LCQ12: Regulation of sale of drugs

Following is a question by the Hon Jeffrey Lam and a written reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (November 18):

Question:

Some members of the trade engaging in the sale of drugs have pointed out that new drugs are constantly being introduced to replace the old ones, and more and more people purchase drugs through the Internet. The fact that the existing legislation regulating the sale of drugs is outdated is not conducive to enhancing the Government's capabilities to respond to emergency public health incidents, and it hinders the channels for selling drugs. In this connection, will the Government inform this Council:

(1) whether it has assessed if the existing legislation has struck a balance between ensuring the safety of drugs purchased online and facilitating the sale of drugs;

(2) of the number of complaints about drug safety received by the Government in each of the past three years and, among such cases, the number of those involving drugs purchased online; the follow-up actions taken by the Government;

(3) of the views received by the Government from members of the trade in the past three years regarding the facilitation of the online sale of drugs, as well as the details of the follow-up work;

(4) given that even if members of the trade engaged in the sale of drugs merely distribute sample packs of innovative western medicines or proprietary Chinese medicines free of charge at exhibitions, they still need to apply for the registration of such medicines in Hong Kong, but the procedure concerned is time-consuming, whether the Government will, in this regard, introduce a simple and easy registration procedure and specify the conditions for registration (such as the requirement for the packaging of drugs to carry the descriptions that the drugs are prohibited from being sold in Hong Kong and are restricted to trial uses), so as to facilitate the trade's drug promotion work; and

(5) whether it will conduct a comprehensive review of, and public consultation on, the legislation regulating drugs, with a view to keeping the relevant legislation in pace with the times?

Reply:

President,

In Hong Kong, regulation of drugs, including pharmaceutical products

(commonly known as "western medicines") and proprietary Chinese medicines (pCm), is essentially governed by the Pharmacy and Poisons Ordinance (Cap. 138) (PPO) and the Chinese Medicine Ordinance (Cap. 549) (CMO), and implemented through a multi-pronged system with the dual targets of regulating the trade and the drugs to safeguard public health and safe use of drugs while allowing convenience for the sale of drugs.

After consulting the Department of Health (DH), the Government's response to the Hon Jeffrey Lam's question is as follows:

(1) and (4) According to the PPO, any products fall within the definition of "pharmaceutical product" must satisfy the criteria of safety, efficacy and quality for registration with the Pharmacy and Poisons Board of Hong Kong before it could be sold, with or without payment, in Hong Kong. According to the PPO, supplying sample of pharmaceutical product without payment also considered as selling. Unregistered pharmaceutical products are not allowed to be supplied to members of the public for use. Apart from the requirement of registration, a pharmaceutical product contains a Part 1 or Part 2 poison listed under the Pharmacy and Poisons Regulations (Cap. 138A), an antibiotic specified under the Antibiotics Ordinance (Cap. 137) or a dangerous drug specified under the Dangerous Drugs Ordinance (Cap. 134) shall be subject to extra sale control.

The PPO also regulates that pharmaceutical product containing Part 1 poison could only be sold at the registered premises of an Authorized Seller of Poisons (commonly known as "pharmacy") under the supervision of a registered pharmacist. In addition, antibiotics, dangerous drugs and certain Part 1 poisons that are classified as prescription medicines must be sold at the Authorized Seller of Poisons upon a doctor's prescription. On the other hand, a pharmaceutical product containing Part 2 poison could only be sold at the registered premises of an Authorized Seller of Poisons or Listed Seller of Poisons (commonly known as "medicine store"). Both Authorized seller of Poisons and Listed Seller of Poisons are not allowed to sell or supply pharmaceutical products containing the above-mentioned controlled substances via online shop. However, if a registered pharmaceutical product does not contain Part 1 or Part 2 poison, antibiotic or dangerous drug, its retail sales are not restricted to the afore-mentioned controls. This arrangement can ensure safe use of drugs while allowing convenience for the public to buy drugs online.

Regarding to sale of Chinese medicines, according to the CMO, no person can sell, import or possess a pCm, within the meaning of interpretation, in Hong Kong unless it is registered with the Chinese Medicines Board (the Board) under the Chinese Medicine Council of Hong Kong (the Council). The CMO also stipulates that Chinese medicines traders who wish to carry on a business in the retail of Chinese herbal medicines (Chm), wholesale of Chm, wholesale of pCm or manufacture of pCm shall first obtain a licence issued by the Board. In addition, Chm retailers or wholesalers can also apply to the Board for online sale of Chm. Upon approval, online sale of Chm shall only be conducted via the website specified in the licence. Any Chm sold over the internet shall be supplied from the premises specified in the licence and

such premises shall comply with the related licensing requirements for retailer or wholesale licence in Chm.

To ensure drug safety, the import and export of pharmaceutical products and pCm are subject to licensing control under the Import and Export (General) Regulations (Cap. 60A). Importation or exportation of pharmaceutical products and pCm must be covered by an import/export licence issued by the Department of Health, otherwise it would be an offence. Since the ingredients of unregistered pharmaceutical products or pCm are not ascertained, their safety, quality and efficacy cannot be guaranteed. If unregistered pharmaceutical products or pCm are allowed to be imported to Hong Kong for purpose of exhibition and supply, it may pose health risks to potential users. Also, the regulatory authority would not be able to trace the flow of unregistered drug.

(2) The Drug Office of the DH is responsible for receiving and handling complaints related to pharmaceutical products or products suspected to be adulterated with western medicine. Between 2017 and 2019, the numbers of complaints related to medicines and those related to medicines supplied on internet are tabulated as follows:

Year	No. of complaints related to medicines	No. of complaints related to medicines supplied on internet
2017	585	124
2018	641	116
2019	2546*	151

*This included about 1 900 complaints related to human papillomavirus vaccine.

In addition, the Chinese Medicine Regulatory Office of the DH is responsible for receiving and handling complaints related to pCm. Between 2017 and 2019, 56 complaints related to pCm were received, two of which were related to online sale of suspected unregistered pCm.

When the DH receives complaints related to medicines, it would follow up every complaint and conduct investigation. If it is found that the relevant Ordinances have been contravened, law enforcement actions would be taken accordingly. If necessary, cases may be referred to relevant law enforcement departments for follow up, or to conduct joint operations with other departments. The DH may, based on risk assessment, make public announcement of certain cases to protect the public health.

(3) In the past three years, the DH has not received any suggestions on online sale of pharmaceutical products. Nevertheless, the DH has been meeting pharmaceutical traders from time to time to receive their views, before making rounds of legislative amendments, seminars were also held and comments from the traders were duly consulted.

Regarding online sale of Chm by Chinese medicines (CM) traders, after meetings between members of the Board and its Chinese Medicines Traders Committee to discuss and collect opinions in 2018, the Board passed the regulatory measure for online sale of Chm by CM traders in May 2018. Licensed retailers and wholesalers in Chm, and Chinese medicines traders associations had been informed the regulatory measure through various means such as letters to facilitate them to have a better understanding of the regulatory measure. At the same time, the DH also organised regular seminars and briefings on various regulatory frameworks to strengthen the communication with the industry while the Council exchanged views with the industry through dissemination of the latest requirement and regulatory information on the website of Council and newsletters to CM traders.

(5) To balance between safe use of drugs and their market supply, the Government reviews the drug regulatory regimes from time to time, and has proposed legislative amendment to the Legislative Council when appropriate. In fact, the Government has proposed legislative amendments related to drug regulations over the past few years, including amending the PPO in 2015 to strengthen regulation on pharmaceutical product and streamline the registration procedures; and further amending the PPO in 2019 to establish a clear regulatory framework for advanced therapy products in order to protect public health and foster the development of these products. In addition, the Government has amended the CMO in 2017 to allow the Director of Health to issue the Chinese medicine safety order in order to prohibit the sale and/or recall of a problematic Chinese herbal medicine or related product. The Government will continue to review drug related regulatory mechanism in accordance with the latest development in both the international and local drug markets.