



中華人民共和國香港特別行政區政府總部食物及衛生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Our Ref.: FHB/H/16/123

Tel.: 3509 8912

Your Ref.:

Fax.: 2537 7319

Dr Ronald LAM, JP
Chairman
The Pharmacy and Poisons Board of Hong Kong
1/F, Shun Feng International Centre
182 Queen's Road East
Wanchai, Hong Kong

4 February 2022

Dear Dr LAM,

The Government of the Hong Kong Special Administrative Region (the Government) would like to inform the Pharmacy and Poisons Board of Hong Kong on the arrangement for "off-label use" of the COVID-19 mRNA Comirnaty vaccine authorized under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) on children aged five to 11.

COVID-19 Vaccination Programme

The COVID-19 epidemic is still rampant across the globe and vaccination is the best measure and hope for Hong Kong and the world to ride out the epidemic. To combat the epidemic, the Government has been strongly appealing to and encouraging the public to get vaccinated, with a view to protecting the community by increasing the vaccination rate in Hong Kong. We are also committed to providing a choice of vaccine for all members of the public depending on individuals' wish.

With a view to widening the vaccination coverage for children, children aged five to 11 can currently receive the Sinovac vaccine through Community Vaccination Centres, Student Health Service Centres, participating private clinics and at school outreach events at a later stage.

“Off-label Use” of the Comirnaty Vaccine

To provide a choice of vaccine for children aged five to 11, the Government strives to extend the administration of the Comirnaty vaccine on children. The Advisory Panel on COVID-19 Vaccines (the Advisory Panel) set up under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation) noted that application on paediatric vial packaging for children aged five to 11 (i.e. 10 mcg per dose) is still pending from Fosun / BioNTech. Having reviewed the relevant efficacy and safety data published, the Advisory Panel suggested allowing children aged five to 11 to receive a fractional dose (i.e. one-third of a dose) of the Comirnaty vaccine for adults for “off-label use”.

The Joint Scientific Committees under the Centre for Health Protection also has no objection on allowing the use of a fractional dose of the Comirnaty vaccine for adults in children, with the experts opining that the Comirnaty vaccine may provide additional protection against Omicron infection. As the Comirnaty vaccine for children requires skillful dilution and dose extraction procedures, in the first phase, the Government will set up three Children Community Vaccination Centres (CCVCs), as part of the Government-led COVID-19 Vaccination Programme, on Hong Kong Island, in Kowloon and in the New Territories for children aged five to 11 to receive the vaccine. The CCVCs will be operated by the Hospital Authority or the University of Hong Kong.

Under the above arrangement, the medical professionals working in CCVCs are required to follow the Operational Manual for Coronavirus Disease 2019 (COVID-19) Vaccination at Community Vaccination Centres, as well as the relevant Standard Operating Procedures for Preparation of Fractional Dose prepared by the Department of Health in consultation with the Society of Hospital Pharmacists of Hong Kong, for administering the “off-label use” of the Comirnaty vaccine on children aged five to 11.

Separately, additional information is provided in the Consent Form for COVID-19 Vaccination for children receiving fractional doses of the Comirnaty vaccine, explaining to parents / guardians that the “off-label use” is not listed in the approved package insert of the Comirnaty vaccine authorized under the Regulation. It is an off-label use allowed in the Government programme under the Regulation, having regard to the advice from panel(s) / committee(s) of experts appointed by the Government upon review of the current and anticipated epidemic situation, as well as the relevant efficacy and safety data published. The person who prescribes, dispenses or is responsible for the administering of the vaccine in fractional dose to the children acts in accordance with the Government’s direction in the Government programme.

Way Forward

We trust the above arrangement would provide a structured and standardised framework to enable frontline medical professionals to implement the Government's policy of providing children aged five to 11 with a fractional dose (i.e. one-third of a dose) of the Comirnaty vaccine for adults under "off-label use". Please feel free to contact me if you need any further information.

Yours sincerely,



(Joan HUNG)

for Secretary for Food and Health