The Pakistan Business Council
FOSTERING ECONOMIC GROWTH

cdpr
Consortium for Development Policy Research

A Health Check for a Better Future: Unleashing the Potential of Pharmaceuticals in Pakistan

The Pakistan Business Council (PBC) and
The Consortium for Development Policy Research (CDPR)

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The Pakistan Business Council: An Overview

The Pakistan Business Council (PBC) is a business policy advocacy platform, established in 2005 by 14 (now 85) of Pakistan's largest private-sector businesses and conglomerates, including multinationals. PBC businesses cover nearly all sectors of the formal economy. It is a professionally-run organization headed by a full-time chief executive officer.

The PBC is a not-for-profit entity, registered under Section 42 of the Companies Ordinance 1984. Though it is not required under the law to do so, the PBC follows to the greatest extent possible, the Code of Corporate Governance as applicable to listed companies.

The PBC is a pan-industry advocacy group. It is not a trade body nor does it advocate for any specific business sector. Rather, its key advocacy thrust is on easing barriers to allow Pakistani businesses to compete in regional and global arenas. The PBC conducts research and holds conferences and seminars to facilitate the flow of relevant information to all stakeholders in order to help create an informed view on the major issues faced by Pakistan.

The PBC works closely with relevant government departments, ministries, regulators and institutions, as well as other stakeholders including professional bodies, to develop consensus on major issues which impact the conduct of business in and from Pakistan. The PBC has submitted key position papers and recommendations to the government on legislation and other government policies affecting businesses. It also serves on various taskforces and committees of the Government of Pakistan as well as those of the State Bank, the SECP and other regulators with the objective to provide policy assistance on new initiatives and reforms.

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Acronyms

API	Active Pharmaceutical Ingredient
ADC	Assistant Drug Controller
AGP	Auditor General of Pakistan
ANP	Anti-Narcotics Force
BAPI	Bangladesh Association of Pharmaceutical Industries
BE	Bioequivalence
BFBL	BF Biosciences Ltd
CAGR	Compound Annual Growth Rate
CBSCR	Center of Bioequivalence Studies and Clinical Research
CDPR	Consortium for Development Policy Research
CPI	Consumer Price Index
CRAMS	Contract Research and Manufacturing Services
CRO	Contract research organizations
CTD	Common Technical Dossier
DCO	Drug Control Organization
DDG	Deputy Director General
DRAP	Drug Regulatory Authority of Pakistan
DTL	Drug Testing Laboratory
ERP	External Reference Pricing
EU	European Union
FBR	Federal Board of Revenue
FDI	Federal Drug Inspector
FSDSL	Federal Drug Surveillance Laboratory
GAVI	Global Alliance for Vaccine and Immunization
GBM	Global Bench Marking
GE	General Electric
GIFF	Growth Identification and Facilitation Framework
GMP	Good Manufacturing Practices
GST	General Sales Tax
HVAC	Heating, Ventilation and Air Conditioning
IP	Intellectual Property
IQVIA	IMS Health-Quintiles
ISO	International Organization for Standardization

LDC	Low Developing Country
MHRA	Medicines and Health Care Products Regulatory Agency
MNC	Multinational Company
MNHSR&C	Ministry of National Health Services, Regulation and Coordination
MRP	Maximum Retail Price
NAB	National Accountability Bureau
NCE	New Chemical Entity
NDA	New Drug Applications
NEML	National Essential Medicine List
NKEA	National Key Economic Area
NOC	No Objection Certificate
OTC	Over-the-Counter
PBC	Pakistan Business Council
PCP	Pharmacy Council of Pakistan
PDTRC	Pakistan Drug Testing and Research Centre
PHARMEXCIL	Pharmaceuticals Export Promotion Council of India
PIC/S	Pharmaceutical Inspection Corporation Scheme
PIRIMS	Pakistan Integrated Regulatory Information Management System
PPMA	Pakistan Pharmaceutical Manufacturers' Association
PVC	Polyvinyl Chloride
QMS	Quality Management Systems
R&D	Research and Development
S&OP	Sales and Operational Planning
SKU	Stock Keeping Units
SOP	Standard Operating Procedure
SRA	Stringent Regulatory Authorities
SRO	Statutory Regulatory Order
TB	Tuberculosis
TGA	Therapeutic Goods Administration
US	United States
USFDA	United States' Food and Drug Administration
USP	United States Pharmacopoeia
WHO	World Health Organization
WHO-PIDM	World Health Organization's Programme for International Drug Monitoring
WLA	WHO Listed Authorities
TRIPS	Trade-Related Aspects of Intellectual Property Rights

Executive Summary

In 2020, the value of the pharmaceutical sector of Pakistan was estimated to be around USD 3.2 billion, doubling from USD 1.64 billion in 2011[1]. Including institutional sales, industry posits that this sector easily becomes a retail market worth USD 4 billion. Total exports in 2019 stood at USD 218 million, from USD 44.4 million in 2003. Yet exports from the sector accounted for only 0.9 per cent of Pakistan's total exports to the world in 2019, paling in comparison to Pakistan's exports of other commodities in the health sector like surgical instruments and medical equipment. Industry insiders claim that exports from the sector could reach USD 0.5-1 billion in about 3 to 5 years—after reaching this critical mass, export growth could become exponential. This target is based on average stakeholder expectations which factor in sensitive nature of product, high lead times to market, meeting increasingly stringent export requirements per product-market, and current regulatory weaknesses in the country. The changes needed to achieve this export target will put the industry on the path to a much higher share of global trade in the medium term. Similarly, due to recent expansion of public healthcare in the 5th largest global market by size, the value of pharmaceuticals manufactured in Pakistan could rise to USD 5 billion by 2024-25.

This study provides an in-depth overview and analysis of the pharmaceutical sector of Pakistan to determine its future outlook. The study is the first of its kind: to date, no dedicated study on this sector has been undertaken, despite its economic significance. A comprehensive assessment is presented that could help Pakistan become a cost-efficient manufacturer of high-quality generic drugs,[2] and potentially evolve into more lucrative product offerings such as super-generics and vaccines.[3] This will require taking key steps today that could help its transition over the next 5-10 years. Through detailed analysis of the bottlenecks at every stage of the pharmaceutical value chain, the study determines the most binding factors that must be overcome to ensure this. This framework of analysis allowed the design of a policy from a competitiveness lens.

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Extensive primary research was undertaken to collect data on the value chain and its various bottlenecks. This data was used to conduct a value chain analysis, with special emphasis on identifying and addressing bottlenecks. Secondary research was used to collate existing information on the sector, which was blended with insights gained from in-depth interviews with more than 12 sector experts, including key stakeholders from manufacturers, exporters, government and industry specialists. These semi-structured interviews solicited feedback on key questions that were pre-circulated (on the value chain and its main gaps) as well as broader comments on sector competitiveness, potential, and future orientation in terms of both products and markets.

1 PACRA, April 2020. Accessed at https://www.pacra.com.pk/uploads/doc_report/SECTOR per cent20STUDY-Pharmaceutical per cent20APRIL per cent202020 per cent20Kanwal1589554722.pdf

2 Generics are copies of synthetic drugs, which are therapeutically equivalent to the brand name product.

3 Super-generics are improved versions of an original drug, either in form of efficacy, delivery, patient convenience/or an improved manufacturing process

This research was complemented with global insights on best practices from peer countries India, Jordan, Bangladesh and Malaysia that were historically similar to Pakistan and have since expanded their exports at least tenfold over the last 15-20 years. The report does not suggest however that their model be replicated as is. Bangladesh for example is included to glean policy insights as it started off from a weaker position than Pakistan, but has grown at a much faster rate. The report recognizes that Bangladesh has access to special waivers due to its LDC status that Pakistan does not. Yet a few steps/policy reforms that may work in Pakistan's context (despite these waivers) and are supported by stakeholders have been recommended.

A global opportunity

Global pharmaceutical markets are in flux due to major restructuring, in terms of both demand and supply. This presents Pakistan with a unique opportunity if the sector can take timely action. There is an opportunity to strategically enter the global off-patent drugs market that will be worth USD 700 billion in branded generics and USD 381 billion in generics by 2025. Generics are copies of synthetic drugs, which are therapeutically equivalent to the brand name product. By the end of 2020, Pakistan can tap into USD 151 billion worth of generics that have already gone off-patent. In 2019 Pakistan's total exports in these lines were USD 210 million. Increasing world export share by just 0.01 percentage point is an opportunity of USD 0.76 billion in the off-patent generics market.

Demand patterns are shifting, with increased life expectancy, literacy rates, incomes and better awareness of health-related issues creating greater demand for pharmaceutical products in developing countries. Developing country diseases can easily be treated with small molecule (that can be chemically synthesized) drugs, often generics. The local pharmaceutical industry is predominantly involved in drug formulation. Firms in Pakistan are already experienced and can easily cater to this demand. 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, competing small-molecule therapeutics, especially for high-quality me-too generics, super-generics, and simpler biologics like vaccines and antisera.

Pakistan, with a local market of 215 million consumers and more than 700 pharmaceutical companies is poised well to gain from opportunities provided under these shuffling global patterns of supply and demand. However, the current practice of simply importing 95 per cent of the raw material, compounding active ingredients with excipients, coating the pills, and packaging the drugs cannot continue to be the long-term goal of the sector. A larger vision recognizes the gains from becoming leading global drug formulators of generics and branded generics, diversifying the product offering to include human vaccines, attracting foreign clients through contract manufacturing (outsourcing) facilities and/or clinical trials or Contract Research and Manufacturing Services (CRAMS), and limited drug discovery.[5] Industry stakeholders feel that Pakistan's current exports of USD 218 million can easily cross USD 0.5 billion in a matter of three to five years. However, the dividend from this opportunity is contingent upon Pakistan introducing effective and timely measures to overcome gaps in the value chain that could help them gain substantial international market share. Critical supply-side factors that could affect firm ability to benefit from these global and domestic growth drivers are discussed in depth at each stage.

The recent positive experience of a local firm in securing a licensed technology transfer from a leading US firm for the COVID-19 antiviral drug is an affirmation of the potential of the sector. Other recent successes include attracting global partners into new avenues such as clinical trials by domestic firms, setting up production

4 Large molecules (biologics) are proteins made in microorganism or other living cells using recombinant DNA technology, with a complex structure, that must be transfused or injected.

5 https://www.grandviewresearch.com/industry-analysis/downstream-processing-market

facilities for oncology drugs, and WHO pre-qualification for two more laboratories in the country (although neither have been notified as reference laboratories). Two to three more success stories could add impetus to the existing momentum, especially at a time when COVID-19 has highlighted the paramount importance of having a state-of-the art pharmaceutical sector, an excellent regulatory framework, and a strategic government vision. This potential can be harnessed through an urgently needed sectoral growth strategy and corresponding action plan, overhaul of the regulatory regime, deregulation of drug prices, strengthening of intellectual property rights and a consistent policy regime. These can address, to a large extent, the unique features of the market that have stunted its transition to maturity.

Characteristics

The Pakistan pharmaceutical sector has certain characteristics that have impeded its progression to a mature pharmaceutical sector. These characteristics to a large extent explain the mixed performance of the sector, which while growing at compound annual growth rates averaging 10 to 12 per cent over the last five years, has been unable to translate it into global success. First, the sector composition is skewed in favor of large companies with the top 10 firms enjoying 46 per cent of market share, significantly more than in India, where it is 39 per cent.[6] Second, prices are heavily controlled with excessive government regulation, by the Drug Regulatory Authority (DRAP).[7] Since 2010, this has caused several MNCs to exit from Pakistan, reducing their market share to 39 per cent from almost 60 per cent. Thirdly is the issue of weak regulation and enforcement of standards by DRAP that was created in 2012 following fatalities caused by a faulty batch of drugs in a leading government hospital. Its main role is to ensure the supply of safe, effective, and high-quality drugs that are at the same time affordable and accessible to the general population. But weak DRAP capacity has led to the coexistence of multiple quality standards of manufacturing facilities. Fourthly, due to existing pricing regime and weak intellectual property rights, MNCs in Pakistan target the local market, do not export from Pakistan, and have not pursued Stringent Regulatory Authority (SRA) approvals for their manufacturing facilities. 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. As healthcare expenditure in Pakistan is primarily financed privately, the affordability of new molecules is also a factor. Large domestic manufacturers have replaced MNCs in product space, but MNC departure has reduced efficiency, skills and technology transfer, investment, quality and capacity upgradation.

With MNCs not contributing to new drug registrations at the same rate as in other regional countries, registration of new molecules in Pakistan has fallen. This may be attributed to two reasons. Firstly, delays in the regulatory channel have led to lower registrations, with new molecule registrations pending before Cabinet for nearly 3 years. So even though DRAP and the pricing committee may complete their evaluation and pricing recommendation in a timely manner, as per the Drug Act 1976 pricing has to be approved by the Cabinet, even for generic molecules. This is unique to Pakistan and leads to unnecessary delays. Secondly, this is because compared to the early years of 2000, the number of new applications has also fallen. Both factors have increased reliance on imported molecules (molecules are the main therapeutic ingredient in a drug), encouraged medicine imports, reduced availability of latest generation drugs, and led to shortages of many essential drugs in the market and public health facilities. Furthermore, established local companies and new entrants in the market focus on low-volume, higher margin drugs, rather than manufacture the high-volume but lower value drugs on the National Essential Medicine List (NEML). Fourth, the 600 plus smaller and medium sized firms (SMEs) supply low-priced drugs to rural/semi-urban markets within the country through wholesale of bulk packaged drugs. These firms produce basic generics, sustained by savings on packaging and marketing costs. The main reasons why the sector cannot transition to the next stage of pharmaceutical manufacturing like other countries are summarized below.

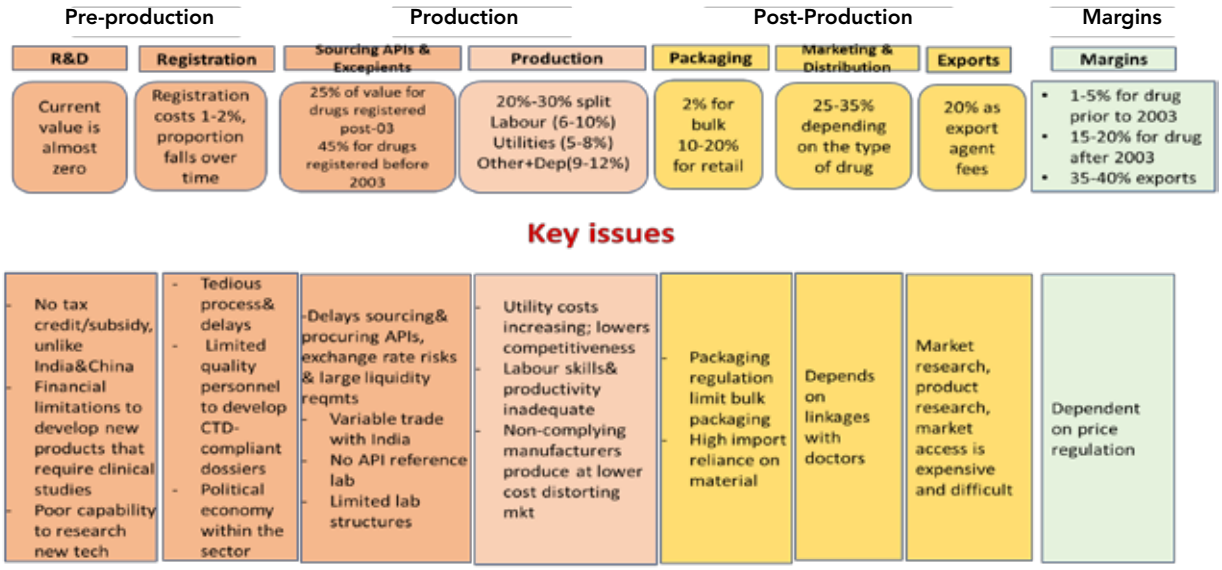
6 https://www.researchgate.net/publication/342711665_Pharmaceutical_Market_Structure_in_India_Competition_Concerns

7 DRAP, similar to the US FDA, falls administratively under the Ministry of National Health Services, Regulation and Coordination.

Issues

Analysis of the issues is grounded in the value chain. The value chain comprises three major components: manufacturing, distribution and dispensing to the end user. These can be further broken down to production; packaging, marketing, as well as distribution and supply chain to final consumer/patient. Some additional activities would be added for exporting firms. Figure 1 shows the breakdown from the input stage comprising mostly of active pharmaceutical ingredients (APIs) and excipients (inactive ingredients that help stability, absorption, efficacy but have no therapeutic function), to the production line itself. Production efficiency depends on the cost and quality of labour, utilities and technology, while packaging, marketing and sales depends on the regulatory structure in place. Exports and overall margins are determined by the pricing policies of the government, quality regulations and international compliances.

FIGURE 1 Value chain for typical product (per cent of revenue)



Source: Stakeholder interviews

Pre-production stages

The main issues at each stage of the value chain are given in the figure above. At the pre-production stage, there is little innovation and R&D. There is weak legal enforcement of intellectual property rights and limited patents to cover the research cost of a single new drug that can range anywhere between USD 500 million and more than USD 2 billion.[8] There is a lack of broad incentives and no government support for research, with the Central Research Fund collected since 1976 from firms (at 1 per cent of profit before tax) unaccounted for. In the absence of an overarching policy framework such as a National Medicine Policy (still awaited since November 2019), firms cannot adequately make investment decisions due to the lack of certainty. The flawed and highly politicized pricing policy of the government has added to the poor state of technology in the industry. As per the 1976 Drugs Act, the government stipulates maximum retail prices (MRPs), after which the Cabinet approves the final price. The latest Drug Pricing Policy 2018, which promised rule-based price setting[9] as well as annual price increases tied to the Consumer Price Index (CPI), was arbitrarily amended in 2020 to allow the government to exercise discretionary pricing controls on certain categories of drugs when required.

8 https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.25.2.420?journalCode=hlthaff#:~:text=However per cent2C per cent20our per cent20estimates per cent20vary per cent20from therapy per cent20or per cent20the per cent20developing per cent20firm.&text=T per cent20he per cent20expected per cent20cost per cent20of,entity per cent20(in per cent202000 per cent20dollars).

9 DRAP uses the External Reference Pricing (ERP) mechanism to determine the maximum price at which each drug will be distributed in the market (India and Bangladesh as benchmarks), with capped adjustments of 7 and 10 per cent of CPI, respectively, for essential versus other drugs.

Absence of market pricing has eroded profitability and dampened investment in capacity. Most research is confined only to packaging, coding, and similar activities rather than development and introduction of new drugs.

The next stage—registration of molecules— is mired with cumbersome registration processes (NOC from DRAP itself requires 14-16 documents), fees (PKR 50,000 and PKR 100,000 for new and old molecules, respectively) and poor technical capacity of DRAP to evaluate compliances, undertake drug registration and evaluation. These challenges arise due to absence of skilled staff, no oversight/audit or accountability of the institution itself, and the fact that DRAP does not have mutual recognition agreements of understanding with leading global regulatory authorities. New molecules can take up to 12 to 18 months to register and generics take up to 3 years.[10] Anecdotal evidence suggests that even new drug applications (NDAs) that are filed based on prior approval of Stringent Regulatory Authority (SRA) countries such as UK, EU, Japan, Canada, and USA can still take almost 2 years for formal licensing in Pakistan. Moreover, there is no mechanism for priority registrations of orphan or medically critical products. The most difficult aspect is sourcing the reference sample or the API to develop the registration requirement. At present the companies need to internationally source the reference drug or API from approved countries. However, this can be made easier if DRAP develops a secondary reference library for APIs that companies can readily access through purchase directly from DRAP rather than going to international sources. However, accuracy of information could be a challenge, and again, DRAP capacity would have to be upgraded to effectively cater to new issues that could arise.

Production stage

The weak domestic supply chain stems from reliance on imported ingredients, as the chemicals industry does not have the capacity to develop the basic components required. Also, an irrational duty structure (amounting to almost 40 per cent tax on imports (assuming import tariffs of 25 per cent), arising from import duty, 17 per cent sales tax and 7 per cent income tax. Despite being located next to the two largest API producers of the world, Pakistan has been unable to add value to the sector. This is due to non-economic factors such as restrictions on trade with regional countries that enjoy economies of scale in API manufacture (such as India). There have been few incentives from government to develop this sector over the years. When viewed holistically, the value chain of a domestic production line is almost 95 per cent import dependent, across APIs, excipients, packaging and so on.[11] Often, there are cumbersome import procedures on essential machinery (like 3-D printers, due to security reasons). This limits the scale, innovation and speed with which local firms can operate, exporting firms can respond to increases in demand and raises the vulnerability of all drug formulators to exchange rates.

At the manufacturing stage, there are overarching issues in terms of efficiency, especially of labour productivity relative to peer countries, as well as electricity supply and costs relative to China, Malaysia and India. Weak capacity of DRAP to regulate the manufacture, import and export of drugs further weakens the value chain at this stage. The main issue is of quality control, with no WHO approved QC lab, and very little ability to even export to semi-regulated markets, like the Philippines, let alone the EU, UK and US. There are only one or two pharmaceutical companies which even qualify to submit the product dossier for export to the Philippines. Of all licensed manufacturing exporting units in Pakistan, none has been approved by the US Food and Drug Administration (FDA). This is primarily due to lack of incentives and lack of government emphasis on enforcing manufacturing compliances. Only three national companies have the World Health Organisation (WHO) pre-qualification certification, which they have achieved at significant individual cost, without any government facilitation or financial support.

10 In January 2020, more than 400 drugs were awaiting approval since February 2019 despite having all the technical testing done by DRAP, due to a delay in approval by the Cabinet. Available https://www.thenews.com.pk/print/686418-drug-pricing-dilemma

11 The MNCs approach, however, differs as they usually source APIs from their own global value chains (GVCs) and hence can get them at more competitive prices and in consistent quality and supply.

These issues are compounded by inflexible production methods, such as strict control over toll/contract manufacturing, i.e., outsourcing of production. For example, despite being allowed legally, *de facto* arrangements only allow 3-month based contract manufacturing, for a period of 2.5 years (extendable to a maximum of 5 years). This is not economically sound practice, as smaller firms only operate at 20-40 per cent of capacity. A possible explanation could be that there are restrictions on the maximum number of products that can be tolled at any one facility (a total of 20 products can be produced through contract manufacturing). In addition, highly demanded, expensive, and often imported psychotropic and narcotic drugs cannot legally be made through toll manufacturing. To maintain stable domestic supplies, surplus capacity can be utilized for contract manufacturing, especially for imported drugs that have excess local demand. Contract manufacturing could ideally improve standards of production, encourage healthy competition, facilitate transfer of technology and enable local manufacturers to gain access to global markets. Above all, contract manufacturing could attract substantial foreign investment. India, has a 40 per cent lower cost of production compared to the USA, and generates USD 5.3 billion via high-quality but low cost outsourcing facilities.

Post-production

Firms face prices not determined by market forces, but rather set through regulation, local procurement, distribution and marketing practices. A peculiar characteristic common to developing country markets such as Pakistan, is the practice of selling drugs in loose packing to meet the demand of a substantially sized low-income population. Smaller companies, which usually sell in bulk packaging, target these markets to provide affordable medicine for low-income customers. Similarly, they are the preferred suppliers of most public healthcare centers and hospitals that provide free medicines, as these bulk suppliers help keep public healthcare costs low. But DRAP regulates which medicines can be packaged in bulk, affecting small wholesalers of generics. In addition, the sale of medicines in Pakistan cannot be done without a wholesale license. This raises costs to the detriment of firms that protect their margins through discounting on bulk sales, packaging, distribution and marketing. At the same time, provincial procurement rules and regulations are tedious and often mired by unethical practices such as lowering quality to get tenders. Each province has its own public procurement rules, raising transaction costs and there is distrust between provincial and DRAP regulators.

Exports

The value chain is more complex for exporters who must meet increasingly strict quality, legal and ethical standards for compliant manufacture. Global industry regulators such as US-FDA, MHRA-UK, TGA-Australia, and MCC-South Africa continue to upgrade their standards, with successful export growing perpetually harder with every subsequent year. Non-tariff measures such as safety and quality standards in export destinations, excessive documentation, and limited local capacity for testing & bioequivalence studies are key export constraints. Both NOC and certificate of current good manufacturing practices (cGMP) are needed from DRAP to export, along with bioequivalence certification. Bioequivalence is needed to establish similarity of a particular drug to match the conditions for sale and use in other countries that have more stringent regulatory conditions. With physical surprise audits a part of plant approvals, the current security situation is another obstacle to raising the quality of the sector. The absence of internationally accredited quality control laboratories are a binding constraint. In addition, there are no internationally recognized facilities in Pakistan that can provide FDA certification for export purposes either. This prevents Pakistani firms from exporting to SRA markets such as the USA, EU, Japan, Australia or Russia.

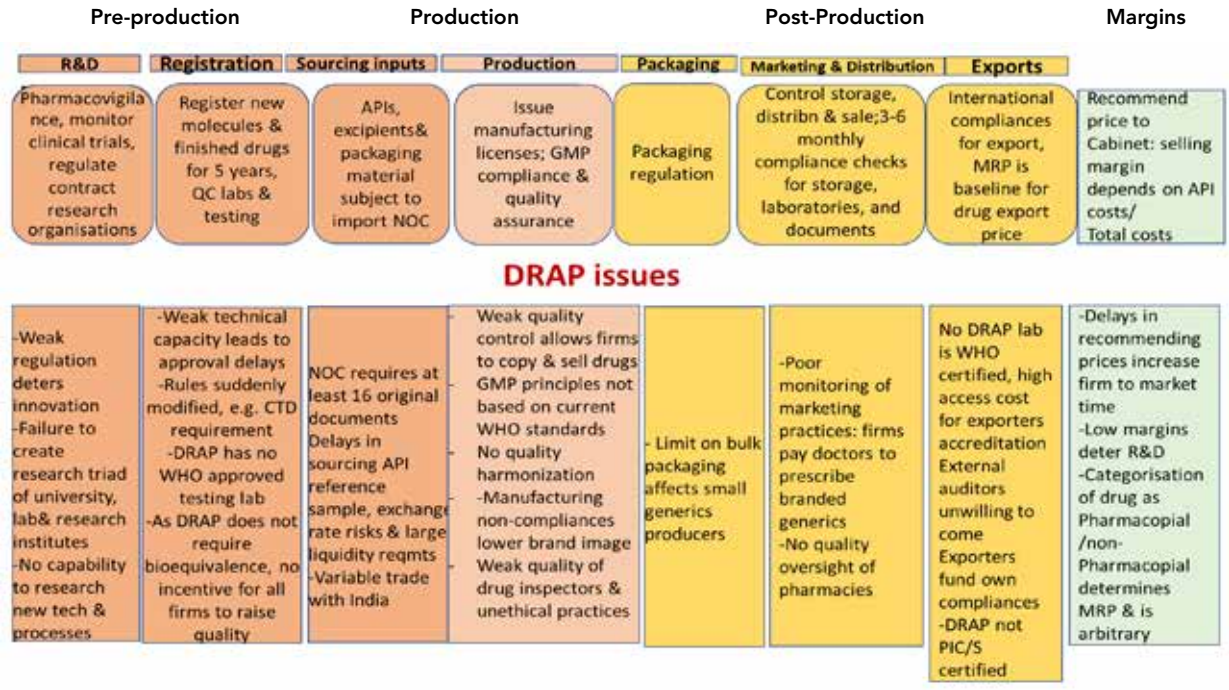
Margins

The value chain analysis shows the impact of extensive regulation on the pharmaceutical industry, with almost zero margins for drugs registered before 2003, but substantially higher margins for drugs registered recently. The innovators get a 30 per cent price edge under the current policy. Most innovator drugs have been registered by MNCs, however, as stated above, the volume of new molecule registrations by MNCs has substantially declined over time. Moreover, production line costs vary by product, for example, ampules are more expensive while tablets cost less. The benchmarking analysis shows that there are efficiency gains possible throughout

the value chain vis-à-vis more mature pharmaceutical sector, such as Jordan. This is especially true at the level of API and excipient costs, as well as of utilities. As a result of this and the other bottlenecks in the value chain analysis highlighted above, margins are relatively lower for firms operating in Pakistan. This has cross-cutting implications for sector growth, MNC presence, attracting FDI, state of research and innovation in the market, and most importantly, the quality and availability of pharmaceutical products.

The cross-cutting implications of weak technical capacity of DRAP across the sector value chain are summarized in Figure 2. While stakeholders are appreciative of recent attempts by DRAP to improve performance, they are wary that much will change due to the current institutional arrangement that weakens DRAP's ability to push for reform. With DRAP reporting to the Discussion with the new CEO of DRAP seemed to reveal an appetite for institutional strengthening, however, political considerations hampered progress due to frequent turnover at the top level and a lack of a permanent board. This has eroded institutional memory and stability and was also acknowledged by DRAP management itself. Recent positive developments such as launch of a new information management system (PIRIMS) to achieve Level 3 Compliance on the WHO global Benchmarking Tool were mentioned by DRAP. If DRAP can continue current reforms, it can proceed further with its application for Pharmaceutical Inspection Convention/Cooperation Scheme (PIC/S), which has been a long-standing demand of the sector.

FIGURE B Impact of weak regulatory capacity of DRAP on the pharmaceuticals value chain



Political economy analysis

In addition to an excessively regulated value chain, the sector operates under a strong political economy environment that impacts the effectiveness of government policies. The state-sector power balance is heavily skewed in favor of the state as the pharmaceutical sector remains greatly regulated. As in most sectors, stark industry fragmentation, between small and large firms and rent-seeking by individual firms has further limited power within the sector, effectively eroding the industry's overall ability (both collectively and individually) to influence policy. The higher number of small (roughly 600-700) than large firms (approximately 100) results in divergent interests, objectives, and capabilities, with negative implications for collective action within the sector. Sector associations and networks have remained ineffective and not matured as compared to competitor countries like India and Bangladesh. India and Bangladesh are on their way to becoming global leaders in pharmaceuticals, despite having a similar industry structure. In Bangladesh, there are 150 firms, out of which the top 20 firms account for about 85 per cent of the market where local firms, instead of MNCs, dominate the market with more than 90 per cent market share. All the top 10 firms are local firms. Similarly, India which is home to more than 3,000 companies with a strong network of over 10,500 manufacturing facilities, also has a fragmented industrial market structure, where the top 20 companies contribute to 50 per cent of total sales. However, the Indian industry overall contributes significantly to the GDP (1.5 per cent directly and another 3 per cent indirectly) as does Bangladesh (more than 5 per cent) compared to Pakistan (at just 1 per cent).

The broader political economy within which the pharmaceutical industry is embedded is not amenable to creating change that could support greater agency of the sector. Bangladesh has had a national strategy focused on manufacturing and saw exports soar at an average annual rate of 15-17 per cent in recent years, as discussed in Section 3.7. Both India and Bangladesh have also seen stability in the macroeconomy with no major balance of payment shocks— this allowed for exchange rate stability. On the other hand, frequent periods of military rule peppered by weak democratic interims, the ever-looming spectre of economic collapse, and a tense geo-political reality have deprived Pakistan of the solid and stable foundation that is required for consistent policymaking. Against these ground realties, it becomes difficult to maintain focus on long-term industrial policies guided by a cohesive economic framework. This instability is particularly damaging for the pharmaceutical industry, as it critically requires a long-term commitment simply because of the nature of the goods and services it produces. A consistent policy regime of at least 3-4 years is needed for investment in even the most basic new products. On the other hand, the garments industry, for example, is likely to adapt better to sudden policy changes as the process of changing the design or quantity of the product is less complicated. As mentioned earlier, lack of a stable policy regime maybe the single most important factor that explains why India and Bangladesh's pharmaceutical industry is on a completely different trajectory.

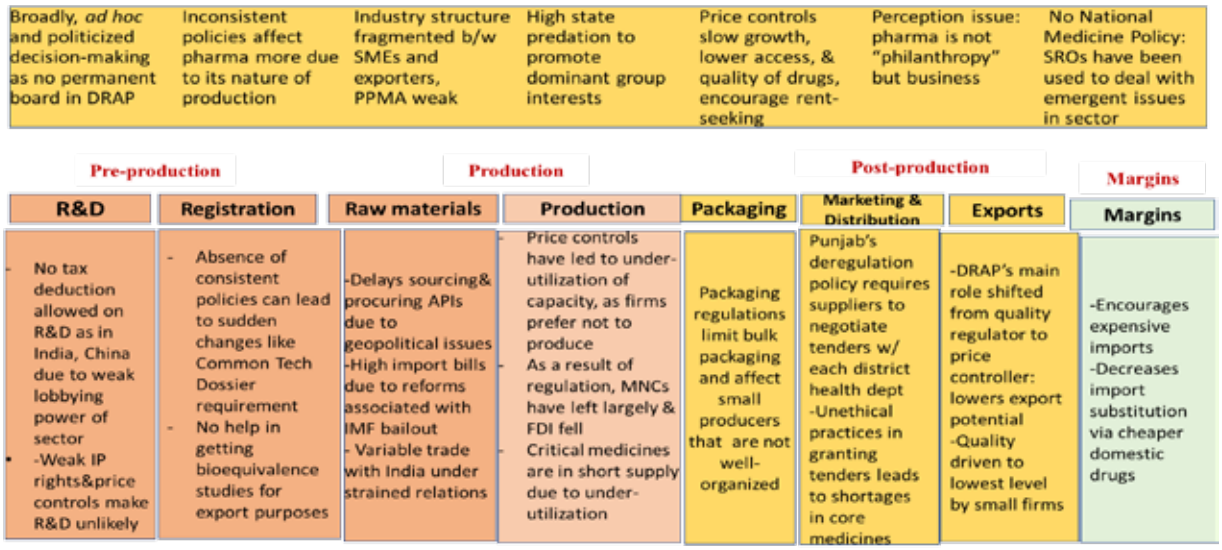
In sectors marked by small and medium-sized enterprises like the pharmaceutical industry, the burden of unfavorable and *ad-hoc* regulation and state predation is often the highest. State predation refers to state tendencies to promote interests of dominant groups, such as the military, bureaucracy, political parties, or private firms with access and power. Here too, the case of *ad-hoc* price increments being given to favoured firms instead of dynamic firms, lowers overall efficiency and competitiveness of the sector. This may make it difficult for some larger firms—due to low exports—to exert much power as they do not contribute much to the economy.[12] Although this may also be true of other sectors, given the fact that pharmaceuticals has never been considered by the government as a promising export sector of the country (unlike the case in Bangladesh and India), the bias is more heavily pronounced and subsequently, more damaging vis-à-vis other industrial sectors. All these factors greatly hamper industry-wide action. In addition, bureaucratic actors themselves exercise a high degree of discretion. Rent-seeking by officials reinforces the same by industry, to the detriment of the sector. Rent-seeking has happened via embedded networks that firms have cultivated in government.[13]

12 Dawani and Sayeed 2020.

13 A recent example in 2014 is that of a large firm based in Lahore, which secured a manufacturing license from US-based firm and maintained monopoly power for three years by delaying government registration of competing generic producers.

This politically charged power structure explains the *ad hoc* pricing regime, characterized by rigidity, that lends itself to substantial rent-seeking and suppression of competition. In the presence of price controls, some firms are tempted to cut costs by comprising on quality. This affects the overall productivity and image of the sector. Given the industry fragmentation and individual firm rent-seeking, power within the sector has been limited. Most of the lobbying for favourable pricing even by larger firms has remained unsuccessful, unless enacted through judicial intervention. Drug prices have come to represent pro-poor commitment, justifying the overall reluctance of the state to deregulate the sector. In this context and given 90 per cent of the firms capture just 3 per cent of the market, industry-wide action is unlikely in the future. Thus, the policy to support the sector should aim at reducing the dysfunctional power balance that is tilted towards the state. This will move the sector towards a more cluster/network-based model, where all power structures work towards common objectives. This will be necessary to overcome the cross-cutting implications of the unique political economy of this sector on the pharmaceutical value chain (see Figure 3). The top part showcases the broader horizontal issues.

FIGURE C Impact of political economy on the pharmaceuticals value chain



Potential for growth

With China and India 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 block-bluster drugs in low & middle-income countries. The sector's latent comparative advantage is revealed by a modified application of the Growth Identification and Facilitation Framework (GIFF), filtered by growth rates of world imports (2015-2019) and industry-validated production capabilities.

In the short-run, there is an opportunity to strategically enter a market that will be worth USD 700 billion in branded generics and USD 381 billion in generics by 2025. 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 USD 210 million only. If Pakistan can increase its world export share by just 0.01 percentage point, an opportunity of USD 0.76 billion opens up in the off-patent generics market. The newly launched public healthcare *Sehat Sahulat Program* (SSP) could provide the scale required to compete globally on cost, given a domestic market of 215 million people, which is the 5th largest in the world. In the long run, the study identifies human vaccines as a prospective sub-sector that Pakistan could focus on. The global human vaccines market was worth USD 33 billion in 2019, and it is projected to reach USD 66.6 billion by 2027. Pakistan has no current exports of human vaccines, and its domestic production is limited to 1-2 rabies vaccines produced in the public sector.

To identify product lines that Pakistan could have latent comparative advantage in, this analysis utilized a modified variant of the Growth Identification and Facilitation framework (GIFF), a policy tool based on insights from New Structural Economics. The framework emphasizes both effective markets and government facilitation in order to achieve industrial diversification and upgrading. Product lines within pharmaceutical sector that were instrumental to peer country growth 20 years ago (that they have since vacated and for which Pakistan has lower wage costs) are identified. A secondary filter for export potential on identified product lines was applied, based on growing global import demand over the last 5 years and domestic capability (based on industry feedback).

Products

A total of 9 product lines (at the HS 6-digit level) that Pakistan can focus on have been identified. While Pakistan already exports these lines, its world export shares were less than 0.5 per cent in 2019, with exports of USD 195.6 million. Validation by sector experts reveals that these are realistic products for firms to focus on, meaning that they have the requisite production capabilities to currently produce, and can expand at scale, if the regulatory structure is streamlined, government adopts a facilitative stance, and other non-tariff measures such as safety requirements and quality compliances can be effectively managed. At the same time, the new products are not too far off from the current technology frontier and could— with the aid of 1-2 well-publicized success stories— create government appetite for sectoral support and reform.

The detailed two-tier analysis has identified 9 product lines, Priority 1 and Priority 2. Priority 1 includes 7 products (at HS 6-digit level) that fall within current top 10 exports of Pakistan. These include medicaments consisting of mixed or unmixed products in dosage form, containing either hormones/steroids, alkaloids, and/or provitamins & vitamins (but not antibiotics); medicaments containing hormones or steroids used as hormones but not antibiotics (excl corticosteroids and insulins); and medicaments containing antibiotics, put up in measured doses (excl. penicillins and streptomycins). Exports of these products were USD 82.4 million, USD 77 million, and USD 16.6 million, respectively in 2019. Global imports in 2019 of just these three product lines were USD 569.5 billion. This figure is expected to rise tremendously, as most of Priority 1 lines include generic drug formulations like vitamins, steroids, and antibiotics that are in high demand for treating COVID-19. Long-term focus should be on Priority 2 products that are growing globally, and in which Pakistan could build export competitiveness over time. These are vaccines for human medicine (HS 300220) and antisera (HS 300210), in which Pakistan has negligible exports.

Markets

The key markets identified are in Africa, East and Central Asia, where Pakistan's main competitors in Priority 1 are India, China, Jordan, Kenya and sometimes, Malaysia. Given that India, Vietnam and Bangladesh are also supplying these markets, Pakistan could potentially gain entry. Of course, tariff access is a preliminary hurdle—firms will have to shape up to meet stringent regulations. 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 overall global competitiveness of the sector and is a win-win for firms and government.

Given the complexities of the sector and differential requirements and standards set by different countries, exporting requires accurate diagnosis of target markets and a realistic assessment of firm capabilities. During the interviews, it was revealed that a comprehensive report done by an internationally credible company such as IQVIA may cost up to USD 300,000 per product per market. For example, Pharmexcil (Pharmaceuticals Export Promotion Council of India), which was established by the Ministry of Commerce & Industry, India issues regular country and product research reports to support their industry in going global. There is no such support extended in Pakistan. This cost is a major deterrent for local companies, especially when the return on such investment remains uncertain.

In light of this, Pakistan could benefit from Jordan's practice of partnering with importer/local distributor companies, which have special warehouses in the target market. Like Jordan, it could create a capable central export body for marketing and branding, and a separate unit for providing export information on new opportunities, changes in regulatory standards, import requirements, non-tariff measures, as well as funding for international trade fairs. The Indian model to penetrate African markets is also useful, where local representative offices were set up in the destination country— otherwise they entered a joint venture (JV) in distribution.[14] This approach is missing in Pakistan, with the government making little effort to engage African countries through trade and diplomatic missions. Similarly, with respect to Southeast Asian countries like Vietnam, a regional leader in production of vaccines (a long-term prospect for the sector), there is no effort to enter into a preferential trade agreement. Vietnam could provide a foothold into the ASEAN market, as it is the third largest FDI destination (USD 15.5 billion in 2018) within ASEAN countries, following Singapore and Indonesia.[15]

APIs

Access to low-priced APIs is critical for any pharmaceutical sector based on drug formulation. The global API sector is projected to grow at a CAGR of 5.8 per cent till 2025, and to reach USD 306 billion by 2027. Demand for APIs is on the rise as 66 drug molecules will go off-patent between 2020 and 2025.[16] Currently, API production is dominated by neighbours India and China, although USA, Switzerland, UK, Germany, and Israel are incumbents. Newer entrants include Thailand, Vietnam, Indonesia Malaysia, and Bangladesh. However, development of the API industry in these countries has required substantial long-term investment and consistent policies, with governments providing a consistent policy regime for at least 10-15 years, given the long gestation period of API manufacturing. The sector is weakly developed in Pakistan, with 6-7 local manufacturers producing a little over 30 APIs. Domestic producers are protected by import tariffs ranging from 5 to 25 per cent and supply 12 per cent of the local market. The sector is mired by issues of low quality, higher prices due to lower scale, and questionable practices of pricing just under the landed price of imported APIs. As a result, roughly 88 per cent of total APIs are still imported. DRAP recently developed an API manufacturing plan, comprising incentives for investment and technology transfer, limited protection, and the use of clustering in API Parks. A supportive regulatory structure and GMP compliance with ICH Q7/Q7

14 GIZ. (2019). Value Chain Analysis of the Pharmaceutical Sector in Jordan Industry Overview in Jordan. Trade for Employment (T4E) Project. Available at https://www.giz.de/de/downloads/Value%20Chain%20Analysis%20of%20the%20Pharmaceutical%20Sector%20in%20Jordan.pdf

15 KPMG (2020). Value of innovation. Unlocking the Potential of the Innovative Pharmaceutical Industry in Vietnam. Available at https://assets.kpmg/content/dam/kpmg/vn/pdf/Event/2020/7/Blue_Sky_Report_2020_EN.pdf

16 GIZ. (2019. Value Chain Analysis of the Pharmaceutical Sector in Jordan Industry Overview in Jordan. Trade for Employment (T4E) Project. Available at https://www.giz.de/de/downloads/Value%20Chain%20Analysis%20of%20the%20Pharmaceutical%20Sector%20in%20Jordan.pdf

global standards is also proposed.[17] The government feels this will have a positive impact on pharmaceuticals by strengthening the local supply chain and reducing the import bill by substituting API imports domestically.

However, the success of this policy is debatable for the following reasons. API production is very intensive in energy, capital (human, financial & physical), land and time. Even fulfilling safety and quality protocols, managing the effluents, and recycling the expensive chemicals for re-use is, in itself, a whole industrial process that will rely mostly on imported materials, defeating the purpose of import substitution. Bangladesh was able to enter API production due to technical assistance from India. But in the case of Pakistan, technical assistance from neighbouring countries is unlikely, due to the poor perception of manufacturing in the country and its bad security image. In addition, stakeholders reveal that prospective partners/investors cite issues of labour productivity and professionalism, energy prices, inconsistent policies, weak intellectual properties, expensive land and an overall lack of complementary downstream linkages as critical entry barriers. Most importantly, perhaps, the feasibility of API production is dependent on scale, which means that large demand is needed for production to be cost-effective. Given the 40 years head start leading producers of API and the economies of scale exhibited in production, it is highly unlikely that locally manufactured APIs can compete on price. Cost of domestic drugs would rise if forced to use local APIs. In turn, low demand (domestic and global) for expensive local APIs would prevent firms from achieving scale, defeating the very purpose of the policy. It seems that with cheaper API alternatives at our doorstep, complexity of API manufacture, and manufacturing realities, there may be more efficient ways of helping the sector achieve its potential. A broader role of providing a level playing field would better serve the government's API strategy. The government should leave investment in API manufacture to the private sector based on feasibility, sustainability, and profitability. A more timely and fruitful strategy would be to pursue the vaccine opportunity identified through GIFF, and more broadly highlighted by COVID-19.

Vaccines and antisera

In a highly populated, resource-constrained country like Pakistan, universal immunization must be the cornerstone of an effective public health strategy. Despite having one of the largest birth cohorts in the world (5.5 million babies in 2019), Pakistan has virtually no domestic vaccine production. This dependency on imported vaccines (mostly from India) presents a serious health security challenge for the country. Pakistan's vulnerability in this area has been further underscored in the context of the Covid-19 pandemic. The acquisition of vaccine manufacturing capabilities can be a first step towards the production of next-generation, high-value pharmaceuticals in Pakistan. The global market for human vaccines was valued at USD 33 billion in 2019 by the WHO Global Vaccine Market Report 2020. It is expected to reach USD 66.6 billion by 2027. With Pakistan exports currently zero, a 0.01 percent share in this market amounts to USD 0.66 million by 2027. In the long run, the study identifies human vaccines as a prospective sub-sector that Pakistan could focus on.

Supply-side dynamics

Amongst other constraints in the provision of public health interventions, supply and provision of vaccines remain a key component requiring attention by the government. The market dynamics of human vaccines are such that sustainable vaccine production requires a Public Private Partnership (PPP) approach: the private market for vaccines is minimal, with the government being a virtual monopoly buyer. Vaccines are procured in bulk directly by the government from vaccine manufacturers or through coordinated multi-country programmes funded by donor agencies such as the Global Alliance for Vaccine and Immunization
GAVI). GAVI vaccine prices, which are set significantly below market prices, may no longer be applicable for Pakistan when it graduates out of the scheme in the next 5 years, as is expected with its GDP increase. Given the overburdened healthcare system and scant resources, meeting the country's immunization requirements could become Pakistan's most serious healthcare challenge in the medium to long-term.

17 Ghani, S. (2020). Building a System for the Manufacturing of APIs: Pakistan's National Strategy and Plan of Action.

COVID-19 has demonstrated that local firms can rapidly develop infrastructure and capability for production if technology is transferred and could provide a possible template for international collaboration and growth for the industry going forward. Gilead Sciences US licensed its technology to a subsidiary of Ferozsons Laboratories Limited for production of an antiviral drug Remdisivir to treat COVID-19. It is the first time that a Pakistani manufacturer has been selected to be part of an international supply chain of this nature. The faith shown by a leading US pharmaceutical firm in entering a proprietary agreement with a local company is a big step towards the production of next-generation, high-value pharmaceuticals in Pakistan. A few other success stories could help the sector gain the necessary knowhow to produce at scale. Diffusion of this knowledge could then spur innovation and discovery, leading to higher local production, and perhaps profitability.

The long-term objective should be to manufacture high-value pharmaceutical products, such as functional materials, biopolymers and recombinant DNA technologies to produce therapeutic proteins, antibodies and vaccines. Biosimilars are large molecule medical product made from living organisms that are similar to already existing approved drugs or "generics" of biologics. They must be injected or transfused and must be tested, as they are not identical to their originator counterpart. Local industry feels that Pakistan could reasonably move towards production of biosimilars, starting from vaccines for human use, within the next 4-5 years.

The market dynamics of human vaccines are such that sustainable vaccine production requires a Public Private Partnership (PPP) approach: the private market for vaccines is minimal, with the government being a virtual monopoly buyer. The requisite capabilities can be acquired through government contracts with leading global vaccine producers such as Moderna, Pfizer and Johnson & Johnson who prefer to deal with governments rather than private sector directly. Local firms can also extend proprietary arrangements with MNCs such as technology licensing agreements through firm-to-firm linkages. Currently, the Biological Production Division (BPD) at the National Institute of Health (NIH) is the sole producer of life-saving vaccines and antisera in the country. Private sector manufacturing of vaccines could supplement NIH's existing capacity while addressing organizational, managerial and financial constraints that prevent the institution from expanding its output. This will build the capacity in the overall health ecosystem to respond to national needs while achieving national vaccine/ immunoglobulins self-sufficiency.

Currently, Pakistan is at Level 1 in terms of indigenization of local vaccine production, i.e., distribution of imported finished vaccines (mostly arranged through GAVI, UNICEF or similar international donor organisations), with minor Level 2 activity by private sector of packaging and labeling imported vaccine products. Based on global and domestic demand, industry-validated production capacity, and national security and public health prerogatives, this study suggests that it is now time to help the sector acquire Levels 3 and 4 of vaccine indigenization. Level 3 corresponds to vaccine product manufacturing from imported bulk vaccine concentrate (fill & finish) and Level 4 is full cycle manufacturing, i.e., production starting from the active components (antigens) of the vaccine itself. Stakeholders believe that the transition from Level 1 to Level 4 can be undertaken over a period of 5 years, sufficient time to ensure that local producers remain compliant to World Health Organization (WHO) standards. This should be a prerequisite to local manufacture to ensure that quality standards are not compromised, and the integrity of the vaccines chain is maintained.

The role of DRAP in creating an enabling environment will be critical, as vaccines require a significantly higher level of regulation than drugs. No vaccine can be procured by GAVI or international multilateral agencies or even exported to regulated markets, unless it is WHO-prequalified. In the case of vaccines, the WHO, before it can prequalify any vaccine manufacturer in a given country, has to first prequalify the monitoring, surveillance and quality assurance system of the country's National Regulatory Authority (NRA). In Pakistan, this is the DRAP National Control Laboratory for Biologics (NCLB), which is responsible for lot release of vaccines and biologics in the country. It needs to build significant capacity and apply for WHO prequalification before any local manufacturer can be approved and is the biggest regulatory barrier for vaccine production.

A two-phased action plan is proposed for indigenization of vaccine manufacture in Pakistan. In Phase I, which can begin immediately, local firms having validated biologic production facilities, or that are willing to invest in the required standards will use imported bulk vaccine concentrate to fill-and-finish vaccines into individual doses. International companies manufacturing WHO pre-qualified vaccines would be approached to enter into an agreement with the Government of Pakistan directly or the government could negotiate with GAVI/ UNICEF on behalf of local firms. As supporting sustainable indigenous capabilities for vaccine production is the stated objective of GAVI and the WHO, this should not pose much difficulty for the Pakistan government. Secondly, the government will provide long-term purchase/buy-back agreements for these locally produced vaccines, under a public private partnership involving the Ministry of National Health Services, Regulation & Coordination (Expanded Program for Immunization) and the private sector. Firms would have the option to make any of the 10 vaccines included under the national EPI program as well as highly needed non-EPI vaccines (such as typhoid or the flu vaccine for elderly, religious pilgrims, etc.). Thirdly, DRAP will be given a 2-year timeframe to achieve WHO pre-qualification for the NCLB to help in transition to Phase II.

In Phase II, with the newly pre-qualified NCLB, local industry can graduate to Level 4 and opt for the vaccines that are currently in the EPI schedule, so that Pakistan is prepared for when it graduates from GAVI support. Other higher volume Pakistan-specific antigens, as well as COVID-vaccines could also be locally manufactured with the help of technology transfer from global partners, JVs with leading MNCs, or hiring commercial consultants to upgrade existing manufacturing capacity. This could take anywhere from 3 to 5 years, from date of approval. A policy framework would be required to ensure the sustainability of domestic production including fiscal incentives in the form of a tax holiday for at least 5 years and duty-free import of plant and equipment, and as mentioned above, long-term buyback arrangements for locally produced vaccines. The terms of buy-back would be at market prices, so that firms can maintain margins to recover investment—firms suggest that an internal rate of return of 9 per cent is sufficient to cover risks associated with production of vaccine raw materials under Level 4. At the same time, the government can subsidise these vaccines for consumers under its newly launched public healthcare *Sehat Sahulat* Program (SSP). This subsidy may be withdrawn after 3-4 years/when firms able to break-even at SSP prices, whichever is sooner.

Technical support could be provided to DRAP through globally certified consultants (that government can bring in from WHO by assuring their security) to continuously upgrade its technical and regulatory capacity, as vaccines require greater pharmacovigilance than drugs.

Recommendations based on value chain analysis

To address impediments to competitiveness with cross-cutting implications for all firms, regardless of size and export orientation, the study makes five recommendations.

There is no current explicit priority focus on pharmaceuticals. In light of this, the most pressing need of the sector is a ***dedicated body that coherently translates a government vision for the pharmaceutical sector of Pakistan***. This body must have the capacity to collect and maintain updated industry data, as well as to identify, target, administer and manage policy interventions that could correct the gaps identified in the value chain analysis. The second most urgent intervention is revisiting the decision of submitting ***DRAP to the control of the Ministry of National Health Services Regulations & Coordination (MNHSR&C)***. The current arrangement reduces its effectiveness due to the ensuing political economy tussle between the two entities. DRAP like other federal authorities such as OGRA, SECP and NEPRA must fall under the purview of the Cabinet. Third, ***the pricing role of DRAP must immediately shift to the Ministry of Commerce.*** The determination of market retail price for new licenses/annual price adjustments can remain with DRAP based on verification and compliance with Drug Pricing Policy 2018. The Federal cabinet can maintain oversight in case of any extraordinary price changes.

The fourth recommendation pertains to ***phased price deregulation***. A liberal and transparent pricing regime will support the performance of the sector and allow firms to invest in technology and R&D. ***Prices of a list of workable medicines—the National Essential Medicine List (in line with WHO guidelines)— should be controlled and pricing for the rest should be deregulated in a phased manner, as approved by industry.*** All other drugs may be regulated with a clear mechanism of automatic price revision on annual basis. Pricing resets would happen every year according to an agreed mechanism, with coverage of drugs revised every three years. This will give both firms and consumers some time before a fully market-based equilibrium emerges, where market-based pricing will determine final prices as opposed to cost-based approach currently taken. Fifth, ***DRAP must be revamped*** to enhance its expertise and capability to undertake quality control and monitoring, which will help in the pre-production, production and export stages of the value chain. To identify key gaps in DRAP capacity, audits of its various departments can be conducted by inviting qualified global consultants to Pakistan on government invitation. This will improve institutional capability in a much better way than sending DRAP officials abroad for training. ***The study also suggests specific interventions based on DRAP's role at each stage of the value chain in the report.***

Recommendations for Export Growth

The key policy recommendations that could support companies in establishing a global presence are given below. Ownership of these recommendations will require a national vision that prioritizes the pharmaceuticals sector not only as a driver of growth and employment, but also as a matter of national security and public health that is integral to the growth of the national economy.

- To indicate intent of supporting the sector, include pharmaceutical sector in the five priority export sectors of the country
- A dedicated body for pharmaceutical sector with trade, diplomatic and technical wings to implement 5-year action plan proposed above, possibly by revamping the Pharmaceutical Export Promotion Council. This would
    - Undertake function of trade promotion and industrialization pertaining to pharmaceuticals
    - These divisions/sub-departments must be given key performance indicators (KPIs), as in Malaysia, for example. This will have cross-cutting implications across the value chain, especially on regulating quality, improving the supply chain, raising profitability and thereby investment in R&D.
- DRAP should ONLY focus on regulations & enforcement, while business, marketing, pricing & incentives to be managed by the proposed dedicated government body.
- Allow contract manufacturing without limitation: Companies be allowed to optimize production configuration (and thereby lower manufacturing costs) by subcontracting manufacturing to other companies, remove limit on maximum products that can be tolled per plant
- Pursue policy of developing vaccine manufacturing capabilities under public private arrangements, where government agrees to long-term buy-back for locally produced vaccines. MNHRS&C will coordinate action between the public and private sector, while NIH can use its national database to provide local firms with vaccine demand estimates to ensure an adequate domestic supply. A two-pronged plan is proposed
    - Phase I: DRAP is given 2 years to get WHO-certification for NCLB. After due diligence, local pre-qualified firms or high-quality firms will be allowed to import bulk vaccine concentrate from WHO-pre-qualified international firms. These will be used to make individual doses through fill-and-finish arrangements. Ensure government procurement through sovereign buyback, Publicise success stories to attract global interest, FDI and technology transfer
    - Phase II: Firms begin to acquire full cycle manufacturing capabilities, starting from raw materials. This could be done through technology transfer licensing from international partners, JVs with international firms, or through technical expertise provided by commercial consultants. Time-bound incentives such as tax holidays and duty-free import of plant & equipment must be provided. The government will commit to buyback at market prices from firms that 100 per cent vertically integrate, but to ensure affordability, it can subsidise end users of vaccines (mostly hospitals involved in EPI and Prevention of Hepatitis programs) under its public healthcare *Sehat Sahulat* Program. Protection should lapse in 5 years or when firms reach scale to break-even at subsidized prices, whichever is sooner.
- The Ministry of Commerce using the Export Development Fund (EDF) may conduct product and market studies focused on Africa, Central and East Asia, as is done in India by PharmExcil. These studies cost USD 300,000 per product per market and should be conducted by internationally reputed specialist companies and shared with DRAP registered companies. The return on these potentially range in export earnings of millions of dollars, as the one-time expenditure per product-market combination would be spread over all licensed firms. Not only could this reduce the access cost for all companies, but it would also help in developing broader firm networks. This network could jointly target markets pooling resources and knowhow, lowering costs for any one firm, and directly support cluster development. Relying on industry associations for this will currently not be possible given their low alignment and capacity for collective action.

- DRAP should continue its reforms for quality regulation and enforcement, for e.g., by DRAP achieving international standards, clearing certifications as per WHO Global Benchmarking Tool, and attaining the PIC/S membership, which could allow access to SRA countries.
- DRAP may also reduce access costs for smaller firms that wish to export by establishing a secondary reference library for molecules and sell these for a suitable charge.
- The government could legislate and enforce minimum consistent quality standards for any manufacturer that wants to operate in Pakistan (e.g., WHO compliant GMP certification for operation of facilities). To facilitate compliance, there could be enhanced credit facilities for long-term lending to invest in GMPs—this can also be tied to export performance or to accreditation by WHO/UK-MHRA/USFDA.
- WHO-approved laboratories that meet international standards and operate independently may be set up as PPPs.
- For vaccines production, DRAP must apply for and achieve WHO certification of its National Control Laboratory for Biologics (NCLB), without which no vaccine manufacturer in Pakistan can be considered for WHO approval.
- A global presence requires upgradation of plants and premises to achieve GMP and other quality compliances. DRAP has failed in this role and would benefit from certified global consultants (whether from WHO or from commercial pharmaceutical consultants) that can provide specialized ***technical and institutional*** support for each of the key regulatory and quality management roles that DRAP undertakes.
- If the government's API Action Plan is approved, its role must be limited to providing an overall enabling environment for manufacturing in industrial parks, no targeted allocation of government funds. The decision to invest in API should be left to the private sector with requirement that investors set up the API plant to meet WHO manufacturing standards.

These recommendations are summarized in Table 1 below.

TABLE A Proposed recommendations for government with timelines and likelihood of success

Recommendation	Implementing body	Timeline	Potential obstacles	Likelihood of success
A dedicated body for pharmaceutical sector with trade, diplomatic and technical wings to implement 5-year action plan (see no.4 below)	Ministry of Industries and Production	Immediate	Lack of ownership that could only be resolved through creation of a Pharmaceutical sector Division within MoC, as it has access to Export Development Funds amongst other that industry may be able to tap into.	Intermediate
Include pharmaceutical sector in the five priority export sectors	Federal Cabinet	Immediate	Minimal, if argument correctly presented in terms of national and social security of country	High
Removal of DRAP from control of Ministry of National Health Services Regulations & Coordination and put under Federal Cabinet	Federal Cabinet	Immediate	Political economy struggle between MNHSR&C and Cabinet could create delay and subsequent paralysis in DRAP, with DRAP leadership unwilling to perform key roles	High
Revision of Drug Pricing Policy 2018 to undo arbitrary amendments of July 2020, move to CPI-indexed formula	Federal Cabinet	Immediate	Consensus has been reached, awaiting approval from Cabinet, but "pro-poor commitment" of govt. will stand in the way	Low
Removal of pricing from DRAP to Ministry of Commerce	Ministry of Commerce and Federal Cabinet	Immediate, as consensus has been reached as per insiders	DRAP would want to retain oversight over prices	High

Recommendation	Implementing body	Timeline	Potential obstacles	Likelihood of success
Phased deregulation of pricing controls historically enacted through Drug Act 1976 (excluding WHO based NEML)	Federal Cabinet, Ministry of Commerce	5 years	Optics and political economy issues likely, even if prices are deregulated gradually, with automatic rule-based annual price resets, and drug coverage revised every 3 years. Requires careful management of perceptions	Low
Expedite National Medicine Policy that contains 5-year action plan for sector	Federal Cabinet	Immediate, as it is awaited "any day" since November 2019	Some conflict of interest between Cabinet, MoC, DRAP over specifics, roles and responsibilities. Alignment issues could arise b/w existing regulatory framework and the overarching Medicine Policy	High
Revamp Pharmaceutical Export Promotion Council (2019) along lines of PharmExcil, India	Ministry of Industries and Production jointly with Export Promotion Bureau	Immediate	Lack of ownership of body, although it exists on paper; need to create technical capacity to undertake product-market research reports by country to be financed through EDF	Intermediate
Develop a molecule reference library to meet registration requirement for export purposes	DRAP/MoC/new Pharmaceutical Export Promotion Council	Immediate	Requires reliable information, following standard protocols as per SRA countries. DRAP can sell these at appropriate cost, which would still be lower than importing from abroad	High
Overhaul technical capacity of DRAP, reform regulatory structure, streamline internal organization via certified international consultants who routinely audit DRAP	DRAP	Immediate, as DRAP Act 2012 has been amended per the newly drafted DRAP Amendment Act 2019 that is awaiting approval	International consultant has already been hired to improve functioning, reforms underway for acquiring global accreditation but slow progress despite existing groundwork due to frequent turnover of top leadership & fear of NAB investigations under guise of corruption. Status quo remains comfortable fallback option	
Broad policy support for API production, leave investment to private sector	Board of Investment, provincial SEZ authorities	First steps taken by DRAP in its Manufacturing of APIs: Pakistan's National Strategy and Plan of Action (2020). Implementation will take 10-15 years at least	Contingent on consistent regime for 10-15 years, gvt. support to ease business, investment, and credit costs, creating linkages with labs & research centres. To minimize impact on firms that use imported APIs, retain existing tariff rates on APIs, and lower them when at least 5 local manufacturers have developed demonstrated capability	Intermediate
Remove timebound policy on contract manufacturing, eliminate restriction on number of drugs tolled/plant	Federal Cabinet and DRAP	Immediate	Could lead to spurious drugs, but stringent quality controls and monitoring by DRAP could prevent malpractice	High
Enter FTA/PTA with Vietnam, encourage vaccines and pharmaceutical collaboration through CPEC, and current FTAs with China, Malaysia and Iran	Ministry of Commerce	2-3 years	Depends on skill of Pakistan's negotiating trade missions, trade attachés, and support staff	Intermediate

CHAPTER 1

Background

The value of Pakistan's pharmaceutical sector has doubled from USD 1.64 billion to roughly USD 3.2 billion over 2011 to 2019, with the number of active manufacturing companies also doubling over this period. The sector provided 240,000 jobs (both directly and indirectly) and met 80 per cent of domestic demand in 2018,[18] almost equally shared between local companies and multinational companies (MNCs). The market structure is constantly changing, from being dominated by a peak of 40 MNCs in the 1990s to just 25 today, with a majority share of local firms. Industry stakeholders assert that more than 700 pharmaceutical manufacturing units exist in Pakistan, signaling substantial over-capacity based on local demand. Total exports increased four-fold to reach USD 218 million in 2019, from USD 44.4 million in 2003. Yet exports from the sector account for only 0.9 per cent of the total Pakistan exports to the world in 2019, paling in comparison to Pakistan's exports of other commodities in the health sector like surgical instruments and medical equipment (combined, in 2019 these two sectors exported USD 0.5 billion and ranked 12th in Pakistan's world exports, while pharmaceuticals ranked at 22nd place).[19] A simple comparison with India shows that while their pharmaceutical sector earns 50 per cent of its revenue from exports, the same is not even 10 per cent for Pakistan.

Global pharmaceutical markets are in flux due to major restructuring, in terms of both demand and supply. This presents Pakistan and other developing countries with a unique opportunity if the sector can take timely action. Pakistan, with a local market of 215 million consumers and more than 700 pharmaceutical companies is poised well to gain from opportunities provided under shuffling global patterns of supply and demand. However, the current practice of simply importing 95 per cent of the raw material, compounding active ingredients with excipients, coating the pills, and packaging the drugs cannot continue to be the long-term goal of the sector. A larger vision recognizes not just from making cheap drugs, but diversifying to value-added products such as biosimilars, attracting foreign clients through contract manufacturing (outsourcing) facilities and/or clinical trials or Contract Research and Manufacturing Services (CRAMS).[20] Industry stakeholders feel that Pakistan's current exports of just over USD 200 million can easily cross USD 0.5-1 billion in a matter of three to five years. Once this critical threshold is reached, exports could double and even triple, within the next 5-10 years. However, the dividend from this opportunity is contingent upon Pakistan introducing effective and timely support measures that could help them gain substantial international market share. Industry feels that after reaching this critical mass, export growth could become exponential.

18 As per industry stakeholders, this figure is roughly 80 per cent, whereas other reports claim it to be 70 per cent, i.e., PRIME (2017). Pakistan's pharmaceutical industry. Study commissioned by the PPMA

19 Trade data taken from ITC TradeMap, as of 29th January 2020

20 https://www.grandviewresearch.com/industry-analysis/downstream-processing-market

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, which requires a structured approach to determine how it can develop requisite scale and reach its export potential. The study identifies specific issues the sector faces in trying to avail these and other opportunities that arise. Findings from the analysis contribute to a time-bound export development strategy that provide a prioritised menu of policy interventions to create the necessary enabling environment. These recommendations are geared towards unlocking the productivity of firms, strengthening their global competitiveness, and helping them achieve their export potential.

At the same time, COVID-19 has presented the pharmaceutical sector with unprecedented challenges but also many opportunities. COVID-19 has highlighted the sector's critical role in achieving the objectives of the national health policy. At the same time, it is a good time to showcase the bottlenecks that have resulted from years of neglect and regulatory inadequacy. In light of this, this study explores COVID-19's impact on Pakistan's pharmaceutical industry.

1.1 Scope of work and outline

There is some literature available on the pharmaceutical industry, but broadly this is divided into studies which either focus on the structure and constraints faced by the sector, or those that delve into the implications of these impediments, for e.g., high market concentration, rent-seeking and political economy, sub-standard quality and low technology, and firm inefficiency, to name just a few. This study is more comprehensive and documents aspects of its structure and political economy, benchmarks its performance relative to countries that were similarly placed to where Pakistan currently is, explores the competitiveness constraints it faces, and proposes recommendations in light of policy lessons, stakeholder input, and ground realities of the sector.

The study utilized extensive primary research to collect data on the value chain and its various bottlenecks. This data was used to conduct a value chain analysis, with special emphasis on identifying and addressing various bottlenecks. Secondary research was used to collate existing information on the sector, which was blended with insights gained from in-depth interviews with more than 12 sector experts, including key stakeholders from manufacturers, exporters, government and industry specialists. These semi-structured interviews solicited feedback on key questions that were pre-circulated (on the value chain and its main gaps) as well as broader comments on sector competitiveness, potential, and future orientation in terms of both products and markets. Special attempts were made to make this process as representative as possible, including manufacturers that were small, medium and large local players, as well as those with an export focus. This research was complemented with global insights on best practices from peer countries, that were historically similar to Pakistan and have since expanded their exports at least tenfold over the last 15-20 years.

It is a fact that this sector has never been prioritized for the economic development of the country. Despite being such a sensitive and critical sector that determines the health outcomes of its entire population, the sector has never been supported as an economic endeavour. It has on occasion been highlighted for spurious/counterfeit drugs or price hikes, or unavailability of medicines on the EDL, or rent-seeking behaviour, but rarely as a business enterprise. In contrast, making the sector an economic priority has been the first successful policy intervention of all the leading pharmaceutical sectors of the world. Once governments recognize the pharmaceutical sector as a driver of economic growth and job creation, they strived to create an enabling economic environment. This study is a first step in the direction of informing policy by highlighting pharmaceuticals as instrumental to Pakistan's growth over the next 25 years and taking timely steps to unleash its potential globally.

The study is structured as follows. Section 2 reviews the economic contribution of the sector and its trade performance relative to peer economies that were historically similarly placed as Pakistan. A comprehensive

examination of the domestic value chain follows in section 3, with emphasis on the level of research & development in the sector. To highlight efficiency gains for the sector, this value chain is benchmarked against a group of comparator countries such as Bangladesh and Malaysia, that were similarly placed to where Pakistan currently is. A political economy analysis of the sector in Section 4 highlights both the appetite and opportunities for sector reform. The power dynamics between the key actors and their level of influence are discussed in terms of their capacity and inclination to shape the policy discourse and their openness to reform. Section 5 explores prospects for export growth based on Pakistan's latent comparative advantage through the identification of short-/long-term export opportunities (products and markets) and how to avail them borrowing best practices from Bangladesh, India and Jordan, that already have an established presence in target markets. However, unlocking competitiveness requires a thorough documentation of the demand- and supply-side constraints (and broader industry issues). Section 6 explores these and also documents COVID-19 related opportunities for Pakistan. Recommendations pertaining to the value chain to unlock the productivity of firms, strengthen global competitiveness, and achieve export potential are presented in Section 7. A more time-bound and streamlined view of the same is outlined in a medium-term export development strategy.

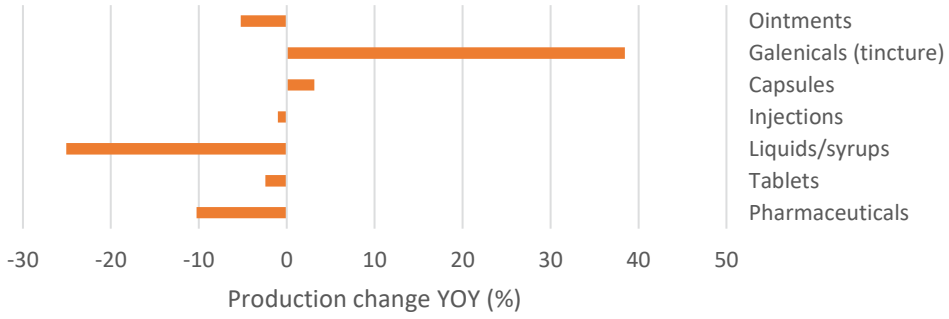
CHAPTER 2

Introduction: Overview of the Pharmaceutical Sector

This introductory section outlines the sector diagnostics and export trends of the pharmaceutical sector of Pakistan. The first sub-section provides a structure of the industry which includes number and types of firms, total production, employment, associations, public sector entities linked with the sector, and technology in place (i.e., in terms of how far behind Pakistan is from the global manufacturing technology frontier). It explores the nature of firm linkages, for e.g., local producer–local seller, local producer–exporter, or MNC-mediated firm networks. Moreover, the section looks at domestic scale and international competitiveness vis-à-vis other key industrial sectors, using relative size of sectors and trade competitiveness. At the same time, a global comparison is made with benchmark countries to contextualize our trade performance globally.

At the time of independence, Pakistan did not have any pharmaceutical manufacturing units. By 1960s this number started to increase with the entry of MNCs and some small manufacturers. However most pharmaceutical products were imported during the early days of this sector. The majority of Pakistan's pharmaceutical industry is concentrated towards drug formulation rather than innovation. As a formulation industry, its pharmaceutical products (HS30) mostly range from tablets, liquids & syrups, injections and capsules to tinctures and ointments. The last fiscal year has been tough on this sector, as can be seen in Figure 2 below, with only tinctures and capsules sub-sectors showing an increase in production.

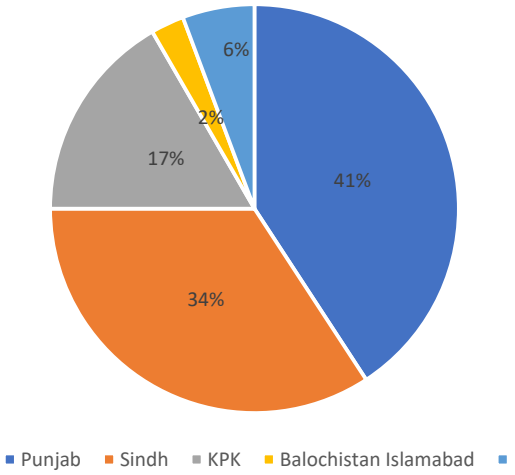
FIGURE 2 Production changes in Pakistan's Pharmaceutical Industry, FY20



Source: SBP Economic data. (2020).

Pakistan currently has around 750 pharmaceutical manufacturing units compared to 304 in 1999, increasing by more than two-fold (PRIME, 2017). However, the official national regulator, the Drug and Regulatory Authority of Pakistan (DRAP) contests this figure, putting it around 620 firms in November 2019, which may be construed as licensed firms. Industry posits this number at slightly above 700, highlighting the evident disparities across different stakeholders (Dawani and Syed, 2019). Around 10 firms are subsidiaries of MNCs, with this number declining from 17 subsidiaries in the mid-2000s.[21] Production is concentrated in the North and South industrial hubs, with most establishments concentrated in Punjab and Sindh, as evident from Figure 3 below.

FIGURE 3 Geographical spread of pharmaceutical establishments

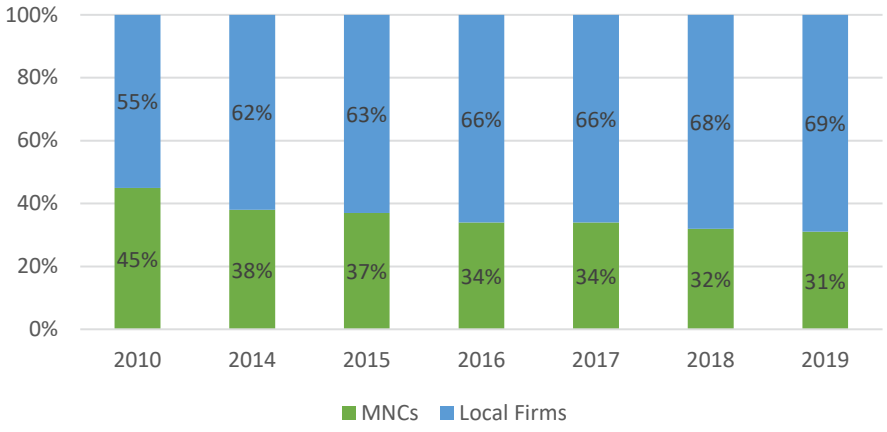


Source: CMI 2005-06

2.1 Market structure

The industry has historically been split between MNCs and local manufacturers, with the former occupying 60 per cent of the market share as of 2010. However, this number has decreased since then from 38 to 22, shrinking the MNC's share of the market to 40 per cent. The majority of pharmaceutical industrial plants are in Punjab (Lahore) and Karachi as seen in Figure 4.

FIGURE 4 Composition by market shares in terms of sales value (per cent)



Source: PACRA, May 2018. Accessed at https://www.pacra.com.pk/uploads/doc_report/PharmaSector_May18.pdf

21 Yusuf, S. (2020). Pharmaceutical Industry: Global trends and local development. Background note for IGC Sector studies.

The market structure for the pharmaceutical industry is also skewed: the top 25 firms occupy 62.6 per cent of the market share, the top 50 firms have 80 per cent of the market share and the top 100 firms command 97 per cent of the market share. This leaves more than 650 small and medium sized firms competing for the remaining 3 per cent of the market.[22] Per the industry, the market is over-saturated. 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. Firms contend that instead of running a forward-looking business enterprise, they are focused on survival: carving out profits on a daily basis by producing a larger menu of less profitable products. This constant juggling between different product segments leaves them little to no time in terms of professional business management and planning.

Table 1 lists the top 10 pharmaceutical firms in Pakistan in 2019.[23] These top 10 per cent of the firms (that include both MNCs and local firms) have 46 per cent of the market share of the industry and are precisely those firms which have consolidated their product offerings and focused on long-term business planning. For example, GSK alone accounts for 7 per cent of total industry revenues, while GETZ Pharma individually exports roughly between USD 50-70 million in any year.

TABLE 1 Top 10 Pharmaceutical Firms in Pakistan

Rank	Name	Type	Listed or not
1	GlaxoSmithKline Pakistan Limited	MNC	Listed
2	Getz Pharma (Private) Limited	National	Unlisted
3	Sami Pharmaceuticals (Private) Limited	National	Unlisted
4	Abbott Laboratories (Pakistan) Limited	MNC	Listed
5	Martin Dow Pharmaceuticals (Pakistan) Limited	National	Unlisted
6	The Searle Company Limited	National	Listed
7	Sano Aventis Pakistan Limited	MNC	Listed
8	OBS Pakistan (Private) Limited	National	Unlisted
9	GSK Consumer Healthcare Pakistan Limited	MNC	Unlisted
10	Hilton Pharma (Private) Limited	National	Unlisted

Source: Author compilation

There are limited local linkages between firms for e.g., local producer–local seller, local producer–exporter, or MNC-mediated firm networks. An important reason for this divide is the diverse quality of drugs produced. MNCs primarily focus their production on originator drugs developed using their own Research & Development (R&D) efforts, secured by a patent. Conversely, smaller firms save on these R&D costs and produce branded generics (copies of synthetic drugs that are therapeutically equivalent to brand name drugs). These firms often compete against each other on price and produce in bulk for immediate local wholesale markets. With toll/contract manufacturing largely discouraged through government policy, there is little scope for local synergies between firms. At the same time, some larger companies (such as Remington Pharmaceuticals) are grooming larger local players to reach global standards.

By and large, most big firms—due to the vast difference in sizes and resulting knowledge—utilize their own R&D to develop originator drugs secured using patents. Large firms also tend to follow certain pre-conditions or 'Good Manufacturing Practices' (GMPs) that ensure resultant drugs are of good quality. Conversely, local smaller firms operating on a much smaller scale focus production on generic drugs sold as branded generics (using molecule names). In Pakistan, these locally produced generic, non-patent drugs compete not only on

22 PACRA, A, April 2020. Accessed at https://www.pacra.com.pk/uploads/doc_report/SECTOR per cent20STUDY-Pharmaceutical per cent20APRIL per cent202020 per cent20Kanwal_1589554722.pdf

23 http://www.pacra.com.pk/uploads/doc_report/PharmaSector per cent20- per cent2029Apr19.pdf

price but also on their brand and reputation. Smaller firms also utilize production facilities of larger firms to process raw materials or semi-finished goods. Such drugs are then re-packaged and subsequently sold under their own brand names. Similarly, smaller firms often partner with larger firms to place consolidated orders in bulk for importing Active Pharmaceutical Ingredients (APIs) and save on shipping costs.

Most small pharmaceutical firms are engaged in compounding and packaging medication, producing well below capacity. A consolidation of the sector could be part of the transition to a market with a few larger firms that can produce generics in scale, do contract production, and raise exports, while a smaller number of SMEs focus on domestic sales.

2.2 Economic contribution and performance

The pharmaceutical sector in Pakistan is estimated to employ around 90,000 workers directly and 150,000 indirectly.[24] The sector meets 80 per cent of domestic demand, hence there is a sizeable contribution to the economy through import substitution (Table 2). In 2019, the size of the sector in Pakistan was estimated to be around PKR 423 billion or USD 3.2 billion.[25] Including institutional sales, industry posits that this sector easily becomes a retail market worth USD 4 billion. It exported USD 218 million in 2019. In global terms, Pakistan's branded generics account for a small fraction of the global USD 700 billion branded generics market. Pakistan makes 80 per cent of its output in its final dosage form whereas the remaining 20 per cent of the formulations are imported.[26] It is largely dependent on imported inputs (95 per cent of raw materials) for production of goods. Net FDI in the sector for July-November FY 20 was estimated at USD 25.6 million but is projected to decline to USD 9 million over July-November FY21. The highest FDI the sector witnessed was in 2008 (USD 46.2 million). This is consistent with the continuous divestment in the sector from MNCs (see below). Pakistan occupies only 0.4 per cent of the global pharmaceutical market, that had a value of USD 1.3 trillion in 2019, and was projected to grow annually at 4-5 per cent during the early part of this decade.[27] US and Europe lead the global market, although several developing countries such as India and China have depicted strong growth trajectories over the last few years, as will be discussed below.

TABLE 2 Contribution of pharmaceuticals to Pakistan's Economy

Variable	Contribution to National Economy
Share in GDP	1 per cent
Employment (direct and indirect)	240,000
Share in national exports	0.9 per cent
Cost savings due to import substitution	USD 2 bn
Share in FDI	2.8 per cent* (net FDI USD 25.6 mn)
Net indirect taxes (2005-06)	Rs. 1.5 bn
Share in industrial value addition	4.2 per cent*

Notes: This is net inflow of FDI in pharmaceuticals and OTC products for FY Jul-Nov 20, from SBP data. https://www.sbp.org.pk/ecodata/Netinflow.pdf

Source: Pakistan Economic Survey 2019-20, State Bank of Pakistan

24 Ahmed and Batool (2017)

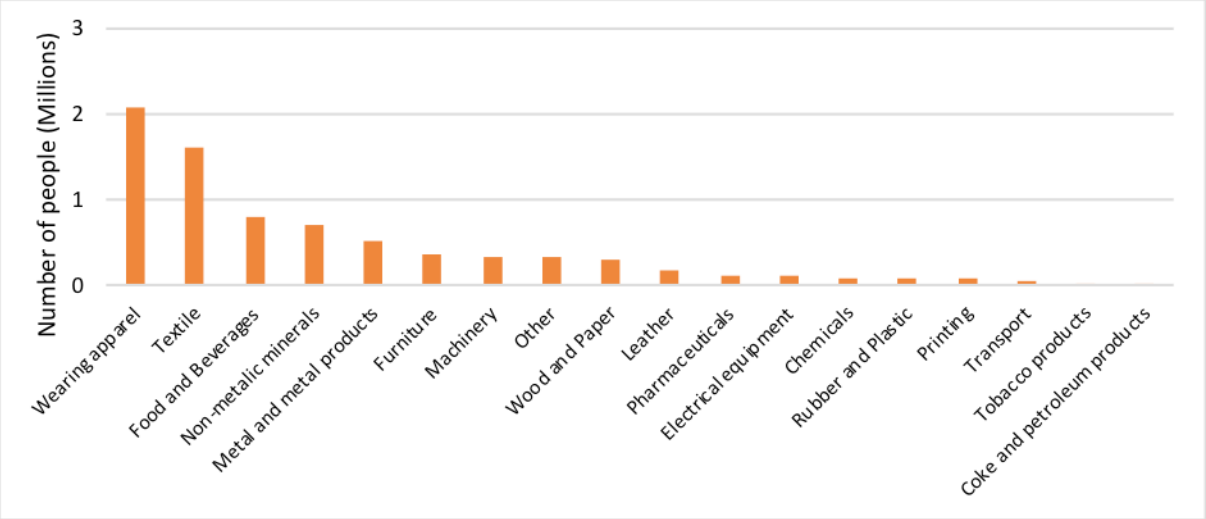
25 PACRA, April 2020. Accessed at https://www.pacra.com.pk/uploads/doc_report/SECTOR per cent20STUDY-Pharmaceutical per cent20APRIL per cent202020 per cent20Kanwal_1589554722.pdf

26 CDPR (2020). Political Economy Analysis (Phase-2) for DFID Pakistan's Real Economy Programme

27 Yusuf, S. (2020)

The sector contributed around one per cent to Pakistan's GDP in 2019. The 5-year compound annual growth rate (CAGR) was 10 to 12 per cent between 2012 and 2017, while IMS/IQVIA (a global healthcare data company) has categorized Pakistan to be a 'pharmerging' country, forecasting it to have robust future growth potential, as it grew by 13.2 per cent over 2018-19.[28] The sector is the 11th largest industrial employer as per the latest Labour Force Survey (see Figure 5 below). However, despite its size and potential, this industry in Pakistan has not realized significant growth and dynamism. In fact, the industry itself claims that barring one to two players, historically growth in the sector has not been strategically designed and was largely an outcome of market conditions and a favourable exchange rate regime in the past. In 2019, exports stood at USD 218 million. This is approximately a third of Jordan's exports of USD 637 million, even though Jordan has a population of only 9 million while India exported pharmaceuticals worth USD 16 billion in 2019.[29]

FIGURE 5 Employment in Major Industries in Pakistan 2014-15



Source: Labour Force Survey 2014-15

Strict regulatory requirements for exportable pharmaceutical goods have also shaped the industry's performance in Pakistan. Approval by the US Food and Drug Administration (USFDA) is considered as the global quality yardstick for producing pharmaceuticals. However, Pakistan does not have any manufacturing unit that is USFDA approved, whereas in India and Bangladesh this number is around 200 and 4 respectively.[30] This effectively precludes Pakistan from developed country export markets with Strict Regulatory Authorities. Due to poor implementation of international standards, Pakistani pharmaceutical exports are mostly oriented towards the less and semi-regulated markets of Asia and Africa. Discussions with industry players reveal issues of both capability and financial viability in getting their units USFDA approved, as discussed in Section 6.

28 https://www.pacra.com.pk/uploads/doc_report/SECTOR per cent20STUDY-Pharmaceutical per cent20APRIL per cent202020 per cent20Kanwal _1589554722.pdf

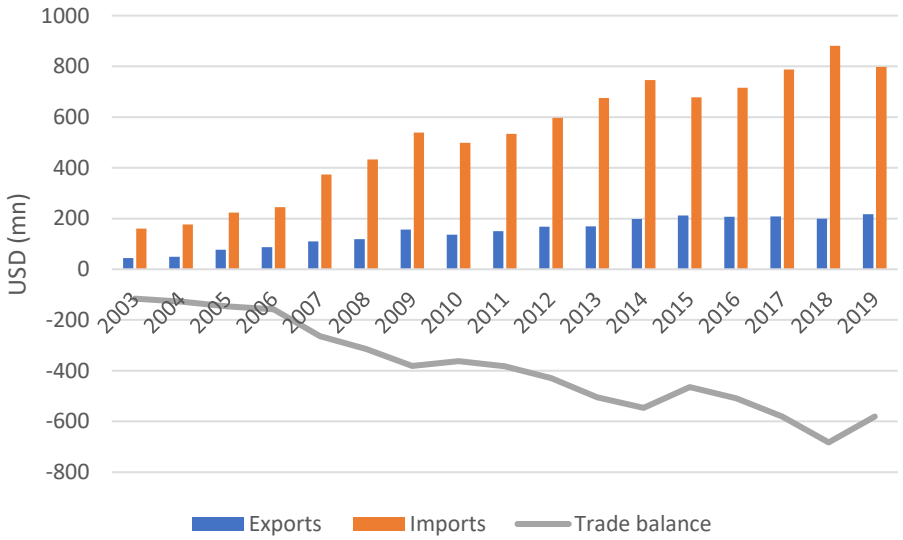
29 UN COMTRADE. Accessed October 2020. Unless otherwise mentioned, all trade data is from UN COMTRADE.

30 Dawani and Sayeed (2019)

2.3 Trade Performance

On the international front, Pakistan is a net importer of pharmaceutical drugs since inception, with imports valued at USD 798 million vis-à-vis exports of USD 218 million in 2019, leaving a deficit of USD 580 million. Figure 6 provides a snapshot of the export and import trajectory of pharmaceuticals in Pakistan.

FIGURE 6 Trade performance of the sector (2009-19)



Source: ITC Trade Map

Figure 6 depicts a rising deficit over the years, with imports increasing significantly but exports rising only marginally. In 2019, pharmaceutical exports contributed less than one per cent to Pakistan's total exports. Recently, the Adviser to the Prime Minister on Commerce has committed that sectoral impediments will be eased so that pharmaceutical exports can reach USD 3 billion especially by targeting African markets that imported USD 16.9 billion worth of HS 30 in 2019 (Box 1).[31] A recent study estimates that in Africa, the sector has the 8th highest untapped potential out of Pakistan's top export categories in value terms, using indicative trade potential and the gravity model approach.[32] Yet no structured plan to realize this has been revealed.[33]

Box 1: Pharmaceutical Export Promotion Committee 2019[33]

The Ministry of National Health, Services, Regulations and Coordination formed the committee, co-chaired by Special Adviser to Prime Minister on Health and Adviser on Commerce. The committee is tasked to review the progress of export of pharmaceutical products, suggest measures for achieving the growth targets and facilitate the production and export of active pharmaceutical ingredients in the country. The export promotion committee will also make appropriate policy recommendations for boosting exports, examine the problems being faced by the exporters of pharmaceutical products in consultation with the stakeholders, prepare short-, medium- and long-term action plans, and identify policy and procedural bottlenecks and suggest ways to eliminate them at all levels. Three is little clarity on how this will be achieved as no strategy or action plan has been revealed.

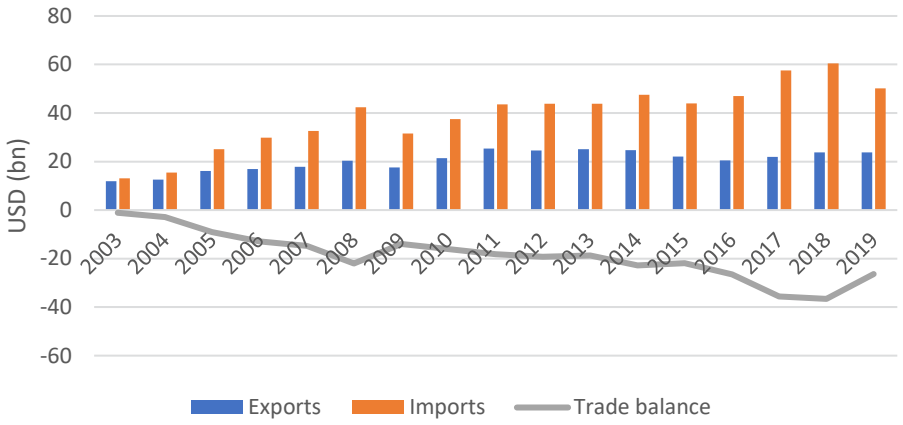
31 https://www.thenews.com.pk/print/616540-govt-envisages-3-billion-in-exports-from-pharma-sector

32 MoC. (2020). Section 5. Pakistan export potential of goods export to Africa. Available at http://www.commerce.gov.pk/wp-content/uploads/2020/10/Pakistan-Export-Potentials-of-Goods-Export-to-Africa.pdf

33 https://www.thenews.com.pk/print/539828-body-set-up-to-promote-pharma-exports

This is however largely in line with Pakistan's overall trade performance (Figure 7), with trade deficits on the rise since 2005. Exports as a share of GDP (not pictured) have also halved over the last decade, from 16.to 8.5 per cent.[34]

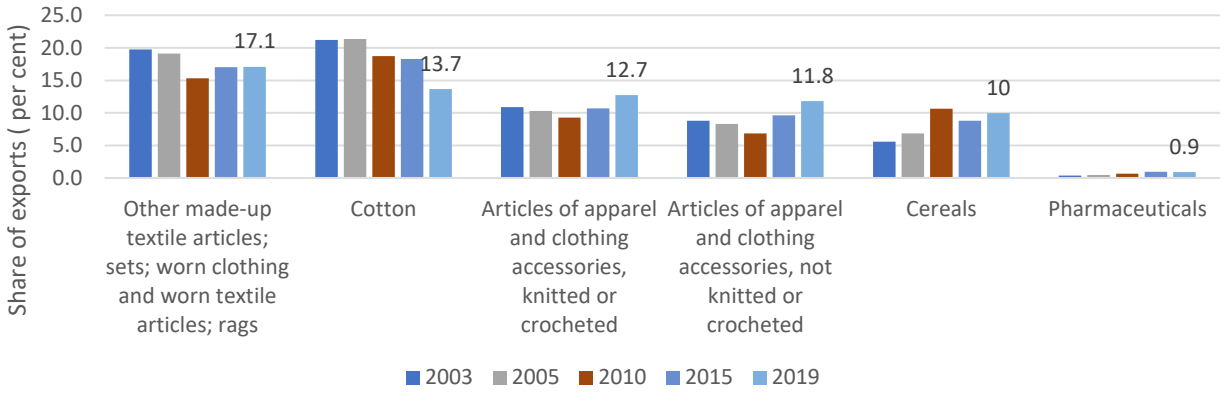
FIGURE 7 Pakistan's overall trade position, 2003-19



Source: ITC TradeMap

This decline can be explained by an export offering that is of low value and covers a narrow economic resource-driven base—the economic complexity of Pakistan's export basket has fallen by 20 places over the last 10 years.[35] According to the Economic Complexity Index, Pakistan ranks 99th out of 133 countries and in the last 5 years, has fallen 3 places, indicating that its exports have become relatively less complex. India's and Bangladesh's export complexity has risen by 10 and 2 positions, respectively over the same time. This shows that Pakistan has been unable to diversify its exports into higher-value added goods such as pharmaceuticals. Its top products continue to be restricted to textiles and agriculture products, which are low complexity products (see Figure 8 below).

FIGURE 8 Pakistan's top five exports vs pharmaceuticals, 2003-2019



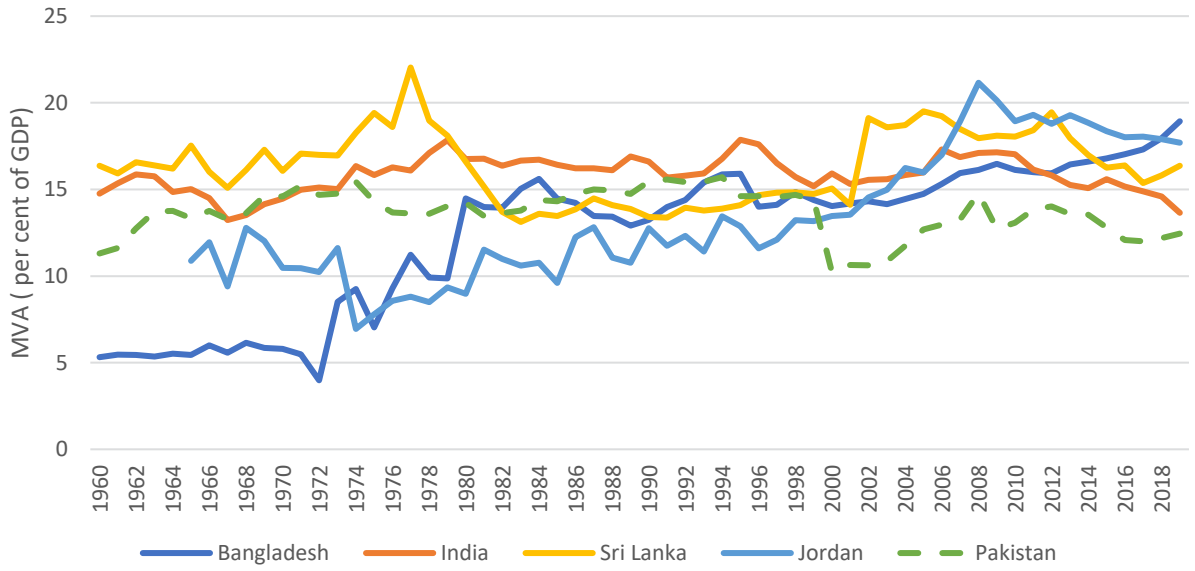
Source: ITC TradeMap

Unsurprisingly then, manufacturing value-added (shown in Figure 9 below) in Pakistan is 12.5 per cent of its GDP in 2019, not much different from 1960 when it was 11.3 per cent. This is an indication of premature deindustrialization in the economy.

34 WDI. Trade indicators.

35 Harvard Atlas of Economic Complexity

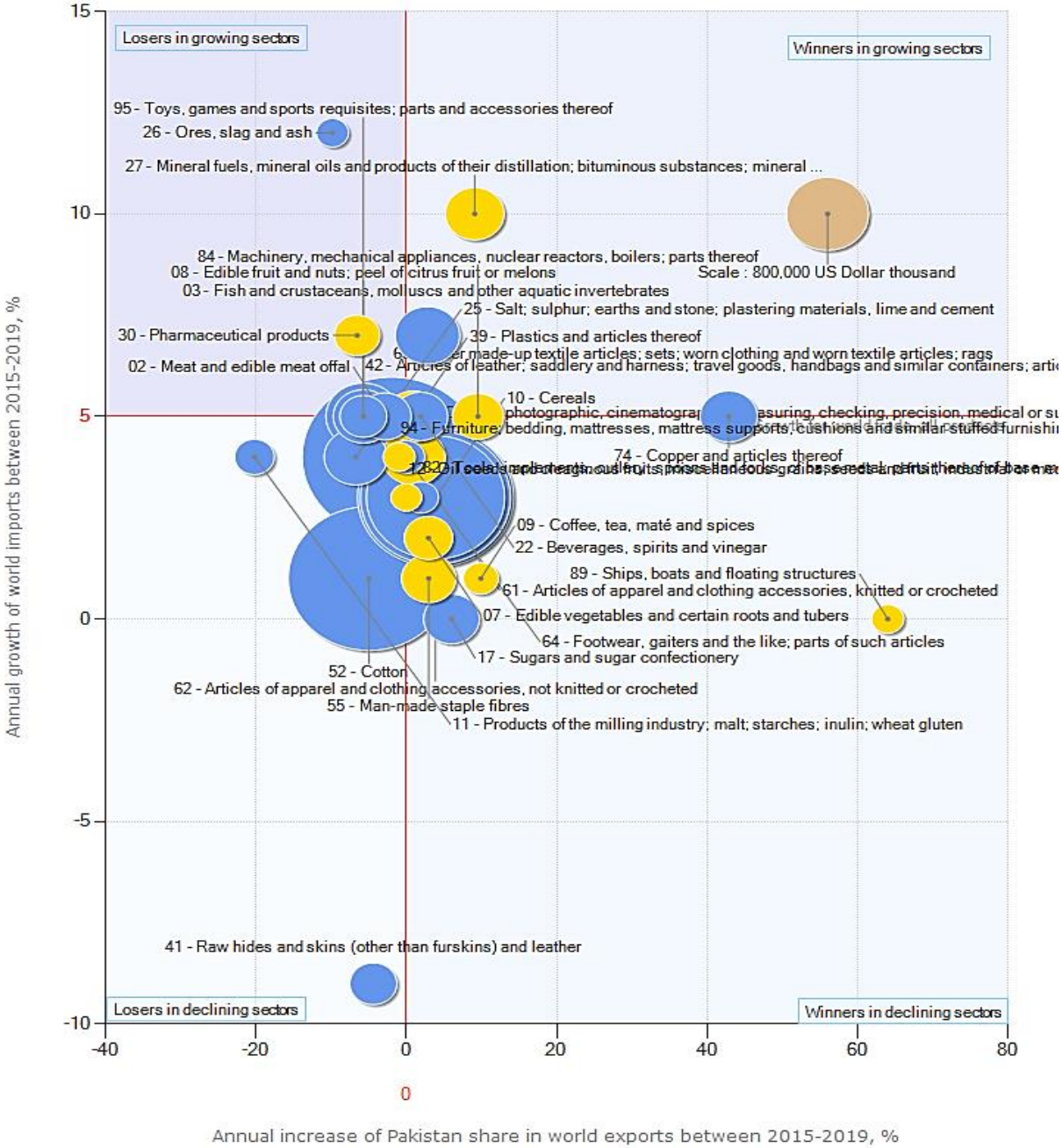
FIGURE 9 Manufacturing value-added (per cent of GDP), 1960-2019



Source: World Development Indicators

As a result, Pakistan is losing out in some of the most lucrative global export segments, as can be seen in Figure 10 below. Two trends emerge: Pakistan is exporting to declining markets as can be seen by the clustering of our HS 2-digit export categories in markets that are growing below 5 per cent per annum over the last five years (the cut-off is 5 per cent, since global exports have grown at 5 per cent per annum over 2015-19). Secondly, we are losing export share in growing markets. This also holds true for HS 30, pharmaceuticals, a global export market of USD 616 billion, growing in export value terms at 6 per cent per annum over 2015-19. Demand for HS 30 (measured by growth in world import values) has similarly risen by 7 per cent per annum over 2015-19. This shows that there is room for more players with a high demand for pharmaceutical products. However, as discussed below, Pakistan's annual export growth rate over the last 5 years remained stagnant at 0 per cent, making it a loser in a growing global export segment.

FIGURE 10 Growth of national supply and demand for HS30 (2019)



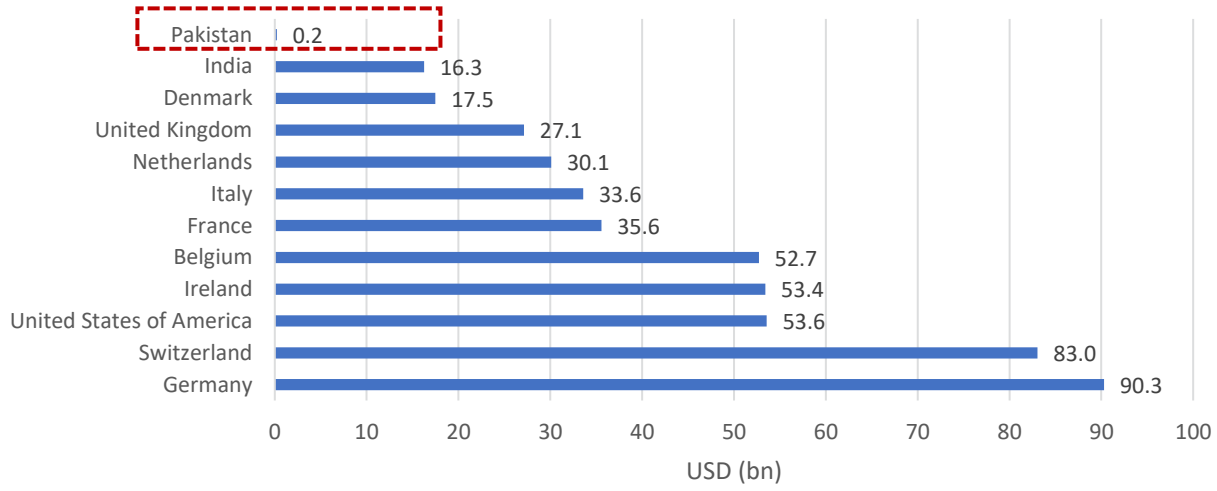
Note: Yellow bubbles show Pakistan is a net importer for that category, while blue bubbles show that it is a net exporter. The bubble size is proprotional to export value.

Source: ITC TradeMap

Relative to comparator countries, Pakistan grossly underperforms. While India ranks 11th globally, ahead of China (15th), and is one of the few lower middle income countries at the top, Pakistan is ranked 62nd in export value terms (Figure 11). European countries formed the highest world export share, occupying the top 5 spots and contributing approximately 48.8 per cent to the global pharmaceutical export market. Switzerland, Germany, and India also registered the highest surpluses for international pharmaceutical trade. In terms of growth numbers, Denmark (up 485.1 per cent), Netherlands (up 60 per cent), Italy (up 47.3 per cent) and Switzerland (up 38.2 per cent) are the largest growing exporters since 2015.[36]

36 http://www.worldstopexports.com/drugs-medicine-exports-country/

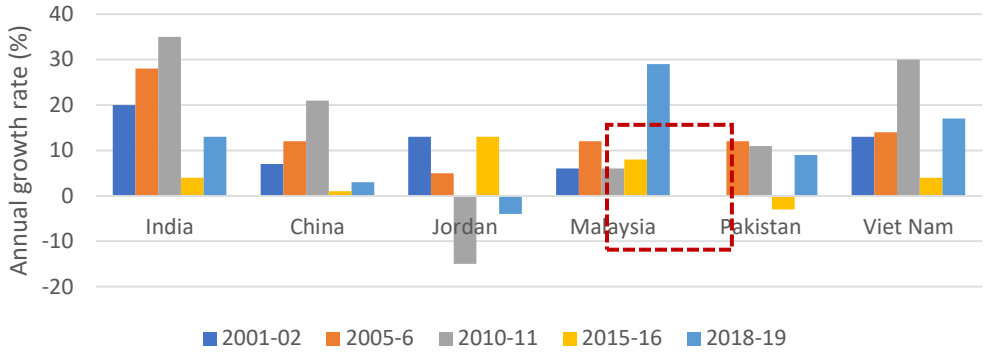
FIGURE 11 Top 10 global exporters of HS 30, 2019



Source: ITC TradeMap

India and China are included as success stories that managed to penetrate the global market over the last 20 years, whereas in value terms, Jordan (ranked 41st), Malaysia (ranked 55th) and Vietnam (ranked 63rd) are comparator countries that have shown consistent growth performance, despite their small size. Of this group, Pakistan shows the lowest growth over the last 20 years (Figure 12).

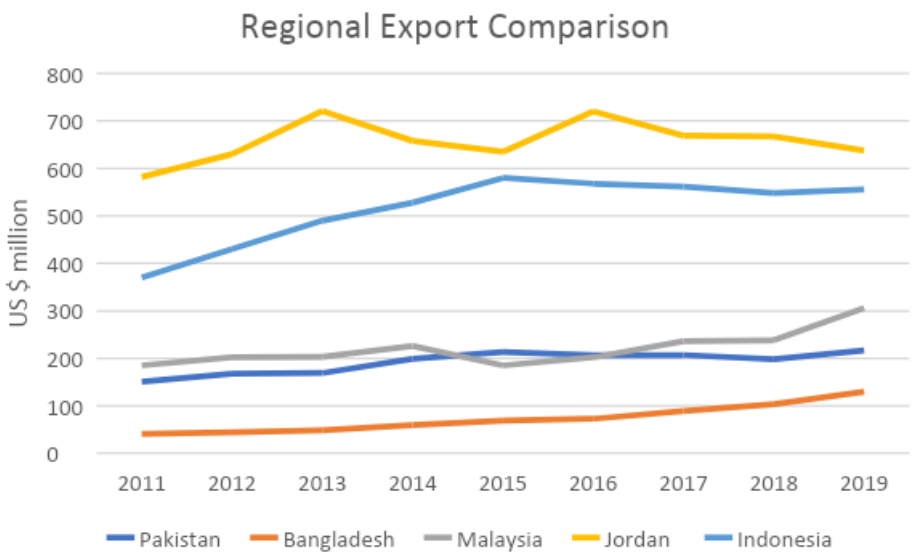
FIGURE 12 Annual growth rates of HS 30 exports for benchmark countries



Source: ITC TradeMap

Pakistan's standing in regional markets over the last 10 years shown in Figure 13, showcases just how quickly this export sector can change.

FIGURE 13 Regional export performance



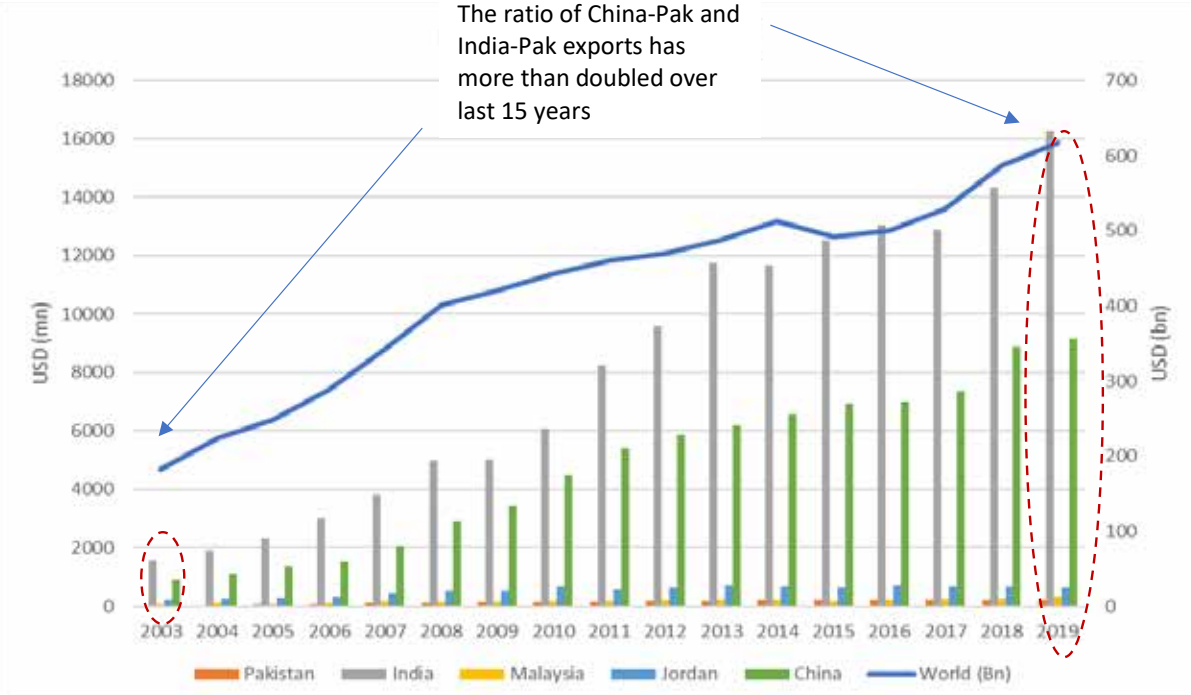
Source: UN Comtrade

Malaysia which started out at approximately the same level as Pakistan in terms of export values in 2011, has since grown significantly, especially over the last 5 years. Bangladesh has also depicted robust growth trends with a CAGR of 15.6 per cent over the past 5 years, catching up to Pakistan (ranking 69th in 2019).[37] The policies followed by both countries, among other realistic benchmark countries, are investigated in sections 3 and 6 to determine how they achieved this remarkable growth.

This has resulted in a widening export differential vis-à-vis these countries, over the last 20 years (Figure 14). With stakeholders claiming that regulations, compliances and standards are only getting more stringent with time, a pharmaceutical sector policy is urgently required by the Ministry of Commerce. Although support for the sector is fragmented across the Strategic Trade Policy 2015-18, the Look Africa Policy Initiative 2020, Pakistan Vision 2025 and other policy documents, a structured, long-term, holistic evidence-based sector growth plan is needed for this critical and strategic sector. This sector plan must be implemented using an action plan. As starkly highlighted by the COVID-19 pandemic that began in mid-2020, a sustainable, vibrant and responsive pharmaceutical sector is a national security imperative.

37 http://www.pharmabiz.com/NewsDetails.aspx?aid=118628&sid=21

FIGURE 14 Exports of benchmark countries 2003-2018



Source: ITC TradeMap

2.4 Zooming in on pharmaceuticals

Pharmaceuticals ranked as the 22nd largest export sector of Pakistan in 2019, with a world export share of 0.4 per cent, and a world export ranking of 62. While globally the sector grew by 6 per cent, Pakistan could not grow its world export share, as its export growth rate over the last 5 years was 0 per cent. In comparison with leading textile and related sectors, which accounted for 55.5 per cent of total world exports in 2019 (HS 63, 52, 61 and 62), pharmaceuticals ranked much lower than other primary export categories such as rice, leather goods, fish, fruits and nuts as well as minerals (Table 3). Surgical and medical equipment is the only diversified and value-added export in the top 10 categories.

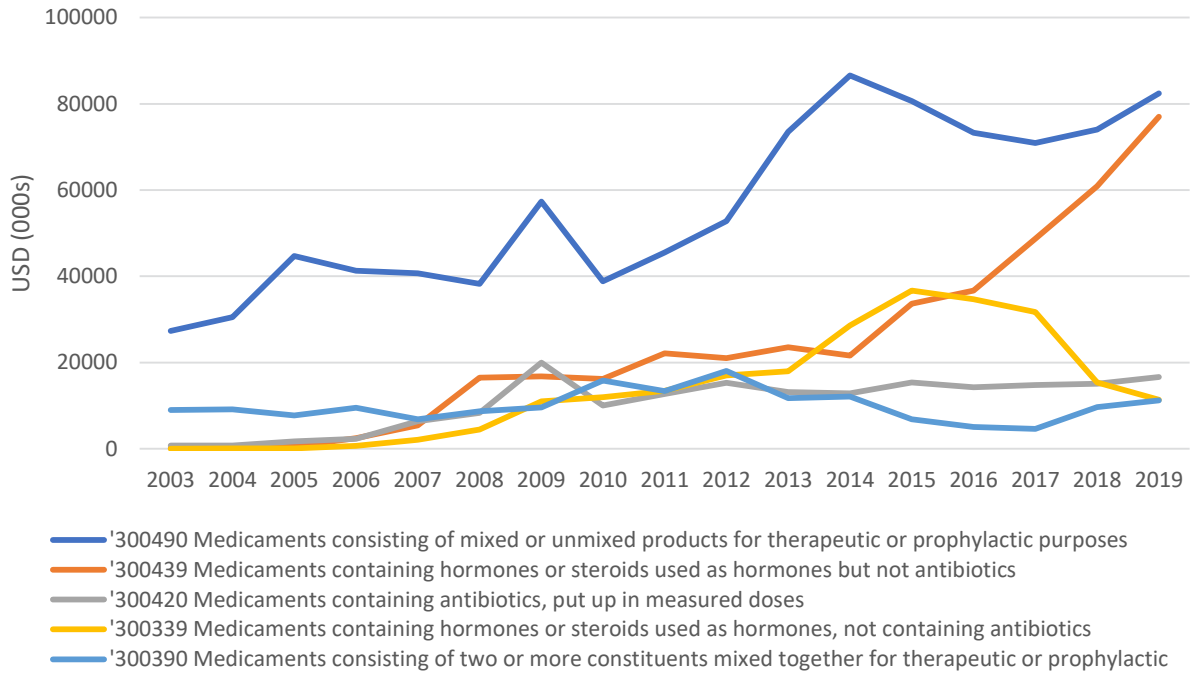
TABLE 3 Top 10 export categories of Pakistan, HS 2-digit level (2019)

Code	Product label	Exports (USD bn)	Trade balance (USD bn)	Annual growth in exp value 2015-2019 (%, p.a.)	Annual growth in exp value 2018-2019 (%, p.a.)	Annual growth of world imports between 2015-2019 (%, p.a.)	Share in world exports (%)	Ranking in world exports
'63	Other made-up textile articles; sets; worn clothing and worn textile articles; rags	4.1	3.8	2	0	4	6.1	3
'52	Cotton	3.3	2.4	-4	-8	1	5.8	4
'61	Articles of apparel and clothing accessories, knitted or crocheted	3.0	3.0	7	5	3	1.3	18
'62	Articles of apparel and clothing accessories, not knitted or crocheted	2.8	2.8	7	8	3	1.2	17
'10	Cereals	2.4	2.3	7	2	3	2.1	13
'42	Articles of leather; saddlery and harness; travel goods, handbags and similar containers; articles ...	0.6	0.6	-1	-5	5	0.7	19
'03	Fish and crustaceans, molluscs and other aquatic invertebrates	0.5	0.5	10	10	7	0.4	46
'90	Optical, photographic, cinematographic, measuring, checking, precision, medical or surgical	0.5	-0.3	5	11	4	0.1	51
'25	Salt; sulphur; earths and stone; plastering materials, lime and cement	0.4	0.3	-3	-4	4	1	31
'08	Edible fruit and nuts; peel of citrus fruit or melons	0.4	0.2	-1	-8	5	0.3	42
'30	Pharmaceutical products	0.2	-0.6	0	9	7	0	62
	All products	23.8	-26.3	3	0	5	0.1	68

Source: ITC TradeMap

Pakistan's main exports within the sector are HS 300490 (medicaments of mixed/unmixed products for therapeutic/prophylactic purposes), HS 300439 (medicaments containing hormones/steroids used as hormones but not antibiotics), and HS 300420 (medicaments containing antibiotics). Together, these three categories comprise 80.7 per cent of total pharmaceutical exports in 2019, indicating the narrow export base of the sector). Unfortunately, UN Comtrade the main data source (used in ITC TradeMap), does not differentiate between branded or generics, so that distinction cannot be made in the data, although it stands to reason that these are mostly generics, as verified by exporting firms during consultations.

FIGURE 15 Top five exports of Pakistan in HS 30 (at HS 6-digit level)



Source: ITC TradeMap

The export performance within these categories is mixed, with half of the top 10 categories showing negative annual export growth over 2015-19 (See Table 4). Similarly, HS 300490 is a very competitive segment, since despite being Pakistan's top export, Pakistan's share in world exports is 0 per cent. However, Pakistan performs well in medicaments containing hormones/steroids (excl. corticosteroids and insulins), and more recently, in medicaments containing antibiotics (excl. pencillins and streptomycins), as well as non-antibiotic medicaments containing mixed or unmixed products for therapeutic or prophylactic purposes, put up in measured doses.

TABLE 4 Top 10 exported categories by Pakistan in HS 30, 2019 (USD millions), at HS 6-digit level

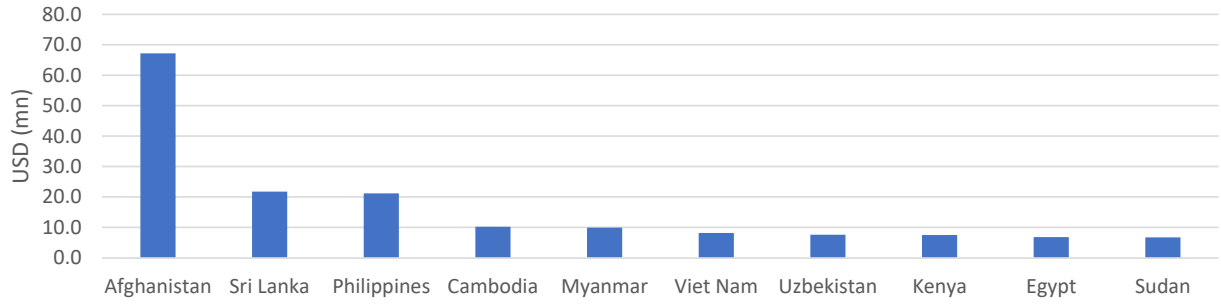
Code	Product label	Exports (USD mn)	Annual growth in value between 2015-2019 (%.)	Annual growth in exp value 2018-2019 (%,p.a.)	Annual growth world imports 2015-2019 (%, p.a.)	Share world exports (%)	Rank in world exports
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, put up in measured doses, not antibiotics, medicines with hormones/steroids, medicaments w/t alkaloids and medicaments containing provitamins, vitamins used as vitamins	82.4	1	11	3	0	70
300439	Medicaments containing hormones or steroids used as hormones but not antibiotics (excl corticosteroids and insulins)	77.0	24	27	9	0.3	21
300420	Medicaments containing antibiotics, put up in measured doses (excl. penicillins and streptomycins)	16.6	2	10	5	0.1	48
300339	Medicaments containing hormones or steroids used as hormones, not containing antibiotics (excl insulin)	11.4	-27	-26	-16	2	13
300390	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic use, not in measured doses (excl antibiotics containing hormones used as hormones)	11.3	18	17	13	0.2	37
300410	Medicaments containing penicillins or derivatives thereof with a penicillanic acid structure, put up in measured doses, in forms or packings for retail use	9.8	0	0	-1	0.3	32
300590	Wadding, gauze, bandages and the like, e.g. dressings, adhesive plasters, poultices, impregnated	3.0	-21	168	3	0.1	48
300450	Medicaments containing provitamins, vitamins, incl. natural concentrates and derivatives thereof	2.5	-13	10	1	0.1	68
300510	Adhesive dressings and other articles having an adhesive layer, impregnated or covered, for medical, surgical, dental use	1.6	-24	-39	6	0	50
300310	Medicaments containing penicillins/ derivatives, or streptomycins/derivatives, not in measured doses or put up for retail use	1.2	-44	-84	-5	0.4	17

Source: ITC TradeMap

The main export destinations of HS 30 in 2019 include neighbours, Southeast Asian countries, and a few African countries, with little diversification over the last 15 years. Afghanistan has by far remained the biggest export destination for Pakistan over the years, accounting for USD 67 million exports in 2019. Most firms operating in Peshawar, Khyber Pakhtunkhwa close to the Afghan border have oriented their production towards Afghanistan and further facilitate other firms within Pakistan in sending products to Afghanistan.[38] Due to a high level of informal trade, actual export figures would be larger than reported. Sri Lanka and the Philippines follow Afghanistan as the other top export destinations, at USD 22 million and USD 21 million, respectively. Figure 16 highlights Pakistan's top 10 pharmaceutical export countries.

38 PRIME (2017)

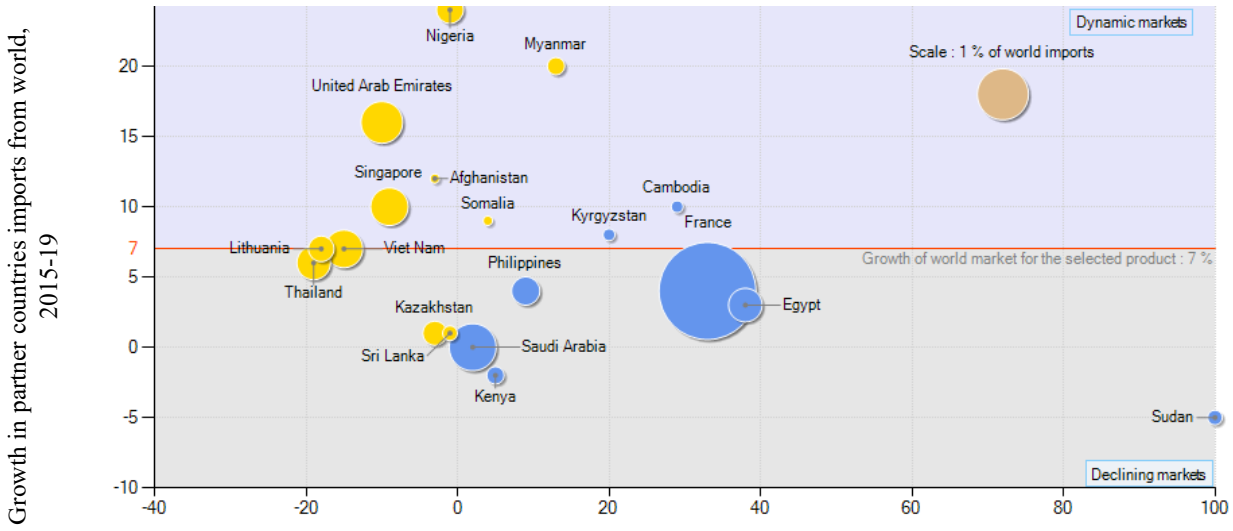
FIGURE 16 Top 10 export destinations for HS 30 (2019)



Source: UN Comtrade

There appears to be untapped trade potential with many of our top 10 import partners, as their import growth from the world exceeds the growth in exports to those markets (yellow bubbles in Figure 17). Secondly, dynamic markets are defined as those where growth in imports from the world exceed 7 per cent (the world market growth rate for HS 30 over 2015-19). Luckily for Pakistan, many of our top 10 export markets are dynamic, whereas new markets such as the UAE, Singapore, China, Russia, and South Korea should be explored.

FIGURE 17 Growth in demand for Pak HS 30 exports, 2019



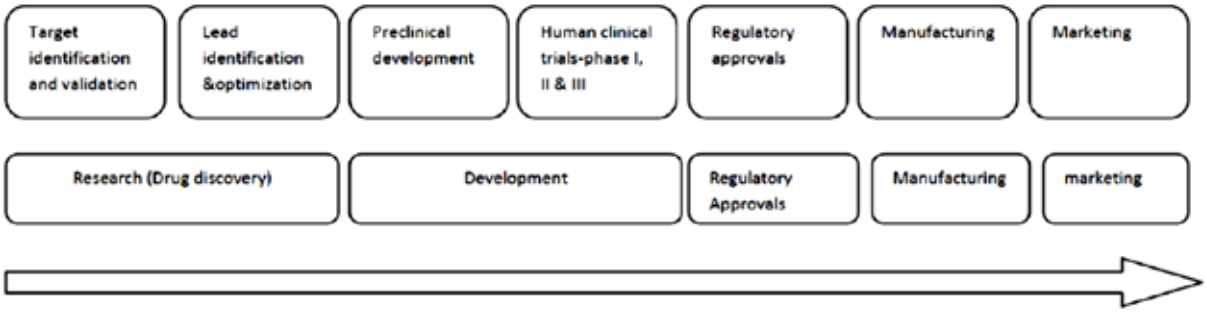
Note: Blue bubbles represent products where Pak's export growth to partner>partner import growth from world
Yellow bubbles represent products where Pak's exports growth to partner< partner import growth from world
The bubble size is proportional to the share in world imports of partner countries for the selected countries

Source: ITC Trade Map

2.5 State of technology in the sector

The pharmaceutical industry is characterized by very high levels of industrial research and technology, and the rapid export growth of our comparator countries stems in large part from policies that increased the pace and transfer of scientific knowledge. The sector is driven by basic and applied research critical to the development cycle of a product: drug discovery, development, clinical testing, final approval, and marketing (Figure 18).

FIGURE 18 Pharmaceutical innovation value chain



Source: Raja and Sambandan (2015). Open Innovation in Pharmaceutical Industry: A case study of Eli Lilly. https://www.diva-portal.org/smash/get/diva2:824465/FULLTEXT01.pdf

Although becoming increasingly complex, the basic process remains the same for new drugs. A lengthy and expensive process, only 1 in 10 molecules (the main therapeutic ingredient in a drug) pass pre-clinical screening. Most of the current big pharmaceutical companies broke into this market through certification for a first-in-class (greater effectiveness than others) drug that became a blockbuster (an extremely popular drug that generates annual sales of at least USD 1 billion for the company that sells it). The current landscape in Pakistan is not conducive to research and innovation: no patent protection, absence of high-tech clusters and no research synergies between firms, universities and public institutions, absence of a financing system that pays for innovation and little regulatory pathways that could spur innovation.

2.5.1 Global trends

Demand patterns are shifting: an ageing population in developed countries has shifted the disease burden towards chronic, non-communicable lifestyle diseases which require expensive, and in many cases, specialized therapies for orphan diseases.[39] This has shifted demand away from small molecules that are chemically synthesized and easier to produce, towards large molecules called biologics that are used to treat ailments with few therapeutic options.[40] They include vaccines, blood, blood components, gene therapy, tissue, and other proteins. As of 2020, seven out of the top 10 best-selling drugs in the world were biologics.[41] At the same time, increased life expectancy and literacy rates, along with rising incomes and better awareness of health-related issues have created greater demand for pharmaceutical products in developing countries. Emerging countries are replacing developed markets as key exporters, a trend likely to continue for the next few decades. China, India, Brazil and Russia are growing rapidly and expanding their market shares globally. At the same time, with rising incomes, collectively, these countries are also accounting for more of global pharmaceutical spending.

As a result, supply-side dynamics are also changing. Production of large molecules is complex, requiring more than 1000 steps. Developed country manufacturing is becoming more stream-lined and drug pipelines have shrunk to reduce costs and production times, with a focus on biologics and biosimilars (these are biologics made from living organisms that are similar to already existing approved drugs or "generics" of biologics).

39 That afflict less than 200,000 people in a country.

40 Large molecules (biologics) are proteins made in microorganism or other living cells using recombinant DNA technology, with a complex structure, that must be transfused or injected.

41 https://www.nuventra.com/resources/blog/small-molecules-versus-biologics/

This has led developed countries to shift production towards continuous manufacturing, integrated IT and manufacturing systems, focus on improved drug delivery systems, as well as alternative modes of production for vaccines. Meanwhile, this has created opportunities for developing countries to fill the gap for production of cost-efficient, competing small-molecule therapeutics, especially for high-quality me-too generics, super-generics, and simpler biologics like vaccines and antisera. Developing country diseases can easily be treated with small molecule drugs, often generics. Almost 90 per cent of drugs on the market in most developing countries are small molecules.

Insights from successful countries

China and India are the only low and middle-income countries engaged in R&D globally. Pakistan focuses mostly on copying innovator drugs, as costs of new drugs has risen to USD 2-3 billion on average, from USD 800 million to USD 1.3 billion.[42] With failure rates higher than ever, costs have risen to factor in failures and inflation. For this reason, Pakistani firms focus on mostly early generation blockbuster drugs, i.e., branded generics, or drugs that have gone off-patent. Once the drug goes off-patent after 17 years, its codified patent data is combined with knowledge accumulated over its lifespan, the compound is produced, and registration is secured through bioequivalence.

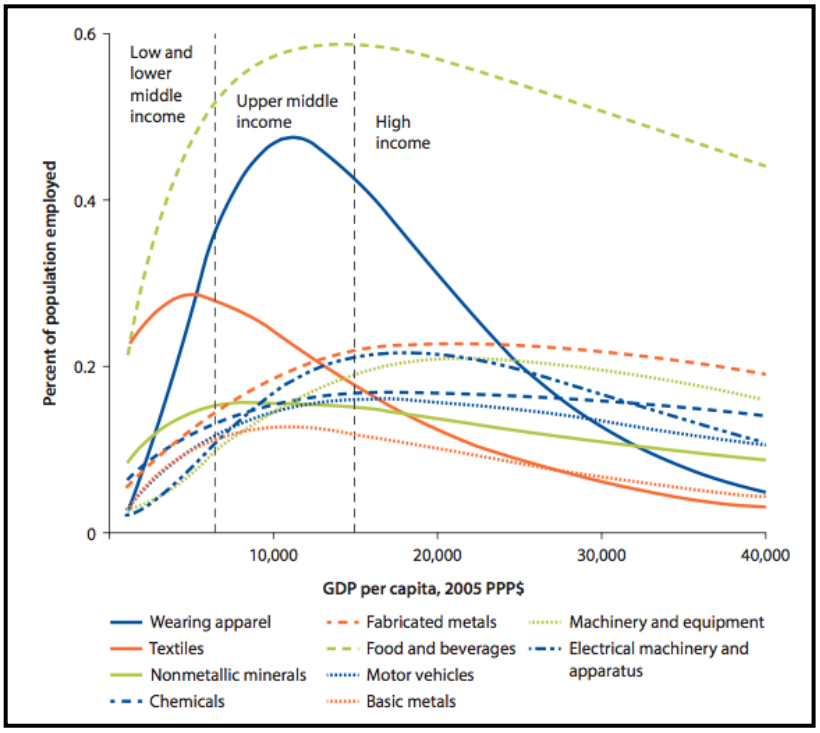
On the one hand these are lucrative products: major pharmaceutical firms have vacated this space as companies are reducing their drug pipelines for small molecule medicines (that can be orally ingested) to focus on applied research. Basic/upstream research has shifted out of the firm to the other two partners of the pharmaceutical research triad, i.e., universities and dedicated institutions. Leading firms are now focused on more profitable biologics (large molecules that are made from living cells), along with specialty drugs for cancer, neurological and psychological disorders that have limited generic equivalents (called biosimilars). The biopharmaceutical sector (vaccines, therapeutics, and diagnostics) can become an important growth driver, as the employment multiplier is also high, with each job in biopharmaceuticals creating five new jobs in other sectors.[43] This industry can be a growth driver that could allow lower middle-income countries like Pakistan to fast-track its growth process,[44] provided Pakistan can effectively occupy the space vacated by leading producers in the branded generics and biosimilars markets.

42 Yusuf, S. (2020)

43 Yusuf, S. (2020)

44 Lopez-Acevedo & Robertson (2016)

FIGURE 19 Pharmaceutical sector as an important employer for LDCs (1963-2007)



Source: Lopez-Acevedo et al., 2016, p. 20

On the other hand, simply importing 95 per cent of the raw material, compounding active ingredients with excipients, coating the pills, and packaging the drugs for the local market is not where the opportunity lies. Currently, the market scale is small, value addition in formulation is low and there are fewer jobs created. The big gains arise through cheaper drugs, new product offerings like vaccines, attracting foreign clients through contract manufacturing facilities and/or clinical trials called Contract Research and Manufacturing Services (CRAMs).[45] Contract manufacturing can begin immediately, as the government only has to revise its current policy (see section 5). Creating an API base would require a more structured strategy, that is given in sections 6 and 7.

Section 3 lays down a basic value chain for the sector based on primary and secondary research. This broader value chain was verified and refined through stakeholder consultations with both larger and smaller firms. To understand the overall structure and bottlenecks in the value chain of the pharmaceutical industry, it is important to compare with regional comparator countries that have grown their pharmaceutical exports tremendously over the last 10-15 years. Malaysia and Bangladesh prove to be good examples as shown by Figure 13. For example, Bangladesh exports are forecasted to reach USD 450 million by 2025. The main policies that have contributed to this success are discussed below.

45 https://www.grandviewresearch.com/industry-analysis/downstream-processing-market

CHAPTER 3

Value chain analysis

The pharmaceutical sector is quite complex and is represented through an overlay of direct (production) and indirect costs (development and regulatory). Value chain analysis done below includes a complete mapping of the process and documentation of all underlying costs (direct and indirect as well as explicit and implicit), differentiating by local versus MNC practices, where required. This is used to identify key gaps across the value chain and how they restrict competitiveness. Next, this value chain is benchmarked with a few regional comparator countries that have grown tremendously over the last 10-15 years. This allows identification of the key factors and policy lessons that have strengthened their global export positions. As provided below, the study develops a complete value chain for a typical product to understand the flow of costs and identify where efficiency gains are possible.

The pharmaceutical value chain can be broadly categorized into three major components: manufacturing, distribution and dispensing to the end user. The major costs incurred, and the value added can be summarized in Figure 20.[46]

FIGURE 20 Pharmaceutical Value Chain— Costs and Value Added

Source: Author compilation from various studies

The largest costs are incurred with drug discovery for originator companies, which involves a long process of identifying the correct molecules for treating certain diseases and testing them through clinical trials. Industry experts claim that it costs around USD 3 to 4 billion to introduce a new drug in the market, which puts off

46 Aitken, Understanding the pharmaceutical value chain. Accessed at https://www.ifpma.org/wp-content/uploads/2016/11/6.-Understanding-the-Pharmaceutical-Value-Chain-1.pdf

many Pakistani firms from venturing into this area.[47]

There are other costs that must be paid to the regulator to register drugs and once approved, to advertise them and their potential benefits to stakeholders. Pharmaceutical firms in Pakistan have to pay a huge amount of fee and charges for every process to DRAP, due to its highly bureaucratic nature, which massively increases the cost of doing business, especially for smaller firms.[48] In addition, due to limited R&D incentives and spending in Pakistan, most pharmaceutical companies face the brunt of their costs in the subsequent stages of the value chain, especially in drug formulation, trade incentives, discounting on bulk sales, packaging, distribution and incentivizing doctors.

Figure 21 depicts a snapshot of key activities in the manufacture of pharmaceuticals in Pakistan.

FIGURE 21 Pharmaceutical Value Chain in Pakistan

Source: Political Economy Analysis (Phase-2) for DFID Pakistan's Real Economy Programme

In addition, there are other regulatory layers to consider (see Figure 29 in Section 4). DRAP is responsible for issuing licenses to manufacturing units and ensuring compliance to GMPs. The provincial health departments are also engaged in key regulatory functions pertaining to sale of pharmaceutical products such as issuing licenses to pharmacies to sell medicines and ensuring quality of products being sold. The Federal Board of Revenue (FBR) and Ministry of Commerce are also involved in this chain, mostly to facilitate and oversee the import and export of raw materials and finished goods.

As R&D for the innovation and production of novel pharmaceutical products is greatly limited (see 3.6 below) 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. Pharmaceutical raw materials consist of Active Pharmaceutical Ingredients (APIs) and excipients.[49] These are researched in advanced countries such as UK, Germany, France, Japan, and US. Pakistan currently imports 95 per cent of its raw material from APIs, excipients, to drugs in semi-finished and finished forms. Most of these are imported from India and China while the rest come from Japan, Spain, and Italy.

The government has tried to facilitate imports of pharmaceutical materials by reducing custom duties under the 5th Schedule of the Customs Act, 1969 and exempted them from GST under the 6th Schedule of the Sales Tax Act, 1990. However, all imported raw materials are required to be cleared from the DRAP subject to a No Objection Certificate (NOC) as per local laws. The over-reliance on imports and a lack of R&D has meant that cheaper imports have significantly reduced local production of pharmaceutical products in Pakistan. The devaluation of the Pakistani Rupee over the last three years has now led to hefty raw material import bills, raising input costs of firms by nearly 50 per cent.[50] During the same period, prices of drugs only increased by 15 per cent, constricting operational margins.

47 PIDE Webinar: Pakistan's Pharmaceutical Industry: Growth, Challenges and Issues -1.

48 PIDE Webinar: Pakistan's Pharmaceutical Industry: Growth, Challenges and Issues -1.

49 These are part of a pharmaceutical dosage form to help the manufacturing process, to protect, support or enhance stability, or for bioavailability or patient acceptability. These substances have no therapeutic function.

50 Sarfaraz, S. (2019). Rupee devaluation main impediment to drug imports. Business Recorder. 19TH November 2019. Available at https://www.brecorder.com/news/545621

Pakistani pharmaceutical companies are also subject to very strict operating requirements issued by DRAP. DRAP visits and tests individual firms every three to 6 months. During these checks, DRAP ensures that firms are adhering to:

1. Current Goods Manufacturing Practices (cGMP): Includes price and quantity checks.
2. Current Goods Storage Practices: Whether a suitable HVAC System (Heating-Ventilation-Air-Conditioning) is installed for the medicines.
3. Current Goods Laboratory Practices: Whether the laboratory meets the safety and health requirements.
4. Current Goods Documents Practices: A check on the legality of operations and decisions taken.

A violation of the above standards could lead to fines, embargoes, or closures. Due to the necessary adherence to these strict compliances, local, smaller firms find it difficult to compete against the larger MNCs. In fact, the top 50 firms adhere to standards and adopt new technology to achieve greater economies of scale and productivity gains. However, smaller local firms tend to use older machinery and technology for production.

3.1 Production

Pharmaceutical raw material is often imported in bulk with larger firms placing the biggest orders. In addition, to benefit from bulk buying, small firms often partner up with larger firms and place consolidated orders.

The next step is producing a final product from that raw material. This can take up 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 is quality and for product recalls. Pharmaceutical products are manufactured in special quality control areas set aside for authorized personnel with gear to enter. DRAP ensures that a Heating, Ventilation and Air Conditioning (HVAC) systems are in place to protect from dust, temperature, and humidity.

The costs of manufacturing are contingent on the product type, capacity and source of plant and equipment. The larger MNCs typically employ their own machinery to ensure quality standards whereas smaller firms usually procure cheaper equipment from China, Korea, and Taiwan. [51]

Another manufacturing concept that exists, albeit on a small scale, is the concept of toll/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 a number of brands as per their demands. This helps in the transfer of technology and exploration of more business activities. This was seen in the 'Make in India Philosophy' where firms like General Electric (GE) can enter markets without big commitments and create economies of scale and technology transfers. This technique allows MNCs to sell medicines at a cheaper rate in the local market.

DRAP however does not seem to realize the full potential of this globally accepted method, fearing quality issues. At the moment, it only issues licenses for contract manufacturing for three months at a time, instead of blanket approvals for two years. Due to the low prices set by the government and the absence of this method, it has resulted in the production of several low quality and unlicensed drugs selling in the market at cheap prices. On the other hand, in India, 40% of the lower cost of drug manufacturing through contract manufacturing has encouraged several MNCs to consider India for their outsourcing needs.[52] There is recent talk of a revision in the 2014 SRO pertaining to the matter that would allow contract manufacturing that is not time-bound, subject to stringent quality control of DRAP. This will help smaller and medium sized firms in the sector that are currently operating at 20-40 per cent of capacity.[53]

51 ICAP – Pharmaceutical Industry

52 https://manufacturingchemist.com/news/article_page/Contract_manufacturing_in_India_grows_at_20/112289

53 Interview with Dr. Sultan Ghani, DRAP external consultant

Another issue that has hindered the industry from realizing its true export potential is the lack of bio-equivalence testing facilities in the country.[54] Bioequivalence is needed to establish similarity of a particular drug to match the conditions for sale and use in other countries having more stringent regulatory conditions, otherwise called SRA markets. However, as bioequivalence is not mandatory in Pakistan, and is expensive—companies therefore do not have an incentive to install such testing facilities. In other countries, bioequivalence is outsourced to contract research organizations (CROs). These are commercial or academic organizations that can be used by sponsor firms for clinical research, bioequivalence, clinical trials, and other bioanalytical studies. This reduces R&D costs for firms and helps them penetrate niche markets successfully. There are around 9 good CROs in Pakistan.[55] Similarly, since 2007 biologics/biosimilars such as vaccines cannot be manufactured and sold unless approved from the National Control Laboratory for Biologicals, Islamabad—they do not have any testing facility and medicines are generally approved after submission of the required paperwork and formulas. But these cannot be accepted or sold globally in any country without WHO pre-qualification of the NCLB (see Section X on Vaccines).

3.2 Packaging, Marketing, Distribution, and Supply Chain

Pharmaceutical industries use different types of packaging materials to pack products. The choice of packaging material depends upon the type of pharmaceutical product and can include materials such as PVC, aluminum foil, cotton, ampules, and vials etc. Distribution and supply chain processes ensure that the medicines are readily available to patients at retail pharmacies and hospitals. In Pakistan, pharmaceutical companies use the process of 'Sales and Operational Planning (S&OP).

S&OP relies on a demand management system by individual Stock Keeping Units (SKU) for each geographical region that estimate 12 to 36-month forecasts based on historical data and number of product lines. These demand estimates are calibrated with procurement, sales and marketing needs to avoid shortages of raw material or supply constraints. A plan with constrained demand is then approved by relevant stakeholders in line with company's Standard Operating Procedures (SOPs). This is then executed with purchase requests for APIs, excipients, packaging material and finished goods.[56]

In Pakistan, MNCs typically utilize an inter-company ordering system to order and supply globally. Companies also ensure that their distributors always have a minimum stock of inventory to fulfill patient demand. In Pakistan, distributors usually keep 6 weeks of stock on average to ensure uninterrupted supply.

Distribution in the pharmaceutical industry also consists of two different systems: under a centralized (nationalized) system, companies appoint a unique distributor responsible for distributing throughout the country using its own warehouse and storage facilities. In the decentralized (regional) model, companies appoint different distributors in different geographical regions that supply at their own cost to pharmacies. The decentralized system is more widely used in Pakistan. Typically, the trade discount for pharmaceutical distributors in Pakistan is around 8-10%.

Furthermore, distribution is done via three main channels. The most widely used are through street sales or pharmacies. More recently, e-commerce ventures (such as dawai.com) have also emerged, having special regulations of their own. For more specialized forms of medicines (for example those that need to be stored in certain temperature settings), doctors can even suggest certain distributors who can then deliver those medicines at the patient's home. The sale of medicines in Pakistan cannot be done without a drug sales/wholesale license documented via invoices which is a requirement under Form 7 of the Drugs Act, 1976.

54 Industry official interview.

55 http://www.pulsepakistan.com/index.php/main-news-feb-1-14/630-essential-role-of-contract-research-organization-cros-in-pakistan#

56 ICAP (2018). Pharmaceutical Industry

3.3 Final Consumer/Patient

As sale of pharmaceutical products is primarily mediated by doctors, except for over-the- counter (OTC) products available from pharmacies, firms in Pakistan have actively tried to establish relationships with doctors through financial and material incentives to promote their products. However, this has often led to deceptive marketing practices through the formation of doctor-firm collusions and over-subscription of medicines by doctors. These have increased out-of-pocket expenditures by patients as well as multiplied health risks on account of increased resistance resulting from excessive use of these medicines.

3.4 Public procurement

Every province has their own public procurement regulatory authority for medicines. Tenders are published in newspapers which detail the conditions for a firm to be eligible to supply medicines at defined rates over yearly contracts. Tender conditions are stringent; for e.g, only registered entities can supply products. Certain marks are allocated for quality plus financial (pricing) aspects. Medicines are required to be manufactured under the GMP. Companies are judged under sales volume for that medicine, IMS ranking, market size etc. 80 marks are allocated for quality and 20 marks for prices of medicines quoted in Punjab and Sindh. KP uses 70 marks for quality and 30 marks for prices. Even educational certificates and experience certificates of people employed by the firm could be requested for approval. After shortlisting the companies based on total marks, the tender is approved. Therefore, it is not necessary that tenders get approved just based on a cheaper price as quality also matters, both in terms of the medicine and the company manufacturing it. Since 2015, all tenders are now approved digitally i.e., all necessary documentation and details need to be filled online to avoid irregularities in the process. Private hospitals in the country have even more stringent conditions for procurement.

3.5 Benchmarking the value chain

The cost break-up of a sample drug is provided below and shows that manufacturing costs and marketing costs account for 40 per cent each, while raw materials comprise the remaining 20 per cent.

TABLE 5 Cost break-up for a drug

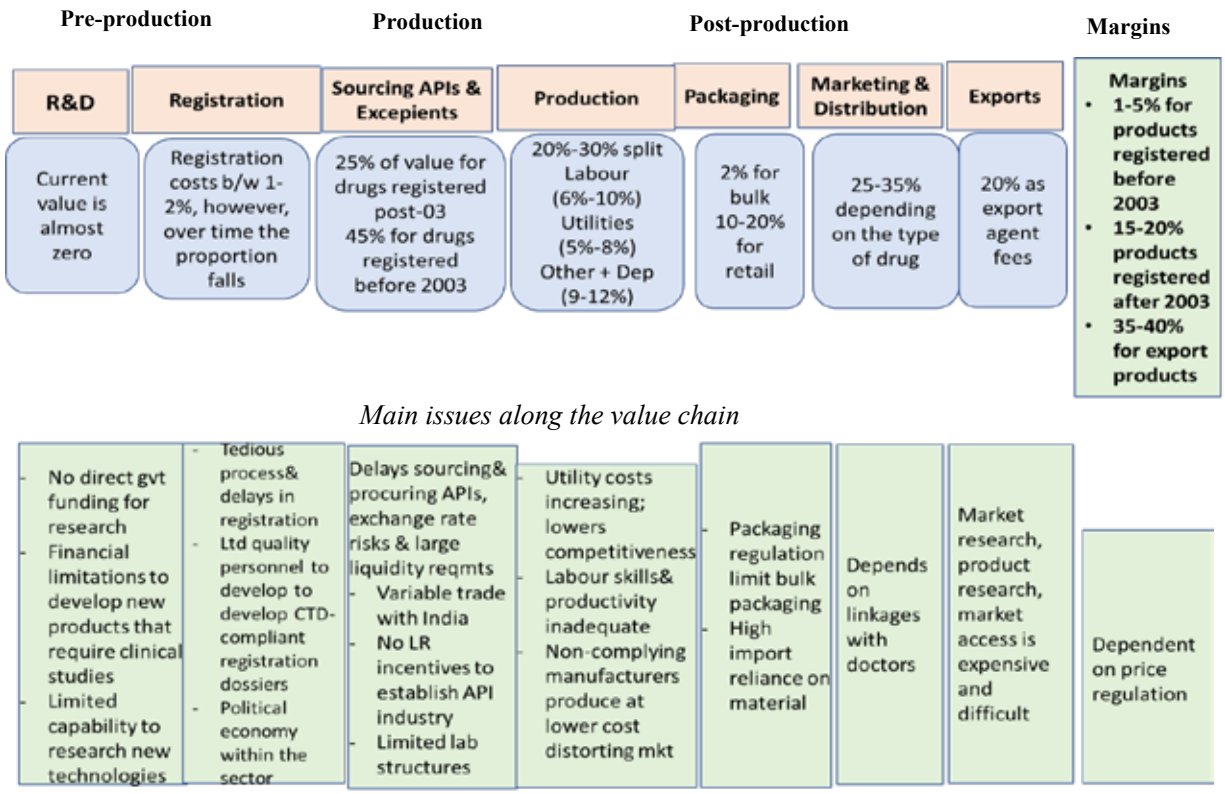
Item No.	Item in Value Chain	Cost in PKR
01	Active Ingredient(s)	16.18
02	Inactive Ingredient(s)	22.16
03	Cost of Packing Material	13.32
04	Total Cost of Production	51.67
05	Marketing Cost	20.66
06	Cost before Distribution	72.33
07	Distributor Margin	7.23
08	Trade Price	79.56
09	MRP approved by DRAP	127.64

Source: Stakeholder consultations
From the above table, the cost-breakdown is as follows.

- **1+2+3** is the total cost of producing the drug in its final packet form, aggregating the cost of Active Ingredients, Inactive Ingredients, and packaging material costs involved.
- **05** is the marketing cost which includes salaries, doctor commissions, advertising etc, which approximately takes up **35-40%** above the total production cost.
- **07** is the distribution margin which is typically **8-10%** in the Pakistan pharmaceutical market.
- **08** is the final trade price the firm can sell the drug in the market for, without making any profits.
- **09** is the Maximum Retail Price (MRP) approved by DRAP—firms can accordingly set their prices below or equal to this limit. It is not a common practice to set prices exactly at the MRP, firms can sell at lower prices if they save on marketing costs and other overheads. The MRP given by DRAP is according to a formula—in this case it is 2.47 times above the total cost of production, given in 04. This ratio of selling margin of 2.47 is not fixed for all medicines though—it is subject to change depending on the ratio of API costs consumed in a drug.

The typical value chain for a drug also varies depending on when the drug was registered. In case the drug was registered before 2002, the price margins are really low, but for drugs registered after 2002-03, the price margins are better. Figure 22 provides estimates on flow of value for the two categories, as well as the main issues faced at each stage. These issues are discussed in detail here, but more cohesively, in section 5.

FIGURE 22 Value chain for typical product (% of revenue) in Pakistan



Source: Stakeholder interviews

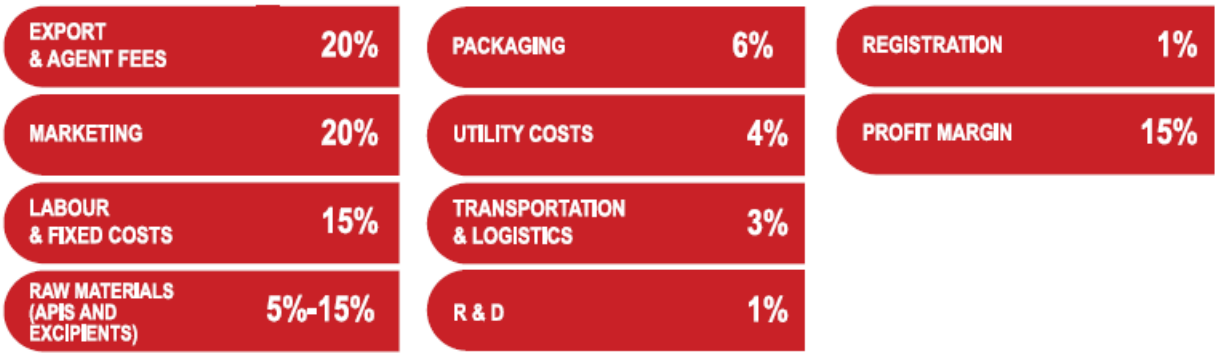
As mentioned above, the value chain comprises three major components: manufacturing, distribution and dispensing to the end user. Figure 22 shows the breakdown from the input stage comprising mostly of active pharmaceutical ingredients (APIs) and excipients, to the production line itself. Production efficiency depends on the cost and quality of labour, utilities and technology, while packaging, marketing and sales depends on the regulatory structure in place. Exports and overall margins are determined by the pricing policies of the government, quality regulations and international compliances.

The field interviews suggest that products registered prior to 2002 are struggling, as pricing set by DRAP is just enough to cover costs. The value chain starts at the input stage that is mostly imported. The MNCs approach differ as they usually source APIs from their own global value chains and hence are able to get them at more competitive prices and in consistent manner. The local firms need to secure APIs by importing and thus face the risk of depreciation and a larger line of credit to import in sufficient quantities.

The production line costs also vary by product, for example, ampules are more expensive while tablet costs are lower. The increasing prices of utilities have increased the cost of production. The cost of electricity for example is higher as compared to India and Bangladesh. In China, electricity is 4 cents per KWh, in Malaysia it is 6 cents per KWh as compared to 11c per KWh in Pakistan.[57] As can be seen from the figure below, there are efficiency gains possible throughout the value chain when benchmarked with a more mature pharmaceutical sector such as in Jordan. This is especially true at the level of API and excipient costs as well as utilities.

57 Stakeholder interview

FIGURE 23 Share of costs, as % of revenue for a typical product in Jordan



Source: GIZ. (2019. Value Chain Analysis of the Pharmaceutical Sector in Jordan Industry Overview in Jordan. Trade for Employment (T4E) Project

The labour wages in terms of productivity are also on the higher side and the skillsets of workers are lacking. The attitude of workers is also an issue which is a big cause of concern for pharmaceutical industry. The industry is not an exception when it comes to facing other regulatory and inspection-related issues. Labour and PESSI were highlighted as the most intrusive departments.

The sector also complains about DRAPs involvement in regulating the packaging. Given the market segmentation in Pakistan, it makes sense that generics are allowed to be sold in bulk packaging. This is allowed in Pakistan on certain products, but is however, regulated by DRAP which means not all generics can be sold in bulk. This is problematic for smaller companies.

3.6 State of Technology in the Sector and R&D

There is an increasing debate for Pakistani pharmaceutical firms to focus on Research and Development (R&D) to increase their share in the global market. In 2019, US USD 186 billion were spent on global R&D spending. Timelines for innovation are also large: it takes around 12-13 years on average from the first synthesis of a new drug to its final product launch in the market, given it passes all intermediary trials. The significant knowledge, costs and time required for R&D makes it difficult for Pakistani pharmaceutical firms to significantly operate in this area.

The flawed pricing policy of the government has directly contributed to the poor technology of the industry. Through the 1976 Drugs Act, maximum retail prices (MRPs) are set by government in a bid to keep medicines affordable, while the final retail price is set by the Cabinet. However, as price increases were not clearly defined, it meant that the once defined, prices remained rigid. This could be seen from 2001 to 2013, when the government maintained a fixed price for all medicines throughout. This led to firms being disincentivized from research due to the prohibitive costs and their inability to recoup those costs, as market prices were controlled.

Secondly, there is weak legal enforcement of intellectual property rights and limited patents to cover the research cost of a single new drug that can range anywhere between USD 500 million and more than USD 2 billion.[58] Already operating on thin margins with rigid prices imposed by the government, firms in Pakistan would incur heavy amounts in developing, introducing, and marketing a new product. Without strong patent and property rights, no firm has the incentive to spend such heavy amounts. On account of these two factors,

58 https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.25.2.420?journalCode=hlthaff#:~:text=However per cent2C per cent20our per cent20estimates per cent20vary per cent20from,therapy per cent20or per cent20the per cent20developing per cent20firm.&text=T per cent20he per cent20expected per cent20cost per cent20of,entity per cent20(in per cent202000 per cent20dollars).

the inability to recover the development costs has meant that R&D has not been a priority. Industry claims that it is much easier to copy and sell existing drugs without any checks. Smaller and medium firms in industry believe that due to pricing constraints, research should be done externally, and firms should instead focus on bioequivalence related research. But R&D has been shown to contribute positively in achieving the export potential of pharmaceutical firms. Goldar (2012) states that the export intensity of Indian pharmaceutical firms increased substantially after 1995, when a new and more restrictive patent regime was introduced in India. He also finds that the closer the firm is to the technology frontier in India, gauged by its productivity, the higher its impact on export competitiveness. Evidence suggests that Indian firms tend to spend almost 9 per cent of their profits on R&D, explaining their continuous advances in product and process innovations using latest technologies.

The fiscal space and incentives given by the government are also restricted for firms to partake in R&D in Pakistan. Globally, many countries reward R&D incentives through tax credits and tax offsets. In India, a 100 per cent deduction is available on expenditures set for scientific research. Similarly, in China, a 150 per cent R&D super deduction is available along with a flat 15 per cent corporate tax rate. In Pakistan, the government has collected a 1 per cent tax on profit before tax via the 1976 Drugs Act for firms engaging in R&D. However, there is little record of how much revenue has been generated over time and how it has been used to promote R&D in Pakistan. Industry officials highly oppose this policy and show little incentive to engage in research. This has led to most research being confined only to packaging, coding, and similar activities rather than development and introduction of new drugs.

3.7 Value Chain Analysis of Regional Comparison Countries

The value chain is benchmarked with a few regional comparator countries that have grown tremendously over the last 10-15 years. Key factors and policy lessons that have strengthened their global export positions are highlighted. Bangladesh and Malaysia are discussed as they have a reasonably similar manufacturing base as Pakistan, and yet have grown exports much faster.

Malaysia

Malaysia's pharmaceutical industry has shown robust growth trends, both in terms of market size and global exports. In 2007, the pharmaceutical industry was valued at USD 1027 million which grew to USD 2.3 billion in 2015 and is expected to reach USD 3.6 billion by 2020. This led to a CAGR of 9.5 per cent over the last 5 years.[59] At the same time, pharmaceutical exports have also grown more than two-fold, from USD 186 million in 2015 to nearly USD 308 million by 2019.[60]

A large part of the success of the Malaysian pharmaceutical industry could be attributed to import-substitution policies employed by the government in a bid to strengthen domestic manufacturing and grow exports. Malaysia has followed the MNC-mediated model of developing the pharmaceutical sector. Malaysian Industrial Development Authority facilitates new entrant under a National Priority Program and their commerce, industry and trade departments have Key Performance Indicators based on how much new investment is brought into the sector. Approvals are streamlined and hardly take 2-3 weeks to go from completion of plant facility to production. Innovator status is given to firms that bring in new technology, who are then given corporate tax holidays for 10 years as well as duty-free import of plant and equipment. Intellectual property rights and other laws are well-defined and the visa regime is very liberal, allowing easy access to world-class global consultants. 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 Kuala Lumpur, Bio-XCell and Penang Science Park were established to accommodate the growing

59 https://www.pharmaceut-ical-technology.com/news/newsreport-malaysian-pharmaceutical-market-to-grow-at-a-cagr-of-95-by-2020-5018511/

60 COMTRADE Data

needs of the industry. To grow the production of generics, R&D research was promoted into new molecules and chemicals. The government also put the design of healthcare under one of the country's twelve National Key Economic Areas (NKEA), focusing on pharmaceuticals under its National Priority Program. Private-public partnerships (PPP) and collaboration with MNCs in the areas of biopharmaceuticals, APIs, herbal medicines, contract manufacturing, general drugs as well as high-end pharmaceutical products is highly promoted.

Malaysia is the current global leader in the certified *Halal* pharmaceutical industry, being the only nation in the world with appropriate licenses to manufacture and export *Halal* products to the world. The *Halal* pharmaceutical industry was valued globally at an estimated USD 87 billion in 2017 and is expected to grow to USD 131 billion by 2022. Malaysia currently holds the MS:2424:2012 *Halal* Pharmaceutical General Guidelines that are implemented throughout its value chain from processing to handling, packaging, labelling and distributing drugs locally and internationally. It has also promoted medical tourism through a Malaysia Healthcare Tourism Council extensively to increase the demand for branded and high-value drug products from MNCs, similar to Thailand. The government has established medical tourism hubs across the country and given tax exemptions to medical tourists. In 2019, 1.3 million medical tourists visited Malaysia, bringing in revenues of USD 400 million.[61]

Bangladesh

The Bangladesh pharmaceutical industry has grown massively over the last seven years, increasing exports up from about USD 58 billion in 2013 to USD 136 million in 2019. Exports increased by 4.5 per cent over the course of the previous year, despite the drop induced by the COVID-19 health crisis that majorly affected other growth sectors. Exports are predicted to increase up to USD 450 million by 2025 and the total value of the industry will cross USD 6 billion by 2025, approximating a CAGR of 12 per cent.[62]

Export promotion policies by the Bangladesh government in recent years have largely supported the country's ability to transform itself into a robust pharmaceutical export market. Similarly, despite being highly reliant on imports and MNCs to meet the needs of its local population, local pharmaceutical companies have emerged as the game-changer in recent times through contributing more than 90 per cent of the medical supply in the market.[63] As a result, local production caters to up to 97 per cent of the total domestic market.[64]

One of the main breakthroughs of the industry was compliance with international manufacturing standards—different manufacturing facilities have received approvals from US FDA as well as other bodies such as the European Union Good Manufacturing Practice, the Medicines and Healthcare Products Regulatory Agency (MHRA) of the UK, and the Therapeutic Goods Administration of Australia. According to the Bangladesh Association of Pharmaceutical Industries (BAPI), approximately 1200 pharmaceutical products received registration for export over the last two years. Manufacturing compliances contributed to an estimated increase in export earnings in a single year, i.e., by 25.6 per cent from 2017-2018 to 2018-19.[65]

Similarly, the adaption of biotechnology by firms in recent times have qualified them to cater to the growing needs of the population. Novel biomolecular techniques and innovations in research and development have allowed it to produce advanced medicines such as biosimilar drugs, vaccines, and oncology products as well as various medical apparatuses. For example, Beximco Pharmaceuticals, a private sector pharmaceutical giant has created a global brand image for Bangladesh amongst pharmaceutical and bio-tech circles around the world due to its quality products.

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61 https://www.imtj.com/news/malaysia-will-open-soon-medical-travellers-six-countries/

62 https://bizdatainsight.com/2020/07/13/pharma-export-of-bangladesh-growing-fast-api-park-to-boost-further-in-future/

63 https://www.globenewswire.com/news-release/2020/07/22/2066033/0/en/Pharmaceutical-Market-in-Bangladesh-to-Cross-6-Billion-by-2025-Growing-With-a-CAGR-of-Approx-12.html

64 Yusuf, S. (2020)

65 https://www.arx.cfa/~/media/2A85F9B2CEAB43CFAF325AB54F3EF404

The industry developed with the help of Indian pharmaceutical giants. Bangladesh attracted the high cadre skilled personnel of the top firms in India through 20-30 per cent higher pay packages. This was made possible by cultural and physical proximity, ease in getting visas, and good security. The same of course would not apply for Pakistan. Compared to Pakistan, Bangladesh has several advantages in the pharmaceutical industry that provides it a significant cost advantage. This has mainly to do with the favorable policies of the government towards the industry, especially the National Drug Policies passed in recent years, the latest being in 2016. But a more important dimension is the access to a special World Trade Organization (WTO) waiver which exempts the industry from the Agreement on Trade- Related Aspects of International Property Rights (TRIPS). The waiver for the pharmaceutical sector is valid till 2033, or until Bangladesh moves out of least developed country status, whichever is earlier. Under this agreement, Bangladesh being a Low Developing Country (LDC) will be exempt from paying royalty in producing generic copies of patented drugs.[66] This facility is of course, unavailable to Pakistan. Bangladesh can produce and export generic versions of patented drugs to any country where those drugs are not covered by patents or where compulsory licenses are issued to treat diseases like cancer or HIV/AIDS. It allows the Bangladesh government to regulate imports and even stipulate *de facto* bans on imports from other countries. For example, if a drug is domestically produced in Bangladesh, any country wishing to export the same drug to Bangladesh will be required to first get approval from an SRA market such as EU, Japan, and US. This effectively bans Pakistan from exporting to Bangladesh.

The Bangladeshi government has also approved and launched several API Parks over previous years through which they would be able to achieve costs saving by at least 70 per cent of import cost of raw material. This will dramatically reduce the cost of production and help Bangladesh to achieve price competitiveness in Global Market. Currently, more than three dozen companies are in process of establishing an industrial park near Dhaka. This is projected to decrease API import reliance from 97 per cent in 2016 to 80 per cent in 2032. In addition, it aims to increase API export income from USD 1.5 million in 2016 to USD 90 million by 2032 as well as creating 0.5 million new jobs.[67] To further boost exports, the government has introduced a 20 per cent subsidy for exporting APIs and a 10 per cent subsidy on finished pharmaceutical products.

In addition, the government of Bangladesh, through its National Drug Policies has approved several legislations to make essential drugs affordable to all in Bangladesh by sealing the upper limits of prices for active pharmaceutical ingredients (API), as well as the prices of finished drug products. The tax regime in the country has also been favorable to the industry—the National Board of Revenue (NBR) has exempted 15 per cent VAT to local API producers on imported raw materials and reagents till December 2025 to support the backward linkage of the country's pharmaceutical industry.

Pharmaceutical Value Chain Comparison

Despite having similar API import trends as Pakistan, Malaysia and Bangladesh seem to fare better in their pharmaceutical industry both in terms of domestic production and exports. The main gaps vis-à-vis Pakistan are evident in a comparison of value chains. While all countries rely on APIs to some extent, the import dependency for Pakistan is more binding, with anecdotal evidence suggesting that even larger local firms prefer to use imported APIs over locally sourced ones due to perceptions of quality. The table below indicates big gaps in R&D that impact almost all pre-production and production stages.

66 https://www.un.org/ldcportal/what-ldc-graduation-will-mean-for-bangladeshs-drugs-industry/

67 http://www.maritimegateway.com/api-park-boost-export-medicines/

TABLE 6 Value Chain Comparison across Malaysia, Bangladesh, and Pakistan

		Malaysia	Bangladesh	Pakistan
Research & Development	FDA Approved Labs	✓	✓	×
	Government Sponsored Industrial API Parks	✓	✓	×
	Intellectual Property (IP) Laws	✓	✓	~
	R&D Tax Fund	×	×	✓
	Private-Public Collaborations	✓	✓	~
Raw Material (Imported/Local)	APIs imported by MNCs/Generics produced by locals	✓	✓	✓
	NOC requirement for import/export	~	✓	✓
Production	Bioequivalence Testing Facility	✓	×	×
	Halal Manufacturing License	✓	×	×
	Patent Waiver for Least Developed Countries (LDCs)	×	✓	×
	Subsidy for pharmaceutical exports	✓	✓	×
	Contract Manufacturing	✓	✓	×
	Enforcement of GMPs	✓	~	~
	Smaller firms producing generics	✓	✓	✓
	Decentralized system of public procurement	✓	✓	✓
Wholesale/Retail	Model Pharmacies and SME loans	✓	✓	~
	Mobile drug courts against drug abuse violators	✓	✓	×
Final Consumer/ Patient	Firm-Doctor collusion	~	✓	✓

Source: Author research

The next section provides a political economy overview of and context for the pharmaceutical sector in Pakistan, to inform potential reforms for improved growth and exports. It provides an overview of the salient features of the key players, the power dynamics within the sector and state-sector relationship and industry-level collective action issues. This will help determine the political feasibility of proposed interventions, both in terms of capacity and appetite for reform.

CHAPTER 4

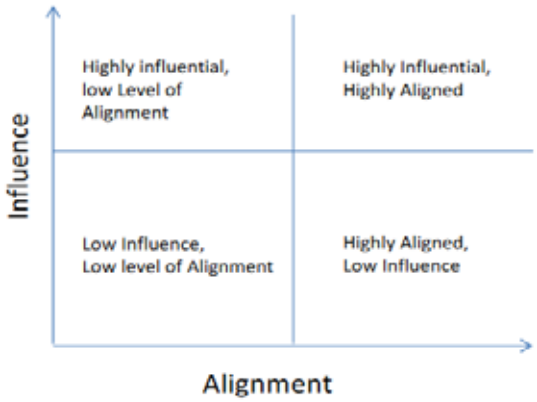
Political Economy Analysis

This section identifies the key players, their power relations, and their capacity to shape or be shaped by policy interventions along the value chain. The distribution of power is often protected and perpetuated—through collusive acts between bureaucracy and industrial allies—to maximize self-interest in economic decisions, creating barriers to reform and equitable development outcomes. Successful reform may therefore require wider dialogue across a range of actors (including government, civil society, private sector, media and politicians). Stakeholder analysis in this section builds insights to assess the capacity (and willingness) of different stakeholders to participate in the reform process and subsequently identifies opportunities for reform. Understanding the political feasibility of a policy prescription is crucial for predicting ownership of any proposed reform and its successful implementation, regardless of its technical merits.

The first important step in understanding the political economy of this sector is to identify the range of key stakeholders, their roles and their power dynamics. This is especially important in light of developments such as the COVID-19 crisis, engagement with China under CPEC, on-going macro-economic stabilization as per IMF loan conditionalities, and a relatively new political government. This section examines how these factors will play out in the pharmaceutical sector's industrial/business landscape and influence economic decision-making.

Key stakeholders specific to the sector are identified in section 4.1 below, in addition to Federal Board of Revenue (FBR), which along with the Ministry of Commerce, also controls the export and import of raw materials and finished goods. They are categorized in terms of their capacity to influence and their level of interest in the performance of the sector as per the framework identified in Figure 24.

FIGURE 24 Stakeholder influence matrix



Source: DFAT

4.1 Key players

Table 7 lists the key stakeholders in the pharmaceutical sector in Pakistan along with their main functions. Broadly, medicine licensing, manufacturing, registration, pricing, imports, and exports fall under the purview of the federal government, while distribution and sales are regulated by the respective provincial governments.

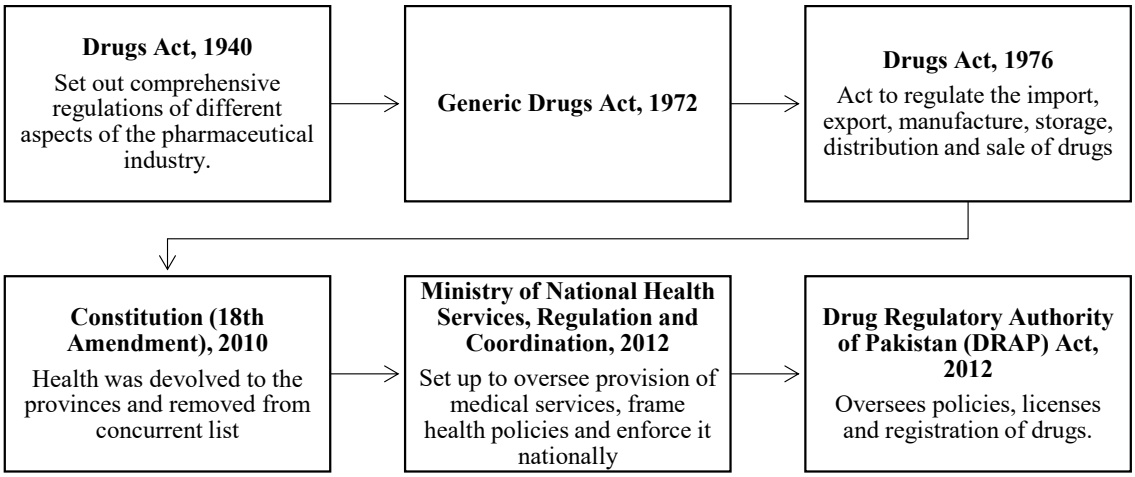
TABLE 7 Key players, by main functions

Name	Classification	Role
The Ministry of National Health Services, Regulation and Coordination	Government Agency	This federal ministry oversees other regulatory bodies in the health sector, including DRAP. Majority of health care provision functions were devolved to provinces following the 18th Amendment to the Constitution. Now its primary role is to coordinate and regulate.
Drug Regulatory Authority of Pakistan (DRAP)	Government Agency	DRAP was created under the Drug Regulatory Authority of Pakistan Act, 2012. It is the main agency responsible to regulate pharmaceutical products, including manufacturing, licensing, product registration, price setting, and quality inspection. It was created as an autonomous body with its own Chief Executive Officer but is under the administrative control of the Ministry of National Health Services.
Provincial Health Departments	Government Agency	The Provincial Health Departments exist in all four provinces and are responsible for implementing the provincial health strategies. They are responsible for regulation of drug sales, licensing of pharmacies as well as drug inspection and drug testing to prevent sale of counterfeit, spurious or sub-standard products.
Pakistan Pharmaceutical Manufacturers' Association (PPMA)	Industry Association	PPMA is the foremost representative body for the pharmaceutical sector in Pakistan, and in particular for national companies. It aims to promote the interests of pharmaceutical manufacturers in this industry and improve their trade potential.
Pharma Bureau	Industry Association	Pharma Bureau is the representative body for MNCs operating in Pakistan with the objective to protect and promote the interests of these companies.
Pharmacy Council of Pakistan	Government Agency	The Pharmacy Council of Pakistan is responsible for accreditation and regulation of both pharmacy education and profession in Pakistan.
Pharmaceutical companies	Private Sector	650+ companies operating in the Pakistani pharmaceutical market, of which less than 25 are multinational companies. These produce around 10,000 actively marketed drugs in Pakistan sold at licensed pharmacies on prescription. In addition, there is a large segment of Over the Counter (OTC) products e.g., multivitamins, pain, cold and flu relief

Source: Adapted from Dawani and Syed's work on Pharmaceutical sector

The most important player in the sector is DRAP, established under the Drug Regulatory Authority of Pakistan Act, 2012 (see Figure 28 for timeline of regulatory changes). It was meant to be set up as an autonomous regulatory body similar to the US FDA and falls administratively under the Ministry of National Health Services, Regulation and Coordination. The agency was tasked with effective coordination and enforcement of the Drugs Act 1976 to regulate, manufacture, import, export, store, distribute and sell therapeutic drugs in the country. Prior to 2012, this role was being carried out by the Drug Control Organization (DCO).

FIGURE 25 Timeline of regulatory changes

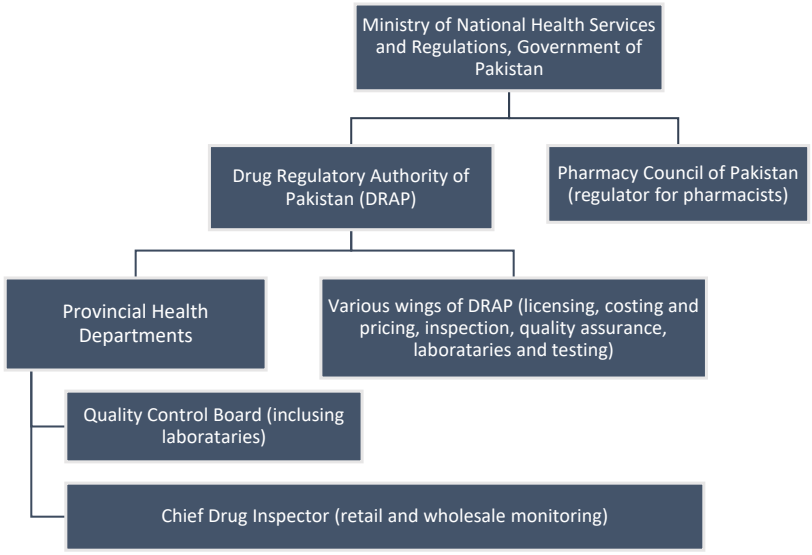


Source: Author Research

The new organizational structure of DRAP consists of eight technical and five supportive divisions. The department of quality assurance has five field offices supported by federal drug inspectors, assistant drug controllers, and an appellate board. The other seven technical divisions include registration, medical devices, biological drugs, controlled drugs, pharmacy services, health & over the counter, costing, and pricing.[68] The pharmacy services division covers pharmacovigilance, clinical trials, regulation of contract research organizations, and research. DRAP is also responsible for issuing licenses to manufacturing units and ensuring compliance to GMPs.

The provincial health departments are engaged in other key regulatory functions pertaining to sale of pharmaceutical products such as issuing licenses to pharmacies to sell medicines, ensuring quality of products being sold. Figure 4.3 below depicts the overall regulatory structure of the pharmaceutical sector in Pakistan.

FIGURE 26 Regulatory structure of Pakistan's pharmaceutical sector



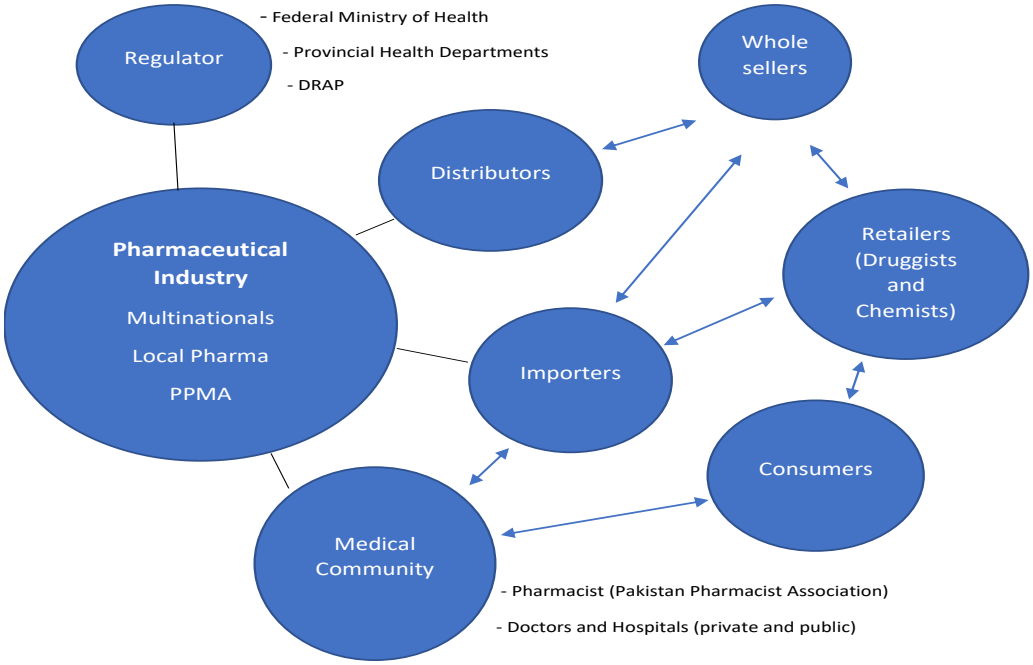
Source: Dawani and Sayeed, 201969

68 Drug Regulatory Authority of Pakistan. Home page. Islamabad, Pakistan. 2018. http://www.dra.gov.pk/. Accessed 21 June 2018.

69 Kabeer Dawani and Asad Sayeed, "Pakistan's Pharmaceutical Sector: Issues of Pricing, Procurement and the Quality of Medicines" (ACE SOAS Consortium, 2019), pp. 1-33.

Figure 27 below shows the relationship between these key stakeholders in Pakistan's pharmaceutical sector. Power dynamics amongst these stakeholders are complex.

FIGURE 27 Networks between Pakistan's Pharmaceutical Stakeholders



Source: Dawani and Sayeed (2019)

Despite having its own Chief Executive Officer (CEO), DRAP remains vulnerable to political pressures similar to other regulatory bodies in Pakistan. Since the new DRAP regime post-2012, structuring of processes has improved quality of regulation, with clear definition of rules and processes across drug registration, drug pricing, manufacturing practices and quality assurance. These reforms have improved outcomes, in terms of quality as well as growth in the industry.

Overall, the organization operates on an *ad-hoc* basis, though attempts are being made to streamline its authority. No structure or board or permanent management exists to run the affairs. The position of CEO of DRAP had been vacant since March 2019 for several months and then the acting CEO was promoted to take this position. He has since been approved by Cabinet and is now the CEO of DRAP.

Senior representatives of DRAP uphold that its policies are non-discriminatory and that big players are unable to influence or take advantage or influence policies.[70] They do acknowledge that absence of a permanent board does politicize hiring decisions, leading to frequent turnover at the top, and an inconsistent regulatory regime that appears "*ad hoc*". The section below documents this.

70 Interview with CEO DRAP.

4.2 Power Relations

The main actors, firms and the state, differ in their ability to shape policy. The most prominent feature of this sector is its fragmentation into small and large firms. There are many more small firms (roughly 600-700) than large firms (approximately 100), but the latter overwhelmingly dominate the market. Top ten percent have close to 50 per cent of the market share. This fragmentation in the industry, as is the case across most sectors in Pakistan, has disincentivized collective action in favor of individual rent-seeking by the larger firms, making associations ineffective.[71]

But we must question if that is the only reason. India and Bangladesh are on their way to becoming global leaders in pharmaceuticals, despite having a similar industry structure. In Bangladesh, there are 150 firms, out of which the top 20 firms account for about 85 per cent of the market where local firms, instead of MNCs, dominate the market with more than 90 per cent market share. All the top 10 firms are local firms.[72] Similarly, India which is home to more than 3,000 pharma companies with a strong network of over 10,500 manufacturing facilities, also has a fragmented industrial market structure, where the top 20 companies contribute to 50 per cent of total sales. However, the Indian industry overall contributes significantly to the GDP (1.5 per cent directly and another 3 per cent indirectly) as does Bangladesh (more than 5 per cent) compared to Pakistan (at just 1 per cent).[73] Bangladesh is also the only least developed country in the world to meet 97 per cent of its local demand for pharmaceutical products.[74]

The broader political economy within which the pharmaceutical industry is embedded is not amenable to creating change that could support greater agency of the sector. Bangladesh has had a national strategy focused on manufacturing and saw exports soar at an average annual rate of 15-17 per cent in recent years, as discussed in Section 3.7. Both India and Bangladesh have also seen stability in the macroeconomy with no major balance of payment shocks— this allowed for exchange rate stability. On the other hand, frequent periods of military rule peppered by weak democratic interims, the ever-looming spectre of economic collapse, and a tense geo-political reality have deprived Pakistan of the solid and stable foundation that is required for consistent policymaking. Lack of an overarching policy to guide industrial growth have led to insulated policymaking that serves the interests of a few as discussed in section 4.1.

In sectors marked by small and medium-sized enterprises like the pharmaceutical industry, the burden of unfavorable and *ad-hoc* regulation and state predation is often the highest. State predation refers to state tendencies to promote interests of dominant groups, such as the military, bureaucracy, political parties, or private firms with access and power. Here too, the case of *ad-hoc* price increments being given to favoured firms instead of dynamic firms, lowers overall efficiency and competitiveness of the sector. This may make it difficult for some larger firms—due to low exports—to exert much power as they do not contribute much to the economy. Although this may also be true of other sectors, given the fact that pharmaceuticals has never been considered by the government as a promising export sector of the country (unlike the case in Bangladesh and India), the bias is more heavily pronounced and subsequently, more damaging vis-à-vis other industrial sectors. All these factors greatly hamper industry-wide action. In addition, bureaucratic actors themselves exercise a high degree of discretion. Rent-seeking by officials reinforces the same by industry, to the detriment of the sector. Rent-seeking has happened via embedded networks that firms have cultivated in government.[75] In addition, the large variety in firm size also affects the power embodied within the sector association.

71 Kabeer Dawani and Asad Sayeed, "Pakistan's Pharmaceutical Sector: Issues of Pricing, Procurement and the Quality of Medicines" (ACE SOAS Consortium, 2019), pp. 1-33.

72 Chaudhuri, Sudip. (2020). Evolution of the Pharmaceutical Industry in Bangladesh, 1982 to 2020. SSRN Electronic Journal. 10.2139/ssrn.3767822. https://www.researchgate.net/publication/343689604_Evolution_of_the_Pharmaceutical_Industry_in_Bangladesh_1982_to_2020

73 https://www.thehindubusinessline.com/opinion/india-can-become-the-pharmacy-of-the-world/article31516558.ece

74 https://core.ac.uk/download/pdf/61804208.pdf

75 A recent example in 2014 is that of a large firm based in Lahore, which secured a manufacturing license from US-based firm and maintained monopoly power for three years by delaying government registration of competing generic producers.

Diverging interests, objectives, and capabilities of SMEs and large players create a weak sector association. The main industry association is the Pakistan Pharmaceutical Manufacturers Association (PPMA), that is dominated by local firms not heavily focused on exports. The internal structure of PPMA into North and South wings further discourages collective action. The industry association for MNCs—which are largely export-oriented— has some political clout. Pharma Bureau has shown limited success in lobbying for a pricing mark up on 'originator drugs',[76] despite them being off-patent. Yet at the same time, there is also some anecdotal evidence that innovator companies and MNCs may engage in "evergreening" patents, i.e., patenting slight modifications of old drugs. This is a global practice but lowers consumer welfare by depriving access to less expensive generics that are priced between 20 to 50 per cent of the price of the same bio-similar drug sold by an MNC or innovator company.

The key concern for most firms in the pharmaceutical sector of Pakistan is prices, but PPMA has little say in the pricing policy debate. Although price is a serious concern for firms that produce branded generics, large players utilise individual rent-seeking networks through government contacts, via price setting and litigation (hardship cases where they argue that production costs exceed the control price). Ad-hoc price increments have often been given to favoured firms in the pharmaceutical sector to the detriment of dynamic firms[77].

At the same time, small firms see no value of joining PPMA. They are able to compete in the local market comfortably by producing drugs at a much lower cost than the market value, as they do not have to incur costs for GMP compliance. For these reasons, PPMA is unable to shape pricing or quality policies through collective action.

In contrast, the state that includes the bureaucracy, the judiciary, the military, and elite politicians, exercises considerable influence over the form and direction of private sector economic activity. For example, the government has developed concessionary policies for certain businesses and entrepreneurs—those that have the capacity to lobby and access political networks. These include politically salient embedded pharmaceutical companies, often to the detriment of higher value-added firms (large firms in pharmaceuticals). And as mentioned above, the introduction of favorable pricing has almost entirely been driven through judicial intervention.

A recent dimension of state-sector interaction, that again tilts the power balance in favour of the state, is an over-active National Accountability Bureau (NAB). This is specific to the present government but not unique to the pharmaceutical sector. The current government is using NAB to carry out its anti-corruption agenda. Regardless of the merits of this approach, the consequence has been bureaucrat's refusal to make routine decisions—from public procurement of medicines for government-run hospitals to registration and pricing of new medicines—in the fear that NAB will arrest and investigate them. This raises the transaction costs of doing business tremendously and is yet another business impediment on an already expansive list.

76 Generally, the product that was first authorized world-wide for marketing (normally as a patented product) on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorization

77 Stakeholder interview (anonymous): "Most of the price increases have been taken by 8 of the top 20 firms and about 15 small firms via a stay order in the High Court justifying the price increase. This was done to prevent DRAP from penalizing them till the case is settled, with the hope that the case would linger on for decades. But when the last (PML-N) government came into power it pursued these firms, and NAB and FIA got some pre-bargain money back. They also filed a suit in the Supreme Court to get prices reversed and the excess price revenues returned. Then the new Chief Justice [Saquib Nisar] gave orders to move ahead and regularize the prices".

4.3 Horizontal constraints

There are certain overarching political economy dynamics in Pakistan that impact all aspects of economic activity. In addition, the pharmaceutical industry is further constrained by the cross-cutting factors discussed below.[78]

Firms in Pakistan operate in an environment of imprudent macroeconomic management embedded in a landscape marred with rent-seeking. Nearly every major industrial and services sub-sector collectively or as individual firms aims to retain cross-party relations to be able to get favours and navigate through enforcements. This results in expanding the number of economic claim-makers within the political sphere and avenues of claim-making. Moreover, the scale of rent-seeking and suppression of competition is usually possible through the utilization of sector-specific Statutory Regulatory Orders (SROs) granting particular types of concessions or exceptions. Although the degree to which SROs are granted varies from sector-to-sector.

The constant involvement of bureaucracy in economic policy formulation and implementation processes also leads to insulated decision-making that creates avenues for preferential treatment either to the bureaucracy itself or to certain players in the private sector (but not representing private sector interests at large). Due to political and bureaucratic instability, there is also no sustained commitment to a policy regime to rationalize business behavior and generate long-term growth. An overall lack of emphasis on industrial policy and investment in the manufacturing sector is also linked intimately to vulnerable political settlements with short time horizons and weak enforcement capacities.

Often policymaking in Pakistan is not subject to any national debate—there is a short-term focus as a means to engage in political firefighting instead of meaningful evidence-based framing for long-term benefits. Moreover, the government's economic agenda is hijacked by the IMF every three years. Pakistan has sought 13 bail-out packages from the IMF since its independence. Against these ground realties, it becomes difficult to maintain focus on long-term industrial policies guided by a cohesive economic framework. This instability is particularly damaging for the pharmaceutical industry, as it critically requires a long-term commitment simply because of the nature of the goods and services it produces. A consistent policy regime of at least 3-4 years is needed for investment in even the most basic new products. On the other hand, the garments industry, for example, is likely to adapt better to sudden policy changes as the process of changing the design or quantity of the product is less complicated. As mentioned earlier, lack of a stable policy regime maybe the single most important factor that explains why India and Bangladesh's pharmaceutical industry is on a completely different trajectory.

Another persisting issue is the general lack of capacity within government on key technical issues pertaining to economic reform. Often generalist bureaucrats continue to occupy senior-most technical offices in ministries such as finance, petroleum, energy, revenue and in other key regulatory and advisory positions. This can be a major hindrance towards sustained private sector-led growth as the state lacks an understanding of the ground realities within which firms operate.

78 Dawani, Kabeer, and Asad Sayeed. *Pakistan's Pharmaceutical Sector: Issues of Pricing, Procurement and The Quality Of Medicines*. Collective for Social Science Research, Karachi, 2019

4.4 Constraints along the value chain

This sub-section discusses how political economy constraints play out across the value chain by presenting binding constraints at each stage. This mapping is done with respect to the broader framework of Section 3.5 for each of the eight stages depicted in Figure 22. More generally the key realities of the political economy that have led to an environment of price rigidity, lack of a stable regulatory regime and excessive use of SROs, stark fragmentation between large and small firms all impact competitiveness of the industry and its capacity to export. The political economy constraints are well reflected along the chain but become especially pronounced in determining the business environment within which firms have to operate and the profitability of the sector.

Pre-production stages (R&D and registration)

This stage mainly entails R&D, pre-production compliances and registrations. Pharmaceutical-related regulations can be introduced suddenly, and such sudden changes create hurdles for firms to invest. For example, in December 2018, a Common Technical Dossier (CTD) was mandated as part of drug registration requirements, which is the same document used by the FDA in US and has complex requirements that take up to a year to fulfil. For semi-regulated markets like the Philippines, Jordan and Vietnam, the CTD comprises 100 documents, and for SRA markets like Europe, USA and Japan this can range up to 800 pages. Companies are also carrying out expenses for bioequivalence and doing R&D to produce formulations with samples and dossiers that meet international standards for export purposes. And unlike the textile sector, there is no tax credit on R&D for pharmaceuticals and no export subsidy as provided in Malaysia and Bangladesh, for reasons more to do with political capture of policymaking than economic prudence. Instead, as mentioned before, the CRF is deducted at 1 per cent of profit before tax, with no accountability of where it has been spent.

Delays in approvals required at the pre-production stage are also tied to a cumbersome political economy. In other countries where a strong regulatory system exists, evaluations take 3-4 months, after which other procedures set in, and the letter of registration is issued within 12 months. In Pakistan, not only are delays longer, but since compliances are voluntary, the cost is even higher for compliant firms when other firms simply choose not to produce at the same quality and standards. This not only distorts the incentive for other firms to be compliant, but also penalises those that are. At the same time, even where bare minimum standards are required, inspectors can be bribed and firms get away with not following these rules owing to a weak regulatory regime. Similarly, the government can take a long time with registration and pricing decisions —sometimes pricing approvals sit with the Cabinet for months, if not years, even if DRAP and the pricing committee undertake due diligence in the required timeframe. This is true even for generic drug pricing— Pakistan is unique in this aspect, as no other country in the world requires Cabinet approval for generic drugs.

Production stage

This stage mainly entails sourcing of APIs & excipients as well as the process of production. Pakistan is active in the formulations end of the value chain, but as mentioned earlier, Pakistan is heavily reliant on China and India for import of APIs. That Pakistan is unable to enjoy any comparative advantage in sourcing the key raw material used in pharmaceuticals vis-à-vis other drug formulators is all the more unfortunate given that the top two API producers of the world are Pakistan's neighbours. In fact, its political economy leaves it at a severe disadvantage. For example, imports from India are subject to an additional layer of uncertainty due to on-going political relations. Close to 50 per cent medicines made in Pakistan use raw materials from India. Pakistan also imports around 150 medicines and vaccines from India each year. Since the ban on imports from India, consignments of medicines and pharmaceutical raw material had been stuck at the Karachi port, diverted to other destinations or returned to India. In September 2020, upon industry request, the federal Cabinet exempted the pharmaceutical industry from this ban. While import of raw materials from Europe or America was a possible alternative, not only would it have increased the cost of production manifold, but also required at least 6-16 months to switch sources, as per industry interviews. However, this is not the first time this has happened. In 2019, in the wake of the Pulwama incident, a complete ban was put on imports from India. This ban was then quickly removed when severe shortage of critical medicines began taking place.

Post-production and Exports

In addition to packaging, marketing and distribution this stage also includes exports. While DRAP is heavily involved in regulating pricing, it currently has limited capacity to undertake its main function of maintaining quality and this may hamper the industries potential to export. While there is tremendous overstaffing in DRAP, quality, oversight and transparency is very limited. The key function of DRAP has shifted from being a quality regulator to a price controller, or enactor of the Drugs Act, 1976, the primary legislation governing the pharmaceutical sector. While DRAP is heavily involved in regulating pricing, it has limited capacity to undertake its main function of maintaining quality.

Moreover, price controls, licensing regimes, multi-tier corruption, bureaucratic predation, and SROs also distort competition. Rent-seeking by government officials is reinforced by similar behavior of some firms, leading to low quality manufacturing that does not meet regulatory standards necessary for exporting. In the presence of price controls, some firms are tempted to cut costs by comprising on quality. This affects the overall productivity and image of the sector. Industry insiders reveal that there are only 1-2 firms which are qualified to submit the product dossier for export even to the Philippines, a semi-regulated market.

Margins

The sector has been facing a distorted pricing structure that has often changed for the worse, with firms engaged in rent-seeking activities in the face of decreased profitability amid higher costs of production.

Price ceilings legislated in terms of maximum retail prices (MRPs) through an opaque pricing rule in an *ad-hoc* manner by DRAP had led to price rigidities and discrepancies. Firms with different brands of the same generic medicine could get different MRPs, creating opportunities for rent-seeking and corruption. With price increases not well-defined and a political consensus to suppress inflationary pressures on prices of essential drugs,[79] there was a *de facto* price freeze between 2001 to 2013.

The distorted pricing structure has led to securing high margins when MRPs are first set, introducing higher-priced substitutes as second and third-generation variants of the same medicine; importing more expensive alternatives, and encouraged firms switching to production of alternative non price-regulated medicines (nutraceuticals). It also encouraged smuggling and hoarding of drugs that were in short supply as production became uneconomical due to the price freeze. Sharp increases in medicine prices have been reported in suspicious circumstances where officials were arrested for colluding with companies to illegally increase prices.[80]

79 This has also been seen in food items in Pakistan, as the example of livestock sector illustrated in the report of the first phase for this project. See also Haris Gazdar, "Food Prices and the Politics of Hunger: Beneath Market and State," IDS Bulletin 46, no. 6 (2015): pp. 68-75, https://doi.org/10.1111/1759-5436.12188.

80 https://www.thenews.com.pk/print/167729-NAB-arrests-DRAP-ex-head-in-mega-corruption-case

81 https://ace.soas.ac.uk/wp-content/uploads/2019/08/ACE-WorkingPaper012-PakistanPharmaSector-190801.pdf

Box 2: Price freezes and their implications—Who benefits?

Consumers may initially get essential drugs at a cheaper price but many of these drugs are not produced eventually and disappear from the market as producer see reduced profits. A study by Diwani and Syed (2019) reveals that there could be four potential beneficiaries of such a price freeze.[81]

1. Importers of drugs which may also include some pharmaceutical companies: When production of a drug halts as a result of it not being profitable anymore, the gap in supply is filled by imports, selling the drug at many multiples of the original price.
2. Producers also benefit: Drugs that have become too expensive to manufacture are usually first-generation drugs and are replaced by more expensive second- or third-generation drugs over the medium term.
3. Producers of alternative medicines: firms that have long produced allopathic drugs and have recently set up production of alternate medicines under a different manufacturing name. In these instances, they produce the same drugs at higher prices by taking advantage of how DRAP categorises medicines (Pharmacopial and non-Pharmacopial).
4. Finally, drugs that are in short supply can be hoarded, or smuggled into the country, and then sold on the black market

Barring a few large players with political connections, the overall low power of the pharmaceutical sector is further compounded by a negative perception of the sector as profit-mongers. The predominant public perception is that the pharmaceutical industry is a philanthropic, not a commercial venture. Even minor increase in prices are sensationalized by the media as much higher. Although drug prices are regulated the world over to ensure availability and access to drugs, governments allow fair margins to drug manufacturers to ensure sustainable supplies.

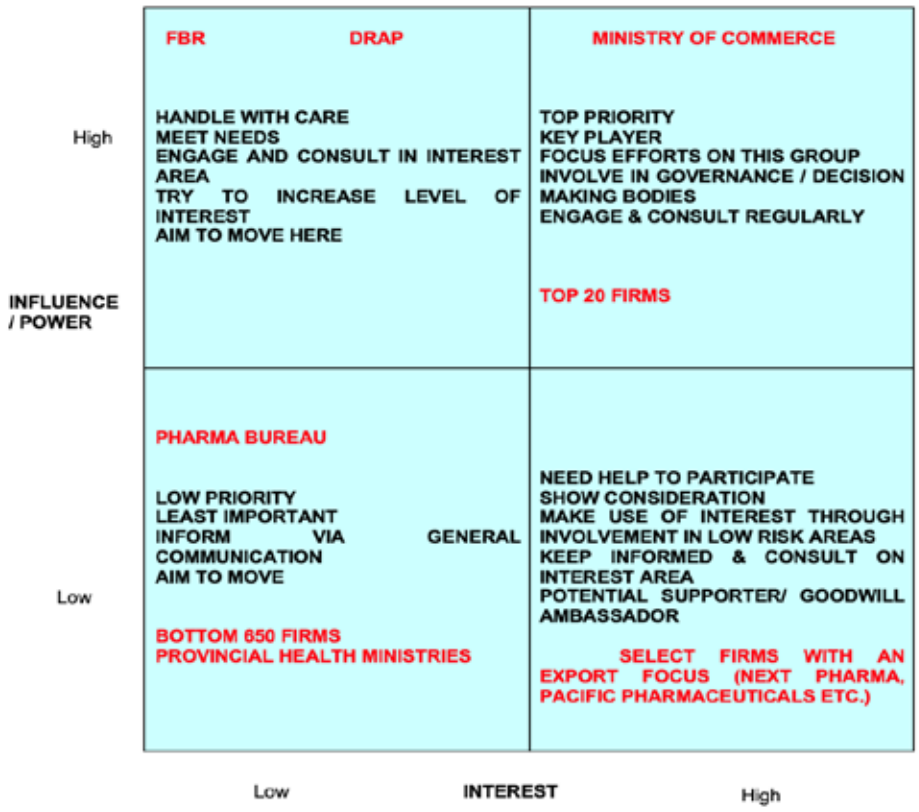
In response to the excessive lobbying by firms through associations, the government increased the price of some goods in 2013. This was contested by consumers and revoked under public pressure. Firms, however, went to court and got a stay order against the revocation. Subsequent events reveal the capacity of key stakeholders to shape policy. In 2015, a Drug Pricing Policy was introduced that was unacceptable to both firms and consumers. In 2018, following litigation the latest pricing policy was launched after consultations with multiple stakeholders on orders from the Supreme Court. This entire process of judicial intervention led to the introduction of a formal Drug Pricing Policy 2018 that enabled rule-based price setting as well as annual price increases tied to the Consumer Price Index (CPI), reducing the opportunity for rent-seeking earlier possible and providing a level playing field. This too did not last, with a new government succumbing to pressures from consumers. By July 2020, it abolished the CPI-based price increases, returning to a system of administered price controls by Cabinet. This will likely result in a new configuration of power relations between the key players.

4.5 Stakeholder analysis

The last segment of this section undertakes a stakeholder analysis which is critical for understanding the overall political and power dynamics. This includes mapping of the key stakeholders at both the country and sector-level. Key stakeholders also include politicians, bureaucrats, industry leaders, trader associations, chambers of commerce, etc. operating both at the macro and sector level, in addition to those mentioned above. Each of these players is categorized in terms of their influence and their level of interest in the performance of the relevant economic sectors (see Figure 31). As you move from left to right, the level of interest goes up. As you move from bottom to top, the level of influence goes up. This sector-level analysis remains critical for deriving recommendations and reform measures that are specific to the Pharma industry. This analysis is

however underpinned by an understanding that opportunities facing the pharmaceutical sector is at some level constrained by the macroeconomic context. There may be sets of stakeholders that feature at the macro-level (FBR for e.g.) and exert influence over outcomes at the sector level.

FIGURE 28 Stakeholder Influence Alignment



Source: Author analysis

The diagram reveals that those with the highest interest and power/influence include the Ministry of Commerce and the top 20 firms. Those with the lowest interest and power/influence include the Pharma Bureau, the 650 SMEs and the provincial health ministries. These players are happy with the *status quo* and have little incentive to transform. Select firms that have an export focus have high interest in change but low power, while organizations like the FBR and DRAP have high influence/power but low motivation/interest to transform this sector. Policies guided by this matrix will help focus on the right stakeholders to enable change.

Having looked at the political economy of the sector in terms of key weakness along the value chain, the next section identifies which products and markets are worth exploring. To ensure export survival, global insights from leading exporters are also presented.

CHAPTER 5

Growth potential

This section explores the growth drivers within this sector, including product lines, markets and processes that represent a realistic opportunity canvas for us. With leading producers such as China and India shifting focus to the more value-added innovative pharmaceutical industry, as mentioned in section 2, Pakistan can strategically enter global markets to meet demand for off-patent original block-bluster drugs that are still widely demanded in low and middle-income countries where disease burdens remain high. A small slice of this huge market (USD 700 billion and USD 381 billion for branded generics and generics, respectively) is still a sizeable share. By the end of 2020, Pakistan can tap into USD 151 billion worth of generics that have already gone off-patent. In 2019 Pakistan's total exports in these lines were USD 210 million. Increasing world export share by just 0.01 percentage point is an opportunity of USD 0.76 billion in the off-patent generics market. Pakistan's main competition will be from countries such as Bangladesh, Vietnam and Jordan that have established trade connections with our selected target markets.

Evidence from other countries shows that size of the domestic market and protection of intellectual property rights are the two main avenues of attracting firms and FDI into the sector. Size leads to economies of scale and increases cost competitiveness, which is essential for any country manufacturing branded generics or generics. Scale can be expected to improve from some recent changes on the demand- and supply-side, for e.g., planned expansion in public healthcare coverage under *Sehat Sahulat* Program; pricing revisions by DRAP to moderately offset inflation and devaluation costs; renewed political interest in pharmaceutical sector in light of COVID-19 and recent attempts by DRAP to strengthen its institutional capacity.

At the same time, increasing the export intensity of the sector is also a priority, if not for government (see below), then at least for the sector itself. To select realistic product lines, this section utilized a modified variant of the Growth Identification and Facilitation framework (GIFF), a policy tool based on insights from New Structural Economics. This emphasizes both effective markets and government facilitation in order to achieve industrial diversification and upgrading. GIFF allows countries to determine latent comparative advantage and utilize it to promote structural change. Usually, GIFF is used to identify potential sectors, however, we will modify the analysis by deploying it at the product level to identify potential products within the pharmaceutical sector. A second filter for export potential on identified product lines is applied, based on growing global demand and domestic capacity. Products are short-listed from the first selection only if global import growth per annum over the last five years has been positive. As exporting drugs is particularly cumbersome and expensive, firms should not target declining product categories. A total of 9 product lines at the (H 6-digit level) that Pakistan can focus on are identified. While Pakistan already exports these lines, its world export shares are less than 0.5 per cent in 2019, with exports of USD 176 million in 2019, in a global market worth USD 569.5 billion. Validation by sector experts reveals that these are realistic products for firms to focus on.

At the next stage, realistic markets for these products are identified, i.e., fastest growing global importers for each of these categories. Markets that are currently being supplied by peer countries will be shortlisted for further analysis. Tariffs faced by Pakistan and its main competitors in these target markets will be briefly

examined, along with other relevant features that could provide Pakistan a competitive edge. Lastly, the section shares policy insights from best practices that have helped other countries penetrate global markets within these product lines. This section builds on insights gained from the key sector and growth specialists that have been discussed in Sections 3-4, which could prove to be critical in unlocking competitiveness and unleashing the growth potential of this sector.

5.1 Growth Identification and Facilitation Framework (GIFF) for Pharmaceuticals

A variant of the GIFF methodology is applied as a first cut to select the products that were critical to successful growth of countries similar to Pakistan 20 years ago. These countries are Pakistan's benchmark countries. Of these, a sub-set of aspirational countries are selected, i.e., those which had higher income per capita growth over 1999-2017 and manufacturing value added than Pakistan (the year 2017 is used as data is not consistently available for the two latest years of 2018 and 2019). These aspirational countries are called transfer countries. Next, the product lines within pharmaceutical sector that were instrumental in transfer country growth, but which they have since vacated, are identified. These lines represent an opportunity for Pakistan: since Pakistan is similar to these transfer countries, and these lines were produced by them quite successfully, Pakistan could have latent comparative advantage in them. Government support should then focus on dismantling any entry barriers, removing existing impediments, attracting investment, financially scaling up self-discoveries, make use of industrial parks and export-processing zones where possible, and preferential access to foreign exchange for importing machinery for technological upgrading purposes. A detailed explanation is provided below.

Benchmark countries are those that have larger economies as compared to Pakistan, but not so large that they are unattainable. Two approaches are used to shortlist such countries. The first approach identifies those countries that had similar levels of per capita income twenty years ago, and the second approach identifies those countries that have 100-300 per cent higher per capita income than Pakistan in 2017.

Table 8 shows the first approach, shortlisting all those countries with similar levels of per capita GDP as Pakistan twenty years ago (between 70-90 per cent of Pakistan's GDP per capita in 1999),[82] and that experienced higher growth in per capita income than Pakistan. Within these set of countries, those with a high growth (averaging above 8.5 per cent since 1999) and higher current level of manufacturing value added contribution to GDP than Pakistan are highlighted. According to this approach, the benchmark countries are India, Sri Lanka, Indonesia, Viet Nam and China.

82 The upper limit has been stretched somewhat to include China, as it is an important transfer country. The existing political and trade ties, and prospective benefits from CPEC justify its inclusion.

TABLE 8 Benchmarked countries with comparable incomes in 1999

Country Name	GDP per capita (current USD) 1999	Ratio of GDP per capita, 1999 (benchmarked country/Pakistan)	GDP per capita growth (1999-2017)[83]	Manufacturing, value added (% of GDP) 2019
Pakistan	465.08	1.00	6.9%	11.98
Kenya	421.43	0.91	7.7%	7.90
Bangladesh	397.35	0.85	7.7%	17.30
Nigeria	497.56	1.07	7.9%	8.74
Ukraine	635.77	1.37	8.2%	12.39
Bhutan	751.58	1.62	8.2%	7.25
India	443.50	0.95	8.7%	14.87
Zambia	332.46	0.71	8.8%	7.55
Sri Lanka	838.62	1.80	9.2%	15.92
Ghana	417.77	0.90	9.2%	10.89
Indonesia	671.11	1.44	10.2%	20.16
Georgia	673.54	1.45	10.5%	10.65
Vietnam	361.29	0.78	10.9%	15.33
Armenia	597.43	1.28	11.0%	10.23
Azerbaijan	573.89	1.23	11.6%	4.72
Mongolia	445.01	0.96	12.5%	9.04
China	873.29	1.88	13.7%	29.34
Angola	385.77	0.83	14.0%	6.58

Data source: World Bank World Development Indicators

Results for the second approach—choosing countries that currently have 100-300 per cent higher GDP per capita than Pakistan's are illustrated in Table 9. We have excluded countries with a lower GDP per capita growth than Pakistan. Highlighted in blue are the countries that have high growth (averaging above 8.5% since 1999) and higher manufacturing value added contribution to GDP than Pakistan. This approach results in a somewhat different set of benchmark countries. Indonesia and Sri Lanka, however, are common to both of these approaches.

83 This is the Compound Annual Growth Rate (CAGR) between 1999 and 2017, using GDP at current USD. Data for 2018 and 2019 is not available consistently for all countries

TABLE 9 Benchmarked countries with 100-300% higher incomes in 2017

Country	GDP per capita 2017	Ratio of GDP per capita 2017 (benchmarked country/Pakistan)	Growth in GDP/ capita (1999-2017)[84]	Manufacturing value added (% of GDP) 2017
Pakistan	1547.85	1	6.9%	11.98
Bolivia	3393.96	2.19	7.0%	10.49
Paraguay	5823.77	3.76	7.1%	19.95
Ecuador	6273.49	4.05	7.9%	14.37
Bosnia and Herzegovina	5148.21	3.33	8.2%	13.12
Bhutan	3130.23	2.02	8.2%	7.25
Albania	4537.58	2.93	8.6%	5.98
Belarus	5733.31	3.70	9.0%	22.22
Sri Lanka	4073.74	2.63	9.2%	15.92
Guyana	4655.14	3.01	9.4%	5.74
Indonesia	3846.42	2.48	10.2%	20.16
Georgia	4045.42	2.61	10.5%	10.65
Armenia	3936.80	2.54	11.0%	10.23
Azerbaijan	4135.14	2.67	11.6%	4.72
Mongolia	3717.47	2.40	12.5%	9.04
Angola	4100.29	2.65	14.0%	6.58

Source: World Bank World Development Indicators

The benchmarked countries are defined by their high growth. As these countries have grown, their development stages and industrial bases have also evolved. Structural transformation changed factor prices and availability, particularly increasing labor costs. These changes have led some of these transfer countries to lose their comparative advantage in some product lines that were drivers of growth in the last two decades. It stands to reason that they may want to relocate to cheaper countries, especially in terms of labour. In the case of Pakistan, a simple way of identifying potential transfer countries is to identify countries that have higher minimum wages. Table 9 shows that this reduces the set of potential transfer countries to Belarus, Viet Nam, Indonesia and China.

TABLE 10 Minimum wages in benchmarked countries[85]

Country	Minimum wage 2018 (USD)
Sri Lanka	56.95
India	106
Pakistan	112.55
Belarus	158.65
Viet Nam	180.44
Indonesia	256.44
China	306.80

Source: https://countryeconomy.com/national-minimum-wage

Notes: 1) Data corroborated by national wage board websites, newspaper articles for Uzbekistan.2) Local currency NMW was converted to USD using nominal exchange rates as of 21.08.2019

84 This has been calculated as the Compound Annual Growth Rate (CAGR) between 1999 and 2017, using GDP at current USD. Data for 2018 and 2019 is not available consistently for all countries

85 Updated data for minimum wages is not available at a single source. Data from different government websites and newsprint has been used for the latest years available

Trade trends for these "transfer countries" in HS 30 are explored in Table 11. Product codes in the top twelve pharmaceutical exports of the reference countries in 1999 (at HS 6-digit level) are listed in Column 1.86 Column 2 indicates if that product code is declining (share of that line within world exports has declined in 2019 relative to 1999) in the transfer country with a "1". Column 3 (the "score") indicates how many out of the four countries experience a decline in that product category since 1999, for e.g., product code HS300410 (medicaments containing penicillins) has declined in three out of the four countries: Belarus, Indonesia and China. These three countries are ideal transfer countries from which to seek transfer in this pharmaceutical product category.

TABLE 11 Declining product categories in transfer countries

Declining product codes (1)	Declining in: (2)				Score (3)	Commodity name (4)
	Belarus	Vietnam	Indonesia	China		
300590	1		1	1	3	Wadding, gauze, bandages and the like, e.g. dressings, adhesive plasters, poultices, impregnated
300490	1				1	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, put up in measured doses, not antibiotics, medicines with hormones/steroids, medicaments w/t alkaloids and medicaments containing provitamins, vitamins used as vitamins
300120				1	1	Extracts of glands or other organs or of their secretions, for organo-therapeutic uses
300190		1			1	Dried glands and other organs for organo-therapeutic uses, whether or not powdered; heparin
300420		1	1		1	Medicaments containing antibiotics, put up in measured doses (excl. penicillins and streptomycins)
300390		1	1		2	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic use, not in measured doses (excl antibiotics containing hormones used as hormones)
300410	1	1		1	3	Medicaments containing penicillins or derivatives thereof with a penicillanic acid structure, put up in measured doses, in forms or packings for retail use
300450				1	1	Medicaments containing provitamins, vitamins, incl. natural concentrates and derivatives thereof
300510			1		1	Adhesive dressings and other articles having an adhesive layer, impregnated or covered, for medical, surgical, dental use
300439		1	1		2	Medicaments containing hormones or steroids used as hormones but not antibiotics (excl corticosteroids and insulins).
300220			1		1	Vaccines for human medicine
300210	1	1	1		3	Antisera and other blood fractions and immunological products, whether or not modified or obtained

Source: ITC TradeMap for data, own calculations

To supplement this analysis, the second filter of growth prospects is applied, i.e., whether the global market for these lines is dynamic or declining. Table 12 shows the rate at which demand for these products has grown over the last 5 years (measured by world import growth rate per annum, 2015-19). This yields 9 growing product categories for Pakistan to invest in. Antisera and other immunological products (HS 300210), medicaments consisting of two or more products mixed together (HS 300390) and hormonal medicaments (HS 300439) are the fastest growing globally. Luckily for Pakistan, HS 330439 and HS 300390 are the second and fifth largest export category of Pakistan, and its share of world exports in these categories is rising gradually.

86 The top 20 HS 6-digit codes were selected, but as there was little variation beyond the top 12, only those were selected.

These nine target products are divided, based on how established Pakistan already is in these products. Priority 1 products rank within the top 10 pharmaceutical exports, while those below are termed as Priority 2. Seven out of the nine identified lines fall within Priority 1, i.e., within Pakistan's top 10 pharmaceutical exports, and therefore present an immediate opportunity with growing global demand.

Within Priority 1, low-hanging fruit are: HS 300490 medicaments consisting of mixed or unmixed products in dosage form, containing either hormones/steroids, alkaloids, and/or provitamins & vitamins (but not antibiotics); HS 300439 medicaments containing hormones or steroids used as hormones but not antibiotics (excl corticosteroids and insulins); and HS 300420 medicaments containing antibiotics, put up in measured doses (excl. penicillins and streptomycins). Exports of these products were USD 82.4 million, USD 77 million, and USD 16.6 million, respectively in 2019.

Priority 2, that are growing globally, and in which Pakistan could build export competitiveness over time, are vaccines for human medicine (HS 300220) and antisera (HS 300210), in which Pakistan has negligible exports. These could be products where Pakistan can focus on in the long term, to develop potential trade advantages. Partnerships with the transfer countries, for example with Vietnam and China in the form of joint collaborations, can help Pakistan upgrade these categories to increase value-addition and form a larger part of Pakistan's export basket.

This data can also be used to take a nuanced approach to sectors. For example, Pakistan exported USD 11.3 million worth of HS 300390 (medicaments containing two or more constituents mixed together for therapeutic or prophylactic purposes) and world imports have grown by 13 per cent per annum over 2015-19. A concerted strategy must be followed to build on Pakistan's existing strengths and labor cost advantages to attract investment from China and Vietnam. These sectors should also receive priority government attention in terms of information, capacity-building of supporting institutions and easing of binding constraints. Other factors such as ease of getting visas, security perceptions and leveraging the excellent infrastructure of Lahore and Karachi, the two main urban areas close to which many manufacturing sites are located, should be highlighted to attract skilled labour, sector experts, and quality auditors.

TABLE 12 Key indicators for target product lines, HS 6-digit level

Code	Commodity name	Pakistan's exports 2019 (USD million)	Annual increase in Pakistan's share of world exports 2015-19, %	Annual growth of world imports 2015-19, %	Rank in Pak exports of HS 30, (2019)	Priority
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, put up in measured doses, not antibiotics, medicines with hormones/steroids, medicaments w/t alkaloids and medicaments containing provitamins, vitamins used as vitamins	82.4	4	3	1	1
300439	Medicaments containing hormones or steroids used as hormones but not antibiotics (excl corticosteroids and insulins).	77	7	9	2	1
300420	Medicaments containing antibiotics, put up in measured doses (excl. penicillins and streptomycins)	16.6	3	5	3	1
300390	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic use, not in measured doses (excl antibiotics containing hormones used as hormones)	11.3	2	13	5	1
300590	Wadding, gauze, bandages and the like, e.g. dressings, adhesive plasters, poultices, impregnated	3	3	3	7	1
300450	Medicaments containing provitamins, vitamins, incl. natural concentrates and derivatives thereof	2.5	0	1	8	1
300510	Adhesive dressings and other articles having an adhesive layer, impregnated or covered, for medical, surgical, dental use	1.6	7	6	9	1
300190	Dried glands and other organs for organo-therapeutic uses, whether or not powdered; heparin	1.2	1	6	13	2
300220	Vaccines for human medicine	0	0	8	20	2
300210	Antisera and other blood fractions and immunological products, whether or not modified or obtained	0	0	17	19	2

Data source: UN Comtrade

Table 13 summarizes the target product lines by transfer country, ranked by world imports. Belarus and China are ideal countries for generic medicaments (excluding antibiotics, steroids, and vitamins) along with vitamins & provitamins products, whilst Indonesia is an ideal country for vaccines. Viet Nam is also an ideal transfer country for antisera; vaccines; along with medicaments used as hormones, antibiotics (excluding penicillins and streptomycins).

TABLE 13 Target product lines for Pakistan (at HS 6-digit level), by transfer country

Code	Commodity Name	Value imported globally in 2019 (USD bn)	Annual growth in global imports between 2015-2019 (%, p.a.)	Pakistan's share in world exports 2019 (%)
Transfer country: Belarus				
300490	Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, put up in measured doses, not antibiotics, medicines with hormones/steroids, medicaments w/t alkaloids and medicaments containing provitamins, vitamins used as vitamins	319.6 bn	3	0
300510	Adhesive dressings and other articles having an adhesive layer, impregnated or covered, for medical, surgical, dental use	4.1 bn	6	0.04
Transfer country: China				
300590	Wadding, gauze, bandages and the like, e.g. dressings, adhesive plasters, poultices, impregnated	4.6 bn	3	0.071
300450	Medicaments containing provitamins, vitamins, incl. natural concentrates and derivatives thereof	4.1 bn	1	0.058
Transfer country: Indonesia				
300210	Antisera and other blood fractions and immunological products, whether or not modified or obtained	157.3 bn	17	0
300439	Medicaments containing hormones or steroids used as hormones but not antibiotics (excl corticosteroids and insulins).	33.2 bn	9	0.31
300220	Vaccines for human medicine	31.9 bn	8	0
300390	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic use, not in measured doses (excl antibiotics containing hormones used as hormones)	10.6 bn	1	0.15
300510	Adhesive dressings and other articles having an adhesive layer, impregnated or covered, for medical, surgical, dental use	4.1 bn	6	0.108
300390	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic use, not in measured doses (excl antibiotics containing hormones used as hormones)	10.6 bn	1	Repeated
300590	Wadding, gauze, bandages and the like, e.g. dressings, adhesive plasters, poultices, impregnated	4.6 bn	3	Repeated
300510	Adhesive dressings and other articles having an adhesive layer, impregnated or covered, for medical, surgical, dental use	4.1 bn	6	Repeated
Transfer country: Viet Nam				
300210	Antisera and other blood fractions and immunological products, whether or not modified	157.3 bn	17	Repeated
300439	Medicaments containing hormones or steroids used as hormones but not antibiotics (excl corticosteroids and insulins).	33.2 bn	9	Repeated
300220	Vaccines for human medicine	31.9 bn	8	Repeated
300420	Medicaments containing antibiotics, put up in measured doses (excl. penicillins and streptomycins)	17.3 bn	5	Repeated

5.2 Potential markets

Next, potential markets for these products are explored. This is done by looking at the top 10 importing countries for each of these goods. Those destinations are selected that are currently being served by countries similar to Pakistan, including the transfer countries. Drug consumption continues to rise in middle-income and low-income countries.[87] African countries stand out as a lucrative market, as imports meet 70 per cent of overall demand. Pakistan's overall HS 30 exports amounted to 0.2 per cent of the African market or USD 35.8 million, while Africa world imports stood at USD 16.9 billion, of which the majority were drug formulations. The main threat is India, with a share in Africa's export of 19.2 per cent in 2019, with South Africa, Nigeria, Kenya and Tanzania dominant partners. Top partners for Pakistan were Kenya, Egypt, Sudan and Nigeria.

For two top HS products in priority 1, i.e., HS 300439 and HS 300490, Pakistan has tariff-free access in most African markets, with a limited number of non-tariff requirements. However, same tariffs are applied to all import partners, so that landed cost of imports depend largely on underlying export prices. India and China are top competitors in Nigeria, commanding 47 and 24 per cent respectively, of the market. In Tanzania, India and Kenya dominate the market, with India accounting for 59 per cent of Tanzanian imports. At the same time, India dominates the Kenyan and South African markets as well.

Other market opportunities for Pakistan are emerging economies such as Brazil, Russia, Indonesia, China, and South Africa. Together these have overtaken European markets as the new import hubs for pharmaceutical sector, accounting for a sizeable share of global demand. USA continues to occupy the top spot, while China replaces Japan as the second largest importer of pharmaceutical goods in 2019. These trends continue for individual tariff lines in Priority 1, with USA and EU dominating, followed by China, Japan and BRICs. Some of these markets are SRA countries including Japan, European countries, UK, Russia, China and the USA, while others are semi-regulated like African and Southeast Asian countries. Some are examined below.

Priority 1 lines: Short-run opportunities

Our main competitor in all markets and product categories in Priority 1 are India, China, Jordan, Kenya and sometimes, Malaysia. Apart from the large, developed country markets, Pakistan can target China. China applies zero tariffs on HS 300490 for Pakistan, but levies tariffs of 0.5 per cent on Jordan, 0.3 per cent on India, and 0 per cent on Vietnam and Malaysia. It applies 4064 non-tariff requirements. For HS 300439, China is the 6th largest import market, and is largely dominated by developed countries, although India is at 14th position. It faces duty-free access to China but must comply with the 984 requirements China levies on all import partners. In USA, it is the 16th largest partner.

Priority 2: Long-term targets

For long-term prospects such as antisera and vaccines, or HS 300210 and HS 300220 respectively. the leading importers include emerging economies of BRICS along with Mexico. Top suppliers to these markets are EU countries (Ireland, Germany, Belgium and Switzerland) , the USA, China and Japan. It is interesting to note that Iran is one of the top 20 exporters in Germany for antisera, whereas Korea, Singapore and China are among the top 20 exporters for vaccines. Human vaccines are mostly imported by emerging economies, including China, Brazil, and Turkey. Again, the top developing country partner that Pakistan could seek to emulate is India. China levies taxes of 3.9 per cent and Brazil 2.1 per cent on India. India's shares in the markets of Brazil and Turkey are 6.4 and 6.1 per cent, respectively.

A potential market in antisera for Pakistan is China, which is the 4th largest importer globally. Under CPFTA-I already, Pakistan had duty-free access to China, however, our main competitors in China would be developed countries, with the exception of South Korea and South Africa (but their shares are less than 0.1 per cent). Similarly, USA imports mostly from Ireland, Singapore and Korea (23, 6 and 5 per cent of the market,

87 Yusuf, S. (2020)

respectively), while China and India have less than 0.5 per cent share in their markets. In fact, India is sending antisera to USA, Netherlands, Canada, Algeria, Kenya, Brazil, Thailand and Mexico. A potential market that Pakistan could target is Russia, where India is ranked 8th and Thailand 10th, both facing duties of 4 per cent and 38 non-tariff requirements.

Notwithstanding the comparison of tariffs done above in 5.2, it is important to caveat those findings by recognizing that pharmaceutical trade is unlike trade in other goods. It is highly regulated, subject to stringent compliances, and sensitive to many parameters. Tariff access is therefore only a very small determinant of competitive access and success in the pharmaceutical sector. This is because successful entry varies for each pharmaceutical product line. In addition to having the required capabilities to meet global standards, the companies will have to develop a marketing strategy in order to gain access and make sales. The companies will have to initially estimate the potential, then assess the competition, determine accessibility, identify key influencers in the target market, comply with the entire regulatory system and be fully aware of the healthcare system in terms of distribution and delivery systems in place.

Vaccines

In a highly populated, resource-constrained country like Pakistan, universal immunization must be the cornerstone of an effective public health strategy. Despite having one of the largest birth cohorts in the world (5.5 million babies born in 2019), Pakistan has virtually no domestic vaccine production. The dependency on imported vaccines (mostly from India) presents a serious health security challenge for the country. Pakistan's vulnerability in this area has been further underscored in the context of the COVID-19 pandemic. Amongst other constraints in the provision of public health interventions, supply and provision of vaccines remain a key component requiring attention by the government.

The acquisition of vaccine manufacturing capabilities can be a first step towards the production of next-generation, high-value pharmaceuticals in Pakistan. The global market for human vaccines was valued at USD 33 billion in 2019 by the WHO Global Vaccine Market Report 2020. It is expected to reach USD 66.6 billion by 2027. With Pakistan exports currently zero, a 0.01 percent share in this market amounts to USD 0.66 million by 2027. In the long run, the study identifies human vaccines as a prospective sub-sector that Pakistan could focus on.

The Pakistan National Institute of Health (NIH) was conceived in the 1960s to facilitate infectious disease control programmes, production of biological medicines such as anti-venoms, and vaccines. The institute collaborates with WHO for viral diagnostics and also serves as a regional reference laboratory for viruses like polio and flu. Unfortunately, NIH never sustained and improved its capability to continue producing vaccines. Its performance has deteriorated over the years, mainly due to a lack of vision, strategic direction, government support and funding. The only public sector manufacturing facility—and sole producer of life saving vaccines and anti-sera for immunization and therapeutic use to control infectious and non-communicable diseases in the country—the Biological Production Division (BPD) at NIH has gradually failed to cater to ever increasing demand. Overall decline of vaccine production is the result of a long-term failure to reinvest in staff, management systems, physical infrastructure, technology, quality assurance and quality control.

In light of these supply constraints, the government relies on international procurement of vaccines. Currently, the production is outsourced as vaccines are provided at subsidized prices from donor agencies under the Global Alliance for Vaccines and Immunization (GAVI) as part of long-term agreements. The private market for vaccines is minimal, with the government being a virtual monopoly buyer. Vaccines are procured in bulk directly by the government from vaccine manufacturers or through coordinated multi-country programmes funded by donor agencies such as GAVI. Demand comes from the Expanded Program for Immunization (EPI), which comprises over 85 per cent of the total vaccine market. Approximately 1.5 billion vaccines are needed just to provide basic EPI vaccine coverage over the next 5 years alone. Local firms indicate capacity to serve the huge domestic market for vaccines but cannot compete with subsidized GAVI prices. To ensure scale, they require a government buyback guarantee, as a simple vaccine plant costs around PKR 20 million.

The market dynamics of human vaccines are such that sustainable vaccine production requires a Public Private Partnership (PPP) approach: the private market for vaccines is minimal, with the government being a virtual monopoly buyer. A PPP approach seems to be both practical and successful, and several examples exist to validate this model. In Pakistan, private sector manufacturing of vaccines could supplement NIH's existing capacity while addressing organizational, managerial and financial constraints that prevent the institution from expanding its output. This will catalyse the capacities in the overall health system to respond to national needs as well as achieving national vaccine/ immunoglobulins self-sufficiency.

Indigenization of Vaccine Production

World vaccine experts recommend the following stages of local vaccine production

- Level 1: Distribution of imported finished vaccine products.
- Level 2: Packaging and Labeling of imported vaccine products following national or international GMP standards.
- Level 3: Vaccine product manufacturing from imported bulk (fill & finish) following national or international GMP standards.
- Level 4: Full cycle manufacturing: Production of active pharmaceutical ingredients and excipients following national or international GMP Standards.
- Level 5: Research and Development of new formulations, processes and new chemical or biological entities following national or international Good Laboratory Practice (GLP) regulations, Good Clinical Practice (GCP) and ethical standards.

Currently, Pakistan is at Level 1 in terms of indigenization of local vaccine production, i.e., distribution of imported finished vaccines (mostly arranged through GAVI, UNICEF or similar international donor organisations), with minor Level 2 activity by 1 Islamabad-based firm of packaging and labeling imported vaccine products. Based on global and domestic demand, industry-validated production capacity, and national security and public health prerogatives, this study suggests that it is now time to help the sector acquire Levels 3 and 4 of vaccine indigenization. Level 3 corresponds to vaccine product manufacturing from imported bulk vaccine concentrate (fill & finish) and Level 4 is full cycle manufacturing, i.e., production starting from the active components (antigens) of the vaccine itself. Stakeholders believe that the transition from Level 1 to Level 4 can be undertaken over a period of 5 years, sufficient time to ensure that local producers remain compliant to World Health Organization (WHO) standards. This should be a prerequisite to local manufacture to ensure that quality standards are not compromised, and the integrity of the vaccines chain is maintained.

Role of partners

In addition to the above, critical success factors for local vaccine production include a key role for partners.

Public Sector: Government of Pakistan / Provincial Governments: Vaccines are public goods, and worldwide, universal vaccination is a goal that is embraced by Governments. Private markets for vaccines, wherever they exist, are much smaller than the public procurement system. Thus, long-term purchase agreements for locally produced vaccines are critical in enabling domestic production to become a reality. Given the importance of universal vaccination in achieving Pakistan's Sustainable Development Goals (SDGs), the Planning Commission, as the custodian of the SDG's for the country, may take the lead in forging a public private partnership involving the Ministry of National Health Services, Regulation & Coordination (Expanded Program for Immunization) and the private sector. Data from the National Institute of Health can be used to prioritize the antigens that need to be produced locally and develop a PPP framework to ensure the sustainability of domestic production.

Drug Regulatory Authority of Pakistan

Vaccines require a significantly higher level of regulation than drugs. As such, the role of the DRAP is critical in the development of an enabling environment for vaccine production. No vaccine can be procured by GAVI or international multilateral agencies or even exported to regulated markets, unless it is WHO-prequalified. In the case of vaccines, before the WHO can prequalify any vaccine manufacturer in a given country, it has to

first prequalify the monitoring, surveillance and quality assurance system of the country's National Regulatory Authority (NRA). This is a critical missing link: the National Control Laboratory for Biologics (NCLB), which is responsible for lot release of vaccines and biologics in the country, needs to build significant capacity and apply for WHO prequalification before any local manufacturer can be approved. The upgradation of NCLB needs to take place immediately.

International private sector: Technology transfer partner

International companies manufacturing WHO pre-qualified vaccines should be approached to enter into an agreement with the Government of Pakistan for technology transfer to local partners. The original manufacturer of the vaccine or a manufacturer with WHO prequalification would be preferred.

Local private sector: Local partner

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 who prefer to deal with governments rather than private sector directly. 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.

Vaccine manufacture: An action plan

Phase I

A two-phased action plan is proposed for indigenization of vaccine manufacture in Pakistan. In Phase I, which can begin immediately, local firms having validated biologic production facilities, or that are willing to invest in the required standards will use imported bulk vaccine concentrate to fill-and-finish vaccines into individual doses. International companies manufacturing WHO pre-qualified vaccines would be approached to enter into an agreement with the Government of Pakistan directly or the government could negotiate with GAVI/UNICEF on behalf of local firms. As supporting sustainable indigenous capabilities for vaccine production is the stated objective of GAVI and the WHO, this should not pose much difficulty for the Pakistan government. Secondly, the government will provide long-term purchase/buy-back agreements for these locally produced vaccines, under a public private partnership involving the Ministry of National Health Services, Regulation & Coordination (Expanded Program for Immunization) and the private sector. Firms would have the option to make any of the 10 vaccines included under the national EPI program as well as highly needed non-EPI vaccines (such as typhoid or the flu vaccine for elderly, religious pilgrims, etc.). Thirdly, DRAP will be given a 2-year timeframe to achieve WHO pre-qualification for the NCLB to help in transition to Phase II.

Phase II

In Phase II, with the newly pre-qualified NCLB, local industry can graduate to Level 4 and opt for the vaccines that are currently in the EPI schedule, so that Pakistan is prepared for when it graduates from GAVI support. Other higher volume Pakistan-specific antigens, as well as COVID-vaccines could also be locally manufactured with the help of technology transfer from global partners, JVs with leading MNCs, or hiring commercial consultants to upgrade existing manufacturing capacity. This could take anywhere from 3 to 5 years, from date of approval of the program. A policy framework would be required to ensure the sustainability of domestic production including fiscal incentives in the form of a tax holiday for at least 5 years and duty-free import of plant and equipment, and as mentioned above, long-term buyback arrangements for locally produced vaccines. The terms of buy-back would be at market prices, so that firms can maintain margins to recover investment—firms suggest that an internal rate of return of 9 per cent is sufficient to cover risks associated with production of vaccine raw materials under Level 4. At the same time, the government can subsidise these vaccines for consumers under its newly launched public healthcare *Sehat Sahulat* Program (SSP). This subsidy may be withdrawn after 3-4 years/when firms able to break-even at SSP prices, whichever is sooner.

Technical support could also be provided to DRAP through globally certified consultants (that government can bring in from WHO by assuring their security) to continuously upgrade its technical and regulatory capacity, as vaccines require greater pharmacovigilance than drugs.

Simultaneously, public sector funding for research in this area has to be significantly increased so that effective support to private sector can be provided. India and Iran have offered many incentives and technology grant supports which translated into the growth of this segment. Other forms of government support can include tax rebates and special cost sharing in certain components (across the board for the vaccine industry), sharing financial burden of technology transfer rights, royalties, etc., as well as loans on soft terms. Moreover, all enabling regulations, such as IPR and biosafety rules should be in place, non-existence of which can be a big hindrance to commercialization.

A new frontier: APIs

Active pharmaceutical ingredients are the backbone of the pharmaceutical industry and are an important ingredient in the manufacture of formulated drugs. In 2019, the global market for APIs was worth USD 170.8 billion, and is projected to grow at a CAGR of 5.8 per cent till 2025, to reach USD 306 billion by 2027.[88] USA, Switzerland, UK, Germany, Israel, India and China dominate this market, with Bangladesh a new entrant.[89] Demand for APIs is on the rise as 66 drug molecules will go off-patent between 2020 and 2025.[90] In response, more developing countries, in addition to the initial incumbents India and China, are focusing on this market, including Thailand, Vietnam, Indonesia and Malaysia. Even Bangladesh is eying an API market that is estimated to expand to USD 250 billion by 2024.[91]

In Pakistan, the last 20 years have witnessed a slow pace of growth in the API sector. There are 6-7 local manufacturers producing a little over 30 APIs. Roughly 88 per cent of total APIs are imported, while 12 per cent are produced by these 6-7 firms. Currently, there are three issues with local API production, First, is the problem of protection. As long as these firms are able to meet 50-70 per cent of local API demand, they are protected from imports by a regulatory duty of 15 per cent. Stakeholders argue that these handful of manufacturers exploit this protection by pricing their local APIs just below the landed price of imported APIs. This defeats the purpose of import substitution, as local APIs are just as costly, and of lower quality than imported ones. So big players and MNCs continue to import, while smaller firms are forced to contend with such dubious market practices by local producers. Secondly, our primary sources of APIs, China and India, are subject to geopolitical tensions. Thirdly, COVID-19 has underlined the significance of having alternative sources of APIs, as it takes between 6-16 months (as per industry) to switch API sources, where possible.

DRAP has recently developed a strategic plan for the development of domestic API manufacturing, using a combination of incentives for investment and technology transfer, limited protection, and the use of clustering in API Parks.[92] A supportive regulatory structure and GMP compliance with ICH Q7/Q7 global standards will be ensured. Although the government has already decided to pursue this policy, it must be heavily caveated that API production is very intensive in energy, capital, skill, and land. In some countries, before APIs can be made, an API R&D plant must be made. In addition, fulfilling the safety protocols, managing the effluents, and recycling the expensive chemicals for re-use itself is a whole industrial process that will rely mostly on imported materials, as Pakistan does not have the chemicals, binders, vats, etc. required. The quality and safety protocols are also completely different and cannot be catered under current systems.

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88 https://www.globenewswire.com/news-release/2020/11/17/2128049/0/en/Global-active-pharmaceutical-ingredient-API-market-size-to-reach-USD-306-1-Billion-by-20277

89 https://www.globenewswire.com/news-release/2019/03/29/1788625/0/en/Global-165-Billion-Active-Pharmaceutical-Ingredients-API-Market-Growth-Trends-and-Forecast-2019-2024.html

90 GIZ. (2019. Value Chain Analysis of the Pharmaceutical Sector in Jordan Industry Overview in Jordan. Trade for Employment (T4E) Project. Available at https://www.giz.de/de/downloads/Value%20Chain%20Analysis%20of%20the%20Pharmaceutical%20Sector%20in%20Jordan.pdf

91 Interview with Dr. Sultan Ghani.

92 Ghani, S. (2020). Building a System for the Manufacturing of APIs: Pakistan's National Strategy and Plan of Action. DRAP

Moreover, unlike Bangladesh, technical assistance in the form of expatriate skilled labour, technicians, quality and safety auditors will also not be forthcoming due to poor perception of state of manufacturing in the country. Many firms spoke of difficulty in attracting partners in general, even from China, despite the Economic Cooperation partnership arrangement under CPEC, saying it was easier to conclude JVs between Chinese firms and Pakistani subsidiaries in Malaysia, rather than in Pakistan. Prospective partners/investors cite issues of labour productivity and professionalism, energy prices, inconsistent policies, weak intellectual properties, expensive land and an overall lack of complementary downstream linkages as key deterrents to produce in Pakistan. These issues are further compounded by security concerns, with partners backing out at the last minute, costing local firms not only money, but more importantly, loss of brand image.

In fact, given the 40 years of experience leading producers of API have enjoyed and the kind of economies of scale exhibited in the production process, even if the plan succeeds, Pakistan would in all likelihood not be able to compete on price with India, China and other API manufacturers. Cost of domestic drugs would rise if forced to use locally manufactured APIs, given that demand (domestic and global) for relatively more expensive locally manufactured APIs would never be sufficient to achieve the minimum efficient scale of production (quantity where average production costs are lowest). In the presence of cheaper global API alternatives, the complexity of API manufacture, and the ground realities of Pakistan, some firms feel a different allocation of the scarce resources could benefit the sector better. In fact, many manufacturers believe that Pakistan may have missed the opportunity on API manufacture years ago. Only after carefully considering the marginal costs and benefits, as informed by broad sector consultation, should the government consider the next step in its API strategy. A broader policy, whereby its role is limited to providing a level playing field by supporting broader manufacturing within an industrial park would be a more suitable and less risky approach. This would leave the decision of investment in API manufacture to the private sector based on feasibility, sustainability, and profitability.

The next sub-section explores how to avail the opportunities arising from these potential growth drivers in product lines, markets and inputs, using policy lessons from peer leaders.

5.3 Policy insights from global success stories

The previous sub-section identified prospective products and markets for firms. This sub-section will present policy insights to build a case for similar interventions in Pakistan, where possible. Section 5.2 revealed the dominant position of India in drugs, vaccines, and APIs. Bangladesh's story and recent API Policy is also discussed. Key policies that were followed by Jordan on accessing markets, another success story, are also explored to determine how firms can raise their chance of successful entry, lower transaction costs, and ensure export profitability.

India

By volume, India supplies one-fifth of globally traded pharmaceutical goods, half its demand for vaccines, and 80 per cent of antiretrovirals demanded in the world. It has the largest number of FDA approved manufacturing plants outside the USA, with 70,000 firms generating industry revenues of USD 36 billion in 2019 and massive FDI inflows amounting to USD 16.4 billion over 2000-19.[93] The world's largest vaccine producer, Serum Institute, is also located in India.

India followed three successful policies that allowed it to become a global leader in generics. Up to 1998, the Patent Act of 1970 governed the pharmaceutical sector—it protected manufacturing processes, not products. Until India signed the TRIPS Agreement in 1998, this allowed local pharmaceutical sector producers to slightly alter their manufacturing process and get their good "patented". Firms proliferated as they could produce

93 https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/mega-fdi-plan-to-focus-on-faster-pharma-approvals/articleshow/75664593.cms?from=mdr

cheaper versions of drugs domestically and compete with MNCs. In addition, patents expired in 7, instead of the usual 15, years. Secondly, there was a strong base of trained pharmacologists, chemists, engineers and technicians that helped meet basic research requirements of local pharmaceutical firms to effectively absorb and utilize scientific know-how. As a result, India could reverse-engineer originator drugs and produce them locally in a slightly different method. Thirdly, 100 per cent greenfield investment was encouraged under the FDI policy, and up to 74 per cent brownfield investment was allowed in the sector without Cabinet approval. This policy and the Patent Amendment Act of 2005 encouraged mergers and acquisitions. [94]

The Act forced local firms to pay royalties to MNCs for making generic copies of blockbuster drugs, for the next 20 years. More MNCs were attracted to India in search of profits, and many acquired local firms or entered joint ventures with them.

Even more importantly, India had a strategic vision about which sectors to target, starting from a big generics market, that would reach USD 381 billion by 2021, and a realization that competing on cost with increased foreign competition after 2005 would be difficult. To that end, bigger Indian firms, such as Dr. Reddy, also acquired foreign MNCs that were making generics. This not only allowed Indian firms to produce at scale, but also generate the revenue streams from generics that could allow them to undertake investments in API manufacturing and new molecule discoveries, post-2005. As a result of its foresight and planning, it is now a leader in not only generics, but also biosimilars and CRAMS. Its highest growth segment in pharmaceuticals is now biopharmaceuticals.[95]

Bangladesh

The pharmaceutical sector in Bangladesh has also grown tremendously, as mentioned in Section 2. With the help of a 15 per cent per annum growth rate, the sector is the largest white-collar employer in the country, its exports doubled over 2014-19, while it can meet 97 per cent of domestic demand. More importantly, its export-orientation is evident from the fact that it began with an initial focus on developing its API industry and achieving global accreditations, which it has secured from the US FDA, the EU, and Australia. Bangladesh followed stringent policies such as the Drug Ordinance of 1982, which prevented MNCs from selling imported drugs in domestic markets, forcing them to make them locally or licensing them to local subsidiaries.

Most of these policies cannot be applied in Pakistan, as Bangladesh is a less developed country, and its pharmaceutical sector is not forced to comply with the Trade-Related Intellectual Property Rights (TRIPS) agreement until its expiry in 2021. First, this allows Bangladesh to produce drugs that are patented abroad and export them to countries where they are not protected under IPs or where licenses are issued to treat diseases such as cancer or HIV/AIDs. These include markets such as Kenya, Myanmar and Vietnam. Secondly, this has allowed the government to actively support the sector through an active industrial policy, using measures that are not permitted for non-LDC members of the World Trade Organisation (fixing prices of imports, banning imports if drugs are domestically produced, withdrawing patent protection for MNCs operating in the country if they don't start manufacturing the drug locally within 4 years, mandator labelling of formulaic information on all imported goods, etc.). These policies largely helped in the creation of large companies such as Beximco and Square with a global presence not only in generics but also APIs, vaccines and injectables.[96] In addition, Bangladesh used Indian pharmaceutical know-how and skilled labour to provide an initial push to its sector, by attracting top professionals from the largest Indian firms.

Recently, the government has shifted its focus to APIs, with an API Policy that aims to reduce import dependency on India, China and South Korea, from 97 to 80 per cent by 2032. This will be achieved by increasing domestic production of APIs from 41 molecules in 2016 to 370 by 2032. Incentives given include: i. unconditional tax

94 Yusuf, S. (2020).

95 http://www.ppma.org.pk/wp-content/uploads/2017/09/Final-Report-Pharma-Industry_August-10.pdf

96 Yusuf, S. (2020); Gay, D. (n.d.). What LDC graduation will mean for Bangladesh's drugs industry. UN LDC portal. https://www.un.org/ldcportal/what-ldc-graduation-will-mean-for-bangladeshs-drugs-industry/

holidays to all APIs and laboratory reagents producers, both local and joint ventures, for five years over 2017-22; ii. 100 per cent tax holiday for 10 years (2022-32) if a producer makes 5 molecules per year; 75 per cent tax holiday for 10 years if they make 3 molecules.[97]

Jordan

Jordan is the regional medicines hub for Middle Eastern and African countries. A late entrant to pharmaceuticals in 1970, this small country produces world-class low-cost generics. Companies such as *Hikma* with 22 subsidiaries in other countries are global success stories, putting it on the map as a high quality but economical producer of branded generics worth USD 1.2 billion in 2018. Currently Jordan serves as an entrepôt between Europe and African countries, re-exporting goods. To do this, it has devised strategic ways of entering new markets not only in the Middle East and Africa, but also in neighbouring European countries. The most relevant ones are discussed briefly below.

Five of its most relevant policies are discussed. Jordan has successfully followed a practice of partnering with importer/local distributor companies, which have special warehouses in the target market, and can move goods for storage and distribution as required. Secondly, they also use a local partner who has an established foothold in the local supply chain to help circumvent extra links in the chain. This helped raise the profitability of Jordan's exports to new markets. Thirdly, firms opt for a variety of distributors in different parts of the target market. Fourth, Jordan prices its branded generics to ensure: i. high profit margins for intermediaries; ii. profitability for importers so that they are incentivised to list them as an alternative on the partner country's vital drugs list; iii. inclusion in government drug programs. Finally, Jordan created a strong and capable central export body for marketing and branding, and a separate unit for providing export information on new opportunities, changes in regulatory standards, import requirements, non-tariff measures, as well as funding for international trade fairs. Where possible, they set up a local representative office in the destination country, otherwise they entered a JV in distribution. [98] This is similar to the model followed by India to penetrate African pharmaceutical markets, whereby they create diplomatic, commercial and then firm-level ties to generate trust in the quality of their pharmaceutical goods. This approach is missing in Pakistan, with the government making little effort to engage African countries through trade and diplomatic missions. Similarly, with respect to Southeast Asian countries like Vietnam, a regional leader in production of vaccines (a long-term prospect for the sector), there is no effort to enter into a preferential trade agreement. Vietnam could provide a foothold into the ASEAN market, as it is the third largest FDI destination (USD 15.5 billion in 2018) within ASEAN countries, following Singapore and Indonesia.[99]

97 Pharmexcil, India. (2020). Bangladesh market regulatory report. Available at https://pharmexcil.com/uploads/countryreports/Bangladesh_Market_Regulatory_report2020.pdf

98 GIZ. (2019). Value Chain Analysis of the Pharmaceutical Sector in Jordan Industry Overview in Jordan. Trade for Employment (T4E) Project. Available at https://www.giz.de/de/downloads/Value%20Chain%20Analysis%20of%20the%20Pharmaceutical%20Sector%20in%20Jordan.pdf

99 KPMG (2020). Value of innovation. Unlocking the Potential of the Innovative Pharmaceutical Industry in Vietnam. Available at https://assets.kpmg/content/dam/kpmg/vn/pdf/Event/2020/7/Blue_Sky_Report_2020_EN.pdf

CHAPTER 6

Unlocking competitiveness

This section looks at the various horizontal and vertical constraints that must be unlocked to realise the potential in Priority 1 and 2 lines. These constraints are faced both by firms for local expansion and export competitiveness. At the same time, COVID-19 has exposed the various inadequacies of Pakistan's health sector, especially in production, distribution, institutional capacity and regulatory framework. These could preclude Pakistan's pharmaceutical sector from adequately responding to COVID-19 and also gaining from other opportunities. The section first provides a comprehensive overview of the various impediments cited above. While most of these issues have been discussed elsewhere in the study, this section categorizes the different constraints in one chapter based on the value chain analysis of Section 3, as summarized in Figure 22. To contextualise issues for firms, these impediments along the value chain are examined through the lens of constraints on competitiveness across the supply-side, demand-side as well as overall business environment.

6.1 Supply-side constraints

Supply-side constraints pertain to infrastructure, credit, testing and certification, trade and competition policy, as well as the availability of inputs and technology.[100] These affect the quality and competitiveness of pharmaceutical products, lowering firm profitability, likelihood of export survival, and investment (foreign and domestic) in the sector.

Weak input quality

Continuous investments need to be made to upgrade a pharmaceutical company to meet WHO requirements. Finances are often limited, especially for the local firms, to introduce new technology and upgrade machinery. Manufacturers often step back when they see the need to invest millions to buy equipment.[101] Excessive duties on imported APIs and other raw materials further raise the cost of production as do shipping and transportation expenses, especially for companies far from the ports in Karachi. Moreover, frequent electricity breakdowns have meant that, except for those with their own electricity supply such as the Sundar Industrial estate in Lahore, quality of production deteriorates. Inconsistent temperature and humidity conditions can also affect the final products. Firms are forced to invest in their own power generator plants or generators.

It is difficult to source the refence sample to develop the registration requirement. At present the companies need to internationally source the reference drug from approved countries. However, this can be made easier if DRAP develops a secondary reference library and the companies can purchase directly from DRAP rather than going to international sources.

100 Reis, J. (2011). Identifying supply-side constraints to exports Jose G Reis OECD Workshop on Aid for Trade Implementation March 28, 2011. Available at https://www.oecd.org/dac/aft/47441603.pdf

101 https://www.researchgate.net/publication/334492159

Increased reliance on imported ingredients

At the same time, the pharmaceutical export market has become increasingly competitive over 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 per cent imported ingredients. Unfortunately, the chemical industry in Pakistan does not have the capacity to develop the basic components required, even though many of the pharmaceutical and food additives Pakistan currently imports are plant-derived carbohydrate polymers extracted from vegetables and fruits. There have been few incentives from governments to develop this sector over the years. This makes the industry more susceptible to impact of exchange range fluctuations. Moreover, all imports of APIs, excipients and packaging material are subject to a No Objection Certificate (NOC) from DRAP that implies all material imported into Pakistan requires attestation from ADC/DRAP as per local laws. This requirement has caused major hurdles for pharmaceutical importers, especially on products imported from India.[102] Moreover, there are excessive duties on pharmaceutical products as well[103] with different percentages applicable, depending on the type of drugs and its specifications (Box 2).

Box 3: Documents needed to obtain DRAP NOC to import

To obtain a DRAP NOC, current regulations require the submission of the following original documents:

- Request Letter for issuance of NOC
- Request for Clearance of Material
- Commercial Invoice
- Packing List
- Airway Bill, Bill of Lading, Courier Slip
- Form 2: Grant/Renewal of an establishment license to import medical devices
- Form 3
- Form 5: Application for registration of drugs for local manufacture
- Form 7: Provisional certificate for enlistment of products
- Form 8: Application form for drug sales license
- Certificate of Origin
- FTA (from China shipments, SAFTA (from India) if required)
- GMP and DML Certificate, Stability Data Sheets, WHO Certificate (if applicable)
- Letter of Credit
- Certificate of Analysis
- Drug Registration and Renewal Certificate

Imports from India are subject to an additional layer of uncertainty. Close to 50 per cent medicines made in Pakistan use raw materials from India. Pakistan also imports around 150 medicines and vaccines from India each year. Since the ban, consignments of medicines and pharmaceutical raw material had been stuck at the Karachi port, diverted to other destinations or returned to India. In September 2020, upon industry request, the federal Cabinet exempted the pharmaceutical industry from this ban. While import of raw materials from Europe or America was a possible alternative, not only would it have increased the cost of production manifold,

102 According to Dr. Faisal Sultan, recently up to 300 consignments were stuck at ports which may be affected due to heavy rains, moisture, and high temperature (https://www.dawn.com/news/157286) . Pakistan Pharma Bureau Executive Director has said that the NOC requirement has caused clearance delays of 3 months, leading to medicine shortages in the market (https://tribune.com.pk/story/2265820/pharma-sector-faces-import-hurdles)

103 Chapter 30 of the Pakistan Customs Tariff deals with import duty on pharmaceutical products. Under the 5th Schedule of the Customs Act, 1969 the government has reduced custom duties to provide relief to the pharmaceutical sector. Typical custom duties on APIs and excipients range from 5 per cent to 25 per cent. On custom duties of 25 per cent, an additional sales tax is also levied despite an absence of a sales tax on the sale of medicines. In addition, an advance income tax of 5.5 per cent of import value is also levied. Import duties on medicines range from 0 per cent to 10 per cent. Medicines for the treatment of cancer, transplants and heart diseases have no custom duty, yet have an advance tax at 5.5 per cent on import value.

but also required at least 6-16 months to switch sources, as per industry interviews. However, this is not the first time this has happened. In 2019, in the wake of the Pulwama incident, a complete ban was put on imports from India. This ban was then quickly removed when severe shortage of critical medicines began taking place.

Regulating quality

While DRAP is heavily involved in regulating pricing, it currently has limited capacity to undertake its main function of maintaining quality. DRAP has created only 25 posts for federal inspectors of drugs to be posted throughout the country.[104] While capacity for drug registration has improved, the process needs to become more streamlines (Box 4). Technical regulation of drugs also remains a low priority of DRAP. New molecules can take up to 12 to 18 months to register and generics take up to 3 years.[105] DRAP also failed to appoint a federal drug analyst for release of biological products, appointed later after a month's delay in back dates. The post is vacant again, as the term ended on June 19.[106] A special audit done by the auditor general of Pakistan (AGP) stated irregularities in DRAP costed Rs 750 million.[107] The audit also observed DRAP management had failed to utilize the Rs 606.6 million from the Central Research Fund for conducting research and evaluation of medicinal drugs. However, the focus on quality control is increasing. DRAP reported suspension of 89 market authorizations and cancelled the licenses of 18 companies between 2013 and 17. Just between January to November 2019, DRAP carried out 51,194 inspections and detected 7,135 violations of the DRAP Act 2012. It is currently sending 25 drug inspectors for training by global experts.

Box 4: Registration and Renewal of Drugs

The Drugs Act 1976 requires that all finished goods be registered with the Drug Registration Board before their sale in the market. Applications for registering a new drug need to be made in Form 5-A in duplicate to the Drug Registration Board addressed to its secretary. A separate application is required to be filed for each drug. All applications for drugs are subject to the following fees:

PKR 50,000 for registration of a new drug/drug not manufactured locally
PKR 100,000 for registering any other drug

All drugs need to go through a stringent clinical check (stability studies) to establish its quality for selling in the local conditions of the Pakistani market. After these are satisfied, the board issues a registration certificate to the applicant. These are valid for a period not exceeding 5 years of its issuance and may thereafter be renewed. In addition, a warranty also needs to be issued in Form 2-A for any drug indented or sold for the purpose of re-sale and distribution.

Applicants for renewal need to be submitted in Form 5-B for all categories of registered drugs with the requisite documents and fees. The renewal process as specified by law should be completed within a period of one to three months. Different fees are levied for renewal, depending on the expiry of the registration certificate, typically PKR 10,000 before the expiry date is charged.

104 https://nation.com.pk/08-Aug-2019/drap-creates-25-new-posts-of-drug-inspectors
105 In January 2020, more than 400 drugs were awaiting approval since February 2019 despite having all the technical testing done by DRAP, due to a delay in approval by the Cabinet https://www.thenews.com.pk/print/686418-drug-pricing-dilemma
106 https://www.thenews.com.pk/print/686418-drug-pricing-dilemma
107 https://nation.com.pk/15-Jan-2019/audit-report-on-drap-detects-over-rs750m-irregularities

Quality control, harmonization of standards and international compliances

Pharmaceutical exports require an extra layer of quality assurances due to the nature of the good in question. Of all licensed manufacturing units in Pakistan, none has been approved by the US Food and Drug Administration (FDA), in strong contrast to India and Bangladesh. Only three national companies including Getz Pharma, exporting to 66 countries, got the World Health Organisation (WHO) pre-qualification certification. In early 2018, moxifloxacin tablets produced by Getz Pharma became the first-ever WHO prequalified pharmaceutical product from Pakistan.[108] CCL Pharma (exporting medicines to 35 countries) has got the WHO pre-qualification certification and Pacific Pharma (exporting medicines to 18 countries) is the only firm that has European GMP and acquired certification from the Medicines and Healthcare products Regulatory Agency (MHRA) based in UK. By investing in compliance to international standards, Pakistan could firstly access more lucrative markets and command better prices globally. Upgraded and compliant companies should get preference not only in the domestic private market, but in institutional and government procurement.

Similarly, coexistence of manufacturing facilities under different GMP standards and interpretations suggest an absence of harmonization in quality standards across the industry. The federal enforcement of GMP principles, responsibility of DRAP, is defined in Schedule BII under the Drug (Licensing, Registering and Advertising) Rules of 1976 and is mandatory for all local pharmaceuticals companies to comply with. However, several studies show this schedule has not been updated to reflect WHO's current standards or the local context.[109] Often inspectors attempt to enforce compliance to current WHO standards via a form that is based on WHO's GMP guidelines. In addition to WHO guidelines, other international GMP standards developed by bodies such as ICH, EU, USFDA and Australia's Therapeutic Goods Administration (TGA) were also considered as references for DRAP.

Enforcers in the form of drug inspectors are very few (49 federal drug inspectors in total, with provinces having their own inspectors) with no oversight on the quality of their inspection or ethical standards. Subsequently practices like selling medicines with fake labels, existence of unregistered medical stores and substandard medicines remain common in Pakistan. There is a high tendency of firms that survive the price regime to produce poor quality medicines, which can be sub-standard, spurious or counterfeit (SF drugs). So far, limited studies have been conducted on poor quality medicines in Pakistani. Periodic incidents/ anecdotal evidence often bring this issue up, but no systematic data exists. Figures range from 3 to 6 per cent, as per DRAP's own end-of-year press releases.

In November 2018, Pakistan acquired full membership status to WHO's Programme for International Drug Monitoring (WHO-PIDM).[110] This would allow Pakistan to monitor quality of medicines as per global standards. Domestic standard setting that would translate into export competitiveness, has however not been achieved due to lax enforcement and corruption on part of drug inspectors. However, recently some good measures have been put in place. DRAP is trying to get all the necessary international accreditations including acquiring the WHO Listed Agency (WLA) status. Registration with the international body will bring an international binding on manufacturers, importers and the regulator to maintain minimum international standard of quality to provide medicines in the market and enable exports to a number of developed countries. The process of getting a WHO Listed agency (WLA) status has been initiated since a year and is still underway.[111]

108 Abbassi W. WHO accredits first-ever Pak drug The News 9 Feb 2018. https://www.thenews.com.pk/print/278741-who-accredits-first-ever-pak-drug. Accessed 17 Oct 2018.

109 https://www.researchgate.net/publication/334492159

110 https://joppp.biomedcentral.com/articles/10.1186/s40545-019-0184-z

111 Earlier Pakistan was trying to get Level III Accreditation of WHO but recently WHO has changed it into WLA which is a bit more advanced and close to level IV accreditation of WHO.

Inflexible production

Pakistan underutilizes its existing capacity to manufacture medicines due to weak incentive structure for increasing production. This is due to stringent restrictions on contract manufacturing (the sub-contracting of manufacturing by the drug's parent firm to another company for a fee). The international norm is to give a license for 2 years. As per policy, the same is true for Pakistan, but in practice, the license is effectively granted for only 3 months for a period of 2.5 years (extendable to a maximum of 5 years).[112]

This has significant repercussions for supply and prospective growth of the sector. Partnerships between local and international companies can help improve standards of production, encourage healthy competition, facilitate transfer of technology and enable local manufacturers to gain access to global markets. Above all, contract manufacturing can result in substantial foreign investment, without too much technological burden on the parent company. In India, contract manufacturing has reduced drug manufacturing costs by almost 40 per cent, encouraging multinational pharmaceutical companies to consider India for their outsourcing needs. Japanese companies are setting up pharmaceutical plants there and signing joint ventures with the local industry. The current market value of contract manufacturing in India is estimated at 50 per cent of domestic production, translating to roughly USD 5.3 billion.[113] Similarly, Bangladesh is also encouraging contract manufacturing to boost its local pharmaceutical industry.

Compared to both these countries, Pakistan's pharmaceutical industry fetches negligible amounts of FDI, for the reasons mentioned above: the price freeze of 2001-13, absence of MNC-mediated investment due to weak intellectual property laws, and no scope for contract manufacturing. Profitability of the sector is also low due to poor quality controls and regulation—Pakistan is hardly an attractive destination for investment by foreign companies.

Limited Innovation and R&D

Pakistan's pharmaceutical industry broadly manufactures 'generic' drugs, with none being 'originator' brands. The low inclination to do research is notwithstanding the fact that many of the top pharmaceutical firms in Pakistan have the infrastructure to compete with global brands and invest in R&D. Brand new medicines enter the market only when they are coming off-patent. Twenty-four MNCs that have captured 44 per cent of the market by value are only producing drugs that have expired patents—this business model does not benefit Pakistan.

This is largely due to the absence of strong intellectual property rights. Research into a New Chemical Entity (NCE), which is the full cost of a single new drug development, can range anywhere between USD 500 million and more than USD 2 billion,[114] depending on the type of drug being developed and intended coverage. Market or negotiated pricing by the government along with a patent for a limited time helps developers recover some of this cost, making the venture economically feasible. This kind of mechanism is absent in Pakistan. For a firm that intends to invest large amounts in R&D, absence of patents and intellectual property rights remains a huge disincentive. As a result, even basic biological goods such as dog and snake-bite vaccines are imported from India.

There is no support from the government either. The Drug Act of 1976 obligates all pharmaceutical companies to deposit 1 per cent of their profit before tax with the government in a Central Research Fund (CRF) for R&D and supportive complementary infrastructure. Much of this is ends up being used in the administrative expenses of DRAP rather than in R&D. There is no accountability of the exact collections or outlays of the CRF.

112 Annual Report on Pharma 2017 – PIDE

113 https://www.thenews.com.pk/magazine/money-matters/243752-Contract-manufacturing

114 https://www.healthaffairs.org/doi/abs/10.1377/

There are a number of smaller reasons that make it harder for companies to conduct research. For example, the import of 3-D printers has been banned in Pakistan, due to security reasons, even as they are being increasingly used in other countries to improve drug quality and shorten drug trial duration. Currently, a very cumbersome procedure exists for getting permission to import 3-D printers.[115] This makes it hard for the industry to innovate in this category.

6.2 Demand-side constraints

Local demand for pharmaceutical products is determined by the prices set through regulation and local procurement, distribution and marketing practices. Global demand is affected by non-tariff requirements such as international quality and safety standards imposed by importing countries.[116]

Pricing Regime

Pricing matters have been addressed to some extent through a revised pricing policy, but issues persist as there is an expected rollback of this policy. The pricing policy is currently under revision, but has been delayed due to COVID-19. Pricing constraints have eroded profitability and dampened investment in capacity. It has not only affected the industry's growth but also impacted the achievement of social objectives (such as availability, affordability and quality).

Medicine prices are tightly regulated and controlled in Pakistan unlike in many other countries. The maximum retail price for any medicine is set by DRAP after vigorous scrutiny. The retail prices are approved by government via the Cabinet. The approval process entails that manufacturers may raise the prices of essential medicines equal to 70 per cent of the increase in the consumer price index (CPI).

The lack of price incentive in a market economy has hampered competitiveness of this industry as prices are largely determined by political rather than market forces (Box 5). Between 2000 and 2013, despite a consistent increase in the cost of production and price of imports of raw material, a price freeze was maintained. It is estimated that Pakistan faced a financial loss of PKR 112 billion annually due to the freeze on drug prices (as was detailed in section 4 Political Economy). [117] Ironically, out-of-pocket health expenditure increased over this period, so the stated objective of lowering health expenditure largely failed.[118]

115 The Ministry of Commerce requires a No Objection Certificate (NOC) by the Ministry of Interior to import all categories of 3-D Printers in Pakistan effective from 18th April 2016.

116 https://unctad.org/system/files/official-document/aldc2017d2_ch02_en.pdf

117 https://fp.brecorder.com/2017/01/20170127133653/

118 Pakistan Bureau of Statistics. National Health Accounts of Pakistan, 2015–2016. 2018.

Box 5: Consequence of persistent price control

1. Often led to shortage of drugs (including at times some essential/life-saving drugs). The price/ affordability of drugs is not determined by supply and demand. Even leading domestic manufacturers have discontinued producing critically required medicines.
2. This price regime also encourages smuggling to bring in medicines otherwise not being produced or available here.
3. Out of over 60,000-70,000 medicines that Pakistani firms have the capacity to manufacture only 10,000[119] are currently being produced. Hence, there is under-utilisation of capacity.
4. Due to over regulation of prices, many MNCs have left the market and inflow of FDI has also become severely restricted. This has resulted in persistent medicine shortages over the years. Domestic manufacturers have replaced these MNCs, but MNCs departure leaves a gap, in terms of greater efficiency, skills and technology transfer, in addition to enhanced production, and a significant investment base, along with quality and capacity upgrades.
5. There has also been a gradual yet persistent shift in the market towards the deregulated sector such as nutraceuticals (where prices are not controlled, and companies can generate more profit).
6. There is increased reliance on imports of medicines. Taking advantage of persistent medicine shortages over the years, importers have been selling drugs at considerably higher prices, costing the economy scarce foreign exchange. Thus, the price regulation policy has helped to erode the industry's productive base, rather than enhance access to medicines.

Despite passing multiple laws (DRAP 2012 and DRAP 2015), which now allow increases in drug prices relative to the CPI, price adjustments allowed were minimal. Most price increases were capped at 10 to 12 per cent and judicial recourse was often sought for relief. *Ad hocism* in regulation of prices is also a result of court litigations (discussed in the section 4) acknowledged as a major constraint by senior policy representatives. The 2018 Pricing Policy replaced the earlier policies of price freeze and adopts reference pricing instead of cost-plus pricing (where the selling price is determined by adding a specific mark-up to a product's unit cost).

DRAP uses the External Reference Pricing (ERP) mechanism to determine the price at which each drug will be distributed in the market. The ERP uses different countries with similar socioeconomic conditions as a benchmark, with India and Bangladesh being Pakistan's benchmarks.[120] Reference pricing allows a price relative to CPI (cap of 7 per cent for essential drugs and 10 per cent for all others). However, the industry claims that a whole range of pricing methods are used, depending on the molecule in question.

Some positive developments with respect to pricing include[121]

1. The basis for hardship price calculation has been changed from a fixed rate of 8 per cent (once in 3 years) to factors of prime costs 2.4 to 3.55, linked with various dosage for locally manufactured drugs.
2. All hardship cases are required to be resolved in 180 days of filing. In case DRAP is unable to resolve it in the stipulated time, prices may be increased by a maximum of 10 per cent. Moreover, the price may be increased as per policy if matter is not disposed within 270 days from date of filing.
3. The allowable price increase per centages linked with CPI have improved in the new Drug Policy 2018. In January 2019, a one-off relief of 15 per cent was given to partially mitigate the impact of massive rupee devaluation.

More recently, the federal cabinet approved increase in the prices of 94 life-saving drugs by up to 260 per cent to ensure their availability in the market.[122] As mentioned though, in a major setback to the sector, the Drug

119 Registered with the DRAP.
120 https://www.dawn.com/news/1417356
121 Pharmaceutical Industry, PACRA, 2019
122 https://www.dawn.com/news/1581136

Pricing Policy 2018 devised on the instructions of the Supreme Court of Pakistan is now being retracted, sending a bad message to foreign investors who may be considering disinvestment.

Lack of proper marketing/distribution channel and opaque procurement rules

Firms claim to spend almost 40 per cent of the total cost of producing medicines on marketing. In the absence of standard marketing mechanisms, large firms develop relationships with doctors, often providing them with financial and material incentives, to prescribe their products (branded generics) as a way of expanding their revenues. The MNCs are an exception to this model of marketing, however, due to strict rules governing their behaviour from their parent companies. Furthermore, small firms that produce generic medicines do not market their products either because they sell in bulk in local markets.

At the same time, demand is also a function of public procurement by government for hospitals, welfare schemes and national health insurance and so on. Matters are complicated as every province has their own public procurement regulatory authority for medicines. Tenders are published in newspapers which detail the conditions for a firm to be eligible to supply medicines at defined rates over yearly contracts. Tender conditions are stringent; for e.g., only registered entities can supply products. Certain marks are allocated for quality plus financial (pricing) aspects. Medicines are required to be manufactured under the GMP. Companies are judged under sales volume for that medicine, IMS ranking, market size etc.

Non-tariff measures in export destinations

A major challenge for pharmaceutical manufacturers that want to export is getting the product certification required by importing countries. Stringent Regulatory Authorities (SRAs) accredited by WHO exist in developed countries which make it difficult to export medicines there. Some drug exporters are unable to meet the stringent technical requirement of foreign markets. Exporting to the US and the UK requires certification, but as mentioned above, there are no internationally recognized facilities in Pakistan that can provide this certification. This is unlike India which has more than 200 US FDA approved plants, or Bangladesh which has 4 approved plants. The European market is also highly regulated. Exporters also report that many countries such as Qatar and the United Arab Emirates do not recognize certificates issued in Pakistan. This has led to Pakistani exports being more concentrated in less regulated markets in Asia and Africa. Automatically, this limits the exporting sample to larger firms that have the capacity to engage in exports because they are able to meet the minimum required quality.

Excessive documentation

To export medicines and lifesaving drugs from Pakistan, exporters also need a No Objection Certificate from DRAP. This process is cumbersome, and many firms find it difficult owing to the need to fulfil excessive documentation (see Box 6).

Box 6: Documentation for export of drugs

The exporting activity is also subject to considerable documentation and requirements in Pakistan. Typically, three sets of documents are prepared: one for the buyer (importing party), one for banks and one for the Additional Drug Controller (ADC). The documentation required for each group is given as follows:

Exports also need to acquire a GMP certificate from DRAP. This again increases burden for documentation, with an additional condition of inspection visit from DRAP at the production site before issuing the certification. This process may take up to three months.[123] Export inspections carried out by Anti-Narcotics Force (ANF) can cause further delays. However, as mentioned below, DRAP is taking steps to address this by setting up the PIRIMs system.

Limited capacity for testing and compliances

Laboratories that meet international standards and operate independently are a condition for exporting, with importing countries usually requiring bioequivalence and bioavailability studies. The alternative to local laboratories is getting these tests done in foreign laboratories, which is much more expensive. The current testing capacity available in public sector (both federal and provincial) laboratories in Pakistan includes twelve Drug Testing Labs (DTLs)—two central laboratories working in Karachi and Islamabad), an appellate laboratory in Islamabad, five DTLs in the province of Punjab, and one in each of the remaining provinces. Three public sector DTLs are certified by the 17,025 standards of the International Organization for Standardization (ISO), whereas only three are prequalified by the WHO namely (1) Pakistan Drug Testing and Research Centre (PDTRC), Lahore, (2) Drug Testing Laboratory, Faisalabad, Government of Punjab and (3) Prime Health Pvt Ltd. [124] The latter two have only been approved in 2020 but have not been notified to be used as reference laboratories and are not utilized by DRAP.

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 license and GMP compliance certification mentioned above. In Pakistan, there are only 1-2 bioequivalence labs. Bioequivalence is also expensive, and companies therefore 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. Each BE study can cost up to USD 300,000, an amount local pharmaceutical companies may not be able to fund. This prevents Pakistani firms from exporting to developed countries such as the EU, Japan, Australia or Russia. To promote new entrants in generic medicine exports, WHO has reduced the requirement of human trials on a few products, reducing its cost to USD 14,500. There are currently two companies, one in Karachi and one in Peshawar, offering the service to conduct such studies in Pakistan. A loan from the Central Research Fund, may assist these firms to conduct these studies.

123 https://www.intracen.org/uploadedFiles/intracenorg/Content/Publications/NTM_Pakistan_final_with per cent20covers.pdf

124 World Health Organization, WHO List of Prequalified Quality Control Laboratories, 2020, https://extranet.who.int/prequal/sites/default/files/documents/PQ_QCLabsList_30.pdf.

6.3 Business environment

In addition to the specific demand- and supply-side impediments pervading the pharmaceutical industry, there are cross-cutting sector-wide constraints that are responsible for its underperformance. Most noteworthy are problems arising from excessive government intervention in the sector, absence of an overarching policy framework, weak federal-provincial coordination, as well as weak capacity for enforcement of quality across the value chain. Without an overarching policy, sector reform runs the risk of going amiss.

Overall, government involvement in the pharmaceutical industry is high.[125] Unlike many other countries, Pakistan's pharmaceutical sector remains highly regulated, more so on price than on quality. DRAP's role in regulation was discussed in detail in section 4. Government ends up developing concessionary policies for those entrepreneurs that have lobbying capacity and can access political networks (such as politically salient embedded pharmaceutical companies), often to the detriment of higher value-added firms (large firms in pharmaceuticals). Domestic approvals can take time and SROs create uncertainty.[126] Simple steps, like establishment of an FDA approved lab and facilitating contract manufacturing are far from the policy agenda of the government.

This issue stems from the fact that there is no overarching policy for the sector. DRAP does not have a National Medicine Policy (it is forthcoming since November 2019).[127] In addition, a number of Statutory Regulatory Orders (SROs) have been issued over the years to address emergent matters pertaining to drug policies.

Also, several provincial policies are also in place.[128] This creates uncertainty regarding government actions at the federal and the provincial level, leading to coordination issues that cause unnecessary delays and create complexity, that could easily be avoided. Medicine licensing, manufacturing, registration, pricing, imports, and exports are dealt by the federal government, whereas distribution and sales are regulated by the respective provincial governments. At the provincial level, despite overall signs of improvement, some policies are unnecessarily cumbersome. A prime example is of Punjab's deregulation policy which suggests that suppliers must negotiate separately with every district's health department to supply drugs. This is a core reason for recurrent drug shortages in the province. Communication challenges between DRAP and provincial drug control units also exist. The provincial governments are responsible for regulation of drug sale only. Miscommunication however can lead to mistrust among the manufacturers. DRAP and provincial inspectors can give conflicting reviews as these authorities lack communication.[129]

However, a recent positive development is that DRAP is taking up the Common Technical Documentation (CTD) system for the registration of pharmaceutical companies, issuance of licenses to them and carrying out all communication with them.[130] In December 2020, a paperless automated system— Pakistan Integrated Regulatory Information Management System (PIRIMS)—was successfully launched.[131] This system is already in place in Europe and the USA. The new system can even expedite international marketing, as all processes are

125 https://www.sbp.org.pk/reports/quarterly/fy20/Second/Complete.pdfs

126 https://www.dra.gov.pk/Home/SRO#gsc.tab=0 – All SROs can be viewed here. For example, following the onset of the COVID-19 global pandemic, there was an opportunity for the export of hand sanitizers, gloves, face masks etc. with significant global demand. Firms with pre-existing quotas of alcohol had standing orders from the US, however, the Ministry of Commerce (through SRO 239(I)/2020, dated 24th March 2020) banned these items from being exported. This ban was subsequently lifted in June, but by then demand had subsided.

127 Pakistan has the Drugs (Generic Names) Act, 1972, The Drug Act 1976, with its many subsequent amendments and rules, The Drug Regulatory Authority of Pakistan Act, 2012, Medical Devices Rules, 2017, Alternative Medicines and Health Products (Enlistment) Rules, 2014 and Bio-study Rules 2017.

128 This includes the NWFP Drug Rules 1982 (with amendments in 2017 and 2018), Sindh Drug Rules, 1979 (with amendments in 2010), Punjab Drug Rules 2007, Northern Areas Drug Rules 1996, Islamabad Capital Territory Drug Sales Rules 2013, and Baluchistan Drug Rules 2018.

129 https://www.researchgate.net/publication/334492159

130 https://mettisglobal.news/drap-to-issue-licenses-to-pharma-companies-through-ctd-systems

131 https://propakistani.pk/2020/12/03/drap-launches-integrated-regulatory-information-management-system/

defined with their timelines.[132] The system integrates licensing, registration, inspections and pharmacovigilance activities and provides a platform to pharmaceutical industry for submission of applications, regulatory correspondence and feedback/complaint mechanism to address problems faced by the applicants. This is being done to ensure Level Three Compliance on the WHO Global Benchmarking Tool, an internationally accepted model to assess regulatory capacity of a country. Once Pakistan clears its compliances, it can proceed further with its application to Pharmaceutical Inspection Convention/Cooperation Scheme (PIC/S), [133] for which DRAP has already hired a regulatory expert. This is an international cooperative scheme to promote consistent application of pharmaceutical guidelines and specifications. It could allow Pakistan to access at least 50 more countries, spanning Asia to Europe through mutual recognition of standards.[134]

This sub-section investigated the underlying reasons for poor competitiveness and higher costs of doing business in Pakistan. Concerns arising due to COVID-19 are briefly investigated in the next sub-section. The recent focus on the pharmaceutical sector of Pakistan has created policy space for tackling the various historical bottlenecks discussed above.

6.4 COVID-19 and the pharmaceutical sector

This section looks at the direct impact of COVID-19 on production and distribution and the constraints in the capacity and regulatory framework that could preclude Pakistan's pharmaceutical sector from adequately responding to COVID-19. With global health care spending expected to rise at an accelerated growth rate, it will likely present many opportunities for the sector. While there will be uncertainties, stakeholders can navigate through them by considering past and current drivers of change when strategizing for 2020 and beyond.

As countries, business and individuals continue to grapple with unprecedented challenges created by the on-going pandemic, its impact on the global as well as local pharmaceutical supply chains remained an area of concern, especially during the initial days of the virus breakout. These concerns were made worse by the fact that COVID-19 hit first, and with much intensity, China, particularly Wuhan, a global leader in exports of active pharmaceutical ingredients. A significant number of pharmaceutical companies in Pakistan and around the world import a bulk of their raw materials from China, which witnessed a complete lockdown of over two months from January 2020 to March 2020, as it dealt with COVID-19.

While Pakistan also faced a strict lockdown from March 2020 till May 2020, a few critical manufacturing industries were spared form strict restrictions, such as food and pharmaceutical industries.[135] This may be one of the reasons why despite a global recession, Pakistan's pharmaceutical industry saw a CAGR of 13.23 per cent during the pandemic.

6.4.1 Risks

How the government chooses to expedite and incentivize the sector will broadly determine the benefit the sector can avail. At broad brush, it does not appear that the Ministry of National Health Services Regulations & Coordination has taken the opportunity of Gilead choosing to license a domestic firm, Ferozsons Ltd., seriously. While Gilead contacted the government and told them it was an affirmation of Gilead belief in Pakistan's pharmaceutical industry to initiate this licensing arrangement, the government did not make the most of it. In fact, Ferozsons Ltd. was not given DRAP approval for manufacturing for two months, i.e., they got Gilead licensing on May 10th 2020, but obtained DRAP approval in July 2020. In the meantime, DRAP

132 CEO DRAP

133 N.A. (2nd December 2020). DRAP launches innovative online platform. The Express Tribune. Available at https://tribune.com.pk/story/2274379/drap-launches-innovative-online-platform

134 https://profit.pakistantoday.com.pk/2018/02/06/pak-pharma-industry-suffers-from-governments-shackles/

135 https://www.sbp.org.pk/reports/quarterly/fy20/Third/Chap-2.pdf

approved a dozen unlicensed domestic firms to produce the drug, in direct violation of intellectual property rights, claiming that Gilead would not enforce patents during a pandemic. This decision undermined the regulators' credibility abroad. It is unclear on what basis the other manufacturers were granted approval, but important to note that despite significant pressure from Indian non-licensed producers, Indian authorities approved only Gilead licensees to produce the drug.

The repercussions of this government decision on future foreign technology transfers through licensing arrangements/JVs/partnerships are extremely harmful, showing disrespect for intellectual property rights. This sends a very bad message to potential MNC-mediated investment in the sector. In addition, given that the vaccine was not tested, and had gotten emergency FDA approval in the USA, this was all the more questionable from a public health perspective. Many approved firms simply copied Ferozsons Ltd. paperwork for registration and had CTDs of just 15 pages. As a result, many of the locally unlicensed vaccines produced were sub-standard, and some even faced recall issues due to shards of glass being discovered in the vaccine vials. The current attitude and lax intellectual property rights regime does not encourage a portfolio approach to global partnerships that could attract investment in the sector.

Nevertheless, Ferozsons Ltd. was able to produce Remdesivir within one month of getting approval from DRAP by August 2020. This was done in record time despite multiple challenges, including a temporary ban on API from India where the licensed API was being produced, and some machinery parts that were unavailable, but were reproduced domestically using 3D-printing from a vendor-partner from the automobile sector in Lahore.

Ironically, despite the fact that the government approved so many manufacturers of Remdesivir in Pakistan, DRAP placed a 3 month ban on exports of the product from Pakistan. Since most importing countries are committed to using Gilead licensed product only owing to quality concerns, this ban hurt BF Biosciences disproportionally. Despite the fact that India had many more cases of COVID-19 than Pakistan at the time, India did not stop exports of Remdesivir for a single day. However, the government started importing the vaccines from Bangladesh via NDMA, while internal delays cost the only local manufacturer two months manufacturing time. This is not economically prudent—if NDMA arranges vaccine supplies from Bangladesh, they should also push to export to Bangladesh, a policy that has not been pursued.

In those three months, Indian competitors were able to establish themselves in the same destination markets that they could potentially target as per their licensing agreement with Gilead. In addition, the government banned Ferozsons from exporting the vaccine for 3 months, despite assurances that the firm would cater the domestic market first. This meant Ferozsons Ltd. was not first to market in any of its target export destinations, it lost on government tenders, and it was essentially playing catch up in every single market once it started exporting. Nevertheless, they were able to use Gilead approved raw materials and technology to supply to 20 countries, including SRA markets like Ukraine and Indonesia, and 2 PICS countries (as their manufacturing facility was accredited following a virtual and physical audit).

Shortage of Raw material

At least 80 per cent of Pakistan's API requirements for most common drugs such as paracetamol, certain anti-infectives and blood pressure medications etc., come from abroad starting with China followed by India, Canada and Europe. China remains a global leading manufacturer of APIs. Lockdown in China weighed heavily on the global supply chain of APIs. APIs cannot be transported via sea as salty air can spoil them. Usually companies, depending on their size, keep a stock of raw material to last them three to six months, but many small companies had run low on stock. A few small manufacturers, in Sindh and Punjab, also had to close operations. But this was not a major concern for the larger companies. A sharp surge in raw material prices due to scarce supply could, however, wipe out small firms. Tensions with India did not help either (as mentioned above). In addition, leading API producers began to restrict API exports to protect their own industry. Unfortunately, Pakistan remains in a precarious position, with little planning for arranging alternative and equally cost-effective API supplies as from China.

Other countries have prepared for the implications of disrupted API supplies from China. For e.g., the Indian government has mapped molecule-by-molecule active pharmaceutical ingredients imported from China to identify molecules for domestic production and is making timely sourcing arrangements with third party suppliers to mitigate the future impact of the COVID-19 pandemic on their pharmaceutical sector. Their government is making special provisions for APIs from China that cannot be substituted.[136]

Poor quality control

There was a risk that due to COVID-19 and its new restrictions, material coming into Pakistan may not be vetted properly for its quality. Most international regulatory authorities were not able to adequately monitor quality. In the absence of a Chinese regulatory body, low quality products could be supplied to Pakistan. There have been incidents before where sub-standard Chinese API have caused adverse reactions.[137] In 2018, USA imported 250,000 DPT vaccine from China, later found to be sub-standard. Recently, Spain was supplied with COVID-19 testing kits by Shenzhen Bioeasy Biotechnology, of which 58,000 were faulty, while Czech Republic imported 150,000 of which 80 per cent were faulty. Netherlands also had to recall masks supplied by China due to quality concerns. Considering these concerns, DRAP must be cautious and ensure that hospitals, and pharmaceutical industry do not procure sub-standard material.

Shortage of drugs

Overall, COVID-19 has made it clear that the regulatory environment for the pharmaceutical industry needs to be aligned with global industry trends if the industry is to develop and survive in an exceedingly competitive environment. Over-reliance on imported raw materials has exposed the vulnerability of this sector to such shocks in the future. The global lockdown did not even spare the pharmaceutical supply chain.

To understand Pakistan's capability of producing medicines, take the example of *Paracetamol* and *Ibuprofen* tablets, both common baseline treatment for COVID-19 and a number of minor ailments like the common cold and flu. Pakistan produces these medicines at a very low cost, but it does not manufacture the active ingredients present in these products. Pakistan would not be able to continue producing these medicines if the supply of these active ingredients gets disrupted from other countries.

6.4.2 Opportunities

Despite disruptions to the supply chain caused due to the pandemic, Pakistan's pharmaceutical industry emerged among the fastest-growing industries in the world, even though it contracted by 6 per cent due to COVID-19. COVID-19 remains a global challenge, yet it also offers an opportunity for Pakistan's pharmaceutical industry to acquire the core capabilities for vaccine manufacturing, which it is currently lacking. The acquisition of vaccine manufacturing capabilities can be a first significant step towards the production of next-generation, high-value pharmaceuticals in Pakistan. The pharmaceutical industry has traditionally focused on small molecule–based classic products. The only way to penetrate the export market is to leap into the next generation of pharmaceutical products. This is why industry insiders claim that the real opportunity does not lie in hand sanitisers and PPE, but rather entering into product segments that are either in heavy demand such as blood thinners, steroids, antibiotics, multivitamins and vaccines, or those that are being vacated as manufacturers focus on COVID-19 and new drug discovery. As 5.1 shows these are precisely the priority lines where Pakistan has an advantage.

The voluntary licensing agreement between Gilead Sciences, US and Ferozsons Laboratories Limited was an example of a recent success. It is a notable exception to the norm for pharmaceuticals in Pakistan and a possible template for international collaboration and growth for the industry going forward. Gilead announced that Pakistani manufacturer BF Biosciences Limited (a subsidiary of Ferozsons Laboratories Limited) was one of 5 South Asian manufacturers (the other 4 were from India) being authorized under a voluntary non-exclusive

136 https://www.marketresearchfuture.com/reports/active-pharmaceutical-ingredients-market-1385
137 https://businessreview.iba.edu.pk/covid19/articles/shagufta-v2.pdf

licensing agreement to produce and distribute an experimental antiviral drug to treat COVID-19, Remdesivir, to 127 countries in the developing world affected by the pandemic.[138] 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. Despite the hurdles mentioned in the previous section, after producing its trial batches and completing the technology transfer process, BF Biosciences was able to produce its first batches of Remdesivir in July and release the product into the market in August, 2021.To date Remidia has been exported to over 20 countries in Asia, Africa, Eastern Europe and Latin America, including PIC/S member countries such as Indonesia and the Ukraine.

The development represented an important step forward for Pakistan on the health, economic and diplomacy fronts, and was the first time that a Pakistani manufacturer was selected to be part of an international supply chain of this nature. It provided an important export opportunity for the country's pharmaceutical sector at a critically important period and could also have positioned Pakistan to play its role on the global public health stage.

A few other success stories could help the sector gain the necessary knowhow to produce at scale. Diffusion of this knowledge could then spur innovation and discovery, leading to higher local production, and perhaps profitability. Ultimately, through contract manufacturing, Pakistan could attract FDI from global players, due to its strategic location, and CPEC benefits. Already, Remington Pharma has won a bid from a Swiss pharmaceutical company to conduct clinical trials for them in Pakistan. They assert that their winning bid faced competition from regional leaders, but it was low wages for quality labour (the company trained them from the best in the world and paid them an excellent salary package) that allowed them to succeed.

The final section synthesizes the findings from the study, with a special focus on addressing the gaps highlighted in sections 3 and 6, bearing in mind the political economy issues of various stakeholders identified in section 4. Cross-cutting policy recommendations are suggested that could allow Pakistan to raise global competitiveness. At the same time, to avail some of the potential gains from the opportunities in products and markets highlighted in section 5, a medium-term export development strategy is put forth for the sector.

138 https://ferozsons-labs.com/covid19/

CHAPTER 7

Way forward—Recommendations and an export strategy for the pharmaceutical sector

This section builds on the analysis from sections 3-6 to first provide broad recommendations that could allow pharmaceutical firms to meet high global standards in a cost-effective manner. A medium- to long-term export strategy for the sector concludes the study.

A decade ago, a report commissioned by the Pakistan government forecast that exports could rise from USD 150 billion to USD 1 billion by 2014. Exports remain stagnant at USD 218 million as of 2019. Pakistan has the requisite scale and growth to sustain a significant pharmaceutical sector. The government has also recently envisaged a near-term export target of USD 3-5 billion, to be supported through a newly created Pharmaceutical Export Promotion Committee. But a combination of weak regulation, poor intellectual property rights, inconsistent and questionable policies, and little strategic focus of the government continue to stifle the sector and prevent it from attaining its true potential. Government recognition of the economic contribution of the sector is inadequate, due to data collection issues and a tendency to lump the sector with chemicals.

In light of these factors, the most pressing need of the sector is a dedicated body that coherently translates a clear government vision for the pharmaceutical sector of Pakistan. This body must have the capacity to collect and maintain updated industry data, identify, target, administer and manage policy interventions that do not distort incentives or prices.

With its vast experience in drug formulation, the sector's transition from production of a handful of branded generics to bulk manufacturing of generics can be hastened through strategic policy support in the form of a pharmaceutical sector growth strategy. This may be considered a pre-requisite for all interventions proposed below. Phased strategic support in the form of an Action Plan in stages of 5 years, if pursued, could propel it to the next stage in the pharmaceutical value chain, allowing it to tap into growing and more lucrative innovative pharmaceutical sectors.

A growth policy housed in a dedicated body that deals with business aspects of pharmaceutical sector is essential. All successful countries studied can trace growth back to an initial dedicated government body just for pharmaceuticals, that was different from a regulatory institution, and was responsible for research, trade promotion and business facilitation. In countries that successfully ventured into innovative pharmaceuticals, these bodies developed corporate investment arms to provide centralized and targeted funding support. This global vision and focus on technology upgradation was supported through explicit policies to attract FDI such as National Bio-Tech Policy in Malaysia and National Innovation Act 2008 in India. These promoted public-private partnerships to commercialize innovation.[139]

139 KPMG (2020). Value of innovation. Unlocking the Potential of the Innovative Pharmaceutical Industry in Vietnam. Available at https://assets.kpmg/content/dam/kpmg/vn/pdf/Event/2020/7/Blue_Sky_Report_2020_EN.pdf

The first main recommendation is strengthening the regulatory and technical capacity of DRAP. DRAP has failed to fulfill its regulatory role for the sector and functions mainly as a price controller. All stakeholders pinpointed the inadequate regulatory and governance framework within pharmaceuticals as the single biggest reason for low growth and exports in the sector. This may be attributed partly to the cross-cutting implications of subjecting DRAP to the control of the Ministry of National Health Services Regulations & Coordination. This reduces its effectiveness due to the ensuing political economy tussle between the two entities. The relationship with DRAP has improved over the last few years and the stakeholders are positive about the changes made to pricing regime as well as the automation of the registration process. They are hopeful that pricing will be removed from the ambit of DRAP under the proposed revisions underway to the DRAP Pricing Policy 2018 and given to the Ministry of Commerce.

Secondly, as detailed in the political economy analysis of Section 4, the sector feels that the institutional clout of DRAP is not suited to needs of the sector. It is important to question why other federal authorities such as Oil and Gas Regulatory Authority, Security and Exchange Commission of Pakistan and National Electric Power Regulatory fall under the purview of the Cabinet, while DRAP which is similarly complex, does not. Moreover, all non-regulatory functions required by the industry that currently fall under DRAP can be better performed by other Ministries. Immediate removal of all trade and commercial roles from DRAP entails broader institutional restructuring. Without implementing these two basic recommendations, all policies proposed below—and elsewhere—will have limited ownership and traction.

7.1 Broader recommendations

This sub-section presents recommendations that focus on improving the pricing regime, lowering production costs, strengthening the regulatory environment, incentivizing technological upgradation, attracting trade-related investment, and raising overall quality.

Improved price regime

The most urgent requirement of the sector is a stable and predictable price regime for pharmaceutical products to improve supply, spur investment and promote exports.

1. **Remove price ceilings:** A lifting of the price ceilings on drugs imposed since 2001 that are squeezing profits, stifling growth and limiting the availability of some medications. A more liberal and transparent pricing regime by the DRAP would benefit industry performance.
2. **Stability of price path:** Moreover, a predictable price path will also ensure commitment to adhere to agreed pricing regime. The frequency to review both prices and drug list should be appropriately selected. The key is stability. Pricing resets can happen every year according to an agreed mechanism, and coverage of drugs can be revised every three years.[140]
3. **Ensure provision of essential drugs:** The National Essential Medicine List (2016) should be controlled and pricing for the rest should be deregulated in a phased manner, as jointly determined with industry input. The Orphan Drugs Act in the United States and the Regulation (EC) No 141/2000 in the European Union are examples where governments ensured the supply of medicines for rare conditions or those which were not economical to produce. A similar process can be developed in Pakistan to identify pharmaceutical products that can be assigned the orphaned status, like cancer-treatment drugs. The government can then take measures to ensure their uninterrupted supply and equitable access. Incentives will have to be managed to ensure that price-controlled drugs are produced efficiently and in adequate amounts. The controlled list should be based on high-priority diseases in Pakistan, those that are most commonly sold, are essential or needed for specialty expensive treatment such as cancer. For example, initially plants set up for producing cancer drugs should be given time-bound

140 McKinsey (2010).

incentives, for 5- 6 years, such as: protection via duty free import of APIs, tax holidays and phased protection of imports from India and other countries through higher duties. Once a critical threshold has been crossed in terms of financial sustainability, these incentives could be withdrawn.

Stable regulatory regime

a. **Redefine role of DRAP:** Instead of focusing on price control, DRAP should develop its expertise and capacity to undertake its main function of quality control and monitoring, similar to regulatory bodies in other countries. The commercial aspects of the industry should not be the concern of DRAP.
b. **WHO accredited laboratories**: Linked to quality control, Pakistan must attain WHO accreditation for its main public laboratories, starting with DRAP's National Control Laboratory for Biologics (NCLB), which since 2007, monitors quality of all vaccines imported or locally manufactured. Without it, all NCLB testing, registration and batch release of biologicals is not internationally recognized. Other private and public laboratories must also be accredited (3 as of 2021) and officially notified for use as reference laboratories for the sector.
c. **Compliance to minimum production standards:** 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). A stable pricing regime will make the sector more profitable and hence increase the incentive for firms to invest in FDA-compliant/approved plants. Clear and basic quality standard for molecules and facilities should be established.
d. **Credit facilities:** There should be enhanced credit facilities for long-term lending to invest in GMPs—this can also be tied to export performance or to accreditation by WHO/MHRA/USFDA. However, this could be difficult to execute due to insufficient capacity to implement and likelihood of rent-seeking.
e. **Build capabilities to inspect and enforce quality standards by creating a fully trained inspection team.**
    i. Academics, professionals, and researchers in the field of pharmaceutical regulation should get training on modern analytical techniques to undertake quality evaluation of pharmaceutical companies and establish a stringent regulatory system. Objective-oriented undergraduate training, in areas focusing on quality evaluation, pharmacovigilance, international regulatory guidelines and pharmaceutical policy must be included in the national curriculums.
    ii. Membership and effective participation in international forums can also help build capacity of regulatory authorities and the drug testing laboratories. Some examples include the European Directorate for the Quality of Medicines (EDQM) that has set up a Network of Official Medicines Control Laboratories (OMCLs) partially funded by the European Commission and the External Quality Control Programs (EQCP) network, which includes the Pan American Health Organization (PAHO) and OMCLs from Latin American and Caribbean countries and the Networks of Official Medicines Control Laboratories (NOMCoL) in Africa, Middle East/North Africa (MENA), and Asia Pacific.
    iii. Membership of the Pharmaceutical Inspection Convention/Cooperation Scheme (PIC/S) would enable Pakistan to benefit from good manufacturing guidelines and export to high income countries. This also requires certification of Pakistani factories by the US FDA and the EMA.
f. **Incentive to invest in FDA-quality plants:** One way to do this could be to allow prices of medicines produced by FDA approved plants to not be controlled for exports. This could also be coupled with a reduction in tax rates and reduction in tariff for utilities e.g., electricity. Since improvements in existing plants and certification is expensive, the government can actively pursue high performance players to build FDA plants.
g. **WHO-Approved Laboratories:** Laboratories that meet international standards and operate independently are a condition for exporting, with importing countries usually requiring bioequivalence and bioavailability studies. The alternative to local laboratories is getting these

tests done in foreign laboratories, which are much more expensive. The addition of two new laboratories in 2020 presents an opportunity that can be leveraged for quicker and cheaper testing, but more CROs should be incetivised through PPP mode.

Improve production & innovation

a. **Allow contract manufacturing without limitation:** Companies should be allowed to optimize production configuration (and thereby lower manufacturing costs) by subcontracting manufacturing to other companies as required. Lifting of restrictions on contract manufacturing may be possible if DRAP's concerns of a consequent drop in quality are also addressed.
b. **Create an innovative eco-system:** In order to compete in the global marketplace and to engage productively in drug discovery using the new tools that are becoming available, Pakistani industry needs the underpinning of an innovation system. The pharmaceutical industry does virtually no R&D nor is there a culture of research in academia. The government must take the lead in creating an innovation ecosystem by stimulating research in leading public universities, incentivizing research by larger pharmaceutical firms and promoting linkages between the two.[141]
c. **Technology transfer through MNCs:** The experience of Argentina, Colombia, Jordan, Indonesia, Uganda, and Bangladesh suggests that technology transfer from MNCs can accelerate the development of domestic capabilities.[142] The contribution that MNCs can make to industrial competitiveness, consolidation, innovation, and exports is substantial. Attracting FDI by the major global MNCs calls for efforts to improve the business environment, provide adequate protection for intellectual property, and incentives that channel foreign investment into the type of activity that will generate the highest returns for Pakistan's economy.
d. **Give public interest groups a seat at the table.** Those directly affected by the said sector should be at the centre of the regulatory effort. To some degree, regulators in Pakistan already accommodate public interest groups (PIGs). All regulatory authorities have governing boards or oversight/steering committees, which have representation of experts and the private sector. But in most cases, these PIGs are under-represented or are in no position to influence the policy of these authorities. DRAP has a policy board where bureaucrats and experts are in a ratio of 9:6, whereas the board chairman is a government official.
e. **Improve the public image of the sector:** Joint efforts by PPMA and government to manage public image to ensure that the sector is not subject to undue scrutiny or criticized for being business-minded.
f. Stakeholders have a positive view of a liberalised import regime with countries that Pakistan has trade agreements with, such as China, Sri Lanka, Malaysia, and Iran. This lowers production costs and provides affordable medicines to consumers. Stakeholders feel that liberalised import of medicines from India should be part of a broader trade relationship when both countries are ready to move in that direction, which would also address industry safeguard issues.

Improve the business environment

In terms of the business regulatory constraints, the two most troubling ones highlighted were taxes and dealing with labour and social security, including PESSI and EOBI. In addition to tax and labour, environmental compliance and getting NOCs is a major issue. There seems to be no timeline for finalizing the NOC and the approval process faces delays, whereas fines are posted at will. Moreover, another issue is to do with the zoning of land. Historically, land has been allocated for industrial establishment, however, with industrial activity, residential and commercial establishments have also cropped up in adjacent areas. Coordination across departments such as labour, PESSI, EOBI and others is necessary. BOI has already started a SMART regulatory reform process; however, these reforms need to speed up and make the business environment more friendly.

141 https://www.apnews.com/Business%20Wire/322e3b38242647dd8797f29b5ac3caf0
142 https://unctad.org/en/PublicationsLibrary/diaepcb2011d7_en.pdf

Production of vaccines

1. For vaccines production, DRAP must apply for and achieve WHO certification of its National Control Laboratory for Biologics (NCLB), without which no vaccine manufacturer in Pakistan can be considered for WHO approval.
2. Pursue policy of developing vaccine manufacturing capabilities as per two-pronged plan
   - Phase I: DRAP given 2 years to get WHO-certification for NCLB. After due diligence, encourage local firms to make high-volume vaccines under fill-and-finish arrangement using imported bulk concentrate from international WHO-certified firms. Ensure government procurement through sovereign buyback for GAVI and non-GAVI vaccines.
   - Phase II: Give time-bound protection to local high-quality firms that undertake Level 4 vaccine production from raw material stage. Protection entails government buyback at market prices from firms that 100% vertically integrate. Government subsidises vaccines for public hospital procurement under its *Sehat Sahulat* Program. Protection will lapse in 5 years/when firms reach scale to break-even at subsidized prices, whichever is sooner.
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7.2 Export strategy

Becoming part of the global pharmaceutical value chain is a matter of committed decision-making, in which both the government and the pharmaceutical companies will have to take a medium to long-term consistent approach towards policy, regulations and investment. As mentioned in section 5, given the complexities of the sector and differential requirements and standards set by different countries, exporting requires accurate diagnosis of target markets.

Mapping out information and assessing a capability match is a dynamic, specialized, time-consuming and costly process. During the interviews, it was revealed that a comprehensive report done by an internationally credible company such as IQVIA may cost up to USD 300,000 per product per market. For example, Pharmexcil (Pharmaceuticals Export Promotion Council of India), which was established by the Ministry of Commerce & Industry, India issues regular country and product research reports to support their industry in going global. This cost is a major deterrent for local companies especially when the return on such investment remains uncertain.

A critical drawback discussed extensively in the sections above is the limited local production base of APIs. The API industry development requires substantial long-term investment and consistent policies. The investors in this sector will only enter if they have a reliable enough incentives regime—some stakeholders suggesting a consistent regime for at least 10-15 years.

Data analysis and stakeholder validation reveal that substantial export potential exists is a variety of product lines and several markets such as Africa, Russia, East and Central Asia. However, these are time-bound opportunities that require firms to meet stringent regulations. 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 overall global competitiveness of the sector and is a win-win for firms and government. The key policy recommendations that could support companies in establishing a global presence are discussed below.

1. The function of trade policy and industrialization linked to the pharmaceutical industry must be formally made part of a dedicated body. DRAP should just focus on regulations and enforcement, while the business, marketing, pricing and incentives should be managed by this dedicated government body.

2. If the government API strategy is approved and API production begins in industrial parks and special economic zones
    - Govt. role must be limited to providing an overall enabling environment for manufacturing in industrial parks
    - No targeted allocation of government funds.
    - The decision to invest in API should be left to the private sector with the requirement that investors set up the API plant to meet WHO manufacturing standards

3. The Ministry of Commerce may conduct product and market studies focused on Africa, Central and East Asia. These studies should be conducted by consultants and shared with DRAP registered companies. These studies could help not only in reducing the access cost for companies but should only be undertaken after a careful cost-benefit analysis.

4. DRAP should continue its reforms for drug registration, for e.g., by establishing a secondary reference library for comparator drug molecules and sell these for a suitable charge.

5. A global presence requires upgradation of plants and premises to achieve GMP and other quality compliances. DRAP would benefit from certified global consultants (whether from WHO or commercial pharmaceutical consultants) who provide technical & institutional support for each of the key regulatory and quality management roles that DRAP undertakes.
6. DRAP should continue its reforms for quality regulation and enforcement, for e.g., by DRAP achieving international standards, clearing certifications as per WHO Global Benchmarking Tool, and attaining the Pharmaceutical Inspection Corporation Scheme (PIC/S) membership, which could allow market access to Stringent Regulatory Authority (SRA) countries

The 2025 targets of increasing pharmaceuticals value from USD 4 billion to USD 5 billion, and exports from USD 218 million to USD 0.5-1 billion appear modest. However, the institutional, pricing and quality control measures put in place will allow this sector to comfortably achieve these targets; and then be on the path to securing a much higher share of global trade—as Pakistan prepares the enabling environment for attracting investment and global recognition as a producer of quality medicines and vaccines. An internationally competitive pharmaceuticals sector will help improve Pakistan's overall image as a modern developing nation contributing to global welfare.

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