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.

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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."

Result of voting

Ballot Information

Ballot reference	N0934_Categorial structures _representation herbal medicants
Ballot type	NP
Ballot title	N0934_Categorial structures for representation of herbal medicants in terminological systems
Opening date	2011-12-20
Closing date	2012-03-20
Note	Categorial structures for representation of herbal medicants in terminological systems - Chicago 2011 Resolution #9 for TC215 WG3.

Member responses:

Votes cast (26)	Armenia (SARM) Australia (SA) Austria (ASI) Belgium (NBN) Brazil (ABNT) Canada (SCC) China (SAC) Czech Republic (UNMZ) Denmark (DS) Finland (SFS) Germany (DIN) India (BIS) Ireland (NSAI) Japan (JISC) Korea, Republic of (KATS) Malaysia (DSM) Netherlands (NEN) Norway (SN) Philippines (BPS) Singapore (SPRING SG) Spain (AENOR) Sweden (SIS) Switzerland (SNV) Turkey (TSE) United Kingdom (BSI) USA (ANSI)
Comments submitted (1)	France (AFNOR)
Votes not cast (6)	Italy (UNI) Kenya (KEBS) Luxembourg (ILNAS) Mexico (DGN) Russian Federation (GOST R) Tunisia (INNORPI)

Questions:	
Q.1	"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"
Q.2	"Action we agree on (when answered Yes to the first question)"
Q.3	"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"
Q.4	"Do you wish to add any additional comments?"
Q.5	"We are committed to participate actively in the development of the project, at least by commenting on working drafts"

Votes by members	Q.1	Q.2	Q.3	Q.4	Q.5
Armenia (SARM)	Yes	Advance for further development of a WD within a WG (stage 20)	No	No	No
Australia (SA)	Yes	Accept the draft document as a WD for further development within a WG (stage 20)	No	Yes	No
Austria (ASI)	Yes	Accept the draft document as a WD for further development within a WG (stage 20)	No	No	No
Belgium (NBN)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No
Brazil (ABNT)	Yes	Addition as a preliminary project (stage 0)	No	No	No
Canada (SCC)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No
China (SAC)	No	Addition as a preliminary project (stage 0)	No	No	Yes (and we nominate an expert below)
Czech Republic (UNMZ)	Yes	Advance for further development of a WD within a WG (stage 20)	No	No	No
Denmark (DS)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	Yes	No
Finland (SFS)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No
Germany (DIN)	Yes	Advance for further development of a WD within a WG (stage 20)	No	Yes	Yes (and we nominate an expert below)
India (BIS)	No	No answer (we did not answer Yes to the first question)	No	Yes	No
Ireland (NSAI)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No

Japan (JISC)	Yes	Advance for further development of a WD within a WG (stage 20)	No	No	Yes (and we nominate an expert below)
Korea, Republic of (KATS)	Yes	Advance for further development of a WD within a WG (stage 20)	No	No	No
Malaysia (DSM)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No
Netherlands (NEN)	Yes	Circulation of the draft document as a DIS	No	Yes	Yes (and we nominate an expert below)
Norway (SN)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No
Philippines (BPS)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No
Singapore (SPRING SG)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No
Spain (AENOR)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No
Sweden (SIS)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No
Switzerland (SNV)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No
Turkey (TSE)	Yes	Addition as a preliminary project (stage 0)	No	No	No
United Kingdom (BSI)	Yes	Accept the draft document as a WD for further development within a WG (stage 20)	No	Yes	Yes (and we nominate an expert below)
USA (ANSI)	Abstention / No interest	No answer (we did not answer Yes to the first question)	No	No	No

Answers to Q.1: "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"

11 x	**Yes**	**Armenia (SARM)** **Australia (SA)** **Austria (ASI)** **Brazil (ABNT)** **Czech Republic (UNMZ)** **Germany (DIN)** **Japan (JISC)** **Korea, Republic of (KATS)** **Netherlands (NEN)** **Turkey (TSE)** **United Kingdom (BSI)**
2 x	**No**	**China (SAC)** **India (BIS)**

13 x	Abstention / No interest	Belgium (NBN) Canada (SCC) Denmark (DS) Finland (SFS) Ireland (NSAI) Malaysia (DSM) Norway (SN) Philippines (BPS) Singapore (SPRING SG) Spain (AENOR) Sweden (SIS) Switzerland (SNV) USA (ANSI)

Answers to Q.2: "Action we agree on (when answered Yes to the first question)"

3 x	Addition as a preliminary project (stage 0)	Brazil (ABNT) China (SAC) Turkey (TSE)
5 x	Advance for further development of a WD within a WG (stage 20)	Armenia (SARM) Czech Republic (UNMZ) Germany (DIN) Japan (JISC) Korea, Republic of (KATS)
3 x	Accept the draft document as a WD for further development within a WG (stage 20)	Australia (SA) Austria (ASI) United Kingdom (BSI)
0 x	Circulation of the draft document as a Committee Draft (CD)	
1 x	Circulation of the draft document as a DIS	Netherlands (NEN)
14 x	No answer (we did not answer Yes to the first question)	Belgium (NBN) Canada (SCC) Denmark (DS) Finland (SFS) India (BIS) Ireland (NSAI) Malaysia (DSM) Norway (SN) Philippines (BPS) Singapore (SPRING SG) Spain (AENOR) Sweden (SIS) Switzerland (SNV) USA (ANSI)

Answers to Q.3: "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"

0 x	Yes (references provided below)	
26 x	No	Armenia (SARM) Australia (SA)

		Austria (ASI) **Belgium (NBN)** **Brazil (ABNT)** **Canada (SCC)** **China (SAC)** **Czech Republic (UNMZ)** **Denmark (DS)** **Finland (SFS)** **Germany (DIN)** **India (BIS)** **Ireland (NSAI)** **Japan (JISC)** **Korea, Republic of (KATS)** **Malaysia (DSM)** **Netherlands (NEN)** **Norway (SN)** **Philippines (BPS)** **Singapore (SPRING SG)** **Spain (AENOR)** **Sweden (SIS)** **Switzerland (SNV)** **Turkey (TSE)** **United Kingdom (BSI)** **USA (ANSI)**

Answers to Q.4: "Do you wish to add any additional comments?"		
6 x	**Yes**	**Australia (SA)** **Denmark (DS)** **Germany (DIN)** **India (BIS)** **Netherlands (NEN)** **United Kingdom (BSI)**
20 x	**No**	**Armenia (SARM)** **Austria (ASI)** **Belgium (NBN)** **Brazil (ABNT)** **Canada (SCC)** **China (SAC)** **Czech Republic (UNMZ)** **Finland (SFS)** **Ireland (NSAI)** **Japan (JISC)** **Korea, Republic of (KATS)** **Malaysia (DSM)** **Norway (SN)** **Philippines (BPS)** **Singapore (SPRING SG)** **Spain (AENOR)** **Sweden (SIS)** **Switzerland (SNV)** **Turkey (TSE)** **USA (ANSI)**

Answers to Q.5: "We are committed to participate actively in the development of the project, at least by commenting on working drafts"		
5 x	**Yes (and we nominate an expert below)**	**China (SAC)** **Germany (DIN)** **Japan (JISC)** **Netherlands (NEN)** **United Kingdom (BSI)**
21 x	**No**	**Armenia (SARM)** **Australia (SA)** **Austria (ASI)** **Belgium (NBN)** **Brazil (ABNT)** **Canada (SCC)** **Czech Republic (UNMZ)** **Denmark (DS)** **Finland (SFS)** **India (BIS)** **Ireland (NSAI)** **Korea, Republic of (KATS)** **Malaysia (DSM)** **Norway (SN)** **Philippines (BPS)** **Singapore (SPRING SG)** **Spain (AENOR)** **Sweden (SIS)** **Switzerland (SNV)** **Turkey (TSE)** **USA (ANSI)**

Comments from Voters		
Member:	Comment:	Date:
Australia (SA)	***Comment File***	2012-03-08 01:39:12
CommentFiles/N0934_Categorial_structures__representation_herbal_medicants_SA.doc		
China (SAC)	***Comment***	2012-03-20 07:47:52
Professor Cui Meng		
China (SAC)	***Comment File***	2012-03-20 07:47:52
CommentFiles/N0934_Categorial_structures__representation_herbal_medicants_SAC.doc		
Denmark (DS)	***Comment***	2012-03-21 08:46:24
"If this new work item is adopted, we think that it is important that any resulting discoveries related to categorical structures necessary for the identification (not the use) of the simple herbal medicaments be also used to amend any shortcomings in that area of the IDMP standard "ISO/FDIS 11238 Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances".		
Germany (DIN)	***Comment***	2012-03-16 14:03:20
Dr. Christine Haas, Deutsches Institut für Medizinische Dokumentation und Information (DIMDI), Waisenhausgasse 36-38a, 50676 Köln, Germany, phone: +49 221 4724359, e-mail:		

christine.haas@dimdi.de		
Germany (DIN)	***Comment File***	2012-03-16 14:03:20
CommentFiles/N0934_Categorial_structures__representation_herbal_medicants_DIN.doc		
India (BIS)	***Comment File***	2012-03-21 06:16:37
CommentFiles/N0934_Categorial_structures__representation_herbal_medicants_BIS.doc		
Japan (JISC)	***Comment***	2012-03-19 06:44:17
Shinya Oku Hiromichi Yasui		
Netherlands (NEN)	***Comment***	2012-03-20 13:47:25
The expert for the Netherlands is mr Kris Oosting, kris.oosting@dfsxpertsys.com.		
Netherlands (NEN)	***Comment File***	2012-03-20 13:47:25
CommentFiles/N0934_Categorial_structures__representation_herbal_medicants_NEN.doc		
United Kingdom (BSI)	***Comment***	2012-03-01 12:02:39
UK Expert - Dr Nicohlas Hardiker Email - N.R.Hardiker@salford .ac.uk		
United Kingdom (BSI)	***Comment File***	2012-03-01 12:02:39
CommentFiles/N0934_Categorial_structures__representation_herbal_medicants_BSI.doc		

Comments from Commenters		
Member:	Comment:	Date:
France (AFNOR)	***Comment File***	2012-01-02 13:49:45
CommentFiles/N0934_Categorial_structures__representation_herbal_medicants_AFNOR.doc		

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted
DE			ge	Should be prepared under Vienna Agreement under ISO-Lead		
Fr				ABSTENTION		
GB			ge	The proposal targets a TS (Technical Specification). This looks unusual given the (necessarily) normative nature of categorial structure to be developed. (to which products can or can't claim conformance...).	Consider targeting an IS (Information Standard) – which will require greater scrutiny during development, or indicate how coding system conformance will be tested if not an IS.	
GB			ge	Herbal medicines are hard to characterise formally (in particular, "active ingredients" are sometimes hard to identify) so whilst this endeavour will be welcome (in order to help define what is and isn't a herbal medicine) its development may well be complicated by this fundamental issue.	It will be important not to underestimate the need for a clear editorial policy. In particular, clear intensional definitions and boundaries will be needed for the participating semantic categories, in order to specify those entities which can be regarded as 'active ingredients'.	
NL			GE	In several European countries the pinyin name is often used to distinguish the medicinal substances. For example, TCM education in the Netherlands uses pinyin names to teach Chinese medicinal substances. Pharmaceutical names are secondary.		
AU	Proposal	Title on Page 1 (but also applicable to whole document)	ge	The English title has herbal in it but the scope also includes non-herbal medicaments such as animal products and minerals.	Consider replacing 'herbal' with 'traditional'. (cf. ISO/TC 249, ISO & http://www.who.int/topics/traditional_medicine/en/)	
AU	Proposal	Scope on Page 1	ge	The definition of proposal [B] is unclear: *"[B] herbal medicaments that are made with the herbal medicaments made of single natural material"* Does it mean – 1. [B] is a multi-ingredient consisting of a number of [A]?	Clarification requested – 1. Suggest the description be rephrased to avoid ambiguity in the definition. e.g. "[B] is a multi-ingredient medicament that is formulated with [A]" 2. Use cases or examples would be very	

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/ Note** (e.g. Table 1)	**Type of comment**[2]	Comment (justification for change) by the MB	Proposed change by the MB	**Secretariat observations** on each comment submitted
				OR 2. [B] is a modification of [A] only?	helpful here. (All comments related to proposal [B] below assume that [B] is a multi-ingredient consisting of a number of [A])	
AU	Reference	[44]	ed	中华人民共和国 药典 2010年版 一部（中药） The Chinese Pharmacopoeia 2005 edition. 2010. The year of publication should be 2010, as shown below. 中华人民共和国 药典 2010年版 一部（中药） The Chinese Pharmacopoeia 2010 edition. 2010.	Update the edition.	
DE	Title		ed	It should read "medicinal product" instead of "medicants"		
AU	Whole document		ge	The technical Specification include animal products and minerals but the terms used in 5.3 and 5.4 use "herbal" only. e.g. "[A]: Name of herbal medicament..."	Consider using a more inclusive term, e.g. traditional, instead of herbal. e.g. "[A]: Name of traditional medicament..." (cf. ISO/TC 249 & http://www.who.int/topics/traditional_medicine/en/)	
AU	Whole document		ed	Spelling errors – e.g 2.3.1 drAg should be drUg Grammatical errors - e.g. 5.4 "In order to conformity, ..."	Grammar and spell checks are strongly recommended	
AU	1.3	Example A)	ed	Spelling error/difference(?) cRUcuma is a spelling error or may be a form of Japanese dialect. cURcuma is more widely accepted.	Suggest using: "CURCUMA related term or name..." "CURCUMAE RHIZOMA..."	
AU	1.3	Example C)	ge	The difference in the number of ingredients may be due to factors other than location alone. (i.e. Not all Wen Jing Tang from China have 11 ingredients) The majority of online sources from China list all 12 ingredients as shown below: (e.g. http://jpkc.bucm.edu.cn/fangjixue/16/ss_b31.htm). China Japan	Consider reviewing the reference to manufacturing origin in the example In addition, as a side issue, the scope for proposal [B] requires further clarification: 1. Is Wen Jing Tang concept for the original 12-ingredient formula only? (if true, there	