PD ISO/TS 18062:2016

BSI Standards Publication

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

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National foreword

This Published Document is the UK implementation of ISO/TS 18062: 2016.

The UK committee are committed to the value of a standard representation of herbal medicaments, however during the development of this technical specification they consistently voted against its approval.

The UK committee was particularly concerned about potential conflict between this standard and the relevant parts of ISO's Identification of Medicinal Products set of standards (IDMP). Notably, this standard covers topics also addressed in BS EN ISO 11238:2012 and the herbal annex to PD CEN ISO/TS 19844:2015.

The UK committee's concerns are acknowledged in the Introduction of this standard. The UK committee further recommend that where there are differences between this standard and other IDMP standards, ISO 11238 IDMP should be followed.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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

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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 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.*

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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

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- 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.

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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.

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