

A STUDY ON AUTHORIZED GENERICS AND BRANDED GENERICS: A PERSPECTIVE ANALYSIS AMONG THE PHARMACY STUDENTS IN BHUBANESWAR CITY, ODISHA

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Abstract:

Consumers nowadays are increasingly opting for generic medicines due to their significantly lower costs. Healthcare expenses, often paid out of pocket, can be substantial. Authorized generic medicines, produced by the same companies that manufacture brand-name drugs, fall under the category of generic medicines. Branded generics are generic drug molecules marketed under unique names. This study aims to explore pharmacy students' knowledge and perspectives on generic drugs and their usage, while also examining the specific differences between branded generics and authorized generics. A standardized questionnaire was administered among pharmacy students for this purpose. The questionnaire is designed to investigate how students from various pharmacy disciplines perceive and understand generic medicines, and to elucidate the reasons behind their preference for using generic drugs, both branded and authorized. One of the major challenges identified is the need to increase awareness, which could be addressed through regular training programmes such as workshops and Continuing Medical Education (CME). Government regulations governing the purchase and sale of generic drugs by patients and pharmacists, in place of costly brand drugs, should be reconsidered.

Keywords: - Pharmacy, Generics Medicine, Brand

Drug, Perspective, Branded Generics.

1. Introduction:

Today, people utilize generic medicines more frequently since they significantly lower the price of the medicines. Healthcare costs are undoubtedly significant expenses that are frequently paid out of pocket. So, in terms of these fallouts, generic drugs have emerged as one of the better options. According to the Food and Drug Administration (FDA), —Generics drug are just as safe and just as effective as their brand-name counterparts, and they are a cost-effective way of achieving substantial savings —. A generic counterpart of the brand-drug has some proofs that makes it as safe as the branded drugs. Generic medications offer patients the same efficacy and safety profile since they have the same active components, potency, dose form, and route of administration. There are a number of explanations that help to explain why generic medicines are less expensive than branded ones. It is regarded as the "Essential Drug Criteria" by the World Health Organization (WHO). Because manufacturers of generic medicines do not need to construct a separate laboratory for research and development, hence their products are so inexpensive. Manufacturers of generic medicines do not squander money on advertising.

2. Concepts regarding authorized generics and branded generics:

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2.1 Authorized Generics Drugs:

Authorized generic drug fall under the generic drug category and are produced by the brand-name drug's producer. They are the drug is similar to the brand-name medicine, except the drug is similar to the brand-name medicine, except is not printed on the label and they could be made of a different material and colour . An authorized generic is not included in the Food and Drug Administration's list of approved pharmaceuticals with therapeutic equivalency evaluation since it is sold with the New Drug Application (NDA) for the brand-name drug. Because it is the same drug, an authorized drug is regarded as being functionally equal to its brand-named counterpart. Authorized generics could be the perfect solution for pharmaceutical companies whose brand-name drug patents have expired. The brand name manufacturers could create their own generics rather than taking a chance on losing market share when other pharmaceutical companies enter the generics market.

2.2 Branded generics drugs:

Generic medicines that have been given a brand name are known as branded generics. They may be marketed in a manner akin to that of branded drugs. Branded generic drugs provide generic drug molecules exclusive names. After the original drug's patent has expired, branded generics may be manufactured by the original manufacturer or a generic drug company and marketed. They are advertised by submitting an abbreviated new drug application (ANDA) to the regulatory authority, and they must be clinically comparable to the original drug whose patent has expired. They are also known as value-added generics, and they can either be a modified form of the drug's molecule or a new dosage form of an off-patent drug produced by a different manufacturer.

2.3 The Hatch-Waxman Amendment regarding Generic drugs (The Bible for the generic medicines)

In accordance with the "Drug Price Competition and Patent Term Restoration Act of 1984," also referred to as the Hatch-Waxman Amendments Section 505(j) of the Federal Food, Drug, and Cosmetic Act allows applicants to submit an abbreviated new drug application (ANDA) to get approval for generic drug products (FD&C Act). The Hatch-Waxman Amendments contain clauses relating to new drug applications' patents, exclusivities, and 180-day privilege for specific ANDA applicants. Generally speaking, these statutory provisions have been used in the context of application-specific regulations by the Food and Drug Administration (FDA or the Agency) decisions. Large corporations are capable of competing with generic firms' drugs during this time without having to cut the price of their own brand-name products thanks to authorized generics. So, it is possible that authorized generics will lower the amount of money that independent generic companies make during this time.

3. Review of Literature:-

Kirtida R. Tandel, Nirav Kumar, M Patel, Sameer M Zaiwala, Milesh B Chavda, Nation V Dhanani in the paper (2018) —A study of knowledge, attitude and practice on generic drugs among teaching faculties at a tertiary care teaching hospital in South Gujarat, India states that the practice of prescribing, dispensing, and substituting generic medications in developing countries has generated debate among doctors, particularly because of concerns about quality, safety, and efficacy. These debates are a result of regional variations in drug policies and laws as well as specialized experts who deal with generic medications. As a result, there is a disparity between awareness about and attitudes toward brand-name and generic medications. Therefore, it

appeared that widespread awareness campaigns were required to close the gap. These initiatives would boost the use of generic drugs, lowering the overall cost of healthcare in the process.

Ajitabh Dash in the paper (2021) —Assessment of patient satisfaction with generic medication in Emerging Economy using the treatment satisfaction on questionnaire for medication explains that one method to raise national health standards is through giving patients access to safe, high-quality medications. The findings of the study revealed an affirmative relationship of effectiveness and convenience with patient's satisfaction with generic medicines.

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 many variables are thought to have a detrimental impact on doctors' perceptions of generic medications. There were two main points of view that emerged from the responses when it came to the efficacy of generic medications and how people perceive them. These are the option to purchase less expensive versions of brand-name medications for personal use and the belief that pharmacists do indeed let patients know they can purchase less expensive versions of brand-name medications when they are prescribed.

4. Objectives of the Study:

The objectives of the study are: -

- ❖ To analyze the specific difference between the authorized and branded generics from the pharmacy students
- ❖ To understand the knowledge and perceptions regarding generic medicines and their use from pharmacy students

5. Hypotheses of the Study:

The hypotheses of the study are as follows:

- ❖ There is no specific difference between the authorized and branded generic drugs that is obtained from the pharmacy students
- ❖ There is no knowledge and perception regarding generic medicines and their use among the pharmacy students.

6. Research Methodology:

Pharmacy students were given a standardized questionnaire designed to explore the rationale for using generic medications and to investigate how various branches of pharmacy perceive and interpret generic medicines, both approved and branded. The questionnaire comprises three sections. A pilot study involving 10 pharmacy students and gathering opinions from 5 professionals was conducted to validate the questionnaire's constructs. The demographic profile of the respondents is presented in the first section of the questionnaire. The second and third sections focus on respondents' knowledge and usage of generic drugs, as well as their perspectives on generics.

7. Analysis of the study:

7.1 Study Design: A systematic questionnaire is given to pharmacy students as part of the study in order to gauge their level of familiarity with generic medicines. In all, there are 15 questions, as well as a demographic profile. A questionnaire is being developed to examine the pharmacy students' knowledge, attitudes, and views of generic medicines as well as to identify the precise distinctions between branded and authorized generics. The below table shows the demographic status of the respondents:-

Table 1: Demographic Variables of the respondent (N=110)

Characteristics	Factors	Frequency (%)
Gender	Male	55
	Female	55
Age(In years)	0-20	07
	20-40	99
	40-60	04
	60-80	Nil
	80 and above	Nil
Qualification	D.Pharma	08
	B.Pharma	68
	M.Pharma	34

Source: Author's own compilation

The above table shows the demographic characteristics of the respondents that include gender, age and qualification of the participants. There is equal distribution of males and females among the sample to provide unbiased results

among the gender criteria. The age-group is divided into 5 major categories for screening purposes. The qualification consists of three main categories; D. Pharma, B. Pharma and M. Pharma respectively.

7.2 Knowledge of Generic Medicine:

Table2: Knowledge of Generic Medicines among the Pharmacy Students

Questions	Yes	No	Neutral
A generic drug has same composition as the branded drug.	80	28	2
Are generic drugs more expensive than the branded drugs?	27	83	
Generic drug companies always need to conduct bio-availability and bio-equivalence to analyse the equivalence between generic and innovator drug.	97	12	1
Are you aware about the scheme of Government of India —Pradhan Mantri Bharatiya Janaushadhi Pariyojana?	102	7	1
Do you know that there is stringent law in the country to prescribe generic drugs?	97	12	1

Source: Author's own compilation

The table above provides some evidence in favour of the claim that pharmacy students who will all go on to manufacture products in the future are cognizant and aware of generic medicines. 73% of the participants agreed that generic medications contain the same ingredients as branded medications. They did not support the idea that both had the same composition, according to 26% of them. Surprisingly, 76% of respondents believed that generic medicines are not more expensive than

name-brand medicines, while just 24% of respondents agreed that generic medicines are more expensive. 88% of the participant respondents believe that there is agreement with the facts that the pharmaceutical drugs producing generic medicine will have to show the bio-equivalency and bio-availability to analyze the difference and equivalence between generic and innovator drug and 11% of them denied the same fact. 93% of the participant respondents actually

knew about the generic medicine and the umbrella scheme of —Pradhan Mantri Bharatiya Janaushadhi Pariyojana. The government has stringent law regarding prescribing generic medicine. The Indian government is aware that the majority of doctors do not prescribe generic medications, despite court rulings and pertinent Medical Council of India regulations. In this regard, clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette

and Ethics) Regulations, 2002 states that all doctors must prescribe drugs with generic names that are readable and, if possible, in capital letters, and they must also make sure that the drugs are prescribed and used in a rational manner. Also, the former Medical Council of India (MCI) has circulated circulars directing all Registered Medical Practitioners to adhere to the aforementioned regulations.

7.3 Knowledge regarding Generic Medicine (Practice & Usage):

Table 3: Practice and Knowledge regarding Generic Medicine related Responses among the Respondents

Questions		Yes	No	Maybe
1.	Do you know the difference between —Branded drugs and —Generic drugs?	95	15	0
2.	Do you the difference between —Authorized generic drug and —branded generic drug?	94	16	0
3.	Do you feel generic drug have same efficacy as the other drugs have?	98	10	2
4.	Do you believe that transferring all the patients from a brand drug to generic versions might affect the treatment's results?	98	12	0

Source: - Author's own compilation

This study reveals that the majority of medical schools currently have significant knowledge about generic medicines, which could leave a lasting legacy for future generations of medical experts. Among the respondents, 86% expressed confidence in their ability to distinguish between branded and generic medicines, while 14% regretted their lack of such distinction. Additionally, 85% of all respondents demonstrated awareness of the differences between branded generics and authorized generics, while 15% did not. Regarding effectiveness, 89% of the interviewees agreed that generic drugs are as effective as other branded drugs, while 9% disagreed. Furthermore, 89% concurred that transitioning patients from brand-name medications to generic equivalents could potentially influence the course of treatment, whether positively or negatively.

Reliability and Adequacy of the Sample

Collected: To assess the sample's strength, the Kaiser-Meyer-Olkin (KMO) test was conducted using SPSS, yielding a result of 0.76, indicating sufficient adequacy for the need of the study. Additionally, the Cronbach's Alpha test was

performed to determine the reliability of the sample, resulting in a high score of 0.90, indicating strong internal consistency.

7.4 Facts about the Jan Aushadhi Scheme:

The Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is a flagship program initiated by the Government of India to provide generic medicines at significantly reduced prices. Pradhan Mantri Janaushadhi Kendras (PMBJKs) have been established nationwide to promote this scheme. The Bureau of Pharma PSUs of India (BPPI) oversees the implementation of PMBJP. All medicines procured under this program undergo quality assurance testing at NABL-accredited laboratories and comply with WHO GMP (World Health Organization's Good Manufacturing Practices) standards.

The government provides incentives up to 2.5 lakhs for setting up PMBJKs, which can be established in various locations, including outside hospital premises, by physicians, pharmacists, business owners, self-help organizations, NGOs, and charity

societies. The Bureau of Pharma PSUs of India (BPPI), under the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, has developed the "Janaushadhi Sugam App." This app helps users locate nearby Janaushadhi Kendras using Google Maps, search for Janaushadhi generic medicines, and compare prices between generic and branded medications, enabling significant cost savings for consumers.

7.5 The Cost Analysis of Janaushadhi Scheme:

Since the acceptance of modern medicine as a dependable and scientific form of treatment, the trend of utilizing drugs to treat illnesses has been rising globally. Medicines and medicines account for a sizeable component of out-of-pocket (OOP) household health spending in India and are becoming a significant source of catastrophic costs for both outpatient services and inpatient (hospitalization) fees. The private OOP spending on medications by low income households is what drives families into poverty.

8. Conclusion:

While most faculty members exhibited positive attitudes and understanding of generic medicines, this sentiment did not translate into the number of prescriptions written, highlighting a gap between theory and practice. A key issue identified was awareness, which could be addressed through regular training programs such as workshops and continuing medical education. It is essential for doctors, starting from their undergraduate studies, to receive early education on generic medications. In addition, clinicians should have access to or be provided with copies of the National Guidelines on Generic Medicines. Government regulations concerning the sale and purchase of generic medications by patients and pharmacists should be revised to prioritize cost-effective alternatives over expensive innovative drugs.

References:-

1. Burns, Joseph. —Challengers of the Status Quo In Pharmacy Benefit Management — Less Wasteful Formularies.¶ *MHE Publication*, vol. 29, no. 10, Mar. 2023. www.managedhealthcareexecutive.co, <https://www.managedhealthcareexecutive.com/view/what-are-authorized-generics>.
2. DrugPatentWatch. —Branded Generics: What They Are and Why They're Profitable?¶ *DrugPatentWatch - Make Better Decisions*, 10 Apr. 2019, <https://www.drugpatentwatch.com/blog/branded-generics-what-they-are-and-why-theyre-profitable/>.
3. Latwal, Bharti, and Amrish Chandra. —Authorized Generics vs. Branded Generics: A Perspective.¶ *Journal of Generic Medicines*, vol. 17, no. 1, Mar. 2021, pp. 5–9. SAGE Journals, <https://doi.org/10.1177/1741134320947773>.
4. Research, Center for Drug Evaluation and. —Hatch-Waxman Letters.¶ *FDA*, Feb. 2022. www.fda.gov, <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters>.
5. Research, Center for Drug Evaluation and. —FDA List of Authorized Generic Drugs.¶ *FDA*, Jan. 2023. www.fda.gov, <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs>.
6. Tandel, Kirtida, et al. —A Study of Knowledge, Attitude, and Practice on Generic Drugs among Teaching Faculties at a Tertiary Care Teaching Hospital in South Gujarat, India.¶ *National Journal of Physiology, Pharmacy and Pharmacology*, 2018, p. 1. DOI.org (Crossref), <https://doi.org/10.5455/njppp.2018.8.0101713012018>.

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