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 (Expert Committee) to provide independent assessments on the potential causal link between AEFIs and COVID-19 vaccinations. 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 an 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 2, 2021, a total of 11,785 persons were infected with COVID-19, and 210 died of the disease in Hong Kong. Separately, there were about 1,491,900 doses of COVID-19 vaccines administered and a total of 2,402 AEFI reports (0.16 per cent of all doses administered) were reported. A total of 16 death reports (0.001 per cent of all doses administered) with a vaccination history within 14 days were received in the same period. The Expert Committee already concluded that four cases had no causal relationship with COVID-19 vaccinations, and the rest were preliminarily considered not associated with COVID-19 vaccinations.

As of 4pm today (May 6), the DH has received one death case reported as a suspected serious adverse event with a 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 a 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 a causality assessment.