

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 (May 18) 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. 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 biweekly. When suspected adverse event fulfilling the reporting criteria of AEFIs involving death case within 14 days of vaccination is received, it will be announced as soon as possible. An updated report (as at May 16) will be uploaded on May 21.

Between May 3 and May 16, 2021, the DH had received four death reports with history of COVID-19 immunisation within 14 days from the Hospital Authority (HA). These cases involved three males and one female aged from 46 to 61 years old (Annex). All the reports did not have clinical evidence to support the events were caused by vaccine. The Expert Committee assessed these four death cases in today's meeting and preliminarily considered that the cases were not associated with vaccination. In addition, the DH had also

received two death reports with history of COVID-19 immunisation more than 14 days. Both cases exceeded the reporting timeframe for AEFI and would be referred to HKU for analysis under the CARE Programme. Based on autopsy findings, the Expert Committee concluded that they were not associated with vaccination.

As of May 16, a total of 11 825 persons had been infected with COVID-19 and 210 had died of the disease in Hong Kong. Separately, about 1.96 million doses of COVID-19 vaccines had been administered for members of the public in Hong Kong. Around 1.16 million people had received at least one dose of a vaccine. In the same period, the DH received about 2 890 reports of adverse events (0.15 per cent of total vaccine doses administered), including 20 death cases with vaccination within 14 days before they passed away (0.001 per cent of total vaccine doses administered). The Expert Committee concluded that five cases had no causal relationship with COVID-19 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 further collect more data for assessment.

According to the local mortality data, in the period between February 26 and May 16 of 2019, among people aged 40 or above, there were 820 deaths (i.e. 19.2 per 100 000 population) and 1 400 deaths (i.e. 32.8 per 100 000 population) due to ischaemic heart diseases and heart disease respectively. In addition, according to information from the HA, during the period from April 12 to May 9 of 2021, the ratio of death cases out of those without a vaccination record was 54.1 cases for every 100 000 people, whereas the ratio of death cases for those with a vaccination record was 2.6 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 3 and May 16, 2021, the DH had received 20 reports of suspected Bell's palsy with history of COVID-19 vaccination. These cases involved 10 males and 10 females between 24 and 80 years old. Six of these cases received CoronaVac vaccine and 14 received Comirnaty vaccine. The Expert Committee reviewed available clinical data of these cases and considered that 11 cases required further clinical information before the assessment could be concluded.

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-year-old or above, there were on average 64.3 new cases of Bell's palsy recorded in the period from May 3 to May 16 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.