



## A REVIEW ARTICLE ON PERCEPTION OF PHYSICIANS AND PHARMACISTS ON THE CHALLENGES AND USE OF GENERIC MEDICINES IN INDIA

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### ABSTRACT :

#### **Back Ground and Objective:**

To minimize the price and maximize the access of the drugs, generic substitution of branded drug has been introduced globally. The control regulations of such medicines vary country to country according to the Drug price control Order (DPCO) of the country. In India, the decision of drug sales and purchase is majorly influenced by prescriber or dispenser. However, this perception about generic drug in India is not well documented. This study has tried to cover the review of physicians and pharmacists related to the perspective on uses and challenges of generic medicines in India.



#### **Methods:**

A systematic literature search was performed by retrieving articles published from 2008 to 2019 regarding physicians' and/or pharmacists' experiences with generic medications and generic substitution.

#### **Results:**

Out of 102 publications were initially identified, 17 were considered for inclusion. The studies discovered that physicians and pharmacists were responsive about the cost-saving drive of generic medicament and use of generic drugs in improving worldwide access to drugs. Variations regarding control routines, bioequivalence necessities, and manufacturer standards were stated in less matured health care system. The physicians and pharmacists mentioned to have lack of trustworthy information and mistrust majorly in quality and efficacy. They reported that if the healthcare system developed, they might prescribe more of generic substitutions. Overall, pharmacists appeared to have better information of the impression of bioequivalence and generic drug facets than physicians.

#### **Conclusion:**

This can be credited to the way that created human services frameworks have progressive public control schedules for drugs when all is said in done just as better bioequivalence necessities concerning generics specifically.

**KEYWORDS :** price and maximize , generic substitution.

## INTRODUCTION :

About 70% market share of Indian pharmaceutical sector is covered by generic medicines. The share has been increasing day by day after the initiative of Ayushman Bharat by government in August, 2016. In the universal level, India provides 20-25% of the generic medicine in the terms of market value. Chopra (2019) United States is the biggest importer of India manufactured generic medicines. Howland (2019) showed that more than 40% of the need of generic pharmaceutical need of USA is fulfilled by India.

The generics business keeps on holding potential for development comprehensively inferable from approaching patent lapses and expanding push from administrative groups of a few nations including India, to shape up of generics to minimize human services costs. NAI, (2018) assures that generic medicine industry is expected to have exponential growth by the rouse of Ayushman Bharat initiative of Indian government. This 2016 launched incentive tries covering the medicinal needs of Indians in very cost friendly manner and has targeted the 100 million poor families of India.

In spite of the fact that we see various open doors for growth in generic medication segment, there are some challenges. (Adams & Brantner, 2017) On one side the high prices of medications open the market for generics and on the other side global generics estimation keeps on being on a deflationary direction. It said that Indian manufacturers keep on distinguishing better approaches to lower cost; this expands rivalry in a previously packed market. (Ghattani, 2016)

As India is one of the most elevated per capita out-of-pocket uses' nations, such generics will set aside a great deal of cash which can be utilized for other medical problems. (Adams & Brantner, 2017) In past few years, the utilization of generic medicines has expanded fundamentally. (Adams & Brantner, 2017)

In 2008, the Government of India, through the Department of Pharmaceuticals, began another initiative called 'Jan Aushadhi'. This program had objective of making unbranded quality medications accessible to needy individuals in the nation at a sensible and moderate cost through retail outlets' arrangement with the assistance of the administration. (Shreekumar, 2018) It has taken responsibility for setting up on Jan Aushadhi stores, which are drug stores selling just conventional name prescriptions to the degree conceivable, offering inclination to pharmaceutical open segment endeavors as well. (Chopra, 2019) In 2018, 3200 Jan Aushadhi stores were working in 33 states/ union territories crosswise over India. There are insufficient Jan Aushadhi stores, potentially 3200 against in excess of 8 lakh retail drug stores in presence, with numerous countryside territories still under served. (Shreekumar, 2018)

The Medical Council of India, in an amendment to the set of conducts for physicians in October 2016, has suggested that each doctor ought to prescribe drugs with generic names and the person in question will guarantee that there is a judicious prescription which advances the utilization of generic medications. In future, the Government of India may bring a legitimate system under which specialists should prescribe generic drugs to patients. (Shreekumar, 2018)

The review article on perspectives of patients on generic medicines has been studied and published many times. But there are various limiting factors with regards on the applicability of the generic medicines and the substitutions of the same in India. (Adams & Brantner, 2017) High illiteracy rates, low educational levels, and reserved access to medicinal services, just as huge contrasts among rural and urban regions were some of the constrained informative components in such articles. The literate patients of developing health care system like India may be treated with adequate generics. (Chopra, 2019) The challenges mentioned above can lead to drug adherence or doubling of drug dosage problems. Sometimes, the issue gets serious health problems if the same patient has been treated by many physicians and they attend various pharmacies. (Aivalli, Elias, Patil, & Bhanuprakash, 2016)

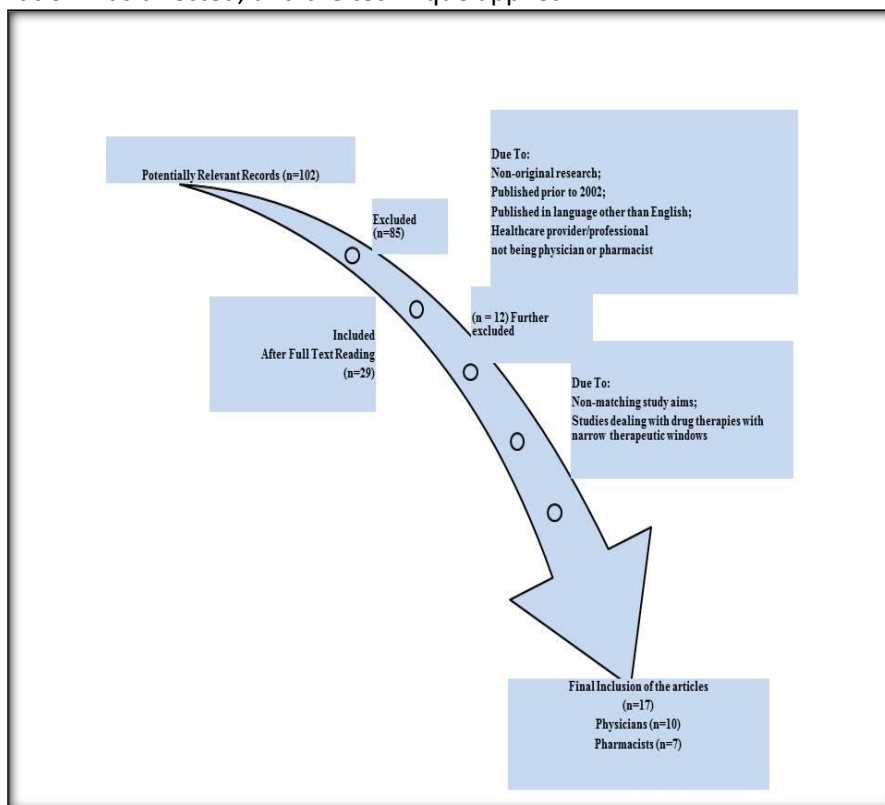
In addition to that the key decision maker in regards of Indian prescribing and dispensing pattern of medicaments are physicians and pharmacists. (Gupta, Malhotra, & Malhotra, 2018) They have their own problems and challenge the prescription and dispensing pattern. Scrutinizing the perception of them may increase the understanding of said challenges. (Bera & Mukherjee, 2012) In addition to that, the health care professionals carry the proficiency of health care systems.

It is important to understand the challenges of penetration and high sales of Indian generic medicines. Here in, the aim of the present study was to know the perspective of physicians and pharmacists on the challenges and use of Generic Medicines in India by systematic review using the obtainable publications regarding Indian generic medicines nationally and internationally.

**METHODOLOGY:**

The systematic literature was searched in the Scopus listed journals, in Medline (PubMed) and Journal of generic medicines by Sage. The articles were peer reviewed which had inventive research regarding the familiarity, practices and attitude of physicians and pharmacists for generic medicaments, generic drugs, prescription pattern of generic medicaments, substitution of branded medicines, and paradigm shift in prescribing generic drugs in India. Some of the terminologies used for refining the search were generic drugs of India, Jan Aushadi, Central Drugs Standard Control Organisation (CDSCO) regulations of Indian generic drugs, combined with health care providers, health stake holders, health care professionals, physicians, doctors or pharmacists and or druggists. Articles published after year 2008, were included for the evaluation. The process of generic substitution was initiated in around 2005-2006 in India and other developing countries, this was the selecting factor of the time frame of review. Publications based on qualitative data and prescription data were omitted.

The following figure (Figure: 1) shows the detailed process of selection of articles in form of numbers. The figure includes the initial identification of articles, the computation of eligible articles (the exclusion criteria were identifies an applied), the number of the final included articles. Over all 16 articles evaluating perception of physicians (n=10) and perception of pharmacists (n= 6) were included for the review. Tables 1 and 2 give an outline of the articles included, recorded by author and publication year, place where the examination was directed, and the technique applied.



**Figure: 1 Detailed Process of selection of Articles**

**Table: 1: Articles concerning Perspective of Physicians on Generic Medicines of India (A Developing Country):**

Reference	Method	Number of Participants
Patel & Paras, 2016	Questionnaire based survey	130
Bera & Mukherjee, 2012	Mail Survey	117
Gupta, Malhotra, & Malhotra, 2018	Observational Study	89
Aivalli, Elias, Patil, & Bhanuprakash, 2016	Observational Study	172
Ojikutu, Jack, & Ramjee, 2012	Semi Structured Interview	120
Patel, Gauld, Norris, & Rades, 2013	Questionnaire Based Study	22
Allghashan, 2010	Semi Structured Interview	73
Jamshed, Hassali, Ibrahim, & Babar, 2014	Questionnaire Based Study	130
Maiti, Bhatia, Padhy, & Hota, 2017	Semi Structured Interview	82
Sashwat & Rao, 2012	Mail Survey	56

**Table: 2 Articles concerning Perspective of Pharmacists on Generic Medicines of India (A Developing Country):**

Reference	Method	Number of Participants
Basak & Satyanarayan, 2012	Structured Personal Interview	66
Patel & Paras, 2016	Questionnaire based survey	56
Gupta P. B., 2009	Questionnaire based survey	100
Patel, Gauld, Norris, & Rades, 2013	Questionnaire based survey	90
Babar & Awaisu, 2010	Personal Interview	87
Chong, Hassali, & Bahari, 2010	Mail Survey	57
Jamshed, Ibrahim, Hassali, Masood, Low, & AShafie, 2013	Questionnaire	212

**RESULT:**

Patel & Paras (2016) conducted a study evaluating the attitudes of 130 Indian General Practitioners concerning generic prescriptions and established that 76 % of the respondents confirmed willingness to prescribe the same. They additionally found out that gender, age, experience of practice, or expertise regarding the degrees were not related with the prescription pattern, the socioeconomically status of the local population even had less of the concern with prescribing generics. The linked meeting more of pharmaceutical sales representatives per week was a factor concerned with reluctance for prescribing generic medications. The major attitude of prescribing was favored by result of therapy, efficacy and safety of generic medicine.

The study regarding the General practitioners' attitude for generic medicaments prescription was done by (Bera & Mukherjee, 2012) in India. The study covers 200 General practitioners by mail survey through questionnaire. The majority of the results indicated that branded medicines are demanded by patients and hospital consultants and they meeting up to the same. The price was not the consideration in 39% of the General practitioners, 21% said that the impact of pharmaceutical industry is relatively huge in India. Moreover, approximately 90% of the physicians perceived that the generics are as effective as the branded medicines. (Ojikutu, Jack, & Ramjee, 2012) Further, 37% said that they will be using generics medicines more freely if clinical trials data were available.

A cross-sectional investigation was completed utilizing a pretested survey in tertiary health care houses of Jammu (J and K). The survey was intended to evaluate the KAP about generic medicines. The specialists working in this foundation during the investigation time frame were incorporated. Information

was aggregated and examined utilizing on the web site, <http://www.graphpad.com>. P-estimations of  $< 0.05$  were considered to demonstrate statistical significance. Though majority of the physicians had vast knowledge and have positive attitude in prescribing generic medicines, the concern regarding quality and availability was there in a considerable proportion of physicians. (Jamshed, Hassali, Ibrahim, & Babar, 2014) Mainly, awareness work is required for the public acceptability of generic medicines and some work regarding the interventions of medical professionals regarding the generics. (Gupta, Malhotra, & Malhotra, 2018)

Aivalli, Elias, Patil, & Bhanuprakash (2016) analyzed the study and explored how physicians find it to reformation of generic substitution amendment by Indian government in the year 2016. The amendment says that physicians need to incorporate generic medicines in their prescribing pattern and pharmacists are obliged to dispense the cost friendly product as a substitute of brand named medicine. The omission of this can be done if the physicians have specifically asked not to substitute the same in some of the medical reasons. In these study 179 physicians including geriatrics, endocrinologists, General practitioners, pediatricians were included on the bases of questionnaire. (Das, et al., 2017) The core findings were that they believe substitution to generic is a good amendment as the cost of prescription reduces markedly. However, the major concern of more than half of them was regarding effectiveness and safety (Bera & Mukherjee, 2012) of these generic medicines.

Basak & Satyanarayan (2012), Patel & Paras (2016) carried out surveys to evaluate knowledge and perception of community pharmacists regarding generic medicines being dispensed in India. The knowledge was relatively high amongst the pharmacist as was reported in most of the articles. (Gupta P. B., 2009) The belief of pharmacist about the therapeutic effect was affirmative and strong. The quality concerns about the medicaments remain same as the physicians in pharmacists too. (Bera & Mukherjee, 2012) There was almost quarter of the pharmacists in both of the research, who were not ready to suggest generic medicines even in the unavailability of branded medicines. (Babar & Awaisu, 2010) ; (Basak & Satyanarayan, 2012)

### **The literature review on the perception regarding generic medicines in Physicians and Pharmacists lead us to following findings:**

#### **a) Awareness on Generic Medicines:**

Both the physicians and pharmacists believed that the major reason of generic penetration in the market is the increasing cost of the health care. The entire cost of health care can be reduced by the utility of generic medicines.

#### **b) Effectiveness**

A high number of physicians held the criticism that generic drugs have lesser efficacy than the brand name medicines in comparison to the pharmacists.

#### **c) Quality:**

Almost 25% of the physicians and pharmacists believed that the quality of generic medicines may be inferior to the branded medicaments. High number of pharmacist held negative perception about the quality standards of medicaments.

#### **d) Safety:**

Physicians and pharmacists did not differ in their view about the safety of the generics. Both of them held the perception that the generic medicines manufacturers just follow GMP (Good Manufacturing Practices) and not USFDA (U S Food and Drug Administration) standards that makes generic medicines less safe.

#### **e) Value Perception:**

Physicians of developing country, including India had the fear of misleading patients if they prescribe generic medicines. However, the pharmacists were willing to dispense if the Physicians will prescribe the same.

**f) Bioequivalence (BE):**

The pharmacists had slightly more knowledge on the Bioequivalence. Doctors said that the prescriptions may include the generic medicines if the bio bio-equivalence data will made available by manufacturers.

**g) Generic substitution:**

Substituting them according to CDSCO was yet very unclear amongst the health professionals of India. The certainty of the amendment may bring the more clarity with the pattern of prescribing the medicines. The physicians and pharmacists suggested that government should provide better information was the view of pharmacists and the physicians. The physicians believed that the pharmacists may educate and provide assurance of generic medical segment.

The major importance of these findings is, Physicians and pharmacists have some of the negative perception with regards to generic medicines. That can be the big challenge in the acceptance and wide spread of the usage of the generic medicaments. The clinic data turned out to be amongst the major consideration by physicians and pharmacists both. The availability of the same may easily catalyzes the switch of generic medicines in regards of side effects, quality and effectiveness. (Gupta P. B., 2008)

**LIMITATIONS:**

- Very less numbers of articles were available in the Indian Context, articles of developing countries have been done. This may have some variables with Indian context have been considered.
- This study is a complete amalgamation of impression of generic medicines among physicians and pharmacists according to secondary data of current research.
- Our review utilized generally acknowledged methodology to assess the literatures and recognized that a wide segment of medical professionals and laypeople hold contrary impression of generic medicines.
- While there are many studies which had attitudes of the general population and of doctors towards generics, only nine articles were there on the views of pharmacists, which may have reduced the accuracy of the estimates in this group.

**CONCLUSION:**

This review article shows that physicians and pharmacists both were, much aware about the potential of generic medication for the improved access of medication in India. The physicians and pharmacist have their concerns regarding quality of the Indian generic medicines as we don't have matured manufacturing circuit and guidelines. The medical council of India and Central Drugs Standard Control Organisation may implement proper amendments with the role clarity of individual amongst the health care system by introducing distribution of duties to the pharmacists which may lead physicians target more up on research.

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