



Association of South East Asian Nations (ASEAN)

ANNEX IX ASEAN GUIDELINES ON LABELLING REQUIREMENTS FOR TRADITIONAL MEDICINES

Disclaimer:

This document is provided for information purpose only and subject to changes, pending the finalisation of the ASEAN Agreement on Regulatory Framework for Traditional Medicines. Official references to this document can only be made once the said Agreement has been finalised.



DOCUMENT INFORMATION

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INTRODUCTION

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

DEFINITIONS

“Traditional Medicines” 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.

“Active ingredient” means a substance produces the intended activity of a traditional medicine.

“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 traditional medicines. 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 Labelling / Labelling” 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 traditional medicines assigned by the National Control / Regulatory Authority.

“Dosage form” means the usual product type of traditional medicines (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 traditional medicines 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 Labelling Requirements for traditional medicines. 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 labelling requirements for traditional medicines 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 traditional medicines is intended to be used.

GUIDING PRINCIPLES

1. Traditional medicines shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any aspect.



2. Traditional medicines shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product.
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.
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 labelling in each Member State are as follows:

- 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 may be 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, may be used.
- 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, Tamil, Arabic.
- 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 Mandarin.



- 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 languages are Malay, Chinese, 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.

GENERAL LABELLING REQUIREMENTS FOR TRADITIONAL MEDICINES

The following information shall appear on the label of traditional medicines.

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.

2. Dosage Form

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. 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.
- 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.
- 6. Directions of use
Directions of use must clearly state the route of administration as well as the dose for each target population for which the product is intended.
- 7. Indication or Intended use
The statement of the purpose or intention of use for traditional medicines should be declared according to the "ASEAN Guidelines on Claims and Claims Substantiation for Traditional Medicines".
- 8. Storage condition
The statement declares a condition to which the traditional medicines should be stored properly until the expiry date. Refer to "ASEAN Guidelines on Stability Study and Shelf-Life of Traditional Medicines".
- 9. Country's registration / listing / notification number (if applicable)
The combination of numbers, symbols and letters assigned to the traditional medicines which is approved by the National Regulatory Authority (NRA) shall be declared, if applicable.
- 10. Name and address of manufacturer
The complete name and address of the manufacturer of the product shall be declared.
- 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.
- 12. Warning (if any)



The statement declares a warning for consumers' awareness before using traditional medicines. 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.

13. Pack size

The net contents shall be declared in the metric system. The net contents shall be declared in the following manner:

- For liquid form, by volume;
- For solid form such as tablet, soft capsule, hard capsule, powder, etc. by weight or amount;
- For semi-solid or viscous form, either by weight or volume.

14. Special statements

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

SMALL LABEL

The small label should declare at least the following:

1. Product name and brand name, if applicable
2. Country's registration / listing / notification number (country specific)
3. Batch or lot number
4. Manufacturing and expiry date, or expiry date only
5. Other information according to general labelling requirements should be declared on package insert and / or another container or accompanied with a catch cover.

STRIP / BLISTER PACK LABEL

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

1. Product name and brand name, if applicable
2. Country's registration / listing / notification number (country specific)
3. Batch or lot number



4. Manufacturing and expiry date, or expiry date only
5. Other information according to general labelling requirements should be declared on package insert and / or another container or accompanied with a catch cover.

COUNTRY SPECIFIC REQUIREMENTS FOR TRADITIONAL MEDICINES

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 traditional medicines from member states in a timely manner.

The compilation of country specific requirement for traditional medicines from member states appears in Appendix 1.



REFERENCES

1. Therapeutic Goods Administration (TGA). Registration of Complementary Medicines. Australian Regulatory Guidelines for Complementary Medicines (ARGCM) 2005.
2. Therapeutic Goods Administration (TGA). General requirements for labels for medicines Therapeutic Goods Act 1989: Therapeutic Goods Order No.69 2001.
3. EUROPEAN COMMISSION. *Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use. Belgium: 2006.*
4. *ASEAN Guideline on Good Manufacturing Practice for Traditional Medicines.*



APPENDIX 1 COUNTRY SPECIFIC REQUIREMENTS FOR TRADITIONAL MEDICINES

| Country | Country Specific Requirements |
|--------------------------|---|
| Brunei Darussalam | Sources of ingredients from animal origin. |
| Cambodia | "Traditional medicines" or alike. |
| Indonesia | Sources if derived from animal origin. <i>Note: If porcine, this parameter is justified by Act & Decrees.</i> |
| | Font size <i>Note: The size of the letter of the traditional medicine's name must be bigger than the size of the other letter.</i> |
| Lao PDR | "Traditional medicines" or alike. |
| | Drug classification statement. |
| Malaysia | "Traditional medicines" or alike. <i>Note: This is a traditional medicine. /Ini adalah ubat tradisional. ATAU This is a homeopathy medicine/ Ini adalah ubat homeopati</i> |
| | Hologram |
| | Source of ingredient derived from animal origin including gelatine . <i>Note :</i> - 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) (porcine/pig). |
| | 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 health supplement traditional medicines for both the local and export market, provided that such products have been certified and approved as HALAL by the local authority. |



| Country | Country Specific Requirements |
|--------------------|--|
| Myanmar | "Traditional medicines" or alike. |
| Philippines | Drug classification statement. <i>Note: Rx, OTC or Household remedy.</i> |
| | Statement on additive added (Preservative, colorant, flavour, sweetener). |
| | Font size <i>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.</i> |
| | Therapeutic claim/ Pharmacologic category <i>Note: As per Administrative Order No. 172 s.2004 Guidelines on the Registration of Herbal Medicines</i> Claimed application/ folkloric use <i>Note: As per Administrative Order No. 184 s.2004 Guidelines on the Registration of Traditionally-Used Herbal Products</i> |
| | 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. <i>Note: As per Administrative Order No. 184 s.2004 Guidelines on the Registration of Traditionally-Used Herbal Products</i> |
| | Official name of the product shall be printed inside an outlined box. <i>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</i> |
| | The following phrases shall be printed on all labelling materials: "If symptoms persist, consult your doctor." "Not allowed for use in pregnant, lactating mothers, and children below 18 years." <i>Note: As per Administrative Order No. 184 s.2004 Guidelines on the Registration of Traditionally-Used Herbal Products</i> |



| Country | Country Specific Requirements |
|------------------|--|
| Singapore | The clause "Allowed for sale as a Chinese Proprietary Medicine based on information submitted to the Authority, Consumer discretion is advised." <i>Note: Legal requirement for Chinese Proprietary Medicine only. Must be stated in both English and Chinese on the outer label.</i> |
| | Statement on additive added (Preservative, colorant, flavour, sweetener) <i>Note: Legal requirement for all traditional medicines. (Labelling of tartrazine, sodium benzoate and/or benzoic acid if these substances present in product)</i> |
| | Font size <i>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.</i> |
| Thailand | "Traditional medicines" or alike. <i>Note: A term "Traditional medicine" needs to be displayed in Thai language.</i> |
| | Drug classification statement. <i>Note: If traditional medicine is classified as "Household remedy", A term "Household remedy" needs to be displayed in Thai language.</i> |
| Viet Nam | Drug classification statement. |