

**The Administration's responses to the enquiries raised by Members
at the Bills Committee meeting on 9 December 2004**

Para. Responses
No.¹

- 2(a) The Administration had a further exchange of ideas with some professional bodies and trade associations in respect of the wording of the disclaimer after the last Bills Committee meeting. On the basis of the views received, it is considered that the version currently used by the Food and Drug Authority of the United States may serve as a good reference for refining our proposed disclaimer. Nonetheless, since the disclaimer is an essential part of the proposed regulatory regime and closely related to the other parts of the Bill (e.g. allowable claims), we suggest that it be prudent to examine any recast to the disclaimer together with other refinements, if any, to the regime.
- (b) The Administration will enlist the participation of the trade and other stakeholders, in an appropriate manner, in any advisory/monitoring bodies to be set up after passage of the Bill.
- (c) A sample warning letter currently used by the Department of Health (DH) is attached. We intend to improve on the warning system by recasting the letter. In this connection, we plan to provide in the warning letter more information to those being warned against on the offence they have potentially made. The remit of the Undesirable Medical Advertisement Ordinance (Cap. 231) (UMAO) will also be set out in the letter. We also plan to provide prominently in the letter a contact telephone number of DH for enquiry purpose.
- (d) As mentioned in our reply to the Clerks to Bills Committee dated 9 December 2004, the warning system is purely an administrative measure. The warning made by the Director of Health ('the Director') is not statutory, and does not prohibit the advertisement concerned from being further published in its present form. The ultimate decision on whether a claim is UMAO-infringing rests with the Court.

¹ The 'para. no.' correspond to the paragraph number of the minutes of the Bills Committee meeting on 9 December 2004 issued by the LegCo.

- (e) With the changes to be introduced to the warning mechanism to make it more open and transparent, it is believed that the whole warning and rectification process between DH and the publisher/wholesaler etc. will become more interactive. The Administration does not consider it to be appropriate to introduce a pre-approval system for advertising claims made by health food products. We envisage that such a system would likely entail significant resource implications to the trade and the Administration. As background information, prior to 1995, the Director had the power to pre-censor television advertisements for any medical preparation. Such power was regarded as a potential infringement to press freedom and freedom of expression, and was subsequently removed by legislative amendment in 1995.
 - (f) The Administration will consider how such information can be collected in a more systematic manner. One possible avenue is the new reporting system for Adverse Drug Reaction (ADR) which has just been introduced on 1 January 2005 for Chinese and western medicines.
- 3 (a) Under section 2 of the Chinese Medicine Ordinance (Cap. 549) (CMO), ‘proprietary Chinese medicine’ is defined as any proprietary product which is composed, as active ingredients, solely of (a) Chinese herbal medicines, or (b) materials of herbal, animal or mineral origin customarily used by the Chinese, or (c) any medicines and materials referred to in (a) and (b) respectively, and formulated in a finished dose form, and 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.

According to the above definition, food containing Chinese medicines are not regarded as ‘proprietary Chinese medicine’ in the context of the CMO if (a) they are used in a form or manner as normal food item (e.g. with no recommended dose regimens), or (b) if they do not claim any curative or health care functions.

- 3 (b) Screening of the advertisement for the enforcement of the provisions in UMAO entails around HK\$480,000 in DH every year. The expenditure includes the salary of Health Programme Assistants who screen advertisements and the purchase of newspapers and magazines.

- 3 (c) From January 2001 to October 2004, 63 persons were convicted under the UMAO. The breakdown of these persons are as follow:
- Distributor/wholesaler of medicines and “health food” products = 46
 - Distributor/wholesaler of equipment/device = 2
 - Chinese Medicine practitioner/clinic = 9
 - Other treatment/service provider = 3
 - Publisher = 3

By Fax and Mail

Fax : XXXX XXXX

dd/mm/yyyy

Company name
Company address

Dear Sirs,

Undesirable Medical Advertisements Ordinance (Cap. 231)

During the course of investigation conducted by our staff, it was realized that there was an advertisement on “(XXX Name of Newspaper or Magazine)”(dd/mm/yyyy, page XX). Enclosed herewith is a copy of the advertisement for your reference.

Advertisement:

Based on the content of the advertisement, it appears that you may have contravened Section (3) of the Undesirable Medical Advertisements Ordinance Cap. 231 which stipulates the following:

“No person shall publish, or cause to be published, any advertisement likely to lead to the use of any medicine, surgical appliance or treatment for –

- a) the purpose of treating human beings for, or preventing human beings from contracting, any disease or condition specified in column 1 of Schedule 1, except for a purpose (if any) specified in column 2 of that Schedule; or
- b) treating human beings for any purpose specified in Schedule 2.”

Enclosed herewith are Schedule 1 and Schedule 2 of the above Ordinance for your reference.

You are hereby warned that if the same or a similar advertisement is found again, prosecution action may be taken against you ***without further warning***.

Yours faithfully,

(XXXXXX)
for Director of Health

附表 1

[第 3 條]

禁止或限制發布的廣告所涉及的疾病
或病理情況

第 1 欄 疾病或病理情況	第 2 欄 准予作廣告宣傳的目的
1. 任何良性或惡性瘤。	沒有。
2. 任何病毒、細菌、真菌或其他傳染性疾病，包括結核病、痢疾、肝炎及麻瘋。	以外用藥物施於身體外部，以治療或預防輕微的皮膚感染，包括使用製劑治療以減輕兒童感染引致的痕癩及紅疹。 減輕口瘡性潰瘍症狀。 減輕感冒、咳嗽等一般稱為流行性感冒及類似的上呼吸道感染情況。 治療口腔前庭及咽部的輕微急性發炎情況。
3. 任何寄生疾病。	治療疥瘡或蟎蟲、虱或蠅蟲等感染，但有關廣告只可刊登於盛載所供應藥物、外科用具或療法的附有標籤的容器或包裹上。
4. 任何性病，包括梅毒、淋病、軟下疳、性病性淋巴肉芽腫、生殖器疱疹、生殖器肉贊、尿道炎、陰道炎、尿道或陰道溢液、愛滋病及任何其他經由性接觸傳染的疾病。	沒有。
5. 任何呼吸系統疾病，包括哮喘、支氣管炎及肺炎。	暫時減輕花粉病、鼻炎或黏膜炎症狀。 減輕塞竇症狀。

SCHEDULE 1

[s. 3]

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, dysentery, hepatitis and leprosy.	Treatment or prevention of minor cutaneous infections where a medicinal product is to be administered to an external surface of the body, including treatment by means of preparations for the relief of pruritis 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 venereum, 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.

第 1 欄 疾病或病理情況	第 2 欄 准予作廣告宣傳的目的
6. 任何心臟或心血管系統疾病，包括風濕性心臟病、動脈硬化、冠狀動脈病、心律失常、高血壓、腦血管病、先天性心臟病、血栓形成、末梢動脈病、水腫、視網膜血管變化及末梢靜脈病。	沒有。
7. 任何胃腸病，包括膽石、肝硬化、胃腸出血、腹瀉、疝、肛門癟及痔。	減輕一般稱為不消化、胃灼熱、胃酸過多、消化不良、口臭或腸胃氣脹的症狀。 減輕腸絞痛、胃痛或惡心症狀。 減輕偶發性或非持續的腹瀉或便秘症狀。 預防旅行病或有關症狀。 以局部有效製劑或軟化糞便劑及潤滑劑治療痔及減輕症狀。
8. 任何神經系統疾病，包括羊癲、精神紊亂、精神發育遲緩及癱瘓。	減輕頭痛。
9. 任何泌尿生殖系統疾病，包括腎石、腎炎、膀胱炎、任何前列腺病及包莖炎。	沒有。
10. 任何血液或淋巴系統疾病，包括貧血、頸腺、出血病症、白血病及其他淋巴增生病。	給予礦物質及維他命作為預防，以避免飲食不適當或需多加調節飲食的人士陷入缺乏狀態。
11. 任何肌與骨骼系統疾病，包括風濕病、關節炎及坐骨神經痛。	使用外用製劑以減輕肌肉疼痛、僵硬及痙攣症狀。
12. 任何內分泌疾病，包括糖尿病、甲狀腺毒症、甲狀腺腫以及與該系統活動過少或過多有關的任何器官或機能性病理情況。	食物補充品。
13. 任何影響視力、聽覺或平衡的器官病理情況。	局部使用眼製劑以減輕症狀。 局部使用耳垢溶劑以減輕症狀。

Column 1 Disease or condition	Column 2 Purposes for which advertising is permitted
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 lympho-proliferative diseases.	Prophylactic administration of minerals and vitamins to avoid deficiency states in persons with inadequate diet or with increased dietary requirements.
11. Any disease of the musculo-skeletal system, including rheumatism, arthritis and sciatica.	External preparations for the relief of 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.

第 1 欄 疾病或病理情況	第 2 欄 准予作廣告宣傳的目的
14. 任何皮膚、頭髮或頭皮疾病。	<p>以外用劑預防或治療頭皮屑。</p> <p>以外用劑施於身體外部，以治療丘疹、濕疹、皮膚敏感及腳癬。</p> <p>以保護性外用劑預防和治療接觸皮炎及曬傷。</p> <p>使用雞眼膏或溶劑以治療硬皮及雞眼。</p> <p>減輕或預防一般輕微皮膚症狀，包括乾燥及破裂皮膚、唇皰疹、痕癢、昆蟲咬傷、汗疹及尿布疹。</p> <p>(附表 I 由 1988 年第 65 號第 8 條增補)</p>

附表 2

- 禁止為以下目的而為任何藥物、外科用具或療法作廣告宣傳
1. 通經、醫治經閉、遲經或任何其他婦產科疾病。
 2. 增強性能力、性慾或生殖能力，或恢復失去的青春。
 3. 矯正畸形或外科整容手術。

(附表 2 由 1988 年第 65 號第 8 條增補)

[第 3 條]

CAP. 231 Undesirable Medical Advertisements

Column 1 Disease or condition	Column 2 Purposes for which advertising is permitted
4. Any disease of the skin, hair or scalp.	<p>Prevention or treatment of dandruff by means of external applications.</p> <p>Treatment, where applied to an external surface of the body, of pimples, eczema, skin allergies and athlete's foot.</p> <p>Prevention or treatment of contact dermatitis and sunburn by means of protective applications.</p> <p>Treatment of hard skin and corns by means of the application of corn plasters or solvents.</p> <p>Relief or prevention of common minor skin conditions including dry and chapped skin, cold sores, pruritus, insect bites, heat rash and napkin rash.</p> <p>(Schedule I added 65 of 1988 s. 8)</p>

SCHEDULE 2

[s. 3]

PURPOSES FOR WHICH IT IS PROHIBITED TO ADVERTISE ANY MEDICINE, SURGICAL APPLIANCE OR TREATMENT

1. The induction of menstruation or relief of amenorrhea or delayed menstruation or any other gynaecological or obstetrical disease.
2. The promotion of sexual virility, desire or fertility, or the restoration of lost youth.
3. The correction of deformity or the surgical alteration of a person's appearance.

(Schedule 2 added 65 of 1988 s. 8)

附表 3
(由 1988 年第 65 號第 11 條廢除)

SCHEDULE 3
(Repealed 65 of 1988 s. 11)