ASEAN GUIDELINES ON LABELING REQUIREMENTS FOR TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS

1. INTRODUCTION

This guideline applies to the traditional medicine and health supplement products to ensure the safe and effective use of traditional medicines and health supplements among consumers and facilitate registration process among ASEAN member states. It also promotes proper storage and logistic condition.

2. DEFINITIONS

"TMHS" means any traditional medicine and health supplement.

"Traditional Medicines, TM" means any medicinal product for human use consisting of active ingredients derived from natural sources (plants, animals and/or minerals) used in the system of traditional practice. It shall not include any sterile preparation, vaccines, any substance derived from human parts, any isolated and characterized chemical substances.

"Health Supplements, HS" means any product that is used to supplement a diet and to maintain, enhance and improve the healthy function of human body and contains one or more, or a combination of the following:

a. Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances
b. Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolite
c. Synthetic sources of ingredients mentioned in (a) and (b)

It is presented in dosage forms (to be administered) in small unit doses such as capsules, tablets, powder, liquid and it shall not include any sterile preparations (i.e. injectables, eye drops).

"Active ingredient" means a substance produces the intended activity of a traditional medicine or health supplement.

"Batch or Lot number" means a designation (in numbers, or letters, or combination of both) that identifies the batch and that permits the complete history of the batch including all stages of production, control and distribution, to be traced and reviewed.

"Container" means an article that contains and protects the product of TMHS. This includes primary packaging components and/or secondary packaging components, if latter are intended to provide additional protection to the product. The packaging components shall be a blister pack, strip pack, bottle, sachet, tube, or other similar articles, but does not include an article intended for ingestion.

"Container Labeling / Labeling" means all information that appears on the container, including that on the outer packaging such as carton.

"Country's registration / Listing / Notification number" means the combination of numbers, symbols and letters reflecting the identification of a TMHS product assigned by the National Control / Regulatory Authority.

"Dosage form" means the usual product type of TMHS (e.g. tablet, capsule, solution, powder, etc) that contains active ingredient (s) generally, but not necessarily, in association with excipients.

"Expiry date" means a date fixed for each individual batch before which the batch still meets the required standard specifications for quality.

"Manufacturing date / Date of Manufacture" means a date fixed for the individual batch, indicating the starting date of the manufacture.

"Manufacturer" means a company that carries out at least one step of production as well as the final release of the finished product.

"Marketing authorisation holder/MAH" means the company or corporate or legal entity in the field of TM / HS in whose name the marketing authorisation has been granted. This party is responsible for all aspects of the product, including quality and compliance with the conditions of marketing authorisation. The authorised holder must be subjected to legislation in the country that issued the marketing authorisation, which normally means being physically located in that country.

"Package insert" means any printed information supplied with the container or primary pack.

"Small label" means a label with very limited space to display minimal information requirements in the small container as described in the General Labeling Requirements for TMHS. The dimension of small label shall be determined by each Member State.

"Strip / Blister pack label" means a label affixed to or printed on the strip or blister pack. The strip / blister pack needs to be repacked in another container or accompanied with a catch cover whose label can display information described in General Labeling Requirements for TMHS so that consumers can obtain such information at the point of purchase.

"Intended use or indication" means a statement of the purpose or purposes for which TMHS is intended to be used."

3. GUIDING PRINCIPLES

3.1 TMHS product shall not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any aspect.

3.2 TMHS product shall not be described or presented on any label or in any labeling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product.

3.3 The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed there on with clarity and conspicuousness and without obscuring design.

3.4 The label information should be English and/or official/national language(s) subject to the regulation of each Member State and be written clearly and easy to understand. Languages other than English may be included on labels with a required declaration to confirm that the meaning in the other languages is the same as that given in the English and/or official language(s).

Languages used for labeling in each Member State are as follows:

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- In Brunei Darussalam, the official language is Bahasa Melayu or Malay language. Label information can appear in Malay language and/or English language. However in the event there is contradiction, the interpretation provided in the Malay language will prevail. Nevertheless the English language is still recognised in Brunei Darussalam as an authentic text.
- In Cambodia, the official language is Khmer. Label information should be in Khmer. However other language such as English and French may be used in addition to Khmer.
- In Indonesia, the official and national language is Indonesian language, therefore the language in the label must be written in Indonesian language. However other language maybe used in addition to Indonesian language.
- In Lao PDR, the official language is Lao. Label information should be in Lao. However other language in smaller fonts such as English, French, Indian, Chinese, etc maybe used in addition.
- In Malaysia, the official language is Bahasa Malaysia however the label information can be in Bahasa Malaysia and/or English. Other languages, if any, may be used in addition to these two languages such as Mandarin.
- In Myanmar, the official language is Myanmar, therefore the language in the label will be Myanmar but other languages may be used such as English or Chinese.
- In the Philippines, the official languages are Filipino and English. Label information should be in English and / or Filipino. Other languages, if any, may be used in addition to these two languages.
- In Singapore, the official language is Malay, Mandarin, Tamil and English. Label Information should be in English. Other languages, if any, may be used in addition to English."
- In Thailand, the official and national language is Thai, therefore the language in the label is Thai however other language may be used such as English.
- In Viet Nam, the official language is Vietnamese. Label information should be in Vietnamese. However other language may be used in a font size not larger than Vietnamese.

4. GENERAL LABELING REQUIREMENTS FOR TMHS

The following information shall appear on the label of TMHS product

4.1 Product name

The product name and the brand name, if applicable should not be misleading or deceptive to the consumer. The product and brand names should be deemed appropriate by the respective Member States.

4.2 Dosage form

4.3 Name and Strength of Active ingredient

The name and quantity of plants or animals from which the active ingredient is derived should be declared in scientific name followed by plant part constituting the crude drug, and type of preparation where applicable. The use of the common / local

name of the active ingredient is optional. For mineral, common / chemical name should be used.

For example :

Each capsule contains : *Curcuma longa* (rhizome) 350 mg.

Each capsule contains : Compound herbal extract 20 mg.

Prepared from leaves of Plant A, Root of Plant B and leaves of Plant C

4.4 Batch or Lot number

Each container shall be printed or permanently marked.
The batch or lot number shall be preceded by title such as “Batch number”, “BN” etc.

4.5 Manufacturing and expiry date or Expiry date only

The manufacturing date and expiry date or expiry date only should be declared as month and year and preceded by title such as “Manufacturing date”, “MFG” “Expiry date”, “EXP” etc.

4.6 Directions of use

Directions of use must clearly state the route of admintration as well as the dose for each target population for which the product is intended**.**

4.7 Indication or Intended use

The statement of the purpose or intention of use for TMHS product should be declared according to the “ASEAN Guidelines on Claim for Traditional Medicines and Health Supplements” and supported by data according to “ASEAN Guidelines on Efficacy Data Requirements”.

4.8 Storage condition

The statement declares a condition to which the TMHS product should be stored properly until the expiry date. Refer to the ASEAN Guideline on Stability Data and Shelf-Life

4.9 Country’s registration / Listing / Notification number (if applicable)

The combination of numbers, symbols and letters assigned to the TMHS product which is approved by the National Regulatory Authority (NRA) shall be declared, if applicable.

4.10 Name and address of manufacturer

The complete name and address of the manufacturer of the product shall be declared.

4.11 Name and address of marketing authorisation holder/importer

The complete name and address of the marketing authorisation holder/importer of the product shall be declared.

4.12 Warning (if any)

The statement declares a warning for consumers’ awareness before using TMHS products. The warning statement assigned by the National Regulatory Authority (NRA) should be declared.The term “Warning” can be used interchangeably, but not limited to terms such as “Side Effects”, “Contra-indications” and “Precautions” as appropriate.

4.13 Pack size

4.13.1 The net contents shall be declared in the metric system

4.13.2 The net contents shall be declared in the following manner:

(i) for liquid form, by volume;

(ii) for solid form such as tablet, soft capsule, hard capsule, powder, etc. by

weight or amount;

(iii) for semi-solid or viscous form, either by weight or volume.

4.14 Special statements:

- alcohol content, if any
- for external use, as applicable

5. SMALL LABEL

The small label should declare at least the following:

5.1 Product name and brand name, if applicable

5.2 Country‘s registration / Listing / Notification number (Country specific)

5.3 Batch or Lot number

5.4 Manufacturing and expiry date or Expiry date only

5.5 Other information according to general labeling requirements should be declared on package insert and / or another container or accompanied with a catch cover.

6. STRIP / BLISTER PACK LABEL

The label on strip / blister pack should declare at least the following:

6.1 Product name and brand name, if applicable

6.2 Country‘s registration / Listing / Notification number (Country specific)

6.3 Batch or Lot number

6.4 Manufacturing and expiry date or Expiry date only

6.5 Other information according to general labeling requirements should be declared on package insert and / or another container or accompanied with a catch cover.

7. COUNTRY SPECIFIC REQUIREMENTS FOR TMHS

Country specific requirements are allowed if they are deemed necessary for the reasons of identification, safety, quality, culture and religion. However, minimization of country specific requirement should be encouraged. Such country specific requirements with reasons should however be made known to the other member states and be updated into the compilation of country specific requirement for TMHS from member states in a timely manner.

The compilation of country specific requirement for TMHS from member states appears in Annex 1

References

1. CODEX Alimentarius International Food Standards. General Standard for the Labelling of Prepackaged Foods. Labelling of Prepackage Food (CODEX STAN 1-1985) 2008:1-7.

2. Therapeutic Goods Administration (TGA). Registration of Complementary Medicines. Australian Regulatory Guidelines for Complementary Medicines (ARGCM) 2005.

3. Therapeutic Goods Administration (TGA). General requirements for labels for medicines Therapeutic Goods Act 1989: Therapeutic Goods Order No.69 2001.

4. EUROPEAN COMMISSION. Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use. Belgium: 2006.

5. The 5th draft guideline on good manufacturing practice for traditional medicines and health supplements.

Country	TM	HS
Brunei Darussalam	Sources of ingredients from animal origin.	Sources of ingredients from animal origin.
Cambodia	"Traditional medicines" or alike.	"Health supplements" / "Food supplements" / "Dietary supplements"
Indonesia	Sources if derived from animal origin. Note: If porcine, this parameter is justified by Act & Decrees.	"Health supplements" / "Food supplements" / "Dietary supplements"
	Font size Note: The size of the letter of the traditional medicine's name must be bigger than the size of the other letter.	Statement on additive added (Preservative, colorant, flavour, sweetener) Note: - Act of the Consumer Protection, No.8 of 1999. - Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.23.3644 of 2004, on Principle of Food Supplement Control. - Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.41.1381 of 2005, on Regulation Guidelines of Food Supplement Control. - Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no.HK.00.05.52.4321 of 2004, on Regulation Guidelines of Food Supplement Control.
		Source of ingredient derived from animal origin inc. gelatin. Note: - Act of the Consumer Protection, No.8 of 1999. - Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.23.3644 of 2004, on Principle of Food Supplement Control. - Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.41.1381 of 2005, on Regulation Guidelines of Food Supplement Control. - Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.52.4321 of 2004, on Regulation Guidelines of Food Supplement Control.
		Recommended daily allowance (RDA) for vitamins/minerals used as health supplements. Note: - Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.52.6291 of 2007, on Nutrition Reference Values.

Country	TM	HS
Lao PDR	"Traditional medicines" or alike.	-
	Drug classification statement.	
Malaysia	"Traditional medicines" or alike. Note : This is a traditional medicine. /Ini adalah ubat tradisional. ATAU This is a homeopathy medicine/ Ini adalah ubat homeopati	Statement on additive added (Preservative, colorant, flavour, sweetener) Note: Name and content of preservative(s), where present
	Hologram	Hologram
	Sources if derived from animal origin inc. gelatin. Note : -For product containing animal part(s), please add this statement: *This product contains animal part(s)*. -For product containing animal origin(s), please add this statement: *This product contains substance(s) from animal origin*. -For product containing porcine, please add this statement: *This product contains animal part(s) (porcinel/pig)*.	Source of ingredient derived from animal origin inc. gelatin. Note : -For product containing animal origin(s) (active, excipient and/or capsule shell) , the source(s) need to be declared
	Keep out of reach of children & Jauhi dari kanak-kanak (in both Bahasa Malaysia and English).	The words " Keep out of reach of children' or words bearing similar meaning in both Bahasa Malaysia & English
	Use of the HALAL logo will be considered for traditional product for both the local and export market, provided that such products have been certified and approved as HALAL by the local authority.	Use of the HALAL logo will be considered for health supplement for both the local and export market, provided that such products have been certified and approved as HALAL by the local authority.
Myanmar	"Traditional medicines" or alike.	Health supplements or alike
Philippines	Drug classification statement. Note: Rx, OTC or Household remedy.	"Food supplements" / "Dietary supplements"
	Statement on additive added (Preservative, colorant, flavour, sweetener).	Recommended daily allowance (RDA) for vitamins/minerals used as food/dietary supplements. Note: Revised standard terms as 2002 Recommended Energy and Nutrients Intakes (RENI) per day (adopted as per Bureau Circular No.16 s.2005)

Country	TM	HS
	Font size Note: For prescription product, the Rx symbol should be printed in a type size no less than 1/5 of the height of the principal display panel.	The caption “NO APPROVED THERAPEUTIC CLAIMS” shall be printed in the principal display panel of all labeling materials, font size 14, font type Arial, all capital and bold letters. Note: As per Bureau Circular No.2 s. 1999
	Therapeutic claim/ Pharmacologic category Note: As per Administrative Order No. 172 s.2004 Guidelines on the Registration of Herbal Medicines Claimed application/ folkloric use Note: As per Administrative Order No. 184 s.2004 Guidelines on the Registration of Traditionally-Used Herbal Products	
	The statement ”The traditional application/use of this product has not been evaluated by the Food & Drug Administration” shall be in an outlined box parallel to the base of the label located in the information panel. Note: As per Administrative Order No. 184 s.2004 Guidelines on the Registration of Traditionally-Used Herbal Products	
	Official name of the product shall be printed inside an outlined box. Note: As per Administrative Order No. 172 s.2004 Guidelines on the Registration of Herbal Medicines and Administrative Order No. 184 s.2004 Guidelines on the Registration of Traditionally-Used Herbal Products	
	The following phrases shall be printed on all labeling materials: “If symptoms persist, consult your doctor.” “Not allowed for use in pregnant, lactating mothers, and children below 18 years.” Note: As per Administrative Order No. 184 s.2004 Guidelines on the Registration of Traditionally-Used Herbal Products	

Country	TM	HS
Singapore	The clause “Allowed for sale as a Chinese Proprietary Medicine based on information submitted to the Authority, Consumer discretion is advised.” Note: Legal requirement for Chinese Proprietary Medicine only. Must be stated in both English and Chinese on the outer label.	
	Statement on additive added (Preservative, colorant, flavour, sweetener) Note: Legal requirement for all traditional medicines. (Labeling of tartrazine, sodium benzoate and/or benzoic acid if these substances present in product)	
	Font size Note: For Chinese Proprietary Medicine label and Package Insert, font size for English words must legally not be less than 1.5 mm in height, and the Chinese characters not less than 2 mm in height.	
Thailand	“Traditional medicines” or alike. Note: A term “Traditional medicine” needs to be displayed in Thai language.	“Dietary supplements” Note: Notification No.293 (2005 Re: Dietary Supplement.)
	Drug classification statement. Note: If traditional medicine is classified as “Household remedy”, A term “Household remedy” needs to be displayed in Thai language.	Statement on additive added (Preservative, colorant, flavour, sweetener) Note: Notification No.293 (2005 Re: Dietary Supplement.)
		“Not recommended to use in children or pregnancy. Note: Food and Drug Administration Notification entitled “Explanation of Ministry of Public Health Notifications No.293 (2005) entitled “Dietary Supplements” and No.294 (2005) entitled “Royal Jelly and Royal Jelly Products”
		“Various food of 5 groups of nutrients should be taken regularly in appropriate proportion.” or similarly meaning statements. Note: Notification No.309 (2007 Re: Dietary Supplement (No.2))
		“No effect on prevention or treatment of diseases. Note: Notification No.309 (2007 Re: Dietary Supplement (No.2))
Viet Nam	Drug classification statement.	“Health supplements” / “Food supplements” / “Dietary supplements”

Country	TM	HS
		Statement on additive added (Preservative, colorant, flavour, sweetener)

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