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

AMENDMENT 1

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

AMENDEMENT 1

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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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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).

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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AMENDMENT 1

Introduction, last paragraph

Replace the paragraph with the following:

> Reference to the use of other normative IDMP and messaging standards for Medicinal Product information is included in this document to support successful information exchange.

7.5.4

Add the following paragraph at the end of the subclause:

Annex C provides translations and synonyms utilized in regulatory, clinical, pharmacovigilance, healthcare and by governmental organisations for IDMP class names and attributes defined in this document on an international scale.

Annex C

Add the following annex after Annex B, before the Bibliography.

Annex C
(informative)

Class name and attribute translations and synonyms for the identification of medicinal products (IDMP)

This annex describes language translation considerations and provides synonyms. An important implementation consideration is the consistent application and regional/local language translations of the semantic definitions for the class names and attributes depicted in the data model referenced in Annexes A and B. Terms and synonyms used throughout this document can be used to assist implementers and help ensure consistent semantic interpretation of the class names, attributes and data elements used in the data model.

The terms are common concepts used in IDMP use cases such as regulatory affairs, pharmacovigilance, health care and governmental organisations involved in the use of IDMP standards.

Translation is the conversion of text written in one language into another language. It always involves interpretation, because a word for word translation of the original document into the target document would change the meaning of the content. The most important aspect of translation is to transfer the same message contained in the original language into a different language. The translations were created under the premise that the meaning of each term is defined by the IDMP model and its relations to other terms. Therefore, it can deviate from word-for-word translations.

This annex also addresses businesses, local authorities, health insurances, hospitals, etc. seeking to implement the IDMP data model. It facilitates the understanding of the IDMP model by breaking down language barriers and ensures the consistency and validity of the different translations available.

The full list of class name and attribute translations and synonyms for the identification of Medicinal Products is available on the ISO Standards Maintenance Portal: https://standards.iso.org/iso/11615/ed-2/en/amd/1.