



Ameliorating Drug¹ Shortages in Pakistan

Introduction

In mid-March 2022, a letter by Pakistan Young Pharmacist Association (PYPA) caught the headline of major newspapers in Pakistan². The letter, written in the context of the prevalent shortage of paracetamol, more or less alleged that the drug manufacturing companies were deliberately causing the shortages. They argued that drug manufacturers wanted to compel customers to buy a higher dose of the said drug (665 mg) since it had a significantly higher price than lower doses³.

The letter again brings to light the critical (but lesser discussed) issue of persistent drug shortages in Pakistan. Every year, critically needed drugs tend to vanish off the shelves, to be either found in black or imported to meet shortages (the below table contains a few sample cases of shortages since two decades). Mehmood (2017)⁴, after a survey of the major drug markets in Rawalpindi and Islamabad, found that 48 registered drugs were unavailable (drug manufacturers had stopped producing them), while 67 registered brands were experiencing shortages of varying degrees. Drug shortages, however, are not a recent phenomenon; in fact, it goes back to the time of the creation of the country. On 30th March 1954, during the Constituent Assembly session, Mr. Abdul Monem Khan pointed to the severe shortages of medicines 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 off medicines was common⁵.

Sample list of drugs THAT EXPERIENCED SHORTAGES

Year	Drug Name	Used for	Regulated Price (Rs.)	Black Market Price (Rs.)
2001	Dalintin	Epilepsy	55 per 100 tablets	500 per 100 tablets
2003	Buscopan	Stomach & Kidney pain	75 per pack	150 per pack
2012	Panadol C.F	Fever and Pain	Rs. 18 per 10 tab's	Rs. 50 per 10 tab's
2013	Typehrix	Typhoid Vaccine	Rs. 400 per injection	Rs. 1,000 per injection
2018	Ritalin	Attention Disorders	Rs. 286 per pack	Rs. 500-700 per pack
2022	Panadol	Fever and Pain	Rs. 1.70 per tablet	Rs. 5 per tablet

The difference is that in 1954, there was hardly any pharmaceutical plant in the country. In 1976, there were less than 100. Now, there are around 750! But shortages persist. What, then, causes these persistent shortages? The following lines briefly present the leading causes and proposes solutions to lessen future shortages.

The role of regulations

Government-mandated regulations is the most significant contributor to the shortages. Readers would need to understand the pharmaceutical industry dynamics to understand the issue. In the context of shortages, two aspects are highly critical - drug pricing policy and that 95 percent of the raw material for manufacturing medicines is imported. First, as 95 percent of the raw material for manufacturing medicines is imported, this puts the industry in a precarious position given global supply disruptions (as in Covid-19) and higher cost of imports (duties, tariffs, rupee depreciation, etc.)

1. 'Drug' is the allopathic name for medicine, and is used here because only allopathic medicines are under consideration. 'Medicine' denotes a wider variety, including allopathic, homeo, and Ayurvedic, etc.

2. 'Pharmacists seek PM Imran's help as Paracetamol shortages gives headache'

3. 665 mg is priced at Rs. 5 per tablet, while lower dose 500 mg is priced at Rs. 1.70

4. 'Access to essential medicines: Findings of survey'

5 'The Dynamics of Health: Islamic Republic of Pakistan'

Presently, industry officials state that not a single Active Pharmaceutical Ingredient (API), out of the 1,200 or so used, is being manufactured in Pakistan (even in normal circumstances, domestic manufacture of APIs was never above 45, and quality-wise, they don't match foreign competitors)⁶. This implies that Pakistan is entirely dependent upon the import of APIs to manufacture drugs at this moment. Given the rupee's losses against the dollar, raw material is now quite expensive. Expensive raw material, in turn, means a higher cost of manufacturing the same product (along with a steep rise in energy prices, etc). Production becomes unfeasible unless the producer gets this cost covered (government pricing policy fixes profit margins).

Historically speaking, the Government of Pakistan (GOP) 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 shortages⁷. That is exactly what we saw in the recent case of a countrywide shortage of Panadol.

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 has asked the GOP to increase the price, met by persistent refusal. As production became financially unfeasible, firms stopped producing products containing the ingredient paracetamol (like Panadol). Only now, as shortages became debilitating amidst consumers' misery, did the official regulator, the Drug Regulatory Authority of Pakistan (DRAP) propose increasing the prices. The proposal, however, remains at the Cabinet table. Meanwhile, consumers have lost millions of rupees in paying for imported paracetamol products⁸ or ones found on the black market.

Government Regulations and the Endemic of Hepatitis-C

Hepatitis-C is a serious threat to health world-over. In Pakistan, an estimated 10 million people were suffering from this disease in 2016, of which 80,000 were expected to die. Yet the government regulations made a mess out of the issue of availability of its treatment drug 'Sovaldi' and its local (cheaper) variants. 'Sovaldi' is considered a miracle drug for curing Hepatitis-C, and had been in market since 2013. But for unexplained reasons, government kept refusing to allow its import. Only in 2016, after Supreme Court took notice of the non-availability of drugs and deaths related to Hepatitis-C, did the government allow its import from the US – allowing only a temporary solution to the grave problem.

It's an expensive medicine. In 2016, it cost Rs. 32,000 per 28 tablets in Pakistan. A cheaper alternative was its proposed manufacture in Pakistan, under the generic name 'Sofosbuvir', costing around Rs. 10,000 per 28 tablets. Since 2014, 14 applications were approved by the regulator (DRAP) out of 61 received for manufacturing this drug locally. In February 2016, only 9 companies were allowed to sell generic brand of Sovaldi in Pakistan. Between 2013 and 2017 (when the domestic manufacturers started manufacturing the drug), however, consumers had to pay billions of rupees extra for imported Sovaldi, mostly found in black at exorbitant rates.

How does the industry respond?

As the recent Panadol shortages became rampant, around 27 thousand boxes containing Panadol tablets were confiscated from Peshawar in one specific instance. As expected, the media blamed the 'drug mafia', inadvertently accusing the pharmaceutical manufacturers, dealers, and sellers of conspiring to cause the shortages. However, this accusation has little substance, often repeated whenever drug shortages occur. As discussed above, pricing and supply-related issues were the foremost reason for these shortages!

6. Discussions with industry officials

7. See box on Hepatitis-C. Taken from 'Access to essential medicines: Findings of survey', PRIME Institute

8. There are online retail shops like MEDICALMARTPK.COM that offer imported Panadol and other such variants, aside from plethora of other imported drugs whose generic variants are manufactured by domestic producers

Regarding the confiscation of Panadol boxes from storage, one big retailer usually mops up the remaining supplies of a drug that suffers shortages and then sells it back at exorbitant prices⁹. Stopping this practice, by law, is the job of provincial governments¹⁰.

Over time, drug manufacturers have responded differently to the issues persistently faced in pricing regulation. One particular strategy is to move to manufacture higher potency doses. The movement towards 665 mg dosages of Panadol, whose price is much higher than 500 mg dose, is a reflection of this strategy. Similarly, another strategy is to stop production of a certain drug, apply for its production under a new generic name, and under a different category (like 'Neutraceuticals', whose prices are less regulated) and at a higher price. Put simply, higher prices of drugs help maintain the profit margin (fixed by pricing policy) and the production costs, making production financially feasible.

Yet another strategy (usually used by lower quality drug manufacturers) is to sell in-demand raw material at black market rates or smuggle it. In March, Anti-Narcotics Force (ANF) caught 1,086 liters of Ketamine (API used in psychotropic drugs) worth Rs. 34 billion that was to be smuggled to the UAE.

CONCLUSIONS

The availability, and affordability of drugs affects our health and lives. Quality and effective medicines have a significant role in ensuring a healthy workforce. Georgieva (2019) estimated 1.5 percent% per annum growth in GDP due to a healthy workforce. Poor health, in contrast, reduces global GDP growth by 15 percent per year (Remes, Dewhurst and Woetzel, 2020).

In Pakistan, unfortunately, the population carries a heavy disease burden¹¹. To make matters worse, many critically needed drugs suffer from persistent shortages, primarily driven by government regulations, especially its pricing policy¹²! There are other factors, which again illustrate gaps in regulations and implementation.

One drug suffering persistent shortage since its introduction in 2001 is Ritalin. An invaluable drug in terms of Attention Disorders (like ADHD), it contains a 'controlled' substance (Methylphenidate), which can have the same effects as opium. There is enough evidence to indicate that due to loose controls on sales, large quantity of Ritalin is consumed by those who don't need it in the first place. A 2019 survey found that the drug was being used extensively by students in Pakistan's medical colleges¹³.

In conclusion, given ground realities, drug shortages will likely be a presence in the future.

Policy suggestions:

The following suggestions are aimed at ameliorating the persistent shortages of drugs-

- a)The GOP should leave drug pricing to the market. It has done enough damage to the industry and consumers. At best, its role in terms of pricing should be that of coordinator of prices. For example, prices should be allowed to move in accordance with input prices, and price adjustments should be immediate rather than late
- b)The federal cabinet should have absolutely no role to play in fixing drug prices because pricing then becomes a political decision, biased toward lowering or maintaining prices
- c)The main job of the federal and provincial drug regulators should be the maintenance of quality, subsidize R&D, and tracking of sales, especially of those substances that fall under the 'controlled' category, so that there is no misuse.

9. Shared with the author by industry officials, retailers and hospital officials. The large retailer gets advanced information on coming shortages, and starts buying all the supply from stores within a city

10. As per DRAP Act 2012, Coordinating and supervising sales of drugs is provincial government's domain

11. For e.g., see 'WHO country cooperation strategic agenda (2011-2017)'; WHO

12. For a detailed discussion on drug pricing and its outcomes, see PIDE evaluation 'Regulating the pharmaceutical industry: An analysis of DRAP'

13. Prevalence of Methylphenidate misuse in medical colleges in Pakistan: A cross-sectional study'

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