



A study on challenges and avenues of pharmaceutical industry in Himachal Pradesh

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Abstract

The pharmaceutical industry in Himachal Pradesh has witnessed a growth at a breakneck speed over the last two decades. This industry is slowly, but surely, becoming paramount to the economy of the state. The economy of the state was heavily dependent on tourism and horticulture in the past. There is an increase in unemployment-like many Indian states- and limited employment opportunities in the state have forced the government to frame attractive industrial policy over the years. These issues also prompted state government to invest in building conducive ecosystem for the industries. This has resulted in an increase of pharmaceutical industries in the state-especially at Baadi, Solan. This study aims to find the challenges and avenue available to the pharmaceutical industries in Himachal Pradesh. It was found in the during this study that there are several avenues that can lead to a healthy growth of pharmaceutical industries in the state, but also there are several barriers that can provide headwind to these growth avenues in the coming years.

Keywords: pharmaceutical industry, tourism and horticulture

Introduction

The Pharmaceutical industry in India has witnessed an impressive growth in the few decades. This growth has been driven mainly by rising consumption levels in the country, sedentary life style, bad eating habits, infrastructure development, buoyant domestic demand for generic drugs, and post covid response by the government. India is ranked at the top among the vaccine manufacturer globally. India is also among the largest producers of Generic drugs, Active Pharmaceutical Ingredients and Drug Intermediates worldwide. To develop pharmaceutical industry into a more competitive in biosimilar drugs market, well-defined and proactive regulations are needed in India. An increase in investment is also required in R&D of innovative drugs. These type of progressive reforms in this industry will lower the cost of production for biosimilar drugs and increased

expenditure on R&D will enhance the efficiency and innovative capabilities of Pharmaceutical companies in the country. Consequently, the exports of pharmaceutical will also become more competitive. The Pharmaceutical industry in India, as a whole has made a remarkable progress. A notable improvement is reflected in infrastructure, innovation and ambit of drugs produced. The ability to produce cost effective drugs by the Indian pharmaceutical companies has led to a steadily growth of demand from the exports market around the world.

Market Size

We can determine the size of the Indian pharmaceutical industry both in term of volume and value. Some of the important data on Indian Pharmaceutical Industry is as under:-

Table 1

The size and scale of the Indian Pharmaceuticals Industry in the world	
Size in terms of volume	3 rd
Size in terms of value	14 th
Scale of annual turnover in year 2019-20	Rs. 2,89,998 crore
Total pharmaceutical exports in year 2019-20	Rs. 1,46,260 crore
Total pharmaceutical import in year 2019-20	Rs. 42,943 crore

India is responsible for supply of over 60% of global vaccine demand, around 40% of US generic demand and also accounts every fourth drug supplied to United Kingdom.

The size of domestic market in India will expand manifold in the coming decades. The value of Indian pharmaceutical market was Rs. 3,44,400 Crores in 2021 and is likely to reach Rs. 5,33,000 crore by 2024. This value of is likely to

Due to the sheer size and scale of Indian market India is considered as an important and rising player in the global pharmaceuticals sector.

Latest policy interventions

COVID-19 pandemic prompted governments worldwide to elicited a wide range of responses in policies making to boost the existing healthcare system. In March 2020, Government of India announced establishment of 3 Bulk

Drug Parks. The Government of India aims to reduce reliance on import of Active pharmaceutical Ingredients and also accelerate the growth and development of domestic

pharmaceuticals industry. The key facts about this scheme is as under: -

Table 2

Scheme Type:-Central or State	Centre Sponsored
Financial Outlay for the Scheme	Rs.3000 crore
Bulk Drug Park proposed to be set up under the scheme	3
Maximum ceiling of Grant-in-Aid for each park	Rs.1000 crore
Implementation Period of the Scheme	2020-2025
Composition of Grant-in-Aid	70% of the project cost for the states/UT except; 90% of the Project Cost for the North Eastern and Hill States (i.e., Uttarakhand, Himachal Pradesh, UT of Ladakh and Jammu & Kashmir)

Another key post COVID-19 policy initiative of Government of India with an objective to reduce dependence on import of APIs from China and others countries, was launch of Production Linked Scheme (PLS) in July 2020. The aim of the scheme was to encourage domestic manufacturing of the following

1. Critical Active Pharmaceutical Ingredients (APIs);
2. Drug Intermediates (DIs) and;
3. Key Starting Materials (KSMs).

The Government of India under this scheme immediately approved funding to Active Pharma Sciences, Aurobindo

Pharma, Rajasthan Antibiotics, Solara Vital Laboratories Pvt. Ltd., etc.

In the year 2022, Ministry of Chemicals and Fertilizers, Government of India issued guidelines for the Scheme "Strengthening of Pharmaceutical Industry (SPI)". The financial provisions made under this scheme is Rs.500 crore for the period from Financial Year 2021-22 to 2025-26. The objective of this scheme is to strengthen the existing infrastructure facilities and make India a pioneer in this sector. There are three components under this scheme which are as under: -

Table 3

Component	Objective
Assistance to Pharmaceutical Industry for Common Facilities (APICF)	To strengthen the existing pharmaceutical clusters capabilities for its sustained growth by building common facilities
Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)	To clear the way for Micro, Small and Medium Pharma Enterprises (MSMEs) to meet national and international regulatory standards set by WHO and USFDA etc.
Pharmaceutical and Medical Devices Promotion and Development Scheme (PMDS)	To promote the growth and development of Pharmaceutical and Medical Devices Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry.

To scale up the Pharmaceutical Industry in India, Government of India in March 2022 also started Strengthening of Pharmaceutical Industry (SPI) Scheme. Under this scheme a financial provision of Rs.500 crore for

the period 2021-22 to 2025-26 was made. In the Union Budget 2022-23 the following measures have been announced to boost Pharmaceutical Industry: -

Table 4

Component for which Budget provision has been made	Amount in Crore
Research and development	Rs. 3,201
Ministry of Health and Family Welfare	Rs. 83,000
National Health Mission	Rs. 37,000
Pradhan Mantri Swasthya Suraksha Yojana	Rs. 10,000
Ministry of AYUSH	Rs. 3,050

Foreign direct investment (FDI) in pharmaceutical industry

The FDI inflows in the pharmaceuticals industry was valued at Rs.1,64,725 crore for the period April 2000 to June 2022. The pharmaceutical exports were valued at Rs.2,01,983 in Financial Year 2021 and at Rs.2,03,638 in Financial Year 2022. From 2017 to 2021 under the brownfield pharmaceutical projects the Government of India has approved 17 proposals with proposed Foreign Direct Investment of Rs. 1,512 crore. This shows that the Pharmaceutical Industry in India is preferred sectors among the foreign investors. The Government of India has allowed 100% foreign investment in Medical Devices Sectors

(automatic route); in greenfield pharmaceutical projects foreign investment up to 100% is also allowed (automatic route). In the brownfield pharmaceutical projects foreign investment over 74% up to 100% requires prior approval of Government of India.

Profile of pharmaceutical industry in Himachal Pradesh

Himachal Pradesh has the presence of over 610 Pharma units in Himachal Pradesh. The major players like Ranbaxy, Abbott, Cipla, GSK, Pfizer, and Torrent have their presence in Baddi, Himachal Pradesh. The state has currently meeting 45 % of India's drug formulations demand, which is a considerable share for the size of such a small state like Himachal.

Table 5

Data on Pharmaceutical industry in Himachal Pradesh	
Annual Turnover	Rs. 40,000 Crore
Total Pharmaceutical Export from the state	Rs 10,000 Crore
Annual raw material requirement	Rs 30,000 Crore
Share of Pharma products in total export from the state	61%
Total annually value of pharma export from the state	Rs.9824 crore
The size of annual pharma export	4,52,22,125 KG

Literature Review

Rossetti *et al.* (2011) documented in his study the complications that supply chains in a Pharmaceutical Industry can face. Their analysis was hinged on interrogation and desk study that provided understanding of Pharmaceutical Industry and the obstacles that it confronts. Giuseppe Festa, Ashutosh Kolte, Maria Rosaria Carli, Matteou Rossi (2021). Their study reflected that future of the Indian pharmaceutical industry is bright at every level, in spite few challenges. A balance has to be achieved Nishith Desai (2022) concluded in his study that Indian pharmaceutical industry has grown over the years and is on right path to harness its full potential. Albeit Indian Pharmaceutical Industry faced various challenges such a price rise, sluggish demand disruption in supply chains due etc to COVID-19 in 2020. But at the same time COVID-19 also opened new avenues for Indian Pharmaceutical Industry. This 'imitation to innovation' driven research strategy is expected to transform Indian pharmaceutical industry to emerge as global hub for innovative medicines This 'imitation to innovation' driven research strategy is expected to transform Indian pharmaceutical industry to emerge as global hub for innovative medicines This 'imitation to innovation' driven research strategy is expected to transform Indian pharmaceutical industry to emerge as global hub for innovative medicines. Sindkhedkar, Milind & Jagtap, Sandeep & Shah, Chirag & Palle, Venkata. (2020) found in their study that 'imitation to innovation' driven research strategy is expected to transform Indian pharmaceutical industry to emerge as global hub for innovative medicines.

Objectives of the study

This study was done with objectives to examine the problems and prospects in the Pharmaceutical Industry in Himachal Pradesh.

1. The following would be the objectives of the study: -
2. An analyze the existing framework of pharmaceutical industries in Himachal Pradesh.
3. Examine the various challenges being faced by the pharmaceutical industries in Himachal Pradesh.
4. To explore the future prospects for promotion of pharmaceutical industries in Himachal Pradesh.

Regulatory Compliance

Pharma industry in India is heavily regulated and rightly so as this sector is directly related to life and safety of public. Still regulatory compliance poses a critical challenge for the pharmaceutical industry, particularly in emerging markets like India. The pharmaceutical industry in India faces compliance issues like government policies, drug safety regulation, information security and privacy, intellectual property protection, adulteration, and other third-party risks. The issue of delay in refund on Integrated Goods and

Services Tax (IGST) is one such challenge that pharma units in Himachal Pradesh are facing.

Infrastructural challenges

No rail connectivity and high cost of transportation compared to other neighbouring states like Punjab, Haryana from where the containers are sent to ports for export. Taking advantage is this Truck Unions act as a cartel and often charge exorbitant transportation cost, making products of pharma companies uncompetitive.

Credibility of drugs produced

The pharmaceutical companies in the Himachal Pradesh and often in the news for wrong reasons. Many incidents of either substandard quality of drugs or failure of samples collected from drug manufacture in Himachal Pradesh have been reported often.

Environmental Issues

The pharmaceutical companies in Himachal Pradesh are becoming a source of environmental pollution. The effluent release by these companies is heavily loaded with antibiotic residue and pollute the soil and water badly. The concentration of ciprofloxacin found more than 1500 times of the safe limit around these pharma companies in the state.

Post Covid response by various Government: -

The COVID-19 pandemic forced the Government to implement schemes to promote and boost API production. Government had to rely on API importation prior to this pandemic and this situation exposed the India to supply chain risk for the first time. In the post covid era various governments have changed their policy stance. States across the country are steadily bringing about health care reforms, attracting investment in pharma sector aggressively, transforming the health care sector from a volume-based to a value-based sector, significantly impacting the Indian pharmaceutical industry. The policies have become more protectionist and most Government are rolling red carpets and policy sops to attract investment in the pharmaceuticals industries. This has put Himachal Pradesh in a tricky situation. The withdrawal tax holiday in the state puts the pharma companies in catch 22 situation, tempting them to shift their base to other states.

Bulk Drug Park

The Government of Himachal Pradesh has made a bid for Bulk Drug Park under the Scheme for Promotion of Bulk Drug Parks of Government of accepted the bid of Himachal Pradesh and sanctioned the Bulk Drug Park proposed to be set up at Haroli, Una. This project will cost Rs.1923 crores, out of which GoI grant would be Rs. 1118 and remaining amount Rs804.54 crores would be borne by the State Government. This project is expected to attract an investment of 8000-10000 cr and would be able to generate 20000 jobs.

Medical Device Park

The Government of Himachal Pradesh also made bid under the scheme for built a Medical Device Park. The Government of India accepted the bid and A Medical Device Park-first in north India- has been sanctioned at Nalagarh, Solan. Rs.350 crores will be spent to set up this park on 265-acre land. It is estimated that this park will attract Rs1000 crore worth of investment.

Encashing the health-tech revolution

At present India is witnessing a health tech revolution driven by heavy tele density and cheap internet data. Indian consumer is having easy access to telemedicine, online diagnostics and e pharmacy sectors. This has promoted Governments to rebuilt and recast the existing healthcare system as per modern demands. The exiting healthcare system in India is also plagued with many problems and shortcomings like lack of adequate investment, shortage of medical professionals, unfordable modern treatment for low income groups and disparity in rural and urban health facilities. This health tech revolution has opened new avenues for pharma industry in Himachal Pradesh to encash. The impact of rapid economic growth post liberalization on income levels in India, along with increase in health insurance coverage will lead to increased expenditure on health care and drugs over the next few decades.

The Way Forward

The pharmaceutical sector in Himachal Pradesh has attracted a substantial investment over the decades. The sector has also remained profitable for investors for years now. The pharmaceutical drugs produced in the state are being supplied to patients across India and around the globe, that too at affordable and inexpensive prices. The pharma companies in Himachal Pradesh also adhere to Good Manufacturing Practices (GMP) in the quality and safety parameters. The standard of clinical trials set by leading organisation like World Health Organisation (WHO) and United States Food and Drug Administration (USFDA) are also followed in letter and spirit. Himachal Pradesh has held the top spot among the pharmaceuticals producing state in India for some time now. The share of expenditure on health care and medicine in India is likely to increase 9-12% in the coming decade. India is also poised to become top spender in healthcare and medicine due to its demography and size of economy.

In the coming years, pharmaceutical drugs have to be positioned in the market by companies as per the diseases arising due to modern lifestyle and eating habits. Over the years, both the Central and State Governments have also started many initiatives to bring more population under insurance coverage so that healthcare expenses of low-income group population can be reduced. One such Central Government initiative is National Health Protection Scheme (NHPS). The objective of this scheme is to cover the older population of India under universal healthcare. The Government of Himachal has also started Himachal Health Care Scheme or Himcare Scheme with objective that the poor and needy people get access to quality medical facilities and also timely cashless treatment of illness and diseases. The pharmaceutical companies in Himachal Pradesh are in constant look out to launch new generic drug in the market and this approach will benefit them in the future. The focus of Central and State Governments on

health programmes, administrating lifesaving drugs and supplies of preventive vaccines and drugs is a harbinger for pharma companies in Himachal Pradesh.

Summary and Conclusion

It's evident from the study that the pharmaceutical industry is already an established industry in Himachal Pradesh. The pharmaceutical industry has undoubtedly given an upward push and boost to the state economy over the past few decades. The current outlook for the pharmaceutical companies in Himachal Pradesh remains favourable, as demand in domestic market is positive. There is a strong growth potential for generics in developed markets in post covid era. The study found that investments in pharmaceutical industry in Himachal Pradesh will increase in the coming years. Also capital expenditure will increase due upcoming Bulk Drug park and Medical Device Park in the state. In spite all the positives, clearly there are some concerning challenges pharmaceutical industry in Himachal is facing that is to be addressed too. Be it the environmental and ecological damage being done to the fragile Shivalik region. The rapid industrialization and urbanization have brought enormous problems to soil and river of the region around these pharmaceutical industries. To maintain the credibility of clinical trial and quality of drugs produced is another such challenge. If these challenges are addressed in the coming times and only genuine entrepreneurs are allotted land Bulk Drug park and Medical Device Park Himachal Pradesh can establish itself on the world map of Pharmaceutical production.

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