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Challenges of Indian Pharmaceutical Industries to Meet World Requirement during COVID-19 Pandemic

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Abstract

The World Health Organization (WHO) declared COVID-19 a pandemic on March 11, 2020, after the outbreak that was first reported in Wuhan, China in December 2019. The COVID-19 pandemic affected world economy including the pharmaceutical sector. The health crisis unleashed in the world because of this pandemic and the attempts of various countries and organizations in the world to contain it have also fuelled the greatest economic crisis in modern history. This study aims to access, analyze, and highlight opportunities and problems of the Indian pharmaceutical sector in the broader national health-care industry during the COVID-19 particularly for contract manufacturing The recent changes in the field, at the institutional and corporate levels, have placed India in the spotlight of the global pharmaceutical market, but several threats and weaknesses could limit this expansion. Descriptive and inferential analyses have been based on questionnaire, data extracted from authenticated data sources. Subsequently, a narrative strengths, weaknesses, opportunities, and threats analysis was performed based on the results of prior investigations and on qualitative data that were retrieved from a marketing intelligence examination to generate an overall scenario analysis. Indian pharmaceutical companies have faced several challenges on various fronts. In the home market, drug prices are controlled by the drug price control order; therefore, there is strong pressure on revenues and subsequently on costs. In the international market, threats derived from pharmaceutical multinational companies are emerging as tough obstacles to overcome. This study provides a global overview of the potential growth and development of the Indian pharmaceutical sector, comparing it with internal trends and external competition. The most relevant contribution of the research relies on the shift to innovative production that Indian companies must adopt (after years of focusing only on generic drugs), and in this vein, appropriate industrial marketing solutions are indispensable.

Keywords: India, Intellectual property, Health-care industry, Pharmaceutical sector, Contract Manufacturing Organizations, Production innovation, Active pharmaceutical ingredients

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Introduction

The pharmaceutical industry is a very important component of the global economy. The long-term growth potentials of the industry remain upbeat given growing and aging population, emerging medical conditions, and emergence of new diseases. The Indian pharma industry has achieved significant growth in both domestic and global markets during the past five decades. From contributing just 5% of the medicine consumption in 1969 (95% share with global pharma), the share of "Made in India" medicines in Indian pharma market is now a robust 80% in 2020. More importantly, during the same period, the country has also established leading position in the global generic pharmaceuticals landscape and is now known as the "Pharmacy of the world". The pharma industry in India contributes more than 20% by volume of global generics market 62% of global demand for vaccines. The Indian domestic pharmaceutical market size has reached US$20.3 billion in 2019 with growth of 9.8% (market size of US$18.12 b in 2018). The domestic market has grown at 2.2% during April–September 2020 compared to the same period last year despite a sluggish start to the year due to the pandemic. Indian pharma exports reached US$20 billion in FY20 with year-on-year growth of 8.4%.[1]

The World Health Organization (WHO) declared COVID-19 infection, that is, severe acute respiratory coronavirus infection (SARS-CoV-2) a pandemic on March 11, 2020, after the outbreak of flulike infection was first reported in Wuhan, China in early December 2019. As countries and companies alike continue to grapple with the unprecedented challenges thrown up by the novel coronavirus (COVID-19), a specific area of concern has been the uncertainty surrounding the impact of the COVID-19 pandemic on the global as well as Indian pharma industry supply chain.

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India imports about 70–75% of active pharmaceutical ingredients (APIs) and key starting raw materials from China, the world's leading producer and exporter of APIs by volume, for meeting the bulk requirements. Due to supply chain disruption, the cost has surged by 40–50% in India for medicines such as paracetamol, penicillin, and anti-asthma drugs. The pharmaceutical units were operated at 40–50% of their capacities because of unavailability of workforce and curtailment to only one shift at various plants. The restrictions on usage of public transport as well as requirement for passes for traveling have also affected movement of workers and they found it difficult time to reach the manufacturing units. The non-availability of transportation facility for dispatching materials was another major challenge during the period. The ancillary industries to pharma industry including some of the packaging materials for medicines were yet to be brought

under the purview of essential services. This posed a serious challenge to packaging vendors to source their raw materials for making the medicine packages and this could be a significant impact on pharmaceutical production. The slowdown in imports has also affected the innovative drug development.[2] The Indian pharmaceutical sector is at the top among the country's science-based industries, having widespread competencies in the complex field of drug manufacturing and technology; before 1991, governmental policies focused on self-reliance, protectionism, and lesser cooperation in trade and services, whereas the world was advancing technologically very quickly, particularly in the information technology sector.[3,4] These factors affected the country in many ways; one of the most relevant impacts was less priority given to the health sector for growth and modernization, with smaller cities and remote areas covered with the inefficient national health-care service or small hospitals and practitioners.[5] The subsequent development of the sector brought India to rank among the top health-care markets in the world by the end of 2020. Various factors have influenced this progress: An increase in per capita income, boosting public awareness of various diseases and preventive measures, decreasing costs of health-care services, effective research and development (R&D) activities, and governmental policies to induce foreign investment (IBEF, 2016). From a quantitative point of view, the Indian health-care sector is expected to surpass US$372bn by 2022 and by 2024–2025, India's biotech industry is estimated to increase to US$100bn (FICCI, 2018). From a qualitative point of view, the Indian health-care sector focuses on several critical pillars: Preventive health care, accessible health care, building medical services and mission style strategies for maternal health, child health, and the marked rise in the burden to fight transmissible and non-communicable diseases.[6] Although its economy is the third-largest in the world after China and the USA in terms of purchasing power parity (Imf.org), India is still characterized by insufficient health-care facilities, scarce physical and medical infrastructure, and insufficient specialized medical staff in smaller cities and rural areas, largely due to a lack of economic resources.[7] The Indian pharmaceutical industry is among the top producers in the world, supplying over 50% of the global demand for various vaccines, 40% of generic demand in the USA, and 25% of all medicines in the UK (IBEF, 2020). Although the sector still shows more relevant values concerning production quantity than production turnover, pharmaceutical exports are expected to reach US$16.28 bn in FY20 (ibidem). At present, there are more than 11,000 manufacturing units and over 3000 pharma companies in India; although the industry is growing at an exceptional rate, it is highly fragmented; the top ten firms, including multinational companies (MNCs), account for only one-third of the total revenues from the sector.[8] The market is dominated by generic products with 71% of the total market share and 20% of global exports in terms of volume, which makes India the largest supplier of generics globally,[9] with particular importance in the field of vaccines.[10]

The pharmaceutical industry required companies to be vertically integrated, that is, the company itself performed all the operations required of its business. Now, investors are demanding continued high financial performance. As a result, "outsourcing" has become a significant way of doing business. Outsourcing is the system of using a nonrelated for another on a contractual basis.[3]

Contract manufacturing is a process that establishes a working agreement between two companies. As part of the agreement, one company custom produces parts or other materials on behalf of their client. In most cases, the manufacturer also handles the ordering and shipment processes for the client. As a result, the client does not have to maintain manufacturing facilities, purchase raw materials, or hire labor to produce the finished goods.[11] It is a form of outsourcing.[11]

Outsourcing has resulted in the development of a new paradigm offers companies new opportunities for improving their bottom lines through the conversion of fixed costs to variable costs. They accomplish this by reducing or eliminating in-house production capabilities and replacing them with contract manufacturers. As a result, contract manufacturers that perform custom synthesis and produce intermediates, API, and dosage forms are becoming increasingly important to the conduct of today's business.[12]

A contract manufacturing organization (CMO) is an organization that serves the pharmaceutical industry and provides clients with comprehensive services from drug development through manufacture.[13]

Services offered by CMOs can be divided into two main activities: Primary manufacturing and secondary manufacturing. Primary manufacturing involves the synthesis of the bulk active ingredients (drug substances) while secondary manufacturing refers to the formulation of bulk drug substances into the final drug products (pills, topical formulations, and injectables).[13-15]

How to Determine when a Contract Manufacturer is Needed[11]

The need for service of a contract manufacturer can occur at any time during the development phase and/or commercial manufacturer of a product's life cycle. Such situations occur when

- Specialized manufacturing capabilities are required that are not available in house.
- Assistance is needed with product and/or process development.
- The need to establish the market potential of a new product is required before investing in specialized capabilities.
- Difficulty is encountered in breaking into the manufacturing schedule in a timely manner to produce small research, clinic, or commercial batches.
- Production requirements cannot be accommodated when sales exceed capacity.

Capacity is needed for the production of new and growing product; yet, a place for the manufacture of products that are at the end of their life cycle still needs to be provided Companies are finding many reasons why they should be outsourcing their production to other companies. However, production outside of the company does come with many risks attached. Companies must first identify their core competencies before deciding about contract manufacture. A company's core competencies are what make them competitive in the market place. If a company allows another company to take control of them, it loses that advantage.[12]

For small companies, contract manufacturing may not be a good business strategy. For large companies that are trying to extend into new markets, contract manufacturing may be a good choice.[12]

Benefits

Cost savings

Companies save on their cost of capital because they do not have to pay for a facility and the equipment needed for production.

They can also save on labor costs such as wages, training, and benefits. Some companies may look to contract manufacture in low-cost countries, such as China, to benefit from the low cost of labor.[2,11]

Mutual benefit to contract site

A contract between the manufacturer and the producing company may last several years. The manufacturer will know that it will have a steady flow of business.[12]

Advanced skills

Companies can take advantage of skills that they may not possess, but the contract manufacturer does.[16]

Quality

Contract manufacturers are likely to have their own methods of quality control in place that helps them to detect counterfeit or damaged materials early.[16]

Focus: Companies can focus on their core competencies better if they can hand off base production to an outside company.[16]

Economies of scale

Contract manufacturers have multiple customers that they produce for. Because they are servicing multiple customers, they can offer reduced costs in acquiring raw materials by benefiting from economies of scale. The more units there are in one shipment, the less expensive the price per unit will be.[16]

Other benefits includes the rapid use of technology, gain a global manufacturing presence, improved asset utilization, gain a window on a new technology, freedom to concentrate on core functions, faster time to market, and access to market.[17]

Risks

Lack of control

When a company signs the contract allowing another company to produce their product, they lose a significant amount of control over that product. They can only suggest strategies to the contract manufacturer; they cannot force them to implement them.[13-15]

Relationships

It is imperative that the company forms a good relationship with its contract manufacturer. The company must keep in mind that the manufacturer has other customers. They cannot force them to produce their product before a competitor's. Most companies mitigate this risk by working cohesively with the manufacturer and awarding good performance with additional business.[13-15]

Quality concerns

When entering into a contract, companies must make sure that the manufacturer's standards are congruent with their own. They should evaluate the methods in which they test the products to make sure they are of good quality. The company has to rely on the contract manufacturer for having good suppliers that also meet these standards.[13-15]

Intellectual property loss

When entering into a contract, a company is divulging their formulas or technologies. This is why it is important that a company not give out any of its core competencies to contract manufacturers.[13-15]

Outsourcing risks

Although outsourcing to low-cost countries has become very popular, it does bring along risks such as language barriers, cultural differences, and long lead times.[13-15]

This could make the management of contract manufacturers more difficult, expensive, and time-consuming.[13]

Capacity constraints

If a company does not make up a large portion of the contract manufacturer's business, they may find that they are deprioritized over other companies during high production periods. Thus, they may not obtain the product they need when they need it.[13-15]

Loss of flexibility and responsiveness

Without direct control over the manufacturing facility, the company will lose some of its ability to respond to disruptions in the supply chain. It may also hurt their ability to respond to demand fluctuations, risking their customer service levels.[13-15]

Some other risk factors include problem of monitoring supplier performance, problems of evaluating supplier performance, need for new management mind set, loss of critical skill, lack of shared vision, objectives, cultural differences, and critical dependence on supplier.[17]

Key Component of the Supply Agreement[5,13-15]

- Contract term
- Testing and specification for release
- Lot quantities, yield
- Price and payment terms
- Capital expenditures
- Minimum and maximum supply
- Lot rejection
- Termination review period
- Forecast and purchase orders and inspections
- Raw material purchase and vender qualifications
- Technical transfer
- Process changes and continuous improvement
- Dispute resolution

India's Contract Manufacturing Opportunity[18]

India has the largest number of United States Food and Drug Administration (USFDA) approved pharma plants worldwide, after the US – a total of 75 plants. This is 3 times more than the number of plants in China which have FDA approval. This not only reflects the quality of the Indian pharma industry but also the depth of expertise that exists industry-wide. More USFDA standard trained personnel area available in India than in China – thus making it easier for newer entrants to get certification. However, for international firms looking at India, there is a bugbear – most of the large Indian firms are key competitors in the generics market – thus there is exposure of process, systems, and quality

standards which makes global firms uneasy. Hence, the field is open for the stand-alone contract manufacturing company. With the global contract manufacturing opportunity expected to rise to 140 Bn US $ by 2009, and Indian contract manufacturing market size expected to be at 1.7 Bn US$ by 2009, the standalone contract manufacturing business is poised to explode in India. Firms that have a head-start, who have experience and systems to handle rigid quality requirements of global firms, can expect to participate strongly in the boom. The other side of the coin, however, could very well be start-up contract manufacturing firms – armed with global contracts and funds from venture capital – they could very well form the next global beaters after IT in India [Figure 1].

Country Except the US[19]

(Source: Crisil Research, Bulk drug exports to scale up in the regulated markets (December 2008) for India; ICICI Securities, Indian Pharma Sector: Sector Update (December 2008) for Italy, China, Spain, Taiwan, Israel and Hungary) Among six offices that the US FDA has overseas, two are located in India, in Delhi and Mumbai.[19]

All domestic producers are also obliged to comply with India's Good Manufacturing mPractices, under Schedule M of the Drugs and Cosmetics Act, 1940. Indian manufacturers are currently facing some scrutiny around quality issues. In 2009, the US FDA took action against a few Indian companies after conducting a series of inspections and issuing warning letters against these drug makers. While such sanctions clearly pose significant challenges, some analysts see an opportunity as well. Indian companies are aggressively improving their manufacturing standards in response and are, therefore, likely to be better positioned to take advantage of the upsurge in generics production expected as patents expire over the next 5 years.[19]

Some Indian manufacturers are also now incorporating lean manufacturing and six sigma principles to help them boost operational efficiency and further improve quality, while facilitating compliance.[19]

Literature Review

The COVID-19 pandemic affected world economy including the pharmaceutical sector. At present, there is no specific treatment guideline and medicine to treat the novel Coronavirus infection. Pharmaceutical industry is assisting governments to address the COVID-19 unmet needs including research and development activity on potential treatment strategies to balance medicine supply chain at the time of crisis.[20] Pandemics such as COVID-19 are associated with high rates of morbidity and mortality which negatively affected the socioeconomic status and livelihoods of communities. The pharmaceutical industry plays a very important role to produce quality health-care services, especially during pandemics, when medicines supply chain can be overwhelmed due to varying reasons. These include over-reliance on traditional manufacturing and distribution routes such as India and China.[21] Furthermore, lockdowns as in during the early days of COVID-19 pandemic led to restriction of in-county and cross border movements, which had a huge impact on how pharmaceutical supplies that are transported and delivered during the period.[22] APIs and other active ingredients required to manufacture drugs by the Indian manufacturers are mainly sourced from India and China due to COVID-19-related interruption, an acute shortage of APIs was started from May 2020, because most of the manufacturing companies maintain 2–3 months stock of bulk drugs.[23] Shortage of APIs and other active ingredients had impacted the capacity of many of Indian pharma manufacturing units by 20–30% of normal production capacity. There were also indications that the costs of acquiring APIs were increasing. Lockdown and governmental guidance on physical distancing in workplace and some other challenges unique to local contexts that had prevented the manufacturing companies from operating at 100% capacity. In general, a typical pharmaceutical company holds up inventories up to 180 days.[23] Retail drug stores allow inventory holding period up to 60 days or less. COVID-19 may be seen as a century's opportunity for pharmaceutical industry as it increases the demand for prescription medicines, vaccines, and medical devices. Demand change, supply shortage due to shortage of inventory of input materials to manufacture drugs, panic buying and stocking, regulation changes and shift of communication, and promotions to remote interactions through technology and research and development process changes can be seen as immediate impact of COVID-19 on health-care industry. Demand change, which leads to shortage in the case of induced demand and panic-buying of oral home medication specially for chronic disease, may be due to the pandemic and shortages in supply-chain inconsistency.[24] The study reported that induced demand in global pharmaceutical market 5 mainly due to "panic-buying" of pharmaceuticals for chronic disorders was estimated +8.9% by March 2020.[25] A study in USA indicated that for March 13–21, 2020, asthma medications sparked by 65% and Type 2 diabetes increased by 25%.[26] This shortage has already begun to affect APIs and bulk prices in Indian trades. The average increase was reported to be about 10–15%; however, it may reach to 50% in some specific cases like APIs of paracetamol.[27] The pharmaceutical sectors are struggling to maintain natural market flow as the recent pandemic affects the access to essential medicines in an affordable price, which is the main goal of every pharmaceutical industry.[28] Coronavirus pandemic resulted in economical slow-downs for many countries, and this will possibly lead to pharma industry growth slow-down.[29] The international shipping disruption increased supply chain cost, local freight charges, air, and sea fair also increased due to the delay in shipping.

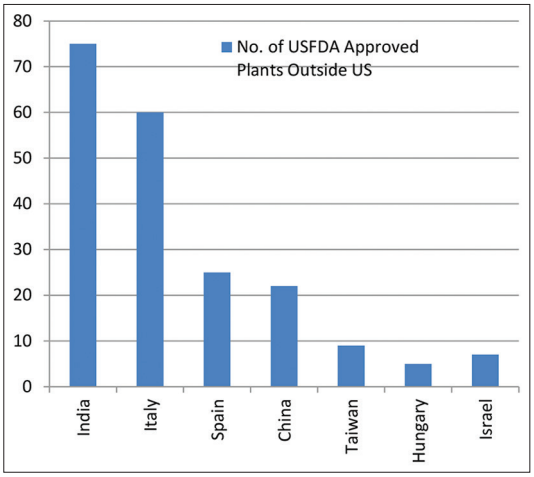


Figure 1: India has more United States Food and Drug Administration-approved manufacturing plants than any

Research Methodology

- Knowing the scope and emergence of outsourcing with new business models particularly during COVID-19 for Indian pharmaceutical industry
- To find out the reasons for the companies to outsource their projects (specially the manufacturing facilities) and to know how to seize the right outsourcing opportunity
- To identify the resource evaluation, selection, business considerations, and relationship management of CMOs
- To study the different agreements and regulatory compliance/ hurdles with special reference to contract manufacturing
- To identify the benefits, potential, and perception of risk for outsourcing within the pharmaceutical organizations.

Based on the above background, the following research questions have been formulated regarding the Indian pharmaceutical sector.

Q1. What does your organization define as an "outsourced" externalized, or contracted out activity?

Q2. Which of the following best describes your company's approach to Outsourcing?

- As a Vendor relationship…….
- As a partnership…….
- As a pure procurement exercise……
- As a captive service provider……
- Acquire the services provider to turn into a group shared services center……..
- Do not know…….

Q3. Why do you outsourced?

- To Focus on Core Competency…….
- Temporary lack of capacity…….
- Cost Savings…….
- Easier and extended access to services…….

Q4. Which services you would like to outsource most commonly?

- Contract research activities
- Contract manufacturing of product Formulation and APIs
- Contact marketing/Comarketing
- Others

Q5. How concerned are you about the following potential risks of outsourcing?

- Weakness in third party's internal control
- Loss in intellectual property
- Lack of direct control over vital processes
- Loss of sensitive corporate information
- Risk of negative publicity

Q6. How much impact of COVID-19 on supply chain of API.

- 1 month delay
- 2 months delay
- 3 months delay
- 4 months delay
- 5 months delay

Q7. Is there any impact of COVID-19 on increase or decrease in new contract manufacturing orders compared with non-COVID time?

- Increase in orders
- Decrease in orders
- Cancellation of orders due to shortage of API
- No increase or decrease in orders

Results and Discussion

Q1. What does your organization define as an "out sourced", externalized, and contracted out activity.

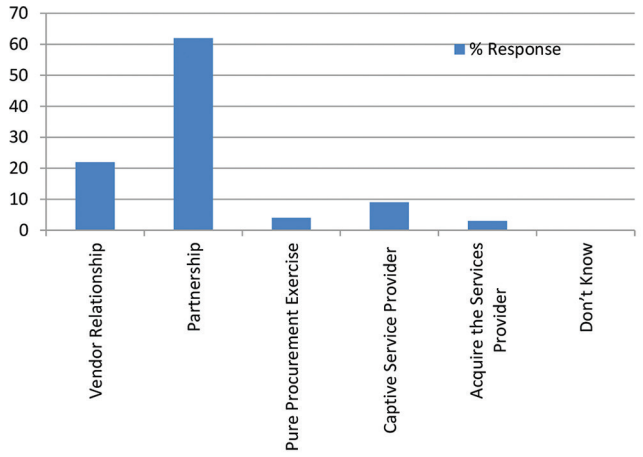
Discussion

In response to this question, no formal organization view or corpora view originally seen as anything contracted out, now outsourcing out, no outsourcing seen as any task that can be done as well or better by others and that either costs less or no more or provides added value. Need a valid reason for doing it-speed skill or cost. No overall strategy in organization.

Q2. Which of the following best describes your company's approach outsourcing?

Result

Approach to outsourcing	*% Response*
Vendor relationship	22
Partnership	62
Pure procurement exercise	4
Captive service provider	9
Acquire the services provider	3
Don't know	0



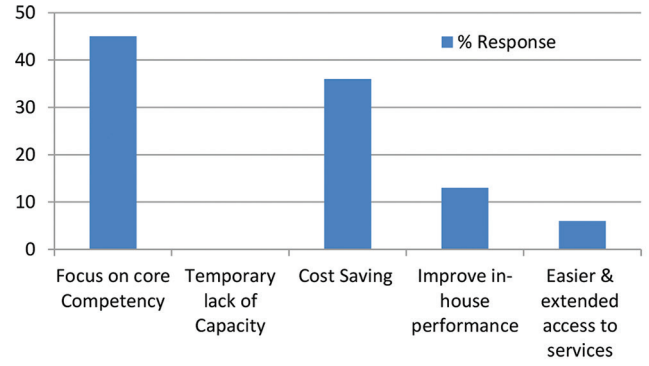
Discussion

To examine the company's approach to outsourcing, respondents were asked to identify their opinions concerning their opinions concerning the approach of their company to outsourcing. The type of business function appears to determine the kind of relationship that arises between outsourcers and service provider. About 60% of the companies executives think that their company's approach with the service provider is a partnership type relationship. Around 24% of executives say that they have vendor type relationship with their service provider. About 10% of the responses say that their company has a captive service provider type of relationship and around 3% have their approach as a pure procurement exercise and remaining 3% think to acquire the service provider. From the survey results, it was concluded that company's approach toward outsourcing were: Most commonly partnership type, including vendor relationship, pure procurement services, and captive service provider.

Q3. Why do you outsource?

Result

Reasons of outsourcing	*% Response*
Focus on core competency	45
Temporary lack of capacity	0
Cost saving	36
Improve in-house performance	13
Easier and extended access to services	6



Discussion

The reason for outsourcing may be difficult with company to company. Every company knows their strengths and weakness areas. Hence, the respondents were quite confused about giving the answer of this question but out of the majority around (45%) say to focus on core competency and around (36%) thinks that cost saving is the reason to outsourcing the project to a CMOs. No one think that they do not have the capacity to do that in house. Some 13% of executives' also say that they wants to improves there in house performance by outsourcing and some 6% says that they outsource their projects for easiness and extended access to service. The top reasons for undertaking outsourcing projects identified by the survey resells were to: Focus on core competency function, reduce costs, and improve in house performance. Other reasons may be easier and extended access to services and reduce the overall amount of specialized skills and knowledge needed for operations.

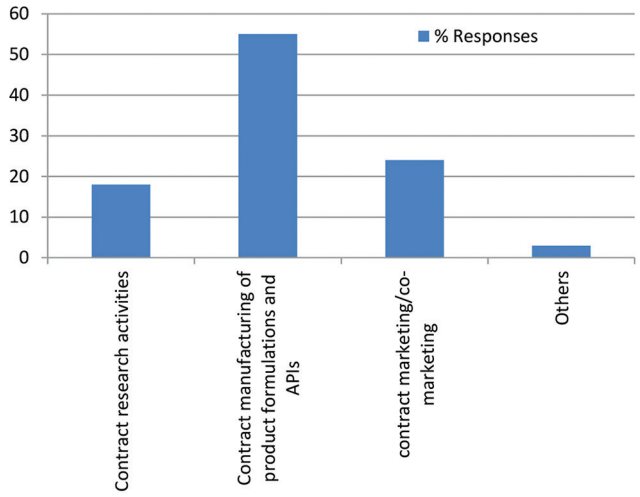
Q4. Which service you would like to outsource most commonly?

Result

Services commonly outsourced	*% Responses*
Contract research activities	18
Contract manufacturing of product formulations and APIs	55
contract marketing/comarketing	24
Others	3

Discussion

Asked about the commonly outsourced services by the company concerned, 55% of the respondents say that contract manufacturing is the largest outsourcing activity. About 8% of respondents says they outsource R and D activities more frequently. Contract research and informatics through currently small are expected to be fast growing outsourcing activities.



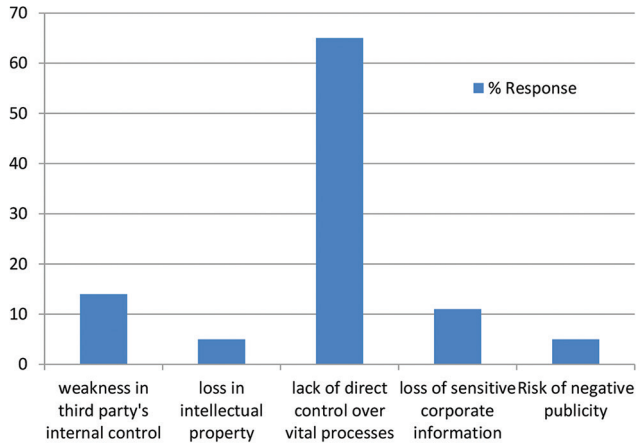
Contract sales (25%) are the commonly outsourced activities of few companies. Contract marketing/comarketing does not offer immediate opportunities due to its very nature (requirement of on-the ground sales team). About 2% responses covers the contract laboratory services commonly outsourced. Given the market potential and established track record, manufacturing will continue to remain the largest outsourcing activity out of India.

Outsourcing projects target specific types of activities or functions. Organizations were asked to identify the types of activities that they outsourced or were attempting to outsource. The top activities or functions identified were: The contract manufacturing, contract sales, and contract research activities most commonly including the contract laboratory activities.

Q5. How concerned are you about the following potential risks of outsourcing?

Result

Potential risks of outsourcing	*% Responses*
weakness in third party's internal control	14
loss in intellectual property	5
lack of direct control over vital processes	65
loss of sensitive corporate information	11
risk of negative publicity	5



Discussion

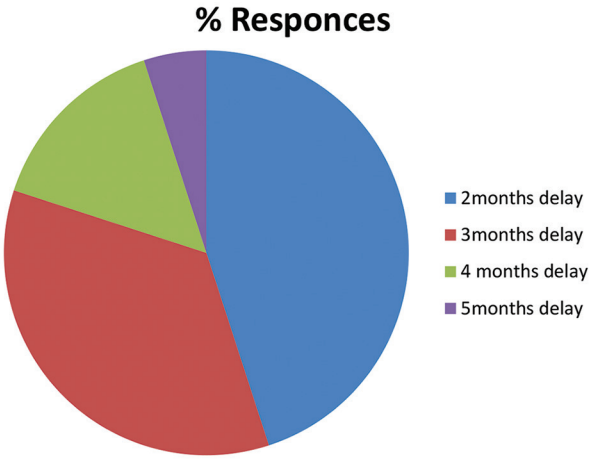
Organizations were asked about the awareness about the potential risks of outsourcing. About 67% of the executives say that the potential risk is the lack of direct control over vital process by the sponsor company. Only 4% of the respondents think the loss of intellectual property because of that strong patent regime in house in India. About 13% of the respondents say the third party's internal control. Loss of sensitive corporate information covered only 10% of response and no-one think about the risk of negative publicity by outsourcing.

Survey results were concluded that lack of direct control over vital processes most commonly affected the outsourcing company including others such as loss of sensitive corporate information, risk of negative publicity, loss in intellectual property, weakness in third party's internal control.

Q6. How much impact of COVID-19 on supply chain of API

Result

Supply chain of API	*% Responses*
2 months delay	45
3 months delay	35
4 months delay	15
5 months delay	5



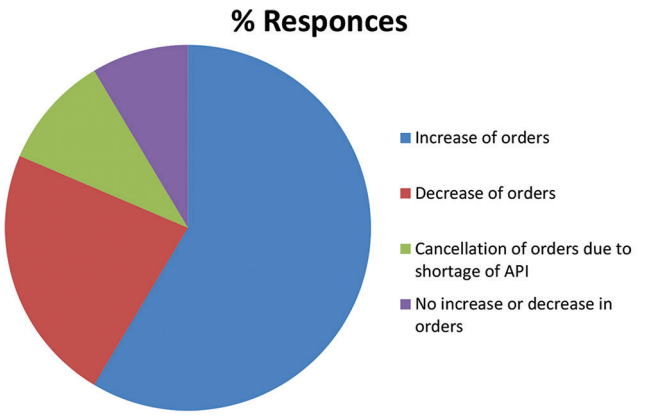
Discussion

All the CMOs admitted that there is impact of COVID-19 on supply chain as the 70% of API were exported from China. Due to lockdown, the supply of API disrupts. As Indian pharmaceutical industry largely depends on China for API. Due to COVID-19, many countries closed their borders and international movement particularly with China as it was assumed that virus is spreading from China as first case of virus found in that country. The shortage of APIs drastically affected the Indian pharmaceutical firms and cost of APIs suddenly shoots up and profit margins declined due to this.

Q7. Is there any impact of COVID-19 on increase or decrease in new contract manufacturing orders compared with non-COVID time?

Result

Contact manufacturing orders	*% Responses*
Increase of orders	30
Decrease of orders	0
Cancellation of orders due to shortage of API	25
No increase or decrease in orders	5



Discussion

As India is third largest producer of medicine in the world. Due to COVID-19, the most of world is looking to India to fulfill their medicine needs. In India, the most of the drugs are produced through the contract manufacturing units. For COVID-19, there was no particular treatment, only hit and trail method was used to treat it and large number of medicines from different segments being recommended and there was sudden shortage of medicine in whole world. An increase of around 30% contract manufacturing orders for medicines received by Indian pharmaceutical organizations was observed.. As Indian pharmaceutical industry depends on China for Active Pharmaceutical Ingredients (API), but due. Due to cancellation of International flights and closed borders; the supply of API from China was not regular whereas Indian pharmaceutical industry received large scale orders from national and international front. Due to shortage of APIs from China due to COVID-19 restrictions, the most of orders received from MNCs were not fulfilled in time and delay of about more than 3 months for fulfilling orders noticed during that period in 2020–2021. The CMOs were not accepting the new orders and the orders received already witness cancellation due to non-delivery of finished product to them in time.

Conclusion

While COVID may be devastating every aspect of life, we should not lose the opportunity to learn and grow. This is the time for the private sector to evolve strategies to think in terms of the whole health system—not just their own sector—in terms of population health and not just individual health. The Indian pharmaceutical industry is the world's third largest drug producer by volume and the country's market manufactures 60% of vaccines globally. This constitutes 40–70% of supply to satisfy the WHO demand for diphtheria, tetanus, pertussis, Bacillus Calmette Guerin vaccines,

and 90% of the global demand for the measles vaccine.

India supplies affordable and low-cost generic drugs to millions of people around the globe and operates more than 250 USFDA and UK Medicine and Healthcare products Regulatory Agency (MHRA) approved plants. Furthermore, its APIs market is forecasted to attain revenue of $8billion by the end of 2022.

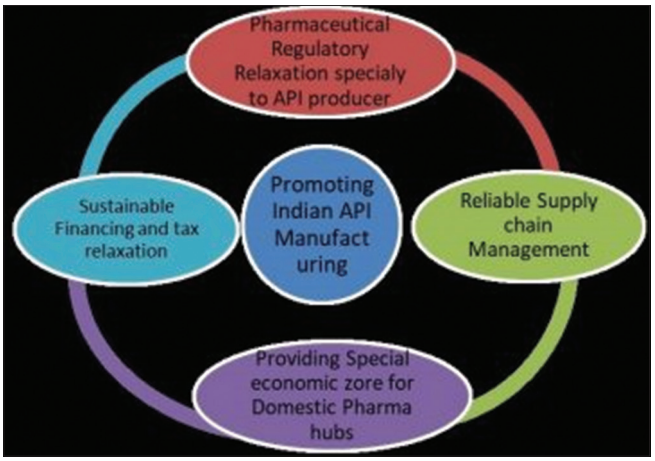
According to a report on the Indian pharmaceutical industry, the source of APIs is a crucial part of the pharma industry's strategic plan to combat the COVID-19 pandemic. The majority of APIs for generic drug manufacturing across the globe are sourced from India, which also supplies approximately 30% of the generic APIs used in the US. However, Indian manufacturers rely heavily on APIs from China for the production of their medicine formulations, procuring around 70% from China, the top global producer and exporter of APIs by volume.

Indian pharmaceutical sector depends on China for the procurement of Active Pharmaceutical Ingredients (API). Supply chain disruptions and product exportation restrictions from India resulted from manpower shortages in China's manufacturing plants. This was caused by the quarantine policies adapted and adopted by different provincial governments in China in response to the virus. Supplies were further impacted by the disruption of logistics and transportation systems, restricting access and movement of products to and from ports.

Before 1991, the Indian pharmaceutical industry only imported 0.3% of its APIs from China; however, the globalization of Indian pharmaceutical companies and the rise in large-scale formulation manufacturing prompted the increase in API procurement from China. The primary driver being the low cost of production.

The current dependency of Indian pharmaceutical companies on Chinese APIs is a serious concern for national health security, prompting the Indian government to set up a taskforce to review the internal API sector. Several key representatives from the pharmaceutical industry and NITI Aayog (an Indian government policy think tank) suggested that fostering the approvals of pharmaceutical infrastructure developments, clearance from the environment ministry and providing tax exemptions and subsidies for the development, and promotion of the pharmaceutical industry hubs could all benefit the market.

Strategies for Promoting Indian API Production



In the present situation, the Indian government should take important steps to remove the technical and financial barriers that will spur the pharmaceutical industry to ramp up API production, reducing the dependency of the pharmaceutical industry as a whole on the heavily impacted Chinese market. The Indian government recently undertook applaudable steps by proposing an incentive package of 13.76 billion Indian Rupees (approximately $181 million) for the promotion of domestic manufacturing of critical key starting materials, drug intermediates, APIs, and medical devices. The Indian pharmaceutical industry maintains great advantages, including the availability of a large labor pool and advanced technologies that enable high regulatory standards of markets like the US and European countries to be met.

COVID-19 has clearly highlighted the importance of a strong health-care system, the lack of which can put an entire nation's economy and society at risk. As India continues to fight COVID-19 and stabilize its economic growth trajectory, it is the right time for the country to apply learning's from the challenges and best practices that emerged during the pandemic. There is a need to swiftly develop the required health-care infrastructure and make it available to the entire population. The Indian pharma industry has been a key contributor in improving the country's healthcare and economic outcomes. The pandemic has accelerated several opportunities and challenges for the industry. While the growing trust deficit with China presents an opportunity for India, there is increasing competition from other countries, such as Vietnam and Malaysia. India is also dependent on China for two-third of its imports of bulk drugs or drug intermediaries. To emerge as a winner in the post-pandemic world, the industry needs to continue building on its strength and at the same time make a giant leap toward innovation. New capabilities need to be introduced across the business functions to bring efficiencies and to help industry move up the value chain. Government also needs to provide the right enablers and business environment conducive for growth.

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