# A Study of India's Policy on Generic Medicine: A Comparative Case Study Analysis between India, China, and Brazil

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***Abstract***

*The study conducts a study of India's generic medicine policies compared to Brazil's and China's. It assesses the respective policies in relation to the promotion of generic medications using four distinct regulatory criteria. The study uses qualitative research and a case study approach to arrive at its conclusions, which are analyzed using secondary literature. It is observed that India has adopted strict policies when it comes to the regulatory criteria considered in this study but comparatively performs poorly in providing access to affordable generic pharmaceuticals. On the other hand, while Brazil does not have as strict regulations as India, the study concludes that the adoption of generic medication policies in the country is a success story.*

## Introduction

Equal access to healthcare is an essential provision that most governments across the globe strive to achieve. However, according to a 2021 report by the "World Health Organization (WHO)" and World Bank- "Tracking Universal Health Coverage: 2021 Global Monitoring Report"- about one-third of the world's population does not have access to "essential health services" (WHO and World Bank, 2021). The report also highlighted that a substantial number of households fall into poverty every year due to out-of-pocket healthcare expenses. Another WHO report highlighted that about 2 billion people across the world do not get "access to

essential medicines" (WHO, 2017). India, being a developing country, is no exception to the above issues. Thus, India's dilemma of fulfilling the healthcare needs of its citizens arises.

While healthcare infrastructure and services are vital components for improving the healthcare ecosystem, "access to essential medicines is a major determinant of health outcomes" (Maiti et al., 2015). According to WHO, essential medicines are "those drugs that satisfy the healthcare needs of [the] majority of the population" (Maiti et al., 2015). Thus, they should be continuously available in sufficient numbers at affordable prices. This definition forms the basis of WHO's essential medicine concept, launched in 1977. The latter is one of the eight verticals of WHO's primary healthcare strategy. India followed through with the concept and issued the first National Essential Medicine List (NEML) in 1996, which has been subsequently revised. This list brings under its ambit several essential medicines on which the government imposes a price ceiling to ascertain higher affordability. This was the start of India's journey towards ensuring universal access to essential medicines.

Ideally, basic essential medicines should be available for the masses at a negligible cost. However, this would entail a significant financial burden. This cost would need to be borne by either the medicine manufacturers, which is not economically sound, or the government, which has limited resources in a developing country like India. This is where generic medicines come in. These are the set of medicines for which patent rights have become invalid, and thus, they can now be replicated and manufactured by companies apart from the one that has its innovation ownership (Dunne et al., 2013). Generic medicines have significantly lower costs than branded medicines as the manufacturers do not have to account for innovation costs in their profit margins. WHO recommends that the availability of generic drugs be an integral element of national drug policy for all countries (WHO, 2001). For India, even with the lower cost of

generic medicines, for a substantial part of its population, the expenditure burden remains too high. Thus, the government initiated India's People's Medicine Scheme under the Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers in 2008. The scheme has since been relaunched as Pradhan Mantri Bhartiya Jan Ausadhi Pariyojana (PMBJP) in 2015. The main aim of PMBJP is to make "quality generic medicines available at affordable prices to all" (MoCF, n.d.).

This paper aims to analyze the evolution of India's generic medicine policy, identify strengths and weaknesses, and propose policy recommendations accordingly. To do so, it undertakes a comparative study to analyze the trajectory of two other countries across the globe parallel to India. The other two countries are Brazil and China, which, as elaborated upon later, make for ideal comparative case studies.

**Theoretical Framework**

The paper undertakes a comparative policy analysis (Peters & Fontaine, 2020, pp. 20–32). It recourses to comparing the generic medicine policies in India, Brazil, and China to examine the relative effectiveness of India's policy compared to the latter three. The rationale for choosing Brazil is the similar demographic, political, and economic profile of the country compared to India (Mohanty et al., 2011; Kappel, 2010). Brazil has a large population and is a democracy like India; it is also considered a major emerging economy today and is a big player in its regions. The rationale for taking China as the second comparison is multipronged. First, being immediate neighbors with rich civilizations and large populations, India and China have always been compared (Shahbaz et al., 2017). In fact, India and China stood in the same position in terms of their economies and growth not too long ago. Despite the vast differences today, with

China's economy being five times bigger than India's, there is merit in comparing the two most populous countries of the world, which historically had a similar trajectory (Kappel, 2010; Shahbaz et al., 2017).

The generic medicine policies across the three countries mentioned before have followed an evolutionary model (Peters & Fontaine, 2020, pp. 385–400). For each of the countries, the policy initiative started with the universalized guidelines on essential medicines from international bodies. Subsequently, it has come to its current form through policy changes over time, which has resulted in the current form of their policies on generic medicines. Like India, the two other countries started their trajectory by releasing their respective "National Essential Medicines List." Brazil released its first list in 1964 (Osorio-de-Castro et al., 2017, p. 402), and China in 1982 (Guan et al., 2011, p. 305)). Subsequently, all three countries today have mandates on generic medicines enshrined in their national drug policies (Osorio-de-Castro et al., 2017; Guan et al., 2011). Which, as mentioned before, has been recommended by WHO. The paper sets out to compare the unique evolutionary changes that the three countries experienced in their policies.

**Methodology**

This paper employs a case study approach to compare the specific evolution in the respective countries (Peters & Fontaine, 2020, pp. 238–253). The paper compares each country's policies on four different aspects relating to the promotion of generic medicines. These are "demonstrated therapeutic equivalence; pharmaceutical packaging and labeling; drug prescription; and drug substitution" (Da Fonseca & Shadlen, 2017). The four indicators answer the following questions-

> …how have generic drug products been demonstrated to be therapeutically equivalent to originator products (equivalence)? Are generic products allowed to display brand names (labeling)? Should doctors prescribe using the generic name or can they use a brand name (prescription)? Are pharmacists authorized to substitute a generic product for an innovator product (substitution)? (Da Fonseca & Shadlen, 2017)

The paper utilizes qualitative research to draw its conclusions. The first indicator ("demonstrated therapeutic equivalence") will be compared based on the presence or absence of the requirement for equivalence tests like "bioequivalence" or "interchangeability" (Alfonso-Cristancho et al., 2015). These tests are used to check whether the generic medicines are identical to the original medicine (Alfonso-Cristancho et al., 2015). The other three indicators will be categorized into yes or no, signaling their presence or absence in the policies of the respective countries. The paper draws information on the above indicators through a study published in "Applied Health Economics and Health Policy," titled "Definition and Classification of generic drugs across the world" (Alfonso-Cristancho et al., 2015).

**Case study analysis of generic drugs policies in Brazil, China, and India**

Brazil

Brazil's national policy on generic medicines proved pivotal in improving access and affordability of essential medicine (Da Fonseca, 2014). A study published in the journal Policy and Society, titled "Reforming pharmaceutical regulation: A case study of generic drugs in Brazil," traces Brazil's generic medicine policy. The evolution of Brazil's generic medicine policy occurred in two stages. Legislative discussions and resolution building followed by the creation of policy instruments for implementation. The policy was brought in as a solution for

the high cost of prescription drugs that made it difficult for many people to get necessary medications. In order to lower pharmaceutical costs and improve Brazilians' access to inexpensive medications, the Brazilian government changed patent rules and regulations and launched extensive programs to support the availability of affordable medications.

The study highlights that Brazil's generic pharmaceutical strategy started to take shape when its government issued a decree requiring the use of generic medications in the early 1990s (Da Fonseca, 2014). However, the directive was not put into effect because of resistance from the pharmaceutical business. A new agenda for the pharmaceutical industry was established by the government's support of significant regulatory reforms in response to the large-scale scandals involving counterfeit medications in the late 1990s. This resulted in the adoption of the generics policy. The policy included several steps to guarantee the quality and effectiveness of generic medications and a mandate for all medications to be prescribed under their generic names. At first, there was disagreement about the policy: global organizations like the World Health Organization supported the restrictions, while regional pharmaceutical businesses opposed them. In order to boost domestic production, the government collaborated with regional medication producers when the program was eventually generally embraced. The supply of necessary medications improved as a result, and drug costs were significantly reduced. The approach also improved health outcomes, resulting in lower rates of morbidity and mortality from a number of illnesses, such as AIDS, malaria, and tuberculosis.

China

A World Bank report titled "A Generic Drug Policy as Cornerstone to Essential Medicines in China" traces the country's generic medicine policy. China's generic drug policy

emanates from its Essential Medicines Program. The latter forms the foundation of the country's essential medicine list and gives priority to affordable generic medications. The Essential Medicines Program first recommended the provision of a generic drug policy. The policy had several key aspects- a modified provider payment system that makes up for lost drug income, greater patient and provider acceptance of generics, flexibility to accommodate a multi-tiered drug market, generic drug promotion, and domestic pharmaceutical industry consolidation. China's strategy was aimed at addressing a number of difficulties, including accessibility, price, and the quality of vital medications. The initiative has lowered the cost of essential medications, improved patient and healthcare provider access to vital medications, and promoted the usage of inexpensive generic medications- which make up the majority of the essential drug list.

More recent studies, titled “The impact of the consistency evaluation policy of generic drugs on R&D investment intensity of pharmaceutical companies” (Wei et al., 2022) and “Regulation of generic drugs in China” (Chen et al., 2022) evaluate the latest developments in China’s generic drug policy. In 2016, China unveiled the Generic Drug Quality and Efficacy Consistency Evaluation Policy (GDQEP), which was later revised in 2020. Before their medicines can be sold, generic drug producers are required by policy to submit to a review of their product's quality and efficacy consistency. Other policies have been implemented in conjunction with the GDQEP, such as the National Essential Medicines List (NEML), a list of medications that the general population should have access to at a reasonable cost. The GDQEP has had a major effect on the pharmaceutical sector. It has encouraged businesses, especially highly profitable ones, to invest in research and development. Accelerated technological advancements among generic medication producers have resulted in new product development and enhanced quality throughout the industry. Furthermore, the policy has improved public

health outcomes by guaranteeing the efficacy and safety of generic medications sold in China. However, because of the unequal distribution of medical resources, the reform's effects are not seen equally across the country. More work is required to enhance the regulation of generic medications, including increased data sharing and transparency, incentives for new ideas, and cooperation amongst stakeholders in the healthcare system.

India

A study titled “Generic drugs- The Indian scenario” (Joshi et al., 2019) traces India’s generic medicine policy. Jan Aushadhi, which translates directly to "Medicine for People" in Hindi, was a new project launched by the Indian government in 2008 under the Department of Pharmaceuticals. Under this concept, government-assisted retail stores would be set up to provide low-income citizens of the nation with high-quality, non-branded medications at a fair price. It has assumed responsibility for opening Jan Aushadhi outlets, which are pharmacies that, to the greatest extent feasible, solely sell generic name medications while also giving priority to public sector pharmaceutical projects. 3200 Jan Aushadhi outlets were open and operating in over 33 states and union territories in India as of March 15, 2018. Compared to the almost 8 lakh retail pharmacies in existence, there are not nearly enough Jan Aushadhi stores, and many rural areas remain neglected. In October 2016, the Medical Council of India amended the code of conduct for doctors and suggested that all doctors prescribe medications with readable generic names, make sure the prescription is logical, and encourage the use of generic medications. The Indian government has recently introduced the mandate requiring physicians to write prescriptions for generic medications for their patients. However, the new legislation is facing severe opposition.

A study titled “Improving access to medicines by popularising generics” (Lavtepatil et al., 2022) provides vital insights into India’s generic medicine policy. The study evaluated the People's Medicine Scheme of India, which was introduced in 2008 and then redesigned and renamed Pradhan Mantri Bhartiya Jan Ausadhi Pariyojana (PMBJP) in 2015. It examined the accessibility, price, and acceptance of PMBJP critical medications. According to the analysis, unbranded generics from PMBJP have excellent chances of achieving significant cost savings. To fully realize the potential of this scheme, however, a few policy actions are desperately needed. These include adding all NLEM-listed essential drugs to the PMBJP drug list, acquiring only drugs that pass the bioequivalence test, mandating the phased de-branding of generics, and reevaluating PMBJP's distribution and procurement policies for medicines in order to address supply chain issues.

Finally, coming to the four variables that form the basis of this study’s evaluation of India’s generic medicine policy in comparison to Brazil and China, the table below lists the policies of all three countries.

| Country | Demonstrated therapeutic equivalence | Pharmaceutical packaging and labeling (brand labelling allowed in generics) | Drug prescription (generic prescription mandated) | Drug substitution (from brand name to generic by pharmacists) |
|---|---|---|---|---|
| India | Yes | Yes | Yes | NA (since generic prescription is mandated) |
| Brazil | Yes | No | Yes (private practitioners not mandated) | No |
| China | Yes | Yes | No | No |

**Discussions and Recommendations**

As can be seen, the three countries have several differences in the manner in which their generic medicine policy has taken shape. It is evident that Brazil presents a story of success. When it comes to the four variables that the study utilizes as parameters to evaluate the generic medicine policies in the countries, India performs the best. However, the case study analysis highlights Brazil as the success story when it comes to the adoption of generic medicine. While India is called the "pharmacy of the world" with large generic exports and market share, it lacks in providing access to affordable generic medicine within its borders (Lavtepatil et al., 2022). This study has a limitation in that it relies on secondary data for its analysis, and thus, only partial analysis can be undertaken. Another parameter that can analysed is the World Health Organization's data on out-of-pocket health expenditure across countries. The use of generic medicines is promoted for its affordability. Thus, a strong generic medicine policy would contribute to decreasing medical expenses for individuals. There are several other factors that can contribute to lower or higher out-of-pocket health expenditures in any country. However, the use of generic medicine can be considered as an attributional variable causing a lower rate of out-of-pocket health expenditure. While the share of out-of-pocket health expenditure as a percentage of total health expenditure is as high as 50.59% for India, it is 34.75 for China and only 22.39% for Brazil.

From the limited scope of the study, only certain broad recommendations can be drawn. Despite a strong push for generic in India and provisions for ensuring quality, there are several aspects that need to be addressed. In spite of the presence of regulations around quality, there are apprehensions when it comes to implementation. Confidence building through a more transparent approach to generic drug approval can prove to be beneficial. Furthermore, the Jan

Aushadhi centers need to be made more accessible through an expansion. This is essential to ensure broad coverage, even in the remote regions of the country. Finally, it is yet to be seen if the mandated prescription of generic medicines by doctors will bring any significant positive change. Since Brazil's partial mandate on generic prescription has proven beneficial for the country, the new regulation in India is likely to bring a positive change.

**Conclusion**

This study's result emphasizes the significance of sensible policies for the success of any intervention. Brazil's example highlights how strict regulations alone are not enough for the success of a policy; there needs to be a focused attempt at cultivating support from the involved stakeholders to ensure effective implementation. Brazil, China, and India all have quite varied policies regarding generic medications, and other nations can learn a great deal from their individual experiences. While Brazil presents an example of a country with successful generic drug regulations, India- dubbed the "pharmacy of the world"- has a big generic export market but inadequate access to reasonably priced medication domestically. The study is limited in its scope to identify the specific reasons for the success of Brazil's policy in comparison to India. However, the recommendations that the study brings out can form a foundation for India's quest to enhance the adoption of generic medicines.

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