

HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

Revised April 2019

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.



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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:
- 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.
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"> • Poisons Act (Chapter 234) & Poisons Rules • Sale of Drugs Act (Chapter 282) & its Regulations • Misuse of Drugs Act (Chapter 285) & its Regulations • ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Health Supplements
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) <ul style="list-style-type: none"> • The guidelines on minimising the risk of TSE are available at: http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Complementary_Health_Products/Health_Supplements.html
v)	Ingredients regulated under the Endangered Species (Import & Export) Act, unless permitted 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

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

Heavy Metal	Quantity (by weight)
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

The revised limits will be implemented on 1 September 2019 for new products, and on 1 September 2020 for existing products.

Heavy Metal	Quantity (by weight)
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

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 5×10^2
Escherichia coli, Salmonellae and Staphylococcus aureus:	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**.

Table 3: Vitamins and Minerals Limits

Nutrient	Maximum Daily Limit
Vitamin A (Retinol)	1.5 mg (5000 IU)
Vitamin D	0.025 mg (1000 IU)
Vitamin E	536 mg (800 IU)
Vitamin K1 / K2	0.12 mg
Vitamin C	1000 mg
Vitamin B1	100 mg
Vitamin B2	40 mg
Vitamin B6	100 mg
Folic acid	0.9 mg
Vitamin B12	0.6 mg
Biotin	0.9 mg
Nicotinic acid	15 mg
Nicotinamide	450 mg
Vitamin B5 (Pantothenic acid)	200 mg
Calcium	1200 mg
Phosphorus	800 mg
Magnesium	350 mg
Boron	6.4 mg
Chromium	0.5 mg
Copper	2 mg
Iodine	0.15 mg
Iron	15 mg
Manganese	3.5 mg
Molybdenum	0.36 mg
Selenium	0.2 mg
Zinc	15 mg

Product Label Information

12. 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.
13. 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 4.

Table 4: 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

14. 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.
15. 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.
16. 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.

17. Health supplements may make general health claims or functional health claims.

A. General Health Claims

- a. General health claims refer to the general health benefits derived from supplementation beyond a person's daily dietary intake.
- b. General health claims include claims that are intended for:
 - i) General health maintenance and well-being.
 - ii) Vitamin and/or mineral supplementation. Such claims are permitted only when the relevant vitamin and mineral used in the product amounts to >30% the RDA value.
 - iii) Supplementation beyond normal nutritional value from food.
- c. Examples of general health claims include:
 - i) Support good health and growth
 - ii) Supplementation for growth and development
 - iii) Strengthen the body
 - iv) Relieve general tiredness, weakness

B. Functional Health Claims

- a. Functional health claims refer to the health benefits relating to the positive contribution to a function or biological activity of the body.
- b. Examples of functional health claims include:
 - i) Support healthy functions of the human body such as maintaining healthy joints, support natural physiological processes e.g. immune system, circulation, etc.
 - ii) Manage mild discomfort associated with menopausal symptoms.
 - iii) Assist in maintaining joint mobility.

PROHIBITED CLAIMS FOR HEALTH SUPPLEMENTS

18. 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 5.

Table 5: Examples of Diseases/Conditions/Disorders Not Allowed for Health Supplements

Body system / organs	Examples of related claims not allowed
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

Body system / organs	Examples of related claims not allowed
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

19. 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 made represents 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.

20. 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

21. 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

22. 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

23. Currently, health supplements are not subject to premarket approval and licensing by HSA for their importation, manufacture and sales in Singapore.
24. 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.

	Ingredients	Constituent(s) of concern	Restrictions
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.	<i>Aristolochia</i> spp	Aristolochic Acids	Not to be used in health supplements. Known to be cancer-causing and toxic to the liver.
4.	<i>Artemesia 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.
5.	<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
6.	β -phenyl- γ -aminobutyric acid (Phenibut)	β -phenyl- γ -aminobutyric acid (Phenibut)	Not to be used in health supplements. It is a synthetic chemical with misuse risk.
7.	<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.
8.	<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.
9.	Cannabidiol	Cannabidiol	Not to be used in health supplements. It is developed for use in medicines. Known to affect the mental state.
10.	Cardarine	Cardarine	Not to be used in health supplements. A synthetic chemical known to cause cancer in animals.
11.	Chaparral	Nordihydro-guaiaretic acid	Not to be used in health supplements. Known to cause liver damage.
12.	<i>Chelidonium majus</i>	Benzophenanthridine alkaloids	Not to be used in health supplements. Known to cause liver damage.
13.	<i>Cimicifuga racemosa</i> (Black cohosh)		Known to cause liver side effects. The following cautionary label or similar wording is required: “This product contains Black cohosh which may harm the liver in some individuals.”
14.	<i>Citrullus colocynthis</i>	Cucurbitacins	Not to be used in health supplements. Known to be strongly irritating and can cause severe gut irritation.
15.	Coenzyme Q10 Ubiquinone Ubidecarenone		Restricted to 150mg per day. Concomitant use with warfarin might reduce the

	Ingredients	Constituent(s) of concern	Restrictions
			anticoagulation effects of warfarin. The following cautionary label or similar wording is required: “Do not take while on Warfarin therapy without medical advice.” .
16.	<i>Colchicum autumnale</i>	Colchicum alkaloids	Not to be used in health supplements. Known to cause blood disorders such as bone marrow damage.
17.	<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.
18.	<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.
19.	Danthron	Danthron	Not to be used in health supplements. It is a synthetic chemical.
20.	<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.
21.	Dehydroepiandrosterone (DHEA)	Dehydroepiandrosterone (DHEA)	Not to be used in health supplements. It is a steroid. Known to increase risk of certain cancers.
22.	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)		
23.	Dimethyl sulphoxide (DMSO)	Dimethyl sulphoxide (DMSO)	Not to be used in health supplements. Typically used as a chemical solvent.
24.	Dimethylaminoethanol (DMAE)	Deanol	Not to be used in health supplements. Known to cause various adverse effects in the body, such as insomnia and depression.
25.	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.
26.	<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.
27.	<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.
28.	<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: “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.” .
29.	<i>Hydrastis canadensis</i> (Golden Seal), <i>Berberis vulgaris</i> (Barberry), <i>Berberis aquifolium</i> (Oregon Grape), <i>Coptis chinensis</i> (Chinese goldthread), <i>Coptis Teeta</i> ,	Berberine	Not to be used in health supplements. Restricted for use in Chinese Proprietary Medicines only.

	Ingredients	Constituent(s) of concern	Restrictions
	<i>Mahonia aquifolium</i> , <i>M. repens</i> , <i>M. nervosa</i> , <i>Phellodendron amurense</i> , <i>P. chinense</i> , <i>Tinospora tuberculata</i>		
30.	<i>Hyoscyamus niger</i> (Henbane, Henblain, Jusquaiame)	Atropine, Hyoscine, Hyoscyamine	Not to be used in health supplements. Known to cause adverse effects on the nervous system.
31.	Ligandrol	Ligandrol	Not to be used in health supplements. It is a synthetic chemical developed for use in medicines.
32.	Lithium and its salts	Lithium	Not to be used in health supplements. Known to cause kidney, nerve and cardiovascular abnormalities.
33.	<i>Piper methysticum</i> (Kava, Kava-kava)	<i>Piper methysticum</i> (kava-kava); kava pyrones (kavalactones)	Not to be used in health supplements. Known to cause adverse effects on the liver.
34.	<i>Lobelia nicotianifolia</i> Roth ex Schantz, <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.
35.	<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.
36.	N-acetyl cysteine (NAC)	Acetyl cysteine	Not to be used in health supplements. It is a synthetic chemical developed for use in medicines.
37.	<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.

	Ingredients	Constituent(s) of concern	Restrictions
38.	<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.
39.	Pituitary gland, Somatotropin, Human Growth hormone, Suprarenal gland, Thyroid gland, Sex hormones, Androstenedione etc	Pituitary gland	Not to be used in health supplements. May contain hormones.
40.	<i>Podophyllum peltatum</i> (Mayapple, American Mandrake)	Podophyllin resin	Not to be used in health supplements. Known to cause poisoning following oral consumption.
41.	<i>Polygoni multiflori</i> (root) (He Shou Wu)		Known to cause liver side effects. The following cautionary label or similar wording is required: “Polygoni multiflori may cause liver problems. Seek medical advice before use.” .
42.	Pomegranate, alkaloids of; its quarternary compounds; their salts; except substances containing less than 0.5% of the alkaloids of pomegranate	Pomegranate alkaloids, pelletierine	Not to be used in health supplements. Known to cause adverse effects on the nervous system.
43.	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.
44.	<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.

	Ingredients	Constituent(s) of concern	Restrictions
45.	<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: “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.” .
46.	<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.
47.	<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: “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.” .
48.	<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.
49.	Silver and its salts	Silver	Not to be used in health supplements. Known to cause permanent grey to blue-black discoloration to the skin, mucous membranes and eyes.

	Ingredients	Constituent(s) of concern	Restrictions
50.	<i>Solanum dulcamara</i> (Bittersweet nightshade)	Solanaceous alkaloids	Not to be used in health supplements. Known to cause death.
51.	Suprofen	Suprofen	Not to be used in health supplements. It is a synthetic chemical.
52.	<i>Symphytum peregrinum</i> , <i>S. officinale</i> (Comfrey)	Pyrrolizidine alkaloids	Not to be used in health supplements. Known to cause liver toxicity.
53.	Pangamic acid, including its salts		Not to be used in health supplements. It is a synthetic chemical.
54.	<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.
55.	Vitamin K ₁ (phylloquinone, phytomenadione, phytonadione) Vitamin K ₂ (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: “Consult a healthcare professional prior to use if you are taking a blood thinner such as warfarin.”
56.	<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

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