

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 7) 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. 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).

According to reporting criteria of AEFIs endorsed by the Expert Committee, when there are obvious medical causes (including clinical diagnosis and pathological evidence) 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 4) will be uploaded on April 9.

Up to April 4, the DH had received a total of 15 death case reports with history of COVID-19 immunisation from the HA. These cases involved 11 males and four females between 55 and 80 years old. Existing information indicates that most of these cases died of cardiovascular diseases. The Expert Committee conducted causality assessment of individual cases based on the

algorithm of the WHO and all available information, including the medical conditions and history of the patient with relevant clinical data, vaccine information and preliminary autopsy findings. The Expert Committee has already concluded three of these reports that there was no causal relationship between the deceased's outcome and COVID-19 vaccination. The medical history and/or preliminary autopsy findings of 11 cases showed that the outcomes of the deceased persons were not directly associated with COVID-19 vaccination and the remaining case had history of vaccination 25 days before passed away. Their assessment will be concluded when necessary information is available.

The Expert Committee assessed three of the above 15 cases in today's meeting. The first case, announced on March 11, involved a 67-year-old man who passed away on March 13. The full autopsy report indicated that the patient died of acute myocardial infarction due to coronary atherosclerosis, other investigation results did not reveal any possible immunological reactions due to vaccine. Based on the WHO algorithm, the Expert Committee considered that the causality of the deceased's outcome with COVID-19 vaccination was inconsistent (i.e. no causal relationship). The second case involved a 68-year-old woman who had hypertension, hypothyroidism and lipid disorder. She passed away on March 29 and she received a dose of CoronaVac 26 days before her death (i.e. March 3). Based on the preliminary autopsy findings of acute myocardial infarction, the Expert Committee considered that the deceased's outcome was not directly associated with COVID-19 vaccination. The last case involved a 62-year-old man with history of newly diagnosed hypertension. He passed away on April 2 and he received a dose of CoronaVac 25 days prior to his death (i.e. March 8). The causality assessment will be conducted when preliminary autopsy findings is available.

According to the local mortality data, in the same period (i.e. February 26 to April 4) of 2019, among people aged 55 or above, there were 438 deaths (i.e. 17.2 per 100 000 population) and 716 deaths (28.1 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 more data for further assessment.