

Template for comments and secretariat observations

Date:2012-05-03

Document: ISO NP18094 Categorial structures for representation of herbal medicants in terminological systems

1	2	(3)	4	5	(6)	(7)
MB <sup>1</sup>	Clause No./ Subclause No./ Annex (e.g. 3.1)	Paragraph/ Figure/ Table/ Note (e.g. Table 1)	Type of comment <sup>2</sup>	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
				<p>1 吳茱萸 吳茱萸(ゴジュユ)</p> <p>2 当归 当歸(トウキ)</p> <p>3 芍药 芍薬(シャクヤク)</p> <p>4 川芎 川芎(センキュウ)</p> <p>5 人參 人參(ニンジン)</p> <p>6 桂枝 桂皮(ケイヒ)</p> <p>7 阿胶 阿膠(アキョウ)</p> <p>8 牡丹皮 牡丹皮(ボタンピ)</p> <p>9 生姜 生姜(ショウキョウ)</p> <p>10 甘草 甘草(カンゾウ)</p> <p>11 半夏 半夏(ハンゲ)</p> <p>12 麦冬 麦冬(マクモドウ) - synonym</p> <p>It is uncertain if the dose combination are the same. However, the two products contain identical ingredients and are in essence the same medicaments used to treat the same condition.</p> <p>N.B. there are numerous variations in the basic Wen Jin Tang formula resulting in many similar medicaments containing more or less ingredient combination.</p> <p><u>XX-WenJingTang (No. of ingredients)</u></p> <p><u>指迷-温经汤 (9 ingredients)</u></p> <p><u>归活-温经汤 (10)</u></p> <p><u>八物-温经汤 (9)</u></p> <p><u>麻桂-温经汤 (8)</u></p> <p><u>加减-温经汤 (8)</u></p> <p><u>托里-温经汤 (10)</u></p> <p>Is it possible the formula with only 11 ingredients could just</p>	<p>exists semantic interoperability issue)</p> <p>OR</p> <p>2. Is Wen Jing Tang concept a grouper or a parent concept that includes all formulation variations being its child concepts? (if true, Wen Jing Tang is not the best example for the issue raised. N.B. example B) already covers the issue of polysemy.)</p> <p>Please also see the comment on example D) below.</p>	

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				be another variation of the original Wen Jin Tang formula?		
AU	1.3	Example D)	te	<p><u>Issue of variation in the formulation with regards to proposal [B].</u></p> <p>Codonopsis pilosula is known as poor man's Panax ginseng. (cf. <a href="http://en.wikipedia.org/wiki/Codonopsis_pilosula">http://en.wikipedia.org/wiki/Codonopsis_pilosula</a>)</p> <p>Dangshen is commonly used as a substitute for ginseng due to its accessibility or cost-effectiveness.</p> <p>The formulation quoted from various pharmacopoeias [43, 44, 46] is probably due to its wide availability and should be considered the standard.</p> <p>It is debatable if this level of distinction is clinically relevant and beneficial. P. ginseng itself may consist of up to 8 different ginsenoside types (Rb1, Rb2, Rc, Rd, Re, Rf, Rg1, Rg2) which are structurally different and hence possess different pharmacokinetic and pharmacodynamic characteristics.</p> <p>The distinction between C. pilosula and P. ginseng would be essential for the purpose of proposal [A] but as one of the constituents of a combination medicament such as Sijunzi Tang, i.e. proposal [B], the differentiation may not be required.</p>	<p>See also query on 2.1 regarding the definition of proposal [B].</p> <p><b>Regarding proposal [B] only</b>, please consider the issues raised:</p> <ol style="list-style-type: none"> <li>1. Is it practical and clinically relevant to distinguish between variations in formulation?</li> <li>2. Is the level of distinction based on species fit for purpose? (See also (B) 'Rehmanniae Radix' example)</li> <li>3. Given the nature of the traditional herbal remedies being individually prescribed based on the condition and needs of each patient, how useful is pre-coordinated terminology going to be, without the support of information model allowing for variations to be captured?</li> </ol> <p>Suggest review of proposal [B] to tighten the scope further. Also, consider separating the project into 2 parts, allowing each proposal to be proceeded independently if possible.</p>	
AU	1.3	Example D)	ed	<p><u>Spelling error</u></p> <p>Should CodoMopsis be CodoNopsis?</p>	Spell check is recommended.	
AU	5.4	1 <sup>st</sup> paragraph 2 <sup>nd</sup> sentence	ge	<ol style="list-style-type: none"> <li>1. Does this mean SNOMED CT will be used as a reference terminology? (i.e. mapping required?) OR does it mean SNOMED CT will be used for validation of concept uniqueness? (N.B the majority of the examples used throughout the</li> </ol>	Clarification requested	

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				document do not exist in SNOMED CT)? OR does it mean SNOMED CT's concept-description-relationship structure will be used as the standard?  2. Under what circumstances are other terminologies used over SNOMED CT? Will there be a list of approved resources or the order of preference?		
AU	5.4	1 <sup>st</sup> paragraph 2 <sup>nd</sup> sentence	ed	SNOMED CT should be used instead of SNOMED.	Replace SNOMED with SNOMED CT	
AU	5.4	[A] & [B]	ge	"Latin name in a pharmacopoeia" Purpose and justification on page 2 states the scope includes minerals. The use of Latin names as the formal name may be appropriate for botanical and zoological products but not for minerals.	Consider using "Scientific name" instead.	
NL	Episode (as an example) on page 17		GE	The example mentions <i>Angelica Radix</i> . According to the Chinese characters 当归 this is However <i>Angelica Radix</i> can also be báizhǐ 白芷. The name <i>Angelica Radix</i> can therefore create some confusion. Both medicinal substances have complete different therapeutic effects. The pharmaceutical name for dāngguī 当归 is sinensis Radix. The pharmaceutical name for báizhǐ 白芷 is <i>Angelica dahuricae Radix</i> . The literal English translation of dāngguī 当归 state of return" according to Chinese Herbal Medicine Materia Medica, 3 <sup>rd</sup> edition, Bensky et al. Eastland Press 2004.	In the example use the complete pharmaceutical name <i>Angelica sinensis Radix</i> . Possibly mention the pinyin name dāngguī for completeness.  The trio <pharmaceutical name> <pinyin name> <name in Chinese characters> is very common in literature.	

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Reference number of working document: **ISO/TC 000/SC 0 N 000**

Date: yyyy-mm-dd

Reference number of document: **ISO/WD nnn-n**

Committee identification: ISO/TC 000/SC 0/WG 0

Secretariat: XXXX

## **Health Informatics — Categorial structures for representation of herbal medicaments in terminological systems**

*Élément introductif — Élément principal — Partie n: Titre de la partie*

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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.

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ISO nnn-n was prepared by Technical Committee ISO/TC 215, *Health Informatics*, Subcommittee WG 3, *Semantic content*.

This second/third/... edition cancels and replaces the first/second/... edition (ISO nnn-n:19xx), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.

ISO nnn consists of the following parts, under the general title *Health informatics — Categorical structures for representation of herbal medicaments in terminological systems*.

The **foreword** shall appear in each document. It shall not contain requirements, recommendations, figures or tables.

## Introduction

For centuries, natural materials have been used by mankind for medicinal purposes. Today herbal medicaments are used extensively both in medicines and in supplements.

In the history of herbal medicaments, they are conceived in a certain area and then they gradually spread to other area. But different climate, geographical features, and habitat of plants might cause availabilities of source materials. Then, as prevalence of herbal medicine, substitutions should become to be required for the people in different area or region [24,56,57].

Such substitutions should contain the ingredients or active substances, or the ingredients that has approximate efficacies. But people in those days had no analysers for scientific assays. Their judgments depended on their clinical experiences and appearance of natural materials [24,57].

And also, traditional medicine recognizes that different climate and/or geographical features influence people's constitutions, so that different medicament might be formulated for the same symptom for different people in different area or region. Those are feasible behaviours to solve health issues, but on the other hand, result in critical problems in health informatics because lots of polysemic terms erupted [24,32-36,47-52,56,57].

Those situation have led to the use of single specific names representing different natural materials or medicaments (polysemy [1]), different names often designate same natural materials or medicament (synonymy [1]). Anyway, such vernacular names have been established as customary in each area and region. Even today, such situation of terms occasionally influences different specialties [40-46].

Polysemy (and synonymy) causes confusion in trade and serious health hazards may occur as a consequence. Then there are discords among existing terminological resources, and scientific papers on clinical research. This means new misunderstandings might be continuously occurring among practitioners and researchers. It might be desperate struggle to establish the safety of herbal medicaments.

These problems should be resolved by standardization of the relations between terms and concepts by following specification for terminological resources.

**Note 1** In this Technical Specification, natural materials include not only plants but also animal products and minerals which occur naturally. In addition, adjuvant materials (e.g. rice, liquor, vinegar, honey) are often used, in order to add flavours, for detoxification, for support of extraction of active substances, etc.

**Note 2** In the trade of wine, tea or coffee, people are interested in the species of source plant, the specific part of source plant, the area or the district of harvest/gather, the timing and condition of harvest/gather (e.g. first flush tea, grapes with noble rot), blend of materials, and the methods of processing. Because herbal medicaments are also made of natural materials, similar properties are also significant not only to the qualities of natural materials but also to the contained chemical substances in them. Needless to say, different ingredients cause different efficacies and effects; some of those may be critical in medical usage and in health claim.

# Health Informatics — Categorial structures for representation of herbal medicaments in terminological systems

## 1 Scope

### 1.1 Main purpose

The scope of the present Technical Specification is to specify categorial structures [3,4] in the subject field of the herbal medicaments in plain medicine and formula. In precise,

[A] herbal medicaments made of single natural material with or without adjuvant material(s), and

[B] herbal medicaments that are composed of the herbal medicaments made of single natural material,

by defining a set of constraints for use within terminological resources.

Note 1 In this Technical Specification, adjuvant material means (e.g. rice, liquor, vinegar, honey) are often used in processing of natural materials, in order to add flavours, for detoxification, for support of extraction of active substances, etc.

Note 2 In this Technical Specification, herbal medicaments made of single natural material [A] are herbal medicament by themselves, while they are usually used as materials in formulas [B], i.e., the herbal medicaments that are made by combination with them [A].

The potential contributions of this conceptual framework are to:

- Support developers of new terminology systems concerning herbal medicaments;
- Support developers of new content areas of existing terminology systems concerning herbal medicaments to enable conformance;
- Facilitate the representation of herbal medicaments using a standard core model in a manner suitable for computer processing;
- Support the development of monitoring systems for adverse events and reactions;
- Provide the characterization of clinical research intervention of herbal medicaments;
- Supports evaluation of herbal formulations in prescriptions, identifying the component(s) which impact upon the effect of the formulation in order to reduce failures in dosages or incompatibilities;
- Promote smooth exchange of information and reduce the risk of adverse reactions and risks affected by the toxicity of herbal medicaments;
- Clarify the polysemy across and within different clinical specialties and systems.

### 1.2 Target groups

The target groups for this Technical Specification are:

- Developers of terminology systems concerning herbal medicaments;
- Developers of information systems that require a structured framework of concepts to facilitate implementation;
- Informaticians, analysts and epidemiologists who require common models of knowledge to facilitate analysis of current and legacy data from one or more information systems;

- Clinicians and coders to provide greater consistency in structure and organisation when entering and retrieving data using one or more terminology systems;
- Managers and administrative personal in providing a benchmark by which to judge terminology solutions: as to whether the potential options will deliver compatibility with legacy data and future proofing to emerging terminology products.

### 1.3 Topics out of scope

Topics considered out of scope of this Technical Specification include:

- The combinations of modern drug(s) and herbal medicament(s) or natural material(s);
- Any implementation models for management of manufactured drug products on herbal medicaments or herb related medicaments;
- Any process models of drug production and manufacturing;
- Any models or frameworks for quality control of
  - Cultivation of natural materials;
  - Drug products from natural materials, herbal medicaments, or the combinations of modern drug(s) and herbal medicament(s) or natural material(s).

The present Technical Specification does not include formulas of products that have already been formulated; therefore the scope of **[B]** is restricted to first order formulas that combine herbal medicaments made of single natural material with or without adjuvant material(s) **[A]**.

The present Technical Specification does not necessarily focus on chemical and physical characteristics of ingredients, although they may be referred to.

Note        Ingredients are not always active substances, but are considered as chemical markers.

## 2 Normative references

The following referenced documents are indispensable for the application 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 1087-1:2000, *Terminology work – Vocabulary – Part 1: Theory and application*

EN 12264:2005, *Health informatics – Categorial structure for systems of concepts*

ISO 17115:2007, *Health informatics – Vocabulary for terminological systems*

ISO/FDIS 11238, *Health Informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated information on substances*

IETF RFC 5646, *Tags for Identifying Languages*, September 2009

ISO 639-1:2002, *Codes for the representation of names of languages – Part 1: Alpha-2 code*

ISO 639-2:1998, *Codes for the representation of names of languages – Part 2: Alpha-3 code*

ISO 639-3:2007, *Codes for the representation of names of languages – Part 3: Alpha-3 code for comprehensive coverage of languages*

ISO 15924:2004, *Information and documentation – Codes for the representation of names of scripts*

ISO 3166-1:2006, *Codes for the representation of names of countries and their subdivisions – Part 1: Country codes*

ISO 3166-2:2007, *Codes for the representation of names of countries and their subdivisions – Part 2: Country subdivision code*

ISO 3166-3:1999, *Codes for the representation of names of countries and their subdivisions – Part 3: Code for formerly used names of countries*

IBC, *International Code of Botanical Nomenclature VIENNA CODE*, 2006

ICSP, *International Code of Nomenclature of Bacteria*, 1990

ICZN, *International Code of Zoological Nomenclature Fourth Edition*, 1999

CNMMN/CNMNC, *International Mineralogical Association Official List of Mineral Names*, 2009

ISO 19115:2003, *Geographic information – Metadata*

ISO 19115:2003, *Geographic information – Metadata, TECHNICAL CORRIGENDUM 1*, 2006

ISO/IEC 8824-1:2002, *Information technology – Abstract Syntax Notation One (ASN.1): Specification of basic notation*

### 3 Terms and definitions

For the purposes of this Technical Specification, the following terms and definitions apply. Only key terms and definitions are provided in this section. Additional background terms and definitions from two normative references: ISO 17115:2007, Health informatics - Vocabulary for terminological systems are provided in Annex A [4]; ISO 1087-1:2000, Terminology work - Vocabulary - Part 1: Theory and application provided in Annex B [1]; EN 12264:2005, Health informatics - Categorial structure for systems of concepts [3]; IETF RFC 5646 [10]; ISO/FDIS 11238, Health Informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances [45].

#### 3.1

##### **natural material**

creature and mineral of which part is able to be utilized for medicinal purpose

#### 3.2

##### **herbal medicament**

medicament made of **natural material(s)** (3.1)

NOTE 1 In this Technical Specification, material(s) by which an **herbal medicament** (3.2) is made of include plants, animals and minerals by the definition of **natural material** (3.1)

NOTE 2 According to the scope (Clause 1.3), this Technical Specification does not include formulas of products that have already been formulated; therefore the scope of [B] is restricted to first order formulas that combine herbal medicaments made of single natural material with or without adjuvant material(s) [A].

#### 3.3

##### **script identifier**

identifier used to indicate the script or writing system variations that distinguish the written forms of a language or its dialects

[2.2.3 - IETF RFC 5646]

#### 3.4

##### **form of a language**

designator represented by a certain script in a certain language

#### 3.5

##### **jurisdiction domain**

territorial range of a law or a set of laws

EXAMPLE science, education, food, health, medicinal product

#### 3.6

##### **jurisdiction type**

extent of right and power of a law or a set of laws

EXAMPLE mandatory, recommendation, optional

#### 3.7

##### **binomial system**

binomial naming system

binomial nomenclature

formal system of naming species of living things by giving each a name composed of two parts, both of which use Latin grammatical forms, the first part is the Genus to which the species belongs and the second part is the species name

#### 3.8

##### **type specimen**

particular specimen or a group of specimens of an living thing to which the scientific name of that living thing is formally attached

**3.9****kind of type**

kind of type specimen classified in delimiting level from other species

EXAMPLE holotype, paratype, neotype, syntype, lectotype, paralectotype, hapantotype

**3.10****kingdom**

one of the three parts into which the natural world is divided

[Longman Dictionary of Contemporary English, 5th]

**3.11****part of interest**

medicinal part

part of origin

part of **natural material** (3.1) that is intended to utilize as raw material for **herbal medicament** (3.2)

EXAMPLE bud, fruit, leaf, bark, rhizome, root

**3.12****initial procedure**

operation(s) carried out just after harvest in the place, usually intended to separate **part of interest** (3.11) from other part of **natural material** (3.1)

EXAMPLE roughly washing, sketchily cutting out from other part e.g. removing shell, drying; mildew and rot

**3.13****processing type**

**superordinate concept** (B.3.2.13) of treatment for making medicinal from **part of interest** (3.11)

EXAMPLE filtering, cutting, washing, decoction, heating, exposure to sunlight, fermentation

NOTE actual **processing method** (3.14) may be classified into several **processing types** (3.13)

**3.14****processing method**

**subordinate concept** (B.3.2.14) of treatment for making medicinal from **part of interest** (3.11)

EXAMPLE filtering by sieve, wind, and water; immersion, stewing, boiling, steaming; frying, calcining, roasting

**3.15****adjuvant material**

adjuvant

**natural material** (3.1) or processed **natural material** (3.1) that is not expected medicinal role by itself but has the role to help or enhance pharmacological efficacies and decrease toxicity of **part of interest** (3.11) during treatment for making medicinal from **part of interest** (3.11)

EXAMPLE rice, liquor, vinegar, honey

**3.16****substance**

any matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical

NOTE 1 In the context of specifying the conceptual framework of herbal medicament, substance is detectable by laboratory test result(s) or the profile of them, and usually perceived by them.

NOTE 2 Substances can be single substances, mixture substances or one of a group of specified substances. Single substances are defined using a minimally sufficient set of data elements divided into five types: chemical, protein, nucleic acid, polymer and structurally diverse. Substances may be salts, solvates, free acids, free bases or mixtures of related

compounds that are either isolated or synthesized together. Pharmacopoeial terminology and defining characteristics will be used when available and appropriate. Defining elements are dependent on the type of substance.

NOTE 3 Discrete existence refers to the ability of a substance to exist independently of any other substance. Substances can either be well-defined entities containing definite chemical structures, synthetic (i.e. isomeric mixtures) or naturally occurring (i.e. conjugated oestrogens) mixtures of chemicals containing definite molecular structures, or materials derived from plants, animals, microorganisms or inorganic matrices for which the chemical structure may be unknown or difficult to define. Substances may be salts, solvates, free acids, free bases and mixtures of related compounds that are either isolated or synthesized together.

[ISO/FDIS 11238] except NOTE 1

### 3.17

#### medical domain type

**sepcific concept** (B.3.2.16) of medical domain **generic concept** (B.3.2.15)

NOTE Broadly prevailed modern medicine is also one of types of medical domain.

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

### 3.18

#### dose form

dosage form

physical form applied to medicament intended for adequate administration and/or consumption

EXAMPLE pill, tablet, capsule, syrup, decocted fluid, aerosol or inhaler, liquid injection, pure powder or solid crystal

### 3.19

#### value

**designator** (B.3.4.1) of **characterizing concept** (A.2.2.2) or **individual concept** (B.3.2.2) within a **characterizing generic concept** (A.2.3.3), i.e., **characterizing category** (A.2.3.3).

### 3.20

**characterizing concept** (A.2.2.2) [ISO 17115:2007]

**concept** (B.3.2.1) that is referenced by a **semantic link** (A.2.2.3) in a **composite characteristic** (A.2.2.1)

EXAMPLES "Bacterium" in the construct "Disease that hasCause Bacterium"; "Yellow" in the construct "SkinLesion that hasColor Yellow".

### 3.21 -1

**characterizing generic concept** (A.2.3.3) [ISO 17115:2007]

characterizing category

value domain

**formal category** (A.2.5.3) whose specialisation by a **domain constraint** (A.2.3.2) is allowed to be used as **characterizing concept** (A.2.2.2) in a particular context

EXAMPLE <INFECTIOUS\_ORGANISM> = {bacterium, virus, parasite}, in the context of "Infection that hasCause INFECTIOUS\_ORGANISM".

NOTE The context includes a **superordinate concept** (B.3.2.13) and a **semantic link** (A.2.2.3)

### 3.21 -2

**characterising category** (C.3.33) [EN 12264:2005]

range

value domain

set of **concepts** (C.3.1) which are allowed by a **domain constraint** (C.3.42) to specialise a concept in a particular **domain** (C.3.40)

NOTE The characterising category is usually described by a superordinate **concept** (3.15).



**EXAMPLE** Cause of inflammation: the set of bacteria, virus, parasite, autoimmune, chemical, physical, unknown, formally expressed e.g. "Cause Of Inflammation can Be (**semantic link**) set {bacteria, virus, parasite, autoimmune, chemical, physical, unknown}" (**characterising category**)

### 3.22 -1

**semantic link** (A.2.2.3) [ISO 17115:2007]

formal representation of a directed **associative relation** (B.3.2.23) or **partitive relation** (B.3.2.22) between two **concepts** (B.3.2.1),

**EXAMPLES** hasLocation (with inverse isLocationOf); isCauseOf (with inverse hasCause)

**NOTE 1** This includes all relations except the **generic relation** (B.3.2.21).

**NOTE 2** A semantic link always has an inverse, i.e. another semantic link with the opposite direction.

**NOTE 3** A semantic link can be part of a **composite characteristic** (A.2.2.1) where it describes the role of the **characterizing concept** (A.2.2.2). Similarly, it defines the role of a **characterizing generic concept** (A.2.3.3) in a sanctioned **characteristic** (B.3.2.4).

### 3.22 -2

**representation of relation type** (C.3.32) [EN 12264:2005]

semantic link

**formal representation** (C.3.5) of a directed **associative relation** (C.3.14) or **partitive relation** (C.3.13) between two y (C.3.1)

**EXAMPLE** has Location (with inverse is Location Of); is Cause Of (with inverse has Cause)

**NOTE 1** This includes all relations except the **generic relation** (3.11).

**NOTE 2** A semantic link always has an inverse, i.e. another semantic link with the opposite direction.

### 3.23

**formal category** (A.2.5.3) [ISO 17115:2007]

**generic concept** (B.2.1.4) represented by a **formal definition** (A.2.4.3)

**NOTE** This implies that the generic concept's **extension** (B.3.2.8) can be determined algorithmically and includes extensionally defined **concepts** (B.3.2.1) and formal **intensional definitions** (B.3.3.2).

### 3.24

**generic concept** (A.2.1.4) [ISO 17115:2007] [ISO 1087-1:2000]

category

**concept** (B.3.2.1) in a **generic relation** (B.3.2.21) having the narrower **intension** (B.3.2.9) [and the wider **extension** (B.3.2.8)]

## 4 Symbols (and abbreviated terms)

### 4.1

#### **HB**

herbal medicament (3.2)

### 4.2

#### **SNM**

single natural material (3.2)

### 4.3

#### **HB-SNM**

herbal medicament (3.2) made of single natural material

### 4.4

#### **HB-SNMs**

herbal medicaments (3.2) made of single natural material

NOTE Plural is targeted to HB (4.1).

## 5 Herbal medicaments made of single natural material

### 5.1 Overview

In the **formal concept representation system** (A.2.5.1) for the **subject field** (B.3.1.2) of the **herbal medicaments** (3.2) that is made of single **natural material** (3.1) with or without **adjuvant material(s)** (3.15) [A] abbreviated as HB-SNM (4.3), HB-SNM (4.3) has **semantic links** (A.2.2.3) to the following **characterizing categories** (A.2.3.3): **Source** (5.2.7), **Processing** (5.2.8), **Basic Characteristics** (5.2.9), **Constituent** (5.2.10), **Laboratory Test Profile** (5.2.11), **Biomedical Effect** (5.2.12), in addition, **Official Name** (5.2.1) and **Vernacular Name** (5.2.2).

For identifying HB-SNM (4.3), additional **characterizing categories** (A.2.3.3) are required, e.g. **Scientific Name** (5.2.3). Those are also specified in Clause 5.2.

**Semantic links** (A.2.2.3) among them are specified in Clause 5.3.

**Sanctioned characteristics** (A.2.3.1) is typically composed with **semantic links** (A.2.2.3) and **characterizing category** (A.2.3.3) to which **semantic link** (A.2.2.3) refers, as defined in EN 12264:2005 and ISO 17115:2007. Some of potential **characterizing categories** (A.2.3.3) in Clause 5.2 may be referred to by different **semantic links** (A.2.2.3) specified in Clause 5.3 because different relations may occur in different **contexts** (B.3.6.10), although the focused **subject field** (B.3.1.2) is adequately limited.

**Concept name** (A.2.4.4) in a **formal concept representation system** (A.2.5.1) is independent from the **terms** (B.3.4.3) used in the actual world, or, should be independently given. However, some International Standards on terminology work feasibly request the analysis of **terms** (B.3.4.3) or words used by people in general and the concept structures behind them [5-8]. In addition, anyway, only those **terms** (B.3.4.3) are able to designate certain **concepts** (B.3.2.1) in the real world. These are the reasons why the **categorial structures** (A.2.4.5) for **designators** (B.3.4.1) are also included in the present Technical Specification.

The outline of the relations among mentioned above is illustrated in a **concept diagram** (B.3.2.12) in Figure 1.

