EXPLAINER: Final steps in US review of COVID-19 vaccine

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Pfizer's COVID-19 vaccine is entering the final phase of review before the U.S. government decides whether to allow millions to get the shots.

The Food and Drug Administration posted a positive review of the Pfizer vaccine on Tuesday and will hold a public hearing on Thursday. Next week, it will do the same thing for Moderna's coronavirus vaccine

candidate.

A look at the process:

FDA REVIEW

The agency's scientific review is a key step—not just for the U.S.—but for countries around the world weighing whether to begin using a vaccine. Teams of FDA scientists scrutinize tens of thousands of pages of technical data provided by the companies, focusing on vaccine effectiveness, safety, side effects and the manufacturing process needed to ensure the quality and consistency of the doses.

Up until now, Pfizer and its partner BioNTech had only released minimal results about their vaccine's safety and performance in company press releases. The details have yet to be reviewed and published in a medical journal.

Unlike most other regulatory agencies worldwide, the FDA reanalyzes raw company data to verify results. FDA Commissioner Stephen Hahn says that careful approach carries weight far beyond the U.S.

"The FDA is known around the world for its rigorous standards for safety and efficacy," Hahn told The Associated Press. "I think you'll see with the data we're going to provide at the meeting that we have done our job."

VACCINE EXPERT MEETING

Next, a group of about two dozen outside experts weighs in on the FDA's findings and gives their own assessment. The panelists have expertise in vaccines, infectious diseases and medical statistics. The FDA is not required to follow their advice, though it usually does.

The daylong event also gives the agency a chance to pull back the curtain on its review process and try to assure the public that the vaccine was independently vetted. That confidence will be critical for the country's largest-ever vaccination effort. The meeting concludes with the panel's non-binding vote on whether the vaccine should be authorized for use in the U.S.

"It's both the transparency and the actual data that I think will be very important," Hahn said. "What are experts outside the agency asking? I think that will be very informative for the American people."

FDA DECISION

How soon does the FDA make a decision? There is no deadline for a ruling, but FDA's Marks said he hoped a decision on the Pfizer vaccine could come by the following week.

Importantly, if the FDA gives the thumbs-up, it would still only allow limited use in certain high-risk groups because final-stage studies are not yet complete. That comes under FDA's "emergency use authorization," which is used to speed up the availability of medical products during a health crisis. The decision amounts to a careful calculation between potential benefits and risks.