Health Canada Santé Canada

Canada

Structured Product Monograph (SPM) Update

Presentation to GERA
September 28, 2017

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SPM Defined

Structured Product Monograph

- Product Monograph content and product details are encoded (structured) using the SPL data standard and 37+ controlled vocabularies

Background

- Health Level 7 (HL7) – international organization dedicated to support electronic standards related to health information and clinical practice

- eXtensible Markup Language (XML) - programming language designed to structure documents; i.e., encodes document content

- Structured Product Label (SPL) standard - XML based HL7 standard used to structure documents

6 Major Components of the SPM

Component		Description
1	Prolog	Technical data meant for software applications and developers • E.g., XML version; public links to schema and style sheet
2	Document	Metadata about the document • E.g., document and template type; unique document identifier; document version and version identifier; language
3	Author	Metadata about the sponsor • E.g., name, address, contact information
4	Product Details	Metadata about the product(s) • E.g., substance name, strength, dosage form, package type, marketing status
5	Document Content (Excluding images)	Text and formatting • E.g., paragraphs, text, tables, bold, underline, bulleted or numbered lists
6	Document Images	Figures and graphics • E.g., chemical structure, instructions for use

SPM Objectives

- Enhance the HPFB's data management capability for product labelling
  - Product information awareness (what, when, who)
  - Standardize terms using controlled vocabularies
  - Search, retrieval and analysis of content
  - Advanced automation, validation and publishing

- Compliance with international standards; e.g., SPL and IDMP

- Interoperability with existing regulatory and health information technology solutions

Scope

In scope

- human prescription pharmaceutical drugs, biologic drugs and radiopharmaceuticals
- ONLY 2004 and 2016 templates
  - Standard, NOCc, Subsequent Entry Product, Schedule C and Schedule D

Out of scope

- Veterinary drugs, self-care products, natural health products, medical devices and food

Draft Process[1]

- SPM submission process replaces the old Pristine PM process
  1. Word and PDF (Clean and annotated) still submitted for the review phase
  2. Upon approval, sponsor submits the Pristine SPM in French and English via eCTD
  3. eCTD lifecycle is similar to current process but with more files; e.g., lifecycle the .xml and .jpg's

[1] This is one variation that is under consideration

Tentative Release Schedule

Milestones		Tentative Timelines[1]
Technical testing and system development	• Technical guidance, validation, business rules, controlled vocabularies • Automation, validation, rendering and publishing	Q4 2017 to Q1 2018
HPFB Documents	• Publish Notice of Intent on SPM and SPL	Q4 2017
	• Publish call for comments on the following: a. Guidance Document - General SPL Validation Rules b. Guidance Document - SPM Validation Rules c. Guidance Document - Object Identifiers and Controlled Vocabularies d. Guidance Document - Question and Answer e. Schema, style sheets, controlled vocabularies	Q2 2018
Go Live (Limited)	• Small number of volunteer sponsors	Q4 2018
Go Live (Full)	• Open use for all sponsors	Q2 2019

[1] All dates are subject to change pending the results of technical testing and the extent of stakeholder feedback.