Government makes Prevention and Control of Disease (Use of Vaccines) Regulation

â€‹The Government published the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation) in the Gazette on December 23, which provides the legal framework under the present state of public health emergency to bring in COVID-19 vaccines which satisfy the criteria of safety, efficacy and quality for emergency use. The Regulation will remain in effect until December 23, 2021.

The Regulation empowers the Secretary for Food and Health to, based on the objective clinical data of a COVID-19 vaccine (including third phase clinical research data), with reference to the expert advice of an independent advisory panel and having regard to the approval given by a regulatory authority in a place outside Hong Kong that performs the function of approving pharmaceutical products (including emergency use), authorise and allow the specified use of the relevant COVID-19 vaccine in Hong Kong under the emergency situation, which is basically for vaccination programmes conducted by the Government. The members of the above advisory panel will be appointed by the Chief Executive. The relevant member list is at Annex.

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. Also, for authorised vaccines approved for emergency use in accordance with the Regulation, members of the public will be clearly informed of the relevant information in relation to the vaccine before vaccination, and the vaccine must be administered with the recipient’s informed consent. To facilitate the above arrangement, the Government will provide the latest information on the relevant vaccines through different channels at appropriate juncture, in order to enable members of the public to receive accurate information with respect to the relevant vaccines.

A spokesman for the Food and Health Bureau stressed, "Allowing members of the public to be administered with safe and effective COVID-19 vaccines is crucial to the resumption of the normal ways of life in Hong Kong. To ensure that authorised COVID-19 vaccines approved for specified emergency use under the Regulation still adhere to the requirements of safety, efficacy and quality, the authorisation by the Secretary for Food and Health must be premised on objective clinical data and experts’ views, and complemented with a mechanism for monitoring any adverse event that occurs to the recipient associated with the administration of the relevant vaccine."

Notwithstanding that the vaccines to soon enter the market have undergone stringent clinical tests to ascertain their safety and that tens of thousands of people have participated in the clinical research, and that the number of people administered with the vaccines in other places continues to increase, it is a matter of fact that the research and development period of

COVID-19 vaccines is greatly compressed as compared to other regular vaccines. Hence, the occurrence of rare or unpredictable severe adverse event after widespread vaccination on the population cannot be completely ruled out. With a view to enabling vaccine manufacturers to provide COVID-19 vaccines as early as practicable, general procurement agreements would provide the vaccine manufacturers with a certain level of immunity. However, the relevant immunity does not cover incidents which involve the gross negligence, fraud or willful misconduct by the vaccine manufacturer; or when the quality of the vaccine does not yet reach requirements or has safety concerns; or the relevant vaccine has yet to fulfill the relevant manufacturing standards or conditions required for drug safety. Having made reference to overseas practices on the relevant issue, the SAR Government plans to set up an indemnity fund. In the event members of the public encounter a rare or unpredicted severe adverse event associated with the administration of the vaccine, they can still take action against the drug manufacturer. The fund will cover the indemnities ultimately determined by court or arbitration and can provide in advance part of the indemnities in order to make available financial assistance to the member of the public as early as possible. The Government is formulating the relevant mechanism and details and will seek funding approval from the Finance Committee of the Legislative Council as soon as possible.

In order that healthcare professionals can provide vaccination to members of the public with peace of mind, the Regulation provides these healthcare professionals with civil immunity, such that they would not have to be civilly liable for any loss or damage attributable to the intrinsic property of the authorised vaccine.

The spokesman supplemented, "The Government will continue to strive for the early supply of COVID-19 vaccines to Hong Kong, and at the same time ensure that all vaccines must satisfy the relevant requirements and procedures, including completion of phase 3 clinical trials and obtaining emergency use approval in accordance with the Regulation, with a view to ensuring safety, efficacy and quality of vaccines."