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## XML PM Validation Rules Version 1.0

| **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 1 - 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 2 - 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] |