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BALANCING ACCESS AND CONTROL: A JUDICIAL INQUIRY OF DRUG PRICING IN PAKISTAN

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Abstract
This article undertakes a critical examination of the judicial scrutiny of the drug pricing mechanism in Pakistan, with specific reference to the Drug Pricing Policy, 2018. It analyses the statutory and regulatory framework governing the fixation and regulation of drug prices in the light of constitutional and administrative law principles as interpreted by the superior Courts of Pakistan. The study traces the genesis of the Drug Pricing Policy, 2018, emphasizing that its promulgation was the outcome of a consultative process involving the Drug Regulatory Authority of Pakistan (DRAP), the Federal Government, and relevant stakeholders, undertaken pursuant to the intervention and directions of the Supreme Court of Pakistan. The article demonstrates that the regulatory actions of DRAP and the Federal Government in matters of drug pricing have been consistently found to be lawful, reasonable, and in conformity with the governing legal framework when subjected to judicial review. It further highlights the settled judicial position that the original jurisdiction of ordinary civil courts stands excluded in such regulatory matters, and that the availing of prescribed statutory remedies, particularly appellate and review mechanisms, constitutes a mandatory precondition before approaching constitutional or other judicial forums. The article concludes by affirming the centrality of judicial oversight in maintaining a balance between public interest, regulatory authority, and the rights of stakeholders within Pakistan's pharmaceutical pricing regime.

Keywords: Drug Pricing; Maximum Retail Price; Drug Pricing Committee; Consumer Price Index; Judicial Review.

1. Introduction

The regulation of drug pricing in Pakistan has assumed increasing complexity following the promulgation of the Drug Pricing Policy, 2015 ("Policy of 2015") and the Drug Pricing Policy, 2018 ("Policy of 2018"). Although these policies were introduced with the stated objectives of ensuring affordability and accessibility of medicines, while simultaneously safeguarding the economic viability of the pharmaceutical industry, ambiguities in statutory provisions and deficiencies in regulatory implementation generated extensive litigation between pharmaceutical stakeholders and the regulator. This research critically examines how the Supreme Court of Pakistan and the High Courts have interpreted and applied constitutional and administrative law principles in disputes relating to drug pricing and regulatory control.

The study evaluates judicial reasoning with reference to:

(i) legislative instruments governing drug pricing, including the Drugs Act, 1976, the Drug Regulatory Authority of Pakistan Act, 2012 ("DRAP Act"), and the Drug Pricing Policies of 2015 and 2018;

(ii) delegated legislation and regulatory actions undertaken by the Drug Regulatory Authority of Pakistan ("DRAP") and provincial authorities; and

(iii) the evolution of case law concerning price fixation, review and appellate mechanisms, and the permissible scope of judicial oversight in matters of economic regulation.

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The central inquiry of this research is whether judicial precedents have enhanced legal clarity, institutional accountability, and the protection of public health interests, or whether judicial intervention has inadvertently disrupted regulatory coherence. By analyzing trends, tensions, and doctrinal gaps in the jurisprudence, the study proposes targeted legal and policy reforms aimed at strengthening Pakistan's drug pricing regime.

Drugs and medicines in Pakistan are regulated under the Drugs Act, 1976, the DRAP Act, 2012, and the rules framed thereunder. DRAP is vested with the responsibility of regulating the pharmaceutical sector, including oversight of the Maximum Retail Price ("MRP") of drugs. Under section 12 of the Drugs Act, 1976, the Federal Government is empowered to fix and regulate the MRP of drugs. For the purpose of determining and scrutinizing costs incurred in the formulation and manufacture of drugs, the Federal Government constituted a Drug Pricing Committee ("DPC") under subsection (3) of section 12 of the Drugs Act, 1976. The DPC is mandated to assess and recommend drug prices, taking into account factors such as manufacturing costs, inflationary trends, currency devaluation, and the commercial viability of production under prevailing economic conditions.[1]

The Policy of 2015 represented Pakistan's first comprehensive pricing policy introduced as delegated legislation for the fixation of drug MRPs. However, the policy was met with serious objections from stakeholders, particularly in relation to the fixation of prices of originator brands and the absence of an effective review mechanism. These deficiencies culminated in widespread litigation between the pharmaceutical industry and DRAP. The matter ultimately came before the Supreme Court of Pakistan in Human Rights Case No. 2858 of 2006, wherein the Policy of 2015 was subjected to judicial scrutiny.[2] The Supreme Court directed all stakeholders to engage in a consultative process to formulate a revised policy capable of resolving outstanding disputes and regulatory ambiguities.[3]

Pursuant to these directions, the Drug Pricing Policy, 2018 was promulgated with the consensus of all stakeholders, including DRAP, and with the express endorsement of the Supreme Court of Pakistan. The Policy of 2018 introduced a structured and transparent mechanism for the fixation of MRPs for new chemical entities and generic drugs. It further provided a formula-based mechanism for periodic price adjustments linked to the Consumer Price Index ("CPI"), pricing for new market entrants, and relief in cases of demonstrated hardship. Significantly, the Supreme Court also discouraged the direct invocation of constitutional jurisdiction or original civil jurisdiction by pharmaceutical companies and emphasised the mandatory exhaustion of statutory remedies, particularly appeals before the Appellate Board of DRAP, prior to approaching judicial forums.[4]

A notable paradigm shift occurred in 2024 when the Federal Government revised the regulatory framework by limiting price regulation to essential medicines included in the National Essential Medicines List ("NEML"), as notified in accordance with World Health Organization ("WHO") guidelines.[5] Concurrently, the Federal Government amended the notification governing the Drug Pricing Committee and introduced an additional internal review forum, namely, the Policy Board of DRAP, prior to submission of pricing recommendations to the Federal Government for final approval. As a result, the regulatory oversight of MRPs is presently confined to essential drugs only.

This partial deregulation has led to a marked reduction in litigation and facilitated more expeditious resolution of stakeholder concerns. Nevertheless, the revised framework itself

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remains under judicial scrutiny before the Lahore High Court, Lahore, thereby underscoring the continuing tension between regulatory autonomy, market dynamics, and judicial oversight in Pakistan's pharmaceutical pricing regime.[6]

2. Judicial Oversight of Drug Pricing in Pakistan: Policy, Litigation, and Regulatory Framework

The Supreme Court of Pakistan took suo moto notice to address long-pending litigation before the Sindh High Court, Karachi, concerning drug pricing disputes that had remained unresolved for several years. To resolve these issues, a mechanism was devised involving drug manufacturers and the Drug Regulatory Authority of Pakistan (DRAP). This consensual mechanism was endorsed by the Supreme Court as a practical solution, concluding the Human Rights Case proceedings in 2018. The Court noted that all stakeholders, including DRAP, had reached a consensus, leaving no reason for further judicial intervention. Consequently, the Drug Pricing Policy, 2018 was promulgated, signaling resolution of the outstanding disputes.[7]

The Supreme Court also established that any party aggrieved by a violation of its order could file an appropriate application. Several review petitions were filed seeking clarification later that year.[8]The Court clarified aspects of the roadmap established in its prior order and emphasized that any company aggrieved by DRAP's actions must appeal under section 9 of the Drugs Act, 1976, before the Appellate Board of DRAP. It expressly discouraged companies from approaching the High Court directly in constitutional or original jurisdiction.

A key distinction between the Policies of 2015 and 2018 concerned the pricing of originator brands. Under the 2018 Policy, reductions in Maximum Retail Price (MRP) for brands not available in Bangladesh or India were determined using a basket of countries, Lebanon, Philippines, Indonesia, Sri Lanka, and Malaysia—rather than developed countries as provided under the 2015 Policy.[9] Despite Supreme Court oversight, this issue remained contentious. The Drug Pricing Committee (DPC) continued to decide price fixation and hardship cases following Court directions. Some companies challenged these determinations before the Appellate Board, while others directly approached the Sindh High Court, arguing that the Appellate Board lacked authority to grant interim relief.

In the case of Pfizer Pakistan Pvt. Ltd., the Court considered whether the Appellate Board had jurisdiction over appeals against Federal Government notifications and whether it could grant interim relief.[10] The Court held that a statutory forum empowered to grant final relief inherently possesses the authority to grant interim relief. The absence of express statutory language does not render the forum powerless; interim relief is a necessary part of appellate jurisdiction.

The Appellate Board subsequently heard matters referred by the Sindh High Court and upheld the DPC's determinations in accordance with Supreme Court directions. However, in the case of Sanofi Aventis Pakistan Limited, the Sindh High Court found that the Appellate Board had incorrectly applied the 2015 Policy for fixing MRPs of originator brands, despite the 2018 Policy being in effect.[11] The Court directed DRAP to undertake a de novo determination under the 2018 Policy while declining to interfere in generic and hardship cases, leaving them to the Appellate Board.

All appeals against this decision were dismissed by the Supreme Court, reaffirming that statutory notifications of drug prices must be challenged before the Appellate Board.[12] This jurisprudence reinforces the mandatory exhaustion of statutory remedies before judicial intervention and underscores the Court's insistence on regulatory coherence.

While the Constitution of Pakistan does not explicitly recognize the "right to health" as a fundamental right, the right to life under Article 9, read with Article 14 guaranteeing

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human dignity, has been interpreted to encompass access to healthcare.[8] This interpretation aligns with Pakistan's obligations under the International Covenant on Economic, Social and Cultural Rights (ICESCR), ratified in 2008, recognizing the right of every individual to the highest attainable standard of health.[13] In the case of Getz Pharma Pvt. Ltd., the Court held that where a drug is essential for treating Hepatitis-C, the Federal Government may invoke compulsory licensing under section 58 of the Patents Ordinance, 2000, allowing local manufacturing at lower cost to ensure public access.[14]

The 2018 Policy also provides a formal mechanism for hardship applications. Under paragraph 9(5), a company may apply once every three years for an MRP adjustment if manufacturing becomes commercially unviable. The DPC must decide the application within 120 days, after which the company may raise the MRP by up to 10% if the DPC fails to act. The Federal Government's approval within 60 days is declaratory, not mandatory; failure to act does not trigger a statutory consequence.[15]

In Getz Pharma & Connected Matters, the Islamabad High Court held that any Federal Government decision in drug pricing must be well-reasoned and just, providing due process in accordance with Section 24A of the General Clauses Act and Article 10A of the Constitution.[16] The Court emphasized that procedural due process applies to Federal Cabinet decisions impacting civil rights, including drug pricing.

The Federal Government deregulated the MRP of non-essential drugs through S.R.O 228(I)/2024, limiting regulation to essential medicines listed in the National Essential Medicines List (NEML).[17] This policy change led to significant increases in non-essential drug prices and raised questions about drug classification in different dosage forms. In the case of GlaxoSmithKline Pakistan Limited, the Islamabad High Court held that once a drug is included in the NEML, its essential status applies to all dosage forms of the same molecule.[18]

In 2022, several companies, including the Pakistan Pharmaceutical Manufacturers Association (PPMA), submitted representations under paragraph 12(8) of the 2018 Policy for MRP adjustments due to currency devaluation.[19] The Policy Board recommended upward revision based on average CPI, and the Federal Government promulgated S.R.O 595(I)/2023, implementing a one-time annual increase for 2023–24. Pending hardship cases were to be reviewed by the DPC. Companies challenging this S.R.O. in the Sindh High Court were directed to the proper forum, with the Appellate Board recognized as competent.[20]

3. Conclusion

From the analysis above, it is evident that drug pricing in Pakistan is primarily governed through delegated legislation, namely the Drug Pricing Policy, 2018. This Policy was developed through consensus among the Drug Regulatory Authority of Pakistan (DRAP), pharmaceutical companies, and the Supreme Court, providing a structured mechanism for fixing Maximum Retail Prices (MRP) of originator and generic drugs, including adjustments linked to the Consumer Price Index and provisions for hardship cases.[21]

The Supreme Court, through HRC 2858/2006, curtailed ongoing and future litigation by limiting the original jurisdiction of civil courts and discouraging direct constitutional petitions without first exhausting statutory remedies.[22] This principle has become a core legal defense in post-2018 drug pricing cases, facilitating effective judicial review while reducing unnecessary litigation.[23]

Judicial oversight ensures that regulatory determinations are transparent, accountable, and consistent with public interest. Courts have emphasized that statutory forums, such as the Drug Pricing Committee and Appellate Board, possess inherent authority to grant interim relief while exercising appellate jurisdiction. This framework has clarified contentious issues,

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including MRP determination for originator brands, hardship applications, and adjustments due to economic variables.

The jurisprudence also links drug pricing to fundamental rights. While the Constitution of Pakistan does not explicitly recognize a "right to health," Articles 9 and 14 have been interpreted to encompass access to affordable medicines, consistent with Pakistan's obligations under the ICESCR. Cases such as Getz Pharma Pvt. Ltd. affirm that the State may invoke compulsory licensing to ensure public access to life-saving drugs, aligning regulatory decisions with public health priorities.

Finally, the judicially endorsed framework fosters predictability, transparency, and equity. By institutionalizing clear appellate and review mechanisms, the Policy of 2018; supported by judicial oversight, ensures pricing decisions are legally sound, commercially viable, and aligned with public health imperatives.[24]

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