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Review Article

# Addressing Awareness and Affordability of Generic Medicines in India: A Data Driven Strategic Framework

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**Abstract**
Access to quality and affordable generic medicines is vital to address the challenging situation which the country is currently facing in the present context. Less than 50% of medications are prescribed in India under their generic (INPN) names, despite the country being one of the leading suppliers of generic medications globally. Up to 90% of the money that impoverished people spend on healthcare can be attributed to medications. Thus, affordability of medications is essential for achieving desired treatment outcome since high drug costs lead to a reduction in access to healthcare. There is a lack of scientific data concerning the understanding of generic medicines among various stakeholders, including physicians, pharmacists, the general public, and health policy advocates, hence a need was felt to do an in-depth introspection of the scientific data centered around awareness and affordability of generic medicines in India and propose a conceptual framework for developing a strategic roadmap for popularizing generic medicines in India. Extensive literature search of research papers with high citations published between 2011–2024 were retrieved and investigated using PRISMA 2020 Flow diagram. In context to physicians the study suggested that physicians should choose less expensive brands of antibiotics and there is a need to design interventions at the fresh graduate level at medical colleges centered around the efficacy of generic drugs over the branded drugs. In context to Govt health policymakers the study suggested that policies towards opening Fair Price Medicine Shop (FPMS) taking the Government of West Bengal model could be taken into consideration and Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) drug policies on medicine distribution and procurement must be revisited with reference to the NELM. In context to pharmacists, community chemists regulatory agencies and educational institutions should work together to raise the level of generic drugs expertise among community chemists and drug store employees. Finally in context to patients, patient centric educational and awareness programs should be developed at the primary care level related to awareness and misconceptions of generic drugs in the public.

**Keywords:** generic drugs, availability, affordability, awareness, out-of- pocket expenditure (OOPE), drug policy

## 1. INTRODUCTION

India with a population base of 1.4 billion is emerging as one of the fastest growing economies of the world. The country has experienced rapid development over the past two decades as social and economic reforms picked up pace. There has been an obvious change in the country's disease pattern over the most recent thirty years. The prevalence of Non-Communicable Diseases (NCDs) has increased from 37.9 to 61.8%, according to the finding of numerous research, while the prevalence of communicable and infectious diseases has remained constant for the past three decades at 27.5% [1]. Access to quality and affordable generic drugs is vital to address this challenging situation which the country is undergoing in the present context. WHO has already stated that, "a generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a license from the innovator company and marketed after the expiration date of the patent or other exclusive rights of the innovator product".

Generic medications typically have a lower price than their branded counterparts because those seeking to market generics are not required to conduct the same animal and human clinical trials needed for brand-name drugs to prove their safety and effectiveness [2]. Due to reduced initial research expenses, generic medications, which offer the same therapeutic benefits as branded options, are generally available at much lower costs, often estimated to be 80 to 85% cheaper than the branded version. As reported by the IMS Health Institute, generic medications contributed nearly $2.2 trillion in savings to the U.S. healthcare system between 2009 and 2019 [3]. Medications with a specific name assigned by a company for promotional purposes are known as branded drugs. These names

differ from the International Non-proprietary Name (INN), or generic name. Branded medicines can be the original medication created by a company, or multiple companies may produce the same generic medication, each giving it a unique brand name.

Generic drugs sold under a brand name instead of a chemical name are known as branded generics. These are developed after the original drug's patent expires and can be created by either the original manufacturer or a generic drug company. Branded generics are bioequivalent to the original brand product, meaning they have the same effect on the body. These are used by companies to enhance consumer brand loyalty and identification. Brand names are utilized for ease of consumer remembrance and marketing, as generic drug names can be challenging for consumers to recall. An example of a well-known branded generic drug is Aviane, which is a birth control pill containing ethinyl estradiol and levonorgestrel. Other branded generics with the same ingredients include Orsythia and Vienva [4]. Companies typically set the price of Branded drugs on the higher side to recuperate the expenses associated with research and development, clinical trials, labor, marketing, and other elements. Brand manufacturers are granted patents and exclusive trusted source protection by the FDA to enable them to profit for several years from their innovation and research. During this time, no generics can contend with the brand. Generics can enter the market with a shorter FDA approval process after the patent expires [5].

The usage of generic medications is rising globally since they play a significant part in delivering cost-effective healthcare. Prescription audits show that more than 80% of the prescriptions prescribed in the USA, UK, China, and Australia are generic drugs. Despite being one of the world's top providers of generic pharmaceuticals, fewer than 50% of prescriptions in India are written for drugs using their generic (INPN) names. Medicines can represent as much as 90% of healthcare expenses for low-income individuals. The high prices of medications lead to reduced accessibility to healthcare; therefore, the affordability of medicines is vital for achieving the intended therapeutic results for medical conditions [1]. There is a dearth of scientific evidence related to the awareness about the generic medicines among multiple stakeholders namely physicians, pharmacists, general public and policy advocates, hence a need was felt to do an in-depth introspection of the scientific studies centered around awareness and affordability of generic medicines in India and propose a conceptual framework for developing a strategic roadmap for popularizing generic medicines in India.

## 2. MATERIALS AND METHODS

### *2.1. Research Methodology*

Extensive literature search of research papers with high citations published between 2011–2024 were retrieved and investigated using PRISMA 2020 Flow diagram [6]. The PRISMA 2020 Flow diagram is depicted in Fig. 1. The major keywords used in the search strategy were generic drugs, branded drugs, availability, affordability, awareness, out-of-pocket expenditure (OOPE), and drug policy.

## 3. RESULTS AND DISCUSSIONS

### *3.1. Proportion of Medications Prescribed using their Generic Names and Included in the* EML

The percentage of prescription drugs that are both generic and from EML shows compliance with

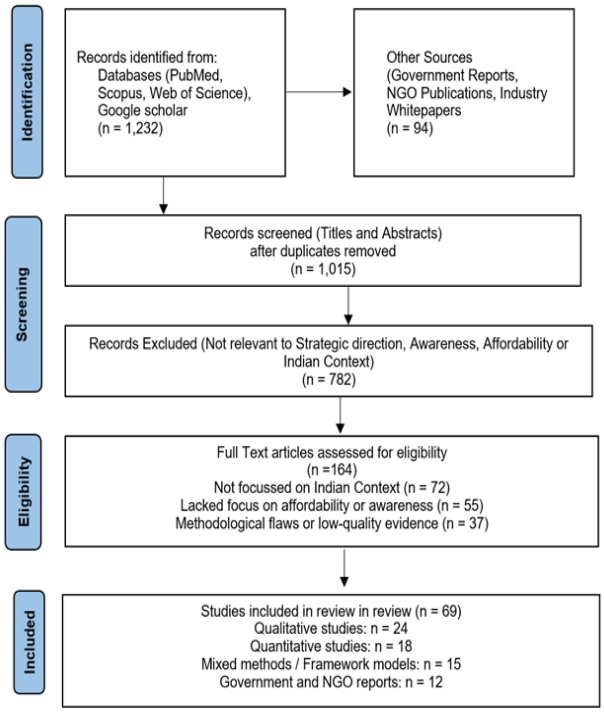


**Figure 1.** PRISMA 2020 flow diagram.

**Table 1.** Percentage of the medicines prescribed with generic name and from the EML.

| Research Study | Year | Private/ Public Sector /Teaching Hospital | Number of Prescriptions | Average of drug prescribed | Prescription/ Drugs with Generic Name Prescribed (%) | Encounters/ Drugs Prescribed from Essential Medicine List (EML) of National/ State (%) | Ref |
|---|---|---|---|---|---|---|---|
| **WHO Standards** | | | | | **100** | **100** | |
| Research study 1 | 2015 | Private Hospital | 250 | 3.30 | 6.70 | 70.00 | [4] |
| Research study 2 | 2022 | Teaching Hospital | 600 | 2.30 | 55.40 | 88.00 | [5] |
| Research study 3 | 2018 | Tertiary care teaching hospital | 1000 | 2.91 | 10.05 | 22.57 | [7] |
| Research study 4 | 2022 | Tertiary care Hospital | 1000 | 2.50 | 87.50 | 65.00 | [8] |
| Research study 5 | 2022 | Multicentric Study by ICMR | 4838 | 3.34 | 42.58 | 44.67 | [9] |
| Research study 6 | 2022 | Tertiary care Hospital | 50 | 3.48 | 13.79 | 27.58 | [10] |
| Research study 7 | 2019 | Rural Hospital | 120 | 3.02 | 85.80 | 88.3 | [11] |
| **Mean±Standard deviation (95% CI)** | | | | **2.98±0.44** | **43.12±34.70** | **52.97±25.69** | |

established prescribing guidelines and the current state of the pharmaceutical industry. For example, a lower percentage of prescribed generic pharmaceuticals may indicate that cost-effective generic medications are not readily available due to patent concerns, physician mistrust of generics, and/(or) patient preference for branded/innovator items. A lower percentage of medications supplied from an EML may indicate a general disregard for prescription regulations or a prescriber's ignorance of the significance of EML in cost-effectiveness optimization [3]. Table 1 lists the most cited research studies conducted in India related to prescription analysis of medicines prescribed in Hospitals. As per the WHO mandate 100% of the medicines prescribed should be generic. None of the study reflected compliance with the WHO guidelines. Out of the seven studies cited in context to the percent of generic drugs prescribed, in four of the studies the percentage of generic drugs prescribed was even below 50%, in three of the studies the proportion of drugs prescribed was above 50%. The EML data excludes one study with missing values, so n = 6n for that calculation.

As depicted in Fig. 2, four research studies reported the percentage of generic drugs prescribed were 6.70%, 10.05%, 42.58%, and 13.79% which shows a very low compliance with the WHO standard. Similarly, as depicted in Fig. 3 in three research studies stated the percentage prescribed from EML were 22.57%, 44.67%, and 27.58% which again shows a very low compliance with the WHO standard.

### *3.2. Out-of- pocket Expenditure and Affordability of Generic Drugs*

Out-of-pocket expenses are the funds that the consumer/patient directly pays for medical services. When a person does not have access to the free services offered by a government health facility and is not protected by any public or private insurance or social security programme, this circumstance arises. This analysis, which was cross-sectional in nature, involved 43,781 patients who were hospitalized and 8,914 outpatients, and it found that medications accounted for 29.1% of OOPE among inpatients and 60.3% among outpatients. Non-medical costs, including travel, lodging, and meals, made up 23.6% of OOPE for inpatients and 14.6%

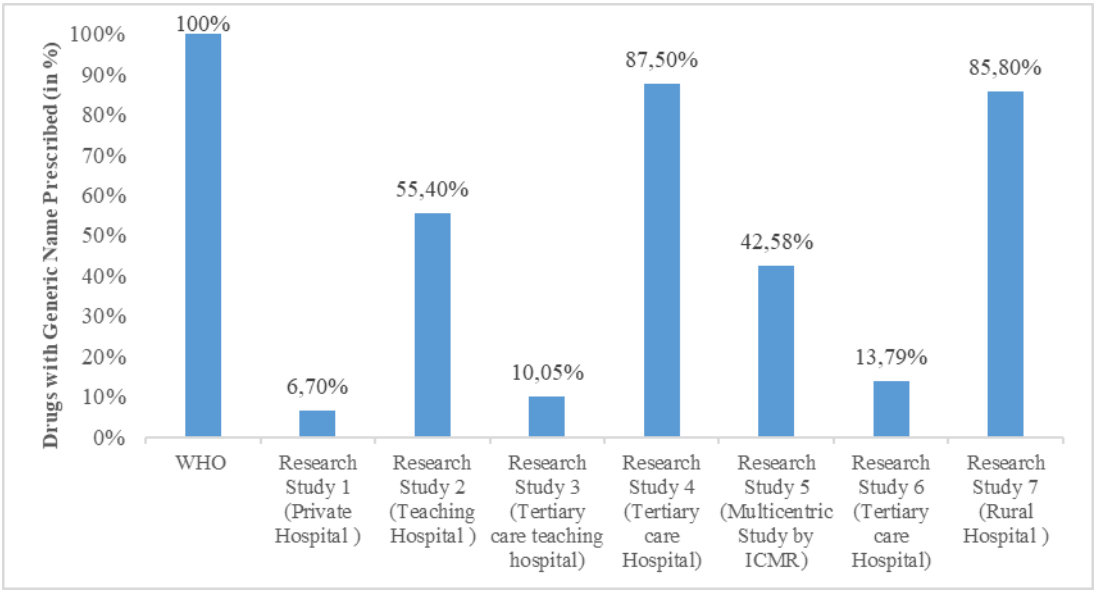


**Figure 2.** Percentage of the medicines prescribed with generic name v/s WHO standard.

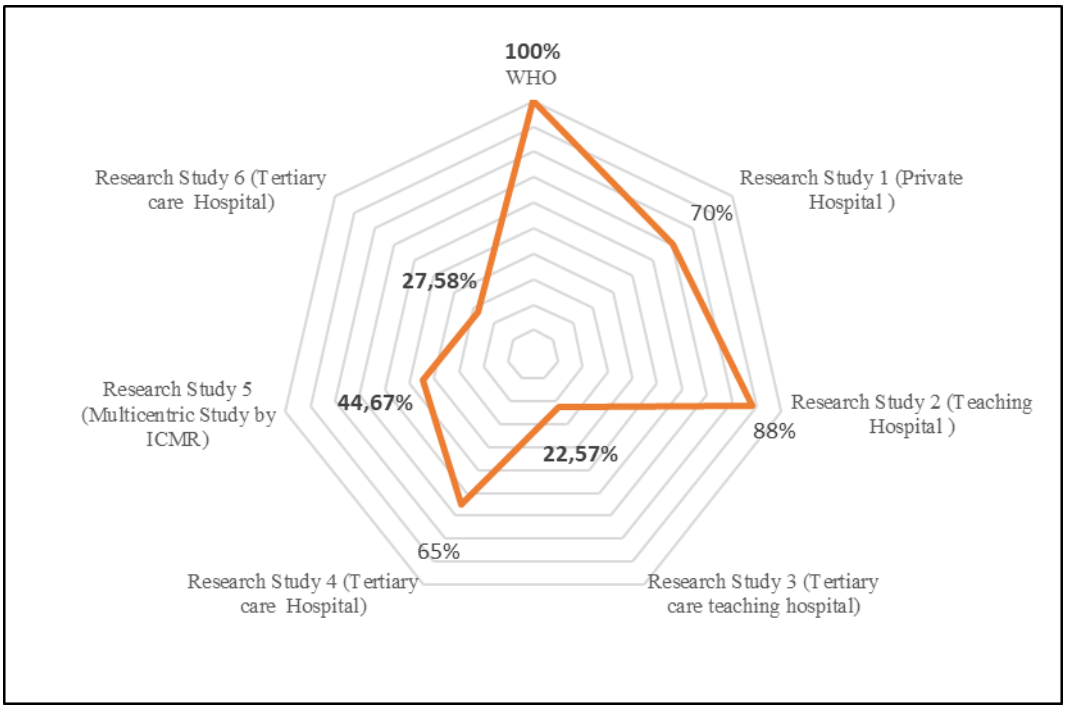


**Figure 3.** Percentage of the medicines prescribed from the EML of National/ State v/s WHO standard.

for outpatients. The share of OOPE attributed to physician consultations and diagnostic tests increased with higher socioeconomic status. Additionally, the yearly costs for outpatient services represented a greater proportion of household income compared to annual inpatient costs [12]. The results are depicted in Fig. 4 and 5.

There was a large price fluctuation for different brands of the same antibiotics, according to a significant investigation on the pricing disparities among various antibiotic brands accessible in the Indian market concerning the national EML. For ciprofloxacin 200 mg/100 mL vial, the smallest cost variance was 7.34%, while the greatest was 1049.82% (for azithromycin 500 mg pill). To ensure that patients finish their treatment and eventually prevent the establishment of antibiotic resistance, the study advised prescribers to choose less expensive kinds of antibiotics [13]. The research stated above makes it clear that OOP prescription spending has a major impact on poverty in many developing nations. Patients' and

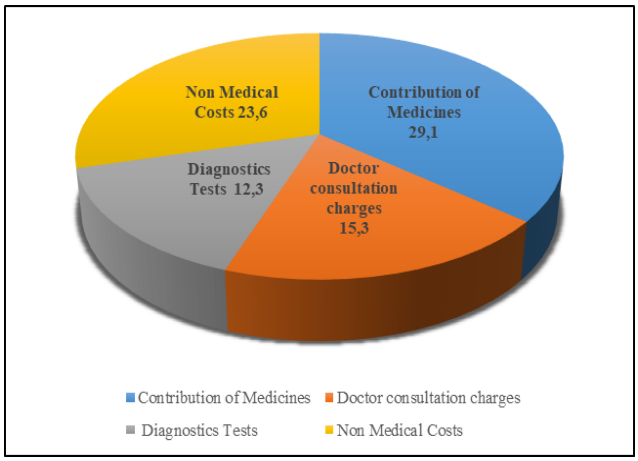


**Figure 4.** Contribution of medicines towards OOPE in patients.

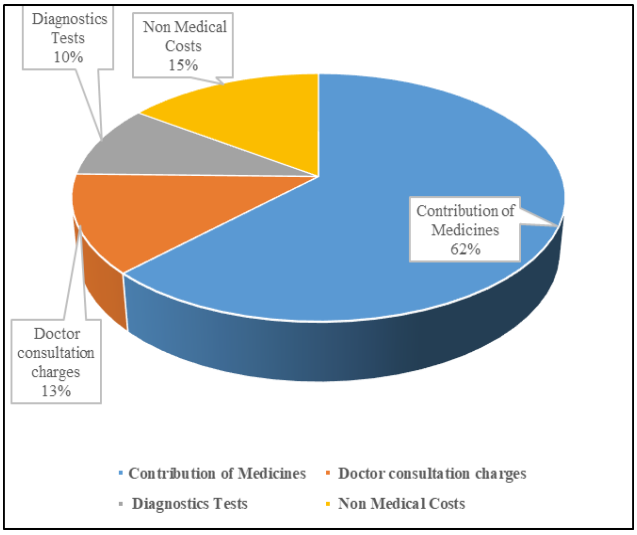


**Figure 5.** Contribution of medicines towards OOPE outpatients.

consumers' financial burden from OOPE drives the economy into poverty. Due to the wide price differences between the many brands of the identical antibiotics mentioned in the national EML, many patients in India do not finish the entire course of therapy, and the incidence of antibiotic resistance is rising.

In a separate research study focused on the cost analysis of the Jan Aushadhi scheme (JAS), the researchers found a significant disparity between the prices of JAS and the most affordable branded medications available in the market. More affordable brands can be found for certain commonly prescribed medications in the Indian pharmaceutical market. From a policy perspective, it raises serious issues regarding the JAS's ultimate goal and medicine pricing. Patients may not find the JAS to be the most economical option since they rely on doctors to prescribe their medications and because they usually are unaware of the differences in price between branded and generic medications. Therefore, it is imperative that the government promptly reassess the JAS rates to fulfil its objective of offering accessible and reasonably priced pharmaceuticals [14].

### *3.3. Awareness of Generic Medicines among Multiple Healthcare Providers in India*

In an observational study evaluating the knowledge, attitudes, and use of generic medications among doctors in a multispecialty private hospital, most doctors (72%) said that subpar manufacturing methods were used to create generic medications. According to the study's findings, most doctors think generic medications are of low-grade quality [9]. In their questionnaire-based cross-sectional study for investigating the attitudes and experiences of patients who were utilizing generic medications purchased from "Fair Price Medicine Shop" (FPMS) it was found that that generic medications were much less expensive than their branded equivalents [15]. In two towns in Tamil Nadu, India a study on the attitudes and knowledge of drug retailers and community pharmacists towards generic medicines reported that, just 63.6% of chemists and drugstore owners agreed that generic pharmaceuticals were effective, and 21 respondents (31.8%) didn't know what generic drugs were. Additionally, nearly 30% thought generic drugs were of poorer quality than branded drugs [16].

In a study carried out on patients visiting the outpatient department of primary care health facility in the city of Patan in Gujarat regarding their awareness and views on generic medicines, it was found that only 33.6% of the 345 participants claimed to be aware of generic drugs. Few (13%) of these patients had previously taken generic medications. Efficacy was cited as the main objection by those who refused to take generic medications [17]. In a multicentric, cross-sectional, questionnaire-based study conducted among 308 Bachelor of Surgery graduates (FMGs) in public and private medical colleges during the internship orientation programme it was found that 31% of FMGs were unaware that generic medications are

just as effective as branded medications [18].

In a study conducted at 11 Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) drug stores in Mumbai and Palghar it was found that the PMBJP medicine list did not cover all essential medicines or fixed dose combinations (FDCs) well. It also found that only 47% of the essential medicines surveyed were available in PMBJP stores. Around 50% and 42% of medicines in Mumbai and Palghar districts were found to be out of stock for three to six months, respectively [19]. A study conducted in Tumkur district of Karnataka, India, investigated the perceptions of patients regarding the quality of generic medications and how those perceptions may affect patients' confidence while seeking care from public facilities. The study indicated that poor opinions of generic pharmaceutical quality, along with other factors, led to the private sector's preference for more expensive medicines [20].

Thus, in brief it was observed that across healthcare settings in India, the percentage of drugs prescribed under their generic names and included in the essential medicines list (EML) varies, with public institutions typically showing more adherence than private ones. Despite the development of affordable generic alternatives, patients still face a substantial financial burden from out-of-pocket medication costs, especially those in low-income groups. Although generic medications are more widely available and more reasonably priced thanks to programs like the JAS, healthcare practitioners' differing degrees of awareness frequently restrict their use. Research shows that even while people are becoming more aware of generic medications, there are still misconceptions about their quality and effectiveness among patients and prescribers. This underscores the need for more stringent regulatory implementation and focused educational initiatives to encourage sensible use.

### *3.4. Conceptual Framework and strategic direction for enhancing the awareness about Generic drugs in India*

To boost awareness of generic medications among doctors in India, a strategic approach should emphasize improving knowledge, altering perceptions, and encouraging their use. A conceptual framework might involve educational programs, policy changes, and quality assurance initiatives to foster confidence and tackle apprehensions.

#### *3.4.1. Strategic Direction and Conceptual Framework in Context to Physicians*

Figure 6, different brands of the same antibiotics that are included in India's National Essential Medicines List (NELM) come in a broad range of price ranges. To guarantee that patients finish the

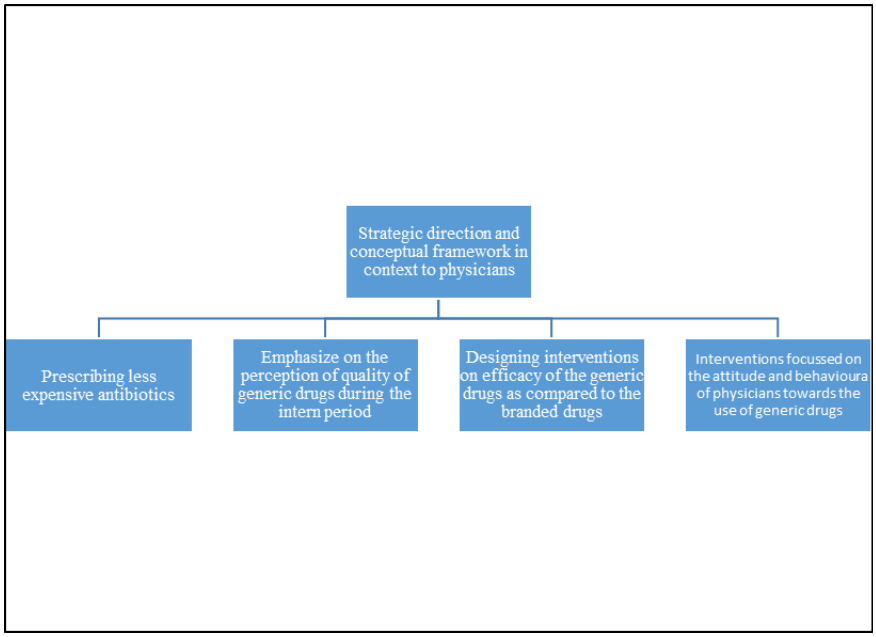


**Figure 6.** Strategic direction and conceptual framework in context to physicians.

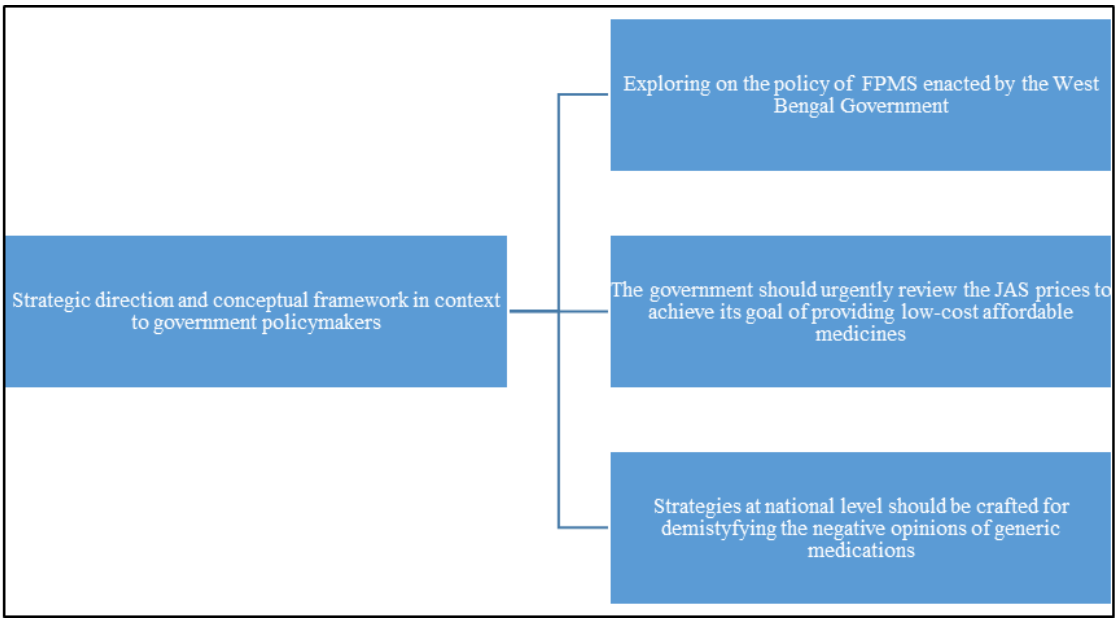


**Figure 7.** Strategic direction and conceptual framework in context to government policymakers.

recommended course of therapy and prevent the emergence of antibiotic resistance, doctors should choose less expensive kinds of antibiotics. From the standpoint of the medical community, a sizable number of medical professionals think that generic medications are of lower quality. To improve doctors' perceptions of generic pharmaceuticals, medical institutions must place a strong emphasis on generic drug orientation during intern year so that information may be applied to the prescription of generic drugs. In the FMGs, especially in the private medical colleges there is a lack of awareness about the efficacy of the generic drugs as compared to the branded drugs which necessitated the need to design interventions at the fresh graduate level at medical colleges centered around the basic concepts and utilities of generic drugs.

Several interventions are needed centered around the attitude and perception of physicians towards the use of generic drugs. Some interventions which can be executed are: Implement campaigns aimed at dispelling myths and misunderstandings regarding generic medications, highlighting their bioequivalence and safety, Provide real-life instances of effective generic drug substitutions and their impact on patient outcomes, Continuously gather input from physicians to pinpoint areas where their worries and inquiries can be resolved.

### *3.4.2. Strategic Direction and Conceptual Framework in Context to Govt Policymakers*

Figure 7, when compared to medications purchased from regular market vendors, the Fair Price Medicine Shops (FPMS) initiative implemented by the West Bengal Government in India appears to be a hopeful option regarding perceived effectiveness, safety, and compliance with generic medications from FPMS. Therefore, this study can serve as motivation for policymakers to launch comparable models across the nation. Although West Bengal was the first state to execute the FPMS concept, other Indian states have not embraced it widely. A few examples of such programs exist, but they don't mimic West Bengal's Public-Private Partnership (PPP) approach. Although it is not a PPP model, Tamil Nadu established a free medication distribution program for people utilizing public health services. Like Tamil Nadu, the state of Rajasthan likewise established a free medication distribution program through public health facilities. Although a few other states have tried comparable programs, they haven't usually followed West Bengal's example of a public-private collaboration with FPMS in public hospital settings.

In context to Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) pharmacies, the list of drugs under PMBJP should include all essential medications identified in the national EML, and the PMBJP's policies on medicine distribution and

procurement must be revised to solve the supply chain difficulties. Major changes in pharmaceutical policy are also required to assist the promotion of generic medications. Additionally, legislation supporting obligatory generic prescribing and generic substitution by chemists are also required.

Pharmaceutical corporation's preferred marketing of branded versus generic drugs and negative opinions of generic medications may have an impact on prescriber conduct and the public's faith in healthcare systems. To be effective, access to medicines campaigns must consistently invest in data on the quality of medications and create plans for fostering confidence in the medical treatment provided by government health services.

### *3.4.3. Strategic Direction and Conceptual Framework in Context to Pharmacists, Community Chemists and Pharmacy Staff*

Figure 8, it was observed that generic substitutions were not promoted by drug stores or community chemists, even when prescribed medications were not readily available. Many chemists and drugstore employees have false beliefs about generic medications. Correct knowledge of generic medications was directly correlated with greater levels of education among the community pharmacists and drug retailers. Thus, regulatory agencies and educational institutions should work together to raise the level of generic medicine expertise among community chemists and pharmacy staff.

Numerous pharmacists recognize that generic medications are biologically equivalent to their brand-name counterparts and come at a lower cost. Nonetheless, there are still some misunderstandings regarding their effectiveness, safety, and general quality.Enhanced dialogue between pharmacists, prescribing physicians, and patients is crucial for encouraging the adoption of generic drugs in India and addressing misunderstandings. Such communication can foster increased confidence in generics, boost adherence to medications among patients, and possibly reduce healthcare expenses.

### *3.4.4. Strategic Direction and Conceptual Framework in Context to Patients*

Figure 8, patients who visit their primary care physician are generally less aware of generic medications. Patient centric educational and awareness programs should be developed at the primary care level related to awareness and misconceptions of generic drugs in the public.

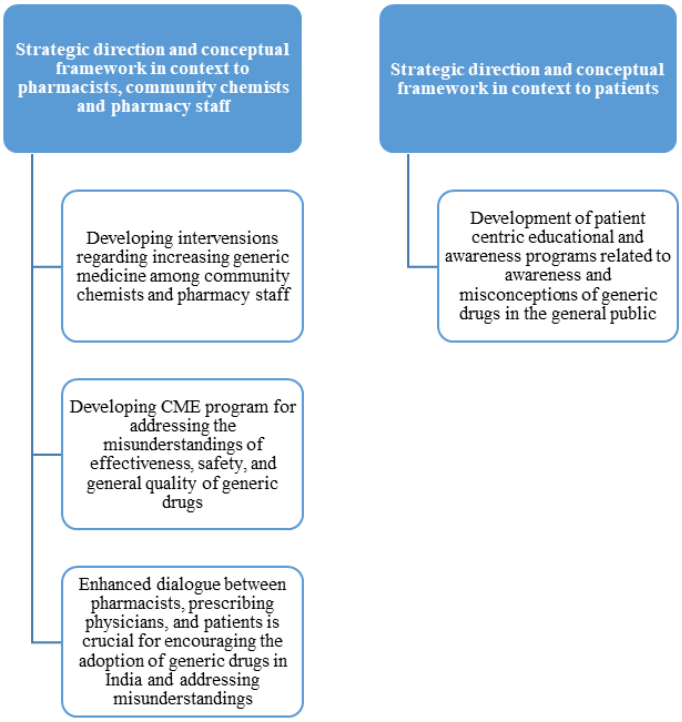


**Figure 8.** Strategic direction and conceptual framework in context to pharmacists, community chemists and patients.

## 4. CONCLUSIONS

To encourage effective prescribing, dispensing, and utilization of generic medications, it is crucial to evaluate a variety of policies on both the supply and demand fronts. Numerous factors, i.e., economic, political, socio-cultural, technological, legal, and structural; can influence the effectiveness of these policies. Analyzing the approaches of nations that have succeeded in this domain can offer important insights for policymakers.

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### Conflicts of Interest

The authors declare no conflict of interest.

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