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Germany restricts use of AstraZeneca vaccine for under-60s

Berlin's move follows 31 brain blood-clotting incidents, 9 deaths in Germany after vaccinations

By Bojan Pancevski | The Wall Street Journal

Germany 'cautiously' reopening small businesses amid coronavirus: KT Guttenberg

Former Defense and Economic Minister under Angela Merkel KT Guttenberg discusses the gradual and cautious reopening of Germany's small businesses as the coronavirus continues.

BERLIN—Germany's government said Tuesday it will restrict the use of <u>AstraZeneca</u> PLC's <u>COVID-19 vaccine</u> for people younger than 60 following <u>fresh</u> <u>blood-clotting incidents</u> among recipients, potentially presenting the country's sputtering vaccine rollout with fresh delays.

As of Wednesday, people under 60 will only be able to receive the vaccine if they specifically demand it, and if their request is granted by a physician, the government said Tuesday.

The decision comes 12 days after the European Medicines Agency or EMA, the EU drug regulator, said the vaccine <u>was "safe and effective"</u> and didn't increase the risk of blood clots.

Chancellor Angela Merkel told reporters on Tuesday night that the change was prompted by the occurrence of what she called very rare but very serious cases of thrombosis among younger and predominantly female recipients of the vaccine. "We cannot ignore those cases," Ms. Merkel said. She added that the EMA and the World Health Organization were notified of the incidents.

Stock Symbol	AZN
Stock Name	ASTRAZENECA PLC
Stock Price	49.53
Stock Change	-0.19
Change %	-0.38%

ASTRAZENECA VACCINE SUSPENSION IN ITALY, GERMANY ROILS EUROPE'S INOCULATION EFFORTS

Like other European Union countries, Germany has struggled to ramp up vaccinations amid a shortage of doses and bureaucratic and logistical bottlenecks. Limiting the availability of the shot for people under 60 could make it hard for the government to reach its revised target of offering all residents a vaccine by the end of September.

"It is without a question a setback that one of our vaccines in this pandemic apparently poses a higher risk for a specific age group," Jens Spahn, the healthcare minister, said at the Tuesday press conference with Ms. Merkel.

However, he said that the country's vaccination plans wouldn't be derailed by the change in rules as long as all vaccine makers stuck to their supply schedules. He added the new rules might even mean the over-60 could be vaccinated faster.

The latest restrictions on the shot's use could exacerbate already widespread misgivings about the vaccine. Germany originally authorized the shot only for those under 65 due to a lack of data about efficacy in older age groups before briefly banning it altogether for several days earlier in March following initial blood-clotting incidents.

Since the product's approval earlier this year, local authorities have reported reluctance to take the shot among those eligible for it. Ms. Merkel acknowledged that the decision

could shake confidence in the vaccine but said that the damage would have been greater had the authorities tried to "sweep the issue under the carpet."

ASTRAZENECA TO BUY ALEXION FOR \$39 BILLION TO EXPAND IN IMMUNOLOGY

The change in Germany comes after authorities there recorded 31 cases of rare blood clotting in the brain among the nearly 2.7 million people who had received the shot by Monday. Nine people died, and all but two of the incidents affected women aged 20 to 63, according to Germany's medicines regulator, the Paul Ehrlich Institute.

"AstraZeneca continues to analyze its database on tens of millions of records for COVID-19 Vaccine AstraZeneca to understand whether these very rare cases of blood clots associated with thrombocytopenia occur any more commonly than would be expected naturally in a population of millions of people," a spokeswoman for AstraZeneca said. "We will continue to work with German authorities to address any questions they may have."

Berlin's decision was based on a new recommendation by the standing vaccination committee of the Robert Koch Institute, Germany's center for disease control, which will be published by the end of the week. The government has so far followed the recommendations of the committee.

The news comes as Germany is <u>facing a sharp increase</u> in COVID-19 infections despite imposing a succession of lockdowns since early November. Chancellor Merkel called an emergency conference with the premiers of Germany's 16 states on Tuesday to discuss the pandemic response, including the future use of the AstraZeneca vaccine.

The European Union, of which Germany is a member, purchased 400 million doses from AstraZeneca and relies on the shot for about 30% of its vaccination program.

AstraZeneca Plc has sold its 7.7% stake in Moderna Inc for more than \$1 billion after the U.S. biotechnology company's shares soared on the back of its coronavirus vaccine breakthrough. (Melissa Melvin/AP Images for Tyson Foods File)

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Germany briefly suspended the AstraZeneca rollout earlier this month after detecting seven cases of cerebral venous sinus thrombosis or CVST, a very rare and potentially deadly condition that causes blood clotting in the brain. France, Italy and other countries also temporarily halted the use of the shot.

Vaccination in most European countries resumed, however, after the European Medicines Agency ruled that the vaccine was safe for general use.

Now, after the number of CVST incidents exceeded three dozen, all of them people of working age, the German vaccine committee decided to recommend against its use in younger people. Officials of the German ministry of healthcare said that the expected incidence of CVST would be about one case in 1.6 million.

Some nations, such as Norway, haven't resumed use of the vaccine despite the EMA ruling and decided to wait for more research into the origin of a condition that appears to affect primarily younger women, a senior Norwegian healthcare official said.

Two medical teams in Germany and Norway separately concluded that the CVST incidents, which are often followed by a condition called thrombocytopenia, were caused by an autoimmune reaction prompted by the vaccine. The German team of Andreas Greinacher, professor of transfusion medicine at the Greifswald University Clinic, published their findings in a study that is yet to be peer-reviewed.

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Prof. Greinacher's team examined nine cases from Germany and Austria, and suggested that the incidents linked to the vaccine resemble a rare disorder known as heparin-induced thrombocytopenia or HIT, which they said is easily treatable with immunoglobulin and blood-thinning medicine if identified promptly. The vaccine, the study argues, generates so-called anti-PF4/heparin antibodies, which then activate thrombocytes that cause blood clotting. The condition can be diagnosed and treated in any midsize or larger clinic, Dr. Greinacher said last week.

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