EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

News announcement

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 4-7 March 2024

PRAC finds no link between postmenopausal bleeding and mRNA COVID-19 vaccines

EMA's safety committee (PRAC) concluded that there was insufficient evidence to establish a causal association between the COVID-19 vaccines Comirnaty and Spikevax and cases of postmenopausal bleeding.

Postmenopausal bleeding is commonly defined as vaginal bleeding occurring 1 year or more after the last menstrual period. Postmenopausal bleeding is always considered abnormal and can be a symptom of serious medical conditions.

Recently, new information emerged from the medical literature and post-authorisation data that prompted investigation into postmenopausal bleeding with the two vaccines.

The PRAC assessed all the available data, including findings from the literature, and available post-marketing spontaneous reports of suspected adverse reactions.

After careful review, the PRAC considered that the available data does not support a causal association and an update of the product information for either vaccine is not warranted.

The committee will continue to monitor this issue for both Comirnaty and Spikevax through the established safety monitoring practices.

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