Product Substitution and Comparative Dynamics in the Indian Pharmaceutical Market

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Abstract
Pharmaceutical product substitution has become a central structural mechanism reshaping pricing, competition, and firm strategy within the Indian pharmaceutical market under an increasingly regulated healthcare environment. This study examines the regulatory, economic, and institutional determinants of generic and therapeutic substitution in India, with particular emphasis on how policy-driven mechanisms shape substitution outcomes across public and private healthcare systems. Using an analytical secondary-data design, the study draws on evidence from the National Pharmaceutical Pricing Authority (NPPA), Health Management Information System (HMIS), National List of Essential Medicines (NLEM), Competition Commission of India (CCI), and international benchmarks from the OECD and WHO. The findings show that generic medicines account for approximately 97% of pharmaceutical sales by volume in India (AIOCD-AWACS), yet represent only around 38% of total market value, yielding an Effective Substitution Efficiency Ratio (ESER) of 0.39, substantially lower than the OECD average of 0.77. While generic entry results in 30–50% revenue erosion for branded products and generics priced 50–80% lower rapidly gain substantial volume share, economic substitution remains incomplete. Institutional procurement systems achieve significantly greater price efficiency, with procurement prices nearly 1.9 times lower than private retail prices for identical molecules. Moreover, extensive brand proliferation is associated with high price dispersion—up to 200%—without commensurate gains in competition. Overall, pharmaceutical substitution in India is institutionally driven rather than market-led, delivering affordability gains but limited value-based substitution, with important implications for health policy and industry strategy.

Keywords: Product substitution, Indian pharmaceutical industry, branded vs generic drugs, regulatory policies, market dynamics

Introduction

The Indian pharmaceutical industry, known as "the pharmacy of the world," has witnessed astonishing expansion, likely to attain a market size of approximately USD 66 billion in 2025. Generics segment has been the major driver for this growth, which contributes roughly 40% of the overall market revenue. Simultaneously, Indian pharma. Industry is facing the growing impact of product substitution—the practice of replacing from branded medicines to alternative generic drugs or alternative treatment line, this has become an important factor affecting the business and increasingly altering the strategies of business conduct. This trend of pharmaceutical substitutions upward geared by the Factors such as rising healthcare expenses, government regulations & initiatives to encourage generic drugs usage, and the expiration of patents on key pharmaceutical drug molecules are further contributing to this trend. (WHO, 2011; Mordar Intelligence, 2025)

In India, Pharmaceutical product substitution occurs mainly in two ways:

1. Generic substitution: exchange of branded medicinal product with bioequivalent generic molecule or alternative drug.
2. Therapeutic substitution: replacement of a prescribed drug with another bio-similar drug that provides a resembling therapeutic effect but having a different chemical or molecular composition.

This research paper explores the key factors those drive product substitution, causing challenges & opportunities that creates because of substitution and focuses on how it alters the market trends, business strategies, and patient outcomes. Major decisive influencers include regulatory policies & government initiatives, cost-economic considerable, and the extent of patient awareness & patient education.

The Indian pharmaceutical market & business growth trends as overall, in generics and branded/patented markets are depicted through various graphs and tabular representations. Market size and growth are measured in Billion USD, are depicted from Figure 1 to Figure 7 and concise in Table 1.

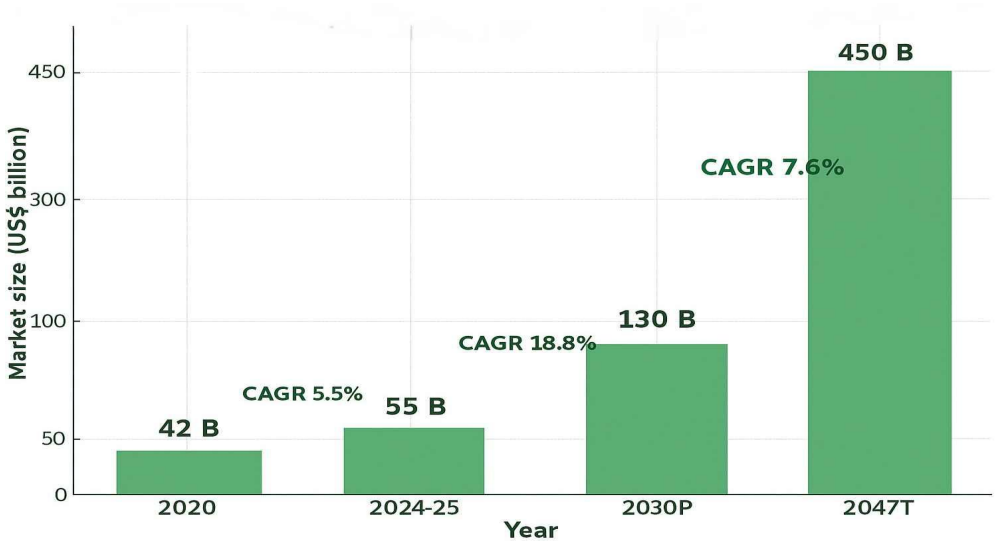

Figure 1: Growth trajectory of the Indian pharmaceutical market (2020–2047).
Source: Indian Brand Equity Foundation (IBEF, 2025)- Indian Ministry of Commerce and Industry (Govt. of India).

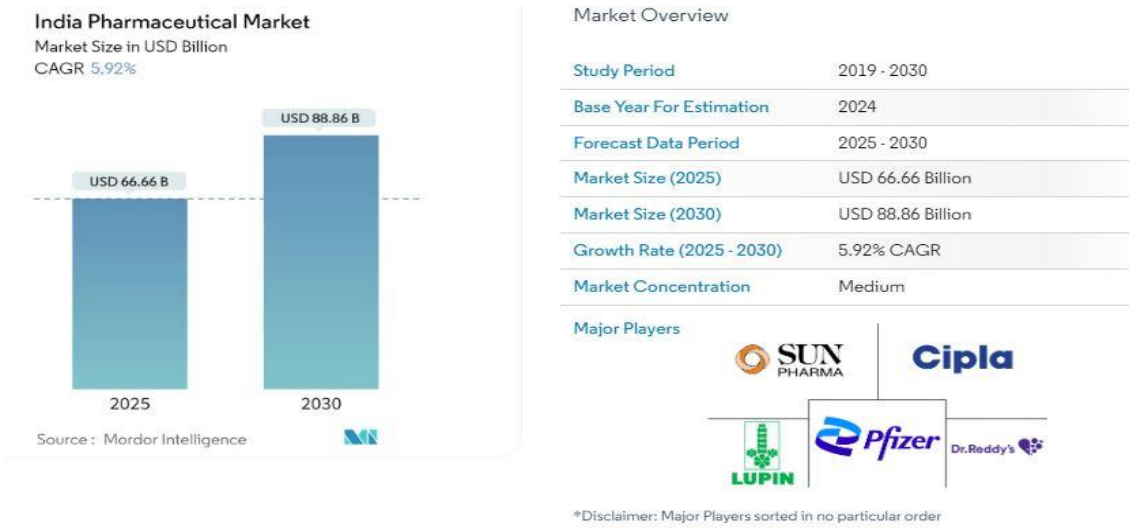

Figure 2. Indian pharmaceutical market outlook, showing growth from USD 66.66 billion in 2025 to USD 88.86 billion by 2030
Source: Mordar Intelligence (2025)

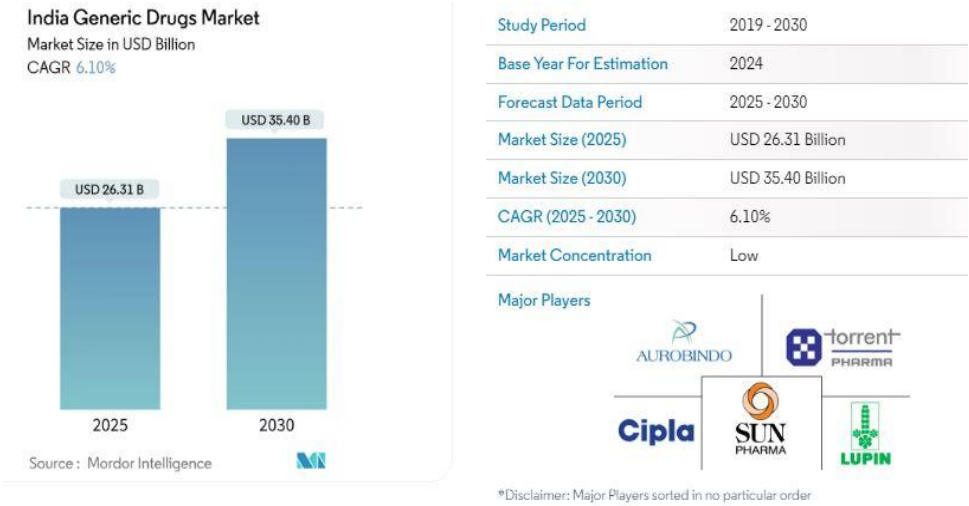

Figure 3. Indian generic drugs market outlook, illustrating growth from USD 26.31 billion in 2025 to USD 35.40 billion by 2030
Source: Mordar Intelligence (2025)

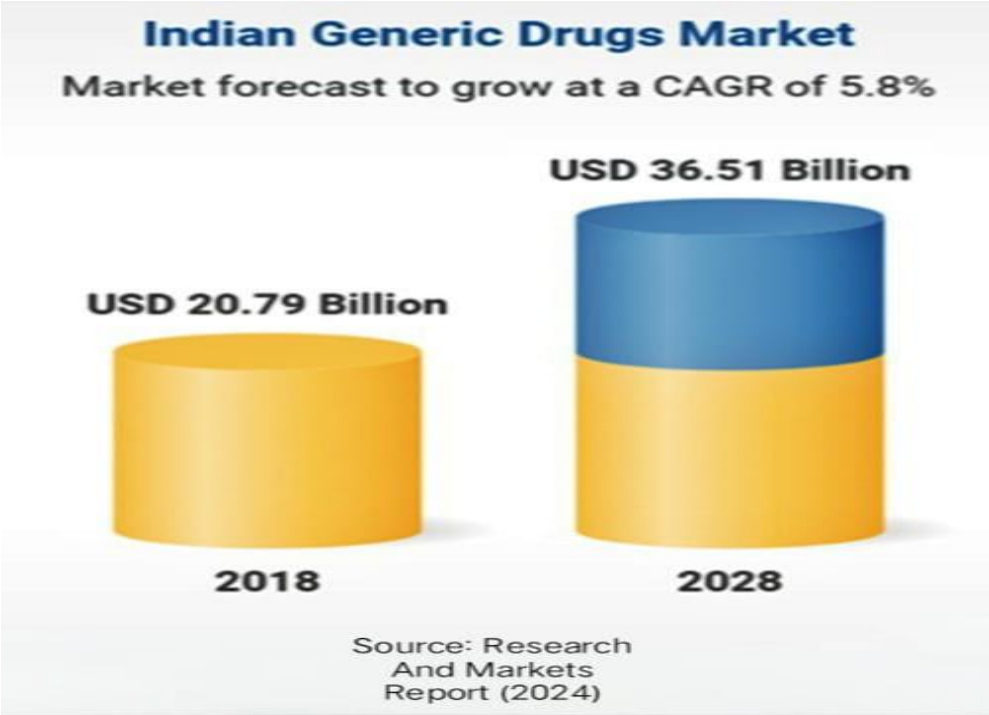

Figure 4. Growth of the Indian generic drugs market from USD 20.79 billion in 2018 to USD 36.51 billion by 2028

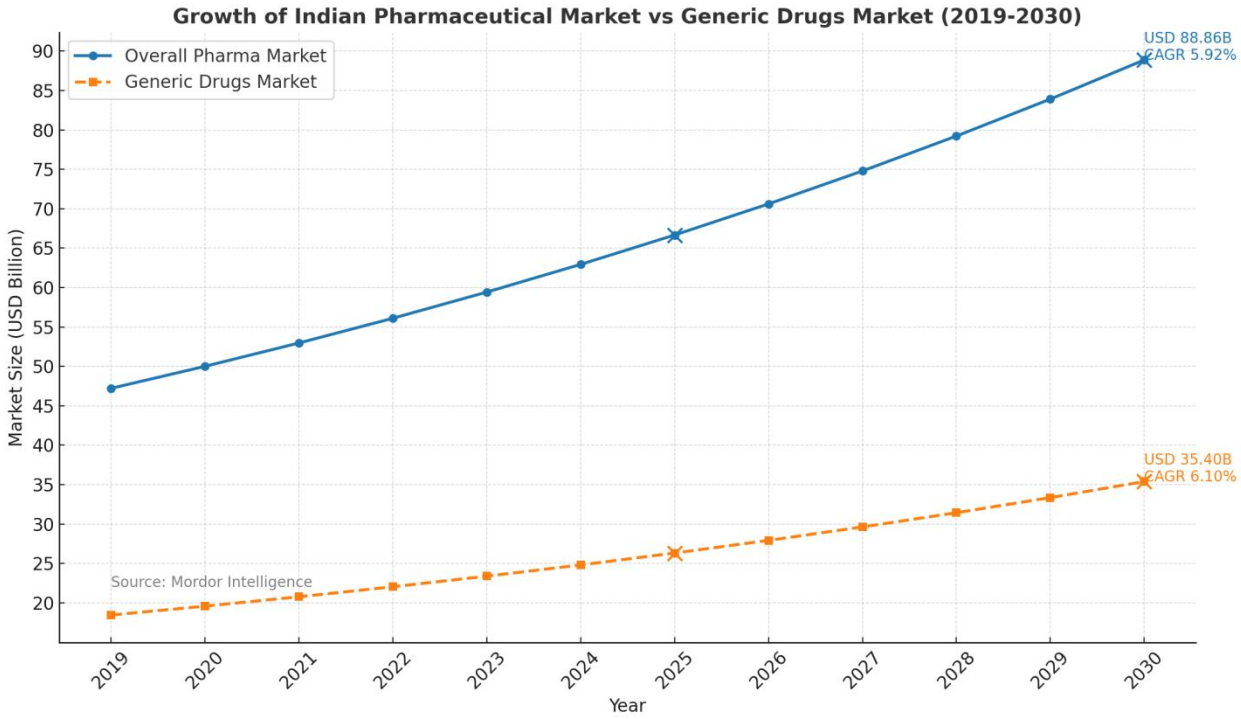

Figure 5. Growth of Indian Pharmaceutical Market vs Generic Drug Market
Source: Mordar Intelligence (2025)

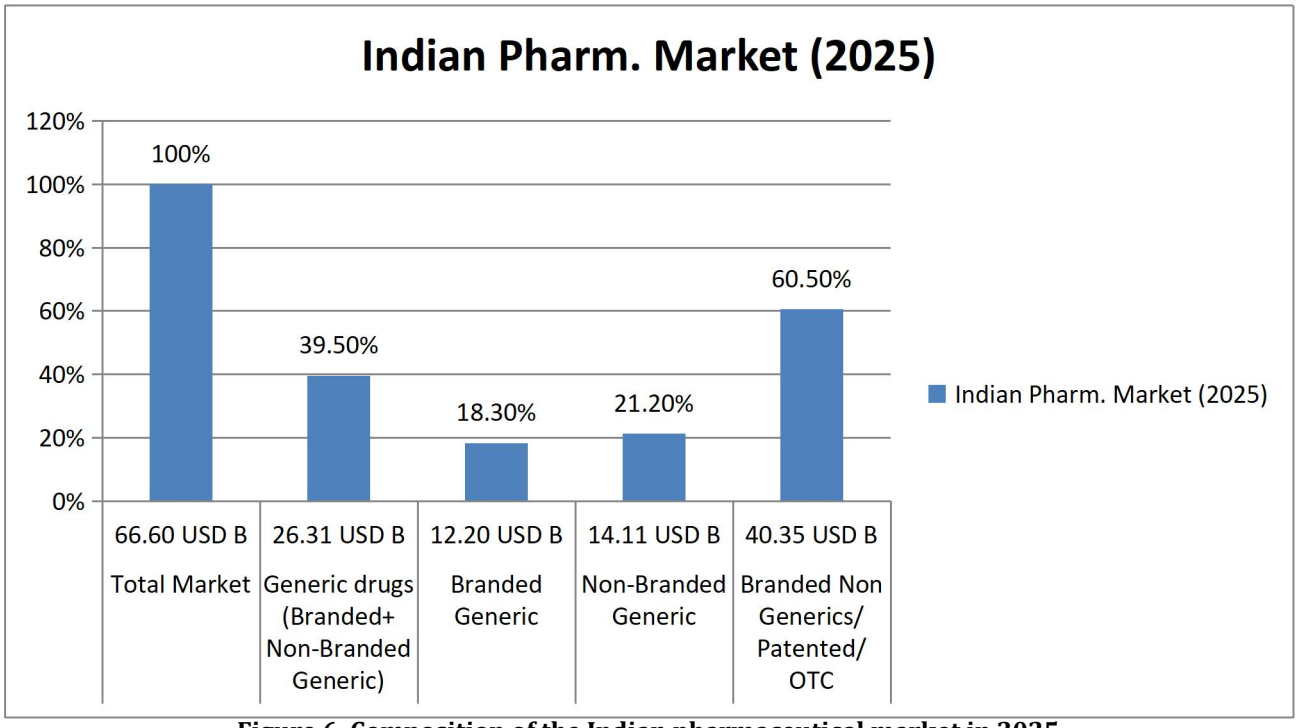

Figure 6. Composition of the Indian pharmaceutical market in 2025
Source: Mordor Intelligence (2025) Industry Reports - Pharmaceuticals Industry in India

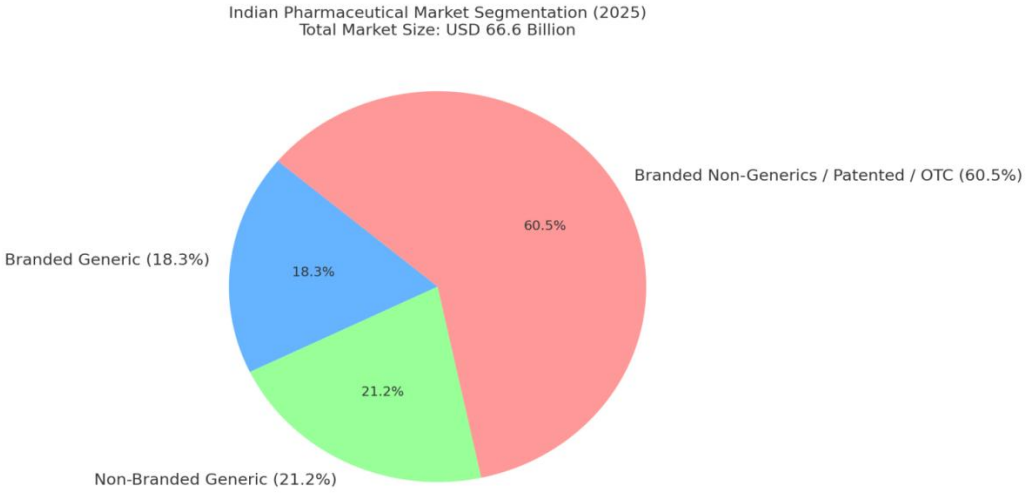

Figure 7. Indian Pharmaceutical Market Segmentation 2025
Source: Mordor Intelligence (2025) Industry Reports - Pharmaceuticals Industry in India

Table 1. Indian Pharmaceutical Market (2025)

Indian Pharmaceutical Market (2025)	Market size	% Share
Total Market Size - Indian Pharma.	66.60 USD B	100%
Generic drugs (Branded+ Non-Branded Generic)	26.31 USD B	39.50%
Branded Generic	12.20 USD B	18.30%
Non-Branded Generic	14.11 USD B	21.20%
Branded Non Generics/ Patented/ OTC	40.35 USD B	60.50%

Source: Industry Reports- Pharmaceuticals Industry in India.
Mordor Intelligence (2025).

Aforementioned Business trends indicate a shift towards affordable healthcare solutions, with government initiatives promoting generics and biosimilars. While this has improved patient access, it has disrupted traditional business models, particularly for branded pharmaceutical companies.

Levels of Product Substitution

Substitution of products is operationalised as the process of systematized replacement, exclusion or prioritization of pharmaceutical products with generic or therapeutically equivalent products, mostly as a result of regulatory price control, formulary design, and availability restriction, not by individual patient or prescribers. In line with the modern research on the topic of pharmaceutical systems, substitution is theorized as a mediated institutional process that is embedded in health-system governance systems (WHO, 2003; OECD, 2018).

This paper considers the product substitution on three analytically different but interrelation levels.

Regulative level, substitution is determined by legal and policy measures of statutory price ceilings and designation of essential medicines, like the Drug (Prices Control) Order and the National List of Essential Medicines. These systems identify the price limits and therapeutic imperatives under the conditions of which substitution is made (WHO, 2017; NPPA, 2013).

On the Institutional level, substitution is controlled by the design and execution of formularies, procurement policies as well as supply-chain regulations inside the public health systems. Substitution can be largely facilitated or limited in decisions of which medicines are selected, procured, stocked, and made available, usually via centralized tendering and essential drug lists, regardless of the prescribing intent of an individual prescribing. Here, substitution is the result of procurement structure and inventory control, and not a clinical choice of discretion (WHO, 2004; Management Sciences for Health, 2012).

Substitution at the Utilization level is manifested in the patterns of dispensing and issuance in the health facilities of the public sector, the patterns that reflect the way regulatory and institutional limitation is embodied in the actual use of the medicine across the varied geographical and demographic backgrounds (WHO, 2003).

This multi-level operationalisation responds to the recent research in the field of pharmaceutical systems, which considers substitution not only as a market reaction but also as an institutional manifestation of the health-system structure and regulation (Bigdeli et al., 2014; OECD, 2018).

Review of Literature

Conceptual Foundations of Pharmaceutical Product Substitution

Substitution of pharmaceutical products, including generic and therapeutic substitution, has become a central concern in health economics and pharmaceutical policy due to its implications for healthcare affordability, market competition, and regulatory control. Contemporary literature increasingly conceptualizes substitution as a policy-driven and institutionally mediated process, particularly in emerging economies with high out-of-pocket health expenditure such as India. Rather than being determined solely by price competition, substitution outcomes are shaped by regulatory design, enforcement capacity, incentive structures, and stakeholder behaviour, including prescribers and pharmacists (Drummond et al., 2015).

Generic Substitution and Healthcare Affordability

The existence of a significant amount of recent literature highlights the use of generic substitution as one of the main tools to decrease the pharmaceutical spending and enhance the access to vital medicines. Salunkhe and Kadbhane (2023) show that generic drugs sold in India are bioequivalent with the brand-name versions at half to three-quarters of the cost, which makes them particularly important in chronic illness treatment where costs are an important consideration in delicate groups. To support this evidence, Singh (2020) states that the rise in the penetration of generic drugs has had a major impact on enhancing the affordability of therapeutic categories. But the research also shows that there remains a high level of mistrust on quality and therapeutic equivalence both to the patient and the prescribers therefore that price benefits alone do not provide sufficient conditions to promote successful substitution.

Regulatory Interventions and Prescription Behaviour

Recent research singles out regulatory intervention as a prominent force that determines the substitution in India. Patel, Kumar, and Desai (2021) are empirical evidence that the price controls of the National Pharmaceutical Pricing Authority (NPPA) have led to significant loss in the prices of branded drugs, which indirectly stimulates the use of generics in various treatment categories. Gupta and Sharma (2022) also record that compulsory generic prescribing standards already started modifying the prescription patterns of the urban healthcare environment. However, resistance to regulatory goals by physicians based on brand loyalty, perceived quality differentials and medico-legal issues still limits the achievement of all regulatory goals. These results indicate that regulating requirements cannot be effective without

accompanying behavioural and informational interventions.

Public Healthcare Initiatives and Access Expansion

The role of the public sector initiatives has become more significant in the operationalization of the substitution policies. The Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) is a historic initiative to systematize generic replacement by supporting government procurement and sale of inexpensive medicines. The reports by the World Health Organization (2022) have shown a reduction in out-of-pocket spending that has been measurable, especially in rural and underserved areas. Nevertheless, the success of such programs will always be dependent on the reliability of the supply chains, physician approval, patient education, and trust in the quality of products- aspects that have a lot of variations across the regions.

Market Structure, Competition, and Firm Strategy

In the case of the industry, substitution has made a big difference in the market structure and competition. According to industry analysis, generic companies have gained dominant quantities, which are changing the competitive equilibrium in the Indian pharmaceutical market essentially. According to Mordor Intelligence (2025), the current market value has seen generics taking almost 40 percent of market value and a much larger portion in terms of volume. Mehta and Reddy (2023) hold that this structural change has forced branded pharmaceutical companies to balance pricing mechanisms, promote more, and justify product portfolios to remain profitable. These changes highlight the importance of substitution as a demand-side process, as well as a driver of strategic reorganization among established companies.

Substitution, Innovation, and Long-Term Industry Sustainability

Pharmaceutical innovation and substitution have been a popular topic among the post-2020 literature. Kumar (2017) warns of the danger of encouraging incremental innovation in small-molecule drugs, at least in very competitive genericized markets, through aggressive price control and substitution requirements. In line with this, companies can shift research and development spending into biosimilars, complex generics and specialty therapeutics. In line with this argument, the OECD (2020) stresses that even though substitution improves the efficiency and cost-containment of systems, innovation-supportive policies are necessary to ensure pharmaceutical research and development are not stagnated in the long term.

Stakeholder Perceptions and Clinical Considerations

The behavior of the stakeholders is a significant factor of substitution results. The article of Chaudhary and Gupta (2020) emphasizes the growing role of pharmacists as powerful intermediaries and states that patient acceptance of generic drugs largely depends on the recommendations made by pharmacists. Simultaneously, apprehension over substitution exists regarding narrow therapeutic index drugs, where the occurrence of any small divergence of bioavailability can have grave clinical consequences. Beran (2021) focuses on the legal and therapeutic risks of inappropriate substitution and requires more subtle regulatory frameworks that can balance affordability and patient safety.

Regulatory, Institutional, and Market Dimensions of Pharmaceutical Substitution in India

Pharmaceutical substitution in India has been shaped primarily through regulatory mandates, institutional mechanisms, and stakeholder behaviour, rather than through market competition alone. The Government of India has explicitly promoted generic prescribing through professional and statutory frameworks. The Indian Medical Council Regulations (2002) and the Code of Medical Ethics require physicians to prescribe medicines using generic names wherever possible and to ensure rational drug use. This regulatory intent was further strengthened under the National Medical Commission Act (2019), which empowers State Medical Councils and the Ethics and Medical Registration Board to initiate disciplinary action against prescribers violating these norms. In parallel, public-sector supply-side interventions under the National Health Mission provide essential generic medicines free of cost at public health facilities, reinforcing institutional substitution mechanisms (PIB, 2022).

At the dispensing level, the World Health Organization's guidelines on Good Pharmacy Practice emphasize the professional responsibility of registered pharmacists to assess prescriptions holistically and to undertake generic substitution where clinically appropriate, considering therapeutic, economic, and legal dimensions (WHO, 2011). However, WHO also cautions that therapeutic substitution should be formalized within institutional frameworks and overseen by physicians and Drugs and Therapeutics Committees to ensure patient safety and stakeholder acceptance. Echoing this, Kairi and Sharma (2017) argue that national regulatory agencies must develop context-specific therapeutic substitution policies rather than relying on ad hoc retail-level decisions.

Empirical studies highlight that substitution in India is frequently driven by availability constraints and patient demand, rather than proactive prescribing behaviour. Katole (2018) finds that brand substitution often occurs due to non-availability of specific formulations or at the patient's request, with respiratory and antihistamine drugs being most affected. Regulatory interventions by the National Pharmaceutical Pricing Authority (NPPA) have further intensified substitution dynamics, with price controls on essential medicines reducing branded drug prices by up to 60 percent and accelerating generic uptake (NPPA, 2023).

From a market perspective, generic medicines dominate India's pharmaceutical landscape, accounting for a substantial majority of domestic consumption and nearly 20 percent of global generic supply by volume (Indian Pharmaceutical Alliance, 2023). Government initiatives such as Jan Aushadhi Kendras have expanded public access to low-cost generics, although consumer perception studies continue to report residual concerns regarding quality and therapeutic equivalence (IMS Health, 2016). Earlier health economics research underscores that generic medicines constitute a dominant share of pharmaceutical consumption, contributing significantly to improved access for economically vulnerable populations (Simoens, 2008).

Patent expirations further accelerate substitution, with branded products typically losing 30–50 percent of market share within the first year of generic entry (Grabowski et al., 2011). Nevertheless, qualitative evidence suggests persistent challenges in aligning substitution practices with patient trust and professional acceptance. Johnston et al. (2011) emphasize that prescribers and pharmacists face ethical and clinical dilemmas in balancing cost containment with perceived quality, advocating for stronger regulatory oversight and standardized substitution protocols.

Research Gap

The contemporary literature (2020–2025) characterizes pharmaceutical product substitution in India as a multi-dimensional process shaped by regulatory mandates, economic incentives, evolving market structures, and stakeholder perceptions. While substitution policies have demonstrably improved affordability and access, they have also disrupted traditional brand-centric business models and raised unresolved concerns regarding innovation sustainability, quality assurance, and clinical risk management. Notably, much of the existing literature examines these dimensions in isolation—focusing separately on regulation, pricing, competition, prescribing behavior, or market outcomes. This fragmentation reveals a significant research gap: the absence of integrated descriptive and comparative analyses that simultaneously examine the economic, regulatory, competitive, strategic, and stakeholder-level implications of pharmaceutical substitution. Addressing this gap, the present study adopts a descriptive research design with comparative analysis, synthesizing secondary data across institutional, market, and policy domains to provide a holistic assessment of substitution dynamics in the Indian pharmaceutical sector.

Research Objectives

- To examine how regulatory price controls, essential medicine frameworks, and public procurement systems shape pharmaceutical product substitution patterns in India and to provide recommendations to balance affordability with R&D innovation for new drugs.
- To comparatively assess substitution outcomes across institutional contexts by analyzing utilization patterns at state and district levels demography, market competition, brand proliferation and benchmarking India against international substitution regimes.

Methodology

Study Design

This research uses a descriptive and comparative analytical design to look into the dynamics of product substitution in Indian pharmaceutical industry. The study reflects an institutional and health-systems take on pharmaceutical governance, which views substitution as a product of regulatory institutions, formulary, and public-sector acquisition schemes, as opposed to being a product of firm policy or consumer behaviour. On this basis, the dynamics are conceptualized as the changing institutional courses in which substitution is created and solidified on spatial and health-system levels. This design suits because the study relies on secondary administrative and policy data, and it is aimed at explaining the mechanism of substitution instead of estimating the treatment effect of causation and financial results at the firm level.

Theoretical Framework

The current research has its basis in a comprehensive theoretical framework that comprises the Industrial organization theory and innovation economics to explain the Indian pharmaceutical substitution.

To begin with, the Porter's Five Forces strategic framework as defined by Michael Porter can be used to examine how substitution changes the competitive forces. Regulatory price ceiling, and generic entry pose a significant risk of substitutes and decrease pricing power of incumbent especially of branded small-molecule medicines. Meanwhile,

the bargaining power of buyers and the bargaining power of suppliers are also increased in institutional bulk procurement systems, and barriers to entry are moderate because of the costs of compliance with regulations. This is the reason why substitution pressurizes prices.

Second, long term implications of substitution are evaluated by the Theory of Innovation especially the Schumpeterian view on the incentives to innovate. Although price control and generic substitution increase the efficiency of the situation in the short term, and access, long-term price compression can undermine the returns to expected R&D, particularly in small-molecule drugs with incremental innovation. This theoretical paradox aids the strategic change that is observed as companies move towards biosimilars, complex generics and specialty therapeutics.

Through a combination of these frameworks, the study conceptualizes pharmaceutical substitution as not just an outcome of pricing, but as a governance-based reorganization of power and incentives and innovation pathways in the Indian pharmaceutical system.

Data Sources

Analyses using only publicly available secondary data, which were chosen to cover complementary dimensions of pharmaceutical substitution.

Drugs Prices Control Order (DPCO) notifications provided by the National Pharmaceutical Pricing Authority (NPPA) were used to obtain regulatory price data. These are messages that identify ceiling prices of scheduled formulations on the list of Essential Medicines (NLEM) and form the regulatory basis of price-mediated substitution in India.(CDSCO NLEM 2022)

The data on the utilisation of medicine were obtained in the Health Management Information System (HMIS), i.e., state-level data on medicine issuance in Madhya Pradesh (2019-20), and district-level data. These data sets capture the item-level distribution of medicine in the public health facilities and allow the spatial contrast of the mixed urban-semi urban and majorly rural environments.

India has a national list of essential medicines; thus, the research relies on the National List of Essential Medicines and the Essential Medicine Lists of Health and Wellness Centres (HWC), Sub-Health Centres (SHC), and Primary Health Centre (PHC). These documents give the definition of authorised medicines on each level of care and operationalises substitution above the prescribing level by constraining procurement and availability levels.

Analytical Strategy

The analysis is done in three steps. To determine trends of price compression and standardisation between vital medicines, first, regulatory price data are analysed by way of descriptive tabulation and comparative price structuring.

Second, the main analytical level is the pharmaceutical product of any molecule-dosage-form defining the product, was consistent with the regulatory price-procurement frameworks. Aggregated facility, district and state levels are used to analyse the utilisation of medicine products to adjust product-level regulatory restrictions to the consumption patterns observed in the system-level HMIS data.

Third, comparative analysis is done in a structured way where comparisons are made between substitution mechanisms in India and other selected international health systems. The emphasis of the study is on descriptive research based on secondary data and comparative analysis systems, but not on the econometric modelling because the goal of the research is not to offer causal, but to explain the institutional substitution channel.

Comparative Framework

Comparative analysis is carried out on the basis of three aspects:

- India vs global health systems, category of price mediated, payer mediated and formulary mediated substitution regimes;
- Urban-rural Compared Urban and rural areas in India with state and district HMIS data;
- Intra-Country difference, contrasting homogenous national policy formulation and local achievement results.

This framework allows not only identifying convergence but also divergence in the dynamics of substitution in the institutional and spatial settings.

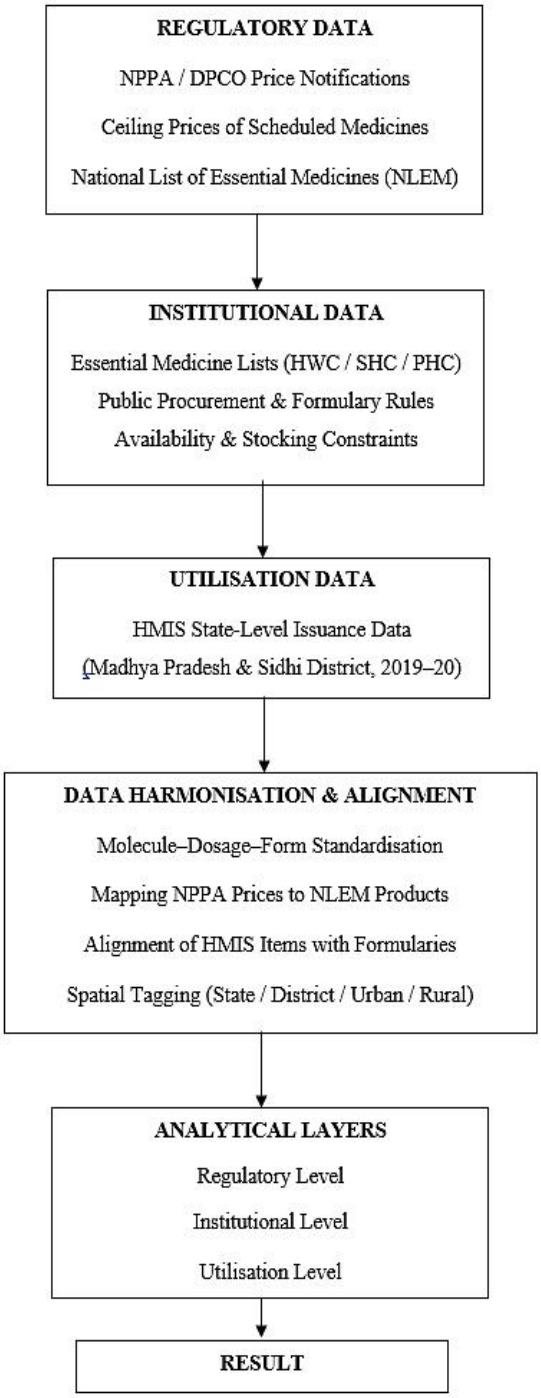

Figure 8. Dataflow diagram represents Analytical strategy of this study

Results and Findings

Socio-Economic Context and Substitution Environment: Madhya Pradesh vs India

The observed patterns of substitution were contextualized by comparing socio-economic indicators of Madhya Pradesh at the state level to the national averages. Madhya Pradesh has a low per-capita income, literacy rate and rural proportion of population, compared to India, in general. Madhya Pradesh per-capita revenue at current prices is INR 54,030, compared with INR 74,920 in the country, and female literacy is 60% as opposed to 65.5% in the rest of the country. The state is further characterized with health burden indices whereby birth rates and infant mortality rates are higher, which implies increased burden on government health facilities. Measurements of financial inclusion also depict lower capacity of the private sector, which is in terms of significantly lower per-capita deposits, credit, and lower credit-deposit ratio. Combined these structural features form the environment where price sensitivity, reliance on the procurement of the government, and uniform treatment procedures become the pillars of pharmaceutical use. The high level of substitution and utilisation concentration of the HMIS data can be explained by the socio-economic profile as being mechanistic. Table 2 shows the main socio-economic pointers that form the basis of the substitution environment.

Table 2. Socio-Economic Characteristics of Madhya Pradesh Compared with India

Indicator	Madhya Pradesh	India
Rural population (%)	72.4	68.9
Per-capita revenue (₹, current prices)	54,030	74,920
Literacy rate (%)	70.6	74.0
Female literacy (%)	60.0	65.5
Infant mortality rate (per 1,000 live births)	56	42
Credit–deposit ratio (%)	56.3	77.7

Source: Census of India 2011; Reserve Bank of India (2013); Ministry of Health and Family Welfare (2013); Government of India.

NPPA Ceiling Prices and Regulatory Drivers of Substitution

Analysis of NPPA ceiling prices for 100 regulated formulations reveals substantial heterogeneity in absolute prices, ranging from ₹0.17 per tablet for commonly used oral medicines such as acetylsalicylic acid to over ₹39,000 per pack for specialized life-saving injectables such as alteplase. This dispersion reflects differences in therapeutic complexity and production costs rather than market-driven brand premiums.

Crucially, high-volume medicines used in primary and secondary care—particularly oral solid dosage forms—are concentrated in very low price bands, typically below ₹10–₹20 per unit. This pattern arises because these medicines are largely off-patent, included in the National List of Essential Medicines, and subject to statutory price ceilings under the Drug (Prices Control) Order. Regulatory intervention therefore compresses prices precisely in segments with the greatest substitution potential due to routine prescribing and large patient volumes.

Within individual molecules, price variation across strengths and formulations is tightly constrained. For widely prescribed drugs such as amlodipine, atenolol, atorvastatin, and acetylsalicylic acid, ceiling prices increase in a predictable and monotonic manner with dosage strength, limiting scope for artificial product differentiation. This structure weakens brand-based pricing strategies and facilitates substitution toward standardized generics.

Importantly, NPPA regulation also extends to high-cost injectables, indicating that price control in India operates system-wide rather than being confined to low-cost medicines. Consequently, substitution dynamics unfold within a highly regulated pricing environment, particularly in the public sector.

Table 3. Distribution of NPPA Ceiling Prices Across Selected Formulations

Category	Typical Ceiling Price Range (₹)	Examples
Oral solid dosage forms	0.17 – 25	Aspirin, Amlodipine, Atenolol
Oral liquids	1 – 5	Amoxicillin suspensions
Injectable generics	15 – 500	Artesunate, Acyclovir
High-cost injectables	>1,000	Alteplase, Amphotericin B

Source: NPPA ceiling price

India–Global Comparison: Effective Substitution Efficiency

An Effective Substitution Efficiency Ratio (ESER) is developed to determine effective substitution by building the ratio between the value and volume of generic shares to determine whether generic availability leads to effective substitution. This ratio will measure the degree to which the generics will replace the branded medicine not only

in terms of quantity but also in terms of expenditure.

Table 4. Effective Substitution Efficiency Ratio (ESER): India vs OECD

Economy	Generic Share (Volume %)	Generic Share (Value %)	ESER
India	~97	~38	0.39
OECD Average	~75	~58	0.77
High-performing OECD	~80	~70	0.88

Source: OECD Health Statistics; NPPA; IMS Health summaries (secondary synthesis)

Although consumption based on volume is almost universal in terms of generic consumption, the ESER of India is lower than the OECD average. It means that there is a strong generic value-volume disparity as generics cannot substitute the branded medicines in more expensive segments. This gap is conceptualized in figure 9, which indicates a broad difference in dominance in volumes and value capture in India as compared to the OECD economies.

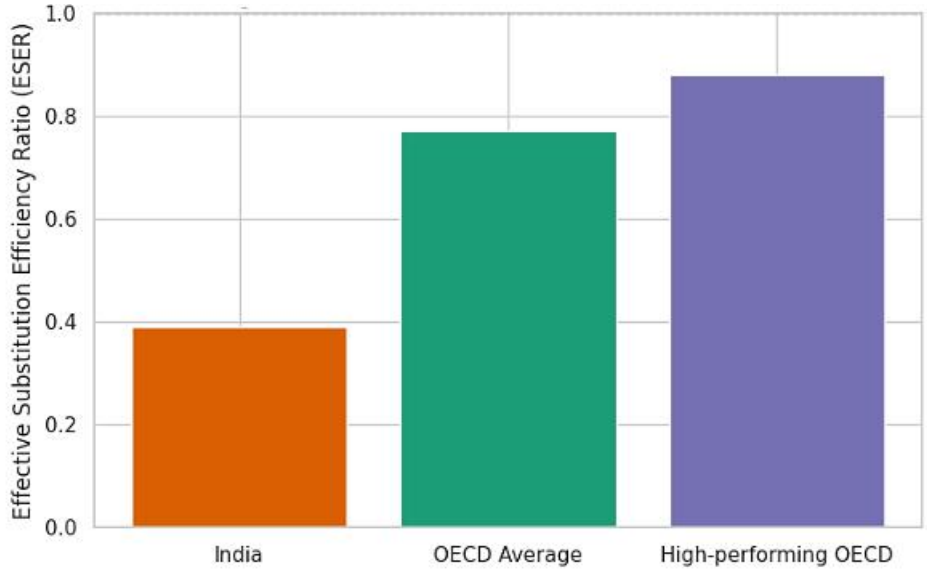

Figure 9. Generic Value–Volume Gap: India vs OECD
Source: OECD Health Statistics

Brand Proliferation and Price Dispersion Analysis

Based on CCI evidence of brand proliferation measured in terms of the number of brands per formulation and observed price dispersion, a Brand-Price Dispersion Elasticity Proxy (BPDEP) is then formulated to study whether brand proliferation improves or hinders price competition.

Table 5. Brand Proliferation and Price Dispersion

Therapeutic Category	Avg. Brands per Formulation	Price Range (%)	BPDEP
Antibiotics	~22	~180	8.2
Vitamins/Minerals	~37	~200	5.4
Cardiovascular	~15	~120	8.0
Overall Average	~17	~150	8.8

Source: CCI Pharmaceutical Market Study; NPPA ceiling prices

The increased number of brands is also systematically related with increased price dispersion and not price convergence. This good correlation between brand proliferation and dispersion is shown in figure 10. The findings disregard the supposition that the extra brands enhance rivalry; rather, branding serves as a strategy of maintaining the price distinction and power in the market.

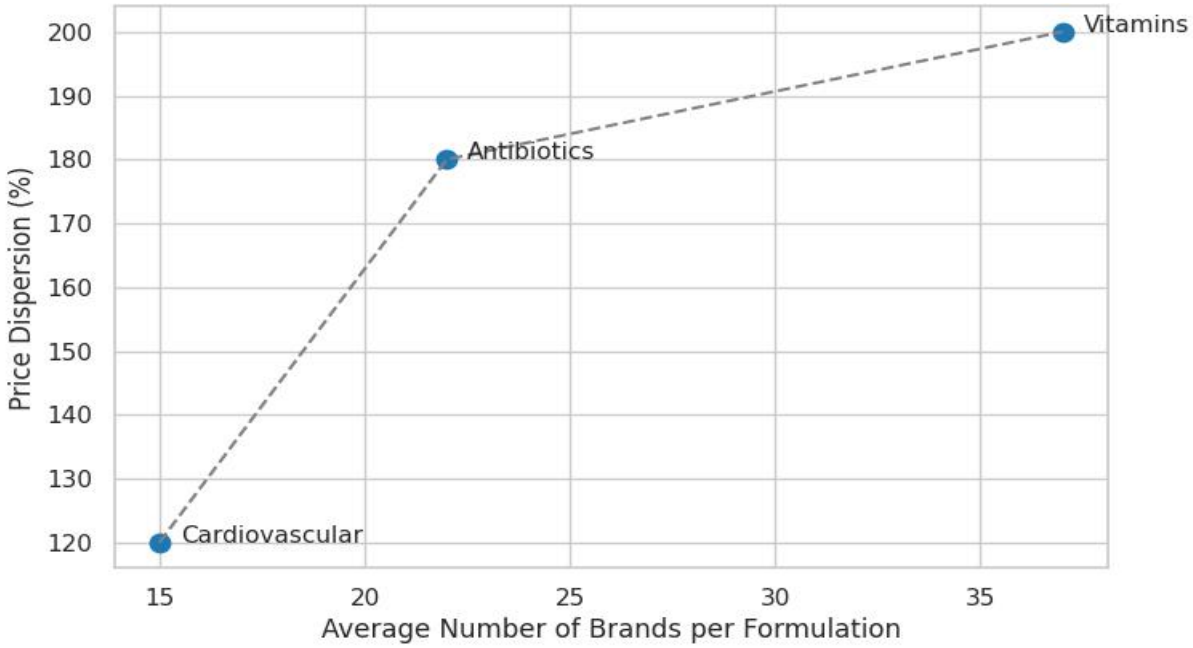

Figure 10. Relationship between Brand Proliferation and Price Dispersion
Source: CCI Pharmaceutical Market Study; NPPA ceiling prices

Institutional Benchmark: Public Procurement vs Private Retail

To assess the possibility of effective substitution in the Indian context, a Procurement Price Efficiency Index (PPEI) is developed by comparing the prices of the same molecules in both the private retail and the public procurement in the CCI study.

Table 6. Procurement Price Efficiency Index (PPEI)

Drug Category	Median PPEI	Price Implication
Essential antibiotics	2.1	Retail prices >100% higher
Chronic disease medicines	1.8	Persistent brand premium
Overall sample	1.9	Systemic inefficiency

Source: CCI procurement data; state medical services corporations

The average cost of the same molecules in the case of private retail is close to two times the cost of procurement in the government. Figure 11 compares these prices and shows that effective substitution can be attained in institutionalized procurement systems, but not in fragmented small retailing markets. This pattern suggests that observed limitations in substitution are more closely associated with institutional design and market organisation than with constraints related to pharmaceutical production or technology.

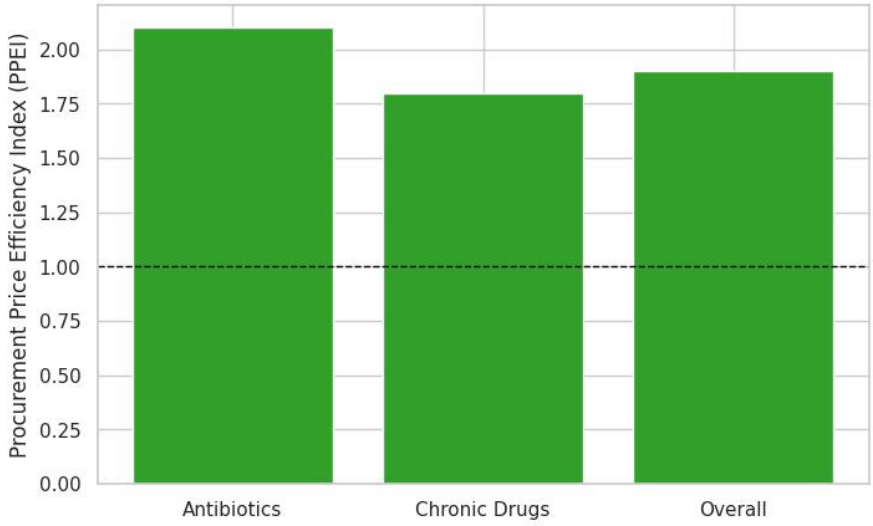

Figure 11. Public Procurement vs Private Retail Prices
Source: CCI procurement data; state medical services corporations

Urban–Rural Substitution Intensity Differential

The analysis of urban-rural differences is based on a Substitution Intensity Differential (SID) that is developed with the help of a generic reliance, price sensitivity, brand exposure variables, according to NSSO summaries.

Table 7. Urban–Rural Substitution Intensity

Region	Generic Reliance	Price Sensitivity	Brand Exposure	SID Score
Urban	Moderate	Moderate	High	0.46
Rural	High	High	Low	0.82

Source: HMIS (2019–21); NSSO; Census 2011

The substitution intensity is almost twice that of the urban markets in rural markets. This differs in rural India as shown in Figure 12; substitution there is chiefly affordability-based, but this is not the case in urban areas, which is restricted by brand loyalty and prescribing doctor behavior.



Figure 12. Urban–Rural Comparison of Substitution Intensity
Source: HMIS (2019–21); NSSO; Census 2011

Findings

Economic Effects of Substituting Pharmaceuticals:-

The results show that the pharmaceutical substitution in India is linked with system-level redistribution of volumes and prices, as opposed to the firm-specific results. Regulatory pricing and utilisation trends of entry into generic alternatives indicate that such entry is normally followed by a shift in demand to less expensive branded formulations, especially in regulated and publicly acquired markets. Past empirical research has also recorded that in these situations, the volume substitution and not the technological displacement occur with the originator products, as a result of significant revenue loss during the initial year of generic entry (Grabowski et al., 2011).

Substitution mediated by price is one of the causes of compression of the margins in the market since ceiling prices and reference benchmarks constrain brand-based price differentiation (Simoens, 2008; IMS Institute for Healthcare Informatics, 2016). Also in line with global data, generics with prices that are significantly lower than branded counterparts raise considerable cost savings in health systems and patients, especially in the institutional procurement practice and in health care facilities funded by the government (WHO, 2022; FDA, 2022).

Substitution Outcomes and Regulatory Policies:-

Regulatory requirements become one of the key sources of substitution. Generics prescribing and procurement policies like the Drug (Prices Control) Order and generic outlets funded by the state have increased the supply and consumption of generics, especially in the rural and public sphere. Government programmes have shown more use of generics as a result of regulation, which is a symptom of an institutionally facilitated substitution, as opposed to the choice of the prescriber (NPPA, 2023; Indian Pharmaceutical Alliance, 2023).

Price controls on key medicines have also added convergence between branded and generic products in price, and this restricts the ability to charge premium prices and strengthens the substitution process in form of procurement and formulary systems (NPPA, 2023; Pattathil et al., 2023).

Competitive Dynamics:-

The evidence indicates that substitution has changed competitive patterns by shifting the focus

on the brand-based differentiation to the scale based generic competition especially in high volume therapeutic products like antibiotics and cardiovascular drugs. Although generic drug companies have increased their work in these segments, competition research evidence shows that widespread brand proliferation persists in privately retailing markets, typically alongside enduring price dispersion (Competition Commission of India, 2021). As a counter, branded companies have been utilizing dual strategies such as entry into the low-pricing tiers and portfolio diversification (Sun Pharma, 2023; Dr. Reddy Laboratories, 2022).

Operational Implications:-

At the operation level, institutional practices influence substitution and not necessarily the intensity of marketing. Standardisation of formularies and procurement consolidation, and optimization of supply-chain minimise variability in products available and strengthens substitution by constraining products available. The responses noted in the industry according to the previous studies are transformation of marketing focus and supply-chain rationalisation, as well as strategic shift to complex generics and biosimilars (Chaudhary and Gupta, 2020; EMA, 2022; Indian Pharmaceutical Alliance, 2023).

Strategic Implications:-

Strategically, there have been substitution pressures along with more focus on product differentiation beyond conventional small-molecule generics, like specialty medicines, and joint ventures like authorised generics and co-marketing deals. The latter strategies are adaptive to long-term price control and competition based on substitution, which is not as short-term as market shocks (Grabowski et al., 2011; Kumar, 2017; Sun Pharma, 2023).

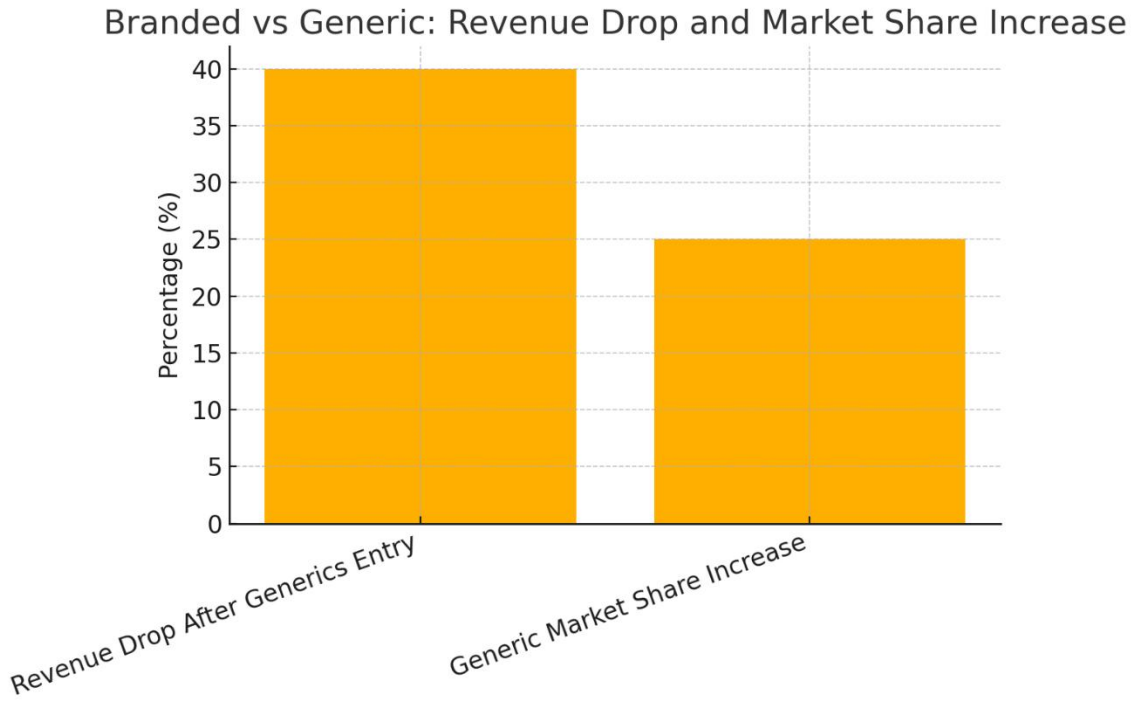

Figure 13. Revenue drop of branded drugs and Generic market share increase
Source: Mordar Intelligence, 2025; NPPA, 2023; IPA, 2023.

Stakeholder Perspectives:-

The results are consistent with the general evidence of substitution, which spreads market shares between branded and generic manufacturers and of which realisation is strongly reliant on the acceptability of prescriber, pharmacist and patient. Healthcare providers are also mediators in the decision of substitution, especially in the cases when regulatory guidance overlaps with clinical discretion (Chaudhary and Gupta, 2020). The views of patients indicate a compromise between better affordability and perceived quality and safety and the significance of regulatory confidence and institutional credibility (WHO, 2022; EMA, 2022).

Institutional, Innovation, and Market Implications of Advanced Substitution:-

International regulatory guidance evidence growing differentiation in substitution strategies between the small-molecule generics and biologics. According to the industry and regulatory position papers, substitution using biologics and biosimilars necessitates increased regulation, such as physician-based decision making, batch identification traceability and post-market surveillance to control safety risks (International Federation of Pharmaceutical Manufacturers and Associations [IFPMA], 2025). These reflections highlight that the intensity of substitution differs depending on the type of product and that risk management

structures limit the institutional options of substitution as opposed to the price factor alone.

The results also indicate that there has been a long-running conflict between substitutions due to affordability and the sustainability of innovations. Generics and price controls have increased access to drugs, especially in the form of public-sector procurement and drug access schemes, like Pradhan Mantri Jan Aushadhi Kendras. But the available evidence demonstrates that structural pressure can be caused by long-term price compression and high-volume replacement that requires strategic adjustment, but not an indication of a firm failure (Grabowski et al., 2011; Indian Pharmaceutical Alliance, 2023). Regulatory intervention, therefore, seems to be a requirement, though an inadequate one, in itselfin order to provide long-run incentives to innovation.

In India, substitution is a phenomenon in a dual market system where there is heterogeneity in socio-economic systems in the region. The purchasing power and brand persistence in urban markets is higher compared to rural markets, whereby its dependence on low-cost generics and public provisioning is higher. The noted substitution trends show that access through affordability gains in rural settings are accompanied by strategic positioning by branded producers, such as the entry into the generic market and strategic alliances in order to increase access in Tier II and Tier III markets (Sun Pharma, 2023; Mordor Intelligence, 2025).

The operations level of substitution content is connected with the change of the engagement strategies of physicians and pharmacists, where the last are increasingly taking part in the decision-making process in dispensing. At the same time, manufacturers are shifting research and development portfolios to biosimilars, combination therapies, and specialised products, in line with adjusting to long-term regulatory and pricing pressures and not sudden competitive shocks (Chaudhary and Gupta, 2020; EMA, 2022; Dr. Reddys Laboratories, 2022).

A combination of these results suggests that pharmaceutical replacement is institutionally mediated and product-class specific, providing sharp affordability benefits and creating differentiated strategic reaction among market segments. Substitution is not an outcome of a unified market but a process that is governed and whose efficacy and consequences are related to regulatory designs, risk characteristics and procurement forms. This supports the perception that on access and innovation, complementary policy tools especially in the case of complex and biologic medicines are needed in addition to the regulation of prices.

Discussion

The findings of this study show strong empirical support on the aspect of argument where the exercise of substitution of pharmaceutical products in India is more of an institutionally grounded phenomenon, rather than a market or consumer-led phenomenon. A descriptive and comparative analytical methodological approach is appropriate because the results keep on demonstrating that the outcome of substitution is contingent upon the regulatory pricing, formulary design, and public procurement structures, rather than competitive brand rivalry or informed patient choice. The NPPA ceiling price analysis illustrates a huge extent of price inhibition on the products of fundamental medicine and particularly in the oral solid dosage that is extensively used at the primary and secondary care levels. In addition, the within-molecule price dispersion between strengths and formulations is also restricted and significantly restricts brand based differentiation. This is a clear indication of the idea of generic substitution because there is no way that the branded products can support premium price in the controlled system. It is important to note that the high cost injectables are included in price control and, therefore, the substitution pressure does not apply only to low-value medicines but is cut across the therapeutic spectrum.

Efficiency in institutional Procurement and Substitution -

The institutional efficiency gap has been observed to be present in the comparison of the prices of the public procurement and the prices on the retail side applied by the privates. The Procurement Price Efficiency Index (PPEI) proves that the retail prices charged by the private are nearly twice the prices of the same molecules charged by the public procurement. Their distinction shows that the only way successful substitution is possible is in institutionalised procurement environments, where the tendering is centralised and standardised formulary, brand premiums are absent. Conversely, fragmented private retail markets are yet to attain the issue of substitution failure not due to technological or quality constraint, but due to branding, asymmetric information, and prescriber-pharmacist incentive. This proves the overall hypothesis of the study, which is that the success of the substitution in India is fundamentally an issue of institutional design and not a pharmacological issue.

Value-Volume Paradox in the generic market -

A remarkable paradox is revealed in the Effective Substitution Efficiency Ratio (ESER) analysis where, despite the near universal consumption rates in terms of volume, the value percentage will remain still below their proportional value in the case of generic medicines. India is also ranked very low as compared to the OECD on ESER, that is, generics are performing too well in the low-value segments but not performing well in the high-value therapeutic

segments. This observation implies that substitution in India is partialized. The mass-consumption medicines guarantee affordability objectives, whereas in the high-value markets the brand product is in the lead due to the effect of prescribers, perceived quality differences, and intricate curative requirements. Substitution is, therefore, an improvement of access but it cannot challenge market power in high-end markets.

Brand Proliferation and Illusion of Competition

The brand proliferation analysis refutes the belief that the more brands, the more the competition. The positive relationship between brand proliferation and price dispersion is noticed and this is an indication that branding is a price-segmentation strategy as opposed to a competitive-equalization strategy. Dispersions in prices of therapeutic groups with the highest brand densities are expansive and efficient price competition is breached. The findings are in line with the observation that substitution pressures and policies of strategic branding that keep the margin exist in the privately owned business, and reaffirm the limitations of the substitution where the institutions were not involved.

Socio-Economic and Spatial Differentiation

The degree of substitution analysis gives a stronger substitution in urban market because the price is highly sensitive and brand and name are not highly unveiled. On the other hand, the substitution is not a weakness of urban markets due to brand loyalty, physicians prescribing habits, and branded promotion exposure. This geographical difference confirms that outcome of the substitution depends on the socio-economic factors and depends on the healthcare system and prevalence of the public sector increases the probability of substitution in the rural cases.

Critical Reflections and Limitations :-

Although the results indicate that the substitution of pharmaceuticals in India has significantly enhanced the affordability and access, especially in government procurement system, such benefits are accompanied by significant drawbacks and trade-offs.

- To begin with, a substitution process led mainly by price control can undermine the long-term incentives to innovate. The continuous pressure on prices and the speed of volume replacement decreases the anticipated returns of branded products which may deter investing in incremental innovation in small-molecule drugs. In as much as companies have acted by moving to biosimilars and specialty products, such a move may not increase the innovation routes but can lead to a tightening of the same. (Kumar, 2017; Mehta & Reddy, 2023; Grabowski et al., 2011; IPA, 2023; Pattathil et al., 2023)

- Second, the substitution effectiveness is still disproportional in product classes. Although generic substitution is very successful with oral solid dosage products, the same is not true of biologics, narrow therapeutic index (NTI) drugs, and complex preparations where clinical risk and pharmacovigilance factors limit interchangeability. (Johnston, A., 2013)

- Third, the research is based on secondary administrative data, which likely underreports the informal market forces and prescriber discretion in the privately-sold retail environment. Institutional utilisation patterns are reflected in HMIS data but not patient-level adherence or quality perception outcomes, which are also very particular determinants of substitution acceptance.

Such constraints imply that substitution is to be perceived as a complete though insufficient policy tool, which must be complemented by innovation-friendly, quality-guaranteeing, and governance policies, to warrant the sustainability of the entire system in a long run.

Conclusion

This paper shows that a substitution of pharmaceutical products in India is basically an institution-based process which is mainly influenced by price regulation policies, essential medicine systems and government procurement systems and not by competitive market forces or consumer preference. Based on data on the NPPA ceiling prices, HMIS utilisation records and necessary medicine lists at levels of care, the analysis reveals that standardized price ceilings and uniformity of formularies structurally inhibit brand-based price differentiation, thus providing a favorable setting to generic substitution into the public health system.

The results also point to the fact that substitution has been successful in enhancing affordability and access especially in the rural and low-income areas where the reliance on provisioning by the government is high. While comply with the govt. regulations, it is struggle to maintain a balance between cost reduction and innovation promotion and this misbalance itself further proliferating the substitution in the market. Product substitution enhances affordability but requires strategic initiatives for sustainability in balance with research innovation.

Nevertheless, substitution is not a complete

economic activity. Although generic drugs represent the majority of the consumption volumes, branded products remain disproportionately positioned in the market value, particularly in more expensive therapeutic areas, as well as in individual retail markets. This chronic value-volume imbalance points to the fact that substitution in India is not comprehensive but segmented and is efficient in institutional buying channels but ineffective in fragmented retailing contexts.

Notably, the research also demonstrates that brand proliferation also fails to improve price competition. Rather, it maintains price dispersion in the private markets which restricts the effectiveness of substitution within the institutional settings. Greater substitution effects are always found in systems with centralized procurement, standardized treatment regimens, and limited formularies that confirm the fact that institutional design and not market size or income levels determines substitution effectiveness. In general, the findings indicate the success of substitution in India is less technologically viable and more a factor of governance structures.

Way Forward and Policy Implementations

Strengthening Firm–Regulator Collaboration

The long-term cooperation between drug companies and regulatory agencies is the key to the stability of the goals in terms of affordability and innovation in the long run. Regulatory institutions have a formal level of interaction whereby firms can have an evidence-based policy dialogue especially on matters of price regulation, substitution protocols and access to the market. Through such interaction, regulators are able to develop substitution-conducive policies which do not negatively impact on the incentives to innovate, and firms have predictability of regulations to make strategic plans.

Prioritizing Research and Innovation

Research and development (R&D) is an important part of a business strategy that needs to be embedded as an ongoing process in the organisation in the pharmaceutical industry that functions in an environment of substitution. Innovation should not only be centred on new molecules, but also on the novel drug delivery system, complex generics, biosimilars and value-added formulations. These innovation channels enable companies to stay competitive despite commoditization through generic substitution and to counter the long term risks of too much commoditization.

Building and Sustaining Patient Trust

The social legitimacy of pharmaceutical substitution is based on trust. Patients need to know that the substituted medicines, be it generic or therapeutic are safe, effective and of certain quality. Patient acceptance can be enhanced with the help of targeted educational campaigns, open communication, and evidence-based substitution guidelines to enhance adherence and overall health care outcomes.

Leveraging Digital Technologies

Digital transformation has now turned out to be a strategic requirement and not a discretionary option. The use of online technologies to monitor the supply-chain, pharmacovigilance, demand forecasting and stakeholder engagement increases the efficiency and responsiveness of operations. Companies, which cannot incorporate the digital systems, face the risk of being beaten by competition in the pharmaceutical industries, which are becoming more data-driven.

Strategic Alliances and Market Integration

Both strategic alliances triggered with licensed generic production entities and co-marketing formulation provide a feasible entry route through which companies can continue to exist in the market in the face of substitution challenges. These partnerships spread the operational risks, enhance market penetration, and offer financial strength. Alliances formed strategically help businesses to survive extended competition and remain large and sustainable.

Exploring New and Emerging Markets

Emerging markets and under-regulated markets allow the company to grow sustainably, especially to companies that are limited by stiff price wars in the developed markets. Geographic diversification helps companies to diversify income streams and eliminate reliance on domestic markets that are highly regulated.

Ensuring Long-term Product Competitiveness

The importance of the process of creating new products is not as great as sustaining the commercial viability of the existing one. Product life cycles can be prolonged through incremental approaches, including reformulation, fixed-dose combinations and new therapeutic indications without making them unaffordable. Such strategies increase returns without weakening access goals.

Enhancing Stakeholder Awareness of Therapeutic Substitution

Awareness of therapeutic substitution is essential in terms of balanced implementation of the practice between physicians, pharmacists, and patients. Acceptability can be improved by using structured guidelines, professional training and involving stakeholders without interfering with the substitution decisions that must be clinically appropriate and ethical.

Addressing Look-Alike and Sound-Alike (LASA) Medicines

To avoid the emergence of medication errors due to

inappropriate substitution, the regulatory agencies should reinforce the measures to prevent the look-alike and sound-alike medicines. There should be clear labelling standards, a distinction in packaging, and a limited dispensing process by qualified personnel to ensure that patients are not at risk of serious health issues, especially in large volume potential health care facilities.

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