

WORKING DRAFT

Phase 1

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Technical Guidance Document

Structured Product Labelling (SPL) – General Validation Rules 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 & General Information

This section will outline the intent of guidance document along with general information on the guidance document.

## Purpose

The purpose of this guidance document is to assist with the overall technical validation of the Structured Product Labeling (SPL) documents.

This document details how the Health Products and Food Branch (HPFB) implements the technical validation of the Structured Product Labeling (SPL) document. In this context technical validation includes ensuring that the business rules are adhered to however the content itself is not validated.

Additionally there is a detailed document per document type instance that provides document type specific details.

The guidance document is limited to the technical aspects of validating the overall SPL document and is a companion to the business related guidance document for the specific document type.

## Inquiries

Questions should be emailed to [hc.hpr-rps.sc@canada.ca](mailto:hc.hpr-rps.sc@canada.ca)

## Content Related

The content along with all associated material such as images, of the SPL labeling files should be placed in a single folder. The file naming conventions for all content shall be adhered to and it is the sponsors responsibility to ensure that there are no content naming collisions.

## ID Related

All ID’s shall be GUIDs (Globally Unique Identifiers) this includes but is not limited to the Document Root ID, ID, SetId, Section ID. Note neither the Hyperlink ID nor the Observation Media ID have to be GUIDs.

All structure, content and formatting rules (including that the letters are lower case, the ID is unique across all versions, documents, sections and any other ids) relating to GUIDs shall be adhered too it is the sponsors responsibility to ensure that there are no ID collisions.

Currently GUIDs are not validated, however all aspect of the GUID will be validated in the future.

## Content Changes and Versioning

Any content change to content that has a direct or indirect ID regardless if it’s a section or metadata requires that information be versioned. Versioning in this context requires either or both the appropriate effectiveTime and ID be updated.

In the case where the content change occurs in an element that does not have an ID and/or effectiveTime then the parent element must be versioned, however the versioning requirement is limited to the closest version-able ancestor (it 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.

## Element Related

The following section describes general element related aspects, this is informational only (there are no validation aspect).

1. 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. For example, contactParty (representedOrganization.contactParty and assignedOrganization.contactParty respectively).
2. Elements that neither contain content nor attributes are not directly validated. Rather, they are validated by the lack of a required child element. Therefore they are omitted from this document, an example is assignedEntity.
3. Any element not explicitly mentioned in the validation rules (the combination of general SPL and the specific DocType) can be left empty where permitted and when it cannot be left empty it can be removed. Note this does not mean non-referenced non-validated elements are not permitted, it simply means they are optional from a business perspective.

## External File References Related

The file naming rules shall be adhered to and it is the sponsors responsibility to ensure that there are no external file name collisions for items such as images. Note this responsibility extends beyond the creation of the file and extends to the publishing/packaging and submission aspects.

## Visual Aids within the Document

There are several visual aids used in this document, they are designed 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 denote sections or content that is under development.

## Scope

This document is limited in scope to Phase 1 of the SPL implementation at HPFB.

# General

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

1. SPL file name is the document id (the value of id@root in the document information section) followed by “.xml”
2. N.B. currently there are no validation aspects for the file name, however it is planned to introduce this in the future.
3. A SPL labeling file contains only the SPL file and associated files.
4. N.B. currently there are no validation aspects for the file package, however it is planned.
5. All files associated with the SPL document are referenced from that SPL document.
6. N.B. currently there are no validation aspects for the orphaned files, however it is planned.
7. XML is well formed and valid against the schema.
8. SPL Rule 1 identifies the outcome of the validation for both well formedness and validity of the document, this includes both the status and the details.
9. There are no elements and/or attributes in addition to those described in the schema.
10. SPL Rule 1 identifies the outcome of the validation for both well formedness and validity of the document, this includes both the status and the details.
11. There are no spaces in codes.
12. N.B. There is currently no single rule that validates that there is no spaces in a code.
13. The case sensitivity rules for display names are document specific.
14. All validation is case sensitive, however there is no general case sensitivity rule.
15. All displayNames are language specific and when derived from a CV they shall be based on the language of the document.
16. N.B. there is no general language rule.
17. There are no spaces in id extensions.
18. N.B. currently there are no validation aspects for spaces in id extensions, however it is planned.
19. There are no empty or incomplete elements except where the element can be empty.
20. SPL Rule 1 identifies the outcome of the validation for both well formedness and validity of the document, this includes both the status and the details.
21. The maximum file size limit is 500MB per individual file.
22. N.B. currently there are no validation aspects for file sizes, however it is planned.
23. The overall SPL labeling file is limited to 5GB in size, should a SPL labeling file exceed 5GB then it must be divided into subsets with a clear explanation of how the data set has been split.
24. N.B. currently there are no validation aspects for file sizes, however it is planned.
25. There are no Processing Instructions included in the SPL file.
26. N.B. currently there are no validation aspects for Processing Instructions, however it is planned.
27. The Schema and Style sheet are a pure adaptation of the HL7 schema.
28. N.B. there is no validation aspect.
29. Images shall be of sufficient quality and size to be legible in the intended context by a user.
30. N.B. there is no validation aspect.
31. The title for labeling section will be the same as the <code@displayName> value when the Title column states Fixed, when it states Manual then the title is free form, in cases when it states N/A then there is no title for the section. OID 2.16.840.1.113883.2.20.6.36 encodes the validation details for sections.
32. SPL Rule 7 is used to perform validation of labels (title’s and displayName).
33. 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 using 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 HPFB only allows for 3 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 depending on the time of the year the reason is that the offset is static and therefore must be manually adjusted for Daylight Saving Time as appropriate.
34. N.B. validation is performed at the element level and is doctype specific.
35. CV Terms shall only be used as applicable. The sponsor is responsible to ensure that Controlled Vocabulary terms are used appropriately. To assist the IG’s identify where there is a scope constraint and OID’s detail the applicable context for each term that have a scope constraint. The majority of the scope constraints are at the Doctype or Doctype/Template level. As an example: an NDS may not contain any superseded or rescinded or rejected terms.
36. SPL Rule 13 and SPL rule 14 are used to validate the context of CV terms.

# Controlled Vocabularies

For a complete overview of the HPFB CV’s please refer to the HPFB CV Overview document, outlined below are CV’s used in the context of HPFB SPL implementation, the usage and validation aspects are detailed throughout the document as appropriate.

| OID | Symbolic Name | Usage |
| --- | --- | --- |
| 2.16.840.1.113883.2.20.6.2 | scheduling-symbol | Short form version of the product schedule; e.g., Pr, N, CT  This OID is currently used only for doctype specific aspects. |
| 2.16.840.1.113883.2.20.6.3 | dosage-form | List of dosage forms; e.g., Aerosol, Drops, Tablet |
| 2.16.840.1.113883.2.20.6.4 | telecom-use | Defines the type of contact information; e.g., Home, Office, Private. |
| 2.16.840.1.113883.2.20.6.5 | pharmaceutical-standard | List of pharmaceopias; e.g., BP, MFR, PH EUR, USP |
| 2.16.840.1.113883.2.20.6.6 | therapeutic-class | List of therapeutic classes; e.g., Chlorhexidine, Cimetidine, Silicones |
| 2.16.840.1.113883.2.20.6.7 | route-of-administration | List of routes of administration; e.g.,  Dental, Epidural, Intracardiac |
| 2.16.840.1.113883.2.20.6.8 | section-id | List of all document section headings; e.g., Indications and Clinical Use, Psychiatric, Geriatrics |
| 2.16.840.1.113883.2.20.6.9 | template-id | List of identifier for each template; e.g., 2004 Product Monograph Template – Standard, 2016 Product Monograph Template - Schedule D |
| 2.16.840.1.113883.2.20.6.10 | document-id | Lists the type of document; e.g., CPID, PM, QOS |
| 2.16.840.1.113883.2.20.6.11 | marketing-category | The regulatory activity the approved PM is associated with; e.g., NDS, SNDS |
| 2.16.840.1.113883.2.20.6.12 | equivalence-codes | Can be used to link a generic to its reference product. |
| 2.16.840.1.113883.2.20.6.13 | identifier-type | All non HPFB assigned part and product ID’s; e.g., sponsor assigned part ID’s for kit components. |
| 2.16.840.1.113883.2.20.6.14 | ingredient-id | List of HPFB substances |
| 2.16.840.1.113883.2.20.6.15 | units-of-measure | List of units of measure; e.g., mg, mm, ml |
| 2.16.840.1.113883.2.20.6.17 | country-code | List of countries; e.g., Canada, USA |
| 2.16.840.1.113883.2.20.6.19 | telecom-capability | Type of telecommunication; e.g., phone, fax or email. |
| 2.16.840.1.113883.2.20.6.20 | product-item-code | This OID is not used at this time.  Once IDMP is implemented this OID will be used to capture Package Identifiers (PCID). |
| 2.16.840.1.113883.2.20.6.21 | information-disclosure | List of terms related to confidentiality and privacy; e.g., |
| 2.16.840.1.113883.2.20.6.22 | schedule | List of product schedules (Spelled out version), Ethical, Schedule G (CDSA IV, CDSA Recommended |
| 2.16.840.1.113883.2.20.6.23 | product-characteristics | List of physical characteristics; e.g., color and shape |
| 2.16.840.1.113883.2.20.6.24 | color | List of colors; e.g., white, yellow, red |
| 2.16.840.1.113883.2.20.6.25 | shape | List of shapes; e.g., oval, square, capsule, triangle |
| 2.16.840.1.113883.2.20.6.26 | flavor | List of flavors; e.g., rose, pepper, sweet, honey |
| 2.16.840.1.113883.2.20.6.27 | product-classification | List of HPFB product classes |
| 2.16.840.1.113883.2.20.6.29 | language-code | List of languages; e.g., ENG, FRA |
| 2.16.840.1.113883.2.20.6.30 | combination-product-type | List of combination products; e.g., ??? |
| 2.16.840.1.113883.2.20.6.31 | company-id | List of companies; e.g., Mylan, Pfizer |
| 2.16.840.1.113883.2.20.6.32 | pack-type | List of packaging types |
| 2.16.840.1.113883.2.20.6.33 | organization-role | List of company roles; e.g., Sponsor, Agent, Importer, |
| 2.16.840.1.113883.2.20.6.36 | structure-aspects | Not used as a CV. This OID is a table concept used to facilitate validation and publishing. |
| 2.16.840.1.113883.2.20.6.37 | status | List of status' used in various contexts, such as when a term can be used (approved, superseded, legacy), a document status (draft, final, approved) or the product status (approved, marketed, cancelled). |
| 2.16.840.1.113883.2.20.6.38 | units-of-presentation | List of units of presentation ; e.g., bag, cup, implant |
| 2.16.840.1.113883.2.20.6.39 | ingredient-role | The role an ingredient plays in a product; e.g., CNTM, ACTIB, IACT |
| 2.16.840.1.113883.2.20.6.42 | din | List of Drug Identification Numbers (DIN); |
| 2.16.840.1.113883.2.20.6.51 | telecom-type | List of Telecommunication Types; |
|  |  |  |

# SPL Documents

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 |  | The XML declaration aspects |
| 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 |
| --- | --- | --- | --- | --- |
| ?xml-stylesheet | N/A | 1:n | N/A | The formatting related aspects are captured in this 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

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"/>

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

<code code="1" codeSystem="2.16.840.1.113883.2.20.6.10" displayName="Product Monograph"/>

<title=”Lipitor”/title>

<effectiveTirme value="20170629235959-0600"/>

<languageCode code="ENG" codeSystem="2.16.840.1.113883.2.20.6.29" displayName="English”/>

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

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

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| document | N/A | 1:1 |  |  |
| 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. SPL Rule 3 identifies that the element has not been defined. 21. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 22. There is one or more templateId elements 23. SPL Rule 3 identifies that the element has not been defined. 24. There is an id element 25. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 26. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 27. There is a code element 28. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 29. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 30. There is an effectiveTime element 31. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 32. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 33. There is a languageCode element 34. SPL Rule 3 identifies that the element has not been defined. 35. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. | | | |

| 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. SPL Rule 5 identifies that the (assigningAuthorityName) attribute has not been defined. 3. SPL Rule 10 identifies that the (assigningAuthorityName) attribute value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| templateId | N/A | 1:n |  | Provides an ID for the document template.  It is used to document the specific template (e.g. 2004 Standard Product Monograph) |
| root | 1:1 |  |  |
|  | extension | 1:1 |  |  |
| Conformance | 1. 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. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (root) attribute has not been defined. 4. SPL Rule 5 identifies that the (extension) attribute has not been defined. 5. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 6. SPL Rule 15 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 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 |
| --- | --- | --- | --- | --- |
| 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 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.10, where the displayName shall display the appropriate label. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (code) attribute has not been defined. 4. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 6. SPL Rule 7 identifies that displayName does not match the CV value. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 identifies that there is a notification flag for the content. | | | |

| 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. SPL Rule 12 identifies that the content is incorrectly formatted. 7. There are no images in the title. 8. SPL Rule 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. SPL Rule 12 identifies that the content is incorrectly formatted. | | | |

| 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. SPL Rule 33 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 |  |  |
|  | displayName | 1:1 |  |  |
| Conformance | 1. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.29, where the displayName shall display the appropriate label. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (code) attribute has not been defined. 4. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 6. SPL Rule 7 identifies that displayName does not match the CV value. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 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 setId element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is a root attribute 5. SPL Rule 5 identifies that the (root) attribute has not been defined. 6. The setId@root is a GUID and does not have an extension. 7. 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. SPL Rule 5 identifies that the (value) attribute has not been defined. 3. SPL Rule 30 identifies that the versionNumber@value is 0. 4. SPL Rule 31 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. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| author | N/A | 1:1 |  | The version of the document. |
| 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 |  | The version of the document. |
| 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 Information sections. | | | |

## 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"/>

<id root="2.16.840.1.113883.2.20.6.33" extension="1"/>

<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" displayName="Canada"/>

</addr>

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

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

<contactPerson>

<name>Smith, Joe</name>

</contactPerson>

</contactParty>

<assignedEntity>

<assignedOrganization>

<assignedEntity>

<assignedOrganization>

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

<id root="2.16.840.1.113883.2.20.6.33" extension="3"/>

<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" displayName="Canada"/>

</addr>

<contactParty>

<contactPerson>

<name>Fred, Last</name>

</contactPerson>

</contactParty>

</assignedOrganization>

</assignedEntity>

</assignedOrganization>

</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>

<name>contact person name for Sponsor/Regulatory Contact</name>

</contactPerson>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| author | N/A | 1:1 |  |  |
| Conformance | 1. There is an author element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 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 |  |  |
| Conformance | 1. There is an assignedEntity element 2. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is an representedOrganization element 5. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 6. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization | N/A | 1:1 |  |  |
| Conformance | 1. The representedOrganization will contain one or more id elements. 2. SPL Rule 3 identifies that the element has not been defined. 3. The representedOrganization must contain an id element that has an root value of 2.16.840.1.113883.2.20.6.33, and an extension value of 1 4. SPL Rule 2 identifies that the OID value is incorrect. 5. SPL Rule 5 identifies that the (root) attribute has not been defined. 6. SPL Rule 5 identifies that the (extension) attribute has not been defined. 7. SPL Rule 10 identifies that no role has been assigned. 8. SPL Rule 10 identifies that more than one role has been assigned. 9. SPL Rule 10 identifies that no Sponsor is identified. 10. SPL Rule 10 identifies that the role is not Sponsor. 11. SPL Rule 15 identifies that there is a notification flag for the content. 12. 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. 13. SPL Rule 2 identifies that the OID value is incorrect. 14. SPL Rule 5 identifies that the (root) attribute has not been defined. 15. SPL Rule 5 identifies that the (extension) attribute has not been defined. 16. SPL Rule 10 identifies that no company ID has been assigned. 17. SPL Rule 10 identifies that more than one company ID has been assigned 18. SPL Rule 10 identifies that the company ID is not in the CV or “Pending”. 19. SPL Rule 15 identifies that there is a notification flag for the content. 20. The representedOrganization will contain a name element. 21. SPL Rule 3 identifies that the element has not been defined. 22. SPL Rule 6 identifies that the name is empty. 23. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 24. SPL Rule 15 identifies that there is a notification flag for the content. 25. The representedOrganization will contain a contactParty element. 26. SPL Rule 3 identifies that the element has not been defined. 27. SPL Rule 4 identifies that the element has been defined more than once. 28. The representedOrganization may contain one or more assignedEntity elements as per the doctype specifics 29. N.B. validation is doctype specific. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.assignedEntity | N/A | 0:1 |  |  |
| Conformance | 1. There may be an assignedEntity element 2. N.B. validation is doctype specific. 3. There is an assignedOrganization element 4. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 5. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.assignedEntity.assignedOrganization | N/A | 0:1 |  |  |
| Conformance | 1. There is an assignedEntity element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 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 |  |  |
| Conformance | 1. There is one or more assignedOrganization elements 2. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.assignedEntity.assignedOrganization.assignedEntity.assignedOrganization | N/A | 0:n |  |  |
| Conformance | 1. The assignedOrganization must contain one or more id elements. 2. SPL Rule 3 identifies that the element has not been defined. 3. The assignedOrganization must contain an id element that has an id@root value of 2.16.840.1.113883.2.20.6.33, and an extension value other than 1. 4. SPL Rule 2 identifies that the OID value is incorrect. 5. SPL Rule 5 identifies that the (root) attribute has not been defined. 6. SPL Rule 5 identifies that the (extension) attribute has not been defined. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 identifies that there is a notification flag for the content. 9. SPL Rule 10 identifies that the (extension) attribute value is incorrect (i.e. equal to 1). 10. 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. 11. SPL Rule 2 identifies that the OID value is incorrect. 12. SPL Rule 5 identifies that the (root) attribute has not been defined. 13. SPL Rule 5 identifies that the (extension) attribute has not been defined. 14. SPL Rule 8 identifies that the company ID is not in the CV or 999999999. 15. SPL Rule 15 identifies that there is a notification flag for the content. 16. SPL Rule 10 identifies that there is no company ID. 17. SPL Rule 10 identifies that more than one company ID is identified. 18. The assignedOrganization shall contain a name element. 19. SPL Rule 3 identifies that the element has not been defined. 20. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 21. The assignedOrganization may contain a telecom element. 22. N.B. there is no validation of optional aspects. 23. The assignedOrganization may contain a contactParty element. 24. N.B. here is no validation of optional aspects. 25. The assignedOrganization may contain one or more assignedEntity elements. 26. N.B. validation is performed at the element level. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedEntity | N/A | 0:1 |  |  |
| Conformance | 1. There is one or more assignedOrganization elements 2. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| id | N/A | 1:n |  |  |
| 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 |  |  |
| 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. SPL Rule 6 identifies that the name is empty. 3. SPL Rule 8 identifies that the code is not in the CV. 4. SPL Rule 15 identifies that there is a notification flag for the content. 5. SPL Rule 10 identifies that name does not match the id@extension value. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.contactParty | N/A | 0:n |  |  |
| 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 shall contain a contactPerson element 6. SPL Rule 3 identifies that the element has not been defined. 7. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| assignedOrganization.contactParty | N/A | 0:n |  |  |
| 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 shall contain a contactPerson element 6. SPL Rule 3 identifies that the element has not been defined. 7. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| representedOrganization.addr | N/A | 0:1 |  | The address for the Sponsor |
| Conformance | 1. There shall be an addr element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There shall be a complete address 5. SPL Rule 3 identifies that the element has not been defined. 6. SPL Rule 9 identifies that there are not 5 elements in the address, therefore some aspect is missing. 7. The addr shall contain a streetAddressLine. 8. SPL Rule 3 identifies that the element has not been defined. 9. SPL Rule 6 identifies that the element is empty. 10. The addr shall contain a city. 11. SPL Rule 3 identifies that the element has not been defined. 12. SPL Rule 6 identifies that the element is empty. 13. The addr shall contain a state. Sponsor 14. SPL Rule 3 identifies that the element has not been defined. 15. SPL Rule 6 identifies that the element is empty. 16. The addr shall contain a postalCode. 17. SPL Rule 3 identifies that the element has not been defined. 18. SPL Rule 6 identifies that the element is empty. 19. The addr shall contain a country element 20. SPL Rule 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 |  | The streetAddressLine is used for capturing the number, apartment, unit, P.O Box as well as the street name or number. |
| Conformance | 1. The element conveys information. 2. SPL Rule 6 identifies that the element is empty. | | | |

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

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

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| postalCode | N/A | 0:1 |  | The postalCode element is used for capturing Postal Codes and Zip Codes |
| Conformance | 1. The element conveys information. 2. SPL Rule 6 identifies that the element is empty. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| country | N/A | 0:1 |  | The country element is used for capturing the country code |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
|  | displayName | 1:1 |  |  |
| Conformance | 1. The country element shall contain code, codeSystem and displayName attributes derived from OID 2.16.840.1.113883.2.20.6.17, where the displayName shall display the appropriate label. 2. SPL Rule 4 identifies that the element has been defined more than once. 3. SPL Rule 2 identifies that the OID value is incorrect. 4. SPL Rule 5 identifies that the (code) attribute has not been defined. 5. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 6. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 7. SPL Rule 7 identifies that displayName does not match the CV value. 8. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 9. SPL Rule 15 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| telecom | N/A | 0:n |  |  |
| value | 1:1 |  |  |
|  | use | 0:1 |  |  |
|  | capability | 0:1 |  |  |
| Conformance | 1. The telecom shall have no content. 2. SPL Rule 11 identifies that content is not allowed. 3. 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 4. SPL Rule 5 identifies that the (value) attribute has not been defined. 5. SPL Rule 8 identifies that the type id is not in the CV or is not contextually correct. 6. SPL Rule 15 identifies that there is a notification flag for the content. 7. SPL Rule 12 identifies that the content is incorrectly formatted. 8. The telecom@use attribute shall only contain values from OID: 2.16.840.1.113883.2.20.6.4 9. SPL Rule 8 identifies that the type id is not in the CV or is not contextually correct. 10. SPL Rule 15 identifies that there is a notification flag for the content. 11. The telecom@capability attribute shall only contain values from OID: 2.16.840.1.113883.2.20.6.19 12. SPL Rule 8 identifies that the type id is not in the CV or is not contextually correct. 13. SPL Rule 15 identifies that there is a notification flag for the content. 14. 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. 15. SPL Rule 12 identifies that the content is incorrectly formatted. 16. 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. 17. SPL Rule 12 identifies that the content is incorrectly formatted. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| contactPerson | N/A | 1:1 |  |  |
| Conformance | 1. The contactPerson shall contain a name element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| name | N/A | 1:1 |  |  |
| Conformance | 1. The name shall be in the form last name, first name. 2. N.B. no validation aspect. | | | |

## 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 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 not validated.

## Document Body

The body of the document includes the structured text such as Warnings and Precautions (see section *4.7 Labeling Content Section Information*) and specific data elements such as ingredients (see section *4.10 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 root="62abedf9-6bde-4787-beb0-abd214307427"/>

<code code="490" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="Opening Disclaimer"/>

<title>Opening Disclaimer</title>

<text>labeling text</text>

<excerpt>excerpt text</excerpt>

<effectiveTime value="20070822"/>

<component/>

### Validation

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| section | N/A | 0:n |  |  |
|  | ID | 1:1 |  |  |
| 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, the value of the ID attribute is a GUID. 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 |
| --- | --- | --- | --- | --- |
| id | N/A | 1:1 |  | Provides a globally unique ID for a specific section. |
| root | 1:1 |  |  |
| Conformance | 1. There is an id element 2. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is a root attribute 5. SPL Rule 5 identifies that the attribute has not been defined. 6. The id@root is a GUID and does not have an extension. 7. 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 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is a code element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.8, where the displayName shall display the appropriate label. 5. SPL Rule 2 identifies that the OID value is incorrect. 6. SPL Rule 5 identifies that the (code) attribute has not been defined. 7. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 8. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 9. SPL Rule 7 identifies that displayName does not match the CV value. 10. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 11. SPL Rule 15 identifies that there is a notification flag for the content. | | | |

| 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, 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. SPL Rule 12 identifies that the content is incorrectly formatted. 7. There are no images in the title. 8. SPL Rule 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 document. |
| 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 4.8 Text Information. 2. N.B. no validation aspect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| renderMultiMedia | N/A | 0:n |  |  |
|  | referencedObject | 1:1 |  |  |
| Conformance | 1. There is a renderMultiMedia element. 2. SPL Rule 11 identifies that the element is not empty. 3. There is a referencedObject attribute. 4. SPL Rule 5 identifies that the attribute has not been defined. 5. SPL Rule 6 identifies that the attribute is empty. 6. SPL Rule 34 identifies that the link target can not be found. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| observationMedia | N/A | 0:n |  |  |
|  | ID | 1:1 |  |  |
| Conformance | 1. There is a observationMedia element 2. N.B. no validation aspect. 3. There is an ID attribute. 4. SPL Rule 5 identifies that the attribute has not been defined. 5. SPL Rule 6 identifies that the attribute is empty. 6. SPL Rule 34 identifies that the link target can not be found. 7. There is a text element 8. SPL Rule 3 identifies that the element has not been defined. 9. SPL Rule 6 identifies that the element is empty. 10. There is a value element 11. SPL Rule 3 identifies that the element has not been defined. 12. SPL Rule 6 identifies that the element is empty. 13. 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. 14. SPL Rule 5 identifies that the (xsi:type) attribute has not been defined. 15. SPL Rule 6 identifies that the (xsi:type) attribute is empty. 16. SPL Rule 10 identifies that the (xsi:type) attribute value is incorrect. 17. SPL Rule 5 identifies that the (mediaType) attribute has not been defined. 18. SPL Rule 6 identifies that the (mediaType) attribute is empty. 19. SPL Rule 10 identifies that the (mediaType) attribute value is incorrect. 20. SPL Rule 8 identifies that the mediatype is not in the CV or is not contextually correct. 21. SPL Rule 15 identifies that there is a notification flag for the content. 22. There is a value.reference element 23. SPL Rule 3 identifies that the element has not been defined. 24. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 25. 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 26. SPL Rule 5 identifies that the attribute has not been defined. 27. SPL Rule 6 identifies that the attribute is empty. 28. SPL Rule 12 identifies that the content is incorrectly formatted (not lowercase). 29. SPL Rule 34 identifies that the link target can not be found. 30. 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. 31. SPL Rule 10 identifies that the (value) attribute value is incorrect or contextually incorrect. 32. The observationMedia element is always contained within a component element. 33. SPL Rule 9 identifies that the element value is incorrect or contextually incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| excerpt | N/A | 0:1 |  | Provides the content for the document. |
| 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 4.9 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.  Please refer to the Doctype for specific details on the usage. |
| value | 1:1 |  |  |
| Conformance | 1. There is an effectiveTime element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is either a direct or indirect value for the effectiveTime 5. SPL Rule 33 identifies that there is no value defined either directly or via a child element. 6. The effectiveTime@value has as a minimum precision of day and follows the appropriate format.   a) N.B. validation is doctype specific. | | | |

### 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" displayName="Part II: Scientific Information"/>

<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" displayName="Pharmaceutical Information"/>

<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" displayName="Drug Substance"/>

<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:

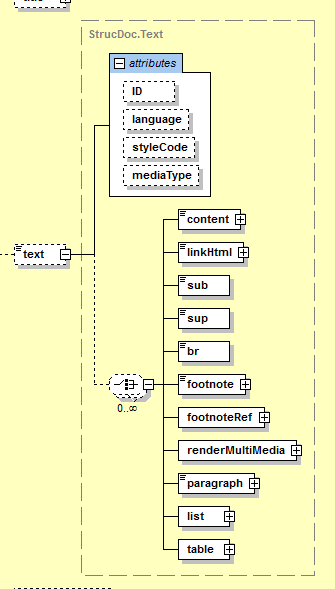
* Capture the section using the <section> element rather than within a <text> element. This allows computer systems to use and display this information properly.
* Capture the section title using the <title> element rather than placing the text of the title within the <text> element. This allows computer 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.



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 the table below are permitted:

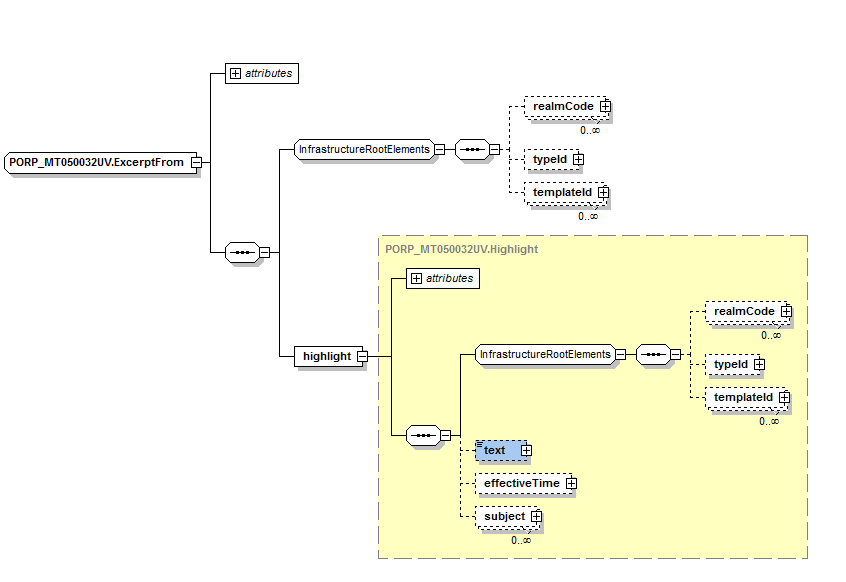
| File Format | Description | Specifications | Extension |
| --- | --- | --- | --- |
| JPEG/JFIF | Joint Photographic Experts Group (JPEG) / JPEG File Interchange Format (JFIF) is a compression standard for encoding and exchanging still digital raster files. | ISO 10918-1 | jpg |
| PDF/A-1 | Portable 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. | World Wide Web Consortium (W3C) XML 1.0 | xml |

## 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.



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" displayName=" Warnings and Precautions"/>

<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:

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.

The coding of the highlights text block is not in a subsection.

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.

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>

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

<code code="48780-1" codeSystem="2.16.840.1.113883.2.20.6.8" displayName="SPL product data elements section"/>

<title/>

<text/>

<effectiveTime value="20151207"/>

<subject>

<manufacturedProduct>

<manufacturedProduct>

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

</manufacturedProduct>

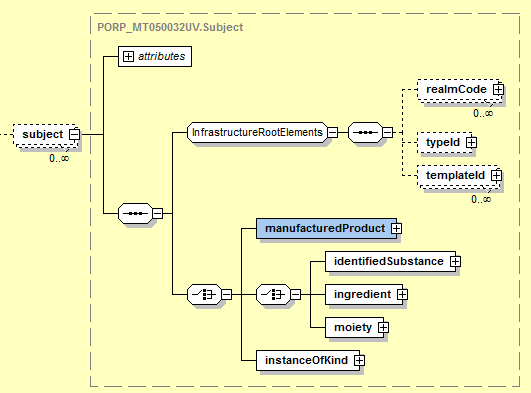
<!-- elements detailed later in this section-->

</manufacturedProduct>

</subject>

</section>

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



The following is an example for a drug product:

<manufacturedProduct>

<manufacturedProduct>

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

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

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

<asEntityWithGeneric>

<genericMedicine>

<name>non-proprietary name</name>

</genericMedicine>

</asEntityWithGeneric>

</manufacturedProduct>

<subjectOf>

<approval>

<!-- possibly approval number -->

<code code="1" displayName="NDS" 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="2.16.840.1.113883.2.20.6.42"/>

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

<formCode code="dose form code" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="display name"/>

<asEntityWithGeneric>

<genericMedicine>

<name>non proprietary name</name>

</genericMedicine>

</asEntityWithGeneric>

</manufacturedProduct>

<subjectOf>

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

<code code="1" displayName="NDS" 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=" 2.16.840.1.113883.2.20.6.42"/>

<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" displayName="model number"/>

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="12345678" codeSystem=" 2.16.840.1.113883.2.20.6.42"/>

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

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

<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" displayName="Midazolam Hydrochloride"/>

<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 and definitions and structure.

| 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” displayName=”Company Confidential Information"/>

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" displayName=”Company Confidential Information"/>

<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" displayName=”Company Confidential Information "/>

<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 2: 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" displayName="oral"/>

</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" displayName="oral"/>

</substanceAdministration>

</consumedIn>

<consumedIn>

<substanceAdministration>

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

</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: 2.16.840.1.113883.2.20.6.20, however it should be noted that at this time HPFB does not use the product ID aspect, therefore the code element shall be omitted. Package identifiers will be revisited at a later date in concert with IDMP.

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="12345678-1234-112233" codeSystem="2.16.840.1.113883.2.20.6.20"/>

<formCode code=“121" displayName="SYRINGE" 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="12345678-1234-445566" codeSystem="2.16.840.1.113883.2.20.6.20"/>

<formCode code=“1" displayName=“Box" 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="11234560012349" codeSystem=" 2.16.840.1.113883.2.20.6.42"/>

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

<formCode code="C47916" displayName="Kit" 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="DIN of kit" codeSystem="2.16.840.1.113883.2.20.6.42"/>

<name>name of kit</name>

<formCode code="C47916" displayName="Kit" 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*" displayName="*form name 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" displayName="package type name" 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" displayName="display name of device part"/>

</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" displayName="Kit" codeSystem="2.16.840.1.113883.2.20.6.32"/>

<asSpecializedKind>

<generalizedMaterialKind>

<code code="*product classification code of kit*" displayName="*display name 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*" displayName="*display name 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="*DIN*" codeSystem="2.16.840.1.113883.2.20.6.42"/>

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

<formCode code="*form code of drug*" displayName="*form display name 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" displayName="form display name 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" displayName="display name 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 Drug Identification Numbers (DIN) OID under <id root>.

<subjectOf>

<approval>

<id extension="application or monograph number" root="2.16.840.1.113883.2.20.6.42"/>

<code code="code for marketing category" codeSystem="2.16.840.1.113883.2.20.6.11" displayName="display name"/>

<author>

<territorialAuthority>

<territory>

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

</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="NDS123456" root="2.16.840.1.113883.2.20.6.42"/>

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

<author>

<territorialAuthority>

<territory>

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

### 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"/>

<statusCode code="active"/>

<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"/>

<statusCode code="active"/>

<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"/>

<statusCode code="active"/>

<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" displayName="value code display name">

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" displayName="Color"/>

<value code="C48325" codeSystem="2.16.840.1.113883.2.20.6.24" displayName="White" 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" displayName="Color"/>

<value code="C48333" codeSystem="2.16.840.1.113883.2.20.6.24" displayName="blue" 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" displayName=”Image”/>

<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" displayName="Shape"/>

<value code="1" codeSystem="2.16.840.1.113883.2.20.6.25" displayName="capsule" 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" displayName=”Flavor”/>

<value code="C73391" codeSystem="2.16.840.1.113883.2.20.6.26" displayName="grape" 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" displayName=”Score”/>

<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" displayName=” Production Amount”/>

<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" displayName=” Combination Product”/>

<value code="C102835" codeSystem="2.16.840.1.113883.2.20.6.30" xsi:type="CV" displayName="Type 2: Prefilled Drug Delivery Device/System">

#### 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" displayName=” Reusability”/>

<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" displayName=” Sterile Use”/>

<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" displayName=” Sterile Use”/>

<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" displayName="Size"/>

<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" displayName=”Imprint”/>

<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" displayName=”Pharmaceutical Standard”/>

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

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="13" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="Pharmaceutical Standard"/>

<value code="7" codeSystem="2.16.840.1.113883.2.20.6.5" displayName="USP" 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" displayName="Scheduling Symbol"/>

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

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="14" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="Scheduling Symbol"/>

<value code="2" codeSystem="2.16.840.1.113883.2.20.6.2" displayName="N" 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" displayName="Therapeutic Class"/>

<value code=" A01AA51" codeSystem="2.16.840.1.113883.2.20.6.6" displayName="Sodium Fluoride, Combinations" xsi:type="CE"/>

</characteristic>

</subjectOf>

<subjectOf>

<characteristic>

<code code="15" codeSystem="2.16.840.1.113883.2.20.6.23" displayName=”Therapeutic Class”/>

<value code=" A03CA02" codeSystem="2.16.840.1.113883.2.20.6.6" displayName=" Clidinium And Psycholeptics" 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" displayName=”Coating”/>

<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 | N/A | 0:1 |  | This relates to the SPL product data elements section (OID: 2.16.840.1.113883.2.20.6.8 code: 48780-1) |
| Conformance | 1. There may be a section element 2. N.B. validation is doctype specific. 3. There is an id element 4. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 5. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 6. There is a code element 7. SPL Rule 3 identifies that the element has not been defined. 8. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 9. There is an title element 10. SPL Rule 3 identifies that the element has not been defined. 11. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 12. There is an text element 13. SPL Rule 3 identifies that the element has not been defined. 14. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 15. There is an effectiveTime element 16. N.B. validation is performed at the element level. 17. There is one or more subject elements 18. SPL Rule 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”].id | N/A | 1:1 |  | This relates to the id element of the SPL product data elements section (OID: 2.16.840.1.113883.2.20.6.8 code: 48780-1) |
| root | 1:1 |  |  |
| Conformance | 1. There is a root attribute 2. SPL Rule 5 identifies that the 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 |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1”].code | N/A | 1:1 |  | This relates to the code element of the SPL product data elements section (OID: 2.16.840.1.113883.2.20.6.8 code: 48780-1) |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.8, where the displayName shall display the appropriate label and the code value is 48780-1. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (code) attribute has not been defined. 4. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 6. SPL Rule 7 identifies that displayName does not match the CV value. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 identifies that there is a notification flag for the content. 9. SPL Rule 10 identifies that the (code) attribute value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1”].title | N/A | 0:1 |  | This relates to the title element of the SPL product data elements section (OID: 2.16.840.1.113883.2.20.6.8 code: 48780-1) |
| Conformance | 1. There is no content in the title element 2. SPL Rule 11 identifies that content is not allowed. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1”].text | N/A | 0:1 |  | This relates to the text element of the SPL product data elements section (OID: 2.16.840.1.113883.2.20.6.8 code: 48780-1) |
| Conformance | 1. There is no content in the text element 2. SPL Rule 11 identifies that content is not allowed. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| component.structuredBody.component[section/code/@code = “48780-1”].subject | N/A | 1:n |  | This relates to the subject element of the SPL product data elements section (OID: 2.16.840.1.113883.2.20.6.8 code: 48780-1) |
| Conformance | 1. There is a manufacturedProduct element 2. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| effectiveTime | N/A | 1:1 |  |  |
| value | 1:1 |  |  |
| Conformance | 1. There is an effectiveTime element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is either a direct or indirect value for the effectiveTime 5. SPL Rule 33 identifies that there is no value defined either directly or via a child element. 6. 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 |
| --- | --- | --- | --- | --- |
| effectiveTime.low | N/A | 1:1 |  |  |
| 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. SPL Rule 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 or equal to the effectiveTime.high@value. 6. SPL Rule 10 identifies that the (value) attribute value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| effectiveTime.high | N/A | 1:1 |  |  |
| 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. SPL Rule 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 or equal to the [effectiveTime.low@value](mailto:effectiveTime.low@value).   a) SPL Rule 10 identifies that the (value) attribute value is incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct | N/A | 1:1 |  |  |
| Conformance | 1. There is one or more subjectOf elements 2. N.B. validation is performed at the element level. 3. There is one or more consumedIn element 4. N.B. validation is performed at the element level. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.subjectOf | N/A | 1:1 |  |  |
| Conformance | 1. There is one or more subjectOf elements 2. SPL Rule 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.consumedIn | N/A | 1:1 |  |  |
| Conformance | 1. There is one or more consumedIn element 2. SPL Rule 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.manufacturedProduct | N/A | 1:1 |  |  |
| Conformance | 1. There is a manufacturedProduct element 2. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is an code element 5. N.B. validation is performed at the element level. 6. There may be a name element 7. N.B. validation is performed at the element level and is doctype specific) 8. There may be a desc element 9. N.B. currently this is not validated, however it is planned to introduce this in the future. 10. There may be a formCode element 11. N.B. validation is performed at the element level and is doctype specific) 12. There may be a asEntityWithGeneric element 13. N.B. validation is performed at the element level. 14. There is an ingredient element 15. N.B. validation is performed at the element level. 16. There may be a part element 17. N.B. validation is performed at the element level. 18. There is an asContent element for all products, however it is optional for parts 19. N.B. validation is performed at the element level. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| manufacturedProduct.manufacturedProduct.code | N/A | 1:1 |  |  |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is an code element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.42, where the displayName shall display the appropriate label. 5. SPL Rule 2 identifies that the OID value is incorrect. 6. SPL Rule 5 identifies that the (code) attribute has not been defined. 7. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 8. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 9. SPL Rule 7 identifies that displayName does not match the CV value. 10. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 11. SPL Rule 15 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 |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is an name element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 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 |  |  |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is an formCode element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.3, where the displayName shall display the appropriate label. If the product has parts, then the code for kits shall be used. 5. SPL Rule 2 identifies that the OID value is incorrect. 6. SPL Rule 5 identifies that the (code) attribute has not been defined. 7. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 8. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 9. SPL Rule 7 identifies that displayName does not match the CV value. 10. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 11. SPL Rule 15 identifies that there is a notification flag for the content. 12. SPL Rule 10 identifies that the (code) attribute value is incorrect based on the product structure. 13. If the product has parts, then at least one part has one or more active ingredients. 14. SPL Rule 33 identifies that there is no active ingredient value defined via a child element. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asEntityWithGeneric | N/A | 1:1 |  |  |
| Conformance | 1. There is an asEntityWithGeneric element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is an asEntityWithGeneric.genericMedicine element 5. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 6. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 7. There is one or more asEntityWithGeneric.genericMedicine.name elements 8. N.B. validation is performed at the element level. | | | |

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

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| ingredient | N/A | 1:n |  |  |
|  | 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. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 5 identifies that the (classCode) attribute has not been defined. 4. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 5. SPL Rule 15 identifies that there is a notification flag for the content. 6. There may be a confidentialityCode element 7. N.B. there is no validation of optional aspects. 8. There may be a quantity element 9. N.B. validation is performed at the element level. 10. There shall be an ingredientSubstance element 11. SPL Rule 3 identifies that the element has not been defined. 12. SPL Rule 4 identifies that more than one element is defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| quantity | N/A | 0:1 |  |  |
|  |  |  |  |  |
| 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. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 5. SPL Rule 15 identifies that there is a notification flag for the content. 6. For percentages the numerator unit is not 1, instead use a volume unit for volume fractions and a mass unit for mass fractions. 7. SPL Rule 10 identifies that the (unit) attribute value is incorrect or contextually incorrect. 8. 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. 9. SPL Rule 10 identifies that the (unit) attribute value is incorrect or contextually incorrect. 10. Active ingredients must have both a numerator and denominator value, the values must both be greater than 0 (zero). 11. SPL Rule 5 identifies that the (numerator.value) attribute has not been defined. 12. SPL Rule 30 identifies that the numerator.value is 0. 13. SPL Rule 31 identifies that the numerator.value is not an integer. 14. SPL Rule 5 identifies that the (denominator.value) attribute has not been defined. 15. SPL Rule 30 identifies that the denominator.value is 0. 16. SPL Rule 31 identifies that the denominator.value is not an integer. 17. In cases that there is no strength, the quantity element is to be omitted. 18. N.B. there is no validation aspect. 19. HPFB currently only support May Contain, Does Not Contain and Trace for Contaminants. 20. SPL Rule 9 identifies that the element value is incorrect or contextually incorrect. 21. SPL Rule 10 identifies that the attribute value is incorrect or contextually incorrect. 22. The denominators values and units for all ingredients in a product are the same. 23. SPL Rule 10 identifies that the (value) attribute value is incorrect or contextually incorrect. 24. SPL Rule 10 identifies that the (units) attribute value is incorrect or contextually incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| numerator | N/A | 0:1 |  |  |
|  |  |  |  |  |
| 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 |  |  |
|  |  |  |  |  |
| 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 |  |  |
|  |  |  |  |  |
| Conformance | 1. There is an code element 2. SPL Rule 3 identifies that the element has not been defined. 3. h) SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error however schema errors are obscure 4. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.14, where the displayName shall display the appropriate label. 5. SPL Rule 2 identifies that the OID value is incorrect. 6. SPL Rule 5 identifies that the (code) attribute has not been defined. 7. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 8. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 9. SPL Rule 7 identifies that displayName does not match the CV value. 10. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 11. SPL Rule 15 identifies that there is a notification flag for the content. 12. There is a name element that shall display the appropriate label. 13. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 14. SPL Rule 4 identifies that more than one element is defined. 15. SPL Rule 7 identifies that label does not match the CV. 16. The same ingredient substance code is not used more than once per product. 17. SPL Rule 10 identifies that the (code) attribute value is contextually incorrect, (not unique). 18. If the product has no parts and is not a part, then there are one or more active ingredients directly under the product. 19. SPL Rule 10 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). 20. If the product has parts, or is a part then the active ingredients are under parts. 21. SPL Rule 10 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) 22. If the strength is based on a reference then, then there is an asEquivalentSubstance element 23. SPL Rule 3 identifies that the (asEquivalentSubstance) element has not been defined. 24. If the strength is not based on a reference then there is no asEquivalentSubstance element 25. SPL Rule 35 identifies that a disallowed element has been included. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asEquivalentSubstance | N/A | 1:1 |  |  |
| Conformance | 1. There is an definingSubstance element 2. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is an definingSubstance.code element. 5. SPL Rule 3 identifies that the element has not been defined. 6. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 7. The definingSubstance.code element shall include the code, codeSystem and displayName attributes and be derived from OID 2.16.840.1.113883.2.20.6.14, the displayName shall display the appropriate label. 8. SPL Rule 2 identifies that the OID value is incorrect. 9. SPL Rule 5 identifies that the (code) attribute has not been defined. 10. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 11. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 12. SPL Rule 7 identifies that displayName does not match the CV value. 13. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 14. SPL Rule 15 identifies that there is a notification flag for the content. 15. There is an definingSubstance.name element, that shall match the [definingSubstance.code@displayName](mailto:definingSubstance.code@displayName) attribute 16. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 17. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 18. SPL Rule 7 identifies that label does not match the CV. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asContent | N/A | 1:1 |  |  |
| Conformance | 1. There is a quantity element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is a quantity.numerator element 5. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 6. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 7. 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 8. SPL Rule 5 identifies that the (value) attribute has not been defined. 9. SPL Rule 5 identifies that the (unit) attribute has not been defined. 10. SPL Rule 8 identifies that the unit is not in the CV or is not contextually correct. 11. SPL Rule 15 identifies that there is a notification flag for the content. 12. SPL Rule 30 identifies that the value is 0. 13. SPL Rule 31 identifies that the value is not an integer. 14. There is a quantity.denominator element 15. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 16. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 17. The denominator element has value attribute and a unit attribute that both equals “1”. 18. SPL Rule 10 identifies that the (value) attribute value is incorrect. 19. SPL Rule 10 identifies that the (unit) attribute value is incorrect. 20. If the product has parts, then the initial numerator value and unit is “1” 21. SPL Rule 10 identifies that the (value) attribute value is incorrect, based on the product structure. 22. SPL Rule 10 identifies that the (unit) attribute value is incorrect, based on the product structure. 23. The unit of the numerator of the initial package is the same as the units for the denominators of all the ingredient quantities (strengths) 24. SPL Rule 10 identifies that the (unit) attribute value is incorrect, based on the product structure. 25. 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. 26. SPL Rule 10 identifies that the (unit) attribute value is incorrect, based on the product structure. 27. There may be a containerPackagedProduct 28. N.B. there is no validation of optional aspects. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| containerPackagedProduct | N/A | 1:1 |  |  |
| Conformance | 1. There is a code element. 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is a formCode element. 5. SPL Rule 3 identifies that the element has not been defined. 6. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 7. There is one or more asManufacturedProduct elements 8. SPL Rule 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| containerPackagedProduct.code | N/A | 1:1 |  |  |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.20 where the displayName shall display the appropriate label. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (code) attribute has not been defined. 4. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 6. SPL Rule 7 identifies that displayName does not match the CV value. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 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 |  |  |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.32 where the displayName shall display the appropriate label. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (code) attribute has not been defined. 4. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 6. SPL Rule 7 identifies that displayName does not match the CV value. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asManufacturedProduct | N/A | 1:1 |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is a subjectOf element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| subjectOf | N/A | 1:1 |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| 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 | 1:1 |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is an id element for each product. 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is a code element for each product. 5. SPL Rule 3 identifies that the element has not been defined. 6. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 7. There is an author element for each product. 8. SPL Rule 3 identifies that the element has not been defined. 9. SPL Rule 4 identifies that the element has been defined more than once. 10. There is an author.territorialAuthority.territory.code element for each product. 11. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 12. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 13. There is an effectiveTime element for each product. 14. SPL Rule 3 identifies that the element has not been defined. 15. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 16. 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. 17. 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 |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is a root and an extension attribute, the root value is 2.16.840.1.113883.2.20.6.42, the extension is derived from the OID and shall display the appropriate label. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (root) attribute has not been defined 4. SPL Rule 5 identifies that the (extension) attribute has not been defined 5. SPL Rule 8 identifies that the extension is not in the CV or is not contextually correct. 6. SPL Rule 15 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 |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.11 where the displayName shall display the appropriate label. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (code) attribute has not been defined. 4. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 6. SPL Rule 7 identifies that displayName does not match the CV value. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 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 |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is a territorialAuthority element 2. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. There is a territorialAuthority.territory element 5. SPL Rule 3 identifies that the element has not been defined. 6. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 7. There is an author.territorialAuthority.territory.code element that contains code, codeSystem and displayName attributes derived from 2.16.840.1.113883.2.20.6.17, where the displayName shall display the appropriate label. 8. SPL Rule 2 identifies that the OID value is incorrect. 9. SPL Rule 5 identifies that the (code) attribute has not been defined. 10. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 11. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 12. SPL Rule 7 identifies that displayName does not match the CV value. 13. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 14. SPL Rule 15 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| territorialAuthority | N/A | 1:1 |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is a territorialAuthority.territory element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| territory | N/A | 1:1 |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Conformance | 1. There is an code element that contains code, codeSystem and displayName attributes derived from 2.16.840.1.113883.2.20.6.17, where the displayName shall display the appropriate label. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (code) attribute has not been defined. 4. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 6. SPL Rule 7 identifies that displayName does not match the CV value. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| confidentialityCode | N/A | 1:1 |  |  |
| Conformance | 1. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.21 where the displayName shall display the appropriate label. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (code) attribute has not been defined. 4. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 6. SPL Rule 7 identifies that displayName does not match the CV value. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asEquivalentEntity | N/A | 1:1 |  |  |
|  | code |  |  |  |
|  | codeSystem |  |  |  |
|  | displayName |  |  |  |
| Conformance | 1. There is a asEquivalentEntity element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.12 where the displayName shall display the appropriate label. 5. SPL Rule 2 identifies that the OID value is incorrect. 6. SPL Rule 5 identifies that the (code) attribute has not been defined. 7. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 8. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 9. SPL Rule 7 identifies that displayName does not match the CV value. 10. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 11. SPL Rule 15 identifies that there is a notification flag for the content. 12. The defining material kind code matches a product/item code in an SPL file with a different set id 13. N.B. currently this is not validated, however it is planned to introduce this in the future. 14. Product/item code for the source is not the same as the product/item code for the product. 15. N.B. currently this is not validated, however it is planned to introduce this in the future. 16. The equivalent Item Code is not the same as the Item Code for the product 17. N.B. currently this is not validated, however it is planned to introduce this in the future. 18. The equivalent Item Code is not the same as the Item Code for another equivalence stated for this product. 19. N.B. currently this is not validated, however it is planned to introduce this in the future. 20. There is only one product source per product. 21. SPL Rule 10 identifies that the attribute value is incorrect, i.e. there is more than one product source for a specific product. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asSpecializedKind | N/A | 1:1 |  |  |
|  | classCode |  |  |  |
| Conformance | 1. There is an asSpecializedKind element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is an asSpecializedKind.generalizedMaterialKind element 5. SPL Rule 3 identifies that the element has not been defined. 6. SPL Rule 4 identifies that more than one element is defined. 7. There is an asSpecializedKind.generalizedMaterialKind.code element 8. SPL Rule 3 identifies that the element has not been defined. 9. SPL Rule 4 identifies that more than one element is defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asSpecializedKind.generalizedMaterialKind.code | N/A | 1:1 |  |  |
| code | 1:1 |  |  |
| codeSystem | 1:1 |  |  |
| displayName | 1:1 |  |  |
| Conformance | 1. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.27, where the displayName shall display the appropriate label. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (code) attribute has not been defined. 4. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 6. SPL Rule 7 identifies that displayName does not match the CV value. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asIdentifiedEntity | N/A | 1:1 |  |  |
|  | 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. SPL Rule 10 identifies that the (classCode) attribute value is incorrect. 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. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 7. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 8. SPL Rule 5 identifies that the (root) attribute has not been defined. 9. SPL Rule 5 identifies that the (extension) attribute has not been defined. 10. SPL Rule 6 identifies that the root is empty. 11. SPL Rule 6 identifies that the extension is empty. 12. The asIdentifiedEntity.id extension attribute is compliant with the code system’s allocation rules. 13. N.B. there is no validation aspect. 14. 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” 15. N.B. there is no validation aspect. 16. 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” 17. N.B. there is no validation aspect. 18. 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” 19. N.B. there is no validation aspect. 20. Each asIdentifiedEntity shall have a single asIdentifiedEntity.code element, the asIdentifiedEntity.code element shall have a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.13, where the displayName shall display the appropriate label. 21. SPL Rule 3 identifies that the element has not been defined. 22. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 23. SPL Rule 2 identifies that the OID value is incorrect. 24. SPL Rule 5 identifies that the (code) attribute has not been defined. 25. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 26. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 27. SPL Rule 7 identifies that displayName does not match the CV value. 28. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 29. SPL Rule 15 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| part | N/A | 1:1 |  |  |
| Conformance | 1. Each part has an overall quantity captured in the partProduct.asContent.quantity element 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 6 identifies that the name is empty. 4. If there is package information it is captured in the partProduct.asContent.containerPackagedProduct element 5. SPL Rule 3 identifies that the element has not been defined. 6. SPL Rule 6 identifies that the name is empty. 7. 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 8. SPL Rule 10 identifies that the attribute value is incorrect or contextually incorrect, based on the structure of the product. 9. If there is no package information in the part, then the numerator unit is 1 10. SPL Rule 10 identifies that the (numerator) attribute value is incorrect or contextually incorrect, based on the structure of the product. 11. If there is a code element, it follows the general rules for product codes. 12. N.B. currently this is not validated. 13. There is a name element captured in the partProduct.asNamedEntity.name element. 14. SPL Rule 6 identifies that the name is empty. 15. Procedures for source, ingredients, characteristics and packaging are the same as for products without parts 16. N.B. there is no validation aspect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| partProduct | N/A | 1:1 |  |  |
| Conformance | 1. There may be one or more asIdentifiedEntity elements 2. SPL Rule 3 identifies that the element has not been defined. 3. There is an asContent element. 4. SPL Rule 3 identifies that the element has not been defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| asNamedEntity | N/A | 1:1 |  |  |
| Conformance | 1. There is an name element, that captures the trade or proprietary name of the medical device or product. Markings such as ®, or ™ should not be included 2. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 3. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 4. SPL Rule 12 identifies that the content is incorrectly formatted. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| consumedIn | N/A | 1:1 |  |  |
| Conformance | 1. There is a substanceAdministration element. 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| substanceAdministration | N/A | 1:1 |  |  |
| Conformance | 1. There may be one or more routeCode elements. 2. N.B. no validation aspects for optional elements. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| routeCode | N/A | 1:1 |  |  |
| Conformance | 1. There is one or more routeCode elements. 2. SPL Rule 3 identifies that the element has not been defined. 3. SPL Rule 4 identifies that more than one element is defined. 4. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.7 where the displayName shall display the appropriate label. 5. SPL Rule 2 identifies that the OID value is incorrect. 6. SPL Rule 5 identifies that the (code) attribute has not been defined. 7. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 8. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 9. SPL Rule 7 identifies that displayName does not match the CV value. 10. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 11. SPL Rule 15 identifies that there is a notification flag for the content. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| marketingAct | N/A | 1:1 |  |  |
| Conformance | 1. There is a code, codeSystem and displayName attribute derived from OID 2.16.840.1.113883.2.20.6.37, where the displayName shall display the appropriate label. 2. SPL Rule 2 identifies that the OID value is incorrect. 3. SPL Rule 5 identifies that the (code) attribute has not been defined. 4. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 5. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 6. SPL Rule 7 identifies that displayName does not match the CV value. 7. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 8. SPL Rule 15 identifies that there is a notification flag for the content. 9. The marketing status must be on procurable packaging regardless of the level of the packaging. 10. N.B. currently this is not validated, however it is planned to introduce this in the future. 11. 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. 12. SPL Rule 10 identifies that the attribute value is incorrect or contextually incorrect. | | | |

| Element | Attribute | Cardinality | Value(s) Allowed  Examples | Description  Instructions |
| --- | --- | --- | --- | --- |
| characteristic | N/A | 1:1 |  |  |
| Conformance | 1. There is a characteristic value with the appropriate type as applicable. 2. SPL Rule 10 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. SPL Rule 10 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. SPL Rule 30 identifies that the versionNumber@value is 0. 7. SPL Rule 31 identifies that the versionNumber@value is not an integer. 8. There is a code element with a code, codeSystem and displayName attributes, the codeSystem is 2.16.840.1.113883.2.20.6.23, and the displayName shall display the appropriate label. 9. SPL Rule 3 identifies that the element has not been defined, this will trigger a schema validation error. 10. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 11. SPL Rule 2 identifies that the OID value is incorrect. 12. SPL Rule 5 identifies that the (code) attribute has not been defined. 13. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 14. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 15. SPL Rule 7 identifies that displayName does not match the CV value. 16. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 17. SPL Rule 15 identifies that there is a notification flag for the content. 18. Coded types shall have a value element, with code, codeSystem and displayName attributes, where the displayName shall display the appropriate label. 19. SPL Rule 2 identifies that the OID value is incorrect. 20. SPL Rule 5 identifies that the (code) attribute has not been defined. 21. SPL Rule 5 identifies that the (codeSystem) attribute has not been defined. 22. SPL Rule 5 identifies that the (displayName) attribute has not been defined. 23. SPL Rule 7 identifies that displayName does not match the CV value. 24. SPL Rule 8 identifies that the code is not in the CV or is not contextually correct. 25. SPL Rule 15 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. SPL Rule 10 identifies that the (codeSystem) attribute value is incorrect based on the code value of the sibling code element. 3. Non-Coded types have a value element with the applicable attributes (unit, value and type) as per the data type. 4. SPL Rule 10 identifies that the attribute value is incorrect or contextually incorrect. 5. The value element shall be empty other than child elements. 6. SPL Rule 11 identifies that the element has content. 7. The value attribute for an imprint may only contain only letters and numbers separated by semicolon without spaces. 8. SPL Rule 12 identifies that the content is incorrectly formatted. 9. 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. 10. SPL Rule 5 identifies that the (xsi:type) attribute has not been defined. 11. SPL Rule 10 identifies that the (xsi:type) attribute value is incorrect or contextually incorrect. 12. SPL Rule 5 identifies that the (mediaType) attribute has not been defined. 13. SPL Rule 10 identifies that the (mediaType) attribute value is incorrect or contextually incorrect. 14. SPL Rule 5 identifies that the (mediaType) attribute has not been defined. 15. SPL Rule 3 identifies that the element has not been defined. 16. SPL Rule 4 identifies that the element has been defined more than once, this will trigger a schema validation error. 17. SPL Rule 34 identifies that a link target can not be found. 18. Combination Products shall only include the physical characteristic on the inner-most packaging unless stated otherwise in the document type specific information. 19. N.B. currently this is not validated, however it is planned to introduce this in the future. 20. Production Amount shall have a value element with an xsi:type of “INT” with a value attribute of “PINF” to indicate unlimited production amounts. 21. SPL Rule 10 identifies that the (value) attribute value is incorrect or 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.

Drug 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" displayName="model number" 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" displayName="Premarket Notification"/>

<author>

<territorialAuthority>

<territory>

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

### 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.