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EUROPE

U.K. Limits AstraZeneca Covid-19 Vaccine to Over-30s Amid Blood-Clot Concerns

European regulator finds link to rare blood clots, but says vaccine's benefits still outweigh risks



A man receives a dose of the AstraZeneca vaccine at a mosque in London.

PHOTO: HOLLIE ADAMS/BLOOMBERG NEWS

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The U.K.'s vaccines advisory body said the Covid-19 vaccine produced by [AstraZeneca PLC](#) should preferably not be given to people under 30 following concerns that it causes potentially deadly blood clots in very rare instances.

The decision Wednesday to restrict the vaccine for younger people is a setback for the U.K.'s flagship inoculation drive and leaves the country increasingly dependent on Covid-19 shots developed and produced in other countries.

It also lands another blow on the vaccine developed by AstraZeneca and the University of Oxford, which have faced questions about its efficacy and potential side effects even as

tens of millions of doses have been administered following safety signoffs in more than 70 countries world-wide.

The vaccine, which unlike others doesn't need to be stored at super-cold temperatures, has been regarded as critical to the vaccine rollout in poorer countries, many with relatively young populations.

The speed of the U.K.'s fast-paced vaccine program shouldn't be affected by the decision as long as vaccine supplies hold up, British officials said. "It is a course-correction, if you like, to the U.K. program," said U.K. deputy chief medical officer Jonathan Van-Tam.

British Prime Minister [Boris Johnson](#) said that he didn't see "any reason at this stage" to alter the country's plan to gradually reopen the economy over summer. He added he was confident about the country's vaccine supply.

Also Wednesday, the European Union's health agency said it had found possible links between the AstraZeneca vaccine and rare blood clots but that the shot's benefits continue to outweigh the potential risks. The European Medicines Agency said it found no specific risk factors linking the vaccine to the clots.

ASTRAZENECA'S VACCINE

[Startup Behind AstraZeneca Covid-19 Vaccine Plans to File Publicly for U.S. IPO Within Days](#) (April 7)

[Oxford Pauses Dosing in Trial of AstraZeneca Covid-19 Vaccine in Children, Teenagers](#) (April 6)

[Scientists Say They Found Cause of Rare Blood Clotting Linked to AstraZeneca Vaccine](#) (March 19)

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A number of EU countries, including France, Germany and Italy, have resumed AstraZeneca vaccinations after temporarily suspending their use last month following reports that people who had received the AstraZeneca shot developed rare blood clots and that some had died, further slowing Europe's vaccination rollout. But last week, Germany's government said it would restrict use of the vaccine for people younger than 60.

Canadian authorities have also urged a halt in use of the Oxford-AstraZeneca vaccine in people under the age of 55, [a sharp shift from officials' earlier view](#) that the vaccine was safe for all ages.

In the U.K., the government said last week that 79 severe blood-clotting cases had been reported in the U.K. out of 20 million administered doses of the vaccine. Nineteen of the people died, the regulator said Wednesday. The blood clotting is “a vanishingly rare but sadly quite serious adverse event,” said Dr. Van-Tam.

The U.K. medicine regulator, the Medicines and Healthcare products Regulatory Agency, estimated the risk of developing a clot after vaccination is about four people in a million.

The regulator said more work is needed to establish the cause of the clotting. Specialists say that blood clotting is common among people with Covid-19 and that the clotting after vaccination may—though they are unsure—be related to a reaction of the immune system.

AstraZeneca said the European and U.K. reviews “reaffirmed the vaccine offers a high level of protection against all severities of Covid-19 and that these benefits continue to far outweigh the risks.” It’s continuing to work with regulators to reflect the recommended changes to information for vaccine recipients and healthcare providers, and to study the rare blood-clotting events and possible causes.

The incidence of blood clotting after vaccination has been proportionately higher among younger people than in older age groups, Dr. Van-Tam said. Given that younger people are less likely to die of Covid-19 than older people, Britain’s Joint Committee on Vaccination and Immunization said it would be preferable if those under 30 received alternative vaccines.

The U.K. decision also reflects progress in bringing down Covid-19 caseloads after months of lockdown. In much of Europe, by contrast, cases are increasing. France last week announced a new national lockdown and German Chancellor Angela Merkel has urged regional authorities to take tougher measures to control infections.

Dr. Van-Tam presented analysis by the University of Cambridge showing that for someone age 20 to 29 years, the benefits of vaccination in preventing illness severe enough to need intensive care would easily outweigh the improbable risk of suffering a blood clot if Covid-19 was spreading as quickly as it was in Britain in February—and even more so if cases were proliferating as fast as they were late last year.

But that calculus changes when case numbers dwindle to the level they have reached recently. The analysis showed that if daily cases numbered two per 10,000 people, as they did in March, vaccination would prevent 0.8 intensive-care admissions among 100,000

20-to-29-year-olds. That compares with a risk of around 1.1 in 100,000 for developing a blood clot after vaccination.

The U.K. authorities have taken a number of calculated risks as they raced to immunize the population against Covid-19. Britain's medicines regulator was the first in the world to sign off on the vaccine. The government also took the controversial decision to delay giving second vaccine doses by up to 12 weeks to allow more people to be inoculated with a first dose.

Currently, Britain has vaccinated a larger share of its population than any other major Western nation. Britain is planning to give all adults who want it a vaccine dose by the end of July, allowing it to reopen its economy faster than other European nations. Some 31.7 million people have received a first vaccine dose and 5.7 million a second.

Much of this is predicated on the AstraZeneca vaccine. Britain has secured access to seven different Covid-19 vaccines and over 350 million doses. So far, most people have received the AstraZeneca shot.

Health regulators now recommend that those under 30 receive the shots developed jointly by Pfizer Inc. and BioNTech SE and by Moderna Inc. The first inoculations of the Moderna vaccine began this week in the U.K.

On Wednesday, officials from the European regulator said that most clots that have been identified were in people under age 60 and women but cautioned that the data didn't pinpoint a link because it remained unclear how representative recipients of the AstraZeneca vaccine are within the overall population.

EMA Executive Director Emer Cooke said that because the clots are so rare, the risk of death from Covid-19 is much greater than the risk of dying from the possible side effects.

Asked at a press conference why the EMA hadn't recommended limiting use of the AstraZeneca vaccine to specific populations, as the U.K. and other countries have done, Ms. Cooke said that information on the cases reviewed by the EMA didn't indicate "any causal link between the different gender or age groups."

Ms. Cooke said that the AstraZeneca vaccine is being given more widely to younger age groups in the U.K. than in parts of the EU, and the EMA will consider the issue in its continuing evaluations.

AstraZeneca's vaccine rollout has been tarnished by a series of stumbles.

They have included communications mishaps with U.S. regulators, confusing results from large-scale trials, and delivery problems in the EU that have brought continuing political criticism.

Last month, AstraZeneca found itself in a public spat with U.S. officials over the precise results of a big U.S. clinical trial of the vaccine. The company's handling of trial results upset regulators and chipped away at the drugmaker's reputation in its biggest market. AstraZeneca has said it would ask U.S. officials by the middle of this month to consider the vaccine for use in the U.S.

—Jason Douglas contributed to this article.

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