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Health informatics — Identification of medicinal products — Core principles for maintenance of identifiers and terms

Informatique de santé — Identification des médicaments — Principes essentiels pour la mise à jour des identifiants et des durées

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document describes the core operating principles and a proposed service delivery model for terminology maintenance services in support of five International Standards on the Identification of Medicinal Products (IDMP), i.e. ISO 11615, ISO 11616, ISO 11238, ISO 11239, ISO 11240. Collectively, the International Standards on IDMP provide the basis for data collection and information exchange about key medicinal product characteristics that support the unique and unambiguous identification of medicinal products for a variety of regulatory and commercial business objectives and use cases.

Since the International Standards on IDMP can be applied to a broad range of use cases, (e.g., regulatory product applications, product registration, creation of drug dictionaries, etc.), adherence to common coordination and maintenance principles is critical to help ensure consistent adoption, use and maintenance of the International Standards on IDMP.

Currently, many organizations serve as data owners or terminology service providers in several jurisdictions. These organizations maintain and distribute their own medicinal product terminology which does not fully correspond to terminology mapping and format criteria described in Technical Specifications on IDMP (i.e., ISO/TS 20443, ISO/TS 20451, ISO/TS 19844, ISO/TS 20440). The terminology maintenance service delivery model proposed in this document is adapted for IDMP based upon well-established IT service models which use a hybrid support approach comprised of centralized and decentralized services (also referred to as service components) for a comprehensive set of IT support services. These IT support models are often referred to as “federated enterprise architecture” models[20]. The success of the IDMP federated service delivery model proposed in this document will help provide a framework to support more collaboration and shared data governance among key IDMP stakeholders and is dependent upon several factors, including the following:

— Adherence to a set of core principles for each of the International Standards on IDMP;

— Adherence to the core principles described in this document;

— Strict enforcement of service level agreements between IDMP terminology service providers and their stakeholders to help address jurisdictional differences.

Since IDMP standards are in the process of adoption internationally, it is anticipated that this document will be revised to reflect real-world experience in how the information models, data elements and their associated terminologies are used, as well as to accommodate any potential gaps in mapping and governance for specific IDMP terminology domains (e.g., substance/specified substance, dosage form, route of administration).

This document leverages and complements several ISO and joint ISO/IEC specifications pertaining to support principles and processes that should be exhibited by developers of healthcare terminologies in support of international healthcare terminology standardization, information technology service management and the design and maintenance of quality systems. The applicable International Standards are ISO/IEC 20000-1:2018, ISO/IEC 20000-2:2012 and ISO/IEC 33002:2015.

The intended audience for this document includes the following:

— Organizations seeking an opportunity to support creation and/or dissemination of IDMP terminologies;

— Organizations interested in implementing or applying the International Standards on IDMP (e.g., technical format and/or scientific content) to their internal processes and systems in support of regulatory or healthcare-related business; and

— Global regulators, pharmaceutical/biopharmaceutical companies, Clinical Research Organizations (CROs) and universities/scientific institutes involved in the development, authorization and marketing of medicinal products.