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(IN REPLY PLEASE QUOTE THIS FILE REF.)

28 Jun 2021

Dear Healthcare Professionals,

Moderna and Pfizer-BioNTech COVID-19 vaccines: increased risks of myocarditis and pericarditis

Your attention is drawn to the United States Food and Drug Administration's (FDA) announcement on revisions to the patient and provider fact sheets for the Moderna and Pfizer-BioNTech COVID-19 vaccines regarding the suggested increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination. For each vaccine, the Fact Sheet for Healthcare Providers Administering Vaccine has been revised to include a warning about myocarditis and pericarditis and the Fact Sheet for Recipients and Caregivers has been revised to include information about myocarditis and pericarditis.

This update follows an extensive review of information and the discussion by Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices meeting. The data presented at this meeting reinforced the FDA's decision to revise the fact sheets and further informed the specific revisions. The warning in the Fact Sheets for Healthcare Providers Administering Vaccines notes that reports of adverse events suggest increased risks of myocarditis and pericarditis, particularly following the second dose and with onset of symptoms within a few days after vaccination. Additionally, the Fact Sheets for Recipients and Caregivers for these vaccines note that vaccine recipients should seek medical attention right away if they have chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after vaccination.

Please refer to the following website in FDA for details:
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021

In Hong Kong, the above products are not registered pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138). The COVID-19 vaccine by Fosun Pharma/BioNTech (i.e. Comirnaty) is authorised for emergency use in Hong Kong in accordance with the Prevention and Control of Disease

(Use of Vaccines) Regulation (Cap. 599K). Related news was previously issued by The European Medicines Agency (EMA), and was posted on the Drug Office website on 12 Jun 2021. The Department of Health will remain vigilant on safety update of the product issued by other overseas drug regulatory authorities.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Joseph LEE)
for Assistant Director (Drug)