Product Report

PHARMACEUTICALS

Overview of Pakistan Pharmaceutical Industry, Identification of Potential Markets and Strategies to Improve Exports.

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EXECUTIVE SUMMARY

- Pakistan's pharmaceutical industry is set to grow at a rate of 11-12% till 2023. Pakistan must capitalize on this opportunity to invest and nurture the growth of its pharmaceutical industry.
- The global growth is expected to go over USD 1.5trn by 2023.
- Pharmerging markets will witness the biggest increase due to more consumption of generics. Developed markets will account for majority of sales in terms of value while pharmerging markets will account for majority of volume.
- Pakistan's pharma industry is set to grow due to ageing population and rising income levels. 67% of sales are accomplished by MNCs while they constitute 3% of the total Pakistani pharma companies.
- Currently drugs for acute diseases dominate the market, however, the market for chronic disease treatments is expected to grow.
- Pharmaceutical companies in Pakistan are governed under Drug Rules 1976. The regulatory authority is DRAP.
- R&D is key to pharma industry. Drug discovery is the first phase, followed by clinical trials. Successful clinical trials lead to regulatory approval. After receiving regulatory approval, manufacturing starts and is followed by marketing and distribution.
- Pakistan meets 80% of its demand from local production while 20% of medicines are imported.
- Raw materials (APIs) are largely imported as Pakistan does not produce them locally.
- Concentrate are imported, diluted and packaged before being sold locally.
- Most of Pakistan's exports are assigned HS code 3004 and HS 3003.
- Pakistan's total exports of medicine have remained around the USD 200mn mark. Exports increased in 2017 to USD 213mn but declined in 2018 to USD 195mn due to challenges faced by the industry such as price ceilings which made it unfeasible to produce certain drugs.
- Due to lack of PIC/S registration and FDA approved lab, Pakistan remains limited in the choice of markets it can export pharmaceuticals to.
- Potential markets for exploration, based on combination of expected market growth and low NTBs are Egypt, Cambodia, Central Asia and West Africa.

- Pakistan should seek to acquire PIC/S registration to assuage the concerns of buyers regarding GMP of Pakistani manufacturers. Training by PIC/S will improve the standards of DRAP and Pakistan's pharmaceutical industry.

- Competitor countries such as India are successful in exports due to import liberalization policies, recognition of global patents and 2 years' license to conduct contract manufacturing.

- India's strategy is to be dominant in low cost generics. Contract manufacturing helps in inviting FDI to the country.

- Other competitors such as Malaysia uplifted their pharma sector by improving its human resource base and enhancing the R&D capabilities of domestic firms. UK pharma companies are free to price drugs but the government has setup restrictions on the rates of return. The British government also fast tracked approval of drugs for critically ill patients.

- IMS Health estimates that the majority of global medicine consumption will be driven by India, China, Brazil and Indonesia.

- Developed markets will use more original branded and specialty medicines while pharmerging markets will use more non-original brands, generics and OTC medicines.

- Penetration in developed markets, such as USA, EU, Japan and Australia is difficult for Pakistani pharmaceutical firms due to lack of compliance with its NTBs and absence of WHO approved laboratory.

- Pakistani manufacturers cite pricing issues as obstacles to doing business. Licenses for contract manufacturing are given for 3 months instead of 2 years. The industry has stated that these policies hurt the pharmaceutical industry.

- The government response is sympathetic but the execution part is missing. PPMA stated that while the Ministry of Health and DRAP held a sympathetic view, their vision should be realized more rapidly.

- DRAP and the pharma industry need to coordinate more together on multiple issues. The Ministry of Commerce and TDAP should give easy installment loans to pharmaceutical companies that have shown exports in excess of PKR 200,000 (figures suggested by Pharma EPC). These companies should have their export registration fees subsidized. This fee could be provided as a loan by TDAP, payable in 2 or 3 years. The R&D Fund at the Ministry of Health could be used for Pharma trade promotions and export development. Companies which have been exporting for the past 3 years could be provided this fund for use to increase their exports. Another suggestion was that the EDF fund should be used to develop dedicated Research Center for Pharma industry.

- The export data suggests lack of exploring new markets by pharma exports. Pakistan should diversify its clientele base instead of concentrating on only a few markets as this poses a

concentration risk. Already market share in Afghanistan has been falling for the past 3 years due to competition from India.

- Better packaging trends are emerging in Europe and Pakistan should learn from European pharmaceutical companies. Biologics are being increasingly packaged in combination with a device. More and more companies are embracing easy to use packaging.

- Pakistan should seek to become a hub of research and clinical trials.

- There exists opportunity to manufacture medicines for Neglected Tropical Diseases identified by WHO. In order to tap into markets where NTDs are prevalent, Pakistani pharmaceutical companies would need to collaborate with international players to form product development partnerships (PDP) which will bring together the expertise of international players combined with the low cost of production of Pakistani players.

- Pakistan should also seek to tap into the vaccines market which is forecasted to grow to USD 57.5bn by 2025.

- There exists opportunity in catering to specialty medicine and personalized healthcare. However, this will require setup of an FDA approved lab and improvement in GMP.

- Digital Therapeutics (DTx) are emerging as a new treatment method which Pakistani players should seek to learn and capitalize on.

- Delays in licensing approvals should be corrected.

- Pakistan can seek to become a hub of contract manufacturing. This will enable Pakistan to develop the capability of producing APIs instead of importing them.

- In order to uplift the pharma industry, Pakistan will need to invest in HR and R&D capability. This will also enable Pakistan to handle outsourced R&D requests thereby creating an additional revenue stream.

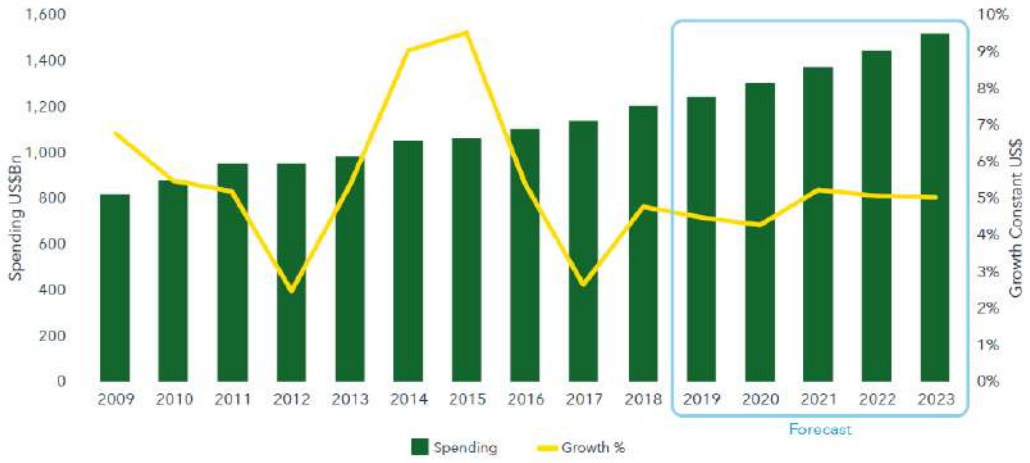
- Counterfeiting needs to be strictly policed. The government and pharmaceutical companies should identify counterfeit networks. Doing so will help the pharmaceutical manufacturers in avoiding negative publicity in the market as well as abroad. Companies are also coming up with smart packaging. These make use of holograms or unique printing to make difficult-to-reproduce labels. Another solution being used is electronic pedigrees, which is similar to RFID tech. they are able to track and trace products as they transfer across the supply chain from manufacturer to distributor to retailer or hospital.

- The government should not let MNCs impose TRIPS++ on the Generics market. TRIPS and TRIPS plus had increased restrictions in bilateral trade and failed to generate substantial gains for the developing nations. According to the recommendations of Mr. Khalid Mahmood, CEO Getz Pharma, the government should also refuse to accept Data Protection/Data Exclusivity for the generics market.

1 THE GLOBAL PHARMACEUTICAL INDUSTRY

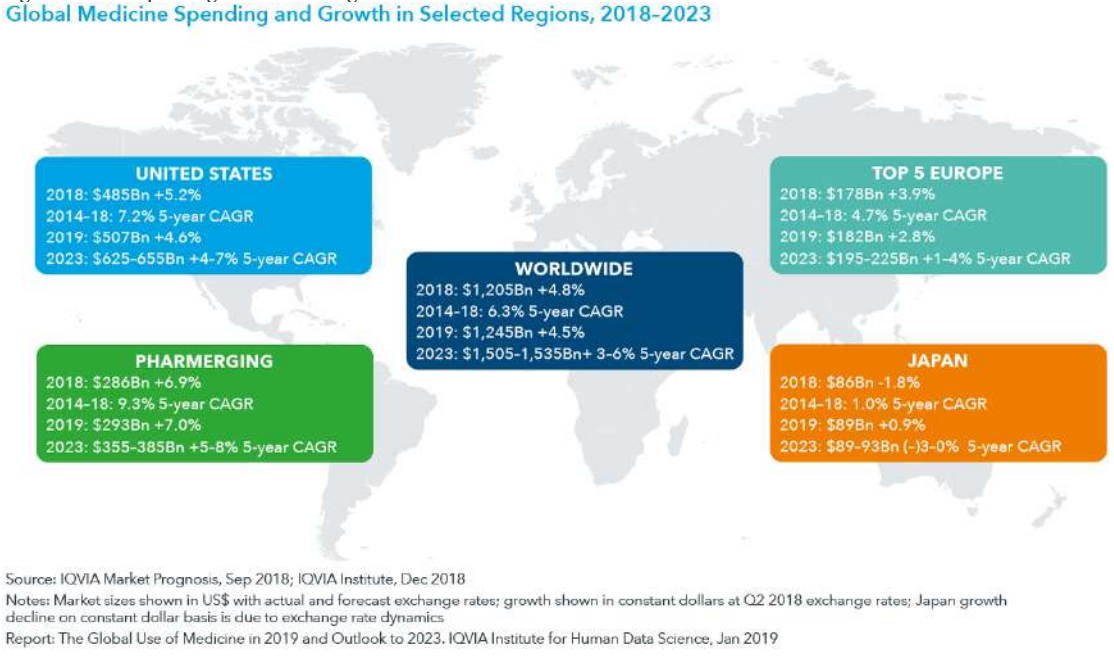
The global pharmaceutical sector has grown to more than USD 1 trillion dollars over the past decade (Choangalia & Deshmukh, 2018). The growth is attributed to market expansion in emerging countries and favorable demographics including an ageing population in developed nations. Further growth is expected to go over USD 1.5 trillion by 2023 as shown in Figure 1 (Aitken, Kleinrock, Simorellis, & Nass, 2019).

Figure 1 Global Spending on medicine



The biggest increase is expected to come in pharmerging markets as two thirds of the generics volume will be consumed in developing nations. There will be an increase in utilization of medicines due to broad based healthcare expansions. The developed markets will continue to account for the majority of value as compared to volume which will be predominantly overshadowed by developing markets. The developed markets are expected to continue paying a higher price per unit (Aitken, Kleinrock, Simorellis, & Nass, 2019).

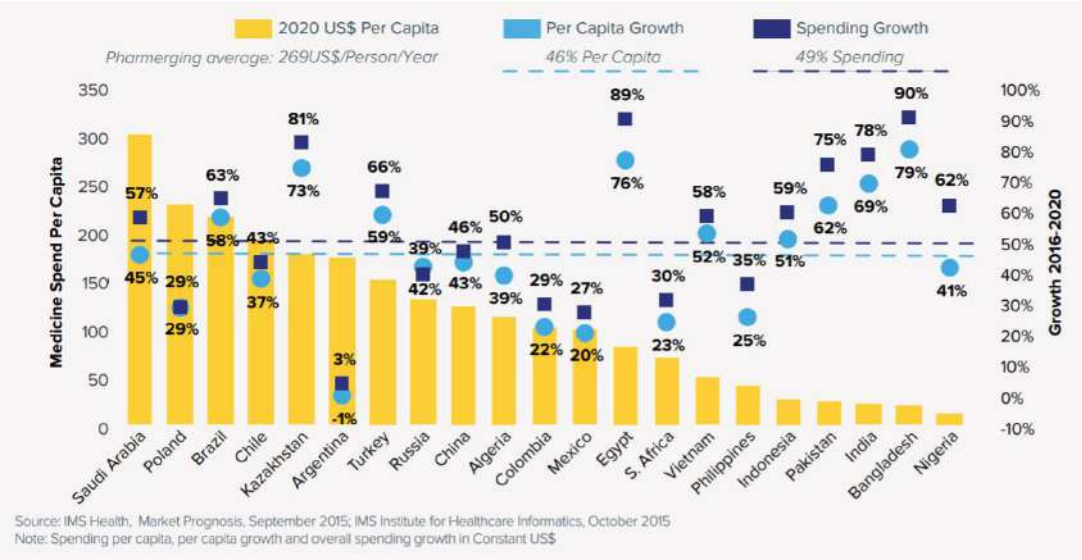
Figure 2 Global spending on medicine region-wise



Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018
Notes: Market sizes shown in US$ with actual and forecast exchange rates; growth shown in constant dollars at Q2 2018 exchange rates; Japan growth decline on constant dollar basis is due to exchange rate dynamics
Report: The Global Use of Medicine in 2019 and Outlook to 2023. IQVIA Institute for Human Data Science, Jan 2019

Pharmaceutical spending shows a strong correlation with income levels. While it may be intuitive to think of pharmaceutical growth to be correlated with population, the Pakistani population under 30-year-old is more than 60% and that particular demographic tends to consume a lower level of medication compared to old people. However, as the Pakistani population ages, drug consumption is expected to go up over the next 40 years. [1]

Figure 3 Medicines Spend and Change per Capita Constant US$ in pharmerging markets



[1] Pharmerging countries are defined as those with >$1 billion absolute spending growth over 2014-18 and which have GDP per capita of less than $30,000 at purchasing power parity (PPP). Tier 1: China; Tier 2: Brazil, India, Russia; Tier 3: Algeria, Argentina, Bangladesh, Chile, Colombia, Egypt, Indonesia, Kazakhstan, Mexico, Nigeria, Pakistan, Philippines, Poland, S. Africa, Saudi Arabia, Turkey, Vietnam.

2 PAKISTAN PHARMACEUTICAL INDUSTRY

2.1 Industry Dynamics

The Pakistani pharmaceutical industry is characterized by low entry barriers and significant regulations. A large part of the market is captured by few big firms. Firms primarily engage in manufacturing formulations by importing Active Pharmaceutical Ingredients (API). Only 5% of the raw materials are produced locally (Choangalia & Deshmukh, 2018). Local players also engage in contract manufacturing for MNCs as they are a low cost option for the multinational players.

Based on the available data, in 2017, the Pakistani pharmaceutical industry registered sales of USD 3.1bn which translated to a global market share of 0.5% (Choangalia & Deshmukh, 2018). During the past 5 years, the pharmaceutical industry in Pakistan has grown at a rate of 11%.

(Source: World Bank, IMS, ITC, JCR-VIS)

The Pakistani pharmaceutical industry is dominated by local manufacturers which account for two thirds of the market while multinationals account for the remaining one third. The top

ten companies have a market share of 46% while the top 50 companies enjoy a market share of 90% (Institute of Chartered Accountants of Pakistan ICAP, 2018).

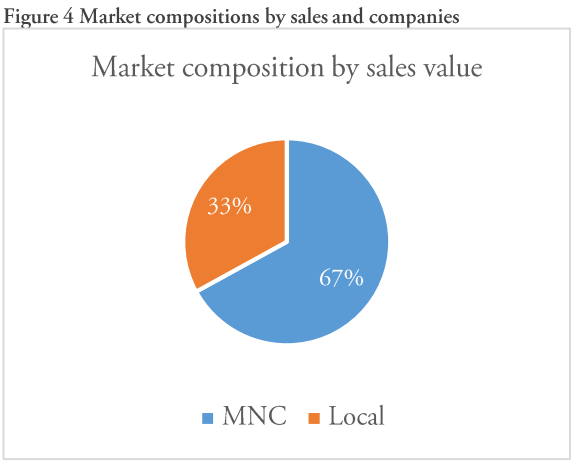
Table 1 Top 10 Pharma companies in Pakistan

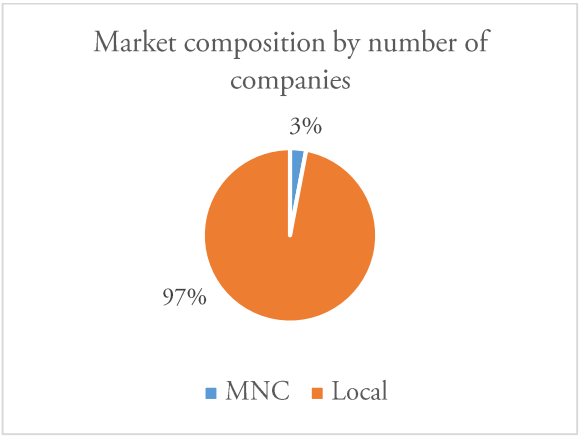
Name	Ranking	National / MNC	Listed
GSK	1	MNC	Listed
Getz Pharma	2	National	Unlisted
Sami Pharmaceutical	3	National	Unlisted
Abbot Laboratories	4	MNC	Listed
Martin Dow Pharmaceuticals	5	National	Unlisted
The Searle Company	6	National	Listed
Sanofi Aventis	7	MNC	Listed
OBS Pakistan	8	National	Unlisted
GSK Consumer Healthcare	9	MNC	Unlisted
Hilton Pharma	10	National	Unlisted

Source: IMS MAT June 2017

There has been more growth for local players as the market is basically a low cost generic market. The Pakistani pharmaceutical industry has 775 units operating in the country including MNCs.

Figure 4 Market compositions by sales and companies





(Source: (Institute of Chartered Accountants of Pakistan ICAP, 2018)

There are approximately 9,000 actively marketed drugs sold in Pakistan at licensed pharmacies on prescription (Institute of Chartered Accountants of Pakistan ICAP, 2018). A large portion of the drugs are Over The Counter (OTC) products such as multivitamins, pain, cold and flu relief.

2.2 Key Therapy Areas and Major Products of Pharmaceutical Companies

GSK

- Pain management, respiratory health, gastrointestinal health, oral health, skin health
- Panadol, Actified, Eno, Augmentin, Horlicks, Sensodyne

Abbot

- Digestive system, cardiovascular disease, respiratory health, neurological disorders, pain management, women's health
- Brufen, Klaricid, Entamizole

Searle

- Analgesics, respiratory disease, hypertension, gastrointestinal
- Nuberal forte, Hydrillin, Extor, Gravinate, Peditral

Highnoon

- Alimentary tract & metabolism, cardiometabolic & respiratory
- Trex Orx forte, Ulsanic & Skilfax

Ferozsons

- Cardiology, gastroenterology, hepatology, oncology, dermatology and anti-infective
- Solvaldi

IBLHL

- Adult nutrition, infant nutrition, medical disposable products
- Mead Johnson Nutrition, Nestle Health Science, Terumo, Meditech, Mechapo

Macter

- Hepatology, Oncology, Anti-Diarrheal, Broad spectrum penicillin, Respiratory, Hepatitis vaccines, Carbapenam antibiotics, Vitamin B12, tranquilizer
- Pec-Heb, Maclinza, Viron, Macdronic, Bismol, Sofomac, Ecavir, Tacip, Adalin, Expectorant, Salmicort, Herberbiovac, Ropen, Cobolmin, Relaxin

Otsuka

- Intravenous solution, Anti-platelet aggregation, Dextrose, Clinical nutrition
- Ringolactin F, Pletaal, Pladexsal, Aminoleban oral powder granules

Currently, drugs for acute diseases dominate the market, however, the increasing infiltration of lifestyle related diseases is anticipated to stimulate the growth of drugs targeting chronic diseases. The growing share of lifestyle segment in the pharma market has led drug companies to restructure their product portfolio to tap the huge opportunity. This means that more medicines will be made catering to cardiovascular disease, cancer and diabetes.

2.3 Regulatory Affairs

Pharmaceutical products in Pakistan are governed under the Drug Rules 1976 which oversee labeling and packing, licensing, registration and advertising, import, export and research of

pharmaceuticals in Pakistan. Pharmaceuticals can include generics and brand medications. The regulatory body is Drug Regulatory Authority of Pakistan (DRAP). The industry is also regulated by Ministry of National Health Services Regulations & Coordination (NHSR&C). The major associations of pharmaceutical firms in Pakistan are Pakistan Pharmaceutical Manufacturers Association (PPMA) and Pakistan Tibbi Pharmaceutical Manufacturers Association (PTPMA). DRAP controls the registration of new medicines and new manufacturing sites. DRAP also determines the Maximum Retail Price (MRP) of all medicines marketed in Pakistan.

The Drug Regulatory Authority of Pakistan (DRAP) is responsible for the enforcement of Drugs Act 1976. The Authority is composed of:

(a) Director Pharmaceutical Evaluations and Registration – in charge of evaluation, assessment and registration of pharmaceutical drugs for humans and animals.
(b) Director Drug Licensing – responsible for licensing of drugs manufacturing facilities.
(c) Director Quality Assurance and Laboratory Testing – responsible for enforcement of Good Manufacturing Practices and testing of drugs to ensure safety, efficacy and quality of registered pharmaceuticals.
(d) Director Medical Devices and Medicated Cosmetics – in charge of registration of medical devices and medicated cosmetics, shampoos and soaps.
(e) Director Biological Drugs – in charge of assessment and licensing of biological drugs.
(f) Director Controlled Drugs – responsible for allocation of quota for narcotic drugs, psychotropic drugs and precursor chemicals.
(g) Director Pharmacy Services – responsible for development and promotion of pharmacy services.
(h) Director Health and OTC (non-drugs) – in charge of licensing of alternative medicines including Ayurvedic, Chinese and homeopathic medicines, registration of nutritional products, and food supplements.
(i) Director Costing and Pricing – responsible for costing and pricing of therapeutic goods.

DRAP inspectors may inspect places where therapeutic drugs are manufactured or sold and may take samples to assess the quality of pharmaceutical products. There are specific special payments made to DRAP for numerous purposes including registration and renewal of licenses. These include:

1. Central Research Fund: Annual levy of 1% of Profit before tax
2. New drug registration fees
3. Drug registration renewal fees
4. Drug manufacturing license fees

2.4 Custom Duties

Custom duties range from 5% to 25%. On 25% custom duties, additional sales tax is also levied despite no sales tax on sale of medicine (Institute of Chartered Accountants of Pakistan ICAP, 2018). In 2018, the advance income tax levied on import of raw materials was at 5.5% of import

value. Import duties on medicine range from 0% to 10%. Certain medicines such as those for cancer, transplant and heart related medicines have 0% custom duty, however there is 5.5% advance tax on import value.

2.5 Taxation

Sales of locally manufactured medicines fall under the Normal Tax Regime (NTR) whereas the Income Tax on sale of imported finished medicines falls under Final Tax Regime (FTR). In the case of exports, the entire export proceeds, whether of locally manufactured medicines or imported medicines also fall under FTR (Institute of Chartered Accountants of Pakistan ICAP, 2018).

Promotional Spend FBR reviews the sales promotional spending of pharma companies. According to the Drug Act, sales promotional spending is limited to 5% of turnover.

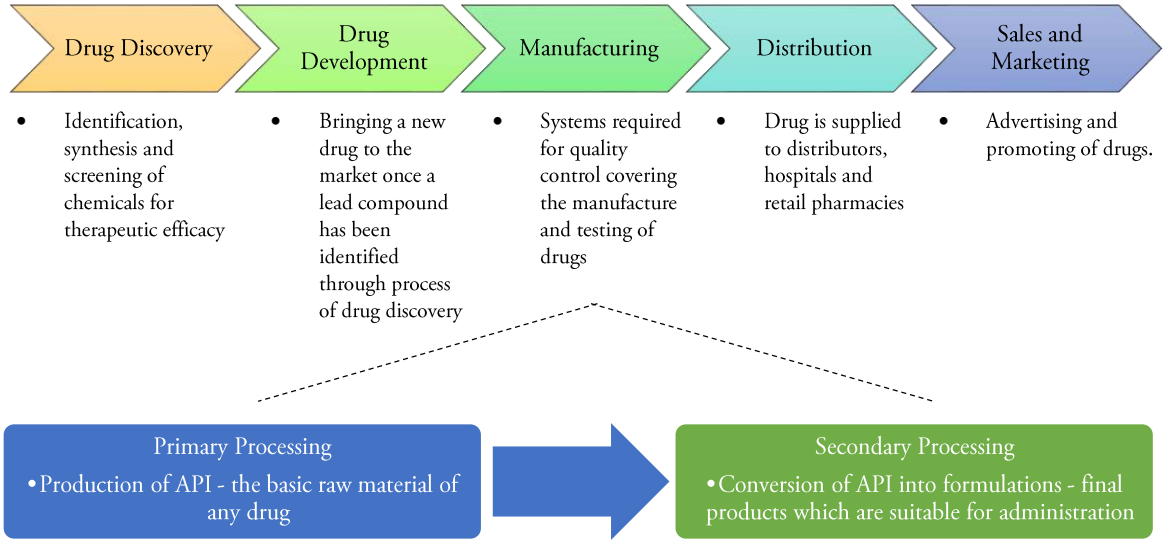
Transfer Pricing The issue of transfer pricing involves MNC pharmaceutical companies where the local affiliate purchases Active Pharmaceutical Ingredients (API) from its parent company worldwide. The Federal Board of Revenue (FBR) has issued notices to MNCs to determine whether the transfer prices of APIs are done at arm's length transaction. Correct arm's length pricing of APIs is necessary because APIs are used to manufacture medicine in Pakistan and those medicines are taxed under NTR.

Sales Tax The pharmaceutical industry has exempt status in GST. There is no sales tax on sale of pharma products. The GST returns are only applicable on disposal of fixed assets and scrap sales.

3 VALUE CHAIN ANALYSIS

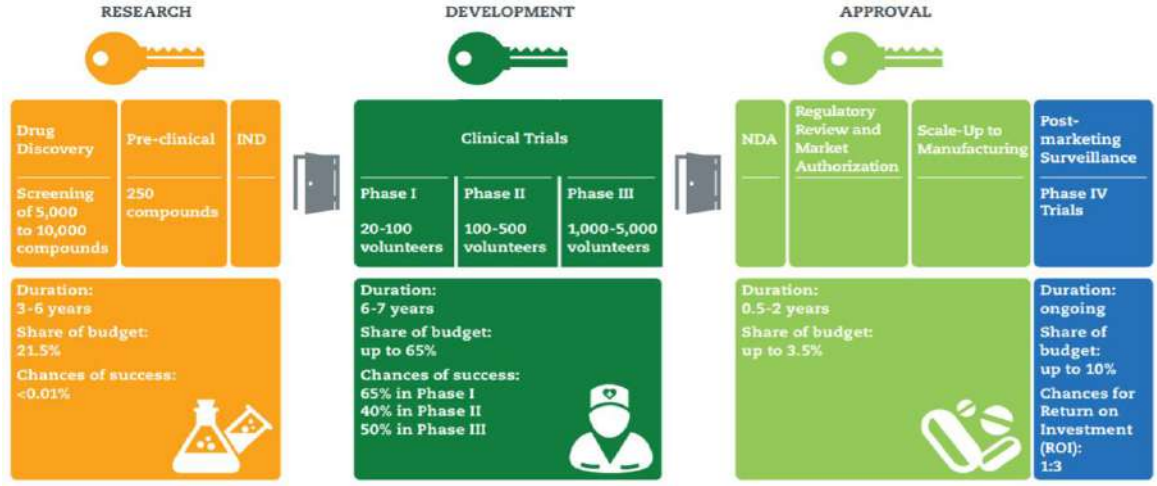
Pharmaceutical companies mainly deal in generic[2], branded[3], branded generics[4] and over the counter[5] drug. Firms may also participate in contract development or manufacturing, where a company provides all-inclusive services from drug development to drug manufacturing for another client firm. The typical pharmaceutical supply chain, which is followed world-wide is given below in Figure 5.

Figure 5 Pharma supply chain



Further zooming in to the stages of drug discovery and drug development, the research and development process looks like this as given in Figure 6:

Figure 6 The R&D Process



[2] Contains the same active ingredient as the branded drug but can be sold in the market only after the patent expires.

[3] Developed originally by a company and sold with patent protection.

[4] Off-patent drug that is re-released into the market with a different brand name.

[5] Medicines sold directly at the pharmacy without requiring a prescription.

[6] IND = Investigational New Drug.

During the research phase, drug discovery leads to pre-clinical study of compounds, which is followed by the discovery phase during which successive clinical trials occur. Approval ensues the positive clinical trials, which leads to regulatory review and authorization. After receiving approval, production and marketing phases follow.

R&D is expensive and technology intensive; therefore, Pakistani companies are unable to conduct research of drugs in the country. Compared with other technology-intensive industries, the yearly spending by the global pharmaceutical industry is 5.5 times greater than that of aerospace and defense industries, 5 times more than chemical industries and 1.8 times more than IT services industry (International Federation of Pharmaceutical Manufacturers and Associations, 2017).

Pakistan meets 80% of its demand from local production while 20% of the medicines are imported. The local production however is largely dependent on imported raw materials as almost no raw materials are produced locally (Pervez, 2008).

Raw materials are imported in the form of 'concentrates' which are then diluted and packaged as medicine before being sold via retail. In Pakistan, the supply chain model follows the ensuing Figure 7.

Figure 7 Pharma supply chain in Pakistan

Pharmaceutical companies generally sell their medicines on advance payment from their distributors. When the distributor sends the cheque or pay order with their order invoice, the Finance Department confirms the amount credited in the company's bank account. The Sales Order is processed and the Delivery Challan along with the Sales Invoice is generated in the ERP system. Due to the practice of advance cash model, the Days Sales Outstanding (DSO) in Pharma industry is generally nil.

Pharmaceutical companies collect most of their data from IMS Health. IMS Health is an American company that provides information, services and technology for the healthcare industry including prescription data and medical records. It is the largest vendor of physician prescription data in the US. Pharmaceutical companies use data/reports provided by IMS to develop their commercial plans and portfolio strategies.

In Pakistan, IMS compiles data on sales made by distributors to chemists and pharmacies. The data is collected on a monthly basis and is available to subscribers on payment of a subscription fee. IMS reports are useful in determining the ranking of pharmaceutical companies by size and growth rate, the market share of the relevant product line vs its competitors, and specific sales information molecule-wise, region-wise, brand-wise etc.

3.1 Sales & Operations Planning (S&OP) process

S&OP is an integrated cross-functional planning method that starts with the demand planning for individual Stock Keeping Units (SKUs). Although the planning horizon varies from company to

company, an average of 12 to 36-month horizon is used. The following steps are usually undertaken:

1. The demand is finalized by the sales and marketing department under the assumption that there is no constraint on product availability. This is referred to as "unrestricted / unconstrained demand".
2. The supply chain department coordinates with the procurement department to see what is an achievable target taking production and supply constraints into consideration. A "restricted / constrained demand" is made after considering all factors such as production plans, import quotas and lead times.
3. This "restricted / constrained demand" is agreed upon by relevant stakeholders depending on the company's Standard Operating Procedures (SOP).
4. Once the demand is finalized, a Purchase Requisition is generated for APIs, excipients, packaging materials and finished medicines.

In the case of MNCs, sourcing is done from within the group. An inter-company ordering system is used to match the quantity and supply dates.

3.2 Sourcing of API and Excipients

Raw materials in the pharmaceutical industry consist of Active Pharmaceutical Ingredients (API) and excipients. Most of the research in pharmaceuticals is done in developed countries such as UK, Germany, Switzerland, France, Japan and the US. Imports of pharmaceuticals takes all forms including APIs, excipients, semi-finished drugs and finished drugs.

Table 2 Top 5 molecules by sales value in Pakistan

Name of molecule	Estimated annual sales (PKR mn)
Ceftriaxone	9,000
Cefixime	8,300
Omeprazole	7,200
Amoxicillin + Clavulanic acid	7,000
Ciprofloaxcin	7,000

(source: IMS MAT June 2017)

3.3 Marketing

Under the Drugs Act 1976, pharmaceutical companies are forbidden from directly contacting patients for promotion of their medicinal products through mass advertising including social media, electronic media, print media and billboards.

However, drugs which fall under the Over The Counter (OTC) category, are allowed to be advertised on print/electronic/social media. For example, OTC brands such as Panadol and Disprin (Aspirin) are widely advertised on TV.

Table 3 Top 5 selling brands in Pakistan

Brand name	Manufacturer	Approximate annual sales (PKR mn)	Launch year
Augmentin	GSK	4,500	1986
Risek	Getz Pharma	3,300	1996
Panadol	GSK Consumer Healthcare	3,200	1976
Brufen	Abbot Laboratories	2,600	1979
Novidat	Sami Pharma Pvt Ltd	2,500	1992

Source: IMS MAT June 2017

Local laws still allow for public awareness on diseases and their treatment through mass media advertisements without revealing product/brand name.

Marketing performs the necessary awareness among Health Care Professionals regarding the latest medical/clinical research on the efficacy of their drugs. These awareness sessions are carried out using promotional activities such as

- Round table discussions with doctors
- Local and foreign scientific conferences sponsorship
- Glucometers, BP apparatus to HCPs
- Symposia and workshops
- Providing weighing machines
- Local speaker programs

Marketing is required to be conducted within set ethical and legal boundaries. Any promotional spending without documentation of purpose may lead to fines and penalties by the regulatory authorities. This is a common practice enforced all over the world. In Pakistan, all promotional material (including packaging) has to be approved by MOH/DRAP.

3.4 Sales

The structure of sales force in a typical pharmaceutical industry is usually presented in the following manner:

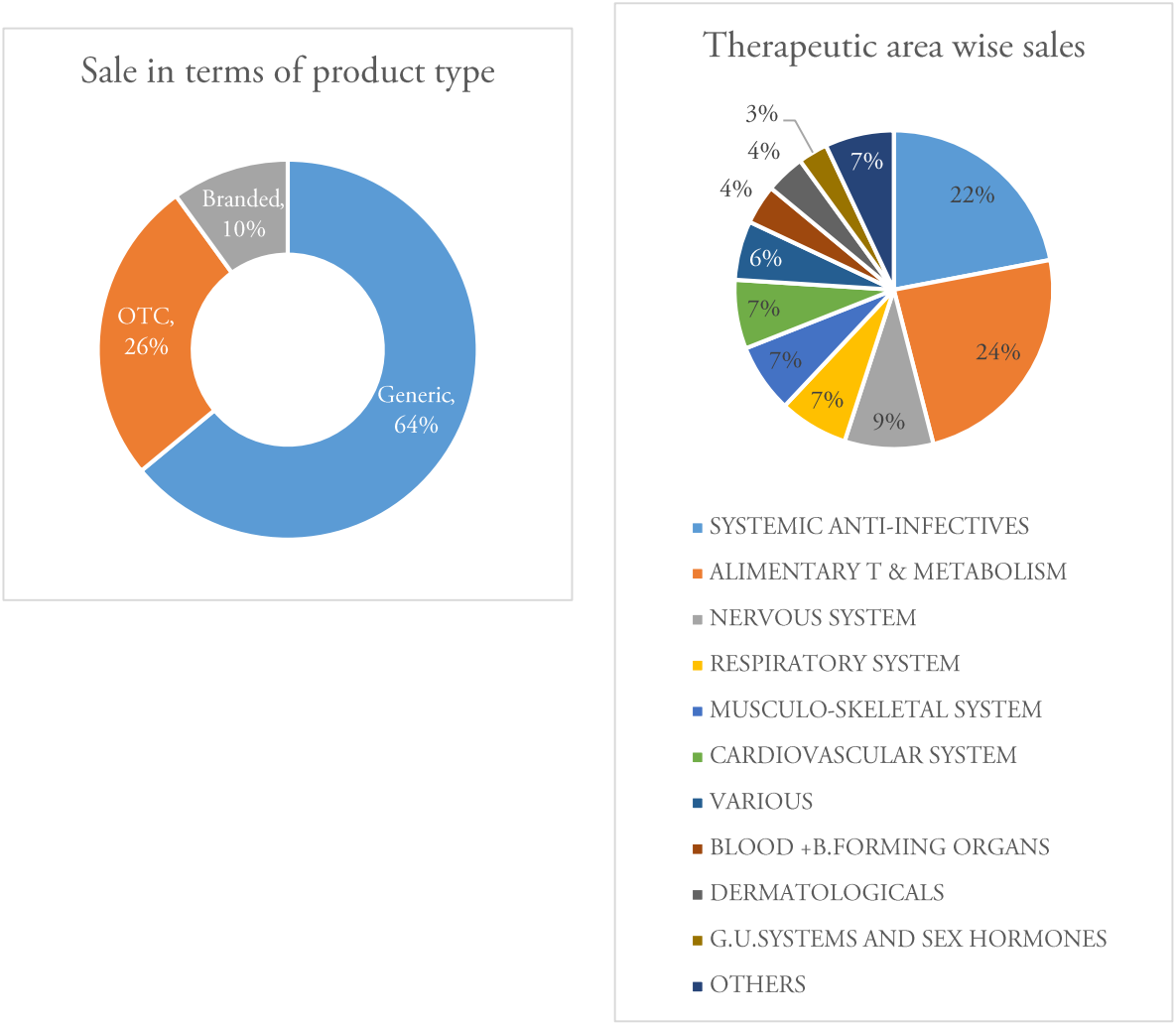
- National Sales manager
- Regional Sales manager
- District Sales manager
- Sales representative (also known as medical rep)
- Trade marketing manager (for OTC)
- Distributor sales representative

The sales force is assigned sales target. This is based on “secondary sales” or “sales out” (referring to distributors’ sales to retail pharmacies, hospitals and wholesalers). “Primary sales” or “sales in” i.e. sales from the company to distributors and overstocking of inventory at the distributor has no effect while calculating the target based achievement. Since the Drug Act 1976 prohibits direct promotion of prescription drugs to the public, companies communicate with HCPs to convey the benefits of their products based on published research. This communication is referred to as “medical detailing” and is conducted by medical reps with HCPs at clinics and hospitals.

The sales unit has a number of KPIs to monitor their performance including number of calls, Call Plan Adherence (CPA), coaching days etc. The majority of pharmaceutical sales in

Pakistan are dominated by systemic anti-infectives and alimentary tract & metabolism as shown in Figure 8. Anti-infectives prevent and eliminate infections and alimentary tract medicines treat disorders of gastrointestinal functions.

Figure 8 Product-wise sales in Pakistan



(Source: (Choangalia & Deshmukh, 2018)

3.5 Regulatory Approvals

All imports are subject to No Objection Certificates (NOC) from DRAP. This means that every material imported in Pakistan requires the attestation of ADC / DRAP according to the local laws. The Government has approved several reliefs to pharmaceutical sector on import of raw material e.g. discount in custom duties under the 5th Schedule of the Customs Act, 1969 and exemption from GST under the 6th Schedule of the Sales Tax Act, 1990.

Certain raw materials have a fixed quota on them by the Government of Pakistan as they are classified as narcotic products. Import of narcotics requires a quota awarded by DRAP which strictly monitors import, consumption, destruction and inventory levels of such restricted items. Companies import a certain extent of their quota which needs to be renewed from DRAP on an annual basis.

Efficacy of the medicine depends on the quality of APIs. MNCs tend to purchase API and finished products from their parent or group companies. Local companies try to procure cost effective ways of buying molecules. Due to the effects of inflation and PKR devaluation, the process of procuring API and excipients needs to remain cost effective in order to protect gross margins. Normally companies try to enter into strategic partnerships with their vendors with long term service contracts based on agreed price and service levels.

3.5.1 Registration and renewal of license for manufacturing and sale of pharmaceutical products

All pharmaceutical companies importing, manufacturing and selling drugs in Pakistan need a license from the Government. These licenses are renewed every 5 years.

3.5.2 Registration of newly launched drugs and application for pricing

New drugs launched by pharmaceutical companies cannot be marketed without registration under the Drugs Act and their prices are determined by DRAP. Pharmaceutical companies ensure that new products are registered in a timely manner and most favorable pricing is obtained from DRAP based on underlying market and cost data.

3.5.3 Pricing, inflationary indexation and hardship cases

The prices of medicines are fixed by DRAP in Pakistan and cannot be changed unilaterally by pharmaceutical companies. Any new price or increase requires approval from DRAP.

3.5.4 Hardship cases

In certain instances, where the cost of manufacturing of a medicine increases to the extent that it becomes non-viable for a company to continue production and marketing of a drug, it can apply to DRAP to increase the price of the product. The hardship cases are reviewed by DRAP and decision is taken whether to accept or reject the application.

For local manufacturers, the MRP is calculated as MRP = (cost of active materials + excipients + cost of packing materials) x factor.

Table 4 MRP determination in Pakistan

Category	Factor
All oral type of drugs(except antibiotics and birth control pills) and tropical preparations	2.40
All type of oral antibiotics, antiviral..	2.45
Sustained released tablets/capsule	2.95
All sterile preparations and birth control pills	2.95
Dispersible tablets	3.15
All aseptic preparations	3.55
Steroids and hormones	3.55

For importers, the price is calculated as Trade Price = Landed cost + markup @ 45%. In case of cancer, biological, immune-suppressant or anti-retroviral drugs the markup is @ 40%.

In 2016-17, drugs were divided into 3 categories w.r.t to price increase policy: Scheduled (50% of CPI - cap of 4%), Non-scheduled (70% of CPI – cap of 6%), and Low Priced Drugs

(100% of CPI). However, effective July 2018, drug pricing was further liberalized through placement of drugs into just two categories: "Essentials" and "All Others".

Manufactures & importers, without prior approval, can increase the MRP (maximum retail price) of "Essential Drugs" equal to 70 percent of CPI with a cap of 7%. Prices of "All Other (biological and low price) drugs" can be increased by 100 percent of CPI with cap of 10%.

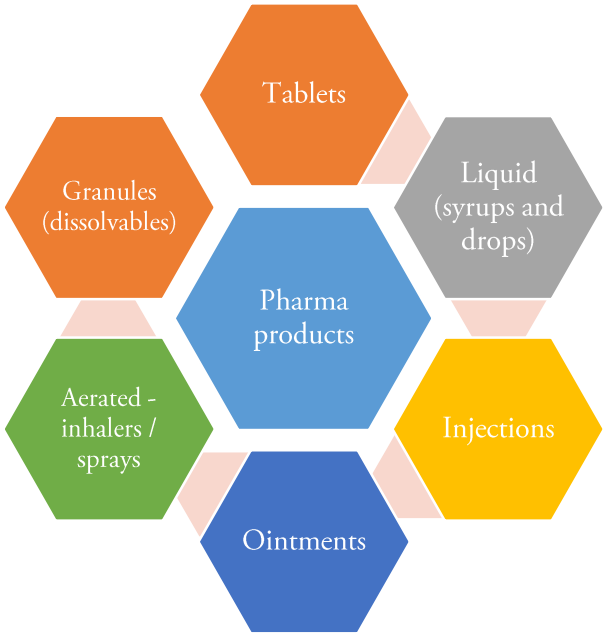
3.5.5 Post registration variations and approvals of pharmaceutical products

After the launch of products, pharmaceutical companies have to renew their licenses after every 5 years. In instances where there is any change in the particulars such as a change in brand names, company name, source of import etc. the company applies to DRAP for change in the registration documents.

3.6 Production

Pharmaceutical products comprise of:

Figure 9 Pharma product types



A particular product can be in one or more different forms. For example, the molecule Ibuprofen is available as tablets, syrup and cream under various brand names while another molecule Metronidazole is being produced / sold as tablets, syrups and injectable (IV).

Each product made locally or imported needs to be tracked with a batch number. Batch numbers help track the medicines from the manufacturing plants to their final consumption. Batch numbers are useful in case of product recall due to quality issues.

Only authorized personnel in special gears are allowed to enter in production areas. These areas have advanced Heating, Ventilation and Air Conditioning (HVAC) systems with separate zoning. The zones are kept dust proof and temperature and humidity is controlled. The authorized personnel have to wear lab coats, caps and face masks to cover their hair, beards and foot covers for shoes. Everything is kept within a controlled environment and strict hygiene measures are observed ensure impurity-free product quality.

The product format, capacity, technology and source of plant equipment affects the cost of manufacturing. MNCs use machines used by their head offices to meet quality and reliability standards. Local manufacturers tend to source manufacturing equipment from China, Korea, Taiwan etc. to procure cost effective equipment. Plant location is critical in addition to trained

work force, engineering suppliers, continuity of power, supply of water, connectivity with road network and cost of land.

3.7 Quality Assurance

All batches undergo quality assurance checks. QA or QC departments draw sample, check it against quality parameters and ensure it is fit for sale. Typical problems with the quality of a product include:

- Discoloration
- Broken or missing tablets
- Melted capsules
- Particles in solutions
- Net weight content
- Cracked vials / bottles
- Mislabeling (misprinted text, incorrect batch numbers or expiry dates)

All deviations are methodically tested and a batch is rejected if deviations are major. Sometimes quality problems are not caught in the sample testing and later surface after the product has reached the market. In cases of an Adverse Reaction (ADR), the problem is reported by the patient or Healthcare Professional (HCP) and the product is recalled by the company from the market. In such instances, DRAP, HCPs, pharmacies and the public need to be informed about particular batch for recall. Pharmaceutical companies provide telephone contact details or websites where anyone can lodge a product complaint or report a quality issues. A Root Cause Analysis (RCA) is carried out to inspect the issue and take corrective measures.

DRAP can also undertake its own inquiry related to quality to check any instances of malpractice. Proper investment needs to be made in QA systems and equipment to ensure reliability of product quality. QA and pharmacovigilance teams ensure that any recalls from ADRs are recorded.

3.8 Medical Affairs Department

Medical Affairs job is to communicate scientific information to HCPs in an objective and ethical manner, educating them on the latest clinical research, treatment guidelines, new medicines, their medical benefits to patients and any side effects.

The medical team undertakes clinical trials to develop medical research evidence on the efficacy of new medicines in treating diseases. Pharmaceutical companies engage hospitals and Clinical Research Organizations for clinical trials. Hospitals enlist volunteer patients in small groups for clinical trials depending on the medicine's type and their development stage. The results of these trials are published in medical journals.

Pharmacovigilance (PV) is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products, i.e. drugs. It is concerned with identifying any risks associated with medicines and try to minimize the risk of

any harm that may come to consumers or patients. Pharmaceutical companies emphasize pharmacovigilance. There is dedicated staff that collects information on any Adverse Drug Reaction (ADR) reported by any doctor, staff or patient. All employees across the organization receive training on intermittent basis in order to recognize the importance of timely ADR reporting (24 hrs). In order to ensure well-timed reporting of ADRs, these companies have dedicated telephone lines, email addresses and social media presence linked to the PV staff.

Medical teams also provide a value added service to HCPs by answering their queries about products, their dosages, side effects and latest research results. These telephone lines or email addresses are also available to the general public for queries.

The medical department ensures that all promotional literature provided to the sales rep is factually correct. The literature has an expiry period to ensure that the information is updated and kept latest by the company. All outdated promotional material is destroyed to ensure no expired information is passed onto the HCPs.

3.9 Centralized vs Decentralized Distribution model

In the pharmaceutical market, both centralized (national) and decentralized (regional) distribution models exist. In a centralized model, companies appoint a national distributor which is responsible for the nation-wide distribution of medicines using their own network of warehouses and delivery teams. Examples of national distributors are Muller & Phipps, IBL, Premier etc. In a decentralized model, companies engage numerous distributors in diverse geographical locations. The companies deliver goods to distributors in their hometowns at their own cost and the distributors ensure that the products are made available to local pharmacies. The majority of pharmaceutical companies are operating on the decentralized model.

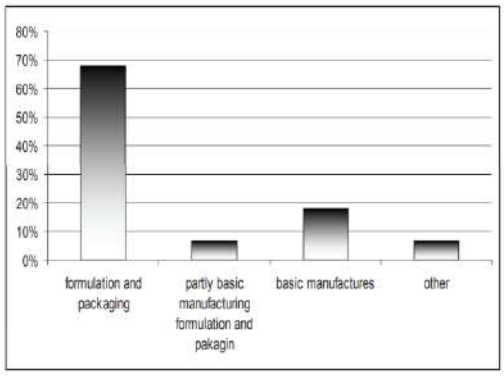
In the case of a centralized distribution model, a pharmaceutical company recognizes its sales made as soon as the medicine is delivered to the national distributor. In a decentralized model, the pharmaceutical company cannot recognize sales made until the medicine reaches the regional distributors in their respective towns. There are some times sub-distributors also involved.

Pharmaceutical companies make certain that their distributors who are the primary suppliers to chemists and pharmacies carry a certain level of inventory of their products at all times to ensure consistent supply of medicine is available in the market.

The inventory levels are carried out by distributors and are based on historical based forecast sale of products and is measured in number of days / weeks of stock cover. The pharmaceutical industry generally requires its distributor to carry 6 weeks of inventory on average to ensure sufficient supply of all drugs. Most of the products are temperature sensitive and therefore require controlled environment during transportation and storage.

The supply chain department ensures that the stock levels are maintained at the distributor locations and that the invoicing is completed in a well-timed manner to restock supplies.

Figure 10 Types of Pharma manufacturing in Pakistan



A survey conducted by Khan A. et al 2009, showed that 15% of the companies surveyed claimed to be involved in some sort of basic manufacturing. The rest were importing basic raw materials and performing formulation and packaging in Pakistan. The degree of basic manufacturing seemed to be limited to the last few stages of imported semi-finished active ingredients. Currently, the production can be deemed to be centered on imported raw materials (Khan & Subzwari, 2009).

3.10 Counterfeiting concerns

Counterfeiting is a chief concern for the local pharmaceutical industry. According to the World Health Organization, "a counterfeit medicine is one, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeit drugs may contain wrong active ingredients, wrong amounts of the ingredients or no active ingredients at all" (World Health Organization WHO, 2019).

Counterfeiting hurts local manufacturers since buyers lose trust in the system. If a purchaser buys counterfeit medicine, they do not receive the expected benefits. This leads to decline in medicinal purchases which hurts sales of companies as well. An estimated 40% to 50% of the medicines marketed in Pakistan qualify for counterfeit by WHO standards (Gibson, 2004). The Pakistan Pharmaceutical Association however claims that these numbers are overstated and the number of counterfeit drugs is not more than 0.4% of the medicines produced in Pakistan (Pakistan Pharmaceutical Manufacturers Association, 2005).

In any case it is a certainty that counterfeiting practices are undermining consumer confidence, giving a bad reputation to the country and undermining profits of manufacturers. Tracking medicine in the downstream channel is of critical importance to the industry.

Usually counterfeits in Pakistan have a label or outer packing that resembles the outer packing of a drug by another manufacturer. Counterfeit drugs are a problem in developed nations as well, however they have reached alarming proportions in Pakistan due to poor law enforcement (Institute of Chartered Accountants of Pakistan ICAP, 2018).

3.11 Security Issues in the Pharmaceutical Supply Chain

Several suggestions are available to enhance security to counter counterfeit medicine. Simple unidirectional bar codes are used to provide information for the sales point, 2D and 3D bar codes and Radio Frequency Identification (RFID) systems are now available to supervise the integrity of medicines.

4 HS CODES

The Harmonized Commodity Description and Coding System, also known as the Harmonized System (HS) of tariff nomenclature is an internationally standardized system of names and numbers to classify traded products. The pharmaceutical products are represented by HS 30 – Pharmaceutical products. The majority of Pakistan's pharmaceutical products (including herbal medicines) lie within HS 3004 and HS 3003.

The full HS description is given below:

HS 3004

- Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale.

HS 3003

- Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic uses, not in measured doses or put up for retail sale.

At the 6-digit level, the majority of Pakistan's pharmaceutical exports lie within HS codes 300490, 300439 and 300339.

The full HS product description is given below:

HS 300490

- Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale (excluding medicaments containing antibiotics, medicaments containing hormones or steroids used as hormones, but not containing antibiotics, medicaments containing alkaloids or derivatives thereof but not containing hormones or antibiotics and medicaments containing provitamins, vitamins or derivatives thereof used as vitamins).

HS 300439

- Medicaments containing hormones or steroids used as hormones but not antibiotics, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale (excluding medicaments containing insulin or corticosteroid hormones, their derivatives or structural analogues).

HS 300339

- Medicaments containing hormones or steroids used as hormones, not containing antibiotics, not in measured doses or put up for retail sale (excluding those containing insulin).

5 PAKISTAN'S EXPORTS

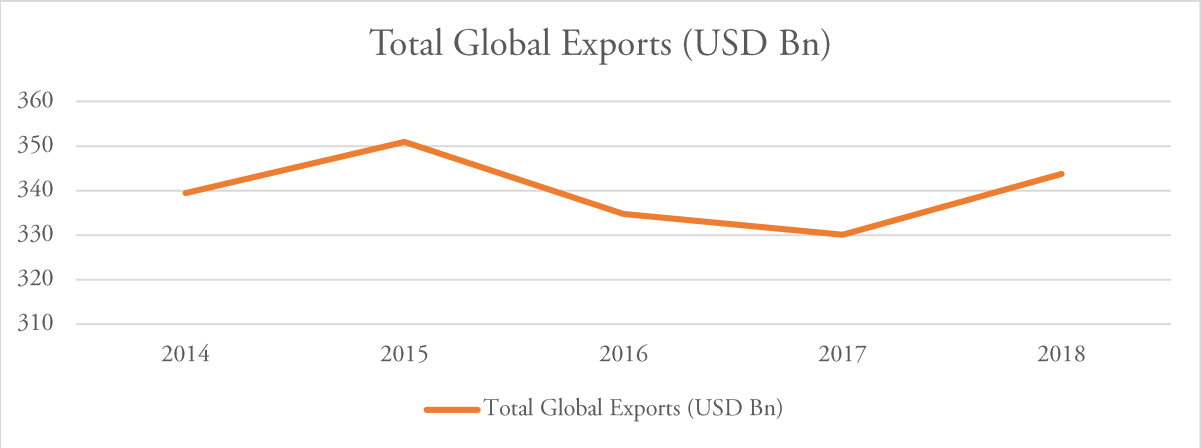
Exports of medicaments from Pakistan amounted to USD 195mn (Pakistan Bureau of Statistics, 2018). The majority of pharmaceutical exports go to Africa, Central Asia and South Asian markets. Highly regulated markets such as USA, Europe, Japan and Australia have been less penetrated by Pakistani pharmaceutical firms due to the fact that they do not meet the stringent compliance requirements of FDA regulations. However, the herbal medicine segment of Pakistan has been able to penetrate these markets more effectively than allopathic drugs.

Pakistan's pharmaceutical export ranks 49th in terms of volume and 16th in value with a global share of 0.06% (International Trade Centre, 2019). A report by McKinsey has dubbed the Pakistani pharmaceutical sector as a sunrise segment. The details of Pakistan's pharma exports are given in the table below:

Table 5 Pakistan's pharma exports

S No.	Year	Exported value (USD'000)	Total Global Exports (USD'000)	Pakistan's Share in Global Exports (%)
1	2014	175,733	339,447,495	0.05%
2	2015	211,839	350,959,617	0.06%
3	2016	204,846	334,730,642	0.06%
4	2017	213,677	330,100,031	0.06%
5	2018	194,910	343,716,401	0.06%
Source: (Pakistan Bureau of Statistics, 2018) (International Trade Centre, 2019)				

Figure 11 Total global export trend



Pakistan's share in global exports has remained negligible over the past 5 years. However, exports have steadily increased over the corresponding time period. Global demand dipped in 2016 due to the shrinking of the global market in 2016 which affected all commodities worldwide, however it has picked up since due to increase in ageing populations worldwide.

Table 6 Pakistan's top markets 2015-17

S. No	Year	Top 5 Markets	Pakistan Export Value (USD '000)	Total Imports of that Country (USD '000)	Pakistan's Share (%)
1	2016	Afghanistan	75,417	193,076	39%
		Sri Lanka	22,205	359,488	6%
		Philippines	15,399	1,103,755	1%
		Vietnam	13,849	2,185,725	1%
		South Sudan	10,110	20,420	69%
2	2017	Afghanistan	74,374	234,955	32%
		Sri Lanka	25,278	403,811	6%
		Philippines	16,611	1,310,485	1%
		Lithuania	8,875	941,680	1%
		Vietnam	8,474	2,396,731	0.4%
3	2018	Afghanistan	65,077	151,475	43%
		Sri Lanka	20,130	393,043	5%
		Philippines	18,089	1,295,024	1%
		Myanmar	10,428	429,921	2%
		Vietnam	9,332	2,644,074	0.4%

(International Trade Centre, 2019)

Over the past 3 years, the top markets for Pakistan have not varied much. Afghanistan, Sri Lanka, Philippines, Vietnam, Lithuania and South Sudan are the biggest markets for Pakistani pharmaceuticals. This stasis reveals the inability of exporters to find new markets. Market share in Afghanistan has been on the decline for the past 3 years, down from USD 75mn in 2016 to USD 65mn in 2018 due to loss of market share to India. Similarly, Pakistan's market share in Vietnam has declined from 1% in 2016 to 0.4% in 2018 due to increasing presence of Indian products. Exports to Sri Lanka were USD 20mn representing a 5% market share. Philippines was Pakistan's third largest customer at USD 18mn. However, Pakistan's market share in Philippines is extremely small at 1.2% due to the large amount of medicine imports by Philippines at USD 1.3bn.

Table 7 Pakistan's competitors in major markets

S. No	Country (Pak Major Market)	Competitors	Export Value 2018 (USD '000)	Share in Imports of that Country (%)
1	Afghanistan	India	60,114	45.4%
		Turkey	15,205	11.5%
		China	1,390	1.1%
2	Sri Lanka	India	173,010	56.6%
		Switzerland	27,744	9.1%
		UK	16,210	5.3%
3	Philippines	India	177,176	13.8%
		Germany	142,834	11.2%
		Switzerland	134,884	10.5%
4.	Vietnam	Switzerland	240,248	14.5%
		France	180,824	10.9%
		Germany	152,364	9.2%

(International Trade Centre, 2019)

Table 7 shows the major competitors of Pakistan in each of Pakistan's major markets. In Afghanistan, the major competitors are India and Turkey with market shares of 45% and 11.5% respectively vs Pakistan's 43%.

In Sri Lanka, the major competitors are India, Switzerland and UK with respective market shares of 57%, 9% and 5% vs Pakistan's 5%. Pakistan's advantage in the Sri Lankan market is due

to its geographical proximity and free trade agreement. In Philippines, Pakistan's major competitors are India, Germany and Switzerland with respective market shares of 14%, 11% and 10.5% vs Pakistan's 1.2%. In most cases, India holds the lead due to its well-developed pharmaceutical sector, compliance with Good Manufacturing Practices (GMP) standards, low AUP due to its generics and import liberalization policies.

The top 5 global importers of pharmaceutical products are given in Table 8:

Table 8 Top 5 global importers of Pharma

S No.	Country	Import Value 2018 (USD '000)	Growth in Imports (%) – Base Year 2017	Pakistan's Exports Value 2018 (USD '000)	Pakistan's Share (%)	Pakistan's Competitors	Competitors Export Value 2018 (USD '000)	Competitors Share (%)
1	**USA**	71,671,045	11%	403	0.00031%	India	6,307,234	8.8%
						China	491,400	0.7%
						Malaysia	4,121	0.013%
2	**Germany**	28,575,888	9%	118	0.0002%	India	311,407	1.2%
						China	50,830	0.195%
						Vietnam	5,682	0.02%
3	**Belgium**	20,342,483	4%	0	0%	India	171,081	0.88%
						China	130,271	0.67%
						Japan	77,640	0.40%
4	**Switzerland**	19,416,798	1%	61	0.0003%	Brazil	20,519	0.11%
						India	17,399	0.09%
						China	10,845	0.06%
5	**China**	18,139,534	6%	567	0.0032%	India	418,905	2.4%
						China	70,977	0.4%
						Brazil	6,657	0.04%

Pakistan's share in these markets is negligible due to the industry's inability to comply with non-tariff barriers (NTBs) such as the US FDA regulations. Currently Getz Pharma has spent PKR 300mn on its manufacturing plant to bring itself compliant with FDA regulations in order to penetrate the US market. As majority of Pakistani companies are unable comply with FDA regulations, they lose the opportunity to export to USA along with other places in Europe, Saudi Arabia and UAE.

The top exporters of Pakistan's pharmaceutical products are given below:

Table 9 Top Pakistani exporters of Pharmaceuticals

Name of Company	Export Value in 2017 (Rs Mn)
Getz Pharma	4,023
Abbot Laboratories	1,362
Novartis Pharma	1,137
Herbion Pakistan	1,100
Searle	884
Merck	796

(PRAL)

The data from Customs indicates Getz Pharma as the top pharmaceutical company in Pakistan. Abbot Laboratories and Novartis have exports over PKR 1bn. Currently Herbion has exports worth PKR 1.1bn. The full list of top exporters is given in Appendix 1.

6 POTENTIAL MARKETS

Since the sale of pharmaceuticals depend on ageing population and rising income levels, Pakistan should look to target countries where such circumstances are conducive to increase in pharma exports from Pakistan.

Figure 12 Countries' Income per person and Life Expectancy

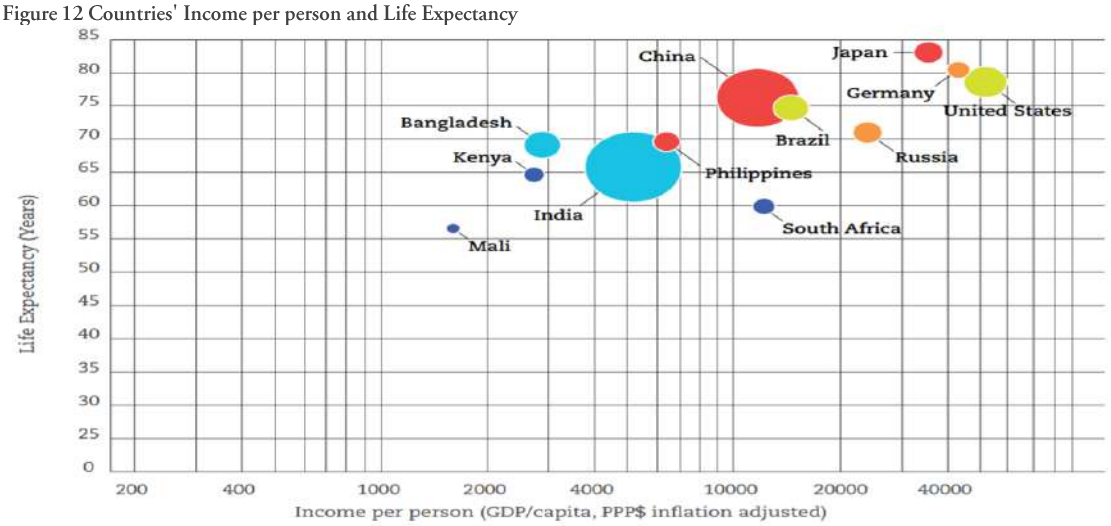
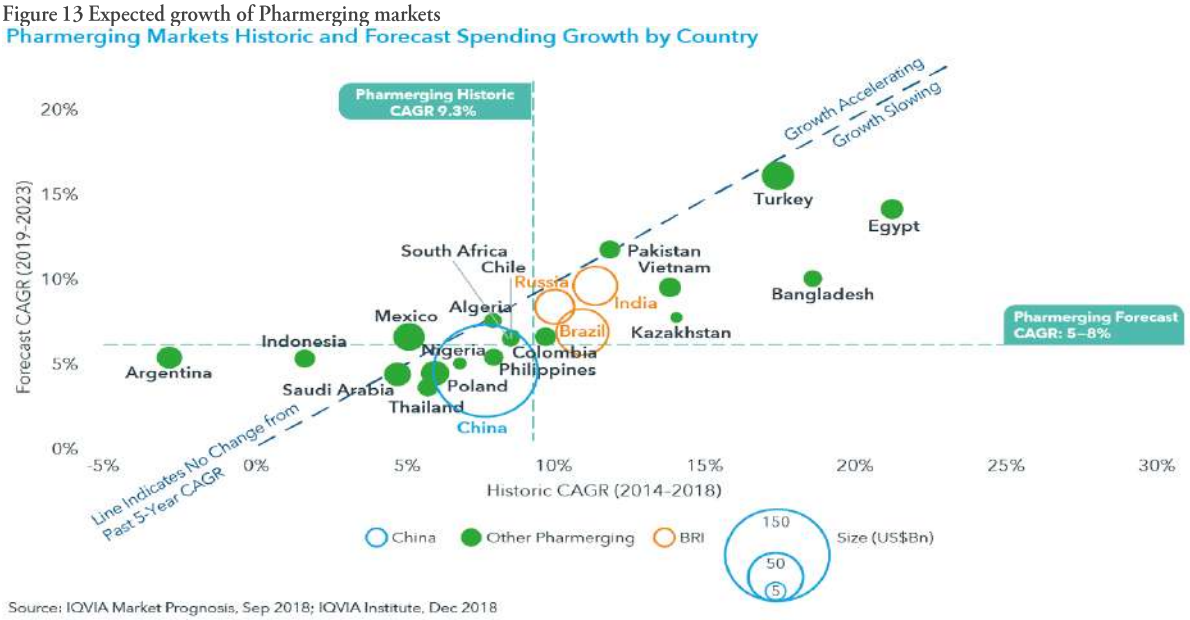


Figure 12 shows that higher income levels and GDP per capita are strongly correlated with life expectancy (Gapminder, 2016) and consequently consumption of pharma products.

Growth in pharma spending of developed countries is expected to slow down. While developed countries will not exhibit any substantial growth, pharmerging markets are expect to show double digit growth in the future. Figure 13 shows that China, Saudi Arabia, Mexico, Algeria and Pakistan will show the highest compounded annual growth rate (CAGR).

Figure 13 Expected growth of Pharmerging markets



Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018
Notes: BRI – Brazil, Russia, India; Argentina is plotted in U.S. dollars
Report: The Global Use of Medicine in 2019 and Outlook to 2023. IQVIA Institute for Human Data Science, Jan 2019

Countries such as Turkey, Egypt, Bangladesh, Vietnam, Kazakhstan and Pakistan will show the highest acceleration in growth rate due to increase in ageing population and rising income

levels. Other countries in high growth quadrant include India, Brazil, Russia, Mexico, Algeria, Chile and Colombia. Countries such as Argentina, Saudi Arabia, Thailand, Poland, Nigeria and Philippines are expected to slow down in terms of growth.

On the basis of data analysis and meetings with members of Pharma Export Council and rising income levels and ageing population, the following potential markets have been identified to increase pharmaceutical exports of Pakistan.

6.1 Egypt

Table 10 Egypt imports, tariff and distance factor

Country	Total Import 2018 (USD Mn)	Growth in imports (%) – Base year 2017	Pakistan's exports 2018 (USD Mn)	Pakistan's share (%)	Tariff %	Distance Factor
Egypt	1,994	2%	3	0.15%	2.55	5,209 km
(International Trade Centre, 2019) (SeaRates Ltd, 2018)						

Table 11 Pakistan's competitors in Egypt

Pakistan's Competitors (Top Three)	Competitors Export Value 2018 (USD Mn)	Competitors Share (%)	Tariff %	Distance Factor
India	11.6	0.6%	2.55	8,119
Russia	0.3	0.01%	2.55	13,303
China	25.8	1.3%	2.55	11,676
(International Trade Centre, 2019) (SeaRates Ltd, 2018)				

The Egyptian market is expected to grow at a rate of 2% till 2023. Egypt has the potential to become a potential customer for Pakistani pharmaceuticals. However, Pakistan would need fulfill Egypt's NTB requirements to gain entry into the market. The prospects of growth in Egypt's pharma spending necessitate looking into this market to increase pharma exports. Egypt's increase in pharma spending will be fueled by increase per capita usage and uptake of newer medicines due to increased affordability.

6.2 Cambodia

Table 12 Cambodia imports, tariff and distance factor

Country	Total Import 2018 (USD Mn)	Growth in imports (%) – Base year 2017	Pakistan's exports 2018 (USD Mn)	Pakistan's share (%)	Tariff %	Distance Factor
Cambodia	194	12%	8	4.2%	0%	6,860 km
(International Trade Centre, 2019) (SeaRates Ltd, 2018)						

Table 13 Pakistan's competitors in Cambodia

Pakistan's Competitors (Top Three)	Competitors Export Value 2018 (USD Mn)	Competitors Share (%)	Tariff %	Distance Factor
India	39	20%	0%	6,020 km
Turkey	2	1%	0%	11,875 km
China	12.3	6.3%	0%	6,346 km
(International Trade Centre, 2019) (SeaRates Ltd, 2018)				

Cambodia's total import of pharmaceuticals amounted to USD 240mn in 2017. Cambodia, along with Vietnam, has a high potential for pharmaceutical imports due to its high dependency on medicinal imports. Medical facilities are not easily available in Cambodia. There

are 29 provincial hospitals, 157 district hospitals, and 1,725 town infirmaries. Majority of medicines are imported from ASEAN countries.

Cambodia's main attractiveness is its low NTB requirements which suits Pakistani pharma companies. Due to the lack of locally manufactured medicine, Cambodia's tariff for medicine are 0%. In-detail viewing of NTBs is available at https://trains.unctad.org.

Table 14 Cambodia NTBs for pharma

UNCTAD, TRAINS NTMs database through Integrated Trade Intelligence Portal (I-TIP)				
Your query covers 28 measures				
Measures:	Sanitary and Phytosanitary [SPS] [A], Technical Barriers to Trade [TBT] [B], Pre-shipment inspection [INSP] [C], Contingent trade protective measures [CTPM] [D], Quantity control measures [QC] [E], Price control measures [PC] [F], Other measures [OTH] [G,H,I,J,K,L,M,N,O], Export-related measures [EXP] [P]			
Country(ies) imposing:	Cambodia			
Partner(s) affected:	Pakistan [Include the category "All partners"]			
Product(s):	HS codes: 300490			
Country imposing	Partner affected	Requirements	Phase	Measures
Cambodia	All Members	Export-related measures	In force	9
Cambodia	All Members	Price control measures	In force	3
Cambodia	All Members	Quantity control measures	In force	1
Cambodia	All Members	Technical Barriers to Trade	In force	14
Cambodia	Bilateral	Technical Barriers to Trade	In force	1

6.3 Central Asian countries

Table 15 Kazakhstan imports, tariff and distance factor

Country	Total Import 2018 (USD Mn)	Growth in imports (%) – Base year 2017	Pakistan's exports 2018 (USD Mn)	Pakistan's share (%)	Tariff %	Distance Factor
Kazakhstan	876	10%	1.1	0.13%	2%	1,975 km
						(International Trade Centre, 2019) (SeaRates Ltd, 2018)

Table 16 Pakistan's competitors in Kazakhstan

Pakistan's Competitors (Top Three)	Competitors Export Value 2018 (USD Mn)	Competitors Share (%)	Tariff %	Distance Factor
India	67	7.6%	2.2%	4,460 km
China	4.5	0.5%	2.2%	4,281 km
Vietnam	1.3	0.2%	2.2%	5,268 km (air)
				(International Trade Centre, 2019) (SeaRates Ltd, 2018)

Countries in central Asia such as Afghanistan, Tajikistan and Kazakhstan are potential markets for Pakistani pharmaceuticals. These countries require quality pharmaceutical products and they have low NTBs which work in Pakistan's favor. IMS Health estimates that Kazakhstan's pharma spending will grow at 14% to 15% till 2023 (Aitken, Kleinrock, Simorellis, & Nass, 2019). Other regions such as Tajikistan and Uzbekistan are also important potential markets.

Table 17 Kazakhstan NTBs for pharma

UNCTAD, TRAINS NTMs database through Integrated Trade Intelligence Portal (I-TIP)				
Your query covers 27 measures				
Measures:	Sanitary and Phytosanitary [SPS] [A], Technical Barriers to Trade [TBT] [B], Pre-shipment inspection [INSP] [C], Contingent trade protective measures [CTPM] [D], Quantity control measures [QC] [E], Price control measures [PC] [F], Other measures [OTH] [G,H,I,J,K,L,M,N,O], Export-related measures [EXP] [P]			
Country(ies) imposing:	Kazakhstan			
Partner(s) affected:	Pakistan [Include the category "All partners"]			
Product(s):	HS codes: 300490			
Country imposing	Partner affected	Requirements	Phase	Measures
Kazakhstan	All Members	Export-related measures	In force	3
Kazakhstan	All Members	Price control measures	In force	2
Kazakhstan	All Members	Sanitary and Phytosanitary	In force	1
Kazakhstan	All Members	Technical Barriers to Trade	In force	20
Kazakhstan	Bilateral	Sanitary and Phytosanitary	In force	1

Table 18 Tajikistan's imports, tariffs and distance factor

Country	Total Import 2018 (USD Mn)	Growth in imports (%) – Base year 2017	Pakistan's exports 2018 (USD Mn)	Pakistan's share (%)	Tariff %	Distance Factor
Tajikistan	34.5	4%	0.4	1.2%	4.9%	961 km
(International Trade Centre, 2019) (SeaRates Ltd, 2018)						

Table 19 Pakistan's competitors in Tajikistan

Pakistan's Competitors (Top Three)	Competitors Export Value 2018 (USD Mn)	Competitors Share (%)	Tariff %	Distance Factor
India	8.8	25%	4.9%	2,100 km (air)
China	1.2	3.5%	4.9%	3,865 km
Turkey	0.6	1.8%	4.9%	4,275 km
(International Trade Centre, 2019) (SeaRates Ltd, 2018)				

Pharmaceuticals exports' growth is primarily dependent on population and these regions are attractive mostly due to geographical proximity to Pakistan and low requirements which can be met by Pakistani companies. Pakistan's main competitors in Central Asian region are primarily India, China and Vietnam due to similar factors such as distance.

Table 20 Tajikistan NTBs for pharma

UNCTAD, TRAINS NTMs database through Integrated Trade Intelligence Portal (I-TIP)				
Your query covers 12 measures				
Measures:	Sanitary and Phytosanitary [SPS] [A], Technical Barriers to Trade [TBT] [B], Pre-shipment inspection [INSP] [C], Contingent trade protective measures [CTPM] [D], Quantity control measures [QC] [E], Price control measures [PC] [F], Other measures [OTH] [G,H,I,J,K,L,M,N,O], Export-related measures [EXP] [P]			
Country(ies) imposing:	Tajikistan			
Partner(s) affected:	Pakistan [Include the category "All partners"]			
Product(s):	HS codes: 300490			
Country imposing	Partner affected	Requirements	Phase	Measures
Tajikistan	All Members	Export-related measures	In force	4
Tajikistan	All Members	Sanitary and Phytosanitary	In force	1
Tajikistan	All Members	Technical Barriers to Trade	In force	7

6.4 West Africa region

Morocco is a prime location for Pakistan to increase its exports of pharmaceutical products. Other countries in the West African region include Mali, Mauritania and Nigeria.

Table 21 West Africa imports, tariffs and distance factor

Country	Total Import 2018 (USD Mn)	Growth in imports (%) – Base year 2017	Pakistan's exports 2018 (USD Mn)	Pakistan's share (%)	Tariff %	Distance Factor
Morocco	423	9%	0.5	0.1%	4%	9,585 km
Mali	146	11%	0	0%	0%	12,570 km
Mauritania	42.3	64%	0	0%	0%	11,922 km
Nigeria	388	26%	4.3	1.1%	0%	13,927 km
(International Trade Centre, 2019) (SeaRates Ltd, 2018)						

Table 22 Pakistan's competitors in West Africa

Country	Pakistan's Competitors (Top Three)	Competitors Export Value 2018 (USD Mn)	Competitors Share (%)	Tariff %	Distance Factor
Morocco	India	25.8	6.1%	4.2%	12,483 km
	China	0.5	0.1%	4.2%	17,551 km
	Mexico	2.1	0.5%	4.2%	12,417 km
Mali	India	20.4	14%	0%	14,735 km
	China	23.7	16%	0%	22,942 km
	Mexico	0.5	0.3%	0%	12,856 km
Mauritania	India	1.8	4.3%	0%	14,087 km
	China	0.5	1.2%	0%	19,912 km
	Turkey	0.008	0.02%	0%	7,247 km
Nigeria	India	178	45.8%	0%	13,713 km
	China	53.5	13.7%	0%	19,254 km
	Indonesia	5.9	1.5%	0%	16,160 km
(International Trade Center, 2018) (SeaRates Ltd, 2018)					

Challenges in export to west African region include language barriers as these are Francophile regions due to colonial legacies of France and Spain, with the exception of Nigeria. However, if the language barrier is overcome, there exists significant potential for customers from these regions. Morocco is at a prime location at the nexus of Europe and Africa. Trade is flourishing in the region due to its strategic location and FTAs with Europe and Arab nations and income levels are increasing. The country is popular in tourism and its GDP per capita is USD 3,000, double that of Pakistan. Morocco is expanding its trade as indicated by the Halieutis Plan, Rawaj Plan and the Industrial Acceleration Plan.

Table 23 Morocco NTBs for pharma

UNCTAD, TRAINS NTMs database through Integrated Trade Intelligence Portal (I-TIP)				
Your query covers 13 measures				
Measures:	Sanitary and Phytosanitary [SPS] [A], Technical Barriers to Trade [TBT] [B], Pre-shipment inspection [INSP] [C], Contingent trade protective measures [CTPM] [D], Quantity control measures [QC] [E], Price control measures [PC] [F], Other measures [OTH] [G,H,I,J,K,L,M,N,O], Export-related measures [EXP] [P]			
Country(ies) imposing:	Morocco			
Product(s):	HS codes: 300490			
Country imposing	Partner affected	Requirements	Phase	Measures
Morocco	All Members	Export-related measures	In force	3
Morocco	All Members	Pre-shipment inspection	In force	1
Morocco	All Members	Price control measures	In force	1

Morocco	All Members	Technical Barriers to Trade	In force	8

Table 24 Mali NTBs for pharma

UNCTAD, TRAINS NTMs database through Integrated Trade Intelligence Portal (I-TIP)				
Your query covers 19 measures				
Measures:	Sanitary and Phytosanitary [SPS] [A], Technical Barriers to Trade [TBT] [B], Pre-shipment inspection [INSP] [C], Contingent trade protective measures [CTPM] [D], Quantity control measures [QC] [E], Price control measures [PC] [F], Other measures [OTH] [G,H,I,J,K,L,M,N,O], Export-related measures [EXP] [P]			
Country(ies) imposing:	Mali			
Partner(s) affected:	Pakistan [Include the category "All partners"]			
Product(s):	HS codes: 300490			
Country imposing	Partner affected	Requirements	Phase	Measures
Mali	All Members	Export-related measures	In force	6
Mali	All Members	Other measures	In force	2
Mali	All Members	Pre-shipment inspection	In force	2
Mali	All Members	Price control measures	In force	4
Mali	All Members	Sanitary and Phytosanitary	In force	1
Mali	All Members	Technical Barriers to Trade	In force	4

Table 25 Mauritania NTBs for pharma

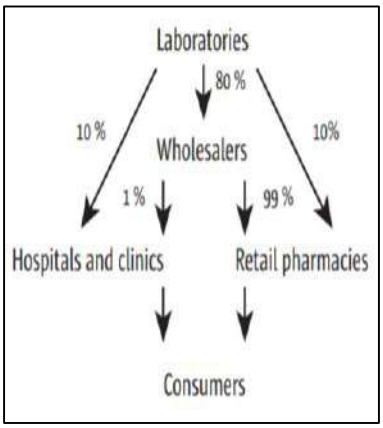
UNCTAD, TRAINS NTMs database through Integrated Trade Intelligence Portal (I-TIP)				
Your query covers 3 measures				
Measures:	Sanitary and Phytosanitary [SPS] [A], Technical Barriers to Trade [TBT] [B], Pre-shipment inspection [INSP] [C], Contingent trade protective measures [CTPM] [D], Quantity control measures [QC] [E], Price control measures [PC] [F], Other measures [OTH] [G,H,I,J,K,L,M,N,O], Export-related measures [EXP] [P]			
Country(ies) imposing:	Mauritania			
Partner(s) affected:	Pakistan [Include the category "All partners"]			
Product(s):	HS codes: 300490			
Country imposing	Partner affected	Requirements	Phase	Measures
Mauritania	All Members	Export-related measures	In force	1
Mauritania	All Members	Other measures	In force	1
Mauritania	All Members	Quantity control measures	In force	1

Table 26 Nigeria NTBs for pharma

UNCTAD, TRAINS NTMs database through Integrated Trade Intelligence Portal (I-TIP)				
Your query covers 6 measures				
Measures:	Sanitary and Phytosanitary [SPS] [A], Technical Barriers to Trade [TBT] [B], Pre-shipment inspection [INSP] [C], Contingent trade protective measures [CTPM] [D], Quantity control measures [QC] [E], Price control measures [PC] [F], Other measures [OTH] [G,H,I,J,K,L,M,N,O], Export-related measures [EXP] [P]			
Country(ies) imposing:	Nigeria			
Partner(s) affected:	Pakistan [Include the category "All partners"]			
Product(s):	HS codes: 300490			
Country imposing	Partner affected	Requirements	Phase	Measures
Nigeria	All Members	Export-related measures	In force	1
Nigeria	All Members	Pre-shipment inspection	In force	1
Nigeria	All Members	Quantity control measures	In force	1
Nigeria	All Members	Technical Barriers to Trade	In force	3

The Moroccan pharmaceutical sector is entirely controlled by the private sector from imports to retail distribution, production and wholesale distribution. The industry is highly dependent on foreign suppliers who control the allocation of the active substances in capsules, pills, syrups, ointments etc. the Moroccan pharmaceutical industry depends on raw materials price fluctuations according to their origin and quality. Even in the case of local manufacturing, since Moroccan companies manufacture under license, usually the company that grants the license requires the Moroccan license holder to get his raw materials from the licensing party.

Figure 14 Pharma supply chain in Morocco



Wholesalers-distributors buy and sell medicines, supplying 80% of the demand. The rest is supplied by pharmaceutical companies themselves. Government institutions purchase from these channels and stock medicine in the warehouse of the Supply Chain division. The division supplies health provincial delegations, which in turn supply health centres, and semi-autonomous hospitals known as SEGMA. The supply chain distribution is given in Figure 14. Control of importations falls in the jurisdiction of Direction of Medicine and Pharmacy. Morocco is the only Arab country to impose VAT payment on medicines. Custom duties and taxes are imposed on the import of several pharmaceutical products.

Mali poses an additional challenge being a landlocked country. However, it posed a 57% growth in pharma imports from 2016 to 2017. The phenomenal rise of pharma demand in Mali makes it an important market for Pakistan to explore.

While growth in Nigeria has slowed down due to increase in local manufacturing, the Nigerian market remains an important option due to its economic challenges. Nigeria's economy is shrinking due to decline in the oil industry and slowing agricultural expansion (Bloomberg, 2017). Therefore, Nigeria is on the lookout for cheaper imports, i.e. imports with low AUPs and Pakistan can capitalize on the opportunity by offering lower prices.

7 PIC/S REGISTRATION

Pharmaceutical Inspection Cooperating Scheme (PIC/S) is a non-binding cooperative agreement between Regulatory Authorities to enforce Good Manufacturing Practices (GMP) of medical products for human and veterinary use.

PIC/S mission statement reads as follows: "To lead the international development, implementation and maintenance of harmonized GMP standards and quality systems of inspectorates in the field of medicinal products" (PIC/S, 2018).

The purpose of PIC/S is to pursue and strengthen the co-operation established between the Participating Authorities in the field of inspection related to the manufacture (or distribution) of medicinal products and improve technical standards and procedures regarding the inspection of medicinal products.

PIC/S also ensures that the quality of medicinal products is strictly in compliance with the marketing authorization and GMP standards via regular inspections.

7.1 PIC/S Members

Countries which have PIC/S membership include:

- Argentina
- Australia
- Austria
- Belgium
- Canada
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hong Kong
- Taiwan
- Hungary
- Iceland
- Indonesia
- Iran
- Ireland
- Italy
- Japan
- Rep. of Korea
- Latvia
- Lichtenstein
- Lithuania
- Malaysia
- Malta
- Mexico
- Netherlands
- New Zealand
- Norway
- Poland
- Portugal
- Romania
- Singapore
- Slovak Republic
- Slovenia
- South Africa
- Spain
- Sweden
- Switzerland
- Thailand
- Turkey
- Ukraine
- UK
- USA

A committee of participating Regulatory Authorities' representative (PIC/S Committee) supervises the operation of the Scheme. The committee is assisted by 7 sub-committees on tasks such as the training of inspectors, GMP harmonization, etc.

7.2 What is GMP?

GMP as defined in PIC/S GMP guide is "Good Manufacturing Practices … part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization or product specification" (PIC/S, 2018). In other words, GMP ensures that the production of medicines meets the required quality standards.

7.3 Main Activities

7.3.1 Training

PIC/S committee arranges for the training of GMP inspectors at the PIC/S Inspection Academy.

7.3.2 Seminars

PIC/S arranges an annual training seminar for inspectors, each one dealing with a separate topic. The seminars are hosted by different participating Authorities. The result of the Seminar is usually the setting up of a Drafting Group which develops new or amends the existing GMP guidance documents. For example, the 2004 PIC/S seminar on the Inspection of Active Pharmaceutical Ingredients resulted in a PIC/S guideline document for inspectors (Aide-Memoir on the Inspection of API).

7.3.3 Joint Visits and Coached Inspections

Another avenue for the training of inspectors is the PIC/S Joint Visits Program. Under this program, 3 inspectors from 3 different countries are teamed up to observe GMP inspections in each country with a view to compare inspection procedures and techniques and to harmonize GMP interpretation.

7.4 How to Join PIC/S?

Before an Authority is accepted by PIC/S, a detailed assessment is undertaken to determine whether the Authority is able to apply an inspection system comparable to that of current PIC/S authorities. This assessment involves an examination of the Authority's GMP inspection and licensing system, quality system, legislative requirements, inspector training etc. It is followed by a visit by a PIC/S delegation to observe the Authority's procedures.

PIC/S membership is open to GMP inspectorates having an inspection system comparable to that of other PIC/S Members. The main conditions are to have a law on medicinal products, a GMP Guide equivalent to that of PIC/S (or the EU GMP Guide), a GMP inspectorate, which fulfils PIC/S quality system requirements, and experienced GMP inspectors.

7.4.1 Requirements for Membership

To gain membership into PIC/S, there exist two phases (1) the pre-accession phase and (2) the accession phase.

7.4.1.1 Pre-Accession Phase

The pre-accession procedure is recommended if the Regulatory Authority does not apply the PIC/S GMP guideline and has not regularly participated in PIC/S training sessions. The interested Authority needs to apply for Pre-Accession including a Questionnaire (PS/W1/2011) and Audit checklist (PS/W1/2005). The Pre-Accession applicant is then visited and reviewed to identify any gaps from the PIC/S GMP guide and basic requirements. The inspectors try to bring the Authority

to similar standards as those set in the member's countries. If the Pre-Accession applicant complies with the PIC/S requirements, they are invited for full membership. The timeframe for Pre-Accession is 2 years from the date of application.

7.4.1.2 Accession Phase

If any Regulatory Authority goes for Accession instead of Pre-Accession, they need to fill the appropriate Questionnaire and Audit checklist and supply the necessary documents. PIC/S will then visit the interested Authority and see if they qualify for membership based on compliance with PIC/S requirements. The total timeframe for the application process is limited to 6 years. Existing PIC/S participating Authorities are reassessed on a regular basis.

PIC/S requirements include a checklist to see the Regulatory Authority's quality management system, manufacturer license system, their communication with pharmaceutical assessors, official medicines control laboratories, enforcement agencies and other bodies of the Authority, their suspected quality defect handling system and Rapid Alert system, training of inspectors, and inspection strategy based on quality risk management.

The full list of procedures, documents required and checklist to fulfill for membership to PIC/S is given at the following URL: https://www.picscheme.org/en/accessions-accession

7.5 Suspension

A participating Authority can be suspended from membership if it does not fulfill any of the requirements of the Scheme or does not participate in the meetings. The suspension remains until the appropriate action is taken to remedy the situation. If that does not happen, the Authority is excluded from the Scheme.

7.6 Financial Costs

For members: The annual ordinary membership fee is currently 8,500 CHF (Swiss Francs). It is paid by full Members.

For Applicants: a registration fee, equivalent to the annual ordinary membership fee (i.e. CHF 8,500), which will be charged once all the complete application has been submitted to the PIC/S Secretariat. In addition, during the whole assessment process, applicants will have to pay an annual fee corresponding to 80% of the annual membership fee paid by members (i.e. CHF 6,800).

For Pre-Applicants: Pre-Applicants do not have to pay a registration fee but during the whole pre-assessment process, Pre-Applicants will have to pay – similarly to applicants - an annual fee corresponding to 80% of the annual membership fee paid by members (i.e. CHF 6,800).

8 COMPETITOR STRATEGIES

8.1 India

The Indian pharmaceutical industry has more than 23,000 companies comprising of large conglomerates and SME firms. R&D spending by the Indian pharma companies is 2-4% of sales. There are 250 large units and 8000 small scale units which form the core of the pharmaceutical industry in India (including 5 Central Public Sector Units).

These units produce the complete range of formulations i.e. medicines ready for consumption by patients and 350 bulk drugs i.e. chemicals having therapeutic value and used for production of pharmaceutical formulations.

After the de-licensing of the pharmaceutical industry, industrial licensing for most of the drugs and pharma products has been done away with. Manufacturers are free to produce any drug duly approved by the Drug Control Authority.

India's growth in this sector began with the signing of the General Agreement on Tariffs and Trade (GATT) in January 2005. India began to recognize global patents and gained recognition in terms of contract research and clinical trials.

The patent period for patented generic products was extended to 20 years, and the Indian companies selling copycat generics of foreign drugs were obligated to pay the foreign firms a considerable royalty. This was an incentive to foreign pharma firms to either invest in India or to state joint ventures with the domestic firms.

India's policy towards generic medication has allowed them to manufacture medicaments at a much lower cost and therefore have an appeal to foreign buyers in its low AUP. India's low cost, generic medicines have made their way into the generics market which are high in demand by the lower SEC segment of the population.

In 2005, the result of recognizing global patents was evident as foreign drug producers filed a record 8,296 patents (Greene, 2007). Many of the MNCs that had earlier left India returned and today, the Indian pharmaceutical industry is considered a leader in low cost innovation and production of Active Pharmaceutical Ingredients (APIs), Contract Research and Manufacturing Services (CRAMS), Formulations and Biosimilars (Singh, 2016).

By 2014-15, India's exports of generic drugs were in excess of USD 12bn (with USD 6bn or more sales in domestic market) (Eck, 2016). It is worthwhile to note that by 2020, the patents of drugs worth USD 150bn in sales are set to expire (PRNewswire, 2016). India is set to capture a large part of this USD 150bn market.

The Indian pharmaceutical industry is getting increasingly US FDA compliant to harness the growth opportunities in areas of contract manufacturing and research. Indian companies such as Ranbaxy, Sun Pharma, Dr Reddy's are increasingly focusing on tapping the US generic market. Ranbaxy Laboratories Ltd received approval from US Food and Drug Administration (FDA) to

manufacture and market Lamivudine tables (150mg) used in treating HIV infections. Over 60% of India's bulk drug production is exported.

With the Industrial Licensing Policy Statement of 1991, India abolished the industrial licensing requirement for most drugs, freed up the import restriction for drugs and adopted a product patent system under the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the WTO (Bose, 2017). After 2000, the Indian pharmaceutical exports witnessed phenomenal growth in part due to its import liberalization and development of the generic drug industry. At present, there are 27,000 units operating in India.

The Indian government's MSME department also created a Cluster Development program for its Pharma sector. A one-time aid was given to small and medium enterprises belonging to the pharma sector for a maximum of INR 200mn (USD 2.8mn) or 70% of the project cost whichever was less (Ministry of Mico, Small & Medium Enterprises, 2015). Details of how to apply for the grant were also given at MSME website and circulated to SME companies by MSME India. Indian companies also sent personnel to obtain training in USA and then brought them back to India to obtain the knowledge transfer.

A Pharmaceutical Research and Development Promotion Fund amounting to INR 150 crore (USD 21mn) was established in India to promote R&D in the pharma sector. Pharma units that get their Research and Development units recognized by CSIR are eligible for Income Tax Exemption (Joseph, 2010).

Contract manufacturing is another area upon which the Indian pharmaceutical industry improvised extensively to expand their business and prospects. Large manufacturers of drugs around the globe have been finding it difficult to stay profitable in a world of cut-throat competition. Their preferable strategy in response to the competitive market developments has been to turn to contract manufacturing, something similar to outsourcing. This outsourcing includes research, conducting clinical trials, joint marketing, cost sharing and other such arrangements that come under the ambit of Contract Manufacturing and Risk Services (CRAMS). For large pharmaceutical firms, this meant a reduction in costs and ease of access to a large consumer market; for Indian firms, it meant access to advanced technology and research base, knowledge spillovers and expanding their presence into the western pharmaceutical market.

In the era of strict regulations, the Indian drug manufacturers concentrated their R&D efforts on reverse engineering patented drugs and making their domestic, generic copies. In the aftermath of the 2005 act, their focus shifted to research into new molecule discovery and addition of more value to their products. Part of this reversal in R&D priorities came from the recognition by Indian firms that opening up the market to competition meant that they would not be able to continue for long with their old ways. So, they needed to improve their capabilities and increased R&D towards value addition and new molecules seemed like a wise strategy.

Although no concise or agreed upon figure is available, top Indian firms were reported to be spending at least 9 percent of their total sales on R&D activities in 2016 (Manufacturingchemist.com, 2016). Another source reported that the R&D expenditures of the

top 25 pharma companies went up to USD 1.7bn in 2015-16 from USD 1.3bn in the previous year (Pingle, 2016). When it came to research in generics only, Indian companies were spending an estimated USD 833mn (Nasdaq, 2016).

In June 2016, the Indian government significantly relaxed regulatory requirements related to various industries and services. Pharmaceuticals were one of them, whereby any foreign firm could buy 74% stake in Brownfield pharmaceutical projects without requiring any approval from the government (SBP, 2016).

The Pharma Export Promotion Council (Pharmexcil) was made with the objective of facilitation of exports of drugs, biotech products and herbal medicines. They also conduct workshops, conferences, seminars and delegate visits for the Indian pharmaceutical companies.

FDI up to 74% in the case of bulk drugs, their intermediate pharmaceuticals and formulations (except those manufactured by the use of recombinant DNA technology) are allowed in India. FDI above 74% for manufacture of bulk drugs is reviewed by the government on case to case basis for manufacture of bulk drugs from basic stages and their intermediates and bulk drugs produced by the use of recombinant DNA technology including the specific cell/tissue targeted formulations provided it involves manufacturing from the basic stage (Joseph, 2010).

Foreign Technology Agreements were granted automatic approval for all bulk drugs cleared by Drug Controller General (India). For imports, a centralized system of registration was introduced under the Drugs and Cosmetics Act and Rules.

Approval was granted for establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the administrative control of the Department of Science and Technology.

India's export promotion schemes are available, such the Merchandise Exports from India Scheme (MEIS). Under this scheme, manufacturers are eligible for Duty Credit Scrips. These scrips can be used for payment of Basic Customs Duty (Mahtani & Joshi, 2017). The Duty Credit Scrips promote exports by giving tax incentives to exporters. It allows the holder to import commodities by not paying a specified amount in import duties. The amount varies from 3% to 5% of FOB value (Jose, 2015).

India has also formed a Committee on Quality Complaints and Trade Disputes to resolve any trade disputes between exporters and buyers. This enables the international buyers to purchase with confidence and assurance that any discrepancy in volume shipped, or quality compromised will be easily resolved.

As a measure of ease of doing business, landing documents of export consignments can be digitally uploaded. Any exporter can upload a scanned copy of Bill of Entry under his digital signature. Exporters have been allowed facility to set up warehouses to help reduce lead time. Exporters with a turnover of INR 100mn and above have been allowed the facility of fast track clearances of import and domestic clearance.

8.2 Malaysia

Since 2000, the growth of the Malaysian pharmaceutical sector has outperformed the growth in Malaysian GDP (Pharmaceutical Executive Editors, 2015). Malaysian pharmaceutical sales have been expanding steadily at a 10 year CAGR of 8% to 10%, reaching as much as USD 2.2bn in 2017. Business Monitor International reports the local medical device segment to be growing at a CAGR of 9.7% up to 2021 (Pharmaceutical Executive, 2018). The main drivers behind this growth are medical tourism, a lack of strict price regulation, rising disease burden and a lack of dependence on imported branded products (GlobalData, 2016).

In the late 1990s, Frost and Sullivan (an international consultancy) conducted an analysis of the Malaysian pharmaceutical market to identify its strengths and weaknesses. The Malaysian government wanted to be less dependent on foreign drugs and to boost the local production, it was pinpointed that in order to do so, the country would need to improve its human resource base and enhance the R&D capabilities of domestic firms. Increasing R&D costs of large pharmaceutical companies created opportunity for Malaysian firms to fulfill that role (Malaysian Pharmaceutical Society, 2001). Malaysian regulatory authorities began to incentivize R&D for manufacture of generic drugs.

Another idea was to boost medical tourism that could give enhance pharma sales. For this purpose, tax breaks were provided to medical tourists. In 2015, 850,000 medical tourists visited Malaysia after these tax exemptions.

8.3 United Kingdom

In UK, the firms working in the pharmaceutical industry are free to price their drugs. The government prefers to let the market forces decide. However, in order to shield the consumer from predatory pricing, the government has set up restrictions on the rates of return (profits), based on historical capital set out in the Pharmaceutical Price Regulation Scheme (PPRS), enacted in 1957.

In 2013, the government backed off from its proposed policy of limiting returns of the pharmaceutical companies and agreed to relax the criterion for profits till 2018.

In 2014, another incentive was provided to the industry by the government when it approved drugs that were under the development and clinical trials phase by establishing a faster clearance process for them. This was primarily done to cater to critically ill patients who are sometimes in need of drugs that have to go through prolonged clearance process. This made it faster to obtain critical drugs while requiring only the relevant data be submitted for quality and safety verification (Pakistan Pharmaceutical Manufacturer's Association, 2017).

Since the early 2000s, many British pharmaceutical companies have outsourced an increasing number of their functions (like R&D) to countries like China and India.

The British government has over time adopted a policy of subsidies and quality controls that assist the consumer. One such initiative is the National Institute for Health and Care Excellence (NICE), established in 1999. Its main function is to meticulously test drugs and detect

their clinical effectiveness. This protects consumers by guaranteeing quality and augments cost effective research through targeted subsidies (Maynard & Bloor, 2015).

9 SWOT

9.1 Strengths

Pharmaceutical industry is the biggest employer in urban areas of Pakistan. The labor is cheap compared to the labor costs of pharmaceuticals in USA or Europe.

Pakistan holds a relative cost advantage in terms of drug production, maintenance of high standards in terms of purity and international safety, health and environment protection.

Pakistan's universities and medical colleges produce strong technical manpower and the scientific know how required in the pharmaceutical industry. Professional services are easily available.

JCR-VIS expects the pharmaceutical industry to have one of the best long term sales prospects compared to other sectors due to ageing population, rise in income levels and anticipated emergence of new diseases.

The increase in revenues in the future will lead to better margins and lower financing cost for the industry.

The pharmaceutical industry is non-cyclical with relatively stable demand. Therefore, impact of broad economic conditions on companies' revenues and profits is likely to be low.

9.2 Weaknesses

Overall balance of trade is negative in Pharma sector.

Chances for contract manufacturing are low as DRAP only gives license for contract manufacturing for 3 months' duration. Industry wants blanket license for 2 years. India is availing this chance for contract manufacturing and many Japanese pharmaceutical companies have set up plants in India.

Pakistan does not have the ability to comply with FDA regulations and other NTBs of various countries

Lack of intellectual property rights enforcement has led to exodus of MNCs from the Pakistani pharmaceutical market.

In case companies cannot pass on costs to consumers due to MRP, they have to apply for "hardship" cases and approval of the same depends on DRAP.

Delays in approvals of new products can impact projected sales growth. Furthermore, non-acceptance and delays in hardship cases can also impact profitability and cash flows.

R&D is limited in Pakistan as it is a very expensive cost component for companies.

9.3 Opportunities

Pakistan is an efficient and cost effective source for manufacturing generic drugs. There exists scope for generic drug production market and contract research opportunities. Pakistan is in a favorable

position to manufacture drugs at a fraction of the international costs due to low labor costs, infrastructure, and quality scientists.

Pakistan has the opportunity to a regional center for clinical trials. Due to increased pressure on profits of major pharmaceuticals firms established in regulated markets, increasing R&D costs and overhead costs, clinical research processes are often outsourced to third parties in developing countries. Pakistan can become a regional hub for contracting such work as this would save 40% to 60% in new drug development.

Pakistan should also seek to acquire PIC/S registration as this will help uplift both the pharma industry and DRAP in terms of technological competence and GMP compliance.

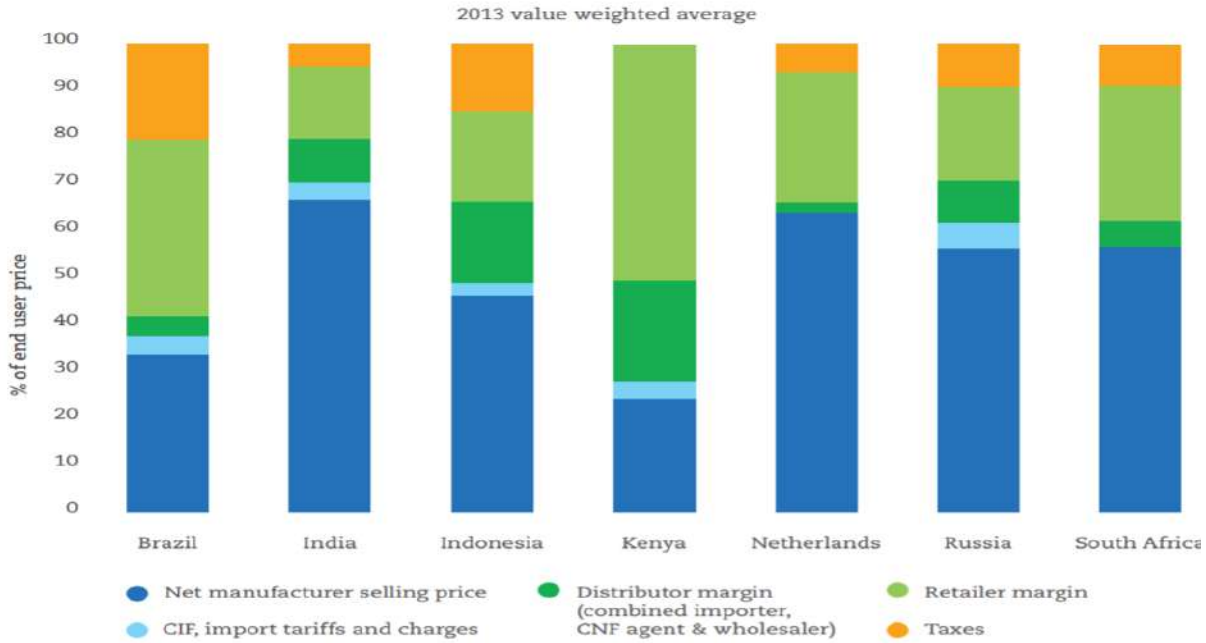
There is opportunity for Pakistan to penetrate the vaccines market. The global vaccine industry is forecasted to grow to USD 57.5bn by 2025 (PRNewswire, 2018). High Income Countries form 82% of global vaccine sales in terms of value and 20% in terms of volume. High Income countries pay more for vaccines and are more likely to implement newer vaccines. Middle and lower income countries account for 18% of global vaccine sales in terms of value and 80% in terms of volume. The majority of this procurement is done by UNICEF and PAHO on behalf of developing nations (World Health Organization, 2018).

9.4 Threats

Barriers to access to medicines and healthcare arise mostly from poverty. Poor health infrastructure in developing countries is often accompanies by shortage of doctors and nurses as well as pharmacies. Healthcare facilities are distant from patients and the transport network is often hazardous. Lack of education and literacy further hinders the access to medicines.

Developing countries, especially least developed countries (LDC), often have high markup costs that result in unnecessary inflation of the prices of essential medicines. These include distribution costs, import tariffs, port charges, importers' margins, VAT on medicines and high margins in wholesale and retail components of the supply chain. An example of various hidden costs of pharmaceutical procurement for different countries is given in Figure 15.

Figure 15 Hidden costs in pharma



(Source: (International Federation of Pharmaceutical Manufacturers and Associations, 2017)

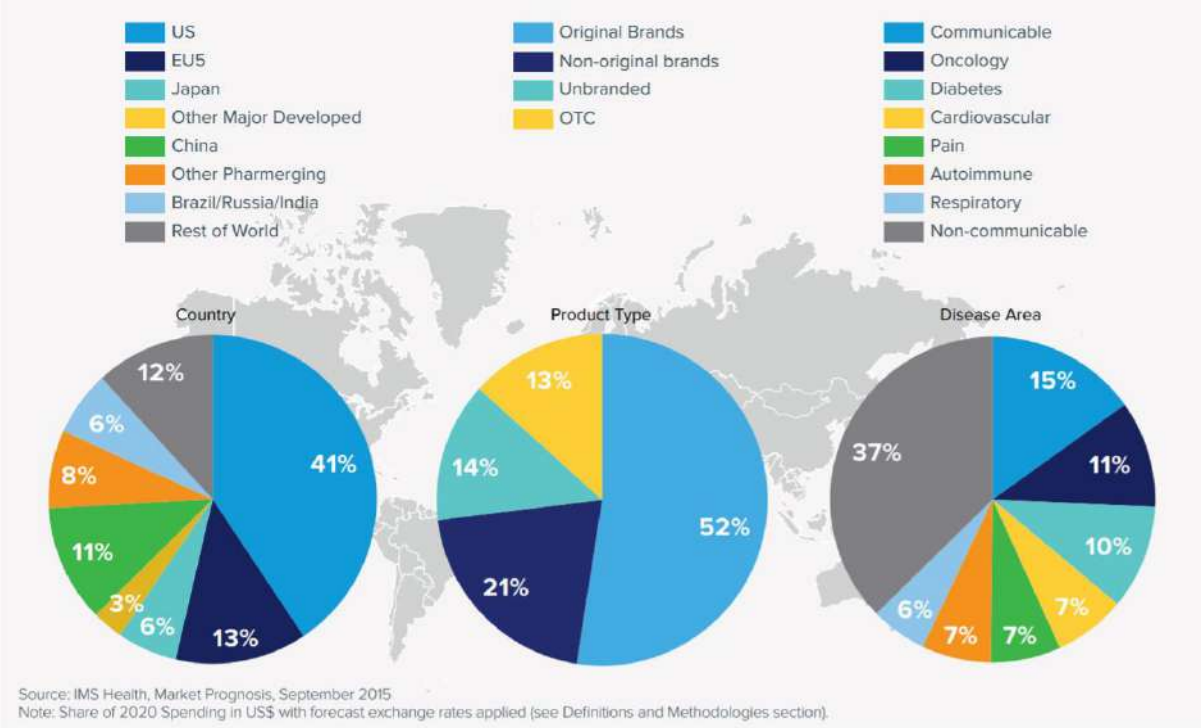
Mergers and acquisitions are expected due to smaller players unable to pass on rising production costs and this will result in a less competitive market overall.

Since API are imported, companies are exposed to risk of currency fluctuation. Depreciation of the Pak Rupee tends to create difficulty for companies to procure APIs cheaply. Since the cost of raw materials increases and the companies' ability to pass on costs to consumers is limited, this cuts into the profitability and growth of the industry.

10 DEMAND SIDE ISSUES

41% of the global medicine spending will be done by the US followed by EU. Original brands will constitute 52% of global spending out of all product types due to their high AUPs. 37% of spending will be done on non-communicable diseases followed by communicable diseases and oncological medicines.

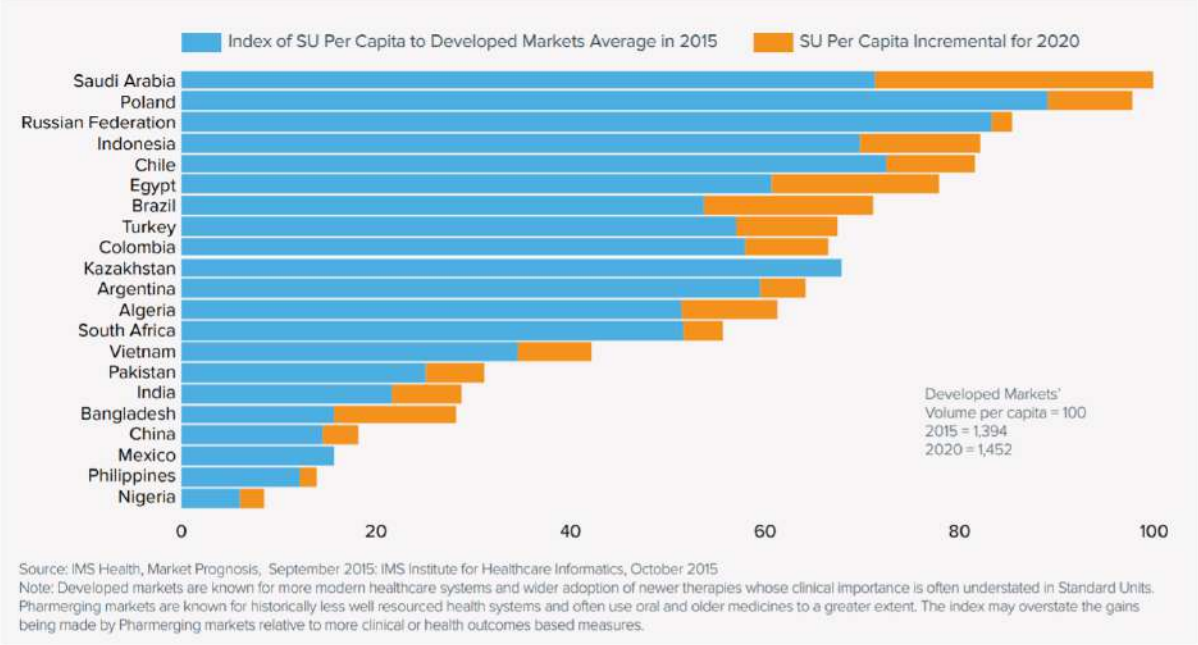
Figure 16 Medicine Spending in 2020 US$ by Geography, Product Type and Disease Area



The majority of the global medicine consumption is expected to be driven by India, China, Brazil and Indonesia. Original brands will comprise 52% of products while unbranded will be 14%.

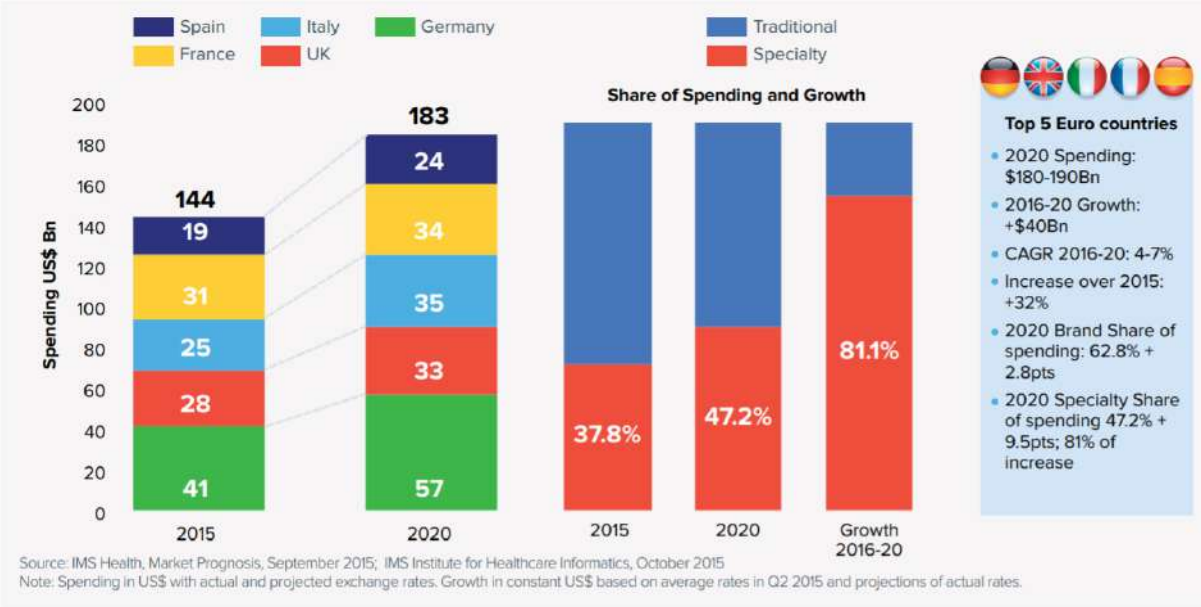
Developed markets will continue to use more original branded and specialty medicines per capita while pharmerging markets will use more non-original brands, generics and Over The Counter (OTC) medicines.

Figure 17 Pharmerging Market Standard Units per Capita 2015 and 2020



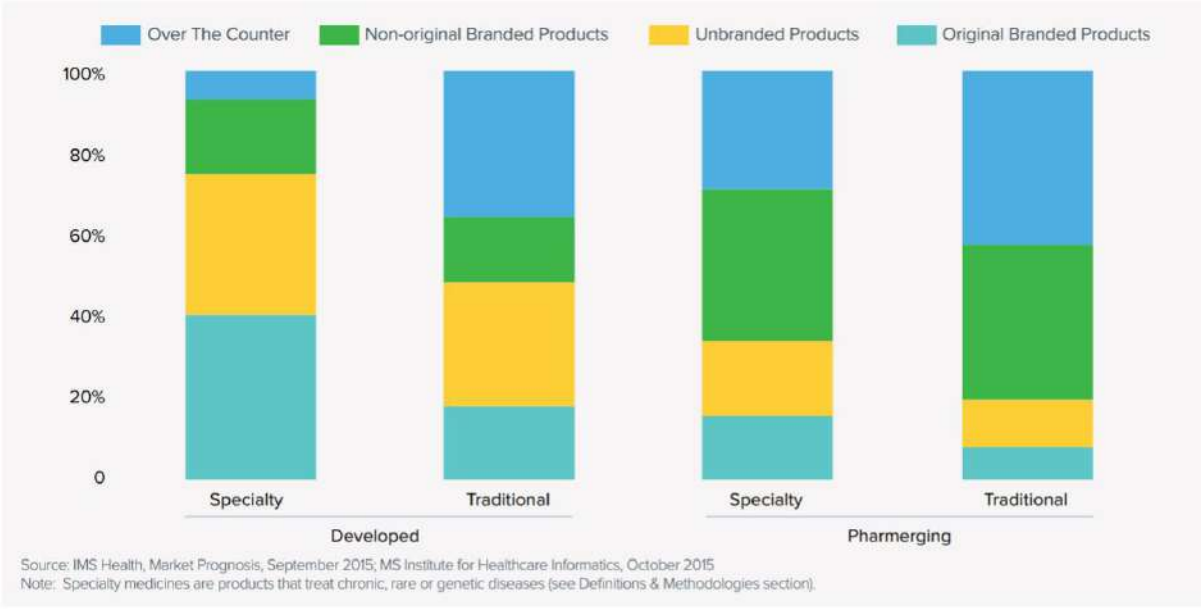
Spending growth will be driven by brands in developed markets and increased usage in pharmerging markets whilst being offset by patent expiries. China, the leading pharmerging market, will reach USD 160-190 bn in spending (Aitken, Kleinrock, Simorellis, & Nass, 2019).

Figure 18 Top 5 European Countries Spending US$Bn, 2015 and 2020



Specialty and biologics medicines is expected to increase in 2020 patients will have greater access to medicines treating hepatitis C, cancers, autoimmune diseases & heart disease. Payment mechanisms are also expected to change due to the ubiquity of smartphones, apps and wearable smart watches.

Figure 19 Standard Units in 2020 by Product Type in Major Developed and Pharmerging Countries



The greatest increase in specialty areas will be in oncology medicines and autoimmune diseases as show in Figure 20. Specialty medicine will comprise 28% of pharma spending in 2020, most of which will be in the developed markets. Specialty medicines will play a smaller percentage in pharmerging markets according to IMS Health.

Figure 20 Specialty Medicines and Leading Therapy Areas in 2020

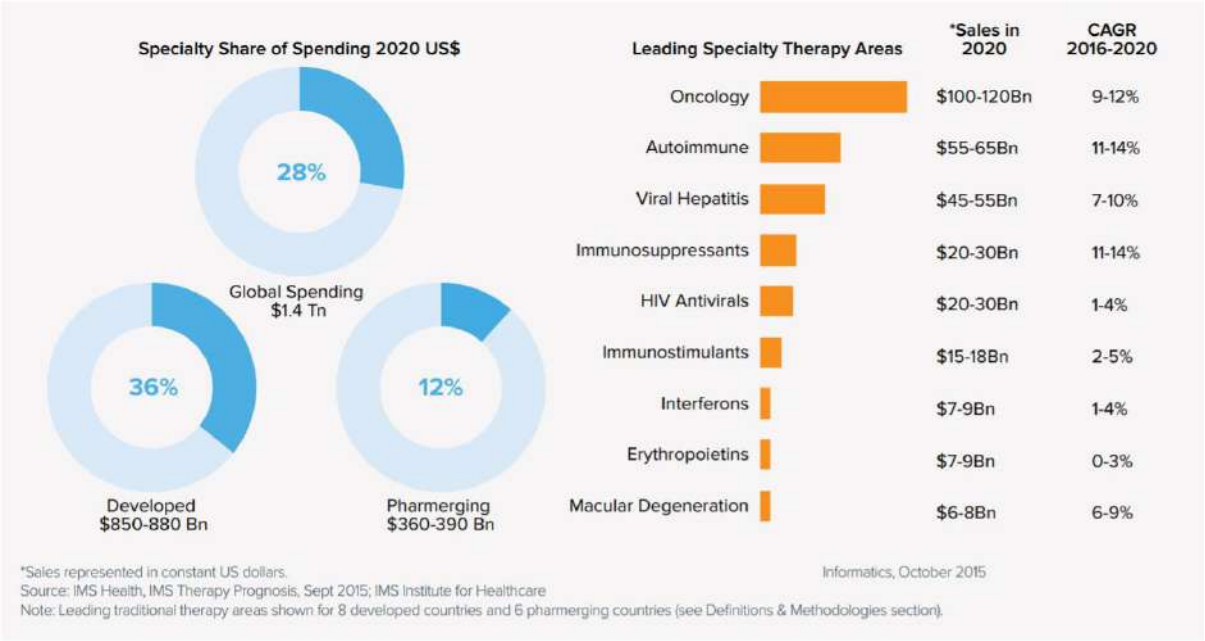
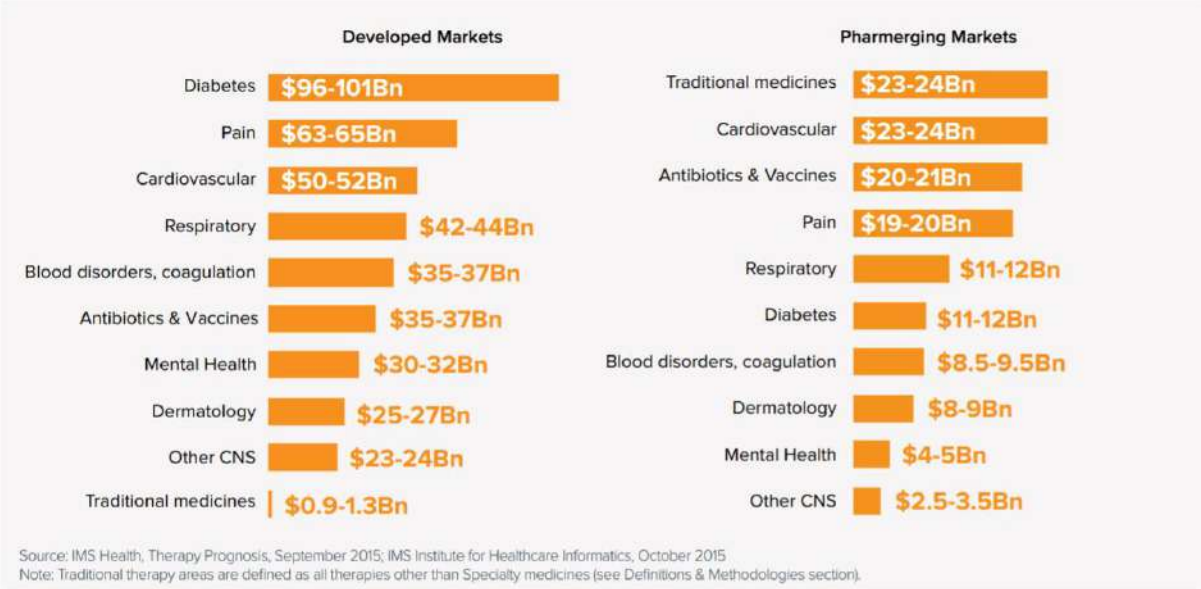


Figure 21 Traditional Medicines Spending in 2020, Constant US$BN



Source: IMS Health, Therapy Prognosis, September 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Traditional therapy areas are defined as all therapies other than Specialty medicines (see Definitions & Methodologies section).

Regulated markets such as USA, Europe, Japan and Australia have high non-tariff barriers (NTBs) which need to be complied with. Penetrating regulated markets, therefore requires investment by Pakistani pharmaceutical firms. Due to lack of compliance, opportunities in these markets is lost by Pakistan. Currently only 2 Pakistani pharmaceutical firms comply with US FDA regulations. Inspectors from regulated markets often visit pharmaceutical firms to see if these firms are in compliance with their checklist. Any firm failing to meet the checklist standards is barred from exporting to the country.

Lesser regulated markets such as those in Africa and Asia are more attractive destinations for Pakistani exporters. Asian importers such as Philippines prefer if their suppliers have PIC/S registration. Buyers are also more prone to buying from companies that have obtained Good Manufacturing Practices (GMP) certification. Given the long lags in innovation of new products, increasing inflexibility in setting higher prices and intense competition from countries like India, large pharmaceutical firms are progressively turning towards research collaboration and portfolio acquisitions. Mergers and acquisitions have seen a pickup in pace as large firms buy off smaller firms. In 1989, there were 30 large pharmaceutical manufacturing firms in the USA. Now, there are only 9 (Taylor, 2015).

Activities such as research collaboration are picking up pace. They are primarily aimed at reducing the overall costs through synergy between research efforts and human capital as productivity of research efforts has declined over time. Companies are now increasingly focusing on rare diseases, biotech, cancer drugs and personalized drugs since profit margins in these categories is substantial (Shukla, 2016).

R&D is a big part of the pharmaceutical industry. Pharmaceutical firms all over the world spend a hefty USD 141bn annually on R&D related activities (Schumacher, Gassmann, & Hinder, 2016). Research into New Chemical Entities is challenging. Generally, the time between the first synthesis of a new product and of the product making it to the market is 12-13 years.

Aside from the time period, the cost is substantial. An estimate by DiMasi et al. stated that it takes USD 2.5bn just to develop a new chemical or biological entity (DiMasi, Grabowski, & Hansen, 2016). Despite this staggering cost and lengthy time, only two out of 10,000 substances pass all the phases of trial and development before it finally becomes a marketable product. This is a confounding number since it shows the difficulty of introducing a new drug in the market. But pharmaceutical firms are willing to take the risk in order to reap rewards later. Moreover, if it were not for R&D in the pharmaceutical sector, there would not have been advances in medicines that have ended up saving millions of lives around the world. In fact, the World Health Organization (WHO) termed innovation in medicines as major contributor to social and economic welfare. This can be judged by looking at the numbers. New and effective medicines reduced global mortality rates by 50 percent or more between 1960's and 1990's. In the least developed countries, the Infant Mortality Rate (IMR) has dropped by more than 60 percent.

11 VIEWS FROM THE INDUSTRY

The following is an excerpt taken from an interview given to Dawn newspaper by Mr. Khalid Mehmood, CEO Getz Pharma. It underlines the concern of the industry about lack of price adjustments in response to rising costs of electricity and raw materials:

"We have had no price increase in the last 11 years. As a result, there hasn't been a lot of investment to grow pharma exports.

The global pharma market is worth $1.4 trillion. Even small countries like Jordan export about $800 billion worth of pharma products. Pakistan's total pharma exports are less than $200 million. There are 700 pharma companies in Pakistan.

We've had 25pc devaluation, 30pc rise in the electricity cost and 35pc increase in the gas cost. So the mindset of the government is that the only good industry is a sick industry. Its officials seem to think that it is not good for the people if a company is generating a profit. The opposite is true as Pakistan does not have even the essential drugs listed by the WHO. This means low-cost molecules are not available to the poor. As a result, Pakistan's infant and maternal mortality rates are twice those of Bangladesh. The number of stunted children up to the age of five is the highest in the world.

The high-end medicines for cancer or products that cure Parkinson's disease and Alzheimer's are also unavailable in the regulated market. But they are all available in the grey market. The government should follow the Indian or Bangladeshi pricing model. Its government regulates essential 200 drugs. It leaves the pricing of the rest of medicines to market forces" (Dawn newspaper, 2018).

In an interview with Mr. Kaiser Waheed, ex-Chairman PPMA, it was recommended that TDAP should help pharma companies with the registration fees. All companies that have exports over PKR 200,000 should be subsidized in terms of export registration fees. This fee could be provided as a loan by TDAP, payable in 2 or 3 years. The R&D Fund at the Ministry of Health could be used for Pharma trade promotions and export development. Companies which have been exporting for the past 3 years could be provided this fund to increase their exports. Another suggestion was that the EDF fund should be used to develop dedicated Research Center for Pharma industry.

The pharmaceutical industry views the present state of affairs as very discouraging for the growth of business and future prospects of this industry in Pakistan. The way regulations are implemented does not help the industry grow. For example, in terms of contract manufacturing, the international norm is to give license for 2 years. But in Pakistan, the license is granted for only 3 months (BR Research, 2017). This has had the negative result of discouraging FDI. Japanese companies are investing in India due to the length of their contract manufacturing licenses as compared to Pakistan's.

There are over 40 Special Economic Zones (SEZs) planned under the CPEC $55 billion initiative (Board of Investment), and all of them are to get favorable treatment in the form of tax

exemptions and other such measures. Yet the pharmaceutical industry has not been contacted once for participation in CPEC, and any SEZ does not include plans for operations of the pharmaceutical industry. The official explanation provided was that since CPEC is a massive project which concentrates on larger scheme of things, contends an official, pharmaceutical industry does not figure in since it's only a $ 3 billion industry (Pakistan Pharmaceutical Manufacturer's Association, 2017). On the contrary, there are possibly tremendous opportunities lying in wait. For example, health care facilities like tertiary care would be required at places where CPEC related activities are taking place. This would be complemented by demand for other services, like provision of drugs and vaccines.

According to Chairman PPMA, the response from the Government side is positive during talks with the industry, but the execution part is missing. PPMA stated that while the Ministry of Health and DRAP held a sympathetic view, their vision should be realized more rapidly. Too much regulation stunted the growth of the industry. The government should let market dynamics play out. PPMA suggested that the government should regulate the drugs included in the WHO list of essential drugs and deregulate all other drugs including the OTC products. The returns will help in generation of funds for investment and thereby growth of the industry (PPMA, 2016).

According to CEO, Getz Pharma there is a lack of coordination between DRAP and the pharma industry. DRAP needs to develop its KPIs. Malaysia facilitates the pharma industry while Pakistan hinders it. DRAP's fee has increased which cuts into the pocket of smaller companies. Over 300 essential drugs are not being made in the country due to price freezing which makes it economically unviable to manufacture these drugs. Therefore, these drugs have to be imported. DRAP also has no actionable plan to become a member of Pharmaceutical Inspection Cooperating Scheme (PIC/S) (PPMA, 2016).

12 MARKET INITIATIVES BY TDAP

The following exhibition calendar is shared by TDAP outlining countries where pharmaceutical exhibitions will be held. Exporters are welcome to participate in these exhibitions and/or provide recommendations on the locations where the most potential for pharma product resides.

Event	Year	Country	Product
Asia (Middle East)			
Global Health Expo, Riyadh	Sept 2019	Saudi Arabia	Pharmaceutical and Surgical
Asia (South East Asia)			
11th International Exhibition on Medical and Hospital Equipment, Jakarta	Mar 2019	Indonesia	Medical & Hospital Equipment, Pharmaceutical Products, Herbal Medicine
Central Asia			
International Universal Exhibition, Dushanbe	Mar 2019	Tajikistan	All products
International Universal Exhibition, Dushanbe	Nov 2019	Tajikistan	All products
Africa			
Medical Expo, Casablanca	Mar 2019	Morocco	Surgical and Pharmaceutical
Mediconex, Cairo	Apr 2019	Egypt	Healthcare
Africa Health Expo, Johannesburg	May 2019	South Africa	Surgical and Pharmaceutical
Medic East Africa Exhibition & Congress, Nairobi	Sept 2019	Kenya	Healthcare
Medic West Africa, Lagos	Oct 2019	Nigeria	Healthcare / Surgical / Pharmaceutical

From TDAP website

13 CONCLUSION AND RECOMMENDATIONS

Pakistan should strive to become a global pharma hub by exporting domestically produced generic products and positioning itself as an offshore destination for clinical and pre-clinical research and other support services. Due to the depreciation of the rupee, pharma companies can capitalize on the benefit presented to them by increasing export sales via lower AUP.

13.1 Lack of exploration in new markets

The exports data suggests that the consistent lack of exploring new markets by Pakistan's pharma exporters, over the past few years, indicates the trend towards stagnation. Their inability to penetrate new markets needs to be addressed. The top buyers are consistently Afghanistan, Sri Lanka, Philippines and Vietnam. The same buyers, year after year, are indicative of a concentration risk. New markets need to be explored. The pharma industry needs to identify newer regions where they can do business and direct the government to set up exhibition stalls in potential regions.

13.2 Packaging trends and other opportunities

The Pakistani pharmaceutical industry should take advantage of the modern advances in biotechnology and IT. The future of the industry will depend on how well it markets its products in different regions and distributes risk. It will depend on its forward and backward integration capabilities, R&D, co-marketing and licensing agreements.

Pharmaceutical packaging is changing with rise in demand for user-friendly packages. More and more companies are embracing the demand for easy-to-use packaging. Production of Biologics is growing and they are being increasingly packaged in combination with a device such as a pre-filled syringe. In addition to that, serialization is set to be enforced in USA in 2018 and in EU at the start of 2019. As manufacturers move towards innovation solutions, so too must the supply chain supporting them, especially packaging material and machinery companies (Euromonitor International, 2018).

13.3 Acquisition of PIC/S membership and creation of WHO qualified labs

DRAP should strive to acquire **membership of Pharmaceutical Inspection Cooperating Scheme (PIC/S)**. This will help assuage the concerns of buyers regarding Good Manufacturing Practices (GMP) of Pakistan. PIC/S membership will certify Pakistan is following GMP which will lead to increase in exports. Inspections by PIC/S members will also help to uplift the Pakistani pharmaceutical industry. DRAP should also have **WHO qualified QC laboratories** in all four provinces and at the Federal level. The EDF fund should be used to develop dedicated Research Center for Pharma industry.

13.4 Becoming a hub of research and clinical trials

According to the WHO, a health system is built on six building blocks (WHO, 2016):

Service delivery	Workforce
Information	Technology
Financing	Governance

For the industry to become a giant player on the regional scale, Pakistan needs to become a hub of research and clinical trials. Pakistan has the potential to become a global pharma hub by exporting domestically produced generic products and positioning itself as an offshoring destination for clinical and preclinical research.

Innovation requires a number of enabling conditions such as access to top-class researchers, political and financial stability and a regulatory framework that safeguards and rewards innovation. Becoming a hub of research and clinical trials requires the following key drivers:

Early Stage Research	World class research institutions
	Highly trained workforce (retrained or attracted back to the country)
	Clusters of innovative companies providing support on core technologies
	Partnership encouraging environment
Clinical trials	Efficient regulatory system for appraising clinical trials design
	Supportive and well-regulated system for enrolment
	Strong medical schools
	Managing and reporting trials design
	Growing market receptive to innovation

13.5 Opportunity in Neglected Tropical Diseases

The World Health Organization (WHO) has identified more than 17 neglected tropical diseases (NTD) which form a substantial portion of the global disease burden and affect the lives of more than 1 billion people (WHO, 2016).

NTDs require a distinctive business/innovation model because countries affected by NTDs do not sufficiently support the traditional R&D investments on a commercial basis.

NTDs require a distinctive business/innovation model because countries affected by NTDs do not sufficiently support the traditional R&D investments on a commercial basis. Therefore, in order to tap into markets where NTDs are prevalent, Pakistani pharmaceutical companies would need to collaborate with international players to form product development partnerships (PDP) which

will bring together the expertise of international players combined with the low cost of production of Pakistani players.

These partnerships are often funded by public or philanthropic organizations. In 2014, PDPs contributed to 22% of the total research funding for malaria, 8.8% for dengue and 19% for tuberculosis (G-Finder, 2015).

Specialty products and personalized healthcare have taken precedence in terms of importance in the modern healthcare industry. Pakistan should target specific medicines and develop its name in that particular area to enhance its reputation on the global stage.

13.6 Opportunity in Vaccines

There is opportunity for Pakistan to **penetrate the vaccines market**. The global vaccine industry is forecasted to grow to USD 57.5bn by 2025 (PRNewswire, 2018). High Income Countries form 82% of global vaccine sales in terms of value and 20% in terms of volume. High Income countries pay more for vaccines and are more likely to implement newer vaccines. Middle and lower income countries account for 18% of global vaccine sales in terms of value and 80% in terms of volume. The majority of this procurement is done by UNICEF and PAHO on behalf of developing nations (World Health Organization, 2018).

13.7 Opportunity in Specialty products and personalized healthcare

Specialty products and **personalized healthcare** have taken precedence in terms of importance in the modern healthcare industry. In the modern era of the industry, targeted products will begin to take priority. Specialty products will give advantage in certain areas. Pakistan should target specific medicines and develop its name in that particular area to enhance its reputation on the global stage. A variety of innovative technologies, such as induced pluripotent stem cells (iPSC) and CRISPR/Cas9 and others consisting of modified cells or gene-modification tools are under development.

13.8 AI and Digital Therapeutics

Over the next 5 years, life sciences companies will continue to build up and invest in artificial intelligence, machine learning and deep learning programs leading to breakthroughs influencing the discovery of molecules and development of medicines (IMS Health Institute and Quintiles, 2018).

Digital therapeutics is also being introduced. In the US, mobile apps are being submitted to the FDA for approval. These prescription digital therapeutics (DTx) are an emergent treatment method with "indications and disease specific treatment effectiveness claims in their software labels" (IMS Health Institute and Quintiles, 2018).

13.9 Technology transfer

In order to move from the current business model of the local pharmaceutical industry where concentrate is imported and diluted, packaged and sold, to a more advanced model, the Pakistani pharmaceutical industry requires technology transfer. Technology transfer benefits the overall economy by increasing the reliability of supply, decreasing reliance on imports and raising the competence level of the domestic workforce. Critical factors that create a favorable environment for pharmaceutical technology transfers include:

Figure 22 Critical factors for pharmaceutical technology transfer

13.10 Licensing prompt

Although annual earnings have been increasing at a rate of 10% over time (Pakistan Pharmaceutical Manufacturer's Association, 2017), there exist a few problems that need to be addressed. One is the exit of MNCs. Increase in earnings over time has not provided any solution for the difficulties troubling the pharmaceutical sector. There exists a vast gap between the regulators and the industry, exports have taken an alarming dive and **delays in licensing approvals** and **lack of infrastructure** are persistent.

Preliminary steps, such as the establishment of an FDA approved lab and facilitating contract manufacturing are in stasis and need focus.

The industry is of the view that the government needs to **reduce transaction costs** through regulations (in licensing, for example). There should be a long term policy and continual engagement with the industry whilst policy making.

13.11 Contract manufacturing Hub

Pakistani firms should also look to secure contract manufacturing due to its lower costs than western countries. If Pakistani firms are able to secure PIC/S membership and make their plants GMP compliant, they will be in a position to secure contracts. They will be able to develop

API and enter strategic alliances with large generic companies in the world for manufacture of off-patent molecules.

DRAP should look to facilitate contract manufacturing by allowing Pakistani companies to acquire the license for contract manufacturing opportunities. According to the industry, DRAP should give the license for 2 years instead of 3 months (Qadri, 2017). The current regulatory mechanism restricts the local industry from forming conglomerates with global players. Contract manufacturing will bring FDI to the country.

In India, companies such as Dishman Pharma, Divis Labs and Matrix Labs have undertaken contract jobs for MNCs in USA and Europe (Joseph, 2010). Shasun Chemicals, Strides Arcolabs, Jubilant Organosys, Orchid Pharmaceuticals and other large Indian companies are starting to undertake contact manufacturing of APIs as part of their additional revenue stream. These companies have made top MNCs like Pfizer, Merck, GSK, Sanofi, Novartis, Teva largely dependent on Indian companies for their APIs.

Table 27 Contract manufacturing examples in India

Select contract manufacturing deals in India		
Indian company	Multinational	Product
Lupin Laboratories	Fujisawa Apotex	Cefixime Cefuroxime Axetil, Lisinopril (Bulk)
Nicholas Piramal	Allergan Advanced Medical Optics	Bulk and Formulations Eye Products
Wockhardt	Ivax	Nizatidine (anti-ulcerant)
Dishman Pharmaceuticals	Solvay Pharmaceuticals	Eprosartan Mesylate
IPCA Labs	Merck Tilomed	Bulk drugs Atenelol
Orchid Chemicals & Pharmaceuticals	Apotex	Cephalosporin and other injectables
Sun Pharma	Eli Lilly	CVS products, anti-infective drugs and insulin
Kopran	Synpac Pharmaceuticals	Penicillin- G Bulk drug
Cadila Healthcare	Altana Pharma Beohringer Ingelheim	Intermediates for Pantoprazole Gastrointestinal and CVS products
Biocon	Bristol Myers Squibb	Bulk drugs

(Joseph, 2010)

Japanese companies are setting up pharmaceutical plants in India because the cost of drug manufacturing is 40% lower through contract manufacturing (Qadri, 2017). Foreign manufacturers are allowed to formulate any drug with any manufacturer, given that it is research based and registered under the same brand name in these countries.

Preliminary steps, such as the **establishment of an FDA approved lab** and facilitating **contract manufacturing** are in stasis and need focus. There is little or no effort to upgrade the pharmaceutical industry's limitations by including them in new ventures.

13.12 Invest in R&D and Human Resource

Sales of drugs will keep on increasing due to ageing population and rising income levels, but the number of firms is likely to decline as smaller players are finding it difficult to survive in the competitive market due to the number of regulations. Capital and quality human resources are likely to remain clustered in the top 100 firms, specifically the top 50. Yet the increase in annual profits will be derived from volumetric production rather than any new innovation or research into New Chemical Entities (Pakistan Pharmaceutical Manufacturer's Association, 2017).

The increase in annual profits will be derived from volumetric production rather than any new innovation or research into New Chemical Entities

However, the industry should be mindful that the growth opportunity should be utilized properly and investments should be made in R&D efforts. In order to stay competitive in the future, Pakistani companies will need to make heavy investments in R&D. Strong patent protection will also need to be enforced to foster R&D efforts in Pakistan. Outsourced R&D is also a viable option as foreign pharmaceutical companies are searching to cut down on their heavy R&D costs. If Pakistan can develop the capability to deliver on R&D at lower costs, Pakistan can create an additional revenue stream for the future.

Industrial R&D groups can conduct primary screening to single out lead molecules or candidate drugs for further in vivo screening, pre-clinical pharmacology, toxicology, animal and human pharmacokinetics and metabolic studies before starting human trials. Standardized screening can be set to ensure good laboratory practices.

13.13 Good Governance Practices

The government and the industry need to chalk out a mutually agreed plan and resolve their differences over the issues plaguing the industry. PPMA estimates that if that were to happen, Pakistan's pharmaceutical industry has the potential to be a star performer in the future.

Regulators need to **liaison** with the industry and study why leading pharmaceutical companies tend to avoid Pakistan and why investment in this sector has almost collapsed. DRAP should be an independent authority, model led like Securities and Exchange Commission (SECP) and Competition Commission of Pakistan (CCP) rather than being placed under health ministry.

The pharma industry should also create a Pharma Policy and Research Advocacy Council with a team of market oriented economists and technocrats so that they can make recommendations to the Government.

13.14 Countering The Counterfeiting

Counterfeiting is also a major concern for Pakistani pharmaceuticals. To combat counterfeits, there needs to be close coordination between the law enforcement agencies and pharmaceutical companies. Although it is primarily the responsibility of the Government and law

enforcement to capture the manufacturers of counterfeit drugs, pharmaceutical companies should also identify such networks and coordinate with law enforcement agencies to bring the culprits to task. Doing so will help the pharmaceutical manufacturers in avoiding negative publicity in the market place as well as abroad. It will also help avoid loss of sales of their own product and avoid possible investigations by DRAP and other agencies.

Companies are also coming up with smart packaging. These make use of holograms or unique printing to make difficult-to-reproduce labels. Another solution being used is electronic pedigrees, which is similar to RFID tech. they are able to track and trace products as they transfer across the supply chain from manufacturer to distributor to retailer or hospital.

13.15 TRIPS and TRIPS Plus

The government should not let MNCs impose TRIPS++ on the Generics market (PPMA, 2016). Trade Related Aspects of Intellectual Property Rights (TRIPS) set the global minimum standards for protection of intellectual property rights. While they have resulted in clear gains for the developed nations, a research study by Prof Richard Smith et al. published in the Lancet volume 373 discovered that TRIPS and TRIPS plus had increased restrictions in bilateral trade and failed to generate substantial gains for the developing nations (Smith, Correa, & Oh, 2009). According to the recommendations of Mr. Khalid Mahmood CEO Getz Pharma, the government should also refuse to accept Data Protection/Data Exclusivity for the generics market (PPMA, 2016).

13.16 Opportunity for Herbal/Unani/Alternative Medicine

WHO estimates that almost 80% of the population of Asian and African countries depend on herbal medicine for their primary health care. Tighter health budgets on modern medicine system have also driven customers towards herbal alternatives. The biggest users of herbal medicine are China and India due to their tradition of using herbal medicine. Europe is the second largest market with growing demand for natural therapies. The biggest market in Europe is France, followed by Germany. The lack of standardization and poor regulatory framework in herbal medicines causes market constraints on the products (MarketResearchFuture, 2018).

Top global players in the herbal market include:

Himalaya Drug Company (India)	Schwabe (Germany)	Madaus (Spain)
Arkopharman (France)	Blackmores (Australia)	Tsumura (Japan)
Sheng Chang Pharmaceutical (Taiwan)	Ricola AG (Switzerland)	Zandu Pharmaceutical Works Ltd (India)
Hamdard laboratories (India)	Dabur (India)	Patanjali Ayurved Ltd (India)
China Herbs Company (U.S.)	Nutraceutical International Corporation (U.S.)	

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15 APPENDIX 1

15.1 Exporters List

PRAL data from Customs

Name of Company	Exported value in Rs
GETZ PHARMA (PRIVATE) LIMITTED	4,023,412,597
ABBOTT LABORATORIES (PAKISTAN) LTD.	1,362,360,087
NOVARTIS PHARMA (PAK) LTD	1,137,074,548
HERBION PAKISTAN PVT LTD	1,100,414,572
SEARLE PAKISTAN LIMITED	883,952,542
MERCK (PRIVATE) LIMITED	796,339,112
CCL PHARMACETUICALS (PVT) LIMITED	497,132,141
ZAFA PHARMACEUTICAL LABORATORIES (PRIVATE) LIMITED	477,035,334
HINOVEX PHARMA/INTERCHEM CORP/INCHEM INTER/HINOVEX	476,884,823
SANOFI AVENTIS PAKISTAN LIMITED	420,903,178
ATCO LABORATORIES LIMITED	393,756,541
GENIX PHARMA (PRIVATE) LIMITED	382,014,068
PFIZER PAKISTAN LIMITED LTD	380,257,896
WYETH PAKISTAN LIMITED	331,689,342
HIGHNOON LABORATORIES LIMITED	267,492,128
SAMI PHARMACEUTICAL PVT LTD	262,882,599
PHARMATEC PAK PVT LTD	251,295,266
GLAXO SMITH KLINE PAKISTAN LIMITED	236,168,835
STAR LABORATORIES PVT LTD.	232,945,783
KAYBEE IMPORTS ENTERPRISES	218,344,254
MEDIPHARM (PVT) LTD	213,759,797
SURGE LABORATORES (PRIVATE) LIMITED	211,720,297
NABI QASIM INDUSTRIES (PRIVATE) LIMITED	205,983,554
FEROZSONS LABORATORIES LT.D	203,150,316
ROYAL GROUP	196,861,055
INDUS PHARMA (PRIVATE) LIMITED	177,278,418
J.A ENTERPRISES	167,211,237
FRONTIER DEXTROSE LIMITED	165,337,303
SANTE (PRIVATE) LIMITED	153,362,370
DELTA INTERNATIOANL/ROCK PHARMACOUTICAL LABORATORI	150,838,976
GEOFMAN PHARMACEUTICALS	150,599,735
RECKITT BENCKISER PAKISTAN LTD	146,977,036
M/S THE SCHAZOO PHARMACEUTICAL LABORATORIES (PVT.)	145,129,293
BOSCH PHARMACEUTICALS (PRIVATE) LIMITED	140,428,418
BROOKES PHARMACEUTICAL LAB PAK LTD	138,359,736
HASNAIN GROUPS OF COMPANIES / SIMBA ENTERPRISES	123,994,493
PHARMEVO (PRIVATE) LIMITED	123,825,507

BAYER PAKISTAN PVT LTD	121,149,741
OBS PAKISTAN (PRIVATE) LIMITED	116,527,533
GENOME PHARMACEUTICALS (PVT.) LIMITED	100,184,920
MEDIPAK LTD	99,907,658
TRADE IMPEX	89,237,195
SAMI TOWER	89,027,085
BABA INTERNATIONAL	83,959,852
TABROS PHARMA (PVT) LTD.	77,129,250
MACTER INTERNATIONAL PVT LTD	74,309,108
UNISA PHARMACEUTICAL INDUSTRIE	73,480,006
BIO-LABS (PRIVATE) LIMITED	70,176,330
MULTINATIONAL BUSINESS LINK	66,878,987
PHARMIX LABORATORIES (PVT) LTD	62,528,996
WILSON'S PHARMACEUTICALS	62,039,915
UMAR ENTERPRISES	60,825,017
HAFSA ENTERPRISES/JALALI TRADERS	60,555,188
WERRICK PHARMACEUTICALS	57,826,716
HAJI SULEMAN ADAM KOTHARI AND CO	55,986,627
REMINGTON PHARMACEUTICAL INDUSTRIE PVT LTD	54,996,449
NAWAN LABORATORIES (PRIVATE) LIMITED	51,757,664
PHARMEDIC LABORATORIES PVT LTD	51,159,079
MURTAZA & BROTHERS	50,618,720
ENGLISH PHARMACEUTICAL INDUSTRIES	49,947,657
MAPLE PHARMACEUTICALS (PVT) LTD	47,902,044
MULTI LINK ENTERPRISES	47,105,808
AMSON VACCINES & PHARMA (PRIVATE) LIMITED	46,884,336
UNICON ENTERPRISES	45,959,435
M/S SHAH ENTERPRISES	45,343,300
INTERNATIONAL BUSINESS LINES	44,696,301
W.WOODWARDS PAKISTAN (PVT) LTD.	41,115,237
SAMZ INTERNATIONAL	40,433,304
LEADS PHARMA PRIVATE LIMITED	40,136,195
M/S GLOBAL PHARMACEUTICALS PVT LTD	39,638,807
PARAGON ENTERPRISES	38,566,042
STANLEY PHARMACEUTICAL PVT LTD	37,978,279
M/S NEXUS PHARMA (PRIVATE) LIMITED	36,583,932
SELMORE PHARMACEUTICALS PVT LTD	35,991,215
SAFFRON PHARMACEUTICALS PVT LTD	34,521,270
SHAIGAN PHARMACEUTICALS PVT LTD	34,261,736
COTTON CRAFT PVT LIMITED	33,803,912
MEDICRAFT PHARMACEUTICAL PVT.LTD.	33,649,684
IRZA PHARMA (PRIVATE) LIMITED	30,411,910
POPULAR CHEMICAL WORKS PVT LTD	29,936,959
PACIFIC PHARMACEUTICAL LTD	29,913,781

MAC & RAINS PHARMACEUTICALS PVT LTD	28,943,559
PLATINUM PHARMACEUTICALS (PVT) LTD	28,882,225
MEDICAIDS PAKISTAN PVT LTD	28,704,437
EFROZE CHEMICAL INDUSTRIES (PRIVATE) LIMITED	28,569,724
CHAS A. MENDOZA	28,542,232
SHAHAZAD ENTERPRISES EXP& IMP	27,520,776
SCHAZOO ZAKA PVT LTD	26,782,194
M.S ENTERPRISES LTD	26,118,711
TAYYAB TRADING COMPANY	24,794,180
MOUMIN EXPORTS (PVT) LTD	24,724,021
M/S EXCEL ENTERPRISES	23,457,409
ALINA COMBINE PAKISTAN PVT LTD	23,455,115
BF BIOSCIENCES LIMITED	22,837,742
NOVAMED PHARMACEUTICALS (PVT)LTD.	22,798,227
BSN MEDICAL(PRIVATE) LIMITED	21,453,265
MUDISURE LABORTORIES PAKISTAN (PVT) LTD.	20,768,551
SWISS PHARMACEUTICAL (PVT) LTD.	20,609,593
ZAKFAS PHARMACEUTICALS (PVT) LTD	19,821,569
M.MANZOOR AND CO PAKISTAN PVT LTD	19,346,721
OPAL LAB PVT LTD	19,185,910
HARMANN PHARMACEUTCAL LABORATORIES PVT LTD.	19,137,455
AL ATTEBI ENTERPRISES	18,782,200
HANSEL PHARMACEUTICAL PVTL TD	18,566,827
FOCUS & RULZ PHARMACEUTICAL PVT LTD	18,257,714
NABI AFRIDI TRADING	18,220,858
ADIL ENTERPRISES	17,750,244
B.M. PRIVATE LIMITED	17,703,597
AMBROSIA PHARMACEUTICALS	17,422,310
SHAZEB PHARMACEUTICAL INDUSTRIES LTD.	17,037,902
S J & G FAZUL ELAHI PVT LTD.	16,657,094
KARACHI CHEMICAL INDUSTRIAL PVT LTD.	16,237,832

15.2 Top Tibbi Pharmaceutical Exporters to USA

Qarshi Industries Pvt Ltd
Herbion Pakistan Pvt Ltd
Hamdard Laboratories (Waqf) Pakistan
Muhammad Hashim Tajir Surma Karachi
Marhaba Laboratories Pvt Ltd Lahore
Source: As communicated by Pakistan Tibbi Pharmaceutical Association via email

16 APPENDIX 2

16.1 Global Country Rankings

Global Top 20 Countries Ranking and Spending Relative to U.S.

2013				2018				2023			
RANK		COUNTRY	% OF U.S.	RANK		COUNTRY	% OF U.S.	RANK		COUNTRY	% OF U.S.
1		U.S.	100	1		U.S.	100	1		U.S.	100
2	▲1	China	28	2		China	28	2		China	27
3	▼1	Japan	24	3		Japan	18	3		Japan	12
4	▲1	Germany	12	4		Germany	11	4		Germany	10
5	▼1	France	10	5		France	7	5	▲2	Brazil	7
6		Italy	7	6		Italy	7	6		Italy	6
7	▲1	U.K.	6	7	▲1	Brazil	6	7	▼2	France	6
8	▲3	Brazil	5	8	▼1	U.K.	6	8		U.K.	5
9	▼2	Spain	5	9		Spain	5	9	▲2	India	5
10	▼1	Canada	5	10		Canada	5	10	▼1	Spain	4
11	▲3	India	3	11		India	4	11	▼1	Canada	4
12	▼2	South Korea	3	12		South Korea	3	12	▲1	Russia	4
13	▼1	Australia	3	13	▲1	Russia	3	13	▼1	South Korea	3
14	▲5	Russia	3	14	▼1	Australia	3	14	▲3	Turkey	3
15	▼2	Mexico	2	15		Mexico	2	15	▲4	Argentina	2
16	▲7	Saudi Arabia	2	16	▲1	Poland	2	16	▼2	Australia	2
17	▲1	Poland	2	17	▲9	Turkey	2	17	▼2	Mexico	2
18	▼1	Belgium	2	18	▼2	Saudi Arabia	2	18	▼2	Poland	2
19	▼3	Netherlands	2	19	▲27	Argentina	1	19	▼1	Saudi Arabia	2
20		Switzerland	1	20	▼2	Belgium	1	20	▲6	Vietnam	1

▲▼ Change in Ranking over Prior Five Years

Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018
Report: The Global Use of Medicine in 2019 and Outlook to 2023. IQVIA Institute for Human Data Science, Jan 2019

17 APPENDIX 3

17.1 Region and Leading Country Spending

Global Spending and Growth in Selected Countries

	2018 SPENDING US$BN	2014-2018 CAGR CONSTANT US$	2023 SPENDING US$BN	2019-2023 CAGR CONSTANT US$
Global	**1,204.8**	**6.3%**	**1,505-1,535**	**3-6%**
Developed	**800.0**	**5.7%**	**90-1,020**	**3-6%**
U.S.	484.9	7.2%	625-655	4-7%
EU5	177.5	4.7%	200-230	1-4%
Germany	53.5	5.0%	65-69	3-6%
France	36.8	1.5%	37-41	(-1)-2%
Italy	34.4	6.3%	40-44	2-5%
U.K.	28.4	6.2%	33-37	2-5%
Spain	24.6	5.4%	27-31	1-4%
Japan	86.4	1.0%	89-93	(-3)-0%
Canada	22.2	5.0%	27-31	2-5%
South Korea	15.8	4.7%	19-23	4-7%
Australia	13.1	4.3%	13-17	0-3%
Pharmerging	**285.9**	**9.3%**	**355-385**	**5-8%**
China	132.3	7.6%	140-170	3-6%
Tier 2	67.7	10.7%	91-95	7-10%
Brazil	31.8	10.8%	39-43	5-8%
India	20.4	11.2%	28-32	8-11%
Russia	15.5	9.9%	21-25	7-10%
Tier 3	85.9	11.3%	105-135	7-10%
Rest of World	**118.9**	**3.2%**	**130-160**	**2-5%**

Source: IQVIA Market Prognosis, Sep 2018; IQVIA Institute, Dec 2018
Notes: Spending in US$Bn, CAGR = Compound Annual Growth Rate using Constant US$ with Q2 2018 exchange rates.
Report: The Global Use of Medicine in 2019 and Outlook to 2023. IQVIA Institute for Human Data Science, Jan 2019

18 APPENDIX 4

18.1 Product Types by Geography

Spending USD 2020	Original Brands	Non-original Brands	Unbranded	Other Products	Global
Global	52%	21%	14%	13%	$1,400-1,430 Bn
Developed	65%	12%	14%	8%	$870-900 Bn
Pharmerging	24%	38%	14%	24%	$345-375 Bn
Rest of World	48%	26%	9%	17%	$150-180 Bn

2016-20 CAGR	Original Brands	Non-original Brands	Unbranded	Other Products	Global
Global	5.1%	6%	6.3%	4.8%	4-7%
Developed	4.9%	4.9%	4.6%	3.1%	3-6%
Pharmerging	8.6%	7.8%	12%	6.9%	7-10%
Rest of World	2.6%	3.4%	3.2%	2.7%	1-4%
Source: IMS Health, IMS Market Prognosis, September 2015; IMS Institute for Healthcare Informatics October 2015					

Countries:

- Developed countries in this report are defined as the U.S., Japan, Top 5 Europe countries (Germany, France, Italy, Spain, U.K.), Canada and South Korea.
- Pharmerging countries are defined as those with >$1 billion absolute spending growth over 2014-18 and which have GDP per capita of less than $30,000 at purchasing power parity (PPP). Tier 1: China; Tier 2: Brazil, India, Russia; Tier 3: Algeria, Argentina, Bangladesh, Chile, Colombia, Egypt, Indonesia, Kazakhstan, Mexico, Nigeria, Pakistan, Philippines, Poland, S. Africa, Saudi Arabia, Turkey, Vietnam.
- Original Brands Prescription-bound products marketed with a brand name, by the originator or their licensee.
- Non-Original Brands Prescription-bound products marketed by a non-originator with a brand name, often but not exclusively without patent protection.
- Unbranded Generic medicines marketed as the international non-proprietary name (INN) of the active ingredient(s).
- OTC All other medicines, the largest subset of which are Over-the-Counter (OTC) products.

19 APPENDIX 5

19.1 Disease Definitions

Disease definition	Includes
Communicable diseases	Antibiotics, antivirals, antiparasitics, vaccines
Oncology	Therapeutic cancer treatments, excluding supportive care
Diabetes	Insulins, traditional and newer generation diabetes treatments
Cardiovascular	Hypertension, Heart disease, cholesterol
Pain	Treatments for musculoskeletal pain, arthritis, anesthesia, analgesics (narcotic & non-narcotic), migraine
Autoimmune	Treatments for rheumatoid arthritis, crohn's disease, ulcerative colitis, psoriasis, psoriatic arthritis and other related diseases
Respiratory	Asthma, COPD, Allergy respiratory/inhaled treatments
Other non-communicable	All other treatments not related to communicable diseases

Therapy definitions	Includes
Oncology	Therapeutic cancer treatments, excluding supportive care
Autoimmune	Treatments for rheumatoid arthritis, crohn's disease, ulcerative colitis, psoriasis, psoriatic arthritis and other related diseases
Viral Hepatitis	Specific treatments for hepatitis, excluding interferons
Immunosuppressants	Suppression of immune response, often for use in organ transplant
HIV Antivirals	HIV antiviral treatments
Immunostimulants	Colony-stimulating factors
Interferons	Interferons
Erythropoietins	Erythropoietin stimulating agents
Macular Degeneration	Treatments for age-related macular degeneration

Definitions	Traditional therapies
Antibiotics & Vaccines	Antibiotics, antifungals, vaccines and antibiotics specifically for the eye and ear
Blood disorders, coagulation	Antithrombotics, Platelet aggregation inhibitors, direct thrombin inhibitors
Cardiovascular	Hypertension, Cholesterol, nitrates/nitrites, diuretics, heart failure, varicose veins
Dermatology	Dermatology treatments
Diabetes	Insulins, traditional and newer generation diabetes treatments
Mental Health	Antipsychotics, Antidepressants, Psychostimulants
Other CNS	Anti-epileptics, Anti-Parkinson's, Anti-Alzheimer's
Pain	Treatments for musculoskeletal pain, arthritis, anesthesia, analgesics (narcotic & non-narcotic), migraine
Respiratory	Asthma, COPD, Allergy respiratory/inhaled treatments
Trad Chinese/Indian/Japanese Medicines	Traditional medicines from China, India, Japan
Others (not shown)	Alimentary products (Vitamins, minerals, digestive enzymes, anti-obesity medicines and laxatives, Hospital solutions, antiparasitics, diagnostics, Erectile dysfunction, Genito-urinary hormones and contraception, Hormones, Gout, Osteoporosis, Ophthalmic (S, anti-infectives are shown), All other non-human use (V)