*Chapter 2*

# Regulating the Pharmaceutical Industry: An Analysis of the Drug Regulatory Authority of Pakistan (DRAP)

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Healthy lives and the longevity of humans over time have critically been dependent upon the availability of quality drugs. Therefore, regulating the pharmaceutical industry for ensuring quality drugs and quality services (like drug dispensing) have traditionally been a priority for governments all around the globe. Pakistan is no exception, and at present has DRAP as its regulator of the pharmaceutical industry. Founded in 2012, few studies have analysed the performance of DRAP to date, and even those are limited in content, coverage and data.

Five criteria are used to gauge the performance of DRAP. It does better than its predecessor in terms of quality of drugs and ensuring quality in dispensing, but significant gaps still remain. Poor quality drugs are still prevalent in markets, and questionable techniques (like mislabeling drugs) still persist. Similarly, there are wide gaps in ensuring that the dispensing practices at public and private healthcare facilities. Additionally, the quality of dispensers is still poor.

Regarding policy consistency, we find a litany of SROs through which policies are constantly being modified. This tends to create uncertainty since the industry is never sure of what the near future would bring? Doing business is still a challenge from the industry's perspective, although there have been certain improvements post-DRAP. Tightly regulated pricing is still the most contentious issue; businesses face a plethora of charges, there are various taxes on products, and even closing a company could be cumbersome.

To have good quality drugs, it is necessary to have quality infrastructure, especially R&D facilities. Since 1976, the federal government has been collecting a research tax, equal to a percent of the industry's gross sales. Yet despite garnering billions of rupees over time, Pakistan lacks quality infrastructure and has little (if any) in terms of quality R&D in drugs.

For an industry that was once described as the 'sunshine industry' by renowned consultant Mckinzey, the net FDI has been dismal in the two decades, since 2000. This state of affairs has to primarily do with government regulation, especially pricing and lack of support for patent protection for originator brand medicine.

Last, but not the least, is the critical question of whether consumers are better off than before DRAP? The simple answer is NO! Over time, their Out-of-Pocket expense has increased despite the government refusing price increases in drugs to, as per their explanation, keep prices 'affordable'. The aim has failed. Similarly, drug shortages are

still persistent and the short medicines have to either be imported or are found in the black market at astronomical prices. The quality of drug dispensers and healthcare providers still remains poor, and most pharmacies operate without a qualified pharmacist. In essence, consumers have not realised much (if any) increase in their utility after founding of DRAP.

In sum aggregate, DRAPs performance is better than its predecessor, but there are still significant gaps to be filled and significant challenges to be addressed.

## 2.1. INTRODUCTION AND CONTEXT

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 Organisation (DCO), which worked under the now-defunct Ministry of Health. Although provinces have their 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[12] (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 emphasising the necessity of effectively coordinating and implementing provisions of the previous Act (the 1976 Act) and to harmonise 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.

An analysis of the regulatory performance is in the offing, given the challenging ground realities. The fact of the matter is that despite having over 700 pharmaceutical firms, Pakistan regularly experiences drug shortages, many of them categorised as 'critical' (or life-saving) drugs. More than 40 Multi-National Corporations (MNCs) worked in Pakistan, bringing with them reputation, experience and FDI. Barely 25 are left now, with several divesting away from manufacturing drugs to other products (like dry milk, baby food, etc.). In the throes of the Corona pandemic, we found that none of the pharmaceutical firms did any research on corona virus to try to manufacture corona vaccines. In fact, the industry does not manufacture a single vaccine! The critical shortages of life-saving drugs and the non-availability of vaccines puts lives in danger.

[12]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 the proposed written piece, drugs will be used for allopathic medicines only.

The industry points towards regressive regulations, especially those concerning pricing, lack of quality control, extractive practices like CRF, etc., as the culprits in terms of the above- mentioned. It claims that adverse regulations and uncertainty have marred the efficiency of an industry that was once labelled as the 'sunshine' industry by McKinsey for its potential. They point to the increasing gap between imports and exports and other factors like dismal FDI numbers (between 2002-03 and 2019-20, the net FDI was only $267 million) as outcomes of the adverse regulations and uncertainty created by the actions of the regulator and the government.

Given what DRAP has been tasked with under the DRAP Act, the central theme of this paper is to analyse its performance keeping these tasks in context, and gauge whether it has been effective in carrying out its responsibilities or not? Further, what has been the outcome of DRAP's actions on the industry, which has traditionally remained at loggerheads with DRAPs predecessor? The study aims to answer whether DRAPs arrival has changed the status quo and lessened the distrust between the industry and the regulator, whether regulations have helped the industry in any manner, or if things have barely changed compared to pre-DRAP days?

## 2.2. LITERATURE REVIEW

When it comes to regulating the pharmaceutical industry and its outcomes, a wide gap exists between the narrative of the industry and the government (specifically the regulator). Credible studies analysing the performance of the regulator and the industry could have given the reader a true picture of where the reality lies? However, not many studies address these two competing narratives in one place. Rashid (2015) undertook an analysis of the DRAP based on policies related to three areas (industry regulation, encouragement of its development and ensuring availability of drugs). She opined that there were significant gaps in regulator's performance that were hampering the development of the industry. The second study that exclusively analysed DRAPs performance was Rasheed et al. (2019), specifically targeting quality of medicines as the central question of their research. They found significant gaps in terms of the regulator's performance and in terms of ensuring the recommended quality of medicines. They further propose improving the overall framework for ensuring quality, like increasing Good Manufacturing Practice Inspections (GMPI).

Mehmood (2018)[13] attempts to compare these two competing narratives by analysing the issues plaguing both the regulator and the industry. He found that although the sector had issues to take care of (producers at lower tiers producing sub-standard medicines, etc.), the main issues hampering the efficient working and development of the industry were traced to how the industry had been regulated historically. Especially vexing was the issue of administered pricing that pushed producers to take specific actions (like putting a stop to the production of certain drugs) that had overall negative welfare repercussions.

The majority of the research on the pharmaceutical industry and public sector regulations usually address a single (or a few) criteria rather than taking a holistic picture. For instance, the aspect related to the shortage of drugs has been touched upon in various

[13] 'Pharmaceutical Industry Report' (2018)

studies. Rizvi (1999) blamed the government policies, especially 'freezing' drug prices, as the primary contributor to shortages of essential drugs in Pakistan. A paper by Third World Network Briefing (2001) touched upon the issue of high-priced imported medicines and the black market in medicines, discussing the role of government mandated quotas in Pakistan and its effects on drug supply. Zaidi et al. (2013) analysed the availability of drugs in government/public sector hospitals. They concluded that lower expenditures per capita (less than $2) as proposed by the World Health Organisation (WHO) for maintaining a steady supply of essential drugs was not being met. 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. Interestingly, their results seemed to confirm earlier estimates by The Network for Consumer Protection (2006) that found a similar percentage in terms of median availability of essential drugs at public sector outlets. Gilani, Babar and Malik (2013) opined that the 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) analysed the performance of the main regulator (DRAP) and issues that lead to expansion of informal channels ('black market'). Sayeed and Dawani (2020) concluded that pricing policies lead to preference for manufacturing drugs which have a high price margin, plus incentivise hoarding and rent-seeking.

Khan, Kundi and Saqib (2019) look at the tort law related to injuries caused by sub-standard drugs. They find that tort laws are weak in their reach, effectiveness and implementation. Saleha, Hassan and Iqbal (2010) analyse industry's returns over a decade, and conclude that the regulations are responsible for the below-par performance of the industry, which could have performed better had the regulations been friendlier. The World Health Organisation (WHO, 2017) assessed the transparency in the public sector policies related to the pharmaceutical industry. They found that perception of corruption for different regulating categories differs, with some higher and some lower. Shahnaz, Bano and Arshad (2009) carried out a technical analysis of 6 generic products of a particular drug (Cefixime 400 mg). They found that all six varieties are effective in treating symptoms and interchangeable. Aqeel, Shabbir, Bashir et al (2014) touch upon the very important issue of self-medication, in Islamabad capital territory. They found that the percentage of self-medication was a staggering 61 percent, reinforcing the generally agreed result that in Pakistan, the rates of self-medication are high.

## 2.3. METHODOLOGY AND LIMITATIONS

The foremost method in such analysis is to consult/ analyse earlier studies and their results. These inform the researcher of the criterion used, while additionally indicating where any shortcoming lies (if any). All this information is then aggregated to produce a final analysis. Primary data will be used from information provided by DRAP that is available on its website, updated from time to time. This will be complemented by reports appearing in the media since there are several aspects of regulation that DRAP may not report on, at least regularly (like quality control).

A thorough analysis of existing literature will be undertaken, aside from the results/outcomes of previous performance appraisals by other authors, to gauge which

criterion and methodology may be adopted. Depending upon data and information availability, an attempt will be made at the end to compare the performance of DRAP with its predecessor.

The paper's main limitation is that the require data on pharmaceutical sector regulation does not exist at a central place or central repository. There is no central, long-term data store of DRAP (and its predecessor) regulatory data; its officials are often reluctant to discuss details of their work and the data put up on its website is often patchy rather than continuous. For example, they remain tight-lipped about the utilisation of money taken from the industry under the Central Research Fund (CRF). Similarly, there is little (if any) information concerning the coordination between the federal and the provincial regulatory authorities. Additionally, there has rarely (if ever) been a study on the monetary costs of regulations that could give us a heads-up in terms of this study.

Another limitation of this study is that it will concentrate mainly upon federal level regulation through its regulatory body (DRAP). Provincial regulatory authorities will not be covered in this research piece. The reason being that as far as regulation of the pharmaceutical industry goes, provincial authorities only deal with distribution and sale of drugs, which is a small part of the industry's functioning, and do not constitute significant factors impinging upon the issues confronted by the industry.

In essence, analysis of five main themes can give us a credible picture of whether DRAPs performance stands up to scrutiny or not? These cover both the demand and supply side of the pharmaceuticals. They are:

(a) Quality of drugs and drug dispensing
(b) Consistency of Policies
(c) Ease of conducting/doing business
(d) Research and Development (R&D), and its supporting infrastructure
(e) Attracting Investment
(f) Are consumer's better off than before?

### 2.4. QUALITY OF DRUGS AND DRUG DISPENSING

There is perhaps no issue more important than ensuring that supplied drugs are of good quality, and they conform to quality standards. Simply put, sub-standard, low quality drugs puts lives at risk. Moreover, it has to be further ensured that those who are dispensing drugs are knowledgeable about the attributes of those drugs. Therefore, one of the foremost reasons for having a drug regulatory authority is to prevent such a happenstance and to ensure standards in drug dispensing practices. In this regard, majority of DRAPs Departments (Quality Assurance, Licensing, Pharmacy Services, Controlled Drugs, Biological Drugs, Health & OTC) deal with these issues pertaining to drug and drug dispensing quality. Field offices spread across the country report their findings to the HQ. For example, the Quality Assurance wing has five field offices all over the country, where day-to-day activities are carried out by federal drug inspectors, assistant drug controllers and an appellate board.

Quality of drugs has been a pervasive issue for a long time. In 1975, the Generic Drugs Act was repealed after 38 companies were found to be producing sub-standard drugs, resulting in the Drugs Act 1976 which proposed heavy fines and imprisonment for producing sub-standard, adulterated drugs. Yet, despite decades, the instances refuse to

die down! In 2011, more than 230 people were killed after being administered adulterated cardiovascular medicine. The reaction led to the immediate formation of DRAP, something that had been in the works since the mid-2000s. In 2012, a contaminated cough syrup claimed numerous lives, bringing the issue of adulterated, low-quality drugs and loose quality control of regulators into the limelight again. In both these cases, public laboratories could not identify the dangerous substance in these drugs (Bigdeli et al., 2017). Pakistan's first 'Stem Cell Policy' acknowledges that Pakistan has no USFDA or EMA (Europe Medicine Agency) approved pharmaceutical protein purification /stem cell production facility in Pakistan, neither in the public sector nor in the private sector.[14]

The attractiveness of indulging in manufacturing sub-standard, low-quality medicines is that nominal pay-off's are quiet high. Blackstone, Pociask and Fuhr (2014) contended that dealing with fake drugs through black market has higher monetary payoffs than even heroin and other narcotics. Therefore, it's imperative to stop such practices through tighter, efficient checks by the regulator.

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.[15]

Between 2013 and early 2017, 18 drug manufacturing licenses were suspended and 89 drugs were banned for being sub-standard. The following table presents available figures of drug tests and their results since 2015, indicating that testing has increased over time.[16]

| Year | Drug Recalls | Samples Tested | Substandard | Spurious | Unregistered | False Warranty | Misbranded Drugs |
|---|---|---|---|---|---|---|---|
| 2015 | | 43,933 | 538 | 252 | | | |
| 2016 | | 74,071 | 813 | 97 | | | |
| 2017 | | 53,371 | 446 | 63 | | | |
| 2018 | | 41,435 | 2,527 | 42 | 497 | | |
| 2019 | | 51,194 | 490 | | 587 | 1,710 | 222 |
| 2020 | 34 | | | | | | |
| 2021 | 7 | | | | | | |

[14] 'National Bio-safety Regulations' (2020), p 'i'.

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

[16] Note that these figures do not include a few categories like sale of prohibited or 'controlled' drugs without authorisation, sale of drugs that were not kept as per the required quality criteria ('unsatisfactory storage'), etc., because the data was not available.

Besides DRAP, Punjab's quality control unit (PDCU) has published data on tests and their results since 2017. Between January and June 2021, over 3,800 inspections were carried out in the Rawalpindi district alone, resulting in sealing of 88 drug selling premises.

For reference, a total of 60,000 tests were carried in 2009 and 2010 in public Drug Testing Laboratories (DTL) by Drug Control Organisation (DCO, DRAPs predecessor), whereby 2 percent failed to comply with quality standards. This implies that testing has picked up after DRAPs founding compared to pre-DRAP days.

Another positive development occurred in the form of DRAP attaining full membership of Uppsala Monitoring Centre (UMC) in 2018. UMC is an independent think tank that works to ensure the safety of drugs for patients through safer use, i-e, pharmacovigilance. UMC helps countries identify dangerous drugs that need to be withdrawn. Formerly, Pakistan was an Associate Member only.

All this, both in the pre-DRAP and post-DRAP period, implies that the issue of quality is still a very pressing matter due to its continuous recurrence under various heads. Rasheed et al. (2019) consider the published DRAP data on quality of the medicines as negligible and unsatisfactory! One further aspect to be noted here, which is critically important, is that the tested samples are almost always from officially procured batches of drugs for public health facilities. That means that a large number of drugs available in the open market remain unchecked, untested. Similarly, DTLs do not carry out all the tests required for the quality purpose, like the 'impurity test' that are considered important.

Last, but the least, there is a dearth of Bioequivilance (BE) labs in the country. These labs are an essential component of ensuring the quality equivalency of generic brands with originator brands[17], something that can really be helpful for consumers since generic brands tend to be cheaper than originator brands. They can additionally be beneficial in boosting exports and bringing in Foreign Direct Investment (FDI). However, there are only two BE labs[18] in the country approved by DRAP under Bio-Study Rules 2017! In 2012, there were seven, whose licenses were not renewed by DRAP.

Available literature tends to support the contention that drug quality is a considerable issue in Pakistan. Rasheed et al. (2019) carried out an investigation into the quality issues of drugs in Pakistan. They found no proper mechanism and neither a concise study that had ever studied this issue in depth. Further, their investigation did not find evidence of a large-scale presence of poor-quality medicines, as alleged by certain quarters. However, they suggest that the overall quality framework (like GMPIs) needs considerable improvement to tackle the issue of the prevalence of low-quality medicines. Additionally, they propose funding comprehensive studies to document this issue properly.

Razvi, Anjum and Ahmed (2015) noted that the pharmaceutical regulators needed to upgrade their skills to regulate in a manner that could help achieve positive outcomes, like increasing prospects of pharmaceutical exports. Godman etal. (2016)

[17] 'Originator' brands are drugs that carry a patent. In Pakistan, they are imported. Generic brands are domestic equivalents to originator brands, but without a patent and carrying their own brand name.

[18] Both are situated in Karachi, one at M/S Pharma International manufacturing facility and the second at Karachi University's Centre for Bioequivalence Studies

undertook a technical assessment of API's in drug registration procedures. They concluded that there was an urgent need to improve the registration process of generic drugs in Pakistan.

At the international level, World Health Organisation's (WHO) Programme for International Drug Monitoring (WHO-PIDM) is a widely followed practice in ensuring drug quality, with the main purpose being to develop a pharmacovigilance system in member countries and coordination at the national and international level for timely intimation on any medicine safety alerts. This concept was put into practice in 1968. Pakistan joined as late as 2018, reflecting poorly on regulator and policy makers' priority in terms of ensuring quality medicines to the population.

Other indicators reflect equally poorly as far as quality of medicines is concerned. By the end of 2018, there was only one drug manufacturing firm that held the Good Manufacturing Practice (GMP) certification issued by the European Medicines Agency. Not a single DTL is United States Food and Drug Administration (USFDA) certified, the international gold standard for quality assurance in drug manufacturing. This is despite the fact that the pharmaceutical industry has been paying 1 percent of their gross sales to the federal government since 1976 for setting up research infrastructure and conducting research. There are 12 DTLs, but except for one or two, none qualifies as per WHO quality standard.[19] Recently, DRAP claimed to have launched a 'world-class' DTL in Karachi.[20]

Quality assurance is not only critical in terms of manufacturing drugs, but also in terms of dispensing practices at pharmacies, with the majority of these activities coming under the 'pharmacovigilance' ambit. Drugs, for example, kept without following specified temperature conditions turn to be ineffective. A year before DRAP's founding, Mahmood et al (2011) bemoaned the fact that there was not even a proper pharmacovigilance policy, let alone system, in place in Pakistan, terming it practically 'non-existent'. In the same year, Azhar, Ibrahim and Baber (2011) carried out a cross-country study of pharmacies, and concluded that the regulatory enforcement in terms of quality assurance of drugs was poor.

The situation has not changed much, unfortunately. Study after study has found questionable dispensing practices at both public and private health facilities. 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[21] on safe dispensing practices in Pakistan came up with a startling revelation that approximately 95 percent of the pharmacies in Pakistan are run without a pharmacist, thus putting a large question mark around which drugs are dispensed. Last, but not the least, the latest outbreak of HIV among children as young as two years old in Larkana (Sindh, with the outbreaks continuously happening for more than a decade) attests to the significant lags in quality dispensing as almost all the studies attribute it to unsafe medical practices, complemented by poor drug quality.

[19] DRAP representatives maintain that WHO certified labs are 5 in total. However, there are no independent sources confirming this statistic

[20] 'Pakistan launches world-class drug testing lab in Karachi'

[21] '95 percent pharmacies in Pakistan are run without a pharmacist'

## 2.5. CONSISTENCY OF POLICIES

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 favoured 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[22] allowed holders of valid Drug Manufacturing Licenses (DML) to manufacture hand sanitisers as per the prescribed formulae, *but only for three months*! There were similar notifications allowing hand sanitiser 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[23] 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, 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.

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[22] F. No 4-2/2017-DD (H&OTC) (Pt), 6th April 2020

[23] F-3-5/2013-DDC (Alt. Med.), dated 10th June 2016

(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.

## 2.6. EASE OF CONDUCTING/DOING BUSINESS

Industry and business will always find it difficult to work in a challenging environment. And one of the biggest impediments to their working could be adverse regulations. Historically, the pharmaceutical industry in Pakistan has had to face a tightly regulated market that has made conducting business difficult. Since DRAP's founding, there have been some good initiatives, like exempting pharmaceutical raw material from import duties, as announced in the recent budget. In this regard, DRAPs work is a continuation of its predecessor, whereby exemptions used to be granted on imported raw material, drug manufacturing equipment, General Sales Tax (GST) exemption, exemptions on drugs imported by United Nations (UN) agencies and donor funded programs (Zaidi et al., 2013).

However, formidable challenges still beckon for the industry which makes doing business difficult.

**Pricing**—Drug pricing has (and still is) arguably been the most contentious issue between the industry and the federal government. Traditionally, the federal government has kept drug pricing strictly regulated, not allowing the industry freedom in pricing. This was especially valid post-2000 when the 'price freeze' policy came into existence. Before that, the government had been relatively more liberal in its approach. Between 1994 and 2001, for example, price increases were allowed yearly[24] but this was discontinued after 2001.

[24] 'Medicines being sold in black market'

Industry officials blame pricing issues as the most detrimental to business operations, having several negative repercussions. For example, up till 1999, there were more than 40 pharmaceutical MNCs in Pakistan. But more than a decade of the government's 'price freeze' policy from 2001 to 2013 led to a large-scale exodus of MNCs from Pakistan. Their present number stands at 22, but not all are manufacturing drugs, as many have divested away to other products (like infant milk, etc.). Aside from the MNCs, even the domestic firms suffered under this policy, as many discontinued producing essential, life-saving medicines.

The main reason for heavy public regulation of drug pricing rests on two misguided beliefs: *a*) government can enhance welfare through administered drug prices, and *b*) government has the wherewithal, knowledge and workforce to efficiently administer drug pricing. Over time, there is enough evidence to completely negate both of these assumptions; instead of 'enhancing welfare', price controls have spawned detrimental repercussions ranging from continued recurrence of drug shortages (endangering the lives of patients) to expansion of black market, where drugs in short supply can be found but at an alarmingly high price[25]. Similarly, drug manufacturing, distribution, dispensing and administration, etc., are technical matters that government regulators never had the proper knowledge to deal with.

Additionally, a critical consideration in public drug pricing decisions has always been politics. Any drug price increase tends to bring a negative response that casts the government of the time in a negative mode, something that could be politically detrimental in the context of populist politics. The tirade against price increases is perpetuated by the media, which usually reports the increase in percentages rather than nominal numbers to make it look substantial. A population- level backlash tends to follow, which more often than not leads governments to back out of any plans for increasing drug prices. For example, as prices were increased in 2016 in line with the 2015 Pricing Policy, a media-led backlash erupted that resulted in legislators in National Assembly and the Senate calling to take back the increases and taking 'strict action against the culprits' (i-e, the drug manufacturers).

There has been a slight improvement on this front. However, pricing still remains a tightly regulated aspect, with the final decision to grant price increases lying with the Cabinet, i-e, even if DRAP allows a drug price increase, the Cabinet can reject it, a common occurrence that has continued to-date. In essence, drug pricing remains a political decision rather than one determined by the market forces of supply and demand. Interestingly, though, the government recently admitted in the Parliament that price increases in drugs were necessary to curtail black marketing and shortages![26]

Post-2012, with DRAP's founding, there was a welcome movement away from the destructive 'price freeze' policy. For pricing, drugs are divided into two categories- Drugs in the National Essential Medicine (NEM) list, and all other drugs. Since DRAPs founding, there have been two pricing policies (2015 and 2018), the latter coming to fore after Supreme Court's intervention. There has been a gradual movement away from complete control over pricing towards one based upon Consumer Price Index (CPI) and Reference pricing, mechanism that is more agreeable to the industry. However, the

[25] Detailed discussion of this aspect is provided in the section titled 'Are consumers betters off'?

[26] 'Minister explains why prices of medicines increased'

government has often, especially post-2015 policy, failed to live up to the agreed-upon pricing formulae, which led to lengthy litigation by the companies. The result, after litigation reached Supreme Court, was the 2018 pricing regulation that is in practice now.

Despite a relatively liberal regime in terms of drug pricing, price increases are still largely a political decision, needing Cabinet's nod. This, maintain the industry representatives and experts, is counterintuitive keeping in context the negative outcomes and especially as government (both federal and provincial) move towards providing health insurance, which also covers drug expenses. 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.

**Contract Manufacturing**—'Contract' or 'Toll' manufacturing is a substantial industry in the pharmaceutical business. Large pharmaceutical MNCs outsource drug manufacturing to developing nations. While contract pharmaceutical manufacturing is an $11 billion industry in India, in Pakistan is not even $5 million! There are thirteen basic steps required to be a contract manufacturer including submitting details of production of each batch manufactured quarterly on Form-7 to the Registration Board. There is a fee for a simple registration, and separate fee for contract manufacturing exclusively for exports (Rs. 30,000). By law, DRAP allows it for two years but that is also contingent upon quarterly renewal, which may not be granted. This makes would-be investors shy as there is a lot of uncertainty created by the presence of such rules. Recently, through SRO No. 421(I) 2021, dated 4th June 2021, rules for contract manufacturing have been proposed to be amended to extending the contract manufacturing for thirty months, further extendable by another 24 months (part'd'). However, it remains to be seen whether it will be implemented or not?

**Manufacturing License**—For manufacturing license, nineteen major and minor steps are required to be met. For instance, after approval of the building unit and granting of manufacturing license, there's a requirement for filing Common Technical Dossier (CTD), a process which itself can take 1 to 1.5 years. As per the industry officials, the on-ground realities present a different picture. First, this whole process takes a very long time, anywhere between 4 to 5 years. The standard SOP in other countries where the pharma industry is thriving (like India or China) is that a drug inspector only visits after the plant starts producing drugs, which are then checked for quality. But over here, a want-to-be producer has to file everything (factory design, buy plot and then submit papers, get approval for building plan, etc.) and only then can he think about production.

Then there are other requirements that create issues. For example, firms are told to locate in designated industrial areas, plots for producing alternative medicines (Herbal, Ayurvedic, etc.) has to be 2 kanals at least (making it an expensive proposition), plus there are limits on vertical expansion of plants. The staff at DRAP and at provincial level lacks the knowhow of how modern pharmaceutical plants operate and their requirements. Most of what they have in terms of skills is in consonance with old rules and regulations that mainly go back to the 1976 Act.

Aside from the above two categories, a number of steps are required for exporting and importing medicines. To become a licensed importer of drugs, an individual/company must meet fourteen basic steps. Additionally, in all of these cases, a plethora of attestations from authorised officers of no less than Grade-17 are required.

**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-[27]

| 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, excise duty, local tax or any other levy on sale of the drug (whichever is applicable).

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

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

**Drug registration**—There has been considerable improvement on this front. Compared to the around 55,000 registered drugs in 2015, there are now 100,000 registered drugs[28], reflecting a faster pace of approval. There are, though, gaps still to be filled. An August 2019 list of requests for registering various medicines, constituting total requests of 21,867 products, showed that 10 percent dated back to 2014[29]. Similarly, a December 2019 provisional list contained the following numbers- A total of 20,263 applications for enlistment. The year and their percentages were as following- 2014 (955 or 5 percent); 2015 (213 or 1.11 percent); 2016 (396 or 2.06 percent); 2017 (1,538 or 8 percent); 2018 (6,922 or 36.13 percent) and 2019 (9,130 or 47.66 percent). 1,109 medicines undated, saying 'evidence of R&I receiving is required'.

More importantly, though, is the fact that not all drugs that are manufactured continue to be produced. A lot of drug production is discontinued as price increase requests are refused by the regulator. As per both industry and regulator, hardly half of the registered medicines are being produced at the moment.

**Winding up manufacturing unit/business**—This might come as a surprise to readers, but even if a manufacturer having a valid Drug Manufacturing License (DML) wants to wrap up his business for any reason, it has to first take permission from DRAP for doing so! DRAP, in return, can opt to reject its closure request, forcing the firm to continue. This, as anybody with even a minute understanding of business and commerce would tell, is highly counterintuitive and illogical. The opening or closure of businesses depend upon many factors, and are supposedly the sole prerogative of the proprietor. But in drug manufacturing, we find this principle turned upside down in the case of a manufacturing plant wanting to close down its drug manufacturing plant. For example, in the 232nd meeting of their Central Licensing Board (CLB), the request by M/s Abbot Laboratories Ltd., (Karachi) was rejected by the Board, raising seven objections/queries to closure, with one query asking why the plant was being closed despite enhanced capacity for drug production?[30]

## 2.7. R&D AND SUPPORTED INFRASTRUCTURE

As mentioned above, not a single DTL in Pakistan meets FDA level criterion despite the federal government extracting 1 percent of their gross sales from the pharmaceutical industry since 1976 for setting up research infrastructure and conducting research. To gauge the ineffectiveness and illogicality of this policy, it's worthwhile to point out that till 2001 the SOPs for using this money were not even approved.

[28] DRAP sources

[29] Statistics from DRAP website

[30] Minutes of the 232nd meeting of the Central Licensing Board (CLB, held on 29th July 2013), p. 15 and 16.

One outcome of failure to enhance R&D and set up quality infrastructure is that 95 percent of the Active Pharmaceutical Ingredients (APIs) are imported, with India and China being the primary sources. From time to time, DRAP does grant a license for manufacturing APIs to the domestic firm. For example, in its 276th meeting held on 3rd September 2020, the Central Licensing Board (CLB) approved the application of M/s Winbrains Research Laboratories (located in Industrial Estate Hattar, KP) to manufacture 45 APIs[31]. But such approvals are a more recent phenomenon, and account for hardly 5 percent of the industry's requirements. They are also basic APIs, with sophisticated, advanced drugs (like cancer) requiring high-quality APIs that have to be imported. Simply put, the research incentive (research support, protecting patent rights) and research infrastructure (high quality, internationally accredited labs) are not available in Pakistan.

So where did all the research money go? Why can't Pakistan manufacture its APIs through research? Why is there no research or effort to produce the APIs in Pakistan rather than being heavily reliant on imports? We find a probable answer in the botched case of manufacturing 'interferon' drug, an initiative gone awry[32]. A production facility was set up at Hattar Industrial Estate for research into stem cells and APIs. But the promised funds never materialised, despite repeated requests for provision of funds for research. The head of the initiative was made to appear repeatedly in front of the Federal Investigation Agency (FIA) on embezzlement charges, which later proved to be completely false. In between, the initiative fizzled out, only to be revived later after SCs intervention.

Another example is the failed attempt to manufacture APIs using 'ephidra sinica' plant, found in abundance in Baluchistan. This is extensively used in cough syrups and low blood pressure drugs during spinal anaesthesia. An attempt was made to set up a plant for its extraction, but eventually had to be shut down, partly due to regulatory barriers.

The above two reflect examples of why few APIs are being manufactured in Pakistan. We 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).

To top it off, as COVID-19 struck the world and the globe scurried for a vaccine, Pakistani's found out the grim reality that vaccines are not manufactured in Pakistan, and neither is there any research on them. This is despite the fact that billions of rupees are collected from the pharmaceutical industry every year in the name of research (CRF, discussed above).[33] Industry officials cite the lack of incentive to indulge in setting up costly R&D infrastructure in lieu of paying a hefty sum to the government for this very purpose, lack of implementing patent related regulations and continuous change in policies that induces considerable uncertainty.

[31]Minutes of the 276th meeting of the Central Licensing Board (CLB, held on 21st September 2020), p. 4.

[32]The episode is discussed in Pakistan's first 'Stem Cell Policy' (2020), p i and ii

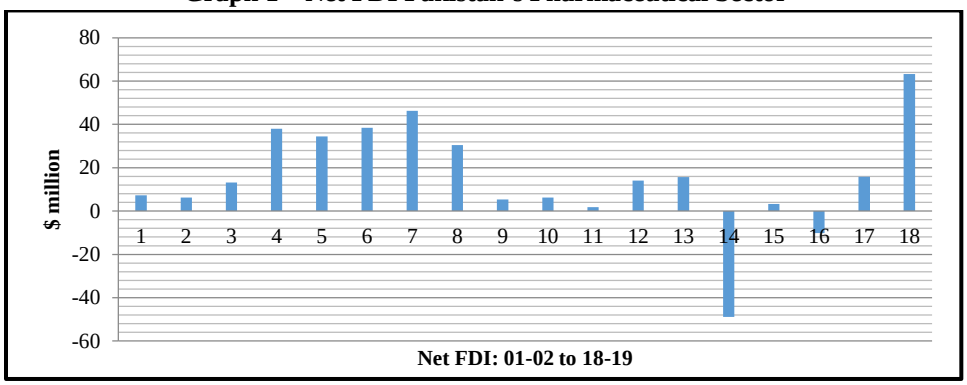
[33]'Economics of Vaccines'

## 2.8. ATTRACTING FDI THROUGH INCENTIVES

A major expected outcome of regulating a particular sector of the economy, either by design or default, is to make its working smooth, hindrance free (from monopolies, for example) so as to make it attractive for both domestic and foreign investors. For a country like Pakistan, FDI is of critical importance.

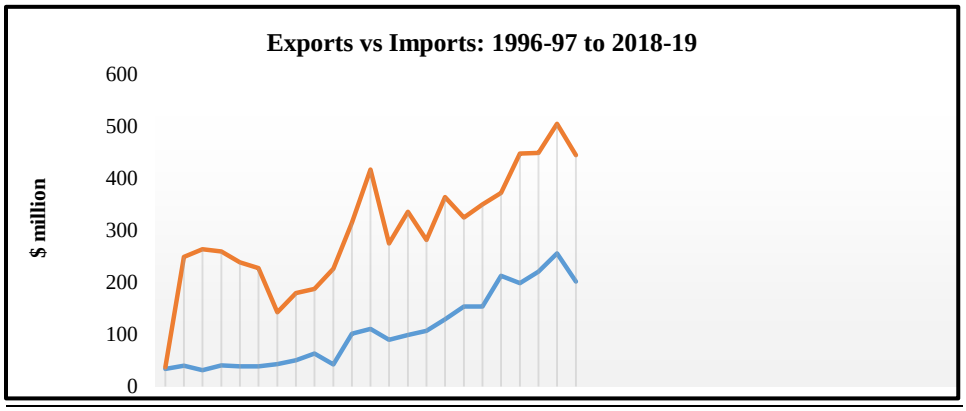
For an industry that was once termed a promising 'sunshine' industry (Mckinzey and Planning Commission, 2010), Net FDI is dismal. Average FDI per FY b/w 01-02 and 18-19 was $15.6 million, with some years experiencing a negative inflow (outflows greater than inflow). On net, only $280 million was received as FDI by the pharmaceutical sector in almost two decades. This is represented by the following graph:-

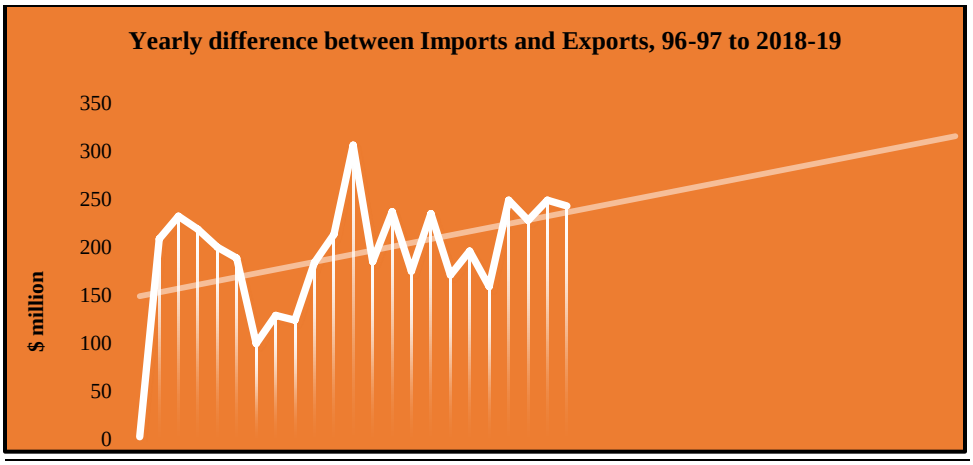
**Graph 1—Net FDI Pakistan's Pharmaceutical Sector**




One indicator of this sector being unattractive to foreign investors is reflected in the gradual exodus of Multi Nationals Corporations (MNCs) over time, with their presence being a major conduit of bringing in much needed foreign capital, technology and skill.

Imports and exports similarly present a subdued picture. At the onset of DRAP, it was estimated that if regulations can be made sound, the export potential could be worth $600 million in a couple of years (Hasan, 2012). However, as the following graphs demonstrate, exports have been much lower than the potential. The gap between imports and exports has widened considerably, with imports growing faster.






The reasons for this poor performance are many, ranging from the high cost of business and manufacturing to regulations. But there is little doubt that regulations have been a major concern. For example, as pointed above, the presence of state of the art Bioequivalence (BE) labs is must to ensure the quality of generic medicines, which then makes it easier for foreign buyers to accept the drugs. One of the main drivers in India and China's increasing pharmaceutical exports has been these labs (Hasan, 2012). In 2012, there were seven BE labs in Pakistan whose licenses were later not renewed by the DRAP. At the moment, there are only 2!

A persistently recurring issue with regards to attracting FDI has been the absence of steps to protect patent rights. This is despite the fact that Pakistan was a signee of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995. World over, it is the responsibility of the government and its concerned regulatory arm to protect these rights. In this regard, DRAP (and especially its predecessor, DCO) have been a failure. Generic copies of patented drugs, duplicate copies of the same drugs, mislabeled drugs, etc., that all defy patent protection laws, are a common recurrence in the domestic market. There is hardly any policy to address this shortcoming on the patent front.

## 2.9. ARE CONSUMERS BETTER OFF NOW?

Whenever states take up market regulation, one of the main reasons was to protect consumers from negative spillovers of imperfections in the market. For example, fixing due to collusion between energy firms can mean higher energy rates for the end consumer. In terms of regulating the pharmaceutical industry, some major considerations for regulating the industry come from ensuring quality drugs, consistent supply of life-saving drugs, affordability and access to medicines, etc. On all these counts, serious shortcomings are observed that need to be addressed. These shortcomings are discussed in the following lines:

**Out-of-Pocket (OOP) expenditures**—OOP expenses on drugs have been dubbed a drain on consumer's financial resources, especially the poorer segment that is hardest hit by OOP expenses on drugs. And the repercussions go far beyond adverse health in case of non-affordability. Datta, Hussain and Fatehin (2020) documented that

expenditures on drugs have a 'crowding out' effect on food consumption, with the effect being substantially stronger on poor households who already experience food insecurity.
A good proxy to identify the effectiveness of regulations in terms of the pharmaceutical industry is the expenses on drugs, something that is importance to the end consumer. The following table contains data on per capita expenses on drugs in Pakistan since 2003-04.[34]

| Year | Expenses on drugs as percentage of total health expenses | Per Capita expense on drugs |
|---|---|---|
| 2004 | 25 | |
| 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 |

As reflected in the table, and despite all regulatory efforts (like price freezes), the expenditure on medicines has refused to budge from its pre-DRAP rates. Especially noticeable is the rise in expenses on drugs between 2004 and 2010, when drug prices were not allowed to rise because the government wanted to make drugs affordable! It is also important to note that although the mean expenses on drugs at public facilities is lower, it should not hide the fact that many essential drugs are usually in short supply in these facilities, compelling customers to buy from private stores. Additionally, many observers of the health sector believe that the expenses are understated, primarily because the sample size used in NHA is small.

**Drug Shortages and black market in drugs** 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).

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[35] to accept the price demanded by the producer. But such refusals have had disastrous consequences, and continue to do so. Two recent 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

[34] Numbers are taken from National Health Account (NHA) surveys, and various Household Income Expenditure Survey (HIES). Note that the 2008 numbers were calculated based on deflating 2009-10 numbers to 2008 by 18.75 percent(explained on p.51 of the survey), which were then used in this table to calculate the given numbers. The per capita expense on drugs is calculated by multiplying the percentage spent on drugs by aggregate per capita expense on health

[35] 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

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 recently did the government agreed to revise the prices upward to Rs. 200 per pack. As a result, the shortage has been ameliorated to a large extent.

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. The same millions could have been saved if the government had the foresight to increase the price in 2017, which would have prevented the occurrence of this adverse event.

Something similar is now occurring in the case of **Pylocarpine** (generic brand name), used in treating dry mouth caused by radiotherapy in patients suffering from head and neck cancer, and Sjogren's syndrome (a condition affecting the immune system). Thus, the issue of persistent drug shortages continues unabated, which clearly is a loss for the consumer (and failure of the government and its regulator). Interestingly, the government recently admitted in the Parliament that price increases in drugs were necessary to curtail black marketing and shortages[36]. This was only after public complaints against shortage of certain drugs assumed a wide proportion. Yet, we still find governments reluctant to increase drug prices when asked by firms.

Drugs that become short in the market or are not available then become available in the black market. 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 medicines 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.

**Reactive rather than pro-active approach**—This aspect was discussed above in terms of regulations. But it is equally valid in ensuring availability of much-needed medicines, an aspect in which DRAP has proven ineffective. As COVID-19 struck the world and the globe scurried for a vaccine, Pakistani's found out the grim reality that vaccines are not manufactured in Pakistan, and neither is there any research on them. This is despite billions of rupees collected from the pharmaceutical industry every year in the name of research (CRF, discussed above)[37]. Any active regulator should have taken care of this even before this pandemic.

Another example comes in the form of domestic non-production of drugs that can cure *cutaneous leishmaniasis*, a dangerous skin disease that has persistently plagued Pakistan, especially its rural areas (MSF, 2018). Yet there has neither been any incentive nor any coordination with the industry from the regulator for producing this drug domestically. As a result, it's found in black at an exorbitant price, and even then its quality is questionable in many instances.

Before DRAP, a third of medicines were imported, as reported by many studies like Baber et al. (2011), this was when the exchange rate was Rs. 98 to a dollar. The situation is still the same in terms of the proportion of the medicines imported, but the exchange rate now hovers around Rs 150 per dollar, meaning that there's now a bigger drain on domestic consumer's resources. This failure has been a continuing trend since decades.

[36] 'Minister explains why prices of medicines increased'

[37] 'Economics of Vaccines'

**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. Hafeez etal. (2004) found that in public sector facilities, cooling equipment was working in only 60 percent facilities while temperature control was present in only 24 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[38] on safe dispensing practices in Pakistan came up with a startling revelation that approximately 95 percent of the pharmacies in Pakistan are run without a pharmacist, thus putting a large question mark around which drugs are dispensed.

## 2.10. THE AGGREGATE SUM

In 2001, a new National Health Policy (NHP) was launched with much fanfare. Among other things, it envisaged:

> *'improving the performance of the drug sector and to ensure the availability, affordability and quality of drugs. In realising these objectives, it has been planned to encourage drug manufacturers through maximum market competition, to manufacture imported drugs within the country, and to increase the investments in the pharmaceutical sector. The document also intends to strengthen the capacity of the Drug Control Organisation in market surveillance and quality control'.*

[38] '95 percent pharmacies in Pakistan are run without a pharmacist'

None of the above stated goals, however, were achieved! DRAPs founding as an autonomous body has not altered the state of affairs by much either. In 2017, Dr. Sania Nishtar, who now heads the country's Social Safety Net efforts and is one of the leading experts on the health sector, stated that there was no difference between DRAP and its predecessor.[39]

Given that the performance of DRAP as a regulator is under consideration, it's always a feasible idea to compare a regulator's performance with its predecessor. In Pakistan's case, we have the Drug Control Organisation (DCO) as the pre-DRAP authority, established in 1976 and working under the Ministry of Health (MOH), just like DRAP. The following table briefly analyses the issues and the situation existing pre and post-DRAP.

Table 1

*A comparison of Pre and post-DRAP policies*

| Category | DCO | DRAP |
|---|---|---|
| Autonomy | DCO was under the control of the now-defunct National Health Ministry. Typical bureaucratic manner of operations, with every aspect of operations needing approval from the federal government | Comparatively greater autonomy in its functions, but still largely under the federal government's control under the National Health Services, Regulations and Coordination Division (NHSRC). Major decisions are put up for approval to policy board, made up of federal secretaries and provincial representatives. |
| Quality of drug dispensing | Both at retail outlets and in health facilities, shortage of trained pharmacists and trained staff with adequate knowledge of drugs and dispensing has been a recurring problem for long. Policies were brought up (like National Good Pharmacy Practice Guidelines in 2011) but rarely implemented. | The void that existed formerly continues on even today. Ensuring quality dispensing remains a dream as significant voids still need to be filled with policy implementation. Despite efforts of both the federal and provincial regulators, the presence of qualified pharmacists and required equipment (like cooling arrangements) are still a major issue. |
| Infrastructure | Poor infrastructure, both in terms of R&D and provision of services that could not only provide good quality services to consumers but also support industry's efforts. Hardly three major DTL labs were operative in Pakistan, none qualifying either the WHO standard or the USFDA standard. There was no BE lab. | Comparatively better performance under DRAP, as now there are 12 DTLs across the country. However, only one of them is WHO certified, while none of them is USFDA certified. Only 2 BE labs at the moment. |
| Pricing of drugs | Mixed performance. Before 2001, room allowed for price increases, although by not a lot. But after 2001, 'price freeze' policy was implemented that continued till 2013, disallowing any increase in drug prices. | After DRAP's founding, there was a push to end the 'price freeze' policy given its adverse nature and outcomes. In 2015, there was a new pricing policy. However, the government refused to honor its commitment several times as per the policy, leading the pharmaceutical companies to litigate. After SCs intervention, there was another policy in 2018. But issues in pricing persist, as drug pricing is still primarily a political issue (requiring Cabinet's nod) rather than one decided by supply and demand. |
| Market Imperfections | Failure to resolve issues like significant price dispersions of a drug with the same molecules, mislabeled drugs and deceptive marketing techniques. The black market in drugs was operating since long, but the regulator could not do much about it. Various taxes and charges on the pharmaceutical company. | ➢ Market imperfections persist. Price dispersions, which can be termed as price differentiation, is quiet prevalent in the market<br>➢ Misleading advertising and misleading branding of medicines are still an issue<br>➢ 'Polypharmacy' practices, whereby a prescription made of a combination of four drugs is prescribed to patients, is prevalent, especially in major urban centres like Karachi and Lahore<br>➢ Collusion between drug companies and medical practitioners is still poorly understood and regulated<br>➢ Black market in drugs is still thriving<br>➢ Taxation and various charges are still an issue for the industry and the market |

[39] 'Pakistani drug regulatory body a complete failure'

Table 1—(*Continued*)

| | | |
|---|---|---|
| Transparency | Typical bureaucratic style. Little information available to the public regarding its operations and the logic underlying regulations. Public would usually learn through WHO or similar reports about its activities. | ➢ Comparatively higher level of transparency. The majority of the decisions, notifications and actions are present on DRAP website<br>➢ But some aspects still remain off-limits and DRAP officials are unwilling to share information about it with the public. For example, there is no information about utilisation figures of CRF money. Similarly, the logic behind short-term policy changes through SROs also non-transparent<br>➢ Recent allegations, backed by proof, of DRAP record being disposed off to hide certain aspects. This led to the removal of DRAP CEO |
| Research | Poor record in terms of research. Very little research on industry's problems, issues confronting smooth functioning of the market, and research into drugs. Only 3 DTLs that were of average quality that could not indulge in quality research. | ➢ No research reports or research effort aimed at addressing the critical, recurring issues<br>➢ Despite the addition of more departments compared to the previous regulator, there is no dedicated research wing in DRAP to analyse critical issues plaguing the pharmaceutical sector<br>➢ No attempt to engage academia in research work or build research linkages with relevant domestic and foreign academic institutions<br>➢ No effort at regular tracking of expenditures on drugs<br>➢ Refusal to give any information about where billions of rupees collected from the industry in the name of CRF was utilised? |
| Access to information | Limited access to information, except for the one given to organisations like WHO or produced in legislature. There was no proper website from where one could gauge the developments | Much better access to information, with a DRAP website now hosting majority of the DRAP-related information and decisions. Further,<br>➢ Information on every departments under DRAP and its decisions available<br>➢ Helped establish a quality control unit in Punjab (PDCU) that publishes updates and newsletters regarding its quality control initiatives<br>➢ Collaborations with external agencies regarding its upgrading and coordination<br>➢ Requirements regarding various issues, like licensing, OTC drug sales requirements, etc. can be found online<br>➢ Different tasks made relatively easier. For example, companies can now apply online for a drug license |
| Attracting Investment | No clear policy on regulating investment attraction through regulations that could make the pharmaceutical sector attractive for domestic and foreign buyers | Same as predecessor's policies. No indication that regulations have enhanced the scope and chances of FDI coming in.<br>➢ No worthwhile FDI; only $53.2 million in net since DRAPs formation<br>➢ No figure available on domestic investment<br>➢ No research on issues that hinder chances of domestic and FDI investment in this sector |
| Intellectual Property/Patent protection | No policy or regulatory measures to protect patented drugs and to prevent cheaper copies of such drugs from being sold in the market. The overall record was poor. This despite Pakistan being a signee of Trade-Related Aspects of Intellectual Property Rights (TRIPS) in1995 | Minimal (if any) regulatory mechanism or policy to take care of patented drugs and their IP rights. Generic brands of patented drugs are readily available in the market, while duplicate labeling is still an issue, as well as 'misbranded drugs'. No policy is in the offing to enforce TRIPS-like mechanism, which is extremely important for attracting investment. |
| Consumer welfare and Utility | Little information was available in terms of regulations/ steps that could increase consumer welfare. What we do know is that consumers found it hard in lieu of recurring drug shortages, increasing OOP expenses and facing low-quality services in terms of drug dispensing and quality healthcare in public plus private facilities. | Some steps, like more access to information and increase in the rate of testing drugs, aimed at enhancing quality and consumer protection. But vexing challenges like persistent shortages of medicines and drug quality still persist. OOP increased over time, and critical drugs suffering from shortage are often found in the black market at exorbitant prices |

In lieu of the above, it is sufficient to state that there is tremendous room for improvement as far as DRAPs performance is concerned. In post-Covid-19 world, the experience of the vagaries unleashed by the pandemic should alert policymakers to the reality that the required improvement needs to be achieved quickly. Otherwise, the state of affairs will remain the same.

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