

Lists of adverse events following immunization (AEFI) and adverse events of special interests (AESI) for COVID-19 vaccines

Two COVID-19 vaccines are currently authorized for use in Hong Kong have been rigorously evaluated by the Advisory Panel on COVID-19 Vaccines (“Advisory Panel”) established under the Prevention and Control of Disease (Use of Vaccines) Regulation, Cap. 599K (“the Regulation”) 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 immunization to prevent COVID-19 caused by SARS-CoV-2 virus. The vaccines not only protect individuals from COVID-19 infection, available data also support that the vaccines could reduce the seriousness of the COVID-19 even if infected.

The rapid development of COVID-19 vaccines may require close monitoring to ensure the safety and to identify potential signals that may indicate causal association between previously unknown adverse events and the vaccines. Therefore, the Department of Health (“DH”) has put in place a pharmacovigilance system for COVID-19 vaccination, including receiving reports of Adverse Events Following Immunization (“AEFIs”) related to the COVID-19 vaccines used in Hong Kong from healthcare professionals and pharmaceutical industries. **According to World Health Organization (“WHO”), AEFIs refer to any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The main purpose of the pharmacovigilance system is to detect signals of possible side effects of the vaccines.**

Pursuant to the requirements of the Regulation to monitor any adverse event that occurs to the recipient associated with the administration of the relevant vaccine, the Director of Health appointed the Expert Committee on Clinical Events Assessment Following COVID-19 Immunization (“Expert Committee”) to provide independent assessment of potential causal link between AEFIs and COVID-19 vaccines used in Hong Kong and to provide expert advice to the Government on safety-related matters.

Healthcare professionals are encouraged to report 16 items of serious or unexpected AEFIs (full list of AEFIs at Table 1) for close monitoring of the safety of the vaccines.

Table 1: List of Serious or Unexpected Adverse Events Following Immunization (AEFI) of COVID-19 Vaccines

1.	Acute peripheral facial paralysis (Bell’s Palsy)
2.	Anaphylactoid reaction
3.	Anaphylaxis
4.	Any other severe and unusual events that are thought by health workers or the public to be related to immunization
5.	Death <i>when associated with COVID-19 vaccine adverse event</i>
6.	Disability <i>when associated with COVID-19 vaccine</i>
7.	Encephalomyelitis
8.	Encephalopathy
9.	Guillain Barre Syndrome
10.	Hospitalization <i>when associated with COVID-19 vaccine adverse event</i>
11.	Myocarditis / Pericarditis
12.	Sepsis
13.	Septicaemia
14.	Thrombocytopenia / Thrombosis with thrombocytopenia syndrome (TTS)
15.	Toxic shock syndrome
16.	Transverse myelitis

Upon receipt of reports of serious or unexpected AEFIs, the DH will contact the healthcare professionals whom reported the AEFI for further information. According to the established mechanism, all the important cases will be considered by the Expert committee while all other serious or unexpected AEFI cases will be assessed by DH based on the causality assessment algorithm of the WHO¹. **The ultimate goal of causality assessment is to detect signals of possible side effects of the vaccines.**

¹ WHO Causality assessment of an adverse event following immunization (AEFI) ([CausalityAssessmentAEFI_EN.pdf \(who.int\)](#))

The DH also partners with the University of Hong Kong (“HKU”) to conduct an active surveillance programme for Adverse Events of Special Interest (“AESIs”) related to COVID-19 vaccines, i.e. the COVID-19 vaccines Adverse events Response and Evaluation Programme (CARE Programme). **According to the WHO, AESI is a pre-identified and predefined medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further specific studies; these events may not have causal relationship with vaccination** (full list of AESIs at Table 2).

Table 2: List of Adverse Events of Special Interest (AESI) of COVID-19 Vaccines

1.	(Idiopathic) Thrombocytopenia	24.	Heart failure
2.	Acute aseptic arthritis	25.	Major congenital anomalies
3.	Acute cardiovascular injury	26.	Maternal death
4.	Acute disseminated encephalomyelitis (ADEM)	27.	Meningoencephalitis
5.	Acute kidney injury	28.	Microangiopathy
6.	Acute liver injury	29.	Microcephaly
7.	Acute pancreatitis	30.	Multisystem inflammatory syndrome in children
8.	Acute respiratory distress syndrome	31.	Myocarditis
9.	Anaphylaxis	32.	Narcolepsy
10.	Anosmia, ageusia	33.	Neonatal death
11.	Arrhythmia	34.	Preeclampsia
12.	Bell’s Palsy (Acute peripheral facial paralysis)	35.	Preterm birth
13.	Chilblain – like lesions	36.	Rhabdomyolysis
14.	Coagulation disorders	37.	Single Organ Cutaneous Vasculitis
15.	Coronary artery disease	38.	Spontaneous abortions
16.	COVID-19 disease (by levels of severity):	39.	Stillbirth

	<p>Level 1: hospitalization for COVID-19 (confirmed or suspected),</p> <p>Level 2: ICU admission in those with COVID-19 related admission;</p> <p>Level 3: Acute respiratory distress requiring ventilation (ARDS) during a hospitalization for COVID-19;</p> <p>Level 4 death during a hospitalization for COVID-19 (any cause)</p>		
17.	Death (any causes)	40.	Stress cardiomyopathy
18.	Erythema multiforme	41.	Subacute thyroiditis
19.	Fetal growth restriction	42.	Sudden death
20.	Generalized convulsion	43.	Termination of Pregnancy for Fetal Anomaly
21.	Gestational Diabetes	44.	Thromboembolism
22.	Guillain-Barré Syndrome	45.	Transverse myelitis
23.	Haemorrhagic disease	46.	Type 1 Diabetes

Through big-data analysis and scientific studies designed when indicated, the CARE Programme would provide more data on the safety profile of the COVID-19 vaccines².

The lists of AEFIs and AESIs serve as a scope of safety monitoring of the COVID-19 vaccines, they are not the lists of adverse effects of the vaccines³. For more

² Further information about the CARE Programme is available at <https://www.hkcare.hku.hk/copy-of-care-programme>.

³ Lists of adverse events of the two COVID-19 vaccines, i.e. CoronaVac and Comirnaty are provided under the respective Fact Sheets. CoronaVac ([COVID19VaccinationFactSheet_CoronaVac_ENG.pdf \(covidvaccine.gov.hk\)](#)) and Comirnaty ([COVID19VaccinationFactSheet_Comirnaty_ENG.pdf \(covidvaccine.gov.hk\)](#)).

information about the safety monitoring of COVID-19 Vaccines, please refer to the “Report on Safety Monitoring of COVID-19 Vaccines in Hong Kong”⁴.

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⁴ Report on Safety Monitoring of COVID-19 Vaccines in Hong Kong
([Safety Monitoring of COVID-19 Vaccines in Hong Kong.pdf \(drugoffice.gov.hk\)](#))