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Correspondence: Muhammad

Aleem Akhter PhD, Drug
Regulatory Expert, Scientific
Researcher and Freelance
Academic Writer, Oulu, Finland.
Tel.: +358 44 9285985

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Review Article

**EXECUTIVE POWER VERSUS PARLIAMENTARY
MANDATE IN PHARMACEUTICAL PRICE REGULATION IN
PAKISTAN: A CRITICAL LEGAL AND PUBLIC-HEALTH
REVIEW OF THE DRAP ACT, 2012 AND THE 2024
DEREGULATION**

**Muhammad Aleem Akhter¹, Taha Nazir^{2,3}, Hina Ishtiaq^{3,4},
Mohammad Shamoon⁵, Nida Taha⁶**

1. Drug Regulatory Expert, Scientific Researcher and Freelance Academic Writer, Oulu, Finland.
2. Scientific Executive, Advanced Multiple Inc., Toronto, ON, Canada.
3. Assistant Professor, Department of Biotechnology, Sardar Bahadur Khan Women University, Quetta, Pakistan.
4. MSCA-Co-Fund Postdoctoral Fellow, Research Unit of Clinical Medicine and Medical Research Center Oulu, Department of Clinical Genetics, Oulu University Hospital, Oulu, Finland.
5. President Pharmacist Federation (Pakistan), Lahore Pb., Pakistan.
6. Scientific Executive (QA) OmniSphere Nexus Inc., Grand Toronto Area, ON Canada.

Abstract

Background: Pharmaceutical pricing in Pakistan lies at the intersection of statutory regulation, constitutional legality, market sustainability, and access to medicines. In February 2024, Pakistan deregulated maximum retail prices (MRPs) for medicines outside the National Essential Medicines List (NEML), creating an important question about the relationship between executive policy-making and the pricing functions assigned to the Drug Regulatory Authority of Pakistan (DRAP) by Parliament. Objective: This critical narrative review evaluates whether the 2024 partial deregulation is readily reconcilable with the DRAP Act, 2012, the Drugs Act, 1976, and relevant constitutional principles, while integrating emerging empirical evidence on medicine prices, affordability, and availability. Methods: A structured legal-policy review was undertaken using primary legal instruments, official DRAP policy documents, constitutional provisions, and peer-reviewed literature on pharmaceutical pricing and access to medicines. Particular attention was given to sections 4(1)(i), 7 and Section 32 of the DRAP Act, section 12 of the Drugs Act, the Drug Pricing Policy 2018, S.R.O. 228(I)/2024, and empirical studies published before and after deregulation. This is a critical narrative review rather than a systematic review or formal legal opinion. Results: The DRAP Act expressly creates a Costing and Pricing Division and assigns DRAP functions concerning regulation for pricing and mechanisms for price fixation. These provisions provide a

substantial statutory basis for continued institutional responsibility over pharmaceutical pricing, but the legal effect of the word “shall” must be interpreted in the context of the complete statutory scheme and the scope of delegated authority. Recent Pakistani studies report post-deregulation increases in prices and deterioration in affordability for oral antidiabetic medicines and insulin, while broader surveys continue to document important deficits in medicine availability and affordability. Conclusion: The central legal issue is not whether deregulation is economically desirable, but whether the Executive possessed sufficiently clear statutory authority to remove a broad class of medicines from governmental price fixation. The available statutory text creates a credible ultra vires and legality question that warrants authoritative judicial determination. From a public-health perspective, the early empirical evidence supports strengthened price surveillance, affordability monitoring, transparent review mechanisms, and explicit parliamentary scrutiny for the implementation and compliance of the enacted legislations.

Keywords

Drug Regulatory Authority of Pakistan; DRAP Act 2012; pharmaceutical pricing; price deregulation; National Essential Medicines List; delegated legislation; ultra vires; access to medicines; Pakistan; constitutional law.

Authors Contributions

Muhammad Aleem Akhter led the pharmaceutical regulatory-law analysis, including interpretation of the DRAP Act, 2012, Drugs Act, 1976, Drug Pricing Policy 2018, S.R.O. 228(I)/2024, delegated powers, and statutory pricing functions; **Taha Nazir** and **Mohammad Shamoan** led the clinical and public-health implications and public-health analysis, focusing on statutory mandates, administrative legality, executive versus parliamentary authority, ultra vires considerations, and access to medicines; **Hina Ishtiaq** contributed to the pharmaceutical, regulatory, statutory, and legislative-policy review; Mohammad Shamoan evaluated the legal-policy of pharmaceutical regulation and pricing; and **Nida Taha** contributed to regulatory compliance, document verification, and quality assurance. All authors critically reviewed and approved of the final manuscript and accept accountability for their respective contributions. Legal analysis represents scholarly academic and regulatory assessment and does not constitute formal legal advice.

Introduction

Pharmaceutical pricing is simultaneously a regulatory, economic, and public-health issue. Prices influence patient affordability, manufacturer viability, market entry, product availability, procurement expenditure, and the financial protection objectives of universal health coverage. International evidence, therefore, treats pharmaceutical pricing as a policy domain in which governments commonly combine several instruments rather than rely on a single mechanism [1,2]. In Pakistan, longstanding concerns include high out-of-pocket expenditure, uneven

medicine availability, affordability constraints, and recurrent controversy over the design and implementation of price controls [3–7].

The legal dimension became especially important after the Federal Government adopted S.R.O. 228(I)/2024 on 19 February 2024, under which MRPs of medicines not included in the National Essential Medicines Lista (NEML) were deregulated while essential medicines remained within the regulated framework [8]. The attached manuscript correctly identifies the resulting core controversy as one of legal authority: whether subordinate executive action can substantially narrow a pricing function that Parliament assigned to DRAP and its Costing and Pricing Division. The original manuscript repeatedly emphasizes sections 4, 7 and 32 of the DRAP Act as the statutory foundation of that argument. This revised review retains that central thesis but qualifies categorical claims, integrates the broader statutory scheme, and adds contemporary empirical evidence. [9]

The review advances three propositions. First, the DRAP Act contains express and clear institutional and functional language concerning pharmaceutical costing and pricing. Second, the validity of partial deregulation depends not on the desirability of deregulation in the abstract, but on the scope of authority conferred by primary legislation. Third, the constitutional analysis should be informed, but not determined, by empirical evidence on affordability, availability, and public-health consequences.

Objectives

This review aims to: (i) examine the statutory architecture governing pharmaceutical pricing under the Drug Regulatory Authority of Pakistan Act, 2012 and the Drugs Act, 1976; (ii) critically assess the legal basis and constitutional implications of the 2024 partial price-deregulation policy; (iii) synthesize empirical evidence on medicine prices, availability and affordability in Pakistan; (iv) identify knowledge and regulatory gaps; and (v) propose legally founded and evidence-responsive recommendations for future research.

Review Methodology

This article is a critical narrative review combining doctrinal legal analysis with pharmaceutical policy and health-services evidence. Primary sources include the Drug Regulatory Authority of Pakistan Act, 2012; the Drugs Act, 1976; the Constitution of the Islamic Republic of Pakistan, 1973; the Drug Pricing Policy, 2018; and S.R.O. 228(I)/2024 [8–11]. Secondary evidence was selected for direct relevance to medicine pricing, affordability, availability, regulatory policy, and the post-2024 deregulation in Pakistan. Peer-reviewed sources indexed in PubMed were prioritized where available, and DOI, PMID, and PMCID identifiers were verified before inclusion.

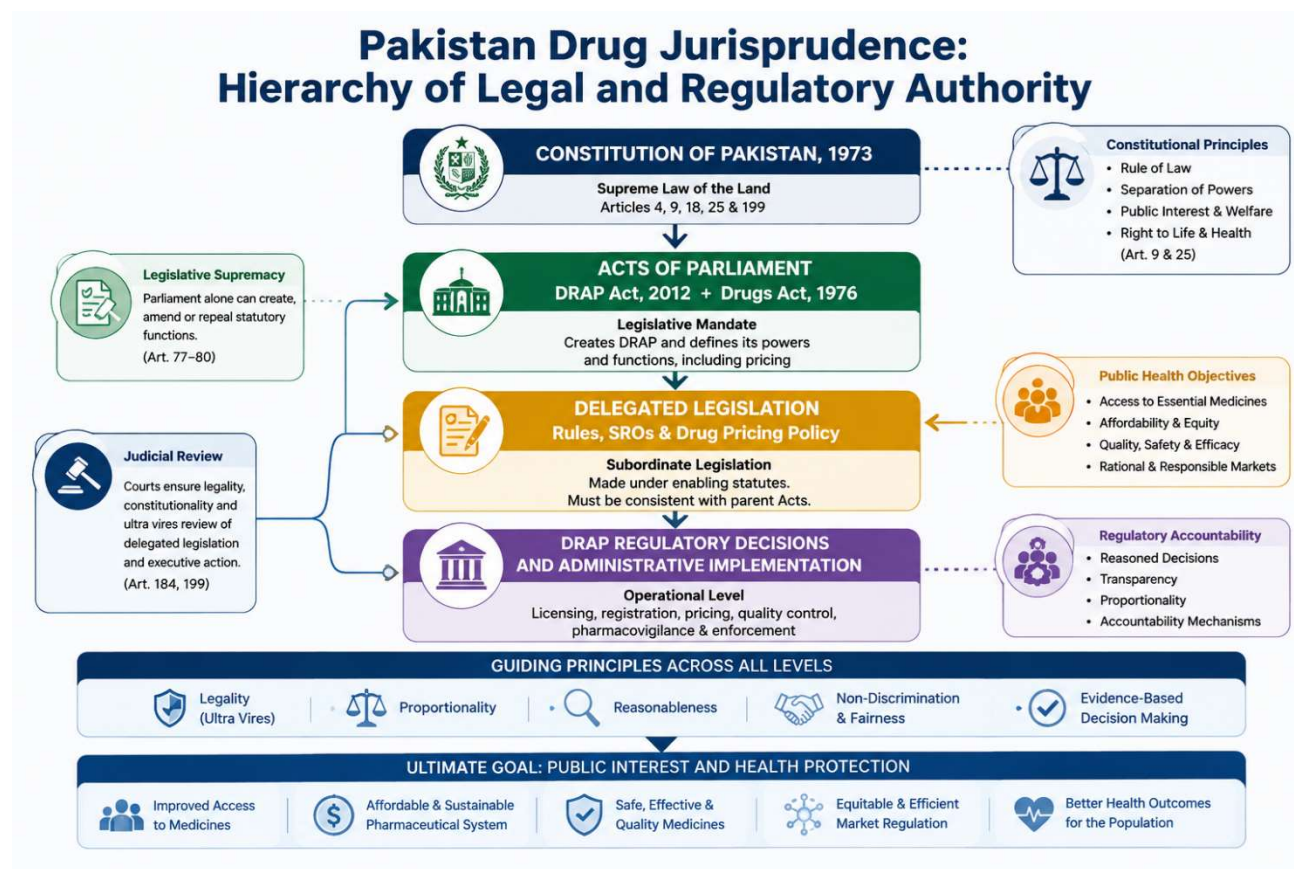


Figure 1. Pakistan drug jurisprudence: hierarchy of constitutional, statutory, delegated and administrative authority relevant to pharmaceutical regulation.

Source: Authors' conceptual synthesis based on the Constitution of Pakistan, 1973; Drugs Act, 1976; DRAP Act, 2012; and DRAP regulatory framework.

Because the article is a legal-policy review rather than a systematic review, it does not claim exhaustive database coverage, pooled effect estimation, or a PRISMA-compliant selection process. It also does not purport to determine the legal validity of S.R.O. 228(I)/2024; that question ultimately belongs to a competent court applying the full statutory record, relevant rules, delegated powers, and binding precedent.

Literature Search Strategy

A targeted literature search was undertaken using PubMed-indexed literature, official DRAP and Government of Pakistan legal and policy documents, and internationally recognized pharmaceutical-policy guidance. Search concepts included Pakistan, pharmaceutical pricing, medicine price deregulation, DRAP, National Essential Medicines List, affordability, availability, access to medicines, delegated legislation and drug pricing policy. Priority was given to primary legislation, official regulatory instruments, WHO/HAI-based studies, peer-reviewed empirical studies and recent post-deregulation evidence. References were cross-checked for bibliographic identifiers, including DOI, PMID and PMCID where applicable.

Because this is a critical narrative legal-policy review, the search was purposive rather than a PRISMA-compliant systematic review, and no meta-analysis was attempted.

Evidence Synthesis

The DRAP Act, 2012 is primary legislation enacted by Parliament. It establishes DRAP and defines its institutional structure, powers, and functions [9]. As a matter of administrative-law hierarchy, all the regulations, notifications, pricing policies, and other forms of delegated or administrative action must remain within the authority conferred by the parent legislation. This proposition is more precise than treating every executive modification of a regulatory regime as inherently unlawful: the decisive inquiry is whether the enabling statute authorizes the action expressly or by necessary implication.

Section 4(1)(i) establishes the office of Director Costing and Pricing Division of DRAP and provides that the Director “shall be incharge” of the Division of Costing and Pricing, which “shall be responsible for the costing and pricing of therapeutic goods” [9]. The significance of this provision is structural. Parliament did not merely mention pricing as a possible policy topic; it created a specialized institutional unit and assigned it an inviolable and mandatory pricing-related responsibility. The breadth of the term “therapeutic goods” is also relevant because the statutory language is not, on its face, limited to medicines appearing on the NEML but even to the medical devices, biologicals, health and over-the-counter (H&OTC) products and even cosmetics also.

Section 7 introduces the powers and functions of DRAP with the formulation that they “shall be to” perform the enumerated functions. Within that enumeration is the regulatory function concerning pricing and the mechanism for fixation of prices of therapeutic goods [9]. Read together, sections 4 and 7 support the view that pharmaceutical pricing is embedded in DRAP’s statutory design rather than arising solely from executive policy which has not left any scope for the authority’s option in this matter to choose between any or few classes of medicines and therapeutic goods to fix their prices and leave or exempt the others from its pricing function.

Furthering with the above discussion, another relevant part of the function of DRAP relating to pricing is the subsection (t) of Section 7 of DRAP Act 2012 which states as under and clearly points out to the intentions of legislature which is that all the therapeutic goods be available to the people at rational price. Thus, parliament has not left any vacuum for such type of arbitrary exercise of power by the authority (DRAP) or the Federal Government to deregulate the prices of any class of medicines and to let the people of Pakistan at the mercy of manufacturers who can increase the prices of medicines at their own will:

(t) develop, issue, adopt, and enforce the standards and guidelines to ensure safety, efficacy, and quality of therapeutic goods with **rational use at reasonable price;**

The original manuscript places substantial weight on the repeated use of “shall.” That emphasis is legally relevant but should be stated cautiously. In statutory interpretation, “shall” is often mandatory, yet its legal effect depends on legislative purpose, context, consequences, and the relationship between the provision and the rest of the enactment. Accordingly, the stronger argument is not that the word “shall” automatically resolves the dispute, but that repeated mandatory language, combined with a specifically constituted Costing and Pricing Division and

an express pricing function, creates a substantial textual and structural obstacle to treating pharmaceutical pricing as wholly or partially optional.

Another argument which may be made is that “The DRAP Act does not operate in isolation. Section 12 of the Drugs Act, 1976 forms part of the statutory framework for fixing maximum prices of drugs, and federal government has discretion to fix maximum prices of a certain classes of drugs. Further, the Drug Pricing Policy, 2018 was promulgated as a pricing mechanism under the relevant provisions of the DRAP Act [10,11]”. Under the coverage of the above argument it is stated that the 2018 Policy demonstrates that price regulation historically involved a structured administrative framework rather than ad hoc price setting. Thus, this argument is used to support that the Executive and DRAP have exercised delegated authority to determine pricing methodologies and adjustment mechanisms.

But the above argument becomes quite vague when analyzed in the light of Section 32 of DRAP Act 2012 which clearly explained that in case of any inconsistency between the Drugs Act 1976 and the DRAP Act 2012 the provision of DRAP Act 2012 shall prevail. In such scenario, the S.R.O 228 (I)/2024 further loses any legal support because after promulgation of DRAP Act, DRAP or Federal Government cannot act in violation of mandatory pricing commandments of this Act. Section 32 of DRAP Act is produced herein-following:

32. Act not to override other laws.- (1) The provisions of this Act shall be in addition to and not in derogation of the provisions made in the Drugs Act, 1976 (XXXI of 1976) and any other law for the time being in force.

(2) In case of inconsistency between the provisions of this Act and any other law for the time being in force, **the provisions of this Act shall prevail.**

S.R.O. 228(I)/2024 introduced a major policy change by deregulating MRPs for medicines outside the NEML while retaining price regulation for NEML medicines [8]. In regulatory terms, this is more than a routine annual price adjustment. A price revision changes the amount of a regulated price; a methodology reform changes the method by which the regulator determines a price; deregulation removes, for the affected category, the governmental price-fixation constraint and shifts a greater degree of price determination to market actors.

Delegated legislation derives validity from the enabling statute. It may operationalize legislation, prescribe procedures, establish formulas, and make classifications where the statute authorizes those functions. It cannot lawfully contradict, repeal, or substantially displace a mandatory provision of the parent Act unless Parliament has conferred adequate authority for that result. The relevant inquiry is thus one of vires: what is the scope of the power delegated, and does S.R.O. 228(I)/2024 remain within that scope?

A key analytical refinement is necessary. Deregulating the MRP of a category of medicines does not necessarily abolish every possible “costing and pricing” function of DRAP. The Authority may retain surveillance, data collection, price transparency, competition monitoring, or other pricing-related responsibilities. Consequently, the legal argument should not assume that deregulation automatically makes section 4(1)(i) meaningless. Instead, the question is whether the statutory phrase “responsible for the costing and pricing of therapeutic goods,” read with section 7, requires an operative governmental price-fixation mechanism for all therapeutic goods

or permits differentiated regulatory treatment, including market-based pricing for some categories.

The NEML is a public-health prioritization instrument, and essential-medicine status is highly relevant to procurement and access policy. However, the legal consequence assigned to NEML status must still be traceable to statutory authority. The DRAP Act's pricing language does not expressly state that only EML medicines are subject to price fixation [9]. Thus, the legality of using NEML status as the dividing line for price deregulation depends on whether the power to create that consequence can be derived from the enabling legislation. This is a more defensible formulation than asserting that the NEML can never lawfully be used for pricing classification.

Article 4 of the Constitution provides a foundational legality principle: state action affecting persons must be in accordance with law [12]. Applied here, the constitutional concern is derivative of the statutory question. If the Executive acted within a valid delegation, Article 4 does not independently prohibit deregulation. If the Executive exceeded the delegation, however, the resulting measure may be vulnerable as action without lawful authority.

Article 9 protects life and security of person [12]. Medicine affordability and availability can plainly affect health and survival, and international health-policy literature recognizes access to essential medicines as a central component of universal health coverage [1,13]. Nevertheless, Article 9 should not be overstated as creating a direct constitutional requirement that every medicine have a government-fixed price. Its stronger role in this review is contextual: where statutory language is ambiguous, the health consequences of the regulatory design may be relevant to purposive interpretation and proportionality.

Article 18 protects lawful trade and business subject to regulation by law; it, therefore, accommodates pharmaceutical regulation while also recognizing legitimate commercial interests [12]. Article 25 permits reasonable classification but guards against arbitrary differential treatment. The NEML/non-NEML distinction may be constitutionally defensible if it rests on an intelligible basis, rationally advances a legitimate objective, and is implemented under lawful authority. Article 38, as a Principle of Policy, adds social-welfare and medical-relief context, although it does not operate in the same manner as an enforceable fundamental right [12].

The legal question should be analytically separated from the empirical consequences of deregulation: an economically harmful policy can still be lawfully authorized, while an economically beneficial policy can still be ultra vires. Nonetheless, outcome evidence is important for evaluating regulatory design and for understanding the stakes of statutory interpretation.

Pakistan had documented medicine-access problems well before the 2024 reform. A national policy analysis identified weaknesses in pharmaceutical regulation, unclear pricing policies, and suboptimal availability as important barriers to essential-medicine access [3]. A WHO/HAI-based survey in Lahore found low availability of lowest-priced generics and excessive prices for substantial proportions of medicines [4]. A national cardiovascular-medicine survey similarly documented availability and affordability challenges [5], while a national insulin survey found that none of the surveyed insulin products achieved ideal availability and that insulin remained unaffordable for the lowest-paid worker [6]. Regional evidence from Balochistan also demonstrated low availability of essential medicines in the public sector [7]. These findings indicate that the pre-2024 price-control system itself did not guarantee equitable access.

Emerging post-reform evidence raises additional concerns. In a 2025 study of oral antidiabetic medicines, Saeed and colleagues reported significant increases in unit prices within six months of deregulation and a significant decline in overall affordability; increases were particularly important among non-NEML products [14]. A 2026 study of insulin reported a 31.87% increase in the median insulin price after deregulation, with non-NEML insulin prices increasing more than NEML comparators in difference-in-differences analysis; the number of days' wages required for a month of insulin also increased [15]. These observational policy evaluations do not, by themselves, establish that deregulation caused every observed market change, but they provide direct empirical evidence that the reform was followed by material affordability pressures.

More recent multi-regional evidence continues to show substantial inequities in the availability and affordability of essential cardiovascular and diabetes medicines across Pakistan, especially in public facilities and rural areas [7]. Taken together, the evidence suggests that Pakistan faces a dual policy problem: rigid or poorly designed price controls may threaten supply and manufacturer viability, whereas deregulation in markets with limited competition and high out-of-pocket payment can expose patients to rapid price escalation. Effective policy, therefore, requires a balanced framework rather than a binary choice between comprehensive price control and unrestricted market pricing [2] but all the functions of authority must conform the principal legislative commandments. DRAP may include the necessary factors as overall productive costs into price fixation mechanisms in order to avoid unjustified losses to the manufacturers. Moreover, DRAP may incentivize and facilitate local production of medicinal agents and excipients so as to avoid international pressures on availability of these agents and their resultant impact on prices.

WHO guidance recommends that countries use context-appropriate combinations of pharmaceutical pricing policies and emphasizes monitoring, transparency, generic and biosimilar competition, procurement strategies, and other measures to improve affordability [1]. International evidence also shows that the effects of pricing policies vary by market structure and implementation capacity. A systematic review of pricing-policy implementation in sub-Saharan Africa found mixed effectiveness and highlighted regulatory capacity, political commitment, stakeholder engagement, and price transparency as important determinants [1,2].

For Pakistan, these findings support a regulatory model in which any degree of market pricing is accompanied by robust price surveillance, publication of price changes, competition assessment, affordability indicators, shortage monitoring, generic and biosimilar promotion, and mechanisms for rapid intervention where prices threaten access. Such measures are compatible with the continuing institutional relevance of DRAP's Costing and Pricing Division even if Parliament ultimately permits differentiated levels of direct price control.

Hierarchy and Analytical Pathway for Pharmaceutical Price Regulation

A Constitution-to-Outcome Framework for Legal Authority, Regulatory Action and Public Health Impact

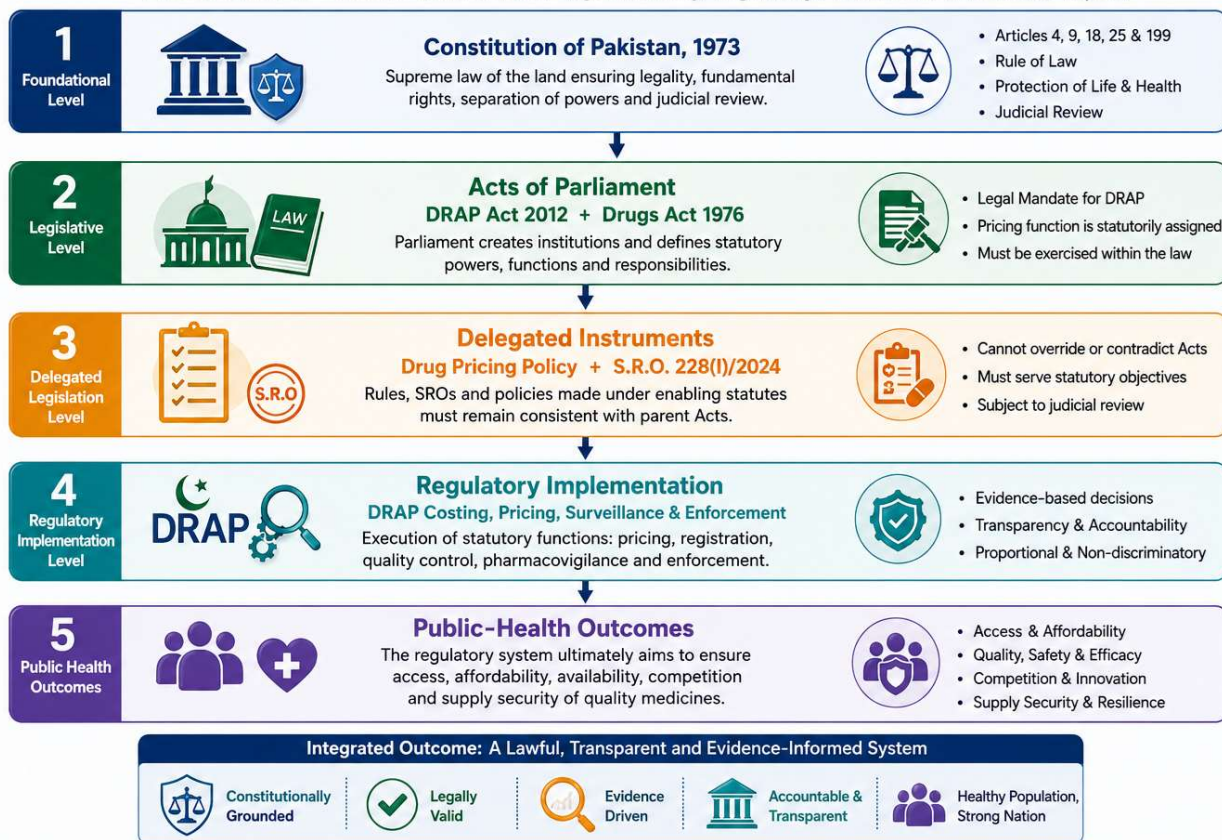


Figure 2. Legal hierarchy and analytical pathway for pharmaceutical price regulation in Pakistan.

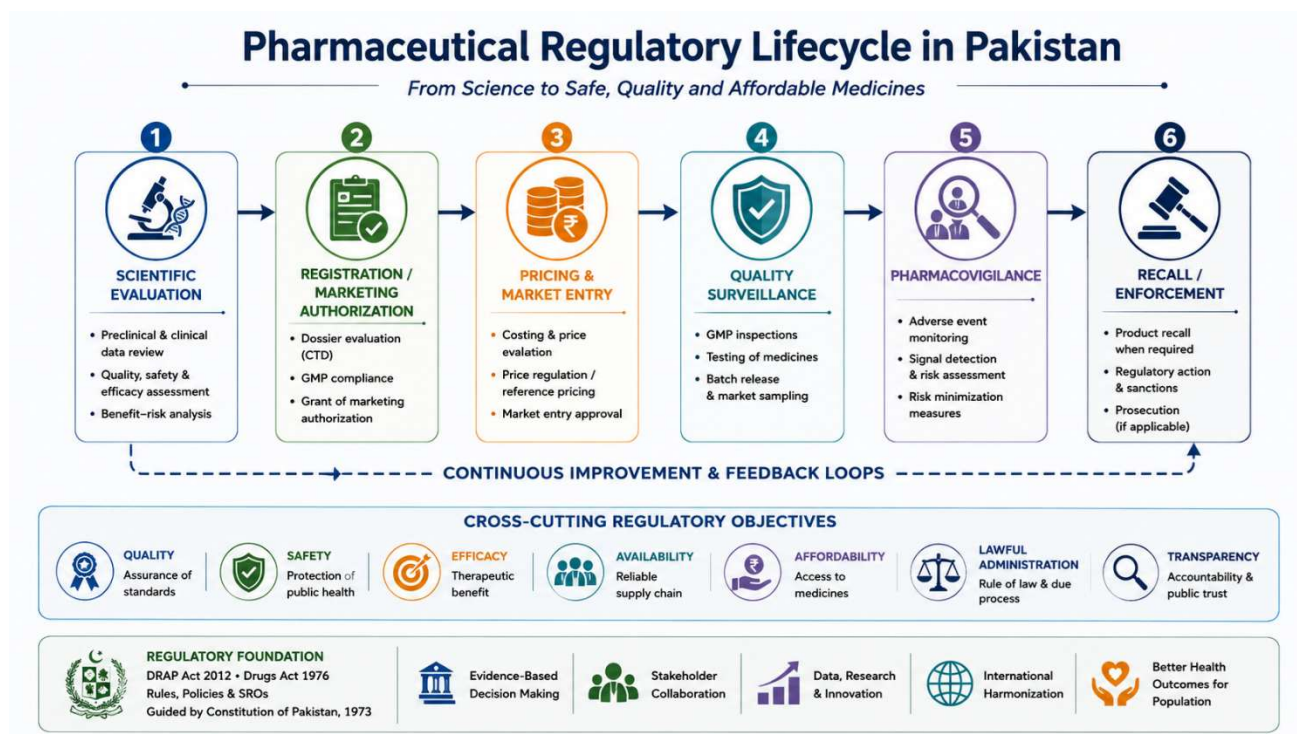


Figure 3. Pharmaceutical regulatory lifecycle in Pakistan and the relationship of pricing to broader regulatory functions.

Source: Authors' synthesis of DRAP regulatory functions and published regulatory procedures. DRAP describes oversight across registration, quality assurance, market surveillance, pharmacovigilance and related therapeutic-goods controls.

Critical Analysis and Discussion

The distinction is legally important because the greater the practical effect of delegated action on the statutory scheme, the more important the identification of a clear enabling power becomes. The issue is, therefore, whether the parent legislation permits the Executive to determine that a substantial class of drugs will no longer be subject to governmental MRP fixation, notwithstanding the continued statutory existence of a Costing and Pricing Division and DRAP's pricing functions.

Delegated legislation derives validity from the enabling statute. It may operationalize legislation, prescribe procedures, establish formulas, and make classifications where the statute authorizes those functions. It cannot lawfully contradict, repeal, or substantially displace a mandatory provision of the parent Act unless Parliament has conferred adequate authority for that result. The relevant inquiry is thus one of vires: what is the scope of the power delegated, and does S.R.O. 228(I)/2024 remain within that scope?

Table 1. Thematic synthesis of empirical evidence relevant to pharmaceutical pricing and access in Pakistan.

Evidence domain	Design/setting	Key finding	Policy interpretation	Reference
Essential medicines	WHO/HAI survey, Lahore	Low availability and affordability constraints were documented before deregulation.	Access problems pre-dated the 2024 reform; price control alone was insufficient.	[4]
Cardiovascular medicines	National WHO/HAI survey	Important gaps in availability, price and affordability were identified.	Pricing must be linked to procurement and supply-side policy.	[5]
Insulin, pre-reform	National cross-sectional survey	Insulin availability was below benchmark and treatment was unaffordable.	High-risk concentrated markets require targeted protection.	[6]
Oral antidiabetics, post-reform	30 private pharmacies; DiD analysis	Prices increased significantly and affordability worsened within 6 months.	Early evidence supports active post-deregulation surveillance.	[14]
Insulin, post-reform	30 private pharmacies; DiD analysis	Median insulin price increased 31.87%; affordability worsened.	Deregulation effects may be amplified in concentrated, life-saving product markets.	[15]

A key analytical refinement is necessary. Deregulating the MRP of a category of medicines does not necessarily abolish every possible “costing and pricing” function of DRAP. The Authority may retain surveillance, data collection, price transparency, competition monitoring, or other pricing-related responsibilities. Consequently, the legal argument should not assume that deregulation automatically makes section 4(1)(i) meaningless. Instead, the question is whether the statutory phrase “responsible for the costing and pricing of therapeutic goods,” read with section 7, requires an operative governmental price-fixation mechanism for all therapeutic goods or permits differentiated regulatory treatment, including market-based pricing for some categories.

The NEML is a public-health prioritization instrument, and essential-medicine status is highly relevant to procurement and access policy. However, the legal consequence assigned to NEML status must still be traceable to statutory authority. The DRAP Act’s pricing language does not expressly state that only NEML medicines are subject to price fixation [9]. Thus, the legality of using NEML status as the dividing line for price deregulation depends on whether the power to create that consequence can be derived from the enabling legislation and where the statute does not permit such differentiation, making of such differentiation is in excess of the lawful authority

of the enforcing agency. This is a more defensible formulation than asserting that the NEML can never lawfully be used for pricing classification.

Article 4 of the Constitution provides a foundational legality principle: state action affecting persons must be in accordance with law [12]. Applied here, the constitutional concern is derivative of the statutory question. If the Executive acted within a valid delegation, Article 4 does not independently prohibit deregulation but binds the authority (DRAP) to strictly act in compliance with the commandments of relevant statutory commandment. If the Executive exceeded the delegation, however, the resulting measure may be vulnerable as action without lawful authority.

Article 9 protects life and security of person [12]. Medicine affordability and availability can plainly affect health and survival, and international health-policy literature recognizes access to essential medicines as a central component of universal health coverage [1,13]. Nevertheless, Article 9 should not be overstated as creating a direct constitutional requirement that every medicine have a government-fixed price. Its stronger role in this review is contextual: where statutory language is ambiguous, the health consequences of the regulatory design may be relevant to purposive interpretation and proportionality.

Article 18 protects lawful trade and business subject to regulation by law; it, therefore, accommodates pharmaceutical regulation while also recognizing legitimate commercial interests [12]. Article 25 permits reasonable classification but guards against arbitrary differential treatment. The NEML/non-NEML distinction may be constitutionally defensible if it is implemented under lawful authority, rationally advances a legitimate objective, and rests on an intelligible basis. Article 38, as a Principle of Policy, adds social-welfare and medical-relief context, although it does not operate in the same manner as an enforceable fundamental right but still its governing article i.e. Article 29, adds to the responsibility of each organ and authority of the State, and of each person performing functions on behalf of an organ or authority of the State, to act in accordance with those Principles in so far as they relate to the functions of the organ or authority [12].

A court or scholarly legal assessment could organize the dispute around the following questions: (1) What is the legal effect of the pricing functions assigned by sections 4(1)(i), 7 and 32 of the DRAP Act? (2) What powers concerning maximum prices, classifications, exemptions, and pricing mechanisms are conferred by the Drugs Act, 1976 and the DRAP Act collectively especially if there is any conflict or contradiction? (3) Does the enabling legislation authorize the Federal Government or DRAP, expressly or by necessary implication, to exempt non-NEML medicines from governmental MRP fixation? (4) Does S.R.O. 228(I)/2024 merely prescribe the manner in which the statutory pricing function is exercised, or does it substantially displace that function? (5) Is NEML status a legally authorized basis for the regulatory distinction? (6) Were procedural requirements, reasons, and relevant considerations observed? (7) Is the resulting classification non-arbitrary and rationally connected to legitimate regulatory objectives? and (8) what remedy, if any, follows if the measure is ultra vires?

This formulation avoids assuming the outcome. It identifies a serious statutory question while recognizing that the Executive may rely on broader delegated powers not fully resolved by the isolated wording of sections 4 and 7. A definitive conclusion, therefore, requires judicial interpretation of the complete legal framework.

Table 2. Core legal and policy questions raised by partial pharmaceutical price deregulation.

Issue	Relevant framework	Analytical significance
Institutional pricing mandate	DRAP Act, s 4(1)(i)	Creates a specialized Costing and Pricing Division responsible for therapeutic-goods costing and pricing.
Pricing function	DRAP Act, s 7	Expressly includes regulation for pricing and mechanisms for fixation of prices among DRAP functions.
Competitive force and authority of DRAP Act 2012 and Drugs Act 1976	DRAP Act, s 32	Expressly provides that in case of any inconsistency the provision of DRAP Act shall prevail.
Maximum-price authority	Drugs Act, 1976, s 12	Cannot be considered when identifying the legal source and limits of MRP regulation.
Policy mechanism	Drug Pricing Policy, 2018	Shows how delegated pricing authority was operationalized before the 2024 reform.
Partial deregulation	S.R.O. 228(I)/2024	Creates the NEML/non-NEML divide and raises the central vires question.
Legality and judicial review	Constitution, arts 4 and 199	Executive action must be legally authorized and may be reviewable for excess of jurisdiction.
Equality and classification	Constitution, art 25	Requires a non-arbitrary, rationally connected basis for differential regulatory treatment.
Public-health context	Constitution, arts 9 and 38; access-to-medicines evidence	Provides context for interpreting regulatory purpose and evaluating policy consequences.

Knowledge Gaps and Limitations

This review has several limitations. It is a critical narrative review rather than a systematic review, and the legal analysis is based on publicly available statutory and policy materials rather than the complete evidentiary record that may be before a court. The post-deregulation empirical literature is still developing, and currently available studies focus on selected therapeutic groups and pharmacy samples. Associations observed after the policy change may also be influenced by exchange rates, inflation, input costs, supply-chain disruptions, manufacturer behavior, and changes in competition. Finally, this article does not provide legal advice and does not assert that S.R.O. 228(I)/2024 has been judicially invalidated.

The evidence base remains limited by the short post-deregulation observation period, heterogeneous medicine baskets, geographic variation, incomplete linkage between retail prices and household-level treatment outcomes, and limited causal evidence separating policy effects from exchange-rate movements, inflation, procurement conditions and supply-chain shocks which may be part of the future studies for researchers. The legal literature also lacks a definitive judicial interpretation specifically resolving whether S.R.O. 228(I)/2024 is consistent with the pricing responsibilities created by the DRAP Act. These limitations require caution against treating either the legal or public-health conclusions as settled.

Recommendations

Pakistan should move from a binary control-versus-deregulation debate toward adaptive pharmaceutical market stewardship strictly keeping in view the statutory commandments. First, Parliament should scrutinize actions of DRAP regarding compliance with statutory functions assigned to it under relevant enactments especially DRAP like price-fixation, price-monitoring, exemption and emergency-intervention powers, including the legal criteria for classifying medicines for regulated or market-based pricing. Second, DRAP should institutionalize a national pharmaceutical price-and-access observatory that publishes medicine-level data on maximum and actual retail prices, price dispersion, market concentration, stock-outs, therapeutic alternatives and affordability. Third, NEML status should not be the sole policy proxy for affordability risk; disease burden, therapeutic indispensability, market concentration, availability of substitutes and household financial exposure should also inform regulatory protection [1,2,14,15].

Pricing reform should be integrated with generic substitution, biosimilar uptake, pooled and transparent procurement, local API and finished-product manufacturing, shortage prevention, health technology assessment and targeted financial protection for chronic and high-cost therapies. The empirical evidence following deregulation is particularly important: oral antidiabetic medicines showed significant price increases and worsening affordability within six months [14], while insulin prices increased by a median 31.87%, with affordability deteriorating from 1.90 to 2.51 days' wages for a month's supply [15]. These findings support strict price ceilings while also recommend prospective monitoring of every price increase.

Regulatory decisions should be accompanied by transparent impact assessments and periodic public reporting. Patient organizations, pharmacists, clinicians, health economists, manufacturers, competition authorities and provincial health systems should participate in structured consultation. Policy performance should be judged against a balanced set of indicators: affordability, availability, continuity of supply, competition, manufacturing viability, quality assurance and equitable access. Such an approach would align economic sustainability with the public-health purpose of medicines regulation [1,13].

Figure 2. Proposed evidence-responsive pharmaceutical market stewardship framework for Pakistan.

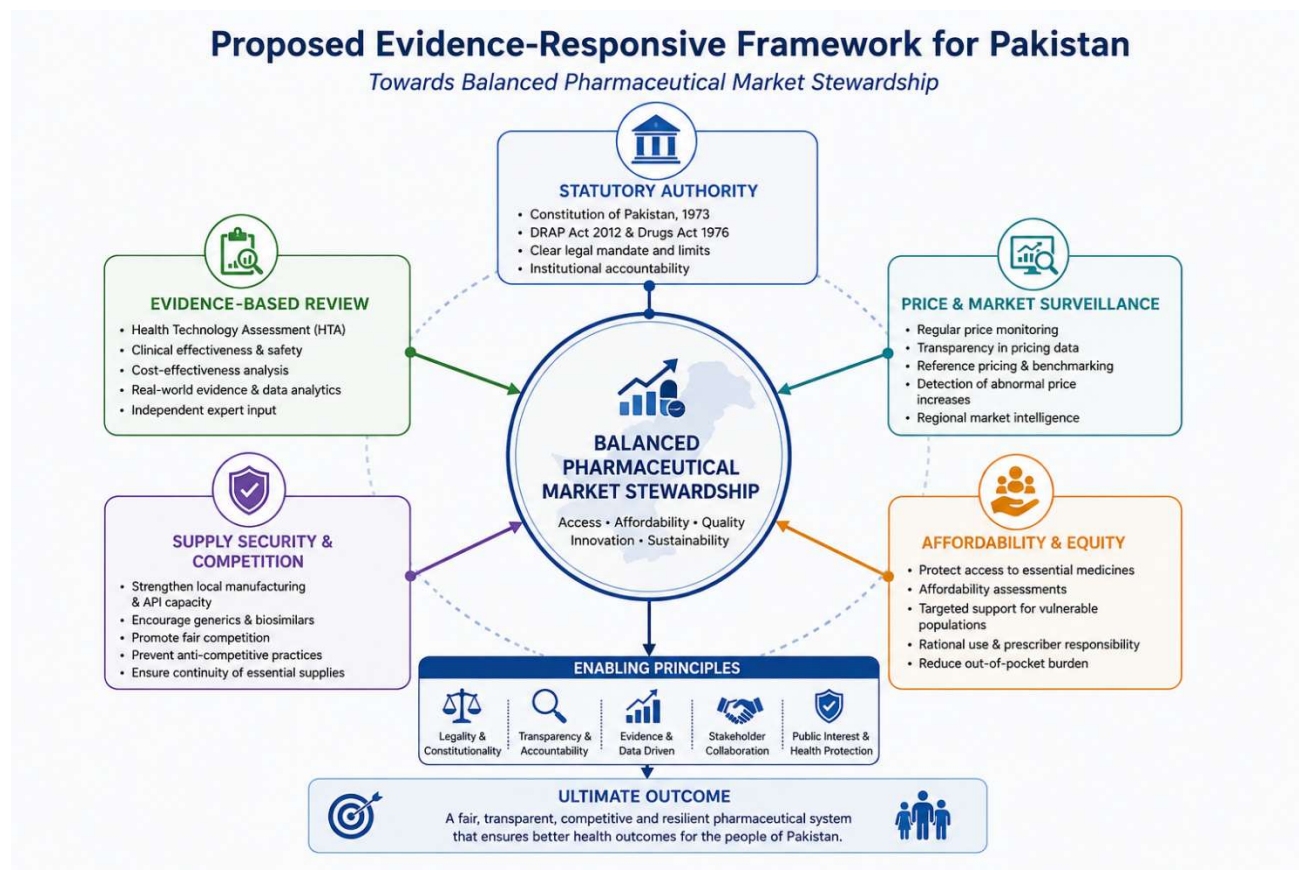


Figure 4. Evidence-informed framework for balancing patient access, regulatory legality and pharmaceutical-sector sustainability.

Source: Authors' conceptual framework for adaptive pharmaceutical market stewardship.

Future Perspectives

Future studies should evaluate the 2024 pricing reform using longitudinal, quasi-experimental and interrupted time-series designs rather than relying only on cross-sectional price comparisons. Priority outcomes include medicine-level price trajectories, affordability measured against household income and wages, availability, stock-outs, discontinuations, market entry and exit, generic and biosimilar penetration, manufacturer concentration and therapeutic substitution. Analyses should stratify NEML and non-NEML products, chronic versus acute therapies, originator versus generic/biosimilar products, and urban versus rural markets [4-7,14,15].

A national medicine-price panel should be developed using routinely collected pharmacy, distributor, hospital, procurement and manufacturer data. Difference-in-differences models could compare products exposed to deregulation with regulated comparators while controlling for inflation, exchange-rate movements, API import costs, energy costs, taxes and supply shocks. Competition metrics such as the Herfindahl-Hirschman Index should be examined alongside price changes to determine whether deregulation behaves differently in competitive and concentrated therapeutic markets.

Further legal research should examine the complete legislative history of sections 4, 7, 11 and 32 of the DRAP Act, section 12 of the Drugs Act, the legal basis and amendment history of the Drug Pricing Policy, and Pakistani superior-court jurisprudence on delegated legislation, excessive delegation, ultra vires action and statutory interpretation of mandatory language. Comparative doctrinal work with medicine-pricing regimes in other common-law and lower-middle-income jurisdictions could clarify when executive flexibility becomes impermissible alteration of a legislative mandate.

Patient-centered research is also required. Household surveys and qualitative studies should measure treatment interruption, dose rationing, switching, catastrophic medicine expenditure and inequities affecting low-income populations. Finally, prospective policy modelling should test hybrid approaches such as reference pricing, negotiated ceilings, competition-triggered deregulation, value-based assessment and targeted subsidies. The objective should be to identify a regulatory architecture that simultaneously protects access, supply resilience, industrial viability and lawful administrative discretion.

Table 3. Priority agenda for future pharmaceutical pricing and regulatory research in Pakistan.

Research priority	Preferred design	Core outcomes	Policy value
Long-term price effects	Interrupted time series / longitudinal panel	Price level, dispersion, inflation-adjusted change	Separates reform effects from macroeconomic trends
Causal policy evaluation	Difference-in-differences / synthetic controls	NEML vs non-NEML prices, affordability, availability	Estimates attributable effect of deregulation
Market structure	Competition and concentration analysis	Brand count, HHI, entry/exit, generic/biosimilar share	Identifies markets requiring safeguards
Patient impact	Household surveys + qualitative studies	Adherence, rationing, switching, catastrophic spending	Measures equity and clinical consequences
Legal authority	Doctrinal and comparative legal research	Delegation, ultra vires, statutory purpose, judicial review	Clarifies lawful scope of executive flexibility

Conclusion

Pakistan's 2024 partial pharmaceutical price deregulation raises a genuine question at the boundary between executive policy discretion and parliamentary mandate. Sections 4(1)(i), 7 and 32 of the DRAP Act embed costing and pricing within DRAP's institutional structure and statutory functions. That language makes it insufficient to justify deregulation solely as a matter of economic preference; the Executive must be able to identify adequate authority in primary legislation for the regulatory consequence it has created.

At the same time, deregulation does not necessarily eliminate all pricing responsibilities of DRAP. The decisive legal question is whether Parliament authorized differentiated regulatory treatment to the extent implemented by S.R.O. 228(I)/2024. That issue requires interpretation of the DRAP Act and Drugs Act as a whole and, ultimately, authoritative judicial determination.

The public-health evidence strengthens the case for close scrutiny. Pakistan had important access problems under the earlier controlled system, but early post-deregulation studies report substantial price increases and worsening affordability in selected antidiabetic medicines and insulin [14,15] which again support the strict regulatory control of prices. The most defensible policy direction is, therefore, a legally explicit, evidence-based, and adaptive pharmaceutical pricing framework that balances affordability, availability, competition, manufacturing viability, and supply security while preserving parliamentary supremacy and accountable regulatory governance.

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No new datasets were generated for this narrative legal-policy review. The legal instruments, policy documents and published research synthesized in the article are publicly available from the cited sources.





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