Pfizer Australia Pty Ltd

Level 15-18

151 Clarence Street

Sydney NSW 2000

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COMIRNATY (BNT162b2 [mRNA]) COVID-19 Vaccine: risk of myocarditis and pericarditis

Dear Healthcare Professional,

PFIZER in agreement with the Therapeutic Goods Administration would like to inform you of the following:

Summary

- **Cases of myocarditis and pericarditis have been reported very rarely following vaccination with COMIRNATY.**
- **The cases primarily occurred within 14 days after vaccination, more often after the second dose and in younger men.**
- **Available data suggest that the course of myocarditis and pericarditis following vaccination is similar to the course of myocarditis and pericarditis in general.**
- **Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis.**
- **Healthcare professionals should advise vaccinated individuals to seek immediate medical attention should they experience chest pain, shortness of breath, or palpitations.**

Background on the safety concern

COMIRNATY (BNT162b2[mRNA]) COVID-19 Vaccine has provisional approval for: Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 12 years of age and older. The use of this vaccine should be in accordance with official recommendations.

Myocarditis and pericarditis have been reported in association with COMIRNATY.

The Therapeutic Goods Administration has evaluated all available data and asked for the Product Information for COMIRNATY to be updated. Sections 4.4 'Special warnings and precautions for use' and 4.8 'Adverse effects (Undesirable effects)' have been updated.

The benefits of vaccination continue to outweigh any risks.

To 11 July 2021, approximately 3.7 million COMIRNATY doses have been administered, and the TGA has received 50 cases of suspected myocarditis and/or pericarditis relating to individuals vaccinated with COMIRNATY. (*COVID-19 vaccine weekly safety report - 15-07-2021* *https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-15-07-2021*)

Call for reporting

This vaccine is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

Australian Distributors' contact points

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