Government explains issues regarding regulation and monitoring of COVID-19 vaccines

In response to media enquiries regarding the regulation and monitoring of COVID-19 vaccines, the Government today (December 17) gave the following response:

"The Government strives to procure for the Hong Kong population COVID-19 vaccines fulfilling the criteria of safety, efficacy and quality. We will ensure that the relevant clinical research data of the relevant vaccine fulfil the safety and efficacy requirements scientifically after having been assessed by experts. The quality assurance of the vaccine must be well-supported in order for the vaccine to be approved for emergency use in Hong Kong. We are now conducting emergency legislative work for introducing COVID-19 vaccines proven to be safe and effective into Hong Kong. The proposed legislative framework will empower the Secretary for Food and Health, on the premise that the relevant vaccine has received the endorsement of one drug regulatory authority, in accordance with objective medical data of the individual vaccine, including making reference to the expert views of an independent expert advisory panel, to allow the relevant vaccine to be put to designated use in Hong Kong.

The Department of Health (DH) has an established mechanism to closely follow up on every report of adverse drug reaction (including vaccines) received. All along, DH has a pharmacovigilance system in place and conducts causality assessment on reports of Adverse Event Following Immunization (in particular serious adverse events) submitted by drug registration certificate holders and healthcare professionals to ascertain whether they are associated with the vaccination. DH also monitors the latest safety and efficacy assessment issued by drug regulatory authorities of advanced countries and jurisdictions and the references promulgated by the World Health Organization. If the benefits of the vaccine are considered to be outweighed by the risks, DH will take appropriate actions including referral of the relevant information to the Pharmacy and Poisons Board of Hong Kong for review and consideration on the necessity to suspend or revoke the drug registration of the vaccine. With regards to the possible adverse effect following immunisation of COVID-19 vaccines, DH will conduct monitoring based on the relevant requirements under the proposed emergency legislation for use of COVID-19 vaccines and make reference to the prevailing mechanism, while maintaining the same level of vigilance for control.

As regards the issue on legal liability for the emergency use of COVID-19 vaccines, the Government is reviewing international practices in the use of vaccines which are recently developed under the public health emergency situation, with a view to formulating an appropriate arrangement. Defining and clarifying the legal responsibility for the emergency use of COVID-19 vaccines will help Hong Kong obtain COVID-19 vaccines which fulfil

the requirements of safety and efficacy as soon as possible, but this does not mean that the drug manufacturer is immune from all relevant responsibilities with regards to the vaccine (including quality assurance etc.).

The Government will on one hand 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 by the drug regulatory authority of the local jurisdiction and Hong Kong pursuant to the emergency legislation under preparation, with a view to ensuring safety, efficacy and quality of vaccines."