HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

SEPTEMBER 2023

GUIDELINES FOR LABELLING STANDARDS OF HEALTH SUPPLEMENTS AND TRADITIONAL MEDICINES

Guidelines Version 4

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.

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1. Introduction

1.1 Dealers of health supplements (HS), traditional medicines (TM), medicated oils, balms (MOB) and medicated plasters 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 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 a leaflet, if any 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, TM, MOB or medicated plaster 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 the 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 type 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 (for overseas manufactured product) or Product Owner (for locally manufactured product)	✓	✓*	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 that 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 its 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, the 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.

Where there is no dosage unit for dosage forms such as ointments and creams, the quantity of each active ingredient may be expressed in terms of weight or volume or as percentage by weight or volume of the total quantity. E.g., Methyl salicylate 9g per 30g or 30% (w/w), Menthol 10mL per 100mL or 10% (v/v), Camphor 1g per 25g or 4% (w/w).

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 a 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 a 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 (for overseas manufactured product) or Product Owner (for locally manufactured product)

This refers to the complete name and address of the local importer or product owner of the product.

If the distributor is the same as the importer or product owner, the distributor's name and address may be printed on the label instead of the importer or product owner 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.

TM 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.

Revision History

Version	Date of publication	Summary of changes*
1	March 2022	New document
2	July 2022	Added Table 2 Examples of Naming of Active Ingredients.
3	July 2023	• Included medicated oils, balms and medicated plasters • Included a paragraph to clarify on how the quantity of a topical preparation is to be declared.
4	September 2023	Included clarification on labelling requirement on the name and address of local dealer for products manufactured in Singapore.

*Editorial changes are not reflected

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