



Regulating Pharmaceutical Industry Post **COVID-19**

WEBINAR BRIEF 42:2021



 www.pide.org.pk

**Pakistan Institute of
Development Economics**

 PIDEIslamabad

 PIDEpk

 PIDE Official

 pide.org.pk





PAKISTAN INSTITUTE
OF DEVELOPMENT
ECONOMICS

REGULATING PHARMACEUTICAL INDUSTRY POST COVID-19

12 April 2021

START 3PM PST

LIVE ON ZOOM, YOUTUBE & FACEBOOK

MODERATOR

NADEEM UL HAQUE
VC, PIDE

THE SPEAKERS



TAUQEER UL HAQ
PRESIDENT, PPMA



OSMAN K. WAHEED
PRESIDENT, FEROZSONS
LABORATORIES LIMITED



Ayesha T. Haq
PRESIDENT,
PHARMA BUREAU



ABOUT WEBINAR

One of the most noticeable aspect of domestic policy related issues in a post-COVID 19 world is the lack of any COVID vaccine being manufactured in Pakistan! At the same time, across our eastern and northern borders, both China and India are rolling out millions of doses of vaccine that are also being used for 'vaccine diplomacy', with Pakistan being one of the recipient under this diplomatic push.

Lack of a local vaccine (not a single vaccine is manufactured in Pakistan) is not the only issue that needs elaboration; in fact, over time, Pakistan's pharmaceutical sector has found it difficult to perform to its potential under plethora of government regulations. Will Covid-19 finally lead to a rethink of how this industry has been regulated, or are we going to see the same status quo prevail?



PIDE Islamabad



PIDEpk



PIDEpk



PIDE Official



PIDE Islamabad

Preamble

Pakistan came into being in 1947; at that time, there was no pharmaceutical operating industry in the country. Now, Pakistan has almost 700 vibrant and forward-looking operating units of pharmaceuticals, including 24 multinationals (MNCs) companies. Around 70% finished the Pakistan pharmaceutical industry fulfills the medicine demand of the country. The share of the market is divided between national and international Pharmaceutical companies. From the previous decade, progressive growth has been shown by the pharmaceutical industry. The company can currently fabricate a variety of drugs oscillating from simple prescriptions to sophisticated oncology, biotech, and value-added generic compounds.

One of the most noticeable aspects of domestic policy-related issues in a post-COVID 19 world is the lack of any COVID vaccine manufactured in Pakistan! At the same time, across our eastern and northern borders, both China and India are rolling out millions of doses of vaccines that are also being used for 'vaccine diplomacy,' with Pakistan being one of the recipients under this diplomatic push. The lack of a local vaccine (not a single vaccine is manufactured in Pakistan) is not the only issue that needs elaboration; over time, Pakistan's pharmaceutical sector has found it difficult to perform to its potential under the plethora of government regulations.

Core Questions

This webinar enlightens us to realize

- What are the major mistakes made in the last decades of adjustment programs in Pharmaceutical industries policy and implementation by the government and policymakers?
- Is the Pakistan pharmaceutical industry ready to take on the challenges of the world?
- Have we done any R&D at all in Pakistan?
- Will Covid-19 finally lead to a rethink of how this industry has been regulated, or are we going to see the same status quo prevail? Would it be a status quo / what post-COVID-19 realities set us for on a new course?
- Is the industry the regulator can reconcile their differences?
- Why has Pakistan not produced generic drugs?
- Are we exporting generic drugs? Why don't we have the vaccine?
- Is DRAP capable of regulating the industry for growth?
- What kind of issues does the regulator cause in the pharmaceutical industry?
- Can regulations be tailored in a manner that the industry finds easy to work to its maximum potential?

Introduction of Pakistan Pharmaceutical Industry by Shahid Mehmood

- Today, pharmaceutical companies cannot produce the vaccine in this pandemic, and no one is ready to invest.
- Pakistan has almost 700 pharmaceutical firms, and their estimated size is about 3.1 billion. In the global context, it is not even 0.3% of the global volume
- The top 100 firms in Pakistan have 95 of the market share in sales
- Out of the total sales, 80% of products are manufactured in Pakistan while 20% imported
- 95 percent of the raw material and active pharmaceutical ingredients for manufacturing are imported basically from China and India
- Market share stands at 40:60 in favor of domestic firms, who are producer of generic brands
- The industry employs 150,000 individuals directly and 300,000 people indirectly
- In the last two decades from 1996 to 2018-19, the average of exports per year has been 103 million dollars but the average of imports has been 300 million dollars. Over time, the difference between imports and exports have widened.

Speaker's Viewpoint

Osman K. Waheed

- There is no issue of talent and ability to invest or willingness to invest, but certain fundamentals would like to bring notice about the unique place of Pakistan in the health care world.
- There will be no market to support vaccine investment.
- Pakistan has no public sector for the flu vaccination program.
- Everybody in Pakistan is left to vaccinate themselves, and despite the flag, the fact that flu is a deadly disease.
- Everybody should be vaccinated on an annual basis.
- The number of people who get vaccinated for the flu annually is not more than 200 to 250,000.
- Pakistan is the only country to leave its citizens to the private sector to the vaccine. There has been no large-scale public procurement of vaccines.
- As a result, we have the lowest vaccination rate in the entire region, fortunately, or unfortunately in the entire world. Even in the wealthiest countries on the planet people don't vaccinate themselves at their own cost; the government vaccinates them.

Tauqeer ul Haq

- All national companies are manufacturing generic products, but the main issue is the inconsistent policies of the DRAP and the government.
- Panelists suggested that the pharmaceutical industry needs a very consistent policy from the DRAP and the government.
- Industry tied up for its survival because there was no price increase from 2001 to 2013, and it was considered the pharmaceutical industry is working on a planet where there is no inflation. The cost of doing business is not increasing.
- This unnatural price mechanism led to a shortage of many medicines, especially life-saving medicines.
- The pharmaceutical industry has finally been able to get a pricing policy in 2018 finally.
- If the CEO of DRAP and the directors are not permanent and after every three months, directors become non-functional, and it takes a month to get them restored. DRAP has not enough human resources to regulate the industry. Government should also make separate departments for the quality and price handling.

Ayesha T. Haq

- Why don't we have the vaccine? Because these are all biological products and we have no policy here regarding biological products, there is no infrastructure here.
- Now the industry is growing and going for vaccines and bringing new molecules, and doing research.
- We should have very consistent policy incentivized schemes, and the policies are for a stable industry.
- There is not a problem with the investment if the opportunity and the regulations are there.
- India set up the pharmaceutical industry as a small enterprise, and people were doing biological stuff in bathtubs, and they were experimenting in their flats.
- Without DRAP approval, no one can manufacture anything in the country.
- We import almost 60% of the anti-rabies vaccine, snakebite vaccine from India.
- India invests a huge amount in research, but no one is willing to invest in research in Pakistan.

Key Messages

- NIH was established in the 1960s, and it has a vaccine production facility, and Pakistan would be the hub from this entire region, but NIH is not certified. It does not have any international accreditation, which means that its processes are not in place.

- Last year 6 billion rupees were given to central research, and no one knows where that money is and what is happening with that money.
- We have no competition in the highly regulated industry.
- Most of the life-saving drugs are short in the market.
- We should deregulate and let the market forces decide about the prices.
- The lifeline of the pharmaceutical industry is the new treatment and new products.
- The new treatment is essential for the pharmaceutical industry and the patients.
- All national companies are manufacturing generic products, but the main issue is the inconsistent policies of the DRAP and the government.
- Assuring quality control and GMPs, especially at lower-tier pharma manufacturers.
- Absence of a long-term, and consistent plan.
- Expensive and time-consuming legal litigation and no alternative forum in Pakistan.
- The availability of medicines at public hospitals is low.
- Pharmacists are non-seriousness about the industry at the decision-making level.
- It is a failure to recognize that adverse regulations are hampering FDI prospects in Pakistan.
- Drug shortages are a regular feature. Many essential, life-saving medicines are in short supply for over a year.
- The combat COVID-19, various varieties of vaccines have propped up all over the globe. In Pakistan's east and north, India and China produce their domestic and international/foreign vaccines under license.
- In Pakistan, no domestically produced COVID-19 vaccine.
- Not just the COVID vaccine, but Pakistan does not produce any vaccine.
- For a country with a heavy disease burden, this state of affairs should bother policymakers, except that it does not.

Suggestions

- The public has relatively very little or low information about the pharmaceutical industry's operations and activities. The Pharma industry should publish annual, bi-annual, or quarterly reports. Overall, a negative image in the media and public courtesy of price increase reported in media headlines. In headlines, price decrease is rarely mentioned. The Pharma industry should give the impression that it's the industry responsible for all the ills like drug shortages.
- Overall, the industry's engagement with the media needs to increase.
- The lack of a self-accountability mechanism should be improved.

Way Forward

- Pakistan needs to deregulate this industry to control pricing, and DRAP should control the prices of medicines.
- The first step to bringing this industry towards growth is depending on the engagement of qualified people for the regulation of the industry.
- The government of Pakistan encourages the industry to compete and let there be free-market pricing and control quality.
- Furthermore, If DRAP decides on price fixation, registration, and giving license on time, the industry will flourish and start its manufacturing.
- The pharmaceutical industry needs very serious scientific research and people for policymaking. Panelists suggested that the pharmaceutical industry needs a very consistent policy from the DRAP.



Prepared by
Amila Rafique
MPhil Scholar, PIDE

Edited by
Hafsa Hina

Design by
Afzal Balti

🌐 www.pide.org.pk
✉ policy@pide.org.pk
☎ 92-51-924 8051
📠 92-51-942 8065

 PIDEIslamabad

 PIDEpk

 PIDE Official

 pide.org.pk

Pakistan Institute of Development Economics