

US expert committee recommends Pfizer Covid vaccine approval

11 December 2020

An expert committee convened by the US Food and Drug Administration voted heavily in favor of recommending the Pfizer-BioNTech Covid-19 vaccine for emergency use approval on Thursday.

The final voting tally was 17 in favor, four against and one abstention.

The committee was tasked with answering whether, "based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech Covid-19 [vaccine](#) outweigh its risk for use in individuals 16 years of age and older?"

The vote by the independent experts and researchers, including infectious disease specialists, biostatisticians and other scientists, isn't binding but the FDA is expected to follow the recommendation within the coming days.

Britain, Canada, Bahrain and Saudi Arabia have already approved the vaccine, the first in the world to complete a large-scale, phase 3 clinical trial.

Russian and Chinese vaccines are already being administered on a large scale, but without having completed comparable [clinical trials](#).

The full results of the trial, which included nearly 44,000 people, were published Thursday in the *New England Journal of Medicine*, another major milestone.

These confirmed the vaccine was 95 percent effective with no serious safety issues, an outcome that was described in an accompanying editorial as a "triumph."

Pfizer scientist Kathrin Jansen told the panel this was a result of the innovative messenger RNA technology behind the vaccine, an approach that has never before been approved.

Britain on Wednesday reported that two [health](#)

[care workers](#) developed significant allergic reactions to the vaccine as the country rolled out its massive drive Tuesday.

The FDA will therefore include a warning label on the vaccine if it's approved, the agency's Marion Gruber said.

© 2020 AFP

APA citation: US expert committee recommends Pfizer Covid vaccine approval (2020, December 11) retrieved 23 August 2022 from <https://medicalxpress.com/news/2020-12-expert-committee-pfizer-covid-vaccine.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.