Medical Product Information (SPLr5)

Drugs, Devices, Biologics, Veterinary Products

May 6, 2010

SPL R4 (drug, biologic, vet)

SPL header
- Style sheet and schema location
- GUIDs
- Version number
- Effective time
- Product distributor

SPL body

Product data elements
- Product
- Ingredients
- Strength
- Dosage form
- Route of administration
- Controlled substance code (UNII)
- Appearance
- How supplied

Content of labeling
- Sections and subsections
- Labeling text
  - Font effects
  - Symbols and special characters
  - Footnotes
  - Lists
  - Tables
  - Image
  - Hypertext
  - Recent major changes in text
- Highlight section

Types of SPL electronic submissions:

1 NDC Labeler Code Request
2 Establishment Registration

3 Listing

4 Content of Labeling

Medical Product Information (r5)

SPL header
- Style sheet and schema location
- GUIDs
- Version number
- Effective time
- Product distributor

SPL body

Product data elements
- Product
- Unique device identifier
- Brand name
- Product code
- Marketing category
- Marketing status
- Device type code
- Reusability
- Environmental conditions
- Allergens
- Device acts (in-vitro, in-vivo diagnostics
- Packaging

Possible subset of data elements for medical devices.

Content of labeling
- Sections and subsections
- Labeling text
  - Font effects
  - Symbols and special characters
  - Footnotes
  - Lists
  - Tables
  - Image
  - Hypertext
  - Recent major changes in text

HL7 Common Product Model (CPM)

CPM

An xml format that can be used by any number of HL7 V3 messages to identify and represent medical products.

Drugs

Biologics

Devices

Combination products

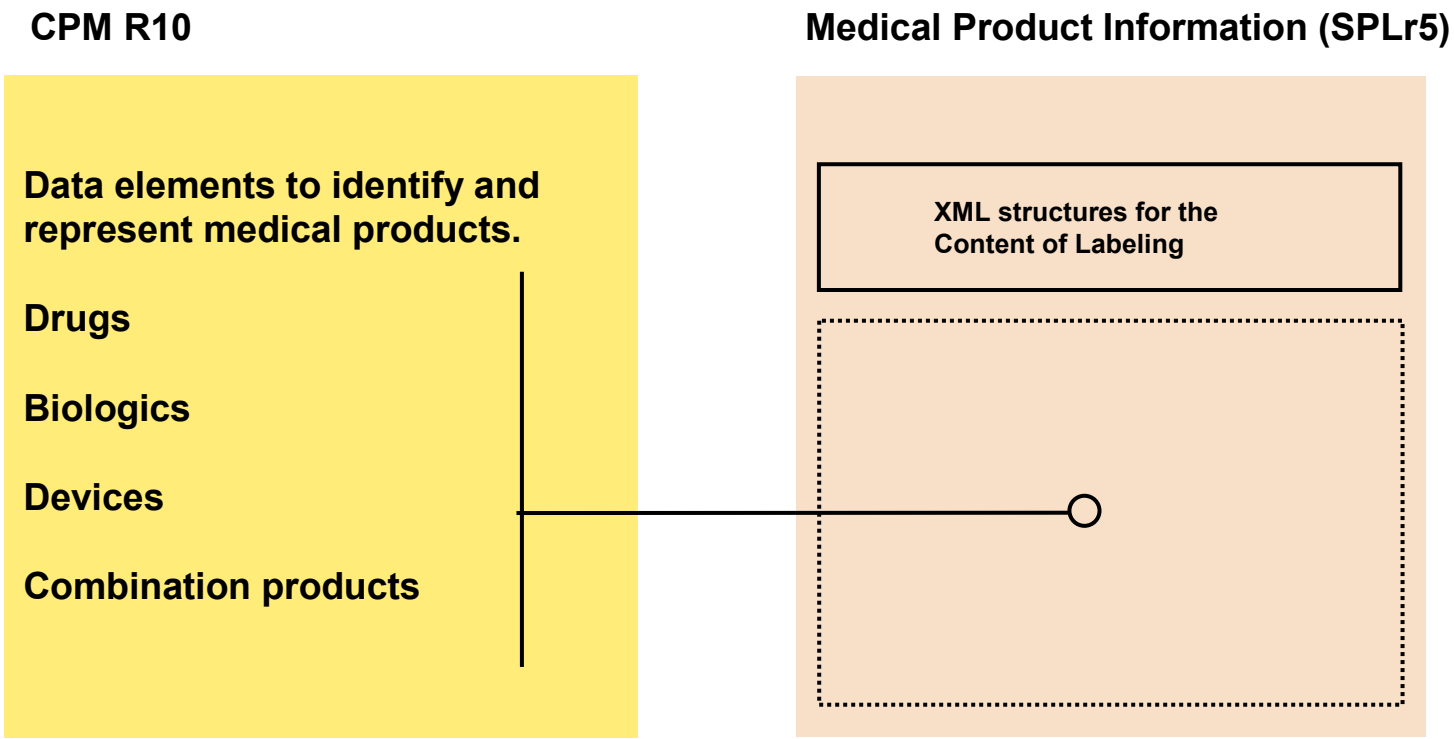
Provides a consistent format to promote harmonization between HL7 messages and electronic documents.

- UDI attributes
- SPL
- RPS
- EHR
- ICSR (eMDR)

CPM

- Developed in the HL7 Orders and Observations (O&O) Work Group.
- Supports many domains of interest:
  - Pharmacy
  - Immunizations
  - Patient Safety
  - Structured Product Labeling
  - Stability Reporting
  - Billing and Accounts
  - Image Integration
  - Substances

Medical Product Information (r5) + CPM



Medical Product Information (r5) + CPM

- SPL R5 is backward compatible with SPL R4.
- Consistent structures for drug, biologic, devices, and combination products.
- Provides a consistent format to promote harmonization between other HL7 messages and electronic documents:
  - Regulated Product Submissions (RPS)
  - Individual Case Study Reports (ICSR) (eMDRs)
  - Others (electronic medical records, clinical studies)

Medical Product Information (r5) + CPM

- SPL R4, balloted on September 2008, added data elements that support medical devices (regulatory approval, product description and packaging information).
- SPLr5 adds the required data elements and attributes to support the Unique Device Identification (UDI) project.
- SPLr5 provides new structures and attributes:
  - Device Act: in-vitro diagnostics
  - Device Act: in-vivo diagnostics
  - Substances.

HL7 May 2010 Ballot cycle

- Two standards:
  - Medical Product Information (SPLr5) for Draft Standard for Trial Use (DSTU).
  - Common Product Model (CPM) R10 for DSTU.
- Balloting:
  - Opened on April 7th
  - Closes on May 9th
  - Ballot reconciliation occurs during the May WGM on May 17th and 18th.
- Next Ballot cycles:
  - Sept/Oct 2010
  - January 2011
  - May 2011
- Goal is to reach Normative standards by May 2011.