

## LCQ12: Administration of human papillomavirus vaccines

Following is a question by the Dr Hon Elizabeth Quat and a written reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (May 29):

Question:

It has been reported that recently, some private healthcare institutions administered to their clients a type of human papillomavirus (HPV) vaccines which were unregistered in Hong Kong and suspected to be parallelly imported. Some people who were administered such vaccines said that they had developed symptoms such as rash. There are comments that this incident may affect public health and tarnish Hong Kong's reputation. Regarding the administration of HPV vaccines, will the Government inform this Council:

- (1) of the current procedure for handling reports of private healthcare institutions administering to their clients parallel-imported vaccines;
- (2) of the number and names of the healthcare institutions involved in the incident; whether it knows the number of people who were administered such vaccines and the total amount of money they paid;
- (3) whether the Department of Health (DH) has conducted laboratory tests on the vaccines concerned; if so, of the outcome; if not, the reasons for that; of the expected dates for completion of the investigation and announcement of the outcome;
- (4) of the measures in place to assist those who were administered such vaccines;
- (5) whether, following the occurrence of the incident, it has stepped up inspections of healthcare institutions to combat the administration of vaccines unregistered in Hong Kong; if so, of the details; if not, the reasons for that;
- (6) whether it will request the pharmaceutical company which is the sole manufacturer of the type of HPV vaccines concerned to publish a list of healthcare institutions to which it has supplied the vaccines; if so, of the details; if not, the reasons for that;
- (7) of the measures in place to prevent similar incidents from occurring in future;
- (8) given that starting from the next two school years respectively, DH will send its staff to schools to administer, free of charge, the first dose of HPV vaccines to Primary Five female students and the second dose of the

vaccines to Primary Six female students, how DH ensures that there will be an adequate stock of HPV vaccines for use; and

(9) whether it will, by drawing reference from the practices in overseas countries, launch a catch-up HPV vaccination programme to administer HPV vaccines to women aged 26 or below who have passed the optimal ages for, but have never been administered, such vaccination; if so, of the details and timetable; if not, the reasons for that?

Reply:

President,

Under the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products must meet the requirements of safety, efficacy and quality as stipulated in the Ordinance, and must be registered with the Pharmacy and Poisons Board of Hong Kong before they can be sold or distributed in Hong Kong. Having consulted the Department of Health (DH) and relevant law enforcement departments, I provide a reply to the question raised by Dr the Hon Elizabeth Quat as follows:

(1) to (3) Upon receiving complaints about pharmaceutical products, the DH will take follow-up actions in accordance with the Ordinance. The DH will conduct joint operations with other law enforcement departments if needed, and the investigations may involve conducting laboratory tests on pharmaceutical products. The DH and other law enforcement departments will, on the advice of the Department of Justice, institute prosecution when there is sufficient evidence. If a major public health incident is involved, the DH will announce the details in a timely manner.

From January 1 to May 22, 2019, the Drug Office of the DH received a total of about 450 complaints regarding human papillomavirus (HPV) vaccines, involving about 30 service providers. Most of the complaints are related to suspected supply of unregistered HPV vaccines by private healthcare institutions. As the investigations are still in progress, the DH is not able to give further information on the cases at this stage.

(4) The DH has reminded the public not to buy or use pharmaceutical products of unknown composition or from doubtful sources through various channels, such as webpages, promotional videos and leaflets. Registered pharmaceutical products should be labelled in accordance with statutory and registration requirements, including carrying a Hong Kong registration number on the package in the format of "HK-XXXXX". The DH will continue to step up public education and publicity in this regard.

Members of the public may also use the "Search Drug Database" on the website of the Drug Office of the DH by entering the particulars of a pharmaceutical product, such as its English product name or Hong Kong registration number, to confirm if the product has been registered in Hong Kong and obtain further information about the product. Should members of the public have any doubt about the product, they may seek assistance from the

Drug Office of the DH. Anyone feeling unwell or having any enquiries after receiving a vaccine should consult registered healthcare professionals.

(5) to (7) According to the Ordinance, illegal possession or sale of unregistered pharmaceutical products is a criminal offence. Upon conviction, the offender is liable to a maximum penalty of a fine of \$100,000 and two years' imprisonment for each offence. Although the pharmaceutical products involved in the suspected cases may be manufactured overseas by pharmaceutical companies according to relevant requirements, they are unregistered pharmaceutical products as they are neither imported by registration holders nor registered in Hong Kong under the Ordinance. Apart from prosecuting the offenders, the DH may also refer the cases concerned to the Medical Council of Hong Kong for follow-up if any registered doctors are involved.

The DH has established a mechanism to monitor the sale of pharmaceutical products in the market, and will collect information through various channels. In light of the recent incidents of suspected supply of unregistered HPV vaccines, the DH has proactively followed up the cases and stepped up inspections. In general, when suspected illegal sale or possession of unregistered pharmaceutical products is detected, the DH will immediately carry out investigations and conduct joint operations with other law enforcement departments where necessary, and any irregularities so found will be dealt with in accordance with the laws. The DH and other law enforcement departments will continue to strengthen inspections and law enforcement actions to safeguard public health.

In addition, the DH will continue to step up public education and publicity, and maintain close liaison with the pharmaceutical company concerned on its supply of 9-valent HPV vaccines to Hong Kong. Members of the public may contact the pharmaceutical company for enquiries about the supply of vaccines.

(8) As regards the arrangements for cervical cancer vaccination under the Hong Kong Childhood Immunisation Programme (HKCIP) in 2019-20, the DH has earlier on procured the required vaccines from suppliers on a contract basis in accordance with the established procedures. The procurement procedures are expected to be completed shortly to ensure an adequate supply of cervical cancer vaccine for the HKCIP.

(9) According to a position paper on cervical cancer vaccines issued by the World Health Organization (WHO) in 2017, the WHO recommended that young women aged nine to 14 years prior to becoming sexually active be included in the primary target group for cervical cancer vaccination for the prevention of cervical cancer.

The Scientific Committee on AIDS and STI and the Scientific Committee on Vaccine Preventable Diseases under the Centre for Health Protection of the DH have kept in close view the scientific evidence on the use of HPV vaccines to prevent cervical cancer. The School of Public Health of the University of Hong Kong completed a cost-benefit study on HPV vaccination for young women

last year. The findings revealed that the provision of HPV vaccination for all young women aged 12 is cost-effective in the prevention of cervical cancer.

In July last year, after reviewing the relevant scientific evidence, both of the above Scientific Committees recommended that HPV vaccination be included in the HKCIP as one of the public health strategies for cervical cancer prevention. Regarding the suggestion of providing HPV vaccination for women of other age groups not covered by the HKCIP, there is currently no sufficient local scientific evidence supporting its cost-effectiveness. The Scientific Committees will continue to closely monitor the latest and relevant scientific evidence and revisit the suggestion when necessary.

Besides, the Government encourages the public to get appropriate vaccination to enhance their immunity. In October 2016, the Community Care Fund launched a three-year Cervical Cancer Vaccination Pilot Scheme (Pilot Scheme) to provide free or subsidised HPV vaccination to eligible young women aged between nine and 18 of low-income families. As at the end of April 2019, the Pilot Scheme has provided HPV vaccination to 22 430 eligible young women.