

# 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, set up under the Department of Health (DH) to provide independent assessment on the potential causal link between Adverse Events Following Immunisation (AEFIs) and COVID-19 vaccination, convened a meeting today (July 5) to assess serious adverse events relating to COVID-19 vaccination.

According to the World Health Organization, an AEFI is any medical occurrence that follows immunisation and that does not necessarily have a causal relationship with the usage of the vaccine. The DH has put in place a pharmacovigilance system for COVID-19 immunisation, and is partnering with the University of Hong Kong to conduct an active surveillance programme for Adverse Events of Special Interest under the COVID-19 Vaccines Adverse Events Response and Evaluation Programme. The main purpose of the pharmacovigilance system is to detect potential signals of possible side effects of the vaccines.

As of June 30, a total of 11 928 persons had been infected with COVID-19 in Hong Kong, of which 211 had died of the disease. Separately, about 3.729 million doses of COVID-19 vaccines had been administered for members of the public in Hong Kong. Around 2.249 million people had received at least one vaccine dose. In the same period, the DH received about 4 010 reports of adverse events (0.11 per cent of total vaccine doses administered), including 23 death cases (Note) with vaccination within 14 days before they passed away (0.0006 per cent of total vaccine doses administered).

As at July 5, the Expert Committee had assessed the 23 death cases and concluded that 13 death cases had no causal relationship with vaccination, and preliminarily considered that 10 cases were not associated with vaccination. The Expert Committee considered there is no unusual pattern identified so far, and it will continue to closely monitor the situation and collect data for assessment.

According to the local mortality data, in the period between February 26 and June 30 of 2019, among people aged 40 or above, there were 1 248 deaths (i.e. 29.2 per 100 000 population) and 2 089 deaths (i.e. 48.9 per 100 000 population) due to ischaemic heart diseases and heart disease respectively. In addition, according to information by the Hospital Authority (HA), during the period from May 31 to June 27 of 2021, the ratio of death cases out of those without a vaccination record was 63.2 cases for every 100 000 people,

whereas the ratio of death cases for those with a vaccination record was 3.2 cases for every 100 000 people. The overall death rate is similar to that recorded in the past three years. Based on the statistical analysis of the above figures, there is no evidence that vaccination increases the risk of death for recipients.

For the serious or unexpected AEFI cases (e.g. Bell's palsy), the Expert Committee has reviewed available clinical data and information for conducting causality assessment. The results will be included in the updated safety monitoring report (as at June 30) to be published at the Government's designated website on July 9. In addition, information related to AEFIs of COVID-19 vaccines and relevant statistics will also be released in the weekly "Update on monitoring COVID-19 vaccination" press release and the Government's designated website regularly. In the meeting, the Expert Committee also endorsed the updated list of serious or unexpected AEFIs to include pericarditis, myocarditis and thrombosis with thrombocytopenia syndrome with effect from today for close monitoring of any potential safety signals associated with the vaccines.

Note: Between May 31 and June 30, 2021, the DH received two death reports with vaccination within 14 days before passing away, involving respectively a 40-year-old male and a 41-year-old male who had received the Sinovac vaccine. There is no clinical evidence that the two events arose from vaccination. Based on the clinical information and the preliminary autopsy findings of acute myocardial infarction and ischaemic heart disease respectively, the Expert Committee preliminarily considered that the two cases were not associated with vaccination.