

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

Dear Healthcare professional,

BIONTECH/PFIZER and MODERNA BIOTECH SPAIN, S.L. in agreement with the European Medicines Agency and <National competent 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.

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.

Marketing Authorisation Holders' contact points

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Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal products/active substances	COVID-19 mRNA vaccines (nucleoside-modified): Comirnaty and Spikevax (previously COVID-19 Vaccine Moderna)
Marketing authorisation holders	BioNTech Manufacturing GmbH and Moderna Biotech Spain, S.L.*
Safety concern and purpose of the communication	Risk of myocarditis and pericarditis
DHPC recipients	General practitioners, cardiologists, specialists in emergency medicine and vaccination centres. The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	All EU member states where the respective vaccines are authorised.
Timetable	Date
DHPC and communication plan (in English) agreed by PRAC	08/07/2021
DHPC and communication plan (in English) agreed by CHMP	09/07/2021
Submission of translated DHPCs to the national competent authorities for review	13/07/2021
Agreement of translations by national competent authorities	14/07/2021
Dissemination of DHPC	19/07/2021

* In cases where the DHPC concerns several marketing authorisation holders of the same active substance or is part of a class review, it is strongly encouraged that a single consistent message is sent to healthcare professionals in each EU Member State.

All concerned marketing authorisation holders in each Member State are strongly encouraged to collaborate, so that a single DHPC is prepared and circulated in each Member State. The letter

circulated in each Member State should cover all active substance-containing products authorised in that Member State.

It is encouraged that the originator marketing authorisation holder (where available) in each Member State acts as the contact point for the national competent authority, on behalf of the other concerned marketing authorisation holders in the same Member State. If no originator product is marketed in the Member State, it is encouraged that one of the concerned generic companies acts as contact point for the competent authority.