The Impact of Culture, Government Will and Economies on the Biopharmaceutical Businesses - the Polio and SARS-CoV-2, Covid-19 Crisis Management

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Abstract:
By 2020 the pharmaceutical market is anticipated to more than double to US$1.3 trillion, with the E7 countries — Brazil, China, India, Indonesia, Mexico, Russia and Turkey — accounting around for one fifth of global pharmaceutical sales. Further, incidence of chronic conditions in the developing world will increasingly resemble those of the developed world.[1](PWC.com/pharma, 2020).

Wayback in 2014, biopharmaceuticals generated global revenues of $163 billion, making about 20% of the pharma market; by far the fastest-growing part of the industry: biopharmaceuticals current annual growth rate of more than 8% is double that of conventional pharma and growth is expected to continue at that rate in the future[2](Ralf Otto, A. S. (2014), 2014).

The current study analyses the overall trends, with the background of the world biopharmaceutical businesses and the huge impact of cultural nuances, politics on the economies of biopharmaceutical businesses with examples.

Key Words:
Biopharmaceutical economy/economies/business, PEST factors and biopharmaceuticals, biopharma, biopharmaceuticals, global biopharmaceuticals, cultural/political impact on biopharmaceuticals, opportunities biopharmaceuticals, and pharma drugs industry, top 10 biopharma

1. Introduction
By 2020 the pharmaceutical market is anticipated to more than double to US$1.3 trillion, with the E7 countries — Brazil, China, India, Indonesia, Mexico, Russia and Turkey — accounting around for one fifth of global pharmaceutical sales. Further, incidence of chronic conditions in the developing world will increasingly resemble those of the developed world.

In 2014, biopharmaceutical industry globally churned out $163bn which is 20% of the global pharma market. It is by far the fastest growing-part of the industry: biopharma’s current growth rate of 8% is also the fastest as compared to the conventional pharma industry[2](Ralf Otto, A. S. (2014), 2014).

Investing in biotech R&D also has a good revenue pipeline. There are approximately 1500 biomolecules under clinical trials and the success rates are twice that of the pharma-pipelines. This will increase the market launch of at least 15 molecules in a year more than the conventional pharma products as the FDA gets more nods than ever[2](Ralf Otto, A. S. (2014), 2014).

There are host of factors that are forcing the pharmaceutical companies to change their focus from conventional pharma to the biopharma way. The companies that were selling conventional pharmaceutical molecules now are moving to better biopharmaceutical drugs/biologicals as the potential dependence of these molecules rakes in higher equity.
2. Global biopharmaceuticals: organizations & markets

The top biopharma/pharma companies globally include the following\textsuperscript{[3]} (Hogg, 2015): 

Table-1: Ranking of Top 10 Global Biopharmaceutical Companies\textsuperscript{[3]} (Hogg, 2015)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Biotech/Pharma</th>
<th>Revenues PA ($Bn)</th>
<th>Country</th>
<th>Top drugs</th>
<th>Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Johnson &amp; Johnson</td>
<td>74.331</td>
<td>USA</td>
<td>HepC, HIV, Arthritis</td>
<td>Virology, immunology, auto-immune disorders, gastroenterology</td>
</tr>
<tr>
<td>2</td>
<td>Novartis</td>
<td>57.996</td>
<td>Switzerland</td>
<td>Gleevec, Gilenya</td>
<td>Biologics, Vaccines, Transplant, Oncology, Nephrology, Pediatrics</td>
</tr>
<tr>
<td>3</td>
<td>Roche</td>
<td>49.86</td>
<td>Switzerland</td>
<td>MabThera, Avastin, Herceptin, Xeloda</td>
<td>Diagnostics, oncology, nephrology, personalized medicine</td>
</tr>
<tr>
<td>4</td>
<td>Pfizer</td>
<td>49.605</td>
<td>USA</td>
<td>Prevnar, Celebrex, Lipitor, Viagr, Hospira products</td>
<td>Vaccines, cardiology, immunology, oncology</td>
</tr>
<tr>
<td>5</td>
<td>Sanofi</td>
<td>43.07</td>
<td>France</td>
<td>Lantus-Insulins, Clexane, Allegra</td>
<td>CVS, CNS, OTC, diabetes, internal medicine, oncology, thrombosis, vaccines</td>
</tr>
<tr>
<td>6</td>
<td>Merck</td>
<td>42.237</td>
<td>Germany</td>
<td>Keytruda, Belsomra &amp; Zerbaxa</td>
<td>Oncology, neurogenerative diseases, fertility, endocrinology</td>
</tr>
<tr>
<td>7</td>
<td>GlaxoSmithKline</td>
<td>USA/UK</td>
<td>37.96</td>
<td>Rotarix, Cervarix, Malaria, Ebola Vaccines, Global leader in Vaccines</td>
<td>Vaccines, consumer healthcare, cvs, respiratory, asthma, oncology, infectious diseases, mental health, diabetes and gastroenterology</td>
</tr>
<tr>
<td>8</td>
<td>AstraZeneca</td>
<td>UK</td>
<td>26.095</td>
<td>Crestor, Symbicort, Nexium</td>
<td>Oncology, cvs, gastroenterology, neurology, respiratory, inflammation</td>
</tr>
</tbody>
</table>
The global biopharma markets are majorly the developed countries with developed capabilities and expertise in the biopharmaceutical arena. USA tops the list of such industry being the leader in the same. With reference to the Table-1, we infer the leadership of USA among the top biopharma companies globally.

In the following Table-2, is the list of top biopharma markets globally\(^4\) (ABPI-Global pharmaceutical industry and market. The Association Of British Pharmaceutical Industry, 2016). This leads us to infer about the capacity to lead the biopharma markets with all the aspects of biopharma industry success factors like, culture of innovative research & development, continuous education & expertise development for skilled manpower, dedicated universities for such education supported by government policy, space for biopharma sectoral policy development, supportive regulation and business facilitation by the biopharmaceutical community in that country. This in turn is influenced by political will and thus impacting the economy positively thereby boosting the biopharma industry.

Table-2: Top global biopharma markets\(^4\) (ABPI-Global pharmaceutical industry and market. The Association Of British Pharmaceutical Industry, 2016)
3. Complexity, IPR and manufacturing landscape

Biopharmaceutical molecules are relatively complex as compared to chemical entities in conventional pharmaceutical products\(^2\) (Ralf Otto, A. S. (2014), 2014).

With disruptive technologies and innovations like the immunotherapies, antibody drug conjugates, and gene & cell therapies all making commercial launches in the years to come. Biopharma is about to make a big splash in the near future as there is now an increasing understanding between the drug interactions and the genetic make up of the individuals. This would be to improve the targeted therapy and healthcare outcomes in a treated individual or treated groups\(^3\) (Mukherjee, S, Mukherjee, Bio Pharma Drive, 2015).

4. Affordability economics, IPR and supply chain dynamics

As the biopharma business moves from the scientific frontiers to the mainstream business, it has to face challenges that the market wants maintaining competitiveness, affordability, quality and delivery performance\(^4\) (Ralf Otto, A. S. (2014), 2014).

Downward cost pressure will intensify as the healthcare system struggle to balance higher demands with lesser or flat budgets. In this environment, payers may find it difficult to justify the annual treatment costs $50,000 to $100,000 that some bioproducts that currently demand\(^5\) (Ralf Otto, A. S. (2014), 2014).

The emerging markets know the true value for boosting the healthcare outcomes & demand for these kind of drugs and therefore, find out alternatives to fulfill the same. The result of these pressures will be inevitable in such industry\(^6\) (Ralf Otto, A. S. (2014), 2014).

Another challenge is the patent protection on complex biosimilar drugs. For example the EU approved Remsia, Celltrion’s biosimilar version of the monoclonal antibody Remicade. In emerging markets, consumers will be able to access the molecules only if these molecules have a lower price range. The enthusiasm for these molecules will be even higher than expected and is likely to generate pressure to make such molecules available on lower prices exerting pressure on the cost of goods sold and therefore, forcing the innovators to find out ways to meet such demands\(^7\) (Ralf Otto, A. S. (2014), 2014).

High premium on these biopharmaceutical products and the relatively smaller share of revenues have led to industry-wide challenges in the supply chain. Complexity, cost and service levels are far from small-molecule best practices, even considering the additional complexity of cold chain requirements\(^8\) (Ralf Otto, A. S. (2014), 2014).

Such dynamics play a major role in distribution in different regions of the world. The biologics and vaccine products form a major chunk in such strategies.

The new classes of molecules discussed above, from drug conjugates to cell and gene therapies arriving in the next five years, will each require its own novel manufacturing, supply, and quality-assurance approaches. Today many companies that are insourcing these products in the late clinical or early commercialisation phase are struggling to set up the novel technologies and processes required to produce them. Making the right decision about how to set up operations for an autologous cell is not an obvious exercise, and there will naturally be sub-optimal solutions before sufficient experience is built\(^9\) (Ralf Otto, A. S. (2014), 2014).

5. Quality compliance and regulations

Quality functions are struggling to keep up with the rising demands of the regulators, primarily the US Food and Drug Administration and others like the UKMHRA, EU-regulatory authorities, the South African Regulatory Authority. The industry keeps up with numerous warning letters issued by these authorities and the scrutiny/assessments will increase by the years to come. The increase in the relevance of the global markets (beyond USA, EU and Japan) is adding the complexity of multiple quality standards and regulatory regimes. Compliance robustness of processes and efficiency will have to be integrated for uniformity. This regime is likely to tilt the weight towards emerging countries.
6. Cultural nuances, politics and related strategies

Culture refers to the collective resultant aspect of knowledge, ideas, customs, behavior, rituals, arts and other manifestations of human intellectual achievement with regard to a particular region, nation, group, formal / informal associations, races or tribes.

Given the definition it becomes imperative to know the finer cultural nuances or aspects that form an emotional connect with the local population. These aspects could be their habits that form their behavior and ultimately their character. This is directly linked to various health related parameters that may become a national issue and therefore a need gap identification for a biopharmaceutical industry.

7. Life-saving vaccine development, administration strategies

A. Polio vaccination programme success

Given the development of life saving vaccines in and the world class manufacturing facilities that exist, India is due to begin transitioning away from Gavi support from 2017 and is expected to begin fully self-financing all its vaccine programmes by 2021. Under the partnership strategy, Gavi will provide up to US$ 500 million between 2016 and 2021 to support India’s immunisation programme, after which India will completely transition out of Gavi support. The new partnership will accelerate the introduction of modern, highly- efficacious vaccines in India, protecting children against the leading causes of disease, including pneumonia and severe diarrhea, which combined claim the lives of more than 200,000 Indian children under the age of five every year.[6] (Historic partnership between Gavi and India to save millions of lives, GACredit: PMO, Government of India, 2016)

Support will also be made available for the measles-rubella combined vaccine. This vaccine protects children against measles, a highly infectious disease that kills almost 30,000 children in India every year, as well as congenital rubella syndrome, which causes severe deformities and disabilities through the spread of the virus from pregnant women to their babies. Gavi will also provide future assistance for India to introduce the human papillomavirus vaccine, should the Government approve its introduction. This vaccine protects women against the leading cause of cervical cancer, a disease that kills 70,000 Indian women every year.[6] (Historic partnership between Gavi and India to save millions of lives, GACredit: PMO, Government of India, 2016)

Through this new partnership Gavi-supported vaccines administered between 2016 and 2021 are expected to prevent several hundred thousand deaths. By helping to establish these vaccines in India’s routine immunisation schedule and by strengthening existing immunisation and health systems to extend coverage and improve access, millions of children will benefit from the work being undertaken now for generations to come.[6] (Historic partnership between Gavi and India to save millions of lives, GACredit: PMO, Government of India, 2016)

The Government of India already has a priority of reaching every child with vaccines, as is evidenced by its new Mission Indradhanush initiative, which aims to reduce the number of children who get sick or die from preventable diseases by ensuring that the number of infants receiving all vaccines included within the Universal Immunisation Programme (UIP) exceeds 90% within the next five years. Through the modernisation and strengthening of health systems under this new partnership, Gavi support will also help towards this goal and help engage with a broader community of stakeholders within India.[6] (Historic partnership between Gavi and India to save millions of lives, GACredit: PMO, Government of India, 2016)

“One sixth of humanity resides in India, equivalent to 30 or 40 other poor countries. Therefore, preventing disease in India will have a truly global impact,” said Prime Minister Narendra Modi. He went on to say that Indian innovation can make a difference not only in India but across the globe.[6] (Historic partnership between Gavi and India to save millions of lives, GACredit: PMO, Government of India, 2016)

“Together with WHO and UNICEF, Gavi’s support will help India to turbo-charge its immunisation programmes, protecting more children more quickly,” said Gavi CEO Dr Seth Berkley. “I applaud the Government of India, in particular the leadership of the Prime Minister and the Health Minister, for taking such a bold position on immunisation and for recognising the role it has to play in protecting
India’s children, and I am pleased with the part the Vaccine Alliance is playing as a partner in this important work.” [9] (Historic partnership between Gavi and India to save millions of lives, GACredit: PMO, Government of India, 2016)

Currently 60% of all Gavi-procured vaccines are manufactured in India. Through the partnership, Gavi and the Government of India will work more closely together to help create a more sustainable global and domestic vaccine manufacturing base within India. This will be crucial to ensuring sufficient vaccine supplies are available for the 27 million children born in India every year, and children living in all 72 other Gavi-supported countries.[10] (Historic partnership between Gavi and India to save millions of lives, GACredit: PMO, Government of India, 2016)

Despite India’s recent successes in eliminating polio and neonatal tetanus, the country is home to four million under-immunised children, about a fifth of the total among Gavi-supported countries. Gavi and its partners will provide targeted support to help India’s immunisation system identify and reach children who are not receiving vaccines, including exploring how India’s vast number of polio workers can support uptake of other routine vaccines, such as the 5-in1 pentavalent vaccine and these new vaccines.

Such is the power of cultural, political and economical factors that affect millions of people in a biopharmaceutical industry. This was a governmental initiative which can be replicated in a private set ups. The message take-away from the above is the fact that political will, infrastructure availability, overcoming local cultural/traditional barriers, fears combined with skilled manpower availability and mass mobilisation for a ‘common good cause’ made the program successful.

The emergence of single factor that can transform a community, country or groups will be a deciding aspect of a successful implementation of a healthcare programme by support of an expert biopharmaceutical group supported by the government.

The above strategies are being adopted by companies like GSK, Bharath Biotech and Shantha Biotechnics Ltd. to introduce vaccines that are needed to combat a lurking perennial problems like malaria, chikungunya and rotavirus infection[3] (ABPI-Global pharmaceutical industry and market The Association Of British Pharmaceutical Industry, 2016).


The whole world went into stand still and helpless when the virus, Covid-19, being the coronavirus infection that started sweeping the world starting February 2019. The world saw the first virus emergence from Wuhan, China in Oct 2018, the origin of the virulent virus.


In the post decades two types of coronaviruses caused SARS and MERS. These have jumped from animals to humans. These infections are called zoonosis. There are four of these coronaviruses that cause cold in humans[8] (Times Of India, 2020).

Scientists have calculated that the bat coronavirus that they found in Yunnan and SARS-CoV-2 would’ve taken at least a few decades of evolution to diverge from one another. So, they are not the same virus. At best, they’re related[8] (Times Of India, 2020).

The spike protein is responsible for the highly infectious nature of SARS-CoV-2. Among these spike proteins are specific binding proteins that recognise specific human cells that will be targets to let this virus attach. These specific binding proteins are different from the ones found on the horseshoe bats[8] (Times Of India, 2020).
Yunnan province, where there are many horseshoe bats, is about 1,500 km from Wuhan, where the first cases were detected.

In the first theory, a bat coronavirus infected an intermediate species before jumping to humans.

Scientists think parts of the receptor-binding domain came from sequences of an animal other than a bat. A coronavirus found in the ant eaters, pangolins, has a near-perfect match for the very specific receptor-binding domain of SARS-CoV-2 spike protein. Some scientists believe a bat coronavirus and a pangolin coronavirus infected one cell and the RNA genetic material recombined to form a hybrid virus. This SARS-CoV-2 ancestor may have taken the pangolin receptor-binding domain gene fragment and inserted it into the bat spike protein gene. This theory is plausible, but right now, it is also speculative because an intermediate has not been found. The absence of a perfect match has prompted many to suggest that the virus was patched up in a laboratory from where it escaped. This is a controversial theory, but it cannot be formally ruled out until we find a match to SARS-CoV-2 in nature. But we do not need to resort to this theory of deliberate genetic engineering, when a simpler natural one exists. The other intermediate hosts and reservoirs are minks, raccoon dogs before it could infect humans[8] (Times Of India, 2020).

All of this makes us fear that it seems unlikely that we might be able to eradicate SARS-CoV-2 completely[8] (Pandemic Preparedness During COVID-19: Biopharma Lessons and Future Eileen Coveney, Apr24, 2020).

Every continent of the world is affected by the novel coronavirus infection Covid-19. Till date, that is 19th April 2021, there are recorded 141 million positive cases[9] (Pandemic Preparedness During COVID-19: Biopharma Lessons and Future Eileen Coveney, Apr24, 2020).

Today, till date, USA, India, Brazil, France and Russia are the top 5 countries showing highest number of cases as recorded through the WHO.

The Indian biopharmaceutical industry is the third largest producer of by volume and manufactures 60% of vaccines globally. This constitutes 40% to 70% of supply for WHO’s demand for Diphtheria, Tetanus and Pertussis (DTP) and Bacillus Calmette Guerin (BCG) and 90% demand for measles vaccines[10] (Dadhich, 2020).

India supplies affordable and low cost generic drugs to millions of people around the globe and operates more than 250 US food and drug administration (USFDA) and UK medicine and healthcare products regulatory agency (UKMHRA) approved plants. According to a report on the pharmaceutical industry, the source of API is a crucial part of the pharma industry’s strategic plan to combat the Covid-19 crisis. The majority of APIs for generic drug manufacturing across the globe are sourced from India, which also supplies approximately 30% of generic APIs used in the US. However Indian manufacturers heavily rely on the APIs sourced from China for the production of the medicine formulations procuring around 70% from China, the top global API producer and exporter by volume[10] (Dadhich, 2020).

The impact of SARS-CoV-2 coronavirus outbreak, Covid-19, has exposed the dependency of the Indian pharma sector on China for its API procurement. Supply chain disruptions and product exportations restrictions from India resulted from manpower shortages in China’s manufacturing plants. This was caused by quarantine policies adapted and adopted by differential provincial governments in China in response to the virus epidemic. Supplies were further impacted by the disruption of the logistics and transportation systems, restricting access and movement of products to and from ports[10] (Dadhich, 2020).

Several key representatives from the pharmaceutical industry and NITI ayog (an Indian government policy think tank) suggested the fostering of the approvals of the development of the pharmaceutical infrastructure, clearance from the environment ministry, and providing tax exemptions/subsidies for the development of this industry that could benefit the market[10] (Dadhich, 2020).

The Indian government proposed an incentive package of Rupees 13.76 billion (approximately $ 181 million) for the promotion of domestic manufacturing and critical key starting materials, drug intermediates, APIs and medical devices[10] (Dadhich, 2020).
The Indian pharmaceutical industry maintains great advantages like the availability of large labour pools and advanced technologies that enable high regulatory standards similar to the markets like the US and the European countries10 (Dudich, 2020)

Looking at the credentials of the Indian biopharmaceutical and vaccines manufacturing, the following highlights further the credibility for its contributions to the world.

The United States and India have engaged in "unprecedented levels of cooperation to combat the coronavirus pandemic," U.S. Under Secretary of State Stephen Biegun said on October 12, 2020. Biegun's comment came during a trip to India, where he praised the deepening U.S.-India relationship and the shared values and goals of the world’s largest democracies. Biegun pointed to this strengthening relationship as leading directly to “cooperation on developing and producing therapeutics and vaccines” to fight COVID-1911 (United States and India partner on vaccine research, https://ge.usembassy.gov/usby U.S. Embassy Tbilisi, 2021).

This statement comes from the fact that India is one of the leading manufacturer of quality vaccines and that the world recognises India as the global manufacturing hub.

One such partnership includes the 33-year-old Indo-U.S. Vaccine Action Program (VAP), a bilateral program between the U.S. National Institutes of Health (NIH) and India’s Department of Biotechnology and the Indian Council of Medical Research12 (United States and India partner on vaccine research, https://ge.usembassy.gov/usby U.S. Embassy Tbilisi, 2021).

Ongoing VAP activities include vaccine research focused on tuberculosis, dengue, chikungunya, respiratory syncytial virus (RSV) and SARS-CoV-2, the virus responsible for COVID-19, as well as research on other emerging pathogens13 (United States and India partner on vaccine research, https://ge.usembassy.gov/usby U.S. Embassy Tbilisi, 2021).

According to this report, Indian institutions and drug manufacturers and producers have partnered with U.S. universities, charities and pharmaceutical companies to test and study potential COVID-19 vaccines. The successful U.S.-India collaboration on vaccines and therapeutics has global implications since India is one of the largest suppliers of affordable drugs in the world14 (United States and India partner on vaccine research, https://ge.usembassy.gov/usby U.S. Embassy Tbilisi, 2021).

Many of India’s largest vaccine manufacturers, including the Serum Institute of India (SII) in Pune and Biological-E and Bharat Biotech in Hyderabad, are playing a vital role in the global fight against COVID-1915 (United States and India partner on vaccine research, https://ge.usembassy.gov/usby U.S. Embassy Tbilisi, 2021).

For example, SII is working to develop a COVID-19 vaccine with U.S. biotech firm Codagenix and is working with GAVI, the Vaccine Alliance and the Bill & Melinda Gates Foundation to produce 200 million doses of COVID-19 vaccines for low- and middle-income countries16 (United States and India partner on vaccine research, https://ge.usembassy.gov/usby U.S. Embassy Tbilisi, 2021).

SII is also manufacturing vaccines developed by U.S.-based Novavax and U.K.-based AstraZeneca, both part of Operation Warp Speed and recipients of funding and support from the U.S. government17 (United States and India partner on vaccine research, https://ge.usembassy.gov/usby U.S. Embassy Tbilisi, 2021).

Operation Warp Speed, initiated by the White House Task Force, coordinated a public-private partnership to develop, manufacture and distribute safe and effective vaccines, therapeutics and diagnostics in historically record times18 (United States and India partner on vaccine research, https://ge.usembassy.gov/usby U.S. Embassy Tbilisi, 2021).

Additionally, the U.S. government announced in September 2020 that Gilead, the U.S. inventor of remdesivir, which is used to treat COVID-19, had granted licenses to several Indian companies to produce a generic version of the drug for "127 low- and middle-income countries."19 (United States and India partner on vaccine research, https://ge.usembassy.gov/usby U.S. Embassy Tbilisi, 2021).
“We know that our continued close cooperation with India will be an important part of the global recovery from the pandemic,” a State Department spokesperson said\cite{11} (United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021)

Fighting the virus: While working with the Indian government and private sector to develop vaccines, the United States is also helping India respond to its own COVID-19 outbreak\cite{11} (United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021).

Since the beginning of 2020, the U.S. Agency for International Development (USAID) has provided $13.1 million and 200 state-of-the-art ventilators to India as part of the United States' more than $900 million in global humanitarian assistance to fight the coronavirus worldwide\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.

Since the pandemic began, India has confirmed more than 15 million cases and over 180,000 deaths. It has the second-highest number of Covid-19 infections in the world after the United States\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.

India expanded its vaccination programme to include all adults over the age of 18 starting 1 May amid a deadly second wave of infections. The country's healthcare system is overwhelmed with more than 200,000 cases and about 1,300 deaths being reported daily. India has so far administered more than 127 million doses of a coronavirus vaccine in what is the world's largest inoculation drive\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.

Another feather in the cap was... In early April, India declared that it was "the fastest country in the world" to give more than 100 million jabs. It achieved the feat in 85 days, whereas the US took 89 days and China 102 days, the health ministry said\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.

India is currently giving jabs of two vaccines - one developed by AstraZeneca with Oxford University (Covishield) and one by Indian firm Bharat Biotech (Covaxin). Both were approved in January ahead of the vaccine rollout.

Looking at the alarming cases in India rising, In April, a third vaccine - Russia's Sputnik V - was approved for use. Several other candidates are at different stages of trials.

India placed a temporary hold on all exports of AstraZeneca to meet domestic demand but the vaccine's maker, Serum Institute of India (SII) recently said its production capacity was "very stressed" and that it was "still short of being able to supply to every Indian"\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.

The federal government has since cleared the way for an "advance payment" of 4,500 crore rupees ($610m; £435m) to Bharat Biotech and SII to boost their supply\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.

Bhramar Mukherjee, a biostatistician at the University of Michigan, told the BBC that India needed to administer 10 million shots daily "instead of being complacent with three million" doses a day\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.

There are challenges to be overcome like experts believed India was well-prepared for the challenge. But the uptake has been slow because of vaccine scepticism as well as a lack of awareness among the poor or in rural areas. Many of the poor have little information on how to register themselves and access the vaccine free of cost. Eligible people can book their jabs online or walk in and register at vaccination centres\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.

The silver lining is that the Vaccination is voluntary. State-run clinics and hospitals are offering free jabs, but people can also pay 250 rupees ($3.4; £2.4) a dose at private facilities\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.

From 11 April, the government allowed people to get paid jabs at private and state-run workplaces\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.

The government is spending around $5bn to provide free doses at state-run clinics, public health centres and hospitals\footnote{United States and India partner on vaccine research, https://ge.usembassy.gov/uly U.S. Embassy Tbilisi, 2021}.
Bottomline is that India is a promise to be explored in case of regulating the spread in these these viral pandemic situation with 1396 million people residing, the quality pharmaceutical manufacturing hub of the world and the credibility of one of the largest vaccines manufacturers of the world.

India is already known for running massive successful vaccination drives as mentioned in an live example before this and India has already fixed a tag of 127 million doses till date, being the highest in the world so far for Covid-19 vaccination injections. With this in the background and the fast approvals by the ministry for a restriction free Covid-19 therapeutic drug manufacturing infrastructure permissions; India will again prove to the world that Indian biopharmaceutical Industry will set an example for control and prevention of such pandemics.

9. Evolution and progression of a progressing industry

Global innovators will have to drive product innovation to command premium pricing, shifting the frontier of technology and exploring new operational setups (design & development of new set ups). Biosimilars will have to focus on cost, quality and scale.

Players in the emerging markets will have to find their own niches with right operational, quality and regional/ traditional nuances so as to make the therapy more population specific. Contract manufacturing will have to develop state-of-the-art operational, quality and delivery excellence to fit into the pressures of cost leadership, niche segment of operations and given the political, regulatory landscape.

The biopharmaceutical companies which are poised for success will have to develop systems, processes, strategies focused on their unique placement, positioning in the market place. This will also be coupled with the stand that the company needs to take in the entire scheme of things.

This will be cultural, political and local economies that will pave way for long term foundation of the companies.

An entire discussion on the technical, operational excellence of the biopharmaceutical company will be beyond the scope of the current paper. Nonetheless, following are the points that needs to be evaluated before even we start thinking of taking a global biopharmaceutical company to the new level:

- The culture plays a major role as it has a direct bearing on the level of education and developing of passionate individuals for such type of work. A well qualified and skilled staff will always be an asset to an organisation to contribute towards growth. In marketing and sales side, a successful contemporary pharmaceuticals should be able to manifest a sophisticated understanding of therapies, scientific merits and be able to communicate patient-centric and value-based outcomes. These companies must also understand the cost-conscious landscape that payers and government health programs are operating in.

- Political environment and will plays a major role in taking the formed biopharma entity to the new level of competency. The organisation needs to comply with the local needs and development of the local population. This will be in terms of understanding the healthcare needs and finding a solution to help reduce suffering. All this will act as a positive impetus in increasing political will and thereby support expanding the organisational operations.

- The understanding of the micro & macro economic factors of the region is extremely crucial in deciding the commercial strategy of a biopharmaceutical organisation. For example, globally the focus is apparently shifting towards emerging economies given the positive growth rates in their production capacity/GDP, target population that are greater than the developed economies\(^7\) (Press Information Bureau, 2016). India and China are two countries that are targeted as future growth areas\(^7\) (Press Information Bureau, 2016). \(^5\) (Mukherjee, S.Mukherjee, Bio Pharma Drive, 2015). Given this fact, it will be useful to consider what percentage of healthcare budgets as a percentage of the GDP (for e.g., in India the total spending on healthcare is only a miniscule 5% to 7% of the GDP which is higher in China and other emerging countries like the Brazil, Venezuela, Mexico etc.)
Therefore, this comparative macro-economic factor would be important consideration along with the other factors like meeting the demands of domestic and international, global quality and raw material dynamics. These would play a crucial role in shaping up the given industry under this study under the present pandemic situation.


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