

# THE STORAGE TALE OF TWO VACCINES

Moderna's vaccine offers great promise, especially for developing countries, compared to Pfizer's vaccine

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A week after Pfizer announced encouraging results of its mRNA vaccine for COVID19 based on an interim analysis of a large Phase3 trial that is underway, data from the Phase3 trial of the vaccine of the U.S. based Moderna revealed very encouraging results. The interim results of Moderna's mRNA vaccine show that it has 94.5% efficacy in preventing COVID19. The interim analysis, which was based on 95 cases, found that 90 participants in the placebo group had symptoms of COVID19, while only five participants in the vaccinated group had developed symptoms. Importantly, Moderna revealed that the vaccine might be able to prevent severe disease.

## A STRIKING DIFFERENCE

More than the marginally better efficacy of the Moderna vaccine compared with the Pfizer vaccine, the striking difference lies in better thermo stability at relatively higher temperatures. The stability of the Moderna vaccine at  $-20^{\circ}\text{C}$  for up to six months,  $2^{\circ}\text{C}$ - $8^{\circ}\text{C}$  for 30 days, and at room temperature for up to 12 hours will be critical for the broad rollout of the vaccine in most countries, particularly in developing countries. In contrast, Pfizer's mRNA vaccine requires storage at  $-70^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$ , which makes vaccine shipping and storage logistics a nightmare even in developed countries. If making available storage facilities at such low temperatures for hundreds of million doses of the vaccine is a challenge even in the U.S. and other developed countries, it will be impossible for countries in the Global South to establish such facilities at scales in a short time. Against this background, Moderna's vaccine offers great promise.

While Pfizer will surely be examining the possibility of reformulating the vaccine to make it stable at higher temperatures without compromising the effectiveness of the vaccine, the ready availability of such a vaccine from Moderna increases the probability of wider access in most countries when millions of doses are manufactured. On November 12, Germany based CureVac too reported that its mRNA vaccine is "stable" for up to three months at  $5^{\circ}\text{C}$  and up to 24 hours at room temperature.

Most districts in India that are under the universal immunisation programme already have facilities to store huge volumes of the oral polio vaccine at  $-20^{\circ}\text{C}$ . Hence, Moderna's mRNA vaccine can be made available in most parts of the country as it remains stable for 30 days at  $2^{\circ}\text{C}$ - $8^{\circ}\text{C}$ . However, no vaccine manufacturer in India has tied up with Moderna to make the vaccine in India, and as on October 31, "discussions about the terms of India's potential participation" in

GAVI's COVAX Advance Market Commitment for COVID19 vaccines were only getting “underway”.

### **A NOVEL TECHNOLOGY PLATFORM**

The Pune based Genova Biopharmaceuticals Limited, a subsidiary of Emcure Pharmaceuticals Limited, is also developing a mRNA vaccine. It has completed animal trials and may soon begin human clinical trials. According to the CEO, Dr. Sanjay Singh, the vaccine has been found to be stable for more than 45 days at 2°C-8° C.

Apparently, Genova was very clear from the beginning that a mRNA vaccine that requires extremely cold storage facilities will not be feasible for India and hence worked on a novel technology platform that will allow the vaccines to remain stable at higher temperatures. Improving the thermo stability of mRNA vaccines boils down to the nature of the lipid nano particle that binds the mRNA and the clean mRNA preparation in cGMP (current Good Manufacturing Practice) conditions.

The charge interaction between the lipid nano particle and the mRNA renders stability to Genova's vaccine at higher temperature — 2°C- 8° C, says Dr. Singh. Margaret Liu, a vaccine researcher who chairs the board of the International Society for Vaccines, explains lipid nano particle encapsulation as “putting chocolate inside a candy coating so the chocolate doesn't melt”. Despite the encapsulation with lipid nano particles, mRNA, which is very fragile, might fall apart, thus necessitating storage at low temperatures.

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