Physical Education, Health and Social Sciences

https://journal-of-social-education.org E-ISSN: 2958-5996

P-ISSN: 2958-5988

The Challenges and Opportunities in Export of Pharmaceuticals from Pakistan

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DOI: https://doi.org/10.63163/jpehss.v3i1.171

Abstract

Pharmaceuticals are major sectors in terms of economic growth and public health, but the pharmaceutical exports from Pakistan are happening on account of various challenges. Some of the prime barriers are delays in regulatory approvals, high registration costs, trade barriers, supply chain inefficiencies, and a lesser local availability of Active Pharmaceutical Ingredients (API). Moreover, a few local bioequivalence testing facilities and their high costs of international certifications also restrict the global competitiveness of Pakistani pharmaceutical exports. The quantitative research method supporting deductive methodology has been applied in this study. A cross-sectional design comprises collecting data from professionals in the pharmaceutical export sector using self-administered questionnaires. Findings indicating the presence of regulatory inefficiency, financial constraints, and infrastructure inadequacy are holding a very significant impact on the export performance of local manufacturers making it difficult to compete globally. The adoption of international certifications and the establishment of bioequivalence testing facilities with export incentives would also pay much contribution to the establishment of a Pharmaceutical Special Economic Zone (SEZ). All of these have to be in place so that these barriers are lifted from struggling pharmaceutical exporters, giving them latitude to work with less operational hurdles and more compliance with global standards in opening up new market opportunities. This research provides appreciation for stakeholders and policymakers, showing how to strengthen Pakistan against the global pharmaceutical market.

Keywords: Pharmaceutical Exports, Regulatory Barriers, Trade Barriers, Supply Chain Infrastructure, Bio-equivalence Testing, Export Incentives, Export Competitiveness.

Introduction

The pharmaceutical sector encompasses the research, manufacturing, distribution, and marketing of medicinal products, including both generic and branded drugs. In Pakistan, the industry primarily revolves around the production of generic medicines due to limited investment in research and development (R&D) for innovative drugs. The market is highly concentrated, with the top 100 companies controlling 97% of sales, leaving little room for small and mid-sized enterprises to expand. Moreover, about 95% of raw materials are imported, making production costs high and increasing reliance on external suppliers. Meeting regulatory standards, particularly those set by the Drug Regulatory Authority of Pakistan (DRAP) and international organizations like the WHO and US FDA, remains a significant hurdle due to inadequate R&D, a lack of skilled professionals, and issues with quality control. Despite these challenges, the

pharmaceutical industry remains an essential part of Pakistan's economy and has immense potential to grow in international markets if compliance and innovation improve. Exporting pharmaceuticals involves selling domestically produced medicines in international markets, which requires strict compliance with global quality and safety standards. At present, Pakistan exports medicines mainly to semi-regulated and unregulated markets, including Afghanistan, Sri Lanka, the Philippines, Myanmar, Vietnam, Cambodia, Uzbekistan, Kenya, Sudan, and Egypt. However, the country struggles to gain access to highly regulated markets governed by authorities such as the US FDA and EMA due to various challenges. These include complex regulatory approval processes, the absence of internationally accredited bioequivalence testing facilities, concerns over counterfeit drug perceptions, and government-imposed pricing regulations that reduce competitiveness. Enhancing regulatory infrastructure and establishing bioequivalence testing facilities that meet international standards can help Pakistan's pharmaceutical industry break into more strictly regulated markets. Ensuring compliance with both national and international regulatory frameworks is crucial for pharmaceutical manufacturing, quality control, and exports. In Pakistan, DRAP oversees regulatory compliance and mandates that manufacturers follow current Good Manufacturing Practices (cGMP). However, aligning with global standards such as those of the WHO, US FDA, and EMA remains a challenge. The lack of bioequivalence testing centers and internationally accredited quality control laboratories further limits export opportunities. Investing in quality assurance, government-backed WHO prequalification initiatives, and stronger industry-academic partnerships for regulatory training could significantly improve compliance and make Pakistani pharmaceuticals more competitive in the global market. Challenges in the supply chain create additional obstacles for pharmaceutical exports. Heavy reliance on imported raw materials, particularly active pharmaceutical ingredients (APIs), exposes the industry to price fluctuations, trade restrictions, and supply disruptions. Weak infrastructure, high transportation costs, and inefficient cold chain logistics further complicate the export of temperature-sensitive products such as vaccines. Additionally, customs delays and bureaucratic inefficiencies slow down shipments, leading to higher costs and reduced global competitiveness. Addressing these challenges by improving local API production, upgrading logistics, and streamlining customs procedures could strengthen Pakistan's pharmaceutical exports. Trade-related obstacles also hinder the growth of Pakistan's pharmaceutical exports. The complex and time-consuming export registration process often delays market entry for pharmaceutical companies. Additionally, high import duties on raw materials significantly drive up production costs, making it difficult for local firms to compete internationally. Since 95% of pharmaceutical raw materials are imported, these tariffs severely impact profit margins. Another challenge is the lack of Free Trade Agreements (FTAs) with major pharmaceutical markets, putting Pakistani exporters at a disadvantage compared to competitors from countries with preferential trade agreements. Intellectual property (IP) and patent-related restrictions further limit expansion, as many local firms focus on generic drug production and struggle to enter markets with strict patent protections. Lowering trade barriers, introducing export incentives, and negotiating FTAs with key markets could help Pakistan's pharmaceutical industry establish a stronger international presence. Trade regulations play a crucial role in determining Pakistan's export competitiveness. Studies show that high tariffs, bureaucratic inefficiencies, and a lack of trade agreements restrict the industry's ability to expand into new markets. The current export landscape is highly concentrated, with limited diversification, making it vulnerable to external disruptions. Reducing tariffs, streamlining customs procedures, and expanding trade agreements with key markets could help Pakistani pharmaceutical exporters compete more effectively on a global scale. Government intervention through export incentives and improved trade policies is essential for strengthening the industry's global positioning.

Background of Study

At the time of Pakistan's independence in 1947, there were no pharmaceutical manufacturing facilities in the country. By the 1960s, local manufacturers had started emerging, but most medicines were still imported, and industry regulations were minimal until 1967. During this period, multinational

corporations (MNCs) began entering the market, contributing to the sector's development. Over the decades, the pharmaceutical industry has grown significantly. According to estimates from Intercontinental Medical Statistics (IMS) Health Quintiles, Pakistan now has 759 active pharmaceutical manufacturers, while DRAP reported 637 registered firms as of September 2018. However, industry experts suggest that the actual number of operating pharmaceutical firms exceeds 700

Pharmaceuticals Industry Size & Growth

Pakistan's pharmaceutical industry is currently valued at approximately USD 3.2 billion, experiencing rapid growth at an annual rate of 15%. Over the past decade, the sector has undergone substantial changes, expanding its role in providing essential healthcare solutions and introducing significant pharmaceutical advancements. With over 700 pharmaceutical manufacturing units operating nationwide, the country exports medicines worth over USD 202 million to more than 60 countries.

Despite this impressive expansion, the industry continues to face numerous challenges, particularly in terms of regulatory constraints and a lack of consistent government engagement with sector stakeholders. Organizations such as PRIME have previously highlighted these concerns, emphasizing the need for policy reforms. Their research and advocacy efforts play a crucial role in supporting industry growth and fostering discussions on economic freedom. As pharmaceutical manufacturers, we acknowledge and value such independent research, hoping it will lead to meaningful dialogue about the industry's future in Pakistan.

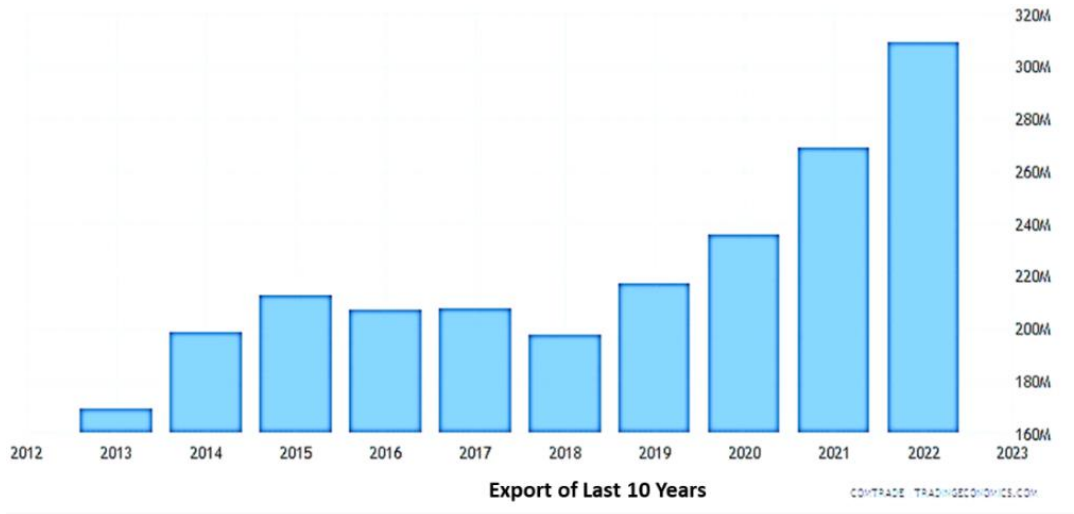
Pharmaceutical Companies Mnc's and Local

The majority of pharmaceutical companies in Pakistan are concentrated in Punjab and Karachi, Sindh. The industry is marked by a clear divide between multinational corporations (MNCs) and domestic manufacturers. Prior to 2010, there were 38 MNCs operating in the country, holding a dominant 60% share of the market. However, in recent years, this number has declined to 22, reducing their market share to 40% and allowing local pharmaceutical firms to expand their presence. The government maintains strict oversight of the pharmaceutical industry through the Drug Regulatory Authority of Pakistan (DRAP), which is responsible for regulating manufacturing standards, registering new medicines, and setting maximum retail prices (MRP) for pharmaceutical products in the country. Despite its significant market presence, the domestic pharmaceutical industry has not achieved the expected growth trajectory seen in other rapidly developing sectors. It remains largely uncompetitive on the global stage, with limited export volume. For instance, in 2015, Pakistan's pharmaceutical exports were valued at just USD 200 million—a stark contrast to India's USD 14 billion and Jordan's USD 800 million, despite Jordan's smaller population of only 9 million. Furthermore, India has 201 US FDA-certified manufacturing plants, while Jordan has four, enabling both countries to access highly regulated markets such as the United States and secure a significant share of the global pharmaceutical trade. In contrast, Pakistan's lack of US FDA-approved facilities and lower export figures highlight persistent challenges related to regulatory compliance and product quality. This study aims to analyze the critical factors affecting Pakistan's pharmaceutical exports, particularly the barriers that restrict market access to countries governed by strict regulatory authorities (SRAs). It will explore the challenges identified by industry experts, the underlying

reasons behind these limitations, and potential solutions. Although this study focuses on Pakistan, its findings may provide valuable insights for other developing nations facing similar export challenges.

Pharmaceutical Export in Pakistan

Expanding international trade is a key driver of economic growth and national development. A robust trade network strengthens diplomatic ties, fosters mutual economic interests, and creates opportunities for foreign investments, employment generation, and technological advancements. A stable political and economic environment encourages stronger trade relationships, positioning Pakistan for greater prosperity. By addressing regulatory barriers, improving compliance with global standards, and enhancing export competitiveness, the pharmaceutical sector can play a more significant role in the country's overall economic progress.



Leading Companies in Export

GETZ PHARMA (PRIVATE) LIMITED	46%
GENIX PHARMA (PRIVATE) LIMITED	7%
THE SEARLE COMPANY LIMITED	6%
SAMI PHARMACEUTICAL PVT LTD	6%
HILTON PHARMA (PRIVATE) LIMITED	5%
CCL PHARMACEUTICALS (PVT.) LIMITED	4%
ATCO LABORATORIES LIMITED	3%
PHARMEVO (PRIVATE) LIMITED	3%
AGP LIMITED	3%
NABI QASIM INDUSTRIES (PRIVATE) LIMITED	2%

Strategic Trade Policy Framework (Stpf)

The Government of Pakistan has introduced various initiatives to boost exports, aiming to drive sustainable economic growth, reduce poverty, and improve living standards. This vision aligns with the Strategic Trade Policy Framework (STPF) 2020–25, which seeks to transform Pakistan into a competitive, export-driven economy while strengthening its domestic market. As part of this framework, the Ministry of Commerce has prioritized the Pharmaceuticals Export Strategy, recognizing pharmaceuticals as a key export sector. This strategy was developed in close collaboration with industry stakeholders, with strong contributions from the private sector. By focusing on export quality, market expansion, and product diversification, the strategy lays the foundation for significant growth in pharmaceutical exports. Additionally, it emphasizes the need for substantial investment to enhance trade potential and access new markets. A detailed five-year action plan has been designed to address industry challenges and streamline export processes based on stakeholder insights. Despite global trade uncertainties and a complex business landscape, this initiative offers a structured approach to improving Pakistan's trade performance. The Ministry of Commerce remains committed to playing an active role in implementing proposed reforms in collaboration with stakeholders. A key focus is empowering the private sector through the Sector Specific Council (SSC) on Pharmaceuticals & Cosmetics, ensuring that industry players take the lead in execution. The government continues to prioritize export-led growth and encourages all stakeholders to work together toward a thriving pharmaceutical sector.

Pakistan's Pharmaceutical Industry and Export Potential

The STPF 2020–25 has recognized the pharmaceutical sector as a priority area for growth and expansion over the next five years. Currently, the industry is valued at USD 3.29 billion, with sustained double-digit growth over the past five years. This sector has seen considerable transformation, improving access to essential medicines and introducing advanced pharmaceutical innovations. At present, Pakistan has 639 pharmaceutical manufacturing units, employing approximately 240,000 people, with exports exceeding USD 200 million to over 60 countries.

Current Industry Landscape

Government reforms have played a crucial role in supporting the sector's growth. Policies such as reduced customs duties on over 300 active pharmaceutical ingredients (APIs) and the duty-free import of plants, machinery, and equipment for registered pharmaceutical manufacturers have strengthened the industry. These measures have positioned pharmaceuticals as a key contributor to the national economy, with plans to further increase export revenues. The domestic pharmaceutical industry currently fulfills over 95% of local demand, with an emphasis on providing high-quality medicines at competitive prices. Moving forward, the goal is to expand exports by targeting value-added markets in Central Asia, the Middle East and North Africa (MENA), Europe, and the United States. However, the industry still faces persistent challenges, including pricing issues, weak intellectual property protections, delays in regulatory approvals, and limited investment in research and development. The Pakistan Pharmaceutical Manufacturers' Association (PPMA) acknowledges the importance of the export strategy in addressing these barriers and anticipates meaningful discussions to support the sector's growth. Pakistan's pharmaceutical sector is highly dynamic and knowledge-intensive, undergoing modernization to improve local production capabilities and gain access to more regulated international markets. Achieving this requires a strong regulatory framework and policy support to facilitate industry expansion. Since the sector has a significant multiplier effect on employment, strategic investments in workforce development, foreign partnerships, and innovation will be crucial. This export strategy provides a comprehensive roadmap for future growth, focusing on quality, competitiveness, research, and new market entry. With

the global pharmaceutical industry evolving—especially in the post-COVID-19 landscape—Pakistan has the opportunity to align with emerging trends and maximize its potential in both existing and new markets.

International Demand for Pharmaceuticals

The global pharmaceutical market is undergoing significant changes, creating new opportunities for Pakistan's pharmaceutical industry. Shifts in demand and supply chains offer a chance for Pakistan to strengthen its position in the international pharmaceutical trade. With a population of 215 million and 639 pharmaceutical companies, the country is well-positioned to capitalize on these evolving market dynamics.

Unlocking Pakistan's Untapped Export Potential

While Pakistan has developed into a regional pharmaceutical manufacturing hub, its presence in the global market remains relatively small. The country's exports are primarily focused on generic medicines and a limited number of markets. However, there is significant untapped potential for growth. This strategy aims to strengthen the pharmaceutical value chain and increase the number of market participants at each stage. Foreign investment could play a crucial role in expanding Pakistan's pharmaceutical sector. To attract investment, Pakistan must ensure political stability, economic growth, access to local raw materials, regional market expansion opportunities, and stronger intellectual property protections. A recent success story is a local company securing a licensed technology transfer from a leading U.S. firm to produce a COVID-19 antiviral drug, demonstrating the industry's potential for advanced pharmaceutical manufacturing.

Challenges Limiting Export Growth

Government incentives could be instrumental in enhancing the capabilities of local manufacturers and attracting multinational pharmaceutical firms to invest in Pakistan. Establishing a robust regulatory system that guarantees the safety, efficacy, and quality of medicines would further strengthen investor confidence. The pharmaceutical value chain is highly sophisticated, involving multiple stages of production and requiring strict compliance with international regulations. In Pakistan, the industry is regulated by a complex network of national, provincial, and semi-autonomous bodies overseeing licensing, drug registration, pricing, and distribution. This fragmented regulatory structure presents challenges related to infrastructure, quality testing, and certification, which can hinder industry growth. By addressing these barriers and implementing targeted reforms, Pakistan has the potential to transform its pharmaceutical sector into a globally competitive industry. With coordinated efforts between the public and private sectors, the country can position itself as a key player in international pharmaceutical trade while meeting domestic healthcare needs.

Problem Statement

Pharmaceutical exports play a crucial role in economic growth, yet developing nations like Pakistan struggle to compete in the global market due to various regulatory, trade, and supply chain challenges. While the industry has significant potential, several constraints hinder its ability to expand internationally and enhance export performance. Drug regulatory constraints, including delayed approvals, high registration fees, and limited adoption of international certifications (e.g., WHO, USFDA, PICS), create barriers to market entry and prolong export processes. Similarly, trade regulatory challenges—such as high tariffs, customs inefficiencies, and inadequate export incentives—restrict the industry's ability to scale globally. Moreover, supply chain limitations, including reliance on imported Active Pharmaceutical Ingredients (APIs), the lack of advanced bioequivalence testing facilities, and inadequate technological infrastructure, contribute to higher production costs and reduced-price competitiveness.

This study aims to examine how these regulatory, trade, and supply chain challenges impact pharmaceutical export performance. By identifying key constraints and assessing their effects, the research will provide valuable insights about policy reforms and strategic interventions that can enhance Pakistan's pharmaceutical exports and global competitiveness.

Research Questions

1. How do drug regulatory constraints impact pharmaceutical export performance?
2. What is the effect of trade regulatory barriers on pharmaceutical export performance?
3. How does supply chain infrastructure influence pharmaceutical export performance?

Research Objectives

➢ To examine the impact of drug regulatory constraints on pharmaceutical export performance.
➢ To analyze the effect of trade regulatory barriers on the export performance of pharmaceuticals.
➢ To assess the role of supply chain infrastructure in shaping pharmaceutical export competitiveness.

Significance of the Study

The pharmaceutical sector is a key driver of economic growth, yet developing economies like Pakistan face persistent challenges in expanding their global market share. This study is significant as it systematically examines the regulatory, trade, and supply chain barriers that limit the country's pharmaceutical export performance. By identifying these constraints, the research provides evidence-based insights for policymakers, industry stakeholders, and pharmaceutical firms to enhance international competitiveness. Understanding the impact of drug regulatory constraints—such as high registration fees, delayed approvals, and limited international certifications—can help shape policy reforms that streamline the export process. Likewise, evaluating trade regulatory barriers, including high tariffs, customs inefficiencies, and insufficient export incentives, will highlight the need for improved trade policies and financial support mechanisms. Furthermore, assessing supply chain infrastructure, particularly the dependence on imported Active Pharmaceutical Ingredients (APIs), inadequate bioequivalence testing facilities, and outdated technological frameworks, will provide a strategic roadmap for strengthening local production capabilities and reducing export costs. The study's findings can guide the development of policies such as adopting international certifications (WHO, USFDA, PICS), improving bioequivalence testing infrastructure, and leveraging financial incentives to create a more export-friendly environment. Additionally, insights from this research can serve as a foundation for the establishment of a Pharmaceutical Special Economic Zone (SEZ), fostering an ecosystem that supports high-value pharmaceutical exports. By bridging the knowledge gap on pharmaceutical export challenges, this research will contribute to academic discourse while offering practical recommendations for industry players and regulatory bodies. It is expected to help stakeholders develop more effective strategies to position Pakistan as a stronger competitor in the global pharmaceutical market.

Literature Review

Theoretical Underpinning

In the context of pharmaceutical exports, several theoretical models provide a foundation for understanding export readiness. This study incorporates Porter's Diamond Model, Rahman's Model of International Positioning, and Sharma et al.'s Multi-Criteria Decision Analysis, which collectively highlight the importance of internal and external factors in shaping a firm's ability to succeed internationally. Porter's Diamond Model explains the competitive advantage of nations in export activities through four components: firm strategy, structure, and rivalry, demand conditions, related and supporting industries, and factor conditions. It underscores the role of staff qualifications and managerial expertise as critical internal factors for export success.

Rahman's model focuses on effective international positioning, helping firms assess internal capabilities, external opportunities, and strategic market positioning. This framework enables pharmaceutical companies to systematically evaluate staff qualifications, export policies, and market strategies to enhance global competitiveness. Sharma et al.'s Multi-Criteria Decision Analysis (MCDA) provides a structured decision-making approach to prioritize factors affecting export performance. It emphasizes the systematic evaluation of internal and external elements, ensuring firms align their resources with global market demands and regulatory compliance. These models collectively establish a robust foundation for analyzing how staff qualification and managerial expertise influence pharmaceutical export readiness. Their integration offers strategic insights to enhance human capital and optimize international market expansion. (Mohammadzadeh, 2012b)

Pharmaceutical Export

Pakistan's pharmaceutical industry faces significant challenges in expanding its exports beyond a limited number of semi-regulated and unregulated markets. While Pakistani medicines are exported to countries such as Afghanistan, Sri Lanka, Myanmar, Vietnam, Cambodia, and Kenya, access to highly regulated markets like the USA, EU, and Japan remains largely restricted. But why? The industry's reliance on generic drug manufacturing is a double-edged sword. While generics are affordable and widely used, they lack the innovation and research-driven appeal needed to compete in strictly regulated markets. Furthermore, the market is heavily concentrated, with 100 dominant firms controlling 97% of the industry, leaving little room for smaller companies to engage in exports. The lack of local bioequivalence testing facilities further exacerbates the issue, as proving drug efficacy is essential for meeting global pharmaceutical standards. Without these facilities, Pakistani firms struggle to secure approvals in high-standard regulatory environments. (Zobia et al., 2024) Despite these challenges, Pakistan's pharmaceutical sector holds significant export potential. A study assessing Pakistan's competitiveness in pharmaceutical exports through the Revealed Comparative Advantage (RCA) index highlights the country's strengths. The findings suggest that Pakistan possesses a comparative advantage in exporting pharmaceuticals. To leverage this advantage, the country must focus on targeted product categories and adopt export-friendly trade policies. Strengthening international market access, supporting domestic manufacturers, and investing in quality standards, production facilities, and research are critical steps toward sustainable growth. These measures will not only enhance long-term competitiveness but also boost the pharmaceutical industry's contribution to national economic development. (Shahzad, Shahzad, & Ahmad, 2024)

Drug Regulatory Barriers

Regulatory compliance hurdles further restrict Pakistan's pharmaceutical exports. Meeting cGMP (Current Good Manufacturing Practices) and WHO prequalification standards is a formidable challenge for most manufacturers. However, a potential solution lies in the establishment of an Export Startup Program. The article suggests that a structured initiative emphasizing compliance, R&D investment, and global partnerships could significantly improve Pakistan's competitiveness in international markets.

Overcoming regulatory barriers is essential for this vision. Pakistani pharmaceutical firms face a complex regulatory landscape that requires compliance with stringent standards set by WHO, FDA, EMA, and PICS. Bureaucratic delays, limited resources, and stringent approval processes create additional obstacles for local manufacturers attempting to enter highly regulated markets. The Drug Regulatory Authority of Pakistan (DRAP) plays a crucial role, yet obtaining a No-Objection Certificate (NOC) and GMP certification is often a lengthy and cumbersome process. Another critical challenge is the absence of internationally accredited quality control laboratories. Without recognized domestic testing facilities, firms must seek costly foreign certifications, increasing export expenses. Negative media narratives surrounding counterfeit and substandard medicines further harm Pakistan's credibility in global markets.

Additionally, government-imposed pricing regulations force manufacturers to sell at fixed low prices, discouraging investment in high-quality, export-standard production. (Zobia et al., 2024)

Trade Barriers

Trade-related barriers also limit Pakistan's pharmaceutical export potential. The lengthy export registration process requires companies to navigate multiple layers of bureaucratic red tape, delaying market entry. High import duties on raw materials further increase production costs, making it difficult for Pakistani firms to compete internationally. Given that 95% of pharmaceutical raw materials are imported, these high tariffs significantly erode profit margins and hinder competitiveness. Another challenge is the absence of Free Trade Agreements (FTAs) with key pharmaceutical markets. While competitors from other countries benefit from preferential trade terms, Pakistani firms struggle to penetrate regions where FTAs could provide easier market access. Additionally, intellectual property (IP) and patent-related restrictions further constrain Pakistan's pharmaceutical exports. Since many local companies specialize in generic drug manufacturing, they face severe limitations in countries with strong patent protections, making expansion into regulated markets difficult. (Zobia et al., 2024) Trade regulatory barriers further influence Pakistan's pharmaceutical exports. Studies indicate that high tariffs, bureaucratic inefficiencies, and limited trade agreements restrict market expansion. The export market remains highly concentrated, with limited diversification, making the industry vulnerable to external disruptions. To address these challenges, reducing trade barriers—such as lowering tariffs and streamlining customs procedures—can enhance export competitiveness. Diversifying export markets through new trade agreements can also reduce dependency on a small number of trading partners. The government must actively implement export incentives and negotiate better trade terms to ensure Pakistan's pharmaceutical sector gains a stronger foothold in the global market. (Shahzad, Shahzad, & Ahmad, 2024)

Supply Chain Barriers

Supply chain barriers present further obstacles to the pharmaceutical export industry. Dependency on imported raw materials is a significant concern, as Pakistan relies heavily on foreign suppliers for Active Pharmaceutical Ingredients (APIs). This dependency exposes the industry to supply chain disruptions and price fluctuations. Infrastructure deficiencies, high transportation costs, and inefficient cold chain logistics further complicate pharmaceutical exports, particularly for products requiring strict temperature control, such as vaccines. Additionally, customs delays and bureaucratic inefficiencies slow down export processes, increasing costs and reducing global competitiveness. (Viviers, Lubbe, Steenkamp, & Olivier, 2014) While existing literature highlights various hurdles that impede the growth of the pharmaceutical industry, few studies have examined the specific reasons behind the persistent lack of resolution for these challenges. Additionally, there has been little focus on medicine exports. The literature identifies both local and international challenges that hinder domestic firms from exporting to markets with stringent regulatory authorities (SRAs) such as those in the USA, European Union, Japan, Australia, and Russia. Within the industry, market share is highly concentrated, with the top 100 firms out of approximately 759 (according to IQVIA) controlling 97% of the market, leaving only 3% for the remaining 650 firms. This imbalanced structure, combined with a lack of competitiveness, suggests that the sector is unable to contribute positively to national economic growth and public health. (Khan U, 2021) A significant issue is the absence of backward linkages to suppliers, as 95% of raw materials are imported. Furthermore, Section 12 of the Drug Act, which grants the authority to fix maximum prices for drugs, is recognized as a major barrier to the export of pharmaceutical products. Previous studies have highlighted challenges faced by the local pharmaceutical sector, including counterfeit medicines, pricing controversies, affordability issues, a lack of genuine research and development (R&D) initiatives, and unethical marketing practices, such as bribery and kickbacks to doctors. While Pakistan has progressively positioned itself as a manufacturing hub for pharmaceuticals, it still plays a minor role on the global stage.

The country's exports primarily consist of generics and are concentrated in a limited number of markets, leaving significant untapped potential in pharmaceutical exports. (Ahmed KA, 2020) This strategy aims to harness that potential by addressing various constraints related to infrastructure, testing and certification, trade policies, competition, and the availability of inputs and technology. These factors impact the quality and competitiveness of pharmaceutical products, which in turn affects profitability, export sustainability, and investment in the sector. (H, 2015) The strategy prioritizes high-demand product segments, including blood thinners, steroids, antibiotics, multivitamins, nutraceuticals, and vaccines. Key target markets will be Africa, Central Asia, and Europe. By implementing this strategy, the goal is to enhance exports through improved quality, increased value addition, and diversification, ultimately strengthening the national image by developing a recognized national medicine brand (https://tdap.gov.pk/pharmaceuticals/, n.d.). The requirement for a no-objection certificate for export, a certificate of current good manufacturing practices (cGMP) from DRAP, and bioequivalence certification from an accredited agency are considered significant barriers to exporting. Local facilities for testing and conducting bioequivalence studies are limited, although the reasons for this lack have not been clearly reported. Additionally, the scarcity of quality control laboratories accredited by WHO, FDA, or EMA, as well as internationally recognized facilities that can provide FDA certification for exports, are considerable constraints. Other obstacles hindering pharmaceutical industry growth include the import of raw materials, insufficient industrial research and development (R&D), lack of internationally-approved laboratory facilities, and limited access to global facilities. (FS., 2021) Exporters face specific challenges related to their destinations, as industrial growth must meet increasingly stringent quality, legal, and ethical standards for export-compliant manufacturing. Global health regulators regularly update their requirements, making successful exports progressively more demanding each year. Non-tariff measures, such as safety and quality standards and extensive documentation, are also mandatory for export compliance. Moreover, bioequivalence studies are necessary to demonstrate that a drug is similar to those sold and used in countries with SRAs. The pharmaceutical sector in Pakistan has significant export potential. With the right trade-friendly policies, Pakistan can achieve sustainable growth and robust industrial development. While there is literature on the export competitiveness of various products, research specifically focused on the pharmaceutical sector has been limited. This study aims to address that gap by examining the Revealed Comparative Advantage (RCA) of Pakistan's pharmaceutical exports. Utilizing the RCA index from 2004 to 2023, the study finds that Pakistan has a comparative advantage in exports in 2 out of 5 product groups at the HS level 4, and in 7 product groups at the HS level 6. With effective policy-making, this advantage can be enhanced, contributing to the sustainable growth of the country. (Shahzad, 2024)

Nutraceutical & Dedicated Export Council

To boost its pharmaceutical exports, experts recommend that Pakistan implement several strategic measures. First, establishing a dedicated agency—Pharmaceutical Council—focused solely on promoting exports could be advantageous. This agency could collaborate with stakeholders such as the Drug Regulatory Authority of Pakistan (DRAP) and the Ministry of Commerce to streamline export processes, offer incentives to export-oriented companies, and identify key markets for export. Additionally, Pakistan should develop a comprehensive market strategy targeting high-growth regions, particularly Africa. The continent's pharmaceutical market is expected to reach between $56 billion and $70 billion by 2030, presenting substantial opportunities for expansion. By focusing on these markets and understanding their specific regulatory requirements, Pakistan can leverage this growth potential to enhance its export presence. Furthermore, addressing issues related to nutraceutical exports could significantly improve Pakistan’s export capabilities. Nutraceuticals have the potential to generate approximately $10 billion in exports to developed countries. However, Pakistan needs to align its regulations with international standards to facilitate these exports and access global markets. (Hussain, 2024).

Challenges in Pakistan Pharmaceutical Market

Pakistan's rapidly growing population is driving an increasing demand for medicines. The local pharmaceutical market is expanding at a faster rate than the international market. Prior to 1990, multinational companies dominated the supply of medicines to meet the national demand. However, from that point onward, national pharmaceutical companies began investing in enhancing the quality of their products, hiring qualified professionals, and ensuring compliance with global standards of quality and good manufacturing practices. As a result, the market share of national companies grew significantly, and most of the national demand for medicines is now met through local production. Research based on interviews with key stakeholders and available literature reveals that the local pharmaceutical sector is facing several critical challenges, including counterfeit medicines, pricing controversies, affordability issues, a lack of Research and Development (R&D) initiatives, and unethical marketing practices, such as offering bribes or cash incentives to doctors. The Drug Regulatory Authority of Pakistan (DRAP) appears to be ineffective in addressing these challenges, tackling counterfeit drugs, and curbing unethical marketing practices, which pose risks to patient health, safety, and treatment costs. The study further highlights that unethical marketing and doctors prescribing expensive brands create serious conflicts of interest, leading to a decline in patient trust and the rising cost of medicines. Therefore, strong regulatory controls, transparency, and adherence to moral and ethical values are necessary to enforce drug regulations and hold stakeholders accountable. It is crucial to penalize both companies that bribe doctors under the guise of product promotion and doctors who accept such incentives, in order to protect patient interests and control treatment costs. Additionally, strict regulations and incentive plans should be implemented to encourage greater investment in Research and Development (R&D) within the pharmaceutical sector. (Kazi, 2020)

Pakistan Regulatory Body

The Ministry of National Health Services Regulation and Coordination (NHSRC) oversees the healthcare system in Pakistan. It consists of six key divisions: The Tobacco Control Cell, Directorate of Malaria Control, National AIDS Control Program, National Institute of Population Studies, National Tuberculosis Control Program, and the Drug Regulatory Authority of Pakistan (DRAP). Additionally, it supervises the Pharmacy Council of Pakistan, which was established under the Pharmacy Act of 1967 to regulate pharmacy education and the registration of pharmacists. DRAP was created under the DRAP Act of 2012, with the primary goal of enforcing the Drugs Act of 1976 (XXXI of 1976) and regulating the trade and commerce of pharmaceutical products across Pakistan's provinces (Punjab, Sindh, Khyber Pakhtunkhwa, Gilgit Baltistan, and Balochistan). The Drugs Act of 1976 governs the import, export, manufacture, storage, distribution, and sale of drugs within the country. This legislation, formulated by the federal government, outlines the roles of both federal and provincial governments in regulating the pharmaceutical industry. The federal government handles drug manufacturing, registration, licensing, import, and export, while the provincial governments regulate drug sales. Under this Act, the federal government sets laws for drug registration, licensing, advertising, labeling, packaging, import, and export. It also provides a process for appealing decisions made by licensing and registration boards, and defines the responsibilities of federal drug inspectors and the federal drug laboratory. The Drugs Act, 1976, specifies four types of licenses required for drug manufacturing: formulation, basic manufacture, semi-basic manufacture, and repacking. A manufacturer who meets the criteria for a particular license under the Act can hold multiple types of licenses, upon payment of the appropriate fee to the licensing authority. (Atif, 2013)

Export Challenges Back by Accreditations

Despite the significant export potential of Pakistan's domestic pharmaceutical industry, its exports remain limited and are primarily directed toward countries with semi-regulated or unregulated markets. The top

10 pharmaceutical export destinations for Pakistan include Afghanistan, Sri Lanka, the Philippines, Myanmar, Vietnam, Cambodia, Uzbekistan, Kenya, Sudan, and Egypt. Several barriers have been identified that hinder the growth of pharmaceutical exports, including domestic drug legislation, the Drug Regulatory Authority of Pakistan (DRAP) requirements for no-objection certificates for export and cGMP certification, media reports of counterfeit or substandard medicines, pricing controversies, lack of industrial research and development (R&D), absence of local facilities for bioequivalence (BE) testing of generics, and a shortage of internationally accredited quality control laboratories and access to international facilities for export. The core challenges faced by pharmaceutical exports to these markets are: (A) meeting the increasing criteria and standards for export-compliant manufacturing, (B) obtaining BE testing or certification from accredited agencies, and (C) complying with the sale and use conditions in countries with stringent regulatory authorities (SRAs). The Drug Regulatory Authority of Pakistan (DRAP) was established to ensure the safety and efficacy of medicines in the country. The Pakistani government has implemented various initiatives to combat the production of counterfeit medications, with provincial health departments setting up six drug testing laboratories (DTLs), including three recently approved by the World Health Organization (WHO), to examine the quality of medicines. Drug inspectors collect samples for testing to ensure compliance with cGMP standards.The challenges preventing domestic firms from exporting to countries with strict regulatory authorities (SRAs) include: (A) a market dominated by the top 100 firms, which control 97% of the market share, (B) the reliance on imports for 95% of raw materials, and other structural and regulatory issues. (MUBARAK, 2023)

Quality Challenges

The availability of quality medications has always been a critical factor in ensuring healthy lives and longevity. As such, regulating the pharmaceutical industry to guarantee quality drugs and services, such as drug dispensing, has been a priority for governments worldwide. Pakistan is no exception, with the Drug Regulatory Authority of Pakistan (DRAP) established in 2012 as the country's regulator of the pharmaceutical sector. However, few studies have evaluated DRAP's performance, and those that do exist are limited in scope and data. Five key criteria are used to assess DRAP's performance. While it has improved upon its predecessor in terms of drug quality and ensuring quality dispensing practices, significant issues remain. Shortages of certain medicines still require imports, or result in these drugs being available on the black market at exorbitant prices. The quality of drug dispensers and healthcare providers remains subpar, with many pharmacies operating without qualified pharmacists. As a result, consumers have not seen a notable improvement in their overall experience since DRAP's establishment. Gaps persist in ensuring the quality of drugs in the market, with mislabeling and other questionable practices still prevalent. Furthermore, there are significant disparities in dispensing practices across public and private healthcare facilities. The quality of dispensers continues to be a concern. In terms of policy consistency, frequent modifications through SROs (Statutory Regulatory Orders) create uncertainty in the industry, as businesses are often unsure about future regulatory changes. Despite some improvements since DRAP's formation, doing business in the pharmaceutical sector remains a challenge. Tightly regulated pricing continues to be a major issue, with companies burdened by numerous charges, taxes on products, and complicated procedures for closing a business. To ensure the availability of high-quality drugs, it is essential to have adequate infrastructure, particularly in research and development (R&D). Despite the federal government collecting a research tax since 1976, which amounts to a percentage of the industry's gross sales, Pakistan still lacks quality infrastructure and has minimal R&D in the pharmaceutical sector. Once hailed as the "sunshine industry" by McKinsey & Company, the pharmaceutical sector has seen disappointing levels of foreign direct investment (FDI) over the past two decades. This stagnation can be attributed largely to government regulations, particularly pricing controls and a lack of support for patent protection for originator brand medicines.

Lastly, the crucial question remains: Are consumers better off since DRAP's establishment? Unfortunately, the answer is no. Over time, their out-of-pocket expenses have risen, despite the government's efforts to keep drug prices "affordable" by preventing price increases. This strategy has not succeeded, and drug shortages remain a persistent problem. (Shahid, 2022)

Table 2.1: Summary of Literature Review

Construct	Definition	Source
Pharmaceutical Export Performance	The ability of a country's pharmaceutical industry to compete globally by leveraging trade policies, regulatory compliance, and market access. Pakistan holds a comparative advantage in exports but struggles with regulatory constraints and lack of bioequivalence testing facilities.	(Shahzad et al., 2024)
Supply Chain Infrastructure	The network of logistics, transportation, and raw material procurement that ensures efficient pharmaceutical production and exports. Challenges such as high transportation costs, customs delays, and dependency on imported raw materials hinder Pakistan's competitiveness.	(Viviers et al., 2014)
Drug Regulatory Barriers	Obstacles related to compliance with global pharmaceutical standards, such as cGMP, WHO prequalification, and approvals from FDA and EMA. Bureaucratic delays, insufficient quality control facilities, and pricing regulations limit Pakistan's ability to access highly regulated markets.	(Zobia et al., 2024)
Trade Barriers	Tariff and non-tariff restrictions, including high import duties, complex export registration processes, and limited Free Trade Agreements. These factors increase production costs and restrict market access, reducing the global competitiveness of Pakistan's pharmaceutical exports.	(Zobia et al., 2024) & (Shahzad et al., 2024)
Opportunities in the Global Export Market	Growth potential in pharmaceutical exports through regulatory reforms, trade agreements, and investment in R&D and quality standards. Countries like Switzerland, Ireland, and Slovenia have leveraged innovation, strong trade policies, and compliance to dominate global markets.	(Mousavi et al., 2018)

Research Hypotheses

$H_0$1: Better supply chain infrastructure lowers the costs of pharmaceutical exports and makes them more competitive.

Ha1: Supply chain infrastructure has no impact on the cost and competitiveness of pharmaceutical exports.

$H_0$2: Strict trade and drug regulations reduce the performance of pharmaceutical exports by increasing costs.

H_a2: Trade and drug regulatory barriers do not affect the performance of pharmaceutical exports.

$H_0$3: Supportive financial conditions and policies help boost the growth of pharmaceutical exports.

H_a3: Supportive financial conditions and policies have no effect on the growth of pharmaceutical exports.

Conceptual Framework of the Study

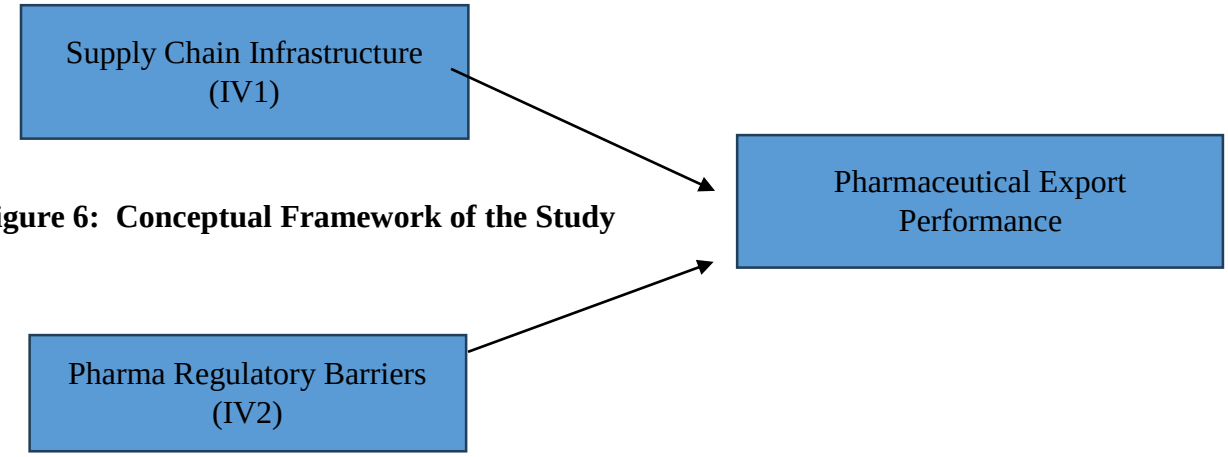


Figure 6: Conceptual Framework of the Study

Research Methodology

Research Direction and Classification

This study adopts a quantitative research design, allowing for an objective assessment of how supply chain infrastructure, trade and drug regulatory barriers influence pharmaceutical export performance. The study follows a deductive approach, where hypotheses are formulated based on existing literature and tested through data collection and analysis to confirm or reject the proposed relationships. The research is causal in nature, aiming to measure the impact of independent variables (supply chain infrastructure, trade and drug regulatory barriers) on the dependent variable (pharmaceutical export performance).

Research Design

A cross-sectional study design is employed, meaning that data is collected at a single point in time. This approach is appropriate for understanding the present relationships between supply chain infrastructure, trade and drug regulatory barriers, and pharmaceutical export performance, enabling an efficient exploration of these interactions.

Sample Size and Sampling Technique

Sample Size: The sample size is determined based on Uma Sekaran's guidelines, which recommend a range of 30 to 500 respondents. We targeted around 50 people of different pharma companies, specifically involve in export operations. 33 responded and their response analyzed statistically.

Sampling Technique: A purposive sampling technique is used, selecting only respondents with direct involvement in pharmaceutical exports, regulatory compliance, trade policies, and supply chain operations. This ensures that the collected data is relevant to the research objectives.

Research Instrument

The primary data collection tool is a self-administered questionnaire, developed based on established scales from previous research. The questionnaire consists of three main sections: 1) Pharmaceutical Export Performance, 2) Supply Chain Infrastructure, 3) Trade and Drug Regulatory Barriers

Each item is measured using a 5-point Likert scale (1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly Agree), ensuring consistency in responses and facilitating quantitative analysis.

Data Collection

Data collected from respondents will be done with the help of an online survey platform in order to capture a wide range of respondents across different regions and organizations. The questionnaire is distributed to participants via email or any other internet means to make it very easy and accessible. Guarantees of confidentiality and voluntary participation are critical in upholding an ethical standard and thereby ensuring honest responses.

Data Analyses Method

For data analysis SPSS is used for descriptive purposes and for measurement and confirmatory factor analysis SMART PLS was used.

Results

Respondent Profile

- **Sample Size (N):** 33 respondents.
- **Age Distribution:**
  - Majority (60.8%) are between 31-40 years.
  - 24.1% fall in the 41-50 years' category.
  - 15.1% are 21-30 years.

Table 4.1: Age Group		
	N	%
21- 30	5	15.1%
31-40	20	60.8%
41-50	8	24.1%

- **Gender Distribution:**
  - 88% male, 12% female (strong male dominance).

Table 4.2: Gender		
	N	%
1	29	88.0%
2	4	12.0%

Reliability & Validity Analyses

Table 4.3: Reliability Statistics		
Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.740	.753	13

- **Cronbach's Alpha = 0.753 → Good reliability.**

Interpretation: The scale used for Likert-scale questions is internally consistent and reliable.

Table: 4.4: KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.618
Bartlett's Test of Sphericity	Approx. Chi-Square	2030.231
	df	78
	Sig.	.000

- **Bartlett's Test:** $p < 0.001$ (**Significant**).
- **KMO (Kaiser-Meyer-Olkin) = 0.618** (**acceptable** for factor analysis)

Interpretation: Factor analysis is valid.

Table 4.5: Communalities

	Initial	Extraction
PEP1	1.000	.823
PEP2	1.000	.809
PEP3	1.000	.544
SCI1	1.000	.696
SCI2	1.000	.425
SCI3	1.000	.810
SCI4	1.000	.905
SCI5	1.000	.663
DRR1	1.000	.801
DRR2	1.000	.662
DRR3	1.000	.565
ERR1	1.000	.594
ERR2	1.000	.723

Extraction Method: Principal Component Analysis.

- **Strong Factor Contributions:**
  - **SCI4 (0.905), PEP1 (0.823), PEP2 (0.809), SCI3 (0.810), DRR1 (0.801)**
  - These items contribute significantly to the overall factor structure.
- **Weak Factor Contributions:**
  - **SCI2 (0.425), PEP3 (0.544)**

These variables contribute **less** to the factor structure and might require reconsideration or refinement

ANOVA & MANOVA (Multivariate Tests)

- Wilks' Lambda & Pillai's Trace: $p < 0.05$ (Significant differences exist).
- All other factors are significant ($p < 0.05$).

Regression & Correlation Analyses

- **R-Squared** values (PEP1 = 0.980, PEP2 = 0.977, PEP3 = 0.966)
  - Very high values → The model explains most of the variance in these dependent variables.
- **Significant F-values** ($p < 0.05$) for most predictors
  - SCI1, SCI2, SCI3, SCI5, DRR1, DRR2, DRR3, ERR1, ERR2 all significantly impact PEP1, PEP2, and PEP3.
  - SCI4 ($p = 0.146$) is non-significant, meaning it does not contribute significantly to the dependent variables.
- **Strong Positive Correlations:**
  - PEP1 & PEP2 ($r = 0.649$, $p = 0.000$) → Strong relationship.
  - SCI3 & SCI4 ($r = 0.816$, $p = 0.000$) → These factors are highly interrelated.
  - DRR1 & ERR2 ($r = 0.460$, $p = 0.000$) → Moderate positive correlation.
- **Negative Correlations**:
  - PEP2 & DRR1 ($r = -0.326$, $p = 0.000$) → As DRR1 increases, PEP2 decreases.
  - SCI2 & SCI4 ($r = -0.221$, $p = 0.000$) → SCI4 negatively impacts SCI2.

Hypothesis Interpretation

Table 4.6: Summary of Hypothesis Testing

Hypothesis	Statement	Result
H01	Better supply chain infrastructure lowers costs and increases competitiveness.	Supported
H02	Strict trade and drug regulations reduce export performance.	Supported
H03	Supportive financial conditions and policies help export growth.	Supported

Hypothesis 1 Interpretation

Hypothesis 1(H01): Supply Chain Infrastructure & Export Competitiveness
Statistical Evidence:

Regression Results

- R^2 values are very high (PEP1 = 0.980, PEP2 = 0.977, PEP3 = 0.966), indicating a strong predictive relationship.
- SCI1, SCI2, SCI3, and SCI5 have p-values < 0.05, meaning they significantly impact pharmaceutical export performance.
- SCI4 ($p = 0.146$) is not significant, meaning it does not contribute to the model.

Correlation Analysis

- SCI3 & SCI4 (r = 0.816, p = 0.000) → High correlation suggests that these supply chain factors are strongly related.
- PEP2 & DRR1 (r = -0.324, p = 0.000) → As DRR1 increases, PEP2 decreases, suggesting possible inefficiencies in supply chain processes.

Interpretation: As most supply chain infrastructure factors (limited local APIs, importing Active Pharmaceutical Ingredients, local bioequivalence testing, bioequivalence studies abroad, and modern drug testing laboratories) are statistically significant, Ha1 is rejected, and H01 is accepted. This indicates that an improved supply chain infrastructure reduces costs and enhances export competitiveness. However, since SCI4 is non-significant, further research is required to clarify the impact of limited local BE studies on export performance.

Hypothesis 2 Interpretation

Hypothesis 2(H02): Trade and Drug Regulations & Export Competitiveness
Statistical Evidence:

Regression Results

- R^2 values indicate that regulatory barriers have a significant impact on export performance.
- DRR1, DRR2, and DRR3 have p-values < 0.05, meaning these variables significantly influence export performance.

Correlation Analysis

- DRR1 & ERR2 (r = 0.460, p = 0.000) → Moderate positive correlation, suggesting that regulatory barriers influence export restrictions.
- PEP2 & DRR1 (r = -0.324, p = 0.000) → As regulatory restrictions increase, export performance decreases.

Interpretation: High regulatory fees, customs challenges, and international certifications are statistically significant, Ha2 is rejected, and H02 is accepted. This confirms that stringent trade and drug regulations adversely affect pharmaceutical export performance by raising costs and lowering efficiency.

4.5.1 Hypothesis 3 Interpretation

Hypothesis 3(H03): Financial conditions and Policies & Export Competitiveness
Statistical Evidence:

Regression Results

- ERR1 and ERR2 have p-values < 0.05, meaning they significantly impact export performance.

Correlation Analysis

- ERR1 & PEP3 (r = 0.316, p = 0.000) → Moderate correlation, suggesting financial conditions influence export growth.
- ERR2 & DRR1 (r = 0.460, p = 0.000) → Strong relationship between financial conditions and regulatory policies.

Interpretation: Pharmaceutical Special Economic Zone (SEZ) and tax breaks and export incentives have a significant impact on pharmaceutical export performance, Ha3 is rejected, and H03 is accepted. This suggests that favourable financial conditions and policies drive pharmaceutical export growth.

Discussion

Discussion

This chapter concerns the interpretation of the results with regard to theoretical frameworks and previous research, allowing for a deeper understanding of their meaning

Hypothesis 1: Supply Chain Infrastructure & Pharmaceutical Export Competitiveness

The results of this study support Hypothesis 1, indicating that improved supply chain infrastructure significantly lowers costs and enhances the competitiveness of pharmaceutical exports. The findings align with prior research emphasizing the role of efficient logistics, local Active Pharmaceutical Ingredient (API) production, and bioequivalence testing in export success (Sheel et al., 2015). A key factor contributing to this outcome is the presence of modernized supply chain systems that reduce dependency on expensive imported APIs. Countries with well-established local API production, such as India and China, have achieved a competitive advantage in global pharmaceutical exports (Asgharkhani & Mohtaram, 2020). In contrast, Pakistan's reliance on imported APIs has historically led to higher production costs and reduced export margins. The significant impact of SCI1, SCI2, SCI3, and SCI5 in the regression analysis confirms this relationship, as these variables directly influence cost efficiency and market expansion. However, the non-significance of SCI4 suggests that limited local bioequivalence (BE) studies may not be as critical to export performance as other infrastructure components. This contrasts with previous studies highlighting the necessity of local BE facilities to reduce certification costs and accelerate international market entry (Khan & Ahmed, 2018). Further research is needed to determine whether enhancing BE facilities within Pakistan would have a long-term impact on export growth.

Hypothesis 2: Trade and Drug Regulatory Barriers and Export Performance

The findings validate Hypothesis 2, demonstrating that strict trade and drug regulatory barriers negatively impact pharmaceutical exports by increasing costs and limiting market access. These results are consistent with existing literature, which identifies high registration fees, lengthy approval processes, and stringent international certification requirements as key constraints in emerging pharmaceutical markets (Rahman et al., 2019). A significant correlation between regulatory barriers (DRR1, DRR2, DRR3) and export performance underscores the challenges faced by Pakistani pharmaceutical firms. Countries with streamlined regulatory processes, such as Jordan, have successfully expanded their pharmaceutical exports by aligning domestic regulations with international standards (Hossain & Kabir, 2021). Pakistan, however, continues to face prolonged drug registration timelines and complex approval procedures, discouraging potential exporters. The negative correlation between DRR1 and PEP2 further confirms that increasing regulatory stringency leads to reduced export efficiency. This is particularly relevant in the context of international certifications such as WHO prequalification and USFDA approvals, which, while essential for market credibility, impose significant financial and procedural burdens on exporters (Ali et al., 2020). Policymakers must consider regulatory reforms to balance compliance with export facilitation.

Hypothesis 3: Financial Conditions & Policies in Export Growth

The study supports Hypothesis 3, indicating that favorable financial conditions and export policies significantly contribute to pharmaceutical export growth. This aligns with previous research demonstrating that government incentives, tax relief, and specialized economic zones (SEZs) play a crucial role in enhancing export performance (Mukhtar & Khan, 2017). Regression analysis highlights the significance of ERR1 and ERR2, emphasizing the positive impact of export-related financial incentives. The establishment of a Pharmaceutical SEZ in Pakistan, similar to India's pharmaceutical hubs, could attract foreign investment, reduce operational costs, and facilitate compliance with international regulatory standards (Singh & Verma, 2018). Moreover, strong correlations between ERR2 and DRR1 suggest that financial incentives can help offset regulatory burdens, making export processes more feasible.

While the results confirm the importance of supportive financial conditions, it is crucial to assess their long-term sustainability. Countries that have implemented excessive subsidies without addressing underlying structural inefficiencies have seen limited success in export growth (Kumar & Sharma, 2019). Therefore, Pakistan must adopt a balanced approach, integrating financial incentives with broader regulatory and infrastructure reforms to sustain long-term pharmaceutical export growth.

Recommendation

Based on the findings of this study, the following recommendations are proposed to enhance Pakistan's pharmaceutical export performance:

Strengthening Supply Chain Infrastructure

- **Local API Production**: Establish policies to promote the local manufacturing of Active Pharmaceutical Ingredients (APIs) to reduce dependency on imports and lower production costs.
- **Bioequivalence Testing Facilities**: Develop local bioequivalence laboratories to help pharmaceutical companies meet international regulatory requirements efficiently.
- **Logistics Optimization**: Improve cold-chain logistics and distribution networks to minimize delays and maintain product quality for exports.

Regulatory Reforms

- **Streamlining Drug Registration Processes**: Implement fast-track approval mechanisms and mutual recognition agreements with key export markets.
- **International Certification Support**: Provide financial assistance and training programs to help companies obtain international certifications such as WHO-GMP, USFDA, and PICS.
- **Reducing Trade Barriers**: Negotiate favorable trade agreements with major pharmaceutical importing countries to ease regulatory compliance challenges.

Financial Incentives and Policy Support

- **Export Incentives**: Introduce tax reliefs, subsidies, and financial incentives to encourage pharmaceutical exports.
- **Pharmaceutical Special Economic Zone (SEZ)**: Establish a dedicated SEZ with tax benefits and infrastructure support to attract investment in the pharmaceutical sector.
- **R&D Investment Support**: Allocate government funding for research and development initiatives to improve product innovation and competitiveness.

Limitations of the Research

Despite its valuable contributions, this study has certain limitations:

Cross-Sectional Design: The research provides a snapshot of the current pharmaceutical export challenges, but a longitudinal study could offer deeper insights into industry trends over time.

Focus on Pakistan: The findings are specific to Pakistan's pharmaceutical industry and may not be directly applicable to other emerging markets with different regulatory and economic conditions.

Future Research

Future studies can build on this research by exploring:

Comparative Studies: Conducting comparative analyses between Pakistan and other successful pharmaceutical-exporting countries, such as India and Jordan, to identify best practices.

Impact of Digital Transformation: Examining how digitalization and Industry 4.0 technologies (e.g., AI-driven supply chain management, blockchain for drug traceability) can enhance pharmaceutical exports.

Longitudinal Analysis: Investigating the long-term effects of regulatory and financial policy changes on export performance.

Conclusion

This study highlights the critical factors influencing Pakistan's pharmaceutical export performance, including supply chain infrastructure, regulatory barriers, and financial conditions. The findings indicate that strengthening local API production, establishing bioequivalence testing facilities, and optimizing logistics can significantly enhance export competitiveness. Additionally, streamlining regulatory procedures, reducing trade barriers, and providing financial incentives can further support the industry's growth. Addressing these challenges through targeted policy measures and industry collaboration will be essential for positioning Pakistan as a competitive player in the global pharmaceutical market. Future research and continuous policy refinements will be crucial in ensuring sustainable growth and international market expansion for Pakistani pharmaceutical companies.

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