Pfizer Suffers Black Eye as Drug Regulators Bar 2.8 Billion People from Company's COVID Vaccine

Description

INDIA/CHINA/USA: Drug-maker Pfizer has backed away from efforts to secure emergency-use authorization in India for its COVID-19 vaccine.

India's Central Drugs Standard Control Organization said its experts did not support the vaccine because there are still investigations taking place into side effects that have been reported in other countries.

Indian officials had demanded Pfizer conduct a safety and efficacy study in India, according to Reuters.

"The firm presented its proposal for emergency use authorization of Covid-19 mRNA Vaccine BNT162b before the committee. The committee noted that incidents of palsy, anaphylaxis and other SAEs (serious adverse events) have been reported during post-marketing and the causality of the events with the vaccine is being investigated," India's ThePrint reported, citing minutes of the Feb. 3 meeting of the group's experts.

The vaccines by Pfizer and Moderna have both been linked to an increased risk of myocarditis in some studies.

China has never approved the vaccine for use there, either, according to Bloomberg. That means that the potential market of China's 1.45 billion people and India's 1.4 billion people appears to be beyond Pfizer's reach.

However, China's National Medical Products Administration has conditionally approved the Pfizer drug Paxlovid for adults with mild to moderate COVID-19 and a high risk of serious illness, Reuters reported.

Although other drugmakers who wanted to enter the Indian market conducted drug trials there, Pfizer had sought an exception to the rule based on trials done elsewhere.

"The data collected has been endorsed by various regulatory agencies (including the most evolved) and they have given EUA [based on] … that data," Pfizer told Reuters in a statement.

Are these drugmakers getting too powerful?

Yes: 99% (2045 Votes)

No: 1% (12 Votes)

“Given our exclusive priority to government supply, we look forward to a confirmation from the government on necessary supplies, [on the] basis [of] which we will take the regulatory process forward, as we have done across the world,” it said.

India’s Central Drugs Standard Control Organization said Pfizer officials were no-shows at meetings after the company’s application was initially submitted in December.

Pfizer, in response, said, “The company representatives have been unable to participate in previous meetings due to extremely short notices of a few hours or less and time-zone limitations,” according to The Print.

“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.

Although Pfizer has not been able to crack the Indian market, a new Russian-made vaccine called Sputnik Light has been approved, according to the BBC.

By Jack Davis
Category

1. Health-Wellness-Healing-Nutrition & Fitness
2. Main
3. Politics-Geopolitics-Gov.-Events

Tags

1. Pfizer

Date Created
02/20/2022