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# "Generic Drugs Vs Branded Drugs"

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## Abstract:-

Branded medications are the original products created by a pharmaceutical company, whereas generic medications are replicas of branded medications after their patents have lapsed. They have the same active ingredients dosage form quality ling etc. people are generally confused because of the difference in packaging and price. In India people have many myths about generics due to lack of knowledge and awareness. Doctors generally not prescribed the generics drug because of they are more doubtful about quality and safety. Pharmacist not dispenses generics because of less commission on sale of generics and less demand by peoples. Government was launched the Jan Aushadhi scheme to provides the quality of medicines at affordable price to all. There are various barriers to move toward the generics drug in India.

***Keywords***: Generic drug, Branded drug, Global comparison, Cost of medicine, Antimicrobial activity

## Introduction :-

A pharmaceutical company creates or finds a novel drug compound. After conducting thorough research and development and expensive trials, they obtain a patent for the drug to prevent other pharmaceutical companies from copying the drug molecule. This category of medications is referred to as branded drugs and is commercially available with the specific brand name.[1] The patent period for a newly developed medication typically lasts for about twenty years, during which the manufacturer holds complete ownership of the drug. No other entity is able to replicate or produce the identical drug molecule. Another class of drugs to receive special attention here are the generic drugs. These medications have the same active ingredient/ingredients, strength, quality, purity, and effectiveness of branded products. Generic drugs can only be made after the patent for a specific branded drug expires. A noteworthy advantage of generic drugs is that they are significantly less expensive than branded drugs because they do not require costly research, development, and trials like new drugs.[2] Generic drugs are just as safe and effective as brand name medications. These medications are not only more affordable than the branded alternatives but also within reach for people of all financial backgrounds. In some countries, where poverty is a critical issue and countless individuals pass away from untreated lethal diseases due to their inability to pay for costly name-brand medications, generic drugs offer a lifeline for them.[2]

## Objectives:-

- To assess the Price-to-patient (MRP) and Price-to-retailers (PTR) as well as Trade margin of "branded" and "branded-generic" versions of popular oral cephalosporin's in the tertiary care hospital pharmacy.
- In order to assess the antibacterial effectiveness of these cephalosporin formulations.

## METHODOLOGY :-

Three popular oral cephalosporins, both in branded and branded-generic forms, were chosen. The formulation packs were used to collect fundamental information about the brands utilized [Table 1].

### 1. Difference in cost:-

Patients can purchase medicines at the maximum retail price (MRP) indicated on the medicine package. PTR is the rate at which the wholesaler sells the product to the retailer, as indicated on the purchase rate vouchers. Both the price for patients and retailers were examined for every combination of cephalosporins, and the retailer's Trade Margin was determined through a specific formula:

$$\frac{100\times(MRP-PTR)}{PTR}$$

Additionally, we also computed the percentage rise in trade margin for the retailer and the percentage cost advantage for the patient when transitioning to generic products.

### 2. Antibacterial activity:-

The effectiveness of the chosen formulations of the 3 cephalosporins against Escherichia coli and Staph aureus strains from various clinical samples was assessed using the "Kirby Bauer" disk diffusion method as per the guidelines of the Clinical and Laboratory Standards Institute (CLSI).[3]

The current research used discs containing 30 µg of Cephalosporin for the study. The three Cephalosporins were labeled as 1, 2, 3 with B suffix for branded and BG for branded generic drug in each pair. The Cephalosporin discs, each containing 30 µg and from various brands, were readied through serial dilution using phosphate buffer 6 or 7 to match the potency of the existing tablets or capsules. The discs were immersed in water for a full day and then placed in the fridge. The following day, they tested the antibacterial activity. Measurement of zones of inhibition in millimeters was done after 24 hours of incubation following the CLSI / Eucast reference for the Disk diffusion (Kirby-Bauer) method.[4,5]

### 3. Data analysis:-

The analysis focused on comparing the PTR, MRP, Trade margin, and percentage difference in trade margin for the retailer, as well as the cost benefit to the patient when switching to the generic brand. In order to measure antibacterial activity, the size of the zone of inhibition was calculated in millimeters (mm).[11]

### 4. Observations and results:-

The 6 formulations samples were stored as per the manufacturer's packaging instructions and remained there until testing. The microbiologist who carried out the investigation was kept unaware. Tables 1 and 2 contain the codes for all brands and drug product details used in this study.[11]

The table above displays the fundamental information of the obtained original and generic branded cephalosporins. Every medication analyzed in May-June 2016 was produced in 2015 and had a expiration date of 2017.[11]

### 5. Assessment of cost benefit:-

Cost benefit to pharmacists (Trade margin) and patients with selected branded generic drugs is displayed in Table 2. The trade margin of 25% for branded cephalexin rose to 130.5% for branded generic cephalexin, resulting in a 422% increase in profit for the pharmacist. The study shows that retailers have much higher mark-ups on branded-generic medicines due to the significantly lower PTR, resulting in a cost benefit of 42.6% to patients compared to just 10% for the retailer. The profit margin of three branded drugs analyzed ranged from 17-25%, while their branded-generic counterparts had a margin ranging from 73-130% [Table 2]. Switching to branded generic medicines resulted in a cost benefit increase for pharmacists from 270% to 422%. The advantage to the patient is determined by the variance in Maximum Retail Price. Patient benefit ranged from 5% to 48.3% for the three drugs examined.[11]

### 6. Assessment of antibacterial activity:-

We have evaluated the antibacterial effects of both branded and generic versions of 3 oral cephalosporins using the disk diffusion method (Kirby-Bauer method). Each tablet within the corresponding pair possessed equal potency [Table 1]. The study provides information on the sizes of zones of inhibition from various cephalosporin tablet brands against bacterial strains in Table 3. Figure 1 displays photos of the

plates showing the zones of inhibition. Based on Table 3, there was no variation in the zones of inhibition between the branded and branded generic formulations for the three pairs of oral cephalosporins. The areas of inhibition for the generic brands were actually a bit bigger than for the original branded versions.[11]

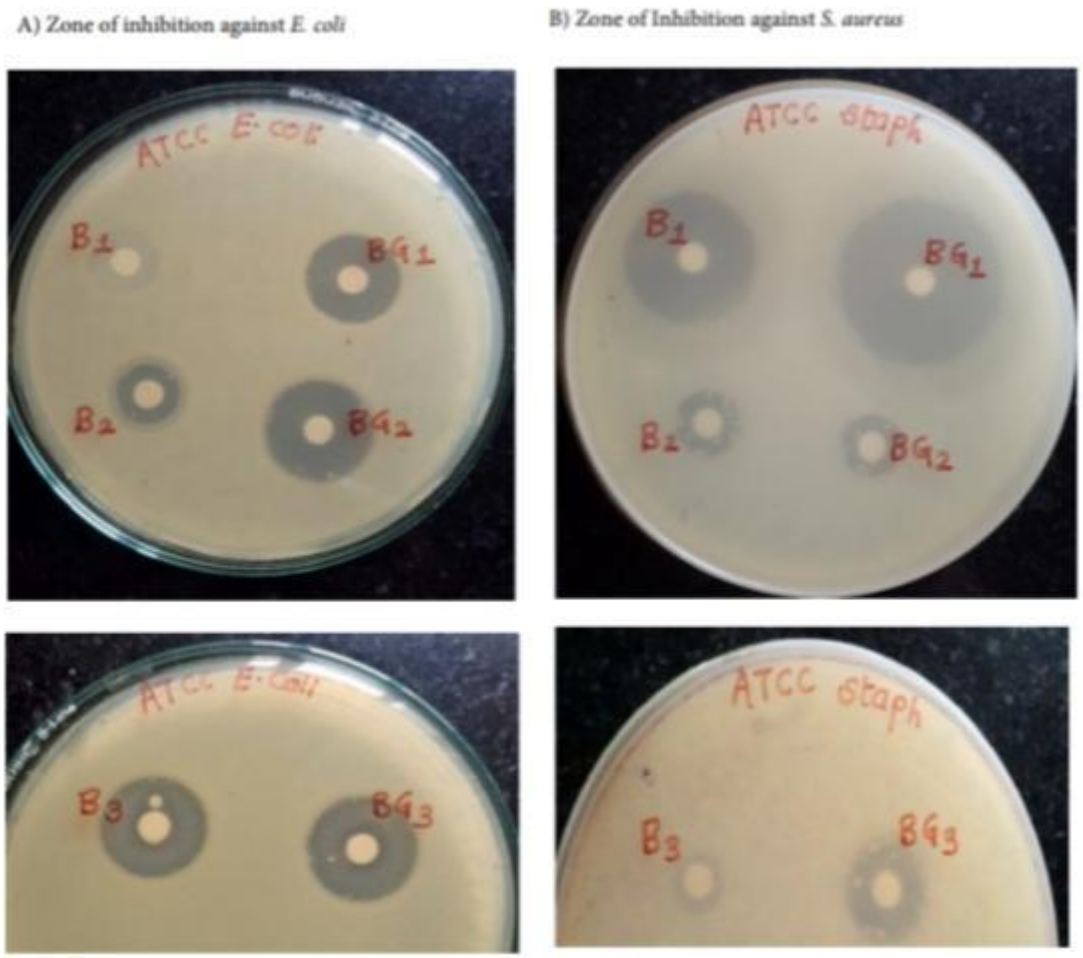



**Figure 1:** Zone of Inhibition of different Pairs of oral cephalosporin



**Table 1:** Details of the drug products selected for comparative analysis

| Cephalosporin | Code | Batch No | Mfg date | Expiry Date | Brand Name & Manufacturer |
|---|---|---|---|---|---|
| Cephalexin | B1 | 2706924 | 6/2015 | 2/2017 | Sporidex 250<br>Sun pharma |
| | BG1 | B651155 | 11/2015 | 6/2017 | Cephadex 250<br>Cipla |
| Cefuroxime Axetil | B2 | 5133176 | 12/2015 | 11/2017 | Zocef 500<br>Alkem |
| | BG2 | WBT-5240B | 10/2015 | 9/2017 | Bullcef 500<br>Ultra-Drugs Pvt. Ltd. |
| Cefixime | B3 | EI 51546 | 11/2015 | 10/2017 | Ziprax-200 DT<br>Cipla |
| | BG3 | TX-7718 | 05/2015 | 4/2017 | Cefixar-200 DT<br>Legen healthcare |

B1, B2, B3 - Branded products, BG1, BG2, BG3-Branded Generic products

**Table 2:** Cost benefit to pharmacist and patient

| Pair Sr. No | Drug Name | PTR | MRP | Trade Margin % | On switching to branded generics | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Increase in trade margin | % increase in trade margin | Cost benefit to the patient | % Cost benefit to Patient |
| 1 | Cephalexin (B1 | 84.8 | 106 | 25 | | | | |
| | Cephalexin (BG1) | 26.40 | 60.8 | 130.5 | 105.5 | 422% | 45.2 | 42.6% |
| 2 | Cefuroxime Axetil (B2) | 460 | 557 | 21.08 | | | | |
| | Cefuroxime Axetil (BG2) | 160 | 288 | 80 | 58.92 | 270% | 269 | 48.3% |
| 3 | Cefixime DT (B3) | 81 | 95 | 17.28 | | | | |
| | Cefixime DT (BG3) | 52 | 90 | 73.07 | 55.79 | 322% | 5 | 5% |

PTR - Price to the retailer; MRP - Maximum retail price; *Branded Generics/Branded* drug products and their trade margins

**Table 3:** Zones of Inhibition of different brands of oral cephalosporin

| Pair Sr. No. | Drug Name | Zone of Inhibition (mm) | | Recommended Zones of inhibition (mm) | |
|---|---|---|---|---|---|
| | | *E. coli* ATCC | Staph ATCC | *E. coli* | *S. aureus* |
| 1 | Cephalexin (B1) | 18 mm | 25 mm | 15-21 | 29-37 |
| | Cephalexin (BG1) | 21 mm | 33 mm | | |
| 2 | Cefuroxime Axetil (B2) | 15 mm | 15 mm | 20-26 | 27-34 |
| | Cefuroxime Axetil (BG2) | 20 mm | 15 mm | | |
| 3 | Cefixime DT (B3) | 20 mm | 10 mm | 23-27 | |
| | Cefixime DT (BG3) | 21 mm | 15 mm | | |

## Similarity Between Generic and Branded Drugs:-

- It needs to have the identical active substances.
- It is required to have identical dosage form.
- They possess identical quality and performance.
- It needs to have the identical method of administration.
- Generic medications are equally as safe as brand-name medications.
- Bioavailability remains consistent.
- They need to administer equal quantities of medication into the bloodstream.
- The dosage strength should be identical (for example, 20 mg or 40 mg).[6]

## Difference Between Generic And Branded Drugs:-

- It should include various non-active components.
- Generic medications cost less than brand-name drugs.
- They appear diverse because of variations in shape, size, colors, marking, in generic and branded medications.
- Branded drugs have exclusive patent rights for manufacturing and distribution for a limited time, while generic drugs do not possess patents for their manufacturing and distribution.[6]

## Effectiveness of Generic Drugs in Comparison to Branded Drugs:-

Bioequivalence studies must be performed on the drug for generic drugs to be approved and introduced to the market. Analyzing the bioequivalence information of a generic medication versus the brand name can suggest the standard, effectiveness, and security of the generic medication if the information aligns. Bioequivalence studies require healthy participants to receive equivalent doses of two medications through the same method, followed by an evaluation of their pharmacokinetics and bioavailability.[7,8,9] Methods like HPLC, GC, and MS are utilized in determining plasma levels of the two types of drugs for the purpose of establishing pharmacokinetics and bioequivalence. The FDA regulations require generic medications to be as effective as the branded ones, and only generic drugs that have been shown to be both effective and bioequivalent are permitted for sale.[9] Active ingredients undergo thorough testing to guarantee that they adhere to FDA regulations in terms of their appearance and content.

Therefore, based on these strict guidelines and approval process for generic drugs, it can be concluded that generic drugs are just as effective as the brand-name ones.[10]

## How the Generic and Branded Drugs Work in the Body:-

Different investigate ponders have appeared that nonexclusive drugs work essentially to branded drugs within the body. Regulatory offices just like the FDA command that bland drugs must meet the same guidelines as branded drugs sketched out in their endorsement rules. They must coordinate their branded partners in each perspective and not be second rate in any way. Bland solutions are broadly inspected and go through a few assessments to comply with strict FDA directions.[12] Furthermore, non specific medicate producers must follow to the same exacting controls as brand sedate producers, agreeing to the FDA. The FDA conducts numerous assessments to confirm that nonexclusive medicate fabricating offices comply with the same measures as branded ones. This indicates that non specific drugs work the same way within the body as branded drugs since they meet the same basic criteria.[13]

## Thinking of people about generic drugs:-

Is it secure or not?

What is the reason for the lower cost of generics?

If the generic is inexpensive, it could be lower in quality.

What is the reason for their appearance discrepancy?

Are generic medications just as effective as branded ones?

## View of Professionals

## Doctors:

Most doctors will not prescribe generic drugs because they are not satisfied with the safety and effectiveness compared to branded drugs. T hey do not receive any generic drug
commission from the manufacturers like branded drugs. Doctors have different beliefs and experiences with different drugs, and medical hi story and preferences can also influence
the doctor's decision. When doctors prescribe generic drugs, they tend to have less effect on patients compared to branded drugs.[14]

## Pharmacist:

They earn the least money from selling generic drugs compared to branded drugs. There are also problems with generic drugs in the Indian market. Consumer demand for generic drugs is decreasing due to poor quality and efficacy. Patients are sticking to their medicines, most of which are branded drugs. While the doctor prescribes the name of the drug,
the pharmacist can give any kind of medicine.[14]

## COSTS OF GENERIC AND BRAND-NAME DRUG TESTING AND PRICES OF DRUGS IN THE MARKET

### • Cost associated with testing of the two drug types

During the development of a brand-name drug, it typically cannot be compared to other medications with the same active ingredient since there are no comparable drugs available in the market at the time of its approval.[15] Consequently, the medication needs to go through thorough safety and efficacy evaluations through preclinical and clinical trials.[16] These trials involve significant financial costs.[17,18] Some sources estimate that companies creating new medications typically allocate $802 million for drug development and testing.[17,19] Nonetheless, the research that produced these findings was carried out on medications for chronic illnesses, which need to be examined over an extended duration to ascertain the long-term negative effects.[15] Although this suggests that the estimated number could be an overestimate, other research indicates that this number may actually be an underestimate.[20] Certain studies have shown that companies creating new medications incur an average of about $868 million in financial costs during the development stage, while additional evidence indicates that this figure might be nearer to $1.3 billion.[20,21] Although numerous estimates have been suggested in the literature, it is clear that the process of developing a new drug incurs expenses reaching hundreds of millions of dollars, leading to a significant depletion of a company's financial resources.

This does not hold true for companies creating generic medications. It is estimated that the typical expense for acquiring FDA approval to sell generic drugs in the US during the early 1990s was approximately $603,000. Although this number may have increased due to inflation since the early 1990s, it is still likely that the expenses associated with the development of generic drugs are now over a hundred times less than those of brand-name drugs. This highlights the significant costs associated with conducting clinical trials, which are not included in the process for obtaining generic drug approval in the US, due to the Waxman-Hatch Act enacted in 1984.[22] Comparable legislation has been enacted in Canada, Japan, and Europe, which has led to considerably lower developmental expenses for generic medications in various regions globally, in contrast to their brand-name versions.[23]

## • Cost Effectiveness of Generic Drugs in Comparison to Branded Drugs

Generic drugs offer a significant cost advantage without sacrificing quality and effectiveness in comparison to branded drugs. The primary cause of this is that they do not necessitate spending money on drug research and development. The expensive clinical trials do not need to be conducted again, thus reducing the cost of these drugs. The expenditure on advertising, marketing, and promotion of these medications is insufficient following the production of generic drugs.[24] Specific studies have shown that substituting generic medications for brand name medications has resulted in annual savings of $10 billion in the US.[25] The data in table No.1 shows the price gap between generic and branded medications, supporting the conclusion that generic drugs are cheaper than branded ones.

**Table 4: Comparison of cost between Generic and Branded drugs in India[26,27,28,29]**

| S. No. | Generic drug | Class of drug | Manufacturer | Market price (Rs) | Branded drug | Manufacturer | Market price(Rs) |
|---|---|---|---|---|---|---|---|
| 1. | Aceclofenac Tablets IP 200 mg | NSAID | Edmund Healthcare Pvt Ltd,Chandigarh (Punjab) | 10 | Aceroc | Wockhardt | 29.10 (10 Units) |
| 2. | Acyclovir 400 mg Tablets | Anti-Viral | Vega Biotech Pvt Ltd,Vadodra (Gujrat) | 31.6 | Acivir DT | Cipla | 60.99(5 Units) |
| 3. | Metformin Hcl 1000 mg SR Tablets | Anti-Diabetic | Care Formlation Labs Pvt Ltd, New-Delhi | 11.05 | Geminor-M Forte | Macleods Pharmaceutical Ltd | 60.50 (10 Units) |
| 4. | Omeprazole 20 mg Capsules | Proton Pump Inhibitor | Schwitz Biotech,Ahmedabad | 7 | Acichek | Sanofi Aventis Pharma India | 29.75 (10 Units) |
| 5. | Folic Acid Tablets IP 5 mg | Anti-Anaemic | Alpha Pharmaceuticals, Faridabad(Haryana) | 2.9 | Folitab | Intas Pharmaceutical Ltd | 30 (30 Units) |
| 6. | Montelukast Sodium Tablets IP 5 mg | Antiasthmatic | Curelife Pharmaceuticals, Ambala (Haryana) | 12 | Singulair | MSD Pharmaceuticals Pvt Ltd | 84 (7 Units) |
| 7. | Lansoprazole 30 mg Capsules | Proton Pump Inhibitor | Actiza Pvt. Ltd,Surat,Gujrat | 42 | Lanzol-30 | Cipla | 54 |
| 8. | Alendronate Sodium 70 mg | Biphosphonates | Radix Pharmaceuticals, | 94 | Osteofos | Cipla | 116 (4 Units) |
| 9. | Cefuroxime Injection 750 mg | Antibacterial | Talent Healthcare,Ahmedabad (Gujrat) | 64 | Supacef Injection | GlaxoSmithkline | 114 |
| 10. | Gabapentin Capsules USP 300 mg | Antiseizure | Dycott Healthcare,Baddi,DisttSolan(HP) | 23 | Gabator 300 mg | Torrent Pharmaceuticals Ltd | 98.75 |
| 11. | Tenofovir Tablets 300 mg | Nucleotide reverse transcriptase inhibitor | Million Health Pharmaceuticals, Chennai | 178 | Tenvir-EM | Cipla | 2000 |
| 12. | Vincristine Injection IP 1 mg | Anti-Cancerous | Lexicare Pharma Pvt. Ltd, Ankleshwar, Gujrat | 25 | Oncocristin-AQ | Sun Pharmaceuticals | 52 (1 ml) |
| 13. | Oxaliplatin Injection 50 mg | Anti-Cancerous | Revacure Lifesciences, New-Delhi | 430 | Dacotin | Dr Reddy's Laboratory Ltd | 4,938 |
| 14. | Progesterone 200 mg SR Tablets | Progestins | Tissue Overseas, Surat, Gujrat | 163 | Algest | Cadila Pharmaceuticals Ltd | 187 |
| 15. | Orlistat 120 mg Capsule | Lipase Inhibitors | Fortune Healthcare, Vadodara, Gujrat | 130 | Olisat | Biocon Ltd | 380 |
| 16. | Temozolamide 100 mg Capsule | Anti-Cancerous | NetcoPharma,Telangna | 1,330 | Temolon | CelonLaboratories Ltd | 9,200 |
| 17. | Leflunomide Tablet IP 20 mg | Anti-Arthritic | Taj Pharmaceuticals Ltd, Rajgad, Maharashtra | 66.38 | Arava | Sanofi Aventis Pharma Ltd | 1,384 |
| 18. | Efavirenz Tablet IP 600 mg | Anti-Retroviral | Medchem International Ltd,Hyderabad | 423 | Odivir | Cipla | 1,070 |

## • Market prices of generic and brand-name drugs

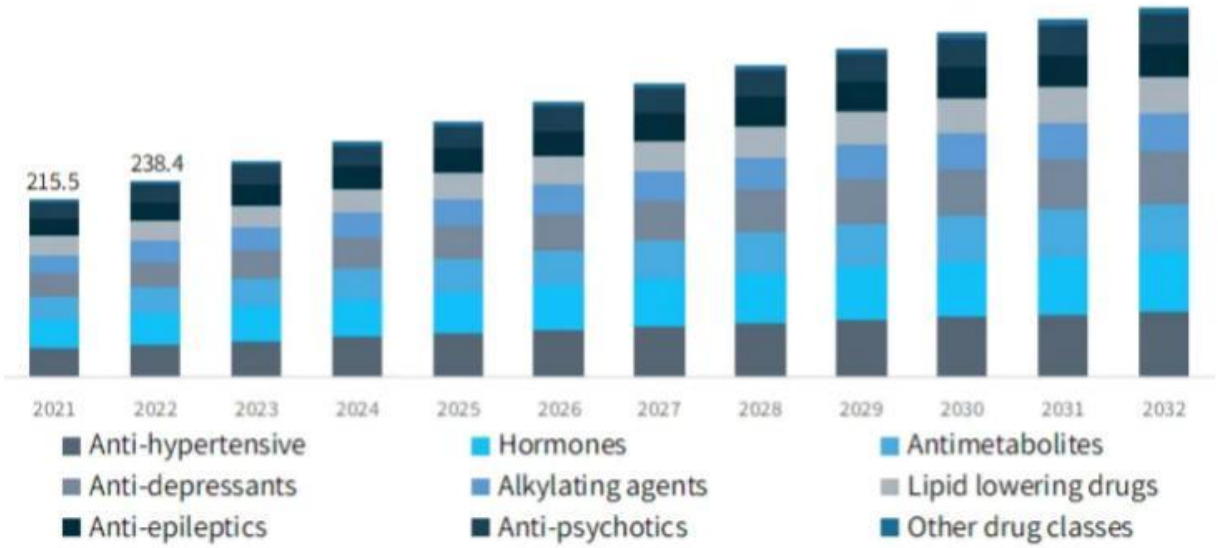
There is a significant price disparity between brand-name and generic medications in many countries across the globe. In the Netherlands, brand-name medications are priced 20 percent more than generic ones, while in Germany, they are 30 percent higher, 50 percent higher in Canada, 50–90 percent higher in the US, and 80 percent higher in the UK. It is estimated that generic medications save Canadian consumers close to $1 billion each year.[30] One possible explanation for the difference in prices between the two classes of drugs is the significant variation in the expenses tied to drug research and development. Firms that allocate substantial resources to create innovative medications probably set high prices for their products to recoup these costs. It is probable that firms launching new medications face significant marketing expenses, owing to the limited understanding physicians have about a newly launched drug's effectiveness in treating a specific illness. This increases the initial expenses of these companies even more.[31]

Although companies that manufacture brand-name medications need to invest substantial amounts in development and marketing expenses, their investments generate considerable income both during and following the drug's patent term. This has been uncovered by multiple studies, one of which analyzed the sales of Fosamax, a medication that generated $3 billion in sales in 2007 alone. Although the sales of this medication decreased after generic alternatives were introduced in February of the next year, they still reached $1.5 billion in 2008. Therefore, Fosamax generated yearly revenue that surpassed the typical overall expenditure on drug research and development, notwithstanding the costs it faced.[32]

It is evident that companies can maintain a significant, though diminished, level of sales even following the introduction of generic medications into the market. This was corroborated by information gathered from a survey carried out in all 50 states of the US, in which 2,500 beneficiaries with commercial insurance took part. An evaluation of the findings indicated that most participants think generic drugs are cheaper and do not believe that generic drugs result in more severe side effects than brand-name medications. Furthermore, they also didn't think that generic medications were less effective than brand-name medications. Regardless of this, the survey results showed that merely 37 percent of the respondents preferred a generic medication to a brand-name one. If this survey accurately reflects the overall US population, then 67 percent of Americans would prefer to take a brand-name medication instead of its generic counterpart.[33] The increased demand for brand-name medications could explain why high prices persist, despite the availability of generic drugs in the market.[34]

As stated, people residing in the US and other 'advanced' countries face high prices for brand-name drugs. However, these medications would be unaffordable for people living in nations with an annual per capita income under $1,000. As a result, international health organizations encourage pharmaceutical firms to provide their drugs at lower costs in these nations. In developing countries, medications may be as much as five times cheaper than the prices found in 'first world' nations. While this marks a positive improvement in delivering medication to individuals who cannot afford it, this considerable global gap in drug costs also presents numerous drawbacks. Initially, the difference in prices enables the export of drugs from areas with lower expenses to those with higher ones, potentially hindering the aim of lowering prices in developing countries. Moreover, the substantial differences in prices across countries result in unfair treatment of people living in 'first world' nations, who must incur high expenses for brand-name drugs irrespective of their financial conditions. The expensive prices of brand-name drugs are an important subject of debate right now. Global regulatory bodies must adopt consistent policies to resolve all conflicts associated with the costs of brand-name pharmaceuticals.[17]

**Figure 2: Branded Generic Market Size By Drug Class, 2021-2032 (USD Billion)**[35]




**• Global Generic Drugs Market By Therapeutic Area, By Route of Administration**

The Global Market for Generic Drugs is anticipated to attain nearly USD 691 Billion by 2033, rising from USD 424.2 Billion in 2023, with a compound annual growth rate (CAGR) of 5.0% during the forecast span from 2024 to 2033.[36]

The profitable pharmaceutical industry plays a key role in providing affordable healthcare and guaranteeing access to essential, life-saving medications for people worldwide. Generic drugs are effective therapies that imitate the composition, efficacy, and standards of brand-name medications offered in the marketplace. Most importantly, they are bioequivalent to the brand-name medications and satisfy safety and efficacy criteria, yet come at a reduced cost. This has allowed healthcare to be delivered to the impoverished and vulnerable.[36]

Generic drugs are produced after the patent on branded drugs runs out, and in a few uncommon instances, if the manufacturing methods have received patents rather than the product itself. Manufacturers of generic drugs reverse engineer the production process to create medications, making slight adjustments to avoid infringing on patents. In this manner, the expiration of patents serves as a catalyst for the market. Additionally, this fosters creativity and rivalry among competitors.[36]

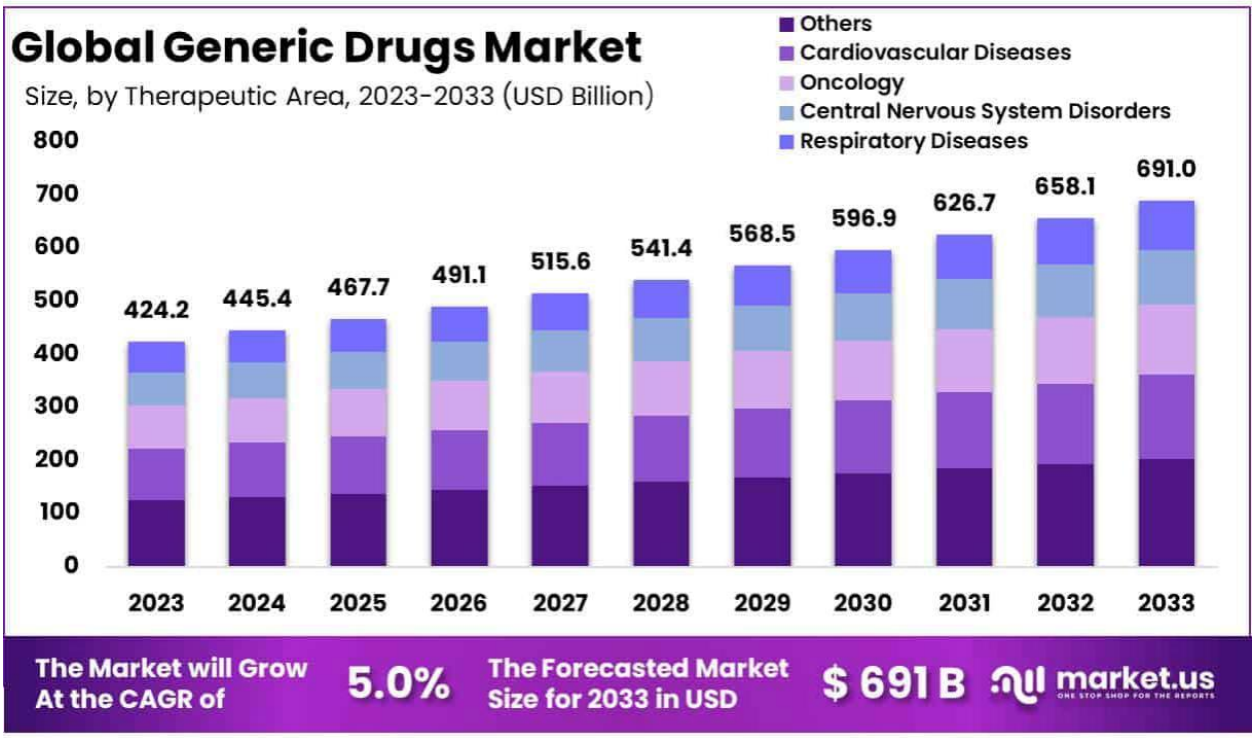



**Figure 3:**

The generic medication market encompasses various therapeutic areas, including cardiovascular diseases, cancer therapies, and respiratory ailments. The increasing prevalence of these chronic diseases has been shown to be an important factor for the market. On the other hand, lengthy regulatory procedures, although advantageous, could hinder market expansion. In general, the generic drug market is still expanding, driven by rising demand for affordable healthcare options, supportive government actions, and collaborative alliances among stakeholders and producers.[36]

- In 2023, the Office of Generic Drugs reported that the FDA approved or tentatively approved 956 applications for generic drugs.[36]
- A report from the International Generic and Biosimilar Medicines Association indicates that generic drugs account for more than 60-80% of total medical sales volume globally.[36]
- A study released in the BMC Pharmacology and Toxicology journal indicates that generic medications are generally 20-90% less expensive than branded alternatives.[36]

## *Main Points :-*

- In 2023, the worldwide generic drugs market produced a revenue of USD 424.2 billion and is projected to attain USD 491.0 billion by the conclusion of the forecast timeframe, with a compound annual growth rate (CAGR) of 5.0%.[36]
- When classifying by therapeutic area, the market encompasses categories including cardiovascular diseases, oncology, central nervous system conditions, respiratory illnesses, and additional segments. The "others" segment held the highest market share in 2023, representing 29.5%.[36]
- Concerning the method of administration, categories consist of oral, topical, parenteral, and additional options. Of these, the oral segment generated the most revenue for the market, with a market share of 66.1% in 2023.[36]
- Regarding distribution channels for generic medicines, the market is categorized into retail pharmacies, hospital pharmacies, and online pharmacies. The retail pharmacy sector topped the market in revenue, holding a share of 56.4% in 2023.[36]
- By region, North America sustained its dominance in the market, holding a market share of 38.4%.[36]

### *Therapeutic Area Analysis*

When categorized according to therapeutic areas, the market segments identified include cardiovascular diseases, oncology, central nervous system conditions, respiratory illnesses, and additional categories. In this category, the others segment captured the highest market share in 2023, which stood at 29.5%. The supremacy of this specific segment is anticipated to persist during the forecast period, mainly because of the rising global demand for generics. Moreover, aging populations influence demand too, given that older individuals are more susceptible to chronic conditions.[36]

### *Route of Administration Analysis*

According to the method of administration, the market segments identified are oral, topical, parenteral, and others. Of these, the oral segment produced the highest revenue for the market, holding a 66.1% market share in 2023. This is attributed to the ease provided by the oral method of administration. These drugs are not only simple to give, allowing for self-administration, but their method of delivery is also regarded as the safest option for extended and frequent use. Oral generics are consequently the majority of produced generics, thus holding the largest market share.[36]

### Regulations and Control of Generic Drugs

Generic drugs can only be produced after the patent for the brand-name medication has expired. A new compound needs a New Drug Application (NDA), while generic versions need an Abbreviated New Drug Application (ANDA) that doesn't have the same strict requirements as the NDA.[37]

**Figure 4:**

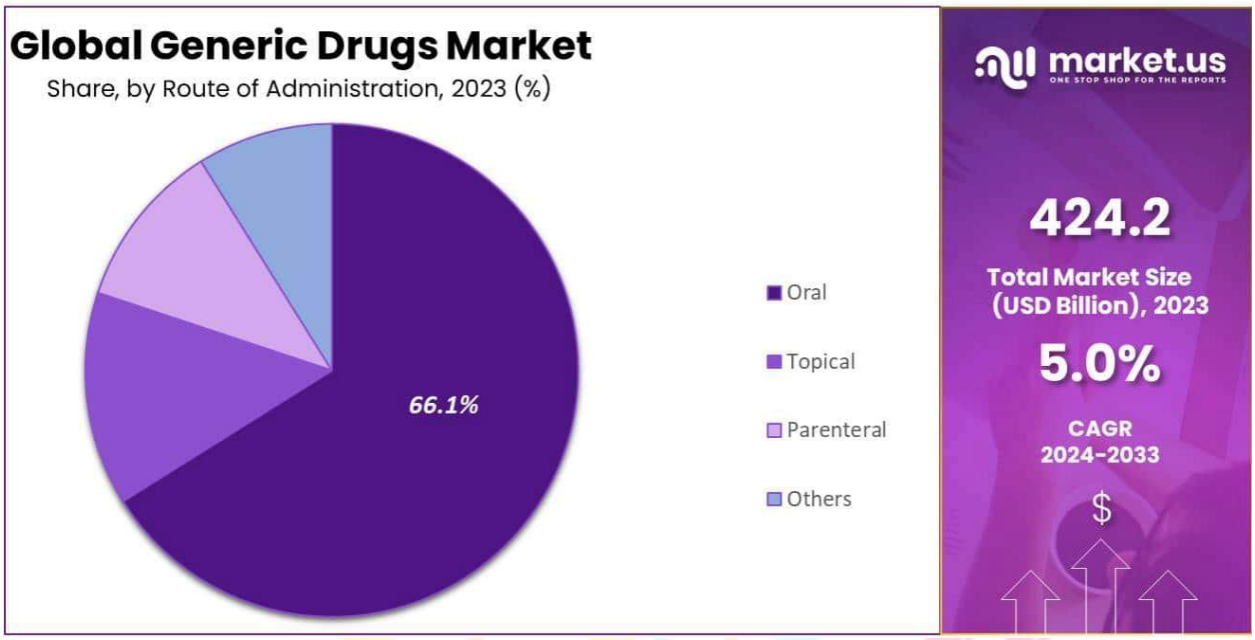



**Figure 4:**

The ANDA system was essentially created by the Hatch-Waxman Act of 1984 in the US for approving generic drugs dating back to 1962.[38] One of the important regulatory requirements for generic drugs is that they must have the identical active ingredient found in the brand name drug. It should have a similar level of potency, form of dosing, and method of delivery. It must also be bioequivalent.[39]

## Jan Aushadhi Scheme:

Providing access to high-quality medications at a low cost for everyone, especially the underprivileged and marginalized populations through specialized stores.

Generic medications are affordable compared to their brand-name counterparts in many other countries, but a significant number of poor individuals in the nation struggle to pay for the higher-cost branded medicines. Therefore, a crucial goal of the Government has been to make sure that high-quality medicines are accessible to everyone at reasonable prices.

## Why scheme being not successful?

The Scheme was assigned to the Public Health Foundation of India (PHFI) for examination and recommendations for improvement. In their report, PHFI highlighted these factors as the main reasons for the scheme's lack of success.

- Excessive reliance on assistance from the State Government.
- Inadequate management of the supply chain.
- Doctors not prescribing generic medications.
- State Governments are initiating the distribution of drugs without charge.
- Public's lack of awareness.[40]

## Conclusion

Generic medications are a safe and effective alternative and represent a suitable choice in comparison to branded pharmaceuticals. These medications are bioequivalent, safe, and significantly less expensive than their branded versions, making them a practical option for treatment. The governments of developing nations are currently emphasizing the use of generics and placing significant importance on educating the public about the sensible use of generic medications. The misunderstanding about generics' safety, effectiveness, and competence is now gradually diminishing in people's minds.

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