HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

Revised February 2015

HEALTH SUPPLEMENTS GUIDELINES

The information in this Guidelines shall be updated or revised from time-to-time. For any new, addition, amendments or deletion made to this Guidelines, please refer to the latest version in our website www.hsa.gov.sg.

HSA
Health Sciences Authority

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Introduction

These guidelines provide information for the trade in the dealing with Health Supplements in Singapore. The information provided in these guidelines serves to supplement understanding and application of the Laws and Regulations and is not at any time meant to supersede or replace any of the legislation. Other national legislative controls may apply where applicable.

Legislation

2. Information on the current legislative control of 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. The Poisons Act (Chapter 234) & The Poisons Rules.

Working Definition

3. A working definition of Health Supplement that may be useful to dealers is described below:

Health Supplements refer to a product that has the following purpose, ingredients and dosage forms:

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.

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: eg 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 injectable and sterile preparation.

Safety & Quality Requirements

5. Currently, Health Supplements are not subjected to premarket approvals and licensing for their importation, manufacture and sales in Singapore. Nonetheless, 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.

6. Health Supplements (HS) shall:

i) not contain any other active substances except those stated on the label;

ii) not contain any human part or substance derived from any part of the human body;

iii) not contain substances controlled under the Poisons Act (Chapter 234) ;

iv) not contain any substances prohibited under the Sales of Drug Act (Chapter 282);

v) not exceed the limits for microbial contamination and toxic heavy metals as specified in Tables 1 and 2;

vi) not contain any substance above the limit specified in the List of Restricted Substances, such as for Vitamins and Minerals shown in Table 3;

vii) not contain any substance specified in the List of Prohibited Substances shown in Annex 1;

viii) not contain any active substance which is a chemically-defined isolated constituent of plants, animals or minerals, or a combination of any one or more of these, that has documented 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;

ix) not contain any substance that may adversely affect the health of the person taking the product;

x) not make any claim to directly or indirectly refer to the lists of conditions, diseases and disorders shown in Tables 5 and 6;

xi) not contain agents that can lead to animal-transmissible diseases such as Transmissible Spongiform Encephalopathy (TSE), if they contain ingredients derived from animal sources. The guidelines on minimising the risk of TSE may be obtained from : http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Complementary_Health_Products/Health_Supplements.html;

xii) be of acceptable standards of quality in terms of product stability, have adequate shelf-life period, proper packaging and labeling; and are manufactured and/or assembled under proper conditions; and

xiii) require the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) import permit if they contain substances (e.g. Hoodia, etc) listed under the Endangered Species (Import & Export) Act. Dealers should contact the Agri-Food & Veterinary Authority (AVA) for further information.

Safety and Quality Specifications

7. The safety and quality levels for heavy metals and microbial limits are specified in the following tables. These limits may be subjected to revisions from time to time, when new information is available.

Table 1: Limits of Heavy Metals

Substance	**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**

For Health Supplements derived from herbs without extraction and heat processing, compliance with microbial count is required.

Table 2: Microbial Contamination Limits

Total aerobic microbial count:	**Not more than 10^5 per gram or ml**
Yeast and mould:	**Not more than 5 x 10^2 per gram or ml**
Escherichia coli, Salmonellae and Staphylococcus aureus:	**Nil in 1 gm or ml of the product**

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.

8. Notwithstanding the limits stated above, it is the obligation of the dealers and sellers to ensure that the microbial content and heavy metals of the product is appropriate and safe when used according to the recommended conditions of use and target users.

Content of Vitamins and Minerals in Health Supplements

9. The following table specifies the limits above which Vitamins and Minerals preparations may be registrable and licences are required for their manufacturing, importation and sale.

Table 3

MINERALS:	
1) Iron	**Yes**; if product contains more than **30mg** of elemental iron per unit dose.
2) Iodine	**Yes**; if product contains more than **300mcg** of elemental iodine per unit dose.
3) Potassium	**Yes**; if product contains more than **200mg** of elemental potassium per unit dose.
4) Copper	**Yes**; if product contains more than **3mg** of elemental copper per unit dose.
VITAMINS:	
1) Vitamin A (acetate or palmitate) Betacarotene	**Yes**; if product contains more than **10,000iu** of vitamin A activity per unit dose.
2) Nicotinic acid	**No**; if the vitamin is added in a nutritional supplement.
	Yes; if product is for specific therapeutic treatment.
3) Vitamin D Cholecalciferol (Vit D3) Ergo-calciferol (Vit D2)	**Yes**; if product contains more than **1,000iu** of vitamin D activity per unit dose.
4) Vitamin E alpha tocopheryl acetate alpha tocopheryl succinate alpha tocopherol	**Yes**; if product contains more than **800iu** of vitamin E activity per unit dose.
5) Vitamin B1 Thiamine (Aneurine) (Hydrochloride or mononitrate)	**Yes**; if product contains more than **50mg** vitamin B1 per unit dose and **also** contains vitamin B6 and/or vitamin B12 together.
6) Vitamin B6 Pyridoxine Hydrochloride	**Yes**; if product contains more than **50mg** vitamin B6 per unit dose and **also** contains vitamin B1 and/or vitamin B12 together.
7) Vitamin B12 Cobalamin Cyanocobalamin Mecobalamin	**Yes**; if product contains more than **100mcg** vitamin B12 per unit dose and **also** contains vitamin B1 and/or vitamin B6 together.
8) Vitamin K Phylloquinone, Menadione etc	**Yes**; if the product does not meet the conditions as stated under Annex 1: List of prohibited/restricted ingredients for Health Supplement products of the Health Supplements guidelines.
	No; if the product meets the conditions as stated under Annex 1: List of prohibited/restricted ingredients for Health

	Supplement products of the Health Supplements guidelines.

10. Please refer to Annex 1 for the list of ingredients that should not be used in Health Supplements unless used under the restricted conditions. Please note that the list is not exhaustive and will be updated from time-to-time, as new information becomes available.

Recommended Basic Product Label Information

11. The product label should be prominently and conspicuously displayed on the product at the point of sale. Where the size, shape or nature of the final product or package does not permit the full listing of labelling information, the use of inserts, leaflets, hang tags, in appropriate format, will be allowed. However, the name of the product, the recommended dosage, the batch reference and relevant precautionary statements should be displayed on the final product or package.

12. The types of information to be provided on the label are shown in Table 4. They should be adequate and truthful. The information shall be in English and shall be printed in a clear and legible manner.

Table 4 Examples of Information Useful to Enable Consumers to make Informed Decisions

Basic Supplemental Facts 1. Name of the health supplement product 2. Names and quantities of all the active ingredients* 3. Product indications/ Intended purpose 4. Recommended daily dosage 5. Instructions on proper usage 6. Pack Size 7. Batch Number 8. Expiry date (or “Use by”, “Use before” or words with similar meaning)
Other information on label / packaging: 9. Names of inactive ingredients* including sweeteners, preservatives, colorants and other additives, if present 10. Name and address of the manufacturer & packer (or local Assembler) 11. Name and address of dealers (or Importer, Wholesale dealer where appropriate) 12. Precautionary Label / Statement, where necessary

* 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 scientific name followed by plant part and type of preparation where applicable. The use of the common name of the active ingredient is optional. For minerals, common or chemical names should be used.

Health Supplement Claims Guidelines

Types and Evidence of Claims for Health Supplements

13. 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.

14. 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.

15. Claims for Health Supplements should be substantiated by good quality evidence that is relevant to the claims. 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.

16. A Health Supplement may make Nutritional (General) Health Claims or Functional Health Claims.

A. Nutritional (General) Health Claims

a. Nutritional Health claims are permissible for products provided that they contain well-documented ingredients, where the function of each ingredient is supported and documented in standard reference texts.

b. Nutritional Health claims include Nutrient-Support claims and General Health 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) Nutritional supplementation beyond normal nutritional value from food.

c. Examples of nutritional health claims include:
    i) Support good health and growth
    ii) Supplementing nutrition
    iii) Nourish the body
    iv) Strengthen the body (without reference to body organs)

v) Relieve general tiredness, weakness

B. Functional Health Claims

a. Functional Health claims must be adequately substantiated through ingredient-based evidence, and when necessary product-based evidence.
b. Examples of functional health claims include:
   i) General support maintenance of healthy functions.
   ii) Supports healthy function of the human body such as maintaining healthy joints, support natural physiological processes e.g. immune system, circulation, etc.
   iii) Manage mild discomfort associated with menopausal symptoms.
   iv) Assist in maintaining joint mobility.

Prohibited Claims for Health Supplements

17. 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

1. Cardiovascular diseases & disorders incl. Hypertension, stroke, cholesterol disorder, reduces cholesterol, etc.	12. Metabolic disorders incl. obesity, etc.
2. Dental & Periodontal diseases and disorders	13. Musculoskeletal diseases & diseases of joint, bone, collagen incl. rheumatic diseases, osteoporosis, anti-inflammatory, etc.
3. Diseases & disorders of the eye, ear or nose likely to lead to severe impairment, blindness or deafness, cataract, etc.	14. Neoplastic disease incl. all types of cancers
4. Diseases of the liver, biliary system or pancreas incl. Hepatitis, fatty liver, liver cirrhosis, hepatitis, etc.	15. Nervous system and neurological disorders incl. epilepsy, fits, paralysis, Alzheimer's disease, dementia, etc.
5. Endocrine diseases & disorders, incl. diabetes, thyroid disorders, thymus disorders, prostatic disease, etc.	16. Physiological processes, enhance or depress, e.g. immunity, enzyme deficiency, anti-aging, hormonal imbalances, hormone release stimulants, etc.
6. Gastrointestinal diseases & disorders incl. ulcers, gastritis, diarrhoea, constipation, etc.	17. Renal diseases, diseases of the genito-urinary tracts incl. urinary tract infection, symptoms of nephritis, etc.
7. Haematological diseases e.g. increases or reduces platelets, etc	18. Respiratory diseases incl. asthma, tuberculosis, etc.
8. Immune disorders & diseases incl. AIDS, allergies, etc.	19. Skin diseases & disorders incl. eczema, fungal infection, ulcers, warts, mole, pigmentation disorder, etc
9. Immunisation e.g. vaccines, protects body against diseases (all types), etc	20. Reproductive disease, disorders & conditions incl. sexual dysfunction, conception and pregnancy, infertility, menstrual disorders, impotency, frigidity, etc.
10. Infectious diseases, incl. sexually transmitted diseases, bacterial or viral infection, leprosy, etc	
11. Mental diseases, disorder & conditions incl. Substance abuse, addiction, depression, eating disorder, etc.	

(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

18. 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, 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. Such as the mention of the disease in the advertisement for a health supplement implies that the product is a medicinal product making a therapeutic claim 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. Such claims 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 of advice or recommendations from healthcare professionals, i.e. visual and/or audio presentation of doctors/dentists/pharmacists or nurses. Testimonials or recommendations by healthcare professionals should not be used in the product label, advertisement or promotion.

d) Testimonials by Non-professionals

Product materials, including label, 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 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-ageing

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 ageing.

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% safety 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.

19. 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. Please check with the Health Supplements Unit on the allowed statements of claims when in doubt.

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)

Examples Of Objectionable Terms And Claims
Efficacious/Effective
Perpetual youth
Anti-aging
Longevity
Anti-stress (unless qualified)
Boost immunity
Enhance immunity
Breast enhancement, enlargement, growth
Height growth
Enhance intelligence / Increase IQ
Increase / improve memory
Memory enhancement
Hormone releaser/enhancer/amplifier
Regulate hormone
Enhancement of sexual organs
Sexual powers
Arousal, Libido

20. The 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 and should not be used e.g. GlucoTreat, CholCure, ColdCure.

Medical Advertisement Control

21. Medicinal products are subjected to medical advertisement control. These include, but are not limited to following:

    a. Vitamins and Minerals preparations

    b. Some herbal preparations.

22. An application for the review of advertising materials may be submitted. More information may be obtained from the HSA Medical Advertisements Unit.

23. Further information on the regulatory control of other health products may be obtained from the following website:

http://www.hsa.gov.sg

Please be reminded that 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.

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ANNEX 1

List of prohibited/restricted ingredients for Health Supplement products

	Ingredients	Constituent(s) of concern	Restrictions & Control in Health Supplements
1.	Aconitum napellus (Monkshood, Aconite) Other spp: A carmichaeli, A. kusnezoffii, A. coreanum	Aconite alkaloids	Controlled under Poisons Act
2.	Aristolochia spp	Aristolochic Acids	Controlled under Poisons Act
3.	Artemesia annua (Quing Hao/Sweet Annie/Sweet Wormwood)	Artemisinin	Controlled under Poisons Act
4.	Atropa belladonna (Deadly nightshade)	Atropine	Controlled under Poisons Act
5.	Catha edulis (Khat)	Cathinone, Cathine	Controlled under Poisons Act, Misuse of Drugs Act
6.	Chaparral		Not suitable for use in Health Supplements.
7.	Cimicifuga racemosa (Black cohosh)		Link with liver adverse reactions. The following cautionary label is required "**Warning: This product contains Black cohosh which may harm the liver in some individuals**"
8.	Coenzyme Q10 Ubidecarenone		Restricted to 150mg per day. The following cautionary label is required "**Do not take while on Warfarin therapy without medical advice**"
9.	Colchicum autumnale	Colchicum alkaloids	Controlled under Poisons Act
10	Corydalis ambigua, C. bulbosa, C. amurensis, C. decumbens, C. pallida, C. racemosa, C. turschaninorii, C. yanhusuo	Corydaline, corydine, tetrahydropalmatine	Controlled under Poisons Act
11	Corynanthe yohimbi, Pausinystalia yohimbe, (Yohimbe)	Yohimbine	Controlled under Poisons Act
12	Danthron, Suprofen	Danthron, Suprofen	Controlled under Poisons Act

	Ingredients	Constituent(s) of concern	Restrictions & Control in Health Supplements
13	Datura stramonium (Jimsonweed, Devil's-Apple, Green Dragon, Zombie's Cucumber, Moon Weed, Trumpet Lily, Stinkweed)	Atropine, Hyoscyamine, Hyoscine	Controlled under Poisons Act
14	Dehydroepiandrosterone (DHEA)	Dehydroepiandrosterone (DHEA)	Controlled under Poisons Act
15	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)	Controlled as a Medicinal Product subject to registration
16	Dimethyl sulphoxide (DMSO)	Dimethyl sulphoxide (DMSO)	Controlled under Poisons Act
17	Dimethylaminoethanol (DMAE)	Deanol	Controlled under Poisons Act
18	Ephedra sinica (Ma huang) Sida cordifolia extract	Ephedrine 1 % and above	Controlled under Poisons Act
19	Hydrastis canadensis (Golden Seal), Berberis vulgaris (Barberry), Berberis aquifolium (Oregon Grape), Coptis chinensis (Chinese goldthread), Coptis Teeta, Chelidonium majus, Mahonia aquifolium, M repens, M nervosa, Phellodendron amurense, P. chinense	Berberine	Controlled under Poisons Act
20	Hyoscyamus niger (Henbane, Henblain, Jusquaime)	Atropine, Hyoscine, Hyoscyamine	Controlled under Poisons Act
21	Piper methysticum (Kava, Kava-kava)	Piper methysticum (kava-kava); kava pyrones (kavalactones)	Controlled under Poisons Act
22	Lobelia inflata, L. tupa	Lobelia alkaloids	Controlled under Poisons Act

	Ingredients	Constituent(s) of concern	Restrictions & Control in Health Supplements
	(Lobelia)	0.1% and above	
23	Mucuna pruriens (Mucuna prurita) (Cowhage, Cowage)	Dopamine, Nicotine, Physostigmine, N, N-dimethyltryptamine (DMT), Bufotenine	Controlled under Poisons Act
24	N-acetyl cysteine (NAC)	Acetyl cysteine	Controlled under Poisons Act
25	Nux vomica (Strychnos nux-vomica)	Strychnine Brucine	Controlled under Poisons Act
26	Pilocarpus jaborandi, P. microphyllus, P. pinnatifolius	Pilocarpine	Controlled under Poisons Act
27	Pituitary gland, Somatropin, Human Growth hormone, Suprarenal gland, Thyroid gland, Sex hormones, Androstenedione etc	Pituitary gland	Controlled under Poisons Act
28	Podophyllum peltatum (Mayapple, American Mandrake)	Podophyllin resin	Controlled under Poisons Act
29	Pomegranate, alkaloids of; its quarternary compounds; their salts; except substances containing less than 0.5% of the alkaloids of pomegranate	Pomegranate alkaloids	Controlled under Poisons Act
30	Rauvolfia serpentina (Rauwolfia, Indian snakeroot, Snakeroot)	Reserpine, Rescinnamine	Controlled under Poisons Act
31	Red Yeast Rice	Lovastatin 1% and above	Controlled under Poisons Act
32	Sanguinaria canadensis (Bloodroot, Indian Paint)	Berberine	Controlled under Poisons Act
33	Solanum dulcamara (Bittersweet nightshade)	Solanaceous alkaloids	Controlled under Poisons Act
34	Symphytum peregrinum, Symphytum officinale (Comfrey)		Not suitable for use in Health Supplements
35	Pangamic acid, including its salts		Prohibited under Sales of Drugs Act
36	Amygdalin		Prohibited under Sales of Drugs Act
37	Vitamin K_1 (phylloquinone, phytomenadione, phytonadione)		Restricted to oral dosage forms of multi-vitamin/mineral preparations for adults with

	Ingredients	Constituent(s) of concern	Restrictions & Control in Health Supplements
	Vitamin K_2 (menaquinone, menatetrenone)		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**"
38	Vinca rosea / Catharanthus roseus (Madagascar Periwinkle, Old Maid)	Vinblastine, Vincristine	Controlled under Poisons Act

Please note:

i) The above list is not exhaustive and will be updated from time-to-time, as new information becomes available.

ii) Where the routes of administration are other than by oral route, and other considerations such as sterility, bioavailability and quality control become important in the overall safety of the final product, pre-market authorization (i.e. approval & licence) is likely to be required.

HEALTH SCIENCES AUTHORITY

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Blood Services Group
Applied Sciences Group

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