EMA says J&J linked to 'rare' clot, but benefits outweigh risks

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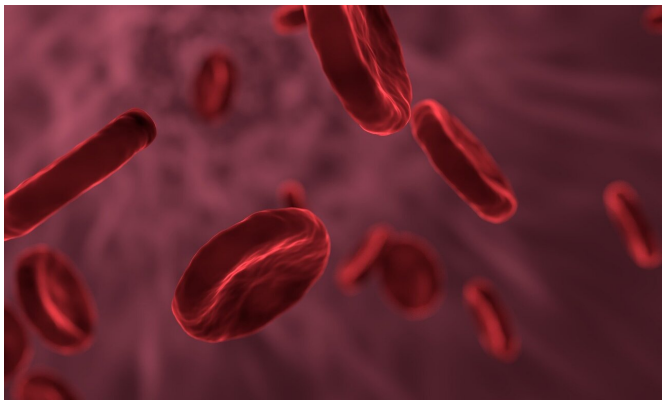

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Blood clots should be listed as a "very rare" side effect of the Johnson & Johnson coronavirus vaccine but its benefits still outweigh the risks, the EU's drug watchdog said Tuesday.

The European Medicines Agency (EMA) said in a statement that it had found a "possible link" between the J&J jab and the clots, following eight such cases in the United States, one of which was fatal.

The US pharmaceutical giant's vaccine is the second to be tied to the rare clots that mainly affect vessels leading to the brain, after the shot made by British-Swedish firm AstraZeneca.

"EMA finds possible link to very rare cases of unusual blood clots with low blood platelets," the Amsterdam-based agency said in a statement, adding that it "confirms (the) overall benefit-risk remains positive".

EMA chief Emer Cooke stressed the number of cases was tiny compared to the seven million J&J vaccinations given so far, but that it was important for people to know.

"This is a very rare effect but it also makes it very important for doctors and patients to be aware of the signs so that they can spot any concerns," Cooke told a virtual press conference.

"Early intervention by a specialist can change the outcome."

The agency, which licences medicines for the 27-nation EU, would continue to investigate the problem and was working with the US Food and Drug Administration, she said.

Johnson & Johnson last week delayed the start of the rollout of its single-shot jab across Europe pending the result of the EMA probe.

The United States has also paused the use of the J&J vaccine pending a decision expected on Friday.

'Very rare side effects'

The EMA statement said its safety committee "concluded that a warning about unusual blood clots with low blood platelets should be added to the product information" for the J&J shot.

Its experts also "concluded that these events should be listed as very rare side effects of the vaccine."

"The cases reviewed were very similar to the cases that occurred with the COVID-19 vaccine developed by AstraZeneca" it added.

The eight US cases all involved people under the age of 60 who had received the J&J shot, the majority of whom were women, it said.

So far there had also been 287 cases of the rare clots worldwide linked to AstraZeneca, 25 to the Pfizer-BioNTech vaccine, and five to the Moderna jab.

The EU approved the Johnson & Johnson shot on March 11 and started taking delivery of the vaccine on April 19.

But with concerns already mounting over clots linked to AstraZeneca, the EMA announced on April 9 that it was also probing cases connected to the J&J vaccine.

Both the Johnson & Johnson and AstraZeneca vaccines use the same adenovirus vector technology.

They use a common-cold causing adenovirus, modified so it cannot replicate, as a "vector" to shuttle genetic instructions into human cells, telling them to create a protein of the coronavirus, and training them to be ready for live COVID.

AstraZeneca opted for a chimpanzee adenovirus, J&J for a human adenovirus.

Other COVID adenovirus vector vaccines include Russia's Sputnik V and China's CanSino.

The EMA was "paying very close attention" to the Sputnik vaccine, which is under review by the regulator, but had not seen any cases of clots linked to it yet, Cooke said.

Many European countries have continued to restrict the use of AstraZeneca, despite the EMA declaring it safe and saying blood clots are only a "very rare" side effect.