PIDE

COVID-19 BULLETIN

No. 8

Time to Get the Pharmaceutical Industry Policies Right

While the outbreak of the Coronavirus has brought to fore what was already well-known, i.e. a dilapidated health infrastructure, a particularly important aspect of the debate remains lesser discussed— Pakistan's pharmaceutical industry. Given the lack of masks, ventilators, medicines, and personal protective equipment (PPE) in the current crisis, the deficiencies in the industry are becoming visible. By now, desperate circumstances have produced some measure of response, with a domestic start-up (Ventilate) claiming to produce low-cost ventilators, and another group (PAC-V) using 3D printing to print necessary medical and safety equipment.

But all this should invite an even more important question: why did all this happen in the presence of an industry that has over 700 listed firms?

Magnitude of Pharmaceutical Industry in Pakistan

Pakistan has an estimated population of 220 million, which is projected to cross 300 million by 2050. Its population carries a high Burden of Disease (BoD), affected by hepatitis, tuberculosis, dengue, malaria, polio, and several water-borne diseases. Such a large population with a substantial disease burden should be a gold mine for pharmaceutical firms, especially the large Multinational Companies (MNCs). In the year 2000, there were around 40 pharmaceutical MNCs operating in Pakistan. Now, there are only a few. Even these have invested away from manufacturing medicines to consumer products (like childcare products). Same is true of leading domestic brands.

Despite the presence of all these firms, medicine shortages are common, many of them being lifesaving. Out of the approximately 70,000 registered drugs, Pakistan's pharmaceutical industry produces hardly 10,000[1]. It should, therefore, not come as a surprise if a certain drug is found to be effective against Coronavirus, and it is found to be short in Pakistan. Despite the 700 firms and its infrastructure, why do we still have to wait for supplies from China and other countries?

Counter-intuitive Policies

A large part of the explanation resides with the lack of 'price incentive'. In a market economy, prices act as signals to producers, and resources are allocated accordingly. Now consider the fact that from the year 2000 to 2013, prices of medicines were not allowed to increase under a 'price freeze' policy. Meanwhile, during this time, the cost of production increased multiple times.

Misguided by the notion that prize freezes would be beneficial for the people, especially the poor, this policy ended up driving out the leading MNCs and have resulted in persistent medicine shortages over the years. Even the leading domestic manufacturers have discontinued producing critically required medicines. Although domestic manufacturers have replaced the MNCs, the latter offered more than just drug manufacturing: larger investment base, relative ease in technology transfer from its parent country, quality and extensive capacity upgrades.

[1] They are registered with the federal Drug Regulatory Authority of Pakistan (DRAP).

The regressive nature of the price freeze policy can be gauged by the fact that it redistributed a substantial portion of profits away from the manufacturers to other parties. For example, importers of drugs made merry, taking advantage of persistent medicine shortages over the years to import and sell drugs at considerably higher prices. Thus, a policy that was supposed to help the poor ended up being a major source of misery for them and the industry, eroding its productive base[2]. Understandably, firms will not produce those drugs having sales that cannot cover their cost of production. In 2017, out of the 100 anti-cancer drugs being manufactured globally, none was being manufactured in Pakistan, and 60 out of that 100 were not available in the country. Similarly, requests for registration of anti-cancer drugs remain unapproved since 2009. It is believed that the drug price freeze policy causes a yearly loss of 112 billion rupees.

Some other policies also defy logic. For example, 95 percent of the raw material for industrial production is imported, mainly from India and China. Last year, without consulting pharmaceutical industry, a complete ban was put on imports from India in the wake of the Pulwama incidence, which was then hurriedly relaxed when a severe shortage of critical medicine took place. At the provincial level, despite overall signs of improvement, some policies make it difficult to support the industry. For example, Punjab's deregulation policy implies that suppliers must negotiate separately with every district's health department in terms of supplying drugs, resulting in drug shortages.

There have been some initiatives taken in the last few years to get the policy on track. For example, reference pricing is now used instead of cost-plus pricing, and provinces have the authority to have their own rules for buying medicines.

Lack of Research and Innovation in the Industry

Pakistan's pharmaceutical industry basically manufactures 'generic' drugs, with none being 'originator' brands[3]. It is not as if pharmaceutical firms in Pakistan are ill-equipped to do their own research. In fact, top 50 firms possess a very good infrastructure to compete with global brands[4].

Several government policies militate against such R&D activities. Research into a New Chemical Entity (NCE), i.e., full cost of a single new drug development, can range anywhere between US$350 million to US$1,395 million, depending upon the type of drug being developed and its intended coverage. But a market pricing mechanism, or a negotiated price (with government) plus a patent for a certain time helps developers recoup the cost. This kind of mechanism, of course, is completely absent in Pakistan. There is an emphasis on publicly administered pricing, with absolutely no patent protection mechanism. Unlike a machine for example, the formula of a drug is written on the back of the pack containing the drug, thus, can be easily copied by others. For a firm that intends to invest such a large amount in R&D, absence of patents and property rights is a huge disincentive.

Another reason, which sounds quite odd, is that the federal government took it upon themselves to do R&D. The Drug Act of 1976 obligated all pharma companies to deposit one percent of their gross revenues to the government for the purpose of R&D and building complementary infrastructure. Since 1976, billions of rupees have been collected under this head, with not a single FDA or WHO approved laboratory in Pakistan. Government officials acknowledge that billions of rupees were collected under this head but remain tightlipped about its utilization[5]. Pharmaceutical manufacturers state that since the government has taken upon itself to conduct R&D on the money they are paying, the industry has no reason to do it.

---

[2] Pharmaceutical Industry Report, PRIME Institute.
[3] Generic' brands are basically local copies of drugs, while 'originator' drugs, as the name suggest, constitute the original drug produced by primary producer.
[4] Op. cit.
[5] Op. cit.

Similarly, some other policies are not conducive to the aim of technological infusion for production purposes. For example, the import of 3D printers is banned in Pakistan, while 3D printers are being increasingly utilized by the pharmaceutical giants to improve drug quality and shorten drug trial duration.

Little Capacity to Enforce Regulation

Even if government were to come up with the right set of policies, a formidable challenge will remain on the implementation side since the enforcers in the form of drug inspectors are few (49 federal drug inspectors in total, with provinces having their own), and there are substantial question marks over their quality and ethical standards. The result of these shortcomings is that practices like selling medicines with fake labels, unregistered medical stores and substandard medicines are common in Pakistan, endangering the lives of the consumers.

What Needs to Be Done

COVID-19 pandemic only serves to remind us of the urgent need for course correction in terms of finding solutions to pharmaceutical industry's problems. The following are a few suggestions in this regard:

a) Recognize the price motive/commercial basis of the industry and refrain from administering prices as per populist wishes.
b) Focus efforts upon expanding the capacity to properly administer laws and regulations at both federal and provincial levels. Revisit regulations that act as disincentives, and concentrate upon improving quality, availability and coverage of drug inspectors.
c) Sensitize the media about why prices are essential to the survival of the industry, quality and availability of medicines and in bringing investment to Pakistan.
d) The pharmaceutical industry, the Pharmaceutical Bureau (PB) and the Pakistan Pharmaceutical Manufacturers Association (PPMA), must point out those manufacturers among them who indulge in unethical practices (smuggling, hoarding, manufacturing sub-standard medicines or mislabeling drugs) to the authorities in order to ensure quality.
e) Put an end to predatory practices, like extracting money equivalent to 1% of the gross sales from pharmaceutical firms in the name of R&D. Let the task of R&D be handled by the firms themselves, while policymakers simply ensure a fair competition between them which would improve pricing and quality.

The COVID-19 outbreak showed how fractured our whole pharmaceutical system is. It is about time we fix all its aspects, including policies, products, processes, resources and their interactions within the broader health system.

By:
Shahid Mehmood
PIDE.

PIDE COVID-19 Bulletin is an initiative by the Institute in response to the current pandemic, which is bound to have serious consequences for the country, specifically for its economy. The Bulletin would carry research that would aid in an informed policymaking to tackle the issue.