

衛生署藥物辦公室  
香港灣仔皇后大道東213號  
胡志大廈18樓1856室



DEPARTMENT OF HEALTH  
DRUG OFFICE  
Rm. 1856, 18/F, Wu Chung House  
213 Queen's Road East, Wan Chai, Hong Kong

本署檔號 Our Ref.: DH DO PRIE/7-30/15  
電話 Tel.: (852) 2961 8857  
圖文傳真 Fax: (852) 2834 5117

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Dear Healthcare Professionals,

### **Regulatory Control of COVID-19 Vaccines in Hong Kong**

COVID-19 vaccine is one of the critical interventions against COVID-19 pandemic, equitable access and distribution of these vaccines becomes a global health concern. The Government strives to procure for the Hong Kong population COVID-19 vaccines fulfilling the criteria of safety, efficacy and quality. The quality assurance of the vaccine must be well-supported in order for the vaccine to be approved for emergency use in Hong Kong. As such, the Government published the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) (the Regulation) in the Gazette on 23 December 2020 to provide the legal framework under the present state of public health emergency to bring in COVID-19 vaccines which satisfy the criteria of safety, efficacy and quality for emergency use.

The Regulation empowers the Secretary for Food and Health to authorise and allow the specified use of the relevant COVID-19 vaccine in Hong Kong under the emergency situation, based on (a) the objective clinical data of a COVID-19 vaccine, (b) the expert advice of an independent advisory panel appointed by the Chief Executive, and (c) the approval (including for emergency use) given by a regulatory authority in a place outside Hong Kong that performs the function of approving pharmaceutical products. The emergency use of a COVID-19 vaccine under Cap. 599K is basically for vaccination programmes conducted by the Government.

In order to ensure that all COVID-19 vaccines available for use in Hong Kong are properly authorised for emergency use, with immediate effect, all applications for import licence of unregistered COVID-19 vaccine for treatment of particular patients would not be accepted for evaluation.

Supply of unregistered pharmaceutical products is an offence under the Pharmacy and Poisons Ordinance (Cap. 138), and the maximum penalty is a fine of \$100,000 and

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two-year's imprisonment upon conviction. Illegal import of pharmaceutical products also contravenes the Import and Export Ordinance (Cap. 60), and the maximum penalty is a fine of \$500,000 and two-year's imprisonment.

Should you suspect any person importing and/or supplying unregistered COVID-19 vaccines, please provide such information to the Drug Office of the Department of Health (Tel: 2572 2068; Email: [pharmgeneral@dh.gov.hk](mailto:pharmgeneral@dh.gov.hk)) for our further action.

Yours faithfully,



(Frank CHAN)  
Assistant Director (Drug)