EMA’s Conclusion on Janssen Vaccine and Blood Clots

The European Medicines Agency has completed its safety review for Johnson & Johnson’s COVID-19 Vaccine Janssen giving conclusions similar to those on AstraZeneca’s Vaxzevria.

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EMA’s safety committee (PRAC) concluded that the product information for the Janssen vaccine should include a warning about unusual blood clots and these events should be listed among the rare side effects for the medicine.

PRAC could not confirm any specific risk factors, but “it is thought that the vaccine may trigger an immune response leading to a heparin-induced-thrombocytopenia like disorder”, EMA’s statement said.

PRAC’s evaluation was based on the available evidence including eight U.S. reports of thrombosis in combination with thrombocytopenia of which one had a fatal outcome. The events occurred mostly in women; all of them in people under 60 years of age and within three weeks after vaccination. These cases were very similar to those related to the Vaxzevria vaccine by AstraZeneca.

By mid-April, more than 7 million people in the U.S. had received the J&J jab. In the EU, the J&J’s vaccine was authorised on 11 March 2021, but the company suspended the rollout after the blood clots reports.

According to the statement, “The reported combination of blood clots and low blood platelets is very rare, and the overall benefits of COVID-19 Vaccine Janssen in preventing COVID-19 outweigh the risks of side effects…. The vaccine is effective at preventing COVID-19 and reducing hospitalisations and deaths.” The agency will continue monitoring of all COVID-19 vaccines, it said. Healthcare professionals are urged to look out for the signs and symptoms of thromboembolism and thrombocytopenia to provide timely treatment.

Source: EMA

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