HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

Revised September 2011

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

Content: **Page**

Introduction 3

Legislation 3

Working Definition 3

Safety & Quality Requirements 4

Safety & Quality Specifications 5
- Table 1: Limits of Heavy Metals
- Table 2: Microbial Contamination Limits
- Table 3: Max Vit & Min Limits Allowed for HS

Recommended Basic Product Label Information 7
- Table 4: Examples of information useful to enable consumers to make informed decisions.

Health Supplements Claims Guidelines 7
- Type and Evidence of Claims for Health Supplements
- Prohibited Claims for Health Supplements
- Table 5: Diseases/Conditions/Disorders Not Allowed for HS
- Table 6: List of Prohibited 19 Diseases and Conditions

General Principles For Claims In Health Supplement 10

Medical Advertisement Control 13

Annex 1: List of ingredients containing prohibited/restricted ingredients for Health Supplement products 15

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.

Legislation

2. Information on the current legislative control of health supplements and related products may be found in the following legislation:

A. Medicines Act 1975 & 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: (note section 9: The Schedule of Diseases and Conditions)

C. Sale of Drugs Act & 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 & The Poisons Rules.

Working Definition

3. Health Supplement includes the following categories of products defined in the Medicines Act and its subsidiary legislation:

a. "**Quasi-medicinal products**" (includes "Vitamins and nutritional preparations from natural sources) under the legislation Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order,

b. "**Traditional Medicines**" (other than CPM, Jamu, Ayurvedics, Homoeopathics) including herbal preparations under the legislation Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order,

c. "**Health Foods with vague and general medicinal claims**" under the legislation Medicines (Non-Medicinal products)(Consolidation) Order.

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

> Health Supplements refers 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 as may be approved by the Licensing Authority.

5. 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

6. Currently, health supplements are not subjected to premarket approvals and licensing for their importation, manufacture and sales in Singapore. The onus of responsibility for the safety and quality of health supplements rests with the dealers (importers, manufacturers, wholesale dealers) and sellers. They must ensure that their products comply with the safety and quality requirements provided in this Guide.

7. Health supplements (HS) shall:

i) not contain any other 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 listed in the Schedule of the Poisons Act;

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

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

vi) not contain any substance specified in the List of Prohibited Substances shown in Table 4;

vii) 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;

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

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

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

xi) 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 Wildlife Regulatory Branch, Agri-Food & Veterinary Authority (AVA) at 5 Maxwell Road #02-03 Tower Block, MND Complex, Singapore 069110, Tel: +65 62270670, Fax: +65 63257646 to obtain the necessary permit or to obtain further information.

Safety & Quality Specifications

8. The safety and quality levels 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 5×10^2 per gram or ml**
Escherichia coli, Salmonellae and Staphylococcus aureus:	**Nil in 1 gm or ml of the product**

The above limits are not applicable to probiotics or products derived from fermentation processes.

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 ingredients containing 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 ingredients containing 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) Names of inactive ingredients including sweeteners, preservatives, colorants and other addictives, if present 4) Recommended daily allowance (RDA) based on approved local standards or authoritative international standards (to specify the standard used) 5) Recommended daily dosage 6) Instructions on proper usage 7) Pack Size
Other information on label / packaging: 8) Expiry date (or "Use by", "Use before" or words with similar meaning) 9) Batch Number 10) Name and address of the manufacturer & packer (or local Assembler) 11) Name and address of dealers (or Importer, Wholesale dealer where appropriate) 12) Mandatory Precautionary Label / Statement, where necessary

13. The names of the ingredients on the label may be the Scientific names, Latin botanical names or Common names. Companies should use acceptable international nomenclature for ingredient names.

Health Supplement 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.

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. The dealers must hold evidence to support these claims, and provide this to the Authority when required to do so.

d. Examples 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. The dealers must hold evidence to support these claims, and provide this to the Authority when required to do so. Please check with the Health Supplements Unit on the allowed statements of claims when in doubt.

b. 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.

c. The claims made should not imply that the product is necessary or play a role in diseased states.

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 prohibited diseases and disorders is provided in Table 5. It should not be labelled, advertised or promoted to give the impression of advice or recommendations from healthcare professionals.

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.)

18. The product claims should be consistent, and in compliance with the general guidelines on product claims in the General Principles For Claims In Health Supplement.

19. In addition, health supplements are not allowed to make any health claim, which cannot be adequately substantiated by scientific evidence. Anyone found to be making false, misleading and deceptive claims, and those who make direct or indirect references to any of the following 19 diseases and conditions listed in the Schedule of the Medicines Act, extracted and shown in Table 6, may be charged with an offence and be liable to legal punishment.

Table 6 List of Prohibited 19 Diseases and Conditions

1. Blindness	**11. Cancer**
2. Cataract	**12. Conception and pregnancy**
3. Dangerous drug addiction	**13. Deafness**
4. Diabetes	**14. Epilepsy or Fits**
5. Frigidity	**15. Hypertension**
6. Infertility	**16. Insanity**
7. Impotency	**17. Kidney diseases**
8. Leprosy	**18. Menstrual disorder**
9. Paralysis	**19. Sexual function**
10. Tuberculosis	

General Principles For Claims In Health Supplement

20. 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