立法會
Legislative Council

LC Paper No. CB(2)712/11-12(06)

Ref : CB2/PL/HS

Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the meeting on 9 January 2012

Regulation of undesirable medical advertisements

Purpose

This paper provides background information on the regulation of undesirable medical advertisements and highlights the major views and concerns of Legislative Council ("LegCo") Members and the Panel on Health Services ("the Panel") on the subject.

Background

2. In Hong Kong, pharmaceutical products for the treatment, or prevention, of a specific disease or disease symptom are regulated under the Pharmacy and Poisons Ordinance (Cap. 138) ("PPO"). PPO provides for pre-marketing registration of individual products to safeguard the safety, quality and efficacy of products, labelling requirements, licensing of manufacturers and sellers and restrictions on retail sale.

3. Proprietary products which are composed solely of Chinese medicines as active ingredients are regulated under the Chinese Medicine Ordinance (Cap. 549) ("CMO"). As stipulated in CMO, all proprietary Chinese medicines ("pCm") manufactured or sold in Hong Kong must be registered. The system of registration of pCm was implemented on 19 December 2003. A transitional registration arrangement is provided under CMO. The mandatory registration of pCm has come into operation on 3 December 2010.

4. The Undesirable Medical Advertisements Ordinance (Cap. 231) ("the Ordinance") prohibits the advertising of medicines, surgical appliances or

treatment for prevention of certain diseases or conditions in human beings as specified in Schedules 1 and 2 to the Ordinance in order to prevent the adverse effects of improper self-medication by members of the public.

5. The Undesirable Medical Advertisements (Amendment) Ordinance ("the Amendment Ordinance") was enacted by LegCo on 29 June 2005. The Amendment Ordinance extends the prohibition/restriction on advertising to six additional groups of claims specified in a new Schedule 4 and applies the prohibition/restriction on advertising using claims specified in Schedule 4 to all orally consumed products, except those customarily consumed as food or drink.

6. The six groups of prohibited or restricted claims set out in the Schedule 4 are subject to two levels of restriction based on the risk-based approach. The first level of restriction applies to the more risky claims, namely the claims relating to the prevention, elimination or treatment of breast lumps; the regulation of the function of the genitourinary system; and the regulation of the endocrine system (items 1 to 3 of Schedule 4). The advertising of such claims will not be allowed under any circumstances. The second level of restriction involves less risky claims, namely regulation of body sugar or glucose, regulation of blood pressure and regulation of blood lipids or cholesterol (items 4 to 6 of Schedule 4). The manufacturers and traders are allowed to make four claims as specified for each type of claim in Schedule 4.

7. For products which are not medicines registered under PPO or CMO, a mandatory disclaimer must be put on the advertisement to inform consumers that they are not pharmaceutical products or pCm registered in Hong Kong.

8. Sections 1, 9 and 11 of and the Schedule to the Amendment Ordinance which relate to the amendments to the existing Schedules of the Ordinance have already come into operation on 20 January 2006. The remaining sections of the Amendment Ordinance will come into operation on a day to be appointed by the Secretary for Food and Health by notice published in the Gazette.

Members' views and concerns

9. The views and concerns expressed by LegCo Members at various platforms, including the Bills Committee on the Undesirable Medical Advertisements (Amendment) (No. 2) Bill 2004 ("the Bills Committee") and the Panel are summarized in the ensuing paragraphs.

Commencement date of the Amendment Ordinance

10. Members of the Bills Committee were advised by the Administration that after the enactment of the Amendment Ordinance, a grace period of 18 months would be allowed for manufacturers and advertisers to make changes and preparation to comply with the new requirements relating to orally consumed products. Members suggested that the Administration should work out a set of guidelines to facilitate the trade's understanding of and compliance with the new legal requirements.

11. The Administration consulted the Panel on the draft "Guidelines on the Implementation of the Undesirable Medical Advertisements (Amendment) Ordinance 2005" ("Guidelines") at the Panel meeting on 12 December 2005. In response to members' enquiry on the commencement of the Amendment Ordinance, the Administration advised that the Amendment Ordinance was targeted to come into operation in 2007 to allow time for manufacturers and advertisers to prepare for the new legal requirements and to dovetail with the completion of the registration of pCm which began in December 2003.

12. There was a view that providing a grace period of at least 18 months upon the passage of the Amendment Ordinance was not desirable. Some members called on the Administration to fix an exact date for manufacturers and advertisers to comply with the new regulation so as to avoid any confusion. They also sought explanation on the need to dovetail with the registration of pCm. The Administration explained that a disclaimer was required for health food products which were not registered under PPO and CMO as specified in column 2 of the new Schedule 4. The Administration would review the progress of the registration of pCm before deciding the most appropriate date to commence the Amendment Ordinance.

Misleading or exaggerated claims relating to slimming/fat reduction products

13. Members raised concern about the regulation of health food products making misleading or exaggerated claims relating to slimming/fat reduction. The Administration advised that a review on inclusion of the promotion of slimming/fat reduction under the Ordinance would be conducted after the registration of pCm that could be manufactured, imported and distributed in Hong Kong had been implemented for a certain period of time. In the interim, the Administration would continue to closely monitor the claims made by health food products relating to slimming/fat reduction. The Department of Health ("DH") would continue to conduct random inspection on products not registered as drug and making claims relating to slimming/fat reduction to see if they contained any western medicine.

Language of claims or disclaimers in the advertisements

14. Members noted from the draft Guidelines that if the advertisement was mainly in the English or Chinese language, a claim stated in column 2 of Schedule 4 to the Amendment Ordinance might be limited to that language. It was required, however, that any other claim or disclaimer stated in column 2 and included in the same advertisement must also be limited to that language. Members were of the view that in order to better help consumers make an informed decision when purchasing health food products, any claim or disclaimer should also be in the Chinese language, even if the advertisement was wholly or mainly in the English language.

15. The Administration explained that the language of claim and disclaimer in the draft guidelines was based on the Note in Schedule 4 to the Amendment Ordinance. The reason for allowing product label to be wholly or mainly in either English or Chinese was due to the size constraint of the packet or container of the product.

16. Members were concerned that the Note in Schedule 4 to the Amendment Ordinance might cause some manufacturers to deliberately state a claim or disclaimer in English only by making the product label and the advertisement wholly or mainly in the English language. They urged the Administration to plug this loophole in its future review on the implementation of the Amendment Ordinance.

Enforcement

17. At the Panel meeting on 25 September 2006, members raised concern about the accusations of selective enforcement against DH by some media organizations. The Administration responded that there was no question of selective enforcement of the Ordinance by DH. The Administration further advised that DH had put in place a warning system to monitor the compliance with the provisions in the Ordinance. A team of trained staff in DH regularly screened over 20 newspapers and magazines published for sale locally. The screeners followed a set of standard procedures in conducting the screening, issuance of warning and identification of cases for referral to the Police for investigation and prosecution. Warning letters would first be issued to the publishers and distributors for the advertisements that appeared to have contravened the Ordinance. If the publishers/distributors disregarded the warning and continued to publish the relevant advertisements, the case would then be referred to the Police for investigation and, if appropriate, prosecution action after being reviewed by the Director of Health.

18. Members also questioned the effectiveness of public education to counter the wrong message impressed upon the public by the numerous advertisements making irresponsible health claims in the published press. The Administration explained that the Ordinance did not seek to regulate the truthfulness of advertisements nor the products which were subjects of separate control. The purpose of the Ordinance was to protect the public from being induced by advertisements to seek improper self-medication or treatment instead of consulting medical practitioners.

19. In response to an enquiry on overseas practice on the regulation of health claims, the Administration responded that there was no universally accepted approach to regulate products or services claiming health benefits. For those overseas jurisdictions with a regulatory framework in place, the types of regulation ranged from pre-marketing approval to prescribing a list of accepted/prohibited claims as in the case of Hong Kong.

Relevant questions raised by Members at Council meetings

20. At the Council meeting of 9 May 2007, a Member raised an oral question about the regulation of advertisement published in print media, enquiring, among others, whether there were measures to regulate the publication in the print media of print advertisement which involved untruthful claims relating to beauty, height enhancement, body trimming and plastic surgery; and whether the Government had studied if the advertisements relating to breast augmentation were subject to the regulation under the Ordinance.

21. According to the Administration, print media were required to register in compliance with the relevant provisions of the Registration of Local Newspapers Ordinance. Descriptions in advertisements of goods were regulated and false claims were prohibited by the Trade Descriptions Ordinance (Cap. 362). "Trade description" included method of manufacture, composition, testing results, fitness for purpose and strength. The Administration further advised that the Association of Accredited Advertising Agents of Hong Kong and the Consumer Council had formulated codes of practice to their members and enterprises respectively. The codes required that their advertisements should be legal and truthful, without any misleading elements.

22. The Administration also pointed out that the Ordinance prohibited the advertisements of any medicine, surgical appliance or treatment for the purpose of correction of deformity or the surgical alteration of a person's appearance, the advertisements relating to breast augmentation was subject to the regulation of the Ordinance. However, members expressed grave concern that some

advertisements making exaggerated claims used the term "breast enhancement" instead of "breast augmentation" as augmentation mammoplasty was regulated by law.

23. In a written question raised at the Council meeting of 9 December 2009, concern was raised about the number of cases and penalties imposed relating to the food products or medicines contained western or Chinese medicine or carried health claims which contravened the Ordinance. Members were advised that DH had successfully proceeded with prosecution with respect to a total of 41 cases under the Ordinance between 2007 and October 2009, including cases in which products were claimed to have beneficial health effects. Fines ranging from $1,000 to $24,000 were imposed.

24. There was also a concern on the regulation of food products carried health claims, such as "dietary supplements" and whether the Administration would reconsider formulating dedicated regulatory framework and legislation.

25. According to the Administration, there were different ordinances to regulate food items claimed to have beneficial health effects, "complementary medicines" or "dietary supplements" according to their ingredients. Products containing western medicine and products composing solely of Chinese medicines as active ingredients for the purpose of treatment and health maintenance were regulated under PPO and CMO. Products should meet the requirements in respect of the safety, quality and efficacy before they could be registered. Under the Public Health and Municipal Services Ordinance (Cap. 132) ("PHMSO"), products which could not be classified as Chinese medicine or western medicine, such as "health food" and "dietary supplements", were required to be fit for human consumption and complied with the requirements in respect of food safety, food standards and labelling. The Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) under PHMSO also stipulated that all prepackaged food should bear labels which correctly list out the ingredients of the food.

26. On the regulation of advertisements of products claimed to have beneficial health effects, "complementary medicines" or "dietary supplements", the Administration pointed out that apart from the Ordinance and the Trade Descriptions Ordinance, PHMSO made it an offence for any person to use or to display a food label which provided false description and misleading information on its nature, substance or quality. With the implementation of the Food and Drugs (Composition and Labelling) (Amendment: Requirements for Nutrition Labelling and Nutrition Claim) Regulation 2008 ("the Amendment Regulation") under PHMSO in July 2010, the nutrition labelling and claims of general food products, including the nutrient function claims on the labels and

advertisements of prepackaged food were required to comply with the statutory requirements. The Amendment Regulation regulated misleading or deceptive nutrition information labels and claims. Given that there were different ordinances regulating the food products and medicines as well as the advertisements making health claims, the Administration did not undertake to reconsider the formulation of a dedicated regulatory framework and legislation.

Latest development

27. At its meeting on 9 January 2012, the Administration will brief the Panel on the commencement of the Amendment Ordinance.

Relevant papers

28. A list of the relevant papers on the Legislative Council website is in the **Appendix**.

Council Business Division 2
Legislative Council Secretariat
4 January 2012

Appendix

Relevant papers on the Regulation of undesirable medical advertisements

Committee	Date of meeting	Paper
Bills Committee on Undesirable Medical Advertisements (Amendment) (No. 2) Bill 2004	---	Report of the Bills Committee on Undesirable Medical Advertisements (Amendment) (No.2) Bill 2004 to House Committee on 17 June 2005
Panel on Health Services	12.12.2005 (Item V)	Agenda Minutes
Panel on Health Services	25.9.2006 (Item II)	Agenda Minutes
Legislative Council	9.5.2007	Official Record of Proceeding (Question 4)
Legislative Council	9.12.2009	Official Record of Proceeding (Question 9)

Council Business Division 2
Legislative Council Secretariat
4 January 2012