CORONAVIRUS | 80,217 views | Apr 9, 2020, 07:40am EDT

India's Drugmakers Ramp Up Production Of 'Game-Changer' Coronavirus Drug Hydroxychloroquine

Anu Raghunathan Contributor ⓘ
Asia
I write about Indian entrepreneurs.

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As the COVID-19 pandemic widens across the world, there has been a sudden interest in an anti-malarial and anti-inflammatory drug called hydroxychloroquine. It's being touted, notably by U.S. president Donald Trump, as "one of the biggest game changers in the history of medicine" and a treatment for the coronavirus despite inconclusive scientific evidence.

India, which manufactures 70% of the world's supply of hydroxychloroquine, banned its export on March 25. But after Trump called Indian Prime Minister

(2% of the global total) in 2018, according to the World Health Organization's 2019 malaria report. Chloroquine phosphate is typically used to treat malaria but hydroxychloroquine, which is a less toxic variant, is also used in some cases.

Meanwhile, the Indian government was also working on creating a reserve to meet domestic needs. Both Zydus Cadila and Ipca Labs have been working to meet the requirements of the Indian government.

"The priority is to manufacture this drug versus anything else," says Sharvil Patel, managing director at Ahmedabad-based Zydus Cadila, which had $1.9 billion in revenues in fiscal 2019. "We have ramped up our production of hydroxychloroquine from 3 metric tons per month to 20 to 30 metric tons per month and can scale it up further to 40 to 50 metric tons if there is a requirement."

Ipca Labs, which has 20-metric-ton capacity, can produce 100 million tablets a month. "The Indian government has placed a significant order," says Ajit Kumar Jain, joint managing director of Ipca Labs. "We can increase our manufacturing capacity to 26 metric tons in a month or two. We are also simultaneously ramping up our packing and labelling lines."

Both pharma companies are backward integrated for production, which means that they have the necessary raw materials and key starting ingredients.

Even though Ipca Labs has been under a U.S. Food and Drug Administration import alert, which has barred it from selling in the U.S. since 2015 for violation of good manufacturing practices, the U.S. FDA made an exception on March 20, allowing the import of active pharmaceutical ingredients of hydroxychloroquine sulphate and chloroquine phosphate produced at its plant in Ratlam and hydroxychloroquine sulphate tablets produced at its formulations plants at Pithampur and Piparia. In a stock exchange filing, the company has stated that the U.S. FDA could reverse this exception if the shortage situation improves.

Ipca Labs produces hydroxychloroquine across four to five plants in western India, while Zydus Cadila also manufactures across multiple plants. "The focus is to ensure that there are sufficient quantities of the drug so that it can be made available to patients," says Zydus Cadila's Patel.

Narendra Modi requesting for supplies, the ban was reversed on Tuesday; Trump had threatened “retaliation” if India were to refuse.

After the ban lifted, Trump was quick to thank India on Twitter.

The U.S., which has reported more than 430,000 COVID-19 cases and over 14,000 deaths as of Wednesday, has bought 29 million doses of hydroxychloroquine. Meanwhile, India has reported almost 6,000 cases and more than 170 deaths.

Against this diplomatic backdrop, two Indian pharmaceutical companies, Zydus Cadila—controlled by billionaire Pankaj Patel—and Ipca Laboratories—a $533 million outfit chaired by Premchand Godha, are ramping up production to meet the sudden surge in demand. Shares of Zydus Cadila and Ipca Labs, both listed in India, are up 40% and 29%, respectively, since March 27.

India is a dominant manufacturer of hydroxychloroquine because it is an inexpensive drug used to treat malaria, rheumatoid arthritis and lupus. India had about 6.8 million malaria cases (3% of the global total) with nearly 8,000 deaths

Smaller players like Goa-based Wallace Pharmaceuticals have the ability to produce, but do not have access to the raw materials like hydroxychlorine sulphate—which is produced by Indian and Chinese manufacturers.

“At this point we are trying to establish a stable source of the bulk drug hydroxychloroquine sulphate, which appears to be tightly controlled by a few manufacturers in India,” says Vinay Pinto, an executive director at Wallace. “I believe a few more active pharmaceutical ingredient manufacturers can produce these in India and China, but prices have spiked several times, so profitability will be a challenge as this is a price-controlled product in India. But in the interest of millions of patients in India, we will continue to manufacture the product.”

Pharma trade bodies have also noted that Indian manufacturers have the ability to ramp up quickly. “This was a dormant molecule,” says Ashok Kumar Madan, executive director of the Indian Drug Manufacturers' Association. “Its use was very limited but now there is sudden surge in demand. We have enough spare capacity.”

Sudarshan Jain, secretary general of the Indian Pharmaceutical Alliance, an industry group, says that “the domestic demand is 3 million tablets a month but we have the capacity to go up to 150 million to 200 million tablets a month easily.” He adds that “it is very difficult to predict demand going forward because we do not know how many will be affected.”

Also, it is not a proven treatment for COVID-19 given that there are no regulatory approvals. However, the Indian Council of Medical Research—India’s highest body—has recommended the use of the drug for healthcare workers on a preventive basis as well as for families of COVID -19 patients. But it is available on a prescription basis only.

Meanwhile, the U.S. FDA has issued an “emergency use authorization” to treat adults and adolescents who cannot participate in a clinical trial. The WHO has also included the drug in an international clinical trial called the “solidarity” trial which is currently evaluating four different treatment options.

But an article in the medical journal published in the Lancet on April 1, warned that “virologists and infectious disease experts caution that the excitement is premature.”

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Anu Raghunathan

I am a contributing editor of Forbes Asia. I cover Indian entrepreneurs and their struggles and successes in their journey to wealth-creation. Previously, I worked as a... **Read More**

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