Government responds to approval of vaccine by Sinovac for emergency use

With regard to a media report casting doubt on the approval procedures for authorising the vaccine by Sinovac and leading people to falsely believe that the Government has lowered the standards for authorising the vaccine by Sinovac, the Government pointed out on February 18 that the relevant report is not truthful and provided a response as follows:

On January 25, Sinovac Biotech (Hong Kong) Limited (Sinovac) submitted an application to the Secretary for Food and Health for the authorisation of its COVID-19 vaccine (CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated) for emergency use in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation). It also then provided supporting documents and information.

The Advisory Panel on COVID-19 Vaccines (Advisory Panel) convened two meetings on February 10 and February 16 respectively for the relevant application. It reached a consensus for submitting a recommendation to the Secretary for Food and Health to approve the vaccine by Sinovac, thereby establishing that the benefits for using the vaccine to protect against COVID-19 outweigh the risks.

The procedures for the Advisory Panel to examine the information and data and the Government to approve the authorisation are stringent and comprehensive. The procedures met all the relevant requirements under the Regulation and were no different from those adopted for approving another vaccine for emergency use in Hong Kong (Comirnaty) earlier.

With respect to the requirement that the information submitted needs to be published in medical journals, Sinovac has indicated that it has considerable difficulties in compiling the relevant information for publication in a short period of time. Sinovac has provided to the Department of Health the Phase 1 and 2 clinical data that it had submitted to the World Health Organization (WHO) and National Medical Products Administration (NMPA), the Phase 3 clinical information of trials conducted in Brazil, as well as the Phase 3 clinical information of trials conducted in Turkey and Indonesia. The relevant data has been examined and assessed by the 12 experts of the Advisory Panel. The experts on the Advisory Panel have all participated in peer reviews in their respective academic fields. With reference to the relevant requirements of WHO guidelines, the Advisory Panel conducted the assessment in a thorough, objective and holistic manner. The relevant procedures are on par with the peer reviews normally conducted for academic journals. The assessment procedures for the relevant information are not different despite the relevant information has not yet been published in medical journals.

According to the Regulation, the Secretary for Food and Health can authorise a vaccine under the following situations: (a) a regulatory

authority in a place outside Hong Kong that performs the function of approving pharmaceutical products has approved the vaccine for administration to persons, including for emergency use; or (b) the vaccine is listed in accordance with the emergency use listing procedure by the WHO or is in the list of prequalified vaccines published by the WHO. In other words, under the framework of the Regulation, approval by the WHO is not an essential requirement for authorising a vaccine for emergency use in Hong Kong. In fact, a number of overseas regulatory authorities have approved vaccines for emergency use before the individual vaccines (including the "Comirnaty" vaccine) were listed for emergency use/prequalified by the WHO. Currently, the Sinovac vaccine has been approved for use by the regulatory authorities of Brazil, Turkey, Indonesia, Chile and Mexico, and the NMPA. Casting doubt on the authorisation procedures for emergency use due to authorisation from the WHO yet to be obtained stems from misunderstanding of the mechanism for authorising vaccines for emergency use in the international arena.

The Government spokesman said, "The Government will ensure that COVID-19 vaccines satisfy the criteria of safety, efficacy and quality before arranging for members of the public to receive the vaccines. Our work will continue to adhere to the principles of openness and transparency, so that the public can grasp correct and comprehensive information on the vaccines."