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| --- |
| Guidance Document  Validation of Product Monographs Prepared in the Extensible Markup Language Format      Draft date: YYYY/MM/DD |

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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**Foreword**

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

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 justification. Alternate approaches should be discussed in advance with the relevant programme 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 document, 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 documents.

**Table of contents**

[1 Purpose/overview 6](#_Toc40280212)

[2 Guidance for implementation 6](#_Toc40280213)

[2.1 Validation severity levels 6](#_Toc40280214)

[2.2 General technical conformance requirements 6](#_Toc40280215)

[2.2.1 Identifiers 6](#_Toc40280216)

[2.2.2 Date and time 7](#_Toc40280217)

[2.2.3 Tracking content changes 7](#_Toc40280218)

[2.2.4 Acceptable file types 7](#_Toc40280219)

[2.2.5 File naming 8](#_Toc40280220)

[2.2.6 External file references 8](#_Toc40280221)

[2.2.7 Codes 8](#_Toc40280222)

[2.2.8 Case sensitivity 8](#_Toc40280223)

[2.2.9 Display name 8](#_Toc40280224)

[2.2.10 Image quality 8](#_Toc40280225)

[2.2.11 Text 8](#_Toc40280226)

[2.2.12 Section headings 9](#_Toc40280227)

[2.3 XML prolog 9](#_Toc40280228)

[2.4 Document 10](#_Toc40280229)

[2.5 Market authorization holder and importer or distributor 10](#_Toc40280230)

[2.6 XML PM body 12](#_Toc40280231)

[2.7 Manufactured product 13](#_Toc40280232)

[2.7.1 Manufactured product code and name 13](#_Toc40280233)

[2.7.2 Manufactured product ingredients 13](#_Toc40280234)

[2.7.3 Packaging 15](#_Toc40280235)

[2.7.4 Regulatory status of packaging 17](#_Toc40280236)

[2.7.5 Regulatory activity and control number 18](#_Toc40280237)

[2.7.6 Regulatory status of the manufactured product 18](#_Toc40280238)

[2.7.7 Route of Administration 19](#_Toc40280239)

[2.7.8 Product characteristics 19](#_Toc40280240)

[2.8 Narrative text sections 20](#_Toc40280241)

[2.9 Text formatting and style 21](#_Toc40280242)

[2.9.1 Recent Major Changes 22](#_Toc40280243)

[2.9.2 Bold, Italics, Underline 22](#_Toc40280244)

[2.9.3 Symbols and special characters 23](#_Toc40280245)

[2.9.4 Superscript and subscript 23](#_Toc40280246)

[2.9.5 Hypertext links and cross-referencing 23](#_Toc40280247)

[2.9.6 Table formatting 24](#_Toc40280248)

[2.9.7 Lists 26](#_Toc40280249)

[2.9.8 Images 26](#_Toc40280250)

[2.10 Special template structures 28](#_Toc40280251)

[2.10.1 Title Page 28](#_Toc40280252)

[2.10.2 Patient Medication Information 30](#_Toc40280253)

[2.10.3 Allowable differences between Title, Name and Display Name 31](#_Toc40280254)

[3 Appendices 32](#_Toc40280255)

[3.1 Appendix 1 - Glossary 32](#_Toc40280256)

[3.2 Appendix 2 - XML PM Validation Rules Version 1.0.0 32](#_Toc40280257)

[3.3 Appendix 3 - code systems identified using the codeSystem attribute 42](#_Toc40280258)

[3.4 Appendix 4 - code systems identified using the root attribute 43](#_Toc40280259)

# Purpose/overview

To provide sponsors with technical guidance on the technical conformance rules and technical validation rules needed to prepare a valid XML PM.

# Guidance for implementation

## Validation severity levels

|  |  |
| --- | --- |
| **Severity** | **Description** |
| **Error** | Critical compliance issue that will compromise usability of the XML PM. The issue must be corrected and the XML PM resubmitted. |
| **Warning** | Context sensitive issue that may compromise usability of the XML PM but requires further inspection to determine whether resubmission is required. |
| **Information** | Context sensitive issue that is not likely to compromise usability of the XML PM but may require further inspection. |

## General technical conformance requirements

Refer to Appendix 2 section 1 for validation rules

### Identifiers

GUID’s must follow the canonical structure, content and formatting rules: five groups separated by hyphens, in the form 8-4-4-4-12 for a total of 36 characters.

The following identifiers shall be Globally Unique Identifiers (GUID):

* document/id/@root
* setId/@root
* section/id/@root

section@ID can be a GUID or user defined.

representedOrganization/id/@extension and assignedOrganization/id/@extension are codes from the Object Identifier (OID) 2.16.840.1.113883.2.20.6.31 for Company Identifier.

The French XML PM and English XML PM are two separate documents. Therefore, they must have separate set ID's. One setId for the French XML PM and another for the English XML PM.

For example, Product AA has a French and an English XML PM.

The French versions of the XML PM for Product AA have the same setId but different document ID's and different versions. This setId is different from the English setId.

| **Drug Product AAA** | **setId** | **Document ID (id root)** | **Version** |
| --- | --- | --- | --- |
| XML PM v1 (French) | d4c004d2-976d-4aec-8cdd-a71bdb11d4b1 | bd28a915-72c1-4c9b-95ec-f80140f9792e | 1 |
| XML PM v2 (French) | d4c004d2-976d-4aec-8cdd-a71bdb11d4b1 | e796df04-2fd5-4894-8b22-6234e96e77d2 | 2 |
| XML PM v3 (French) | d4c004d2-976d-4aec-8cdd-a71bdb11d4b1 | 11d3fb08-035d-4b32-9d63-4d37dfad1685 | 3 |
| XML PM v4 (French) | d4c004d2-976d-4aec-8cdd-a71bdb11d4b1 | 0a421143-0b81-4002-83ff-95ed389356df | 4 |

The English versions of the XML PM for Product AA have the same setId but different document ID's and different versions. This setId is different from the French setId.

|  |  |  |  |
| --- | --- | --- | --- |
| **Drug Product AAA** | **setId** | **Document ID (id root)** | **Version** |
| XML PM v1 (English) | c99b9224-f519-4e52-bdbe-1750a5b1a26e | 1262a4e6-bc34-413e-bbf4-a8ec3fb512e1 | 1 |
| XML PM v2 (English) | c99b9224-f519-4e52-bdbe-1750a5b1a26e | 944364a1-0f76-44b3-b2f6-60cf61df8a1d | 2 |
| XML PM v3 (English) | c99b9224-f519-4e52-bdbe-1750a5b1a26e | aee16a81-8021-4058-86dc-154ba5b0516c | 3 |
| XML PM v4 (English) | c99b9224-f519-4e52-bdbe-1750a5b1a26e | 92f9efa1-9ae3-462e-b2ca-9d34381c3e93 | 4 |

### Date and time

The Date of Initial Approval and the Date of Last Revision on the Title Page shall be presented in the fully written date format Month Day, Year. For example, January 15, 2019.

All dates captured within effectiveTime using the @value attribute (or effectiveTime/low/@value or effectiveTime/high/@value) shall be presented in the format YYYYMMDD.

### Tracking content changes

Changing the content of a subsection requires both the section/id/@root and the effectiveTime/@value of the subsection to be updated. The effectiveTime and the section/id/@root of any ancestor sections must also be updated.

### Acceptable file types

Only the file formats listed in **Table 1** are permitted for use in an XML PM.

**Table 1 - List of acceptable file types**

| **File Format** | **Description** | **Specifications** | **Extension** |
| --- | --- | --- | --- |
| JPEG/JFIF | Joint Photographic Experts Group (JPEG) / JPEG File Interchange Format (JFIF) is a compression standard for encoding and exchanging still digital raster files. | ISO 10918-1 | .jpg |
| XML | Extensible Markup Language (XML) is a markup language that defines document encoding rules. | W3C XML 1.0 | .xml |

### File naming

The .xml file shall be named with the Document ID (document/id/@root) which is the GUID for this version of the XML PM.

The .jpg’s should be named with the following best practices to improve search engine visibility:

* Avoid generic filenames like "image1.jpg" or phrases like "image of" or "graphic of"
* briefly describe what the image shows
* be short (five words or less)
* separate words with hyphens (no spaces)
* Accented characters are not permitted

For example, glucose-chemical-structure.jpg

NOTE: Sponsors must ensure there are no file name collisions between files.

### External file references

All .jpg files associated with the XML PM are referenced in the .xml.

### Codes

There are no spaces in codes.

### Case sensitivity

All data elements associated with controlled vocabularies are case sensitive. There are no other case sensitivity rules aside from what is described in the SPL schema or XML specification.

### Display name

All display names are language specific and shall match the language of the document. French display name for French documents and English display names for English documents.

NOTE: The display name shall be present for all code systems unless disallowed by the schema. The only coded elements without an associated display name are document/templateId, representedOrganization/id and assignedOrganization/id.

### Image quality

Image quality is not validated. However, images should use sufficient resolution to be easily readable across different screen sizes or devices.

### Text

Only the following elements are allowed as children of the <text> element: <paragraph>, <list>, <table> and images <renderMultimedia>.

**Table 2 - Example of non-compliant vs. compliant text structure**

| **Non-compliant** | **Compliant** |
| --- | --- |
| <text>  Lorem ipsum dolor sit amet, ligula suspendisse nulla pretium, rhoncus tempor.  </text> | <text>  <paragraph>  Lorem ipsum dolor sit amet, ligula suspendisse nulla pretium, rhoncus tempor.  </paragraph>  </text> |

The following elements are allowed within <paragraph>, <table> and <list>: superscripts (<sup>), subscripts (<sub>), links (<linkHtml>), line breaks (<br>), footnotes (<footnote>), footnote references (<footnoteRef>).

<renderMultimedia> can be a child of <text> or a child of <paragraph>.

Text can be placed under the major section heading RECENT MAJOR LABEL CHANGES and placed directly under sections. For example, text cannot be placed directly under the major section heading *PART I: HEALTH PROFESSIONAL INFORMATION* but can be placed directly under the section *1 INDICATIONS*.

### Section headings

All XML PM section and sub-section headings are managed as controlled vocabularies. Only Health Canada approved section headings are allowed for use.

Sponsors can use the ‘UNASSIGNED’ heading to create sponsor defined headings. However, UNASSIGNED can only be used as a child of appropriate Health Canada sub-section headings.

For example, UNASSIGNED sections shall not be placed directly under the following Level 1 Headings:

* TITLE PAGE
* PART I: HEALTH PROFESSIONAL INFORMATION
* PART II: SCIENTIFIC INFORMATION
* PATIENT MEDICATION INFORMATION

## XML prolog

Refer to Appendix 2 section 2 for validation rules.

Provides the XML version, character encoding, schema and the location of the schema.

**Figure 1 - Example of compliant XML prolog section**

<?xml version="1.0" encoding="UTF-8"?><!--UTF is capitalized-->  
<?xml-stylesheet type="text/xsl" href="https://raw.githubusercontent.com/HealthCanada/HPFB/master/product-monograph/style-sheet/spl\_canada.xsl"?>  
<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/product-monograph/schema/SPL.xsd">

## Document

Refer to Appendix 2 section 3 for validation rules

Provides general information about the overall document:

* The templateId/@extension specifies the regulatory activity associated with this version of the product monograph.
* The id/@root is a GUID and is unique for each version of the document. Letters used in a GUID are lower case.
* The <code> is the HPFB code that specifies the document type.
* The <title> data element is used for the title for the product monograph.
  + Images are not included in the title.
  + Do not include multiple lines or break <br/> tags in the <title>.
* The effectiveTime/@value specifies the Date of Initial Approval or Date of Last Revision for this version.
* The languageCode/@code is the HPFB code that specifies the language of the document.
* The setId/@root is a GUID and must remain constant through all versions of the XML PM.
* The versionNumber/@value is an integer greater than zero.

**Figure 2 - Example of compliant document metadata**

<templateId extension="NDS" root="2.16.840.1.113883.2.20.6.37"/>  
 <id root="df363dae-0612-4be7-bb92-a8381fa1da35"/>  
 <code code="1" codeSystem="2.16.840.1.113883.2.20.6.10"  
 displayName="2016 PRODUCT MONOGRAPH TEMPLATE - STANDARD"/>  
 <title>Brand name (non-proprietary name), dosage form</title>  
 <effectiveTime value="20180101"> <!-- Date of Initial Approval or Date of Last Revision -->  
 </effectiveTime>  
 <languageCode code="1" codeSystem="2.16.840.1.113883.2.20.6.29" displayName="ENGLISH"/>  
 <setId root="aeb4ec67-8764-4b72-b7a5-0bae88db11a3"/>  
 <versionNumber value="3"/>

## Market authorization holder and importer or distributor

Refer to Appendix 2 section 4 for validation rules

Provides the company name, identifier, address, phone number, email and website for the market authorization holder. In addition to company details for the Market Authorization Holder, the company details for the Canadian importer or distributor must be listed if the Market Authorization Holder is not located in Canada.

* The <representedOrganization> is the Health Canada company ID and name for the market authorization holder.
* <assignedOrganization> is the Health Canada company ID and name for the Canadian importer or distributor.

The notation for phone numbers, email addresses and web addresses are as follows:

* **Notation for phone numbers:** Phone numbers must be written with the prefix ‘tel:’ and always followed by the phone number in international dialing format: the plus (+) sign followed by the country code, area code and number. Recommend separating each segment of the number with a hyphen for easier reading and better auto-detection. For example, <tel:+1>‑-123-‑456-‑7891.
* **Notation for email Addresses:** Email addresses are written with the prefix ‘mailto:’ followed by the SMTP style email address. For example, [mailto:example@example.com](mailto:mailto:example@example.com)
* **Notation for Web Addresses:** Web addresses are written with the prefix ’http:' or 'https:'. For example, http://www.domain.com or https://www.domain.com.

NOTE: <contactPerson> shall be left as a self-closing tag with no content <contactPerson/>

**Figure 3 - Example of compliant organization details**

<author><!--Organization Information-->  
 <time/>  
 <assignedEntity>  
 <representedOrganization><!--Market Authorization Holder-->  
 <id extension="1111" root="2.16.840.1.113883.2.20.6.31"/>  
 <name>Acme Pharma Inc.</name>  
 <contactParty>  
 <addr>  
 <streetAddressLine>9526 Columbia St.</streetAddressLine>  
 <city>Hanover Park</city>  
 <state>Illinois</state>  
 <postalCode>60133</postalCode>  
 <country code="USA" codeSystem="2.16.840.1.113883.2.20.6.17"  
 displayName="UNITED STATES OF AMERICA (THE)"/>  
 </addr>  
 <telecom value="tel:+1-202-555-0178"/>  
 <telecom value="mailto:test@canada.ca"/>  
 <telecom value="http://www.test.ca"/>  
 <contactPerson/>  
 </contactParty>  
 <assignedEntity>  
 <assignedOrganization><!-- Importer/Distributor -->  
 <id extension="0000" root="2.16.840.1.113883.2.20.6.31"/>  
 <name>Acme Distributing Ltd.</name>  
 <contactParty>  
 <contactParty>  
 <addr>  
<streetAddressLine>250 Lanark Ave.</streetAddressLine>  
<city>Ottawa</city>  
<state>Ontario</state>  
<postalCode>K1Z 6R5</postalCode>  
<country code="CAN" codeSystem="2.16.840.1.113883.2.20.6.17"  
 displayName="CANADA"/>  
 </addr>  
 <telecom value="tel:+1-416-555-0134"/>  
 <telecom value="mailto:test.2@canada.ca"/>  
 <telecom value="http://www.test.ca"/>  
 <contactPerson/>  
 </contactParty>  
 </assignedOrganization>  
 </assignedEntity>  
 </representedOrganization>  
 </assignedEntity>  
 </author>

## XML PM body

Refer to Appendix 2 section 5 for validation rules.

The body of the XML PM includes manufactured product details and the narrative text sections of the product monograph (Title Page, Recent Major Label Changes, Part I: Health Professional Information, Part II: Scientific Information, Patient Medication Information and Instructions for Use).

All sections are captured with the following elements:

* component
  + structuredBody
    - component
      * section/@ID
        + id/@root
        + code/@code @codeSystem @displayName
        + title
        + text (where applicable)
        + effectiveTime/@value

In the SPL schema, the <structuredBody> element contains multiple <component>s and each <component> contains a <section>.

The <section> tag can be nested to form sub-sections if the <section> tag is first nested inside a <component> tag.

All content must be nested correctly to ensure the XML PM passes validation and ensures the style sheet can display the content properly.

**Figure 4 - Example of compliant XML PM body structure**

<component>  
 <structuredBody>  
 <component>  
 <section ID="">  
 <id root=""/>  
 <code code=" " codeSystem="" displayName=""/>  
 <title></title>  
 <text></text>  
 <effectiveTime value=""/>  
 </section>  
 </component>  
 </structuredBody>  
</component>

## Manufactured product

Refer to Appendix 2 section 6 for validation rules.

### Manufactured product code and name

Provides information about the manufactured product(s) associated with this product monograph. This includes:

* The code/@code is the Drug Identification Number (DIN) for this manufactured product.
* The <name> is the proprietary name or brand name for this manufactured product.
* The formCode/@code is the manufactured dosage form of the manufactured product.
* The asEntityWithGeneric/genericMedicine/name is the non-proprietary name for this manufactured product.

**Figure 5 - Example of compliant Manufactured Product section**

<subject>  
 <manufacturedProduct>  
 <manufacturedProduct>  
 <code code="12345678"/><!-- DIN Number -->  
 <name>LORUM IPSUM TABLETS</name><!-- Brand Name -->  
 <formCode code="10219000" codeSystem="2.16.840.1.113883.2.20.6.3"  
 displayName="TABLET"/><!-- Dosage Form -->  
 <asEntityWithGeneric>  
 <genericMedicine>  
 <name>acetaminophen</name><!-- non-proprietary name -->  
 </genericMedicine>  
 </asEntityWithGeneric>

### Manufactured product ingredients

Provides information about the ingredients in this manufactured product.

* Ingredient/@classCode is the ingredient information characterized by role (active or inactive), strength, ingredient code and ingredient name.
* The <asContent> is the packaging information based on pack code, quantity, pack type and regulatory status of the packaging.
* The subjectOf/approval contains the regulatory activity information associated with this manufactured product based on the control number, regulatory activity type and country.
* The subjectOf/marketingAct contains the regulatory status for this manufactured product as well as the <effectiveTime>
* The subjectOf/characteristic identifies the characteristics of this manufactured product; (Shape, size, score, imprint, flavour, pharmaceutical standard, schedule, therapeutic class).
* The consumedIn/substanceAdministration/routeCode/@code identifies the route of administration for this product.

**Figure 6 - Example of compliant ingredients section**

<ingredient classCode="ACTIR">  
 <quantity>  
 <numerator value="45" unit="mg"/>  
 <denominator value="1" unit="1"/>  
 </quantity>  
 <ingredientSubstance>  
 <code code="7IC4BO7D3R" codeSystem="2.16.840.1.113883.2.20.6.14"

displayName="ACEXAMIC ACID"/><!-- @displayName and <name> must be the same-->  
 <name>ACEXAMIC ACID</name><!-- same as @displayName -->  
 <activeMoiety>  
 <activeMoiety>  
 <code code="7IC4BO7D3R" codeSystem="2.16.840.1.113883.2.20.6.14"  
 displayName="ACEXAMIC ACID"/>  
 <name>ACEXAMIC ACID</name>  
 </activeMoiety>  
 </activeMoiety>  
 <asEquivalentSubstance>  
 <definingSubstance>  
 <code code="7IC4BO7D3R" codeSystem="2.16.840.1.113883.2.20.6.14"  
 displayName="ACEXAMIC ACID"/>  
 <name>ACEXAMIC ACID</name>  
 </definingSubstance>  
 </asEquivalentSubstance>  
 </ingredientSubstance>  
</ingredient>  
<ingredient classCode="IACT">  
 <ingredientSubstance>  
 <code code="EWQ57Q8I5X" codeSystem="2.16.840.1.113883.2.20.6.14"  
 displayName="LACTOSE MONOHYDRATE"/>  
 <name>LACTOSE MONOHYDRATE</name>  
 </ingredientSubstance>  
</ingredient>

### Packaging

#### Single part packaging

Refer to Appendix 2 section 7 for validation rules.

Packaging is represented as a quantity, a package ID (if available), a package type and the relevant levels of packaging related to the salable unit or stock keeping unit (SKU).

The quantity is represented as a numerator (with @unit and @value) and denominator (with only an @value). The Unit of Measure (the numerator/@unit) is derived from OID 2.16.840.1.113883.2.20.6.15, while the Packaging Type code is derived from OID 2.16.840.1.113883.2.20.6.32.

**Figure 7 - Example of compliant packaging (single part format)**

<asContent><!-- Packaging -->  
 <quantity>  
 <numerator value="10" unit="1"/><!-- Number of items in the blister -->  
 <denominator value="1"/>  
 </quantity>  
 <containerPackagedProduct>  
 <code code="ABC-5678"/><!-- company defined pack ID -->  
 <formCode code="30007000" codeSystem="2.16.840.1.113883.2.20.6.32"  
 displayName="BLISTER"/><!-- inner most level of packaging -->  
 <asContent>  
 <quantity>  
 <numerator value="4" unit="1"/><!-- Number of blisters in the box -->  
 <denominator value="1"/>  
 </quantity>  
 <containerPackagedProduct>  
 <code code="ABC-6789"/>  
 <formCode code="30009000" codeSystem="2.16.840.1.113883.2.20.6.32"  
 displayName="BOX"/><!-- outer most level of packaging -->  
 </containerPackagedProduct>

</asContent>

</containerPackagedProduct>

</asContent>

#### Multi-part packaging

Refer to Appendix 2 section 8 for validation rules.

The manufactured product’s XML structure is different with the multi-part package format. Normally, packaging is nested within the product. With multi-part packaging, the outer most level of packaging is described first and product details are nested within that outer package.

The multi-part structure is made up of the following components:

* the <asContent> element describes the kit and includes: <formCode> as KIT rather than a normal dosage form; pack quantity; package type; the regulatory status of the package
* within <asContent>, the <part> element describes the quantity of product in this part
* within <part>, the <partProduct> element reuses the normal structure to describe the drug product (strength; ingredients; pack quantity for this part; pack type for this part).

**Figure 8** provides an example of a multi-part package. The outermost level is one box that includes two parts. The first part is a vial and the second part is a pre-filled syringe.

**Figure 8** - **Example of compliant packaging (multi-part format)**

<manufacturedProduct>  
 <manufacturedProduct>  
 <code code="12345678"/><!-- DIN Number -->  
 <name>brand name</name>

<formCode code="C43197" codeSystem="2.16.840.1.113883.2.20.6.3"

displayName="KIT"/><!-- Select dosage form=KIT for the multi-part pack format -->  
 <asEntityWithGeneric>  
 <genericMedicine>  
 <name>non-proprietary name</name>  
 </genericMedicine>  
 </asEntityWithGeneric>

...

<asContent><!-- Packaging -->  
 <quantity>  
 <numerator value="1" unit="1"/><!-- Number of items in the box-->  
 <denominator value="1"/>  
 </quantity>  
 <containerPackagedProduct> <!-- package type for the kit -->  
 <code code="ABC-5678"/>  
 <formCode code="30009000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="BOX"/>

</containerPackagedProduct>  
 <subjectOf>  
 <marketingAct>  
 <code code="1" codeSystem="2.16.840.1.113883.2.20.6.11"  
 displayName="APPROVED"/>  
 <effectiveTime><!-- regulatory status of this package -->  
 <low value="20170102"/><!-- Date of initial approval -->  
 <high value="20180101"/><!-- Date of cancellation -->  
 </effectiveTime>  
 </marketingAct>  
 </subjectOf>  
</asContent>

…

<part> <!-- First part of the package -->

<quantity>  
 <numerator value="5" unit="mg"/><!--quantity of the product in this part-->  
 <denominator value="1" unit= "1" />  
 </quantity>  
 <partProduct> <!-- Dosage form of product in this part/package-->

<formCode code="10110000” codeSystem="2.16.840.1.113883.2.20.6.3"

displayName="POWDER FOR ORAL SOLUTION"/>

…

<asContent> <!-- Packaging for this product/part -->

<quantity>

<numerator value="5" unit="mg"/>

<denominator value="1"/>

</quantity>

<containerPackagedProduct>

<formCode code=”30069000” codeSystem="2.16.840.1.113883.2.20.6.32"

displayName="VIAL"/>

</containerPackagedProduct>

</asContent>

</partProduct>

</part>

...

<part> <!-- Second part of the package -->

<quantity>  
 <numerator value="5" unit="mL"/><!--quantity of the product in this part-->  
 <denominator value="1" />  
 </quantity>  
 <partProduct> <!-- Dosage form of individual part/product in the kit-->

<formCode code="11201000” codeSystem="2.16.840.1.113883.2.20.6.3"

displayName="SOLUTION FOR INJECTION"/>

…

<asContent> <!-- Packaging for this product/part -->

<quantity>

<numerator value="5" unit="mL"/>

<denominator value="1"/>

</quantity>

<containerPackagedProduct>

<formCode code=”30029000” codeSystem="2.16.840.1.113883.2.20.6.32"

displayName=" INJECTION SYRINGE"/>

</containerPackagedProduct>

</asContent>

</partProduct>

</part>

### Regulatory status of packaging

Refer to Appendix 2 section 9 for validation rules

The pack status specifies whether the package is approved or cancelled.

The effectiveTime/low/@value is used to capture the Date of Initial Approval and the effectiveTime/high/@value is used to capture the date the DIN was cancelled.

**Figure 9 - Example of compliant regulatory status of packaging**

<subjectOf>  
 <marketingAct><!-- regulatory status of this package -->  
 <code code="1"codeSystem="2.16.840.1.113883.2.20.6.11" displayName="APPROVED"/>  
 <effectiveTime>  
 <low value="20170101"/><!-- Date of initial approval -->  
 </effectiveTime>  
 </marketingAct>  
</subjectOf>

### Regulatory activity and control number

Refer to Appendix 2 section 10 for validation rules

The <approval> structure specifies the regulatory activity and, if applicable, the control number associated with the regulatory activity. The control number is captured in the id/@extension.

**Figure 10 - Example of compliant regulatory activity and control number section**

<subjectOf><!--Regulatory Activity associated with this products status-->  
 <approval>  
 <id extension="123456"/><!-- Control Number -->  
 <code code="2" codeSystem="2.16.840.1.113883.2.20.6.37"  
 displayName="SNDS"/>  
 <author>  
 <territorialAuthority>  
 <territory>  
 <code code="CAN"  
 codeSystem="2.16.840.1.113883.2.20.6.17"  
 displayName="CANADA"/>  
 </territory>  
 </territorialAuthority>  
 </author>  
 </approval>  
</subjectOf>

### Regulatory status of the manufactured product

Refer to Appendix 2 section 11 for validation rules

The <code> is used to specify whether the DIN for this product is active (status = approved) or cancelled (status = cancelled). The Date of Initial Approval or NOC date is represented using the effectiveTime/low/@value. The DIN’s date of cancellation is represented using the effectiveTime/high/@value.

**Figure 11 - Example of compliant regulatory status of manufactured product**

<subjectOf><!--Regulatory status of this product-->  
 <marketingAct>  
 <code code="1" codeSystem="2.16.840.1.113883.2.20.6.11"  
 displayName="CANCELLED"/>  
 <effectiveTime>  
 <low value="20170101"/><!-- Date of initial approval -->

<high value="20180101"/><!-- Date of DIN cancellation -->  
 </effectiveTime>  
 </marketingAct>  
</subjectOf>

### Route of Administration

Refer to Appendix 2 section 13 for validation rules

Provides the route(s) of administration for this manufactured product.

Multiple routes of administration can be expressed through repeating tags and will be separated by commas when rendered.

**Figure 12 Example of compliant structure for route of administration section**

<consumedIn>  
 <substanceAdministration>  
 <routeCode code="20053000" codeSystem="2.16.840.1.113883.2.20.6.7"  
 displayName="ORAL USE"/>  
 </substanceAdministration>  
</consumedIn>

### Product characteristics

Refer to Appendix 2 section 12 for validation rules.

Product characteristics include: Product Type, Colour, Shape, Size, Score, Imprint, Flavour, Pharmaceutical Standard, Schedule, Therapeutic Class.

Characteristic value types are as follows:

* **Physical Quantity (PQ):** A quantity expressed as a value and a unit. When expressing product characteristics, the value must be an integer and the unit must represent a unit of measure.
* **Coded Value (CV):** Coded data, specifying only a code, code system, display name and optionally original text.
* **Character String (ST):** Text data, primarily intended for machine processing.

Multiple instances of the following characteristics can be expressed through repeating tags and will be separated by commas or carriage returns when rendered:

* Colour
* Shape
* Flavour
* Therapeutic Class
* Schedule
* Pharmaceutical Standard
* Combination Product Type

**Figure 13** - **Example of compliant product characteristics**

<subjectOf>  
 <characteristic>  
 <code code="4" codeSystem="2.16.840.1.113883.2.20.6.23"  
 displayName="SIZE"/>  
 <value value="10" unit=”mm” xsi:type="PQ"/>  
 </characteristic>  
</subjectOf>  
<subjectOf>  
 <characteristic>  
 <code code="1" codeSystem="2.16.840.1.113883.2.20.6.23"  
 displayName="PRODUCT TYPE"/>  
 <value code="1" codeSystem="2.16.840.1.113883.2.20.6.53"  
 displayName="PHARMACEUTICAL" xsi:type="CV">  
 <originalText>PHARMACEUTICAL</originalText>  
 </value>  
 </characteristic>  
</subjectOf>  
<subjectOf>  
 <characteristic>  
 <code code="2" codeSystem="2.16.840.1.113883.2.20.6.23"  
 displayName="COLOUR"/>  
 <value code=" C48325" codeSystem="2.16.840.1.113883.2.20.6.24"  
 displayName="WHITE" xsi:type="CV">  
 <originalText>white to off white</originalText>  
 </value>  
 </characteristic>  
</subjectOf>

<subjectOf>  
 <characteristic>  
 <code code="6" codeSystem="2.16.840.1.113883.2.20.6.23"  
 displayName="IMPRINT"/>  
 <value xsi:type="ST">A;45</value>

</characteristic>  
</subjectOf>

## Narrative text sections

Refer to Appendix 2 section 14 for validation rules.

Provides the narrative text that makes up the Title Page, Recent Major Label Changes, Part I: Health Professional Information, Part II: Scientific Information and Patient Medication Information.

NOTE:

* If a section consists only of nested sections, the <text> tag shall not be included.
* Images may be included using the <renderMultiMedia> tag. This must only be used as a direct child of <text> for ‘block’ images or as a child of <paragraph> for inline images.
* <title> must only contain text. No special formatting, such as line breaks, shall be added within <title> elements

**Figure 14 - Example of compliant narrative text sections**

<component>  
 <section ID="f2aa7e0e-2042-4a4c-a783-9ad4e8717a32">  
 <id root="b9db4ce0-3f46-434a-bd7b-4a3e010adaad"/>  
 <code code="pi01.1" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="1.1 Pediatrics"/>  
 <title>1.1 Pediatrics</title>  
 <text>  
 <paragraph>[One of the following or similar statements should be used:]</paragraph>  
 <paragraph><content styleCode="bold">Pediatrics (age range):</content> Based on  
 the data submitted and reviewed by Health Canada, the safety and efficacy of  
 Brand name in pediatric patients has been established; therefore, Health  
 Canada has authorized an indication for pediatric use. (cross-reference to  
 relevant sections)</paragraph>  
 <paragraph>[or]</paragraph>  
 <paragraph><content styleCode="bold">Pediatrics (age range):</content> No data  
 are available to Health Canada; therefore, Health Canada has not authorized an  
 indication for pediatric use.</paragraph>  
 <paragraph>[or]</paragraph>  
 <paragraph><content styleCode="bold">Pediatrics (age range):</content> Based on  
 the data submitted and reviewed by Health Canada, the safety and efficacy of  
 Brand name in pediatric patients has not been established; therefore, Health  
 Canada has not authorized an indication for pediatric use. (cross-reference to  
 relevant sections)</paragraph>  
 </text>  
 <effectiveTime value="20180822"/>  
 </section>  
</component>

## Text formatting and style

Refer to Appendix 2 section 14 for validation rules.

### Recent Major Changes

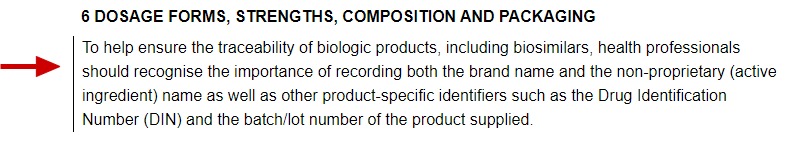
The <content styleCode="xmChange"> is used to identify recent major changes to text in <paragraph> or list/item.

**Figure 15 - Example of compliant recent major change notation**

<paragraph>  
 <content styleCode="xmChange">To help ensure the traceability of biologic products, including biosimilars, health professionals should recognise the importance of recording both the brand name and the non-proprietary (active ingredient) name as well as other product-specific identifiers such as the Drug Identification Number (DIN) and the batch/lot number of the product supplied.

</content>  
</paragraph>

**Figure 16 - Style sheet view of text marked with the recent major change label**



### Bold, Italics, Underline

The <content styleCode=””> is used to apply ‘bold’, ‘italics’ and ‘underline’ formatting.

**Figure 17 - Example of compliant bold, italics and underline text formatting**

<text>  
 <paragraph>  
 <content styleCode="bold italics underline">Lorem ipsum dolor sit amet</content>.  
 </paragraph>  
</text>

The <content styleCode=””> can be nested to apply multiple formats.

**Figure 18 - Example of compliant nested bold and italics text formatting**

<text>  
 <paragraph>  
 <content styleCode="bold”>  
 <content styleCode="italics”> Lorem ipsum dolor sit amet</content>  
 </content>  
 </paragraph>  
</text>

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.

### Symbols and special characters

The following characters must be escaped to prevent misinterpretation of the xml, which will result in validation errors.

| **Special characters** | **Escape string** |
| --- | --- |
| " | &quot; |
| ' | &apos; |
| < | &lt; |
| > | &gt; |
| & | &amp; |

In some cases, codes can be used in place of commonly used symbols. For example, ‘&reg;’ or ‘&#174;’ can be used for a registered trademark symbol. ‘&trade;’ or ‘&#8482;’ can be used for a trademark symbol.

### Superscript and subscript

Enclose text the <sup> tag for superscript and enclose text within the <sub> tag for subscript.

### Hypertext links and cross-referencing

Web links are specified using <linkHtml>. The linkHtml/@href attribute is the target of the link and the text within the element is the display text for the link.

For example, <linkHtml href="link target">Link display text</linkHtml>.

To insert a cross-reference to content within the product monograph, the href attribute is ‘#’ and the section ID or id root from the relevant <section>, <paragraph>, <table>, <list>, <content>,<renderMultimedia> element.

For example, <linkHtml href="#be75cfb9-3131-4903-800b-267427398a13"> Refer to section 3 Serious Warnings and Precautions Box</linkHtml>.

To insert a website link, the linkHtml/@href attribute is the website URL (without the ‘#’ prefix).

For example, <linkHtml href=”<https://www.canada.ca/en/health-canada.html>”>Health Canada</linkHtml>

#### Footnotes

Footnotes are defined using the <footnote> element within the following: <paragraph>, <list>, <table>, <th>, <td> or <tbody> elements.

The style sheet automatically renders footnotes at the end of a section. The style sheet renders footnotes in <paragraph> and <list> as Arabic numbers. For example, 1, 2, 3. Footnotes within tables are rendered at the bottom of the table using symbols.

Unique identifiers can be added to each footnote using the footnote/@ID attribute. Thereafter, the <footnoteRef> element and its footnote/@IDREF attribute can be used to cross-refer to that specific footnote. For example, <footnote ID=”f1”>sample text</footnote> generates the footnote ‘sample text’ at the end of a section or table. Adding the element <footnoteRef IDREF=”f1”/> will create a link to the footnote with @ID=”f1”.

### Table formatting

Tables are defined with the <table> tag. Each table row is defined with the <tr> tag. A table header is defined with the <th> tag and regular table cells/data is defined with the <td> tag**.**

The following table aspects are controlled by the style sheet: Table border colour; table header shading; table header text is bold and left aligned; table titles are bold and centered.

**Table Width:** Always set width to 100% (<table width=”100%”/>). This ensures the style sheet resizes tables consistently across all product monographs and across any screen size. If a table width is not explicitly declared, the style sheet will render the table width as 100% by default.

**Table ID**: use the table/@ID attribute to give the table a unique identifier. For example, <tbody ID="t1" width=”100%”>. Use the linkHtml/@href attribute to create cross-reference links to that table. For example, <linkHtml href="#t2"> Refer to Table 2 </linkHtml> creates a link to the table with @ID=”t2”.

**Cell border lines:** use the table/@frame and table/@rules attributes to apply border lines to the table and its cells.

To create a safety or warnings box use frame="box" to create a dark black border around the table (one cell table or two cell table with no inside lines).

To create all other tables, use frame="border" to create a border around the table and rules="all" to create lines around all cells within the table. <table frame="border" rules="all">

For more fine control of where border lines appear or do not appear, use th/@styleCode or td/@stylecode to set table cell border lines (values are case sensitive):

|  |  |
| --- | --- |
| **Valid value** | **Result** |
| Lrule | left vertical border line |
| Rrule | right vertical border line |
| Toprule | top horizontal line |
| Botrule | bottom horizontal line |

NOTE: More than one rule control may be used in a cell. For example, <td styleCode code=”Toprule Botrule Lrule Rrule”>text</td>.

Rather than setting the border for each cell, table borders may also be controlled according to entire rows or columns using the @styleCode attribute with <col>, <colgroup>, <tfoot>, <tbody> and <tr> elements.

**Figure 19 - Example of compliant table structure (with borders applied to each row)**

<table ID="t5" width="100%">  
 <caption> Table #- Dosage Forms, Strengths, Composition and Packaging</caption>  
 <tbody>  
 <tr>  
 <th styleCode="Toprule Botrule Lrule Rrule">Route of Administration </th>  
 <th styleCode="Toprule Botrule Lrule Rrule">Dosage Form / Strength/Composition </th>  
 <th styleCode="Toprule Botrule Lrule Rrule">Non-medicinal Ingredients</th>  
 </tr>  
 <tr>  
 <td styleCode="Toprule Botrule Lrule Rrule">oral</td>  
 <td styleCode="Toprule Botrule Lrule Rrule">tablet 5 mg, 10 mg</td>  
 <td styleCode="Toprule Botrule Lrule Rrule">[List all non-medicinal  
 ingredients in alphabetical order.]</td>  
 </tr>  
 </tbody>  
</table>

**Figure 20 - Example of compliant table structure (with borders applied to the entire table)**

<table ID="t5" width="100%" frame=”border” rules=”all”>  
 <caption> Table #- Dosage Forms, Strengths, Composition and Packaging</caption>  
 <tbody>  
 <tr>  
 <th>Route of Administration </th>  
 <th>Dosage Form / Strength/Composition </th>  
 <th>Non-medicinal Ingredients</th>  
 </tr>  
 <tr>  
 <td>oral</td>  
 <td>tablet 5 mg, 10 mg</td>  
 <td>[List all non-medicinal  
 ingredients in alphabetical order.]</td>  
 </tr>  
 </tbody>  
</table>

**Merge cells:** To merge cells vertically and horizontally, use @rowspan and @colspan attributes with the <th> or <td> elements. For example, <th colspan="2">sample text</td>

**Horizontal text alignment:** use the @align attribute with the following valid values (values are case sensitive):

|  |  |
| --- | --- |
| **Valid value** | **Result** |
| left | Left align cell content |
| center | centre align cell content |
| right | Right align cell content |
| justify | Justify align cell content |
| char | Character align cell content |

Use col@align to set alignment for all cells in the column.

**Vertical text alignment:** use the @valign attribute with <th> or <td> to set vertical alignment.

**Table text spacing:** use the nonbreaking space code ‘&#160;’ to insert a tab or text indentation in a table cell. The nonbreaking space can also be used to keep text in a table from breaking inappropriately due to browser resizing.

### Lists

Insert a list using the <list> tag and each line in the list is created using the <item> tag. Lists can be numbered or bulleted using the list/@listType attribute with the value “ordered” for numbered items and the value “unordered” for bulleted items.

**Figure 21 - Example of compliant list structure**

<text>  
 <list listType="unordered" styleCode="disc">  
 <item>text</item>  
 <item>text</item>  
 </list>  
</text>

Use the following values to set the style for ordered lists (values are case sensitive):

|  |  |
| --- | --- |
| **Valid value** | **Result** |
| 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 ordered using little alpha characters: a, b, c |
| BigAlpha | List is ordered using big alpha characters: A, B, C |

For example, <list listType="ordered" styleCode="Arabic">

Use the following values to set the style for unordered lists (values are case sensitive):

|  |  |
| --- | --- |
| **Valid value** | **Result** |
| 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”>

NOTE: If the list type and style is not specified, the stylesheet defaults to unordered and disc.

### Images

Refer to Appendix 2 section 15 for validation rules

The <observationMedia> identifies image files to be rendered by the style sheet. The <observationMedia> element does not contain the image file, but instead points to the .jpg file. The .jpg shall always reside in the same output folder as the .xml.

The image file is rendered wherever it is referenced by renderMultimedia/@referencedObject.

**Figure 22 - Example of compliant reference to .jpg image file**

<component>  
 <observationMedia ID="m1">  
 <text>chemical structure</text>  
 <value xsi:type="ED" mediaType="image/jpeg">  
 <reference value="structure.jpg"/>  
 </value>  
 </observationMedia>  
</component>

The referencedObject attribute of the renderMultiMedia element identifies the corresponding observationMedia using its identifier such as <renderMultiMedia referencedObject="image1"/>. See **Figure 23** for an example of how to reference the image shown in **Figure 22**.

**Figure 23 - Example of compliant instruction to render a .jpg image file**

<component>  
 <section ID="ee2875272-8229-4c12-919e-827854dcd76a">  
 <id root="d134d52c-f9d4-4698-a082-84b29ee3d95a"/>  
 <code code="pii13" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="13 Pharmaceutical Information"/>  
 <title>13 Pharmaceutical Information</title>  
 <text>  
 <paragraph>Proper name: text</paragraph>  
 <paragraph>Chemical name: text</paragraph>  
 <paragraph>Molecular formula and molecular mass: text</paragraph>  
 <paragraph>Structural formula:<renderMultiMedia referencedObject="m1"/></paragraph>  
 <paragraph>Physicochemical properties: text</paragraph>  
 </text>  
 <effectiveTime value="20170101"/>  
 <component>  
 <observationMedia ID="m1">  
 <text>chemical structure</text>  
 <value xsi:type="ED" mediaType="image/jpeg">

<reference value="structure.jpg"/>  
 </value>  
 </observationMedia>  
 </component>  
 </section>  
</component>

For image placement,

* To make the image appear in line with text, insert renderMultimedia between <paragraph> elements.
* To make the image appear with text wrapping, insert renderMultimedia in the text of a <paragraph>.

## Special template structures

Refer to Appendix 2 section 16 for validation rules.

All XML PM’s must adhere to the structure and section heading hierarchy defined in the relevant product monograph guidance and template.

The Title Page and Patient Medication Information sections use a special structure that is required for all product monographs. These structures are in place to ensure the style sheet can present the title page and Patient Medication Information consistently across all product monographs regardless of the product type.

### Title Page

The title page of the product monograph must always and only consist of the following sections.

NOTE: No modifications to the sections or additional sections shall be made to the title page.

| **Title Page Sections** | **Description** |
| --- | --- |
| Title | Scheduling symbol, BRAND NAME, Proper name, Dosage Form(s), Strength(s) and Route(s) of Administration, Pharmaceutical Standard (if applicable) Therapeutic Classification, NOC/c statement |
| Company name and address | Company name(s) and address(es) |
| Date of initial approval | Original NOC date |
| Date of last revision | Most recent NOC date |
| Submission control number | Health Canada control number associated with the most recent NOC |
| Footer | Registered trademark, trademark or licensing text |

**Figure 24 - Example of compliant title page structure**

<component> <!--Title Page section-->  
 <section ID="d8d30d86-e343-48f4-9cec-524834b3803b">  
 <id root="eed00b53-cdb2-4aa6-9e82-88b7d793b208"/>  
 <code code="0TP" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="TITLE PAGE"/>  
 <title>TITLE PAGE</title>  
 <effectiveTime value="20180101"/>  
 <component>  
 <section ID="be75cfb9-3131-4903-800b-267427388a13">  
 <id root="b9db4be0-3f46-437a-bd7b-4a3e010afaad"/>  
 <code code="0tp1.1" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="Title"/>  
 <title>Title</title>  
 <text>  
 <paragraph> Scheduling Symbol, Brand Name, Proper name, Dosage  
 Form(s), Strength(s) and Route(s) of Administration,  
 Pharmaceutical Standard, Therapeutic Classification </paragraph>  
 </text>  
 <effectiveTime value="20180101"/>  
 </section>  
 </component>  
 <component>  
 <section ID="f187daf9-5e75-425a-9de6-f6ce1af2a965">  
 <id root="ac26f58c-721a-4c51-8bbc-c9dddb1f1233"/>  
 <code code="0tp1.2" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="Company Name and Address"/>  
 <title>Company Name and Address</title>  
 <text>  
 <paragraph>Company Name</paragraph>  
 <paragraph>Street address</paragraph>  
 <paragraph>City</paragraph>  
 <paragraph>Province</paragraph>  
 <paragraph>Country</paragraph>  
 <paragraph>Postal code</paragraph>  
 </text>  
 <effectiveTime value="20180101"/>  
 </section>  
 </component>  
 <component>  
 <section ID="bf2dab4e-fd04-4ec9-9cdc-247188622d0f">  
 <id root="e5f1dea3-d907-4664-b46f-e1d9736d47af"/>  
 <code code="0tp1.3" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="Date of Initial Approval"/>  
 <title>Date of Initial Approval</title>  
 <text>  
 <paragraph>December 20, 2019</paragraph>  
 </text>  
 <effectiveTime value="20180101"/>  
 </section>  
 </component>  
 <component>  
 <section ID="d0184119-8fd7-4378-af77-b227c39e8445">  
 <id root="ad78301c-29a9-41af-96f8-d58815fed296"/>  
 <code code="0tp1.4" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="Date of Revision"/>  
 <title>Date of Revision</title>  
 <text>  
 <paragraph>December 20, 2019</paragraph>  
 </text>  
 <effectiveTime value="20180101"/>  
 </section>  
 </component>  
 <component>  
 <section ID="ebc3f3dc-71be-424f-91ef-8aca8c138b21">  
 <id root="efd8c4c1-d0dd-434d-b1c2-4daa18752fa8"/>  
 <code code="0tp1.5" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="Submission Control Number:"/>  
 <title>Submission Control Number:</title>  
 <text>  
 <paragraph>123456</paragraph>  
 </text>  
 <effectiveTime value="20180101"/>  
 </section>  
 </component>  
 <component>  
 <section ID="e2d4279e-5fca-4d26-898d-02548a217ab9">  
 <id root="f17bc229-d609-460a-b9dc-418008d47c90"/>  
 <code code="0tp1.6" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="Footer"/>  
 <title>Footer</title>  
 <text>  
 <paragraph>[BRAND NAME<sup>&#174;</sup> or &#8482;] is a registered  
 trademark of [COMPANY]</paragraph>  
 </text>  
 <effectiveTime value="20180101"/>  
 </section>  
 </component>  
 </section>  
</component>

### Patient Medication Information

This section begins with 'PATIENT MEDICATION INFORMATION' as the parent section. All other sections are children of this major section. Brand name, proper name, read this carefully… and the Serious Warnings and Precautions table are captured as text under the 'READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE' section (as shown in **Figure 25**).

**Figure 25 - Example of compliant Patient Medication Information section**

<section ID="baa4d498-0fc3-4e44-b4b6-550140d4de5d">  
 <id root="be74b6e6-c461-4a5f-a18e-ed321b381456"/>  
 <code code="pmi00" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="PATIENT MEDICATION INFORMATION"/>  
 <title>PATIENT MEDICATION INFORMATION</title>  
 <effectiveTime value="20170101"/>  
 <component>  
 <section ID="ea4ec98b-b2d3-4d73-877c-aaa5eb28997d">  
 <id root="067c0a3b-5869-43a7-baff-ce6de72ae1e5"/>  
 <code code="pmi01" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE"/>  
 <title>READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE</title>  
 <text>  
 <paragraph>[BRAND NAME]</paragraph>  
 <paragraph>[PROPER NAME IN FINAL DOSAGE FORM]</paragraph>  
 <paragraph>Read this carefully before you start taking [Brand name] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about [Brand name].</paragraph>  
 <table width="100%">  
 <tbody>  
 <tr>  
 <td align="center" colspan="2" styleCode="Lrule Rrule Toprule">  
 <content styleCode="bold">Serious Warnings and Precautions</content></td>  
 </tr>  
 <tr>  
 <td styleCode="Lrule Rrule Botrule">  
 <list>  
 <item>text</item>  
 <item>text</item>  
 </list>  
 </td>  
 </tr>  
 </tbody>  
 </table>  
 </text>  
 <effectiveTime value="20170101"/>  
 </section>  
 </component>

### Allowable differences between Title, Name and Display Name

Regarding product details, the @displayName must always match the <name>.

Regarding the narrative text sections, the @displayName must always match the <title>.

However, there are two exceptions to the above-mentioned rules: the UNASSIGNED heading and the Patient Medication Information.

With UNASSIGNED, the @displayName must always match the code, codeSystem and displayName from the controlled vocabulary with the product monograph template headings. However, the <title> can be modified to suit the appropriate subheading. For example,

Within the PATIENT MEDICATION INFORMATION section heading, the @displayName must always match the code, codeSystem and displayName from the controlled vocabulary. However, the <title> can be modified where there is bracketed text. For example, the displayName is always ‘What is [Brand name] used for?’. The <title> is modified to replace the bracketed text with the brand name 'What is LORUM IPSUM used for?'.

**Figure 26 - Example of compliant use of the UNASSIGNED section heading**

<component>  
 <section ID="baa4d498-0gc3-4e44-bcb6-550140d4de5d">  
 <id root="be74b6e6-1431-4a5f-a18e-ed321b381456"/>  
 <code code="US" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName="UNASSIGNED"/>  
 <title> Cardiovascular </title>  
 <text>  
 <paragraph>text</paragraph>  
 </text>  
 <effectiveTime value="20170101"/>  
 </section>  
</component>

**Figure 27 – Example of compliant use of Patient Medication Information section headings**

<component>  
 <section ID="baa4d498-0gc3-4e44-bcb6-550140d4de5d">  
 <id root="be74b6e6-1431-4a5f-a18e-ed321b381456"/>  
 <code code="pmi02" codeSystem="2.16.840.1.113883.2.20.6.60"  
 displayName=" What is [Brand name] used for? "/>  
 <title> What is LORUM IPSUM used for? </title>  
 <text>  
 <paragraph>text</paragraph>  
 </text>  
 <effectiveTime value="20170101"/>  
 </section>  
</component>

# Appendices

## Appendix 1 - Glossary

|  |  |
| --- | --- |
| GUID | Globally Unique Identifier |
| JFIF | JPEG File Interchange Format |
| JPEG | Joint Photographic Experts Group |
| SKU | Stock Keeping Unit |
| XML | Extensible Markup Language |

## Appendix 2 - XML PM Validation Rules Version 1.0.0

| **ID#** | **Rule Name** | **Rule Description** | **Severity** |
| --- | --- | --- | --- |
| **1** | **General** | | |
|  | XML file | Checks to ensure the XML file is well formed and valid against the schema | Error |
|  | File types | Checks to ensure only JPEG image files are referenced in the .xml and the image file has the extension “.jpg” | Error |
|  | Folder structure | Checks to ensure the .xml file and its referenced .jpg files are in the same folder | Error |
|  | File naming | Checks to ensure the .xml file is named with the GUID from the document ID (i.e., id root) | Error |
|  | File references | Checks to ensure all .jpg files referenced in the .xml file are present (i.e., there are no missing .jpg files) | Error |
|  | Date and Time (effective time) | All Date values associated with <effectiveTime> must be provided in the format YYYYMMDD | Error |
|  | Text structure | Checks to ensure <text> or <paragraph> elements do not appear immediately under the following major section headings.   * TITLE PAGE * PART I: HEALTH PROFESSIONAL INFORMATION * PART II: SCIENTIFIC INFORMATION * PATIENT MEDICATION INFORMATION   With respect to the above-mentioned major section headings, <text> or <paragraph> elements can only appear under the sub-headings; e.g., cannot appear immediately under PART I but appear under section *1 INDICATIONS*.  <text> and <paragraph> elements shall appear directly under the RECENT MAJOR LABEL CHANGES major section heading. | Error |
|  | GUID | Checks to ensure Globally Unique Identifiers (GUID) within the document are unique and follow the canonical structure, content and formatting rules: displayed in five groups separated by hyphens, in the form 8-4-4-4-12 for a total of 36 characters (32 alphanumeric characters and four hyphens) and permitted characters only include a-f,0-9,-  Rule applies to the following data elements:   * id root * setId root   Rule does not apply to the following document locations where an id root represents a code system and should be populated with an OID value (not a GUID):   * Organization Information - Represented Organization * Organization Information - Assigned Organization | Error |
|  | Undefined data elements and attributes | Checks to ensure that there are no undefined data elements and attributes outside of those described in the guidance document | Error |
|  | Coded values | All values associated with a coded element must be an exact match | Error |
|  | Code system | Checks to ensure coded values include a valid code system using either the codeSystem or root attribute (*see Appendix*) | Warning |
|  | Display name | Checks to ensure display names adhere to the following:   * Use the correct case * English language product monographs use English display names * French language product monographs use French display names   The following do not have display names defined in XML, but the validation does check the code against the associated display name within the Health Canada controlled vocabulary.  Template Id - Regulatory Activity Type (2.16.840.1.113883.2.20.6.37)  Id extension - Company ID and Name (2.16.840.1.113883.2.20.6.31) | Error |
|  | Identifier extensions | Checks to ensure there are no spaces in id extensions | Error |
|  | Empty elements | Checks to ensure that the following elements have content between opening and closing tags:  <text>, <title>, <caption> and <content> | Error |
|  | Characteristics | Checks to ensure characteristics have no class code | Error |
|  | Confidentiality code | Checks to ensure there are no confidentiality codes | Error |
| **2** | **XML Prolog** | | |
|  | XML version | Checks XML reference to ensure it is for version “1.0” and encoding “UTF-8”. | Error |
|  | Stylesheet | Checks for XML-stylesheet reference to ensure it is https://raw.githubusercontent.com/HealthCanada/HPFB/master/product-monograph/style-sheet/spl\_canada.xsl | Error |
|  | Schema Location | Checks to ensure the schemaLocation of the urn:hl7-org:v3 namespace is provided as <https://raw.githubusercontent.com/HealthCanada/HPFB/master/product-monograph/schema/SPL.xsd> | Error |
|  | Processing Instructions | Checks to ensure there are no processing instructions other than the xml and xml-stylesheet declarations | Error |
|  | Comments | Checks to ensure there are no comments in the XML file | Error |
| **3** | **Document** | | |
|  | Document identifier | Checks to ensure the document id (id root) is present and the document id (id root) is a GUID | Error |
|  | Document type code | Check to ensure that the code for document type from the code system is 2.16.840.1.113883.2.20.6.10 and the display name corresponds to the code | Error |
|  | Date of Initial Approval / Date of Last Revision | Checks to ensure there is a date value within effective time with the format YYYYMMDD | Warning |
|  | Language code | Checks to ensure that the code for language is from the code system 2.16.840.1.113883.2.20.6.29 and the display name corresponds to the code | Error |
|  | Identifier type <set id> | Checks to ensure the set id is present and the set id is a GUID | Error |
|  | Version number | Checks to ensure the version number is present with non-negative integer value greater than 0 | Error |
| **4** | **Organization (Market Authorization Holder / Importer or Distributor)** | | |
|  | Company code | Checks to ensure the id extension value is from the code system 2.16.840.1.113883.2.20.6.31 | Error |
|  | Company name | Checks to ensure the company name provided within <name> corresponds to the id extension value and display name in the code system 2.16.840.1.113883.2.20.6.31 | Error |
|  | Address of Market Authorization Holder (Represented Organization) | The following company contact information is required.   * Street name and number * City * Province * Postal Code * Country * Corporate email * Corporate phone number * Corporate website   If the country is not ‘CANADA’,   * The value in the Province field should be the closest equivalent subdivision or territory (e.g., prefectures for Japan). * Do not use abbreviations or acronyms. Spell out all provinces, countries and street names. * The value in the Postal Code field should be the closest equivalent (e.g., ZIP code for USA or postcode for United Kingdom). | Error |
|  | Address of Canadian Distributor or Importer (Assigned Organization) | Checks to ensure that all Canadian contact address information for the Canadian distributor or importer is present if the market authorization holder’s country is not CANADA.  Checks to ensure the id extension value is from the code system 2.16.840.1.113883.2.20.6.31  Checks to ensure the company name provided within <name> corresponds to the id extension value and display name in the code system 2.16.840.1.113883.2.20.6.31  Address is made up of the following:   * Street name and number * City * Province * Postal Code * Country * Corporate email * Corporate phone number * Corporate website   NOTE: This section is required if the Market Authorization Holder’s country is not Canada.  This address must be located in Canada. If the Market Authorization Holder is located in Canada, then this information is not required. | Warning |
|  | Country code | Checks to ensure that the country code is from the code system 2.16.840.1.113883.2.20.6.17 and the display name corresponds to the code (full country name). The only permitted country code for a Canadian Importer or Distributor is the one corresponding to Canada. | Error |
|  | Postal code format | Checks to ensure that the postal code contains only alphanumeric characters. For Canadian addresses, the format “A1A 1A1” with a single white space is permitted, separating the third and fourth characters. | Information |
|  | <telecom> | Checks to ensure there are exactly three <telecom> elements. One each of the following:   1. <telecom> tel: 2. <telecom> mailto: 3. <telecom> http: OR <telecom> https: | Information |
|  | <telecom> = “tel:” | Checks to ensure the telecom value begins with “tel:+” | Information |
|  | <telecom> = “mailto:” | Checks to ensure the telecom value beginning with “mailto:” is a valid e-mail address and is in the format local-part@domain | Information |
|  | <website>= http | Checks to ensure the telecom value for website is beginning with “http:” or ‘https:’ | Information |
| **5** | **SPL Body** | | |
|  | Sections | Checks for the presence of the major section headings   * TITLE PAGE * PART I: HEALTH PROFESSIONAL INFORMATION * PART II: SCIENTIFIC INFORMATION | Error |
|  | Sections | Checks for the presence of the major section headings   * RECENT MAJOR LABEL CHANGES * PATIENT MEDICATION INFORMATION | Warning |
|  | Id root | Checks to ensure that the id root associated with each section does not contain any extensions or any other data elements | Error |
|  | Id root | Checks to ensure that each id root is present and is a GUID | Error |
|  | Code system | Checks to ensure each section heading has a code and displayName from the code system associated with each product monograph template. The display name corresponds to the code. | Error |
|  | Section effective time | Checks to ensure that each section has an effective time with the format YYYYMMDD | Error |
|  | Section headings | Checks to ensure that the display name and <title> associated with each section is identical.  This rule does not apply to any section declared with the displayName ’UNASSIGNED’, or any section within the major section heading ‘PATIENT MEDICATION INFORMATION’, with the exception of those declared with code values ‘pmi00’ and ‘pmi01’. | Warning |
| **6** | **Manufactured Product** | | |
|  | DIN code | Checks to ensure a DIN is present (DIN is represented by an 8-digit string which may contain leading zeroes) and permitted characters only include 0-9. | Warning |
|  | Proprietary name | Checks to ensure a proprietary name is present within manufactured product <name> | Warning |
|  | Form Code | Checks to ensure there is a formCode from the code system 2.16.840.1.113883.2.20.6.3 and the display name corresponds to the code | Error |
|  | Non-proprietary name | Checks to ensure a non-proprietary name is present within <name> under <genericMedicine> | Warning |
|  | Code system | Checks to ensure that for each product there is a regulatory status from the code system 2.16.840.1.113883.2.20.6.11 and the display name corresponds to the code | Error |
|  | Code system | Checks to ensure there is a valid class code (ingredient role) associated with each ingredient from the code system 2.16.840.1.113883.2.20.6.39. | Error |
|  | Code system | Checks to ensure there is a strength with a numerator and denominator if the ingredient role is ACTIB, ACTIM or ACTIR. | Error |
|  | Quantity | Checks to ensure the numerator and denominator have a value greater than zero and a unit. | Error |
|  | Code system | Checks to ensure the value provided for unit matches the code in the code system 2.16.840.1.113883.2.20.6.15 (Units of Measure). | Error |
|  | Quantity | Checks to ensure the denominator values and units for all ingredients within a product are the same. | Error |
|  | Code system | Checks to ensure there is an ingredient code from the code system 2.16.840.1.113883.2.20.6.14 (ingredient id) and the display name corresponds to the code. | Error |
|  | Ingredient code | Checks to ensure the same ingredient code is not used more than once per product. | Error |
|  | Ingredient code | Checks to ensure there is an ingredient name. Name shall match the display name associated with the code. | Error |
|  | Active ingredient quantity range | Checks to ensure that when an active ingredient quantity (i.e., strength) is expressed as a range:   * The range is only associated with active ingredients (i.e., ingredient classCode is ACTIB, ACTIM or ACTIR) * The <numerator> has the xsi:type attribute and the xsi:type value is URG\_PQ * The lower limit of the range is expressed as <low value=”” unit=””> * The upper limit of the range is expressed as <high value=”” unit=””> * The <low> and <high> units must have the same unit of measure value * The <denominator> must not have a range and is expressed as <denominator value=”1” unit=”1”> | Error |
| **7** | **Packaging (single part format)** | | |
|  | As content element | Checks to ensure the product has an <asContent> (package information) element | Error |
|  | Quantity of package information | Checks to ensure the quantity (for package information) includes a value for numerator and denominator | Error |
|  | Numerator value | Checks to ensure the numerator (for package amount) has a value greater than zero and a unit is present.  Checks to ensure the numerator unit value is a unit of measure from code system 2.16.840.1.113883.2.20.6.15 and the unit value matches the code. | Error |
|  | Numerator of initial package | Checks to ensure the ingredient quantity (strength) denominator unit is the same as the packaging numerator unit. | Error |
|  | Numerator of outer package | Unit of the numerator (for package amount) of an outer package is the same as the unit for the denominator of the quantity of the inner package | Warning |
|  | Denominator | Checks to ensure that the denominator associated with the innermost layer of packaging has value 1 and either no unit or unit “1”. | Error |
|  | Pack Type Code system | Checks to ensure that there is a pack type code from the code system 2.16.840.1.113883.2.20.6.32 and the display name matches the code | Error |
|  | Package item code | Checks to ensure a package item code is present only on the outer level of packaging.  Note: Package item codes are meant to represent the unit of sale or stock keeping unit. | Information |
|  | Package type code | Checks to ensure the package type code does not match any other package item code in the same package hierarchy | Error |
| **8** | **Packaging (multi-part format)** | |  |
|  | Product part | Checks to ensure that if the product has parts that the initial numerator value and unit are equal to ‘1’. | Error |
|  | Package type | Checks to ensure that if the package type is Kit, then there is one or more associated <part> elements | Error |
|  | Pack quantity | Checks to ensure that each part has an overall quantity | Error |
|  | As content data element | Checks to ensure that if there is an <asContent> (packaging) element in the part, then the overall quantity numerator unit is the same as the numerator unit for the <asContent> element | Error |
|  | As content data element | Checks to ensure that if there is no <asContent> (packaging) element in the part, then the overall quantity numerator unit is 1 | Error |
|  | Package item code | Checks to ensure a package item code is present | Information |
| **9** | **Regulatory status of packaging** | | |
|  | Regulatory status | Checks to ensure that there is not more than one regulatory status on any one package | Error |
|  | Regulatory status code | Checks to ensure that the regulatory status code is from the code system 2.16.840.1.113883.2.20.6.11 and the display name corresponds to the code | Error |
|  | Status code and effective time | Checks to ensure that if the status code is:   * 1 = ‘APPROVED’ then there is an effectiveTime low value (Date of Initial Approval) * 2 = ‘CANCELLED’ then there is an effectiveTime high value (Date of Cancellation) | Error |
|  | Effective time values | Checks to ensure that if there is an effectiveTime high value, then it is not less than the low value | Error |
| **10** | **Regulatory Activity and Control Number** | | |
|  | Regulatory Activity | Checks to ensure that there is only one Regulatory Activity for every product and product part | Error |
|  | Code system | Checks to ensure that there is a regulatory activity code from the code system 2.16.840.1.113883.2.20.6.37 and the display name corresponds to the code | Error |
|  | Territorial authority | Checks to ensure that the Territorial authority is the code for Canada from the code system 2.16.840.1.113883.2.20.6.17 and the display name corresponds to the code | Error |
|  | Control Number | Checks to ensure the Control Number is present | Warning |
| **11** | **Regulatory Status of the Manufactured Product** | | |
|  | Regulatory status | Checks to ensure that there is only one regulatory status on any one product | Error |
|  | Regulatory status code | Checks to ensure that the Regulatory Status code is from the code system 2.16.840.1.113883.2.20.6.11 and the display name corresponds to the code | Error |
|  | Effective time | Checks to ensure that if the regulatory status code is:   * 1 = ‘APPROVED’ then there is an effectiveTime low value (Date of Initial Approval) * 2 = ‘CANCELLED’ then there is an effectiveTime high value (Date of cancellation) in addition to a low value | Error |
|  | Effective time values | Checks to ensure that if there is an effectiveTime high value, then it is not less than the low value | Error |
| **12** | **Product Characteristics** | | |
|  | Characteristic code | Checks to ensure that there is a characteristic code from the code system 2.16.840.1.113883.2.20.6.23 and the display name corresponds to the code | Error |
|  | Characteristic value code | Checks to ensure that there is a characteristic value code from the corresponding code system and the display name corresponds to the code.  See below for the characteristic code systems:   1. Product Type: 2.16.840.1.113883.2.20.6.53 2. Colour: 2.16.840.1.113883.2.20.6.24 3. Shape: 2.16.840.1.113883.2.20.6.25 4. Size: Not a coded value 5. Score: 2.16.840.1.113883.2.20.6.4 6. Imprint: Not a coded value 7. Flavour: 2.16.840.1.113883.2.20.6.26 8. Combination Product: 2.16.840.1.113883.2.20.6.8 9. Pharmaceutical Standard: 2.16.840.1.113883.2.20.6.5 10. Schedule: 2.16.840.1.113883.2.20.6.2 11. Therapeutic Class: 2.16.840.1.113883.2.20.6.6  * Note: Product Type, Pharmaceutical Standard, Schedule and Therapeutic Class are required for all products. The other characteristics are context sensitive depending on the dosage form. For example, shape, size, score, imprint are not applicable for liquids. | Error |
|  | Characteristic value code | Checks to ensure that the characteristic value code is compliant with the specified value type   1. Product Type: xsi:type="CV” 2. Colour: xsi:type="CV” 3. Shape: xsi:type="CV” 4. Size: xsi:type="PQ” 5. Score: xsi:type="CV” 6. Imprint: xsi:type="ST” 7. Flavour: xsi:type="CV” 8. Combination Product: xsi:type="CV” 9. Pharmaceutical Standard: xsi:type="CV” 10. Schedule: xsi:type="CV” 11. Therapeutic Class: xsi:type="CV” | Error |
|  | Characteristic value type | Checks to ensure that the XSI Value type is either PQ, CV or ST | Error |
|  | Characteristic value type | Checks to ensure that any value associated with XSI Value type PQ is a non-negative integer. | Error |
| **13** | **Route of Administration** | | |
|  | Administration code | Checks to ensure that there is a route of administration code, from the code system 2.16.840.1.113883.2.20.6.7 and the display name corresponds to the code | Error |
| **14** | **Narrative Text Sections** | | |
|  | Internal cross-references | Checks to ensure that each instance of <linkHtml href:””> </linkHtml> correctly references the ID attribute value of a <section>, <paragraph>, <table>, <list>, <content>, <renderMultimedia> or an id root within the document. The reference to the ID or id root must begin with a ‘#’.  Any instance of <linkHtml href:””></linkHtml> without the ‘#’ prefix must point to a valid external website. The ‘#’ prefix is reserved only for cross-references within the document. | Error |
|  | Text elements | Checks to ensure that narrative text is only enclosed under <paragraph>, <list>, or <table> elements.  Text is not to be enclosed directly within the <text> element | Error |
| **15** | **Images** | | |
|  | Image description | Checks to ensure that an image description is present within the <text></text> element associated with the <observationMedia> element | Information |
|  | Image data type | Checks to ensure that the value xsi:type is ED | Error |
|  | Image media type | Checks to ensure that the media type is ‘image/jpeg’ | Error |
|  | Reference value | Checks to ensure that the reference value is the file name for a valid image | Error |
|  | Image size | Checks to ensure that the size of the image file does not exceed 1 MB | Information |
|  | Image components | Checks to ensure that for each image .jpg file referenced via an <observationMedia> element, there is at least one corresponding instance of <renderMultimedia referencedObject=""></renderMultiMedia> in the document | Error |
|  | Image reference | Checks to ensure that references to image ID’s (<renderMultiMedia referencedObject=""></renderMultiMedia>) correspond to an <observationMedia> element with a matching ID | Error |
| **16** | **Title Page** | | |
|  | Dates | Checks to ensure that the date of initial approval and date of revision are present.  Note: in this context the date is in the written format (For example, January 15, 2020). | Information |
|  | Control number | Checks to ensure that the control number is present as a seven digit integer with no other text | Information |

## Appendix 3 - code systems identified using the codeSystem attribute

| **#** | **Document Location** | **Controlled Vocabulary (OID)** | **Attribute** |
| --- | --- | --- | --- |
|  | Document Metadata - Template Definition | Document Type (6.10) | code[@codeSystem] |
|  | Document Metadata - Language Code | Language Code (6.29) | languageCode[@codeSystem] |
|  | Company Information - Market Authorization Holder | Country Code (6.17) | country[@codeSystem] |
|  | Company Information - Canadian Distributor/Importer | Country Code (6.17) | country[@codeSystem] |
|  | Manufactured Product - Product Information | Dosage Form (6.3) | formCode[@codeSystem] |
|  | Manufactured Product - Ingredients | Ingredient Identifier (6.14) | code[@codeSystem] |
|  | Manufactured Product - Packaging | Package Type (6.32) | formCode[@codeSystem] |
|  | Manufactured Product - Packaging | Regulatory Status (used for Packaging) (6.11) | code[@codeSystem] |
|  | Manufactured Product - Regulatory Information | Regulatory Activity of Product (6.37) | code[@codeSystem] |
|  | Manufactured Product - Regulatory Information | Regulatory Authority (6.17) | code[@codeSystem] |
|  | Manufactured Product - Regulatory Information | Regulatory Status (used for Product) (6.11) | code[@codeSystem] |
|  | Manufactured Product - Product Characteristics | Product Characteristics (6.23) | code[@codeSystem] |
|  | Manufactured Product - Product Characteristics | Product Type (6.53) | value[@codeSystem] |
|  | Manufactured Product - Product Characteristics | Colour (6.24) | value[@codeSystem] |
|  | Manufactured Product - Product Characteristics | Shape (6.25) | value[@codeSystem] |
|  | Manufactured Product - Product Characteristics | Score (6.4) | value[@codeSystem] |
|  | Manufactured Product - Product Characteristics | Flavour (6.26) | value[@codeSystem] |
|  | Manufactured Product - Product Characteristics | Combination Product (6.8) | value[@codeSystem] |
|  | Manufactured Product - Product Characteristics | Pharmaceutical Standard (6.5) | value[@codeSystem] |
|  | Manufactured Product - Product Characteristics | Schedule (6.2) | value[@codeSystem] |
|  | Manufactured Product - Product Characteristics | Therapeutic Class (6.6) | value[@codeSystem] |
|  | Manufactured Product - Substance Administration | Route of Administration (6.7) | routeCode[codeSystem] |
|  | Document Body - Section Headings | 2016 Product Monograph Template - Standard (6.60) | code[@codeSystem] |
|  | Document Body - Section Headings | 2016 Product Monograph Template - Notice of Compliance with Conditions (6.61) | code[@codeSystem] |
|  | Document Body - Section Headings | 2016 Product Monograph Template - Subsequent Entry Product (6.62) | code[@codeSystem] |
|  | Document Body - Section Headings | 2016 Product Monograph Template - Schedule C (6.63) | code[@codeSystem] |
|  | Document Body - Section Headings | 2016 Product Monograph Template - Schedule D (6.64) | code[@codeSystem] |
|  | Document Body - Section Headings | 2016 Product Monograph Template - Schedule D - Biosimilar Biologic Drug (6.65) | code[@codeSystem] |

## Appendix 4 - code systems identified using the root attribute

| **#** | **Document Location** | **Controlled Vocabulary (OID)** |  |
| --- | --- | --- | --- |
|  | Document Metadata - Regulatory Activity Type | Regulatory Activity of Document (6.37) | templateId[@root] |
|  | Company Information - Market Authorization Holder | Company Identifier (6.31) | id[@root] |
|  | Company Information - Canadian Distributor/Importer | Company Identifier (6.31) | id[@root] |