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Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

Informatique de santé — Identification des médicaments — Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les formes pharmaceutiques, les unités de présentation, les voies d'administration et les emballages

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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 document 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,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 11239:2012), which has been technically revised.

The main changes are as follows:

— it is now specified that pharmaceutical dose form attributes can in some cases be used directly in order to describe features of a medicinal product, rather than just serving as internal attributes to classify the pharmaceutical dose form.

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.

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Introduction

This document was developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. It is one of a group of five International Standards, which together provide the basis for the unique identification of medicinal products; the four other International Standards are ISO 11615, ISO 11616, ISO 11238 and ISO 11240.

These International Standards on the identification of medicinal products (IDMP) can be used in the activities of medicines regulatory agencies worldwide. 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.

The International Standards on IDMP therefore can be used in the following interactions (this is not an exhaustive list):

— regulator to regulator;

— pharmaceutical company to regulator;

— sponsor of clinical trial to regulator;

— regulator to other stakeholders;

— regulator to worldwide-maintained data sources.

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

Unique identifiers produced in conformance with the International Standards on IDMP are aimed at supporting applications where it is needed 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.

In the context of identification of pharmaceutical dose forms, units of presentation, routes of administration and packaging, this document describes the essential elements for the specification, translation and versioning of the specified controlled terms. Also described are recommendations concerning the mapping of terms that are already used by stakeholders to the concepts arising from the implementation of this document.

The high-level concepts described consist of:

— pharmaceutical dose form;

— unit of presentation;

— route of administration;

— packaging.

The supporting, more mechanical, components are described separately from the high-level clinical concepts. The supporting concepts consist of:

a) terms and codes;

b) translations;

c) versioning;

d) mapping.

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Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

1 Scope

This document specifies:

— the data elements, structures and relationships between the data elements required for the exchange of information, which uniquely and with certainty identify pharmaceutical dose forms, units of presentation, routes of administration and packaging items (containers, closures and administration devices) related to medicinal products;

— a mechanism for the association of translations of a single concept into different languages, which is an integral part of the information exchange;

— a mechanism for the versioning of the concepts in order to track their evolution;

— rules to help regional authorities to map existing regional terms to the terms created using this document, in a harmonized and meaningful way.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 code*

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country code*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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