

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 (March 30) 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 immunization. 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 Immunization (AEFIs) and encourages and receives from healthcare providers and pharmaceutical industry AEFI reports of COVID-19 immunization. The DH also partners with the University of Hong Kong (HKU) to conduct an active surveillance programme for Adverse Events of Special Interest (AESI) 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 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 involving death case within 14 days of vaccination is received, it will be announced via press release as soon as possible.

Up to March 28, the DH had received a total of 13 death case reports with history of COVID-19 immunization from the HA. These cases involved 9 males and 4 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 two of these reports that there was no causal relationship between the deceased's outcome and COVID-19 vaccination. The medical history and preliminary autopsy findings of other cases showed that the outcomes of the deceased persons were not directly associated with COVID-19 vaccination. Their assessment will be concluded when necessary information is available.

The Expert Committee assessed six of the above 13 cases in today's meeting. The first case, announced on March 6, involved a 55-year-old lady who passed away on the same day. The full autopsy report indicated that the patient died of acute myocardial infarction due to aortic dissection, 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). Four other cases involved four gentlemen, aged 59 to 66 years old. Their preliminary autopsy findings were coronary artery disease, ruptured myocardial infarction and coronary thrombosis, coronary and hypertensive heart disease, as well as coronary artery disease with acute ischaemia. Together with the remaining case who died of acute myocardial infarction, the Expert Committee considered that the outcomes of the deceased persons were not directly associated with COVID-19 vaccination.

According to the local mortality data, in the same period (i.e. February 26 to March 28) of 2019, among people aged 55 or above, there were 362 deaths (i.e. 14.2 per 100 000 population) and 602 deaths (23.7 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.