

Dilemma to Dominance: Decoding the Evolution of the Indian Pharmaceutical Industry - A Case Study

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ABSTRACT

The Indian pharmaceutical industry has undergone a significant evolution, transitioning from a domestically-focused sector to a global powerhouse. Initially, Indian pharmaceutical companies primarily catered to domestic healthcare needs. However, with the implementation of economic reforms in the 1990s, the industry witnessed rapid growth and expanded into international markets. The Indian pharmaceutical industry has experienced a remarkable transformation, establishing itself as a global leader in the production and export of generic drugs. The industry has demonstrated superior growth performance, making it one of the fastest-growing sectors worldwide. Productivity levels and innovation play a significant role in determining competitiveness, and the Indian pharmaceutical industry has shown impressive capabilities in these areas. Government policies have been instrumental in driving the industry's self-sufficiency and internationalization. The establishment of public sector pharmaceutical enterprises and the introduction of intellectual property regulations, pricing control, and research and development (R&D) support have propelled the industry's growth.

This case study aims to provide an in-depth analysis of the journey of the Indian pharmaceutical industry, exploring its growth, challenges, and the dilemma it faces in balancing innovation and affordability. By examining the sector's perspective, challenges, and identified dilemmas, this case study aims to equip readers with a comprehensive understanding of the industry. The case delves into the journey and challenges faced by the Indian pharmaceutical industry. It investigates the industry's growth, the perspective of Indian pharmaceutical companies, the challenges they encounter, and the identified dilemmas. The case also provides teaching notes and objectives to enhance the readers' knowledge and decision-making skills within the pharmaceutical industry.

Keywords: pharmaceuticals, pharmaceutical industry, indian pharma sector, challenges in indian pharma sector

I. CASE INTRODUCTION

The Indian pharmaceutical industry has emerged as a major player on the global market, and its competitiveness can be evaluated through various indicators such as size, growth performance, productivity, innovation, export market share, and import coverage. Indian pharmaceutical industry plays a significant role in the Industrial domain of the Nation. The Industry is one among the leading employers and gets immensely connected with the Academia. The Pharma Sector has specialized courses on Pharmaceutical in Graduation and Post Graduation level which enables the Industry to generate good minds and contribute to the success of the Industry. The Pharma Sector plays a vital role in providing affordable medicines to a vast population. By implementing strategic policy changes, the Indian pharmaceutical industry can enhance its global competitiveness, drive economic growth, improve healthcare outcomes, and ensure sustainable and ethical practices. The industry's journey showcases its immense potential for growth and its ability to navigate the evolving global pharmaceutical landscape.

Indian pharmaceutical companies have adopted an internationalization strategy through acquisitions and collaborations with foreign companies, enabling them to emerge as formidable global competitors. However, the industry also faces certain challenges. The fragmented policy landscape designed to support small- and medium-sized companies has limited the industry's capacity for technological progress and production scalability. Addressing these challenges requires comprehensive policy reforms that strike a balance between nurturing smaller players and enabling larger companies to invest in advanced technologies. Reforms targeting collaboration, innovation, and research capabilities are necessary to unleash the industry's full potential. The evaluation of the Indian pharmaceutical industry's competitiveness involves assessing various indicators, such as size, growth performance, productivity, innovation, export market share, and import coverage. The industry has demonstrated superior growth performance, making it one of the fastest-growing sectors worldwide. Productivity levels and innovation play a significant role in determining competitiveness, and the Indian pharmaceutical industry has shown impressive capabilities in these areas. Government policies have been instrumental in

driving the industry's self-sufficiency and internationalization. The establishment of public sector pharmaceutical enterprises and the introduction of intellectual property regulations, pricing control, and research and development (R&D) support have propelled the industry's growth.

II. JOURNEY OF INDIAN PHARMACEUTICAL INDUSTRY

The Indian pharmaceutical industry has undergone a significant evolution, transitioning from a domestically-focused sector to a global powerhouse. Initially, Indian pharmaceutical companies primarily catered to domestic healthcare needs. However, with the implementation of economic reforms in the 1990s, the industry witnessed rapid growth and expanded into international markets. This section provides an in-depth exploration of the historical development, key milestones, and factors that have propelled the industry's growth. The journey of the Indian pharmaceutical industry is marked by several noteworthy achievements. It has emerged as the largest provider of generic drugs globally, supplying cost-effective medications to both developing and developed countries. The success of the industry can be attributed to factors such as a skilled workforce, low manufacturing costs, a robust regulatory framework, and strong intellectual property laws. Furthermore, strategic partnerships with multinational corporations and investments in research and development (R&D) have significantly bolstered the industry's capabilities. The Indian pharmaceutical industry has emerged as a major player on the global market, and its competitiveness can be evaluated through various indicators such as size, growth performance, productivity, innovation, export market share, and import coverage. This comprehensive analysis aims to shed light on the strengths, challenges, and policy imperatives of the Indian pharmaceutical industry, providing valuable insights into its competitive prowess and the necessary steps to enhance its global position.

Evaluating the Competitiveness: Indian Pharmaceutical Industry

When evaluating the competitiveness of an industry, a straightforward approach involves assessing its relative size and growth performance in terms of value-added. A sector that demonstrates superior growth performance and robustness of output becomes a potential global contender. In the case of the Indian pharmaceutical industry, its consistent growth performance has positioned it as one of the fastest-growing sectors worldwide. Productivity levels play a significant role in achieving higher growth performance among countries, and variations in productivity often stem from differences in innovation. In the knowledge-based pharmaceutical sector, innovation is crucial in gauging the competitive strength of companies and countries. Therefore, evaluating the level of innovation in the Indian pharmaceutical industry provides valuable insights into its competitive prowess. Additionally, key indicators such as export market share and import coverage serve as essential measures of competitive strength. An industry that excels on the global stage and demonstrates a substantial competitive edge over its rivals strengthens its position as a supplier. By analyzing these indicators, a comprehensive understanding of the Indian pharmaceutical industry's competitive position and trajectory can be obtained, paving the way for strategic decision-making and future growth.

Local to Global: India's Thriving Pharmaceutical Sector

The Indian Drug and Pharmaceutical Industry (ID&PI) has undergone remarkable growth and transformation, emerging as a highly dynamic and thriving sector in the global market for generic medications. Over the years, it has established itself as a prominent player, propelled by technological advancements and the introduction of the process patent regime in the 1970s. In this article, we will delve into the industry's evolution, examining its key milestones and the impact of regulatory changes, with a focus on the years 1990 to 2013.

1990-2001: Limited R&D Engagement and Divergent Priorities

During this period, Indian pharmaceutical companies allocated minimal resources to research and development (R&D). In contrast to their Western counterparts, R&D investments averaged only around 2% of sales revenue. This discrepancy can be attributed to different priorities and the protected environment in which Indian businesses operated, focusing on replicating and marketing medications at a lower cost.

2001-2005: Pre-Product Patent Regime:

Prior to the implementation of the Product Patent Act in 2005, the ID&PI witnessed limited focus on new drug discovery and development. Research studies revealed the industry's modest output and minimal R&D investments. Indian pharmaceutical companies recognized the need to adapt to changing global intellectual property regulations to achieve their expansion goals.

2005-2006: Shift towards Higher R&D Intensity

With the introduction of the Product Patent Act in 2005, the ID&PI underwent a transformative phase. Companies realized the importance of bolstering their R&D efforts to secure their positions on the global stage. Amidst this shift, the Indian government's visionary R&D tax benefits program acted as a powerful incentive, encouraging companies to amplify their R&D pursuits.

2006-2012: Post-TRIPS Era and Strategic Surge

Navigating the post-Trade-Related Aspects of Intellectual Property Rights (TRIPS) era, the ID&PI experienced a strategic surge in R&D intensity. Pharmaceutical businesses recognized the need for greater investments in R&D to compete globally. The industry witnessed a remarkable shift, with major corporations emerging as frontrunners, spearheading the industry's transformation.

2013 and Beyond: R&D Renaissance and a Brighter Future

By 2013, the Indian pharmaceutical industry had undergone a significant R&D renaissance. With a newfound emphasis on research and development, the landscape transformed from limited engagement to vibrant innovation. The industry now stands as a testament to the power of evolution and strategic foresight. Greater R&D investments have fueled scientific discoveries, global competitiveness, and a promising future for the ID&PI.

The evolution of the Indian Drug and Pharmaceutical Industry over the years reflects a journey of innovation and global leadership. From limited R&D engagement to a strategic surge, the industry has adapted to regulatory changes and transformed itself into a thriving sector. With a renewed focus on research and development, the ID&PI has embraced innovation, paving the way for scientific advancements, enhanced competitiveness, and a brighter future on the global stage.

III. INSIGHTS INTO THE INDIAN PHARMACEUTICAL INDUSTRY: ASSESSING STRENGTHS, WEAKNESSES, OPPORTUNITIES, AND THREATS (SWOT)

The Indian pharmaceutical industry has undergone a significant transformation over the years, transitioning from a state of dilemma to achieving dominance in the global market. This case presents a comprehensive analysis of the industry's journey, highlighting key developments and examining various factors that have shaped its evolution. The Indian pharmaceutical industry's growth has been driven by multiple factors, including increasing per capita income, growing disease awareness, affordable healthcare, and favorable research and development (R&D) policies. Prior to 1991, government policies focused on independence and limited trade cooperation, resulting in underdevelopment in the healthcare sector. However, progress has been made in modernizing healthcare coverage, with the pharmaceutical industry playing a crucial role.

A detailed assessment of the strengths, weaknesses, opportunities, and threats (SWOT) of the Indian pharmaceutical industry reveals a complex landscape. The industry demonstrates potential for growth, but it also faces challenges in various areas. Government regulation of drug prices in the domestic market puts pressure on revenues and costs. Additionally, global market dynamics and multinational pharmaceutical corporations pose threats to Indian companies.

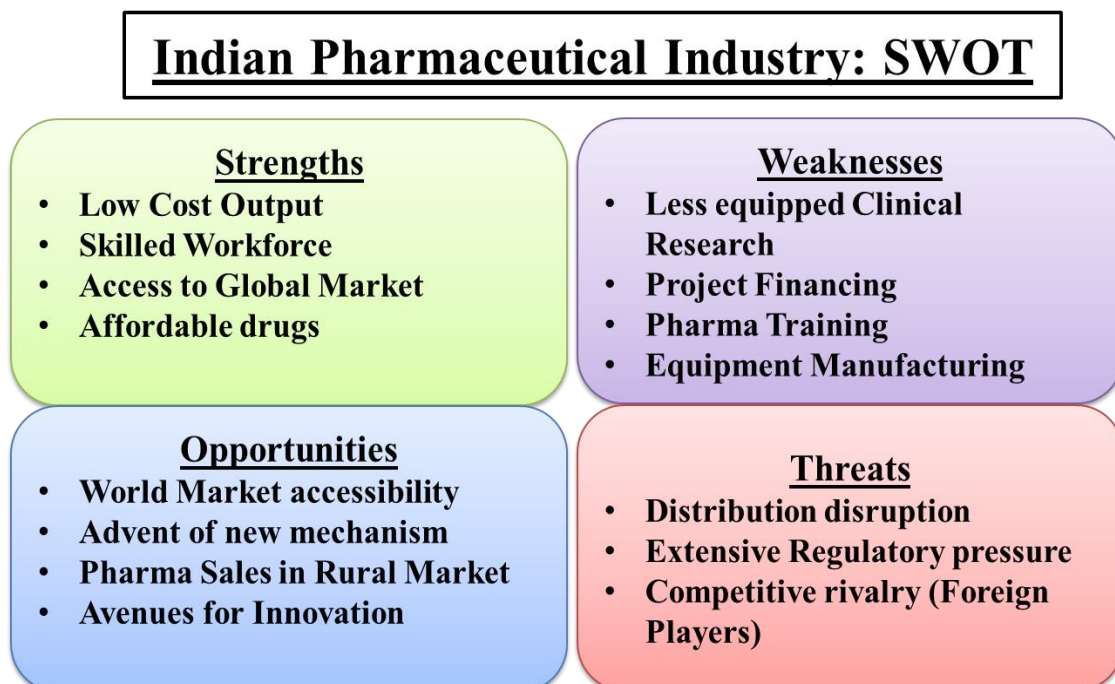


Chart No. 1: SWOT – Pharma Industry

Source: Authors' Study

IV. INDIAN PHARMACEUTICAL COMPANIES: GENERATING PERSPECTIVE OF THE SECTOR

Indian pharmaceutical companies have played a pivotal role in the industry's success. This section focuses on the perspective of these companies, highlighting their strengths, strategies, and contributions to the industry's growth. Indian companies have excelled in the production of generic drugs, leveraging their expertise in reverse engineering and process innovation. Their ability to offer affordable medicines has been instrumental in addressing global healthcare challenges. Moreover, Indian pharmaceutical companies have demonstrated significant competence in contract manufacturing and contract research. They have become preferred partners for multinational corporations, providing quality manufacturing facilities and cost advantages. This section also explores the factors that have enabled Indian pharmaceutical companies to gain a competitive edge in the global market, such as compliance with international quality standards, regulatory harmonization, and investments in technology and infrastructure.

Self-Sufficiency and Internationalization: Indian Pharmaceutical Industry

Government policies have played a pivotal role in transforming the Indian pharmaceutical industry from a heavy reliance on imports to becoming self-sufficient and competitive on the global stage. The establishment of public sector pharmaceutical enterprises served as a pivotal step in promoting indigenous drug production and reducing dependence on imported medicines. Over time, the government introduced intellectual property regulations, pricing controls, and research and development (R&D) support to further develop the industry. These measures have propelled the growth of a robust pharmaceutical sector, positioning India as a competitive developing nation on the global stage. To enhance and sustain their competitive position in the global market, Indian pharmaceutical companies have adopted an internationalization strategy that complements and enhances their technological prowess. One effective approach is through the acquisition of foreign companies that offer fresh product portfolios, advanced technology, and expertise. This enables Indian pharmaceutical firms, many of which lack the technological capabilities for product development, to emerge as formidable global competitors.

Additionally, strategic collaborations with established global pharmaceutical corporations from developed nations can play a vital role in internationalization. Such collaborations can encompass contract manufacturing, research partnerships, and joint marketing efforts. These initiatives facilitate the expansion of Indian enterprises' global operations and enhance their ability to compete on a global scale. By implementing an internationalization strategy that bolsters their technological strength and fosters collaborations with global players, Indian pharmaceutical companies can fortify their competitive position and drive further growth in the global pharmaceutical landscape.

V. INDIAN PHARMACEUTICAL INDUSTRY: CHALLENGES

Despite its impressive growth, the Indian pharmaceutical industry faces several challenges. This section examines the key challenges that hinder the sector's progress, including regulatory complexities, intellectual property issues, quality control concerns, and pricing pressures. Regulatory complexities pose a significant challenge, with varying regulations across different countries affecting the industry's ability to efficiently enter new markets. Intellectual property issues, including patent disputes and generic drug approvals, require careful navigation to strike a balance between innovation and affordability. Ensuring quality control throughout the manufacturing process is another crucial challenge. The industry must adhere to international standards and stringent quality requirements to maintain its reputation as a reliable supplier of medicines. Additionally, pricing pressures from both domestic and international markets pose challenges for Indian pharmaceutical companies, necessitating innovative pricing strategies and cost management practices.

Balancing between Challenges and the Growth Path of the Indian Pharmaceutical Industry

While the Indian pharmaceutical industry has witnessed remarkable growth, the policy regime that facilitated this expansion also presented certain challenges. The fragmented policy landscape, designed to support numerous small- and medium-sized pharmaceutical companies, has inadvertently limited the industry's capacity for further technological progress and production scalability. While the policy framework contributed to the initial success of these smaller players, it created challenges in terms of low productivity and limited research and development (R&D) intensity compared to other countries. As a consequence, the export contribution of the Indian pharmaceutical Industry currently stands at a modest 1%, despite maintaining a positive trade balance.

To overcome these challenges and chart a trajectory towards sustained growth and global competitiveness, a comprehensive policy approach is necessary. This approach should strike a delicate balance between nurturing the growth opportunities for smaller players and providing an enabling environment for larger companies to scale up operations and invest in advanced technologies. Reforms targeting collaboration, innovation, and research capabilities hold the key to unleashing the industry's full potential. Encouraging partnerships between academia, research institutes, and pharmaceutical companies can drive innovation and bridge the existing knowledge gaps. Incentivizing R&D investments and streamlining regulatory processes can further foster a culture of innovation and expedite the development of new drugs and technologies.

Moreover, promoting a conducive business environment that supports intellectual property rights and encourages technology transfer can attract foreign investment and foster international collaborations. These measures will contribute to enhancing the technological capabilities and competitiveness of the Indian pharmaceutical industry on a global scale. While navigating the policy challenges, it is imperative to ensure that the growth trajectory aligns with sustainable and ethical practices. Striking a balance between industry expansion and affordability of healthcare is essential, as the Indian pharmaceutical industry plays a crucial role in providing affordable medicines to a vast population.

To enhance the global competitiveness of the Indian pharmaceutical industry, strategic policy changes are necessary. Evaluating the industry's size, growth performance, productivity, innovation, export market share, and import coverage provides valuable insights into its competitive strengths. Government policies have been instrumental in driving self-sufficiency and internationalization, but certain challenges and policy imperatives need to be addressed. By implementing comprehensive policy reforms that strike a balance between nurturing smaller players and enabling larger companies to invest in advanced technologies, India can position itself as a competitive global player in the pharmaceutical sector. This will drive economic growth, improve healthcare outcomes, and ensure the industry's sustainability and ethical practices.

VI. INDIAN PHARMACEUTICAL INDUSTRY: DILEMMA IDENTIFIED

The Indian pharmaceutical industry grapples with a unique dilemma, attempting to balance innovation and affordability. This section analyzes the tension between the need for pharmaceutical companies to invest in research and development (R&D) and their commitment to providing affordable medicines. Investing in R&D is essential for developing new drugs, improving existing treatments, and addressing unmet medical needs. However, the costs associated with R&D, including clinical trials, regulatory approvals, and patent protection, are substantial. These costs often need to be recouped through higher drug prices, posing challenges in terms of affordability, particularly in developing countries. The industry's commitment to affordability stems from its social responsibility to ensure access to medicines for all segments of society. The Industry also experiences seasonal fluctuations with typical diseases around specific seasons like Rainy season or Winters. The Companies face the dilemma on Production capacity as it needs to be in multiple products to avoid season impacts. Indian pharmaceutical companies have excelled in manufacturing low-cost generic versions of drugs, enabling greater affordability. However, striking a balance between innovation and affordability remains a complex dilemma that requires collaboration among stakeholders, including governments, pharmaceutical companies, and healthcare providers.

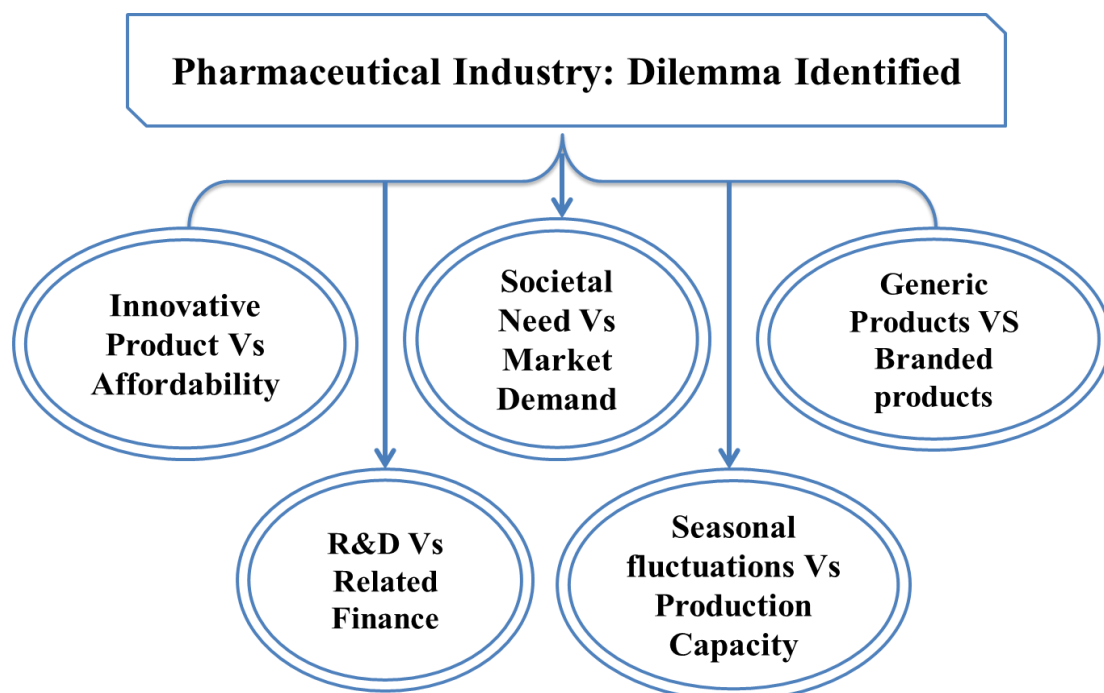


Chart No. 2: Dilemma Identified

Source: Authors' Study

VII. CONCLUSION

The Indian pharmaceutical industry has undergone a remarkable evolution, transforming from a state of dilemma to achieving dominance on the global stage. Through strategic policy shifts, the industry has harnessed its strengths and addressed challenges to emerge as a major player in the global market for generic medications. The industry's competitiveness is evident from its consistent growth performance, productivity levels, innovation, export market share, and import coverage. Government policies have played a crucial role in driving self-sufficiency and internationalization, enabling Indian pharmaceutical companies to expand their global operations and compete with established players. The industry has embraced an internationalization strategy that focuses on technological prowess, acquisitions of foreign companies, and collaborations with global pharmaceutical corporations. These strategies have propelled the industry's growth and enhanced its competitive position.

However, the industry still faces certain policy challenges that need to be addressed for sustained growth and global competitiveness. The fragmented policy landscape and limited research and development (R&D) intensity compared to other countries pose obstacles to further technological progress and production scalability. To overcome these challenges, comprehensive policy reforms are necessary, striking a balance between nurturing smaller players and enabling larger companies to invest in advanced technologies. Encouraging partnerships between academia, research institutes, and pharmaceutical companies, incentivizing R&D investments, and streamlining regulatory processes will foster a culture of innovation and expedite the development of new drugs and technologies. It is crucial to ensure that the growth trajectory aligns with sustainable and ethical practices. Balancing industry expansion with the affordability of healthcare is essential, as the Indian pharmaceutical industry plays a vital role in providing affordable medicines to a vast population. By implementing strategic policy changes and embracing innovation, the Indian pharmaceutical industry can strengthen its global competitiveness, drive economic growth, improve healthcare outcomes, and ensure sustainable and ethical practices. With its continued evolution and focus on research and development, the industry is poised for a brighter future on the global stage.

TEACHING NOTES FOR THE CASE

TEACHING OBJECTIVES:

The following Teaching Objectives may be considered with respect to the case:

1. To equip the participants / readers with domain knowledge on Pharmaceutical Industry, its growth in Indian Context and global positioning.
2. To engage the participants / readers in discussing the challenges to Indian Pharma Sector.
3. To identify & discuss the dilemma based situation surrounding the Indian Pharmaceutical Industry in order to enhance the decision-making quotient of the participants / readers.

LEVEL OF ANALYSIS:

The present case is a type of Teaching case with a focus on the Illustrative & Appraisal Case approach. The analysis attracts an understanding of the domain of Pharmaceutical Industry and Associate Businesses like equipment manufacturing companies. This case is suitable for the case study approach at the Management Students level and also the Pharma Education Students. Management Consultants with special reference to the Entrepreneurship Development would also be major beneficiaries along with the Core Pharma sector companies & start ups.

CASE ASSIGNMENTS:

As part of case study delivery, participants may be assigned tasks pre & post delivery of case.

Pre discussion Task: Gather fair understanding on Pharmaceutical Sector through observations, meeting Industry representatives, reading journals & books in Library and through E-Sources.

Post discussion Task: Conduct review of further literature pertaining to the theme of the case & practical exposure through meeting further industry representatives & Pharma Institutions. Post discussion schedule shall also include discussion round on a few questions pertaining to the case.

BROAD DISCUSSION QUESTIONS:

Q.1: Discuss the Essence of Pharmaceutical Industry in Indian Context.

Q.2: "Pharmaceutical Industry is paving its way towards global excellence by capturing market beyond Indian boundaries." Critically evaluate while citing examples.

Q.3: Explain the dilemma experienced by the Indian Pharmaceutical Industry in current context.

Q.4: "Every Industry has its own share of success and respective challenges. The Strengths keep them going and the weaknesses alert their performances." Discuss in the context of Indian Pharmaceutical Industry.

POTENTIAL BENEFITS OF THE CASE:**Pharma Company Executives:**

- The Pharma Company representatives may benefit from such cases that orient them about the Industry at large.
- The Pharma companies may generate their perspectives through the case and it may get helpful in strategizing for future.
- The Start ups in Pharma sector may benefit from the case in terms generating an outlook towards the Industry and creating a framework.

Students:

- The Pharma Education students will be a straight beneficiary to the case learnings. They may learn the Industry wide avenues and the respective challenges awaiting their career path.
- The Management Education Students and to some extent the Under Graduate students inclined toward Medical representative jobs, may look forward to the learnings from this case.

Proposed Session Plan:

The case study delivery on academic front may have the following session plan:

<u>Action sequence</u>	<u>Session Details</u>	<u>Duration</u>
Action – 1	<p style="text-align: center;">Pre-Case Discussion</p> <ul style="list-style-type: none"> ▶ State the objectives of the Case ▶ Announce the students to gather understanding on Pharma Industry 	3 Days before the discussion session
Action – 2	<p style="text-align: center;">Case Discussion</p> <ul style="list-style-type: none"> ▶ Nominate specific sections to students to narrate (Soft copy Display / Hard Copy distribution) ▶ Appoint a set of 3 students to record the key points ▶ Allow the appointed students to narrate the key points after case narration ▶ Facilitator to conclude with major learning from the case and the case implications. 	1 ½ Hours
Action - 3	<p style="text-align: center;">Post Discussion</p> <ul style="list-style-type: none"> ▶ Submission of written responses to the discussion questions for the case ▶ Select a set of Two teams comprising of 4 students each (during Action -2) and assign the task of presenting the same case one by one in front of the class. (Action -3) ▶ Open the forum for discussion & conclusion of the case. 	3 days post the discussion 15 minutes presentation time to each team 30 minutes
Action – 4	<p style="text-align: center;">Case study Test</p> <ul style="list-style-type: none"> ▶ The case may be presented with precise draft (case let) as a question of General Management Strategic Subject & Pharma Courses. ▶ A 20 marks allocation to case with 30 minutes time slot 	As per Examination Schedule
Teaching Aid	<ul style="list-style-type: none"> ▶ Projector to display the Soft copy of the Case and handover of the same through respective online mode. ▶ Black / White teaching Board for facilitator & student presenters 	

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REFERENCES

1. Chittoor, R., Sarkar, M., Ray, S., & Aulakh, P. S. (2009). Third-world copycats to emerging multinationals: institutional changes and organizational transformation in the Indian pharmaceutical industry. *Organization Science*, 20(1), 187–205. doi:10.1287/orsc.1080.0377.
2. Dinar Kale, & Steve Little. (2007). From imitation to innovation: The evolution of R&D capabilities and learning processes in the Indian pharmaceutical industry. *Technology Analysis & Strategic Management*, 19(5), 589-609. doi: 10.1080/09537320701521317.
3. Nandy, M. (2022). Global competitiveness of pharmaceutical industry of India: Trends and strategies. in *Relationship between R&D and Financial Performance in Indian Pharmaceutical Industry*. Singapore: Palgrave Macmillan. doi: 10.1007/978-981-16-6921-7_5.
4. <http://dx.doi.org/10.1108/JBIM-0r7-2020-0365>.
5. Siagian RC, & Ayuningtyas D. (2019). Gap analysis for drug development policy-making: An attempt to close the gap between policy and its implementation. *PLoS ONE*, 14(8), e0220605. doi: 10.1371/journal.pone.0220605.
6. Hoque, A., & Das, S. (2021). Trends in productivity growth of Indian pharmaceutical industry: A growth accounting analysis. *Journal of Pharmaceutical Research International*, 33(47A), 437–446. doi: 10.9734/jpri/2021/v33i47A33031.
7. Zoltán Lakner, Anna Kiss József Popp, Zoltán Zéman, Domicián Máté and Judit Oláh. *From basic research to competitiveness: An econometric analysis of the global pharmaceutical sector*. doi: 10.3390/su11113125.
8. Singh, K., & Azhar, N. (2022). Impact of patent (Amendment) act, 2005 on Indian pharmaceutical industry with reference to R&D expenditure, profit, export and sales. *International Journal of Health Sciences*, 6(S2), 11538–11557. doi: 10.53730/ijhs.v6nS2.8112.