Motion on
"Urging the Government to regulate health food products"
Moved by Dr Hon Joseph LEE
at the Legislative Council meeting of 12 December 2012

Progress Report

Purpose

This reports sets out the follow-up actions taken by the Administration in respect of the captioned Motion. The Motion carried by the Legislative Council is enclosed at Annex 1.

2. At present, there is no uniform international standard for the term and definition for health food products. In Hong Kong, there is currently no specific legislation for regulation of "health food products". Nevertheless, orally consumed products sold in the market are classified into two categories, namely, medicine and food, according to their ingredients and subject to more specific regulation under different legislation according to the content of their claims. To protect public health, we are now implementing a number of measures to monitor the relevant products in the market to ensure their safety, efficacy and quality.

Follow-up actions

3. As pointed out by the Secretary for Food and Health at the captioned meeting, the Administration will take follow-up actions in the following four areas.

(I) Stepping up law enforcement under existing legislation

Pharmacy and Poisons Ordinance

4. Under the Pharmacy and Poisons Ordinance (Cap 138), all products with western drug ingredients must be registered with the Pharmacy and Poisons Board of Hong Kong before they can be sold in Hong Kong. Such products must meet the requirements in respect of safety, quality and efficacy before they could be registered. The sale of unregistered pharmaceutical products is a criminal offence and subject to a fine of $100,000 and imprisonment for two years.

5. When western drugs which are not registered or do not meet registration requirements are found, or when health food products are found to have been adulterated with western drug ingredients, actions will be taken by DH, including tracing the source of the products in question, instituting prosecution and requiring the shops involved to recall the products concerned immediately. DH will also inform the public, the trade or the relevant overseas drug authorities of the incident. If a licensee registered under the Pharmacy and Poisons Ordinance is involved, DH will also refer the case to the Pharmacy and Poisons Board as appropriate.

6. In 2012, DH conducted random tests on a total of 995 samples of health food products, among which 52 were found to contain unregistered western drug ingredients, and the rate of non-compliance was around 5%. During the period from 2010 to 2012, a total of 171 cases suspected to have breached the Pharmacy and Poisons Ordinance were found through DH's surveillance system, involving labels which did not state the presence of western drug ingredients. Of these 171 cases, follow-up investigations and prosecutions could be instituted in 39 of them with successful convictions in 30 cases. Please refer to the table below for details.

Year	**No. of prosecutions instituted with successful convictions**	**Penalties imposed**
2010	15	Fines ranging from $1,000 to $10,000 ; imprisonment for a period ranging from 6 weeks suspended for 18 months to 4 months suspended for 2 years; and community service orders of 120 to 160 hours
2011	14	Fines ranging from $1,000 to $15,000; imprisonment for 1 month suspended for 1 year; and community service orders of 120 to 150 hours
2012	1	Fine of $3,000

Chinese Medicine Ordinance

7. The provisions governing the mandatory registration of proprietary Chinese medicines (pCms) came into force on 3 December 2010. As stipulated in these provisions, all pCms must be registered with the Chinese Medicine Council before they can be imported, manufactured or sold in Hong Kong. Offenders are liable to a maximum fine of $100,000 and to imprisonment for two years. To be registered, all pCms must meet the registration requirements prescribed by the Chinese Medicine Council regarding their safety, quality and efficacy. Legislative provisions governing the label and package insert of pCms also came into force on 1 December 2011. It is stipulated in these provisions that no person shall sell, or have in his possession for the purpose of selling, any pCm without a label or a package insert which complies with the prescribed requirements. Offenders are liable to a maximum fine of $100,000 and to imprisonment for two years.

8. When products are found to be in contravention of the Chinese Medicine Ordinance, actions will be taken by DH, including tracing the source of the products in question, instituting prosecution, requiring the shops involved to recall the products immediately and informing the public of the incident as and when necessary. Where appropriate, DH will refer the Chinese medicines traders in question to the Chinese Medicine Council of Hong Kong for considering whether disciplinary action should be taken.

9. In 2012, DH conducted random tests on 2 127 samples of pCms by way of market surveillance with 13 of them found to have problems like adulteration with western drug ingredients and presence of excessive levels of heavy metals. The rate of non-compliance was 0.61%.

10. Between January 2010 and December 2012, DH found a total of 178 cases involving pCms suspected to be in contravention of the Chinese Medicine Ordinance. The suspected contraventions were violation of the labelling requirements for pCms, possession of unregistered pCms and engaging in Chinese medicines business without a license. The distribution of these cases in terms of the types of suspected contraventions is as follows:

Item	**Suspected contraventions**	**No. of cases**
1	Unregistered pCms	46
2	Labeling requirements for pCms	124

3	Engaging in wholesale dealing in/manufacture of pCms	7
4	Failing to keep records of wholesale dealing in/manufacture of pCms	1
	Sub-total	**178**

11. Follow-up investigations and prosecutions could be instituted in ten of these cases. Set out in the table below are the numbers of cases in respect of which prosecutions were instituted with successful convictions[1] as well as the penalties imposed.

Year	**No. of prosecutions instituted with successful convictions**	**Penalties imposed**
2011	1	Fine of $5,000
2012	5	Fines ranging from $500 to $10,000

Undesirable Medical Advertisements Ordinance

12. The Undesirable Medical Advertisements Ordinance (Cap. 231) prohibits the publication of any advertisement likely to lead to the use of any medicine, surgical appliance or treatment for prevention or treatment of certain diseases or conditions in human beings as specified in the Schedules to the Ordinance. The Ordinance aims to protect the public from being induced by advertisements or health claims to seek improper self-medication, which may result in delay in seeking treatment. Since 1 June 2012, The Undesirable Medical Advertisements Ordinance has also prohibited or restricted the advertising of six types of health claims as specified in the newly added Schedule for some orally consumed products. Details of the health claims are set out in Annex 2.

13. Between 2010 and 2012, DH examined a total of 202 937 advertisements, issued a total of 5 899 warning letters and successfully instituted prosecution in 60 cases (including cases involving products with health claims) under the Undesirable Medical Advertisements Ordinance (Cap. 231) with the imposition of fines ranging from HK$100 to HK$30,000.

[1] The remaining 4 prosecutions are being processed.

14. DH has put in place a regular surveillance mechanism, a mechanism for reporting adverse drug reactions and a complaint mechanism against any persons violating the above legislations. DH will keep in close view of its surveillance and take appropriate follow-up actions.

Food and Drugs (Composition and Labelling) Regulations

15. According to the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W), prepackaged foods shall be marked or labelled as appropriate. Besides, pursuant to Section 61 of the Public Health and Municipal Services Ordinance (Cap. 132), any person who sells any food which is presented with a label that falsely describes the food, or is calculated to mislead, shall be guilty of an offence. The Ordinance also stipulates that if any person publishes an advertisement which falsely describes any food, or is likely to mislead, he shall be guilty of an offence. The Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department will take enforcement action in respect of any non-compliant food products.

16. Between 2010 and 2012, CFS received a total of 95 complaints involving food products with health claims. Warning letters were issued in 8 cases, and prosecution were instituted in 6 cases under the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W). CFS will step up law enforcement in 2013, including random compliance tests for nutrition labelling on prepackaged foods with health efficacy claims on sale in the market.

Other relevant legislation

17. Like other commodities, the claims of health food products are also subject to the regulation by the Trade Description Ordinance. The Customs and Excise Department (C&ED) has been taking rigorous enforcement actions against the sale, distribution, storage, manufacture, import and export of counterfeit goods (including counterfeit health food products) in accordance with the provisions against trademark counterfeiting under the Ordinance. It also maintains close liaison with the business sector and trade mark proprietors for joint surveillance of the market situation and takes prompt enforcement action against those shops which have breached the law. In addition, the claims of health food products are also subject to the regulation by the relevant provisions or codes under the Broadcasting Ordinance and the Broadcasting (Miscellaneous Provisions) Ordinance. C&ED and the Communications Authority will continue their law enforcement and regulatory actions in accordance with the relevant provisions and codes.

(II) Stepping up surveillance of food products with health efficacy claims

18. Targeting at food products with health efficacy claims, CFS will step up safety surveillance of such products in 2013 by conducting tests on food additives, contaminants/harmful substances (e.g. metallic contaminants, pesticide residues, plasticisers, etc.) and micro-organism based on the types and nature of the food products to ensure that they are in compliance with the law and fit for human consumption. CFS has consulted and obtained the consent of the Expert Committee on Food Safety on the surveillance scheme.

(III) Stepping up publicity and education

19. Since its establishment in September 2011, the Drug Office under DH has stepped up publicity and education among the public. This includes strengthening the efforts in issuing safety alerts and announcements on drugs or health products which are not in compliance with requirements, full updating of the Drug Office's website to enhance information dissemination, and providing more health information on different categories of drugs and health products. Last year, DH conducted four exchange sessions on the content of the Undesirable Medical Advertisements Ordinance and disseminated the message about the safe use of Chinese medicines to the general public, the trade and other stakeholders through various channels.

20. Preparatory work is also being undertaken by DH for new APIs to be released in 2013 to educate the public about avoiding any indiscriminate purchase and use of medicines or health products of unknown origin.

(IV) Studying the regulatory control in overseas countries

21. There are currently no uniform international standards for regulation of health food products. As regards the regulation of similar products in other countries or regions including the Mainland, the United States, the United Kingdom, Australia, Canada and Singapore, etc., our preliminary findings indicate that the regulatory requirements for these similar products mainly involve the following four aspects:

i. To restrict the products from containing some specific ingredients, e.g. vitamins, minerals, herbal ingredients, etc.;

ii. To restrict the dosage form of the products, e.g. the products are required to be in oral dosage form;

iii. To restrict the products from touching upon any therapeutic claims in the claims or labels of the products, e.g. the products should not be used in the treatment and prevention of cancer, diabetes and hypertension; and

iv. To require label information to be shown on the products, such as the product name, ingredients and assay, recommended dosage and method of consumption, batch number, pack size, shelf life, storage method and points to note, etc.

22. In addition to the above regulatory requirements, countries like China, Canada and Australia require that pre-market approval for registration of similar products must be obtained from the regulatory authority concerned before they can be legally sold in the market. In the United States, the United Kingdom and Singapore, however, no pre-market approval for registration of "health food products" is required but the manufacturers or distributors are duty-bound to ensure the safety and quality of the "health food products".

23. We will continue our efforts in strengthening the enforcement of existing laws and the relevant publicity and education work among the public. We will also collect further information of various aspects in a more extensive and in-depth manner to help decide whether to propose an independent legislation for regulating health food products. In the course, consideration must also be given to the priority of various other tasks under our purview.

Food and Health Bureau

February 2013

(Translation)

Motion on
"Urging the Government to regulate health food products"
Moved by Dr Hon Joseph LEE
at the Council meeting of 12 December 2012

Motion as amended by Hon Alice MAK, Hon Vincent FANG and Hon Alan LEONG

That, given that at present, there are countless and multifarious health food products in the market, the number of people consuming health food products also increases gradually, and different practices of selling health food products come up incessantly, but the existing legislation is neither comprehensive nor stringent, failing to effectively regulate health food products in many respects, such as safety, efficacy and ingredients, etc., as well as the sales practices for health food products; moreover, members of the public do not know much about health food products, and health food products not up to standard are definitely no less harmful to the human body than drugs, and even pose direct threat to public health; in this connection, this Council urges the Government to:

(1) expeditiously and comprehensively regulate health food products and ensure that their safety and efficacy, etc. are assessed, tested and monitored comprehensively before their introduction to the market, and at the same time, to enhance public awareness of health food products, so as to protect public health more effectively;

(2) review the existing legislation to strengthen the regulation of sales advertisements of health food products, for example, sellers must submit relevant reports or proofs regarding health claims in product advertisements to avoid the public being misled; and

(3) regarding the increase in complaints received by the Consumer Council in recent years about business operators promoting and selling health food products to the public in the form of lecture, physical check-up and celebrity sharing, etc., and that there were elderly persons feeling unwell due to consumption of health food products and needed treatment in hospital, strengthen the regulation of the sales practices for health food products to protect public health;

(4) formulate a definition of health food products, and separately categorize health food products from 'medicine' and 'food' to facilitate regulation;

(5) comprehensively consult the relevant industries to explore the introduction of 'claim requirements' for health food products, i.e. products must be provided with empirical proofs such as inspection and test reports, etc.; and

(6) conduct 'regulation risk assessment' beforehand if the Government plans to regulate health food products to ensure that small and medium enterprises will not be affected; and

(7) step up prosecution against counterfeit health food products, and conduct sample tests on health food products in the market to ensure that such products contain the health ingredients as claimed and do not contain bacteria or harmful substances such as heavy metals.

Schedule:	4	**Claims for Orally Consumed Products in respect of which Advertisements are Prohibited or Restricted**	E.R. 2 of 2012	02/08/2012

[section 3B]

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 and uncontrollable urinary discharge or incontinence.	None.
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, improving the function of the pancreas, stimulating the secretion of insulin.	(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

為對象。" ; 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。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。" .

(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.

(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為對象。" ; 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—

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	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)
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, being suitable for people with high blood lipids or high cholesterol.	(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／膽固醇的人士為對象。”；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。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。”. (See Note)

Note: If the advertisement is wholly or mainly in the English or Chinese language, a claim stated in column 2 may be limited to that language, 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.

(Schedule 4 added 16 of 2005 s. 10)