Harmonization, Convergence, Cooperation: A Case Study

The ISO Standards for the Identification of Medicinal Products (IDMP)

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Presentation Goals

- Introduce the IDMP standards as a transformational undertaking – a high level (not comprehensive) orientation
- Share how the development of the IDMP standards represent a unique harmonization effort – adaptation of approaches to meet a need

What are they?

The Five Standards for Reference

Data elements and structures for unique identification and exchange of regulated information for:

- Substances (ISO 11238)
- Dosage Form, Unit(s) of Presentation, Route(s) of Administration (ISO 11239)
- Units of Measurement (ISO 11240)
- Pharmaceutical Product Identification (ISO 11616)
  - PhPID: An algorithm associating the elements of the standards to uniquely identify medicinal products
- Medicinal Product Identification (ISO 11615)
  - MPID: Globally unique identifiers assigned to a medicinal product in a given region

Why were they created?

The Problem

Medical products are a key component of healthcare, BUT

- Information systems referencing those products across the health sector are not interoperable resulting in:
  - Missed opportunities for streamlining data management – if use one source of "truth" could avoid redundant data entry with the possibility of error
  - Missed opportunities for enhanced data analysis – e.g., identifying AEs from global data sources; identifying counterfeit product across marketplaces

The Value-Added of IDMP

- Uniquely/unambiguously identify/describe a medical product
- Serve as common messaging standards (data elements & structures) for improved IT system communication – don't replace national identification numbering systems, but complementary
- Form an internationally accepted framework for consistent documentation, coding and exchange of product information among regulators, manufacturers, suppliers and distributors
- In addition to regulatory use, utility across the healthcare setting (e-health records, e-prescribing, reimbursement, etc.)

Why are they important to Regulators?

The Role of the Regulator in Product Identification

- When a product is first being developed, the developer typically structures the data in a form that the regulator requires – the regulator then becomes the first player (the "point of entry") to define data structures/standards
- The structure of product information is regulated itself as part of the evaluation, approval and registration process of medical products
- Regulators are responsible for maintenance of product identifiers in their jurisdictions

Benefits of IDMP for Regulators

- Patient safety via better pharmacovigilance reporting
- Enables streamlined regulatory decisions based on accurate data and enhances life cycle management
- Facilitates the reliable exchange of product information among all key players (regulators, sponsors, manufacturers, etc.)
  - Enabling regulatory collaboration

Value Possible with Limited Implementation

- Tho maximum benefit from complete implementation across data systems, more limited implementation also can provide benefit
  - For example, AE reporting system alone
    - WHO UMC AE reports will be IDMP compliant in the future

Examples of IDMP Value-Added in the Americas

SALUD
SECRETARÍA DE SALUD
Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios
PANDRH
Pan American Network for Drug Regulatory Harmonization
Pan American Health Organization
World Health Organization
Americas

Mutual Recognition Context

- A number of countries in the Americas now operate under agreements that support the mutual recognition of product authorizations
- However, to effectively operate, it is necessary to have confidence that the identity of the product authorized in one country is the same as the proposed product authorization in a second
- Cases have occurred where identity of product not clear

Product Purchases Absent an NRA

- Some countries without an NRA (or small) have had a need to purchase products authorized by an NRA in the region but where manufactured in third country
- Again, identity of product to be purchased has at times been ambiguous – is it indeed the same product authorized?

Current status

Current Status in Regulatory Domain

- Standards are finalized, implementation underway by a number of regulators as early adopters
- FDA and HC implementation in process
- WHO UMC committed to adopt for Vigibase
- Use of the standards in EU being applied to systems in which product sponsors will have mandated reporting in 2017

A Unique Harmonization Effort

Refresher on ISO

The International Organization for Standardization (ISO)

- ”an independent, non-governmental international organization with a membership of 163 national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.”

The Path for IDMP to be ISO Standards

- Path has been technically & politically complex
- Initially, an ICH undertaking but recognition of need for broader technical expertise and of broader constituency
- ICH proposed IDMP topic to ISO
  - Became a “Liaison” party

ISO's Creative Response to Achieve Synergies

- Due to overlap in other standards development organizations, a formal "Joint Initiative" launched
  - ISO, CEN, HL7, CDISC, IHTSDO
  - Individual regulatory agencies participated
  - Healthcare systems users and developers

Collaboration in Implementation

- An ad hoc collective of interested regulators and industry have been, and continue, working to progress implementation of the standards

Resources for the Americas

Resources for the Americas (1)

Learning venue: International Pharmaceutical Regulators Forum (IPRF)

Goal: a venue to facilitate the harmonized implementation of IDMP among interested international regulatory bodies

- For new "entrants," an informational venue to learn
- Early adopters can share their experience and status of implementation
- Will function via telecons
- Any regulator can participate (PANDRH, Brazil, Mexico participate in IPRF)

Resources for the Americas (2)

- WHO Uppsala Monitoring Center: over time, may be able to provide outreach
- Regional NRAs – US FDA, HC, AEMPS (Spain)
- Data and software for substance registration: web-based Global Substance Registration System to be hosted by US NIH National Center for Advancing Translational Sciences

Conclusions

- The IDMP standards represent a tool that can provide a foundation for regulatory information exchanges and cooperative efforts – broad regulatory uptake, even if limited in scope, can assure the vision is realized
- To complete the global IDMP standards, different initiatives and parties needed to cooperate – a model for other cross-cutting initiatives/efforts

Discussion/Q&A