# The Veeda Newsletter

ISSUE 06: JUN 2020


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## Indian Pharma

India simplifies clinical trial rules for Covid-19 vaccine manufacturing

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## FDA will make some changes amid COVID-19 permanent

The US Food and Drug Administration (FDA) will look to permanently implement some of the processes and policies adopted in its response to the coronavirus disease (COVID-19) pandemic, FDA Commissioner Stephen Hahn said during a virtual briefing hosted by the Alliance for a Stronger FDA on Monday.


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## CDSCO rapid response framework for COVID-19 vaccines

As part of its rapid response regulatory framework for handling COVID-19 vaccines, the Central Drugs Standard Control Organization (CDSCO) of India says that it is open to considering data generated outside of the country and to otherwise truncating development to cut the time it takes to access a vaccine.


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## FDA Publicly Shares Antibody Test Performance Data from Kits as Part of Validation Study

Today, the U.S. Food and Drug Administration publicly posted test performance data from four more antibody, or serology, test kits on open.fda.gov from its independent performance validation study effort with the National Institutes of Health's (NIH) National Cancer Institute (NCI).


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## FDA Provides Free eConsent Platform for Eligible Clinical Trials during COVID-19

The FDA announced that its previously developed FDA My Studies app is now available to investigators "as a free platform to obtain informed consent securely from patients for eligible clinical trials when face-to-face contact is not possible or practical due to COVID-19 control measures."


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## European Commission, EMA and FDA agree new priorities to strengthen their collaboration on medicines

Senior officials from the European Commission (EC - DG SANTE), EMA and the United States Food and Drug Administration (FDA) held their 2020 bilateral regulatory dialogue meeting on 18 and 19 June. During this virtual two-day meeting, the authorities reviewed their ongoing joint initiatives, discussed strategic priorities for the coming years and identified areas where their already close collaboration can be further strengthened.


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## COVID-19 drug Remdesivir's price in India is a concern; Pharma cos free to set price


The Indian Government approved US-drug major Gilead Sciences Inc's antiviral drug Remdesivir for emergency use, only up to five doses in treating moderately-ill COVID-19 patients. The drug Remdesivir is to be administered intravenously. It is the first drug to show improvement in formal clinical trials.

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## Limited Impact on Indian Pharmaceuticals; Market to Grow in Size

Indian pharmaceuticals market is likely to grow 3%-5% in size during FY21, despite the COVID-19 related lockdown and there would be monthly revenue improvements from June 2020, says India Ratings and Research (Ind-Ra).

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## Indian pharma back in favour on improving fundamentals

It took a global pandemic to rekindle investor interest in pharma stocks. The ET Pharma Index has gained more than 40% since the lockdown began. After peaking in 2015, Indian pharma stocks are back in favour due to improved fundamentals of the companies. While some have better growth drivers than others, almost all are working towards becoming more efficient.

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## EU in advanced talks with Johnson & Johnson on COVID-19 vaccine deal - sources


The European Commission is in advanced talks with pharmaceuticals giant Johnson & Johnson to reserve or make an up-front purchase of its COVID-19 vaccine under development, two officials familiar with the talks told Reuters.

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## Industry and government pledge $8.8bn to global immunisation efforts

The pledges were made at the Global Vaccine Summit 2020, which was hosted by UK prime minister Boris Johnson. The virtual summit was attended by representatives from 52 countries, as well as vaccine manufacturers, leaders of global health organisation and others from the private sector.

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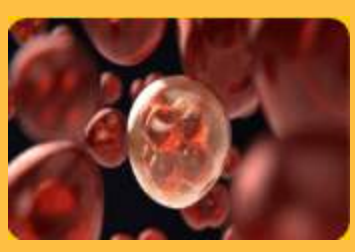
## CLINICAL TRIAL SHOWS PROMISING NEW TREATMENT FOR RARE BLOOD CANCER



Scientists have found that chemotherapy combined with drug “rituximab” coupled with treatment for the secondary Central Nervous System (CNS) problem, shows promising results for patients suffering from a rare subtype of Lymphoma (blood cancer). A group of scientists, led by researchers from Nagoya University and Mie University, Japan, attempted test in a new clinical trial, published in the journal The Lancet Oncology.

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## The challenge of conducting clinical research during a pandemic

One of the largest efforts, a multinational clinical mega-trial called Solidarity, was launched by the World Health Organization to test several regimens: the antimalarial drug hydroxychloroquine; an experimental antiviral drug, remdesivir; and a combination of two anti-HIV drugs, lopinavir and ritonavir, with or without the immune-system modulator interferon-beta-1a.

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## COVID-19 Pandemic Highlights Advantages of Digital Technology in Clinical Research

As the COVID-19 pandemic has disrupted many routine medical services and discretionary surgical procedures, little attention has been paid to its impact on clinical research. Many clinical trials and other medical research activities came to a sudden halt in March when the World Health Organization declared COVID-19 to be a pandemic.

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## Health Ministry publishes New Drugs and Clinical Trials (Amendment) Rules

The Union Health Ministry has come up with draft New Drugs and Clinical Trials (Amendment) Rules, inserting provisions for "compassionate use" of any unapproved drug that is in the phase-III clinical trial, either in India or abroad, by importing or indigenous manufacturing.

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## How Covid-19 is accelerating adoption of decentralized clinical trials

Late last month, one of the largest contract research organizations and its parent company announced a partnership with a technology company to promote adoption of virtual clinical trials. But an important subtext to the trend is what has helped drive it over the past few months: the Covid-19 pandemic.

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## Zentiva Expands Production Capacity by Completing Acquisition of Ankleshwar Manufacturing Site

Zentiva Group announces the completion of its acquisition of a manufacturing site in Ankleshwar, India, from Sanofi. The finalization of the deal increases the number of wholly-owned Zentiva production sites worldwide.

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## Tetraphase Pharma (TTPH) Announces Deal to be Acquired by Melinta Therapeutics

Tetraphase Pharmaceuticals, Inc. (Nasdaq: TTPH), a biopharmaceutical company focused on commercializing its novel tetracycline XERAVA™ to treat serious and life-threatening infections, today announced that it has entered into a definitive merger agreement with Melinta Therapeutics, Inc. (“Melinta”), pursuant to which Melinta would acquire Tetraphase, through a tender offer.

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## Cipla to acquire 21.85 pc stake in GoApptiv

Pharma major Cipla on Wednesday said it will acquire 21.85 per cent stake in GoApptiv on a fully-diluted basis in two phases. The cost of acquisition is Rs 9 crore (Rs 5.80 crore in the first stage and Rs 3.20 crore in the second stage), it said in a regulatory filing.

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## Dr Reddy's completes acquisition of Wockhardt's India generics biz, amends Rs 1,850 cr deal over Covid-19 impact

Pharma major Dr Reddy's Laboratories Ltd on Wednesday said it has completed the acquisition of select divisions of Wockhardt Limited’s branded generics business in India as well as some international territories of Nepal, Sri Lanka, Bhutan and Maldives.

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## Naari completes acquisition of ANDAs from Intas Pharmaceuticals

Leading women’s health company Naari Pte Limited (“Naari”), a Singapore-incorporated wholly-owned subsidiary of Naari Pharma Private Limited, has entered into a definitive asset purchase agreement to acquire 10 Abbreviated New Drug Applications (ANDAs) for the U.S. market from Intas Pharmaceuticals Ltd, the largest privately held pharmaceutical company in India.

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veeda clinical research

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## India simplifies clinical trial rules for Covid-19 vaccine manufacturing

The health ministry has allowed some relaxations to the Drugs and Cosmetics Act, 1940, and the subsequent rules. This has been done to make “suitable vaccines” available to meet emergency requirements arising due to the pandemic.

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## Coronavirus: ‘Pharmacy of the world’ India in overdrive

India’s ability to deliver cost-effective and quality generic drugs, such as those that helped millions living with HIV, earned it the reputation of being the “pharmacy of the world”. This attribute has come into greater salience amid a global quest for potential treatment options and vaccines for Covid-19.

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## Central govt may allow import of untested drugs under trial

The Ministry of Health and Family Welfare has been amending the New Drugs and Clinical Trial Rules, 2019. The amendment will enable any government or medical institution or private hospital to import the medicines required for the treatment of life-threatening diseases.

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## Reality check for Indian pharma as growth slides in May

Indian pharmaceutical companies have seen a decline in growth in May since the covid-19 pandemic curbed patient mobility and hospital footfalls. The pharma sector growth fell 8.6% year-on-year (y-o-y) in May.

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## Making bulk drugs in India will need policy stability

Soon after the Modi Government assumed office in 2014, India’s National Security Advisor Ajit Doval had warned “India runs the risk of a severe shortage of medicines because of its over-dependence on China for sourcing raw material for drugs”. But the ministries did not take his concerns seriously as India was focused on reducing drug prices and China was the cheapest.

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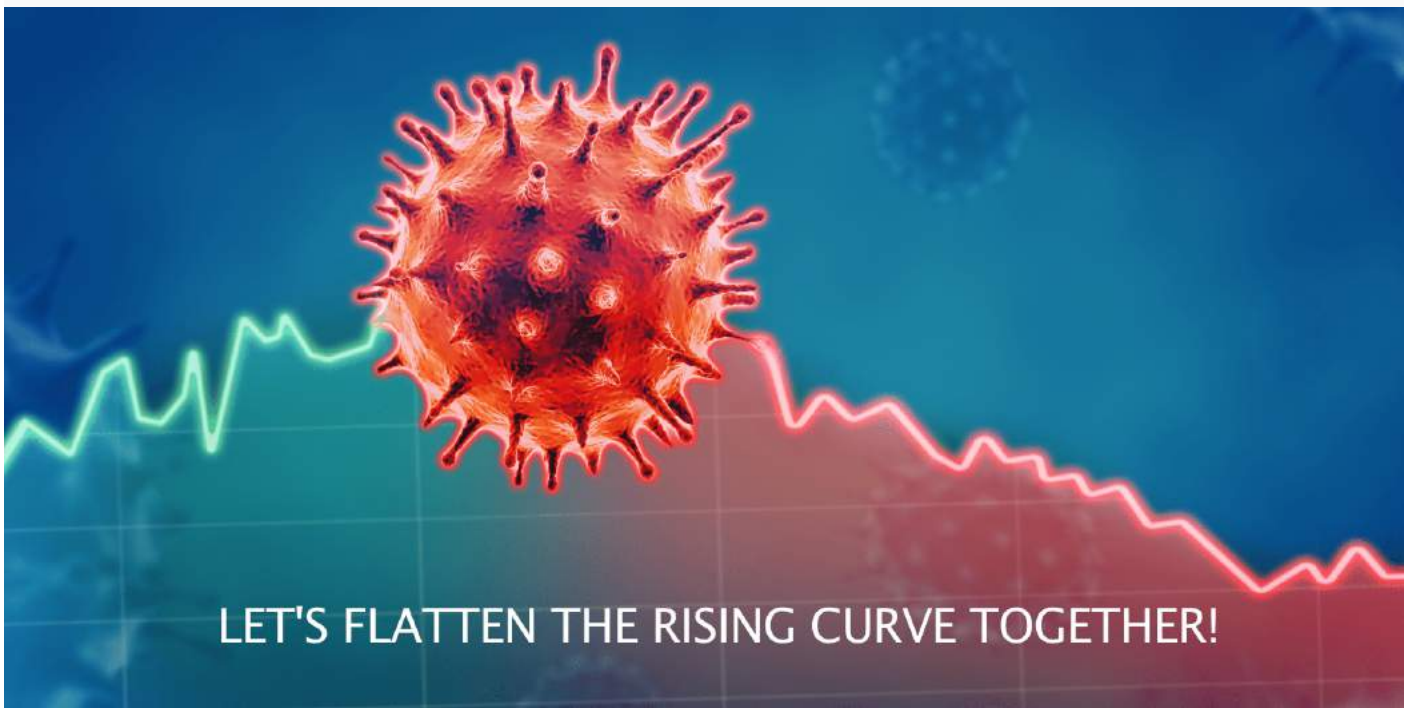


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