HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

NOVEMBER 2024

TRADITIONAL MEDICINES GUIDELINES

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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
Health Sciences Authority

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1. Introduction

1.1 These guidelines provide regulatory information for companies dealing with Traditional Medicines (TM) in Singapore. The information provided in these guidelines is not meant to supersede or replace any of the legislation. Other national legislative controls may apply where applicable.

2. Legislation

2.1 The current legislative control that may apply to TM may be found in the following legislation:

a. Medicines Act 1975 & its Subsidiary Legislation especially:
   i. Medicines (Prohibition of Sale, Supply and Importation) Order;
   ii. Medicines (Traditional Medicines, Homoeopathic Medicines and Other Substances) (Exemption) Order;
   iii. Medicines (Labelling) Regulations;
   iv. Medicines (Medical Advertisements) Regulations;
   v. Medicines (Licensing, Standard Provisions & Fees) Regulations

b. Medicines (Advertisement & Sale) Act 1955

c. Poisons Act 1938 & Poisons Rules

3. Working Definition

3.1 A working definition of TM is described below:

In the local context, TM refer to Malay and Indian traditional medicinal products. They are finished products containing ingredients with uses documented in relevant TM references.

TM are presented in dosage forms to be administered in small unit doses such as capsules, softgels, tablets, powders, and liquids. Forms which may be perceived as food or confectionery, such as sweet, chewable outer shell with semi-solid or liquid core would not be appropriate as TM dosage forms.

3.2 TM shall not include any of the following:

a. Any product as a sole item of a meal or diet;
b. Any product that is defined otherwise in the legislation; and
c. Any preparation required to be sterile such as injections and eye drops.

3.3 Notwithstanding the above, the HSA reserves the right in determining the final product classification.

4. Safety and Quality Standards

4.1 Dealers (importers, manufacturers, wholesale dealers) and sellers have the obligation to ensure that their products are not harmful or unsafe, and that they conform with the applicable safety and quality standards.

4.2 TM MUST NOT contain the following:

a.	Substances listed in: i. Poisons Act 1938 & Poison Rules ii. Misuse of Drugs Act 1973 & its Regulations iii. ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Traditional Medicines
b.	Synthetic drugs
c.	Ingredients derived from human parts
d.	Substances that may affect the human health. The Guidelines for Establishing the Safety of Ingredients of Health Supplements and Traditional Medicines are available here.
e.	Ingredients that contain agents that can lead to animal-transmissible diseases such as Transmissible Spongiform Encephalopathy (TSE). The Guidelines on Minimising the Risk of TSE in Chinese Proprietary Medicines, Health Supplements & Traditional Medicines are available here.
f.	Ingredients regulated under the Endangered Species (Import & Export) Act, unless permitted. A Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) import permit is needed from NParks
g.	Active ingredients that are not stated in the label

4.3 TM must not exceed the following heavy metals, microbial, diethylene glycol and ethylene glycol limits as specified in **Tables 1, 2, 3 and 4**.

Table 1: Heavy Metals Limits

Heavy Metal	Quantity (by weight)
Arsenic	5 parts per million
Cadmium	0.3 parts per million
Lead	10 parts per million
Mercury	0.5 parts per million

Table 2: Microbial Limits

Microbe	Quantity (colony-forming units (CFU)) per g or ml of product
Total aerobic microbial count:	Not more than 10^5
Yeast and mould count:	Not more than 5 x 10^2
Escherichia coli, Salmonellae and *Staphylococcus aureus*:	Absent

Table 3: Microbial Limits for Topical Use Products

Microbe	Quantity (colony-forming units (CFU)) per g or ml of product
Total aerobic microbial count:	Not more than 10^4
Yeast and mould count:	Not more than 5 x 10^2
Pseudomonas aeruginosa and *Staphylococcus aureus*:	Absent

Table 4: Diethylene Glycol and Ethylene Glycol Limits

Substance	Quantity (by weight)
Diethylene glycol	1000 parts per million
Ethylene glycol	1000 parts per million

The above limits for diethylene glycol and ethylene glycol are applicable to oral liquid preparations.

4.4 Dealers should perform routine testing on the finished products in accordance with HSA's Guidelines on Testing Requirements of Health Supplements and Traditional Medicines, to ensure that the products meet appropriate safety and quality standards. Dealers are to refer to the Guidelines for Testing Requirements of Health Supplements and Traditional Medicines for more information.

4.5 The physical test parameters for the different dosage forms of the finished products should also be monitored to ensure they consistently meet the required standards throughout the product life cycle. Dealers are to refer to the Guidelines for Physical Test Parameters Based on Dosage Forms of Health Supplements and Traditional Medicines for more information.

4.6 Dealers should ensure that the ingredient and finished product manufacturers comply with the manufacturing standards recommended in the Guidelines for Manufacturing Standards of Health Supplements and Traditional Medicines, such as compliance with the principles of quality system, personnel, equipment, sanitation, hygiene, production, quality control, complaint handling, product recalls, and oversight of outsourced activities.

4.7 Dealers should hold product-related information and documents, including the following:

a. Name of manufacturer and country of manufacture of each ingredient used in the product
b. Name of manufacturer and country of manufacture of the finished product
c. Certificate of analysis (including appropriate test parameters, their specifications and test method references) for each active ingredient used in the finished product
d. Product specification and certificate of analysis for every batch of finished product
e. Product distribution records
f. Records of reported adverse events, product defects, and product recalls

5. Product Label Information

5.1 The product label should be prominently displayed on the product. The information on the product label should be adequate and truthful to enable consumers to make informed decisions and use the product correctly. Dealers are to refer to the Guidelines for Labelling Standards of Health Supplements and Traditional Medicines for more information.

6. Traditional Medicines Claims

6.1 A claim refers to any message or representation made on a product in relation to its indications, benefits or action. Claims may be stated directly or inferred indirectly through, but not limited to, the following:

a. Product label
b. Advertisements
c. Point of sales materials
d. Product brochures

6.2 In general, the claims made must be consistent with the definition of TM. The claims made should be:

a. Limited to supporting and enhancing health
b. For managing or symptomatic relief of non-serious medical conditions, e.g. cough, cold, diarrhoea; and
c. Not directly or indirectly referring to the prevention, alleviation, treatment or cure of any of the 19 diseases or conditions specified in the First Schedule of Medicines Act

6.4 Claims for TM must be in line with the respective TM principles (such as Jamu, Ayurvedic Medicine) and supported by adequate evidence from TM-based references.

6.5 Dealers are to refer to the Guidelines for Claims and Claims Substantiation of Health Supplements and Traditional Medicines for more information including the general claim principles available here.

7. Medical Advertisements and Sales Promotion Control

7.1 TM are subject to medical advertisements and sales promotion permit control. A valid advertisement and sales promotion permit is required before publishing any medical advertisements or conducting any sales promotion activities directed to the general public.

7.2 Dealers are to refer to the advertisements and promotion guidelines for more information on what is required before you run any advertisements and promotions for your products.

8. Product and Dealer Licensing Control

8.1 Currently, TM are not subject to premarket approval and licensing by HSA for their importation, manufacture and sales in Singapore.

8.2 Dealers (importers, manufacturers, wholesale dealers) and sellers have the obligation to ensure that their products are not harmful or unsafe, and that they conform with the applicable quality standards.

References

1. ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Traditional Medicines

Revision History

Version	Date of publication	Summary of changes*
1	March 2022	New document
2	November 2024	Added diethylene glycol and ethylene glycol limits

*Editorial changes are not reflected

HEALTH SCIENCES AUTHORITY

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