Baker McKenzie Wong & Leow.

Healthcare
Singapore

Health Supplements

In Singapore, the Health Products Regulation Group of the Health Sciences Authority administers regulatory control of health supplements. More information on the HSA is available at www.hsa.gov.sg. In 2022, HSA issued its revised Health Supplement Guidelines along with brand new sets of guidelines relating to (i) claims and claims substantiation; (ii) labelling standards; (iii) ingredient safety; (iv) manufacturing standards; (v) physical test parameters based on dosage forms; and (vi) testing requirements. For copies 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 pre-market 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:

"A health supplement is a product that is used to supplement a diet and to support or maintain, enhance and improve the healthy functions of the human body. It cannot be an injectable or a preparation that needs to be sterile, such as injections and eyedrops. It cannot be an item of a meal or diet.

A health supplement must also contain one or more, or a combination of the following ingredients:

a) Vitamins, minerals, amino acid, fatty acids, enzymes, probiotics and other bioactive substances;

Awards & Accolades

Band 1 for Life Sciences
Chambers Asia Pacific 2014 - 2024

Medical and Healthcare Law Firm of the Year
Asian Legal Business Southeast Asia Law Awards 2020 and 2021

Band 1 for Intellectual Property
Chambers Global 2009 - 2024

Band 1 for Intellectual Property
Chambers Asia Pacific 2010 - 2024

Tier 1 for Intellectual Property
Legal 500 Asia Pacific 2010 - 2024

Tier 1 for Patents and Copyrights/Trademarks in Singapore
ALB Asia IP Rankings 2018 - 2024

Asia Pacific Patents Firm of the Year
Asia IP Law 2023

Tier 1 for Copyright, Trademark Contentious and Trademark Prosecution in Singapore
Asia IP Law 2023

Asia Pacific IP Firm of the Year
Managing IP Asia Pacific Awards 2018 - 2022

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Managing IP Asia Pacific Awards 2017, 2018 and 2022

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).

A health supplement must be administered in small unit doses in dosage forms such as the following:

- Capsules
- Softgels
- Tablets
- Liquids
- Syrups

Products used on animals, as well as products presented in the form of food and beverages, such as biscuits, cookies, coffee, and juice are not health supplements."

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 a "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 Singapore Food Agency. 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 for Labelling Standards of Traditional Medicines and Health Supplements distinguishes between four different types of product labels:

- Outer label: the product packaging in which the immediate packaging of the finished product is contained e.g., the package or carton box containing the bottle, strips or blister packs
- Inner label: the label affixed on the primary container of the finished product e.g., the immediate label affixed to a bottle where the finished product is contained
- Small label: the label on a small primary container, usually a unit dose container e.g., sachets or a small single dose bottle
- Strip or blister pack label: the label affixed or printed on the strip or blister pack

Depending on the type of label, the Labelling Guidelines stipulate the following information to be provided on the packaging and labels of the health supplements:

i. Product name of the health supplement product including the brand name;
ii. Dosage form;
iii. Names and quantities of all the active ingredients;
iv. Intended purpose;
v. Dosage and directions of Use;
vi. Batch number/lot number;
vii. Pack size/net content;
viii. Expiry date (or "use by", "use before" or words with similar meaning);
ix. Name and address of the manufacturer;
x. Name and address of local importer;
xi. Contraindications, if any;
xii. Other warnings (such as side effects, contraindications, precautions, and inactive ingredients that exhibit sensitising effects); and
xiii. Storage condition

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.

Additionally, the new Guidelines for Claims and Claim Substantiation of Traditional Medicines and Health Supplements sets out general principles that all health supplement claims should adhere to, to avoid instances of inappropriate use or undue harm to the public such as:

- Claims should be truthful and not misleading due to brevity or any other reason;
- Claims should be written in simple-to-understand language;

- Companies should ensure that it is permitted to use logos, initials and trade marks featured on the product label, advertisements and promotional materials. Companies are also prohibited from using logos belonging to the HSA and any of its professional groups;
- Scientific data cannot be used to imply greater validity than the product can provide for the general population. Additionally, terms such as "Proven by Clinical Trials" and "Clinically Proven" may not be used 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 adverse condition;
- Endorsements or testimonials by healthcare professionals should not be used on product labels, advertisements or promotions;
- Claims cannot mislead the public into believing that the product relates to any traditional healing paradigm when that is not the case;
- Claims cannot discourage the public from seeking medical advice or the appropriate use of medication;
- Claims cannot arouse fear or exploit public superstition;
- Claims cannot imply the product's efficacy, superiority or safety;
- Claims cannot cast doubt on the nutritional properties of food;
- Claims should avoid references to stress, performance in studies, anti-aging, sexual function, hormonal levels, or the reduction or management of blood sugar levels.

Should the health supplement in question be classified as a quasi-medicinal product, additional requirements set out in the Guide on Advertisements and Sales Promotion of Medicinal Products will also apply. This includes a requirement to apply for a valid permit with the HSA prior to carrying out any medical advertisement or sales promotion.

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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