Corona Virus Outbreak and it's Impact on the Global Pharmaceutical Industries

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ABSTRACT

There is other general wellbeing emergency undermining the world with the rise and spread of 2019 novel coronavirus (2019-nCoV) or the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The infection started in bats and was transmitted to people through yet obscure go-between creatures in Wuhan, Hubei territory, China, in December 2019. There are more than 48,15,484 infected cases all around the globe. This can be transmitted from one to another very quickly only by coughing or sneezing or direct contact with infected person. World Health Organization has also stated that no future course of this virus is available until now. As a preventive measure, the complete stop on outgoings i.e., lockdown, is surrendered. The lockdown all over the country or worldwide is becoming a huge crisis for the economy and of countries the life cycle of humans. The lockdown has affected all the businesses, works, private sectors, as well as government sectors. The impact of lockdown on the pharmaceutical industries can be a great boon if its taken positively.

Keywords: Coronavirus, Crisis, Impact, Lockdown, SARS-CoV 2, Transmitted, Wuhan.

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INTRODUCTION

When everyone had been partying hard or seeking blessings on the eve of December 31 2019, no one would had not even imagined in their darkest dreams that this year is going to be one of the most eventful year ever. The year where the whole of mankind will stand together to fight against a deadly pandemic: the Coronavirus. Coronavirus which was later officially renamed as Covid-19 by WHO, is a virus belonging to the family of Coronavirus, the family which contains various other widely known virus known to cause diseases such as SARS, MERS and even common cold.^[1]

The name "Coronavirus" is derived from the Latin word "corona" meaning crown or wreath due to the appearance it gives off when observed under a microscope.^[2] It is spread from person to person by physical contact, sneezing, and coming in with coughing droplets of infected individuals. Its high epidemiological rate and easy spreadability make the virus so dangerous, hence a global threat.^[3] Due to above reason it is necessary to put a hold on its spread, which have been brought on by the implementation of complete lockdown in different countries across the world. However, due to this move, all the industries, government and private agencies, market, businesses have been affected in a terrible manner. Even the daily life of a normal individual had undergone a drastic change.

To counter this threat, pharmaceutical and biotechnological companies around the world are collaborating with the government to address the Covid-19 outbreak, from supporting the development of a vaccine to devising plans to handle medicine supply chain challenges.^[4]

The effect shown by Coronavirus on global pharmaceutical industries are stated below and summarised in the given Figure 1:

1) Import and export

Persisting Covid-19 infections has gravely affected the import and export of pharmaceutical products. The import of active pharmaceutical ingredients to the India and export of finished final medicaments to other countries has been affected due to the outbreak caused by Covid-19, as amid the ongoing pandemic, transporting goods carries a great risk of transmitting the virus itself. ¹Department of Pharmaceutical Chemistry, Noida Institute of Engineering and Technology (Pharmacy Institute), Plot No. 19, Knowledge Park-2, Greater Noida, Uttar Pradesh-201306, India

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2) Economical Point

The cost of branded and generic medicines is predicted to increase because many countries import the active pharmaceutical ingredient from foreign countries. So due to the complete lockdown in other countries, the supply chain of active pharmaceutical ingredients or other pharmaceutical ingredients is affected, which is increasing the cost of the product. For example, the price of Vitamin D and penicillin have increased by 40 to 50% in India.^[5]

3) Effect on market dynamics

Healthcare systems, pharmaceuticals, or biotechnological companies are also suffering from the disturbance caused by Covid-19.^[6] The supply of medicines by market representative is also affected as he/she is unable to survey the market amid the lockdown. Market surveys are required for the growth of any pharmaceutical industry globally as well as domestically.^[7]

4) Link with a health care professional

The outbreak caused by Covid-19 also has broken the chain of

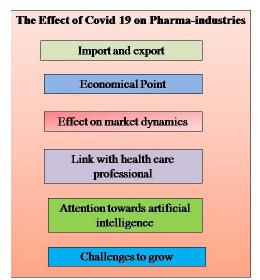


Figure 1: Main effects of COVID-19 on Pharmaceutical industries globally.

a link between the pharmaceutical industry representative and healthcare professionals. Pharmaceutical industry representatives awares the health professional on the current, upcoming, or recent studies of treating patients. There should be the maintenance of open lines of communication with healthcare professionals for effectively combating this new threat.

5) Attention towards artificial intelligence

Coronavirus's impact and the situation caused by it are pulling the attention of pharmaceutical industries towards artificial intelligence. Artificial intelligence is having appreciable outcomes when it comes to predicting Covid-19 spread and incidence of infection. Artificial Intelligence can also be applied to the research and development sector of Pharma industries. Computer-aided drug design can also be for improving R and D Labs.

6) Challenges to grow

Globally, every pharmaceutical sector or biotechnology field need to learn a lesson from Covid-19. If I talk about India only than its 60% of active Pharmaceutical ingredient is being imported from other countries. So we need to focus and invest on our own research and development section to be self-dependent for the better addressal of such situations in the future. The covid-19 outbreak is presenting a golden chance to Indian pharmaceutical companies to be a preferred alternative hub for the manufacturing of active pharmaceutical ingredients and intermediates.

7) Current Research

There are three significant research headings right now drove by pharmaceutical organizations: repurposed drugs, antibodies, and vaccines.

The test of clinical preliminaries

Clinical preliminaries are a pivotal advance to survey the viability and resistance of treatment. After HCQ, it's the ideal opportunity for azithromycin and sedate pneumonia combo to go under clinical preliminary. Researchers in the US have propelled a clinical preliminary to test the blend of azithromycin and atovaquone in patients with moderate-to-extreme Covid-19 contamination.

Another examination, distributed in the Journal of The American Medical Association, reported "improvement in the clinical status" of five basically sick covid-19 patients utilizing plasma treatment. $^{\left[5,8\right]}$

8) Opportunities for Pharma Industries

Pfizer has likewise surprisingly picked up from the coronavirus flare-up. Pfizer's pneumonia immunization Prevnar13 has seen a surprising hop in deals, most likely because of the course of the Coronavirus, which in serious cases causes pneumonia with high death rates. Pfizer's expanded income will be coordinated and surpassed if its joint effort with BioNTech for a Covid-19 antibody is fruitful. However, pharmaceutical organizations become the overwhelming focus in the Covid-19 battle; for example, Gilead and Eli Lilly see positive development on the financial exchange and another eruption of advancement in the irresistible malady landscape the race for treatment endorsement for a Covid-19 treatment takes off. The USFDA has made certain exemptions from import alerts for organizations who fabricate basic medication. Pharmaceutical organizations are working alongside offices to test mixes of prescriptions for potential fixes against the infection. For online drug stores - conveyance of meds has been influenced because of staff not turning up and non-accessibility of passes. With no present explicit treatment for covid-19, the race is on to create or repurpose medications to help end the pandemic.^[9] The World Health Organization has now propelled the SOLIDARITY preliminary to examine four potential medications: remdesivir, chloroquine/hydroxychloroquine, lopinavir, and ritonavir; and lopinavir and ritonavir in addition to interferon-β. The preliminary won't be twofold visually impaired, as WHO said it expected to discover a harmony between best guality level research practice and speed, yet it will incorporate a great many patients from a few nations. These are not, be that as it may, the main medications being considered for covid-19. Here is a breakdown of the medications that have been proposed up until this point.^[10]

9) Heterogeneous Impact on Clinical Trials, Biopharmas

Momentary effect: Short term effect

On March 18, the US FDA issued guidance on conducting clinical trials during the pandemic and the EMA (as well as several nationallevel European governments) have done as such as well as of late. The guidance documents stress the paramount significance of securing tolerant safety, trailed by keeping up preliminary uprightness. They also included guidance on adjusting trials to meet the current situation; stated their goal to be adaptable in evaluating convention changes, deviations, and information; and emphasized the significance of thorough documentation.^[11,12]

Reactions to the guidance documents have been positive. Experts accept that the FDA and EMA have given a sufficient system to sponsors to push ahead and adjust to preliminary changes progressively, without being excessively prescriptive. Nonetheless, progressively express guidance on the use of remote checking is normal. Consistent with this input, a survey conducted by BioCentury among 99 pharma and biotech companies found that unequivocal guidance on telemedicine and remote visits was one of the top areas where companies would like extra guidance.^[13]

The pandemic has prompted a substantial number of trials being paused or postponed. Examples go from biotechs like Provention Bio (who paused their Phase III Type 1 diabetes preliminary for PRV-03^[14]) and Iveric Bio (who paused their essential preliminary for Zimura in geographic atrophy^[15] to enormous pharma companies including Eli Lilly, BMS, and Pfizer (multiple programs paused or delayed.^[16,17] While the effect on trials is required to be expansive, the magnitude and nature of effect vary from preliminary to preliminary. Trials with the accompanying characteristics are especially prone to be deferred:

Preliminary Populations—trials with vulnerable populations (for example, the older, the immunocompromised, patients with pulmonary conditions [e.g., COPD])

Endpoint Type—any endpoint which warrants hospital infrastructure for assurance (for example, imaging-based endpoints like CT and PET scans)

Indications—trials in indications with minor safety or QoL implications for patients (for example, "lifestyle drugs"); trials in indications where tolerant condition strongly affects therapeutic success (for example, psychiatric and neurological indications)

Preliminary Stages and Phases—trials that are currently in recruitment, Phase I trials with solid volunteers

Preliminary Site Locations—preliminary sites that are situated inside hospitals or tertiary scholarly centers, preliminary sites in areas with high Covid-19 case density (for example, possibly reducing the accessibility of staff to perform required activities and increasing probability of AEs and patient loss)

Treatment MOA—immunosuppressive therapies, therapies that require intricate and delayed hospital visits (for example, Vehicle T therapies, quality therapies)

Preliminary Size—trials with insignificant margins of statistical force, uncommon disease trials (tolerant accrual is now difficult with the pandemic increasing the risk for an understanding loss).^[18]

Medium-to-long haul sway

In the medium-to-long haul, implications arise from COVID-19related clinical preliminary delays from money related, regulatory, and arrangement perspectives.

The money related implications of preliminary delays could be significant with various consequences for small biotech companies versus bigger pharmaceutical companies. Venture capitalists foresee cash stream issues for small biotechs, particularly single-asset companies. Many biotechs have limited monetary runways attached to tight improvement timelines. Delays in clinical trials may lead them to seek extra funding at once in which their stock values are probably going to have dropped substantially (in accordance with the rest of the stock market). This could result in some small companies being compelled to settle on difficult cuts or prioritization decisions in their clinical improvement plans and additionally face acquisitions on unfavorable standing. The last may present an opportunity for pharma companies who might be looking to inlay their pipelines and lost revenue.^[19,20]

Delays in clinical trials will probably translate into delays in launch timelines. This may result in shorter periods of patent exclusivity post-launch (excepting patent term restoration12) and lower forecast revenues for products than initially envisioned. Postponed launches will neither effect periods of vagrant exclusivity (which are resolved comparatively with launch date) nor periods of market exclusivity due to new indications. Launch delays also will have implications for serious dynamics as landscapes shift. This opens opportunities for companies who act with readiness and adjust to fast changes in their serious condition. From a regulatory perspective, COVID-19 will have implications in terms of required documentation, convention changes and deviations, information assortment, and the understanding of preliminary results.^[21]

RESULT AND **C**ONCLUSION

Covid-19 has shown a positive impact on the pharmaceutical industry, globally. We Pharma Industry need to grow more and more. We need to seek the lesson from the things going on and reproduce better results in every situation. Success doesn't wait for anyone; it's always in the hands of those who strive to achieve it.

While the effect of the COVID-19 pandemic on the pharmaceutical industry will probably be immense and extensive, the magnitude and nature of the risks introduced by preliminary delays will contrast substantially across trials and companies. Preliminary sponsors should adjust persistent safety, preliminary honesty, and statistical force considerations against funding and revenue considerations on an organization by-organization and preliminary by preliminary basis.

Smaller companies with restricted budgetary resources will probably have less options accessible to them. They might be compelled to settle on difficult cuts or prioritization decisions, struggle to raise funds on capital markets, or potentially face acquisitions on unfavorable footing. This could present an opportunity for huge pharmaceutical companies to alleviate losses in revenue arising from product launch delays by inlaying their pipeline with assets purchased at what would have been substantially discounted rates pre-crisis.

Notwithstanding reevaluating clinical advancement plans, biotech and pharma companies should reevaluate their assumptions around the serious landscape for both their pipeline and in-line products. Preliminary delays may upend years of arranging and serious insight assumptions and companies that quickly distinguish these shifts and respond will have a bit of leeway over those that don't.At long last, biotech and pharma companies should reevaluate estimating and revenue assumptions for their pipeline assets. Clinical preliminary delays combined with delays in valuing negotiations in some markets likely will result in shorter periods of post-launch patent exclusivity and a corresponding decrease in revenue. Further, the pending worldwide recession and shifting wellbeing spending priorities may decrease payers' willingnessto-pay and put valuing, and thus further revenue, pressure on companies.

The implications of clinical preliminary delays arising from the COVID-19 pandemic will be heterogeneous and there won't be a one-size-fits-all solution to the resulting challenges. With the end goal for companies to adjust, they should individually assess risk and create setting specific remediation strategies toweather this crisis.

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