

# 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 (June 1) to assess serious adverse events relating to COVID-19 vaccination.

The Department of Health (DH) has put in place a pharmacovigilance system for COVID-19 immunisations, including receiving reports of Adverse Events Following Immunisation (AEFIs) related to the COVID-19 vaccines used in Hong Kong from healthcare professionals and pharmaceutical industries, and setting up the Expert Committee to provide independent assessment on the potential causal link between AEFIs and COVID-19 vaccination. The DH is also 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.

According to the World Health Organization (WHO), an AEFI is any medical occurrence that follows immunisation and that does not necessarily have a causal relationship with the usage of the vaccine. As endorsed by the Expert Committee, when there are obvious medical causes for certain clinical events including death cases or the events have exceeded the reporting time frame, the healthcare professionals may consider the events not fulfilling the criteria for reporting as AEFIs. On the other hand, under the CARE Programme, death cases not fulfilling reporting criteria of AEFIs are referred to HKU for surveillance and analysis.

With reference to the experience since the commencement of the COVID-19 Vaccination Programme, the Expert Committee reviewed the risk communication plan on clinical events following immunisation. Starting from July 2021, a monthly report on safety monitoring of COVID-19 vaccines will be published in the Government's designated website and relevant statistics will be released through the website regularly. As endorsed by the Expert Committee, with immediate effect, public announcement on individual death cases would only be made if potential association with the vaccination is detected.

Between May 17 and May 30, 2021, the DH had received one death report fulfilling the criteria for reporting as serious AEFIs from the Hospital Authority (HA). This case involved a 44-year-old female announced on May 21. Based on the clinical information and the preliminary autopsy findings of

ischaemic heart disease, the Expert Committee preliminarily considered that the case was not associated with vaccination.

As of May 30, a total of 11,838 persons had been infected with COVID-19 and 210 had died of the disease in Hong Kong. Separately, about 2.364 million doses of COVID-19 vaccines had been administered for members of the public in Hong Kong. Around 1.359 million people had received at least one dose of a vaccine. In the same period, the DH received about 3289 reports of adverse events (0.14 per cent of total vaccine doses administered), including 21 death cases with vaccination within 14 days before they passed away and fulfilling the criteria for reporting as serious AEFI (0.0009 per cent of total vaccine doses administered) . So far, there is no case identified as having causal relationship with the COVID-19 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 May 30 of 2019, among people aged 40 or above, there were 957 deaths (i.e. 22.4 per 100 000 population) and 1,635 deaths (i.e. 38.3 per 100 000 population) due to ischaemic heart diseases and heart disease respectively. In addition, according to information by the HA, during the period from April 26 to May 23 of 2021, the ratio of death cases out of those without a vaccination record was 54 cases for every 100 000 people, whereas the ratio of death cases for those with a vaccination record was 2.9 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.

Between May 17 and May 30, 2021, the DH had received 14 reports of suspected Bell's palsy with history of COVID-19 vaccination. These cases involved 10 males and four females between 27 and 76 years old. Four of these cases received CoronaVac vaccine and 10 received Comirnaty vaccine. The Expert Committee reviewed available clinical data of these cases and considered that eight cases required further clinical information before the assessment could be concluded. In addition, the HKU has reported the progress of the CARE Programme on Bell's palsy to the Expert Committee.

Bell's palsy (acute peripheral facial paralysis) is a common neurologic disorder. Majority of the patients will have complete recovery even without treatment and early use of a short course of treatment within 3 days of symptoms onset will further enhance the recovery rate. According to the preliminary information collected by the HKU from HA, for people of 16 years old or above, there were on average 72.3 new cases of Bell's palsy recorded in the period from May 17 to May 30 of 2018, 2019 and 2020.

The two COVID-19 vaccines authorised for use in Hong Kong have been rigorously evaluated by the Advisory Panel on COVID-19 Vaccines established under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) that they are safe, effective and of good quality. Current

scientific evidence indicates that the benefits of the two COVID-19 vaccines outweigh their risks for use as active immunisation to prevent COVID-19. The surveillance system put in place by the DH aims at identifying potential signals that may indicate association between unknown adverse events and the vaccines. If a signal is identified and confirmed, appropriate regulatory measures would be instituted. The updated COVID-19 vaccines safety monitoring report (as at May 30) will be uploaded on June 4.