

## EU watchdog monitoring Pfizer, Moderna jabs for clot risks

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Europe's medicines watchdog said Friday it was checking whether COVID-19 vaccines made by Pfizer/BioNTech and Moderna could be



linked to rare cases of blood clotting, but there was no indication so far.

The European Medicines Agency last month linked two other EU-approved vaccines, one made by AstraZeneca and another by Johnson & Johnson, to rare but occasionally fatal clots, however it stressed the vaccines' benefits in fighting the <u>coronavirus</u> pandemic outweighed the risks.

The EMA's safety committee "is closely monitoring whether mRNA vaccines might also be linked to cases of rare, unusual blood clots with low blood platelets."

"Following a review of reports of suspected side effects, the (committee) considers at this stage that there is no safety signal for the mRNA vaccines," the Amsterdam-based EMA said.

US drugs giant Pfizer and its German partner BioNTech as well as the US-based pharmaceutical Moderna base their vaccines on mRNA genetic technology that trains the body to reproduce spike proteins, similar to that found on the coronavirus.

When exposed to the real virus later, the body recognises the spike proteins and is able to fight them off.

So far, only few cases of blood clots with low blood platelets have been reported among the users of the mRNA vaccines.

Compared to the millions of people who have been vaccinated with them, "these numbers are extremely low, and their frequency is lower than the one occurring in people who have not been vaccinated," the EMA said.

"In addition, these cases do not seem to present the specific clinical



pattern observed with Vaxzevria and COVID-19 Vaccine Janssen," the EMA said, using the <u>brand names</u> for AstraZeneca and J&J's vaccines.

"Overall, the current evidence does not suggest a causal relation," the medicines watchdog said.

The EMA also announced it has started reviewing data on a British and US-made antibody to treat coronavirus patients, but that it was too early to rule on its risks and benefits.

The EMA started a "rolling review" of data on sotrovimab, a monoclonal antibody developed by Britain's GlaxoSmithKline and Vir Biotechnology based out of California.

Sotrovimab is a monoclonal antibody, a type of protein that attaches to the spike protein of the coronavirus, reducing its ability to enter the body's cells.

The rolling review is a precursor to accelerated authorisation for use within the 27-nation European Union.

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