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Review Article

**A BALANCED PHARMACEUTICAL PRICING
FRAMEWORK FOR PAKISTAN: INTEGRATING
AFFORDABILITY, INDUSTRIAL GROWTH, SUPPLY
SECURITY, AND INTERNATIONAL REGULATORY
PRACTICE**

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Abstract

Pharmaceutical pricing remains one of the most debated areas of healthcare policy because medicines simultaneously function as essential healthcare interventions and commercial products. In Pakistan, discussions surrounding medicine prices intensified deregulated the maximum retail prices (MRPs) of medicines excluded from the National Essential Medicines List (NEML). Public debate has increasingly focused on apparent differences between government procurement prices and retail pharmacy prices for medicines such as omeprazole, montelukast, escitalopram, pregabalin, atorvastatin, ceftriaxone, losartan, fluconazole, and numerous other pharmaceutical products. In several instances, procurement prices have been compared directly with retail prices, leading to claims of excessive markups or profiteering. However, such comparisons may be scientifically misleading unless the products being compared are identical in manufacturer, dosage form, pack size, procurement period, regulatory status, and commercial transaction conditions. This analytical review examines the scientific validity of comparing public procurement prices with open-market retail prices in Pakistan. It argues that procurement transactions and retail pharmaceutical markets operate under fundamentally different commercial, regulatory, and economic environments. Government procurement commonly involves competitive tenders, and reduced marketing costs, whereas retail pricing incorporates distribution expenses, inventory management, taxes, and other commercial factors.

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Introduction

Access to safe, effective, quality-assured and affordable medicines is an essential component of functioning health systems. Medicine price, however, cannot be examined independently of availability. A medicine that carries a low officially approved price but is unavailable from pharmacies provides little therapeutic benefit. Conversely, a continuously available medicine whose price exceeds the patient's ability to pay also fails the fundamental objective of pharmaceutical policy.

This creates what may be described as the pharmaceutical pricing equilibrium problem:

Affordability must be protected without destroying availability, while industrial sustainability must be protected without permitting unjustifiable pricing.

WHO recognizes precisely this complexity. High pharmaceutical prices can impose substantial financial hardship on individuals and undermine health-system capacity to provide equitable access. At the same time, pricing policies must be planned, monitored and periodically revised according to changing circumstances.

Pakistan provides an important case for studying this policy dilemma. The pharmaceutical sector supplies a substantial proportion of medicines consumed domestically and operates within an economic environment affected by currency fluctuations, inflation, imported APIs and excipients, energy and financing costs, international freight conditions, taxation, regulatory compliance requirements and global supply-chain disruptions.

Pakistan has historically relied substantially upon administrative pharmaceutical pricing mechanisms. DRAP's regulatory framework continues to identify the Drug Pricing Policy 2018 and subsequent amendments as part of the country's pricing-policy architecture.

The fundamental policy question is therefore no longer simply:

Should Pakistan control pharmaceutical prices?

A more scientifically appropriate question is:

Which medicines require price regulation, which can safely operate under competitive pricing, how should prices be adjusted, and how can affordability and supply security be simultaneously protected?

That distinction forms the analytical foundation of this review.

Conceptual Background

Pharmaceutical markets differ fundamentally from ordinary consumer markets. Patients frequently cannot independently determine which medicines they require. Physicians prescribe, pharmacists dispense, manufacturers produce, distributors supply, regulators determine market authorization and quality standards, and governments may finance or influence procurement. Consequently, the person consuming the product may neither select the product nor possess sufficient information to evaluate therapeutic alternatives.

Several forms of market failure, therefore, occur simultaneously.

- **Information asymmetry** exists because manufacturers, healthcare professionals and patients possess unequal information concerning therapeutic effectiveness, alternatives and prices.
- **Agency relationships** exist because prescribing decisions are frequently made by clinicians rather than consumers.
- **Demand inelasticity** can arise for lifesaving therapies because patients cannot simply postpone consumption when prices increase.
- **Patent or technological exclusivity** can create temporary monopoly conditions.
- **Brand differentiation** can weaken generic price competition even when pharmacologically equivalent products exist.
- **Supply concentration** may make markets vulnerable when only a small number of manufacturers produce particular medicines.

For these reasons, pharmaceutical pricing cannot be governed exclusively by conventional assumptions of unrestricted market competition.

At the same time, pharmaceutical manufacturing is capital intensive and highly regulated. Manufacturers must maintain GMP systems, validated production environments, analytical laboratories, trained personnel, stability programs, quality-control procedures, pharmacovigilance responsibilities and regulatory documentation. Persistent prices below economically viable production costs can, therefore, reduce manufacturing incentives.

The policy objective should consequently be sustainable affordability, rather than simply the lowest administratively achievable price.

Origins and Development of Pharmaceutical Pricing Regulation in Pakistan

Pakistan's pharmaceutical pricing regime developed through a broader legislative structure governing medicines, manufacturing, registration, importation, distribution and sale. The establishment of DRAP created a federal regulatory institution with responsibilities extending across therapeutic goods.

The Drug Pricing Policy 2018 represented an important effort to introduce a more structured pricing methodology. Subsequent amendments modified elements of that framework, and DRAP currently provides an amended version of the policy and its amendment history through its official regulatory resources.

The policy contains mechanisms addressing matters such as maximum retail prices and hardship circumstances. The amended policy documentation, for example, contains procedures relating to hardship applications for critically needed medicines.

These mechanisms illustrate an important regulatory reality: pharmaceutical prices cannot remain completely static when production economics change substantially.

Yet repeatedly modifying individual prices through administrative procedures can itself become inefficient. A sustainable system, therefore, requires predictable adjustment rules, exceptional review procedures and clearly differentiated categories of medicines.

Competing Interpretations of Pharmaceutical Price Regulation

Two broad perspectives frequently dominate pharmaceutical pricing debates.

One emphasizes patient affordability. According to this interpretation, medicine is not an ordinary commodity. Governments have a responsibility to intervene where monopoly power, information asymmetry, poverty or limited insurance coverage could prevent patients from obtaining necessary treatment.

The alternative perspective emphasizes industrial viability and medicine availability. Manufacturers argue that when production costs rise while permissible prices remain relatively static, some products become economically unsustainable. Manufacturers may reduce production, withdraw products or avoid investment in low-margin therapeutic categories.

Both arguments contain legitimate economic considerations.

The mistake occurs when either is treated as universally applicable.

Complete deregulation assumes that competition will adequately constrain prices across pharmaceutical markets. That assumption is weak where only one or two manufacturers supply a medicine.

Conversely, universal rigid price control assumes that administrative ceilings can indefinitely suppress prices without influencing manufacturing incentives or supply.

The appropriate regulatory response is therefore risk-stratified pricing.

Theoretical and Institutional Analysis: A balanced pharmaceutical pricing model can be conceptualized through four principal objectives.

Public-health objective: Medicines should remain affordable and accessible, particularly those necessary for preventing death, disability or serious disease.

Economic objective: Manufacturing should remain sufficiently viable to maintain production and encourage investment.

Supply-security objective: Pakistan should minimize medicine shortages and excessive dependence on geographically concentrated foreign suppliers.

Regulatory objective: Pricing decisions should be transparent, predictable, evidence-based and subject to periodic review.

These objectives are mutually dependent rather than competing in absolute terms.

A pharmaceutical company cannot sustainably supply medicines if production becomes financially impossible. Patients cannot benefit from industrial growth if medicines become unaffordable. Governments cannot guarantee access if international supply chains collapse. Regulators cannot maintain public confidence if pricing decisions appear arbitrary.

Thematic Evidence Synthesis

Medicine Affordability as the Primary Public-Health Safeguard

Affordability should remain the foundational principle of Pakistan's pharmaceutical pricing system.

WHO recommends comprehensive national medicines policies aimed at ensuring reliable availability, appropriate use, affordability and protection from catastrophic expenditure.

However, affordability should not be defined exclusively by the nominal retail price.

A more useful concept is:

Effective access = affordability × availability × quality × appropriate use

If any one of these approaches zero, effective access deteriorates.

This distinction is especially important for low-income households, patients with chronic diseases and individuals requiring multiple medicines continuously.

Essential Medicines Require Stronger Protection

Not every pharmaceutical product has equivalent public-health importance.

A lifesaving injectable antibiotic, insulin, anticonvulsant or emergency cardiovascular medicine should not necessarily be governed by the same pricing rules as a highly competitive non-essential consumer pharmaceutical product.

Pakistan should, therefore, establish differentiated pricing tiers.

Table 1. Proposed Risk-Based Pharmaceutical Pricing Classification for Pakistan

Category	Characteristics	Proposed Regulatory Approach
Tier I	Essential, lifesaving, critical medicines	Strong price oversight
Tier II	Essential medicines with multiple suppliers	Reference/competitive ceiling pricing
Tier III	Chronic-disease medicines	Affordability-linked regulation
Tier IV	Innovative/patented medicines	HTA/value-informed negotiated pricing
Tier V	Highly competitive non-essential medicines	Conditional market pricing
Tier VI	Shortage-prone medicines	Supply-security pricing intervention
Tier VII	Orphan/very low-volume medicines	Special negotiated mechanism

Regulation becomes more intensive where therapeutic necessity, monopoly power, affordability risk or supply vulnerability increases.

Generic Medicines as an Affordability Strategy

Competition among quality-assured generic medicines represents one of the most sustainable mechanisms for reducing pharmaceutical expenditure.

WHO specifically recognizes promotion of quality-assured generics and biosimilars as a mechanism for increasing access to lower-priced alternatives.

Pakistan, therefore, requires a pricing policy that rewards genuine generic competition rather than relying exclusively upon administrative price suppression.

Measures should include faster registration of quality generics, stronger bioequivalence capacity, enforcement against substandard products, prescribing by generic name where clinically appropriate, pharmacist and patient education and procurement systems that encourage competition without compromising quality.

External Reference Pricing

External reference pricing compares the price of a medicine with prices charged in selected foreign markets.

It can provide useful regulatory information but should not operate mechanically.

Pakistan differs from high-income jurisdictions in income levels, taxation, insurance coverage, exchange rates, distribution structures and pharmaceutical purchasing power. Consequently, copying a foreign list price without adjustment can produce distorted outcomes.

WHO recognizes external reference pricing as one of the tools available within national pharmaceutical pricing systems.

Pakistan should, therefore, use external reference pricing as a **benchmark**, not an automatic formula.

Appropriate comparator countries should ideally have similar economic characteristics, pharmaceutical-market structures or regional conditions.

Internal Reference Pricing

Internal reference pricing groups therapeutically similar medicines and establishes a reimbursement or pricing benchmark.

WHO also recognizes internal reference pricing within the range of pharmaceutical pricing interventions.

For Pakistan, this approach may be particularly useful for mature therapeutic classes containing numerous generic alternatives.

Rather than regulating every manufacturer's production cost individually, DRAP could establish therapeutic reference bands while allowing competition beneath the ceiling.

Value-Informed Pricing for Innovative Medicines

Innovative therapies create another challenge.

Simple cost-plus pricing may not adequately capture therapeutic benefit, while unrestricted monopoly pricing can create affordability problems.

Organisation for Economic Co-operation and Development (OECD) experience demonstrates that several health systems incorporate therapeutic outcomes, economic evaluation, disease severity, innovativeness and budget impact when determining pharmaceutical value.

Pakistan should gradually develop a Health Technology Assessment (HTA) mechanism for selected expensive medicines.

Evaluation could incorporate:

1. clinical effectiveness;
2. incremental therapeutic benefit;
3. quality-adjusted health outcomes where appropriate;
4. budget impact;
5. disease severity;
6. availability of alternatives;
7. size of eligible patient population; and
8. affordability within Pakistan's health system.

Industrial Growth and Pharmaceutical Manufacturing

Price regulation should recognize that pharmaceutical manufacturing constitutes both a public-health infrastructure and an industrial sector.

Sustainable manufacturers create employment, technical skills, tax revenue, research capability, exports and domestic medicine availability.

Policies that consistently make essential medicines economically unattractive may unintentionally increase dependence on imports.

Conversely, excessive protection from competition can reduce efficiency.

The objective should therefore be competitive industrial development, rather than permanent protectionism or uncontrolled market liberalization.

Imported APIs and Exchange-Rate Exposure

A particularly important structural vulnerability is dependence upon imported pharmaceutical inputs.

Even medicines formulated and packaged domestically may rely on imported APIs, excipients, specialized packaging materials, laboratory reagents and manufacturing equipment.

Consequently:

Local formulation does not necessarily equal pharmaceutical self-sufficiency.

Exchange-rate depreciation can rapidly increase production costs.

A rational pricing mechanism, therefore, requires an objective Pharmaceutical Input Cost Index (PICI).

The index could incorporate:

1. API prices;
2. exchange rates;
3. energy costs;
4. wages;

5. packaging materials;
6. transportation;
7. regulatory compliance; and
8. inflation.

Rather than politically negotiated irregular price increases, predetermined adjustment thresholds could trigger structured reviews.



Figure 1. Pharmaceutical manufacturing and industrial production as components of national medicine security.

A resilient pricing framework should treat domestic production capacity as an element of public-health infrastructure while maintaining requirements for quality, competition and affordability.

Supply Security and Medicine Shortages

Medicine shortages represent one of the most important reasons pharmaceutical pricing policy must extend beyond retail affordability.

Pakistan-specific research has previously identified multiple actors within the shortage environment, including manufacturers, distributors, wholesalers, pharmacies, healthcare institutions and regulators.



Figure 2. Pharmaceutical supply-chain structure relevant to medicine availability in Pakistan.

Supply security depends upon coordinated activity among manufacturers, distributors, wholesalers, pharmacies, healthcare institutions and regulatory authorities.

A low-price medicine supplied by only one economically marginal manufacturer may present greater public-health risk than a slightly more expensive medicine supplied by several reliable manufacturers.

This leads to an important proposed indicator:

Supply Security Score

Each essential medicine could receive a supply-security rating based upon:

1. number of active manufacturers;
2. API source concentration;
3. import dependence;
4. inventory duration;
5. historic shortages;
6. therapeutic substitutability;
7. domestic production capacity: and
8. strategic clinical importance.

A deteriorating score would trigger regulatory review before an actual national shortage develops.

International Comparative Analysis

International systems demonstrate that pharmaceutical regulation generally uses combinations of interventions rather than one universal pricing mechanism.

India provides an especially relevant regional comparison. Its National Pharmaceutical Pricing Authority (NPPA) operates statutory pricing mechanisms for specified medicines while

monitoring other pharmaceutical prices. NPPA describes its role as including price fixation or revision, implementation of drug-price-control provisions and monitoring of controlled and decontrolled medicines.

OECD countries employ combinations of reimbursement negotiations, reference pricing, economic evaluation, generic competition and value assessment.

European pharmaceutical policy increasingly demonstrates another important development: **supply resilience is becoming part of medicines policy**. The European Commission's Critical Medicines Act proposal seeks to strengthen production and availability of critical medicines through strategic projects, resilient procurement, collaborative purchasing and diversification of supply chains.

Table 2. Comparative Pharmaceutical Pricing and Supply Approaches

System	Major Mechanism	Principal Strength	Lesson for Pakistan
WHO guidance	Multiple evidence-based pricing interventions	Flexible policy toolkit	Avoid reliance on one instrument
India	Essential/scheduled medicine price regulation	Protects priority medicines	Selective controls
OECD systems	Reference/value-informed pricing	Links price with comparative value	Develop HTA capacity
European Union	Pricing/access plus supply resilience	Recognizes strategic supply risk	Integrate security into pricing
Proposed Pakistan model	Risk-stratified hybrid framework	Balances affordability and sustainability	Context-specific integration

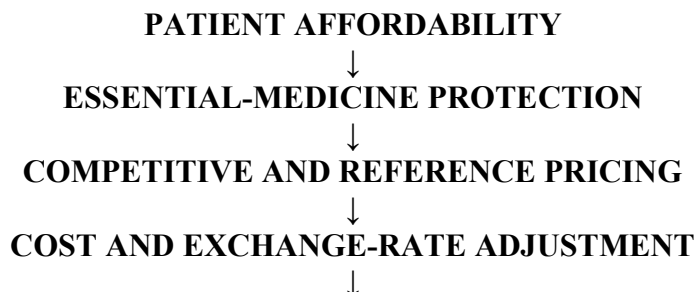
Caption: Table 2. Comparative lessons from international pharmaceutical pricing and supply-security approaches.

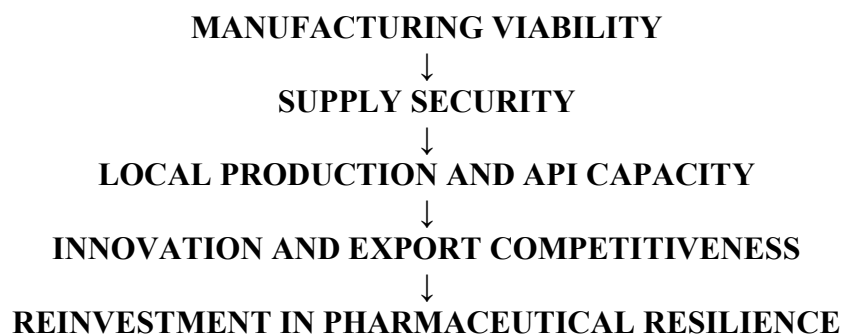
International experience supports policy combinations rather than universal reliance upon either unrestricted pricing or comprehensive price controls.

Proposed Pakistan Balanced Pharmaceutical Pricing Framework

The central proposal of this review is the **Pakistan Balanced Pharmaceutical Pricing Framework (PBPPF)**.

Its conceptual structure is:





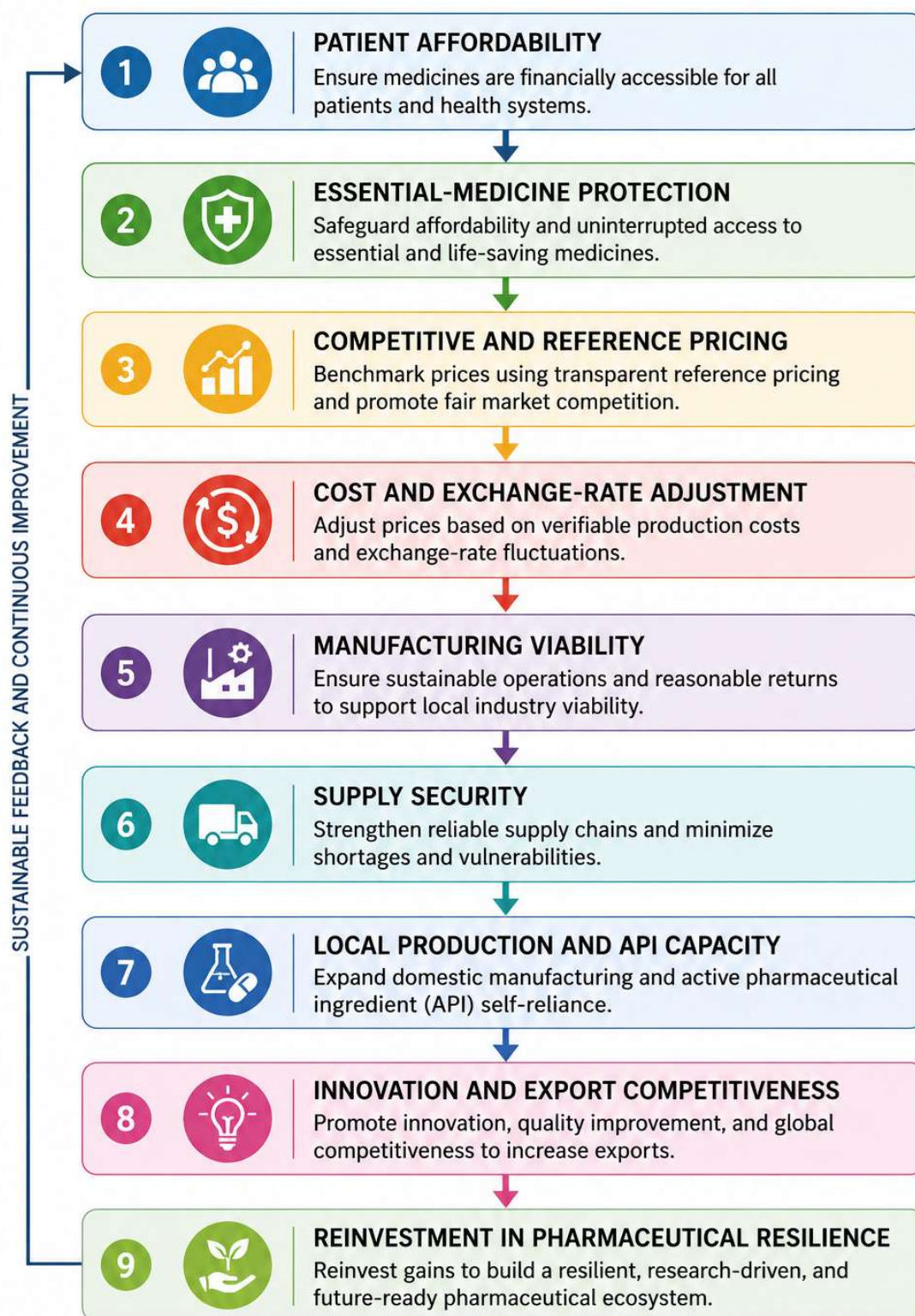


Figure 3. Proposed Pakistan Balanced Pharmaceutical Pricing Framework (PBPPF).

The model treats affordability, industrial sustainability and supply resilience as components of a continuous pharmaceutical-policy system rather than mutually exclusive objectives.

The framework rests on four pillars:

Affordability — Availability — Industrial Sustainability — Supply Security

These are supported by transparency, competition, quality assurance and evidence-based regulation.

A Dynamic Price-Adjustment Model

Pakistan could replace irregular broad price adjustments with a transparent formula.

Conceptually:

Permissible Price Adjustment = f(CPI + Exchange Rate + API Cost + Energy Cost + Supply Risk – Competitive Pressure)

This does not imply automatic pass-through of every cost increase.

Rather, it provides regulators with an objective analytical basis.

For example, a medicine supplied by eight manufacturers would receive a stronger competition adjustment than an essential medicine supplied by only one manufacturer.

Similarly, unusually high API inflation could justify a targeted adjustment without increasing prices across the entire pharmaceutical market.

Affordability Protection Index

Industrial cost indicators alone are insufficient.

Pakistan should simultaneously develop a **Medicine Affordability Index (MAI)**.

The MAI could estimate the number of daily wages required to purchase a standard course of treatment.

Where affordability deteriorates beyond predetermined thresholds, policymakers could respond through targeted subsidy, procurement intervention, reimbursement, price negotiation or social-health protection rather than forcing every manufacturer to operate below sustainable cost.

This represents a crucial conceptual shift:

Patient protection does not always require suppressing the manufacturer's price.

Sometimes the economically superior intervention is targeted financing.

Pharmaceutical Price and Availability Observatory

Pakistan should establish a national digital **Pharmaceutical Price and Availability Observatory** under or in coordination with DRAP.

WHO supports greater pharmaceutical market transparency and maintains information resources concerning prices, registrations and shortages.

Pakistan's observatory should continuously monitor:

1. MRPs;

2. actual retail prices;
3. manufacturer availability;
4. regional shortages;
5. hospital procurement prices;
6. API costs;
7. import values;
8. exchange-rate exposure;
9. manufacturer concentration; and
10. medicine discontinuations.

Artificial intelligence and statistical anomaly detection could identify unusual price increases or developing shortages.

Supply-Security Pricing

Traditional pharmaceutical pricing asks:

What is an acceptable price?

A modern pharmaceutical-security framework must additionally ask:

What price is necessary to maintain reliable supply?

This distinction is especially important for low-volume injectables, antidotes, pediatric formulations, emergency medicines and older essential medicines whose manufacturing margins may be limited.

For strategically critical products, regulators should permit evidence-based viability adjustments where credible evidence demonstrates that existing prices threaten continued production.

Such adjustments should be conditional upon supply commitments.

A manufacturer receiving exceptional pricing relief could be required to maintain defined inventory, production capacity or supply obligations.

Local API Manufacturing

Pakistan's long-term pharmaceutical security cannot depend solely upon formulation capacity.

Domestic API manufacturing should, therefore, become a strategic industrial objective.

Policy incentives could include concessional financing, accelerated approvals, industrial clusters, tax incentives for qualifying investments, technology-transfer partnerships and university-industry research programs.

Priority should initially be given to APIs associated with essential medicines and products with high import dependence.

Procurement Reform

Government procurement can exert enormous influence on pharmaceutical markets.

Procurement based exclusively on the lowest acquisition price may produce false economies if suppliers subsequently fail to deliver or quality deteriorates.

Pakistan should gradually transition toward **Most Economically Advantageous Pharmaceutical Procurement**.

Evaluation could incorporate:

1. Price;
2. Quality;
3. Regulatory compliance;
4. Supply reliability;
5. Domestic production resilience;
6. Historic delivery performance; and
7. API diversification.

This concept parallels emerging European approaches in which procurement policy can explicitly support resilient medicine supply chains.

Critical Evaluation

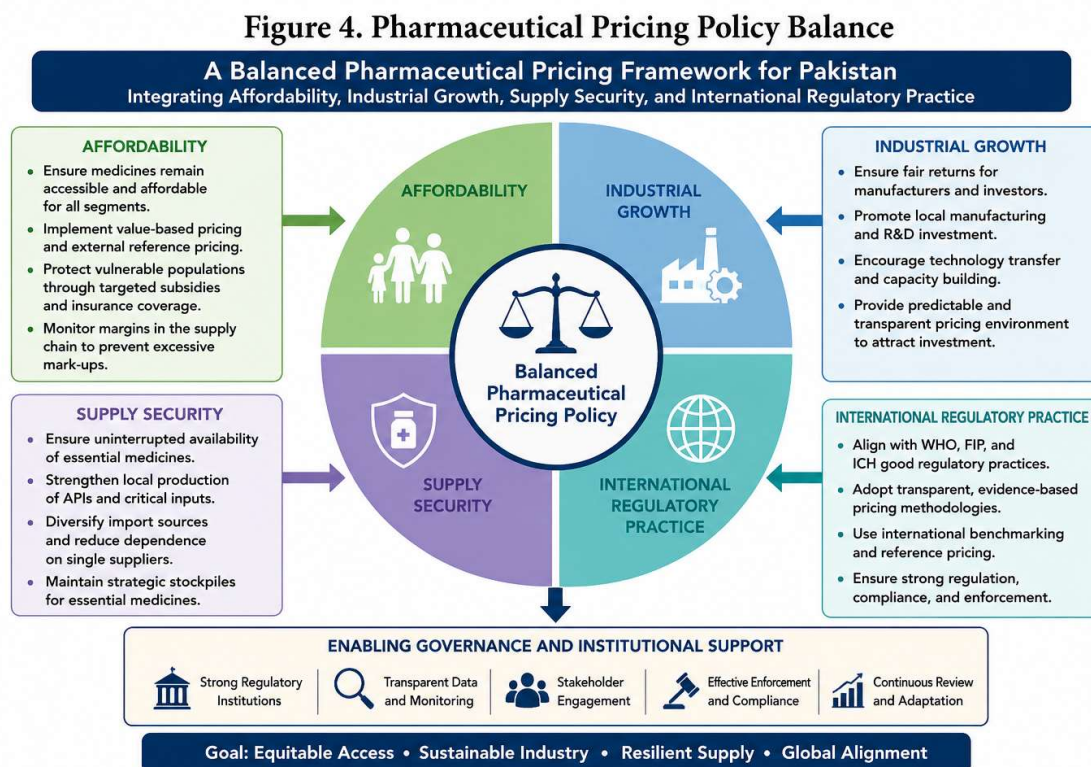
A balanced pricing model is not without risks.

Greater pricing flexibility can be abused if competition is weak.

External reference pricing can become distorted by confidential rebates and differences between list and transaction prices.

- Cost-based pricing can reward inefficient manufacturers.
- Value-based pricing requires sophisticated health-economic expertise.
- Domestic-manufacturing incentives can become protectionist.
- Procurement preferences can reduce competition if poorly designed.
- Price controls can generate shortages.
- Deregulation can generate affordability problems.

Therefore, no pricing instrument should operate without monitoring. The fundamental regulatory principle should be “Intervene where market failure exists; permit competition where competition demonstrably works”.



Source: Author's compilation based on WHO (2020), World Bank (2021), OECD (2022), and national policy documents.

Figure 4. Pharmaceutical Pricing Policy Balance

Too much price suppression

- declining profitability
- product withdrawal
- shortages
- import dependence
- reduced competition
- eventual price pressure

Too little price oversight

- excessive pricing
- reduced affordability
- treatment interruption
- inequitable access
- increased household expenditure

Balanced regulation

- reasonable prices
- sustainable manufacturing
- competitive markets
- stable supply
- patient access

Caption: Figure 4. The pharmaceutical pricing policy balance. Both excessive price suppression and inadequate market oversight can ultimately reduce medicine access; optimal regulation lies within a dynamic affordability–sustainability corridor.

Implications

The proposed framework has important implications for public health, pharmaceutical regulation and industrial development.

Figure 5. Implications of the Balanced Pharmaceutical Pricing Framework for Pakistan

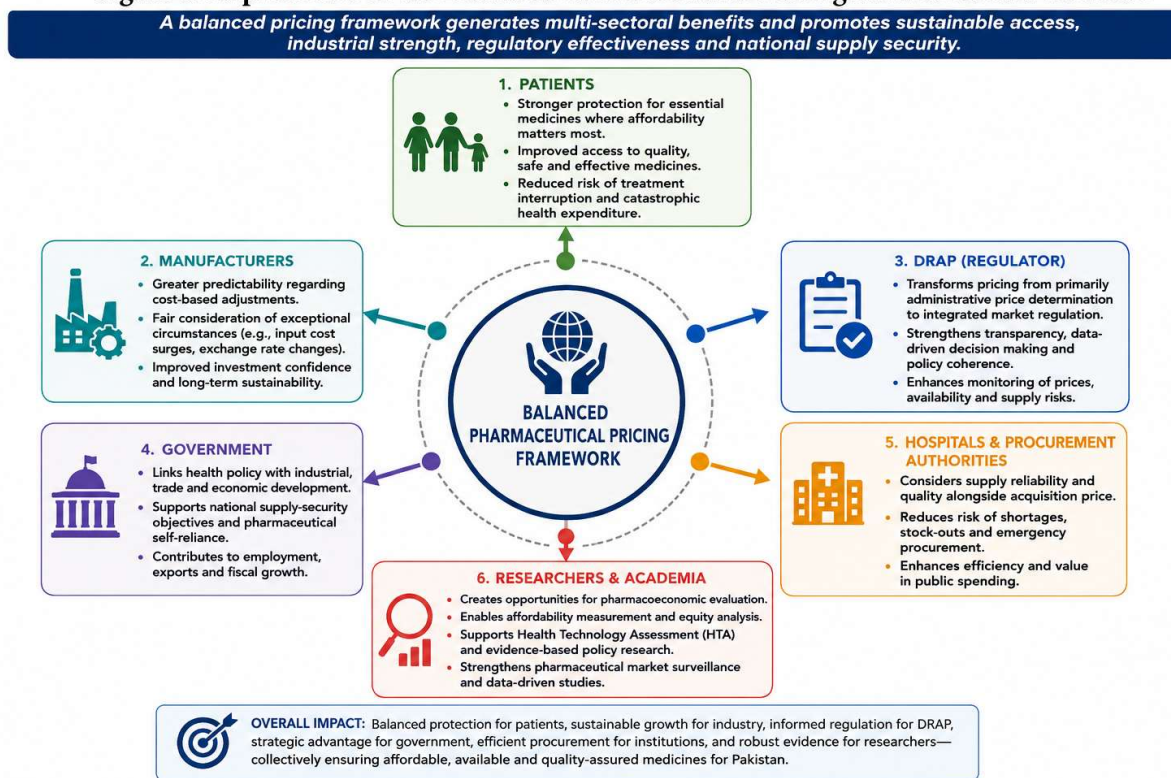


Figure 5. Implications of the balanced Pharmaceutical Pricing

For patients, it provides stronger protection for medicines where affordability matters most.

For manufacturers, it creates greater predictability regarding cost-based adjustments and exceptional circumstances.

For DRAP, it transforms pharmaceutical pricing from primarily administrative price determination toward integrated market regulation.

For government, it links health policy with industrial, trade and national supply-security objectives.

For hospitals and procurement authorities, it introduces supply reliability and quality alongside acquisition price.

For researchers, it creates opportunities for pharmacoeconomic evaluation, affordability measurement, HTA and pharmaceutical-market surveillance.

Major Findings

The analytical evidence supports several principal findings.

1. Pharmaceutical affordability and pharmaceutical availability are inseparable policy objectives.
2. Uniform pharmaceutical price regulation is economically inefficient because therapeutic importance, competition and supply risk differ substantially among medicines.
3. Unrestricted deregulation cannot reliably protect patients in monopoly or concentrated pharmaceutical markets.
4. Excessive administrative price suppression can undermine production incentives and contribute to withdrawal or shortage risks.
5. Essential and strategically critical medicines justify stronger regulatory protection than competitive non-essential products.
6. International practice supports combining multiple mechanisms—including generic competition, reference pricing, negotiation, value assessment, procurement and market monitoring—rather than relying upon a single pricing instrument.
7. Pharmaceutical supply resilience is increasingly becoming an explicit policy objective internationally, as demonstrated by the EU's approach to critical medicines.
8. Pakistan requires a transition from price regulation alone to pharmaceutical market governance.

Conclusion

Pakistan's pharmaceutical pricing debate should move beyond the traditional opposition between regulation and deregulation. Both extremes contain substantial risks. Rigid price suppression may protect nominal affordability temporarily but can weaken manufacturing incentives, discourage investment and contribute to medicine shortages. Unrestricted pricing may strengthen commercial incentives but expose patients to excessive prices, particularly where competition is weak. A scientifically defensible pharmaceutical pricing system must, therefore, distinguish among products according to therapeutic importance, competition, affordability, manufacturing economics and supply vulnerability. The proposed Pakistan Balanced Pharmaceutical Pricing Framework provides such an approach. Its central principle is straightforward “Regulate according to risk, encourage competition where possible, protect affordability where necessary, and preserve supply at all times”. Under this model, essential medicines would receive stronger regulatory oversight; competitive products could receive greater pricing flexibility; innovative medicines could undergo value-informed assessment; shortage-prone products could receive supply-security intervention; generic competition would be strengthened; price and availability data would become transparent; and industrial policy would progressively reduce dependence upon imported pharmaceutical inputs.

Such an approach would align Pakistan more closely with the broader direction of international pharmaceutical policy, in which medicine price, patient access, market competition and supply resilience are increasingly treated as interconnected objectives. WHO itself emphasizes that pharmaceutical pricing policies should be carefully designed, implemented, monitored and

periodically revised according to evolving conditions. The ultimate measure of pharmaceutical pricing policy should therefore not be whether medicine prices are administratively **low** or commercially high. It should be whether safe, effective and quality-assured medicines remain continuously available and genuinely affordable to the population while the pharmaceutical system remains economically sustainable.

Future Perspectives

1. Develop a technology-driven pharmaceutical regulatory system over the next decade.
2. Introduce digital price reporting for near-real-time pharmaceutical market surveillance.
3. Apply predictive analytics for early identification of medicine shortages.
4. Expand electronic procurement systems for price and supply comparisons across provinces and hospitals.
5. Integrate API import, manufacturing, and supply data to identify strategic vulnerabilities.
6. Institutionalize Health Technology Assessment (HTA) for innovative medicines, biologics, oncology treatments, and advanced therapies.
7. Strengthen international regulatory harmonization and quality standards to facilitate pharmaceutical exports.
8. Promote domestic API manufacturing to reduce dependence on vulnerable international supply chains.
9. Recognize pharmaceuticals as a component of national health-security infrastructure.
10. Progress from static price administration toward adaptive pharmaceutical market stewardship.

Recommendations

1. Establish a National Pharmaceutical Pricing and Access Strategy involving DRAP, health authorities, industry, academia, healthcare professionals, patients, and health economists.
2. Legally classify medicines as essential, critical, competitive, innovative, orphan, and shortage-prone.
3. Maintain strong price oversight for essential medicines and products with limited competition.
4. Allow greater pricing flexibility in genuinely competitive markets, supported by mandatory reporting and market surveillance.
5. Develop a Pharmaceutical Input Cost Index incorporating API costs, exchange rates, inflation, energy, and manufacturing inputs.
6. Establish a Medicine Affordability Index reflecting patients' ability to pay.
7. Introduce a national Supply Security Score for strategically vulnerable medicines.
8. Establish a public Pharmaceutical Price and Availability Observatory under DRAP.
9. Require advance notification of essential-medicine discontinuation.

10. Link exceptional price relief for shortage-prone medicines to enforceable supply commitments.
11. Strengthen generic and biosimilar competition, bioequivalence capacity, quality assurance, and professional education.
12. Develop formal HTA capacity for high-cost and innovative therapies.
13. Incorporate quality and supply reliability, not price alone, into public pharmaceutical procurement.
14. Provide targeted support for domestic API production and pharmaceutical manufacturing capacity.
15. Strengthen GMP standards, regulatory convergence, complex generics, biologics, and value-added pharmaceutical exports.
16. Conduct periodic regulatory impact assessments covering affordability, availability, shortages, production, competition, quality, and exports.
17. Pursue the overarching objective of ensuring that patients can afford medicines, manufacturers can sustainably produce them, regulators can effectively supervise the market, and Pakistan can reliably secure its pharmaceutical needs.



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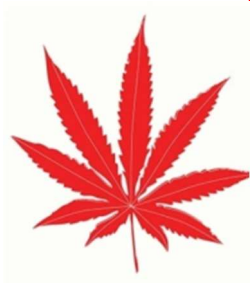
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