WoC 14/04
(for discussion on
8 July 2004)

WOMEN'S COMMISSION
Undesirable Medical Advertisement (Amendment) Bill 2004

INTRODUCTION

This paper informs Members of the proposed control on claims in orally consumed products as specified in the Undesirable Medical Advertisement (Amendment) Bill 2004.

BACKGROUND

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 Legislative Council 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. 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. However, products which are not composed of Chinese medicines as active ingredients fall outside the

ambit of this Ordinance.

6. The Public Health and Municipal Services Ordinance (PHMSO)(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 UMAO in order to prevent the adverse effects of improper self-medication by members of the public. Currently, certain diseases which are of constant concern to women, like tumour and venereal diseases, have already been specified in the UMAO for which advertisements are prohibited. The induction of menstruation, relief of amenorrhea or delayed menstruation or any other gynaecological or obstetrical diseases are also among the purposes for which advertising of any medicine, surgical appliances or treatment is also prohibited.

8. 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 (e.g. regulation of blood pressure, blood lipids or cholesterol, etc.).

9. In view of the proliferation of the health food products and also their claims, we decide to amend the UMAO as soon as possible to protect public health. In the Policy Agenda 2003, the regulation of undesirable health claims through the amendment of the UMAO was stated as one of the Key Result Areas.

10. 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 using a risk-based approach. The recommended regulatory framework for the health claims was set out in the Administration's consultation paper, which was released on 26 September 2003.

11. During the public consultation period which ended on 15 November 2003, we have held 6 open forums and 12 small-group meetings with representatives from 190 professional associations and stakeholders. A total of 1637 written submissions were received. The Panel on Health Services of the Legislative Council was also consulted on the Administration's proposal on 8 December 2003.

12. Taking into account the different views collected in the consultation process, we have drawn up an amendment bill, which proposes to add a new Schedule 4 to the UMAO to bring additional groups of claims under the regulation of the Ordinance. The bill was endorsed by the Executive Council in January 2004, and was introduced to the LegCo in February 2004.

THE PROPOSED REGULATION

13. The amendment bill sets out six groups of claims, which are subject to two levels of risk-based restrictions. A simplified list of the schedule of the prohibited claims (and the exemptions for each of the claim) is set out at Annex.

14. The first level of restriction would apply to the three most risky claims. One of them is highly specific to women: the prevention, elimination or treatment of breast lumps. The other two include the regulation of function of the genitourinary system and the regulation of the endocrine system (items (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. Moreover, for products making the specified claim under the second level of restriction, and which are not registered under PPO or CMO, they must explicitly say so in the form of a disclaimer both on the packaging and in the advertisement.

Orally consumed products

15. 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

16. 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.

17. 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 enforce the UMAO.

WAY FOWARD

18. Owing to other competing bills, the proposed amendments, despite introduced to LegCo in 2004, were not assigned with a Bills Committee slot and would hence lapse in this legislative session. We intend to re-introduce the Bill to the LegCo in the next term.

ADVICE SOUGHT

19. Members are invited to note the contents of this paper.

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Health, Welfare and Food Bureau
July 2004

Annex

A list of the schedule of the prohibited claims under the Undesirable Medical Advertisements (Amendment) Bill 2004

Column 1 Prohibited claim	**Column 2** **Exemption**
1. Prevention, elimination or treatment of breast lumps.	None.
2. Regulation of the function of the genitourinary system and/or improvement of symptoms of genitourinary problems.	None.
3. Regulation of the endocrine system and/or maintenance or alteration of hormonal secretions.	None.
4. Regulation of body sugar or glucose and/or alteration of the function of the pancreas.	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。" may be allowed.
5. Regulation of 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。" may be allowed.
6. Regulation of blood lipids or cholesterol.	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. 或有助於穩定血脂/膽固醇。" may be allowed.

(Note: Please refer to the amendment bill for detailed version of the schedule.)