GOVERNMENT OF PAKISTAN

Pakistan Export Strategy Pharmaceuticals

2023-2027

This Pharmaceuticals sector strategy is part of the National Priority Sectors Export Strategy (NPSES) initiative which contributes to the implementation of Pakistan's Strategic Trade Policy Framework (STPF) 2020-2025.

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Pakistan Export Strategy

Pharmaceuticals

2023-2027

Forewords

Message from the Ministry of Commerce

Increasing international trade is not only a means of boosting economic growth and the nation's welfare, but also contributing to strengthening international relations. The stabilization of economic and political affairs paves the way for reinforcing friendly relations based on mutual interests with a wide range of trade partners. Trade is thus one of the most important forms of exchange between countries and fostering this will lead to connections such as foreign investments, better employment opportunities, and scientific and technical exchanges, all of which will contribute to Pakistan's growth and prosperity.

The Government of Pakistan has taken a series of initiatives to promote exports to achieve sustainable and inclusive economic growth, poverty reduction and improvement in the living standard of Pakistani people. This is also aligned with the government's vision of the Strategic Trade Policy Framework (STPF) 2020–25 for 'Pakistan to become a dynamic and efficient domestic market as well as a globally competitive export-driven economy'. In this context, the Ministry of Commerce supported the preparation of the Pharmaceuticals Export Strategy, a priority export sector under the STPF, which will contribute to export diversification of Pakistan. This sector export strategy has been formulated in close consultation with all the stakeholders; and the Ministry of Commerce appreciates all those involved in the process, particularly the private sector.

As a priority export product within the framework of the STPF 2020-25, pharmaceuticals presents a new export avenue and an opportunity for Pakistan. The strategy encompasses trade-related factors such as ensuring export quality, greater market access and product diversification. In addition, substantial investment to expand export potential and grow foreign trade requires strategic targeting. All activities in the strategy design framework have outlined a detailed five-year plan of action to tackle issues and facilitate export procedures, and as identified by all the stakeholders pharmaceuticals sector in Pakistan.

Despite challenges in the international trade scenario and the global business environment, I am confident that this initiative will serve as an action-oriented blueprint to enhance trade performance and develop a coordinated mechanism with participation from both the public and private sector, increasing its competitiveness in the international market.

To maintain the momentum sparked by the consultations, the Ministry of Commerce committed to play a constructive and facilitative role, while making it our top priority to execute the activities and reforms proposed in the Plan of Action in consultations with the stakeholders. We are particularly committed to continue keeping the private sector in the driving seat for the implementation process through the Sector Specific Council (SSC) on Pharmaceuticals & Cosmetics. The Government of Pakistan is fully committed to promoting export-led economic growth and encourages all to join hands and work together in making the vision of a flourishing Pharmaceutical sector a reality.

Message from Pakistan Pharmaceutical Manufacturers' Association (PPMA)

The Strategic Trade Policy Framework (STPF) of Pakistan has identified pharmaceuticals as a priority focus export sector for growth and development for the next five years. Pharmaceuticals in the Islamic Republic of Pakistan presently form a $3.29 billion industry, growing in double digits in the last five years. The sector has seen massive changes in the past decade, providing essential health care products to citizens and introducing them to revolutionary pharmaceutical preparations. Today, there are 639 pharmaceutical manufacturing units in Pakistan, employing approximately 240,000 people and exporting products worth more than $200 million to more than 60 countries.

The sector is helped by progressive government reforms, notably the customs duty reduction for more than 300 active pharmaceutical ingredients (API), and for the import of plant, machinery and equipment by registered pharmaceutical manufacturers. These have helped the sector to grow in prominence in the national economic landscape and it has its sights set on playing a larger role in export revenues in the years ahead.

Currently, the pharma industry fulfils more than 95% of domestic pharmaceutical requirements. Our goal is to ensure the availability of quality medicines to all at a reasonable price and to enhance the country's exports by accessing more value-added markets of Central Asia, the Middle East and North Africa (MENA), Europe, and the United States.

However, despite its rapid growth and massive reach, the pharmaceutical industry continues to face issues related to drugs pricing, limited intellectual property rights protection, lack of timely regulatory approvals, and negligible investments for research and technological upgradation. On behalf of the members of the Pakistan Pharmaceutical Manufacturers' Association (PPMA), we appreciate the strategy and its efforts to campaign for the sector and are hopeful that this will initiate a much-needed dialogue on the state of Pakistan's pharmaceutical sector.

Pakistan's pharmaceuticals industry is a very dynamic, knowledge-based industry. It is going through a transition phase of modernization to cater to local pharmaceutical requirements and to access a more regulated market. To support this process, conducive policy measures for the industry and a favourable regulatory framework will certainly help grow industry volumes and, in the process, create more jobs, as the pharmaceuticals industry has a high multiplier effect.

As this strategy has rightly identified, our industry must focus on developing the skilled workforce available, welcoming more foreign investment, and encouraging innovation and research targeted towards developing new products and tapping into new markets. This strategy provides an excellent roadmap for the sector's future growth, with a focus on quality, competitiveness, innovation and export market expansion. As the global pharmaceuticals sector evolves significantly in the coming years, especially in the aftermath of the COVID-19 pandemic, our sector would work on capitalizing on these new trends, while continuing to maximize potential in current segments.

The recommendations of the Pharmaceuticals Export Strategy are a combined effort of public and private sector stakeholders to optimize strengths and overcome constraints. As the sector's apex stakeholders, we are committed to implementing this strategy, to make Pakistan an emerging leader in the pharmaceuticals sector to cater to regional and global markets, while meeting domestic demand.

Qazi M. Mansoor Dilawar
Chairman, PPMA

Acknowledgments

The Pharmaceuticals Export Strategy forms an integral part of Pakistan's Strategic Trade Policy Framework (STPF). It was developed under the aegis of the Government of Pakistan and the leadership of the Ministry of Commerce (MoC) and the Trade Development Authority of Pakistan (TDAP), in close collaboration with the Ministry of National Health Services Regulations and Coordination (MNHSRC) and the Pakistan Pharmaceutical Manufacturers' Association (PPMA).

The document benefited particularly from the inputs and guidance provided by the sector stakeholders that steered the strategy's formulation, namely the following key sector institutions:[1]

Institutions	
ATCO Lab	Pharmaroya Pakistan
Athix Pvt Ltd	PharmEvo Pvt Ltd
Brookes Pharma	Punjab University
CCL Pharmaceuticals	Renacon Pharma Ltd
Dawn Lab International Private Limited	Royal Group
Drug Regulatory Authority of Pakistan	SAMI Pharmaceuticals
Frontier Dextrose Limited	Sante Private Limited
FYNK Pharmaceuticals	Schazoo Zaka (Pvt) Ltd
Highnoon Laboratories Limited	Scilife Pharma
Horizon Pharmaceuticals Pvt Ltd	SJ&G Pharmaceutical Group
IBL Group	Sois Life Sciences
Nathanies International Services	Swiss Pharma
Ophth Pharma	Tabros Pharma (Pvt) Limited
Otsuka Pakistan Limited	ZAFA Pharmaceutical Laboratories
PDH Laboratories (Pvt) Ltd	

Technical support and guidance from ITC was rendered by the following people:

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Alexandra Golovko	Advisor, Export Strategy and Competitiveness
Mario Ottiglio	International expert, pharmaceuticals sector
Aishwarya Nahata	International consultant

1.– The full list of public–private stakeholders that participated in the consultations and their names is available in Annex II.

Note for the reader

In order to boost export growth, the Ministry of Commerce (MoC) has developed the Strategic Trade Policy Framework (STPF) 2020-25, which was approved in November 2021. ITC provided technical support to MoC and the Trade Development Authority of Pakistan (TDAP) to design selected sector export strategies of the STPF priority sectors. This initiative, called the National Priority Sectors Export Strategy (NPSES), focused on 10 of the 18 STPF priority sectors through a consultative process.

The Pharmaceuticals Export Strategy was developed on the basis of a participatory approach, during which more than 55 Pakistani industry leaders, small business owners and public sector representatives held consultations to reach consensus on key sector competitiveness issues and priority activities. These inclusive consultations were held in a hybrid model owing to the travel restrictions imposed due to the COVID-19 pandemic.

Besides in-depth qualitative and quantitative research and value chain analysis, these consultations were complemented by visits and interviews by the national consultants with domestic firms to guide the strategy with insights and market intelligence as well as buyers' requirements in terms of quality standards, packaging, distribution channels and prices, etc.

The Pharmaceuticals Export Strategy builds on the ongoing initiatives in areas of private sector development, regional integration, investment and economic empowerment of youth. Equally importantly, the sector strategy is complemented by an effort to establish the proper implementation responsibilities among key stakeholders early on to ensure timely implementation of activities, whether by the public sector, private sector or international development agencies. This strategy's principal outputs are an endorsed, coherent and comprehensive document with a five-year detailed plan of action (PoA) and implementation management frameworks.

This document was approved as the official export strategy for the Pharmaceuticals Sector 2023-2027 by the Pharmaceuticals Sector Specific Council and endorsed by the Ministry of Commerce of Pakistan.

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Acronyms and abbreviations

Unless otherwise specified, all references to dollars ($) are to United States dollars, and all references to tons are to metric tons.

APAC	Asia-Pacific
API	Active pharmaceutical ingredient
B2B	Business-to-business
BOI	Board of Investment
CAGR	Compound annual growth rate
DRAP	Drug Regulatory Authority of Pakistan
EMA	European Medicines Agency
FDA	Food and Drug Administration
FDI	Foreign direct investment
GDP	Gross domestic product
GMP	Good Manufacturing Practices
ITC	International Trade Centre
MNC	Multinational company
MNHSRC	Ministry of National Health Services, Regulation and Coordination
MOC	Ministry of Commerce
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PPMA	Pakistan Pharmaceutical Manufacturers' Association
R&D	Research and development
STPF	Strategic Trade Policy Framework
TDAP	Trade Development Authority of Pakistan
WHO	World Health Organization

EXECUTIVE SUMMARY

The present strategy outlines a proposed path for the development of the pharmaceuticals industry in Pakistan. It is a five-year endeavour that was defined through a consultative process between public and private sector stakeholders. The strategy addresses constraints in a comprehensive manner and defines concrete opportunities that can be realized through the specific steps detailed in its plan of action (PoA). The Pharmaceuticals Export Strategy is an integral part of Pakistan's Strategic Trade Policy Framework (STPF).

THE INTERNATIONAL DEMAND FOR PHARMACEUTICALS

The global pharmaceutical market is in a state of flux due to major restructuring, both in terms of the demand and supply. This presents a unique opportunity for the sector in Pakistan to take timely action by positioning itself strategically to enter the global drugs market. Pakistan, with a local market of 215 million consumers and 639 pharmaceutical companies, is well poised to gain from opportunities provided under these shuffling global patterns of demand and supply.

PAKISTAN'S TREMENDOUS EXPORT POTENTIAL IN PHARMACEUTICALS REMAINS LARGELY UNTAPPED

While Pakistan has established itself progressively as a manufacturing platform for pharmaceuticals, the country remains a small player in the global scenario. Exports are largely dominated by generics and concentrated on limited number of markets. A significant untapped export potential exists in the exports of pharmaceuticals from Pakistan. This strategy's aim is to assist local pharmaceutical companies and other sector actors to tap into the potential by strengthening the value chain and increasing the number of players at every step.

Pakistan has the potential to attract foreign investment in the pharmaceutical industry if it creates a conducive environment in the country, including political stability, economic growth and development, accessibility to local inputs and opportunity for regional market, clear development plan, and protection and enforcement of copyright and patent laws. The recent positive experience of a local firm in securing a licensed technology transfer from a leading US firm for manufacturing a COVID-19 antiviral drug is an affirmation of the sector's potential.

A NUMBER OF FACTORS IMPEDE EXPORT GROWTH

A government incentive policy could play a determinant role in sustaining and developing the capacity of local manufacturers, and inviting multinational corporations to set up units in the country. An effective regulatory system that strives to ensure safety, efficacy and quality of medicines could go a long way to ensuring investment opportunities for the sector.

The pharmaceuticals value chain reflects the complexity and high level of technological sophistication required in the manufacturing process. It encompasses several distinct components following the different production stages. In the case of Pakistan, from licensing to registration, to pricing and then finally retail, the pharmaceutical sector is fully regulated by various national, provincial and semi-autonomous bodies, directly or indirectly. It also means that there are constraints pertaining to the infrastructure, testing and certification,

trade and competition policy, as well as the availability of inputs and technology. These affect the quality and competitiveness of pharmaceutical products, lowering firm profitability, likelihood of export survival and investment (foreign and domestic) in the sector.

Strengthening the pharmaceuticals sector will strongly contribute to bringing further revenue to Pakistan. Ultimately, this strategy's implementation will lead to increased exporting through reduced uncertainty and improved connections, expanded downstream activities for increased domestic value-added and export diversification, increased efficiency and sustainability in natural resource usage, a sustainable income and an improved national image through the development of a national medicine brand.

VISION AND STRATEGIC OBJECTIVES

In line with the strategic approach presented above, the following is a delineation of the proposed vision. The vision statement was discussed and agreed on with all stakeholders in the pharmaceuticals sector.

> **"To increase the international market share by innovation and compliance with international quality standards."**

The strategic plan of action (PoA) responds to this vision by addressing key constraints and leveraging opportunities in a comprehensive manner. Emphasis is on the following strategic orientations. To this end, particular efforts will be made to realize the following strategic and operational objectives.

Strategic Objective 1: Improve the national framework for regulatory and institutional management, as well as the business environment governing the pharmaceutical sector	•1.1. Revisions of laws and policies governing the sector •1.2. Support a stable regulatory regime by redefining the roles of agencies in the sector •1.3. Improve the overall business environment by encouraging policy coherence and facilitating investments in the sector
Strategic Objective 2: Strengthen the export competitiveness of Pakistani pharmaceutical companies	•2.1. Facilitate access to and development of new products •2.2. Define the positioning of pharmaceutical products in the target export markets •2.3. Develop market intelligence and information services on target export markets •2.4. Build company capacities to enter domestic and international market
Strategic Objective 3: Domestically support the development and upscaling of the Pakistani pharmaceutical sector to be more compliant	•3.1. Compliance with international production standards •3.2. Attract investment to foster innovation and technological upgrading to strengthen firm capacities •3.3. Establish internationally accredited laboratories to maintain quality control •3.4. Invest in scientific, technical and managerial training to strengthen skills and know-how and build linkages with universities

IMPLEMENTATION MANAGEMENT

The strategy process considered current capabilities, constraints, and future shifts and opportunities for Pakistan's pharmaceuticals sector, and industry stakeholders extensively evaluated future orientations and upgrading trajectories. The strategy has developed a pragmatic and forward-looking roadmap for upgrading and internationalization, which can be driven successfully through timely and appropriate resource allocation and effective public–private collaboration for implementation.

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Coordinating activities between the public and private sectors, mobilizing resources and providing an enabling business environment will be crucial for strategy implementation. Having a functional and efficient public–private coordination mechanism (sector advisory/development committee) is the key.

The following key areas of intervention are priorities to facilitate the strategy's implementation:

- Allow duty-free imports of API to reduce reliance on neighbouring countries such as the People's Republic of China and the Republic of India;
- Conduct quality control audits to enforce stringent regulations for quality and ethical standards, to reduce illicit trade and counterfeit medicines, which tarnish the sector's reputation internationally;
- Nationally scale up well-performing firms to meet the demand for off-patent original blockbuster drugs[1] in low- and middle-income countries, while ensuring intellectual property (IP) protection;
- Attract foreign direct investment (FDI) into well-performing firms or domestic 'trusted partners' with support from the Board of Investment (BOI), and bring them into fairs and business-to-business (B2Bs) transactions to bring in FDI;
- Identify product lines and key markets in which Pakistan could have latent comparative advantage.

1.– A blockbuster drug is an extremely popular drug that generates annual sales of at least $1 billion for the company that sells it. Blockbuster drugs are commonly used to treat common medical problems such as high cholesterol, diabetes, high blood pressure, asthma and cancer.


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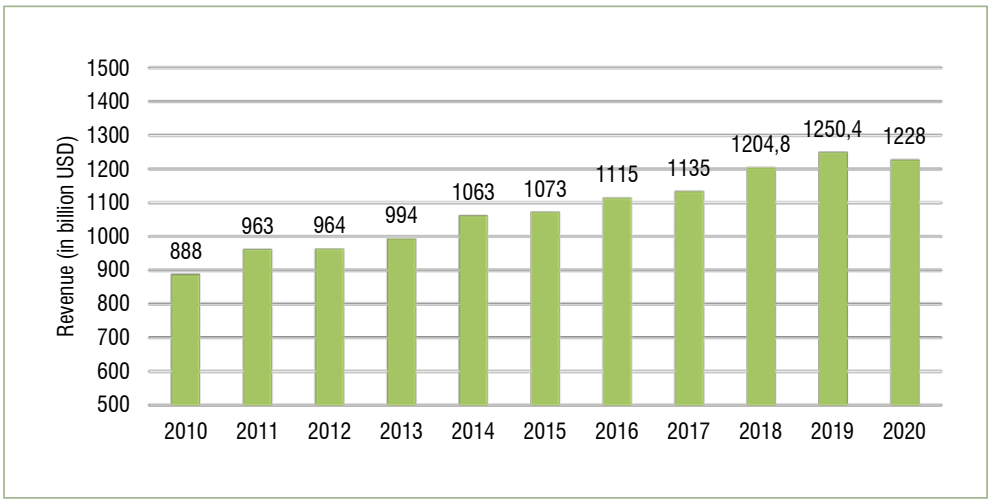
A HIGHLY REGULATED AND CONCENTRATED GLOBAL SECTOR ON ITS WAY TO DECENTRALIZATION

In recent decades, the pharmaceutical industry has experienced massive growth, driven by numerous new market entrants, innovative avenues for pharmacological treatments and therapies, and consumer demands. Based on a survey conducted in March to April 2020 by the Deloitte Center for Health Solutions, which targeted pharmaceutical and biomedical firm leadership, most firms believe that consumer attitudes, behaviour and spending will have the largest impact on company performance in coming years (Ford et al, 2020). In 2020, the global market was worth approximately $1,228 billion, and by 2025 (Figure 1), revenue is expected to swell to $1,700 billion (Global Newswire, 2021). In 2019, almost 80% of revenue was the result of retail purchasing, demonstrating the ever-present importance of consumer attitudes and spending power (Grand View Research, 2020). Furthermore, approximately 10% of all 2019 pharmaceutical revenue was from cancer treatments and drugs, hence the massive rise of research and development (R&D) investments for this disease group (Grand View Research, 2020). Additionally, growing public health concerns such as antimicrobial resistance, and new technologies such as innovative cancer treatments have made investments in pharmaceutical innovation more critical than ever. More than 60% of surveyed global pharmaceutical firms stated that R&D was a key strategic priority for the medium term (Ford et al., 2020).

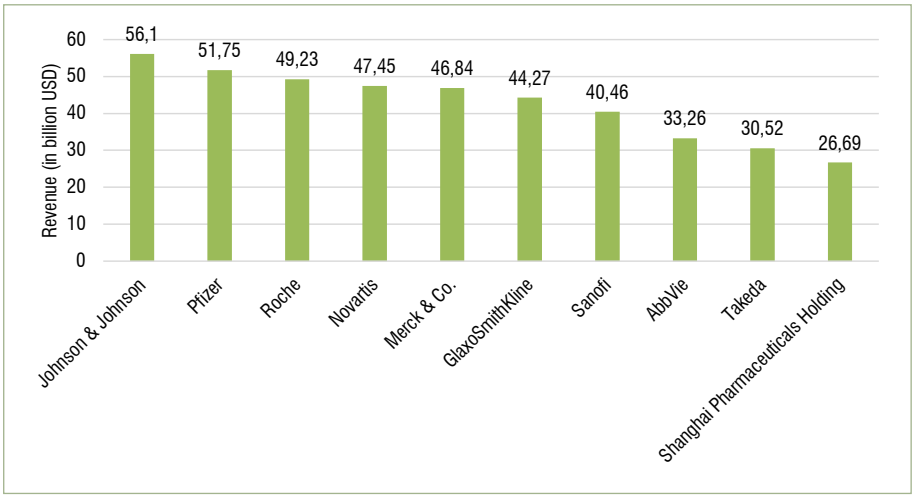
Figure 1: Global pharma market revenue (2010-20)



Source: Statista, revenue of the worldwide pharmaceutical market in 2001–20 (2021).

It should be noted that – like many globalized markets – the pharmaceutical industry is very concentrated among established players, with the Top 10 largest pharma firms by revenue representing more than one-third (34.74%) of global revenue for 2020 (Pharmaceutical Technology, 2020). Likewise, these firms are representative of the largest pharmaceutical markets, led by the United States, which accounted for almost 45% of global pharmaceutical revenue in 2019 (Statista, 2020). There are, however, trends demonstrating a shifting landscape, with China's growing share of global revenue at almost 10% (only behind the United States) (Statista, 2020). Though this is partially due to China's explosive population growth in recent decades, it has also become a leader amongst p*harmerging markets*.

Figure 2: Pharmaceutical technology.



Source: Author generated, derived from Pharmaceutical Technology.

European countries formed the highest world export share, occupying the Top 4 out of 5 spots and contributing approximately 44.96% to the global pharmaceutical export market. Significant expansion of the pharmaceuticals industry has been observed in several countries, including developing countries in Asia (Figure 3).

Figure 3: Main exporting countries for pharmaceutical products (HS 30) in 2020

Source: ITC calculations based on UN Comtrade statistics since January 2020.

Box 1: The future prospects of pharmaceuticals lie in Asia

India: The pharmaceuticals sector is the largest provider of generic drugs globally (India Brand Equity Foundation, n.d.) and is ranked 3rd in terms of total pharmaceutical manufacturing by volume (HEALTHCAREASiA, 2021). Moreover, the country caters to more than half of the worldwide demand for various vaccines and 80% of the antiretroviral drugs used globally to combat AIDS (HEALTHCAREASiA, 2021). It has the largest number of Food and Drug Administration (FDA) approved manufacturing plants outside the United States, with 70,000 firms generating industry revenues of $36 billion in 2019 and massive FDI inflows amounting to $17.7 billion in 2000–20 (Department for Promotion of Industry and Internal Trade, 2020). According to the Indian Economic Survey 2021, the domestic market is expected to grow from $42 billion in 2021 to $65 billion by 2024 and further expand to reach approximately $120–$130 billion by 2030. It is appropriate to conclude that India enjoys an important position in the global pharmaceuticals sector.

Bangladesh: The local pharmaceutical companies are moving forward with great potential, contributing approximately 97% of the overall available medicines in the market (Bangladesh Association of Pharmaceutical Industries). With a market value of $3 billion, the sector contributes 1.8% to the gross domestic product (GDP) of the People's Republic of Bangladesh (Business Inspection, 2021) and is expected to grow at a compound annual growth rate (CAGR) of more than 12% in the forecast period of 2019–2025 (The Daily Star, 2020). The share of generic drugs is expected to surpass 85% by 2025, which will further strengthen the dominance of local pharmaceutical companies in the market (The Daily Star, 2020). In addition to this, the government is focusing on reducing imports and to establish an active pharmaceutical ingredients (API) park, which will act as a turning point for the pharmaceutical industry in Bangladesh (The Financial Express, 2020).

Malaysia: The pharmaceutical industry has shown robust growth trends, both in terms of market size and global exports. In 2007, the pharmaceutical industry was valued at $1.03 billion, which grew to $2.3 billion in 2015 and reached $3.6 billion in 2020. This led to a CAGR of 9.5% in the last five years (Pharmaceutical Technology, 2016). At the same time, pharmaceutical exports have also grown more than twofold, from $186.5 million in 2015 to nearly $330.5 million in 2020 (ITC Trade Map). The Malaysian Investment Development Authority facilitates new entrants under a national priority programme and its commerce, industry and trade departments have key performance indicators based on how much new investment is brought into the sector. Intellectual property rights and other laws are well defined, and the visa regime is liberal. Moreover, state-of-the art amenities, cheaper utilities and an efficient regulatory system make Malaysia an excellent manufacturing location to attract subsidiaries of foreign firms. Specialized parks such as the Technology Park Malaysia in Kuala Lumpur, Bio X Cell and Penang Science Park were established to accommodate the industry's growing needs. Malaysia is the current global leader in the certified halal pharmaceutical industry, being the only nation in the world with appropriate licences to manufacture and export halal products to the world. The halal pharmaceutical industry was valued globally at an estimated $87 billion in 2017 and is expected to grow to $174.6 billion by 2025 (Halal Watch World, 2021).

Pakistan: Pakistan's pharmaceutical industry is a growing, fast-paced market. Domestic pharmaceutical sales have grown 13.1%, compounded annually in 2018–21, outperforming multinational companies (MNCs), which saw a global growth of 9.34% CAGR (The Free Library, 2020). Pakistan's pharmaceutical market is dominated by locally manufactured pharmaceuticals, predominantly generic drugs, which meet approximately 70% of the country's needs. Imported retail medicaments account for the remainder of the market, although manufacturers rely heavily on imported raw materials for production.

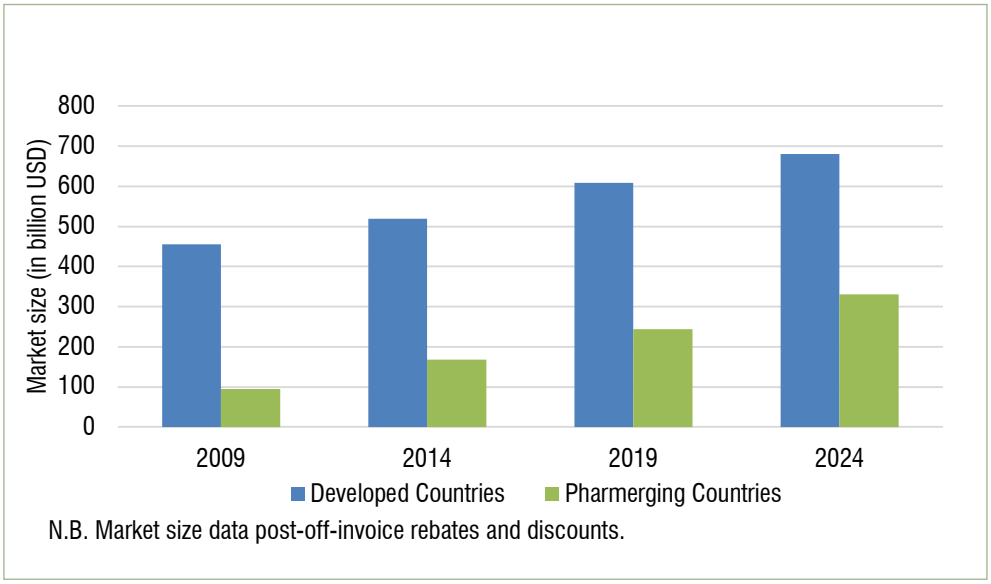
In the next section, the strategy investigates how the pharmaceuticals sector can lead exports sophistication when accompanied by the required regulatory changes.

GROWING COMPETITION FOR PHARMERGING MARKETS

In the past decade, market analysts have increasingly looked to the so-called pharmerging markets for growth and investment. These are a group of countries with a low position in pharmaceutical production, but with a speedy growth pace. The markets have been defined as countries with a per capita GDP of less than $25,000 and more than $1 billion spending growth in 2012–16. These have been segmented into three tiers: Tier I (China), Tier II (the Federative Republic of Brazil, India, and the Russian Federation), and Tier III (the People's Democratic Republic of Algeria, the Argentine Republic, the Republic of Poland, the Republic of Colombia, the Arab Republic of Egypt, the Republic of Indonesia, the United Mexican States, the Federal Republic of Nigeria, Pakistan, Romania, the Kingdom of Saudi Arabia, the Republic of South Africa, the Kingdom of Thailand, the Republic of Turkey, Ukraine, the Bolivarian

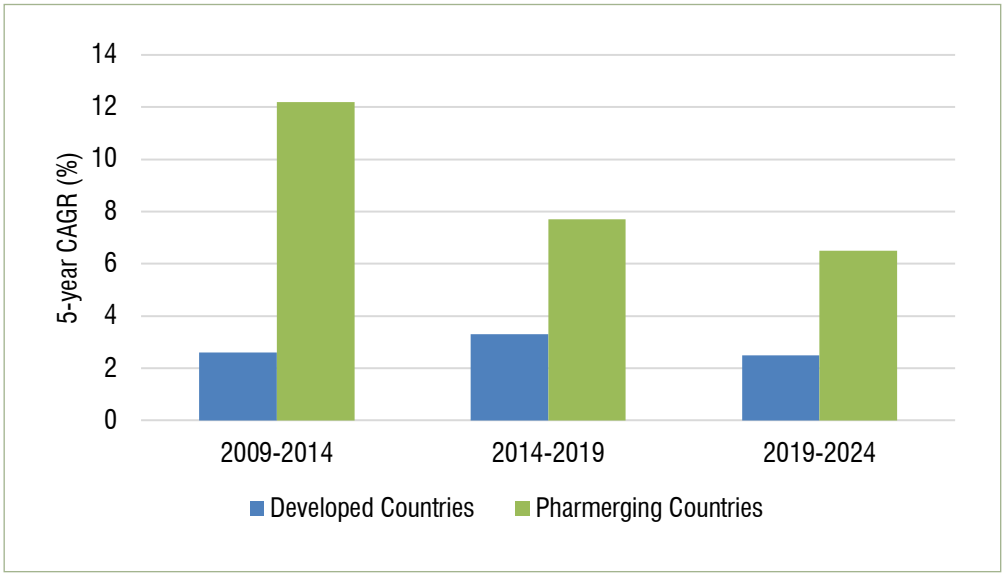
Republic of Venezuela, and the Socialist Republic of Viet Nam) (Research and Markets, 2016). The growth in these markets has been attributed to several key drivers, including a growing number of public hospitals, increasing chronic disease burden, ageing societies and overall rising healthcare expenditures (Doughman, 2019). Though there are trends of increasing modern medicine usage in these pharmerging markets, per capita use of pharmaceuticals is still well behind that seen in more developed markets and estimated market growth rates do not indicate that this gap will close in the near future (Rickwood, 2017). Furthermore, as the growth pace in these countries has begun to plateau, China has come to assert its dominance in the group. Now, China represents almost 50% of total revenue in pharmerging markets and the trend indicates this will only increase, forcing other emerging markets to accelerate their development (Agarwal et al., 2017).

Figure 4: Developed and pharmerging market size comparison (2009-24)



Source: IQVIA Market Prognosis, Sept. 2019, IQVIA Institute.

Figure 5: Five-year CAGR developed and pharmerging market comparison (2014-24)



Source: IQVIA Market Prognosis, Sept. 2019, IQVIA Institute.

Equally, global pharmaceutical players are continuing to expand their reach to previously untapped markets, as consumer trends in less developed regions demonstrate the potential for huge market growth, and thereby increasing competition in pharmerging markets. Unsurprisingly, 58% of global players surveyed cited further market expansion as an objective for the next five years (Ford et al, 2020). Therefore, international pharmaceutical firms have increased investments in regional manufacturing capabilities, such as AstraZeneca's recent investment of $133 million in an Australian manufacturing site (Grand View Research, 2020).

TOWARDS A SLOW DECENTRALIZATION OF R&D CAPABILITIES FOSTERED BY THE COVID-19 CRISIS

With the rapid development of vaccines for COVID-19, the pandemic has only drawn greater attention to the industry as a powerhouse with profound global impacts, and some believe these vaccine successes will encourage greater R&D collaboration in coming years, which could serve to accelerate innovation (Dekou, 2021). The pharmaceutical industry is by no means a homogeneous group, with innovation and R&D largely centred on highly developed regions (i.e. Europe and North America), while the industry is more focused on generic production in low- to middle-income countries. This is slowly changing, as large venture capital investments have enabled pharmaceutical start-ups to access the tools and settings necessary for drug development globally (Bell, 2020). Some experts predict that the Japanese pharmaceutical industry's R&D capabilities will soon rival that of the arguably most-established industry in the United States (Dekou, 2021). In the past decade, the number of pharmaceutical launches from new entrant firms has tripled, and these firms are expected to account for more than half of new launches in the next five years (Harputlugil et al., 2021). Equally, established firms are increasingly dedicating more funding to innovation to cement their leadership, with Eli Lilly and Company, Bristol Myers Squibb, AstraZeneca, Roche, Merck & Co., and Johnson & Johnson all dedicating more than 20% of sales revenue to R&D (Parrish, 2020).

This R&D has largely been focused on the pursuit of orphan drugs,[2] which have been become increasingly popular due to their increasing share of market revenue and incentives related to their development in high-income markets (Pharmaceutics International, Inc., n.d.). In 2019, the global orphan drug market was worth an estimated $132 billion and is expected to grow to more than $300 billion by 2026, capturing approximately 20% of global prescription sales (Pharmaceutics International, Inc., n.d.). However, it should be noted that the development of these drugs is extremely difficult and requires firms to surmount high regulatory barriers, so orphan drug developers are often either large established firms or those with high levels of expertise and investment backing (Pharmaceutics International, Inc., n.d.).

MAJOR CONSTRAINTS AND BARRIERS IN THE GLOBAL SETTING

The pharmaceutical industry faces some concerning trends that require the attention of industry stakeholders, including firms, regulatory agencies and governments.

Some experts predict that COVID-19 will change how venture capital invests in exploratory drug firms:

Although the biotech firms had been experiencing a period of relative growth, wherein it was easier to source investments and venture capital viewed the field as highly favourable, the unpredictable markets and a changing healthcare wrought by the pandemic has forced investors to evaluate their approach and exposure (Bell 2020). Investments already made have not been abandoned, but the volume of new venture deals for biotech firms has shrunk, leading many in the industry to worry about funding their projects (Bell, 2020). Likewise, it is unclear how 'cross-over' investors, who often have greater access to capital than venture capital firms and invest to help bring biotech companies public, will act in the post-COVID-19 marketplace (Bell, 2020). In more frontier-like markets, such as Pakistan, there is additional uncertainty that will likely compound the trepidation felt by investors.

The general costs of drug development are rising, driving a focus on biosimilars:

With an estimated cost growth of 10% year-on-year, there is a clear indication that drug development will become much less attractive than biosimilars (Kruglyak, 2022). Subsequently, as patents expire, experts predict that few drugs will have no alternative in the coming years (Kruglyak, 2022). With long roads to market approval, no predictors of success, and huge capital outlays needed, the pursuit of drug development has been made more exclusive, especially in

2.– Orphan drugs are medicinal products intended for the diagnosis, prevention or treatment of rare diseases. According to the FDA, an orphan drug is one 'intended for the treatment, prevention or diagnosis of a rare disease or condition, which is one that affects less than 200,000 persons in the US'. In the European Union (EU), the European Medicines Agency (EMA) defines a drug as 'orphan' if it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically and seriously debilitating condition affecting not more than 1 in 2,000 EU people.

light of the aforementioned investment scarcity. Thus, as fewer firms will be able to afford R&D, biosimilars[3] that are consumed by a larger market, it will continue to represent a strong opportunity for pharmerging markets (Dekou, 2021) such as Pakistan, unable to compete with global drug developer hegemons.

Surveyed global pharmaceutical leaders cited other products as threatening the industry:

In the next 10 years, industry leaders estimated that the growth of customizable treatments (72%) and non-pharmacological interventions (72%) present the largest threat to industry (Ford et al., 2020). Customizable treatments present a partial opportunity for the pharmaceutical industry, though the reality is that personalized medicines will greatly reduce the scalability of profits (Ford et al., 2020). Largely driven by innovative digital interventions, non-pharmacological treatments will also continue to erode the need for drugs and instead lead to a focus on preventative and monitoring tools (Ford et al., 2020). Thus, countries like Pakistan need to assess which drugs or drug types will be less affected by these developments (e.g. antibiotics).

Despite increases in use and production, investments in environmental impact are lacking:

Although the pharmaceutical industry continues to grow overall, there has not yet been a concerted effort to research the industry's effects on the environment or public health, such as through pharmaceutical residues in water and wastewater (Peña et al., 2021). Now, governments and regulators have been working with industry to bolster limitations, but this trend is less common in non-Western countries. Therefore, Pakistan and its peers must work to ensure that environmental regulations and oversight mechanisms are robust enough to match those of the West. Otherwise (much like with lacking quality or safety controls), the market could be seen as unreliable for procurement and investment.

THE GLOBAL REGULATORY FRAMEWORK: STRIKING THE BALANCE BETWEEN SUPPORTING DEVELOPING PHARMA INDUSTRIES AND PREVENTING DANGEROUS COUNTERFEIT DRUGS

While the globalized nature of the pharmaceutical industry brings health benefits to individuals around the world, expansion also brings with it added regulatory concerns and can, in some cases, threaten domestic producers and markets. While many pharmaceutical firms in low- to middle-income countries hope to enter more highly regulated markets for the chance at increased sales and profits, counterfeit drugs in many regions, such as South Asia, continue to raise concern (Ford et al., 2020). United Nations estimates suggest that, in the region, consumers annually spend more than $2.5 billion on drugs with little to no API present, and therefore, no clinical benefit (CPhI Pharma Insights, 2020).

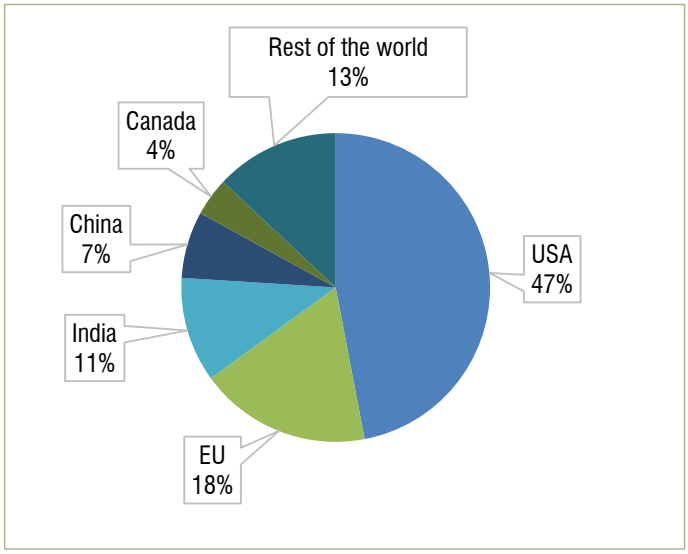
The World Health Organization's (WHO) Good Manufacturing Practices (GMP) are seen by many as the baseline necessary to begin playing at global level in the pharmaceutical industry and have been integrated into the national guidelines of more than 100 countries (World Health Organization). Likewise, the Pharmaceutical Inspection Co-Operation Scheme (PIC/S) represents an important certification scheme for countries and membership is expanding, yet the process for accreditation is slow and there are no guarantees for improved access to other markets (PIC/S, 2005). Further, many in the industry are vying for more GMPs to cover previously unaddressed concerns such as environmental effects, and country-level regulators remain the main barrier for market entry, which often move quicker than international GMP-setting bodies.

There have been efforts to increase synergies between regulatory agencies, which could help ease access to other markets and facilitate greater innovation, including work led by the International Coalition of Medicines Regulatory Authorities (ICMRA). This includes representatives from the FDA (United States), the European Medicines Agency (EMA) (European Union), the Pharmaceuticals and Medical Devices Agency (PMDA) (Japan) and several other highly regulated markets (ICMRA, n.d.). However, only a few markets in the Asia-Pacific (APAC) region have strong national regulatory infrastructure that is mature enough to benefit from these increased synergies for export strategies (L.E.K. Consulting, n.d.). Additionally, these select markets also attract more foreign investment due to their regulatory environment and are being used as regional hubs for established global firms (L.E.K. Consulting, n.d.). To surmount these high hurdles for entry, nascent and emerging markets must often wait until their regulatory environment matures to match the enforcement and monitoring required by highly regulated markets, such has been seen with the evolution of Chinese intellectual

3.– Note: Production of biosimilar (medicines that are made from living microorganisms found in plant or animal cells) is expected to be spurred by the loss of patent protection for best-selling biologics. Industry reports indicate that 66 innovator biologics are due to come off patent in the market in 2020–25. This is especially attractive to the pharmaceutical sector, as the sector offers more lucrative opportunities, as this type of product is mostly destined to premium, high-value-added drugs.

property protections in the sector (PricewaterhouseCoopers, n.d.). This has been accelerated in some cases with the import and opening of domestic markets to established firms from these more mature markets, which can then help direct the development of regulatory infrastructure, though if done too early this can precipitate a bleeding of domestic industry. As one can see from Figure 6, the US finished drug market (accounting for 45% of global pharmaceutical revenue) is almost half self-reliant and trade partners are mostly other highly regulated markets or India, despite having the highest fail rate (17%) of denoted markets (FDA, 2019).

Figure 6: Location of manufacturing facilities for finished medicines on the US market (2019)



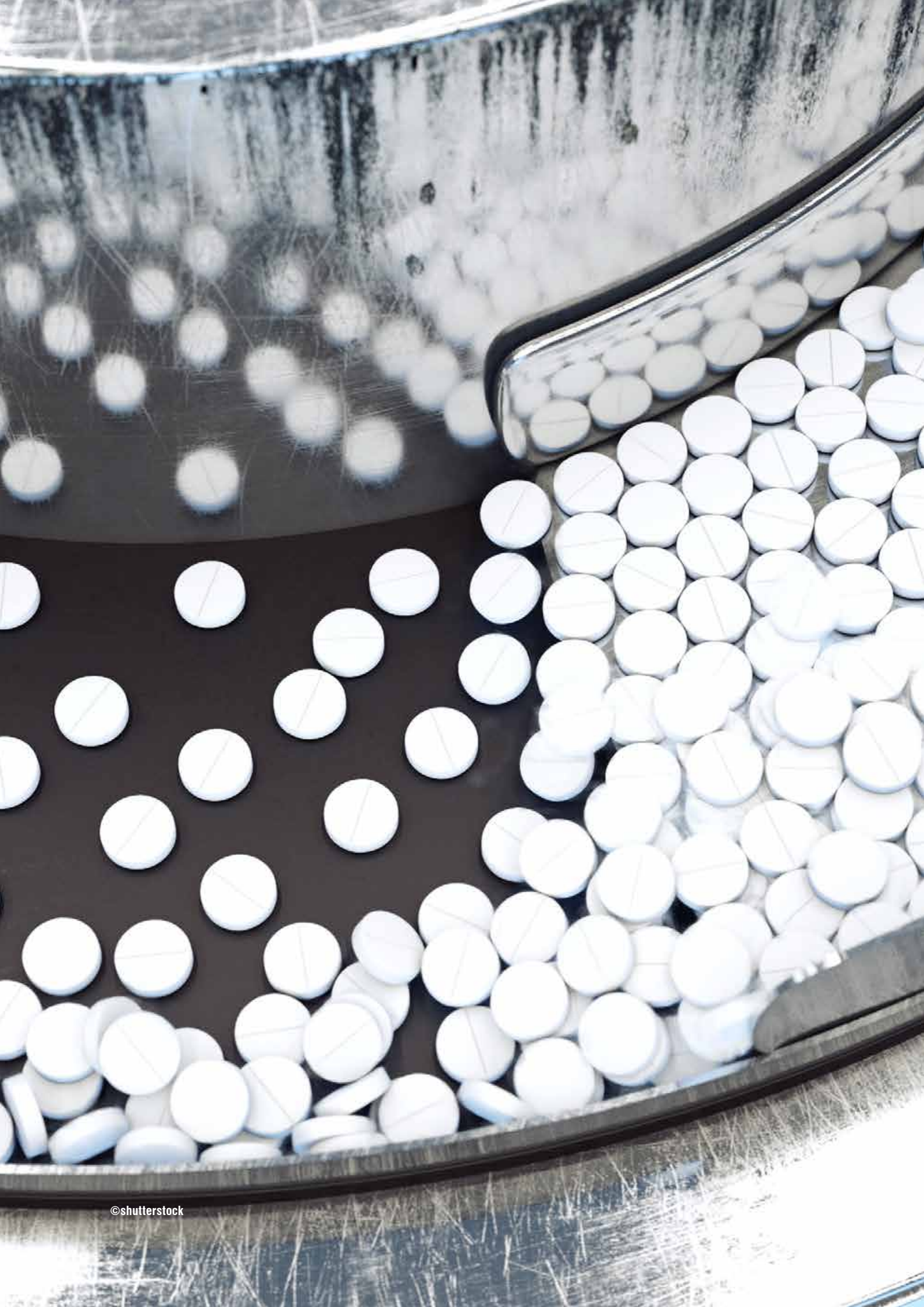
Source: 'Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program', December 2019.

A REGIONAL SECTOR SLOWLY GAINING MOMENTUM THROUGH THE GROWING MIDDLE CLASS AND DEMAND

The pandemic has accentuated several other regional barriers, such as increased strains leading to pharmaceutical trade unions demanding more favourable terms (IndustriALL Union, 2020). Though supply chains have been shown to be weaker than hoped globally, COVID-19 revealed challenges in South Asia. Many countries in the region are focused on the domestic market and heavily rely on imported APIs from China, India and Europe (CPhI Pharma Insights, 2021). Equally, poor financing of pharmaceutical R&D across the region leaves many questioning whether local producers will grow beyond generic production for the domestic market (Jack, 2005).

Regardless of the various concerns expressed above, experts have estimated that the APAC pharmaceutical market will grow from approximately $44 billion in 2020 to an estimated $63 billion by 2026 (Grand View Research, 2019). Regional and global pharmaceutical players agree that the largest growth opportunities for the industry in the region are generics (by a wide margin), small patented molecule drugs and biosimilars (CPhI Pharma Insights, 2021). These targeted growth areas are partially the result of a regional growing middle class, which is able to spend more on over-the-counter drugs (Cekindo, n.d.). Furthermore, the emergence of new healthcare reimbursement legislation across the region has introduced new funding pools for the industry, while also expanding the volumes necessary for domestic markets (Baur et al., 2018). In some cases, amendments to foreign ownership policies have also opened local markets to more global investment and competition (CPhI Pharma Insights, 2021).

The global pharmaceutical market is in a state of flux due to major restructuring, both in terms of demand and supply. This presents a unique opportunity for the sector in Pakistan to take timely action by positioning itself strategically to enter the global drugs market. With a local market of 215 million consumers and 639 pharmaceutical companies, Pakistan is well poised to gain from opportunities provided under these shuffling global patterns of demand and supply.



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PHARMA SECTOR GROWTH COULD LEAD PAKISTANI EXPORT SOPHISTICATION IF ACCOMPANIED BY THE REQUIRED REGULATORY CHANGES

Demand patterns are shifting, with increased life expectancy, literacy rates, incomes and better awareness of health-related issues. As such, greater demand is created for pharmaceutical products in Pakistan. The local pharmaceutical industry is predominantly involved in drug formulation. Firms in Pakistan are already experienced and can easily cater to this. At the same time, supply-side dynamics are also changing. Developed countries have shifted focus to large molecules, called biologics.[4] This has created opportunities for developing countries to fill the gap for production of cost-efficient small molecule therapeutics, especially of high-quality follow-on generics, super generics and simpler biologics.

The recent positive experience of a local firm in securing a licensed technology transfer from a leading US firm for manufacturing the COVID-19 antiviral drug is an affirmation of the sector's potential (BBC, 2020). Other recent successes include attracting global partners into new avenues such as clinical trials by domestic firms, setting up production facilities for oncology drugs (*Dawn*, 2022) and WHO pre-qualification for laboratories in the country (WHO, 2020). This potential can be harnessed through an overhaul of the regulatory regime, deregulation of drug prices, strengthening of intellectual property rights and a consistent policy regime.

A fast-growing sector driven by local demand embarking towards export

In 2021, the value of Pakistan's pharmaceutical sector was estimated at $3.29 billion, with 70% of the market's domestic need being met by local manufacturers and suppliers (Pakistan Business Council – PBC, 2021). The value doubled from $1.64 billion in 2011 (Business Recorder, 2021). The share of national companies was $2.3 billion and that of multinationals was $993 million. Table 1 presents the value for the sector divided between local companies and MNCs.

4.– Large molecules (biologics) are proteins made in microorganisms or other living cells using recombinant DNA technology, with a complex Structure, which must be transfused or injected.

According to the Drug Regulatory Authority of Pakistan (DRAP), there are 639 pharmaceutical manufacturing units in Pakistan, (Pakistan Institute of Development Economics, 2021) signalling that active manufacturing companies have also doubled in the last two decades. Moreover, the industry employees approximately 240,000 people (both directly and indirectly). Domestic manufacturers control 68% of total sales in Pakistan and foreign manufacturers the remaining 32%, with the two respectively experiencing 10% and 8% growth in 2019–20 (Pakistan Today, 2020). The market structure is also constantly changing, from being dominated by a peak of 40 MNCs in the 1990s down to just 25 today, accounting for 44.3% of the Pakistani market's value (*The News*, 2020).

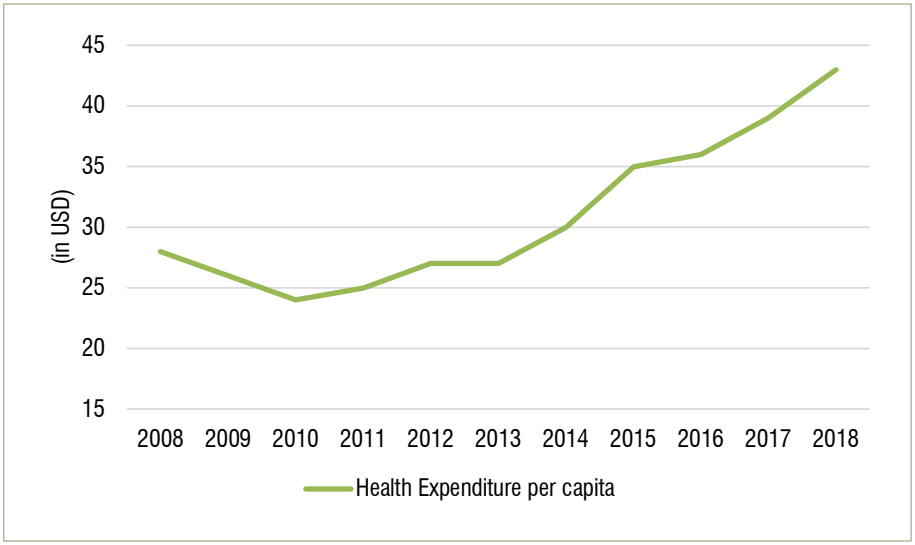
Table 1: Pakistan's retail pharmaceutical business (in PKR)

Years	2017 (USD billion)	2018 (USD billion)	2019 (USD billion)	2020 (USD billion)	2021 (USD billion)	Growth 2020/21	Growth 2017/21
Total market	1.94	2.2	2.5	2.77	3.29	18.8%	14.12%
Nationals	1.3	1.5	1.7	1.97	2.3	16.8%	15.33%
MNCs	0.64	0.7	0.8	0.8	0.99	23.8%	11.52%

Source: IQVIA.

The Pakistani domestic pharmaceutical market is certainly expanding, as health expenditure (private and public combined) has increased dramatically alongside health expenditure as a percentage of GDP in recent years (Knoema, n.d.). These parallel – but not necessarily reliant – trends represent promising growth, which will likely only be further compounded by strong GDP recovery from COVID-19 and forecasts for the upcoming year (4.8% growth target) (Reuters, 2021).

Figure 7: Health expenditure per capita, Pakistan (2008-18)

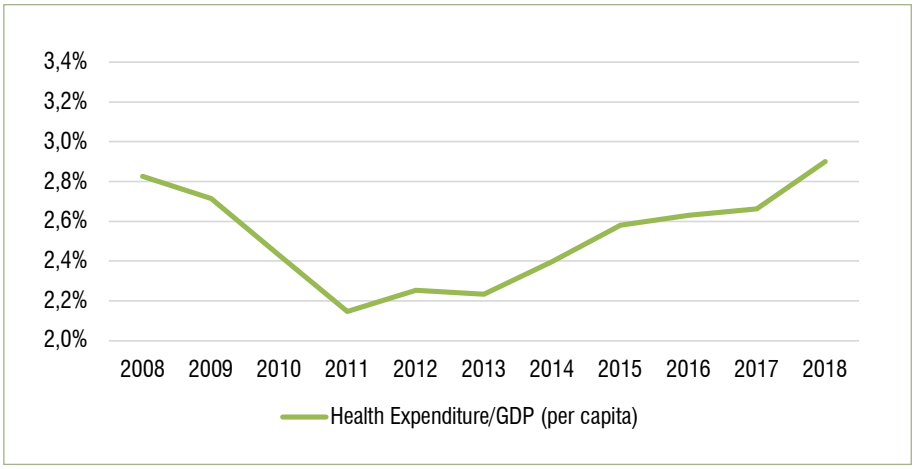


Source: World Bank data, derived from the World Health Organization Global Health Expenditure database.

Industry stakeholders feel that Pakistan's current exports of $235 million5 can easily cross $500 million in a matter of few years as Pakistan emphasizes public healthcare. However, export penetration can only increase if regulation and governance improve, constraints on firms are eased and their competitiveness is enhanced. The pharmaceutical industry is a complex sector that requires a structured approach to determine how it can develop requisite scale and reach its full export potential.

5.– Pakistan's exports in 2020 accounted for $22.24 billion (ITC Trade Map, 2020).

Figure 8: Health expenditure as a percentage of GDP per capita



Source: World Bank data, derived from the World Health Organization Global Health Expenditure database.

The market structure for the pharmaceutical industry is also skewed – the Top 25 firms occupy 62.6% of the market share, the Top 50 companies hold nearly 80% of the market share and the Top 100 firms command 97% of the market share. This leaves more than 500 small and medium-sized enterprises competing for the remaining 3% of the market (Pakistan Credit Rating Agency, 2021). Table 2 lists the Top 10 pharmaceutical firms in Pakistan. These firms (that include both MNCs and local firms) have 46% of the industry's market share and are those firms that have consolidated their product offerings and focused on long-term business planning (Institute of Chartered Accountants of Pakistan, 2018). This has implications for quality and technology levels in the sector, as well as the viability of firms that are forced to operate on relatively narrow margins.

Table 2: Top 10 pharmaceutical companies in Pakistan

Name	National/multinational
GlaxoSmithKline Pakistan	Multinational
Getz Pharma (Private) Limited	National
SAMI Pharmaceuticals (Private) Limited	National
Abbott Laboratories Pakistan Limited	Multinational
Martin Dow	National
The Searle Company Limited	National
Sanofi Aventis Pakistan Limited	Multinational
OBS Pakistan (Private) Limited	National
GSK Consumer Healthcare Pakistan Ltd	Multinational
Hilton Pharma (Private) Limited	National

Source: Institute of Chartered Accountant of Pakistan (ICAP), 2018.

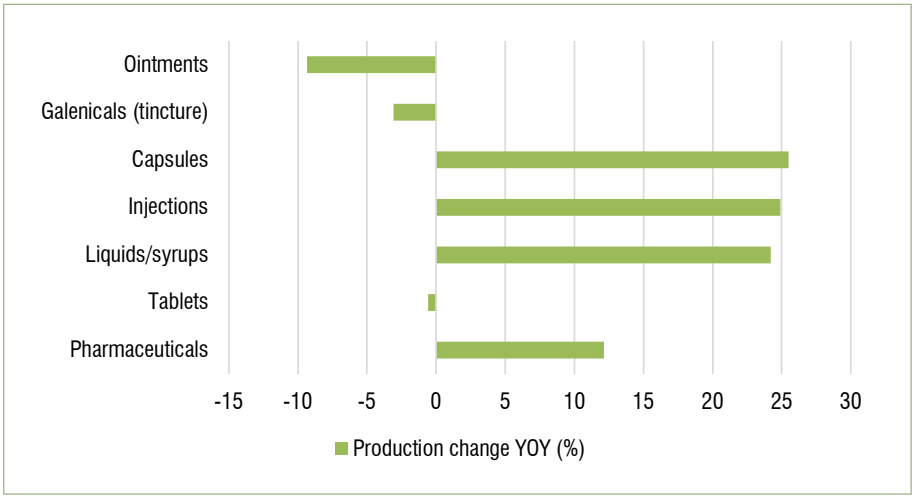
One of the rationales for selecting the sector is to tap into its potential to increase the sophistication and technological value addition of Pakistani exports, therefore positioning the country as an emerging, but trustworthy pharmaceuticals supplier. However, this can only be done through a careful analysis of the sector's competitiveness constraints and opportunities. Furthermore, there are limited local linkages between firms, for example, local producer–local seller, local producer–exporter or MNC-mediated firm networks. With limited contract manufacturing, there is little scope for local synergies between firms and MNCs. The findings from the sector diagnostic contribute to a time-bound export development strategy that provide a prioritized list of policy interventions to create the necessary enabling environment. These recommendations are geared towards unlocking firms' productivity, encouraging sectoral coordination, strengthening their global competitiveness and helping them achieve their export potential.

A sector concentrated on drug formulation with an ambition for diversification

The majority of Pakistan's pharmaceutical industry is concentrated on drug formulation rather than innovation. As a formulation industry, its pharmaceutical products (HS 30) mostly include tablets, liquids and syrups, injections, capsules, tinctures and ointments (Figure 9).

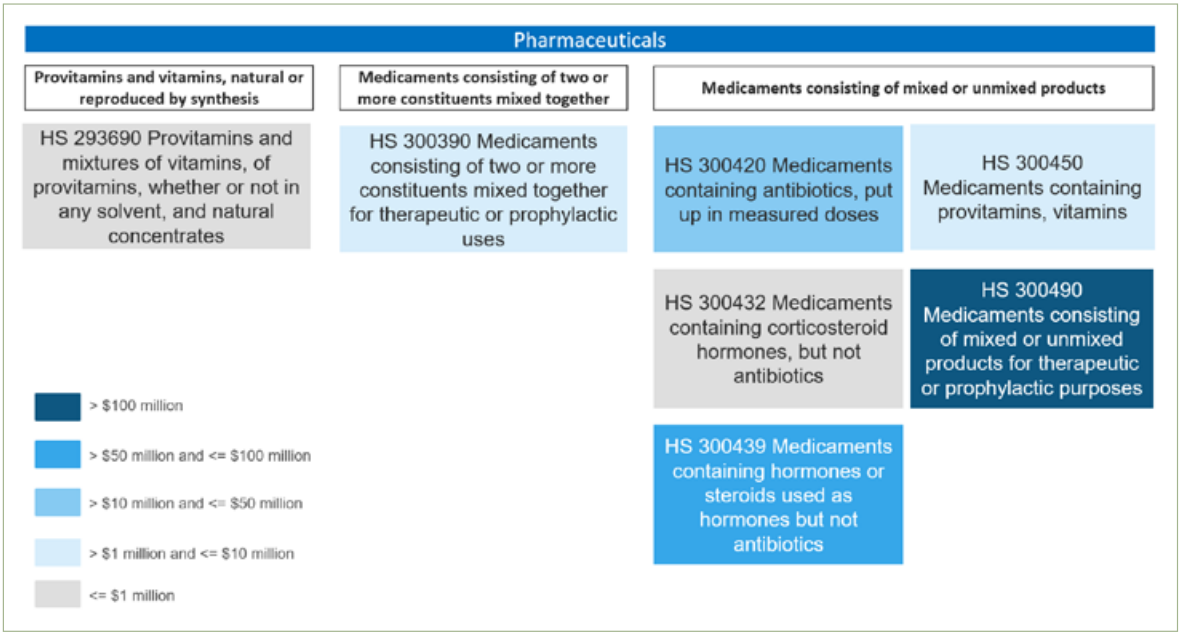
However, within this strategy's framework, Pakistan's pharmaceuticals sector covers the manufacture of provitamins and vitamins, natural or reproduced by synthesis, medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic uses, and medicaments consisting of mixed or unmixed products (including those containing antibiotics, provitamins and vitamins, corticosteroid hormones, hormones or steroids and mixed or unmixed products for therapeutic or prophylactic purposes) (Figure 10).

Figure 9: Production changes in Pakistan's pharmaceutical industry (FY 2021)



Source: State Bank of Pakistan Economic Data, Production of Selected Large-scale Manufacturing Items, Updated July 2021.

Figure 10: Pharmaceutical product map



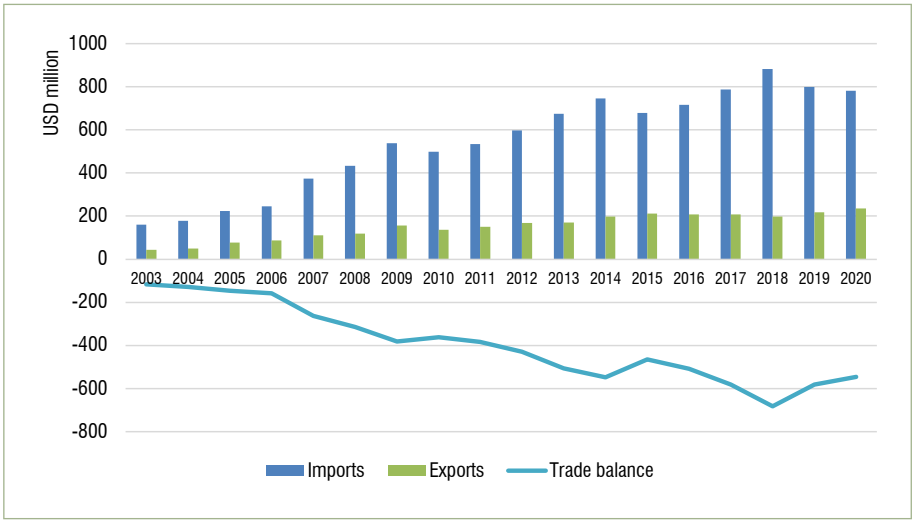
Source: ITC, validated by the TDAP.

Demand patterns are shifting, with increased life expectancy, literacy rates and incomes and better awareness of health-related issues, which unfolds a greater demand for pharmaceutical products in Pakistan. The local pharmaceutical industry is predominantly involved in drug formulation. At the same time, supply-side dynamics are also changing. Developed countries have shifted focus to large molecules, called biologics. This creates opportunities for developing countries such as Pakistan to fill the gap for production of cost-efficient small molecule therapeutics.

Steadily growing export sector

Even though Pakistan has managed to establish itself progressively as a manufacturing platform for pharmaceuticals, the country remains a small player in the international scene. Within the Asian region, few countries have a trading surplus for pharmaceuticals, so it is rather unsurprising that Pakistan has a $545.75 million pharmaceutical trade deficit (Trading Economics, n.d.). However, 2020's rates of import and export change are promising, with imports down 1.7% and exports up 11.4% from 2019 (Trading Economics, n.d.). Additionally, there is a possible market tailwind, with the government proposing a reduction on import tax to 0% on hundreds of APIs, although it is still too early to determine its effects (Business Recorder, 2021). Figure 11 provides a snapshot of the export and import trajectory of pharmaceuticals in Pakistan. The figure depicts a rising deficit over the years, with imports increasing significantly, but exports rising only marginally. Despite the low increment, the sector's exported value has increased more than fivefold since 2003, although from a very low base.

Figure 11: The sector's trade performance (2003-20)

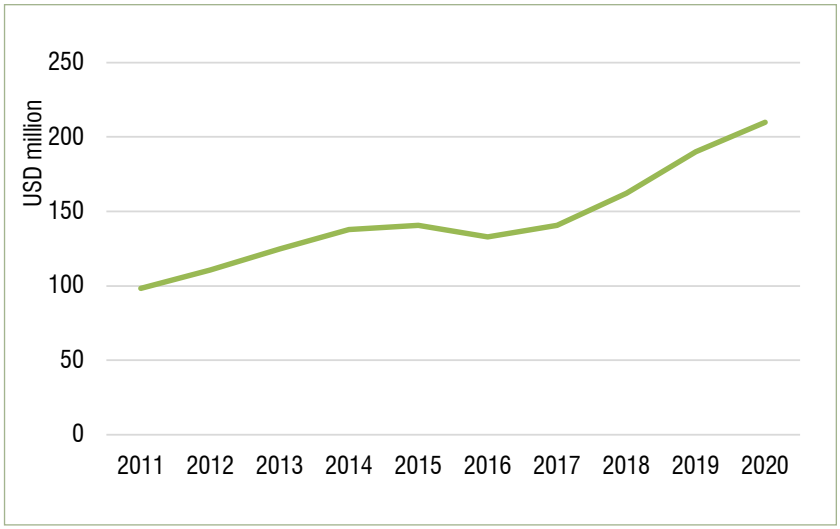


Source: ITC calculations based on UN Comtrade statistics as of January 2020.

Pharmaceuticals (HS 30) ranked as the 17th largest export sector for Pakistan in 2020, with a world export ranking of 62. Globally, the sector witnessed a growth of 8.3% CAGR in 2016–20, and Pakistan's exports grew by only 3.3% in the same period.

However, exports from Pakistan of the selected products identified under the study's scope have expanded over the years, growing at an impressive CAGR of 12.1% in 2016-20), and 8.8% in the past decade to reach $204 million in 2020 (Figure 12). Nevertheless, this amount represents approximately 1% of Pakistan's total exports in 2020.

Figure 12: Pakistan's exports of pharmaceutical products (2011-20)

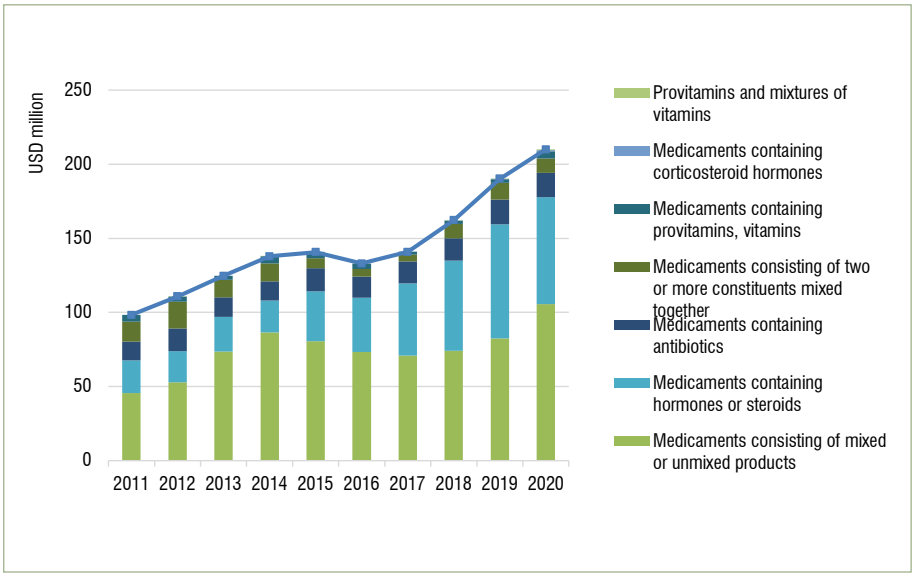


Note: Only includes pharmaceutical products identified in the product map above (Figure 10).
Source: ITC calculations based on UN Comtrade statistics as of January 2020.

Most Pakistani pharmaceutical exports – with a still growing proportion – are from two categories of medicaments: mixed or unmixed products for therapeutic or prophylactic use and those with hormones or steroids, accounting for 87.5% of exports (Figure 13). This product group could become an even more attractive export opportunity, as an import tax cut on syringes, used to package some of these products for transdermal injection, has been proposed (ITC, n.d.). Furthermore, the retail mixed and unmixed medicament area has huge unrealized export potential, as current estimates are that the export of these products only represents 17% of possible export sales (ITC, n.d.). This demonstrates the need for an increased focus on high-quality exportable versions of these products, which equally will be more demanded domestically, as the above health expenditure trends suggest.

Unfortunately, the UN Comtrade data source, used in the ITC Trade Map, does not differentiate between branded and generics. Therefore, the distinction cannot be made in the data, although it stands to reason that these are mostly generics, as validated by exporting firms during the consultation sessions.

Figure 13: Pakistan's exports of pharmaceuticals, by product (2011-20)



Source: ITC calculations based on UN Comtrade statistics as of January 2020.

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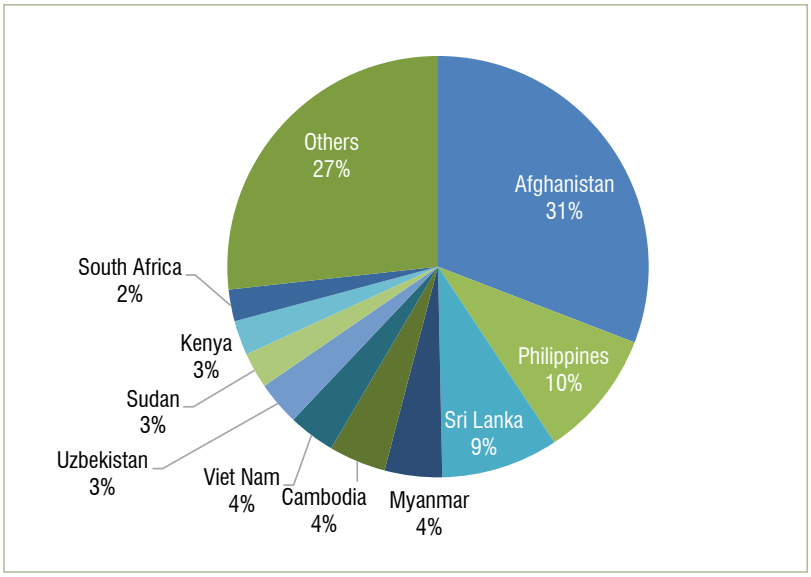
Exports of the selected Pakistani pharmaceuticals are concentrated in a limited number of markets, with only three countries importing more than $10 million worth of goods in 2020. The Afghan market alone captured approximately 31% of Pakistan's exports that year, for a total exported value amounting to $64.8 million. The trade of pharmaceuticals with the Islamic Republic of Afghanistan is largely dominated by medicaments of mixed or unmixed products for therapeutic or prophylactic purposes, and medicaments containing hormones or steroids. This predominance is partly explained by the fact that most firms operating in Peshawar, Khyber Pakhtunkhwa are in close proximity to the Afghan border. Moreover, over the years, they have established connections that further facilitate other firms within Pakistan to send medicines over the border (PPMA, 2017). Due to a high level of informal trade, actual export figures could be larger than reported. The Republic of the Philippines and the Democratic Socialist Republic of Sri Lanka follow Afghanistan as the other top export destinations, at $20.6 million and $18.9 million respectively. The domestic industry has recently penetrated non-traditional markets such as Africa and East and Central Asia, but the value of the commodities traded remains limited. Figure 14 highlights Pakistan's Top 10 pharmaceutical export countries.

Figure 14: Importing market of pharmaceutical products exported from Pakistan (2020)



Source: ITC calculations based on UN Comtrade statistics as of January 2020.

THE PHARMACEUTICALS SECTOR HAS THE POTENTIAL TO CONTRIBUTE TO EXPORT GROWTH

Pakistan is tapping into the growing sectors, especially the one for which global demand is high, but mostly as a net importer, as illustrated in Figure 15.

A significant untapped export potential exists in the exports of pharmaceuticals from Pakistan. There are opportunities in the development of new export sectors and upgrading of existing ones, including through increased domestic value added. According to the ITC Export Potential Map, the sector has a total untapped export potential of $256.1 million. Realizing this untapped potential in exports could create more jobs and revenue for the sector.

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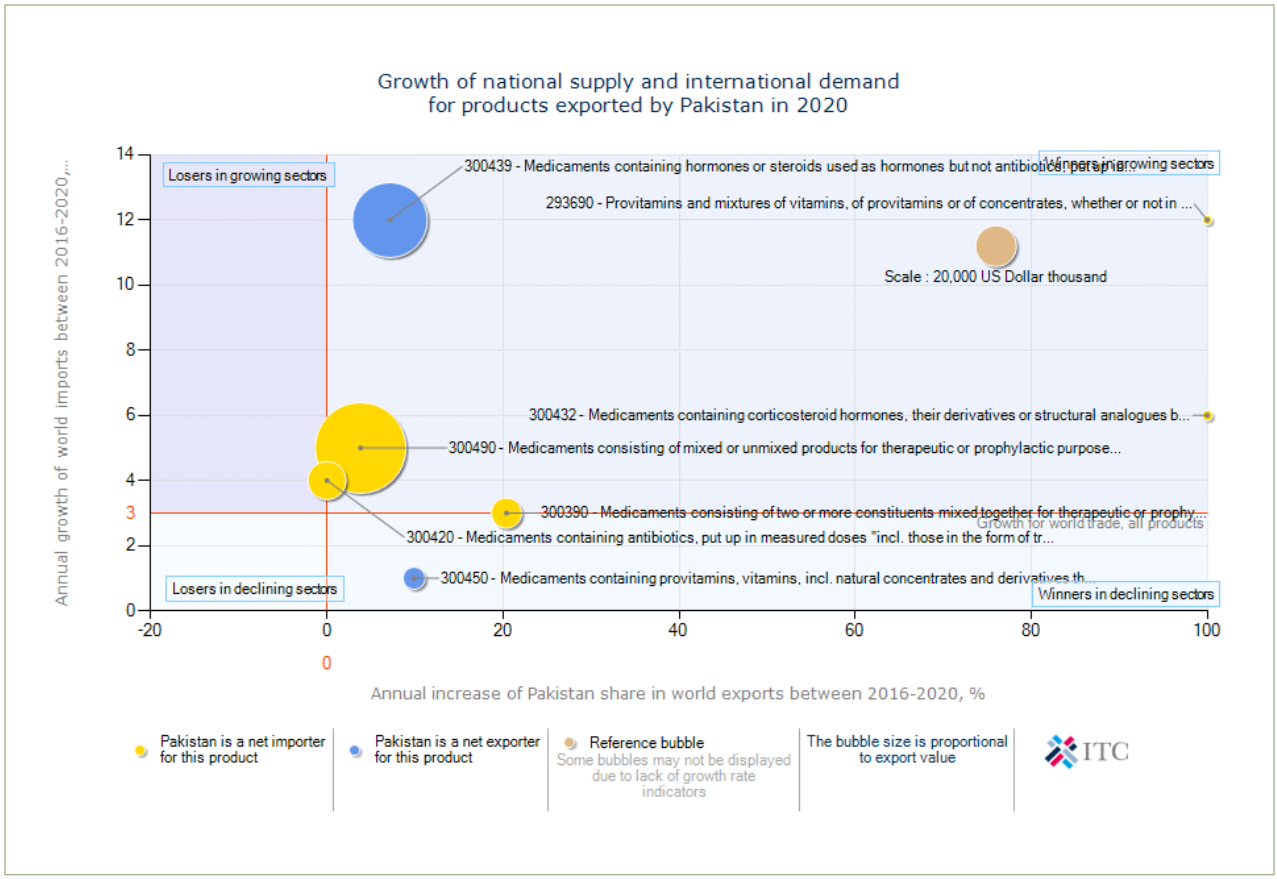
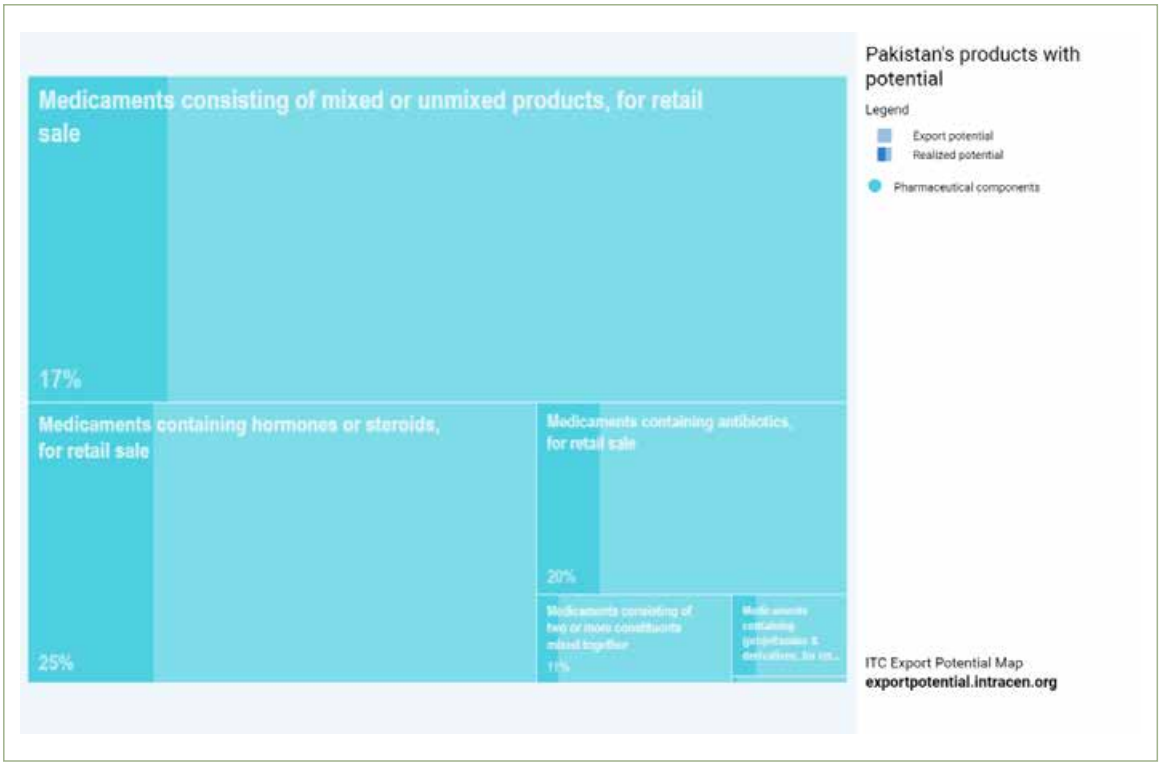
Figure 15: Growth of national supply and demand for pharmaceutical products exported by Pakistan (2020)



Note: Yellow bubbles show Pakistan is a net importer for that category; blue bubbles indicate that it is a net exporter. The bubble size is proportional to the export value.

Sources: ITC calculations based on UN Comtrade data and ITC statistics.

Figure 16: Pakistan's products with potential



Source: ITC Export Potential Map.

While Pakistan has established itself progressively as a manufacturing platform for pharmaceuticals, the country remains a small player in the global scenario. The pharmaceuticals sector was ranked as the 17th largest export sector for the country in 2020. Pakistan's main exports are largely dominated by generics, and exports are concentrated in a limited number of markets. The Afghan market alone captured approximately 31% of Pakistan's exports in 2020. The domestic industry has recently penetrated non-traditional markets such as Africa and East and Central Asia, but the value of the commodities traded remains limited. Significant untapped export potential exists in the exports of pharmaceuticals from Pakistan. This strategy's aim is to assist local pharmaceutical companies and other sector actors to tap into the potential by strengthening the value chain and increasing the number of players at every step.

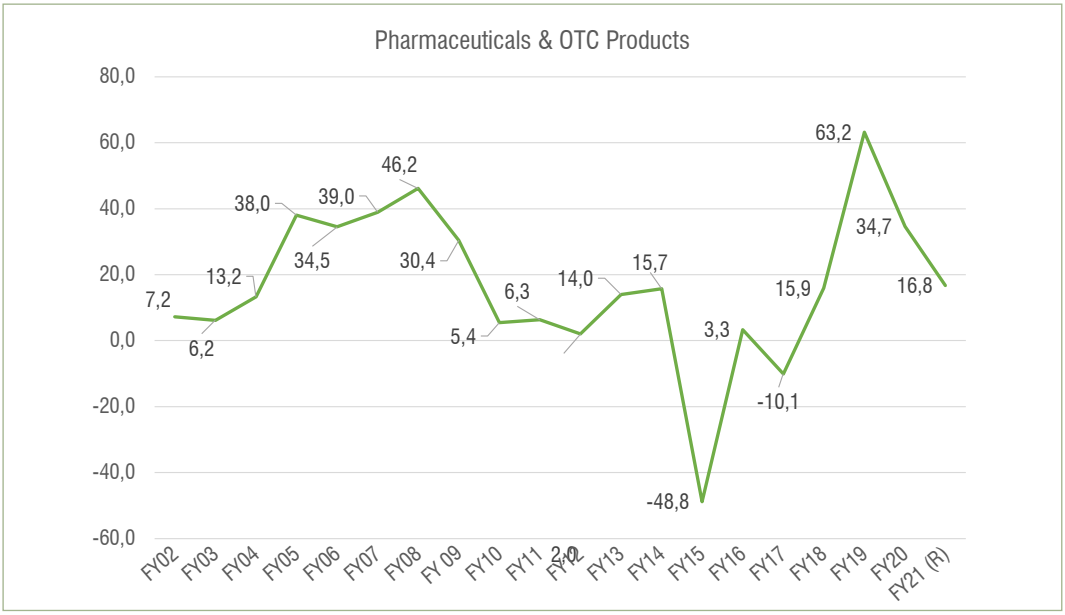
Despite potential, regulatory barriers have prevented FDI from booming until now

Pakistan has one of the highest population growth rates in the world along with one of the lowest accesses to quality healthcare, so investment in the pharmaceutical industry (foreign and domestic) needs to be substantial. This is especially true of foreign companies that are always on the lookout for growing markets like Pakistan, where there is not only a substantial demand for pharmaceutical products, but also where the pharmaceutical industry set-up offers additional advantages such as lower wages and a greater domestic market. Market demand and lower wages are influential factors in explaining the rise of pharmaceutical markets

such as that of India. Unfortunately, in Pakistan, investment (especially foreign) has plunged over the years.

In 2002, FDI in the Pakistani pharmaceutical sector was $7.2 million. By 2008, this number increased to $46.2 million. Since then, it has been dropping continuously, even going down to negative in 2015 and 2017. Worryingly, with little or no FDI coming in, the Pakistani pharmaceutical sector continues to witness profit repatriation. However, since 2017, net FDI in the sector has increased. The highest FDI the sector witnessed was in 2019 ($63.2 million). However, the fluctuation in the net FDI is consistent with the continuous divestment in the sector from the dwindling number of MNCs (see Figure 16).

Figure 17: Net FDI in pharmaceuticals and over-the-counter products



Note: This is net inflow of FDI in pharmaceuticals and over-the-counter products for FY 2002/21, from State Bank of Pakistan data; (R): Revised.

Source: Author generated from State Bank of Pakistan data. See https://www.sbp.org.pk/Ecodata/NetInflow-EcoGroup.xls.

Estimates of domestic investment are difficult to ascertain. As per the estimates in the PPMA report from 2017, domestic investments in 2014 were equivalent to $500 million. However, there is no information publicly available on the distribution of the investment, including merger, takeover, new plant and equipment, etc.

The failure to enforce copyright and patent laws is also thought to be another detriment to foreign investment coming into Pakistan. Since drugs can be easily copied and sold without a proper check, it makes little sense for potential investors to introduce their products in a non-protected environment. Drugs usually go through an extensive research, trial and market introduction procedure, and millions of dollars are spent in this process. Investors and manufacturers aim to recoup their costs through sales, and copyright protection ably complements this effort. However, in the absence of copyright and intellectual property (IP) enforcement, firms have little incentive to carry out research or invest in drugs.

Pakistan has the potential to attract FDI in the pharmaceutical industry if it creates a conducive environment in the country, including political stability, economic growth and development, accessibility to local inputs and opportunity for regional market, a clear development plan, and protection and enforcement of copyright and patent laws.

Moreover, a government incentive policy could play a determinant role in sustaining and developing the capacity of local manufacturers and inviting MNCs to set up units in the country. An effective regulatory system that strives to ensure safety, efficacy and quality of medicines could go a long way to ensuring investment opportunities for the sector.

VALUE CHAIN AND COMPETITIVENESS DIAGNOSTIC

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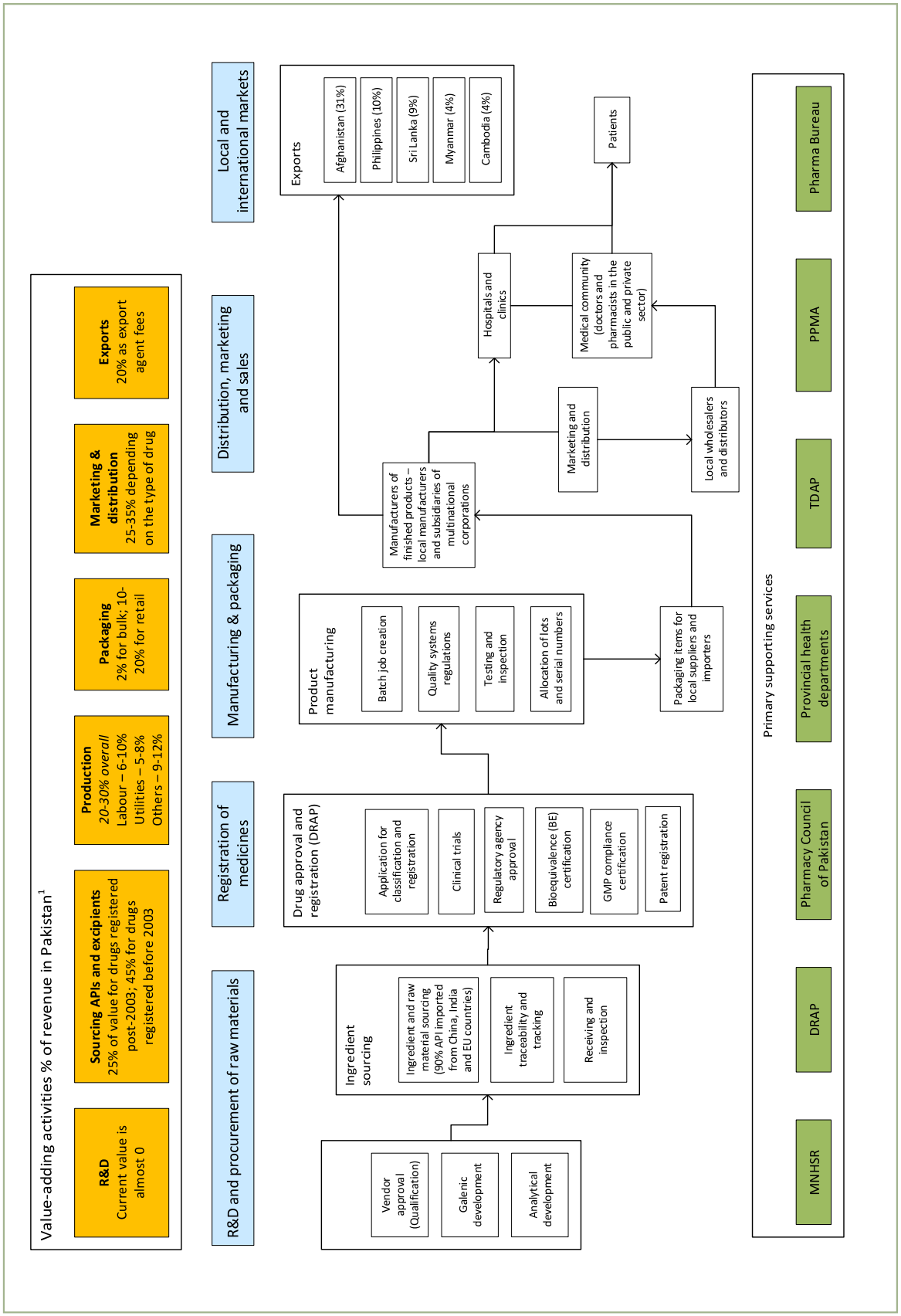
Value chain mapping

The pharmaceuticals value chain reflects the complexity and high level of technological sophistication required in the manufacturing process. It encompasses several distinct components following the different production stages.

Given the high level of the sector's integration, the value chain depicted in Figure 18 is represented through an overlay of direct (production) and indirect (development and regulatory) steps. The value chain analysis includes a complete mapping of the process and documentation to understand the flow of procedures and identify where efficiency gains are possible.

Figure 18: Pakistan's pharmaceutical sector value chain



Source: ITC.

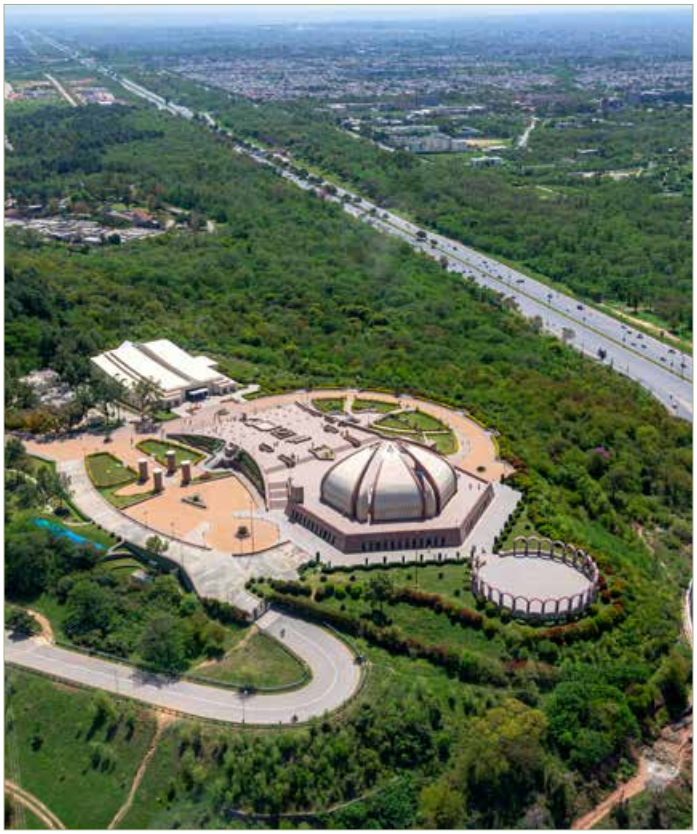
[1]**CPDR:** 'Unleashing the Potential of Pharmaceuticals in Pakistan'.

INSTITUTIONAL AND POLICY SUPPORT ECOSYSTEM

The pharmaceutical sector's success will not only depend on the internal capacities of the companies operating in the industry, but also on the role of the various ministries and public institutions, as well as other technical agencies. For the sector to achieve long-term sustainable growth, participating enterprises must be able to rely on a capable network of government and private sector support institutions. The overall trade support network (TSN) of Pakistan's pharmaceuticals sector is considered for this sector strategy as the aggregate institutional framework in the country, bringing together those institutions that have a particular interest in or bearing on the sector's export development and competitiveness.

Broadly, the TSN presented in Table 3 comprises the following support areas: policy support network, trade services network, and educational services and civil society network. DRAP is responsible for issuing licences to manufacturing units and ensuring compliance with GMPs. The provincial health departments are also engaged in key regulatory functions pertaining to sale of pharmaceutical products, such as issuing licences to pharmacies to sell medicines and ensuring quality of products that are being sold. The Federal Board of Revenue (FBR) and the Ministry of Commerce are also involved in this chain, mostly to facilitate and oversee the import and export of raw materials and finished goods.

A more detailed assessment of the key industry stakeholders/institutions alongside their capability to support sector development and influence policies and programmes for it are presented in detail in Annex III.



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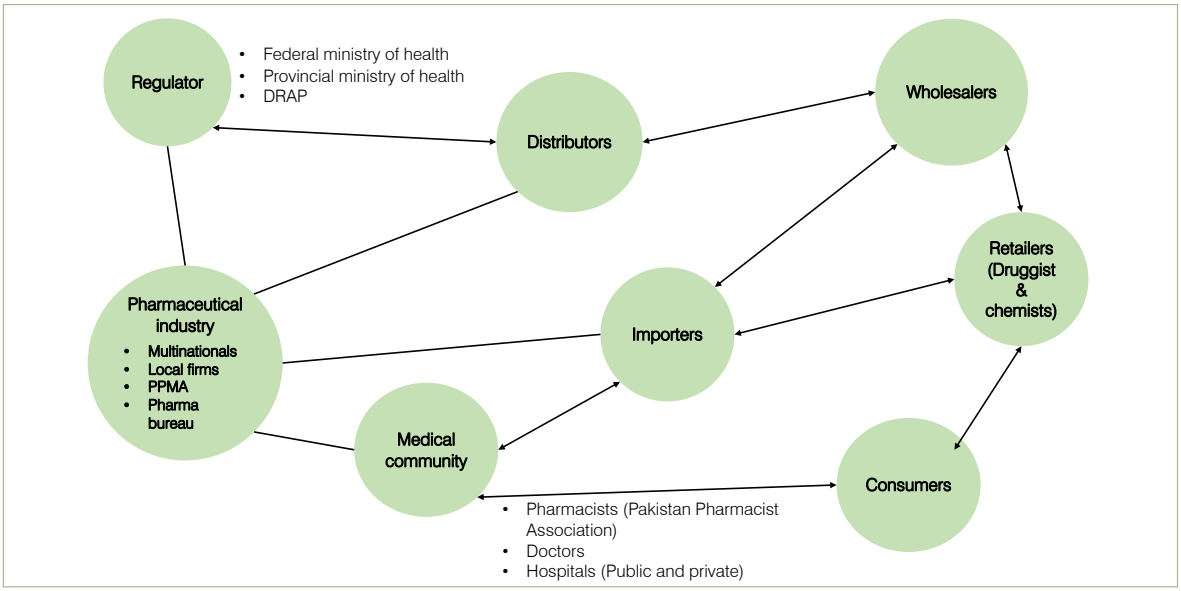
These stakeholders are mapped in Figure 19, along with their relationships. As is evident from the diagram, this is a complex landscape with each actor having multiple relationships with other actors.

Table 3: Trade and investment support institutions supporting the pharmaceutical sector

Policy and regulatory support	Ministry of National Health Services, Regulation and Coordination (MNHSRC) • Drug Regulatory Authority of Pakistan Act, 2012 Ministry of Commerce (MoC) Ministry of Finance and Revenue • Federal Board of Revenue (FBR) Provincial health departments
Trade and investment services	Ministry of Industries & Production • Small and Medium Enterprises Development Authority (SMEDA) • Ministry of Commerce • Trade Development Authority of Pakistan (TDAP) State Bank of Pakistan Pakistan Pharmaceutical Manufacturers' Association (PPMA) Pharma Bureau Druggists and Chemists Association Pakistan Pharmacist Association
Business services	Ministry of Maritime Affairs • Directorate General Ports & Shipping • Pakistan Army and Ministry of Narcotics Control • Anti-Narcotics Force
Academia and civil society	Pharmacy Council of Pakistan (PCP)

Figure 19: Networks between the key players in the sector



Source: Dawani and Sayeed, 2019.

Competitiveness constraints

The value chain diagnostic above outlines the operations of Pakistan's pharmaceuticals industry and provides an overview of the constraints faced by stakeholders at each stage in the chain. At the same time, COVID-19 has also exposed the various inadequacies of Pakistan's health sector, especially in production, distribution, institutional capacity and regulatory framework.

To remain realistic and resource-efficient, this strategy will not be able to focus on all the issues affecting the value chain. An informed selection of the most important issues that must be unlocked to realize the sector's potential was made. These constraints are faced by firms for local expansion and export competitiveness. To assess relative importance, criteria used are the level of disturbance (perceived by national stakeholders) and the ease of resolution (both in terms of cost and time involved).

To contextualize issues for firms, these impediments along the value chain are examined through the lens of constraints on competitiveness across the supply side, demand side and overall business environment. These are constraints pertaining to infrastructure, credit, testing and certification, trade and competition policy, as well as the availability of inputs and technology. These affect the quality and competitiveness of pharmaceutical products, lowering firm profitability, likelihood of export survival and investment (foreign and domestic) in the sector.

Box 2: Illicit trade of pharmaceuticals from Pakistan

One of the most severe constraints is the worrying crisis with neighbouring Afghanistan, which is endemic of other illicit pharmaceutical operations, such as the smuggling ring with the Middle East and Africa discovered earlier in 2021 (Geo News, 2021). Additionally, the effect of the illegal substance market on the pharmaceutical market should not be discounted. A perverse quid pro quo exists, as Pakistan remains a key market and waypoint for illegal substances from Afghanistan and pharmaceutical compounds that are necessary for the production of 'finished' illegal substances are smuggled into Afghanistan from Pakistan, such as iodine to produce methamphetamine (The Express Tribune, 2020). These challenges all serve to discount the reputation of Pakistani pharmaceutical manufacturers on the global stage and displace industry resources to illicit channels, while also generally derailing regulatory efforts in the country to manage the import and export of pharmaceutical products.

Table 4: Constraints along the value chain

Constraints	Root causes	Ease of resolution (Grade 1-5; 5- very difficult)	Urgent action needed (Grade 1-5; 5- very difficult)
Input level			
Overall poor regulatory approvals	New molecules can take 12–18 months to register and generics take up to three years. The process is non-transparent and cumbersome.	2	5
Lack of quality control, harmonization of standards and international compliance	None of the licensed manufacturing units in Pakistan have been approved by the FDA. Only three national companies exporting to 66 countries got the WHO pre-qualification certification.	4	4
	Similarly, coexistence of manufacturing facilities under different GMP standards and interpretations suggests an absence of harmonization in quality standards across the industry.	3	4
Weak input availability	Finances are limited, especially for small and medium-sized enterprises (SMEs), to introduce new technology and upgrade machinery.	2	3
	Frequent electricity breakdowns mean that production quality deteriorates – inconsistent temperature and humidity conditions also affect the final products.	2	4
	No secondary reference library for APIs.	3	3
Increased reliance on imported ingredients	Excessive duties on imported APIs and other raw materials raise the cost of production. Previously, the customs duty structure included a range of 5%–20% on ingredients and, if the customs duty was 25%, it attracted an additional sales tax and 5.5% withholding tax at the import stage.	3	3
Production and processing levels			
Pakistan's pharmaceutical industry fetches negligible investments from MNCs	The combination of price regulation, weak intellectual property rights and negligible investment in technology has lowered the incentive for MNCs to register innovator (new) molecules.	4	3
	The sector's profitability is also low due to poor quality controls and regulations – Pakistan is hardly an attractive destination for investment by foreign companies.	4	3
Firms pay a significant fee to DRAP, which increases the cost of doing business	Multiple fees charged by DRAP for: new drug registration, drug renewal registration, drug manufacturing fees and the Central Research Fund (1% on manufacturer profit before taxation). In addition, the process is also cumbersome to clear. Delays over several years in approving new molecular licensing is another factor that slows industrial growth.	5	3
Lack of strong patent and intellectual property rights discourages R&D	Weak legal enforcement of intellectual property rights and limited patents to cover the research cost of a new drug that can range anywhere between $500 million to more than $2 billion (Health Affairs, 2006), which discourages firms from spending in developing, introducing and marketing a new product.	3	5
Limited capacity for testing and compliance	The current testing capacity available in public sector (both federal and provincial) laboratories in Pakistan is not sufficient for the sector. Moreover, to be able to export medicines to developed countries that meet international standards, a pharmaceutical company also needs to fulfil bioequivalence (BE) certification in addition to the licence and GMP compliance certification. In Pakistan, there are only 1–2 BE labs.	3	5
Constraints at logistics and distribution at market access levels			
Lack of proper marketing and distribution channel	Lack of standard marketing mechanisms. Large firms develop relationships with doctors to prescribe their products (branded generics). Furthermore, small firms that produce generic medicines do not market their products mostly because they sell in bulk in the local markets.	3	3
Issues of counterfeit drugs leading to Pakistan's poor international reputation	Enforcers in the form of drug inspectors are very few, with little oversight on the quality of the inspection or ethical standards. Subsequently, practices such as selling medicines with fake labels, the existence of unregistered medical stores and substandard medicines remain common in Pakistan.	4	5
Missing certification measures for export destinations	A major challenge for pharmaceutical manufacturers that want to export is getting the product certification required by importing countries. Stringent regulatory authorities accredited by WHO exist in developed countries, which makes it difficult to export medicines there.	4	3

Deeper discussion of selected priority issues

INPUT LEVEL

Limitation in quality control, harmonization of standards and international compliance

Pharmaceutical exports require an extra layer of quality assurances due to the nature of the goods. None of the licensed manufacturing units in Pakistan have been approved by the FDA, only three national companies exporting to 66 countries have received the WHO pre-qualification certification, and only one of them has the European GMP and certification from the Medicines and Healthcare products Regulatory Agency (MHRA) based in the United Kingdom. Similarly, the coexistence of manufacturing facilities under different GMP standards and interpretations suggest an absence of harmonization in quality standards across the industry.

However, a domestic standard setting that would translate into export competitiveness has not been achieved. DRAP is trying to get all the necessary international accreditations, including acquiring the WHO Listed Authority (WLA) status. Registration with the international body will bring an international binding on manufacturers, importers and the regulator to maintain a minimum international standard of quality to provide medicines in the market and enable exports to several developed countries.

Increased reliance on imported ingredients

The pharmaceutical export market has become increasingly competitive in the past decade, as pharmaceutical products are produced in India and China at a very low cost. It is challenging for Pakistani products to compete in the international market when medicines rely on 95% imported ingredients. Moreover, all imports of APIs, excipients and packaging material are subject to a No Objection Certificate (NOC) from DRAP. This requirement has caused major hurdles for pharmaceutical importers. Moreover, there are excessive duties on pharmaceutical products, with different percentages applicable, depending on the type of drug and its specifications.

» Relevant activities in the PoA for supply level: 1.1.6; 1.2.2; 3.1.1; 3.1.3; 3.3.2; 3.3.3.

TOP ISSUES AT PRODUCTION AND PROCESSING LEVEL

Lack of strong FDI stemming from weak intellectual property rights and patent protection and ineffective enforcement

Partnerships between local and international companies can help improve production standards, encourage healthy competition, facilitate technology transfer and enable local manufacturers to gain access to global markets. Above all, investment through international companies can result in substantial FDI, technological transfer and R&D.

Currently, Pakistan's pharmaceutical industry fetches negligible amounts of FDI due to the absence of MNC-mediated investment, fostered by weak intellectual property laws and patent protection. The sector's profitability is also low due to poor quality controls and regulations.

Limited capacity for testing and compliance with export requirements

The current testing capacity available in public sector (both federal and provincial) laboratories in Pakistan includes 12 drug testing labs.[6]

To be able to export medicines to developed countries that meet international standards, a pharmaceutical company also needs to fulfil bioequivalence (BE) certification in addition to the licence and GMP compliance certification. In Pakistan, there are only two bioequivalence labs. Bioequivalence is also expensive and companies do not have an incentive to invest in it. This process has to be repeated for each product line to be exported, without which import partners will not allow the product to be registered in their market. This prevents Pakistani firms from exporting to developed countries such as the European Union, Japan, Australia or the Russian Federation.

» Relevant activities in the PoA for supply level: 1.1.5; 1.2.3; 3.2.1; 3.2.2; 3.3.1; 3.3.2; 3.3.3; 3.4.6.

6.– Two central laboratories working in Karachi and Islamabad, an appellate laboratory in Islamabad, five drug testing labs in Punjab and one in each of the remaining provinces. Three public sector drug testing labs are certified by the 17,025 standards of the International Organization for Standardization (ISO), whereas only three are prequalified by the WHO, of which two were approved in 2020.

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TOP ISSUES AT MARKET ACCESS LEVEL

Missing certification measures for export destinations

A major challenge for pharmaceutical manufacturers that want to export is getting the product certification required by importing countries. Drug exporters cannot meet foreign markets' strict technical requirements. Exporting to the United States and the United Kingdom requires FDA certification of conformity, but there are no internationally recognized facilities in Pakistan that can provide this certificate. Similarly, exporters report that the State of Qatar and the United Arab Emirates do not recognize the certificates issued in Pakistan. This has led to Pakistani exports being more concentrated in the less-regulated markets of Asia and Africa.

To export medicines and life-saving drugs from Pakistan, exporters must obtain a No Objection Certificate from DRAP. Pakistani companies find it difficult to get this certificate, because the agency demands many documents. Likewise, these exporters must also obtain a GMP certificate from DRAP. This process can take up to three months. Pharmaceutical exporters consider the export inspections carried out by the Anti-Narcotics Force and the strict regulations of State Bank of Pakistan to be major hindrances (ITC, 2020).

Issues of counterfeit drugs leading to Pakistan's poor international reputation

There is a consistent issue of local drug smuggling, with experts estimating that almost $65 million worth of drugs – more than 25% of total pharmaceutical exports – are illicitly transported to and then sold in Afghanistan annually. Furthermore, as recently as 2014, almost half of Pakistani pharmaceutical manufacturers were producing low-quality drugs – many of which are effectively counterfeits – for the illicit Afghani market (*AP News*, 2014). Enforcers in the form of drug inspectors are very few, with no oversight on the quality of their inspection or ethical standards.

» Relevant activities in the PoA for supply level: 2.1.1; 2.1.2; 2.1.4; 2.2.1; 2.2.2; 2.3.1; 2.4.1; 2.4.2.

The pharmaceuticals value chain reflects the complexity and high level of technological sophistication required in the manufacturing process. It encompasses several distinct components following the different production stages. In the case of Pakistan, from licensing to registration, to pricing and then finally retail, the pharmaceutical sector is fully regulated by various national, provincial and semi-autonomous bodies, directly or indirectly. It also means that there are constraints pertaining to the infrastructure, testing and certification, trade and competition policy, as well as the availability of inputs and technology. These affect the quality and competitiveness of pharmaceutical products, lowering firm profitability, likelihood of export survival and investment (foreign and domestic) in the sector.

THE WAY FORWARD

The global pharmaceutical market is in a state of flux due to major restructuring, both in terms of demand and supply. This presents a unique opportunity for the sector in Pakistan to take timely action by positioning itself strategically to enter the global drugs market. With a local market of 215 million consumers and 639 pharmaceutical companies, Pakistan is well poised to gain from opportunities provided under these shuffling global patterns of demand and supply.

While Pakistan has established itself progressively as a manufacturing platform for pharmaceuticals, the country remains a small player in the global scenario. Even though the domestic industry has recently penetrated non-traditional markets such as Africa and East and Central Asia, the value of the commodities traded remains limited. A significant untapped export potential exists in the exports of pharmaceuticals from Pakistan. In addition, Pakistan has the potential to attract FDI in the industry if it creates a conducive environment in the country, including political stability, accessibility to local inputs and protection and enforcement of copyright and patent laws.

This strategy's aim is to assist local pharmaceutical companies and other sector actors to tap into the potential of this highly technologically sophisticated industry, by strengthening the value chain and increasing the number of players at every step. Moreover, a government incentive policy could play a determinant role in sustaining and developing local manufacturers' capacity, and inviting MNCs to set up units in the country.

Upgrading within the pharmaceuticals sector will thus require transitioning from poor regulations and weak domestic capacities to robust mechanisms for the monitoring and testing of pharmaceutical quality, which rely progressively on a more technically skilled labour force, and infrastructure. Moreover, exports and overall margins are also determined by government pricing policies, quality regulations and international compliances.

Prerequisites for growing pharma in Pakistan

BUILD SOLID REGULATORY FOUNDATIONS FOR EXPORT AND INVESTMENT GROWTH

The 2018 pricing legislation established by the Supreme Court of Pakistan satisfied stakeholders, but recent straying from the policies has left many industry investors feeling uneasy and led some to relocate facilities outside of Pakistan altogether (*The News,* 2020). A full reversion to the 2018 policy or an updated version, with robust and broad implementation, will engender the stability needed to justify increased investment in the industry that will improve the industry generally and massively expand export opportunities. As indicated in Figure 20, Pakistan's pharmaceutical regulatory landscape is not rated as favourably as peers with larger export and more developed domestic markets (*Globalization and Health,* 2016).

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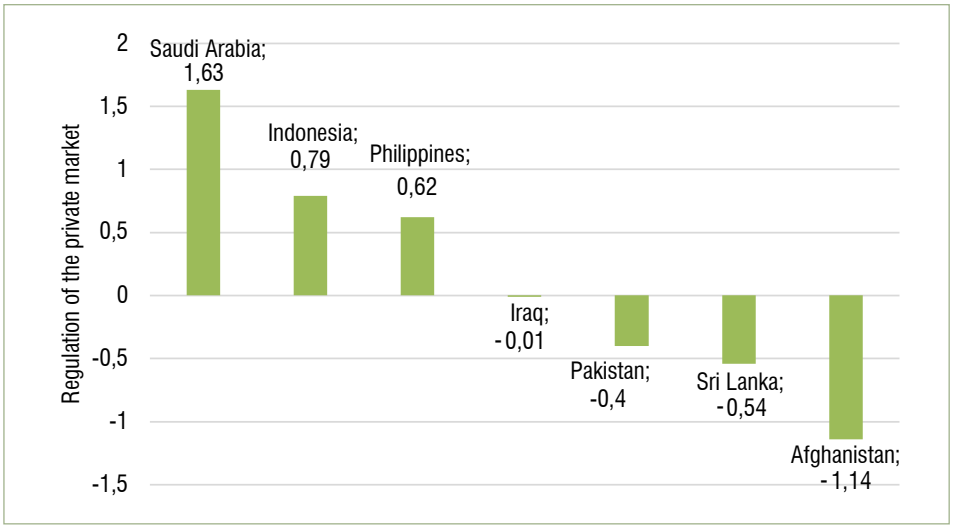
Figure 20: Pharmaceutical regulatory infrastructure index scores



Source: Globalization and Health, 2016.

A large part of an improved regulatory landscape will rely on more robust mechanisms and infrastructure for the monitoring and testing of pharmaceutical quality (Rasheed et al., 2019). The creation and development of these tools will help elevate the Pakistani market (see Table 5).

Table 5: Regulation adjustments in the pharmaceuticals sector

Regulations and acts adjustments	Remarks
SOP No. 004-QA-GMP Certificate- Issuance of GMP Certificate	Conduct a review every two years to assess the dividends and examine the further gaps.
Drugs Act, 1976	The Drugs Act, 1976 and the rules framed by it regulate the registration, manufacturing, marketing, sales, import, export and quality assurance of medicines in Pakistan. However, because of the 18th amendment to the Constitution of Pakistan in 2010, health has been devolved to the provincial level, necessitating the formulation of new laws by the provincial governments (World Health Organization, 2017).
The Drugs (Licensing, Registering & Advertising) Rules, 1976	The area of medicine registration has been determined to be moderately vulnerable to corruption. The time-frame for processing the application is not stated. A comprehensive up-to-date list of all pharmaceutical establishments (manufacturers, retailers and distributers) is not available from any of the authorities. The principal weakness in medicine registration is the absence of written conflict of interest guidelines (PBC and Consortium for Development Policy Research, 2021).
Drugs Pricing Policy, 2018	The strict price controls increase the production costs of drugs, which means that pharmaceutical manufacturers employ multiple mechanisms to continue to grow and profit (ACE SOAS Consortium, 2020). A high-level committee under the sector specific council headed by the Ministry of National Health Services Regulations and Coordination and DRAP with the private sector lead association and the Federation of Pakistan Chambers of Commerce and Industry (FPCCI) should intervene on the policy changes needed under the Drugs Pricing Policy, 2018.
National Essential Medicines List	The decision-making process of the committee responsible for revision of the National Essential Medicines List, and finalization of the list of medicines to be procured, is random and does not follow any set of standard operating procedures. Members' terms of reference are also not available. There are no written guidelines to address possible conflicts of interest by officials and members of the selection committees. In practice, no declarations are signed by the experts engaged in the selection process at the federal or provincial level. No criteria are publicly available for the selection process for including or deleting medicines in the indented medicine list (WHO, 2017).

Source: ITC.

- Capacity building will involve the establishment of strong training regimes, so the latest, most accurate techniques are being used for the testing of pharmaceutical quality and safety.
- National GMPs should also be updated and implemented to closely match those of the WHO to ensure successful interventions and greater compliance.
- In the same vein, the WHO pre-qualification scheme should be adopted to protect against subpar medicines entering the pharmaceutical supply gain, further developing trust with trade partners (Tordrup et al., 2013).
- Post-market surveillance and adverse drug reporting must be made more common and consistent in the Pakistani market (Rasheed et al., 2019).

These mechanisms are commonplace in more highly regulated markets and are a necessary facet of trust building for the industry. Without sweeping efforts to change the current pharmacovigilance culture, external trust is also less likely.

Pakistan is not the only player in the region attempting to expand its pharmaceutical industry. While some have been more successful than others have, Bangladesh presents an analogous case for sustainable systematic success. For Pakistan to reap the same rewards as Bangladesh has, there must be an investment in regimenting and strengthening local regulations and policies (Rasheed et al., 2019). There is no shortage of the human capital or the capacity necessary to facilitate a renaissance for the Pakistani pharmaceutical industry. However, there are numerous regulatory challenges that must be surmounted for these facets to be properly leveraged (The News, 2020). At the top of the list of concerns for many pharmaceutical firms is the establishment of consistent pricing policies, which would increase manufacturers' willingness to invest in FDA-approved plants, thereby driving improved and reliable pharmaceutical quality for domestic and export sales.

REDUCE TRADE BARRIERS FOR EASE OF DOING BUSINESS

The disruptions caused by COVID-19 and import bans enacted in 2020–21 have also demonstrated the fragility of Pakistani API access (BioWorld, 2020). The sector is currently reliant on imports for 95% of APIs (Rasheed et al., 2019), with the overwhelming majority being sourced from Chinese producers (Shagufta Shabba, n.d.). To avoid further pitfalls in the future, there must be a concerted effort to safeguard the bedrock of the pharmaceutical industry through the strategic prioritization of API production (*Dawn*, 2020). Proposals to correct this imbalance require delicate manoeuvring. Short-sighted hikes in import duties could dampen the market's prospects, but some combination of policies, such as incentives for local API producers in conjunction with stricter quality controls for imports, could provide an effective route for the industry's long-term sustainability (*Dawn*, 2020).

Box 3: Learning lessons from regional experiences: A case study of Bangladesh

Bangladesh has seen huge success in the past decade in increasing trade, now exporting to more than 140 countries, including highly regulated markets such as the European Union and Australia (Shet, 2021). Despite the economic impact of COVID-19, the pharmaceutical industry in Bangladesh experienced 15% growth in 2021, with local producers now accounting for 90% of the domestic pharmaceutical market (Shet, 2021). By 2025, the market is expected to reach $6 billion, representing an absolute growth of 114% from 2019, while export opportunity is also expected to grow to $450 million and the domestic generics market is set to grow by 85% (mostly fuelled by local manufacturers) (GlobeNewswire, 2020). These figures represent enviable trends, a portion of which can be explained by the Bangladeshi industry's commitment to R&D and innovation (Chaudhuri, 2020), which has been made possible by local generic markets that have encouraged and funded a stronger pharmaceutical industry (Azam, 2016).

Like Bangladesh, Pakistani manufacturers have a strong local foothold with generics – a market with the potential to expand – that can be used a stepping stone to a more mature industry that is more competitive globally. Despite Pakistan's 972 clinical trials to Bangladesh's 533 (WHO, 2020), Pakistani pharmaceutical R&D investment as a proportion of sales is less than 1% (Shet, 2021). Worryingly, this implies that the actors within the industry might be content with the status quo and unwilling to pursue long-term growth for the sector. Within the Bangladeshi pharmaceutical industry, investments in R&D teams have demonstrated a commitment to the development of innovative products and – crucially – processes to improve the industry's standing and long-term prospects (BRAC Business School, BRAC University, 2014). Further, even market analysts have pointed to several Bangladeshi firms as high-growth investments due to their commitments to innovation, thus adding momentum to the maturation and advancing of the sector (EBL Securities Ltd, 2019).

IMPROVE THE ROLE OF PHARMACEUTICALS IN PUBLIC HEALTH

The government's recently released 2021–22 health budget does not indicate a huge investment in public programmes. With no large increase in allocation and with a large proportion of available funds being directed towards COVID-19 immunization, there is little money for financing new initiatives and improving access to healthcare (*The News*, 2021). On the heels of the recent restructuring of the public health system, which decentralized structures to address localized needs and populations, the implementation of programmes intended to reduce inequity and improve access has been poor (Malik & Bhutta, 2018). Naturally, expanded access and increased public investment in the health system will precipitate an increase in health expenditures and money flows into the pharmaceutical industry.

The adoption and broader coverage of the public health system would spur growth and innovation in the pharmaceutical industry. Although Pakistan certainly faces greater financial constraints due to the pandemic – as most governments are – there is still currently political will to work on the further implementation and expansion of universal health coverage and, in recent years, great progress has been made (Healthy Developments, n.d.). However, the aforementioned small funding pool available to programmes that could effectively expand access and decrease out-of-pocket healthcare costs (currently approximately 56%) (Healthy Developments, n.d.) has made some wary of the country's ability to meet the WHO's health security Sustainable Development Goals.[7] Pakistan's pharmaceutical industry must understand that universal coverage is not only a necessity for the population's general well-being, but is also strongly correlated to the industry's development (Bigdeli et al., 2015). In most low- to middle-income countries, spending on pharmaceuticals accounts for almost two-thirds of total health expenditure (Bigdeli et al., 2015), a figure that will only rise should more Pakistanis be given the chance to access the nascent universal health coverage system more reliably. Thus, growing public health programmes can only serve to feed the organic maturation of the local industry and drive foreign investment, while preparing local firms for entering global trade.

Box 4: Pharma industry providing impetus to the public health sector: A case of Indonesia

Indonesia's newly adopted care legislation – in tandem with lowered barriers for foreign investment – are expected to draw in $20 billion in foreign financing in 2022–26 (CPhI Pharma Insights, 2020). The Indonesian market grew 10%–13% since 2015, and many have pointed to the roll out of national insurance as a key driver (ASEAN Briefing, 2020). Indonesia represents a regional trend, whereby the recent establishment of universal health coverage is met with a boon period for national pharmaceutical markets, not only drawing in funds from abroad, but also providing incentives and financing for the expansion of local industry (CISION PR Newswire, 2021). Ideally, this will produce a more developed and resilient domestic market that will be more capable of trading on the global pharmaceuticals market.

Drivers of change and orientations for sector growth amid global transition

Changing patterns of demand and production in the global pharmaceuticals sector means that Pakistani producers will need to adapt to succeed in international markets. The strategy design process considered current capabilities, constraints, and future shifts and opportunities for Pakistan's pharmaceuticals sector, and industry stakeholders extensively evaluated future orientations and upgrading trajectories.

To better understand the disruptive changes and how it will affect the current ways of working within the sector, the participants of the Pakistani pharmaceuticals sector consultation used the Ride Two Curves tool.

7.– See https://www.who.int/health-topics/sustainable-development-goals#tab=tab_1.

As the name indicates, this tool comprises two curves: one symbolizes the current way of doing things and the other one is the new disruptive one. The challenge is to know when to jump from one curve to the other to make the most of it.

Moreover, by solving some of the key competitiveness and growth constraints, Pakistan's pharmaceutical manufacturers can position strongly for export growth. It is necessary to set some strategic objectives for the short to medium term to drive sector transformation, and prioritize key actions. These strategic objectives for the sector's development are reflected in the future value chain, which is the result of consultations, surveys and analysis conducted as part of the pharmaceuticals sector strategy design process, and is rooted in the diagnostic section of the document. The future perspective offers resolution to the current issues and provides the responses to the opportunities, and has two main components:

- A market-related component involving identification of key markets for Pakistani exporters;
- Structural changes to the value chain that result in strengthening of linkages or introduction of new linkages.

STRATEGIC FORESIGHT

As the world grapples with the changes occurring due to the pandemic, Pakistan's pharmaceutical sector must leverage on its strengths and overcome its weaknesses to explore new possibilities within the sector in the future. The Ride Two Curves exercise was used to analyse broad phenomena and evaluate the changes in the industry – focusing on the disruptions caused by a specific technology. Figure 22 is a visual representation of the Ride Two Curves[8] exercise conducted with the participants. Deriving from this are the orientations outlined below. Table 6 captures the summary of stakeholders' analysis of future trajectories along the two curves. The first assesses today's ways of doing things and which of those will remain strong and competitive into the future (i.e. will remain as residual assets for Pakistan). The second assesses the current innovations and trends already seen in Pakistan and globally, and how these will influence the future strategic orientation of Pakistan's pharmaceuticals sector (i.e. tomorrow's way of doing things). Some key messages that emerge from this exercise are presented in Table 6.

Table 6: Summary of stakeholder perspectives on future trajectories

Residual assets	Strategic shifts
Some compelling residual assets include the low production cost, investment in technology and human capital, improvement in production facilities (and thus, upgrading quality assurance requirements), and investment in market research and development.	Some compelling strategic future shifts would include exports to regional economies in Africa and Central Asia, forming joint ventures with technologically advanced producers, using contract manufacturing for high-tech product development like biologicals and vaccines, and developing skills for production of natural products (nutraceuticals and galenic products).

Source: ITC.

THE FUTURE VALUE CHAIN

Developing Pakistani pharmaceuticals' quality and sustainability will require transformations throughout the value chain. The structural improvements explained in the previous section are reflected in the future value chain schematic (Figure 23) and provide an overview of the adjustments to be done in relation to markets, value chain operations, institutions, regulations and investments.

Improvements to exporting will be made by reaching new markets and pursuing more intensive trade with existing partners. In addition to sector-level factors, the choice of target markets should consider factors such as political relationships, transportation links, and economic and political stability in the target market, among others.

Pakistan's recent trade performance has shown success in the exports of pharmaceutical products. There is great potential for sector growth, expansion of existing products, development of new products and timely entry into new markets. Achieving the strategic objectives and realizing the future value chain depend heavily on sector stakeholders' ability to start implementing and coordinating the activities defined in the strategy's PoA.

8.– The Ride Two Curves tool is used to better understand disruptive change and how it will affect our current ways of working, so we can get ready for it. This tool comprises two curves: one symbolizes the current way of doing things and the other one is the new disruptive one. Ride Two Curves © 2017 Institute for the Future. All rights reserved.

Leveraging market opportunities

Based on Pakistan's trading relationship and expectations for future growth, Central Asia, Western Africa and East Asia are expected to be particularly important export markets for pharmaceutical products from Pakistan. Succeeding in these markets will require exporters to adapt to these markets' requirements and expectations, including investing in R&D facilities and maintaining strong regulatory compliance. Gradual approaches will be needed in moving into these markets, scaling from jointly working together on knowledge exchange with local trusted partners in Pakistan to building Pakistani firms' presence as experience and expertise is gained.

While Pakistan's exports of pharmaceuticals is improving, tremendous export potential remains largely untapped. An analysis of the source of export performance (Figure 21) confirms that the majority of growth in Pakistani pharmaceuticals exports in 2009–20 was generated by an increase in exports of traditional products to existing markets. There has been a very small product diversification with registered growth in new products to new markets. The low degree of diversification in the last decade reflects weak technology adoption, lack of quality control, harmonization of standards and international compliances, interrupted flow of raw materials, and over-dependence on API imports, which have all had a bearing on the sector's trade performance.

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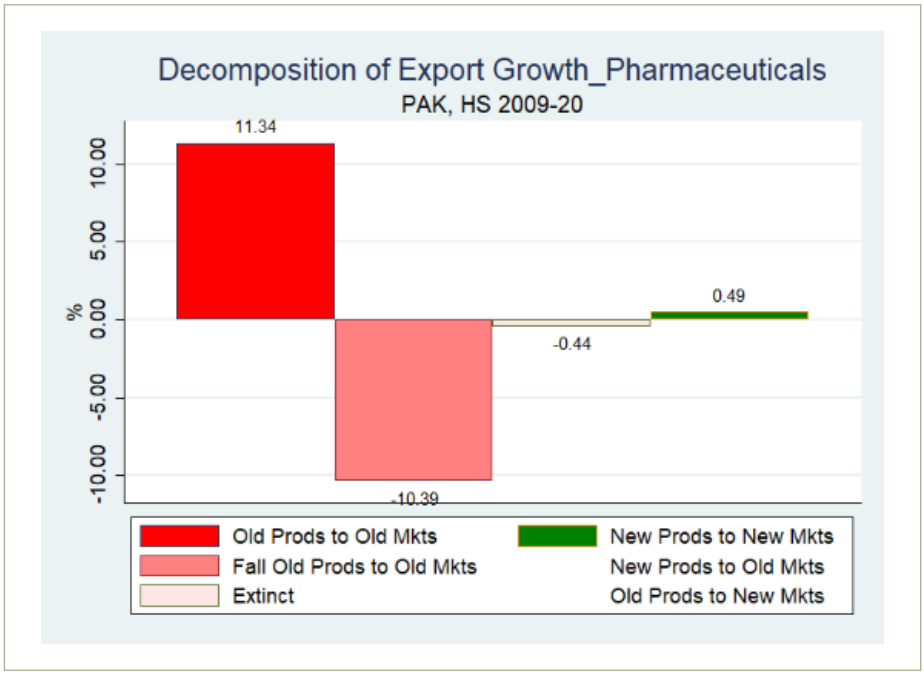
Structural adjustments to the value chain

Tapping into the robust growth potential of Pakistan's pharmaceuticals sector will require modifications throughout the value chain, especially to establish local producers as trusted partners capable of developing genuine, high-quality medicines. Moreover, reducing dependency on the imports of APIs, improving GMP-compliant manufacturing units, and enforcing copyright and intellectual property rights protection laws are required adjustments that will allow the sector to offer competitive levels of both quantity and quality of produce. The following segments of the value chain are foreseen as key areas of focus for achieving the future value chain.

Figure 21: Decomposition of Pakistan's export growth

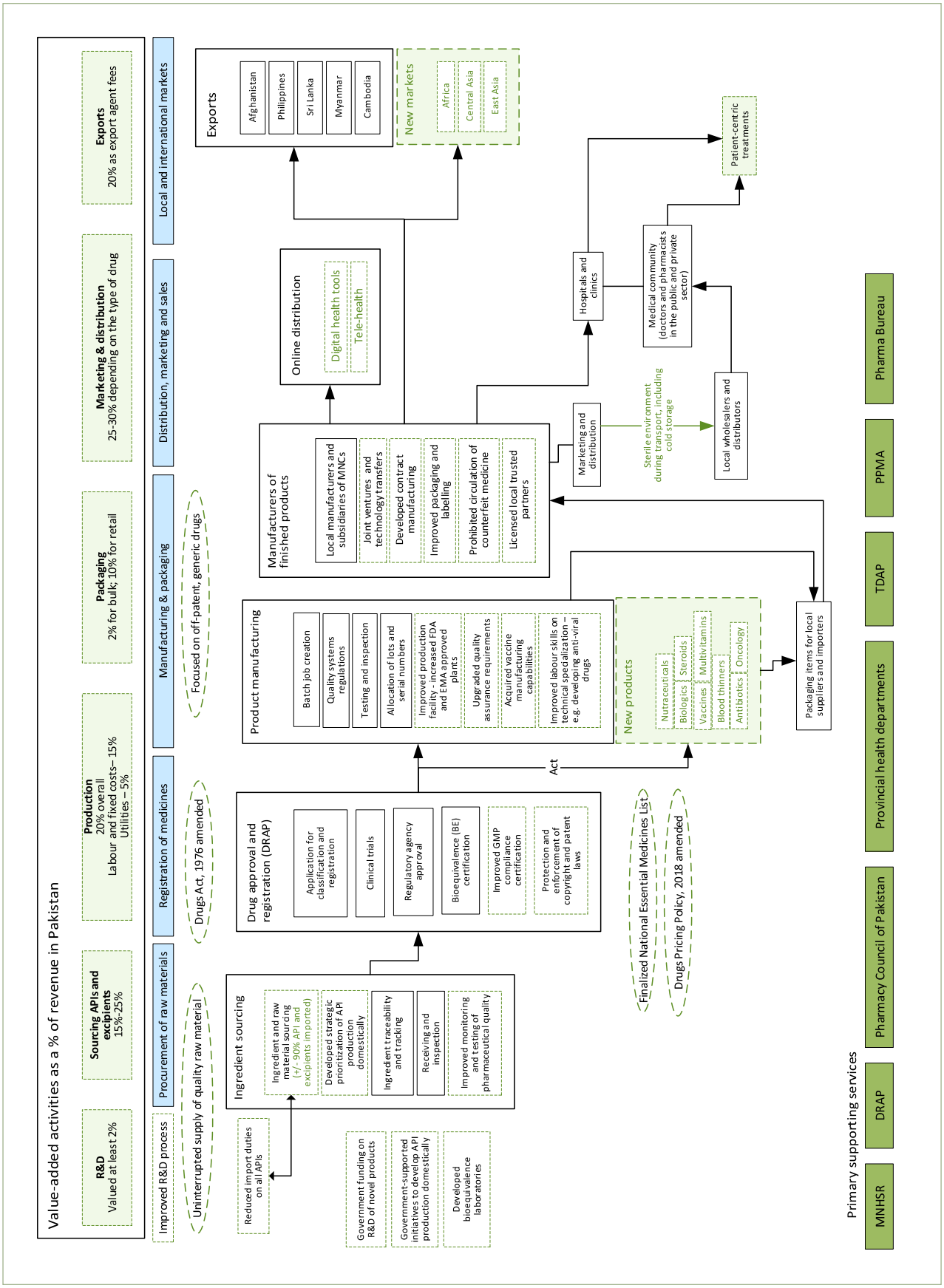


Source: ITC calculations based on United Nations Comtrade statistics.

Figure 22: Ride Two Curves exercise

Source: ITC, adapted from the Institute for the Future.

Figure 23: Future value chain



Source: ITC.

ORIENTATION 1: CEASING COVID-19 OPPORTUNITIES FOR THE PHARMACEUTICALS SECTOR

COVID-19 remains a global challenge. During the pandemic, the industry operations leaders rallied to enable the supply of key medicines across borders, manage workforce safety and handle evolving government restrictions. These challenging times also offer an opportunity for Pakistan's pharmaceutical industry to acquire the core capabilities and skills for advanced drugs and vaccines manufacturing, which it is currently lacking. This can include the manufacturing of generic pharmaceutical drugs such as vitamins, steroids and antibiotics that are in high demand for treating COVID-19 and secondary infections caused by it, and can be the first significant step, followed by the acquisition of vaccine manufacturing capabilities towards the production of next-generation, high-value pharmaceuticals in Pakistan.

With these initiatives established, companies can begin taking stock of what lies ahead. Given the shifts that have taken place seemingly overnight in response to the crisis, there have been fundamental changes in overall pharma operations. While individual companies have and will continue to drive many of these changes, some will be driven industry-wide, and external factors, including government involvement, will also shape opportunities for Pakistan post-COVID-19.

Market and product focus

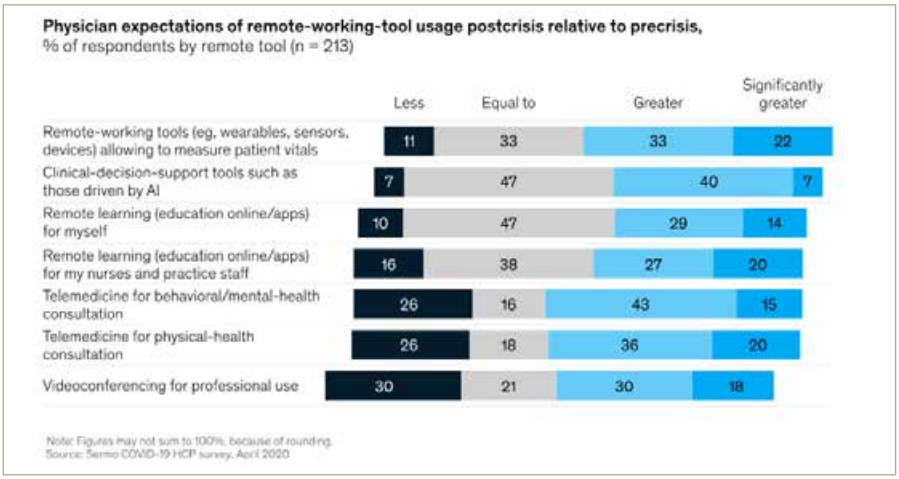
The key markets identified for generic pharmaceuticals are in Africa and East and Central Asia, where Pakistan's main competitors are India, China, the Hashemite Kingdom of Jordan, the Republic of Kenya, and Malaysia. Tariff access is a preliminary hurdle – firms will have to make progress to meet stringent regulatory requirements. Here, the government can play a key role in helping firms acquire key compliances and tighten domestic quality regulations to meet world standards. This will raise the sector's overall global competitiveness.

Currently, the pharmaceutical industry is focused on small molecule-based classic products. The future of Pakistan's exports market lies in the next generation of pharmaceutical products – entering product segments that are in heavy demand such as blood thinners, steroids, antibiotics, multivitamins, nutraceuticals and vaccines, or those that are being vacated such as Infliximab, Ezetimibe and Telmisartan as manufacturers focus on COVID-19 and new drug discovery *(PoA Activities 2.1.1 and 2.1.6).*

Required investments

Due to the pandemic, global supply chains have become increasingly patient-centric with different end points of delivery and information. Increased adoption of digital tools, telehealth and app-based ecosystems make patient-level data more available. In the survey of physicians by McKinsey, significant increases in telemedicine, video conferencing, remote working tools and clinical decision support tools are all expected (Figure 24) as a result of COVID-19 (McKinsey & Company, 2020). To leverage on this trend, Pakistani drug manufacturers need to invest in developing a robust online distribution channel and connect with online healthcare service providers, both nationally and internationally *(PoA Activity 2.4.3).*

Figure 24: Physicians expect significant growth in the use of digital tools



Source: Sermo COVID-19 HCP survey, April 2020.

Box 5: A case of technology transfer in Pakistan

Gilead Sciences, Inc. announced that Pakistani manufacturer BF Biosciences Limited (a subsidiary of Ferozsons Laboratories Limited) was one of five South Asian manufacturers being authorized under a voluntary non-exclusive licensing agreement to produce and distribute an experimental antiviral drug (Remdesivir) to treat COVID-19 to 127 countries in the developing world affected by the pandemic (Pakistan Today, 2021). It was the first time that a Pakistani manufacturer had been selected to be part of an international supply chain of this nature. The company has been supplying Remdesivir to Ukraine and Indonesia and both the countries are highly regulated markets that normally do not buy medicines from Pakistan.

Under the agreements, the companies received a technology transfer of the Gilead manufacturing process for Remdesivir to enable them to ensure product quality and to scale up production quickly. The development represented an important step forward for Pakistan on the health, economic and diplomacy fronts. Ferozsons' partnership with Gilead represents an effective bridge enabling access to greater export and technology transfer opportunities, but is not a sustainable solution (Pakistan Today, 2021).

Following this example, for Pakistan to seize the opportunities offered by the pandemic, investment is needed in the following areas:

- Invest in R&D to improve the environment for clinical trial, which can be a big export earner *(PoA Activity 1.3.3)*.
- Investment is required to simplify contract manufacturing procedures, which will allow opportunities for international collaboration for high-tech products like biologicals, and vaccines highlighted by COVID-19 *(PoA Activity 1.3.3)*.
- Pakistan-specific antigens and COVID-vaccines need to be locally manufactured with the help of technology transfer from global partners or joint ventures with leading MNCs to upgrade existing manufacturing capacity *(PoA Activity 2.2.2)*.

Required regulatory adjustments

- Improving regulatory frameworks to accelerate innovation and R&D (*PoA Activities 1.2.3 and 1.3.1*).

Required skills

Pakistan will need to implement significant soft-skilling, upskilling and capability-building efforts in the areas of information technology (IT), data management, industrial automation and management, as well as technical specialization related to antiviral drugs development specific to COVID-19. The latter will specifically require participating in international research groups (*PoA Activities 2.4.1, 3.4.3 and 3.4.5*).

ORIENTATION 2: BUILD INDUSTRY CHAMPIONS AND INVESTMENT ANCHORS

The growth and development of the Pakistani pharmaceutical manufacturing sector is based on the value chain approach, which is a spectrum of progress from the current import-led to a more research-based industry. This shift could contribute towards a knowledge economy with trusted local skilled professionals, regulatory institutional development, business and market development, interdisciplinary confluence and R&D.

Market focus

It is crucial to stress the importance of adopting a progressive strategy when considering opening the domestic market to foreign investments. Firstly, as a prerequisite, government support should focus on dismantling any entry barriers, removing existing impediments on attracting investment and improving the drug quality and regulatory environment to counter illegitimate drugs. The main focus areas should include strengthening intellectual property (IP) protection, deregulating drug prices that lead to insufficient profitability, reduction in duties on imported APIs (this has already been initiated under the FY 2020/21 budget) and increasing the focus on quality control.

Moreover, support should be provided to financially scale up and make use of industrial parks and export processing zones where possible. A favourable government policy towards the industry, especially expediting the launch of the national medicine policy aimed at reformulating the pharmaceutical industry, could help in doing business in the sector.

Along these lines, it will be vital to liberalize the price control regime, which is highly regulated, with the government fixing drug prices. Consequently, margins remain relatively thin for the entire pharma industry, with many companies exiting the market completely due to the high costs of production and insufficient profitability.

Phasing out the price control regime by establishing a free market whereby, except for the prices of medicines in the National Essential Drugs List, all the rest are determined by a demand–supply balance would make the domestic market more attractive to foreign investors, if quality standards are effectively enforced.

The pharmaceuticals sector in Pakistan could benefit if the government entered into a preferential trade agreement with Viet Nam (Tribune, 2021). Viet Nam is a regional leader in vaccine production (a long-term prospect for the sector) and could provide a foothold into the ASEAN market, as it is the 3rd largest FDI destination ($15.5 billion in 2018) within ASEAN countries, following the Republic of Singapore, and Indonesia (KPMG, 2020).

Required investments

- A first avenue for investment should be to nationally scale up a selection of well-performing firms in generics, while ensuring intellectual property (IP) protection. Scale can be expected to improve from some recent changes on the demand and supply side, for example, planned expansion in public healthcare coverage under the Sehat Sahulat Program and pricing revisions by DRAP. Scaling up should be the focus for the BOI through national investment first (*PoA Activities 1.3.1 and 2.1.1*).
- After scaling up efforts are achieved nationally, attract FDI into well-performing firms (or trusted partners). The BOI should identify the list of local trusted partners and bring them into fairs and business-to-business transactions to bring in FDI *(PoA Activity 3.2.2).*
- Conduct an investment-targeting campaign to attract MNCs to the sector *(PoA Activity 1.3.2).*

Required skills

- Producing APIs and excipients locally is essential in order to lower the costs of production in the mid-term or long term. This depends on a larger set of skills that go beyond simple formulation capabilities – developing reverse engineering skills that are primarily chemistry based, with some expertise in biotechnology and genomics *(PoA Activities 1.1.6 and 2.1.7).*
- In order to fully develop and realize its potential, the industry needs to attract highly skilled personnel, including knowledge exchange, technical assistance and trainings (*PoA Activities 3.4.1, 3.4.2, 3.4.4 and 3.4.6*).
- The BOI and PPMA need to focus on national image building, which will require the development of a sales-minded organizational culture and corresponding skills (*PoA Activities 2.1.2 and 2.2.3*).
- For the BOI to have a strong investor targeting, there is a need to develop soft skills as well strong public relations skills. This will help with individual inquiry responses and investor-targeting campaigns (KPMG, 2020) (*PoA Activities 2.4.1, 3.4.3 and 3.4.5*).

Required regulatory adjustments

- Liberalize the price control regime by amending the Drugs Pricing Policy, 2018 (*PoA Activity 1.1.1*).
- Revise the National Essential Drugs List in line with the WHO Model Lists of Essential Medicines (*PoA Activity 1.1.2*).

ORIENTATION 3: PREPARE THE SECTOR FOR EXPORT GROWTH

Exports of pharmaceuticals will only follow when the sector builds its domestic capacity. The current local environment and the lack of trusted domestic partners has led to an outflow of multinational firms that otherwise bring in technological expertise and knowledge spillovers. It has also put pressure on existing firms to fulfil domestic needs, especially considering the strong reliance on imports.

Product focus

China and India, two of the largest pharmaceuticals manufacturers, have started shifting focus to the more value-added innovative pharmaceutical industry, shrinking drug pipelines in developed countries, and a scramble to capture off-patent generic drugs. Pakistan can meet global demand for off-patent original blockbuster drugs in low- and middle-income countries. Pakistan already has 17 pharmaceutical manufacturing units in Nigeria (PricewaterhouseCoopers, 2014).

In the short term, there is an opportunity to strategically enter a market that will be worth $700 billion in branded generics and $381 billion in generics by 2025 (PBC & Consortium for Development Policy Research, 2021). By the end of 2020, almost $151 billion worth of generics have already gone off-patent, where

Pakistan's total exports in these lines amounted to only $210 million (PBC & Consortium for Development Policy Research, 2021).

In the long term, human vaccines could be a prospective subsector on which Pakistan could focus. The global human vaccines market was worth $33 billion in 2019, and it is projected to reach $66.6 billion by 2027. Pakistan currently has no exports of human vaccines, and its domestic production is limited to 1–2 rabies vaccines produced in the public sector.

Required investments

Focus on vaccine manufacturing by approaching international companies manufacturing WHO pre-qualified vaccines and entering into an agreement with the Government of Pakistan for technology transfer to Pakistani firms.

- Invest in National Control Laboratory for Biologicals (NCLB), which is responsible for much of the release of vaccines and biologics in Pakistan, to apply for WHO pre-qualification *(PoA Activity 3.3.1).*
- Trusted local vaccine partner having validated biological production facilities, or those that are willing to invest in the required standards would be ideal local partners for international companies providing the technology transfer. The requisite capabilities can be acquired through government contracts with leading global vaccine producers such as Moderna, Pfizer and Johnson & Johnson (*PoA Activity 3.2.1).*
- Local firms can also extend proprietary arrangements with MNCs such as technology licensing agreements through firm-to-firm linkages, or contract consultants to upgrade their existing facilities.

Investment in cold chain logistics, which is a vital factor for pharmaceuticals sector

Given the sector's complexities and differential requirements and standards set by different countries, exporting requires accurate diagnosis of target markets. These comprehensive market reports can be very costly for firms. A pharmaceutical sector specific council can disseminate regular country and product research reports to support the pharmaceuticals industry in going global.

- The sector specific council can create a central export body for marketing and branding, and a separate unit for providing export information on new opportunities, changes in regulatory standards, import requirements and non-tariff measures, as well as funding for international trade fairs *(PoA Activity 1.3.1).*

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To penetrate African markets, invest in opening local representative offices in the destination country, or entering via a joint venture in distribution with local importers *(PoA Activities 2.1.5, 2.2.1, 2.2.2, 2.3.3 and 2.3.5).*

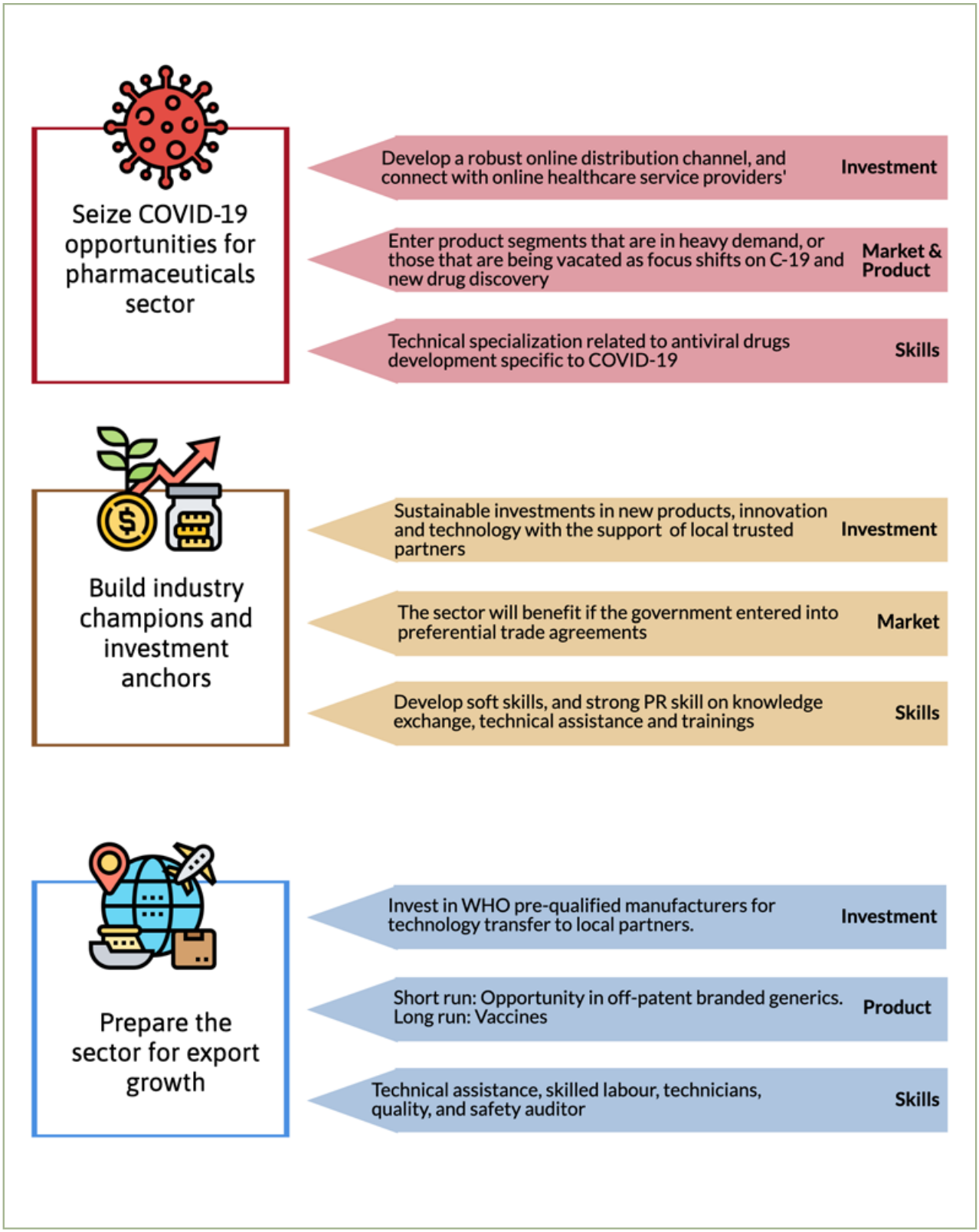
Required regulatory adjustments

- DRAP should continue its reforms and invest in quality regulation and enforcement, for example, DRAP achieving international standards, clearing certifications as per the WHO Global Benchmarking Tool and attaining the PIC/S membership could allow access to Stringent Regulatory Authority (SRA) countries *(PoA Activity 3.3.1).*

Required skills

- Technical assistance in the form of expatriate skilled labour, technicians, quality and safety auditors could be initiated. This will also change the poor perception of state of manufacturing in the country.
- Securing better market access conditions for pharmaceuticals in strategic markets with require the strengthening of Pakistani trade officers' trade negotiating capacity *(PoA Activities 2.3.2 and 2.4.1).*

Figure 25: Key drivers of change



Source: ITC.

The strategic framework

THE VISION

The pharmaceutical sector's strengths need to be leveraged to overcome its challenges and realize the potential for more efficient and export-oriented growth. While exports currently remain stagnant, Pakistan has the requisite scale and growth to sustain a significant pharmaceuticals sector. Specifically, the sector can build on to streamline the domestic structural, regulatory and institutional changes.

The current landscape calls for a strategic response around:

- Developing local firms' technical capacity as trusted partners to attract international investments;
- Strengthening safeguards and frameworks to maintain the highest level of production quality;
- Building the skills of the local industry through vocational training and higher education.

This strategy's implementation will thus lead to a robust and thriving domestic industry, ready to increase its exports through reduced uncertainty, improved connections with high-potential markets, and increased domestic value added and export diversification. Finally, an internationally competitive pharmaceuticals sector will help improve Pakistan's overall image as a modern developing nation contributing to global welfare.

In line with the strategic approach presented above, the following delineates this strategy's proposed vision and strategic approach to develop the Pakistani sector. The vision statement was discussed and agreed on by all stakeholders in Pakistan's pharmaceuticals industry.

> **"To increase the international market share by innovation and compliance with international quality standards."**

THE STRATEGIC OBJECTIVES

The plan of action (PoA) will respond to this vision by addressing the sector's constraints and leveraging opportunities in a comprehensive manner. The PoA will be structured around the following strategic objectives, agreed with all sector stakeholders.

Strategic Objective 1: Improve the national framework for regulatory and institutional management, as well as the business environment governing the pharmaceutical sector	•1.1. Revisions of laws and policies governing the sector •1.2. Support a stable regulatory regime by redefining the roles of agencies in the sector •1.3. Improve the overall business environment by encouraging policy coherence and facilitating investments in the sector
Strategic Objective 2: Strengthen the export competitiveness of Pakistani pharmaceutical companies	•2.1. Facilitate access to and development of new products •2.2. Define the positioning of pharmaceutical products in the target export markets •2.3. Develop market intelligence and information services on target export markets •2.4. Build company capacities to enter domestic and international market
Strategic Objective 3: Domestically support the development and upscaling of the Pakistani pharmaceutical sector to be more compliant	•3.1. Compliance with international production standards •3.2. Attract investment to foster innovation and technological upgrading to strengthen firm capacities •3.3. Establish internationally accredited laboratories to maintain quality control •3.4. Invest in scientific, technical and managerial training to strengthen skills and know-how and build linkages with universities

IMPLEMENTATION FRAMEWORK

The objective of the Pharmaceuticals Export Strategy for Pakistan is to create an enabling environment for the pharma industry to realize its potential and benefit the country's image by following the vision 'To increase the international market share by innovation and compliance with international quality standards'. Achieving this ambitious objective will depend on the industry's ability to implement the activities defined in this strategy. To structure sector development, it is recommended that the following interventions be implemented with priority:

- Allow duty-free imports of API to reduce reliance on neighbouring countries like China and India (PoA Activity 1.1.6).
- Conduct quality control audits to enforce stringent regulations for quality and ethical standards, to reduce illicit trade and counterfeit medicines, which is tarnishing the sector reputation internationally (PoA Activity 1.2.3).
- Nationally scale up well-performing firms to meet the demand for off-patent original blockbuster drugs in low- and middle-income countries, while ensuring intellectual property (IP) protection (PoA Activities 1.1.5, 1.3.1 and 2.1.1).
- Attract FDI into well-performing firms or domestic trusted partners with support from the BOI and bring them into fairs and business-to-business transactions to bring in FDI (PoA Activity 3.2.2).
- Identify product lines and key markets in which Pakistan could have latent comparative advantage (PoA Activities 2.1.2, 2.1.5, 2.1.6 and 2.3.1).

MANAGING FOR RESULTS

The translation of priorities into implementable projects will contribute to achieving the substantial increase in export competitiveness and export earnings envisaged under the strategy. These will be driven by reforming the regulatory framework, optimizing institutional support to exporters and strengthening private sector capacities to respond to market opportunities and challenges. Allocation of human, financial and technical resources is required to efficiently coordinate, implement and monitor overall implementation.

Successful execution of activities will depend on stakeholders' abilities to plan and coordinate actions in a tactical manner. Diverse activities must be synchronized across public and private sector institutions to create sustainable results, and it is therefore necessary to foster an adequate environment and create an appropriate framework for the strategy's successful implementation.

Key to achieving the targets will be coordination of activities, monitoring progress and mobilizing resources for implementation. To that effect, industry representatives recommended that a public–private sector specific council for the pharmaceuticals industry be rapidly established, operationalized and empowered. The sector specific council is to be responsible for overall coordination, provision of policy guidance and the monitoring of industry development along the strategic orientation.

PHARMACEUTICALS SECTOR SPECIFIC COUNCIL

It is recommended that a pharmaceutical sector specific council be rapidly established by the Minister of MoC and effectively organized by the TDAP and MoC to support the industry with the capacity to steer its development strategically. The committee is to be facilitated by a secretariat coordinated by the TDAP, supported and advised by the Pakistan Pharmaceutical Manufacturers' Association.

Industry representatives recommend that the pharmaceuticals sector specific council be composed of the following members:

- Ministry of National Health Services Regulations and Coordination;
- Drug Regulatory Authority of Pakistan;
- Pharmacy Council of Pakistan;
- National Institute of Health;

- Pakistan Health Research Council;
- Health Services Academy;
- College of Physicians and Surgeons Pakistan;
- Ministry of Industries & Production;
- Small and Medium Enterprises Development Authority (SMEDA);
- Board of Investment, Invest Pakistan;
- Ministry of Science and Technology;
- Pakistan Standards & Quality Control Authority (PSQCA);
- Pakistan National Accreditation Council;
- Ministry of Commerce;
- Trade Development Authority of Pakistan (TDAP);
- Ministry of Finance and Revenue;
- Federal Board of Revenue (Customs).

It is recommended that the sector specific council be empowered to meet quarterly and to implement the following functions:

- Create a shared understanding of key market challenges and opportunities facing the sector;
- Set goals and targets that, if achieved, will strengthen the sector's competitive position and enhance Pakistan's overall capacity to meet the changing market demands;
- Propose key policy changes to be undertaken and promote these policy changes among national decision makers;
- Support the coordination, implementation and monitoring of activities in the sector by the government, private sector, institutions or international organizations to ensure alignment to goals and targets, as required to contribute to resource identification and alignment.

As part of the Strategic Trade Policy Framework (STPF) and the sector strategy design process, it has been recommended that an *inter-ministerial and multi-industry private sector* council be organized and structured to address overall challenges and opportunities to Pakistan's trade performance. It is recommended that chairs of the sector specific council be members of the council to consult on key trade thematic areas ranging from policy to regulations and trade negotiations.

KEY SUCCESS FACTORS FOR EFFECTIVE IMPLEMENTATION

The presence of the sector specific council to oversee the strategy's implementation is a key success factor, but it is not sufficient to effectively fulfil its assigned functions.

Private sector support and participation in implementation

The private sector clearly expressed its willingness to contribute, directly or in partnership with public institutions, to the strategy's implementation. Their implementation efforts can range from providing business intelligence to institutions to contributing to project design, promotion and branding, and policy advocacy, etc. In brief, the private sector's practical knowledge of business operations is essential to ensuring that the strategy remains aligned to market trends and opportunities.

Proactive networking and communication

The key implementing institutions detailed in the PoA need to be informed of the strategy's content and the implications for their 2022–26 programming. This networking and communication is essential to build further ownership and provide institutions with the opportunity to confirm the activities they can implement in the short to long term. It will be important for the TDAP, MoC and members of the sector specific council to reach out to relevant institutions nationally to create awareness and support for the development of the pharmaceutical industry.

Resources for implementation

The sector specific council, in collaboration with the TDAP and the Secretariat at MoC, will need to leverage additional support for efficient implementation. Effective planning and resource mobilization is indispensable in supporting strategy implementation. Resource mobilization should be carefully planned and organized.

As the pharmaceutical industry is a priority sector of the STPF, the Government of Pakistan should define annual budget allocations and supports to drive the industry's growth. This commitment will demonstrate clear engagement towards strengthening the sector and will encourage private partners to support development. In addition to national budget support, resource identification will require the BOI to effectively target foreign investors in line with the strategy's priorities, such as the attraction of more commercial farmers. Investment flows to Pakistan should also be considered as a valuable driver of strategy implementation and overall industry development.

The various implementation modalities detailed will determine the success of the strategy's implementation. However, high-level support from the government, in collaboration with strong championship by the private sector, will be the real driver of successful strategy implementation.

To achieve the vision and strategic objectives discussed, a robust, actionable and realistic strategic plan of action (PoA) is required. This is provided in the section below, and constitutes the heart of this strategy.

The PoA is structured along the three strategic objectives and operational objectives described. For each objective, the PoA outlines detailed activities and their implementation modalities, which include:

- ·**Priority level:** Priority 1 being the highest and 3 the lowest.
- ·**Period:** The desired time-frame of the activity.
- ·**Reform or project:** Defines whether the activity entails a legal action.
- ·**Targets:** Quantifiable targets that allow completion monitoring of the activity during the implementation stage.
- ·**Leading implementing partners:** One single accountable lead institution per activity. (The institution can also have a technical role or can solely have an oversight and coordination role.)
- ·**Supporting implementing partners:** Any institution that should be involved at any stage of the activity's implementation.

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PLAN OF ACTION (2023–2027)

Strategic objective	Operational objective	Activity	Priority (1=Highest)	Period					Reform or project	Targets	Leading implementing partners	Supporting implementing partners
				2023	2024	2025	2026	2027				
1. Improve the national framework for regulatory and institutional management, as well as the business environment governing the pharmaceutical sector	1.1 Revisions of laws and policies governing the sector	1.1.1. Amend the Drugs Pricing Policy, 2018 to control the prices of essential medicine and deregulate the prices for others in a phased manner (before a fully market-based equilibrium emerges, where market-based pricing will determine final prices as opposed to cost-based approach currently taken).	1						Reform	• Prices revised by DRAP and MNHSRC • At least 50% of firms (majority small and medium-sized enterprises) report positive outcome from the policy	Drug Regulatory Authority of Pakistan	• Ministry of National Health Services Regulations and Coordination • Federal Cabinet • Provincial governments • Private sector
		1.1.2. Update the National Essential Drugs List in line with the WHO Model Lists of Essential Medicines.	3						Reform	• National Essential Drugs List updated annually	Drug Regulatory Authority of Pakistan	• Ministry of National Health Services Regulations and Coordination
		1.1.3. Update the Drugs (Licensing, Registering & Advertising) Rules, 1976 to establish a time-frame for processing the application of the new drug licensing.	1						Reform	• Time-frame for processing the application established. Reviewed once in two years if required.	Drug Regulatory Authority of Pakistan	• Ministry of National Health Services Regulations and Coordination
		1.1.4. Rapidly approve the national medicines policy that contains a five-year action plan aimed at promoting essential dugs.[9]	2						Project	• National medicine policy launched	Ministry of National Health Services Regulations and Coordination	• Ministry of Industries& Production • Ministry of Commerce
		1.1.5. Strengthen intellectual property rights and patents protection by improving staff's skills through training in collaboration with the Intellectual Property Organisation of Pakistan (IPOP).	2						Project	• Training conducted for staff in the vigilance division with IPOP. Awareness among DRAP staff increases by at least 70% • 60% of firms report a reduction in IPOP-related delays	Drug Regulatory Authority of Pakistan	• Intellectual Property Organization of Pakistan • Federal Board of Revenue (Customs)

9.– See https://www.thenews.com.pk/print/616699-national-medicine-policy-to-be-announced-shortly.

Strategic objective	Operational objective	Activity	Priority (1=Highest)	Period					Reform or project	Targets	Leading implementing partners	Supporting implementing partners
				2023	2024	2025	2026	2027				
1. Improve the national framework for regulatory and institutional management, as well as the business environment governing the pharmaceutical sector	1.2 Support a stable regulatory regime by redefining the roles of agencies in the sector	1.2.1. Review DRAP's mandate to assess their operations and capabilities, and overall future readiness relative to manufacturers' requirements. Based on the results of the benchmarking exercise, reorient products, staff training and services (and organizational structures, if necessary).	1						Project	• Capacity-building modules developed and disseminated every year	Ministry of National Health Services Regulations and Coordination	• Drug Regulatory Authority of Pakistan
		1.2.2. Create a dedicated team/division within DRAP to conduct quality control audits to enforce stringent regulations for quality and ethical standards, while also encouraging harmonization between DRAP, the TDAP, MoC and Border Control to reduce illicit trade and counterfeit medicines, which is currently tarnishing the sector's reputation internationally.	2						Project	• Dedicated team for countering illicit trade set up under the Quality Assurance Division of DRAP	Drug Regulatory Authority of Pakistan	• Ministry of National Health Services Regulations and Coordination • Ministry of Commerce • Border Control
		1.2.3. Re-activation and institutional strengthening of the Pakistan Drugs Testing and Research Center (PDTRC) *(Activity linked to STPF 2020–25)*	1						Project	• MNHSRC provides funds to the PDTRC and devises a policy that limits local government intervention in the PDTRC	Ministry of National Health Services Regulations and Coordination	• Pakistan Drugs Testing and Research Center
	1.3. Improve the overall business environment by encouraging policy coherence and facilitating investments in the sector	1.3.1. Conduct an investment-targeting campaign towards attracting MNCs to the sector.	1						Project	• Pharma made a priority sector for the BOI • Pharma-specific investment-targeting campaign completed	Board of Investment	• Ministry of Commerce • Pakistan Pharmaceutical Manufacturers' Association • Trade missions

Strategic objective	Operational objective	Activity	Priority (1=Highest)	Period					Reform or project	Targets	Leading implementing partners	Supporting implementing partners
				2023	2024	2025	2026	2027				
1. Improve the national framework for regulatory and institutional management, as well as the business environment governing the pharmaceutical sector	1.3. Improve the overall business environment by encouraging policy coherence and facilitating investments in the sector	1.3.2. Simultaneously with the price deregulation, add a levy of 2% of total sales tax on pharmaceutical sales.	1						Reform	• SROs issued on the pharmaceutical prices deregulation and the levy.	Ministry of National Health Services Regulations and Coordination	• Ministry of Commerce • PPMA • Drug Regulatory Authority of Pakistan
2. Strengthen the export competitiveness of Pakistani pharmaceutical companies	2.1 Facilitate access to and development of new products	2.1.1. Incentives pharmaceutical companies by providing rebate if they get WHO prequalification, FDA recognition, or export to non-traditional markets, e.g. export to EU.	1						Reform/ Project	• Companies with WHO prequalification / FDA recognition or export to non-traditional markets increase	Ministry of National Health Services Regulations and Coordination	• Ministry of National Health Services Regulations and Coordination • Supporting: Ministry of Commerce • Drug Regulatory Authority of Pakistan
		2.1.2 Promote pharma exports and new pharma products in trade shows to improve the national brand and public image of the pharmaceuticals sector through facilitating business-to-business meetings, organizing meetings with potential buyers and providing market intelligence to exporters, etc., backed by media campaigns aimed at industry professionals and the business community.	2						Project	• Participation of pharmaceutical companies in at least three trade shows • Brand-building programme launched and executed in at least five priority markets	Trade Development Authority of Pakistan	• Board of Investment • Ministry of National Health Services Regulations and Coordination • Ministry of Commerce • Pakistan Pharmaceutical Manufacturers' Association • Trade missions
		2.1.3 Create an innovative ecosystem by increasing funding for pharmaceutical research in leading public universities, involving at least one large national firm, in research papers as per their needs, and involving the pharma sector in steering research areas. *(Link with Activity 3.4.1)*	2						Project	• Funding increased for pharma university research • At least five collaborations between the industry and academia set up	Ministry of Federal Education and Professional Training	• Ministry of Commerce • Trade Development Authority of Pakistan • Private sector • Pharma departments of all universities

Strategic objective	Operational objective	Activity	Priority (1=Highest)	Period					Reform or project	Targets	Leading implementing partners	Supporting implementing partners
				2023	2024	2025	2026	2027				
2. Strengthen the export competitiveness of Pakistani pharmaceutical companies	2.1 Facilitate access to and development of new products	2.1.4 Develop a comprehensive market penetration plan to identify unique products such as biosimilars, herbal medicine line, surgical goods like masks, gloves and instrument for diversification in international regional markets (such as Africa and Central Asia). As an incentive for firms to seek accreditation, access to these market penetration plans be tied to firms already or in the process of being accredited.	1						Project	• Develop one product and market penetration plan each year	Trade Development Authority of Pakistan	• Drug Regulatory Authority of Pakistan • Ministry of Commerce • Pakistan Pharmaceutical Manufacturers' Association
		2.1.5 Prepare a roadmap to develop an API industrial park in Pakistan equipped with a common effluent plant to incentivize the private sector to enter into API production in the long term.	2						Project	• Roadmap to build an API park prepared with location and blueprint identified	Export Processing Zones Authority (EPZA)	• Ministry of Commerce • Ministry of National Health Services Regulations and Coordination • Pakistan Pharmaceutical Manufacturers' Association
	2.2 Define the positioning of pharmaceutical products in the target export markets	2.2.1. Develop detailed market entry plan for Central Asian and African region, including specific approach on how to break into identified specific markets, regulatory conditions, listing of potential partners and holding business-to-business meetings, etc.	1						Project	• Central Asian and African market entry plan developed • At least 10 firms have won regional business	Ministry of Commerce	• Trade Development Authority of Pakistan • Trade missions
		2.2.2. Penetrate African markets through joint ventures in distribution.	3						Project	• At least three FDI joint ventures forged	Board of Investment	• Trade missions • Ministry of Commerce
		2.2.3. Review the efforts by the PPMA and the government to manage public image to ensure that the sector is not subject to undue scrutiny or criticism.	2						Project	• Capacity building for sector advisers provided annually • At least 60% of the firms report improved sector image globally	Trade Development Authority of Pakistan	• Pakistan Pharmaceutical Manufacturers' Association • Ministry of National Health Services Regulations and Coordination • Federal Board of Revenue • Board of Investment

Strategic objective	Operational objective	Activity	Priority (1=Highest)	Period					Reform or project	Targets	Leading implementing partners	Supporting implementing partners
				2023	2024	2025	2026	2027				
2. Strengthen the export competitiveness of Pakistani pharmaceutical companies	2.3. Develop market intelligence and information services on target export markets	2.3.1. Involve consular authorities to collect information on the needs of target markets and strengthen their capacity to promote Pakistani pharmaceutical products and economic intelligence on export markets.	1						Project	• 10 international missions trained to gather information on market needs	Pakistan Institute of Trade and Development (PITAD)	• Ministry of Commerce • Trade Development Authority of Pakistan
		2.3.2. Develop a standardized entry training package on pharmaceuticals sector for trade attachés.	1						Project	• All newly posted attachés trained	PITAD	• Ministry of Commerce • Trade Development Authority of Pakistan
		2.3.3. Set up a dedicated structure with a clear mandate as an advisory body for the pharmaceutical sector, with trade, diplomatic and technical wings like the Pharmaceutical Export Promotions Council of India). *(This activity is linked to the formation of a sector specific council)*	1						Project	• Pharmaceutical export promotion council of Pakistan formed	Trade Development Authority of Pakistan	• Ministry of Commerce • Pakistan Pharmaceutical Manufacturers' Association
		2.3.4. Task the TDAP to monitor the pharmaceuticals sector's performance under the STPF and National Priority Sectors Export Strategy (NPSES) through trade statistics and suggest (through the MoC) measures to improve the pharma sector's potential.	2						Reform	• The TDAP shares regular reports of the progress of the pharmaceutical sector under the STPF and NPSES with the sector specific council	Trade Development Authority of Pakistan	• Pakistan Pharmaceutical Manufacturers' Association • Ministry of Commerce
		2.3.5. Ensure participation of the MNHSRC, DRAP and pharmaceutical sector associations in the conclusion of bilateral agreements with African and Central Asian countries for drug registrations.	2						Project	• MNHSRC, DRAP and PPMA involved in all trade policy meetings	Ministry of Commerce	• Drug Regulatory Authority of Pakistan • Pakistan Pharmaceutical Manufacturers' Association • Pharma Bureau • Ministry of National Health Services Regulations and Coordination

Strategic objective	Operational objective	Activity	Priority (1=Highest)	Period					Reform or project	Targets	Leading implementing partners	Supporting implementing partners
				2023	2024	2025	2026	2027				
2. Strengthen the export competitiveness of Pakistani pharmaceutical companies	2.4. Build company capacities to enter domestic and international market	2.4.1. Conduct training courses to improve staff's soft skills in pharmaceutical firms (e.g. negotiation, communication and interpersonal skills), especially among the business development/prospecting, marketing and client engagement teams.	1							• At least 30% of PPMA members trained per year	Pakistan Pharmaceutical Manufacturers' Association	• Provincial health departments • Ministry of National Health Services Regulations and Coordination
		2.4.2. Carry out capacity-building trainings to comply with quality control, GMP, safety and packaging requirements, and on accessing potential market information, targeting small and medium-sized enterprises (SMEs) through the sector association (PPMA).	1							• Capacity-building modules developed and disseminated every year	Pakistan Pharmaceutical Manufacturers' Association	• Provincial health departments • Trade Development Authority of Pakistan • Ministry of National Health Services Regulations and Coordination • Drug Regulatory Authority of Pakistan
		2.4.3. Promote start-up culture for investing in developing a robust online distribution channel, and connect with online healthcare service providers (health-tech), both nationally and internationally.	2							• At least three pharmaceutical start-ups identified and mentored for seed A funding	Pakistan Pharmaceutical Manufacturers' Association	• Ministry of Information Technology and Telecommunication • Trade Development Authority of Pakistan • P@SHA • Securities & Exchange Commission of Pakistan (SECP)
3. Domestically support the development and upscaling of the Pakistani pharmaceutical sector to be more compliant	3.1. Compliance with international production standards	3.1.1. Support DRAP to obtain PIC/S membership, which will enable Pakistan to benefit from good manufacturing guidelines and export to high-income countries. *(Activity linked to STPF 2020–25)*	1						Project	• Assessment on the advantages of PIC/S membership conducted • DRAP gains PIC/S membership	Ministry of National Health Services Regulations and Coordination	• Ministry of Foreign Affairs • Ministry of Commerce

Strategic objective	Operational objective	Activity	Priority (1=Highest)	Period					Reform or project	Targets	Leading implementing partners	Supporting implementing partners
				2023	2024	2025	2026	2027				
3. Domestically support the development and upscaling of the Pakistani pharmaceutical sector to be more compliant	3.1. Compliance with international production standards	3.1.2. Support DRAP to apply for the mutual recognition agreements of understanding with leading global regulatory authorities following a two-step approach: 1. Recognition through bilateral agreements such as with the FDA and United Arab Emirates, then 2. Regional and multilateral agreements such as the European Medicines Agency (EU-EMA) market.	2						Project	• DRAP gains MRA with at least two leading global authorities	Drug Regulatory Authority of Pakistan	• Ministry of Commerce • Ministry of National Health Services Regulations and Coordination • Trade missions
		3.1.3. Set and enforce minimum and consistent quality standards for any manufacturer that wants to operate in Pakistan (e.g. WHO-compliant GMP certification for operation of facilities). Establish clear and basic quality standards for molecules and facilities.	1						Project	• At least 50% increase in internationally compliant facilities	Pakistan Standards & Quality Control Authority	• Drug Regulatory Authority of Pakistan • Pakistan Pharmaceutical Manufacturers' Association
		3.1.4. Launch a programme to encourage Pakistani firms to comply with ISO 14001 international standard.	2						Project Reform	• Awareness of international standards certification requirements improves by 70%	Pakistan Standards & Quality Control Authority	• Ministry of Commerce • Drug Regulatory Authority of Pakistan • Ministry of National Health Services Regulations and Coordination
		3.1.5. Explore possibility to become a member of International Coalition of Medicines Regulatory Authorities (ICMRA) to use their resources for medicine regulation, development and implementation.	3						Project Reform	• Scoping plan to be a member of ICMRA prepared and disseminated among stakeholders	Ministry of National Health Services Regulations and Coordination	• Drug Regulatory Authority of Pakistan
	3.2. Attract investment to foster innovation and technological upgrading to strengthen firm capacities	3.2.1. Incentivize firms financially through tax breaks to develop API, GMP-, FDA- or EMA-approved plants to be seen as trusted facilities within the country for international partners.	1						Project	• Tax break incentive provided • At least 30% of firms develop GMP-, FDA- or EMA-approved plants	Federal Board of Revenue	• Ministry of Commerce • Ministry of National Health Services Regulations and Coordination

Strategic objective	Operational objective	Activity	Priority (1=Highest)	Period					Reform or project	Targets	Leading implementing partners	Supporting implementing partners
				2023	2024	2025	2026	2027				
3. Domestically support the development and upscaling of the Pakistani pharmaceutical sector to be more compliant	3.2. Attract investment to foster innovation and technological upgrading to strengthen firm capacities	3.2.2. Attract FDI into well-performing firms (or trusted partners). The BOI to identify the list of local trusted partners and bring them into fairs and business-to-business meetings to bring in FDI.	1						Project	• At least three trusted firms shortlisted to attend business-to-business meetings and fairs	Trade Development Authority of Pakistan	• Board of Investment
	3.3. Establish internationally accredited laboratories to maintain quality control	3.3.1. Attain WHO accreditation for main public laboratories, starting with DRAP's National Control Laboratory for Biologicals (NCLB). Without it, all NCLB testing, registration and batch release of biologicals is not internationally recognized.	1						Project	• Public laboratories are all WHO accredited	Drug Regulatory Authority of Pakistan	• Ministry of National Health Services Regulations and Coordination • Pakistan National Accreditation Council (PNAC)
		3.3.2. Accredit the three other private and public laboratories and extend to all other public sector labs, and officially notify for use as reference laboratories for the sector.	2						Project	• All laboratories are accredited	Drug Regulatory Authority of Pakistan	• Ministry of National Health Services Regulations and Coordination • Pakistan National Accreditation Council (PNAC)
		3.3.3. Set up research laboratories with private sector participation specialized in nutraceuticals and alternative medicines.	2						Project	• At least three research laboratories set up with industry firm(s) or associations that regularly disseminate research findings to the firms	Drug Regulatory Authority of Pakistan	• Ministry of National Health Services Regulations and Coordination • Pakistan Standards & Quality Control Authority (PSQCA) • PPMA
	3.4. Invest in scientific, technical and managerial training to strengthen skills and know-how and build linkages with universities	3.4.1. Include objective-oriented undergraduate training in Doctor of Pharmacy (PharmD), in areas focusing on quality evaluation, pharmacovigilance, international regulatory guidelines and pharmaceutical policy in the national curriculums.	2						Project	• Universities taken on board as research and development centres	Pharma departments of all universities	• Ministry of National Health Services Regulations and Coordination

Strategic objective	Operational objective	Activity	Priority (1=Highest)	Period					Reform or project	Targets	Leading implementing partners	Supporting implementing partners
				2023	2024	2025	2026	2027				
3. Domestically support the development and upscaling of the Pakistani pharmaceutical sector to be more compliant	3.4. Invest in scientific, technical and managerial training to strengthen skills and know-how and build linkages with universities	3.4.2. Expand technical and academic training in pharmaceuticals and health-related industries. This can be done through: • Involving universities across the country through the pharmacy departments. Encouraging the funding for the training/schooling through grants; • Provide incentives for experts/professionals who left the country to return and teach/train. Dedicating funding for promoting open-source innovative development through crowdsourcing, undertaking through the Export Development Fund (EDF) and donor support.	1						Project	• Network of pharmacy departments of national universities created • Diaspora programme in place • Open-source innovation scheme in place	Ministry of National Health Services Regulations and Coordination	• Pakistan Medical & Dental Council
		3.4.3. Develop new curricula, focusing on both on-the-job training and classroom training for agents specialized in the packaging, logistics and traceability of drugs.	2						Project	• Specialized skills curriculum developed	Pakistan Pharmaceutical Manufacturers' Association	• Ministry of National Health Services Regulations and Coordination
		3.4.4. Adapt a training of trainers module on GMP for the inspectors to develop the required competencies of international recognition.	1						Project	• Training module on GMP developed	Pakistan Pharmaceutical Manufacturers' Association	• Ministry of National Health Services Regulations and Coordination
		3.4.5. Strengthen the competence of health inspectors and technical experts through trainings and knowledge exchanges according to international standards and increase the number of federal drug inspectors to maintain better quality regulations. Currently, there are 25 inspectors posted throughout the country.	2						Project	• At least two rounds of training and improvement programmes conducted	Drug Regulatory Authority of Pakistan	• Ministry of National Health Services Regulations and Coordination
		3.4.6. Set up training programmes on super generic drugs production. Foreign companies can invest in training programmes and scientific support for sample studies focused on the production of super generic drugs.	1						Project	• Training programmes introduced • Share of super generic drugs production trained employees increased 30% from baseline	Higher Education Commission	• Ministry of National Health Services Regulations and Coordination • Pakistan Pharmaceutical Manufacturers' Association

ANNEXES

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Annex I:
Detailed value chain assessment

REGISTRATION OF MEDICINES

In Pakistan, Section 7 of the Drugs Act, 1976 regulates the registration of drugs. The applications for registration are decided by the registration board set up in accordance with Rule 24 of the Drugs (Licensing, Registration and Advertisement) Rules, 1976. At present, a separate application is required for each drug on Forms 5/5-A/5-D/5-E for locally manufactured/imported/new molecule/patent drugs respectively. The registration board can reject the application or cancel the registration if it is not satisfied.

Clinical trials of medicines in Pakistan are regulated under the Drug Research Rules, 1978, amended in 2013. National guidelines on the principles of good clinical practice are available from the pharmacy services division of DRAP. Recently, in August 2021, a flow chart explaining the process of applications for clinical studies along with the stipulated time-line was put up on the DRAP website (Figure 1).

PRODUCTION

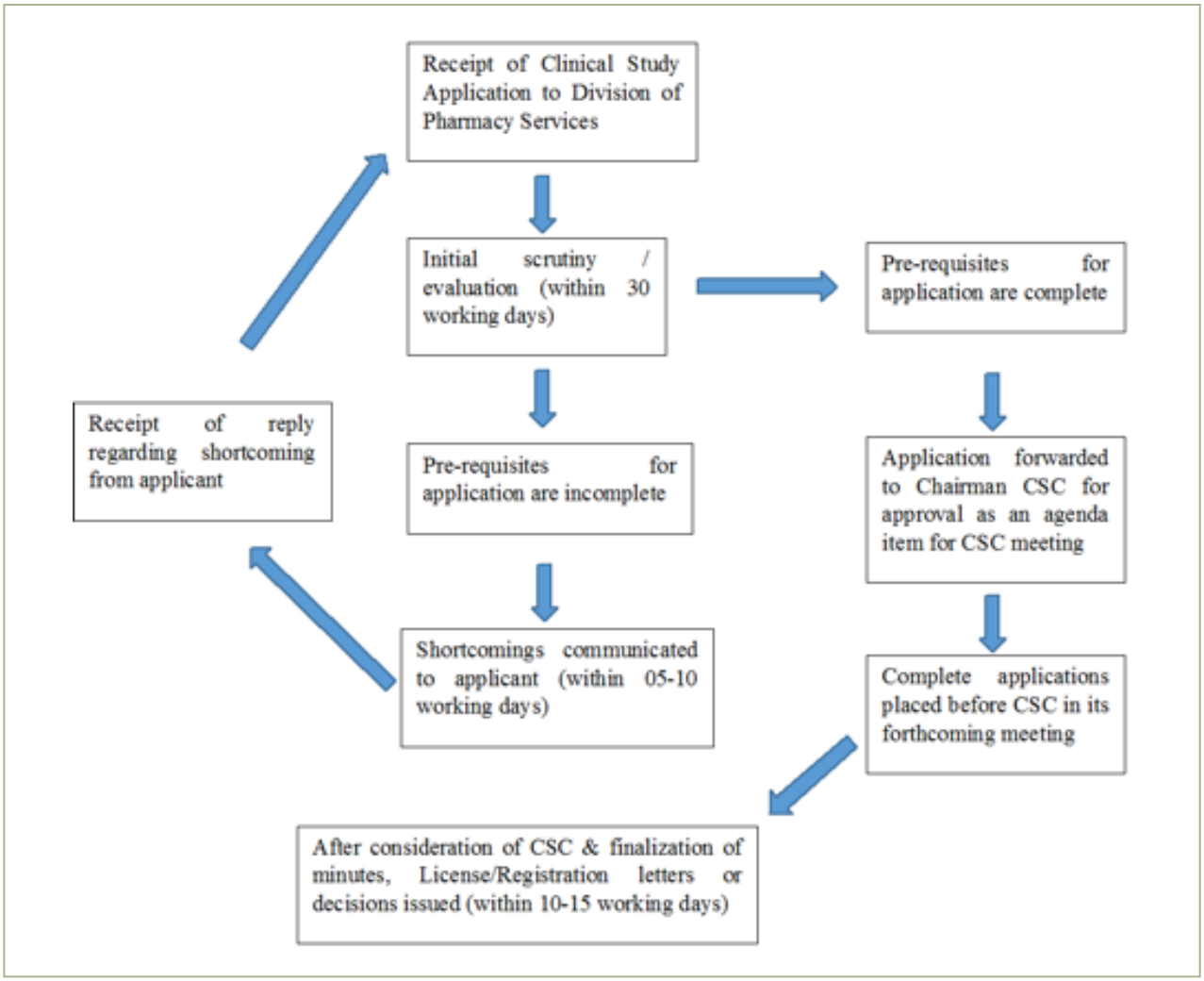
As R&D for the innovation and production of novel pharmaceutical products is limited in Pakistan, firms usually import the raw material or finished pharmaceutical product and compete more on the packaging, marketing and sale of the product to end consumers. Pakistan currently imports 95% of its raw material from APIs, excipients, to drugs in semi-finished and finished forms. Most of these are imported from India and China.

The next step is producing a final product from that raw material. This can take several forms in the shape of tablets, liquids (syrups), injections and ointments, etc. Every product manufactured either locally or imported is assigned a batch number to track the medicines from manufacturing plants in case issues arise in quality and for product recalls.

The larger MNCs typically employ their own machinery to ensure quality standards, whereas smaller firms usually procure cheaper equipment from China, Korea and Taiwan (Institute of Chartered Accountant of Pakistan; 2018).

Another manufacturing concept that exists, albeit on a small scale, is the concept of contract manufacturing. In this process, certain production activities are outsourced to another manufacturer or a third party. Typically, MNCs use this technique to hire domestic firms to produce for several brands as per their demands. This helps in the transfer of technology and exploration of more business activities.

Figure 1: Flow chart for processing of applications for clinical studies



Source: DRAP, 2021.

PACKAGING

Pharmaceutical industries use different types of packaging materials to pack products. The choice of packaging materials depends on the type of pharmaceutical product and can include materials such as polyvinyl chloride (PVC), aluminium foil, cotton, ampules and vials, etc.

MARKETING, DISTRIBUTION AND SUPPLY CHAIN

Distribution and supply chain processes ensure that medicines are readily available to patients at retail pharmacies and hospitals.

A decentralized distribution system is widely used in the pharmaceutical industry in Pakistan. In the decentralized (regional) model, companies appoint different distributors in different geographical regions that supply at their own cost to pharmacies. Furthermore, distribution is done via three main channels. The most widely used are street sales or pharmacies. More recently, e-commerce ventures (such as Dawaai) have also emerged, having special regulations of their own. The sale of medicines in Pakistan cannot be done without a drug sales/wholesale licence documented via invoices, which is a requirement under Form 7 of the Drugs Act, 1976.

The licences for sale, storage and distribution of drugs and medicines are issued by provincial governments. Authority has been delegated to the respective executive district health officer and licensing branches have been established in the respective offices.

MARKET ACCESS – FINAL CONSUMER/PATIENT

Sale of pharmaceutical products is primarily mediated by doctors, except for over-the-counter products available from pharmacies. Firms in Pakistan have actively tried to establish relationships with doctors to promote their products.

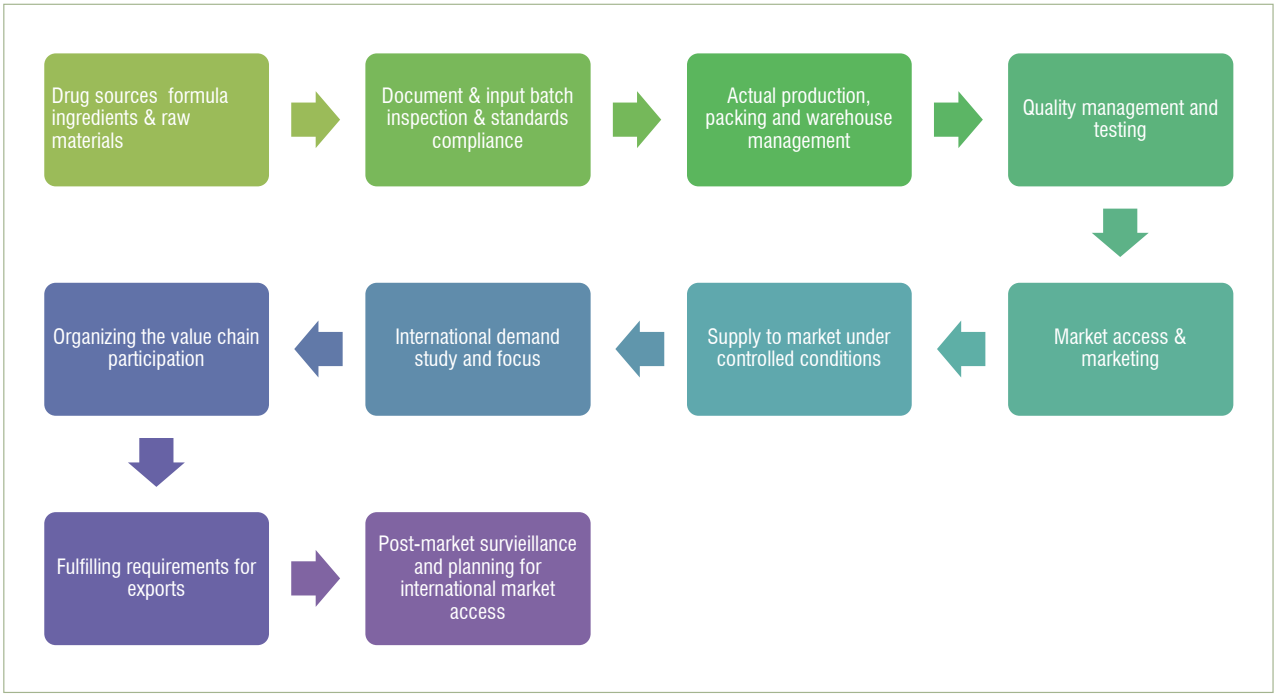
STATE OF TECHNOLOGY IN THE SECTOR AND R&D

There is an increasing debate for Pakistani pharmaceutical firms to focus on R&D to increase their share in the global market. Pakistan's adherence to international standards through laboratory testing for quality controls is gaining share in the international value chain, but it still requires strong focus by the public sector.

Pertinently, although in Pakistan's context there is presently no FDA- or EMA-approved labs and only one WHO-accredited Good Practices Pharmaceutical Quality Control Lab (GPPQCL), and that recently established in the private sector, it would not decrease costs for aspiring exporters. Recognizing that many countries have domestic governmental certifying agencies like DRAP for mandatory certification, these further lead to an additional cost of doing business for pharmaceuticals industries. Although certain multi-national pharma companies operating in Pakistan have laboratories and research facilities for their product development strategies and three more laboratories await international accreditation, there needs to be a cohesive effort in this direction.

Resultantly, until the public sector, through DRAP, takes ownership to provide a comprehensive and cost-competitive WHO/FDA international standards laboratory for promoting pharmaceutical exports, quality control certification will continue to add costs in the value chain for pharmaceuticals exports.

Figure 2: Summary of the manufacturing process flow



Source: ITC.

Annex II:
List of participants in the public-private consultations

Name of the participants	Organization	Designation
Tauqeer Ul Haq	PPMA	Chairman
Khalid Munir	PPMA	Chairman (north)
Junaid Khan	ATCO Lab	General manager
Jeannine Coelho	ATCO Lab	Assistant Manager Business Development
Shahid Jawed	Swiss Pharma	
Shahzad Jarani	Scilife Pharma	Manager International Business Development
Muhammad Khan	Scilife Pharma	Business manager (international business)
Sohaib Mullick	Sante Private Limited	Head of International Business
Azeem Suleman	Athix Pvt Ltd	Director
Mubbsher Khan	Punjab University	Dean
Kaleem Ali	Tabros Pharma (Pvt) Limited	Manager, exports
Dr. Mohsin	Pharmaroya Pakistan	Director
Arshad Jamal	FYNK Pharmaceuticals	Export manager
Syed Umair Maroof	CCL Pharmaceuticals	Business Head – South Asia and Central Asia
Syed Umair Zaidi	CCL Pharmaceuticals	Export operations manager
Anam Mukhtar	CCL Pharmaceuticals	Assistant Manager Regulatory Affairs
Muhammad Hamzah Qureshi Qureshi	SAMI Pharmaceuticals	Assistant Manager Export Marketing (international business)
Shahid Jawaid	SAMI Pharmaceuticals	General manager – Export
Farhan Ahmed	Royal Group	Marketing manager
Mohammad Ashraf	Royal Group	General manager
Shoaib Jawaid	Royal Group	Supply chain head
Sahbbir Ahmed	Royal Group	Senior export manager
Moeen Ansari	Otsuka Pakistan Limited	Manager, Export and institution
Abdul Waseem	SJ&G Pharmaceutical Group	Marketing head
Mahwash Khan	Ophth Pharma	Managing director
ADNAN KHAN	Brookes Pharma	Director Global Business
Yasir Yaqoob	IBL Group	Assistant Manager Regulatory Affairs
Tahir Hussain Hashmi	Horizon Pharmaceuticals Pvt Ltd	Head of Marketing (domestic and international business)
Dr Syed Qamar Ali	ZAFA Pharmaceutical Laboratories	Director
Salman Inayat Ali	Nathanies International Services	Proprietor
Naoman Ramzan	Athix Pvt Ltd	Head of International Business
Abdul Khabir	PDH Laboratories (Pvt) Ltd	CFO

Name of the participants	Organization	Designation
Asad Sami	ZAFA Pharmaceutical Laboratories	Business manager
Khalid Munir	Otsuka Pakistan Limited	Head of Sales
Irfan Anjum	Dawn Lab International Private Limited	Chief executive
Muhammad Sohail Qureshi	Renacon Pharma Ltd	Trade manager
Musharraf Ali	Sois Life Sciences	General Manager Operations & International Marketing
Zeeshan Yousaf	Frontier Dextrose Limited	Finance manager
Syed M. Sikandar	Highnoon Laboratories Limited	Head of International Business
Adnan Azam	Schazoo Zaka (Pvt) Ltd	Manager, export and institutions
Ishtaiq Shafiq	Drug Regulatory Authority of Pakistan	Assistant director import and export
Muhammad Yasir Hashmi	PharmEvo Pvt Ltd	Director International Market
Umair Zubair	PharmEvo Pvt Ltd	Sr. Manager Business Development
Farhan Feroz	PharmEvo Pvt Ltd	Deputy Director Business Development
Fayyaz Ahmed	Fasra Institute of Professional Learning Development and Growth	General manager, Marketing & Sales
Shumaila Sikandar	TDAP	Deputy director
Sana Khokhar	TDAP	Assistant manager
Muhammad Amir Khan	TDAP	Product officer
Sumair Ahmad	MoC	Research associate

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Annex III:
Sector-relevant institutions assessment

This assessment is based on stakeholders' perspectives and feedback. According to stakeholders, most institutions are scored at a level 2 out of 3 across the criteria of resources, capability and influence. Interestingly, though, stakeholders perceive the MNHSRC, DRAP and TDAP's capacity for sector development to be limited. The role that these key trade-related bodies play in the sector development may still be relatively nascent and underdeveloped, despite being resource rich and influential. The key private sector bodies are seen mostly 'excelling' – rated between 1 and 2. However, focusing on strengthening both the apex state institutions and the apex industry associations are equally important in driving holistic growth in the sector. Having robust, well-structured, inclusively represented industry associations to effectively dialogue with the state institutions helps improve the quality of discussions and solutions sought and received.

Table 1: Assessment of institutions relevant to the sector

Name of institution	Type of institution[1]	Role played by the institution[2]	Capability check		
			Resources[3]	Capacity[4]	Influence[5]
MNHSRC	A	MNHSRC oversees other regulatory bodies in the health sector, including DRAP. The primary role is to coordinate and regulate the sector.	2	3	1
Pharmacy Council of Pakistan	B	The professional body responsible for the registration of pharmacists and the promotion and regulation of pharmacy education in the country.	2	3	2
Provincial health departments	A	Responsible for implementing the provincial health strategies, the regulation of drug sales, licensing of pharmacies as well as drug inspection and drug testing to prevent sale of counterfeit products.	2	3	2
Ministry of Commerce	A	Responsible for trade- and commerce-related policymaking at national level.	1	2	1
DRAP	B	Main agency to regulate pharmaceutical products, including manufacturing, licensing, product registration, price setting and quality inspection.	2	3	1
Federal Board of Revenue	A	To ensure trade facilitation, enforcement and revenue realization, and implementation of taxation, both domestically and at border crossings.	1	2	2
Trade Development Authority Pakistan	B	Responsible for promoting trade and commerce in Pakistan and enhancing the country's trade potential.	1	3	2
Pakistan Pharmaceutical Manufacturers' Association (PPMA)	C	Foremost representative body for Pakistan's pharmaceutical sector, and for national companies. Aims to promote the interests of pharmaceutical manufacturers and improve their trade potential.	1	2	2
Pharma Bureau	C	Representative body for MNCs operating in Pakistan with the objective to protect and promote the interests of these companies.	1	2	1

Name of institution	Type of institution[1]	Role played by the institution[2]	Capability check		
			Resources[3]	Capacity[4]	Influence[5]
Druggists and Chemists Association	C	A retailer's association who belong to sales and distribution.	1	2	1
Pakistan Pharmacist Association	C	National professional body of pharmacists engaged in various facets of the profession of pharmacy.	2	3	3

Source: ITC.

[1] A) Public sector ministry; B) Public sector specialized agency/statutory body; C) Private sector chamber or trade association; D) Private sector support service provider *(e.g. a private testing lab)*; E) Donor agency/aid project; F) Other.

[2] The role played by the institution in summary.

[3] How well financially resourced to support sector development needs: 1. Very well resourced; 2. Somewhat well resourced; 3. Poorly resourced.

[4] Capacities in the institution to support sector development needs: 1. High capacity; 2. Moderate capacity; 3. Low capacity.

[5] How influential is this institution to drive sector development: 1. Very influential; 2. Somewhat influential; 3. Not influential.

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