

SFH authorises COVID-19 vaccine by Fosun Pharma/BioNTech for emergency use in Hong Kong

The Secretary for Food and Health (SFH) authorised today (January 25) the COVID-19 vaccine by Fosun Pharma/BioNTech (i.e. Comirnaty COVID-19 mRNA Vaccine (BNT162b2) Concentrate for Dispersion for Injection) for emergency use in Hong Kong in accordance with the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation).

According to the Regulation, SFH may, with reference to the advice of the Advisory Panel on COVID-19 Vaccines (Advisory Panel), authorise the use of COVID-19 vaccines which fulfil the criteria of safety, efficacy and quality for specified use in Hong Kong under emergency situation, which is basically for vaccination programmes led by the Government. The Advisory Panel has submitted its recommendations to SFH. It considers that, under the current epidemic situation, the benefits of authorising the use of the COVID-19 vaccine by Fosun Pharma/BioNTech for protecting against COVID-19 outweigh the risks.

Having regard to the advice of the Advisory Panel and having considered the threat to public health posed by COVID-19, SFH considers that the authorisation is necessary and is in the public interest. SFH has exercised the powers conferred upon her under section 3 of the Regulation to authorise the use of the COVID-19 vaccine by Fosun Pharma/BioNTech in Hong Kong for a specified purpose. The relevant authorisation will take effect from January 25, 2021. To ensure that the relevant vaccine continues to fulfil the requirements of safety, efficacy and quality, SFH has attached conditions to the aforesaid authorisation, including requiring the applicant to continue providing the latest clinical data on the vaccine, safety update reports, and quality certification documents by the drug manufacturer for each batch of vaccines, etc.

The Advisory Panel also noted reports of suspected adverse events in some overseas countries after administration of the Fosun Pharma/BioNTech vaccine. According to the information released by the relevant authorities, some common side effects of the vaccines, such as fever or nausea, may affect individuals who already have serious illnesses and are particularly weak. In response to the recommendations of the Advisory Panel, the Department of Health (DH) has requested the vaccine supplier to provide the relevant information. The Joint Scientific Committees under the Centre for Health Protection will review the relevant information in order to assist with determining the precautions for use by priority groups for receiving the relevant vaccine. With a view to strengthening the transparency of information regarding vaccines, the expert advice on vaccines given by the Advisory Panel has been uploaded to the website of the Food and Health Bureau. (www.fhb.gov.hk/en/our_work/health/rr3.html)

According to the information provided by the vaccine supplier, the first batch of 1 million doses of the Fosun Pharma/BioNTech vaccine to be supplied to Hong Kong have completed production and are undergoing safety and quality testing. Subject to the completion and passing of the relevant tests, the relevant vaccines are expected to arrive Hong Kong from Germany in late February. The territory-wide vaccination programme led by the Government will be launched as soon as possible after completing all necessary quality assurance procedures. The Government will continue to actively follow up on the emergency use authorisation and supply schedule of the remaining vaccines already purchased and make preparations for the arrangements for administration of the relevant vaccines. The Government will also continue to adhere to the vaccine procurement strategy and make advance purchases of vaccines which fulfil the criteria of safety, efficacy and quality, including vaccines which are still in the development stage, with a view to ensuring availability of different types of vaccines and sufficient supplies for the whole of Hong Kong.

To tie in with the vaccination programme as well as to monitor any adverse event that occurs to the recipient associated with the administration of the relevant vaccine, the Government has set up the Expert Committee on Clinical Events Assessment Following COVID-19 Immunisation (the Committee). The Committee will perform continuous monitoring of the possible adverse event following administration of COVID-19 vaccines, and provide professional views and suggestions on safety monitoring of the authorised vaccines. The Committee will be co-chaired by the Clinical Professor of Department of Medicine of the University of Hong Kong, Professor Ivan Hung, and the Chief Executive and Medical Director of Hong Kong Red Cross Blood Transfusion Service, Dr Lee Cheuk-kwong. Other members of the Committee are from local universities, the Hospital Authority and the DH. Their professional disciplines cover forensic pathology, haematology, immunology, microbiology, neurology, pediatrics, pharmacology, pharmacy, etc. The membership list of the Committee is at Annex.

The Government spokesman reiterated, "The Government will ensure that vaccines satisfy the requirements of safety, efficacy and quality, and obtain emergency use approval in accordance with the relevant requirements as well as stringent approval procedures under the Regulation, before arranging for members of the public to receive the vaccines. We noticed the statement issued by the World Health Organization (WHO) Global Advisory Committee on Vaccine Safety that after reviewing the deaths reported in Europe and in the WHO global database, it was considered that the reports were in line with the expected, all-cause mortality rates and causes of death in the sub-population of frail, elderly individuals. There were no unexpected or untoward increase in mortality rate after frail, elderly individuals were vaccinated with BNT162b2 (COVID-19 vaccine by Fosun Pharma/BioNTech), and the administration of the vaccine was still considered to be beneficial for the elderly. To enhance the public's confidence in vaccines, the Government's work in vaccine administration will be based on scientific evidence and adhere to the principles of openness and transparency. At the same time, we will continue to monitor the use of the vaccines. The Government will provide members of the public with the latest information on the relevant vaccines through

different channels in a timely manner, and make public the views of experts on the vaccines, so that the public can grasp correct and comprehensive information on them."