Safety monitoring of COVID-19 vaccines

With the implementation of the COVID-19 Vaccination Programme, the Department of Health (DH) is closely monitoring the potential adverse events after COVID-19 vaccinations by enhancing the existing passive surveillance and conducting active surveillance.

The Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation) stipulates that it is necessary to put in place a mechanism for the monitoring of any adverse event occurring to the recipients associated with the administration of COVID-19 vaccines authorised for emergency use under the Government Vaccination Programme in Hong Kong.

Currently, the DH has established a pharmacovigilance system to receive and assess reports of adverse events following immunisations (AEFIs) submitted by healthcare professionals (for example, registered medical practitioners, nurses and pharmacists) and the pharmaceutical industry, in particular serious AEFIs, and conduct causality assessments to ascertain whether the adverse events were associated with the vaccinations.

For the COVID-19 Vaccination Programme, apart from requiring the authorisation applicant to report local AEFIs, the DH will keep in view and refer to the safety and efficacy assessment of the vaccines promulgated by the drug regulatory authorities of various countries and regions and the World Health Organization (WHO).

Besides publication of Vaccination Fact Sheets which list the expected side effects after vaccination and when it is necessary to seek the advice of healthcare professionals, the DH has made reference to the COVID-19 vaccines safety surveillance strategies recommended by the WHO to enhance the existing passive surveillance and conduct active surveillance. The surveillance measures include:

(i) A dedicated COVID-19 Vaccine Adverse Event Online Reporting system has been set up (www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html) to receive AEFI reports of COVID-19 vaccines from healthcare professionals and the pharmaceutical industry;

(ii) Letters to healthcare professionals and relevant organisations have been issued to encourage them to report suspected serious or unexpected AEFIs (www.drugoffice.gov.hk/eps/upload/eps_news/43289/EN/1/DHPL_Reporting%20of%20Adverse%20Event%20following%20Immunization%20(AEFI)%20of%20COVID-19%20Vaccine.pdf); and

(iii) For active surveillance, the DH has partnered with the Department of Pharmacology and Pharmacy of the University of Hong Kong to actively collect data of potential adverse events of authorised vaccines, in particular rare or serious adverse events of special interest (AESI) (e.g. Guillain Barre syndrome, acute disseminated encephalomyelitis) from public and private

healthcare facilities and conduct causality assessments. At the same time, comprehensive monitoring of all potential adverse events amongst the different authorised COVID-19 vaccines from selected target groups will also be conducted.

To tie in with the aforementioned surveillance measures, the DH has established the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation (Expert Committee) for continuous monitoring of potential clinical events (including AEFIs and AESIs) associated with COVID-19 vaccinations and provide expert opinions and advice on the safety monitoring of authorised vaccines. The Expert Committee has formulated the risk communication plan, which covers the monitoring, notification and follow up of reported clinical events. Follow up actions include safety alerts on the concerned vaccine to healthcare professionals, updates of product labels and product information, and instructing the vaccine supplier to conduct recalls, etc. If the risks of the authorised vaccine outweigh the benefits, the DH will take appropriate actions, which include providing the relevant information to the Advisory Panel established under the Regulation to review and consider whether to recommend the Secretary of Food and Health to revoke the authorisation of the concerned vaccine.

The Government is committed to closely monitor the potential serious clinical events after immunisation of COVID-19 vaccines and address public concerns for the protection of public health, and is expected to release and update the data collected on the designated website (www.covidvaccine.gov.hk) regularly starting from mid-March.