

## LCQ5: Supply and safety of seasonal influenza vaccines

Following is a question by the Hon Wilson Or and a reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (November 11):

Question:

It has been reported that amid the haze of the coronavirus disease 2019 epidemic, this year's global demand for seasonal influenza vaccines has increased drastically, resulting in a tight supply of the vaccines. On the other hand, there have been successive cases in Korea and Taiwan in which some residents felt unwell or died soon after receiving influenza vaccination, which are suspected to be related to the vaccines. One of the pharmaceutical companies involved is a major vaccine supplier of Hong Kong. Hong Kong people are at sixes and sevens as they are worried that no vaccine is available for injection while they are concerned about the safety of the vaccines. In this connection, will the Government inform this Council:

(1) whether it has assessed the impacts on the supply of vaccines to Hong Kong brought about by the successive cases in overseas places in which some people who had received influenza vaccination developed health problems; of the plans in place to resolve the shortage of influenza vaccines, so as to ensure that both the public and private healthcare systems have sufficient influenza vaccines to meet the demand;

(2) of the measures in place to ensure the safety and efficacy of the influenza vaccines supplied to Hong Kong, and to prevent defective vaccines from being imported into Hong Kong; and

(3) of the details of the existing mechanism for conducting tests and random checks on the quality of imported influenza vaccines; whether it will test the vaccines from different suppliers and conduct tests on antigen content or animal testing, so as to ensure that the vaccines meet the quality and safety requirements?

Reply:

President,

In consultation with the Department of Health (DH), consolidated reply to the various parts of the question raised by the Hon Wilson Or is as follows:

(1) In relation to the earlier reports from certain overseas places of adverse reactions and deaths following influenza vaccination, DH has liaised with the World Health Organization (WHO), the health authorities concerned at

relevant places and the vaccine supplier, and noted that relevant health authorities considered that there was no evidence on safety concerns of relevant influenza vaccines. Health authorities at Korea and Taiwan had also announced investigation results of relevant incidents. Singapore and Malaysia which had earlier suspended their relevant vaccination programmes due to these incidents have also resumed their vaccination programmes. The DH also confirmed with the vaccine supplier that the influenza vaccine supplied to Hong Kong was of a different batch. The DH will continue to closely monitor the development and ensure the implementation of the vaccination programmes while maintaining the safety of influenza vaccines and risk of vaccination at an acceptable level.

For supply of influenza vaccine under vaccination programmes, the DH has procured a total of 878 000 doses of inactivated influenza vaccine for the 2020/21 season vaccination programmes, comprising 628 000 doses for the Government Vaccination Programme and 250 000 doses for the "Seasonal Influenza Vaccination School Outreach (Free of Charge) – Primary Schools" for eligible high-risk groups to receive influenza vaccination free-of-charge in phases. The vaccine suppliers have undertaken to ensure a steady supply of vaccines procured by the Government.

According to the established practice, influenza vaccines for the "Vaccination Subsidy Scheme" (VSS) and the "Seasonal Influenza Vaccination School Outreach (Free of Charge) – Kindergartens, Kindergartens-cum-Child Care Centres and Child Care Centres" would be procured by participating doctors. In view of the keen demand for seasonal influenza vaccines by members of the public recently and its tight supply around the world, the Government announced on October 22 that it would procure additional vaccines, as well as provide an additional 100 000 doses of vaccines in phases to Public-Private-Partnership Team which provides vaccination for schoolchildren and doctors enrolled in the VSS which require the vaccines. This facilitates high-risk groups to receive vaccination early and helps relieve the tight supply in the private healthcare sectors.

The DH has earlier contacted more than 1 600 doctors who have enrolled in the "2020/21 Seasonal Influenza Vaccination School Outreach (Free of Charge)" and the VSS on their demands for seasonal influenza vaccines and to inform them of the relevant arrangements. Separately, the Home Affairs Department will allocate additional influenza vaccines to non-governmental organisations and district organisations partnering with healthcare facilities/doctors/clinics enrolled in the VSS across the 18 districts to provide influenza vaccination for the public. The allocation exercise is currently under way and is expected to be completed in December 2020.

Regarding the supply of vaccines in the local private healthcare sector, the DH has been closely in touch with the vaccine suppliers and noted the arrival of a new batch of influenza vaccines of around 85 000 doses in mid to late November 2020 for supply to local private healthcare sector. The DH will ensure a steady supply of seasonal influenza vaccines under vaccination programmes and closely liaise with vaccine suppliers on supply of vaccine to the local private healthcare sector.

(2) and (3) Any products (including vaccines for human use) fall within the definition of "pharmaceutical product" under the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance) must satisfy the criteria of safety, efficacy and quality for registration with the Pharmacy and Poisons Board of Hong Kong before they could be sold or distributed in Hong Kong.

For manufacturers of pharmaceutical products, the most important and effective way to ensuring the quality and safety of their products is to strictly comply with the Good Manufacturing Practices (GMP) for medicines. Manufacturers of locally manufactured and imported pharmaceutical products have to comply with the requirements of GMP under the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

The Ordinance also stipulates that only licensed manufacturers or wholesale dealers could carry on business as an importer/exporter of pharmaceutical products. Licensed manufacturer could only import pharmaceutical products for its own manufacturing or export its own manufactured products. Import and export of pharmaceutical products are subjected to the control under the Import and Export Ordinance (Cap. 60). Licensed wholesale dealers are required to apply for Import/Export licence for each import/export shipment of pharmaceutical products (including vaccines) from the DH.

With regard to the quality assurance of vaccines, according to the WHO guidelines on regulatory preparedness for provision of marketing authorisation of human pandemic influenza vaccines in non-vaccine-producing countries, the procured vaccines should be produced in compliance with GMP, tested for quality and safety by the vaccine manufacturer, and went through the procedures for quality control testing and released by the responsible national control laboratory in accordance with "WHO's guidelines for independent lot release of vaccines by regulatory authorities".

The DH normally does not conduct sampling checks on pharmaceutical products (include vaccines) at the time of import to avoid delaying their import to and supply in the local market. On the other hand, the DH has put in place a regular market surveillance mechanism to collect samples of both locally manufactured and imported pharmaceutical products (including vaccines) from suppliers and the market for analysis. The sampling strategy is based on the risk assessment with the information collected from overseas drug regulatory authorities, rapid alert mechanism of the PIC/S, complaint or enquiries made by local suppliers or healthcare professionals.