

***Regulation of Health Food  
in Hong Kong***

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**Prepared by**

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## EXECUTIVE SUMMARY

1. In Hong Kong, health food is not defined in law. Health food products, depending on their ingredients, are regulated under four different ordinances. These are the Public Health and Municipal Services Ordinance (PHMSO), the Pharmacy and Poisons Ordinance (PPO), the Chinese Medicine Ordinance (CMO), and the Undesirable Medical Advertisements Ordinance (UMAO).
2. Health food products as general food products are subject to the regulation of the PHMSO which provides that manufacturers and sellers of food have a responsibility to ensure that their products are fit for human consumption. The Food and Environmental Hygiene Department is responsible for enforcing the Ordinance.
3. Health food products which contain western medicines are regulated under the PPO. The PPO provides for the registration of products containing western medicines to safeguard the safety, quality and efficacy of products, and includes the requirement that claims in the product descriptions must be truthful. The Ordinance also requires the licensing of manufacturers, importers, wholesalers and retailers of these products. The Department of Health is responsible for enforcing the Ordinance.
4. Health food products which contain Chinese medicines are regulated under the CMO. According to a survey conducted by the Department of Health in 1996, 67% of health food products available on the market contained Chinese medicines. The CMO provides for a registration system of proprietary Chinese medicines. In approving applications for registration, the safety, quality and efficacy of the medicines, including the truthfulness of the claims in the product descriptions, will be examined. Under the Ordinance, manufacturers, importers, wholesalers, and retailers must obtain a license before manufacturing or selling such medicines in Hong Kong. The Department of Health is responsible for enforcing the Ordinance.
5. The UMAO provides that no person should publish any advertisements claiming that any medicine or treatment has curative or preventive effects on any of the 14 specified diseases as specified in the Schedule of the Ordinance. Under the Ordinance, health food products are prohibited to make claims in treating or preventing the specified diseases. The Department of Health is responsible for enforcing the UMAO.
6. Some concerns are raised in regulating health food in Hong Kong. These are: (a) the relevant subsidiary legislation to regulate health food products which contain Chinese medicines has not yet been introduced; (b) health food products making untruthful and exaggerated health claims; and (c) regulation of health claims under the UMAO.
7. The Administration has proposed to devise a regulatory framework to regulate health claims made by food products. Food products claiming health benefits will fall under two categories: (a) claims to prevent or cure a **specific disease or clinical condition** are required for pre-market approval; and (b) claims to have **general beneficial effects** on health are exempted from registration.
8. We have some general comments on the Administration's initial proposal on the regulation of health claims. The Administration may need to consider (a) determining what are health issues; (b) establishing an appropriate mechanism to distinguish the two types of claims; (c) establishing an advisory committee to provide professional advice in examining health claims; and (d) establishing an appeal system for health food traders to make any appeal.

# **REGULATION OF HEALTH FOOD IN HONG KONG**

## **PART 1 - INTRODUCTION**

### **1. Background**

1.1 In March 2000, the Panel on Health Services requested the Research and Library Services Division to conduct a research on the regulation of health food in overseas places.

### **2. Scope of the Research**

2.1 The objective of this research is to study the regulation of health food in Australia, Taiwan, the United States and Hong Kong. The scope includes differentiation of health food from conventional food and medicine, the relevant regulation and its enforcement, and the channel through which health food is marketed. This study mainly discusses food products not sold in their conventional forms: they include products sold in the form of capsules, pills, tablets or powder, etc.

2.2 In this report, we discuss the existing regulatory framework of health food in Hong Kong, some concerns raised in regulating health food, and the Hong Kong Special Administrative Region Government's initial proposal to develop a statutory framework to monitor and regulate health claims advertised in the market.

2.3 This research report forms part of a series of reports discussing the regulation of health food. There are four separate research reports on this subject.

### **3. Methodology**

3.1 Information for this research is obtained from the Internet, government reports and relevant reference materials. Telephone interviews with officers of the Health and Welfare Bureau, the Environment and Food Bureau, and the Consumer Council were also conducted.

**PART 2 - DEFINITIONS OF RELEVANT TERMS IN HONG KONG****4. Terms and Definitions**Food

4.1 Under section 2 of the Public Health and Municipal Services Ordinance (Cap. 132), food includes --

- (a) drink;
- (b) chewing gum and other products of a like nature and use;
- (c) smokeless tobacco products; and
- (d) articles and substances used as ingredients in the preparation of food or drink or of such products,

but does not include --

- (i) live animals, live birds or live fish (excluding shell fish);
- (ii) water, other than -- (A) aerated water; (B) distilled water; (C) water from natural springs, either in its natural state or with added mineral substances; and (D) water placed in a sealed container for sale for human consumption;
- (iii) fodder or feeding stuffs for animals, birds or fish; or
- (iv) articles or substances used only as drugs.

4.2 Food products sold in the form of capsules, pills, tablets or powder, etc. are regulated as food so long as they do not contain any drugs.

Drugs

4.3 According to the Public Health and Municipal Services Ordinance (Cap. 132), drugs include pharmaceutical product and medicine, Chinese herbal medicine, or proprietary Chinese medicine for internal or external use by man.

*Pharmaceutical Product and Medicine*

4.4 Under section 2(1) of the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical product and medicine mean any substance or mixture of substances manufactured, sold, supplied or offered for sale or supply for use in --

- (a) the diagnosis, treatment, mitigation, alleviation or prevention of disease or any symptom thereof;
- (b) the diagnosis, treatment, mitigation, alleviation of any abnormal physical or physiological state or any symptom thereof;
- (c) altering, modifying, correcting or restoring any organic function,

in human beings or in animals.

### *Chinese Herbal Medicine*

4.5 Under the Chinese Medicine Ordinance (Cap. 549), Chinese herbal medicine means any of the substances specified in Schedule 1 or 2.

### *Proprietary Chinese Medicine*

4.6 Under section 2 of the Chinese Medicine Ordinance (Cap. 549), proprietary Chinese medicine means any proprietary product --

- (a) composed solely of the following as active ingredients<sup>1</sup> --
  - (i) any Chinese herbal medicines; or
  - (ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or
  - (iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;
- (b) formulated in a finished dose form; and
- (c) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body.

### Health Food

4.7 In Hong Kong, health food is not defined in law. The Government ("the Administration" hereafter) has indicated that there is no universally accepted definition of health food. Different terms such as dietary supplements, functional foods, nutraceuticals, designed foods and natural health products are used in different context to refer to similar products.

### Advertisements

4.8 The Undesirable Medical Advertisements Ordinance (Cap. 231) prohibits or restricts advertisements likely to lead to the use of any medicine, surgical appliance or treatment for a list of diseases as set out in a Schedule. The intent is to prevent the general public from being misled into using improper medicinal products for self-medication in respect of these diseases. The Schedule setting out the relevant diseases is attached at Appendix I for easy reference.

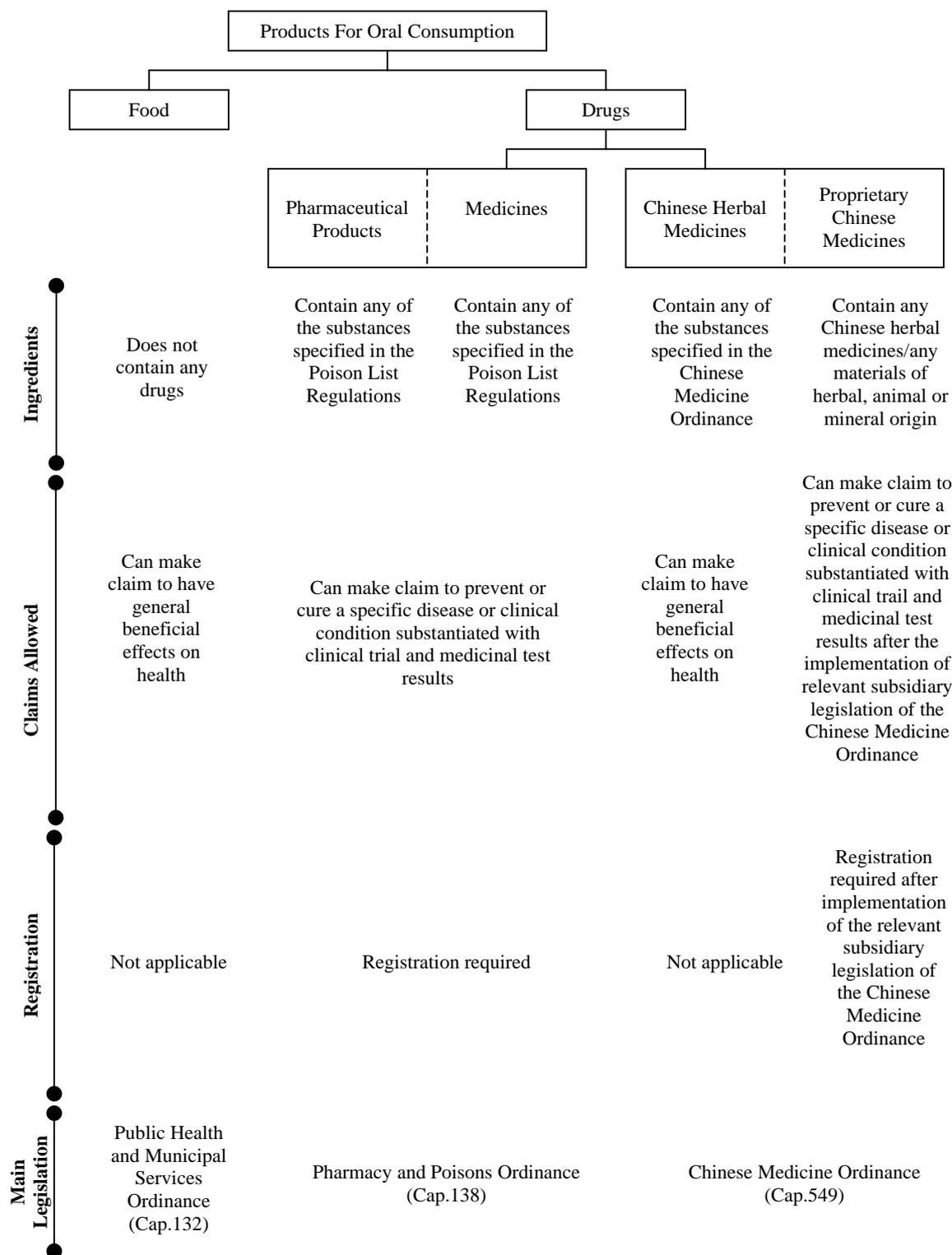
4.9 This Ordinance also applies to health food products. In other words, health food products are prohibited to make claims in treating or preventing the diseases specified in the Ordinance.

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<sup>1</sup> Active ingredient means a substance or compound that is used or is intended to be used in the manufacture of the proprietary Chinese medicine and that contributes to the pharmacological effect or effects of the proprietary Chinese medicine.

4.10 The regulation of products for oral consumption in Hong Kong is summarized in the following diagram.

**Diagram -- Regulation of Products for Oral Consumption**



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## PART 3 - SOME FACTS ABOUT HONG KONG'S HEALTH FOOD MARKET AND THE USE OF HEALTH FOOD AMONG ADULTS

### 5. Market Situation

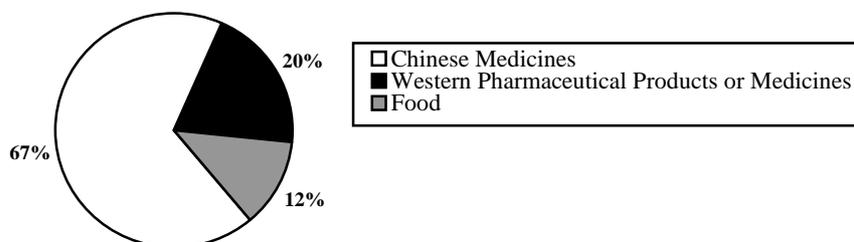
5.1 Many Hong Kong people yearn for better health or appearance. Capitalizing on the strong demand for health food, Hong Kong companies have been actively promoting a variety of products claiming certain beneficial effects on health, including "detoxify the body"<sup>2</sup>, "strengthen immunity system", "whiten skin", "improve skin texture", "nourish the liver and kidneys", "reduce the cholesterol level", "remove blemishes", and "enhance metabolism". However, these claims may or may not be substantiated with sufficient scientific evidence.

5.2 At present, health food products commonly sold in Hong Kong include vitamin and mineral supplements, shark liver oil capsules, shark cartilage capsules, deep-sea fish oil capsules, Chinese medicinal fungi and herbs pills, royal jelly extracts, pollen tablets, and aloe extracts.

5.3 Health food products are sold in a whole range of outlets which include drug stores, pharmacies, health food stores, and supermarkets.

### 6. Major Findings of a Survey of Health Food Conducted by the Department of Health in 1996

6.1 The Department of Health conducted a survey of health food products on sale at retail shops in 1996 and published a summary of the findings in 1997.<sup>3</sup> Of the 769 products surveyed, 518 (67%) were found to contain Chinese medicines. These products would be registered under the Chinese Medicine Ordinance (Cap. 549) when the relevant provisions come into effect in due course. Another 156 (20%) were western pharmaceutical products or medicines which should have been registered under the Pharmacy and Poisons Ordinance (Cap. 138). The remaining 95 (12%), which could not be classified as Chinese medicine or western medicine, were regulated as food (see the following chart for details).



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<sup>2</sup> Consumers buy these products in the hope that they can purportedly rid the body of the toxins and wastes that are harmful to health.

<sup>3</sup> The Health and Welfare Bureau turned down our request for a copy of the full document.

6.2 The Administration indicated that the bulk of health food products were already subject to or would be subject to the control provided under the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance. A proportion of the total (12%), hitherto regulated as food products, "would require additional control measures to address the concerns of misleading or exaggerated health claims."<sup>4</sup>

## **7. Major Findings of a Research Studying the Use of Health Food Among Adults in Hong Kong in Year 2000**

7.1 Dr Georgia Guldan, a professor in nutrition at the Department of Biochemistry of the Chinese University of Hong Kong, conducted a research studying the use of health food<sup>5</sup> among adults in Hong Kong between October 1999 and January 2000.<sup>6</sup> A total of 1 802 interviews were completed, with 765 males (43%) and 1 037 females (57%). The major findings of the research are summarized below.

7.2 The study found that 10% of males and 18% of females reported taking health food. The respondents who reported taking health food spent on average about \$300 per month on health food. Females in the 25-44 years old groups purchased health food at the highest rate (21%), while the highest rate (16%) of purchasing these among males was in the 25-34 years old group. Respondents who had full-time employment (12% of males and 23% of females) of both genders purchased health food more often than people with a different employment status (i.e. employed part-time, unemployed, housewife, and student).

7.3 The more educated respondents of both genders purchased health food more often than the less educated respondents. As income increased, the prevalence of purchasing health food also increased. For the group with reported household income above \$40,000 per month, 15% of males and 36% of females purchased health food. Common types of health food were vitamin and mineral supplements, pollen tablets, shark liver oil capsules, and Chinese medicinal fungi and herbs drinks.

7.4 The findings of the study showed that most people learnt the use of health food mainly from friends or colleagues, and the next most common source of information was their doctors. Benefits sought included general health, nutritional wellness, disease prevention, and better appearance (such as healthier skin).

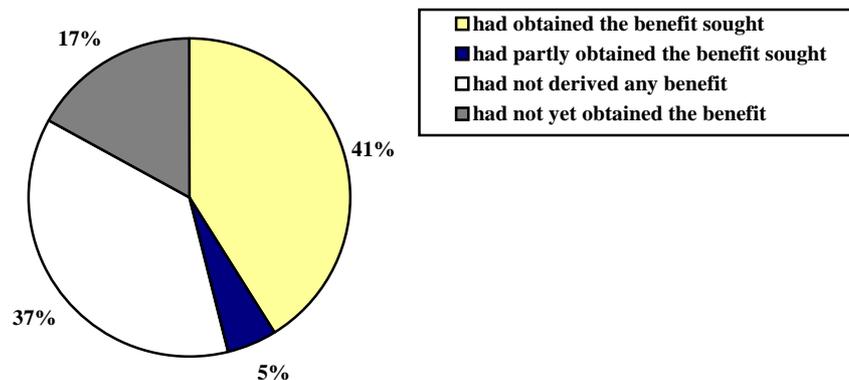
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<sup>4</sup> Legislative Council Panel on Health Services, Regulation of Health Claims, 12 December 2000, Paper No. CB(2)412/00-01(03), paragraph 7.

<sup>5</sup> In the study, the term "health food" refers to nutrient supplements that are intended to supplement the diet so as to provide health benefits. Nutrient supplements are intended for ingestion in pill, capsule, tablet, or liquid form.

<sup>6</sup> Georgia Guldan, Hong Kong Adult Nutrition Awareness Survey: 1999, The Chinese University of Hong Kong.

7.5 Less than half (41%) of the users of health food felt that they had obtained the benefits sought, with another 5% indicated that they had partly obtained the benefits. More than one-third of the users (37%) reported that they had not derived any benefit at all. The remaining 17% of subjects reported that they had “not yet” obtained benefits or else they did not know or were uncertain if they had (see the following chart for details).



## **PART 4 - EXISTING REGULATORY FRAMEWORK OF HEALTH FOOD IN HONG KONG**

### **8. Legislation Regulating Health Food**

8.1 Health food products, depending on their ingredients, are regulated under four different ordinances detailed as follows.

#### Public Health and Municipal Services Ordinance (Cap. 132)

8.2 Health food products as general food products are subject to the regulation of the Public Health and Municipal Services Ordinance (Cap. 132) which provides that manufacturers, importers and sellers of food have a responsibility to ensure that their products are fit for human consumption.

8.3 The Ordinance also makes it an offence for any person to give or to display a food label which falsely describes the food or is calculated to mislead as to its nature, substance or quality. The Food and Drugs (Composition and Labelling) Regulations made under the Ordinance set out the labelling requirements for prepackaged food: (a) name or designation; (b) list of ingredients and food additives; (c) durability period; (d) special condition for storage or instruction for use; (e) name and address of manufacturer or packer; and (f) count, weight or volume.

8.4 All imported food products are required to meet the same standard as domestically-produced products, i.e. food is sound, wholesome or fit for human consumption.

8.5 The Food and Environmental Hygiene Department is responsible for enforcing these provisions and testing samples of various types of food, including health food products. The Food and Environmental Hygiene Department issues a warning or advisory letter to any trader of a health food product suspected of carrying descriptions which are false or misleading in terms of the nature, substance, or quality of the food product. If the trader of a health food product does not take any action to rectify the problematic descriptions, the Food and Environmental Hygiene Department will consider prosecuting the trader.

8.6 In year 2000, the Food and Environmental Hygiene Department issued 20 warning or advisory letters to health food traders in respect of labelling of squalene product. Of these cases, 18 of them concerned the breach of the Food and Drugs (Composition and Labelling) Regulations regarding (a) incomplete indication of food name, (b) list of ingredients not indicated on label, (c) unclear indication of "best before" date, and (d) incomplete indication of name and address of manufacturer. Two cases concerned advertisement likely to mislead as to the quality of the product. All the health food traders concerned withdrew their products from the market and rectified their problematic descriptions. The Food and Environmental Hygiene Department had not taken any prosecution regarding health food products under the Public Health and Municipal Services Ordinance (Cap. 132) in year 2000. The details of these 20 cases are attached at Appendix II for reference.

### Pharmacy and Poisons Ordinance (Cap. 138)

8.7 Health food products which contain western medicines are regulated under the Pharmacy and Poisons Ordinance (Cap. 138). The Ordinance provides for the registration of products containing western medicines to safeguard the safety, quality and efficacy of products, and includes the requirement that claims in the product descriptions must be truthful. The Ordinance also requires the licensing of manufacturers, importers, wholesalers and retailers of these products.

8.8 The Pharmacy and Poisons Regulations made under the Ordinance also provide that products which contain western medicines should be labelled with detailed description of the dosage, the route and frequency of administration.

8.9 All products containing western medicines, whether or not they are locally manufactured or imported from other places, are required to comply with the Pharmacy and Poisons Ordinance (Cap. 138) and the Pharmacy and Poisons Regulations.

8.10 The Pharmacy and Poisons Board, chaired by the Director of Health and comprising relevant government officials, medical practitioners, pharmacists and academics, is responsible for overseeing the implementation of controls under the Ordinance. Inspectors of the Department of Health inspect pharmacies and medicine shops. They check the validity of product descriptions and descriptions which differ from those approved when the products were registered.

### Chinese Medicine Ordinance (Cap. 549)

8.11 Health food products which contain Chinese medicines are regulated under the Chinese Medicine Ordinance (Cap. 549). This Ordinance, enacted in July 1999, provides for a regulatory framework for monitoring the safe use of proprietary Chinese medicines. According to the survey conducted by the Department of Health in 1996, 67% of health food products available on the market contained Chinese medicines. (Please see paragraphs 6.1 and 6.2 above for the major findings of their survey on health food.)

8.12 The Ordinance empowers the Chinese Medicine Council to regulate proprietary Chinese medicines. The Council consists of the Director of Health, public officers, Chinese medicine practitioners, persons from the trade of Chinese medicines, persons from educational or scientific research institutions in Hong Kong, and lay persons. The Department of Health is responsible for enforcing the provisions under the Ordinance.

8.13 The Ordinance provides for a registration system of proprietary Chinese medicines. In approving applications for registration, the safety, quality and efficacy of the medicines, including the truthfulness of the claims in the product descriptions, will be examined. Under the Ordinance, manufacturers, importers, wholesalers, and retailers must obtain a license before manufacturing or selling products that contain such medicines in Hong Kong.

8.14 All products which fall into the domain of proprietary Chinese medicines, whether or not they are domestically-made or imported from other places, are required to comply with the Chinese Medicine Ordinance (Cap. 549).

#### Undesirable Medical Advertisements Ordinance (Cap. 231)

8.15 The Undesirable Medical Advertisements Ordinance<sup>7</sup> (Cap. 231) provides that no person should publish any advertisements (including trade descriptions and labels) claiming that any medicine or treatment has curative or preventive effects on any of the 14 diseases as specified in the Schedule of the Ordinance (see Appendix I for details.)

8.16 The Ordinance also applies to health food products. In other words, health food products are prohibited to make claims in treating or preventing the diseases specified in the Ordinance.

8.17 The Department of Health is responsible for monitoring medical and health advertisements in the media including newspapers and magazines. The Department of Health also investigates complaints received from members of the public or referred by organizations such as the Consumer Council<sup>8</sup>. The Department of Health issues warning letters to the persons who have published or caused to publish the undesirable advertisement or product labels which contravenes the Ordinance. If a person, upon receiving a warning letter, does not remove the undesirable advertisements involved or recall products with undesirable labels, the Department of Health will inform the Commissioner of Police, who will investigate and initiate prosecution action where necessary. Any person who contravenes the Ordinance and is found guilty of the offence is liable upon a first conviction to a maximum fine of \$10,000, and upon a second or subsequent conviction to a maximum fine of \$25,000 and imprisonment for one year.

#### *Statistics of Enforcement Actions Taken from 1997 to 2000*

8.18 The number of warning letters issued by the Department of Health increased four-fold from 86 in 1997 to 394 in year 2000. However, in the past four years, only one prosecution was made. A breakdown of the statistics of enforcement actions taken from 1997 to 2000 is as follows –

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<sup>7</sup> The Undesirable Medical Advertisements Ordinance came into effect in 1953 and was last amended in 1988.

<sup>8</sup> In January 2000, the Consumer Council notified the Department of Health of the 11 shark liver oil capsules with claims about curing or preventing diseases possibly in contravention of the Undesirable Medical Advertisements Ordinance (Cap. 231).

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**Table 1 - Statistics of Enforcement Actions Taken from 1997 to 2000**

	1997	1998	1999	2000
Number of newspaper/magazine screened	544	321	612	529
Number of warning letters issued by the Department of Health	86	121	178	394
Number of prosecution	1	0	0	0

Sources: Health and Welfare Bureau  
Legislative Council Panel on Health Services, Regulation of Health Claims Under the Undesirable Medical Advertisements Ordinance (Cap. 231), 8 May 2000, CB(2)1857/99-00(4).

8.19 The prosecution made under the Undesirable Medical Advertisements Ordinance (Cap. 231) in 1997 was a case regarding an advertisement on cancer treatment and not related to health food. The person concerned was fined \$4,000. The Administration explained that in their experience, the persons who had received the warning letter would stop advertising, therefore the number of prosecutions had been very low.

8.20 The breakdown of the warning letters issued by the Department of Health made under the Undesirable Medical Advertisements Ordinance (Cap. 231) from 1997 to 2000 is set out in Table 2. It can be seen that the number of warning letters issued by the Department of Health regarding Chinese medicines and food products continued to increase from 1997 to 2000. In year 2000, these two categories altogether accounted for 70% of the total number of warning letters issued by the Department of Health.

**Table 2 - Breakdown of the Warning Letters Issued by the Department of Health Made under the Undesirable Medical Advertisements Ordinance (Cap. 231) from 1997 to 2000**

	1997	1998	1999	2000
Western medicines	3	6	22	41
Chinese medicines	31	46	70	122
Food products	20	36	50	155
Others	32	33	36	76
<b>Total</b>	<b>86</b>	<b>121</b>	<b>178</b>	<b>394</b>

Source: Health and Welfare Bureau

## **PART 5 - SOME CONCERNS RAISED IN REGULATING HEALTH FOOD IN HONG KONG**

### **9. The Relevant Subsidiary Legislation to Regulate Health Food Products Which Contain Chinese Medicines Has Not Yet Been Introduced**

9.1 As discussed in paragraphs 6.1, 6.2, and 8.11 above, about 70% of the health food products available on the market contained Chinese medicines. However, at present, these products are not yet subject to proper control because the Administration has not yet introduced the relevant subsidiary legislation to implement the registration system.

### **10. Health Food Products Making Untruthful and Exaggerated Claims**

10.1 Many food products claiming certain beneficial effects on health are found in the local market. As these products, generally described by the manufacturers/sellers as "health food", become increasingly popular, the numbers of consumer complaints received by the Consumer Council against misleading or exaggerated health claims and even allegations of presence of harmful elements in these products increased from 1998 to 2000. The Consumer Council received 56 complaints on "health food" in 1998, 293 complaints in 1999, and 308 complaints in year 2000.

10.2 The Consumer Council tests the efficacy of "health food" to protect the interests of consumers. Their tests revealed that some health food products could not meet the specification of the World Health Organization standard and made untruthful and exaggerated health claims. The Consumer Council has raised concerns over the issue of making untruthful and exaggerated health claims.

10.3 The Consumer Council conducted three studies on health food products in year 2000. In January 2000, the Council<sup>9</sup> reported that at least five brands of shark liver oil capsules were contaminated with a suspected carcinogenic substance polychlorinated biphenyls (PCBs), and casted serious doubts on the validity of health claims that included, for example, "strengthen immunity system", "anti-cancer", and "anti-ageing", etc. In April 2000, to assess the efficacy of "detoxifying" dietary supplements, the Council sought expert opinions from Chinese herbalists and western medical doctors. Both had their doubts over the necessity of the body for such dietary supplements.<sup>10</sup> In November 2000, a Consumer Council test found that none of the 14 samples could fully meet the specification of the World Health Organization standard laid down for active ingredients and allergen of Ginkgo biloba leaf products. These herbal preparations have been marketed as health food to improve mental alertness.<sup>11</sup>

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<sup>9</sup> Consumer Council, *CHOICE*, January 2000.

<sup>10</sup> Consumer Council, *CHOICE*, April 2000.

<sup>11</sup> Consumer Council, *CHOICE*, November 2000.

## 11. Regulation of Health Claims under the Undesirable Medical Advertisements Ordinance

### Interpretation of Advertisement

11.1 Some members of the Legislative Council Panel on Health Services and the Consumer Council have expressed concerns about the interpretation of "advertisement" under the Undesirable Medical Advertisements Ordinance (Cap. 231). The term "advertisement" includes any notice, poster, circular, label, wrapper or document, and any announcement made orally or by any means of producing or transmitting light or sound but does not include a package insert. Many health food promoters may have used this loophole to make misleading or even false health claims.<sup>12</sup>

11.2 The Department of Health considered that information supplied inside any container or package containing any medicine, surgical appliance or treatment is not an advertisement because it is not on display and is only visible to the purchaser of the product after the sale takes place. Information containing particulars such as composition, indications, directions, side-effects, name and address of manufacturers, etc. is also useful for the reference of doctors and pharmacists. As such, it should not constitute publication of an advertisement.<sup>13</sup>

11.3 Some members of the Legislative Council Panel on Health Services held the view that the package inserts should also be regulated. The Administration responded that "*during the scrutiny of the then Undesirable Medical Advertisements Bill, it was a conscious decision made by the Bills Committee concerned that the term "advertisement" should not include a package insert. ... Chinese medicines were subject to the regulation by Chinese Medicine Ordinance, there would be control measures introduced to regulate them as well as health food products since most of them contained Chinese medicines.*"<sup>14</sup>

### Prosecution Policy

11.4 There has only been one prosecution under the Ordinance so far. The present practice of first issuing a warning letter to anyone found misleading the public by inducing them to use improper medicinal products is ineffective in protecting consumers. Many unscrupulous operators may have taken advantage of the lenient enforcement policy by mounting a large scale promotion to sell their products and cease operation upon being warned by the Department of Health without suffering any penalty. The Administration may need to consider reviewing its enforcement policy and stepping up prosecutions in the enforcement of the Undesirable Medical Advertisements Ordinance in an effective way.

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<sup>12</sup> Consumer Council, *CHOICE*, August 1998.

<sup>13</sup> Consumer Council, *CHOICE*, August 1998.

<sup>14</sup> Legislative Council Panel on Health Services, Minutes of Meeting held on 8 May 2000, Paper No. CB(2)2223/99-00, Paragraph 38.

### Scope of Control Against Undesirable Medical Advertisements

11.5 Some members of the Legislative Council Panel on Health Services expressed concerns that the Schedule of the Undesirable Medical Advertisements Ordinance was too disease-oriented and it is considered that the scope of control against undesirable advertisements should be extended to cover health claims of any products.<sup>15</sup>

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<sup>15</sup> Legislative Council Panel on Health Services, Minutes of Meeting held on 8 May 2000, Paper No. CB(2)2223/99-00, Paragraph 41.

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## **PART 6 - THE ADMINISTRATION'S INITIAL PROPOSAL ON THE REGULATION OF HEALTH FOOD**

### **12. An Interdepartmental Task Force to Study the Need to Strengthen the Regulation of Claims Carried by Health Food**

12.1 To review the current situation concerning claims carried by health food in the market and to consider the way forward, an Interdepartmental Task Force comprising members from the Health and Welfare Bureau, Environment and Food Bureau, Department of Health, and Food and Environmental Hygiene Department was set up in March 2000. The Administration will study in 2001 the feasibility of developing a regulatory framework to monitor and regulate health claims advertised in the market so as to protect the consumers from misleading information and exaggerated claims.

### **13. The Administration's Initial Proposal on the Regulation of Health Claims**

13.1 In December 2000, the Administration submitted a paper entitled *Regulation of Health Claims*<sup>16</sup> to the Panel on Health Services setting out an initial proposal on the regulation of health claims.

13.2 The Administration has proposed to devise a regulatory framework to regulate the health claims carried by food products in order to protect the consumers from misleading information and exaggerated claims. The Director of Health will be empowered to prohibit products from making irresponsible health claims. Initially, the Administration has proposed to confine the restriction to food products, and to expand the restriction to cover other products, in light of experience in due course.

13.3 The Administration has proposed that food products claiming health benefits would fall under two categories:

- (a) Those claiming to be able to prevent or cure a **specific disease** or **clinical condition** should be first registered with the Director of Health for pre-market approval, with claims properly substantiated by research or trials; and
- (b) Those claiming to have **general beneficial effects** on health will be exempted from registration, with the Director of Health retaining the power to determine whether the claim made is a general or specific one.

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<sup>16</sup> Legislative Council Panel on Health Services, Regulation of Health Claims, 12 December 2000, Paper No. CB(2)412/00-01(03).

13.4 The Director of Health will maintain surveillance of the market and give guidelines to the traders, who may consult the Director of Health beforehand to determine whether the claim falls under (a) or (b) in paragraph 13.3. In either case the food product in question will be still subject to regulation under the Public Health and Municipal Services Ordinance (Cap. 132), i.e. the product must be fit for human consumption.

13.5 At present, the Administration's view is that a claim, for example, that the product can strengthen the body or improve blood circulation can be accepted as a general claim, but one which says that the product can enhance the immunity system of the body will be taken as a specific claim that requires substantiation. The Administration will determine what are health issues. For example, are issues such as weight control, hair loss or breast enhancement "health" issues and claims related to them should be regulated? The Administration has proposed to carry out extensive consultation in order to propose a regulatory regime that is acceptable to the manufacturers, traders and the public.

## **PART 7 - ANALYSIS**

### **14. The Relevant Subsidiary Legislation to Regulate Health Food Products Which Contain Chinese Medicines Has Not Yet Been Introduced**

14.1 As discussed in paragraphs 6.1, 6.2, and 8.11 above, about 70% of the health food products available on the market contained Chinese medicines. However, at present, these products are not yet subject to proper control because the Administration has not yet introduced the relevant subsidiary legislation to implement the registration system. As the Interdepartmental Task Force (see paragraph 12.1 above) will not address this problem specifically, it is important for the Administration to introduce the relevant subsidiary legislation as soon as possible to regulate products containing Chinese medicines, including health food products, in an effective way.

### **15. Regulation of Health Claims under the Undesirable Medical Advertisements Ordinance**

15.1 The Administration may need to consider amending the Undesirable Medical Advertisements Ordinance (Cap. 231) (a) to regulate information or claims in package inserts (paragraphs 11.1 and 11.2 above) and (b) to extend the scope of control against undesirable advertisements to cover health claims carried by food products (paragraph 11.5 above).

15.2 In addition, in view of the widespread marketing of health food products through the Internet, there may be a case for the Administration to consider amending the Undesirable Medical Advertisements Ordinance (Cap. 231) to explore the possibility of covering advertisements posted on the Internet.

### **16. Some General Comments on the Administration's Initial Proposal on the Regulation of Health Claims**

16.1 The Administration has proposed that food products claiming health benefits would fall under two categories: (a) claims to prevent or cure a **specific disease** or **clinical condition** are required for pre-market approval; and (b) claims to have **general beneficial effects** on health are exempted from registration.

16.2 The Administration may need to determine what are health issues. For example, are issues such as "detoxify the body" and "nourish the liver and kidneys" health issues and claims related to them should be regulated?

16.3 In addition, it may not be easy to determine whether a claim is a specific disease or clinical condition claim or a general beneficial effects on health claim. To avoid seeking pre-market approval, health food traders in Hong Kong may claim to have general beneficial effects on health, rather claim to prevent or cure a specific disease or clinical condition. Consumers may not be able to distinguish between these two types of claims. Hence, the Administration may need to consider establishing an appropriate mechanism to distinguish these two types of claims and give consumers access to such information.

16.4 The Administration has proposed that the Director of Health will be responsible for determining whether the claim falls under (a) or (b) in paragraph 16.1 above. To examine health claims, the Administration may need to consider establishing an advisory committee which consists of medical officers, Chinese medicine practitioners, academics, and medical researchers, etc. to provide professional advice. In addition, the Administration may need to consider establishing an appeal system for health food traders to make any appeal.

## **17. Strengthening Public Education on the Use of Health Food**

17.1 In view of the speed at which health food products are introduced into the local market and the variety of health food products available, it is important that members of the public be well informed about nutrition and the use of health food. There seems to be a case for the Administration to strengthen public education through various means such as exhibitions, publications, enquiry hotlines and the Internet. The public can then be equipped to scrutinize health claims made by food products.

## Appendix I

### **Diseases in Respect of which Advertisements are Prohibited or Restricted Under the Undesirable Medical Advertisements Ordinance**

1. Any benign or malignant tumour.
2. Any viral, bacterial, fungal or other infectious disease, including tuberculosis, hepatitis and leprosy.
3. Any parasitic disease.
4. Any venereal disease, including syphilis, gonorrhoea, soft chancre, lymphogranuloma venereum, genital herpes, genital warts, urethritis, vaginitis, urethral or vaginal discharge, acquired immunodeficiency syndrome (AIDS), and any other sexually transmitted disease.
5. Any respiratory disease, including asthma, bronchitis, and pneumonia.
6. Any disease of the heart or cardiovascular system, including rheumatic heart disease, arteriosclerosis, coronary artery disease, arrhythmias, hypertension, cerebrovascular disease, congenital heart disease, thrombosis, peripheral artery disease, oedema, retinal vascular change and peripheral venous disease.
7. Any gastro-intestinal disease, including gallstone, cirrhosis, gastro-intestinal bleeding, diarrhoea, hernia, fistula-in-ano and haemorrhoids.
8. Any disease of the nervous system, including epilepsy, mental disorder, mental retardation and paralysis.
9. Any disease of the genito-urinary system, including kidney stone, nephritis, cystitis, any prostatic disease and phimosis.
10. Any disease of the blood or lymphatic system, including anemia, neck glands, bleeding disorders, leukemia and other lympho-proliferative diseases.
11. Any disease of the musculo-skeletal system, including rheumatism, arthritis and sciatica.
12. Any endocrine disease, including diabetes, thyrotoxicosis, goitre and any other organic or functional condition related to under or over activity of any part of the system.
13. Any organic condition affecting sight, hearing or balance.
14. Any disease of the skin, hair or scalp.

Source: Undesirable Medical Advertisements Ordinance (Cap. 231)

## Appendix II

**Details of the 20 Warning or Advisory Letters Issued by  
the Food and Environmental Hygiene Department in Year 2000  
in Respect of Labelling of Health Food**

Serial No.	Description of Product	Offence: Breach of Public Health & Municipal Services Ordinance	Result
1	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of food name. (b) List of ingredients not indicated on label. (c) Incomplete indication of name & address of manufacturer.	Product withdrawn from market.
2	Squalene product	Sec. 61 of the Ordinance – Advertisement likely to mislead as to the quality of the product.	Advertisement revised.
3	Squalene product	Sec. 61 of the Ordinance – Advertisement likely to mislead as to the quality of the product.	Advertisement withdrawn from the media.
4	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of list of ingredients. (b) Unclear indication of “best before” date. (c) Name & address of manufacturer not indicated on label.	Product withdrawn from market.
5	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of list of ingredients. (b) Unclear indication of “best before” date. (c) Statement of storage instruction not indicated on label. (d) Name & address of manufacturer not indicated on label.	Product withdrawn from market.
6	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Unclear indication of “best before” date. (b) Name & address of manufacturer not indicated on label.	Product re-labelled to comply with legal requirements.

Serial No.	Description of Product	Offence: Breach of Public Health & Municipal Services Ordinance	Result
7	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of food name. (b) List of ingredients not indicated on label. (c) Unclear indication of “best before” date. (d) Incomplete indication of name & address of manufacturer.	Product withdrawn from market.
8	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of food name. (b) List of ingredients not indicated on label. (c) Unclear indication of “best before” date. (d) Incomplete indication of name & address of manufacturer.	Product withdrawn from market.
9	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Unclear indication of “best before” date. (b) Address of manufacturer not indicated on label.	Product withdrawn from market.
10	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Name & address of manufacturer not indicated on label. (b) Unclear indication of “best before” date. (c) Indication of food name & list of ingredients not in both English and Chinese languages.	Product withdrawn from market.

Serial No.	Description of Product	Offence: Breach of Public Health & Municipal Services Ordinance	Result
11	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Unclear indication of “best before” date. (b) Address of manufacturer not indicated on label.	Product withdrawn from market.
12	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of food name. (b) List of ingredients not indicated on label. (c) Unclear indication of “best before” date. (d) Incomplete indication of name & address of manufacturer.	Product withdrawn from market.
13	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Unclear indication of “best before” date. (b) Incomplete indication of name & address of manufacturer.	Product re-labelled to comply with legal requirements.
14	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of list of ingredients. (b) Unclear indication of “best before” date. (c) Incomplete indication of name & address of manufacturer. (d) Count, weight or volume not indicated on label. (e) Indication of food name & list of ingredients not in both English and Chinese languages.	Product re-labelled to comply with legal requirements.

Serial No.	Description of Product	Offence: Breach of Public Health & Municipal Services Ordinance	Result
15	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of list of ingredients. (b) Unclear indication of “best before” date. (c) Statement of storage instruction not indicated on label. (d) Incomplete indication of name & address of manufacturer.	Product withdrawn from market.
16	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of list of ingredients. (b) Statement of storage instruction not indicated on label. (c) Incomplete indication of name & address of manufacturer.	Product withdrawn from market.
17	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of list of ingredients. (b) Unclear indication of “best before” date. (c) Count, weight or volume not indicated on label. (d) Indication of food name & list of ingredients not in both English and Chinese languages.	Product withdrawn from market.
18	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of name & address of manufacturer. (b) Unclear indication of “best before” date. (c) Indication of food name & list of ingredients not in both English and Chinese languages.	Product re-labelled to comply with legal requirements.

Serial No.	Description of Product	Offence: Breach of Public Health & Municipal Services Ordinance	Result
19	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of list of ingredients.	Product withdrawn from market.
20	Squalene product	Reg. 4A(1) & 5(1) of Food & Drugs (Composition & Labelling) Regulations – (a) Incomplete indication of list of ingredients. (b) Unclear indication of “best before” date. (c) Statement of storage instruction not indicated on label. (d) Incomplete indication of name & address of manufacturer.	Product withdrawn from market.

Source: Environment and Food Bureau

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