India's expert panel rejects Pfizer's application for Covid-19 vaccine

Cites serious adverse events

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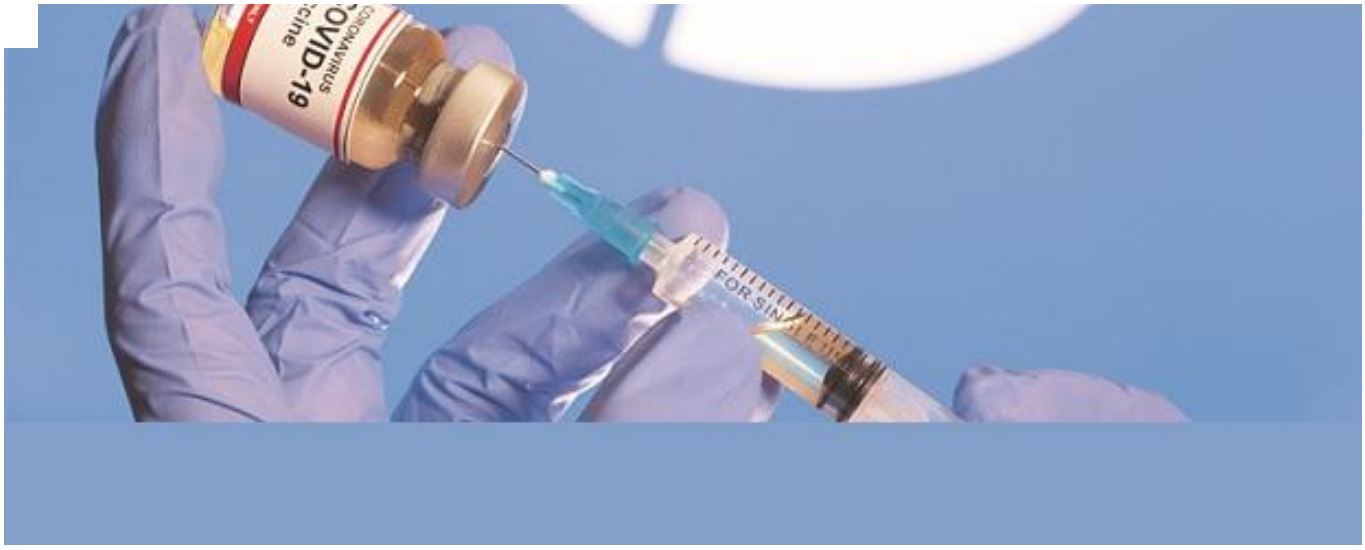
Last Updated at February 6, 2021 02:27 IST



Pfizer on Friday said it had withdrawn its application, and would submit additional data as it becomes available in the near future

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India's expert panel on Covid-19 drugs and vaccines has turned down US pharmaceutical major Pfizer's application for emergency use authorisation for its vaccine candidate -- already in use in the US and UK -- in the absence of any plan on the firm's part to generate safety and immunogenicity data in the local population.

Immunogenicity means the ability of a vaccine candidate to generate the desired immune response against the pathogen.

Pfizer on Friday said it had withdrawn its application, and would submit additional data as it becomes available in the near future.

India has insisted on having a safety and immunogenicity trial in the country. This became an important consideration for the expert panel, which noted that there had been several serious adverse events in the case of the Pfizer-BioNTech vaccine and the causality of these events was being investigated.

The company met the subject expert committee (SEC) on February 3. Sources revealed that the Indian drug regulator had decided to not allow emergency use approval for any vaccine candidate unless it was backed by data from a local bridge trial. "Safety and immunogenicity data from at least a 1,600-volunteer bridge trial in India is a must for the expert panel to recommend approval to any vaccine candidate," said a source in the know.

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A spokesperson for Pfizer, however, said, “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. Pfizer will continue to engage with the authority and resubmit its approval request with additional information as it becomes available in the near future.”

The SEC noted, “The firm presented its proposal for emergency use authorisation of its Covid-19 mRNA vaccine, BNT162b, before the committee. The committee noted that incidents of palsy, anaphylaxis, and other serious adverse events (SAEs) have been reported during post marketing, and the causality of the events with the vaccine is being investigated. Further, the firm has not proposed any plan to generate safety and immunogenicity data in Indian population. After detailed deliberations, the committee has not recommended for grant of permission for emergency use in the country at this stage.”

Earlier, the firm had missed appearing before the SEC thrice, blaming a short notice and time-zone difference for it.

The source added that Pfizer had also indicated there were no plans to manufacture the vaccine in India. “Pfizer's shipments have been falling globally, and the firm may have decided to focus on these geographies for the moment and increase production. To get approval in India, it would not only have to come back wit data on facial palsy cases, but also with the clinical trial protocol for the bridge trial," said the source.

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The US administration is trying to order more Covid-19 vaccines from Pfizer and Moderna through the summer. These companies have to supply 100 million doses each to the US and will have to significantly increase the number of weekly doses they release to achieve that goal.

While it has withdrawn the application, the firm said committed to making the vaccine available for use in India.

”Pfizer remains committed to making its vaccine available for use by the government in India and to pursuing the requisite pathway for emergency use authorisation that enables the availability of this vaccine for any future deployment," it said. Pfizer did not wish to comment on when it can re-apply for approval in India.

The vaccine requires refrigeration at minus 70 degree Celsius. The company had drawn up elaborate

d-chain plans for the same.

ead our full coverage on Pfizer

First Published: Sat, February 06 2021. 02:19 IST

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