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European Drug Regulator Slaps Safety Warning on J&J Jab Due to Blood-Clot Links

By Zero Hedge
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While Europe grapples with its own vaccine safety scandal, the EMA, the same EU pharma regulator that has insisted that the AstraZeneca-Oxford jab's benefits far outweigh its risk, has just poured cold water on J&J's vaccine.

Although the EMA said the reported combination of blood clots and low blood platelets is very rare, and the overall benefits of J&J's COVID-19 Vaccine Janssen in preventing COVID-19 outweighs the risks of side effects, the EMA has decided to affix a safety warning to the J&J jab – a warning that EMA neglected to impose on the AstraZeneca jab that is so critical to the Continent's vaccination program.

> EMA's safety committee (#PRAC) recommends adding 'very rare cases of unusual blood clots with low blood platelets' to the list of side effects for Janssen #vaccine.
>
> Overall benefit-risk remains positive.
> https://t.co/hNusE5blWm pic.twitter.com/5kX1ECgogz
>
> — EU Medicines Agency (@EMA_News) April 20, 2021

> EMA says its safety committee concluded a warning about unusual blood clots with low platelets should be added to product information for J&J #covid19 vaccine, and that the events should be listed as very rare side effects of the vaccine: https://t.co/IEuPm36R3R
>
> — Meg Tirrell (@megtirrell) April 20, 2021

> EMA notes it confirms the overall benefit-risk of the J&J #covid19 vaccine remains positive. Notes it considered all currently available evidence of unusual clots, including 8 reports from the US.
>
> — Meg Tirrell (@megtirrell) April 20, 2021

The EMA's safety committee, known as PRAC, determined that blood clots caused by the vaccine occurred mostly at unusual sites such as in veins in the brain (cerebral venous sinus thrombosis, CVST) and the abdomen (splanchnic vein thrombosis) as well as in the arteries. They're often accompanied with low levels of blood platelets and sometimes bleeding. The cases reviewed were very similar to the cases that occurred with the COVID-19 vaccine developed by AstraZeneca, Vaxzevria, the committee said.

Healthcare professionals and people who will receive the vaccine "should be aware of the possibility of very rare cases of blood clots combined with low levels of blood platelets occurring within three weeks of vaccination," the committee added.

Mirroring comments from a top CDC doctor delivered at a press conference in the US last week which was called to discuss the blood clots tied to J&J, the PRAC said the blood clots were likely an autoimumune response to the jab. The response mirrors the reaction sometimes seen in patients treated with heparin, a blood-thinning agent, which is called heparin induced thrombocytopenia. Questions about the AstraZeneca jabs' link to these dangerous blood clots let US authorities to halt its Phase 3 trial for more than a month.

It's believed that the roots of the problem lie in the adenovirus platform upon which both J&J and AstraZeneca jabs were built.

The PRAC said it would make "further recommendations" about the J&J jab's safety once it finally finishes its accelerated safety review. Meanwhile, J&J jabs remain on hold in the US.

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