

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

The Advisory Panel on COVID-19 Vaccines (Advisory Panel) convened a meeting today (January 18) on the application for emergency use of COVID-19 vaccine by Fosun Pharma. 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, Fosun Pharma submitted to the Secretary for Food and Health an application for the authorisation of the COVID-19 vaccine it developed with German drug manufacturer BioNTech for emergency use. At the same time, it also submitted the Phase 3 clinical data of the vaccine concerned, overseas authorisation obtained, and other information relevant to the safety, efficacy and quality of the vaccine. For this application, the Advisory Panel convened a meeting today to examine the information and reports submitted by Fosun Pharma related to safety, efficacy and quality.

The Advisory Panel considered that, under the current epidemic situation, the benefits of authorising the use of the COVID-19 vaccine by Fosun Pharma/BioNTech 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 suggested adding conditions to require the applicant to continue providing the latest clinical data, safety update reports, and quality certification documents by the drug manufacturer for each batch of vaccines, etc. As regards the use of the vaccine in other places, the Advisory Panel suggested that Fosun Pharma be requested to obtain more information from the relevant health authorities. The relevant information should be provided to the Joint Scientific Committees under the Department of Health for examination, in

order to assist with determining the priority groups for receiving the relevant vaccine. The Advisory Panel will compile its views and submit the above advice to the Secretary for Food and Health for consideration. 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 reiterated, "The Government welcomes the submission of 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 requirements 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 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."