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Review paper

## Clearing the Path for Generic Drug Utilization:

Lessons from Worldwide Investigations

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### ABSTRACT

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Generic medications, Proprietary pharmaceuticals, Severe healthcare costs, Consciousness, Impediments to Integration This review aims to provide concise insights into global consumer awareness of generic drugs, challenges identified in diverse studies regarding their adoption, and proposed solutions to enhance availability, accessibility, and affordability. Despite the economic benefits of generic drugs, patient reluctance persists. Aligned with the UN's Sustainable Development Goals, this exploration delves into historical perspectives, patenting challenges, and the impact on healthcare costs. Drawing from various online sources, research articles, and reviews, the study concludes that, although generic drugs are equally effective and cost-effective, barriers to adoption stem from consumer perceptions influenced by factors like age, education, health literacy, income, and trust in prescribers. Additionally, country-specific policies and regulatory frameworks play a crucial role in shaping adoption rates, suggesting a need for targeted educational interventions to address these challenges and promote wider acceptance of generic medications.

## 1. 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. 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).

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



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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.

## 2. 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), 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).

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".

## 2.1 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.

## 2.2 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.

## 2.3 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 .

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).

# 3. Availability of generic drugs: A Challenge or an opportunity for the patients

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.

# 4. 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 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).

## 5. 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 costeffectiveness, 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. 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 brandname 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 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 costeffective medications can lead to better acceptance. Moreover, updating prescription regulations, improving supply chain management, strengthening regulatory oversight are necessary steps to ensure the quality and availability of generic drugs. In summary, generic drugs have the potential significantly impact the affordability accessibility worldwide. of healthcare 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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## References

 Alongi, Al-Gedadi, N. A., Hassali, M. A., & Shafie, A. A. (2008). A pilot survey on perceptions and knowledge of generic medicines among consumers in Penang, Malaysia. *Pharmacy Practice*, 6(2), 93–97. https://doi.org/10.4321/s1886-36552008000200006

- Kapczynski, A. (2009). Harmonization and its discontents: A case study of TRIPS implementation in India's pharmaceutical sector. *California Law Review*, 97, 1571.
- 3. IvyPanda. (2019, November 22). 'The Indian Challenge: The Evolution of a Successful New Global Strategy in the Pharmaceutical Industry' by D. Jane Bower and Julian C. Sulez.
- 4. Tripathi, S., & Bhattacharya, S. (2018). Patient perception about generic vs. branded medicines prescribed in a tertiary care hospital in northern India A descriptive study. *Indian Journal of Pharmacy Practice*, 11(2), 91–95. https://doi.org/10.5530/ijopp.11.2.19
- Wyszewianski, L. (1986). Financially catastrophic and high-cost cases: Definitions, distinctions, and their implications for policy formulation. *Inquiry*, 23(4), 382– 394. PubMed: 2947859
- Bertoldi, A. D., Barros, A. J. D., & Hallal, P. C. (2005). Generic drugs in Brazil: Known by many, used by few. Cadernos de Saúde Pública, 21(6), 1808–1815. https://doi.org/10.1590/s0102-311x2005000600029

