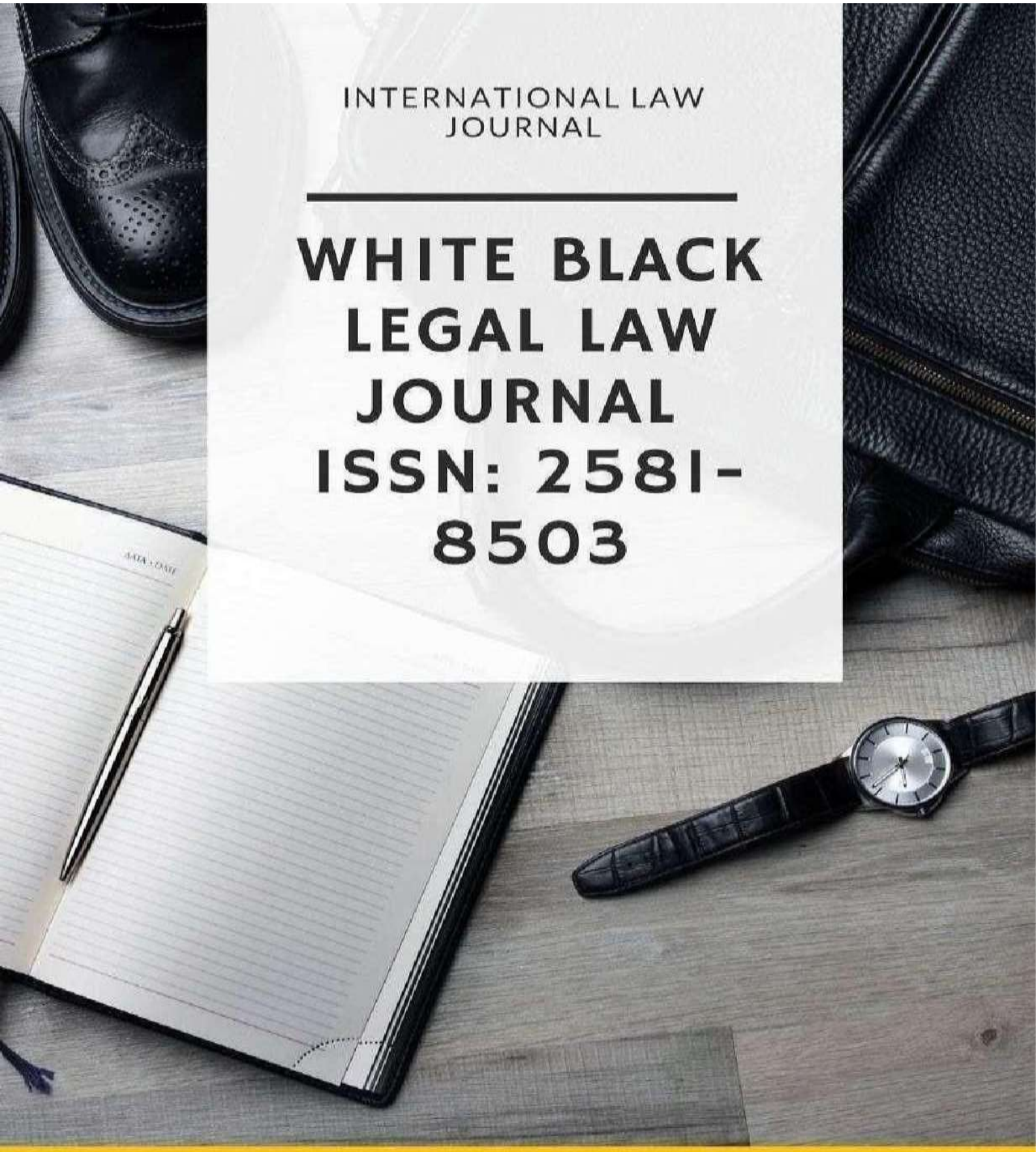

INTERNATIONAL LAW JOURNAL

# WHITE BLACK LEGAL LAW JOURNAL

ISSN: 2581-8503

## Peer - Reviewed & Refereed Journal

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Subhrajit did his LL.M. in Sports Law, from Nottingham Trent University of United Kingdoms, with international scholarship provided by university; he has also completed another LL.M. in Energy Law from University of Petroleum and Energy Studies, India. He did his B.B.A.LL.B. (Hons.) focussing on International Trade Law.

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WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal providededicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

# ACCESS AND ACCEPTANCE: EXPLORING THE PERCEPTION OF GENERIC MEDICINES IN INDIA

AUTHORED BY - DARRYL KLETH QUADROS,
LLM, Christ (Deemed to be University), Bangalore
CO-AUTHORE - DR. CHAITRA R.B.,
Professor, School of Law, Christ (Deemed to be University), Bangalore

## ABSTRACT

A nation's health system benefits significantly from the availability of therapeutically similar generic medications, which would not have been affordable for a significant portion of the populace if only proprietary medications were permitted to be sold. With 20% of global generic pharmaceutical exports, India is the world's biggest exporter of generic medicines. However, because the cost of medications to treat different diseases is so enormous, some 40 million Indians are forced into poverty each year. Despite their desire to produce medicines in India, generic pharmaceutical companies would instead concentrate solely on exporting their products rather than trying to establish a presence in the local market. This study aims to investigate the discrepancy between the supply and production of generic medications in India to identify the reasons for the generic drug companies' lack of interest in entering the Indian market.

With the economic downturn triggered by the pandemic, there has been a heightened awareness of cost-effectiveness in healthcare. Generic medicines, which are typically cheaper than their branded counterparts, have gained favour among consumers who are looking forward to save money on healthcare expenses. This shift is particularly notable among individuals who have faced financial hardships due to job losses or reduced incomes during the Covid-19 pandemic.

During the pandemic, disruptions in the global pharmaceutical supply chain have led to shortages of branded medicines in some regions. In contrast, generic medicines, which are often produced locally or in nearby countries, have remained more accessible. This has highlighted the importance of ensuring reliable access to essential medications, further bolstering the perception of generics.

The Indian government has been promoting the use of generic medicines as part of its efforts to improve healthcare affordability and accessibility. Various initiatives, such as the Jan Aushadhi Scheme, aim to make quality generic medicines available at affordable prices across the country. The pandemic has underscored the importance of such initiatives, leading to increased support and acceptance of generic medicines among policymakers and the general public alike.

**Keywords:** generic drugs, medicines, pandemic, healthcare, income

# Introduction:

"*The idea of a better-ordered world is one in which medical discoveries will be free of patents, and there will be no profiteering from life and death"*

*-Indira Gandhi (at the World Health Assembly, Geneva, May 1982).*

In the realm of healthcare, access to affordable and effective medicines stands as an indispensable pillar for the well-being of individuals and the prosperity of nations. In India, a nation renowned for its rich heritage in pharmaceuticals and its burgeoning healthcare sector, the availability and accessibility of generic drugs and other affordable medicines hold paramount significance.

It has to be noted that, neither the two Indian legislations, i.e., the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945 define what constitutes a generic drug. Reference however can be drawn from the United States Food and Drug Administration (FDA), that has defined a "generic drug" as "a drug product that is comparable to a brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use".[1]

It also lays down the criteria that a pharmaceutical product has to satisfy in order to gain marketing approval as a generic drug: (a) contain the same active ingredients as the innovator drug (inactive ingredients may vary); (b) be identical in strength, dosage form, and route of administration; (c) have the same use indications; (d) be bioequivalent; (e) meet the same batch requirements for identity,

[1] U.S. Food and Drug Administration, *What are Generic Drugs?*

strength, purity, and quality; (f) be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products.[2]

One of the primary advantages of generic drugs lies in their cost-effectiveness. Unlike branded medications, which are often priced higher due to research and development costs, marketing expenses, and patent protection, generic drugs offer comparable quality at a fraction of the price.[3] This affordability is especially significant for individuals facing financial constraints, allowing them to access vital treatments without undue financial burden.

In many regions, access to healthcare remains a pressing issue, with disparities in access to essential medications disproportionately affecting marginalized communities. Generic drugs play a pivotal role in bridging this accessibility gap.[4] Due to their lower production costs and absence of patent protection, generic drugs can be manufactured and distributed more widely, reaching remote areas and underserved populations where branded medications may be scarce or prohibitively expensive.[5] Governments around the world are increasingly recognizing the importance of generic drugs in promoting healthcare accessibility. Initiatives such as India's Jan Aushadhi Scheme and similar programs in other countries aim to make quality generic medications available at affordable prices.[6] By subsidizing or incentivizing the production and distribution of generic drugs, governments can ensure that essential treatments are within reach of all segments of society, regardless of socioeconomic status.

One common concern surrounding generic drugs is the perception of inferior quality compared to their branded counterparts.[7] However, stringent regulatory standards ensure that generic drugs undergo rigorous testing to demonstrate bioequivalence to their branded counterparts. In many cases,

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[2] *Ibid.*

[3] Das M, Choudhury S, Maity S, Hazra A, Pradhan T, Pal A, Roy RK. *Generic versus Branded Medicines: An Observational Study Among Patients with Chronic Diseases Attending a Public Hospital Outpatient Department*. J Nat Sci Biol Med. 2017 Jan-Jun;8(1):26-31. doi: 10.4103/0976-9668.198351. PMID: 28250671; PMCID: PMC5320819.

[4] Aswini Priya, "*The Role of Generic Medicines in Bridging Healthcare Gaps on a Global Scale*," Invimeds (Mar. 01, 2024), https://invimeds.com/updates/the-role-of-generic-medicines-in-bridging-healthcare-gaps-on-a-global-scale/. (last visited Mar. 15, 2024)

[5] *Ibid*

[6] George, Thomas & Baliga, Shrinath. (2021). *Generic Anticancer Drugs of the Jan Aushadhi Scheme in India and Their Branded Counterparts: The First Cost Comparison Study*. Cureus. 13. e19231. 10.7759/cureus.19231.

[7] Yuxi Tian, Berthold Reichardt, Daniela Dunkler, Milan Hronsky, Wolfgang C. Winkelmayer, Anna Bucsics, Susanne Strohmaier & Georg Heinze, Comparative effectiveness of branded vs. generic versions of antihypertensive, lipid-lowering and hypoglycemic substances: a population-wide cohort study, Sci Rep 10, 5964 (2020).

generic drugs are manufactured by reputable pharmaceutical companies with a proven track record of quality and safety.[8] As a result, healthcare professionals and consumers alike can trust in the efficacy and reliability of generic medications.

The COVID-19 pandemic has served as a stark reminder of the importance of a resilient healthcare system. In times of crisis, ensuring uninterrupted access to essential medications is paramount. Generic drugs contribute to healthcare system resilience by reducing dependence on expensive branded medications and mitigating the risk of supply chain disruptions.[9] Their widespread availability and affordability help safeguard against shortages and ensure that healthcare systems can effectively respond to emergencies.

## Importance of Generic Drugs:

Firstly, pharmaceutical drugs are, *prima facie,* one of the most important components of health care. It has been noted that expenditure on drugs constitute anywhere between 40 to 80% of the total cost of medical treatment[10]. Secondly, generic drugs allow the public greater access to health care[11]. This is because patented drugs are developed after spending exponentially on research and development by the innovator drug company and are priced at rated that are intended to recoup the expenditure incurred on the developing, filing and approval processed.

On the other hand, the development of generic drugs neither the high amount of research and development expenditure that goes into the invention (as a comparable excipient is simply substituted in place of the excipient in the patented dosage form) nor the regulatory expenditure in conducting expensive clinical trials to prove pharmacological efficiency (as the innovator drug has already established evidence of the same). Thus, generic drugs can be priced much lower than their branded counterparts and are able to reach the larger masses of the population who are suffering from a

[8] Ibid.
[9] Government of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, 'Jan Aushadhi Scheme: Making Medicines Affordable for All,' Indian Journal of Pharmaceutical Sciences (2021), https://janaushadhi.gov.in/article.php?id=1234
[10] Parliamentary Standing Committee on Health and Family Welfare, Forty-Fifth Report on Issues Relating to Availability of Generic, Generic-Branded and Branded Medicines, their Formulation and Therapeutic Efficacy and Effectiveness, Aug. 4, 2010.
[11] U.S. Food and Drug Administration, *Understanding Generic Drugs*, https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ (last visited Jan. 15, 2024).

particular disease but are unable to obtain the cure as the medicines are priced out of their reach.

A simple illustration of this proposition is Novartis' Drug 'Gleevec' that is prescribed for treating chronic myeloid leukemia. This patented drug is priced at Rs. 1.2 Lakh per month. The generic version of the same drug, manufactured by Cipla, is priced at Rs. 8000 per month[12].

## Wrongful Perceptions Amongst Policymakers, Pharmacists and Patients About Branded Drugs and Generic Drugs.

The ambiguities and incorrect information in relation to generic medicine preparations are widespread and highly prevalent. Confusion is shared among stakeholders including the public, prescribers, policy makers and pharmaceutical trade organizations. The importance of access to generic medicines, and rightly so have been stressed upon time and again by the state heads at various points of time owing to the reason that generic drugs worldwide are seen as a befitting response to the ever-increasing costs of medicines and health care[13]. For an illustrative purpose one could consider America where not only are six out of ten prescriptions comprised of generic drugs but also goes onto allow chemist to a substitute or replace branded drugs the generic versions of the same[14]. In contrast, India is home to one fifth of the world's generic drug production however the sad part still remains that a consumer believes it is immensely difficult to get access to generic drugs at affordable prices[15]. The root cause for this misinformation that is present in the minds of the Indian masses can be changed and corrected by making aware the common man and woman of our country about the misinformation that is spread around about branded and non-branded drugs[16]. It is important to understand that generic drugs are defined as those products which are comparable to brand or reference listed pharmaceutical product in quality and performance characteristics and most importantly, its intended use[17]. In those nation where product patents are recognized by law, the firm which is the originators that holds the patent markets for the medicines under a trademarked name with no competition for a period of up to twenty years are well existing in the world. In countries like these, generic medicines

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[12] Puskar, *Generic Drugs – Why is it Important?*, (Oct. 23, 2011) http://greencleanguide.com/generic-drugs/
[13] Viral Shah, *Evolution of Pharmaceutical Industry: An Indian Perspective* 2 JPSBR: Issue 5, 219, 229 (2012).
[14] Pradeep Agarwal and P. Saibaba, *TRIPS and India's Pharmaceutical Industry*, Economic and Political Weekly, Vol.36, No.39 (Sep. 29- Oct. 5, 2001), 3787
[15] Richard A. Spinello, *Ethics, Pricing and the Pharmaceutical Industry*, The Journal of Law & Economics, Vol.43, No.2 (October 2000), 311.
[16] *Ibid.*
[17] *Ibid.*

are nothing but comparatively low-cost versions of the innovator product which are produced by a number of manufacturers cumulatively or alone by themselves after the patent on the medicine has reached its expiry. Therefore, it can be said that generic medicines are basically nothing but non patented medicine made by companies other than the originator company and that which is usually marketed under a trade name (branded generic) or else alternatively under its respective international non-proprietary name, or INN (unbranded generic). A popular example would be that of Paracetamol which is marketed and distributed across the world as Crocin, Calpol or Metacin (branded generic) itself without any alterations or changes. All generic versions or substitutes of the original patented drug or that which is chemically identical to the originator drug are required to satisfy the same standards of quality and must be identical in efficacy, risks, benefits, and intended use as per law. The issue arises when sceptics raise claims as to how the bioequivalence and therapeutic equivalence of generic and brand/ reference products are not in consonance with their branded counterparts. In factuality, pharmaceutical drug products are considered bioequivalent if there is no clinically significant difference in their bioavailability (as measured by extent and rate of absorption, and maximum blood concentration)[18]. Generic drugs are ideally expected to be identical and bioequivalent to its original innovator brand company. If it is oral drugs in question, then if the true blood concentrations of the two drugs in comparison turn it to be similar then it is been scientifically proved that the component concentration of the two drugs at their site of action and their effectiveness will also perfectly match as the core of the two drugs irrespective of their dosages and additions are structurally and formatively the same[19]. However, it is possible that in certain scenarios that those two medicinal drugs with the same active ingredient in essentially the same dosage could have varying bioavailability.

## Generic Inflation and Price Gouging:

One of the most alarming trends in the generic drug market is the phenomenon of generic inflation, wherein the prices of generic medications surge inexplicably, often without any clear rationale. While generics are generally priced lower than brand-name drugs, they are not immune to price hikes. In recent years, numerous instances have been documented where the prices of generic drugs have

[18] Sanjaya Lall, *Multinational Companies and Concentration: The Case of the Pharmaceutical Industry*, Social Scientist, Vol.7, No.8/9, (Mar. – Apr, 1979), pp.3-29.
[19] *Ibid.*

skyrocketed, leaving patients and healthcare providers grappling with exorbitant costs.[20]

Moreover, some pharmaceutical companies have been accused of engaging in price gouging tactics, exploiting market monopolies or shortages to artificially inflate the prices of essential generic medications. These practices not only erode the cost-saving benefits of generic drugs but also pose significant challenges for patients, particularly those with chronic conditions who rely on affordable medication for long-term management.[21]

## Pricing regulation and mechanism under The Drug Price Control Orders (DPCO) and National Pharmaceutical Pricing Authority (NPPA):

Under the Essential Commodities Act, 1955, the government issues Drug Price Control Orders to regulate the prices of essential medicines in India. These orders aim to ensure affordability of pharmaceutical products, including generic medicines, by fixing their maximum retail prices.

The soaring price of medicines has been receiving growing attention from regulatory authorities for decades. The primary regulatory body concerned with the price regulation of medicines in India is the National Pharmaceutical Pricing Authority (NPPA).[22] Although the NPPA was established under the Ministry of Chemicals and Fertilizers in 1997, the prices of medicines in India have been regulated since the 1970s through a series of Drug Prices Control Orders (DPCOs)[23]. The DPCO is a government-issued order promulgated under Section 3 of the Essential Commodities Act of 1955. The first DPCO was introduced in 1970, which was subsequently revised in 1979, 1987, 1995, and the most recent revision in 2013[24]. DPCO 2013 was enforced on the 13th of May, 2013, to implement the National Pharmaceutical Pricing Policy (NPPP) of 2012[25]. The objective of the policy was to harmonize pharmaceutical innovation and improve the accessibility of medicines for the general

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[20] Viral Shah, *Evolution of Pharmaceutical Industry: An Indian Perspective* 2 JPSBR: Issue 5, 219, 229 (2012).
[21] *Ibid.*
[22] National pharmaceutical pricing authority. https://pharmaceuticals.gov.in/national-pharmaceutical-pricing-authority 2013;13 [Google Scholar]
[23] Bhaskarabhatla A, Chatterjee C, Anurag P, Pennings E, *Mitigating regulatory impact: the case of partial price controls on metformin in India*. Health Policy Plan. 2017;32:194–204
[24] Ahmad A, Khan MU, Patel I., *Drug pricing policies in one of the largest drug manufacturing nations in the world: are affordability and access a cause for concern?* J Res Pharm Pract. 2015;4:1–3.
[25] Bharuga M., An overview on the National Pharmaceutical Pricing Policy. http://www.iclr.in/assets/pdf/AN%20OVERVIEW%20ON%20THE%20NATIONAL%20PHARMACEUTICAL%20PRICING%20POLICY,%202012.pdf 2012, (last visited 01 Mar, 2024)

population. DPCO 2013 aimed to do so through its three key principles, which contrast it with its previous counterparts[26]. One, DPCO 2013 is formulation-specific and not drug-specific, i.e., it regulates the prices of certain strengths and dosage forms (such as tablets, capsules, etc.) of a bulk drug in contrast to the immediate prior order (DPCO 1995), which regulated prices of the bulk drug. A bulk drug is an active drug substance, which alone or in combination with inactive ingredients form the final medicinal product (known as formulation). Two, DPCO 2013 replaced the cost-based pricing of the earlier orders with market-based pricing (MBP) approach and computed a ceiling price of each formulation. Ceiling price refers to the maximum price of a formulation at which it is sold to the consumer, excluding the local taxes. Ceiling price calculation using MBP involved calculating an average price to retailer (PTR) of medicines having a market share of more than equal to 1%. A fixed 16% margin to the retailer was then added to the average PTR to obtain the ceiling price of a formulation. Also, unlike the previous versions of DPCO, which lacked provision for revising the prices, the current DPCO revises the ceiling price of each formulation on the 1st of April of every year, based on the wholesale price index (WPI) of the formulation for the preceding year. Three, the DPCO 2013 regulates the prices of essential formulations only, i.e., the formulations listed in the National List of Essential Medicines (NLEM)[27]. Thus, when DPCO 2013 was enforced, it regulated the prices of 348 essential medicines listed in NLEM 2011, of which 40 were anticancer drugs (corresponding to 63 anticancer formulations). But currently, the policy regulates the prices of 376 essential medicines listed in NLEM 2015, of which 59 are anticancer medicines (corresponding to 108 anticancer formulations)[28].

The ceiling prices of essential anticancer formulations were notified gradually, rather than at a single time point. NPPA notified ceiling prices of anticancer formulations over a period of 14 months (June 2013 to July 2014), which denotes the implementation period of the policy (DPCO 2013) for anticancer formulations. But, as per the norms of the policy, each ceiling price notification was followed by providing an additional 45 days to its manufacturer to fix/revise the maximum retail price (MRP) of the formulation. Therefore, for anticancer formulations, the price adjustment period was extended from August 2014 to the end of September 2014[29].

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[26] *Ibid*
[27] *Ibid*
[28] National list of essential medicines of India. https://pharmaceuticals.gov.in/sites/default/files/NLEM.pdf 2011
[29] An overview on the National Pharmaceutical Pricing Policy. Bharuga M. http://www.iclr.in/assets/pdf/AN%20OVERVIEW%20ON%20THE%20NATIONAL%20PHARMACEUTICAL%20PRICING%20POLICY,%202012.pdf, (last visited 01 Mar, 2024)

Policy evaluation studies for anticancer drugs have been conducted in countries of varying income groups, including the U.S., Italy, and China[30]. But, most of these studies evaluated the impact of the addition of anticancer medicines in insurance coverage or modification of existing cancer-related reimbursement schemes. These studies demonstrated either no systematic change or an improvement in the utilization of anticancer medicines after the implementation of the policy[31]. In 2017, an Indian study evaluated the impact of Drug Prices Control Order 2013 on the average price of an antidiabetic formulation (metformin 500mg). The study found that, as compared to unregulated metformin, the price of regulated metformin formulations increased prior to the policy implementation, which later declined after the policy was implemented[32]. Another Indian study in 2019 evaluated the impact of DPCO 2013 on statins and found a shift in utilization from unregulated to regulated statins after the policy was implemented.[33]

The cumulative utilization of price-controlled formulations in 2015 was 22.4 thousand SUs higher than that in 2012 (a relative increase of 27.2%). In terms of monthly utilization, the growth of price-controlled formulations became stagnant as DPCO 2013 came into force. While the manufacturers were revising the maximum retail prices of formulations in the adjustment period (August 2014 to September 2014), the price-controlled market showed a negligible reduction or no change in the monthly utilization. But, immediately after the adjustment period, the sales volume of formulations declined minimally.

## Impact Of Government Schemes Post 2014 On Affordability And Accessibility Of Generic Medicines:

The year 2014 marked a significant turning point in India's healthcare policy landscape, with a renewed emphasis on promoting generic medicines. The government recognized the potential of generics to significantly reduce healthcare costs while maintaining therapeutic efficacy.

[30] Guan X, Wushouer H, Yang M, Han S, Shi L, Ross-Degnan D, Wagner AK. *Influence of government price regulation and deregulation on the price of antineoplastic medications in China: a controlled interrupted time series study.* BMJ Open. 2019;9:0.
[31] Hsu JC, Wei CF, Yang SC, *Effects of removing reimbursement restrictions on targeted therapy accessibility for non-small cell lung cancer treatment in Taiwan: an interrupted time series study*. BMJ Open. 2019;9:0.
[32] Bhaskarabhatla A, Chatterjee C, Anurag P, Pennings E. *Mitigating regulatory impact: the case of partial price controls on metformin in India.* Health Policy Plan. 2017;32:194–204.
[33] Selvaraj S, Farooqui HH, Mehta A. *Does price regulation affect atorvastatin sales in India? An impact assessment through interrupted time series analysis*. BMJ Open. 2019;9:0.

Consequently, a series of initiatives were launched to encourage the use of generic drugs and curb the dominance of branded pharmaceuticals in the market.

**Constitution of Pradhan Mantri Bharatiya Janaushadi Pariyojana (PMBJP):**

With an objective of making quality generic medicines available at affordable prices to all, Pradhan Mantri Bharatiya Janaushadi Pariyojana (PMBJP) was launched by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India in November, 2008. Under the scheme, dedicated outlets known as Janaushadhi Kendras are opened to provide generic medicines at affordable prices. As on 31.01.2024, 10607 Janaushadhi Kendras ARE functional across the country. Product basket of PMBJP comprises 1965 drugs and 293 surgical items. The scheme is implemented by a society registered under the Societies Registration Act, viz, Pharma & Medical Bureau of India (PMBI) [erstwhile Bureau of Pharma PSUs of India (BPPI)].[34]

**Objectives of the Scheme:**

1. Ensure access to quality medicines for all sections of the population especially the poor and the deprived ones.
2. Create awareness about generic medicines through education and publicity to counter the perception that quality is synonymous with high price only.
3. Generate employment by engaging individual entrepreneurs in opening of PMBJP Kendra.[35]

Accordingly, franchisee like model was adopted and an intensive media campaign in national and regional newspapers inviting individual entrepreneurs to apply for establishing and running PMBJP Kendra was undertaken. In response, the applications received were scrutinized and eligible applicants were assisted with drug license and other infrastructure facilities to open the Kendras. The gate was opened for private participation in procurement as well as sale of medicines.[36]

The target of opening 3000 Kendras was achieved in December 2017. Further, revised target of total 6000 outlets was achieved in March, 2020. As on 31.12.2021, 8640 Janaushadhi Kendras are functional across the country. Product basket of PMBJP comprises 1451 drugs and 240 surgical

[34] https://janaushadhi.gov.in/pmjy.aspx (last visited Mar. 11, 2024).
[35] *Ibid.*
[36] Government of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, Annual Report 2021-22 available at https://janaushadhi.gov.in/annual_report.aspx (last visited Mar. 11, 2024)

equipment. PMBJP has decided to include AYUSH products, specifically 75 Ayurvedic drugs in the product basket of the Pariyojana. An e-tender has been prepared by PMBI for procurement of the same.[37]

## Affordable Medicines and Reliable Implants for Treatment (AMRIT) Program:

Under the AMRIT (Affordable Medicines and Reliable Implants for Treatment) programme medicines will be provided at an affordable cost. More than 195 drugs for treatment of cancer are dispensed. For example1, AMRIT will sell anticancer drug 'Docetaxel 120mg' used for chemotherapy cycle at Rs 888.75 (93 %) for one cycle whereas Maximum retail price of the injection is Rs 13,440. Similarly, another 'Caboplatin 450mg' sold at Rs 1,316.25 (50%) of its MRP. More than 1.77 lakhs patients have been benefitted2. This has resulted in saving of around Rs 13 crores out of pocket expenditure to the patients (average discount of 69 percent on MRP). The government is planning to open 300 outlets of AMRIT pharmacy in the country with the aim to reduce the expenditure incurred by common patients on treatment of cancer and heart disease.[38]

More than 195 drugs for treatment of cancer and 186 drugs for treatment of cardiovascular diseases are being sold through AMRIT with a discount of more than 90 percent are available to patients. More than 1.77 lakhs patients have been benefitted till date. This has resulted in saving of around Rs 13 crores out of pocket expenditure to the patients which translates into an average discount of 69 percent on MRP.[39]

## Conclusion:

Ensuring equitable access to generic drugs and essential medicines is fundamental to achieving universal health coverage and promoting public health in India. While challenges persist, concerted efforts from policymakers, healthcare stakeholders, and civil society are essential to address regulatory gaps, promote generic medicine adoption, and strengthen healthcare infrastructure.

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[37] *Ibid.*

[38] Sajitha Venkatesan, *Most recent cancer drugs offer few benefits, India's top cancer hospital says,* BMJ 2017;357:j2129

[39] https://www.business-standard.com/content/b2b-pharma/govt-plans-to-open-300-amrit-pharmacies-to-dispense-low-cost-drugs-116081600610_1.html (last visited, 15. Mar. 2024)

One of the key findings of this paper is the significant role that generic drugs play in enhancing accessibility and affordability of essential medicines for the population. The promotion and utilization of generic medications have emerged as a crucial strategy to address the healthcare needs of India's vast and diverse population, particularly those from economically disadvantaged backgrounds. Moreover, the implementation of policies such as the Jan Aushadhi Scheme and the National List of Essential Medicines (NLEM), where all medications included in the list are approved by the Drugs Controller General of India and are recommended by the respective national programs.[40] This has played a pivotal role in improving the availability and accessibility of essential drugs across the country.

However, despite these efforts, several challenges persist in ensuring universal access to generic drugs and essential medicines. Issues such as inadequate infrastructure, supply chain inefficiencies, regulatory hurdles, and insufficient awareness among healthcare professionals and consumers continue to impede the effective distribution and utilization of these medications. Additionally, the prevalence of counterfeit drugs in the market poses a grave threat to public health and further exacerbates the accessibility crisis.

Furthermore, the disparities in access to healthcare services between urban and rural areas, as well as among different socio-economic groups, remain a pressing concern. While initiatives such as telemedicine and mobile health (mHealth) have the potential to bridge these gaps to some extent, comprehensive measures are needed to address the underlying structural inequalities in the healthcare system.[41]

Moving forward, it is imperative for policymakers, healthcare providers, pharmaceutical companies, and civil society stakeholders to collaborate effectively in implementing evidence-based strategies to improve the availability and access of generic drugs and essential medicines in India. This requires a holistic approach that encompasses regulatory reforms, investment in healthcare infrastructure, capacity building, public awareness campaigns, and the promotion of rational drug use practices.

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