REVIEW ARTICLE

A Contemporary Use of Generic drugs in the Healthcare System

Neeta Rai[1], Jayesh Baldota[1], Anjita Singh Thakur[2], Amit Subhashchand Lunkad[3], Amrita Thakur[1], JE Rachel Nivedita[4], Jyoti Sahu[1], Alifeya Fidaali[1], Vipul Parab[1], Sabeena H. Syed[1], Jisha Joseph[1]

[1]Department of Pharmacy, School of Pharmacy, Vishwakarma University, Pune, Maharashtra, India, [2]Department of Pharmacy, NRI Group of the Institute, Bhopal, Madhya Pradesh, India, [3]Department of Pharmaceutical Chemistry, Sitabai Thite College of Pharmacy, Shirur, Maharashtra, India, [4]Department of Pharmacy, Bharat Institute of Technology, Hyderabad, Telangana, India

Abstract

The term "drugs" or "medicines" refers to substances used in the treatment, diagnosis, mitigation, and prevention of disease. However, the price is high. Not for everyone, however, the expense of the medications makes receiving therapy very challenging for lower and middle-class individuals. The patient's inability to pay for the cost of the medications contributes to a great number of deaths. The health-care system underwent a revolution when generic medications entered the market, and their market share is still growing today. Because these are genuine, trustworthy, safe, affordable, and available to everyone, society's poor and needy groups benefit. Now, there is a substitute for expensive branded medications. The Indian government is doing a lot to increase access to generic medications in both urban and rural areas, as well as to raise awareness among the public that these medications are just as effective and safe as name-brand medications. Generic medications are produced by numerous pharmaceutical companies and distributed through retail outlets. In addition, operating and delivering generic medications to customers' homes are e-pharmacies. Numerous Pradhan Mantri Bhartiya Janaushadhi Kendra (PMBJK) locations have been established by the government nationwide, where people can get generic medications for a significantly reduced price. The history of generic medicine shows, how the prices are less than standard medicines and how it can be beneficial for economic factors.

Key words: Drugs, generic, health, medication, prices, standard

INTRODUCTION

As believed by the WHO, roughly 50% of Asia and Africa's population does not have access to essential medications. India's health-care scenario is not notably improved, marked by a health-care expenditure of merely 1.2% of GDP and an individual health spending of USD 160, significantly lower than the OECD average of USD 3484. It is anticipated that drug expenses will make up the majority – around two-thirds – of the overall health-care expenses. As stated by Proteesh and Vandana, medicines are inaccessible for economically struggling people in India. The high prices of branded medications often restrict access to drugs for the economically challenged. Promoting generic drugs, which can be up to 90% cheaper than their branded equivalents, presents a practical solution to meet health-care needs while reducing spending on medications.[12] Pharmacists play a crucial role in advocating for generic drugs by being actively engaged in their development and distribution shows on figure 1.[1]

Over the past 10 years, tremendous progress has been made in the clinical activities of pharmacists to guarantee safe and effective pharmaceutical usage. However, effective generic medication use can only be accomplished if pharmacists obtain adequate training in generic medications as part of their degrees.[12] The timely and efficient administration of medications can help patients avoid or delay the need for pricey medical care and guarantee the effective treatment of

Address for correspondence:
Neeta Rai, School of Pharmacy Vishwakarma University, Pune, Maharashtra, India. Phone: 8602740665.
E-mail: neeta.rai@vupune.ac.in

Received: 22-07-2024
Revised: 01-09-2024
Accepted: 11-09-2024

numerous ailments. Importantly, using generic medications can substantially reduce costs for both patients and health-care systems while still effectively treating many prevalent illnesses. Branded drugs have certainly changed how people approach medication usage, but generics, which are identical to their brand-name counterparts in terms of effectiveness, are increasingly viewed as safe and cost-effective options. Global economic constraints on health-care budgets have driven a growing adoption of generic medications. In this research, "Consumer" denotes an individual purchasing medication(s) for personal use or to address a specific health issue.[1]

The knowledge, attitudes, and perspectives of consumers and patients on the usage of generic pharmaceuticals are reviewed historically in this article. In a narrative format, this study presents consumer opinions from various environments. The analysis also makes many suggestions that medical practitioners might put into practice to increase how often their patients use generic medications. Employing generic medications for existing treatments, it can free up funds within the health-care systems and for patients to allocate toward newer, typically pricier treatments for conditions lacking effective pharmacological options. However, public perspectives on the risk and perceptions surrounding generic medications have often been overlooked in the branded versus generic drugs discourse.[1,2]

A universal drug is a prescription medication that is similar to a brand-name drug in terms of strength, dosage, route of administration, quality, how well it works, and its intended purpose. It can also refer to several medications that are sold below its generic name without any promotional campaigns to the chemical makeup of a medication rather than its brand name. Generic medications are subject to certain government rules that are relevant to each country even though they might not be connected to a single manufacturer. The non-proprietary name of the drug and the name of the manufacturer are both listed on the labels of generic medications. The same active components included in the original brand-name formulation must be present in a generic medicine shows in figure 2.[2]

The U.S. Food and Drug Administration (FDA) requires that generic drugs have the same pharmacokinetic and pharmacodynamic characteristics as their brand-name counterparts, or fall within an approved bioequivalent range.

- Most patients in India still struggle to get and use necessary medications, particularly those who need therapy for acute or chronic illnesses
- A sudden hospitalization or surgery could be added to this, pushing people into bankruptcy or the verge of poverty. The Indian government (GOI) intends to enact legislation requiring doctors to provide patients with generic medications, which are less expensive than their branded equivalents. While not a novel initiative, this one is appreciated
- The medical council of India has already announced a modification to Clause 1.5 of the Indian Medical Council (Professional conduct, Etiquette, and Ethics) Rules, 2002. It is worth noting that the profit margins for branded generic medications may sometimes exceed those for branded medications, even if they are sourced from the same establishment, according to doctors who have studied the price of branded versus generic drugs. Moreover, fixed-dose combinations, or FDCs, made from a variety of other pharmacological substances, account for about 40% of the 60,000 medication formulations estimated to be sold in India and are only offered under brand names. Government intervention is required in India to lower the cost of medications. The government should receive support from the most disadvantaged members of our society to achieve social progress and improve the well-being of everyone. There are "significant differences in drug concentrations and physical properties" between generic formulations and branded drug formulations, as per new studies on a generic form of eye solution for the therapy of glaucoma, which discourages patients from using generic drugs.

According to experts, the government ought to create a set of laws to ensure that generic drugs undergo thorough testing for quality. These medications should not just be effective but also consistently reliable in their therapeutic effects. Such standards would bolster doctors' trust in prescribing them, knowing they deliver consistent results. Many have observed that generic versions of commonly used medications in the country have not passed quality assessments, the generic medicine business must also make efforts to ensure that products meet quality standards. Because there are not enough regulations, drug inspectors, and laboratory space to examine the quality of the pharmaceuticals, the drugs were evaluated and it was discovered that they violated labeling guidelines and contained insufficient amounts of ingredients. The literacy rate of our society is a significant determinant of whether generic medications are used instead of their branded counterparts.[2,3]

Many people in our nation lack basic literacy skills and lack familiarity with medical terminology and prescription formulations. When a patient is given a prescription that includes information about the medication's composition, the chemist is still responsible for selecting the best medication. Since the chemist is almost never aware of the patient's financial or medical situation, the success of the proposed legal initiative would depend on including all relevant parties, including doctors and pharmacists, in its purview. The Janaushadhi campaign (people's medicine in Hindi) was started by the Indian government in 2008 to increase access to generic medications by establishing a nationwide network of generic medicine pharmacies under access. In Tumkur district, Karnataka, Southern India, the Institute of Public Health, Bangalore, partnered with the Alliance for Health Policy and Systems Research, WHO,

to conduct a research project on generic medicine usage perceptions.

The Clinical Trials Registry of India received a copy of the study registration. The data gathered indicated that in addition to focusing on expanding access to generic medications, policies, and programs should also ensure that the population groups that most need them are receiving high-quality public health care. In comparison to the rise in health-care spending, the percentage spent on developing pharmaceutical medications has been rising globally. Many portions of the population lack access to essential health-care services and medications as a result of the bloated national expenditures caused by this enormous gap. The fact that India is a major producer of generic medications attests to the well-known fact that using generic medications could reduce health-care costs. This has not, however, resulted in trustworthy, affordable generic medications becoming available to the general public.

The cost of healthcare has significantly increased in the last year as a result of numerous laboratory tests, the use of more expensive name-brand medications, Advanced diagnostic techniques utilizing state-of-the-art technology, strict security and sterilization agreements, routine institution (hospital) preservation charges, etc. The majority of the money spent on health care is spent on these medications.[4] Several developing and impoverished nations require households to cover a large amount of health costs out of their own pockets, which can result in a financial crisis, limiting access to healthcare, or in financial ruin or impoverishment.

It will be beneficial to reduce these costs as much as possible without sacrificing health-care quality. The introduction of generic medications by the Indian government in 2008 was done only to offer the general public access to affordable healthcare. In the Pradhan Mantri Bhartiya Jan Aushadhi Kendra, generic medications were made available (PMBJP). Using generic prescription drugs could help manage the increasing costs of medicines without compromising the quality of health care. Increased use of generic medications can make health care more affordable without sacrificing quality as we work to deliver a high-quality health-care system to the community with limited resources at our disposal. Generic medications may be offered as branded generics or under non-proprietary names. Branded generic drugs combine the generic medication's common name with the manufacturer's name to create a distinct brand identity.[4]

As a result, the producer can advertise the output (product) in an approach that is comparable to the proprietary product. When a non-branded version of an innovative drug is introduced, its cost drops significantly, making it far more affordable for a greater number of patients. Mainly through the treating physicians, generic medicine information can be spread within the patient community. However, there has not been much emphasis placed in the medical curriculum on the use of generic medications. As a result, it appears that the medical community lacks a comprehensive understanding of generic medications. The best use of generic medications is being hampered by this many studies have shown that patients taking generic pharmaceuticals followed their regimens significantly more faithfully than those taking brand-name meds. Therefore, the current study was created with the objectives of evaluating doctors' knowledge, attitudes, and practices regarding the use of generic medications, identifying the key elements that may serve as obstacles to the widespread use of generics, and providing suggestions to lessen such elements.[4,5]

Every pharmaceutical drug has a brand when it is initially released. Pharmaceutical firms invest a significant sum of money in the creation of new medications. The businesses that created these drugs have filed patents to recoup these costs, which amount to an average of US$1.2 billion per drug to keep others from producing and marketing the medication so they can recoup their research and development (R&D) costs. These patents are valid for a set period, typically lasting between 10 and 15 years on average. After the specified duration, the patent for the medication lapses, permitting other companies to manufacture and sell it, now known as a generic version. Pharmaceutical firms have been known to extend their exclusive rights in the USA to increase revenues by paying generic producers to continue producing affordable copies of the drug.

There are around 10,000 drug manufacturing facilities and 800,000 retail locations in India; yet, only 100 corporations produce 95% of the country's pharmaceuticals, primarily through contract manufacturing. The regulatory and control system for drugs. India's health-care system is fractured between the federal government, the states, and the Ministry of Chemicals and Fertilizers' Medicine division. There are two ways that generic medications can be prescribed: either using just the generic name or by including the manufacturer's name in brackets alongside the generic name. Brand-name medications and generic medications are equally effective; they are just available at a later stage in the life cycle of a drug.

The firm that produces and sells a generic version of a brand-name drug is not the one that developed it. Generic medications are far less expensive than branded medications, costing between 25% and 10% of the cost according to Rao (2017); offer a substantial opportunity to reduce health-care expenses for individuals and the government alike when widely adopted. According to information from the US FDA in 2016, generic drugs are typically 80–85% cheaper than brand-name equivalents.[5,6]

However, there is no established method to regulate the margins within the supply chain. As a result, alongside promoting the use of generic medications, the government intervenes by setting prices for essential drugs through

a designated list. In addition, in India, there is a prevalent issue with the extensive use of Fixed Medicine Combinations (FMCs). The government takes action against irrational FMCs by banning them based on recommendations from expert committees, such as the instance in March 2016 when 344 combination drugs were prohibited. Despite these measures, pharmaceutical companies often challenge these decisions in court to safeguard their profits. The use of generic medications is growing around the world. Let's use the USA and Canada as two examples of nations. Almost 80% of all drug sales in the USA are made up of generic and over-the-counter medications. The USA receives several generic medications from India. In 2009, India and China provided 40% of the generic medications to the USA, and this percentage is rising. More than 75% of all prescriptions in Canada are for generic drugs, whereas only 20% of the money is spent on them.[7]

INDIAN GENERIC MEDICINES

The Indian government and the Medical Council of India have freshly stepped up their initiatives to encourage the use of generic drugs in an effort to lower health-care costs and make it more affordable for the country's poor. The government in line with the recently published 2017 Health Policy, betterment is dedicated to achieving universal health care and moving toward the right to health. The promotion of generic medications builds on a wealth of experience from several states, particularly Rajasthan and Tamil Nadu, which were early adopters of integrating generic medications into the public health system. To reduce stock-outs and significantly lower drug costs, these governments have enhanced their procurement processes by implementing e-tendering systems, which promote transparency, ensure quality control, and enable electronic monitoring of pharmaceutical inventory. India, the "World's Pharmacy," exports high-quality generic medications to 215 nations. The pharmaceutical sector in India is experiencing robust growth, estimated at around 20–21% according to reports from 2017. A recent nationwide study, known as the Medicine Survey – Core, analyzed a total of 47,954 samples of both branded and generic drugs mention in figure 3.[8]

3.2.2016 Expert Committee – According to the 2016 Medicine Survey – Core Expert Committee, 3% of drugs were of a subpar nature, and >1% were fake. These medications comprised the two branded and generic drugs. The claim that "branded medications are good quality whereas generic medications are poor" is untrue. In India, quality control must be made sure for both generic and branded medications.[8]

The process of creating new medications is expensive and fraught with failure. For instance, the likelihood that a drug undergoing phase I trials will successfully reach the market reduced from 10% in 2002 to 5% in 2008. By creating new drugs, innovative enterprises take a big risk but are rewarded.[8,9]

In accordance with patents that defend the innovator in medicine, drug patents in the EU currently have a 20-year lifespan starting with the submission of a patent application. Since the development of a new drug typically takes 10 years, this typically results in market protection of 10 years, for which an extension of up to 5 years can be granted by utilizing a supplemental protection certificate. Companies can charge more for new pharmaceuticals with proven health benefits than current norms since they have the only right to the patent during market protection, allowing them to recuperate their significant investments. After the patent protection period expires, there is no longer a justification for premium prices. Now that generic medications are allowed on the market, there should be open competition. Generic medications are alternatives to brand-name medications that have the same quality, safety, and effectiveness as the brand-name medication and whose bioequivalence with the brand-name counterpart has been established by suitable bioavailability tests. If bioequivalence has been established, as with generic clopidogrel, then this may hold true even when the generic is a different salt from the original. A narrative overview of cost savings from generic medications is what this article seeks to deliver. It will then consider how the generic drug market is evolving and the difficulties it is currently experiencing.[9]

CHANGES OF INDUSTRY STRATEGY

Pharmaceutical companies have altered their development and commercial strategies as the industry is experiencing a decline in the quantity of small molecules in its development pipeline. Over the past 10 years, there has been a notable shift toward the formation of mixed corporations through mergers and acquisitions, rather than the previous pattern of intense rivalry between original and generic companies following patent expiry in certain nations. Nowadays, many businesses have both an original and a generic division so that their sales do not decline when the patents on their best-selling medications expire. For instance, Ranbaxy Laboratories was purchased by Daiichi Sankyo, and Novartis has its own generic division with Sandoz. The opposite of this tendency is also true; Teva, the biggest generic business globally, today receives about 40% of its revenue from original pharmaceuticals.[10]

CURRENT OBSTACLES FACING THE GENERIC MEDICINE SECTOR

Despite the necessity of creating a market for unbranded drugs to assist in controlling rising health-care costs, the generic medication sector is now dealing with a number of difficulties that could jeopardize its long-term viability. A significant obstacle for the generic medicine sector is the delayed market access of generic medications following the patent expiration of originator medications. Originator companies

employ various tactics to prolong their market exclusivity for medications. These tactics include patenting minor features of drugs to create dense patent networks, engaging in legal battles in national courts, and intervening in the generic drug development process. These strategies, often referred to as "evergreening" or "product life-cycle management," are aimed at delaying the entry of generic competitors into the market. Delayed generic drug availability lowers the return on investment in a fair amount of time, which could impair the competitiveness of the generic drug market and potentially jeopardize its long-term viability. Since the global market for pharmaceutical products is expected to reach US$50–100 billion in sales between 2008 and 2013 and US$255 billion between 2011 and 2016, delayed access to generic medications is also bad for health-care payers and patients, whose access to reasonably priced medications is restricted. Therefore, steps should be taken by authorities to ensure that generic medications have quick access to the market after their patents expire, provided that they comply with the most recent marketing authorization standards, such as those established by the European Medicines Agency (EMA) and FDA.

Recently, a few encouraging steps have been made in Europe to facilitate faster entry of generic drugs into the market. Instead of 180 days, a change to the transparency mandate suggests a time frame of 60 days for pricing and reimbursement decisions involving generic medications. Following the submission of multiple amendments by the European Parliament, the Commission's proposed language is still being considered. In addition, the recent of a Unitary Patent and a Unified Patent Court across the European Union, embraced by all member states except Italy and Spain, is expected to enhance legal clarity for all stakeholders, guarantee consistency in how patents are interpreted across the board, and shorten market access delays.[10]

Branded medications typically cost 2.6 times as much as generic versions. In certain nations, The price difference is greater than ten-fold. As health-care costs rise and insurance coverage falls below 17%, a quarter of Indians experience poverty as a result of excessive out-of-pocket (OOP) medical spending. Drugs account for the biggest budget percentage of OOP spending or over 80% of the total.

The majority of the time, the public sector in the nation purchases unbranded generic medications. Yet, assessments have shown that public sector hospitals have a very low supply of necessary medications. Low-income patients are thus forced to forgo therapy altogether or purchase more expensive medications from the private sector. Strong advertising is used to market branded medications, and these costs are included in their MRPs. Moreover, studies indicate that contact with medical professionals may affect prescribing decisions and lead to cognitive dissonance among prescribers. The common man cannot afford the necessary medications due to pharmaceutical firm's unethical practice of bribing doctors to write more and more prescriptions. Although prescription standards encourage the use of generic prescriptions, the majority of the prescriptions list branded medications.

The topic of discussion is – doctors are worried about the effectiveness and quality of generic drugs given by Indian producers. According to the FDA, generic medications are subject to strict quality assurance and bioequivalence rules and are equally as effective as branded medications. Nonetheless, India has been criticized for its supply of phony and fake drugs sold as generics. According to a survey from the Central Drugs Standard Control Organization, the prevalence of fake pharmaceuticals in retail pharmacies is substantially lower than many sources had predicted. Merely 0.046% according to research, the World Health Organization, and the media.[5] Originator businesses also adopt measures to maintain their market share after generic medications have entered the market. Some original product firms simultaneously lower the price of their goods in response to the decreased cost of generic medications, especially in nations where the cost of generics is already high. It is debatable whether this is an issue, particularly from the perspectives of those who pay for healthcare and the patients.

From their perspective, it should not matter if the medication is a brand-name or un-brand name seeing they receive reduced costs. Nevertheless, the generic drug industry's business strategy is predicated on the provision of medications in large quantities at low costs. It is possible that this business model will not last in the long run when generic businesses provide low pricing without gaining significant market shares. The prices in the market for generic medications are likewise consistently under downward pressure. For instance, the tender-like "preference policy" in the Netherlands reduced the cost of generic medications by 76–93% or more. Companies have pulled some of their items off the market as a result of these reduced price levels. In addition, pharmacies' long-term viability is in jeopardy because they depend on manufacturer discounts that have since been withdrawn due to the absurdly low-profit margins. Revision of the chemist compensation system similar to that in the UK is one method to get around this. Pharmacies in Denmark are required to submit their minimum expenses every 2 weeks, and alone the most affordable drugs will be completely satisfied. Due to this, businesses that specialize in providing cheap generic medications in small quantities have gained popularity, driving away pharmaceutical enterprises that provide a wide variety of medications.[10]

In Canada, the federal government recently opted against using a bidding process because they considered a steady and diverse medicine supply to be of utmost importance. Instead, the government chose to lower the cost of six popular generic medications. To reduce their spending on pharmaceuticals, in 2010, the Spanish government introduced significant price cuts of up to 30% for both branded and patented medicines

and their generic counterparts. The Australian government has reduced the cost of drugs with an equivalent treatment. Depending on the quantity of discounting provided to pharmacies, these price cuts varied in size.

The cost of so-called F2A medications, which were not subject to significant discounts for pharmacies, had to reduce by 2% in August 2008, 2009, and 2010, as well as in October 2010. F2T medications, or medications entitled to significant discounts to pharmacies, were required to lower their prices by 25% in August 2008 and 5% in October 2010. In addition, the government has implemented a generic pricing disclosure mechanism to help people better understand the extent of savings provided by generic manufacturers and to lower their costs appropriately. The use of external price referencing, utilized by 23 EU member states along with Norway, has effectively driven down the cost of generic drugs. All nations that have this country in their reference basket see their prices reduced as a result of this inclusion. A country with cheap drug prices is added to the reference basket. For instance, Greece, a nation with affordable drug pricing, is one of the 12 European nations listed in the reference basket. All of these tendencies could endanger the long-term viability of the generic manufacturing sector, particularly if these measures are not supported by policies that promote and increase the utilization of generic drugs.[9,10]

FOCUS ON THE DEMAND SIDE

The government should prioritize implementing demand-side strategies alongside measures to enhance market entry for generic medications. This dual approach is crucial for ensuring the generic medicine industry can achieve competitive and lasting pricing. These strategies should focus on encouraging the use of generics over branded and patented alternatives, particularly in cases where generic and brand-name drugs are essentially identical for all patients, like certain classes of medications such as proton pump inhibitors, statins, and renin-angiotensin inhibitors. Physicians, pharmacists, and patients should all be the focus of demand-side measures.[11]

A range of strategies, such as counseling, promoting the adoption of international non-proprietary names (INN), setting standards through benchmarking, offering financial rewards, establishing clear prescribing goals, and implementing prescribing guidelines can encourage and support doctors to preferentially prescribe generic medications. By enabling generic substitution, pharmacists can be encouraged to dispense generic medications. Targets for substitution are also included, as shown in France. However, it is crucial to modify their compensation structure so that the distribution of generic medications is either profitable or cost-neutral.

In addition, their compensation should reflect the counseling role they play in educating patients about their new generic medication, which may differ by brand, color, shape, flavor, and other factors. The patient might experience confusion and inadvertently consume both their previous medication and the new one simultaneously if they are not well-informed about this new drug, or they may even skip taking any medication altogether. A highly effective approach might involve compensating pharmacists based on their performance through a fee-for-service model, which includes talking with patients and allaying any anxieties. In addition to this, INN prescribing ought to be promoted, with the exception of a small number of well-known examples. As a result, when the original inventor loses its patent, the prescription will not alter. This reduces patient confusion, improves the perception of generics, and eliminates the need to pay pharmacists to consult with patients about their prescriptions.[11]

The community's health can be upgraded and kept up with the assistance of pharmaceuticals. Controlling their taken a toll on health-care budgets, be that as it may, may be a noteworthy concern for all governments. Health-care costs are too rising as a result of the maturing populace, longer life anticipations, rising non-communicable infection dreariness, and the disclosure of newer biomolecules. When other pharmaceutical companies begin making "non-exclusive" forms of the initial trend-setter item, the cost of a sedate ordinarily drops when the drug obviously terminates. A non-exclusive medication, as defined by the World Health Organization (WHO), maybe a medicine delivered without authorization from the initial innovator and presented to the showcase once licenses or select rights have passed. These solutions are planned to be conversely with the first item and are comparable in terms of dose shape, quality, organization strategy, quality, security, execution, and expected utilization. Concurring to the (FDA), created to be the same as a medication that has as of now gotten authorization, a non-specific sedate is what the EMA depicts as such.

A non-specific medicine has the same dynamic fixings as a reference medication and is managed at the same dose to treat the same diseases as the reference drug. In any case, the medication's moniker, appearance, and packaging may vary from the reference medicine. The Drug Cost Competition and Patent Term Restoration Act, sometimes known as the Hatch–Waxman Act, was passed by the American Congress in 1984. This Act was given for the recording of Abbreviated New Drug Applications, which simply required the non-specific businesses to show that their item is indistinguishable from the original in terms of bioavailability and pharmacological impacts.[10,11]

The Hatch–Waxman Act ensured the faster and easier availability of generics at the same time. Enacted by the US Congress in March 2010, the Biologics Price Competition and Innovation Act expedites the licensing process for bio-similar products, which are considered, for regulatory reasons, generic versions of biotechnology medications. Over the past 20 years, many other countries most notably developing countries such as China and India have created

their own regulatory systems for the approval of generic copies of cutting-edge drugs. These standards are generally similar across countries, with the exception of a few minor variations in the minimum stability threshold and the number of show batches.[10,11]

EXTEND OF USE OF GENERIC MEDICINE

There has been a global uptick in the use of generic medications due to their cost-effectiveness. Prescription data shows that the percentage of prescriptions written for generic drugs varies from under 50% in countries such as India, Canada, Japan, and Africa to over 80% in the USA, the UK, China, and Australia. Since the mid-1970s, the pharmaceutical industry has witnessed a surge in the generic drug market, particularly in the US, which was highlighted between 1975 and 1987 when patent protection for more than 56 significant drugs expired. The top five international markets for unbranded generic drugs are the USA, EU (Germany, United Kingdom, and France), Canada, Japan, China, and India. In 2010, the global generic market was valued at around $110 billion out of a total pharmaceutical market of $800 billion. By 2015, it is projected that the global generic market will have grown at an annual rate of 9%, reaching $129.3 billion.[12]

COST AND AFFORDABILITY

Generic medications are more affordable than innovator drugs because generic manufacturers do not invest in R&D, marketing, or advertising. They compete with branded drugs by offering lower prices after the patent expires, ensuring that patients can afford them. The use of generic drugs has led to over $1.2 trillion in cost savings in the US over the past decade, particularly during times of high demand such as health-care crises or pandemics. Competition among generic manufacturers drives prices down, improves access, and ensures a consistent supply. Generic drugs are especially beneficial for patients with chronic diseases, as they have been found to improve long-term treatment compliance compared to branded drugs, possibly due to the lower cost. While generic medications help reduce health-care costs, their development has become more expensive due to stricter regulations and the depletion of innovative compounds. Over the next 3 years, health-care costs are expected to increase by 5%, but increasing the use of generic drugs could help mitigate this cost increase without compromising health-care outcomes.[11,12]

LEGAL ISSUE

Pharmaceutical breakthroughs are considered intellectual property, granting creators the exclusive right to set their price above production costs for a specified time, thereby controlling manufacturing and marketing. This exclusivity can lead to high costs for patented drugs, making them unaffordable for many, particularly the poor in developing and impoverished nations. The high prices help protect the innovator's investment in the new product. To strike a balance between societal affordability and inventor reward, the World Trade Organization established the Trade-Related Aspects of Intellectual Property Rights Agreement.[13]

QUALITY ISSUES

Due to ongoing worries about their quality among doctors and patients, the usage of generic medications is still not ideal. In terms of safety and efficacy, generic medications are frequently thought to be of lower quality than their branded counterparts. Even though generic versions of medications are readily available and more affordable, brand-name medications are frequently prescribed. One reason for this is that doctors do not trust the quality of generic medications. These are some of the explanations for this view of generic drug quality.[12,13]

INADEQUATE GOOD MANUFACTURING PRACTICES (GMP)

Once a generic drug has received marketing approval, there is no requirement for quality retesting; it is assumed that the manufacturer is adhering to GMP standards. However, this assumption proved faulty in 2010 when the EMA recalled all batches of eight centrally authorized generic clopidogrel-containing medicines from AcinoPharma GmbH. The active ingredient for these drugs was produced by an Indian company, Glochem Industries Ltd. An inspection of the Glochem production facility in Visakhapatnam revealed GMP violations, highlighting the limitations of relying solely on GMP standards and assumptions of quality in generic drugs.[12,13]

ISSUES IN BIOEQUIVALENCE TESTING

The FDA withdrew approval for budeprion XR 300 mg, a generic version of bupropion because a study found it was not sufficiently bioequivalent to the brand-name Wellbutrin XL 300 mg. The study used healthy volunteers for ethical reasons, as bioequivalence studies are typically conducted in this manner. The main issue was that the approval for generic budeprion XR 300 mg was based on tests at a 150 mg dose, which was not an appropriate bioequivalence testing approach. The FDA authorized the waiver because the higher dose of bupropion might cause seizures in healthy individuals.[13]

PHYSICIAN PERCEPTION

The negative perception of generic medications by many doctors serves as a substantial impediment to their broad adoption. In a poll of physicians' opinions about generic medications, it was discovered that 25% of respondents voiced concern about their effectiveness, and more than half had reservations about the standard of generics. Furthermore, about 25% of people said they did not want to utilize generics as their first choice of prescription for themselves or their loved ones. Perhaps because younger physicians receive their training in a setting where generic medications are more commonly used, older physicians specifically had the worse impressions of generic medications. The reasons why doctors recommend branded medications are influenced by a number of factors. Therefore, it is essential that the value of adopting non-proprietary names be highlighted to medical trainees from starting of training, and service. The use of generic nomenclature should also be given in medical colleges and hospitals.[14]

PATIENT'S PERCEPTION

While generic medications are generally cheaper, many people still prefer to buy the more expensive branded ones. Several psychological factors could influence this decision. The proper management of many illnesses can be ensured by the timely and effective administration of medications, which can also help patients avoid or delay the need for expensive medical care. Importantly, using generic medications has the potential to significantly reduce costs for patients and health-care budgets while still effectively treating many of today's illnesses. Branded medications have undoubtedly influenced how people use medications, but generic medications, which are bioequivalent to their brand-name counterparts, are seen as both safe and affordable alternatives. Economic pressures on medication budgets have led to a steady increase in the use of generic medications worldwide.[14]

In this study, a "consumer" refers to someone who buys medication for personal use or to treat a condition. Given that they are usually cheaper than their brand-name counterparts, generic medications offer the potential for significant health-care spending reductions, benefiting both consumers and governments. Using generic medications for established therapeutic care, health-care systems and patients would have more funds to spend on the generally more expensive, new products needed to treat diseases for which there are currently no effective pharmacological treatments.[14]

Consumer perspectives on the risk associated with using generic medications have been overlooked in this conversation, and their views on whether to use branded or generic medications have been considered. Early research on generic drugs has examined the attitudes, risk perceptions, knowledge, and satisfaction of patients, doctors, and pharmacists. Most of these studies were conducted in the United States. A Florida-based study looked at the preferences of 510 customers for accepting generic medications. Regardless of potential savings, approximately 66% of survey respondents rejected less expensive generic options. Older and wealthier individuals who rejected them believed the drugs were less effective. Only two of the 18 variables studied significantly affected a person's preference for generic medications. The first was age, with older respondents being more hesitant to switch to generic alternatives. The second was efficacy beliefs, with those who rejected believing that cheaper medications were less effective in treating illnesses.

In a 1978 study by Bearden and Mason, 105 consumers were asked about their perceptions of the risks associated with using generic drugs. The theory of reasoned action by Fishbein and Ajzen, which suggests that an individual's behavior is influenced by their beliefs about the risks or consequences of that behavior, weighted by the perceived value of these consequences, served as the theoretical basis for this study. The potential and importance of loss were measured across six dimensions: financial, social, drug performance, psychological, physical, and convenience.[7]

In a survey of customers, it was found that about one-third had a favorable attitude toward using generic medications, another third had a negative view, and the remaining third were neutral. People who were against using generic drugs perceived higher risks and gave them more importance in six key aspects compared to those who favored generic drugs. However, those in favor believed that generic drugs were of good quality, safe, made by reliable manufacturers, and would work well. Further research showed that customer concerns about drug performance, financial loss, and safety influenced their attitude toward generic medications.

In another study, consumers generally believed that using generic prescriptions would not expose them to higher risks, and they saw prescription generics as a reliable and consistent source of medicine. They also agreed that brand-name drugs were more expensive due to advertising costs and were hesitant to use drugs from unknown manufacturers. However, they believed that generic drugs would still be effective. Overall, consumers were open to the idea of using generic drugs as they believed it would save them money. The study highlighted the importance of educating doctors about prescribing generic drugs early in their careers and the role of other health-care professionals, such as pharmacists, in health-care delivery.

In a survey of 621 customers in Texas in 1988, about 33% said they had never bought generic prescription drugs. Consumers generally saw generic drugs as lower quality, more dangerous, less effective, and less healthy compared to branded drugs. However, older respondents were more likely to see generic drugs as higher quality than younger ones. In another study of 389 college students, branded drugs were

perceived as more valuable, effective, and less likely to cause side effects than generics. The more dangerous a prescription drug was perceived, the more likely the respondent was to view a brand-name drug favorably.[15]

In a field experiment in Canada, about 80% of patients accepted a generic drug when offered as an alternative to a brand-name drug. Patients were less likely to accept a substitution if they were older, less educated, or had insurance covering prescription drugs. Satisfaction with generic drugs was lowest among those who had no choice but to use them and those who received them for free.

The decision to choose a generic drug, the belief in significant cost savings, and the need to cover some or all of the medication's cost all influenced the decision to buy another generic drug product in the future. Kendall *et al*. reached a similar conclusion to earlier authors: the rate of generic replacement would rise if pharmacists actively promoted generic medications and patients paid a portion of the medication's cost. More than 84% of consumers were aware of the term "generic drug," according to an AARP survey conducted and published in 1994. According to the study's author, over 33% of Americans aged 45–65 had asked their doctor for a generic drug and requested their pharmacist to fill a prescription for one. However, a slightly lower percentage (29%) of people aged 65 and older were likely to ask for a generic version of a medication. In 1994, Muirhead surveyed 876 Americans to understand their attitudes toward managed care and generic drugs. About 40% of those surveyed said they were inclined to request generic substitution. According to the research, 36% of doctors and 34% of pharmacists had requested generic substitution on behalf of their patients. Twenty-nine percent of consumers believed generic products and name-brand products were "equal" in terms of quality, whereas 45% thought they were "about the same." Those with lower incomes were more likely to believe that generic medications were of lower quality than those with higher incomes.[15]

The concept of risk associated with the use of generic medications was revisited by a consumer survey completed in 1995 but released in 2000. In a survey of 355 individuals in central Wisconsin, United States, Ganther and Kreling found that consumers' perceptions of the risks associated with generic prescription medications varied depending on the medical condition being treated. Participants were asked to evaluate the relative risk of choosing a generic medication over a name-brand one for heart conditions, high blood pressure, streptococcal throat infection, pain, and cough. The majority of respondents (54%) said that substituting generic prescription medications when treating heart conditions was riskier than when treating streptococcal throat infection (14%). In addition, respondents stated the amount of cost savings they would need to experience before choosing a generic drug over a branded one. For a cost savings of less than US$2, more respondents were willing to take the generic medication as the risk rating for the medical condition fell. The percentage of people who required a cost savings of at least $15 or who refused to purchase the generic product at any cost savings rose in proportion to the risk rating. The authors concluded that providing consumers with financial incentives may help them adopt generic items more frequently. Ganther and Kreling highlighted patient education by the pharmacist as another crucial element in promoting generic medicine use for medical diseases viewed by patients as high risk, in line with authors of earlier studies.[15]

Consumer knowledge of medication-management techniques (formularies, prescription co-payments, prior authorization, and generic substitution) in a study that was published in 2000. A total of 303 managed care organization members in the US states of West Virginia, Pennsylvania, and Maryland received this mail survey. A little over 51% of those surveyed said that their health plan required generic substitution. Customers agreed that generic substitution had an impact on their adherence to medication. The customers' opinions on the claims that "generic substitution makes it more convenient to get my medicines" and "generic substitution limits my chances to get the best medicine" were both unfavorable. The assertions "generic substitution results in less effective medicines" and "generic substitution compromises the quality of my medicines" received only moderate support from consumers.

While consumers' responses to a general question about their attitudes toward generic substitution were somewhat positive (mean SD=4.6 1.99 on a seven-point scale where 1 is negative and 7 is positive), even though these statements suggested a slightly negative view of generic substitution. Overall, the consumers in this group had a slightly positive attitude toward generic medications, according to the authors, and they were most aware of generic substitution and prescription co-payments as ways to control drug costs.[14,15]

The acceptance of substituting brand-name drugs with generic ones for chronic conditions was evaluated in primary health-care practices in Spain, where drug patent legislation was introduced in late 1997 and generic drugs only accounted for 0.15% of the Spanish drug market. During a 12-month prospective randomized multicenter study, an educational intervention on generic drugs was provided to patients receiving medications for chronic diseases during their visits to various medical practices in Barcelona for repeat prescriptions. A total of 27 public primary care facilities were randomly assigned to either an intervention group (eight facilities) or a control group (19 facilities). In the intervention practices, generic prescribing increased to 5.9% of the total population, compared to 2.8% in the control group. Individual educational interventions led to a high incidence of generic acceptability among patients who received repeat prescriptions shows in figure 4.

Only one study from Brazil was found regarding emerging

nations. In this study, the authors assessed the population's awareness of generic medication characteristics, estimated the fraction of generic drug use from the overall amount of medicines consumed, and examined the most prevalent factors that consumers consider when making drug purchases. A representative household sample was selected, resulting in a final sample of 3182 people. Data were collected using structured interviews. Interviewees were asked about their medication use in the previous 15 days and were asked to show the packaging and prescriptions. Based on this information, drugs were classified as branded or generic. The study also examined the strategies used by interviewees for selecting medications for their most recent purchase made during the preceding 15 days or their habitual technique if they had not bought any medications during that time.

INTERVIEWEES WERE ASKED IF THEY

1. Always buy the exact prescription medication?
2. Always replace the prescription medication with the corresponding generic medication?
3. Always replace the prescription medication with a formulated product? Moreover,
4. Always replace the prescription medication with a less expensive alternative, regardless of whether it is a generic, formulated, or similar medication?

The findings indicated that 3.9% of all medications were generics. However, only 57% of individuals were aware of any packaging features that distinguish generic medications from others, despite the fact that 86% were aware that generic drugs are less expensive and 70% were aware that their quality is comparable to that of brand-name medications. The majority of individuals reported purchasing exactly what was prescribed, leading to the conclusion that price and medical prescription are the two most significant factors in drug selection.[16]

In a recent Australian study, researchers employed qualitative methodology to investigate consumers' thoughts and attitudes toward generic medications and to identify any barriers that might prevent their use. Thematic content analysis of interviews with 16 customers in Melbourne, Australia, ages 22–80, revealed four topics related to the use of generic medications. These included generics-related knowledge, generics acceptance, generics rejection, and generics-related educational needs. According to this survey, the majority of patients were more familiar with the term "cheaper brand of medicine" than they were with the term "generic medicine." Cost was the main factor in acceptability, while influence from doctors, side effects from generic brands, and confusion from using many brands were the main hurdles.[7]

The authors concluded that individuals generally held favorable views regarding the use of generic medications. They suggested that direct patient education by health-care professionals on matters related to the safety and effectiveness of generic medications could further enhance their acceptance. Bristol-Myers Squibb recognized three generic brands of warfarin as bioequivalent to Coumadin in Canada since 2000. Generic warfarin has also been incorporated into provincial drug formularies. Pereira *et al*. investigated individuals' attitudes and beliefs toward the use and prescription of generic versions of brand-name warfarin in this context. Respondents were asked to rate their agreement with 10 statements about generic brands and, more specifically, the safety and effectiveness of generic brands of warfarin compared to brand-name warfarin on a scale of 1–7 (1 being "strongly disagree" and 7 being "strongly agree"). A total of 81 participants in a clinic for anticoagulation out of 500 completed the surveys. Overall, respondents were comfortable using generic brands of medications and were familiar with them (42.5% and 46.9%, respectively). Less than 5% of all respondents agreed or strongly agreed that taking generic warfarin instead of brand-name warfarin was a good idea because it was less expensive.

Patients taking branded warfarin, on the other hand, did not believe that the reduced cost of generic warfarin was a good reason to take it. According to 14% of respondents, generic warfarin is neither as safe nor as effective as brand-name warfarin. In addition, 32.1% of respondents agreed or strongly agreed that they knew that generic versions of medications such as warfarin had to go through bioequivalence testing with brand-name versions of the same medication, and the same percentage felt that this testing was necessary to ensure the safety of the generic versions. Brand-name warfarin users were less likely to concur that generic warfarin products are equally secure and efficient as branded warfarin. The majority of people who responded to the questionnaires said they were not aware that generic medications go through the same rigorous testing as brand-name medications such as warfarin. The authors came to the conclusion that most patients had an unfavorable opinion of generic warfarin, but a small number of them expressed worries about generic substitution and a clear ignorance of warfarin's bioequivalence laws. Norway's new pharmacy law, which went into effect in March 2001, permitted Norwegian pharmacists to substitute a generic version of the initial prescription drug. According to a list created by the Norwegian Medicines Agency, pharmacists in Norway are required to notify the patient about the least expensive generic medication that is readily available. The patient may opt out of generic substitution with the help of the doctor, although in some circumstances the patient may end up paying more. To evaluate patients' attitudes toward and experiences with generic substitution 3 years after it was made legal for prescription drugs to be replaced with generic versions.[16]

Kjoenniksen *et al*. performed a study in 2006. The poll found that a significant portion of patients (41%) declined to have their drugs changed, two-thirds of those who utilized generic

medications expressed satisfaction, and around one-third of those who switched reported having bad experiences. This shows that some patients do not see the use of generic drugs as a comparable replacement for branded drugs, and these patients might need more information and assistance. This demonstrates that initiatives to encourage generic substitutes should concentrate on health-care professionals in the first place. When it came to whether or not patients converted to generic medications, information about generic substitution had a major impact. Doctors and pharmacy personnel working together appeared to be the most successful strategy.

Beginning in April 2003, Finland implemented generic substitution in an effort to slow the rise in societal and individual medical costs. Unless the patient rejects or the doctor forbids replacement, which the doctor can do for medical or therapeutic reasons, pharmacists are required to substitute the cheapest or nearly cheapest medicine for prescription medicine. A descriptive study was done by Heikkila *et al*. to investigate the views, attitudes, and experiences of physicians and customers regarding this legislative reform. Two questionnaires were used to examine customers' opinions: the first was given to customers (n = 544) who had refused generic substitution in 15 pharmacies across five different regions of Finland, and the second was given to customers (n = 214) who had accepted substituted medications at least once in 18 pharmacies across six different regions.[17]

They discovered that the majority of clients agreed with the physicians that generic substitution was a suitable reform strategy. Customers who had accepted it and had experience with it believed that generic substitution was a good reform strategy. Customers who had rejected substitutions might have had a bad impression of them or they might have been cautious about this reform. The main justifications for accepting alternatives were the cost savings on medical bills and the pharmacists' recommendations. The pleasure of previously used medications was the main justification for rejecting substitution. Most of them believed that less expensive medications were just as potent and secure as more expensive ones. The authors came to the conclusion that generic replacement had been a successful reform strategy, but that some customers had initially been uncertain and wary because of the unfamiliarity of the situation. To investigate the impact of sociodemographic factors on lay beliefs about generic medicines, Figueiras *et al*. conducted a cross-sectional survey in Portugal in 2007 to examine the relationship between the prevalence of common illnesses such as angina pectoris, asthma, and influenza on the level of agreement with the prescription of generic medications. Over the course of 4 weeks, 1278 people from Portugal's general population were recruited for the opportunistic sample. A total of 101 questionnaires were left blank, and 52 respondents opted out, resulting in a final sample of 1125 Portuguese (88% response rate; 61% females; and mean age 33 years).

Participants' perceptions about generic pharmaceuticals' effectiveness and likeness to name-brand medications appeared to be well-defined. Depending on the age group and education level, there were considerable differences in attitudes toward the effectiveness of generic medications. Participants showed a moderate level of agreement with the prescription of generic medications for angina pectoris, asthma, and influenza, but their agreement fell down dramatically as the severity of the illness increased. Overall, the findings showed that participants usually thought generic drugs worked and were comparable to name-brand drugs. The more educated and younger individuals had the strongest opinions regarding the effectiveness of generic medications, whereas the older participants held the strongest opinions regarding the likeness of generics to their branded counterparts. Iosifescu *et al*. examined socioeconomic and health status characteristics, health literacy, and physician communication skills as potential predictors of older individuals' opinions about generic medications in a study they published in 2008.

Interviews with adults over 65 (n=311) took place in two primary care clinics of a tertiary care hospital. A scale that contrasted generic and brand-name medications across four dimensions was used to examine participants' beliefs regarding generic medications. The non-white race, lower levels of education and wealth, and having Medicaid coverage were all linked to negative generic drug attitudes. People who indicated that their doctors had poor communication skills and had little health literacy were more likely to have negative opinions. Consumer views and understanding regarding the problems with generic medications were examined in a recent study conducted in Malaysia. A total of 400 respondents received survey forms over the course of 5 days at an annual university open day.[17]

Only 28.3% of respondents to the 396 usable forms that were analyzed knew what the term "generic medicine" meant. Seventy percent of the respondents were unaware that generic medications were being marketed under alternative names, and 34% of the respondents said that pharmacists had given them information on generic medications. The majority of consumers (64%) acknowledged that generic drugs are less expensive than their branded counterparts, and 32% believed that generic drugs have more negative effects. This investigation revealed a gap in consumer knowledge and comprehension concerning generic medications; health care providers' educational outreach may be the key to boosting generic acceptance.

Table 1 compares the studies that have been examined, highlighting techniques, research settings, sample sizes, results, and limitations.[7] The World Health Organization (WHO) defines generic medications or generics as pharmaceutical products that are often marketed after the expiration of a patent or other exclusivity rights and are designed to be interchangeable with the innovator product.

Table 1: Generic versus branded medicines dosage

Pharmacological group	Brand-name (strength)	Brand name price per unit dose (LYD)	Generic (strength)	Generic price per unit dose (LYD)
Antibiotic	Cipro (750 mg)	0.70	Ciprofloxacin (750 mg)	0.65
Antibacterial	Flagyl (500 mg)	0.85	Amidazole (500 mg)	0.10
Heartburn/Ulcer	Zantac (150 mg)	0.45	Ranitidine	0.10
Hypertension	Renitic (20 mg)	0.25	Enalapril	0.25

Figure 1: Generic medicines

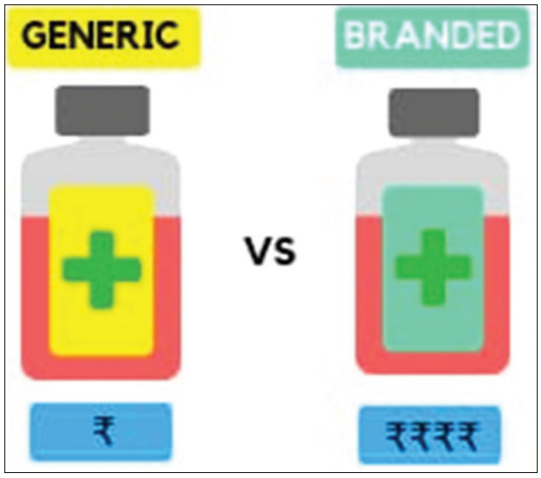


Figure 2: Generic versus branded

Figure 3: Safety effect and quality of generic versus branded

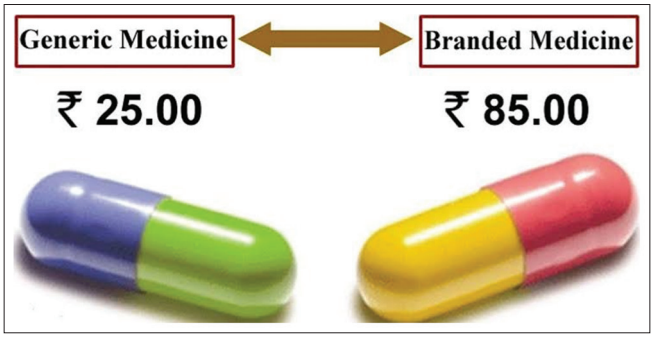


Figure 4: Prescription drug cost comparison

Generic medications are a blessing for those who typically disregard the risky effects on their health that only the expensive, branded medications may have. Because of this, it helps to improve the nation's health-care system. India's population finds it challenging to decide between branded and non-branded goods. However, in Western nations, where the idea of generic medications is widely established, there is no confusion between the two. In the United States, generic drugs were used to fill roughly 89% of all prescriptions, whereas India is still in its infancy shows in figure 5.[18]

The Medicines and Cosmetics Act, 1940, and Regulations, 1945 do not specifically define generic or branded medications. Generic medications, however, are those that include the same active ingredient(s) in the same dosage form, with the same amount supplied through the same route of administration, and with comparable safety and efficacy to those found in the branded medication. The standard of generic drugs Medicines and Cosmetics Act, 1940, and Regulations, 1945, which set the requirements for quality and efficacy for domestically produced generic and branded medications, must be followed by these products. Each is anticipated to have comparable outcomes.

Generic drug prices that are lower – Prescriptions must be written with generic names, and every doctor must administer medications in accordance with Clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Rules, 2002, Prescription drugs should be labeled with generic names. Medicines prescribed should be written

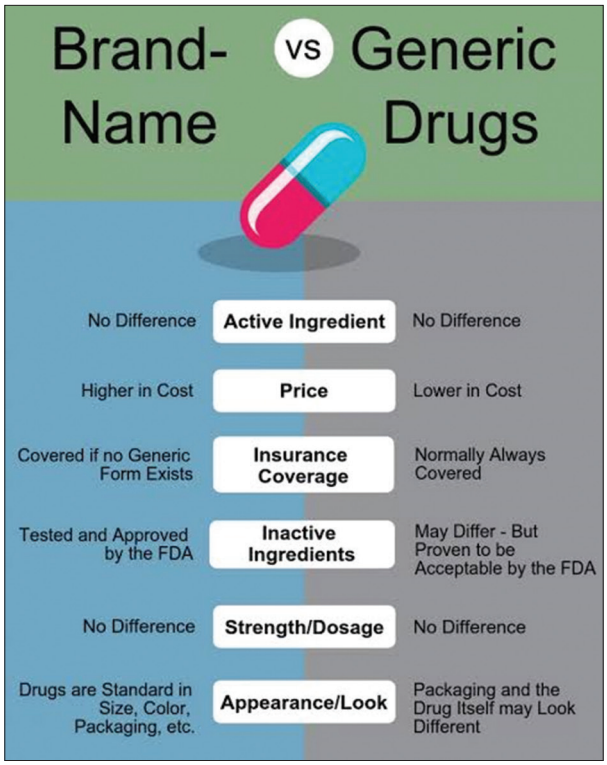
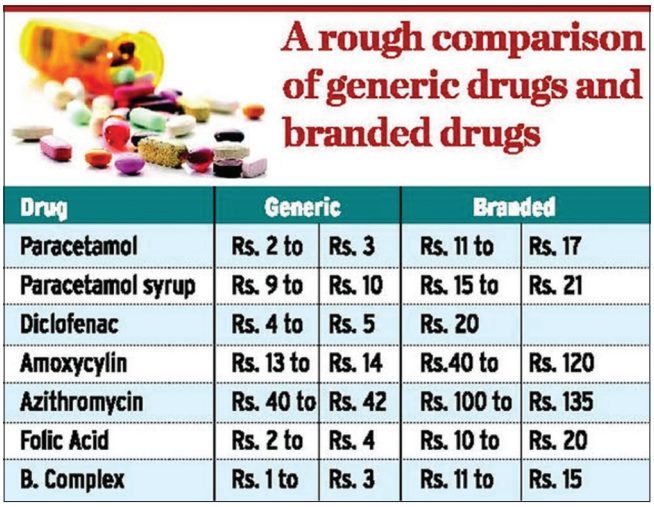


Figure 5: Brand name versus generic drugs



Drug	Generic		Branded	
Paracetamol	Rs. 2 to	Rs. 3	Rs. 11 to	Rs. 17
Paracetamol syrup	Rs. 9 to	Rs. 10	Rs. 15 to	Rs. 21
Diclofenac	Rs. 4 to	Rs. 5	Rs. 20	
Amoxycylin	Rs. 13 to	Rs. 14	Rs.40 to	Rs. 120
Azithromycin	Rs. 40 to	Rs. 42	Rs. 100 to	Rs. 135
Folic Acid	Rs. 2 to	Rs. 4	Rs. 10 to	Rs. 20
B. Complex	Rs. 1 to	Rs. 3	Rs. 11 to	Rs. 15

Figure 6: Comparison of generic and branded drugs

in capital letters, ensuring judicious medicine prescription and administration.

In addition, according to a Medical Council of India (MCI) circular dated April 21, 2017, all Registered Medical Practitioners (RMPs) are required to abide by the aforementioned rules. If a doctor violates the terms of the aforementioned Regulations, MCI, or State Medical Councils may take disciplinary action against them. MCI refers complaints on violations of the code of ethics for doctors to the relevant State Medical Councils (where the doctors/medical practitioners are located are authorized) to take the required measures. Furthermore, per Tele-Medicine Guidelines 2020 requirements, which were announced on May 22, 2020, all RMPs must utilize the drug's generic name in capital letters on the prescription format.

MEASURES TAKEN BY THE INDIAN GOVERNMENT

The Ministry of Health and Family Welfare of the Government of India has implemented a number of regulatory measures, including the requirement that licensing authorities will only issue or renew licenses to manufacture pharmaceuticals for sale or distribution when they are accompanied by correct or generic names. According to the 1945 amendment to the Drugs and Cosmetics Rules, it is now necessary to grant a license for a drug composition including a single active component listed exclusively by proper name. The Regulations, 1945's clause states that for some medications, submitting the results of bioequivalence research along with a request to be granted a manufacturing license is required. According to a law, drug inspectors from the central and state governments may conduct combined inspections of a manufacturing facility.[19]

A RISE IN THE MARKET SHARE OF GENERIC DRUGS

According to an economics-related scenario, the price of generic pharmaceuticals will decrease as their supply rises, which is an inverse relationship. What's the cause? The factors driving generics' growing market share. Medicines including drugs become public domain after their patents expire, making them more readily available and less expensive for pharmaceutical companies to produce. A high proportion of patients lack medical insurance or health insurance, Because they have been approved by regulatory agencies such as the FDA, generic pharmaceuticals and medications are seen as equally as safe and effective as branded ones. Heightened price competition shows in figure 6.[18,19]

ADVANTAGES AND DISADVANTAGES

Generic drugs are significantly cheaper than branded medications, often costing between 80% and 85% less. They are widely viewed as safe and reliable and are subject to the same governance and quality criteria as branded medications. Once their patents have expired, branded medications become public domain, allowing the production of generic equivalents by any manufacturer. This has pressured pharmaceutical companies to lower the prices of their branded versions due to the increased competition and lower cost of generic medications.

Several studies and regulatory measures have demonstrated the potential for significant savings through the use of generic drugs. For instance, a Dutch study estimated that replacing the branded versions of simvastatin and pravastatin with generic versions could save €4.2 million annually. In the Netherlands, a shift to a "preferred policy" for non-patent pharmaceuticals resulted in savings of €0.75 to €0.90 billion over 5 years. In Germany, savings from bid and rebate agreements totaled €2.09 billion in 2012, while in France, demand-side initiatives led to annual savings of €1 billion to €1.01 billion.[19]

In Scotland, specific measures to lower the price of generic medications and improve their prescribing versus patented products resulted in savings of GB£159 million for proton pump inhibitors and GB£290 million for statins in 2010. In Sweden, required generic substitution produced €700 million in savings from 2002 to 2005, with annual savings of €960 million anticipated through monthly generic medicine tendering.

A study in Ireland estimated that switching to the least expensive generic versions of the top 30 drugs could save €21.8 million while switching to the most expensive generic versions could save €15.4 million. The introduction of a generic form of fluoxetine in the Valencian region of Spain led to €8.3 million in savings for the health system.

In 11 European countries, enhanced generic substitution was projected to save €3 billion, around 38% of public spending on original medication. In the US, $1.07 trillion was saved on generic medications from 2002 to 2011, with $192.8 billion in savings in 2011 alone.

Overall, generic medications offer a cost-effective option for health-care delivery and have the potential to spur innovation by original manufacturers. Their lower prices result in reduced patient co-payments and improved adherence and can provide governments with additional funds for R&D of new medicines.

However, concerns have been raised that the growth of the generic drug industry could negatively impact pharmacological innovation, leading to reduced investments in R&D. India, often referred to as the "Pharmacy of the Third World," offers high-quality, reasonably priced generic medications while maintaining its public health protection and intellectual property laws.

Despite efforts by the Indian government to promote the use of generic medications, many doctors remain uncertain about their quality and effectiveness. A Knowledge, attitude, and practices survey approach is being used to study the attitudes, barriers, and actual practices of RMPs in Nanded City regarding the use of generic medications, with a focus on clinicians' knowledge and awareness of these medications, their attitudes and opinions toward them, and the factors that influence their prescription practices.[20]

DISCUSSION

We discovered that moving from branded generic to unbranded generic medications would result in significant cost reductions for drug customers. According to estimates, switching to generic drugs without brands would save patients' expenditures on medications by 6–129%. In addition, unbranded generic medications are discovered to be reasonably priced. These findings are in line with evidence from research in other LMICs. Major changes to pharmaceutical policy are required to effectively market generic medications. Regulations are required to facilitate chemists' use of generics in place of brand-name medications. In addition, CDSO is required to make sure that all generic medications offered on the Indian pharmaceutical market are bioequivalent, and any that pass bioequivalence tests must be displayed alongside their branded counterparts and prices on a public or PMBJP portal. The pharmaceutical business saves money by not promoting their product.

The pharmaceutical industry's motive for the selling of generic medications is to maintain a strong trading margin for wholesalers and retailers. Pharmaceutical corporations want patent protection for newly created molecules. Having a patent prevents any other pharmaceutical business from producing it for a 20-year period. They charge more to sell that chemical after it has been created since they hold the exclusive manufacturing rights. After 20 years, the patent expires and the formula enters the public domain, meaning that other pharmaceutical businesses can produce it. If multiple companies produce the same product, the price will naturally decrease. Particularly during times of elevated demand brought on by an unanticipated healthcare crisis or pandemic, competition among generic producers lowers costs while also ensuring enhanced access and consistent supply. Invariably due to limited economic potential and earnings, generic medications maintain continued supply even years after the innovator product has expired or such chemicals have been removed from the market. Furthermore, it has been discovered that chronic disease patients who are started on generic medications have greater long-term treatment compliance than those who are started on branded medications, probably as a result of the latter's higher price.

Thus, in addition to saving money, generic medications can increase patient compliance. The adoption of generic drugs appears to be influenced by consultation with health-care providers. When consumers had discussed a generic alternative with their healthcare professionals and those professionals had favorable opinions of generic medications,

the drugs were more likely to be accepted or used. In addition, it was discovered that customers' perceptions of generic medicine products were significantly influenced by their prior experiences with generics, their understanding of them, and the hazards related to them. According to several studies, past usage of generic products (such as non-prescription medications, groceries, etc.) and knowledge or awareness of generic medications have a significant impact on present or future use.

The less likely a consumer was to select or accept a generic drug product for treatment, the more serious or risky they perceived their medical condition to be. Last but not least, the prescription itself has a significant impact on the use of generic medications, particularly in underdeveloped nations where patients seek to purchase exactly what is recommended. Governments must create a cogent pharmaceutical strategy to assist the generic industry because today's innovator medications are tomorrow's generic medications. This is crucial for biosimilars since fewer small compounds in places with plenty of prescriptions are losing their patent protection than are biological pharmaceuticals, which make up a rising fraction of novel therapies under research. Biosimilars are drugs that are identical to biological drugs that have already received prior authorization. Conceptually, they are completely distinct from generic medications and, in certain instances, can even be thought of as unique products. There have only been a few discounts so far because of the intricacy of their production and perceived limitations on alternative opportunities.

SUMMARY AND CONCLUSION

According to this study, most of the medical students and interns were familiar that the indications for generic pharmaceuticals are likewise to those for standard medications in terms of effectiveness, safety, composition, dose, and other characteristics. They also support administering generic drugs to their patients and members of their own households.However, ignorance of the Janaushadhisugam app and the locations of nearby generic pharmacies posed the biggest obstacle to making the best use of generic medications through this several problems faced by generic medicines and the advantages, and disadvantages of generic medicines are elaborated on. Here, the topic of why branded medications are more expensive than generic medications when everything is the same arises. A generic medication typically costs less than its related branded medication. Since the pharmaceutical company does not advertise their product, money is saved. The pharmaceutical industry's motive for the selling of generic medications is to maintain a strong trading margin for wholesalers and retailers. Pharmaceutical corporations want patent protection for newly created molecules. Having a patent prevents any other pharmaceutical business from producing it for a 20-year period. They charge more to sell that chemical after it has been created since they hold the exclusive manufacturing rights. After 20 years, the formula's patent expires and enters the public domain, making it available to other pharmaceutical businesses to make something, and if numerous businesses produce the same item, the price will inevitably decrease.

REFERENCES

1. Rana P, Roy V. Generic medicines: Issues and relevance for global health. Fundam Clin Pharmacol 2015;29:529-42.
2. Chattoraj A, Pareek M, Thomas B, Doss S. Prospects and challenges of generic medicines adoption in India: Consumer and physician perspectives: Pharmaceutical science-pharma. Int J Life Sci Pharma Res 2022;12:51-60.
3. Chaudhary AP, Nelson KA, Sonar NS, Jamuna TR. Knowledge and perception of pharmacy students about generic medicine in India: Web-based cross-sectional study. J Young Pharm 2021;13:417-22.
4. Ahlqvist V Dube N, Jahre M, Lee JS, Melaku T, Farstad Moe A, et al. Supply chain risk management strategies in normal and abnormal times: Policymakers' role in reducing generic medicine shortages. Int J Phys Distrib Logist Manage 2023;53:206-30.
5. Jyothi B, Shetty R, Rai M. A study on assessment of knowledge and attitude about generic medicines among interns in a tertiary care hospital. J Pharm Biol Sci 2022;10:88-91.
6. Postma DJ, Notenboom K, De Smet PA, Leufkens HG, Mantel-Teeuwisse AK. Medicine shortages: Impact behind numbers. J Pharm Policy Pract 2023;16:44.
7. Lavtepatil S, Ghosh S. Improving access to medicines by popularising generics: A study of 'India's People's Medicine' scheme in two districts of Maharashtra. BMC Health Serv Res 2022;22:643.
8. Dylst P, Vulto A, Godman B, Simoens S. Generic medicines: Solutions for a sustainable drug market? Appl Health Econ Health Policy 2013;11:437-43.
9. Mahato TK, Raulji D. Present scenario of generic medicines in India: A comparative study. World J Biol Pharm Health Sci 2021;7:53-9.
10. Dixit A, Kumar N, Kumar S. Use of generic medicines: Challenges and benefits. J Health Manage 2018;20:84-90.
11. Khadke VV, Khanda SY. To study doctor's beliefs, barriers, awareness, and actual practices regarding use of generic medicines. Int J Basic Clin Pharmacol 2017;6:1871-9.
12. Hassali MA, Shafie AA, Jamshed S, Ibrahim MI, Awaisu A. Consumers' views on generic medicines: A review of the literature. Int J Pharm Pract 2009;17:79-8.
13. Shalini H, Shubha DB. Knowledge, attitude and practice

of generic medicines-an explorative study among interns of a tertiary care teaching hospital of Central Karnataka. Med Innov 2022;11:75.
14. Manasa CR, Kalpana L, Veena RM. Generic drugs: A study on awareness among medical students and interns. Int J Basic Clin Pharmacol 2020;9:1877-82.
15. Bera A and Mukherjee A. The importance of generic drugs in India. Int J Pharma Chem Biological Sci 2012;2:575-7.
16. Depression and Bipolar Support Alliance 730 N. Franklin St., Ste. 501 Chicago, Illinois, USA.
17. Midha KK, McKay G. Bioequivalence its history practice and future. AAPS J 2009;4:664-70.
18. Mathew P. Generic drugs: Review and experiences from south India. J Family Med Prim Care 2015;4:319-23.
19. Nagappa AN, Kavya HB, Chikkamath V, Naik V. Brand V/S generic-value based pricing for pharmaceutical in India. Juniper Online J Case Stud 2017;4:2-4.
20. Cameron A, Mantel-Teeywusse A, Leufkens H, Laing RO. Switching from originator brand medicines to generic equivalents in selected developing countries; how much could be saved? Value Health 2012;15:664-73.

Source of Support: Nil. **Conflicts of Interest:** None declared.