Identification of Medicinal Products (IDMP):

Health Canada – An Opportunity to Enable Interoperability with Domestic and International Partners to Improve Patient Safety

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Overview

Purpose of Presentation: Provide a overview of Health Canada’s thinking on the implementation of IDMP

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What is IDMP?

The Identification of Medicinal Product (IDMP) is an ISO standard that:

- **Uniquely and unambiguously** identifies drugs across regions & borders
- Creates common vocabulary for improved people communication
- Creates common messaging standards for improved IT system communication
What is IDMP for Health Canada?

- The Drug Identification Number (DIN) is a Canada-specific identifier
- IDMP not a replacement but complementary to the DIN
- IDMP has more specificity than DIN

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<thead>
<tr>
<th>Drug Identification Number (DIN)</th>
<th>Identification of Medicinal Ingredient (IDMP)</th>
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<tr>
<td>DIN is a computer-generated number assigned by HC</td>
<td>Will be generated by a standard “algorithm” certified by ISO</td>
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<td>Uniquely identifies a drug in Canada</td>
<td>Uniquely identifies a drug worldwide</td>
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<td>A DIN uniquely identifies the following characteristics: • manufacturer • product name • active ingredient(s) • strength(s) of active ingredient(s) • pharmaceutical form • route of administration</td>
<td>IDMP uniquely identifies all the DIN characteristics PLUS+++  • where the substance was manufactured  • the grade and purity of the substance  • manufacturing process of the substance  • where the product was manufactured  • other characteristics</td>
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Why is it important to Health Canada?

- Data standards, like IDMP, creates common language that enables **INTEROPERABILITY**
  - Regulator to regulator;
  - Pharmaceutical company to regulator;
  - Clinical trial sponsor to regulator;
  - Regulator to healthcare institutions (Provinces/Territories)

- IDMP helps improve **PATIENT SAFETY**
  - Is critical for pharmacovigilence & risk analytics - more specificity leads to more accuracy
  - Improves the reporting & tracking of patient safety issues on an international level

- IDMP improves **MONITORING OF THE GLOBAL SUPPLY CHAIN**
  - IDMP identifiers will be used to verify packages and batches, screen counterfeits
  - Helps agencies authorize alternative products when there are shortages

- IDMP foundational to ICMRA priorities on pharmacovigilence and global supply chain

- IDMP helps improve **TRANSPARENCY AND OPENNESS**
  - Improves enabling Health Canada’s Regulatory Transparency and Openness Framework

- The International Pharmaceutical Regulators Forum is proposing global WG on IDMP implementation
Interoperability with other Regulators

Example 1: Sharing Generic Drug Reviews

Current Process without IDMP incorporated into tracking systems

- **Step 1**: HC identifies candidate submission for work sharing with TGA
- **Step 2**: Determine if drug submitted to HC and TGA are identical
- **Step 3**: Proceed with Sharing Reviews

With IDMP incorporated into tracking systems

- **Step 1**: HC identifies candidate submission for work sharing with TGA
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Example 1: Sharing Generic Drug Reviews

- **Current Process without IDMP incorporated into tracking systems**
- **With IDMP incorporated into tracking systems**
Interoperability with other Regulators

Example 2: International Work Sharing in Compliance & Enforcement Area

Current Process without IDMP incorporated into tracking systems

- Step 1: FDA Warning
- Step 2 – several weeks: HC determines if products/sites impact Canadians
- Step 3: Proceed with appropriate C&E action

With IDMP incorporated into tracking systems

- Step 1: FDA Warning
- Step 2 – hours / days: HC determines if products/sites impact Canadians
- Step 3: Proceed with appropriate C&E action
Interoperability with Healthcare system

Example: Interoperability with Electronic Prescription

- As P/Ts move from paper to e-prescribing, they must create data standards
- Those data standards must consider how to identify drugs in the e-prescription
- *EU has stated “the implementation of IDMP … will introduce additional benefits to cross-border ePrescription business cases”*
- Canada Health Infoway is asking for HPFB support in the move to e-prescribing

IDMP - Health Canada Status

• Health Canada has not yet formally declared its intentions on IDMP

• There are significant benefits to adoption but also significant challenges

• A policy decision on the adoption of IDMP needs to be developed
  – HPFB participation on the IPRF WG regarding IDMP Implementation
  – Need to decide on HPFB IP investments – start preparing new systems and tools for IDMP or continue with status quo DIN
  – Decide on HPFB support on e-prescribing
Operational Impacts to Implementing IDMP at Health Canada

Multiple Source Applications

- Product Monographs
- DPD
- LAN
- DSTS
- eCES
- Docubridge
- Patent Register
- Drug & Health Product Register

Operational impacts for changing to IDMP common vocabulary (transforming & cleaning data) are being assessed
A step towards IDMP Implementation - The Drug and Health Product Register (DHPR)

- New “web portal” designed to give Canadians easy access to consumer-friendly information on a wide range of health products.
- Brings together and organises health product information drawn from various areas and databases on Health Canada’s website and present the information in a consolidated, user-friendly way.
- Mobile friendly so Canadians can access health product information on the go.
- “Pilot” launch provides practical drug information on the top prescribed drugs “empowering with information” to make better informed decisions about their health.
- Major milestone under Health Canada’s Regulatory Transparency and Openness Framework.
- Demonstrates concrete progress to improve access to timely, useful and relevant regulatory information for Canadians.
Current DHPR Publishing Processes and Challenges

• The current DHPR was developed utilizing agile approaches to quickly and economically achieve and demonstrate the objectives.

• Existing data repositories and manual extraction tools were used where feasible and content was manually selected, cleansed and assembled. Pristine copies of Product Monograph are only available in PDF or Word format and were manually transformed to XML format.

• Current transformation process of PM content to structured format is a manual, labor intensive, non scalable and lengthy process that is highly susceptible to error that required extensive QA validation by business subject matter experts and correction processes.

• Expansion of content beyond current content (Part III only) is not feasible.
Near-Term DHPR R2.0 Objectives

- Next Release of the DHPR
  - Incorporation of bilingual PM Part I & II to supplement Part III.
  - Integration of other datasets like Medical Device and NHP product content.
  - Strategic proposal to incorporate other HC/HPFB published information.
  - Enhanced functionality and content to enable the decommissioning of existing public facing applications (DPD Online, CVP Online, LNHPD, AR Reporting, etc.).
  - Improved Structured, standardised, bilingual PM content received directly from Industry to be utilised as the pristine PM copy for publishing into the DHPR and promote interoperability.
Structured Content

- Introduce structured content as an integral part of the HC submission process.

- Receive the bilingual pristine PM (parts I, II & III) in a structured XML document directly from Industry through the gateway to provide content that is incorporated into the DHPR and published as required. This will enhance the publishing volume, quality and currency and start to promote interoperability.

- Introduction of Health Canada pick lists for certain fields (i.e. Dosage Form and Routes of Administration)
Structured Product Monograph Approach

- HC current PM templates are unstructured and no longer suitable in a rapidly modernizing healthcare environment
- HC has developed a standards based Structured Product Monograph Parts I, II & III
- Application that uses e-form approach to generate a valid XML file
- Validation guidance that will enable manual and procedural validation of XML content
- To be utilized by Industry to provide content to HC for efficient input into DHPR
- Starts to promote interoperability
- Introduction of pick lists and Controlled Vocabulary (CV)
  - Health Canada Pick lists (i.e.: routes of administration, dosage form)
  - Controlled Vocabularies (i.e.: Marketing Status, Language Code)
Why Controlled Vocabularies

• Interoperability
  – The ICH is currently focused on implementing data standards which enables interoperability within their Health Care System by using common vocabularies/terms. These standards are known as Health Level 7 (HL 7) standards. These common standards are the basis for interoperability between regulator to regulator, regulatory to industry, and regulator to the Health Care System. In fact, these HL 7 standards are being used by Canada Health Infoway to enable interoperability between provinces and territories.

• Data Quality
  – They reduce the risk of data entry variations. Spelling errors, abbreviations, acronyms are wonderful examples of why free form fields are hard to ensure consistency.
Next Steps

• Obtain feedback on the need for Health Canada to adopt & implement IDMP

• BEC Decision on HC participation on the International Pharmaceutical Regulators Fourm’s WG on IDMP implementation

• Policy analysis and decision on IDMP adoption & implementation

• Proceed with function and non-functional pilot – Structured Product Monograph

Questions? Comments? Feedback?