Branded Generic Drugs and Competition

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Abstract- **The pharmaceutical sector is distinguished by a complicated interaction between branded and generic medications. Branded pharmaceuticals manufactured and marketed by pharmaceutical corporations sometimes have exclusivity periods due to patents, allowing them to fetch higher costs. When patents expire, generic rivals join the market and offer comparable drugs at reduced prices. This dynamic fosters fierce rivalry, affecting pricing tactics, market share, and innovation.**

This research investigates the dynamics of competition between branded and generic medications. It investigates the variables that influence generic market entrance, such as legislative channels and litigation, as well as pharmaceutical corporations' strategy for maintaining market dominance. It also analyses how healthcare policy and regulations shape this competitive landscape. Furthermore, the research explores how branded-generic rivalry affects healthcare accessibility, pricing, and patient welfare. It emphasizes the importance of generic medicine availability in lowering healthcare costs and boosting pharmaceutical accessibility, particularly in poor nations. However, it notes concerns about the quality and safety of generic pharmaceuticals, as well as the possible influence on innovation incentives in the pharmaceutical business.

Overall, this article sheds light on the intricacies of branded-generic medication rivalry and its ramifications for stakeholders throughout the healthcare ecosystem, including patients, providers, governments, and pharmaceutical corporations. It emphasizes the significance of combining innovation incentives with the requirement for inexpensive and accessible pharmaceuticals in order to achieve optimal healthcare outcomes for all.

Keywords: **Branded generic drug, pharmaceutical industry, drug competition.**

INTRODUCTION:

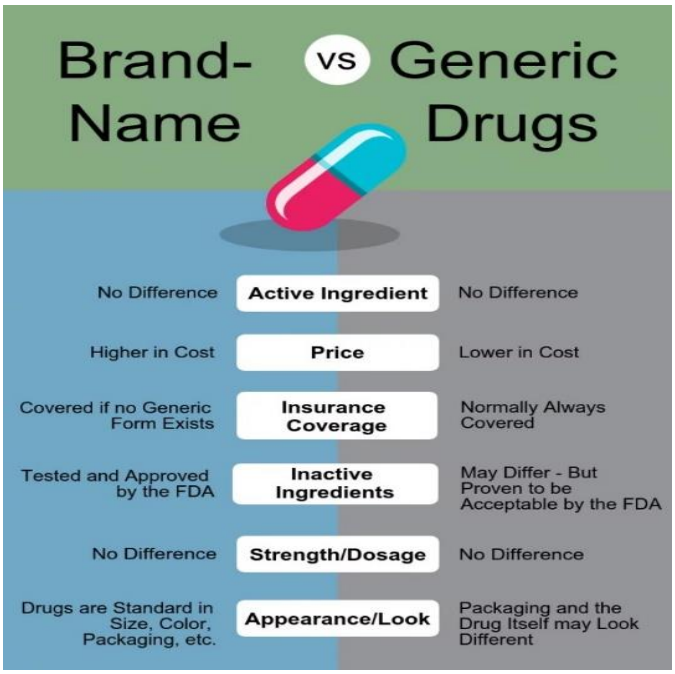
Branded generic pharmaceuticals play an important role in the global pharmaceutical landscape, providing cost-effective alternatives to brand-name treatments while preserving customer awareness and confidence. These medications, often known as "branded generics," are basically generic equivalents of brand-name pharmaceuticals that are marketed under a brand name other than the original patented drug.

Pharmaceuticals account for 43.2% of total out-of-pocket expenditure (OOPE) on healthcare in India. This makes it the single largest contributor to OOPE, which contributes for around 62.7% of overall health spending in the country. Thus, the cost of medications has a considerable impact on access to healthcare. While price regulation affects around 17.7% of India's pharmaceuticals industry, competition is likely to be the primary source of price discipline for the remaining market. [1, 2]

Patented/originator drugs8 are protected from competition for the duration of the patent, resulting in a secured return on R&D spending. After the patent expires, price competition from generic replacements can result in considerable cost reductions for customers. Generic pharmaceuticals ('generics') play a key role in generating the competitive forces that allow prescription medication prices to remain low, lowering healthcare expenditures and increasing access. By definition, generics have identical active components to the patented/originator medicine and are low-cost, functionally undifferentiated goods, making generic markets fundamentally very competitive. [3-5]

India has a thriving generic medication business and is the world's largest supplier of generic pharmaceuticals.10 Generics dominate the Indian pharmaceutical sector, accounting for around 97% of total medication consumption. However, only around 10% of medications in the domestic market are unbranded/generic generics, which are sold only by their chemical identities as commodity generics; these pharmaceuticals are mostly obtained and distributed in public health facilities. 87% of medications delivered in India are branded generics, which are generic pharmaceuticals sold under a brand name. 11 The market for 'branded generics' is essentially exclusive to India.

Figure 1: Branded & Generic drugs availability



The market analysis aimed to assess the impact of branded generics on competitiveness and pharmaceutical costs in India. The goal was to get a better knowledge of competition dimensions in the generics market in order to identify possible areas for increasing effective price competition in generics, which can benefit consumers and increase access to affordable healthcare. [6]

PHARMACEUTICAL SECTOR IN INDIA

In recent decades, India's pharmaceutical industry has experienced extraordinary expansion. India has progressed from being a net importer of medications in the 1970s to being a significant exporter of drugs and vaccines, ranking third and thirteenth internationally in terms of volume and value, respectively. From INR 1,750 crores in 1990 to INR 2.89 lakh crores in 2019-20, the pharma industry's revenue increased dramatically, with exports accounting for half of the total. Rapid and significant improvements in manufacturing processes to improve drug quality have resulted in a situation in which India now has the most US FDA-approved facilities in the world, with approximately 665, 14 in addition to 1,400 WHO GMP-approved plants and approximately 253 European Directorate of Quality Medicines-approved production plants. [7, 8]

Retail sales were INR 141,102 crores between August 2019 and July 2020, with cardiac and anti-infective categories accounting for 13% apiece, followed by gastro-intestinal (11%), anti-diabetic (10%), vitamins/minerals (9%), and the remainder (44%). In terms of volume, cardiac accounted for the largest part (17%), followed by gastro-intestinal (16%), pain/analgesics (10%), hormones (9%), anti-diabetic (9%), vitamins/minerals (9%), and the remainder (30%).

In recent years, the market for branded generics has grown significantly, owing to reasons such as growing healthcare costs, patent expirations of blockbuster pharmaceuticals, and increased demand for affordable healthcare in both developed and developing nations. This spike in demand has resulted in heated rivalry among pharmaceutical companies vying for market dominance in this profitable category.

The dynamics of competition in the branded generic medication market are complicated and multidimensional, impacted by factors such as pricing tactics, regulatory frameworks, manufacturing capabilities, and marketing initiatives. This rivalry has far-reaching repercussions for healthcare systems, patients, and pharmaceutical corporations alike, influencing access to critical pharmaceuticals, stimulating innovation, and redefining market dynamics. [7-10]

PRICE COMPETITION

In India, the coexistence of "generic-generics" and "branded-generics" completely undermines government efforts to keep medicine prices reasonable. The only difference between the two is that one has a brand name while the other does not. For example, the price differential between unbranded and branded metformin formulations might be at least 10 to 12 times. The branded pill, which costs approximately 12 times more than the generic-generic, sells the most on the market. The government's price ceiling for this medicine combination, derived from the simple average of the most popular brands of these pharmaceuticals, exceeds Rs. 24.00 per unit, and this is the drug's 'regulated' price under DPCO.

As a result, the profit produced by the branded-generic producer of the identical medicine is 12 times more than that of the generic manufacturer.

The Indian pharmaceutical business is well-known for its dominance in branded generics, which make up more than 70% of the market. The branded generic market is predicted to increase at a 10.3% CAGR between 2020 and 2027, owing to rising demand for inexpensive healthcare and the availability of a diverse variety of branded generics. However, the prevalence of branded generics in India has resulted in a dearth of understanding regarding generics among patients and doctors.

The Indian market lacks branded medicines (a term commonly used to describe an innovator product) because, prior to January 2005, many pharmaceutical companies in India manufactured two types of products for the same molecule: the branded product, which they advertised and pushed through doctors, and the branded-generic, which they expected retailers to push.
The Indian pharmaceutical business is also facing issues as a result of the government's prescription mandate for generic drugs. A significant decline in branded generics sales share will have an impact on Indian pharmaceutical businesses' profitability, as would drastically reduce average pricing.

To summarize, while competition among branded generics in India is anticipated to result in price reductions, making vital pharmaceuticals more accessible for patients, there are hurdles to this competitive environment. The dominance of branded generics in India has resulted in a lack of generics knowledge among patients and physicians, and the government's generic medicine prescription mandate is having an impact on the profitability of Indian pharmaceutical businesses. The Indian pharmaceutical sector is also facing issues as there is growing concern over whether the reduced cost of generic pharmaceuticals would put pressure on enterprises to pursue manufacturing cost-cutting tactics, potentially leading to supply disruptions and shortages. [11, 12]

QUALITY CONCERN

Quality concerns regarding branded generic drugs and competition can arise due to several factors:

1. Manufacturing Standards:

While branded generics may contain the same active components as branded equivalents, differences in manufacturing standards and methods might have an impact on the finished product's quality and consistency. Substandard manufacturing processes can cause changes in medication potency, dissolving rates, and stability, thereby affecting therapeutic efficacy and patient safety. Quality issues about manufacturing standards might apply to different stages of the production process, such as raw material procurement, formulation, processing, and packaging. Variations in production techniques between sites or nations might result in discrepancies in medication quality. Differences in equipment calibration, mixing techniques, or storage conditions, for example, might have an impact on the end product's uniformity and stability. GMP is a quality control measure that ensures pharmaceutical producers follow defined standards. [13]

2. Supply Chain Integrity:

The complexities of worldwide supply chains for pharmaceutical materials and final products raise the possibility of quality concerns such as contamination, adulteration, and counterfeit pharmaceuticals. Maintaining the integrity of the supply chain is critical for the quality and safety of branded generic pharmaceuticals. The pharmaceutical supply chain is complex and involves several stakeholders, including raw material suppliers, manufacturers, distributors, and retailers. Quality concerns exist at every stage of the supply chain, including contamination, ingredient substitution, and inappropriate handling/storage procedures. To prevent possible dangers and protect product quality from source to distribution, strong quality assurance techniques are required, such as supplier audits, traceability systems, and risk management strategies. [14]

3. Regulatory Oversight:

Regulatory monitoring and enforcement vary by area, resulting in variations in quality standards and market access. Inadequate regulatory supervision can lead to the spread of substandard or counterfeit medications, endangering public health. Regulatory authorities are crucial in guaranteeing the safety, effectiveness, and quality of pharmaceutical goods by implementing and enforcing strict standards and rules. However, regulatory monitoring can range dramatically among locations due to disparities in resources, infrastructure, and legal frameworks. Weak regulatory enforcement or weak surveillance measures may allow inferior or counterfeit medications to reach the market, endangering patient safety. Strengthening regulatory competence and encouraging international collaboration are critical for improving supervision and aligning quality standards across global pharmaceutical markets. [15]

4. Bioequivalence and Therapeutic Equivalence:

Branded generic medications must exhibit bioequivalence to the original branded product, which means they should have equivalent absorption and effectiveness. However, differences in formulation, excipients, and manufacturing methods can have an impact on bioavailability and therapeutic equivalency, raising questions regarding the interchangeability and efficacy of branded generics. Bioequivalence testing is an important part of generic medicine approval, confirming that generic goods have equivalent pharmacokinetic features to the reference branded drug. However, obtaining actual therapeutic equivalence entails more than simply satisfying bioequivalence standards. Variations in formulation, excipients, or manufacturing procedures might affect drug release patterns, absorption rates, and overall therapeutic effects. Robust comparison research and clinical trials are required to determine the interchangeability and efficacy of branded generic medications, especially in sensitive patient populations. [16]

5. Post-Market Surveillance:

Continuous monitoring of medication safety and quality through effective pharmacovigilance and post-market surveillance systems is critical for detecting and correcting quality issues with branded generic pharmaceuticals. Timely discovery and mitigation of adverse events, as well as product recalls, essential to protect patient health and maintain public faith in pharmaceuticals. Even after a medicine has been licensed and sold, continuing monitoring of its safety and quality is required to discover and resolve any adverse events, quality deviations, or new concerns. Pharmacovigilance systems, adverse event reporting methods, and product quality complaints programs let regulatory bodies and manufacturers to quickly evaluate and address safety problems. Product recalls, market withdrawals, and remedial measures are critical for avoiding patient exposure to faulty or hazardous pharmaceuticals and maintaining public trust.

Addressing quality problems in the context of branded generic pharmaceuticals necessitates collaboration between pharmaceutical makers, regulators, healthcare professionals, and consumers. Implementing strong quality control methods throughout the drug research, manufacturing, distribution, and post-market surveillance phases is critical to assuring the safety, effectiveness, and dependability of branded generic drugs. [17]

MARKET DYNAMIC

Here is an analysis of the key market dynamics and competitive factors related to branded generic drugs based on the typical landscape in the pharmaceutical industry:

1) Brand Recognition and Loyalty: Companies want to capitalize on the original branded drug's brand equity while introducing their own branded generic equivalent when the patent expires. Brand loyalty among patients and prescribers acquainted with the brand can offer the branded generic an early competitive edge over other generic entrants.

2) Pricing Strategies: Branded generics are often more expensive than plain generic counterparts from other manufacturers, but less than the former branded pricing. This enables for the capture of market share from individuals switching from higher-priced branded drugs while also competing on price with generics. Over time, increased generic competition reduces possible premium price for branded generics.

3) Marketing and Promotion: To differentiate their product, branded generic businesses make significant investments in marketing to providers and consumers. Direct-to-consumer advertising, pharmaceutical rep details, and copy cards/coupons are among of the tactics employed. Creates apparent distinctions from simple generics notwithstanding bioequivalence.

4) Distribution Advantages: Companies with a well-established distribution network and supply chain for their branded medicine may quickly switch to distributing the branded generic equivalent. This gives an edge over generic competitors that are still gaining distribution in the market.

5) Generic Entry Dynamics: The 180-day exclusivity periods accorded to initial generic filers result in times of lower competition. Over time, more generic approvals increase price competitiveness and reduce branded generic premium pricing.

6) Regulatory Environment: Rules governing automatic generic replacement and the necessity for physician clearance influence branded generic acceptance. FDA clearance processes and patent lawsuits also influence the timing of generic and branded generic arrivals.

While chemically identical, good branding, advertising, price, and the use of existing commercial infrastructure enable branded generic producers to distinguish and grab market share, at least immediately after patent expiration. However, over time, the competitive generic market puts pricing pressure on branded generics. [18-21]

HEATHCARE ACCESS

Branded generics can increase access to healthcare, especially in underprivileged and rural areas where access to patented medications may be restricted by cost. Because they don't incur the same costs for research and development, branded generics are frequently more affordable than their name-brand equivalents. Patients, particularly those in

underserved and rural areas who may have low financial means, will find them more affordable as a result. Because they are frequently made by several manufacturers, branded generics are usually more accessible than brand-name medications. Patients in isolated or underserved locations are more likely to have access to the necessary medications without having to drive far to find them because to this enhanced availability.

With the help of wide distribution networks, several pharmaceutical businesses that manufacture branded generics are able to reach even the most remote locations. This guarantees that patients in underserved and rural locations can obtain a variety of medications without experiencing supply shortages or lengthy wait times. Branded generics are occasionally produced locally thanks to license agreements or joint ventures with nearby pharmaceutical firms. This lowers transportation costs while simultaneously promoting economic growth and employment creation in underserved and rural areas. In underprivileged and rural areas, branded generics contribute to the overall health infrastructure by making pharmaceuticals more accessible and inexpensive. Long-term health outcomes are improved when patients have access to the necessary medications because they are more likely to seek medical attention and follow their recommended regimens. All things considered, branded generics are essential for expanding access to healthcare in underserved and rural areas since they offer broadly accessible, reasonably priced drugs that satisfy local populations' demands. Here are some of the key regulatory implications and considerations around branded generic drugs and competition. [22, 23]

REGULATORY IMPLICATIONS

Here are some of the key regulatory implications and considerations around branded generic drugs and competition:

1) **Approval Process:** FDA bioequivalence data requirements and additional standards are part of the approval process for generic medication versions. Regulations pertaining to the 180-day market exclusivity timeslots awarded to first-time generic applicants. The process and obstacles involved in obtaining approval for branded generic versions once the primary medicine loses its patent
2) **Substitution Laws:** State-level policies that specify when pharmacists are able to automatically fill prescriptions for generic drugs instead of name brands. Any restrictions on using a branded generic in place of the recommended brand, such as needing a doctor's approval? Education requirements for pharmacists teaching patients on the use of branded generic alternatives FDA monitoring of branded generic advertising claims and promotional materials is part of prescription drug marketing. Laws pertaining to comparison marketing between generic rivals. Limitations on advertising targeted at consumers that may unduly influence prescription decisions Pricing and Reimbursement: Requirements for reporting and price transparency. How branded generics are divided up and treated differently from brands and generics in insurance formularies. Policies aimed at managing branded generic pricing schemes and limiting "product hopping"
3) **Anti-Competition Monitoring:** regulatory and FTC examination of generic company practices under brand names for any instances of anti-competitive behaviour. Evaluating adherence to the Hatch-Waxman Act and other legislation controlling competition in the generic sector. keeping an eye out for pay-for-delay arrangements that hinder the entrance of generics after patents expire
4) **Manufacturing Standards:** Ensuring that Good Manufacturing Practices are adhered to by branded generic factories. Supply chain monitoring to avoid hiccups or shortages. regulatory actions in the event that branded generic products have quality problems. [24-26]

PATIENT PERCEPTION

1) **Brand Recognition and Trust:** Patients may believe that branded generics from the original brand manufacturer are more dependable and trustworthy than generics from unidentified companies. The branded generic may benefit from a "halo effect" caused by the brand name recognition and association with the original branded medication.
2) **Perceived Quality and Efficacy:** Some patients may believe that branded generics are better or more potent than generic medications, even when they are bioequivalent. Perceived distinctions in quality can be strengthened by branded generic manufacturers through effective marketing and promotional campaigns.
3) **Cost Sensitivities**: Because branded generics are usually more expensive than generic alternatives, patients on a tight budget may choose not to use them. But since they cost less than the original branded medication, some people might see them as a familiar and more cost-effective substitute.
4) **Confusion and Understanding:** The technical distinctions between branded pharmaceuticals, branded generics, and regular generic counterparts might not be completely understood by patients. Pharmacists should provide patients with clear counselling so they may comprehend what they are obtaining and make educated decisions.
5) **Habitual Behaviours:** For those stable on a branded medication, there may be inertia or reluctance to switch to an unfamiliar generic maker's version, even if costs are lower. The branded generic allows sticking with a known manufacturer's product line. [27-29]

HOW GENERIC MANUFACTURER CAN ENTER THE MARKET AFTER A BRANDED DRUG LOOSES ITS PATIENT PROTECTION

The sources cited indicate that the Indian market for branded and generic pharmaceuticals is a complicated one with distinct features. Generic drugs provide less expensive options, however branded pharmaceuticals are created and sold in India by pharmaceutical corporations with exclusive patent protection. The government has implemented initiatives to encourage the supply of high-quality generic drugs, such as the Jan Aushadhi program, which offers generic drugs at a reasonable price.

It is advised that doctors in India write prescriptions for generic medications, which are usually 30–80% less expensive than name-brand medications. Nonetheless, branded generics are widely available in India, where many businesses sell them under their own brand names. Due to this, it has become difficult to distinguish between branded and generic medications; currently, just 10% of drugs on the domestic market are unbranded or generic, and the majority of them are obtained through public healthcare systems.

India's ability to provide its people with accessible and reasonably priced medications depends on the availability of generic drugs. The Central Drugs Standard Control Organization (CDSCO) is in charge of approving and regulating generic medications in India. It also conducts routine inspections to uphold quality standards and makes sure that all manufacturers follow Good Manufacturing Practices (GMP).

In India, there is a big difference between branded and generic medications. Companies that sell branded medications do so under distinct brand names, whereas generic medications are supplied under their chemical names without any branding. Given that they both contain the same active components, generic pharmaceuticals are equivalent to name-brand ones in terms of quality and efficacy. India's generic drug market has played a significant role in lowering the cost of healthcare for patients by offering reasonably priced substitutes for name-brand drugs. [30, 31]

NUMBER OF FORMULATIONS, BRANDS, AND BRANDS PER FORMULATION IN BRANDED GENERIC DRUG STATISTICS

Manufacturers of branded generic drugs frequently create several versions of the same prescription. Different dose strengths (10 mg, 20 mg, and 30 mg), dosage forms (10 mg, 20 mg, and 30 mg), and delivery methods (immediate-release, extended-release) can all be found in these formulations. Depending on the drug's popularity, therapeutic adaptability, and market demand, there may be a handful, dozens, or even hundreds of formulations available for a given medication.

Several pharmaceutical companies may manufacture their own versions of the same medication and sell it under different brand names inside the branded generic drug market. Within a given pharmacological category, the number of rival brands might differ greatly; for certain treatments, there may be very few, and for others, there may be numerous. The number of brands that are available for a particular drug can be influenced by a number of factors, including market dynamics, patent expiration, and regulatory restrictions.

Depending on variables including consumer preferences, regulatory rules, and market rivalry, the average number of brands per formulation may differ. There may be just one or two rival brands in a formulation at times, or there may be multiple brands fighting for the same formulation's market share. Rivalry between brands using the same formulation can result in efforts to differentiate products through packaging, technology used in the formulation, and marketing tactics, as well as price and promotional rivalry. [32, 33]

Table no. 1: Number of formulations, brands, and brands per formulation in branded generic drug statistics

THERAPY AREAS	NO. OF FORMULATIONS	NO. OF BRAND	NO. OF BRANDS OF PER FORMULATION
Gastro intestinal	407	5555	14
Anti-infective	380	5357	14
Cardiac	423	4669	11
Dermatologic	502	4230	9
Pain / analgesics	308	4518	15
Respiratory	512	4780	10
Neuro / cns	308	4528	15
Ophthal / otologicals	127	2669	21
Vitamins / minerals / nutrients	251	6242	24
Anti-neoplastics	430	1990	5
Gynaecological	452	2918	6
Anti diabetic	323	2671	8
Blood related	75	613	8
Hormones	100	728	7

Urology		58	592	10
Vaccines		47	255	6
Anti malarials		52	210	4
Stomatologicals		25	420	16
Sex stimulants / rejuvenators		12	280	23
Others	92	3148		34

Chart No. 1 : No of Formulations

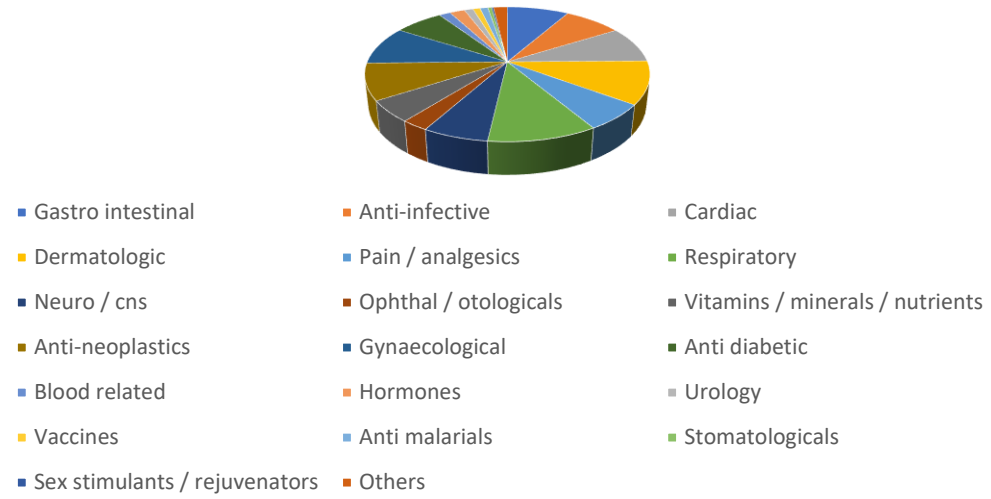
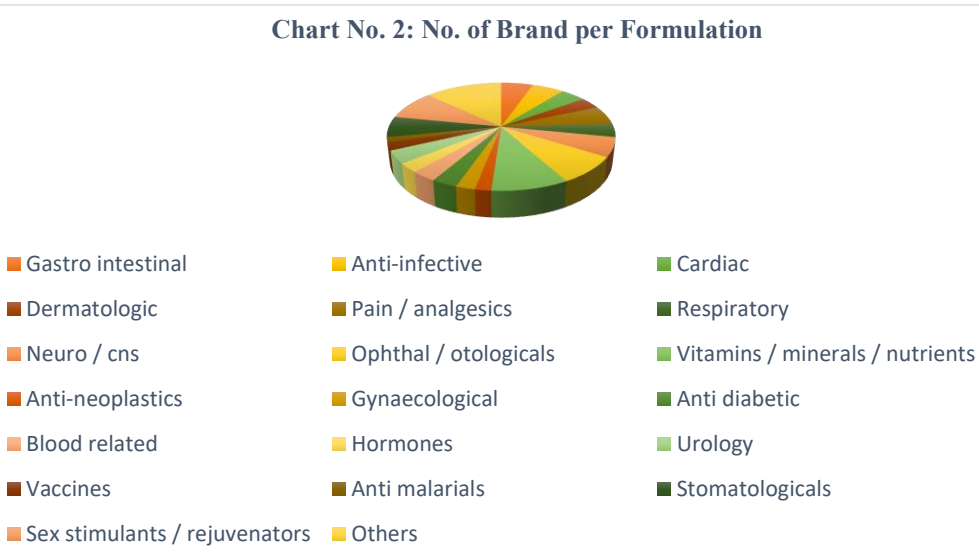


Chart No. 2: No. of Brand per Formulation



DISCUSSION:

Medications released under a new name but essentially equivalent to the original branded drug are known as branded generics. They bear the manufacturer's or distributor's branding even if they provide a less expensive substitute for the name-brand medication. The fact that branded generics provide customers additional options at perhaps cheaper prices and hence improve competition in the pharmaceutical sector is one of the main reasons in favor of them. Branded generics assist lower costs via competition by offering substitutes for name-brand medications, which is advantageous to both patients and healthcare systems.

Nonetheless, some detractors contend that branded generics might not always promote healthy rivalry. Concerns have also been expressed concerning the effectiveness and quality of branded generics in comparison to their name-brand equivalents.

Concerns have also been expressed concerning the effectiveness and quality of branded generics in comparison to their name-brand equivalents. Although branded generics must adhere to the same regulatory requirements as their name-brand counterparts, there have been cases in which the quality of these drugs has been questioned, sparking discussions about whether or not they provide the same degree of safety and effectiveness.
All things considered, the debate around branded generics and competition is complex, encompassing issues with patient outcomes, market dynamics, price, and regulatory control. Ensuring the availability of safe and high-quality pharmaceuticals while fostering competition continues to be a significant problem for governments and pharmaceutical industry stakeholders.

CONCLUSION:

The conclusion on branded generics and competition highlights how important they are to the pharmaceutical industry. Generic medications sold under a brand name are known as branded generics, and they have several benefits. They uphold quality and efficacy requirements while offering consumers reasonably priced substitutes for name-brand drugs.

Competition among branded generic manufacturers encourages innovation, lowers costs, and increases accessibility to necessary pharmaceuticals. Pharmaceutical firms are encouraged to spend in research and development by this competitive climate, which results in the development of more affordable therapies. By guaranteeing that patients, irrespective of their financial situation, have access to reasonably priced pharmaceuticals, the availability of branded generics advances healthcare equity.

To sum up, branded generic medicines are critical for increasing competition, lowering costs, and increasing accessibility to necessary pharmaceuticals.

REFERENCES:

1. Grabowski, H. (2007). Competition between generic and branded drugs. Pharmaceutical innovation: incentives, competition, and cost-benefit analysis in international perspective, 153-73.
2. Grabowski, H., Long, G., Mortimer, R., & Bilginsoy, M. (2021). Continuing trends in US brand-name and generic drug competition. Journal of medical economics, 24(1), 908-917.
3. Grabowski, H., Long, G., Mortimer, R., & Boyo, A. (2016). Updated trends in US brand-name and generic drug competition. Journal of medical economics, 19(9), 836-844.
4. Gupta, R., Shah, N. D., & Ross, J. S. (2019). Generic drugs in the United States: policies to address pricing and competition. Clinical Pharmacology & Therapeutics, 105(2), 329-337.
5. Berndt, E. R., & Aitken, M. L. (2011). Brand loyalty, generic entry and price competition in pharmaceuticals in the quarter century after the 1984 Waxman-Hatch legislation. International Journal of the Economics of Business, 18(2), 177-201.
6. Wouters, O. J., Kanavos, P. G., & McKee, M. (2017). Comparing generic drug markets in Europe and the United States: prices, volumes, and spending. The Milbank Quarterly, 95(3), 554-601.
7. Mazumdar, M., & Mazumdar, M. (2013). An overview of the Indian pharmaceutical sector. Performance of pharmaceutical companies in India: A critical analysis of industrial structure, firm specific resources, and emerging strategies, 17-44.
8. Akhtar, G. (2013). Indian pharmaceutical industry: an overview. IOSR journal of Humanities and Social Science, 13(3), 51-66.
9. Govindaraj, R., & Chellaraj, G. (2002). The Indian pharmaceutical sector: issues and options for health sector reform.
10. Shastri, M. (2014). An empirical study of pharmaceutical sector in India. International Journal of Education and Science Research Review, 1(3), 82-96.
11. Sivadasan, J. (2009). Barriers to competition and productivity: Evidence from India. The BE Journal of Economic Analysis & Policy, 9(1).
12. Mehta, F. A. (1957). Price-Competition Between India, Japan, and the UK in the Indian Cotton Textile Market During the Nineteen-Thirties. The Review of Economics and Statistics, 39(1), 75-78.
13. Singh, N. (2010). Adoption of industry-specific quality management system standards: determinants for auto component firms in India. International Journal of Productivity and Quality Management, 5(1), 88-107.
14. Siddh, M. M., Soni, G., Jain, R., Sharma, M. K., & Yadav, V. (2021). A framework for managing the agri-fresh food supply chain quality in Indian industry. Management of Environmental Quality: An International Journal, 32(2), 436-451.

15. Varghese, D., Karbelkar, S., Ravikumar, S., Jadhav, M., & Gota, V. (2021). Current State of Regulatory Oversight of Biosimilars in India and Its Implications on the Quality of Drugs: A Comparative Assessment with EU and FDA Regulations. Journal of Biotechnology & Bioinformatics Research, 3(4), 1-7.
16. Kaushal, N., Singh, S. K., Gulati, M., Vaidya, Y., & Kaushik, M. (2016). Study of regulatory requirements for the conduct of bioequivalence studies in US, Europe, Canada, India, ASEAN and SADC countries: impact on generic drug substitution. Journal of Applied Pharmaceutical Science, 6(4), 206-222.
17. Hegde, S., Gogtay, N. J., & Kshirsagar, N. A. (2005). Postmarketing surveillance: An overview from India. International journal of pharmaceutical medicine, 19, 141-151.
18. Saha, A., & Roberts, H. (2020). Pharmaceutical industry's changing market dynamics. International Journal of the Economics of Business, 27(2), 159-175.
19. Mukherjee, P., & Roy, M. (2016). What drives the stock market return in India? An exploration with dynamic factor model. Journal of Emerging Market Finance, 15(1), 119-145.
20. Kambhampati, U. S., & Kattuman, P. A. (2003). Growth response to competitive shocks: Market structure dynamics under liberalisation-the case of India. University of Cambridge, ESRC Centre for Business Research.
21. Mahajan, V., Nauriyal, D. K., & Singh, S. P. (2020). Domestic market competitiveness of Indian drug and pharmaceutical industry. Review of Managerial Science, 14(3), 519-559
22. Ilan, Y. (2021). Improving global healthcare and reducing costs using second-generation artificial intelligence-based digital pills: a market disruptor. International Journal of Environmental Research and Public Health, 18(2), 811.
23. Francisquinho, A. M. N. (2013). Consumer attitudes and perceptions towards medicine types: Brand medicines versus generic medicines (Doctoral dissertation).
24. Kanavos, P., Costa-Font, J., & Seeley, E. (2008). Competition in off-patent drug markets: Issues, regulation and evidence. Economic policy, 23(55), 500-544.
25. Frank, R. G. (2007). The ongoing regulation of generic drugs. New England Journal of Medicine, 357(20), 1993.
26. Frank, R. G., & Hartman, R. S. (2015). The nature of pharmaceutical competition: Implications for antitrust analysis. International Journal of the Economics of Business, 22(2), 301-343.
27. Dunne, S., Shannon, B., Dunne, C., & Cullen, W. (2014). Patient perceptions of generic medicines: a mixed-methods study. The Patient-Patient-Centered Outcomes Research, 7, 177-185.
28. Shrank, W. H., Cox, E. R., Fischer, M. A., Mehta, J., & Choudhry, N. K. (2009). Patients' perceptions of generic medications. Health affairs, 28(2), 546-556.
29. Kesselheim, A. S., Gagne, J. J., Franklin, J. M., Eddings, W., Fulchino, L. A., Avorn, J., & Campbell, E. G. (2016). Variations in patients' perceptions and use of generic drugs: results of a national survey. Journal of general internal medicine, 31, 609-614.
30. Dhamija, P., Sharma, P. K., & Kalra, S. (2015). Only generics (drugs/names): Is India ready?. Indian journal of endocrinology and metabolism, 19(5), 541-545.
31. 31.Prasada, S., Khemlani, S., Leslie, S. J., & Glucksberg, S. (2013). Conceptual distinctions amongst generics. Cognition, 126(3), 405-422.
32. Singal, G. L., Nanda, A., & Kotwani, A. (2011). A comparative evaluation of price and quality of some branded versus branded-generic medicines of the same manufacturer in India. Indian journal of pharmacology, 43(2), 131-136.
33. Al Ameri, M. N., Nayuni, N., Kumar, K. A., Perrett, D., Tucker, A., & Johnston, A. (2012). The differences between the branded and generic medicines using solid dosage forms: In-vitro dissolution testing. Results in pharma sciences, 2, 1-8.