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Paper for the House Committee meeting
on 17 June 2005

Report of the Bills Committee on the
Undesirable Medical Advertisements (Amendment) (No. 2) Bill 2004

Purpose

This paper reports on the deliberations of the Bills Committee on the Undesirable Medical Advertisements (Amendment) (No. 2) Bill 2004.

Background

Existing regulatory controls of medicines and medical advertisements in Hong Kong

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 (PPO) (Cap. 138). The 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 (CMO) (Cap. 549). 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 (SHWF).

4. The Undesirable Medical Advertisements Ordinance (UMAO) (Cap. 231) 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 of the Ordinance in order to prevent the adverse effects of improper self-medication by members of the public.

5. Some orally consumed products, such as “health food” and “dietary

supplements", are not classified as medicines and are therefore not subject to the regulation of the PPO or CMO. There have been complaints against misleading or exaggerated claims of "health food" products with claims of specific beneficial health effects, 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.

Previous study and consultation

6. An Expert Committee comprising representatives from the Consumer Council, Chinese medicine practitioners, medical practitioners and 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. Adopting a risk assessment approach, the Expert Committee reviewed 13 groups of claims and recommended that the following nine groups of claims should be prohibited and be included as a schedule to the UMAO -

(a) regulation of body sugar or glucose including alteration of functions of the pancreas;

(b) regulation of blood pressure;

(c) regulation of blood lipid or cholesterol;

(d) prevention, elimination or treatment of breast lumps;

(e) regulation of function of the genitourinary system, including improvement of symptoms of genitourinary problems;

(f) regulation of the endocrine system, including maintenance or alteration of hormonal secretions;

(g) claims relating to slimming or fat reduction of the body, including fat burning, eliminating fat, controlling appetite, absorbing fat and eliminating fluid retention;

(h) regulation of body immune system against diseases, including cancer, chronic diseases and infection; or alteration of the effects of treatment, e.g. chemotherapy and radiotherapy; and

(i) promotion of detoxification.

7. Based on the Expert Committee's recommendations, the Administration issued a consultation document on "Regulation of Health Claims" in September 2003 proposing to include in the UMAO a list of prohibited claims as a new schedule to address the undesirable claims of orally consumed products. Having regard to the

views of the trade during the public consultation period and the concerns expressed by some members of the Legislative Council (LegCo) Panel on Health Services, the Administration revised the proposed new schedule by excluding three types of claims which posed relatively lesser risk to public health, namely, the regulation of the immune system, the promotion of detoxification and slimming/fat reduction.

8. The Administration introduced the Undesirable Medical Advertisements (Amendment) Bill 2004 into the Council on 11 February 2004. A Bills Committee was formed by the House Committee on 13 February 2004 to scrutinise the Bill. As a vacant slot was not available to activate the Bills Committee before the end of the second term, the Bill lapsed without having been scrutinised by the Bills Committee concerned.

The Bill

9. The Bill seeks to -

(a) extend the prohibition/restriction on advertising to the six additional groups of claims specified in a new Schedule 4; and

(b) apply the prohibition/restriction on advertising of claims specified in the proposed Schedule 4 to all orally consumed products, except those customarily consumed only as food or drink and those customarily consumed to satisfy a desire for taste, texture or flavour.

10. The six groups of prohibited or restricted claims set out in the proposed Schedule 4 are subject to two levels of restriction based on the risk-based approach. The first level of restriction will apply to the most 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 making of such claims will not be allowed under any circumstances. For the second level of restriction which is applicable to regulation of body sugar or glucose and/or alteration of the function of the pancreas, regulation of blood pressure and regulation of blood lipids or cholesterol (items 4 to 6 of Schedule 4), the Administration proposes to allow the manufacturers and traders to make two permissible claims as specified for each type of claim in the new Schedule.

11. 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 the advertisement to inform consumers that they are not products registered under the two Ordinances.

The Bills Committee

12. At the House Committee meeting on 15 October 2004, Members formed a Bills Committee to study the Undesirable Medical Advertisements (Amendment) (No. 2) Bill 2004. The membership list of the Bills Committee is in **Appendix I**.

13. Under the chairmanship of Hon Mrs Selina CHOW, the Bills Committee has held nine meetings with the Administration and met with representatives of 33 organisations. A list of the individuals/organisations who/which have given views to the Bills Committee is in **Appendix II**.

Deliberations of the Bills Committee

Definition of "orally consumed product"

14. Members have asked the Administration to review the above definition in the Bill and consider making clearer the meaning of "health food" and "customarily consumed food".

15. The Administration has pointed out that there is no universally accepted legal definition for "conventional food". In coming up with the proposed definition of "orally consumed product", the Administration has made reference to the way "food" is described in the laws in Hong Kong and other jurisdictions. The Administration considers that by excluding a product which is customarily consumed only as food or drink, and a product which is customarily consumed to satisfy a desire for taste, texture or flavour, from the definition of "orally consumed product", the Bill can already achieve its intended purposes effectively. Nonetheless, as the Administration's policy intention is to regulate advertisements of so-called "health foods" that mostly appear in certain forms, the Administration considers that specifying the form of the product to be regulated will better reflect its policy intention.

16. The revised definition, as set out in the Administration's proposed Committee Stage amendments (CSAs) in **Appendix III**, is supported by the Bills Committee.

Regulation of body immune system, the promotion of detoxification and the promotion of slimming/fat reduction

17. Hon Fred LI and Dr Hon KWOK Ka-ki share the views of the medical profession and the Consumer Council that orally consumed products making claims relating to the regulation of the immune system, the promotion of detoxification and slimming/fat reduction should also be regulated.

18. In response to the concerns expressed by the two members, the Administration has explained that the purpose of the UMAO is to prevent the adverse effects of

self-medication by members of the public and the delayed proper treatment of diseases. In considering the health claims to be prohibited under the proposed Schedule 4, a risk-based approach is adopted. The first level of restriction applies to the most risky claims which relate to the treatment of diseases, i.e. treatment of breast lumps; regulation of function of the genitourinary system; and regulation of the endocrine system (categories 1 to 3 in Schedule 4). The making of such claims will not be allowed. The next level of restriction applies to claims relating to the regulation of bodily conditions which are potentially risk factors of diseases which may warrant proper medical consultation. Claims under this category are those relating to the regulation of blood sugar, blood pressure and blood lipid or cholesterol.

19. As to claims relating to detoxification and improvement of the immune system, the Administration considers that they are more related to improvement and strengthening of health and bodily conditions for the purpose of disease prevention. The risk of delayed proper treatment of diseases due to orally consumed products with claims on "raised immunity", "detoxification" and "promotion of slimming" is considered relatively low.

20. In order that the Bill may be enacted as soon as possible, Dr Hon KWOK Ka-ki has indicated that he will not propose amendments to include the claims relating to the regulation of the immune system, the promotion of detoxification and slimming/fat reduction. Instead, Dr KWOK has requested SHWF to give an undertaking in his speech at the resumption of the Second Reading debate on the Bill that the Administration would review the inclusion of the regulation the immune system, the promotion of detoxification and slimming/fat reduction under the UMAO and to indicate in the undertaking the timing of the review.

Collection of relevant statistics

21. In response to members' request, the Administration has agreed to consider how statistics on the number of people who suffered ill health as a result of health food products making claims relating to regulation of body immune system, the promotion of detoxification and the promotion of slimming/fat reduction can be collected in a more systematic manner. The Administration considers that one possible avenue is to adopt the approach along the lines of the new reporting system for Adverse Drug Reaction introduced on 1 January 2005 for Chinese and western medicines.

Consumers' right to information on medical and health products

22. The pharmaceutical industry has expressed concern about restriction on access to information. In the light of the concerns of the industry, members have asked the Administration to either -

(a) separate the regulation of health claims of health food products from the regulation of health claims made by registered medicines, having regard

to the fact that the latter's safety, quality and efficacy have to be vetted and approved by the relevant authorities before they could be sold in Hong Kong; or

(b) consider recasting the allowable claims in the Bill along the lines which would allow manufacturers of registered pharmaceutical products and registered proprietary medicine to advertise the health claims of their products more explicitly.

23. In response, the Administration has pointed out that people with certain diseases or bodily functions should seek proper medical consultation instead of relying on self-medication. Enacted to promote this objective, the UMAO therefore prohibits or regulates the publication of certain advertisements that are likely to lead to the use of, inter alia, medicines for treating diseases or conditions specified in the Ordinance.

24. To further promote the objective, the Administration proposes to widen the existing scope of the UMAO and impose restrictions on publishing advertisements which make certain types of claims for "registered drugs" (i.e. products which are registered under the PPO or the CMO) or "health food". It is intended that advertisements for both types of products should be subject to the control stipulated in the proposed new section 3B and Schedule 4.

25. However, in view of the fact that "health food" products, unlike "registered drugs", are not evaluated by the authority, the Administration considers it desirable to add a further requirement in relation to "health food" products and require that a disclaimer as specified in the Bill should be added on the advertisement whenever the advertisement makes an allowable claim as specified in the Bill.

Allowable claims and disclaimer

26. In the proposed Schedule 4, there are two allowable claims in respect of items 4, 5 and 6 (blood sugar, blood pressure and blood lipids/cholesterol). The allowable claims are -

"Suitable for people concerned about (blood sugar, blood pressure, blood lipids/cholesterol);" and
"適合對（血糖，血壓，血脂/膽固醇）關注的人士服用"及

"May assist in stabilising (blood sugar, blood pressure, blood lipids/cholesterol)".
"或有助於穩定（血糖，血壓，血脂/膽固醇）"

27. To address the pharmaceutical industry's concern, the Administration proposes to extend the type of allowable claims relating to items 4, 5 and 6 of the proposed Schedule 4 to cover -

"This product is **intended for** people concerned about (blood sugar, blood pressure, blood lipids/cholesterol)"
"此產品以關注（血糖，血壓，血脂/膽固醇）的人士爲對象"

"This product is **for the consumption by** people concerned about (blood sugar, blood pressure, blood lipids/cholesterol)"
"此產品供關注（血糖，血壓，血脂/膽固醇）的人士服用"

The proposed amendments provide more choices to the industry in respect of "allowable claims", and enable the industry to choose the claims for the product it intends to promote based on the characteristics of the product and other related factors. For the sake of consistency, the Administration also proposes to slightly amend the wording of the first two allowable claims set out in paragraph 26 above to read as follows -

"This product is suitable for people concerned about (blood sugar, blood pressure, blood lipids/cholesterol)".
"此產品適合關注（血糖，血壓，血脂/膽固醇）的人士服用。"

"This product may assist in stabilising (blood sugar, blood pressure, blood lipids/cholesterol)".
"此產品或有助於穩定（血糖，血壓，血脂/膽固醇）。"

28. Apart from the two additional allowable claims, the Administration has also considered whether the law should provide the option for all registered drugs to state their registered status outright. However, the Administration has pointed out that there are legal difficulties in doing so as according to legal advice, Hong Kong is not a place where everything is forbidden except what is expressly permitted. If, as a matter of fact, the drug is a registered drug and has been evaluated, the pharmaceutical companies concerned are not prohibited from making such a claim in the advertisement. It is therefore unnecessary to provide in the Bill a right that the industry is already enjoying. To do so may give rise to a suggestion that the Government is changing the fundamental principle of the common law legal system to require everything to be forbidden except what is expressly permitted.

29. Taking into consideration the concerns of the industry and the above legal advice, the Administration proposes that SHWF reaffirms in his speech to be given at the resumption of the Second Reading debate on the Bill that there is nothing in the UMAO that prohibits the industry from stating in the advertisement of a specific drug its registration status and the fact that it has been evaluated. The Department of Health (DH) will also reiterate this in the guideline that they will issue in the future. A registered drug will of course need to comply with the registration conditions, if any, imposed by the Pharmacy and Poisons Board or the Chinese Medicines Board.

30. For products which are not registered drugs, on top of the two allowable claims

at present, the Administration would allow the two additional claims mentioned above. However, the allowable claims would need to be used together with the mandatory disclaimer worded as follows, in English and Chinese -

> "This product is not registered under the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance. Any claim made for it has not been subject to evaluation for such registration. This product is not intended to diagnose, treat or prevent any disease."
>
> "此產品沒有根據《藥劑業及毒藥條例》或《中醫藥條例》註冊。為此產品作出的任何聲稱亦沒有為進行該等註冊而接受評核。此產品並不供作診斷、治療或預防任何疾病之用。"

Enforcement provisions

31. 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.

32. In response to members' questions, the Administration has informed the Bills Committee that the public officers who may be authorised to be inspectors under clause 8 are mainly staff from the professional grades including pharmacists, doctors, and Chinese medicine practitioners.

33. Under the proposed new section 8(5), an inspector may enter and search non-domestic premises and seize and detain anything which appears to him to be or to contain evidence of the commission of an offence, without a warrant having been issued under subsection (3), if it is not reasonably practicable to obtain a warrant in respect of the premises before exercising those powers. Having regard to the fact that the inspectors were not disciplinary personnel and the misleading or exaggerated claims of health food or registered drugs are most likely to have already been published, members have asked the Administration to consider deleting the proposed new section 8(5). On review, the Administration has agreed to do so.

34. Members have also asked the Administration to state in the speech to be given by SHWF at the resumption of the Second Reading debate on the Bill that in the case where the inspector under clause 8 needs to obtain a product, such as a medicine, an orally consumed product, or a surgical appliance, during the course of inspection, the Administration is prepared to pay for the product concerned.

Exemption power of the Director of Health under section 3

35. Clause 5 of the Bill adds a new section 3B setting out the prohibition of advertisements relating to certain orally consumed products and exceptions from such

prohibition.

36. The Administration has agreed to add a provision to the new section 3B to make it clear that where section 3(1) of the UMAO does not apply to an advertisement by virtue of section 3(2), if the advertisement in question is an advertisement of an orally consumed product, new section 3B(1) will not apply to the advertisement either.

Improvements to the enforcement of the UMAO

37. Members have asked the Administration to consider providing for an appeal channel against the decision made by the Director of Health to prohibit/restrict an advertisement for an orally consumed product, or alternatively to consider establishing a pre-approval system for advertising such claims.

38. The Administration has explained that the DH has put in place a warning system, through which parties involved in the publication of a health claim, which are considered by the DH to be potentially UMAO-infringing, are forewarned on the possible legal actions to be taken against them if the claim concerned continues to be published. The system, which is purely an administrative measure, has been working satisfactorily.

39. The Administration has pointed out that the warning letter issued by DH is purely advisory and is not a legal instrument to restrict/prohibit the parties concerned from continuing to publish the claims. The ultimate decision on whether a claim is UMAO-infringing rests with the Court.

40. In view of the concerns of the Bills Committee about the clarity of messages contained in the warning letter the DH has been issuing in the past to parties which might have contravened the UMAO, the Administration has made some improvements to the letter. More information has been provided to those being warned against on the offence that they have potentially made. The remit of the UMAO is set out in the new letter and a contact telephone number of the DH for enquiry purpose is also provided in the letter.

41. As for the proposal to set up a pre-approval system for advertising such claims, the Administration considers that the current Ordinance and the warning system provide clear guidance to parties concerned and the proposed pre-approval system will compromise DH's role as an enforcement agency of the Ordinance, and may provide an unintended avenue for people to circumvent the concerned provisions of the Ordinance.

42. As regards a pre-marketing approval system, given the potential burden on the trade and the regulator in setting up a comprehensive approval system, the Administration does not recommend this option at this stage as more in-depth consideration is required to weigh the costs of this approach against the benefits it could bring, i.e. the additional protection which could be offered to consumers.

Commencement date, grace period and guideline for the industry

43. Members note that the Bill, if enacted, will come into operation on a day to be appointed by SHWF. After the enactment of the Bill, a grace period of 18 months will be allowed for manufacturers and advertisers to make changes and preparation to comply with the new requirements relating to orally consumed products.

44. The Administration has also informed the Bills Committee that in response to public expectation of better enforcement of the law, preparation of a guideline which sets out more details of orally consumed products and the criteria the DH will look at when screening problematic advertisements and examples of similar claim not allowed is underway. The guideline is expected to be completed within six months following the enactment of the Amendment Ordinance. At the request of the Bills Committee, the Administration has agreed to consult the Panel on Health Services on the guideline before the end of 2005 and to give an undertaking that it would do so in the speech to be given by SHWF at the resumption of the Second Reading debate on the Bill.

Revamping of the UMAO

45. As the pharmaceutical industry is of the view that the UMAO should be revamped to make it better able to meet present day circumstances, the Bills Committee has requested the Administration to respond to this suggestion in the speech to be given by SHWF when the Second Reading debate on the Bill is resumed.

Information notes on regulation of health food in the Mainland and other places

46. In their consideration of the Bill, the Bills Committee has made reference to information notes on regulation of health food in the Mainland, Taiwan, the United States, the United Kingdom and the European Union prepared by the Research and Library Services Division of the LegCo Secretariat.

Committee Stage amendments

47. The CSAs to be moved by the Administration are in **Appendix III**. The CSAs are supported by the Bills Committee.

Follow-up actions by the Administration

48. The Administration has undertaken to include in the speech to be given by SHWF when the Second Reading debate on the Bill is resumed that the Administration will -

(a) prepare a guideline for the trade on the implementation of the new provisions within six months following the enactment of the Amendment Ordinance and to consult the Panel on Health Services on the proposed guideline (paragraph 44 above refers);

(b) review the inclusion of the regulation of the immune system, the promotion of detoxification and slimming/fat reduction under the UMAO and indicate the timing of the review (paragraph 20 above refers);

(c) pay for the product taken by an inspector under the proposed new section 8 (paragraph 34 above refers);

(d) state that there is nothing in the UMAO that prohibits the industry from stating in the advertisement of a specific drug its registration status and the fact that it has been evaluated (paragraph 29 above refers); and

(e) respond to the request made by the pharmaceutical industry with regard to revamping the UMAO to make it better meet present day circumstances (paragraph 45 above refers).

49. The Administration has also agreed to consider how statistics on the number of people who suffered ill health as a result of health food products making claims relating to the regulation of the immune system, the promotion of detoxification and slimming/fat reduction can be conducted in a more systematic manner (paragraph 19 above refers).

Resumption of Second Reading debate

50. The Bills Committee supports the resumption of the Second Reading debate on the Bill at the Council meeting of 29 June 2005.

Advice sought

51. Members are invited to note the deliberations of the Bills Committee.

Council Business Division 2
Legislative Council Secretariat
16 June 2005

Appendix I

Bills Committee on Undesirable Medical Advertisements (Amendment) (No.2) Bill 2004

Membership List

Chairman	Hon Mrs Selina CHOW LIANG Shuk-yee, GBS, JP
Members	Hon Fred LI Wah-ming, JP
	Dr Hon LUI Ming-wah, JP
	Hon CHAN Yuen-han, JP
	Hon TAM Yiu-chung, GBS, JP
	Hon Vincent FANG Kang, JP
	Hon LI Kwok-ying, MH
	Dr Hon Joseph LEE Kok-long
	Dr Hon KWOK Ka-ki
	Hon WONG Ting-kwong, BBS
	(Total : 10 Members)
Clerk	Ms Doris CHAN
Legal adviser	Miss Anita HO
Date	2 November 2004

Appendix II

Bills Committee on Undesirable Medical Advertisements (Amendment) (No.2) Bill 2004

List of individuals/organisations who/which have given views to the Bills Committee

A.S. Watson & Co Ltd – PARKnSHOP

Better Hong Kong Movement Association

Chinese Medicine Merchants Association Ltd.

Consumer Council

Democratic Party

Easy Finder Limited

Faculty of Medicine, The University of Hong Kong

Hong Kong Academy of Medicine

H.K. & Kln. Chinese Medicine Merchants Association Ltd.

Hong Kong Chinese Herbalists Association Ltd.

Hong Kong Chinese Patent Medicine Manufacturer's Association Ltd.

Hong Kong Chinese Prepared Medicine Traders Association Ltd.

Hong Kong Doctors Union

Hong Kong General Chamber of Pharmacy Ltd.

Hong Kong Health Food Association

Hong Kong Retail Management Association

Hong Kong Society of Practitioners of Chinese Herbal Medicine

Hong Kong Suppliers Association

Hong Kong Yee Yee Tong Chinese Medicine Merchants Association Ltd.

International General Chinese Herbalists and Medicine Professionals Association Ltd.

Modernized Chinese Medicine International Association

Mr Alexander YUEN

Mr YIP Ming

Ocean Pharmaceutical (Hong Kong) Limited

SIN-HUA Herbalists' and Herb Dealers' Promotion Society Ltd.

Society for Community Organization

The Assn. of Accredited Advertising Agents of Hong Kong

The Chinese Manufacturers' Association of Hong Kong

The Dairy Farm Co Ltd - Mannings

The Direct Selling Association of Hong Kong Ltd.

The Hong Kong Association of the Pharmaceutical Industry

The Hong Kong Medical Association

The Hong Kong Medicine Dealers' Guild

The Hong Kong Pharmaceutical Manufacturers Association Ltd.

The Hong Kong Society of Chinese Medicines

The Lion Rock Institute

The Society of Hospital Pharmacists of Hong Kong

Watson's The Chemist

Drafter: Ms Frances Hui **Appendix III**

File ref: LDT/470/00/2 'A' VI

DRAFTING HISTORY TABLE

Draft no.	Release date	Doc. no. & version
1st working draft	25.5.2005	#123666 v2
1st working draft	25.5.2005	#123666 v3
1st (revised) working draft	26.5.2005	#123666 v4
2nd working draft	26.5.2005	#123666 v5
3rd working draft	30.5.2005	#123666 v6
4th working draft	31.5.2005	#123666 v7
4th working draft	31.5.2005	#123666 v8
5th working draft	9.6.2005	#123666 v9

COMMITTEE STAGE AMENDMENTS

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

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

COMMITTEE STAGE

Amendments to be moved by the Secretary for Health, Welfare and Food

Clause	Amendment Proposed
4(b)	By deleting the proposed definition of "orally consumed product" and substituting -

""orally consumed product" (口服產品) –

(a) means a product (whether or not it is a medicine) for human consumption which is intended to be taken orally and is in any of the following forms –

(i) pill;

(ii) capsule;

(iii) tablet;

(iv) granule;

(v) powder;

(vi) semi-solid;

(vii) liquid; or

(viii) a form similar to

any of the forms mentioned in subparagraphs (i), (ii), (iii), (iv), (v), (vi) and (vii); and

(b) 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 In the proposed section 3B –

(a) in subsection (1), by deleting "specified in column 2 of that Schedule, and any Note to that Schedule, in relation to that claim" and substituting "allowed under the provisions in column 2 of that Schedule (as read subject to the Note in that Schedule)";

(b) by adding -

"(1A) Where section 3(1) does not apply to an advertisement by virtue of section 3(2), in so far as the advertisement is also an advertisement for an orally consumed product, subsection (1) does not apply to the advertisement.";

(c) in subsection (2)(c), by deleting "效果" and substituting "意思".

8 In the proposed section 8 –

(a) in subsection (2)(b), by deleting "or on";

(b) in subsection (2)(c) –

(i) by deleting "samples of packaging and labels and";

(ii) by deleting "the purposes of the inspection" and substituting "such purpose";

(c) in subsection (2), by adding "的目的" after "是否獲遵從";

(d) by deleting subsection (5).

10 In the proposed Schedule 4 –

(a) in item 4, by deleting everything in column 2 and substituting –

“(a) Subject to paragraph (b), the following claims are allowed –

(i) “This product is suitable for people concerned about blood sugar. 此產品適合關注血糖的人士服用。”;

(ii) “This product may assist in stabilizing blood sugar. 此產品或有助於穩定血糖。”;

(iii) “This product is intended for people concerned about blood sugar. 此產品以關注血糖的人士爲對象。”; and

(iv) “This product is

for the consumption by people concerned about blood sugar.
此產品供關注血糖的人士服用。”.

(b) In relation to a product which is not registered under the Pharmacy and Poisons Ordinance (Cap. 138) or the Chinese Medicine Ordinance (Cap. 549), the claims referred to in paragraph (a)(i), (ii), (iii) and (iv) are allowed only if the advertisement clearly includes the following disclaimer -

“This product is not registered under the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance. Any claim made for it has not

been subject to evaluation for such registration. This product is not intended to diagnose, treat or prevent any disease. 此產品沒有根據《藥劑業及毒藥條例》或《中醫藥條例》註冊。爲此產品作出的任何聲稱亦沒有爲進行該等註冊而接受評核。此產品並不供作診斷、治療或預防任何疾病之用。”.

(See Note)”;

(b) in item 5, by deleting everything in column 2 and substituting –

“(a) Subject to paragraph (b), the following claims are allowed –

(i) “This product is suitable for people concerned about blood pressure. 此產品適合關注血壓的人士服

用。”;

(ii) “This product may assist in stabilizing blood pressure. 此產品或有助於穩定血壓。”;

(iii) “This product is intended for people concerned about blood pressure. 此產品以關注血壓的人士爲對象。”; and

(iv) “This product is for the consumption by people concerned about blood pressure. 此產品供關注血壓的人士服用。”.

(b) In relation to a product which is not registered under the Pharmacy and

Poisons Ordinance (Cap. 138) or the Chinese Medicine Ordinance (Cap. 549), the claims referred to in paragraph (a)(i), (ii), (iii) and (iv) are allowed only if the advertisement clearly includes the following disclaimer -

"This product is not registered under the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance. Any claim made for it has not been subject to evaluation for such registration. This product is not intended to diagnose, treat or prevent any disease.

此產品沒有根據《藥劑業及毒藥條例》或《中醫藥條例》註冊。爲此產品作出的任何聲稱亦沒有

爲進行該等註冊而接受評核。此產品並不供作診斷、治療或預防任何疾病之用。”.

(See Note)”;

(c) in item 6, by deleting everything in column 2 and substituting –

“(a) Subject to paragraph (b), the following claims are allowed –

(i) “This product is suitable for people concerned about blood lipids/ cholesterol. 此產品適合關注血脂/膽固醇的人士服用。”;

(ii) “This product may assist in stabilizing blood lipids/ cholesterol. 此產品或有助於穩定血脂/膽固醇。”;

(iii) “This product is intended for people concerned about blood lipids/ cholesterol. 此產品以關注血脂/膽固醇的人士爲對象。”; and

(iv) “This product is for the consumption by people concerned about blood lipids/ cholesterol. 此產品供關注血脂/膽固醇的人士服用。”.

(b) In relation to a product which is not registered under the Pharmacy and Poisons Ordinance (Cap. 138) or the Chinese Medicine Ordinance (Cap. 549), the claims referred to in

paragraph (a)(i), (ii), (iii) and (iv) are allowed only if the advertisement clearly includes the following disclaimer -

"This product is not registered under the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance. Any claim made for it has not been subject to evaluation for such registration. This product is not intended to diagnose, treat or prevent any disease. 此產品沒有根據《藥劑業及毒藥條例》或《中醫藥條例》註冊。爲此產品作出的任何聲稱亦沒有爲進行該等註冊而接受評核。此產品並不供作診斷、治療或預防任何疾病之用。".

(See Note)";

(d) in the Note –

(i) by deleting "both the product label and the advertisement are" and substituting "the advertisement is";

(ii) by deleting "any claim or disclaimer" and substituting "a claim stated in column 2";

(iii) by adding ", but where there is included in the same advertisement any other claim or disclaimer that is stated in column 2, that other claim or disclaimer (as the case may be) shall also be limited to that language" before the full stop.