Guidance for Industry

Frequently Asked Questions about

ASEAN Guidelines on Claims and Claims Substantiation for

Traditional Medicines (Version 2.0) and ASEAN Guidelines on Claims and

Claims Substantiation for Health Supplements (Version 2.0)

Introduction

This document is a collation of Questions and Answers (Q&As) that provide clarifications and references that may be referred to by the industry in order to have a better understanding of the ASEAN guidelines. It is developed by HSA based on discussions between HSA and the industry experts.

Industry may refer to it for products intended for the Singapore market. For products to be marketed in other ASEAN Member States, the industry is advised to refer to the regulatory guidelines provided by the regulatory authorities of the respective AMS where your product is exported to.

This document may be revised from time to time, to include new Q&As or to update the information if there are changes made to the ASEAN guidelines.

Questions & Answers

1. What are Traditional Medicines (TM)?

Traditional Medicines (TM) refer to any medicinal products for human use consisting of active ingredients derived from natural sources (plants, animals and/or minerals) used in the system of traditional Chinese or Indian medicinal practice or Jamu theory. They shall not include any preparations that needs to be sterile (e.g. eye drops, injectable), vaccines, any substances derived from human parts, any isolated and characterised chemical substances.

2. What are Health Supplements (HS)?

Health Supplements (HS) refer to any products that are used to supplement a diet and to maintain, enhance and improve the healthy function of the human body and contain 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).

3. What is the definition of a TM or HS claim?

A claim refers to any message that states, suggests or implies that an ingredient/product has positive contribution and benefit to human health.

4. What is the difference between the 3 different types of TM claims (Traditional Health Use, Traditional Treatment and Scientifically Established Treatment)?

Traditional Health Use claims are claims that refer to general health maintenance or enhancement such as 'Tonic traditionally used to strengthen body by nourishing blood and invigorating vital energy'.

Traditional Treatment claims are claims that refer to the relief of a symptom or treatment of a disease or medical condition according to the principles of traditional medicine. It can also refer to claims to prevent/stop/slow down the progress of a mild or self-limiting disease or medical condition based on principles of traditional medicine, such as 'traditionally used to relieve cold and sore throat'.

Scientifically Established Treatment claims are claims that refer to the relief of a symptom or treatment of a disease or medical condition, that are substantiated by scientific evidence and are corroborated by TM principles. The use of such claims is to be determined by HSA.

In addition, TM claims may not stipulate any of the 19 diseases/conditions specified in the First Schedule of the Medicines Act, namely blindness, cancer, cataract, drug addiction, deafness, diabetes, epilepsy or fits, hypertension, insanity, kidney diseases, leprosy, menstrual disorders, paralysis, tuberculosis, sexual function, infertility, impotency, frigidity, conception and pregnancy.

5. What is the data required for substantiating a Traditional Health Use or Traditional Treatment TM claim?

Evidence of documented traditional use or history of use that may be found in the following:

- Classical TM Texts (e.g. The Chinese Herbal Medicine Materia Medica《本草纲目》)
- Recognised Pharmacopoeias and Monographs
- Reference Textbooks/Journals

6. What is considered as a well-documented Traditional Health Use or Traditional Treatment TM claim?

A well-documented TM claim is one that is documented in the TM references in accordance with accepted TM principles and practice.

7. What is the difference between the 3 types of HS claims (General/Nutritional Claims, Functional Claims, Disease Risk Reduction Claims)?

General or Nutritional Claims are claims that refer to supporting general health due to benefits derived from supplementation beyond a person's daily dietary intake, such as 'helps to maintain good health'.

Functional Claims are claims relating to the improvement of the body's structure or function to modify or preserve health status, but do not include disease related claims. Examples of such claims are 'promotes healthy skin', 'maintain/support alertness'.

Functional Claims also include claims to relieve/reduce/lessen/ease minor body discomforts in some physiological processes (such as ageing, menopause, pregnancy), but do not include disease-related claims. Examples of functional claims are 'helps to

relieve post-menopausal discomforts', 'support health in ageing'. The use of such claims is to be determined by HSA.

Disease Risk Reduction Claims relate to significantly altering or reducing a risk factor of a disease or health related condition such as 'reduce risk of osteoporosis', 'reduce risk of dyslipidaemia'. The use of disease risk reduction claims is to be determined by the regulatory authority of each ASEAN Member State. Currently, Disease Risk Reduction claims are not allowed for HS in Singapore.

8. What is the data required for substantiating a General/Nutritional HS claim?

At least 1 of the following evidence:

- Authoritative reference texts e.g. reference textbooks, pharmacopoeias, monographs and scientific journals
- Scientific opinion from scientific organisations
- Scientific opinion from regulatory authorities
- Documented history of use e.g. classical texts, published document from scholar or expert

9. What Is the data required for substantiating a Functional HS claim?

At least 1 of the following evidence:

- Good quality scientific evidence from human studies. In case the endpoint of a human study is not feasible, a surrogate endpoint can be used.
- Authoritative reference texts e.g. reference textbooks, pharmacopoeias, monographs
- Scientific opinion from scientific organisations
- Scientific opinion from regulatory authorities

At least 1 additional evidence:

- Scientific evidence from animal studies
- Documented history of use (e.g. classical texts, published document from scholar or expert)
- Evidence from published scientific review

The total available published and/or unpublished scientific data should be summarised as part of the substantiation documentation. It should contain the following information:
(a) Product/Ingredient Studied
(b) Intended Use
(c) Type of Claim
(d) Dosage and Administration
(e) Type of Study (e.g. Human or Animal)
(f) Study Design (e.g. Observation or Experimental)
(g) Study population
(h) Duration of the Study
(i) Study End points
(j) Limitation of the Study
(k) Study Results
(l) Source of Evidence (Author, Title, Publication Details, Type)
(m) Other information, if any (e.g. Ethics Committee approval)

In addition, summary of empirical or historical data shall be submitted. Raw data should be submitted when required by HSA.

10. What are the criteria to consider a claim as a well-documented General/Nutritional HS claim?

The claim is:

- Related to human health and in line with scientific or traditional knowledge;
- Documented in authoritative reference texts;
- Recognised by reputable or international organisations or regulatory authorities; and
- Adheres to the key principles of ASEAN HS claims.

For a HS making a nutritional claim based on a vitamin and/or mineral, it is recommended to contain a minimum of 15% Codex NRV (Nutrient Reference Value) per daily dose of the vitamin and/or mineral to qualify it being the source of that vitamin or mineral, or as determined by HSA.

11. What are the criteria to consider a claim as a well-documented Functional HS claim?

The claim is:

- In line with established knowledge on nutrition and physiology;
- Documented in authoritative reference texts;
- Recognised by reputable or international organisations or regulatory authorities; and
- Adheres to the key principles of ASEAN TM/HS claims.

For a HS making a functional claim based on a vitamin and/or mineral, it is recommended to contain a minimum of 15% Codex NRV (Nutrient Reference Value) per daily dose of the vitamin and/or mineral to qualify it being the source of that vitamin or mineral, or as determined by HSA.

12. How does evidence required for substantiating the HS claims (General/Nutritional claims, Functional Claims, Disease Risk Reduction Claims) differ?

There is a proportional degree of supporting evidence corresponding to the type of HS claims. The evidence for Functional Claim is stronger than that required for General/Nutritional Claim. In turn the Disease Risk Reduction Claims will require proportionally stronger scientific support than Functional Claims.

13. How extensive should the review of the available scientific data be? Can it be focused only on evidence that supports the claims?

The totality of the evidence to the HS claims is important. All relevant scientific evidence relating to the claimed benefit of the product or ingredient should be reviewed. The review should not focus only on evidence that supports the claimed effect.

Scientific substantiation should demonstrate a consistent beneficial effect of the product or ingredient on specific health aspects or recognised biomarkers based on totality of scientific evidence.

14. Can we provide animal studies if human experimental studies are unethical for HS claims?

Results from animal studies may be provided. However, other epidemiological studies data or other scientific literature and documented traditional use must be provided as well.

15. Can scientific data on ingredient(s) be used to substantiate the Scientifically Established Treatment claim of a TM?

For Scientifically Established Treatment claim, scientific data conducted on the finished product should be submitted. Justification must be provided to the regulatory authority if evidence provided is based on ingredient.

16. Can the claims of a product be solely based on the benefit/efficacy of the active ingredient(s) in the product and can a company make more than one claim for each active ingredient in the product, assuming every claim is adequately substantiated by evidence?

HS claim substantiation should be based on the finished product. If it is based on the ingredient(s) in the product, justification (e.g. rationale of the combination) should be provided to HSA when required.

17. What are some of the prohibited HS claims? Is there a prescribed list of diseases that cannot be mentioned in Disease Risk Reduction claims for HS?

HS claims are not allowed to imply treatment, cure or prevention of all diseases or medical conditions, including directly or indirect claim relating to any of the 19 diseases/conditions specified in the First Schedule of the Medicines Act, namely blindness, cancer, cataract, drug addiction, deafness, diabetes, epilepsy or fits, hypertension, insanity, kidney diseases, leprosy, menstrual disorders, paralysis, tuberculosis, sexual function, infertility, impotency, frigidity, conception and pregnancy.

Currently, Disease Risk Reduction claims are not allowed for Health Supplements in Singapore.