

Indian Pharma Industry: Accepting The Challenges For More Challenges To Accept

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ABSTRACT

Purpose: Analysis of the various issues and challenges, likely to be faced by the Indian Pharmaceutical Industries and probable policy initiatives for addressing those issues to meet future challenges.

Methodology / Approach: After briefly putting the issues and challenges before Indian Pharma Sector, papers published on these issues are reviewed for getting more insight. Then, the Policy initiatives from the government side for addressing these issues are analysed against their intended outcomes. Finally, Researchers' own observations have been elaborated along with the comments on what these policies ought to be.

Findings: The paper points out the challenges which are either being there at present or likely to emerge in coming future before the Indian Pharma Industries. After analysis of the policies, initiatives taken to address those issues, which are the key factors in bringing out the structural changes in the sector, along with analysing the probable lacuna in these initiatives, especially those related to Pricing as well as Research and Development (R & D), have been discussed. Further, it has also been brought out that, as the substantive outcomes of those policies are still awaited, it is only premature to make any meaningful comment on them.

Originality / Value: Researchers have put their observations on the comprehensive R & D Policy that can be addressed with proper discussion at various levels. Further, issue of pricing of off-patented drugs has also been raised, that is to be addressed with the support of effective policy mechanism in place.

Keywords: Research and Development (R & D), Active Pharmaceutical Ingredients (APIs), Key Starting Materials (KSMs), Good Manufacturing Practices (GMPs), Small and Medium Enterprises (SMEs).

BACKGROUND OF THE TOPIC

India, very often titled as "Pharmacy of the World" is 3rd largest producer of the drugs in terms of volume and 14th in terms of value. Given the size of the population and being a developing country, there is a vast scope and need for developing the better health care services, which is on the path of growth trajectory only. During the last few years, the term "medical tourism" is very often in vogue for serious diseases like Tuberculosis, Cancer, Cardiac Complications etc. India is poised to take up the challenges at dual front i.e. one on the better health services to its own citizen and

another on the export of the medicines to different parts of the world, which is a huge source of earning foreign exchange with diplomatic edge as well. There is very much applauded in "vaccine diplomacy" during the recent pandemic of covid 19. However, the same pandemic situation has also exposed many of cracks and lacunas in Indian Healthcare system, as it did for other countries as well. As medicines are major part of health care system, the present paper attempts to analyse the prospects of Indian Pharma Industry, which are not only promising a bright future, but also visualising the challenges,

which are to be met successfully, before making it possible for them to take a big leap.

A POSITIVE NOTE ON PHARMACEUTICAL INDUSTRY IN INDIA

When we look at the positive side, in the span of last few decades, India's pharmaceutical growth has transformed the country from net importer to one of the major exporters of drugs and vaccines of Quality Medicines-approved production plants According to Indian Brand Equity Foundation (IBEF) Report (March 2022)¹, the sector is poised to grow at a Compound Annual Growth Rate (CAGR) of 22.4% in the near future and medical device market expected to grow up to US\$ 25 billion by 2025. India is the second-largest contributor of global biotech and pharmaceutical workforce. The Indian pharmaceutical industry has generated a trade surplus of US\$ 17.5 billion in FY21 and is expected to reach US\$ 130 billion by 2030 with a strong network of 3,000 drug companies and 10,500 manufacturing units on domestic front. India is the largest producer of vaccines in the world, i.e. around 60%, stood at US\$ 24.44 billion in FY21 and US\$ 22.21 billion in FY22 (until February 2022). Indian healthcare sector, one of the fastest growing sectors, is expected to cross US\$ 372 billion by 2022. The Indian biotechnology industry was valued at US\$ 70.2 billion in 2020, which is expected to reach US\$ 150 billion by 2025. The biotechnology industry in India comprises 600+ core biotechnology companies, 2700 biotech startups and 100 plus biotech incubators. Furthermore, India's production cost was lower to US by around 33%.

Industry in general, has also welcomed the taxation reforms, such as implementation of Goods & Services Tax (GST), as the Research Papers by Jadhav Bhika Lala (2017)², Srinivasan, S. and Babu, M. and Hariharan, C. (2019)³, Marinal, SK. and Rao, J. (2019)⁴, Thyagaraju, N. (2020)⁵ etc. point out, while enumerating the various benefits like unification of several taxes into one, reduction of cost to manufacturers and reduction of cascading burden to the general consumers. Further, Vyas, A. M., & Ved, M. L. S. (2018)⁶ opine that the Healthcare industry in general and Pharma Industry in particular, may experience constructive impact of implementation of GST. Merger of different

types of taxes may ease the way of doing business, supported with further improvement in the transportation and supply network.

India emerged as a large supplier of Covid-19 vaccines, supplying to 75 countries. Significantly, over 80% of the antiretroviral drugs, used globally to combat AIDS, are also supplied by Indian pharmaceutical firms, according to the government.

WORDS OF CAUTION

Lack of Backward Integration: High dependence on China for APIs:

India's pharmaceutical sector is highly dependent on China for key Active Pharmaceutical Ingredients (APIs), which infuse the therapeutic value in drugs. Due to cheaper option of imports, India imports about 68% of its requirements of APIs from China. The Trade Promotion Council, puts the figure of API dependence on China at about 85%. India's dependence can be understood from the fact, that during the year 2021, overall 70%, of APIs in general and 90% of APIs in particular for "certain life-saving antibiotics" like penicillin, cephalosporin and azithromycin were imported from China. In 1991, India imported only 1% of its APIs from China, but the things changed, when China ramped up API manufacturing in the 1990s across its 7,000 drug parks with infrastructure, such as effluent treatment plants, subsidized power and water. Production costs in China fell sharply and drove Indian companies out of the API market.

Lagging behind in Research and Development (R & D) activities:

During Covid 19 pandemic, a bitter lesson has been learnt by the country, when drugs for the complications like Black Fungus or say, Mucormycosis were desperately being imported from other countries. Further, Monoclonal Anti Bodies (MABs) are also largely being imported. This has exposed the weakness of Research and Development (R & D) activities in pharma sector in India. This factor practically eradicates the virtual leadership of Indian pharma sector, reducing it to mere producer of generic drugs, while lions' share goes to innovative big Multi-National Companies (MNCs) of the developed countries.

LITERATURE REVIEW

After straight forward references of strength and weaknesses of Indian Pharmaceutical Industry in the previous paras, now, it is worthwhile to analyse the different papers available over the issue.

Vyas, V., & Narayanan, K. (2016)⁷ have tried to look into the effects of Merger & Acquisition (M & A) on innovative performance of firms in Indian pharmaceutical sector, in terms of R & D activities. They concluded that M&A facilitate the acquiring firm to promote in-house R&D expenditure and also lower its need of importing disembodied technology as they may be acquired through acquisition process.

Meeting the dual goals of opposite ends i.e. making drugs available at affordable prices at one hand and encouragement of investments in R & D in pharma sector on the other, is a major challenge and requires appropriate trade-off. Differential pricings as well as incentivising the innovations in drugs to India specific needs (through patent extensions, subsidizing R&D, etc.) might be a way forward. Another important factor is Pharmaceutical advertising that may be both informative and persuasive. The former is taken in positive note that relates to new advances, whereas the latter relates to promotion of particular brand which is often taken in negative sense. (Mondal, S. S., & Pingali, V. (2015)⁸.

Smriti, N., & Das, N. (2017)⁹ have tried to establish the relationship between human capital and firms' market value in pharma sector and concluded that, their productivity is unaffected from Human Capital. This lack of relation between market valuation and productivity in Indian market can be attributed to lack of training to employees and earmark the training programs as a vital tool for employees and managers' performance.

Good Manufacturing Practices (GMP) compliance is necessary to enhance the industry 's credibility within the domestic and international markets (Nayak, N. (2011))¹⁰. There is an urgent need to establish robust guidelines for the approval of Biosimilars in India for demonstrating safety, quality and efficacy in patients. This may allow the export of these products to other developed nations as well.

The challenges on patents' front, are formidable for India, which is having matured

pharmaceutical industries. The Country has to review constantly the newly amended Patents Act, besides ensuring that, the objectives of access to medicines at affordable prices are met without allowing the firms reaping undue benefits. Legal provisions are required to be in place for achieving these goals. (Dhar, B., & Gopakumar, K. M. (2006)¹¹.

Painoli, A. K., & Joshi, P. (2013)¹² opine that job satisfaction of employees in pharma sector, especially in case of MSMEs, play important role in their growth as they have lesser number of workers and performance of even single person matters much.

Nauriyal, D. K. (2006)¹³ observes that changed patent regime are to have significant impact on both Indian as well as foreign firms. Indian firms and R & D institutions may gear up for internal networking for creating innovative chain with sound Industry-Academia linkages as well as the public funded labs like CSIR, CDRI, ICMR etc. for discovery of new drug, with the purpose to fulfil the needs of the masses.

Joseph, R. K. (2012)¹⁴ throws some light on the reason of heavy dependence of Indian pharma firms for cheap imports of inputs on China. He observes that the change in business priorities towards the export orientation has caused the pressure to maintain the price competitiveness in the international market, which ultimately require to reduce the costs, while backward integration domestically continues to decline.

Madhavan, H. (2014)¹⁵ focussed his study on the issue of research in Ayurvedic medicines. He adds that research in this field may be initiated in tropical drugs and regional epidemiology, where Ayurveda could play a crucial role. If proper investment and regulation are in place, this aspect bears huge potential in itself with promises of universalisation at large.

Athreye, S., Kale, D., & Ramani, S. V. (2009)¹⁶ find the positive effect of regulatory changes on the creation of dynamic capabilities of the firms, even in case of less radical innovations in the Indian pharmaceutical industry. They further state that dynamic capabilities can be so designed, that the firm strategies can exploit new opportunities evolved due to regulatory changes.

In order to obtain significant success, policy makers should opt for significant changes in innovation capacity by targeting direct support for R&D and facilities for clinical trials. private sectors should be encouraged to coordinate with the public for developing innovation capacities. (Abrol, D. (2004))¹⁷

Singh, M. M. (2006)¹⁸ has the opinion that India must decipher the nuances of ascending the value chain from generics to drug delivery and finally to drug discovery. It will have a long-term focus on sustainable competitive advantage through innovation and capacity building. This will facilitate India to become a global R & D hub in drugs, which ultimately will lead to enhanced shareholders' wealth and beneficial to the patients also.

Exports, R&D expenditure and past profits are the determinants of high importance in positive growth of Small and Medium Enterprises (SMEs), which provide them very powerful tools for increasing their growth rate. However, the negative and substantial impact of advertising and marketing expenditure necessitate the need to adjust strategies at firm level for increasing their growth rate. (Niño-Amézquita, J., Legotin, F., & Barbakov, O. (2017))¹⁹

Small units which are playing important role in pharmaceutical production and employment generation, along with achieving self-sufficiency in technology-intensive bulk drugs and raw materials, for maintaining the prices of life-saving drugs at affordable level, deserve to be given strong policy supports for increasing their competitive capabilities. (Pradhan, J. P. (2011))²⁰.

Mishra, R. (2018)²¹ has the opinion that, though the Investments in R&D by Pharma Industries have grown largely; they are still at lower pace. This is due to The Low Profitability, Lesser Market Capitalization alongwith comparatively small size of the Companies. It is still lower in traditional systems of medicine, where only limited R&D is taking place on the standardisation of raw materials and final products as well.

Soroush, F. (2020)²² focusses on the governance and the environmental issues in the pharma sector. For the purpose, capacity of institutions on this front should be enhanced through investments into the infrastructure,

good salaries of the staff, training of the staff, creation of reliable data generation tools and autonomy of the pollution control boards, which may be used for making a blend to stand up to the challenge.

LONG AND SHORT OF LITERATURE SURVEY

Literature Survey in the previous paragraphs support the following outlooks:

- a. Indian Pharma Industry has adapted itself to the GST system of Taxation quite comfortably and unification of various taxes may contribute somehow to ease of doing business.
- b. Merger and Acquisitions (M & A) at corporate levels may facilitate acquisition of high end technologies in pharma industry and promote in house Research and Development (R & D). On the other hand, adherence to fair Regulatory mechanism and Good Manufacturing Practices (GMP) may ensure the robust quality and acceptability of the products at international level. Further, proper training to the employees can add values to the human capital and enhance market capitalization of the firm. Human capital is much more critical for Small and Medium Enterprises (SMEs), which are instrumental for providing sound base to the industry and export as well.
- c. In a quest for achieving cost effectiveness and competitiveness in international market, pharma companies have resorted to options of cheap imports of Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs), rather than manufacturing them in India. This has resulted in overdependence of Indian firms on China for these inputs.
- d. A handful of papers have dedicated themselves to R & D in pharma sector in India and have pointed out the following issues:
 - i. Policy initiatives and supports are required for trade-off between Incentivization & investment in innovation in pharma research and Ensuring availability of medicines to the masses at affordable prices. Patent regimes should be constantly reviewed, so that incentivization to R & D is not unduly used by the firms to reap

benefits at the cost of affordability and availability.

- ii. Direct support for R&D and facilities for clinical trials, along with encouragement of private sector to encourage Industry-Academia linkage and to co-ordinate with public institutions like CSIR, CDRI, etc., will support in developing national innovation capacities. Facilitating value chain from generics to drug delivery and finally to drug discovery will create R & D hub in India and give it a definite competitive advantage.
- iii. R & D in traditional medicines like ayurvedic system and region specific needs of medical treatments may play a crucial role in harvesting huge potential in this country with chances of universalization in subsequent stages.

POLICY SUPPORT BY THE GOVERNMENT

Government Departments and Ministries like Department of Health & Family Welfare (DoH&FW), Department of Bio-technology (DBT), Ministry of Ayush, Department of Science & Technology (DST) etc. are promoting and undertaking R & D activities in the respective fields of Pharma and Medical Devices Sector, through the designated labs and institutions.

Central Drugs Standards Control Organisation (CDSCO) under Ministry of Health & Family Welfare (MoH&FW) is responsible for regulation of drugs quality. Similarly, National Pharmaceutical Pricing Authority (NPPA), an attached office to the Department of Pharmaceuticals (DoP), under the Ministry of Chemicals & Fertilizers (MoC&F), is responsible for regulating the prices of drugs and ensuring their availability at affordable costs to masses. Both of the above regulatory authorities' work in tandem to ensure the availability of quality drugs and medical devices at affordable prices to common people.

Department of Pharmaceuticals (Website of Department of Pharmaceuticals: <https://pharmaceuticals.gov.in>)²³ is making tireless efforts for providing various policy support in the form of Profit Linked Incentive (PLI) Schemes to encourage Brownfield and Greenfield investments in Pharma sector. Similarly, Bulk Drugs Parks Scheme, Medical

Devices Parks Schemes and Cluster Development Schemes are visualised for creating common industrial bases and testing facilities so that it becomes cost effective to operate in those specified parks and clusters, especially for the manufacturers, for whom, it may require big investments otherwise. Another one i.e. Pharma Technology Upgradation Assistance Scheme (PITUAS) is aimed at assisting SMEs of Pharma Sector, having proven track records, to migrate from Schedule M to World Health Organisation (WHO) / Good Manufacturing Practices (GMP) norms to enable them to compete in international markets and to earn valuable foreign exchanges. Research Linked Incentive (RLI) Scheme is also being visualised for encouragement of R & D in pharma sector. Pharmaceuticals & Medical Devices Bureau of India (PMBI) under this department is engaged in procuring and selling generic medicines to common people with the help of its more than 8600 Janaushadhi Kendras spread throughout the country. Its product basket includes 1616 medicines and 250 surgicals with total sales turnover of Rs. 893.56 crores in FY 2021-22.

RESEARCHERS' OBSERVATIONS ON THE TOPIC

Indian Pharmaceutical Industries have come up with the production of low cost drugs and large share in international market with high forex earner, having a big share in Indian Economy. During the Pandemic situation, the sector was able to supply medicines and vaccines to many other nations of the world. However, as pointed out earlier, Indian pharma industries' over dependence on China for import of APIs and KSMs are ringing the alarming bell. So, though the achievements may be glorifying, but in the absence of backward integration resulting which are denying self-dependence on input materials, such glorification may prove to be hollow, especially during critical and emergency periods.

Despite the acceptance of taxation reforms, ease of doing business to pharma industries cannot be enhanced, until and unless the structural reforms are materialised in this sector. These may be enumerated as imports' substitution, enhancement of R & D facilities and policy support for making patent regimes favourable to these aspects. The impacts of policy initiatives, as enumerated in previous paras are still in nascent stage and it is only

premature to make a meaningful comment about their outcomes.

Another major issue is the pricing of off patented drugs, which has been recently the point of differences between patent holders at one side, while on the other side, they are the government and new players, who intend to ensure affordability to the masses and enter in production and marketing of those drugs respectively. Another issue is pricing at abnormal situations. Further, medical devices have also been declared as drugs and their pricing issues are also to be handled now. These issues are required to be addressed with proper policy support mechanism. Though the Drug Prices Control Order (DPCO), 2013, whose guiding principle is the National Pharmaceuticals Pricing Policy (NPPP), 2012, are presently in force, the issues discussed here need overhauling of the whole NPPP and DPCO. This will facilitate an efficient mechanism in place meant for effectively preventing the frequent fire breakouts, rather than always resorting to emergency firefighting measures.

Final para of this paper is worth to be elaborated relating to the issue of R & D policy in Pharma Sector. An effective and efficient policy from the government is required across the functional domains of the different departments and ministries including the elite institutions like Council of Scientific and Industrial Research (CSIR), Central Drug Research Institute (CDRI), Indian Institutes of Technology (IITs), National Institutes of Pharmaceutical Education and Research (NIPERs) and Eminent industrial players as well. Core specialization and financial resources of these organisations are required to become part of an integrated network, guided towards a common goal. This will prevent the unhealthy competition and prepare a synergic ground for ensuring the outcome, conforming to intended goals. Vision of the policy should be, that Institutions and Organisations may not end up creating the problem of plenty. Finances covered under Corporate Social Responsibility (CSR) may also be guided towards the funding of R&D activities as well as Industry-Academia linkages. Further, Traditional Medicines and Ayurvedic Medicines also need proper attentions, which remain mostly untapped. India being a tropical country with vast geographical stretch and diversity on

meteorological front, has also health problems specific to different regions. This also provides big research opportunities on drugs by looking into traditional medicines available for their remedy. The institutes, labs and hospitals situated in those areas can go for initial study and share their research outcomes with such organisations situated in other zones as well, thus ensuring mutual benefits and enrichment of the whole research work. At the first stage, these will create the standardised remedies for local population, which may be universalized for other parts of the countryside and carried out, even to the international level at subsequent stages.

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