

# HEALTH SCIENCES AUTHORITY

## REGULATORY GUIDANCE

**NOVEMBER 2024**

# HEALTH SUPPLEMENTS GUIDELINES

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The information in these Guidelines may be updated from time-to-time. For the latest version of the Guidelines, please refer to our website at [www.hsa.gov.sg](http://www.hsa.gov.sg).



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## 1. Introduction

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

## 2. Legislation

- 2.1 The current legislative control that may apply to HS may be found in the following legislation:
- a. Medicines Act 1975 & its Subsidiary Legislation especially:
    - i. Medicines (Prohibition of Sale, Supply and Importation) Order;
    - ii. Medicines (Traditional Medicines, Homoeopathic Medicines and Other Substances) (Exemption) Order;
    - iii. Medicines (Labelling) Regulations;
    - iv. Medicines (Medical Advertisements) Regulations;
    - v. Medicines (Licensing, Standard Provisions & Fees) Regulations
  - b. Medicines (Advertisement & Sale) Act 1955
  - c. Poisons Act 1938 & Poisons Rules

## 3. Working Definition

- 3.1 A working definition of HS is described below:

HS are products that are used to supplement a diet and to maintain, enhance and improve the healthy functions of the human body and contains one or more, or a combination of the following ingredients:

- a. Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances;
- b. Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates; and
- c. Synthetic sources of ingredients mentioned in (a) and (b).

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

- 3.2 HS shall not include any of the following:

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

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

## 4. Safety and Quality Standards

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

- 4.2 HS MUST NOT contain the following:

a.	Substances listed in: <ol style="list-style-type: none"> <li>i. <u>Poisons Act 1938 &amp; Poison Rules</u></li> <li>ii. <u>Misuse of Drugs Act 1973 &amp; its Regulations</u></li> <li>iii. <u>ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Health Supplements</u></li> </ol>
b.	Ingredients derived from human parts
c.	Substances that may affect the human health (see <b>Annex A</b> ). The Guidelines for Establishing the Safety of Ingredients of Health Supplements and Traditional Medicines are available <a href="#">here</a> .
d.	Ingredients that contain agents that can lead to animal-transmissible diseases such as Transmissible Spongiform Encephalopathy (TSE). The Guidelines on Minimising the Risk of TSE in Chinese Proprietary Medicines, Health Supplements & Traditional Medicines are available <a href="#">here</a> .
e.	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
f.	Active ingredients that are not stated in the label
g.	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

- 4.3 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.

- 4.4 HS must not exceed the following heavy metals, microbial, diethylene glycol and ethylene glycol limits as specified in **Tables 1, 2 and 3**.

**Table 1: Heavy Metals Limits**

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

**Table 2: Microbial Limits**

Microbe	Quantity (colony-forming units (CFU)) per g or ml of product
Total aerobic microbial count:	Not more than 10 <sup>5</sup>
Yeast and mould count:	Not more than 5 x 10 <sup>2</sup>
<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.

**Table 3: Diethylene Glycol and Ethylene Glycol Limits**

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

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

- 4.5 Dealers should perform routine testing on the finished products in accordance with HSA's Guidelines on Testing Requirements of Health Supplements and Traditional Medicines, to ensure that the products meet appropriate safety and quality standards. Dealers are to refer to the [Guidelines for Testing Requirements of Health Supplements and Traditional Medicines](#) for more information.
- 4.6 The physical test parameters for the different dosage forms of the finished products should also be monitored to ensure they consistently meet the required standards throughout the product life cycle. Dealers are to refer to the [Guidelines for Physical Test Parameters Based on Dosage Forms of Health Supplements and Traditional Medicines](#) for more information.
- 4.7 Dealers should ensure that the ingredient and finished product manufacturers comply with the manufacturing standards recommended in the [Guidelines for Manufacturing Standards of Health Supplements and Traditional Medicines](#), such as compliance with the principles of quality system, personnel, equipment, sanitation, hygiene, production, quality control, complaint handling, product recalls, and oversight of outsourced activities.
- 4.8 Dealers should hold product-related information and documents, including the following:

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

## **VITAMINS AND MINERALS LIMITS**

4.9 HS for use by the general adult population should not contain vitamins and minerals exceeding the stipulated limits stated in **Tables 4 and 5.**

**Table 4: 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 5: 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.

4.10 Higher levels of vitamins and minerals in HS for use in specific adult population groups that require higher levels of supplementation must be justified with:

- a. Credible authoritative references or expert opinion to show that supplementation over and above the established limits for the general adult population is needed; and
  - b. Medical professional's assessment and recommendation on specific patient's additional supplementation needs
- 4.11 Product intended for supplementation in patients with specific condition should be labelled with statements indicating:
- a. the product must be used under recommendations by healthcare professionals
  - b. the product poses a health hazard when consumed by persons who do not have the conditions for which the product is intended
- 4.12 Examples of supplements intended for specific adult population groups that require higher levels of supplementation are:
- a. Zinc for patients with wounds or metabolic conditions
  - b. Vitamin B2 for patients with certain genetic or metabolic disorders
  - c. Folic acid for pregnant women to prevent against recurrence of neural tube defects or for patients with folic acid deficiency
  - d. Iron for patients with low blood haemoglobin level

## 5. Product Label Information

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

## 6. Health Supplements Claims

- 6.1 A claim refers to any message or representation made on a product in relation to its indications, benefits or action. Claims may be stated directly or inferred indirectly through, but not limited to, the following:
- a. Product label
  - b. Advertisements
  - c. Point of sales materials
  - d. Product brochures
- 6.2 In general, the claims made must be consistent with the definition of HS. The claims made should not imply that the product is necessary or play a role in diseased states.
- 6.3 HS 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.

## 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 the List of Health Claims for Health Supplements and Traditional Medicines available [here](#).

- 6.4 Claims for HS should be substantiated by good quality 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 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.
- 6.5 Dealers are to refer to the Guidelines for Claims and Claims Substantiation of Health Supplements and Traditional Medicines for more information including the general claim principles available [here](#).

## **PROHIBITED CLAIMS FOR HEALTH SUPPLEMENTS**

- 6.6 HS 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>
Blood and circulatory system	Hypertension, stroke, cholesterol disorders, reduces cholesterol, regulates platelet aggregation, coagulation defects, arteriosclerosis
Brain and nervous system	Epilepsy, fits, paralysis, Alzheimer's disease, Parkinsonism, dementia, neuropathies, drug addictions, depression, eating disorders
Digestive system	Ulcers, gastritis, hepatitis, liver cirrhosis, fatty liver, diarrhoea, constipation, inflammation of the intestines, liver or pancreas
Endocrine system	Diabetes, thyroid disorders, hypothyroidism, prostate diseases, thymus disorders, hormonal regulation
Eyes and ears	Blindness, cataract, deafness
Immune system	Leprosy, AIDS, allergies, immunisation
Metabolic system	Obesity, gout
Muscular, connective tissues and skeletal system	Osteoporosis, arthritis, sclerosis, autoimmune diseases, inflammation of joints, dental and periodontal diseases



Body system / organs	Examples of related claims not allowed
Renal system	Kidney stones, renal failure, nephritis, urinary tract infection, incontinence, cystitis
Reproductive system	Menstrual disorders, sexual dysfunction, infertility, frigidity, impotency, conception, pregnancy
Respiratory system	Asthma, tuberculosis, bronchitis, sinusitis, cough, cold, flu
Skin, hair and nails	Fungal infection, eczema, ulcers, warts, moles, pigmentation disorders, alopecia
Others	Cancers, infectious diseases, inflammatory conditions or diseases

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

## 7. Medical Advertisements and Sales Promotion Control

- 7.1 Some types of HS are subject to medical advertisements and sales promotion permit control. These include Quasi-Medicinal (QM) vitamins and/or mineral HS, as well as some other HS (e.g. St John's wort, melatonin products).
- 7.2 Dealers may refer to the QM classification flowchart in **Annex C** for self-help in the classification of HS containing vitamins and minerals.

## 8. Product and Dealer Licensing Control

- 8.1 Currently, HS are not subject to premarket approval and licensing by HSA for their importation, manufacture and sales in Singapore.
- 8.2 Dealers (importers, manufacturers, wholesale dealers) and sellers have the obligation to ensure that their products are not harmful or unsafe, and that they conform with the applicable quality standards.

## Annex A - List of Prohibited/Restricted Substances 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 legislation.
- Dealers are advised to refer to the legislation stated in Section 2 of these guidelines for the full list of substances controlled under the legislation.
- In addition to the list of substances 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: <https://asean.org/wp-content/uploads/2021/01/ASEAN-Guiding-Principles-for-Inclusion-Into-or-Exclusion-from-the-Negative-List-of-Substances-for-Health-Supplements-1.pdf>.
- 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.

	Substance	Constituent(s) of concern	Restriction(s)
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 HS. Known to affect the heart and nervous system.
2.	<i>Actaea 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>
3.	<i>Adonis vernalis</i>	Cardiac glycosides e.g. adonitoxin	Not to be used in HS. Known to have adverse effects on the heart.
4.	Andarine	Andarine	Not to be used in HS. It is a synthetic chemical developed for use in medicines.
5.	<i>Aristolochia</i> spp	Aristolochic acids	Not to be used in HS. Known to be cancer-causing and toxic to the liver.
6.	<i>Artemisia annua</i>	Artemisinin	Not to be used in HS. Use of this herb may lead to parasite resistance as it is

	Substance	Constituent(s) of concern	Restriction(s)
	(sweet Annie/qing hao/ sweet wormwood)		also an anti-malarial treatment.
7.	<i>Atropa belladonna</i> (deadly nightshade)	Atropine	Not to be used in HS. Known to have adverse effects on the nervous system.
8.	$\beta$ -phenyl- $\gamma$ -aminobutyric acid (phenibut)	$\beta$ -phenyl- $\gamma$ -aminobutyric acid (phenibut)	Not to be used in HS. It is a synthetic chemical with misuse risk.
9.	<i>Calotropis gigantea</i> <i>C. procera</i>	Cardiac glycosides e.g. calotropin	Not to be used in HS. Known to have adverse effects on the heart.
10.	<i>Catha edulis</i> (khat)	Cathinone Cathine	Not to be used in HS. Known to be addictive, has effects on the heart and central nervous system.
11.	Cannabidiol	Cannabidiol	Not to be used in HS. It is developed for use in medicines. Known to affect the mental state.
12.	Cardarine	Cardarine	Not to be used in HS. A synthetic chemical known to cause cancer in animals.
13.	Cetilistat	Cetilistat	Not to be used in HS. It is a synthetic chemical developed for use in medicines.
14.	Chaparral	Nordihydro-guaiaretic acid	Not to be used in HS. Known to cause liver damage.
15.	<i>Chelidonium majus</i>	Benzophenanthridine alkaloids	Not to be used in HS. Known to cause liver damage.
16.	<i>Citrullus colocynthis</i>	Cucurbitacins	Not to be used in HS. 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 warfarin. The following cautionary label or similar wording is required: <b>“This product contains coenzyme Q10. Do not take while on warfarin</b>

	Substance	Constituent(s) of concern	Restriction(s)
			<b>therapy without medical advice.”.</b>
18.	<i>Colchicum autumnale</i>	Colchicum alkaloids	Not to be used in HS. 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 HS. 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 HS. Known to cause anxiety, agitation and heart abnormalities.
21.	Danthron	Danthron	Not to be used in HS. 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 HS. Known to cause adverse effects on the central nervous system.
23.	Dehydroepiandrosterone (DHEA)	Dehydroepiandrosterone (DHEA)	Not to be used in HS. 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-methyl-2-hexyl-amine, dimethylpentylamine, methylhexanamine)	Dimethylamylamine (DMAA)	Not to be used in HS. It is a synthetic chemical. Known to have adverse effects on the heart and circulatory system.
25.	Dimethyl sulphoxide (DMSO)	Dimethyl sulphoxide (DMSO)	Not to be used in HS. Typically used as a chemical solvent.

	Substance	Constituent(s) of concern	Restriction(s)
26.	Dimethylaminoethanol (DMAE)	Deanol	Not to be used in HS. 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 HS. It is a synthetic chemical. Known to raise blood pressure.
28.	2,4-dinitrophenol	2,4-dinitrophenol	Not to be used in HS. It is a synthetic chemical known to cause serious adverse effects.
29.	<i>Drimia maritima</i>	Cardiac glycosides e.g. bufadienolide glycosides	Not to be used in HS. Known to have adverse effects on the heart.
30.	<i>Ephedra sinica</i> (ma huang) <i>Sida cordifolia</i>	Ephedrine	Not to be used in HS. Known to cause adverse effects on the heart and circulatory system.
31.	<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> .
32.	<i>Hydrastis canadensis</i> (goldenseal) <i>Berberis vulgaris</i> (barberry) <i>Berberis aquifolium</i> (Oregon grape) <i>Coptis chinensis</i> (Chinese goldthread) <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>	Berberine	Not to be used in HS. Restricted for use in Chinese Proprietary Medicines only.

	Substance	Constituent(s) of concern	Restriction(s)
33.	<i>Hyoscyamus niger</i> (henbane, henblain, jusquaime)	Atropine Hyoscine Hyoscyamine	Not to be used in HS. Known to cause adverse effects on the nervous system.
34.	Insulin-like growth factor 1 (IGF-1, somatomedin C)	IGF-1	Not to be used in HS. May cause heart diseases and diabetes.
35.	Ligandrol	Ligandrol	Not to be used in HS. It is a synthetic chemical developed for use in medicines.
36.	Lithium and its salts	Lithium	Not to be used in HS. Known to cause kidney, nerve and cardiovascular abnormalities.
37.	<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 HS. Known to cause various adverse effects in the body, such as heart abnormalities and convulsions.
38.	<i>Mucuna pruriens</i> ( <i>mucuna prurita</i> , cowhage, cowage)	Dopamine Nicotine Physostigmine N,N-dimethyltryptamine (DMT) Bufotenine	Not to be used in HS. Known to affect the mental state.
39.	N-acetyl cysteine (NAC)	Acetyl cysteine	Not to be used in HS. It is a synthetic chemical developed for use in medicines.
40.	<i>Nux vomica</i> ( <i>strychnos nux-vomica</i> )	Strychnine Brucine	Not to be used in HS. Known to cause seizures, breathing difficulties and death.
41.	Ostarine (MK-2866, GTx-024, enobosarm)	Ostarine	Not to be used in HS. It is a synthetic chemical developed for use in medicines.
42.	Pangamic acid, including its salts		Not to be used in HS. It is a synthetic chemical.
43.	<i>Pilocarpus jaborandi</i> <i>P. microphyllus</i> <i>P. pinnatifolius</i>	Pilocarpine	Not to be used in HS. Known to cause adverse effects on heart and respiratory system.
44.	<i>Piper methysticum</i> (kava, kava-kava)	Piper methysticum (kava-kava) Kava pyrones (kavalactones)	Not to be used in HS. Known to cause adverse effects on the liver.

	Substance	Constituent(s) of concern	Restriction(s)
45.	Pituitary gland Somatropin Human growth hormone Suprarenal gland Thyroid gland Sex hormones Androstenedione etc.	Pituitary gland	Not to be used in HS. May contain hormones.
46.	<i>Podophyllum peltatum</i> (American mandrake, mayapple)	Podophyllin resin	Not to be used in HS. Known to cause poisoning following oral consumption.
47.	<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>
48.	<i>Prunus armeniaca</i> <i>Amygdalus armeniaca</i> <i>Armeniaca vulgaris</i>	Amygdalin	Not to be used in HS. Known to cause cyanide poisoning.
49.	Pomegranate, alkaloids of; its quaternary compounds; their salts	Pomegranate alkaloids Pelletierine	Not to be used in HS. Known to cause adverse effects on the nervous system.
50.	Aniracetam Oxiracetam Pramiracetam Phenylpiracetam (fonturacetam)	Aniracetam Oxiracetam Pramiracetam Phenylpiracetam (fonturacetam)	Not to be used in HS. These are synthetic chemicals developed for use in medicines.
51.	<i>Rauwolfia serpentina</i> (Indian snakeroot, rauwolfia, snakeroot)	Reserpine Rescinnamine	Not to be used in HS. May cause adverse effects on the central nervous system.
52.	<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</b>

	Substance	Constituent(s) of concern	Restriction(s)
			<b>experience muscle aches or weakness.”.</b>
53.	<i>Sanguinaria canadensis</i> (Indian paint, bloodroot)	Berberine	Not to be used in HS. Known to cause adverse effects on the central nervous system.
54.	<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>
55.	<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 HS. Known to cause liver toxicity.
56.	Silver and its salts	Silver	Not to be used in HS. Known to cause permanent grey to blue-black discoloration to the skin, mucous membranes and eyes.
57.	<i>Solanum dulcamara</i> (bittersweet nightshade)	Solanaceous alkaloids	Not to be used in HS. Known to cause death.
58.	Stenabolic (SR9009) and other synthetic REV-ERB agonists e.g. SR9011)	Stenabolic	Not to be used in HS. It is a synthetic chemical. May increase cancer risk, affect sleep and metabolism, and cause mental health problems.
59.	Suprofen	Suprofen	Not to be used in HS. It is a synthetic chemical.
60.	<i>Symphytum peregrinum</i> , <i>S. officinale</i> (comfrey)	Pyrrolizidine alkaloids	Not to be used in HS. Known to cause liver toxicity.
61.	Testolone (RAD-140)	Testolone	Not to be used in HS. It is a synthetic chemical. Known to cause heart attack, stroke and liver damage.



	Substance	Constituent(s) of concern	Restriction(s)
62.	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>“This product contains vitamin K. Consult a healthcare professional prior to use if you are taking a blood thinner such as warfarin.”</b>
63.	Vitamin K3 (menadione)		Not to be used in HS. It is a synthetic chemical. Known to be associated with neonatal haemolysis and liver damage.
64.	<i>Vinca rosea</i> / <i>Catharanthus roseus</i> (Madagascar periwinkle, old maid)	Vinblastine Vincristine	Not to be used in HS. 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. TRC Natural Medicines
4. Martindale: The Complete Drug Reference
5. Micromedex Solutions, 2017 Truven Health Analytics Inc
6. PDR for Herbal Medicines

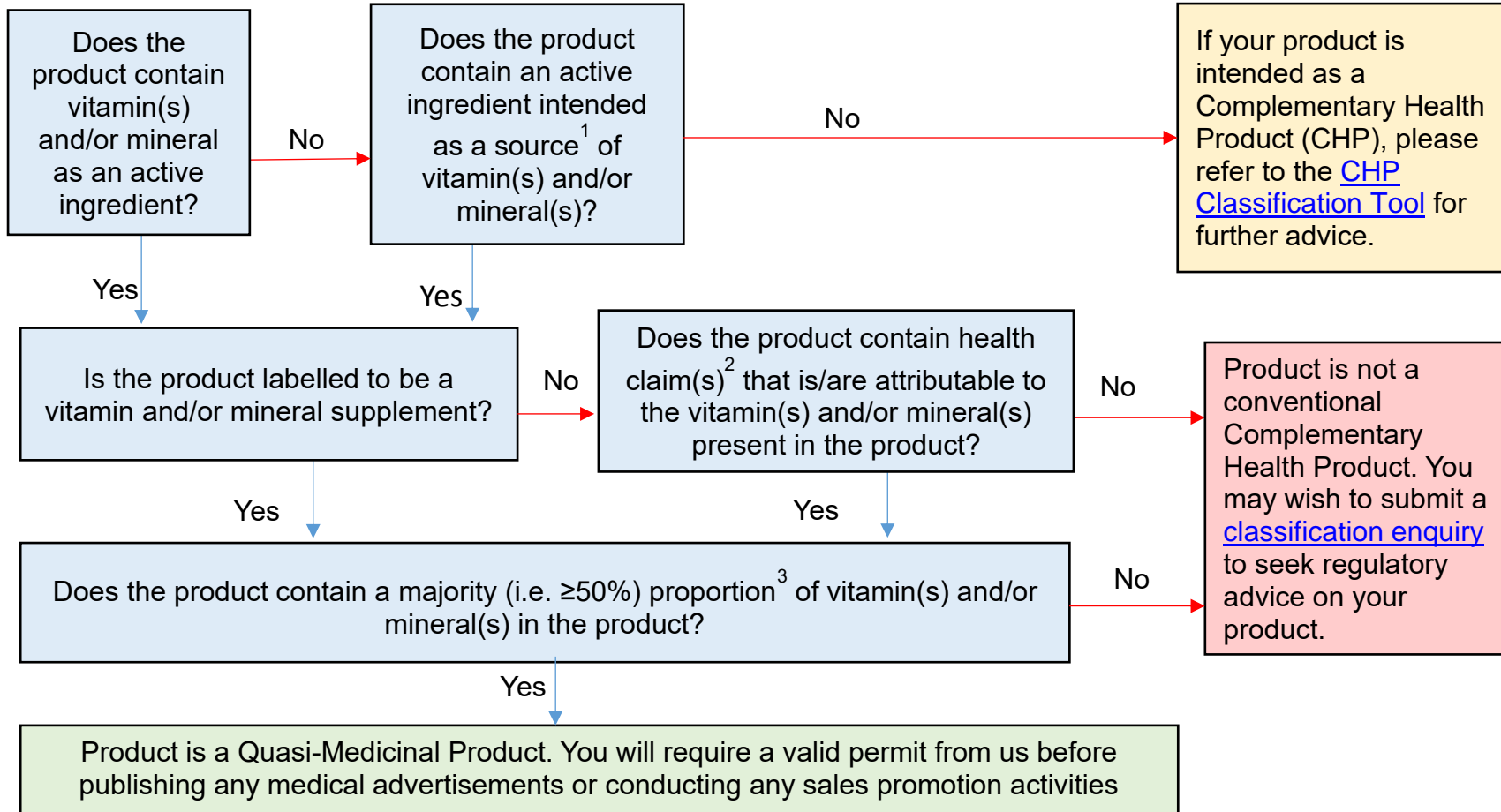
## Annex B - List of Ingredients for Health Supplements with Specific Concerns

- 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>

	Ingredients	Concerns / Issues
		<ul style="list-style-type: none"> <li>- Information to highlight to consumers the potential interaction of <i>Hypericum perforatum</i> with certain medicines thus reducing the medicines' therapeutic effects.</li> <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 - Classification Flowchart for Health Supplements containing vitamin(s) and/or mineral(s)



**Notes:**

1. For example, rosehip fruit intended to provide vitamin C is considered as an “active ingredient intended as a source of vitamin(s) and/or mineral(s)”.
2. Please refer to the list of health claims that are attributable to vitamin(s) and/or mineral(s) below.
3. Proportion is based on number of active ingredients. For example, a product containing vitamin D, calcium and glucosamine, regardless of the strength of the ingredients, would be considered as containing 67% vitamin and mineral and is considered as a majority proportion.

**List of Health Claims that are attributable to vitamin(s) and/or mineral(s)**

- The list should be used in conjunction with the flowchart in **Annex C**. Dealers should ensure that health claims made are substantiated by evidence that is relevant to the claims, as laid out in the [Guidelines for Claims and Claims Substantiation of Health Supplements and Traditional Medicines](#).
- Dealers should note that whether a claim is acceptable would require consideration of the product materials such as label and advertisement and its context in its entirety.

Health claims		Vitamin(s) and/or mineral(s)
1.	Contribute to maintenance of normal red blood cells	<ul style="list-style-type: none"> <li>• Folic acid, vitamin B2, B6, B12</li> </ul>
2.	Contribute to normal red blood cell formation	<ul style="list-style-type: none"> <li>• Folic acid, vitamin B2, B6, B12</li> </ul>
3.	Help form red blood cells	<ul style="list-style-type: none"> <li>• Folic acid, vitamin B2, B6, B12</li> <li>• Copper, iron</li> </ul>
4.	Help form red blood cells and help in their proper function	<ul style="list-style-type: none"> <li>• Folic acid, vitamin B2, B6, B12</li> <li>• Copper</li> </ul>
5.	Help maintain normal red blood cells	<ul style="list-style-type: none"> <li>• Folic acid, vitamin B2, B6, B12</li> <li>• Copper</li> </ul>
6.	Help support/maintain healthy blood glucose levels	<ul style="list-style-type: none"> <li>• Chromium</li> </ul>
7.	Maintain/support healthy thyroid gland function	<ul style="list-style-type: none"> <li>• Iodine, selenium</li> </ul>
8.	A factor in maintenance of good health	<ul style="list-style-type: none"> <li>• All vitamins and minerals</li> </ul>
9.	Contribute to maintenance of normal connective tissues	<ul style="list-style-type: none"> <li>• Copper, manganese</li> </ul>
10.	Contribute to maintenance of normal hair	<ul style="list-style-type: none"> <li>• Biotin</li> <li>• Selenium, silicon, zinc</li> </ul>
11.	Contribute to maintenance of normal mucous membranes	<ul style="list-style-type: none"> <li>• Biotin, vitamin A, B2, B3</li> <li>• Selenium, silicon</li> </ul>
12.	Contribute to maintenance of normal nails	<ul style="list-style-type: none"> <li>• Selenium, zinc</li> </ul>
13.	Contribute to maintenance of normal teeth	<ul style="list-style-type: none"> <li>• Vitamin D</li> <li>• Calcium, magnesium, phosphorus</li> </ul>
14.	Contribute to maintenance of normal vision	<ul style="list-style-type: none"> <li>• Vitamin A, B2</li> <li>• Zinc</li> </ul>
15.	Contribute to maintenance of tooth mineralisation	<ul style="list-style-type: none"> <li>• Fluoride</li> </ul>
16.	Contribute to normal acid-base metabolism	<ul style="list-style-type: none"> <li>• Zinc</li> </ul>
17.	Contribute to normal collagen formation for normal function of cartilage	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>
18.	Contribute to normal collagen formation for normal function of gums	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>

	<b>Health claims</b>	<b>Vitamin(s) and/or mineral(s)</b>
19.	Contribute to normal collagen formation for normal function of skin	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>
20.	Contribute to normal collagen formation for normal function of teeth	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>
21.	Contribute to normal cysteine synthesis	<ul style="list-style-type: none"> <li>• Vitamin B6</li> </ul>
22.	Contribute to normal DNA synthesis	<ul style="list-style-type: none"> <li>• Zinc</li> </ul>
23.	Contribute to normal energy-yielding metabolism	<ul style="list-style-type: none"> <li>• Biotin, vitamin B1, B2, B3, B5, B6, C, D</li> <li>• Calcium, copper, iodine, iron, magnesium, manganese, phosphorus</li> </ul>
24.	Contribute to normal function of cell membranes	<ul style="list-style-type: none"> <li>• Phosphorus</li> </ul>
25.	Contribute to normal functioning of connective tissue	<ul style="list-style-type: none"> <li>• Manganese</li> </ul>
26.	Contribute to normal growth of children	<ul style="list-style-type: none"> <li>• Iodine</li> </ul>
27.	Contribute to normal hair pigmentation	<ul style="list-style-type: none"> <li>• Copper</li> </ul>
28.	Contribute to normal homocysteine metabolism	<ul style="list-style-type: none"> <li>• Folic acid, vitamin B6, B12</li> </ul>
29.	Contribute to normal physiological function	<ul style="list-style-type: none"> <li>• Biotin, folic acid, vitamin B1, B3, B6, B12, C</li> <li>•</li> </ul>
30.	Contribute to normal skin pigmentation	<ul style="list-style-type: none"> <li>• Copper</li> </ul>
31.	Contribute to normal sulphur amino acid metabolism	<ul style="list-style-type: none"> <li>• Molybdenum</li> </ul>
32.	Contribute to normal synthesis and metabolism of steroid hormones, vitamin D and some neurotransmitters	<ul style="list-style-type: none"> <li>• Vitamin B5</li> </ul>
33.	Contribute to protection of cells from oxidative stress	<ul style="list-style-type: none"> <li>• Vitamin B2, C, E</li> <li>• Copper, selenium, manganese, zinc</li> </ul>
34.	Help enhance/promote collagen formation	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>
35.	Help enhance/promote connective tissue health	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>
36.	Help enhance/promote general health and wellbeing	<ul style="list-style-type: none"> <li>• All vitamins and minerals</li> </ul>
37.	Help enhance/promote gum health	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>
38.	Help enhance/promote healthy growth and development	<ul style="list-style-type: none"> <li>• All vitamins and minerals</li> </ul>
39.	Help enhance/promote teeth health	<ul style="list-style-type: none"> <li>• Vitamin C, D</li> <li>• Calcium, magnesium, phosphorus</li> </ul>
40.	Help in collagen formation to maintain healthy bones, cartilage, teeth and/or gums	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>
41.	Help in connective tissue formation	<ul style="list-style-type: none"> <li>• Vitamin C</li> <li>• Copper, manganese, zinc</li> </ul>

Health claims		Vitamin(s) and/or mineral(s)
42.	Help in energy metabolism in the body	<ul style="list-style-type: none"> <li>• Vitamin B2, B3, B5, B6, B12</li> <li>• Magnesium, zinc</li> </ul>
43.	Help in energy metabolism, tissue formation and bone development	<ul style="list-style-type: none"> <li>• Vitamin B2, B3, B5, B6, B12</li> <li>• Magnesium, zinc</li> </ul>
44.	Help in the development and maintenance of bones and teeth	<ul style="list-style-type: none"> <li>• Vitamin A, D</li> <li>• Calcium, magnesium, phosphorus, zinc</li> </ul>
45.	Help in the development and maintenance of bones, cartilage, teeth and/or gums	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>
46.	Help in the development and maintenance of night vision	<ul style="list-style-type: none"> <li>• Betacarotene, vitamin A</li> </ul>
47.	Help in tissue formation	<ul style="list-style-type: none"> <li>• Vitamin B2, B3, B5, B6</li> <li>• Magnesium, zinc</li> </ul>
48.	Help build strong bones and teeth	<ul style="list-style-type: none"> <li>• Vitamin A, D</li> <li>• Calcium</li> </ul>
49.	Help maintain healthy bones, hair, nail and/or skin	<ul style="list-style-type: none"> <li>• Zinc</li> </ul>
50.	Help maintain healthy hair, nail, mucous membranes and/or skin	<ul style="list-style-type: none"> <li>• Biotin</li> </ul>
51.	Help maintain healthy metabolism	<ul style="list-style-type: none"> <li>• Vitamin B12</li> </ul>
52.	Increases iron absorption	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>
53.	Maintain good health	<ul style="list-style-type: none"> <li>• All vitamins and minerals</li> </ul>
54.	Maintain healthy hair, skin and nails	<ul style="list-style-type: none"> <li>• Zinc</li> </ul>
55.	Maintain/support body electrolyte balance	<ul style="list-style-type: none"> <li>• Magnesium</li> </ul>
56.	Maintain/support energy production	<ul style="list-style-type: none"> <li>• Vitamin B1, B5</li> <li>• Iron</li> </ul>
57.	Maintain/support general health and wellbeing	<ul style="list-style-type: none"> <li>• All vitamins and minerals</li> </ul>
58.	Maintain/support healthy eye function	<ul style="list-style-type: none"> <li>• Vitamin A</li> </ul>
59.	Maintain/support healthy eyesight/vision	<ul style="list-style-type: none"> <li>• Betacarotene, vitamin A</li> </ul>
60.	Maintain/support healthy growth and development	<ul style="list-style-type: none"> <li>• All vitamins and minerals</li> </ul>
61.	Provitamin A/vitamin A to help maintain eyesight, skin, membranes and immune function	<ul style="list-style-type: none"> <li>• Betacarotene, vitamin A</li> </ul>
62.	Antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effects of/the oxidative damage caused by/cell damage caused by) free radicals	<ul style="list-style-type: none"> <li>• Vitamin B6, E</li> <li>• Selenium</li> </ul>
63.	Beta-carotene, a provitamin A, to help maintain eyesight, skin, membranes and immune function	<ul style="list-style-type: none"> <li>• Betacarotene</li> </ul>
64.	Vitamin(s)/mineral(s)/vitamin(s) and mineral(s) to support biological functions	<ul style="list-style-type: none"> <li>• All vitamins and minerals</li> </ul>



	<b>Health claims</b>	<b>Vitamin(s) and/or mineral(s)</b>
	which play a key role in the maintenance of good health	
65.	Vitamin(s)/mineral(s)/vitamin(s) and mineral(s), a factor/factors in normal growth and development	<ul style="list-style-type: none"> <li>All vitamins and minerals</li> </ul>
66.	Vitamin(s)/mineral(s)/vitamin(s) and mineral(s), a factor/factors in the maintenance of good health	<ul style="list-style-type: none"> <li>All vitamins and minerals</li> </ul>
67.	An antioxidant that protects the fat in body tissues from oxidation	<ul style="list-style-type: none"> <li>Vitamin E</li> </ul>
68.	Contribute to maintenance of normal function of the immune system during and after intense physical exercise	<ul style="list-style-type: none"> <li>Vitamin C</li> </ul>
69.	Help enhance/improve/promote immune system function	<ul style="list-style-type: none"> <li>Folic acid, vitamin A, B6, B12, C, D</li> <li>Copper</li> </ul>
70.	Help in the normal function of the immune system	<ul style="list-style-type: none"> <li>Folic acid, vitamin A, B6, B12, C, D</li> <li>Copper</li> </ul>
71.	Maintain/support healthy immune system function	<ul style="list-style-type: none"> <li>Folic acid, vitamin A, B6, B12, C, D</li> <li>Copper</li> </ul>
72.	Maintain/support immune system health	<ul style="list-style-type: none"> <li>Folic acid, vitamin A, B6, B12, C, D</li> <li>Copper</li> </ul>
73.	Contribute to normal muscle function	<ul style="list-style-type: none"> <li>Vitamin D</li> <li>Calcium, potassium, magnesium</li> </ul>
74.	Help maintain heart muscle function	<ul style="list-style-type: none"> <li>Magnesium</li> </ul>
75.	Contribute to normal mental performance	<ul style="list-style-type: none"> <li>Vitamin B5</li> </ul>
76.	Contribute to normal neurotransmission	<ul style="list-style-type: none"> <li>Calcium</li> </ul>
77.	Contribute to normal psychological function	<ul style="list-style-type: none"> <li>Biotin, folic acid, vitamin B1, B3, B6, B12, C</li> <li>Magnesium</li> </ul>
78.	Maintain/support cognitive development	<ul style="list-style-type: none"> <li>Iron</li> </ul>
79.	Maintain/support cognitive function/mental function	<ul style="list-style-type: none"> <li>Iodine, iron, zinc</li> </ul>
80.	Maintain/support nervous system function	<ul style="list-style-type: none"> <li>Biotin, vitamin B1, B2, B3, B6</li> <li>Copper, iodine, magnesium, potassium</li> </ul>
81.	Aid/assist/help protein synthesis in the body	<ul style="list-style-type: none"> <li>Magnesium, zinc</li> </ul>
82.	Contribute to normal amino acid synthesis	<ul style="list-style-type: none"> <li>Folic acid</li> </ul>
83.	Contribute to normal macronutrient metabolism	<ul style="list-style-type: none"> <li>Biotin</li> <li>Zinc</li> </ul>
84.	Contribute to normal metabolism of fatty acids	<ul style="list-style-type: none"> <li>Zinc</li> </ul>

Health claims		Vitamin(s) and/or mineral(s)
85.	Contribute to normal protein and glycogen metabolism	<ul style="list-style-type: none"> <li>• Vitamin B6</li> </ul>
86.	Help in the absorption and use of calcium and phosphorus	<ul style="list-style-type: none"> <li>• Vitamin D</li> </ul>
87.	Help maintain normal iron transport in the body	<ul style="list-style-type: none"> <li>• Copper</li> </ul>
88.	Help maintain normal metabolism of iron	<ul style="list-style-type: none"> <li>• Vitamin A, B2</li> </ul>
89.	Help maintain the body's ability to metabolise nutrients	<ul style="list-style-type: none"> <li>• Vitamin B6, B12, C</li> <li>• Boron, magnesium, manganese, phosphorus, molybdenum, zinc</li> </ul>
90.	Provide support for healthy glucose metabolism	<ul style="list-style-type: none"> <li>• Chromium</li> </ul>
91.	Contribute to maternal tissue growth during pregnancy	<ul style="list-style-type: none"> <li>• Folic acid</li> </ul>
92.	Contribute to normal fertility and reproduction	<ul style="list-style-type: none"> <li>• Zinc</li> </ul>
93.	Contribute to normal spermatogenesis	<ul style="list-style-type: none"> <li>• Selenium</li> </ul>
94.	Increase maternal folate status	<ul style="list-style-type: none"> <li>• Folic acid</li> </ul>
95.	Maintain/support testosterone level	<ul style="list-style-type: none"> <li>• Zinc</li> </ul>
96.	Aid/assist healthy bone development/growth/building	<ul style="list-style-type: none"> <li>• Magnesium, manganese</li> </ul>
97.	Contribute to normal collagen formation for normal function of bones	<ul style="list-style-type: none"> <li>• Vitamin C</li> </ul>
98.	Help reduce the loss of bone mineral in postmenopausal women	<ul style="list-style-type: none"> <li>• Vitamin D</li> <li>• Calcium</li> </ul>
99.	Maintain/support bone health	<ul style="list-style-type: none"> <li>• Vitamin D, K</li> <li>• Boron, calcium, magnesium, manganese, phosphorus, zinc</li> </ul>
100.	Contribute to maintenance of normal skin	<ul style="list-style-type: none"> <li>• Biotin, vitamin A, B2, B3</li> <li>• Iodine, zinc</li> </ul>
101.	Healthy skin and/or mucous membranes support	<ul style="list-style-type: none"> <li>• Vitamin A</li> </ul>
102.	Maintain healthy skin	<ul style="list-style-type: none"> <li>• Vitamin A</li> <li>• Zinc</li> </ul>

## References

1. Singapore Food Agency - A Guide to Food Labelling and Advertisements.
2. European Union Register of Nutrition and Health Claims
3. Health Canada Multi-Vitamin/Mineral Supplements Monograph

**Revision History**

Version	Date of publication	Summary of changes*
17	September 2023	<ul style="list-style-type: none"><li>• Updated scientific name of black cohosh</li><li>• Updated collagen health claims for vitamins</li></ul>
18	December 2023	<ul style="list-style-type: none"><li>• Removed “Medicines (Non-Medicinal Products) (Consolidation) Order” from list of legislation</li><li>• Added “SR9011” in Annex A</li></ul>
19	November 2024	<ul style="list-style-type: none"><li>• Updated information on HS dosage forms</li><li>• Updated information on quality and safety standards</li><li>• Added clarification on cautionary statements for coenzyme Q10 and vitamin K</li></ul>

\*Editorial changes are not reflected

# HEALTH SCIENCES AUTHORITY

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Blood Services Group  
Applied Sciences Group

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