NOTE 2 The latter part of the NOTE in the definition in ISO/FDIS 11238 [45] "Constituents shall have an associated role and amount. Constituent specifications shall be used to describe components as well as limits on impurities or related substances for a given material" is handled in **laboratory test profile** (5.2.11) in this Technical Specification.

NOTE 3 **constituent** (5.2.10) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 4 some **values** (3.19) for the subordinate **characterizing categories** (A.2.3.3) of **constituent** (5.2.10) are described in some references listed in bibliography [25-29,31-38,47-53,55] but not limited to them.

NOTE 5 **constituent** (5.2.10) is contained in herbal medicament (3.2). **constituent** (5.2.10) is provided from **source** (5.2.7). **constituent** (5.2.10) may be modified, destroyed or degraded by **processing** (5.2.8). **constituent** (5.2.10) is detected by laboratory test result(s) or the **laboratory test profile** (5.2.11) of them. Some of **constituents** (5.2.10) determine or influence **biomedical effect** (5.2.12) of a herbal medicament (3.2).

5.2.11 Laboratory Test Profile

collection of analyzing test results on a **source** (5.2.7) or a herbal medicament (3.2)

NOTE 1 **laboratory test profile** (5.2.11) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes: { test purpose }, { test method }, { test procedure }, { reference data }, { result(s) of a test }, { permissible limit }, { system adequacy }.

NOTE 2 { permissible limit } subordinate **characterizing category** (A.2.3.3) of **laboratory test profile** (5.2.11) implies that { result(s) of a test } subordinate **characterizing category** (A.2.3.3) of **laboratory test profile** (5.2.11) shall have an **semantic link** (A.2.2.3) to amount.

NOTE 3 some **values** (3.19) for the subordinate **characterizing categories** (A.2.3.3) of **laboratory test profile** (5.2.11) are described in some references listed in bibliography [28,29,32-38,47,52-55] but not limited to them.

NOTE 4 Needless to say, each government keeps the right to independently decide the official **values** (3.19) of those **characterizing categories** (A.2.3.3) within each county, in order to protect life and health of their citizens. Governmental decision is out of scope of this Technical Specification. This Technical Specification only intend to clarify the extent and degree of identification, biomedical activity and impurities in order to provide additional information for estimation of reliabilities of **biomedical effect** (5.2.12).

NOTE 5 **laboratory test profile** (5.2.11) detects **constituent** (5.2.10) contained in **source** (5.2.7) or herbal medicament (3.2). Some of detected **constituent** (5.2.10) affects **biomedical effect** (5.2.12) of a herbal medicament (3.2).

5.2.12 Biomedical Effect

consequent reaction in body of living thing caused by **constituent**(s) (5.2.10) contained a herbal medicament (3.2)

NOTE 1 Main interest is focused on human but many pharmacological reports utilize animals or animal's cells in fundamental research to speculate effects to human body.

NOTE 2 **biomedical effect** (5.2.12) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes: { medical domain type }, { effect type }, { effect }, { precondition }.

NOTE 3 **medical domain type** (3.17) is defined in Cause 3 of this Technical Specification.

NOTE 4 { effect type } subordinate **characterizing category** (A.2.3.3) of **biomedical effect** (5.2.12) is able to be roughly classified into "preferred" and "not preferred". More specified classification of biomedical effects varies [25-29,32-38] because issues can be classified in several way from point of view. See Annex E.

NOTE 5 { precondition } subordinate **characterizing category** (A.2.3.3) of **biomedical effect** (5.2.12) has at least two sides of aspect; physical and mental status of patient or targeted living things before or without intervention, and factors that is brought about by intervention(s).

NOTE 6 **values** (3.19) for the subordinate **characterizing categories** (A.2.3.3) of **biomedical effect** (5.2.12) are described in some references listed in bibliography [25-29,32-38,47-52,54] but not limited to them.

NOTE 7 **biomedical effect**(s) (5.2.12) arise from **constituent** (5.2.10) contained in herbal medicament (3.2), with depending on **dosage** (5.2.13).

5.2.13 Dosage

act, manner, and amount of using medicinal(s)

NOTE 1 **dosage** (5.2.13) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes, but not limited to: { dose }, { dose unit }, { dose form }, { route }, { frequency }, { period }.

NOTE 2 **dose form** (3.18) is defined in Cause 3 of this Technical Specification.

NOTE 3 some **values** (3.19) for the subordinate **characterizing categories** (A.2.3.3) of **dosage** (5.2.13) are described in some references listed in bibliography [25-29,32-38,47-52,54] but not limited to them.

NOTE 4 **dosage** (5.2.13) affects **biomedical effect** (5.2.12).

5.3 Semantic Links

5.3.1 hasOfficialName

semantic link (A.2.2.3) between the herbal medicament (3.2) and **official name** (5.2.1) which the herbal medicament (3.2) has

NOTE 1 **official name** (5.2.1) should be qualified by { official names of herbal medicaments addressed in pharmacopoeias } with **source identifier** (B.3.8.10), **country identifier** (B.3.8.9), **language identifier** (B.3.8.8), **script identifier** (3.3), **jurisdiction domain** (3.5), and **jurisdiction type** (3.6) if needed [49,51,52,54].

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.2 hasScientificName

semantic link (A.2.2.3) between **origin** (5.2.4) and **scientific name** (5.2.3) which **origin** has

NOTE 1 **scientific name** (5.2.3) should be qualified by { scientific name of origin addressed in authorized terminological resources } with **source identifier** (B.3.8.10), **type specimen** (3.8) and **kind of type** (3.9), if needed.

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.3 hasVernacularName

semantic link (A.2.2.3) between the herbal medicament (3.2) or **origin** (5.2.4) or **source** (5.2.7) and **vernacular name** (5.2.2) which the herbal medicament (3.2) or **origin** (5.2.4) or **source** (5.2.7) has

NOTE **vernacular name** (5.2.2) should be qualified by { vernacular name } with **source identifier** (B.3.8.10), **country identifier** (B.3.8.9), **language identifier** (B.3.8.8), **script identifier** (3.3).

5.3.4 hasSynomym

semantic link (A.2.2.3) between a certain name and other name(s) within the relation of **synonymy** (B.3.4.19)

NOTE 1 Occurrence of **synonymy** (B.3.4.19) may be classified three types: (i) **official name** (5.2.1) and other **official names** (5.2.1), a certain **scientific name** (5.2.3) and other **scientific names** (5.2.3), (ii) a certain **vernacular name** (5.2.2) and other **vernacular names** (5.2.2), (iii) a certain **vernacular name** (5.2.2) and **official names** (5.2.1) or **scientific names** (5.2.3).

NOTE 2 **polysemes** (B.3.4.24) also occur in some cases.

5.3.5 designatesHB

semantic link (A.2.2.3) between **official name** (5.2.1) and the herbal medicament (3.2) which **official name** (5.2.1) designates, or, **semantic link** (A.2.2.3) between **vernacular name** (5.2.2) and the herbal medicament (3.2) which **vernacular name** (5.2.2) designates

NOTE There are lots of **synonyms** (B.3.4.19), **polysemes** (B.3.4.24), and **homonyms** (B.3.4.25). A **vernacular name** (5.2.2) often designates **origin** (5.2.4), the **source** (5.2.7) from it, and the herbal medicament (3.2) made of the **source** (5.2.7).

5.3.6 designatesOrigin

semantic link (A.2.2.3) between **scientific name** (5.2.3) and **origin** (5.2.4) which **scientific name** (5.2.3) designates, or, **semantic link** (A.2.2.3) between **vernacular name** (5.2.2) and **origin** (5.2.4) which **vernacular name** (5.2.2) designates

NOTE There are lots of **synonyms** (B.3.4.19), **polysemes** (B.3.4.24), and **homonyms** (B.3.4.25). A **vernacular name** (5.2.2) often designates **origin** (5.2.4), the **source** (5.2.7) from it, and the herbal medicament (3.2) made of the **source** (5.2.7).

5.3.7 designatesSource

semantic link (A.2.2.3) between **official name** (5.2.1) and **source** (5.2.7) which **official name** (5.2.1) designates, or, **semantic link** (A.2.2.3) between **vernacular name** (5.2.2) and **source** (5.2.7) which **vernacular name** (5.2.2) designates

NOTE There are lots of **synonyms** (B.3.4.19), **polysemes** (B.3.4.24), and **homonyms** (B.3.4.25). A **vernacular name** (5.2.2) often designates **origin** (5.2.4), the **source** (5.2.7) from it, and the herbal medicament (3.2) made of the **source** (5.2.7).

5.3.8 isMadeOfSource

semantic link (A.2.2.3) between the herbal medicament (3.2) and **source** (5.2.7) of which the herbal medicament (3.2) is made of

NOTE 1 **source** (5.2.7) shall be qualified by **part of origin** (3.11) and **source** (5.2.4), and recommended with **harvest** (5.2.6) and **basic characteristics** (5.2.9). In this **context** (B.3.6.10), **scientific name** (5.2.3) of **origin** (5.2.4) shall be referred as a result.

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.9 isPartOfOrigin

semantic link (A.2.2.3) between **source** (5.2.7) and **origin** (5.2.4) of which **source** (5.2.7) is

NOTE 1 **origin** (5.2.4) shall be qualified with: { kingdom }, { part of interest }; and { scientific name }, { botanical feature }.

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.10 predetermines

semantic link (A.2.2.3) between **origin** (5.2.4) and **source** (5.2.7) of which characteristics **origin** (5.2.4) genetically predetermines, as a consequence, especially biomedical active **substances** (3.16) that **source** (5.2.7) contains

5.3.11 hasBotanicalFeature

semantic link (A.2.2.3) between **origin** (5.2.4) and **botanical feature** (5.2.5) which **origin** (5.2.4) has

NOTE 1 **botanical feature** (5.2.5) shall be qualified with, but not limited to: { habit }, { geographical distribution }, { morphology }, { size }, { flowering time }, { vegetation }, { life cycle }.

NOTE 2 In monographs or textbooks on identification of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.12 isIdentifiedByBotanicalFeature

semantic link (A.2.2.3) between **origin** (5.2.4) and **botanical feature** (5.2.5) by which **origin** (5.2.4) is identified

NOTE 1 In rarely, **designation** (B.3.4.1) with **binomial system** (3.7) with suffixed cannot identify living things. In such case, other **designator** (B.3.4.1) and/or **botanical feature** (5.2.5) **characterizing category** (A.2.3.3) may be utilized in order to identify **origin** (5.2.4), as a result, in identification of **source** (5.2.7) and HB-SNM (4.3) **object** (B.3.1.1).

NOTE 2 Ordinary people who harvest **natural materials** (3.1) do not necessarily use **scientific names** (5.2.3) in **binomial system** (3.7) but **vernacular names** (5.2.2) and **botanical features** (5.2.5). Anyway, **scientific names** (5.2.3) are also defined majorly from morphological features.

5.3.13 isCharacterizedByHarvest

semantic link (A.2.2.3) between **source** (5.2.7) and **harvest** (5.2.6) by which **source** (5.2.7) is characterized

NOTE 1 **harvest** (5.2.6) shall be qualified with, but not limited to: { region }, { season }, { weather }, { age }, { condition }, { cultivation }; and { initial procedure }.

NOTE 2 In monographs or textbooks on identification and/or quality of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.14 isIdentifiedByBasicCharacteristics

semantic link (A.2.2.3) between the herbal medicament (3.2) and **basic characteristics** (5.2.9) by which the herbal medicament (3.2) may be identified, or, **semantic link** (A.2.2.3) between **source** (5.2.7) and **basic characteristics** (5.2.9) by which **source** (5.2.7) may be identified

NOTE Ordinary people who trade **source (5.2.7)** or the herbal medicament (3.2) do not necessarily use **scientific names** (5.2.3) in **binomial system** (3.7) or **official names** (5.2.1), but **vernacular names** (5.2.2) and **basic characteristics** (5.2.9).

5.3.15 providesConstituent

semantic link (A.2.2.3) between **source** (5.2.7) and **constituent** (5.2.10) to which **source**(s) (5.2.7) provide(s)

NOTE 1 **constituent** (5.2.10) shall be qualified with: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 2 In official documents, monographs or textbooks on identification and/or pharmacological aspect of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.16 isProcessedByProcessing

semantic link (A.2.2.3) between **source** (5.2.7) and **processing** (5.2.8) by which **source** (5.2.7) is processed

NOTE 1 **processing** (5.2.8) shall be qualified with **processing type** (3.13), **processing method** (3.14) and **adjuvant material** (3.15).

NOTE 2 In monographs or textbooks on identification and/or quality of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.17 hasBasicCharacteristics

semantic link (A.2.2.3) between the herbal medicament (3.2) and **basic characteristics** (5.2.9) which the herbal medicament (3.2) has, or, **semantic link** (A.2.2.3) between **source** (5.2.7) and **basic characteristics** (5.2.9) which **source** (5.2.7) has

NOTE 1 **basic characteristics** (5.2.9) shall be qualified with, but not limited to: { shape }, { size }, { color }, { gloss }, { texture }, { heaviness }, {smell }, { taste }, { condition }.

NOTE 2 In monographs or textbooks on identification and/or quality of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3). In this **context** (B.3.6.10), **basic characteristics** (5.2.9) of **source** (5.2.7) and those of HB-SNM (4.3) should be described separately in order to avoid confusion.

5.3.18 areAffectedByProcessing

semantic link (A.2.2.3) between **basic characteristics** (5.2.9) and **processing** (5.2.8) by which **basic characteristics** (5.2.9) are affected

NOTE 1 **basic characteristics** (5.2.9) shall be qualified with, but not limited to: { shape }, { size }, { color }, { gloss }, { texture }, { heaviness }, {smell }, { taste }, { condition }.

NOTE 2 In monographs or textbooks on identification and/or quality of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3). In this **context** (B.3.6.10), **basic characteristics** (5.2.9) of **source** (5.2.7) and those of HB-SNM (4.3) should be described separately in order to avoid confusion.

5.3.19 isCharacterizedByProcessing

semantic link (A.2.2.3) between the herbal medicament (3.2) and **processing** (5.2.8) by which the herbal medicament (3.2) characterized

NOTE 1 **processing** (5.2.8) shall be qualified with **processing type** (3.13), **processing method** (3.14) and **adjuvant material** (3.15).

NOTE 2 **processing** (5.2.8) affects **basic characteristics** (5.2.9) of **source** (5.2.7), and may modify **constituent** (5.2.10) provided from **source** (5.2.7). Therefore both **basic characteristics** (5.2.9) and **constituent** (5.2.10) after **processing** (5.2.8) should be separately described in this **context** (B.3.6.10).

NOTE 3 In monographs or textbooks on processing and/or identification of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.20 isFollowedByProcessing

semantic link (A.2.2.3) among **processing**(s) (5.2.8) by which the previous **processing** (5.2.8) is followed

NOTE 1 **processing** (5.2.8) shall be qualified with **processing type** (3.13), **processing method** (3.14) and **adjuvant material** (3.15).

NOTE 2 Usually, a **processing** (5.2.8) is performed in a series of **processings** (5.2.8).

NOTE 3 In monographs or textbooks on processing and/or identification of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.21 modifiesConstituent

semantic link (A.2.2.3) between **processing** (5.2.8) and **constituent** (5.2.10) which **processing** (5.2.8) may modifies, destroys or degrade

NOTE 1 **constituent** (5.2.10) shall be qualified with: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 2 In monographs or textbooks on identification and/or pharmacological aspect of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.22 containsConstituent

semantic link (A.2.2.3) between the herbal medicament (3.2) and **constituent** (5.2.10) which the herbal medicament (3.2) contains

NOTE 1 **constituent** (5.2.10) shall be qualified with: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 2 In official documents, monographs or textbooks on identification and/or pharmacological aspect of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.23 hasBiomedicalEffect

semantic link (A.2.2.3) between the herbal medicament (3.2) and **biomedical effect** (5.2.12) which the herbal medicament (3.2) has, or, **semantic link** (A.2.2.3) between **constituent** (5.2.10) and **biomedical effect** (5.2.12) which **constituent** (5.2.10) has

NOTE 1 **biomedical effect** (5.2.12) shall be qualified with: **medical domain type** (3.17), { effect type }, { effect }, { precondition }.

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.24 arisesFromConstituent

semantic link (A.2.2.3) between **biomedical effect** (5.2.12) and **constituent** (5.2.10) from which **biomedical effect**(s) (5.2.12) arise(s)

NOTE 1 **constituent** (5.2.10) shall be qualified with: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 2 In documents on pharmacological aspect of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.25 dependsOnDosage

semantic link (A.2.2.3) between **biomedical effect** (5.2.12) and **dosage** (5.2.13) on which **biomedical effect**(s) depend(s)

NOTE 1 **dosage** (5.2.13) shall be qualified with, but not limited to: { dose }, { dose unit }, { dose form }, { route }, { frequency }, { period }.

NOTE 2 In documents on biomedical effects of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.26 hasLaboratoryTestProfile

semantic link (A.2.2.3) between the herbal medicament (3.2) and **laboratory test profile** (5.2.11) which the herbal medicament (3.2) has

NOTE 1 **laboratory test profile** (5.2.11) shall be qualified with: { test purpose }, { test method }, { test procedure }, { reference data }, { result(s) of a test }, { permissible limit }, { system adequacy }.

NOTE 2 In official documents, monographs or textbooks on identification and/or pharmacological aspect of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.27 detectsConstituent

semantic link (A.2.2.3) between **laboratory test profile** (5.2.11) and **constituent** (5.2.10) which **laboratory test profile** (5.2.11) detects

NOTE 1 **constituent** (5.2.10) shall be qualified with: { substance name }, { substance structure }, { related substances }, { physical characteristics }, { chemical characteristics }; and { biomedical effect }.

NOTE 2 In official documents, monographs or textbooks on identification and/or purity of herbal medicament (3.2), every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

5.3.28 isIdentifiedByLaboratoryTestProfile

semantic link (A.2.2.3) between the herbal medicament (3.2) and **biomedical effect** (5.2.12) by which the herbal medicament is identified by its **constituent** (5.2.10)

NOTE In this **context** (B.3.6.10), identification means to identify what it truly is, or discriminate forgeries.

5.3.29 isInspectedByLaboratoryTestProfile

semantic link (A.2.2.3) between the herbal medicament (3.2) and **biomedical effect** (5.2.12) by which the herbal medicament (3.2) is inspected by its **constituent** (5.2.10)

NOTE In this **context** (B.3.6.10), inspection means that inspection of impurities, amount of biomedical active **substances** (3.16), degree of biomedical activities, and so on.

6 Herbal medicaments composed of the herbal medicaments made of single natural material

6.1 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 composed of HB-SNMs (4.4) **[B]**, the **herbal medicaments** (3.2) that is composed of HB-SNMs (4.4) **[B]** has **semantic links** (A.2.2.3) to the following **characterizing categories** (A.2.3.3): **Required HB-SNM** (6.2.2) **[A]**, **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 the **herbal medicaments** (3.2) that is composed of HB-SNMs (4.4) **[B]**, additional **characterizing categories** (A.2.3.3) are required, but they are equivalent to **characterizing categories** (A.2.3.3) already specified in Clause 5.2.

Semantic links (A.2.2.3) among them are specified in Clause 6.3, except redundancies.

The outline of the relations among mentioned above is illustrated in a **concept diagram** (B.3.2.12) in Figure 2.

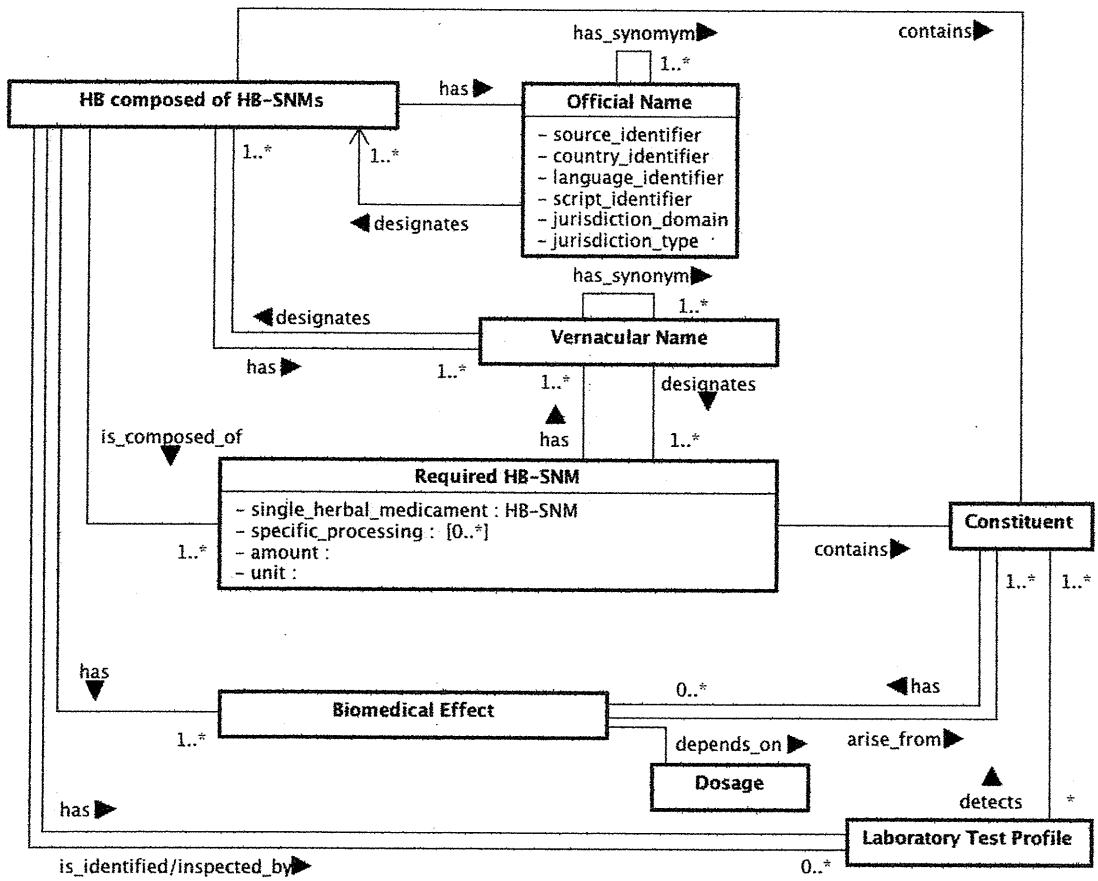

Figure 2 — Characterizing categories for herbal medicaments composed of HB-SNMs

6.2 Characterizing Categories (except redundancies)

6.2.1 List of main categories

Almost all **characterizing categories** (A.2.3.3) used for expression of herbal medicament (3.2) composed of HB-SNMs (4.4) **[B]** are same as HB-SNM (4.3) **[A]** except **Required HB-SNM** (6.2.2).

— Official Name

— Vernacular Name

— Required HB-SNM

— Constituent

— Biomedical Effect

— Laboratory Test Profile

6.2.2 Required HB-SNM

necessary HB-SNM (4.3) [**A**] for composing a herbal medicament (3.2) composed of HB-SNMs (4.4) [**B**], i.e. a formula composed of HB-SNMs (4.4)

NOTE 1 **required HB-SNM** (6.2.2) **characterizing category** (A.2.3.3) that are valid for representation of a herbal medicament (3.2) includes: { HB-SNM (4.3) }, { specifying certain processing }, { amount }, { unit }.

NOTE 2 The representation of **required HB-SNM** (6.2.2) is defined in Cause 5 as HB-SNM (4.3) [**A**] in this Technical Specification.

NOTE 3 **values** (3.19) for the subordinate **characterizing categor**ies (A.2.3.3) of **required HB-SNM** (6.2.2) are described in some references listed in bibliography [47,49,51-52] but not limited to them.

NOTE 4 **required HB-SNM** (6.2.2) contains **constituent** (5.2.10) and has **biomedical effect** (5.2.12) by itself. Further expression is described in the previous Cause 5.

6.3 Semantic Links (except redundancies)

6.3.1 List of main semantic links

semantic links (A.2.2.3) used for expression of HB-SNM (4.3) [**A**] are also used for expression of herbal medicament (3.2) composed of HB-SNMs (4.4) [**B**], except those are only used for expression of the relations to HB-SNM (4.3) [**A**], **source** (5.2.7), and **source** (5.2.7) related **characterizing categor**ies (A.2.3.3).

semantic links (A.2.2.3) of **isComposedOfRequiredHB-SNM** (6.3.2), designatesHBcomposedOfHB-SNMs and designatesRequiedHB-SNM newly appear in the expression of herbal medicament (3.2) composed of HB-SNMs (4.4) [**B**]. However, the second and the third are essentially same as designatesHB.

— hasOfficialName

— hasVernacularName

— designatesHB (i.e. designatesHBcomposedOfHB-SNMs and designatesRequiedHB-SNM)

— isComposedOfRequiredHB-SNM

— containsConstituent

— hasBiomedicalEffect

— arisesFromConstituent

— detectsConstituent

— hasLaboratoryTestProfile

— isIdentifiedByLaboratoryTestProfile

— isInpectedByLaboratoryTestProfile

6.3.2 isComposedOfRequiredHB-SNM

semantic link (A.2.2.3) between the herbal medicament (3.2) composed of HB-SNMs (4.4) [**B**] and **required HB-SNM** (6.2.2) of which herbal medicament (3.2) composed of HB-SNMs (4.4) [**B**] is composed

NOTE 1 **required HB-SNM** (6.2.2) shall be qualified with: { HB-SNM (4.3) }, { specifying certain processing }, { amount }, { unit }.

NOTE 2 Every herbal medicament terminological phrase complying with this Technical Specification shall have this **semantic link** (A.2.2.3).

7 Conformance

7.1 Conformance principles

To be conformant with EN 12264:2005 [3] and ISO 17115:2007 [4], any categorial structure for representation of herbal medicaments in a terminological system shall be provided the followings:

- **categories** that organise the health care **objects** for representation of herbal medicaments in the **terminological system** and subdividing their representation in the **domain**;
- a list of the **semantic links** (or **representations of relations**) authorised by **domain constraints**;
- the goal of the **terminological system** for which the **categorial structure** is set;
- a list of minimal **domain constraints** required by the goal of the **categorial structure**.

7.2 Goal of the terminological system for which the categorial structure is set

The goal of each herbal medicaments terminology used in terminological system(s) of health, healthcare and biomedical science shall be defined by the users and make statement on situations and applications for which the categorial structure is intended and the limits of use.

EXAMPLE controlled vocabulary, comparison with another terminological system for coding, some kinds of official document, monograph for domain experts, product for clinicians, textbook for education

7.3 List of minimal domain constraint

The list shall contain the different semantic links clause 5.3 or 6.3, and the different categories from specified clause 5.2 or 6.2, that are valid and necessary for the intended goal of setting categorial structures in a terminological system for representation of herbal medicaments.

7.4 Conformity to this Technical Specification

A categorial structure for a terminology representing herbal medicaments claiming conformance to this Technical Specification shall provide the information described in clause 7.1, 7.2, and 7.3, and shall be conformant to the following minimum rules:

- a herbal medicament made of single natural material **[A]** shall consist of **origin** (5.2.4), **processing** (5.2.8), **constituent** (5.2.10) and **biomedical effect** (5.2.12), with related **characterizing categories** (A.2.3.3) if necessary for detailed description in order to achieve the intended goal.
- a herbal medicament composed of the herbal medicaments made of single natural material **[B]** shall consist of **required HB-SNM** (6.2.3), **constituent** (5.2.10) and **biomedical effect** (5.2.12), with related **characterizing categories** (A.2.3.3) if necessary for detailed description in order to achieve the intended goal.

Annex A
(normative)

Selected definitions from ISO 17115:2007

The following terms and definitions are selected from ISO 17115:2007. They are included here as background to the key terms and definitions in Clause 3 of this Technical Specification. The numbering in this Annex reflects the numbering in ISO 17115:2007, for consistency.

A.1 Specialization

A.2.1.1
specialize
form a more **specific concept** (B.3.2.16) [by constraining the **extension** (B.3.2.8) of a more **generic concept** (B.3.2.15)]

EXAMPLE 1 Infection that hasCause Bacteria can be specialized to Infection that hasCause.

EXAMPLE 2 Pneumococcus Hepatitis can be specialized to NonA-NonB-hepatitis.

NOTE 1 To specialize is to increase the intension and decrease the extension of a concept. The more **specific concept** (B.3.2.16) has a larger **intension** (B.3.2.9), but a smaller extension than the **general concept** (B.3.2.3). Specialization and generalization can be achieved in many ways, including replacing a semantic link with a more specific semantic link (and vice versa for generalization).

NOTE 2 The more specific concept has a broader intension, but a narrower extension than the generic concept.

NOTE 3 Ways to specialize concepts include
- adding one or more **composite characteristics** (A2.2.1),
- replacing the **characterizing concept** (A2.2.2) in one or more **characteristics** (B.3.2.4) with a more **specific concept** (B.3.2.16), and
- forming an intersection of two concepts (where the intersection is a specialization of both the "parents").

NOTE 4 The opposite is **generalize** (2.1.2).

A.2.1.2
generalize
form a more **generic concept** (B.3.2.15) [that represents a superset of the **extension**(s) (B.3.2.8) of one or more **specific concepts** (B.3.2.16)]

EXAMPLE Infection that hasCause Pneumococcus can be generalized to Infection that hasCause Bacterium.

NOTE 1 To generalize is to decrease the **intension** (B.3.2.9) and increase the extension of a concept. Specialization and generalization can be achieved in many ways, including replacing a semantic link with a less specific semantic link (and vice versa for specialization).

NOTE 2 This can be done by removing one or more **characteristics** (B.3.2.4) or by replacing the **characterizing concept** (A2.2.2) in one or more characteristics with a more generic concept.

NOTE 3 The opposite is **specialize** (A2.1.1).

A.2.1.3
level of specialization
property of a **concept** (B.3.2.1) reflecting the number of and detail of **characteristics** (B.3.2.4) in its **intension** (B.3.2.9)

NOTE A **specific concept** (B.3.2.16) has a high level of specialization and a fine granularity; a **generic concept** (B.3.2.15) has low level of specialization and coarse granularity.

A.2.1.4
generic concept
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)]

A.2 Formal representation of characteristics

A.2.2.1
composite characteristic
qualifier
representation of a **characteristic** (B.3.2.4)

EXAMPLE hasCause Bacteria; Location = LeftUpperLobeOfLung

NOTE 1 Typically expressed by a **semantic link** (A.2.2.3) and a **characterizing concept** (A.2.2.2)

NOTE 2 Can be compared to an attribute-value pair in a **compositional system** (A.2.5.2)

NOTE 3 A qualifier often denotes **characteristics** with a small simple **characterizing generic concept** (A.2.3.3), such as laterality (left or right), or severity (low, moderate, high).

A.2.2.2
characterizing concept
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".

A.2.2.3
semantic link
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).

A.3 Sanctioned specialization

A.2.3.1
sanctioned characteristic
formal representation of a **type of characteristic** (B.3.2.5)

EXAMPLE 1 performedUsing <INSTRUMENT>; hasLocation <BodyPartOrImplantedDevice>.

EXAMPLE 2 "CauseOfInflammation canBe set{ bacteria, virus, parasite, autoimmune, chemical, physical }", where "canBe" is the **semantic link** (A.2.2.3), and "set{ bacteria, virus, parasite, autoimmune, chemical, physical }" is the **characterizing generic concept** (A.2.3.3)

NOTE A sanctioned characteristic is typically made up of a combination of a semantic link and a characterizing generic concept, and can be used in **domain constraints** (A.2.3.2).

A.2.3.2
domain constraint
sanction rule prescribing the set of **sanctioned characteristics** (A.2.3.1) that are valid to **specialize** (A.2.1.1) a **concept** (B.3.2.1) in a certain **subject field** (B.3.1.2)

EXAMPLE "Infection possibly hasLocation SkeletalStructure" describes that an infection in a certain context can be located in a structure that is a kind of skeletal structure

NOTE 1 The rule describes the set of sanctioned **characteristics** (B.3.2.4) by combining the **semantic link** (A.2.2.3) and the **characterizing generic concept** (A.2.3.3) it links to, possibly by enumeration of the concepts in the characterizing generic concept

NOTE 2 Different levels of sanctioning are possible (e.g. conceivable, sensible, normal, usuallyInTheContextOf, necessary).

A.2.3.3
characterizing generic concept
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)

A.4 Formal concept representation

A.2.4.1
compositional concept representation
intensional definition (B.3.3.2) of a **concept** (B.3.2.1) using as **delimiting characteristics** (B.3.2.7) one or more **composite characteristics** (A.2.2.1)

NOTE This allows inference and subsumption within a **compositional system** (A.2.5.2). It is usually expressed in a formalism, such as description logic.

A.2.4.2
axiomatic concept representation
axiom concept representation present in a **formal system (A.2.5.1)** without a **formal definition (A.2.4.3)**

EXAMPLES Liver; Incision act; Pain

NOTE This often represents a "natural kind" from the perspective of a particular terminology system; i.e. something that "just exists". It may have a definition or description outside the system but by choice, this is not represented in the system.

A.2.4.3
formal definition
definition within a **formal system** (A.2.5.1)

NOTE This can be done by a **compositional concept representation** (A.2.4.1) or a formal **extensional definition** (B.3.3.3)

NOTE It is usually automatically processable and governed by explicit rules

A.2.4.4
concept name
canonical expression
term (B.3.4.3) which uniquely designates a **concept** (B.3.2.1) within a **concept system** (B.3.2.11)

EXAMPLE 1 Machine readable: <Inflammation that <hasCause Bacteria hasLocation Lung>> (with compositional characteristics sorted alphabetically after semantic link) instead of <pulmonaryInfection that hasCause Bacteria>

EXAMPLE 2 General language: Inflammation that has cause bacteria and has location lung (with compositional characteristics sorted alphabetically after semantic link) instead of pulmonary infection that has cause bacteria.

NOTE 1 It is preferred expression to represent a **concept** (B.3.2.1) in a given terminology system

NOTE 2 It is unique within the system unambiguous

A.2.4.5
categorial structure
minimal set of **domain constraints** (A.2.3.2) for representing **concepts systems** (B.3.2.11) in a **subject field** (B.3.1.2).

A.2.4.6
precoordinated concept representation
compositional concept representation (A.2.4.1) within a **formal system** (A.2.5.1), with an equivalent single unique identifier

EXAMPLE Problem=Fracture that hasLocation Femur. This is an example of how a precoordinated concept is represented

NOTE The identifier (code, term etc) may be within or outside the terminology system in question.

A.2.4.7
post-coordinated concept representation
compositional concept representation (A.2.4.1) using more than one **concept** (B.3.2.1) from one or many **formal systems** (A.2.5.1), combined using mechanisms within or outside the formal systems

EXAMPLE Problem.Main = Fracture, Problem.Location = Femur within a template for a problem description

NOTE Combining concepts from disparate terminologies can cause problems with overlapping and/or conflicting concepts. Typically, the mechanisms for making **compositional concept representations** (A.2.4.1) are specified in an information model (e.g. as templates for a certain type of concept).

A.5 Terminology and information models, concept systems

A.2.5.1
formal [concept representation] system
set of machine processable definitions in a **subject field** (B.3.1.2)

A.2.5.2
compositional system
system that supports the creation of **compositional concept representations** (A.2.4.1)

A.2.5.3
formal category
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).

A.6 Specified concepts

A.2.6.1
mapping
assigning an element in one set to an element in another set through **semantic correspondence** (A.2.6.2)

NOTE It is the relation with the best semantic correspondence between an element in one set and an element in another set

A.2.6.2
semantic correspondence
measure of similarity between two concepts

NOTE The opposite semantic distance

A.2.6.3
instance of a concept
member of the **extension** (B.3.2.8) of a **concept** (B.3.2.1)

A.2.6.4
focus concept representation
specified representation of the **concept** (B.3.2.1) of interest within a **formal system** (A.2.5.1)

EXAMPLE "Moderately severe inflammation caused by pneumococci located in the upper lobe of the left lung, ascertained by plain film pulmonary X-ray and sputum culture" in the context of a diagnosis with confirmatory evidence.

NOTE It including context information, enabling independent use

A.2.6.5
generic relation
subtype relation
relation between two **concepts** (B.3.2.1) where the **intension** (B.3.2.9) of one of the concepts includes that of the other concept and at least one additional **delimiting characteristic** (B.3.2.7)
[ISO 1087-1:2000, A.3.2.21]

NOTE All individuals in the **extension** (B.3.2.8) of the second are included in the extension of the first.

EXAMPLE A generic relation exists between the concepts 'internal organ' and 'heart', 'surgical deed' and 'appendectomy', 'inflammatory disease' and 'pericarditis'.

A.7 Terminological systems

A.2.7.1
classification
exhaustive set of mutually exclusive **categories** (A.2.1.4) to aggregate data at a pre-prescribed **level of specialization** (A.2.1.3) for a specific purpose

EXAMPLE ICD 10

A.2.7.2
coding scheme
collection of rules that maps the elements in one set, the "coded set" onto the elements in a second set "the code set"

[ISO 2382-4]

NOTE The two sets are not part of the coding scheme.

A.2.7.3
coding system
combination of a set of **concepts** (B.3.2.1) [coded concepts], a set of code values, and at least one **coding scheme** (A.2.7.2) mapping code values to coded concepts

NOTE Coded concepts are typically represented by **terms** (A3.4.3), but can have other representation. Code values are typically numeric or alphanumeric.

A.2.7.4
reference terminology
set of atomic level designations structured to support representations of both simple and compositional concepts independent of human language (within machine)

NOTE 1 Reference terminology is designed to uniquely represent **concepts** (A.3.2.1)

NOTE 2 The terminology lists the concepts and specifies their structure, relationships and, if present, their systematic and **formal definitions** (A.2.4.3).

A.2.7.5
clinical terminology
terminology required directly or indirectly to describe health conditions and healthcare activities

NOTE 1 Health conditions include symptoms, complaints, illness, diseases, disorders etc.

NOTE 2 It is used in, for example, medical records, clinical communication, and medical science.

Annex B
(normative)

Selected definitions from ISO 1087-1:2000

The following terms and definitions are selected from ISO 1087-1:2000. They are included here as background to the key terms and definitions in Clause 3 of this Technical Specification. The numbering in this Annex reflects the numbering in ISO 1087-1:2000, for consistency.

B.1 Language and reality

B.3.1.1
object
anything perceivable or conceivable

NOTE Objects may be material (e.g. an engine, a sheet of paper, a diamond), immaterial (e.g. conversion ratio, a project plan) or imagined (e.g. a unicorn).

B.3.1.2
subject field
domain
field of special knowledge

NOTE The borderlines of a subject field are defined from a purpose-related point of view.

B.2 Concept

B.3.2.1
concept
unit of knowledge created by a unique combination of **characteristics** (B.3.2.4)

NOTE Concepts are not necessarily bound to particular languages. They are, however, influenced by the social or cultural background which often leads to different categorizations.

B.3.2.2
individual concept
concept (B.3.2.1) which corresponds to only one **object** (B.3.1.1)

NOTE 1 Examples of individual concepts are 'Saturn', 'the Eiffel Tower'.

NOTE 2 Individual concepts are usually represented by **appellations** (B.3.4.2).

B.3.2.3
general concept
concept (B.3.2.1) which corresponds to two or more **objects** (B.3.1.1) which form a group by reason of common properties

NOTE Examples of general concepts are 'planet', 'tower'.

B.3.2.4
characteristic
abstraction of a property of an **object** (B.3.1.1) or of a set of objects

NOTE Characteristics are used for describing **concepts** (B.3.2.1).