Why Is China Importing COVID-19 Vaccine Now?

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Currently, there is a lot of discussion globally, and in India, regarding coronavirus disease 2019 (COVID-19) pandemic and its vaccine.[1-3] The earliest regulatory approval for COVID-19 vaccine was for Sputnik V in Russia. And now Pfizer's BioNTech mRNA vaccine has become the first vaccine to receive regulatory approval in the Western world (UK, Canada, Belgium, Bahrain, Mexico, USA, Israel, Saudi Arabia, and now Peru and Chile). The hot debate now in everyone's mind is whether to be vaccinated or not.

The development of a vaccine for this pandemic in less than 1 year has been a remarkable achievement. Yet many questions remain. The emergency use authorization has been a delicate balance in the urgency to gain the upper hand against the COVID-19 pandemic on the one hand and ensuring the safety (and efficacy) for the millions who will potentially be vaccinated without the backing of robust data on the other hand. We only know the short-term outcome taking the help of surrogate end points that varied from trial to trial. Even the dose of the same vaccine has been different from country to country. No trial has vaccinated anyone below the age of 15 years.

Let us take a step back and look at the status of COVID-19 in the country where it all started, China.

By December 17, 2020, China had an overall COVID-19 death toll of 4,634 people with a total of 86,777 infected cases.[4] Eight months earlier, on April 17th, they had reported 325 new cases, after which the pandemic seemed to have ceased for them, with no active cases (►**Fig. 1**); the only exception being 15 new cases discovered on May 13th in Wuhan.[5]

How did China manage this while COVID-19 continued to be on rampage in many other parts of the world still remains an enigma. Did they manage it because of rapid development, manufacture, and deployment of an effective vaccine? (We believe, probably not, vide infra).

On September 25th, it was reported that China shall produce 610 million doses of COVID-19 vaccine before the end of 2020.[6] Also they would be geared up to produce another billion doses in 2021. They claimed a leadership position with 59 vaccine candidates being developed, 11 Chinese vaccines having reached human clinical trials, 4 of them in phase three. Their ministry of science and technology claimed that trials were "progressing smoothly." They also claimed that "hundreds of thousands" of frontline workers had been vaccinated from July onward (under emergency use license) without any serious adverse reactions.

Three specific vaccines (two produced by China National Biotec Group [CNBG], subsidiary of Sinopharm; one by Sinovac) had already been tested in 35,000 plus volunteers as part of phase three trials in the Middle East, South America, and Southeast Asia.[6] In addition, they claimed that a fourth vaccine jointly developed by the Chinese military and CanSino Biologics was entering phase three trials in Europe and Asia.

Subsequently, based on phase three trial data (from 50,000 recipients), CNBG applied to Chinese regulators for marketing approval, hoping to beat Western drug makers like Moderna and Pfizer in the race to contain the global pandemic.[7]

In the meantime, Pfizer (USA) and BioNTech (Germany) were jointly and simultaneously developing four mRNA candidate vaccines—collectively called the BNT162 vaccine program. Of these, BNT162b1 and BNT162b2 were the most promising and received fast track designation in USA. This was based on their U.S. Food and Drug Administration (FDA) analysis of animal studies as well as human phase one and two studies conducted in USA and Germany. Both these vaccine candidates were nucleoside-modified RNAs formulated in lipid nanoparticles. The difference was that BNT162b1 encoded severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) receptor-binding domain antigen, whereas BNT162b2 had the SARS-CoV-2 full-length spike protein antigen.[8]

But safety continued to be a top priority for health authorities and drug regulators. Three companies (China's Sinovac

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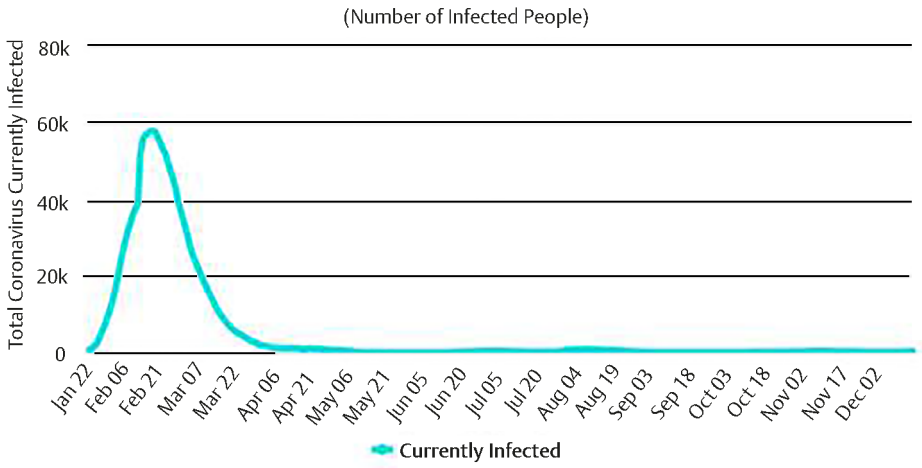

Fig. 1 Active coronavirus disease 2019 cases in China—January to December 2020.

Biotech Ltd.; UK's AstraZeneca; and USA's Johnson & Johnson) had to pause their trials, albeit temporarily, after participants developed serious adverse reactions.[9]

Another concern of ours was also regarding the efficacy data. While Pfizer (90% protection) and Russia (Sputnik V, 92% protection) had revealed this data, CNBG failed to publicly release efficacy data (although, in December 2020, United Arab Emirates (UAE) and Bahrain had given full approval to the Sinopharm Chinese vaccine on the basis of 86% claimed efficacy).[10,11]

With a UAE press release claiming 99% of vaccinated individuals developed neutralizing antibodies, even before Sinopharm made any statements, we are left with more questions than answers. This is in stark contrast to their rival publishing their phase three trial results in the *New England Journal of Medicine*.[12]

Chinese state media have stated that Sinopharm's vaccine has prepurchase orders of billions of doses from more than 100 countries, including USA, in Europe and in Africa.[6,7]

With this background, we cannot be blamed in assuming that China has achieved freedom from COVID-19 (like New Zealand) and that their indigenous vaccine development program was on schedule to protect their community.

So, recent developments came as an unexpected surprise. A commercial Chinese pharma company decided to sign up, conduct trials and plans to apply for Chinese marketing approval for Pfizer's COVID-19 vaccine.[13] Shanghai-based Fosun Pharmaceutical Group signed up with Pfizer for the BioNTech mRNA vaccine. They have begun phase two clinical trials in China as part of the mandatory requirement before filing for marketing authorization.[14] This deal worth 135 million USD was signed as early as June 2020—for the BNT162b2 "safer" version of the Pfizer vaccine (approved by UK on December 2, 2020 and US FDA on December 11, 2020).[15,16] The clinical trial is being conducted by the Chinese government's Center for Disease Control and Prevention in the Jiangsu Province. It is expected to enroll 960 subjects between the age of 18 and 85 years in a 1:3 randomization (75% receiving the vaccine and 25% receiving the placebo). The company is calling it a bridging study to extrapolate the BioNTech vaccine Western world data and show its equivalence in the Chinese population.[13,14]

Under the circumstances, the world should be asking the following questions:

1. How come China has no COVID-19 case since May 2020?
2. If there are no new cases, why are they still developing COVID-19 vaccines?
3. If their vaccine development is on track, why is China not divulging/publishing/providing public access to its safety and efficacy data?
4. If their own vaccine has robust safety and efficacy data, why is a commercial Chinese health care company willing to pay millions of dollars for the Pfizer vaccine?
5. In view of no reported COVID-19 cases in China since May 2020 and Chinese vaccine gaining approved from use in two international countries, what is the business plan for the imported Pfizer vaccine that will make commercial sense (and profit) for Fosun Pharmaceutical in China?
6. Why is the Chinese government, through Fosun Pharmaceutical, actively promoting the Pfizer vaccine study only in China's Jiangsu Province?

Conflict of Interest
None declared.

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