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

The Department of Health (DH) has put in place a pharmacovigilance system for COVID-19 immunisations, 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 to provide independent assessment on the potential causal link between AEFIs and COVID-19 vaccination. The DH is also partnering with the University of Hong Kong to conduct an active surveillance programme for Adverse Events of Special Interest under the COVID-19 Vaccines Adverse Events Response and Evaluation Programme. 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 of May 9, a total of 11 808 persons had been infected with COVID-19 and 210 had died of the disease in Hong Kong. Separately, about 1.74 million doses of COVID-19 vaccines had been administered for members of the public in Hong Kong. Around 1.07 million people had received at least one dose of a vaccine, accounting for 16.3 per cent of the population aged 16 or above. In the same period, the DH received about 2 660 reports of adverse events (0.15 per cent of total vaccine doses administered), including 19 death cases with vaccination within 14 days before they passed away (0.0011 per cent of total vaccine doses administered). The Expert Committee concluded that four cases had no causal relationship with COVID-19 vaccination and preliminarily considered that 12 cases were not associated with vaccination, while three cases were pending assessment. The Expert Committee considered there is no unusual pattern identified so far, and it will continue to closely monitor the situation and further collect more data for assessment. An updated report (as at May 16) will be uploaded on May 21.

According to information from the Hospital Authority (HA), during the period from April 5 to May 2, the daily average figure for inpatient discharges and deaths due to acute stroke was 47.3, and the number of deaths due to acute stroke averaged 3.9 per day. In addition, in the same period, the ratio of death cases out of those without a vaccination record was 53.1 cases for every 100 000 people, whereas the ratio of death cases for those with a vaccination record was 2.3 cases for every 100 000 people. The overall death rate is similar to that recorded in the past three years. Out of those without a vaccination record, the ratio of death cases with acute stroke or

acute myocardial infarction was 2.7 cases for every 100 000 people, whereas the ratio of death cases under the same category for those with a vaccination record was 0.4 cases for every 100 000 people. Based on the statistical analysis of the above figures, there is no evidence that vaccination increases the risk of death for recipients.

As of 4pm today (May 17), the DH had received one death case reported as a suspected serious adverse event with history of COVID-19 vaccination within 14 days from the HA in the past 24 hours (please refer to the Annex). According to the report, the provisional cause of death was brainstem haemorrhage. The initial clinical assessment considered the event was not related to vaccination and the HA had referred the case to the Coroner. So far, there is no clinical evidence indicating that the event was caused by the vaccine. The DH will pass the case based on the established mechanism to the Expert Committee for conducting causality assessment.