Innovations

Overcoming Barriers to Generic Drug Adoption: Insights from Global Studies

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Abstract

Objective: *This review paper aims to provide insights into the awareness of generic drugs among consumers, challenges in the adoption of generic drugs identified in various studies conducted in different countries, and proposed remedies to make generic drugs more available, accessible, and affordable to consumers. Generic drugs, produced and marketed by entities other than the original innovators, are often priced significantly lower than branded drugs. However, patients sometimes exhibit reluctance towards generic versions. This article reviews findings, challenges, and potential solutions recorded in past research from sources like PubMed and Google Scholar.* ***Data:*** *Generic drugs are a vital component of healthcare affordability and accessibility, aligning with the United Nations' Sustainable Development Goals. We explore historical and evolving concepts of generic drugs, challenges posed by patenting, and the overarching issue of catastrophic medical expenditures.* ***Study Selection:*** *This review compiles information from diverse online sources, research articles, and review papers related to generic drugs.* ***Conclusion:*** *While generic drugs are equally effective and more affordable, consumers' awareness and perceptions often present barriers to adoption. Factors such as age, education level, health literacy, income, and trust in prescribers influence willingness to accept generic drugs. Country-specific healthcare policies, prescription regulatory frameworks, and reimbursement mechanisms also affect adoption. Addressing the perception of generic drugs, increasing knowledge, and improving educational interventions can enhance adoption. Making the prescription guidelines more binding and updating legal frameworks for generic substitution are essential steps. Generic drugs are a powerful tool for making healthcare more accessible and affordable, but these challenges must be overcome to realize their full potential.*

Keywords: *Generic Drugs, Branded Drugs, Catastrophic Medical Expenditures, Awareness, Perception, Adoption, Barriers to Adoption.*

Introduction

Healthcare facilities when provided timely and effectively may help achieve one (provision of affordable and effective healthcare) of the objectives of any welfare state and simultaneously it will add to the health status and the standard of living of the national households, will contribute to the economic prosperity and productivity through positively affecting the labor. Healthcare facilities make a difference in the lives of

people by providing diverse services along with curative and preventive care services (Xu et al., 2003) Low and middle-income countries are home to the majority (more than 90 percent) of the impoverished population (Xu et al., 2003, Xu et. al., 2007) and rely heavily on out-of-pocket expenses for financing their health care needs (Xu et al., 2003, Mills, 2014). Around the globe, nearly 150 million people experience catastrophic healthcare expenditures (CHE) each year and 100 million are pushed into poverty due to these huge expenditures (Xu et. al., 2007). High-cost medication may not always result in catastrophic health care expenditures but, rather it is an individualistic phenomenon (Wyszewianski, 1986) any cost when borne by cutting down the basic expenditure of household, becomes catastrophic. For instance, a tiny amount paid out of pocket, for a medical test by a patient whose medical expenses are not covered by any insurance scheme, might seem disastrous to him as opposed to a huge payment made by some third-party insurer, for his medical treatment or tests might not be any matter of concern for the same patient and these costs may create an enormous barrier to the treatment of any disease. Making medicines affordable and accessible for the masses is one of the seventeen Sustainable Development Goals (SDGs) targeted by the United Nations (Trade Flows in Medical Goods and Services,2022). Generic Drugs are the safest, most affordable, and most accessible option that can be considered for making the drugs available universally. This review focuses on the awareness, accessibility, affordability, and availability of generic drugs.

History and Evolution of the Concept of Generic Drugs

history and the evolution of the concept of generic drugs are associated with the discovery of drugs which started by the end of the 18th century according to the available literature (Rana and Roy, 2015), and with the inception of the next century this discovery derived the need of patenting, Aspirin, a product of Bayer's pharmacological laboratory was world's first medicine to be successfully protected by a patent in the year 1899 on 6th of March (Jack, 1997).

Patent and Patenting: Theoretically, the patent is a "monopoly based on intellectual property" (Potts, 1944) and the act of patenting is defined as WIPO (*Patents*,)as, "granting an exclusive right for an invention, for a product or a process that provides, in, general, a new way of doing something, or offers a technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in the patent application"The concept of patenting brought many questions to be addressed by the authorities shortly such as for how long a patent should be granted. on which terms and conditions low-priced generics could be manufactured once the formulation gets off-patent. Induced by such questions a heated debate ignited on the "term of the patent" and "the terms and conditions of patenting and off-patenting" (Rana and Roy, 2015)

Challenges posed by Patenting: These questions were addressed by making state-specific laws and regulations which sometimes correlated with the international legislation for patenting and sometimes overruled the provisions of global treaties and agreements, (Kapczynski, 2009) whereas, this legislation matter has always been a subject of nations own sovereignty. Hence most countries today have their laws related to the patenting of medicines and their production after their patent expires (Rana and Roy, 2015).

In the USA the Drug Price Competition and Patent Term Restoration Act 1984 (Waxman-Hatch Amendments) was passed in the year 1984 and marked a landmark in the US drug regulation history (Dylst et. al., 2013). Although, TRIPS, the most comprehensive multilateral agreement on Intellectual Property Rights (IPR) signed on 1st January 1995, includes some "relatively clear" obligations such as "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." (supra note 1, 1995) with some vague and undefined commitments such as Article 31 (b) while providing provisions regarding "Other Use Without Authorization of the Right Holder" states that "such use may only be permitted

if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time." (TRIPS) This requirement of the agreement to engage in "reasonable efforts" within "reasonable time" to negotiate with the patent holder makes the agreement unnecessarily flexible. This seemingly unwanted and attention grabbing flexibility has provided basis for the mechanisms like "compulsory licensing" in developing nations like india. This mechanism has gotten the lion's share of attention in recent years particularly when it came to access the medication during the latest covid-19 pandemic.

Compulsory licensing: A TRIPS provision, under which the government supplies its citizens with generic versions of patented treatments either through domestic production or imports, overriding the exclusivity of the patent (WTO | Intellectual Property (TRIPS) - TRIPS and Public Health: Compulsory Licensing of Pharmaceuticals and TRIPS.

Affordability of medication and its Impoverishment effect in developed and developing nations: The affordability of medication can be understood using WHO's standard method for assessing the same according to which after buying the necessary medicines if the residual income was not more than USD 1.25/day or USD 2/day and taking the salary of lowest paid government worker (LPGW) as base a criterion is further added that a month's treatment should not exceed the wages of one day. But if, the cost of one month of treatment is more than the said limit it creates the "impoverishing effect of medicine" as per the World Health Organization and by Niënset. al. (Niëns, et.al. 2010, WHO, 2008).

The burden of CHE can either be shared by the state by providing insurance services or by the pharmaceutical sector by providing quality-assured generic substitutes of the expensive branded formulations (Niëns et al. 2010) because the majority of the population in the developing nations have no medical insurance facilitybut in the hours of need, in most cases, free medicines provided by the public sector are "out-of-stock"(Cameron et. al., 2009) furthermore, some other faults in the system like, inaccurate demand forecasting system, the inefficiency of the distribution mechanism and leakage of drugs for private re-sale (Cameron et. al., 2009) widen the gaping hole between patients and their reach to medicines. As a result, people have to opt for other options available for drug procurement, they hesitate to buy costly medicines out-of-pocket because in most "free market economies" drug prices are decided by the interaction of buyers and sellers interaction at the marketplace, without government interaction. Developing and free market economies instead of containing the cost of medication make innovative, novel, essential, and legally protected medicines unaffordable for the masses, and therefore people either forgo the treatment or go into poverty (Kurlander et. al. 2009, Suh, G. H., 2011).

Despite being the "pharmacy of the world" the cost of medicines is the main constraint (Roy et. al., 2012) to the Utilization of healthcare facilities in India. During FY 2017-18, public healthcare facilities accommodated only 30 percent of the entire healthcare expenditures of the country, as per the report presented by (the National Sample Survey Organization) NSSO, and nearly 83 percent of healthcare expenditures were paid to private healthcare facility providers. (Ranjan&Crasta, 2022) because according to an estimate, access to essential medicines is less than 35% in India. As a result of such poor accessibility and non-availability of services in pharmacies of public hospitals patients end up procuring medicines from the private sector only (Tripathi et. al., 2018). Huge medical expenses have pushed the majority of the population under the poverty line as reported by WHO (WHO, 2004), essential medicines were inaccessible for nearly 650 million (65%) Indians and access to healthcare facilities constituted 63% of their entire household expenditures (WHO, 2004, Selvaraj et. al.,2018).

At a global level, nearly half of the population is unable to attain essential healthcare services, and a huge number of households have been pushed into poverty after paying their healthcare expenditures because according to WHO "800 million people spend at least 10 percent of their household budgets on health expenses for themselves, a sick child or other family member". Out of these 800 million, 100 million are so vulnerable that these expenses are enough to push them into "extreme poverty", and to compel them to make a living on just $1.90/day or less than that (World Health Organization: WHO, 2017).

Availability of generic drugs; A Challenge or an opportunity for the patients:

Availability and Affordability: Branded drugs are more easily accessible and available as and when required, forget about the affordability. But finding an "affordable" generic version for any branded formulation might appear very challenging at times (Tripathi& Bhattacharya, 2018). Literature verifies the successful history of the generic drugs market in developed and developing economies (IvyPanda, 2019) and no fetal impacts of the substitution have been recorded so far. Furthermore, according to the available literature these substitutions have been considered healthy for the patient himself and his pocket also. So generic adoption is a safe and healthy option for cost containment and disease prevention and cure. But certain challenges have been posed to the adoption of generic drugs as recorded by the previous researches. Table 1 presents impediments to the adoption of generic drugs and the recommendations that were provided by the authors in their corresponding work.

Factors	Impact	Way forward	References
Consumer specific a. Age b. Education level c. Health literacy d. Income e. Mental disposition about generics f. Past experience with drug g. Their trust in the prescriber	Willingness to accept generic drugs tended to increase with education, health literacy, and income, and decrease with age. Consumers are unaware of the term "Generic Drugs" and different marketing practices.	Patients' confidence increased in Generic Drugs, when recommended by their prescriber. Frequent utilization of the generic drugs also boosts consumers' confidence in generic drugs.	Colgan et. al.(2016), Kendall et. al. 1995, Iosifescu et. al. (2008), Al-Gedadi et. al. (2008), Podulka et. al. 1989), Fabiano et. al. 2012, Podulka et. al. (1989), Shepherd(1988) Rosendahl, (1994), Kendall et. al.(1995).
Country specific a. Health policy b. Prescription Regulatory framework c. economic development level d. Expenses Reimbursement mechanism	Lack of substitution regulation hinders generic medicine adoption in developing countries. Patients pay 70% out-of-pocket; needing doctor's consent delays substitution, leading to expensive branded medicine purchases.	Indian chemists cannot substitute prescriptions with generics, unlike the UK and USA. Legal frameworks need updating. Patients trust their prescribers, so binding prescription guidelines are necessary.	Kaplan et. al. (2012), WHO (2004), Bertoldi et. al.(2005), Chan et. al. (2004), Podulka et. al. (1989)
Drug specific a. Price of the drug b. Perceived quality c. Perceived effectiveness d. Manufacturer's reputation e. Perceived safety	Price is pivotal in generic drug adoption, but manufacturer reputation, manufacturing process, safety perceptions, and side effect concerns also impede their spread, as studies indicate.	Educational interventions impact patients' perception of generic drug efficacy, supported by past research. Manufacturers can bolster trust through GMP compliance, improving reputation, outperforming rivals, and enhancing drug efficacy.	Pereira et. al.(2005, Bertoldi et. al.(2005), van Boxtel, (2004), Al-Gedadi et. al.(2008) , Fabiano et. al.(2012), Kesselheim et. al. (2008)
Disease specific a. Type of ailment b. Severity of the ailment	Patients with severe illnesses are less inclined to accept generic drugs. In contrast, they readily accept substitution for common conditions like influenza and asthma due to their perceived prevalence.	studies confirm generic cardiovascular drugs are as effective as branded ones. For chronic diseases like diabetes, cancer, and hypertension, generic drugs have shown equal efficacy.	Podulka et. al. 1989, Ganther&Kreling, (2000), Figueiras et. al. (2008)Leighl et. al.(2021)McManus et. al. (2012)Shrank et. al., (2011), Fischer &Avorn(2004)

Table:1 Factors Influencing the Adoption of Generic Drugs

Knowledge, Awareness, and perception about the generic drugs:-

Several factors affecting the perception of customers towards generic medicines have been documented in different studies conducted during past decades such as the age, income of consumer, education and knowledge about the concept of generics, characteristics of the drug product, pharmaceutical expenditures reimbursement system, socio-economic characteristics of the respondents, related country's health policy, the effectiveness of communication between consumer-prescriber, type of ailment, the severity of the disease or seriousness of the medical condition, patients' experience with the generic drug and the pattern of prescribing these drugs. Given below are some of the factors that have posed barriers to the adoption of generic drugs and the remedial actions that were taken. 86.95% of Respondents to an Indian study unleashed their physician or pharmacist had never recommended them to switch from branded to generic (Podulka et. al. 1989) on the contrary 34% of Malaysians stated that information about low-cost generic drugs was passed to them by their physician (Al-Gedadi et. al., 2008). In addition, When asked frequently to substitute their drugs with generics by their prescribers patients were more likely to opt for the generic medicines (Bertoldi et. al., 2005).

In a recent study conducted in Australia in 2022 by the National Medical Council (NMC), a qualitative research approach was employed to delve into the perceptions and viewpoints of consumers regarding generic medicines. The primary aim was to uncover the obstacles preventing consumers from using generic drugs. The study involved interviews with 16 participants, ranging in age from 22 to 80, all residing in the metropolitan region of Melbourne, Australia. Through a comprehensive thematic content analysis, the researchers identified four key themes associated with the utilization of generic medicines: knowledge about generics, acceptance of generics, non-acceptance of generics, and educational requirements concerning generics.

A noteworthy discovery in the study was that the majority of patients were unfamiliar with the term "generic medicine," but they readily recognized the term "cheaper brand of medicine." The predominant reason for embracing generic medicines was their cost-effectiveness. Conversely, the major barriers to their acceptance included influence from medical practitioners, concerns about potential side effects from generic brands, and confusion stemming from using various brands. Ultimately, the researchers concluded that consumers generally held positive attitudes toward the use of generic medicines. They recommended that healthcare providers play a more direct role in educating patients about the safety and effectiveness of generic medicines, as this could significantly enhance the adoption of these cost-efficient alternatives.

Pros and Cons of Generic Drugs:

Pros:

1. Cost-Effective: Generic drugs are typically more affordable than their brand-name counterparts, making healthcare more accessible and sustainable for patients (Dunne & Dunne, 2015).

2. Quality (Established Bioequivalence): Generics must meet the same quality and safety standards as brand-name drugs, ensuring comparable effectiveness (Midha& McKay, 2009).

3. **Wider Availability:** Generic drugs increase the availability of essential medications, benefiting a larger population (Bloom, 2015).

4. **Market Competition:** Competition from generic manufacturers can drive down drug prices, ultimately reducing healthcare costs. (Simoens, 2012)

5. **Research Not Required:** Generic drug makers do not need to invest in extensive clinical trials, which can expedite the drug development process (Prendergast & Marr, 1997).

6. **Prescription Adherence:** when the prescriptions were filled with less expensive generic drugs, the patients were more likely to adhere to the prescriptions because of the financial benefits provided by these medicines (Gagne &Choudhry et. al. 2014).

Cons:

1. **Not favored clinically:** it was found that doctors perceived generic drug manufacturing was not as per the good manufacturing practices and hence the products had substandard quality (Gupta &Malhotra et. al. 2018, Dixit & Kumar et. al. 2018).

2. Bioequivalence is not a proof of quality: studies revealed that generic substitution can be problematic for many diseases because the established bioequivalence could not ensure the quality of medicines (Meredith, 2003).

3. Faulty Supply Chain Management (SCM): Ahlqvist and others wrote that the accessibility to generic drugs had been severely disrupted during the latest pandemic (Ahlqvist&Dube et. al. 2023) even in general the supply of generic alternatives is not ensured by the authorities making the poor even more vulnerable to suffer poverty resulting out of the OOP (Out-Of-Pocket) health expenditures done on the Branded Medicament.

4. Perceptual barriers: The quality of generic drugs has been questioned from time to time by prescribers and pharmacists because of the inadequate monitoring of the regulation authorized by the manufacturing firms combined with even more intense factors such as drug failure in disease treatment. Hence, the perception of prescribers is not in favor of generic drugs (Colgan&Faasse et. al. 2015).

5. Inadequate Monitoring: the entire process of drug manufacturing, distribution as well and pricing lacks an adequate monitoring system at various stages as revealed by Kanavos &Wouters, 2014).

Conclusion:

In conclusion, this review paper has explored the awareness, challenges, and potential remedies for the adoption of generic drugs, shedding light on a crucial aspect of healthcare access and affordability. Generic drugs offer several advantages, such as cost-effectiveness, established bioequivalence, wider availability, and the potential to drive down drug prices through market competition. However, there are significant challenges that need to be addressed for their widespread adoption. One key challenge is the perception and

awareness of consumers regarding generic drugs. Factors like age, education, income, and past experiences influence the willingness to accept generics. Educational interventions and trust in healthcare providers are effective in changing these perceptions. Additionally, the regulatory framework in different countries, prescription guidelines, and patient-physician communication play critical roles in the adoption of generic drugs. Another challenge is the perception of quality and safety, as some patients question the effectiveness and reputation of manufacturers. While price is a crucial factor, perceived quality and effectiveness can also impact the adoption of generics. However, it's important to note that generic drugs are subject to the same quality and safety standards as their brand-name counterparts. Disease-specific factors, including the type and severity of the ailment, can also affect patients' willingness to accept generic drugs. Educational interventions and evidence of the effectiveness of generic drugs for various conditions can help address these challenges.

The review also highlights the pros and cons of generic drugs. They offer significant cost savings, contribute to prescription adherence, and can be equally effective as brand-name drugs. However, concerns about manufacturing quality, supply chain management, and the inadequacy of monitoring and regulation create perceptual barriers. To enhance the adoption of generic drugs, campaigns to increase awareness and educational interventions are essential. Modifying patients' beliefs and perceptions about these cost-effective medications can lead to better acceptance. Moreover, updating prescription regulations, improving supply chain management, and strengthening regulatory oversight are necessary steps to ensure the quality and availability of generic drugs.

In summary, generic drugs have the potential to significantly impact the affordability and accessibility of healthcare worldwide. While challenges persist, addressing them through education, regulation, and better communication between healthcare providers and patients can pave the way for more widespread adoption of generic medications, ultimately saving individuals from catastrophic medical expenditures and contributing to the overall well-being of society.

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