

**For discussion
12 December 2000**

**LegCo Panel on Health Services
Meeting on 12 December 2000**

Regulation of Health Claims

Introduction

This paper sets out the Administration's initial proposals on the regulation of health claims.

Background

2. An increasing number of food products claiming specific beneficial effects on health are found in the local market in recent years. As these products, generally described by the manufacturers/sellers as "health food" or "functional food", become increasingly popular, we have seen complaints from the consumers against misleading or exaggerated health claims and even allegations of presence of harmful elements in these products. There are suggestions that Government should tighten control of these "health food" products.

3. There is no universally accepted definition of "health food" products. Different terms such as dietary supplements, nutraceuticals, designed foods, functional foods and natural health products are used on different occasions to refer to similar products. While the increasing popularity of these "health food" products has attracted the attention of the regulatory authorities around the world, there is yet no generally agreed approach to regulate such products.

Existing regulatory framework in Hong Kong

4. "Health food" products, depending on their ingredients, may be regulated under the following ordinances in Hong Kong :-

- (a) if the products contain medicines or claim to have medicinal effect, they are required to be registered as pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138). The claims

have to be substantiated.

- (b) if the products contain Chinese medicines, they will be required to be registered as proprietary Chinese medicines under the Chinese Medicine Ordinance (Cap. 549) when the relevant provisions of the Ordinance become effective. The claims will also have to be substantiated.
- (c) “health food” products as general food products are subject to the regulation of the Public Health and Municipal Services Ordinance (Cap. 132). The manufacturers and sellers of food should ensure that their products are fit for human consumption.

5. Furthermore, the Undesirable Medical Advertisements Ordinance (Cap. 231) prohibits advertisements claiming that a product has curative or preventive effects on any of the diseases listed in a schedule to the Ordinance.

Situation in Hong Kong

6. The Department of Health conducted a survey of “health food” products on sale at retail shops in 1996. Of the 769 products surveyed, 518 (67%) were found to contain Chinese medicines. These products should be registered under the Chinese Medicine Ordinance when the relevant provisions come into effect next year. Another 156 (20%) were western pharmaceutical products which should have been registered under the Pharmacy and Poisons Ordinance. The remaining 95 (12%), which could not be classified as Chinese medicine or western medicine, are regulated as food.

7. The above survey indicated that the bulk of “health food” products are already subject to or will be subject to stringent control provided under the Pharmacy and Poisons Ordinance or the Chinese Medicine Ordinance. They should not be a cause of concern. Only a small proportion (12%), hitherto regulated as food products, would require additional control measures to address the concerns in paragraph 2 above.

The Proposal

8. We propose to devise a regulatory framework to regulate the health claims made by food products in order to protect the consumers from misleading information and exaggerated claims. The Director of Health (DH) should have the power to prohibit products from making irresponsible health claims. Initially, we propose to confine the restriction to food products, and to expand the restriction to cover other products, in light of experience in due

course.

9. We propose that food products claiming health benefits should fall under two categories:-

- (a) Pre-market approval: Those claiming to be able to prevent or cure a specific disease or clinical condition should first register with DH, with claims properly substantiated by research or trials; and
- (b) Those claiming to have general beneficial effects on health will be exempted from registration, with DH retaining the power to determine whether the claim made is a general or specific one.

DH will maintain surveillance of the market and give guidelines to the traders, who may consult DH beforehand to determine whether the claim falls under (a) or (b). In either case the food product in question is still subject to regulation under the Public Health and Municipal Services Ordinance, i.e. the product must be fit for human consumption.

10. At present, our thought is that a claim, for example, saying that the product can strengthen the body or improve blood circulation can be accepted as a general claim, but one which says that the product can enhance the immunity system of the body will be taken as a specific claim that requires substantiation. We shall also have to determine what are health issues. For example, are issues such as weight control, hair loss or breast enhancement “health” issues and claims related to them should be regulated? We need to carry out extensive consultation to reach decisions acceptable to the manufacturers, traders and the public.

Advice sought

11. Members are invited to advise on the proposed framework in paragraphs 8 – 10. After listening to Members’ views, we shall develop some detailed proposals and seek the advice of Members again .

Health and Welfare Bureau
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