



INDIA TOP NEWS

FEBRUARY 5, 2021 / 5:30 AM / UPDATED 12 HOURS AGO

Pfizer drops India vaccine application after regulator seeks local trial

By Krishna N. Das



NEW DELHI (Reuters) - Pfizer Inc said on Friday it had withdrawn an application for emergency-use authorisation of its COVID-19 vaccine in India, after failing to meet the drug regulator's demand for a local safety and immunogenicity study.

A vial and sryinge are seen in front of a displayed Pfizer and Biontech logo in this illustration taken January 11, 2021. REUTERS/Dado Ruvic/Illustration/File Photo



The decision means the vaccine will not be available for sale in the world's two most populous countries, India and China, in the near future. Both countries are running their immunisation campaigns using other products.

Unlike other companies conducting small studies in India for foreign-developed vaccines, Pfizer had sought an exception citing approvals it had received elsewhere based on trials done in countries such as the United States and Germany.

Indian health officials say they generally ask for so-called bridging trials to determine if a vaccine is safe and generates an immune response in its citizens. There are, however, provisions under India's rules to waive such trials in certain conditions.

The U.S. company, which was the first drugmaker to seek emergency approval in India for its vaccine developed with Germany's BioNTech, made the withdrawal decision after a meeting with India's Central Drugs Standard Control Organisation (CDSCO) on Wednesday.

The drug regulator said on its website its experts did not recommend the vaccine because of side effects reported abroad were still being investigated. It also said Pfizer had not proposed any plan to generate safety and immunogenicity data in India.

"Based on the deliberations at the meeting and our understanding of additional information that the regulator may need, the company has decided to withdraw its application at this time," Pfizer said in a statement.

"Pfizer will continue to engage with the authority and re-submit its approval request with additional information as it becomes available in the near future."

Reuters was the first to break the news.

Pfizer had sought authorisation for its vaccine in India late last year, but the government in January approved two much cheaper shots - one from Oxford University/AstraZeneca and another developed in India by Bharat Biotech with the Indian Council of Medical Research.

 companies had applied for approval of their vaccines after Pfizer, and their trials are ongoing in India. Local company Dr. Reddy's Laboratories Ltd is running trials for Russia's

Sputnik V vaccine, which is expected to be approved this month or next.

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