

## LCQ5: COVID-19 Vaccination Programme

Following is a question by Dr the Hon Cheng Chung-tai and a reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (March 24):

Question:

The Government authorised the Coronavirus Disease 2019 (COVID-19) vaccines "Comirnaty" and "CoronaVac" on January 25 and February 18 this year respectively for emergency use in Hong Kong. It has been reported that since the commencement of the Vaccination Programme on February 26, a number of members of the public have felt unwell after receiving vaccination, and there have been several incidents in which members of the public died within a short period of time after vaccination. As a result, the daily number of people receiving vaccination has shown a downward trend. In this connection, will the Government inform this Council:

(1) whether it will urge the company which researched and developed CoronaVac to expeditiously publish the third phase clinical research data of the vaccine in medical journals, or make public the relevant data by other means; and

(2) whether the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation has studied the circumstances under which the Vaccination Programme needs to be suspended pending re-assessment of the pros and cons of receiving vaccination?

Reply:

President,

Since the launch of the COVID-19 Vaccination Programme on February 26, more than 400 000 citizens have received the first dose of the vaccine. The goal of our vaccination programme is very clear, which is to implement the vaccination programme in a progressive and orderly manner and expand the priority groups to provide vaccine protection to all people in Hong Kong, having regard to the proposed framework on priority of vaccination by the Joint Scientific Committees under the Centre for Health Protection of the Department of Health (DH). With regards to Dr Hon Cheng Chung-tai's point that some citizens felt unwell or passed away within a short period of time after receiving the vaccine, I wish to provide a simple response. According to the assessment of relevant experts, so far no death case has been proven to have causal relationship with the administration of COVID-19 vaccines. From the medical professional and science perspectives, so far there is no evidence pointing to the need for us to cast doubt on the safety of the two COVID-19 vaccines (i.e. Sinovac and BioNTech/Fosun vaccine) now made available to members of the public. The relevant vaccines are effective and of good quality.

My consolidated reply to the other parts of the question is as follows:

In accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation), as the Secretary for Food and Health, after making reference to the advice of the Advisory Panel on COVID-19 Vaccines (Advisory Panel) and having considered the threat to public health posed by COVID-19, I considered that the authorisation of the Sinovac vaccine is necessary and in the public interest. I have authorised the emergency use of the relevant vaccine in Hong Kong according to the Regulation on February 28.

As part of the application of the relevant vaccine for emergency use in Hong Kong in accordance with the Regulation, Sinovac has provided to the Advisory Panel the Phase 1 and 2 clinical data that it had submitted to the World Health Organization (WHO) and National Medical Products Administration, the Phase 3 clinical information of trials conducted in Brazil, as well as the Phase 3 clinical information of trials conducted in Turkey and Indonesia. The information and data of the clinical trials submitted by Sinovac have been examined and assessed in a thorough, objective and holistic manner by the 12 experts of the Advisory Panel with reference to the relevant requirements of WHO guidelines. These experts have all participated in peer reviews in their respective academic fields. Their assessment conducted for the Sinovac vaccine is on par with the peer reviews normally conducted for academic journals, and the assessment procedures for the relevant information are not different despite the information has not yet been published in medical journals. With a view to strengthening the transparency of information regarding vaccines, the expert advice on the Sinovac vaccine given by the Advisory Panel has been uploaded to the website of the Food and Health Bureau. To ensure that the Sinovac vaccine continues to fulfil the criteria of safety, efficacy and quality, I have attached conditions to the relevant vaccine authorisation, including requiring the drug manufacturer to execute a relevant risk management programme, and continue to provide the latest clinical data and laboratory analysis certificates for each batch of vaccines, as well as timely updates of quality reports.

Ensuring that the COVID-19 vaccines meet the requirement of safety, efficacy and quality is the primary consideration of the Government when implementing the vaccination programme. Since the launch of the vaccination programme, DH has put in place a pharmacovigilance system for adverse events associated with COVID-19 vaccines in accordance with WHO guidelines. It has continued to receive reports of Adverse Events Following Immunisations (AEFIs) related to the COVID-19 vaccines used in Hong Kong from healthcare professionals and pharmaceutical industries. Furthermore, the Government has established the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation (Expert Committee) for continuous monitoring of AEFIs associated with COVID-19 vaccinations and provide expert opinion and advice on the safety monitoring of authorised vaccines. Regarding the serious adverse events following COVID-19 vaccination in Hong Kong, the Expert Committee would review the cases having regard to the available information, including the medical conditions and history of the patient as well as relevant clinical data, available information related to the vaccine and

preliminary autopsy findings (if applicable), and conduct causality assessment based on the algorithm of the WHO. So far, the assessment results of the Expert Committee have not indicated any causal relationship between death cases and the administration of vaccines. Put in simple terms, from the medical professional and science perspectives, so far there is no evidence pointing to the need for us to cast doubt on the safety of the two COVID-19 vaccines now made available to citizens. The relevant vaccines are effective and of good quality.

Based on science and following the principles of openness and transparency, DH published on March 12 the regular summary report on AEFIs associated with COVID-19 vaccinations. The results of the report showed that the vaccination situation was in line with expectations and was similar to the experience of other places. There is no particular significant factor that raise concerns on unexpected AEFIs due to COVID-19 vaccination. In view of this, we believe that there is no basis for the suspension of the vaccination programme. We will also regularly update and publish the relevant report. If citizens have any questions about their physical condition or whether they are fit for COVID-19 vaccination, they should first consult their family doctor or attending doctor before getting the vaccine.

I would like to stress that vaccination is an important public health measure to control COVID-19 effectively. The Government has all along been implementing the vaccination programme based on scientific evidence and in adherence to the principles of openness and transparency, providing members of the public with the choice of vaccines from different technology platforms. Faced with the raging epidemic, the community should work together to fight the virus. We encourage citizens to actively get vaccinated so as to protect themselves, their families, the healthcare system, and even the whole population, so that Hong Kong can successfully overcome the epidemic as soon as possible.

Thank you, President.