

# Advisory Panel on COVID-19 Vaccines convenes meeting on application for emergency use of COVID-19 vaccine by Sinovac

The Advisory Panel on COVID-19 Vaccines (Advisory Panel) convened a meeting today (February 10) on the application for emergency use of COVID-19 vaccine by Sinovac Biotech (Hong Kong) Limited (Sinovac). The meeting was chaired by convenor Professor Wallace Lau Chak-sing.

According to the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation), the Secretary for Food and Health may, under the state of public health emergency, authorise the use of COVID-19 vaccines which fulfil the criteria of safety, efficacy and quality for the purpose of vaccination programmes led by the Government. The Regulation also specifies the conditions and procedures which the vaccine manufacturer or its representative, importer, or wholesale dealer must follow when submitting application for seeking authorisation for emergency use. The Advisory Panel appointed by the Chief Executive under the Regulation will examine the information of relevant vaccine and provide a clear recommendation to the Government. The Secretary for Food and Health will consider the advice of the Advisory Panel before authorising a vaccine for emergency use.

Earlier, in accordance with the Regulation, Sinovac submitted to the Secretary for Food and Health an application for the authorisation of its COVID-19 vaccine (CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated) for emergency use. At the same time, it also provided Phase 1 and 2 clinical data of the vaccine that it had submitted to the World Health Organization (WHO) and National Medical Products Administration (NMPA), among other information. Moreover, Sinovac provided the Phase 3 clinical information of its trials conducted in Brazil that it had submitted to the NMPA, as well as the Phase 3 clinical information of the trials conducted in Turkey and Indonesia.

The Advisory Panel takes note that the Department of Health has, following relevant guidelines, requested Sinovac to have relevant research data published in medical journals. In view that Sinovac indicated that it has considerable difficulties in compiling the relevant information for publication in medical journals within a short period of time, having regard to the urgency for vaccination, the Advisory Panel has assessed and examined the information on safety, efficacy and quality submitted by Sinovac as mentioned in the above paragraph. The Advisory Panel considers the relevant clinical research data provided by Sinovac to be positive, but the panel requested Sinovac to provide additional data and information to establish that the benefits of using its COVID-19 vaccine for protection against COVID-19 outweigh the risks. The Advisory Panel will convene a meeting two weeks later after receiving the relevant information.

The Government spokesman reiterated, "After the Advisory Panel provides a recommendation on the application for authorisation of the vaccine, the Secretary for Food and Health will 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 Regulation, 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 continue to 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."