

# 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 in Hong Kong, convened a meeting today (September 30) 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 (AESI) 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 September 25, a total of 945 643 cases had tested positive for the SARS-CoV-2 virus by nucleic acid tests and 803 891 positive cases through rapid antigen tests in Hong Kong, of which 10 128 died. Separately, about 19.34 million doses of COVID-19 vaccines had been administered for members of the public in Hong Kong. Around 6.86 million people had received at least one vaccine dose. In the same period, the DH received 7 945 reports of adverse events (0.04 per cent of the total vaccine doses administered), including 120 death cases with vaccination within 14 days before they passed away (0.0006 per cent of the total vaccine doses administered).

So far, the Expert Committee has assessed these 120 death cases and concluded that 111 death cases had no causal relationship with vaccination, one case of which causal relationship with vaccination could not be established, preliminarily considered that four cases were not associated with vaccination, and four cases pending further information for assessment. 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, among people aged 30 or above, there were 3 856 deaths (i.e. 70.5 per 100 000 population) and 6 546 deaths (i.e. 119.6 per 100 000 population) due to ischaemic heart diseases and heart disease respectively in 2020. In addition, according to information from the

Hospital Authority, during the period from August 29 to September 25 of 2022, the overall ratio of death cases was 48.3 cases for every 100 000 people, whereas the average ratio of death cases for the same period in 2018 to 2020 was 42.0 cases for every 100 000 people. 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 September 30) to be published at the Government's designated website on October 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.