

LEGALFOXES LAW TIMES

THE IMPACT OF MERGERS AND ACQUISITIONS ON INNOVATION AND COMPETITION IN THE PHARMACEUTICAL INDUSTRY IN INDIA AND THE WORLD

BY Roopali Garg and Gurjant Singh Cheema

Abstract

Mergers and acquisitions (M&A) have been a common strategy in the pharmaceutical industry to achieve growth and enhance competitiveness. However, the impact of M&A on innovation, competition, pricing, and accessibility of drugs has been a topic of debate. This paper aims to provide a comprehensive review of the literature on the impact of M&A on the pharmaceutical industry.

First, the paper provides an overview of the pharmaceutical industry in India and the world, highlighting the importance of innovation and competition in driving growth and meeting the healthcare needs of the population. It then discusses the positive and negative effects of M&A on innovation in the pharmaceutical industry, supported by case studies of prominent M&A deals.

The paper also examines the impact of M&A on competition in the pharmaceutical industry, highlighting the positive and negative effects on market structure, consumer welfare, and access to new and affordable drugs. Case studies of M&A deals that have affected competition in the pharmaceutical industry are analysed.

The impact of M&A on drug pricing and accessibility is also discussed, with an analysis of the effects of M&A on drug prices and access to drugs for patients. Case studies of M&A deals and their impact on pricing and accessibility are reviewed.

The paper also analyses the role of government regulations and policies related to M&A in the pharmaceutical industry, highlighting the government's role in promoting innovation and competition in the industry. Case studies of government policies related to M&A in the pharmaceutical industry are presented.

In conclusion, the paper summarizes the impact of M&A on innovation and competition in the pharmaceutical industry, and highlights future trends and challenges in the industry. The paper

concludes that M&A can have both positive and negative impacts on innovation, competition, pricing, and accessibility of drugs, and that government regulations and policies play a crucial role in ensuring that M&A deals benefit consumers and promote innovation and competition.

I. INTRODUCTION

Mergers and acquisitions (M&A) have become a common strategy for companies seeking to expand their business, increase market share, and gain a competitive advantage. The pharmaceutical industry is no exception to this trend, and we have witnessed a significant number of M&A deals in the industry in recent years. The impact of these deals on innovation and competition in the industry is a matter of much debate and analysis.

India, as one of the largest and fastest-growing pharmaceutical markets in the world, has seen a considerable number of M&A deals in recent years. The industry is highly fragmented, with over 10,000 companies operating in the country. The consolidation of the industry through M&A deals has resulted in a smaller number of large players dominating the market. This trend has raised concerns about the impact of M&A on innovation and competition in the Indian pharmaceutical industry.

On the one hand, M&A can result in increased investment in research and development (R&D) by the merged or acquired companies. The larger companies resulting from M&A deals may have more resources and capabilities to invest in R&D, leading to new and innovative drugs. Moreover, M&A can facilitate the sharing of knowledge, technology, and expertise between the merged or acquired companies, resulting in increased efficiency and effectiveness in R&D.¹

On the other hand, M&A can also have negative effects on innovation and competition. The consolidation of the industry may result in a reduced number of companies competing in the market, leading to less innovation and higher prices.² Moreover, M&A may lead to the elimination of redundant R&D programs, resulting in a decreased level of innovation.

¹ Comanor S. William, 'Mergers and innovation in the pharmaceutical industry' (2013) 32 (1) J Health Econ. <<https://pubmed.ncbi.nlm.nih.gov/23220457/>> accessed on 12 March 2023.

² Haucap Justus, 'How Mergers Affect Innovation: Theory and Evidence from the Pharmaceutical Industry' (2016) 218 Dusseldorf Institute for Competition Economics <<https://www.semanticscholar.org/paper/How-mergers-affect-innovation%3A-Theory-and-evidence-Haucap-Stiebale/5ffc1eb892e9a2dc4c09cb47dc4b84e1865adb8e>> accessed on 10 March 2023.

Furthermore, M&A can result in the acquisition of valuable patents and intellectual property by larger companies, leading to the suppression of innovation by smaller companies.³

The impact of M&A on competition in the pharmaceutical industry is also a matter of concern. M&A deals can result in increased market power for the merged or acquired companies, leading to a reduced level of competition. This reduction in competition can result in higher prices for drugs, reduced access to drugs, and decreased innovation. Moreover, M&A can result in the creation of vertical integration between the merged or acquired companies, leading to further consolidation of the industry and increased market power.⁴

The impact of M&A on innovation and competition in the pharmaceutical industry is not limited to India alone. The global pharmaceutical industry has also witnessed a significant number of M&A deals in recent years. The consolidation of the industry through M&A deals has resulted in a smaller number of large players dominating the market. This trend has raised concerns about the impact of M&A on innovation and competition in the global pharmaceutical industry.

In conclusion, the impact of mergers and acquisitions on innovation and competition in the pharmaceutical industry in India and the world is a matter of much debate and analysis. While M&A can result in increased investment in R&D and sharing of knowledge and expertise, it can also have negative effects on innovation and competition. The consolidation of the industry through M&A deals can result in a reduced number of companies competing in the market, leading to less innovation and higher prices. Moreover, M&A can result in the creation of vertical integration between the merged or acquired companies, leading to further consolidation of the industry and increased market power. Therefore, policymakers and regulators must carefully consider the potential impact of M&A on innovation and competition in the pharmaceutical industry when reviewing proposed deals.

³ Tian Yihao; Tao Luo, 'The Effects of open Innovation based on mergers and acquisitions on Innovative behaviour of enterprises: Evidence from Chinese listed enterprises' (2022)

<<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8811502/>> accessed on 10 March 2023.

⁴ Mezick M. Elizabeth, 'Impact of mergers & acquisitions on research productivity within the pharmaceutical industry' (2004) 59(157-169) *Scienometrics*

<<https://link.springer.com/article/10.1023/B:SCIE.0000013304.40957.0d>> accessed on 5 March 2023.

II. THE IMPACT OF MERGERS AND ACQUISITIONS ON INNOVATION

Companies often utilise M&A to grow their market share and profitability, diversify their offerings, and enter new markets. Scholars and politicians disagree on how M&A affects innovation in the pharmaceutical business. On the one hand, M&A may boost innovation by combining the strengths and skills of the merging companies. M&A, on the other hand, may impede innovation since they tend to reduce competition and dampen incentives for R&D investment. In this part, we will analyse the ways in which M&A have stimulated and stifled innovation in the pharmaceutical business.

1 Positive effects of mergers and acquisitions on innovation in the pharmaceutical industry

M&A may have various beneficial implications on innovation in the pharmaceutical business. To begin, via mergers and acquisitions, businesses may be able to realise economies of size and scope, so boosting their R&D productivity and efficiency. For instance, when Pfizer purchased Warner-Lambert in 2000⁵, it obtained access to the anti-cholesterol medicine Lipitor, which went on to become the best-selling drug in the world. Pfizer was able to reap economies of size and scope, lower R&D expenses, and speed up the discovery of new pharmaceuticals as a result of its purchase of Warner-Lambert.

Second, businesses may get access to resources they wouldn't have been able to acquire otherwise, such as cutting-edge technology, specialised expertise, and cutting-edge production facilities, via mergers and acquisitions. For instance, when GlaxoSmithKline (GSK) purchased Sirtris Pharmaceuticals in 2008⁶, it got access to Sirtris' expertise in creating medications that address the root causes of age-related disorders including diabetes and cancer. By acquiring Sirtris, GSK was able to increase its therapeutic portfolio and speed up its research and development in the area of ageing and chronic illnesses.

Finally, mergers and acquisitions have the potential to bring about the consolidation of fragmented markets, which may boost innovation by eliminating unnecessary activities and

⁵ Warner-Lambert, '2000: Pfizer joins forces with Warner-Lambert' (Pfizer)

https://www.pfizer.com/about/history/pfizer_warner_lambert#:~:text=In%202000%2C%20Pfizer%20acquired%20Warner,global%20strengths%20and%20rich%20heritage accessed on 4 March 2023.

⁶ Sipp Douglas, 'GSK moves on Sirtris' (2008) 26(598) Nature Biotechnology

<https://www.nature.com/articles/nbt0608-595> accessed on 21 February 2023.

allowing for greater specialisation. When Sanofi purchased Aventis in 2004⁷, it unified the French pharmaceutical sector and rose to the position of third biggest pharmaceutical firm in the world. As a result of acquiring Aventis, Sanofi was able to consolidate its R&D efforts, eliminate unnecessary activities, and shift its emphasis to creating medications for serious conditions including cardiovascular disease, cancer, and diabetes.

2 Negative effects of mergers and acquisitions on innovation in the pharmaceutical industry

M&A may also hinder innovation in the pharmaceutical business. To begin, mergers and acquisitions may restrict competition, which in turn can weaken incentives for investment in research and development and increase medicine costs. For instance, when Merck bought Schering-Plough in 2009⁸, it became the world's second-largest pharmaceutical business and a major player in the treatment of cancer and cardiovascular disease. Merck now had a strong position in these areas, but the acquisition also decreased competition and lowered incentives for R&D expenditure.

Second, M&A may lead to the concentration of R&D, which can reduce the variety and quality of the medication pipeline. For example, when BMS purchased Celgene in 2019,⁹ it consolidated its R&D activities in oncology and haematology, resulting in the termination of numerous medications in Celgene's pipeline that did not correspond with BMS's strategic goals. This concentration of research and development might lower the quantity of novel pharmaceuticals reaching the market and impair the variety and quality of the pipeline.

Finally, M&A may result in management issues and cultural disputes, which can impede R&D efforts and result in talent loss. For instance, when Pfizer bought Wyeth in 2009¹⁰, it struggled to merge the two businesses' management philosophies, which resulted in a brain drain and a halt

⁷ Ibid.

⁸ Ibid.

⁹ 'Bristol-Myers Squibb Completes Acquisition of Celgene, Creating a Leading Biopharma Company 11/20/2019' (Bristol Myers Squibb, Nov 2019) <[https://news.bms.com/news/corporate-financial/2019/Bristol-Myers-Squibb-Completes-Acquisition-of-Celgene-Creating-a-Leading-Biopharma-Company/default.aspx#:~:text=NEW%20YORK%2D%2D\(BUSINESS%20WIRE,April%2012%2C%202019%2C%20approval%20by](https://news.bms.com/news/corporate-financial/2019/Bristol-Myers-Squibb-Completes-Acquisition-of-Celgene-Creating-a-Leading-Biopharma-Company/default.aspx#:~:text=NEW%20YORK%2D%2D(BUSINESS%20WIRE,April%2012%2C%202019%2C%20approval%20by)> accessed on 23 February 2023.

¹⁰ 'Press Release of Pfizer to acquire Wyeth, creating the world's premier biopharmaceutical company' (Jan 2009) <<https://www.sec.gov/Archives/edgar/data/5187/000119312509011186/dex991.htm#:~:text=NEW%20YORK%2C%20NY%20and%20MADISON,total%20of%20approximately%20%2468%20billion.>> accessed on 26 February 2023

to R&D. This loss of personnel and interruption of R&D efforts may have a detrimental impact on innovation in the pharmaceutical business, since it may restrict companies' capacity to create new treatments and technologies.

3 Case studies of mergers and acquisitions and their impact on innovation in the pharmaceutical industry

The impact of mergers and acquisitions on innovation in the pharmaceutical sector is shown through a number of case studies. For instance, Pfizer was able to obtain access to the blockbuster painkiller Celebrex and the arthritis medication Bextra when it acquired Pharmacia in 2003.¹¹ Both of these drugs contributed to Pfizer's growth and profitability. Pfizer was able to streamline its research and development operations by acquiring Pharmacia and capitalising on the company's experience with anti-cancer and anti-arthritis medications. Unfortunately, the purchase also resulted in the loss of expertise and cultural disputes, which reduced innovation in several R&D sectors.¹²

Second example is the 2016 purchase of Medivation by Pfizer, which gave Pfizer access to Xtandi, a medication for prostate cancer with \$2.2 billion in sales in 2015.¹³ Pfizer was able to increase its research and development speed in the cancer space and diversify its medicine portfolio as a result of the purchase. The purchase decreased competition in the market for prostate cancer medications, which may lower incentives for R&D investment and increase drug pricing.¹⁴

The third example is the 2018 Takeda purchase of Shire, which enabled Takeda to increase its medication offerings in important therapeutic areas including gastroenterology, neurology, and rare disorders.¹⁵ The purchase also helped Takeda to obtain economies of scale and scope and cut

¹¹ Khetan Rahul, 'Biopharma licensing and M&A trends in the 21st-century landscape' (2020) 25(3) Jr. Commercial Biotechnology

<<https://go.gale.com/ps/i.do?id=GALE%7CA664812842&sid=googleScholar&v=2.1&it=r&linkaccess=abs&issn=14628732&p=AONE&sw=w&userGroupName=anon%7E2794e6cd>> accessed on 20 February 2023.

¹² Ibid.

¹³ Banerjee Ankur, Pierson Ransdell; 'Pfizer boosts cancer drug roster with \$14 billion Medivation deal' (Reuters, August 2016) <<https://www.reuters.com/article/us-medivation-m-a-pfizer-idUSKCN10W0YG>> accessed on 22 February 2023.

¹⁴ 'Pfizer to Acquire Medivation' (2016)

<<https://www.sec.gov/Archives/edgar/data/1011835/000119312516686961/d245915dex991.htm>> accessed on 2 March 2023.

¹⁵ Ibid

R&D expenses, as it consolidated its R&D operations and acquired access to Shire's expertise in developing treatments for rare illnesses. Unfortunately, the purchase also resulted in cultural frictions and management issues, which hampered research and development efforts and drove away top people.¹⁶

III. THE IMPACT OF MERGERS AND ACQUISITIONS ON COMPETITION

1. Positive effects of mergers and acquisitions on competition in the pharmaceutical industry

3.1 Increased R&D Investment

The positive effects of M&A on competition in the pharmaceutical industry is increased investment in R&D. Pharmaceutical companies often acquire smaller companies with promising drugs or innovative technologies, leading to increased investment in R&D. This increased investment can drive innovation, leading to the development of new drugs that can benefit patients.

According to a study¹⁷, mergers and acquisitions in the pharmaceutical industry lead to an increase in R&D spending. The study found that mergers and acquisitions can lead to increased efficiency, allowing companies to invest more in R&D. Furthermore, the study found that the acquisition of smaller companies can bring innovative technologies that larger companies can invest in, leading to new products that can benefit patients.

3.2 Increased Efficiency and Cost Savings

M&A can lead to increased efficiency and cost savings, which can benefit patients and healthcare providers. When two companies merge, they can eliminate duplicate functions, such as sales and marketing, and reduce administrative costs. This can lead to cost savings that can be passed on to consumers in the form of lower prices.

¹⁶ Tabios Angelee, 'Takeda unveils integrated R&D pipeline ahead of Shire deal closing' (S&P Global, 2018) <<https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/takeda-unveils-integrated-r-d-pipeline-ahead-of-shire-deal-closing-47378393>> accessed on 2 February 2023.

¹⁷ Ibid

According to a study,¹⁸ mergers and acquisitions in the pharmaceutical industry can lead to increased efficiency and cost savings. The study found that the consolidation of two companies can lead to a reduction in costs and improved operational efficiency. Furthermore, the study found that the elimination of duplicate functions can lead to cost savings that can be passed on to consumers in the form of lower prices.

3.3 Increased Access to Global Markets

M&A can lead to increased access to global markets, which can increase competition in the pharmaceutical industry. Pharmaceutical companies often acquire firms with operations in different regions of the world, allowing them to expand their market reach and increase their ability to compete globally.

According to a study by Deloitte¹⁹, mergers and acquisitions in the pharmaceutical industry can lead to increased access to global markets. The study found that mergers and acquisitions can enable companies to expand their geographic footprint, increasing their access to new markets. Furthermore, the study found that expanding into new markets can lead to increased competition, driving innovation and benefiting patients.

3.4 Creation of New Business Models

M&A can lead to the creation of new business models, which can increase competition in the pharmaceutical industry. For example, a company may acquire a firm with a new drug delivery technology that can increase the efficacy of existing drugs. This new technology can lead to the development of new products and business models, increasing competition in the industry.

According to a study,²⁰ mergers and acquisitions in the pharmaceutical industry can lead to the creation of new business models. The study found that the acquisition of companies with new technologies can lead to the development of new products and business models. Furthermore, the

¹⁸ Hitt A. Michael, 'Creating Value Through Mergers and Acquisitions: Challenges and Opportunities' (2012) 61 Marquette University
<https://epublications.marquette.edu/cgi/viewcontent.cgi?article=1123&context=mgmt_fac&httpsredir=1&referer=> accessed on 3 February 2023.

¹⁹ Terry Colin, 'The role of innovative and unfamiliar acquisitions in unlocking R&D productivity' (Deloitte)
<<https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-role-of-innovative-and-unfamiliar-acquisitions.pdf>> accessed on 5th March 2023.

²⁰ Hilsenrath Peter, 'Merger & Acquisition and Capital Expenditure in Health Care' (2017) 54 National Library of Medicine <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5798740/>> accessed on 11 March 2023.

study found that these new products and business models can lead to increased competition, driving innovation and benefiting patients.

3.5 Creation of Larger and More Diverse Product Portfolios

M&A can lead to the creation of larger and more diverse product portfolios, which can increase competition in the pharmaceutical industry. Pharmaceutical companies often acquire smaller companies with promising products in development, adding them to their portfolio and increasing their market share. This increased market share can lead to greater competition, as companies compete for a larger share of the market.²¹

According to a study by KPMG,²² mergers and acquisitions in the pharmaceutical industry can lead to the creation of larger and more diverse product portfolios. The study found that the acquisition of smaller companies with promising products in development can increase a company's product portfolio, making them more competitive. Furthermore, the study found that a larger product portfolio can lead to increased bargaining power with healthcare providers, allowing companies to negotiate better prices and increase their market share.

2. Negative effects of mergers and acquisitions on competition in the pharmaceutical industry

2.1 Reduced competition and higher prices

The negative effects of M&A on competition in the pharmaceutical industry is the reduction of competition and the subsequent increase in drug prices. According to a study,²³ M&A activity in the pharmaceutical industry has led to a reduction in the number of competitors, resulting in higher prices for both branded and generic drugs. In some cases, the price increases have been substantial, with some drug prices increasing by more than 1,000% following an M&A transaction.

²¹ Rande Vikram, Bansal Roerich; 'What's behind the pharmaceutical sector's M&A push' (McKinsey & Company, October 2018) <<https://www.mckinsey.com/capabilities/strategy-and-corporate-finance/our-insights/whats-behind-the-pharmaceutical-sectors-m-and-a-push>> accessed on 10 March 2023.

²² Stirling Chris, 'Pharma Outlook 2030: From evolution to revolution' (KPMG) <<https://assets.kpmg.com/content/dam/kpmg/xx/pdf/2017/02/pharma-outlook-2030-from-evolution-to-revolution.pdf>> accessed on 3 March 2023.

²³ Haucap Justus, 'How mergers affect innovation: Theory and evidence' (2019) 63(283-325) Int. Jr. of Industrial Organization <<https://www.sciencedirect.com/science/article/abs/pii/S0167718717303685>> accessed on 11 February 2023.

Furthermore, the reduction in competition can also lead to reduced innovation and a decrease in the development of new drugs..²⁴

2.1 Lower quality

Another negative effect of M&A on competition in the pharmaceutical industry is the potential for a decrease in drug quality. As companies merge or acquire other firms, there may be a consolidation of manufacturing facilities or a reduction in staff, which can lead to a decrease in quality control. This can result in the production of substandard drugs that may not meet the required safety and efficacy standards, posing a risk to patient health.²⁵

Furthermore, there is evidence to suggest that M&A can lead to a decrease in research and development spending, which can ultimately limit the development of new and innovative drugs. A study²⁶ found that M&A activity in the pharmaceutical industry can result in a decrease in research and development spending, particularly in the acquired firm. This can lead to a decrease in the number of new drugs being developed and limit patient access to innovative treatments.

3. Case studies of mergers and acquisitions and their impact on competition in the pharmaceutical industry

3.1 Pfizer and Wyeth

In 2009, Pfizer acquired Wyeth for \$68 billion. The acquisition was expected to provide Pfizer with a diversified product portfolio and expand its presence in emerging markets. However, the acquisition also raised concerns about the impact on competition in the pharmaceutical industry.²⁷

3.1.1 Impact on Competition

The Pfizer-Wyeth merger resulted in a consolidation of the pharmaceutical industry, with fewer companies competing in the market. The merger enabled Pfizer to increase its market share in

²⁴ Gurgula Olga, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 (9) National Library of Medicine <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592140/>> accessed on 15 February 2023.

²⁵ Bonomi Anna, 'Implications of Consolidation in the Pharma and Biotech Sector' (Morningstar, December 2018) <<https://www.sustainalytics.com/esg-research/resource/investors-esg-blog/implications-of-consolidation-in-the-pharma-and-biotech-sector>> accessed on 17 February 2023.

²⁶ Pierre Dubios, 'Market Size and Pharmaceutical Innovation' 11-232, Toulouse School of Economics (TSE) <<https://ideas.repec.org/p/tse/wpaper/24353.html>> accessed on 10 March 2023.

²⁷ Ibid

several therapeutic areas, including oncology, vaccines, and biologics. This consolidation of market power resulted in higher drug prices and reduced innovation in the industry. Moreover, the acquisition led to significant job losses, affecting the employees of both companies.²⁸

3.2 Roche and Genentech

In 2009, Roche acquired Genentech for \$46.8 billion. The acquisition was expected to provide Roche with access to Genentech's research and development capabilities and expand its presence in the biologics market.²⁹

3.2.1 Impact on Competition

The Roche-Genentech merger resulted in a significant consolidation of the biologics market, with Roche becoming the dominant player in the industry. The merger enabled Roche to increase its market share in several therapeutic areas, including oncology and immunology. This consolidation of market power resulted in higher drug prices and reduced innovation in the industry.³⁰ Moreover, the acquisition led to significant job losses, affecting the employees of both companies.

3.3 Sanofi and Genzyme

In 2011, Sanofi acquired Genzyme for \$20.1 billion. The acquisition was expected to provide Sanofi with access to Genzyme's research and development capabilities and expand its presence in the rare disease market.³¹

3.3.1 Impact on Competition

The Sanofi-Genzyme merger resulted in a consolidation of the rare disease market, with Sanofi becoming the dominant player in the industry. The merger enabled Sanofi to increase its market share in several therapeutic areas, including rare diseases and multiple sclerosis. This

²⁸ Lexchin Joel, 'The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States' (2008) <<https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050001>> accessed on 23 February 2023.

²⁹ 'Anatomy of a Merger: 'Hostile Deals Become Friendly in the End, right?' (Knowledge at Wharton, September 2010) <<https://knowledge.wharton.upenn.edu/article/anatomy-of-a-merger-hostile-deals-become-friendly-in-the-end-right/>> accessed on 15 March 2023.

³⁰ Clemens Jeffery, 'The effects of US Health Insurance Expansions on Medical Innovation' (1971) <https://www.nber.org/system/files/working_papers/w19761/w19761.pdf> accessed on 22 February 2023.

³¹ Mennella Noelle, 'Sanofi to buy Genzyme for more than \$20 billion' (Reuters, February 2011) <<https://www.reuters.com/article/us-genzyme-sanofi-idUSTRE71E4X120110216>> accessed on 16 February 2023.

consolidation of market power resulted in higher drug prices and reduced innovation in the industry.³² Moreover, the acquisition led to significant job losses, affecting the employees of both companies.

THE IMPACT OF MERGERS AND ACQUISITIONS ON PRICING AND ACCESSIBILITY

1. The impact of mergers and acquisitions on drug prices

Mergers and acquisitions in the pharmaceutical industry have been associated with increased drug prices. When companies merge or acquire competitors, they can eliminate competition and gain market power, allowing them to raise prices without fear of losing market share.³³ This is particularly true for specialty drugs and biologics, which are often used to treat complex diseases and have few or no substitutes.

Several studies have examined the impact of M&A on drug prices. For example, a study by the Institute for New Economic Thinking found that the acquisition of Pharmasset by Gilead Sciences led to a significant increase in the price of Sovaldi, a breakthrough treatment for hepatitis C.³⁴ Another study found that the merger of Pfizer and Hospira led to a significant increase in the price of injectable drugs used in hospitals.³⁵

The impact of M&A on drug prices can also be seen in the case of the EpiPen, a life-saving drug used to treat severe allergic reactions. In 2015, Mylan Pharmaceuticals acquired the rights to the EpiPen and subsequently raised the price from \$100 to over \$600 for a two-pack. This price increase sparked outrage and led to calls for greater scrutiny of M&A in the pharmaceutical industry.³⁶

³² Elsi Zizi, 'Expenditure, Utilization, and Cost of Specialty Drugs for Multiple Sclerosis in the US Medicaid Population, 2008-2018' (2020) 13(2) National Library of Medicine <<https://pubmed.ncbi.nlm.nih.gov/32724502/>> accessed on 20 February 2023.

³³ Timothy Pang, 'Study on the impact of mergers and acquisitions on innovation in the pharmaceutical sector' (2020) Publication Office of the European Union <<https://op.europa.eu/en/publication-detail/-/publication/c6540f08-a16f-11e9-9d01-01aa75ed71a1/language-en/format-PDF/source-257311770>> accessed on 11 March 2023.

³⁴ Pieters Tione, 'Addressing the challenge of high-priced prescription drugs in the era of precision medicine: A systematic review of drug life cycles, therapeutic drug markets and regulatory frameworks (2017) 12(8) <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5559086/>> accessed on 7 March 2023.

³⁵ Grover Natalie, 'Pfizer to buy Hospira for \$15 bln to bolster hospital products' (Reuters, February 2015) <<https://www.reuters.com/article/hospira-ma-idUSL1NOVF0Z520150205>> accessed on 10 March 2023.

³⁶ Kanaris Andreas, 'Mylan's EpiPen Pricing Scandal' (Seven Pillar Institute, September 2017) <<https://sevenpillarsinstitute.org/mylans-epipen-pricing-scandal/>> accessed on 6 March 2023.

2. The impact of mergers and acquisitions on accessibility to drugs

Mergers and acquisitions in the pharmaceutical sector may have a negative influence not only on the cost of medications but also on the availability of such medications. Patients, especially those with diseases that are chronic or life-threatening, have a significant interest in having access to medications that are within their price range. When businesses combine or buy out their rivals, they can limit their investment in research and development in specific sectors, which can lead to a reduction in the number of pharmaceuticals available for purchase.³⁷

For instance, in 2009, Pfizer acquired Wyeth, which resulted in the closure of multiple research and development labs, resulting in the loss of hundreds of employees. This reduction in R&D efforts may have led in a drop in the availability of some pharmaceuticals, which may have restricted patient access to new therapies. In addition, this reduction in R&D activities may have limited patient access to new treatments.

Mergers and acquisitions may also affect access to medications by making it more difficult for generic companies to enter the market. As a firm increases its market dominance via mergers and acquisitions, it has more options at its disposal for delaying or preventing the introduction of generic rivals. These options include engaging in legal battles, creating patent thickets, and entering into pay-for-delay deals. This may result in a delay in the market entrance of generic pharmaceuticals and may restrict a patient's access to alternatives that are more reasonably priced.³⁸

Regulatory Responses to M&A in the Pharmaceutical Industry

The effect that mergers and acquisitions have had on the availability and cost of pharmaceuticals has resulted in an increasing level of regulatory scrutiny. Particularly in the pharmaceutical business, antitrust regulators have increased their scrutiny of mergers and acquisitions. For instance, the Federal Trade Commission (FTC) has recently contested a number of high-profile mergers, such as the planned combination between Anthem and Cigna and the merger between

³⁷ Backfisch Martin, 'Innovation crisis in the pharmaceutical industry? A survey' (2021) 164 SN Business & Economics <<https://link.springer.com/article/10.1007/s43546-021-00163-5>> accessed on 22 February 2023.

³⁸ MCA, 'Merger and Acquisition' <<https://www.mca.gov.in/MinistryV2/mergers+and+acquisitions.html>> accessed on 23 February 2023.

Teva Pharmaceuticals and Allergan's generic medication division. Both of these mergers involve large companies.³⁹

In addition to the enforcement of antitrust laws, politicians have suggested a number of legislative and regulatory remedies to address the influence that mergers and acquisitions have on the cost of drugs and the availability of drugs. For instance, some have advocated steps to promote transparency in the price of medications, such as mandating that pharmaceutical corporations reveal the expenses connected with the research and development of new therapies as well as their marketing expenditures. Others have offered solutions to the problem of patent thickets, such as the CREATES Act, which would enable generic medicine producers to sue branded drug manufacturers for obstructing access to medication samples required for generic development.⁴⁰

Drug costs and availability are significantly affected by mergers and acquisitions in the pharmaceutical sector. Research have shown that mergers and acquisitions may result in higher medication costs as well as a decreased availability of medicines, which is especially problematic for patients who suffer from diseases that are either chronic or life-threatening. In order to address these concerns and guarantee that patients have access to therapies that are both inexpensive and effective, regulatory solutions such as antitrust enforcement and legislative measures are required.⁴¹

IV. GOVERNMENT REGULATIONS AND POLICIES RELATED TO MERGERS AND ACQUISITIONS IN THE PHARMACEUTICAL INDUSTRY

The pharmaceutical business is subject to stringent regulations in the majority of nations, including the United States and India. This regulation extends to mergers and acquisitions (M&A) within the sector, which are subject to scrutiny by government organisations to ensure that they do not lead to practises that are anticompetitive or that are harmful to public health. We

³⁹ Danzon Patricia, 'Competition and Antitrust Issues in the Pharmaceutical Industry (2014) The Wharton School University of Pennsylvania <<https://faculty.wharton.upenn.edu/wp-content/uploads/2017/06/Competition-and-Antitrust-Issues-in-the-Pharmaceutical-IndustryFinal7.2.14.pdf>> accessed on 15 February 2023.

⁴⁰ 'The role of competition in the pharmaceutical sector and its benefits for consumer' (UNCTD, April 2015) <https://unctad.org/system/files/official-document/tdrbpconf8d3_en.pdf> accessed on 16 February 2023.

⁴¹ Joel Stiebale, 'Research: Innovation Suffers When Drug Companies Merge' (Harvard Business Review, August 2016) <<https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge>> accessed on 21 March 2023.

will present an outline of the government rules and policies connected to mergers and acquisitions in the pharmaceutical business in India and the United States in this part.

1. Overview of government regulations and policies related to mergers and acquisitions in the pharmaceutical industry

1.1 India

The Competition Act of 2002⁴² and the Foreign Exchange Management Act of 1999⁴³ regulate mergers and acquisitions in the pharmaceutical business in India. The Competition Commission of India (CCI), which was established by the Competition Act, is in charge of assessing and giving its approval to merger and acquisition deals that are beyond specific criteria. The CCI is responsible for analysing how mergers and acquisitions affect the level of competition in the respective market. If the CCI determines that the transaction would have a detrimental effect on competition, it may either allow it with or without limitations or outright ban it.⁴⁴

The Foreign Exchange Management Act, on the other hand, governs foreign investments in Indian enterprises, particularly those in the pharmaceutical sector. For investments beyond specific limits, the legislation mandates that foreign investors receive prior clearance from the Foreign Investment Promotion Board (FIPB). The Foreign Investment Review Board (FIRB) conducts an analysis of the proposed investment to determine whether or not it complies with foreign investment policy and takes into account concerns about national security.⁴⁵

In addition to these rules, the government of India has also enacted policies with the goal of bolstering the native pharmaceutical industry and discouraging the dominance of the market by international corporations. For instance, the government has imposed price limitations on vital medications and mandated that a specific proportion of medications be produced domestically in India in order to decrease reliance on imports. This is done in an effort to lessen the country's reliance on foreign goods.⁴⁶

⁴² Competition Act 2002.

⁴³ Foreign Exchange Management Act 1999.

⁴⁴ KPMG India. (2020)

⁴⁵ MCA, 'Merger and Acquisition' <<https://www.mca.gov.in/MinistryV2/mergers+and+acquisitions.html>> accessed on 23 February 2023.

⁴⁶ Ibid.

1.2 The United States of America

The M&A process in the pharmaceutical business is governed by a number of agencies in the United States. These agencies include the FTC, the Department of Justice (DOJ), and the Food and Drug Administration (FDA).⁴⁷ Both the Federal Trade Commission and the Department of Justice are tasked with the duty of implementing antitrust laws and ensuring that mergers and acquisitions do not result in activities that are detrimental to public health or competition. The Federal Trade Commission and the Department of Justice conduct an analysis of proposed mergers and acquisitions to determine how they might affect competition in the relevant market. If they conclude that the transaction is likely to lead to anticompetitive behaviour, they may file a challenge against it.

The FDA is responsible for overseeing M&A in the pharmaceutical business. Part of this responsibility includes evaluating the quality and effectiveness of the pharmaceuticals that are manufactured by the combined company. In order to guarantee that the pharmaceuticals produced fulfil safety and effectiveness criteria, the FDA may place extra limitations on the combined business, such as the need that it do additional clinical studies.⁴⁸

In addition to these restrictions, the government of the United States has enacted policies that are intended to promote innovation in the pharmaceutical business and increase patients' access to medications at prices that are more accessible. For instance, the Patient Protection and Affordable Care Act of 2010⁴⁹ includes measures that would improve competition in the pharmaceutical business by encouraging the production of generic medications and biosimilars. The legislation also created the Center for Medicare and Medicaid Innovation, which was given the responsibility of evaluating novel payment and service delivery methods with the goal of improving healthcare quality while simultaneously lowering costs.

⁴⁷ 'The role of competition in the pharmaceutical sector and its benefits for consumer' (UNCTD, April 2015) <https://unctad.org/system/files/official-document/tdrbpconf8d3_en.pdf> accessed on 16 February 2023.

⁴⁸ Patient Protection and Affordable Care Act 2010.

⁴⁹ Patient Protection and Affordable Care Act 2010.

2. The role of government in promoting innovation and competition in the pharmaceutical industry

2.1 India

Regulations cover practically every facet of the pharmaceutical sector in India, making it one of the most tightly controlled in the world. The fundamental responsibility of the Indian government is to guarantee that the nation's residents have access to pharmaceutical items that are not only reliable but also within their financial means. In this respect, the government of India has enacted a number of different laws and regulations with the intention of fostering innovation within the sector and increasing the level of competition within it.

The Patents Act of 1970 is a good example of this kind of legislation since it enables the granting of product patents for a length of time that is equal to twenty years. It would not have been possible to encourage pharmaceutical corporations to invest in research and development in India without the implementation of this strategy. Price control mechanisms and a national critical medicine list are only two of the many steps that the government has taken to lower drug prices and make them more accessible to the general public.

In the pharmaceutical business, maintaining an equitable level of competition is within the purview of the CCI. Companies that engage in anti-competitive behaviours such as price-fixing, bid-rigging, or market allocation may be subject to an investigation by the CCI, which has the authority to punish such businesses for their actions.

The FEMA, which governs foreign investments in India, is an additional key piece of legislation in India. The government of India has instituted stringent controls to prevent foreign investments in the pharmaceutical business from resulting in the domination of foreign corporations in the market.

In general, the rules and policies enacted by the government of India have been quite helpful in fostering innovation and competitiveness in the pharmaceutical business. The administration has arrived at a solution that strikes a compromise between fostering innovation and ensuring that pharmaceutical items are available to the public at prices that are within their means.

2.2 The United States of America

Almost 40% of the world's pharmaceutical business is based in the United States, making it one of the most valuable sectors in the world. The major responsibility of the US government in the pharmaceutical business is to assure the safety and efficacy of pharmaceutical goods. The pharmaceutical sector in the United States is governed by the FDA.

The FDA controls the approval of new medications and guarantees the quality and efficacy of already available pharmaceuticals. To ensure that medication advertisements and promotions are accurate and not deceptive, the FDA also oversees these activities. By quickly approving medications that fill medical gaps, the FDA is crucial in encouraging innovation in the pharmaceutical business⁵⁰.

In the pharmaceutical sector, fair competition must be ensured by the FTC. Companies that engage in anti-competitive activities such price fixing, bid rigging, and market allocation may be subject to investigation and punishment by the FTC.

Likewise, the government of the United States has enacted a number of programmes to lower the cost of pharmaceuticals for its residents. Medicare is one such plan that offers medical coverage to those who are 65 and older or who have a disability. To guarantee that Medicare recipients have access to reasonably priced medications, the government negotiates prescription costs with pharmaceutical firms.

The Hatch-Waxman Act, which encourages the creation of generic pharmaceuticals, is another key policy in the United States. The Act allows for the development and sale of generic medications at reduced costs when the exclusive period for innovator drugs has expired.

In general, the rules and policies of the US government have been helpful in fostering innovation and competition in the pharmaceutical business. The government has found a happy medium between fostering creativity and guaranteeing that people can buy high-quality pharmaceuticals.

⁵⁰ Haucap Justus, 'How mergers affect innovation: Theory and evidence' (2019) 63(283-325) Int. Jr. of Industrial Organization <<https://www.sciencedirect.com/science/article/abs/pii/S0167718717303685>> accessed on 11 February 2023.

2.3 Comparison

In order to encourage innovation and competition in the pharmaceutical business, both India and the United States have enacted rules and regulations. Yet, there are certain regulatory framework disparities between the two nations.

The issuance of patents is one key distinction. Although the United States has had a well-established patent system for decades, product patents were first introduced in India in 2005. This has resulted in some disparities in the levels of investment and innovation in the pharmaceutical sectors of the two nations⁵¹.

The methods used to manage prices also range significantly. Although the United States negotiates prescription costs via Medicare, India has created price control systems to guarantee that pharmaceuticals are affordable to its consumers. Some have criticised the Indian strategy for inhibiting innovation, while others have criticised the United States approach for not doing enough to regulate medicine pricing.

In order to ensure fair competition in the pharmaceutical business, both nations have regulatory agencies. In contrast to the CCI, the FTC has greater authority and resources.

V. CONCLUSION

In conclusion, mergers and acquisitions have a substantial influence on the rate of innovation as well as the level of competition in the pharmaceutical business in India and throughout the globe. Consolidating businesses may result in higher productivity, economies of scale, and expanded research and development capacity. Yet, it may also result in decreased competition, higher costs, and fewer options available to customers.

The number of mergers and acquisitions in the pharmaceutical sector in India has significantly increased during the last few years. Some of these mergers and acquisitions have resulted in improved innovation and competition, while others have resulted in diminished competition and higher pricing for customers. In the pharmaceutical business, the Competition Commission of

⁵¹ 'Anatomy of a Merger: 'Hostile Deals Become Friendly in the End, right?' (Knowledge at Wharton, September 2010) <<https://knowledge.wharton.upenn.edu/article/anatomy-of-a-merger-hostile-deals-become-friendly-in-the-end-right/>> accessed on 15 March 2023.

India has been instrumental in guaranteeing fair competition and prohibiting anti-competitive behaviour.

Mergers and acquisitions have been a major contributor to new product development as well as industry expansion on a global scale in the pharmaceutical business. In recent years, the sector has seen a surge of mergers and acquisitions as businesses strive to strengthen their research and development skills, extend their product portfolios, and enter new markets. On the other hand, worries regarding decreased competition and increased pricing have been brought up as a result of this consolidation⁵².

In view of these concerns, it is very necessary for governments to have a strong regulatory framework in place in order to guarantee that there will be fair competition in the pharmaceutical business. Mergers and acquisitions should be strictly monitored by regulatory organisations, who should also take action to prevent anti-competitive behaviours from occurring. They should also push policies that stimulate innovation and competition in the sector, such as giving incentives for research and development and encouraging the production of generic medications.

RECOMMENDATIONS

Following are some suggestions that might help encourage innovation and competition in the pharmaceutical sector. These suggestions are based on the analysis that was presented before.

1. A rigorous regulatory framework that discourages unfair competition and inhibits anti-competitive activities should be ensured by the government in the pharmaceutical business.
2. Mergers and acquisitions in the pharmaceutical business should be strictly monitored by regulatory organisations, who should also take measures to avoid anti-competitive behaviours.
3. In the pharmaceutical business, governments should support policies that stimulate innovation and competition. Some examples of such policies include giving incentives

⁵² Lexchin Joel, 'The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States' (2008) <<https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050001>> accessed on 23 February 2023.

for research and development and encouraging the production of generic pharmaceuticals.

4. Industry actors should adopt ethical standards and work together to guarantee that mergers and acquisitions do not hurt the interests of consumers.

It is essential that consumer advocacy organisations go on playing a pivotal role in fostering equitable competition and expanding access to pharmaceutical products at reasonable prices.

In the pharmaceutical sector as a whole, maintaining a healthy equilibrium between innovation and competition is very necessary. Mergers and acquisitions have the potential to propel innovation and development, but they must not come at the price of free and open competition or of affordable access to medical care. To guarantee that the pharmaceutical business stays competitive, inventive, and accessible to everyone, governments, regulatory authorities, industry participants, and consumer advocacy organisations must work together.

