Medicines & Healthcare products
Regulatory Agency

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12 February 2024

Dear [redacted]

FOI 24/063

Thank you for your request for information dated 20 January 2024 regarding section 4.4 of the Summary of Product Characteristics (SmPC) for Spikevax XBB.1.5 COVID-19 vaccine concerning myocarditis and pericarditis. You have asked for:

1. *Brief details of the **fatal cases** and **cases that required intensive care**.*

2. *Details of the **action taken** by MHRA to mitigate risk of further serious adverse reactions and fatalities from Myocarditis and Pericarditis following market authorisation of Spikevax XBB.1.5.*

We can confirm that we hold the information requested although some of the information requested is available in the public domain and therefore is exempt under Section 21 of the Freedom of Information Act[1]. We have however provided links to the publicly available information. Please note that in relation to your first request, we have interpreted this as requesting the details of the fatal cases and cases that required intensive care on which the wording in section 4.4 of the SmPC concerning myocarditis and pericarditis is based on.

Section 4.4 of the SmPCs for all Spikevax COVID-19 vaccines, including Spikevax XBB.1.5 COVID-19 vaccine, contains the following warning about myocarditis and pericarditis:

4.4 Special warnings and precautions for use
Myocarditis and pericarditis
There is an increased risk for myocarditis and pericarditis following vaccination with Spikevax.

These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often in younger males, and more often after the second dose compared to the first dose (see section 4.8).

[1] https://ico.org.uk/for-organisations/foi-eir-and-access-to-information/freedom-of-information-and-environmental-information-regulations/section-21-information-accessible-to-the-applicant-by-other-means/

Available data indicate that most cases recover. Some cases required intensive care support and fatal cases have been observed.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination.

Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.

This warning includes updated wording on the cases of myocarditis and pericarditis reported post-authorisation, to add that some cases required intensive care support and that fatal cases have been observed. This information on patient outcomes was added following the European Union (EU) Pharmacovigilance Risk Assessment Committee (PRAC) review of the Spikevax Periodic Safety Update Report (PSUR) covering the period 19/06/2022 to 17/12/2022. The PRAC PSUR assessment report and the PSUR are available on the European Medicines Agency website at the following link: https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/spikevax-periodic-safety-update-report-assessment-19-june-2022-17-december-2022_en.pdf.

The PRAC assessment report and PSUR include brief details of the cases of myocarditis and pericarditis considered in the PRAC review. In particular, you are directed to section 2.3.1.2 of the PRAC assessment report and section 16.3.1.2. of the PSUR.

Following the PRAC assessment of the PSUR, the EU marketing authorisations for all Spikevax products were updated to amend the warning regarding myocarditis and pericarditis, as outlined on page 9 of the PRAC assessment report. The same updates to the product information for GB Spikevax products were subsequently approved by the MHRA via the European Commission (EC) Decision Reliance Route on 15/09/2023. Please note that the updated wording was included in the Spikevax XBB.1.5 product information approved at the time of authorisation of this product by the MHRA on 14/09/2023.

The MHRA has taken a number of actions to mitigate the risk of myocarditis and pericarditis in association with Spikevax, and also with the Pfizer/BioNTech (Comirnaty) COVID-19 vaccine, since this issue was first identified for the mRNA vaccines. Warnings about the risk of myocarditis and pericarditis have been added to the Spikevax and Comirnaty product information to advise of the symptoms and signs of myocarditis, the typical time to onset and which patient groups are at particular risk. This includes advice in the patient information leaflet so that patients can recognised possible signs and symptoms of myocarditis and pericarditis and take appropriate action. Other actions taken by the MHRA include: 1) circulation of a healthcare professional letter by the MHRA to relevant UK healthcare professionals to emphasise the warnings and precautions, 2) publication of regular updates on myocarditis and pericarditis in association with COVID-19 vaccines in the MHRA's Coronavirus vaccine summary of yellow card reporting, 3) publication of multiple updates in Drug Safety Update to present the developing data and updates to advice, 4) communication to the public and healthcare professionals via a MHRA press release and 5) updates to the 'Regulatory Approval' pages of the MHRA website for the vaccines (please see information for Spikevax and Spikevax bivalent products and Comirnaty and Comirnaty bivalent products.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,

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