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## XML PM Validation Rules

| **ID#** | **Rule Name** | **Rule Description** | **Severity** | **Guidance Section** |
| --- | --- | --- | --- | --- |
| **1 - General** | | | |  |
|  | XML file | Checks to ensure the XML file is well formed and valid against the schema | Error | 2.1.1, 2.1.12 |
|  | File types | Checks to ensure only .xml and .jpg files are included in the package | Error | 2.1.3, 2.2.3 |
|  | Folder structure | Checks to ensure the spl folder contains exactly one .xml file | Error | 2.1.4 |
|  | File naming | Checks to ensure the .xml file is named with the GUID from the document ID (i.e., id root) | Error | 2.1.4, 2.2.3 |
|  | File references | Checks to ensure all files associated with the document are referenced in the .xml (i.e., there are no missing or extra files) | Error | 2.1.5, 2.2.3 |
|  | Date and Time | All Date values associated with <effectiveTime> must be provided in the format YYYYMMDD | Error | 2.1.10 |
|  | 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 * PART III: 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 | 2.1.11 |
|  | 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 * Manufactured Product - Regulatory Activity - Control Number | Error | 2.1.12 |
|  | 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 | 2.1.12 |
|  | Coded values | All values associated with a coded element must be an exact match | Error | 2.1.12 |
|  | Code system | Checks to ensure coded values include a valid code system using either the codeSystem or root attribute (*see Appendix*) | Warning | 2.1.12 |
|  | 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)  Code - DIN (2.16.840.1.113883.2.20.6.42)  Extension – Control Number (2.16.840.1.113883.2.20.6.49) | Error | 2.1.12 |
|  | Identifier extensions | Checks to ensure there are no spaces in id extensions | Error | 2.1.12 |
|  | Empty elements | Checks to ensure that the following elements have content between opening and closing tags:  <text>, <title>, <caption> and <content> | Warning | 2.1.12 |
|  | Characteristics | Checks to ensure characteristics have no class code | Error | 2.1.12 |
|  | Confidentiality code | Checks to ensure there are no confidentiality codes | Error | 2.1.12 |
| **2 - XML Prolog** | | | |  |
|  | XML version | Checks XML reference to ensure it is for version 1.0 and encoding “UTF-8”. | Error | 2.2.3 |
|  | Stylesheet | Checks for XML-stylesheet reference to ensure it is <https://raw.githubusercontent.com/HealthCanada/HPFB/master/Structured-Product-Labeling-(SPL)/Style-Sheets/current/spl_canada.xsl> | Error | 2.2.3 |
|  | Schema Location | Checks to ensure 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> | Error | 2.2.3 |
|  | Processing Instructions | Checks to ensure there are no processing instructions other than the xml and xml-stylesheet declarations | Error | 2.2.3 |
|  | Comments | Checks to ensure there are no comments in the XML file | Error | 2.2.3 |
| **3 - Document** | | | |  |
|  | Document identifier | Checks to ensure the document id (id root) is present and the document id (id root) is a GUID | Error | 2.3.3 |
|  | 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 | 2.3.3 |
|  | Date of Last Revision | Checks to ensure there is a date value within effective time with the format YYYYMMDD | Warning | 2.3.3 |
|  | Date of Initial Approval | Checks to ensure there is a date in the original text description with the format YYYYMMDD | Warning | 2.3.3 |
|  | 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 | 2.3.3 |
|  | Identifier type <set id> | Checks to ensure the set id is present and the set id is a GUID | Error | 2.3.3 |
|  | Version number | Checks to ensure the version number is present with non-negative integer value greater than 0 | Error | 2.3.3 |
| **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 | 2.4.3 |
|  | 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 | 2.4.3 |
|  | 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 | 2.4.3 |
|  | Address of Canadian Distributor or Importer (Assigned Organization) | Checks to ensure that all Canadian contact address information is present. Address is made up of the following:   * Street name and number * City * Province * Postal Code * Country * Corporate email * Corporate phone number * Corporate website   This address must be located in Canada. If the Market Authorization Holder is located in Canada, then this information is not required. | Warning | 2.4.3 |
|  | 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 | 2.4.3 |
|  | 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 | 2.4.3 |
|  | <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 | 2.4.3 |
|  | <telecom> = “tel:” | Checks to ensure the telecom value beginning with “tel:” includes a valid telephone number compliant with E.164:   1. Contains no hyphens or parenthesis; 2. Contain no letters or spaces; 3. Beginning with “+”; 4. Global telephone number not exceeding 15 digits; 5. If there is a semicolon in the telephone number, then it is followed by ext. | Information | 2.4.3 |
|  | <telecom> = “mailto:” | Checks to ensure the telecom value beginning with “<mailto:>” is a valid e-mail address as per IETF RFC 2822 and is in the format local-part@domain | Information | 2.4.3 |
|  | <website>= http | Checks to ensure the telecom value beginning with “http” is a valid website as per IETF RFC 1738 | Information | 2.4.3 |
| **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 | 2.5.1 |
|  | Sections | Checks for the presence of the major section headings   * RECENT MAJOR LABEL CHANGES * PART III: PATIENT MEDICATION INFORMATION | Warning | 2.5.1 |
|  | Id root | Checks to ensure that the id root associated with each section does not contain any extensions or any other data elements | Error | 2.5.4 |
|  | Id root | Checks to ensure that each id root is present and is a GUID | Error | 2.5.4 |
|  | Code system | Checks to ensure that each section contains a valid code from the code system associated with the corresponding product monograph template, including a valid display name corresponding to the code.  For example, 2.16.840.1.113883.2.20.6.60 contains the section headings corresponding to the template: *2016 PRODUCT MONOGRAPH TEMPLATE – STANDARD;*  2.16.840.1.113883.2.20.6.64 contains the section headings corresponding to the template: *2016 PRODUCT MONOGRAPH TEMPLATE - SCHEDULE D* | Error | 2.5.4 |
|  | Section effective time | Checks to ensure that each section has an effective time with the format YYYYMMDD | Error | 2.5.4 |
|  | Section headings | Checks to ensure that the display name and title associated with each section is identical | Warning | TBD |
| **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 | 2.6.1.2 |
|  | Proprietary name | Checks to ensure a proprietary name is present within manufactured product <name> | Warning | 2.6.1.2 |
|  | 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 | 2.6.1.2 |
|  | Non-proprietary name | Checks to ensure a non-proprietary name is present within <name> under <genericMedicine> | Warning | 2.6.1.2 |
|  | 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 | 2.6.1.2 |
|  | 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 | 2.6.2.6 |
|  | Code system | Checks to ensure there is a strength with a numerator and denominator if the ingredient role is ACTIB, ACTIM or ACTIR. | Error | 2.6.2.6 |
|  | Quantity | Checks to ensure the numerator and denominator have a value greater than zero and a unit. | Error | 2.6.2.6 |
|  | 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 | 2.6.2.6 |
|  | Quantity | Checks to ensure the denominators values and units for all ingredients within a product are the same. | Error | 2.6.2.6 |
|  | 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 | 2.6.2.6 |
|  | Ingredient code | Checks to ensure the same ingredient code is not used more than once per product. | Error | 2.6.2.6 |
|  | Ingredient code | Checks to ensure there is an ingredient name. Name shall match the display name associated with the code. | Error | 2.6.2.6 |
|  | 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=”” unit=””> | Error | 2.6.2.6 |
| **7 – Packaging (with no parts)** | | | |  |
|  | As content element | Checks to ensure the product has an <asContent> (package information) element | Error | 2.6.3.3 |
|  | Quantity of package information | Checks to ensure the quantity (for package information) includes a value for numerator and denominator | Error | 2.6.3.3 |
|  | Numerator value | Checks to ensure the numerator (for package amount) has a value greater than zero and a unit is present | Error | 2.6.3.3 |
|  | Numerator of initial package | Checks to ensure the products state of matter has a container with a matching state of matter. Therefore, ingredient denominator unit is the same as the packaging numerator unit for each product. | Error | 2.6.3.3 |
|  | Numerator of outer package | Checks to ensure that the unit of the numerator of an outer layer of packaging is the same value as the unit of the denominator for the corresponding layer of packaging contained within that same outer layer, when an inner layer is present. Rule does not check the numerator for the innermost layer of packaging | Error | 2.6.3.3 |
|  | 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 | 2.6.3.3 |
|  | 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 | 2.6.3.3 |
|  | Package item code | Checks to ensure a package item code is present. | Information | 2.6.3.3 |
|  | Package type code | Checks to ensure the package type code does not match any other package item code in the same package hierarchy | Error | 2.6.3.3 |
| **8 – Packaging (with parts)** | | |  |  |
|  | Product part | Checks to ensure that if the product has parts that the initial numerator value and unit are equal to ‘1’. | Error | 2.6.3.3 |
|  | Package type | Checks to ensure that if the package type is Kit, then there is one or more associated <part> elements | Error | 2.6.3.6 |
|  | Pack quantity | Checks to ensure that each part has an overall quantity | Error | 2.6.3.6 |
|  | 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 | 2.6.3.6 |
|  | 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 | 2.6.3.6 |
|  | Package item code | Checks to ensure a package item code is present | Information | 2.6.3.6 |
| **9 – Package Description** | | | |  |
|  | Regulatory status | Checks to ensure that there is not more than one regulatory status on any one product | Error | 2.6.4.3 |
|  | 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 | 2.6.4.3 |
|  | Status code | Checks to ensure that if the status code is:   * 1 = ‘APPROVED’ then there is a effectiveTime low value (Date of Initial Approval) * 2 = ‘CANCELLED’ then there is a effectiveTime high value (Date of Cancellation) | Error | 2.6.4.3 |
|  | Regulatory status code | Checks to ensure that if the status code is:   * 2 = ‘CANCELLED’ then there is an effectiveTime value for both low and high. | Error | 2.6.4.3 |
|  | Effective time values | Checks to ensure that if there is an effectiveTime high value, then it is not less than the low value | Error | 2.6.4.3 |
| **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 | 2.6.5.3 |
|  | 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 | 2.6.5.3 |
|  | 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 | 2.6.5.3 |
| **11– Regulatory Status of the Manufactured Product** | | | |  |
|  | Regulatory status | Checks to ensure that there is only one regulatory status on any one product | Error | 2.6.6.3 |
|  | 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 | 2.6.6.3 |
|  | Effective time | Checks to ensure that if the regulatory status code is:   * 1 = ‘APPROVED’ then there is a effectiveTime low value (Date of Initial Approval) * 2 = ‘CANCELLED’ then there is a effectiveTime high value (Date of cancellation) in addition to a low value | Error | 2.6.6.3 |
|  | Effective time format | Checks to ensure that the effectiveTime low value (Date of Approval) and effectiveTime high value (Date of Cancellation) have the format YYYYMMDD | Error | 2.6.6.3 |
| **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 | 2.6.7.2 |
|  | 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   The following characteristics are not required for non-solid dosage forms:   * Colour * Shape * Size * Score * Imprint * Flavour | Error | 2.6.7.2 |
|  | 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 | 2.6.7.2 |
|  | Characteristic value type | Checks to ensure that the XSI Value type is either PQ, CV or ST | Error | 2.6.7.2 |
| **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 | 2.6.8.3 |
| **14 – Narrative Text Sections** | | | |  |
|  | References | Checks to ensure that each instance of <linkHtml href:””> </linkHtml> references a valid Section ID or id root | Error | 2.7.1.6 |
|  | 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 | 2.7.1.9 |
| **15 - Images** | | | |  |
|  | Image description | Checks to ensure that an image description is present within the <text></text> element <observationMedia> element | Information | 2.7.2.2 |
|  | Image data type | Checks to ensure that the value xsi:type is ED | Error | 2.7.2.2 |
|  | Image media type | Checks to ensure that the media type is ‘image/jpeg’ | Error | 2.7.2.2 |
|  | Reference value | Checks to ensure that the reference value is the file name for a valid image | Error | 2.7.2.2 |
|  | Image size | Checks to ensure that the size of the image file does not exceed 1 MB | Information | 2.7.2.2 |
|  | Image file extension | Checks to ensure that the file is a JPEG image and the name has the extension “.jpg” | Error | 2.7.2.2 |
|  | 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 | 2.7.2.2 |
|  | Image reference | Checks to ensure that references to image ID’s (<renderMultiMedia referencedObject=""></renderMultiMedia>) correspond to an <observationMedia> element with a matching ID | Error | 2.7.2.2 |
| **16 – Title Page** | | | |  |
|  | Dates | Checks to ensure that the date of initial approval and date of revision are present and in the format YYYYMMDD | Information | 2.7.3.3 |
|  | Control number | Checks to ensure that the control number is present as a six digit integer with no other text | Information | 2.7.3.3 |

## Appendix A

The following table lists the code systems identified usingthe **codeSystem** attribute.

|  |  |  |  |
| --- | --- | --- | --- |
| # | Document Location | OID | Attribute |
| 1 | Document Metadata – Template Definition | 2.16.840.1.113883.2.20.6.10 | code[@codeSystem] |
| 2 | Document Metadata – Language Code | 2.16.840.1.113883.2.20.6.29 | languageCode[@codeSystem] |
| 3 | Company Information – Market Authorization Holder | 2.16.840.1.113883.2.20.6.17 | country[@codeSystem] |
| 4 | Company Information – Canadian Distributor/Importer | 2.16.840.1.113883.2.20.6.17 | country[@codeSystem] |
| 5 | Manufactured Product – Product Information | 2.16.840.1.113883.2.20.6.42 | country[@codeSystem] |
| 6 | Manufactured Product – Product Information | 2.16.840.1.113883.2.20.6.3 | formCode[@codeSystem] |
| 7 | Manufactured Product – Ingredients | 2.16.840.1.113883.2.20.6.14 | code[@codeSystem] |
| 8 | Manufactured Product – Packaging | 2.16.840.1.113883.2.20.6.32 | formCode[@codeSystem] |
| 9 | Manufactured Product – Packaging | 2.16.840.1.113883.2.20.6.11 | code[@codeSystem] |
| 10 | Manufactured Product – Regulatory Information | 2.16.840.1.113883.2.20.6.37 | code[@codeSystem] |
| 11 | Manufactured Product – Regulatory Information | 2.16.840.1.113883.2.20.6.17 | code[@codeSystem] |
| 12 | Manufactured Product – Regulatory Information | 2.16.840.1.113883.2.20.6.11 | code[@codeSystem] |
| 13 | Manufactured Product – Product Characteristics | 2.16.840.1.113883.2.20.6.23 | code[@codeSystem] |
| 14 | Manufactured Product – Product Characteristics | 2.16.840.1.113883.2.20.6.53 | value[@codeSystem] |
| 15 | Manufactured Product – Product Characteristics | 2.16.840.1.113883.2.20.6.24 | value[@codeSystem] |
| 16 | Manufactured Product – Product Characteristics | 2.16.840.1.113883.2.20.6.25 | value[@codeSystem] |
| 17 | Manufactured Product – Product Characteristics | 2.16.840.1.113883.2.20.6.4 | value[@codeSystem] |
| 18 | Manufactured Product – Product Characteristics | 2.16.840.1.113883.2.20.6.26 | value[@codeSystem] |
| 19 | Manufactured Product – Product Characteristics | 2.16.840.1.113883.2.20.6.8 | value[@codeSystem] |
| 20 | Manufactured Product – Product Characteristics | 2.16.840.1.113883.2.20.6.5 | value[@codeSystem] |
| 21 | Manufactured Product – Product Characteristics | 2.16.840.1.113883.2.20.6.2 | value[@codeSystem] |
| 22 | Manufactured Product – Product Characteristics | 2.16.840.1.113883.2.20.6.6 | value[@codeSystem] |
| 23 | Manufactured Product – Substance Administration | 2.16.840.1.113883.2.20.6.7 | routeCode[codeSystem] |
| 24 | Document Body – Section Headings | 2.16.840.1.113883.2.20.6.60 | code[@codeSystem] |
| 25 | Document Body – Section Headings | 2.16.840.1.113883.2.20.6.61 | code[@codeSystem] |
| 26 | Document Body – Section Headings | 2.16.840.1.113883.2.20.6.62 | code[@codeSystem] |
| 27 | Document Body – Section Headings | 2.16.840.1.113883.2.20.6.63 | code[@codeSystem] |
| 28 | Document Body – Section Headings | 2.16.840.1.113883.2.20.6.64 | code[@codeSystem] |
| 29 | Document Body – Section Headings | 2.16.840.1.113883.2.20.6.65 | code[@codeSystem] |

The following table lists the code systems identified using the **root** attribute.

|  |  |  |  |
| --- | --- | --- | --- |
| # | Document Location | OID |  |
| 1 | Document Metadata – Regulatory Activity Type | 2.16.840.1.113883.2.20.6.37 | templateId[@root] |
| 2 | Company Information – Market Authorization Holder | 2.16.840.1.113883.2.20.6.31 | id[@root] |
| 3 | Company Information – Canadian Distributor/Importer | 2.16.840.1.113883.2.20.6.31 | id[@root] |
| 4 | Manufactured Product – Regulatory Information | 2.16.840.1.113883.2.20.6.49 | id[@root] |