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 (April 21) 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 results) for certain clinical events including death cases, the healthcare professionals may consider the event not fulfilling the reporting criteria of 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. When suspected adverse event fulfilling the reporting criteria of AEFIs involving death case within 14 days of vaccination is received, it will be announced via press release as soon as possible. An updated report (as at April 18) will be uploaded on April 23.

Between April 5 and April 18, 2021, the DH had received four death reports with history of COVID-19 immunisation from the HA. These cases involved four males aged from 54 to 92 years old. All had history of COVID-19 vaccination more than 14 days before passed away and the reports did not have clinical evidence to support the events were caused by vaccine. The Expert

Committee assessed these four death cases in today's meeting. The first case involved a 92-year-old man who had hypertension, ischaemic heart disease, atrial flutter, ischaemic stroke, hyperlipidaemia and renal impairment. He passed away on April 5 and he received a dose of CoronaVac 18 days before his death (i.e. March 18). Based on the preliminary autopsy findings of left haemothorax and ruptured dissecting aneurysm of aorta, the Expert Committee considered there was no evidence indicating association between the deceased's outcome and vaccination. The second case involved a 58-year-old man who was a chronic smoker. He passed away on April 8 and he received a dose of CoronaVac 23 days before his death (i.e. March 16). Based on the preliminary autopsy findings of coronary artery disease, the Expert Committee considered that there was no evidence indicating association between the deceased's outcome and vaccination. The third case involved a 72-year-old man who had history of chronic renal failure on regular haemodialysis. During a haemodialysis visit at the hospital on April 16, he suddenly developed cardiac arrest and passed away. He received a dose of CoronaVac 23 days before his death (i.e. March 24). Provisional causes of death were haemodialysis catheter related sepsis and hyperkalaemia. There was no evidence indicating association with vaccination. The last case involved a 54-year-old man who was a smoker. He passed away on April 18 and he received a dose of CoronaVac 16 days before his death (i.e. April 2). Based on the preliminary autopsy findings of hypertensive heart disease, the Expert Committee considered that there was no evidence indicating association between the deceased's outcome and vaccination, and would require full autopsy report to conclude the causality assessment.

According to the local mortality data, in the period between February 26 and April 18 of 2019, among people aged 55 or above, there were 573 deaths (i.e. 22.5 per 100 000 population) and 964 deaths (i.e. 37.9 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 5 and April 18, 2021, the DH had received 20 reports of suspected Bell's palsy with history of COVID-19 immunisation. These cases involved 9 males and 11 females between 31 and 71 years old. Twelve of these cases received CoronaVac vaccine and eight received Comirnaty vaccine. The Expert Committee has reviewed available clinical data of these cases, it was considered that three cases were not Bell's palsy and further clinical information was required for three cases 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 56 new cases of Bell's palsy recorded in the period from April 5 to April 18 of 2018, 2019 and 2020.

In addition, the Expert Committee conducted causality assessment of other clinical events including the reports of two pregnant women. The two women, both aged 32, received treatment in the HA due to miscarriage and fetal death respectively. The cases were reported as AEFI because of their history of COVID-19 immunisation. After reviewing the relevant clinical information and pathology results, the Expert Committee concluded that there was no evidence indicating association with vaccination and noted that the concerned hospital would further investigate the cause of the fetal death.

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 causal association between unknown adverse events and the vaccines. If a signal is identified and confirmed, appropriate regulatory measures would be instituted.