

# 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 (September 1) 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 (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). The main purpose of the pharmacovigilance system is to detect potential signals of possible side effects of the vaccines.

As of August 31, a total of 12 113 persons had been infected with COVID-19 in Hong Kong, of which 212 had died of the disease. Separately, about 7.59 million doses of COVID-19 vaccines had been administered for members of the public in Hong Kong. Around 4.14 million people had received at least one vaccine dose. In the same period, the DH received 5 579 reports of adverse events (0.07 per cent of total vaccine doses administered)(Note), including 38 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 38 death cases and concluded that 19 death cases had no causal relationship with vaccination, and preliminarily considered that 19 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 August 31 of 2019, among people aged 30 or above, there were 1 893 deaths (i.e. 34.8 per 100 000 population) and 3 122 deaths (i.e. 57.4 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 August 2 to August 29 of 2021, the ratio of death cases out of those without a vaccination record was 6.3 cases for every 100 000 people,

whereas the ratio of death cases for those with a vaccination record was 3.4 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.

In August 2021, the DH had received 40 reports of suspected myocarditis or pericarditis with vaccination within 14 days before onset of symptoms. Among these, 38 cases had received Comirnaty vaccine, involving 32 males and six females between 12 and 43 years old. The remaining 2 cases received CoronaVac vaccine involving two females aged 58 and 63 respectively. In addition, there were six reports of suspected myocarditis with vaccination history of more than 14 days involving five males and one female between 15 and 74 years old; all received Comirnaty vaccine. These cases will be referred to the HKU for analysis under the CARE Programme.

Myocarditis and pericarditis refer to the inflammation of the heart muscle and the inflammation of the tissue surrounding the heart respectively. While most affected cases will respond well to treatment and can usually return to their normal daily activities after their symptoms improved, the Expert Committee noted that there were reports, from overseas and local, involving suspected myocarditis or pericarditis with serious outcomes also had history of Comirnaty vaccination. As the Expert Committee has considered that further investigations of cases with serious outcomes are required, the association between these events and vaccination is yet to be established. Members of the public should avoid strenuous exercise one week after Comirnaty vaccination. They should also seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as acute and persisting chest pain, shortness of breath, or palpitations following vaccination. The Expert Committee would closely monitor the situation.

The Expert Committee has also reviewed available clinical data and information for conducting causality assessment of other serious or unexpected AEFIs. The results will be included in the updated safety monitoring report (as at August 31) to be published at the Government's designated website on September 3. 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.

Note: Provisional figures.