Original Article

Benefits Of Outsourcing Of Medicine In Indian Pharmaceutical Industry

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Abstract

Forecasts indicate that by 2025, India's pharmaceutical market would be worth $100 billion. 1 India's pharmaceutical exports were worth $16.3 billion in fiscal year 2019/2020. As of 2019, the Indian biotechnology market was valued at $64 billion, and by 2025, that number is expected to grow to $150 billion. Generic pharmaceutical production and export constitute the majority of the industry. After modifications to the Indian patent system in 2005 made it possible to patent pharmaceutical items, the focus shifted to the development of novel medications. Slower growth in the U.S. market is only one of these factors, alongside a decrease in the discovery, development, and commercialization of new chemical entities despite an increase in the number of blockbuster medications, competition from generic pharmaceutical goods, and regulatory obstacles. The commercial components of the sector are the primary focus of this research, which also suggests some changes to the existing business model and future directions.

Keywords: Medicine, pharmaceutical, Outsourcing, Industry, encourages

1. INTRODUCTION

India has one of the biggest and most developed pharmaceutical industries in the developing world, ranking number four globally in terms of production volume and number thirteen in terms of domestic consumption value. In 2005, India's pharmaceutical market was estimated at $5.30 billion, or less than one percent of the $550 billion worldwide pharmaceutical market. 3 In only 30 years, India has gone from having a virtually nonexistent pharmaceutical sector to becoming a global leader in the manufacture of high-quality generic pharmaceuticals. India's generic medication industry has become well-known for its affordable quality and widespread distribution. Currently, the sector supplies all of India's bulk medication requirements and almost all of its formulation requirements, with the remaining coming from international pharmaceutical conglomerates (MNCs).

The pharmaceutical business in India has grown at a pace of 14% per year on average between 2002 and 2005, making it one of the fastest-growing sectors of the Indian economy. Between 2005 and 2010, the Indian pharmaceutical market is expected to expand by an average of 15 to 20 percent each year. India's ability to reverse-engineer patented drug molecules, the growth of contract manufacturing and outsourcing, value-added foreign acquisitions and joint ventures, and India's efforts to comply with the World Trade Organization's Trade Related Intellectual Property Agreement (TRIPs) obligations have all contributed to the surge in production. India's pharmaceutical exports were worth less than $600 million in 1995, when the country joined the WTO. Over 61% of industry revenue in 2005 came from exports, which had increased to $3.7 billion by 2005. There are now 60,000 available finished medications and almost 400 available bulk pharmaceuticals used in formulations, with Indian pharmaceutical firms accounting for 20-22% of global generic drug production (in value terms).

'Reverse engineering' became a specialty for India's pharmaceutical industry when the country's patent laws were liberalized in the early 1970s, allowing the country to make cheaper knockoffs of the world's best-selling patent protected pharmaceuticals. Despite government price limitations on many pharmaceutical formulations and bulk medications, India's pharmaceutical sector developed and thrived under strict regulation. India's pharmaceutical patent rules were updated in January 2005 to comply with the World Trade Organization's TRIPs agreement. The new patent legislation prevents Indian pharmaceutical companies from producing and selling generic copies of patented pharmaceuticals made in other countries. In order to make up for revenue lost due to TRIPs compliance, many of India's top pharmaceutical producers have increased exports of generic drugs to the United States and Western Europe and entered into research and development agreements, mergers and acquisitions, and other alliances with foreign pharmaceutical firms.

The implications of these shifts for pharmaceutical company business strategies are substantial. Historically, most Big Pharma firms have handled every stage, from R&D through commercialization, in-house. We believe that by the year 2020, this business model will no longer be viable for the majority of existing businesses. They need to increase their R&D productivity, decrease their costs, capitalize on the opportunities presented by developing markets, and shift their focus from selling medications to controlling outcomes, all of which are difficult tasks that few businesses are capable of doing alone. To create efficient new medications, assist patients in health management, and guarantee the efficacy of their goods and services, pharmaceutical giants like Pfizer will need to work with other entities. As an added complication, they may have to go well beyond the industry for some of the partners they need. As Pharma looks into the future, we anticipate the rise of two primary business models: the federated model and the completely diversified model. Furthermore, we believe that the current economic downturn will hasten the transition to these new models by reinforcing one of the key causal factorsthe pressure on healthcare payers to maximize the value they get for the money they spendand by creating new opportunities to construct or acquire the networks that will be necessary. In the pages that follow, we'll examine the key developments that are driving the need for more cooperation. We will also compare the strengths and weaknesses of the various business models in light of the difficulties now confronting the market.

2. LITERATURE REVIEW

Valentina Marinkovic, et al. (2020),With the Critical Incident Technique as the basis, this study aims to provide a workable framework for the effective combination of contract organizations and purchasers (CIT). The original set of scenarios was inductively crafted using qualitative input from 10 professionals in the area of outsourcing in the pharmaceutical supply chain. A second panel of specialists assessed the realistic and applicable nature of these scenarios and classified them into one of five categories: employee competency, management commitment, communication between companies, organizational culture, and regulatory framework. The study's results suggest that regulatory framework is the least common cause of critical occurrences during outsourcing, whereas communication is the most common cause. Both the contracting party and the service provider have different opinions on how realistic and important the scenarios are. The interrater agreement study reveals that the complexity and multidimensionality of key episodes make it difficult to assign them to a single construct. Preventive behavior-based quality management in the pharmaceutical supply chain is the unique contribution of the critical incidents database and the given approach.

András Domokos, et al. (2021),Research and development of novel active compounds has been the primary source of innovation in the pharmaceutical business for quite some time, but the structure of manufacturing, driven by batchwise methods, has remained largely unchanged. Continuous manufacturing (CM) provides significant benefits over batch operations, as has been shown in a number of different industries. A far higher standard of quality assurance allows for the development of quicker, cheaper, and more adaptable manufacturing. Recent years have seen a rise in the promotion of continuous technologies and the encouragement of pharmaceutical firms to develop and adapt such processes on the part of the key regulatory authorities, signalling a shift in the industry's focus toward more efficient

methods of drug manufacture. Thus, by now, a lot of study has been done across the board in pharmaceutical technologies, from the production of drug substances through finished pharmaceutical products. Continuous filtering, drying, granulating, and mixing have all been researched to varying degrees on the formulation side, and many papers deal with continuous synthesis stages performed in flow reactors and crystallizations conducted in a continuous way. Additionally, fresh, inherently continuous technologies are being investigated alongside the adaptation of existing conventional processes to continuous operation. End-to-end systems, including everything from primary resources to finished dosages, are necessary to fully realize CM's potential benefits. However, combining even two technical processes is no easy feat. Building complete systems calls for an in-depth knowledge of processes and an integrated strategy for their improvement. In order to shed light on the current landscape and promising future of integrated continuous pharmaceutical technology, this paper provides a comprehensive overview of the most recent research in the subject.

Sia Chong Hock et al. (2021),When making pharmaceuticals, continuous manufacturing (CM) involves integrating a number of unit activities such that raw materials are always being processed. Pharmaceutical CM has gone from buzzword to reality in recent years, with at least eight authorized medications having been developed using CM. Manufacturers and regulators, propelled by various forces, have recognized the benefits of CM and are waiting for the completion of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q13, a harmonized guideline on CM that would be implemented by ICH members. Although there has been substantial development, the pharmaceutical sector has been slow to implement CM owing to the various obstacles that have prevented manufacturers from doing so. Uncertainty in manufacturing regulations and high startup costs are two of the biggest challenges today. Manufacturers and regulators may both gain from CM if these challenges are resolved. CM's unrealized potential has far-reaching effects on patients' access to life-saving drugs. Few publications have reviewed the present regulatory requirements, highlighted the most recent issues, and proposed suggestions that are relevant to all medicines and biopharmaceuticals, despite the large number of research. Therefore, the purpose of this critical evaluation is to discuss the latest advancements and current issues in order to shed light on CM for manufacturers. The study also includes important suggestions for the future. Included in this category are regulatory harmonization, financial risk management, hybrid processes, capacity expansion, quality culture, and Pharma 4.0. Manufacturers should concentrate on resolving the economic, technical, and cultural barriers to CM deployment while regulators and the industry work towards harmonizing a guideline on CM.

KurucPoje D. et al. (2019),Shortages of essential medicines pose a major threat to the healthcare system, negatively impacting patient care. More adverse effects and longer lengths of stay in hospitals have been documented from studies conducted in the United States and Canada. Research in Europe mostly considers the perspectives of stakeholders, community and hospital pharmacists, with little attention paid to the clinical effect or the perspectives of patients. The European Association of Hospital Pharmacists (EAHP) conducted the two largest cross-European studies on the effects of drug shortages on hospital pharmacists in 2014 and 2018. From 2014 to 2018, they saw a rise in the frequency of drug shortages. In 2018, 92% of hospital pharmacists indicated that pharmaceutical shortages were preventing them from providing optimal treatment to patients and/or running the pharmacy smoothly, up from 86% in 2014. Infectious illnesses, cancer treatment, the ER, cardiovascular care, and anesthesia were the worst hit therapeutic areas. Negative consequences on patients were also recorded, such as delays in care, cancellations of care, prescription mistakes, poor treatment/inferior effectiveness, needless side effects experienced by patients, worsening in patients' health, and even death. As an added complication, the research lacks a comprehensive account of how patients feel about drug shortages in hospitals. In order to assess the impact of drug shortages on patient outcomes, qualitative research is now being conducted in many European countries. Gaining a deeper understanding of patients' problems, desires, and necessities is facilitated by this research. In addition, it will collect up-to-date information on these patient care difficulties and address data gaps from earlier surveys.

Pooja Thakur-Wernz, et al. (2020), Both consumers and service providers may gain significantly by considering the study's conclusions. The authors show how R&D outsourcing to countries with a less developed legal system may convert service providers into formidable rivals for their client companies, thanks to the spread of information. This study aids companies in developing countries by demonstrating that learning from their international counterparts by becoming vendors for R&D offshore outsourcing is a realistic possibility. There may be significant challenges for these developing economy businesses to expand internationally due to limited resources. One possible way for these businesses to improve is by offering offshore outsourcing services for certain segments of research and development. This report is pioneering in that it is one of the first to statistically examine the innovation output of vendor enterprises from developing countries. The authors also make a contribution to the sparse literature on innovation in emerging market businesses by demonstrating that offering R&D offshore outsourcing services to client firms from developed nations may boost firms' innovation performance.

3. RESEARCH METHODOLOGY

The efficient method of data collecting was used for this investigation. Different methods of data gathering have introduced errors into the study's conclusions. Numerous methods exist for gathering information. Primary data gathering method allows for data categorization in this research. Our definition of an OI practice, a standalone business process inside the company that works toward OI paradigm objectives, serves as the case study's unit of analysis. However, the OI activities we take into account operate at separate levels of the firm's business model - namely, strategy and open sources practices; as a result, we must treat this as an embedded case study.

4. DATA ANALYSIS

Benefits/ Disbenefits of Outsourcing

Table 1:Outsourcingimprovescost management

		Frequency	Percent	ValidPercent	CumulativePercent
Valid	Stronglydisagree	12	11.3	11.3	11.3
	Disagree	15	14.2	14.2	25.5
	Not sure	3	2.8	2.8	28.3
	Agree	37	34.9	34.9	63.2
	Stronglyagree	39	36.8	36.8	100.0
	Total	106	100.0	100.0	

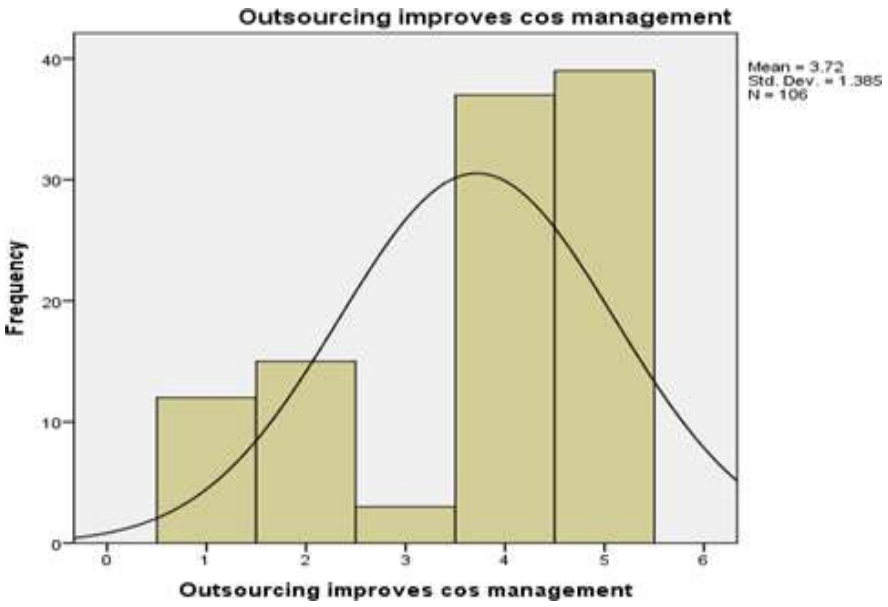

Figure 1:Outsourcing improves cost management

Table 1 and Figure 1 show that 39 respondents (36.8%) highly agreed, 37 respondents (34.9%) agreed, 15 respondents (14.2%) disagreed, 12 respondents (11.3%) strongly disagreed, and 3 respondents (2.8%) were unsure. As a result, outsourcing helps with budgeting on projects.

Table 2:Outsourcingencouragesemployeeinnovation

		Frequency	Percent	ValidPercent	CumulativePercent
Valid	Stronglydisagree	40	37.7	37.7	37.7
	Disagree	13	12.3	12.3	50.0
	Not sure	1	.9	.9	50.9
	Agree	52	49.1	49.1	100.0
	Total	106	100.0	100.0	

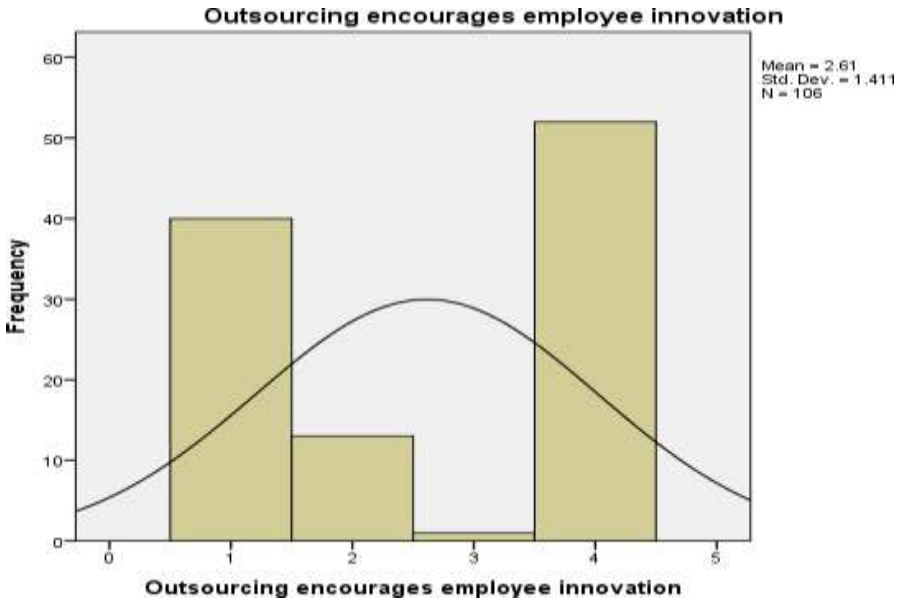

Figure 2:Outsourcingencourageemployeeinnovation

Table 2 and Figure 2 show the results of the author's survey on the topic of whether or not employees should profit from outsourcing in terms of creativity (49.1% agree, 37.7% disagree, 12.3% disagree), and 1.9% are unsure. It follows that the employees gain from the outsourcing approach in terms of the creativity of the project.

Table 3:Outsourcinghashelpedtoincreaseproductivity

		Frequency	Percent	ValidPercent	Cumulative Percent
Valid	Stronglydisagree	1	.9	.9	.9
	Disagree	10	9.4	9.4	10.4
	Agree	56	52.8	52.8	63.2
	Stronglyagree	39	36.8	36.8	100.0
	Total	106	100.0	100.0	

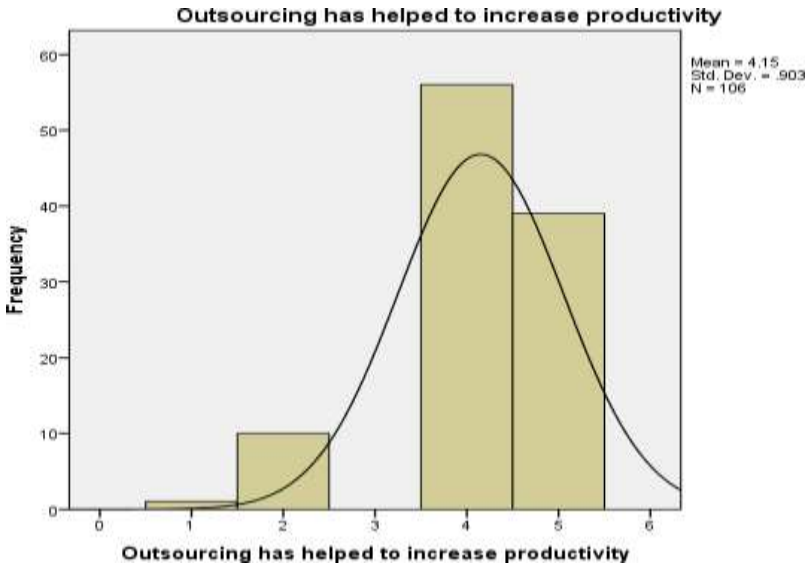

Figure 3:Outsourcinghashelpedtoincreaseproductivity

Table 3 and Figure 3 reveal that 56 respondents (52.8% of total) agree with the statement, 39 (36% of total) strongly agree, 10 (9.4% of total) disagree, and 1 (0.9%) severely disagree. Therefore, the project's productivity was boosted by the outsourcing technique.

Table 4:Outsourcinghashelpedtoincreaseefficiency

		Frequency	Percent	ValidPercent	Cumulative Percent
Valid	Stronglydisagree	3	2.8	2.8	2.8
	Disagree	13	12.3	12.3	15.1
	Not sure	10	9.4	9.4	24.5
	Agree	55	51.9	51.9	76.4
	Stronglyagree	25	23.6	23.6	100.0
	Total	106	100.0	100.0	

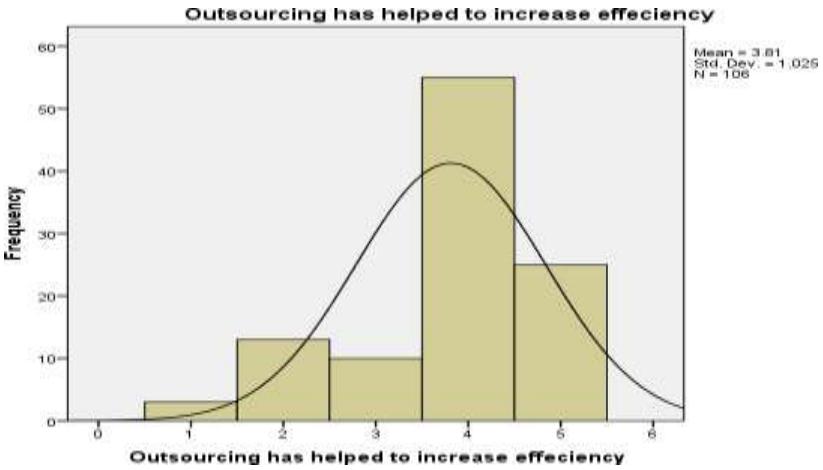

Figure 4Outsourcinghashelpedtoincreaseefficiency

Table 4 and Figure 4 reveal that overall, 51.9% of respondents felt that outsourcing was a good idea, while 23.6% strongly agreed, 12.3% disagreed, 9.4% were unsure, and 2.8% were severely disagreed. Based on these findings, it is possible to determine whether or not an organization might profit from outsourcing.

Table 5:Outsourcinghashelpedtoimprove infrastructure

		Frequency	Percent	ValidPercent	CumulativePercent
Valid	Stronglydisagree	6	5.7	5.7	5.7
	Disagree	8	7.5	7.5	13.2
	Not sure	32	30.2	30.2	43.4
	Agree	36	34.0	34.0	77.4
	Stronglyagree	24	22.6	22.6	100.0
	Total	106	100.0	100.0	

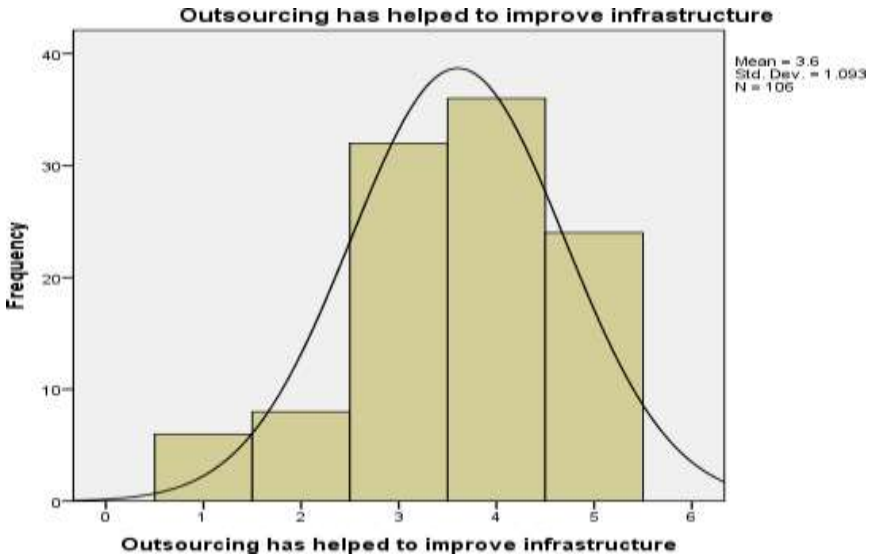

Figure 5:Outsourcinghashelpedtoimproveinfrastructure

As can be seen in Table 5 and Figure 5, the responses of 36 (34%), 32 (30.2%), and 24 (22.6%) respondents show agreement, uncertainty, and uncertainty, respectively, whereas the responses of 8 (7.5%), disagreement, and 6% (5.7%) show significant disagreement. As a result, the DART and NICTBB infrastructure projects benefit from the outsourcing approach.

Table 6:Outsourcinghashelpedtoimprove Technology

		Frequency	Percent	ValidPercent	umulativePercent
Valid	Stronglydisagree	5	4.7	4.7	4.7
	Disagree	11	10.4	10.4	15.1
	Not sure	3	2.8	2.8	17.9
	Agree	52	49.1	49.1	67.0
	Stronglyagree	35	33.0	33.0	100.0
	Total	106	100.0	100.0	

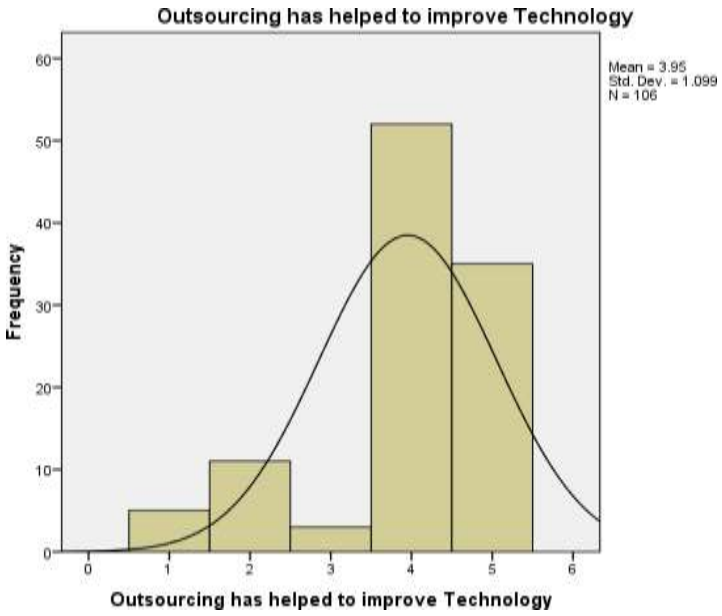

Figure 6:outsourcinghashelpedtoimprove technology

Table 6 and Figure 6 reveal that fifty-two respondents (49.1%) agreed, thirty-five (33.1%) were very much in agreement, eleven (10.4%) disagreed, five (4.7%) very much disagreed, and three (2.8%) were unsure.

5. CONCLUSION

A rise in GDP and large cost savings have contributed to the rapid expansion of the Indian pharmaceutical business, which has had a CAGR of 20% over the last several years. India's formulation and bulk medication exports have grown significantly as the country's pharmaceutical companies become more active participants in the global pharmaceutical sector. These financial restraints have increased the cost of hiring an inventor but have also encouraged the growth of contract research organizations.

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