Government responds to clinical data of Sinovac vaccine

Regarding media reports on the submission of Phase 3 clinical data of the vaccine by Sinovac Biotech (Hong Kong) Limited (Sinovac) to the Department of Health (DH), the Government today (February 5) gave the following responseï¼š

The Advisory Panel on COVID-19 Vaccines (Advisory Panel) set up under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) is empowered to examine, based on scientific evidence, whether COVID-19 vaccines satisfy the criteria of safety, efficacy and quality, and then provide a recommendation to the Secretary for Food and Health. Scientific evidence must include the examination of Phase 3 clinical data. Phase 3 clinical data can provide objective information to assist with the assessment of the effectiveness of the vaccine after application on a relatively larger pool of users, as well as the relevant risks and benefits. On the other hand, the publication of research reports and data in medical journals is generally another point of reference, indicating that the relevant research has undergone peer review and has a higher level of objectivity and acceptance.

With respect to the Sinovac vaccine, the DH has been actively following up with Sinovac, with a view to obtaining as soon as possible the relevant information of its vaccine to commence the approval procedures. However, there is no setting of any deadline as today as reported in individual media reports. In accordance with the guidance of the Advisory Panel, the DH has previously requested Sinovac to have the relevant clinical data published in medical journals. However, Sinovac indicated that it has considerable difficulties compiling the relevant information for publication in a short period of time, having regard to the urgency for vaccination, the DH has in turn requested Sinovac to provide its Phase 3 clinical data submitted to the World Health Organization (WHO) for assessment purpose.

Up till now, Sinovac has provided to the DH its Phase 1 and 2 clinical data submitted to the WHO and drug regulatory authorities of other jurisdictions, among other information. Sinovac has also provided to the DH a set of its Phase 3 clinical data of trials conducted in Brazil that it had submitted to drug regulatory authorities of other jurisdictions. Furthermore, Sinovac indicated that it can provide the Phase 3 clinical information of its trials conducted in Brazil and Turkey, etc that it submitted to the WHO to the DH as early as this week. After compilation of all the information, the DH will submit the documents to the Advisory Panel next week for review and arrange a meeting for the Advisory Panel to assess and put up a recommendation as soon as possible, so as to examine that the relevant vaccine satisfies the criteria of safety, efficacy and quality.

The Government spokesman said, "The Government will ensure that the

authorised COVID-19 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."