



## Chinese Scientists Believe New Drug Can Stop Covid-19 'Without Vaccine', Claim Success at Animal-testing Stage



A Chinese laboratory has been developing a drug it believes has the power to bring the coronavirus pandemic to a halt. The outbreak first emerged in China late last year before spreading across the world, prompting an international race to find treatments and vaccines.

A drug being tested by scientists at China's prestigious Peking University could not only shorten the recovery time for those infected, but even offer short-term immunity from the virus, researchers say.

Sunney Xie, director of the university's Beijing Advanced Innovation Center for Genomics, told AFP that the drug has been successful at the animal testing stage.

"When we injected neutralising antibodies into infected mice, after five days the viral load was reduced by a factor of 2,500,"

said Xie. "That means this potential drug has (a) therapeutic effect." The drug uses neutralising antibodies -- produced by the human immune system to prevent the virus infecting cells -- which Xie's team isolated from the blood of 60 recovered patients. A study on the team's research, published Sunday in the scientific journal *Cell*, suggests that using the antibodies provides a potential "cure" for the disease and shortens recovery time.

Xie said his team had been working "day and night" searching for the antibody. "Our expertise is single-cell genomics rather than immunology or virology. When we realised that the single-cell genomic approach can effectively find the neutralising antibody we were thrilled."

He added that the drug should be ready for use later this year and in time for any potential winter outbreak of the virus, which has infected 4.8 million people around the world and killed more than 315,000.

"Planning for the clinical trial is underway," said Xie, adding it will be carried out in Australia and other countries since cases have dwindled in China, offering fewer human guinea pigs for testing.

"The hope is these neutralised antibodies can become a specialised drug that would stop the pandemic," he said. China already has five potential coronavirus vaccines at the human trial stage, a health official said last week. But the World Health Organization has warned that developing a vaccine could take 12 to 18 months.

Scientists have also pointed to the potential benefits of plasma -- a blood fluid -- from recovered individuals who have developed antibodies to the virus enabling the body's defences to attack it. More than 700 patients have received plasma therapy in China, a process which authorities said showed "very good therapeutic effects".

"However, it (plasma) is limited in supply," Xie said, noting that the 14 neutralising antibodies used in their drug could be put into mass production quickly. Prevention and cure Using antibodies in drug treatments is not a new approach, and it has been successful in treating several other viruses such as HIV, Ebola and Middle East Respiratory Syndrome (MERS).

Xie said his researchers had "an early start" since the outbreak started in China before spreading to other countries.

Ebola drug Remdesivir was considered a hopeful early treatment for COVID-19 -- clinical trials in the US showed it shortened the recovery time in some patients by a third -- but the difference in mortality rate was not significant. The new drug could even offer short-term protection against the virus. The study showed that if the neutralising antibody was injected before the mice were infected with the virus, the mice stayed free of infection and no virus was detected. This may offer temporary protection for medical workers for a few weeks, which Xie said they are hoping to "extend to a few months".

More than 100 vaccines for COVID-19 are in the works globally, but as the process of vaccine development is more demanding, Xie is hoping that the new drug could be a faster and more efficient way to stop the global march of the coronavirus. "We would be able to stop the pandemic with an effective drug, even without a vaccine," he said. (Source: News18)

## India Can Become the Pharmacy Of the World

There is an opportunity for the Indian pharmaceutical industry to play a larger role in global drug supply-security. Financial and policy incentives will help make this happen. In 1969, Indian pharmaceuticals had a 5 per cent share of the market in India, and global pharma had a 95 per cent share. By 2020, it was the reverse, with Indian pharma having an almost 85 per cent share and global, 15 per cent. Over the last 50-plus years — in terms of both meeting the domestic needs as well as building a leading position in the global pharmaceuticals landscape — Indian firms have been successful. India already contributes over 20 per cent by value to the global generics market, with Indian products contributing over 40 per cent (by volume) of US drugs.

There is a saying — why waste a good crisis? The Covid-19 crisis provides an opportunity to the Indian pharmaceutical industry to play an even more important role in global healthcare. There is a potential opportunity for India to truly play the role of ‘pharmacy of the world’. How can the pharmaceuticals industry in India use the opportunity to leapfrog into the future using the impetus provided by Covid-19?

The industry in India is worth about \$37 billion, with exports accounting for about \$18 billion. Interestingly, the prices of medicines in India are amongst the lowest in the world, partly because they are characterised by very high competition. The Herfindahl index is a measure of competitive intensity of an industry, and measures the size of firms in relation to the industry. Unconcentrated markets have a Herfindahl index value less than 0.15 while highly concentrated markets have Herfindahl index values greater than 0.25. We calculated the Herfindahl index for top seven therapeutic categories from the molecules in India, with an annual sale of at least ₹100 crore. The results show the sample having an Herfindahl index of less than 0.15, indicating unconcentrated markets with very high levels of competition. On the whole, the analysis of the Indian pharmaceutical industry reveals a highly competitive industry structure, and based on the standard economic theories, the competitive market structure should lead to market clearing prices and increased consumer surplus. With increased competition comes an automatic downward price pressure.

An AIOCD-AWACS MAT 2019 report shows that 11 per cent of the formulations in India are under the price point of ₹5. There are studies which document that prices of Indian generic medicines are amongst the lowest in the world.

How does this help at this time of Covid-19? Despite having some of the lowest prices in the world, leading Indian firms have the capacity to not only serve the Indian market for essential drugs but also supply the world.

So we should first use this opportunity to increase the production of drugs in India by supporting and streamlining pharmaceutical manufacturing through initiatives such as consistent implementation of policies on manufacturing personnel movement across all States (including formal notification to all State governments/local authorities); consistent implementation of policies across all States to ensure streamlined logistics for pharmaceuticals material, eg material movement across State borders; and support to ancillary suppliers (eg packaging material, solvents) of pharmaceutical manufacturers. The low prices make the drugs acceptable everywhere in the world. With quality that is enforced by the USFDA (India has the largest number of USFDA-approved plants in the world), which has a reputation for top-notch standards, India will be able to supply quality medicines at low prices. Second, to increase production, the government needs to launch targeted financial incentives to promote the manufacturing of diagnostic kits and other medical devices — especially given that the raw material for manufacturing of these devices is heavily dependent on imports. This is also an opportunity to bring a much larger proportion of manufacturing of APIs back into India, so that the country is not dependent on imports of critical inputs.

In this connection, the government’s decision to promote domestic manufacturing of KSMs, intermediates and APIs (through the setting up of bulk drug parks and production-linked incentives) is a very welcome policy for the industry. Going forward, India’s self-reliance in pharmaceutical manufacturing can be further enhanced by providing incentives / support to API and Intermediates/KSM manufacturing such as provision for SEZ’s for manufacturing bulk drugs.

Third, the Indian pharma industry is now at the cusp of developing new molecules for treatment of various medical conditions at scale. Many Indian firms already have molecules in clinical trials. Developing new drugs costs money, and the government needs to provide the conditions for sufficient profits for investment in new molecules while holding the firms accountable for producing new drugs for India and the world.

At this time, Indian medicine prices are already amongst the lowest in the world. In addition, research evidence from IIM-Ahmedabad based on data from 2011-2018 for 108 molecules suggests that price control has not increased access and affordability. There is, thus, a need to fine-tune the drug pricing policy to generate enough surpluses to invent new molecules while keeping the price levels reasonable with the objective of providing affordable healthcare. In this connection, the government can boost Indian pharma R&D by implementing streamlined and accelerated regulatory and testing pathways for all drugs (including those for Covid-19). The increase in overall innovation/R&D can provide a long-term thrust to Indian pharmaceuticals. Three recommended moves to enable this are encouragement of R&D expenses and outcomes; increase in availability of funding for R&D; and creation of a closer cooperation process between public institutions like CSIR laboratories and NIPERs with private R&D.

The industry has already taken some significant steps during the Covid-19 crisis by providing drugs to many friendly countries. This initiative can be made much more broad-based by launching a structured export-incentive plan for Indian pharmaceutical manufacturers, to promote greater supply of drugs to global markets in the medium term.

There is an opportunity for the Indian pharmaceutical industry to play a larger role in ensuring global drug supply-security, and potential financial incentives can play a significant role in making this happen. This is, of course, subject to the availability of essential medicines in India at a reasonable cost.

The Indian pharmaceutical industry is a strategic industry for the nation, with the advantage of scale (at \$37 billion in 2019-20, it contributed 1.5 per cent to the GDP directly, with another 3 per cent coming indirectly). The industry also has global reach, and is a net foreign exchange earner of more than \$10 billion annually. Pharma can do for India what software was able to do in the 1990s and 2000s. India became the back office. Let this be the moment that triggers the acceleration of the movement to becoming the ‘Pharmacy to the World’.

(Source: Business Line) The writer is Professor of Marketing and International Business at IIM-Ahmedabad

## The Indian Pharmaceutical Industry Might Be A Ray of Hope In the Feared Economic Slowdown



The coronavirus pandemic has hit us hard, socially, financially and emotionally. By now, we are familiar with the need to flatten the curve by practicing social distancing. But what will happen after the lockdown?

While there are fears about an economic slowdown and unemployment, could the Indian pharmaceutical industry blossom in the post Covid-19 world? Sritama Pramanik got a job offer while India is in lockdown and has started working from her home in Berhampore, Murshidabad. "We track all phases of drug development from discovery through clinical trials to launch. We help the global pharmaceutical companies gain insight into the drug development trends across the industry and identify new business opportunities," says Pramanik who has just completed her MBA in healthcare management from the Goa Institute of Management and is now working as an external consultant, Pipeline Intelligence, IQVIA, Bangalore. While it is a time of nail-biting anxiety for most final year students, people like Sritama might gain an upper hand as demand in the pharma and allied industries is likely to spike.

Researchers in laboratories all over the world are working to develop a cure to the novel coronavirus. Prasanta Kumar Das, associate manager of R&D at Zydus Wellness Products Limited in Ahmedabad, too is busy researching new products. "We are working from home and at the laboratory on alternate days as our core work is laboratory-based. While working from home, we focus on documentation, strategy planning and studying research papers.

We work in the lab with 3050 per cent strength to maintain physical distance," says the man who did his MPharm from the Bengal Institute of Pharmaceutical Sciences in Kalyani.

A degree in pharmaceutical or life sciences may help students get absorbed by the industries now at the frontline in the Covid19 battle -- whether it be making diagnostic kits, drugs or vaccines. Avishek Shah is a researcher at a top multinational IT company in Noida and is currently working from his home in Kanchnara, North 24-Parganas, on drug repurposing for Covid-19. "I basically deal with in silico [using the computer] drug discovery, especially drug repositioning and drug repurposing using artificial intelligence and machine learning. This involves use of known information of drugs to allow usage in other fields. It is the time of big data and data-driven discoveries and there is a lot of scope in this field in healthcare," says Shah who has done his masters in biotechnology from IIT Bombay. (Source: The Telegraph)

## India To Send Nearly 1,000 Tonnes Of Paracetamol Raw Material To Europe



New Delhi: India will supply Europe with about 1,000 tonnes of the active pharmaceutical ingredient (API) for common pain reliever paracetamol, a top exports body said, easing export controls on over-the counter medicines used to cope with COVID-19 symptoms.

The government in March put a hold on exports of several drugs including paracetamol to secure supplies for its people after the coronavirus outbreak disrupted the industry's supply chain globally. COVID-19 is the respiratory disease caused by the novel coronavirus. Europe has sought up to 800 tonnes of paracetamol APIs every month, said Dinesh Dua, chairman of the Pharmaceuticals Export Promotion Council of India (Pharmexcil).

"We have been under immense pressure from the European Union for the last 10 days," Mr Dua said.

The European Union delegation in India did not immediately reply to an email from Reuters requesting comment on the planned shipment. Authorities have asked drugmakers to ensure the country is adequately stocked for up to four months of domestic requirements, Dua said.

India, the world's main supplier of generic drugs, has shipped 1.9 million tablets and other forms of paracetamol to 31 countries, the foreign ministry said late last month, adding that consignments of anti-malaria drug hydroxychloroquine and paracetamol were being sent to 87 countries on a commercial basis.

Europe is the country's biggest buyer of paracetamol APIs and imports around 12,000 tonnes annually, according to Pharmexcil estimates. The common pain reliever is also sold as acetaminophen. The novel coronavirus outbreak has killed more than a quarter of a million people and Europe has accounted for 57% of the global death toll.

India has so far reported more than 49,000 cases of COVID-19. The outbreak has not shown any signs of slowing despite a severe lockdown that has confined its population of 1.3 billion to their homes since late March.

Health experts warn a surge of infections can overwhelm the country's medical services. Indian pharmaceutical companies get almost 70% of the active pharmaceutical ingredients (APIs) for their medicines from China, where the virus had emerged late last year. "The country is vulnerable in terms of importing the drug's intermediates from China," Dua said.

Pharmexcil counts dozens of pharmaceutical firms such as Pfizer Ltd and Abbott among its members. The council falls under the federal commerce ministry. (Source: NDTV)

## India's Jubilant Signs Licensing Deal For US Pharma Firm Gilead's COVID-19 Drug



India's Jubilant Life Sciences Ltd said it had signed a non-exclusive licensing agreement for selling Gilead Sciences Inc's experimental COVID-19 treatment remdesivir in 127 countries, including India. The drug earlier this month received the US Food and Drug Administration's emergency use authorization to treat COVID-19 patients.

Jubilant also gets the rights to manufacture the drug and scale up production in nearly all low-income and middle-income countries, as well as some high-income nations. Gilead has said it was negotiating long-term licenses with several generic drugmakers in India and Pakistan to produce remdesivir for developing countries and that it would provide technology to aid the production.

With no approved treatment for COVID-19, the respiratory illness caused by the novel coronavirus, interest in remdesivir has been growing, and the company is being closely watched on the pricing and distribution of the limited supply of the drug. Not-for-profit Medecins Sans Frontières (MSF), also known as Doctors Without Borders, criticized Gilead for a lack of transparency on the terms of the agreement.

"We believe that instead of business as usual, such agreements should be made public and licenses have to be global including all countries - low, middle and high income," said Leena Menghaney, the South Asia head for MSF's Access Campaign. Gilead did not immediately respond to a request for comment on the agreement with Jubilant. The pandemic has killed nearly 286,000 people globally, according to a Reuters tally, and several drugmakers are racing to develop a viable treatment or vaccine to combat the outbreak. (Source: NDTV)

## India's Pharma Exports Up 7.57% at \$20.5 b in FY20



The country's pharmaceutical exports increased 7.57 per cent in the financial year ended March 31, at \$20.58 billion, against \$19.13 billion in the previous year.

The growth in FY19 was however an increase of 10.72 per cent over FY18,, according to Pharmaceutical Export Promotion Council's (Pharmexcil) data.

"The slowdown in growth rate was due to reduction of exports in February and March 2020. While February showed 7.7 per cent growth, exports declined 23.24 per cent in March affecting the overall performance of exports in the pharma industry," R Uday Bhaskar, Director-General, Pharmaexcil, said on Friday.

Due to the lockdown, the last quarter saw a negative growth of 3 per cent without which the overall growth for the full year would have been around 11 per cent as the first nine months' growth in pharma exports in FY20 was at 11.5 per cent.

In a way, Covid-19 and lockdown had offset the positive impact of surge in pharma exports in the first three quarters of the year under review. The growth in the first three quarters was at 11.21 per cent, 8.69 per cent, 14.64 per cent respectively.

Drug formulations and biologicals contributed to 72 per cent of total exports, with growth of 9.5 per cent. However, the second largest category of exports — bulk drugs and intermediaries — declined by 0.75 per cent. Vaccines and surgicals recorded 22 per cent and 10.5 per cent growth respectively.

Of the 202 destinations for Indian drugs, North America had the largest share of 34 per cent, with 15 per cent growth in overall exports. Exports to the US stood at \$6.7 billion with a 32.74 per cent share in total exports and showed 15.8 per cent growth.

On the expectations for the current year, the Pharmexcil chief said: "We expect double-digit growth in FY21 as there could be higher demand for generics if countries across the world want to cut healthcare expenses due to economic slowdown. However, given the continuing Covid-19 impact, this could be too early for a forecast."

It may be noted that though India started exporting Covid-19 related drugs to many countries, they are not high value products and may not lead to a significant jump in export earnings, he added. (Source: Business Line)