

Government actively follows up on Phase 3 clinical data for Sinovac's COVID-19 vaccine

A Government spokesman said today (February 3) that the Department of Health (DH) has been actively following up with Sinovac Biotech (Hong Kong) Limited (Sinovac), with a view to obtaining as soon as possible the Phase 3 clinical data of its COVID-19 vaccine, so as to ensure that the vaccine fulfils the criteria of safety, efficacy and quality and can be authorised for emergency use. According to the latest reply from Sinovac, it is preparing the relevant information and will submit the information to the DH as soon as possible.

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 conducted 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 on COVID-19 Vaccines (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.

In order to complete the authorisation process in a timely and smooth manner, the DH has already been processing part of the information provided by Sinovac. The DH has also requested Sinovac to provide to it as soon as possible the Phase 3 clinical data Sinovac has submitted to the World Health Organization. After receiving the necessary information and relevant clinical data, the Advisory Panel will review them and make a recommendation in accordance with the Regulation, with a view to ensuring that the relevant vaccine fulfils the criteria of safety, efficacy and quality.

The Government spokesman said, "The Government will ensure that the authorised vaccines satisfy the criteria of safety, efficacy and quality before providing vaccination for members of the public. Our work will continue to adhere to the principles of openness and transparency so that members of the public can obtain the latest information on vaccines."