INTERNSHIP TRAINING

at

COGNITIO ANALYTICS

A COMPARATIVE STUDY OF THE GENERIC DRUG SUBSTITUTION POLICY OF USA AND INDIA

by

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Enroll No.- PG/21/048

Under the guidance of

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PGDM (Hospital & Health Management)

2021-23

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01-Jun-2023

TO WHOM IT MAY CONCERN

This is to certify that **Kinshuk Jain**, in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Delhi has successfully completed her internship at Cognitio Analytics India Pvt.Ltd. during **20-Feb-2023 to 31-May-2023**.

Since his appointment, **Kinshuk** delivered very good quality work on the assigned tasks whileadhering to timelines. It was a pleasure working with him.

Warm regards,

For, Cognitio Analytics

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This is to certify that **KINSHUK JAIN** student of PGDM (Hospital & Health Management) from International Institute of Health Management Research, New Delhihas undergone internship training at **COGNITIO ANALYTICS** from 20th Feb. 2023 to 31st May 2023.

The Candidate has successfully carried out the study designated to him during internshiptraining and his/her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his/her future endeavors.

Dr. Sumesh Kumar
Associate Dean, Academic and Student Affairs
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Dr. Sukesh Bhardwaj
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Certificate of Approval

The following dissertation titled **"A COMPARATIVE STUDY OF THE GENERIC DRUG SUBSTITUTION POLICY OF USA AND INDIA"** at **"COGNITIO ANALYTICS"** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **PGDM (Hospital & Health Management)** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation.

Name	Signature
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Certificate from Dissertation Advisory Committee

This is to certify that **Mr. Kinshuk Jain,** a graduate student of the **PGDM (Hospital & Health Management)** has worked under our guidance and supervision. He/ She is submitting this dissertation titled **"A Comparative Study Of The Generic Drug Substitution Policy Of USA And India"** at **"Cognitio Analytics"** in partial fulfillment of the requirements for the award of the **PGDM (Hospital & Health Management).**

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.

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Assistant Professor and Mentor
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NEW DELHI

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled "**A COMPARATIVE STUDY OF THE GENERIC DRUG SUBSTITUTION POLICY OF USA AND INDIA**" and submitted by **KINSHUK JAIN**, Enrollment No. **PG/21/048** under the supervision of **Dr. Sukesh Bhardwaj** for award of PGDM (Hospital & Health Management) of the Institute carried out duringthe period from **20th February 2023** to **31st May 2023** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Signature

FEEDBACK FORM

Name of the Student: Kinshuk Jain

Name of the Organisation: Cognitio Analytics

Area of Dissertation: Healthcare Analytics

Attendance: Regular

Objectives achieved: Yes

Deliverables: Project deliverables

Strengths:

- Good problem solving skills
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- Team Player

Suggestions for Improvement:

Suggestions for Institute (course curriculum, industry interaction, placement, alumni):

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Place: Gurugram

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About the Organization

Cognitio Analytics was founded in 2013 with the goal of helping clients drive higher productivity in their operations, using data and analytics. We aspire to be the preferred provider of AI/ML driven productivity improvement solutions to large companies. Driving higher productivity requires smart, intelligent digital operations that enable an engaged and healthy workforce to deliver their best. Our two solutions sets do just that: Smart Operations Solutions help clients in their digital transformation efforts by unlocking the value of operations data that has so far been ignored. Total Rewards Analytics Solutions help our clients get the most out of their investments in human capital. We are world class in our chosen areas of focus, having won awards at the Business Process Intelligence Challenge 2018 and the Celonis Hackathon in 2022.

Our Total Rewards Analytics solution is leveraged by Fortune 100 organizations to drive key decisions. We actively invest in keeping this edge sharp by conducting R&D, trying out new technologies and methodologies, and building innovative solutions for old and new challenges faced by our clients. Our team of passionate analytics, technology and business professionals is constantly pushing these solutions forward, to create sustained value for our clients. We take pride in the impact we deliver, the quality of our work, the passion we bring to work everyday and how we work together to grow as individuals and as Cognitio Analytics.

We take pride to announce that our company has been certified as a "Great Place to Work." This prestigious recognition reflects our unwavering commitment to fostering an innovative work environment and prioritizing employee satisfaction. As we continue to grow, we are constantly looking for similar, passionate individuals who have a strong desire to create impact, have skills in data science and technology or have deep experience in domains we focus on (Healthcare, Insurance and Banking).

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Introduction

In healthcare, a drug refers to any substance or medication that is used for the prevention, treatment, or management of medical conditions or diseases. Drugs can be administered through various routes, such as oral (by mouth), intravenous (through veins), topical (applied to the skin), inhalation (breathed in), or rectal (administered through the rectum). They can come in different forms, including tablets, capsules, liquids, injections, creams, ointments, inhalers, and patches.

The primary purpose of drugs in healthcare is to produce a desired therapeutic effect on the body. This can involve alleviating symptoms, curing infections, managing chronic conditions, reducing pain, improving organ function, or restoring physiological balance. Drugs act by interacting with specific molecules or targets in the body, such as receptors, enzymes, or cellular processes, to produce their intended effect.

Drugs are developed through a rigorous process that includes extensive research, preclinical studies, clinical trials, and regulatory approval. Pharmaceutical companies invest significant resources in discovering and developing new drugs, which involves identifying potential drug candidates, testing their efficacy and safety, and conducting studies to determine proper dosage, administration, and potential side effects.

Once a drug is approved and made available to the public, it undergoes post-marketing surveillance to monitor its safety and effectiveness in real-world conditions. This allows for the identification of any rare or long-term side effects that may not have been detected during the clinical trial phase.

It's important to note that drugs should be used in accordance with healthcare professionals' recommendations and prescriptions. They should be taken at the prescribed dosage and frequency to ensure optimal therapeutic outcomes while minimizing potential risks. Patients should also be aware of any precautions, contraindications, or potential drug interactions associated with the drugs they are taking.

Overall, drugs are crucial components of modern healthcare, providing effective interventions for a wide range of medical conditions and improving patients' quality of life. They are integral to the prevention, treatment, and management of diseases, and they play a vital role in advancing medical science and improving patient outcomes.

In the field of pharmaceuticals, two important categories of drugs are branded drugs and generic drugs. **These categories are differentiated based on their development, marketing, and availability in the market**. Let us explore each category in detail:

Branded Drugs:
Branded drugs are pharmaceutical products that are developed, manufactured, and marketed by pharmaceutical companies under a specific brand name. They undergo extensive research, preclinical studies, and clinical trials to demonstrate their efficacy, safety, and quality. Branded drugs are protected by patents, which provide exclusive rights to the pharmaceutical company to manufacture and sell the drug for a specified period of time.

Characteristics of Branded Drugs:

1. Unique Brand Name: Branded drugs are marketed under a distinct brand name, which is often trademarked to identify the product and differentiate it from other drugs in the market.

2. Research and Development: Pharmaceutical companies invest significant resources in research and development activities to discover, design, and formulate new drugs. This includes identifying potential drug candidates, conducting laboratory studies, and evaluating their effectiveness and safety in clinical trials.

3. Patent Protection: Branded drugs are protected by patents, which grant the pharmaceutical company exclusive rights to manufacture and sell the drug for a specific period (typically 20 years). This exclusivity allows the company to recoup the investments made in research and development and make a profit.

4. Higher Cost: Branded drugs are often associated with higher costs compared to generic drugs. The pricing reflects the expenses incurred in research, development, clinical trials, marketing, and brand recognition efforts.

Generic Drugs:
Generic drugs are pharmaceutical products that are equivalent to branded drugs in terms of active ingredients, dosage form, strength, route of administration, and therapeutic effect. These drugs are developed and manufactured by different pharmaceutical companies once the patent protection of the original branded drug expires. Generic drugs offer a more affordable alternative to branded drugs while maintaining comparable safety and efficacy.

Definition: Generic drugs are pharmaceutical products that have the same active ingredients, dosage form, strength, and route of administration as the corresponding branded drug.

Purpose: Generic drugs are developed to provide affordable alternatives to branded drugs once the patent protection of the branded drug expires. They offer the same therapeutic effect as their branded counterparts, allowing patients to access cost-effective medication options.

Bioequivalence of Generic Drugs:
Bioequivalence Testing: Generic drugs undergo rigorous testing to demonstrate bioequivalence to the branded drug. Bioequivalence studies compare the pharmacokinetic parameters, such as the rate and extent of drug absorption, between the generic drug and the branded drug. These studies ensure that the generic drug delivers the same amount of active ingredient into the bloodstream as the branded drug, within an acceptable range.

Therapeutic Equivalence: Bioequivalence is a critical factor in establishing therapeutic equivalence between generic and branded drugs. Therapeutic equivalence means that the generic drug produces the same therapeutic effects as the branded drug when administered to patients in the same dosage form, strength, and route of administration.

Manufacturing and Regulation of Generic Drugs:
Manufacturing Process: Generic drugs are manufactured using the same standards and quality control as branded drugs. Generic manufacturers must adhere to Good Manufacturing Practices (GMP) to ensure the safety, efficacy, and quality of their products.

Regulatory Approval: Generic drugs undergo a regulatory approval process to ensure they meet the same standards as branded drugs. Health authorities review data from bioequivalence studies, manufacturing processes, and quality control procedures to grant regulatory approval for generic drugs.

Cost-effectiveness and Availability:
Affordability: One of the primary advantages of generic drugs is their affordability. Since generic manufacturers do not bear the costs of extensive research and development, they can offer their products at lower prices compared to branded drugs.

Increased Access: The availability of generic drugs increases access to essential medications for patients. They provide cost-effective options, particularly for individuals with limited financial resources or those reliant on healthcare systems with budget constraints.

Competition and Market Dynamics: The entry of generic drugs into the market creates competition, which can help drive down the overall cost of medication. This competition encourages innovation and further research in the pharmaceutical industry.

There are 2 categories of the drug depending on the source i.e., Biologics and Non-biologics.

Biologic drugs, also known as biologics, are a class of pharmaceutical products that are derived from living organisms or contain components of living organisms. These drugs are produced through biotechnology processes and are used to treat various diseases, including cancer, autoimmune disorders, and genetic conditions. Biologic drugs are complex in nature and differ from traditional non-biologic drugs in several key aspects. The generic version of Biologics are known as Biosimilars. Data related to Biologics is available in a database known as Purple Book.
Non-biologic drugs, also known as small molecule drugs, are traditional pharmaceutical products that are chemically synthesized rather than derived from living organisms. These drugs are typically composed of small molecules and have been the primary form of medication for many years. Non-biologic drugs differ from biologics in their composition, manufacturing processes, and mechanisms of action. The generic version of non-biologics are known as generics. Data related to nonp-biologic is available in a database known as Orange Book.

In the U.S., the Food and Drug Administration (FDA) is responsible for approving generic drugs as safe and effective alternatives to brand-name drugs. Once a generic drug is approved, it is considered interchangeable with the brand-name version and can be substituted by a pharmacist unless otherwise specified by the prescribing physician.

State laws may vary in terms of the requirements and restrictions for generic drug substitution. Some states have mandatory generic substitution laws, which allow or require pharmacists to dispense a generic drug in place of the brand-name drug, unless the prescribing physician specifically indicates "dispense as written" or "brand medically

necessary" on the prescription. Other states have permissive substitution laws, giving pharmacists the discretion to substitute generic drugs but not requiring them to do so.

It's important to note that individual insurance plans may also have their own policies regarding brand and generic drug substitution. These policies can affect how medications are covered and reimbursed by insurance companies.

In India, the regulation for generic drug substitution is primarily governed by the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945. These regulations provide guidelines and requirements for the substitution of branded drugs with their generic equivalents. The emphasis is on promoting the use of affordable generic drugs to increase access to healthcare and reduce healthcare expenditure. However, it is important to note that the specific implementation and enforcement of generic drug substitution policies may vary across different states and healthcare facilities in India.

Rationale

The availability and affordability of essential medicines are crucial for the overall well-being of a nation's population. In this regard, generic drugs play a significant role as they offer cost-effective alternatives to brand-name medications. Generic drug substitution policies are implemented by governments to promote the use of generic drugs and control healthcare expenditure. This rationale aims to highlight the importance of conducting a comparative analysis of generic drug substitution policies in India and the USA, considering their diverse healthcare systems and policy approaches.

Importance of the Topic:

Public Health Impact:
Access to affordable medicines is a global public health concern. Generic drug substitution policies aim to increase access to essential medicines, reduce the financial burden on patients, and improve health outcomes. Analyzing the policies in India and the USA will provide valuable insights into their effectiveness, strengths, and weaknesses.

Economic Considerations:
Healthcare expenditure is a significant component of national budgets. By promoting generic drug usage, countries can achieve substantial cost savings. A comparative analysis of India and the USA will shed light on the economic impact of their respective policies and identify potential areas for improvement.

Health Equity:
Generic drug substitution policies contribute to promoting health equity by ensuring that essential medicines are accessible to all segments of society. However, policy effectiveness can vary across countries with different healthcare systems. By comparing India and the USA, we can identify best practices and potential areas for policy transfer or improvement.

Learning from Diverse Approaches:
India and the USA represent two distinct healthcare systems with different policy frameworks. India has a more centralized approach, with a focus on price regulation and generic drug production, while the USA relies more on market competition and regulatory processes. A comparative analysis will allow us to understand the impact of these differing approaches and identify potential lessons for both countries.

Policy Relevance:
Generic drug substitution policies are continually evolving as governments strive to strike a balance between accessibility, affordability, and quality. By studying the policies in India and the USA, policymakers, researchers, and healthcare professionals can gain insights into the strengths and limitations of current approaches. This knowledge can guide the development and refinement of future policies to maximize their impact.It is seen in India that, there are no justified rules regarding generic drug substitution which acts as a wall between doctor, pharmacist, and patient. United States of America’s generic drug substitution policy is a big solution to bring a transparency between the stakeholders of healthcare system. Through this study, I will review the policy in both the countries, identify gaps and make recommendation for Indian health system.

Literature Review

1. Using a legal database, a cross-sectional analysis was conducted to investigate the differences in state drug product selection regulations with relation to elements that could influence the version of a drug that is prescribed. According to the findings, 19 states mandated that pharmacists perform generic substitution for small-molecule medications, while 7 states and Washington, DC required patient consent, 31 states and Washington, DC required patient notification independent of the drug's packaging, and 24 states did not expressly shield pharmacists from greater liability. For small-molecule pharmaceuticals, nine states and the District of Columbia had a generic substitution score of three or higher, and 45 states had stricter rules for interchangeable biologic substitution, most frequently requiring obligatory physician notification. (1)
2. The study was conducted using a national claims database, individuals were studied with medicare advantage plans or commercial insurance who newly initiated one of 34 prescription drugs to justify any association between generic usability and 3 different features of state laws. 409 856 (81.6%) of the 502 763 people who started taking one of the medications also received a generic version. The usage of generics was lower among those who resided in states that required patient agreement or notification. In contrast, it did not seem to make a difference whether generic replacement was required or allowed, and whether chemists were shielded from liability. The usage of less priced and equally potent generic medications could be improved by amending the laws in 39 states plus the District of Columbia. (2)
3. In this study the international viewpoint and probable legal repercussions of prescribing or dispensing generic medications to people with epilepsy (PWE) are discussed. About 70% of seizures are controlled by anti-seizure drugs (ASM). Generic substitutes are not evaluated against one another but must adhere to a bioequivalence range of -20% to +25% of the "parent" drug. Patients who receive a generic alternative without being informed of the hazards and suffer catastrophic effects may file a lawsuit for medical malpractice. The provision and failure to warn, whether by a physician, chemist, or institution, fall under this responsibility. There is also the possibility of professional misconduct when a chemist disobeys a doctor's advice. In the USA, legal action against manufacturers was unsuccessful, but it is still feasible to sue prescribers or dispensers. US doctors have the discretion to refuse brand substitution even though generic substitution is recommended. Other countries support generics as well, some even making them mandatory, but most give people the choice to forgo brand substitution. Generic substitution could be quite harmful, especially for PWE. It is your responsibility to alert them to these risks. It is the provider's duty to offer this warning in order to obtain informed consent. (3)
4. The study used two methods to assess the effects of state drug substation laws: difference-in-differences and a discrete choice model that demonstrate that although the presumed consent rules have a smaller impact than obligatory switching laws, they nonetheless reduce consumers' likelihood of buying brand-name medications by 3.2% points. It has been suggested that the best way to limit the development of prescription drug expenditures in the US is to substitute generic medications whenever possible. This study examines two categories of state regulations that govern the processes by which chemists replace brand-name medications with bioequivalent generic equivalents. Presumptive consent regulations let chemists to assume that the patient has given consent to the

substitution, while mandatory substitution laws mandate that the generic be used by default. The patient has the power to change either circumstance. The legislation' varying efficacy is most likely due to chemists' financial interests. These findings have significant policy consequences since they encourage the use of generic medications, which aims to lower drug costs. (4)

5. A descriptive cross-sectional study to evaluate the Generic Drug User Fee Act (GDUFA). Based on the primary analysis, this report considers the Generic Drug User Fee Act's (GDUFA) implications on the Indian generic pharmaceutical business. The study's participants, a sample size of 250 randomly chosen personnel from India's generic industry, completed a closed-ended questionnaire. Using the SPSS version 21.0 software, descriptive and inferential analysis are performed on the survey answer. The main conclusions of this study were that the advantages of GDUFA outweighed the difficulties facing the Indian pharmaceutical industry. Furthermore, it was discovered that the many difficulties brought on by the GDUFA had little impact on how much the Indian generic business paid attention to the other markets. Accordingly, the statistical results of the respondents' opinions suggested that the GDUFA had a greater overall impact on the return on investments for the Indian pharmaceutical business. It is implied that the GDUFA has forced the Indian pharmaceutical business to always comply with the US Food and Drug Administration. However, India continues to be one of the leading suppliers of generic medications to the US. Fundamentally, the GDUFA has had a positive impact on the Indian pharmaceutical industry. (5)
6. A cross-sectional study to understand the Knowledge and Perceptions of Generic Drugs. Convenient sampling was used to evaluate a total of 12 items, of which 2 were based on demographics and the remaining 8 on a 3-point scale. Nine preliminary questions were asked, and some data was presented to see if the respondents' perceptions had changed. The participants came from various backgrounds and were of various ages. The use of generic medications at government hospitals should be made necessary by law in order to save healthcare costs, although 120 (50.9%) of the participants were undecided on the subject, 90 (38.1%) agreed, and 26 (11.0%) disagreed. The poll also reveals the respondents' openness to switching to generic medications. Additionally, these respondents thought that legislation and training programmes for medical practitioners should be established to facilitate and broaden their selection of pharmaceuticals. The effectiveness of novel medications has come under scrutiny. Therefore, changing perceptions about drugs does not just require awareness. To make a difference, pharmaceutical businesses must adhere to strict legislation and good manufacturing practises. Pharmacovigilance and bioequivalence studies are also essential components of drug trials. The public's perception of generic medications would be significantly influenced by extensive peer-reviewed studies. The research on active pharmaceutical ingredients (APIs), which are used in both branded and generic drugs, will also assist close the gap between them. (6)

Objectives

Primary Objective:
To conduct a comparative analysis of the generic drug substitution policies in the USA and India.

Secondary Objectives:

1. To analyze and compare the legislative and regulatory frameworks governing generic drug substitution in the USA and India.
2. To identify best practices and lessons learned from the generic drug substitution policies in the USA and India that can inform policy development and improvement in both countries.

By addressing these primary and secondary objectives, the research aims to provide a comprehensive comparative analysis of generic drug substitution policies in the USA and India, contributing to the understanding of policy effectiveness, identifying areas for improvement, and informing evidence-based decision-making in the field of pharmaceutical policy and public health.

Methodology

To conduct a comparative analysis of generic drug substitution policies in India and the USA, a descriptive review study can be adopted. This approach could involve a comprehensive literature review and policy document analysis.

I. Research Design:

The research will adopt a descriptive review approach which will include socio-political analysis. The study will involve a comprehensive literature review and policy document analysis.

II. Study Area:

The study area is 2 countries i.e., India and USA. Since I pursued my dissertation in a US healthcare based company which allowed me to go through the state laws, hereby USA is selected as the choice of country.

III. Duration of Study:

The study was conducted in a time period of 3 months.

IV. Data Collection:

Extensive literature review was conducted to gather relevant scholarly articles, research papers, policy documents, and reports related to generic drug substitution policies in the USA and India. More than 20 articles were found regarding generic drug substitution policy. The articles in which country other than USA and India was mentioned were excluded from the study.
There were 6 articles which were relevant for the study was considered. Other than that an important report by Competition Commission of India was released which consisted of rich data was considered for the study.

V. Data Analysis:

Data was analysed considering the 3 main laws in USA i.e., DAW, patient's consent and physician's consent with respect to laws and report given by Indian articles and CCI (Competition Commission of India) report.

VI. Ethical Considerations:

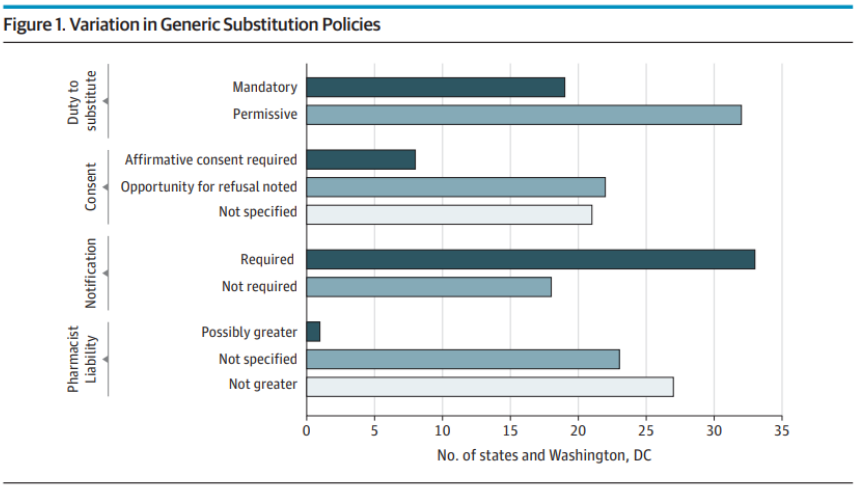
By following this comprehensive methodology, the research aims to provide an in-depth comparative analysis of generic drug substitution policies in the USA and India, offering valuable insights into policy effectiveness, identifying areas for improvement, and informing evidence-based decision-making in pharmaceutical policy and public health. Respective articles are cited in the end of this document.

Result

Comparative Analysis of Policy Frameworks:

The literature review and policy document analysis revealed that the USA and India have distinct approaches to generic drug substitution policies. The USA relies more on market competition and regulatory processes, while India adopts a more centralized approach with price regulation and emphasis on generic drug production. Despite these differences, both countries share common objectives of increasing access to affordable medicines and reducing healthcare expenditure.

Variation in Laws:
As shown in Figure 1, there is significant variation in drug product selection laws across US states. Regarding small-molecule drugs, less than half of the states (19 out of 50) mandate generic substitution by pharmacists, while the rest permit but do not require it. Four states require pharmacies to notify patients about the possibility of substitution. Seven states and Washington, DC, require patient consent for substitution, while 22 states allow patients to refuse substitution without consent. In cases of substitution, 32 states and Washington, DC, mandate patient notification. Most states (27 out of 50) explicitly protect pharmacists from liability for substitution, while 23 states do not mention liability, and one state (Connecticut) acknowledges the possibility of increased liability.



Variation in generic substitution policies for small-molecule generic drugs related to pharmacist duty to substitute, patient notification and consent, and pharmacist liability adopted by 50 states and Washington, DC.

As shown in Table 1, 90% of the states (n = 45) have stricter rules for replacing interchangeable biologics than for replacing generic medications. 40 states adopted the most widespread heightened requirement, which required physicians to be advised of substitution. California mandated that the chemist must notify the prescriber of the substitution within 5 days of dispensing by "an entry that can be electronically accessed by the prescriber."24 Patient notice requirements for interchangeable biologic substitution were present in seven states but not for generic substitution. Interchangeable biologic substitution was made permissible in four states (Indiana, Massachusetts, New Jersey, and Tennessee) that required generic drug substitution, two states (Kansas and Vermont) added a requirement that physicians authorise substitution for refills, and one state (Alaska) added a requirement for patient consent. (1)

Table 1

Variation in Policy Changes for Interchangeable Biologic Substitution Compared With Each State's Generic Drug Substitution Policies

Policy change for interchangeable biologic vs generic substitution	States enacting the policy change[a]
Antisubstitution changes	
From mandatory to permissive substitution	Indiana, Massachusetts, New Jersey, Tennessee
From no patient notification to patient notification requirement	Alabama, Arizona, Illinois, Massachusetts, Missouri, Nebraska, Rhode Island
From no physician notification to physician notification requirement	Alabama, Arizona, California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, Wyoming
From no physician authorization for substitution of refill prescriptions to physician authorization for substitution of refill prescription requirement	Kansas, Vermont
Prosubstitution changes	
From no statement about liability for substitution to statement that pharmacists have no greater liability for substitution	Arizona, California
Neutral changes	
From pharmacist determination of interchangeability to FDA determination of interchangeability	Alabama, California, Connecticut, Delaware, Georgia, Iowa, Massachusetts, Minnesota, New Jersey, Nevada, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, Tennessee, Washington
From no cost requirement to requirement that cost of substitute product be less expensive than substituted product	North Carolina, North Dakota, Rhode Island

Abbreviation: FDA, US Food and Drug Administration.

[a] Arkansas, Maine, Oklahoma, Texas, Washington, DC, and Virginia are not represented in the table as they had not enacted interchangeable biologic substitution carve outs as of September 1, 2019.

Another study revealed that US state laws regulating generic substitution vary in their impact on the use of generic drugs. A study on individuals with commercial insurance or Medicare Advantage plans found that states requiring patient consent or notification for generic substitution had lower generic drug use (81.1% vs 82.9%). Mandating substitution and protecting pharmacists from liability did not have significant effects. The study suggests that improving laws in 39 states plus the District of Columbia could enhance the utilization of cost-effective generic drugs.(2)

Dispense as Written aka Brand medically necessary:

Azmi Hassali et al. conducted a study comparing generic substitution policies in eight jurisdictions, including the USA, UK, Sweden, Finland, Australia, Japan, Malaysia, and Thailand. They found that these countries had different policies regarding generic substitution, with the USA focusing on health economic considerations and financial incentives. In the UK, pharmacists could only substitute with generics if supported by the prescribing doctor, while in Australia, it depended on the pharmacist's compliance. In Finland, generic substitution was mandated, but patients had the right to refuse. Informed consent was emphasized as crucial to provide patients with options for accepting or refusing alternative medications.

Despite possible differences in shape, scoring configuration, release mechanisms, packaging, excipients (including colouring, flavouring, and preservatives), expiration date/time, minor aspects of labelling (such as the presence of specific pharmacokinetic information), and storage conditions, products that meet the necessary US Federal Drug Administration (FDA) criteria are still considered therapeutically equivalent. The FDA does acknowledge that it may be reasonable for the prescribing physician to demand the dispensing of the prescribed proprietary named brand ("dispense as written") as a medical necessity ("brand medically necessary") when such variances are pertinent to the care of a specific patient.(3)

Presumed consent and Explicit consent:

The study analyzed the impact of presumed consent and mandatory substitution laws on the purchase of brand name and generic drugs. In Table 2, the results indicate that

presumed consent laws have a negative and significant effect on brand name drug purchases across several individual drug regressions. For example, the presumed consent law reduces the probability of purchasing brand name Pravachol by about 10%. In contrast, mandatory substitution laws did not show significant effects. Table 3 presents pooled results, confirming that the presumed consent law reduces the probability of buying brand name drugs by an average of 3.2% points. The effect is slightly larger for antidepressants and smaller for statins. Additionally, the study examines the impact of policy history, revealing that a switch from presumed to explicit consent has a larger effect than the opposite switch, suggesting familiarity with generic drugs diminishes response to explicit consent laws. (4)

Table 2

Effects of state pharmacist regulations on use of specific brand name drugs, compared with their generic equivalent

Antidepressants					
	Prozac	**Paxil**	**Zoloft**	**Celexa**	**Lexapro**
Presumed consent	−0.098** (0.037)	−0.053** (0.026)	0.066 (0.039)	−0.034** (0.013)	−0.021*** (0.007)
Mandatory substitution	0.131 (0.084)	−0.047 (0.044)	0.061 (0.038)	−0.021 (0.041)	0.417 (0.264)
Dependent variable mean	0.179	0.190	0.288	0.081	0.392
Observations	11,549	9,273	15,272	12,061	826
R^2	0.12	0.21	0.33	0.14	0.29
PPIs					
	Prevacid	**Prilosec**			
Presumed consent	−0.007 (0.058)	−0.044** (0.017)			
Mandatory substitution	−0.065 (0.089)	−0.053 (0.068)			
Dependent variable mean	0.622	0.164			
Observations	2,959	26,666			
R^2	0.56	0.15			
Statins					
	Pravachol	**Zocor**			
Presumed consent	−0.097** (0.041)	−0.009 (0.012)			
Mandatory substitution	0.030 (0.055)	−0.031 (0.025)			
Dependent variable mean	0.135	0.097			
Observations	12,673	50,313			
R^2	0.37	0.31			

Note. Difference-in-differences results from nine different regressions, using event level drug utilization data from Medical Expenditure Panel Survey. Dependent variable is an indicator for is the drug in question was a brand name, rather than its generic bioequivalent. All regressions feature state and year fixed effects, as well as controls for patient's race, wage quartiles, sex, age, and insurance status. Clustered standard errors shown in parentheses.

*$p < 0.1$. **$p < 0.01$. ***$p < 0.001$.

Table 3

Effects of state pharmacist regulations on the use of 10 brand name drugs, compared with generic drug equivalents

	Baseline	**Antidepressants**	**PPIs**	**Statins**	**Explicit to presumed**	**Presumed to explicit**
Presumed consent	−0.032*** (0.015)	−0.030** (0.013)	−0.034* (0.018)	−0.022*** (0.008)	−0.041*** (0.009)	−0.017* (0.009)
Mandatory substitution	−0.001 (0.025)	0.038 (0.030)	−0.036 (0.080)	−0.022 (0.019)	−0.001 (0.025)	0.001 (0.006)
Dependent variable mean	0.158	0.194	0.210	0.105	0.167	0.166
Observations	141,592	48,981	29,625	62,986	114,681	122,598
R^2	0.16	0.14	0.13	0.31	0.16	0.16

Note. Difference-in-differences regression results, using event level drug utilization data for antidepressants, proton pump inhibitors (PPIs), and statins from Medical Expenditure Panel Survey. Dependent variable is an indicator for if the prescription was for a brand name drug, rather than its generic bioequivalent. All regressions feature state and year fixed effects, as well as controls for patient's race, sex, age, wage quartile, and insurance status. The fifth column drops states with policies that switched from presumed to explicit, and the sixth column drops states that switched from explicit to presumed consent. Clustered standard errors shown in parentheses.

*$p < 0.1$. **$p < 0.01$. ***$p < 0.001$.

GDUFA:

GDUFA stands for the Generic Drug User Fee Act. It is a law in the United States that affects how generic drugs are made and sold. Under GDUFA, pharmaceutical companies that produce generic drugs have to pay fees to the US Food and Drug Administration (FDA) in order to get their products approved. The purpose of GDUFA is to ensure that generic drugs are safe, effective, and meet quality standards. It helps the FDA review and approve generic drugs more efficiently, making them available to consumers at a lower

cost.
In a study, 250 employees were surveyed and found that the benefits of GDUFA were greater than the challenges. The industry still focused on other markets despite the challenges. GDUFA increased the industry's return on investments and made sure Indian pharmaceutical companies follow the rules of the US Food and Drug Administration. India is still a major exporter of generic drugs to the US, and overall, GDUFA has had a positive impact on the Indian pharma sector. (5)

In a study it was stated that doubts have been raised regarding the effectiveness of branded drugs. Therefore, merely having knowledge about drugs is insufficient to change perceptions. It is essential to have stringent regulations and high manufacturing standards for pharmaceutical companies. Conducting thorough drug trials that include pharmacovigilance and bioequivalence studies is necessary to make a significant impact. Extensive research that undergoes peer review would greatly influence consumer opinions about generic drugs. Additionally, investing in healthcare and research on active pharmaceutical ingredients (API) would help close the gaps between branded and generic drug formulations in India. (6)

CCI report:
Retailers are not permitted to replace a prescribed brand with another brand that contains the same chemical, according to the legislation as it stands. Substitution by retailers or chemists is also illegal in India, according to the law. However, prescriptions with generic chemical names give merchants and chemists more authority, allowing them to select and dispense from among the brands that will provide them the biggest profit margin, independent of the brand's effectiveness. Retailers' discretion in how they dispense medications shouldn't be a cause for worry from the aspect of therapeutic advantages in a situation where quality is uniform across brands. However, this group of interested parties, which included some of the study's medical professionals, did not attest to the homogeneity of the pharmaceuticals sold on the market in terms of their efficacy and safety.

Retail pharmacies have significant influence on drug purchases despite regulations against brand substitution. Manufacturers offer high retail margins to incentivize pharmacies to stock and sell their brands, even though there are multiple generic options available. Due to limited space and cost constraints, pharmacies cannot stock all brands, so they prioritize those that offer higher profits. For non-regulated drugs, higher maximum retail prices ensure higher retail margins. This competition among manufacturers for higher margins does not benefit consumers with competitive prices. Instead, it leads to increased prices, undermining the advantages of generic competition and potential cost savings for manufacturers.

The threat of substitution by online pharmacies not supported by a prescription, patient data and prescription privacy, and risks of self-medication are the primary issues that have come up in relation to online pharmacies. Since e-pharmacies have access to important customer information such age, sex, geolocation, epidemiological profile, diagnostics, diseases, and medication history, they act as a significant source of important health information. During the stakeholder consultation, experts expressed their worries over the storage, security, and sharing of data with third parties online.

Only when all generic drugs in a therapeutic class in their unbranded and branded versions are viewed interchangeably and equally effective by stakeholders can pro-competitive strategies like generic drug entry facilitation, prescription by generic drug name, and

generic substitution by chemists result in the desired outcome of exposing pharmaceutical expenditure to significant price competition. Therefore, allaying worries about medicine quality is a requirement for generic competition to move from non-price to price dimension.

According to reports, the Indian government is trying to replace the current legislation with a new law that will control medications, cosmetics, and medical equipment in line with changes in the pharmaceutical business. In order to fill the legislative void and establish the required regulatory protections for the online distribution and sale of medications, e-pharmacy may be included within the scope of the proposed law.

The scope of India's antitrust laws allows for the examination of any potential harm to the competition from the disproportionate gathering or use of data by digital organisations with market dominance. The collecting, usage, sharing, and privacy of data are areas where internet pharmacies should employ self-regulatory mechanisms. However, until the nation passes its data protection law, the essential laws must be enforced to preserve patient privacy and sensitive personal medical data.

Formulating policies in the pharmaceutical sector comes with its own set of difficulties. Achieving public health goals involves implementing various policy and regulatory measures, with competition being just one aspect. Apart from ensuring public access to medicines, it is crucial for the government and regulators to actively influence the structure of the pharmaceutical market. The findings obtained from market studies will greatly assist in designing the Indian pharmaceutical market in a way that enables affordable medicines for everyone.

If there was consistent uniformity in quality expectations, the intricate dynamics of branded generic markets and their influence on price competition would diminish. The Commission, as part of its advocacy role, will strongly recommend a comprehensive and coordinated regulatory approach to address the issue of drug quality. The following specific measures, when implemented together, can significantly improve the perception of quality and promote price competition in generic drugs:

A. Uniform and Effective Implementation of Quality Standards:

Addressing inconsistent interpretation and enforcement of quality regulations across states.
Strengthening state-level regulatory apparatus with adequate personnel, infrastructure, and resources.
Creating awareness, harmonizing training, and ensuring consistent application of quality standards.

B. Better Transparency:

Bridging information gaps through real-time data on licensing, inspections, and non-compliance prosecutions via a central online portal.

C. Periodic and Scientific Testing of Drugs:

Increasing sample collection and testing using robust methodologies.
Enhancing drug testing capacity in central and state labs as well as accredited private labs.

D. National Digital Drugs Databank:

Establishing a centralized online database of pharmaceutical manufacturers, approved products, and relevant entities.
Enhancing information access for regulators, industry, physicians, and consumers.

E. Quality Control across the Supply Chain:

Implementing Good Distribution Practices (GDP) guidelines to maintain product quality during handling, storage, transportation, and distribution.
Sensitizing stakeholders and enforcing GDP guidelines for effective quality management in pharmaceutical distribution.

F. Quality Control in Public Procurement:

Implementing multiple layers of quality checks through pooled/centralized procurement systems to improve drug quality in public health facilities.

G. Standard Compliance Marks for Unbranded Generic Drugs:

Introducing institutional quality signaling through standard compliance marks on unbranded drugs meeting quality standards.
Building confidence among physicians and consumers in unbranded generic drugs.

H. Awareness Creation:

Launching public information campaigns to educate consumers about the cost-efficiency and efficacy of generic drugs.
Developing price-comparison software and mandating the display of price lists for standard-compliant products at retailers' premises.

I. Improved Availability:

Increasing availability of standard-compliant unbranded generic drugs in private retail markets.
Strengthening supply chain management and expanding the network of Janaushadhi Kendras (generic drug stores).

Discussion

The comparative analysis of policy frameworks between the USA and India sheds light on the distinct approaches to generic drug substitution and the variations in laws and regulations governing the use of generic drugs. The USA relies heavily on market competition and regulatory processes, while India adopts a more centralized approach with price regulation and a focus on generic drug production. Despite these differences, both countries share a common objective of increasing access to affordable medicines and reducing healthcare expenditure.

In the USA, there is significant variation in drug product selection laws across states. While some states mandate generic substitution by pharmacists, others permit it but do not require it. Patient consent and notification requirements also vary, with some states mandating them and others allowing patients to refuse substitution without consent. Liability protection for pharmacists also differs among states. These variations in laws have implications for the utilization of generic drugs, as states with stricter requirements for substitution may have lower generic drug use.

India, on the other hand, has its own set of regulations governing generic drug substitution. Retailers and chemists are not permitted to replace a prescribed brand with another brand containing the same chemical. However, there are concerns about the uniformity of pharmaceuticals in terms of their efficacy and safety. The Indian government is considering new legislation to regulate medications, cosmetics, and medical equipment, which may address these concerns and provide regulatory protections for online pharmacies.

Both countries also face challenges in ensuring the quality of generic drugs. In the USA, the Generic Drug User Fee Act (GDUFA) has been implemented to enhance the review and approval process of generic drugs, ensuring their safety, efficacy, and quality. This act has had a positive impact on the Indian pharmaceutical sector, as India is a major exporter of generic drugs to the US. However, doubts about the effectiveness of branded drugs persist, and stringent regulations, including thorough drug trials and peer-reviewed research, are necessary to address these concerns.

The study highlights the importance of uniform and effective implementation of quality standards, transparency in information dissemination, periodic and scientific testing of drugs, and the establishment of a national digital drugs databank. These measures can contribute to improving the perception of quality and promoting price competition in generic drugs. Additionally, awareness campaigns, improved availability of standard-compliant generic drugs, and better supply chain management are crucial for increasing consumer confidence and access to affordable medicines.

It is worth noting that formulating policies in the pharmaceutical sector comes with challenges, and achieving public health goals requires a multifaceted approach. While competition is an important aspect, it is essential for governments and regulators to actively shape the pharmaceutical market to ensure affordable medicines for all. Harmonizing regulations, strengthening regulatory bodies, and creating awareness among stakeholders are vital steps in achieving these goals.

Conclusion

In conclusion, the comparative analysis of policy frameworks surrounding generic drug substitution in the USA and India reveals distinct approaches and varying regulations. The USA relies on market competition and regulatory processes, while India adopts a centralized approach with price regulation and a focus on generic drug production. Despite these differences, both countries share the common objectives of increasing access to affordable medicines and reducing healthcare expenditure.

The variation in laws across US states highlights the complex landscape of drug product selection regulations. While some states mandate generic substitution by pharmacists, others only permit it without requiring it. Patient consent, notification, and liability protection also vary across states. Studies suggest that improving laws in several states could enhance the utilization of cost-effective generic drugs.

The concept of "dispense as written" or "brand medically necessary" acknowledges that certain patients may require specific brand-name drugs due to individual needs or medical reasons. However, therapeutically equivalent generic drugs that meet FDA criteria are considered interchangeable. Ensuring stringent regulations, high manufacturing standards, and comprehensive research can bridge the gaps between branded and generic drug formulations.

Presumed consent and explicit consent laws have been found to impact the purchase of brand name drugs. Presumed consent laws decrease the probability of purchasing brand name drugs, while mandatory substitution laws do not show significant effects. Familiarity with generic drugs diminishes the response to explicit consent laws, suggesting that consumer education plays a crucial role in influencing perceptions.

GDUFA, the Generic Drug User Fee Act in the USA, aims to ensure the safety, effectiveness, and quality standards of generic drugs. It has had a positive impact on the Indian pharma sector, as India remains a major exporter of generic drugs to the US. However, maintaining stringent regulations, conducting thorough drug trials, and investing in healthcare and research are essential for bridging the gaps between branded and generic drugs.

In India, regulations regarding generic drug substitution and brand substitution by retailers and chemists need improvement. Retail pharmacies hold significant influence over drug purchases, prioritizing brands that offer higher profits despite the availability of multiple generic options. Online pharmacies raise concerns about substitution without prescription, data privacy, and self-medication risks. A comprehensive regulatory approach, including uniform quality standards, transparency, periodic testing, a digital drugs databank, and quality control across the supply chain, can enhance drug quality, promote price competition, and ensure public access to affordable medicines.

To address these issues, a coordinated effort is required involving effective implementation of quality standards, transparency in licensing and inspections, periodic and scientific drug testing, establishment of a national digital drugs databank, enforcement of good distribution practices, quality control in public procurement, compliance marks for unbranded generic drugs, awareness creation, improved availability, and strengthening the supply chain management.

Overall, the findings from this study emphasize the importance of policy and regulatory measures to achieve public health goals, ensure access to affordable medicines, and actively influence the structure of the pharmaceutical market. By implementing the suggested measures and addressing the identified challenges, the Indian pharmaceutical market can be designed to provide affordable medicines for all while maintaining high quality standards.

Limitations

Limited Scope: The study focused primarily on the comparison of policy frameworks and regulatory approaches to generic drug substitution between the USA and India. Therefore, the findings may not be generalizable to other countries or regions with different healthcare systems and policy contexts.

Lack of Primary Data: The study relied on existing literature reviews, policy documents, and secondary data sources for analysis. The absence of primary data collection, such as interviews or surveys, limits the depth of understanding and may not capture nuanced perspectives or current developments in the field.

Lack of Stakeholder Perspectives: The study did not include direct input from key stakeholders, such as healthcare professionals, policymakers, pharmaceutical industry representatives, or patients. Incorporating their perspectives through interviews or surveys could have provided valuable insights and a more comprehensive understanding of the topic.

Generalization Challenges: The study identified variations and differences in policy frameworks between the USA and India. However, caution should be exercised when generalizing these findings to the entire countries, as policy implementation and outcomes may vary within different states or regions, even within a country.

Future Research Direction: The study identified several areas for further research, including the impact of policy changes, the role of stakeholders, and the effectiveness of specific interventions. However, this study itself does not delve into these areas in depth, highlighting the need for future research to address these gaps.

Recommendations

Based on the comparative analysis of policy frameworks and the findings from the literature review and policy document analysis, several recommendations can be made to enhance generic drug substitution policies and improve access to affordable medicines in the USA and India:

1. Harmonization of Generic Drug Substitution Laws: In the USA, there is significant variation in drug product selection laws across states. It is recommended to work towards harmonizing these laws to create consistent regulations for generic drug substitution. This can help streamline the process and provide clarity to healthcare providers, pharmacists, and patients.

2. Strengthening Physician Involvement: In both the USA and India, involving prescribing physicians in the decision-making process of generic drug substitution can help build trust and ensure patient safety. Policies should encourage collaboration between pharmacists and physicians to promote the use of cost-effective generic drugs when appropriate.

3. Public Awareness and Education: Public information campaigns should be launched to educate consumers about the benefits, cost-efficiency, and efficacy of generic drugs. Emphasizing the therapeutic equivalence of generic drugs and dispelling any misconceptions or doubts can help increase acceptance and utilization of generics.

4. Quality Assurance and Standards: Enhancing quality control measures throughout the generic drug supply chain is crucial. This includes implementing robust testing methodologies, increasing sample collection and testing, and ensuring adherence to quality standards. The establishment of a national digital drugs databank can improve information access and transparency for regulators, industry, physicians, and consumers.

5. Encouraging Competition and Price Transparency: Policies should aim to promote healthy competition among manufacturers and increase price transparency in the generic drug market. Measures such as standardized compliance marks for unbranded generic drugs, price-comparison software, and displaying price lists for standard-compliant products at retailers' premises can empower consumers to make informed choices and foster price competition.

6. Strengthening Regulatory Infrastructure: Adequate resources, personnel, and infrastructure should be allocated to state-level regulatory bodies to ensure consistent enforcement of quality regulations. This will help address inconsistent interpretation and enforcement of quality standards across states.

7. International Collaboration: Countries like the USA and India can collaborate on sharing best practices and lessons learned in generic drug substitution policies. Knowledge exchange and collaboration can help improve policy frameworks and facilitate access to affordable medicines globally.

8. Data Protection and Privacy: As the use of online pharmacies increases, it is essential to enforce regulations to protect patient privacy and sensitive medical data. Until a comprehensive data protection law is enacted, self-regulatory mechanisms should be employed by internet pharmacies to ensure secure storage, sharing, and usage of data.

9. Research and Development: Investing in healthcare research, active pharmaceutical ingredient (API) development, and drug trials can bridge the gaps between branded and generic drug formulations. Thorough research, including peer-reviewed studies and pharmacovigilance, can contribute to changing consumer perceptions and building confidence in generic drugs.

10. Government Leadership and Policy Support: The government and regulatory authorities play a crucial role in shaping the pharmaceutical market and ensuring access to affordable medicines. Continued leadership, policy support, and coordination with stakeholders are essential to implement the recommended measures and address the challenges in the generic drug sector.

By implementing these recommendations, policymakers can work towards creating a favorable environment for generic drug substitution, improving healthcare affordability, and maximizing the potential benefits of generic competition in both the USA and India.

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