Advisory Panel on COVID-19 Vaccines convenes meeting to review supplementary data and information submitted by Sinovac

â€‹The Advisory Panel on COVID-19 Vaccines (Advisory Panel) convened a meeting today (February 16) to review the supplementary data and information submitted by Sinovac Biotech (Hong Kong) Limited (Sinovac) on its COVID-19 vaccine. The meeting was chaired by convenor Professor Wallace Lau Chak-sing.

The Advisory Panel held a meeting on February 10 on the application for emergency use of the COVID-19 vaccine by Sinovac. Having reviewed the relevant information on safety, efficacy and quality, the Advisory Panel requested Sinovac to provide supplementary data and information to establish that the benefits of using its COVID-19 vaccine for protection against COVID-19 outweigh the risks. Sinovac later compiled the relevant data as requested and submitted supplementary information to the Department of Health to clarify that save for emergency situations, it is recommended that the first and second dose of vaccine should be received with an interval of 28 days. As regards the development of antibodies after vaccination to support the interval for vaccination, the Phase 1 and 2 clinical data previously submitted by Sinovac indicated that the vaccine could effectively trigger an immune response and create antibodies in adults and the elderly. Furthermore, Sinovac has also provided information on the relevant tests on the immunogenicity of the vaccine under Phase 3 clinical trials conducted in Brazil (triggering of immune response including the creating of antibodies).

At the meeting today, the Advisory Panel reviewed the information submitted earlier and later supplemented by Sinovac on safety, efficacy and quality. The Advisory Panel considers that the relevant clinical information, based on the results of different situations such as the trial design, countries (including Brazil, Turkey and Indonesia), target groups (such as healthcare staff with higher risks, people with mild symptoms who need no treatment), as well as the testing targets etc., indicated that the efficacy of Sinovac's vaccine was 50.65% to 91.25% for people over 18 years old and that the safety of the vaccine was satisfactory. The information on quality also indicated that the manufacturer has met the Good Manufacturing Practice standards, and has obtained approval for use from the National Medical Products Administration and other overseas drug regulatory authorities. The Advisory Panel considers that, under the current global epidemic situation, the benefits of authorising the use of the COVID-19 vaccine by Sinovac for protecting against COVID-19 outweigh the risks. To ensure that the relevant vaccine continues to fulfil the requirements of safety, efficacy and quality, the Advisory Panel recommends attaching conditions to require the applicant to execute relevant risk management programme, and continue to provide the latest clinical data, laboratory analysis certificates for each batch of

vaccines, as well as timely update of quality reports, etc. With a view to strengthening the transparency of information regarding vaccines, the expert advice on vaccines given by the Advisory Panel will be made publicly available. The relevant documents will later be uploaded to the website of the Food and Health Bureau.

The Government spokesman said, "The Government welcomes the recommendation by the Advisory Panel on the authorisation application for the vaccine. The Secretary for Food and Health will consider the relevant recommendation and come to a decision on the authorisation of the vaccine for emergency use as soon as possible. The Government will ensure that vaccines satisfy the criteria of safety, efficacy and quality, and obtain emergency use approval in accordance with the relevant requirements as well as stringent approval procedures under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K), before arranging for members of the public to receive the vaccines. To enhance the public's confidence in vaccines, the Government's work in vaccine administration will be based on scientific evidence and adhere to the principles of openness and transparency. We will provide members of the public with the latest information on the relevant vaccines through different channels in a timely manner, and make public the views of experts on the vaccines, so that the public can grasp correct and comprehensive information on them."