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Analytical Review

**DRUG REGULATORY SYSTEMS AND PHARMACEUTICAL GOVERNANCE
IN PAKISTAN: ALIGNING WITH GLOBAL LANDSCAPE OF PATIENT-
CENTRED PHARMACEUTICAL CARE**

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ABSTRACT

Pharmaceutical governance is the cornerstone of ensuring medicine safety, efficacy, quality, and equitable access, particularly as health systems worldwide transition toward patient-centered pharmaceutical care. In Pakistan, the Drug Regulatory Authority of Pakistan (DRAP), established under the DRAP Act 2012, has made notable strides through recent reforms, including the 4th edition of the National Pharmacovigilance Guidelines (2025), mandatory electronic adverse event reporting via the Med Vigilance platform, full adoption of PIC/S Good Manufacturing Practice (GMP) standards, and accelerated implementation of serialization/2D barcoding for traceability. Nevertheless, systemic challenges persist: a high prevalence of substandard and falsified medicines, heavy dependence on imported active pharmaceutical ingredients (APIs), regulatory capacity constraints, and incomplete integration of pharmacist-led, outcome-focused care models. This structured narrative review critically examines Pakistan's regulatory framework against international benchmarks set by the World Health Organization (WHO), International Council for Harmonization (ICH), U.S. Food and Drug Administration (FDA), and European Medicines Agency (EMA). It identifies persistent gaps and offers evidence-based, actionable recommendations to accelerate alignment with contemporary patient-centered paradigms.

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Ethical Considerations No human or animal subjects were involved; this is a review of publicly available data.

Disclaimer The views expressed are those of the authors and do not necessarily reflect the official positions of affiliated organizations or regulatory bodies.

Authors' Contributions SC: Conceptualization, literature search, initial drafting. TN: Corresponding author, methodological framework, critical revisions, final approval. MTA: Critical review of governance structures and policy implications. SR: Comparative global analysis, editing for international context. All authors read and approved of the final manuscript.



Introduction:

Pharmaceutical governance encompasses the policies, institutions, and enforcement mechanisms that safeguard the quality, safety, and efficacy of medicines across their entire lifecycle. Globally, the field has shifted decisively from a product-centric focus to patient-centered pharmaceutical care, which prioritizes individualized therapeutic outcomes, integration of real-world evidence, robust pharmacovigilance, and expanded multidisciplinary roles for pharmacists. In low- and middle-income countries (LMICs) such as Pakistan, progress is constrained by persistent challenges, including a high burden of substandard and falsified medical products, over 90% reliance on imported APIs, and limited clinical integration of pharmacy services.

The establishment of DRAP in 2012 centralized previously fragmented functions under the Drugs Act 1976. Subsequent reforms (2024–2025) have introduced enhanced pharmacovigilance protocols, digital reporting systems, and international harmonization efforts. This review synthesizes these developments, benchmarks them against global standards, and delineates strategic pathways for deeper alignment with patient-centered care principles.

PRISMA-Informed Systematic Search Methodology

Although framed as a narrative review to allow critical synthesis and contextual interpretation, the literature search was conducted systematically in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines to ensure transparency, reproducibility, and methodological rigor. Comprehensive searches were performed in PubMed, MEDLINE, Google Scholar, and DOI-indexed repositories, supplemented by official DRAP, WHO, ICH, FDA, and EMA documents and policy reports published between 2000 and 2025.

Search Strategy and Selection Criteria

Keywords and Boolean combinations targeted regulatory evolution, pharmacovigilance, governance challenges, digital transformation, and patient-centered care in Pakistan and comparable LMICs. Records were screened independently by two reviewers; duplicates were removed, and eligibility was assessed at

title/abstract and full-text stages using predefined inclusion/ exclusion criteria focused on relevance, quality, and recency.

Data Extraction and Synthesis

Eligible data were extracted into a standardized Excel matrix, thematically coded, and synthesized through narrative integration supported by descriptive statistics where appropriate. This hybrid approach combines the breadth of a narrative review with the systematic rigor of PRISMA, enabling both evidence-based correlations and expert interpretation.

Evolution of Drug Regulatory Systems in Pakistan

Prior to 2012, regulation under the Drugs Act 1976 was decentralized and weakly enforced. The creation of DRAP centralized key functions—including product registration, GMP oversight, pricing, and post-market surveillance, marking a foundational step toward modernization.

Key recent advancements include:

- Pharmacovigilance Rules 2022 and the National Pharmacovigilance System Guidelines (4th edition, effective 2025), which mandate National Pharmacovigilance Centre (NPC)-led signal detection and mandatory electronic reporting through the Med Vigilance platform.
- PIC/S GMP adoption (2025) via S.R.O. 1587(I)/2025, aligning manufacturing inspections with international standards.
- Mandatory serialization and 2D barcoding for all batches (accelerated 2025) to enhance traceability.
- Digital transformation toward full e-governance, with a target of 100% implementation by late 2026.

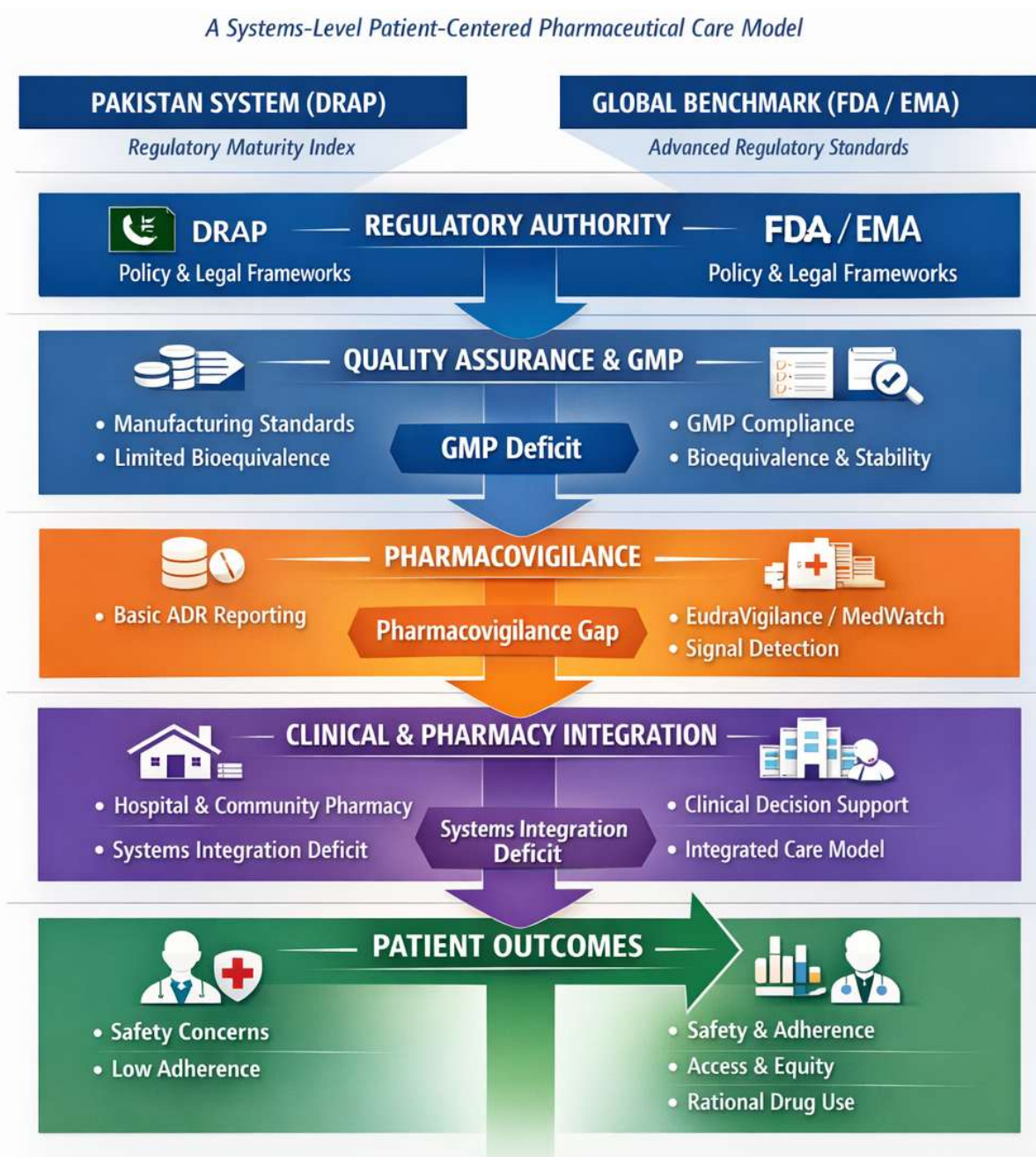
These reforms reflect a clear trajectory from basic regulatory control toward a more mature, digitally enabled system.

Core Components of Pharmaceutical Governance

Table 1: Core Regulatory Components in Pakistan (2025 Status)

Component	Key Functions	Current Status (2025)	Challenges
Drug Registration	Pre-market safety, efficacy, quality evaluation	Centralized via e-portal; persistent delays	Procedural inefficiencies
GMP Compliance	Manufacturing oversight and inspections	PIC/S-aligned; variable enforcement	Capacity and compliance gaps
Pharmacovigilance	ADR monitoring, signal detection, risk assessment	Med Vigilance e-reporting mandatory; NPC-led	Underreporting; emerging maturity
Clinical Trials	GCP and ethical oversight	ICH-aligned; expanding ecosystem	Limited infrastructure
Pricing & Market Surveillance	Affordability control; post-market monitoring	Hybrid model with recent deregulation pilots	Stakeholder tensions; supply shortages

Conceptual Framework



Source: WHO, FDA, EMA, DRAP | Prepared by: Dr. Taha Nazir

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Figure 1. Drug Regulatory System and Pharmaceutical Governance Framework; Pakistan Vs Global Benchmark.

There is a conceptual framework of pharmaceutical governance leading to patient-centered outcomes in Pakistan (mentioned in Figure 1). This sequential pathway illustrates the logical progression from regulatory

foundations through quality assurance, pharmacovigilance, and clinical integration to measurable patient outcomes in Pakistan’s evolving system.

Comparative Analysis of Regulatory Maturity (2025–2026)

Table 2: Pakistan (DRAP) vs. Advanced Systems (FDA/EMA, 2025)

Indicator	Pakistan (DRAP Status 2026)	Global Benchmark (FDA/EMA)	Strategic Gap / Action Required
Pharmacovigilance	Active; Med Vigilance mandatory; NPC-led signals	Proactive; AI-driven real-time detection; Big Data integration	Transition to predictive, AI-based risk modelling
Pricing Model	Hybrid; deregulation of non-essentials; MRP caps	Value-based; prices linked to outcomes/HTA	Institutionalize HTA frameworks
Supply Chain	Secured; 2D barcoding/serialization mandatory	Interconnected; blockchain/GS1 global standards	Achieve 100% retail-level compliance in rural sectors
Clinical Role	Emerging; pharmacist ADR reporting recognized	Embedded; clinical pharmacists lead MTM	Update Pharmacy Act 1967 to mandate ward-based roles

Global Trends in Pharmaceutical Governance

International regulatory science now emphasizes patient-centered models that link regulatory decisions to clinical outcomes, integrate real-world evidence, and embed clinical pharmacists in medication therapy management (MTM). Regulatory harmonization (ICH/WHO), AI-driven pharmacovigilance, blockchain-enabled supply chains, and health technology assessment (HTA) for value-based pricing represent the current benchmark. While DRAP’s ambition for complete digital integration by 2026 is commendable, the “digital divide” between urban Tier-1 manufacturers and rural pharmacies remains a critical bottleneck. True patient safety gains require the digital loop to close at the point of dispensing.



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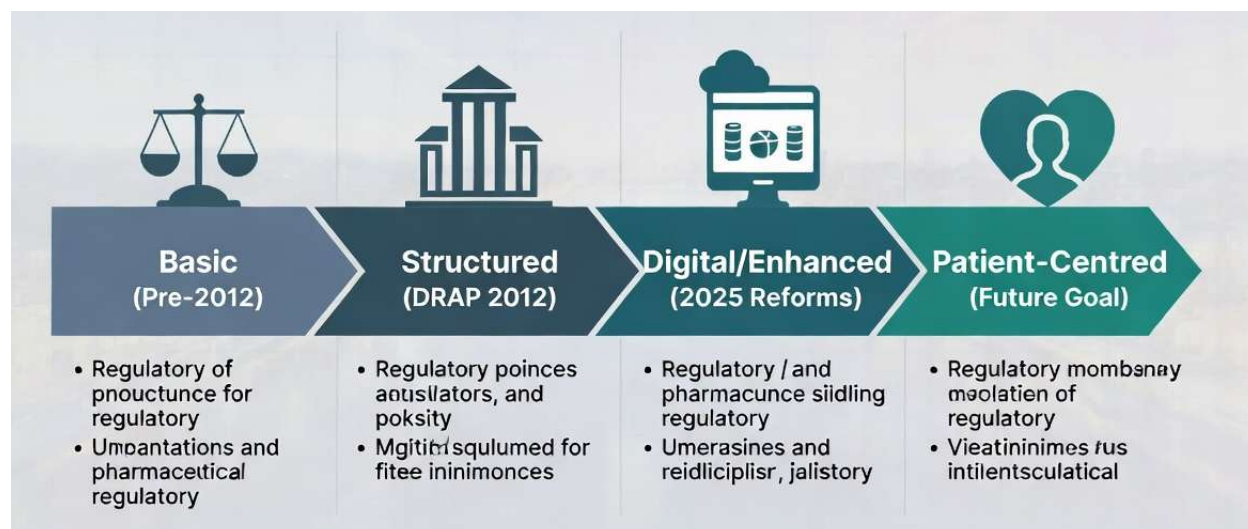
Figure 2. Conceptual Framework of Pharmaceutical Governance in Pakistan.

The framework given in Figure 2 illustrates the sequential pathway from regulatory foundations to improved patient-centered outcomes in Pakistan's evolving pharmaceutical governance system.

Potential Challenges

Despite progress, Pakistan continues to face:

- A significant burden of substandard and falsified medicines (WHO estimates >10% in LMICs; ongoing 2025 rapid alerts).
- Institutional constraints, including shortages of trained regulatory personnel and infrastructure.
- Underutilization of pharmacists beyond dispensing roles.
- Supply-chain vulnerabilities and persistent regulatory delays.
- Slow adaptation to personalized and digital health technologies.



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Figure 3. Regulatory Maturity Model: Progression of Pakistan's Pharmaceutical Governance.

This progressive model given in Figure 3 depicts the evolutionary stages of regulatory development, highlighting the strategic pathway toward full alignment with global patient-centred pharmaceutical care standards.

Patient-Centred Pharmaceutical Care Perspective Contemporary global standards position pharmacists as integral members of multidisciplinary teams, leading medication reconciliation, therapeutic monitoring, and patient education. In Pakistan, emerging evidence (e.g., Hamza *et al.*, 2025; Khan *et al.*, 2024) demonstrates that pharmacist-led interventions improve adherence and clinical outcomes. However, policy gaps and structural barriers limit translation from regulatory intent to bedside practice. To bridge this divide, Pakistan must adopt a dual strategy: (1) legislative mandates for clinical pharmacy services in tertiary care, and (2) full empowerment of pharmacists within the Med Vigilance ecosystem as frontline generators of real-world evidence. Such integration would directly reduce medication errors, enhance therapeutic equity, and ensure that 2025 reforms deliver measurable patient benefit.

Conclusion DRAP's 2024–2025 reforms - particularly in pharmacovigilance, GMP alignment, and digital traceability—represent a substantial leap forward in Pakistan's pharmaceutical governance. Yet, sustained investment in regulatory capacity, technological innovation, and pharmacist integration is essential to achieve full alignment with global patient-centred standards and to deliver safer, more equitable health outcomes for the Pakistani population.

Recommendations

1. Accelerate capacity-building through structured training programmes and sustained WHO/ICH technical collaboration.
2. Prioritize AI-enhanced pharmacovigilance and complete e-governance rollout, ensuring rural pharmacy inclusion.
3. Enact national policies mandating pharmacist participation in multidisciplinary care teams and ward-based services.
4. Strengthen supply-chain transparency via public databases and end-to-end track-and-trace systems.
5. Promote local API synthesis through targeted tax incentives and industry-academia partnerships to reduce import dependence.

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