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LEGISLATIVE COUNCIL BRIEF

Undesirable Medical Advertisements Ordinance (Cap. 231)

Undesirable Medical Advertisements (Amendment) (No.2) Bill 2004

INTRODUCTION

At the meeting of the Executive Council on 28 September 2004, the Council advised and the Chief Executive ordered that the Undesirable Medical Advertisements (Amendment) (No.2) Bill 2004, at **Annex A**, should be introduced into the Legislative Council (LegCo) to provide legislative backing to prohibit/restrict selected health claims.

JUSTIFICATIONS

2. An increasing number of so-called "health food" products claiming beneficial health effects are found on 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. There are calls from the public and the LegCo that control on these irresponsible claims should be introduced for the sake of public health.

Existing regulatory controls in Hong Kong

3. At present, there is no universally accepted approach to regulate "health food" products or health claims. For those jurisdictions with a regulatory framework in place, the types of regulation range from pre-marketing approval to prescribing a list of accepted/prohibited claims.

4. In Hong Kong, the Pharmacy and Poisons Ordinance (PPO) (Cap. 138) controls as "pharmaceutical products" any product for the treatment, or prevention, of a specific disease or disease symptom. The controls are in the form of pre-marketing registration of individual products (the criteria for registration being safety, efficacy and quality), labelling requirements, licensing of manufacturers and sellers, and restrictions on retail sale (i.e. sale by pharmacists only, or sale on a doctor's

prescription only). However, this Ordinance does not apply to so-called "health food" products, which are not pharmaceutical products.

5. The Chinese Medicine Ordinance (CMO) (Cap. 549) controls products which are composed of Chinese medicines as active ingredients. The licensing of manufacturers, importers and wholesalers of Chinese medicines has already commenced in May 2003. The registration system for proprietary Chinese medicines has begun in December 2003 and all unregistered proprietary Chinese medicines will not be allowed to be manufactured or sold in Hong Kong after a date to be announced by the Secretary for Health, Welfare and Food. The claims for registered products must be substantiated with different levels of evidence, such as history of use or traditional references and clinical trial data. However, products which are not composed of Chinese medicines fall outside the ambit of this Ordinance.

6. The Public Health and Municipal Services Ordinance (Cap. 132) prohibits the sale, and possession for the purpose of sale, of any food which is unfit for human consumption. Therefore, the safety of so-called "health food" products for human consumption purposes is already subject to a form of control.

7. The Undesirable Medical Advertisements Ordinance (UMAO) (Cap. 231) prohibits the advertising of medicines, surgical appliances or treatments for prevention or treatment of certain diseases or conditions in human beings as specified in Schedule 1 and 2 of the Ordinance in order to prevent the adverse effects of improper self-medication by members of the public (e.g. inadequate, inappropriate and incorrect treatment that they may receive, no supervision of treatment outcome, no monitoring for adverse effects and delayed treatment). However, some orally consumed products (e.g. "health foods", "dietary supplements") are not classified as medicines and are therefore not subject to the regulation of PPO or CMO. They may, however, be labelled, or advertised, with claims of specific beneficial health effects which may exist in the domain of drugs, but are currently not specified in the UMAO. These claims can be broadly grouped into the following two categories:

(a) **Claims relating to body functions -** Examples include regulation of blood pressure, regulation of blood lipids or cholesterol, etc. As UMAO deals with the prevention or treatment of specific diseases, these claims are generally outside the control of the existing legislation.

(b) **Exaggerated or misleading health-related claims -** Examples include misleading claims relating to slimming, weight reduction, breast enhancement, detoxification etc. Regulation of these claims requires consensus in the community. In regulating these claims, a balance has to be struck between protection of public health and freedom of choice by consumers.

The proposed regulation

8. The UMAO makes it an offence to publish, or cause to be published, an advertisement likely to lead to the use of any medicine, surgical appliance or treatment for treating or preventing a disease or condition specified in Schedule 1 or 2. The purpose of this Bill is to widen the scope of the Ordinance in two aspects: -

(a) To extend the prohibition/restriction on advertising to the claims specified in the proposed Schedule 4; and

(b) To apply the prohibition/restriction on advertising of claims specified in Schedule 4 to all orally consumed products, except those customarily consumed as food or drink.

In view of the proliferation of health claims in advertisements of so-called "health foods", we propose to add a new Schedule 4 to the UMAO to bring six additional groups of claims under the regulation of the Ordinance. These claims are considered undesirable because they may imply the prevention or treatment of certain diseases, which may delay the public from seeking proper medical advice and management.

9. Under existing section 7 of the UMAO, the Director of Health has the power to amend the new Schedule so as to add or delete claims for orally consumed products and to vary the exemptions. We propose in addition that the Director of Health should have power to authorize public officers to be inspectors, and that they should have investigative powers to enable them to enforce the UMAO.

Exemptions

10. Schedule 4 of the Amendment Bill sets out six groups of prohibited or restricted claims, which are subject to two levels of restriction based on the risk-based approach. 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 Schedule 4). The making of such claims will not be allowed under any circumstances. For the second level of restriction which is applicable to three other types of claims (item (4) to (6)), we propose to allow manufacturers or traders to make the two permissible claims as specified for each type of claim in the new Schedule. For products under the second level of restriction which are attached with the specified claims, and which are not registered under the PPO or CMO, a disclaimer must be put on both the packaging and in the advertisement to inform consumers that they are not products registered under the two Ordinances. If both the product label and the advertisement are wholly or mainly in the English or Chinese language, we allow that any claim or disclaimer may be limited to that language.

Orally consumed products

11. While the proposed regulation is intended to target at the claims of orally consumed products, e.g. medicines, shark's cartilage capsules and fish oil capsules, which are usually manufactured specifically for the claimed purposes, some conventional food may be affected as they can also be described as orally consumed products. As it is not our intention to regulate conventional food e.g. cereals, cooking oil, fruits and vegetables, we propose to define "orally consumed products" in such a way 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, would not be subject to regulation.

Grace period

12. Upon the enactment of the new schedule of prohibited claims, the "health food" industry would be given a grace period of appropriate duration to enable them to make changes and preparation in order to comply with the new requirements. A grace period of at least 18 months is considered necessary.

Amendments to the existing Schedule 1 and the Short Title

13. We have also 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 can be added to Column 2 of Schedule 1 while some restrictions on the permitted claims can be removed. The proposed changes are set out in the Schedule of the Amendment Bill. Moreover, with reference to the risk associated with the first level of restriction mentioned in para. 10, we propose to remove the sentence "Provision of dietary supplements." from Item 12 in Column 2 of Schedule 1 of the UMAO. Any claims related to the endocrine system or functions will contravene item 3 of the new schedule and therefore cannot be permitted. Separately, there were opinions that the Chinese version of the short title of the UMAO should also be amended to avoid confusion about its meaning. Hence, we also propose to amend the Chinese version of the short title in order to better reflect the object of the Ordinance.

OTHER OPTIONS

14. One alternative option is to maintain the status quo, i.e. no amendment to the UMAO. This option would have no impact on the trade, but it is not recommended because it fails to address concerns about misleading and exaggerated health claims.

15. The second option is the introduction of a self-regulatory system, where

manufacturers or importers are required to keep on file the scientific documents which should be available on demand by DH. However, it cannot be certain that all manufacturers or importers of the products will abide by this requirement voluntarily.

16. The third option is to institute a pre-marketing approval system for the claims. Given the potential burden on the trade and the regulator in setting up a comprehensive approval system which would verify the truthfulness of claims by the criteria of safety, efficacy and quality, more in-depth consideration is required to weigh the costs of this approach vis-à-vis the benefits it could bring, i.e. the additional protection which could be offered to the consumers. This option is therefore not recommended at this stage.

THE BILL

17. The main provisions are as follows:-

(a) **Clause 1** provides that, if enacted, the Bill shall come into operation on a day to be appointed by the Secretary for Health, Welfare and Food by a notice published in the Gazette;

(b) **Clause 2** amends the long title of UMAO to reflect its wider scope;

(c) **Clause 4** provides a definition for orally consumed products;

(d) **Clause 5** adds a new section to widen the scope of regulation of UMAO so as to include the publishing of advertisements which make certain types of claims for certain health-related products;

(e) **Clause 7** amends UMAO to increase the penalty for contravention of UMAO from $10,000 to level 5 ($50,000) and imprisonment for six months for a first offence and from $25,000 and imprisonment for one year to level 6 ($100,000) and imprisonment for one year for a second or subsequent offence;

(f) **Clause 8** provides that the Director of Health may appoint inspectors to enforce both the existing and the new prohibition/restriction. Under the proposed new section 8, inspectors will have powers of investigation and, on obtaining a magistrate's warrant, will be able to enter and search premises and take possession of property for purposes of a prosecution;

(g) **Clause 9** sets out the proposed amendments to the existing Schedule 1;

(h) **Clause 10** provides for a new Schedule of prohibited/ restricted claims;

(i) **Clause 11 and the Schedule** to the Bill make some minor textual

amendments to the existing Schedules to UMAO, in order to keep the language up-to-date.

18. Apart from some fine-tuning of drafting, the Bill is the same in substance as the previous one introduced into LegCo on 11 February 2004.

LEGISLATIVE TIMETABLE

19. The Legislative timetable is as follows –

Publication in the Gazette	8 October 2004
First Reading and commencement of Second Reading debate	13 October 2004
Resumption of Second Reading debate, committee stage and Third Reading	To be notified

IMPLICATIONS OF THE PROPOSAL

20. The economic implications of the proposal are set out as **Annex B**. The proposal in the Bill has no financial, civil service, productivity or environmental implications, and does not have significant sustainability implications. DH will absorb the workload arising from the enforcement of the new regulation through internal redeployment of staff and necessary resources. The amendments will not affect the current binding effect of UMAO.

PUBLIC CONSULTATION

21. Public consultation had been conducted before the introduction of the Bill into LegCo during its second term. Details of consultation are recapitulated in the following paragraph(s).

22. The Administration proposed the regulatory framework for nine groups of health claims in its consultation paper released on 26 September 2003. During the public consultation period which ended on 15 November 2003, we held six open fora and twelve small-group meetings with representatives from 190 professional associations and stakeholders. A total of 1637 written submissions were received. In general, the medical professional bodies and academics are supportive of the proposal, while the major opposing views come from the trade.

23. We have revised our proposal in the light of comments received and presented a revised proposal to the LegCo Panel on Health Services on 8 December

2003. Panel Members supported some forms of regulation on the claims on a risk-based approach. Some Members asked for a comprehensive regulatory system to control "health food" products in the longer term. To address Members' concerns, we have further revised Schedule 4 of the Bill to exclude three types of claims, namely, the regulation of the immune system, the promotion of detoxification and slimming/fat reduction, since these claims pose relatively lesser risk to public health and views on their regulation are divided.

PUBLICITY

24. A press release will be issued on 8 October 2004. A spokesperson will be available to handle enquiries.

BACKGROUND

25. The Undesirable Medical Advertisements (Amendment) Bill 2004 was introduced into LegCo on 11 February 2004 but was not scrutinised due to limited time available in the last legislative session of its second term of office. Pursuant to section 9(4) of the Legislative Council Ordinance, the consideration of the Bill is to lapse at the end of the term, i.e. on 30 September 2004. We need to re-introduce the Bill into LegCo at the earliest possible juncture in the 2004-05 legislative session.

ENQUIRIES

26. Enquiries on this brief should be addressed to Mr. Tony Chan, Assistant Secretary (Health) of Health, Welfare and Food Bureau at 2973-8120.

Health, Welfare and Food Bureau
October 2004

Annex A

UNDESIRABLE MEDICAL ADVERTISEMENTS (AMENDMENT)(NO. 2) BILL 2004

CONTENTS

Consequential Amendments

Specification of Public Offices

A BILL

To

Amend the Undesirable Medical Advertisements Ordinance.

Enacted by the Legislative Council.

1. Short title and commencement

(1) This Ordinance may be cited as the Undesirable Medical Advertisements (Amendment)(No. 2) Ordinance 2004.

(2) This Ordinance shall come into operation on a day to be appointed by the Secretary for Health, Welfare and Food by notice published in the Gazette.

2. Long title amended

The long title to the Undesirable Medical Advertisements Ordinance (Cap. 231) is amended by adding "and health" after "medical".

3. Short title amended

Section 1 is amended by repealing "醫藥廣告" and substituting "廣告(醫藥)".

4. Interpretation

Section 2(1) is amended –

(a) in the definition of "medicine" by repealing the full stop at the end and substituting a semicolon;

(b) by adding –

""orally consumed product" (口服產品) means a product for human consumption which is intended to be taken orally, but does not include a product which is customarily consumed only as food or drink (that is to say, to provide energy, nourishment or hydration) or to satisfy a desire for taste, texture or flavour.".

5. Section added

The following is added –

"**3B. Prohibition of advertisements relating to certain orally consumed products; exceptions therefrom**

(1) No person shall publish, or cause to be published, an advertisement for an orally consumed product which makes for the product a claim specified in column 1 of Schedule 4, or any similar claim, except as specified in column 2 of that Schedule, and any Note to that Schedule, in relation to that claim.

(2) For the purposes of this section –

(a) the sale or supply, or offer or exposure for sale or supply, of an orally consumed product in a labelled container or package shall constitute the publication of an advertisement;

(b) the supply, inside any container or package containing any orally consumed product, of information relating to that or any other product shall not constitute the publication of an advertisement;

(c) "any similar claim" (任何類似的聲稱) means a claim that can reasonably be understood to be to the like effect as the specified claim, by reference to all the relevant circumstances.

(3) Where, in an advertisement for an orally consumed product published in contravention of subsection (1), a person named in that advertisement is held out as being a manufacturer or supplier of the product, that person is presumed, until the contrary is proved, to have caused the advertisement to be published.

(4) Where an advertisement for an orally consumed product published in contravention of subsection (1) gives the name, address or telephone number of, or indicates some other means of contacting, a person,

and that person manufactures or supplies the product, that person is presumed, until the contrary is proved, to have caused the advertisement to be published.".

6. Certain defences; provision as to Chinese medicine practitioners

Section 5(1) is amended –

(a) by adding ", 3B" after "section 3";

(b) by repealing paragraph (c) and substituting –

"(c) the medical and para-medical staff of –

(i) any hospital or maternity home to which the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) applies;

(ii) any clinic to which the Medical Clinics Ordinance (Cap. 343) applies;

(iii) any hospital, maternity home or clinic maintained by the Government, the Chinese University of Hong Kong or the University of Hong Kong;

(iv) any hospital, maternity home or clinic managed or controlled by the Hospital Authority established under the Hospital Authority Ordinance (Cap. 113);".

7. Penalty

Section 6 is amended –

(a) by adding ", 3B" after "section 3";

(b) by repealing "of $10,000" and substituting "at level 5 and imprisonment for 6 months";

(c) by repealing "to a fine of $25,000" and substituting "for an offence under the same section to a fine at level 6".

8. Section added

The following is added –

"**8. Enforcement provisions**

(1) The Director of Health may in writing authorize any public officer to be an inspector for the purposes of this Ordinance.

(2) For the purpose of ascertaining whether the provisions of this Ordinance are being complied with, an inspector may –

(a) at any reasonable time enter –

(i) any premises at which any medicine, surgical appliance or orally consumed product is manufactured, stored or sold;

(ii) any premises at which any treatment is provided;

(b) require any person found in or on the premises and whom the inspector reasonably suspects to have committed an offence under section 3, 3B or 4, to give to the inspector the person's name and address and evidence of identity;

(c) in the premises make such examination and inquiry and do such other things, including the taking of samples of packaging and labels and copies of advertisements, as are reasonably necessary for the purposes of the inspection.

(3) If a magistrate is satisfied by information upon oath that there are reasonable grounds for believing that –

(a) an offence against section 3, 3B or 4 is being or has been committed in any premises; or

(b) there is or may be in any premises anything which is or contains, or which is likely to be or to contain, evidence

of the commission of an offence against any of those sections,

the magistrate may issue a warrant authorizing any inspector to enter and search the premises.

(4) If a warrant has been issued under subsection (3) in respect of any premises, an inspector may –

(a) at any time, using such force as is necessary, enter and search the premises;

(b) remove anything which obstructs such entry and search;

(c) detain any person found in the premises, for such period as is reasonably required to permit the search to be carried out, if the person might prejudice the search if not so detained; and

(d) inspect, seize and detain anything which is or contains, or which appears to the inspector to be or to contain, evidence of the commission of an offence against section 3, 3B or 4.

(5) An inspector may in relation to premises other than domestic premises exercise any of the powers mentioned in subsection (4), without a warrant having been issued under subsection (3), if -

(a) the inspector has reason to believe that –

(i) an offence against section 3, 3B or 4 is being or has been committed in the premises; or

(ii) there is or may be in the premises anything which is or contains, or which is likely to be or to contain, evidence of the commission of an offence against any of those sections; and

(b) it is not reasonably practicable to obtain a warrant in respect of the premises before exercising those powers.

(6) When exercising any of the powers conferred by subsection (2) or (4), an inspector must, if so requested by any person, produce for inspection by that person written evidence of the inspector's authority.

(7) A person who –

(a) wilfully delays or obstructs an inspector in the exercise of the powers conferred by subsection (2) or (4); or

(b) fails without reasonable excuse to give any information which the inspector reasonably requires the person to give under subsection (2),

commits an offence and is liable on conviction to a fine at level 3.".

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

Schedule 1 is amended –

(a) in item 2, in column 2, by adding at the end -

"Prevention of common colds.";

(b) in item 3, in column 2, by repealing everything after "roundworm" and substituting a full stop;

(c) in item 5, in column 2, by repealing "Temporary relief" and substituting "Relief";

(d) in item 12, in column 2, by repealing "Provision of dietary supplements" and substituting "None";

(e) in item 14, in column 2, by repealing the second sentence and substituting –

"Prevention of pimples.

Relief of symptoms of eczema and allergies by oral antihistamine preparations.

Treatment, where applied to an external surface of the body, of pimples, eczema, skin allergies, athlete's foot and fungal nail infection.".

10. Schedule 4 added

The following is added –

"SCHEDULE 4 [s. 3B]

CLAIMS FOR ORALLY CONSUMED PRODUCTS IN RESPECT OF WHICH ADVERTISEMENTS ARE PROHIBITED OR RESTRICTED

	Column 1 Claim	Column 2 Exemption
1.	Prevention, elimination or treatment of breast lumps, 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.	None.
2.	Regulation of the function of the genitourinary system and/or improvement of symptoms of genitourinary problems such as frequent urination, urgent urination, dripping urination, poor stream, difficulty in urination, urination at night, impeded prostatic function	None.

	and uncontrollable urinary discharge or incontinence.	
3.	Regulation of the endocrine system and/or maintenance or alteration of hormonal secretions, 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 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.	None.
4.	Regulation of body sugar or glucose and/or alteration of the function of the pancreas, including regulating blood sugar, 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,	The claims "Suitable for people concerned about blood sugar. 適合對血糖關注的人士服用。" and "May assist in stabilizing blood sugar. 或有助於穩定血糖。" are allowed, provided that if the product is not registered under

	improving the function of the pancreas, stimulating the secretion of insulin.	either the Pharmacy and Poisons Ordinance (Cap. 138) or the Chinese Medicine Ordinance (Cap. 549), both the product label and the advertisement clearly include the disclaimer: "This is not a registered pharmaceutical product or a registered proprietary Chinese medicine. Any claim made for it has therefore not been subject to evaluation. 此產品並非註冊藥劑製品或註冊中成藥。爲此產品作出的任何聲稱因而未經評核。". (See Note)
5.	Regulation of blood pressure, including regulating blood pressure, controlling blood pressure, reducing blood pressure, being suitable for people with high blood pressure.	The claims "Suitable for people concerned about blood pressure. 適合對血壓關注的人士服用。" and "May assist in stabilizing blood pressure. 或有助於穩定血壓。" are allowed, provided that if the product

		is not registered under either the Pharmacy and Poisons Ordinance (Cap. 138) or the Chinese Medicine Ordinance (Cap. 549), both the product label and the advertisement clearly include the disclaimer: "This is not a registered pharmaceutical product or a registered proprietary Chinese medicine. Any claim made for it has therefore not been subject to evaluation. 此產品並非註冊藥劑製品或註冊中成藥。爲此產品作出的任何聲稱因而未經評核。". (See Note)
6.	Regulation of blood lipids or cholesterol, including preventing 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,	The claims "Suitable for people concerned about blood lipids/cholesterol. 適合對血脂/膽固醇關注的人士服用。" and "May assist in stabilizing blood lipids/ cholesterol. 或有助於穩定

being suitable for people with high blood lipids or high cholesterol.	血脂/膽固醇。” are allowed, provided that if the product is not registered under either the Pharmacy and Poisons Ordinance (Cap. 138) or the Chinese Medicine Ordinance (Cap. 549), both the product label and the advertisement clearly include the disclaimer: “This is not a registered pharmaceutical product or a registered proprietary Chinese medicine. Any claim made for it has therefore not been subject to evaluation. 此產品並非註冊藥劑製品或註冊中成藥。爲此產品作出的任何聲稱因而未經評核。”. (See Note)

Note: If both the product label and the advertisement are wholly or mainly in the English or Chinese language, any claim or disclaimer may be limited to that language.”.

11. Minor amendments

The provisions of the Ordinance specified in column 2 of the Schedule to this Ordinance are amended in the manner specified in column 3 of that Schedule.

Consequential Amendments

Specification of Public Offices

12. Schedule amended

The Specification of Public Offices (Cap. 1 sub. leg. C) is amended, in the Schedule, in the entry relating to "衞生署署長", by repealing "醫藥廣告" and substituting "廣告(醫藥)".

SCHEDULE [s. 11]

MINOR AMENDMENTS TO UNDESIRABLE MEDICAL ADVERTISEMENTS ORDINANCE (CAP. 231)

Item	Provision	Amendment
1.	Section 2(1)	In the definition of "藥物", repeal "專有" and substitute "專賣".
2.	Schedule 1	(a) In the heading, repeal "病或" and substitute "病及". (b) In item 2, in column 2 – (i) repeal "外用"; (ii) in the Chinese text, repeal the third sentence and substitute – "減輕以下症狀：傷風、咳嗽、一般稱爲流行性感冒的情況及類似的上呼吸道感染。". (c) In item 4, in column 1, repeal "愛滋病" and substitute "後天免疫力缺陷綜合症(愛滋病)". (d) In item 5, in column 2, repeal "塞竇症狀" and substitute "塞竇". (e) In item 7, in column 2 – (i) repeal "nauseau" and substitute "nausea"; (ii) repeal "便秘症狀" and substitute "便秘"; (iii) repeal "痔及" and substitute "痔以".

(f) In item 8 –

(i) in column 1, repeal "精神發育" and substitute "智力";

(ii) in column 2, add "症狀" after "痛".

(g) In item 9, in column 1, repeal "genito-urinary" and substitute "genitourinary".

(h) In item 10, in column 2, repeal "適當或需多加調節飲食" and substitute "足或有增加飲食需要".

(i) In item 12, in column 1, repeal "活動過少或過多有關的任何器官或機能性病理" and substitute "任何部分活動過少或過多有關的任何其他器官性或機能性的".

(j) In item 13 –

(i) in column 1, repeal "病理" and substitute "性的";

(ii) in column 2, add "部" after "眼".

(k) In item 14, in column 2 –

(i) add "external" after "protective";

(ii) repeal "皮膚症狀" and substitute "皮膚方面的情況".

3. Schedule 2 — In item 1, repeal "醫治" and substitute "舒緩".

Explanatory Memorandum

The Undesirable Medical Advertisements Ordinance (Cap. 231) ("the Ordinance") makes it an offence to publish, or cause to be published, an advertisement likely to lead to the use of any medicine, surgical appliance or treatment for treating or preventing a disease or condition specified in Schedule 1 to the Ordinance. The purpose of this Bill is to widen the scope of the Ordinance so as to include the publishing of advertisements which make certain types of claim for certain health-related products (clause 5). The opportunity is also taken to make certain minor amendments to both the English and Chinese texts of the Ordinance (clause 11 and the Schedule).

2. The products covered by the Bill are orally consumed products other than food and drink (clause 4). The types of claim which are prohibited are set out in a new Schedule 4 and fall into 2 categories (clause 10). The categories are - those for which no advertising is allowed; and those for which claims may be made that the product is suitable for people concerned about certain health conditions. In respect of the second category, there is a requirement that if the product is not registered under the Pharmacy and Poisons Ordinance (Cap. 138) or the Chinese Medicine Ordinance (Cap. 549), a disclaimer to that effect must be included with the advertisement and on the product. Claims and disclaimers must be in both English and Chinese unless the advertisement and the product label are in only one language.

3. The existing presumptions and defences relating to medical advertisements are retained in respect of the new offence, but the opportunity is taken to clarify the meaning of "professional staff" (clause 6). In addition, the Bill provides that the Director of Health may appoint inspectors to enforce both the existing and the new prohibition (clause 8). Under proposed new section 8, inspectors will have powers of investigation and, on obtaining a magistrate's warrant, will be able to enter and search premises and take possession of property for purposes of a prosecution.

4. The Director of Health will have power to amend the new Schedule 4, under existing section 7 of the Ordinance. The Director also has power to amend Schedule 1, but the opportunity is taken in the Bill to amend Schedule 1 by varying in a number of respects the purposes for which advertising is permitted (clause 9).

5. Clause 7 increases the maximum penalties for a contravention of the Ordinance from $10,000 to level 5 ($50,000) and 6 months imprisonment for a first conviction and from $25,000 and 12 months imprisonment to level 6 ($100,000) and 12 months imprisonment for a second or subsequent conviction.

6. Clause 2 amends the long title to the Ordinance to reflect its wider scope. Clause 3 amends the short title in the Chinese text to better reflect the purpose of the Ordinance. Clause 12 makes a consequential amendment.

7. The Bill if enacted will come into operation on a day to be appointed by the Secretary for Health, Welfare and Food (clause 1(2)). This will enable the Secretary to defer the commencement of the Bill when enacted so as to allow a grace period for manufacturers and advertisers to comply with the new requirements relating to orally consumed products.

Economic Implications

The Bill will incur compliance costs to the trade, which 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 some products with claims that are to be prohibited. These costs should not be appreciable in most cases relative to the market value of the products, and are justified to incur in the interest of better protection of public and personal health, as well as on general consumer information and protection grounds. More accurate claims and labelling should be conducive to better development of the so-called "health food" trade in the long run.