

EU regulators move up Pfizer vaccine assessment to Dec. 21

December 15 2020, by Kirsten Grieshaber and Frank Jordans



Christmas lights shine over a virtually empty shopping street in the old town of Duesseldorf, Germany, on Monday afternoon, Dec. 14, 2020. Chancellor Angela Merkel and the governors of Germany's 16 states agreed Sunday to step up the country's lockdown measures beginning Wednesday and running to Jan. 10 to stop the exponential rise of COVID-19 cases. (AP Photo/Martin Meissner)

Facing strong pressure from Germany and other European Union



nations, the bloc's medicines agency on Tuesday moved up a meeting to assess the Pfizer-BioNTech coronavirus vaccine to Dec. 21, likely bringing vaccinations a step closer for millions of EU citizens.

The agency said it made the decision after receiving additional data from the vaccine makers. The announcement came after Germany's <u>health</u> <u>minister</u> and others had publicly demanded that the agency move quicker than its previously planned Dec. 29 meeting at which it was to discuss approving the vaccine.

The vaccine is already being given daily to thousands of people in Britain, Canada and the United States, galling some Europeans who note that BioNTech is a Germany company.

The European Medicines Agency said it's human medicines committee "will conclude its assessment at the earliest possible timepoint and only once the data on the quality, safety and effectiveness of the vaccine are sufficiently robust and complete to determine whether the vaccine's benefits outweigh its risks."

After the committee recommends a marketing authorization, the EU's Executive Commission will "fast track its decision-making process" to giving the vaccine approval for all 27 EU nations and a few others within days, the EMA said.

"Our goal is an approval before Christmas," German Health Minister Jens Spahn told reporters earlier Tuesday in Berlin. "We want to still start vaccinating this year."





German Health Minister Jens Spahn wears a face mask as he arrives for a press conference in Berlin, Germany, Tuesday, Dec. 15, 2020 in Berlin on the new coronavirus Covid-10 pandemic. (Tobias Schwarz/Pool Photo via AP)

Asked by The Associated Press whether he had received direct confirmation that the vaccine would be approved by Dec. 23, Spahn said he had, "otherwise I wouldn't have said that."

He added, however, "the EU has to announce it."

Spahn has expressed impatience with the EMA for days, noting that Germany has created some 440 vaccination centers, activated about 10,000 doctors and <u>medical staff</u> and was ready to start mass vaccinations immediately.



Italy, where Europe's <u>coronavirus</u> outbreak erupted in February and which now leads the continent in the COVID-19 death count, also was pressing for a safe, accelerated approval process.

"My hope is that the EMA, in compliance with all safety procedures, will be able to approve the Pfizer-BioNTech vaccine earlier than expected and that vaccinations can also begin in the countries of the European Union as soon as possible," Italian Health Minister Roberto Speranza said in a statement.



A woman walks by the old town's most famous traditional pub "Uerige', closed due to pending coronavirus lockdown measures, in Duesseldorf, Germany, on Monday afternoon, Dec. 14, 2020. Chancellor Angela Merkel and the governors of Germany's 16 states agreed Sunday to step up the country's lockdown measures beginning Wednesday and running to Jan. 10 to stop the exponential rise of COVID-19 cases. (AP Photo/Martin Meissner)



The new vaccine developed by Germany's BioNTech and American drugmaker Pfizer is already being used in Britain, the United States, Canada and other countries. But Germany cannot start vaccinations because it is still waiting for approval by the EMA, which evaluates drugs and vaccines for the EU's 27 nations.

"It cannot be that a vaccine that has been developed in Germany is only approved and vaccinated (here) in January," said Christine Aschenberg-Dugnus, a federal lawmaker with the pro-business Free Democrats.

The German Hospital Association chimed in Tuesday, demanding that the EU shorten its lengthy approval process and issue emergency authorization for the Pfizer-BioNTech <u>vaccine</u>.

"I am asking myself if we really need time until Dec. 29 to reach the approval of the vaccination in Europe—Europe should try to get an emergency authorization earlier," Gerald Gass, president of the hospital association, told the RND media group. "That way we could still go into nursing homes with mobile teams before Christmas and vaccinate the residents."





People with masks pass a Christmas booth in the city center of Duesseldorf, Germany, on Monday afternoon, Dec. 14, 2020. Chancellor Angela Merkel and the governors of Germany's 16 states agreed Sunday to step up the country's lockdown measures beginning Wednesday and running to Jan. 10 to stop the exponential rise of COVID-19 cases. (AP Photo/Martin Meissner)

Part of the problem could be that the EU is seeking to kick off vaccinations in all of its nations at the same time, and Germany could be more prepared than others.

Spahn's growing anxiety comes as Germany has been hitting records of new daily infections and virus deaths in recent weeks. Hospitals and medical groups across Germany have also repeatedly warned they are reaching their limits in caring for COVID-19 patients. On Tuesday, 4,670 COVID-19 patients were being treated in German ICUs.



The nation is going into a hard lockdown Wednesday with schools and most stores shutting down at least until Jan. 10 to stop the exponential rise of COVID-19 cases.

Spahn's ministry says Germany is ready to give 3 million to 4 million BioNTech vaccination doses in January and up to 11 million doses in the first quarter of 2021.



Lights on in an apartment building in Frankfurt, Germany, Monday, Dec. 14, 2020, two days before the country heads into a hard lockdown that will shut most stores, tighten social distancing rules and close schools across the country. (AP Photo/Michael Probst)





A few people walk at the old town Christmas market in front of the town hall in Duesseldorf, Germany, Monday afternoon, Dec. 14, 2020. Chancellor Angela Merkel and the governors of Germany's 16 states agreed Sunday to step up the country's lockdown measures beginning Wednesday and running to Jan. 10 to stop the exponential rise of COVID-19 cases. (AP Photo/Martin Meissner)





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People queue in front of a shop in the city center of Essen, Germany, Monday, Dec. 14, 2020. Germany goes into a nationwide lockdown on Wednesday, Dec. 16, 2020 to fight the COVID-19 pandemic. (AP Photo/Martin Meissner)





People walk in the main pedestrian zone in Frankfurt, Germany, Monday, Dec. 14, 2020. The German government is calling on citizens to forgo Christmas shopping two days before the country heads into a hard lockdown that will shut most stores, tighten social distancing rules and close schools across the country. (AP Photo/Michael Probst)





People walk in the main pedestrian zone in Frankfurt, Germany, Monday, Dec. 14, 2020. The German government is calling on citizens to forgo Christmas shopping two days before the country heads into a hard lockdown that will shut most stores, tighten social distancing rules and close schools across the country. (AP Photo/Michael Probst)





Decoraters put a special offer advertising for the next two days at a shopping window in the city center of Essen, Germany, Monday, Dec. 14, 2020. Germany goes into a nationwide lockdown on Wednesday, Dec. 16, 2020 to fight the COVID-19 pandemic. (AP Photo/Martin Meissner)





The city centre and pedestrian zone are almost deserted in Dueren, Germany, Monday, Dec. 14, 2020. Due to the night-time exit restriction between 9 p.m. and 5 a.m., the people of in the city are only allowed to leave their apartment for important reasons. (Henning Kaiser/dpa via AP)





German Health Minister Jens Spahn speaks during a press conference in Berlin, Germany, Tuesday, Dec. 15, 2020 in Berlin on the new coronavirus Covid-10 pandemic. (Tobias Schwarz/Pool Photo via AP)

The country would be able to vaccinate up to 60% of Germany's citizens by the end of the summer, Spahn said Monday night on public broadcaster ZDF. The World Health Organization says around 60% to 70% of a population needs to be vaccinated to successfully tamp down the pandemic.

The Robert Koch Institute, Germany's central disease control center, on Tuesday reported 14,432 new confirmed cases and 500 new deaths, the third-highest number of daily deaths since the pandemic began. Germany has counted over 22,600 virus deaths overall, which is still one-



third the toll of Italy or Britain.

The institute's chief warned that the case numbers would still go up for some time despite Germany's new lockdown.

"Those older than 80 are getting more and more affected, and those are the people who get severely ill or die." Lothar Wieler warned.

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