TECHNICAL SPECIFICATION

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Health informatics — Categorial structure for representation of herbal medicaments in terminological systems

Informatique de santé — Structure catégorielle pour la représentation de médicaments à base de plantes dans les systèmes terminologiques

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Contents

Page

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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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html

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

Introduction

Medicinal or *pharmaceutical products* (3.11, 3.12) derived from plants have complicated backgrounds and a wide range of uses in traditional and western medicine.

Medicinal plants contain many constituent substances and the content of these substances differ throughout parts of some plants. Medicinal plants may be used individually or in combination with other medicinal plants[32]–[63]. The combination of medicinal plants and the rules and methods used to achieve this combination is conventionally called a "formula." The constituents of formulas are determined by the species of the source materials, which parts of the plants are used, and the quantity of each source material used. The quantity of active substances used directly influences the efficacy and side effects of herbal medicines.

A *medicine regulatory agency* (3.10) controls pharmacopoeias that define the "requisites" for each herbal *pharmaceutical* and/or *medicinal product* and the "name" by which the product is to be referred. It should be noted that a pharmacopoeia does not define a product itself, but rather its "design" under its "common name." In other words, pharmacopoeias define "a set of concepts" with a "common name" and regulate the fundamental characteristics of a certain group of *pharmaceutical* or *medicinal products*.

However, there are many *synonyms*, *homonyms* and *polysemes* used in pharmacopoeias: the same species of source material is often represented by different expressions, and *vice versa*. In addition, a single "common name" often designates different compositions of formulas in different pharmacopoeias[28]–[30], [52]–[63]. Disagreement on the definitions of "sets of concepts" and "common names" of herbal medicines in various *terminological resources* (3.7)[10] have caused confusion in international trade which increases risk of harm to patients and negative impact to scientific research including clinical tests.

This problem should be resolved by standardization, while according respect to each pharmacopoeia and avoiding market distortion. ISO 860[2] has already proposed an approach to this issue in preparing the harmonization of necessary concepts before "term standardization." This approach implicitly requires the prior building of a well-structured backbone, i.e. "a set of concepts" for terms. For this purpose, ISO 1087-1, EN 12264 and ISO 17115 [4] –[7] define the structures of concepts and provide the necessary terms that designate the elements of concept structures. This framework is called "categorial structure."

This document uses a *categorial structure* to represent the concepts required in order to contribute to both international harmonization and supporting the ability to *map* with appropriate *semantic correspondence* between the terms on herbal medicines in various pharmacopoeias. Please refer to ISO 17115:2007, Annex A, as well as ISO 1087-1.

This document provides initial guidance to those developing and implementation systems to represent herbal medicaments. Users should understand that this work has identified several issues, which require further investigation in order to develop a future International Standard:

— need to clarify and describe the relationship of the concepts described in the categorial structure to existing standards including IDMP; where there are differences, ISO 11238 IDMP should be followed;

— definitions used in this document are those used in some cultures, countries and areas of clinical practice (e.g. traditional medicine) which use words differently to that of IDMP (see Annex B);

— these variations may also arise from the focus on terminological and ontological specifications rather than pharmaceutical concepts; there is a recognized need to undertake further work to clarify these definitions and to identify where there is

  — more than one term is used to describe a single thing and agree on synonyms or preferred terms,

  — single term used with different meanings in different contexts, and

  - a need to define a term or concept not currently defined or confusing, e.g. active substance, herbal substance, botanical substance, source material and source;
- the relationship between medicinal regulatory agencies and pharmacopoeia;
- the use of the term concept has been used in this document from a terminological perspective not from a pharmaceutical one and this requires clarification.

Health informatics — Categorial structure for representation of herbal medicaments in terminological systems

1 Scope

The document aims to

a) specify the minimal *characterizing generic concepts* in *herbal medicament* (3.2) within *terminological systems* (3.8), that are required for terms used to identify of herbal medicines regulated by *medicine regulatory agencies* (3.10), and

b) facilitate the consistency and interoperability of the *terms* and their designating concepts in *terminological systems*.

In order to achieve these goals, this document specifies the minimal *compositional concept representation* of herbal medicament for use in *terminological systems* (3.8), while expressing *semantic links* and *characterizing categories* for *formal definitions*, with a set of *domain constraints* in the *subject field*[6] [7].

Herbal medicaments (3.2) can be classified into

1) single herbal medicament (SHM), and

2) herbal medicament composed of several kinds of SHM.

NOTE Single herbal medicament is composed of only one herbal medicament. Herbal medicament composed of several kinds of *SHMs* is conventionally called "formula." This document is not intended to include the mixture of formulae.

The specific intended use of this *compositional concept representation* is to

— provide a well-structured backbone for *terminological systems*,

— clarify the synonymy, homonymy and polysemy across different clinical specialties and terminological resources,

— promote meaningful exchange of information among different terminological systems,

— promote consistency and interoperability or re-use of terms among different terminological systems,

— facilitate the representation of herbal medicines in a manner suitable for computer processing,

— support developers and maintainers of *terminological resources* (3.7) to facilitate conformance,

— support knowledge management on herbal medicines with facilitating analysis of concerned data, and

— support the reduction of confusion in trade and of health hazard in consequence.

The following topics are out of scope for this document:

— any implementation models or database schemas, and manufacturing models;

— any models or frameworks for quality control, and models for chemical and physical characteristics;

— any individual pharmaceutical or medicinal products, and combinations use with modern medicines.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1087-1, ISO 17115, EN 12264 and the following apply.

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

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

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

3.1
herbal substance
botanical substance
source material (context: pharmacy)
source (context: pharmacy)
physical matter of the plant used as medicines, including plant, algae, fungi or lichen, used in whole or in part

Note 1 to entry: In this document, *herbal substance* (3.1) is used in the meaning of *source material*. The ingredients of it are determined by the *part(s) of interest* (3.3) of an origin.

Note 2 to entry: The definitions of "herbal substance" in E.1.3 (herbal substance), E.1.5 (herbal substance, according to the pharmacopoeia), E.1.6 (herbal preparation), E.2.1 (European Directives: Article 30, 31, 32) and E.2.2 (European Pharmacopoeia) in ISO/TS 19844:2015, Annex E[26] are different from the definition in this document. The former definitions should be respected when implementing an IDMP family or referring to European Pharmacopoeia. Where IDMP applies in the jurisdiction, IDMP definitions should be given priority.

3.2
herbal medicament
minimal concepts for representation of regulated design or identification of *pharmaceutical products* (3.12) or *medicinal products* (3.11) made of *herbal substance(s)* (3.1)

Note 1 to entry: This document does not mention any individual *pharmaceutical products* (3.12) or *medicinal products* (3.11). *Herbal medicament* (3.2) designates the "design" or the concepts of herbal *pharmaceuticals* or *medicinal products* at an abstract or design level regulated by *medicine regulatory agencies* (3.10). Pharmacopoeias defined them with their name, therefore, that are also regulated by *medicine regulatory agencies*.

Note 2 to entry: This document does not include the mixture of formulas.

3.3
part of interest
medicinal part
partofinterest
part of the plant that is intended for use as a *herbal substance* (3.1)

EXAMPLE Seed, root, rhizome, stem, bark, leaf, bud, flower, fruit.

3.4
assistant material
adjuvant material
substance added during processing in order to enhance the therapeutic usefulness of pharmaceutical *herbal medicament* (3.2) treatment

Note 1 to entry: "*Adjuvant*" in this context does not mean the adjuvant in modern scientific parlance, rather, is used to support elution of bioactive substrates, enhancing efficacy and reducing toxicity, flavouring and taste masking, or as a filler.

