<u>Advisory Panel on COVID-19 Vaccines</u> <u>convenes meeting to conduct continuous</u> <u>benefit-risk analysis of authorised</u> <u>COVID-19 vaccines</u>

The Advisory Panel on COVID-19 Vaccines (Advisory Panel) convened a meeting today (April 29) to conduct continuous benefit-risk analysis of the authorised COVID-19 vaccines. The meeting was chaired by convenor Professor Wallace Lau Chak-sing.

The Secretary for Food and Health authorised two COVID-19 vaccines, namely the Comirnaty vaccine and the Sinovac vaccine, in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation) on January 25 and February 18 respectively. To comply with the conditions of authorisation, the authorisation applicants are required to submit the latest clinical data on the vaccines, safety update reports and quality certification documents, etc. for continuous review and monitoring.

The Advisory Panel held a meeting today to review the continuous benefit-risk balance of the two authorised vaccines. After reviewing all the latest available clinical and safety data related to the Comirnaty and Sinovac vaccines, the Advisory Panel still considered that the benefits of the two vaccines outweighed the risks. There was no need to recommend changes regarding the use of these two vaccines.

Regarding the Comirnaty vaccine, the latest data from continuous Phase 3 clinical study and data from vaccine recipients indicated that the efficacy of the vaccine maintained at around 90 per cent seven days after administration of the second dose. Taking into consideration the local and overseas safety data, including safety reports submitted by the applicant, the Advisory Panel considered that there was no new significant safety signal identified, though continuous monitoring was required. The Advisory Panel also noted that the quality issue related to packaging defects of the vial caps of a batch of Comirnaty vaccines imported had been promptly rectified. The vaccine manufacturer confirmed that the quality of the vaccines was intact and there was no evidence indicating that there were any safety risks for the affected batch of vaccines. The quality of the subsequent batches of Comirnaty vaccine imported has already passed the certification and appropriate testing for quality control.

With regard to Sinovac vaccine, preliminary data on vaccine efficacy from a study conducted in Chile indicated that the efficacy of preventing symptomatic COVID-19 was 66.96 per cent upon 14 days after two doses of vaccination. Taking into consideration the local and overseas safety data available, including safety reports submitted, the Advisory Panel considered that there was no new significant safety signal identified, though continuous monitoring was required. The quality of the batches of Sinovac vaccine imported has already passed the certification and appropriate testing for quality control.

The Advisory Panel will submit the views to the Secretary for Food and Health. Relevant information will be uploaded to the website of the Food and Health Bureau later on.

"The Government will continue to ensure that the authorised vaccines satisfy the criteria of safety, efficacy and quality, and keep on disseminating to the public and relevant stakeholders the latest safety and scientific information on the relevant vaccines in a timely manner," the Government spokesman said.