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| Guidance Document  Preparation of Product Monographs 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.

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# Introduction

## Purpose/Overview

To provide sponsors with guidance on the technical and business conformance rules needed to prepare a product monograph using the Extensible Markup Language (XML) format.

## Scope and application

In-scope

* Human pharmaceutical, radiopharmaceutical and biologic drugs
* Regulatory activities in the electronic Common Technical Document (eCTD)
* Product monographs prepared using the 2016 templates
* Sponsors must not add any content, sections or sub-elements other than what is listed in this guidance. Adding non-compliant content or sections will result in a validation fail.

Out of scope

* Over the counter (non-prescription) drugs, self-care products, natural health products, medical devices, food and veterinary drugs
* Product monographs prepared using pre-2004 and 2004 templates

## Policy objectives

Health Canada continues to improve the accessibility and quality of drug product information for Canadians. The Department is making drug product information more relevant and easier to understand so that consumers and patients can make informed decisions about their medications and health professionals can access critical safety information quickly.

With respect to international standards, Health Canada aims to align its use of XML with other international regulators, Health Level (HL7) standards and the International Organization for Standardization’s (ISO) standard for the Identification of Medicinal Products (IDMP).

## Policy statements

This guidance document is to be used in the preparation and filing of XML product monographs (XML PM) and is to be read in conjunction with the *Guidance Document Product Monograph* and *Guidance Document Validation of product monographs prepared in the XML format*.

## Background

### Extensible Markup Language (XML)

XML is a text-based markup language used to encode electronic documents in a structured format that is machine-readable. XML is used as a common format to facilitate the interchange of data over the Internet.

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

### Health Level 7 (HL7) International

HL7 is a not-for-profit organization dedicated to the development of standards for the exchange and management of electronic health information.

### Structured Product Labeling (SPL) standard

Structured Product Labeling (SPL) is a HL7 standard which defines the content of human prescription drug labeling in an XML format. In the Canadian context, the product monograph is the ‘label’ or ‘the document’ being structured.

### Structured document

In this context, structure refers to the act of using XML to encode product monograph content. The content has been ‘marked up’ with XML to make it machine-readable. As a result, the narrative text (For example, section headings, text and tables) and product details (For example, ingredients, dosage forms and packaging) can be indexed and searched easily.

# Guidance for implementation

## Structure and concepts

### XML Structure

**Table 1 - Summary of the six components that make up every XML PM**

| **Component** | | **Description** |
| --- | --- | --- |
| 1. | Prologue | Instructions to software programs, for example, XML version, character encoding, references to the style sheet and schema. |
| 2. | Document Metadata | Identifies the type of document, its unique identifier, its version and its language (French or English). |
| 3. | Organization Metadata | Information about the sponsor, for example, company name, Health Canada issued company identifier, address and role. |
| 4. | Manufactured Product Metadata | Information about the product, for example, brand name, dosage form, proper name/common name, active ingredients, inactive ingredients, packaging, units of measure, marketing status and route of administration. |
| 5. | Narrative Text | Product monograph content (excluding images), for example, section headings, paragraphs, formatting, text and tables. |
| 6. | Images | Encoded references to all accompanying images, for example, figures, chemical structure and instructions for use. |

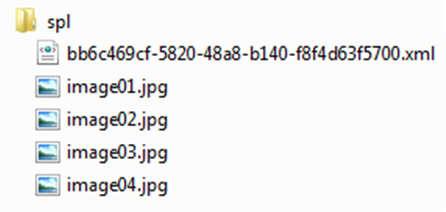
### Output file structure

XML files end with a .xml file extension and only contain text. As a result, the XML product monograph (XML PM) is made up of a single .xml file and separate image files as .jpg files.

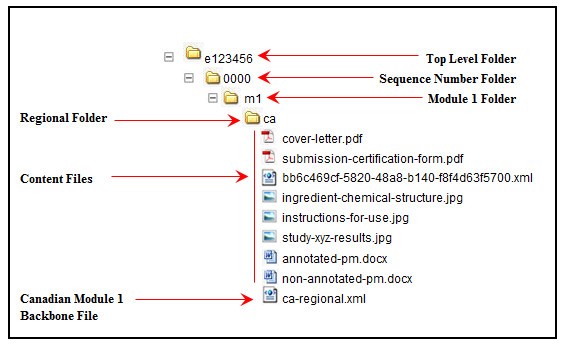
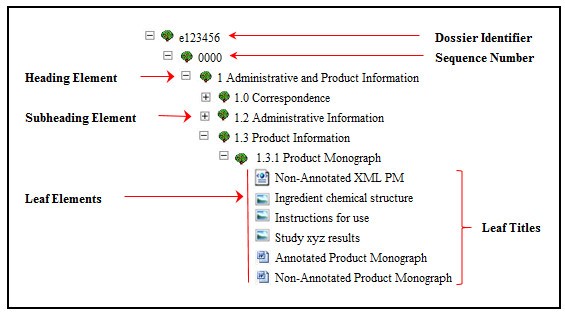
The .xml file contains text, formatting (For example, bold, underline, italics), metadata and references to the relevant image files.

The .xml is always named with a Globally Unique Identifier (GUID). The accompanying .jpg files must always remain together with the .xml. The .jpg file names are up to the discretion of the sponsor but they must be unique to avoid naming conflicts with other files and to ensure the .xml file can reference the correct .jpeg file.

**Figure 1 - Example of a XML PM file output**



**Figure 2 - Example of a XML PM in an eCTD sequence**

NOTE: The XML PM is to be filed in Module 1, section m1-3-1-product-monograph of an eCTD sequence without any node extensions or subfolders. Node extensions and subfolders will cause validation issues.

### Style sheet

A style sheet is used to describe how the XML content should be presented and formatted. For example, layout, colours and fonts. The style sheet only handles presentation and does not change the source content.

The XML PM style sheet is based on the World Wide Web Consortium’s (W3C) Cascading Style Sheet (CSS) standard and the Government of Canada’s Aurora Design System.

**Figure 3 - XML before and after the application of a style sheet**



Style Sheet

NOTE: The style sheet displays all images as is without modification. Therefore, images should use a sufficient resolution to be clear and easily readable across different screen sizes or devices.

### Schema

The schema is a set of rules describing what data is permitted in the XML PM.

### Validation

Validation is the process of checking the XML PM to make sure it meets the established requirements prescribed in the schema and validation rules.

For example,

* The XML is considered well-formed if it conforms to the W3C’s XML standard.
* The XML is considered valid if it conforms to the associated schema’s rules.

### Standard Terminology (Controlled Vocabulary)

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

The XML PM is accompanied by a mandatory set of Health Canada approved standard terms that includes the following: dosage form, route of administration, package type, units of measure, section headings, ingredients and ingredient role.

## Submission process

Step 1: Hold technical pre-submission consultation

This consultation is for Health Canada to offer assistance and guidance on the technical, scientific or regulatory aspects of the XML PM.

Request a consultation by contacting the Office of Submissions and Intellectual Property (OSIP) at [hc.ereview.sc@canada.ca](mailto:hc.ereview.sc@canada.ca). Include the following information in the request:

1. The purpose of the meeting.
2. A brief description of the product to be discussed at the meeting.
3. Three proposed dates for the meeting, including proposed meeting times.
4. Type of meeting requested, in person or web conference.
5. An agenda for the meeting.
6. The names of sponsor representatives attending the meeting.

The technical consultation:

* May take place separate from the regulatory pre-submission meeting.
* Typically takes place remotely via teleconference.
* Is optional. However, sponsors are strongly encouraged to file a sample XML PM if it is their first time to avoid unnecessary validation failures.

Step 2: File a sample XML PM

Sponsors should submit sample XML PM’s to Health Canada via the Electronic Submission Gateway (ESG).

Health Canada will validate the sample and ensure it is properly viewable in the Health Canada style sheet. Health Canada will then notify the sponsor of the results via email. If validation errors/ issues are identified the sponsor will receive a validation failure report. Once the sponsor resolves the errors or issues, the sample is resubmitted again to Health Canada. This process is iterative until all the errors/issues are resolved.

Step 3: File the regulatory activity including the XML PM

Sponsor files the XML PM in module 1, subfolder 1.3.1 Product Monograph, of the regulatory transaction:

1. Health Canada validates the XML PM to identify errors/issues.
2. **If errors/issues are identified:** Health Canada sends a XML PM validation failure report to the sponsor via email. The sponsor resolves the issues and resubmits the XML PM for revalidation via email [hc.ereview.sc@canada.ca](mailto:hc.ereview.sc@canada.ca). Health Canada will notify the sponsor via email once the XML PM passes validation and the sponsor can submit a transaction with the cleared XML PM via the ESG.
3. **If no errors/issues identified:** there is no need for another transaction. A validation report will not be sent to the sponsor in this case.

## Product monograph filing formats

Sponsors can choose to file in French or English as their primary language. This is the ‘first language’ product monograph. See Table 2 for a summary of what filing formats are required during the filing process.

**Table 2 - Summary of the filing formats associated with regulatory activities**

| **Stage of regulatory process (Regulatory Activity)** | **Product monograph format** |
| --- | --- |
| Initial regulatory activity  (NDS, SNDS, ANDS, SANDS) | 1. XML PM (clean) - first language 2. MS Word PM (clean) - first language 3. MS Word PM (annotated) - first language |
| Within 20 days of acceptance into review | 1. MS Word PM (clean) - Second language PM |
| During regulatory review (clarification request) | 1. MS Word PM (clean) - primary language 2. MS Word PM (annotated) - primary language |
| Final product monograph  (Filed within 20 calendar days of the Notice of Compliance (NOC))1 | 1. XML PM (clean) - English 2. XML PM (clean) - French |

1 The final French and English XML PMs must be filed in one transaction.

NOTE: The French XML PM and the English XML PM are two separate documents.

## Lifecycle for regulatory activities in the eCTD Format

The following eCTD lifecycle operation attributes are used to manage Word and XML PMs:

* **‘NEW’** when a non-annotated or annotated product monograph is provided as part of the first transaction of a regulatory activity (For example, NDS, SNDS, ANDS, SANDS). Or when a final XML PM is provided for the first time after receiving a Notice of Compliance (NOC).
* **‘REPLACE’** when a non-annotated or annotated product monograph is provided again with amendments as part of a subsequent transaction (For example, response to clarification request). Or when a final XML PM is provided to replace the previously approved final XML PM.

NOTE:

* Whenever the XML PM is submitted the transaction must always include the complete document with the .xml and all associated .jpg files.
* If REPLACE or DELETE attributes are used then they must be applied to each component of the XML PM. Meaning, the .xml and all associated .jpg files.

## Important considerations

* The XML PM is the legal document. The MS Word versions are considered convenience copies to facilitate review.
* Once a sponsor files a regulatory activity with a XML PM, all subsequent product monographs for that product (dossier) must also be filed in XML format.
* The French XML PM and the English XML PM are two separate documents
* Sponsors are expected to validate their XML PM and correct error/ issues before filing to Health Canada.
* Sponsors are expected to review their XML PM in the style sheet view before filing to Health Canada to ensure there are no content or formatting issues.
* Health Canada will only provide copies of validation reports if there is a validation fail.

# Business conformance rules

The following section provides compliance instructions for each of the major sections of the XML PM and their respective sub-elements.

NOTE: Sponsors must not add any content, sections or sub-elements other than what is listed below. Adding non-compliant content or sections will result in a validation fail.

## XML prolog

### XML version and character encoding

The version of XML and the character encoding which is Unicode Transformation Format (UTF).

### Stylesheet location

Reference to the Health Canada stylesheet.

### Schema location

Reference to Health Canada’s copy of the HL7 SPL schema.

## Document metadata

### Regulatory activity (templateId; OID .37)

The type of regulatory activity for this version of the XML PM is chosen from the Health Canada controlled vocabulary.

NOTE: Sponsors are expected to choose “LEVEL III CHANGE” as the regulatory activity type from the Health Canada controlled vocabulary when they update their XML PM with a Level III Change.

### Document ID (id root)

The unique identifier only for this version of the XML PM. Unlike the set ID, Document ID is different for each version of the product monograph.

Document ID is a Globally Unique Identifier (GUID).

The French XML PM and English XML PM are two separate documents. Therefore, they must have separate document ID's.

### Document type (code; OID .10)

The type of document template is chosen from the Health Canada controlled vocabulary.

### Document title (title)

A brief summary name describing the product. The title should include:   
BRAND NAME (common name) DOSAGE FORM.

For example, LORUM (lorum ipsum) TABLETS

### Date of last revision (effectiveTime value)

The Date of Initial Approval is used for the first Health Canada approved version of the XML PM. The Date of Last Revision is used for all subsequent Health Canada approved versions of the product monograph.

The date format is YYYYMMDD

NOTE:

* Sponsors can use placeholder dates until the NOC date is known. For example, use a future date ‘22001231’. The NOC date is added to the XML PM when final XML PM is filed following the issuance of a NOC.
* The Date of Last Revision is always the most recent NOC date. In the case of a Level III Change, the Date of Last Revision must not be changed and remains the NOC date.

### Document language (languageCode; OID .29)

The language the content is based is chosen from the Health Canada controlled vocabulary.

### Set ID (setId)

The unique identifier that remains the same for all versions of this product monograph. Unlike the Document ID, the Set ID remains the same through all versions of the product monograph.

The purpose of this ID is to ensure all versions of a product monograph can be collected as a set under a common parent ID.

set ID is a GUID.

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.

### Document version number (versionNumber)

The unique version number specific to this version of the XML PM. The version number is a non-negative integer greater than zero.

## Organization metadata

### Market authorization holder (representedOrganization; OID .31)

The company name, Health Canada issued company identifier, address and contact information for the legal entity that holds the NOC and the Drug Identification Number (DIN).

Company name and the Health Canada issued company ID are chosen from the Health Canada controlled vocabulary. Company address and contact information are specified in text.

* **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 ’**Error! Hyperlink reference not valid.**' or 'https:'. For example, http://www.domain.com or https://www.domain.com.

NOTE: Only include corporate contact information (company website, email and toll-free number).

### Canadian importer/distributor (assignedOrganization; OID .31)

If the Market Authorization Holder is NOT located in Canada, the Canadian organization responsible for the sale of this product in Canada must be specified here.

Company name and ID are chosen from the Health Canada controlled vocabulary. Company address and contact information are text.

See section 3.3.1 for the notation format for phone numbers, email addresses and web addresses.

NOTE: Only include corporate contact information (company website, email and toll-free number).

## Manufactured product metadata

This section captures details about the manufactured form of the drug product.

The manufactured form describes the product dosage form as manufactured, in its primary packaging and before transformation into the administrable dosage form of the product.

NOTE: One manufactured product section is required for each product. A separate product must be added if any of the following parameters is different: brand name, proper name/ common name, ingredients (active or inactive), strength, dosage form.

### Drug Identification Number (DIN) (code)

The DIN assigned to this product by Health Canada is specified as text.

NOTE: Sponsors can use a placeholder number until the DIN is known. For example, ‘12345678’. The DIN is added to the XML PM when final XML PM is filed following the issuance of a NOC.

### Brand name (name)

The brand name is specified as text.

### Dosage form (formCode; OID .3)

The manufactured dosage form is chosen from the Health Canada controlled vocabulary.

### Proper name / common name (name)

The non-proprietary name for the active ingredient(s) is specified as text.

### Ingredients (ingredientSubstance; OID .14)

The ingredient name and identifier are chosen from the Health Canada controlled vocabulary.

Each ingredient has an associated role, which is chosen from the Health Canada controlled vocabulary. The ingredient role (classCode; OID .39) determines whether the ingredient is active or inactive.

The role of an ingredient (classCode) is chosen from one of the following controlled terms:

**Table 3 - List of valid class codes and their basis of strength description**

| **Ingredient Role (classCode; OID .39)** | **Description** |
| --- | --- |
| Active ingredient - basis of strength (ACTIB) | The active ingredient substance itself is the basis of strength. The strength specifies the quantity of the substance in the formulation. |
| Active ingredient - moiety is basis of strength (ACTIM) | The active ingredient’s therapeutic moiety, not the ingredient, is the basis of strength. The strength specifies the quantity of the substance's active moiety in the formulation. |
| Active ingredient - reference substance is basis of strength (ACTIR) | Another reference substance with the same active moiety, is the basis of strength. The strength specifies the quantity of the reference substance, similar but different from the player substance in the formulation. |
| Inactive ingredient (IACT) | An ingredient that is not considered therapeutically active; e.g., colours, flavours, stabilizers, preservatives, fillers or structural components added to an active ingredient to facilitate administration of the active ingredient but without being considered therapeutically active. |

### Ingredient strength (quantity)

The strength is specified as a physical quantity using a numerator (value and unit of measure) and a denominator (value and unit of measure). Strength information shall be populated for all ingredients with an ingredient role classified as active.

A unit of measure (unit; OID .15) is chosen from the Health Canada controlled vocabulary.

**Table 4 - Examples of how to present the strength of active ingredients**

| **Example** | **Numerator** | | **Denominator** | |
| --- | --- | --- | --- | --- |
| **Value** | **Unit of Measure** | **Value** | **Unit of Measure** |
| 10 mg | 10 | mg | 1 | 1 |
| 2 mg in 1 mL | 2 | mg | 1 | mL |

Ingredient strength can also be presented as a range. In this case the numerator has a lower limit of the range (value and unit of measure), an upper limit of the range (value and unit of measure) and a common denominator (value and unit of measure).

**Table 5 - Example of active ingredient strength presented as a range**

| **Example** | **Numerator** | | | | **Denominator** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Lower Limit Value** | **Lower Limit Unit of Measure** | **Upper Limit Value** | **Upper Limit Unit of Measure** | **Value** | **Unit of Measure** |
| 2,000,000 - 60,000,000 Cells | 2000000 | CELLS | 60000000 | CELLS | 1 | 1 |

NOTE: Quantity is mandatory for active ingredients and optional for inactive ingredients.

### Packaging

The XML PM captures packaging in one of the following two formats:

1. **Single part format**

Contains a single drug product wholly contained within a single package or a single package hierarchy. The pack status and Pack ID are applied to the single drug product’s outermost level of the package in this format. For example,

* tablets in a blister, blister in a box = regulatory status and Pack ID are applied to the box
* pre-filled syringe in a tray, tray in a box = regulatory status and Pack ID are applied to the box

NOTE: Pack ID is optional (refer to section 3.4.7.2 for details).

1. **Multi-part format**

Depending on the context, this format contains:

1. two or more separately packaged drug components in one combined package to be used together to produce one final drug product (For example, powder and diluent reconstituted into one product)
2. two or more drug products contained within a single package (For example, birth control tablets)
3. two or more separately packaged drug products in one combined package regulated as a kit.

Example 1, powder and diluent for reconstitution packaged separately

* A pack status and Pack ID are applied to the outermost level of the combined package.
* A product status and DIN are not applied to the individual package parts contained within the package.
* Package = Vials in a tray, tray in a box (Status = Approved, Pack ID, DIN = 12345678 applied to the box as the outermost level of the package)
  + Part 1 vial with powder (no status and no DIN)
  + Part 2 vial with diluent (no status and no DIN)

Example 2, birth control tablets

* A pack status and Pack ID are applied to the single package for birth control tablets. The Pack ID encompasses all associated product parts contained within the single package.
* A product status and DIN are applied to the outermost level of the package.
* Birth control tablets = Part 1 and 2 in a single blister, blister in a box (Status = Approved, Pack ID and DIN = 11112222 applied to the box as the outermost level of the package)
  + Part 1 active (no status and no DIN)
  + Part 2 inert (no status and no DIN)

Example 3, Kit with two separate drug products (tablet and cream)

* A pack status and Pack ID are applied to the outermost level of the kit.
* A product status and DIN are applied to the outermost level of the kit.
* A product status and DIN are applied to the individual package parts contained within the kit if available.
* Kit = tablets in a blister, cream in a tube, blister and tube in a box (Status = Approved, Pack ID, DIN = 44445555 applied to the box as the outermost level of the kit)
  + Part 1 tablets in blister (Include status and DIN if available)
  + Part 2 topical cream in tube (Include status and DIN if available)

NOTE:

* Drug/device combinations and drug/delivery system products are not considered to be multi-part products or kits. They are to be described in the narrative text section and not described in product details metadata. For example, a single-part format should be used to capture this packaging.
* Pack ID is optional (refer to section 3.4.7.2 for details)

#### Packaging quantity (quantity)

The quantity of the packaging is specified using a numerator (value and unit of measure) and a denominator (value). The following table provides examples of how packaging quantity is managed.

A unit of measure (unit; OID .15) is chosen from the Health Canada controlled vocabulary.

**Table 6 - Examples of how to present packaging quantity**

| **Example** | **Numerator** | | **Denominator Value** | **Pack Type** |
| --- | --- | --- | --- | --- |
| **Value** | **Unit of Measure** |
| 10 tablets in 1 bottle | 10 | 1 | 1 | BOTTLE |
| 1 mL in 1 syringe | 1 | mL | 1 | SYRINGE |
| 10 blisters in 1 box | 10 | 1 | 1 | BOX |

#### Pack ID (code)

The sponsor can specify a value to identify this package and distinguishes it from other packs.

NOTE: Only include identifiers for the outer layer of packaging at the stock keeping unit (SKU) or item for sale level.

#### Pack type (containerPackagedProduct, formCode; OID .32)

The type of packaging is chosen from the Health Canada controlled vocabulary.

#### Regulatory status of packaging (marketingAct; OID .11)

The status of the package, APPROVED or CANCELLED, is chosen from the Health Canada controlled vocabulary.

The date the packaging was approved (NOC date) or cancelled (DIN cancellation date) is expressed in YYYYMMDD format.

NOTE: The low date value represents the NOC date and the high value represents the cancelled date.

### Regulatory Activity Information

#### Regulatory activity (approval; OID .37)

The regulatory activity associated with this product and the associated NOC. For example, NDS/ANDS for a new product. SNDS/SANDS if this product’s details are updated. Regulatory activity is chosen from the Health Canada controlled vocabulary.

#### Control Number (id)

The Control Number for this regulatory activity is expressed as text.

NOTE: Sponsors can use a placeholder number until the Control Number is known. For example, ‘123456’. The Control Number is added to the XML PM when the final XML PM is filed following the issuance of a NOC.

#### Regulatory authority (territorialAuthority; OID .17)

The authority is CANADA and is chosen from the Health Canada controlled vocabulary.

#### Regulatory status of product (marketingAct; OID .11)

The status of the product, APPROVED or CANCELLED, is chosen from the Health Canada controlled vocabulary.

The date the product was approved (NOC date) or cancelled (DIN cancellation date) is expressed in YYYYMMDD format.

NOTE: The low date value represents the NOC date and the high value represents the cancelled date.

#### Route of Administration (consumedIn; OID .7)

A route of administration is chosen from the Health Canada controlled vocabulary.

### Product Characteristics (OID .23)

Each type of characteristic is chosen from the Health Canada controlled vocabulary.

#### Product Type (OID .53)

The type of manufactured drug product is chosen from the Health Canada controlled vocabulary.

#### Colour (OID .24)

The colour of the product is chosen from the Health Canada controlled vocabulary.

NOTE: Brief descriptive text can be added to the chosen colour term. For example, WHITE (white to off white).

#### Shape (OID .25)

The shape is chosen from the Health Canada controlled vocabulary.

NOTE: Brief descriptive text can be added to the chosen shape term.

#### Size

The size or dimensions of the product are specified as a physical quantity in terms of a value and unit of measure (for example, 20 mm).

#### Score (OID .4)

The type of score is chosen from the Health Canada controlled vocabulary.

#### Imprint

The imprint is specified as text.

#### Flavour (OID .26)

The flavour is chosen from the Health Canada controlled vocabulary.

NOTE: Brief descriptive text can be added to the chosen flavour term.

#### Combination product type (OID .8)

The type of combination product is chosen from the Health Canada controlled vocabulary.

#### Pharmaceutical standard (OID .5)

The pharmaceutical standard is chosen from the Health Canada controlled vocabulary.

#### Schedule (OID .2)

The schedule is chosen from the Health Canada controlled vocabulary.

#### Therapeutic class (OID .6)

The therapeutic classification is chosen from the Health Canada controlled vocabulary.

## Narrative text

Narrative text includes paragraphs, lists, tables; formatting instructions (bold, underline, italics); sections and subsection headings.

The XML PM has six major section headings:

1. Product/Company Details
2. TITLE PAGE
3. RECENT MAJOR LABEL CHANGES
4. PART I: HEALTH PROFESSIONAL INFORMATION
5. PART II: SCIENTIFIC INFORMATION
6. PATIENT MEDICATION INFORMATION

### Section heading text and numbering

The XML PM section heading numbers are fixed and must not be re-numbered.

The XML PM’s section headings are managed as controlled vocabularies and must not be modified. There are only two exceptions:

(1) in the Patient Medication Information section, sponsors will modify heading text identified with square brackets. For example, the title “What is [BRAND NAME] used for?” is modified to include the brand name. However, the display name must not be modified and will remain as defined in the controlled vocabulary.

(2) Sponsors can modify the title of the “UNASSIGNED” heading to add sponsor defined subheadings. For example, sponsors can use UNASSIGNED to create a subsection under Warnings and Precautions called “Cardiovascular”. However, the display name must not be modified and will remain as defined in the controlled vocabulary.

## Considerations for style and accessibility

### Language

Separate product monographs are required for each official language: One XML PM in English and one XML PM in French. The English product monograph and the French product monograph are expected to:

* have equivalent content
* be professionally translated
* reflect Canadian writing conventions and Canadian spelling
* ensure the text in images matches the language of the document (For example, French document has images with French text)

### Fonts and font styles

The XML PM’s style is based on the Government of Canada’s Aurora design system.

Aurora uses two open source font families: Rubik for titles and headings; Nunito Sans for sub-headings and paragraph text. Both fonts were chosen to enhance accessibility and readability. Users with reading disabilities or visual impairments are able to more easily decipher characters in these fonts.

### Images, screen size, colours and visual representation

Images are rendered by the style sheet as provided, with no resizing or adjustments to resolution made by the style sheet. Only include images that are clear and easy to read.

All images require a meaningful description in the text element to allow screen reader software to describe the image to visually impaired audiences. Images should also have descriptive, yet simple, file names (For example, glucose-chemical-structure.jpg). This helps search engines find the image.

Colours should meet the WCAG AA accessibility level for contrast.

When authoring the XML PM, take into consideration the fact that it will be viewed on different screen sizes. Small screens may require more steps to access the same amount of information than on desktop or laptop screens.

### Hypertext links and formatting (underline, bold and italics)

Assistive technology can navigate web content using links. For example, screen readers list all links on a page without the contextual content. Links should be descriptive and able to stand alone so it is clear what people can expect if they click on them.

Bold, underline or italic formatting is applied using style codes rendered by the style sheet. Certain areas of the document will have font styles applied automatically in order to convey a common look and feel and a common hierarchical structure. For example, font, font size and table appearance are controlled by the style sheet.

Other formatting considerations:

* Avoid combining styles. For example, applying both underline and bold.
* Reserve underline for hypertext links.
* Avoid italics for design or decorative purposes since some may find it difficult to read italicized text. Use bold sparingly instead to emphasize a word or phrase.
* Research whether symbols are understood by a wide audience before using them.
* Ensure all symbols are compliant with XML and UTF-8 before use. Non-compliant symbols may cause a validation failure.

### Tables

Make the information useful to the widest possible audience by using a simple structure. It can be difficult to make tables accessible and easy to read for screen readers or mobile devices.

Avoid blank cells. Assistive technologies like screen readers will notify the person if the cell is blank. If a cell has no value, explain why in the legend or surrounding content. Consider also using ‘n/a’, ‘not applicable’ or ‘no data’.

Table captions are used as the table title. Provide meaningful descriptions to allow screen reader software to describe the table to visually impaired audiences.

# Appendices

## Appendix 1 – Glossary

|  |  |
| --- | --- |
| ANDS | Abbreviated New Drug Submission |
| DIN | Drug Identification Number |
| eCTD | Electronic Common Technical Document |
| ESG | Electronic Submission Gateway |
| GUID | Globally Unique Identifier |
| HL7 | Health Level 7 International |
| HPFB | Health Products and Food Branch |
| HTML | Hypertext Markup Language |
| ID | Identifier |
| IDMP | Identification of Medicinal Product |
| ISO | International Organization for Standardization |
| JFIF | JPEG File Interchange Format |
| JPEG | Joint Photographic Experts Group |
| NDS | New Drug Submission |
| NOC | Notice of Compliance |
| NOD | Notice of deficiency |
| NON | Notice of Non-Compliance |
| OID | Object Identifier |
| PDF | Portable Document Format |
| SANDS | Supplement to an Abbreviated New Drug Submission |
| SDN | Screening deficiency notice |
| SKU | Stock Keeping Unit |
| SNDS | Supplement to a New Drug Submission |
| SPL | Structured Product Labeling |
| UTF | Unicode Transformation Format |
| W3C | World Wide Web Consortium |
| XML | Extensible Markup Language |

## Appendix 2 – References

1. Guidance Document - Validation of Product Monographs Prepared in the Extensible Markup Language Format
2. Guidance Document - Product monograph
3. Health Canada product monograph website
4. Health Canada product monograph template
5. Guidance Document Questions and Answers: Plain Language Labelling Regulations
6. HL7 SPL Release 7 specification
7. Government of Canada Aurora design guide