

**For discussion  
8 December 2003**

## **LegCo Panel on Health Services Regulation of Health Claims**

### **Introduction**

In response to demands for regulation of exaggerated and undesirable health claims, the Administration consulted this Panel on 9 December 2002 on its proposal to introduce a new schedule of prohibited claims to the Undesirable Medical Advertisements Ordinance (UMAO) (Cap. 231). This paper reports on the progress of our proposal.

### **Background**

2. An increasing number of so-called “health food” products claiming beneficial health effects are found in the local market in recent years. There have been complaints from consumers against misleading or exaggerated claims of these products, which may result in improper self-medication, thereby causing harm as a result of either the improper self-medication itself, or the delayed proper treatment the consumer should receive. An Expert Committee consisting of representatives from the Consumer Council, Chinese medicine practitioners, medical practitioners, pharmacists and a nutritionist was set up at the end of 2002 to study and recommend a list of health claims to be prohibited in orally consumed products. The Expert Committee adopted a risk assessment approach in considering the health claims to be prohibited. It generally agreed that claims which might affect the health of the public should be prohibited, while claims with less risk could be allowed.

### **Proposed Schedule of Prohibited Claims**

3. The Expert Committee has reviewed 13 groups of claims and recommended that the following nine groups of health claims should be prohibited: -

- (i) Regulation of body sugar or glucose including alteration of functions of the pancreas.
- (ii) Regulation of blood pressure.
- (iii) Regulation of blood lipid or cholesterol.
- (iv) Prevention, elimination or treatment of breast lumps.

- (v) Regulation of function of the genitourinary system, including improvement of symptoms of genitourinary problems.
- (vi) Regulation of the endocrine system including maintenance or alteration of hormonal secretions.
- (vii) Claims relating to slimming or fat reduction of the body including fat burning, eliminating fat, controlling appetite, absorbing fat and eliminating fluid retention.
- (viii) Regulation of body immune system against diseases including cancers, chronic diseases and infection; or alteration of the effects of treatment e.g. chemotherapy and radiotherapy, etc.
- (ix) Promotion of detoxification.

4. The Expert Committee also agreed not to prohibit the following 4 groups of claims:

- (i) Correction or alleviation of symptoms relating to menopause.
- (ii) Stimulation of hair growth or prevention of hair loss.
- (iii) Promotion of enlargement or firmness of the breast.
- (iv) Regulation or alteration of structure of the genitourinary system.

5. The proposal is to include a list of prohibited claims in the UMAO as a new schedule. The Director of Health will have the power to amend the new schedule and to authorize public officers to be inspectors to enforce the relevant provisions of the UMAO.

6. Upon enactment of the new schedule of prohibited claims, we propose to give the “health food” industry a grace period of appropriate duration, say, 18 months, to enable them to make changes and preparations in order to comply with the new requirements.

## **Public Consultation**

7. We issued a consultation document and consulted the public on our proposal to prohibit nine groups of health claims as set out in paragraphs 3 to 6 above during 26 September to 15 November 2003. During the public consultation period, we have held 6 open forums and 12 small-group meetings with representatives from 190 professional associations and stakeholders. As of 30 November 2003, a total of 1637 written submissions were received.

8. In general, the medical professional bodies and academics are supportive of the proposal. Indeed, they not only support the regulation of the health claims proposed in the consultation document, they also ask for a wider scope and more stringent forms of regulation. For instance, there are

suggestions that health claims with lower risks (e.g. the promotion of hair growth) should also be subject to regulation, and that the regulation should be extended to non-oral health products and services. Moreover, the penalties for the offences should also be raised.

9. The major opposing views come from the trade. Representatives of the manufacturers and the retailers of so-called “health foods” claim that the prohibition of health claims through legislation would result in substantial losses in business for the “health foods” sector and the advertising market. They are of the view that the proposed regulation would inhibit investment and thus dampen the development of the “health food” industry, which in turn would adversely affect employment opportunities in the sectors concerned. Consumers would also be affected as the proposal would deprive them of information and choice when products with proven health effects cannot make claims. Among other suggestions, a major counter-proposal from the trade is that suitable health warnings be added to the package or the advertisements of the health products.

### **Revised Framework of Regulation**

10. The compliance costs to be borne by the trade will cover replacement of labels for products already packaged, design and application of new labels for products under manufacture, and possibly registration for new brand names of products with claims that are to be prohibited. Our assessment is that these costs should not be appreciable in most cases relative to the market value of the products, and is justified to incur in the interest of better protection of public and personal health, as well as on general consumer information and protection grounds. Furthermore, we are of the view that better regulated claims for forestalling malpractice should be conducive to better development of the so-called “health food” trade in the long run.

11. Nonetheless, to address the trade’s concerns, we propose to revise the scope of regulation as follows: -

- (a) We propose to restrict the definition of orally consumed products used in the new Schedule so that a product which is customarily consumed only as food or drink to provide energy, nourishment or hydration, or to satisfy a desire for taste, texture or flavour will be outside the scope of regulation.
- (b) We propose to prohibit or restrict specified claims based on the risk-based approach. The revised Schedule is attached at **Annex A**. The first level of restriction would apply to the most risky claims, namely the

claims relating to the prevention, elimination or treatment of breast lumps; the regulation of function of the genitourinary system, and the regulation of the endocrine system (item (1) to (3) in Annex A). The making of such claims would not be allowed under any circumstances. For the second level of restriction which are applicable to three other types of claims (item (4) to (6)), we propose to allow manufacturers or traders to make only the permissible claims as specified by the Director of Health in the new Schedule. For claims subject to the third level of restriction, namely those related to the regulation of immune system, detoxification and slimming (item (7) to (9)), we propose that they could be allowed if made in a very general sense without reference to improvements to any specific body functions. Any slimming claims made should be accompanied by a health advice specified by the Director of Health. For products making certain claims which are under the second and third level of restriction, and which are not registered under the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance, they must explicitly say so in the form of a disclaimer both on the packaging and in the advertisement.

12. We have taken the opportunity to review the existing Schedule 1 and 2 of the UMAO. Based on the risk assessment approach, we consider that some permitted claims, e.g. prevention of common colds, prevention of pimples, and relief of symptoms of eczema and allergies by oral antihistamines preparations, can be added to Column 2 of Schedule 1 (**Annex B**), as they carry relatively little risk.

13. Members are invited to comment on the revised proposal on the regulation of health claims in paragraphs 10 to 12 above. Subject to Members' view, we will introduce a bill into the Legislative Council early next year to amend the UMAO.

**Health, Welfare and Food Bureau**  
**December 2003**

**Claims in respect of which advertisements are prohibited or restricted for orally consumed products**

<b>Column 1 Claim</b>	<b>Column 2 Exemption</b>
<p>1. <b>Prevention, elimination or treatment of breast lumps</b>, including eliminating the blockage of milk ducts of the breast, helping to eliminate disease-causing factors or lumps, relieving the associated discomfort symptoms, helping to improve the metabolism of breast tissue, effectively disintegrating and eliminating abnormal cell tissues and lumps.</p>	<p>None.</p>
<p>2. <b>Regulation of the function of the genitourinary system and/or improvement of symptoms of genitourinary problems</b> such as frequent urination, urgent urination, dripping urination, poor stream, difficulty in urination, urination at night, impeded prostatic function and uncontrollable urinary discharge / incontinence.</p>	<p>None.</p>
<p>3. <b>Regulation of the endocrine system and/or maintenance or alteration of hormonal secretions</b>, including helping to maintain hormones at optimal level, stimulating the hypothalamus, increasing secretion of oestrogen, promoting normal secretion of the female hormone, regulating the female endocrine function, improving</p>	<p>None.</p>

<p>imbalance of male hormone secretion, helping to maintain balance of hormonal secretions in men and women, stimulating hormonal secretions, regulating endocrine secretion, balancing endocrine secretion, increasing secretion of growth hormone, stimulating the thyroid gland.</p>	
<p>4. <b>Regulation of body sugar or glucose and/or alteration of functions of the pancreas,</b> including regulating or stabilizing blood glucose, suppressing or reducing the absorption of glucose, reducing the blood sugar level, increasing the metabolism of body sugar, being suitable for diabetic patients, being against blood sugar, being suitable for people with high blood sugar, improving the function of the pancreas, stimulating the secretion of insulin.</p>	<p>The claim “Suitable for people concerned about blood sugar” is allowed, provided that if the product is not registered under either the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance, both the product label and the advertisement clearly include the disclaimer: “This is not a registered pharmaceutical product or a registered proprietary Chinese medicine.”</p>
<p>5. <b>Regulation of blood pressure,</b> including regulating or stabilizing blood pressure, controlling blood pressure, reducing blood pressure, being suitable for people with high blood pressure.</p>	<p>The claim “Suitable for people concerned about blood pressure” is allowed, provided that if the product is not registered under either the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance, both the product label and the advertisement clearly include the disclaimer: “This is not a registered pharmaceutical product or a registered proprietary Chinese medicine.”</p>
<p>6. <b>Regulation of blood lipids or cholesterol,</b> including preventing</p>	<p>The claim “Suitable for people concerned about blood</p>

<p>high blood lipids, helping to maintain normal blood lipids, lowering blood lipids, reducing or regulating cholesterol, balancing blood cholesterol, excreting cholesterol in the blood vessel outside the body, being suitable for people with high blood lipids or high cholesterol.</p>	<p>lipids/cholesterol” is allowed, provided that if the product is not registered under either the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance, both the product label and the advertisement clearly include the disclaimer: “This is not a registered pharmaceutical product or a registered proprietary Chinese medicine.”</p>
<p><b>7. Regulation of the body immune system against diseases (including cancers, chronic diseases and infection) or alteration of the effects of treatment (including chemotherapy and radiotherapy),</b> including enhancing the ability of white blood cells to engulf microscopic invaders, suppressing the growth of harmful cells, strengthening the immunity of cancer patients, enhancing the immune function of AIDS patients, reducing the side effects of chemotherapy or radiotherapy, being a supplementary treatment for cancer.</p>	<p>A general claim about immunity such as “Improves body resistance”, “Improves immunity”, “Strengthens the immune system”, “Stimulates the immune system”, or similar, is allowed, provided that if the product is not registered under either the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance, both the product label and the advertisement clearly include the disclaimer: “This is not a registered pharmaceutical product or a registered proprietary Chinese medicine.”</p>
<p><b>8. Promotion of detoxification,</b> including eliminating heavy metals, removing carcinogenic substances in the body, removing drug remnants.</p>	<p>A general claim on detoxification such as “Eliminates toxins”, “Cleanses toxin elements in the body”, or similar, is allowed, provided that if the product is not registered under either the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance, both the product label and the advertisement clearly include the</p>

	<p>disclaimer:          “This is not a registered pharmaceutical product or a registered proprietary Chinese medicine.”</p>
<p><b>9. Any claim relating to slimming or fat reduction of the body.</b></p>	<p>An advertisement for a product may make this claim provided –</p> <p>(a) both the product label and the advertisement clearly include wording on the proper method of weight control, as specified by the Director of Health by notice in the <i>Gazette</i>;</p> <p>(b) if the product is not registered under either the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance, both the product label and the advertisement clearly include the disclaimer:          “This is not a registered pharmaceutical product or a registered proprietary Chinese medicine.”</p>



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

**Schedule 1:**

**Diseases and conditions in respect of which advertisements are prohibited or restricted**

	Column 1 Disease or condition	Column 2 Purposes for which advertising is permitted
1.	Any benign or malignant tumour.	None.
2.	Any viral, bacterial, fungal or other infectious disease, including tuberculosis, hepatitis and leprosy.	Treatment or prevention of minor cutaneous infections where a dysentery, medicinal product is to be administered to an external surface of the body, including treatment by means of preparations for the relief of pruritus or exanthematous rashes of childhood infection.  Relief of symptoms of aphthous ulcer.  Relief of symptoms of common colds, coughs, conditions commonly referred to as influenza and similar upper respiratory tract infections.  Treatment of minor acute inflammatory conditions of the buccal cavity and pharynx.
3.	Any parasitic disease.	Treatment of scabies or an infestation by threadworms, lice or roundworm, provided that the advertisement consists solely of a labelled container or package in which a medicine, surgical appliance or treatment is supplied.
4.	Any venereal disease, including syphilis, gonorrhoea, soft chancre, lymphogranuloma venerum, genital herpes, genital warts, urethritis, vaginitis, urethral or vaginal discharge, acquired immunodeficiency syndrome (AIDS), and any other sexually transmitted disease.	None.

5.	Any respiratory disease, including asthma, bronchitis, and pneumonia.	Temporary relief of symptoms of hay fever, rhinitis or catarrh.  Relief of blocked-up sinuses.
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.	None.
7.	Any gastro-intestinal disease, including gallstone, cirrhosis, gastro-intestinal bleeding, diarrhoea, hernia, fistula-in-ano and haemorrhoids.	Relief of such symptoms as are commonly referred to as indigestion, heartburn, hyperacidity, dyspepsia, halitosis (bad breath) or flatulence.  Symptomatic relief of colicky pain, stomach ache or nausea.  Relief of occasional or non-persistent diarrhoea or constipation.  Prevention of travel sickness or related symptoms.  Treatment of haemorrhoids for relief of symptoms by means of locally effective preparations or stool-softening agents and lubricants.
8.	Any disease of the nervous system, including epilepsy, mental disorder, mental retardation and paralysis.	Symptomatic relief of headaches.
9.	Any disease of the genito-urinary system, including kidney stone, nephritis, cystitis, any prostatic disease and phimosis.	None.
10.	Any disease of the blood or lymphatic system, including anemia, neck glands, bleeding disorders, leukemia and other lymphoproliferative diseases.	Prophylactic administration of minerals and vitamins to avoid deficiency states in persons with adequate diet or with increased dietary requirements.
11.	Any disease of the musculo-skeletal	External preparations for the relief of

	system, including rheumatism, arthritis and sciatica.	symptoms of muscular pain and stiffness and cramp.
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.	Provision of dietary supplements.
13.	Any organic condition affecting sight, hearing or balance.	Relief of symptoms by means of the local administration of eye preparations.  Relief of symptoms by means of local administration of preparations as a solvent for ear wax.
14.	Any disease of the skin, hair or scalp.	Prevention or treatment of dandruff by means of external applications.  Treatment, where applied to an external surface of the body, of pimples, eczema, skin allergies and athlete's foot.  Prevention or treatment of contact dermatitis and sunburn by means of protective applications.  Treatment of hard skin and corns by means of the application of corn plasters or solvents.  Relief or prevention of common minor skin conditions including dry and chapped skin, cold sores, pruritus, insect bites, heat rash and napkin rash.