

Pakistan's Pharmaceutical Industry



July 2017



Message from Chairman, PPMA

Pakistan's pharmaceutical industry is one that has never been studied so extensively. We would like to thank Policy Research Institute of Market Economy (PRIME) for lending their research expertise to this project, and bringing to light the various aspects of this sector and illuminating examples from the rest of the world.

Pharmaceuticals in Pakistan presently form a USD 3.2 billion industry, growing at a swift 15% annually. The sector has seen massive changes over the past decade, providing essential health care products to citizens and introducing them to revolutionary pharmaceutical preparations. Today, there are more than 700 pharmaceutical manufacturing units in Pakistan and medicines worth more than USD 202 million are exported to more than 60 countries from Pakistan.

In spite of its rapid growth and massive reach, the pharmaceutical industry faces various issues, most of all the continued regulation of the drugs market and lack of government support or dialogue with the industry. PRIME has lent a voice to these issues in the past, and we hope the organization's excellent research and advocacy capacity will continue to be of support to us. We pharmaceutical manufacturers appreciate PRIME's efforts to campaign for economic freedom and produce independent market research, and are hopeful that this study will initiate much-needed dialogue on the state of the pharmaceutical sector in Pakistan.

Dr. Shaiekh Kaiser Waheed
Chairman
Pakistan Pharmaceutical Manufacturers' Association (PPMA)

PPMA Central Executive Committee Members



Mr. Haroon Qassim

Former Chairman PPMA

Member CEC South



Mr. Ijaz A. Siddiqui

Senior Vice Chairman



Dr. Riaz Ahmad

Vice Chairman PPMA



Dr. Muhammad Tahir Azam

Zonal Chairman, PPMA North



Mr. Tauqeerul Haq

Zonal Chairman, PPMA South



Mr. Asad Mumtaz

Member CEC North



Mr. Ch. Ansar Farooq

Member CEC North



Mr. Ehsan Awan

Member CEC South



Mr. Haseeb Khan

Member CEC North



Mr. Humayun Kabir

Member CEC North



Mr. Ilyas Nanitalwala

Member CEC South



Mr. Nadeem Chandna

Member CEC South



Mr. Shuja Malik

Member CEC South



Mr. Tahir Latif

Member CEC North



Mr. Nadeem Zafar

Member CEC North



Mr. Ch. Israr Sharif

Member CEC South



Dr. Qurratul Ain

Member CEC North



Mr. Khurram Nanitalwala

Member CEC South



Mr. Khawaja Shahzeb

Member CEC North



Ms. Mahvash Tariq Siddiqui

Member CEC South



Mr. Mubashar Javaid

Member CEC North



Mr. Mian Yasir Liaqat

Member CEC North



Mr. Saleem Iqbal

Member CEC North



Mr. Najeeb ur Rehman

Member CEC South



Mr. Naveed Ali Hakim

Member CEC South



Mr. Waqas Ali Khan

Member CEC South

Table of Contents

Preamble	7
Overview	8
Resource Base	10
Major Drivers of Expansion	10
Drivers of Future Growth.....	15
The Business Environment	15
Structure of the Industry:.....	15
The Decline of MNCs	16
Government Procurements	17
Investment	18
Technology, Research and Development	20
Technology adaption and use	20
Importance of Research &Development (R&D)	20
R&D in the Pakistani Pharmaceutical Industry.....	21
Emerging Global Trends and the Pakistani Pharmaceutical Industry	23
Government and the Pharmaceutical Industry – A Brief Overview	24
Industry’s Point of View	25
International Experience of Regulating the Pharmaceutical Markets	27
Complementary and Alternative Medicines (CAM)	29
Consumption of Drugs in Pakistan	30
Comparative Analysis with Other Countries	31
India.....	31
Malaysia	33
Britain	34
Conclusion	35
Works Cited	36

Preamble

The 17 Sustainable Development Goals (SDGs), adopted by 194 member countries of UN in 2015, are a roadmap for future human development. One of the pillars of SDGs is health, covered under SDG 3. As defined by the World Health Organization (WHO), this goal envisions ensuring promotion of healthy lives and wellbeing for people of all ages. It is further sub-divided into 13 goals. The WHO also considers other SDGs to be closely linked to SDG 3 as they are directly related to health or will indirectly affect health outcomes. Health related targets are divided into categories like Mortality (infant, child and maternal), Non-communicable diseases, Mental health, Malnutrition, Vaccine coverage, etc. Achieving these would require the critical contribution of the pharmaceutical industry in the form of research and manufacturing of drugs that alleviate diseases and improve the quality of life indicators.

Pakistan is one of the signatories to the SDGs, and its population is beset with many of the health problems mentioned above. Its human development indicators are poor, and expenditure on health is minimal. Like the global scenario, the achievement of health-related SDGs is critically linked with the performance of the pharmaceutical industry. In this respect, the pharmaceutical industry in Pakistan has the potential to cater to the requirements and challenges posed by SDGs. It has the required infrastructure, dynamism, quality, human resources and the experience to provide quality drugs that can improve Pakistan's health related outcomes. However, achievement of health-related SDGs, and pharmaceutical industry's active participation in it, would be critically dependent upon surmounting the road blocks that have impeded its development in Pakistan. Specifically, a lot would depend upon how government led regulations and the aspirations of the pharmaceutical industry find a common ground. Once this happens, it will be much easier for the industry to be part of official efforts to achieve the SDGs, and improve overall wellbeing of Pakistani citizens.

Other than the SDGs, the pharmaceutical industry in Pakistan is well set to offer quality products at competitive rates. Its top 100 firms, specifically, can compete with the best in the region in terms of products. It's a competitive industry that has seen healthy returns (on average), and has the potential to do even better if some of the outstanding issues facing the industry can be resolved.

Overview

At the time of independence in 1947, there were no pharmaceutical firms in Pakistan. Today, the country boasts more than 700 pharmaceutical manufacturing units. In fact, QuintileIMS in its latest quarterly report¹ puts the 'Active Manufacturers' at 759, up from a total of 304 in 1999. However, official sources dispute this figure, contending that there are no more than 650 licensed manufacturers in Pakistani pharmaceutical industry². This indicates a wide gulf between industry and the government that is characteristic of the pharmaceutical landscape in Pakistan. Taking the QuintileIMS figure as a reference point, only 27 are Multi-National Corporations (MNCs) while Pakistani firms account for 645 of the total³. The generally accepted figure of MNCs, though, is 17 or 18⁴, down from 40 or more in the 1990s.

There is also a difference in the reported total number of 'active' plants, especially those operated by MNCs. According to a MNC representative; there are hardly 5 or 6 of them that are actively producing pharmaceutical products. Similar reservations can be found about the number of active plants of domestic firms. Industry insiders are apprehensive that all the licensed manufacturing plants are utilizing their production capacity and actively producing products. The 1999 IMS report concluded that out of the 274 plants operated by domestic pharmaceutical manufacturers, only 120 were involved actively in manufacturing. Many of these were operating at only one-third of their total production capacity.

The growth of the pharmaceutical manufacturing plants is reflected in the table given below.

TABLE 1: NUMBER OF PHARMACEUTICAL FIRMS IN PAKISTAN (ESTIMATES BY IMS)

Year	No. of Pharmaceutical Firms
1999	304
2007	406
2017	759

Pharmaceutical companies are geographically spread all over Pakistan. Pharmaceutical production units in provinces tend to concentrate in major cities like Karachi, Lahore and Peshawar. Although the numbers reflect that majority of firms are in the province of Punjab, but in terms of production, capacity utilization, volume and size of business, Karachi leads the way as far as pharmaceutical firms are concerned. The following table gives the number of pharmaceutical establishments by province.

¹ QuintileIMS Q1 2017 Report

² Information provided by Licensing section of Drug Regulatory Authority (DRAP)

³ QuintileIMS Q1 2017 Report

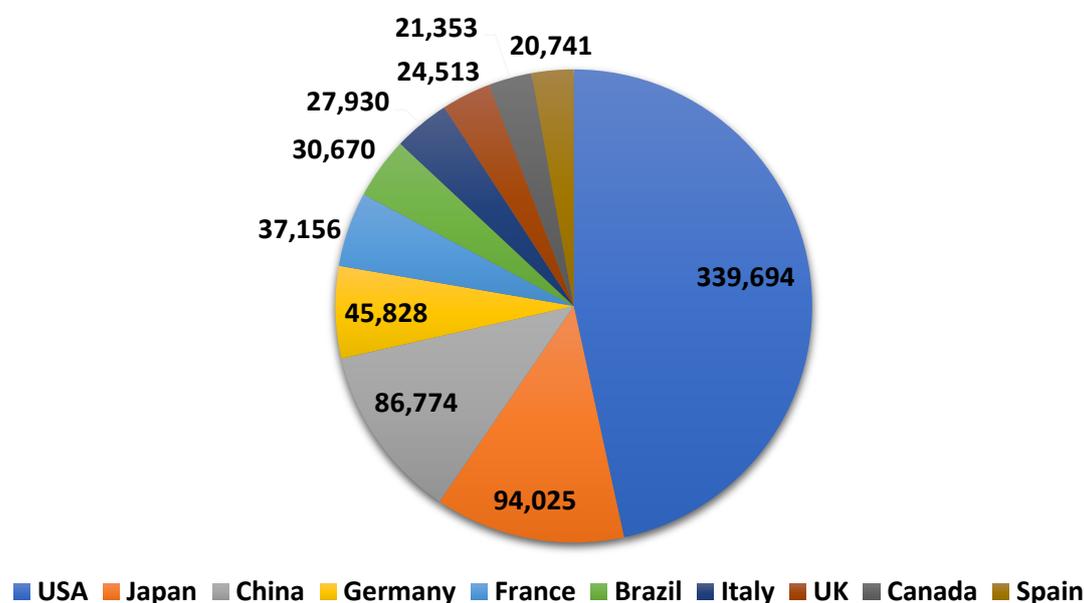
⁴ See 'Problems faced by Pakistan's pharma industry', BR, 6th January 2017.

TABLE 2: NUMBER OF PHARMACEUTICAL FIRMS BY PROVINCE

Province/ Area	1999	2017 ⁵	2017 ⁶
Punjab	160	370	440
Sindh	101	163	183
KP	32	98	114
Baluchistan	2	13	15
AJK	9	6	7
Total	304	650	759

In terms of monetary value, the size of the pharmaceutical industry in Pakistan is \$3.10 billion (Rs. 325, 596 billion, as per IMS). Given that the total size of the global pharmaceutical market is estimated to be over \$ 1 trillion, Pakistan is hardly 0.5 percent of the market. A snapshot of the global market for pharmaceutical market, its value and distribution by country wise share is given in the following graph.

FIGURE 1: VALUE OF PHARMACEUTICAL MARKET (\$MILLION)



⁵ As per Drug Regulatory Authority of Pakistan (DRAP)

⁶ Per QuintileIMS figures. Notice that distribution is based upon relative percentages (by provinces) calculated from 2015 official figures of manufacturers. QuintileIMS data also does not contain the distribution of manufacturers by province.

Within the Pakistani market, however, the sale of the pharmaceutical products has seen a healthy growth over time. Between 2012 and 2017, for example, the Compounded Annual Growth Rate (CAGR) has been estimated to be around 10 to 12 percent⁷. Within this growth, the percentage growth numbers of domestic firms and MNCs vary, but overall, the industry has seen a healthy growth rate over time, although the CAGR in the last 5 years (on average) has been falling.

Although there are no agreed upon estimates, the industry employs around 90,000 people directly and 150,000 people indirectly in various capacities. The employee turnover rate, at least for the top 100 firms, is low. The main reason is that the top-level firms are known to offer reasonable pay packages plus complementary facilities, which help in retaining their staff⁸. Plus, trainings and other extracurricular activities are offered regularly to train, retain and enhance their capabilities.

The above-mentioned aspects of the pharmaceutical industry are normally found in related news and research, but two laudable aspects of this industry rarely get a mention. Top pharmaceutical firms run an impressive array of charitable institutions and initiatives from their own resources that concentrate on socio economic wellbeing of the citizens through work in fields such as education and health. Also, pharmaceutical firms in Pakistan contribute substantial tax revenue to the government kitty. Put another way, the growth of the industry represents a win-win situation for the government since not only do they contribute to socio-economic wellbeing of citizens without any government support, but also fill the government coffers with much needed tax revenue.

Resource Base

Pharmaceutical manufacturers in Pakistan have a set resource base whereby access to resources for doing business is relatively easier. This is despite the fact that almost 95 percent of the raw material for manufacturing drugs has to be imported, and only 5 percent requirement is met domestically. The government has taken steps to make it easier for the manufacturers to import raw material by progressively slashing duties on imported raw material over time. The recently announced budget proposes to cut duties further, a move welcomed by the industry.

Major Drivers of Expansion

It has been stated above that the growth rate of sales over time of pharmaceutical companies (reflected by CAGR) has been healthy. But what drives this significant growth in sales? Is it the growth in population (one of the highest in the world), disease burden, innovation in drugs, good marketing skills, or drug over-prescription by doctors? Opinions are divided with regards to this question. These opinions are summarized as follows.

Innovation through research⁹, which could lead to discovery and introduction of new drugs, is an unlikely factor since there is no research taking place in the Pakistani pharmaceutical sector.

⁷ Estimates and calculations by IMS, and industry sources

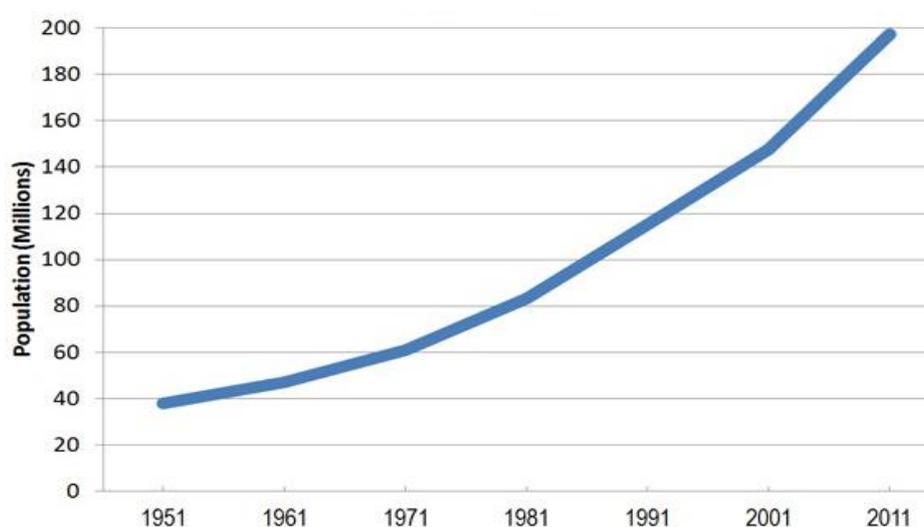
⁸ Pharmaceutical industry sources

⁹ Aspects related to Research & Development (R&D) are to be discussed under a separate heading later in the document.

Out of the 1,465 active molecules used in manufacturing drugs in Pakistan¹⁰, none of the molecules is the outcome of research in the Pakistani pharmaceutical sector. The industry is basically working on the research carried out on New Chemical Entities (NCE) around the globe, thereby manufacturing drugs based on research done elsewhere.

Next, we consider increase in population as the driving force behind the increase in sales of drugs in Pakistan. It is generally agreed that this factor one of the major driving force behind drug sales in Pakistan, which has historically had one of the highest population growth rates in the world, and that trend still continues¹¹. This is reflected in the diagram below, which shows growth in Pakistan's population over the decades.

FIGURE 2: PAKISTAN POPULATION BY DECADE (1951 – 2011)



As per the estimates by various organizations like United Nations (UN), Pakistan's population is set to touch 250 million people by 2030, and 300 million by 2045¹². This growth in population is complemented by the lack of a viable and productive health infrastructure given that the Pakistani government, as a percentage of GDP, spends hardly 1 percent on health¹³. An indirect implication is that the government investment on health per capita is one of the lowest in the world and in the South Asian region. This in turn helps propel the increase in the prevalence, length, severity and burden of disease.

Other factors like environmental changes are also predicted to increase this burden in the coming years¹⁴. Combine all this, and the inescapable fact is that higher population would induce more demand for drugs. That is at least theoretically how the higher demand of drugs can be linked with population growth. For experts, though, this is not an ideal case since growth should be

¹⁰ QuintileIMS Q1 2017 Report

¹¹ This is despite the fact that the Total Fertility Rate (TFR) has seen a drop from 7 in 1960s to 3 at present. But this drop is slower compared to the drop witnessed around the globe and in the region. Source: World Bank databank for Pakistan.

¹² Based on projections by global organizations like the UN and government statistics.

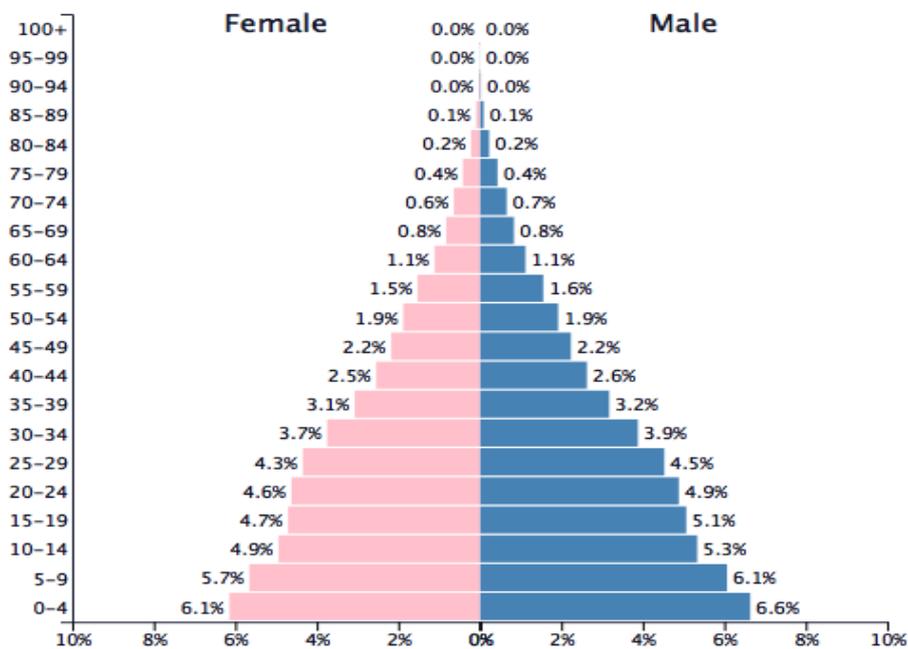
¹³ It should be noticed that a large chunk of this puny expenditure goes towards 'current expenditures', i-e, monthly wages, maintenance costs, etc. Source: Pakistan Economic Survey (various editions), and World Bank.

¹⁴ 'Climate change increasing Pakistan's disease burden', 11th May 2015, Pakistan Today.

related to other factors and not just population. Take the example of Jordan, which is a country of only 7.59 million people. Yet it manages to export \$951 million worth of pharmaceutical products¹⁵ owing to factors other than population (research, value chains, trade agreements, etc.), and has a strong domestic market.

There are, however, those who disagree that population is the driver of growth for the pharmaceutical industry. They point out that major portion of the Pakistani population (60 percent) consists of young people¹⁶, a fact reflected in the graph representing pyramidal distribution of Pakistan’s population.

FIGURE 3: PAKISTAN'S POPULATION DISTRIBUTION



Young people do not consume a large quantity of medicines, and therefore it is difficult to accept that population growth is the major driver of the consumption of drugs in Pakistan. However, the point that younger population consumes fewer drugs is anecdotal and lacks research and data to back up the claim. The contention that younger people’s consumption of drugs is lower compared to older people, although accepted in general, needs to be backed up by verifiable data. In Pakistan, such data is hard to come by.

The most important factor which has driven sales of drugs, according to experts, is the growth of income over time (reflected by the growth in per capita income). The growth in per capita income, in turn, has provided people with access to better drugs and healthcare facilities. This

¹⁵ Interview with industry officials, confirmed by numbers available on the net.

¹⁶ ‘Youth Bulge: Pakistan must leverage its young population’, Express Tribune, 6th April 2017.

increased access is, in turn, reflected in the increase in life expectancy over time. The growth in per capita income and life expectancy is stated in the following tables.

TABLE 3: LIFE EXPECTANCY IN PAKISTAN

Year	Life Expectancy (Years)
1960	45
1970	53
1980	57
1990	60
2000	63
2010	65
2015	68

TABLE 4: INCREASE IN PAKISTAN'S PER CAPITA INCOME

Year	Per Capita Income (\$)
2000	503
2005	847
2011	1,254
2013	1,380
2015	1,460
2016	1,531
2017	1,629

And the increase in per capita income is set to continue as growth picks up momentum. The Economic Survey 2016-17 put the figure at \$1,629. With the increase in per capita income, we can expect increase in access to quality healthcare and increase in use of drugs¹⁷.

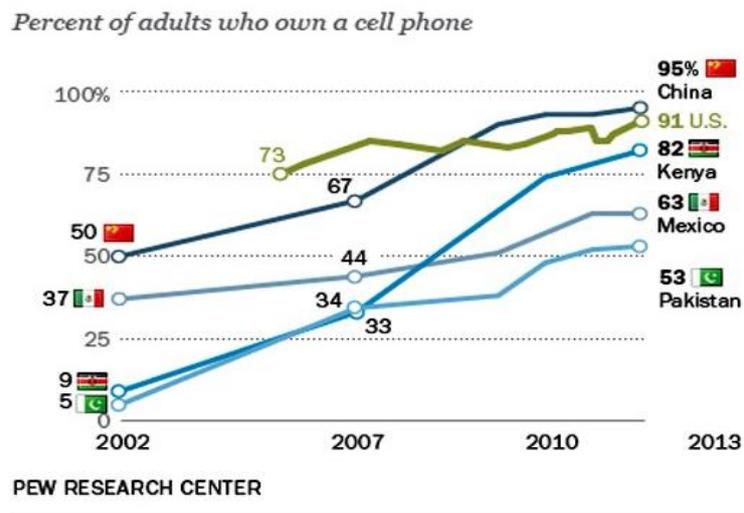
The growth, spread and access to various forms of media has also underpinned the increase in the sale of drugs in Pakistan. Although Television remains the most used and watched media platform in Pakistan, the growth of mobile phone usage and increase in media access through it has been even more impressive. In 2014, Gallup Pakistan reported that almost two-thirds of the adult population in Pakistan watches TV frequently¹⁸. Although the access to TV has been steadily increasing over time, the exponential rise in the use of cell phones has been phenomenal. Research conducted by the Pew Research Centre revealed that the percentage of people using cell phones in Pakistan rose from a paltry 5 percent in 2000 to a phenomenal 53 percent of the population in 2013¹⁹. Even though this is the lowest amongst countries like USA, Mexico, China and Kenya, the trend is shows sharp increase over time.

¹⁷ The numbers in Table 3 and 4 have been taken from World Bank statistics and various editions of Economic Survey plus independent estimates.

¹⁸ Gallup Pakistan Survey (2014) question on 'Contemporary media use in Pakistan'

¹⁹ 'The rise of mobile and social media use in Pakistan', DAWN, 10th April 2015.

FIGURE 4: SHARP RISE OF CELL PHONE OWNERSHIP IN SELECT COUNTRIES



What this tremendous growth in access to, and use of, mobiles and internet has done is that it has made consumer more conscious of their health needs. Moreover, it has also sought to turn them away from non-allopathic towards the use of allopathic medicines, a factor in the rise of sales of allopathic drugs.

Marketing practices and over-prescription of drugs by doctors are the two other factors typically mentioned in this equation. The common belief is that these two are closely related, although this belief is not shared universally. For example, one study²⁰ found that the relationship is significant. Close relations between doctors and pharmaceutical manufacturers for drug marketing falls under the category of ethical considerations, to be covered in a later section. A recent addition to the marketing category has been the fast expanding online retail business. Pakistan's pharmaceutical industry is yet to catch onto this trend since the online business is still in its infancy. Websites like 'Dawaii.pk', that guarantees delivery of quality medicines, are exceptions rather than the norm.

*Increase in per capita income over time is a major driver for
Pharmaceutical Industrial growth*

Another factor, that is usually not considered important or ignored all together, is the rate of self-prescription or self-medication by individuals. Abdul Haseeb and Muhammad Bilal estimated the use of drugs through self-prescription in rural areas by taking a sample of 595 people. A staggering amount of 85 percent people in the sample turned out to be using this method²¹. And this phenomenon is not limited to the rural areas only where there is a critical lack of basic health facilities and qualified physicians. In urban areas, research suggests that self-medication and self-prescription is quite prevalent. For example, Mahmud Ahmad Akhtar cites a study in his

²⁰ 'The impact of doctor-pharma relationships on prescribing practices', by Imran Asif and Shehzad Amin.

²¹ 'Prevalence of using non-prescribed medications in economically deprived rural populations of Pakistan'.

research²² about university students in Karachi. The self-medication rate in this stratum was as high as 76 percent. Thus, not only is this a driving factor in drug sales in rural areas but also in urban areas.

The above was a brief description of the factors driving drug sales in Pakistan. Some, like per capita income, are considered major factors while others like increase in self-medication are minor factors that drive the sale of drugs.

Drivers of Future Growth

One of the likely candidate is growth in population. The global population is expected to reach 9.7 billion in 2050²³, and a substantial portion of this population is expected to be middle or older aged people. The proportion of people above 60-year-old by 2050 is expected to triple. Their consumption of medicines and healthcare facilities tends to be considerably higher than the younger population. This projected aging of future population is supposed to be true for countries like India and Pakistan, where the youth bulge is expected to plateau in the coming years, giving way to increase in proportion of older people. Moreover, the fact that life expectancy is also expected to increase globally implies that consumption of drugs would be higher than the present level.

Another major factor would be increase in per capita income driven by higher growth rates in the future, which would allow more people to afford health facilities and allow access to quality drugs. Besides these primary factors, there are factors like marketing that will probably play a secondary role.

The Business Environment

Structure of the Industry:

A mere look at the numbers suggests that Pakistan's pharmaceutical industry represents a highly competitive environment in which 759 manufacturing units are competing for a share in the more than Rs. 300 billion market. This impression was confirmed during interviews with various stakeholders related the pharmaceutical industry. The industry may be highly competitive, but it also tends to mask the highly skewed distribution of earnings and market shares within this industry. The top 50 firms have 89 percent market share, while the top 100 have almost 97 percent of the market share²⁴. When it comes to market share comparison between MNCs and local firms, the distribution ratio is roughly 40:60 in favor of local firms, a reversal from the earlier trends whereby it was MNCs that used to hold the major share. But their gradual exodus has led to local firms capturing the larger share. A particular feature of the local companies is that only a few are listed on the stock market.

This distribution of market share raises an intriguing question: if 97 percent of the market share is being captured by the top 100 firms, how do the remaining 659 manufacturing units survive?

²² 'Self-Medication'

²³ 'World population projected to reach 9.7 billion by 2050' (2015), United Nations Department of Economic and Social Affairs.

²⁴ Interview with industry officials, research and QunitileIMS Q1 2017 report

Converting the question into numbers, it implies that more than 600 pharmaceutical firms are competing for a meager share of Rs. 10 billion²⁵ (or Rs. 0.016 billion per firm). It is hard to imagine that this much income would be a strong enough incentive for new entrants to enter the pharmaceutical market. Still there has been growth in the overall industry.

One reason for this is that many of these firms do not produce to cater to the local demand. Rather, they produce drugs to export to neighboring countries like Afghanistan²⁶. This is especially believed to be true of firms operating in towns like Peshawar (Khyber Pakhtunkhwa) that is in proximity to the Afghan border (and established connections that spawn decades of trade) make it easier to get medicines through the border²⁷. Given their comparative advantage, they also facilitate exports of drugs of pharmaceutical firms all over Pakistan that send their products to Afghanistan (and to other markets from there).

Another theory to explain this is based on asymmetries in information and irrational exuberance on part of potential investors. It contends that potential investors are swayed by the top line (the annual earning percentages) of the industry, which gives

*Top 100 firms have 97 per cent
of market share*

them a faulty impression that the earning probabilities are same for all firms (while ignoring factors like skewed distribution of earnings, etc.). This leads them into the pharmaceutical industry, only to realize later that their estimates were wrong. Resultantly, their production capacities remain underutilized, and they only produce to the extent to just scrape. Some opine that these smaller firms survive on outsourcing by top firms and toll manufacturing. Others survive by selling expensive raw material used in the process of manufacturing drugs.

The Decline of MNCs

MNCs are the leaders in the field of research as far as NCEs are concerned, and invest considerable capital in Research and Development (R&D). It is well recognized that this in turn has positive 'spillover' effects. For example, knowledge spillovers within an industry due to presence of leading firms tend to benefit all.

The first MNC came to Pakistan in 1951. By 1954, the number had increased to 9. The numbers grew until 1990s, after which a decline started to set in. Their relative market share and their numbers have witnessed a gradual descent. The number of MNCs has now shrunk from 40 to 17, although industry insiders maintain that only 6 to 7 are actively engaged in producing drugs. Others have either divested away from manufacturing drugs or outsourced production or broken down their operations into smaller (local) units.

One reason for this decline is that MNCs were either lax or could not keep up pace with local developments that affected their business. One such development was the increase in medical reps that resulted in more choice for the doctors in terms of prescribing medicine. The local

²⁵ Total percentage of market share by these firms multiplied by total market size

²⁶ Government officials widely subscribe to this theory

²⁷ 'Killing, not curing: Deadly boom in counterfeit medicines in Afghanistan', *theguardian*, 7th January 2015.

firms, as they started to gain more market share, started offering competitive pay packages that resulted in human capital migrating to top local firms. Some observers, however, put it the other way around. Local firms, they contend, were forced to offer good pay packages and other incentives in order to be competitive. Also, the firms buying up operations of MNCs that left Pakistan had to maintain the same level of remuneration and compensation in order to achieve quality levels equivalent to that of MNCs.

Another oft cited reason has to do with government regulation regarding pricing. The government, for many years, had been following the policy of 'price freeze', whereby prices of medicines remained frozen at a particular level for some time. The last price freeze went into effect in 2001, and remained intact till 2013. This policy, among other things, meant that firms could not increase the price of their medicines despite substantial increase in the cost of production. For MNC's, additional cost pressure comes in the form of maintaining a certain level of quality as per their own high standards. But given policies like centrally administered prices, this proved unsustainable since not only were there lesser Returns on Investment (ROI), but profit repatriation also suffered. This led the MNCs to look to other places like Bangladesh, where regulations are less stifling and cost of production is lower.

The number of MNCs has shrunk from 40 to 17

Two other factors that are cited for the gradual decline of MNCs are the lack of Intellectual Property (IP) rights enforcement and tough competition from the local firms. The lax implementation of IP laws meant that generic substitutes and copies having different brand names printed on them appear quickly in the market,

with little oversight. Moreover, local pharmaceutical manufacturers have improved leaps and bounds in terms of quality and variety in drug manufacturing, thereby giving a very tough time to the MNCs. These all combined to make life difficult for them, and explains to a large extent the decline in their presence over time.

There are many within the industry who feel that this exodus needs to be halted and steps need to be taken to encourage the presence of MNCs in Pakistan. They offer certain advantages that local firms don't. For example, MNCs have been known to train their staff in high quality institutions around the world, in turn having a positive effect upon human capacity and quality within the industry.

Government Procurements

Procurements by the government sector are a substantial part of the overall sale of drugs in Pakistan. Estimates suggest that in developing countries like Pakistan, at least one third of the population is dependent upon access to needed drugs through the government sector²⁸, while the rest is provided by the private sector.

The National Drug Policy of 1997 promotes the use of medicines designated in the essential drugs list by giving mandate to government and semi-government health organizations to procure medicines in bulk. The policy seemed in consonance with the populist aim of providing

²⁸ For example, see State Bank of Pakistan (SBP), Annual report 2008-09, p.234.

drugs at affordable prices to the public. During interviews, government officials were adamant in terming this policy a success by asserting that pharmaceutical companies sell to the government at lower prices compared to the one prevalent in the market²⁹. Yet, this should not be surprising since this practice is prevalent all around the globe.

No concise figures, though, are publicly available on the total percentage of the health budget spent on buying medicines for government run facilities, both at the federal and the provincial level. The National Health Account 2013-14 mentions the figure (federal plus provincial) as Rs. 362 million³⁰, but this amount is portrayed as lump sum under the head 'Medical products, Appliances and Equipment' and gives no distribution of expenditures by category. Therefore, one cannot tell how much is spent on buying drugs. However, one source with knowledge of this issue put the figure at 15 percent of total health expenditure³¹.

Investment

For a country like Pakistan, which has one of the highest population growth rates in the world along with one of the lowest access to quality healthcare, investment in pharmaceutical industry (foreign and domestic) should have been substantial. This is especially true of foreign companies that are always on the lookout for growing markets like Pakistan, where there is not only a substantial demand for pharmaceutical products but where the pharmaceutical industry setup offers additional advantages like lower wages. Demand and lower wages are influential factors in explaining the rise of pharmaceutical markets like that of India. Unfortunately, in Pakistan, investment (especially foreign) has taken a nosedive over the years.

In 2002, the Foreign Direct Investment (FDI) in the Pakistani pharmaceutical sector was \$7.2 million. By 2008, this number increased to \$46.5 million. By the end of 2012, this number dropped to \$3 million³². By 2014, it recovered somewhat to \$15.7 million, but actually went down to negative in 2015 after which it rose up to only \$3.3 million in 2016³³ (Figure 5). Worryingly, with little or no FDI coming in, the Pakistani pharmaceutical sector continues to witness profit repatriation. In 2014, the repatriation was equivalent to \$36.7 million, while in 2016 it was \$35.6 million³⁴, implying that nothing is being re-invested. Therefore, not only is Pakistan losing foreign reserves, but almost nothing is coming in.

²⁹ However, no public information exists concerning the companies that sell to the government.

³⁰ See Table 5 of the report.

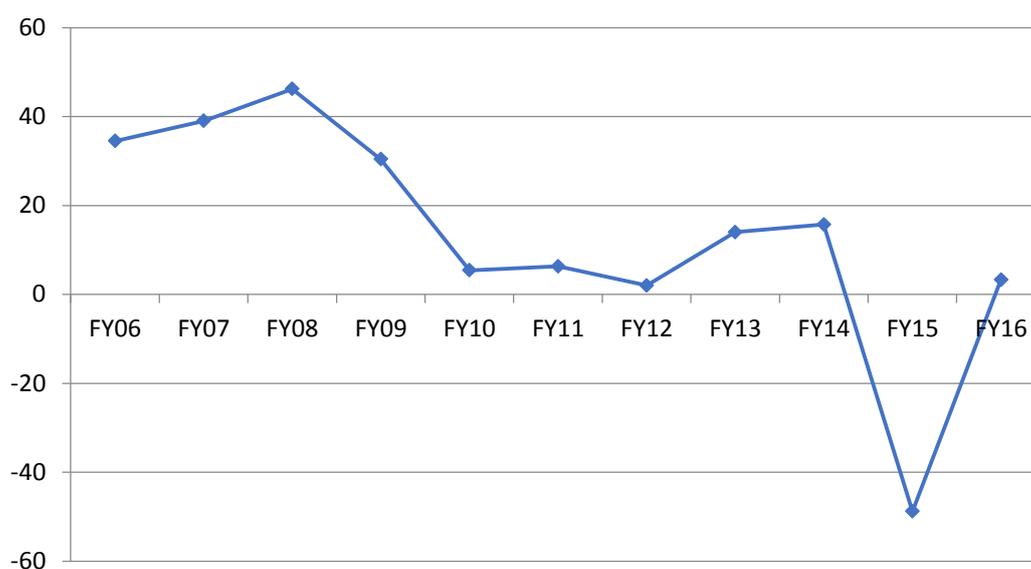
³¹ Interview with respected Abdul Haseeb Khan, ex-Senator. It is to be noted here that procurements are categorized under the 'development' head of health expenditures rather than as a whole.

³² Figures taken from SBP's 'Net Inflow of FDI by economic group till FY 12'.

³³ See Table 9.10 of the Statistical Appendix, SBP Annual Report for 2015-16, under the heading 'External Sector'.

³⁴ See SBP Annual Report for 2015-16, p.79, table 6.4.

FIGURE 5: FDI (\$MILLION) FY06 - FY16



Source: SBP

This state of affairs is also reflected in the dwindling numbers of MNCs. These issues were noted by the State Bank of Pakistan (SBP) Annual report 2015-16, which showed concern over the continued divestment in this sector³⁵. Estimates of domestic investment are hard to come by. As per estimates by Nasir Chaudhry³⁶, the domestic investment in 2014 was equivalent to \$ 500 million. However, no distribution of the investment (merger, takeover, new plant and equipment, etc.) is publicly available. We can only conclude that the growth in the number of firms to a total of 759 is indicative of investment over time.

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

³⁵ See last paragraph on p. 75 of the said report.

³⁶ 'Growth challenges of pharmaceutical industry in Pakistan' (2014), Nasir Chaudhry.

Technology, Research and Development

Technology adaption and use

Pakistani pharmaceutical firms, at least the top 50, are apt at adapting and using new technology. As per industry experts, part of this is explained by the obligation to adhere to Good Manufacturing Practices (GMP), which the firms have to comply with to stay at the top. These firms continuously strive to have the latest equipment at their disposal since there is realization of importance of technology, thereby not only meeting GMP requirements but also helping them to have latest production technology at their disposal. These, in turn, help achieve more economies of scale and impart productivity gains. But not all firms are good at this aspect. It's only the top-level firms that are keen to make use of new technology. At the lower end of the spectrum, there are many firms that are known to use older machinery and technology for production.

Importance of Research & Development (R&D)

R&D is a big part of the pharmaceutical industry. Pharmaceutical firms all over the world spend a hefty \$ 141 billion yearly on R&D related activities³⁷. Research into NCEs is a long, arduous, complex, challenging and risky venture. Generally, the time between first synthesis of a new product and of the product making it to the market (if it passes all the trials) is 12-13 years.

Aside from the length, the cost is considerable. An estimate by DiMasi and colleagues³⁸ stated that it takes \$ 2,558 million just to develop a new chemical or biological entity. 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 product³⁹. 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.

Only two out of 10,000 substances pass all the phases of trial and development before it finally becomes a marketable product

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 welfare⁴⁰. This can be gauged by looking at 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.

³⁷ This is the 2015 estimate. See Schumacher, Hinder and Gassmann, 'Changing R&D models in research based pharmaceutical companies', Journal of transnational medicine, April 2016.

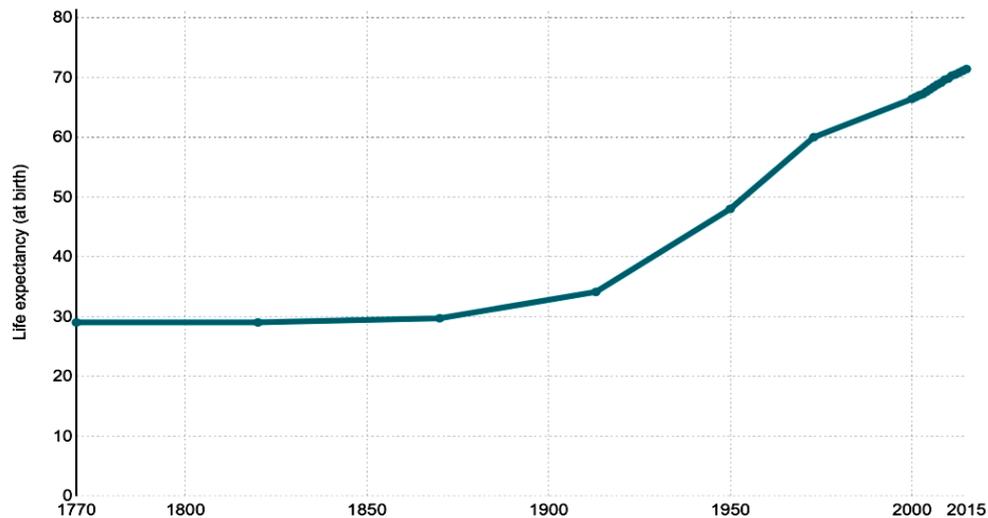
³⁸ Di Masi et.al, Journal of Health Economics, January 2016.

³⁹ 'The pharmaceutical industry in figures' (2016), European Federation of Pharmaceutical Industries and Associations.

⁴⁰ 'The pharmaceutical innovation platform' (2004), WHO.

These and other such numbers present a considerable achievement in which new medicines, the result of R&D, had a large role to play. The following graph⁴¹, which shows the increase in life expectancy, is illustrative of this fact:

FIGURE 6: LIFE EXPECTANCY GLOBALLY SINCE 1770



Source: Life expectancy – James Riley for data 1990 and earlier; WHO and World Bank for later data (by Max Roser) OurWorldInData.org/life-expectancy/ • CC BY-SA

By ensuring a healthier population, a country can realize a healthy workforce that enables them to earn well and contribute towards economic development. The monetary benefits of having better access to better drugs through innovation have been long established. For example, G. Milne estimated the potential economic benefits from innovation in areas of cancer, diabetes, ulcer and schizophrenia running into billions of dollars⁴². For pharmaceutical companies around the world, research into new molecules and drugs is a given. Without research, there would not be any advances in medical sciences and nor in producing new drugs. In 2016, an estimated \$154 billion were spent by pharmaceutical companies for the purpose of R&D. This amount is projected to go up to \$182 billion by 2022⁴³.

In short, advances in human welfare and human development are positively linked with R&D in the pharmaceutical sector. Therefore, it would be instructive to analyze R&D in the Pakistani pharmaceutical industry.

R&D in the Pakistani Pharmaceutical Industry

In Pakistan, the 1976 Act obligates the pharmaceutical companies to pay one percent of their gross profits to the government for conducting R&D. This charge has been collected since the passage of the said Act, but there is no data to show the realized total amount accruing over time into the government account, how much has been utilized, and what impact did it have on drug related R&D in the country.

⁴¹ Taken from our world in data.

⁴² 'The pharmaceutical innovation platform' (2004), WHO. See Box-2, page 17.

⁴³ 'Total global R&D spending from 2008 to 2022', STATISTA.

Independent analysts, however, contend that research in Pakistan's pharmaceutical sector is non-existent or very little to make any impact⁴⁴ and there is only 'development' in the form of packaging, coding, and similar activities. This impression was confirmed during interview with the industry officials, who point out that government already collects a tax in the name of R&D so it is not their obligation to indulge in it. Government officials, on their part, openly admit to the utter failure of this policy. The amount collected in the name of R&D is in billions of rupees, and is lying in the accounts of the health ministry. Yet the government is just clueless when it comes to using this amount and lacks the human capital to properly invest in pharmaceutical research⁴⁵.

This seems a very surprising stance since Pakistan, for example, lacks even a single Federal Drug Authority (FDA) or WHO standard lab, considered a prerequisite for quality assurance. It's not too hard to fathom that setting up such plants would be an initiative that merits expenditure by the health ministry, which has billions of unutilized rupees lying in their account. Yet there is no such development. Surely, this failure to utilize funds should be reason enough to repeal this tax and instead leave it to pharmaceutical firms to carry out research. Government, at best, can monitor these expenditures to ensure that research is taking place.

*Pakistan lacks even a single
FDA or WHO standard lab*

Other factors, beside the government led policies, also hinder any move towards pharmaceutical research. Firms usually incur a hefty amount in terms of developing a new drug or molecule, then introducing and marketing it. It takes considerable time to recoup the development costs and to make a healthy profit on the drug. However, if the drug can easily be copied and sold without any checks, there is little incentive to indulge in research. Moreover, if the government forces price upon a manufacturer rather than manufacturer's charging a market price, it usually implies a loss. In Pakistan, government has long practiced the policy of forcing prices (of essential drugs) upon the producers. Therefore, it is not surprising that there is little or no investment in research. There are many within the industry who feel that basic research is not possible (given the prohibitive cost), and more importantly, not needed. Ideally, they contend, Pakistani pharmaceutical industry should just improvise upon outside research and instead concentrate on (for example) bioequivalence related research.

For a country like Pakistan, the probable economic benefits of research into new drugs could be substantial. It could help them save billions of rupees in annual expenditures on treatment of diseases through innovation in new, more effective drugs. But firms in Pakistan remain dependent upon the research done elsewhere, and the access to quality drugs remains a problem. There is no estimate of the probable socio-economic cost of not having research in this sector, but what we do know is that government and its regulation is largely responsible for this state of affairs.

⁴⁴'Politics of medicine pricing', by Hassan Mansoor, NEWS, 16th October 2016.

⁴⁵ Interview with government officials.

Emerging Global Trends and the Pakistani Pharmaceutical Industry

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 as firms like Pfizer bought off other companies⁴⁶.

Pakistan's Pharmaceutical Industry development not in line with global trend

Activities like 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 (in the form of new products that could recoup costs of research) 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 substantial⁴⁷.

When it comes to the Pakistani pharmaceutical industry, except for mergers and acquisitions, it cannot be counted in terms of other developments mentioned above. Mergers and acquisitions are likely to pick up pace in the future as the top 100 firms consolidate their position further. Industry officials admitted in their interviews that there will be more concentration of the top firms in the future as smaller level firms would find it hard to stay afloat in an increasingly competitive environment, where the costs of production are highly unlikely to come down. Given that there is less likelihood of regulators and industry officials reconciling their differences, the ease of doing business is unlikely to improve. As pointed above, many MNCs have left Pakistan due to these kinds of problems. Their operations, not surprisingly, have been overtaken by local firms.

The previous section clearly reflected the woeful state of affairs as far as research is concerned, and there is no indication from either the government or the industry that things on this front will change. Government seems unlikely to repeal the enforced tax in the name of research, and industry officials are unwilling to spare any money for this purpose, arguing that they are fulfilling their obligation by giving money to the government for research. Therefore, it is the government's job to carry out and incentivize it, which they have not done over all these years. In the future, therefore, the possible expansion of Pakistani pharmaceutical market is going to be driven not by research priorities or new products, but by economies of scale in production and making use of outside research to come up with generic substitutes.

⁴⁶ 'The pharmaceutical industry and future of drug development' (2015), David Taylor.

⁴⁷ 'Rare disease, cancer drugs will drive pharma M&A's growth', Anjali Shukla.

Government and the Pharmaceutical Industry – A Brief Overview⁴⁸

Before the advent of Pakistan, the major Act that governed the pharmaceutical industry in the sub-continent was the Drug Act of 1940. This act set out comprehensive regulations regarding the different facets of the pharmaceutical industry, unlike the previous acts⁴⁹ which were mainly concentrated on preventing and regulating the use of dangerous drugs. This Act remained the primary regulation tool even after the establishment of Pakistan (with minor additions), till the enforcement of Drug Act of 1976. In between, there were complementing legislations like the Pharmacy Act of 1967, but these tended to cover only specific areas rather than the pharmaceutical sector as a whole⁵⁰.

In 1972, the Generic Drugs Act was passed which was later annulled and replaced by the 1976 Act. From 1976 to 2012, the Act of 1976 remained the primary document for regulating the pharmaceutical sector. It was complemented over time by legislations like Northern Areas Drug Rules of 1996 and Drug Act of 1997. In 2012, the Drug Act of 2012 replaced the Drug Act of 1976. It is basically an extension of the 1976 Act. At present, it is the primary means of regulating pharmaceutical industry, with Drug Regulatory Authority of Pakistan (DRAP) administering the regulations.

The present regulatory environment is characterized by a centrally led regulation agency: DRAP

The process of making regulations, however, can be cumbersome and lengthy. Take the 2012 Act as an example. It was conceived in 2005⁵¹, but kept dragging on till finally being implemented in 2012. It was enforced only after the Supreme Court took notice of deaths caused by sub-standard medicines.

Industry representatives are not happy with the way things have progressed on regulations over the years, specifically the failure to take their demands into perspective. Honorable Mr. Abdul Haseeb Khan is a former Senator. He was also a leading member of the 7-member committee (comprising of Senators) tasked with designing the 2012 Act. He recalls that their cumbersome work, based on 18 meetings, resulted in a draft that proposed the appointment of a professional person at the helm of regulatory affairs. To his astonishment, and of others, when the final draft reached the Prime Minister (PM) for approval, their recommendation for an expert to head the regulations was replaced by proposal to place Secretary Health⁵² at the helm of

⁴⁸ A detailed discussion of regulations and its outcomes can be found in PRIME Institute's study on Pharmaceutical Regulation (unpublished draft).

⁴⁹ For example, 'The Poison Act, 1909' and 'Dangerous Drug Act, 1930'.

⁵⁰ For example, the Pharmacy Act of 1967 was exclusively concentrated on ensuing quality qualification of the pharmacist.

⁵¹ 'The drug debacle- A way forward', by Dr. Sania Nishtar, Heart File Policy Brief No. 132.

⁵² Interview with respected Senator Abdul Haseeb, May 2017.

affairs. This is just one example of the reasons that explain the considerable gulf between the government machinery and the industry.

The present regulatory environment is characterized by a centrally led regulation agency, the DRAP, which works under the Federal Health Ministry. Thus, the experiment of devolving health related issues that began with the passing of the 18th Amendment, whereby powers were devolved to the provinces for enacting regulations, ended with the formation of DRAP. Major aspects of regulations, like pricing and licensing, are the domain of the DRAP, while provinces have the authority to deal with the minor aspects like distribution and sale of medicines.

The pace of changing pharmaceutical related regulations at the provincial level mirrors the generally sluggish pace witnessed over the years at the federal level. The Punjab government and the Khyber Pakhtunkhwa government recently announced changes to their rules that were enacted in 1976 and 1982 respectively. The results and the reaction, however, could vary from province to province. Punjab's proposed amendments to its drug laws invited stern opposition from drug sellers and chemists, who took to the street in agitation⁵³. Changes in law in both the provinces are basically aimed at regulating sale of medicines in order to ensure quality, ensuring the presence of qualified chemists at every retail outlet, outlawing herbal medicine sales, and ensuring the presence of refrigerators/cooling equipment for the drugs, etc.

Industry's Point of View

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 months⁵⁴. Hence, given the state of affairs, many industrialists shared their plans to leave the business altogether and invest in some sector which offers better returns. It is not as if the industry is against regulations. In fact, they believe that regulations are necessary and critical for the pharmaceutical sector. But the regulations should be such, they contend, that it should help the industry thrive rather than prove to be a detriment.

The Industry wants a collaborative effort instead of a top down approach

In Pakistan regulations have followed the typical bureaucratic top down approach, without much input from the industry. The incidence of changing the draft for DRAP, prepared after meticulous work by ex-Senator Abdul Haseeb Khan and his colleagues, has been shared in one of the above sections. It contained inputs from the industry, yet it was changed at the last minute. This top down approach, without any consultation with the industry officials, has hurt the industry's growth.

⁵³ See 'Pharmacies observe strike across Punjab', DAWN, 14th February 2017, and 'Dawn of best practices' by Asif Khan Turk, the NEWS, 29th May 2017.

⁵⁴ 'A case for contract manufacturing', BR, 5th June 2017.

One recent example is reflective of this practice. The government recently announced steps related to barcoding of medicines, aimed primarily at ensuring quality and countering counterfeit drugs. While the aim is positive, the method has come under criticism from the industry which was never consulted about this step. Pharmaceutical officials point out that in order to make this suggestion work, every consumer of a drug would need to have a smart phone and industry will come under increased cost burden in order to comply with new coding guidelines. This added cost would not be allowed to be recouped through price increases by the government. Therefore, despite the noble aim, the method of implementation will end up saddling the industry with more cost.

Similarly, the requirement that every manufacturer has to have a separate manufacturing facility without the possibility of optimizing upon the idle capacity of an already existing plant creates overcapacity in production.

The China Pakistan Economic Corridor (CPEC) is another case in point. There are over 40 Special Economic Zones (SEZs) planned under this \$55 billion initiative⁵⁵, 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 a single time regarding their participation in CPEC, and neither does any SEZ include plans for operations of the pharmaceutical industry. This speaks volumes about official apathy towards one of the most promising industry in Pakistan. Even more startling is the official explanation of why pharmaceutical industry is not part of this grand project. 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 industry⁵⁶. 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.

In short, what the industry wants is a collaborative effort rather than a top down approach. Regulators need to liaison with the industry and study why leading pharmaceutical companies shun Pakistan and why investment in this sector has almost collapsed. It is imperative that the government and its regulators understand that the industry is not a charity but one that is based on commercial principles. DRAP needs to 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. Until this aspect is properly understood, the gulf between both camps is likely to remain wide.

⁵⁵ Source: Board of Investment (BOI), Government of Pakistan.

⁵⁶ Interview with a government official.

International Experience of Regulating the Pharmaceutical Markets

Pakistan is not the only country where the pharmaceutical market is regulated. Barring a few countries, which are usually beset with challenging conditions (like Afghanistan), governments all over the world regulate pharmaceutical industry. However, this regulation comes in varying degrees and with different strategies. The following is a brief look at selected global experience of regulating pharmaceutical industry, and what research suggests about outcomes of regulation.

Hewitt, Maynard, Lee and Bloor undertook an evaluation of studies conducted on the various aspects of the health sector from 1980 to 2012, including pharmaceutical industry regulations⁵⁷. When it came to pricing, they found that the evidence of the consumer saving from government enacting price controls is either weak or non-existent. In instances where little cost saving was recorded, it did not come courtesy of government led price controls but by substitution in use. In fact, they found that price controls have an overall negative impact on equity in access to medicines.

A 2004 study by the US Department of Commerce⁵⁸, which looked at instances of international price controls in eight OECD countries, concluded that they reduce R&D by 11 to 16 percent due to lost revenue. The Kaiser Institute of Health Policy, in its study⁵⁹, compared US pharmaceutical regulations to three other countries (Britain, Australia and Germany). It concluded that when it comes to regulating the pharmaceutical industry, there are many questions to be answered which need research (for example, is the healthcare industry structured such that regulations can be effectively enacted?). It did see government's role in regulation in instances where there are unethical practices being carried out (for example, if pharmaceutical companies are found overstating their R&D expenditures).

Management Sciences for Health (MSI), an international organization working in the health sector, outlined the prerequisites for a good regulatory system in lieu of its global experience⁶⁰. The best possible public good through regulation can come, MSI argues, through ensuring safety, efficacy and quality of medicines. It also argues for doing away with unnecessary and non-regulatory functions of a regulatory authority like service delivery, manufacturing and medicine procurement, etc.⁶¹ Their report further contends that most important factor in evaluating successful functioning of any regulatory authority is the extent of its framework that is in tune with the existing situation of the pharmaceutical sector in the country⁶². Robert Galvin and Roger Longman, while opining upon criticism of the US government policy to not interfere

⁵⁷ 'International experience in controlling pharmaceutical expenditure: Influencing patients and providers and regulating industry-a systematic review' (2015), Journal of Health Services Research and Policy.

⁵⁸ 'Pharmaceutical price controls in OECD countries-Implications for US consumers, pricing, R&D, and innovation', US Department of Commerce.

⁵⁹ 'Pharmaceutical pricing: Lessons from abroad' (2015).

⁶⁰ 'Pharmaceutical legislation and regulation' (2015), CH 6, MSI. See section 6.16 and 6.17.

⁶¹ Ibid, section 6.17.

⁶² See section 6. 8. If this criterion is to be sued, then pharmaceutical regulation in Pakistan has been a complete failure since regulatory authorities and the industry have been at loggerheads for long.

in the pricing of drugs by companies, stated that high drug prices have little to do government's free hand given to firms. Rather, it was the competing incentives and interests of various groups that resulted in higher prices of drugs⁶³. In their proposals, there is no room for government directly regulating drug prices.

Judith Wagner, in her commentary⁶⁴ on a book written by a former editor of *New England Journal of Medicine*, gave an insider account of what kind of regulations would work. She draws upon her experience of the field to contend that any regulatory body's emphasis should be upon marketing costs and the direction of expenditure of R&D. In other words, Wagner points towards ethical issues that require regulatory oversight rather than regulatory administering of other aspects. Steve Forbes, noted businessman and the editor of the famous *Forbes* magazine, came down heavily upon drug regulations, blaming them for problems like lower innovation rates and decline in R&D⁶⁵. In contrast to Forbes' belligerence against all kinds of regulations, a more balanced approach (backed up by history and research) is taken by Stewart Lyman⁶⁶. Tracing the context of regulation and historical incidents related to drugs, Lyman advocates a regulatory course which is similar to Judith Wagner (discussed above). In other words, pharmaceutical regulations should be concentrated upon preventing ethical malpractices (lobbying, marketing and emphasis of R&D upon 'me-too' drugs) rather than other aspects.

Hence, it would be fair to conclude that the matter of regulating the pharmaceutical sector have undergone an evolution in views. Earlier, regulations were supposed to encompass everything related to pharmaceutical industry. By now, majority of experts on this sector advocate regulating the ethical issues like expenditure on marketing practices, financing of medical practitioners by pharmaceutical firms and particular direction of R&D. Exports and imports of pharmaceuticals has almost vanished as an area of pharmaceutical regulations, and issues related to pricing of medicines have been handled without any attempt at coercing manufacturers into selling at an official price. The example of the British pharmaceutical regulations, stated above, is a reflection of this fact. Instead of administering drug prices, the authorities there found an alternative, agreeable solution in the form of regulating profit margins (which is related more to the ethical domain). Thus, it is safe to assume that the views over time (at least that of the majority) have evolved from outright regulation of every aspect of the pharmaceutical industry to targeting specific areas for regulations.

⁶³ Robert Galvin and Roger Longman (2015), 'Who has the power to cut prices? Employers', *Harvard Business Review*.

⁶⁴ Judith Wagner (2014), 'Should the pharmaceutical industry be a regulated utility?'

⁶⁵ 'How the FDA may kill millions of us', 26th January 2011, *Forbes* magazine.

⁶⁶ Stewart Lyman, 'Why do I love drug regulation? Simple: it keeps us safe', 15th April 2011.

Complementary and Alternative Medicines (CAM)⁶⁷

The subcontinent has a very rich history of using alternative medicines. Pakistan has largely carried over this tradition of the past as CAM practices are prevalent in all areas of Pakistan. This is especially true of rural areas where health facilities are either poor or non-existent, and low literacy levels mean that people are more likely to choose medicines without any evidence backing its efficacy. Low literacy levels and poor health facilities are only two of the variables that affect the access to and use of CAMs. Others include family and community beliefs, proximity to the consumer, and very affordable fee. Pakistan is the only country in the region to officially recognize *Unani* (Greeko-Arabic) teaching institutions and medicine, and has regulatory rules regarding its practice. Regulated under the 1965 Act that deals with CAMs, the 2011-12 National Health Accounts reported that around 4 percent of the population uses CAMs instead of allopathic medicines⁶⁸.

Pakistan is the only country in the region to officially recognize Unani (Greeko-Arabic) teaching institutions and medicine, and has regulatory rules regarding its practice.

A 2005 report⁶⁹ estimated that there were 45,000 traditional healers, 52,600 registered Unani practitioners, and 360 tibb dispensaries and clinics under the provincial health departments that were dispensing free medication to the public. At present, there are an estimated 130,000 CAM service providers all over Pakistan. But they largely remain outside the ambit of proper regulations. This has given rise to concerns about them helping the spread of sub-standard and spurious drugs which are marketed under the 'herbal' drugs headings. Also, some of the CAMs sold in the market contain ingredients like vitamins and steroids to increase their efficacy and give the drugs a promotional boost⁷⁰.

The growth of CAMs and their use is not just a phenomenon limited to Pakistan as alternative medicines sales have witnessed sale increases all around the globe. The reasons for their increasing popularity range from rising healthcare costs (industrialized countries) to lack of basic health facilities (developing nations).

However, according to the industry experts, CAMs do not present any viable competition or threat to Pakistan's pharmaceutical manufacturers. First, CAMs have a small share of the market. Second, established pharmaceutical firms (especially top 100) invest heavily in marketing and human resources, something that CAM producers cannot match. Third, CAM providers do not have the capital outlay and size to challenge the allopathic medicines. And finally, the expansion

⁶⁷ Various categories covered under CAM and techniques include Homeopathy, Herbs, Relaxation techniques, Yoga, Special diet, and Tai Chi, etc.

⁶⁸ 'Pakistan National Health Accounts 2011-12', table 27.

⁶⁹ Babar Shaikh and Juanita Hatcher (2005), 'Complementary and alternative medicines in Pakistan: Prospects and limitations', Agha Khan University.

⁷⁰ 'Chokes Pipes' (2010), SaniaNishtar, p. 159.

and use of media to all parts of the country has given rise to a more knowledgeable customer that prefers allopathic remedies to CAMs.

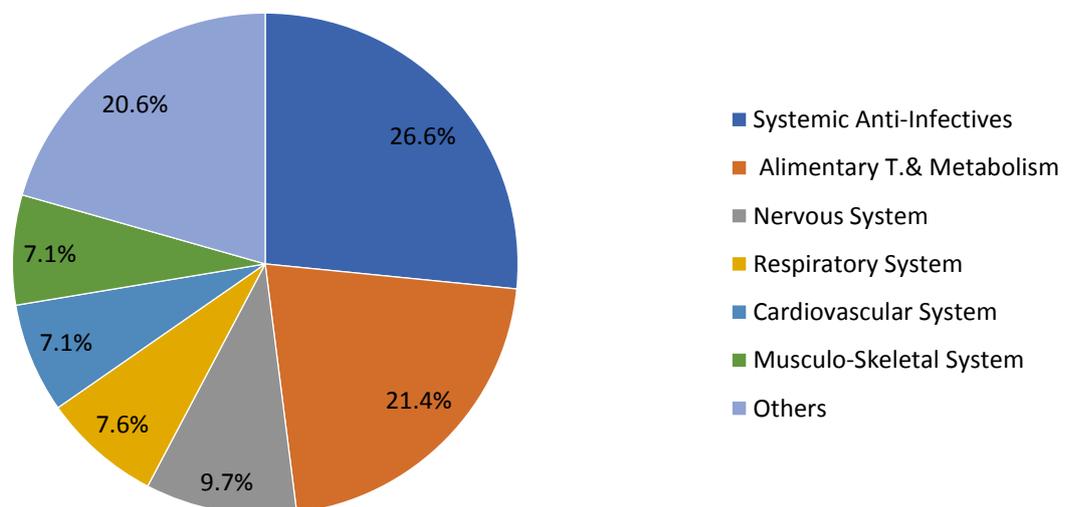
In short, CAMs do not represent any threat to the pharmaceutical industry now, nor is it likely to present a competitive threat to the industry in the future. However, if the poor rate of investment in healthcare by the government continues as it is, then the lack of quality healthcare (complemented by a growing population) may even prove beneficial for CAMs in the future.

Consumption of Drugs in Pakistan

The general perception is that consumption of drugs may be substantial and above the regional average. This includes self-prescription and consumption of drugs in Pakistan. But not all industry officials are convinced that this is true. Their belief stems from a) the number and variety of drugs consumed in Pakistan per month by citizens, and b) the presence of a youth bulge that rules out over-use of drugs since young people tend to consume lesser amounts of it. In short, opinions differ in this regard, even within the pharmaceutical industry.

National Health Accounts 2013-14⁷¹ can be studied to see the types of drugs being used. Of the total purchases reported in the table, the largest category belongs to 'Systemic Anti-Infectives' (26.58 percent), followed by categories 'Alimentary T.& Metabolism' (21.41 percent) and 'Respiratory System' (7.61 percent). Systemic Anti-Infectives include antibiotics, antifungals, antivirals and antiprotozoal, and their percentage is a reflection of the spread of major diseases in Pakistan. The following figure shows the consumption of different kinds of drugs in Pakistan.

FIGURE 7: DISTRIBUTION OF DRUG CONSUMPTION



⁷¹ National Health Accounts Pakistan, Pakistan Bureau of Statistics (Table 19) <http://www.pbs.gov.pk/sites/default/files//NHA%20report%202013-14....pdf>

Comparative Analysis with Other Countries

The following is a brief account of three cases from around the globe which illustrate success stories in pharmaceutical market.

India

As the pharmaceutical industry in Pakistan struggles to come to terms with the bevy of challenges that are impeding its growth, the pharmaceutical industry in India offers a shining example of how to take full advantage of the potential offered by this industry. A mere look at the figures tells a success story of epic proportions. We can take export figures as an example to illustrate this. In 1999, this number was \$516 million, which reached \$1.3 billion by 2005. Within a decade, India's pharmaceutical exports stood at \$14 billion (in 2015), projected to cross \$20 billion by 2020⁷². In contrast, Pakistan's exports were \$30 million in 1999, \$55 million in 2005, and at present it stands at \$190 million. Also, the total size of Indian pharmaceutical market has grown from \$3 billion in 2000 to \$20 billion in 2016, and is expected to reach \$55 billion by 2020⁷³.

The tremendous growth of the Indian pharmaceutical industry is a long story which would require a separate paper to be compiled on this subject. But a short explanation would suffice to show how a government and its regulatory arm can play a helpful hand in development of the pharmaceutical industry.

India once had a highly-regulated drug market which impeded competition and resulted in a state of affairs whereby a quality drug and raw material had to be imported. It was the consumer who suffered the most due to the unavailability of quality, effective drugs at economical prices. The Indian government, in its quest to ensure 'affordable' prices, enacted the Patent Act of 1970. A salient feature of this act was that it did away with 'western style' patents, and introduced 'manufacturing process' patents. The aim was to let domestic producers produce cheap copies of imported drugs, to be preferably sold at a lower price. The expiry time for patent was set at 7 years, half of the normal 15 years as per international standards. Complementing the patent act was the Drug Price Control Order (DPCO) of 1970, aimed at further tightening of price controls that were already in place.

However, over time, the futility of these regulations and price controls gradually sunk in. By 1995, the number of drugs with controlled prices was reduced to only 74, compared to 347 in 1987 (and more earlier). By 2005, with the introduction of the Patent Amendment Act of 2005, the once heavily regulated industry suddenly took off. The 'process patent' of the 1970 act was abolished, and the 'western style' patent protection was re-introduced. The patent period for patented generic products was in fact 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 start joint ventures with the domestic firms.

⁷² 'Pharma exports from India to reach \$20 billion by 2020', thedollarbusiness.com.

⁷³ Source: Indian Brand Equity Foundation (IBEF).

The results were quite remarkable, to say the least. In 2005, the year of passage of this Act, foreign drug producers filed a record 8,926 patents⁷⁴. Many of the MNCs that had earlier left India returned after the passage of this act. Today, 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 Biosimilars⁷⁵.

One of the things that happened in the aftermath of the 2005 act was an increasing number of Indian companies acquiring foreign pharmaceutical companies manufacturing generic drugs. One such transaction was Dr. Reddy's purchase of Betafarm Arzneimittel of Germany for \$572 million in 2006. In hindsight, the acquisition reflects a clear understanding of the Indian policymakers and their industry regarding where their comparative advantage lay. In 2015, the total market for generic drugs stood at \$200 billion, expected to reach \$381 billion by 2021. By 2014-15, India's exports of generic drugs were in excess of \$ 12 billion (with \$6 billion or more sales in domestic market)⁷⁶. It is worthwhile to note that by 2020, the patents of drugs worth \$150 billion in sales are set to expire⁷⁷. India is set to capture a large part of this \$150 billion market.

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 akin to outsourcing. This outsourcing includes outsourcing of research, conducting clinical trials, joint marketing, cost sharing and other such arrangements that come under the ambit of Contract Manufacturing and Risk Services (CRAMS). The advantage: for large pharmaceutical firms, this meant a reduction in costs and ease of access to a large consumer market (to which Indian pharmaceutical firms already had access); for Indian firms, it meant access to advanced technology and research base, knowledge spillovers and expanding their presence into the western pharmaceutical market. The result is reflected in the tremendous growth of the size of the Indian market, as pointed above.

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

⁷⁴ William Greene (2007), 'The emergence of Indian pharmaceutical industry and implications for US generic drugs market', US International Trade Commission.

⁷⁵ 'India continues to lead China in Pharma exports', Kritika Singh, 8th July 2016.

⁷⁶ 'Why India is so Important for Global Pharma', by Van Eck, 21st March 2016.

⁷⁷ 'Global generics market growing at 10.53% CAGR by 2020', reported by prnewsire.com, 15th June 2016.

spending at least 9 percent of their total sales on R&D activities in 2016⁷⁸. Their research efforts are recognized for their quality and productivity around the globe.

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 percent stake in Brownfield pharmaceutical projects without requiring any approval from the government⁷⁹.

The above is but a snapshot of what the right regulation and business environment could do for the development of an industry. In the story of the rise of the Indian pharmaceutical industry, the government and the pharmaceutical industry both played their roles, and are on one page when it comes to promotion and development of the pharmaceutical industry.

Malaysia

Since 2000, the Malaysian pharmaceutical sector growth has outpaced the growth in Malaysian GDP⁸⁰. That year, the pharmaceutical market was valued at \$315 million. In 2015, the size of Malaysian pharmaceutical market had grown to \$2.3 billion, expected to reach \$3.6 billion by 2020⁸¹. There are various drivers of this expansion in the pharmaceutical market. From policymaking and regulatory point of view, two of the important ones are less dependency upon imported drugs and less emphasis on price regulations⁸².

In late 1990s, Frost and Sullivan (an international consultancy) did a study of the Malaysian pharmaceutical market to point out its deficiencies and strengths. Since the government wanted to be less dependent upon imported drugs and bring in more generics, the firm pointed out that it cannot be done without improving the Human Resource base and significantly enhancing the R&D of the domestic firms. The report pointed out the growing trend of rising healthcare prices and consistent increase in R&D costs of the large pharmaceutical companies. This had pushed the companies towards looking for markets where they could not only expand their product reach but also to engage local human capital for R&D which would lessen the cost of research into new molecules and drugs⁸³.

Taking its cue from the report, Malaysian authorities followed a strategy similar to that followed by India by incentivizing R&D towards manufacture of generic medicines. To complement the strategy, other policy initiatives like National Key Economic Areas and Entry Point Projects.

⁷⁸ 'Indian pharma firms increase R&D budgets significantly', 14th June 2016, reported by manufacturingchemist.com. Another source reported that the R&D expenditures of the top 25 pharma companies went up to 11,710 crore Indian rupee in 2015-16 from 9,439 crore Indian rupees in the previous year. See 'R&D spending by Indian pharma co.'s jump by 24 percent in 2015-16', reported by Sanjay Pingle, 10th October 2016. When it came to research in generic drugs only, Indian companies were spending an estimated to be spending \$833 million by 2015. See 'India's generic manufacturers: Poised for continued growth', 29th February 2016, Nasdaq.com.

⁷⁹ This was stated in the SBP's Annual Report 2015-16, p.75 and 76. The SBP was commenting on the decline of FDI in the pharmaceutical sector of Pakistan, comparing Pakistan's pharmaceutical problems it to India's success story.

⁸⁰ 'Country Report: Malaysia', Pharmaceutical Executive, Issue 1, 1st January 2015.

⁸¹ Ibid, and 'Comfortable growth of pharmaceutical market', Business Times, 16th April 2001.

⁸² 'Malaysian pharmaceutical market forecast to see impressive growth', 30th September 2016, by GlobalData.

⁸³ 'Comfortable growth of pharmaceutical market', Business Times, 16th April 2001.

Another idea was to enhance medical tourism that could give boost to pharmaceutical product sales. For this purpose, tax breaks were given to medical tourists. In 2015, 850,000 medical tourists visited Malaysia, buoyed by these tax exemptions. It is also important to point out that Malaysian authorities ensured that their overall health policy and policy to promote pharmaceutical promotion policies work in consonance with each other rather than contradicting each other.

Britain

In Britain, the firms operating in the pharmaceutical industry are free to price drugs. Government does not intervene in this process. However, in order to protect the consumer from predatory pricing, the government has set up limits on the rates of return (profits), based on historical capital set out in the Pharmaceutical Price Regulation Scheme (PPRS), enacted in 1957.

Over time, there have been changes to this scheme. Most of these changes have come in lieu of the British government's efforts to preserve and enhance the local pharmaceutical industry. For example, the last change to this scheme came in 2013 when the government backed off from its proposed policy of limiting returns of the pharmaceutical companies, and instead agreeing to relax the criterion for profits till 2018.

In 2014, another boost to the industry was provided by the government when it approved the use of drugs still under development and clinical trials by instituting a faster clearance process for them. Although it may give the misleading impression that it was done under industry pressure, this incentive was enacted in lieu of the fact that critically ill patients are sometimes in need of drugs that have to go through lengthy clearance process despite data backing up their effectiveness and safety. The government thus made it easier to obtain these critical drugs while requiring only that all the relevant data be submitted for quality and safety verification.

Since the early 2000s, as many pharmaceutical firms have outsourced an increasing number of their functions (like R&D) to countries like China and India, the British government has been very mindful of protecting its pharmaceutical industry while also protecting consumers. Instead of intruding directly into the pricing domain, the government has over time adopted a policy of subsidies and quality controls that benefit the consumer.

One such initiative is the National Institute for Health and Care Excellence (NICE), established in 1999. Its main function is to rigorously test drugs and identify their clinical effectiveness, and also to rout government backed subsidies for research. Looked at another way, it's an institution that protects consumers by ensuring quality and for enhancing cost effective research through targeted subsidies. Although pharmaceutical firms have over time found its presence to their dislike, they are willing to exist with this arrangement since government has given them a free hand at other things (pricing drugs and requesting cost reimbursements). Therefore, the government has been successful in maintaining a balance between the interests of the industry while also maintaining and preserving quality for the consumers⁸⁴.

⁸⁴ See Alan Maynard and Karen Bloor (2015), 'Regulating the pharmaceutical industry: Protecting health or protecting wealth?', Journal of Royal Society of Medicine.

Conclusion

For people not conversant with facts regarding the pharmaceutical industry and its working, it would seem that the industry has a bright future. A major part of that belief stems from the growth in annual earnings, which have shown a healthy increase of over 10 percent over time. However, these numbers tend to mask the wide variety of problems faced by the industry. The fact is that things are not as bright as they seem.

One reflection of this comes in the form of the exodus of MNCs. Interviews with the industry related people revealed complete disappointment with how things are progressing and shared issues related to regulations. Many intimated their plans to leave the sector altogether in the near future. Other than that, the growth rate in earnings over time has not proved to be any panacea for the troubles afflicting the pharmaceutical sector and other related problems. There exists a huge gulf between the regulators and the industry, exports have taken an alarming dive, and lags in licensing approvals and lack of infrastructure still persists. These are few of the problems faced by the industry.

Government's approach to the industry is based on arbitrariness, suspicion, unable to bring down transaction costs through regulations (in licensing, for example) and lack of communication with the industry. For the pharmaceutical industry, the biggest problem they have to encounter in terms of public policy is that there is no consistency in policies, a lack of any long-term policy and negligible discussion with the industry during policy making. This has given rise to uncertainty regarding government actions (both at the federal and the provincial level). Simple steps, like establishment of a FDA approved lab and facilitating contract manufacturing continue to elude policymaking. There is little or no effort to ameliorate the pharmaceutical industry's shortcomings through including them in new ventures.

In reality, Pakistan's pharmaceutical industry faces a challenging time. Sales of drugs are likely to keep registering an increase, but the number of firms is likely to decline given the present situation. Capital and quality human resources are likely to remain concentrated in the top 100 firms, specifically top 50. Yet the increase in annual profits is to come from volume production rather than any new innovation or research into NCE. This volume production will be closely related to increase in per capita income, general awareness, increase in literacy, investment in health and its related infrastructure, growth in population and expansion of health facilities. An ideal situation would be for the government and the industry to chalk out a mutually agreed plan and resolve their differences over the issues plaguing the industry. If that were to happen, Pakistan's pharmaceutical industry has all the potential to be a star performer in the future.

Works Cited

- "A case for contract manufacturing." *Business Recorder*. N.p., 5 June 2017. Web.
- "A case for contract manufacturing." *Business Recorder*. N.p., 5 June 2017. Web.
- "Pharma exports from India to reach \$20 bn by 2020." *The Dollar Business*. N.p., n.d. Web.
- "Youth bulge: Pakistan must leverage its young population." *The Express Tribune*. N.p., 6 Apr. 2017. Web.
- "89 medicines banned." *DAWN*, 9 Mar. 2017, www.dawn.com/news/1319290.
- "Drug lawyers, pharmacists condemn DRAP, Ministry of Health for 'legalizing corruption'." *THE NEWS*, 2 June 2017, www.thenews.com.pk/print/208080-Drug-lawyers-pharmacists-condemn-DRAP-Ministry-of-Health-for-legalising-corruption.
- "How the FDA May Kill Millions of Us." *Forbes*, 26 Jan. 2011.
- "Imported medicines have no alternatives in Pakistan." *The Express Tribune*, 9 Apr. 2016, www.tribune.com.pk/story/1081845/imported-medicines-have-no-alternatives-in-pakistan.
- "Pakistan pharmaceutical industry: Facts and Figures." *TIMES OF ISLAMABAD*, 8 Sept. 2016, www.timesofislamabad.com/42965-2/2016/09/08.
- "Pakistan's pharma market growing 12 percent annually." *Business Recorder*, 5 Aug. 2016, www.fp.brecorder.com/2016/08/2016080572070.
- "Pakistan's pharma market growing 12 percent annually." *Business Recorder*, 5 Aug. 2016, www.fp.brecorder.com/2016/08/2016080572070.
- "Pakistani's spend most on healthcare in the region." *DAWN*, 16 June 2013, www.dawn.com/news/1018604.

- “Pharmacies observe strike across Punjab.” *DAWN*, 14 Feb. 2017.
- “SC hints at drug regulatory authority shakeup.” *The Nation*, 8 Feb. 2017, www.nation.com.pk/editors-picks/08-Feb-2017/sc-hints-at-drug-regulatory-authority-shakeup.
- Asif, Imran, and Shehzad Amin. "The Impact of Doctor–Pharma Relationships on Prescribing Practice." *Journal of Basic & Applied Sciences* 8 (2012): 174-80. Web.
- Azad, Arif. “Flaws in drug law.” *DAWN*, 30 Oct. 2012, www.dawn.com/news/760123.
- Azad, Arif. “Flaws in drug law.” *DAWN*, 30 Oct. 2012, www.dawn.com/news/760123.
- Galvin, Robert, and Roger Longman. “Who Has the Power to Cut Drug Prices? Employers.” *Harvard Business Review*, 1 Dec. 2015, www.hbr.org/2015/12/who-has-the-power-to-cut-drug-prices-employers.
- Haq, Ayesha T. "Problems faced by Pakistan’s Pharma Industry." *DailyTimes*. N.p., 6 Jan. 2017. Web.
- Haq, Ayesha T. "Problems faced by Pakistan’s Pharma Industry." *DailyTimes*. N.p., 6 Jan. 2017. Web
- Haq, Ayesha T. "Problems faced by Pakistan’s Pharma Industry." *DailyTimes*. N.p., 6 Jan. 2017. Web
- Haseeb, Abdul and Bilal, Muhammad. “Prevalence of using non-prescribed medications in economically deprived rural populations of Pakistan”, *Arc Public Health*, 2016, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4722669/>
- Junaidi, Ikram . “Cabinet approves barcoding to check spurious drugs.” *DAWN*, 13 Apr. 2017, www.dawn.com/news/1326660.

Junaidi, Ikram. "Companies should manufacture three to five essential drugs each". *DAWN*, 26 Mar. 2017, www.dawn.com/news/1322832.

Mansoor, Hasan. "The politics of medicine pricing." *DAWN*, 16 Oct. 2016, www.dawn.com/news/1289752.

Mansoor, Hasan. "The politics of medicine pricing." *DAWN*, 16 Oct. 2016, www.dawn.com/news/1289752.

Mansoor, Hasan. "The politics of medicine pricing." *DAWN*, 16 Oct. 2016, www.dawn.com/news/1289752.

Mansoor, Hasan. "The politics of medicine pricing." *DAWN*, 16 Oct. 2016, www.dawn.com/news/1289752.

Staff Report. "Climate change increasing Pak's disease burden'." *Pakistan Today*. N.p., 11 May 2015. Web.

Turk, Asif Khan , editor. "Dawn of best practices." *THE NEWS*, 29 May 2017.

World Health Organization (WHO), Sustainable Development Goals (SDGs). <http://www.who.int/sdg/en/>