HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

**JULY 2022**

# GUIDELINES FOR LABELLING STANDARDS OF HEALTH SUPPLEMENTS AND TRADITIONAL MEDICINES

The information in these Guidelines may be updated from time-to-time. For the latest version of the Guidelines, please refer to our website at www.hsa.gov.sg.

HSA
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# 1. Introduction

1.1 Dealers of Health Supplements (HS) and Traditional Medicines (TM) are required to ensure that their products are labelled properly. Labels are used for product identification and provide relevant information to enable consumers to ensure safe and appropriate use of the product, store the product correctly and make informed purchase decisions.

1.2 The objective of these guidelines is to provide guidance for labelling standards of HS and TM in Singapore, to ensure proper labelling of these products.

# 2. Labelling Standards

2.1 Labelling refers to any printed or graphic representation that appears on or is attached to the product or any part of its packaging and includes leaflet that accompanies the product when it is being supplied.

2.2 All product labelling must be in English. Labelling information in other languages, if any, should be consistent with the English text.

2.3 The information on the product label should be adequate and truthful.

2.4 All labelling of containers and packages of HS and TM should be printed or marked in a legible and indelible manner.

2.5 The following are the different types of product labels:

- **Outer label** refers to the product packaging in which the immediate packaging of the finished product is contained, e.g., the package or carton box containing the bottle, strips or blister packs.
- **Inner label** refers to the label affixed on the primary container of the finished product, e.g., the immediate label affixed to a bottle where the finished product is contained.
- **Small label** refers to label on a small primary container, usually a unit dose container, e.g., sachets or small single dose bottle.
- **Strip or blister pack label** refers to the label affixed or printed on the strip or blister pack.

2.6 Table 1 provides the labelling information required for each product label types and leaflet.

**Table 1 Labelling Standards**

| Information | Outer Label | Inner Label | Small Label, Strip or Blister Pack Label | Leaflet, if any |
|---|---|---|---|---|
| 1. Product Name including Brand Name | ✓ | ✓ | ✓ | ✓ |
| 2. Dosage Form | ✓ | ✓* | N/A*** | ✓ |
| 3. Name and Quantity of Active Ingredients | ✓ | ✓ | N/A*** | ✓ |
| 4. Intended Purpose | ✓ | ✓ | N/A*** | ✓ |
| 5. Dosage and Directions of Use | ✓ | ✓ | N/A*** | ✓ |
| 6. Batch Number | ✓ | ✓ | ✓ | N/A |
| 7. Expiry Date | ✓ | ✓ | ✓ | N/A |
| 8. Country of Manufacture | ✓ | ✓* | N/A*** | N/A |
| 9. Name and Address of Local Importer | ✓ | ✓* | N/A*** | N/A |
| 10. Contraindications, if any | ✓ | ✓* | N/A*** | ✓ |
| 11. Other warnings, if any | ✓** | ✓* | N/A*** | ✓ |
| 12. Storage Condition | ✓ | ✓* | N/A*** | ✓ |
| 13. Pack Size / Net Content | ✓ | ✓* | N/A*** | ✓ |

* May be omitted if the product is supplied with an outer label
** May be omitted if the accompanying product leaflet provides this information
*** The small label, strip or blister pack label should minimally display the product name, batch number and expiry date. In such instances, the full product information should be displayed on the label of an accompanying outer carton box

2.7 The inclusion of a leaflet is optional. Information provided within the leaflet should be consistent with those presented on the outer or inner label. Companies who are interested to implement an electronic product leaflet are to refer to the Guidelines on Voluntary Electronic Labelling for Complementary Health Products

2.8 More explanation on the labelling information can be found in Appendix 1.

# 3. References

3.1 ASEAN Guidelines on Labelling Requirements for Health Supplements

3.2 ASEAN Guidelines on Labelling Requirements for Traditional Medicines

# Appendix 1 – Labelling Information

## 1. Brand Name and Product Name

"Brand Name" generally refers to a name given by the company or manufacturer to a product or range of products. A product may or may not have a "Brand Name". "Product Name" refers to the name given to a specific product to distinguish itself from other similar products in the market.

Refer to the Guidelines for Claims and Claims Substantiation of Health Supplements and Traditional Medicines for guidance on the appropriate brand name and product name.

## 2. Dosage Form

"Dosage Form" refers to the final physical form of the product that contains the active ingredient(s) and may be used directly by the consumer, e.g., tablet, capsule, soft gel, liquid, etc.

## 3. Name and Quantity of Active Ingredients

"Active ingredient" refers to the ingredient that contributes to the intended function of the product. It is recommended that internationally accepted nomenclature be used for ingredient names.

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

**Table 2 Examples of Naming of Active Ingredients**

| Full Labelling Name | Scientific Name | Part | Type of Preparation | Common Name |
|---|---|---|---|---|
| 1. *Eurycoma longifolia,* root, 200mg, extract 100:1 equivalent to 20,000mg of fresh root (Tongkat Ali) | *Eurycoma longifolia* | Root | Extract 100:1, equivalent to 20,000mg of fresh root | Tongkat Ali |
| 2. *Silybum marianum,* seed, 200mg, extract standardised to 80% silymarin (Milk Thistle) | *Silybum marianum* | Seed | Extract standardised to 80% silymarin | Milk Thistle |
| 3. *Withania somnifera*, root, 125mg, extract dry concentration (Ashwagandha) | *Withania somnifera* | Root | Extract dry concentration | Ashwagandha |

For vitamins and minerals, common or chemical name should be used. E.g., Vitamin C / Ascorbic acid 500mg; Vitamin A (as Retinyl Ascorbate) 300mcg.

For mineral supplements in the form of a salt, the strength of the element should be declared. E.g., Ferrous sulfate 50mg (providing 10mg elemental Iron).

"Quantity of active ingredients" refers to the quantity of each active ingredient in each dosage form or the recommended dose.

**4. Intended Purpose**

"Intended Purpose" refers to a statement in relation to a product's indications, benefits, or actions. The statement of the intended purpose or intention of use should be declared according to the Guidelines for Claims and Claims Substantiation of Health Supplements and Traditional Medicines.

**5. Dosage and Directions of Use**

The recommended dosage and directions of use provide information on the route of administration, dose, frequency, and duration of use (where applicable) for which the product is intended for use.

**6. Batch Number or Lot Number**

"Batch Number" or "Lot Number" refers to a designation (in numbers, or letters, or combination of both) that identifies the product batch and allows traceability of the complete history of a specific product batch including all stages of production, control, distribution, and raw materials used. The Batch Number should be preceded by title such as "Batch Number", "Batch No." or "BN".

**7. Expiry Date**

"Expiry Date" refers to the date assigned for each individual batch before which the batch still meets the required standard specifications for quality. Expiry date should be declared in month and year (e.g., Jan/2022, 01/2022) and preceded by title such as "Expiry date" or "EXP" to avoid ambiguity and confusion.

**8. Country of Manufacture**

This refers to the country where the product is manufactured.

**9. Name and Address of Local Importer**

This refers to the complete name and address of the local importer of the product. If the distributor is the same as the importer, the distributor information may be printed in replacement of the importer information.

**10. Contraindications**

The statement declares situations where the product should not be used.

**11. Warnings**

The statement declares a warning for consumers' awareness before using the product. Warnings may include side effects, contraindications, and precautions as appropriate.

Certain inactive substances that exhibit sensitising effects are required to be declared:

- Benzoic acid
- Sodium benzoate
- Tartrazine

Dealers are encouraged to review the safety of other sensitising agents that may be present in their products and declare their presence on the product label where necessary.

Traditional medicines making claims on symptomatic relief for non-serious medical conditions would be required to include the statement “If symptoms persist, talk to your healthcare professional”, to ensure that consumers do not delay in seeking appropriate treatment should their symptoms persist.

## 12. Storage Condition

The statement declares a condition to which the product should be stored properly to maintain the quality of the product throughout its declared shelf life.

## 13. Pack Size or Net Content

Pack size or net content refers to the amount of the product in a pack or container. This can be presented in absolute quantity (for solid dosage form) e.g., 30 capsules/container or net content (for liquid, powder, or semi-solid dosage forms), e.g., 500mL/bottle.

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