Updates on report of suspected serious adverse event with history of COVID-19 vaccination

The two COVID-19 vaccines authorized for emergency use in Hong Kong have been evaluated by the Advisory Panel on COVID-19 Vaccines, set up under the Prevention and Control of Disease (Use of Vaccines) Regulation, Cap. 599K, that they are safe, effective and of good quality. Current scientific evidence indicates that the benefits of the two COVID-19 vaccines outweigh their risks for use as active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus. The vaccines not only protect individuals from COVID-19 infection, available data also support that the vaccines could reduce the seriousness of the COVID-19 even if infected.

The Department of Health (DH) has put in place a pharmacovigilance system for COVID-19 immunisation, including receiving reports of Adverse Events Following Immunisation (AEFIs) related to the COVID-19 vaccines used in Hong Kong from healthcare professionals and pharmaceutical industries, and setting up the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation (Expert Committee) to provide independent assessment on the potential causal link between AEFIs and COVID-19 vaccination. The main purpose of the pharmacovigilance system is to detect potential signals of possible side effects of the vaccines.

According to the World Health Organization (WHO), an AEFI is any medical occurrence that follows immunisation and that does not necessarily have a causal relationship with the usage of the vaccine. The Expert Committee conducts causality assessments based on the WHO algorithm for suspected serious adverse events.

As endorsed by the Expert Committee, figures and summaries of clinical events received will be released and updated through the designated website biweekly. When a suspected adverse event fulfilling the reporting criteria of AEFIs involving a death case within 14 days of vaccination is received, it will be announced as soon as possible. When there are obvious medical causes (such as clinical diagnosis and pathological evidence) for certain clinical events including death cases, the healthcare professionals may consider the event not fulfilling the criteria for reporting as AEFIs. These cases would be monitored under the COVID-19 Vaccines Adverse Events Response and Evaluation Programme (CARE Programme) conducted by the University of Hong Kong in partnership with the DH.

As of April 25, 2021, a total of 11 737 persons were infected with COVID-19 and 209 died of the disease in Hong Kong. Separately, there were about 1 275 300 doses of COVID-19 vaccines administered and a total of 2 131 AEFI reports (0.17 per cent of all doses administered) were reported. A total of 14 death reports (0.001 per cent of all doses administered) with vaccination history within 14 days were received in the same period and none

of them had clinical evidence to support the events were caused by the vaccines.

As of 4pm today (May 2), the DH has received one death case reported as suspected serious adverse event with history of COVID-19 vaccination within 14 days from the Hospital Authority (HA) in the past 24 hours (please refer to Annex). The report did not provide clinical evidence to support that the event was caused by the vaccine. The DH has contacted the HA upon receiving the report to obtain further information to facilitate causality assessment. So far, there is no clinical evidence indicating that the event was caused by the vaccine. The HA will refer the case to the Coroner. Also, the DH will pass the case based on the established mechanism to the Expert Committee for conducting causality assessment.