Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 29 November - 2 December 2021

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PRAC update on risk of myocarditis and pericarditis with mRNA vaccines

EMA's safety committee (PRAC) has assessed recent data on the known risk of myocarditis and pericarditis following vaccination with COVID-19 vaccines Comirnaty and Spikevax (previously COVID-19 Vaccine Moderna). This review included two large European epidemiological studies. One study was conducted using data from the French national health system (Epi-phare) and the other one was based on Nordic registry data.

Overall, the outcome of the review confirms the risk of myocarditis and pericarditis, which is already reflected in the product information for these two vaccines, and provides further details on these two conditions.

Based on the reviewed data, the PRAC has determined that the risk for both of these conditions is overall "very rare", meaning that up to one in 10,000 vaccinated people may be affected. Additionally, the data show that the increased risk of myocarditis after vaccination is highest in younger males.

The PRAC has recommended updating the product information accordingly.

Myocarditis and pericarditis can develop within just a few days after vaccination, and have primarily occurred within 14 days. They have more often been observed after the second vaccination.

The French and Nordic studies provide estimates of the number of extra cases of myocarditis in younger males following the second dose, compared to unexposed persons of the same age and gender.

For Comirnaty, the French study shows that, in a period of seven days after the second dose, there were about 0.26 extra cases of myocarditis in 12- to 29-year-old males per 10,000 compared to unexposed persons. In the Nordic study, in a period of 28 days after the second dose, there were 0.57 extra cases of myocarditis in 16- to 24-year-old males per 10,000 compared to unexposed persons.

In the case of Spikevax, the French study showed that in a period of seven days after the second dose there were about 1.3 extra cases of myocarditis in 12- to 29-year-old males per 10,000 compared to unexposed persons. The Nordic study shows that in a period of 28 days after the second dose of Spikevax there were around 1.9 extra cases of myocarditis in 16- to 24-year-old males per 10,000 compared to unexposed persons.

Myocarditis and pericarditis are inflammatory conditions of the heart that present a range of symptoms, often including breathlessness, a forceful heartbeat that may be irregular (palpitations), and chest pain. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general.

EMA will continue to closely monitor this issue and will communicate further when new information becomes available.

EMA confirms that the benefits of all authorised COVID-19 vaccines continue to outweigh their risks, given the risk of COVID-19 illness and related complications, and as scientific evidence shows that they reduce deaths and hospitalisations due to COVID-19.

Agenda

Zusammenfassung auf deutsch (Dr. R.-P. Oelsner):

Die Arztneimittel-Kommission der EU (EMA) stellt Anfang Dezember 2021 fest:

Die Auswertung grosser europäischer Studien zeigt ein erhöhtes Risiko für Myocarditis und Perimyocarditis (Herzmuskel- u. Herzbeutelentzündung) nach einer Corona-Impfung mit dem Impfstoff Spikevax von Moderna bei männl. Jugendlichen und Männern im Alter von 12-29 Jahren mit. Die Häufigkeit ist mit 1:5000 bis1:8000 angegeben im Vergleich zu nicht Geimpften. Beschwerden in Form von Luftnot unter Belastung und/oder Brustschmerzen sowie unregelmässiger Herzschlag (Palpitationen) treten meist in den ersten 2-3 Wochen nach der Impfung auf. Das Risiko ist nach Zweitimpfung höher als nach der Erst-Impfung.

Nach Einschätzung der EMA überwiegt jedoch der Nutzen einer Impfung mit allen zugelassenen Impfstoffen das Risiko, da Impfungen Hospitalisierungen und Todesfälle reduzieren.