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Pfizer Withdraws EUA Application for COVID Shot in India After Regulator Asks for Independent Safety Study

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Pfizer, Inc. has withdrawn its emergency use authorization (EUA) application for its experimental BNT162b2 (also known as "Comirnaty") messenger RNA (mRNA) COVID-19 biologic (developed in collaboration with Germany's BioNTech) in India.[1]

Pfizer was the first pharmaceutical company to apply for an EUA to distribute a COVID biologic in India in 2021. However, India's regulatory agency approved two other COVID vaccines that are more cost effective: AstraZeneca/Oxford University's experimental AZD1222 vaccine and the locally-manufactured BBV152 ("Covaxin") vaccine by Bharat Biotech.[2]

During Pfizer's meeting with India's drug regulatory agency, the Central Drugs Standard Control Organization (CDSCO), the pharmaceutical decided to withdraw its application after the regulator requested a local trial on the vaccine's safety and immunogenicity specifically for Indians.[3]

After a meeting with Pfizer officials, CDSCO said, "After detailed deliberation, the committee has not recommended grant of permission for emergency use in the country at this stage."[4]

Pfizer Refused to Conduct Local Safety Trial for Its COVID Biologic Before Being Denied EUA in India

In order for the CDSCO to grant Pfizer an EUA for BNT162b2, the drugmaker was required to conduct a local clinical trial in India to determine if the vaccine is safe and generates an adequate immune response in its citizens.[5]

Vinod K. Paul, head of India's government panel on vaccine strategy said that all foreign developed vaccines have to undergo a "bridging trial" in India in order to receive approval.

A “bridging trial” is required to determine the immune response and safety record of the vaccine in population with a different genetic makeup than in Western nations.[6]

Pfizer applied for an exemption from India’s “bridging trial” requirement by citing that it has received EUA approvals in other countries based on clinical trials conducted in the United States and Germany. Although there are provisions under India’s law to waive the requirements of “bridging trials” in certain circumstances, India’s regulatory agency decided not to waive the requirement for BNT162b2.[7]

The CDSCO’s website states:

> The firm presented its proposal for emergency use authorization of COVID19 mRNA Vaccine BNT162b before the committee. The committee noted that incidents of palsy, anaphylaxis and other SAE’s 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 deliberation, the committee has not recommended for grant of permission for emergency use in the country at this stage.[8]

Since BNT162b2 must be stored at a low temperature of minus 94 Fahrenheit, Indian Health Ministry officials said that the biologic is not the best option for the country given that it requires expensive freezers that are not readily available in India.[9]

Currently, a local pharmaceutical company in India known as Dr. Reddy’s Laboratories is conducting a “bridging trial” for Russia’s COVID vaccine called Sputnik Light (a component of Sputnik V) developed by Moscow’s Gamaleya Institute of Epidemiology and Microbiology, which is expected to be approved for EUA in India.[10]

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Notes

[1] CNBC. Pfizer withdraws application for emergency use of its Covid-19 vaccine in India. Feb. 5, 2022.

[2] Ibid.

[3] Ibid.

[4] Deutsche Welle. India: Pfizer withdraws COVID vaccine application for emergency use. Feb. 5, 2022.

[5] Das K. Pfizer drops India vaccine application after regulator seeks local trial. *Reuters* Feb. 5, 2022.

[6] Deutsche Welle. India: Pfizer withdraws COVID vaccine application for emergency use. Feb. 5, 2022.

[7] Das K. Pfizer drops India vaccine application after regulator seeks local trial. *Reuters* Feb. 5, 2022.

[8] Central Drugs Standard Control Organization. Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 141st meeting held on 03.02.2021 at CDSCO, HQ New Delhi. Feb. 3, 2022.

[9] Deutsche Welle. India: Pfizer withdraws COVID vaccine application for emergency use. Feb. 5, 2022.

[10] Das K. Pfizer drops India vaccine application after regulator seeks local trial. *Reuters* Feb. 5, 2022.

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