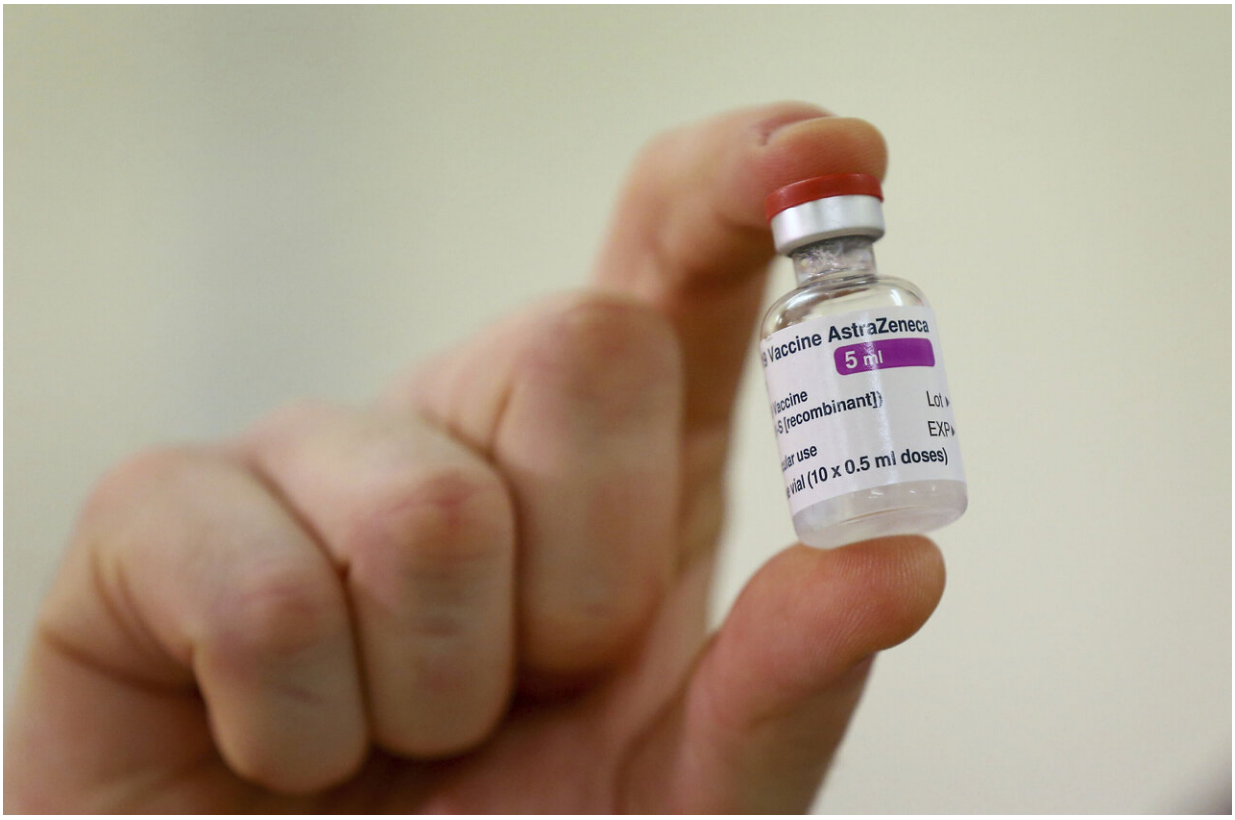
Germany expects EU to OK AstraZeneca vaccine with age caveat

January 29 2021, by Frank Jordans and Maria Cheng



In this Jan. 2, 2021 file photo a vial of the COVID-19 vaccine developed by Oxford University and U.K.-based drugmaker AstraZeneca is checked as they arrive at the Princess Royal Hospital in Haywards Heath, England. The European Medicines Agency is expected on Friday Jan. 29, 2021 to authorize use of the vaccine AstraZeneca developed with Oxford University. It would be the third cleared for use in the EU, after the BioNTech-Pfizer and Moderna vaccines. (Gareth Fuller/Pool via AP, File)

Germany's health minister said he expects the European Union's drug regulator to authorize a coronavirus vaccine made by AstraZeneca on Friday, but it may not be recommended for older adults because of insufficient data.

Jens Spahn said it wasn't clear whether the decision by the European Medicines Agency would explicitly recommend against using the vaccine in people over 65, or whether it would merely note the lack of data for older people, meaning "no restrictions but caution in certain areas." Germany will adjust its own guidance once it sees the EMA's decision.

"We don't expect an unrestricted approval," Spahn told reporters in Berlin. "The data available for older people, and that's been the debate in recent days, isn't sufficient for that."

While the AstraZeneca vaccine has been authorized for all adults in other countries, only 12% of the participants in its research were over 55 and they were enrolled later, so there hasn't been enough time to get results.

A recommendation that only people under 65 get the vaccine could complicate the rollout in many European countries that have focused on giving shots to older people first. Whatever the recommendation, the 3 million doses Germany expects to receive from AstraZeneca next month would be used, but perhaps for younger people, Spahn said.

In this Monday, Jan. 4, 2021 file photo, 82-year-old Brian Pinker receives the Oxford University/AstraZeneca COVID-19 vaccine from nurse Sam Foster at the Churchill Hospital in Oxford, England. The European Medicines Agency is expected on Friday Jan. 29, 2021 to authorize use of the vaccine AstraZeneca developed with Oxford University. It would be the third cleared for use in the EU, after the BioNTech-Pfizer and Moderna vaccines. (Steve Parsons/Pool Photo via AP, File)

On Thursday, a draft recommendation from Germany's vaccination advisory committee said the AstraZeneca vaccine should only be given to people aged 18-64 for now. Britain's medicines regulatory agency also acknowledged the limited data in older people but still cleared the shot last month for all adults, with some caution for pregnant women.

A separate study testing the AstraZeneca vaccine in the U.S. is still underway.

Julian Tang, a virologist at the University of Leicester, said he thought any recommendation to limit the vaccine's use to people under 65 was understandable, but "overly cautious."

He said that although data on the vaccine's effectiveness in older populations was limited, it was reasonable to extrapolate that it would help protect older people against COVID-19, even though there are not yet enough numbers of older people enrolled in trials to know for certain.


COVID-19 Vaccine
Injection
COVID-19 Vaccine
(ChAdOx1-S [recomb
Intramuscular use
Multidose vial (10 x

In this Jan. 11, 2021 file photo a paramedic draws a syringe of the Oxford/AstraZeneca vaccine at the mass vaccination centre in Newcastle Upon Tyne, England. The European Medicines Agency is expected on Friday Jan. 29, 2021 to authorize use of the vaccine AstraZeneca developed with Oxford University. It would be the third cleared for use in the EU, after the BioNTech-Pfizer and Moderna vaccines. (AP Photo/Scott Heppell, File)

"The vaccine clearly offers some protection and since the older 65's are your most vulnerable population, I'd think you want to get some vaccine into them sooner rather than later," he said. "If Europe and the Germans want to be nitpicky, they can restrict its use, but I think giving older people this vaccine is better than nothing."

The AstraZeneca shot would be the third COVID-19 vaccine given the greenlight by the EMA, after ones made by Pfizer and Moderna. Those were authorized for all adults.

The expected authorization of the AstraZeneca vaccine comes amid a bitter dispute between the drugmaker and the 27-nation bloc over expected supply delays.

Earlier this week, the EU lashed out at the British-Swedish drugmaker after it said it would sharply reduce initial deliveries from 80 million doses to 31 million, blaming manufacturing problems. The EU then threatened to stop any vaccines made in Europe from leaving its borders.

In this Saturday, July 18, 2020 file photo a general view of AstraZeneca offices and the corporate logo in Cambridge, England. The European Medicines Agency is expected on Friday Jan. 29, 2021 to authorize use of the vaccine AstraZeneca developed with Oxford University. It would be the third cleared for use in the EU, after the BioNTech-Pfizer and Moderna vaccines. (AP Photo/Alastair Grant, File)

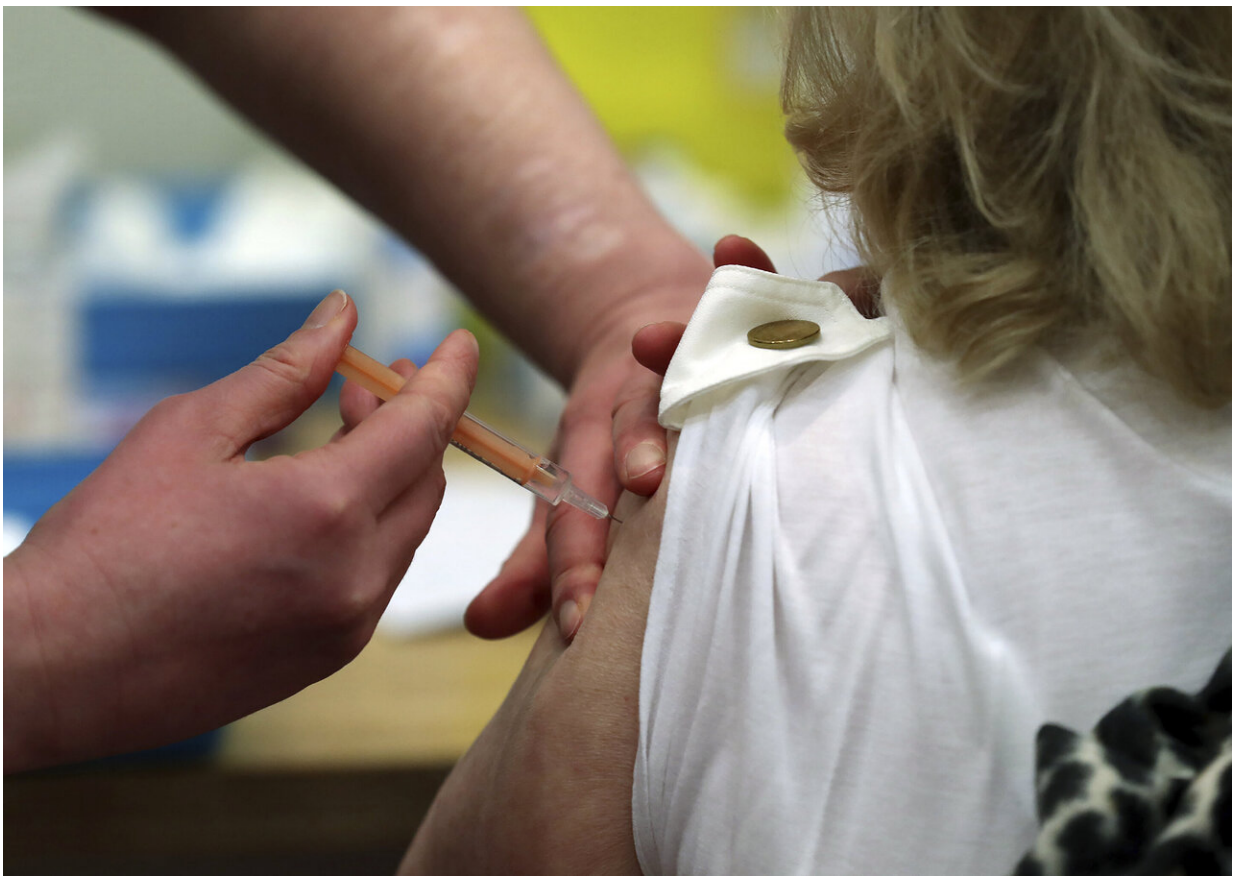
Many countries on the continent have been struggling to vaccinate people as quickly as Britain, Israel, the U.S. and elsewhere. While politicians have blamed supply problems for the slow rollout, other factors, like onerous paperwork and poor planning, have also played a role.

The AstraZeneca vaccine has already been authorized in several

countries, including Britain, India, Argentina and Mexico. The World Health Organization is also reviewing it; a recommendation from the U.N. health agency would allow its purchase and distribution to developing countries from a global program known as COVAX.

Separately, the EMA said Friday that no new side effects linked to the coronavirus vaccine made by Pfizer and its German partner BioNTech were identified in the regulator's first safety update.

Its expert committee assessed reports of people who died after getting the vaccine and said their review "did not suggest a safety concern." Earlier this month, Norwegian officials amended their vaccination advice to say that doctors should assess frail and severely ill elderly people to decide if they should be immunized.



In this Jan. 11, 2021 file photo Mary Williams, right, receives an injection of the Oxford/AstraZeneca vaccine at the mass vaccination centre in Newcastle Upon Tyne, England. The European Medicines Agency is expected on Friday Jan. 29, 2021 to authorize use of the vaccine AstraZeneca developed with Oxford University. It would be the third cleared for use in the EU, after the BioNTech-Pfizer and Moderna vaccines. (AP Photo/Scott Heppell, File)

In this Dec. 1, 2020, file photo the exterior of the European Medicines Agency is seen in Amsterdam, Netherlands. The European Medicines Agency is expected on Friday Jan. 29, 2021 to authorize use of the vaccine AstraZeneca developed with Oxford University. It would be the third cleared for use in the EU, after the BioNTech-Pfizer and Moderna vaccines. (AP Photo/Peter Dejong, File)

The EMA concluded that safety data collected on the Pfizer vaccine are "consistent with the known safety profile of the vaccine" and noted that severe allergic reactions are a known, rare side effect.

The EMA authorized the Pfizer vaccine on Dec. 21 and granted it a conditional license; Pfizer and BioNTech must submit safety reports every month in line with a heightened monitoring process.