HOW ACCESS TO GENERIC MEDICINES IS DIRECTLY RELATED TO OUT-OF-POCKET EXPENDITURE IN HEALTH

PREPARED BY: DR. SUDHA CHANDRASHEKAR

DR. ANUSHREE

INTRODUCTION

Generic drugs have been defined by various agencies across the world as follows:

i) The World Health Organization (WHO) defines a Generic Medicine as 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 expiry date of the patent or other exclusive rights.[1]

ii) According to the Food and Drug Administration (FDA) a Generic medicine is a drug product that is bioequivalent to a brand or reference listed drug product in terms of dosage form, strength, route of administration, quality, safety, performance characteristics and intended use.[2]

iii) The European Medical Agency (EMA) defines a generic medicine as a medicine that is developed to be the same as a medicine that has already been authorized. A generic medicine contains the same active substance(s) as the reference medicine, and it is used at the same dose(s) to treat the same disease(s) as the reference medicine. However, the name of the

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4519628/
[2] https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers

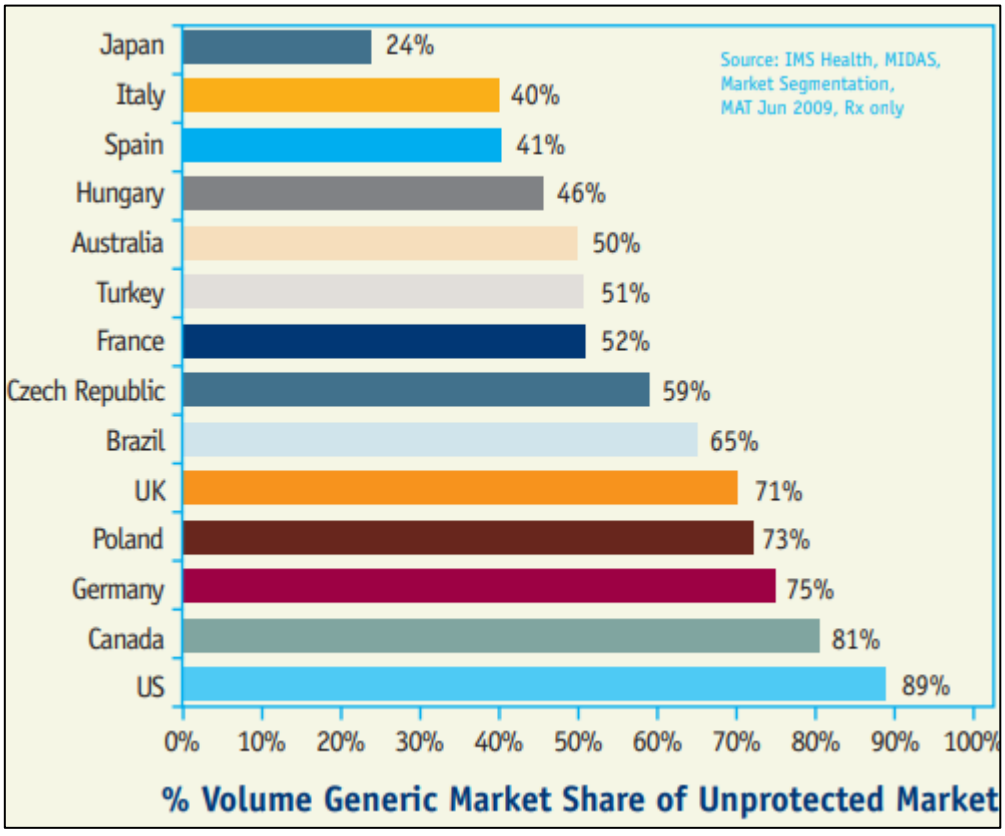
medicine, its appearance and its packaging can be different from those of the reference medicine.

Access to medicine is defined as having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population.

According to WHO estimates, nearly a third of the world's population lacks access to the most basic essential medicines, while in the poorest parts of Africa and Asia this figure climbs to a half.[3] Additionally, in developing countries, pharmaceutical drugs now account for 30% to 50% of total health care expenditure, compared with less than 15% in established market economies.

Although, with the recent advancements and focus of the world on universal health coverage, the access to medicines has improved over the years but the conditions of the marginalised still remains poor. The strata of poorest of the poor still lives in substandard conditions and the coverage of health sector reforms and services has a long road to cover in this direction. This trend of limited access to affordable medicines and high out-of-pocket expenditure (OOPE) forces the poor to either forgo treatment—resulting in lost workdays, reduced productivity, and lower income—or to seek care in private or unregulated drug markets. This often leads to catastrophic medical expenses, where costs for a single illness exceed 40% of a family's annual non-food expenditure, pushing them into a medical poverty trap.[4]

Medicines form an inexplicable part of treatment procedures and are a major load of healthcare expenditure. No cure is complete without the right medicine prescribed, dispensed and consumed by the patient. In this light the generic medicines from a long time have proved to be a plausible source of saving health expenditure for various diseases.



[3] https://www.who.int/publications/i/item/WHO-EMP-MIE-2011-2.4

[4] https://onlinelibrary.wiley.com/doi/10.1002/hpm.2671

Fig: Market Utilisation of Generic Drugs across the world

The states of Asia and Africa have been from a long time been centres of lower coverage of health services, low quality of healthcare, lower share of GDP expenditure on health, and relatively low access to medicine. What has constantly remained high is the cost and catastrophic bill payouts of the medical services, of which medicines form the major chunk. In chronic diseases this outcome is even worse as therein the medicines are the major treatment protocols and inability to spend on the medicines for the poor leads to failed compliance or incomplete course of treatment.

HOW MEDICINES CONTRIBUTE TO HIGH OOPE

Global and Indian evidence highlights significant barriers to accessing medicines, particularly in low- and middle-income countries (LMICs). In most LMICs, healthcare financing is largely driven by the private sector, with India leading this trend—70% of healthcare financing comes from households, and 70% of this household expenditure is on medicines from the private market. Persistent underinvestment in public healthcare has allowed the private medicine market to dominate, forcing households to bear catastrophic out-of-pocket (OOP) payments.

Of the 100 million people globally pushed into poverty due to OOP healthcare costs, over 40 million are in India. Since medicines constitute the largest share of OOP healthcare spending, they are a leading cause of medical impoverishment. The lack of financial risk protection for Indian households, resulting from insufficient public investment in healthcare, has severely restricted access to essential medicines.

A study based in Sweden shows how the overall expenditure of the patients and society has been reduced after the government has made prescribing generic medicines mandatory in the country. From the reform of October 2002, prescriptions were required to include workplace codes, and mandatory generic substitution was introduced for drugs with medically equivalent alternatives.[5] Before the reform, both the average co-payment and subsidised cost showed a slight increase, but after the introduction of generic substitution in October 2002, both began to decline. The reform led to a statistically significant change in patient co-payment and subsidised costs, with the slope shifting from an increase to a decrease across Sweden ($p < 0.005$ for co-payment, $p < 0.001$ for subsidised costs). This pattern was observed for all prescribed pharmaceuticals and across all county councils.

[5] https://www.sciencedirect.com/science/article/abs/pii/S0168851006001709

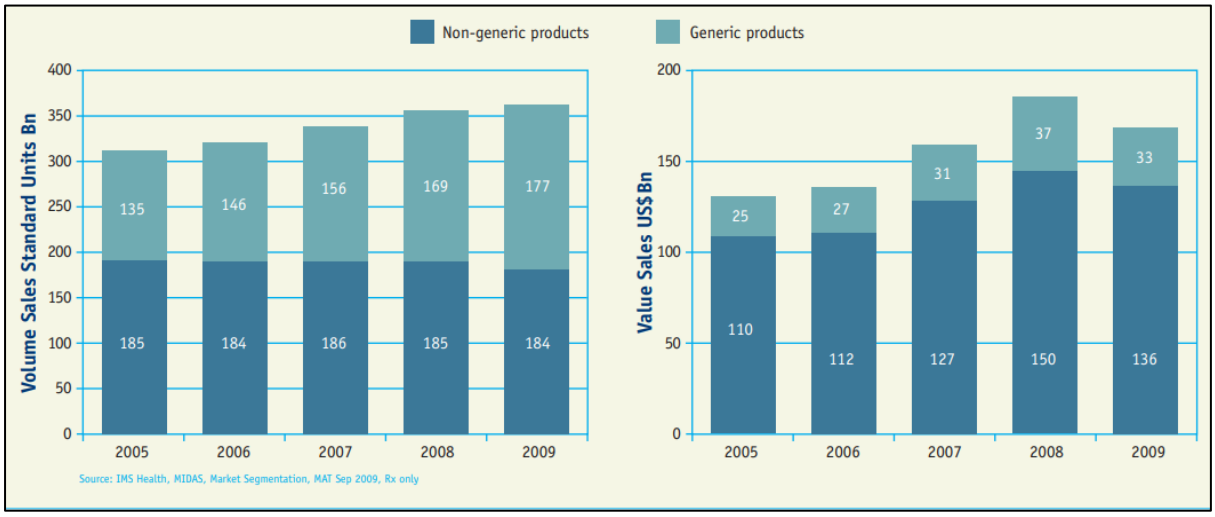
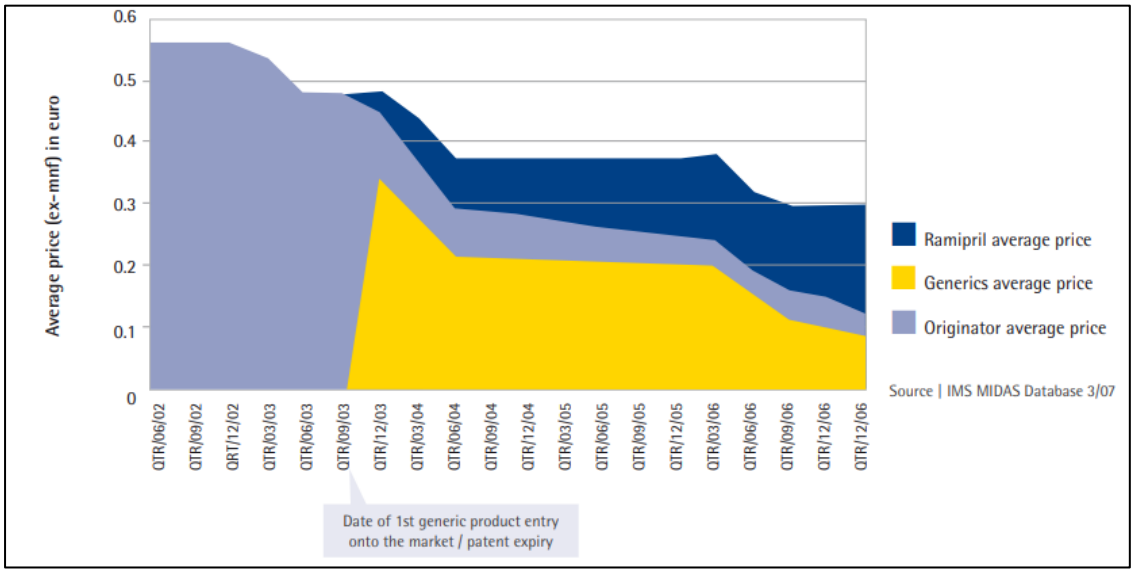


Fig: European market in terms of volume and value for generic pharmaceuticals.

The European government relies heavily on the generic drug market to control its costs of health care services. Generic medicines play a crucial role in ensuring the sustainability of healthcare delivery, a growing concern for European governments. As pharmaceutical expenses form a substantial part of total healthcare costs, the demand for more affordable therapeutic options highlights the importance of generic medicines in reducing these expenditures.[6] In Europe, generics make up almost one half of volume sales, but merely a fraction of value sales.[7]In 2006 it was highlighted: "*Generic medicines create major savings for healthcare providers and stimulate innovation. However, the EU is not maximizing its full potential in generic medicines. Added savings of 27%-48% could be attained if the appropriate measures were taken by EU countries.*"



[6] https://www.medicinesforeurope.com/wp-content/uploads/2016/03/Market_Barriers_Report_FINAL_update_How_to_Increase_Patient_Access_to_Generic_Medicines.pdf

[7] https://www.aeseg.es/Generic_Medicines_GA.pdf

Fig: The graph indicates the average price for a particular drug Ramipril across Europe for different manufacturers.

ACCESS TO GENERIC MEDICINES IN INDIA

India, known as the "*global pharmacy of South*,"10 has 65% population suffering from lack of access to medicine, primarily due to absence of sound public distribution facilities. Studies identify that this deficiency in access to medicines has resulted in the highest share of OOPE on health care, arguably the most regressive kind of health finance option. Using Consumer Expenditure Survey data from the National Sample Survey in India, Garg and Karan, estimates that purchase of drugs constituted 70% of the total OOPE on health, and approximately 32.5 million persons slipped below the poverty line in 1999 to 2000 due to this.[4]

In India, the National Rural Health Mission has been a leader since 2004 in providing universal health coverage and free medicines.The National Health Policy 2017 emphasizes on provision for free medicines and diagnostics at government health facilities. Union Cabinet (2018) announced National Health Mission (NHM) would have a "special focus" with intensification of initiatives such as **Free Drugs and Diagnostics Services**.

Delhi (1992) and Tamil Nadu (1994) were the first states to introduce state-specific policies to improve access to medicines through strong monitoring systems. Tamil Nadu's model, widely regarded as a benchmark, involves the Tamil Nadu Medical Services Corporation, an autonomous public sector body that procures high-quality generic medicines through a transparent bidding process. These medicines are then supplied to public health facilities based on demand.

Other states like Bihar, Delhi, Madhya Pradesh, Kerala, and Rajasthan implemented similar, though slightly varied, models. In 2011, Rajasthan adopted the Tamil Nadu model by establishing the Rajasthan Medical Services Corporation and launching the Mukhyamantri Free Fund Scheme. Within two years, this led to improvements in healthcare access, financial risk protection, and health system expansion.

Although these models have improved access to medicines to varying degrees, they required significant public investment, which has been feasible only for states with strong budgetary positions or generous central government support.

Today almost all the states have either developed their own model of healthcare delivery or have implemented the NHM norms across the districts to provide low cost or free of cost medicines for all. The procedure for the procurement and distribution of these medicines is rather simplified and unified for all the participatory states under NHM. The procurement, warehousing, distribution, monitoring, and quality assurance systems under NHM are interconnected through a comprehensive and systematic supply chain management approach. NHM ensures efficient drug procurement and distribution through a well-structured e-Tendering process, primarily handled by the Directorate of Health Services, follows a systematic process based on the Essential Drugs List (EDL). District Drug Store Managers (DDSMs) gather projected drug demand from peripheral health facilities using past consumption data. Tenders are publicly advertised, and bids are assessed on the total cost. The

procurement is approved by different authorities based on order value, with systematic monitoring by technical experts.

This is supported by robust warehousing infrastructure and real-time monitoring systems. The warehouses are identified and maintained by the state and district officials. Stringent quality assurance protocols ensure the safety and efficacy of medicines supplied across the state, while the integration of technology facilitates efficient management and accessibility of essential drugs.[8] Through this process it is ensured that essential drugs are throughout available in the facilities and the load of patients is met upon.

EXAMPLES FROM OTHER STATES:

Tamil Nadu & Bihar

In a cross-sectional survey done to assess the similarities and differences in the health service model of Tamil Nadu and Bihar. Bihar and Tamil Nadu both utilize a pooled procurement system for drugs, but they implement different models. In Bihar, the required volumes of medicines are aggregated at the state level through an open tender process, inviting bidders to submit the lowest rates for a list of medicines. However, invoicing and payments are handled at the district level. Conversely, in Tamil Nadu, while medicine quantities are also pooled at the state level, payments are processed at the state level after receiving laboratory quality-assurance reports on the medicines.

The procurement agency in Tamil Nadu is the Tamil Nadu Medical Services Corporation (TNMSC), an autonomous body operating under the Tamil Nadu Transparency in Tenders Act of 1998. This Act outlines the tendering processes, publicity requirements, technical specifications, commercial conditions, evaluation criteria, submission timelines, and procedures for bid evaluation and award of tenders. In contrast, Bihar's procurement agency is the State Health Society, which operates under the guidelines of the centrally-funded National Rural Health Mission (NRHM). The Directorate of Health Services oversees the procurement process in Bihar, adhering to the procedures established in the Bihar Finance (Amendment) Rules 2005. While these rules define the procurement process, they do not provide detailed criteria for technical and commercial bids.

The study observed that the TNMSC model is a good example of how clear rules and regulations, along with clearly outlined processes for implementation, can help in attainment of a high level of transparency and accountability. However, in Bihar's cash and carry model, because of decentralized payment structures and uncertainty in payment schedules, the bidders tend to quote higher prices for drugs on tender. Similar observations have emerged from analysis of private-sector drug prices, where assumed delays in payments have contributed to higher drug prices[9]. The study shows that between 2006 and 2008, Tamil Nadu secured suppliers for 100% of its drugs, while Bihar managed only 38% to 56%, leading to inefficiencies and irrational procurement practices. Additionally, Bihar paid significantly higher prices for many drugs, with some procurement costs exceeding those of Tamil Nadu by more than double.

[8] https://nhm.assam.gov.in/schemes/free-drugs-service
[9] https://pubmed.ncbi.nlm.nih.gov/28607278/

Rajasthan

In 2011, the Rajasthan government adopted a healthcare reform inspired by the success of Tamil Nadu model, significantly increasing its budget allocation for public health. From 2011–2012 to 2013–2014, funding for the scheme rose from ₹0.38 billion to ₹3.20 billion. Before this initiative, Rajasthan spent less than 5% of its public expenditure on medicines, with per capita health spending at ₹5.7 in 2010–2011, which surged to ₹50 by 2013–2014. This increase positively impacted out-of-pocket (OOP) payments, with early data showing a reduction in household OOP expenses from 85% in 2004–2005 to 75% in 2011–2012. The percentage of poverty caused by high OOP spending on medicines decreased from 3.2% to 2.1%.

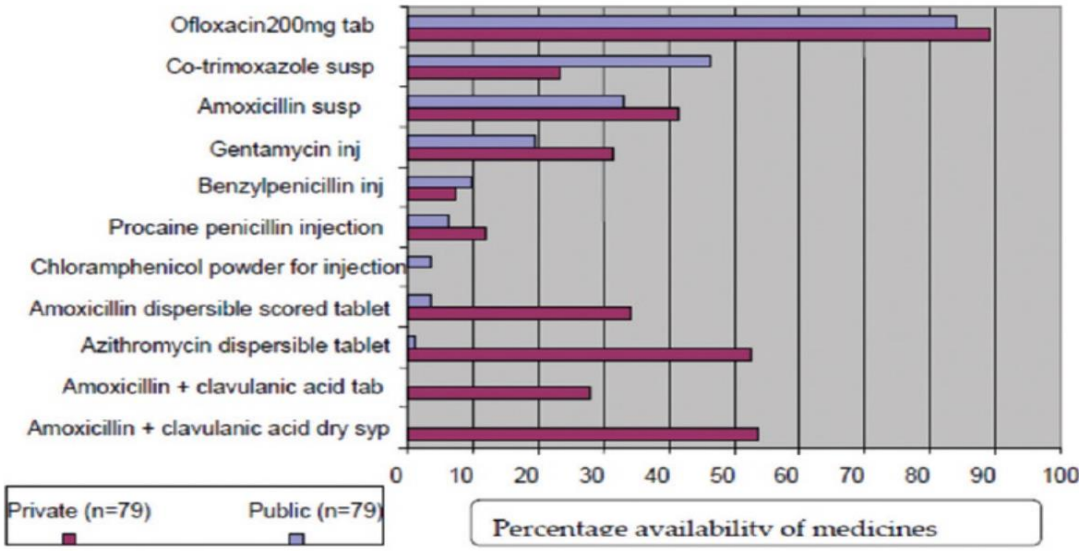
The initiative provided free medicines to patients visiting public healthcare facilities, eliminating the need for them to purchase medicines from retail outlets, as was the practice before. The program introduced a cashless and paperless system for medicine and diagnostic provision in public facilities. As a result, outpatient visits increased from 3.44 million in 2010 to 7.77 million in 2013, alongside a moderate rise in inpatient admissions. Additionally, 600 new drugs have been identified and added to the procurement list to improve the coverage of health concerns.[10]

Odisha

The state of Odisha has been diligently working towards providing universal health coverage to all. Several schemes have been launched in this direction. One such pioneering step is the roll out of Niramaya Yojana in the state. Its digital counterpart: *e niramaya* is largely popular in the cities. Odisha established Odisha Medical Services Corporation Limited (OMSCL) in 2013 making huge investments in drug warehouses, supply chain & IT systems. Recent Comptroller Audit General (CAG) Report has however highlighted inefficiencies due to non-utilisation of the e-Niramaya application leading to ineffective indenting, distribution, consumption, unavailability of real time stock position and expiry of drugs. The study focuses on the varying trends of drug availability at private and public sector of Odisha healthcare services. The availability and dispensing of branded drugs is primarily the core of treatment procedure in private sector. Public sector mostly suffers with lack of supply of essential medicines and this forces the care seekers to buy medicines from outside, which affects the OOPE[11]

[10] https://pubmed.ncbi.nlm.nih.gov/28612814/

[11] https://journals.lww.com/iphr/fulltext/2015/47050/pricing_and_availability_of_some_essential_child.6.aspx



DISCUSSION

Generic medicines have proved to be of prime importance in saving excessive expenditure on the treatment of various disease. They have also showed increased compliance and completion of treatment protocols in cases of chronic illness or drugs following a long course of treatment. The below table shows how the generic drugs are beneficial in reducing the costs of treatment in selected areas of Maharashtra.

Sr. No	Condition	Medicine	Strength	Dosage Form	Standard Treatment	Cost of unit x dosage frequency (in Rs.)		
						Cost as per MRP of popular brand	Cost of PMBJP drugs	Cost Difference [7-8] (%)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
1	Asthma	Salbutamol	o.1 mg/ dose	Inhaler	1 inhaler of 200 doses	105	37	68 (184)
2	Diabetes	Glimepiride	1 mg	Cap/ Tab	1 cap/tab x 2 / day x 30 days = 60	73	24	49 (204)
3	Hypertension	Atenolol	50 mg	Cap/ Tab	1 cap/ tab x 30 days = 30	88.92	84	5 (6)
4	Hypertension	Enalapril	5 mg	Cap/ Tab	1 cap/tab x 2 / day x 30 days = 60	198.48	24	174 (725)
5	Hypercholesteremia	Atorvastatin	10 mg	Cap/ Tab	2 cap/tab x 2 / day x 30 days = 120	1031.92	84	948 (1129)
6	Anticoagulant	Clopidogrel	75 mg	Cap/ Tab	1 cap/tab x 2 / day x 30 days = 60	823.14	90	733 (814)
7	Adult Respiratory tract infection	Ciprofloxacin IP	500 mg	Cap/Tab	1 cap/tab x 3 / day x 7 days = 21	138.60	36	103 (286)
8	Adult Respiratory tract infection	Ceftriaxone	1 g/vial	Injection	1 injection	160	24	136 (567)
9	Adult Respiratory tract infection	Amoxicillin	500 mg	Cap/Tab	1 cap/tab x 3 / day x 7 days = 21	128	61	67 (110)
10	Anxiety	Diazepam	5 mg	Cap/Tab	1 cap/tab x 7 days = 7	19.42	4	15.4 (385)
11	Arthritis	Diclofenac	50 mg	Cap/Tab	1 cap/tab x 2 / day x 30 days = 60	166.26	18	148.3 (824)
12	Depression	Amitriptyline	25 mg	Cap/Tab	1 cap/tab x 3 / day x 30 days = 90	179	169	10 (6)
13	Ulcer	Omeprazole	20 mg	Cap/Tab	1 cap/ tab x 30 days = 30	240	21	219 (1043)

Maximum retail price (MRP) is the price to patient and is printed on the package

Fig: Cost comparison of Branded drug vs Generic drug in India[12]

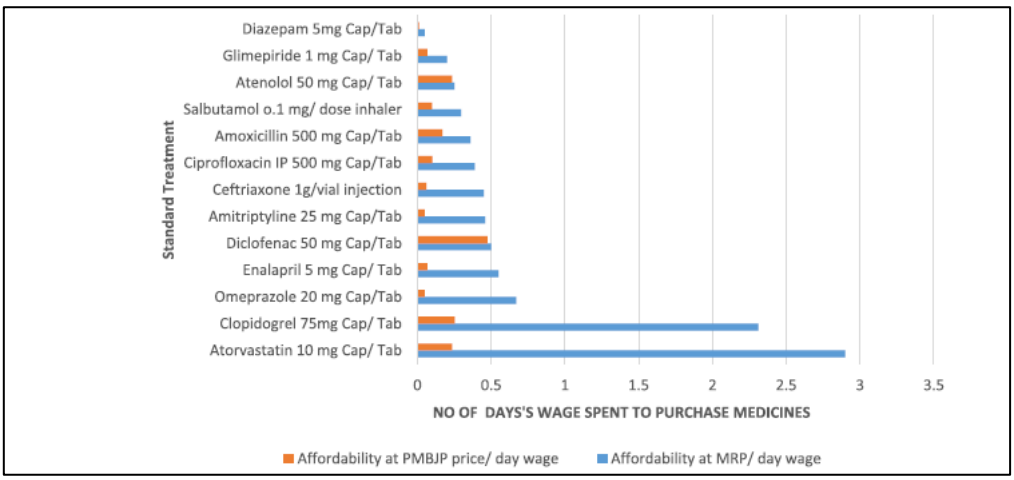


Fig: Affordability of Branded drug vs Generic drug in India[11]

The two figures clearly indicate that PMBJP's unbranded generics present significant cost-saving opportunities. However, several policy actions are essential to fully leverage the scheme's potential. These include:

- The PMBJP drug list should align with the EDL of the country.
- The drugs that pass bioequivalence tests should only be procured
- Procurement and distribution policies should be reviewed to resolve supply chain issues.
- Pharmaceutical policy reforms like mandating generic prescribing and allowing pharmacists to substitute with generics should be introduced.

CONCLUSION

Creating access to medicines is undoubtedly a critical aspect of health policy in developing countries. However, the main challenge lies in the scarcity of public funds, as well as the inefficient allocation and use of available resources. The presence of multiple stakeholders, such as the pharmaceutical industry, wholesalers, retailers, doctors, and medical representatives, with their own interests, further complicates the issue. This problem could be mitigated if public policy effectively harnesses the contributions of these key players in a more collaborative framework. While the private sector naturally seeks profit-maximizing opportunities, it can, and should, collaborate with the public sector to find solutions that improve access to medicines.

[12] https://link.springer.com/article/10.1186/s12913-022-08022-1