Ref: 07/2021/PLD
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Direct Healthcare Professional Communication

Dear Healthcare Professional,

COVID-19 mRNA Vaccines Comirnaty and Spikevax: risk of myocarditis and pericarditis

BIONTECH/PFIZER and MODERNA BIOTECH SPAIN, S.L. in agreement with the European Medicines Agency and Medicines Authority would like to inform you of the following:

Summary

- **Cases of myocarditis and pericarditis have been reported very rarely following vaccination with the COVID-19 mRNA Vaccines Comirnaty and Spikevax.**
- **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

The COVID-19 mRNA vaccines, Comirnaty and Spikevax, have been approved in the EU under conditional marketing authorisation for active immunisation to prevent COVID-19 infection caused by SARS-CoV-2, in individuals 12 years of age and older (Comirnaty) and 18 years of age and older (Spikevax), respectively.

Myocarditis and pericarditis have been reported in association with the COVID-19 mRNA vaccines.

The European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has evaluated all available data and concluded that a causal association between COVID-19 mRNA vaccines and myocarditis and pericarditis is at least a reasonable possibility. Accordingly, the Summary of Product Characteristics, sections 4.4 (‘Special warnings and precautions for use’) and 4.8 (‘Undesirable effects’) have been updated.

The benefits of vaccination continue to outweigh any risks.

Up to 31 May 2021 in the EEA, 145 cases of myocarditis occurred among people who received Comirnaty and 19 cases among people who received Spikevax. In addition, 138 cases of pericarditis occurred following the use of Comirnaty and 19 cases following the use of Spikevax.

It is estimated that around 177 million doses of Comirnaty and 20 million doses of Spikevax have been administered in the EEA up to 31 May 2021.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via their national reporting system and include batch/Lot number if available. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Post-licensing directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt

▼ These medicinal products are subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Companies' contact point

Should you have any questions or require additional information, please contact Moderna BIOTECH SPAIN, S.L. and BioNTech Manufacturing GmbH An der Goldgrube at:

Company	Product Name	Website	Phone
MODERNA BIOTECH SPAIN, S.L. Calle Monte Esquinza 30 28010 Madrid Spain medinfo@modernatx.com	Spikevax dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	https://www.modernacovid19global.com/	+356 80062397
BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz Germany medinfo@biontech.de	Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)	www.comirnatyglobal.com	+35621 344610

Yours faithfully,

Post-Licensing Directorate
Medicines Authority

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of Moderna BIOTECH SPAIN, S.L. and BioNTech Manufacturing GmbH An de Goldgrube.