

Government announces ending emergency use regime for COVID-19 vaccines as planned and cessation arrangement of accepting Indemnity Fund applications by late December

Subsequent to the resumption of normalcy in Hong Kong after the COVID-19 epidemic, COVID-19 is now being managed as a type of upper respiratory tract illness. The Government announced today (December 18) that the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K), which is the public health emergency regulation on the emergency use of COVID-19 vaccines and also the only remaining effective regulation among the various public health emergency regulations under the Prevention and Control of Disease Ordinance (Cap. 599) enacted by the Government during the epidemic, will expire at midnight on December 23. The expiry implies the end of emergency use regime for COVID-19 vaccines.

The Government enacted Cap. 599K on December 23, 2020, to authorise the emergency use of COVID-19 vaccines developed and tested within a short period of time and with evidence proving their safety and efficacy; and to enable the on-going monitoring of data concerning the safety, quality and efficacy of vaccines during the emergency use so as to support the eventual transition of emergency approval to registration in accordance with the Pharmacy and Poisons Regulations (Cap. 138A). To date, sufficient scientific evidence and safety data are in place to indicate that the benefits of COVID-19 vaccines outweigh the risks. The vaccines not only protect individuals from COVID-19 infection but also reduce the seriousness of the condition of infected persons who have received vaccination. Currently, there are COVID-19 vaccines fulfilling safety, efficacy and quality requirements registered under the Pharmacy and Poisons Regulations (Cap. 138A). As such, COVID-19 vaccines will be arranged for use in Hong Kong under the regular regulatory system for pharmaceutical products, and the Advisory Panel on COVID-19 Vaccines set up in accordance with Cap. 599K, will be disbanded at the same time. The Government is earnestly thankful to the experts for their objective and expert advice which were conducive to bringing Hong Kong back to normalcy.

The Indemnity Fund for Adverse Events Following Immunization with Coronavirus Disease-2019 Vaccines (AEFI Fund) was established in February 2021 to provide instant financial support to eligible individuals who have proof of suffering from unexpected serious adverse events (SAEs) associated with COVID-19 vaccines administered under the government vaccination programme. Following the cessation of the arrangement for emergency use of COVID-19 vaccines by midnight on December 23 and the normal use of COVID-19 vaccines in Hong Kong under the regular regulatory system for pharmaceutical products, the AEFI Fund arrangement will end at the same time. The AEFI Fund

will cease accepting new applications involving COVID-19 vaccines administered on or after December 24. In other words, cases involving COVID-19 vaccines administered at or after midnight on December 23 will be ineligible to apply for the AEFI Fund. A spokesman of the Health Bureau emphasised that the AEFI Fund is an administrative arrangement. Ending such an arrangement will not affect the right of relevant individuals in seeking legal recourse for damages or losses against the vaccine manufacturer. Affected individuals can still undertake civil action for claims against any person responsible for their bodily injury.

For vaccines administered under the Government's COVID-19 Vaccination Programme on or before December 23, 2023, individuals holding proof of suffering from the SAEs certified by a Registered Medical Practitioner are still eligible to apply for the AEFI Fund within two years after receiving the last dose of COVID-19 vaccine under the government vaccination programme. For details and the documents required for submitting an application, citizens may refer to the website (www.axa.com.hk/en/aefi-fund) or call the hotline at 2894 4699. The hotline is manned from 9am to 5.30pm from Monday to Friday (except public holidays).

During the epidemic, the Government had enacted a number of other public health emergency regulations (viz. Cap. 599C to Cap. 599J and Cap. 599L) under the Prevention and Control of Disease Ordinance (Cap. 599). Those regulations have expired and been invalidated in early to mid-2023 respectively.