Purpose and justification (attach a separate page as annex, if necessary)

The purpose of this Technical Specification is to specify categorial structures in the subject field of the herbal medicaments [A] herbal medicaments made of single natural material with or without adjuvant material(s) and [B] herbal medicaments that are made with the herbal medicaments made of single natural material, by defining a set of constraints for use within terminological resources.

For centuries, natural materials have been used by mankind for medicinal purposes. 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, spirit, vinegar, honey) are often used, in order to add flavors, for detoxification, for support of extraction of active substances, and so on. Today herbal medicaments are used extensively both in medicines and in supplements.

However, regional differences and history have lead to the use of single specific names representing different natural materials or herbal medicaments, or different names often designate same material or medicament. This situation often causes confusion in international trade and serious health hazards may occur as a consequence. These problems should be resolved by standardization of the relations between terms and concepts by following the standardization of terminological resources.

This Technical Specification describes categorial structures detailing a domain constraint of sanctioned characteristics each composed of a semantic link and an applicable characterizing category.
1) support developers of new terminology systems concerning herbal medicaments;
2) support developers of new content areas of existing terminology systems concerning herbal medicaments to enable conformance;
3) facilitate the representation of herbal medicaments using a standard core model in a manner suitable for computer processing;
4) support the development of monitoring systems for adverse events and adverse reactions;
5) provide the characterization of clinical research intervention of herbal medicaments;
6) 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;
7) promote smooth exchange of information and reduce the risk to patients of adverse reactions and risks affected by the toxicity of herbal medicaments;
8) clarify the polysemy across and within different clinical specialties and systems.

Target date for availability (date by which publication is considered to be necessary)

Proposed development track ☐ 1 (24 months) ☒ 2 (36 months - default) ☐ 3 (48 months)

Relevant documents to be considered
Standards produced by TC215

Relationship of project to activities of other international bodies
WHO International Standard Terminology on Traditional Medicine in the Western Pacific Region, WHO monographs on selected medicinal plants

Liaison organizations	**Need for coordination with:**
IHTSDO (International Health Technology Standards Development Organisation) WHO especially WPRO(Western Pacific Region)/FHH(Forum for the Harmonization of Herbal Medicines)	☐ IEC ☐ CEN ☐ Other (please specify)

Preparatory work (at a minimum an outline should be included with the proposal)

☐ A draft is attached ☒ An outline is attached. It is possible to supply a draft by **Mar 31, 2012**

The proposer or the proposer's organization is prepared to undertake the preparatory work required ☒ Yes ☐ No

Proposed Project Leader (name and address)	**Name and signature of the Proposer** (include contact information)
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Comments of the TC or SC Secretariat

Supplementary information relating to the proposal

☒ This proposal relates to a new ISO document;

☐ This proposal relates to the amendment/revision of an existing ISO document;

☐ This proposal relates to the adoption as an active project of an item currently registered as a Preliminary Work Item;

☐ This proposal relates to the re-establishment of a cancelled project as an active project.

Other:

Voting information

The ballot associated with this proposal comprises a vote on:

☒ Adoption of the proposal as a new project

☐ Adoption of the associated draft as a committee draft (CD)

☐ Adoption of the associated draft for submission for the enquiry vote (DIS or equivalent)

Other:

Annex(es) are included with this proposal (give details)

☐

Date of circulation	Closing date for voting	Signature of the TC or SC Secretary
20 December 2011	20 March 2012	Lisa Spellman, TC 215 secretary

Use this form to propose:

a) a new ISO document (including a new part to an existing document), or the amendment/revision of an existing ISO document;

b) the establishment as an active project of a preliminary work item, or the re-establishment of a cancelled project;

c) the change in the type of an existing document, e.g. conversion of a Technical Specification into an International Standard.

This form is not intended for use to propose an action following a systematic review - use ISO Form 21 for that purpose.

Proposals for correction (i.e. proposals for a Technical Corrigendum) should be submitted in writing directly to the secretariat concerned.

Guidelines on the completion of a proposal for a new work item

(see also the ISO/IEC Directives Part 1)

a) Title: Indicate the subject of the proposed new work item.

b) Scope: Give a clear indication of the coverage of the proposed new work item. Indicate, for example, if this is a proposal for a new document, or a proposed change (amendment/revision). It is often helpful to indicate what is not covered (exclusions).

c) Envisaged publication type: Details of the types of ISO deliverable available are given in the ISO/IEC Directives, Part 1 and/or the associated ISO Supplement.

d) Purpose and justification: Give details based on a critical study of the following elements wherever practicable. *Wherever possible reference should be made to information contained in the related TC Business Plan.*

1) The specific aims and reason for the standardization activity, with particular emphasis on the aspects of standardization to be covered, the problems it is expected to solve or the difficulties it is intended to overcome.

2) The main interests that might benefit from or be affected by the activity, such as industry, consumers, trade, governments, distributors.

3) Feasibility of the activity: Are there factors that could hinder the successful establishment or global application of the standard?

4) Timeliness of the standard to be produced: Is the technology reasonably stabilized? If not, how much time is likely to be available before advances in technology may render the proposed standard outdated? Is the proposed standard required as a basis for the future development of the technology in question?

5) Urgency of the activity, considering the needs of other fields or organizations. Indicate target date and, when a series of standards is proposed, suggest priorities.

6) The benefits to be gained by the implementation of the proposed standard; alternatively, the loss or disadvantage(s) if no standard is established within a reasonable time. Data such as product volume or value of trade should be included and quantified.

7) If the standardization activity is, or is likely to be, the subject of regulations or to require the harmonization of existing regulations, this should be indicated.

If a series of new work items is proposed having a common purpose and justification, a common proposal may be drafted including all elements to be clarified and enumerating the titles and scopes of each individual item.

e) Relevant documents and their effects on global relevancy: List any known relevant documents (such as standards and regulations), regardless of their source. When the proposer considers that an existing well-established document may be acceptable as a standard (with or without amendment), indicate this with appropriate justification and attach a copy to the proposal.

f) Cooperation and liaison: List relevant organizations or bodies with which cooperation and liaison should exist.

Outline of the NWIP on

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

This document describes preparatory works for the development of a Technical Specification on categorial structures [1-3] for representation of herbal medicaments. This document initially illustrates the background of the proposal then explains purpose and justification, next, reviews the existing terminologies on herbal medicaments and finally shows current works.

1. Introduction and background

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

> Note In the proposed Technical Specification, natural materials include not only plants but also animal products and minerals.

Regional differences and histories [explained in Section 1.2] have led to the use of single specific names representing different natural materials or medicaments, on the hand, different names often designate same one. This situation causes that confusion in international trade and serious health hazards may occur as a consequence.
These problems should be resolved by clarifying the relations between terms and concepts, subsequently by the optimization and/or the harmonization of terminological resources.

1.1. Analogies

In trading 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 or the 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, same characters are 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.

Examples

A) `Material/Medicament` : CRUCUMA

Genus of CRUCUMA, turmeric, consists of *Curcuma kwangsiensis*, *C. longa*, *C. phaeocaulis*, *C. wenyujin*, *C. zedoaria*, and *C. aromatica*. All of them contain diarylheptanoids, but the kinds and the amounts of chemical substances differ from each species. Then, both efficacies of medicament and market prices of material vary as each species.

B) `Material/Medicament` : ASIASARI RADIX

ASIASARI RADIX consists of the dried root part of *Asiasarum siebordii*, and it is used for head pain, joint pain and coughs. The aerial part of this plant contains aristolochic acid that is commonly found in the *Aristolochiaceae* family of plants. It is known as carcinogenic, mutagenic, and nephrotoxic compounds, and frequently induces nephropathy.

C) Material/Medicament : EPHEDRAE HERBA

EPHEDRAE HERBA is the dried aerial part of *Ephedra sinica*, which contains ephedrine. On the other hand, ephedradines A-D and ephedrannin A are found in root part of same plant and those have anti-hydrotic and hypotensive effects. Each part has nearly opposite effects.

D) Material/Medicament : CARYOPHYLLI FLOS

CARYOPHYLLI FLOS is the flower bud of *Syzygium aromaticum* (i.e. *Eugenia aromatica*) which is known as clove. It is harvested in flower bud season, because its flavor is lost in flowering season. Change of flavor means the change of ingredients.

E) Material/Medicament : GINSENG RADIX

GINSENG RADIX is the dried root of *Panax ginseng*, which contains ginsenosides. The amount of it are depend on growth year, so age of plant is an important factor. It is required for medical use that the contents of ginsenoside Rg1 shall be over 0.10-0.30 % and ginsenoside Rb1 shall be over 0.20 % in Pharmacopoeia of China and of Japan. Therefore, the plant should be harvested among 4 to 6 years growth.

1.2. Prevalence and diversity

In history of herbal medicaments, they are conceived in a certain area and then they would be 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 distinct [4,5]. Such substitutions should contain same ingredients or active substances, or the ingredients that has approximate efficacies. But people in those days had no analyzers for scientific assays. Their judgments depended on their clinical experiences and appearance of natural materials [4,5].

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 behaviors to solve health issues,

but on the other hand, result in critical problems in health informatics because lots of polysemic terms erupted [4-6,20-24,30,31,36-39].

1.3. Polysemy and synonymy

Those situation mentioned above have led to the use of single specific names representing different natural materials/medicaments [polysemy; ref. 1], different names often designate same natural materials/medicament [synonymy; ref. 1]. Anyway, such vernacular names have been established as customary in each area/distinct. Furthermore, even in today, those terms and situation occasionally influence different specialties [4,6,20-24,30,31, 36-46].

Examples

A) `Material/Medicament` : CRUCUMA related term or name

In CRUCUMA genus, the followings are used as herbal medicaments: *Curcuma kwangsiensis*, *C. longa*, *C. phaeocaulis*, *C. wenyujin*, *C. zedoaria*. The medicinal parts of them are rhizome and root, so the number of the combination counts ten.

For instance, the term, medicament name CRUCUMAE RHIZOMA, means the rhizome of *C. longa* in Japan, but means *C. phaeocaulis*, *C. kwangsiensis*, *C. wenyujin*, in China. If considering the terms in East Asian ideographical characters in pharmacopoeias [4,6,41-47], relations among terms and concepts are complex. Moreover, at the extremity of confusion when considering vernacular names [20-24,40] commonly used in trading.

B) `Material/Medicament` : REHMANNIAE RADIX

REHMANNIAE RADIX is the root of *Rehamnnia glutinosa*. The term, medicament name REHMANNIAE RADIX, means fresh or dried root in China, but only dried root in Japan. The difference exists in processing but same name (i.e. designator) designates different medicaments [4,6,41-46].

C) `Formula/Medicament` : WenJing Tang (温経湯)

Principally used for women's diseases such as irregular menstruation, dysfunctional uterine bleeding and leucorrhoea. The formula contains eleven herbal medicaments in China but twelve in Japan; furthermore, the combinations of single herbal medicaments are quite different [4,6,41-46].

Nevertheless same name designates both, but an issue among different countries.

D) Formula/Medicament : Sijunzi Tang or Sijunzi Wan (四君子湯 or 四君子丸)

Formula Sijunzi Tang consists of the combination of four single herbal medicaments, Renshen, Baizhu, Fuling, zhi Gancao, in textbooks of education domain [32,37,39]. However, pharmacopoeias in the same country regulate the formula as the combination of Dangshen, Baizhu, Fuling, and zhi Gancao [43,44,46]. The origin of Renshen (人参) is *Panax ginseng* which contains ginsenosides, and other chemical substances [30]. On the other hand, the origin of Dangshen (党参) is *Codomopsis pilosula* or some other *Codomopsis* genus, those contains taraxerol, tangshenoside, and other substances [30]. Although Renshen and Dangshen have quite different ingredients respectively, same term is used in different domains in a same country if those domains can be recognized as different.

1.4. Problems

Polysemy (and synonymy) cause 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.

2. Scope

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

2.1. Scope

The scope of the proposed Technical Specification is to specify categorial structures [1-3] in the subject field of the herbal medicaments [A] herbal medicaments made of single natural material with or without adjuvant

material(s) and [B] herbal medicaments that are made with the herbal medicaments made of single natural material, by defining a set of constraints for use within terminological resources. [Typically and compactly represented in ref. 30-32, 36-39]

> Note 1 In the proposed Technical Specification, adjuvant material means (e.g. rice, sand, spirit, vinegar, honey) are often used in processing of natural materials, in order to add flavors, for detoxification, for support of extraction of active substances, and so on [28].
>
> Note 2 In the proposed 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].
>
> * Episode is described at the end of this document as example.

The proposed Technical Specification will not include contents of herbal medicament concept representations that would represent particular concepts of particular herbal medicaments, but it specifies the structural model of the concept representing herbal medicament in concept system, by defining a minimum set of constraints. Then, on this concept model, the contents in terminological systems can be developed and maintained, with consistency and with interoperability.

2.2. Out of scope

The proposed 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.

The proposed Technical Specification does not define

(1) Any information models for drug products from herbal medicament(s),
(2) The combinations of modern drug(s) and herbal medicament(s) or

natural material(s),

(3) Any process models of drug production or manufacturing, and

(4) Any models or frameworks for quality control of

(i) Cultivation of natural materials,

(ii) Drug products from herbal medicaments, natural materials, or the combinations of modern drug(s) and herbal medicament(s) or natural material(s).

The proposed 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 single herbal medicaments with or without adjuvant material(s) [A].

2.3. Avoidance of overlaps or conflictions

Therefore conflictions or overlaps are feasibly avoided.

2.3.1. TC 215 / WG 6 (and ICH / M5)

The task of TC215/WG6 focuses on "Pharmacy and Medicines Business." IDMPs define the schemes for identifying drug product, in order to specifying identifiers of each drug products, then, to support information exchange of drug products among authorities, manufacturers and other stakeholders. The information elements in IDMPs are defined to satisfy the requirements to identify each drag products; in other words, the designator [1,2] or identifier in IDMPs designates a 'real' thing in the 'real world' [11-15].

On the other hand, the proposed Technical Specification "Categorial structures for representation of herbal medicaments in terminological systems" focuses on the minimum conceptual model, which represents herbal medicaments in concept system(s) in mind, in order to support consistency and interoperability of development and maintenance of terminological systems.

Therefore, the proposed Technical Specification and IDMPs would work complementary.

2.3.2. TC 249

The task of TC249 focuses on "Traditional Chinese Medicine (provisional title but anyway focused on the traditional medicine originated from ancient China)". The scope of the proposed Technical Specification "Categorial structures for representation of herbal medicaments in terminological systems" is not limited within so-called TCM because TC215/WG3 handles worldwide items, in the senses of nations and also peoples [16,17].
The proposed Technical Specification should only specify the minimum set of constraints in the field of herbal medicaments, so that it would be helpful to the model(s) focused on TCM that might be handled in JWG-TCM between TC215 and TC249.

2.3.3. TC 34

The task of TC34 focuses on "Food products" [18,19], therefore the scope of the proposed Technical Specification is different [please refer to the third paragraph in Section 1.1].

2.4. Possible contributions

The proposed Technical Specification describes categorial structures detailing a domain constraint of sanctioned characteristics each composed of a semantic link and an applicable characterizing category.

1) Support developers of new terminology systems concerning herbal medicaments;
2) Support developers of new content areas of existing terminology systems concerning herbal medicaments to enable conformance;
3) Facilitate the representation of herbal medicaments using a standard core model in a manner suitable for computer processing;
4) Support the development of monitoring systems for adverse events and adverse reactions;
5) Provide the characterization of clinical research intervention of herbal medicaments;
6) 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;

7) Promote smooth exchange of information and reduce the risk to patients of adverse reactions and risks affected by the toxicity of herbal medicaments;
8) Clarify the polysemy across and within different clinical specialties and systems.

3. Purpose and justification

Purpose and Justification are already mentioned above. [Please refer to whole of Chapter 1, and Section 2.1 and 2.4]

The proposed Technical Specification is to specify categorial structures in the subject field of the herbal medicaments by defining a set of constraints for use within terminological resources. It specifies the structural model in which such content can be developed and maintained with consistency and interoperability.

The outcome of this work would be helpful to detect and clarification of polysemy which mainly causes misunderstanding both in trade and in scientific discussion.

4. Existing resources

There are some international terminological resources related to the concept structure of herbal medicaments [7,20-26]:

- WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region
- WHO Monographs on Selected Medicinal Plants Volume 1 - 4
- WHO Monographs on medicinal plants commonly used in the Newly Independent States (NIS)
- ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products 2nd Edition and Supplement

5. Current works

The proposed Technical Specification specifies two kinds concept of herbal medicaments:

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

[B] Herbal medicaments that are made with the herbal medicaments made of single natural material

They were separately proposed in TMTF meeting in Kuopio, but after some discussion in WG3 meeting in Chicago, combined into one item.

5.1. Elements in resources

The project leader, the proposer and colleagues have investigated the resources describe in Chapter 4 in order to make sure what characters are needed as child/grandchild and what granularity is feasible for the generic concept of herbal medicaments.

Non-international terminologies [8-10], monograph [27], textbooks [28-39], handbook [40], and pharmacopoeias [41-51] are also referred in order to (i) find the elements that are important for herbal medicament at least in a certain aspect, and/or (ii) find values which should be hold in characteristics in categorial structures specified in this work.

For elements of [A], we have mainly looked into 20-24, 30, 31, 36, 38, 40, 42, and partially 25-27, 41, 43-51. For elements of [B], mainly 28, 29, 32, 37, 39, and partially 41-51.

Thereby, we have found hundreds elements are related to herbal medicaments. Such a large number is mostly caused by (i) chemical and physical characteristics and (ii) characteristics in botany, but they are out of scope in this proposed Technical Specification.

5.2. Minimization and conformance

Results of Section 5.1 show various resources contains large amount of characteristics. However, characteristics required for identification of herbal

medicament in concept systems seem not so many. In other words, many elements found as child/grandchild in Section 5.1 might to be handled as value [1,3].

Anyway, whole of extracted elements is not always required to constitute a generic concept of herbal medicament. Once again, the proposed Technical Specification will specify only the minimum set of constraints.

In order to support the conformity in various terminological resources, 'generosity' is one of significant issues. It would consequently lead to the consistency and interoperability of the concept of herbal medicament in development and maintenance of terminological systems.

5.3. Core of characteristics

We recognize the essential characteristics [1,2] and the delimiting characteristics [1,2] of herbal medicament in concept systems are as the followings:

[A]:

Origin [in the sense defined in ref. 7]
Processing [in the sense defined in ref. 7]
Effect(s) on health issues(s) recognized in a certain medical domain
Relation to designator

[B]:

Required single herbal medicaments (defined in [A])
Amount of it in a formula
Effect(s) on health issues(s) recognized in a certain medical domain
Relation to designator

Each element can be decomposed into some child/grandchild elements.

5.4. Detailed characterising categories

We have specified the categorial structures for representation of herbal medicaments in terminological systems as followings, but this work is still in progress. From now on, SNOMED should be referred, and Indian or other areas' herbal medicines should be circumstantially investigated.

With that being said, if characteristics described in Section 5.3 are crucial and indispensable, or higher level characterising concepts that specify the concept of 'herbal medicament', unfolding of them must be essential.
We propose the followings as a proposal for discussion, taking into account Section 2.1, 2.2, 2.3, 5.1, 5.2, and 5.3.

[A]:

- Name of herbal medicament made of single natural material
  - Latin name in a pharmacopoeia
    - Country identifier
    - Synonyms if exists
    - Name in country language in the pharmacopoeia
      - Synonyms if exists
    - Name in English in the pharmacopoeia if exists
      - Synonyms if exists
  - Vernacular names
    - Identifier of language
    - Identifier of script
- Origin
  - Category of source (i.e. plant/animal/mineral)
  - Scientific name of source
    - Botanical description of source if needed
    - Synonyms if exists
  - Vernacular names of source
  - Part of source for medicinal use
  - Area/District of harvest/gather
  - Timing/Condition of harvest/gather
  - Initial procedure
  - Morphological description of the herbal medicament
  - Flavor/Taste description of the herbal medicament
- Processing
  - Processing method
    - Category of processing method
    - Processing method
      - Remarks in processing method
  - Adjuvant material(s) if used
  - Morphological description of the herbal medicament after Processing
  - Flavor/Taste description of the herbal medicament after Processing
- Effect(s) on health issues(s)
  - Efficacy recognized in a certain medical domain
    - Identification of a medical domain
  - Adverse effect recognized in a certain medical domain
    - Identification of a medical domain

Pharmacological remarks/precautions
Other characteristics those are specific to a certain medical domain
Identification of a medical domain
Indication
Signs/Symptoms/Syndrome/Disease in a certain medical domain
Identification of a medical domain
Contraindication
Signs/Symptoms/Syndrome/Disease in a certain medical domain
Identification of a medical domain
Usage
Usage in a certain medical domain
Identification of pharmacopoeias
Identification of a medical domain
Dose in usage

[B]:

Name of herbal medicament that are made with [A]
Latin name in a pharmacopoeia
Country identifier
Synonyms if exists
Name in country language in the pharmacopoeia
Synonyms if exists
Name in English in the pharmacopoeia if exists
Synonyms if exists
Vernacular names
Identifier of language
Identifier of script
Required single herbal medicament (defined in [A])
Amount in a formula (i.e. dose)
Unit of amount
Specific processing if needed
Effect(s) on health issues(s) recognized in a certain medical domain
Efficacy recognized in a certain medical domain
Identification of a medical domain
Adverse effect recognized in a certain medical domain
Identification of a medical domain
Pharmacological remarks/precautions
Other characteristics those are specific to a certain medical domain
Identification of a medical domain
Indication
Signs/Symptoms/Syndrome/Disease in a certain medical domain
Identification of a medical domain
Contraindication
Signs/Symptoms/Syndrome/Disease in a certain medical domain
Identification of a medical domain
Dosage form

Usage
Usage in a certain medical domain
Identification of pharmacopoeias
Identification of a medical domain
Dose in usage

This proposed Technical Specification might be referred by many concerned in various field, so that, too less for some but too much for others. In order to conformity, minimum sets shall be specified in ISO/TC 215/WG 3.
Comments and suggestions are welcome. We are looking forward to many international experts participate in this work.

6. Time scale

We will finish the Working Draft by 31 Mar 2012.
The development of the proposed Technical Specification is anticipated to take three years, and completion of the final document in autumn 2014.

7. References

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[11] ISO/TC 215/WG 6. ISO/DIS 11238 Health Informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances.

[12] ISO/TC 215/WG 6. ISO/DIS 11239 Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging.

[13] ISO/TC 215/WG 6. ISO/DIS 11240 Health informatics - Identification of medicinal products - Data elements and structures for unique identification and exchange of units of measurement.

[14] ISO/TC 215/WG 6. ISO/DIS 11615 Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated medicinal product information.

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Episode (as an example)

Herbal medicaments made of single natural material can be used as medicaments. For example, ANGELICAE RADIX. The name of it in East Asia spells 當歸 (or 当帰, 当归) in ideographical characters. Those name means "You should come back to me immediately".

In ancient days, a lady suffered from women's symptoms in the change of life, and her husband went away. When she tried ANGELICAE RADIX, she was quickly getting better. Then she sent a letter to her husband, "I have recovered from my illness, so please come back to me right now. You would be happy again with me, with kiss and smile, lots of love."