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Traditional Chinese medicine — Controlled vocabulary on Japanese Kampo formulas and the indication codes for the products

Médecine traditionnelle chinoise - Vocabulaire contrôlé relatif aux formules Kampo japonaises et codes d'indication des produits

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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. www.iso.org/directives

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This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Introduction

Herbal medicines have been developed around the world by utilizing available vegetation to develop uses suitable for the physical constitution of the target population in each area.

Consequently, herbal prescriptions with the same name sometimes have different qualitative composition and quantitative composition strength in different parts of the world. In other words, there are plenty of polysemes (see ISO 1087-1) in the origin of crude drugs among some traditional medicines[20]. The resulting confusion is further complicated by the use of similar letters[12] in some countries.

These issues cannot be ignored in the process of standardizing contemporary terminology for medicinal products to keep with up-to-date drug information management policies, from clinical trials to post-market surveillance in the periodic safety update report (PSUR).

Furthermore, therapeutic indications are defined only for medicinal products, but not for formulas specified in some pharmacopoeias including Japan's[21][22]. It is important to take this into account in international standardization though this has not yet been achieved in ISO/TC 249.

Therefore, this document describes the controlled vocabulary for formula names used in Japanese Kampo formulas with the respective indications and efficacies of each product to avoid market distortions and health hazards. The information provided in this document is expected to encourage international trade.

Formulas or traditional medicines that are not controlled by the Japanese Pharmacopoeia and the related official documents published by the Medicinal Regulatory Agency in Japan are beyond the scope of this document.

Traditional Chinese medicine — Controlled vocabulary on Japanese Kampo formulas and the indication codes for the products

1 Scope

This document specifies the controlled vocabulary for formulas used in Japanese Kampo medicine with the therapeutic indications of each product according to the subset of IDMPs (ISO 11238, ISO 11615, ISO 11616[10], ISO 19844[15], ISO/TS 20443[16], ISO/TS 20451[17]).

This document is intended to be used by:

— traders and distributors of medicinal products in Kampo formulas and crude drugs used in Kampo medicine;

— terminologists and developers of new terminological resources concerning herbal medicines in Kampo medicine, and maintenance officers of existing terminological resources concerning Kampo medicine to enable their conformance;

— informaticians, developers, or managers of HIS, EMR, or EHR systems concerning Kampo medicine;

— officers, analysts or maintenance personnel of national health statistics, and policy proposal staff of national health policies;

— officers of WHO, and WHO statistics.

This edition of this document describes only medicinal products in accordance with the Kampo formula in Japan. Both OTC Kampo formula medicinal products and in-pharmacy formula medicinal products are omitted, although they are permitted under Japanese jurisdiction.

Topics considered out of scope of this document are:

— any medicinal products manufactured in accordance with the formula of traditional medicines that are not permitted under the Japanese jurisdiction;

— whole information models of medicinal products, pharmaceutical products and substances (see ISO 11238) because those are already specified in IMDPs;

— any categorical structure(s) of herbal medicaments (see ISO/TS 18062, ISO 17115[13] and EN 12264[18]).

The controlled vocabulary for formulas used in Japanese Kampo medicine is given in Annex A.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1087-1, *Terminology work — Vocabulary — Part 1: Theory and application*

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

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

ISO/TS 18062, *Health informatics — Categorial structure for representation of herbal medicaments in terminological systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1087-1, ISO 11238, ISO 11615 and ISO/TS 18062 and the following apply.

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

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

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

3.1
ingredient
material (3.8) that is used in the preparation of a *medicinal product* (3.9)/*pharmaceutical product* (3.13)

Note 1 to entry: An ingredient is a part of a *medicinal product* (3.9), either by itself or in combination with one or more ingredients. An ingredient is also a component of a *pharmaceutical product* (3.13). An ingredient is equal to a detailed description of a substance playing a role in a product.

3.2
jurisdiction
geographical area or subject matter in which the authority of the Medicines Regulatory Agency applies

3.3
legal status of supply
jurisdictional rule on whether a medicinal product requires a medical prescription before it can be supplied to a patient or consumer

3.4
manufactured item
qualitative and quantitative composition of a product as described in the packaging of the *medicinal product* (3.9)

Note 1 to entry: A medicinal product may contain one or more manufactured items.

Note 2 to entry: *Pharmaceutical product* (3.13) and manufactured item are sometimes different when manufactured item(s) are processed before administration to the patient (as the pharmaceutical product).

Note 3 to entry: The manufactured item is not in direct contact with the outer packaging except where the outer packaging also serves as the immediate container.

3.5
marketing authorization
authorization issued by a Medicines Regulatory Agency allowing a *medicinal product* (3.9) to be sold on the market

3.6
marketing authorization holder
organization that holds the authorization for marketing a *medicinal product* in a jurisdiction

3.7
marketing authorization number
identifier assigned by a Medicines Regulatory Agency to a *medicinal product* (3.9)

3.8
material
substance or a specified substance of which a certain component is made

Note 1 to entry: This applies to *medicinal products* (3.9), packaging items (container), packages (component), and devices.

3.9
medicinal product
any substance or combination of substances that may be administered to human beings (or animals) to treat or prevent disease, to make a medical diagnosis, or to restore, correct, or modify physiological functions

Note 1 to entry: A medicinal product may contain one or more manufactured items, and one or more *pharmaceutical products* (3.13).

Note 2 to entry: In certain jurisdictions, a medicinal product may also be defined as any substance or a combination of substances that may be used to make a medical diagnosis.

Note 3 to entry: [SOURCE: ENV 13607:2000, modified]

3.10
medicinal product identifier
MPID
unique identifier allocated to a *medicinal product* that supplements any existing *marketing authorization number* as ascribed by a Medicines Regulatory Agency within a jurisdiction

Note 1 to entry: This identifier is for indexing purposes to contribute to improved patient safety by allowing for the unique identification of *medicinal products* worldwide.

3.11
medicinal product name
name as authorized by a Medicines Regulatory Agency

Note 1 to entry: This may either be an invented name not liable to be confused with the common name, or a common or a scientific name accompanied by a trademark or any other applicable descriptor.

3.12
medicines regulatory agency
institutional body that, according to the legal system under which it has been established, is responsible for the granting of marketing authorization for medicinal products

Note 1 to entry: In certain jurisdictions, the role of the institutional body, which grants the marketing authorization of medicinal products according to the legal system, may be complemented by an additional institutional body responsible for the evaluation and supervision of medicinal product. For example, in the EU, the European Commission is the institutional body that grants the marketing authorization of medicinal products, and the European Medicines Agency is the body responsible for the evaluation and supervision of medicinal products.

3.13
pharmaceutical product
qualitative and quantitative composition of a medicinal product in the dose form approved for administration in line with regulated product information

Note 1 to entry: A medicinal product can contain one or more pharmaceutical products.

Note 2 to entry: Pharmaceutical product and *manufactured item* (3.4) are sometimes different when manufactured item(s) are processed before administration to the patient [as the *pharmaceutical product* (3.13)].

3.14
pharmaceutical product identifier
PhPID
unique identifier for a pharmaceutical product

3.15
product classification
categorization or grouping of medicinal products based on specific properties

EXAMPLE Pharmacological classification, classification by therapeutic effect.

3.16
qualitative composition
composition of all the constituents of the investigational or authorized medicinal product, if applicable, after reconstitution, and the functioning of the constituents of:

— the substance and the specified substance;

— the constituent(s) of the excipients, whatever their nature or quantity used, including colouring materials, preservatives, adjuvants, stabilizers, thickeners, emulsifiers, flavouring, and aromatic substances, etc.

3.17
quantitative composition strength
amounts of substance and specified substance constituents in the investigational or authorized medicinal product expressed in a ratio scale

Note 1 to entry: It is necessary for the quantitative composition of the substance(s) or the specified substance descriptions of the finished investigational or authorized medicinal products (depending on the pharmaceutical form concerned) to specify the mass, or the number of units of biological activity, either as a per dosage unit or as per unit of mass or volume, of each substance or specified substance.

Note 2 to entry: Substance or specified substance descriptions present in the form of compounds or derivatives are always designated quantitatively by their total mass and, if necessary or relevant, by the mass of the active entity, or entities, of the molecule.

3.18
target population
type of patients or consumers for which the indication of a *medicinal product* (3.9) is authorized

3.19
therapeutic indication
intended use of the *medicinal product* (3.9) as authorized by the Medicines Regulatory Agency in a jurisdiction

Note 1 to entry: For clinical trials, this refers to the intended use under investigation and as described in the clinical trial protocol.

3.20
Kampo
kampo medicine
traditional medicine that has been developed in Japan

Note 1 to entry: Ancient Chinese medicine was introduced to Japan. After around 1 600 years, Kampo medicine has diverged from the ancient Chinese medicine.

3.21
kampo formula
combination of *crude drugs* (3.24) used in *Kampo medicine* (3.20), that is defined or authorized by the Medicines Regulatory Agency[21][22][23] and in Japan

Note 1 to entry: *Medicinal products* (3.9) made with this type of formula are supplied only when modern medical doctors order prescriptions. Cf. *legal status of supply* (3.3).

3.22
OTC kampo formula
combination of *crude drugs* (3.24) based on *Kampo medicine* (3.20), that is defined or authorized by the Medicines Regulatory Agency[21][22][23] in Japan

Note 1 to entry: *Medicinal products* (3.9) in accordance with this type of formula are supplied for the use of self-medication. Cf. *legal status of supply* (3.3).

3.23
in-pharmacy Kampo formula
combination of crude drugs based on Kampo medicine, defined or authorized by the Medicines Regulatory Agency in Japan

Note 1 to entry: *Medicinal products* (3.9) in accordance with this type of formula are produced in pharmacies. Cf. *legal status of supply* (3.3).

3.24
crude drug
natural medicine that is used as a component of a *Kampo formula* (3.21) defined or authorized in the Japanese Pharmacopeia and its addenda[21][22]

3.25
part of interest
medicinal part
part of a natural *material* (3.8) that is usable as source material for a *crude drug* (3.24)

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

3.26
origin
definition of *crude drug* (3.24) including the name of the natural *material* (3.8) and the part of interest for medicinal use

3.27
medical domain
specific concepts *and* generic concepts of various medical systems

Note 1 to entry: Modern medicine is also a type of medical domain.

EXAMPLE Modern medicine, Ayurveda, traditional African medicine, traditional Australian (Aboriginal), traditional Canadian, Chinese or traditional Chinese (TCM), traditional Japanese (Kampo), traditional Korean, Mongolian, New Zealand (Maori), Thailand, Tibetan, or Vietnamese, and so on.

Note 2 to entry: Other country's pharmacopeia(s) or portion(s) of it may substantially indicate a certain medical domain.

3.28
batch
specific manufacturing release of a *medicinal product* (3.9) or item by the manufacturer

4 Abbreviated terms

BAID_1 Medicinal Product Batch Identifier (outer packaging)

BAID_2 Medicinal Product Batch Identifier (immediate packaging)

5 Conformance

The Japanese jurisdiction claims the following:

— crude drugs and pharmaceutical products using the Kampo formula shall conform to the Japanese Pharmacopeia and its addenda[21][22];

— medicinal products using the Kampo formula shall conform to the Japanese Pharmacopeia and its addenda[21][22];

— the medicinal product names of Kampo formula and their expression with letters shall conform to the Japanese Pharmacopeia and its addenda[21]21].

NOTE 1 Chemical and physical identification methods for substances in Kampo medicine are described in the Japanese Pharmacopeia and its addenda[21][22]. Some examples of these methods as well as genetic data are accessible from the website of the Research Center for Medicinal Plant Resources of the National Institute of Biomedical Innovation[24].

NOTE 2 Many crude drug names[20][21][22] in traditional medicines are polysemes. Such confusion is further aggravated by the use of similar letters or scripts[3] in various countries.

NOTE 3 To avoid confusion caused by similarities in naming, the names of the Kampo formula defined by the Japanese Medicines Regulatory Authority[21][22][23] are expressed with a superscript symbol <JP>. Such a symbol <XX> has three purposes: 1) to give attention to the recognition of the different meaning, 2) to prohibit inaccurate conversion of letters, and 3) to help distinguish between homonyms and polysemes (see ISO 1087-1 and References [1][2][3] and [12].

NOTE 4 Each medicinal product name using the Kampo formula contains names defined by the Japanese Medicines Regulatory Authority [21][22][23]. In other words, medicinal product names using the Kampo formula in the same product classification contains the name of the Kampo formula defined by the Japanese Medicines Regulatory Authority[21][22][23].

EXAMPLE 1 The symbol <JP> is added as superscript to the Latin name of crude drugs used in Kampo medicine in this document in order to distinguish crude drugs in Kampo medicine from those in the Chinese Materia Medica[14], 3.86. For example, the Latin name BUPLEURI RADIX<JP>[21], 7.2.29, is defined as the root of *Bupleurum falcatum* Linné (Umbelliferae), but the Latin name of Bupleuri radix in the Chinese Materia medica[14], 3.86, is defined as the root of *Bupleurum chinense* DC. or *Bupleurum scorzonerifolium* Willd.

EXAMPLE 2 ANGELICAE RADIX<JP>, Japanese Angelica Root<JP>, and □□<JP> is defined as the root of *Angelica acutiloba* Kitagawa or *Angelica acutiloba* Kitagawa var. *sugiyamae* Hikino (Umbelliferae), usually after being passed through hot water (7.2.9 in Reference [21]). This is different from □□in the Chinese Materia medica[14], 3.38, which is defined as the root of *Angelica sinensis* (Oliv.) Diels.

6 Coding system

ISO 11615 requires the description of the concepts of MPID with PhPID(s), BAID_1, and BAID_2. Those mainly focus on the following entries:

— name of the medicinal product;

— legal status of supply;

— terms of the marketing authorization;

— marketing authorization (licence) holder;

— manufacturer(s);

— authorizing Medicines Regulatory Agency;

— qualitative and quantitative compositions;

— ingredients, strength, pharmaceutical form, route of administration;

— device(s) as part of a medicinal product;

— clinical particulars, especially authorized therapeutic indication(s);

— product classification(s);

— package description;

— regulated product information and documentation.

It is explicitly or implicitly expected that the above are described with the following:

— country code[6][7][8];

— the marketing authorization number;

— unique identification of a medicinal product and the associated PhPID(s).

Annex A
(informative)

Controlled vocabulary of Japanese Kampo formulas

A.1 Names and the specifics of Japanese Kampo formulas

This document covers only Kampo medicine. In Japan, the Medicines Regulatory Agency is the Ministry of Health, Labour, and Welfare (of Japan).

Authorized formulas and their names are defined in Japanese Pharmacopeia, its official addenda and related document[21][22]. Some formula has variation in qualitative and quantitative composition.

Qualitative and quantitative composition is simply expressed as the composition of crude drugs and their amount in weight.

The Kampo formulas consist of some crude drugs, and both of them are defined in Japanese Pharmacopeia and its official addenda[21][22]. The definitions of crude drug are not only specifying scientific names of the origins and the part of interest(s) but also laboratory tests and test methods.

The "approved number" are able to use as the marketing authorization number. The minister or the prefectural governors hold the authority to provide those numbers, and this information is also embedded in the marketing authorization number.

Authorized names of medicinal products in Kampo medicinal product are expressed in Japanese Katakana, Hiragana, Kanji letters, and English text.

No therapeutic indications are specified in Japanese Pharmacopeia and in its official addenda[21][22]. One reason is that medicinal products are manufactured with various ingredients other than active substances (ISO 1087-1, References [7] and [8]). Consequently, the characteristics of medicinal products are different from each other although they are manufactured conforming to the same formula and then they are belonging to the same product classification. Another reason is because therapeutic indications and contra-indications are immediately updated on the results of "post marketing surveillance" in Japan.

In this document, therapeutic indications are described in English text as well as ICD codes that are linked from the "medical insurance reimbursement code in Japan" used in EMR systems or HIS.

Table A.1 — Summary of fixed values for indication coding of medicinal products in Kampo in Japan

authorizing Medicines Regulatory Agency	fixed: the Ministry of Health, Labour, Welfare
with country code	fixed: Japan
name of authorized formula	
with country code	fixed: Japan
authorized qualitative and quantitative composition and its authorized variation, if existing	
marketing authorization (licence) holder	embedded in marketing authorization number. actually fixed for the medicinal product for Kampo formula, the Minister of MHLW.