

# 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 (January 4) 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 (AESIs) 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 December 31, 2021, a total of 12 650 persons had been infected with COVID-19 in Hong Kong, of which 213 died. Separately, about 9.93 million doses of COVID-19 vaccines had been administered for members of the public in Hong Kong. Around 4.88 million people had received at least one vaccine dose. In the same period, the DH received 6 621 reports of adverse events (0.07 per cent of total vaccine doses administered), including 53 death cases with vaccination within 14 days before they passed away (0.0005 per cent of total vaccine doses administered).

So far, the Expert Committee had assessed the 53 death cases and concluded that 38 death cases had no causal relationship with vaccination, and preliminarily considered that 15 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 December 31 of 2020, among people aged 30 or above, there were 5 573 deaths (i.e. 101.8 per 100 000 population) and 3 292 deaths (i.e. 60.2 per 100 000 population) due to ischaemic heart diseases and heart disease respectively. In addition, according to information by the Hospital Authority, during the period from November 29 to December 26 of 2021, the ratio of death cases out of those without a vaccination record was 138.3

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

The Expert Committee has also reviewed available clinical data and information for conducting causality assessment of other serious or unexpected AEFIs and AESIs. The results will be included in the updated safety monitoring report (as at December 31, 2021) to be published on the Government's designated website on January 7. 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.