ISSN–2278-5655

AMIERJ

AARHAT MULTIDISCIPLINARY INTERNATIONAL EDUCATION RESEARCH JOURNAL

Volume–X, Issues– III May - June 2021

A STUDY OF FACTORS AFFECTING THE ACCEPTANCE OF GENERIC MEDICINES

Miss. Purva Pantawane,

Dr. Ambedkar Institute Of Management Studies and Research, Deekshabhoomi, Nagpur

Dr. Ashutosh A Paturkar,

Dr. Ambedkar Institute Of Management Studies and Research

Abstract

As India is one of the highest per capita out-of-pocket expenditures' countries, generics will save a lot of money which can be used for other health issues. In all the countries, use of generic drugs has increased significantly in recent years.

In 2008, the Government of India, through the Department of Pharmaceuticals, started a new initiative "Jan Aushadhi" (a Hindi word literally translated as "Medicine for People"). This program envisaged making unbranded quality medicines available to poor people in the country at a reasonable and affordable price through retail outlets' setup with the help of the government. It has taken ownership of setting up Jan Aushadhi stores, which are pharmacies selling only generic name medicines to the extent possible, giving preference to pharmaceutical public sector undertakings too. There are not enough Jan Aushadhi stores, possibly 3200 against more than 8 lakh retail pharmacies in existence, with many rural areas still underserved. The Medical Council of India, in an amendment to the code of conduct for doctors in October 2016, has recommended that every physician should prescribe drugs with generic names legible and he or she shall ensure that there is a rational prescription which promotes the use of generic drugs. In future, the Government of India may bring a legal framework under which doctors will have to prescribe generic medicines to patients.

For this study a survey was conducted in Nagpur city. The Sample size for the study was 80 and Sampling technique used here is stratified random sampling. The primary data was collected using questionnaire and secondary data was collected through online websites, e - journals and research paper. The study concludes that doctors prescribe generic medicines on

ISSN–2278-5655

AMIERJ

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their own and also on patient's request as generic medicines are affordable at a lower cost. Generic medicine produces the same therapeutic effect as the patented medicines (branded generics). Mostly doctors agree generic medicines are as safe as branded medicines. The doctors are found switching the patient's medication from patent medicine to generic medicine in some cases. Generic medicines are appropriate for less serious condition of patient but treatment with generic medicine take a longer duration.

Key Words: *Generic Medicines, Branded Generics, Affordable Medicines*

Introduction

The generic medicines (generics) are the medicines which are off patent and can be manufactured and marketed by any company. A generic medicine must contain the same ingredients as the original formulation. According to the US Food and Drug Administration (FDA), generic medicines are identical or within an acceptable bioequivalent range to the brand name counterpart with respect to pharmacokinetic and pharmacodynamics properties. By extension, therefore, generics are considered (by the FDA) identical in dose, strength, route of administration, safety, efficacy and intended use. In most cases, generic medicines are available once the patent protections afforded to the original developer have expired. When generic medicines become available, the market competition often leads to substantially lower prices for both the original brand name (innovator) and the generic forms. Generic medicines are economical than their equivalent brand medicines and are available as standard therapy for many acute and chronic diseases. Thus, wide use of generic medicines would not only decrease medicine expenditure but also be essential for the sustainability of the health care system. Therefore, in recent years, to confront the escalation of health care expenditure in general, and pharmaceutical expenditure in particular, many governments and third-party payers have encouraged the use of generic medicines as an integral part of the health care system by instigating and implementing various policies, initiatives, and strategies. However, in Indian context the generic medicines are available with brand names, manufactured by a many companies and are referred to as "branded generics". Yet other generic medicines (commodity generics) are sold under the generic name and may be manufactured and marketed by many companies. This is a highly price competitive sub-

ISSN–2278-5655

AMIERJ

AARHAT MULTIDISCIPLINARY INTERNATIONAL EDUCATION RESEARCH JOURNAL

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market, as buyers can choose among several sources of supply of chemically identical medicines.

In many cases branded medicines are unaffordable for large sections of the population and are a major burden on government budgets. Generics are essential since they are necessarily less-expensive choices to their brand name equivalents. The accessibility and use of generic choices to brand name medicine have an important result on cost savings for health care users.

According to the FDA, all medicine consists of brand name medicine and generic medicine, which should work well and be safe. Generic medicine utilizes the same active ingredients as their brand name equivalent and hence have the same benefits. Many people are worried about the value of generic medicine. To guarantee safety, quality, and effectiveness, the FDA places all generic drugs during a detailed reassess method including a review of scientific information about the elements and performance of the standard medicine. Additionally, the FDA needs that a basic medicine built-up plant meets the same high standards as a place for a brand name medicine. About half of all generic medicines are made by brand name companies. They can make copies of their own medications or other company's brand medicines and then sell them without the brand name.

As similar to the brand medicines these generic medicines also need to get approval from FDA mentioning the composition, administration dosage, medicines kinetics is same as to the brand-named medicines. The FDA needs the generic medicine to be high in quality, and same as pure, strong and stable as brand name medicine. Following the regulatory agencies and manufacturing techniques the tests are performed. To get approval, the criteria of dissolution rate of both the brand and generic medicine should be same along with same safety, dosage and efficacy. Generics have the same strength and dosage as the brand-name medicine. They're developed with the same standards, and are just as safe and effective.

The FDA tests and approves a generic medicine if it:

1. Contains the same active ingredients as the brand-name medicine.
2. Treats the same medical condition.
3. Is identical in strength, purity, quality, dosage form and method by which someone takes the drug
4. Absorbs into the bloodstream at a similar rate as the brand-name

ISSN–2278-5655

AMIERJ

AARHAT MULTIDISCIPLINARY INTERNATIONAL EDUCATION RESEARCH JOURNAL

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5. Generic medicines are often manufactured by companies that also make brand-name medicines.

Hospitals and physicians prescribe generics more than brand-name medicine. In fact, they make up more than 80 percent of prescriptions filled in the U.S.

Review of literature

Health of the society is always paramount. However, the cost of treatment also assumes importance as no person should die for lack of medicines. Since generic medicines have certain advantages a many studies have been done to explore the advantages and disadvantages of the generic medicines.

Hassali MA, Shafie AA, Awaisu A, Ibrahim MI, Chong Chee P, Jamshes S.(1980-2008) studied the Physicians' view on generic medicines: A narrative review by Hassali et al. which collated international studies. This article coalesced the collective views of physicians as accepting of generic substitution (GS) under policy and economic pressures, but having concerns regarding the overall quality, reliability and switch ability of generic drugs. This review further theorised that those concerns may prevent full adoption of generic drug prescribing and substitution by physicians, which could lead to escalation in healthcare costs for governments, insurers or consumers directly.

Rohit Kumar, Mohamed Azmi Hassali, Fahad Saleem, Alian A Alrasheed, Navneet Kaur, Zhi Yen Wong, and Muhamad Ali SK Abdul Kader (2015) analysed the Knowledge and perceptions of physicians from private medical centres towards generic medicines: a nationwide survey from Malaysia. In this qualitative study, it was reported that the physicians interviewed had a general idea about bioequivalence, but this quantitative study provides further insight in this topic. 97.7% of the physicians were unaware of the bioequivalence criteria for generic medicines set by the Malaysian Regulatory Agency i.e., the National Pharmaceutical Control Board (NPCB). This finding is similar to those reported from other countries where the physicians had a poor knowledge of the bioequivalence acceptability criteria set by their respective drug regulatory agencies. Hence, both the qualitative and quantitative studies, involving physicians from the private medical centres in Malaysia, revealed that the respondents have a rough idea about bioequivalence, and its role in the generic industry, but they lacked a detailed knowledge about this subject. Surprisingly, 51.3% of the

ISSN–2278-5655

AMIERJ

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respondents considered that generic products are bioequivalent, but still 74% (combining both always and usually categories) prefer to write their prescriptions using brand names.

David Flood, Irène Mathieu , Anita Chary, Pablo García and Peter Rohloff (2017) studied the Perceptions and utilization of generic medicines in Guatemala: a mixed-methods study with physicians and pharmacy staff. Pharmacy staff and physicians' perceptions of the safety and efficacy of generic medicines are summarized. In general, physicians were more likely than pharmacy staff to perceive generic medications to be less safe or less effective. The study demonstrates that physician and pharmacy staff's perceptions of low-cost generics influence the utilization of these medicines in clinical practice, especially in relation to the treatment of NCDs like diabetes and hypertension. Interventions to improve the perception of generics and increase their utilization by physicians and pharmacy staff are critical. At the same time, additional research on changing dispensing practices of medications for both acute and chronic illnesses is needed.

Emily Leonard, PharmD Candidate; Michael Wasco ich, PharmD, MBA, and Delesha Carpenter, PhD, MSPH (January 2019) stated the Factors Affecting Health Care Provider Knowledge and Acceptance of Biosimilar Medicines: A Systematic Review. this review indicate that U.S. and European health care providers still approach biosimilar medicines with caution, citing limited biosimilar knowledge, low prescribing comfort, and safety and efficacy concerns as main deterrents for biosimilar use. To realize the full cost-saving potential of biosimilar medicines, clinician-directed biosimilar education will be imperative to address gaps in biosimilar knowledge, facilitate prescribing changes, and ultimately increase biosimilar use.

Sanjiv Kumar and Neeta Kumar (January 2018) stated use of Generic Medicines: Challenges and Benefits Article. This research concluded that the recent decisions by the Medical Council of India (2017) and efforts of the government to promote generic medicines are welcome. These will increase the availability of medicines at an affordable cost and contribute to reducing poverty while accelerating progress towards achievement of health goals in the country. The concerns of the Indian Medical Association and other professional bodies regarding the quality of generic medicines need to be taken seriously and addressed by the government.

ISSN–2278-5655
AMIERJ
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It is important for the professional bodies to collaborate with the government in improving access to quality medical treatment that is affordable, including medicines. There is a need for the government to engage all stakeholders in its noble efforts to improve access, affordability, timeliness of high-quality medical care to reach Universal Health Care and move towards the right to health in the country.

The Indian pharma industry contributions to global health outcomes. The Indian pharmaceutical industry is the world's third largest of medicine by volume. The Industry's journey to annual revenues of about USD 38 billion today can be attributed to world-class capabilities in formulation development, the entrepreneurial ability of the firms and the vision of the industry to establish India's footprint in large international markets such as the United States. The industry has played a key role in driving better health outcomes across the world through its affordable and high-quality generics medicine. Increased accessibility to affordable medicine has been one of the key enablers for lowering the disease burden in India. India's per person disease burden measured as Disability Adjusted Life Years (DALYs) dropped by 36 percent between 1990 and 2016 after adjusting for changes in the population age structure.

The lowered disease burden was driven by a reduction in infectious and associated diseases from a 61 percent disease burden in 1990 to 33% in 2016. During the same period, medicines penetration in India increased by 50 percent. India has now become Polio-free, as a result of strong collaboration among vaccine manufacturers, healthcare providers, the government and development organisations. The industry has also helped in bringing down the treatment costs of life-threatening diseases such as Chronic Myeloid Leukaemia and Hepatitis C, to less than five percent of the original cost. While shaping public health outcomes, the industry has contributed to India's economic growth. Estimates suggest that the industry directly and indirectly provides employment to over 2.7 million people, in high-skill areas like R&D and manufacturing.

The objectives of the study

To study the factors that influence doctors to prescribe generic medicines

To examine the indications in which doctors prefer to prescribe generic medicines.

Sample Design:

Target population for this study was Doctors of Nagpur. Total of 80 respondents were considered for the study. The sampling unit consisted of General Practitioners, Consulting

ISSN–2278-5655

AMIERJ

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Physicians, Cardiologist, Surgeons, Gynaecologists, Patricians etc. The sampling technique used was Stratified Random Sampling.

Data Collection:

For the study primary data was collected with the help of a structured questionnaire & interview.

For this study the generic medicines are considered as those medicines which are available by generic name and not by brand name. As a matter of fact, almost entire Indian pharmaceutical industry is of "branded generic".

"Branded generics "are those medicines which are off patent but marketed by companies with their own brand name. The respondents for the study have considered branded generic as branded medicines and those without brand name are considered as generic medicine.

Secondary data for the study was collected from various Websites, Research papers, E - Articles and E-Journals.

Limitation:

This study was restricted to Nagpur City only and the study is mainly concentrating on generic medicines. The respondents are doctors. The sample of the size will be limiting to time and resources. The result is assuming the respondents have given accurate information.

Data Analysis and Interpretation

The data was collected from 80 doctors across specialties. 71 per cent of the respondents were general practitioners, and 29 percent were from different specialties viz. dentist, surgeons, physicians, and pediatricians.

It was found that 95 percent of the doctors were using branded generics, and only 5 percent were prescribing generic medicines. 91.3 percent doctors were aware about the cost advantage of the generic medicines. 84 percent doctors believed that generic medicines produce same therapeutic effect as patented one, but these doctors were referring to the branded generics. Only 9 percent doctors were strictly against prescribing generic medicines, though they preferred branded generics. 15 percent doctors expressed their apprehension about the quality of generic medicines, whereas 22 percent doctors were not sure if the quality of the generic medicines is inferior. 63 percent doctors felt that the quality of the medicines is same.

On safety front 81 percent doctors felt that the generic medicines are safe where as 16 percent doctors were not sure about the safety and only 3 percent doctors felt that the generic medicines

ISSN–2278-5655

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are not safe.

96 percent doctors agreed that the generic medicines are more affordable.

95 percent doctors were of the opinion that the patients should be given an option of choosing the affordable medicines.

Only 7 percent doctors were of the opinion that when the innovators brand is available then they would prefer the innovator brand only. However, 39 percent doctors were of the opinion that they would prefer branded generic to innovators brand.

63 percent doctors were willing to shift to generic brand once it was available. However, 18 percent doctors were not willing to shift the patients to generic branded.

When asked if the preference would be different for non-serious conditions, 57 percent of the doctors were willing to use generic medicines. When asked about the efficacy, 36 percent of the respondents felt that it takes longer time to resolve relevant condition with generic medicines than branded generics. 60 percent of the doctors felt that the quality checks are lacking in case of generic medicines.

Recommendations

This study has found that there is acceptance to branded generics. However, when it comes to the generic medicines the acceptance is low.

Few doctors such as dermatologists disagree that generic medicines are as safe as branded medicines whereas, dentists, General Surgeon have a neutral opinion about the same. Doctors such as dentists have a neutral opinion that generic medicines are more affordable as compared to branded medicines.

The three major obstacles for acceptance to generic medicines are the quality, safety and efficiency. Thus, this study recommends that the promoters of generic medicines should emphasize and assure the practitioners about quality, safety and efficiency. In India pharmaceutical products are voluntarily not advertised by the manufacturers.

The Only promotional tool available for promotion of medicines is personal selling and through medical representatives. All the branded generics are promoted through this channel which increase the cost of promotion and hence, the price of the medicines.

However, generic medicines are not promoted through medical representatives and thus the costs are lower compared to branded generic. To promote generic medicines effectively and in

a cost-effective manner the study recommends promoters to participate in various CME (Continuous medical education)

This will create awareness as well as communicate about the quality, safety and efficiency of generic medicines. Promoters of generic medicines should also advertise in reputed trade journals. Promotors of generic medicines should build company image which will eventually help all the molecules marked by the company, which will be cost-effective way of developing corporate brand.

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