## AstraZeneca withdrawing Covid vaccine worldwide

Company says decision is purely commercial as jab has been superseded by alternatives

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The Oxford-AstraZeneca Covid vaccine is being withdrawn worldwide, months after the pharmaceutical giant admitted for the first time in court documents that <u>it can cause a rare and</u> <u>dangerous side effect</u>.

The vaccine can no longer be used in the European Union after the company voluntarily withdrew its "marketing authorisation". The application to withdraw the vaccine was made on March 5 and came into effect on Tuesday.

Similar applications will be made in the coming months in the UK and in other countries that had approved the vaccine, known as Vaxzevria.

The decision to withdraw it brings to an end the use of the jab, which was <u>heralded by Boris</u> <u>Johnson as a "triumph for British science"</u> and credited with saving more than six million lives. AstraZeneca said the vaccine was being removed from markets for commercial reasons. It said the vaccine was no longer being manufactured or supplied, having been superseded by updated vaccines that tackle new variants.

Vaxzevria has come under intense scrutiny in recent months over a very rare side effect, which causes blood clots and low blood platelet counts. AstraZeneca admitted in court documents lodged with the High Court in February that the vaccine "can, in very rare cases, cause TTS".

TTS – which stands for Thrombosis with Thrombocytopenia Syndrome – has been linked to at least 81 deaths in the UK as well as hundreds of serious injuries. AstraZeneca is being sued by more than 50 alleged victims and grieving relatives in a High Court case.

But AstraZeneca has insisted the decision to withdraw the vaccine is not linked to the court case or its admission that it can cause TTS. It said the timing was pure coincidence.

In a statement the company said: "We are incredibly proud of the role Vaxzevria played in ending the global pandemic. According to independent estimates, over 6.5 million lives were saved in the first year of use alone and over three billion doses were supplied globally. "Our efforts have been recognised by governments around the world and are widely regarded as being a critical component of ending the global pandemic.

"As multiple, variant Covid-19 vaccines have since been developed, there is a surplus of available updated vaccines. This has led to a decline in demand for Vaxzevria, which is no longer being manufactured or supplied. AstraZeneca has therefore taken the decision to initiate withdrawal of the marketing authorisations for Vaxzevria within Europe.

"We will now work with regulators and our partners to align on a clear path forward to conclude this chapter and significant contribution to the Covid-19 pandemic."

The Telegraph has been told that the company will withdraw marketing authorisations in other countries, including the UK, where it has regulatory approval. AstraZeneca never had approval for the vaccine to be used in the US.

The company said: "We will partner with regulatory authorities globally to initiate marketing authorisation withdrawals for Vaxzevria, where no future commercial demand for the vaccine is expected."

The Government largely stopped using the Oxford-AstraZeneca vaccine by the autumn of 2021, by which time it had supplied about 50

million doses in the UK. It was replaced in the UK with Pfizer and Moderna jabs in time for the winter booster campaign at the end of 2021.

Marco Cavaleri, head of vaccines at the European Medicines Agency, the body which is responsible for drug and medicine safety within the EU, told Italian media: "The authorisation of the anti-Covid vaccine Vaxzevria by AstraZeneca will be withdrawn and the process has already officially started with the European Commission. This is in line with the expectations that no-longer-used and updated vaccines will be withdrawn, as per our indication."

Mr Cavaleri said he expected all the "monovalent" vaccines – which dealt only with the original Wuhan strain – to be withdrawn in time.

AstraZeneca accepted the vaccine can cause TTS in a legal document in February this year. The causal mechanism is not known.



Workers producing the vaccine in October 2021 Credit: JOHN LAWRENCE

Lawyers for claimants in the High Court case argue that the drug caused vaccine-induced immune thrombocytopenia and thrombosis (VITT) – a subset of TTS – and that it was not as safe as individuals were entitled to expect. AstraZeneca has always insisted that "patient safety is our highest priority".

The company has said: "From the body of evidence in clinical trials and real-world data, the AstraZeneca-Oxford vaccine has continuously been shown to have an acceptable safety profile and regulators around the world consistently state that the benefits of vaccination outweigh the risks of extremely rare potential side effects."

But Kate Scott, whose husband Jamie was left with a permanent brain injury after having the vaccine and who was the first person in the UK to bring a legal action, said: "AstraZeneca's Covid vaccine no longer being used in the UK or Europe, and soon the rest of the world, means no one else will suffer from this awful adverse reaction.

"They say it is for commercial reasons, but maybe it's because it can no longer be seen as being within the acceptable safety parameters, with 445 confirmed cases of VITT, 81 of these fatal in the UK alone." Mr Scott, 47, a father of two who has had to give up work, said: "This is good news, but I will always wish they had, like they did in other countries, paused it in the UK after just one case. More lives could have been saved and I would not be suffering the way I am."



Mr Scott, pictured with his wife, wishes the vaccine had been withdrawn much earlier Credit: ANDREW FOX

Sarah Moore, a partner at law firm Leigh Day, which is bringing the legal claims, said: "To those who we represent, all of whom have suffered bereavement or serious injury as a result of the AstraZeneca vaccine, this decision to withdraw marketing authorisation, ending the usage of the AstraZeneca vaccine in the EU, will be welcomed.

"It will be seen as a decision linked with AstraZeneca's recent admission that the vaccine can cause TTS, and the fact that regulators across the world suspended or stopped usage of the vaccine following concerns regarding TTS.

"This is an important regulatory step, but still our clients remain without fair compensation. We will continue to fight for the compensation our clients need and campaign for reform of the vaccine damage payment scheme."

The scheme, run by the Government, has paid out to victims. But it has been branded inadequate, prompting them to bring separate civil claims against AstraZeneca, which the drugs firm is contesting.