

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

19 July 2021

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**