# Overview of Health Supplement Regulations in Hong Kong: A Comparison with Drug Regulations

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## ABSTRACT

**As the demand for health supplements rapidly grows, nutraceuticals have become a significant part of the pharmaceutical industry. Therefore, pharmacists working in the industry should have a good understanding of the laws that regulate health supplements in Hong Kong. This article introduces the major regulations for health supplements, namely safety, quality, labeling, and claims. Food and drug regulations may seem vastly different, but the underlying principles are similar. Using the format of comparison tables, this article aims to highlight the required documents for the launch of health supplements. Overall, both pharmaceutical and supplement product regulations aim to safeguard safety and quality.**

**Keywords:** *Health supplement, Food supplement, Laws and regulations*

## INTRODUCTION

An increase in the geriatric population, rising health awareness, and preventive healthcare measures have spurred demand for health supplements, and hence drive the growth of the nutraceutical industry. Starting from 2020, the annual health spending on supplements has surpassed Over-the-counter (OTC) drugs. In 2022, the global supplement market size exceeded US$ 120,000 million, and the increasing trend is expected to continue.[1] Apart from supporting normal body functions, studies have shown that supplements have a wide range of benefits to physical and mental health. However, at the same time, taking supplements could also impose health risks. Therefore, health authorities play an important role in monitoring and regulating health supplements, including their manufacturing process, quality, safety, labeling, and claims. This article will provide you with an overview of the health supplement regulations in Hong Kong.

## WHAT ARE 'HEALTH SUPPLEMENTS'?

Different regions have different terms for "health supplements." For example, they are termed "dietary supplements" in the United States, "food supplements" in the European Union, "complementary medicine" in Australia, and "health supplements" in countries of the Association of Southeast Asian Nations (ASEAN).

In general, the definition covers the following elements:[2]

- They are marketed in dosage form and not in conventional food form, such as tablets, capsules, pills, sachets of powder, and ampoules of liquids
- They contain concentrated sources of substances, alone or in combination, such as vitamins, minerals, fish oils, herbs, microorganisms
- They are used to supplement diet and provide a health or physiological benefit

**Table 1. Definition of "food" and "orally consumed products" according to Cap. 132 and Cap. 231.**

| Food[3] | Orally consumed products[4] |
|---|---|
| • **Including articles and substances used as ingredients in the preparation of food**<br>• **Excluding medicine as defined by Cap. 138 and Cap. 549** | • For human consumption<br>• Intended to be taken orally<br>• In any of the following forms: pill, capsule, tablet, granule, powder, semi-solid, liquid |

In Hong Kong, there is no legal definition for health supplements. They are classified as "food" and "orally consumed products" under Cap. 132 and Cap. 231 respectively, as shown in **Table 1**. It is also crucial to identify what is not a health supplement, based on the ingredients, intended uses, and claims **(Table 2)**.

### Implications to Pharmacists

In general, health supplements are regulated as food. The laws and standards are different from those of drugs, so pharmacy law training does not cover health supplement regulations. However, many pharmaceutical companies also sell nutraceutical products. Hence, regulatory affairs (RA) officers are responsible for preparing documents, maintaining records, and ensuring legal compliance of health supplement products. Therefore, it is important that pharmacists who are interested in regulatory works to understand the regulations and standards for health supplements.

| Table 2. Descriptions on what products are classified as "drugs", "Chinese medicine", or "conventional food products". | |
|---|---|
| **Drugs** | Health supplements are **not** for treating or preventing diseases or modifying physiological functions. If a product contains ingredients from the Schedule 10 Poisons List or fulfills the definition of a pharmaceutical product under the Pharmacy and Poisons Ordinance (Cap. 138), it will be regulated as a drug. Below are scenarios when vitamin products may be considered as pharmaceutical products:[5][6]<br>• Vitamin A with not less than 10000 IU daily dose<br>• Vitamin $B_3$ (nicotinic acid) with more than 200mg daily dose<br>• Vitamin D with more than 1000 IU daily dose<br>• Vitamin K, except vitamins $K_1$ or $K_2$ with 120mcg or less daily dose |
| **Chinese medicine** | If a product is composed solely of Chinese herbal substances specified in Schedule 1 and 2 of the Chinese Medicine Ordinance (Cap. 549) as active ingredients, they are regarded as proprietary Chinese medicine.[7] |
| **Conventional food products** | Meat, bread, and chewing gum are generally not regarded as health supplements. |

## FOOD REGULATIONS

### How are Health Supplements Regulated?

In Hong Kong, health supplements, namely vitamins and glucosamine containing products, were once considered as drugs in Hong Kong. However, in December 2015, after reviewing the regulations in other countries and available scientific information, the Pharmacy and Poisons Board (PPB) decided that these supplements are no longer considered as pharmaceutical products unless certain criteria are met. Therefore, health supplements are generally regarded as food and are regulated by the Food and Environmental Hygiene Department (FEHD) under the Public Health and Municipal Services Ordinance (Cap. 132 Part V) and Undesirable Medical Advertisements Ordinance UMAO (Cap. 231). This change meant that local manufacturers, importers, and distributors should register their products with the FEHD, instead of the Drug Office under the Department of Health.[8] Unlike pharmaceutical products, health supplements are not subjected to pre-market evaluation and registration by government authorities, and hence there are no sales restrictions for health supplements. Manufacturers are responsible for evaluating product safety, quality, and efficacy, and ensuring compliance with legal requirements. In addition, the Centre for Food Safety (CFS) has a food surveillance program, which is responsible for regular inspections and sample-takings at import, wholesale, and retail levels for microbiological, chemical, and radiation testing.[9] In the following sections, more details on the different aspects of health supplement regulations will be discussed.

### Food Quality and Safety Standards

Similar to pharmaceutical products, quality and safety are the top priority of food products. Therefore, there are regulations regarding ingredient restrictions, and heavy metal and microbial limits. First, all food manufacturers should have Good Manufacturing Practices (GMP) or equivalent certifications. GMP covers all aspects of food production – from the environment and the equipment to personnel and record management. Therefore, GMP certification is used as one of the guarantees that food products are manufactured under good control and are safe for consumption.

As for ingredients, unlike foreign countries, Hong Kong does not have an authoritative list of permitted or prohibited active ingredients, but there are restrictions on food additives and excipients. Products that exceed the concentration limits or contain prohibited substances are banned from sale. Related regulations are as follows:[10]

- Coloring Matter in Food Regulations (Cap. 132H)
- Sweeteners in Food Regulations (Cap. 132U)
- Preservatives in Food Regulations (Cap. 132BD)
- Pesticide Residues in Food Regulation (Cap. 132CM)
- Mineral Oil in Food Regulations (Cap. 132AR)
- Harmful Substances in Food Regulations (Cap. 132AF)[11] – Partially hydrogenated oil is prohibited in all food products. If the product contains fully hydrogenated oil, there should be a specification on the product packaging.
- Food Adulteration (Metallic Contamination) Regulations (Cap. 132V)[12] – Food groups have different heavy metal maximum limits as listed in the Schedule. If the supplement product does not fall into any food groups, CFS will continue to conduct a risk assessment to determine if the product may contain metal in a harmful amount. In such cases, suppliers can obtain a declaration from the manufacturing site to confirm that the heavy metal standard of the manufacturing country is met.

**Microbial Limits** [13]

| Microbial | Standard |
|---|---|
| *Escherichia coli* | < 20 cfu/g |
| *Listeria monocytogenes [ISO11290-2:1998/Amd1:2004]* | < 10 cfu/g |
| *Vibrio parahaemolyticus* | < 20 cfu/g |
| *Staphylococcus aureus* and other coagulase-positive staphylococci | < 20 cfu/g |
| *Clostridium perfringens* | < 10 cfu/g |
| *Bacillus cereus* | < $10^3$ cfu/g |
| *Campylobactoer spp.* (thermotolerant) | not detected in 25g |
| *Escherichia coli* O157 (and other Shiga toxin-producing E.Coli (STEC)) | not detected in 25g |
| *Salmonella spp.* | not detected in 25g |
| *Vibrio cholerae* (O1 and O139) | not detected in 25g |

## Product Labeling Requirements

Under Food and Drugs (Composition and Labeling) Regulations (Cap. 132W), schedules 3 and 5 specifies the labeling requirements for all pre-packaged food.[14, 15] The information required on the label is as follows:

- Name of the food
- Ingredient list
  - Listed in descending order of weight or volume
  - Additives listed by functional class and the specific name/ identification number
  - Allergen declaration
- Nutrition label
  - Label should include energy, core nutrients (carbohydrates, sugars, total fat, saturated fat, trans fat, protein, sodium), and claimed nutrients
  - The declared value should be based on respective tolerance limits:

| Energy/ Nutrient | Tolerance Limits |
|---|---|
| Energy, total fat, saturated fat, trans fat, cholesterol, sodium and sugars | < 120% declared value |
| Protein, polyunsaturated fat, monounsaturated fat, carbohydrates, starch, dietary fibre, soluble fibre, insoluble fibre, individual component of fibre | > 80% declared value |
| Vitamins and minerals (other than Vitamin A, Vitamin D and added vitamins and minerals) | > 80% declared value |
| Added vitamins and minerals (other than Vitamin A and Vitamin D) | > 100% declared value |
| Vitamin A and Vitamin D (including added ones) | 80% - 180% declared value |

- Indication of “use by” (此日期或之前食用) or “best before” (此日期前最佳) date
- Count, net weight, or volume of food
- Special conditions for storage or instructions for use
- Name and address of manufacturer or packer

The labeling can be in Chinese or English. However, if both languages are used in the labeling, then the name of the food ingredient list must appear in both languages. Examples of proper labeling are shown in **Figures 1** and **2**.[16]

## Promotion and Nutritional Claims

No prior authority approval is needed for promotional materials like television advertisements or posters. However, companies should ensure that there are no medicinal claims, misleading claims, or violations of UMAO. Under Cap. 132W, three types of nutritional claims are permitted with specific requirements.[14, 15] Claims can only be made for nutrients included in Schedules 7 and 8.

*Nutrient content claim* refers to the claim that describes the energy value or the content level of a nutrient contained in a food. Common wordings include “contain”, “low”, “high” and “zero”. Cap. 132W Schedule 8 listed the conditions for nutrient content claims for respective nutrients. Nutrients must meet the conditions to make nutrient content claims.

*Nutrient comparative claim* refers to the claim that compares the energy value or the content level of a nutrient in the same or similar types of food, for example, different brands of the same or similar food items. Common wordings include “less”, “reduced”, “extra” and “more”. To make nutrient comparative claims, both the absolute and relative difference criteria should be met. Concerning the core nutrients and energy, the content should have a relative difference of at least 25%. Concerning vitamins and minerals, the content should have a relative difference of at least 10% Chinese nutrient reference value (NRV). The absolute difference should


***Figure 1 and 2**: Examples of appropriate labeling of prepackaged food.*

be greater than the figure defined as “low” or “source” in column 4 of Schedule 8. In addition, the comparison should be based on the same quantity of food and the description of food being compared should be placed close to the nutrient comparative claims.

*Nutrient function claim* refers to the claim that describes the physiological role of a nutrient in the growth, development, and normal functions of the body. The claims should be based on scientific evidence. Also, the content of the nutrient concerned should not be less than the minimum amount set out in column 4 of Schedule 8.

## COMPARISON OF FOOD AND DRUG REGULATIONS

In Hong Kong, there are different laws and ordinances for food supplements and pharmaceutical products. Hence, there are different quality, sales, claims, and labeling requirements as shown in **Table 3**. One key difference is pre-market evaluation and approval. Pharmaceutical companies are required to submit new drug applications and dossiers, which are subjected to review by the Department of Health. In contrast, there is no pre-market approval for food products, so companies only need to prepare all the documents and conduct internal evaluations before market launch. For both, food supplements and pharmaceutical products, RA officers are involved in reviewing and ensuring legal compliance. **Table 4** shows a comparison of the required documents for new drug registration and food product launch, which highlights some similarities.

## CONCLUSION

As health supplements is one of the leading trends in the healthcare industry, the aim of the article is to increase pharmacists’ awareness about food regulations. In the pharmaceutical industry, it is becoming increasingly common for RA officers in pharmaceutical companies to handle the launch of food products. Since pre-market evaluation by health authorities is not required, RA officers are the final guardians before the official product launch. Thus, the role of RA officers is crucial to manage product launch, and handle inspections and enquiries. As this article provides a brief overview of health supplement regulations, more detailed guidance can be found in the technical guidelines provided on CFS websites or the Ordinance.

**Table 3: General comparison of food and drug regulations**

| | **Drug** | **Food** |
|---|---|---|
| **Law & Ordinance** | Cap. 138, Cap. 137, Cap. 134,<br>Cap. 231 UMAO, Cap. 60A Import Export, Cap. 132 Part V | Cap. 132 Part V<br>Cap. 231 UMAO |
| **Governing authority** | Department of Health (DoH) | Food Hygiene and Environmental Department (FEDH) |
| **Pre-market approval** | **Yes**<br>- Need to register and approve label<br>- Evaluates quality, safety, efficacy<br>- Need renewal every 5 years<br>- Need approval for Change of Registered Particulars (CORP) | **No**<br>- internal evaluations only<br>- No renewal required |
| **Sales** | Regulated sales:<br>Prescription/Pharmacy-only/ OTC | Not regulated<br>Allow e-commerce |
| **Promotion** | No authority approval needed | No authority approval needed |
| **Claims requirement** | **UMAO**<br>- prohibited: claims related to abortion<br>- Schedule 1: prohibited disease and permitted purpose<br>- Schedule 2: prohibited purpose<br>- Schedule 4: prohibited high-risk claims and restricted claims (BG, BP, lipids), examples of allowable claims<br>**Cap 132:**<br>prohibited any false or misleading claims | **UMAO**<br><br>**Cap 132**<br><br>Additional nutrition labeling guidance (Cap. 132W):<br>- Nutrient content claims<br>- Nutrient comparative claims<br>- Nutrient function claims |
| **Labeling** | Ingredient declaration for Active Pharmaceutical Ingredient (API) only<br>Additional warning statements for some drugs | Cap 132Q: full list of ingredients, additives and their function, and potential allergen |
| | Nutrient claim for active nutrients | Nutrition label: Energy, core nutrients and claimed nutrients |
| **Quality standards (microbiology & impurities)** | **Harmonized standards:**<br>Pharmacopoeia<br>International Council for Harmonisation (ICH)/ World Health Organization (WHO) guidelines | **Separate guidelines:**<br>Coloring Matter (Cap. 132H)<br>Sweeteners (Cap. 132U)<br>Harmful Substances (Cap. 132AF)<br>Preservatives (Cap. 132BD)<br>Pesticide Residues (Cap. 132CM)<br>Mineral Oil in Food Regulations (Cap. 132AR)<br>Metallic Contamination (Cap. 132V)<br>Microbiology Guidelines for Food |

| Table 4: Comparison of the documents required for authority submission or internal review | |
|---|---|
| **New drug registration**<br>Documents for authority submission | **New food product launch**<br>Documents for internal review |
| 3.2.P.1 Description and composition of the Drug Product | Master Formulation<br>- Composition compliance<br>- In descending order<br>- Food additives and their functions |
| 3.2.P.5.1 Specification derived based on pharmacopoeia | Specification derived based on importing country quality standard and risk assessment |
| 3.2.P.5.2 Analytical Procedures | --- |
| 3.2.P.5.3 Validation of Analytical Procedures | --- |
| 3.2.P.5.4 Batch Analysis (COA) | Certificate of Analysis (COA) |
| 3.2.P.8.3 Stability Data | Stability Data |
| Manufacturer licenses (Bulk, packer etc.) | Manufacturer license<br>Manufacturer details |
| Certified Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP for all the above manufacturers | GMP, Hazard Analysis and Critical Control Point (HACCP) or equivalent certification |
| Site Master File | --- |
| Manufacturing flow chart indicating the manufacturing process, name/address & role of the manufacturer(s) involved and proposed updates. | Manufacturing process |
| Final product picture (dosage form) | --- |
| Manufacturer declaration to clarify the relationship between the Marketing Authorization (MA) holder & the manufacturer | --- |
| Certificate of Pharmaceutical Product (CPP) (marketed) from country of Origin together with the approved labels | Free Sale Certificate from other countries (Optional) |
| If the country of origin is not one of the following recognized reference countries, we also need to get a CPP (marketed) from the following countries with the approved labels :- Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Holland, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, South Korea, Spain, Sweden, Switzerland, UK and USA. | --- |
| Proposed pack sizes and labels | Labels fulfilling local labeling regulations, including<br>- nutrition information<br>- allergen declaration |

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