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Research Article

Investigate The Influence Of Supply Chain Dynamics On The Availability And Price Of Generic Alternatives To Branded Drugs, With A Focus On Diabetes And Hypertension Treatments.

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ABSTRACT

This study investigates the impact of supply chain dynamics on the availability and affordability of generic alternatives to branded pharmaceuticals, with a focus on diabetes and hypertension treatments. Given the global frequency of many chronic illnesses, access to cheap pharmaceuticals is crucial for controlling and minimising their impact on public health. The availability and affordability of generic alternatives are heavily influenced by the complex interaction of supply chain factors such as regulatory frameworks, distribution networks, pricing systems, and market rivalry. This study attempts to understand the mechanisms by which supply chain dynamics influence the accessibility and affordability of diabetes and blood pressure drugs through a comprehensive inquiry that includes both qualitative and quantitative evaluations.

Using data from a wide range of sources, including regulatory documents, market studies, and stakeholder interviews, the study aims to identify important barriers and facilitators influencing the availability and pricing of generic alternatives along the supply chain. The study's findings, which shed light on these dynamics, have the potential to improve legislative actions, corporate tactics, and healthcare practices targeted at improving access to vital pharmaceuticals for those suffering from diabetes and high blood pressure.

Keywords: Supply chain dynamics, Availability, Affordability, Generic alternatives, Diabetes treatments, Hypertension treatments.

Introduction

Since independence, India's pharmaceutical industry has grown to become a major provider of pharmaceuticals and healthcare products. The Indian pharmaceutical business is currently the global leader in expanding manufacturing enterprises, offering diverse skills in technology and medicine manufacture. The Indian pharmaceutical market is rapidly expanding, currently ranking third globally in terms of volume and fourteenth in terms of value ("Drug & Pharmaceutical Industry in India," n.d.). A generic drug is a pharmaceutical that is identical to an approved brand name drug in terms of dose, safety, strength, route of administration, quality, and performance (Generic Drug Facts, 2018).

Generic drug companies in India possess extensive technological capabilities and have diversified market reach. With the expiration of patents, the generic segment of the pharmaceutical market is anticipated to witness a surge in sales. These Indian companies' scientific prowess in manufacturing and supplying generic drugs is expected to position them as key players in the global generics market. India's strong pool of skilled talent is attractive to foreign investors, further enhancing its competitiveness. Additionally, a favorable environment for basic research and drug discovery augments this positive outlook. However, sustained growth hinges on the ability to compete effectively in developed markets. Addressing challenges such as enhancing

regulatory frameworks for detailed drug classification and managing high R&D costs are crucial for the sustained success of generic manufacturers (Swain et al., 2014).

A supply chain is a dynamic process that involves the continual movement of information, materials, and funds between various functional areas inside and among member entities (Jain et al., 2004, 2005, and 2006a).

Introduction to Supply Chain Dynamics in the Pharmaceutical Industry

The pharmaceutical supply chain is a complicated network of parties involved in the development, distribution, and delivery of pharmaceutical products to end users. This sophisticated ecosystem often includes manufacturers, wholesalers, distributors, pharmacies, and healthcare professionals, all of whom have a substantial impact on medicine availability and pricing. Understanding the inner workings of this supply chain is critical to comprehending the different elements that influence the availability and cost-effectiveness of pharmaceuticals, particularly generic alternatives.

Manufacturers: Manufacturers are at the heart of the pharmaceutical supply chain, responsible for drug research, development, and production. These organisations invest heavily in drug discovery, clinical studies, and regulatory clearances. Following approval, manufacturers increase output to fulfil market demand. Branded medicine makers have exclusive rights to create and distribute pharmaceuticals under patents that normally last 20 years. When these patents expire, generic producers can enter the market and sell comparable copies of the drug at lower prices (Adams & Brantner, 2006).

Wholesalers and distributors: As intermediaries between manufacturers and pharmacies, wholesalers and distributors play an important role in ensuring the smooth flow of drugs throughout the supply chain. They buy pharmaceuticals in bulk from producers and then distribute them to pharmacies, hospitals, and other healthcare facilities. These organizations' help manage inventory levels, facilitate timely deliveries, and ensure medicine availability (Ganley, 2014).

Pharmacies: Pharmacies are the last link in the pharmaceutical supply chain, dispensing pharmaceuticals directly to patients. They obtain pharmaceuticals from wholesalers and distributors, keep inventory, and provide essential counselling and medication management services. Pharmacies sell both branded and generic pharmaceuticals, depending on patient choices, insurance coverage, and recommendations from healthcare providers (Dunne & Dunne, 2004).

Generic Drugs and Their Role:

Generic pharmaceuticals, which are bioequivalent versions of brand-name prescriptions, are critical for increasing access to cheap treatments. These drugs use the same active components, dosing forms, and strengths as their branded counterparts, but are marketed under chemical or generic names. Generic medications enter the market as brand-name drug patents expire, stimulating competition and driving down prices, promoting cost-effective healthcare (Danzon & Furukawa, 2006).

In the generic pharmaceutical industry, typical supply chains consist of the following components: manufacturing raw materials, manufacturing pharmaceuticals, distributing centers, retail pharmacies/hospitals, and patients (Shah, 2004). Due to economic changes, pharmaceutical industry member companies have been endeavoring to restructure their supply chains (Singh, 2005). The pharmaceutical business is a multipart enterprise accompanied by conflicting purposes and several troublesome limitations. A highly regulated setting combined with the life-changing nature of the products describe the pharmaceutical industry as a special challenging system (Wang, Huang, & Dismukes, 2005). As Wang (2005) stated, "the crucial aim of SCM in the pharma industry is to make the right product, for the right customer, in the right amount, at the right time" (p. 93).

Access to low-cost medications for chronic conditions such as diabetes and hypertension is critical for optimal disease management and public health outcomes. While generic alternatives to branded drugs have the potential to reduce healthcare costs and provide access to critical therapies, their availability and pricing are affected by a variety of supply chain variables. Understanding how these factors affect the generic medicine market is critical for establishing policies that provide fair access to cheap treatments. The purpose of this study is to look into the relationship between supply chain dynamics and the availability and pricing of generic alternatives for chronic diseases, with the ultimate goal of providing evidence-based recommendations to governments, healthcare providers, and pharmaceutical companies.

Problem statement

Access to affordable drugs for chronic illnesses such as diabetes and hypertension is critical for optimal disease management and public health outcomes. While generic alternatives to branded pharmaceuticals appear to be a viable answer for lowering healthcare costs and increasing access to vital therapies, their availability and pricing are influenced by a variety of supply chain variables. Understanding the intricate interplay between supply chain issues and generic drug market dynamics is critical for policymakers, healthcare providers, and pharmaceutical corporations in developing measures to assure fair access to cheap medications.

Literature review

Factors Influencing Availability of Generic Alternatives:

1. Regulatory Environment: Pharmaceutical sector regulations have a substantial impact on the availability of generic alternatives to branded pharmaceuticals.

- Patent Expiration: When branded medicine producers' patents expire, generic alternatives might enter the market, increasing competition and lowering prices (Grabowski & Vernon, 2002).
- The FDA's Abbreviated New medicine Application (ANDA) process expedites generic medicine approval while guaranteeing safety and bioequivalence to branded treatments (U.S. FDA, n.d.).
- Generic Substitution Laws allow pharmacists to provide cost-effective alternatives, increasing availability (Gupta & Bhatia, 2015).

2. Market Competition: Competition amongst generic manufacturers is critical in influencing the availability of generic medications for diabetes and hypertension therapy.

- Increased rivalry among manufacturers leads to higher availability of generic alternatives as they compete for market share (Frank, 2007).
- Price competition reduces drug costs, benefiting patients and healthcare systems (Berndt et al., 2007).

3. Supply Chain Efficiency: Effective supply chain management is critical to assuring the availability of generic medications.

- Manufacturing Capacity: Scaling up manufacturing can improve medicine availability and reduce the likelihood of shortages (Hemphill & Sampat, 2012).
- Established distribution networks ensure timely and uninterrupted drug supply (Qi et al., 2018).
- Effective inventory management reduces stockouts and guarantees medicine availability (Bhaskaran et al., 2015).

Understanding these characteristics sheds light on the dynamics that influence the availability of generic alternatives to branded drugs for chronic conditions such as diabetes and hypertension. Addressing regulatory, competitive, and supply chain obstacles can improve access to cheap medications, which benefits both patients and healthcare systems.

Dynamics affect patient medication affordability

1.Supply Chain Dynamics and Pricing Tactics:

Pricing techniques for generic medicines are influenced by supply chain dynamics such as manufacturing capacity, distribution networks, and regulatory constraints.

- Manufacturing Capacity: A company's ability to efficiently scale up production to meet market demand might influence price decisions. Higher manufacturing capacity may result in cheaper production costs, allowing businesses to charge competitive prices (Hemphill & Sampat, 2012).
- Distribution Network: Efficient distribution networks allow producers to decrease logistics costs while reaching a larger market, potentially affecting price tactics. Manufacturers may change prices based on distribution efficiencies and market access (Qi et al., 2018).
- Manufacturers' pricing strategies are influenced by regulatory restrictions such as FDA approval and patent expiration. Generic manufacturers may modify prices depending on the legal environment and market exclusivity periods. (Grabowski & Vernon, 2002; U.S. FDA, n.d.).

2. Impact on Patient Medication Affordability:

The interaction of supply chain dynamics and pricing strategies has a direct impact on patient medication affordability via a variety of processes.

- Efficient supply chains and increased competition among generic manufacturers can result in lower drug pricing, making it more affordable for patients (Berndt et al., 2007).
- Regulatory factors effect pharmaceutical availability and pricing, affecting patient affordability. Patent expiration and accelerated FDA clearance processes may result in earlier market introduction of generic medications, providing patients with cost-effective options (Grabowski & Vernon, 2002; U.S. FDA, n.d.)

3.Market Positioning and Patient Outcomes:

Manufacturers' pricing strategies, which are driven by supply chain dynamics, can have an impact on patient outcomes and total healthcare expenditures.

- Manufacturers may intentionally price their medications to increase market share, potentially improving adherence and patient outcomes. Lower pharmaceutical costs can reduce the financial strain and enhance treatment adherence, eventually enhancing patient health (Frank, 2007).
- Healthcare system costs: Affordable pharmaceuticals, which are the product of efficient supply chains and competitive pricing, can help the healthcare system save money on chronic disease management. Lower drug prices lead to lower healthcare expenses and greater patient access (Berndt et al., 2007).

Understanding these connected elements provides insights into how supply chain dynamics and pricing methods influence patient pharmaceutical affordability, eventually impacting healthcare outcomes.

Research objectives

1. Identify and analyze the specific supply chain characteristics that significantly influence the availability of generic alternatives to branded medications for chronic diseases such as diabetes and hypertension.
2. To examine the relationship between supply chain dynamics and generic medicine manufacturers' pricing tactics, with a focus on how these dynamics affect patient medication affordability.

Research Hypothesis:

Objective 1: Identify and analyze the specific supply chain characteristics that significantly influence the availability of generic alternatives to branded medications for chronic diseases such as diabetes and hypertension.
Null Hypothesis (H0): The availability of generic pharmaceuticals is unaffected by the regulatory framework, distribution networks, pricing systems, or market rivalry.

Alternative Hypothesis (H1): At least one of the elements - regulatory framework, distribution networks, pricing systems, or market rivalry - has a major impact on generic drug availability.

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.872[a]	.760	.738	7.299

a. Predictors: (Constant), IMPACT OF MARKET RIVALRY, IMPACT OF DISTRIBUTION NETWORKS, IMPACT OF REGULATORY FRAMEWORK, IMPACT OF PRICING SYSTEMS

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	7429.860	4	1857.465	34.862	.000[b]
	Residual	2344.344	44	53.281		
	Total	9774.204	48			

a. Dependent Variable: NUMBER OF GENERICMEDICINES
b. Predictors: (Constant), IMPACT OF MARKET RIVALRY, IMPACT OF DISTRIBUTION NETWORKS, IMPACT OF REGULATORY FRAMEWORK, IMPACT OF PRICING SYSTEMS

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
1	(Constant)	40.109	5.691		7.048	.000
	IMPACT OF REGULATORY FRAMEWORK	14.784	1.325	.846	11.160	.000
	IMPACT OF DISTRIBUTION NETWORKS	2.024	1.325	.118	1.527	.134
	IMPACT OF PRICING SYSTEMS	-1.721	1.311	-.101	-1.313	.196
	IMPACT OF MARKET RIVALRY	-.805	1.337	-.046	-.602	.550

a. Dependent Variable: NUMBER OF GENERICMEDICINES

The decision to reject the null hypothesis is based on the p-value associated with the coefficient of the independent variable in the regression analysis. The p-value represents the probability of observing the data if the null hypothesis is true. If the p-value is less than the significance level (α), typically 0.05, then the null hypothesis is rejected.
In the provided coefficients table:
The p-value associated with the coefficient for the "Impact of Regulatory Framework" is $p < 0.001$, which means it is less than 0.05.
Since the p-value is less than the significance level (α), we reject the null hypothesis.
Rejecting the null hypothesis implies that there is a statistically significant relationship between the regulatory framework and the availability of generic medicines.

The regression model is statistically significant ($F(4, 44) = 34.862$, $p < 0.001$), indicating that at least one of the independent variables (regulatory framework, distribution networks, pricing systems, or market rivalry) plays a significant role in predicting generic medicine availability.
The model's R-squared value of 0.760 indicates that the independent variables included in the model account for about 76.0% of the variability in the availability of generic drugs.
The general formula for a linear regression model with one independent variable (simple linear regression) is:

$Y=\beta 0+\beta 1X+\epsilon$

Where:
Y is the dependent variable (outcome variable),
X is the independent variable (predictor variable),
$\beta 0$ is the intercept (the value of $Y$when $X$is zero),
$\beta 1$ is the slope (the change in $Y$for a one-unit change in X),
ϵ represents the error term (the difference between the observed and predicted values of Y).
For multiple linear regression models with more than one independent variable, the formula extends as follows:
$Y=\beta 0+\beta 1X1+\beta 2X2+...+\beta nXn+\epsilon$

Where:
$X1,2,...,Xn$ are the independent variables,
$\beta 0,1,\beta 2,...,\beta n$ are the coefficients (intercept and slopes) associated with each independent variable.
In the context of the specific regression model discussed earlier:

Availability of Generic Medicines=40.109+14.784*(Impact of Regulatory Framework)+2.024*(Impact of Distribution Networks)−1.721*(Impact of Pricing Systems)−0.805*(Impact of Market Rivalry)

In this equation:
"Availability of Generic Medicines" represents the predicted availability of generic medicines.
"Impact of Regulatory Framework", "Impact of Distribution Networks", "Impact of Pricing Systems", and "Impact of Market Rivalry" are the respective impacts of each factor on the availability of generic medicines.
The coefficients (14.784, 2.024, -1.721, and -0.805) represent the slopes or weights associated with each independent variable.
The constant term (40.109) represents the intercept, indicating the expected availability of generic medicines when all independent variables are zero.

This formula represents a multiple linear regression model with four independent variables (regulatory framework, distribution networks, pricing systems, and market rivalry) predicting the availability of generic medicines

Objective 2: To examine the relationship between supply chain dynamics and generic medicine manufacturers' pricing tactics, with a focus on how these dynamics affect patient medication affordability.

Null Hypothesis (H0): The average price of generic alternatives to branded pharmaceuticals is not influenced by the regulatory framework, distribution networks, pricing systems, or market rivalry.
Alternative Hypothesis (H1): At least one of the elements - regulatory framework, distribution networks, pricing systems, or market rivalry - has a significant impact on the average price of generic alternatives.

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.718[a]	.516	.472	1.319

a. Predictors: (Constant), IMPACT OF MARKET RIVALRY, IMPACT OF DISTRIBUTION NETWORKS, IMPACT OF REGULATORY FRAMEWORK, IMPACT OF PRICING SYSTEMS

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	81.477	4	20.369	11.712	.000[b]
	Residual	76.523	44	1.739		
	Total	158.000	48			

a. Dependent Variable: average price of generic alternatives to branded pharmaceuticals
b. Predictors: (Constant), IMPACT OF MARKET RIVALRY, IMPACT OF DISTRIBUTION NETWORKS, IMPACT OF REGULATORY FRAMEWORK, IMPACT OF PRICING SYSTEMS

Coefficients[a]

Model		Unstandardized Coefficients B	Unstandardized Coefficients Std. Error	Standardized Coefficients Beta	t	Sig.
1	(Constant)	12.494	1.028		12.152	.000
	IMPACT OF REGULATORY FRAMEWORK	-1.484	.239	-.668	-6.200	.000
	IMPACT OF DISTRIBUTION NETWORKS	-.422	.239	-.193	-1.764	.085

IMPACT OF PRICING SYSTEMS	-.056	.237	-.026	-.237	.814
IMPACT OF MARKET RIVALRY	.208	.241	.093	.861	.394

a. Dependent Variable: average price of generic alternatives to branded pharmaceuticals

The regression model demonstrates statistical significance ($F(4, 44) = 11.712$, $p < 0.001$), suggesting that one or more independent variables significantly influence the average price of generic alternatives. The R-squared value of 0.516 indicates that approximately 51.6% of the variability in the average price of generic alternatives can be explained by the independent variables in the model.
The regression formula for predicting the average price of generic alternatives is:

Average Price = 12.494 - 1.484*(Impact of Regulatory Framework) - 0.422*(Impact of Distribution Networks) - 0.056*(Impact of Pricing Systems) + 0.208*(Impact of Market Rivalry)

This formula represents a multiple linear regression model with four independent variables (regulatory framework, distribution networks, pricing systems, and market rivalry) predicting the average price of generic alternatives to branded pharmaceuticals.
This regression model suggests that a stronger regulatory framework and less impact from distribution networks tend to decrease prices, while the influence of pricing systems and market rivalry has minimal effect. These findings can inform strategies to optimize regulatory policies and distribution networks for improved affordability of generic medications.
In the provided coefficients table:
The coefficient for the "Impact of Regulatory Framework" is statistically significant ($p < 0.001$, Beta = -0.668), indicating that changes in the regulatory framework have a substantial impact on the average price of generic alternatives. Specifically, for every one-unit increase in the impact of the regulatory framework, the average price of generic alternatives decreases by 1.484 units.
The impacts of distribution networks, pricing systems, and market rivalry are not statistically significant ($p > 0.05$).
The analysis shows a substantial correlation between supply chain dynamics and generic pharmaceutical pricing strategies ($p < 0.001$). However, whereas the regulatory framework has a considerable impact on pricing, distribution networks, pricing systems, and market rivalry have little effect. These factors influence patient pharmaceutical affordability, necessitating greater research into pricing schemes and their consequences for accessibility.

Findings and conclusions:

The study's findings provide numerous critical insights into the relationship between supply chain dynamics and the availability and affordability of generic alternatives to branded medications, particularly for chronic conditions such as diabetes and hypertension.
The analysis reveals that the regulatory framework has a major impact on both the availability and price of generic drugs. Strengthening regulatory processes and expediting permits can speed up market entry, increasing affordability and accessibility.
Regulatory Framework Dominance: Regulatory variables have a substantial impact on the availability and pricing of generic pharmaceuticals, outweighing the influence of distribution networks, pricing systems, and market competition. Policymakers should prioritise regulatory reforms to speed up market entrance and ensure fair competition.
Tailored Pricing Strategies: Manufacturers must modify pricing strategies to meet regulatory requirements and market realities. They can balance affordability and profitability by leveraging distribution efficiency and market access, hence improving access to important pharmaceuticals.
Policymakers should promote market competition among generic manufacturers in order to boost availability and drive down prices. Preventing monopolistic activities and promoting fair competition are critical steps towards increasing drug price and access.
Policy Intervention chances: Policymakers have numerous chances to act and alleviate access obstacles in the pharmaceutical industry. Improving regulatory frameworks, increasing market competition, and optimising supply chain efficiency can all help to provide fair access to cheap drugs for all segments of society.

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