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Research Paper

Barriers to Export Expansion in Pakistan's Pharmaceutical Sector: A Structural Analysis

Dr Aneel Salman
Sheraz Ahmad Choudhary

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Abstract

The pharmaceutical industry in Pakistan is a very vital sector of the national healthcare and industrial development, but has structural and regulatory bottlenecks that restrict the growth of the pharmaceutical industry as well as competitiveness in exports. The lack of innovation and foreign investment is restricted by overdependence on imported raw materials, poor adherence to international standards, and inconsistent pricing policies. Although the digitisation of approvals and deregulation of the non-essential prices of drugs like DRAP are positive moves, the industry is still in need of structural improvement in terms of quality infrastructure, localisation of API, and facilitation of exports as a way of realising the full potential of the sector and making it grow sustainably.

Introduction

The pharmaceutical industry in Pakistan is a vital component of the healthcare system and the country's industrial economy. The Pakistan Credit Rating Agency Limited (PACRA, 2025) estimated Pakistan's gross domestic product (GDP) at around PKR 114. 7 trillion in 2025 (FY 25), with a real growth rate of 2.7%, up from 2.5% in FY 24. The pharmaceutical sector, a key component of large-scale manufacturing (LSM), continues to significantly contribute to Pakistan's growth due to its close ties with other manufacturing sectors. (PBS 2025)

In recent years, the sector has undergone major changes and consolidation. Lucky Core Industries Limited acquired Pfizer Pakistan, marking the exit of one of the largest multinational pharmaceutical firms from the domestic market. This acquisition highlights the increasing strength and confidence of local companies in the Pakistani health sector. Similarly, Searle Company Limited became the first Pakistani pharmaceutical firm to achieve a significant milestone in export growth, signalling increasing global competitiveness. Other notable multinational companies like GlaxoSmithKline Pakistan, Abbott Laboratories Pakistan Ltd., and Haleon Pakistan Ltd. continue to dominate the branded pharmaceutical sector (PACRA, 2025).

The industry also relies heavily on foreign firms for active pharmaceutical ingredients (APIs) and raw materials, primarily through imports. In FY 24, imports reached PKR 304.1 billion, reflecting a 7.1% annual growth. China accounted for the largest share of pharmaceutical imports at 58.6%, followed by India at 13.5%, Korea at 4.5%, Germany at 4.2%, and Italy at 3.6%. This dependence indicates a low level of API localisation and exposes the supply chain to fluctuations in the global market. In terms of exports, Afghanistan is the main destination for Pakistani pharmaceutical products, accounting for about 38% of total exports in FY 24, with other markets in the Middle East and Africa (SBP, 2025).

The local market trends have been changing in demand trends as influenced by the environment and the health of the people. The use of medicines to treat flu and throat infections has been on the rise, which is mainly because of the health problems brought about by smog in the heavily populated regions. This highlights the connection between environmental degradation and the demand for pharmaceuticals. On the financial side, the pharmaceutical companies in Pakistan have low profitability owing to fluctuations in exchange rates and price regulation that have been imposed by DRAP, which restricts the capability of companies to entirely transfer the price changes to consumers (PACRA, 2025). The numbers presented in the State Bank of Pakistan (SBP), the Pakistan Bureau of Statistics (PBS), and the Economic Survey of Pakistan give more macroeconomic background to this analysis.

The Drug Regulatory Authority of Pakistan (DRAP), established in 2012 under the DRAP Act, is responsible for registering medicines, setting prices, and ensuring quality to meet international standards of safety and efficacy. The Pakistan Pharmaceutical Manufacturers Association (PPMA), along with DRAP, represents local pharmaceutical producers and coordinates industry compliance. (DRAP, 2025). The Drug Regulatory Authority of Pakistan (DRAP) has embarked on a major regulatory and pricing agenda with deregulation of the prices of non-essential drugs and digitisation of drug approvals to enhance efficiency (Pakistan Today, 2025). The government aims to have an annual growth of exports of up to 5 billion dollars, and these aims are backed by the pledges of development of quality infrastructure, membership of the PIC/S, and trade diplomacy and incentives (Business Recorder, 2025). These are the steps which are evidence of increasing awareness that structural and regulatory reforms, as opposed to subsidies, are necessary to tap the pharmaceutical potential of Pakistan and enable sustainable export growth.

Problem Statement

The pharmaceutical industry in Pakistan is still a fringe player in the global markets though there is a high domestic base and increased global demand of generics. The annual exports have not yet reached USD 0.5billion- less than 2 percent of the estimated potential of the sector- because the system failed to pull through the market, there is no integrated structure and institutional capacity to integrate with the global market. Basic issues on the part of the regulatory regime include slow drug approval, lack of adherence to international quality standards, and reliance on imported APIs, and unreliable pricing, which indicates a lack of maturity and credibility in the regulatory system. Meanwhile, the vast majority of companies do not have the magnitude, certification, and innovativeness to enter more valuable markets.

Such gridlock in structure creates a chronic lack of performance at a time when even other countries of the world, such as Bangladesh and Jordan, have used focused reforms to grow exports exponentially. In the absence of necessary reform, Pakistan will be missing out on the multi-billion-dollar export market, losing the potential of both important foreign exchange earnings and industrial development in 5-10 years.

Diagnostic Framework: Explaining Systemic Failures in Pakistan's Pharmaceutical Exports

Framework Tool	Focus of Diagnosis	Key Findings	Reform Leverage Points
Value Chain Analysis	Identifies bottlenecks from R&D to export delivery	• Weak R&D investment• Dependence on imported APIs• Poor compliance with global GMP• Limited export logistics	• API localization support• GMP upgrade subsidies• Export facilitation centers
Regulatory Maturity Analysis	Benchmarks DRAP against global regulatory standards (e.g. WHO, PIC/S, FDA/EMA)	• DRAP lacks WHO Maturity Level 3• No PIC/S membership• No FDA/EMA-approved plants	• DRAP institutional reform• Join PIC/S• WHO-prequalification technical assistance
Export-Readiness Benchmarking	Evaluates firm-level capacity (quality, certification, product mix, marketing)	• Few firms internationally certified• Over-reliance on basic generics• Weak foreign presence	• Certification grants• R&D tax incentives• Export branding and B2B support
Comparative Competitiveness Scoring	Scores Pakistan vs. peer exporters (India, Bangladesh, Jordan) on critical indicators	• Pakistan lags in API self-sufficiency, regulatory credibility, and global market share	• Learn from peer strategies (e.g. Bangladesh's TRIPS use, India's API parks)• Policy prioritization

There are a number of structural issues affecting the pharmaceutical industry in Pakistan that impede the development of the industry and its exportation capabilities. The time-consuming drug approval process and weak pricing regulations have not encouraged investment and some multinational companies have opted out in the market. Lack of strong compliance with international quality standards and non-participation in international regulatory programs restricts access to high-value export markets. The reliance of the industry on imported raw materials and high input costs and foreign exchange limit have led to delays in production and high cost of production. The weak research capacity, the disunity of the industrial structure, and the lack of technical skills also limit the innovativeness and competitiveness. Moreover, inadequacy in infrastructure, constant power outages, and limited access to financing are additional factors that are increasing the cost of operations so that the sector has not been able to realize sustainable growth.

No.	Constraint	Description	Source
1	**Regulatory Bottlenecks and Policy Unpredictability**	Slow drug approval processes (often exceeding a year) and erratic pricing policies, including ad-hoc price freezes, have reduced profitability and discouraged new product launches. Some multinationals exited Pakistan due to these regulatory inefficiencies.	(Attarwala, 2022)
2	**Weak Quality Compliance Infrastructure**	Many local manufacturers fail to meet international Good Manufacturing Practice (GMP) standards. Pakistan is not part of PIC/S, lacks FDA or EMA-approved plants, and has only one WHO-prequalified medicine, limiting access to regulated export markets.	(Krishnan & John, 2025)
3	**High Input Costs and Foreign Exchange Hurdles**	Heavy dependence on imported active pharmaceutical ingredients (APIs) and raw materials, combined with tariffs, taxes, and currency devaluation, has driven up costs. Import restrictions and foreign exchange shortages have caused material scarcity and production disruptions.	(WTO, 2023)
4	**Limited Technical Capacity in R&D and Testing**	Pakistan lacks accredited laboratories and advanced research centers. Firms must send samples abroad for testing, increasing costs and delays. Investment in R&D and specialized skills (e.g., biotechnology and regulatory science) remains very low.	(WTO, 2023)
5	**Fragmented Industry and Weak Export Orientation**	The industry is dominated by small firms with limited capacity to modernize or access foreign markets. Pakistani companies have minimal international presence, weak branding, and limited experience in global distribution.	(WTO, 2023)
6	**Infrastructure and Financing Issues**	Persistent infrastructural problems (e.g., electricity load-shedding, poor logistics) raise operational costs. Financing is constrained by high interest rates and limited access to subsidized credit or export financing for pharmaceutical firms.	(WTO, 2023)

Strengths and Capabilities

The pharmaceutical industry of Pakistan have capabilities that are composed to achieve its growth in the future. The industry has the potential to expand with an already developed manufacturing base, experience in the production of cheap generic drugs, and a huge domestic market. It has competitive advantage in regional exports due to its partial local input production, low-cost production and strategic geographic location. Initiatives in enhancing quality and initial biopharmaceutical innovation show the ankle strides in world standards. In addition, the increased attention given to the potential of the sector as an economic and industrial development driver can be seen through the recent governmental support offering investment facilitation, reduction of tariffs, and stimulating exports.

No.	Strength Area	Description
1	**Extensive Manufacturing Infrastructure**	Around 800 licensed units across major hubs (Karachi, Punjab, Islamabad) provide ample production capacity to meet domestic needs and potentially expand exports.
2	**Expertise in Generic Medicines**	Local firms specialize in low-cost branded generics, benefiting from low labor costs, skilled workforce, and decades of production experience.
3	**Large and Growing Domestic Demand**	A population of over 240 million ensures sustained demand for medicines, especially for infectious and non-communicable diseases.

4	**Partial Local Supply Chain**	Pakistan produces some APIs, excipients, and packaging materials locally, supported by its textile and chemical industries, reducing limited import reliance.
5	**Improving Quality and Compliance**	Select firms are upgrading to meet international standards (e.g., WHO prequalification, pharmacovigilance programs), signaling commitment to global compliance.
6	**Cost and Geographic Advantages**	Low manufacturing costs and proximity to Central Asia, the Middle East, and Africa provide logistical and price competitiveness.
7	**Emerging Diversification and Innovation**	Early ventures into biopharmaceuticals, clinical trials, and technology transfer projects indicate gradual industry modernization.
8	**Supportive Policy Focus**	Recent government initiatives (SIFC, tariff reductions, export financing) show increasing policy support for sectoral growth and export promotion.

Domestic Market Dynamics

The dynamics of the domestic pharmaceutical market in Pakistan are shaped by robust demand drivers on one hand and regulatory/economic frictions on the other. Understanding these factors is important, as the health of the local market underpins the sector's overall performance and its ability to eventually expand internationally.

Strong Health Demand, with Epidemiological Challenges: The increasing population and dual disease burden in Pakistan, infectious diseases such as tuberculosis and hepatitis and the increasing non-communicable diseases such as diabetes, hypertension, etc. maintain the high demand of medicine. The rate of chronic disease development is growing at an alarming rate, and the cost of access to complicated treatment is constrained. Demographic factors will also drive demand because life expectancy will increase (World Bank, 2021).

Out-of-Pocket Spending and Access Constraints: It is estimated that over 85% of pharmaceutical expenditures in Pakistan are paid directly by households rather than covered by insurance or government programs (World Bank, 2021). Pharmaceutical expenditures are out-of-pocket, and the affordability is a major concern (World Bank, 2021). The sensitivity of prices and income inequality limits access to medicines particularly in rural environments. The per capita expenditure is low at an average of 15- 20 a year. Government programs such as Sehat Sahulat Program will increase insurance coverage and access.

Public vs. Private Sector Roles: Approximately 75 percent of the distribution of medicine is in the private sector with the free but limited supplies being offered by the public hospitals. There is lack of procurement efficiency, tender prices extremely low, and provincial purchasing in fragments, which causes shortages and quality issues. Small-scale NGO-based interventions still have not served rural regions (World Bank, 2021).

Pricing Regulation and Market Economics: Pakistan has a hard pricing of drugs where the government has stipulated Maximum Retail Prices. In 2018, the Drug Pricing Policy added some inflation-based changes, and in 2024, the non-essential drugs were deregulated to market (Pakistan Today, 2025). Necessary drugs are kept under check. Production costs had been reduced due to tax incentives such as the reduction in GST and importation duties (WTO, 2023). These measures enhanced stability of supply and promoted local production but the issue of affordability versus sustainability of the industry is vital.

Market Outcomes and Trends: The domestic market can be characterized as high-volume, low-value. A large number of medication units are sold, but mostly cheap generics, resulting in a low average spending per person. It is a high-volume but low-margin market that is dominated by generics. The cost of medicines is relatively low but heavy to the low-income group. Local production helps in supplying necessities to supply drugs, but there are limited levels of innovation and export competitiveness. The confidence in the industry has been boosted

through pricing reforms and a reduction in taxes, which however require long-lasting policy stability to improve growth (Pakistan Today, 2025).

"The lack of structural capabilities and unmatched growth policies hinder the growth of the pharmaceutical industry in Pakistan by deterring long-term investments and subsidiary growth in the industry. The unpredictability of regulations, scattered approval procedures and outlived quality requirements- coupled with constrained financing on R&Ds and reliance on imported raw material- have provided an ecosystem where firms are finding it challenging to scale or innovate. The regulatory structure of DRA, despite its good intentions, tends to decelerate competitiveness as it has long registration processes, ambiguous pricing algorithms, and lacks expeditious tracks in which companies investing in quality or export preparedness can be registered. To recover investor confidence, Pakistan needs to embrace timeless approvals, open-minded pricing systems, and systematic and informative regulation-industry dialogue. The sector is further undermined by vulnerabilities in supply chain, particularly the high degree of importation of APIs. The stabilization of supply chains will entail specific incentives to produce APIs locally, the establishment of pharmaceutical clusters with common facilities, sourcing diversification, and enhanced foreign exchange and Global Customs.

This industry is still largely generics-driven as innovation-based manufacturing including biosimilars, biotech, and complex preparations is costly in terms of capital, technical, and marketing policy. The ways that can influence Pakistan towards more value products include providing incentives in the field of R and D, create biotech centers of excellence, enhance the industry-academic relationships, and develop differentiation regulatory routes in complex formulations.

In the meantime, the regional rivals (India, Bangladesh) have developed international credibility with WHO prequalification and internationally recognized certifications, which allows them to scale exports. This should be the same quality-led approach that Pakistan should employ by investing in the modernization of manufacturing facilities, assisting in certifications expenses, enhancing the DRAP to meet the global standards of greater maturity, and using diplomatic efforts to penetrate the markets in Africa, Middle East, and Central Asia. An issue that stands out in all these problems is the lack of engagement between industry and policymakers and in particular, pricing, regulation, and export incentives. This must be overcome by an institutionalized institutional partnership between the government and the pharmaceutical industry, whether as a standing Pharmaceutical Competitiveness Council, or with task forces on API self-reliance, exports, and R&D. A structured, coordinated and collaborative policy environment is the only way in which Pakistan can give its pharmaceutical sector a chance to realize its full potential and become a credible regional exporter."

Dr Nasir Abbas, RUB Associates, Eastern Farms

Export Challenges

Pakistan's pharmaceutical exports remain disproportionately small given the size of its domestic industry. The country's annual pharma exports have hovered below $0.5 billion, which is modest compared to peers – for context, Jordan's pharmaceutical exports are roughly $700–800 million and Bangladesh's about $200+ million (Krishnan & John, 2025; Business Recorder, 2025). More strikingly, India's pharmaceutical exports exceed $25 billion annually, underscoring how far Pakistan lags in global market integration. Several factors explain why Pakistan isn't exporting more pharmaceuticals:

- **Compliance and Regulatory Recognition Deficit:** The pharmaceutical sector in Pakistan is not globally regulated, as there are no pharmaceutical manufacturing

facilities in the United States of America and Europe, which are approved by the FDA or EMA, as of 2025. Some of the rival countries such as India and Bangladesh have various approvals. PIC/S does not have Drug Regulatory Authority of Pakistan (DRAP) as its member; its inspections are not recognized internationally. Paquistani products have not been prequalified by WHO except one, which sharply limits exports to African and Central Asian markets that are less regulated. The absence of mutual recognition agreements does mean that firms would have to request approvals on a country-by-country basis had to deal with trust and perception of quality that limits Pakistan to low-tier markets.

- **Limited Export Product Portfolio:** The majority of exports in Pakistan are basic generics (tablets and capsules to treat common ailments), which comprise more than 95% of all exports (WTO, 2023). The industry is small in high value segments like vaccines, biotech drugs, APIs or advanced formulations. In contrast to India and China, Pakistan is not diversified and specialized in its export, as it is based on the products with low margins and competitiveness in prices, which are the reflections of the domestic production trends.
- **Weak Branding and International Business Development:** The local brands of Pakistani companies are domestic based and do not have worldwide branding. Not many of them have export offices or foreign marketing departments and depend on the middlemen who decrease profits and market dominance.
- **Minimal Export Promotion and Trade Support:** Pharmaceutical export support is not high in the government. Pakistan does not have any good trade agreements or harmonized regulatory frameworks to facilitate market entry. Bonuses such as 1.5 per cent export rebate were not created until 2018, and their rivals have an organized scheme and subsidies. Despite postulating plans of a Pharma Export Cell and WHO-related rebates (Business Recorder, 2025), there has been a slow and fragmented pace in its implementation, which ensures that the export promotion is weak and inconsistent.
- **Competition in Target Markets:** Pakistan experiences severe rivalry in the markets where India, China and Bangladesh are leading merchants in exports. These nations enjoy the economies of scale, API control and favourable trade agreements. Having a higher cost and similar generic offerings, the Pakistani companies do not manage to compete in terms of price and market penetration, as they have no trade leverage and product differentiation.
- **Perception and Reliability Issues:** The overall attitude to the pharmaceutical quality in Pakistan is poor because of the contamination cases in the past and the inability to control the quality of the offered products. Buyer confidence is undermined by continued economic instability, restrictions on imports and currency volatility. International customers feel that Pakistani suppliers cannot be trusted in terms of long-term contracts and high quality of products or services and that solid quality and consistency of work are necessary to restore its reputation.

"Pakistan has a total of 629 pharmaceutical companies. Despite the huge potential of this industry in Pakistan, which is estimated to be in the range of USD 1 billion, the industry is still facing a number of challenges that have threatened to impede its growth. At the moment, Pakistan does not have any significant position in markets that are highly regulated, like that of the United States, mainly because of structural and regulatory deficiencies. The pharmaceutical industry has a number of challenges despite its potential, such as corruption,

poor governance, systemic ineffectiveness, and is lack of trust. In addition, Pakistan has never had the capacity to satisfy the standards demanded by the developed nations. This has meant that no pharmaceutical production plant has the FDA approval in Pakistan, and this greatly restricts the export opportunities.

The other gap that is very critical is the inefficiency in communication and cooperation between industry and academia. Pakistan is also relying on India as a source of raw materials in the pharmaceutical manufacturing business, and this makes it more vulnerable and restricts its growth. The local industry is not well supported by the government. Rather, multinational companies are given special treatment, particularly in issues concerning exports, since they are likely to be given monetary rewards. The government needs to support local pharmaceutical companies to ensure sustainable growth.

Some of the major measures entail lowering registration charges, enhancing the international mechanism of money transfer, as Pakistan is already experiencing problems with sending money abroad in USD, and offering trusted third-party facilitation where the need arises. A single-window registration would also make the administration processes very easy. Moreover, the government needs to establish the regulation standards that are similar to the FDA to make the local manufacturing more credible and allow it to export. Pakistan's pharmaceutical industry also has an opportunity to explore and enter the potential markets in Africa and the Middle East with the proper aid of the concerned ministries, especially the Ministry of Foreign Affairs."

Nasir Qureshi, CEO Paramount Pharmaceutical

Policy and Regulatory Landscape

Pakistan's current policy and regulatory framework for the pharmaceutical sector is a mix of modern statutes and legacy mechanisms. The government's role is multifaceted: it regulates drug quality, safety and efficacy; controls medicine prices; imposes or waives import duties and taxes; and provides industrial incentives or trade support. A clear understanding of this landscape helps identify where reforms are most needed.

Identified Constraint	Targeted Policy Intervention	Sequencing	Outcome
1. Weak regulatory maturity and credibility	• Strengthen DRAP's staffing and digital approval system• Fast-track WHO Maturity Level 3• Join PIC/S and enable mutual recognition	Short-term (0–2 yrs)	Increased trust, faster approvals, access to regulated markets
2. Poor quality infrastructure and GMP non-compliance	• Launch a GMP Certification Incentive Program• Fund upgrades in labs and inspection systems	Short–Mid (1–3 yrs)	More firms achieve WHO/FDA compliance
3. Import dependence on APIs and cost vulnerability	• Establish national API clusters with tax exemptions and capital grants• Incentivize local production via interest-free credit	Mid-term (2–4 yrs)	Lower input costs, improved supply resilience
4. Firm-level export unreadiness (scale, certification, marketing)	• Provide export certification grants• Support international branding and trade fair access	Mid-term (2–4 yrs)	More export-ready firms with stronger global presence
5. Fragmented public-private coordination	• Create a permanent Pharmaceutical Export Council• Institutionalize industry-government engagement	Immediate (0–1 yr)	Sustained reform alignment and faster issue resolution

6. Limited export facilitation and finance	• Establish export facilitation centers• Expand concessional credit for quality-linked exporters	Short–Mid (1–3 yrs)	Eased export processes and greater investment in compliance

Findings

- The pharmaceutical industry in Pakistan faces difficulty in the form of slow approval of drug market, unpredictable pricing interests and lack of credibility of its regulatory credibility. Pakistan lacks WHO ML-3 status, PIC/S membership and any FDA/EMA approved facilities.
- There is a poor compliance in quality in the industry where most of the firms cannot comply with global standards of the GMP, poor WHO prequalification and lack of modern testing and inspection facility.
- The high reliance on the imported active pharmaceutical ingredients (APIs) which are mostly Chinese and Indian products have high production costs, high foreign exchange exposure and frequent supply chain interruptions.
- The Innovation and export readiness are low due to low R&D capacity of firms, lack of accredited labs, small scale business and low quality of export portfolio consisting of low valued generic medicines.
- There are structural constraints that limit the global competitiveness of the industry and its capacity to compete with regional counterparts such as India, Bangladesh, and even Jordan, which include poor financing, high operation and logistic costs, weak trade diplomacy, and the little government support.

Policy Recommendations

- Pakistan should introduce strict 90-day timelines for registration decisions with automatic escalation of pending files, fully digitise all DRAP approval and inspection processes, and establish a transparent Pricing Review Board that issues quarterly pricing updates based on inflation, exchange rates, and input costs.
- A national WHO ML-3 Upgradation Roadmap should be launched with dedicated funding and external technical assistance, while selected pharmaceutical clusters should receive fast-track support to upgrade infrastructure and attract international consultants to move facilities toward FDA and EMA compliance.
- Pakistan should establish ISO-accredited national reference laboratories in major industrial hubs, implement mandatory annual GMP audits conducted by accredited third-party bodies, and create a GMP Upgrade Fund to help firms modernise cleanrooms, HVAC systems, and microbiology labs.
- A Pharmaceutical Quality Training Academy within DRAP is needed to train workers on international quality standards, while the publication of a public GMP compliance scorecard for all manufacturers would enhance transparency and incentivise quality competition.
- Pakistan should develop specialised API Industrial Parks with shared utilities to offer long-term tax holidays and duty-free import of API manufacturing equipment, and provide subsidised financing through the State Bank for the establishment of fermentation-based or chemical synthesis-based API plants.
- Technology-transfer agreements with global API producers should be actively pursued, and a national priority API list should be introduced with enhanced incentives for local production to improve supply chain resilience.

- Pakistan should expand low-interest export refinancing schemes, establish dedicated Customs Desks at major ports to reduce clearance times for pharmaceutical consignments, and negotiate mutual recognition agreements with regional trade blocs to facilitate easier market entry.
- Dedicated pharmaceutical export zones with reduced electricity tariffs and subsidised logistic facilities should be developed, complemented by a government-backed credit guarantee scheme to help smaller firms access financing. Additionally, a global outreach initiative should be launched to promote Pakistani pharmaceuticals at major international exhibitions and strengthen trade diplomacy.

Conclusion

The pharmaceutical industry in Pakistan is at a crossroad- between chronic systemic problems and the new reform wave. Regulatory credibility needs to be institutionalized in Pakistan, and quality assurance mechanisms need to be enhanced to shift the industry, which is locally focused and driven by generic aspects, to a globally competitive sector. The level of maturity of WHO Maturity Level 3 and PIC/S membership would make the world more confident and unlock regulated markets and expansion of exports. At the same time, the modernization and transparent governance of DRAP must also be given priority ensuring an efficient approval process, equitable price structure, and regular implementation of the policy.

The increase of R&D and local manufacturing of API is also important to decrease the foreign reliance and enhance the cost-competitiveness. The financial aid, including concessional credits and incentives based on exports, should be directed to companies that are seeking quality certifications and global conformity. The digitalization of the integration of the DRAP, customs, and trade authorities will help facilitate procedures and enhance transparency. Further, the set-up of export facilitation centres and industry-academia collaborations will facilitate skill training and readiness to comply.

Action Matrix

Action Area	Pathways to Solution	How to Implement Each Solution	Actor Responsible	Timelines
Strengthen the Institutional Capacity of DRAP	Increase technical staffing, digitise approval processes, and introduce performance-based monitoring	• Conduct skills-gap assessment and hire technical experts • Deploy digital approval & licensing system • Implement KPIs and quarterly audits	DRAP, MoNHSRC, Public Service Commission, Planning Commission	6–18 months
Predictable & Transparent Pharmaceutical Pricing	Link pricing with inflation & input costs; reduce ad-hoc interventions	• Develop pricing policy using CPI & input cost index • Annual/bi-annual adjustments • Publish pricing dashboard	DRAP Pricing Division, MoNHSRC, Ministry of Finance	12–24 months
Promote Local API Production	Targeted subsidies, tax relief, R&D partnerships	• Capital subsidies for API plants • 5–10 year tax exemptions • Joint R&D centers with universities • National API Development Fund	Ministry of Industries, DRAP, FBR, HEC, Private Sector	18–36 months
Improve Export Competitiveness	Establish export facilitation centers; regulatory compliance support	• Export hubs in major cities • WHO & GMP compliance training • Support for export documentation	TDAP, DRAP, Ministry of Commerce	6–18 months
Enhance Access to Finance	Concessional loans & export credit for quality upgrades	• SBP refinance schemes • Low-interest credit for GMP certification	SBP, EXIM Bank, Ministry of Finance	3–12 months
Develop Digital/AI Regulatory Channel	Unified digital platform linking DRAP, Customs & Trade	• Build interoperable digital system • AI-based verification tools	DRAP IT Division, FBR Customs, TDAP, Ministry of IT	12–30 months

Theory of Change

	Inputs	Activities	Outputs (1–3 Years)	Short-/Mid-Term Outcomes (3–5 Years)	Long-Term Outcomes (5–10 Years)	Impact (10+ Years)
Description for Pakistan's Pharmaceutical Sector Reform	• Government budget for DRAP strengthening and API localisation incentives. • Technical specialists in GMP, regulatory science, QC, and digital regulation. • Partnerships with WHO, USP, PIC/S, international regulators, and universities. • Digital infrastructure (drug registration portals, inspection software, integrated databases). • SBP refinance schemes, EXIM Bank credit lines, tax incentives for API and quality upgrades. • Industry engagement platforms (Pharma Competitiveness Council).	Regulatory Strengthening: Skills-gap assessments; hiring experts; digitizing approvals and inspections; implementing predictable pricing policy. Quality Infrastructure Improvement: Upgrading drug testing labs; risk-based inspections; WHO/GMP certification training. API Localisation: Subsidies for API plants; zero-duty input policies; API clusters; joint R&D with academia. Export Competitiveness Measures: Export facilitation centers; export documentation support; market-entry and compliance training. Financing Reforms: Refinancing through SBP; concessional credit for facility upgrades; credit guarantees for exporters.	• DRAP technical capacity expanded; digital approval and pricing systems operational. • Updated GMP guidelines and trained inspectors; accredited, upgraded QC labs. • API subsidy/tax frameworks implemented; at least two API clusters initiated. • Export support centers operational in Karachi, Lahore, Islamabad. • Availability of concessional financing and EXIM Bank support for exporters.	1. Regulatory Maturity Strengthened: Faster approvals, predictable pricing, improved GMP enforcement. 2. Improved Quality Compliance: More firms achieving WHO GMP, validated manufacturing systems, stronger QA/QC. 3. Expanded Export Readiness: Increased firms entering African, Middle Eastern, and Central Asian markets. 4. Growing API Production Capacity: Reduced import vulnerability; lower production costs.	• DRAP advances to WHO Maturity Level 3 (ML-3); PIC/S membership achieved. • Firms secure FDA/EMA/WHO certifications and access high-value regulated markets. • 20–30% API localization achieved, reducing forex risk and improving cost competitiveness. • Sector develops innovation capabilities (biotech, biosimilars, complex generics).	• Pakistan becomes a globally credible pharmaceutical exporter, achieving USD 3–5 billion annual exports. • A resilient, quality-driven sector that contributes significantly to GDP, skilled employment, and health security. • Improved international reputation, stronger industrial self-reliance, and sustainable export-led growth.

About the Authors

Dr. Aneel Salman holds the distinguished OGDCL-IPRI Chair of Economic Security at the Islamabad Policy Research Institute (IPRI) in Pakistan. As a leading international economist, Dr Salman specialises in Monetary Resilience, Macroeconomics, Behavioural Economics, Transnational Trade Dynamics, Strategy-driven Policy Formulation, and the multifaceted challenges of Climate Change. His high-impact research has been widely recognised and adopted, influencing strategic planning and policymaking across various sectors and organisations in Pakistan. Beyond his academic prowess, Dr Salman is a Master Trainer, having imparted his expertise to bureaucrats, Law Enforcement Agencies (LEAs), military personnel, diplomats, and other key stakeholders, furthering the cause of informed economic decisionmaking and resilience.

Sheraz Ahmad Choudhary is a Research Associate at IPRI. He is affiliated with the University of Sussex and his areas of expertise are Macroeconomics, Trade Public Finance, and Environmental Economics

Annex-1

Table 1: Pakistan Pharmaceutical Trade by HS Code (2020)

HS Code & Description	**Exports (2020)**
HS 3004	Medicaments in measured doses (e.g. tablets, capsules), common finished drugs
HS 3003	Medicaments not in measured doses (bulk formulations)
HS 3002	Immunological products (vaccines, blood products, etc.)
HS 3005	Dressings, gauze, bandages etc.
HS 3006	Pharmaceutical goods (e.g. test kits, reagents)
Others	(3001: organo-therapeutic, etc.)
Notes: *Pakistan's pharma exports are dominated by finished generic drugs (HS 3004), while imports include a large proportion of vaccines/biologics (HS 3002). This highlights the opportunity for local vaccine production. Data: UN Comtrade via Trendeconomy.*	

Annex-II

Table 2: Major Players in Pakistan's Pharmaceutical Industry

Sr.	Company Name	National / MNC
1	Getz Pharma	National
2	Sami Pharmaceuticals	National
3	GlaxoSmithKline Pakistan	MNC
4	Abbott Laboratories Pakistan Ltd.	MNC
5	The Searle Company	National
6	Martin Dow Ltd.	National
7	Hilton	National
8	OBS	National
9	High-Q International	National
10	Haleon Pakistan Ltd.	MNC

Source: IQVIA, PARCA Database

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