Health Product Register

Presentation to
The Canadian Association of Professionals in Regulatory Affairs (CAPRA)

April 30, 2014

Vikesh Srivastava

Associate Director, Business Informatics Division
Health Products and Food Branch



Canada

What is the Product Register?

- *Why does HPFB need a Project Register?* Currently HPFB publishes a considerable amount of information and data on the Health Canada website. However, the site is difficult to navigate, often redundant, and uses inconsistent search tools. In addition, there is a high cost to manage, publish, and maintain this content.

- *What is the Health Product Register?* It is a storage and information management component of the HPFB IT Framework that extracts data and information from the various stages and processes involved in doing the work of HPFB.

- This is the key to HPFB client-centric data and information access and allows the development of applications that search, package, and present this relevant information.

Vision

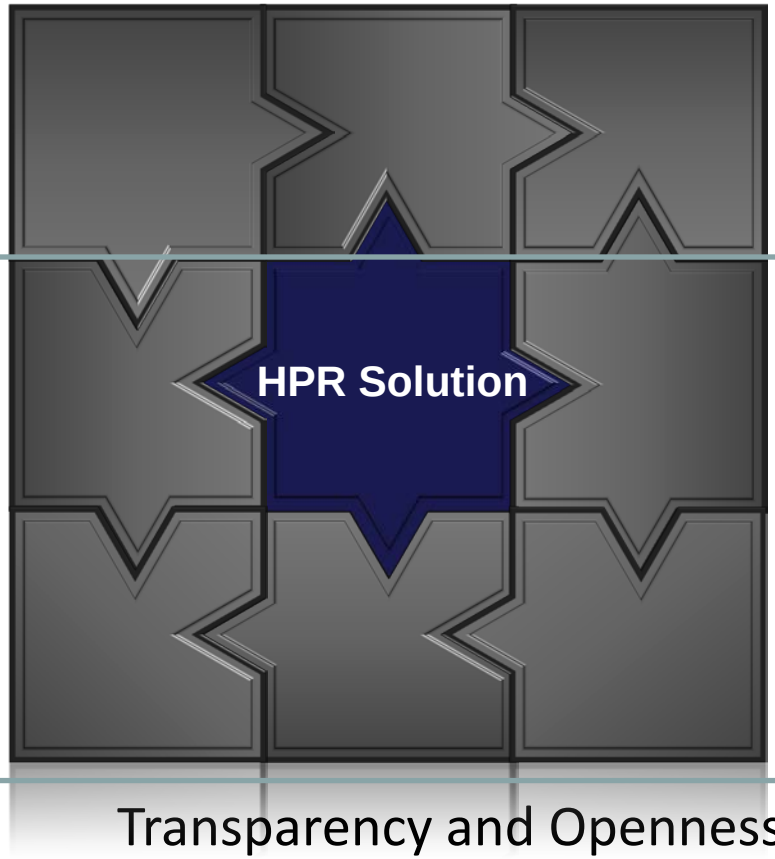
- The Health Product Register is a key element of the Department's Transparency and Openness Framework.
- The Health Product Register project introduces a new methodology for managing regulatory content, opening up opportunities to streamline operations while enhancing transparency.
  - This is particularly relevant when regulations are drafted where the Minister exercises the authority to collect information in a "prescribed format and manner".
- Implementation of the project will also trigger the expansion of the "Health Theme' within the Government of Canada Web Renewal Action Plan.
- The launch of the Health Product Register supports a key government priority referenced in the Speech from the Throne – *"ensuring that drug labels are written in plain language, and that potential side effects of medication are accurately indicated"*.

Multi Purpose Solution

Easy to Use – Authoritative Information

Canada.ca
Health Theme

Sustainable
Publishing



Structured Content
Management

Prescribed Format
and Manner

Standard Based
Approach

Enriched XML
Documents

Transparency and Openness

Conceptual Framework

Content Sources

Take any of the existing data sources at Health Canada

Information Architecture

Profile the sources by adding metadata that is so rich it serves as stand alone content

Content Store

Aggregate the content into an XML content store with all of the meta content applied

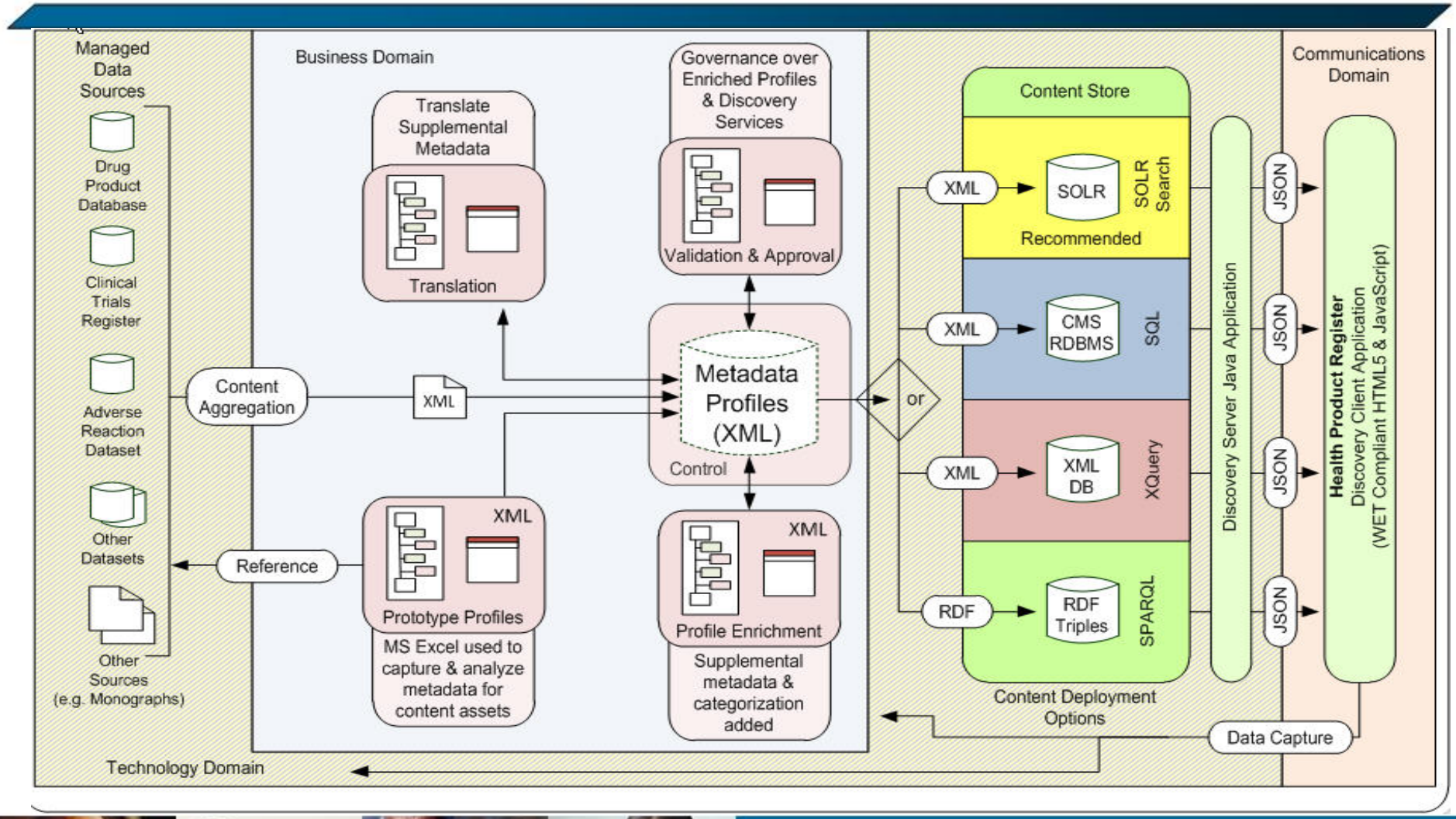
User Interface

Leverage the content to serve the user in a meaningful, easy to access, easy to read way

Content Governance for a Better Stakeholder Interaction

- Content Governance is a critical prerequisite to the transformed information experience
- Content Governance empowers Health Canada to integrate & balance industry & citizen perspectives
- Information & Process Architecture is core and central to the experience (i.e. Product Monograph)

Open & Extensible Solution Architecture Framework



Progress to Date (last 3 months)

- Usability Validation Pilot was conducted in February with external stakeholders to ensure the “discovery client” is responsive to their needs.
- Re-design of the application was enhanced based on the knowledge / feedback received.
- Iterative approach to development has been undertaken affording HPFB early reviews and enhancement to the application.
- Defined an elaborate aggregation process, enrichment and staging of the content.
- Engagement of key internal partners (IMSD/SSC, CPAB) to ensure smooth delivery of the application.
- Announced (April 8, 2014) by the Minister as part of the Regulatory Transparency and Openness Framework to be implemented this year.

Scope of Phase 1 Release

- Early June 2014 implementation
- Content:
  - Tombstone data for all marketed Pharma and Biological drugs;
  - Consumer information (PM Part III of the Pristine Monograph) for selected top drugs sold in 2013 and associated generic drug products; and
  - Associated reported adverse effects.
- Voluntary adverse event reporting capability
- Basic Search capability (by Brand Name, Active Ingredient or DIN)
- Integrated with Canada.ca Health Theme
- Mobile Device Access

Scope of Phase 2 Release

- Q3 FY2014/15 implementation
- Integration of drug product information
  - Drug Safety Reviews , SBDs, Drug Shortages (T&O)
- Advanced search capability
- Streamlined and sustainable refresh/update processes for all content.
- Subset of Directives for Pharm & Biological
  - Guidance / Policies, Fact Sheets

Scope Diagram

IP 106B – Health Product Register

Phase 1 Scope (June 2014)

- Drug Tombstone Details
- Adverse Reactions
  - Summary
  - Reports
- Product Monograph Part III
- Mechanism to Report Voluntary Adverse Reactions
- Basic Search Functionality → DIN, Ingredient, Product Name
- PAL Platform Architecture upon which other projects can be on-boarded

Phase 2 Scope (Q3 FY14-15)

MedEffect Refresh

- Voluntary AR Reporting
- CVP Online Database

Transparency & Openness Initiatives

- Drug Safety Reviews (i.e.: Diane 35)
- Summary Basis of Decision (SBD)
- Drug Shortages
- Inspection Summary Reports

Subset of Directives *(for Pharmaceuticals & Biologics)*

- Guidance Document
- Policies
- Fact Sheets
- Forms

Advanced Search Capability → By new Search Facets, date ranges, etc.

Expanded PAL Information Architecture

(to accommodate new product lines / departmental initiatives)

Phase 3 Scope (Q4 FY14-15)

Expand HPR by integrating new new product lines / datasets

- MDALL
- LNHPD
- MDEL Listing

Transparency & Openness Initiatives

- Advertising Complaints
- Annual Inspection Summary

Subset of Directives *(for NHP / Medical Devices)*

- Guidance Document
- Policies
- Fact Sheets
- Forms

Decommissioning of Application

- Drug Product Database Online
- Canada Vigilance / MedEffect Online

Future Release Scope (FY15-16)

Build by adding new product lines / datasets

- Patent Register
- NOC Database
- DEL Listing
- Other HPFB Datasets
- Food related datasets

Other T&O Initiatives

Other GoC / HPFB Priorities (ie: Orphan Drug)

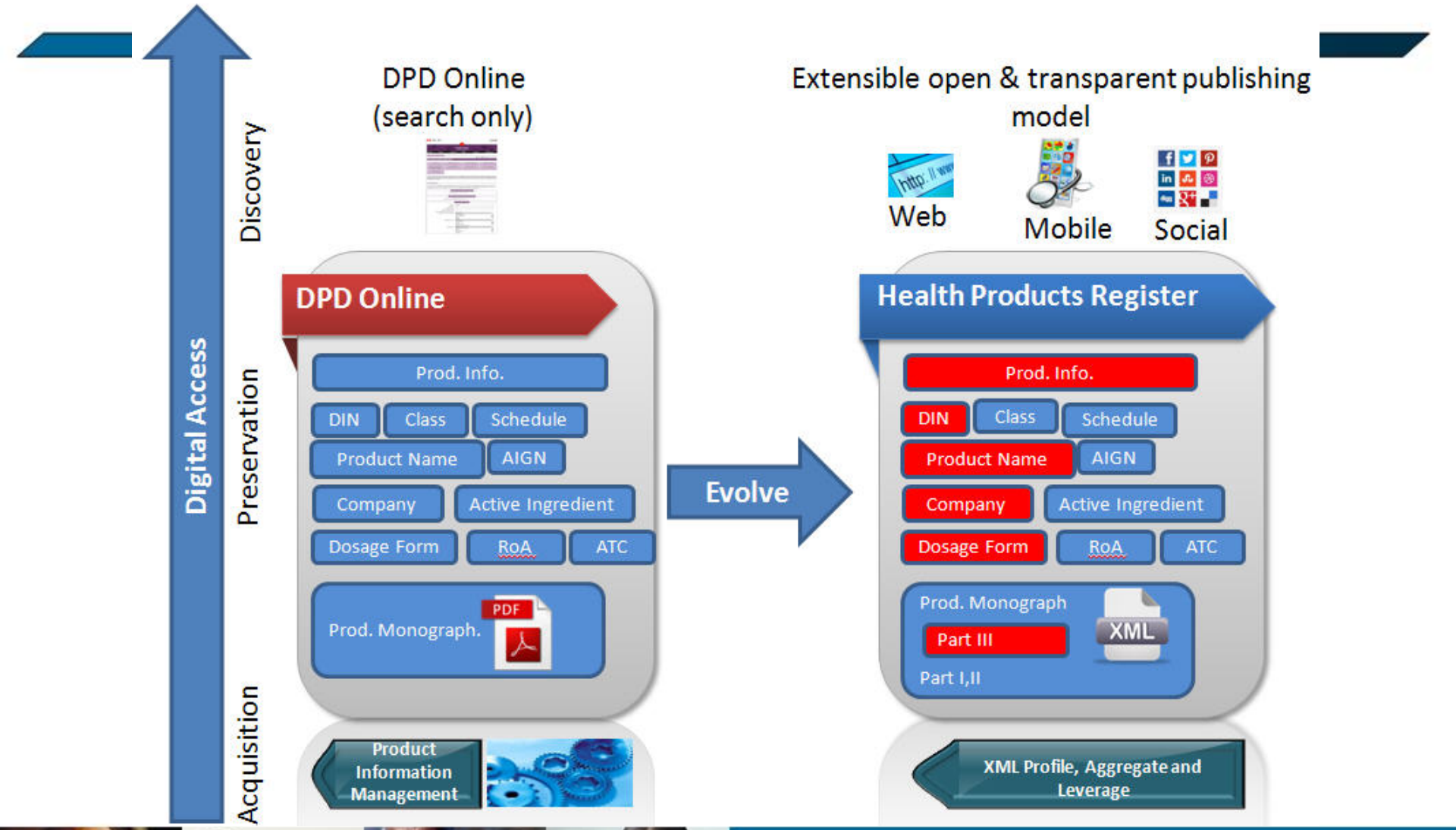
Regulatory Modernization Initiatives (ie: Prescription Drug List)

Future Items to be placed

Decision Letters & Reports (Positive / negative / administrative) for:

- SAP/CT Letters
- MA Reports / Letters
- Compliance & Enforcement - Surveillance & Monitoring
- DHCPL / QN / Fact Sheets
- Product Categorization / Classification Decisions

Going forward: DPD Online & HPR Transition



What this means to the CAPRA community?

- Collaborative partnership will be necessary to provide clear understanding of standards and define structured content for Health Canada authorized information.
- Opportunity to introduce Extensible markup language (XML) files in a ‘SPL-like’ manner and the standard format for the exchange of product information (i.e.: Product Monograph).

Potential Benefits

- Data Maintenance
  - Content of Monograph in one file
  - Manage one file instead of several pdf and MS Word Files
- Reduces the amount of time for HC to receive, process, and publish information
- Eliminates Data entry errors

Challenges

- Transition Management will need to employ a phase approach for HC and industry via GERA
- Establish clear guidance, tools, policies

Upcoming Key Dates

- Announced (April 8, 2014) by the Minister as part of the Regulatory *Transparency and Openness Framework* to be implemented this year.
- Implementation of Phase 1 by planned June 2014
- Ministerial announcement on the HPR (planned June 2014)