International Journal for Multidisciplinary Research (IJFMR)



# Generic Drugs & Its Rare Use in the Indian Market

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#### Abstract:

Generic drug use is high and is rapidly increasing in all the countries of the world. In India, inspite of different amendments and schemes, it is seen that generic drugs are preferred less than the brand drugs. The purpose of the present study is to determine the reasons behind preferring brand drugs over generic drugs by physicians and customers (patients) in India and to fill-up the gaps by suggesting intervention/law/act to eliminate the differences in between generic and brand drugs. The present study is a questionnaire-based study conducted among 50 medical practitioners who are currently practicing in Government Hospital in different parts of India & 50 patients who are currently under treatment for long prolonged diseases. It had been found that, out of the 50 physicians, 48 physicians, (96%) have heard about generic drugs and 42 physicians (84%) always take into consideration the socioeconomic status of the patient while prescribing medicines. Reasons behind prescribing or not prescribing generic drugs by the physicians were, 44% physicians preferred generic drugs as they think generic drugs have same therapeutic effects like the Brand drugs. Among the others who do not prefer, stated their reasons as, generic drugs do not have same therapeutic effects like the original brand drugs, have lower quality, do not have much knowledge about generic drugs, are not safe to use like the original brand drugs. Among the patients, it had been determined that out of the 50 patients, only 24 patients (48%) had heard about generic drugs. The reasons behind using/not using generic drugs by the patients were, 14% patients preferred generic drugs over brand drugs as they think generic drugs have same characteristics like the Brand drugs. Others who do not prefer using generic drugs stated their reasons as, they do not have much knowledge about generic drugs, generic drugs would cause side effect, have less therapeutic effects than original brand drugs. Quality control & different therapeutic characteristics of the generic drug should be matched with the same original brand drug before producing and launching the generic drug in the market. Awareness campaigns should be there for generic drugs. There should be law in India such as, "if a patient possesses BPL (Below Poverty Line) card, the doctor should ask the patient and prescribe generic drugs to the patient and this should be made mandatory for all physicians in all the parts of the country and strict actions should be taken against those who would be found violating the law". Implementing such laws would force the physicians to prescribe generic drugs if the patient is poor. Thus, if generic drugs are prescribed/used equally like the brand drugs then it could be a help to lakhs of people as more people could afford to buy medicines for their treatment, leading to a healthy population.

**Keywords:** Generic Drugs, Jan Aushadhi Scheme, Mortality, Morbidity, Original Brand Drugs, Route Of Administration, Therapeutic, Quality Control.



# I. INTRODUCTION

Generic Drugs are the drugs which are same as the Brand Drugs in strength, safety, quality, dosage form, route of administration, characteristics etc. These medicines have same functions as the brand medicines and it could be used as a substitute for the original brand drugs. Generic medicines manufactured under a brand name drug must possess the same medicinal qualities and standards like its counterparts. Both the drugs, generic and brand drugs, have equal pharmacological effects. [1]

Generic drugs are cheaper in cost than the brand drugs. The reason behind this is not bad quality or poor effectiveness of the drug which had been compromised to make the drug into a cheaper one. But the actual cause behind its cheap price is that manufacturers, who manufacture such drugs, do not have enough budgets for marketing and developing a new drug in the market. When a pharmaceutical company develops a new drug into the market, the company spends a lot of expenses on the research, marketing, development, and promotion of the drug. The company gets a patent grant that gives right to the company to sell the drug until the patent is effective. Once the patent expires, drug manufacturing companies can take permission from FDA (Food and Drug Administration) to manufacture and sell the generic form of the drug. Companies, other than the one who manufactured the drug, can develop, and sell the drug as well and they could sell it in a cheaper price. When various such pharmaceutical companies develop and sell the drug, competition among them is high and as such the price becomes low. [2]

FDA had set up same standards for the pharmaceutical companies and it was seen that most of the pharmaceutical companies manufactures both the brand and generic drugs and it had been estimated by FDA that brand drug companies manufacture approximately 50% generic drugs. Checking of the generic drugs, whether it meets the same standards as the original drug, the FDA Generic Drugs Program conducts reviews to meet these standards. For getting approval to manufacture and sell generic drugs, having same constituents like its counterpart brand drugs, pharmaceutical companies could submit an "Abbreviated New Drug Application" (ANDA) where the company should show and provide evidence that generic drugs and brand drugs are equivalent in active ingredients, type, strength, use indicators, route of administration etc. [2,3] Many a times it had been noticed that generic drugs varied with the brand drugs in terms of colour, flavors, inactive ingredients etc. Generic drugs, according to the Trademark Law in the US, does not allow the generic drugs and brand drugs to be exactly same in case of its colour, flavors etc but the active ingredients should be exactly same so that both the drugs, generic and brand drugs, have same medicinal effects. [2]

Generic drug use is high and is rapidly increasing in all the countries of the world. In India, it is seen that generic drugs are preferred less than the brand drugs. [1]. In India, the poor population and most of the middle-class people are unable to buy medicines for their diseases and cannot afford treatment due to the high price of the medicines. It mainly becomes difficult for those people who need to take medicine for long duration of time or for whole life. [3,8,9]. It was seen that, in India, people due to high price of medicines, most of the days go without drugs or they buy small proportion of drugs which are essential to them. This situation is deteriorating everyday as prices of medicines are increasing at a very fast pace. [4,6,11]

Generic medicines play a major role in providing healthcare which is very cost effective. About 80% of medicines prescribed in countries like USA, Australia, and UK etc are generic medicines, as revealed during Prescription Audits. However, India accounts for less than 50% of generic drug use despite the fact, that in case of generic drugs, India is one of the largest exporters in worldwide. [3]

Government of India, in the year 2008, launched the Scheme "Jan Aushadhi" which initiated to provide



cost effective generic medicines through "Jan Aushadhi Medical Store" in many districts of India. In October 2016, in an amendment to the code of conduct for doctors, the Medical Council of India suggested physicians to prescribe generic drugs and those physicians should prescribe generic drugs as much as possible and should use capital letters and ensure that there is a logical prescription which would promote the use of generic drugs. [1,3]

Inspite of all the schemes and amendments, the use of generic drug is still low in the country. Is it since doctors are not confident enough regarding the prescription of generic drugs or is it that the patients are not sure of the composition and quality of the drug or is it due to some other reason behind less or rare use of generic drugs in India despite being one of the largest exporters. [7,10] The debate between generic and brand drugs is mainly focused to make medicines available at a cheaper rate so that everyone, rich or poor can buy those medicines for their treatment and can treat their diseases to live a long and healthy life. [1,3,5]

The study has determined the lacunas/reasons behind preferring brand drugs over generic drugs by physicians and patients in India and suggested measures to eliminate the differences in between generic and brand drugs so that generic drugs are prescribed/used equally like the Brand drugs.

#### **II. METHODOLOGY**

The study was a cross-sectional mix-method study conducted among 50 MBBS, BDS pass-out students and practitioners who are currently practicing in Government Hospitals in different parts of India and 50 consumers (patients) who are taking medicine for any prolonged disease. Among the postgraduates, participants from different departments such as Ophthalmology, Cardiology, Psychiatry, Gynecology, Biochemistry etc were taken so that there are different opinions from different field of doctors regarding the usage and prescribing pattern of generic drugs. Doctors from different long-term diseases and are currently under medication were taken as participants in the study. Ayurvedic doctors, Homeopathy doctors, unregistered medical practitioners and patients who are not under treatment were excluded from the study. Data collection had been done through Google form document. Two different questionnaires in English language were there, one was for the physicians, while the other was for the patients. The questionnaires consisted of two sections, section 1 contained socio-demographic and background characteristics of the participants and Section 2 contained knowledge, perception of generic drug among physicians and patients, drug efficacy and safety related questions.

#### III. RESULT

In the study "Generic Drugs and its rare use in the Indian market" the data was collected from 50 registered physicians (medical practitioners) and 50 patients who are undergoing or had undergone treatment for any prolonged disease. Most of the doctors are MBBS, BDS, MD/MS and few doctors are super specialists, all currently practicing in government hospitals in different parts of India. Among the patients, all of them have been taking medicines for prolonged illnesses.

## Knowledge & prescribing pattern of physicians regarding generic drugs -

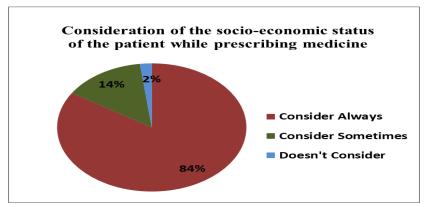
Out of the 50 physicians, 48 physicians, (96%) have heard about generic drugs and only 4% have no idea regarding generic drugs. Amongst all the doctors who had participated in the study, only 4% physicians always prescribe generic drugs to their patients while 14% frequently prescribes, 52% prescribes generic drugs to their patients sometimes, 18% rarely prescribes generic drug and the rest 12% doctors had never

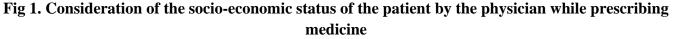


prescribed generic drugs to their patients.

#### Consideration of socioeconomic status of patient while prescribing medicines -

It had been seen that out of 50 physicians, 42 physicians (84%) takes into consideration the socioeconomic status of the patient while prescribing medicines, 14% sometimes consider the socioeconomic status while 2% doesn't consider the socioeconomic status while prescribing medicines.





23 physicians (46%) ask the patients if they would like to go for generic drugs instead of the original brand drugs while the rest 27 physicians (54%) never asked their patients if they would prefer generic drugs in replacement of original brand drugs. While it had been estimated that as many as 90% physicians prescribe generic drugs to the patients if the patient states that their original brand drugs are too costly for them and the remaining 10% do not prescribe generic drugs even if their patients complain them regarding the high price of brand drugs.

## Knowledge of physicians regarding new drugs in the market -

Different physicians have different sources through which they come to know about a new drug that has been launched in the market. Out of 50 physicians, 30 physicians (60%) get to know about a new drug through Medical Representatives, 22% through Research Articles and Journals, 16% through clinical trial published results and only 2% physicians come to know about a new drug through promotional meetings of pharmaceutical companies.

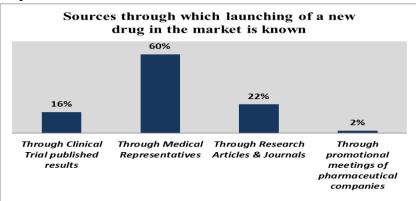


Fig 2. Different sources through which launching of a new drug in the market is known by the physician



It had also been seen that most of the physicians i.e. 24 out of 50 (48%) add a new drug to their prescribing pattern after the drug had been used by other physicians for quite sometime, 34% adds after clinical trial of the drug had been done and published, 14% adds after getting information from Medical Representatives. And the remaining 4% adds a new drug in their prescribing pattern only after the medicines had been proved to have their characteristic effects and causes no side effects to the patients.

# Reasons behind prescribing / not prescribing generic drugs by the physicians -

Reasons behind prescribing or not prescribing generic drugs by the physicians were determined. It had been stated by 44% physicians that they do prescribe generic drugs as they think generic drugs have same therapeutic effects like the Brand drugs and that patients can get it in a cheaper price and can save money. 26% physicians think generic drugs do not have same therapeutic effects like the original brand drugs and so they do not prescribe generic drugs. Among the other physicians, 12% physicians do not prescribe generic drugs as they think generic drugs have lower quality than brand drugs and 2% physicians stated that they think generic drugs are not safe to use like the original brand drugs whereas the rest 16% do not prescribe as they do not have much knowledge about generic drugs.

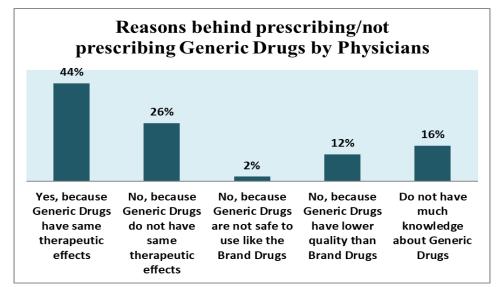


Fig 3. Reasons behind prescribing / not prescribing Generic Drugs by Physicians

The Government of India had implemented different amendment and scheme for generic drugs but inspite of the different Amendments and Schemes on generic drug; generic drugs are not prescribed by most physicians in India. According to the physicians it was because, knowledge of generic drug is less as compared to the brand drugs, which had been stated by 34% physicians, while 36% physicians stated that generic drugs were not used as these drugs couldn't be trusted on efficacy and safety issues, 18% physicians think brand drugs are always given more preference than generic drugs whereas the rest 12% physicians stated generic drugs were not used in India as much as brand drugs as because proper initiatives were not taken by the Government for spreading the usage of generic drugs.

## Side effects/disorders caused by the usage of generic drugs -

The physicians, who had prescribed generic drugs, revealed that only 24% patients came back to them after they had got side effects/disorders due to the usage of generic drugs. On the other hand, 44% doctors



think generic drugs take longer to cure a disease than the original brand drugs.

#### Knowledge & usage of generic drugs by the patients -

Among the patients, it had been determined that out of the 50 patients, only 24 patients (48%) had heard about generic drugs whereas 26 patients (52%) are not aware about generic drugs. Only 12% patients had used generic drug while 88% patients never used generic drugs. The sources from where the patients gained knowledge about generic drugs are, 16% of the patients came to know about generic drugs through mass media ie. through television, radio, newspaper, internet etc. 12% through relatives, friends and colleagues, 10% through pharmacists, 6% through doctors, 6% patients know about generic drugs as they had studied in their course.

#### Recommendation of generic drug to the patients by their doctors & pharmacists -

It was revealed only 2% patients were asked about choosing generic drugs over brand drugs by their doctors to save money whereas 98% patients were never asked by their doctors if they would like to prefer generic drugs for brand drugs. Similarly, only 20% patients were recommended generic drugs by their pharmacists in replacement of the brand drug. The rest 80% patients stated that their pharmacist did not recommend them generic drugs.

#### Reasons behind using/not using generic drugs by patients -

The reasons behind using/not using generic drugs by the patients were, among the users, 14% patients preferred generic drugs over brand drugs as they think generic drugs have same characteristics like the Brand drugs and that they could save money. None of the patient uses generic drugs as per their doctor's recommendation. 64% patients do not use as they do not have much knowledge about generic drugs, 12% patients think generic drugs would cause side effect, 10% stated that generic drugs would have less therapeutic effects than original brand drugs.

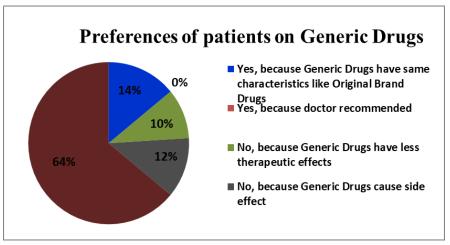


Fig 4. Preferences of patients on Generic Drugs

#### **IV. DISCUSSION**

The study was done in 100 participants, 50 physicians and 50 patients, to determine the knowledge and perception of the prescribers and users if generic drugs. Among the physicians most of them were BDS, MBBS and MD/MS. Physicians where various departments have participated in the study such as



Ophthalmology, Gynecology, Orthopedic, Cardiology, Psychiatry, Biochemistry etc. Among the patients most of them were graduates and postgraduates and were undergoing treatments for diseases such as Diabetes, Hypertension, Thyroid, Anemia, Depression etc.

The findings of this study evaluated that majority of the physicians have heard about generic drugs and have knowledge about it. It had been seen most of the physicians consider the socioeconomic condition while prescribing medicines, only few of them do not consider the socioeconomic condition of the patients while prescribing drugs. Majority of the physicians do not ask the patients if they would like to go for generic drugs instead of the original brand drugs. Reasons behind prescribing or not prescribing generic drugs by the physicians were determined. Physicians who prescribed generic drugs believed generic drugs and brand drugs have same therapeutic effects. Many physicians stated negative opinion on generic drugs. They do not have a trust on generic drug and believed generic drugs and original brand drugs were not same and have different therapeutic effects. Others believed generic drugs have lower quality than brand drugs, were not safe to prescribe, whereas the rest, do not prescribe as they do not have much knowledge about generic drugs. Among the patients it had been determined that only 48% had heard about generic drugs and only 12% patients had used generic drugs. According to the patients the reasons behind using/not using generic drugs by the patients were, majority of the patients do not prefer as they do not have much knowledge about generic drugs, other reasons were, the patients had a believe that generic drugs would cause side effect, have less therapeutic effects than original brand drugs. While among the users, only 14% patients preferred generic drugs as they believe generic drugs have same therapeutic effects and characteristics like the Brand drugs.

The present study confirmed those of previous studies done on generic medicines. The present study determined that majority of the physicians have a good and proper knowledge of generic drugs but do not prefer to prescribe it to the patients which is like the findings of the previous studies where they had evaluated that maximum physicians preferred prescribing original brand and believed that generic drugs have less therapeutic effect unlike the brand drugs and would cause side effect to the patients. Prescribing brand drugs were better as brand drugs were safe and highly efficacious as compared to the generic drugs. In case of the patients, similar observations were done. Patients preferred brand drugs over generic drugs which were reviewed in the previous studies. Majority of patients lack knowledge of generic drugs and very few patients stated that their doctors and pharmacists ask them and recommends them about generic drugs while prescribing medicines which needs to increase as most of the patients do not have much knowledge about generic drugs and if their doctors and pharmacists recommends them generic drugs, it would be feasible and easier for them.

Different amendments and scheme such as "Jan Aushadhi Scheme" were implemented in India in the year 2008 and 2016 which initiated to provide cost effective generic medicines through Jan Aushadhi Medical Stores in many districts of India. An amendment to the code of conduct for doctors was also done where the Medical Council of India suggested physicians to prescribe generic drugs as much as possible and should use capital letters and ensure that there is a logical prescription which would promote the use of generic drugs. 13,14,15] But inspite of all the schemes and amendment, the use of generic drug is still low in the country, are not given much importance like the original brand drugs and are not preferred by most physicians in India. In the present study, according to the physicians generic drug was not so much popular in India as, knowledge of generic drug is less as compared to the brand drugs, generic drugs couldn't be trusted on efficacy and safety issues, brand drugs are always given more importance and preference than



generic drugs, whereas the rest stated that, proper initiatives were not taken by the Government for spreading the usage of generic drugs.

The policies on generic drug, in India, were not properly implemented and needs to get better. The Indian Government should strengthen the "Jan Aushadhi Scheme" and more Jan Aushadhi Medical Stores should be setup in more districts of the country. Proper legislation supports of the media, involvement of the Government in spreading about the Scheme, should be enhanced. [13, 15,18] Quality control, therapeutic characteristics, composition, side effects of the generic drug should be there and should be matched with the same original brand drug before producing and launching the generic drug in the market as most of the physicians in India didn't prefer prescribing generic drugs as they have a believe that generic drugs do not have same therapeutic effects like the original brand drugs, were low in quality and would cause side effect to the patients. [14] Awareness campaigns should be there for generic drugs and the awareness should be spread through the mass media (television, radio, newspaper, internet etc). Doctors and pharmacists should ask and recommend generic drugs to all their patients.

There should be law in India which needs to be implemented. The law should be, "if a patient possesses BPL (Below Poverty Line) card, the doctor should ask the patient and prescribe generic drugs to the patient and this should be made mandatory for all physicians in all the parts of the country and strict actions should be taken against those who would be found violating the law". Implementing such laws would force the physicians to prescribe generic drugs if the patient is poor and by looking at the socioeconomic condition of the patients. If generic drugs are prescribed similarly like the Brand drugs, then lakhs of people, who were not able to buy medicines due to its high price, now would be able to buy medicines for their treatment. This would reduce the mortality and morbidity rates from the country. And if the population of the country is healthy, they would have a longer life span increasing their ability to work for more years and thus increasing the economic status of the country.

## V. CONCLUSION

The research on "Generic Drugs and its rare use in the Indian Market" focuses on the limited use of generic drugs in the market. Though, both the drugs, Generic and Brand Drugs have same composition, ingredients, strength, quality etc but both the drugs are not used equally. In this study, we estimated the percentage of physicians and customers who prefer brand drugs over generic drugs. Majority of the physicians considered the socioeconomic status of the patients while prescribing medicines but it was determined that physicians do not ask their patients about their opinion, whether the patients would like to go for generic drugs or brand drugs. Lacunas behind not prescribing/using generic drugs by the physicians were, many physicians do not prefer generic drugs as they believed generic drugs do not have same therapeutic effects like the brand drugs, were not safe like brand drugs, have lower quality than brand drugs etc. On the other hand, it had been seen that majority of the patients lack knowledge in generic drugs. It had been seen that physicians preferred brand drugs as they believed that generic drugs do not have the same therapeutic effects like the original brand drugs, were low in quality and would cause side effect to their patients and so they preferred prescribing brand drugs over generic drugs. To overcome and improve this issue, measures should be taken such as - Quality control, therapeutic characteristics, composition, side effects of the generic drug should be checked and should be matched with the same original brand drug before producing and launching the generic drug in the market. Awareness campaigns should be there for generic drugs and the awareness should be spread through the mass media (television, radio, newspaper, internet etc.). Doctors and pharmacists should ask and recommend generic drugs to all



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their patients. There should be law in India which needs to be implemented. The law should be, "if a patient possesses BPL (Below Poverty Line) card, the doctor should ask the patient and prescribe generic drugs to the patient and this should be made mandatory for all physicians in all the parts of the country and strict actions should be taken against those who would be found violating the law". Implementing such laws would force the physicians to prescribe generic drugs if the patient is poor and by looking at the socioeconomic condition of the patients. Thus, if generic drugs are prescribed/used equally like the brand drugs then it could be a help to lakhs of people as people would get the same medicines with equal efficacy, strength, quality in a cheaper price and when more people could afford to buy medicines for their treatment, it will lead to a healthy population, thus reducing the rate of mortality and morbidity from the country.

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