Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information

Informatique de santé — Identification des médicaments — Éléments de données et structures pour l'identification unique et l'échange d'informations sur les médicaments contrôlés
Contents

Foreword.................................................................................................................................................................................................................................. vi

Introduction......................................................................................................................................................................................................................... vii

1 Scope......................................................................................................................................................................................................................... 1

2 Normative references.................................................................................................................................................................................................. 1

3 Terms, definitions and abbreviated terms................................................................................................................................................................. 2

4 Message exchange format.................................................................................................................................................................................................. 13

5 Conformance terminology and context as it relates to the ISO IDMP standards and corresponding IDMP technical specifications................................................................................................................................................................................. 14

6 Concepts required for the unique identification of Medicinal Products................................................................................................................................................................ 14

7 Description of the information modelling principles and practices................................................................................................................................................................................................. 17

8 Identifying characteristics for authorised Medicinal Products................................................................................................................................................................................................. 20

9 Information for an authorised Medicinal Product................................................................................................................................................................. 24

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10 Identifying characteristics for Investigational Medicinal Products

10.1 General

10.2 Primary identifiers

10.2.1 General considerations

10.3 Investigational Medicinal Product Identifier (IMPID)

10.3.1 General considerations

10.3.2 IMPID code segments

10.4 Investigational Medicinal Product Package Identifier (IPCID)

10.4.1 General provisions

10.4.2 Package description code segment

10.5 Investigational Medicinal Product Batch Identifier (BAID1)

10.6 Investigational Medicinal Product Batch Identifier (BAID2)

11 Information for an Investigational Medicinal Product

11.1 General

11.2 Conceptual overview of the information for an Investigational Medicinal Product

11.2.1 General

11.2.2 Investigational Medicinal Product

11.2.3 Investigational Medicinal Product name

11.2.4 Header

11.2.5 Manufacturer/Establishment (organisation)

11.2.6 Clinical trial authorisation

11.2.7 Investigational Packaged Medicinal Product

11.2.8 Pharmaceutical product

11.2.9 Ingredient

11.2.10 Clinical particulars

11.3 Investigational Medicinal Product

11.3.1 General

11.3.2 Detailed description of Investigational Medicinal Product information

11.4 Clinical trial authorisation

11.4.1 General

11.4.2 Detailed description of clinical trial authorisation information

11.5 Manufacturer/Establishment (organisation)

11.6 Investigational Packaged Medicinal Product
11.7 Pharmaceutical product

11.7.1 General

11.7.2 Pharmaceutical product

11.7.3 Dosing and route of administration

11.8 Ingredient

11.9 Clinical particulars

11.10 PhPID sets

11.11 Device nomenclature

11.12 Device batch identifier

11.13 Physical characteristics

11.14 Other characteristics

Annex A (normative) Full model — Authorised Medicinal Products detailed diagram

Annex B (normative) Full model — Investigational Medicinal Products detailed diagram

Bibliography
Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 11615:2012), which has been technically revised.
Introduction

This document was developed in response to a worldwide demand for internationally harmonised specifications for Medicinal Products. It is part of a set of five ISO Standards and four ISO Technical Specifications which together provide the basis for the unique Identification of Medicinal Products (IDMP).

These sets of standards and technical specifications comprise:

- ISO 11615
- ISO/TS 20443;
- ISO 11616;
- ISO/TS 20451;
- ISO 11238;
- ISO/TS 19844;
- ISO 11239;
- ISO/TS 20440;
- ISO 11240.

These standards and technical specifications for the identification of Medicinal Products (IDMP) support the activities of medicines regulatory agencies worldwide by region. These include a variety of regulatory activities related to development, registration and life cycle management of Medicinal Products, as well as pharmacovigilance and risk management.

To meet the primary objectives of the regulation of medicines and pharmacovigilance, it is necessary to reliably exchange Medicinal Product information in a robust and consistent manner. The IDMP standards therefore support, at a minimum, the following interactions:

- regulatory medicines authority to regulatory medicines authority;
- pharmaceutical company to regulatory medicines authority;
- sponsor of a clinical trial to regulatory medicines authority;
- regulatory medicines authority to other stakeholders (as applicable);
- regulatory medicines authority to worldwide-maintained data sources.

The necessary messaging specifications are included as an integral part of the IDMP standards to secure the interactions above.

Unique identifiers produced in conformance with the IDMP standards are aimed at supporting applications where it is necessary to reliably identify and trace the use of Medicinal Products.

There are many terms in use to describe basic concepts in the regulatory, pharmaceutical and healthcare standards development domain for different purposes and in different contexts. The terms and definitions given in this document are to be applied for the concepts which are required to uniquely identify, characterise and exchange regulated Medicinal Products and associated information.

The terms and definitions adopted in this document are intended to facilitate the interpretation and application of legal and regulatory requirements.

This document has been developed in conjunction with the Common Product Model (CPM) and Structured Product Labelling (SPL) in HL7.
In the context of exchange of regulatory information, the purpose of this document is twofold:

— to specify data elements, structures and relationships between the data elements which are required to uniquely and with certainty identify Medicinal Products for human use;

— to specify definitions of terms for all data elements required to uniquely and with certainty identify Medicinal Products for human use.

In addition, reference to the use of other normative IDMP and messaging standards for Medicinal Product information is included in this document in order to support successful information exchange.