Original Article

The Paradox In The Use Of Generic Medicines In India: An Assessment

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Abstract

Background of the study: - While the trusted sources of Medical Council of India suggests that India is one of the largest exporter of generic medicine that constitutes almost 22% of the total export of the country, still a mass scale inaccessibility persists in the use of the generic drugs, in India itself. Being the replica of the branded drugs, there is a gap in-between availability and accessibility of these drugs. The scheme 'Pradhan Mantri Bharatiya Janausadhi Pariyojana (PMBJP)', is a central-flagship programme in order to reduce the out-of-pocket expenditure in medicines. However, the market structure shows that there are certain anomalies involved in it. This is a virtual gap in the real health market. The medicines are exported on a large scale to various developed nations but the country's scenario is way different. Since physicians predominately prescribe drugs in medical settings, they are at the epicenter of the medication usage process. Therefore, it is prudent to think about how they perceive generic medications. Physicians still express concerns regarding the general reliability and quality of generic pharmaceuticals as well as generic substitution of specific drug categories, despite the fact that they accept generic substitution due to regulatory and economic pressures.

Objectives of the study: - The objective of the study is to analyze and comprehend the inaccessibility, from supply side in terms of prescriptions by doctors, in using generic medicines in the country, being the largest exporter of generic drug.

Research Methodology: - To assess this paradox, this paper will focus on the supply side constraints for this inaccessibility. A primary survey is carried out through a structured questionnaire circulated among the physicians who are the prescribers of all kinds of medicines. The questionnaire contained relevant questions related to the issues under the study. While convenience sampling was carried out to reach the physicians nearby, the physicians within this designated location were chosen at random in order to avoid biasedness. The sample was collected from Cuttack and Bhubaneswar, the twin cities of Odisha that is home to a wide range of medical facilities, from small clinics to multi-specialty hospitals, and thus regarded as the health hub for the entire state. Statistical measures and other techniques are used as per relevance to analyze the data using SPSS and AMOS software.

Keywords: - Drugs, generic, medicines, prescribers, physicians

I. Introduction:-

The cost of medicine is one of the main component of the total health expenditure of a patient, which comprises a significant factor of his overall expenditure. It is one of the most important expenditures for the society. Generic medicines are identical versions of already approved medications that share the same chemicals as their brand-name drugs but are packaged, marketed, and marketed differently. In order to deliver generic medicines to the public at a far lower cost than branded versions, the department of pharmaceuticals developed the generic medicines in India as mentioned in the Pharmaceuticals and Medical devices Bureau of India website. In many developing nations, healthcare costs are regarded as out-of-pocket expenses. In India, out-of-pocket spending accounts for approximately 70% of all expenditures made by individuals, which is more than the average when compared to other nations. India is the top exporter of these generic medications in the world, making up to 22% of all exports, as per a 2017 report by the Medical Council of India. India has a significant impact on the global pharmaceutical industry. Many industrialized economies, including the USA and Europe, had trouble keeping up with the demand for pharmaceutical products, but India was able to meet the majority of the demands on its own. India's exports of generic drugs in FY2021 surged significantly by 19.53%, from 1.4 trillion to 1.8 trillion, as to FY2020. India is the top supplier of generic medications to more than 200 nations around the world, including the highly regulated markets of the US, Europe, Japan, and Australia. However, it's a paradox that in India itself the cost of medicines are very high and virtually unregulated, thereby burgeoning the overall healthcare expenditure of a patient, making health care inaccessible. Though this inaccessibility has both the its demand and supply side constraints, the focus of this paper is to highlight the factors working on the supply side in terms of the doctors prescribing

these generic drugs, which would encourage their use. So this paper would impartially explore, this gap if any, on the supply side.

II. Review of literature:-

Gin Nie Vhua, Mohamed Azmi Hassali Shatie, Ahmed Awaisu (2010) in the paper entitled "A survey exploring knowledge and perceptions of generic practitioners towards the use of genric medicine in the northern state of Malaysia" states that in the northern state of Malaysia, general practitioners' perceptions and knowledge about generic medicine are evaluated in this article. It is clear that the majority of doctors do recommend generic medicines. There are still misunderstandings concerning the reliable bioequivalence, effectiveness, and safety requirements of these medicines.

Hale Z. Toklu, Hasin Gunes, et.al in the paper entitled "Knowledge and attitude of the pharmacists, prescribers and patients towards generic drugs use in the Istanbul, Turkey" (2012) states that the use of generic drugs has increased significantly in recent years. As generic drugs are available at lower costs, they provide an opportunity to save drug expenditure. Findings of the paper demonstrate that the healthcare providers and the consumers have insufficient knowledge about generic drugs. Hence better education is necessary.

Pawel Lewek, Janusz Smigeiski and Przemyslaw Kardas(2015) in the paper entitled "Factor affecting the opinions of the family physicians regarding generic drugs- a questionnaire based study" states that a range of factors are believed to exert a negative influence on opinions of physicians about generic drugs. Two key opinions were identified among the responses concerning the effectiveness of generic drugs and about its perceptions has been identified. They are the choice of cheaper equivalents of brand name drugs for personal use and the opinion that pharmacists do inform patients about the possibility of buying cheaper equivalents of prescribed brand-name drugs.

Rajesh B. Hadia, Dhaval B. Joshi, Kushal H. Gohel and Nikhil Khambhati in the paper "Knowledge, attitude and practice of generic medicines among physicians at multispecialty hospital: an observational study" (2021) states that brand-name drugs are increasingly being paid for out of pocket, accounting for 80% of healthcare costs. Generic medicines, though they have the same therapeutic effects as brand-name prescription drugs, are less expensive, yet many currently practising doctors have opposing beliefs and don't prescribe them. Regarding the effectiveness and safety of generic medicines, the majority of doctors held an open mind. However, a significant portion of doctors think that generic medicines are of lower quality.

III. Objectives of the study:-

This paper has following objectives:-

(a) To study the supply side constraints in prescribing generic medicine among the physicians.
(b) To study the awareness and knowledge of the practitioners about the generic medicines and its uses in the country under the scheme Pradhan Mantri Bhartiya Janaushadhi Pariyojna (PMBJP)

IV. Hypothesis of the study :-

(a) There is no inaccessibility in using generic medicines in the country.
(b) There are no discrepancies on the supply side in prescribing generic medicines among the physicians.
(c) There is no awareness and knowledge of the practitioners about the generic medicines among the prescribers.

V. Research Methodology:-

This paper has used both the primary and secondary data for its study. The secondary data was used to access the present status of generic medicine at national and international level. Primary data has been collected from expert doctors and physicians about:

a. Their knowledge related to generic medicine
b. Awareness about Medical Council of India Act on generic medicine
c. Practice related to generic medicine
d. Factors affecting prescribers in mentioning generic medicine to the patients

Hypothesis	Methodology
a. There is no inaccessibility in using generic medicines in the country	Exploratory and Confirmatory Data Analysis
b. There is no discrepancy in prescribing generic medicines among the physicians	Exploratory and Confirmatory Data Analysis

c. There is no awareness and knowledge of the practitioners about the generic medicines among the prescribers.	Exploratory and Confirmatory Data Analysis

VI. A Brief About the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) Scheme of Generic Medicines:

The Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP) campaign was launched by the Department of Pharmaceuticals of the Government of India to provide the general public with high-quality medicines at affordable prices through specialized stores known as Pradhan Mantri Bharatiya Janaushadhi Pariyojana Kendras (PMBJPK). In order to deliver generic medicines that are less expensive while maintaining the same level of quality and efficacy as expensive branded prescribed drugs, PMBJPK was founded. To coordinate the purchase, distribution, and marketing of generic medicines through the Pradhan Mantri Bharatiya Janaushadhi Pariyojana Kendra, the Department of Pharmaceuticals of the Government of India established the BPPI (Bureau of Pharma Public Sector Undertakings of India). This was done with the support of all Central Public Sector Enterprises (CPSUs). Some of the main objectives of the government's aforementioned programme is to create jobs by enlisting the help of individual business owners in the establishment of PMBJP Kendras, to ensure that all sections of the population, especially the poor and the disadvantaged, have access to high-quality medicines, and to combat the misconception that quality is only associated with a high price by increasing public awareness of generic medicines through education and publicity.

VII. Analysis of the study:-

Supply side analysis of the generic medicines: - This section will highlight the analysis of generic medicines in the context of the prescriber's point of view.

Sample profile:-

A set of questionnaire was circulated among the medical experts working in various medical colleges and institutions. The experts are confined to the twin cities of Odisha (Bhubaneswar and Cuttack) being the medical hub of the state. Table 1 shows the basic demographic profile of the physicians and the response rate is 100%. A total of 120 questionnaires were distributed at random.

Table 1: Shows the demographic profile of the samples:-

Parameters	Demographic information	Frequency
Gender	**Male**	**75**
	Female	**45**
Qualification	**MBBS**	**30**
	MD	**62**
	DM	**28**
Working in	**Private hospitals**	**60**
	Public hospitals	**60**

Author's own compilation

Table 2:- Knowledge related questions on generic medicine (n=120)

Sl.No	Questions	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1.	A generic drug is bio-equivalent to a name brand drug.	32(26.66%)	6(5%)	15(12.5%)	17(14.16%)	50(41.66%)
2.	A generic drug has the same dosage as a brand-named drug.	32(26.66%)	6(5%)	15(12.5%)	22(18.33%)	45(37.5%)
3.	Compared to other drugs, the brand drugs adhere to greater safety regulations.	32(26.66%)	6(5%)	14(11.66%)	23(19.16%)	45(37.5%)

The information regarding the knowledge-related questions and the respondents' level of responses, gathered on a Likert scale, is shown in the above table. The notion that a generic drug is bio-equivalent to a brand-named drug, a generic drug has the same dosage as brand-named drugs, and that brand-named drugs comply with stricter safety rules than other drugs is strongly disagreed with by nearly 26% of respondents. On this point, about 40% of respondents strongly concur (Table 2).

Author's own compilation

1.	Are you aware of the scheme of the Government?	65(54.16%)	45(37.5%)	10(8.33%)
2.	Are you aware about the Indian Medical Council Act to Prescribe drugs with generic names?	65(54.16%)	47(39.16%)	8(6.66%)
3.	Are you satisfied with the quality control measure of generic medicines by the Regulatory Authority?	50(41.66%)	48(40%)	22(18.33%)

Author's Own compilation

Table 3 shows how much the respondent were informed regarding giving patient's generic medicines. Nearly 54% of respondents are aware of the government's plan (PMBJP) and are familiar with the Indian Medical Council Act, which allows doctors to prescribe generic medications to patients. About 41% of them are satisfied with the regulatory authority's quality control measures for generic medications. The Medical Council Act and the programme are not at all familiar to about 37% of the respondents. About 15% of them are unaffected by any of these circumstances.

Table 4:- Practice related response on generic medicine (n=120)

Sl.No	Questions	No	Sometimes	Often	Frequently	Yes
1.	Do you prescribe generic medicines to your patients?	40(33.33%)	10(8.33%)	15(12.5%)	8(6.66%)	47(39.16%)
2.	Have you ever taken generic medicine?	41(34.16%)	10(8.33%)	18(15%)	6(5%)	45(37.5%)
3.	Have you ever prescribed generic medicines to your family?	41(34.16%)	12(10%)	18(15%)	5(4.16%)	44(36.5%)
4.	Do you believe that transferring all the patients from brand drug to a generic version might affect the treatment results?	41(34.16%)	12(10%)	12(10%)	8(6.66%)	47(39.16%)

Author's own compilation

The responses to generic medicine from the practice related are presented in Table 4. Regarding their prescription practices for generic medicines, 39% of the respondents gave positive responses. And roughly 35% of them outright claimed that they do not provide their patients with generic drug.

Table 5:- Factors affecting prescribers response (n=120)

Factors affecting prescribing authority	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Quality of medicines	45(37.5%)	5(4.16%)	5(4.16%)	20(16.66%)	45(37.5%)
Availability	40(33.33%)	6(5%)	8(6.66%)	30(30%)	36(30%)
Socio-economic status of the patients	40(33.33%)	6(5%)	15(12.5%)	22(18.33%)	37(30.8%)
Price	40(33.33%)	10(8.33%)	5(4.16%)	25(20.83%)	40(33.33%)
Seriousness of the patient's diseases	40(33.33%)	10(8.33%)	6(5%)	24(20%)	40(33.33%)

Author's own compilation

Table 5 displays the factors affecting the prescription type and how it affects the behavior of the prescriber in the context of generic medicine. There are a few significant aspects that collectively influence the physician's perspective, knowledge, and conduct while prescribing generic medicines. One of the most significant factors influencing a prescriber's decision to prescribe generic medications is the quality of the medicine. Despite having the same active component that has been put through all clinical trials and quality testing, there are still concerns about the quality of these drugs. The accessibility of these medicines is another factor that influences a physician's decision to prescribe a generic prescription. The availability of generic medicines and the lack of knowledge about these drugs are the physicians' key concerns. There are still some doctors who are against the availability of generic drugs on the market. Socio-economic status of the patient affects the prescription of the patient and the perception of the physicians. Price is one of the most concerned issue that affect the physician perception the most. Generic medicine can be made without repeating research and testing, which results in a significant drop in medicine prices. The seriousness of the patient and the impact of the diseases hampers the physician's prescription.

I. Qualitative data analysis: - Major findings:

By using the maximum likelihood technique and rotating varimax, factors were identified. Exploratory factor analysis is a data- driven method that is required to explore the latent variable in a data set. One of a group of multivariate statistical techniques called exploratory factor analysis (EFA) aims to find the fewest possible hypothetical constructs (also known as factors, dimensions, latent variables, synthetic variables, or internal attributes) that can parsimoniously explain the co-variation seen between a number of measured variables (also called observed variables, manifest variables, effect indicators, reflective indicators, or surface attributes). That is, to determine the shared elements that account for the arrangement and structure of the measured variables. In the behavioral sciences, factors are thought to be unobservable traits of individuals that manifest as variations in how those individuals perform on the measured measures. The below table shows the factor loadings of the constructs. Factor analysis is a technique that is used to reduce a large number of variables into fewer numbers of factors. This technique extracts maximum common variance from all variables and puts them into a common score. The table shows the rotating varimax, which attempt to clarify the statistical relationship between the below mentioned variables.

Table 6:- Exploratory Factor Analysis and Factor Loadings (n=120)

Items	Factor loadings (1)	Factor loadings (2)	Factor loading (3)	Factor loadings (4)
A generic drug is bio-equivalent to a name brand drug.	0.775			

A generic drug has the same dosage as a brand-named drug.	**0.774**			
Compared to other drugs, the brand drugs adhere to greater safety regulations.	**0.771**			
Are you aware of the scheme of the Government?		**0.774**		
Are you aware about the Indian Medical Council Act to Prescribe drugs with generic names?		**0.847**		
Are you satisfied with the quality control measure of generic medicines by the Regulatory Authority?		**0.987**		
Do you prescribe generic medicines to your patients?			**0.891**	
Have you ever taken generic medicine?			**0.897**	
Have you ever prescribed generic medicines to your family?			**0.874**	
Do you believe that transferring all the patients from brand drug to a generic version might affect the treatment results?			**0.987**	
Factor affecting the prescribers prescription (Quality of medicine)				**0.981**
Factors affecting the prescribers prescription(Availability)				**0.881**
Factor affecting the prescribers prescription(Socio-economic status of the patient)				**0.847**
Factor affecting the prescribers prescription(Price)				**0.874**
Factor affecting the prescribers prescription(Seriousness of the patient)				**0.854**

Author's own compilation using SPSS

Table 7:- Shows confirmatory factor analysis and computed results of the model

Model Fit Indices	Recommended Value	Computed value
Absolute fit measure	**--**	**--**
Chi-square/df	**<3**	**2.181**
GFI (Goodness of Fit Index)	**<0.9**	**0.898**
RMSEA	**<0.10**	**0.937**
AGFI (Adjusted Goodness of fit index)	**>0.90**	**0.981**
NFI (Normality Fit Index)	**>0.90**	**0.927**
CFI (Comparative Fit Index)	**>0.90**	**0.946**

Author's own compilation using AMOS

Confirmatory factor analysis is a theory driven model that requires a hypothesis testing to test whether the data set is suitable for the model or not. The Chi-square estimate is 2.181, which is lower than the suggested value of 3. The approved value is 9, however the goodness of fit Index is indeed 0.898, which is lower explains the fact that it is excellent in measure. The root mean squared error of approximation (RMSEA) is 0.937 and its suggested value is 10. The normality fit index is 0.927, the comparative fit index is 0.946, and the modified goodness of fit index is 0.981, all of which have suggested values of >0.90. All the values obtained through CFA is absolutely fit with Excellency.

II. Findings of the study:-

It is undeniable that the use of generic medicines has greatly expanded in recent years. However, there is a gap in prescriber's knowledge and perceptions of generic medicines. The components of generic medicines, specifically their composition, effectiveness, and safety precautions, are some of the major concerns of the medical professionals. The distribution of those who accept and don't accept generic drugs is roughly equal. The results reveal an astounding fact that the cost, quality, and severity of the patients' illnesses are the three variables that have the biggest impact. These

aforementioned elements have an impact on the prescriptions given by the medical professionals who prescribe these drugs. The utilization of these medicines is still debatable, although they do assist in lowering the patient's drug expenditures to a greater extent. The lack of the physicians' confidence in the efficacy of unbranded generic medicines is the main barrier to their prescribing them to their patients. Pharmaceutical corporations' aggressive marketing of branded generic medicines makes the issue worse. There are serious concerns about pharmaceutical corporations' lack of Good Manufacturing Practices (GMPs), which has led to questions about the effectiveness and safety of generic medicines.

III. Conclusions:-

To conclude, the Government of India has built up many opportunities in popularizing the schemes of healthcare expenditure among the people. There are many awareness programmes and announcements that are done by the government officials and administrative works are also initiated. To promote and ensure the reliability of generic medicines, the Ministry of Health & Family Welfare has implemented a number of regulatory procedures. This includes amending the Drugs and Cosmetics Rules, 1945 to make it mandatory to grant licenses for drug formulations containing a single active ingredient in proper name only, and including a provision in the Rules, 1945 for the submission of the result of a bioequivalence study along with an application for grant of manufacturing permit. The use of technology will also help in promoting awareness about generic medicine among the practitioners. However, though the use of these generic medicines have the feasibility to reduce the healthcare costs to a significant extent, there are strong supply side constraints in realizing these potentialities. Appropriate policy initiatives are needed to address this virtual gap of inaccessibility identified.

Declaration of the study:-

I hereby declare that the above particulars of facts and information stated are true, correct and complete to the best of my belief and knowledge. No funding has been received to carry out this survey and all the means are ethical by nature. It has not been submitted to publish anywhere.

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