TECHNICAL SPECIFICATION

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Health informatics — Business requirements for a syntax to exchange structured dose information for medicinal products

Informatique de santé — Exigences d'affaire pour une syntaxe d'échange d'informations de dose structurée pour les produits médicaux

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Foreword

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

Introduction

The requirements for the exchange of structured dose instructions are intended to be independent of any technology standard or software platform and have been developed with the aim of specifying the necessary clinical and business requirements precisely and unambiguously. Implementation of the requirements within a suitable medium designed to support communication of healthcare information can provide support to clinicians and their applications in storing, retrieving, using, and above all, communicating dose instructions information to other clinicians, their applications, and most importantly, to the patient.

The primary audiences for this Technical Specification are software developers building clinical IT systems.

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1 Scope

This Technical Specification specifies the business requirements for the structured content of structured or semi-structured dose instructions for recording dose instructions in the electronic health record (EHR), supporting clinical decision support, and in exchanging medication orders, as applicable to primary, secondary and tertiary care.

NOTE See 2.9, note to entry, regarding the use of "medication order" and "prescription".

Comprehension of dose instructions by the patient is an overarching consideration for patient safety and the best patient outcomes. Related factors are discussed, but are not part of the primary scope.

This Technical Specification does not define an information model, except to the extent that those information model concepts are necessary to define business requirements.

Outside the scope of this Technical Specification are:

— the functionality of health, clinical and/or pharmacy systems;

— other kinds of content of health, clinical or pharmacy systems that are needed to support the whole process of health care providers, such as:

  — wide range of knowledge about medicines that would be handled in drug knowledge databases and decision support systems;

  — the complete medical record (EHR);

  — a medicinal product dictionary.

2 Terms and definitions

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

2.1
dose instructions
instructions pertaining to the medication, which describe the amount of medication per dose, method of administration, the frequency or interval of dose, associated instructions for dosing or skipped doses, and other associated parameters necessary for appropriate administration of the medication

2.2
dose syntax
structured dose instructions
structured set of data elements which represent the dose instructions in a consistent, computable format

2.3
structured information
information assembled from predefined concepts (vocabulary or code set) using an organizational scheme (information model)