



Profile of
Definition, Terminology,
and Technical Requirement of
Traditional Medicines and Health Supplements
among ASEAN Member Countries

Compiled by :
Indonesia

**THE ASEAN CONSULTATIVE COMMITTEE FOR
STANDARDS AND QUALITY (ACCSQ)
PRODUCT WORKING GROUP ON TRADITIONAL
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FOREWORD

In an effort to harmonize regulation of traditional medicines and health supplements in ASEAN, Indonesia was appointed to lead a survey on definitions, terminologies and technical requirements of traditional medicines and health supplements currently used by ASEAN member countries. Information was gathered through the circulation of a questionnaire that allowed exchange of information between ASEAN member countries followed by a compilation of the completed questionnaire according to a certain order.

It is understood that not all member countries have a legal definition of traditional medicines and health supplements, but alternative approach such as a common definition which includes scope of definition that addresses areas on safety, quality and efficacy, and what could and could not be included is utilized in a comparative study to a benchmarked regulation. The compiled information then was analyzed and expanded into a Profile of Definitions, Terminologies, and Technical Requirements of Traditional Medicines and Health Supplements among ASEAN Member Countries.

After some changing and correction, Indonesia has finally completed the **Profile of Definitions, Terminologies, and Technical Requirements of Traditional Medicines and Health Supplements among ASEAN Member Countries.**

The Profile includes both comparative matrix of definitions and terminologies of traditional medicines and health supplements, followed by detail information regarding technical requirement available to every member countries regulation. The information for the available technical requirement is arranged for easy reading.

Therein, we wish to thank those who participated in the exchange of information and our special appreciation to all ASEAN member countries for their great contribution to the profile.

1. INTRODUCTION

During the last decade, the use of traditional medicines and health supplements has expanded globally and has gained popularity. It has not only been used for primary health care in developing countries, but also in countries where conventional medicines is predominant in their national health care system.

With the tremendous expansion in the use of traditional medicines and health supplements, safety and efficacy as well as quality control of traditional medicines and health supplements have become important concern for both health authorities and the community.

Because of the global trend on the use of traditional medicines and health supplements, cooperation amongst regulatory authorities is needed to ensure the safety and quality of the products for consumers, while on the other hand, appropriate measures to facilitate market access for these products in ASEAN also need to be addressed.

In an effort to harmonize the regulation of traditional medicines and health supplements in ASEAN especially in applying technical requirements for product placement purposes, member countries should come up with a common understanding on the definitions of traditional medicines and health supplements.

In order to obtain a set of common terminologies and definitions of traditional medicines and health supplements accepted by all ASEAN member countries, to identify regulation profiles of traditional medicines and health supplement in ASEAN member countries, and to harmonize specific areas of technical requirements, Indonesia has distributed a questionnaires to all ASEAN member countries in February 2005. The objective of this survey was to promote exchange of information with regards to existing terminologies, definitions and technical requirements among ASEAN member countries.

The Questionnaires covered :

- Terminologies
- Definition
- Product Placement
- Technical Requirement for product placement
 - Administrative aspects
 - Technical aspects
- Pre Marketing Evaluation
 - Quality evaluation
 - Safety evaluation
 - Efficacy evaluation
 - Claims
 - Labeling information
 - Advertisement
- Post Marketing Control

2. COMPILATION OF THE QUESTIONNAIRES

All the ASEAN member countries (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam), has responded and completed the questionnaire.

Information to obtain one common terminology of traditional medicines and health supplements, and possible technical requirements needed has been compiled and analyzed from the distributed questionnaire.

1. Terminologies

a. Traditional Medicines

Comments :

- ❖ Nine members (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Singapore, Thailand, and Vietnam) use the terminology of “Traditional medicines”
- ❖ One member (Philippines) uses the terminology of “Herbal medicines” or “Traditionally-Used Herbal Products”.

b. Health Supplement

Comments :

- ❖ Health supplements is used by 4 countries (Brunei Darussalam, Cambodia, Malaysia and Singapore) whereas “Food Supplements” is used by 3 countries (Indonesia, Philippines, Vietnam). The terminology “Dietary Supplements” is used by 3 countries (Myanmar, Philippines, Thailand)

COMPARATIVE MATRIX : TERMINOLOGY OF TRADITIONAL MEDICINES AND HEALTH SUPPLEMENT

A. TRADITIONAL MEDICINES

Country Terminology	Brunei Darus salam	Cambo dia	Indonesia	Lao PDR	Malaysia	Myanmar	Philippines	Singapore	Thailand	Vietnam
<i>TRADITIONAL MEDICINE</i>										
Traditional Medicine	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes
Complementary Medicine										
Herbal Medicine							Yes			
Natural Medicine										
Natural Product										
Botanical Product										
Others							Traditionally- used Herbal Products	Chinese Proprietary Medicines (CPM)		

B. HEALTH SUPPLEMENTS

Country Terminology	Brunei Darus salam	Cambo dia	Indonesia	Lao PDR	Malaysia	Myanmar	Philippines	Singapore	Thailand	Vietnam
<i>HEALTH SUPPLEMENT</i>										
Food Supplement			Yes	-			Yes			Yes
Health Supplement	Yes	Yes			Yes			Yes		
Complementary Medicine										
Dietary Supplement						Yes	Yes		Yes	
Nutritional Supplement										
Others	Border line food/ drug									

2. Definition

1. BRUNEI DARUSSALAM

Traditional Medicines

Any product used in the practice of indigenous medicine, in which the drug consist solely of one or more naturally occurring substances of a plant, animal or mineral, or parts thereof, in the un-extracted or crude extract form, and a homeopathic medicine.

“Indigenous medicine” means a system of treatment and prevention of disease established through traditional use of naturally occurring substances. “Homeopathic medicine” means any pharmaceutical dosage form used in the homeopathic therapeutic system in which diseases are treated by the use of minute amounts of such substances which are capable of producing in healthy persons symptoms similar to those of the disease being treated.

Health Supplement

A product that is used to supplement a diet, with benefits beyond those of normal nutrients, and/or to support or maintain the healthy functions of the human body. Health supplements contain one or more, or a combination of the following ingredients :

- a). vitamins, minerals, amino acids (natural and synthetic);
- b). substances derived from natural sources, including animal and botanical material in the form of extract, isolates, concentrates; and are presented in any of the following dosage forms to be administered in small unit doses such as capsules, tablets, soft gel, liquid forms, and any other dosage forms as may be approved by the regulatory authority.

Health supplements shall be taken not to include any of the following :

- a). any product for use as a conventional food or as the sole item of a meal or diet;
- b). any product that is defined otherwise in the legislation; and
- c). any injectable and sterile preparations.

2. CAMBODIA

Traditional Medicines

A traditional medicine is one or many kinds of drug substances which are primarily from herbals, plants, animals or minerals in order to use in the prevention or treatment human or animal diseases.

Health Supplement

Health Supplement are the product which have been derived from plants, animals, with a physiological effect alone or in combination with vitamins, protein, enzymes, extract from organ, minerals.

Health supplement can also be marketed in various forms such as tablets, capsules, soft capsules, pastilles, ampoules of liquid, powder, drops dispensing bottle and other forms designated to be taken in measured small unit quantities.

Health supplement means products the purpose of which are :

- a). to improve and maintain healthy condition,
- b). to supplement the normal diet
- c). to use for patient under dietary regime such as obesity, diabetic patients, hypertension, slimming, etc.

3. INDONESIA

Traditional Medicines

Substance or mixture of substances forming from herbals, plants, animal parts and /or mineral raw materials, galenic preparation that has long historical used (it is the sum total of the knowledge, skills and practices based on the theories, believes and experiences indigenous to different cultures) empirically being used for maintenance of health as well as in the treatment use.

Health Supplement

Product which is purposed to supplement the normal diet and which are concentrated sources of one or more of vitamins, minerals, amino acids or other substances (plant/animal origin, herbal, enzymes, metabolites, extracts) with a nutritional or physiological effect.

4. LAO PDR

Traditional Medicines

Traditional medicine is a drug derived from plants, trees, minerals, or animals which is prepared, packaged and labeled and characteristics and active affect of which are not scientifically proved but shall be approved by Ministry of Health. The Health sector must organize a survey and establish a list of trees, plant, minerals and animals, which are traditional medicine in order to manage them

Health Supplement

Products intended to supplement the normal diet for improving health, whose ingredients consist of one or more vitamins, minerals, amino acids or other substances eg: plant, herbal, animal origin, enzymes, metabolites, and extracts, with a nutritional or physiological effect (drafted)

5. MALAYSIA

Traditional Medicines

Means any product used in the practice of indigenous medicine in which the drug consist solely of one or more naturally occurring substances or a plant, animal or mineral or parts there of in the un-extracted or crude extract form and a homeopathic medicine.

Health Supplement

Products intended to supplement the diet taken orally in forms such as pills, capsule, tablets, liquid or powders and not represented as conventional food / sole item of a diet or meal. May include ingredient such as vitamins, minerals, amino acids, natural substances of a plant/animal origin, enzymes, and substances with nutritional/physiological function.

6. MYANMAR

Traditional Medicines

Medicine for the physical well-being and longevity of people in accordance with anyone of the four nayas of traditional medicine, namely Desana naya, Bethitsa naya, Netkhata Veda naya and Vissadara naya.

Health Supplement : -

7. PHILIPPINES

Traditional Medicines

Herbal Medicines are finished, labeled medicinal products that contain as active ingredient(s) aerial or underground part(s) of plants or any other plant material, or combination there of, whether in the crude state or as plant preparations. Herbal medicines may contain excipients in addition to the active ingredient(s). Additionally, such medicinal plant products shall have specific therapeutic claim(s) and shall be intended for use in the diagnosis, alleviation, cure or treatment of disease, promotion of health or intended to affect or modify the structure or any function of the body of humans or animals. Drug preparations containing plant material(s) combined with therapeutically active substances, including chemically defined isolated constituents of plants used in conventional/western medicines are not considered to be herbal medicines.

Traditionally-Used Herbal Products

Refer to preparations from plant materials whose claimed application/s is/are based only on traditional experience of long usage which should be at least five (5) or more decades as documented in medical, historical and ethnological literature.

Health Supplement

Refer to those used for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral or other dietary property

8. SINGAPORE

Traditional Medicines

“Traditional medicine” means any medicinal product consisting of one or more substances derived from natural sources, that is to say, plants, animals or minerals or a combination of any one or more of them, but shall not include –(a) any medicinal product to be injected into the human body;(b) any vaccine to be used by human beings;(c) any product derived from human blood;(d) any item specified in the Poisons List in the Schedule to the Poisons Act; and(e) any Chinese proprietary medicine.

Chinese Proprietary Medicines

“Chinese proprietary medicine” means any medicinal product used in the system of therapeutics according to the traditional Chinese method, that is to say, any medicinal product which has been manufactured into a finished product and contains one or more active substances, all of which are derived wholly from plants, animals or minerals or a combination of any one or more of them, and the

medicinal product or all of its active substances are described in the current edition of (i) A dictionary of Chinese pharmacy, (ii) The Chinese Herbal Medicine Materia Medica or such other publication as may be approved by the Minister, but shall not include –(i) any medicinal product to be injected into the human body;(ii) any items specified in the Poisons List in the Schedule to the Poisons Act (Cap. 234) or(iii) any medicinal product which contains as an active substance any chemically defined isolated constituent of plants, animals or minerals or a combination of any one or more of them;

"current edition", in relation to any publication, means an edition which is current at the time the Chinese proprietary medicine in question is sold or supplied, and includes any amendment, addition or deletion made to it up to that time.

Health Supplement

refers to a product that has the following purpose, ingredients and dosage forms:

Purpose

A product that is used (i) to supplement a diet, with benefits beyond those of normal nutrients, and / or (ii) to support or maintain the healthy functions of the human body, and

Ingredients

contain one or more, or a combination of the following:

- a. Vitamins, minerals, amino acids (natural and synthetic)
- b. Substances derived from natural sources, including non-human animal and botanical materials in the forms of extracts, isolates, concentrates; and

Presentation

is presented in any of the following dosage forms to be administered in small unit doses: capsules, softgels, tablets, liquids, syrups, etc

9. THAILAND

Traditional Medicines

Traditional medicines is drug intended for using in the practice of traditional medicines or the cure of an animal disease which appears in a pharmacopoeia of traditional medicines notified by the minister, or a drug notified by the minister as a traditional drug or a drug of which formula has been registered as that a traditional drug.

Health Supplement

Dietary Supplement means a product that is intended to be consumed in addition to the normal food intake. It contains “nutrients or other ingredients” presented in a variety forms such as tablet, capsule, powder, liquid, or other form, differing from conventional food from which consumers anticipate health benefits.

“Nutrients or other ingredients” are defined as

- 1.) Vitamins, amino acids, fatty acids, minerals, and products derived from plants or animals
- 2.) Concentrates, metabolites, constituents, or extracts of any ingredients in 1.)
- 3.) Synthetic substances replicating any substances as in 1.) or 2.)
- 4.) Any combinations of substances in 1.) 2.) or 3.)
- 5.) Any other ingredients on the list prescribed by Thai Food and Drug Administration and approved by the Food Committee.

10. VIETNAM

Traditional Medicines

Traditional medicine is medicine prepared directly from plants/animal parts/natural minerals in different dosage forms. They may contain one or several natural pharmacological substances in the natural form or powdered/extracted form (contain a group of purified, active chemicals extracted from natural pharmacological materials) prepared either by traditional or modern techniques.

Addition : Drug preparations containing plant, material (s) combined with therapeutically active substances including chemically defined isolated constituents of plants used in western medicines are not considered to be Traditional Medicine.

Health Supplement

Food used as nutrition to enhance human body's functions enabling body to relax, improving the immunity and minimizing disease prevalence.

To set up : Table of strength of vitamins to decide drug or Health Supplement or drug interface

Excerpted information on Definition :

After compilation and analysis of all definitions of traditional medicines and health supplement, three similar keywords were found in almost all responded questionnaire, and that is ingredients, intended use/purpose, how to prove/dosage form and other information, as follows :

Traditional medicines

1. Ingredients	: herbs/plants	: 10 countries used herbal plants (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Myanmar, Malaysia, Philippines, Singapore, Thailand, Vietnam).
	: animal parts	: 9 countries used animal parts (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Singapore, Thailand, Vietnam)
	: mineral raw materials	: 9 countries used mineral raw material (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Singapore, Thailand, Vietnam)
2. Intended use/purpose	: Practice of indigenous medicine	: 6 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Myanmar, Thailand)
	: Maintenance of Health	: 3 countries (Indonesia, Singapore, Thailand)
	: Treatment Use	: 3 countries (Indonesia, Singapore, Thailand)
	: Pharmacological/active substances	: 2 countries (Lao PDR, Vietnam)
	: Diagnosis	: 3 countries (Philippines, Singapore, Thailand)
	: Alleviation	: 3 countries (Philippines, Singapore, Thailand)
	: Treatment of Disease	: 3 countries (Philippines, Singapore, Thailand)
	: Promotion of Health	: 3 countries (Philippines, Singapore, Thailand)
	: Affect structure or any function of the body	: 3 countries (Philippines, Singapore, Thailand)
3. How to Prove	: Empirically has long historical used	: 3 countries (Indonesia, Myanmar, Thailand)
	: Not scientifically prove but shall be approved by MOH	: 2 countries (Lao PDR, Thailand)

	: Traditional experience of long usage at least 5 decade	: 1 country (Philippines)
	: Published in the Traditional Pharmacopeia under Ministerial notification or published in the ministerial notification as Traditional Medicine or other scientific evidence	: 1 country (Thailand)
4. Other Informations	: Pharmacological / Active substances	: 3 countries (Lao PDR, Philippines, Vietnam)
	: Included Homeopathy	: 2 countries (Brunei Darussalam, Malaysia)
	: Prepared, package and labeled	: 1 country (Lao PDR)
	: Shall not include : injection, vaccine, blood product and poison list	: 1 country (Singapore)
	: Shall not include : Injection, vaccine and Human blood	: 1 country (Thailand)
	: Prepared either by traditional or modern techniques	: 2 countries (Thailand, Vietnam)

Health supplement

1. Ingredients	: Vitamin	: 9 countries (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Philippines, Singapore, Thailand, Vietnam) Note : In Vietnam, Vitamin : to set up table of strenght g vitamins (limited), to decide drug or drug interface or health supplement
	: Mineral	: 10 countries (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam).
	: Amino Acids	: 7 countries (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Singapore, Thailand) Note : Philippines use vitamin, mineral or other dietary property for Food Supplements.
	: Plants	: 9 countries (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Singapore, Thailand, Vietnam)

Note : In Vietnam, Plant : to set up table of strength vitamins (limited), to decide drug or drug interface or health supplement

	: Animals	: 9 countries (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Singapore, Thailand, Vietnam)
	: Metabolites	: 3 countries (Indonesia, Lao PDR, Thailand)
	: Enzyme	: 5 countries (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia)
	: Extract	: 5 countries (Brunei Darussalam., Cambodia, Indonesia, Lao PDR, Malaysia, Thailand)
	: Isolated	: 4 countries (Brunei Darussalam, Indonesia, Malaysia, Thailand)
	: Concentrate	: 4 countries (Brunei Darussalam, Indonesia, Malaysia, Thailand)
2. Purpose	: To support or maintain the healthy function of human body	: 2 countries (Brunei Darussalam, Singapore)
	: To improve and maintain healthy condition	: 2 countries (Cambodia, Lao PDR)
	: To supplement the normal diet	: 5 countries (Cambodia, Indonesia, Lao PDR, Malaysia, Singapore)
	: To use for patient under dietary regimes such as obesity, diabetic patients, hypertension, slimming, etc	: 1 country (Cambodia)
	: Supplementing or fortifying the ordinary or usual diet	: 1 country (Philippines)
	: For general person who expect to improve health	: 1 country (Thailand)
	: Enhance human body's function / anticipate health benefits	: 1 country (Vietnam)

3. TECHNICAL REQUIREMENTS

Technical requirements for product placement includes :

1. Registration and Evaluation
 - a. Registration
 - b. Timeline for evaluation
 - c. Product evaluation
 - d. Data that should be evaluated for product registration

2. Pre marketing evaluation
 - a. Quality
 - b. Safety
 - c. Efficacy
 - d. Claims
 - e. Labeling
 - f. Advertisement approval

3. Post marketing control
 - a. Monitoring of labeling, packaging, advertisement
 - b. Monitoring of adverse effect
 - c. Post marketing surveillance
 - d. Sampling and laboratory test
 - e. Inspection to the manufacturer and distributor

Response on the questionnaires on technical requirements aspects for product placement is as follows and also described as table in attachment :

1. Registration and Evaluation

- a. Registration

Seven countries mentioned to register their TM HS product before marketed (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam).

Myanmar : only TM products have to be registered

Singapore : No licensing requirements for TM HS products, for Chinese Proprietary Medicines (CPM) products, the dealers (importer, wholesale dealer, local manufacturer, local repacker) must be licensed and the CPM products must be listed with Health Sciences Authority (HSA).

No information : 2 countries (Cambodia, Lao PDR)

Note : In Philippines , Traditionally-Used Herbal products is registered before Marketed too

In Vietnam, TM and Food-drug interface have to be registered

b. Timeline for evaluation

Traditional medicines

- * Not applicable : 1 country : (Brunei Darussalam)
- * 2-3 months : 2 countries : (Indonesia)
Singapore : for CPM products listing
- * 6 months : 5 countries : (Lao PDR, Malaysia, Myanmar, Thailand, Vietnam)
- * 6-12 months : 2 countries : (Cambodia, Philippines)
Note : In Philippines, applicable for Traditionally-Used Herbal Products too

Health supplement

- * Not applicable : 2 countries : (Brunei Darussalam, Singapore)
- * No information : 2 countries : (Lao PDR, Myanmar)
- * 2-3 months : 3 countries : (Indonesia, Philippines, Vietnam)
- * 6 months : 2 countries : (Malaysia, Thailand)
- * 6-12 months : 1 country : (Cambodia)

Note : In Vietnam, Food-drug interface is in 6 months

c. Evaluation

Traditional medicines

- * Not Applicable : 1 country : (Brunei Darussalam)
- * Both : 9 countries : (Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam)
Note : In Philippines, applicable for Traditionally-Used Herbal Products too
In Singapore, applicable for CPM

Health supplement

- * Not applicable : 2 countries : (Brunei Darussalam, Singapore)
- * Both : 5 countries : (Cambodia, Indonesia, Malaysia, Philippines, Thailand)
- * Pre Marketing : 1 country : (Vietnam)
- * No Information : 2 countries : (Lao PDR, Myanmar)

d. Data that should be evaluated for product registration

Administrative data

- * CFS / CPP
 1. Applicable for TM and HS :
6 countries (Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)
Note : In Philippines, applicable for Traditionally-Used Herbal Products too
 2. Applicable for TM only : 1 country (Lao PDR)
 3. Applicable for CPM : 1 country (Singapore)
 4. Not Applicable : 1 country (Brunei Darussalam)
 5. No Information : 1 country (Myanmar)

- * GMP certificate
 1. Applicable for TM and HS :
4 countries (Cambodia, Indonesia, Malaysia, Philippines)
Note : In Philippines, applicable for Traditionally-Used Herbal Products too
 2. Applicable for TM only :
4 countries (Lao PDR, Myanmar, Singapore, Vietnam)
In Singapore, manufacturer's license (or equivalent document) applicable for CPM
 3. Applicable for HS only :
1 country (Thailand)
 4. Not Applicable : 1 country (Brunei Darussalam)

- * Letter of Authorization
 1. Applicable for TM and HS :
3 countries (Indonesia, Malaysia, Philippines)
 2. Applicable for TM only :
3 countries (Lao PDR, Myanmar, Vietnam)
 3. Not Applicable :
4 countries (Brunei Darussalam, Cambodia, Singapore, Thailand)

Technical data

- * Quality
 1. Applicable for TM and HS :
6 countries (Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)
Note : In Philippines, applicable for Traditionally-Used Herbal Products too
 2. Applicable for TM only :
2 countries (Lao PDR, Myanmar)
 3. Applicable for CPM : 1 country (Singapore)
 4. Not Applicable : 1 country (Brunei Darussalam)

* Safety

1. Applicable for TM and HS :
6 countries (Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)
Note : In Philippines, applicable for Traditionally-Used Herbal Products too
2. Applicable for TM only : 1 country (Myanmar)
3. Applicable for CPM : 1 country (Singapore)
4. Not Applicable : 1 country (Brunei Darussalam)
5. No Information : 1 country (Lao PDR)

* Efficacy

1. Applicable for TM and HS :
3 countries (Cambodia, Indonesia, Thailand)
2. Applicable for TM only :
2 countries (Philippines, Vietnam)
Note : In Philippines, used Claimed Application/folkloric use for Traditionally-Used Herbal Products
3. Not Applicable :
4 countries (Brunei Darussalam, Malaysia, Myanmar, Singapore)
4. No Information :
1 country (Lao PDR)

2. Pre marketing evaluation

a. Quality

a). Applicable for TM and HS :

7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand and Vietnam)

Note : In Philippines, applicable for Traditionally-Used Herbal Products too
In Vietnam, applicable for TM and Food-drug interface

b). Applicable for TM only:

3 countries (Myanmar, Lao PDR, Singapore)

Note : In Singapore, applicable for CPM

* GMP Certificate

1. Applicable for TM and HS :

5 countries (Cambodia, Indonesia Malaysia, Philippines, Vietnam)

Note :

- In Vietnam, GMP Certificate for TM will be applied by 2010; Food-drug interface must have GMP certificate at present

- In Philippines, applicable for Traditionally-Used Herbal Products too

2. Applicable for TM only :

2 countries (Lao PDR, Singapore)

Note :

In Singapore, manufacturer's licence (or equivalent document) applicable for CPM

3. Applicable for HS only :

1 country (Thailand)

4. Not applicable :

2 countries (Brunei Darussalam, Myanmar)

* Formula

1. Applicable for TM and HS :

7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)

2. Applicable for TM only :

3 countries (Lao PDR, Myanmar, Singapore)

Note : In Singapore, applicable for CPM

* Raw material specification

1. Applicable for TM and HS :

7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)

2. Applicable for TM only :

2 countries (Lao PDR, Myanmar)

3. Not applicable: 1 country (Singapore)

- | | |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| * Manufacturing Process | <ol style="list-style-type: none"> 1. Applicable for TM and HS :
6 countries (Cambodia , Indonesia, Malaysia, Philippines, Thailand, Vietnam) 2. Applicable for TM only:
2 countries (Lao PDR, Myanmar) 3. Not applicable :
2 countries (Brunei Darussalam, Singapore) |
| * Finished product specification | <ol style="list-style-type: none"> 1. Applicable for TM and HS :
6 countries (Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam) 2. Applicable for TM only:
3 countries (Lao PDR, Myanmar, Singapore)
Note: In Singapore, applicable for CPM. Test reports of toxic heavy metals (mercury, lead, arsenic and copper) and microbe contamination must comply with legal requirements (the toxic heavy metal, cadmium may be included in the future). For high-risk products, test reports to show absence of specific types of adulterants and/or toxic substances are required. 3. Not applicable : 1 country (Brunei Darussalam) |
| * Stability study | <ol style="list-style-type: none"> 1. Applicable for TM and HS :
4 countries (Indonesia, Malaysia, Philippines, Vietnam) 2. Applicable for TM only: 1 country (Lao PDR) 3. Not applicable :
5 countries (Brunei Darussalam, Cambodia, Myanmar, Singapore, Thailand) |
| * Water content | <ol style="list-style-type: none"> 1. Applicable for TM and HS :
2 countries (Indonesia, Philippines) 2. Applicable for TM only:
1 country (Vietnam) 3. Not applicable :
7 countries (Brunei Darussalam, Cambodia, Lao PDR, Malaysia, Myanmar, Singapore, Thailand) |
| * Disintegration time test result | <ol style="list-style-type: none"> 1. Applicable for TM and HS :
5 countries (Cambodia, Indonesia, Malaysia, Philippines, Vietnam)
Note : * In Cambodia only for solid form (tablets & capsules) 2. Not applicable :
4 countries (Brunei Darussalam, Lao PDR, Myanmar, Singapore) 3. Applicable for TM only: 1 country (Thailand) |
| * Microbial conta- | <ol style="list-style-type: none"> 1. Applicable for TM and HS : |

minant test result

5 countries (Cambodia, Indonesia, Philippines, Thailand, Vietnam)

Note : in Vietnam, Identification, reaction of Thin Layer Chromatography, if appropriate, assay of group of main active ingredients, water content, contamination of microbiology, heavy metal (lead, arsen, mercury)

2. Applicable for TM only :

2 countries (Malaysia, Singapore)

Note : In Singapore, applicable for CPM

3. Not applicable :

3 countries (Brunei Darussalam, Lao PDR, Myanmar)

b. Safety

a) Applicable for TM and HS :

7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)

Note :

a. In Brunei Darussalam : Document : Product label/ insert.

b. In Malaysia : Proof of long term use, Test on limits on heavy metal (for Traditional Medicines), allowable limit for vitamin and minerals (for Health Supplements)

c. In Myanmar : Document on examination of Heavy Metals (for Traditional Medicines).

d. In Philippines: Applicable for Traditionally-Used Herbal Products too
For HS : Proof of use as food and analysis report of microbial, chemical test and other requirement for special product

e. In Thailand : Proof of use in Traditional Medicines and analysis report of microbial test (for traditional medicines).

HS: any raw materials that have no historic usage as food, chronic toxicity test on animal is required and analysis report of chemical and microbial contamination

f. In Vietnam : Heavy metal (lead, arsen, mercury), contamination of microbiology (for Traditional Medicines and Health Supplements)

b) Applicable for TM only :

2 countries (Myanmar, Singapore)

Note : In Singapore : Applicable for CPM: Test reports of toxic heavy metals (mercury, lead, arsenic and copper) and microbe contamination must comply with legal requirements (the toxic heavy metal, cadmium may be included in the future). For high risk product, test reports to show the absence of specific types of adulterants and/or toxic substances are required

1. *References to Support The Safety :*

- * Monographs
 - 1. Applicable for TM and HS :
6 countries (Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)
Note : In Philippines, applicable for Traditionally-Used Herbal Products too
 - 2. Applicable for TM only:
2 countries (Myanmar, Singapore)
Note : In Singapore, applicable for CPM
 - 3. Not applicable :
1 country (Brunei Darussalam)

- * Materia Medica
 - 1. Applicable for TM and HS :
5 countries (Cambodia, Indonesia, Malaysia, Thailand, Vietnam)
 - 2. Not applicable :
3 countries (Brunei Darussalam, Myanmar, Philippines)
 - 3. No Information : 1 country (Lao PDR)
 - 4. Applicable for TM only: 1 country (Singapore)
Note : In Singapore, applicable for CPM

- * Encyclopedia
 - 1. Applicable for TM and HS :
5 countries (Cambodia, Indonesia, Malaysia, Thailand, Vietnam)
 - 2. Not applicable :
3 countries (Brunei Darussalam, Myanmar, Philippines)
 - 3. No Information : 1 country (Lao PDR)
 - 4. Applicable for TM only: 1 country (Singapore)
Note : In Singapore, applicable for CPM

- * Pharmacopoeia
 - 1. Applicable for TM and HS :
6 countries (Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)
Note : In Philippines, applicable for Traditionally-Used Herbal Products too
 - 2. Applicable for TM only: 1 country (Singapore)
Note : In Singapore, applicable for CPM
 - 3. Not applicable :
2 countries (Brunei Darussalam, Myanmar)
 - 4. No Information : 1 country (Lao PDR)

- * Others
 - 1. Applicable for TM and HS :
4 countries (Indonesia, Philippines, Thailand, Vietnam)
Note:
 - Published Journal from Relevant Areas: Indonesia
 - applicable Internet (for Traditional Medicines) and PDR, RDA, Codex, Internet (for Health Supplements) : Philippines
 - In Philippines, applicable for Traditionally-

Used Herbal Products too

- Text book/ Published Journal from relevant areas : Thailand

2. Not applicable : 2 countries (Brunei Darussalam, Singapore)
3. No information : 5 countries (Cambodia, Lao PDR, Malaysia, Myanmar)

2. Toxicity Study

1. Applicable for TM and HS : 5 countries (Indonesia, Malaysia, Philippines, Thailand, Vietnam)
Note : In Thailand : For HS, Toxicity study only for new substances
2. Applicable for TM only: 2 countries (Cambodia, Myanmar)
Note : In Myanmar, document required is acute
3. toxicity test on laboratory animals (mice and rabbits)
Not applicable : 2 countries (Brunei Darussalam, Singapore)
4. No Information : 1 country (Lao PDR)

c. Efficacy

- 1). Applicable for TM and HS : 2 countries (Indonesia, Thailand)
- 2). Applicable for TM only : 4 countries (Cambodia, Myanmar, Philippines, Vietnam)
- 3). Not applicable : 3 countries (Brunei Darussalam, Malaysia, Singapore)
- 4). No Information : 1 country (Lao PDR)

1. References to Support The Efficacy/Claims

* Monographs

1. Applicable for TM and HS : 4 countries (Indonesia, Philippines, Thailand, Vietnam)
2. Applicable for TM only : 1 country (Myanmar)
3. Not applicable : 2 countries (Brunei Darussalam, Singapore)
4. No information : 3 countries (Cambodia, Lao PDR, Malaysia)

* Materia Medica

1. Applicable for TM and HS : 5 countries (Cambodia, Indonesia, Philippines, Thailand, Vietnam)
2. Applicable for TM only : 1 country (Myanmar)
3. Not applicable : 2 countries (Brunei Darussalam, Singapore)
4. No information : 2 countries (Lao PDR, Malaysia)

* Encyclopedia

1. Applicable for TM and HS : 4 countries (Cambodia, Indonesia, Thailand, Vietnam)
2. Not applicable : 2 countries (Brunei Darussalam, Singapore)
3. No information : 4 countries (Lao PDR, Malaysia, Myanmar, Philippines)

- * Pharmacopoeia
 1. Applicable for TM and HS :
5 countries (Cambodia, Indonesia, Philippines, Thailand, Vietnam)
 2. Not applicable :
2 countries (Brunei Darussalam, Singapore)
 3. No Information :
3 countries (Lao PDR, Malaysia, Myanmar)
- * Others
 1. Applicable for TM and HS :
3 countries (Indonesia, Philippines, Thailand)
Note:
 - Published Journal from Relevant Areas (Indonesia)
 - Applicable Internet (for Traditional Medicines) and PDR, RDA, Codex, Internet (for Health Supplements) (Philippines)
 - For TM : Research document from the credible source and accepted scientific review and scientific substantiation.
For HS : Accepted scientific review and scientific substantiation (Thailand)
 2. Not applicable :
2 countries (Brunei Darussalam, Singapore)
 3. No information : 5 countries (Cambodia, Lao PDR, Malaysia, Myanmar, Vietnam)

2. Clinical Trials

- 1). Applicable for TM and HS : 2 countries (Indonesia, Thailand)
Note : design method must RCT
- 2). Applicable for TM only : 3 countries (Cambodia, Philippines, Vietnam)
- 3). Not applicable : 2 countries (Brunei Darussalam, Singapore)
- 4). No information : 3 countries (Lao PDR, Malaysia, Myanmar)

Document :

1. Applicable for TM and HS : 2 countries (Indonesia, Thailand)
Note :
In Thailand : Clinical trials needed for health claims or indications not followed with the traditional knowledge
 - for Traditional Medicines / Phytopharmaca :
 - Pre Clinical Study, consist of toxicity study and pharmacodynamic study
 - Pharmaceutical standardization
 - Clinical Trial
 - for Health Supplements :
 - Which indication for prevention or treatment of diseases/dysfunction of organ

2. Applicable for TM only : 2 countries (Philippines, Vietnam)
 Note : In Vietnam : According to Regulations on clinical trial on traditional medicine issued by MOH
 In Philippines : Phase I Clinical Trial for galenical products
 Phase I, II & III Clinical Trials for products in Pharmaceutical dosage forms
3. No information : 5 countries (Brunei Darussalam, Cambodia, Lao PDR, Malaysia, Myanmar)
4. Not applicable : 1 country (Singapore)
 Note : For HS : Documents required for efficacy comply with the scientific criteria for Health related claims developed by the Codex committee (Thailand)

2. Claims

1. Referring to efficacy of each raw materials :
 1 country (Malaysia) (Low level claims of the product based on the information on any of the raw material)
2. Referring to efficacy of finished product :
 1 country (Lao PDR) for TM only
3. Referring to efficacy of finished product :
 1 country (Vietnam) only for HS
4. Both (For TM and HS) :
 5 countries (Cambodia ,Indonesia, Philippines, Singapore, Thailand).
5. Both (For TM only) :
 2 countries (Myanmar, Vietnam).

Note :

- * Brunei Darussalam and Singapore :
 Claims relating to the treatment of major diseases/medical conditions e.g. cancer, diabetes, impotency are legally not allowed on the packaging materials of TM and CPM products. For HS, medical claims are not allowed.
- * Philippines : For Traditionally-Used Herbal Products, evidence of claimed application/s (**not termed as efficacy**), is/are based on medical/pharmaceutical literature or similar sources or a documentation of the knowledge on the application of such product through medical, historical, and ethnological documents.

3. Labeling

- * Product name
 1. Applicable for TM and HS :
 7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)
 2. Applicable for TM only:
 3 countries (Lao PDR, Myanmar, Singapore)
 Note : In Singapore, applicable for CPM
- * Composition
 1. Applicable for TM and HS :

- | | |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| | 6 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Vietnam) |
| | 2. Applicable for TM only:
3 countries (Lao PDR, Myanmar, Singapore)
Note : In Singapore, applicable for TM, including CPM |
| | 3. Applicable for HS only:
1 country (Thailand) |
| * Dosage form | 1. Applicable for TM and HS :
6 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Vietnam) |
| | 2. Applicable for TM only:
2 countries (Lao PDR ,Myanmar,) |
| | 3. Applicable for HS only:
1 country (Thailand) |
| | 4. Not applicable : 1 country (Singapore) |
| * Administration and Doses | 1. Applicable for TM and HS :
7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam) |
| | 2. Applicable for TM only:
3 countries (Lao PDR, Myanmar, Singapore)
Note : In Singapore, applicable for CPM |
| * Packaged Size | 1. Applicable for TM and HS :
7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam) |
| | 2. Applicable for TM only:
2 countries (Lao PDR, Myanmar) |
| | 3. Not applicable:
1 country (Singapore) |
| * Manufacturer name and address | 1. Applicable for TM and HS :
7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam) |
| | 2. Applicable for TM only:
3 countries (Lao PDR, Myanmar, Singapore)
Note : In Singapore, applicable for CPM |
| * Distributor/ importer name and address | 1. Applicable for TM and HS :
4 countries (Indonesia, Philippines, Thailand, Vietnam) |
| | 2. Applicable for TM only:
3 countries (Lao PDR, Myanmar, Singapore)
Note : In Singapore, applicable for CPM |
| | 3. Not applicable :
3 countries (Brunei Darussalam, Cambodia, Malaysia) |
| * Registration Number | 1. Applicable for TM and HS :
5 countries (Brunei Darussalam, Indonesia, Malaysia, Thailand, Vietnam) |

- | | | |
|----------------------------------------|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | 2. | Applicable for TM only:
3 countries (Lao PDR, Myanmar, Philippines)
Note : In Philippines, Optional (for Health Supplements) |
| | 3. | Not Applicable :
2 countries (Cambodia, Singapore) |
| * Batch Code | 1. | Applicable for TM and HS :
6 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Vietnam) |
| | 2. | Applicable for TM only:
3 countries (Myanmar, Singapore, Thailand)
Note : In Singapore, applicable for CPM |
| | 3. | No information :
1 country (Lao PDR) |
| * Expiry Date
mm/yy or .. | 1. | Applicable for TM and HS :
6 countries (Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)
note : in Thailand, for TM, covers expiry date only for house hold remedies. For HS covers expiry date <u>and</u> manufacturing date |
| | 2. | Applicable for TM only:
4 countries (Brunei Darussalam, Lao PDR, Myanmar, Singapore)
Note : In Singapore, applicable for CPM |
| * Side effect, if any | 1. | Applicable for TM and HS :
6 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Vietnam) |
| | 2. | Applicable for TM only:
3 countries (Lao PDR, Myanmar, Singapore) |
| | 3. | Applicable only for HS : 1 country (Thailand) |
| * Contraindication,
if any | 1. | Applicable for TM and HS :
7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam) |
| | 2. | Applicable for TM only :
3 countries (Lao PDR, Myanmar, Singapore)
Note : In Singapore, applicable for CPM |
| * Warning/
Precaution, if
any .. | 1. | Applicable for TM and HS :
7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam) |
| | 2. | Applicable for TM only:
2 countries (Lao PDR, Myanmar) |
| | 3. | Not Applicable :
1 country (Singapore) |

- * Interaction, if any
 1. Applicable for TM and HS : 7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam,)
 2. Applicable for TM only: 1 country (Myanmar)
 3. Not Applicable : 1 country (Singapore)
 4. No information : 1 country (Lao PDR)
- * Alcohol content for oral solution
 1. Applicable for TM and HS : 5 countries (Brunei Darussalam, Indonesia, Malaysia, Philippines, Vietnam)
 2. Applicable for TM only: 2 countries (Myanmar, Thailand)
Note : Malaysia also “preservatives”
 3. Not Applicable : 2 countries (Cambodia, Singapore)
 4. No information : 1 country (Lao PDR)
- * Halal (not contain any prohibited material for Moslem)
 1. Applicable for TM and HS : 2 countries (Brunei Darussalam, Indonesia)
 2. Applicable for TM and HS (Optional) : 2 countries (Malaysia, Thailand)
 3. Applicable for TM only: 1 country (Vietnam)
 4. Applicable for HS only (Must be supported by documents) : 2 countries (Myanmar, Philippines)
 5. Not Applicable : 3 countries (Cambodia, Singapore, Thailand)
 6. No information : 1 country (Lao PDR)
- * Storage condition
 1. Applicable for TM and HS : 7 countries (Brunei Darussalam, Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam)
Note: Thailand for optional
 2. Applicable for TM only: 1 country (Myanmar)
 3. No information : 1 country (Lao PDR)
 4. Not applicable : 1 country (Singapore)

f. Advertisement Approval

1. Applicable for TM and HS : 4 countries (Indonesia, Malaysia, Thailand, Vietnam)
2. Applicable for TM only: 3 countries (Lao PDR, Myanmar, Singapore)
Note : In Singapore, applicable for TM, including CPM
3. Not Applicable : 2 countries (Cambodia, Philippines)

4. No legal requirement :

2 countries (Brunei Darussalam, Philippines)

Note : In Philippines, Advertisement in print, radio, television, outdoor advertisement or other medium is monitored concurrently upon release/airing of the advertisement

3. Post Marketing Control

* Monitoring of labeling, packaging, advertisement

1. Applicable for TM and HS :
6 countries (Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam)
2. Applicable for TM only:
3 countries (Brunei Darussalam, Myanmar, Lao PDR)
Note : in Brunei Darussalam, only monitoring of labeling and packaging
3. No information :
1 country (Cambodia)

* Monitoring of Adverse Effect

1. Applicable for TM and HS : 6 countries (Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam)
2. Applicable for TM only: 1 country (Myanmar)
3. No information : 3 countries (Brunei Darussalam, Cambodia, Lao PDR)

* Post Marketing Surveillance

1. Applicable for TM and HS :
7 countries (Brunei Darussalam, Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam)
2. Applicable for TM only:
1 country (Myanmar)
3. No Information :
2 countries (Cambodia, Lao PDR)

* Sampling and Laboratory Test

1. Applicable for TM and HS : 5 countries (Brunei Darussalam, Indonesia, Philippines, Malaysia, Thailand)
2. Applicable for TM only: 3 countries (Myanmar, Singapore, Vietnam)
3. No information :
2 countries (Cambodia, Lao PDR)

* Inspection To The Manufacturer and Distributor

1. Applicable for TM and HS : 5 countries (Brunei Darussalam, Indonesia, Malaysia, Philippines, Thailand)
2. Applicable for TM only: 3 countries (Lao PDR, Myanmar, Vietnam)
3. Applicable for CPM : 1 country (Singapore)
4. No information : 1 country (Cambodia)

ATTACHMENT

Traditional Medicines

COMPONENTS	BD	C	I (*)	L	M (*)	Myr	P (*)	S (*)	T (*)	V (*)
1. Ingredient										
- herbs/plants	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
- Animal Parts	✓	✓	✓	✓	✓	✓	X	✓	✓	✓
- Mineral Raw Materials	✓	✓	✓	✓	✓	✓	X	✓	✓	✓
2. Intended use/purpose										
- Practice of indigenous medicine	✓	✓	✓	X	✓	✓	X	X	✓	X
- Maintenance of Health	X	X	✓	X	X	X	X	✓	✓	X
- Treatment Use	X	X	✓	X	X	X	X	✓	✓	X
- Pharmacological/active substance	X	X	X	✓	X	X	X	X	X	✓
- Diagnosis	X	X	X	X	X	X	✓	✓	✓	X
- Alleviation	X	X	X	X	X	X	✓	✓	✓	X
- Treatment of Disease	X	X	X	X	X	X	✓	✓	✓	X
- Promotion of Health	X	X	X	X	X	X	✓	✓	✓	X
- Affect structure or any function of the body	X	X	X	X	X	X	✓	✓	✓	X
3. How to Prove										
- Empirically has long historical used	X	X	✓	X	X	✓	X	X	✓	X
- Not scientifically prove but shall be approved by MOH	X	X	X	✓	X	X	X	X	✓	X
- Traditional experience of long usage at least 5 decade	X	X	X	X	X	X	✓	X	X	X
- Published in the Traditional Pharmacopeia under Ministerial notification or published in the ministerial notification as Traditional Medicine or other scientific evidence	X	X	X	X	X	X	X	X	✓	X
4. Other Information										
- Included homeopathic	✓	X	X	X	✓	X	X	X	X	X
- Prepared, package, and labeled	X	X	X	✓	X	X	X	X	X	X
- Shall not include : injection, vaccine, blood product and poison list	X	X	X	X	X	X	X	✓	X	X
- Shall not include : injection, vaccine and human blood	X	X	X	X	X	X	X	X	✓	X
- Prepared either by traditional or modern techniques	X	X	X	X	X	X	X	X	✓	✓

Singapore's Comment: The term "medicinal product" forms part of the legal definition of "traditional medicine" in the Medicines Act of Singapore. The definition of "medicinal product" in the Medicines Act include purposes such as treating and preventing disease, diagnosing disease etc.

Health Supplements

COMPONENTS	BD	C	I (*)	L	M	Myr	P (*)	S (*)	T (*)	V
1. Ingredient										
- Vitamin	✓	✓	✓	✓	✓	X	✓	✓	✓	✓*
- Mineral	✓	✓	✓	✓	✓	✓	✓**	✓	✓	✓
- Amino Acids	✓	✓	✓	✓	✓	X	X	✓	✓	X
- Plants	✓	✓	✓	✓	✓	✓	X	✓	✓	✓*
- Animals	✓	✓	✓	✓	✓	✓	X	✓	✓	✓
- Extract	✓	✓	✓	✓	✓	X	X	X	✓	X
- Isolate	✓	X	✓	X	✓	X	X	X	✓	X
- Concentrate	✓	X	✓	X	✓	X	X	X	✓	X
- Metabolites	X	X	✓	✓	X	X	X	X	✓	X
- Enzymes	✓	✓	✓	✓	✓	X	X	X	X	X
2. Function										
- To support or maintain the healthy function of human body	✓	X	X	X	X	X	X	✓	X	X
- To improve and maintain healthy condition	X	✓	X	✓	X	X	X	X	X	X
- To supplement the normal diet	X	✓	✓	✓	✓	X	X	✓	X	X
- To use for patient under dietary regimes such as obesity, diabetic patients, hypertensions, slimming, etc	X	✓	X	X	X	X	X	X	X	X
- Supplementing or fortifying the ordinary or usual diet	X	X	X	X	X	X	✓	X	X	X
- For general person who expect to improve health	X	X	X	X	X	X	X	X	✓	X
a) Enhance human body's function	X	X	X	X	X	X	X	X	X	✓
3. Dosage Form										
- Tablet	✓	✓	✓	X	✓	X	X	✓	✓	X
- Capsule	✓	✓	✓	X	✓	X	X	✓	✓	X
- Softgel	✓	X	✓	X	✓	X	X	✓	✓	X
- Liquid form	✓	✓	✓	X	✓	X	X	✓	✓	X
- Pastilles	X	✓	✓	X	✓	X	X	X	X	X
- Powder	X	✓	✓	X	✓	X	X	X	✓	X
- Syrup	X	X	✓	X	✓	X	X	✓	X	X
- Pil	X	X	X	X	✓	X	X	X	X	X

Note : *) = legal definition

The matrix fulfill based on last questionnaire

Note :

* In Vietnam, under

Vitamin: to set up table of strength g vitamins (limited), to decide drug or drug interface or health supplement

Plant: to set up table of strength g vitamins (limited), to decide drug or drug interface or health supplement

** Philippines use vitamin, mineral or other dietary property for Food Supplements.

I. Registration and Evaluation

COMPONENTS	BD	C	I	L	M	Myr	P	S	T	V
1. Registration										
a. Registered before marketed	TM HS	TM HS	TM HS	-	TM HS	TM	TM* HS	CPM **	TM HS	TM HS
b. Timeline for Evaluation										
- 2-3 months	N/A	-	TM HS	-	-	-	HS	CPM ***	-	TM HS
- 6 months	N/A	-	-	TM	TM HS	TM	-	-	TM HS	TM *****
- 6-12 months	N/A	TM HS	-	-	-	-	TM ****	-	-	

Note :

* In Philippines , Traditionally-Used Herbal products is registered before marketed too.

** No licensing requirements for TM HS products, for Chinese Proprietary Medicines (CPM) products, the dealers (importer, wholesale dealer, local manufacturer, local repacker) must be licensed and the CPM products must be listed with Health Sciences Authority (HSA).

*** For CPM product listing

**** In Philippines, applicable for Traditionally-Used Herbal Products too

***** In Vietnam, Food-drug interface is in 6 months

Continued ...

COMPONENTS	BD	C	I	L	M	Myr	P	S	T	V
c. Evaluation										
- Pre marketing	N/A	TM HS	TM HS	TM	TM HS	TM	TM* HS	CPM	TM HS	TM HS
- Post marketing	N/A	TM HS	TM HS	TM	TM HS	TM	TM* HS	CPM	TM HS	TM
d. Administrative Data										
- CFS/PPP	N/A	TM HS	TM HS	TM	TM HS	-	TM* HS	CPM	TM HS	TM HS
- GMP certificate	N/A	TM HS	TM HS	TM	TM HS	TM	TM HS	CPM	HS	TM
- Letter of Authorization	N/A	N/A	TM HS	TM	TM HS	TM	TM HS	N/A	N/A	TM
e. Technical Data										
- Quality	N/A	TM HS	TM HS	TM	TM HS	TM	TM* HS	CPM	TM HS	TM HS
- Safety	N/A	TM HS	TM HS	-	TM HS	TM	TM* HS	CPM	TM HS	TM HS
- Efficacy	N/A	TM HS	TM HS	-	N/A	N/A	TM**	N/A	TM HS	TM

Note :

* In Philippines, applicable for Traditionally-Used Herbal Products too

** In Philippines, used Claimed Application/folkloric use for Traditionally-Used Herbal Products

2. Pre Marketing Evaluation

EVALUATION COMPONENTS	BD	C	I	L	M	Myr	P	S	T	V
1. Quality	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	CPM	TM HS	TM HS
a. GMP Certificate	N/A	TM HS	TM HS	TM	TM HS	N/A	TM HS	CPM	HS	TM HS
b. Formula	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	N/A	TM HS	TM HS
c. Raw Material	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	N/A	TM HS	TM HS
d. Manufacturing Process	N/A	TM HS	TM HS	TM	TM HS	TM	TM HS	N/A	TM HS	TM HS
e. Finished Product Specification	N/A	TM HS	TM HS	TM	TM HS	TM	TM HS	CPM	TM HS	TM HS
f. Stability Study	N/A	N/A	TM HS	TM	TM HS	N/A	TM HS	N/A	N/A	TM HS
g. Water Content	N/A	N/A	TM HS	N/A	N/A	N/A	TM HS	N/A	N/A	TM

EVALUATION COMPONENTS	BD	C	I	L	M	My r	P	S	T	V
h. Disintegration Time Test Result	N/A	*TM HS	TM HS	N/A	TM HS	N/A	TM HS	N/A	TM	TM HS
i. Microbial Contaminant Test Result	N/A	TM HS	TM HS	N/A	TM	N/A	TM HS	CPM	TM HS	TM HS*
2. Safety	TM HS *	TM HS	TM HS	-	TM HS*	TM *	TM HS *	CPM	TM HS*	TM HS*
a. References to support safety - Monographs	N/A	TM HS	TM HS	-	TM HS	TM	TM HS *	CPM	TM HS	TM HS
- Materia Medica	N/A	TM HS	TM HS	-	TM HS	N/A	N/A	CPM	TM HS	TM HS
- Encyclopedia	N/A	TM HS	TM HS	-	TM HS	N/A	N/A	CPM	TM HS	TM HS
- Pharmacopoeia	N/A	TM HS	TM HS	-	TM HS	N/A	TM HS *	CPM*	TM HS	TM HS
- Others	N/A	-	TM HS *	-	-	-	TM HS *	N/A	TM HS	TM HS*
b. Toxicity Study	N/A	TM	TM HS	-	TM HS	TM *	TM HS	N/A	TM HS*	TM HS
3. Efficacy	N/A	TM	TM HS	-	N/A	TM	TM	N/A	TM HS	TM
a. References to support efficacy / claims - Monographs	N/A	-	TM HS	-	-	TM	TM HS	N/A	TM HS	TM HS
- Materia Medica	N/A	TM HS	TM HS	-	-	TM	TM HS	N/A	TM HS	TM HS
- Encyclopedia	N/A	TM HS	TM HS	-	-	-	-	N/A	TM HS*	TM HS
- Pharmacopoeia	N/A	TM HS	TM HS	-	-	-	TM HS	N/A	TM HS	TM HS
- Others	N/A	-	TM HS	-	-	-	TM HS	N/A	TM HS	-
b. Clinical Trials	N/A	TM	TM HS *	-	-	-	TM	N/A	TM HS	TM
- Documents	-	-	TM HS	-	-	-	TM *	N/A	TM HS	TM*
4. Claims										
- Efficacy of each raw materials	TM HS *	TM HS	TM HS	-	TM HS* CPM	TM	TM HS *	CPM	TM HS	TM

EVALUATION COMPONENTS	BD	C	I	L	M	My r	P	S	T	V
- Efficacy of finished product	-	TM HS	TM HS	TM	TM HS* CPM	TM	TM HS	CPM	TM HS	TM HS
5. Labeling										
a. Product Name	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	CPM*	TM HS	TM HS
b. Composition	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	CPM	HS	TM HS
c. Dosage Form	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	N/A	HS	TM HS
d. Administration & Doses	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	CPM	TM HS	TM HS
e. Packaged Size	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	N/A	TM HS	TM HS
f. Manufacturer Name & Address	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	CPM	TM HS	TM HS
g. Distributor / Importer Name & Address	N/A	N/A	TM HS	TM	N/A	TM	TM HS	CPM	TM HS	TM HS
h. Registration Number	TM HS	N/A	TM HS	TM	TM HS	TM	TM HS *	N/A	TM HS	TM HS
i. Batch Code	TM HS	TM HS	TM HS	-	TM HS	TM	TM HS	CPM	TM	TM HS
j. Expiry Date	TM	TM HS	TM HS	TM	TM HS	TM	TM HS	CPM	TM HS	TM HS
k. Side Effect, if any	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	CPM	HS	TM HS
l. Contraindication, if any	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	CPM	TM HS	TM HS
m. Warning / Precaution, if any	TM HS	TM HS	TM HS	TM	TM HS	TM	TM HS	N/A	TM HS	TM HS
n. Interaction, if any	TM HS	TM HS	TM HS	-	TM HS	TM	TM HS	N/A	TM HS	TM HS
o. Alcohol Content for Oral Solution	TM HS	N/A	TM HS	-	TM HS*	TM	TM HS	N/A	TM	TM HS
p. Halal (not containing any prohibited material for Moslems)	TM HS	N/A	TM HS	-	TM HS*	HS	HS	N/A	TM HS*	TM
q. Storage Condition	TM HS	TM HS	TM HS	-	TM HS	TM	TM HS	N/A	TM HS	TM HS
6. Advertisement Approval	No*	N/A	TM HS	TM	TM HS	No*	N/A No*	CPM	TM HS	TM HS

* Under 'quality' - microbial contaminant test result, in Vietnam, identification, reaction of Thin Layer Chromatography, if appropriate, assay of group of main active ingredients, water content, microbiological contamination, heavy metal (lead, arsenic and mercury) are also carried out.

- * Under **'safety'**, please note the following country specific requirements:
 - a. In Brunei Darussalam, safety information is required in product label / insert.
 - b. In Malaysia, proof of long term use, test on limits on heavy metal, allowable limit for vitamin and minerals (for Traditional Medicines and Health Supplements).
 - c. In Myanmar, document on examination of Heavy Metals (for Traditional Medicines).
 - d. In Vietnam, heavy metal (lead, arsenic, mercury), contamination of microbiology (for Traditional Medicines and Health Supplements).
 - e. In Thailand, proof of use in Traditional Medicines and analysis report of microbial test (for traditional medicines).
 - f. In Philippines, applicable for Traditionally-Used Herbal Products too. For HS, proof of use as food and analysis report of microbial, chemical test and other requirement for special product are required.
 - g. In Singapore, for high risk product, test reports to show the absence of specific types of adulterants and/or toxic substances are required (for Traditional Medicines).
- * Under **'safety' – references to support safety**, in Philippines, **references to monographs and pharmacopeias** are applicable for Traditionally-Used Herbal Products too.
 In singapore, references to pharmacopoeia is applicable for CPM
 In Indonesia, **'other'** sources of reference include published journal from relevant areas.
 In Philippines, **'other'** sources of reference include applicable Internet websites are used for Traditional Medicines and PDR, RDA, Codex as well as Internet websites also for Health Supplements. This is applicable for Traditionally-Used Herbal Products too.
- * Under **'safety' – toxicity study**, in Thailand, for HS, toxicity study is required for new substances only.
 In Myanmar, document required is acute toxicity test on laboratory animals (mice and rabbits).
- * Under **'efficacy' – references to support efficacy / claims**, in Indonesia, **'other'** sources of reference include published journal from relevant areas.
 In Philippines, **'other'** sources of reference include applicable Internet websites are used for Traditional Medicines and PDR, RDA, Codex as well as Internet websites also for Health Supplements.
 In Thailand, research document from the credible sources are used for traditional medicines and certain textbooks.
- * Under **'efficacy' – clinical trials**, in Indonesia, the design method must RCT.
- * Under **'efficacy' – documents**, in Indonesia, for traditional medicines / phytopharmaca, the following is required,
 - Pre Clinical Study, consist of toxicity study and pharmacodynamic study
 - Pharmaceutical standardization
 - Clinical Trial

For health supplements, the following is required,

- Which indication for prevention or treatment of diseases/dysfunction of organ

In Philippines, Phase I Clinical Trial is required for galenical products, and phases I, II & III clinical trials for products in pharmaceutical dosage forms.

In Vietnam, conduct must be according to Regulations on clinical trial for traditional medicine issued by MOH.

For HS : Documents required for efficacy comply with Codex Guideline. (Thailand)

- * Under **'claims'**, Malaysia refers to efficacy of each raw materials used for TMHS whereas Lao PDR refers to efficacy of finished product for TM only and Vietnam refers to efficacy of finished product for HS only.

In both Brunei Darussalam and Singapore, claims relating to the treatment of major diseases/medical conditions e.g. cancer, diabetes, impotency are not legally allowed on the packaging materials of TM and CPM products. For HS, medical claims are not allowed.

In Philippines, for Traditionally-Used Herbal Products, evidence of claimed application/s (**not termed as efficacy**), is/are based on medical/pharmaceutical literature or similar sources or a documentation of

the knowledge on the application of such product through medical, historical, and ethnological documents.

- * Under **‘labeling’ – registration number**, in Philippines, it is optional for Health Supplements.
- * Under **‘labeling’ – expiry date**, in Thailand the expiry date or manufacturing date must appear on the label, and for HS, the expiry date and manufacturing date must appear on the label.
- * Under **‘labeling’ – alcohol content in oral solution**, in Malaysia, even if alcohol is used as preservative, it must be stated.
- * Under **‘labeling’ – halal**, in Malaysia and Myanmar, it is optional for HS. However, to include halal on labeling of HS in Myanmar, it must be supported by appropriate documents.
- * Under **‘advertisement approval’**, in Brunei Darussalam there no legal requirement for advertisement approval, and in Philippines, advertisement in print, radio, television, outdoor advertisement or other medium is monitored concurrently upon release/airing of the advertisement.

3. Post-Marketing Control

COMPONENTS	BD	C	I	L	M	Myr	P	S	T	V
1. Monitoring of labeling, packaging, advertisement	TM*	-	TM HS	TM	TM HS	TM	TM HS	TM HS	TM HS	TM HS
2. Monitoring of Adverse Effect	-	-	TM HS	-	TM HS	TM	TM HS	TM HS	TM HS	TM HS
3. Post-Marketing Surveillance	TM HS	-	TM HS	-	TM HS	TM	TM HS	TM HS	TM HS	TM HS
4. Sampling & Laboratory Test	TM HS	-	TM HS	-	TM HS	TM	TM HS	TM	TM HS	TM
5. Inspection of Manufacturer and Distributor	TM HS	-	TM HS	TM	TM HS	TM	TM HS	CPM	TM HS	TM

Note

- * In Brunei Darussalam, post-marketing control is only monitoring of labeling and packaging.

Abbreviations Used in Tables

B	- Brunei Darussalam
C	- Cambodia
CPM	- Chinese Proprietary Medicine
HS	- Health Supplement
I	- Indonesia
L	- Lao PDR
M	- Malaysia
Myr	- Myanmar
P	- Philippines
S	- Singapore
T	- Thailand
TM	- Traditional Medicine
V	- Vietnam

LIST OF RESPONDERS :

No.	Country	Responsible Person	Designation	Organization
1.	Brunei Darussalam	Ms. Zubaidah Hj. Mahmud	Scientific Officer	Department of Pharmaceutical Services, Ministry of Health
2.	Cambodia	Kouch Virya		Ministry of Health, Directorate General for Health, Departments of Drugs and Food
3.	Indonesia	Dr. Niniek Soedijani	Director of Traditional Medicines, Food Supplement and Cosmetics Evaluation	National Agency of Drug and Food Control, The Republic of Indonesia
4.	Lao PDR	Many Thammavong	Deputy Head of Traditional Medicines Division	Food and Drug Department MOH, Vientiane, LAO PDR
5.	Malaysia	Saleha M, Ewan	Principal Assistant Director	National Pharmaceutical Control Bureau
6.	Myanmar	DR Sein Winn	Director	Department Traditional Medicine
7.	Philippines	Melody M. Zamudio	Food-Drug Regulation Officer III	Bureau of Food & Drugs Department of Health
8.	Singapore	Mrs Marie Tham	Deputy Director (International & External Programs)/(Complementary Medicines Branch)	Health Science Authority (HSA) Singapore
9.	Thailand	Mr. Vinit Usavakidviree	Director of Drug Control Division FDA	Ministry of Public Health
10.	Vietnam	Do Minh Hung	Senior Officer Drug Registration Division	Drug Administration of Vietnam, Ministry of Health