Baker McKenzie Wong & Leow.



In Singapore, the Health Supplements Unit, Centre for Drug Administration of the Health Sciences Authority administers regulatory control of health supplements. More information on the HSA is available at www.hsa.gov.sg. The HSA has issued Health Supplement Guidelines to supplement the understanding and application of the legislation, and guidelines on the sale and supply of health supplements. For a copy of the Guidelines, please visit HSA's website.

In general, the HSA adopts a largely hands-off approach to health supplements. In Singapore, health supplements are not subjected to premarket approval by the HSA and can be manufactured, imported, and sold without a license from the HSA. However, the onus of responsibility in ensuring the safety and quality of health supplements, and compliance with the Guidelines rests with the dealer.

Definition of Health Supplements

"Health supplements" are not defined in legislation. However, the working definition of "health supplements" adopted by the HSA is as follows:

"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.

Awards

Ranked Band 1 for Life Sciences Chambers Global rankings 2014 - 2020

Ranked Band 1 for Intellectual Property Chambers Global 2009 - 2020

Medical and Healthcare Law Firm of the Year Asian Legal Business Southeast Asia Law Awards

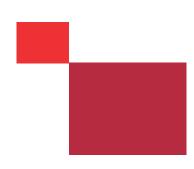
Tier 1 Intellectual Property Firm in Asia ALB IP Rankings 2018 - 2019

Asia Pacific IP Firm of the Year Managing IP Asia Pacific Awards 2018 - 2019

Ranked Band 1 for Intellectual Property Firm in Singapore Chambers Asia Pacific 2010 - 2020

Ranked Tier 1 for Intellectual Property Firm in

Legal 500 Asia Pacific 2010 - 2019





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

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

A review of the ingredients and claims made in relation to the health supplement should be undertaken to consider if the health supplement falls within the definition of "medicinal product" under the Medicines Act, for which a much stricter regulatory regime applies. In some situations, a health supplement may also interface with the regulatory regime for food and supplements of food nature, which come under the purview of a separate governmental authority, the Agri-Food and Veterinary Authority. The correct classification of the product(s) in question is therefore the foremost step to be taken in assessing the relevant regulatory requirements.

Labelling Requirements

The Guidelines stipulate the following information to be provided on the packaging and labels of the health supplements:

- i) Name of the health supplement product;
- ii) Names and quantities of all the active ingredients:
- iii) Names of inactive ingredients including sweeteners, preservatives, colourants and other additives (if present);
- iv) Recommended daily allowance based on approved local standards or authoritative international standards (to specify the standard used);
- v) Recommended daily dosage;

- vi) Instructions on proper usage;
- vii) Pack size;
- viii) Expiry date (or "use by",

 "use before" or words with
 similar meaning);
- ix) Batch number:
- Name and address of the manufacturer and packer (or local assembler);
- xi) Name and address of dealers (or importers, wholesale dealer where appropriate); and
- xii) Mandatory precautionary label/statement (where necessary).

The information provided must be in the English language and presented in a clear and legible manner.



Advertisement and Claims for Health Supplements

In general, health claims made must be consistent with the definition of health supplements. The HSA provides a specific list of diseases and disorders, which health supplements are expressly prohibited from advertising or promoting for the treatment or prevention. In addition, claims in relation to health supplements must be capable of adequate substantiation by scientific evidence.

Separately, all advertisements for health supplements should also comply with the Singapore Code of Advertising Practice. The Code, which is administered by the Advertising Standards Authority of Singapore, regulates local advertising activities in general, and is not aimed at specific industries. The scope of the Code extends to any form of commercial communication for any goods or services, regardless of the medium used, including advertising claims on packs, labels and point of sale materials, as well as internet advertisements.

Although the Code does not have statutory force, it should be noted that the ASAS may import sanctions upon determination of a breach of the Code (including withholding advertising space or time from advertisers as well as adverse publicity from investigation reports).

The general principles and/or guidelines of the Code that are commonly applicable to cosmetic products are highlighted below:

- Truthful presentation: Advertisements should not mislead in any way by inaccuracy, ambiguity, exaggeration, omission or otherwise.
- Claims: Advertisements should not misuse research results or quotations from technical and scientific publications. Statistics should not be presented so as to imply a greater validity than they really have. Scientific terms should not be misused; scientific jargon and irrelevancies should not be used to make claims appear to have any scientific basis which they do not possess.
- Matters of fact: All descriptions, claims and comparisons which relate to matters of objectively ascertainable facts should be capable of substantiation.
- Use of research results: When a factual claim in an advertisement is said to be supported by the results of independent research, the advertiser and sales promoter should be able to show that those responsible for the research accept the advertisement as an accurate account of the research.
- Use of testimonials: 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 or endorsement. Testimonials or endorsements which are 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. Advertisers and advertising agencies are required to show substantiation that such testimonials or endorsements reflect the typical experience of ordinary users.

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