

# HEALTH SCIENCES AUTHORITY

## REGULATORY GUIDANCE

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# HEALTH SUPPLEMENTS GUIDELINES

The information in this 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](http://www.hsa.gov.sg).



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## Introduction

These guidelines provide regulatory information for companies dealing with health supplements 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.

## Legislation

2. The current legislative control that may apply to health supplements may be found in the following legislation:

- A. Medicines Act (Chapter 176) & its Subsidiary Legislation especially:
  - i. Medicines (Prohibition of Sale & Supply) Order;
  - ii. Medicines (Traditional Medicines, Homoeopathic Medicines and Other Substances) (Exemption) Order;
  - iii. Medicines (Non-Medicinal Products) (Consolidation) Order;
  - iv. Medicines (Labelling) Regulations;
  - v. Medicines (Medical Advertisements) Regulations;
  - vi. Medicines (Licensing, Standard Provisions & Fees) Regulations
- B. Medicines (Advertisement & Sale) Act (Chapter 177)
- C. Sale of Drugs Act (Chapter 282) & its Regulations especially:
  - i. Sale of Drugs (Prohibited Substances) Regulations;
  - ii. Sale of Drugs (Prohibited Drugs) (Consolidation) Regulations;
  - iii. Sale of Drugs (Rhodamine B) Regulations 1993
- D. Poisons Act (Chapter 234) & Poisons Rules.

## Working Definition

3. A working definition of health supplements is described below:

Products that are used to supplement a diet, with benefits beyond those of normal nutrients, and / or to support or maintain the healthy functions of the human body.

Health supplements contain one or more, or a combination of the following ingredients:

- a. Vitamins, minerals, amino acids (natural and synthetic);
- b. Substances derived from natural sources, including non-human animal and botanical materials in the forms of extracts, isolates, concentrates; and
- c. Are presented in any of the following dosage forms to be administered in small unit doses: e.g. capsules, softgels, tablets, liquids, syrups, and any other dosage forms deemed suitable by the HSA.

4. Exceptions: Health supplements shall not include any of the following:
- Any product as a sole item of a meal or diet;
  - Any product that is defined otherwise in the legislation; and
  - Any preparation required to be sterile such as injections and eye drops.
5. Notwithstanding the above, the HSA reserves the right in determining the final product classification.

## Safety & Quality of Health Supplements

6. 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.
7. Additionally, Health supplements MUST NOT contain the following:

i)	Substances listed in: <ul style="list-style-type: none"> <li><a href="#">Poisons Act (Chapter 234) &amp; Poison Rules</a></li> <li><a href="#">Sale of Drugs Act (Chapter 282) &amp; its Regulations</a></li> <li><a href="#">Misuse of Drugs Act (Chapter 185) &amp; its Regulations</a></li> <li><a href="#">ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Health Supplements</a></li> </ul>
ii)	Ingredients derived from human parts
iii)	Ingredients that may affect the human health (see Annex A)
iv)	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 are available at: <ul style="list-style-type: none"> <li><a href="https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/tse-guidelines.pdf">https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/tse-guidelines.pdf</a></li> </ul>
v)	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
vi)	Active ingredients that are not stated in the label
vii)	Active ingredients documented to have inherent pharmacological properties that could lead to the use of the substance for a medicinal purpose of treatment or prevention of any disease or disorder, including its related conditions

In addition, dealers are encouraged to take note of the list of ingredients highlighted in Annex B that have been reported to have potential to affect the health of some individuals.

## **SAFETY AND QUALITY STANDARDS**

8. The safety and quality standards for health supplements include heavy metals and microbial limits as specified in the following tables.

**Table 1: Heavy Metals Limits**

<b>Heavy Metal</b>	<b>Quantity (by weight)</b>
1. Arsenic	5 parts per million
2. Copper	150 parts per million
3. Lead	20 parts per million
4. Mercury	0.5 parts per million

Revised limits have been implemented on 1 September 2019 for new products, and on 1 September 2020 for existing products.

<b>Heavy Metal</b>	<b>Quantity (by weight)</b>
1. Arsenic	5 parts per million
2. Cadmium	0.3 parts per million
3. Lead	10 parts per million
4. Mercury	0.5 parts per million

**Table 2: Microbial Limits**

<b>Microbe</b>	<b>Quantity (colony-forming units (CFU)) per g or ml of product</b>
Total aerobic microbial count:	Not more than $10^5$
Yeast and mould count:	Not more than $5 \times 10^2$
<i>Escherichia coli</i> , <i>Salmonellae</i> and <i>Staphylococcus aureus</i> :	Absent

The above limits for total aerobic microbial count, and yeast and mould may not be applicable to certain products such as probiotics or products derived from fermentation processes.

9. Notwithstanding the limits stated above, it is the responsibility of the dealers and sellers to ensure that the limits of microbial content and heavy metals of the product are appropriate and safe when used according to the recommended conditions of use and target users. Dealers are encouraged to comply to the ASEAN Guidelines on Limit of Contaminants for Health Supplements for heavy metals and microbial limits. Companies who wish to take reference from the ASEAN technical guidelines can refer to the applicable guidelines at: <http://asean.org/asean-economic-community/sectoral-bodies-under-the-purview-of-aem/standards-and-conformance/policy-and-guidelines>
10. In addition, the product should be of acceptable standards of quality in terms of product stability, adequacy of shelf-life period, proper packaging and labeling; and are manufactured and/or assembled under proper conditions.

**VITAMINS AND MINERALS LIMITS**

11. Health supplements for use by the general adult population should not contain vitamins and minerals exceeding the stipulated limits stated in **Table 3 and 4.**

**Table 3: Vitamins Limits**

<b>Nutrient</b>	<b>Maximum Daily Limit</b>
Biotin	0.9mg
Folic acid	0.9mg
Nicotinic Acid	15mg
Nicotinamide	450mg
Vitamin A (Retinol)	1.5mg (5000IU)
Vitamin B1	100mg
Vitamin B2	40mg
Vitamin B5 (Pantothenic acid)	200mg
Vitamin B6	100mg
Vitamin B12	0.6mg
Vitamin C	1000mg
Vitamin D	0.025mg (1000IU)
Vitamin E	536mg (800IU)
Vitamin K1 / K2	0.12mg

**Table 4: Minerals Limits**

<b>Nutrient</b>	<b>Maximum Daily Limit</b>
Boron	6.4 mg
Calcium	1200 mg
Chromium	0.5 mg
Copper	2 mg
Iodine	0.15 mg
Iron	15 mg*
Magnesium	350 mg
Manganese	3.5 mg
Molybdenum	0.36 mg
Phosphorus	800 mg
Selenium	0.2 mg
Zinc	15 mg

\*For multivitamin and mineral supplements for pregnant women, a higher iron limit of 30mg/day may be considered.

12. Higher levels of vitamins and minerals in health supplements for use in specific adult population groups that require higher levels of supplementation must be justified with:

- Credible authoritative references or expert opinion to show that supplementation over and above the established limits for the general adult population is needed
- Medical professional's assessment and recommendation on specific patient's additional supplementation needs

13. Product intended for supplementation in patients with specific condition should be labelled with statements indicating:
- the product must be used under recommendation by healthcare professionals
  - the product poses a health hazard when consumed by persons who do not have the conditions for which the product is intended
14. Examples of supplements intended for specific adult population groups that require higher levels of supplementation are:
- **Zinc** for patients with wounds or metabolic conditions
  - **Vitamin B2** for patients with certain genetic or metabolic disorders
  - **Folic acid** for pregnant women to prevent against recurrence of neural tube defects or for patients with folic acid deficiency
  - **Iron** for patients with low blood haemoglobin level

## Product Label Information

15. The product label should be prominently displayed on the product. In the event that there is a limitation of label space when the product is packed in small containers such as unit dose sachets and blister strips, the product name, batch number and expiry date must be on the product. The full product information should be on an accompanied outer container such as an outer box.
16. The information on the product label should be adequate and truthful to enable consumers to make informed decisions and use the product correctly. The information must be in English and must be printed in a clear and legible manner. Information that should be included in the product label are shown in **Table 5**.

**Table 5: Types of Information Useful to Enable Consumers to make Informed Decisions**

1.	Product name
2.	Names and quantities of all the active ingredients*
3.	Product indications/ Intended purpose
4.	Daily dosage
5.	Directions of use
6.	Pack Size
7.	Batch Number
8.	Expiry date (or "Use by", "Use before" or words with similar meaning)
9.	Cautionary label or statement, where necessary
10.	Name and address of the local manufacturer or local importer
11.	Name of the country of manufacture for imported products

\* It is recommended that internationally accepted nomenclature be used for ingredient names. For example, the name of plants or animals from which the active ingredient is derived should be declared in the scientific name followed by the plant or animal part and type of preparation where applicable. The use of the common name of the active ingredient is optional. Common or chemical names should be used for minerals.

# Health Supplements Claims Guidelines

## TYPES AND EVIDENCE OF CLAIMS FOR HEALTH SUPPLEMENTS

17. 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:
- Graphics or logos on product packaging
  - Product and/or brand name
  - Media advertisements (print, sound and light & sound)
  - Point of sales materials
  - Product brochures or information sheets distributed with/separately from the product.
18. In general, the claims made must be consistent with the definition of health supplements i.e. a product that is used to supplement a diet, with benefits beyond those of normal nutrients, and / or to support or maintain the healthy functions of the human body. The claims made should not imply that the product is necessary or play a role in diseased states.
19. Claims for health supplements should be substantiated by good quality evidence that is relevant to the claims. Evidence may be based on finished products or ingredient(s) if justifiable. The evidence used to substantiate claims should be based on authoritative references, documented history of use, scientific opinion from scientific organizations or regulatory authorities and good quality scientific evidence from human studies. It is the responsibility of dealers to hold evidence to support these claims, and provide the evidence to the Authority when required to do so.
20. Health supplements may make general health claims or functional health claims.

### A. General Health Claims

- General health claims refer to the general health benefits derived from supplementation beyond a person's daily dietary intake.
- Vitamin and/or mineral supplementation claims are permitted only when the relevant vitamin and mineral used in the product amounts to >30% the Recommended Dietary Allowances (RDA)\* value.

### B. Functional Health Claims

- Functional health claims refer to the health benefits relating to the positive contribution to a function or biological activity of the body.

Examples of general and functional health claims can be found in Annex C.

\*Recommended dietary allowance (RDA) may be based on approved local standards from Health Promotion Board (HPB) or authoritative international standards.

**PROHIBITED CLAIMS FOR HEALTH SUPPLEMENTS**

21. Health supplements must not be labelled, advertised or promoted for any specific medicinal purpose, i.e. treatment or prevention, implied or otherwise, of any disease or disorder, including its related conditions. A list of examples of prohibited diseases and disorders is provided in **Table 6**.

**Table 6: Examples of Diseases/Conditions/Disorders Not Allowed for Health Supplements**

<b>Body system / organs</b>	<b>Examples of related claims not allowed</b>
Circulatory system	Hypertension, stroke, cholesterol disorders, reduces cholesterol, regulates platelet aggregation, coagulation defects, arteriosclerosis
Eye, Ear, Nose	Blindness, cataract, deafness, inflammation
Digestive system	Periodontitis, ulcers, gastritis, hepatitis, liver cirrhosis, fatty liver, diarrhoea, constipation, inflammation of the intestines/liver/pancreas
Endocrine system	Diabetes, thyroid disorders, hypothyroidism, prostate diseases, thymus disorders, hormonal regulation
Metabolic system	Obesity
Respiratory system	Asthma, tuberculosis, bronchitis, sinusitis
Skin, Hair, Nails	Fungal infection, eczema, ulcers, warts, moles, pigmentation disorders
Immune system	Leprosy, AIDS, allergies, immunisation
Muscular, connective tissues and skeletal systems	Osteoporosis, arthritis, sclerosis, autoimmune diseases, sclerosis, inflammation of joints
Nervous system	Epilepsy, fits, paralysis, Alzheimer's disease, Parkinsonism, dementia, neuropathies, drug addictions, depression, eating disorders
Renal system	Kidney stones, renal failure, nephritis, urinary tract infection, incontinence, cystitis
Reproductive system	Menstrual disorders, sexual dysfunction, infertility, frigidity, impotency, conception, pregnancy
Others	Cancers, infectious diseases

The above list is not exhaustive and may be revised from time to time when new information is available.

## General Principles for Claims in Health Supplements

22. The following reflects the general principles and practices to be adopted 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.

### a) Truthfulness

All claims should truthfully state the nature, quality and properties of the health supplement. 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 health supplement. The mention of a disease in the advertisement for a health supplement implies that the product is a medicine and is thus prohibited. 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 health supplement should be avoided.

### b) Substantiation

All claims made should be substantiated. The literature should be of established sources, e.g. Martindale, peer-reviewed scientific journals.

### c) Endorsements and Testimonials from Healthcare Professionals

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

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

### d) Testimonials by Non-professionals

Product materials, including labels and advertisements, should not contain or refer to any testimonial or endorsement unless it is genuine and related to the personal experience of the party who provided the testimonial. The company should hold proof of identity of the party who provided the testimonial.

Traders should be able to show substantiation that such testimonials reflect the typical experience of ordinary users. 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.

Testimonials that are obsolete or otherwise no longer applicable should not be used.

### e) Claims related to Traditional Use

Product 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 traditional medicine, when it is not intended as a traditional medicine.

### f) Logos, Initials and Trademarks

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

**g) Discourage from Medical Advice**

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.

**h) 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.

**i) Reference to Stress**

Claims on label, advertisement or promotion should not claim that the use of a particular health supplement is needed to prevent/reduce the stress of modern living. Any reference to stress should be accompanied by an explanation of how a product may assist in stress management, such as by providing nutritional support, energizing etc.

**j) Reference to Performance in Studies**

Claims on label, advertisement or promotion should not imply that the consumption of a particular health supplement can improve performance in studies, make a person smarter, improve IQ or improve memory.

**k) Reference to Anti-aging**

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

**l) Reference to Sexual Function and Relationships**

There should not be any implication that a health supplement can induce sexual virility or manage sexual weakness or sexual excess and conditions such as premature ejaculation, erectile dysfunction.

Claims on label, advertisement or promotion should not imply that the use of a particular health supplement can affect one's love life or relationship with others.

**m) Reference to Consumption**

Product claims should refrain from encouraging indiscriminate, unnecessary or excessive use of the health supplement.

**n) Claims of Safety**

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".

**o) Use of Scientific Data**

The ignorance of the public should not be exploited by including scientific data that the general public cannot verify or validate. Traders should not misuse or

exaggerate research results or extract unnecessary quotations from technical and scientific publications to imply a greater validity than they really have such as with the use of exaggerated graphics or language.

The use of terms such as “Proven by Clinical Trials” and “Clinically Proven” for health supplements would be objectionable 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.

**p) Language**

Claims should be in simple-to-understand language. The use of confusing jargons and scientific terms should be avoided. Scientific terms should not be used to make claims appear to have a scientific basis they do not possess. Examples of such terms would be “nanoclusters”, “pharmaceutical grade”.

**q) 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 to the Consumers Association of Singapore. All health supplement advertisements must also comply with the SCAP guidelines.

23. The following is an illustrative list of objectionable terms and claims. The list is not exhaustive. It will be updated from time-to-time; as new information becomes available.

**Examples of Objectionable Terms and Claims**

Miraculously  
 The only product to use  
 World’s best  
 100% safe  
 No side effects  
 Guaranteed  
 Other drugs / products cannot compare with it  
 Sensational relief  
 The No. 1 (unless substantiated)  
 Efficacious/Effective  
 Perpetual youth  
 Anti-aging  
 Longevity  
 Anti-stress (unless qualified)  
 Breast enhancement, enlargement, growth  
 Height growth  
 Enhance intelligence / increase IQ  
 Increase / improve memory  
 Memory enhancement  
 Hormone releaser / enhancer / amplifier  
 Regulate hormones  
 Enhancement of sexual organs  
 Sexual powers  
 Arousal, libido  
 Prevent hangover

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

## **Medical Advertisements and Sales Promotion Control**

25. Vitamins and minerals as well as some other health supplements (e.g. St. John's Wort, melatonin products) are subject to medical advertisements and sales promotion permit control.

## **Product and Dealer Licensing Control**

26. Currently, health supplements are not subject to premarket approval and licensing by HSA for their importation, manufacture and sales in Singapore.
27. 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. To ensure that the product is of acceptable standards of quality, dealers should ensure that good practices in the manufacture, storage and distribution of health supplements are in place to ensure that the quality and integrity of the products are maintained throughout the supply chain.

**ANNEX A****List of Prohibited/Restricted Ingredients for Health Supplements**

- This list aims to highlight the substances of concern when used in health supplements and is not meant to be an exhaustive list. It may not be used as support or evidence in any disagreement or dispute pertaining to the legal classification of products or substances, or used to supersede or replace any of the legislations.
- Dealers are advised to refer to the legislations stated in Paragraph 7 of this guidelines for the full list of substances controlled under the legislations.
- In addition to the list of ingredients in this Annex A, reference should be made to those substances specified in the ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Health Supplements, which is available at: <http://asean.org/asean-economic-community/sectoral-bodies-under-the-purview-of-aem/standards-and-conformance/policy-and-guidelines/>.
- Dealers are responsible in ensuring that any other cautionary statements, for example the use of the product by pregnant women, children etc., are included on the label to guide the safe use of a product.

	<b>Ingredients</b>	<b>Constituent(s) of concern</b>	<b>Restrictions</b>
1.	<i>Aconitum napellus</i> (Monkshood, Aconite) Other spp: <i>A. carmichaeli</i> , <i>A. kusnezoffii</i> , <i>A. coreanum</i>	Aconite alkaloids	Not to be used in health supplements. Known to affect the heart and nervous system.
2.	<i>Adonis vernalis</i>	Cardiac glycosides e.g. adonitoxin	Not to be used in health supplements. Known to have adverse effects on the heart.
3.	Andarine	Andarine	Not to be used in health supplements. It is a synthetic chemical developed for use in medicines.
4.	<i>Aristolochia</i> spp	Aristolochic Acids	Not to be used in health supplements. Known to be cancer-causing and toxic to the liver.
5.	<i>Artemisia annua</i> (Quing Hao/Sweet Annie/Sweet Wormwood)	Artemisinin	Not to be used in health supplements. Use of this herb may lead to parasite resistance as it is also an anti-malaria treatment.
6.	<i>Atropa belladonna</i> (Deadly nightshade)	Atropine	Not to be used in health supplements. Known to have adverse effects on the nervous system.

	Ingredients	Constituent(s) of concern	Restrictions
7.	$\beta$ -phenyl- $\gamma$ -aminobutyric acid (Phenibut)	$\beta$ -phenyl- $\gamma$ -aminobutyric acid (Phenibut)	Not to be used in health supplements. It is a synthetic chemical with misuse risk.
8.	<i>Calotropis gigantea</i> , <i>C. procera</i>	Cardiac glycosides e.g. Calotropin	Not to be used in health supplements. Known to have adverse effects on the heart.
9.	<i>Catha edulis</i> (Khat)	Cathinone, Cathine	Not to be used in health supplements. Known to be addictive, has effects on the heart and central nervous system.
10.	Cannabidiol	Cannabidiol	Not to be used in health supplements. It is developed for use in medicines. Known to affect the mental state.
11.	Cardarine	Cardarine	Not to be used in health supplements. A synthetic chemical known to cause cancer in animals.
12.	Cetilistat	Cetilistat	Not to be used in health supplements. It is a synthetic chemical developed for use in medicines.
13.	Chaparral	Nordihydro-guaiaretic acid	Not to be used in health supplements. Known to cause liver damage.
14.	<i>Chelidonium majus</i>	Benzophenanthridine alkaloids	Not to be used in health supplements. Known to cause liver damage.
15.	<i>Cimicifuga racemosa</i> (Black cohosh)		Known to cause liver side effects. The following cautionary label or similar wording is required: <b>“This product contains Black cohosh which may harm the liver in some individuals.”</b>
16.	<i>Citrullus colocynthis</i>	Cucurbitacins	Not to be used in health supplements. Known to be strongly irritating and can cause severe gut irritation.
17.	Coenzyme Q10 Ubiquinone Ubidecarenone		Restricted to 150mg per day. Concomitant use with warfarin might reduce the anticoagulation effects of

	Ingredients	Constituent(s) of concern	Restrictions
			warfarin. The following cautionary label or similar wording is required: <b>“Do not take while on Warfarin therapy without medical advice.”</b>
18.	<i>Colchicum autumnale</i>	Colchicum alkaloids	Not to be used in health supplements. Known to cause blood disorders such as bone marrow damage.
19.	<i>Corydalis ambigua</i> , <i>C. bulbosa</i> , <i>C. amurensis</i> , <i>C. decumbens</i> , <i>C. pallida</i> , <i>C. racemosa</i> , <i>C. turschaninorii</i> , <i>C. yanhusuo</i>	Corydaline, corydine, tetrahydropalmatine	Not to be used in health supplements. Known as a sedative, with effects on the central nervous system.
20.	<i>Corynanthe yohimbe</i> , <i>Pausinystalia yohimbe</i> , (Yohimbe)	Yohimbine	Not to be used in health supplements. Known to cause anxiety, agitation and heart abnormalities.
21.	Danthron	Danthron	Not to be used in health supplements. It is a synthetic chemical.
22.	<i>Datura stramonium</i> (Jimsonweed, Devil's-Apple, Green Dragon, Zombie's Cucumber, Moon Weed, Trumpet Lily, Stinkweed)	Atropine, Hyoscyamine, Hyoscine	Not to be used in health supplements. Known to cause adverse effects on the central nervous system.
23.	Dehydroepiandrosterone (DHEA)	Dehydroepiandrosterone (DHEA)	Not to be used in health supplements. It is a steroid. Known to increase risk of certain cancers.
24.	Dimethylamylamine (DMAA) (1,3-Dimethylamylamine, 1,3-Dimethylamylamine HCL, 1,3-dimethylpentylamine, 2-amino-4-methylhexane, 4-methyl-2-hexanamine, 4-	Dimethylamylamine (DMAA)	Not to be used in health supplements. It is a synthetic chemical. Known to have adverse effects on the heart and circulatory system.

	Ingredients	Constituent(s) of concern	Restrictions
	methyl-2-hexyl-amine, Dimethylpentylamine, Methylhexanamine)		
25.	Dimethyl sulphoxide (DMSO)	Dimethyl sulphoxide (DMSO)	Not to be used in health supplements. Typically used as a chemical solvent.
26.	Dimethylaminoethanol (DMAE)	Deanol	Not to be used in health supplements. Known to cause various adverse effects in the body, such as insomnia and depression.
27.	1, 3-dimethylbutylamine (DMBA)	1, 3-dimethylbutylamine (DMBA)	Not to be used in health supplements. It is a synthetic chemical. Known to raise blood pressure.
28.	<i>Drimia maritima</i>	Cardiac glycosides e.g. bufadienolide glycosides	Not to be used in health supplements. Known to have adverse effects on the heart.
29.	<i>Ephedra sinica</i> (Ma Huang), <i>Sida cordifolia</i>	Ephedrine	Not to be used in health supplements. Known to cause adverse effects on the heart and circulatory system.
30.	<i>Ginkgo biloba</i> (leaf)		Concomitant use with blood thinning medicines may increase risk of bleeding. The following cautionary label or similar wording is required: <b>“Ginkgo may increase the risk of bleeding. Seek medical advice before use if you are already taking blood thinning medicines (e.g. aspirin, warfarin) or if you have bleeding tendency.”.</b>
31.	<i>Hydrastis canadensis</i> (Golden Seal), <i>Berberis vulgaris</i> (Barberry), <i>Berberis aquifolium</i> (Oregon Grape), <i>Coptis chinensis</i> (Chinese goldthread),	Berberine	Not to be used in health supplements. Restricted for use in Chinese Proprietary Medicines only.

	<b>Ingredients</b>	<b>Constituent(s) of concern</b>	<b>Restrictions</b>
	<i>Coptis teeta</i> , <i>Mahonia aquifolium</i> , <i>M. repens</i> , <i>M. nervosa</i> , <i>Phellodendron amurense</i> , <i>P. chinense</i> , <i>Tinospora tuberculata</i>		
32.	<i>Hyoscyamus niger</i> (Henbane, Henblain, Jusquaime)	Atropine, Hyoscine, Hyoscyamine	Not to be used in health supplements. Known to cause adverse effects on the nervous system.
33.	Insulin-like Growth Factor 1 (IGF-1) (Somatomedin C)	IGF-1	Not to be used in health supplements. May cause heart diseases and diabetes.
34.	Ligandrol	Ligandrol	Not to be used in health supplements. It is a synthetic chemical developed for use in medicines.
35.	Lithium and its salts	Lithium	Not to be used in health supplements. Known to cause kidney, nerve and cardiovascular abnormalities.
36.	<i>Lobelia nicotianifolia</i> <i>Roth ex Schult</i> , <i>L. inflata</i> L. <i>L. chinensis</i> Lour. <i>L. tupa</i> L. (Lobelia)	Lobelia alkaloids	Not to be used in health supplements. Known to cause various adverse effects in the body, such as heart abnormalities and convulsions.
37.	<i>Mucuna pruriens</i> ( <i>Mucuna prurita</i> ) (Cowhage, Cowage)	Dopamine, Nicotine, Physostigmine, N, N-dimethyltryptamine (DMT), Bufotenine	Not to be used in health supplements. Known to affect the mental state.
38.	N-acetyl cysteine (NAC)	Acetyl cysteine	Not to be used in health supplements. It is a synthetic chemical developed for use in medicines.
39.	<i>Nux vomica</i> ( <i>Strychnos nux-vomica</i> )	Strychnine Brucine	Not to be used in health supplements. Known to cause seizures, breathing difficulties and death.
40.	Ostarine (MK-2866, GTx-024, Enobosarm)	Ostarine	Not to be used in health supplements. It is a synthetic chemical

	Ingredients	Constituent(s) of concern	Restrictions
			developed for use in medicines.
41.	Pangamic acid, including its salts		Not to be used in health supplements. It is a synthetic chemical.
42.	<i>Pilocarpus jaborandi</i> , <i>P. microphyllus</i> , <i>P. pinnatifolius</i>	Pilocarpine	Not to be used in health supplements. Known to cause adverse effects on heart and respiratory system.
43.	<i>Piper methysticum</i> (Kava, Kava-kava)	Piper methysticum (kava-kava); kava pyrones (kavalactones)	Not to be used in health supplements. Known to cause adverse effects on the liver.
44.	Pituitary gland, Somatropin, Human Growth hormone, Suprarenal gland, Thyroid gland, Sex hormones, Androstenedione etc	Pituitary gland	Not to be used in health supplements. May contain hormones.
45.	<i>Podophyllum peltatum</i> (Mayapple, American Mandrake)	Podophyllin resin	Not to be used in health supplements. Known to cause poisoning following oral consumption.
46.	<i>Polygoni multiflori</i> (root) (He Shou Wu)		Known to cause liver side effects. The following cautionary label or similar wording is required: <b>“Polygoni multiflori may cause liver problems. Seek medical advice before use.”</b>
47.	<i>Prunus armeniaca</i> , <i>Amygdalus armeniaca</i> , <i>Armeniaca vulgaris</i>	Amygdalin	Not to be used in health supplements. Known to cause cyanide poisoning.
48.	Pomegranate, alkaloids of; its quaternary compounds; their salts	Pomegranate alkaloids, pelletierine	Not to be used in health supplements. Known to cause adverse effects on the nervous system.
49.	Aniracetam, Oxiracetam, Pramiracetam, Phenylpiracetam (Fonturacetam)	Aniracetam, Oxiracetam, Pramiracetam, Phenylpiracetam (Fonturacetam)	Not to be used in health supplements. These are synthetic chemicals developed for use in medicines.

	Ingredients	Constituent(s) of concern	Restrictions
50.	<i>Rauwolfia serpentina</i> (Rauwolfia, Indian snakeroot, Snakeroot)	Reserpine, Rescinnamine	Not to be used in health supplements. May cause adverse effects on the central nervous system.
51.	<i>Monascus purpureus</i> (Red Yeast Rice)	Lovastatin	Restricted to less than 1% lovastatin. Known to cause body and muscle aches. The following cautionary label or similar wording is required: <b>“This product contains naturally-occurring lovastatin. Seek medical advice before use if you are already taking cholesterol-lowering medicines. Discontinue use of the product if you experience muscle aches or weakness.”</b> .
52.	<i>Sanguinaria canadensis</i> (Bloodroot, Indian Paint)	Berberine	Not to be used in health supplements. Known to cause adverse effects on the central nervous system.
53.	<i>Senna alexandria</i> , <i>Cassia angustifolia</i> , <i>Cassia senna</i> (Senna)	Sennosides	Known to cause cramping, diarrhoea and loss of essential minerals. The following cautionary label or similar wording is required: <b>“This product contains sennosides. Prolonged use may cause serious bowel problems and loss of essential minerals. Seek medical advice for use beyond 1 to 2 weeks.”</b> .
54.	<i>Senecio aureus</i> <i>S. jacobaea</i> <i>S. bicolor</i> <i>S. nemorensis</i> <i>S. vulgaris</i> <i>S. longilobus</i> <i>S. scandens</i>	Pyrrolizidine alkaloids e.g. senecionine, riddelliine	Not to be used in health supplements. Known to cause liver toxicity.
55.	Silver and its salts	Silver	Not to be used in health supplements. Known to cause permanent grey to

	Ingredients	Constituent(s) of concern	Restrictions
			blue-black discoloration to the skin, mucous membranes and eyes.
56.	<i>Solanum dulcamara</i> (Bittersweet nightshade)	Solanaceous alkaloids	Not to be used in health supplements. Known to cause death.
57.	Stenabolic (SR9009)	Stenabolic	Not to be used in health supplements. It is a synthetic chemical. May increase cancer risk, affect sleep and metabolism, and cause mental health problems.
58.	Suprofen	Suprofen	Not to be used in health supplements. It is a synthetic chemical.
59.	<i>Symphytum peregrinum</i> , <i>S. officinale</i> (Comfrey)	Pyrrolizidine alkaloids	Not to be used in health supplements. Known to cause liver toxicity.
60.	Testolone (RAD-140)	Testolone	Not to be used in health supplements. It is a synthetic chemical. Known to cause heart attack, stroke and liver damage.
61.	Vitamin K <sub>1</sub> (phylloquinone, phytomenadione, phytonadione)  Vitamin K <sub>2</sub> (menaquinone, menatetrenone)		Restricted to oral dosage forms of multi-vitamin/mineral preparations for adults with maximum limit of 120mcg per day for general health.  The following cautionary label or similar wording is required: <b>“Consult a healthcare professional prior to use if you are taking a blood thinner such as warfarin.”</b>
62.	Vitamin K3 (menadione)		Not to be used in health supplements. It is a synthetic chemical. Known to be associated with neonatal haemolysis and liver damage.
63.	<i>Vinca rosea</i> / <i>Catharanthus roseus</i> (Madagascar Periwinkle, Old Maid)	Vinblastine, Vincristine	Not to be used in health supplements. Known to cause liver toxicity.

**References**

1. ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Health Supplements
2. Reference agencies and organisations: World Health Organisation, European Food Safety Authority, Therapeutic Goods Administration, Food and Drug Administration, Health Canada
3. Natural Medicines Comprehensive Database
4. Martindale: The Complete Drug Reference
5. Micromedex Solutions, 2017 Truven Health Analytics Inc
6. PDR for Herbal Medicines

## ANNEX B

**List of Ingredients for Health Supplements with Specific Concerns**

- This list aims to highlight ingredients that have been reported to have potential to affect the health of some individuals. HSA advises companies dealing with products containing such ingredients to be aware of these risks. Companies are advised to monitor feedback from consumers and report to HSA.
- Dealers are advised to take into consideration risk mitigation measures if their products contain such ingredients.
- The list and suggested risk mitigation measures are not exhaustive. Dealers are responsible to ensure that their products are safe and appropriate for the target consumers.
- Dealers are responsible in ensuring that any other cautionary statements, for example the use of the product by pregnant women, children etc., are included on the label to guide the safe use of the product.

Ingredients		Concerns / Issues
1	Caffeine	<ul style="list-style-type: none"> <li>- Known to have stimulatory effects</li> <li>- Excessive use may cause nervousness, irritability, sleep disturbances, diuresis, increased blood pressure, heart rate and gastrointestinal disturbances.</li> </ul> <p><u>Some risk mitigation measures include:</u></p> <ul style="list-style-type: none"> <li>- Information to advise consumers to limit concurrent use of caffeine-containing products such as tea and coffee when taking this product.</li> <li>- Indicate the amount of caffeine in your product so that consumers are aware of the amount consumed.</li> </ul>
2	<i>Camellia sinensis</i> (extract) (Green Tea)	<ul style="list-style-type: none"> <li>- Rare and unpredictable cases of liver injury have been reported in some individuals overseas. In most cases, liver functions recovered upon stopping use.</li> <li>- Underlying reasons for the liver injury are not well understood.</li> </ul> <p><u>Some risk mitigation measures include:</u></p> <ul style="list-style-type: none"> <li>- Information to users to highlight potential liver injury risks</li> </ul>
3.	<i>Hypericum perforatum</i> (St John's Wort)	<ul style="list-style-type: none"> <li>- <i>Hypericum perforatum</i> affects the metabolism of some medicines thus reducing the medicines' therapeutic effects, e.g. Warfarin, Digoxin, oral contraceptives, anticonvulsants, SSRIs, etc.</li> </ul> <p><u>Some risk mitigation measures include:</u></p> <ul style="list-style-type: none"> <li>- Information to highlight to consumers the potential interaction of <i>Hypericum perforatum</i></li> </ul>

Ingredients		Concerns / Issues
		<p>with certain medicines thus reducing the medicines' therapeutic effects.</p> <ul style="list-style-type: none"> <li>- Caution consumers to consult doctor prior to use of product if they are on medication.</li> </ul>
4	L-Tryptophan	<ul style="list-style-type: none"> <li>- Known to interact with serotonergic antidepressants, e.g. SSRIs, MAOIs and might increase the risk of serotonergic side effects including serotonin syndrome, and cerebral vasoconstrictive disorders.</li> <li>- Known to interact with sedative medications, e.g. Clonazepam, Lorazepam, etc and may cause drowsiness.</li> </ul> <p><u>Some risk mitigation measures include:</u></p> <ul style="list-style-type: none"> <li>- Information to highlight to consumers the potential interaction of L-Tryptophan with certain medications thus increasing the risk of associated side effects.</li> <li>- Caution consumers to consult doctor prior to use of product if they are on medication.</li> </ul>

**ANNEX C****List of Health Supplement Claims**

Health Supplements may make claims that support or maintain health, well-being or physiological process. These claims can be classified as general claims, or specific claims to maintain or enhance a specific body function or structure. The list below can be used as a general guide on permissible health supplement claims.

<b>GENERAL HEALTH CLAIMS</b>
For general health/health support/health maintenance Support/promote/maintain health A factor in the maintenance of good health Provides/source of antioxidants for maintenance of good health For healthy growth and development Helps normal growth and development Helps the body to metabolize carbohydrates/proteins/fats For maintenance of men's health For maintenance of women's health Provides/Source of fatty acids/omega acids for the maintenance of good health
<b>SPECIFIC HEALTH CLAIMS</b>
<b>For cardiovascular/circulatory health</b>
Support/promote blood circulation For healthy blood circulation Support peripheral circulation Support/promote/maintain heart/cardiovascular health For a healthy heart and cardiovascular system For healthy blood sugar levels For healthy blood cholesterol levels
<b>For gastric/digestive health</b>
Support/promote/maintain healthy digestion Support/promote/maintain digestive health/digestive system/gut Source of fibre for the maintenance of good health As a digestive aid Support regular bowel movements Support/promote/maintain liver health
<b>For immune support</b>
For immune health Support/promote/maintain immune health
<b>For exercise performance/weight management</b>
Support/maintain/promote vitality Support/promote physical performance/muscle recovery Helps to overcome/relieve general weakness/fatigue/tiredness Support/promote/maintain healthy body weight
<b>For exercise performance/weight management</b>
Helps in weight management/to lose weight A complement to a healthy lifestyle and regular physical activity for individuals involved in a weight management program Help/support fat metabolism

<b>SPECIFIC HEALTH CLAIMS</b>
<b>For reproductive/urinary health</b>
Support health during pregnancy Help relieve/manage mild discomfort/climacteric symptoms associated with menopause (e.g. hot flushes) Help/support healthy mood balance during menopause Help/support prostate health Support/promote/maintain urinary health
<b>For bone and joint health</b>
Support/promote/maintain joint health/healthy joints Support/promote/maintain bone health/healthy bones Support/promote/maintain healthy muscles Support/promote/maintain joint cartilage Assist in maintaining joint mobility
<b>For cognitive/mental health</b>
Support/promote/maintain cognitive health/brain functions/brain health Support blood circulation to the brain Help/support cognitive function in older adults Helps with concentration/focus Help/promote healthy mood balance Support/promote restful sleep
<b>For eye and skin health</b>
Support/maintain eye health/healthy vision Support/promote/maintain healthy complexion Support/promote/maintain healthy skin/hair/nails

Note:

The use of these health claims should not convey misleading messages that could lead to inappropriate use of the product or bring undue harm to the public.

Companies/dealers are responsible for determining that the claims made on their products are accurate and truthful, and can be substantiated with good quality evidence. In addition, whether a claim is acceptable on an advertisement would require consideration of the advertisement and its context in its entirety.

# HEALTH SCIENCES AUTHORITY

Health Products Regulation Group  
Blood Services Group  
Applied Sciences Group

[www.hsa.gov.sg](http://www.hsa.gov.sg)

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