DISSECTING THE EFFECT OF INTERNAL R&D, IMPORTED INPUT VARIETY AND EXTERNAL TECHNOLOGY ACQUISITION ON EXPORT COMPETITIVENESS OF PHARMACEUTICALS IN PAKISTAN

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ABSTRACT

Exports are critical for employment generation, poverty alleviation and sustainable economic growth. It is also a significant source of international technology spillovers through learning-by-exporting channel. Most of the developing countries face resource, productivity and competitiveness constraints to achieve a remarkable export growth. Further, some sectors, e.g., pharmaceuticals, face extremely stringent standardization requirements from international regulatory bodies which restricts firm's entry to export market. Thus, understanding the regulatory barriers, relative importance of the different channels of technological innovation and firm/industry specific export challenges is critical for export competitiveness in developing countries. The study examines the regulatory issues, R&D rigidities and export challenges of pharmaceutical firms in Pakistan and empirically investigates the impact of indigenous innovation, foreign technology spillovers and sector/firm-specific factors on firm export performance. The study utilizes primary data collected through a survey of the pharmaceutical firms located in Punjab, Sindh, KPK provinces and Islamabad Capital Territory in 2024 using stratified random sampling method. Drawing on the nature of data, we utilized Firth Logistic regression method to estimate the empirical model. The analysis we provided confirm that pharmaceutical firms face several regulatory barriers, innovation challenges and other sector-specific constraints which hamper their capability to enter the export market. The empirical results of the study and policy implications are summarised. First, the results suggest that internal R&D and external technology acquisition from domestic and foreign sources are critical determinants of firm-level export performance. The findings emphasis the necessity of a prudent R&D strategy to promote basic research and foreign technology transfer for high-value generics and new therapeutic avenues such as the production of biologicals. Second, the results show a positive effect of process innovation and innovation variety on export performance. The study emphasizes improvement in production processes and distribution methods as critical determinant of firm-level export. It also reveals that firms' involvement in technological- and non-technological innovation activities reduces the production costs and enhance innovative capability of firms which is crucial for sustained export growth. Third, the estimates show a positive effect of product diversification and the development of technical infrastructure on export performance. Thus, the findings confirm the need to initiate the domestic production of vaccines, sera, blood products and narrowing down the gap in the production of nutraceuticals and herbal products. The findings also confirm the critical importance of Bioequivalence/Bioavailability (BE/BA) study centres and drug testing laboratories for export because furnishing the data of BE study is a mandatory requirement for exporting. Fourth, the results of the study show a positive effect of firm size and firm membership of international regulatory bodies on their export performance. Thus, it is critical to develop a prudent firm/drug registration mechanism to avoid making pharma a cottage industry without hurting competition. The findings also reveal the importance of the membership of firms, and respective plant accreditation and other compliance, from United States Food and Drug Administration (US FDA), UK Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Agency (EMA), Japanese Pharmaceutical and Medical Devices Agency (PMDA) and others for entry into the stringent regulatory authority (SRA) market. Likewise, DRAP membership of the Pharmaceutical Inspection Co-operation Scheme (PICS) countries is also critical for capacity building and the clarity of guidelines to be issued for implantation in the pharmaceutical sector. Fifth, the results show a critical role of government support in overcoming the regulatory barriers, innovation rigidities and export challenges through incentives and facilitation. Lastly,

the study finds a favourable impact of knowledge spillovers from FDI and contract research and manufacturing services (CRAMS) as well as research collaborations through university-industry linkages and strategic partnerships among firms on innovation and hence export performance of firms. The findings highlight the critical role of basic research through strengthening university-industry linkages and a vibrant clinical trials platform. The findings of the study draw important policy recommendations for industry, DRAP, the Federal Government, the Ministry of commerce, SBP and academia.

PREFACE

Pharmaceuticals is a USD 3.45 billion industry in 2024. It has seen a CAGR of 17% during FY19-FY24. The sector is among a few leading sectors in large scale manufacturing (LSM) which has seen double-digit (23.19%) growth during FY-2024. The sector plays a vital role in national healthcare system by fulfilling 80% of domestic medication demand and it provides employment to approximately half a million people. However, the effect of somehow dynamic growth has not reflected in global competitiveness of the sector. The pharmaceutical exports have increased at a CAGR of 12% during the period 2019-2023 with exports value reaching USD 328 million FY-2023 and projected to reach USD 350 million in 2024, contributing only 1% to GDP. Thus, it is critical to investigate the export challenges of the pharmaceutical firms in Pakistan. Further, pharmaceutical sector is classified as medium-high and high-technology for which technological innovation can play a crucial role in developing its sustained competitive advantage. Drawing on this background, the study examines the regulatory issues, R&D rigidities and export constraints of pharmaceutical firms and empirically investigates the impact of indigenous innovation, foreign technology spillovers and sector/firm-specific factors on firm-level export performance utilizing primary data collected from a survey of the pharmaceutical firms.

We are grateful of our mentors, Dr. Ahmed Waqar Qasim and Mr. Shahid Mehmood, for their valuable guidance and support throughout the study period. We highly appreciate the valuable comments of the anonymous reviewers, participants of the mid-term review workshop, the Research Advisory Committee (RAC), and the Project Management Unit (PMU) at Research for Social Transformation and Advancement (RASTA) PIDE.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

INTRODUCTION

Exports are critical for employment generation, poverty alleviation and sustainable economic growth (Santacreu, 2015). Exporting also makes firms absorb knowledge spillovers from destination markets, increase plant productivity and improve innovative as well as absorptive capacity of firm (Baldwin & Gu, 2004; Liang et al., 2024). Further, manufacturing sector exports, which is a low trading cost sector, have a favourable impact on current account balance of a country (Boz et al., 2019). Thus, the export volume of a country is critical. Nonetheless, most of the developing countries succeed to export but fail to achieve remarkable growth. One possible reason is that their export basket contains low value-added products which may provide a temporary advantage because the rival country can easily gain the ability to produce low quality products (Zhu & Fu, 2013). Thus, it is vital to explore the export challenges of manufacturing firms in developing countries.

There are multiple challenges in the way of a remarkable export performance. The differences in export propensity, export intensity and export quality of firms in developing countries is mainly attributed to firm's size, age, skill level, industry structure, the possession of tangible and intangible resources, amongst others (Chudnovsky et al., 2006; Rodríguez & Rodríguez, 2005). Besides, the government support in export promotion, enhancing market competition, credit availability and providing a facilitative business environment is also crucial (Xuan & Tan, 2024). Additionally, specific industries including pharmaceuticals face extremely stringent standardization requirements from international regulatory bodies including the United States Food and Drug Administration (US FDA) and European Medicines Agency (EMA) and national drug authorities such as Drug Regulatory Authority of Pakistan (DRAP).

Besides, extant literature has revealed that technological innovation is a crucial determinant of export competitiveness. Technological innovation (TI) directly and indirectly affects export competitiveness: internal and external R&D activities directly increase export propensity and intensity of firms (Harris & Li, 2009; Becker & Egger, 2013); TI indirectly affects firm's decision to export and export intensity via its influence on total factor productivity (TFP) (Yu et al., 2022; Hou & Mohnen, 2013). In the other words, innovation activities increase productivity which in turn affect export. Moreover, product and process innovation cause export quality upgrading (Zhu & Fu, 2013) which leads to a sustained global competitiveness. Thus, TI is critical to enhance the value and quality content of exports (Hausmann, Hwang, Rodrik 2007). The current firm-level study intends to examine the effect of the indigenous and foreign innovation efforts on export performance in developing countries.

Although TI is a significant determinant of exporting, there are several issues and challenges which hinder innovation performance of firms in developing countries. Broadly, limited Research and Development (R&D) activities, low skill level, high innovation cost, lack of firm-specific tangible and intangible resources, lack of motivation for R&D and others hamper innovation in these countries (D'Este et al., 2012; Rodríguez & Rodríguez, 2005). Further, financial constraint, innovation-unfriendly macroeconomic landscape, regulatory hurdles stifle innovation activities (Lachenmaier & Wößmann, 2006). These are some major factors but several firm-, industry-, region- and country-specific factors requires attention of researchers and policy makers. Thus, it is critical to seek the answers to the following questions in this regard: What is the extent of innovation and export capability of firms in developing countries? What are the obstacles which hamper innovation and export upgrading in them? How can innovation capability of firms be enhanced? What is the relative importance of the different channels of TI for export

competitiveness of firms in developing countries? In this study we intend to seek answers to these questions by examining the issues and challenges hindering export potential of pharmaceutical firms in Pakistan as well as by investigating the export performance of pharmaceutical firms conditioned on different channels of TI. despite its viable economic significance, the studies which provide a systematic empirical analysis of the association of firm-level export to TI in Pakistan's pharmaceutical sector Pakistan are scarce.

Among the various channels of TI, the study specifically emphasises internal R&D and external technology acquisition as important determinants of firm-level export competitiveness. Internal R&D affect export directly (Rodríguez & Rodríguez, 2005) and through its association with TFP (Yu et al., 2022). However, unlike developed countries, developing countries allocate fewer resources to internal R&D. Thus, they rely on importing intermediate inputs within which technologies developed in advanced countries are embedded (Santacreu, 2015). Evidence shows that the knowledge created in developed countries transcends national boundaries through external technology acquisition and provides crucial knowledge spillovers to developing countries (Wang et al., 2013). In this regard, import of advanced machinery and equipment, technology licensing and hiring of technological development personnel from external sources are important channels of knowledge diffusion which helps firms in developing countries to adapt and innovate (Baldwin & Gu, 2004). It also provides an opportunity to build new capabilities and to lie at the higher end of the value chain. Moreover, the existing literature has also shown that a minimum level of internal R&D capability (i.e., absorptive capacity) is necessary to reap the advantage of the technology acquired from domestic and foreign sources (Cassiman & Veugelers, 2006). Thus, it is critical to identify the appropriate channel of technology for export competitiveness in developing countries.

1.1. Significance of the Study

The study examines the export challenges of pharmaceutical firms in Pakistan. In addition, it provides a systematic empirically assessment of the impact of internal innovation and external technology acquisition on firm's export performance. Although, the firm-level analysis provides an understanding of the micro aspects of the concerned issue which is crucial to an effective public policy, the studies which present firm level evidence are generally rare in developing countries due to data limitations. Specifically, more attention is provided on textile and apparel sector (Wadho & Chaudhry, 2018 and 2024) and ICT sector (Shah et al., 2024) while the studies which provides a systematic empirical assessment of the innovation-export interplay in Pakistan's pharmaceutical sector are scant despite the sector's plentiful economic significance. Further, previous studies on pharmaceutical sector (e.g., Khan et al., 2021) are confined to providing a descriptive analysis of the sector-level export potential. A firm-level study in pharmaceutical sector has been broadly neglected mainly due to its complicated landscape and hurdles in data collection efforts. Second, pharmaceuticals are classified as a 'Medium-high and High-technology' industry as per the technology intensity of manufacturing industries by 'The UN Industrial Development Organization (UNIDO)'. Thus, it's appropriate to conduct an in-depth analysis of the extent of innovation and technology adoption and its impact on export performance of firms which are more likely to utilize innovation. Evidence shows that modern and more technical industries may create impulses beneficial for overall innovation activities (Lachenmaier & Wößmann, 2006). Third, the pharma industry in Pakistan is dominated by a small number of large firms such that top 10 firms constitute 43% and top 50 firms possess 93% of market share. Large firms are more likely to engage in innovation activities, innovators have

high productivity (Chudnovsky et al., 2006) and more productive firms enter the export market (Haddoud et al., 2023). Thus, assessing the impulses and obstacles to innovation and its linkages to exporting using a sample of pharmaceutical firms is meaningful. Fourth, the 'Pharmaceuticals Export Strategy Framework (2023-27)' which aligns with Strategic Trade Policy Framework (STPF) declares it a priority sector for export diversification. Lastly, the literature on firm level evidence has grown at the astounding rate in recent years and it is critical to contribute to this emerging strand of literature.

1.2. Purpose and Scope of the Study

• To examine the regulatory issues, R&D rigidities, and export challenges of Pharmaceuticals in Pakistan.

• To analyse the extent of domestic and foreign innovation efforts in pharmaceutical firms.

• To empirically assess the impact of internal innovation and external technology acquisition on export performance of pharmaceutical firms.

Developing countries are relatively resource-deficient and possess a limited adaptability to different kinds of technological knowledge while innovation is risky, costly and path dependent. It is also conditioned on the firm/plant-specific, industry-specific, state-level, or region-specific characteristics, as well as on firms' willingness to adopt and internalize new technologies. Firms may also incur switching costs to switch across different sources of technology and/or may face diseconomies of scope (Rothaermel & Hess, 2007; Hess & Rothaermel, 2011). Further, firms may leverage imported technology in processes in which they have accumulated skill and innovative capability to decrease switching costs. Similarly, a technology may be labour-using or labour-saving. Developed countries often use labour-saving technology while developing countries may opt labour using technologies. This selection may prove to be cost-prohibitive. Moreover, different types of innovation activities (internal and external) may lead to similar innovation outcomes, creating a conflict of scope. Thus, it is tricky to assess the relative importance of different channels of technology for export competitiveness in developing countries.

1.3. Research Questions

1. What are the challenges hindering export competitiveness of pharmaceutical firms?

2. What is the importance of technological innovation for export competitiveness of pharmaceutical firms?

3. What is the way forward for a prudent pharmaceuticals export strategy?

1.4. Relevance to Public Policy

The study is pertinent as it addresses the potent issue of low export performance of the pharmaceutical sector in Pakistan. The industry has a viable economic and strategic significance. The innovative capability of Pakistani firms has seen numerous development stages. Thus, assessing the effect of internal R&D and external technology acquisition on the export performance of firms is relevant to public policy. It is also critical because it highlights the relative importance of different innovation channels for export. The study highlights the innovation challenges and impediments to firm-level export performance of an industry recording an impressive growth in large scale manufacturing sector. This research is useful for policymakers engaged in formulating innovation policy and it will provide useful insights for a prudent export strategy. The results of the study will provide policy points for the Strategic Trade Policy

Framework (2020-25) and Pharmaceuticals Export Strategy Framework (2023-27). The findings can be utilised by DRAP to further identify its priority areas for a decent export growth and the tax authorities engaged in finding and allocating effective tariff rates on the import of machinery and equipment. Moreover, the findings of the study is helpful for State Bank of Pakistan (SBP) to revise its compliance policies and policy rates pertinent to the pharmaceutical sector.

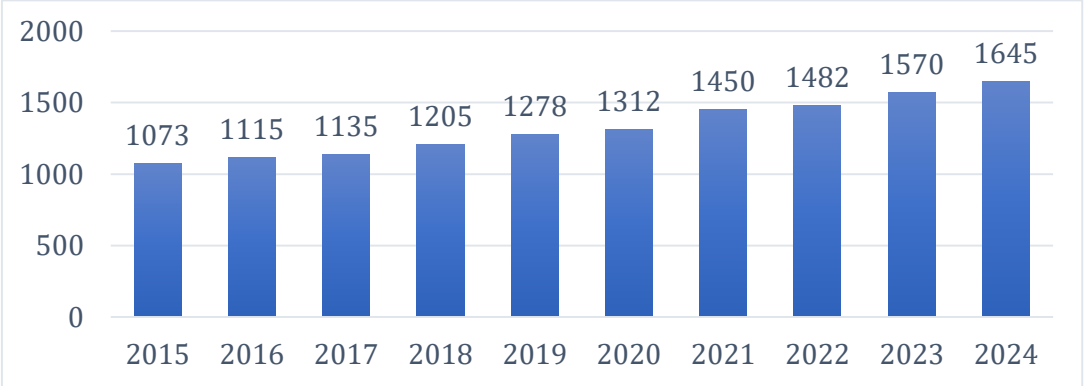
OVERVIEW OF PHARMACEUTICAL SECTOR IN PAKISTAN

2.1. Global Pharma Market

Pharmaceutical is a highly knowledge-intensive sector. The product cycle of a drug involves discovery, development, manufacturing and marketing. Drug discovery requires significant R&D which mainly large firms perform and attain patents. Small firms develop off-patent drugs or offer toll/contract manufacturing services to develop and manufacture drug on large firms' behalf. In addition, there are Contract Research Organisations (CROs) who involve in clinical trials management and respective data analysis. To do toll/contract manufacturing or contract research, there should be a strong linkage between large and small firms while having a minimum level of innovative capability (or absorptive capacity) is a pre-requisite for small firms.

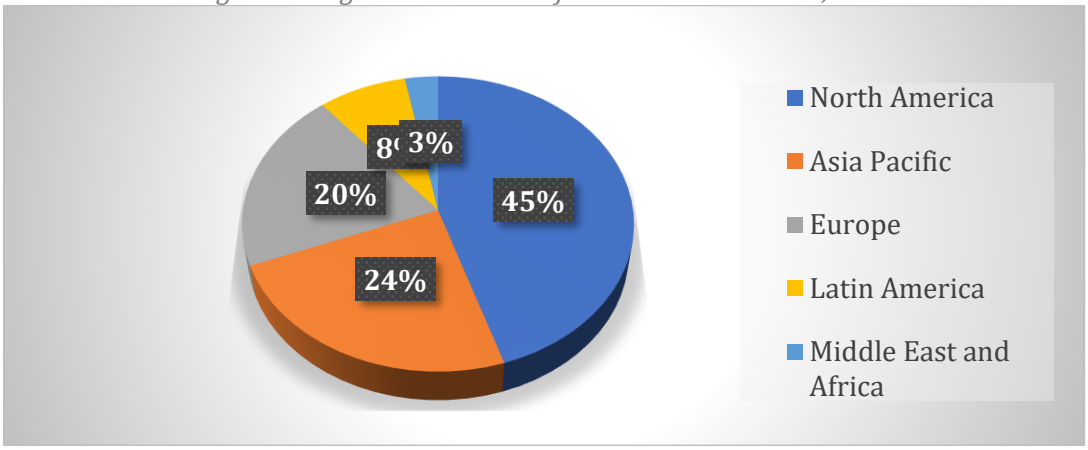
The global pharma market has shown a rapid growth in recent years. The high medication demand is attributed to increase in life expectancy and aging population, rise in per capita income, increasing awareness, innovative therapeutic avenues and market expansion. The global pharma market size was USD 1.31 trillion in 2020 which has increased to USD 1.65 trillion in 2024, and it has anticipated to reach 1.8 trillion in 2026.

Figure 1: Global Pharma Market Size (2015-2021) (USD billion)



Source: VIS credit rating company limited (2023).

Figure 2: Region-wise Share of Global Pharma Sales, 2023



Source: VIS credit rating company limited (2023).

The regional pharmaceutical market is concentrated in North America who possesses the dominant 45% share in 2023, followed by 24% of Asia and the Pacific who is the next emerging market which has just outperformed Europe's share of 20%, while Latin America and Middle East and Africa has a relatively lower share of 8% and 3% respectively. At the country level, USA leads the global pharma market with a sales share of 43% followed by China, Japan, Switzerland and

the Europe. As for established players, Pfizer (USA), Johnsons & Johnsons (USA) and Sinopharm (China) are three largest pharmaceutical companies in the world. Further, top 10 companies collectively share approximately 35% of the global pharma market and amongst them five companies belong to USA. In fact, developed countries are leaders in knowledge creation and technology adoption thus knowledge-intensive industries like pharmaceuticals attain a conducive environment for researching, developing and manufacturing drugs in them.

Table 1: Therapeutic Class (Disease Burden) of Global Pharma Market (2023)

Oncology	**Diabetes**
Ophthalmology	Endocrinology
Cardiovascular Diseases	Central Nervous System/Neuro Disorders
Gastrointestinal Disorders	Nephrology

Source: ICAP (2024).

As for the therapeutic class of global pharma market or disease burden, Oncology comes at first place followed by Diabetes, Ophthalmology and so on as depicted above.

2.2. Pakistan's Pharmaceutical Sector

Pakistan pharmaceutical sector has gone disruptive evolution process, and it is now USD 3.3 billion industry. The sector has seen a remarkable growth in recent years, recording a 24% year-on-year (YoY) growth in FY-2024 with a CAGR of 17% during FY19-FY24 (IQVIA, 2024). The sector is among a few leading sectors in large scale manufacturing (LSM) which has seen double-digit growth during FY-2024. Among LSM industries, during July to March 2023-24, the pharma industry has seen a decent growth of 23.19% comparing to wood products 12.09%, Fertilizers 16.40%, Machinery and Equipment 61.54% and Furniture 23.13% (GOP, 2024).

The pharma sector is playing a vital role in national healthcare system by fulfilling 80% of domestic medication demand while the remaining 20% is provided by MNCs.

Table 2: Main Characteristics of Pakistan Pharmaceutical Sector

1	**Market Size**	**USD 3.3 billion (2024)**
2	Export value (pharmaceutical products)	USD 341 million (2024)
3	Average Annual Growth Rate	17%
4	R&D intensity	1-2%
5	Employment	90000 individuals directly 150,000 individuals indirectly
6	Contribution to GDP	1%
7	Contribution to Exports	1%
8	Contribution to domestic drug demand	80%
10	Resource base	Narrow: 90% of APIs are imported mainly from China and India

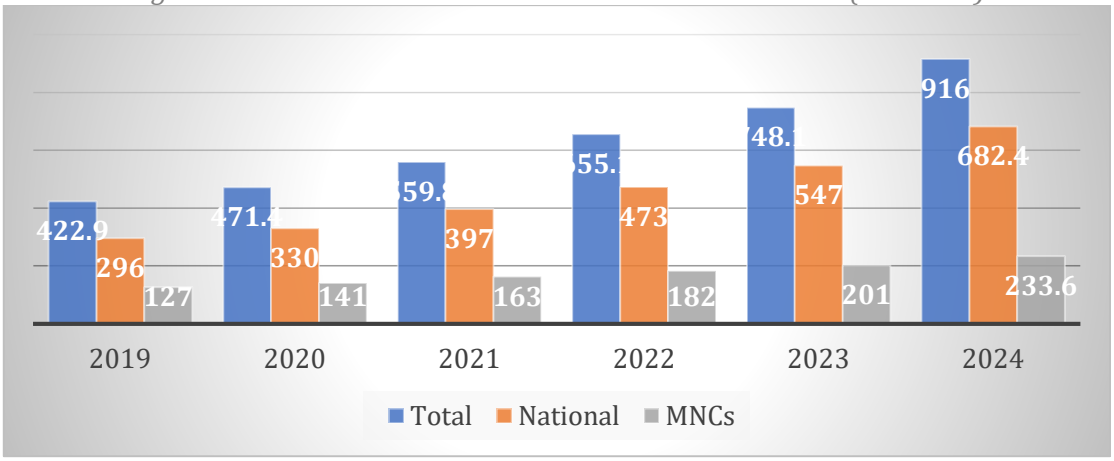
Source: Authors' own compilation based on data from IQVIA (2024).

The sector is dynamic in terms of significant graduate employment possibilities as it is the technology-intensive sector which is skill hungry. It is providing direct employment to 90000 individuals and indirectly to 150,000 persons approximately (IQVIA, 2024). Its contribution to GDP and total exports is approximately 1% each. The sector significantly contributes to current account through import substitution of USD 2 billion approximately (Ahmed, 2024). The sector has a weak resource base and 90% of the raw material including Active Pharmaceutical Ingredients (APIs), excipients and concentrates are imported from other countries mainly China, Germany and India. The main production activity is formulation, including mixing, dilution and

packaging of final products which is a low value-added activity having limited linkages to export upgrading.

There are approximately 11000 actively marketed drugs sold at licensed pharmacies while a significant proportion of drugs include Over-the-Counter (OTC) drugs such as multivitamins, pain/cold/flu relief medications sold directly to patient.

Figure 3: Pakistan Pharmaceutical Market Size 2019-2024 (Rs Billion)



Source: VIS credit rating company limited (2023).

As for the market share of domestic and foreign firms, the domestic firms dominate the market with Rs 682.4 billion sales (74.5%) in 2024 comparing to Rs 233.6 billion sales (35.5%) of MNCs. The data show that the domestic firms has outperformed the MNCs and the sales gap between the two is increasing as MNCs size is dwindling in the market. The total number of MNCs has decrease from 40 in 2000 to 17 in 2016 and it has confined to only 5 in 2024. Furthermore, among the big 10 firms, 7 are domestic firms. MNCs are crucial in skill and knowledge spillovers to domestic firms.

Pharma is a very concentrated market in Pakistan within which a few large firms control significant market share, with top 10 firms holding approximately 49% of market sales in 2024 Q1.

Table 3: Top 10 Pharmaceutical Firms in Pakistan (2024)

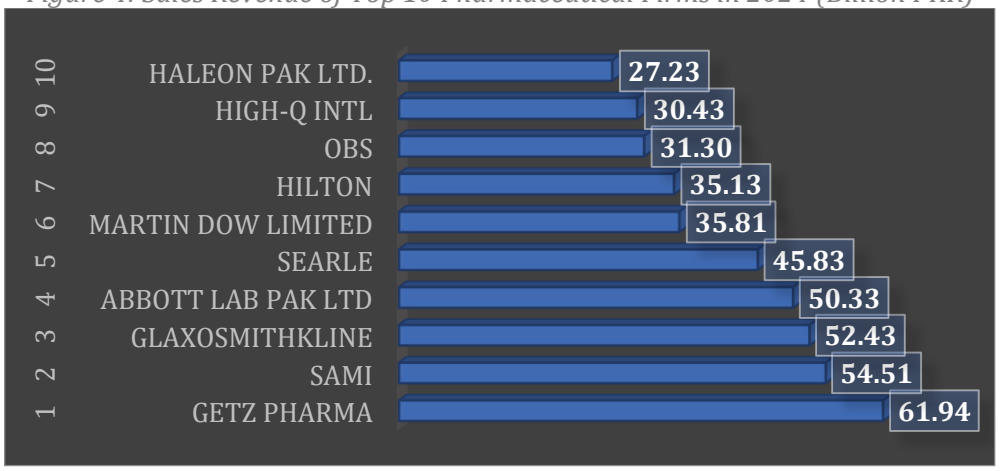
Rank	Pharmaceutical Firm	Market share (%)	National /MNC	Listed /Not listed
1	GETZ PHARMA	7.13	National	Not listed
2	SAMI	6.27	National	Not listed
3	GLAXOSMITHKLINE	6.03	MNC	Listed
4	ABBOTT LAB PAK LTD	5.79	MNC	Listed
5	SEARLE	5.27	National	Listed
6	MARTIN DOW LTD	4.12	National	Not listed
7	HILTON	4.04	National	Not listed
8	OBS	3.60	National	Not listed
9	HIGH-Q INTL	3.50	National	Not listed
10	HALEON PAK LTD	3.13	MNC	Listed

Source: IQVIA (2024).

Table 3 outlines Getz Pharma leading at 7.13% of the total market, followed by SAMI (6.27%), and GlaxoSmithKline (6.03%). These three companies collectively share approximately 20% of market sales, showing the dominance of large firms in the pharmaceutical market. Other major contributors include Abbott Lab Pakistan (5.79%), Searle (5.27%), and Martin Dow Limited

(4.12%). It reflects the leadership as well as the competitive presence of large firms in the industry. In the technologically matured countries, large firm do knowledge creation and innovation while small firms perform outsourcing, but this linkage is limited in Pakistan.

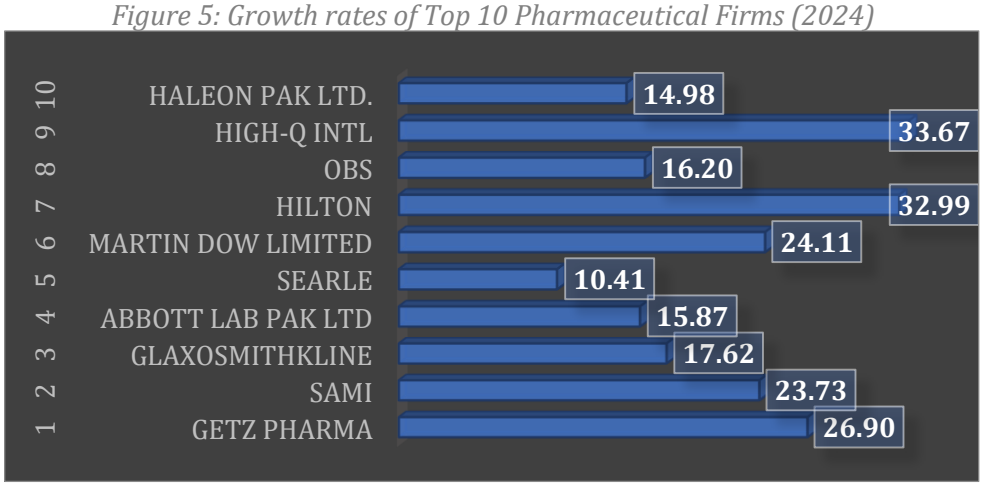
Figure 4: Sales Revenue of Top 10 Pharmaceutical Firms in 2024 (Billion PKR)



Source: IQVIA (2024).

In terms of sales revenue, Getz Pharma leads significantly with 61.94 billion PKR, followed by SAMI (54.51 billion PKR) and GlaxoSmithKline (52.43 billion PKR). Other major contributors include Abbott Lab Pakistan (50.33 billion PKR), Searle (45.83 billion PKR), and Martin Dow Limited (35.81 billion PKR). The remaining companies, such as Hilton (35.13 billion PKR) and High-Q International (30.43 billion PKR), demonstrate strong competitive performance. The data reveals that top 5 companies have created a significant sales gap with their subsequent counterparts.

Figure 5: Growth rates of Top 10 Pharmaceutical Firms (2024)



Source: IQVIA (2024).

The growth rates of leading pharmaceutical companies show that High-Q International (33.67%) and Hilton Pharma (32.99%) dominate with the highest growth in 2024 outperforming Getz Pharma (26.90%), Martin Dow Limited (24.11%), and SAMI (23.73%). This indicates strong competition among top players and the potential of High-Q and Hilton pharma to catch up leading players.

The pharmaceutical market is concentrated at the product level as well. Among the 11000 marketed drugs, top 10 brands collectively hold approximately 9% of market sales. Table 4 shows the market share of top 10 pharmaceutical products in Pakistan in 2024 Q1.

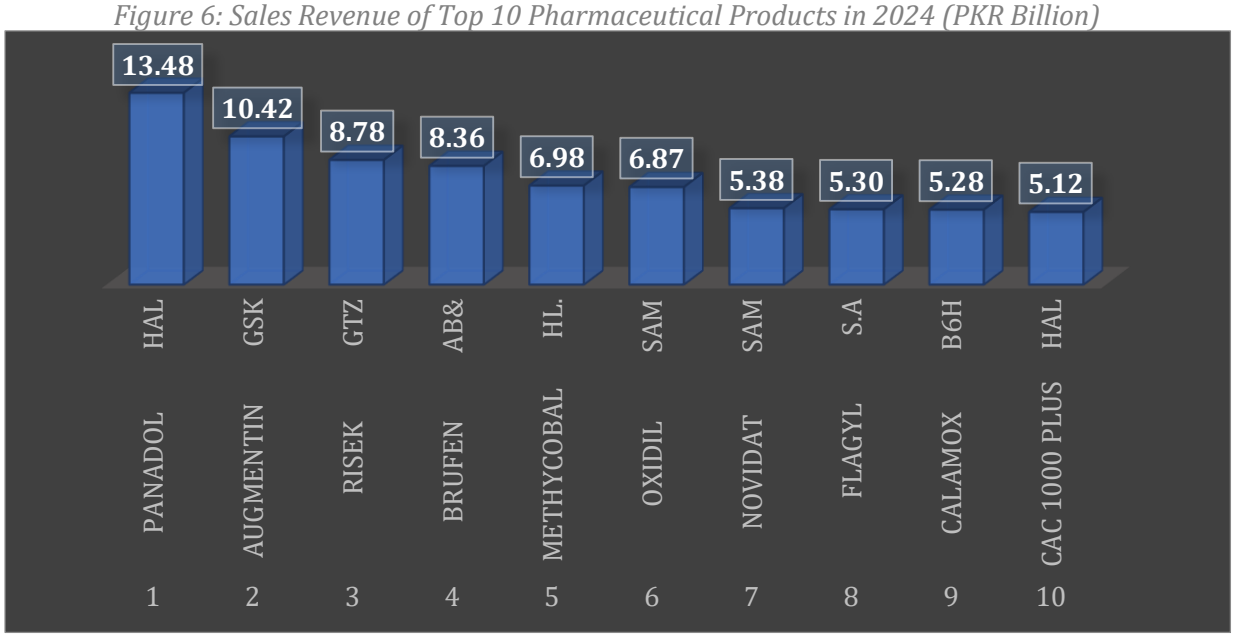
Table 4: Top 10 Pharmaceutical Product in Pakistan (2024)

Rank	Pharmaceutical Product	Market Share (%)
1	PANADOL (HAL)	1.55
2	AUGMENTIN (GSK)	1.20
3	RISEK (GTZ)	1.01
4	BRUFEN (AB&)	0.96
5	METHYCOBAL (HL)	0.81
6	OXIDIL (SAM)	0.79
7	NOVIDAT (SAM)	0.62
8	FLAGYL (SA)	0.61
9	CALAMOX (B6H)	0.61
10	CAC 1000 PLUS (HAL)	0.59

Source: IQVIA (2024).

The data highlights that Panadol leads the market with a significant share of 1.55%, followed by Augmentin (1.20%), Risek (1.01%), and Brufen (0.96%). Other notable products include Methycobal (0.80%), Oxidil (0.79%), and Novidat (0.62%). It shows the influence of leading brands in pharmaceutical products' sales. As for the market value, Figure 6 shows that Panadol leads with 13.48 billion PKR, followed by Augmentin (10.42 billion PKR) and Risek (8.78 billion PKR).

Figure 6: Sales Revenue of Top 10 Pharmaceutical Products in 2024 (PKR Billion)

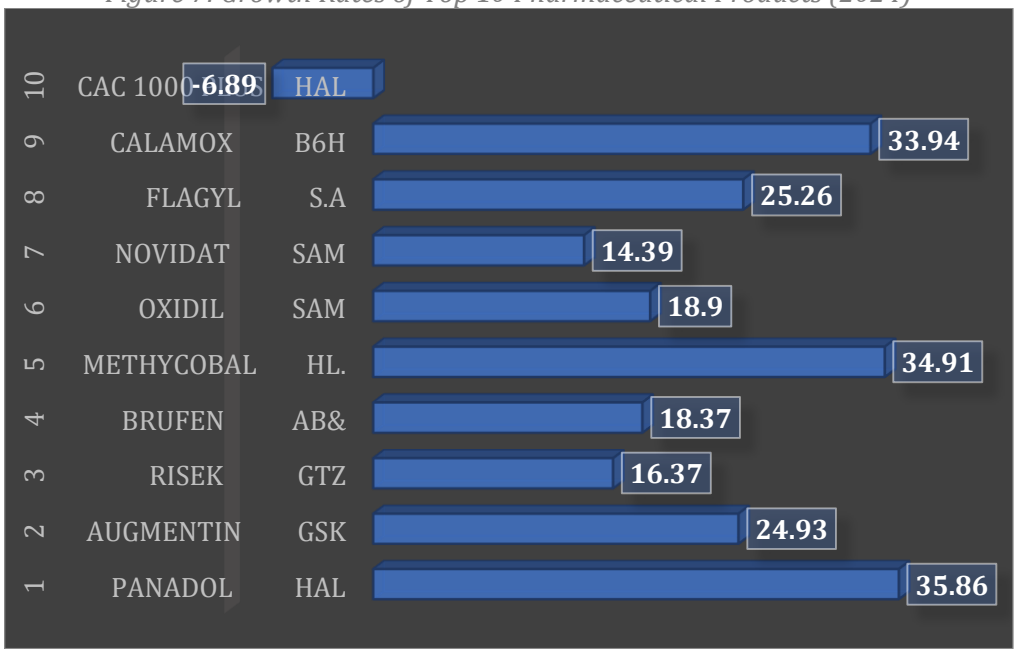


Source: IQVIA (2024).

Other notable products include Brufen (8.36 billion PKR) and Methycobal (6.98 billion PKR). It reveals the dominance of blockbuster drugs in driving market sales. It also shows the demand pattern for medication. Panadol is an OTC drug which can be sold without prescription. It, to some extent, highlights the self-medication trend in Pakistan.

As for the growth rate, Panadol leads with a remarkable growth of 35.86%, followed by Methycobal (34.91%) and Calamox (33.94%). Other notable products include Augmentin (24.93%), Flagyl (25.26%), and Oxidil (18.90%). However, CAC 1000 Plus showed a decline of -6.89%. It indicates mixed performance among key products. Panadol is anticipated to sustain the top brand position with Methycobal and Calamox showing tremendous growth signaling the catch-up potential.

Figure 7: Growth Rates of Top 10 Pharmaceutical Products (2024)



Source: IQVIA (2024).

2.2.1. Geographical Distribution

There is total 639 pharmaceutical firms in Pakistan. As for the geographical distribution of firms, Punjab hosts the largest number of pharmaceutical firms, i.e. 344, followed by 142 in Sindh and 92 in Khyber Pakhtunkhwa (KPK) provinces while Islamabad attracts 45 firms. Balochistan has the lowest number of pharmaceutical firms i.e. 11. As for city wise distribution of pharmaceutical firms, Lahore and Karachi are the favourite destinations having 175 and 130 firms respectively. Rawalpindi and Islamabad jointly attract 128 pharmaceutical firms while Peshawar hosts 41 and Faisalabad/Sheikhupura region show 33 firms. The Hattar industrial estate which is the manufacturing hub of KPK province attracts 23 firms. The statistics also show that pharmaceutical firms are located in clusters/ industrial hubs in cities of major economic activities within respective provinces. It reveals that the industry is largely dispersed and unevenly distributed in different regions. The possible reasons of these clusters can be relatively conducive business environment, the availability of raw material and other essential utilities, distance from the domestic/export market, duty and tax remission opportunities, the segregation of regulatory functions among provinces among others.

The uneven geographical distribution of pharmaceutical firms may have both positive and negative implications. Firms dispersed in different geographical regions may reap the benefits of diverse markets and can efficiently cater for the demand of a broader customer base which provide growth opportunity (e.g., firms in Peshawar may easily export to Afghanistan). It also enhances the demand for technology adoption to stay at a diverse market. For example, firms located closer to an industrial hub are required to be more innovative. Likewise, geographical dispersion may put competitive pressure on firms and make them to innovate. Further, firms can get the benefits of local resources and expertise. However, uniform technology adoption in dispersed units is costly and hard to manage. Further, local infrastructure constraints and the fragmentation of regulatory functions at different locations may complicate the technology adoption process affecting firms' export performance.

Table 5: Geographical Distribution of Pharmaceutical Industry in Pakistan (2024)

Province Wise Distribution (No. of firms)			
Punjab	344	Islamabad	45
Sindh	142	Balochistan	09
KPK	92	Others	07
City Wise Distribution (No. of firms)			
Lahore	175	Haripur (Hattar)	23
Karachi	130	Multan	14
Rawalpindi/Islamabad (Rawat)	128	Sargodha	13
Peshawar	41	Gujranwala/Gujrat/Sialkot	12
Faisalabad/ Sheikhupura	33		

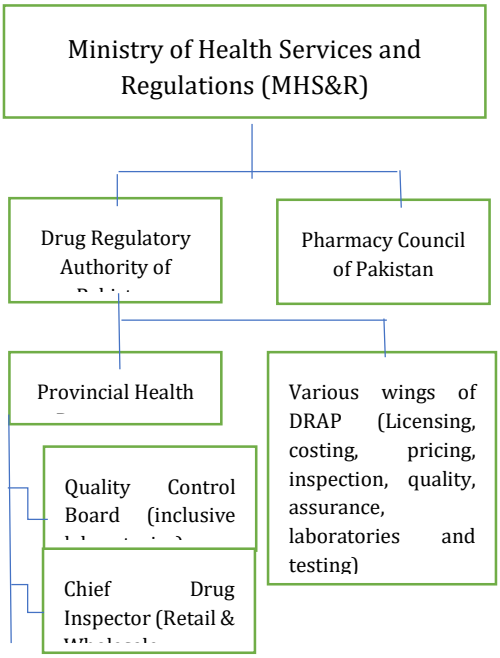
Source: Authors' own compilation based on data from DRAP (2024).

2.2.2. Regulatory Environment

The pharmaceutical is a strictly regulated market globally. Drug Regulatory Authority of Pakistan (DRAP) is a national drug regulator which works under the control of Ministry of National Health Services Regulations and Coordination (MNHSR&C).

DRAP is established under DRAP Act 2012 and is responsible for the enforcement of Drugs Act 1976. DRAP controls the registration of new drug/new manufacturing facility and issuance of manufacturing licenses and set the maximum retail price (MRP) of medicines in coordination with the cabinet division. Further, the Pharmacy Council of Pakistan (PCP) is regulator for pharmacies. Besides, there are provincial health departments which inspect quality and safety of the drug at the disaggregated level. Figure 8 shows the segregation of regulatory functions at different levels.

Figure 8: The Segregation of Regulatory Functions

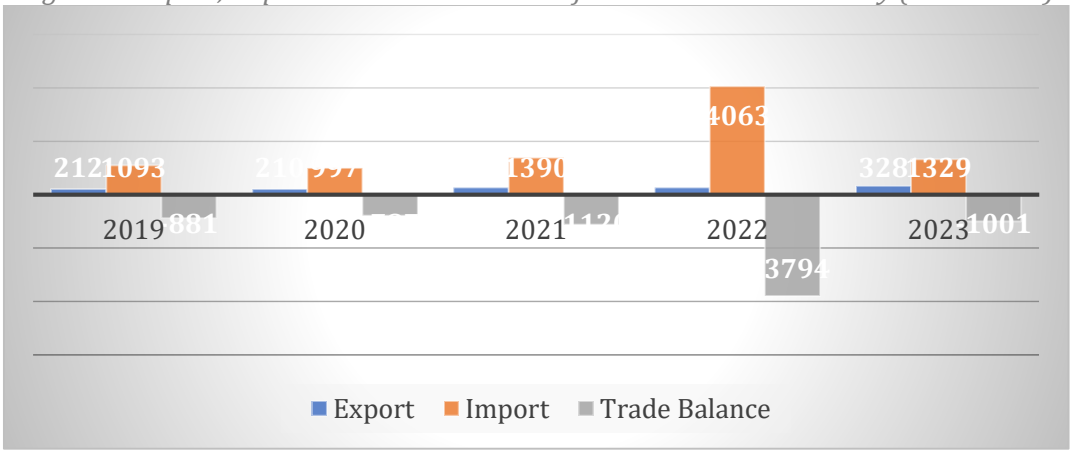


2.3. Export Performance of Pakistan's Pharmaceutical Sector

The preceding discussion reveals that the pharmaceutical sector has emerged as a dynamic sector. However, this dynamism has not reflected in global competitiveness as shown by industry's export performance. The pharmaceutical exports have increased at CAGR of 12%

during the period 2019-2023 with exports value reaching USD 328 million FY-2023 and projected to reach USD 350 million in 2024. The sector is ranked at 17th in industry-level exports and contributes only 1.1% to total manufactured exports comparing to 17% of Textile, 14% of Apparel and 11% of cereals. Further, it ranks 56th in world export of pharmaceuticals. This is a quite low place especially for an industry having more than 17% average annual growth rate in recent years. The figure below show export, import and respective trade balance of pharmaceuticals during 2019-2023 period. Although the data show an increase in the export value over years, the trade deficit has expanded with reaching approximately USD 3.8 billion in 2022 owing to expanded imports during Covid-19 period. It is now USD 1 billion, around three times the value of exports in 2023.

Figure 9: Export, Import and Trade Balance of Pharmaceutical Industry (2019-2023)



Source: VIS Credit rating company limited (2023).

One prominent reason for the significant trade deficit in the sector is heavy reliance on imported APIs. The current domestic APIs market is valued at USD 175 million approximately which is around 10% of APIs demand (Ahmed, 2024). The remaining 90% is imported from China, Germany and India leading to a significant trade deficit.

A significant share of pharmaceutical exports is possessed by few large companies. Table 6 highlights the top exporters by value (Rs bn) in 2023 and 2024, ownership structure and growth rate.

Table 6: Top 15 Exporting Pharmaceutical Firms (2023-2024)

Rank	Company Name	National /MNC	Export Value (Rs Billion)		Growth (%)
			2023	2024	
1	GETZ PHARMA (PVT) LTD	National	21.94	27.58	25.7
2	HILTON PHARMA (PVT) LTD	National	2.793	4.208	50.6
3	SAMI PHARMA (PVT) LTD	National	2.421	3.614	49.2
4	THE SEARLE COMPANY LTD	National	3.333	3.485	4.5
5	HERBION PAK (PVT) LTD	National	2.977	3.276	10.1
6	GENIX PHARMA (PVT) LTD	National	3.689	3.074	-16.6
7	CCL PHARMA (PVT) LTD	National	1.950	2.975	52.6
8	ABBOTT LAB (PAK) LTD	MNC	2.132	2.596	21.7
9	PHARMEVO (PVT) LTD	National	1.457	2.512	72.4
10	NABI QASIM IND (PVT) LTD	National	1.997	2.055	2.9
11	ATCO LABORATORIES LTD	National	1.591	1.958	23.1
12	MARTIN DOW LTD	National	1.621	1.843	13.7

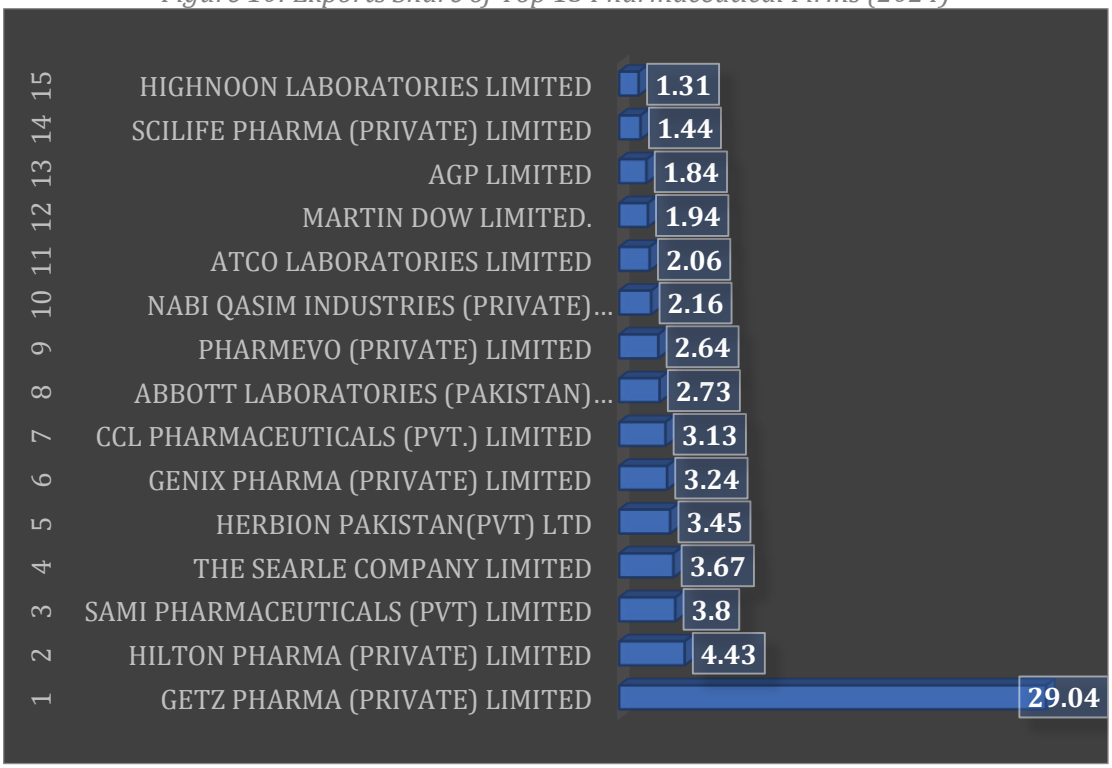
13	AGP LTD	National	1.252	1.751	39.8
14	SCILIFE PHARMA (PVT) LTD	National	0.793	1.371	72.9
15	HIGHNOON LAB LTD	National	0.992	1.248	25.8

Source: Government of Pakistan (2024) Customs Trade Statistics

Getz Pharma leads significantly with exports of Rs 27.58 billion, followed by Hilton Pharma Rs 4.20 billion. Getz Pharma has a tremendous gap of Rs 23.38 billion with its predecessor showing its dominance in foreign markets as well. The data shows that Sami Pharmaceuticals, The Searle Company, Herbion Pakistan, Genix Pharma and CCL Pharma have recorded exports of approximately Rs 3 billion each in 2024. Other notable contributions include Abbott Laboratories (2.60 billion PKR), Pharmevo (2.51 billion PKR) and Nabi Qasim Industries (2.06 billion PKR), respectively. As for the growth rate, Scilife Pharma, Pharmevo and CCL Pharma have been the leading growing companies with a growth rate of 72.9, 72.4 and 50.6 respectively. It reveals a strong potential for catch-up with the big three firms in the industry. The data also show that most of the leading export firms have seen massive growth in 2024 except Genix Pharma who witnessed a negative growth of -16.6%.

Figure 10 shows the export shares of pharmaceutical firms in 2024 which are highly skewed towards large firms as the top 15 firms contribute 67% of export share within which a single firm Getz Pharma contributes 29.04%. Hilton Pharma (4.43%) and Sami Pharmaceuticals (3.80%) follow as strong performers, far behind Getz though. Other key exporters include The Searle Company (3.67%), Herbion Pakistan (3.45%), Genix Pharma (3.24%) and CCL (3.13%), reflecting a highly competitive market. Pharmevo and Nabi Qasim Industries also contribute to the export market with shares above 2%, while smaller players like Scilife Pharma and Highnoon Laboratories show lower but notable contributions.

Figure 10: Exports Share of Top 15 Pharmaceutical Firms (2024)

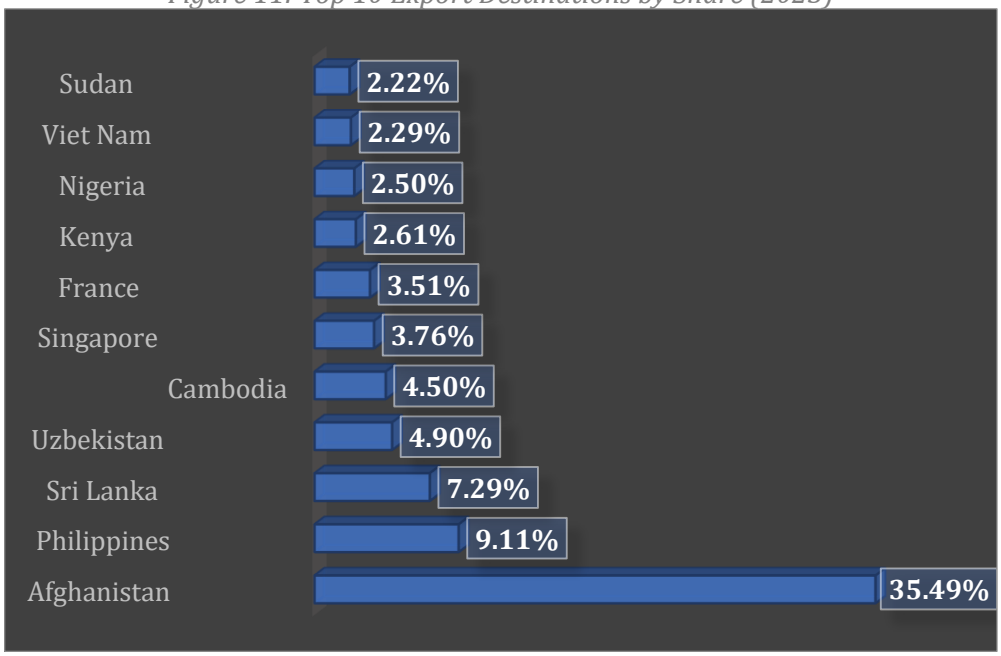


Source: Government of Pakistan (2024) Customs Trade Statistics

The statistics provided in Table 6 and Figure 9 summarise that export market shares are more concentrated in the favour of a few large firms such as Getz Pharma than domestic sales. In the other words, there are a few big players in export market comparing to many large players in domestic markets. It reveals that other large and more productive firms have a greater scope to enter the export market by enhancing domestic and foreign innovation activities.

Learning-by-exporting is a significant source of international knowledge spillovers.

Figure 11: Top 10 Export Destinations by Share (2023)

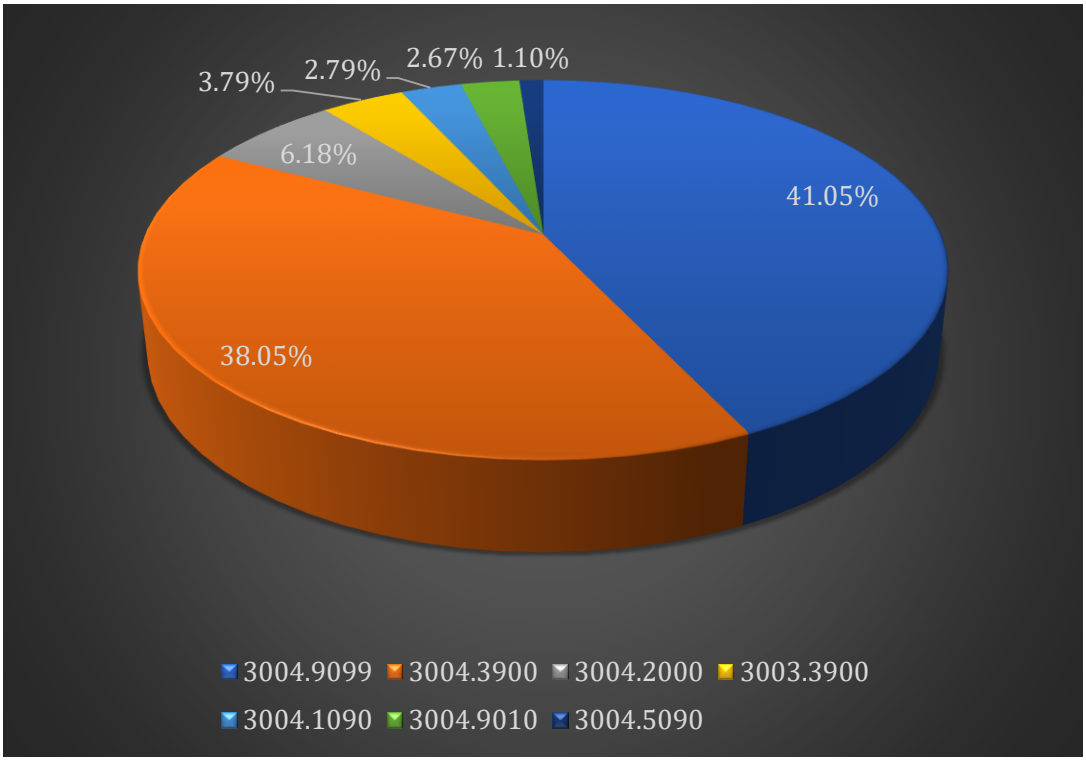


Source: Government of Pakistan (2024) Customs Trade Statistics

Export destinations of firms reveal the learning-by-exporting oppertunities, suggesting that firms who export to advanced countries succeed to enhance their innovation capability by learning to adopt and internalize advanced technologies. Figure 11 shows major destinations of Pakistan's pharmaceutical products exports. The data reveals Afghanistan as the dominant export destination, accounting for 35.49% of the total value, significantly higher than other countries. The Philippines (9.11%) and Sri Lanka (7.29%) are also major contributors. Other key destinations include Uzbekistan (4.90%) and Cambodia (4.50%), while several countries like Kenya, Nigeria, and Sudan represent smaller shares. This highlights a heavy reliance on Afghanistan, with diversification in secondary markets. Furthermore, it reveals that pharmaceutical exports are destined for semi-regulated markets of Asia. It has serious repercussions for learning-by-exporting and restricts international technology spillovers which is an important source of technology upgrading in developing countries.

Moreover, the composition of exports examines the quality and technological content of exported products. Evidence reveals that technology-intensive products constitute the fastest growing share of world trade (Lall, 2000). Figure 11 highlights the export distribution by HS Code during January to August 2024.

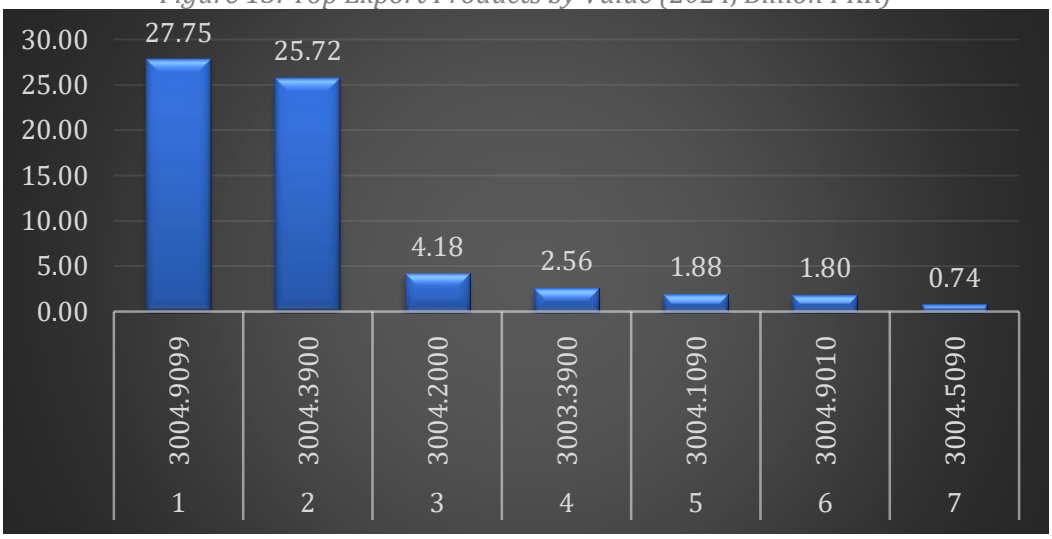
Figure 12: Exports Shares by HS Code (2024)



Source: Government of Pakistan (2024) Customs Trade Statistics

The data show that HS Code 3004.9099 (medicaments in specific forms e.g., tablets, capsules, syrups) dominates with 41.05% of total exports, closely followed by 3004.3900 (Medicaments containing hormones but not containing antibiotics) with 38.05%. These codes involve formulated drugs in which APIs are formulated with appropriate excipients and packaged for retail. Other significant contributors include 3004.2000 (6.18%) and 3003.3900 (3.79%). It reflects the concentration of exports in a few products and the lack of export product diversification. The composition of exports also show that the formulation is the main activity of pharmaceutical firms in Pakistan with a less focus on drug discovery and/or drug development. Low value added through formulation may not lead a country to export upgrading. TI may play a role in product diversification and export quality upgrading.

Figure 13: Top Export Products by Value (2024, Billion PKR)



Source: Government of Pakistan (2024) Customs Trade Statistics

The data provided in figure 13 highlight that HS Code 3004.9099 leads with 27.75 billion PKR, followed by 3004.3900 (25.72 billion PKR) and 3004.2000 (4.18 billion PKR). Other significant contributors include 3003.3900 (2.56 billion PKR) and 3004.1090 (1.88 billion PKR), showcasing the dominance of a few pharmaceutical products in exports and a huge gap between top two and subsequent products.

2.4. Opportunities

2.4.1. Evolving Drug Demand Patterns

Global pharmaceutical market is undergoing extensive structural changes on both demand and supply fronts. An increase in life expectancy, aging population, increase in per capita income, rise in health spending and an ever-greater awareness of healthcare system has substantially increased global drug demand. It has also diversified the composition of demand in favour of a variety of drugs including pharmaceuticals, nutraceuticals, herbal medicines and biologicals. The global market size of nutraceuticals has reached to USD 419.9 billion in 2023, and it is projected to reach USD 976.7 billion till 2032 (Fortune Business Insights, 2024). Similarly, the global herbal medicine market size is USD216.4 billion in 2023 and projected to reach USD 437.2 billion till 2032 (Fortune Business Insights, 2024).

Further, the demand for small molecules is increasing in developing countries as developed countries are now shifting to biologicals and therapeutic avenues concerning personalised medicine and effective treatment. This evolving global drug demand pattern is an opportunity for Pakistan to enhance its export share by producing small molecule therapeutics especially high-quality branded generics, dietary supplements (Vitamins), indigenously developed herbal medicines, biosimilars and simple biologicals including vaccines.

2.4.2. Global Off-patent Market

The global off-patent market will worth USD 700 billion in branded generics and USD 381 billion in generics by 2025 (Khan et al., 2021). It provides developing countries a unique opportunity to produce the generics of the original drugs at a low R&D cost. Thus, it not only provides a cheaper alternative drug to domestic market but also enhances the export potential of a country who can meet the international regulatory standard of drug approval. Further, targeting the generics of the off-patent drugs accelerate the process of innovation activities in them which in turn leads to export quality upgrading.

2.4.3. Outsourcing Opportunities

Outsourcing is an efficient medium of technology transfer in developing countries who heavily rely on foreign technology spillovers owing to low domestic R&D spending and weak indigenous innovative capability. In pharmaceuticals, large firms outsource different stages of drug development through Contract Research and Manufacturing Services (CRAMS) to save on cost. CRAMS is a rapidly growing industry globally. Its market size has reached to USD 145.37 billion in 2024 with a CAGR of 9.6% (Research and markets, 2024). Developing countries with an experienced pharmaceutical sector like Pakistan can avail this opportunity to uplift the indigenous innovative capability via training of paramedics, standardisation of laboratory/hospital/site which is helpful to be certified from international regulatory bodies, establishment of BE study centres and labs and others. Thus, it can help to fulfilling the stringent export requirements of international regulatory bodies.

2.4.4. Indigenous Vaccine Development

The global vaccine market volume is 12.7 billion doses valued at USD 122 billion in 2022 as per WHO Global Vaccine Market Report 2023 with leading manufacturers being Pfizer (36%), Moderna (15%), Merck/MSD (9%). As it is already established that developed countries are now shifting to biologicals and personalised treatments, countries with an experiences pharmaceutical sector and those who have strengthened their regulatory frameworks can excel in the production of biosimilars and simpler biologics including vaccine and antisera. Recently, the demand of vaccine has increased in Pakistan due to governments focus of national immunization. Pakistan imports of human vaccine was USD 37.05 million in 2023 of which around 46% from India and 27% from Germany (WITS, 2024). Further, Pakistan's import of Antisera and other blood fractions amounts to USD 245.27 million in 2023 of which 48% from Belgium and 14% from India (WITS, 2024). The domestic production of vaccine is very limited. Technology adoption for indigenous vaccine development is vital and it requires only a little effort and support with the given industry exposure. A major driver may be public-private partnership such as collaboration of pharmaceutical firms with National Institute of Health. It is a tool of import substitution as well. Asian countries are relatively less stringent markets for vaccine export.

2.5. Issues and Challenges

2.5.1. Regulatory Barriers

Stringent Requirements: Many countries, especially those with high and medium regulatory standards, have rigorous drug approval processes (e.g., Bioequivalence studies) including preclinical and clinical trials to manufacturing, marketing and post-marketing vigilance, to ensure their safety, efficacy and quality. Pakistani pharmaceutical companies often struggle to meet the high-quality standards required by international regulatory bodies like the US Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Agency (EMA), Japanese Pharmaceutical and Medical Devices Agency (PMDA) and others. A pharmaceutical firm who is a member of these regulatory bodies may be facilitated to fulfil these requirements. Membership requires a rigorous and costly process of inspections and guidelines for plant accreditation, product testing and other related practices. Table 7 show that among regional countries, India has the highest number of FDA approved plants which has reflected in the remarkable export performance of the pharmaceutical sector.

DRAP Capacity and Membership: The Drug Regulatory Authority of Pakistan (DRAP) issues guidelines to stakeholders to ensure safety, quality and efficacy of the formulated drugs. The clarity of guidelines has substantially improved over time, but the implementation side remains weak. Further, DRAP is not a member of any international regulatory body, which poses significant challenges, particularly in medium-regulated markets such as the Pharmaceutical Inspection Co-operation Scheme (PICS) countries. PICS membership evaluates the comprehensive nature of the regulatory standards adopted by a country and the skill and technological capacity of the pharmaceutical firms as well as the regulatory bodies among others. DRAP is striving to fulfill these standards in collaboration with the industry players. It requires capacity (especially human resources) enhancement and legislative amendments for compliance with international standards. Moreover, the technical capacity of DRAP concerning new therapeutic avenues of biologicals and AI-based medicine is limited.

Bioequivalence (BE) Studies: Every country, regardless of its regulatory status, now requires BE studies. The purpose of BE studies of a drug is to evaluate its therapeutic equivalence to the reference drug in the other countries and its regulatory compliance. However, Pakistan lacks BE centers that are approved or partnered with major regulatory authorities. There are only five Bioequivalence and Bioavailability (BE/BA) study centers in Pakistan having a very limited scope (DRAP, 2024).

Lagging in the above-mentioned requirements, Pakistan's drug exports are destined to semi-regulated, low-income countries. Economic theory reveals that exporting is an important source of foreign technology spillovers via learning-by Exporting. However, this benefit will accrue only in case of exporting to advanced countries and maintaining a threshold level of absorptive capacity. Table 7 show that India's main export destinations include the highly regulated markets of USA, Netherlands, UK and other countries. The data also show that India has one of the largest group of US FDA approved manufacturing plants in the world. China competes in the production and export of biologicals to European countries and USA. China also has a decent number of manufacturing plants approved by US FDA and it is also among PICS member countries. Pakistan and Bangladesh are lagging in this regard and destined to export to semi-regulated countries of Asia although Bangladesh has three US FDA approved plants and it pharmaceutical exports are emerging while Pakistan has no US FDA approved plants.

Table 7: Export Value, Destinations and Regulatory Status of Regional Countries (2023)

Country	Export Value ($)	Major Export Destination	US-FDA App	PICS Member	Nature of Product
China	11.3 b	Germany, Switzerland, USA, Belgium, Ireland	28	Yes	Biologicals (Antibiotics etc.)
India	27.9 b	USA, Netherlands, UK, South Africa, Brazil	650	No	Branded Generics
Pakistan	328 m	Afghanistan, Philippines, Sri Lanka, Uzbekistan, Cambodia,	0	No	Branded Generics
Bangladesh	175.4 m	Myanmar, Sri Lanka, USA, Philippines, Afghanistan	3	No	Branded Generics

Source: United Nations (2024), US FDA (2024)

Burdensome Molecule Registration Criteria: The current molecule registration criteria cause delays in approval and encourage more spending at the post-production stage which leaves a small R&D budget. For instance, as soon as the molecule is available for formulation, 350 to 400 firms apply for generic registration. Although it increases competition, it causes registration delays as well as so many firms competing for one single molecule makes them spend more on advertising and they are at the discretion of doctor who prescribe this medicine. Similarly, in a market with a large number of small firms, the low turnover make them less capable of quality compliance and the cost of doing business for those firms operating at low standards is low. Moreover, it causes disruption to the process of capturing the opportunity of off-patent market. Suppose 200 molecules are going off patent and so many firms are interested in getting it registered, how many registrations applications are there at DRAP? And how much delay does it cause? A specific criteria concerning the molecule launch permission is crucial. However, this is not very straightforward, DRAP is legally bound to give permission to a firm who fulfill all the registration requirements.

Price Rigidity: DRAP controls the MRP utilising a specific criterion in coordination with the Cabinet Division. Before the establishment of DRAP, pharma industry witnessed a price freeze during 2001 to 2012. As per the Drug Pricing Policy (2018) pharmaceutical companies can increase MRP of essential drugs by 70% of CPI with capping to 7% and non-essential drugs with 100% of CPI with capping to 10%. Further, DRAP is also directed to entertain the hardship cases where it becomes viable to increase the price in consultation with the federal government. Economic theory postulates several repercussions of a price control: First, it distorts competition; Second, it discourages incentive for being innovative due to a narrow price margin; Third, it encourages rent seeking activities including using unfair means for getting exemptions and concessions, reporting a false cost of material, creating artificial shortages, lobbying to get monopolistic advantage and others; Fourth, the price control and resulting narrow margin leads to low quality and counterfeit medicines and make firms to introduce expensive next generation versions of a low-price medicine. Lastly, price control in an industry who rely on 90% of imported APIs with an approximately 10% currency depreciation annually and the highest utility cost in the region confine business opportunities. With regards to innovation, price control decreases the revenue from R&D and limit further R&D spending on subsequent drug discovery, restricting innovation activities. Keeping in view the discussed obstacles, in February 2024, government has deregulated the prices of drugs not listed on the National Essential Medicines List (NEML).

Legal and Operational Barriers to Toll/Contract Manufacturing Activities: Contract Research and Manufacturing Services (CRAMS) is a proven business model to save on drug manufacturing cost. In this method, a firm outsource the clinical trials or manufacturing of an innovative drug (in full or a single stage) to another firm. Incumbent firms spend a lot of resources on innovation and other less innovative firms can leverage the external expertise when they collaborate with them through outsourcing.

Table 8: Clinical Research Landscape in Pakistan

1	**Contract Research Organisations (CROs)**	**26**
2	Bioequivalence/Bioavailability (BE/BA) Centres	05
3	Bioequivalence Studies	05
4	Clinical Trail Sites	103
5	Bioanalytical Laboratories	05

Source: DRAP (2024).

Table 9: Clinical Trails Map

1	**Region Name**	**No of Studies**
2	World	468,457
3	South Asia	8690
4	India	5287
5	Pakistan	2675
6	Bangladesh	572
7	Nepal	267
8	Sri Lanka	101

Source: ClinicalTrials.gov.

This opportunity is more attractive for firms in developing countries where internal R&D is negligible. Specifically, it is beneficial for pharma sector to attract foreign clients through clinical trials, outsourcing or contract manufacturing especially in a scenario where a significant number of SMEs are operating at below 50% capacity. Further, a low-cost drug manufacturing through contract manufacturing attracts MNCs. There are a very limited number of CROs (26 in total), BE/BA centres (05 in total), Bioanalytical Labs (05 in total) and Clinical Trials sites (105 in total)

in Pakistan with a very limited coverage. The university-industry linkage is weak due to which firms are reluctant to reach out medical universities for clinical trials. Industry may provide incentive to academia in the form of the development conducive to conduct clinical trials in this regard. Pakistan lags India and South Asian average in number of clinical trials studies. Moreover, there are certain legal and operational barriers to outsourcing activities in pharmaceutical industry such as delayed clinical trials approvals, short license time and limited number of products among others.

2.5.2. Innovation Challenges

Low Overall Innovative Capability: The innovative capability of Pakistan economy is low owing to lower R&D spending, per capita health expenditure and education expenditure as compared to regional average. The data provided in Table 10 show that R&D spending in Pakistan in 2021 is one-fourth of South Asian average. So is the case with expenditure on health and education. Statistics also show that per capita health expenditure in Pakistan is USD 43.09 which is far lower than South Asian average of USD 70.18 in 2021. Similarly, government expenditure on education is 1.69% of GDP which is slightly lower than the average education expenditure of South Asian countries which is 1.83% of GDP in 2021.

Table 10: Innovative Capability: Pakistan Vs South Asia (2021)

1	**Gross Expenditure on R&D (% GDP)**	**South Asia 0.63**
		Pakistan 0.16
2	Health Expenditure per capita (current USD)	South Asia 70.18
		Pakistan 43.09
3	Govt Expenditure on education (% GDP)	South Asia 1.83
		Pakistan 1.69

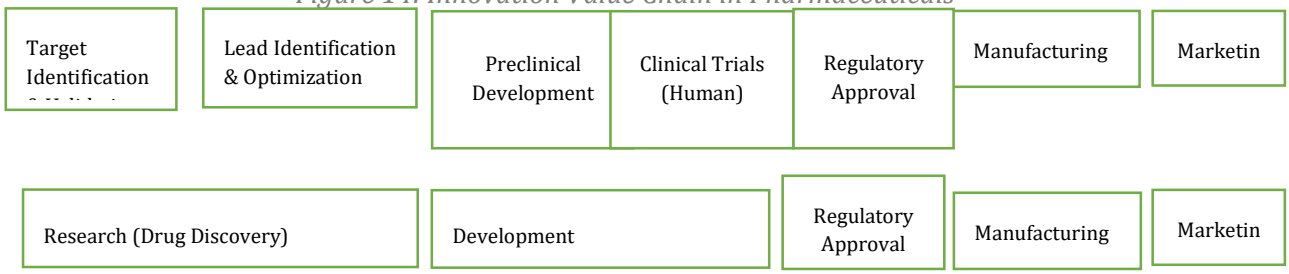
Source: World Bank (2024).

This has resulted in low absorptive capacity and the absence of innovation culture in the economy, adversely affecting the firm-level innovation. The weak innovative capability has resulted into the low share of medium- and high-tech value added in manufacturing value added and the low technological content of overall exports. The share of medium- and high-tech in total manufactured export is 12% in 2021 comparing to 36% of India and 62% of China, signalling a huge gap in terms of the technical content of export basket with the regional countries (World Bank, 2024). Similarly, the share of medium- and high-tech value added in manufacturing value added is half (i.e., 23%) of what is in India (i.e., 46%) and in China (i.e., 42%), showing the low technological intensity of the manufacturing value addition in the economy.

Weak Innovation Value Chain in Pharmaceuticals: Pharmaceutical is a high technology industry the tremendous growth of which hinges upon the pace of the production of scientific knowledge. The examples of Leading exporters showcase this phenomenon. The innovation value chain comprises different stages from basic research for drug discovery to raw material to production and post-production (i.e., marketing) activities. The drug discovery stage is costly and risky and the drug discovery research depends upon the quality of basic research and the knowledge collaboration between firm-university-public research institution. The drug development stage is dependent upon the quality of clinical research organisations and related infrastructure. Drawing on the weak overall innovative capability of the economy, there is the issue of weak innovation value chain in pharmaceutical sector. The disruption at the initial stages is caused by the absence of internal and external R&D and high-quality drug testing laboratories (e.g., US FDA approved labs), lack of knowledge sharing platforms in the wake of public-private

collaboration and high-tech clusters, weak IPRs, lack of clinical research sites and delays in regulatory approvals. At the raw material stage, relying on the imported APIs cause several disruptions pertaining to cost, trade barriers and local and global macroeconomic landscape. At the manufacturing stage, rigidities are caused by the lack of medium and advanced manufacturing facilities and the inadequacy of bioequivalence testing labs. Although relatively more attention is levied on the post-production stages in Pakistan, we have a fragile distribution channel which disrupt the value chain. Specifically, there is lack of model pharmacies and efficient drug courts. Further, there is a strong firm-doctor collaboration which is costly and burdensome for patients. More spending at this stage leave less funds to be utilised at the drug discovery and development stage.

Figure 14: Innovation Value Chain in Pharmaceuticals



Narrow Product Base and Less Technical Product Specialisation: Figure 12 and 13 above highlights that the export basket is less technical and less diverse. The data show that 79.1% of exports are mainly concentrated in two products including (HS 3004.9099 and HS 3004.3900) which two are less technical products and involve the simple formulation of respective APIs and excipients. The low value-added formulation activity hampers technology upgrading. With regards to the extent of product diversification within the sector, there is a negligible share of nutraceutical products, dietary supplements (Vitamins) and indigenous herbal products in total turnover. The production and export of these products can be substantially increase in a span of 3 to 5 years if appropriate measures in terms of regulatory and financial support are taken and incentives in terms of duty and tax remission are provided for top performers.

As for the industrial specialisation, there is a low state of intermediate and advanced manufacturing facilities, improving in recent years through, which leads to a limited production of quality products., 95% of the firms are engaged in the formulation of Active Pharmaceutical Ingredients (APIs) and excipients while only 5% of firms are involved in the semi-basic or basic manufacturing (Table 11). Such type of production specialization has implications for export performance. Only by importing APIs and formulating it into tablets, syrups and liquids, injections and ointments and not being innovative cannot lead to Stringent Regulatory Authority (SRA) markets. Entry to SRA market is crucial for a sustained export growth and international technology spillovers (e.g., Learning by exporting).

Table 11: Production Specialisation

Production Activity	***No of firms***	**Share in total (%)**
Formulation	623	95%
Semi Basic Manufacture	23	4%
Basic Manufacture	7	1%

Source: Authors' own compilation based on data from DRAP (2024).

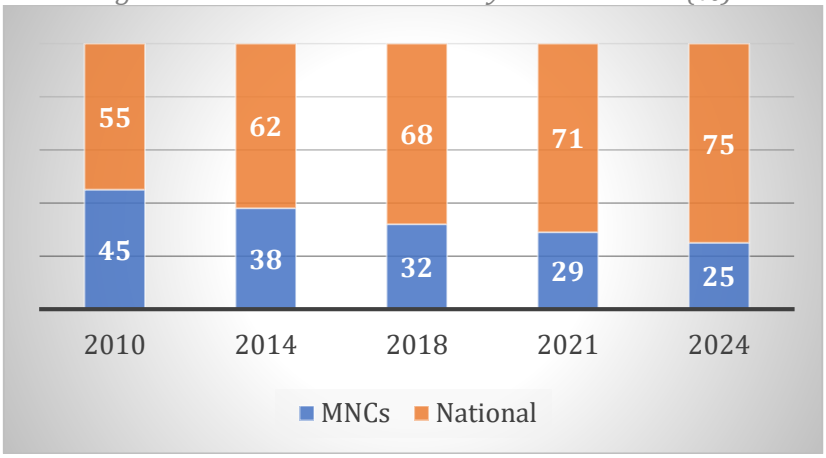
Poor Problem Identification at the Basic Research Institutions: The applicability and industry use of the knowledge created from basic research is critical for innovation output. There is a lack

of longitudinal or horizontal studies in this regard. For example, academic research papers investigate that honey is the cure for typhoid, but they often fail to furnish further information such as in what dosage form? For how may days? etc. Further, the existing curriculum in national universities has limited content on the established standards and pharmacovigilance systems, leading to skill matching problems. The possible reason is that there are weak university-research center-industry linkages. In case of strong related linkages industry disseminates the specified needs to the universities and universities update curriculum including the modern and relevant content. The problem identification and putting it into curriculum to cater industry needs is missing. Likewise, the office of commercialization (ORIC) in most of the universities is less capable or interested in startups execution or entrepreneurial contribution of students.

Dwindling sizes of MNCs in the Pharmaceutical Industry: MNCs market share has dwindled from 45% in 2010 to 30% in 2020 and recently it has declined to 25% in 2024. As for the total number of firms, only 5 MNCs show significant presence in 2024 decreasing from 40 in 2000. MNCS role is critical in an economy i.e., skill and knowledge transfer to domestic firms. Further, MNCs have a strategic importance in terms of drug availability at the time of crisis or pandemic. For instance, MNCs played a critical role in timely vaccine availability during Covid-19 pandemic. The current state of MNCs has led to low opportunities of technology transfer to local firms.

The possible reason is the price cap amidst a substantial increase in cost of production mainly due to currency devaluation and hike in utility prices besides an inconducive macroeconomic landscape and uncertain security situation. Further, a significant obstacle is the uncertainty associated with the protection of the intellectuals' property rights. The generics of originally produced synthetic drugs come very soon in market. It decreases the monopoly rent for the innovator firms and discourage the production of new medicines. It has also created low synergy between MNCs and local firms pertaining to secrecy issues, leading to low skill and knowledge transfer. This low technology transfer opportunity from foreign firms bars the innovation capacity of small domestic firms who cannot afford internal R&D.

Figure 15: MNCs Market Share by Sales Revenue (%)



Source: VIS Credit rating company limited (2023).

2.5.3. The Low Retention Rate of the Export Proceeds

Exporters are allowed to retain their exports proceeds in a special foreign currency account to discharge their foreign liabilities. The allowed rate is up to 33.3% for publishers, up to 50% for Export of Software, IT Enabled Services and Freelance Services, up to 15% for pharmaceutical products, up to 5% for cement, up to 2% for cotton and up to 10% for all other goods as specified in chapter 12 of Foreign Exchange Manual.

The retention rate of 15% is low, especially for firms executing branding activities for export promotion in foreign markets. These firms incur various expenses including advertising costs, staff salaries, monitoring costs and others. Further, buying and sending foreign exchange, especially USD from other modes is expensive. Thus, it poses a serious limit on ne market search and export promotion activities. SBP has relaxed this limit for leading exporters (i.e., firms with an increase of 10% in net exports proceeds) in which the retention rate of up to 50% is allowed on the additional export proceeds. However, industry experts consider a flat increase in the rate to be more effective even in the case of potential exporters.

2.5.4. The Skewed Structure of Pharmaceutical Sector

Currently there are nearly 639 pharmaceutical firms in Pakistan. The market structure is highly skewed with top 5 firms constituting 30%, top 10 firms 43%, top 25 firms 75%, and top 50 firms possessing 93% of the market share respectively.

Table 12: The Industry Structure of Pharmaceutical Market

Corporates with 40 Billion Above Value		**Corporates with 10 Billion Above Value**	**Corporates with 5 Billion Above Value**	**Corporates with 1 Billion Above Value**
No of Firms	5	20	12	40
Value (Bn)	Rs 277	Rs 414	Rs 88	Rs 101
Rank/Total	1-5	6-25	26-37	38-77
Market Share:	30.19%	45.19%	9.54%	11.04%
Growth:	20.27%	27.72%	19.31%	20.57%

Source: IQVIA (2024).

The remaining 590 small firms face survival issues while competing for a meagre share of 7%. It reveals that there is a small group of large firms in the market. It has implications for product quality and technology transfer opportunities across firms as well as for export competitiveness. Large firms are more likely to engage in innovative activities and innovators have high productivity (Chudnovsky et al., 2006) and they are more likely to enter the export market. The large firms have a significant R&D budget for product development while small firms face resource constraints. It reveals that large firms compete on product quality basis while small firms compete on low price (but low quality) basis. It also shows that small firms operate on low margins without having any urge to innovate. Furthermore, small firms provide outsourcing services to large firms but there is a little synergy between large and small pharmaceutical firms. It limits the skill and technology transfer opportunities. Only a few small firms rely on the contracts outsourced by large firms with a greater possibility of mergers and acquisitions. Moreover, this type of industry structure has implications for product quality as well. The cost structure is different for large and small firms. Similarly, small firms possess a low capacity of compliance to DRAP guidelines who seek the harmonization of international standards. In the last five years, DRAP has cancelled the licenses of more than 100 small firms on compliance issues.

2.5.5. High Production Costs

High Dependence on Imported APIs, Excipients and Packaging Material: Drugs production in Pakistan is highly dependent on imported APIs, excipients and packaging material. For instance, Pakistan imports 90% of APIs and executes the formulation process developing tablets, syrups, ointments and others. Thus, with some exceptions, there is no significant value addition or product innovation. Further, using costly raw material directly increases the production costs making firms unable to compete on price or low-cost basis with rival countries in the global

markets. Moreover, relying on imported raw material in a market with rapid exchange rate fluctuations, an approximately 10 percent average annual currency devaluation, double-digit inflation and high financing cost has significantly decreased the profitability of firms (*Business Recorder*, 2024).

High Energy and Other Utility Cost: Pharmaceutical is an energy hungry industry. The APIs must go through 10 to 12 processes comprising intense heat and pressure to be formulated into the finished medicines. Energy cost is very high in Pakistan. For instance, electricity cost is 7-8 cents per Kwh in India and Malysia, but it is 20-22 cents per kwh in Pakistan. Still, it may not consistently available, and firms must arrange a self-owned standby supply which costs around 50 to 52 cents per kwh. Moreover, due to sensitive nature of the product, resource impurity may have serious consequences for drug safety and efficacy. Water in many cities of Pakistan has a high TDS value. For example, water supplied to pharmaceutical firms has a TDS value as higher as 10000 to 11000 as compared to 75 to 90 TDS in India and 55 to 60 TDS in Malysia. So, water is purified by specialised RO plants imported from USA and other developed countries, escalating average cost of production. Likewise, in February 2024, the government increase gas tariff by upto 35 percent despite a substantial increase in gas prices in November 2023.

Lack of Government Support: There is a lack of government support in terms of the following:

- Policy support in terms of subsidies, tax relief, or export incentives to expand firms' export potential and/or easing out the slow and complicated procedures for export rebates and Duty and Tax Remission for Exporters (DTRE).
- Limited trade facilitation in terms of sharing market information, trade shows/exhibitions of importers by embassies/consulates and facilitation in visits of regulators, importers and tender personnel from targeted markets to inspect the manufacturing site of domestic firms in Pakistan.
- Subsidy scheme for product registration, GMP audit fee, Bioequivalence studies (BE) study fee, clinical trials cost, and others for exporter. Likewise, lack of facilitation in manufacturing plant upgradation cost through low commercial bank mark-up rates for accreditation of GMP approval from WHO, USFDA, MHRA, TGA, EMA Regulatory Authorities.
- Financial support for technology transfer projects in Vaccines, Anti-cancers, Bio-technology products in terms of reduction in tariff rate for material and machinery.
- Incentives for local production of APIs especially for top performers. In 2022, DRAP has issued APIs policy in which financial and non-financial incentives are provided for local APIs manufacturing including reduction in customs duty for material and machinery for five years and others. A tariff is also imposed on the import of tariff manufactured in Pakistan (DRAP, 2022)

LITERATURE REVIEW

Standard classical and neo-classical models assume technology to be exogenous and identically available to countries. Among the early frameworks which consider that technology affects production and trade are neo-technology models and technology gap theories (Krugman, 1979). In his insightful study, Krugman (1979) argues that technology is developed and matured in advanced countries and then diffused to developing countries, creating a possibility of trade. These models consider firms' heterogeneity and product differentiation as major drivers of trade (Grossman & Helpman, 1995; Melitz, 2003). However, these models represent developed countries' phenomena assuming learning is a constant factor and considering a limited role of technology adoption. An early framework concerning capability improvement in developing countries via learning and foreign knowledge adoption is provided by the resource-based view (RBV) which presents that firms' capabilities are driven by firms' resources (assets, organization, attributes, and knowledge, among others) which are heterogenous and immobile, thus the difference in resource-based capabilities among firms determine their sustained competitive advantage (Barney, 1991). The capability approach (Lall, 2000) considers that the innovation capability of firms can be enhanced through learning and knowledge spillovers from trade and FDI. The government's trade and innovation policies are also critical in this regard (Rodrik, 2006). Its extension is the dynamic capability view which corroborates the thesis of creating new capabilities by firms and using internal and external competencies to adapt to technological change. Recently, endogenous growth models associated with new trade theories highlight the role of technology in intra-industry and intra-product trade based on scale and agglomeration economies, examining that product variety determines its export potential (Schott, 2008).

The effect of technological innovation on export involves multiple channels. Among others, the existing literature reveals two main channels including internal R&D and external technology acquisition (Herzer, 2022). Internal R&D is created by developing a culture of innovation in the economy. In this regard, universities and public institutions are critical to initiate basic research while industries provide the landscape for the application of basic research outcomes i.e., applied research (Loof & Heshmati, 2002). Further, external technology diffusion through imports and direct technology acquisition is an effective medium in developing countries because they lack the skills and resources for the development of indigenous technology (Rauf et al., 2023). The integrated efforts concerning a significant increase in internal R&D and external technology diffusion increase labour productivity and decrease the average cost of production, making firms compete in the global market on low cost, high quality and product diversification basis (Coe & Helpman, 1995; Cassiman & Veugelers, 2006).

It is established in existing literature that different dimensions of technological innovation increase a firm's export propensity and export intensity (Becker & Egger, 2013). In developing countries, this phenomenon is attributed to innovation-induced productivity improvement (Herzer, 2022), differences in firms' resources (Barney, 1991; Lööf & Heshmati, (2002), differences in firm level absorptive capacity (Harris & Li, 2009), technology transfer through trade and FDI (Lall, 2000), product variety (Schott, 2008), external technology acquisition (Hou & Mohnenn, 2013) and others. However, there is a little empirical evidence on the role of innovation in export performance of firms in developing countries. Among the available studies, Wang et al. (2013) and Yu et al. (2022) finds a positive effect of domestic and external technology acquisition on TFP and firms' export performance in China. Herzer (2022) finds a positive effect of domestic and foreign R&D on export in 32 developing countries. Rijesh (2020) and Barasa et

al. (2021) also find similar type of results in case of India and Sub-Saharan Africa respectively. In Pakistan, Wadho & Chaudhry (2018) provide a useful insight into innovation-firm performance interplay finding the positive effect of innovation on firm performance of textile and apparel industry. However, the study neglects firm's export performance. To our knowledge, this study is first to provide a systematic empirical analysis of the relationship between innovation and firms' export performance in the pharmaceutical sector of Pakistan. The pharma sector is neglected in this regard despite its viable economic significance.

A summary of related studies' objectives and findings is presented in Table 13 below.

Table 13: Summary of Literature Review

Author(s)	Objective and Results of the Study
Coe & Helpman (1995)	This seminal study assesses the role of international R&D spillovers through trade in the productivity growth of firms concluding that the R&D capital of trading partners significantly affects innovation in domestic enterprises.
Alvarez (2001)	The study concludes that there is a two-way causation between exports and technological innovation in Chilean manufacturing industry. Further, FDI and technology licensing also affect innovation but to a lesser extent than indigenous innovation.
Lööf & Heshmati (2002)	The study assesses the relationship between knowledge capital and performance heterogeneity of 619 Swedish manufacturing firms during 1995-1998. The results show a positive relation between knowledge capital and performance heterogeneity. The result holds after controlling human capital, firm size, type of output and other related factors.
Baldwin & Gu (2004)	Using a dataset of 1430 Canadian manufacturing plants, the study mainly retrieve three findings. First, Trade liberalization stimulates exports growth. Second, Firm's participation in export market is attributed to plant's productivity growth. Third, technology transfer attributed to exporting enhances absorptive capacity of firms.
Rodríguez & Rodríguez (2005)	The study investigates the impact of technological capacity on export behavior of 1234 Spanish firms in 1998-99 finding a positive impact of technological capacity of firms on export propensity and export intensity.
Cassiman & Veugelers (2006)	The study investigates the complementarity between internal R&D and knowledge acquisition from foreign sources in the Belgian manufacturing industry. The results show that internal R&D and foreign knowledge acquisition are complementary and that the extent of this complementary depends upon basic R&D capability.
Chudnovsky et al. (2006)	The study argues that Internal R&D and external technology acquisition increase the likelihood of firms' involvement in new product and process innovation. Large firms are more likely to engage in innovative activities and innovators have high productivity.
Lachenmaier & Wößmann (2006)	The study investigates whether innovation causes exports using a sample of 981 German manufacturing firms in 2002. The results of the study show that specific impulses and obstacle cause variation in innovative activity of firms and are exogenous to firms exporting activity. Innovation associated with this variation induce export.
Rothaermel & Hess (2007)	The study develops a multilevel (individual, firm and network or external level) model of innovation strategies corroborating that knowledge spillovers from technology alliances and technology acquisition induce firms' innovation performance.
Şentürk and Erdem (2008)	The differentiating factors of exporting firms from non-exporting firms include the number of employees, firms operating in cities having above zero development index and others. Further, the exporting intensity growth of firms

	is determined by having a marketing department, number of employees, firms, having quality standard certificate, having promotion activities and operating businesses in more developed regions.
Lages et al., (2009)	The paper utilizes resource-based view (RBV) to examine the impact of firms' capabilities (learning capability, quality capability, among others) on product quality and export performance. The results of the study show that firms' diverse capabilities improve product quality and induce export competitiveness.
Foster & Rosenzweig, (2010)	The authors study the barriers to international technology diffusion to low-income countries by reviewing related microstudies. The findings of the study reveal that the difference in own and social learning, skill of workers, innovation externality and scale economies are barriers to technology diffusion to firms in developing countries.
Lileeva & Trefler (2010)	The study assesses the role of input variety owing to higher access to foreign markets and technology, arguing that input variety enhances labour productivity, promotes product innovation and accelerates the rate of adopting imported manufacturing technology.
Hagedoorn & Wang (2012)	The study examines the substitutability or complementarity of internal and external R&D efforts for the innovation output of pharmaceutical firms. The results show that the internal and external R&D are complements for firms with higher levels of R&D capability, while substitutive for firms with low levels of R&D capability.
D'Este et al. (2012)	Revealed and deterring barriers hinder innovation activity of firms. Firms that actively engage in innovative activities face revealed barriers which can be minimized by micro level policies leading to better innovation management. Firms who do not engage in innovation face deterring barriers such as the high cost of innovation. Revealed and deterring barriers may simultaneously present.
Becker & Egger (2013)	The findings of the study show that product and process innovation increase a firm's propensity to export but the product innovation induces export propensity to a greater extent.
Zhu & Fu (2013)	The paper assesses the drivers of export sophistication in low-, middle- and high-income countries. The study finds that knowledge creation activities, import of intermediate products and absorptive capacity contribute to export upgrading.
Wang et al. (2013)	External technology acquisition (domestic and foreign) has a positive and significant impact on exports performance of the Chinese firms.
Santacreu (2015)	The paper develops a multi-country endogenous growth model in which countries are grouped as emerging, less innovative and more innovative. The study confirms that domestic innovation and the adoption of imported technology are crucial drivers of growth. Further, the study finds that the import of technology is a relatively more significant channel to enhance the innovation capability of enterprises in developing countries which account for 65% of embodied growth.
Feng et al., (2016)	The paper estimates the impact of imported intermediate input use on exports in China. The results suggest that firms in the import of intermediate inputs increase volume as well as scope of export. Further, the benefit of imported input use depends upon the firms' ownership structure, R&D capability, and innovation capability of source and destination countries. The study finds that, In terms of magnitude, a 1% increase in intermediate input raises exports by 1.6%. However, Liu and Qiu (2016) find that tariff reduction for intermediate input decelerates innovation in Chinese firms.
Atkin et al., (2017)	The study employs an experimental approach to study the barriers to technology adoption in soccer ball firms in Sialkot, Pakistan. The study performed two experiments by providing employees with a new technology to witness its

	adoption. The study finds the misalignment of incentives between owners and employees as a barrier to technology adoption.
Wadho & Chaudhry (2018)	The paper utilizes a multi-stage structural model to determine the link of production innovation to firms' performance using a sample of textile and apparel industry firms in Pakistan. The study finds that innovation enhances labour productivity and firm performance while the role of foreign knowledge spillovers is critical for firms' innovation performance.
Wang & Tao (2019)	The study finds that firms with both product exports and technology import mechanism have higher growth rates. Firm's entry into export leads to an increased probability of engaging in technology import. Thus, there is a complementary effect of export entry and technology import for growth rate.
Rijesh (2020)	Using a sample of 3209 Indian firms during 1995-2016, The study show that the embodied technological knowledge promotes the export of intermediate and capital goods while disembodied technological knowledge fosters the export of consumer and capital goods.
Khan et al. (2021)	The study seeks to unleash the potential of pharmaceuticals in Pakistan suggesting that different kinds of regulatory, market structure and value chain related issues may be resolved to improve its economic significance.
Yu et al. (2022)	The study examines the effect of the different channels of technology transfer and absorptive capacity on total factor productivity (TFP) of 420 Chinese firms during 2004 to 2017. The results show that cross-national knowledge transfer (CNKT) enhances the TFP and provides absorptive capacity to absorb international knowledge spillovers.
Herzer (2022)	Domestic R&D and international R&D spillovers induce total factor productivity (TFP) in developing countries while domestic R&D has a much greater effect on TFP in them.
Rauf et al. (2023)	The paper investigates the role of imported technology in the export performance of manufacturing industries in China finding that although technology embedded in imported intermediate goods directly affects export upgrading, the technology acquired through licensing does not directly affect export rather requires a threshold level of absorptive capacity.
Haddoud et al. (2023)	Using a Sample of 446 Moroccan SMEs, they study show that R&D expenditure and licensing of foreign technology foster innovation which in turn enhance export intensity
Wadho & Chaudhry (2024)	The study constructs five metrices of process innovation using primary data collected from textile sector of Pakistan to assess innovation-performance interplay. The findings show that process innovation enhances labour productivity and sales revenue, suggesting significant firm heterogeneity in the extent of the impact.
Xuan & Tan (2024)	Government support directly affect export performance of Vietnamese SMEs as well as it indirectly affects export through its interaction with a firms' internal export stimuli.
Audretsch & Belitski (2024)	The findings of the study show that knowledge collaboration at the regional/national/international level and firm productivity promote TI.

Source: Authors' own compilation.

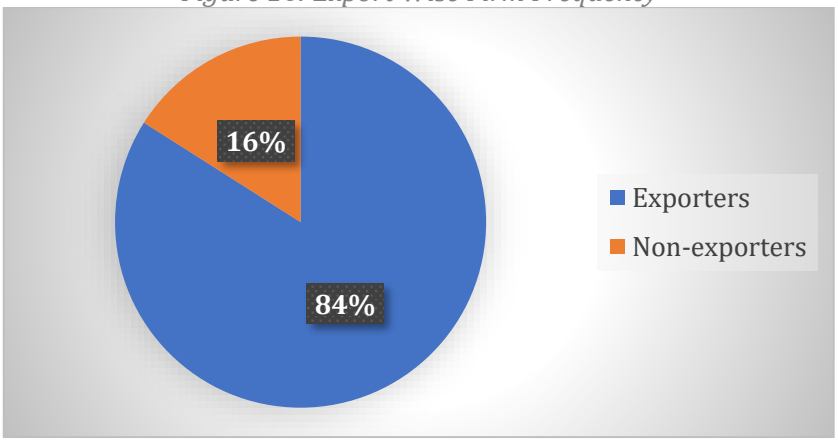
DATA AND METHODOLOGY

3.1. Data Description

The pharmaceutical sector is defined as all manufacturing activities classified under section 21 (Class 2100) of Pakistan Standard Industrial Classification (PSIC) revision 4.0, 2010 and under International Standard Industrial Classification (ISIC) revision 4.0, 2008. The research design of the study is based on primary data. During August to October in 2024, we surveyed the pharmaceutical firms located in Punjab, Sindh, KPK provinces and Islamabad Capital Territory. Total population of the pharmaceutical firms is 639 in which 623 are located in these provinces which is 97% of the population. We used the directory of pharmaceutical manufacturing firms as issued by DRAP as sampling frame which include the list of all pharmaceutical firms registered in Pakistan (DRAP, 2024). We used stratified random sampling method with strata being the geographical location of a firm based on the information in our sampling frame. Our sample is representative at provincial level and regional/district level.

Our sample size is 100 which is 16% of the population. We surveyed all the regional/district-level industrial clusters having more than 15 pharmaceutical firms. The response rate is 51 percent owing to the sensitive nature of the industry. Further, many firms consist of two or three sections only and are less involved either in innovation activities or export. It reduced our main sample to 51 firms within which 43 firms (84%) had positive exports value in 2023-24.

Figure 16: Export Wise Firm Frequency



Source: Authors' own compilation.

Table 14 shows region/district-wise distribution of respondents. 12 each belongs to Lahore, Karachi and Islamabad which is 7%, 9% and 9% of total numbers of firms respectively. 9 responses are collected from Peshawar which is 22% of total while 3 each respondent belong to Faisalabad and Hattar industrial estate Haripur which is 9% and 13% of population respectively.

Table 14: Region/District Wise Distribution of the Main Sample

	Total	Responses	%
Lahore	175	12	7%
Karachi	130	12	9%
Rawalpindi/Islamabad (Rawat)	128	12	9%
Peshawar	41	9	22%
Faisalabad/ Sheikhupura	33	3	9%
Haripur (Hattar)	23	3	13%

Source: Authors' own compilation based on survey response.

Section 2 above explains the regulatory barriers, R&D rigidities and export challenges of pharmaceutical firms in Pakistan. The study also intends to empirically investigate the impact of the different channels of TI and other crucial factors as discussed in section 2 on export performance of pharmaceutical firms. We develop and utilize structured questionnaires and collected information on firms' characteristics (size, productivity, absorptive capacity), firms' engagement in innovation activities including sources (internal and external, domestic and foreign) and types (product, process and organisational) of innovation, the factors hampering innovation activities and the factors promoting TI. Besides, the study covers the information on other supply and demand side factors induce the export performance of firms. We also executed 12 semi-structured interviews of key stakeholders from manufacturers, pharma association (PPMA), academia and DRAP to refine and consolidate the collected information.

With regards to the firms' characteristics, *Firm size* (Size) and *Firm productivity* (Productivity) are measured by the number of employees and the share of sales revenue in employment while firms' absorptive capacity is proxied by two variables including *Human capital* (HCAP) which is taken as the share of university graduates in total employment and training and hiring of R&D personnel (*Training*). With regards to the source and types of innovation, the former is proxied by two variables including *Internal R&D* (Int_R&D) and *External technology acquisition* (Ext-Tech) from domestic and foreign sources while the types are measured by three variables including *Process innovation* (Process), *Organisational innovation* (ORGINV) and *Innovation variety* (Variety). As for factors accelerating TI we cover the following dimensions: technology transfer through FDI (*FDI*), *Infrastructure development* (Infrastructure), *Research collaboration* (*Collaborate*) and *Knowledge spillovers* (*Spillovers*). With regards to the factors hampering TI, we include the following measures: *Industry structure* (Ind_*Structure*); *Regulatory factors* (*Regulatory*) and *Financial/cost factors* (*Financial*). With regards to the other crucial factors promoting (hindering) export we measure *Product diversification* (*Diversify*), membership of regulatory bodies (*Membership*), Infrastructure development (*Infrastructure*) Government incentives and facilitation (*Gov-support)*. The detailed description of the variables is provided in Table 1A of appendix to the study.

3.2. Methodology

We develop two single-equation empirical models including innovation equation and export equation. The objective is twofold: first, to empirically assess the factors which significantly induce firms' innovation performance; second, to systemically estimate the impact of diverse channels of TI and other crucial determinants on firms' export performance. This holistic approach allows a comprehensive empirical assessment of the determinants of firm-level export performance. The innovation equation takes the following form:

$$Innovation_i = \alpha + \beta_1 Size_i + \beta_2 HCap_i + \beta_3 Prductivity_i + \beta_4 Ex\_Tech_i + \beta_5 FDI_i + \beta_6 Training + \beta_7 ORGINV_i + \beta_8 Spillovers_i + \beta_9 Collaborate_i + \beta_{10} Regulatory_i + \beta_{11} Ind\_Structure_i + \beta_{12} Financial_i + \varepsilon_i \quad (1)$$

Where the dependent variable of *Innovation* is measured by firm's decision to innovate (*Decision*) and R&D intensity (R&DINT) which is then regressed on several determinants including *Firm size*, *Firm productivity*, *Human capital*, *Training* and *External technology acquisition* (Ext_Tech). The equation (1) also includes measures on factors accelerating innovation including *Knowledge spillovers* and *Research Collaboration*, and factors restricting innovation including *Regulatory factors*, *Industry structure* and *Financial factors*.

Similarly, our export equation takes the following form:

$$EXP_i = \alpha + \beta_1 Size_i + \beta_2 Int\_R\&D_i + \beta_3 Ex-Tech_i + \beta_4 PROCESS_i + \beta_5 Variety_i$$
$$+\beta_6 Diversify + \beta_7 Infrastructure_i + \beta_8 Membership_i + \beta_9 Gov\_Support_i + \varepsilon_i \quad (2)$$

Where the dependent variables of *EXP* is measured by two variables including export propensity (EXPPRO) and export intensity (EXPINT) which is then estimated on *Firm size*, *Internal R&D*, *External technology acquisition*, *Innovation variety*, *Product diversification*, *Infrastructure development*, firm's membership of stringent regulatory bodies (*Membership*) and government incentives and facilitation (Gov-Support).

Table 1A show that two of our dependent variables including *Decision* and *EXPPRO* and several independent variables are dichotomous having binary outcomes 0 and 1. It is well established that binary data are prevalent in numerous practical problems across various disciplines, notably in social and medical sciences. Models with binary variables are commonly estimated using standard logistic regression. However, we have three issues in our data set. First, a small sample size. That is, we have only 50 observations. In this case, the standard logistic regression may be unstable and prone to be bias. Because, with regards to drawing the inferences, there is an ample discussion on the merits of the large sample for the data distribution. Second, there is a severe imbalance in data points. For example, the dependent variable of *Decision* contains 45 cases of "1s" and only 5 cases of "0s". Thus, it is greatly likely that this imbalance increases the likelihood of separation, and the predicted logistic probability may occur close to 1. In this case, the logistic regression model struggles to distinguish between the two outcomes because the zeros are so sparse. Third, there is the risk of separation. The issue of separation happens when the independent variables perfectly (or nearly perfectly) predict the dependent variable for the '1' category. In our case, with so few 0s, the model may assign extreme probabilities. The standard logit model predicted the probability of 0.97. This will surely cause standard maximum likelihood estimates to diverge to infinity.

Keeping these three econometric issues in mind, we utilize the Firth Logistic (FL) regression to estimate equation (1) and (2). The FL regression[1] is designed to apply a penalization method. It reduces bias in maximum likelihood estimates, which may arise due to small samples and imbalances in data points as well as it ensures that the regression produces stable and finite estimates, even when the separation is present. In a nutshell, the FL regression allows us to gain meaningful insights despite the skewed distribution of the dependent variable.

Consider the logistic regression model, the log-likelihood function for n subjects:

$$l(\beta) = \sum_{i=1}^{n}\left[y_i \beta^T x_i - log\left(1 + exp(\beta^T x_i)\right)\right] \quad (3)$$

The Firth Method modifies the log likelihood function by introducing a penalty term

$$l^*(\beta) = l(\beta) + \frac{1}{2} log|(I\beta)| \quad (4)$$

Where $I(\beta)$ is the information matrix evaluated at β

[1] Firth (1993) proposed a way to adjust the calculations used in generalized linear models to reduce bias. Later, Heinze & Schemper (2002) applied Firth's method to handle a problem in logistic regression called "separation." Separation happens when the data makes it impossible to estimate some values, causing the calculations to go to infinity. Firth's method solves this issue by ensuring the model produces realistic, finite results, even in cases where separation occurs in logistic regression.

It is important to mention a limitation that the magnitude of the coefficients in a FL regression model is not directly interpretable as odds ratios or the marginal effects in the standard logit models. While these values do not translate directly into changes in odds ratios, they credibly indicate the significance, relative strength and direction of the influence of the independent variables on the dependent variable. Further, to enhance the reliability of our results, we applied the bootstrap method to obtain robust standard errors. This approach involves resampling the data multiple times to create various subsets and recalculating the estimates for each sample. By doing so, we account for variability in the estimates caused by the small and imbalanced dataset. The bootstrap-derived standard errors provide a more accurate measure of uncertainty around the coefficients, ensuring that the interpretations remain robust and dependable even under challenging data conditions. This combination of FL regression and bootstrap methodology strengthens the credibility of our findings. Moreover, we estimate bivariate specifications of the estimation equation to tackle the strong association in independent variables in the wake of binary outcomes.

RESULTS AND DISCUSSIONS

The FL regression estimates of the innovation equation and export equation are provided in Table 16 and Table 17 respectively. However, we first conduct correlation analysis using correlation matrix provided in Table 15. The correlation coefficients reveal significant associations between the independent and the dependent variables. *Firm size*, for instance, demonstrates a positive correlation with *Decision* to innovate and *R&D intensity*, suggesting that larger firms are more likely to allocate resources towards innovation. *Firm Productivity* records a positive association with *Decision* and *R&D intensity* showing that more efficient firms are more likely to innovate. Similarly, *Human capital* and *Training* show a meaningful connection with *Decision* and *R&D intensity*, emphasizing the role of absorptive capacity in driving innovation activities.

Table 15: Correlation Matrix

Variable	*Decision*	*R&DINT*	Variable	*EXPPRO*	*EXPINT*
Firm Size	0.1676	0.2335	***Firm Size***	0.3271	0.2734
Human Capital	0.1410	0.2436	***Internal R&D***	0.4677	0.198
Firm's Productivity	0.1831	0.2464	***External Technology Acquisition***	0.5789	0.2451
External Technology Acquisition	0.8079	0.6692	***Process Innovation***	0.4677	0.198
FDI	0.5059	0.4880	***Innovation Variety***	0.5789	0.2451
Training	1.0000	0.6876	***Product Diversification***	0.4677	0.198
Organizational Innovation	1.0000	0.6876	***Infrastructure***	0.5789	0.1386
Knowledge Spillovers	0.8079	0.6692	***Membership***	0.5789	0.2451
Research Collaboration	0.8079	0.6692	***Gov_Support***	0.5789	0.2451
Regulatory Factors	0.6999	0.4812			
Industry Structure	0.6999	0.4812			
Financial Factors	0.6999	0.4880			

Source: Authors' own compilations.

External technology acquisition and *FDI* are also strongly associated with both dependent variables, highlighting that external R&D and foreign technology transfer is strongly linked with firm's innovation performance. *Organizational innovation* is also positively associated with *Decision* and *R&D intensity*, suggesting that internal capacity-building efforts are highly linked to fostering an innovative capability of firms. *Knowledge spillovers* and *Research collaborations* which are the collaborative drivers of firm's innovation show a positive association with *Decision* and *R&D intensity* pointing to the benefits of knowledge-sharing and cooperative endeavours for them. Interestingly, Table 15 shows that *Regulatory factors* and *Industry structure* and *Financial factors* also influence these outcomes, reflecting how an enabling or restrictive framework is linked to innovation decisions. However, these factors should appear negative according to the a priori expectation. This type of ambiguity motivates us to conduct a systematic empirical assessment of the determinants of firm's innovation performance.

Similarly, the association of the *Propensity to export* and *Export intensity* variables with the selected variables is also provided in Table 15. The correlation coefficients show that *Firm size, Internal R&D*, *External technology acquisition* and *Innovation variety* have a positive association with the *Propensity to export* and *Export intensity*, showing that firm size and types and sources of innovation are critical for firms' export performance. Similarly, *Product diversification*,

Infrastructure, *Membership* and *Gov_Support* emerge as factors positively associating both export propensity and intensity by equipping firms with the capabilities needed to compete in international markets.

The preceding discussion provides a strong rationale for an in-depth empirical assessment of the determinants of innovation and export performance of pharmaceutical firms.

4.1. Empirical Estimates of the Determinants of Firm's Innovation Performance

Table 16 shows the FL regression estimates of the determinants of firm's decision to innovate (*Decision*). The sign and significance of the estimated coefficients show the direction and relative influence of the independent factors. Generally, the estimates are fair and plausible as shown by the diagnostics of the model provided at the bottom of Table 16. The McFadden R^2 ranges from 0.649 to 0.688 and Cragg-Uhler R2 ranges from 0.689 to 0.735 rendering a reasonable goodness of fit.

The estimated coefficients for '*External Technology Acquisition*, *FDI* and *Firms productivity* provided in Model 1 are positive and significant. The results are consistent across Models 1 to 10. The estimates reveal the positive effect of the acquisition of technology from external (domestic and foreign) sources in the form of the import of machinery and equipment (embodied knowledge) and the licensing of technology (disembodied knowledge) on a firm's decision to innovate. The results confirm that FDI is critical for firms' decision to invest in innovation activities, suggesting the importance of MNCs in skill and knowledge spillovers to domestic firms. The estimates also show a positive and significant coefficient for *Firm productivity* which reveals that more productive firms are more likely to involve in innovation activities. With regards to the relative importance of these variables for innovation, the coefficient magnitudes show 2.676, 1.39 and 1.6148 for '*External Technology Acquisition*, *FDI* and *Firms productivity* respectively. A higher coefficient for *External Technology Acquisition* suggests that external technology acquisition has a stronger effect on firm's decision to innovate as compared to *FDI* and *Firms productivity*.

The estimated coefficients of *Training* and *Human capital* appeared in Models 2 to 4 are significant and positive, suggesting the positive influence of firm's absorptive capacity on its decision to innovate. It reveals that skill and technical expertise of the employees as well as the internal and external training is crucial to develop a sizable absorptive capacity and to witness its favourable impact on firm's involvement in innovation. Economic theory reveals that firms should attain and maintain a threshold level of absorptive capacity to reap the advantage of indigenous innovation and to internalize and adopt foreign technology spillovers. Similarly, the estimated coefficients of the *Organisational innovation* variable is positive and significant in Model 5, implying that implementing modern organizational methods, business practices and workplace organization is important to strengthen the innovative capability of firms which in turn facilitate firm's involvement in innovation activities.

Table 16: Empirical Estimates of the Determinants of Firm's Decision to Innovate

Regressors	**Dependent Variable *Decision to Innovate***									
	Model 1	**Model2**	**Model 3**	**Model 4**	**Model5**	**Model6**	**Model 7**	**Model 8**	**Model 9**	**Model10**
Constant	-23.8655*	-9.66944	-2.0237	-2.3887	-1.6094	-23.8655	-23.8655	-19.1173	-20.5233	-20.5211
	(12.7244)	(7.20998)	(0.5056)	(0.7480)	(0.4278)	(12.2963)	(13.0424)	(10.0235)	(11.2652)	(11.7770)
External Technology Acquisition	2.6769***	1.3837**	1.0224*	0.9363*	1.0986*	1.6148**	0.9911*	2.1101**	2.4451***	2.0341**
	(1.0800)	(0.6391)	(0.5849)	(0.5481)	(0.5713)	(0.8650)	(0.5122)	(1.0991)	(1.0413)	(1.1405)
FDI	1.3933*	1.4254***	1.4786***	1.4721***	2.2687***	1.3933*	1.3933*	2.2974**	1.3192*	1.3192*
	(0.8494)	(0.5693)	(0.5082)	(0.4933)	(0.4909)	(0.8542)	(0.7723)	(1.0413)	(0.6761)	(0.8013)
Firm's Productivity	1.6148*	0.5775*	--	--	--	--	1.6148	1.3079	1.4100	1.4221
	(0.8973)	(0.3128)	--	--	--	--	(0.9099)	(0.9454)	(0.8172)	(0.7221)
Training	--	1.9725***	2.6300***	2.6067***	--	--	--	--	--	--
	--	(0.8259)	(0.5649)	(0.5271)	--	--	--	--	--	--
Human Capital	--	--	0.1530*	--	--	--	--	--	--	--
	--	--	(0..0901)	--	--	--	--	--	--	--
Organizational Innovation	--	--	--	--	2.7081***	--	--	--	--	--
	--	--	--	--	(0.5486)	--	--	--	--	--
Research Collaboration	--	--	--	--	--	2.6769***	--	--	--	--
	--	--	--	--	--	(1.1228)	--	--	--	--
Knowledge Spillover	--	--	--	--	--	--	2.6769***	--	--	--
	--	--	--	--	--	--	1.0659	--	--	--
Regulatory Factor	--	--	--	--	--	--	--	1.3339	--	--
	--	--	--	--	--	--	--	1.3962	--	--
Industry Structure	--	--	--	--	--	--	--	--	-0.1917	--
	--	--	--	--	--	--	--	--	0.2043	--
Financial Factors	--	--	--	--	--	--	--	--	--	-0.1916
	--	--	--	--	--	--	--	--	--	(0.2811)
Observation	50	50	50	50	50	50	50	50	50	50

Diagnostic Test										
Mcfadden R2	0.6780	0.649	0.6890	0.668	0.6730	0.678	0.6710	0.655	0.6320	0.6880
Cragg-Uhler R2	0.7210	0.701	0.7350	0.718	0.7250	0.721	0.7110	0.688	0.6860	0.7322
Log-likelihood (intercept)	-10.0770	-11.927	-11.2340	-11.529	-11.9960	-10.077	-11.5580	-6.987	-11.9190	-11.2265
Log-likelihood (Full Model)	-3.2440	-4.192	-3.4960	-3.824	-3.9170	-3.244	-3.8145	-4.5858	-4.3810	-3.4489

*Notes: Standard errors are in parenthesis. * Significance level of 10%, ** Significance level of 5%, *** Significance level of 1%.*

With regards to the results of *Knowledge spillovers* and *Research collaborations* variables, the estimates are positive and significant in Models 6 and 7. It reveals that knowledge spillovers are critical for innovation performance of firms. In the pharmaceutical sector, the contract research and manufacturing services (CRAMS) are crucial sources of knowledge spillovers amongst others. The results advocate the significance of contract research organisations (CROs) and toll/contract manufacturing services for firm's innovation performance. The results also confirm that research collaborations among firms through strategic partnerships and joint ventures are critical drivers of firm's innovation decisions. It also hints at the critical importance of the university-research institution-industry linkages for a firm's engagement in innovation. Further, a higher coefficient magnitude of *Knowledge spillovers* and *Research collaborations* variables than *External technology acquisition* and *FDI* suggests the relative importance of these somewhat inward oriented factors on outward oriented determinants of innovation.

Measuring the effect of factors restricting firm's involvement in innovation activities the empirical estimates of the *Industrial structure* and *Financial factors* appeared in Models 8 to 10 are negative but insignificant while the estimated coefficient of *Regulatory factors* is also insignificant which is against a priori expectations. The possible reason is that these factors are kind of stagnant and observe a little change unless there is a significant policy shift which is less captured due to data limitations.

4.2. Empirical Estimates of the Determinants of Firm's Export Performance

The FL regression estimates of the determinants of a firm's propensity to export are provided in Table 17. The rationale for estimating bivariate models is discussed in detail in methodology section. In general, the results are fair and show a reasonable goodness of fit as shown by McFadded R^2 which ranges from 0.364 to 0.51 and Cragg-Uhler R^2 which ranges from 0.46 to 0.62.

The estimated coefficient of *Firm size* is positive and significant, confirming that larger firms are more likely to enter the export market. The results are consistent across Models 1 to 8. Evidence show that large firms allocate more resources to innovation activities and maintain an R&D friendly organisational structure. Further, we have already seen in the preceding section that firm size is a critical determinant of innovation performance. The findings reveal that the more innovative firms are more productive and hence more likely to enter the global export market.

The estimates of *Internal R&D* and *External technology acquisition* are also positive and significant as shown in Model 1 and 2. It reveals that internal R&D activities are critical for entry into the export market. The results confirm to the neo-technology models which explain the role of R&D in production and trade structure (Krugman, 1979). R&D activities increase the design, variety, quality and reliability of products (Rodil et al., 2016). In addition, R&D activities increase the productivity of labour which contribute to a significant share of average cost in developing countries, providing a firm competitive advantage in the global market (Rauf et al., 2021). The results also confirm that the acquisition of external technology through the import of advanced machinery and equipment (i.e., embodied knowledge) and licensing of technology (i.e., disembodied knowledge) are critical determinants of a firm's entry into the export market. Evidence show that external technology complements the internal R&D to make a significant effect on export performance of enterprises (Hagedoorn & Wang 2012). This result is crucial in the case of a developing country because the phenomenon is already established in middle and high-income countries. It reveals that firms in developing countries can enhance their export performance through accelerating indigenous innovation activities and adopting and internalizing international technology spillovers. The coefficient magnitude of the variables also

confirm that *Internal R&D* and *External technology acquisition* are more significant determinant of export propensity than *Firm size*.

Similarly, the estimated coefficients of *Process innovation* and *Innovation variety* variables are also positive and significant in Models 3 and 4. It reveals that process innovation and firm's involvement in variety of technological and non-technological innovation activities are critical for its likelihood to export to the global market. In fact, involvement in a variety of the types of innovation activities reduces the production costs and help firms to comply with GMP practices which is critical for export performance of the pharmaceutical firms. Further, the estimates of *Product diversification* and *Infrastructure* appeared in Model 5 and Model 8 are positive and significant, confirming that both variables induce firm's entry into the global market. Findings reveal that the products focusing emerging therapeutic avenues are critical for export. In the context of Pakistan, it broadly involves the production of high-quality generics and simpler biologicals such as vaccines and others. Besides, findings pertinent to infrastructural development show that establishment of drug testing laboratories and Bioequivalence/Bioavailability study centres are crucial for export propensity of firms.

As for the estimates of *Membership* and *Gov_Support* variables in Model 6 and 7, they have a positive and significant effect on firm's propensity to export. It reveals that the membership of firms of international regulatory bodies (e.g., US FDA) and the membership of the drug regulatory body of a country of PICS countries is critical for entry into the export market. Further, incentive provided by government for local production of APIs, import of machinery and equipment, export rebates, financial support for BE studies and GMP inspections and facilitation for drug registration, capacity enhancement and commercial activities are critical for export performance of firms in developing countries.

Table 17: Empirical Estimates of the Determinants of Export Propensity

Regressors	**Dependent Variable *Export Propensity***							
	Model 1	**Model 2**	**Model 3**	**Model4**	**Model5**	**Model6**	**Model7**	**Model 8**
Constant	-5.9989***	-6.1852***	-5.9989***	-6.1852***	-5.9989***	-6.1852***	-6.1852***	-6.1855***
	(1.8077)	(1.7631)	(1.8230)	(1.7555)	(1.7695)	(2.0456)	(2.1103)	(2.1997)
Firm Size	1.1164***	1.0256***	1.1164***	1.0256***	1.1164***	1.0256**	1.0256***	1.0352*
	(0.4384)	(0.4139)	(0.4575)	(0.4036)	(0.4397)	(0.4852)	(0.4913)	(0.4661)
Internal R&D	1.7040**	------	------	------	------	------	------	------
	(0.8418)	------	------	------	------	------	------	------
External Technology Acquisition	------	2.4908***	------	------	------	------	------	------
	------	(0.8422)	------	------	------	------	------	------
Process Innovation	------	------	1.7040**	------	------	------	------	------
	------	------	(0.8721)	------	------	------	------	------
Innovation Variety	------	------	------	2.4908***	------	------	------	------
	------	------	------	(0.8283)	------	------	------	------
Diversification	------	------	------	------	1.7040**	------	------	------
	------	------	------	------	(0.8256)	------	------	------
Membership	------	------	------	------	------	2.4908***	------	------
	------	------	------	------	------	(0.8541)	------	------
Gov_Support	------	------	------	------	------	------	2.4908**	------
	------	------	------	------	------	------	(0.9039)	------
Infrastructure	------	------	------	------	------	------	------	2.4908***
	------	------	------	------	------	------	------	(0.9087)
Observation	50	50	50	50	50	50	50	50
Diagnostic Test								
Mcfadden R2	0.3640	0.4150	0.4250	0.4004	0.4565	0.4675	0.4404	0.5022
Cragg-Uhler R2	0.4610	0.5150	0.6145	0.5071	0.5665	0.6760	0.5578	0.6232
Log-likelihood (intercept)	-20.5520	-20.3770	-19.2514	-22.6072	-22.4147	-21.1765	-24.8679	-24.6562
Log-likelihood (Full Model)	-13.0730	-11.9180	-10.2344	-14.3803	-13.1098	-11.2578	-15.8183	-14.4208

*Notes: Standard errors are in parenthesis. * Significance level of 10%, ** Significance level of 5%, *** Significance level of 1%*

4.3. Sensitivity Analysis

For concreteness, we also conduct the sensitivity analysis of our estimates. In this regard, we take *R&D intensity* as measured by the share of R&D expenditure in sales revenue and *Export intensity* measured by the share of exports in sales revenue as dependent variables. We develop bivariate models to preserve our dataset's available degree of freedom and estimate them using the ordinary least squares method.

The results are broadly consistent with the FL regression estimates provided in Tables 16 and 17. It reveals that our results are robust to changes in the proxy of variables and the estimation method[2]. This consistency across variables and methods reduces our concern about the potential bias. Specifically, in the context of bivariate models, the results are not only logical but also follow the expected theoretical directions, which further strengthens our confidence in their reliability and relevance.

4.4. Discussion

The results of the study highlight the importance of the domestic and foreign R&D for export performance of firms. R&D in pharma is conducted for formulation stability and for new molecule discovery. With some exceptions, we are currently at basic dosage formulation stage and new drug discovery is absent. More R&D in formulation industry may leads to value addition and facilitate the production of high-quality generic drugs which may achieve competitive advantage in global market. Who will do basic research for new molecule discoveries? A traditional model of basic research is that it is conducted in universities or public research institutions. Our results also suggest that university-industry linkage is critical for firm's innovation performance. A strong problem identification mechanism at universities and updating curriculum to meet industry needs is critical. Moreover, the applicability and industry use of academic research is critical to be enhanced in the context of more longitudinal or horizontal studies. Besides, a modern approach of basic research in pharma is that scientists in academia who are specialists in drug discovery create small research groups or specialized research labs and execute research till phase 1 while clinical trials are offered to CROs, and manufacturing is conducted by toll or contract manufacturing. We can learn from China who formulated and successfully implemented this policy 8 years ago. FDI is another crucial factor for providing related knowledge spillovers as suggested by the empirical results of the study. One of the limitations is that discovery is costly and risky, and it is not broadly encouraged in an industry with weak IPRs. Further, for discovery one needs to develop testing labs first. Thus, a roadmap for discovery is inevitable at this stage.

Globally, a shift has occurred from conventional dosage form to novel practices such as biologicals. Till 2033, 30% of the medicines or treatments will be shifted to biologicals. The limitation for the pharmaceutical sector of Pakistan is that shifting to biologicals needs advanced technology with high sunk cost. Thus, there is an issue of skill and affordability. Likewise, technology has shifted from

[2] we needed to run 32 regressions for two different specifications considering the bivariate specifications. If we present them here, then it would take up too much space without adding significant new information. Therefore, we deliberately did not present the results in a tabular form keeping brevity in view and to avoid unnecessary repetition.

mechanical to electrical to electronic to digital with AI based mechanisms. Now it requires a high acquisition price and consistent updating expenses. Government in collaboration with leading industry players and academia has a significant role to play for technology upgrading. In a short to medium run, Pakistan may prioritize to kickstart the production of biosimilars (a low-cost alternative to biologicals) and simple biologicals including vaccines, sera and blood products. It suggests a critical role of biotechnology. The role of joint ventures and strategic partnerships is also crucial in this regard.

The findings of the study suggest that knowledge spillovers through contract research and manufacturing services (CRAMS) are crucial for innovation and in turn firm's export performance. CRAMS provide firms with exposure to science and technology which facilitates technology upgrading of domestic firms, implementation of GMPs and Good Clinical Practices (GCPs) and the establishment of drug testing laboratories and related infrastructure including the establishment of bioequivalence/bioavailability study centers which itself is a mandatory requirement for drug export. Pakistan is a crucial place for CROs as a large number of the different types of diseases are prevalent here making it an ideal place for stage 3 trials. Our positive result of the impact of infrastructure on firm's export performance further confirms this argument further.

The results also confirm that WHO accreditation and the membership of regulatory authority to PICS countries and of individual firms to international regulatory bodies including US FDA and others induce firm-level export. Membership enhances the likelihood of compliance. For example, PICS mainly conducts training of the regulatory body on GMPs, quality control, auditing etc. However, the membership involves a rigorous, consistent and costly process which requires a holistic approach and facilitation from different stakeholders including government. It also causes substantial costs to occur due to which firms may suffer in the domestic market. Thus, the firm strategy to create a balance between local and foreign business is reflected in the membership. The 'Seth' mentality may oppose PICS certification due to rise in cost of doing business. However, it may lead to consistent and high growth in future.

With regards to the 15% retention rate against export proceeds stakeholders from industry consider it insufficient to meet foreign liabilities. In this regard, to encourage exports the State Bank of Pakistan (SBP) has taken the following measures: First, as per Para. 36 of chapter 12 of foreign exchange manual, exporters manifesting at least 10% increase in their net export proceeds in terms of USD over the last financial year's exports have been allowed to retain 50% of their additional export proceeds in their foreign currency account; Second, Para 40 of chapter 12 of Foreign Exchange Manual which restricted the utilization of funds retained in special foreign currency account has been withdrawn and utilization of such funds to make external payments of current account nature has been liberalized. These steps may provide leverage to leading exporters if disseminated in a good manner.

The result of the study confirms to the extant literature on the positive effect of firm size, productivity and absorptive capacity on export propensity. However, the things are complex in the case of Pakistan pharmaceutical sector. On the one hand, around 640 companies competing for USD 3.5 billion in 2024 makes the average firm's market size nearly to cottage firm. Further, except for the top 100 firms, the remaining 540 firms show little involvement in innovation activities as they face survival issues. The turnover of such firms is so small that they feel difficulty in GMP compliance. It

restricts the scope of the sector for innovation activities. On the other hand, the top 100 firms constitute 98% of the market size, have the capability to innovate and producing quality generic drugs. Some of them have earned WHO, MHRA and PICS prequalification. The net effect is based on the domestic and/or foreign market focus of these large firms and their willingness to involve in innovation activities.

Two aspects of the price control by the government are worth discussing. First, Price approvals go to the cabinet which cause delays, restrict price adjustment as per the changes in the cost of production and hamper gross margins. The deregulation of prices of non-essential drugs in February 2024 to absorb the substantial rupee devaluation has seen a welcoming response. The sector witnessed the highest ever sales growth of 25% in 4th quarter of FY-2024 of which 20% was attributed to price increase though and 5% to volumetric increase. However, consistent price change criteria and a dedicated price board are critical to eliminate the unfavorable effect of price rigidity on re-investment of funds into R&D.

The findings of the study suggest that product diversification promotes export performance. Two avenues are utilized at the sub-optimal level in this regard: production of nutraceuticals; and production and branding of herbal products. Capacity enhancement in the favor of these products may facilitate import substitution first, and then it may lead to exporting. A relevant example can be of Chinese traditional medicines which provides plentiful competitive advantage to China.

POLICY RECOMMENDATIONS

For Industry

- A prudent R&D-based development framework for the pharmaceutical sector is inevitable for sustained export growth. We recommend a three-pronged R&D strategy: First, R&D for the formulation industry to enhance their capability of producing high-quality generics and capturing off-patent market; Second, R&D especially basic research for the discovery of new molecules through university-research group-industry linkages; Third, R&D to gain the capability of the production of synthetics or biologicals. This can happen if firms, in the short to medium run, increase their R&D intensity and the government utilizes the Central Research Fund (CRF).
- We propose that in the next 3 to 5 years large pharmaceuticals firms (i.e., firms with an annual turnover of more than PKR 10 billion) develop an R&D consortium. Government to allocate a portion of CRF and additional funds from S&T allocation. The industry may invite scientists and researchers to conduct basic research for high-value formulation, drug discovery and building capability to move to biologicals, the next generation of medicines.
- Firms should focus on accreditation of plants from international regulatory bodies including US FDA, MHRA, EMA, WHO amongst others to enter the SRA countries. Technology upgrading through external technology acquisition is a necessary condition in this regard. Firms may collaborate with DRAP to receive the guidelines for the technology upgrading processes.
- Besides basic research, Pakistan may become the source by offering pre-clinical and clinical trials facility. The study recommends the establishment of CROs/Analytical labs and their affiliation with hospitals in medical universities like Agha Khan University, DOW University of Health Sciences etc. The government is then required to facilitate the visits of inspectors from WHO, US FDA and other stringent bodies to attain Good Clinical Practices (GCP) certificates. It will also lead to the establishment of Bioequivalence/Bioavailability (BE/BA) study centers. The proof of BE study is an essential document in the drug registration folder.
- The study proposes for firms who are less capable of doing basic research to involve in toll/contract manufacturing at low R&D cost. It will make domestic firms gain the capability to manufacture for MNEs and regional countries.
- We suggest that the leading exporters in industry may internalize and take advantage of the expanded USD retention limit up to 50% of additional exports proceeds for exporters manifesting at least 10% increase in their net export proceeds in terms of USD.
- There is a need to:
    - Explore the untapped potential of herbal medicines. M/S Herbion may be an effective case study in this regard
    - Prioritize the production of nutraceuticals
    - devise a mechanism to rule out pharma being the out-of-pocket market so that the production of specialized but expensive medicines may encourage.
- We recommend a decrease in expenses a firm incurs on the post-production stage and more spending on drug discovery and development stage. A fair mechanism may be the upper limit of the firms seeking permission to launch a molecule may be decreased but not at the cost of competition.

For Academia

- We recommend a change in curriculum pertinent to understanding the global standards and pharmacovigilance system.
- There is a need to develop a viable university-industry linkage where the problem identification and implementation into the curriculum will be smooth.
- We recommend more longitudinal and horizontal studies, keeping in view the applicability, industry use and commercialization of knowledge created in academia. Drafting of KPIs on how many startups have been executed and what is the entrepreneurial contribution of students is critical.
- The study proposes an increase in the biotechnology schools and research labs in order to gain the capability to move to new therapeutic avenues.
- There is a need to gradually move away from the content on pure mechanical machinery and equipment to a digital and AI based equipment.

For DRAP

- DRAP to materialize the use of CRF and seek amendments in the Drug Act 1976 for this purpose if necessary. Further, we recommend the use of CRF for R&D projects in academia and industry and the upgradation of public laboratories.
- We suggest that approval time of the phase 2-3 trials which are offered through bid should be minimum to avoid the expiry of bid.
- We recommend human resource capacity enhancement at DRAP and legislative changes to Drugs Act 1976 and to expedite the process of PICS membership. Until DRAP becomes PICS member, the government should facilitate GMP inspections, including issuing visas and fast-tracking immigration for GMP inspection teams.
- DRAP to revise the toll manufacturing policy to provide time and resource flexibility and ease out the max limit of products to be tolled to firms capable to involve in toll manufacturing.
- To arrange CRO (Clinical Research Organization) site inspection for accreditation of CROs from US FDA, EU, MHRA (UK) regulatory bodies so that Clinical trials & Bio-equivalence studies will be accepted internationally and fulfill the requirement of stringent developed markets like South Africa, Eastern Europe, USA & Canada.
- Permission to manufacture dietary (Vitamins) supplements and nutraceuticals in pharmaceuticals site (without compromising the compliance of international standards, for export purpose only in order to penetrate nutraceuticals and herbals exports market. This will also help us to reduce imports of nutraceuticals from China and others.
- There is a need to devise a criterion to limit the registration of a single molecule by so many firms to avoid more spending at the post-production stages. One criterion may be that molecule registration for life saving drugs will be awarded based on the success record.
- The capacity development of DRAP for guidelines and its implementation of AI-based/biological drugs.
- There is a need for the upgradation of the automated management system which, for instance, provides a fast-track drug registration system for off-patent markets.

- There is a need to develop a mechanism to prioritize commercial activities and they should not be hampered by the coherence with technical regulations.

For Federal Government

- We recommend a decrease in the tariff rate on the import of machinery and equipment for pharmaceutical manufacturing.
- The price decision should not go to the cabinet. There should be a dedicated price board which decides the pricing criterion and implements it keeping in view the cost of production and other related factors.
- We suggest the revision of existing APIs policy based on the available experience and setting up a task force to examine its implementation.
- Electricity tariff for industry should be decreased and there should be a mechanism to treat water especially used by pharma firms. Water supply line is a better solution than water tanks which confront greater impurity.
- Government should devise and implement indigenization policy for MNCs and set a specific criterion (e.g., joint ventures) for technology transfer from MNCs.
- Government to invite and facilitate the visit of regulators, inspectors, importers to visit the manufacturing facility for accreditation or building confidence.
- Government to offer incentive (e.g., financial subsidy) for technology transfer for the production of vaccine, antisera, blood products and other biologicals. Similarly, government to prioritize of the establishment of BE/BA study centers and testing laboratories.

For SBP

- We suggest an increase in the USD retention limit of the exports proceeds of pharmaceutical firms. A possible mechanism may be similar to as adopted in the case of IT sector and freelancers which were temporarily allowed to retain as much as up to 50% of their export proceeds in their special foreign currency account on the condition that they will exhibit a sustainable growth in their exports. Afterwards, showing satisfactory performance, the relevant clauses of the foreign exchange manual were amended accordingly and the retention rate was allowed to 50%.
- There is a need to eliminate non-uniformity in compliance departments of different commercial banks authorized for export by SBP

For Ministry of Commerce

- MoC may liaison with DRAP on commercial activities of the pharmaceutical firms to speed up execution.
- The export development funds may be utilized for BE studies which is an essential document for drug export.
- Embassies and Consulates to share market and importers' information for correspondence with pharma exporters. TDAP to arrange healthcare products exclusive exhibitions in the targeted market.

Future Research

Pharmaceuticals is classified as a medium-high and high-technology sector. Thus, a dedicated study to exploring complex innovation and firm performance interplay will be critical. Further, studies in future may undergo an in-depth analysis of the factors accelerating (hindering) the process of capacity enhancement for the production of biologicals, a modern therapeutic avenue.

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APPENDIX

Table 1A: Description of Variables

Variable Name	Acronym	Description
Decision to innovate	Decision	1 if a firm in 2024 has invested in internal R&D and/or external technology acquisition; 0 otherwise
R&D intensity	R&DINT	The share of R&D in sales revenue
Export Intensity	EXPINT	The share of exports in sales revenue
Export Propensity	EXPPRO	1 for positive export sales in 2024; 0 otherwise
Internal R&D	Int_R&D	1 if a firm in 2024 has invested in any of the following: (i) internal R&D, (ii) internal and external training of workers
External Technology Acquisition	Ext_Tech	1 if a firm in 2024 has invested in any of the following (i) import of machinery and equipment, (ii) licensing of technology, (iii) hiring of R&D personnel from external sources; 0 otherwise
Firm Size	Size	Total number of employees
Human Capital	HCAP	Share of employees with a university degree
Firm Productivity	Productivity	The ratio of sales revenue to employment
Foreign Investment	FDI	1 if a firm considers MNCs as highly important external source for skill and knowledge spillovers during 2021-24; 0 otherwise
Training of workers	Training	1 if a firm in 2024 has engaged in the training of internal workers and hiring of R&D personnel from external (domestic and foreign) sources; 0 otherwise
Process innovation	PROCESS	1 if a firm during 2021-24 has actively engaged in process innovation; 0 otherwise
Organisational Innovation	ORGINV	1 if a firm during 2021-24 has actively engaged in organisational innovation; 0 otherwise
Innovation Variety	Variety	1 if a firm in 2024 has engaged in both TI and non-technological innovation (marketing and organisational innovation); 0 otherwise
Product Diversification	Diversify	1 if a firm considers the following modes of sector diversification as very important for export growth during 2021-24: products focusing emerging therapeutic avenues; nutraceutical & Herbal products; indigenous vaccine development; 0 otherwise
Infrastructure Development	Infrastructure	1 if a firm considers the following factors as highly important for innovation and export: Drug testing laboratories; Clinical Trials Facility; Bioequivalence/bioavailability study centres during 2021-2024; 0 otherwise
Membership	Membership	1 if a firm considers any of the following factors very important to fulfil stringent regulatory requirements for export during 2021-24: Membership of firms of international regulatory bodies e.g., US FDA, MHRA etc; WHO prequalification of Pharmaceuticals (WHO PQP); Membership of DRAP of Pharmaceutical Inspection Cooperation Scheme (PICS) countries; 0 otherwise
Government Incentives and Facilitation	Gov_Support	1 if firm considers the following factors very important for export competitiveness during 2021-24: Incentives for local production of APIs; Incentive for import of machinery and equipment; Export

		rebates for the leading exporters; Financial support for BE studies and GMP inspection expenses; Facilitation for drug registration and export NOCs; Facilitation through capacity enhancement; commercial activities related facilitation; Facilitation in GMP inspections; Trade facilitation; 0 otherwise
Research Collaboration	Collaborate	1 if a firm considers the following factors as highly important collaborative sources accelerating innovation during 2021-24: university-Research group/centre-industry linkages; Strategic partnership; joint ventures; network resources; 0 otherwise
Knowledge Spillovers	Spillovers	1 if a firm considers knowledge spillovers from Contract Research and Manufacturing Services (CRAMS) as highly important for innovation activities during 2021-24; 0 otherwise
Regulatory Factors	Regulatory	1 if a firm considers any of the following factor as highly important restricting innovation activities during 2021-24: Price regulations; weak intellectual property rights; underutilisation of central research fund; relatively higher tariff rate on machinery and equipment; Regulatory control on CRAMS; 0 otherwise
Industry Structure	Ind_Structure	1 if a firm considers any of the following factor as highly important restricting innovation activities during 2021-24: A significant share of few large firms in market share; limited linkages for technology transfer between domestic large firms and SMEs, domestic and foreign firms; high production cost of drugs; more spending on postproduction (e.g., Packaging, Marketing etc.) activities but less spending on innovation; 0 otherwise
Financial Factors	Financial	1 if a firm considers any of the following factors as highly important hampering innovation activities during 2021-24: lack of funds within enterprise; limited credit availability; limited fiscal space and tax incentives for innovation; short-term scope of allocated fund; high fixed cost of innovation; slow or no recovery of drug development cost; high operating cost of high-tech machinery and equipment; 0 otherwise

Source: Authors' own compilation.