LCQ11: Import and export trading of pharmaceutical products and medicines

Following is a question by the Hon Frankie Yick and a written reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (June 9):

Question:

It is learnt that in recent years, there has been a surge in the quantities of pharmaceutical products and medicines (collectively referred to as "medicines") purchased by Mainland residents from Hong Kong's online traders. However, the development of such business has been hindered by the complicated procedure involved in the import and export of medicines. In this connection, will the Government inform this Council:

(1) of the respective quantities and total values of medicines (i) imported to and (ii) exported from Hong Kong in each of the past three years, and the year-on-year rates of change of such figures, and a breakdown of such figures by (a) type of medicines (i.e. health supplements, over-the-counter drugs, prescribed drugs and dangerous drugs) and (b) whether the Mainland was the import/export destination as well as the relevant percentages;

(2) given that the application procedure for an import licence/export licence for medicines is complicated and time-consuming (e.g. (i) that application is required for every instance of importation/exportation of medicines, (ii) that the application forms are available for sale only at specified locations, (iii) that application for re-export of unregistered medicines may only be made through the electronic system, and (iv) that the relevant arrangements have been designed on the basis of bulk trading of medicines), whether the Government will streamline such procedure (e.g. granting exemption to small-volume trading of medicines between enterprises and consumers), and shorten the time taken for vetting and approval of applications;

(3) whether it will discuss with the authorities of the Mainland cities in the Guangdong-Hong Kong-Macao Greater Bay Area (Greater Bay Area) the introduction of measures to promote the trading of medicines in the Greater Bay Area, with a view to developing Hong Kong into a trading hub for medicines in the Greater Bay Area; if so, of the details; if not, the reasons for that; and

(4) of the measures in place to assist Hong Kong businessmen in tapping the business opportunities in the import/export trade of medicines on the Mainland?

Reply:

President,

According to the Pharmacy and Poisons Ordinance (Cap. 138) (PPO), "pharmaceutical products" must satisfy the criteria of safety, efficacy and quality, and must be registered with the Pharmacy and Poisons Board of Hong Kong (PPB) before they can be sold, offered for sale, distributed or possessed for the purposes of sale, distribution or other use in Hong Kong. The above control does not apply in the case of possession or use where the unregistered pharmaceutical product (UPP) or substance has been imported into Hong Kong (i) to be exported outside Hong Kong; or (ii) by a licensed manufacturer for the purpose of manufacture or the compounding of pharmaceutical preparations.

Under the PPO, holders of valid wholesale dealer licence or manufacturer licence issued by the PPB may carry on business as an importer/exporter of pharmaceutical products, and the licensed manufacturer can only import pharmaceutical products for the purpose of manufacturing the person's own pharmaceutical products or the products to be exported are manufactured by the person. In addition, the import and export of pharmaceutical products are subjected to control of Import and Export Ordinance (Cap. 60) (the IEO). Licensed wholesaler must apply for import or export licences for each shipment of pharmaceutical products with the Department of Health (DH) beforehand.

After consulting the DH and the Trade and Industry Department (TID), the Government's consolidated response to the Hon Frankie Yick's question is as follows:

(1) The number of import and export licences for pharmaceutical products issued by the DH over the past three years are listed below. The DH does not maintain the total figure nor value of the relevant pharmaceutical products, and does not classify the pharmaceutical products in accordance with the product category and sales control.

Year	No. of Import Licence Issued	No. of Export Licence Issued	No. of Import and Export Licence Issued
2018	44 117	124 493	168 610
2019	48 119	120 047	168 166
2020	47 409	150 873	198 282

(2) In response to the recommendation by the Review Committee on Regulation of Pharmaceutical Products in Hong Kong in 2009, and to strengthen the monitoring of the flow of pharmaceutical products as well as prevent unregistered drugs imported for re-export purposes from entering the local market illegally, the DH has set up the electronic "Pharmaceuticals Licence Application and Movement Monitoring System" (PLAMMS) in 2015 and licensed wholesalers must lodge applications for import and export licences of pharmaceutical products via PLAMMS.

Each licensed wholesaler which carries on the business of import of UPP for re-export must first enlist the product intended for such purpose via PLAMMS individually before applying for the relevant import/export licences. This process aims to ascertain such products fulfil the legal definition of pharmaceutical product, to classify the pharmaceutical substances in accordance with their legal classification, and to require the wholesaler to be a holder of a valid permit (e.g. Antibiotics Permit) to deal in such substance or preparation. Furthermore, the movement of such UPP into or out of Hong Kong is monitored via PLAMMS together with inspection of the licenced premises of the wholesalers conducted by the DH to audit the imported UPP for re-export purpose. It is unnecessary to enlist registered pharmaceutical products with DH and applications for import/export licences for such products can be lodged via PLAMMS.

Currently, except from import/export licence applications for the import for re-export of UPP that must be submitted and processed via PLAMMS, other applications of import/export licences for pharmaceutical products can be submitted and processed via PLAMMS or in paper application forms. To provide greater convenience for applying for import/export licences, the DH has planned that with effect from December 31, 2021, all import/export licence applications must be lodged via PLAMMS and by then, licensed wholesalers are no longer required to purchase the paper application forms from specified locations.

Pharmaceutical products, medicines, Chinese herbal medicines and proprietary Chinese medicines may be exempted from the DH's licensing requirements if they are only being shipped to another place via Hong Kong and there are relevant supporting documents (including through bill of lading) to prove that they are transhipment cargoes, except for the dangerous drugs as defined by Section 2 of the Dangerous Drugs Ordinance (Cap. 134) (DDO). According to the Transhipment Cargo Exemption Scheme (TCES) administered by the TID, subject to conditions, shipping companies and airlines, or their appointed freight forwarders registered under TCES are exempted from the import/export licensing requirements under the IEO and the Reserved Commodities (Control of Imports, Exports and Reserved Stocks) Regulations (Cap. 296A) in respect of specified types of transhipment cargo. The relevant licensing authorities would devise different exemption conditions for the specified cargoes.

For pharmaceutical products and medicines, as well as Chinese herbal medicines and proprietary Chinese medicines, the exemption conditions include storing the transhipment cargo separately and apart from any other merchandise, and in premises registered by the company under the TCES; keeping physical custody of the transhipment cargo by the company at all times while the transhipment cargo is in Hong Kong; keeping up-to-date books and records by the company in respect of all transhipment cargo handled; allowing authorised officers of the Customs and Excise Department to inspect its godown premises, transhipment cargo, and books and records relating to the transhipment cargo whenever required. Companies successfully registered under TCES would be issued with an exemption certificate which will be valid

for two years. Registration can be done electronically in respect of such as submitting the application forms, tracking the applications and receiving the certificates.

(3) and (4) In order to seize the tremendous opportunities in the Guangdong-Hong Kong-Macao Greater Bay Area (GBA) development, the Hong Kong Special Administrative Region (HKSAR) Government has been strengthening economic and trade cooperation with the Mainland in all aspects, with a view to promoting the integration of the two places and assisting Hong Kong's business community, service providers and investors to expand into the Mainland market. Under the framework of the Mainland and Hong Kong Closer Economic Partnership Arrangement (CEPA), all "goods of Hong Kong origin" that comply with the relevant origin rules can enjoy zero tariff preference upon importation into the Mainland. In the CEPA Agreement on Trade in Goods implemented since January 1, 2019, there is also a dedicated chapter on "Trade Facilitation Measures in the Guangdong-Hong Kong-Macao Greater Bay Area" setting out the trade facilitation measures between Hong Kong and the nine Pearl River Delta municipalities. The measures include publishing periodically the overall customs clearance time for goods and further shortening the overall customs clearance time for goods, with a view to facilitating movement of goods in the GBA.

In addition, in terms of the pharmaceutical industry, the Central Government has promulgated the Work Plan for Regulatory Innovation and Development of Pharmaceutical and Medical Device in the Guangdong-Hong Kong-Macao Greater Bay Area at the website of the National Medical Products Administration on November 25, 2020, allowing designated healthcare institutions operating in the GBA to use Hong Kong-registered drugs with urgent clinical use, and medical devices used in Hong Kong public hospitals with urgent clinical use (Measure), subject to the approval of Guangdong Province. The HKSAR Government has been maintaining close liaison with the relevant Mainland authorities to discuss the implementation of the Measure at the University of Hong Kong-Shenzhen Hospital (HKU-SZH) on a trial basis, including establishing a collaborative platform and making agreement on the directory of drugs and medical devices that can be used in designated healthcare institutions in the GBA. The Guangdong Provincial Medical Products Administration (GDMPA) has commenced the Measure to use the relevant drugs and medical devices at the HKU-SZH on a trial basis, with a trial period up till July 31. Through the Measure, the first drug item and first medical device have already been delivered to the HKU-SZH in April for clinical use.

The HKSAR Government will continue to work and liaise closely with the GDMPA to implement the Measure, with a view to expanding the directory of drugs and medical devices as soon as possible, and extending the arrangement gradually to cover more designated healthcare institutions in the GBA after achieving phased progress under the trial arrangement at the HKU-SZH. We hope to foster mutual benefits, connectivity and in-depth integration of the medical and pharmaceutical industries in the GBA, as well as attract medical and pharmaceutical companies to utilise the opportunity to develop in the GBA.