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) 10-13 January 2022

Vaxzevria and COVID-19 Vaccine Janssen: update on very rare cases of transverse myelitis

The PRAC has recommended a change to the product information for Vaxzevria and COVID-19 Vaccine Janssen to include a warning to raise awareness among healthcare professionals and people receiving the vaccines of very rare cases of transverse myelitis (TM) reported following vaccination. TM has also been added as an adverse reaction of unknown frequency.

TM is a rare neurological condition characterised by an inflammation of one or both sides of the spinal cord. It can cause weakness in the arms or legs, sensory symptoms (such as tingling, numbness, pain or loss of pain sensation) or problems with bladder or bowel function.

The Committee has reviewed available information on globally reported cases, including those in the European database for suspected side effects (EudraVigilance) and data from the scientific literature, with both vaccines[1]. The PRAC has concluded that a causal relationship between these two vaccines and transverse myelitis is at least a reasonable possibility. The benefit-risk profile of both vaccines remains unchanged.

Healthcare professionals should be alert to signs and symptoms of TM, allowing early diagnosis, supportive care and treatment. People receiving either of these vaccines are advised to seek immediate medical attention if they develop symptoms of the condition.

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

Vaxzevria: fewer cases of thrombosis with thrombocytopenia reported after second dose

The PRAC has recommended updating the product information for Vaxzevria to add more information about the very rare cases of thrombosis with thrombocytopenia (TTS) that occurred following vaccination.

[1] In total, 38 globally reported cases were considered, 25 cases with Vaxzevria and 13 with COVID-19 Vaccine Janssen. Respectively, global exposure to the vaccines was estimated at 1,391 billion doses for Vaxzevria and at 33,584,049 for COVID-19 Vaccine Janssen. These numbers refer to suspected and not adjudicated cases of TM.

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A review of cumulative data has highlighted that the majority of suspected TTS events were reported worldwide after the administration of the first dose. Fewer events have been observed after the second dose. In fact, out of 1,809 thromboembolic events with thrombocytopenia reported worldwide, 1,643 were reported after the first dose and 166 after the second dose.

As per the current product information, the administration of a second dose of Vaxzevria is contraindicated in people who have experienced TTS following vaccination with this vaccine.

New safety information for healthcare professionals

As part of its advice on safety-related aspects to other EMA committees, the PRAC discussed direct healthcare professional communication (DHPC) containing important safety information for Mavenclad.

Mavenclad: risk of serious liver injury

This DHPC aims to inform healthcare professionals about adverse events of liver injury with Mavenclad (cladribine), and gives new recommendations about liver function monitoring.

Mavenclad is a medicine used to treat adults with the relapsing forms (repeated flare-ups of the symptoms) of multiple sclerosis, a disease in which inflammation damages the protective sheath around the nerve cells in the brain and spinal cord (demyelination). Mavenclad is used in patients whose disease is highly active.

Liver injury, including serious cases and cases leading to discontinuation of treatment, has been reported in patients treated with Mavenclad. A recent review of available safety data has concluded on an increased risk for liver injury following treatment with Mavenclad. Most patients who experienced liver injury had mild clinical symptoms. However, in some cases, transitory high levels of enzyme transaminase exceeding 1000 units per litre and jaundice (liver affection causing, amongst others, yellowing of the skin and eyes) were described.

Liver injury will be included in the product information of Mavenclad as an adverse drug reaction of uncommon frequency.

Healthcare professionals are advised to perform a detailed review of patient history of underlying liver disorders or episodes of liver injury with other medicines before initiating patient treatment. During treatment, liver function tests should be conducted, and repeated as necessary. In case a patient develops liver injury, treatment with Mavenclad should be interrupted or discontinued, as appropriate.

Patients should be advised to report immediately to their healthcare professional any signs or symptoms of liver injury. Healthcare professionals are asked to report any suspected adverse reactions via their national reporting system. Reporting suspected adverse reactions after authorisation of the medicinal product is important to ensure patient safety.

The DHPC for Mavenclad will be forwarded to EMA's human medicines committee, the CHMP. Following the CHMP decision, the DHPC will be disseminated to healthcare professionals by the marketing authorisation holder, according to an agreed communication plan, and published on EMA's website and in national registers in EU Member States.