IPRP
International Pharmaceutical Regulators Programme

Mandate Document

Identification of Medicinal Products Working Group

IDMP WG

Version 1.0

endorsed by the MC on 2 November 2018

Document History

Version number	Action	Date of endorsement
v1.0	First version of the Mandate document endorsed by the MC.	**2 November 2018**

1. General Considerations

The International community in the health domain identified a need for the development of international standards, via the International Organization for Standardization (ISO), for the global identification of medicinal products (IDMP). This includes the development of both ISO standards and corresponding ISO Technical Specifications for use as implementation guides. The standards provide definitions and conceptual models for the unique identification of medicinal products throughout the product lifecycle for improved regulatory and clinical activities. Although the application of the standards is broader than the regulatory domain, there is a unique role for regulators in implementing the standards with potential value not only to regulatory business processes, but more broadly to healthcare systems.

To optimize the utility of the standards in the regulatory domain, broader regulatory uptake is desirable. However, outside of the early adopters of the standards, there is limited awareness of what the standards are, what the regulatory use-cases are (the value of the standards to regulators), and what resources exist to facilitate the implementation of the standards. There is a need for a venue in which regulators can exchange information around the implementation of the standards. The IPRP IDMP Working Group will provide such a venue for regulators to learn about the IDMP standards.

Overall benefit is enhanced individual and collective management of regulatory assessment and decision- making around:

a. Data analytics (improving quality and integrity)

b. Investigational/pre-market assessment

c. Surveillance and global supply chain management

d. Pharmacovigilance (adverse events)

2. Scope

Provide an understanding/comprehension of the ISO IDMP standards and their implementation by:

a. Sharing strategies around implementation approaches such as limited, phased, or more fully across the product lifecycle
b. Clarifying the use cases (i.e., the regulatory and public health value), e.g., in the areas of pharmacovigilance, compliance, clinical decision support, e-prescribing/dispensing, risk management and lifecycle management activities (from investigational phase through product registration)
c. Updating members of on the status, progress, and challenges of implementation activities by early adopters
d. Exploring approaches in which local systems can include features specific to the needs of individual regulators while realizing the benefits of IDMP adoption
e. Identifying available technical resources that can facilitate implementation

3. Objectives and Key Deliverables

3.1. Objectives

- Objective 1: ensure the awareness and understanding of the standards of the IDMP standards more globally by pharmaceutical regulators
- Objective 2: clarify how and why these standards can add value to regulator business processes to

improve the quality and effectiveness of shared regulatory functions

- Objective3: share strategies and experiences for their successful and consistent implementation

3.2. Key deliverables

Outreach and communication on ISO IDMP:

- Deliverable 1: Publication of documents in relation to the activities identified in the Scope of the WG and sharing of the public documentation produced by the early adopters for their regional/national implementation.
- Deliverable 2: Publication of a yearly report providing an overview of the implementation of IDMP by early adopters and of ongoing activities for a consistent international implementation

4. COMPOSITION

a. IDMP Subject Matter Experts
b. Regulatory leaders interested in the use/applicability of IDMP whether on a limited scale or applied throughout the product lifecycle
c. WHO

5. SPECIFIC ORGANISATION