The Pharmaceutical Industry in Pakistan

Past, Present and the Future

Message by Mr. Tauqir ul Haq , Chairman PPMA

The pharmaceutical industry of Pakistan stands as one of the nation's greatest strengths, not only in safeguarding the health of its people but also in shaping the economic future of our country. It is a matter of immense pride that local manufacturers are fulfilling more than 90% of our domestic requirements, ensuring that essential medicines remain accessible and affordable to every citizen. This self-reliance is not just an achievement, but it is a foundation upon which we can build a healthier and more prosperous Pakistan.

The future of our industry is filled with promise. With the guidance and support of our regulatory bodies, forward-looking and industry-friendly policies are being implemented that will allow our sector to flourish like never before. Pakistani manufacturers are embracing the highest standards of quality, aligning themselves with the most rigorous international benchmarks. Already, 10 companies have received PIC/S recognition, and within the next two years, this number will rise to 20. Alongside this, WHO prequalification and MHRA accreditations have been secured by local companies, proving that Pakistan's pharmaceutical sector is ready to compete with the very best in the world.

Our vision is not confined to today's needs alone. We are investing in the future by channeling our focus towards biologicals and vaccines, areas of immense importance where self-sufficiency is vital. This shift represents not just a response to global healthcare challenges but a commitment to innovation and progress that will secure Pakistan's position on the world stage.

Equally inspiring is the journey of our exports. With a 34% increase and a milestone of $750 million achieved, the momentum is clear. In the next three years, we have the potential to reach $3 billion in exports. This is more than a number; in fact, it is a symbol of how the pharmaceutical industry can become a strong pillar of our economy, creating jobs, attracting investment, and projecting the image of Pakistan as a reliable global partner in healthcare.

As we look ahead, the pharmaceutical industry of Pakistan is not just evolving but transforming. With unity of purpose, collaboration with regulators, and the relentless pursuit of excellence, we are poised to write a new chapter of success. Together, we will ensure that the medicines made in Pakistan bring healing not only within our borders but across the world, and that our industry becomes a beacon of quality, innovation, and hope.

Message from Mr. Haroon Qasim, former Chairman PPMA

Reading this book felt like walking through the corridors of our pharmaceutical industry's memory: some lined with achievements that make us proud, others with reminders of the lessons we seem destined to relearn. It is both a history and a mirror, but more importantly, a guide to where we stand today.

The narrative takes us from the early days when Pakistan had only a handful of factories producing tinctures and galenicals, to today, where nearly 800 firms serve a market worth over a trillion rupees. We see how, in the space of a few decades, local companies that once lived in the shadow of multinationals have come to dominate the landscape. This transformation is a story of grit and adaptation, but it also carries within it signs of fragility.

The book lays bare our vulnerabilities: an industry that still imports 95% of its raw materials, that spends far too little on R&D and that remains trapped in the web of rigid price controls, which too often turn medicines into political bargaining chips rather than instruments of health. Time and again, policies framed as 'for the people' have resulted in shortages, black markets and public anger. The account of the 'seized Panadol stock' - a shortage born not of hoarding but of regulatory paralysis, is only one among many that this book documents. Such episodes illustrate how perception has too often been stacked against industry, eroding public trust even when firms quietly carry the weight of keeping life-saving medicines available.

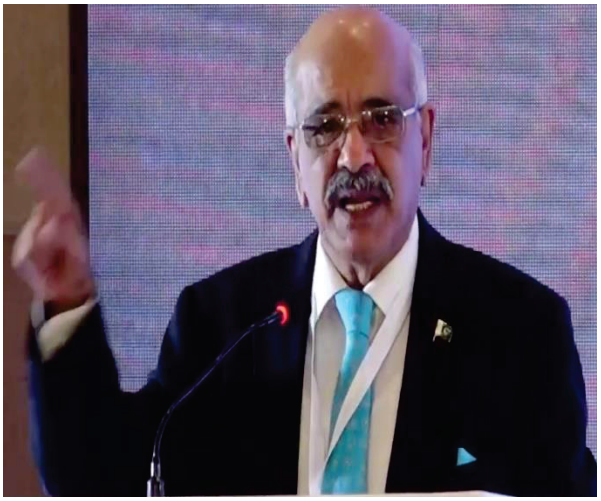
And yet, what emerges from these pages is not a tale of despair, but of resilience. Local firms have held their ground where global giants have retreated. The shift in market share from multinationals to domestic companies is not just a statistic, but evidence of an industry that has learned to survive in tough conditions. At the same time, the book points us toward opportunities that can change our trajectory: establishing functional API parks, building credible vaccine production capacity, nurturing genuine R&D and making policy frameworks consistent across governments. Reforms like the strengthening of DRAP and the adoption of the Pakistan Single Window are not minor technicalities, they are small but vital steps in modernizing our ecosystem.

This book is more than a record of challenges. It is a call to recognize the pharmaceutical sector not merely as a commercial venture but as a partner in public health and national self-reliance. If policymakers, regulators and industry heed the insights captured here, we can shift from survival mode to a future defined by innovation, exports and ethical growth.

The crossroads are clear. The choice is ours!

Message by Dr. Kaiser Waheed, ex-Chairman PPMA

The Pakistani Pharma Odyssey: From Foundations to the Future



The story of Pakistan's pharmaceutical industry is one of resilience, innovation, and an unwavering commitment to human health. In a world increasingly defined by global health challenges, this sector has emerged not merely as a domestic necessity but as a pivotal player on the world stage, earning Pakistan the rightful title of "The Medicine Chest of Asia."

This book is a journey through that remarkable evolution. It begins with the humble foundations laid post-independence and traces the sector's dramatic transformation into a multi-billion dollar enterprise, now home to over 800 manufacturing units. We delve into the critical junctures: the patent law reforms of the 2000s that unlocked a wave of generic drug production, the relentless pursuit of quality compliance leading to international certifications, and the bold foray into complex biologics and vaccines.

But this is more than just a story of economic success. It is about the millions of lives touched by affordable, quality medicines—both within Pakistan and across the globe, from Afghanistan to Africa to the Americas. It is about the scientists, the regulators, the entrepreneurs, and the visionaries who dared to believe that a nation facing its own myriad challenges could become a beacon of health and hope for others.

However, the odyssey is far from over. This book also confronts the formidable challenges that lie ahead: the imperative for local API production, navigating the complexities of TRIPS compliance, and fostering a culture of radical R&D to move from replication to genuine innovation and the regulatory challenges.

It is my hope that this comprehensive account will serve as an essential resource for policymakers, industry professionals, investors, and students. May it inspire a new generation to build upon this legacy, ensuring that the Pakistani pharmaceutical industry not only continues to thrive but also leads the way in shaping a healthier, more equitable future for all.

Author's note with acknowledgements

My journey as a researcher on Pakistan's pharmaceutical sector bean in 2014-15. What began as a minor query on 'welfare' related implications of regulations, later transformed into a full-fledged interest in one of the most dynamic industry in Pakistan, one that holds tremendous value and potential for the country and its economy, but also the one that has probably been regulated most stringently (and illogically).

In 2018, I got the chance to write my first industry report. Then, at Pakistan Institute of Development Economics (PIDE), the opportunity came along to peer deeper into this area and its regulations. The end product was several short papers, a full-fledged analysis of the regulator (DRAP) and a chance to mingle further with the industry officials. That journey has continued, and it gave me immense pleasure to write this Industry Report, which presents all the cumulative knowledge I have gained over time.

The novelty of this report is that the reader would find the research findings related to the lesser discussed and lesser researched areas like the huge market for smuggled drugs and the estimates of investment (Gross and Net) of this industry over the last two decades, something that has never been done before. There is a whole section on the evolution of the pharmaceutical industry. Moreover, it also shed light on public sector policies via its 5-Year Plans and identified the future trends that are likely to shape the global and local pharmaceutical industry. The oft-repeated and trite discussions, readily and frequently available at other places, are either avoided or presented in shortened form.

Last, but not the least, I would like to acknowledge the individuals who have been of tremendous help in this research journey of mine. The first is Dr. Kaiser Waheed, ex-Chairman PPMA, without whose help my research work would have been hardly half of what it is. His remarkable generosity in extending whatever help he could is profound, and made it possible for me to achieve whatever I could in this field. The second is Dr. Nadeem Ul Haq, ex Deputy Chairman Planning Commission and PIDE, who encouraged me to pursue research into pharmaceuticals and gave me a free hand in this regard. Finally, acknowledgement is due for Ali Salman, CEO PRIME Institute, who helped me make a start in this area back in 2015. The generous help of all three will not be forgotten.

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1- Introduction- The importance of Pharmaceutical Industry

For thousands of years, smallpox had been ravaging human populations across the globe. The scale of its destruction could be gauged by the fact that an estimated 400,000 Europeans died every year from it in the 18th century. Despite the advances wrought on by industrialization, it remained a formidable killer. Up till the first half of the 20th century, the mortality rate from smallpox affliction remained at a staggering 30 percent.

In 1979, World Health Organization (WHO) declared an end to this terror, proclaiming a world free of the scourge of smallpox. There was no miracle and neither any magic that finally freed humanity of its exertions, but development of drugs[1] in the form of vaccine that put an end to this destructive killer. Were it not for inoculation of our parents' generation against it, millions of us may not even have been present today. Similarly, were it not for the availability of modern blood pressure drugs since the last fifty years, a vast number of people would have suffered from debilitating conditions like liver damage, loss of vision, memory loss and higher probability of stroke that paralyzes its victim forever.

There are countless such examples which bring to fore the undisputed fact that were it not for development of various forms of medications and their availability, humanity would not have realized the tremendous gains in terms of life expectancy and a healthy lifestyle. Critically, from an economic growth point of view, the importance of having access to life-saving drugs is of utmost importance, especially in terms of having a healthy workforce that has tremendous positive spillovers. A healthier workforce, in turn, has been shown to positively affect GDP growth (Georgieva, 2019), while poor health has been estimated to reduce global GDP growth by 15 percent per year (Remes, Dewhurst and Woetzel, 2020).[2]

The challenge of ensuring defense against various diseases is not over. Pandemics like COVID-19 and drug resistant super bacteria are a reflection of the new challenges confronting the globe. Moreover, infectious disease used to kill most people — now, chronic diseases are the biggest killers, as depicted in the graph below-

[1] Although 'medicines' and 'drugs' are used interchangeably, 'drug' is the reference term for allopathic medicines. 'Medicines', in contrast, cover a wider range of products including homeopathic and Ayurvedic medicines. For this paper, only allopathic medicines ('drugs') will be covered.

[2] 'Healthy people drive strong economies' (2019), Kristalina Georgieva, *World Bank* (WB) and 'Research: Poor health reduces global GDP by 15% each year' (2020), Jaana Remes, Martin Dewhurst, and Jonathan Woetzel, *Harvard Business Review*

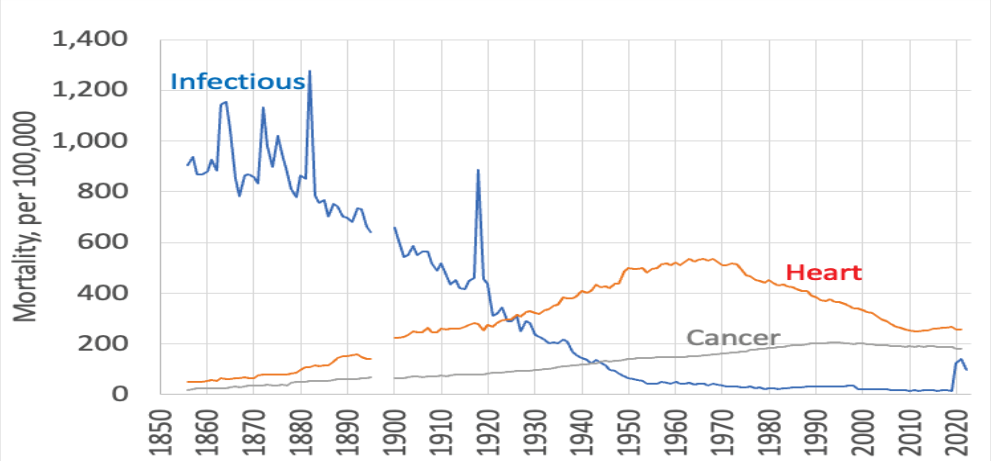


Figure 1 Death rate of infectious diseases, cancer, and cardiovascular disease (heart disease and stroke), Massachusetts 1856-1895, US 1900-2022, crude mortality rate per 100,000. Sources: Massachusetts, US 1900-1998, US 1999-2019, US 2020-21, Covid just for 2022.

This calls for effective policies against chronic diseases, which can end up in estimated savings of $4.4bn/yr — aside from saving lives.[3] An essential part of such policies will have to be in the form of ensuring manufacture, access and affordability of quality drugs. This aim, in turn, can only be achieved with a viable, thriving pharmaceutical industry.

2- Pakistan's pharmaceutical Industry- History, dynamics and characteristics[4]

Pakistan's pharmaceutical industry has gone through a non-linear evolution, whereby there were times that industry thrived (like the 1960s) and at other times it struggled (1970s Nationalization era and early 2000s under the 'prize freeze' policy). A brief glimpse of this evolution is presented in the following lines.

Development of Industry- Past and the Present

In terms of historical development of the pharmaceutical industry, Weiss (1985) opined that it went through four 'waves' of growth (till the time she wrote her paper, explaining in detail each of the phase). Her study the best effort to document the development of the industry till the mid-1980s.[5] The early industrialization in this sector had to contend with some formidable socio-economic barriers. Industrial history in the region under the British colonial administration preferred industry like cotton ginning (providing it incentives), while pharmaceuticals was low in their priorities. It was more of a trade, not

[3] https://www.copenhagenconsensus.com/publication/halftime-sdgs-chronic-diseases

[4] The current state of Pakistan's pharmaceutical market makes use of PIDEs recent research report (authored by this report's author) on Investment in the pharmaceutical sector, titled 'Investment in Pakistan's pharmaceutical sector' (2025)

[5] 'Medicine for the masses: Development of the Pharmaceutical industry in Pakistan' (1985), Anita M. Weiss, *Journal of South Asian and Middle Eastern Studies, Vol. IX, No. I, Fall 1985*

industry, as most allopathic drugs were imported from England. At home, after partition, issues like population's long-held affinity for traditional medicine (primarily Unani) and lack of organizes labor at industrial scale proved to be substantial barriers.

At the time of partition, there were only six factories that were producing a variety of drugs, tinctures, chemicals and galenicals. By end 1955, the government had counted fifty six factories in both East and West Pakistan producing the same products. Of these, thirty three were producing galenicals and tinctures with a capacity of 0.2 million gallons per year.[6] It really took off in the 1960s 'Growth Era' under Ayub Khan, contracted after large-scale 'Nationalization' of industry under Z.A Bhutto, and then regained momentum in the mid-80s, expanding since that time (specifically the local pharmaceutical firms).[7]

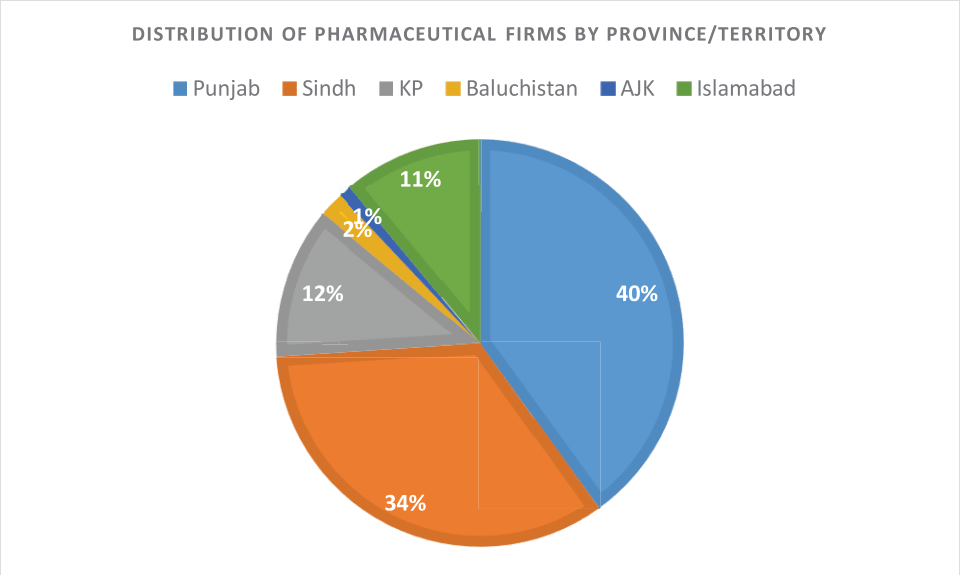
In terms of the public sector policies, despite its importance, pharmaceutical industry has usually remained low in priority. This can be gauged by the fact that pharmaceutical industry comes under the Commerce ministry's supervision rather than Ministry of Industry's. The thrust of most of its policies, outlined in national health policies and development plans (like Five-year Plans) has mostly been upon import substitution through development of local industry via various incentives (specifically public investment incentives, discussed later in Investment section). For example, in 1996 a comprehensive National Drug Policy was drafted that included the objective of increased local production and procurement of essential medicines. It was followed in 1997 by another Drug Policy.

At the moment, as per the industry sources, there are more than 800 pharmaceutical firms. This differs significantly from DRAPs count which puts the number around 650, a good reflection of how views differ between public and private sector. The distribution of pharmaceutical production units by province/territory is presented in the following graph-[8]

[6] 2nd Five-Year Plan (1955-1960), No. 106, p.455

[7] Weiss (1985) mentions that at the time of announcing Nationalization, there were more than 400 pharmaceutical production units in Punjab. By the time PPPs Govt was overthrown in 1977, there were hardly 50 units remaining in the province

[8] The numbers do not shed light upon the distribution by characteristics like size, sales, workforce, etc. This is important to keep in mind since distribution by sales, for example, would put Karachi (let alone Sindh) on top. Also, this graph takes into account the number of firms tabulated for this research paper through available evidence/documents, some of whom were not in the DRAP list



The pharmaceutical market size in Pakistan is a question that needs more research as the one generally quoted is that of firms like IQVIA, based on reported sales of only five hundred and twenty five firms. But this number misses two important portions of the total market for pharmaceuticals-

a) the market created by public sector procurement
b) the market for smuggled pharmaceutical products (drugs, APIs)

If one only considers the stats of firms like IQVIA, Pakistan's total market size for pharmaceutical products currently stands at an estimated **Rs. 1 trillion**.[9] In dollar terms, at the current exchange rate, this means that the market size is approximately $3.6 billion, which is not even a percent of the global pharmaceutical market, estimated to be around $1.5 trillion, a sorry state of affairs for a country with more around 800 pharmaceutical firms.

In terms of the market created by public procurement, the numbers are hard to come by since federal and provincial governments rarely make their drug procurement numbers public. Since provinces call for the lowest bids, top of the line pharmaceutical firms usually stay away from these tenders and it's the firms at the lower end of the quality ladder (and sales, not reported to IQVIA or others) that bid in these tenders. Bits of information, though, do appear here and there regarding the quantum of procurements, but there is no unified repository of information regarding these purchases. For example, in FY 2016-17, the combined expense of provincial governments on purchase of drugs was reported to be Rs. 41 billion (approximately).[10] By now, the provincial expense on

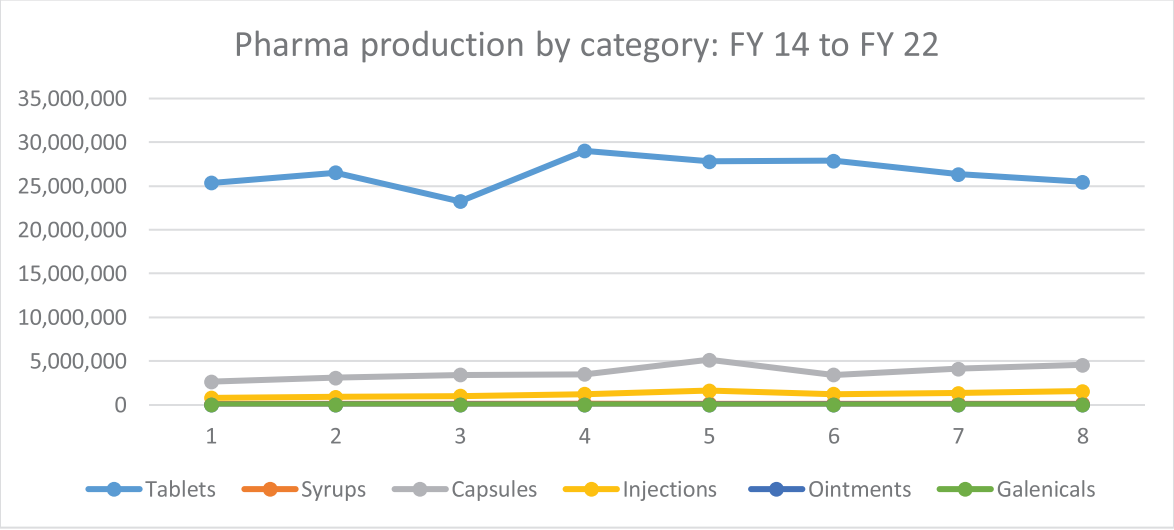
[9] Source: IQVIA and pharma industry representatives
[10] 'Pakistan's pharmaceutical sector: issues of pricing, procurement and the quality of medicines', p.27. This does not include estimates of Federal government procurements that were not available

drug procurement has crossed Rs. 75 billion.[11] If combined with the federal drug procurement, which stood at approximately Rs. 13 billion in the last fiscal, the estimated market size of this segment is close to **Rs. 90 billion**.[12]

The third segment of the market (market for smuggled drugs) is also a matter of conjecture as there is no single number and various sources report different numbers. A lot of Pakistani firms, especially the lower tier firms (registered and unregistered), smuggle their low quality medicines to Afghanistan and other places where regulations are lax or non-existent. A recent Commerce ministry report put the quantum of this market at **Rs. 65 billion**.[13] But most independent analysts consider this number to be on the lower side.

If we consider the above quoted numbers of the two segments, then the total pharmaceutical market sales in Pakistan exceeds of **Rs. 1 trillion, 150 billion.**

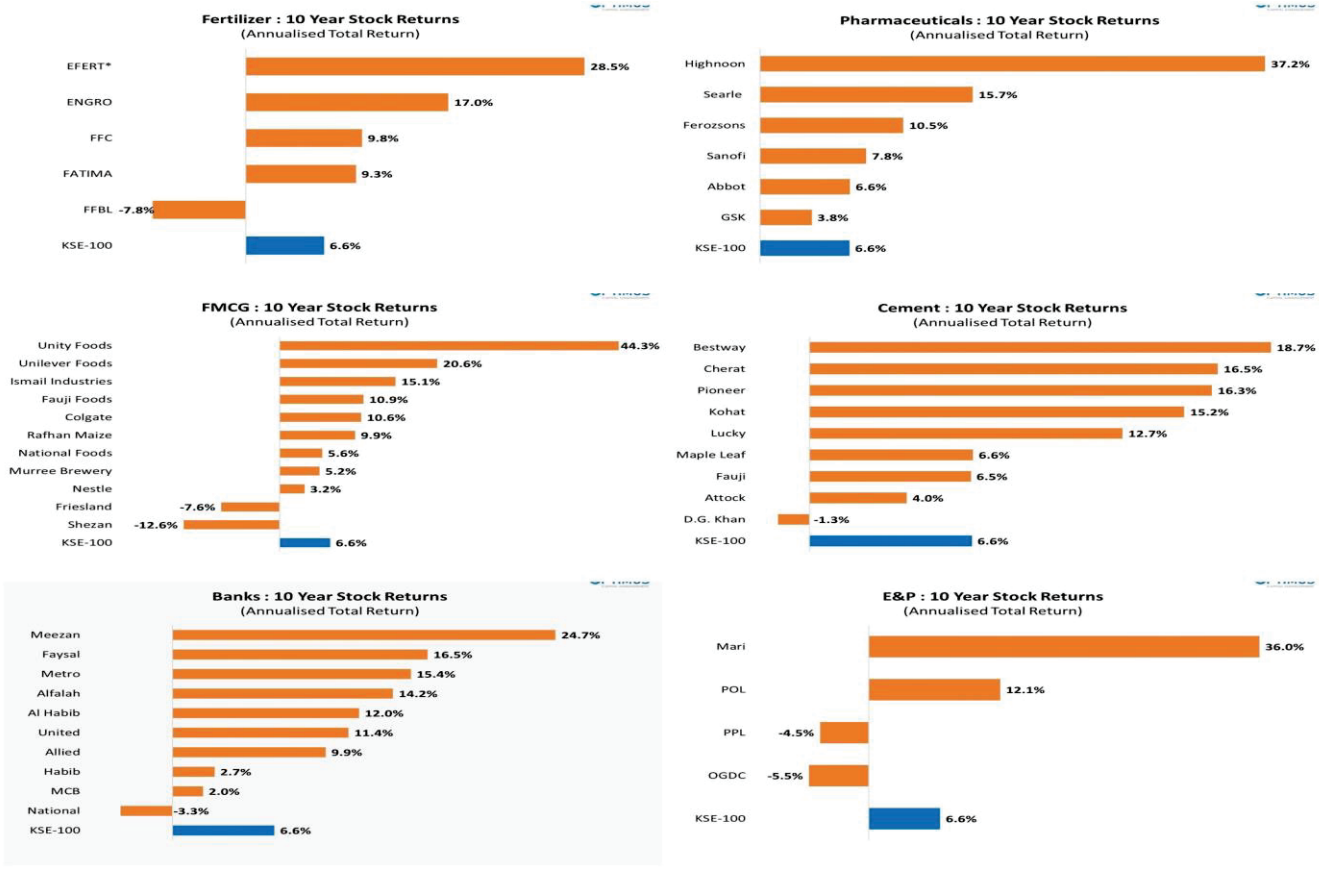
Total sales of drugs constitute different categories, with some categories clearly dominating in terms of sales. Their dominance owes to the disease burden in the country. For example, the prevalence rate (and growth) of diabetes in Pakistan is one of the highest in the world. Not surprisingly, anti-diabetic drugs garner one of the highest sales in the country. Estimates provided by Statista, for example, suggest that in the year 2016, diabetic drugs earned the pharmaceutical firms $217 million in sales. In 2023, the sales had reached $502 million (approximately).[14] The total production by different categories is presented in the graph below.[15]



[11] Discussion with provincial health department officials as well as respective provincial audit offices
[12] The federal procurement number comes via federal health officials
[13] 'Illicit Trade, Smuggling', Mushtaq Ghumman, *Business Recorder*, 6th June 2025
[14] STATISTA Market Insights, Pharmaceuticals, Pakistan
[15] Based on PBS data on pharmaceutical production. However, PBS data is limited in its scope since hardly takes 300 pharmaceutical firms into account

Aside from the questions concerning total size, the market (by sales) is highly skewed! The top fifteen firms have approximately 60 percent of the reported market share, while the top one hundred have 95-97 percent of the total market share. The rest survive on the remaining 3-5 percent as well as well as on sales and transactions in the two unreported segments described above.

Interestingly, only forty four pharmaceutical firms are listed at Pakistan Stock Exchange (PSX). The primary reason that most pharmaceutical firms do not list at PSX is that they usually have alternate sources of arranging funds. To a lesser degree, the abstention has to do with desire to run the firm without any shareholder pressure. Sales are highly correlated to a few factors, specifically pricing regulations of the government. When price regulations are stringent, aggregate sales seem to be subdued, and vice versa. For example, the year 2024 saw listed pharmaceutical companies on PSX outperform the KSE-100 Index by 118 percent, a staggering performance that was largely due to deregulated prices of non-essential drugs.[16] When it comes to listed pharmaceutical companies, their performance has been impressive if compared to returns to other sector in Pakistan Stock Exchange (PSX), reflected in the following graph that depicts returns from 2013 to 2023.[17]

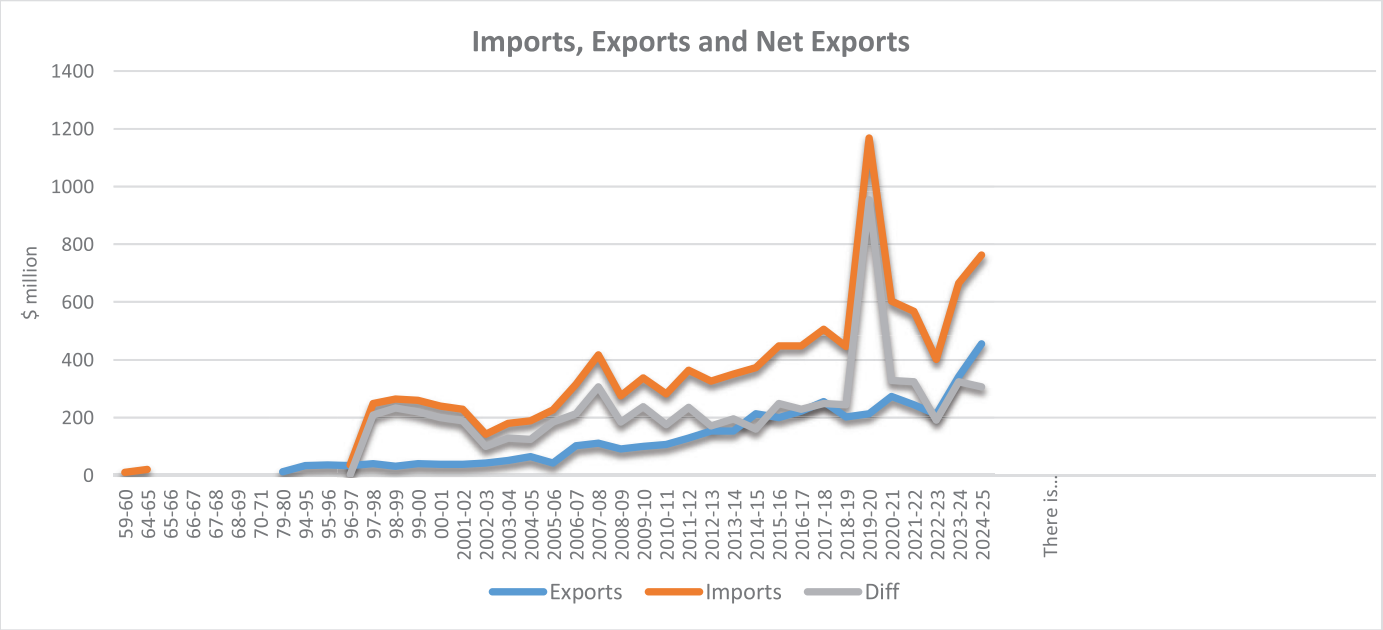


[16] 'Pharma: Shines with outperformance; triggers ahead', *JS Global*, December 2024.

[17] Source: Umair Naseer @UN_99, 4th June 2023 https://x.com/UN_99/status/1665242467971547136

In terms of Pharmaceutical exports, the situation is dismal for a country that has more than 800 pharmaceutical firms. In FY 23, Pakistan's total exports were merely $210 million while imports were almost double that number ($401 million). The gap between exports and imports has been growing persistently, partly for the reason that around 95 percent of the raw material needed to manufacture drugs has to be imported (since raw material and Active Pharmaceutical Ingredients or APIs manufacturing is limited). Imports tend to jump in urgencies like COVID-19 since critical drugs (like cancer drugs) and vaccines are not manufactured in Pakistan. Pakistan is exporting drugs to more than sixty countries. These countries include Central Asian Republics, Russia, Sri Lanka, Philippines, Vietnam and African countries.

Pakistan's pharmaceutical Exports, Imports and their difference (Net Exports) is depicted in the graph below.



The market share is approximately 75:25 in favor of local pharmaceutical companies (about four decades ago it was the reverse), reflecting evolution of sector that has seen local pharmaceutical firms gradually rise in terms of sales, displacing MNCs. They produce generics and 'branded generics', whose consumption has risen significantly over time owing to various factors.[18] Local firms like Getz Pharma now regularly top pharmaceutical sales charts.

[18] One leading factor of generic drug consumption is their lower price, which is a big plus point in low income countries like Pakistan. Overall, consumption of allopathic drugs has increased over time, to the extent that non-allopathic medicines like homeo, unani, ayurvedic constitute a very small proportion of sales market. Factors like higher media access, increased rural to urban migration, rising incomes and rising literacy rates have all led to this increase. These are discussed in detail in Pharma Industry 2018 Report by *PPMA*

How did this transition in favor of the local firms come about? Part of the explanation lies in nature of operations of MNCs. In Pakistan, they have been hampered by stringent price regulations and other pressing issues like limits imposed upon profit repatriation, especially in times of economic stress when foreign exchange reserves of SBP decline (as in 2022). Being subsidiaries of global level firms who mostly deal in originator brand drugs rather than generics, they are critically dependent upon a favorable pricing environment and exclusive IP rights to a product. Both of these do not exist in Pakistan, thus making it difficult for them to operate. At the start of the 21st century, there were around 42 MNCs in the pharmaceutical sector of Pakistan. By now, there are hardly 10, as per the industry sources, with some closing shop altogether while others merging into local firms over time. The most recent case of an MNC closing shop in Pakistan is that of Lundbeck, which announced its plans to departure in end-August 2025.

The domestic pharmaceutical companies, however, have managed to somewhat align themselves with the regulatory environment, especially pricing restrictions, by adopting various strategies. Chief amongst these is dependence upon sales volumes that result in higher profit margins, a strategy opposite to that of MNCs that are more dependent upon pricing rather than volume.[19] The main factor, though, is that they are manufacturers of generic brands. In a low income country like Pakistan with a heavy disease burden, major portion of the population can only afford the cheaper generic drugs, which gives local firms an advantage over the MNCs.

It's also worthwhile to mention that government policies have also been biased towards import-substitution that has ended up favoring local firms. The first major incentive to the domestic manufacturers came in the form of Drug Act 1972 (Generic Names). This legislation prohibited manufacturing, distribution and prescription by brand or proprietary name. Similarly, the National Drug Policy (1997) incentivized generic essential medicines concept and the use of the National Essential Drug list by mandating all government and semi-government health institutions to conduct bulk procurement in accordance with the list.

Overall, amongst all industries in Pakistan, the pharmaceutical industry is probably the most competitive and dynamic industry. The competition is partly reflected in the change in sales volume of companies over the years. The following two tables show sales for 2020 and 2023, reflecting change in the firms in Top 10 list by sales.

Top 10 firms by sale-2020			
	Company name	Domestic/MNC	Total Sales (PKR Billion)
1	GSK	MNC	34
2	Getz Pharma	National	32

[19] 'Pharmaceuticals: how the locals are beating the multinationals' (2021), Farooq Tirmizi, *PROFIT*, 20th June 2021

3	Abbot Laboratories	MNC	31
4	Searle Company	National	29
5	Sami Pharmaceuticals	National	28
6	Martin Dow Marker	National	21
7	GSK Consumer	National	16
8	High-Q International	National	15
9	Hilton Pharma	National	14
10	Bosch Pharma	National	13

Top 10 firms by sale-2023			
	Company name	**Domestic/MNC**	**Total Sales (PKR Billion)**
1	Getz Pharma	National	57
2	GSK	MNC	50
3	Sami Pharmaceuticals	National	39
4	Abbot Laboratories	MNC	41
5	Searle Company	National	36
6	Martin Dow Marker	National	26
7	Hilton Pharma	National	23
8	High-Q International	National	21
9	Haleon Pakistan	MNC	20
10	OBS Group	National	18

The pharmaceutical companies spend a major chunk of its expenses upon promotional activities or marketing. As such, this is not surprising since this is commensurate with majority of the pharmaceutical firms around the globe. There are times, though, that such promotion catches the attention of regulators. For example, CCP has fined several pharmaceutical companies on account of false promotion. In the 7th Five-Year Plan (1988-93), government even recommended curtailing the amount spent on advertising by the pharmaceutical companies.[20]

At present, the industry employs an estimated 100,000 people directly while 150,000 are employed indirectly. Cumulatively, the pharmaceutical industry is one of the highest taxpayers in the country.

Last, but not the least, overall public perception of the industry amongst the masses remains negative. This is amply reflected in the attempts to increase prices even in line with official pricing policies that can lead to a huge public outcry, especially by the print media. On 26th June 2020, the then Chief Justice while hearing a petition on increase in drug prices termed pharmaceutical manufacturers a 'mafia', and reprimanded DRAP for

[20] 7th Five-Year Plan, #140, p.43

doing nothing. The aspect that pharmaceutical business is a commercial venture, just like any other commercial venture, that runs on profit is hardly appreciated. A former President, while meeting pharma industry officials who had come to apprise him of the harm inflicted by stringent price regulations, asked the pharma representatives to consider giving out drugs for free as an act of charity! The fact that many pharmaceutical companies run an impressive gamut of welfare activities from their own resources is entirely lost in this prevalent negative perception.

'Seized' Panadol, media and the 'greedy' pharma industry

In late September 2022, all the major newspapers in the country and media cried foul as news surfaced of large batch of Panadol (48 million tablets) being seized by provincial drug inspectors. The news of this seizure came amidst Panadol shortage (due to a dispute on pricing between the manufacturer and the government). Demands like 'putting greedy industrialists behind bars', trials, and arrests of manufacturers, etc., were raised in unison.

Few days later, as the dust began to settle, it turned out that there was no illegality ('hoarding') involved. In fact, it turned out that it was company's own stock, at its own Godown, which was marked for export, worth two days of normal production (at peak production rates), and in line with official regulations concerning stocks of drugs.

On 7th October 2022, government acknowledged its mistake, terming the seized stock as 'normal course of businesses'. But by that time, the damage had already been done. As usual, the government was able to divert public anger from its own shortcomings towards the pharmaceutical industry, painting it as a villain in the eyes of the public. And as usual, the pharmaceutical industry turned out to be weak in terms of its media presence to counter the general negative perception about its operations.

What gave rise to this shortage is the political nature of drug pricing. Historically speaking, the Government has always been shy of granting drug price increases, primarily because it is seen as a politically sensitive issue. The political maneuverings, however, have ended up propelling shortages, which is what happened in the case Panadol shortages. Depreciation of the rupee and other factors (like supply disruptions, higher freight costs) shot up the raw material price of paracetamol from Rs. 600/kg to Rs. 2,600/kg. The industry asked the GOP to increase the price, but was met with persistent refusal. As production became financially unfeasible, firms stopped producing products containing the ingredient paracetamol (like Panadol). But as shortages became debilitating amidst consumers' misery, only then did the official regulator, DRAP, propose increasing the price. The proposal, however, remained on the Cabinet table. Meanwhile, consumers lost millions of rupees in paying for imported paracetamol products or ones found on the black market.

Source: "Raiding party red-faced after govt finds no illegality in 48m seized Panadol tablets", *DAWN*, 8th October 2022

3- Production of Vaccines and Active Pharmaceutical Ingredient (API)

Although it is the private firms constituting the pharmaceutical industry that produces almost all the allopathic drugs, vaccines and APIs, a limited amount of drugs and vaccines are produced in the public sector. National Institute of Health (NIH) has been producing vaccines since the 1970s. Similarly, Pakistan Institute of Nuclear Medicine and Oncology (INMOL) Lahore and Nuclear Medicine Oncology and Radiotherapy Centre (INOR) in Abbottabad have been producing radiopharmaceuticals for theranostic procedures.

What follows is a brief description of Vaccine and API production (allopathic production stats have already been presented above).

Vaccines

The onset of COVID-19 in Pakistan exposed some of the bitter realities of our dilapidated health system. One of these was the absence of needed vaccines and lack of its complementary set-up (R&D facilities, laboratories, capacity expansion, investment in new and existing vaccine manufacture, etc.). Some of these were pointed out at that time, indicating that leave alone the COVID-19 vaccine, Pakistan hardly manufactures basic vaccines, even as basic as snake bite and rabies vaccine that are imported.[21] In contrast, India serves as one of the main global manufacturers and providers of vaccines across the world (including Pakistan), with its Serum Institute having the largest vaccine producing facility in the world.

Resultantly, Pakistan had to bear a hefty import bill in the form of COVID-19 vaccines.[22] One would have thought that perhaps, Pakistan's governing circles would learnt a lesson or two and accordingly revisit regulations that militate against vaccine manufacturing in Pakistan. However, up till now, there is little indication of any improvement. At best, the National Institute of Health (NIH) managed to contract assembling of Chinese anti-Covid vaccines, with other critical vaccines still being imported.[23]

Simply put, just like life-saving drugs, vaccines have had a tremendous contribution in terms of saving countless lives over time. The graph at Annexure-A is an excellent demonstration of the remarkable reduction (or complete wiping out) of diseases by use of vaccines in the US that would affect a substantial portion of its population.[24] The same

[21] 'The economics of vaccines'

[22] Import data from various government sources like Health Ministry and Finance Division indicate that more than $1 billion were spent

[23] Recently, the Sindh government, in collaboration with DOW University of health sciences, decided to import these vaccines from China and package it here. This follows an earlier decision in August 2022 by the provincial government, seeking to manufacture the vaccines in provincial health facilities. Source- Daily Jang, 16th August 2022 and 3rd January 2023

[24] Our world in data

is true of the world! As per the World Health Organization (WHO), vaccines prevents deaths of 3.5-5 million lives yearly.[25]

And it's not just the lives saved, but also the economic benefits that accrue due to it that make vaccines of critical importance. A study by Ozawa et.al (2016) of 94 middle and low income countries, for e.g, estimated that the use of vaccines during the 2010-2020 decade alone would result in 40 times more benefits compared to costs of manufacturing and administering vaccines. In financial terms, this translated into costs of $34 billion spent on immunization programs resulting in savings of $586 billion and $1.53 trillion in broader economic benefits.[26] Briefly put, the benefits are far greater than the costs of their production.

Operation 'Warp Speed'

In lieu of the devastation caused by the spread of COVID-19 virus, the US government speeded up its efforts to develop and deploy COVID-19 vaccines. The effort, which brought together numerous government agencies, aided the development of six different pharmaceutical companies for development and production of anti-COVID-19 vaccines. Additionally, funds were earmarked for expanding vaccine production capacities at firms, buying those vaccines in large numbers and supporting the supply chains involved in all this development. The total cost of this initiative was $19.56 billion, with $18.56 billion going to the development, capacity expansion and buying vaccines while approximately $1 billion went to supporting complementing supply chain.

Source: 'Operation Warp Speed contracts for COVID-19 vaccines and ancillary vaccination materials', Congressional Research Services

Vaccine production, like a new 'innovator' drug brand, is a very expensive and prolonged process since the safety threshold for producing them is far higher than other drugs. Vouters, McKee and Luyten highlighted that the mean cost of developing new drugs (including vaccines) range between $314 million to 2.8 billion[27]. The final sale price is dependent upon the nature and severity of the disease or viral infection. For example, flu vaccines are comparatively cheaper than cancer vaccines. In terms of time, there are (in general) five phases (before sales approval and monitoring, which is the sixth phase)[28].

This is one reason that for a considerable time, vaccines remained out of reach of middle and lower income countries. It was only after the wealthy countries pooled resources to start the Expanded Immunization program (EIP) that vaccines started reaching the poor

[25] 'Vaccines and Immunization', *WHO*
[26] 'Returns on investment from childhood immunization in low and middle income countries, 2011-20'
[27] 'Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018'
[28] Basic Research, Discovery, Pre-Clinical Studies, Clinical Studies/Trials (with two sub-phases, i.e., safety and effectiveness) and Follow-up studies. Source: CDC

countries. Simply put, vaccines, like new innovator brands, need a price incentive for research and production without which there is very slim chance of their production (at least in the private sector).

Globally, governments are major sponsors of vaccine production (indirectly) as they procure vaccines in substantial quantities, thus allowing for economies and scale that leads to profits for firms, who can then plough it in R&D related activities. The basis and logic of such support has already been pointed above: the positive spillovers of vaccination comfortably outweigh its costs! Further, governments tend to subsidize vaccine production and R&D. Two of the earliest Covid-19 vaccines, from Moderna and Pfizer, contain the novel mRNA technology, developed with more than $1 billion grant by the US government.

Pakistan has a long history when it comes to vaccine production, going back to late 1960s, when it started producing anti-snake venom vaccine. Production efforts got a tremendous boost with the onset of Expanded Immunization Program (EIP) in 1978. Since the public expense on healthcare, especially procurement of drugs, was too little to act as any incentive for the private sector to produce vaccines, the task was given to Pakistan National Institute of Health (PNIH, now NIH), which had previous experience of producing measles, rabies, and tetanus toxoid. The first vaccine on the list was polio vaccine, for which an Oral Polio Vaccine Processing Laboratory was established in 1981, which has produced polio vaccines since then (though not continuously). Initially, frozen polio bulk concentrate was provided by Canadian firm CLL, through efforts of the Canadian government.

Next up was the Measles vaccine whose production started in 1983, followed by Rabies vaccine. With time, relevant facilities and production numbers have gone up. Aside from the above mentioned, at present, NIH produces a plethora of vaccines like anti-allergy, anti-tetanus, anti-diphtheria vaccines, etc.

There were cases of noticeable delay, though, something typical of government plans in Pakistan. For example, NIH was slated to produce Hepatitis-B vaccines since early 90s, but this did not go according to plan. Similarly, although it had established rabies vaccine facilities in early 1980s, the said vaccine suffers from persistent shortages[29] and has to be imported. By 1998, three decades after its founding, NIH was producing only a limited range of vaccines which did not even cater for domestic demand. The production of OPV vaccine was covering only 8.3 percent of local demand, Measles vaccines covered about half of the demand, while TT vaccines covered 8.6 percent of local demand.[30] Pakistan either had to import the vaccines or look to outside help,

[29] 'The crux of Pakistan's prolonged Rabies vaccine shortage: A rising moral threat in COIVD-19 pandemic'

[30] 'REGIONAL SELF-SUFFICIENCY IN VACCINE AND DRUG PRODUCTION' (1998), Table. 4, p.9, *WHO Regional Office for Eastern Mediterranean*

which came in the form of vaccine alliance under GAVI. Pakistan has been a major beneficiary of this expanded immunization program. Currently, Pakistan is largest recipient of its aid under Strategic Phase 4 and 5. Over a million children in Pakistan miss routine vaccination every year.[31] Worryingly, though, GAVIs support, which covers major portion of vaccine provision to Pakistan, is going to end in 2031. After that, government funding would be even more critical to ensure vaccine provision as GAVI withdraws.

Still, Pakistan imports over 90 percent of vaccines utilized in the country, including essential ones like anti-rabies, anti-snake venom, Hepatitis-B and Polio vaccines. Local vaccine production is limited, and is mostly of the Ready-to-Fill (RTF) variety. None of the domestic vaccine manufacturing facilities, though, is WHO pre-qualified. There are temporary initiatives at the public level, like Sindh Government's financial support to Dow University of Medical Sciences for manufacturing anti-rabies vaccine (DowRab), but they fizzle out quickly. There is no long-term financial incentive or support to sustain continuous vaccine manufacturing at home. Plus, there are quality issues with locally produced vaccines.[32]

At this moment, majority of the vaccines produced in institutes like NIH are basically 'assembled' vaccines rather than home produced! Private sector does produce vaccines (under license), but mostly on demand rather than being incentivized by a market price incentive. As explained above, this unfortunate situation owes to the fact that the financial outlay required to whip up continuous vaccine production has never been there. A senior pharmaceutical industry producer confided to the author, giving the example of flu vaccines, that unless the government orders these in bulk or firms can price as per the market fundamentals, there is little incentive to bulk produce a vaccine. He gave the example of the US government that procures flu vaccine shots every year, which acts as a powerful price incentive for the firms to produce these vaccines in large numbers.

Vaccine manufacturing in Pakistan faces the following major challenges-

a) Lack of demand from federal and provincial governments, especially over the longer time horizons, which would make vaccine manufacturing financially feasible/viable
b) Lack of indigenous Research and Development (R&D) on vaccines
c) Lack of human capital expertise, specifically in terms of formulation
d) High initial cost of setting up GMP-compliant manufacturing facilities

[31] 'Lifeline delivered: WHO-GAVIs immunization impact in Pakistan', WHO and GAVI

[32] For example, Asghar et.al carried out an analysis of domestically manufactured and imported vaccines for treating Livestock illnesses. They found the efficacy of imported vaccines to be much superior to those of domestically produced vaccines

e) A long process of getting manufacturing license from DRAP (could be much easier if Biologics are treated separately and there's a separate window/procedure for approval of this manufacturing)

APIs[33]

The total global market for APIs is $ 193 billion and anticipated to witness a significant rise, climbing to approximately $ 285.29 billion by 2028. China and India, two of Pakistan's major import destinations in terms of APIs, have been the main success stories over the last three decades, with 57 percent of the APIs listed by WHO originating from India.

Pakistan, like most aspects of its economic and industrial management, has been left behind in this race. At present, it imports approximately 95 percent of its needed APIs for drug manufacturing, with around 46 types of APIs being manufactured locally. A total of 23 licenses have been issued by DRAP for local API manufacturing, but only 7 of them are producing at the moment.

After independence, government granted legal protection for production of opium in the Tribal areas and small parcels in NWFP, to be used as an API for use in domestic drug production (it had remained a traditional medicinal produce there since centuries, primarily as a sedative). By end 1955, approximately 20,000 pounds of santonine and ephedrine were being produced annually from artemesia and ephedra herbs found in the Kurram agency (ex-FATA).[34] After 1955, the Lahore Opium Factory was constructed and, under the Opium Act of 1857, farmers were licensed in the Punjab Province to produce opium. This turned out to be ineffective and in 1956 the districts of Peshawar, Mardan and Abbottabad in the North West Frontier Province (NWFP) were chosen for this purpose.[35]

The Eight Five-year Plan (1993-98) noted that at least five hundred distinct herbs had been identified within the country, of which about 200 were being used by the traditional medicinal practitioners (hakeems, yunani tibb) aside from ten 'leading manufacturers' who were using these to produce products with a high turn-over.[36]

However, API production declined over time despite few attempts to increase it. One such attempt came in the form of failed attempt to manufacture APIs using 'ephidra sinica' plant, found in abundance in Baluchistan. It is extensively used in cough syrups and low blood pressure drugs during spinal anesthesia. An attempt was made to set up

[33] Some of the information related to APIs in Pakistan is taken from recent study by Dr. Afaq Ahmed for PIDE, titled 'API Manufacturing- Case study of Pakistan' (2024)
[34] 1st Five-Year Plan (1955-1960), No. 106, p.455
[35] Windle, J. (2012). 'Insights for Contemporary Drug Policy: A Historical Account of Opium Control in India and Pakistan', *Asian Journal of Criminology*, Vol. 7(1), pp. 55-74
[36] 'Eighth Five-year Plan (1993-98)', p.343

a plant for its extraction, but eventually had to be shut down, partly due to regulatory barriers.

The estimated size of domestic API market of Pakistan is around $150 million. The total reported volume of API imports was an estimated $300 million in FY 22-23, with six companies accounted for 40 percent of total API imports.[37] In 2022, the Government of Pakistan introduced an API Promotion Policy to incentivize API production at home. Almost three years down the line, though, the results have been disappointing as there has been little change in terms of lessening dependence upon imported APIs. Key initiatives outlined in the policy, such as reducing customs duty, combating dumping practices, establishment of facilitation center by Drug Regulatory Authority (DRAP), API Mega Parks and facilitating financing, etc., have remain as hurdles to progress. The lack of coordination among regulatory bodies, industry stakeholders, and government entities has contributed to the policy's underwhelming implementation thus far.

Various factors militate against the local production of APIs, primarily the relatively cheaper option of importing APIs rather than setting up plant and manufacturing it here with high costs of production. We also see a non-continuation of policies in the form of first providing an incentive and then withdrawing it (set up a production plant but then refuse support), the paucity and dubious use of funds (why did DRAP or Health Ministry not provide funds from CRF when they are needed?), and that regulator works on a reactive basis (the 'stem cell' policy, for example, was adopted as a result of Supreme Court intervention in case No. 69699-P of 2018).

3- Pharmaceutical Regulations and their outcomes[38]

Governments all over the globe tend to have regulatory presence to various extents. Pakistan is no exception to the trend, with both its federal and provincial governments having a substantial regulatory presence in various spheres of socio-economic activities. Haq and Rafi (2022) estimated federal government's regulatory footprint to be 67 percent of the economic activity, reflecting heavy regulatory presence.[39] Another reflection of this heavy-handed government presence is the 120 plus regulatory agencies just in the federal capital, Islamabad.[40]

[37] 'API Manufacturing- Case study of Pakistan' (2024), Dr. Afaq Ahmed, *PIDE*

[38] This section draws upon the earlier work by Shahid Mehmood (2023) who analyzed DRAPs performance, with substantial portions from the study reproduced here. The study is titled 'Regulating the Pharmaceutical industry: An analysis of DRAP', *PIDE*

[39] 'Estimating the footprint of government on the economy' (2023), Nadeem Haq and Raja Rafi, *PIDE*

[40] SLUDGE, *PIDE*

In general, regulations are enacted wherever there is some deficiency in market operations or negative 'spillover' from private sector activities or operations. Put another way, regulations are enacted to protect public and consumer interest from negative repercussions of transactions between individuals or parties or their actions, such as vehicular pollution.

Health sector, in general, is heavily regulated around the globe, with significant government presence. Same is true of pharmaceutical industry that is closely tied to health outcomes. The groundwork for regulating the pharmaceutical sector was laid by Nobel Prize winner economist Kenneth Arrow's famous research paper in which he argued in favor of public sector presence and regulation rather than leaving it completely to the private sector.[41] Without going into technicalities, Arrow reached this conclusion based on his interpretation of how the best welfare outcomes can be achieved, whereby information asymmetries in some markets (like health) are more pronounced than other markets. An implication of such heightened asymmetries is that the consumer (patient in health sector) is always at a disadvantage concerning his choices and information, being at the mercy of the physician and the healthcare system. Put another way, the health service provider has a monopoly built on information asymmetry which would likely end up hurting the consumer.[42] In lieu of these, Arrow concluded that

'It is the general social consensus, clearly, that the laissez-faire solution for medicine is intolerable'

Besides information asymmetries and monopolistic competition, later research has also supported the case for public sector intervention, especially in consideration of economic spillovers of having a healthy population (already stated above).

Pakistan's pharmaceutical industry has been governed by various regulatory laws (Acts') over time. What follows is a brief description of those laws and whether the intended outcomes of those laws (especially the Act of 1976 and 2012 were achieved?).

Drug Act 1940

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 acts[43] which were mainly concentrated on preventing and regulating the use of dangerous drugs and chemicals. 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,

[41] 'Uncertainty and the welfare economics of medical care' (1963), *The American Economic Review, Volume LIII, Number 5*

[42] For example, physician may prescribe drugs that are not required, private hospitals may charge excessively citing paucity of available services or prescribing elongated stays than ae necessary

[43] For example, 'The Poison Act, 1909' and 'Dangerous Drug Act, 1930'.

but these tended to cover only specific areas rather than the pharmaceutical sector as a whole[44].

One of the most noticeable feature of this Act, which appears at the very start, is that it was only designed and passed after approval from provincial legislatures. In other words, the center came up with this policy only after getting the nod from provincial governments, a testament to the decentralized nature of this issue at that time. The title of the Act[45] clearly reflects that the regulations were meant to govern import, export, manufacturing, sale and distribution of drugs.

Through this legislation, a 'Drugs Technical Advisory Board', 'Central Drugs Lab' and 'Drugs Consultative Committee' was constituted to advise federal and provincial governments on technical issues related to drugs, testing and analyzing drugs, and for achieving harmony between various organs to achieve desired goals. 'Drugs' to be regulated included allopathic, homeopathic, ayurvedic, Unani and biochemic medicines.

For imported drugs, the regulation's main thrust concerned quality of the drug and protecting a patent[46]. Interestingly, it allowed for importing sub-standard medicines as a special case, after approval from the Board. The state government's custom officers were conferred the authority to seize imported drugs in case they did not meet the prescribed criteria. In case they deemed necessary, they could send the medicine to testing lab, otherwise there was no compulsion upon them[47] to do so. Interestingly, an exemption to these laws/regulations is provided (if approved by board) for drugs that are imported into the country for the purpose of either transporting to another country or for its use as an export[48].

When it came to export of drugs, the exporter needed to get permission for doing so. A sample of the drug had to be sent to the central testing laboratory before exporting, and license had to be sought. Special permission was needed for exporting drugs that were prohibited under this act. 'Misbranded Drugs' are basically defined as drugs that has some deceptive feature attached to it[49]. The sale of such drugs exhibiting some sort of deceptive element were also prohibited. Any drug offered for sale had to first go through testing from the central testing laboratory, where at least two samples of the drugs had

[44] For example, the Pharmacy Act of 1967 was exclusively concentrated on ensuing quality qualification of the pharmacist.
[45] 'An Act to regulate the import, export, manufacture, distribution and sale of drugs'
[46] The Act states that the imported drug shall not be 'misbranded', of low quality, patent and proprietary rights must be displayed on label and it should not be for cures other than stated on it
[47] Point 11 (1) and 11(2).
[48] Point 12(2) 'j'.
[49] The real place of its manufacturing is not told, its efficacy is not the same as advertised, its advertised as a substitute when it's not, it's sold in the same name as any other drug, and if it is not properly labelled.

to be provided. To ensure proper regulation, the sale of any sort of medicine was banned in public places like foot paths, highways or streets[50].

The provincial government, in consultation with the board, had the independence to deal with these issues of quality, sale and manufacture. It could amend the rules as per its standards, and notify the central government thereof through the official gazette. Moreover, the inspectors chosen for enforcing the regulations were to be selected by provincial governments[51] rather than the central government. They had to exhibit a certain qualification and also demonstrate that there was no conflict of interest in their duties as drug inspectors.

Drug Act 1976

Like the Drug Act of 1940, this act was also meant to regulate import, export, distribution, sale and manufacturing of drugs. It carries the same connotation of 'misbranded drug' as in the 1940 act, with the addition of 'counterfeit', 'adulterated', 'spurious' and 'sub-standard' drug.[52] For the first time, Drug Courts were approved to deal with problems pertaining to drug regulations. Import of drugs was allowed after getting proper approval/license, and only for category of drugs that were already being sold in the markets of West Europe, USA, Japan and Australia.

When it came to granting license for manufacturing drugs and registration of drugs, the authority lay with a 'Central Licensing Board' and a 'Registration Board' respectively. The former contained representatives from the federal and the provincial governments, while it is mentioned for the latter that only those persons will be its Members who are 'qualified'. In terms of registration, an important distinction is made between 'single ingredient' drug that were to be sold under their generic name, and 'compound ingredient' drug that was to be sold under proprietary name. The registration board had the power to cancel registration of any approved drug if found to be in breach of regulations. An 'Appellate Board' was set up for hearing appeals against decisions of the above two forums.

Regulations regarding sale of drugs were marked as provincial government's domain. The provincial government was also given the power to appoint 'Provincial Quality Control Board' that was to oversee matters related to quality control (training, upgrading facilities, etc.). They were also to setup drug testing laboratories, as was obligatory upon

[50] Point 36

[51] Point 21

[52] An 'adulterated' drug is defined as containing putrid, filthy or expired substances, manufactured in unsanitary conditions and that is less effective than shown on label. 'Counterfeit drug' relates to deceptive practices of improper labelling of a drug in order to market as a substitute/same as another drug. 'Spurious' drug is primarily defined in terms of lack of an active ingredient. Moreover, it is also defined in terms of deceptive practices (containing false information about manufacturing country, etc). A 'sub-standard' drug, meanwhile, is a drug that does not meet 'specifications'.

the federal government. However, despite powers given to provincial governments, the federal government retained the right to 'direct' provincial governments in terms of enforcing necessary regulations.[53] Moreover, unlike the Act of 1940, the federal government anointed itself the right to appoint drug inspectors besides allowing the provincial governments to do so.

For the first time, we see the introduction of price controls in drug regulations[54] whereby the federal government took it upon itself to fix the prices of a drug and also to fix the rate at which a certain percentage of manufacturers' profit was to be utilized for research (the Central Research Fund). In terms of import, export, manufacturing and sale of drugs, all the drugs had to follow the procedures and regulations outlined in the act.[55]

Act of 2012

The Drug Regulatory Authority of Pakistan (DRAP) Act was conceived not as a completely new Act, but for enforcement and coordination of the earlier 1976 Act. Moreover, another of its aim is to 'bring harmony' in inter-provincial trade of therapeutic medicines, and to regulate sale, manufacture, store, import and export of medicines. This act was passed after the Parliament got approval from principal assemblies for passing this legislation.

For the first time, Over the Counter (OTC) products like baby milk, medicated soaps, etc., were brought under the regulatory framework. Also, for the first time, DRAP had been anointed to the status of a 'body corporate'. All the existing federal laboratories came under the supervision of DRAP after the passage of this act. Approval was given for appointment of a Chief Executive Officer (CEO) and thirteen directors. The DRAP has been tasked with 'advising' the Provincial governments in enforcing the regulations. The supervision of DRAP is to be carried out by a Board that constitutes 15 members (including representation from the provincial government).

Other than these, the regulations regarding import, export, sale and manufacture of medicines follows the criteria laid out in the 1976 Act.

At present, The Drug Regulatory Authority of Pakistan (DRAP) is the main regulator of the pharmaceutical industry in the country. Created in 2012 in the aftermath of deaths due to sub-standard medication at Lahore Institute of Cardiology, it was perceived as an autonomous body under the Federal Government's domain, as an autonomous arm of the Ministry of National Health Services Coordination and Regulation (MNHSCR). It succeeded the previous federal regulatory entity, the Drug Control Organization (DCO), which worked under the now-defunct Ministry of Health. Although provinces have their

[53] Point 13
[54] Point 12
[55] Details can be found in point 23

drug regulatory authorities, their domain of influence and work pales in comparison to the extent of powers and regulatory roles conferred upon the DRAP. Except for distribution and sales, all other aspects related to drugs (licensing, pricing, import, export, manufacturing, etc.) are dealt by the federal government. Post 18th Amendment, there was a push towards devolving even these to the provinces but they, through the Council of Common Interest (CCI), agreed to let these be in federal government's regulatory realm.

The tasks to be performed under the DRAP Act 2012 are vast, diverse and challenging. It starts by emphasizing the necessity of effectively coordinating and implementing provisions of the previous Act (the 1976 Act) and to harmonize inter-provincial trade in therapeutic goods. The canvass of responsibilities gradually assumes a broader role, from import/export of drugs, storage and distribution issues, to coding and marketing practices and maintaining the quality of products (through Goods Manufacturing Practices or GMP). Suffice to say, the set of rules to govern the working of the pharmaceutical industry are immense in their aggregate.

The above was a brief description of the main laws. What follows is a brief overview of the various issues/themes that have historically proven to be a source of discomfort for both the industry and the consumers. Although the main focus is DRAP, the regulatory areas discussed also cover the ambit of provincial regulators.

Price Controls

Pricing of pharmaceutical products, especially drugs, is one of the most critical areas in global health regulation. This is especially true of low- and middle-income countries (LMICs) where the issue of affordability is exacerbated by factors like low levels of health insurance coverage and low per capita income. For households at the lower strata of income, there is heavy reliance on allopathic drugs for health treatment due to a lack of access to medical facilities and trained medical professionals. While drugs (especially life-saving drugs) represent about 30-40 percent of total public and private health expenditures in developing countries, they comprise between 50-80 percent of total health spending amongst low-income households in these countries.[56] Even within generic drugs there can be large price dispersions despite development of mature generic markets, making affordability difficult. Simply put, drug price regulation is about affordability and greater, population-wide access.

Overall, a large portion of the population around the globe lacks access to life-saving drugs, which in substantial number of cases is of originator brand. Therefore, historically, the governments of low-income countries have always favored (and incentivized) generic drug production with the aim of propagating affordability and

[56] Source: *WHO*

availability. In Pakistan, this has been the aim at least since promulgation of Drug Act of 1976, with tightly regulated prices of allopathic drugs.

But how successful have price control policies been around the globe and in Pakistan? And what does the literature say about the effectiveness of price controls? The literature on price controls in drugs is extensive, and there seems to be unanimous opinion that strict controls on the pricing of drugs is counterproductive in the long-run as it gives rise to lower innovation, reduced instances of new drug varieties, lower investment, expansion in black market in drugs and substantially higher prices than envisaged under price controls. Some of these studies and their findings are briefly described in the following paragraph.

One of the major studies on drug price regulations was carried out by Lanjouw (2005), with a large sample size of 68 countries for the analysis (at all income levels). All drug launches over the period of 1982-2002 were covered in this research. The conclusion was that price controls discourage introduction of new products and investment, with a significant lag in introduction of new drug varieties compared to if there had been lesser controls.[57] Santerre and Vernon (2006) did a cost-benefit analysis of drug pricing control policy from 1960 to 2000, taking into account the social costs and benefits, the authors conclude that drug price controls do more harm than good. More than 200 needed drugs could not get introduced in the period due to price restrictions. [58]

Dean (2020) carried out an extensive analysis of the Indian pharmaceutical market (one of the largest market in the world) and Indian government's price regulations, concluding that the decline in prices (or the slow down in price increases) is only temporary. At the same time, though drug sales (especially generic drugs) declined, the quality of drugs deteriorated, and the worst affected from price controls were the poor for whom, ironically, price controls were enacted in the first place.[59] Roger and Ji (2024) investigated the effects of forced price cuts upon the medical device manufacturing. They found that the price cuts not only reduce market entry and innovation substantially, but also led to a 75 percent decrease in patent filings.[60]

Turning to Pakistan, research based evidence conforms to the above findings. Government derives its regulatory power over pricing through Drugs Act 1976, which has been modified in Acts of 2015 and 2018 by bringing in CPI based price increase

[57] 'Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry' (2005), Jean O Lanjouw

[58] 'Assessing Consumer Gains from a Drug Price Control Policy in the United States' (2006), Rexford E. Santerre and John A. Vernon; *Southern Economic Journal* Vol. 73, No. 1 (Jul., 2006), pp. 233-245)

[59] 'Who Benefits from Pharmaceutical Price Controls? Evidence from India' (2019), Emma Boswell Dean, *Center for Global development (CGDEV)*, W.P 509

[60] 'THE LONG-RUN IMPACTS OF REGULATED PRICE CUTS: EVIDENCE FROM MEDICARE' (2024), Yunan Ji and Parker Rogers, Working Paper 33083, *NBER*

provisions and reference pricing (but pricing is still tightly controlled by government, especially that of life-saving drugs). Section 12 of Drugs Act 1976 states that power to fix maximum prices of drug, etc.- (1) The Federal Government may, by notification in the official Gazette,-

(a) fix the maximum price at which any drug specified in the notification is to be sold
(b) and (b) specify a certain percentage of the profits of manufacturers of drugs which shall be utilized, in accordance with the rules for purposes of research in drugs

However, by the time of the 7th Five-Year Plan (1988-93), government acknowledged that the process of price fixing of drugs is cumbersome and public sector lacked professionals who could properly handle this issue. Further, it contends that quality of drugs was the 'weakest link' in the system. Importantly, the plan recommends doing away with price controls for all drugs that do not fall in 'life-saving' or 'essential' category. [61] In recognition of this, the government did take some steps to de-regulate pricing of 'non-essential' drugs, which was later withdrawn and 'prize freeze' introduced in 2001, continuing till 2013.[62]

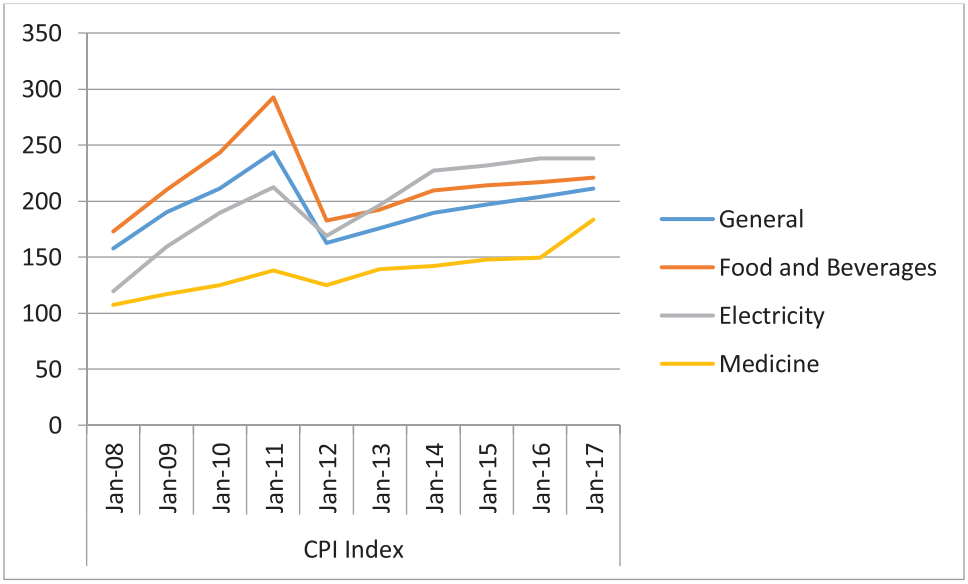
What did these price control policies achieve in the end? Pakistan falls into the low income category with its low per capita expense and an inefficient healthcare system, and also the fact that a large portion of healthcare expenditures of its citizens tend to be Out-of-Pocket (OOP) expenses. A WHO report in 2004, for example, estimated that OOP expenses were 77 percent of the total health expenses, with almost half being spent on drugs.[63] Worryingly, research indicates that the percentage has remained the same or near about over the years despite regulations (especially price regulations concerning drug pricing). For example, Ahmad and Khattak (2019) opined that 70-75 percent of total health expense was OOP, of which half was on drugs.[64]

This, and other such indicators, leave no doubt that the policy to 'control' drug prices with the aim of affordability has been a continuous failure. Even government's own statistics affirm this contention. Data from the National Health Accounts (NHA) over the years prove that despite stringent price control measures, the percentage spent of drugs (as a total of health expenses) has consistently risen over time. [65]

[61] The 7th Five-Year Plan (1988-93), #135 and #139
[62] SRO 471(1)/93 dated 6th July 1993 provided a list of 821 medicines and gave blanket approval for rest of medicine prices to be de-controlled
[63] 'The World Medicines Situation' (2004). *World Health Organization*
[64] 'Drug Pricing Insight of Pakistan' (2019), Fazl e Hakeem Khattak and Irfan Ahmed, PIDE
[65] 'Regulating the pharmaceutical industry: An analysis of DRAP' (2022), PIDE, table on p.19

Year	Expenses on drugs as percentage of total health expenses	Per Capita expense on drugs
2004	40	
2008	56	Rs. 900
2010	56	Rs. 920
2012	50	Rs. 822
2014	53	Rs. 1,338
2016	50	Rs. 1,400
2018	51	Rs. 1,580
2022	60	Rs. 1,750

It is argued that these policies have been highly counter-intuitive, illogical and completely ineffective. They have had highly negative spillovers, especially in the form of debilitating drug shortages. Between 2001 and 2013, the most stringent form of administered pricing, the 'price freeze' policy was applied. But as shown above, OOP expenditures on drugs and percentage of expenses on drugs (as percent of total expense on health) kept increasing during that time. The policies also completely discounted the rising costs of production for the industry, which have ballooned over time, especially during price freeze era, as depicted in the graph below.



For any sensible person with business acumen, the continuation with such policies would be illogical. Yet the government kept persisting with the price freeze policy, giving rise to shortages, black marketing and other issues that put the industry and consumers under

tremendous duress.[66] Also consider the important fact that the rupee's value against the dollar during the price freeze episode (2001-2013) fell by 65 percent, jacking up the costs of local production significantly since almost 90-95 percent of APIs are imported. Between 2001 and 2023, the value of rupee against the dollar declined by a staggering 352 percent, yet the government and its regulations never took that into account.

As the domestic costs of production rise while the profit margins are squeezed due to stringent regulations, the relative price structure and incentives go through a change. In Pakistan's case, for example, over time, importing APIs and drugs became profitable compared to local production. Resultantly, only a small percentage of APIs is being produced here and many drugs have been discontinued over time or are discontinued temporarily, resulting in shortages (discussed below).[67] Penicillin is one such example amongst many, once produced in the country in biological production facilities using microorganisms. But the production was stopped as it became financially unfeasible while importing Penicillin became more profitable compared to producing at home. To demonstrate, a select list of discontinued drugs is given in the table below-

Name	Category	Name	Category
Losan Plus	Antacid	**Primaverine**	Antispasmodic
Lansoprazole	Antipeptic Ulcerant	**Phloroglunicol**	Antispasmodic
Pantoprazole	Antipeptic Ulcerant	**Lavosulpiride**	Antiemetic
Rabeprazole	Antipeptic Ulcerant	**Sylcol**	Hepatic Preps
Orlisat	Anti-obesity	**Sym**	Hepatic Preps
Pioglitazone	Hypoglyceamic	**Glimeperide**	Hypoglyceamic
Metformin	Hypoglyceamic	**Rosiglitazone**	Hypoglyceamic
Alfacalcidol	Supplement	**Cholecalciferol**	Supplement
Osteocur-c	Supplement	**Casan**	Supplement
Durabolin	Anabolic	**Asacol**	Alimentary Tract Preps
Anagrelide	Anticoagulant	**Prasugrel**	Anticoagulant
Enoximone	Cadiac Therapy	**Trimetazidine**	Cadiac Therapy
Citicoline	Vasotherapeutic	**Candesartan**	Angiotensin Antagonist
Atorvastatin	Anti-atheroma	**Ezitimibe**	Anti-atheroma
Croconazole	Anti-fungal	**Trbianfine**	Anti-fungal

Additionally, over time, many producers have found ways to circumvent the tight price restrictions. One favored strategy, for example, is to stop producing a drug that does not get the requested price increase, and start producing it under different name at a higher

[66] CPI data taken from PBS statistics. It is also this time (during price freeze policy) that many MNCs started packing up or merging with other firms due to adverse circumstances

[67] An example is eye drops 'Medicor', used for curing corneal issues like childhood blindness. The manufacturer discontinued its manufacturing due to stringent price controls

price.[68] Another one is increasing production of Nutraceuticals that do not have the same stringent pricing restrictions as allopathic drugs.

Despite overwhelming evidence that stringent price regulations have failed to achieve its intended purpose, successive governments in Pakistan seem unwilling to let go of their power to set prices, clinging to the discarded fancy that their actions can make drugs affordable and widely available. To achieve this end, innovative tactics are adopted that even violate the pricing tenets of 2015 and 2018 Policies. One such recent example came in the form of a case involving non-essential drugs (Brufen tablets, Brufen Suspension and Thyronorm). The new pricing policies provide for a 10 percent rise in their MRPs, but DRAP refused to allow the price increase, arguing that the categorization of the drugs in question had now changed to 'other drugs', which lowered their price increase threshold to only 7 percent.[69]

Similar, despite a relatively liberal regime in terms of drug pricing under 2015 and 2018 policies, price increases are still largely a political decision needing Cabinet's nod. Moreover, legislation has been tinkered with in order to maintain a hold over the pricing one way or another. For example, under SRO No. F.11-2/2020-DD (P) dated 15th July 2020, the rule for 'hardship' cases was modified to reduce the number of decision-making days from 180 to 120. One important part of this SRO, though, is part 'vii' of 'b', whereby the Federal Government can nullify price agreed upon price increase in line with CPI if it has a 'cogent' reason, thus keeping a window open for government nullifying agreed-upon price increases.

Finally, there is always the danger of someone in authority nullifying polices. For example, in 2019, as proposal for increase in drug prices was forwarded in lieu of exchange rate depreciation and uptick in inflation, as per the agreed price mechanism, the then PM Imran Khan refused to grant the proposed price increase, apparently under tremendous pressure from the press which always creates an uproar at any possibility of raising drug prices.

Other public sector policies, like DRAPs 2021 directive to all provincial governments to ensure that doctors prescribe drugs only with their generic names, have also failed to make any substantial mark in terms of affordability and availability. This step was taken in lieu of countering the trend of medical practitioners favoring a particular brand that in turn perpetuates drug price inflation. Theoretically, such a step would have led to lowering of OOP expenses on drugs as consumers would buy lowering priced generics rather than brands.

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[68] 'Pakistan's hike in drug prices may be painful, but it is necessary' (2021), Kabeer Dawani, *SOAS Consortium*

[69] 'SHC rejects pharma firm's pleas seeking hike in drug prices', Muhammad Saqib, *Business Recorder*, 20th June 2025

Industry representatives and experts maintain that this is counterintuitive keeping in context the negative outcomes, and especially as government (both federal and provincial) move towards providing health insurance, which (theoretically speaking) also covers drug expenses. In fact, Punjab government initiated a 'medicine card' scheme in 2020, aimed at paying for expenses of drugs of TB, AIDS and Hepatitis patients. Over time, the provision of health insurance has been demonstrated to be an effective instrument in reducing overall expenses on drugs. For example, Barwick, Swanson and Xia (2025) found that China's National Reimbursement Drug List (NRDL) Reform, which combines centralized drug price negotiation with expanded insurance coverage, led to reduced retail prices by 48 percent and out-of-pocket costs by 80 percent, while increasing drug utilization by 350 percent.[70]

The crux of the above is that stringent price controls have failed to achieve the government's stated objectives of controlling drug prices and making drugs (especially life-saving drugs) more affordable. Instead, what has happened is that these controls have resulted in frequent, rampant drug shortages that have put lives at risk, led to an expanding black market in drugs, higher smuggling, dis-incentivized production, led to lower investment in the pharmaceutical sector, and has also been a substantial factor in exodus of pharmaceutical MNCs from Pakistan.

The recent 'liberalization' of non-essential drugs is perhaps an intimation that governance circles are acknowledging their price control failures. However, as sated above, such an acknowledgement has happened before, only for another government to renege upon it, reflecting lack of consistency.

There are other, 'minor' reasons for drug price spikes of which public regulations can be absolved. One is 'brand' loyalty, and other is seasonal spikes that suddenly increase a particular drug's demand (as in floods). Ectemra, not on DRAP regulated list, is one such example whose many alternatives of same chemical formulation manufactured by local companies can be found in Pakistan but consumers wouldn't budge from it as COVID spiked.[71]

Drug shortages and availability

On 30th March 1954, during the Constituent Assembly session, Mr. Abdul Monem Khan pointed to the severe shortages of drugs in the country. The Health Minister, Mr. Tafazzal Ali, replied that import orders had been placed to ameliorate the shortages. In 1976, Arthur Homer Furnia, a US Health sector specialist, noted the shortages of medicines, especially in government facilities where the trend of siphoning of

[70] 'A double dose of reform: Insurance and centralized negotiation in drug markets' (2025), Panle Jia Barwick, Ashley T. Swanson and Tian Li Xia, *NBER*, WORKING PAPER 33832

[71] 'Black market thrives as demand for anti-virals increases', *Pakistan Today*, 9th June 2020

medicines was common.[72] This is a reflection of the fact that drug shortages and availability issue is quiet old in this country, and as discussed above, it is one primary outcome of the stringent price control regulations.

Although price control policies over time have been the major factor in causing drug shortages, but they are not the only factor. Seasonal and geo-political factors also play a role in it. A prime example is Pakistan's medicinal imports from India, which include APIs, Vaccines and other drugs. In 2019, it imported Rs. 136 crore of drugs from India. But suddenly the import was stopped due to geopolitical tensions, resulting in shortages of drugs (especially anti-cancer drugs and anti-Serra vaccines).[73] Similarly, hoarding and opportunistic middlemen also play a part. For example, as soon as hydroxycloroquine was pointed out as an effective remedy against COVID-19, it vanished off the shelves of pharmacies within a day or two.

The issue of rampant drug shortages in Pakistan has been extensively documented, both officially and in literature. A 2004 survey of 29 drugs (of which 25 were essential) found the availability of essential drugs to be extremely low in public sector health facilities.[74] Shamim Rizvi (1999) blamed the government policies, especially 'freezing' drug prices, as the main contributor to shortages of essential drugs in Pakistan.[75] A paper by Third World Network Briefing (2001) touched upon the issue of drug shortages, discussing the role of government mandated quotas in Pakistan and its effects on drug supply. Zaidi et al. (2013) were of the view that the shortage of drugs in the public sector owes to the lower expenditures per capita (less than $2) as proposed by the World Health Organization (WHO) for maintaining a steady supply of essential drugs. A paper by Noureen and Zaidi (2013), researchers at the Agha Khan University, put the essential drugs availability in the public sector at a dismal 3.3 percent, much lower than Zaidi et al. estimate of 15 percent.[76] Interestingly, their results seemed to confirm earlier estimates by The Network for Consumer Protection (2006), who found a similar percentage in terms of median availability of essential drugs at public sector outlets.[77] Gilani, Babar and Malik (2013) opined that non-availability of essential medicine at government facilities explains why 67 percent of total patients consult private physicians, thus increasing their expenditures on healthcare. Hira Rashid (2015) opined that the shortage of price-controlled drugs leads to expansion of informal channels ('black market') for provision

[72] ''The Dynamics of Health: Islamic Republic of Pakistan' (1976), Arthur Homer Furnia

[73] 'Pakistan imported medicines worth Rs. 136 cr from India in 2019', *The Statesman*, 14th July 2019

[74] 'Medicine prices, availability, affordability and price components' (2004), *Network for Consumer Protection and WHO*

[75] 'Import of Raw Material for Medicines Manufacture' (1999), Shamim Ahmed Rizvi, *Pakistan and Gulf Economist,* July 12-18, 1999

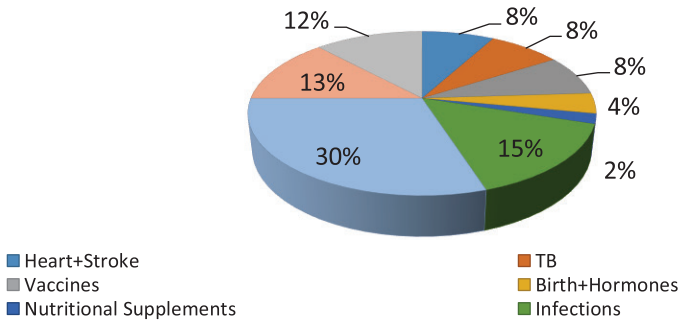
[76] 'Access to essential medicines in Pakistan' (2013), Shehla Zaidi and Noureen Nishtar, *Agha Khan University*

[77] 'Prices, availability and affordability of medicines in Pakistan' (2006), *The Network for Consumer Protection*

of needed drugs, at a considerably higher price.[78] Sayeed and Dawani (2020) are of the view that the main driver of shortages are rigid pricing policies administered by the government, which has driven the industry to concentrate only on drugs that have a high price margin, plus incentivize hoarding and rent-seeking.

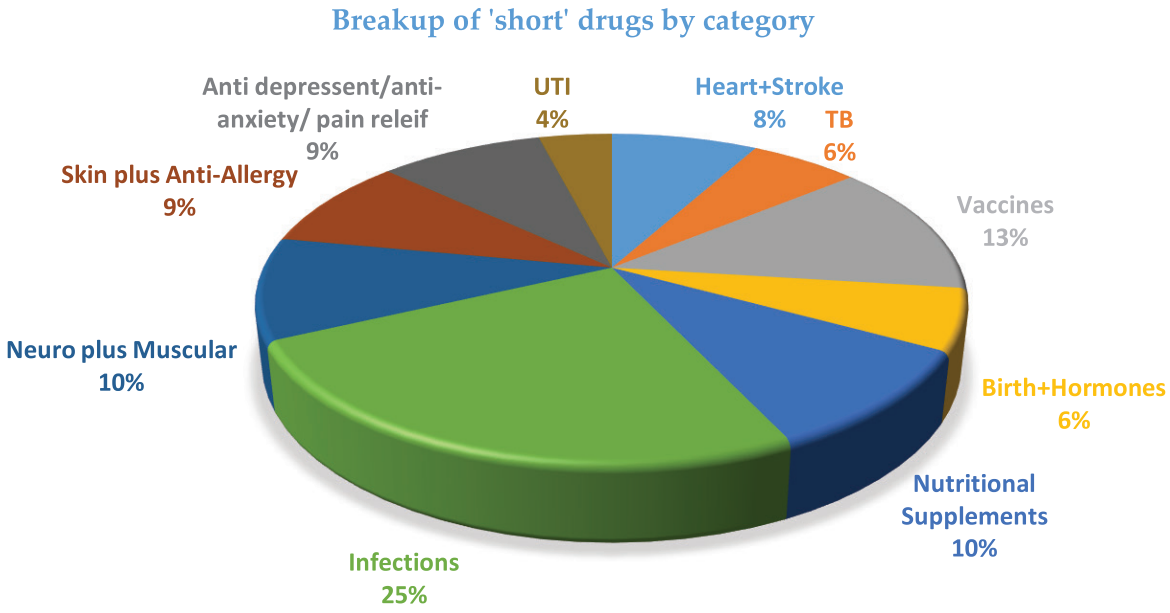
Atif, Malik and Asghar (2018) carried out a survey in three cities (Islamabad, Karachi and Bahawalpur) and found that drug shortages were frequent, main reasons being issues in raw material availability, pricing issues and demand fluctuations.[79] Another indicator that substantiates the severity of this issue is the difference between the numbers of drugs registered for manufacturing versus the number manufactured in reality. In 2016, for example, out of the approximately 70,000 registered drugs, hardly 10,000 were being produced! A 2024 report revealed that over 50 percent of the life-saving drugs recommended by the WHO were not available in the local market.[80] Recently, the official German broadcaster, DW, did a story on the morphine shortages plaguing the pharmaceutical market of Pakistan for long.[81]

An initial attempt was made by Mehmood (2017) to document drug shortage through a structured survey in twin cities of Islamabad and Rawalpindi.[82] The survey revealed that availability of both essential and non-essential, frequently used drugs remained a major problem. From the compiled list of drugs, 48 (42 percent) were found to be the ones that had been short for a long time ('not available' category, some were discontinued by their producers), while 67 (58 percent) were found to have experienced a shortage in the last 6 months. Out of the total of 48 drugs that fell in the 'Not-Available' category, the majority belonged to drugs used for treating neurological and muscle related medical conditions, followed by medicine belonging to the skin diseases/anti-allergy category. The total breakup, in percentages, is reflected in the following pie- chart.[83]



[78] 'Impact of Drug Regulatory Authority, Pakistan: An evaluation' (2015), Hira Rashid
[79] 'Medicines shortages in Pakistan: a qualitative study to explore current situation, reasons and possible solutions to overcome the barriers' (2018), M. Atif, Iram Malik, Saima Asghar, Irem Mushtaq
[80] 'Over 50% of WHO-listed lifesaving medicines unavailable', 28th September 2024, *Express Tribune*
[81] 'Inside Pakistan's morphine crisis' (2025), Sara Gill, *DW*, 11th July 2025
[82] 'Access to essential medicines: Findings of Survey' (2017), Shahid Mehmood, *PRIME Institute*
[83] Taken from the same survey

In the 'shortage' category, the majority belonged to drugs used for treating various infections (fungal, viral, bacterial), followed by 'vaccine' category.



Then came a seminal paper on drug shortages by Yusuf (2022, supervised by Mehmood who had carried out the above-mentioned survey on drug shortages) that not only built a five year database of 'essential' drug shortages but also documented the severe repercussions of these shortages, including worsening of illnesses and even death.[84] In 2024, Hayat extensively documented the pain and the threat to lives inflicted by adverse regulations concerning import of morphine for cancer patients.[85] The absurdity of regulations can be gauged by the following (summarized from her paper)-

a) company cannot apply for quota renewal until after most of its existing stock has finished. However, the supplier (a Swiss company) had their own lead time for placing order before delivery: four months
b) Even before placing order with the supplier, after a company submits its application, drug inspector will come to the factory, inspect invoices, and check if all the stock has been consumed. The lag between application submission and approval is easily a few months and varies case by case. If approved, only then can the company request new stock from the supplier
c) The end result is that for several months of the year, there is severe shortage of morphine as there is none to supply

[84] 'Welfare Impact of Generic Drug Shortages in Pakistan' (2022), Kainat Yusuf, *PIDE*
[85] 'Regimes of pain: The geopolitics of cancer palliation in Pakistan' (2024), Zahra Hayat, *Medical Anthropology Quarterly, April 2024*

d) even after receiving morphine from foreign supplier, clearing customs and is ready to be dispatched to the hospitals, there are further permissions required and procedures. Hospitals must secure a no-objection certificate ("NOC") from the DRAP and are required to repeat this process for every morphine purchase, whether for one pack or 1000 packs. Sometimes, NOCs are delayed to the point that suppliers' stock expires

Unfortunately, the availability of drugs, both at the federal and provincial levels, have hardly shown any considerable improvement over the years despite founding of DRAP and despite 18th Amendment which gave extra resources to the provinces to spend on healthcare. Various indicators of health support this conclusion. For example, the global survival rate children suffering from cancer is 80 percent, but the same rate stands at a dismal 30 percent in Pakistan, partly because required cancer treatments are either unavailable or short. Shortages in public health facilities are rampant, and pilferage is common. In 2021, in a raid conducted in an area famous for manufacturing spurious, counterfeit drugs, DRAP recovered considerable amounts of drugs stolen from NICVD and Dr. Ruth Fao Hospital in Karachi. In 2023, large quantities of anti-malarial drug Primaquine 7.5 mg, provided by the WHO to Sindh government for free, vanished off the dispensaries of provincial hospitals and sold in black at exorbitant prices. In November of same year, a gathering of Doctors' Forum, Pakistan Medical Association and others heavily criticized public sector procurements, alleging that equipment and drugs worth millions was being bought in billions while availability of drugs remained a substantial issue.[86]

Drug Quality and the issue of sub-standard, low quality drugs

Sub-standard drugs, categorized under various names like falsified, spurious, low-quality, adulterated, counterfeit, etc., are a global problem that have attracted significant attention from regulators. The following excerpt from Mackey, Clark and Breman gives us a fair picture of the issues associated with such drugs-

'Falsified and substandard medicines are associated with tens of thousands of deaths, mainly in young children in poor countries. Poor-quality drugs exact an annual economic toll of up to US$200 billion and contribute to the increasing peril of antimicrobial resistance. The WHO has emerged recently as the global leader in the battle against poor-quality drugs, and pharmaceutical companies have increased their roles in assuring the integrity of drug supply chains. Despite advances in drug quality surveillance and detection technology, more efforts are urgently required in research, policy, and field monitoring to halt the pandemic of bad drugs. In addition to strengthening international and national pharmaceutical governance, in part by national implementation of the Model Law on Medicines and Crime, a quantifiable

[86] Source- https://jang.com.pk/news/1287869

Sustainable Development Goal target and an international convention to insure drug quality and safety are urgent priorities'.[87]

Another reason for worry is the quality of tests being performed. In 2023, an article published in the reputed magazine 'Nature' put forth some startling statistics. A careful scrutiny was carried out of all the reported Randomized Control Trials (RCT) of drugs between 2017 and 2020, submitted to Journal *Anesthesia*. The researchers concluded that almost a quarter of these reported trials were suspicious, unreliable and non-credible. They labelled them 'zombie trials'.[88]

It occurs that zombie trials are quiet prevalent in other fields of health/medicine like bone health, viral infections, pain, etc., and have found hundreds to cases of trials with unreliable data. A Japanese researcher, who died in 2016, had 113 of his papers on drug and supplement efficacy retracted after a review of these found them to be suspicious on account of fudged data and other information.[89] The resulting drugs courtesy of such fudged data can, not surprisingly, cause harm to the individual consuming it. Besides drugs based on spurious, questionable data, low quality drugs could result from several other factors including (non-deliberate) API mixing in wrong proportions, lost potency due to climatic conditions (hot weather specifically), illegal mixing of different imported and local manufactured drugs, etc.

In essence, in terms of quality, it is often the generic drugs that attract most attention at the global level. A report on the samples of generics tested in Notre Dame University revealed that one-fifths of the generics (mostly Indian, a major export power of pharmaceuticals) failed quality control tests.[90]

Briefly put, in Pakistan, generics and branded generics being produced by top pharmaceutical firms in Pakistan have rarely encountered quality issues, and compete well with innovator brands in local market due to their good quality.

However, that does not mean that the country does not have a poor quality drugs problem. In fact, Pakistan has had a long history of questionable, poor quality drugs. It is mentioned in the 2nd Five-Year Plan (1955-1960) that the medical profession was reluctant in prescribing syrups and other medicinal products produced domestically due to quality issues.[91] In 1967, the National Assembly unanimously passed a law aimed at regulating pharmacies across the country after persistent complaints regarding

[87] 'Falsified and sub-standard drugs- stopping the Pandemic' (2019), Joel Breman, Tim Mackey, John Clark, *The American Journal of Tropical Medicine and Hygiene*

[88] 'Medicine is plagued by untrustworthy clinical trials. How many studies are faked or flawed?', Richard Von Noorden, *NATURE*, 18th July 2023

[89] 'What universities can learn from one of science's biggest frauds' (2019), Holly Else, *NATURE*, 18th June 2019

[90] 'Medicines that hinder rather than help healing', *Business Recorder*, 5th July 2025

[91] 2nd Five-Year Plan (1955-1960), No. 106, p.455

quality of drugs sold at the pharmacies, mixing up of various low quality drugs and their overall unethical behavior, using words like 'harmful', 'fake' and 'impure' medicines. The debate itself is quiet revealing as Members talked of 'people losing faith in locally manufactured medicines' due to their poor quality. Counter examples of ethical and honest British pharmacy practices were alluded to, to set up punishments for unethical, dishonest behavior of manufacturers and pharmacists at home.[92]

In 1975, government suspended manufacturing licenses for 38 local companies on account of manufacturing substandard drug, which led to deaths of more than 30 people. In 1976, after scrutiny of this experience, the Director General of Health issued orders that terminated the compulsory requirement of manufacturing and marketing by generic names.

The 7th Five-Year Plan (1988-93) envisioned setting up drug quality testing laboratories in each province, aside from one at the federal level, for which total expenditure of Rs. 400 million was proposed to be spent over the five years of the Plan. Further, a 'National Biological Evaluation Centre' was proposed to be set up federal level, with funding coming from the pharmaceutical industry R&D fund (the 'Central Research Fund').[93]

However, all these proposed expenses and aims seemed to have had little effect in the end. In 2010, the then Interior Minister of Pakistan, Mr. Rehamn Malik (late), stated in the National Assembly that more than 45-50 percent of the drugs sold in the country were fake/counterfeit or substandard. This was an astonishing claim, but one that was never backed up by any solid evidence. That number, highly exaggerated, though, has stayed in public discourse, oft repeated without any evidence. In 2021, for example, one of Pakistan's leading business paper, PROFIT, published a piece upon counterfeit drugs that repeated the same number. This was aside from the other highly exaggerated numbers in the article, like 4,000 registered pharmaceutical companies and 100,000 companies manufacturing questionable quality drugs without anyone's permission.[94] In the same year, another publication claimed the same percentage without giving details of the methodology applied.[95]

In a famous incident in 2012, 120 patients at Punjab Institute of Cardiology died after being administered low-quality drug. The incident led to the establishment of Drug Regulatory Authority of Pakistan (DRAP). In 2015, CNN reported that a high percentage of counterfeit, fake drugs were being produced in Pakistan using pesticides, rat poison,

[92] National Assembly debates, 7th June 1967, Bill to establish Pharmacy Council to regulate the practice of Pharmacy ('The Pharmacy Bill, 1967')
[93] 7th Five-year Plan (1988-93), p.43
[94] 'Pakistan's counterfeit medicine problem' (2021), Shahab Omar, *PROFIT*, 12th September 2021
[95] 'PRIVATE HEALTHCARE IN PAKISTAN' (2021), p.25, *KARANDAAZ*

brick dust and paint, among other ingredients.[96] In May 2016, while answering a question in the Senate regarding spurious, sub-standard and fake drugs, the then Minister for National Health, Miss Saira Afzal Tarar, had the following to state-

"The Federal and provincial Governments after analysis of 85146 samples of suspected drugs during the last two years and registered/processed 409 cases for spurious drugs and 1235 substandard drugs. (b) The Federal government has taken strict action to control manufacturing and eradication of spurious and substandard medicines in the country. Steps taken for eradication of Spurious and substandard medicines in the country 1. More than 4000 prosecutions were launched in the drug courts (established by the Federal Governments u/s 31 of the Drugs Act, 1976) during the year 2015. More than 1600 hundred cases were decided by the courts and more than 40,000,000 Rs. fine was imposed by the drug courts. The DRAP suspended the production activities of 20 firms and 18 were served show cause notices on non-compliance of cGMP. 3. Recently the DRAP through Registration Board meetings suspended/ cancelled the registration of 41 drugs. 4. Several successful raids have been conducted by the DRAP officers, in the different provinces of the country and the culprits involved in this criminal activity have been arrested and are under investigation/trial".[97]

In 2016, the then Chief Minister (CM) of Punjab, Mr Shehbaz Sharif, threatened to buy all drugs from abroad after 41 percent of the samples of drugs bought by the Punjab government were declared substandard by the Laboratory of the Government Chemist (LGC) UK for drug testing.[98] This came as a shock to local health officials since these drugs had been procured following due process of law and had been tested at local Drug Testing Laboratories (DTLs) where they had been declared fit for use in government hospitals.

Prior to this incidence, the CM had travelled to Britain in 2015 and requested the LGC to carry out a gap analysis of the Drug Testing Labs (DTL) in Punjab. The resulting analysis revealed severe deficiencies in the testing system, mainly in terms of quality of human capital and equipment. Consequently, it was opined that the analysis of drugs by these DTLs could not be relied upon to give true picture of quality and efficacy of drugs.[99]

This particular instance, although related to the province of Punjab, serves as a good proxy for the overall situation concerning the quality of DTLs in the country and the

[96] 'Patients fooled by fake drugs made with poison and brick dust' (2015), Gena Somra, *CNN*, 30th August 2015
[97] 'Questions for Oral Answers and Their Replies', Q#175, *Senate of Pakistan*, 19th May 2016
[98] 'Challenges of public sector change management: The case of medicine provision in public hospitals in Punjab' (2017), Muhammad Azfar Nisar and Muhammad Ahsan Rana, *LUMS*
[99] The report did not mention the firms from whom the drugs were bought for government hospitals, or their ranking in terms of sales. This is an important consideration since more often than not, it is not the leading firms who sell to the government sector

questions surrounding the quality of drugs. And this was not the first instance of questionable quality of drugs being found out.

Perhaps a good reflection of the comparatively lower quality of local drugs comes in the form of Pakistan's pharmaceutical exports, which are mostly concentrated in countries and regions where the criterion regulating quality is comparatively lower (like Afghanistan and Africa). Except for Getz, Searle and Citi Pharma, that became the first local companies to sell their products in Europe and UAE, no local company has managed to enter these markets.

What does the literature/research say upon this aspect of pharmaceuticals? In general, opinions remain divided on this issue. In 2004, a study conducted on a specific generic drug by University of Karachi concluded that it was equivalent to branded drugs in terms of pharmacokinetic behavior, in-spite of having different excipients different concentration, sources of raw materials, manufacturing processes, machinery, etc.[100] A study on six major generic brands containing the API Cefixime concluded that all of them met prescribed quality standards. All brands met pharmacopoeial specifications in terms of content of active ingredient, time of dissolution test for the release of cefixime, and antimicrobial action of the different studied brands of cefixime showed positive results.[101]

Godman, Khan and Babar (2015) analyzed the quality of generic drugs in Pakistan. From their elected samples, all but one sample passed the spectroscopy identification tests. However, 81.5 percent of samples failed to comply with pharmacopeia assay limits. They advocated implementing Common Technical Documents (CTDs) based on international standards (which was implemented by DRAP later on).[102]Tauqir, Myhr and Gopinatahn (2019) carried out a survey on quality standards in Pakistan's pharmaceutical industry, and concluded that manufacturing facilities operated under different GMP standards and interpretations, pointing towards an absence of harmonization in quality standards across the industry. Views diverged about the status of GMP compliance, with interviewees from academia presenting a more critical view compared with regulators who promoted a more positive story.[103]

A major survey carried out by the WHO in 2017 evaluated the performance of the regulators (federal and provincial) upon several criterion, ranking them from less to

[100] 'Pharmacokinetic differences of some generic tablet Gliclazide 80 mg on Pakistani population' (2004), *Pakistan Journal of Pharma Sciences,* 2004; 17: 55-64

[101] 'PHARMACEUTICAL EVALUATION OF COMMERCIAL BRANDS OF CEFIXIME 400MG CAPSULES MARKETED IN KARACHI (PAKISTAN)' (2009), *Journal of Pharmaceutical Research* Vol. 8, No. 2, April 2009 : 98-104.

[102] 'Assessment of Active Pharmaceutical Ingredients in drug registration procedures in Pakistan: implications for the future' (2015), Babar Khan,Brian Godman, Ayesha Babar, Shahzad Hussain, Sidra Mahmood, Tahir Aqeel

[103] 'Institutional barriers and enablers to implementing and complying with internationally accepted quality standards in the local pharmaceutical industry of Pakistan: a qualitative study' (2019), Fatima Tauqeer, Kirsten Myhr and Unni Gopinathan, *Health Policy and Planning, 34, 2019, 440–449*

highly corruption prone. One of its criterion was evaluation of 'Clinical Trials of Medicines', which was termed as 'highly vulnerable' to corrupt practices, raising significant concerns and questions regarding the prevalent quality standards.[104] The report noted that

> 'Written guidelines on submission of applications to DRAP prior to conducting a clinical trial are not publically available, but a form for submission of a clinical trial proposal along with a checklist can be obtained from DRAP. There is no written policy or procedure for submission of a clinical trial application to the independent ethics committee that covers the acceptability of trial investigators, suitability of trial protocols, means of recruiting trial subjects, adequacy and completeness of information, provision of compensation in case of injury or death of subjects and form of payment or remuneration by the trial sponsor. The form for submission of a clinical trial proposal requires submitting prior approval from an ethics committee with the name and designation of its members. Conflict-of-interest guidelines on clinical trial activities have not been notified so far and there is no list or database of those clinical trial applications approved or rejected by the authority'.

Similarly, Former Health Minister, Mr. Zafar Mirza, has also opined his dissatisfaction with the quality of drugs and drug testing facilities on several occasions.[105] It is pertinent to mention here that a number of pharmaceutical companies have been banned by Health Insurance companies for providing low-quality medicines to public hospitals.

Suffice to say, quality and availability of drugs remains a major concern despite some improvements on this front, like WHO pre-qualified two DTLs in Punjab under the WHO's good practices for pharmaceutical Quality Control Laboratories guidelines in 2023. Part of the problem lies in the design of the procurement systems at both the federal and the provincial levels, whereby the lowest bidder is given priority. However, except for earning a few political brownie points, this mechanism ends up compromising on quality of drugs, a contention which finds ample support amongst the health practitioners and professionals. For example, M. Amir Qidwai, manager of pharmacy at Lady Reading Hospital, Peshawar, opined that most drugs bought by the provincial governments are of inferior, questionable quality.[106]

The problem in Pakistan is that there is hardly any global quality bio-equivalency lab where the generics can go through vigorous testing to determine their efficacy and safety (especially in the case of firms that do not have any significant market share, i.e, the ones that fall below the top 100 companies by sales). In terms of quality, quality Bio-Equivalence (BE) labs are needed for not only ensuring drug quality at local level but also

[104] 'Measuring transparency to improve good governance in the public pharmaceutical sector' (2017), p.17, *WHO*
[105] 'Healthy trends', Zafar Mirza, *DAWN*, 25th March 2022
[106] 'Drug pricing Problem' (2022), *DAWN*, 13th October 2022

for the purpose of enhancing export of drugs, both for in vitro (outside the body) and in vivo (inside the body) studies. Recently, two Bio-Equivalence labs under the Bio-Study Rules 2017 were approved by DRAP in October 2019 and February 2020.

Generally speaking, the most successful brands in terms of sales are the ones most at danger of being undermined by cheaper, low quality copies. Drugs like Novidat, Risek, Voltral, Cefiget, etc., are just a few names whose low-quality copies are usually available in the market. Novidat has a cheap copy under the name Novaedaxin, available at around Rs. 50 compared to Rs 450/- of the Novidat. Similarly, Risek's low-quality copies are widespread. In 2022, FIA arrested several individuals who were manufacturing copies of famous brands like CEFIM, CEFIM-D suspension, Cefixime base salt and Dispirin. In 2023, a huge consignment of counterfeit Risek was unearthed in a manufacturing facility in Peshawar. The following table presents a list of the brands and their sub-standard copies available in the market at considerably lesser prices.[107]

Drugs and their copies			
Original	**Copy**	**Original**	**Copy**
Novidat	Novaedaxin	Rizek	Renzik
Falgyl	Metronedazol	Cofigel	Ceffest
Oxidil	Sodocef	Consticare	Skilaa
Myteka	Melukast	Nims	Nimex
		Voren	Voweron

Back in the 90s and early 2000s, leading pharmaceutical firms (especially MNCs) used to have their own intelligence wings that were exclusively devoted to checking and reporting activities related to counterfeit, low-quality copies of their products. However, these were discontinued over time.

DRAP has gradually picked up pace since its founding in terms of enhancing and ensuring quality. There has been progress on this end under various heads through regulations. Separation of allopathic and alternative medicine facilities was ordered due to risk of contamination. Only a common lab is allowed for both products but to be manufactured separately (something that was not happening before), and with the manufacturer having area above 4 kanals. Similarly vitamins and other Neutraceuticals (basically 'food supplements') are to be treated separately under separate regulations to ensure 'truthful labelling', efficacy of ingredients and from discouraging manufacturers/distributors in terms of making fallacious claims about the cure or prevention of disease through their products[108]. Between 2013 and early 2017, 18 drug

[107] Source: Author's own survey of the markets

[108] F. No 1-78/2018-DD (H&OTC) (Pt), 2nd September 2019

manufacturing licenses were suspended and 89 drugs were banned for being sub-standard. But much needs to be done.

Just recently, cognizant of all these issues and serious shortcomings in terms of quality of drugs, the federal government launched a major scheme ('Drug Control Administration') worth Rs. 330 million in 2024 to ensure the prevalence of quality drugs in the federal capital Islamabad. The scheme involves the purchase of Raman Spectrophotometer Mobile Drug Testing equipment to gauge the quality of drugs within a minute or two.

The market for smuggled drugs

By all available accounts, the market for smuggled drugs (also known as 'black market') in Pakistan is huge, with yearly smuggling in billions of rupees. What exactly is the size of this market in smuggled drugs is a matter of conjecture as estimates vary. Government's own sources, as mentioned above, believe that the market for smuggled pharmaceuticals in Pakistan stands at around Rs. 60-65 billion. Other estimates put the number higher. Majority of the drugs sold in the black market are the ones that disappear from shelves as companies stop producing them due to several factor, with the primary one being pricing disputes with the government.[109] The attractiveness of this market lies in the outsized returns on drugs that are short, way above the official price ceiling. In early 2024, for example, a widely used drug for seizures ('Tegral') experienced shortages as government inordinately delayed agreed-upon upward revision in its prices, resulting in its availability in black market at around Rs. 3,000, which was four times the officially stipulated price.

The following table offering a small reflection of the yearly shortages of critically needed drugs in 2022 and 2023, which in turn help black markets thrive.

2022		2023	
Drug Name	**Use**	**Drug Name**	**Use**
Panadol (Tablets)	Fever/Pain	Ketaconzole	fungal infection
Panadol (Syrup)	Fever/Pain	Risek injection	gastroesophageal issues
Epival	Depression	Vita 6	tuberculosis
Rivotril	Epilepsy	Treviament	diabetes
10 mm Inslin 70/30	Diabetes	Neuromet	anemia and nerve damage
Tegral	Epilepsy	Herparin injection	Blood Thinner
Epival	Epilepsy	Tegral	Epilepsy
Alcaline	Eye Drops	Doxorubicin	Cancer
Mixtard 30 mm	Insulin Treatment	Kopaque	Cancer
Dioven 80 mg	BP	Frasium	Epilepsy
Exforge 80 mg	BP	Salbo	Asthma
		Ventolin	Asthma

[109] Others include a company closing down

A surprising outcome of this black market in drugs is that it is seen as having several positive spillovers, with the biggest spillover being making available life-saving drugs that otherwise would not have been available. One of their biggest attractiveness is their lower price compared to even locally generics, especially in the peri-urban and rural areas. Aside from consumers, the sellers (pharmacies) also earn more on their sale, with third countries serving as a conduit for the smuggled drugs, as in the case of Afghanistan acting as a conduit for smuggling these drugs into the province of KP.

The market in smuggled pharmaceutical goods is not limited to finished products only, but also includes semi-manufactured items and APIs. In 2015, a Custom, Taxation & Anti-Smuggling court in Karachi sentenced several companies for import of banned APIs under 'preservatives' head, with substantially low declaration of price at $0.3/kg when the real market price was $9/kg and more.[110]

Many essential medicines vanish every year or are unavailable in the market, causing tremendous stress to the consumers, especially patients who need it the most. This is not a relatively recent phenomenon either. The shortages are, in turn, complemented by the expansion of black market activities whereby the drugs experiencing shortages are available at exorbitant rates (Junaidi, 2013). Similarly, reported sale of huge quantities of fake, spurious and counterfeit medicines in Peshawar (capital of province KP) also serves as a reflection of the extent of smuggle drugs in Pakistan. Majority of these were found to be injurious to health.[111]

Post-DRAP, and despite changes in pricing policies, drug shortages are still persistent. One of the main reasons is the refusal by the government and its regulator[112] to accept the price demanded by the producer. But such refusals have had disastrous consequences, and continue to do so. Two examples are ***Acetazolamide*** and ***Pylocarpine***. Acetazolamide (generic brand name) treats headaches, tiredness, shortness of breath and nausea. Around 2017, the drug started experiencing shortages as the manufacturer refused to produce at officially determined rates of Rs. 60 per pack. As shortages became pronounced, the drug completely vanished off the shelves, only to be found in the black market at an astronomical rate of around Rs. 3,000 per pack (both the short domestically produced pack or the imported ones). Only later did the government agreed to revise the prices upward to Rs. 200 per pack. As a result, the shortage was ameliorated to a large extent.

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[110] 'MCC appraisement East submits final challan in banned pharmaceutical raw material import case', Mashud Aslam, 3rd December 2015

[111] 'Iran, China reap huge profits from counterfeit drug sales in Pakistan' (2020), Ashfaq Yousafzai, *Pakistan Asia News*, 6th August 2020

[112] Sometimes the refusal is at the DRAP stage, while at other times the Cabinet refuses to grant the asked-for price even after approval by DRAP

But within these three years or so, millions of rupees would have flown out of the users' pockets in buying this drug from the black market. There are multitudes of such examples.

Drugs that become short in the market or are not available usually become available in the black market. As stated above, there is no concise estimate of the Pakistan's black market size in drugs, but it is well know that it tends to expand as needed drugs become short. The consumer ends up paying an astronomical amount, besides getting drugs that are of questionable quality. Since the availability of critical drugs in public and private health facilities is at best 20 and 40 percent respectively, it's not difficult to guess that many of the non-available drugs are found in the black market. This areas constitutes one of the most profound failures of public sector pharmaceutical regulation.

Policy Consistency

Uncertainty in policies can induce negative repercussions in an economy. With businesses being unsure of whether a policy would continue or not, it can be difficult to plan for the future, especially long-term investments. Pakistani governments, over time, have been notorious for being inconsistent in their policies. We normally witness either the same government making frequent changes to the existing policies, or a new government coming up with a set of new policies. The favored instrument for carrying out these frequent changes is the Statutory Regulatory Order (SRO).

The pharmaceutical sector of Pakistan, like many other sectors, has been at the receiving end of frequent policy changes for decades. And the situation continues unabated in the post-DRAP era. The following is a selective list of instances whereby the government over-turned its own regulations concerning various areas under its ambit:

a) An April 2020 notification[113] allowed holders of valid Drug Manufacturing Licenses (DML) to manufacture hand sanitizers as per the prescribed formulae, *but only for three months*! There were similar notifications allowing hand sanitizer manufacturing on the 10th, 14th and 17th April 2020. But suddenly, within a month, all these four notifications were withdrawn on 21st May 2020 under Cabinet's directive! There was no reason mentioned for the decision.

b) The rules for Alternative Medicines and Health Products were approved through an SRO 412 (I)/2014 (titled 'Alternative Medicines and Health Products (Enlistment) Rules, 2014'), dated 27th May 2014, which was amended through another SRO[114] in 2016.

c) While SRO No. 28(1)2013, dated 22nd January 2013 and SRO No. 334(1)2010, dated 18th May 2010 (and likewise SROs) were aimed at discouraging imports, SRO No. 577(1)2016,

[113] F. No 4-2/2017-DD (H&OTC) (Pt), 6th April 2020
[114] F-3-5/2013-DDC (Alt. Med.), dated 10th June 2016

dated 15th May 2016 allowed a five year exemptions for the import of drugs meant for donations. But there is no fool-proof mechanism to check the abuse of this exemption by individuals or companies, especially by informal market participants.

d) Under SRO No. F.11-2/2020-DD (P) dated 15th July 2020, the rule for applying for 'hardship' cases was modified to reduce the number of days from 180 to 120, which are ultimately approved by federal government after being forwarded by DRAP. An important part of this is part 'vii' of 'b', whereby the Federal Government can nullify agreed upon price increase in line with Consumer Price Index (CPI) if it has a 'cogent' reason, thus keeping a window open for government nullifying agreed upon price increases.

e) Policy inconsistency was recently witnessed in terms of importing much-needed COVID-19 vaccines. SRO, No. 113(I)/2021, dated 2nd February 2021 was issued by DRAP, allowing unfettered, unrestricted import of vaccines from abroad, allowing the importer to sell it as per the market price. However, on 18th March 2021, another SRO (No. 308(I)/2021) rescinded the previous SRO, leaving the population without a shot at more vaccines.

f) SRO No. 307 (I)/2021, dated 18th March 2021, regarding COVID-19 vaccines. SRO stipulates that the vaccine shall be first approved by DRAP. Recently, however, new vaccines landed in Pakistan (bought by the federal government) without DRAP even knowing anything about it.

g) Four SROs were issued between 6th and 17th April 2020, all cancelled by SRO (F. NO 4-2/2017-DD (H&OTC) in lieu of Cabinet's decision on 5th May 2020

h) In 2013, SRO No. 1002(1)/2013, dated 27th November 2013, was initiated to end the more than decade-long 'prize freeze' policy. Within two days, it was cancelled after the then PM ordered to cancel drug price increases.

The above were a few instances that reflect poorly upon consistency of policies by the government and its regulator.

Apart from lacking in consistency of policies, there is also the fact that DRAP, like its predecessor DRO, displays a reactive rather than pro-active approach in many cases. This also is one factor that leads to changes in policies/ regulations. For example, SRO No.F.296-DRB/2020 (PE&R) (ft.), dated 4th February 2021, directs manufacturers to disclose 'gluten/lactose' on labels/packs. But this happened only after persistent complaints by patients suffering from Celiac disease. Similarly, through notification No. F.1-21/2019-Add; Dir. (PE&R), DRAP called for clearing manufacturing license of Fludrocortisone tablets (for Congenital Adrenal Hyperplasia) in Pakistan on a fast track

basis as debilitating shortages started to surface in Pakistan. But DRAP only came to know about it after complaints from PM Citizen's Portal.

Pharmacovigilance and pharmacy practices

Another major quality related issue in the context of consumer's well-being occurs in drug dispensing practices at retail and health facility levels. Traditionally, Pakistan has always experienced significant quality gaps in terms of retail outlets supplying drugs due to the unavailability or absence of qualified pharmacists. The government- led efforts that came up with policies like National Good Pharmacy Practice Guidelines in 2011 remained un-implemented. Similarly, the lack of effective regulations at the public and private sector health facilities has meant that the dispensing quality healthcare aspect remains unfulfilled.

There is ample research to affirm lack of quality. Hafeez etal. (2004) found that in public sector facilities, cooling equipment was working in only sixty percent facilities while temperature control was present in only twenty four percent. Even more damning was the fact that the manual for procedures was available in only five percent of these facilities, with most of the staff unaware of healthy dispensing practices. There was minimal restriction in terms of dispensing Over-the-Counter (OTC) medicines at community pharmacies.

Almost a decade after this research, Zaidi and Nishtar (2011) and Zaidi et al. (2013) found a similar state of affairs. In the approximately 80,000 drug stores in the country, the majority did not have a pharmacist, with shopkeepers acting as one. Only 0.06 pharmacists were available per 10,000 people, while the standard recommended ratio is five pharmacists per 10,000 people. In terms of traditional medicines (ayurvedic, homeo, Unani, etc.), more than estimated 130,000 practitioners largely remain unregulated. This weakness to properly regulate dispensation of drugs has resulted in excessive use of medicines, with self-prescription and over-prescription among consumers common in Pakistan.

A further decade after the above findings, the situation has not improved much. Hussain and Hassali (2019) assessed the overall system and the new Pharmacovigilance policy in Pakistan, concluding that the whole system needed a major revamp. Hashmi et.al (2020) assessed physicians in terms of reporting Adverse Drug Reaction (ADR), an essential part of pharmacovigilance. They found that majority of them were unaware of the requirements of proper ADR. Atif and Malik (2020) found that the community pharmacists, besides being low in number relative to demands of services, were poorly trained to meet the Covid related challenges. A recent report[115] on safe dispensing practices in Pakistan came up with a startling revelation that approximately 95 percent

[115] '95 percent pharmacies in Pakistan are run without a pharmacist'

of the pharmacies in Pakistan are run without a pharmacist, thus putting a large question mark around which drugs are dispensed.

Intellectual Property Rights

It is important to distinguish two main types of patents: "process patents", those that protect methods of manufacture, and "product patents", those that protect pharmaceutical products. Amongst these, process patents represent the relatively weaker link since it is difficult to keep the process, ingredients and mixture used as a secret for long. By law, the formulation/combination contained in a particular product has to be displayed on the packing. This makes it easier for other firms at local level to come out with the same product under a different generic brand name, cutting through the expected profits of the firm with originator brand who may have spent millions of dollars in its research.[116] Many countries, though, prefer this kind of patent regime as an incentive for domestic industry to develop generic brands of the same product.[117]

"Product patents" tend to be a different game altogether, with the firm manufacturing originator brand drugs enjoying a long-term monopoly over its exclusive manufacture and pricing, and global agreements like TRIPS complementing the exclusive rights. However, majority of the countries (especially middle and lower income countries) try to avoid this kind of patent due to monopoly and affordability concerns. Moreover, countries and regions have found ways to get around these kinds of IP regulations. For example, 'price arbitrage' is legal within the European Union (EU), which ensures the flow of originator brand drugs from lesser priced regions to higher priced regions of EU, thus negating the strict regulations surrounding product patents.

When it comes to research on patents in the pharmaceutical industry and their effects upon various aspects, Jean Lanjouw is arguably the authority, carrying out a vast array of research work. In Lanjouw (2005), the author studied the effects of IP Rights and pricing regulations upon drugs, covering 68 countries for the analysis (at all income levels). All drug launches over the period of 1982-2002 were covered in this research. Pakistan is also covered, whereby only 1 drug was launched there ('first time') in 22 years before being marketed in other places. The lag or time-lapse of introduction of a New Chemical Entity (NCE) in Pakistan was at least 38 months after introduction of that same NCE in originator country. The conclusion was that ensuring IP rights do make a country an attractive place for pharmaceutical investment, although they may also strengthen MNCs control over pricing in the local market.[118] The paper pointed to Gilead's example

[116] In countries like Pakistan, the problem is compounded by the fact that copies and counterfeits of the original product can appear within months

[117] Government regulations in India provide one such example. In 1972, it replaced the earlier colonial era patent system in favor of a system allowing only short (5-7 year) process patents for drugs

[118] 'Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry' (2005), Jean O Lanjouw

in this regard. Although it had offered to expand its coverage to 95 countries in terms of provision and production of this new anti-retroviral drug 'at cost', it was pointed out that only 22 of the eligible 68 countries in Gilead's list were getting the drug due to weak IP rights.

An earlier paper by the same author in 2002 questioned the efficacy of extending the standard model of patents as practiced (and implemented) in the developed world, arguing that due to lower purchasing power, the standard IP framework is unfit for Least Developed Countries (LDC), therefore extending standard IP rights will not guarantee flow of investment in local pharmaceutical sector. Instead, the author advocated a 'differentiated' IP model that would be more in consonance with the realities of the LDCs, especially its purchasing power.[119] In support of his argument, he brings forth an interesting statistic, which shows that adoption of IP Rights in industrialized world was not a uniform process; rather, some of the countries were late in adopting these, only once their per capita income crossed a specific limit.[120]

Pakistan, unfortunately, has a very poor history when it comes to enforcing IPRs. This aspect is important for several reasons, chief amongst them being FDI related, and one that MNCs tend to be sensitive about. One of the above sections has a table in which available copies of some famous brands had been stated. In the early years, it was pointed out in the National Assembly that an imitation of Waterbury Compound existed in Pakistan without any permission for its manufacturing.[121] It was an early indication of IPR infringements that continues till this day.

Due to persistent failures in enforcing IP Rights, Pakistan was put on a Special 301 Watch List in May 1989 under Omnibus Trade and Competitiveness Act. In accordance with the Doha Declaration (WTO, 2001), Pakistan's IPR legislation provides for key flexibilities under TRIPS, like parallel importing provisions. Up till 2010, however, no compulsory licenses had been issued. As per Babar, Malik and Gilani (2013),

> 'Patents are granted irrespective of whether drugs are produced locally or imported. There are no legal provisions for data exclusivity or for patent extension for pharmaceuticals. Also, there is no legal provision for linkage between patent status and marketing authorization'.[122]

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[119] 'Intellectual Property and the Availability of Pharmaceuticals in Poor Countries' (2002), *Center for Global Development*, Working Paper No. 5

[120] Spain and Norway introduced Patent Protection for pharmaceuticals in 1992, after GDP per capita crossed $14,430 and $30,387 respectively

[121] National assembly debates, 7th June 1967, Bill to establish Pharmacy Council to regulate the practice of Pharmacy ('The Pharmacy Bill, 1967')

[122] 'The Pharmaceutical industry, Intellectual Property Rights and access to medicines in Pakistan' (2013), Zaheer ud Din Babar, Ashar M. Malik, Anwar Ul Hassan Gilani

Overall, IP regime in Pakistan remains extremely weak for several reasons like lack of experience in courts dealing with such issues and bureaucracy's hold over the matter despite having no or little experience. A report in 2021 opined that

> 'Instead of promoting officers of the IPO team, officers of different ministries are sent to lead the organizations. They just bide their time. Such appointees are neither capable nor interested in the highly technical world of intellectual property rights. IPO was created as an autonomous body with its own cadre of qualified staff. Instead of strengthening the pool of expertise, it was diluted by mismanagement, leading to confusion surrounding enforcement agencies and weak enforcement of IP laws'.[123]

Unethical practices

One of the major concerns over the conduct of pharmaceutical companies over time, which has led to plethora of regulations around the globe, has been various unethical practices associated with their operations. It's a global phenomenon, and there are countless such examples. A recent, prominent example is the thousands of deaths in the US due to the opioid Oxycontin and Fentanyl. In the aftermath of the investigations, it was found that a few members of the US Congress were also involved in protecting the firm (Purdue) because the firm in question had aided their political campaigns through large financial contributions.[124] The firm, as in other such cases, had also employed a large number of lobbyists that are a frequent presence in every field, including pharmaceuticals (at present, the number of lobbyists lobbying for pharmaceutical products in the US stands at 1,886).[125]

These ethical concerns are related to both the public as well as the private sector.

In the past, the Pakistan Medical & Dental Council (PMDC) established a code of ethics for practitioners (1962) and its final revised form was introduced in 2001. In 2004, WHO strategized a program entitled "Good Governance for Medicine" (GGM), its initiative to concretely address the need for transparency and unethical marketing of medication in various parts of world. In September 2016, DRAP stepped forward to draft a code of conduct for pharmaceutical companies in an attempt to monitor drug promotion activities.

As pointed out in the introductory section, a significant portion of the demand for drugs comes via public sector purchases. However, these purchases have persistently raised

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[123] 'IPRs suffering from multi-organ disorder' (2021), Afsha Subohi, *DAWN*, 9th August 2021

[124] The story of how this opioid crises spread in the US, resulting in thousands of deaths, has been recounted in extensive detail by Nobel prize winner Angus Deaton in his book 'economics in America', as well as his lecture on this topic, reproduced in Boston Review under the title 'How misreading Adam Smith helped spawn deaths of despair' (2023), 2nd August 2023

[125] 'Annual number of lobbyists lobbying health' (2025), available at opensecrets.org https://www.opensecrets.org/federal-lobbying/sectors/lobbyists?cycle=2023&id=H

corruption related concerns over time. The WHO carried out a major survey in 2017, gauging the performance of pharmaceutical regulators. In terms of criterion regarding 'procurement of medicinal products', WHO survey ranked it as vulnerable to corruption. Only 20 percent of the Key Informants (KIs) were willing to agree that there is transparency in public sector procurement of drugs. Political favoritism, administrative and political pressures, etc., were found to be rampant in public sector procurement of drugs.[126]

Surprisingly, regulations themselves make it legal to undertake operations which clearly imply Conflict of Interest. For example, Clause (3)(4)of the SOP for inspection of manufacturer abroad states that after intimation of nominations from Drug Regulatory Authority of Pakistan, applicant shall coordinate the members of the team to arrange visit of manufacturer. Passport, Visa, Boarding/Lodging, Return Air Ticket, Accommodation and all such transport which will be necessary for inspection shall be necessary for inspection shall be the responsibility of the applicant. Moreover daily pocket money US $ 100/- shall be given to the each member of the team prior to proceeding to the inspection through Bank Draft/Demand Draft/Pay order in the name of concerned member of the panel and this draft shall be submitted to DDO (Health) for onward transmission at the rate of two days per inspection. In case of more than one inspection in different cities of the same country/group, the inter city and intra city transport, daily expenses shall be the responsibility of the manufacturer/applicant. Stay of the team shall be at five star hotel(s).[127]

Available evidence (research and anecdotal) suggests that the doctor-pharmaceutical company (specifically the lower tier companies with lower percentage of total market sales) nexus is quiet strong in Pakistan. For example, Andrade, Sheikhani and Jaffery (2019) documented widespread nexus between medical practitioners and pharmaceutical companies in Pakistan.[128] Recently, Dr. Zafar Mirza, who is a former federal health Minister, shared findings of his research (along with his co-authors) which established rampant alliance between doctors and pharma companies that is undermining patients.[129] This was not his first attempt at exposing this nexus; back in 2021, he wrote an article that elaborated upon this issue.[130] In the former piece, Dr. Mirza shared the results of his randomized trial that tried to gauge the level of nexus after a select group

[126] 'Measuring transparency to improve good governance in the public pharmaceutical sector' (2017), p.12, WHO
[127] In 2015, federal auditors pointed out this conflict of interest and advocated ending it. Source: DRAP Audit Report 2015
[128] 'The ethics of pharma– physician relations in Pakistan: "When in Rome" (2019)', 'de Andrade M, Jafarey A, Shekhani SS, et al., *Ethics Behavior*, 2019;29:473–89.
[129] 'Doctors taking bribes from pharmaceutical companies is common and not substantially reduced by an educational intervention: a pragmatic randomised controlled trial in Pakistan' (2025), Zafar Mirza et.al, *BMJ Global Health Journal*
[130] 'An unholy alliance' (2021), Zafar Mirza, *DAWN*, 3rd December 2021

of more than 400 doctors (general medical practitioners) went through training, with almost half exposed to unethical practices as a topic. The results showed that despite the training, prescriptions based on bribes were still common.

At other places, even the doctors themselves admit to their profession becoming compromised due to pursuit of wealth. Back in 2020, Dr. Shershah Syed, former Secretary General of Pakistan Medical Association (PMA) and a practicing doctor, bemoaned the fall of his profession and loss of respect for doctors, partly due to acceptance of bribes and corruption.[131] Last year, the famous podcast, RAFTAR, carried out a documentary that brought forth the extent of this issue.[132]

The advertisements for pharmaceutical products is another area attracting ethical concerns from citizenry and regulators. Again, there is ample evidence pointing towards unethical, misleading advertising. For example, Rohra, Gilani and Kumar et al. (2006) carried out an extensive survey to determine the truth of information contained in advertising brochures of pharmaceutical companies. They analyzed 345 distinct advertisements covering 182 drugs from different manufacturers were. Sixty two out of 345 (18 percent) of the reviewed advertisements were adjudged to be misleading / unjustifiable, exaggerated and false. The primary source of information (approximately 78%) about the newly launched drugs for the GPs was found to be the pharmaceutical representatives followed by hospital doctors (5%) and colleagues (5%). Furthermore, 110 (90%) GPs were of the view that the drug promotion has definitely an influence on their prescribing pattern.[133]

In 2020, Competition Commission of Pakistan (CCP) imposed a record penalty of Rs. 150 million upon a company for deceptive marketing of its product.

Similarly, there are concerns related to unethicality's surrounding clinical trials of drugs. As discussed above, the process of drug testing is plagued by unethical practices like questionable clinical trials, fudged data, etc.

Suffice to say, DRAP has its work cut out in this regard.

Research and Development (R&D)

How important is R&D for development of pharmaceutical industry? For this, the following statistic should suffice- Between 2012 and 2021, the 14 biggest pharmaceutical companies in the world (by sales) spent an estimated $660 billion on R&D activities.

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[131] 'Health: Why are doctors losing their respect' (2020), Dr. Shesha Syed, *DAWN*, 20th September 2020

[132] 'Inside look at Pakistan's pharmaceutical industry and how doctors are bribed?' (2024)

[133] 'Critical evaluation of the claims made by pharmaceutical companies in drug promotional material in Pakistan' (2006), Dileep Kumar Rohra, Anwarul Hassan Gilani, Ismail Kamal Memon, *Journal of Pharmaceutical Sciences 9(1):50-59, 2006*

How much do Pakistan's pharmaceutical firms and the government's own institutes related to pharmaceuticals spend on research? There is no data or figures that can give us an answer, and there is relatively scarce information on private and public sector expenses on pharmaceutical R&D. what we do know, however, that both of them do spend a certain amount of financial resources on research activities. The following is a brief description of the available information.

Under the Drug Act 1976, pharmaceutical firms are obligated to deposit 1 percent of their gross earnings in a government account, under the Central Research Fund (CRF) initiative, whereby government intends to use these funds primarily for research purposes. Since 1976, the industry has been regularly paying this charge to the federal government. However, till this day, no one has any idea of where all the accumulated fund went or what was it utilized for? The government officials in Health Ministry and the regulator (DRAP) remain tight-lipped about this issue.

But some facts are known, and random information about this aspect does tend to surface from time-to-time through various sources. The funds are currently deposited in DRAPs account in a bank at Islamabad.[134] Despite receiving payments since 1976, the federal government did not have an SOP for the use of these finances, and there are no world class facilities at the public level that came up with anything innovative (like a new molecule) or helped in promotion of investment (like FDA standard laboratory, which is considered the gold standard around the globe in terms of quality). An audit carried out in 2018 revealed that a total of Rs. 236 million was in the account, while Rs. 1,245 million had been 'invested' (there was no information on where the said amount was invested and for what purpose). Further, cumulative amount of Rs. 975 million was available to the relevant authority prior to DRAPs formation in 2012. As per the rules, this amount was to be transferred to DRAPs account. However, it was never transferred and no one knows where that fund went.

Similarly, what is also known is that over the decades, the federal government has provided funds worth billions of rupees to various public sector institutes, mainly through the Ministry of Science and Technology. However, the exact details regarding the quantum and bifurcated details are not available.[135] In the Fiscal Year 2024/25, it allocated over Rs. 32,000 million for 30 R&D projects, of which one was growing medical cannabis at NUST (Islamabad) greenhouses, with a total outlay of Rs. 1,946 million, as

[134] Fund A/c No. 0010008463700024 in ABL, Civic Centre Melody Branch, Islamabad
[135] Ministry officials refuse to share any information

detailed below.

Sr. No	PSDP No.	Name of Project	Total Cost
27	945	Quality Seed Production and Supply to the Farming Community for Ensuring Food Security in Pakistan (Revised)	4518.053
28	946	Research, Development and Technology Transfer of Selected Active Pharmaceutical Ingredients (APIs) for Import Substitution (PCSIR)	1067.639
29	947	Establishment of Medical Cannabis Greenhouses for Biotechnology Derived Bio-Products, National Hemp & Cannabis Analytical Laboratory and National Industrial Hemp & Medicinal Cannabis Authority	1946.014
30	948	Extension of Display Exhibits, Collection Repositories Improvement and Research Facilities Enhancement at Pakistan Museum of Natural History, PMNH	1866.640
		Total Ongoing	32992.289

On 5th June 2024, a letter from Director of Institute of Chemical and Biological Sciences (Dr. Panjwani Institute of chemical and biological research) was addressed to VC Karachi University, accusing its former director of interfering in institute's workings and failing to give account of the Rs. 4 billion or more in grants for research that it had received from HEC in the last 20 years.

In conclusion, if compared to global standards, the funds devoted to R&D are zilch. Research into molecules leading to innovator brands is almost non-existent, and whatever research is done at public and private level has little publically available information. As argued before in the section on vaccines, Public sector R&D support to the pharma industry is vital. In Pakistan, the financial requirement for developing a single drug molecule is an estimated $1 billion.[136] Domestic firms (MNC's plus others) simply don't have that much in their kitty. Even if they had that much amount in their possession, the incentive to carry out research is non-existent. Perhaps a diversion of CRF charge back to the industry as a 'grant' or 'subsidy' exclusively for R&D would be helpful in this regard.

[136] 'Research in Pharmaceuticals: Pakistani companies Lag behind their Indian and Chinese Counterparts'; by Farhan Zaheer, *Express Tribune*, 15th August 2011.

Litany of charges

A wide array of charges continue to be charged from the industry, aside from the CRF tax equal to 1 percent of the industry's gross sales. These add to the overall cost of doing business. Some of these are as follows.[137]

Category	Total Charges (In rupees)
Grant of drug manufacturing license (Basic and semi-basic manufacturing)	45,000
Grant of drug manufacturing license (by way of formulation)	150,000
Grant of drug manufacturing license (by way of repacking)	90,000
Renewal of drug manufacturing license (Basic and semi-basic manufacturing)	22,500
Renewal of drug manufacturing license (by way of formulation)	75,000
Renewal of drug manufacturing license (by way of repacking)	45,000
Site verification and layout (site inspection and verification), Approval layout plan, Revision/Extension of layout plan	7,500 (each)
Grant of drug registration (New drug or molecule / drug not manufactured locally)	75,000
Grant of drug registration (Any other drug for import)	150,000
Grant of drug registration (Drug for local manufacture)	30,000
Advertisement (per advertisement Print Media)	15,000
Advertisement (per advertisement radio/audio)	22,500
Advertisement (per advertisement TV/Cinema)	37,500
Drug Pricing (grant of an additional pack)	7,500
Drug Pricing (price increase for hardship cases)	30,000
Drug Pricing (price increase linked with CPI)	2,000

Taxation

How many taxes does a business pay or are applied on a product make a substantial difference to the working of a business and the sale chance of a product. In the above-stated table, we observed a litany of charges applied by DRAP on the industry for meeting its functions. Additionally, aside from the recent exemption of imported pharmaceutical raw material, the industry's products are taxed heavily, as the following examples would demonstrate.

There are the following taxes on imported products- LC charges, Insurance, Rate of Customs duty, Rate of Income Tax, Rate of Federal Excise Duty (FED), any other import duty, clearing charges if any, and Civil Aviation / Port charges. The costing criteria for imported drugs that are bulk imported and repackaged locally is the same except for the addition of repackaging costs (cost of inner packing, cost of outer packing, etc.). Similarly, in terms of reference pricing for 'Originator' brands, there is VAT, sale tax, education cess, excise duty, local tax or any other levy on sale of the drug (whichever is applicable).

Then there are different charges that businesses find cumbersome to meet. Junaidi (2013), in the aftermath of DRAPs founding, noted that the first meeting of its policy board resulted in the approval of numerous taxes and fees on the industry for the provision of services. The extent of these fees and taxes could be gauged by the fact that $ 4 million

[137] SRO No. F.7-11/2012-B&A/DRAP, dated 7th May 2021

were collected under multiple heads (drug registration applications, manufacturing license applications, contract extensions, etc.) within two months.

Conclusion-some improvements, but a lot more needs to be done

In a seminal paper that tried to quantify the costs of government regulations upon the pharmaceutical sector, Mehmood (2015) came up with the following estimates that depicted a heavy cost inflicted upon the industry, consumer and the country.[138]

Quantified losses due to lower levels of investment:[139] The following table represents the Foreign Direct Investment (FDI) figures over the years. The domestic investment figures are presented separately.

Year	FDI ($ mil.) 'a'	Increase/Decline	Exchange Rate 'b'[49]	Pak Rupee equivalent (mil.)=a*b	Increase/Decline
07-08	46.2		62.54	2889	
08-09	30.4	-51.5%	78.49	2386	-21.08%
09-10	5.4	-463%	83.80	453	-426%
10-11	6.3	+14.28%	85.50	539	+16%
11-12	2	-215%	89.23	178	-202%
12-13			96.37		
Total	**90.3**	**- 715**		**6445**	**-633**

Quantified cost of counterfeit medicines sold: Rate of prevalence of counterfeit medicines of total sales= 40 percent (0.40). Total monetary loss to consumer from counterfeit medicine sale= 0.40*per year total sale of medicines

Year	Estimated total sale of medicines (a)[47]	Prevalence rate of counterfeits (b)	Losses= a*b
2013	Rs. 209 billion	0.40	Rs. 83.6 billion
2012	Rs. 190 billion	0.40	Rs. 76 billion
2011	Rs. 170 billion	0.40	Rs. 68 billion
2010	Rs. 153 billion	0.40	Rs. 61.2 billion
2009	Rs. 136 billion	0.40	Rs. 54.4 billion
Total			**Rs. 343 billion**

Quantified losses due to public sector procurement: The numbers for calculation have been outlined in the methodology section. The relevant calculations are as follows.

Year	Medicine Sale 'a'	Govt. Procurement (of total) 'b'	Total Govt. Procurement 'c'=a*b	Non-availability percentage 'd'	Loss=c*d
2013	Rs. 209 billion	0.20	41.8 billion	0.90	37.62 billion
2012	Rs. 190 billion	0.20	38 billion	0.90	34.20 billion
2011	Rs. 170 billion	0.20	34 billion	0.90	30.60 billion
2010	Rs. 153 billion	0.20	30.6 billion	0.90	27.54 billion

[138] 'Pricing out Welfare: The Effects of Government Regulations on Pakistan's Pharmaceutical Market' (2015), *PRIME Institute*

[139] Data used for calculation based on Taken from SBP 'Net Inflow of FDI by Economic Group', till FY 12

2009	Rs. 136 billion	0.20	27.2 billion	0.90	24.48 billion
Total					**154.44 billion**

Quantified losses due to production underutilization: The relevant numbers to be used for calculation have been outlined in the methodology section. The calculations are as follows.

Year	Medicine Sale 'a'	Profit Margin 'b'	Total Gross Profit 'c'=a*b	Rate of under-utilization 'd'	Forgone Earnings=c*d
2013	Rs. 209 billion	0.15	31.35 billion	0.15	4.7025 billion
2012	Rs. 190 billion	0.15	28.5 billion	0.15	4.275 billion
2011	Rs. 170 billion	0.15	25.5 billion	0.15	3.825 billion
2010	Rs. 153 billion	0.15	22.95 billion	0.15	3.4425 billion
2009	Rs. 136 billion	0.15	20.4 billion	0.15	3.06 billion
Total					**19.30 billion**

As the above stated write-up on regulations show, there are still formidable challenges in terms of regulations and the kind of policymaking that incentivizes industrial expansion, investment, production and research. Part of the issue lies in selection of regulators and their knowhow. Former Special Assistant to PM on Health, Zafar Mirza, admitted that appointments in regulatory bodies dealing with health are made overnight without the appointees having any academic background. He further said that those approving regulations in the sector have little or no idea what health regulations are?[140]

However, if one compares DRAP to its predecessor (Drug Regulatory Authority or DRA), the overall conclusion is that things are relatively better. PIDE (2022), for example, assessed the performance of DRAP, and found it to be better in its workings and outcomes than the predecessor.[141] Perhaps a good reflection of the relative improvement compared to pre-DRAP era is that two new 'Acts' have come about (in 2015 and 2018), a long time after 1976 Act, which have pricing clauses that indirectly acknowledge failure of policies like 'price freeze' or stringent pricing policies, trying to strike a balance between welfare priorities of the government while providing room for pharmaceutical industry to grow.

A major step in the direction of regulatory improvements comes in the form of Pakistan Single Window (PSW) initiative under the Board of Investment (BOI), with several steps

[140] 'Call for imposing strict ban on sale of antibiotics like candies' (2023), M. Waqar Bhatti, 8th October 2023, *the NEWS*

[141] 'Regulating the Pharmaceutical Industry: An Analysis of the Drug Regulatory Authority of Pakistan' (2022), in 'EVALUATIONS OF REGULATORY AUTHORITIES, GOVERNMENT PACKAGES, AND POLICIES', *PIDE*

like introduction of digital certification for pharmaceutical exports that introduces electronic version of key export documents.

All in all, there are improvements in terms of regulations, but there is substantial work to be done. Also, it remains to be seen whether the improvements would stick around.

4- Investment in the pharmaceutical Sector[142]

When it comes to investment in the pharmaceutical sector, nobody associated with the industry denies that investment has taken place. But that is pretty much what everyone agrees upon; the details are either unavailable or murky, and vary from source to source. Specifically, no one seems to have any idea of total quantum of investment. Both Pakistan Pharmaceutical Manufacturers Association (PPMA) and Pharma Bureau (PB) have little or no inkling of the total quantum of investment and neither do they maintain any record. The Pakistan Bureau of Statistics (PBS) numbers on aggregate pharmaceutical investment is unreliable, with pharma industry officials giving it little credence.

Even more perplexing is the absence of any literature or research on this issue. Estimates of domestic investment are difficult to ascertain. In 2009, the then President of PPMA, Mr. Zahid Saeed, stated that the total investment in pharma industry in that year stood at $1.3 billion (or Rs. 107 billion, considering the dollar to rupee rate that year).[143] As per the estimates in the PPMA report from 2017, domestic investments in 2014 were equivalent to $500 million. However, there is no information publicly available on the distribution of the investment, including merger, takeover, new plant and equipment, etc.

But other than these, it is hard to find estimates of aggregate investment in the pharmaceutical industry. And when it comes to measuring or research upon 'net' investment in the sector, neither any literature nor any discussion exists in this regard. The author of this report, however, undertook the task of estimating quantum of private investment in this sector. The end result is a report for PIDE whose selected excerpts are being produced her. The novelty of this research paper, aside from estimating long-term investment trends (both foreign and domestic), also lies in that it would be the first of its kind in terms of coming up with a measure and estimation of both gross and net investment in the pharmaceutical sector.

Pharmaceutical investments, just like any investment, have always been a function of certain factors like pricing, industrial policy, total sales, regulations and the overall geo-

[142] This section relies heavily on PIDEs recent research work on pharmaceutical investment, titled 'Investment in Pakistan's pharmaceutical sector' (2025)

[143] https://www.newsonprojects.com/news/pharmaceutical-industry-to-invest-in-pakistan

political atmosphere in a country (or the risk associated with the country). In terms of pharma investments, there are two types- public and private investment.

Surprisingly, some of the innovations in drugs have come via public investments which are quiet considerable in some cases. US National Institutes of Health, for example, spends $40 billion/year on drug innovation. The Federal government of US has been funding vaccine research since 1966. Basic science research on mRNA has been going on since the 1970s. The case of their government providing $1.5 billion grant for development of revolutionary mRNA vaccine is well documented by now (described in the box above, in section of Vaccines).

From policy point of view, the real question is how to make sure that investment is governed for the public interest and not private profit.

Pharmaceutical investments in Pakistan seem to be no exception to this rule. Perhaps the more surprising aspect is that the public sector has been an investor in the sector since long, primarily through 'development allocations'. Pharmaceutical industry has always managed to gain attention in governance halls when it came to investment strategies. For example, in FY 1952-53, Pakistan Industrial Finance Corporation (PIFC) sanctioned Rs. 300,000/- as loan for pharmaceutical industry. What follows is a brief account of public sector investment in historical context.

The main avenue for public investment in pharmaceuticals, as with other industries, has traditionally been the Five-year Plans. The 1st Five-Year Plan (1955-1960) envisaged total public sector investment of Rs. 20.4 million in pharmaceuticals over the five years of the plan by Pakistan Industrial Development Corporation (PIDC). Of this, Rs. 10 million for setting up a mega production plant in East Pakistan, Rs.0.4 million as investment in Kurram Chemical Company and remaining Rs. 10 million for development of pharmaceutical industry in various parts of West Pakistan. Another Rs. 9.1 million (with a foreign exchange component of Rs. 5.7 million) were set aside for establishing a Penicillin plant in West Pakistan, with a capacity to produce 8 million mega-units per annum. WHO was to provide the initial training, manpower and equipment. Besides these, plans were made for allocation of Rs. 15 million for establishing an anti-biotic plant in East Pakistan (if the plans were approved).[144]

Surprisingly, in the 3rd Five-Year Plan (1965-1970), there is scant mention of the pharmaceutical industry. In the whole report, we find a single paragraph that basically bemoans increasing import of pharmaceutical products (specifically drugs) despite 'considerable indigenous capacity for production'. Further, there is mention of domestic

[144] 1st Five-Year Plan (1955-1960), No. 106, p.455 and 456

capacity of production of Penicillin, Vaccine and Sera, etc., and that a new facility was being set up in East Pakistan for anti-TB, anti-malaria and anti-dysentery drugs.[145]

In the 4th Five-Year Plan (1970-75), we get a mention of Pharmaceuticals under the head 'Chemical Industries'. Again, the plans for the industry are covered in two paragraphs only on separate pages (p.378 and p.389), pointing out that whatever capacity expansion was achieved under the previous 5-year plan (i.e, the 3rd Plan), it was being used basically to package imported material rather than manufacturing drugs from scratch. There is further mention of setting up new facilities, but the details are absent.

In the Sixth Five-year Plan (1983-88), the envisaged investment in 'Basic Chemicals and Pharmaceutical' was set at Rs. 4,260 million, approximately 7 percent of the total investment envisaged under in the 5-Year period. To complement the plan, in 1984, the then government announced a major package of Rs. 130 billion for 202 earmarked industries ('Industrial Investment Schedule'), of which Rs. 22 billion were marked as allocation for Chemicals, Pharmaceuticals and Fertilizers.

Also, historically, to attract foreign investment, various schemes and incentives have been put forth from time to time. Waiver of import duties on pharmaceutical raw material, for example, is s frequently employed strategy. MNCs have been offered loyalties as an attraction for investing in the country. The Sixth Five-year Plan (1983-88), for example, proposed a 3 percent Royalty on MNCs setting up plant in Pakistan. Under the SAP 1992, one aim was to finance availability of life-saving drugs.

Whether the envisaged levels of investment ever materialized, or what levels of investment have actually taken place over the years, is a matter of conjecture since these plans were never followed up in terms of assessment, and there is no organization in the public sector that has any reliable data regarding the levels of investment. The Pakistan Bureau of Statistics (PBS) does publish figures related to investment. However, industry officials and independent analysts usually discard these numbers as mostly made-up and unreliable.

Unfortunately, the attention has mostly remained on papers. Practical implementation has seldom matched the verbal platitudes.

When it comes to substantial investment in the pharmaceutical sector of Pakistan, it has been undertaken by the **private sector**. In sum aggregate, it can be broken down into the two usual categories: *fixed investment* and *variable investment*. The following is a brief description of the kinds of investment in these two categories-

Fixed Investment:

[145] 3rd Five-Year Plan (1965-1970), p.472

- Investment in Land- every pharmaceutical firm has to buy a certain amount of land, fixed by regulation, to set up production facilities. Depending upon where the plant is being set up, its percentage share in initial investment differs. In Karachi, for example, where land is expensive, investment in land could be anywhere from thirty to forty percent of initial investment, depending upon land is bought in which locality (of the four major areas where pharmaceutical industry is located in Karachi, i.e., Korangi, Sight, Landhi and Bin Qasim, land tends to be most expensive in Korangi industrial area). For example, half an acre plot in Korangi could be bought for around Rs 5 million (fifty lakh rupees). Nowadays, the same land would cost in excess of Rs. 200 million (twenty crore rupees), constituting almost forty to fifty percent of fixed cost. In places like Lasbela or Quetta (Baluchistan), though, land is comparatively inexpensive, making up fifteen to twenty percent of initial, fixed investment
- Investment in Machinery- Most of the machinery for manufacturing and quality control is imported since it is not manufactured in Pakistan. Therefore, exchange rate is a substantial factor in the final tally of percentage wise fixed investment. In early 2000s, when exchange rate was stable, the percentage used to vary between 35-45 percent, depending upon the source and quality. But as exchange rate has declined over the years, sometimes precipitously, the percentage has gone up, costing between 45-60 percent of initial fixed investment
- Investment in Human Resource (HR) and Marketing- From managing the initial set-up to starting initial production, the firm needs a dedicated, full-time team of HR professionals, including those of marketing. Marketing is treated as a fixed investment in the start because a firm needs minimum number of people for sales for its products. Afterwards, as sales increase, additional marketing force is hired, which becomes part of variable cost

The above constitute main categories of fixed investment. The categories constituting 'Variable' Investment are as follows-

- Investment in quality maintenance/quality control: Pharmaceutical firms have to continually follow certain quality related requirements/protocols, otherwise they risk action taken against them by the regulator. Around the globe, Good Manufacturing Practices (GMP), Good Packaging Practices (GPP) and Good Distribution Practices (GDP) are followed for quality manufacturing and assurance. Whether its expense on maintaining the premises (Brick and Mortar), or on keeping raw material and drugs in inventory on a certain temperature under the GMP, maintaining air purity for efficacy of drugs, pharmaceutical firms have to continually expend financial resource to meet all the quality criterion. Also, requirements for quality maintenance may change over time, usually requiring more expense. HVAC costs, for example, were not a major factor in early 2000s,

but are more now since it became compulsory in 2020. It is compulsory upon every pharma firm to change accessories per quarter or bi-annual, like lab equipment (FTIR is compulsory, costing 40-50 lakh nowadays). Similarly, NJP machine used to cost Rs 5-6 lakhs in early 2000s. Nowadays, their cost is above 80 lakh rupees

- Investment in Marketing: On average, and for most pharmaceutical firms, investment in marketing is the largest portion of variable expense. The size of the marketing force is critically dependent upon the quantity of sales; not surprisingly, top firms (by sales) have a huge sales force compared to smaller firms. Getz pharmaceutical, the largest firm by sales, employs thousands of individuals in its sales force. Searle, another large firm, employs between 500 to 600 individuals in this category. In contrast, a small firm that is heavily dependent upon government contracts and whose sales are mostly in semi-urban, rural areas, employs 40-50 individuals at most. It is pertinent to mention here that there is a very high turnover in case of sales workforce, which means that firms have to continually expend on hiring, training and retaining individuals related to sales. On average, of the Rs. 100 spent, at least Rs. 30-35 goes to marketing and advertisement
- Investment in Networking and new drugs- Top firms in Pakistan do not operate only in the domestic market but invest in alliances around the globe for their business and network expansion. Searle, for example, has entered into business alliance with international pharmaceutical firms like MSD, Vifor and Santen.[146] Similarly, over time, firms also invest in new drugs either under temporary arrangements or for long-term. For example, during COVID-19, Feroze Sons was given permission by Gilead to manufacture Remdesevir. Temporary manufacturing arrangements are also catered under 'toll manufacturing'[147]
- Investment in external branches- It is usually the top 50 firms that invest in establishing their sales offices outside of Pakistan, in markets where they sell their products. These usually serve as 'distribution points'

The above are the major categories of variable investments in the pharmaceutical sector.

[146] https://www.psx.com.pk/psx/themes/psx/uploads/Notice_for_seeking_public_comments_-_Searle_Pakistan_1.pdf

[147] Another example is of Getz Pharma recently introducing the 'Insulin Pen' alongside its Insulin vial, gauging the heightened demand in the market due to shortages of Insulin, partly due to closure of Eli lilley, a MNC providing insulin to the domestic market

Box: Initial Investment of a firm

What does the initial investment in a pharmaceutical firm look like? The following is a real example of a firm that set up its plant in Peshawar in 2003.

8 kanal plot- Rs. 60 lakh;
Production machinery- Rs. 1 crore;
Quality Control machinery- Rs. 65 lakh;
Technical labor (15-20 people) and **Marketing work force** (20-25 people)- Rs 15 lakh;
5 sections for production – Rs. 30 lakh;
Quality Control Lab equipment- Rs. 25 lakh;

Total cost - 2 crore, 10 lakh rupees

The same plant, if set up in Karachi at that time, would have cost around 3.5 to 4 crore rupees. Nowadays, the same plant in Peshawar would cost a total of Rs. 12-13 crore

The gross investment in setting up and running a pharmaceutical firm depends upon what a firm wants to make (sterile solutions, pills, liquid, etc.). More often than not, firms start with oral dosage forms. Cost of land differs by locality, Karachi being most costly, while Peshawar and areas in Baluchistan like Hub and Lasbela being least expensive. Over time, as one would expect, the costs of setting up pharmaceutical production facilities has gone through significant upward revisions, primarily due to exchange rate losses and domestic costs of production. For example, a basic manufacturing plant in Rawat or Islamabad (ready) would cost around Rs. 25 million in early 2000s. Nowadays, it would cost an estimated Rs. 750 million to Rs. 1 billion. In end 2023/early 2024, a well-equipped plant in Lahore was sold for Rs. 5 billion rupees (containing 3-4 sections for manufacturing drugs). A recently planned plant with five to six production sections and top quality equipment was estimated to cost Rs. 14 to 15 billion before commencing operations.

An example of why exchange rate movements affect the investment decisions is the fact that ninety percent of the machinery has to be imported, whether setting up the factory or upgrading the equipment. The main reason that imported equipment is preferred rather than getting in with Pak engineering manufacturers is the want for continuity of services since pharma manufacturing is a very sensitive requirement/process which needs continuous support, which Pakistani engineering firms don't necessarily provide. Similarly, ninety five percent of the raw material for manufacturing drugs is also imported.

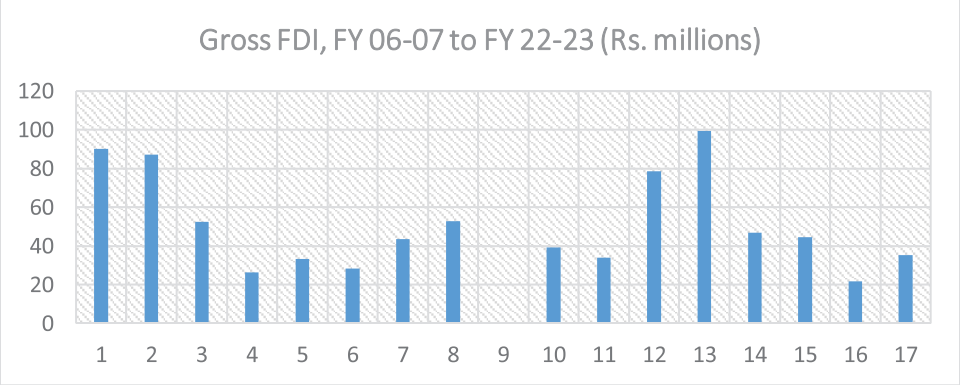
The differences in investment level depend upon whether a completely new firm is being set up or whether an already established firm intends to invest in upgrading facilities. Getz Pharma, Pakistan's largest and top firm by sales, took five to six years to set up a

top-notch plant, which will be Food and Drug Authority (FDA) compliant, with the total investment coming to approximately $300 million.

The total gross investment is made up of gross foreign investment and gross domestic investment. The following sections break down the gross investment levels by both, taking average investment levels (fixed and variable) into account.

Gross Foreign Investment

The total quantum of gross foreign investment in the pharmaceutical sector since FY 06 stands at $814 million (approximate)[148], way below what was envisaged in the government plans, like the Planning Commission/McKinsey consultancy report (2007) that envisaged FDI in billions of dollars over the next decade. Individually, over the course of almost two decades, we do not find a single year where gross investment either reached or crossed $100 million, a very disappointing predicament for a country of 250 million people and carrying a considerable disease burden. In fact, there were eleven years within the eighteen years under consideration where gross investment fell below $50 million (one FY, 14-15, had gross investment in the negative)



Source: State Bank of Pakistan (SBP)

In rupee terms, using the dollar to rupee conversion rates of a particular fiscal years and multiplying by the gross FDI figure, the total investment in these years was equivalent to **Rs. 101 billion, 547 million**.[149]

Gross Domestic Investment

Over time, with the number of domestic firms rising, domestic gross investment has also picked up (especially in context of the reduction in number of MNCs). There are various components constituting both the fixed and variable gross investment. Specifically, the changes (rise or decline) are in consonance in dollar to rupee exchange rate, cost of power

[148] The figures before FY 05-06 were not available in SBP dataset, and neither with PB

[149] Unlike gross domestic investment, the breakup between fixed and variable investment in foreign gross investment was not available

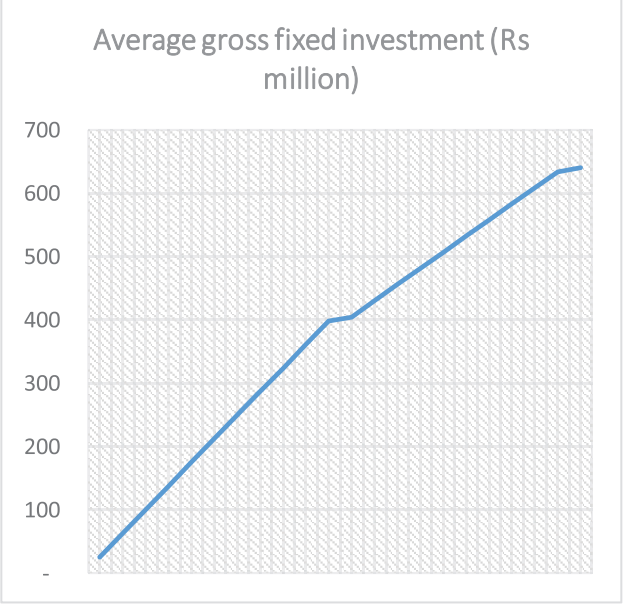
consumption and domestic regulatory requirements. For example, the introduction of compulsory Common Technical Document (CTD) dossier by the regulator, before the introduction of a new product, has increased the variable investment by fifteen to twenty million rupees.

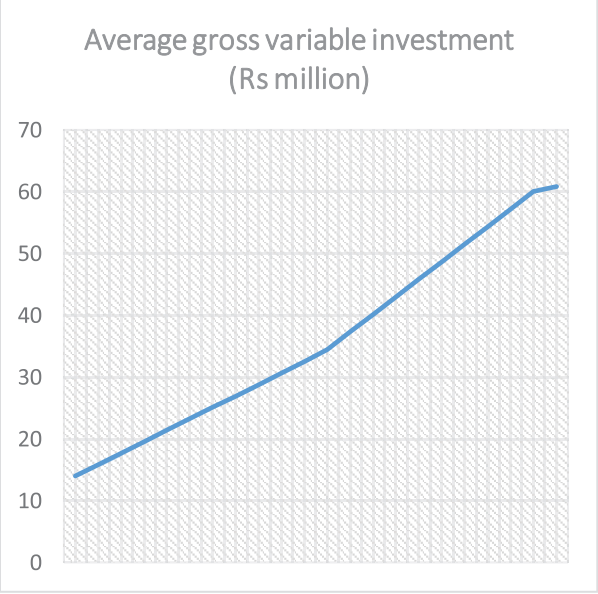
Similarly, a minor investment is the investment of Pakistan based firms in establishing their branches outside of Pakistan. Although the firms are few, those who have invested in expanding their business outside of Pakistan have, by now, an impressive presence in foreign destinations. _For example, Hilton Pharma, have moved into the Middle East, Far East, Africa, Sri Lanka, and Latin America with strong support from Pakistan's Export Promotion Bureau. Getz Pharma (Karachi) has successfully partnered with companies such as Sicor (Vilnius, Lithuania), and E-Pharma (Ravina di Trento, Italy) in pharma licensing.[150]

The formulae used for calculation of total gross domestic investment is as follows-

Aggregate Gross Domestic Investment- (Average fixed cost +Average variable cost (over time-frame of study) *total no. of firms (i.e., 404)[151]

The graph below reflects the total estimated quantum of yearly average fixed and average variable investments in the pharmaceutical sector by domestic firms-





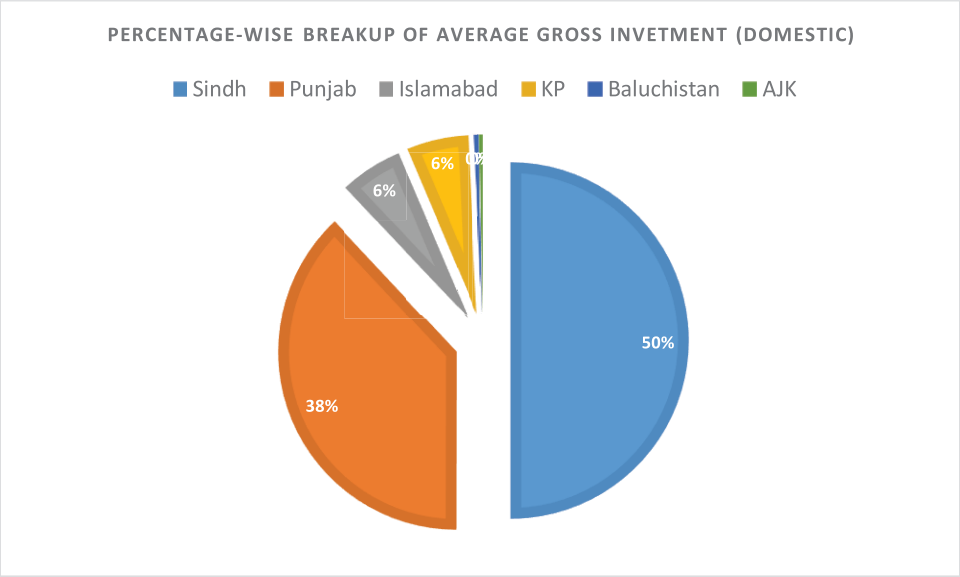
[150] Source: pharmatech.com/view/report-pakistan

[151] Same formulae is used for calculating gross investment by provinces, making use of each province/territory's own averages*the number of firms established in that province/territory

The total gross investment (fixed plus variable) in this sector from FY 01-02 to FY 22-23 equaled **Rs. 255 billion, 701 million** rupees, of which average gross fixed investment totaled **Rs. 234 billion, 340 million** while **Rs. 21 billion, 361 million** constituted the average gross variable investment.

The bifurcation of average total gross investment (fixed plus variable) by province/territory is provided in the table below-

Province/Territory	Total Gross Investment (Rs. millions)
Sindh	127,926
Punjab	97,132
Islamabad	14,520
KP	14,256
Baluchistan	1,152
AJK	715



Combining the gross foreign and gross domestic investment over the time period of the study, the total gross investment in the pharmaceutical sector comes to **Rs. 357 billion, 248 million**.

Net Investment in the Pharmaceutical Sector

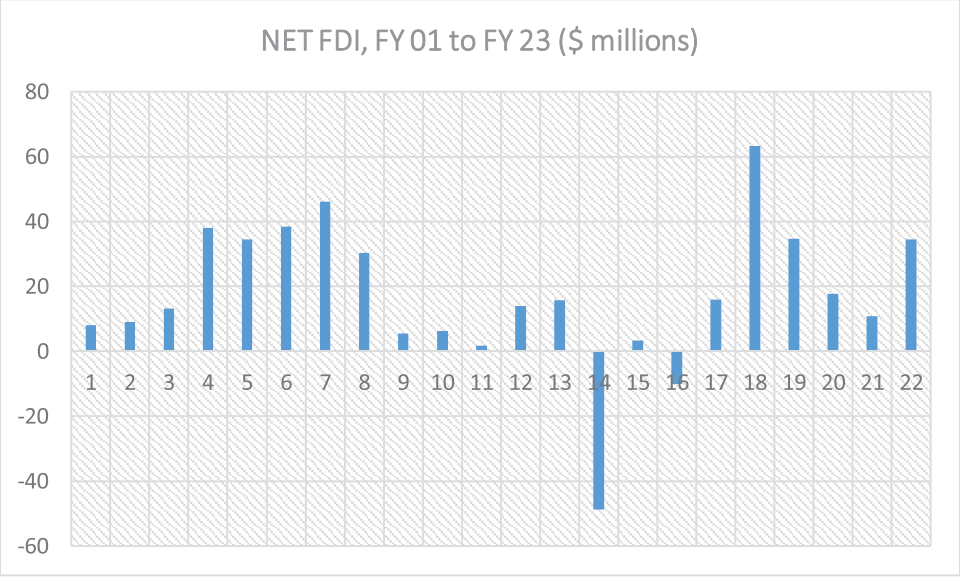
The total quantum of gross investment, as calculated above, does not reflect some of the underlying issues and trends that truly reflect the levels of investment in the pharmaceutical sector. For a genuine picture of what is happening in terms of investment in the pharmaceutical sector, it is necessary to peer deeply into the numbers of gross investment and sift out some of the finer details. For example, gross investment numbers do not reflect the net foreign investment trends in this sector (inflows minus profit

repatriation or outflows) and the loss of investment due to closure of firms (permanently or for certain period) when their licenses were cancelled, which directly affects the levels of variable investment.

The calculations of net foreign and net domestic investment is given in the following lines-

Net Foreign Investment

The graph below indicates the total net investment between the FY 01 to FY 23.[152]

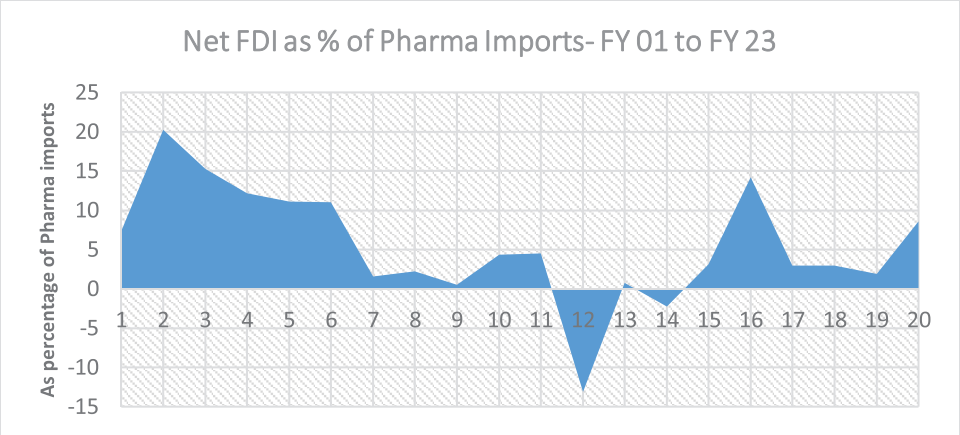


Source: State Bank of Pakistan (SBP)

The total net FDI since FY 01-02 turns out to be a paltry **$382 million**. Converted to rupees using yearly dollar to rupee exchange rate, the sum total comes to **Rs. 47 billion, 402 million**.

The net FDI as percentage of total pharmaceutical import coverage over the course of two decades stands at an abysmal average of 5.5 percent! This is presented in the graph below-

[152] Unlike the gross FDI figure, net FDI series goes back to FY 01



Source: Authors' calculation using SBP data

An interesting aspect to note about the repatriation of profits/dividends is that it shows a declining trend after FY 2018-19, to the point that the total repatriation in the last FY went down to a trickle, i.e., $10 million only. The likely reason for this is the stringent measures in place by the SBP and federal government in terms of taking dollars out of Pakistan rather than the firms deciding to lessen their repatriation.

Net Domestic Investment

Not all firms that got a DML continued to operate in the timeframe of the study. DRAPs list shows a number of firms whose licenses were cancelled over the course of time, with the total coming in at 69. Each firms whose license is cancelled, in turn, entails the loss of variable investment.[153]

Bifurcating by province/territory, the following formulae is used for calculating net domestic investment.

Net domestic investment= Gross domestic investment- (No. of firms by province/territory*average variable investment of that province/territory*2)

=255,701- 6,946= **Rs. 248 billion, 755 million**

The Total Net investment (FDI plus domestic), therefore, comes to **Rs. 296 billion, 157 million**

[153] The number of firms facing permanent closure during timeframe of the study were negligible. Majority of the times, the firm is bought by another firm. Therefore, this possibility (which would have entailed loss of fixed investment too in the form of 'sunk cost') In the case of MNCs who did not face any license cancellation or closure, for example, they were all bought by domestic investors on either leaving Pakistan or merging with other pharmaceutical firms. The average time for renewal of license is 2 years

5- Pharmaceutical Sector- Conclusion and the Way Forward

Pakistan's pharmaceutical industry has gone through significant changes amidst some tough times and in the face of public sector regulations that have usually ignored this industry as anything significant, specifically when compared to the likes of textile industry that has found considerable support from successive governments. To put it mildly, pharmaceutical industry in the governance halls has always been viewed with suspicion and as an outlier rather than a competitive industrial structure that can bring forth several advantages to the country and its economy. It is this thinking, primarily, that has seen illogical regulations like stringent price controls and refusal to allow Toll Manufacturing for longer than a few months.

Although there have been regulatory improvements since the advent of DRAP, the process remains slow, cumbersome and important decisions like drug pricing still remain political in nature rather than decided on the basis of market forces and competition. The industry still has to dish out illogical charges like the CRF related charge despite realizing no support in terms of needed research or top class facilities. And above all, there is no assurity that a helpful policy (like the recent decision to deregulate non-essential drugs) will continue, as has happened before. Briefly put, significant uncertainty remains, which is one reason why FDI in this sector has been very low, and even local investment has been below its potential.

Despite all these odds, the pharma industry, specifically the top level pharmaceutical firms, have shown remarkable resilience and have made considerable strides in establishing themselves as brands with quality products. Local firms have grown by leaps and bounds and are now easily at par with MNCs in the Pakistani pharmaceutical market.

These achievements, though, should not make the industry and regulators oblivious to the developments happening now and the ones expected in the future, which will definitely affect the fortunes of the Pakistani pharmaceutical industry. The rapid strides in technological advancement, specifically those related to Artificial Intelligence (AI), are already making strides in biological and pharmaceutical sciences. The pace of innovation and technological change is expected to further fasten these trends. Once challenging areas like genetics and genetically linked diseases, obesity and Alzheimer's are being addressed with tremendous, ground-breaking advances in biological sciences. Value creation in health is now moving towards prevention, personalization of medicines as per the biological makeup, increased use of AI to come up with new effective combinations in chemical makeup of drugs, and an emphasis upon predictive power using advanced AI tools and data.

The following table provides a summary of the use of AI and its implications for some of the critical areas of the pharmaceutical industry-

Area/Specification	AI Use	Benefits
New Drugs	Identification of new molecular structures and innovator molecules; APIs; personalized medication'	Reduction in failure rates during discovery process; increased speed of R&D
Clinical Trials	Better risk analysis; simulated trials and less risks to trial patients	Shorter trial durations with greater chance of identifying issues during early stages
Manufacturing	Significant improvements in overall production process with greater flexibility in specific drug production; easier, automated maintenance reducing chances of human error; better prediction in terms of issues that may arise in production process	Possibility of significant reduction in variable and operating costs through prevention of human induced errors and automated processes
Supply chain, sales and marketing	Better demand forecasting, personalized marketing and automated sales content	Lesser waste of available resources meaning higher productivity; more focused sales strategies

These kinds of forces will push forth some fundamental changes in the way pharmaceutical business is conducted around the globe, and Pakistan's pharmaceutical industry will not be an exception to the spillovers of these trends. There will be more innovative drugs of personalized nature, and more competitors are expected to enter the field, vying for the chunk of the expanding market that is already above a trillion dollar. Consumers are expected to significantly spend more on their healthcare in the future, and more segmentation in personal care products is expected. Just to give an idea of the opportunities that lie ahead, the global 'wellness' industry, of which pharmaceutical products are a big part, is expected to reach $8.5 trillion by end 2027.[154]

The use of AI in drug discovery, coming up with novel APIs and their combinations, and clinical trial optimization are leading to significantly reduced time in terms of trials-to-market for new treatments. Research efficiency is improving by leaps and bounds, allowing companies to scour massive health data sets with ease and coming up with personalized medicine solution and reducing the possibilities of costly drug trial mistakes. Breakthrough technological developments like CRISPR gene editing and stupendous strides in biologics imply that previously untreatable conditions and ailments are now on the cusp of being treated properly. These treatments, of course, would require new, innovative drugs, creating a substantially huge market of its own.

[154] 'The Global Wellness Economy Reaches a Record $5.6 Trillion—And It's Forecast to Hit $8.5 Trillion by 2027', *Global Wellness Institute*

Can Pakistan's regulators and its pharmaceutical companies rise to these challenges and adapt? A probable answer to these comes in the form of analyzing the history of pharmaceutical industry's growth and its current standing, as has been described above. Briefly put, as far as the pharmaceutical industry is concerned, it has always managed to rise to the challenge despite odds. The top level companies in Pakistan can easily compete at the international level as well as adapt to the AI opportunities. The issue, as usual, lies at the regulatory end and the overall governance environment in the country which tends to affect risk-taking and investment. The investor, for example, will remain shy of investing if there is no certainty in decision-making and important regulatory issues like drug pricing are not decentralized. There has to be a wholesale revision of powers endowed to the regulators to facilitate the growth and transition of the industry. Some of the important revisions need to be done to the following-

a) Drug-pricing: the philosophy and strategy to increase access of drugs and making them affordable through stringent price controls has been a miserable failure. Attention now needs to turn towards optimizing upon competition within the industry for this purpose and provision of information about drugs with similar pharmacologic properties to achieve this end
b) Efforts should be solely concentrated on ensuring quality, and how drug quality can be enhanced? Without this, there is little hope of increasing Pakistani pharma industry's footprint in the global market
c) Supporting industry in R&D: this is a rather ignored aspect of the regulatory operations, but nonetheless a very important one at the global level due to its importance. Leading global pharmaceutical companies spend billions of dollars on research for a reason, and find active fiscal support of government for that purpose (as in the case of mRNA vaccines for COVID-19 and more). In Pakistan, though, it has been the opposite, with government extracting considerable amounts from the industry in the name of research (since 1976) but showing zero results in terms of state-of-the-art infrastructure that is compatible with global standards like US FDA. Further, government has rarely provided any subsidy to fund industrial research to the pharma firms. This model has to change to private firms getting to keep the CRF for research purposes, complemented by active government fiscal support. History and evidence shows that the spillovers of research and discovery are tremendous, and will be so given the wave of AI in pharmaceuticals
d) Regulators have to think in terms of difficulties that keep the domestic as well as foreign investors away. For example, profit repatriation in dollars has been a real headache for foreign MNCs in Pakistan's pharmaceutical market, and part of the reason why they ended up leaving Pakistan. Similarly, the persistent refusal to extend Toll Manufacturing beyond a few months (it has been extended to a year

or two now, but still needs permission every few months) has had negative impact upon the operations and utilization of existing capacity. There should be no or minimal procedural work, for example, when a world renowned company itself wants to do toll manufacturing with a local firm after inspecting all its facilities

These considerations would be critical in Pakistan's pharmaceutical industry moving forward with the emerging trends, and assimilating accordingly. Otherwise, they risk being outpaced in a world that has already leapt ahead by quite a bit.

ANNEXURE-A


Vaccine-preventable diseases in the US
Shown is the reduction of cases and deaths after the introduction of the vaccine
Cases
All post-vaccine cases refer to 2006
Deaths
All post-vaccine deaths refer to 2004
Diphtheria
Pre-vaccine: 158 cases per million per year (1936-45)
100% Reduction
Post-vaccine: 0 cases per million per year
Pre-vaccine: 13.7 deaths per million per year (1936-45)
100% Reduction
Post-vaccine: 0 deaths per million per year
Measles
Pre-vaccine: 3044 cases per million per year (1953-62)
99.99% Reduction
Post-vaccine: 0.2 cases per million per year
Pre-vaccine: 2.5 deaths per million per year (1953-62)
100% Reduction
Post-vaccine: 0 deaths per million per year
Mumps
Pre-vaccine: 830 cases per million per year (1963-68)
97.4% Reduction
Post-vaccine: 22 cases per million per year
Pre-vaccine: 0.2 deaths per million per year (1963-68)
100% Reduction
Post-vaccine: 0 deaths per million per year
Pertussis
Pre-vaccine: 1534 cases per million per year (1934-43)
96.6% Reduction
Post-vaccine: 52 cases per million per year
Pre-vaccine: 30.8 deaths per million per year (1934-43)
99.7% Reduction
Post-vaccine: 0.09 deaths per million per year
Acute Poliomyeltis
Pre-vaccine: 141 cases per million per year (1941-50)
100% Reduction
Post-vaccine: 0 cases per million per year
Pre-vaccine: 10 deaths per million per year (1941-50)
100% Reduction
Post-vaccine: 0 deaths per million per year
Paralytic Poliomyeltis
Pre-vaccine: 103 cases per million per year (1951-54)
100% Reduction
Post-vaccine: 0 cases per million per year
Pre-vaccine: 11.8 deaths per million per year (1951-54)
100% Reduction
Post-vaccine: 0 deaths per million per year
Rubella
Pre-vaccine: 242 cases per million per year (1966-68)
99.98% Reduction
Post-vaccine: 0.04 cases per million per year
Pre-vaccine: 0.09 deaths per million per year (1966-68)
100% Reduction
Post-vaccine: 0 deaths per million per year
Congenital Rubella Syndrome
Pre-vaccine: 0.76 cases per million per year (1966-69)
99.6% Reduction
Post-vaccine: 0.003 cases per million per year
Pre-vaccine: no data (1966-69)
no data
Post-vaccine: 0 deaths per million per year
Smallpox
Pre-vaccine: 250 cases per million per year (1900-49)
100% Reduction
Post-vaccine: 0 cases per million per year
Pre-vaccine: 2.9 deaths per million per year (1900-49)
100% Reduction
Post-vaccine: 0 deaths per million per year
Tetanus
Pre-vaccine: 4 cases per million per year (1947-49)
96.6% Reduction
Post-vaccine: 0.14 cases per million per year
Pre-vaccine: 3.2 deaths per million per year (1947-49)
99.6% Reduction
Post-vaccine: 0.01 deaths per million per year
Hepatitis A
Pre-vaccine: 465 cases per million per year (1986-95)
89% Reduction
Post-vaccine: 51 cases per million per year
Pre-vaccine: 0.5 deaths per million per year (1986-95)
88.7% Reduction
Post-vaccine: 0.06 deaths per million per year
Acute Hepatitis B
Pre-vaccine: 273 cases per million per year (1982-91)
83.9% Reduction
Post-vaccine: 44 cases per million per year
Pre-vaccine: 1 death per million per year (1982-91)
83.6% Reduction
Post-vaccine: 0.16 deaths per million per year
Haemophilus Influenza type b
Pre-vaccine: 84 cases per million per year (1980s)
99.8% Reduction
Post-vaccine: 0.17 cases per million per year
Pre-vaccine: no data (1980s)
no data
Post-vaccine: 0.02 deaths per million per year
Pneumococca Disease
Pre-vaccine: 233 cases per million per year (1997-99)
40.5% Reduction
Post-vaccine: 139 cases per million per year
Pre-vaccine: 24 deaths per million per year (1997-99)
31.3% Reduction
Post-vaccine: 16.5 deaths per million per year
Varicella
Pre-vaccine: 16018 cases per million per year (1990-94)
87.2% Reduction
Post-vaccine: 2046 cases per million per year
Pre-vaccine: 0.41 deaths per million per year (1990-94)
84.3% Reduction
Post-vaccine: 0.06 deaths per million per year

ANNEXURE-B

GOVERNMENT OF PAKISTAN

Ministry of National Health Services, Regulations & Coordination

Drugs Regulatory Authority of Pakistan

PUBLIC NOTICE

1. In pursuance of the Drug Pricing Policy-2015 and for transparency, fair practices and uniform application, annual increase in prices of drugs has been linked with Consumer Price Index (CPI) which is announced by Pakistan Bureau of Statistics, Government of Pakistan.
2. Pakistan Bureau of Statistics has announced CPI for Financial Year 2015-16 as 2.86%.
3. As per CPI rate of 2.86% under formulae in the Drug Pricing Policy-2015 as approved by the Economic Coordination of the Cabinet (ECC), price increase on the existing approved MRPs of drugs has been notified as under:
   1. Scheduled drugs (50% of CPI)* **1.43%**
   2. Non-scheduled drugs (70% of CPI)* **2.002%**
   3. Lower priced drugs (equal to CPI)* **2.86%**
4. These rates of price increase are not applicable on drugs, whether scheduled, non-scheduled or lower priced drugs, whose cases are pending adjudication before the courts of law.
5. **If any pharmaceutical company or retailer increases price of any drug at more than notified rate, complaints may be lodged at following telephone numbers / email address:**

Tel: 051-9107315, 051-9262060, email: ddcpricing@gmail.com & contact@dra.gov.pk

* Scheduled drugs are those which are listed in the schedule to the Drug Pricing Policy-2015, non-scheduled drug are those which are other than the scheduled drugs and lower priced drugs are drugs whose current approved MRPs are less than the following threshold:

(I). Rs.3/- per tablet / capsule / respule / caplet / patch

(ii). Rs.3/- 5ml of syrup /suspension/elixir

(iii). Rs.6/- per sachet

(iv). Rs.15/- per injection

(v). Rs.3/- per 1 gm of cream/ ointment/ gel (non sterile) subject to maximum pack size of 20 gm.

(vi). Rs.4/- per 1 gm of cream/ ointment/ gel (sterile) subject to maximum pack size of 20 gm.

(vii). Rs.4/- per ml of eye/ ear /nasal drops /nasal spray / inhalation solution (sterile) subject to maximum pack size of 10ml.

Drugs Regulatory Authority of Pakistan,
TF Complex, G-9/4, Islamabad

PID(I)362/16