Irish Standard
I.S. EN ISO 11238:2012

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances (ISO 11238:2012)

I.S. EN ISO 11238:2012

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EUROPEAN STANDARD

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English Version

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances (ISO 11238:2012)

Informatique de santé - Identification des médicaments - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les substances (ISO 11238:2012)

Medizinische Informatik - Identifikation von Arzneimitteln - Struktur und kontrollierte Vokabularien zur Identifikation und Beschreibung von Substanzen und Inhaltsstoffen (ISO 11238:2012)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 11238:2012) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 11238:2012 has been approved by CEN as a EN ISO 11238:2012 without any modification.

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I.S. EN ISO 11238:2012

INTERNATIONAL STANDARD

ISO 11238

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

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

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11238 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This International Standard was developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. It is one of a group of five standards which together provide the basis for the unique identification of medicinal products. The group of standards comprises:

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*;

ISO 11616, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*;

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*;

ISO 11239, *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*;

ISO 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*.

These standards for the identification of medicinal products (IDMP) support the activities of medicines regulatory agencies worldwide by jurisdiction. 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 reliable manner. The IDMP standards therefore support the following interactions:

— between one medicine regulatory agency and another, e.g. European Medicines Agency to the US Food and Drug Administration (FDA), or vice versa;

— between pharmaceutical companies and medicine regulatory agencies, e.g. “Pharma Company A” to Health Canada;

— between the sponsor of a clinical trial to a medicine regulatory agency, e.g. “University X” to the Austrian Medicines Agency;

— between a medicine regulatory agency and other stakeholders, e.g. UK Medicines and Health Care Products Regulatory Agency (MHRA) to the National Health Service (NHS);

— between medicine regulatory agencies and worldwide-maintained data sources, e.g. the Pharmaceutical and Medical Device Agency (PMDA) and the organization responsible for assigning substance identifiers.

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

Unique identifiers produced in conformance with the IDMP standards will support applications for which it is necessary to reliably identify and trace the use of medicinal products and the materials within medicinal products.

This International Standard provides a structure that enables the assignment and maintenance of unique identifiers for all substances in medicinal products or in packaging materials in which medicinal products are contained. This International Standard sets out the general rules for defining and distinguishing substances, and provides a high-level model that structures substances and specified substances for the organization and capturing of data.

This International Standard has been developed using HL7’s Common Product Model, and detailed modelling of substances and specified substances has been undertaken in that domain. It is anticipated that implementation will use the HL7 substances implementation guide and messaging to deliver a strong, non-semantic unique identifier for every substance present in a medicinal product. It is anticipated that a single organization will be

responsible for the generation of identifiers for every substance and that such an organization would retain the defining elements upon which the substance identifier was based. At the specified substance level, a more regional approach may be necessary because of the proprietary nature of much of the information.

The use of the identifier is essential for the description of substances in medicinal products on a global scale. This International Standard does not involve developing nomenclature for substances or specified substances, but common and official substance names in current use can be mapped to each identifier.

Materials used in medicinal products range from simple chemicals to gene-modified cells to animal tissues. To unambiguously define these substances is particularly challenging. This International Standard defines substances based on their scientific identity (i.e. what they are) rather than on their use or method of production. Molecular structure or other immutable properties, such as taxonomic, anatomical and/or fractionation information, are used to define substances. This International Standard contains five groups of elements that are sufficient to define all substances. Although it is certainly possible to define or classify substances in other ways, this International Standard uses a minimalist structured scientific concept approach focusing on the critical elements necessary to distinguish two substances from one another. There are frequently interactions between substances when they are mixed together, but this International Standard has intentionally not included these supramolecular interactions at the substance level because of the variable nature and strength of such interactions. This International Standard also allows for the capture of multiple terms which refer to a given substance and a variety of reference information that could be used to classify substances or relate one substance to another.

In addition to the substance level, this International Standard also provides elements for the capture of further information on substances, such as grade, manufacturer, manufacturing specifications, and also to capture information on substances that are frequently combined together in commerce but are not strictly a medicinal product. At the specified substance level, four groups of elements provide information essential to the tracking and description of substances in medicinal products.

The basic concepts in the regulatory and pharmaceutical standards development domain use a wide variety of terms in various contexts. The information models presented in this International Standard depict elements and the relationship between elements that are necessary to define substances. The terms and definitions described in this International Standard are to be applied for the concepts that are required to uniquely identify, characterize and exchange information on substances in regulated medicinal products.

The terms and definitions adopted in this International Standard are intended to facilitate the interpretation and application of legal and regulatory requirements, but they are without prejudice to any legally binding document. In case of doubt or potential conflict, the terms and definitions contained in legally binding documents prevail.