



Guidance Document: Preparation of the XML Product Monograph (XML PM)

Date: March 28, 2025



Version	Brief Description of Changes	Date
1.0	Initial document. The amalgamation of two previous drafts: <ul style="list-style-type: none">• Preparation of Product Monographs in the Extensible Markup Language Format• Validation of Product Monographs in the Extensible Markup Language Format	October 29, 2021
1.01	Revised based on comments.	November 18, 2021
1.02	Revised based on comments.	December 14, 2021
1.03	Revised based on comments from the Industry working group.	April 20, 2022
1.04	Draft for public consultation	August 15, 2023
1.05	Finalization of guidance document	March 28, 2025

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.

Également disponible en français sous le titre :
Préparation d'une monographie de produit en format XML (monographie XML)

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: publications-publications@hc-sc.gc.ca

© His Majesty the King in Right of Canada, as represented by the Minister of Health, 2025

Publication date: March 28 2025

This publication may be reproduced for personal or internal use only without permission provided the source is fully acknowledged.

Cat.: H164-388/2025E-PDF

ISBN: 978-0-660-76247-0

Pub.: 240786

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

Foreword.....	4
1. Introduction	7
1.1 Purpose/Overview	7
1.2 Scope and Application.....	7
1.3 Policy Objectives	7
1.4 Policy Statements.....	7
1.5 Background	7
2. Regulatory Guidance for Submitting the XML PM.....	8
2.1 Regulatory Activities with an XML PM	9
2.1.1 Requirements at the time of filing.....	9
2.1.2 Requirements post-authorization.....	9
2.2 Setting up the XML PM in a Regulatory Transaction	10
3. Guidance for Creating the XML PM	10
3.1 Overview	10
3.2 Controlled Vocabulary	11
3.2.1 Types of Controlled Vocabulary.....	11
3.2.2 Controlled Vocabulary Listing Website.....	16
3.2.3 Use of Controlled Vocabulary	17
3.3 High-Level XML Structure and Document Set-Up.....	17
3.4 Product Monograph Content.....	19
3.4.1 Setting up Major Section Headings.....	20
3.4.2 Title Page.....	22
3.4.3 Notice of Compliance with Conditions and Biosimilar Biologic Drug	24
3.4.4 Recent Major Label Changes.....	25
3.4.5 Part 1: Healthcare Professional Information and Part 2: Scientific Information	27
3.4.6 Patient Medication Information	28
3.5 Organization Details.....	28
3.6 Product Details.....	30
3.6.1 Product Composition	31
3.6.2 Packaging Status	35
3.6.3 Product Status.....	37
3.6.4 Product Characteristics	39
3.6.5 Multi-Part Products.....	41
3.7 Additional Concepts.....	43

3.7.1	Format.....	43
3.7.2	Images.....	44
3.7.3	Tables	46
3.7.4	Hyperlinks	47
3.7.5	Boxed Statements.....	48
3.7.6	Footnotes.....	49
3.7.7	Special Characters.....	50
3.8	Relationship of Unique Identifiers	51
4.	Validation	51
5.	Appendices.....	53
	Appendix A - Scope of Mandatory Requirement for the XML PM.....	53
	Appendix B - Codes, Display Name and Source of Terms in the Controlled Vocabulary List	54
	Appendix C - Definitions.....	55
	Appendix D - Long descriptions and/or raw XML snippets for images	56

1. Introduction

1.1 Purpose/Overview

This guidance is intended to assist sponsors in developing an Extensible Markup Language Product Monograph (XML PM).

1.2 Scope and Application

The scope of this guidance and the use of the XML PM is limited to the following product lines:

- Pharmaceutical drugs for human use (prescription and non-prescription)
- Biologic drugs for human use
- Radiopharmaceuticals

The following product lines are out of scope:

- Self-care products
- Natural health products
- Medical devices
- Veterinary drugs
- Food

1.3 Policy Objectives

The objective of this document is to provide both technical and operational direction, in addition to guidance for sponsors and Health Canada (HC) staff on the requirements for the preparation of the XML PM.

1.4 Policy Statements

This guidance document applies to preparing and filing an XML PM in the context of a drug regulatory activity. While it is expected that all guidance and policy documentation related to regulatory activities be consulted, the following documents have a direct impact on the filing and content of the XML PM.

- XML PM Samples
- [Validation rules for Product Monographs in the Extensible Markup Language \(XML\) format](#)
- [Controlled Vocabulary List](#)
- [Guidance Document: Product Monograph](#)
- [Product Monograph Master Template](#)

1.5 Background

The Product Monograph (PM) provides the necessary information for the safe and effective use of a drug product. It is comprised of three major sections, two of which target healthcare professionals. The third section targets the patient or consumer. The PM is submitted by sponsors for review in Microsoft Word format. The authorized document is converted to Portable Document Format (PDF) and published to the Drug Product Database ([DPD Online](#)) and the [Drug and Health Product Portal \(DHPP\)](#).

The XML PM represents a major step towards Health Canada's goal of improving access to drug information for Canadians and prepares us for future technological advancements. The structure combined with the use of and adherence to controlled vocabulary will increase semantic consistency, searchability, and innovation while positioning us for interoperability with other standard formats. The Authorized XML PMs will be stored in a fully searchable database. A style sheet will enable transformation into a human-

readable format. The .xml format will enable Health Canada to provide information in ways that are most relevant to different user groups. This includes providing Canadian pharmacies with reliable access to Health Canada authorized Patient Medication Information. It will also facilitate further collaboration with our international partners related to drug clinical trials, risk assessments, and potential shortages.

2. Guidance for Submitting the XML PM

As outlined in the “Change in filing requirements for the extensible markup language product monograph (XML PM): Notice” dated November 18, 2024, Health Canada is taking a phased approach to the implementation of the XML PM requirement. Appendix A lists the in- and out-of-scope regulatory activity types for the mandatory XML PM requirement. As the scope expands, additional information will be provided in an updated Notice and the list in Appendix A will be revised.

As is the current practice, the PM (MS Word format) that is reviewed and authorized by Health Canada will continue to be the official version. Therefore, at this time, the XML PM is considered to be an unofficial/convenience copy.

Sponsors may voluntarily submit an XML PM as part of their next PM update, except in the following circumstances:

- Generic products should not submit an XML PM until the Canadian Reference Product (CRP) has an authorized XML PM. Once a CRP has an authorized XML PM posted on the DHPP, all associated generic products are expected to submit an XML PM in the next regulatory activity.
- Generic products that already have an authorized XML PM should continue to file the XML PM. However, changes to the controlled vocabulary must be consistent with the CRP, even if it results in an XML PM validation error.
- Cross-licensed products should not submit an XML PM until the licensor’s product has an authorized XML PM. Once a licensor’s product has an authorized XML PM posted on the DHPP, the cross-licensed product is expected to submit an XML PM in the next regulatory activity.

Biosimilar products do not have to wait until the Canadian Reference Biologic Product has an authorized XML PM.

As part of the transition to the XML PM, it is expected that terminology used in authorized PMs will need to be amended to align with the terminology required by the controlled vocabulary. The amendments to most terms can be made without significant change, however, some will require additional oversight. Therefore, terminology sourced from the following controlled vocabulary can only be made as part of a regulatory activity that includes a quality review stream.

- Ingredient Identifier
- Dosage Form
- Route of Administration
- Package Type (only for packaging that comes into contact with the product or provides a functional purpose)

Health Canada recognizes that multiple regulatory activities may be required to properly align all terminology. During the transition, sponsors should populate the Product Details section with terminology for the above controlled vocabulary from the authorized PM until they can be aligned through a regulatory activity that includes a quality component. Health Canada recognizes that this may result in (temporary) validation errors. These temporary errors will be considered acceptable during this transition period.

2.1 Regulatory Activities with an XML PM

An XML PM can only be submitted as part of a regulatory activity that includes the PM (new or updated). XML PMs cannot be provided outside the context of a regulatory activity. XML PMs cannot be submitted for the first time for regulatory activities that are processed administratively (excluding License Agreements) or Quality Notifiable Changes (Biologic and Radiopharmaceutical Drugs Directorate only).

Once an XML PM has been filed and authorized for a given product, it is required for all subsequent PM updates.

All image files must be re-submitted each time the .xml file is submitted. Failure to do so will result in a validation error and prevent the images from displaying in the XML PM.

The XML PM validation results do not impact the processing of a regulatory activity. Once the regulatory activity has been accepted into screening, the XML PM validation report will be sent to the sponsor by email from the XML PM team. Sponsors are encouraged to address any validation issues and may request a manual validation from the XML PM team. However, a revised XML PM should not be submitted in an Electronic Common Technical Document (eCTD) transaction until the final version is submitted post-authorization.

2.1.1 Requirements at the time of filing

When a regulatory activity requires an XML PM, it is expected to be provided at the time of filing in the first language only. Sponsors may choose to submit both languages at the time of filing.

If the XML PM is not submitted when required it will be requested in a clarification request or a negative decision during screening.

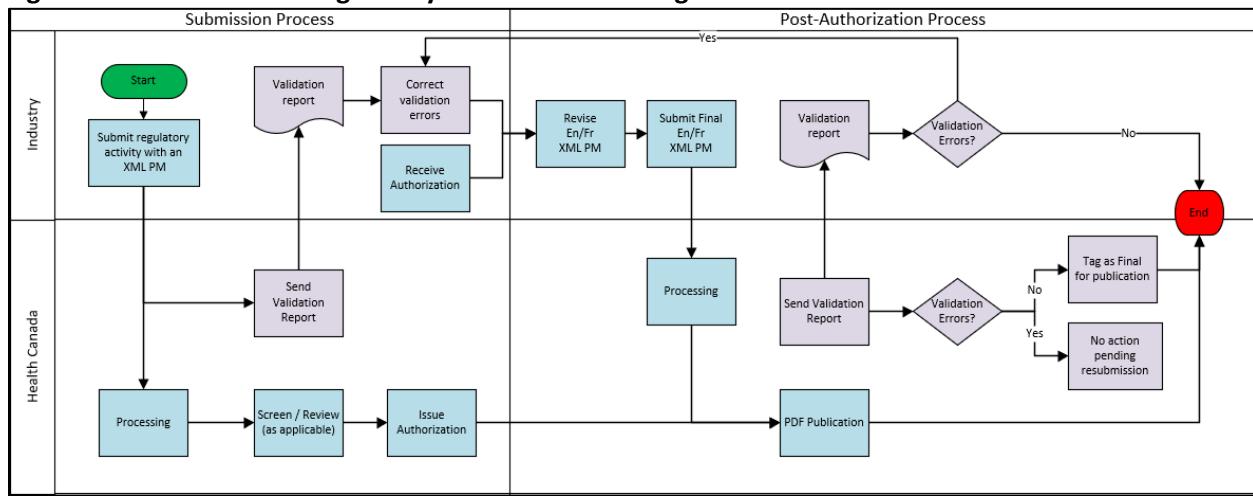
2.1.2 Requirements post-authorization

Sponsors are required to submit the final first- and second-language XML PMs post-authorization for all regulatory activity types. At a minimum, regulatory activities processed administratively need to add the control number and date of authorization. The first-language XML PM must be identical to the authorized first-language PM, except for the Product Details section.

The final first and second-language XML PMs are to be submitted in the same post-authorization regulatory transaction as all other required labeling documentation, as applicable.

The XML PM validation report will be sent to the sponsor once the second-language PM has been posted to the DPD Online (see Figure 1).

All final XML PMs are expected to have no errors or warnings. If there are any outstanding errors or warnings (as outlined in [Section 4](#)) sponsors are required to revise the XML PMs (including images as per [Section 2.2](#)) and resubmit in a subsequent transaction.

Figure 1 Process flow for regulatory activities containing an XML PM

Legend:

Blue: Regulatory activity process
 Purple: Processes related to the XML PM

2.2 Setting up the XML PM in a Regulatory Transaction

The XML PM is to be provided in Module 1, section m1-3-1-product-monograph in a regulatory transaction without any node extensions or subfolders.

The first time an XML PM is submitted, the operation attribute NEW should be used for the .xml and .jpg files. The REPLACE value must be used when the files (.xml and all associated .jpg files) are provided again in a subsequent transaction.

File names for the .xml and .jpg files should not be changed when preparing the regulatory transaction. The file names should conform to XML PM specifications to avoid impact on the validation and viewing of the XML PM.

Sponsors must include the eCTD language attribute on the leaf element for each .xml file (e.g. xml:lang = "en"). The language attribute is not required for image files. The English and French XML PMs are to be provided in the same regulatory transaction.

Sponsors are expected to review their XML PM in Hypertext Markup Language (HTML) format before filing to Health Canada to ensure there are no content or formatting issues.

3. Guidance for Creating the XML PM

3.1 Overview

This is the technical implementation guide for Product Monographs (PM) in the xml format, known as the XML PM. This document contains multiple examples of screenshots of the human-readable XML PM (HTML) accompanied by raw XML snippets. These images are intended to show specific technical details for creating a valid XML PM. Most screenshots have been taken from the XML PM Sample. In some cases, the XML has been collapsed to highlight relevant information and to ensure readability. A collapsed section can be identified by both a plus sign within a square and a line through the XML snippet (⊕—). Therefore, it is important to consult the actual sample for full context.

The overall structure of the XML PM is based on the Health Level Seven (HL7) Structured Product Labeling (SPL) standard and all XML PM submissions should be validated against the standard's associated schema to be considered a well-formed document.

All guidance for the PM content is provided in the Product Monograph Guidance Document and Master Template, with the exception of the Product Details section, which is only available in the XML PM.

There are three pieces of information that may be unknown at the time of filing: the control number, the date of authorization, and the Drug Identification Number (DIN). These are to be omitted when unknown, even though their omission will result in a validation warning. Placeholders or dummy data (e.g., TBD or Unknown) are not to be used. It is acceptable to omit a piece of information when it is not yet known. This information must be included in the final XML PM submitted post-authorization.

3.2 Controlled Vocabulary

A Controlled Vocabulary is an established list of pre-approved terms and ensures that a subject will be described using consistent terminology. Health Canada has developed controlled vocabularies that support the XML PM, and which have been leveraged from international standards where appropriate. Where an international standard does not exist or cannot be currently applied to Canadian products, the controlled vocabulary is either specific to Health Canada or is based on the Structured Product Labeling (SPL) terminology set by the U.S. Food and Drug Administration (FDA). A summary of the controlled vocabulary is available in Appendix B.

3.2.1 Types of Controlled Vocabulary

The list of controlled vocabularies can be split into 3 groups based on function.

1. Document information (document metadata)
2. Document structure
3. Product information (Product Details)

The following sections will provide additional details regarding how to correctly use controlled vocabularies when creating an XML PM.

It is strongly recommended that sponsors confirm that all applicable terms are available in the Controlled Vocabulary List in advance of filing an XML PM. Unless otherwise specified below, please consult with the XML PM team via email (xmlpm-pxml@hc-sc.gc.ca) when a term is not present. Any errors related to terms that are under review by Health Canada will be considered acceptable at that point in time.

3.2.1.1 Document metadata

The following controlled vocabularies provide details about the document that are not visible in the human-readable rendering of the document.

Document Type (6.10) indicates which Health Canada Product Monograph template is being used. This information is required to be considered well-formed and the validation profile also uses this code to determine which template to validate the document against.

Ingredient Role (6.39) is used to indicate the role of each ingredient in a drug product. The ingredient role differentiates ingredients based on their role in the product. There are 4 roles currently used by Health Canada:

- ACTIB - Used to identify active ingredients when the basis of strength is based on the active ingredient

- ACTIM - Used to identify active ingredients when the basis of strength is based on the active ingredient's active moiety¹
- ACTIR - Used to identify active ingredients when the basis of strength is based on another reference substance² with the same active moiety
- IACT - Used to identify inactive Ingredients

Additional details are provided in Section 3.6.1.1.1. The style sheet also uses the ingredient role to determine how the ingredients will be displayed within the Product Composition section of the Product Details.

Style Sheet Version (6.65) indicates which style sheet the XML PM should use when rendering into HTML. This has been implemented to future-proof the style sheet for the possibility of multiple versions when major changes are required.

Language Code (6.29) is used to indicate the language of the document. The validation profile uses this code to determine which display names (English or French) to validate the controlled vocabulary codes against. The style sheet also uses this code to render the XML PM to HTML in the corresponding language.

3.2.1.2 Document Structure

The following controlled vocabularies provide the structure of the document.

Master Template (6.63) provides the display name for the numbered section and subsection headings for Part 1, Part 2, and the Patient Medication Information, as specified by the Product Monograph Master Template.

Product Characteristics (6.23) provides the display name used by the stylesheet for the product characteristics used in the Product Details section.

3.2.1.3 Product Details

The following controlled vocabularies support the company and product metadata. Unless otherwise specified, all are required.

Company Identifier (6.31) is a unique 4 or 5-digit code that is assigned by Health Canada the first time an organization submits information related to human drugs, biologics, and radiopharmaceuticals. This code is used to populate the Company Details section. If an assigned Company ID is not present on the Controlled Vocabulary List, please email a request to have it added.

Country Code (6.17) is part of the addresses associated with the Market Authorization Holder and Canadian importer/distributor. The validation profile uses this code to determine if a Canadian importer/distributor is required.

Route of Administration (6.7) is a list of terms sourced from the European Directorate for the Quality of Medicines and HealthCare's (EDQM) [Standard Term database](#)³. The Standard Term listing includes a definition⁴ that should be considered when selecting the appropriate term for use in the Product Details section of the XML PM.

¹ This term is non-regulatory and solely used to populate the Product Detail information

² This is not the Canadian Reference Product

³ An account is required to access the website, but it is free

⁴ Health Canada intends to add definitions to the Controlled Vocabulary Listing

Dosage Form (6.3) is a list of terms currently sourced from the DPD's list of authorized dosage forms.

Note: Initially, the controlled vocabulary list was sourced from the EDQM's standard terms for dosage form. However, Health Canada decided to use the DPD's list of terms until such time that a complete analysis and mapping of Canadian terms to the EDQM terms can be completed. Therefore, while both DPD and EDQM terms are listed in the controlled vocabulary, only the DPD terms have an active status.

Ingredient Identifier (6.14) is used to populate both the active and inactive ingredients that make up a formulation (see [Section 3.6.1](#)). This list of terms is based on the [Global Substance Registration System \(GSRS\)](#) and the Unique Ingredient Identifier (UNII). The GSRS is a global collaboration to efficiently and accurately exchange information about substances in regulated products. UNIIs are generated based on scientific identity characteristics outlined in the International Organization for Standardization's standard ISO 11238, which is the section of Identification of Medicinal Products (IDMP) that deals with substances. The GSRS currently has information available for over 150,000 unique substances and may include many known synonyms for each.

HC Ingredient Controlled Vocabulary = GSRS UNII + Canadian preferred term (English & French)

Health Canada's list of ingredient identifiers is a small subset of the ingredients available in the GSRS. This subset includes ingredients used in Canadian products. The display names are Health Canada's preferred terms which are based on pre-established criteria and are linked to the UNII through the list of synonyms found in the GSRS. The Canadian preferred term doesn't always match the preferred term shown prominently in the GSRS.

Selecting the correct UNII and Canadian Preferred term

It can be difficult to determine the correct UNII and associated display names to use. The reason for this is twofold: 1) many ingredients have multiple synonyms and 2) the specificity has increased to unambiguously identify the ingredient.

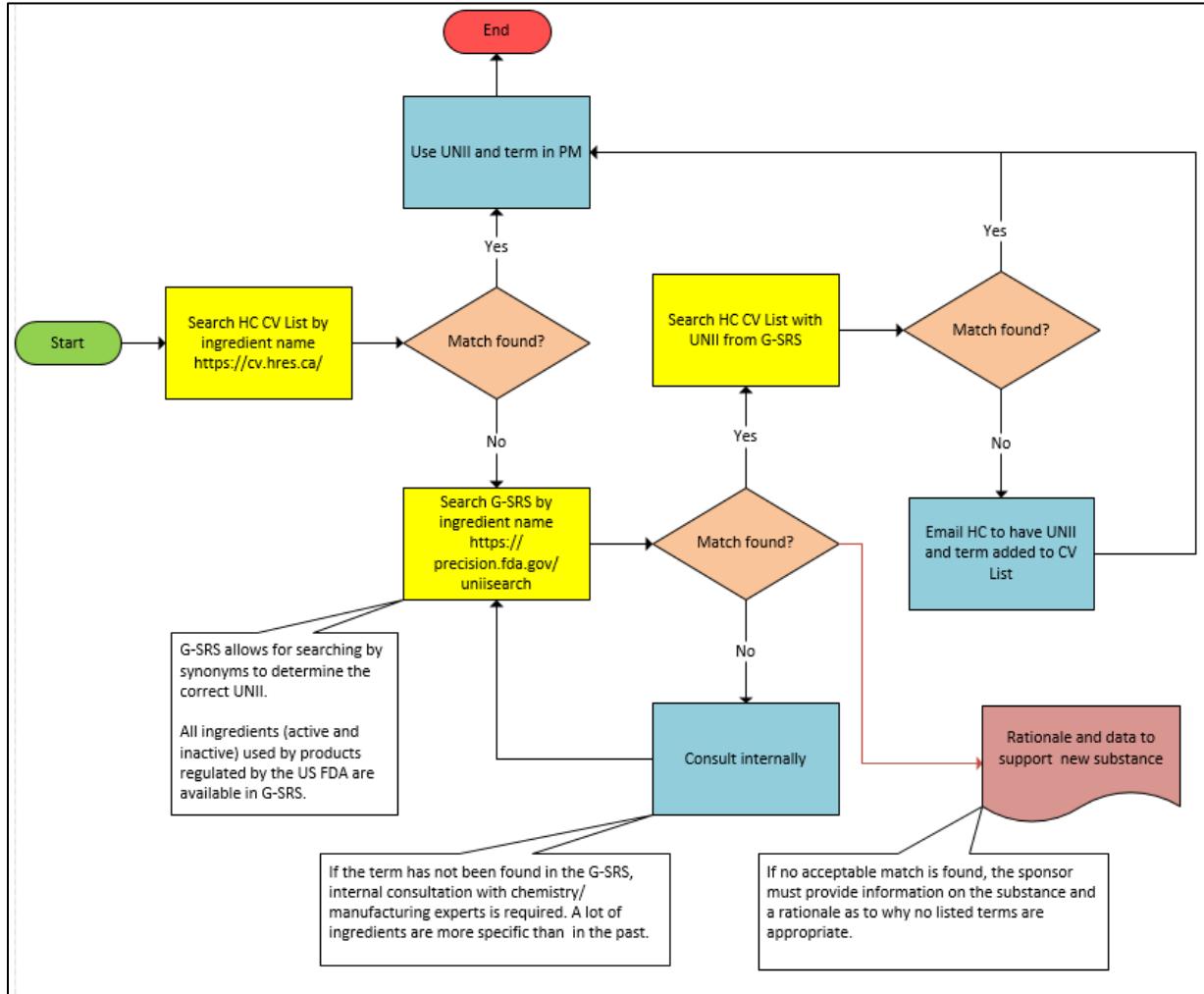
The following is a step-by-step process that can be used to assist in the determination.

1. Search Health Canada's [Ingredient Identifier Controlled Vocabulary List](#) using the known ingredient name. If an exact match is found, use that UNII along with the Canadian preferred term (display name) in the XML PM.
2. If an exact match is not found, repeat the same search in the GSRS. If a match is found, use the associated UNII to search Health Canada's Ingredient Identifier Controlled Vocabulary List.
 - a. If a match is found for the UNII, use the Canadian preferred term (display name) in Health Canada's Ingredient Identifier Controlled Vocabulary List.
 - b. If the UNII is not found, email the XML PM Team with the UNII and suggested term. The XML PM Team will confirm the Health Canada preferred term via return email and make the addition to the Ingredient Identifier Controlled Vocabulary List.
3. If no match is found in the GSRS, it may be necessary for sponsors to consult with their internal chemistry and manufacturing experts.
4. If no acceptable UNII is found for a substance, it is likely that the ingredient has not been registered with GSRS. In these cases, the sponsor is advised to submit a request for a new UNII through the FDA by emailing FDA-SRS@fda.hhs.gov. Please copy the XML PM team on the request to proactively inform us of a potential validation error at the time of filing. This will be considered acceptable, however, this must be resolved by the time the final XML PM is submitted post-authorization.

Generally speaking, the information requested is regarding the structure (e.g., molecular formula, sequence, linkages, subunits), modifications to molecular structures, and source material for naturally derived substances. For specified substance group 1 substances, (i.e., mixtures that are not naturally

occurring) the constituents of the mixture are also required. Once the UNII has been assigned, please email the details to the XML PM team to have it added to the Controlled Vocabulary List.

Figure 2 Process Flow to Find the Correct Name and Code for Ingredients



Units of Measure (6.15) is used for the expression of strength in the composition section and size in product characteristics. It is based on the [Unified Code for Units of Measure \(UCUM\)](#), which is a code system intended to include all units of measure being contemporaneously used in international science, engineering, and business. Health Canada's Controlled Vocabulary List contains a subset of units used in Canadian products.

Product Type (6.53) is a product characteristic. This is a Health Canada-specific list of product types and only one can be selected.

Colour (6.24) is a product characteristic. This list is sourced from the FDA's Structured Product Labeling Resources. This characteristic is intended to reflect the main colour of the product in its manufactured dosage form. Additional text (in brackets) may be included to better reflect the actual colour of the product. For example, if the description in section 6 states the product is dark red, then the entry for Product Details should be RED (DARK RED). This characteristic is intended to reflect the colour only, and should not include the degree of transparency. This characteristic can be omitted if it does not apply to the product.

Size is a product characteristic. Size can be expressed using single or multiple dimensions, depending on the shape of the product. Each numerical measurement should also include a unit of measure. This characteristic can be omitted if it does not apply to the product.

Shape (6.25) is a product characteristic. This list is sourced from the FDA's Structured Product Labeling Resources. This characteristic is intended to reflect the shape of the product in its final manufactured dosage form. Additional text (in brackets) may be included to better reflect the actual shape of the product. This characteristic can be omitted if it does not apply to the product.

Score (6.4) is a product characteristic. This list is a Health Canada-specific list that is intended to reflect the number of deep lines that pre-divides a solid dosage form into partial exact doses. This is not intended to reflect the number of pieces the product could be broken into. For clarity and safety purposes, score = 2 has been broken down into two different terms.

Figure 3 Example of tablets with “score” = 2

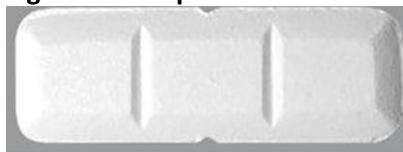


Figure 4 Example of tablets with “score” = 2 (quadrisection)



This characteristic can be omitted if it does not apply to the product.

Imprint is a product characteristic. Only the alpha-numeric text imprinted on the solid dosage form should be included. A comma should be used to separate text that appears on different lines on a single side, while a semi-colon should be used to separate the text from different sides, as applicable. There should be no white space between characters unless the actual imprint itself shows a white space. This characteristic can be omitted if it does not apply to the product.

Flavour (6.26) is a product characteristic. This list is sourced from the FDA's Structured Product Labeling Resources and is intended to reflect the flavour of the product. Additional text (in brackets) may be included to better reflect the actual flavour. This characteristic can be omitted if it does not apply to the product.

Pharmaceutical Standard (6.5) is a product characteristic. This is a Health Canada-specific list intended to reflect the standard of manufacture of the drug product. This characteristic can be omitted if it does not apply to the product.

Schedule (6.2) is a product characteristic. This is a Health Canada-specific list of drug schedules and categories for products regulated under the Food and Drugs Act and the Controlled Drugs and Substances Act. All terms that apply to a product should be provided.

Therapeutic Class (6.6) is a product characteristic. This list is sourced from the World Health Organization's [ATC Index](#). The Anatomical Therapeutic Chemical (ATC) classification system is a hierarchy with 5 different levels, and 14 different main groups. Each ATC main group is divided into 2 levels which could be either

pharmacological or therapeutic groups. The 3rd and 4th levels are chemical, pharmacological, or therapeutic subgroups and the 5th level is the chemical substance.

The ATC code in the Product Details section is required to be very specific. While the therapeutic classification on the title page is expected to be at the second or third level (therapeutic or pharmacological subgroups), it is expected to be at the fourth or fifth level (chemical subgroup and chemical substance) in the Product Details section. This information is required for different purposes than the information on the title page.

Following the example of [metformin used on the ATC website](#), the therapeutic class used in the Product Details section is A10BA02 metformin (5th level, chemical substance). The therapeutic classification on the title page could be either the therapeutic subgroup (drugs used in diabetes) or the pharmacological subgroup (Blood glucose lowering drugs, excl. insulins).

In order to avoid any confusion to the reader, only the ATC code (not the display name) will be visible in the Product Details section when the XML PM is rendered into a human-readable format. For products that are already authorized in Canada, sponsors can consult the DPD Online for the correct ATC code for use in the Product Details section.

Regulatory Activity (6.37) is a Health Canada-specific list of regulatory activity types that a product or composition could be authorized under. The terms on this list are used to populate the Regulatory Status section. This section is intended to reflect the Regulatory Activity under which the composition was first authorized in Canada, regardless of ownership at the time.

Package Type (6.32) is intended to reflect the primary packaging (i.e., packaging that comes into contact with the product) and any applicable secondary packaging. Packaging that is used for shipping purposes only should not be included. This list is sourced from the EDQM's [Standard Term database](#). The Standard Term listing includes a definition that should be considered when selecting the appropriate term for use in the Product Details section of the XML PM.

3.2.2 Controlled Vocabulary Listing Website

The Controlled Vocabulary Listing supports the XML PM and its validation process. This website provides the ability to search for terms directly through its user interface or by downloading in XML genericode format for import into authoring and validation tools. Each list contains terms that include the code, English display name, French display name, source, status, and date it was last updated.

Note: the same code is used for both the English and French display names.

Sponsors can use the filter items field to search within a controlled vocabulary for a term or code. Each column can also be sorted.

Figure 5 Screenshot from the Controlled Vocabulary Listing website

Terms for 2.16.840.1.113883.2.20.6.53					
OID: 2.16.840.1.113883.2.20.6.53	Source: HPFB	Status: Active	Last updated: 2021-06-09 15:39:38	Download XML	
English Display Name: PRODUCT TYPE					
French Display Name: CLASSE DE PRODUIT					
Filter items <input type="text"/> Showing 1 to 3 of 3 entries Show 10 entries					
Code ↑↓	English Display Name ↑↓	French Display Name ↑↓	Source ↑↓	Status ↑↓	Last updated ↑↓
1	PHARMACEUTICAL	PHARMACEUTIQUE	HPFB	Active	2021-06-09 15:34:07
2	BIOLOGIC	BIOLOGIQUES	HPFB	Active	2021-06-09 15:34:07
4	RADIOPHARMACEUTICAL	RADIOPHARMACEUTIQUE	HPFB	Active	2021-06-09 15:34:07

Long description for figure 5

3.2.2.1 Status of Controlled Vocabulary

All controlled vocabularies are assigned a status against which they are validated as outlined in Table 1. This includes both the vocabularies (e.g., Object Identifier (OID) 2.16.840.1.113883.2.20.6.10 / DOCUMENT TYPE) and the vocabulary related terms (e.g., code 4 / MASTER TEMPLATE).

Table 1 Definition of Controlled Vocabulary Status and Corresponding Validation Message

Status	Definition	Validation
Active	Available for use. Expected.	Pass
Inactive	No longer available for use, may be permitted under specific circumstances.	Warning
Temporary	Under review by HC. Not permitted in the final version.	Warning
Deprecated	Do not use	Error

3.2.3 Use of Controlled Vocabulary

The majority of the published terms are used to populate the Product Details section of the XML PM. When used in this section, the terms must be identical to what is in the controlled vocabulary listing for validation purposes, which is case-sensitive. Sponsors are also required to use the controlled vocabulary terms throughout the Product Monograph to ensure consistent and standardized content. The only controlled vocabulary terminology that is validated in Parts 1, and 2 and the Patient Medication Information (PMI) are those in the Master Template list. The remaining controlled vocabulary terms are not validated when used in narrative content within Parts 1, and 2 and the PMI. Therefore, it is acceptable to grammatically adjust the term to allow for proper sentence structure and natural language in other parts of the document. For example, ‘Intramuscular use’ can be adjusted to ‘... as a single intramuscular injection into the deltoid or gluteal muscle...’.

3.3 High-Level XML Structure and Document Set-Up

The figure below is representative of the overall XML PM structure, with all of the <component> elements collapsed. This includes the prolog, document metadata, organization metadata (<author>), and the content (<component> <structuredBody>). Each of these will be further elaborated upon below.

Figure 6 High-Level Structure Shown in Raw XML Snippet

```
<?xml version="1.0" encoding="UTF-8"?>
<?xmlstylesheet type="text/xsl" href="https://health-products.canada.ca/product-monograph/style-sheet/v_1_0/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://health-products.canada.ca/product-monograph/schema/SPL.xsd">
  <id root="e24f574b-7e12-4374-b010-b808e0b108aa" />
  <code code="4" codeSystem="2.16.840.1.113883.2.20.6.10" displayName="MASTER TEMPLATE" />
  <title>Sample Only - Not Intended to Reflect Actual Products.</title>
  <effectiveTime value="20241201"></effectiveTime>
  <languageCode code="1" codeSystem="2.16.840.1.113883.2.20.6.29" displayName="ENGLISH" />
  <setId root="ac9c8e28-2798-4134-8197-2b249d836002" />
  <versionNumber value="10" />
  <author>
    <component>
      <structuredBody>
        <component>
          <component>
            <component>
              <component>
                <component>
                  <component>
                    <component>
                      <component>
                        <component>
                          <component>
                            <component>
                              </structuredBody>
                            </component>
                          </component>
                        </component>
                      </component>
                    </component>
                  </component>
                </component>
              </component>
            </component>
          </component>
        </structuredBody>
      </component>
    </author>
  </document>
```

Screen readable XML snippet for figure 6

XML Prolog

The first three lines in the figure above are considered to be the XML Prolog. The first line contains the version of the XML standard this file conforms to, as well as indicates that the character encoding of the document should be understood as UTF-8. This line is expected to be common across all instances of the XML PM.

The following lines contain declarations of the storage locations of Health Canada's style sheet, as well as the schema used to validate that an XML PM is well formed. The style sheet location endpoint contains a version number, which may change over time as updates are applied to it. This version number is selected from the controlled vocabulary (OID 6.65). The schema location endpoint is not expected to change unless its actual storage location is updated.

Document Name (<setId>)

The <setId> must be a Globally Unique Identifier (GUID) and is the unique identifier that remains the same for all instances for a single language of the XML PM⁵.

.xml File Name (<id>)

The .xml file name and <id> must be identical, must be a GUID, and must be unique for each authorized version of the XML PM. The XML PM submitted at the time of filing and post-authorization may have the same file name⁵.

Document Type (<code>)

The document type represents the PM template used in the XML PM. The code and display name for the PM template are selected from the controlled vocabulary (OID 6.10).

Document Title (<title>)

The document title should be reflective of all products captured by the XML PM. The format of the title should be BRAND NAME (non-proprietary name), DOSAGE FORM, as outlined in the PM Guidance. The title should only be 1 line and images are not to be included.

⁵ See Section 3.8 for relationship context

Document Language (<languageCode>)

The code and display name for the language of the document are selected from the controlled vocabulary (OID 6.29)⁵.

Dates (<effectiveTime>)

There are many instances of dates throughout the XML PM where <effectiveTime> is used, and they fall into two groups.

1. Dates visible in the human-readable format. This includes the dates required on the title page and in the Product Details section. Specific guidance is provided for those dates in the applicable sections throughout this document.
Note: The date at the end of the PMI does not use <effectiveTime> and is provided as part of the text.
2. Dates that are not visible in the human-readable format which are required for schema validation. Each subsection (<component> <section> <component> <section>) in Parts 1, and 2 and the PMI requires a date.

Health Canada is not actively using these dates at this time, therefore the sponsors may define how they would like to use them. A suggestion is that these dates be updated if the content of that subsection is changed.

The date format is YYYYMMDD.

Document Version (<versionNumber>)

The document version is required for schema validation, however it is not actively used by Health Canada. Therefore, sponsors can choose how they would like to use it, however, it must be a whole number that does not contain letters, symbols, or decimals.

3.4 Product Monograph Content

The XML PM follows the PM Guidance Document and Master Template. To accommodate all requirements of the Master Template, the XML PM has seven major sections. Major sections may contain sections and subsections, which further organize content. Text is allowed to directly follow only three of the major section headings, the rest must have a section or subsection before any text can be added. An additional major section is included in the XML PM for the Product Details section.

Table 2 Requirements for the Major Section Headings

Major Section Heading	Inclusion in XML PM	What is allowed to follow
TITLE PAGE	Required	Sections and Subsections
NOTICE OF COMPLIANCE WITH CONDITIONS	Optional ⁶	Text
RECENT MAJOR LABEL CHANGES	Required	Text
BIOSIMILAR BIOLOGIC DRUG	Optional ⁶	Text
PART 1: HEALTHCARE PROFESSIONAL INFORMATION	Required	Sections and Subsections
PART 2: SCIENTIFIC INFORMATION	Required	Sections and Subsections
PATIENT MEDICATION INFORMATION	Optional ⁷	Sections and Subsections
Product Details	Required	Sections

3.4.1 Setting up Major Section Headings

Each major section is a component within the structured body (<component> <structuredBody> <component>) and is followed by sections or subsections (<component>) or text (<text>) or a manufactured product (<subject> <manufacturedProduct>).

Figure 7 Product Metadata Second Level Structure Shown in Raw XML Snippet

```

<component>
  <structuredBody>
    <component>
      <section ID="f6ac9de5-be91-442c-9579-5bc9ebd36902">
        <id root="bdeefc11-4315-41e3-8c56-83e8bf4f770b" />
        <code code="0MP" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="MANUFACTURED PRODUCT" />
        <title>MANUFACTURED PRODUCT</title>
        <effectiveTime value="20241201" />
        <subject>
          <subject>
            <subject>
              <subject>
                <subject>
                  <subject>
                    <subject>
                      <subject>
                        <subject>
                          <subject>
                            <subject>
                              <subject>
                                <subject>
                                  <subject>
                                    <subject>
                                  </subject>
                                </subject>
                              </subject>
                            </subject>
                          </subject>
                        </subject>
                      </subject>
                    </subject>
                  </subject>
                </subject>
              </subject>
            </subject>
          </subject>
        </subject>
      </section>
    </component>
  </structuredBody>
</component>
```

Screen readable XML snippet for figure 7

Section Identification (<section> ID attribute)

The <section> ID is required, must be a GUID, and be unique within this instance of the XML PM.

Root Identification (<id> root attribute)

The <id> root is required, must be a GUID, and must be unique within this instance of the XML PM.

Major Document Section Heading Code and Name (<code>)

The code and display name for the product metadata section are selected from the controlled vocabulary (OID 6.63).

⁶ If not applicable, the whole major section should be omitted.

⁷ From a technical standpoint only. See PM Guidance for requirements for this section.

Title (<title>)

The title must match the display name.

Section Date (<effectiveTime>)

The section date is required for schema validation. See Section 3.3 for details. The date format is YYYYMMDD.

Figure 8 Section or Subsection Following a Major Section Heading Shown in Rendered HTML and Supporting Raw XML Snippet

PART 1: HEALTHCARE PROFESSIONAL INFORMATION	
1 INDICATIONS	
<pre><component> <section ID="d6a947eb-e2be-45c0-8b2e-15d0d0eebea8"> <id root="e6bb83b9-2602-4f96-9077-b8b9535c254e" /> <code code="pi00" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="PART 1: HEALTHCARE PROFESSIONAL INFORMATION" /> <title>PART 1: HEALTHCARE PROFESSIONAL INFORMATION</title> <effectiveTime value="20241201" /> <component> <section ID="c2ea4fad-2b79-4dbc-8d99-6843adc2dec8"> <id root="aa3f869a-7734-425a-85d8-b8bd4d3500a5" /> <code code="pi01" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="1 INDICATIONS" /> <title>1 INDICATIONS</title> <text> <effectiveTime value="20210101" /> <component> <component> </component> </component> </text> </section> </component></pre>	

Long description including screen readable XML snippet for figure 8

Figure 9 Text Following a Major Section Heading Shown in Rendered HTML and Supporting Raw XML Snippet

BIOSIMILAR BIOLOGIC DRUG
<p><i>Biosimilar BRAND NAME (non-proprietary name) is a biosimilar biologic drug (biosimilar) to Reference biologic drug BRAND NAME (non-proprietary name). A biosimilar is a biologic drug that was granted authorization based on a demonstration of similarity to a version previously authorized in Canada, known as the reference biologic drug.</i></p>
<pre><component> <section ID="d7ceb5c1-7ee9-4fd2-884e-7a50c06b27e1"> <id root="dd1e1c41-f0d3-4ba8-b1f5-bd009a5dd5a8" /> <code code="0BBD" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="BIOSIMILAR BIOLOGIC DRUG" /> <title>BIOSIMILAR BIOLOGIC DRUG</title> <text> <paragraph> <content styleCode="italics"> Biosimilar BRAND NAME (non-proprietary name) is a biosimilar biologic drug (biosimilar) to Reference biologic drug BRAND NAME (non-proprietary name). A biosimilar is a biologic drug that was granted authorization based on a demonstration of similarity to a version previously authorized in Canada, known as the reference biologic drug. </content> </paragraph> </text> </section> </component></pre>

Long description including screen readable XML snippet for figure 9

All major section headings, section headings, and subsection headings are managed as controlled vocabularies and must not be modified. The code and display name for the section headings are selected from the controlled vocabulary (OID 6.63). The content in the title element is used to display the section heading in the HTML-rendered PM. The display name and the title must match except for the following cases:

- [Clinical Group](#)
- [Unassigned](#)
- [Patient Medication Information \(PMI\)](#)

3.4.2 Title Page

The title page is the first major section in the narrative section of the XML PM as outlined in the PM Guidance. There are distinct six areas (<component> <section>) within the title page.

Figure 10 The Top Section of the Title Page Shown in Rendered HTML and Supporting Raw XML Snippet

TITLE PAGE
<p>PRODUCT MONOGRAPH INCLUDING PATIENT MEDICATION INFORMATION</p> <p>Pr BRAND NAME ® non-proprietary name Dosage Form, For RoA use, Strength Pharmaceutical Standard Therapeutic Classification</p> <pre><component> <section ID="d8d30d86-e343-48f4-9cec-524834b3803b"> <id root="eed00b53-cdb2-4aa6-9e82-88b7d793b208" /> <code code="OTP" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="TITLE PAGE" /> <title>TITLE PAGE</title> <effectiveTime value="20210101" /> <component> <section ID="be75cfb9-3131-4903-800b-267427388a13"> <id root="b9db4be0-3f46-437a-bd7b-4a3e010afaad" /> <code code="0tp1.1" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Title" /> <title>Title</title> <text> <paragraph>PRODUCT MONOGRAPH</paragraph> <paragraph>INCLUDING PATIENT MEDICATION INFORMATION</paragraph>
 <paragraph> <content styleCode="bold"><sup>Pr</sup> BRAND NAME <sup>®</sup></content> </paragraph> <paragraph>non-proprietary name</paragraph> <paragraph>Dosage Form, For RoA use, Strength</paragraph> <paragraph>Pharmaceutical Standard</paragraph> <paragraph>Therapeutic Classification</paragraph>
 </text> </section> </component> </section> </component></pre>

Long description including screen readable XML snippet for figure 10

Figure 11 Company Information on the Title Page Shown in Rendered HTML and Supporting Raw XML Snippet

Company Name 1 Street address City, PROV Postal code Web address	<pre><component> <section ID="f187daf9-5e75-425a-9de6-f6celaf2a965"> <id root="ac26f58c-721a-4c51-8bbc-c9dddb1f1233" /> <code code="0tp1.2" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Company Name and Address" /> <title>Company Name and Address</title> <text> <paragraph>Company Name 1
Street address
City, PROV Postal code
Web address</paragraph> </text> <effectiveTime value="20210101" /> </section> </component></pre>
---	---

Long description including screen readable XML snippet for figure 11

Title Area (<text> <paragraph>)

This area shows the standard information about the product that is required on all PMs.

Company Name and Address (<text> <paragraph>)

The information required is outlined in the PM Guidance.

A separate <component> element is required for each company. A single <paragraph> element should be used for all the company information. Within that <paragraph> element a
 element can be used to separate each piece of information (e.g., company name, street, city).

Use the Canada Post abbreviations for provinces and territories, without any periods. The postal code may be placed on the same line as the province, with two spaces between them. Do not put a comma between the province and the postal code.

Figure 12 Date of Authorization on the Title Page at the Time of Filing Shown in Rendered HTML and Supporting Raw XML Snippet

Date of Authorization:	<pre><component> <section ID="bf2dab4e-fd04-4ec9-9cdc-247188622d0f"> <id root="e5f1dea3-d907-4664-b46f-e1d9736d47af" /> <code code="0tp1.3" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Date of Authorization:" /> <title>Date of Authorization:</title> <text> <effectiveTime value="20241201" /> </text> </section> </component></pre>
-------------------------------	--

Long description including screen readable XML snippet for figure 12

Figure 13 Date of Authorization on the Title Page Post-Authorization Shown in Rendered HTML and Supporting Raw XML Snippet

Date of Authorization: 2010-02-15	<pre><component> <section ID="bf2dab4e-fd04-4ec9-9cdc-247188622d0f"> <id root="e5f1dea3-d907-4664-b46f-e1d9736d47af" /> <code code="0tp1.3" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Date of Authorization:" /> <title>Date of Authorization:</title> <text> <paragraph>2010-02-15</paragraph> </text> <effectiveTime value="20241201" /> </section> </component></pre>
---	--

Long description including screen readable XML snippet for figure 13

Date of authorization (<text> <paragraph>)

The date of authorization is unknown at the time of filing, and therefore should not be provided (Figure 12). Do not include a placeholder date. Dates formatting is YYYY-MM-DD.

This date is required in the final version of the XML PM submitted post-authorization in English and French (Figure 13).

Figure 14 Control Number on the Title Page Shown in Rendered HTML and Supporting Raw XML Snippet

Control Number:
123456

```
<component>
<section ID="ebc3f3dc-71be-424f-91ef-8aca8c138b21">
<id root="efd8c4c1-d0dd-434d-b1c2-4daa18752fa8" />
<code code="0tp1.5" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Control Number:" />
<title>Control Number:</title>
<text>
<paragraph>123456</paragraph>
</text>
<effectiveTime value="20210101" />
</section>
</component>
```

Long description including screen readable XML snippet for figure 14

Control Number (<text> <paragraph>)

The control number for the submission under which the updates are authorized. When the control number is not known (at the time of filing only), the <text> and <paragraph> should be omitted.

Figure 15 Trademark declaration on the Title Page Shown in Rendered HTML and Supporting Raw XML Snippet

BRAND NAME ® is a registered trademark of COMPANY NAME
<component> <section ID="e2d4279e-5fca-4d26-898d-02548a217ab9"> <id root="f17bc229-d609-460a-b9dc-418008d47c90" /> <code code="0tp1.6" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Footer" /> <title>Footer</title> <text> <paragraph>BRAND NAME [®] is a registered trademark of COMPANY NAME</paragraph> </text> <effectiveTime value="20210101" /> </section> </component>

Long description including screen readable XML snippet for figure 15

Footer (<text> <paragraph>)

If a trademark declaration is included, it should be added as a footer on the title page. Since the XML PM doesn't have traditional page numbers, the footer as outlined in the Master Template is not required.

3.4.3 Notice of Compliance with Conditions and Biosimilar Biologic Drug

The standard statements should be provided when required as per the Product Monograph Guidance. These sections should be omitted when not required.

Figure 16 The Notice of Compliance with Conditions Statement Shown in Rendered HTML and Supporting Raw XML Snippet

NOTICE OF COMPLIANCE WITH CONDITIONS

What is a Notice of Compliance with Conditions (NOC/c)?

A NOC/c is a form of market approval granted to a product on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada.

Products authorized under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

```

<component>
  <section ID="d7ceb5c8-7ee9-4fd2-884e-7a50c06b27e1">
    <id root="dd1e1c43-f0d3-4ba8-b1f5-bd009a5dd5a8" />
    <code code="ONOC" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="NOTICE OF COMPLIANCE WITH CONDITIONS" />
    <title>NOTICE OF COMPLIANCE WITH CONDITIONS</title>
    <text>
      <paragraph>
        <content styleCode="bold">What is a Notice of Compliance with Conditions (NOC/c)?</content>
      </paragraph>
      <paragraph>
        <content styleCode="italics">A NOC/c is a form of market approval granted to a product on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada.</content>
      </paragraph>
      <paragraph>
        <content styleCode="italics">Products authorized under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.</content>
      </paragraph>
    </text>
    <effectiveTime value="20210101" />
  </section>
</component>
```

Long description including screen readable XML snippet for figure 16

3.4.4 Recent Major Label Changes

The Recent Major Label Changes (RMLC) section is always required.

Figure 17 The Recent Major Label Changes Table Shown in Rendered HTML and Supporting Raw XML Snippet

RECENT MAJOR LABEL CHANGES	
Section	Date
1 INDICATIONS, 1.1 Pediatrics	2023-12
<pre> <component> <section ID="d7cee5c8-7ee9-4fd2-184e-a50c06b27e1"> <id root="dd1e1c93-f0d3-4ba8-b1f5-ad009a5dd5a8" /> <code code="1RMLC" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="RECENT MAJOR LABEL CHANGES" /> <title>RECENT MAJOR LABEL CHANGES</title> <text> <table ID="TableRMLC" rules="all" frame="border"> <thead> <tr> <th>Section</th> <th>Date</th> </tr> </thead> <tbody valign="top" align="left"> <tr> <td align="left">1 INDICATIONS, 1.1 Pediatrics</td> <td>2023-12</td> </tr> <tr> <td align="left" style="vertical-align: top;"> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="padding: 5px; width: 10%;">Section</pre>	

Long description including screen readable XML snippet for figure 17

The RMLC is provided in a table format and includes an internal hyperlink to the changed section. The date format is YYYY-MM in this table only.

Figure 18 The Vertical Line Annotation Shown in Rendered HTML and Supporting Raw XML Snippet

1.1 Pediatrics
Text
<pre> <component> <section ID="f2aa7e0e-2042-4a4c-a783-9ad4e8717a32"> <id root="b9db4ce0-3f46-434a-bd7b-4a3e010adaad" /> <code code="pi01.1" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="1.1 Pediatrics" /> <title>1.1 Pediatrics</title> <text> <paragraph> <content styleCode="xmChange">Text</content> </paragraph> </text> <effectiveTime value="20210101" /> </section> </component></pre>

Long description including screen readable XML snippet for figure 18

A vertical line is added in the body of the PM to indicate specific changes listed in the RMLC section only. The styleCode attribute 'xmChange' is added to the text within the XML to accomplish this.

Figure 19 The RMLC with no Changes Required Shown in Rendered HTML and Supporting Raw XML Snippet

RECENT MAJOR LABEL CHANGES	
None at time of the most recent authorization	
	<pre> <component> <section ID="d7cee5c8-7ee9-4fd2-184e-7a50c06b27e1"> <id root="dd1e1c93-f0d3-4ba8-b1f5-ad009a5dd5a8"/> <code code="1RMLC" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="RECENT MAJOR LABEL CHANGES"/> <title>RECENT MAJOR LABEL CHANGES</title> <text> <paragraph>None at time of the most recent authorization</paragraph> </text> <effectiveTime value="20210101"/> </section> </component></pre>

Long description including screen readable XML snippet for figure 19

When no changes are required in the RMLC section, do not create a table. The statement “None at time of the most recent authorization” should be added.

3.4.5 Part 1: Healthcare Professional Information and Part 2: Scientific Information

The content should be provided as per the Product Monograph Guidance and Master Template. The subsections can be omitted when not required, however, the numbering must be maintained to comply with the controlled vocabulary.

3.4.5.1 Clinical Group

Sponsors should use “Clinical Group” to insert organizational subheadings in section 14.1 Clinical Trials by Indication. The code and display name for the clinical group (“CG”) are selected from the controlled vocabulary (OID 6.63). The `<title>` should be modified as per the Product Monograph Guidance.

Figure 20 A Clinical Group Shown in Rendered HTML and Supporting Raw XML Snippet

14.1 Clinical Trials by Indication	
Indication 1	
	<pre> <component> <section ID="a2875272-8229-4c12-919e-827854ddd78a"> <id root="e134d52c-f9d4-4698-a082-84b29ee3d95a" /> <code code="piii4.1" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="14.1 Clinical Trials by Indication" /> <title>14.1 Clinical Trials by Indication</title> <effectiveTime value="20210101" /> <component> <section ID="a2875272-8229-4c12-919e-827854dc0101"> <id root="e134d52c-f9d4-4698-a082-84b29ee3d95a" /> <code code="CG" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Clinical Group" /> <title styleCode="bold">Indication 1</title> <text> <effectiveTime value="20210101" /> </text> </section> </component></pre>

Long description including screen readable XML snippet for figure 20

3.4.5.2 Unassigned

Unassigned is a mechanism used to add a new subsection for an emerging or product-specific requirement that is not covered by the current Master Template. The expectation is that this would be used as an interim measure to address a gap pending an update to the Master Template. Any new subsections should be added after the existing Master Template subsections to maintain the template numbering.

The code and display name for unassigned (“UA”) is selected from the controlled vocabulary (OID 6.63). The `<title>` should be modified to reflect the new subsection. The use of Unassigned results in an additional

entry in the Table of Contents. Unassigned must not be used for creating subsections for content that is already in the Master Template.

Figure 21 Use of Unassigned Shown in Rendered HTML and Supporting Raw XML Snippet

TABLE OF CONTENTS	6.3 Example of Unassigned
	<p>6.3 Example of Unassigned</p> <p>Text</p> <pre><component> <section ID="ac2875272-8229-4c12-919e-827854ddd85b"> <id root="c334d52c-f9d4-4698-a082-84b29ee3d78b"/> <code code="UA" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="UNASSIGNED"/> <title>6.3 Example of Unassigned</title> <text> <paragraph>Text</paragraph> </text> <effectiveTime value="20210101"/> </section> </component></pre>

Long description including screen readable XML snippet for figure 21

3.4.6 Patient Medication Information

The content should be provided as per the PM Guidance.

Figure 22 Modifications in Title for PMI Shown in Rendered HTML and Supporting Raw XML Snippet

<p>How BRAND NAME works:</p> <p>Narrative</p>	<pre><component> <section ID="bca4d498-0gc3-4e44-bcb6-550140d4de5d"> <id root="be7ab6e6-c431-4adf-a18e-ed321b381456" /> <code code="pmi03" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="How [Brand name] works:" /> <title>How BRAND NAME works:</title> <text> <paragraph>Narrative</paragraph> </text> <effectiveTime value="20241201" /> </section> </component></pre>
--	--

Long description including screen readable XML snippet for figure 22

The code and display name for the PMI section headings are selected from the controlled vocabulary (OID 6.63). The code and display names must match the controlled vocabulary, however, the <title> can be modified to be different from the display name within that section. When several PMIs are required, multiple instances of the <component> are permissible.

3.5 Organization Details

The organization details identify the Market Authorization Holder and Canadian importer/distributor of the product.

Figure 23 Company Details Section Shown in the Rendered HTML and Supporting Raw XML Snippet

COMPANY DETAILS
Market Authorization Holder - Acme Pharma Inc. (1111)
Canadian Importer/Distributor - Acme Distributing Ltd. (0000)
<pre> <author> <time/> <assignedEntity> <representedOrganization> <id extension="1111" root="2.16.840.1.113883.2.20.6.31"/> <name>Acme Pharma Inc.</name> <contactParty> <assignedEntity> <assignedOrganization> <id extension="0000" root="2.16.840.1.113883.2.20.6.31"/> <name>Acme Distributing Ltd.</name> <contactParty> </assignedOrganization> </assignedEntity> </representedOrganization> </assignedEntity> </contactParty> </representedOrganization> </author></pre>

Long description including screen readable XML snippet for figure 23

Market Authorization Holder (<representedOrganization>)

The Market Authorization Holder (MAH) is the legal entity that holds the Notice of Compliance and the Drug Identification Number (DIN).

Importer/Distributor (<assignedOrganization>)

When the Market Authorization Holder is not located in Canada, a Canadian importer and/or distributor is required. Multiple instances of <assignedOrganization> are permitted.

Company Identifier and Name (<id>)

The code and display name for the company identifier are selected from the controlled vocabulary (OID 6.31).

Contact Information (<contactParty>)

Contact information is required for both the MAH and importer/distributor. Multiple instances of <contactParty> are only permitted for importers/distributors.

Figure 24 Contact Information Section Shown in the Rendered HTML and Supporting Raw XML Snippet

Contact Address
9526 Columbia St. Hanover Park, Illinois, 60133 United States of America (the)
<pre> <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> <contactPerson /> </contactParty></pre>

Long description including screen readable XML snippet for figure 24

Address (<addr>)

The address fields include <streetAddressLine>, <city>, <state>, <postalCode> and <country>. These fields are mandatory for addresses associated with the Market Authorization Holder and the Canadian importer/distributor (when one is required).

The <streetAddressLine> and <city> are both string values which should contain the official address of the organization being described.

The <state> is a string value that should be populated with the full name of the province or territory when the address is in Canada.

The <postalCode> is a string value that should be populated with the Canadian postal code associated with the organization's address when the address is in Canada. If outside Canada, an appropriate postal or zip code from that country should be populated.

The <country> should be populated with the code and display name selected from the controlled vocabulary (OID 6.17).

Contact Person (<contactPerson>)

This element is required for schema validation, however it is not used. No information is required and is always an empty element.

3.6 Product Details

The Product Details section captures metadata about a drug product at the composition level. The product metadata provides product information on composition, characteristics, packaging and regulatory status as discrete data elements. The vocabulary used in the narrative text must match the controlled vocabulary that is used in the product metadata.

All compositions covered by a PM must have their own Product Details section. At a minimum, each Drug Identification Number (DIN) requires its own Product Details section (<component> <section> <subject> <manufacturedProduct>). Sponsors may choose to provide additional sections for other differences that are not subject to a new DIN (e.g. different colours or flavours).

If the DIN is cancelled for one of the multiple compositions, the Product Details section for that composition must be maintained. The appropriate cancellation date should be added during the submission to remove the information related to the cancelled DIN from the other sections of the PM/XML PM as per the Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs).

Figure 25 Product Information Shown in the Rendered HTML and Supporting Raw XML Snippet

Product Information	
Brand Name	BRAND NAME1
Non-Proprietary Name	example of ACTIB
Drug Identification Number (DIN)	01234561
Route of Administration	Oral use
Manufactured Dosage Form	Tablet (chewable)
<pre> <subject> <manufacturedProduct> <manufacturedProduct> <code code="01234561" /> <name>BRAND NAME1</name> <formCode code="151" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="Tablet (chewable)" /> <asEntityWithGeneric> <genericMedicine> <name>example of ACTIB</name> </genericMedicine> </asEntityWithGeneric> <consumedIn> <substanceAdministration> <routeCode code="20053000" codeSystem="2.16.840.1.113883.2.20.6.7" displayName="Oral use" /> </substanceAdministration> </consumedIn> </manufacturedProduct> </subject></pre>	

Long description including screen readable XML snippet for figure 25

Drug Identification Number (DIN) (<code>)

The DIN should be provided here. When the DIN is unknown (at the time of filing only), the <code> should be omitted. Do not use placeholder or dummy data. A validation warning message is expected at the time of filing when the DIN is unknown.

Brand Name (<name>)

Include the product Brand Name here.

Manufactured Dosage Form and Name (<formCode>)

The code and display name for the manufactured dosage form are selected from the controlled vocabulary (OID 6.3).

Non-Proprietary Name (<genericMedicine> <name>)

Include the non-proprietary name of the drug product here.

Route of Administration (<routeCode>)

The code and display name for the route of administration are selected from the controlled vocabulary (OID 6.7). To confirm the proper placement of this element, please refer to the XML PM sample (.xml).

3.6.1 Product Composition

There are several concepts that need to be taken into consideration when setting up the Product Composition section. First, ingredients are split into active and inactive ingredients. The active ingredients are further differentiated by role, which is based on how the basis of strength is calculated. Lastly, there are several different ways that the strength of a product can be represented.

Figure 26 Product Composition Section Shown in the Rendered HTML

Product Composition			
Active Ingredient	Active Moiety	Basis of Strength	Strength
ACETAMINOPHEN (36209ITL9D)	ACETAMINOPHEN (36209ITL9D)	ACETAMINOPHEN (36209ITL9D)	160 mg
Inactive Ingredients			
ANHYDROUS CITRIC ACID (XF417D3PSL)			
DEXTROSE (IY9XDZ35W2)			
D&C RED NO. 30 ALUMINUM LAKE (GE75M6YV5W)			

Long description for figure 26

3.6.1.1 Active Ingredients

For each composition, all active ingredients, ingredient roles and strength must be provided.

Figure 27 Structure for Active Ingredients Shown in a Raw XML Snippet

<manufacturedProduct>
<manufacturedProduct>
<code code="01234561" />
<name>BRAND NAME1</name>
<formCode code="151" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="Tablet (chewable)" />
<asEntityWithGeneric>
<genericMedicine>
</asEntityWithGeneric>
<ingredient classCode="ACTIB">
<quantity>
<ingredientSubstance>
</ingredientSubstance>
</ingredient>

Screen readable XML snippet for figure 27

Active Ingredient Role (<ingredient>)

The code for the active ingredient role is selected from the controlled vocabulary (OID 6.39).

Active Ingredient Strength (<quantity>)

Strength information is required for all active ingredients. The ingredient strength is specified as a physical quantity using a numerator and a denominator.

Numerator and Denominator (<numerator> and <denominator>)

The numerator and denominator are composed of a value attribute and a unit attribute. The unit is selected from the controlled vocabulary (OID 6.15)

Numeric value of strength (value attribute)

Whole numbers must always be provided without spaces or commas in both English and French. Numbers containing decimals must always use a period in both English and French. The style sheet will render the numbers appropriately in each language.

When a range is required, there are two value attributes represented by a <low> element and a <high> element. See 3.6.1.1.2 for different representations of strength.

3.6.1.1.1 Active Ingredient Roles

All active ingredients in a composition must be assigned a role, which is defined by how the basis of strength is calculated.

Table 3 Active Ingredient Roles

Code	Description
ACTIB	The basis of strength is the active ingredient
ACTIM	The basis of strength is the active ingredient's active moiety
ACTIR	The basis of strength is another reference substance ² with the same active moiety

Figure 28 Active Ingredient with Ingredient Role ACTIB Shown in Rendered HTML and Supporting Raw XML Snippet

Product Composition		
Active Ingredient	Active Moiety	Basis of Strength
ACETAMINOPHEN (362O9ITL9D)	ACETAMINOPHEN (362O9ITL9D)	ACETAMINOPHEN (362O9ITL9D)
<pre> <ingredient classCode="ACTIB"> <quantity> <ingredientSubstance> <code code="362O9ITL9D" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ACETAMINOPHEN" /> <name>ACETAMINOPHEN</name> <activeMoiety> <activeMoiety> <code code="362O9ITL9D" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ACETAMINOPHEN" /> <name>ACETAMINOPHEN</name> </activeMoiety> </activeMoiety> </ingredientSubstance> </quantity> </ingredient></pre>		

Long description including screen readable XML snippet for figure 28

Ingredient (<ingredientSubstance>) and active moiety (<activeMoiety>)

The code and display name for the active ingredient are selected from the controlled vocabulary (OID 6.14).

Ingredient Name (<ingredientSubstance> <name>) and active moiety name (<activeMoiety> <name>)

The name must match the display name.

Figure 29 Active Ingredient with Ingredient Role ACTIM Shown in Rendered HTML and Supporting Raw XML Snippet

Product Composition		
Active Ingredient	Active Moiety	Basis of Strength
OMEPRAZOLE MAGNESIUM (426QFE7XLK)	OMEPRAZOLE (KG60484QX9)	OMEPRAZOLE (KG60484QX9)
<pre> <ingredient classCode="ACTIM"> <quantity> <ingredientSubstance> <code code="426QFE7XLK" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="OMEPRAZOLE MAGNESIUM" /> <name>OMEPRAZOLE MAGNESIUM</name> <activeMoiety> <activeMoiety> <code code="KG60484QX9" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="OMEPRAZOLE" /> <name>OMEPRAZOLE</name> </activeMoiety> </activeMoiety> </ingredientSubstance> </quantity> </ingredient></pre>		

Long description including screen readable XML snippet for figure 29

Figure 30 Active Ingredient with Ingredient Role ACTIR Shown in Rendered HTML and Supporting Raw XML Snippet

Product Composition		
Active Ingredient	Active Moiety	Basis of Strength
TELOTRISTAT ETIPRATE (3T25U84H4U)	TELOTRISTAT (381V4FCV2Z)	TELOTRISTAT ETHYL (8G388563M7)
<pre> <ingredient classCode="ACTIR"> <ingredientSubstance> <code code="3T25U84H4U" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="TELOTRISTAT ETIPRATE" /> <name>TELOTRISTAT ETIPRATE</name> <activeMoiety> <activeMoiety> <code code="381V4FCV2Z" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="TELOTRISTAT" /> <name>TELOTRISTAT</name> </activeMoiety> </activeMoiety> <asEquivalentSubstance> <definingSubstance> <code code="8G388563M7" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="TELOTRISTAT ETHYL" /> <name>TELOTRISTAT ETHYL</name> </definingSubstance> </asEquivalentSubstance> </ingredientSubstance> </ingredient></pre>		

Long description including screen readable XML snippet for figure 30

Reference substance (<asEquivalentSubstance> <definingSubstance>)

The code and display name for the active ingredient are selected from the controlled vocabulary (OID 6.14). For use with ACTIR only.

Reference substance Name (<asEquivalentSubstance> <definingSubstance> <name>)

The name must match the display name. For use with ACTIR only.

3.6.1.1.2 Active Ingredient Strength

The strength of an active ingredient is represented differently depending on the type of product. The following three examples show a solid, liquid and a range.

Figure 31 Strength for a Solid Shown in Rendered HTML and Supporting Raw XML Snippet

Strength	<pre> <quantity> <numerator value="160" unit="mg" /> <denominator value="1" unit="1" /> </quantity></pre>
160 mg	

Figure 32 Strength for a Solution Shown in Rendered HTML and Supporting Raw XML Snippet

Strength	<pre> <quantity> <numerator value="10" unit="mg" /> <denominator value="1" unit="mL" /> </quantity></pre>
10 mg in 1 mL	

Figure 33 Strength for a Range Shown in Rendered HTML and Supporting Raw XML Snippet

Strength	<pre><quantity> <numerator xsi:type="URG_PQ"> <low value="2000000000" unit="[CFU]" /> <high value="10000000000" unit="[CFU]" /> </numerator> <denominator value="1" unit="1" /> </quantity></pre>
2,000,000,000 - 10,000,000,000 [CFU]	

3.6.1.2 Inactive Ingredient

All inactive ingredients in a composition should be listed in this section and have the assigned role of IACT. The inactive ingredients are built the same way as the active ingredients. The active moiety (`<activeMoiety>`) and reference substance (`<asEquivalentSubstance>`) do not apply to inactive ingredients.

Amount (`<quantity>`)

A quantity is not required for inactive ingredients, however, if it is provided it will be displayed. The quantity is specified using a numerator and a denominator.

Figure 34 Inactive Ingredients Shown in Rendered HTML and Supporting Raw XML Snippet

Inactive Ingredients	
CROSCARMELLOSE SODIUM (M28OL1HH48)	5 mg
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (RFW2ET671P)	
	<pre><ingredient classCode="IACT"> <quantity> <numerator value="5" unit="mg" /> <denominator value="1" unit="1" /> </quantity> <ingredientSubstance> <code code="M28OL1HH48" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="CROSCARMELLOSE SODIUM" /> <name>CROSCARMELLOSE SODIUM</name> </ingredientSubstance> </ingredient> <ingredient classCode="IACT"> <ingredientSubstance> <code code="RFW2ET671P" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="HYDROXYPROPYL CELLULOSE (1600000 WAMW)" /> <name>HYDROXYPROPYL CELLULOSE (1600000 WAMW)</name> </ingredientSubstance> </ingredient></pre>

Long description including screen readable XML snippet for figure 34

3.6.2 Packaging Status

Information on all packaging formats, including healthcare professional samples that differ from their commercial package sizes, should be provided in this section. Packaging formats that are no longer available should also be provided with the “Date Removed” populated.

At least one packaging format is required for each product. Packaging formats should be listed in the order that they were introduced. Health Canada recognizes that the information in this section does not reflect availability on the Canadian market and the style sheet adds a statement to that effect in the rendered XML PM.

Packaging formats may consist of a single layer of packaging (primary packaging only, e.g., a bottle) or multiple layers (primary and secondary packaging, e.g., a blister in a box). All primary and any applicable secondary packaging should be listed. Packaging that is used for shipping purposes only should not be included. Any difference in how a product is packaged requires a separate entry. Each packaging format exists within its own `<asContent>`.

3.6.2.1 Single layer of packaging

A single package type is used when the product is in direct contact with the outer level of packaging. For example, tablets in a bottle that are not in an additional box.

Figure 35 Single Layer Packaging Shown in Rendered HTML and Supporting Raw XML Snippet

Packaging Status (does not reflect availability on the Canadian Market)				
#	Package Identifier	Package Description	Date Introduced (YYYY-MM-DD)	Date Removed (YYYY-MM-DD)
1		15(Tablet (chewable)) in 1 Bottle	2000-05-22	2009-11-28
2		25(Tablet (chewable)) in 1 Bottle	2005-07-12	
<pre> <asContent> <quantity> <numerator value="15" unit="1" /> <denominator value="1" unit="1" /> </quantity> <containerPackagedProduct> <formCode code="30008000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Bottle" /> </containerPackagedProduct> <subjectOf> <marketingAct> <effectiveTime> <low value="20000522" /> <high value="20091128" /> </effectiveTime> </marketingAct> </subjectOf> </asContent> <asContent> <quantity> <numerator value="25" unit="1" /> <denominator value="1" /> </quantity> <containerPackagedProduct> <formCode code="30008000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Bottle" /> </containerPackagedProduct> <subjectOf> <marketingAct> <effectiveTime> <low value="20050712" /> </effectiveTime> </marketingAct> </subjectOf> </asContent> </pre>				

Long description including screen readable XML snippet for figure 35

Quantity within the package type (<quantity>)

The <quantity> is required for each package type within a packaging format. The quantity is specified using a numerator and a denominator.

Numerator and Denominator (<numerator> and <denominator>)

The <numerator> and <denominator> are composed of a value attribute and a unit attribute. The unit is selected from the controlled vocabulary (OID 6.15). When no units are required (e.g., for a solid dosage form) "1" should be used.

Packaging (<containerPackagedProduct>)

Each instance declares a layer of packaging which includes a package type and may include a package identifier.

Package Identifier (<code>)

Health Canada does not currently use the package identifier at this time, however, it may be used in the future. Therefore, content is not required and there is no specified format for any information that may be provided. If a value is provided, it will be displayed.

Package Description (<formCode>)

The code and display name for the package type are selected from the controlled vocabulary (OID 6.32).

Date Introduced (<effectiveTime> <low>)

This date reflects the authorization date for the submission that included this packaging format. Where the packaging format was introduced via Annual Notification, the date of implementation should be used.

The date format is YYYYMMDD. When this date is not known (at the time of filing only), the <effectiveTime> and <low> should be omitted.

Date Removed (<effectiveTime> <high>)

The Date Removed reflects the end of a packaging format lifecycle. This date should take into account the expiration date of the last lot of the packaging format. This date is not intended to show a temporary removal from use and should be considered final.

This date should be added as part of the next submission that includes a PM update. The date format is YYYYMMDD. The <effectiveTime> and <high> should be omitted until required.

3.6.2.2 Multiple Layers of Packaging

For packaging formats that contain multiple package types (e.g., blisters in a box), multiple <asContent> are required. Any difference in how a product is packaged requires a separate instance. For example, if a product can be packaged with either 1 or 4 vials in a box, then 2 separate packaging formats would be required.

For each packaging format, the first occurrence of <asContent> represents the package type that is in contact with the product (e.g., the blister that contains the tablets). Additional package types are nested within their own <asContent> (e.g., the box that contains the blisters).

Figure 36 Multi-layer Packaging Configuration Shown in Rendered HTML and Supporting Raw XML Snippet

Packaging Status (does not reflect availability on the Canadian Market)				
#	Package Identifier	Package Description	Date Introduced	Date Removed
1	XYZ-988 XYZ-987	2 (Vial) in 1 Box 10 mL in 1 Vial	2015-10-31	
<pre> <asContent> <quantity> <numerator value="10" unit="mL" /> <denominator value="1" /> </quantity> <containerPackagedProduct> <code code="XYZ-987" /> <formCode code="30069000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Vial" /> <asContent> <quantity> <numerator value="2" unit="1" /> <denominator value="1" /> </quantity> <containerPackagedProduct> <code code="XYZ-988" /> <formCode code="30009000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Box" /> </containerPackagedProduct> <subjectOf> <marketingAct> <effectiveTime> <low value="20151031" /> </effectiveTime> </marketingAct> </subjectOf> </asContent> </containerPackagedProduct> </asContent></pre>				

Long description including screen readable XML snippet for figure 36

3.6.3 Product Status

The product status reflects the submission under which a composition was first authorized for use in Canada. This is intended to reflect the Canadian experience with this composition from a safety and pharmacovigilance perspective. The product status information should not change over the lifecycle of the product, regardless of ownership or the assignment of a new DIN. This should only be a single row, that

reflects the beginning and end of a product lifecycle, and not a cumulative list of submissions over the lifecycle of the product.

For generics, the product status should reflect the submission under which the generic was first authorized (not the CRP authorization).

For cross-licensed products, the product status should reflect the submission under which the cross-licensed product was first authorized (not the licensor's authorization).

For biosimilars, the product status should reflect the submission under which the biosimilar was first authorized (not the BRP authorization).

Figure 37 Product Status Shown in Rendered HTML and Supporting Raw XML Snippet

Product Status			
Regulatory Activity Type	Control Number	Date First Authorized in Canada (YYYY-MM-DD)	Date of Cancellation (YYYY-MM-DD)
SNDS	206254	1989-07-12	2015-03-31
<pre> <subjectOf> <approval> <id extension="206254" /> <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> <subjectOf> <marketingAct> <effectiveTime> <low value="19890712" /> <high value="20150331" /> </effectiveTime> </marketingAct> </subjectOf> </pre>			

Long description including screen readable XML snippet for figure 37

Control Number (<approval> <id>)

This is the control number under which this composition was first authorized for use in Canada. This control number will remain the same throughout the life cycle of the product, even if there is a change of ownership. It is recognized that this is not always known at the time of filing, and is considered an expected warning. The control number must be present in the final version submitted post-authorization.

Regulatory Activity Type (<approval> <code>)

This is the regulatory activity type under which this composition was first authorized in Canada. The code and display name for the regulatory activity type are selected from the controlled vocabulary (OID 6.37).

Approval Authority (<territory> <code>)

This is the approval authority under which the product was initially authorized. The value selected is always "CAN", however, this content is not rendered by the style sheet. The code and display name for the regulatory activity type are selected from the controlled vocabulary (OID 6.17).

Date First Authorized in Canada (<marketingAct> <effectiveTime> <low>)

This date of authorization is for the submission under which a composition was first authorized for use in Canada. Different compositions may be authorized at different times and therefore may have different dates. The date format is YYYYMMDD. When this date is not known at the time of filing, the <effectiveTime> and <low> should be omitted. The date is required in the final XML PM submitted post-authorization.

Date of Cancellation (<marketingAct> <effectiveTime> <high>)

The date of cancellation is the date that the DIN for a composition was cancelled. Different compositions may be cancelled at different times and therefore would have different dates. Cancellation date(s) should be added during the submission to remove the information related to the cancelled DIN from the other sections of the PM/XML PM. The product should remain listed even after cancellation if any other compositions are still active. The date format is YYYYMMDD. When this date is not applicable, the <effectiveTime> and <high> should be omitted. The date should be added to the XML PM the next time it is submitted after the cancellation.

3.6.4 Product Characteristics

Product characteristics include physical characteristics and regulatory information about each composition. There are 10 product characteristics (<characteristic>) for each product. Not all characteristics will apply to all products, however all that do apply should be provided. For example, a colourless solution for injection would not have anything listed for colour, shape, size, score, imprint or flavour, while a white, chewable tablet could have all of those characteristics.

Product characteristics are set up to allow for specific types of data to be provided. Some characteristics rely on controlled vocabularies, some allow for additional text to be added to the controlled vocabulary, and some allow for multiple entries for a characteristic to be listed.

Table 4 Product Characteristic Information

Characteristic	Data Type	Object Identifier	Additional text allowed	Multiple entries allowed
Product Type	CV	6.53		
Colour	CV	6.24	Yes	Yes
Shape	CV	6.25	Yes	Yes
Size	PQ	6.15		Yes
Score	CV	6.4		
Imprint	ST	N/A		
Flavour	CV	6.26	Yes	Yes
Pharmaceutical Standard	CV	6.5		Yes
Schedule	CV	6.2		Yes
Therapeutic Class	CV	6.6		Yes

CV (Coded Value): Coded data, specifying a code, OID, display name and in some cases, additional descriptive text.

PQ (Physical Quantity): Quantity, specifying a value and a unit of measure.

ST (String): Free text used for imprint.

Figure 38 Product Characteristic using a Coded Value Shown in Rendered HTML and Supporting Raw XML Snippet

Product Characteristics	
Colour	RED (Red-brown)
	<pre> <subjectOf> <characteristic> <code code="2" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="COLOUR" /> <value code="C48326" codeSystem="2.16.840.1.113883.2.20.6.24" displayName="RED" xsi:type="CV"> <originalText>Red-brown</originalText> </value> </characteristic> </subjectOf></pre>

Long description including screen readable XML snippet for figure 38

Product Characteristic Name (<characteristic> <code>)

The code and display name for the product characteristics are selected from the controlled vocabulary (OID 6.23).

Product Characteristic Value (<characteristic> <value>)

See [Table 4](#) for data types and applicable controlled vocabularies.

Original Text (<originalText>)

Original text is used to further refine the selected characteristics. The length of this text should be kept to a minimum.

Figure 39 Product Characteristic using a Physical Quantity Shown in Rendered HTML and Supporting Raw XML Snippet

Product Characteristics	
Size	5 mm
	<pre> <subjectOf> <characteristic> <code code="4" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="SIZE" /> <value value="5" unit="mm" xsi:type="PQ" /> </characteristic> </subjectOf></pre>

Long description including screen readable XML snippet for figure 39

Product Characteristic Unit (<characteristic> <value>)

The size is composed of at least one value attribute and one unit attribute. Additional pairs of value and unit attributes are permitted to describe the size in two and three dimensions. The value must be an integer (whole number), therefore the unit should be chosen accordingly. The unit is selected from the controlled vocabulary (OID 6.15).

Figure 40 Product Characteristic using a String Shown in Rendered HTML and Supporting Raw XML Snippet

Product Characteristics	
Imprint	ABC;123
	<pre> <subjectOf> <characteristic> <code code="6" codeSystem="2.16.840.1.113883.2.20.6.23" displayName="IMPRINT" /> <value xsi:type="ST">ABC;123</value> </characteristic> </subjectOf></pre>

Long description including screen readable XML snippet for figure 40

Product Characteristic (<characteristic> <value>)

This is the text imprinted on a solid dosage form. The imprint <value> is provided as text. Semi-colons should be used to differentiate the text that appears on one side from the other. If there are line breaks on

a single side, a comma may be used to indicate the line break. There should be no spaces between the characters unless the imprint itself contains a white space.

3.6.5 Multi-Part Products

A multi-part product is any product that has multiple formulations. This concept enables the product information to be captured for each part of the product as well as the overall product.

A multi-part product could have a single DIN (e.g., a multiphasic birth control pill where there are different parts and only the overall product has a DIN) or multiple DINs (e.g., powder for solution with a diluent where each part has its own DIN and the overall product has a DIN). Not all multi-part products are considered kits as defined in [Directive: Assignment of Drug Identification Numbers for Drug Products in Kits, 1997](#).

Multi-part products are coded/created/built similarly to regular products, with a few exceptions to the structure, as follows.

3.6.5.1 The Product

The product information is provided for the multi-part product and each of its parts.

The multi-part product follows the same overall structure as a regular product. It will include some of the product information, the product status, and the packaging status. The route of administration, ingredients, and product characteristics are present in the individual parts only. The manufactured dosage form should always be “Multi-part product” (OID 6.3).

The multi-part product will include a summary of the packaging information and total quantities from each of the parts in a table called “Quantity of Parts”. The information displayed comes from the data provided in each of the parts.

Figure 41 Multi-Part Product Shown in Rendered HTML and Supporting Raw XML Snippet

HC-BRAND NAME6				
example of multipart product single din				
Product Information				
Brand Name		HC-BRAND NAME6		
Non-Proprietary Name		example of multipart product single DIN		
Drug Identification Number (DIN)		01234566		
Route of Administration		See below		
Manufactured Dosage Form		See below		
Product Status				
Regulatory Activity Type	Control Number	Date First Authorized in Canada (YYYY-MM-DD)	Date of Cancellation (YYYY-MM-DD)	
ANDS	210325	2004-08-04		
Packaging Status (does not reflect availability on the Canadian Market)				
#	Package Identifier	Package Description	Date Introduced (YYYY-MM-DD)	Date Removed (YYYY-MM-DD)
1		7(Blister) in 1 Box 1(Multi-part product) in 1 Blister	2004-08-04	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1			2	
Part 2			2	
Part 3			4	
<pre> <subject> <manufacturedProduct> <manufacturedProduct> <code code="01234566" /> <name>HC-BRAND NAME6</name> <formCode code="32" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="Multi-part product" /> <asEntityWithGeneric> <genericMedicine> <name>example of multipart product single DIN</name> </genericMedicine> </asEntityWithGeneric> <asContent> <quantity> <containerPackagedProduct> <formCode code="30007000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Blister" /> <asContent> <quantity> <numerator value="7" unit="1" /> <denominator value="1" /> </quantity> <containerPackagedProduct> <formCode code="30009000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Box" /> </containerPackagedProduct> </asContent> <marketingAct> <effectiveTime> </marketingAct> </subjectOf> </asContent> </asContent> </part> <part> <part> </manufacturedProduct> <subjectOf> <approval> </subjectOf> <subjectOf> <marketingAct> </subjectOf> </manufacturedProduct> </subjectOf> </approval> </subjectOf> </part> </part> </asContent> </manufacturedProduct> </subject> </pre>				

Long description including screen readable XML snippet for figure 41

3.6.5.2 The Parts

Each part of a multi-part product will contain all the product detail information applicable to that part. The parts also follow a similar overall structure as a regular product, except that they are contained within <part> and <partProduct> elements.

Figure 42 Part of a Multi-Part Product Shown in Rendered HTML and Supporting Raw XML Snippet

HC-BRAND NAME7a
example of actim tablet
Product Information
Product Composition
Product Characteristics
Product Status
Packaging Status (does not reflect availability on the Canadian Market)
<pre> <part> <quantity> <partProduct> <code code="01234568" /> <name>HC-BRAND NAME7a</name> <formCode code="85" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="Tablet" /> <asEntityWithGeneric> <ingredient classCode="ACTIM"> <ingredient classCode="IACT"> <ingredient classCode="IACT"> <ingredient classCode="IACT"> <ingredient classCode="IACT"> <asContent> </partProduct> <subjectOf> <subjectOf> <subjectOf> <subjectOf> <subjectOf> <subjectOf> <subjectOf> <subjectOf> <consumedIn> </part></pre>

Long description including screen readable XML snippet for figure 42

Total Product Quantity (<part> <quantity>)

This is the total quantity of each part.

Package Quantity (<part> <partProduct> <asContent>)

This is a summary of the package description of each part. This is handled in the same way as for a single product (see 3.6.2)

3.7 Additional Concepts

3.7.1 Format

It is highly recommended that sponsors review their rendered XML PM prior to submitting to ensure that the content is in line with the PM Guidance and Master Template.

The style sheet controls the majority of the formatting, including bolding and spacing based on the PM Master Template and its related controlled vocabulary.

The following recommendations should be applied throughout the XML PM where formatting is not covered by the style sheet.

- Formatting should be in line with the PM Master Template
- Underlining should only be used for hyperlinks
- Use of bold and italics should be limited
- Limit the use of line breaks to avoid unnecessary white space

3.7.2 Images

The XML PM uses .jpg files to render images. No other file formats are permitted. All images must be defined and provisioned for use to be placed within the XML PM. Each distinct image is assigned a unique ID attribute within the document, which allows an image to be referenced multiple times throughout the XML PM. The .jpg files should be placed in the same folder as the .xml file within a regulatory transaction.

The style sheet displays all images without modification. No resizing or resolution changes are made, so all images are rendered as-is. Therefore, images should use a sufficient resolution to be clear and readable across different screen sizes and devices. Image files must not exceed 1MB.

When an image contains language-specific text, separate image files are required. For example, when text is included within the image, the image in the French XML PM should have French text. When an image contains no text, it can be used for both the English and French XML PM, allowing the same file to be referenced in both.

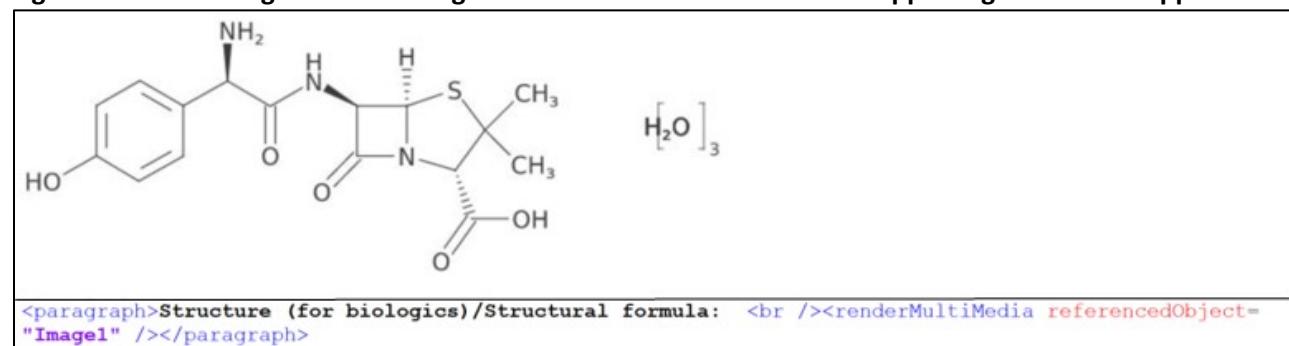
Figure 43 Image Definition Supporting Raw XML Snippet

```
<component>
  <observationMedia ID="Image1">
    <text>Structural formula of amoxicillin</text>
    <value xsi:type="ED" mediaType="image/jpeg">
      <reference value="Structural-formula-amoxicillin.jpg" />
    </value>
  </observationMedia>
</component>
```

Definition of image (<observationMedia> ID attribute)

This ID is used when defining an image. The identification should be assigned a unique value within the XML PM. Once an image has been defined, it must be referenced where the image is to be shown.

Figure 44 Referencing a Defined Image Shown in Rendered HTML and Supporting Raw XML Snippet



Alternative Text (<text>)

Alternative text is a written short description of an image that assistive technologies like screen readers can read out loud, or convert to Braille. It also can be displayed in place of the image if it cannot be displayed. This provides valuable information and context for users who can't see the image.

The images included in the XML PM must have alternative text, however, the requirements differ depending on the complexity or use of the image. Three types of images tend to be included in the XML PM, each of which has different requirements for alternative text

1. The chemical structure

This is the only image required by the PM Master Template. The alternative text for this image should state "structural formula of ..." or 'structure of...', as applicable.

2. Dosing instructions

These images are accompanied by nearby text that communicates the intent of the image. For example, the image below provides written instructions that the image portrays. In these cases, the alternative text should only state "decorative".

Figure 45 An example of a decorative image

Step 4: Choose and clean the injection site

a) Choose an injection site (Fig. D) on:

- Top of the thighs.
- Abdomen (inject at least 5 centimeters away from the belly button).



Fig. D

3. Complex images and graphs

These images tend to be found in Part 2, supporting clinical trial results. These are very complex and contain a lot of information. For accessibility purposes, the short alternative text alone is not sufficient for these images, a long description is also required.

Recognizing that this accessibility requirement is not limited to the XML PM, a comprehensive approach is needed. Therefore, implementation will be incremental. Initially, the image title (<caption>) will be repeated as alternative text. While this is not optimal, it will allow for the development of guidelines and review processes to support full implementation.

Naming of .jpg file (<renderMultiMedia> referencedObject attribute)

The .jpg file names must be unique across both the English and French versions of the XML PM to avoid naming conflicts with other images. This allows the .xml file to reference the correct .jpg file.

The image files should be named with the following best practices:

- Lowercase only (as per eCTD specification)
- Should be concise
- Separate words with hyphens (no spaces)
- Only alpha-numeric characters should be used, which means accented characters are not permitted

Other than a short hyphen to separate words, no punctuation or other characters should be included.

3.7.3 Tables

Tables are used throughout the XML PM. There are several items to consider to ensure that the data within these tables are rendered correctly regardless of the screen size and are accessible.

Figure 46 Creation of a Table Shown in Rendered HTML and Supporting Raw XML Snippet

Table 1 - Reconstitution			
Vial Size	Volume of Diluent To Be Added to Vial	Approximate Available Volume	Concentration Per mL
Text	Text	Text	Text
<pre><table ID="Table1" rules="all" frame="border"> <caption>Table 1 - Reconstitution</caption> <thead> <tr align="center"> <th>Vial Size</th> <th>Volume of Diluent To Be Added to Vial</th> <th>Approximate Available Volume</th> <th>Concentration Per mL</th> </tr> </thead> <tbody> <tr> <td>Text</td> <td>Text</td> <td>Text</td> <td>Text</td> </tr> </tbody> </table></pre>			

Long description including screen readable XML snippet for figure 46

Table Identification (`<table>` ID attribute)

This ID is used when creating a hyperlink to the table. The identification should be assigned a unique value within the XML PM.

Table border and gridlines (`<table>` rules and frame attributes)

This defines the border and the gridlines of the table. Tables should be defined with `rules="all"` `frame="border"`. While other table attributes are supported, these have been tested using different screen sizes and will allow the style sheet to make the required adjustments to ensure the rendered table is readable.

Table Title (`<caption>`)

A caption functions like a heading for a table. Most accessibility tools identify the content of these captions. Captions help users to understand what the table is about and decide if they want to read it. All tables in the PM must have a caption, with the RMLC being the only exception.

Table Headers (`<thead>`)

Table Header is used to group header cells.

Header Cells (`<th>`)

Header cells define column headings. This is important for accessibility tools to identify the contents of the column.

Table Body (`<tbody>`)

Table Body is used to group table rows and data cells.

Table Rows (<tr>)

Table rows are used to group one or more header cells or data cells.

Data Cells (<td>)

Data cells define table data.

3.7.3.1 Table Formatting

The style sheet has been designed to ensure a consistent display of the PM on different devices and screen sizes. Sponsors should not add formatting that will override the style sheet.

The style sheet controls the following table formatting characteristics:

- Captions (bold and centered)
- Border colour (black)
- Header row shading (grey)
- Header text (bold and center-aligned)
- Table width (100%)

3.7.3.2 Cell Shading

Cell shading can be used to identify cells where a value is not applicable or not expected. To shade cells, use the styleCode attribute “table-secondary”.

Figure 47 Cell Shading within a Table Shown in Rendered HTML and Supporting Raw XML Snippet

T _{MAX} ³ (h)			
T _{1/2} ⁴ (h)			
<pre> <tr> <td>T<sub>MAX</sub><footnote>Expressed as the median (range) only</footnote>
(h)</td> <td /> <td /> <td styleCode="table-secondary"></td> </tr> <tr> <td>T<sub>1/2</sub><footnote>Expressed as the arithmetic mean (CV %) only</footnote>
(h)</td> <td /> <td /> <td styleCode="table-secondary"></td> </tr> </pre>			

Long description including screen readable XML snippet for figure 47

3.7.4 Hyperlinks

There are two types of hyperlinks used in the XML PM: external and internal, and both are underlined by the style sheet.

Hyperlink (<linkHtml> href attribute)

This is used to place a hyperlink within the XML PM.

3.7.4.1 External Hyperlinks

External hyperlinks are used to link to a website. The URL does not display on the rendering - only the human-readable name of the link (e.g., “Health Canada website”) is shown. Unlike the Word/PDF version, the URL is not required to be visible when reading the rendered representation of the XML PM through a web browser. If the XML PM is printed (either to paper or to PDF), it will show the URL immediately after the name of the link.

Figure 48 An External Hyperlink Shown in Rendered HTML and Supporting Raw XML Snippet

- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the [Health Canada Drug Product Database](#), the [manufacturer's website](#), or by calling 1-800-phone number.

```
<item>Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the <linkHtml href="https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html">Health Canada Drug Product Database</linkHtml>, the <linkHtml href="https://www.yourwebsite.com">manufacturer's website </linkHtml>, or by calling 1-800-phone number.</item>
```

Long description including screen readable XML snippet for figure 48

3.7.4.2 Internal Hyperlinks

Internal hyperlinks are used to link to other content in the PM which is indicated by an href attribute that starts with '#' followed by the ID attribute. The ID attribute must be assigned a unique value within the XML PM to ensure it functions correctly. Internal hyperlinks can be made to point to a section or to content within a section.

To link to a section within the XML PM, the <section ID> or the <id root> from that section is referenced.

Figure 49 A Hyperlink to a Section Shown in the Rendered HTML and the Supporting Raw XML Snippet

1 INDICATIONS, 1.1 Pediatrics	2023-12
<pre><tr> <td align="left">1 INDICATIONS, <linkHtml href="#b9db4ce0-3f46-434a-bd7b-4a3e010adaad">1.1 Pediatrics </linkHtml></td> <td>2023-12</td> </tr></pre>	

Long description including screen readable XML snippet for figure 49

To link to specific content within a section, a hyperlink needs to be first defined where it will point to using the ID attribute. This can be linked to <paragraph>, <table>, <list>, <content>, or <renderMultimedia>. The ID should be assigned a unique value within the XML PM. The unique ID can then be hyperlinked to anywhere within the XML PM.

Figure 50 A Hyperlink to content within a Section Shown in the Rendered HTML and the Supporting Raw XML Snippet

Hyperlink definition – where the hyperlink goes to
Narrative. Example of end point when creating an internal hyperlink to specific information.
<pre><paragraph ID="Hyperlink1">Narrative. Example of end point when creating an internal hyperlink to specific information.</paragraph></pre>
Hyperlink reference – starting point of hyperlink
This is an example of an internal hyperlink (see Specific information)
<pre><paragraph>This is an example of an internal hyperlink (see <linkHtml href="#Hyperlink1">Specific information</linkHtml>)</paragraph></pre>

Long description including screen readable XML snippet for figure 50

3.7.5 Boxed Statements

Boxed statements are required by the PM Master Template, and are used to draw attention to specific safety-related information. These statements should only be boxed using the styleCode attribute. Creating boxed statements using single-celled tables causes accessibility issues and must not be used.

Figure 51 Boxed Text with a Single Text Style Shown in the Rendered HTML and the Supporting Raw XML Snippet

- Text
- Text

```
<text>
<list styleCode="Boxed First Last">
    <item>Text</item>
    <item>Text</item>
</list>
</text>
```

In this example, a single styleCode attribute is used with a value of “Boxed First Last”.

Figure 52 Boxed Text with Multiple Text Style Shown in the Rendered HTML and the Supporting Raw XML Snippet

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](#) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

```
<paragraph styleCode="Boxed First">
    <content styleCode="bold">Reporting side effects</content>
</paragraph>
<paragraph styleCode="Boxed">You can report any suspected side effects associated with the use of health products to Health Canada by:</paragraph>
<list styleCode="Boxed unordered">
    <item>Visiting the Web page on <linkHtml href="https://www.canada.ca/drug-device-reporting">Adverse Reaction Reporting</linkHtml> for information on how to report online, by mail or by fax; or</item>
    <item>Calling toll-free at 1-866-234-2345.</item>
</list>
<paragraph styleCode="Boxed Last">
    <content styleCode="italics">NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</content>
</paragraph>
```

Long description including screen readable XML snippet for figure 52

In this example, multiple styleCode attributes are used. The first occurrence has a value of “Boxed First”, followed by occurrences of “Boxed”, and finishing with a value of “Boxed Last”.

3.7.6 Footnotes

The style sheet automatically renders footnotes using numbers. Footnotes are defined using the `<footnote>` within the following: `<paragraph>`, `<list>` `<item>`, and within tables in the `<th>` `<td>`.

Figure 53 Footnotes Shown in the Rendered HTML and the Supporting Raw XML Snippet

Table 3 - Dosage Forms, Strengths, and Composition		
Route of Administration ¹	Dosage Form/Strength/Composition ²	Non-Medicinal Ingredients
oral	tablet 5 mg, 10 mg	Ingredient ¹ , Ingredient, Ingredient
1 This is an example of long footnote text that will span all of the table columns and uses the full width of the table.		
2 This is an example of a second footnote text.		
<pre> <table ID="Table3" rules="all" frame="border"> <caption>Table 3 - Dosage Forms, Strengths, and Composition</caption> <colgroup span="3" /> <thead> <tr align="center"> <th>Route of Administration<footnote ID="Footnote1">This is an example of long footnote text that will span all of the table columns and uses the full width of the table.</footnote></th> <th>Dosage Form/Strength/Composition<footnote>This is an example of a second footnote text.</footnote></th> <th>Non-Medicinal Ingredients</th> </tr> </thead> <tbody> <tr> <td>oral</td> <td>tablet 5 mg, 10 mg</td> <td>Ingredient<footnoteRef IDREF="Footnote1" />, Ingredient, Ingredient</td> </tr> </tbody> </table></pre>		

Long description including screen readable XML snippet for figure 53

Footnote Identification (`<footnote>` ID attribute)

This ID is used when creating a footnote. The identification should be assigned a unique value within the XML PM.

Footnote content (`<footnote>`)

The text of the footnote.

Footnote Reference (`<footnoteRef>` IDREF attribute)

The footnote reference allows the use of a previously defined footnote in a different location.

Footnote Content Width (`<colgroup>` span attribute)

When table footnotes are used, the `<colgroup>` span attribute should be set to the number of columns to use the full table width. This is important so that the footnotes run the width of the whole table instead of just one column. While there may be other ways to achieve this, the use of `<colgroup>` allows for the correct rendering on various screen sizes.

3.7.7 Special Characters

XML uses five symbols to mark how content is being used within the .xml document. When those symbols are part of the content, the use of escape characters is required to be a valid XML file.

Table 5 Symbols and Associated Escape Characters

Symbol	Escape character
"	"
'	'
<	<
>	>
&	&

Figure 54 Escape Character Use Shown in the Rendered HTML and the Supporting Raw XML Snippet

D&C RED NO. 30 ALUMINUM LAKE (GE75M6YV5W)
<pre> <ingredient classCode="IACT"> <ingredientSubstance> <code code="GE75M6YV5W" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="D&amp;C RED NO. 30 ALUMINUM LAKE" /> <name>D&amp;C RED NO. 30 ALUMINUM LAKE</name> </ingredientSubstance> </ingredient></pre>

3.8 Relationship of Unique Identifiers

Figure 55 Relationship of Unique XML PM Identifiers to Health Canada's Unique Identifiers

Dossier ID		
Regulatory activity #1 Control number 123456	Regulatory activity #2 Control number 123432	Regulatory activity #3 Control number 123454
Language of document <languageCode> ENGLISH	<p>.xml file name <id> id root="bd28a915-72c1-4c9b-95ec-f80140f9792e"/></p> <p>Document name <setId> <setId root="d4c004d2-976d-4aec-8cdd-a71bdb11d4b1" /></p>	<p>.xml file name <id> id root="e796df04-2fd5-4894-8b22-6234e96e77d2"/></p>
Language of document <languageCode> FRENCH	<p>.xml file name <id> id root="1262a4e6-bc34-413e-bbf4-a8ec3fb512e1"/></p> <p>Document name <setId> <setId root="c99b9224-f519-4e52-bdbe-1750a5b1a26e" /></p>	<p>.xml file name <id> id root="aee16a81-8021-4058-86dc-154ba5b0516c"/></p>

Long description for figure 55

Language Code `<languageCode>`

This is what determines the language of the XML PM. The English and French XML PMs cannot be authored as one document. They must be provided as two separate, language-specific XML PMs.

.xml file name `<id>`

For each regulatory activity, there is a unique document ID for each language-specific XML PM. The document ID doesn't need to change for revisions made during that regulatory activity's review process.

Document Name `<setId>`

Over the lifecycle of the product, the English and French XML PMs have their own unique `<setId>`. The `<setId>` links together all the XML PMs for a specific language over the lifecycle of the product.

4. Validation

Validation of the XML PM is completely independent of the eCTD validation. The XML PM validation results have no impact on the eCTD validation or the progression of a submission. The XML PM validation is based on the [published rules](#), the purpose of which is to ensure a valid XML file (and associated images) is

provided to Health Canada. Sponsors are encouraged to use a commercially available tool to validate their XML PM prior to filing to Health Canada.

Health Canada validates each XML PM upon receipt via the Gateway. An XML PM validation report is emailed as a PDF attachment to the contact listed on the regulatory transaction file provided in the eCTD transaction associated with the XML PM. This report will describe all error, warning, and information messages.

The XML PM validation is technical in nature and does not validate the content. It is based on schema constraints and business rules that confirm the document is authored correctly and that the controlled vocabulary terms match the published controlled vocabulary list. The rules also ensure that any images are referenced correctly and include alternative text. Rules are assigned a level of severity based on the level of impact on the XML PM, should the rule not pass. The XML PM validation report lists all the rules and indicates the results of each as either a pass or a message related to the severity of the rule, which helps to indicate the cause of a rule not passing.

1. Error

Critical compliance issues that may compromise the usability of the XML PM.

- Errors in the XML PM submitted at the time of filing should be addressed prior to submitting the final XML PM. Do not submit a revised version during the screening or review of the submission.
- Errors in the XML PM submitted post-authorization that are not related to approved content must be corrected immediately.
- Errors related to approved content (e.g. controlled vocabulary term change) should be resolved during a subsequent submission that requires a PM update.

2. Warning

An issue that may compromise the usability of the XML PM but requires further inspection.

- Warnings in the XML PM submitted at the time of filing related to information that is unknown (e.g., DIN, dates, control number) are expected.
- Any warnings for unknown information in the XML PM submitted post-authorization must be corrected immediately.
- Warnings for statements that may not apply to a product (e.g., Notice of Compliance with conditions (NOC/c) statement) require no further action.

3. Information

Issue that is not likely to compromise the usability of the XML PM but may require further inspection. These information messages serve as a reminder that optional information has not been provided.

Assistance with validation and correction of errors or warnings is available from the [XML PM Team](#).

5. Appendices

Appendix A - Scope of Mandatory Requirement for the XML PM

In-scope submission types:

- New Drug Submissions (NDS)
- Extraordinary Use New Drug Submission (EUNDS)

Out-of-Scope submission types

- Administrative New Drug Submission (Admin NDS)
- New Drug Submission for Priority Review
- New Drug Submission - Covid (NDS-CV)
- Advanced Consideration for Notice of Compliance with Conditions (NOC/c)
- Supplement to a New Drug Submission (SNDS)
- Abbreviated New Drug Submission (ANDS)
- Supplement to an Abbreviated New Drug Submission (SANDS)
- Supplement to an Extraordinary Use New Drug Submission (EUSNDS)
- Abbreviated Extraordinary Use New Drug Submission (EUANDS)
- Supplement to an Abbreviated Extraordinary Use New Drug Submission (EUSANDS)
- Supplement to a New Drug Submission - Confirmatory (SNDS-c)
- Supplement to an Abbreviated New Drug Submission - Confirmatory (SANDS-c)
- Application for a Drug Identification Number for a pharmaceutical product (DINA)
- Application for a Drug Identification Number for a biological product (DINB)
- Notifiable Change (NC)(for human biologic or radiopharmaceutical drug quality changes)
- Post-authorization Division 1 Change for a pharmaceutical product (PDC-prescription)
- Post-authorization Division 1 Change for a biologic drug product (PDC-B)

Appendix B - Codes, Display Name and Source of Terms in the Controlled Vocabulary List

Table 6 Codes, Display Name and Source of Terms in the Controlled Vocabulary List

OID / Code	Display Name (EN)	Source
2.16.840.1.113883.2.20.6.10	DOCUMENT TYPE	HPFB
2.16.840.1.113883.2.20.6.14	INGREDIENT IDENTIFIER	FDA
2.16.840.1.113883.2.20.6.15	UNITS OF MEASURE	UCUM
2.16.840.1.113883.2.20.6.17	COUNTRY CODE	ISO
2.16.840.1.113883.2.20.6.2	SCHEDULE	HPFB
2.16.840.1.113883.2.20.6.23	PRODUCT CHARACTERISTICS	HPFB
2.16.840.1.113883.2.20.6.24	COLOUR	FDA
2.16.840.1.113883.2.20.6.25	SHAPE	FDA
2.16.840.1.113883.2.20.6.26	FLAVOUR	FDA
2.16.840.1.113883.2.20.6.29	LANGUAGE CODE	HPFB
2.16.840.1.113883.2.20.6.3	DOSAGE FORMS	HPFB
2.16.840.1.113883.2.20.6.31	COMPANY IDENTIFIER	DPD
2.16.840.1.113883.2.20.6.32	PACKAGE TYPE	EDQM
2.16.840.1.113883.2.20.6.37	REGULATORY ACTIVITY	HPFB
2.16.840.1.113883.2.20.6.39	INGREDIENT ROLE	HL7
2.16.840.1.113883.2.20.6.4	SCORE	HPFB
2.16.840.1.113883.2.20.6.5	PHARMACEUTICAL STANDARD	DPD
2.16.840.1.113883.2.20.6.53	PRODUCT TYPE	HPFB
2.16.840.1.113883.2.20.6.6	THERAPEUTIC CLASS	WHO
2.16.840.1.113883.2.20.6.63	MASTER TEMPLATE	HPFB
2.16.840.1.113883.2.20.6.65	STYLE SHEET VERSION	HPFB
2.16.840.1.113883.2.20.6.7	ROUTE OF ADMINISTRATION	EDQM

Appendix C - Definitions

Attributes

The XML attribute is a part of an XML element. The addition of an attribute in an XML element gives more precise properties of the element.

Elements

The XML elements are the basic building blocks of the XML document. It is used as a container to define text elements, attributes, media objects, etc.

Extensible Markup Language (XML)

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

Globally Unique Identifier (GUID)

A GUID is a unique number that is used as an identifier. GUIDs are used to name XML PM files and as unique identifiers within XML PM files.

Rendering

A means of displaying the XML content in a display that is easy to read and compatible with accessibility tools. Rendering of the XML PM files is performed using a Health Canada-defined style sheet.

Structured Product Labeling (SPL)

SPL is a document markup standard approved by Health Level Seven (HL7) and adopted by the FDA as a mechanism for exchanging product and facility information. Health Canada is adopting the SPL for the XML PM. The SPL Schema is a set of rules describing what data is permitted in the XML PM, as well as the overall structure of data elements.

Style Sheet

The XML PM style sheet defines the layout and formatting of the XML PM content will be made available in a human-readable format. XML PM style sheet is based on the World Wide Web Consortium's (W3C) Cascading Style Sheet (CSS) standard specification and the Government of Canada's Aurora Design System.

Validation

XML PMs are being validated against a pre-specified set of rules. Each XML PM is validated upon receipt. The validation process ensures the XML PM meets the established requirements prescribed in the SPL schema and the Health Canada validation rules.

Appendix D - Long descriptions and/or raw XML snippets for images

Long description 1: Long description for figure 5

A screenshot of the Controlled Vocabulary Listing website is used to show an example of the information and layout of the webpage. The information in the screenshot is grouped into 4 sections.

The first section is the title: Terms for 2.16.840.1.113883.2.20.6.53

The second section contains 6 pieces of information about the controlled vocabulary list organized into two columns. 1=OID (2.16.840.1.113883.2.20.6.53); 2=English Display Name (Product Type); 3=French Display name (CLASSE DU PRODUIT); 4=Source (HPFB); 5=Status (Active); 6=Last updated (2021-06-09 15:39:38). To the far right is a button labelled 'Download XML'.

The third section contains 3 functional tools for the list of terms that follows. The first tool is a filter. The term 'Filter items' is followed by a box in which text would be added on the live webpage to filter the content. The second tool is a summary of entries being shown and includes the total. The number of entries will adjust based on the filter. In this case, showing 1 to 3 of 3 entries. The third tool provides an option to different numbers of entries that are selected from a drop down list. This screenshot is showing 10 entries.

The final section is a table lists the terms that are part of the controlled vocabulary. The table has 6 columns and this example shows 4 rows. The first row of the table states the title of each column.

Subsequent rows each contain the applicable information for each term listed. Table Headings: Column 1=Codes; Column 2=English Display Name; Column 3=French Display Name; Column 4=Source; Column 5=Status; Column 6=Last updated. Each column can be sorted ascending or descending, marked by two arrows – one pointing up and the other pointing down. In this example, there are three rows of data. Row 1: Code=1; English Display Name=Pharmaceutical; French Display Name=Pharmaceutique; Source=HPFB; Status=Active; Last updated=2021-06-09 15:34:07. Row 2: Code=2; English Display Name=Biologic; French Display Name=Biologiques; Source=HPFB; Status=Active; Last updated=2021-06-09 15:34:07. Row 3: Code=4; English Display Name=Radiopharmaceutical; French Display Name=Radiopharmaceutique; Source=HPFB; Status=Active; Last updated=2021-06-09 15:34:07. Back to Figure 5.

Long Description 2: Screen readable XML snippet for figure 6

Raw XML snippet: <?xml version="1.0" encoding="UTF-8"?><?xml-stylesheet type="text/xsl" href="https://health-products.canada.ca/product-monograph/style-sheet/v_1_0/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://health-products.canada.ca/product-monograph/schema/SPL.xsd"> <id root="e24f574b-7e12-4374-b010-b808e0b108aa" /><code code="4" codeSystem="2.16.840.1.113883.2.20.6.10" displayName="MASTER TEMPLATE" /><title>Sample Only - Not Intended to Reflect Actual Products.</title><effectiveTime value="20241201"></effectiveTime> <languageCode code="1" codeSystem="2.16.840.1.113883.2.20.6.29" displayName="ENGLISH" /><setId root="ac9c8e28-2798-4134-8197-2b249d836002" /><versionNumber value="10" /><author><component>(structuredBody)<component><component><component><component><component><component><component><component><component></structuredBody></component></component></document>. Back to Figure 6

Long description 3: Screen readable XML snippet for figure 7

Raw XML snippet: <component><structuredBody><component><section ID="f6ac9de5-be91-442c-9579-5bc9ebd36902"><id root="bdeefc11-4315-41e3-8c56-83e8bf4f770b" /><code code="OMP" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="MANUFACTURED PRODUCT" /><title>MANUFACTURED PRODUCT</title><effectiveTime value="20241201" /><subject><subject><subject><subject><subject><subject><subject></section></component>. Back to Figure 7.

Long description 4: Long description including screen readable XML snippet for figure 8

A screenshot of the HTML rendering shows a major section heading followed by a subsection heading. In this example, the major section heading is PART 1: HEALTHCARE PROFESSIONAL INFORMATION, written in all capital letters in white bold font on a dark blue background. The subsection heading is 1 Indications written in all capital letters in black bold font on a white background. This is followed by the xml snippet used to produce it. Some elements have been collapsed for brevity.

```
<component><section ID="d6a947eb-e2be-45c0-8b2e-15d0d0eebea8"><id root="e6bb83b9-2602-4f96-9077-b8b9535c254e" /><code code="pi00" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="PART 1: HEALTHCARE PROFESSIONAL INFORMATION" /><title>PART 1: HEALTHCARE PROFESSIONAL INFORMATION</title><effectiveTime value="20241201" /><component><section ID="c2ea4fad-2b79-4dbc-8d99-6843adc2dec8"><id root="aa3f869a-7734-425a-85d8-b8bd4d3500a5" /><code code="pi01" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="1 INDICATIONS" /><title>1 INDICATIONS</title><text><effectiveTime value="20210101" /><component><component></section></component>
```

Back to Figure 8.

Long description 5: Long description including screen readable XML snippet for figure 9

A screenshot of the HTML rendering shows a major section heading followed by text. In this example, the major section heading is written in all capital letters in white bold font on a dark blue background: BIOSIMILAR BIOLOGIC DRUG. The text that follows is written in black italic font on a white background: Biosimilar BRAND NAME (non-proprietary name) is a biosimilar biologic drug (biosimilar) to Reference biologic drug BRAND NAME (non-proprietary name). A biosimilar is a biologic drug that was granted authorization based on a demonstration of similarity to a version previously authorized in Canada, known as the reference biologic drug.

This is followed by the xml snippet used to produce it.

```
<component><section ID="d7ceb5c1-7ee9-4fd2-884e-7a50c06b27e1"><id root="dd1e1c41-f0d3-4ba8-b1f5-bd009a5dd5a8" /><code code="0BBD" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="BIOSIMILAR BIOLOGIC DRUG" /><title>BIOSIMILAR BIOLOGIC DRUG</title><text><paragraph><content styleCode="italics">Biosimilar BRAND NAME (non-proprietary name) is a biosimilar biologic drug (biosimilar) to Reference biologic drug BRAND NAME (non-proprietary name). A biosimilar is a biologic drug that was granted authorization based on a demonstration of similarity to a version previously authorized in Canada, known as the reference biologic drug.</content></paragraph></text><effectiveTime value="20241201" /></section></component>
```

Back to Figure 9.

Long description 6: Long description including screen readable XML snippet for figure 10

A screenshot of the HTML rendering shows the top section of the Title Page. The text “TITLE PAGE” is shown in bold, white letters on a dark blue background. That is followed by seven lines of text, which is all centered in regular black font on a white background unless otherwise noted. Line 1=Product Monograph (written in all capital letters). Line 2=Including Patient Medication Information (written in all capital letters). Line 3= Pr (superscript) Brand Name (Bold font, all capital letters) registered trademark symbol (superscript). Line 4=non-proprietary name (regular font, lower case letters). Line 5=Dosage Form, For RoA use, Strength (regular font, lower case letters except for first letter of each word). Line 6=Pharmaceutical Standard (regular font, lower case letters except for first letter of each word). Line 7=Therapeutic Classification (regular font, lower case letters except for first letter of each word).

This is followed by the xml snippet used to produce it.

```
<component><section ID="d8d30d86-e343-48f4-9cec-524834b3803b"><id root="eed00b53-cdb2-4aa6-9e82-88b7d793b208" /><code code="OTP" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="TITLE PAGE" /><title>TITLE PAGE</title><effectiveTime value="20210101" /><component><section ID="be75cfb9-3131-4903-800b-267427388a13"><id root="b9db4be0-3f46-437a-bd7b-4a3e010afaad" /><code code="0tp1.1" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Title"
```

/><title>Title</title><text><paragraph>PRODUCT MONOGRAPH</paragraph><paragraph>INCLUDING PATIENT MEDICATION INFORMATION</paragraph>
<paragraph><content styleCode="bold">^{Pr} BRAND NAME [®]</content></paragraph><paragraph>non-proprietary name</paragraph><paragraph>Dosage Form, For RoA use, Strength</paragraph><paragraph>Pharmaceutical Standard</paragraph><paragraph>Therapeutic Classification</paragraph>
. Back to Figure 10.

Long description 7: Long description including screen readable XML snippet for figure 11

A screenshot of the HTML rendering shows the company information portion of the Title Page. There are four lines of text, in regular black font on a white background. Line 1= Company Name 1. Line 2=Street address. Line 3=City, PROV, Postal code. Line 4=Web address.

This is followed by the XML snippet used to produce it. <component><section ID="f187daf9-5e75-425a-9de6-f6ce1af2a965"><id root="ac26f58c-721a-4c51-8bbc-c9dddb1f1233"/><code code="0tp1.2" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Company Name and Address"/><title>Company Name and Address</title><text><paragraph>Company Name 1
Street address
City, PROV Postal code
Web address</paragraph></text><effectiveTime value="20210101"/></section></component>. Back to Figure 11.

Long description 8: Long description including screen readable XML snippet for figure 12

A screenshot of the HTML rendering shows the date of authorization on the title page when the date is unknown (at the time of filing). There is only one line of text: Line 1=Date of authorization: (written in bold black letters on a white background).

This is followed by the XML snippet used to produce it. <component><section ID="bf2dab4e-fd04-4ec9-9cdc-247188622d0f"><id root="e5f1dea3-d907-4664-b46f-e1d9736d47af"/><code code="0tp1.3" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Date of Authorization:" /><title>Date of Authorization:</title><effectiveTime value="20241201"/></section></component>. Back to Figure 12.

Long description 9: Long description including screen readable XML snippet for figure 13

A screenshot of the HTML rendering shows the date of authorization on the title page when the date is known (post-authorization). There are two lines of text: Line 1=Date of authorization: (written in bold black letters on a white background); Line 2=2010-02-05 (written in plain black text on a white background).

This is followed by the XML snippet used to produce it. <component><section ID="bf2dab4e-fd04-4ec9-9cdc-247188622d0f"><id root="e5f1dea3-d907-4664-b46f-e1d9736d47af"/><code code="0tp1.3" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Date of Authorization:" /><title>Date of Authorization:</title><text><paragraph>2010-02-15</paragraph></text><effectiveTime value="20241201"/></section></component>. Back to Figure 13.

Long description 10: Long description including screen readable XML snippet for figure 14

A screenshot of the HTML rendering shows the control number on the title page. There are two lines of text: Line 1=Control Number: (written in bold black letters on a white background); Line 2=123456 (written in plain black text on a white background).

This is followed by the XML snippet used to produce it. <component><section ID="ebc3f3dc-71be-424f-91ef-8aca8c138b21"><id root="efd8c4c1-d0dd-434d-b1c2-4daa18752fa8"/><code code="0tp1.5" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Control Number:" /><title>Control Number:</title><text><paragraph>123456</paragraph></text><effectiveTime value="20210101"/></section></component>. Back to Figure 14.

Long description 11: Long description including screen readable XML snippet for figure 15

A screenshot of the HTML rendering shows the trademark statement as a footer on the title page. A single line of plain black text on a white background: BRAND NAME (superscript registered trademark symbol) is a registered trademark of COMPANY NAME.

This is followed by the raw XML snippet used to produce it. <component><section ID="e2d4279e-5fca-4d26-898d-02548a217ab9"><id root="f17bc229-d609-460a-b9dc-418008d47c90" /><code code="0tp1.6" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Footer"></code><title>Footer</title><text><paragraph>BRAND NAME [®] is a registered trademark of COMPANY</paragraph></text><effectiveTime value="20210101" /></section></component>. Back to Figure 15.

Long description 12: Long description including screen readable XML snippet for figure 16

A screenshot of the HTML rendering shows “Notice of Compliance with Conditions” in bold white all capital letters on a dark blue background. It is followed by “What is a Notice of Compliance with Conditions (NOC/c)?” in bold black text on a white background with each word capitalized. The following two paragraphs are in sentence case italic black letters on a white background: “An NOC/c is a form of market approval granted to a product on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada.”

“Products authorized under Health Canada’s NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.”

This is followed by the raw XML snippet used to produce it. <component><section ID="d7ceb5c8-7ee9-4fd2-884e-7a50c06b27e1"><id root="dd1e1c43-f0d3-4ba8-b1f5-bd009a5dd5a8" /><code code="0NOC" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="NOTICE OF COMPLIANCE WITH CONDITIONS"/><title>NOTICE OF COMPLIANCE WITH CONDITIONS</title><text><paragraph><content styleCode="bold">What is a Notice of Compliance with Conditions (NOC/c)?</content></paragraph><paragraph><content styleCode="italics">An NOC/c is a form of market approval granted to a product on the basis of promising evidence of clinical effectiveness following review of the submission by Health Canada.</content></paragraph><paragraph><content styleCode="italics">Products authorized under Health Canada’s NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating illness. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.</content></paragraph></text><effectiveTime value="20210101" /></section></component>. Back to Figure 16.

Long description 13: Long description including screen readable XML snippet for figure 17

A screenshot of the HTML rendering shows “Recent Major Label Changes” in bold white all capital letters on a dark blue background. It is followed by a two-column table.

Row 1 is a header row: Column 1=Section; Column 2=Date, written in bold black font on a light grey background. The rest of the table is in plain black font except for hyperlinked text, which is blue and underlined. Row 2: Section=1 INDICATIONS, 1.1 Pediatrics (hyperlinked); Date=2023-12. Row 3: Section=3 SERIOUS WARNINGS AND PRECAUTIONS BOX, Lactic acidosis; Date=[Removed]2023-04 Row 4: Section=7 WARNINGS AND PRECAUTIONS, 7.1.1 Pregnant Women (hyperlinked); Date=2024-05.

This is followed by the XML code used to produce it. Two elements have been collapsed for brevity.

```
<component><section ID="d7cee5c8-7ee9-4fd2-184e-7a50c06b27e1"><id root="dd1e1c93-f0d3-4ba8-
```

b1f5-ad009a5dd5a8" /><code code="1RMLC" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="RECENT MAJOR LABEL CHANGES" /><title>RECENT MAJOR LABEL CHANGES</title><text><table ID="TableRMLC" rules="all" frame="border"><thead><tr><th>Section</th><th>Date</th></tr></thead><tbody valign="top" align="left"><tr><td align="left">1 INDICATIONS, <linkHtml href="#b9db4ce0-3f46-434a-bd7b-4a3e010adaad">1.1 Pediatrics</linkHtml></td><td>2023-12</td></tr><tr></tbody></table></text><effectiveTime value="20241201" /></section></component>. Back to Figure 17.

Long description 14: Long description including screen readable XML snippet for figure 18

A screenshot of the HTML rendering shows two lines of text, the second of which has a simple vertical line to the left side of the text. Line 1= 1.1 Pediatrics (Bold black font). Line 2=Text (plain black font). This is followed by the raw XML snippet used to produce it. <component><section ID="f2aa7e0e-2042-4a4c-a783-9ad4e8717a32"><id root="b9db4ce0-3f46-434a-bd7b-4a3e010adaad" /><code code="pi01.1" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="1.1 Pediatrics" /><title>1.1 Pediatrics</title><text><paragraph><content styleCode="xmChange">Text</content></paragraph></text><effectiveTime value="20210101" /></section></component>. Back to Figure 18.

Long description 15: Long description including screen readable XML snippet for figure 19

A screenshot of the HTML rendering shows “Recent Major Label Changes” in bold white all capital letters on a dark blue background. This is followed by plain black text on a white background in sentence case “None at time of most recent authorization”. This is followed by the raw XML snippet used to produce it. <component><section ID="d7cee5c8-7ee9-4fd2-184e-7a50c06b27e1"><id root="dd1e1c93-f0d3-4ba8-b1f5-ad009a5dd5a8" /><code code="1RMLC" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="RECENT MAJOR LABEL CHANGES" /><title>RECENT MAJOR LABEL CHANGES</title><text><paragraph>None at time of the most recent authorization</paragraph></text><effectiveTime value="20210101" /></section></component>. Back to Figure 19.

Long description 16: Long description including screen readable XML snippet for figure 20

A screenshot of the HTML rendering shows two lines of text in bold black letters on a white background. Line 1: 14.1 Clinical Trail Design and Results. Line 2: Indication 1. This is followed by the raw XML snippet used to produce it. A text element has been collapsed for brevity. <component><section ID="a2875272-8229-4c12-919e-827854ddd78a"><id root="e134d52c-f9d4-4698-a082-84b29ee3d95a" /><code code="pii14.1" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="14.1 Clinical Trial Design and Results" /><title>14.1 Clinical Trial Design and Results</title><effectiveTime value="20210101" /><component><section ID="a2875272-8229-4c12-919e-827854dc0101"><id root="e134d52c-f9d4-4698-a082-84b29eec0101" /><code code="CG" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="Clinical Group" /><title styleCode="bold">Indication 1</title><text><effectiveTime value="20210101" /></section></component>. Back to Figure 20.

Long description 17: Long description including screen readable XML snippet for figure 21

A screenshot of the HTML rendering is demonstrating the use of “Unassigned” and how it populates both the Table of Contents and the content of the PM. On the left hand side of the page, the HTML rendering shows “TABLE OF CONTENTS” in bold white all capital letters on a dark blue background. Below, indented in regular light blue font are three lines of text as follows: Line 1=6.3 Example of Unassigned. In the right hand side of the page is the PM Content. There are 2 lines of black text on a white background as follows: Line 1=Example of Unassigned (bold font). Line 2=Text (plain font).

This is followed by the raw XML snippet used to produce it. <component><section ID="a63c98a5-e08a-400c-b8a2-a12dba105f5a"><id root="a473c162-e176-44d0-b797-212b60000e33"/><code code="pi06.1" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="6.1 Physical Characteristics"/><title>6.1 Physical Characteristics</title><text><paragraph>Table</paragraph></text><effectiveTime value="20210101"/></section></component><component><section ID="a63c90a5-e08a-400c-b8a2-a12dba105f5a"><id root="a473c162-e176-44d0-b797-214b60000e33"/><code code="pi06.2" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="6.2 External Radiation"/><title>6.2 External Radiation</title><text><paragraph>Table</paragraph></text><effectiveTime value="20210101"/></section></component><component><section ID="ac2875272-8229-4c12-919e-827854ddd85b"><id root="c334d52c-f9d4-4698-a082-84b29ee3d78b"/><code code="UA" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="UNASSIGNED"/><title>6.3 Example of Unassigned</title><text><paragraph>Text</paragraph></text><effectiveTime value="20210101"/></section></component>. Back to Figure 21.

Long description 18: Long description including screen readable XML snippet for figure 22

The HTML rendering is demonstrating how modifications can be made in the title element of the PMI.

There are two lines of text: Line 1=How Brand Name works: (bold font). Line 2=Text (plain font).

The HTML rendering is followed by the XML code used to produce it. <component><section ID="bca4d498-0gc3-4e44-bcb6-550140d4de5d"><id root="be74b6e6-c431-4adf-a18e-ed321b381456" /><code code="pmi03" codeSystem="2.16.840.1.113883.2.20.6.63" displayName="How [Brand name] works:" /><title>How BRAND NAME works:</title><text><paragraph>Narrative</paragraph></text><effectiveTime value="20241201" /></section></component>. Back to Figure 22.

Long description 19: Long description including screen readable XML snippet for figure 23

A screenshot of the HTML rendering shows the company details section. Within the company details section are two subsections with sample data. The first subsection shows Market Authorization Holder - written in bold black text, followed by Acme Pharma Inc. (1111) in plain black text. The second section shows Canadian Importer/Distributor – in bold black text, followed by Acme Distributing Ltd. (0000) in plain black text.

This is followed by the raw XML snippet used to produce it. <author><time /><assignedEntity><representedOrganization><id extension="1111" root="2.16.840.1.113883.2.20.6.31" /><name>Acme Pharma Inc.</name><contactParty><assignedEntity><assignedOrganization><id extension="0000" root="2.16.840.1.113883.2.20.6.31" /><name>Acme Distributing Ltd.</name><contactParty></assignedOrganization></assignedEntity></representedOrganization></assignedEntity></author>. Back to Figure 23.

Long description 20: Long description including screen readable XML snippet for figure 24

A screenshot of the HTML rendering of the contact information within the company details section. The contact information includes the street address, city, state and zip code and country.

This is followed by the XML code used to produce it. <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><contactPerson /></contactParty>. Back to Figure 24.

Long description 21: Long description including screen readable XML snippet for figure 25

A screenshot of the HTML rendering of the product information section. This section is in tabular format with two columns and five rows. The heading is Product Information, written in bold black font on a grey background. The first column contains the table headers in bold black font on a light grey background = Brand Name, Non-proprietary name, Drug Identification Number (DIN), Route of Administration,

Manufactured Dosage Form. The second column contains the product specific information in regular black font on a white background. Brand Name=BRAND NAME1; Non-proprietary name=example of ACTIB; Drug Identification Number (DIN)=01234561; Route of Administration=Oral use; Manufactured Dosage Form=Tablet.

This is followed by the XML snippet used to produce it. Several elements have been omitted from the image for brevity. These elements are described in subsequent sections.

```
<subject><manufacturedProduct><manufacturedProduct><code code="01234561" /><name>BRAND NAME1</name><formCode code="85" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="Tablet" /><asEntityWithGeneric><genericMedicine><name>example of ACTIB</name></genericMedicine></asEntityWithGeneric> (Omitted elements)<consumedIn><substanceAdministration><routeCode code="20053000" codeSystem="2.16.840.1.113883.2.20.6.7" displayName="Oral use" /></substanceAdministration></consumedIn></manufacturedProduct></subject>. Back to Figure 25.
```

Long description 22: Long description for figure 26

A screenshot from the HTML rendering of the product composition section shows two tables, one for the active ingredients, the second for the inactive ingredients. The active ingredient table is comprised of 4 columns with the following headers: active ingredient, the active moiety, basis of strength and strength. There is one row of sample data: active ingredient=ACETAMINOPHEN (362O9ITL9D); the active moiety=ACETAMINOPHEN (362O9ITL9D); basis of strength=ACETAMINOPHEN (362O9ITL9D); and strength=160 mg. The Inactive Ingredient table is comprised of two columns (no headers) – one column is for the ingredient name and code, the second is for the quantity (if provided). There are three rows of data. Row 1=ANHYDROUS CITRIC ACID (XF417D3PSL); Row 2=DEXTROSE (IY9XDZ35W2); Row 3=D&C RED NO. 30 ALUMINUM LAKE (GE75M6YV5W). Back to Figure 26.

Long description 23: Screen readable XML snippet for figure 27

```
Raw XML snippet: <manufacturedProduct><manufacturedProduct><code code="01234561" /><name>BRAND NAME1</name><formCode code="151" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="Tablet (chewable)" /><asEntityWithGeneric><genericMedicine></asEntityWithGeneric><ingredient classCode="ACTIB"><quantity><ingredientSubstance></ingredient>. Back to Figure 27.
```

Long description 24: Long description including screen readable XML snippet for figure 28

A screenshot from the HTML rendering shows the first three columns of the active ingredient table within the product composition section. This is an example of ACTIB, when the active ingredient is the basis of strength. The 3 columns displayed are: Active Ingredient, Active Moiety, and Basis of Strength. This sample has only one row: Active Ingredient=ACETAMINOPHEN(362O9ITL9D); Active Moiety=ACETAMINOPHEN(362O9ITL9D); Basis of Strength= ACETAMINOPHEN(362O9ITL9D).

This is followed by the XML snippet used to produce it. <ingredient classCode="ACTIB"><quantity><ingredientSubstance><code code="362O9ITL9D" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ACETAMINOPHEN" /><name>ACETAMINOPHEN</name><activeMoiety><activeMoiety><code code="362O9ITL9D" codeSystem="2.16.840.1.113883.2.20.6.14" displayName="ACETAMINOPHEN" /><name>ACETAMINOPHEN</name></activeMoiety></activeMoiety></ingredientSubstance></ingredient>. Back to Figure 28.

Long description 25: Long description including screen readable XML snippet for figure 29

A screenshot from the HTML rendering shows the first three columns of the active ingredient table within the product composition section. This is an example of ACTIM, when the active moiety is the basis of strength. The 3 columns displayed are: Active Ingredient, Active Moiety, and Basis of Strength. This sample

has only one row: Active Ingredient=OMEPRAZOLE MAGNESIUM(426QFE7XLK); Active Moiety= OMEPRAZOLE(KG60484QX9); Basis of Strength= OMEPRAZOLE(KG60484QX9).

This is followed by the XML snippet used to produce it.

```
<ingredient>
  <classCode>ACTIM</classCode><quantity><ingredientSubstance><code code="426QFE7XLK">
    <codeSystem>2.16.840.1.113883.2.20.6.14</codeSystem>
    <displayName>OMEPRAZOLE MAGNESIUM</displayName>
  </ingredientSubstance></activeMoiety><activeMoiety><code code="KG60484QX9">
    <codeSystem>2.16.840.1.113883.2.20.6.14</codeSystem>
    <displayName>OMEPRAZOLE</displayName>
  </activeMoiety></activeMoiety></ingredientSubstance></ingredient>
```

[Back to Figure 29.](#)

Long description 26: Long description including screen readable XML snippet for figure 30

A screenshot from the HTML rendering shows the first three columns of the active ingredient table within the product composition section. This is an example of ACTIR, when the active moiety is the basis of strength. The 3 columns displayed are: Active Ingredient, Active Moiety, and Basis of Strength. This sample has only one row: Active Ingredient=TELOTRISTAT ETIPRATE(3T25U84H4U); Active Moiety= TELOTRISTAT(381V4FCV2Z); Basis of Strength= TELOTRISTAT ETHYL(8G388563M7).

This is followed by the XML snippet used to produce it.

```
<ingredient>
  <classCode>ACTIR</classCode><quantity><ingredientSubstance><code code="3T25U84H4U">
    <codeSystem>2.16.840.1.113883.2.20.6.14</codeSystem>
    <displayName>TELOTRISTAT ETIPRATE</displayName>
  </ingredientSubstance></activeMoiety><activeMoiety><code code="381V4FCV2Z">
    <codeSystem>2.16.840.1.113883.2.20.6.14</codeSystem>
    <displayName>TELOTRISTAT</displayName>
  </activeMoiety></activeMoiety><asEquivalentSubstance><definingSubstance><code code="8G388563M7">
    <codeSystem>2.16.840.1.113883.2.20.6.14</codeSystem>
    <displayName>TELOTRISTAT ETHYL</displayName>
  </definingSubstance></asEquivalentSubstance></ingredientSubstance></ingredient>
```

[Back to Figure 30.](#)

Long description 27: Long description including screen readable XML snippet for figure 34

A screenshot from the HTML rendering shows the inactive ingredient table within the product composition section. There are two ingredients listed – one with a quantity and one without. CROSCARMELLOSE SODIUM (M28OL1HH48) with a quantity of 5 mg and HYDROXYPROPYL CELLULOSE (1600000 WAMW) (RFW2ET671P) with no quantity.

This is followed by the XML snippet used to produce it.

```
<ingredient>
  <classCode>IACT</classCode><quantity><numerator value="5" unit="mg" /><denominator value="1" unit="1" /></quantity><ingredientSubstance><code code="M28OL1HH48">
    <codeSystem>2.16.840.1.113883.2.20.6.14</codeSystem>
    <displayName>CROSCARMELLOSE SODIUM</displayName>
  </ingredientSubstance></ingredient><ingredient>
  <classCode>IACT</classCode><ingredientSubstance><code code="RFW2ET671P">
    <codeSystem>2.16.840.1.113883.2.20.6.14</codeSystem>
    <displayName>HYDROXYPROPYL CELLULOSE (1600000 WAMW)</displayName>
  </ingredientSubstance></ingredient>
```

[Back to Figure 34](#)

Long description 28: Long description including screen readable XML snippet for figure 35

A screenshot of the HTML rendering of the Packaging Status section shows two examples of packaging formats, each with one layer packaging. One of the two packaging formats has the date removed field populated, while the other does not. This section is presented in tabular format, with five columns: #, Package Identifier, Package Description, Date Introduced (YYYY_MM_DD), Date Removed (YYYY_MM_DD). The sample data is as follows: Packaging format 1: #=1, Package Identifier=NIL, Package Description=15 (Tablet) in 1 Bottle, Date Introduced=2000-05-22, Date Removed=2009-11-28.

Packaging format 2: #=2, Package Identifier=NIL, Package Description=25 (Tablet) in 1 Bottle, Date Introduced=2005-07-12, Date Removed=NIL.

This is followed by the XML snippet used to produce it. `<asContent><quantity><numerator value="15" unit="1" /><denominator value="1" unit="1" /></quantity><containerPackagedProduct><formCode code="30008000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Bottle" /></containerPackagedProduct><subjectOf><marketingAct><effectiveTime><low value="20000522" /><high value="20091128" /></effectiveTime></marketingAct></subjectOf></asContent><asContent><quantity><numerator value="25" unit="1" /><denominator value="1" /></quantity><containerPackagedProduct><formCode code="30008000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Bottle" /></containerPackagedProduct><subjectOf><marketingAct><effectiveTime><low value="20050712" /></effectiveTime></marketingAct></subjectOf></asContent>. Back to Figure 35.`

Long description 29: Long description including screen readable XML snippet for figure 36

A screenshot from the HTML rendering shows the packaging status section with a packaging format that has two layers of packaging. This section is presented in tabular format, with five columns: #, Package Identifier, Package Description, Date Introduced, Date Removed. In this example, there are 2 entries each for package identifier and package description. The sample data is as follows: #=1, Package Identifier=XYZ-988 and XYZ-987, Package Description=2 (Vial) in 1 Box and 10 mL in 1 Vial Box Date Introduced=201131, Date Removed=NIL.

This is followed by the XML snippet used to produce it. `<asContent><quantity><numerator value="10" unit="mL" /><denominator value="1" /></quantity><containerPackagedProduct><code code="XYZ-987" /><formCode code="30069000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Vial" /><asContent><quantity><numerator value="2" unit="1" /><denominator value="1" /></quantity><containerPackagedProduct><code code="XYZ-988" /><formCode code="30009000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Box" /></containerPackagedProduct><subjectOf><marketingAct><effectiveTime><low value="20151031" /></effectiveTime></marketingAct></subjectOf></asContent></containerPackagedProduct></asContent>. Back to Figure 36.`

Long description 30: Long description including screen readable XML snippet for figure 37

A screenshot of the HTML rendering of the product status section. This section is presented in tabular format, with four columns: Regulatory activity type; Control number; Date first authorized in Canada (YYYY-MM-DD); Date of Cancellation (YYYY-MM-DD). In this example, Regulatory activity type= SNDS; Control number=206254; Date first authorized in Canada (YYYY-MM-DD)= 1989-07-12; Date of Cancellation (YYYY-MM-DD)=2015-03-31.

This is followed by the XML snippet used to produce it. `<subjectOf><approval><id extension="206254" /><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><subjectOf><marketingAct><effectiveTime><low value="19890712" /><high value="20150331" /></effectiveTime></marketingAct></subjectOf>. Back to Figure 37`

Long description 31: Long description including screen readable XML snippet for figure 38

A screenshot of the HTML rendering of size in the product characteristic section to demonstrate the use of the coded value (CV) data type. The first column contains the table headers (bold black font on light grey background) and the second column contains the sample data (regular black font on white background. In this example, Colour=RED(Red-brown). This is followed by the xml snipped used to create it.

```
<subjectOf><characteristic><code code="2" codeSystem="2.16.840.1.113883.2.20.6.23">
displayName="COLOUR" /><value code="C48326" codeSystem="2.16.840.1.113883.2.20.6.24">
displayName="RED" xsi:type="CV"><originalText>Red-
brown</originalText></value></characteristic></subjectOf>. Back to Figure 38.
```

Long description 32: Long description including screen readable XML snippet for figure 39

A screenshot of the HTML rendering of size in the product characteristic section to demonstrate the use of the physical quantity (PQ) data type. The first column contains the table headers (bold black font on light grey background) and the second column contains the sample data (regular black font on white background). In this example, size=5 mm. This is followed by the xml snipped used to create it.

```
<subjectOf><characteristic> <code code="4" codeSystem="2.16.840.1.113883.2.20.6.23">
displayName="SIZE" /><value value="5" unit="mm" xsi:type="PQ"
/></characteristic></subjectOf><subjectOf>. Back to Figure 39.
```

Long description 33: Long description including screen readable XML snippet for figure 40

A screenshot of the HTML rendering of size in the product characteristic section to demonstrate the use of the string (ST) data type. The first column contains the table headers (bold black font on light grey background) and the second column contains the sample data (regular black font on white background). In this example, Imprint=ABC;123. This is followed by the xml snipped used to create it.

```
<subjectOf><characteristic><code code="6" codeSystem="2.16.840.1.113883.2.20.6.23">
displayName="IMPRINT" /><value xsi:type="ST">ABC;123</value></characteristic></subjectOf>. Back to Figure 40.
```

Long description 34: Long description including screen readable XML snippet for figure 41

A screenshot from the HTML rendering shows the product level details of a multi-part product. Similar to single products, this includes the Product Information, Product Status and Packaging Status. The multi-part product also includes a summary of the products parts, specifically the package quantity and total product quantity. This information is displayed in multiple tables.

The first table shows the product information for the multi-part product. The first row is the title of the section and is in bold black font on a grey background. The next 5 rows have two columns, the first column (bold black font on a light grey background) is the title of the information provided in the second column (regular black font on a white background).

In this example: Product Information: Brand Name=HC-BRAND NAME6; Non-Proprietary Name=example of multipart product single DIN; Drug Identification Number (DIN)=01234566; Route of Administration=See below; Manufactured Dosage Form=See below.

The second table shows the product status of the multi-part product. The first row is the title of the section and is in bold black font on a grey background. The next 2 rows have 4 columns, and the first row (bold black font on a light grey background) is the title of the information provided in the second row(regular black font on a white background).

In this example: Product Status: Regulatory Activity Type=ANDS; Control Number 210325; Date first authorized in Canada (YYYY-MM-DD)=2004-08-04; Date of Cancellation (YYYY-MM-DD)=Null.

The third table shows the packaging status of the multi-part product. The first row is the title of the section and is in bold black font on a grey background. The next 2 rows have 4 columns, and the first row (bold black font on a light grey background) is the title of the information provided in the second row(regular black font on a white background).

Packaging Status: #=1; Package Identifier=Null; Package Description=1 (Blister) in 1 box and 1 (multi-part product) in 1 Blister; Date Introduced (YYYY-MM-DD)=2004-08-04; Date Removed (YYYY-MM-DD)=Null.

The fourth table shows the quantity of parts in the multi-part product. The first row is the title of the section and is in bold black font on a grey background. The next 4 rows have 3 columns, and the first row

(bold black font on a light grey background) is the title of the information provided in the subsequent rows (regular black font on a white background).

Quantity of Parts: Part #=**Part 1**; Package Quantity=Null; Total Product Quantity=2. Part #=**Part 2**; Package Quantity=Null; Total Product Quantity=2. Part #=**Part 3**; Package Quantity=Null; Total Product Quantity=4.

This is followed by the XML code used to produce it. Several elements have been collapsed for brevity.

```
<subject><manufacturedProduct><manufacturedProduct><code code="01234566" /><name>HC-BRAND NAME6</name><formCode code="32" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="Multi-part product" /><asEntityWithGeneric><genericMedicine><name>example of multipart product single DIN</name></genericMedicine></asEntityWithGeneric><asContent><quantity><containerPackagedProduct><formCode code="30007000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Blister" /><asContent><quantity><numerator value="7" unit="1" /><denominator value="1" /></quantity> <containerPackagedProduct><formCode code="30009000" codeSystem="2.16.840.1.113883.2.20.6.32" displayName="Box" /></containerPackagedProduct><subjectOf><marketingAct><effectiveTime></marketingAct></subjectOf></asContent></containerPackagedProduct><asContent><part><part><part><manufacturedProduct><subjectOf><approval></subjectOf><subjectOf><marketingAct><effectiveTime></marketingAct></subjectOf></manufacturedProduct></subject>. Back to Figure 41.
```

Long description 35: Long description including screen readable XML snippet for figure 42

A screenshot from the HTML rendering shows a single ‘part’ in a multi-part product. Only the section headings are shown – the content has been removed for brevity. This ‘part’ includes the Product Information, Product Composition and Product Characteristics, Product Status and Packaging Status.

This is followed by the XML code used to produce it. Several elements have been collapsed for brevity.

```
<part><quantity><partProduct><code code="01234568" /><name>HC-BRAND NAME7a</name><formCode code="85" codeSystem="2.16.840.1.113883.2.20.6.3" displayName="Tablet" /><asEntityWithGeneric><ingredient classCode="ACTIM"><ingredient classCode="IACT"><ingredient classCode="IACT"><ingredient classCode="IACT"><asContent></partProduct><subjectOf><subjectOf><subjectOf><subjectOf><subjectOf><subjectOf><subjectOf><subjectOf><subjectOf><subjectOf><consumedIn></part>. Back to Figure 42.
```

Long description 36: Long description including screen readable XML snippet for figure 46

A screenshot of the HTML rendering shows table 1 in the sample XML PM to demonstrate how to create a table. Table 1 is titled Reconstitution. The table consists of four columns: Vial size; Volume of diluent to be added to vial; approximate available volume; Concentration per mL. In this example, there is no content in the table, only the word ‘text’ as a placeholder.

This is followed by the XML snippet used to create it: <table ID="Table1" rules="all" frame="border"><caption>Table 1 - Reconstitution</caption><thead><tr align="center"><th>Vial Size</th><th>Volume of Diluent To Be Added to Vial</th><th>Approximate Available Volume</th><th>Concentration Per mL</th></tr></thead><tbody><tr><td>Text</td><td>Text</td><td>Text</td><td>Text</td></tr></tbody></table>. Back to Figure 46.

Long Description 37: Long description including screen readable XML snippet for figure 47

A screenshot of the HTML rendering shows part of table 11 from the sample XML PM in order to show how to add shading to select cells within that table. The screenshot shows two rows of the four column table with shading in columns 3 and 4 of both rows. The two rows are titled T_{max} (h) and T_{1/2} (h). There is no data in the table.

The screenshot is followed by the XML snippet used to create it.

```
<tr><td>T<sub>MAX</sub><footnote>Expressed as the median (range) only</footnote><br/>(h)</td><td>
```

/><td /><td styleCode="table-secondary"></td><td styleCode="table-secondary"></td></tr><tr><td>T_{1/2}<footnote>Expressed as the arithmetic mean (CV %) only</footnote>
(h)</td><td /><td styleCode="table-secondary"></td><td styleCode="table-secondary"></td></tr>. Back to Figure 47.

Long description 38: Long description including screen readable XML snippet for figure 48

A screenshot to demonstrate how to create external hyperlink. The screenshot of the HTML rendering shows text with two external hyperlinks (underlined in blue font). The text reads: Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database ([hyperlink](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html)), the manufacturer's website ([hyperlink](https://www.yourwebsite.com)) or by calling 1-800-phone number.

This is followed by the raw xml snippet used to create it. <item>Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the <linkHtml href="https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html">Health Canada Drug Product Database</linkHtml>, the <linkHtml href="https://www.yourwebsite.com">manufacturer's website</linkHtml>, or by calling 1-800-phone number.</item>. Back to Figure 48.

Long description 39: Long description including screen readable XML snippet for figure 49

A demonstration of how to create internal hyperlinks. The screenshot of the HTML rendering shows an internal hyperlink followed by the raw XML snippet used to create it. The text in the first column is: 1 INDICATION, 1.1 Pediatrics (1.1 Pediatrics is hyperlinked). The second column contains a date (2023-12). This is followed by the raw xml snippet used to create it. <tr><td align="left">1 INDICATIONS, <linkHtml href="#b9db4ce0-3f46-434a-bd7b-4a3e010adaad">1.1 Pediatrics</linkHtml></td><td>2023-12</td></tr>. Back to Figure 49.

Long description 40: Long description including screen readable XML snippet for figure 50

A demonstration of how to create an internal hyperlink to specific content within a section of the XML PM. The screenshot consists of two parts, each with their own title.

Part 1: Hyperlink definition - where the hyperlink goes to

The screenshot of the HTML rendering is plain black text that says: Narrative. Example of endpoint when creating an internal hyperlink to specific information. This is followed by the xml snippet: <paragraph ID="Hyperlink1">Narrative. Example of end point when creating an internal hyperlink to specific information.</paragraph>.

Part 2: Hyperlink reference - starting point of the hyperlink

The screenshot of the HTML rendering is plain black text that says: This is an example of an internal hyperlink (see Specific Information). "Specific Information" is hyperlinked. This is followed by the xml snippet: <paragraph>This is an example of an internal hyperlink (see<linkHtml href="#Hyperlink1">Specific information</linkHtml>)</paragraph>. Back to Figure 50.

Long description 41: Long description including screen readable XML snippet for figure 52

A demonstration of how to create a box around text with multiple text styles. A screenshot of the HTML rendering shows the Reporting Side Effects boxed statement from the Patient Medication Information. It includes plain text, text with bullets, italic text and a hyperlink.

Specifically, this is an image of text framed by a 4 black lines to draw attention to its contents.

Line 1= Reporting Side Effects (written in bold, black font)

Line 2= You can report any suspected side effects associated with the use of health products to Health Canada by: (written in plain black font)

Line 3= (bullet point) Visiting the Web page on Adverse Reaction Reporting for information on how to report online, by mail or by fax; (written in plain black font; hyperlink on Adverse Reaction Reporting)

Line 4= (bullet point) Calling toll-free at 1-866-234-2345. (written in plain black font)

Line 5= NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice. (written in black italic font)

This is followed by the XML code used to produce it. <paragraph styleCode="Boxed First"><content styleCode="bold">Reporting Side Effects</content></paragraph><paragraph styleCode="Boxed">You can report any suspected side effects associated with the use of health products to Health Canada by:</paragraph><list styleCode="Boxed unordered"><item>Visiting the Web page on <linkHtml href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html"> Adverse Reaction Reporting </linkHtml>for information on how to report online, by mail or by fax; or</item><item>Calling toll-free at 1-866-234-2345.</item></list><paragraph styleCode="Boxed Last"><content styleCode="italics">NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</content></paragraph>. Back to Figure 52.

Long description 42: Long description including screen readable XML snippet for figure 53

A screenshot of the HTML rendering is demonstrating how to create footnotes for a table. This example uses the table from Section 6 of the XML PM.

Footnote 1= This is an example of long footnote text that will span all of the table columns and uses the full width of the table.

Footnote 2= This is an example of a second footnote text.

Footnote 1 is referenced twice in the table. The first reference is made in the header row of the first column (Route of Administration- superscripted and hyperlinked 1). The second reference is made to specific content in the first row of the third column (Ingredient-superscripted and hyperlinked 1).

Footnote 2 is referenced in the header row of the second column (Dosage Form/Strength/Composition - superscripted and hyperlinked 2).

This is followed by the XML code used to produce it. <table ID="Table3" rules="all" frame="border"><caption>Table 3 - Dosage Forms, Strengths, and Composition</caption><colgroup span="5" /><thead><tr align="center"><th>Route of Administration<footnote ID="Footnote1">This is an example of long footnote text that will span all of the table columns and uses the full width of the table.</footnote></th><th>Dosage Form/Strength/Composition<footnote>This is an example of a second footnote text.</footnote></th><th>Non-Medicinal Ingredients</th></thead><tbody><tr><td>oral</td><td>tablet 5 mg, 10 mg</td><td>Ingredient<footnoteRef IDREF="Footnote1" />, Ingredient, Ingredient</td></tr></tbody></table>. Back to Figure 53.

Long description 43: Long description for figure 55

A graphical representation of the relationships between unique identifiers including:

- Dossier ID
- Language of document(<languageCode>)
- Document name (<setId>)
- .xml file name (<id>)
- Control number

The dossier ID is the highest level of identifier for the XML PM, and will remain constant over a product's lifecycle (with some exceptions). The dossier ID is represented as a box around the whole graphic.

Within the graphic, there are two horizontal swim lanes, representing two separate documents – one for the English XML PM and one for the French. Each of these documents will have a document name (setId) that remains the same over the XML PM's lifecycle.

There are also 3 columns that stretch over the two swim lanes, representing the different versions authorized under different control numbers over time. The .xml file name (id) must be different for each of these versions.

These concepts are also shown using sample GUIDs for the document name and file name:

English XML PM <setId> (<setId root="d4c004d2-976d-4aec-8cdd-a71bdb11d4b1" />)

- Regulatory Activity #1, control number 123456; file name <id> (id root="bd28a915-72c1-4c9b-95ec-f80140f9792e"/>)
- Regulatory Activity #2, control number 123432; file name <id> (id root="e796df04-2fd5-4894-8b22-6234e96e77d2"/>)
- Regulatory Activity #3, control number 123454; file name <id> (d root="11d3fb08-035d-4b32-9d63-4d37dfad1685"/>)

French XML PM <setId> (<setId root="c99b9224-f519-4e52-bdbe-1750a5b1a26e" />)

- Regulatory Activity #1, control number 123456; file name <id> (id root="1262a4e6-bc34-413e-bbf4-a8ec3fb512e1"/>)
- Regulatory Activity #2, control number 123456; file name <id> (id root="944364a1-0f76-44b3-b2f6-60cf61df8a1d"/>)
- Regulatory Activity #3, control number 123454; file name <id> (d root="aee16a81-8021-4058-86dc-154ba5b0516c"/>)

[Back to Figure 55.](#)