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APPLICATION SUBMITTED MONTHS AGO: DRUGMAKER

Pfizer in talks with govt over 'expedited nod' for vaccine

ENS ECONOMIC BUREAU
NEW DELHI, MAY 3

DRUG MAJOR Pfizer on Monday said it was in talks with the government to seek an "expedited approval pathway" for its Covid-19 vaccine, adding that while application to register its vaccine "was submitted months ago", it has not been done yet.

"Pfizer is aware that access to vaccines is critical to ending this pandemic. Unfortunately, our vaccine is not registered in India although our application was submitted months ago. We are currently discussing with the Indian government an expedited approval pathway to make our Pfizer-BioNTech vaccine available for use in the country," the company's chairman and CEO Albert Bourla wrote to Pfizer's India employees in a letter, which was posted on LinkedIn.

The pharmaceutical company had earlier said that it had decided to prioritise orders from the government, and supply doses of its Covid-19 vaccine "only through government contracts" in India.

On December 4, the New York-headquartered firm had approached India's drug regulator for restricted use permission of its Covid-19 vaccine — becoming the first vaccine maker to approach the authorities. However, on February 5, the company said it was withdrawing its application after an expert body under the Central Drugs Standard Control Organisation (CDSCO) raised safety concerns, and asked it to conduct local trials in the country to prove the safety of the vaccine in the Indian population.

While Pfizer had not conducted local trials or bridging studies of its vaccine in India, provisions under India's Clinical Trial Rules, 2019, allowed the company to seek approval with waivers on local testing, as it had already received approval from a foreign regulator recognised by the CDSCO.

However, with the second surge of Covid-19 cases in the country and a potential shortage of vaccine doses from the two domestic manufacturers — Covishield by Serum Institute of India and Covaxin by Bharat Biotech — the Union Government reversed its position early last month and allowed vaccines with Emergency Use Authorisations (EUAs) in the US, UK, EU and Japan, as well as those with WHO Emergency Use Listing, to receive restricted use approvals in India before conducting bridging studies.

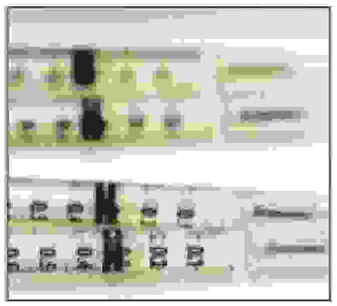
This was done with an aim to attract more foreign vaccine into the country, particularly considering that the government opened up the inoculation drive for the population in the age bracket of 18-44 years May 1 onwards.

In his letter, Bourla also wrote that Pfizer's distribution centres in the US, Europe and Asia were "rushing shipments of Pfizer medicines" that the Government of India has identified as part of its Covid-19 treatment protocol.

"We are donating these medicines to help make sure that every Covid-19 patient in every public hospital across the country can have access to the Pfizer medicines they need free of charge. This includes steroid medications to reduce inflammation, anticoagulants to prevent blood clotting and antibiotics that treat secondary bacterial infections…These medicines, valued at more than $70 million, will be made available immediately, and we will work closely with the government and our NGO partners to get them where they are needed most," he wrote.

DONATES DRUGS WORTH $70 MN

PFIZER CHIEF Albert Bourla said on Monday the firm is donating medicines worth $70 million for treatment of Covid patients in India. "We are deeply concerned by the critical Covid situation in India, and our hearts go out to you, your loved ones and all the people of India," he said.



Syringes with Pfizer's Covid vaccine in Miami. *AP file*