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Portal on Covaxin major boost for tackling Covid-19: Experts

SHARDUL NAUTIYAL, MUMBAI

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According to an ICMR spokesperson, "August 15, 2020, timeline should not be talked about as it was meant to prompt and motivate principal investigators at all clinical trial sites to expedite clinical trial process as per global regulatory norms to come out with a vaccine as soon as possible."

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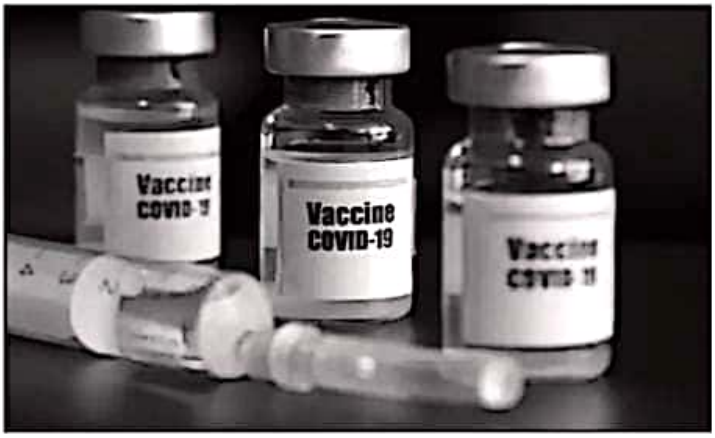

July 2, 2020, had written to all 12 trial sites for the Covid-19 vaccine candidate, Covaxin, that all clinical trials had to be completed by August 15, in time for a public launch. As per CTRI, the expected duration of the trial for Covaxin vaccine is one year and three months.

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The Serum Institute of India (SII) and Indian Council of Medical Research are jointly conducting a Phase II/III, Observer-Blind, Randomized, Controlled Study to Determine the Safety and Immunogenicity of Covishield (COVID-19 Vaccine). Promising result of Pre-clinical animal studies have shown. DCGI approval for Phase II & Phase III human clinical trials has been received. Phase II human clinical trial is ongoing.

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Talking with reference to developments, pharma consultant Anshu Yadav said, "Quality assurance department of companies acts as a crucial link between enabling the sales force to adhere to the guidelines of regulatory authorities and maintaining high standards. At the same time, they need to ensure that they find the right markets for their products. The export-focussed Indian pharma needs to comply with stringent quality standards and process documentation. Impacted by warning letters and import recalls due to regulatory issues, Indian pharma companies need to continuously upskill their quality assurance workforce. In[illegible] results like in quantity, quality and output for Covid-19 vaccine development."

"At this juncture of unprecedented human health crisis and vaccine development, it is neither practicable nor advisable to begin research in conventional way to find a cure. Exploring the approved medicines for this new indication and compounds which have already shown promising results in pre-clinical studies but not pursued further are perhaps the best bet. These, if found effective would receive early regulatory approval on emergency use authorisation," remarks Ahmedabad-based pharma consultant Dr Sanjay Agrawal concluding that one more challenge in front of the researcher as the new study says the virus which emerged from Wuhan was the D strain. Most vaccine under development have been modeled on the original strain, which was common among sequences published early in the pandemic. The virus meanwhile evolved to G strain, the result of a mutation known as D614G. This has become an urgent concern as G stain has replaced D strain all over the world.

Drug discovery needs a long time research

DR SANJAY AGRAWAL

Covid-19 is the greatest threat to human beings around the world in recent times. World Health Organization has given its official name as, the disease: coronavirus disease (Covid-19) and it causes by the virus - severe acute respiratory syndrome coronavirus (SARS-CoV-2). This deadly virus has originated in December, 2019, in the city of Wuhan.

Coronavirus is known to cause infections in animals but when infects a human it usually causes mild respiratory infections. Coronavirus can cause respiratory tract infections in humans, that can be mild like any flu infection but some coronavirus can cause deadly infections and it is very dangerous.

In 2002–03, there was an outbreak of novel coronavirus called SARS (Severe Acute Respiratory Syndrome) related coronavirus in China and Hong Kong, which was then spread to other countries also. Since then, no further SARS reported from any regions.

In 2012-16, a new virus, called MERS (Middle East Respiratory Syndrome) virus spread in countries like Cyprus, the Asian part of Turkey, Syria, Lebanon, Israel, the West Bank and Gaza, Jordan, Iraq, Iran, the countries of the Arabian peninsula, Egypt and Libya.

China claims that this Covid-19 has originated from a bat species. However, it has not been proved scientifically yet.

The virus is carried by aerosol droplets in the air, released from any infected person and enters the human body through the respiratory system (nose to lungs). After entering the lungs, this virus tries to invade the tissue cells of the lungs. This virus can only enter the lungs cell with the help of a protein called Angiotensin converting enzyme 2 (ACE2). The ACE2 protein has a receptor and the coronavirus has also spike protein (S-protein) on its body. This virus attaches itself to the ACE2 protein by docking its S-protein onto the ACE2 receptor. Another protein called serine protease (TMPRSS2) helps the virus to attach itself to the ACE2 protein and activates the docking process. After attaching itself to ACE2 protein, it transfers its mRNA to the host cells (lungs cells).

Corona disease has brought in challenges, at individual level and society at large. More than ever before, clinical trial has generated a lot of interest during the times of Covid-19. All over the world, people are waiting to get a vaccine that can cure this dreaded disease or prevent it.

Immunity

The concept of herd immunity is to try to create an extremely large group of people who have immunity against an infectious agent. This means either vaccinating or allowing people to get infected and recover, so they have developed memory against the infecting agent and can produce antibodies when encountering the infectious agent again. This halts the pandemic from spreading, as it will not find susceptible host to infect. This constitutes the concept of herd immunity.

Research for vaccine

Drug discovery needs a long time research involving pre-clinical, clinical studies. The studies need testing of potential molecules, which must show promising results in pre-clinical studies, in healthy volunteers. At this junction of unprecedented human health crisis, it is neither practicable nor advisable to begin research in conventional way to find a cure. Exploring the approved medicines for this new indication and compounds which have already shown promising results in pre-clinical studies but not pursued further are perhaps the best bet. These, if found effective would receive early regulatory approval on emergency use authorisation.

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Leaders across the globe pledged to speed up work on tests, drugs, vaccines against Covid-19 and to share them around the globe. Global research is being carried out to discover vaccine to combat the virus. World Health Organization director general says all new vaccines, diagnostics and treatments against the coronavirus must be made equally available to everyone across the globe.

Oxford University in collaboration with AstraZeneca is working on potential Covid vaccine and it is started human trials with a vaccine they developed. The UK govt has funded the vaccine project with 20 mn pounds to Oxford University and another 22 mn pounds to a second vaccine project at Imperial College, London last month.

Challenges in health care sector

Challenges and the uncertainty have been further accentuated due to Covid pandemic and the subsequent lockdown. Most private healthcare facilities activated their epidemic plans that required huge investments in making facilities prepared for infection control and prevention, creating infrastructure for isolation and Covid treatment, as well as equipping them with appropriate medical supplies and additional healthcare workforce. Revenues of hospitals have seen in a sharp dip owing to stalled medical tourism and elective procedures. The OPDs had also been discontinued following the advisory released by the governments across the country.

According to various studies released on economic impact of the pandemic on healthcare sector, virus outbreak had resulted in around 70-80 per cent drop in footfall, test volumes, and about 50-70 per cent drop in revenues at the end of March 2020. The study also revealed that the sector is expected to witness short-term operating losses to the tune of Rs 14,000-24,000 crore for a quarter.

Need sops for healthcare

The industry had also proposed solutions of providing government grant for loss of business due to the pandemic or bringing in moratorium on all working capital, principal, interest payments on loans and overdrafts, bringing in liquidity and allowing for business continuity. Zero-rating of GST has been a long-standing request from the sector, which can bring maximum relief at a time like this. Government may consider zero-rating of healthcare services, which will not only ensure that the credit chain is intact but also ensure that the input taxes are not loaded into the cost of healthcare services.

It is a little worrying to contemplate the effect of Covid on the healthcare sector, especially on drug discovery and production. Although India manufactures one third of the global supply of medicines, over 80 per cent of the raw materials needed for the drug are imported from China. This gives our neighbour a virtual monopoly over supply and pricing to the point that there are no domestic producers for most medicines in India. The total import of drug intermediates and bulk drugs exceeds Rs 25,000 crore and China accounts for over 67 per cent of it.

India has also significantly increased the import of antibiotics from China in the recent years, and the trade is currently worth billions of dollars. If China decides to pull the plug on supply, it will lead to a huge public health crisis in India. Drug companies claim that low-cost imports have forced a lot of manufacturers to shut up shop. A number of them have given up manufacturing ingredients for other drug makers and have started manufacturing complex formulations on their own. These are then exported to developed markets in first world countries.

This pandemic presents us with the opportunity to turn things around with government support. With the coronavirus outbreak restrict-

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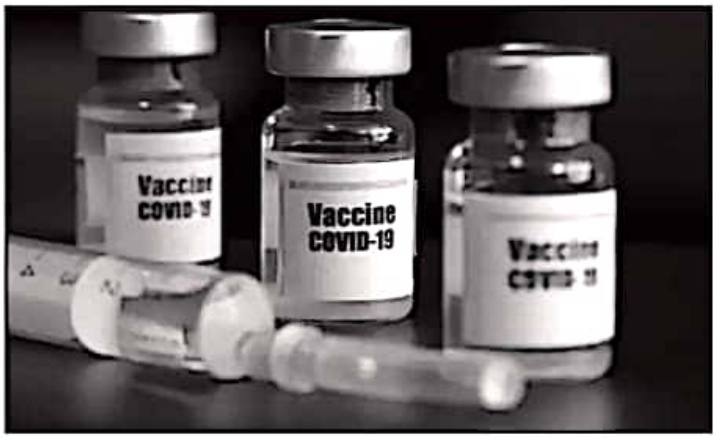

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