# EVALUATING INDIA'S PHARMACEUTICAL PRICING POLICY: A CONSTITUTIONAL & REGULATORY STUDY OF PHARMA SAHI DAAM APP

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## INTRODUCTION

The India's pharmaceutical pricing policy operates at the intersection of constitutional morality, international trade obligations, patent law, and public health realities. Access to affordable medical products by all countries has long been a subject of debate and deliberation at the World Health Assembly(WHA). Although India is celebrated as the " Pharmacy of the World" supplying affordable generic medicines to large parts of Global South, this global image often masks serious inequalities in access to medicines within the country. High out of pocket expenditure, escalating prices of patented drugs, uneven implementation of price control mechanisms, and structural gaps in health governance continue to place essential and life saving medicines beyond the reach of a significant portion of the population. In response to these challenges, the Government of India has increasingly relied on interventions and digital tools to promote transparency and affordability. The launch of the Pharma Sahi Daam App represents one such initiative, aimed at empowering consumers with price information for scheduled medicines. However, the effectiveness of such initiatives must be evaluated not merely in terms of technological innovation, but through a deeper constitutional and regulatory analysis that situates pricing policy within the broader framework of the right to health and access to medicines.

## ACCESS TO MEDICINES AS A HUMAN RIGHT

Access to medicines has evolved into a central concern of international human rights law, public health policy, and domestic constitutional jurisprudence. It is no longer sufficient to just ensure that medicines exist in the market; what matters is whether people can actually obtain and use them when needed. Contemporary human rights discourse conceptualizes access to medicines through multiple interrelated dimensions. Availability encompasses physical access to healthcare facilities, economic affordability of medicines, and informational access that

enables patients to make informed choices. Acceptability and quality further require that medicines be culturally appropriate, scientifically validated, and safe. In the Indian context, where availability of generic medicines is relatively strong, accessibility – particularly economic accessibility remains deeply problematic. The Pharma Sahi Daam App primarily addresses informational accessibility by enabling consumers to compare prices of medicines listed under the Drug Price Control Order, 2013. Yet, informational access alone cannot overcome structural barriers such as patent monopolies, weak enforcement of public ceilings, and limited public provisioning of healthcare.

The constitutional foundation aligns closely with international human rights norms. Article 25 of the Universal Declaration of Human Rights, 1948 recognises the right to a standard of living adequate for health and well-being, including medical care. This provision laid the normative groundwork for later developments in international human rights law that explicitly recognize the right to health. The obligation of States to respect, protect, and fulfill human rights implies that governments must take proactive measures to ensure access to essential healthcare services and medicines. The Supreme Court has repeatedly reaffirmed that access to medical care is integral to the right to life, thereby imposing a positive obligation on the State to protect and promote public health. This understanding is reinforced by the Directive Principles of State Policy, particularly Article 47, which mandates the State to improve public health, and Articles 38 and 39(e), which emphasizes social justice and protection of health. Although non-justiciable, these principles inform the interpretation of fundamental rights and guide legislative and executive action. The linkage between health and dignity underscores the moral and constitutional imperative for the State to intervene when market mechanisms fail to deliver affordable medicines.

## TRIPS, PATENTS, AND PHARMA PRICES: INDIA'S BALANCING ACT

At the international trade level, India's pharmaceutical pricing policy is significantly influenced by its obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights(TRIPS). While TRIPS establishes minimum standards of patent protection, it also incorporates flexibilities designed to safeguard public health. These include provisions for compulsory licensing, government use of patents, and parallel importation. The Doha Declaration on the TRIPS Agreement and Public Health reaffirmed the right of WTO members to use these flexibilities to promote access to medicines for all. India has historically played

leading role in advocating for a pro-public health interpretation of TRIPS, both domestically and internationally. However, the exercise of these flexibilities has often been constrained by diplomatic and economic pressures from developed countries. One manifestation of such pressure is the annual Special 301 Report issued by the Office of the United States Trade Representative. The 2025 report continues to criticize India's patent regime, particularly provisions perceived as limiting pharmaceutical patent monopolies. Sections such as 3(d), 84, and 100 of the Indian Patents Act are frequently portrayed as barriers to innovation, despite their clear public health rationale. This external scrutiny raises concerns about regulatory chill, where the threat of trade sanctions or diplomatic repercussions may discourage the robust use of lawful TRIPS flexibilities. The tension between international pressure and domestic public health priorities highlights the need for a constitutionally grounded approach to pharmaceutical governance that prioritises the welfare of citizens over external commercial interests. The landmark compulsory licensing decision in Bayer Corporation vs Nacto Pharma Ltd. illustrates how Indian patent law can be deployed to advance access to medicines. In this case, the Controller of Patents granted a compulsory license for the kidney cancer drug "Nexavar", citing its exorbitant price and inadequate availability. The decision emphasized that patents are not granted solely to reward innovation, but to ensure that inventions are worked in India on a commercial scale and made available to the public at a reasonable prices. This principle is explicitly reflected in Section 83 of the Indian Patents Act, 1970 which states that patents should not be abused to create monopolies that harm public interest. Despite the significance of the decision in Bayer vs Nacto case, compulsory licensing has remained an exception rather than the norm, raising questions about institutional reluctance and political will.

## CASE STUDY ON HIGH COST MEDICINES AND ACCESS BARRIERS

Contemporary pharmaceutical controversies further reveal the limitations of India's current pricing and patent framework. The case of Lenacapavir, a long acting HIV prevention drug, highlights concerns about patent evergreening, where minor modifications are used to extend monopoly protection without commensurate therapeutic benefit. Such practices delay generic entry and perpetuate high prices, undermining access to medicines for vulnerable populations. Similarly, the pricing of Trikafta for cystic fibrosis patients and Pertuzumab for breast cancer treatment demonstrates how patented medicines can remain inaccessible despite clear clinical necessity. These cases underscore the inequitable production and consumption of health products, where life-saving innovations are available are available globally but remain out of

reach for most patients in low and middle income countries. Voluntary licensing has emerged as a partial solution to the access dilemma, allowing patent holders to license their technologies to generic manufacturers under agreed terms. Initiatives such as the Medicines Patent Pool have facilitated access to treatments for HIV, hepatitis C, and tuberculosis. However, voluntary licences are often limited in geographic scope and may exclude countries like India on the assumption that they are commercially viable markets. Moreover, the discretionary nature of voluntary licensing place access at the mercy of corporate strategies rather than legal entitlement. While voluntary licensing can complement public health objectives, it cannot substitute for statutory mechanisms such as compulsory licensing and government use. India's domestic pharmaceutical policy also relies on public procurement and distribution schemes to improve efficiency. The Padhan Mantri Bhartiya Janaushadhi Pariyojana aims to provide quality generic medicines at affordable prices through a network of dedicated outlets. This scheme plays a crucial role in enhancing economic accessibility, particularly for low-income populations. However, reports by the Comptroller and Auditor General have highlighted persistent challenges, including supply chain inefficiencies, stock shortages, and limited public awareness. These findings point to a broader governance deficit, where policy design is not always matched by effective implementation and monitoring. The National List of Essential Medicines, informed by World Health Organization guidelines, represents another key policy tool for prioritizing public health needs. Inclusion of medicines in this list enables price control under the DPCO and guides public procurement decisions. The UN Special Rapporteur on the Right to Health has repeatedly emphasized the importance of essential medicines lists as instruments for realising the right to health. However, the effectiveness of such lists depends on timely updates, rigorous enforcement of price ceilings, and integration with broader health system strengthening efforts. From a legal perspective, India possesses a range of statutory tools to facilitate access to medicines, yet these tools remain underutilized. Section 100 of the Patents Act empowers the government to authorize the use of patented inventions for public purposes, including public health emergencies. Despite its potential, this provision has rarely been invoked, reflecting a cautious approach to state intervention in the pharmaceutical market. Another significant gap lies in the limited role accorded to patients and civil society organizations in seeking remedies under patent law. Unlike competition law, where consumer interests are more directly recognized, patent law enforcement remains largely state-centric, reducing opportunities for participatory justice.

## PHARMA SAHI DAAM APP: LEGAL EVALUATION AND POLICY IMPACT

The Pharma Sahi Daam app must be understood within this broader legal and policy landscape. Beyond pricing and patent structures, access to medicines is also shaped by prescribing practices within the healthcare system. In India, concerns have long been raised about the influence of pharmaceutical marketing on doctors' prescriptions. The widespread practice of incentivizing doctors through commissions, gifts, or sponsorships has contributed to the over-prescription of high cost or high dosage medicines, often without proportional therapeutic justification. Such practices raise serious ethical and legal concerns, as they shift the focus of medical decision- making from patient welfare to commercial gain. From a rights-based perspective, irrational or profit-driven prescribing undermines the patient's right to informed choice and safe treatment, and exacerbates the financial and physical burden of illness. This issue is not merely theoretical but reflects lived realities. When I was in the eleventh grade, I was prescribed a very high-dosage medicine for a common fever. While the medication did succeed in reducing the fever, it also caused prolonged drowsiness and a significant loss of appetite, leaving me physically weakened for days. The experience illustrated how powerful medicines, when prescribed without adequate justification, can cure an immediate symptom while simultaneously worsening overall health. For patients and families lacking medical literacy, questioning such prescriptions is rarely an option, reinforcing informational asymmetry and dependence on medical authority. This dimension of access highlights the importance of informational transparency not only about prices, but also about medicines themselves. The Pharma Sahi Daam app offers an indirect but meaningful corrective by empowering patients to know the price range of prescribed drugs and compare them with lower-cost alternatives. When patients are aware that equally effective medicines are available at significantly lower prices, it creates space for dialogue with healthcare providers and reduces blind dependence on expensive branded prescriptions. In this sense, the app contributes to curbing exploitative prescribing practices by strengthening patient agency, promoting rational drug use, and aligning medical decisions more closely with affordability and necessity. By enhancing price transparency, the app contributes to informational accessibility and consumer awareness. It aligns with the objective of the DPCO to prevent overpricing of essential medicines and reflects the State's evolving role in digital governance. However, transparency without enforcement risks becoming a superficial solution. When patented medicines lie outside the scope of price control, and when enforcement of existing ceilings is weak, access

remains elusive. The app does not address structural issues such as patent monopolies, regulatory capture, or inadequate public provisioning of healthcare.

## CONCLUSION

The role of the State in the pharmaceutical sector is multifaceted. As a regulator, it must enforce price controls and patent standards. As a purchaser and distributor, it must ensure efficient public procurement and distribution of essential medicines. As a constitutional duty-bearer, it must actively intervene to correct market failures that threaten the right to health. Balancing these roles requires a coherent policy framework that integrates digital tools, legal mechanisms, and public health objectives. Ultimately, access to medicines is not merely a question of market efficiency or technological innovation; it is a matter of constitutional morality and human rights. The right to health, derived from the right to dignity(Article21 of the Indian Constitution), demands that the State move beyond symbolic gestures towards substantive reform. Law and policy tools- ranging from patent flexibilities and compulsory licensing to price control orders, digital transparency initiatives, and public distribution schemes must operate in synergy rather than isolation. Evaluating India's pharmaceutical pricing policy through the lens of the Pharma Sahi Daam app reveals both the promise and the limitations of transparency-driven reform. For India to truly fulfill its constitutional and international commitments, pharmaceutical governance must prioritise affordability, accountability, and equity, ensuring that life-saving medicines are not privileges for the few but rights for all.

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