The United States: FDA approves required updated warning in labeling of mRNA COVID-19 Vaccines regarding myocarditis and pericarditis following vaccination

The United States Food and Drug Administration (FDA) announces that it has required and approved updates to the Prescribing Information for Comirnaty (COVID-19 Vaccine, mRNA) manufactured by Pfizer Inc. and Spikevax (COVID-19 Vaccine, mRNA) manufactured by ModernaTX, Inc. to include new safety information about the risks of myocarditis and pericarditis following administration of mRNA COVID-19 vaccines. Specifically, FDA has required each manufacturer to update the warning about the risks of myocarditis and pericarditis to include information about (1) the estimated unadjusted incidence of myocarditis and/or pericarditis following administration of the 2023-2024 Formula of mRNA COVID-19 vaccines and (2) the results of a study that collected information on cardiac magnetic resonance imaging (cardiac MRI) in people who developed myocarditis after receiving an mRNA COVID-19 vaccine. FDA also required each manufacturer to describe the new safety information in the Adverse Reactions section of the Prescribing Information and in the Information for Recipients and Caregivers.

The Fact Sheets for Healthcare Providers and for Recipients and Caregivers for Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19, which are authorized for emergency use in individuals 6 months through 11 years of age, have also been updated to include the new safety information in alignment with the Comirnaty and Spikevax Prescribing Information and Information for Recipients and Caregivers.

Updated Warning for Myocarditis and Pericarditis

The warning on myocarditis and pericarditis in the Prescribing Information for Comirnaty and Spikevax has been updated to convey that the observed risk of myocarditis and pericarditis following vaccination with mRNA COVID-19 vaccines has been highest in males 12 through 24 years of age and to include the following new language:

> Based on analyses of commercial health insurance claims data from inpatient and outpatient settings, the estimated unadjusted incidence of myocarditis and/or pericarditis during the period 1 through 7 days following administration of the 2023-2024 Formula of mRNA COVID-19 vaccines was approximately 8 cases per million doses in individuals 6 months through 64 years of age and approximately 27 cases per million doses in males 12 through 24 years of age.
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> Follow-up information on cardiovascular outcomes in hospitalized patients who had been diagnosed with COVID-19 vaccine-associated myocarditis is available from a longitudinal retrospective observational study. Most of these patients had received a two-dose primary series of an mRNA COVID-19 vaccine prior to their diagnosis. In this study, at a median follow-up of approximately 5 months post-vaccination, persistence of abnormal cardiac magnetic

resonance imaging (CMR) findings that are a marker for myocardial injury was common. The clinical and prognostic significance of these CMR findings is not known.

Information about myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) following vaccination with these mRNA COVID-19 vaccines has been included in the labeling since 2021. FDA closely monitors the safety of all vaccines, including the COVID-19 vaccines, during postmarket use.

About the Study on Cardiovascular Outcomes in mRNA COVID-19 Vaccine Recipients Diagnosed With Myocarditis

In a post-approval U.S. study funded and co-authored by FDA and published in September 2024, follow-up information was collected on approximately 300 people who developed myocarditis after receiving the original formula of an mRNA COVID-19 vaccine. Some people in the study reported having heart symptoms approximately 3 months after developing myocarditis. Some people in the study had cardiac MRIs (scans that show detailed images of the heart muscle) initially after developing myocarditis and again approximately 5 months later. The initial and follow-up cardiac MRIs commonly showed signs of injury to the heart muscle, with improvement over time in some but not all people. It is not known if these cardiac MRI findings might predict long-term heart effects of myocarditis.

Safety Monitoring Continues

Continuous monitoring and assessment of the safety of all vaccines, including the mRNA COVID-19 vaccines, is an FDA priority and we remain committed to informing the public when we learn new information about these vaccines.

In addition, as part of the approvals of Comirnaty and Spikevax, each manufacturer is required by FDA to conduct a study to assess if there are long-term heart effects in people who have had myocarditis after receiving an mRNA COVID-19 vaccine. These studies are underway.

Please refer to the following website in FDA for details:
http://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-approves-required-updated-warning-labeling-mrna-covid-19-vaccines-regarding-myocarditis-and

In Hong Kong, there are 4 Comirnaty vaccine products which are registered by Fosun Industrial Co., Limited, namely:

- Comirnaty Dispersion For Injection COVID-19 mRNA Vaccine (Nucleoside Modified) 30 Micrograms/Dose (HK-67665);
- Comirnaty Original/Omicron BA.4-5 Dispersion For Injection COVID-19 mRNA Vaccine (Nucleoside Modified) (15/15 Micrograms)/Dose (HK-67666);
- Comirnaty Omicron XBB.1.5 Dispersion For Injection COVID-19 mRNA Vaccine (Nucleoside Modified) 30 Micrograms/Dose (HK-68019); and

- Comirnaty JN.1 Dispersion For Injection COVID-19 mRNA Vaccine 30 Micrograms/Dose (HK-68417).

There are 5 Spikevax vaccine products which are registered by Moderna Hong Kong Limited, namely:

- Spikevax Bivalent Original/Omicron BA.4-5 Dispersion For Injection COVID-19 mRNA Vaccine (Nucleoside Modified) (50 Micrograms/50 Micrograms)/ml (HK-67830);
- Spikevax Bivalent Original/Omicron BA.4-5 Dispersion For Injection In Pre-filled Syringe COVID-19 mRNA Vaccine (Nucleoside Modified) 25 Micrograms/25 Micrograms (HK-67831);
- Spikevax XBB.1.5 Dispersion For Injection In Pre-filled Syringe COVID-19 mRNA Vaccine 50 Micrograms/Dose 0.5ml (HK-68081);
- Spikevax 2023-2024 Formula (XBB.1.5) Suspension For Injection COVID-19 mRNA Vaccine 250 Micrograms/2.5ml (HK-68127); and
- Spikevax JN.1 Dispersion For Injection In Pre-filled Syringe COVID-19 mRNA Vaccine 50 Micrograms/Dose 0.5ml (HK-68388).

All products are prescription-only medicines. Related news was previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 12 Jun 2021, with the latest update posted on 4 Dec 2021. Letters to inform local healthcare professionals were issued by the DH on 28 Jun 2021. The current product inserts of the locally registered Comirnaty and Spikevax products already include warnings on the risk of myocarditis and pericarditis following vaccination.

In light of the above FDA's announcement with updated warning regarding myocarditis and pericarditis, letters to inform local healthcare professionals will be issued, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Ends/Thursday, Jun 26, 2025
Issued at HKT 17:30