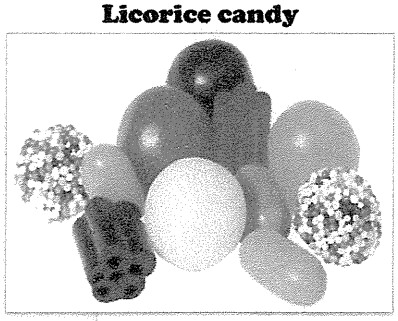
Polysemy

- Because of historical and vernacular reasons, single specific name frequently designates different natural materials or medicament formulas.
- Such situation often causes confusion in international trading and serious health hazards occur in consequence.
- These problems should be resolved by standardization of the relations between terms and concepts by the standardization of terminological resources.

Licorice candy

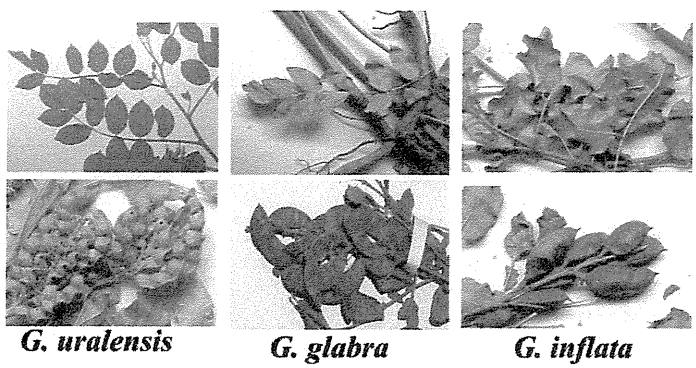


Three kind of *Glycyrhiza spp.*

~~Leaves~~

~~Seeds~~

Root



G. uralensis *G. glabra* *G. inflata*

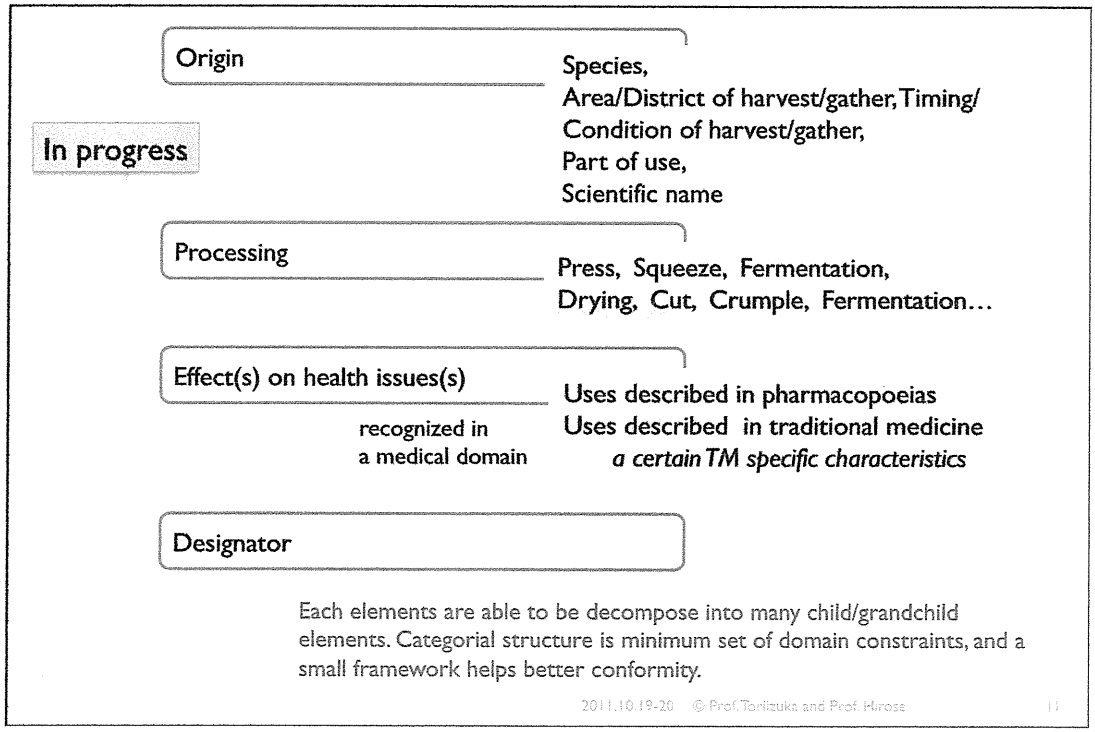
Core structure

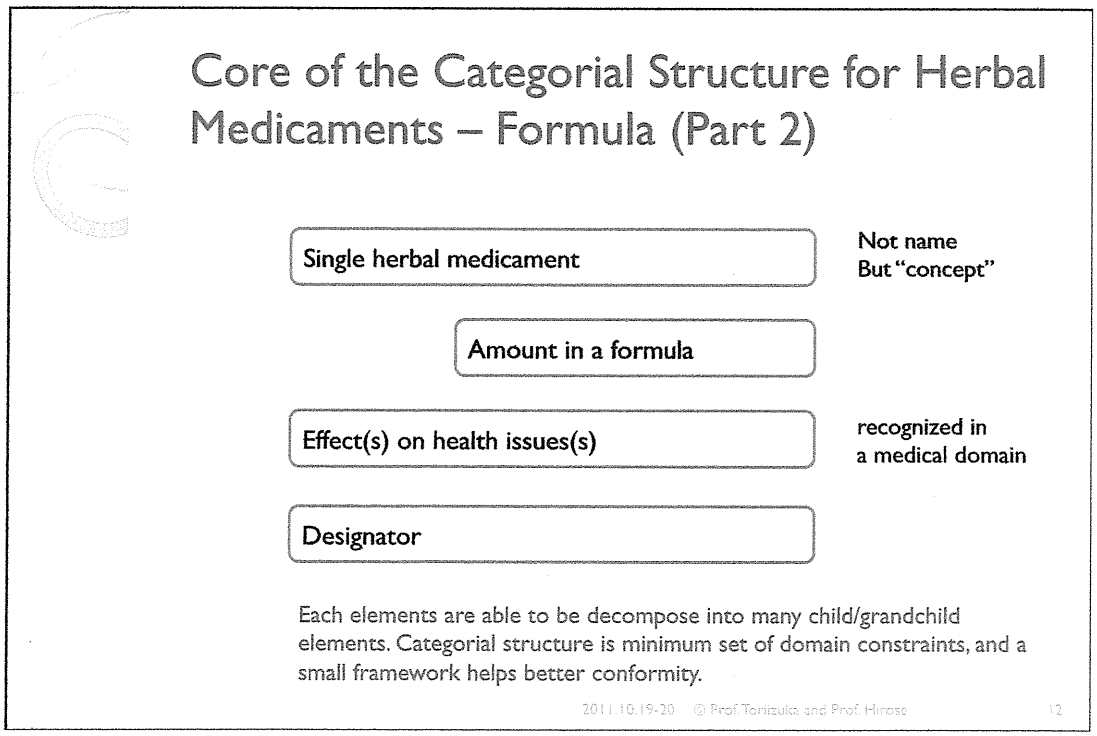
Core of the Categorial Structure for Herbal Medicaments - Single herb (Part 1)

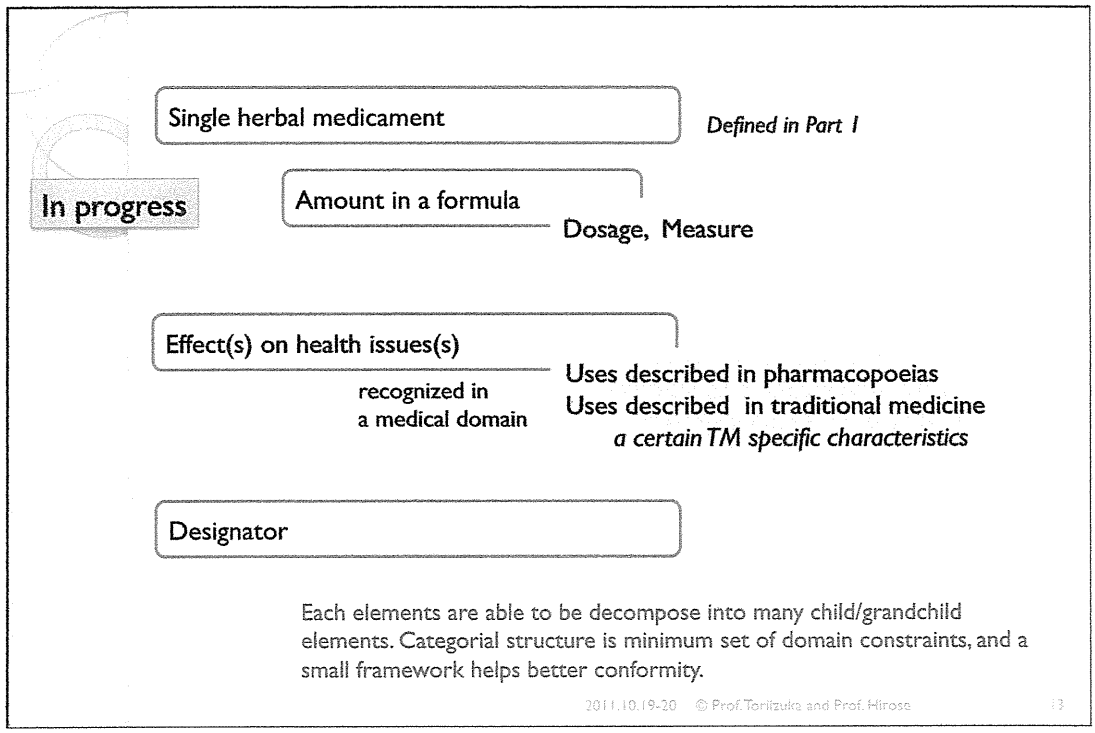
- Origin (part/whole of source material)
- Processing (w/wo supplement)
- Effect(s) on health issues(s)
- Designator

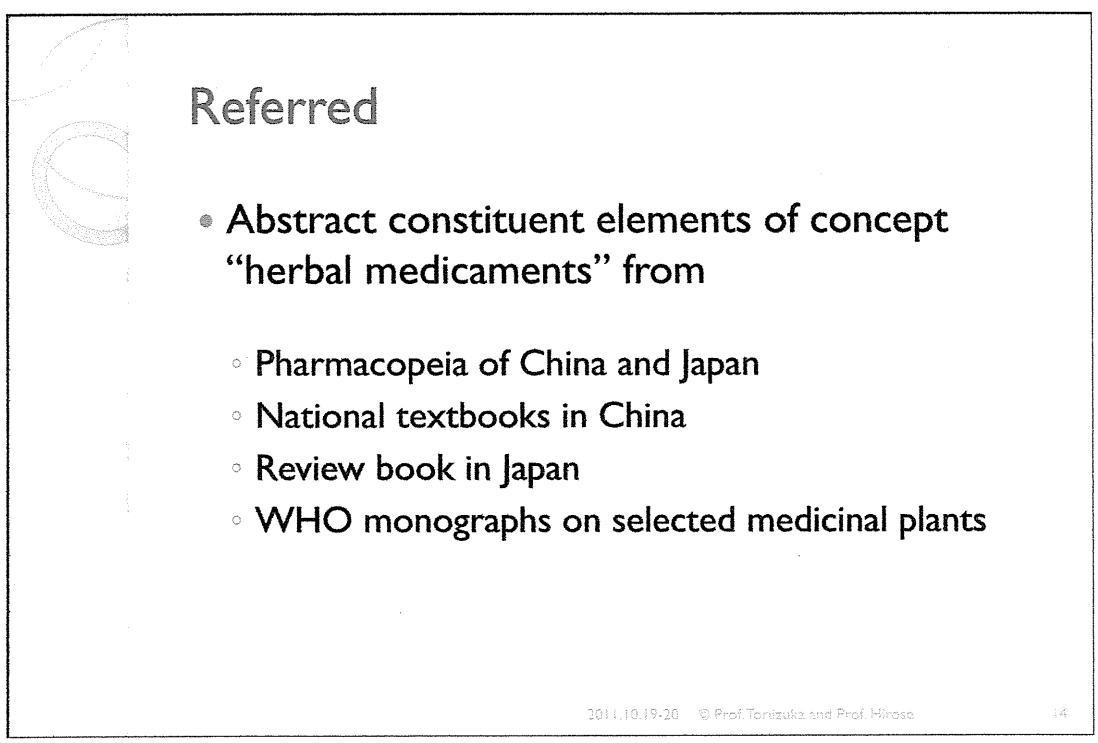
recognized in a medical domain

Each elements are able to be decompose into many child/grandchild elements. Categorial structure is minimum set of domain constraints, and a small framework helps better conformity.


Origin
Species,
Area/District of harvest/gather, Timing/
Condition of harvest/gather,
Part of use,
Scientific name
In progress
Processing
Press, Squeeze, Fermentation,
Drying, Cut, Crumple, Fermentation…
Effect(s) on health issues(s)
Uses described in pharmacopoeias
Uses described in traditional medicine
recognized in
a medical domain
a certain TM specific characteristics
Designator
Each elements are able to be decompose into many child/grandchild elements. Categorial structure is minimum set of domain constraints, and a small framework helps better conformity.
2011.10.19-20 © Prof. Toriizuka and Prof. Hirose 11


Core of the Categorial Structure for Herbal Medicaments – Formula (Part 2)
Single herbal medicament
Not name
But "concept"
Amount in a formula
Effect(s) on health issues(s)
recognized in
a medical domain
Designator
Each elements are able to be decompose into many child/grandchild elements. Categorial structure is minimum set of domain constraints, and a small framework helps better conformity.
2011.10.19-20 © Prof. Toriizuka and Prof. Hirose 12


Single herbal medicament
Defined in Part I
In progress
Amount in a formula
Dosage, Measure
Effect(s) on health issues(s)
recognized in
a medical domain
Uses described in pharmacopoeias
Uses described in traditional medicine
a certain TM specific characteristics
Designator
Each elements are able to be decompose into many child/grandchild elements. Categorial structure is minimum set of domain constraints, and a small framework helps better conformity.
2011.10.19-20 © Prof.Toriizuka and Prof.Hirose 13


Referred
Abstract constituent elements of concept "herbal medicaments" from
Pharmacopeia of China and Japan
National textbooks in China
Review book in Japan
WHO monographs on selected medicinal plants
2011.10.19-20 © Prof.Toriizuka and Prof.Hirose 14

Title and Scope

Title

Part 1
- Health Informatics: Categorial structures for representation of herbal medicaments - Part 1: Single natural material

Part 2
- Health Informatics: Categorial structures for representation of herbal medicaments - Part 2: Formula of single natural materials

Scope

Part 1

- To specify categorial structures in the subject field of the herbal medicaments of single natural material, by defining a set of constraints for use within terminological resources

Part 2

- To specify categorial structures of the formula with single natural materials in the subject field of the herbal medicaments, by defining a set of constraints for use within terminological resources.

Out of scope #1

- define any information models for drug products from herbal materials and/or the combinations of herbal materials and modern drugs

- define any process models of drug product manufacturing and specifications of each ingredient captured in modern western medicine either, although they may be referred as values if needed.

Out of scope #2

- define any models or frameworks for quality control of (i) cultivation of natural materials and (ii) drug products from herbal materials and/or the combinations of herbal materials and modern drugs

The potential uses of this categorial structure are to: #1

- support developers of new terminology systems concerning herbal medicaments;
- support developers of new detailed content areas of existing terminology systems concerning herbal medicaments to ensure conformance;
- facilitate the representation of herbal medicaments using a standard core model in a manner suitable for computer processing;
- provide the monitoring system for adverse events and adverse reactions;
- provide the characterization of clinical research intervention of herbal medicaments;

The potential uses of this categorial structure are to: #2

- permit physicians to compare herbal formulations with prescriptions on the component(s) which perform(s) same effect and exclude failures in dosages or incompatibilities;
- promote smooth exchange of the information and prevent patients from adverse reactions and risks affected by the toxicity of herbal medicaments;
- provide the characterization of clinical research intervention of herbal medicaments.
- clarify the polysemy across different clinical specialties and the one sometimes subsisted in themselves internally.

No confliction /w IDMPs in WG6

- IDMPs:
  - Identification of drug products
  - Information models for the identifiers of drug products
- Herbal Medicaments
  - Identification of concepts of herbal medicaments
  - Categorial structures for use within terminological resources
  - Support IDMPs

N0934_Categorial structures _representation herbal medicants

ISO/TC 215 Secretariat: **ANSI (USA)**

Vote begins on: **2011-12-20** Vote terminates on: **2012-03-20**

ISO/TC 215

Health informatics

Informatique de santé

NP Ballot : N0934_Categorial structures _representation herbal medicants

N0934_Categorial structures for representation of herbal medicants in terminological systems

Source	
Project	
Medium	Electronic ballot on ISOTC
Note	Categorial structures for representation of herbal medicants in terminological systems - Chicago 2011 Resolution #9 for TC215 WG3.

Summary of questions:	
We agree that a globally relevant International Standard on this subject is feasible and therefore agree to the addition of the proposed new work item to the program of work of the committee	Yes No * Abstention / No interest
Action we agree on (when answered Yes to the first question)	Addition as a preliminary project (stage 0) Advance for further development of a WD within a WG (stage 20) Accept the draft document as a WD for further development within a WG (stage 20) Circulation of the draft document as a Committee Draft (CD) Circulation of the draft document as a DIS No answer (we did not answer Yes to the

	first question)
Standard(s), regulation(s), and other relevant documentation existing in our country, with any remarks concerning their application if necessary and consequences for global relevance, as well as copyright information on these documents, are attached	Yes (references provided below) * No
Do you wish to add any additional comments?	Yes * No
We are committed to participate actively in the development of the project, at least by commenting on working drafts	Yes (and we nominate an expert below) * No
	(*) A Comment is required for this answer value

NEW WORK ITEM PROPOSAL	
Date of presentation 20 December 2011	Reference number (to be given by the Secretariat)
Proposer Kazuo TORIIZUKA	ISO/TC 215 / SC **N** 934
Secretariat ANSI	

A proposal for a new work item within the scope of an existing committee shall be submitted to the secretariat of that committee with a copy to the Central Secretariat and, in the case of a subcommittee, a copy to the secretariat of the parent technical committee. Proposals not within the scope of an existing committee shall be submitted to the secretariat of the ISO Technical Management Board.

The proposer of a new work item may be a member body of ISO, the secretariat itself, another technical committee or subcommittee, or organization in liaison, the Technical Management Board or one of the advisory groups, or the Secretary-General.

The proposal will be circulated to the P-members of the technical committee or subcommittee for voting, and to the O-members for information.

See overleaf for guidance on when to use this form.

IMPORTANT NOTE: Proposals without adequate justification risk rejection or referral to originator.
Guidelines for proposing and justifying a new work item are given overleaf.

Proposal (to be completed by the proposer)

Title of proposal (in the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

English title: **Health Informatics: Categorial structures for representation of herbal medicaments in terminological systems**

French title (if available): **to be supplied**

Scope of proposed project

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.

This work will not include content of herbal medicament concept representation that would represent concepts of herbal medicaments, but it specifies the structural model in which such content can be developed and maintained with consistency and interoperability.

Out of scope:

This Technical Specification does not focus on chemical and physical characteristics of ingredients, although they may be referred to. N.B. Ingredients are not always active substances, but are considered as chemical markers.

This Technical Specification does not define (1) any information models for drug products from herbal medicament(s), and (2) the combinations of modern drug(s) and herbal medicament(s) or natural material(s). It also does not define (3) any process models of drug production or manufacturing, and (4) any models or frameworks for quality control of (i) cultivation of natural materials, and (ii) drug products from herbal medicaments, natural materials, or the combinations of modern drug(s) and herbal medicament(s) or natural material(s).

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 single herbal medicaments with or without adjuvant material(s).

Concerns known patented items (see ISO/IEC Directives Part 1 for important guidance)

☐ Yes ☒ No If "Yes", provide full information as annex

Envisaged publication type (indicate one of the following, if possible)

☐ International Standard ☒ Technical Specification ☐ Publicly Available Specification ☐ Technical Report

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)
Yasuyuki HIROSE Medical Informatics, University of the Ryukyus 207 Uehara, Nishihara, Okinawa 903-0215, JAPAN E-mail: hirose@m.hosp.u-ryukyu.ac.jp Vox: +81(98)895-1343 Fax: +81(98)895-1475	Kazuo TORIIZUKA School of Pharmacy, Showa University 1-5-8, Hatanodai, Shinagawa-ku, Tokyo 142-8555, JAPAN E-mail: k-tori@pharm.showa-u.ac.jp Vox: +81(3)3784-8189 Fax: +81(3)3784-8191

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