

HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

JULY 2022

GUIDELINES FOR CLAIMS AND CLAIMS SUBSTANTIATION 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.



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1. Introduction

- 1.1 Dealers of Health Supplements (HS) and Traditional Medicines (TM) are required to ensure that health claims made for their products are consistent with the definition of a HS or TM respectively and are substantiated with evidence.
- 1.2 The objective of these guidelines is to provide guidance on the health claims that are allowed for use in HS and TM in Singapore, as well as the evidence that is required to substantiate these claims.

2. Health Supplement and Traditional Medicine Claims

- 2.1 A health claim refers to any message or representation in relation to its indications, health benefits or action. Claims may be stated through, but not limited to, the following:
 - product label
 - advertisements
 - point of sales materials
 - product brochures

Health claims made must be consistent with the definition of a HS or TM respectively.

Criteria for Claims

- 2.2 Health claims in HS should be limited to supporting or enhancing general health, or a function or biological activity of the body. They must not be labelled, advertised or promoted for the diagnosis, prevention, alleviation, treatment or cure, implied or otherwise, of any disease, disorder, or medical condition.
 - Some examples are support healthy growth and development, relieve fatigue/tiredness, support/maintain joint mobility/flexibility and support/maintain immune health.
 - Vitamin and/or mineral supplementation claims are permitted only when the relevant vitamin and mineral used in the product contains at least 15% of the Codex Nutrient Reference Values (NRVs) published by Codex Alimentarius or local Recommended Dietary Allowance¹ (RDA) values published by the Health Promotion Board, per daily dose of the vitamin and/or mineral.
- 2.3 The health claims in TM should be:
 - limited to supporting and enhancing health;
 - for managing or symptomatic relief of non-serious medical conditions, e.g. cough, cold, diarrhoea; and

¹Health Promotion Board Recommended Dietary Allowances for Normal Healthy Persons in Singapore (Adults) (https://www.healthhub.sg/live-healthy/192/recommended_dietary_allowances)

- 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.

3. Substantiation Requirements for Claims

- 3.1 All health claims must be substantiated by evidence that is relevant to the claims. Evidence may be based on finished products. If such evidence is not available, evidence based on ingredients may be used. The evidence should be held by the dealer at all times and provided to HSA when requested. HSA may request for justification if it is not clear how the evidence is related to the claims on the product.
- 3.2 The substantiating evidence could be based on the information listed in Table 1 below. TM claims must be in line with the respective TM principles (such as Jamu, Ayurvedic Medicine) and supported by adequate evidence from TM-based references.

Table 1: Substantiation Evidence for Health Claims

| Literature and Regulatory Evidence for General, Functional and Traditional Treatment Health Claims |
|--|
| <ul style="list-style-type: none"> • Literature references supporting health use: <ul style="list-style-type: none"> ▪ European Scientific Cooperative on Phytotherapy Monographs for Herbal Medicinal Plants ▪ The Complete German Commission E Monographs ▪ Indian Materia Medica ▪ Handbook of Ayurvedic Medicinal Plants ▪ British Pharmacopoeia ▪ British Herbal Pharmacopoeia ▪ Chinese Pharmacopoeia ▪ European Pharmacopoeia ▪ United States Pharmacopeia ▪ World Health Organisation's Monographs on Selected Medicinal Plants ▪ Dictionary of Chinese Pharmacy <中药大辞典> • Product monograph or assessment from the following regulatory authorities or scientific bodies/institutions: <ul style="list-style-type: none"> ▪ European Food Safety Authority ▪ Health Canada ▪ Therapeutic Goods Administration ▪ FDA Significant Scientific Assessments on Authorised Health Claims |

- 3.3 If the evidence based on published references is not available for claims relating to general, functional and traditional treatment claims, scientific evidence from human studies may be used. Scientific data could be derived from observational or interventional human studies that are well-designed in accordance with recognised scientific principles. The acceptable principles for human studies can be referenced from internationally accepted guidelines, for example, International Conference on Harmonisation - Good Clinical Practice Guidelines.

- 3.4 Information from open internet sources such as Google, WebMD, Wikipedia, 百度百科, product websites and blogs, personal testimonials or endorsements, and solely animal or in-vitro studies would not be considered as acceptable evidence to substantiate claims.

Other Claims and Labelling Requirements

- 3.5 TM can make claims on symptomatic relief for non-serious medical conditions. To ensure consumers do not delay in seeking appropriate treatment should their symptoms persist, TM with claims on symptomatic relief of non-serious medical conditions (e.g. cough, cold, diarrhoea) would be required to include the statement “If symptoms persist, talk to your healthcare professional” on the product label.
- 3.6 Dealers of HS and TM products must ensure that they meet the labelling requirements as laid out in the [Guidelines for Labelling Requirements for HS and TM](#).

4. List of Health Supplement and Traditional Medicine Claims

- 4.1 The Health Sciences Authority (HSA) has compiled a comprehensive list of health claims allowed for use in HS and TM, that can be accessed from this link: https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chpb-tmhs/tmhs_claims_list.pdf. These claims are referenced from overseas regulatory agencies that have been assessed to be substantiated by documented evidence.
- 4.2 The same wording of the claim(s) should be reflected on the product label. However, variations to the wordings used can be accepted, as detailed below.

Acceptable Variations for Claims

- 4.3 In general, all health claims have an action and a target. The action describes the effect of the ingredient or product, while the target is either a function, biological activity, physiological process or a non-serious medical condition.

Examples of ‘action’: support, improve, help, relieve

Examples of ‘target’: immune system, joint health, blood circulation, cough/cold

- 4.4 Dealers may use action variants for the health claims stated in the list of TM and HS claims, provided the criteria for claims are adhered to and the claim can be supported by evidence. Acceptable action variants are listed below:

- Aid/assist/help
- Maintain/support/contribute to
- Nourish/supplement
- Tonify
- Decrease/reduce/relieve

- Increase/enhance/improve/promote
- 4.5 The use of variants must not change the intended meaning of the claim. The claim must still be consistent with the scope of a HS or TM. Should the qualifier “may” be used in health claims, dealers should ensure that evidence is held to substantiate the health claim made accordingly.

Examples of Permitted and Not Permitted Action Variants

| Claim | Variation |
|----------------------------|--|
| Support healthy libido | ✓ Promote healthy libido ✗ Increase libido |
| Support hormone production | ✗ Enhance hormone production |
| Support blood sugar levels | ✓ Maintain blood sugar levels in healthy adults ✗ Reduce blood sugar levels |
| Relieve symptoms of cold | ✓ Traditionally used to decrease/reduce symptoms of cold |

- 4.6 Terms that qualify the scope of the action or target for a specific period or population may be included as qualifiers, to provide context to the said claim.

Examples of Qualifiers

| | |
|--|--|
| Qualifier (Degree) | Mild, symptoms of, general |
| Qualifier (Period) | Temporarily, short-term use, for the duration of |
| Qualifier (Population) | Healthy adults, infants, children, elderly |
| Qualifier (Traditional context for TM) | Traditionally used to |

Addition of New Claims

- 4.7 Dealers can submit a request to HSA for new claims to be added to the existing list of HS and TM claims using this [form](#). Dealers are to ensure that the proposed new claim meets the Criteria for Claims stated in paragraph 2.2 and 2.3 above. Dealers may refer to [Appendix 1](#), the Health Claims Assessment Checklist, for self-assessment to ensure that the new claim they wish to submit for inclusion into the list is suitable and meets the criteria for claims. Dealers would have to submit the substantiation evidence as laid out in Table 1 above and the completed [Appendix 1](#), for review by HSA.

5. General Principles for Claims

- 5.1 The following reflects general principles that must be adhered to so that product claims do not convey misleading messages that could lead to inappropriate use of the product or bring about undue harm to the public.

5.1.1 Truthfulness

All claims should truthfully state the nature, quality and properties of the HS or TM. Claims on any product materials, including packaging and advertisements, should not mislead in any way by ambiguity, exaggeration, omission or otherwise imply that the product has properties and benefits beyond that of a HS or TM. Unqualified superlatives must not be used.

Claims in the form of slogans, taglines, headlines, which, because of brevity or for any other reason, are capable of being misinterpreted; and may mislead as to the nature, quality and properties of the HS or TM and therefore should be avoided.

5.1.2 Use of Scientific Data

Dealers should not use information such as research results or extract partial out-of-context quotations from technical and scientific publications to imply a greater validity than the product can provide for the general population.

The use of terms such as “Proven by Clinical Trials” and “Clinically Proven” for HS and TM are not allowed if there is an implied claim to treatment efficacy in relation to disease or an adverse condition or that the product has met the appropriate efficacy test in relation to a disease or an adverse condition.

5.1.3 Endorsements from Healthcare Professionals

Product should not be labelled, advertised or promoted to give the impression that the claims represent advice or recommendations from healthcare professionals.

5.1.4 Testimonials

Testimonials by healthcare professionals should not be used on the product label, advertisement or promotion of the product.

Product materials, including labels and advertisements, should not contain recommendations or endorsement from celebrity figures, or give the impression of advice or support from a celebrity.

If testimonials are used, they must be current, genuine, authenticated, for example, via signed testimonials. Dealers must also hold substantiation that such testimonials reflect the typical experience of the ordinary user. Testimonials that are of exceptional experiences (i.e. which do not reflect the experience that an average user of the product would ordinarily expect to have) should not be used.

5.1.5 Claims related to Traditional Use

HS should not be labelled, advertised or promoted in such a way that potentially misleads the general public into believing that the product relates to any traditional healing paradigm, such as being a TM, when it is not intended as a TM.

5.1.6 **Logos, Initials and Trademarks**

It is the responsibility of companies to ensure they have the permission of the firm, company or institution prior to using the names, initials, logos or trade service marks from the concerned firm, company or institution on their product label, advertisements and promotional materials. The names and logos of the Health Sciences Authority and any of its professional groups must not be used for any HS or TM product materials including label, packaging, advertisement and sales promotion in any media (print, sound and light & sound).

5.1.7 **Discourage from Seeking of Medical Advice or Appropriate Use of Medication**

Claims on label, advertisement or promotion should not in any way create an impression that the public need not seek the advice of a medical professional or replace medication prescribed by their medical doctor.

5.1.8 **Exploitation of Fear**

Claims on label, advertisement or promotion should not arouse fear in the minds of the public nor should they exploit the public's superstition.

5.1.9 **Definitive Efficacy, Superiority or Safety**

The product must not contain any implication that it is infallible, unailing, magical, miraculous, or that it guarantees definitive efficacy or safety. It should also not claim that there are no side effects or is effective in all cases or situations. The claims must not imply superiority over therapeutic drugs or medication or encourage indiscriminate, unnecessary or excessive use of the product.

There should not be any words, phrases, or illustrations which claim or imply the product has no adverse effects; 100% safe or suggest that the safety of the product is the result of it being a "natural product".

5.1.10 **Substitution of a Proper Diet or Lifestyle**

The claims must not cast doubt on the nutritional properties of food. They must not imply that a balanced and varied diet cannot provide adequate quantities of nutrients, which can only be obtained from supplementation with health products. It should also not imply that consumption of the product can substitute a healthy lifestyle.

5.1.11 **Reference to Stress**

Claims should not imply that the use of a particular HS or TM helps to prevent/reduce the stress of modern living, which may be caused by external events or situations, or personal attitudes or expectations. However, a health product may assist in the management of stress, such as by means of providing nutritional support.

5.1.12 **Reference to Performance in Studies**

Claims should not imply that the consumption of a particular HS or TM can improve performance in studies, make a person smarter or improve one's IQ.

5.1.13 Reference to Anti-aging

There should not be any direct or indirect suggestion that a particular HS or TM can prevent, retard or reverse the physiological changes and degenerative conditions brought about by or associated with aging.

5.1.14 Reference to Sexual Function

There should not be any direct or indirect suggestion that a HS or TM can improve, increase or manage sexual virility or manage conditions related to sexual dysfunction, such as premature ejaculation and erectile dysfunction.

5.1.15 Reference to Hormonal Levels

There must not be any claims that a product can increase, decrease, balance or manage hormone levels or its production. The general public would not be aware of their hormonal levels and their appropriate levels. Increasing or decreasing hormone levels above or below the specific individual's requirements can have undesirable health effects. The management of hormonal levels should be under the supervision of medical professionals.

5.1.16 Reference to Reduction or Management of Blood Sugar Levels

There must not be any direct or indirect suggestion that a product can lower or raise blood sugar or glucose levels outside the normal healthy range in an individual. The product must also not make reference to use in pre-diabetic or diabetic individuals, or those predisposed to this condition. It should not refer to blood sugar biomarker terminology such as insulin or HbA1C, which cannot be well-understood by the general public.

5.1.17 Language

Claims should be written in simple-to-understand language. The use of confusing jargons and scientific terms should be avoided. Examples of such terms would be “nanoclusters” and “pharmaceutical grade”.

Product names, in the context of the other claims, may collectively infer the use of the product for a purpose to prevent, manage, treat a disease or condition e.g. GlucoTreat and CholCure. Such product names should not be used.

5.1.18 Conformance with SCAP

The Singapore Code of Advertising Practice (SCAP) regulates all local advertising activities. It is administered by the Advertising Standards Authority of Singapore Council for Consumers Association of Singapore. All HS and TM advertisements must also comply with the SCAP guidelines, where applicable.

6. References

- 6.1 ASEAN Guidelines on Claims and Claims Substantiation for Health Supplements
- 6.2 ASEAN Guidelines on Claims and Claims Substantiation for Traditional Medicines
- 6.3 European Food Safety Authority - Register of Nutrition and Health Authorised Claims
- 6.4 Health Canada – Natural Health Product Ingredient Monographs
- 6.5 Singapore Food Agency – A Guide to Food Labelling and Advertisements
- 6.6 Therapeutic Goods Administration – Permitted Indications for Listed Medicines Guidance and Permissible Indications List

Appendix 1

Health Claims Assessment Checklist

Please choose the appropriate response to the questions/statements based on your proposed health claim.

| Questions | Yes | No |
|--|-----|----|
| 1. Does the claim contain an action, e.g. support, aid, relieve? | | |
| 2. Does the claim contain a target, e.g. joint health, cough/cold? | | |
| 3. Is the claim pertaining to the use of the product in humans only? | | |
| 4. The claim does not directly or indirectly refer to any of the 19 diseases or conditions stated in the Medicines Act. | | |
| 5. Is the claim for one of the following: <ul style="list-style-type: none"> • Supporting/enhancing health? • Supporting/enhancing physiological function/ biological activity in the human body? • Managing symptomatic relief of non-serious medical conditions, e.g. cough, cold, diarrhoea? | | |
| 6. <u>For HS only</u> The claim does not directly or indirectly imply use for a specific medicinal purpose, i.e. the treatment or prevention or any disease or disorder, including its related conditions. | | |
| 7. <u>For TM only</u> If the claim is referring to a disease or condition, is the disease or condition self-diagnosable or self-manageable such that it does not require regular supervision by a medical professional? | | |
| 8. Is the phrasing of the claim consistent with the relevant paradigm (scientific or traditional use) of the product? | | |
| 9. Can the claim be substantiated with the required evidence based on Table 1 above? | | |
| 10. Is the claim truthful and not misleading the consumer in any way, based on the General Principles for Claims listed in Section 5 above? | | |
| If you have responded with a NO to any of the questions or statements numbered 1 to 10, the claim is NOT SUITABLE for use as a health claim in a HS or TM. You may wish to reassess the information related to the claim before going through the checklist again. | | |

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