Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation assesses serious adverse events relating to COVID-19 vaccination

The Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation (Expert Committee) convened a meeting today (May 4) to assess serious adverse events relating to COVID-19 vaccination.

The Department of Health (DH) has been closely monitoring possible adverse events following COVID-19 immunisation. Based on the guidelines of the World Health Organization (WHO), the DH enhanced the existing surveillance system and carried out active surveillance. Under the surveillance system, the DH monitors Adverse Events Following Immunisation (AEFIs) and encourages and receives from healthcare providers and pharmaceutical industry AEFI reports of COVID-19 immunisation in Hong Kong. The DH also partners with the University of Hong Kong (HKU) to conduct an active surveillance programme for Adverse Events of Special Interest under the COVID-19 Vaccines Adverse Events Response and Evaluation Programme (CARE Programme) for provision of data on the safety profile of the COVID-19 vaccines via big data analysis and scientific studies.

According to reporting criteria of AEFIs endorsed by the Expert Committee, when there are obvious medical causes (including clinical diagnosis and pathology reports) for certain clinical events including death cases, the healthcare professionals may consider the event not fulfilling the criteria for reporting as AEFIs. On the other hand, under the CARE Programme, the DH and the Hospital Authority (HA) have set up mechanism to refer death cases not fulfilling reporting criteria of AEFIs to HKU for surveillance and analysis. The HKU would provide regular reports to the Expert Committee; if unusual pattern is detected, the DH will be notified and the information will be referred to the Expert Committee for assessment as soon as possible. In addition, according to the risk communication plan endorsed by the Expert Committee, figures and summary of clinical events received will be released and updated through the designated website biweekly. When suspected adverse event fulfilling the reporting criteria of AEFIs involving death case within 14 days of vaccination is received, it will be announced as soon as possible. An updated report (as at May 2) will be uploaded on May 7.

Between April 19 and May 2, 2021, the DH had received eight death reports with history of COVID-19 immunisation from the HA and another Coroner’s case handled by public mortuary. These cases involved five males and four females aged from 43 to 76 years old. All the reports did not have clinical evidence to support the events were caused by vaccine. The Expert

Committee assessed these nine death cases in today's meeting (Annex). Four cases had history of COVID-19 vaccination more than 14 days before they passed away, the Expert Committee concluded that two of these cases had no causal relationship with COVID-19 vaccination based on the assessment and diagnosis made by the attending doctor(s), and preliminary considered that the other two were not associated with vaccination. For the other five cases with history of vaccination within 14 days, the Expert Committee preliminary considered them not associated with COVID-19 vaccination based on clinical information and preliminary autopsy findings.

In addition, the Expert Committee also concluded the causality assessment of two previous cases. The first case, first announced on March 7, involved an 80-year-old man who passed away on March 13. Full autopsy report indicated that the cause of death was acute myocardial infarction and ischaemic bowel, other investigation results did not reveal any possible immunological reactions due to vaccine. Based on the WHO algorithm, the Expert Committee concluded that there was no causal relationship between the deceased's outcome and COVID-19 vaccination. The second case, first announced on April 21, involved a 72-year-old man who passed away on April 16. Attending doctor(s) considered causes of death were haemodialysis catheter related sepsis and hyperkalaemia, and no clinical reason to suspect association with vaccine. The Expert Committee concluded that there was no causal relationship between the deceased’s outcome and COVID-19 vaccination.

According to the local mortality data, in the period between February 26 and May 2 of 2019, among people aged 40 or above, there were 684 deaths (i.e. 16 per 100 000 population) and 1,154 deaths (i.e. 27 per 100 000 population) due to ischaemic heart diseases and heart disease respectively. The Expert Committee reviewed these data and considered there is no unusual pattern identified so far. The Expert Committee will continue to closely monitor the situation and collect data for assessment.

Between April 19 and May 2, 2021, the DH had received 16 reports of suspected Bell's palsy with history of COVID-19 vaccination. These cases involved 10 males and six females between 20 and 87 years old. Seven of these cases received CoronaVac vaccine and nine received Comirnaty vaccine. The Expert Committee reviewed available clinical data of these cases and considered that three cases requiring further clinical information before the assessment could be concluded.

Bell's palsy (acute peripheral facial paralysis) is a common neurologic disorder. Majority of the patients will have complete recovery even without treatment and early use of a short course of treatment within 3 days of symptoms onset will further enhance the recovery rate. According to the preliminary information collected by the HKU from HA, for people of 16-year-old or above, there were on average 65.7 new cases of Bell's palsy recorded in the period from April 19 to May 2 of 2018, 2019 and 2020.

The two COVID-19 vaccines authorised for use in Hong Kong have been rigorously evaluated by the Advisory Panel on COVID-19 Vaccines established 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. The surveillance system put in place by the DH aims at identifying potential signals that may indicate association between unknown adverse events and the vaccines. If a signal is identified and confirmed, appropriate regulatory measures would be instituted.