LCQ22: Regulating health food products

Following is a question by the Hon Chan Hoi-yan and a written reply by the Secretary for Health, Professor Lo Chung-mau, in the Legislative Council today (June 5):

Question:

It has been reported that earlier on, there were overseas cases of kidney ailments and deaths after consuming health food products. While the company involved claimed that the products concerned had not been imported to Hong Kong, they may possibly appear in the market as parallel-imported products (parallel imports). Moreover, there are views that there is no well-established regulatory mechanism for health food products available in the market in Hong Kong, which are respectively regulated under various legislations such as the Pharmacy and Poisons Ordinance (Cap. 138), the Chinese Medicine Ordinance (Cap. 549) and the Undesirable Medical Advertisements Ordinance (Cap. 231). In this connection, will the Government inform this Council:

(1) given that in its reply to a question raised by a Member of this Council on April 24 this year, the Government indicated that it did not keep statistics on the number of health food products available in the market, of the reasons for that; whether it has plans to conduct the relevant statistical work;

(2) of the number of complaints related to health food products received by the Department of Health in the past three years and, among them, the respective numbers of cases in which warnings were issued and prosecutions were instituted;

(3) whether it (i) educated members of the public on the points to note when purchasing health food products, and (ii) assisted health food product manufacturers in understanding the contents of the relevant legislation and upgrading the quality of their products, in the past three years; if so, of the details, and whether it has plans to step up the relevant work;

(4) whether it has considered conducting a comprehensive review of the relevant regulation under Cap. 231 concerning health claims of health food products, so as to ensure that the ordinance can keep pace with the market development and protect the rights and interests of consumers; if so, of the details; if not, the reasons for that;

(5) in the light of the new means of shopping such as online shopping, shopping agents and parallel imports shops, of the work the Government will undertake to protect members of the public and prevent them from buying health food products with potential risks; and

(6) whether it has considered formulating a registration system or a similar mechanism for health food products, so as to delineate the responsibilities

of manufacturers and importers, and facilitate the work of tracing and recalling in the event of occurrence of incidents; if so, of the details; if not, the reasons for that?

Reply:

President,

In consultation with the Environment and Ecology Bureau, the Commerce and Economic Development Bureau, and the Department of Health (DH), the reply to the question raised by the Hon Chan Hoi-yan is as follows:

(1), (3), (4) and (6) There are many types of "health food products" with different ingredients and properties. The international community has no consistent definition and regulation of "health food products". Such products may contain different names, e.g. dietary supplements, nutraceuticals, natural health products. Indeed, the nature and risks associated with different types of "health food products" differ. Different regions have adopted various practices as to whether to adopt more specific regulatory regimes for "health food products".

The Hong Kong Special Administrative Region (HKSAR) Government has been adopting a multi-pronged strategy in regulating these products. In Hong Kong, depending on their individual nature, composition, content of the claims made, usage, dosage, packaging specifications, etc, such products are regulated under different legislations and respective government departments, including the Pharmacy and Poisons Ordinance (PPO) (Cap. 138), the Chinese Medicine Ordinance (CMO) (Cap. 549), the Undesirable Medical Advertisements Ordinance (UMAO) (Cap. 231), the Trade Descriptions Ordinance (TDO) (Cap. 362) and the Public Health and Municipal Services Ordinance (Cap. 132).

Food in general is regulated under relevant provisions of the Public Health and Municipal Services Ordinance. The Centre for Food Safety under the Food and Environmental Hygiene Department, as the enforcement agency, carries out relevant work to ensure that relevant food is fit for human consumption, and is in compliance with relevant food safety standards and food labelling requirements. The relevant requirements also apply to those "health food products" which fall within the definition of "food".

In addition, the claims of "health food products"in licensed broadcasting services are subject to regulation by the relevant provisions or codes under the Broadcasting Ordinance (Cap. 562) and the Broadcasting (Miscellaneous Provisions) Ordinance (Cap. 391). The Communications Authority will continue to take enforcement and regulatory actions in accordance with the relevant provisions and codes.

Pharmaceutical products that fall within the definition under the PPO and proprietary Chinese medicine (pCm) under the CMO must comply with the respective regulatory requirements for safety, quality and efficacy and be registered before they can be sold and supplied in Hong Kong. The PPO and the CMO also stipulate the licensing and practicing requirements for drug dealers. The DH has a market surveillance mechanism in place to monitor the

safety, efficacy and quality of drugs. To protect the public from being induced by medical or health claims and thereby seeking improper self-medication that may result in delay in seeking medical treatment, the Government also regulates the labelling and promotion of products with medical or health claims (including products that are not pharmaceutical product or pCm) through the UMAO.

To further regulate the advertisement and promotion of orally consumed products, the scope of regulation of the UMAO has been extended by the Government to cover the advertising of six groups of health claims (Note) specified in Schedule 4 since June 2012, thereby safeguarding public health. The Customs and Excise Department (C&ED), as the principal enforcement agency of the TDO, will take enforcement actions against unfair trade practices (including false trade descriptions) prohibited under the Ordinance.

The DH has all along been adopting a multi-pronged approach to disseminate safety messages about drugs (not including "health food products" that are not drugs) to the general public, the sector and other stakeholders through various channels, such as publicity, education, promotion, legislation and regulation, to strongly urge members of the public not to buy products of unknown or doubtful composition, or to consume products from unknown sources as their safety, quality and efficacy are not guaranteed. The approach includes issuing safety alerts and announcements on drugs which do not comply with the relevant requirements, preparing safety messages about the purchase and use of medicines, including "Be Cautious when Buying Medicines on Internet", "General Knowledge on Registered Medicines", and "Points to note when buying proprietary Chinese medicines", for consumers and upload to the websites of the Drug Office or the Chinese Medicine Regulatory Office. In addition, the DH conducts briefing sessions on the UMAO on a regular basis and has prepared the Guidelines on UMAO (including the Supplementary Guidelines on Regulation of Six Groups of Health Claims of Orally Consumed Products) and the Frequently Asked Questions for the trade’s reference on the Drug Office’s website.

The Government will continue to closely monitor the latest international regulatory developments and the market situation for "health food products", conduct risk assessments and review the relevant legislation and regulatory arrangements in a timely manner. At this stage, the Health Bureau is of the view that, from the risk perspective, the safety of the products concerned has already been appropriately regulated under the prevailing framework, and that it would be more appropriate to strengthen relevant public education and publicity as well as the provision of information than to directly regulate the health claims of "health food products".

(2) & (5) As mentioned above, the HKSAR Government has been adopting a multi-pronged regulatory strategy, depending on their individual nature, composition, content of the claims made, usage, dosage, packaging specifications, etc, "health food products" are regulated under different legislations and respective government departments.

The DH has been monitoring the safety, efficacy and quality of drugs (not including "health food products" that are not drugs) through an

established market surveillance mechanism. The DH collects samples of products in the market from various channels (including the Internet) for drug-related testing. If a product is found to have failed to comply with relevant statutory requirements (such as not being registered, or being found to have quality defects or adulterated with harmful substances), the DH will issue a press release as soon as possible to safeguard public health. Upon receipt of reports of suspected contravention of drug-related ordinances, including suspected illegal sale or possession of unregistered pharmaceutical products or pCm, the DH will follow up on the cases immediately. If any contravention is found, the DH will take enforcement action and conduct joint enforcement operations with the C&ED or the Hong Kong Police Force, or refer the cases to other law enforcement departments for follow-up actions.

In the past three years (from 2021 to 2023), the DH conducted about 27 410 inspections against Authorized Sellers of Poisons (commonly known as pharmacies) and Listed Sellers of Poisons (commonly known as medicine stores), and about 23 400 test purchase operations (which included about 16 800 test purchase operations against pharmacies). In addition, the DH also conducted a total of about 17 600 inspections against licensed Chinese herbal medicines retailers. During the same period, the DH handled 74 conviction cases involving unregistered pharmaceutical products, with the highest penalty of an imprisonment of 10 months or a fine of up to HK$70,000. There were also three other cases involving unregistered pCm, and the maximum fine was HK$6,000. The above 74 convictions involving unregistered pharmaceutical products included three cases in which the products claimed to be "health food products" were actually found to contain controlled drug ingredients. Furthermore, the DH has put in place an established mechanism to frequently monitor advertisements published via different media in Hong Kong and take enforcement actions against individuals who have breached relevant ordinances. In the past three years (from 2021 to 2023), the DH screened 128 365 advertisements and issued 1 344 warning letters.

In addition, the DH has also established a surveillance mechanism against online sales platforms and social media platforms. In the past three years (from 2021 to 2023), the DH detected about 11 534 Internet links that might involve suspected illegal sale of controlled drugs and about 329 Internet links involving suspected illegal sale of unregistered pCm. The relevant platforms have removed the problematic links as requested by the DH.

Other relevant bureaux and departments do not keep the information relating to "health food products" as mentioned in the questions.

Note: The six groups of claims included (1) prevention, elimination or treatment of breast lumps; (2) regulation of the function of the genitourinary system; (3) regulation of the endocrine system; (4) regulation of body sugar or glucose; (5) regulation of blood pressure; and (6) regulation of blood lipids or cholesterol.