

## EU regulator 'convinced' AstraZeneca benefit outweighs risk

March 16 2021, by Raf Casert and Frank Jordans



In this March 8, 2021 file photo, German police officer Dirk Moeller gets an AstraZeneca vaccination against Covid-19 at a new vaccination centre at the former Tempelhof airport in Berlin, Germany. The German government says it is suspending use of AstraZeneca's coronavirus vaccine over fresh reports of dangerous blood clots in connection with the shot. (Tobias Schwarz / Pool via AP, File)



The European Union's drug regulator insisted Tuesday that there is "no indication" the AstraZeneca vaccine causes blood clots as governments around the world faced the grimmest of dilemmas: push on with a vaccine known to save lives or suspend its use over reports of clotting in some recipients.

The European Medicines Agency urged governments not to halt use of the vaccine at a time when the pandemic is still taking thousands of lives each day. And already there are concerns that even brief suspensions could have disastrous effects on confidence in inoculation campaigns the world over, many of which are already struggling to overcome logistical hurdles and widespread hesitancy about experimental vaccines.

"We are still firmly convinced that the benefits of the AstraZeneca vaccine in preventing COVID-19 with its associated risk of hospitalization and death outweigh the risk of the side effects," said Emer Cooke, the head of the agency.

Many scientists have argued that even the loss of a few days in vaccinating vulnerable people could be far costlier than the impact of any rare phenomenon.

But <u>a cascading number of countries</u> have taken a different view and locked away shots from the Anglo-Swedish company, awaiting the results of an EMA review, promised Thursday.

Sweden was the latest to do so Tuesday, choosing caution over speed, even as Cooke insisted "that at present there is no indication that vaccination has caused these conditions."

Highlighting the difficulty of making such decisions at a time when people are voraciously following the ups and downs of every vaccine candidate, Sweden's state epidemiologist Anders Tegnell said that the



risk, if it existed, was rare but the country's authorities "have felt compelled to pause AstraZeneca's vaccine" after receiving ever more reports of blood clots.

Europe has the luxury to be able to pick from several vaccine candidates—but the decision of whether to suspend use of the vaccine is still not an easy one on the continent where the virus has already killed over half a million people, is surging again and where the vaccination campaign has repeatedly stumbled.



In this March 3, 2021 file photo ,a package of the AstraZeneca COVID-19 vaccine is shown in the state of Brandenburg where the first coronavirus vaccinations are given in doctors' surgeries, in Senftenberg, Germany. The German government says it is suspending use of AstraZeneca's coronavirus vaccine over fresh reports of dangerous blood clots in connection with the shot.



(Hannibal Hanschke/Pool via AP, File)

The choice may be even more fraught elsewhere because many countries are relying heavily on AstraZeneca, which is cheaper and easier to handle than some other shots. The vaccine has so far played a huge role in the global initiative to ensure vaccines get to poorer countries known as COVAX.

For instance, when Congo decided to hold off on the vaccine, it put its entire campaign on hold before it even began since it has not yet received doses of any other shot. Somalia, by contrast, went ahead with its first shots of AstraZeneca on Tuesday—including one for the health minister, who received the jab publicly to reassure the nation about its safety.

The AstraZeneca shot has already struggled to gain public trust after troubles with reporting of its data and <u>concerns about its effectiveness in</u> <u>older people</u>. The current debate could further erode confidence in the vaccine—and that skepticism could even spread to others.

"We are worried that there may be an effect on the trust of the vaccines. But our job is to make sure that the products that we authorize are safe," Cooke said.

The EMA chief noted that thousands of people across the EU develop blood clots every year for a variety of reasons and that there were no reports of increased clotting incidents in the clinical studies of the AstraZeneca vaccine. Still, experts would undertake a "very rigorous analysis" and make a recommendation Thursday.

The difficulty of the decision was clear in Thailand, the first country



outside Europe to temporarily suspend use of the AstraZeneca vaccine, only to recant on Tuesday—when its prime minister received a dose.

"There are people who have concerns," Prayuth Chan-ocha said after getting the shot. "But we must believe doctors, believe in our medical professionals."

Many other countries in Asia have likewise shrugged off concerns, but Indonesia, a nation of over a quarter-billion people, halted use of the shot this week, saying it would wait for a World Health Organization report on the issue.



In this photo released by Government Spokesman Office, Thailand's Prime Minister Prayuth Chan-ocha, front left, receives a shot of the AstraZeneca's COVID-19 vaccine at government house in Bangkok, Thailand, Tuesday, March



16, 2021. (Government Spokesman Office via AP)

In addition to the EMA, AstraZeneca and the WHO have said there is no evidence the vaccine carries an increased risk of blood clots. There have been 37 reports of blood clots among the more than 17 million people who have received the vaccine across the EU and Britain, the company said.

"This is much lower than would be expected to occur naturally in a general population of this size and is similar across other licensed COVID-19 vaccines," the drugmaker said.

But the number of countries in the bloc that are sticking with the shot is falling after heavyweights like Germany, Italy, France and Spain all said they were suspending it.

That left Belgium—and a handful of others such as Poland, Romania and Greece—increasingly isolated in their insistence that halting the shots now would cause more harm than the side effects so hotly debated.

"When you know how the virus is making the rounds, it would be very imprudent to stop," Belgian Health Minister Frank Vandenbroucke told VRT network early Tuesday.

Experts have noted that such concerns are inevitable in mass vaccination campaigns—with so many people getting shots, some are bound to get sick even if the vaccine is not to blame. That would mean "we'd have to incessantly interrupt campaigns during the coming months," Vandenbroucke said.

Still, the torrent of decisions casting doubt on the AstraZeneca vaccine



despite assurances of experts is testing public opinion.

But Bogdan Grecu, 26, who works in Romania's petroleum sector, was unfazed when he got his shot Tuesday.

"I'm pretty sure it's worth the risk," he said. "I don't think it's possible for the vaccine to create a worse reaction than the virus."

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