<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 (January 12) to conduct continuous benefit-risk analysis of the authorised COVID-19 vaccines. The meeting was chaired by convenor Professor Wallace Lau Chak-sing.

At the meeting today, the Advisory Panel reviewed the continuous benefit-risk balance of the two authorised vaccines. After reviewing all the latest clinical and safety data related to the Comirnaty and Sinovac vaccines (including safety reports submitted by the authorisation applicants), the Advisory Panel considered that there was no new significant safety signal identified, though continuous monitoring was still required. The quality of the Comirnaty and Sinovac vaccines imported has already passed the certification and appropriate testing for quality control. In summary, the Advisory Panel still considered that there was no need to recommend changes regarding the use of the two vaccines.

The Advisory Panel will submit the relevant views to the Secretary for Food and Health (SFH) for consideration. The information concerned will be uploaded to the website of the Food and Health Bureau later on.

Regarding the administration of the Comirnaty vaccine on children aged five to 11, the Advisory Panel noted that application on a paediatric vial packaging for children aged five to 11 (i.e. 10mcg per dose) is still pending. Having reviewed the relevant efficacy and safety data published, the Advisory Panel suggested allowing children aged five to 11 to receive a fractional dose (i.e. one-third of a dose) of the Comirnaty vaccine for adults for "off-label use" and to make reference to the recommendations of relevant scientific committees for implementing the vaccination programme.

Having regard to the current and anticipated epidemic situation, the Advisory Panel recommended that the Government should provide the relevant information to the Joint Scientific Committees (Scientific Committee on Vaccine Preventable Diseases and Scientific Committee on Emerging and Zoonotic Diseases) under the Centre for Health Protection of the Department of Health for consideration on whether and how fractional dose (i.e. onethird of a dose) of the Comirnaty vaccine for adults should be administered to children aged five to 11, with a view to facilitating the timely extension of the Comirnaty vaccine to the relevant age groups.

"The Government will continue to follow up with Fosun Pharma on extending the age eligibility of the Comirnaty vaccine to cover children aged five to 11. The Government will also continue to ensure that the authorised vaccines satisfy the criteria of safety, efficacy and quality, and continue to disseminate the latest safety and scientific information on the relevant vaccines to the public and relevant stakeholders in a timely manner," a Government spokesman said.

The SFH 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) on January 25 and February 18, 2021 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.