PHARMACEUTICAL REGULATION, DRUG PRICING AND ACCESS TO MEDICINES IN KERALAM: A CONSTITUTIONAL, STATUTORY AND INSTITUTIONAL ANALYSIS

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ABSTRACT

Access to medicines is meaningful only when patients can obtain treatment that is safe, effective, therapeutically appropriate, continuously available and affordable. India has developed a substantial legal framework for regulating drug quality, controlling prices, identifying essential medicines and balancing pharmaceutical patents against public-health needs. In Keralam, however, the effectiveness of this framework also depends on the performance of public procurement and distribution systems, particularly the Kerala Medical Services Corporation Limited (KMSCL), alongside the regulatory functions of the State Drugs Control Department. This article combines constitutional and statutory analysis with an institutional examination of medicine procurement. It argues that price control, although indispensable, cannot by itself ensure access: medicines may remain unavailable because of inaccurate forecasting, unsuccessful tenders, supplier non-performance, payment delays, weak inventory management or distribution failures. It further analyses the Kerala High Court's September 2026 decision concerning government use under Section 100 of the Patents Act, 1970. The article proposes an access-oriented framework built around transparent procurement, real-time stock monitoring, quality assurance, accountable emergency purchasing and reasoned assessment of unaffordable patented medicines. It concludes that pharmaceutical governance should be assessed by patient-level outcomes rather than by the mere existence of regulations, price notifications or procurement procedures.

Keywords: Right to health, Essential medicines, Drug pricing, DPCO 2013, NLEM 2022, NPPA, KMSCL, Procurement, patents, Keralam.

INTRODUCTION

Medicines occupy a distinctive place in the healthcare system. They are commercial products, but they are also indispensable means through which medical care is delivered. A hospital may have qualified personnel and adequate infrastructure yet be unable to provide effective treatment if prescribed medicines are absent, unsafe or beyond a patient's financial means. Pharmaceutical regulation must therefore address more than the licensing and sale of drugs. It must connect quality control and price regulation with procurement, distribution and continuity of supply.

The constitutional significance of access to healthcare emerges principally from Article 21 of the Constitution of India, read with the Directive Principles of State Policy. In *Consumer Education & Research Centre v Union of India*[1], the Supreme Court recognised the relationship between health and the protection of life. In *Paschim Banga Khet Mazdoor Samity v State of West Bengal*[2], the Court held that the failure of government hospitals to provide timely medical treatment could violate Article 21[3]. Those cases did not establish an unconditional right to every medicine in every circumstance. They do, however, support the proposition that the State's healthcare responsibilities must be assessed by reference to practical treatment, not merely the formal existence of medical institutions.

The problem has two connected dimensions. Affordability concerns whether patients and public healthcare systems can bear the cost of medicines. Availability concerns whether the required medicine is present in the appropriate institution and quantity when treatment is needed. The World

Health Organization's essential-medicines approach treats continuous availability, adequate quantities, assured quality and affordability as linked objectives.[4] A price ceiling cannot ensure that a medicine is manufactured, procured, delivered or stocked. Conversely, a well-stocked pharmacy cannot ensure access if the medicine is financially inaccessible or of uncertain quality.

[1] *Consumer Educ. & Research Ctr. v. Union of India*, (1995) 3 SCC 42.
[2] *Paschim Banga Khet Mazdoor Samity v. State of W.B.*, (1996) 4 SCC 37.
[3] INDIA CONST. art. 21.
[4] World Health Org., *Essential Medicines* (Jan. 26, 2026), https://www.who.int/news-room/fact-sheets/detail/essential medicines.(last visited Oct.9,2026).

This distinction is especially relevant to Keralam's public healthcare system. KMSCL publishes procurement and re-tender records for ordinary, specialty, anti-cancer and rare-disease medicines for 2026–27. These records demonstrate the scale and procedural complexity of procurement, but the existence of re-tenders does not, by itself, prove statewide shortages or administrative wrongdoing.[5] Such conclusions require evidence of stock levels, delivery performance and patient-level nonavailability. This article therefore examines the legal architecture and institutional arrangements, identifies the gap between regulatory design and operational access, and proposes reforms that can be assessed through transparent data.

OBJECTIVES AND METHODOLOGY

The article has three objectives: first, to examine the constitutional and statutory foundations of access to medicines; second, to analyse how price regulation, essential-medicines policy, quality control and public procurement interact in Keralam; and third, to evaluate the implications of the Kerala High

Court's 2026 decision on government use of patented medicines. The method is doctrinal and policyoriented. It relies on constitutional provisions, legislation, delegated legislation, reported judicial decisions, official institutional material and WHO guidance. Procurement records are treated as evidence of administrative processes, not as conclusive proof of shortage or misconduct. Contemporary media reporting is used cautiously to identify the context of the 2026 patent decision; the legal analysis is based on the reported decision and the statutory text.

CONSTITUTIONAL FOUNDATIONS OF ACCESS TO MEDICINES

ARTICLE 21 AND THE STATE'S HEALTHCARE OBLIGATIONS

Article 21 protects life and personal liberty, and judicial interpretation has given the right to life substantive content. In Paschim Banga case, the Supreme Court held that the State has an obligation to provide adequate medical services and that financial constraints cannot automatically excuse a failure to discharge that obligation. *State of Punjab v Mohinder Singh Chawla*[6] likewise recognised health as integral to the right to life.[4] These authorities are relevant to pharmaceutical access because medicines are often necessary to make diagnosis and

[5] Kerala Med. Servs. Corp. Ltd., *Essential Drugs Division: Procurement and Re-Tender Notices for 2026–27*, https://kmscl.kerala.gov.in/KMSCL/index.php/ckmscl/menucontentview/35 (last visited Oct. 9, 2026).
[6] *State of Punjab v. Mohinder Singh Chawla*, (1997) 2 SCC 83.

treatment effective.

The constitutional argument must nevertheless be framed carefully. Not every stock-out, procurement delay or disagreement over a particular medicine automatically amounts to a fundamental-rights violation. Supply interruptions can result from unexpected manufacturing problems, global shortages or emergencies. The stronger constitutional question is whether the State has maintained reasonable systems to anticipate foreseeable needs, procure essential medicines, monitor stock and respond promptly when shortages occur. Persistent and unexplained failures may raise concerns under Article 21, particularly where the medicine is medically necessary and the patient cannot reasonably obtain it privately.

DIRECTIVE PRINCIPLES AND SUBSTANTIVE EQUALITY

Articles 38, 39(e)–(f), 41 and 47 support the State's responsibility to promote welfare and public health. Article 47 expressly identifies improvement of public health as a primary duty of the State.[5] Although the Directive Principles are not independently enforceable in the same manner as fundamental rights, they inform the interpretation of constitutional obligations and the design of public policy.

Article 14 is also relevant where supply failures or access programmes operate arbitrarily or disproportionately burden economically vulnerable patients. When public-hospital shortages force patients to purchase medicines privately, patients with greater means may continue treatment while poorer patients may delay, reduce or discontinue it. This unequal impact makes medicine availability a question of distributive justice as well as administrative efficiency. The appropriate legal response is not to presume that every shortage is unconstitutional, but to require rational planning, transparent decisions and a defensible response to foreseeable risk.

THE STATUTORY FRAMEWORK FOR PHARMACEUTICAL REGULATION

India regulates medicines through a network of statutes and subordinate legislation rather than a single comprehensive pharmaceutical code. The Drugs and Cosmetics Act, 1940, together with the Drugs and Cosmetics Rules, 1945, provides the principal framework for regulating the import, manufacture, distribution and sale of drugs and for maintaining standards of quality and safety.[7] Price regulation operates through a separate but complementary framework.

[7] Drugs and Cosmetics Act, No. 23 of 1940, India Code (1940); Drugs and Cosmetics Rules, 1945.

Section 3 of the Essential Commodities Act, 1955 authorises the Central Government to regulate the production, supply and distribution of essential commodities in the public interest.[8] The Drugs (Prices Control) Order, 2013 (DPCO) was made under this framework and provides for ceiling prices for scheduled formulations, together with controls applicable to price increases in non-scheduled formulations.[9] The National Pharmaceutical Pricing Authority (NPPA), under the Department of Pharmaceuticals, administers key price-fixation and monitoring functions.

The Patents Act, 1970 introduces a further dimension. Patent protection can support innovation, investment and disclosure, but exclusive rights may also affect the affordability of particular medicines. Sections 83, 84 and 100 are especially relevant to the public-health balance: Section 83 states general principles governing the working of patents; Section 84 provides for compulsory licences on specified grounds; and Section 100 addresses government use of patented inventions.[10] These provisions are distinct mechanisms and should not be treated as interchangeable.

DPCO, NPPA AND THE NATIONAL LIST OF ESSENTIAL MEDICINES

The DPCO's ceiling-price mechanism is intended to prevent manufacturers from charging more than the permitted price for scheduled formulations. Paragraph 4 provides the framework for fixing ceiling prices, while other provisions regulate price increases and compliance [11] . NLEM 2022 was incorporated into Schedule I of the DPCO through the 2022 amendment.[12] The Ministry of Health and Family Welfare's NLEM identifies medicines considered important for priority healthcare needs, while the DPCO connects that policy selection with price control.[13]

The NPPA's work includes fixing and revising prices of scheduled formulations, monitoring compliance, addressing overcharging and monitoring the availability of medicines. These functions are important, but price regulation has inherent limits. A lawful ceiling price establishes a maximum permissible price; it does not necessarily establish that the medicine is

[8] Essential Commodities Act, No. 10 of 1955, § 3, India Code (1955).
[9] Drugs (Prices Control) Order, 2013, Gazette of India, Extraordinary, pt. II, sec. 3(ii), S.O. 1221(E) (May 15, 2013).
[10] Patents Act, No. 39 of 1970, §§ 83–84, 100, India Code (1970).
[11] Drugs (Prices Control) Order, 2013, ¶ 4.
[12] Ministry of Health & Family Welfare, Gov't of India, National List of Essential Medicines 2022 (2022).
[13] Drugs (Prices Control) Amendment Order, 2022, Gazette of India, Extraordinary, pt. II, sec. 3(ii), S.O. 5249(E) (Nov. 11, 2022).

affordable for every patient, nor does it compel a supplier to deliver a required quantity to a particular public hospital. Medicines outside the scheduled framework may also present affordability concerns, particularly where patent protection limits competition.

The essential-medicines concept is broader than a list of price-controlled products. WHO describes essential medicines as those that should be available within functioning health systems at all times, in adequate quantities, in appropriate dosage forms, of assured quality and at prices individuals and health systems can afford.[14] NLEM therefore has implications for selection, forecasting, procurement and distribution, not merely for ceiling-price notifications. A medicine's inclusion on a list has limited practical value if the health system cannot ensure that it reaches the patient.

PUBLIC PROCUREMENT AND MEDICINE AVAILABILITY IN KERALAM

KMSCL is a central institutional actor in the procurement of medicines and medical supplies for public healthcare institutions in Keralam. Its official website publishes essential-drug information, tender documents, technical and financial bid evaluations, final bid statuses and re-tender notices. The 2026– 27 records include procurement processes for general drugs, anti-cancer medicines, specialty drugs and medicines for rare diseases.[15] These materials provide a useful starting point for examining how the State translates medicine requirements into procurement contracts.

Public procurement is constrained by competing obligations. It must promote competition, value for public money, transparency, quality assurance and financial accountability. Yet medicines are timesensitive products: a tender process that is lawful but too slow to respond to a foreseeable need may undermine treatment continuity. Tenders can fail because eligible bids are insufficient, bids do not meet technical requirements, prices become unattractive to suppliers, or selected suppliers fail to deliver. Re-tendering may be justified, but repeated procedural cycles can expose weaknesses in forecasting, specifications, contract management or contingency planning.

It is essential to distinguish four levels of shortage: procurement-level insufficiency, depletion

[14] World Health Org., *Essential Medicines*, supra note 4.
[15] Kerala Med. Servs. Corp. Ltd., Essential Drugs Division: *Procurement and Re-Tender Notices for 2026–27*, supra note 5.

at a central warehouse, a stock-out at an individual hospital, and a patient's inability to obtain a prescribed medicine. These are related but not equivalent. A central warehouse may have low stock while hospitals retain supplies; alternatively, a warehouse shortage may later produce hospital-level depletion. Patient-level access is the most important outcome, but it cannot be inferred solely from the number of tenders or re-tenders. A credible assessment should compare demand forecasts, contracted quantities, actual deliveries, warehouse inventory, hospital stocks and records of prescriptions that could not be filled.

The Kerala Drugs Control Department has a separate regulatory role in relation to drug quality, licensing, inspection, sampling, testing and action against substandard or spurious medicines.

KMSCL's procurement responsibilities and the Drugs Control Department's regulatory responsibilities are complementary. Their effectiveness depends on timely sharing of quality alerts, rejected-batch information, supplier-performance records and relevant stock data.[16] Procurement at the lowest price should never displace the requirement that medicines meet applicable standards.

GENERIC MEDICINES, AFFORDABILITY AND THERAPEUTIC SUITABILITY

Generic medicines can improve affordability where they are quality-assured and therapeutically appropriate. Lower prices do not, by themselves, establish inferior quality; equally, the word "generic" should not be treated as a substitute for regulatory oversight. Manufacturing standards, licensing, quality control and any applicable bioequivalence requirements remain important. Public programmes such as the Pradhan Mantri Bhartiya Janaushadhi Pariyojana seek to widen access to lower-cost medicines, while KMSCL states that its procurement system includes competitive e-tendering for generic drugs.[17]

Generic substitution must remain clinically responsible. Two medicines used within the same broad therapeutic category are not necessarily interchangeable for every patient. The active ingredient, dosage, formulation, indication, contraindications and treating clinician's judgment matter. A procurement policy focused exclusively on the lowest price risks inappropriate substitution; a policy that ignores price can make treatment unattainable. The proper objective

[16] Drugs Control Department, Gov't of Kerala, Departmental Functions and Mission (2026).
[17] Department of Pharms., Ministry of Chems. & Fertilizers, Gov't of India, *Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)* (official programme materials); Kerala Med. Servs. Corp. Ltd., Essential Drugs Division, *Procurement and Re-Tender Notices for 2026–27*, supra note 5.

is cost-conscious treatment that respects therapeutic suitability and quality.

PATENTS, PUBLIC HEALTH AND THE KERALA HIGH COURT'S 2026 DECISION

The tension between patents and access to medicines is particularly acute where a patented medicine is medically necessary and its price is beyond the patient's means. Section 83 of the Patents Act states that patents should not impede protection of public health and that patented inventions should be available to the public at reasonably affordable prices. Section 84 provides a compulsory-licensing route on statutory grounds, while Section 100 permits government use of patented inventions, subject to the Act's conditions and safeguards.[18]

In *Novartis AG v. Union of India* [19] , the Supreme Court considered the patentability of a pharmaceutical product under Section 3(d). The case is not a general ruling that patents must yield whenever a medicine is expensive, but it remains important to understanding how Indian patent law addresses the public-health implications of pharmaceutical exclusivity.[15] Patent rights and access obligations must be analysed through the actual statutory provisions rather than through a simplistic opposition between innovation and public health.

The Kerala High Court's decision in *In re Exorbitant Pricing of Life Saving Patented Medicines*[20], decided on September 28, 2026, brings government use directly into this debate. The proceedings concerned the patented breast-cancer medicine Ribociclib and the possible use of Section 100. The

Court interpreted "purposes of Government" as capable of including government use of a patented invention to manufacture a medicine and supply it to a needy patient on a non-commercial basis. It also recognised the relevance of public health to the statutory purpose.

The decision should not be overstated. The Court did not itself order the Central Government to invoke Section 100 for Ribociclib or establish an automatic entitlement to government manufacture of every expensive patented medicine. It left the ultimate decision to the Central Government, which was to collate the necessary information and assess affordability. The judgment therefore clarifies the potential reach of an existing statutory power while leaving its

[18] Patents Act, 1970, No. 39 of 1970, §§ 83–84, 100, India Code.
[19] *Novartis AG v. Union of India*, (2013) 6 SCC 1.
[20] In re Exorbitant Pricing of Life Saving Patented Medicines, W.P.(C) No. 18999 of 2022 (Ker. H.C. Sept. 28, 2026) (2026 LiveLaw (Ker) 528; neutral citation 2026:KER:74251).

exercise to executive decision-making. The key policy question is whether that discretion will be exercised through transparent criteria, timely evidence-gathering and reasoned decisions when access to life-saving treatment is at stake.

The proceedings also highlight the importance of therapeutic equivalence. The existence of a cheaper medicine in the same general therapeutic area does not necessarily prove that it can replace the patented medicine in an individual case. Affordability assessment must therefore be informed by clinical evidence and specialist advice, rather than by price comparison alone. A coherent policy must protect incentives for pharmaceutical innovation while ensuring that the patent system's public interest safeguards are meaningful in practice.

THE LIMITS OF THE EXISTING FRAMEWORK: FROM PRICE CONTROL TO ACCESS GOVERNANCE

India's legal framework contains separate mechanisms for quality, price control, essential-medicines selection, patents and procurement. The main weakness is not necessarily a complete absence of law; it is the risk that the institutions responsible for different stages of access operate in isolation. The NPPA can regulate prices, but it does not manage every hospital's inventory. KMSCL can procure medicines, but it does not replace the regulatory function of drug-quality authorities. Patent law contains public-interest mechanisms, but statutory authority alone does not make an unaffordable medicine available.

For that reason, access should be evaluated through five interdependent elements: physical availability, affordability, quality, therapeutic suitability and continuity of supply. A medicine that is affordable but absent from the hospital pharmacy is inaccessible. A medicine that is available but unsafe cannot satisfy public-health objectives. A medicine that is available and quality-assured but clinically unsuitable is not an adequate response to the patient's need. This framework moves analysis from the formal existence of legal mechanisms to their combined effect on the patient.

Procurement failures may also transfer costs from the public system to individual households. When patients must purchase medicines privately because a public hospital has no stock, out-of-pocket expenditure rises. The effect is distributively unequal: wealthier patients may absorb the additional cost, while poorer patients may delay treatment or go without it. A medicine shortage is therefore not simply a logistical inconvenience; it can undermine the equity

objectives of public healthcare.

RECOMMENDATIONS FOR REFORM

INTEGRATED STOCK AND SHORTAGE MONITORING

Keralam should strengthen a shared digital system linking KMSCL warehouses and government hospitals. The system should show current stock, average consumption, pending orders, expected delivery dates and minimum stock thresholds for essential medicines. A shortage alert should identify the medicine, location, severity, expected duration and action taken. Public reporting should aggregate data where disclosure of sensitive operational details is not appropriate.

EVIDENCE-BASED FORECASTING AND CONTINGENCY PROCUREMENT

Annual procurement requirements should combine historical consumption with epidemiological trends, seasonal demand, specialist treatment needs and anticipated changes in service use. For critical medicines, procurement plans should include contingency arrangements for failed tenders and supplier default. Emergency purchasing should be permitted only within lawful rules, supported by recorded reasons and subjected to post-procurement audit.

SUPPLIER ACCOUNTABILITY AND PAYMENT DISCIPLINE

Supplier evaluation should consider delivery reliability, quality compliance and past contractual performance alongside price. Contracts should specify delivery schedules, inspection procedures, consequences for non-performance and proportionate remedies. Where verified payment delays contribute to supply disruption, legitimate invoices should be processed within predictable timelines.

Performance data should inform future procurement without creating arbitrary or opaque exclusion.

TRANSPARENCY AND PUBLIC ACCOUNTABILITY

KMSCL and relevant departments should publish accessible information, to the extent legally permissible, on tender participation, awarded prices, quantities ordered, actual deliveries,

rejected batches, delays, penalties and stock-outs. Publication alone is insufficient: repeated failures should trigger documented review, corrective action and, where warranted, formal investigation. Allegations of irregularity should not be treated as proven without findings by a competent authority.

COORDINATED QUALITY ASSURANCE

Procurement and regulatory authorities should promptly exchange information on quality failures, recalls, supplier suspensions and laboratory results. Emergency procurement must not dilute quality standards. Hospital-level storage and stock rotation should also be monitored, because procurement at the central level does not guarantee that a medicine remains safe and usable when it reaches the patient.

A REASONED PROCESS FOR UNAFFORDABLE PATENTED MEDICINES

The Central Government should develop transparent criteria for assessing when government use under Section 100 may warrant consideration. Relevant factors may include clinical necessity, the absence of suitable therapeutic alternatives, the price in relation to patient and public-system resources, the number of affected patients, the availability of supply and the feasibility of lawful non-commercial access. Decisions should be evidence-based and reasoned, with appropriate engagement of clinical experts, patent holders and public-health authorities. Such a framework would not make Section 100 automatic; it would make the exercise of discretion more predictable and accountable.

PATIENT-LEVEL INDICATORS

Performance should be measured not only by expenditure saved or tenders completed but also by the percentage of essential-medicine prescriptions filled, the duration and frequency of stock-outs, emergency purchases, delivery compliance and patient-reported inability to obtain prescribed medicines. These indicators would help distinguish administrative activity from effective access.

CRITICAL EVALUATION

The regulatory framework governing medicines in India is substantial, but its parts pursue different objectives and are administered by different institutions. Price controls can restrain

excessive prices; quality regulation can reduce the risks posed by unsafe or substandard products; essential-medicines lists can guide public priorities; procurement systems can aggregate demand; and patent law can provide mechanisms to address certain public-interest concerns. None of these mechanisms is sufficient in isolation.

The key challenge is coordination and implementation. Regulatory availability means that a medicine is legally authorised and, where applicable, subject to price control. Operational availability means that the appropriate medicine is actually accessible to the patient at the relevant time and place. A system may perform well in the first sense while failing in the second. Keralam's procurement records justify close examination of how procurement stages translate into delivery and hospital stocks, but they do not alone establish the scale of shortages. A rigorous policy evaluation must be based on verified operational data.

Similarly, the Section 100 decision is significant because it recognises that government use can serve public-health purposes and may extend to non-commercial supply to needy patients. Yet a judicial clarification does not itself resolve the affordability problem. The executive must gather evidence, assess alternatives and determine whether the statutory power should be used. Accountability requires that such decisions be made transparently and within a reasonable time, while respecting the statutory framework and the legitimate interests attached to patents.

CONCLUSION

Access to medicines in Keralam is a constitutional, statutory and institutional question. Article 21, read in the light of the Directive Principles, provides a strong basis for treating effective access to necessary treatment as an important public responsibility. The Drugs and Cosmetics Act and the State Drugs Control Department address quality and safety; the DPCO, NLEM and NPPA contribute to affordability; KMSCL plays a central role in public procurement; and the Patents Act provides mechanisms for balancing exclusive rights with public interest.

The central lesson is that price regulation cannot guarantee supply, procurement cannot replace quality control, and patent safeguards cannot achieve their purpose without informed administrative action. Keralam should develop a coordinated system that links forecasting, tendering, supplier performance, warehouse inventory, hospital stock and patient-level outcomes. Critical shortages should trigger documented action, and procurement transparency should be matched by meaningful accountability.

Ultimately, pharmaceutical governance should be judged by whether patients can obtain safe, effective and therapeutically appropriate medicines in adequate quantities, at an affordable cost and without unreasonable interruption. A shift from narrow price control towards integrated access governance would better align pharmaceutical administration with constitutional commitments to health, dignity and equality.

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