

Europe needs to be clearer about Covid-19 vaccines



[Madeleine Armstrong](#)



Confusion over blood clot numbers with all four approved Covid-19 vaccines could cause more vaccine hesitancy.

“What we want to do is make sure that people have the facts.” So said Emer Cooke, executive director of the European Medicines Agency, during a call yesterday to discuss thromboembolic events with Johnson & Johnson’s Covid-19 vaccine JNJ-78436735.

But the EMA has caused confusion about whether any of the unusual blood clots have been seen with Pfizer/Biontech’s and Moderna’s Covid-19 vaccines in the US. The EU agency needs to clarify these numbers to restore confidence, or risk making people even more hesitant about getting a Covid-19 shot.

Restoring confidence is clearly the EMA’s goal. Ms Cooke and her colleagues stressed several times yesterday that the unusual blood clots, seen with both JNJ-78436735 and Astrazeneca’s vaccine Vaxzevria, were very rare.

J&J relaunch

The agency has now said that these events should be listed as a side effect of the J&J shot, but it will allow the product onto the market after a delay last week when the [blood clot worries were first raised](#) – and J&J has already [said it will restart its rollout](#). This decision is similar to the one the EMA made on [Vaxzevria earlier this month](#).

So far, so sensible: allowing the vaccines to stay in use looks like a good move given the risks associated with Covid-19, especially in old and vulnerable populations. It will now be up to individual countries whether they limit JNJ-78436735’s use to certain age groups as, for example, the UK has done with Vaxzevria.

And the EMA should be applauded for the swiftness of its action. US use of JNJ-78436735 remains paused pending a reconvened Advisory Committee on Immunization Practices panel on Friday.

How many?

However, on the question of how many worrying blood clots have been seen across the Covid-19 vaccines, the EMA’s communications leave a lot to be desired, and this is especially true of the mRNA shots developed by Pfizer/Biontech and Moderna.

These have so far avoided links with these unusual blood clots, and yesterday the EMA's Sabine Straus said there was "no signal" in the US with Comirnaty, and for mRNA-1273 that "in the cases that were identified in the US there was no thrombocytopenia".

But Peter Arlett, the EMA's head of pharmacovigilance, said thrombosis specifically with thrombocytopenia had been seen in 25 people receiving Pfizer/Biontech's Comirnaty and five people receiving Moderna's mRNA-1273, on further questioning confirming that these were worldwide cases.

And it later emerged that 11 of the cases seen with Comirnaty and two with mRNA-1273 had occurred in the European Economic Area, [as first reported by Science magazine's Kai Kupferschmidt](#). The EMA later confirmed these numbers to *Evaluate Vantage*; this leaves 14 cases with Comirnaty and three with mRNA-1273 that are unaccounted for.

And where?

It would seem a fair assumption that some of these occurred in the US, the biggest market for the mRNA jabs.

This appears to contradict Ms Straus as well as a separate statement made by the FDA's Peter Marks last week that: "There have been over 180 million doses of [Comirnaty and mRNA-1273] administered, and at this time we have not found any reports of cerebral venous sinus thrombosis combined with thrombocytopenia."

Countries using the mRNA vaccines include [Israel, UAE and Japan](#), so it is possible that the cases could have occurred in these locations.

However, the EMA could have saved the speculation by presenting these numbers clearly in the first place. As it stands, this debate risks overshadowing the agency's core message: that the benefits of the Covid-19 vaccines outweigh their risks.

Cases of thromboses with thrombocytopenia after selected Covid-19 vaccines

Vaccine	Developer	Cases adjudicated	Implied incidence
AZD1222/Vaxzevria	Astrazeneca/University of Oxford/Vaccitech	142 in 16 million*	8.9 per million
JNJ-78436735	Johnson & Johnson	8 in 7 million**	1.1 per million
mRNA-1273	Moderna	2 in 5 million*	0.4 per million
Comirnaty/BNT162b2	Pfizer/Biontech	11 in 59 million*	0.2 per million

*EEA only; **US only. Source: EMA, Kai Kupferschmidt of Science magazine.

This story has been updated to note that the EMA has confirmed to Evaluate Vantage the numbers on thrombosis plus thrombocytopenia in the European Economic Area.

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