an activeMoiety.code element. 4. An instance of Rule Category 3 identifies that the element has not been defined. 5. The activeMoiety.code element shall include the code and codeSystem attributes derived from OID 2.16.840.1.113883.2.20.6.14. 6. An instance of Rule Category 2 identifies that the OID value is incorrect. 7. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 8. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 9. An instance of Rule Category 8 identifies that the code is not in the CV. 10. An instance of Rule Category 14 identifies that value is contextually incorrect. 11. An instance of Rule Category 10 identifies that there is a notification flag for the content. 12. There is an activeMoiety.name element, the content shall match the  [activeMoiety.code@code](mailto:%20activeMoiety.code@code) attribute 13. An instance of Rule Category 7 identifies that label does not match the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asEquivalentSubstance | N/A | 0:1 |  | Details the reference ingredient aspect. |
| Conformance | 1. There is an definingSubstance element 2. N.B. there is no validation aspect. 3. There is an definingSubstance.code element. 4. An instance of Rule Category 3 identifies that the element has not been defined.      1. The definingSubstance.code element shall include the code and codeSystem attributes and be derived from OID 2.16.840.1.113883.2.20.6.14. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that code value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. 8. There is an definingSubstance.name element, that shall match the [definingSubstance.code@code](mailto:definingSubstance.code@code) attribute. 9. An instance of Rule Category 7 identifies that label does not match the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asContent | N/A | 1:1 |  | Details the package quantity aspects of the product. |
| Conformance | 1. There is a quantity element 2. An instance of Rule Category 3 identifies that the element has not been defined.      1. There is a quantity.numerator element 2. N.B. there is no validation aspect. 3. The numerator element has a value attribute that is greater than zero and a unit attribute derived from OID 2.16.840.1.113883.2.20.6.38 4. An instance of Rule Category 5 identifies that the (value) attribute has not been defined. 5. An instance of Rule Category 5 identifies that the (unit) attribute has not been defined. 6. An instance of Rule Category 8 identifies that the unit is not in the CV. 7. An instance of Rule Category 14 identifies that the unit value is contextually incorrect. 8. An instance of Rule Category 10 identifies that there is a notification flag for the content. 9. An instance of Rule Category 8 identifies that the value is 0. 10. There is a quantity.denominator element 11. N.B. there is no validation aspect. 12. The denominator element has value attribute and a unit attribute that both equals “1”. 13. An instance of Rule Category 8 identifies that the (value) attribute value is incorrect. 14. An instance of Rule Category 8 identifies that the (unit) attribute value is incorrect. 15. If the product has parts, then the initial numerator value and unit is “1” 16. An instance of Rule Category 8 identifies that the (value) attribute value is incorrect, based on the product structure. 17. An instance of Rule Category 8 identifies that the (unit) attribute value is incorrect, based on the product structure. 18. The unit of the numerator of the initial package is the same as the units for the denominators of all the ingredient quantities (strengths) 19. An instance of Rule Category 8 identifies that the (unit) attribute value is incorrect, based on the product structure. 20. The unit of the numerator of an outer package is the same as the unit for the denominator of the quantity of the inner package. 21. An instance of Rule Category 8 identifies that the (unit) attribute value is incorrect, based on the product structure. 22. There may be a containerPackagedProduct element 23. N.B. there is no validation of optional aspects. 24. There may be a subjectOf element 25. N.B. there is no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| containerPackagedProduct | N/A | 1:1 |  | Describes the product packaging ID. |
| Conformance | 1. There is a code element. 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. There is a formCode element. 4. An instance of Rule Category 3 identifies that the element has not been defined. 5. There may be an asContent element 6. N.B. there is no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| containerPackagedProduct.code | N/A | 1:1 |  | Details the PCID of the product |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| Conformance | 1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.56. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 6. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| containerPackagedProduct.formCode | N/A | 1:1 |  | Details the package type |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| Conformance | 1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.32. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| subjectOf | N/A | 1:1 |  | This is a placeholder element that encapsulates marketing, approval or a characteristic of the product |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There may be one of the following (characteristic, marketingAct or approval) element. 2. N.B. there is no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| approval | N/A | 0:1 |  | Details the approval aspects for a product. |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is an id element for each product. 2. An instance of Rule Category 3 identifies that the element has not been defined.      1. There is a code element for each product. 2. An instance of Rule Category 3 identifies that the element has not been defined.      1. There is an author element for each product. 2. An instance of Rule Category 3 identifies that the element has not been defined. 3. An instance of Rule Category 4 identifies that the element has been defined more than once. 4. There is an effectiveTime element for each product. 5. An instance of Rule Category 3 identifies that the element has not been defined. 6. If the application number was already submitted, then the ingredients are the same as in the previous submission of a product with the same application number. 7. N.B. currently not validated, however it is planned to introduce this in the future. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| approval.id | N/A | 1:1 |  | Details the regulatory activity ID |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is a root and an extension attribute, the root value is 2.16.840.1.113883.2.20.6.54, the extension is derived from the OID. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (root) attribute has not been defined 4. An instance of Rule Category 5 identifies that the (extension) attribute has not been defined 5. An instance of Rule Category 8 identifies that the extension is not in the CV. 6. An instance of Rule Category 14 identifies that the extension value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| approval.code | N/A | 1:1 |  | Details the Regulatory Activity Type (Marketing Category) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.11. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| approval.author | N/A | 1:1 |  | Details the party whom approved the content (scope is element specific) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is a territorialAuthority element 2. N.B. there is no validation aspect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| territorialAuthority | N/A | 1:1 |  | Details the approval authority (via the region). |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is a territory element 2. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| territory | N/A | 1:1 |  | Identifies a specific region. |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is a code element that contains code and codeSystem attributes derived from 2.16.840.1.113883.2.20.6.17. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| confidentialityCode | N/A | 0:1 |  | Enables content to be flagged as confidential. |
| Conformance | 1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.21. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asEquivalentEntity | N/A | 0:1 |  | Enables referencing information already submitted for a source drug. |
|  | code |  |  |  |
|  | codeSystem |  |  |  |
| Conformance | 1. There is a classCode attribute with the value "EQUIV". 2. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 3. An instance of Rule Category 2 identifies that the value is incorrect. 4. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.12. 5. An instance of Rule Category 2 identifies that the OID value is incorrect. 6. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 7. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 8. An instance of Rule Category 8 identifies that the code is not in the CV. 9. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 10. An instance of Rule Category 10 identifies that there is a notification flag for the content. 11. The defining material kind code matches a product/item code in an SPL file with a different set id. 12. N.B. currently this is not validated, however it is planned to introduce this in the future. 13. Product/item code for the source is not the same as the product/item code for the product. 14. N.B. currently this is not validated, however it is planned to introduce this in the future. 15. The equivalent Item Code is not the same as the Item Code for the product 16. N.B. currently this is not validated, however it is planned to introduce this in the future. 17. The equivalent Item Code is not the same as the Item Code for another equivalence stated for this product. 18. N.B. currently this is not validated, however it is planned to introduce this in the future. 19. There is only one product source per product. 20. An instance of Rule Category 4 identifies that there is more than one product source for a specific product. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asSpecializedKind | N/A | 0:1 |  | Used to detail information for devices. |
|  | classCode |  |  |  |
| Conformance | 1. There is an asSpecializedKind element 2. N.B. currently this is not validated, however it is planned to introduce this in the future. 3. There is an asSpecializedKind.generalizedMaterialKind element 4. N.B. currently this is not validated, however it is planned to introduce this in the future. 5. There is an asSpecializedKind.generalizedMaterialKind.code element 6. N.B. currently this is not validated, however it is planned to introduce this in the future. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asSpecializedKind.generalizedMaterialKind.code | N/A | 1:1 |  | Details the device type. |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| Conformance | 1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.27. 2. N.B. currently this is not validated, however it is planned to introduce this in the future. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asIdentifiedEntity | N/A | 1:1 |  | Enables sponsor, 3rd party or other non regulator identifiers on items. |
|  | classCode | 1:1 | IDENT |  |
| Conformance | 1. There may be one or more additional identifiers, including model number, catalog number, and reference number. Each identifier shall have a single asIdentifiedEntity element. 2. N.B. there is no validation of optional aspects. 3. Each asIdentifiedEntity shall have a classCode attribute with a value of “IDENT”. 4. N.B. currently this is not validated, however it is planned to introduce this in the future. 5. Each asIdentifiedEntity shall have a single asIdentifiedEntity.id element with both root and extension attributes. The root attribute shall contain the Sponsors OID (see below) and an extension attribute captures the actual identifier. 6. N.B. currently this is not validated, however it is planned to introduce this in the future. 7. The asIdentifiedEntity.id extension attribute is compliant with the code system’s allocation rules. 8. N.B. there is no validation aspect. 9. There is at most one asIdentifiedEntity.id used to capture the Model Number reference. The id root can be any root OID over which the Sponsor has authority. If the Sponsor has no such root OID of its own, then the root is constructed by concatenating the Company ID (without leading zeroes) to the fixed string “2.16.840.1.113883.2.20.6.13” 10. N.B. there is no validation aspect. 11. There is at most one asIdentifiedEntity.id used to capture the Catalog Number. The id root can be any root OID over which the Sponsor has authority. If the Sponsor has no such root OID of its own, then the root is constructed by concatenating the Company ID (without leading zeroes) to the fixed string “2.16.840.1.113883.2.20.6.13” 12. N.B. there is no validation aspect. 13. The product may have multiple asIdentifiedEntity.id elements used to capture reference numbers (i.e., secondary identifiers). The id root can be any root OID over which the Sponsor has authority. If the Sponsor has no such root OID of its own, then the root is constructed by concatenating the Company ID (without leading zeroes) to the fixed string “2.16.840.1.113883.2.20.6.13” 14. N.B. there is no validation aspect. 15. Each asIdentifiedEntity shall have a single asIdentifiedEntity.code element, the asIdentifiedEntity.code element shall have a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.13. 16. N.B. currently this is not validated, however it is planned to introduce this in the future. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| part | N/A | 1:1 |  | Enables for identifying relationships and quantities on parts. |
| Conformance | 1. Each part has an overall quantity captured in the partProduct.asContent.quantity element 2. N.B. currently this is not validated, however it is planned to introduce this in the future. 3. If there is package information it is captured in the partProduct.asContent.containerPackagedProduct element 4. N.B. currently this is not validated, however it is planned to introduce this in the future. 5. If there is package information in the part, then the numerator unit is the same as the numerator unit for the “as content” data element 6. N.B. currently this is not validated, however it is planned to introduce this in the future. 7. If there is no package information in the part, then the numerator unit is 1 8. N.B. currently this is not validated, however it is planned to introduce this in the future. 9. If there is a code element, it follows the general rules for product codes. 10. N.B. currently this is not validated. 11. There is a name element captured in the partProduct.asNamedEntity.name element. 12. N.B. currently this is not validated, however it is planned to introduce this in the future. 13. Procedures for source, ingredients, characteristics and packaging are the same as for products without parts 14. N.B. there is no validation aspect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| partProduct | N/A | 1:1 |  | Identifies the discrete parts when a product has more than one part. |
| Conformance | 1. There may be one or more asIdentifiedEntity elements 2. N.B. currently this is not validated, however it is planned to introduce this in the future. 3. There is an asContent element. 4. N.B. currently this is not validated, however it is planned to introduce this in the future. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asNamedEntity | N/A | 1:1 |  | Used to identify alternative names, this can be at the product or company level. |
| Conformance | N.B. currently this is not validated, however it is planned to introduce this in the future. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| consumedIn | N/A | 1:1 |  | Placeholder element |
| Conformance | 1. There is a substanceAdministration element. 2. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| substanceAdministration | N/A | 1:1 |  | Wrapper element for the Route of Administration. |
| Conformance | 1. There is a routeCode element. 2. An instance of Rule Category 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| routeCode | N/A | 1:1 |  | Details a specific Route of Administration |
| Conformance | 1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.7. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| marketingAct | N/A | 1:1 |  | Details the marketing status and date information. |
| Conformance | 1. There is a code and codeSystem attribute derived from OID 2.16.840.1.113883.2.20.6.37. 2. An instance of Rule Category 2 identifies that the OID value is incorrect. 3. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 4. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 5. An instance of Rule Category 8 identifies that the code is not in the CV. 6. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 7. An instance of Rule Category 10 identifies that there is a notification flag for the content. 8. The marketing status must be on procurable packaging regardless of the level of the packaging. 9. N.B. currently this is not validated, however it is planned to introduce this in the future. 10. If the marketing start or end date is on a package, then the start date is not before the marketing start date of the product and the end date not after the end date of the product. 11. An instance of Rule Category 8 identifies that the attribute value is incorrect. 12. An instance of Rule Category 14 identifies that value is contextually incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| characteristic | N/A | 1:1 |  | Details a specific product characteristic, such as colour, flavour, shape, therapeutic class, pharmaceutical standard, imprint, schedule, ... |
| Conformance | 1. There is a characteristic value with the appropriate type as applicable. 2. An instance of Rule Category 8 identifies that the attribute value is contextually incorrect, meaning type to value mismatch. 3. There is only one instance per characteristic type, other than for Pharmaceutical Standard, Scheduling Symbol and Therapeutic Class. 4. An instance of Rule Category 8 identifies that the (code) attribute value is contextually incorrect, implying more than the number of allowed characteristics for the specified type. 5. When values are numbers they shall be an integer greater than zero. 6. An instance of Rule Category 8 identifies that the versionNumber@value is 0. 7. An instance of Rule Category 8 identifies that the versionNumber@value is not an integer. 8. There is a code element with a code and codeSystem attributes, the codeSystem is 2.16.840.1.113883.2.20.6.23. 9. An instance of Rule Category 2 identifies that the OID value is incorrect. 10. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 11. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 12. An instance of Rule Category 8 identifies that the code is not in the CV. 13. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 14. An instance of Rule Category 10 identifies that there is a notification flag for the content. 15. Coded types shall have a value element, with code and codeSystem attributes. 16. An instance of Rule Category 3 identifies that the value element has not been defined. 17. An instance of Rule Category 2 identifies that the OID value is incorrect. 18. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 19. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 20. An instance of Rule Category 8 identifies that the code is not in the CV. 21. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 22. An instance of Rule Category 10 identifies that there is a notification flag for the content.      1. The codeSystem for the value element is context specific as per the following:    * Scheduling Symbol = 2.16.840.1.113883.2.20.6.2    * Pharmaceutical Standard = 2.16.840.1.113883.2.20.6.5    * Therapeutic Class = 2.16.840.1.113883.2.20.6.6    * Color = 2.16.840.1.113883.2.20.6.24    * Shape = 2.16.840.1.113883.2.20.6.25    * Flavour = 2.16.840.1.113883.2.20.6.26    * Combination Product = 2.16.840.1.113883.2.20.6.30 2. Non-Coded types have a value element with the applicable attributes (unit, value and type) as per the data type. 3. An instance of Rule Category 8 identifies that the attribute value is incorrect. 4. An instance of Rule Category 3 identifies that the value element has not been defined. 5. An instance of Rule Category 2 identifies that the OID value is incorrect. 6. An instance of Rule Category 5 identifies that the (code) attribute has not been defined. 7. An instance of Rule Category 5 identifies that the (codeSystem) attribute has not been defined. 8. An instance of Rule Category 14 identifies that the code value is contextually incorrect. 9. An instance of Rule Category 10 identifies that there is a notification flag for the content. 10. The value element shall be empty other than child elements. 11. An instance of Rule Category 11 identifies that the element has content. 12. The value attribute for an imprint may only contain only letters and numbers separated by semicolon without spaces. 13. An instance of Rule Category 12 identifies that the content is incorrectly formatted. 14. The attributes for an image shall have include, an xsi:type attribute of “ED”, a mediaType attribute of “image/<file type>” where the file type is a permitted file format (see the Images section for details), a reference element with a value attribute which is the file name for a valid image, and the image file is submitted together with the SPL file. 15. An instance of Rule Category 5 identifies that the (xsi:type) attribute has not been defined. 16. An instance of Rule Category 8 identifies that the (xsi:type) attribute value is incorrect. 17. An instance of Rule Category 14 identifies that the xsi:type value is contextually incorrect. 18. An instance of Rule Category 5 identifies that the (mediaType) attribute has not been defined. 19. An instance of Rule Category 8 identifies that the (mediaType) attribute value is incorrect. 20. An instance of Rule Category 14 identifies that the mediType value is contextually incorrect. 21. An instance of Rule Category 5 identifies that the (mediaType) attribute has not been defined. 22. An instance of Rule Category 3 identifies that the element has not been defined. 23. An instance of Rule Category 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 24. An instance of Rule Category 6 identifies that a link target can not be found. 25. Combination Products shall only include the physical characteristic on the inner-most packaging unless stated otherwise in the document type specific information. 26. N.B. currently this is not validated, however it is planned to introduce this in the future. 27. Production Amount shall have a value element with an xsi:type of “INT” with a value attribute of “PINF” to indicate unlimited production amounts. 28. An instance of Rule Category 8 identifies that the (value) attribute value is incorrect. 29. An instance of Rule Category 14 identifies that the value value is contextually incorrect. | | | |

## Product Data - Drug Products

This section extends the Product Data Section and outlines additional items relating to drug products that apply to the product data section.

Drug products are products with the marketing category “Pharmaceutical” or “Biologic” in OID: 2.16.840.1.113883.2.20.6.27

## Product Data - Device Products

This section extends the Product Data Section and outlines additional items relating to device products that apply to the product data section.

Device products are products with the marketing category “Device” in OID: 2.16.840.1.113883.2.20.6.27

### Additional Device Identifiers

<document>

<section>

<subject>

<manufacturedProduct>

<manufacturedProduct>

<asIdentifiedEntity classCode="IDENT">

<id extension="ST2000/A" root="1.2.3.99.1"/>

<code code="C99286" codeSystem="2.16.840.1.113883.2.20.6.13"/>

</asIdentifiedEntity>

These additional identifiers may also appear under device parts:

<part>

<partProduct>

<asIdentifiedEntity>

### Device Ingredient

Ingredients included in devices that are not identified as active ingredients include the ingredient class code, ingredient name, identifier, and strength. The element <ingredient> is a child of <manufacturedProduct>, where the class code, and units adhere to the specifications outlined in the Ingredient section.

<ingredient classCode="INGR">

<quantity>

<numerator value="value" unit="code"/>

<denominator value="value" unit=" code"/>

</quantity>

<ingredientSubstance>

<code code="code" codeSystem="2.16.840.1.113883.2.20.6.14"/>

<name>ingredient name</name>

</ingredientSubstance>

</ingredient>

Note that devices may have active ingredients as well, such as in a medicated stent, i.e., where the device serves in part the function of releasing a built-in drug. This is to be distinguished from devices such as syringes which are delivery devices for a drug product that they contain.

### Device Parts

Device parts may be specified for the product in the same way as for other product kits (see section Kits, Parts, Components and Accessories)

<partProduct>

<code code="91234561234569" codeSystem="2.16.840.1.113883.2.20.6.131234"/>

<name>SuperTape 2000</name>

<asSpecializedKind classCode="GEN">

<generalizedMaterialKind>

<code code="MCA" codeSystem="2.16.840.1.113883.2.20.6.27"/>

</generalizedMaterialKind>

</asSpecializedKind>

### Part of Assembly

When products are used together but packaged separately, the data element <asPartOfAssembly> is used to identify the other product. The products could be drugs or devices.

<asPartOfAssembly>

<wholeProduct> <!-- this is the assembly, but has no identifier -->

<part>

<partProduct>

<code code="item code of accessory component" codeSystem="code system OID"/>

### Regulatory Identifiers

Regulatory identifiers, marketing status and characteristics are all connected through the <subjectOf> element which may appear on the main product:

<subject>

<manufacturedProduct>

<manufacturedProduct/>

<subjectOf/>

The regulatory identifier:

<subjectOf>

<approval>

<code code="C80442" codeSystem="2.16.840.1.113883.2.20.6.11"/>

<author>

<territorialAuthority>

<territory>

<country codeSystem="2.16.840.1.113883.2.20.6.17" code="1"/>

### Marketing status and date

The procedures for marketing status and date (if any) are the same for all products and are described in section Marketing status.

# Appendices

## Appendix 1 Glossary

[To be added]

## Appendix 2 Reference Documents

[To be added]

## Appendix 3 Sample XML

[To be added]