Export Growth & Challenges of Indian Pharmaceutical Industry

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Abstract

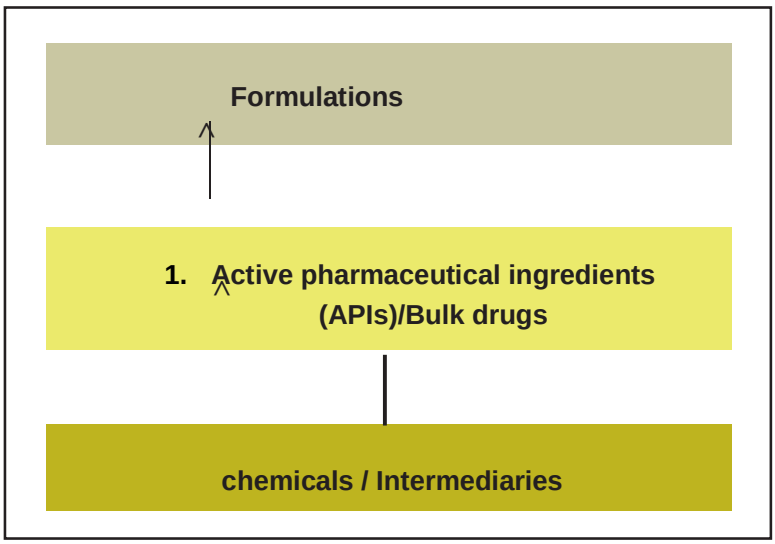
This paper analyzes the export growth and Challenges of the Indian Pharmaceutical Industry using time series data Indian pharmaceutical industry can be broadly divided into two periods, the pre-patent regime (before 2005) and the post-patent regime. While the pre-patent or process patent regime helped the industry develop into a world-class generics industry, the post-patent or product patent regime is aimed at encouraging new drug discoveries over the long-term. However, the launch of patented products in India has been slow. India gained a foothold in the global arena, with reverse-engineered generic drugs and active pharmaceutical ingredients (API), and now seeks to become a major player in outsourced clinical research and contract research and manufacturing services (CRAMS) segments. According to the study, India's performance in exports has improved expressively during the post-reform period and a perceptible change in the value can be noticed in the composition and direction of India's exports. This paper tries to scrutinize the link between economic growth and exports. In order to achieve this purpose, annual data was tested.

KEYWORD: Pharmaceutical Industry,, Economic Growth, India's Exports, Challenges, Value Chain

Indian Pharmaceutical Industry

The evolution of the Indian pharmaceutical industry can be broadly divided into two periods, the pre-patent regime and the post-patent regime. In the pre-patent regime (before 2005), India recognized only process patents, which helped in building the basis of a strong and competitive domestic industry. In 2005, India entered the product patent regime which marked the end of a protected era and signaled a new phase in the integration of Indian players into the global market. While the earlier process patent regime helped the Indian pharmaceutical industry develop into a world-class generics industry, the product patent regime is aimed at encouraging new drug discoveries over the long-term. However, the launch of patented products in India has been slow.

Exhibit 1: Indian Pharmaceutical Industry Value chain

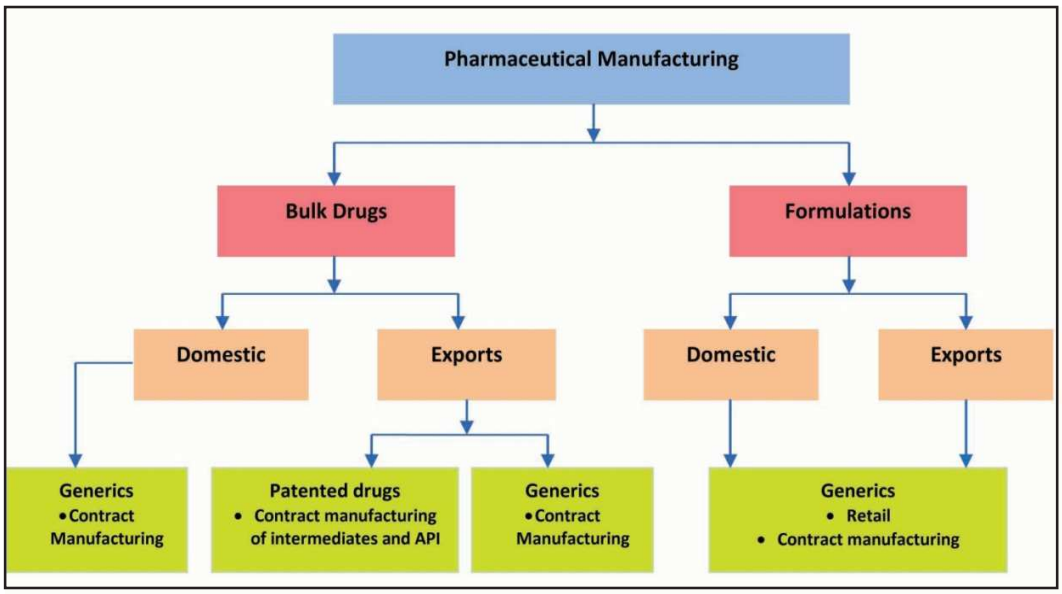


Source: CRISIL Research

India gained a foothold in the global arena, with reverse-engineered generic drugs and active pharmaceutical ingredients (API). India now seeks to become a major player in outsourced clinical research and the contract research and manufacturing services (CRAMS) segments. India has the highest number of manufacturing facilities (332 sites) approved by the US Food and Drug Administration (US FDA). Further, in 2011, one-third of all Abbreviated New Drug Applications (ANDA) approved by the US FDA, belonged to Indian companies.

Indian pharmaceutical companies have manufacturing opportunities in two segments - formulations and bulk drugs. The formulations segment can be further categorized into domestic consumption and exports. Traditionally, the domestic segment accounts for 40-50 percent of the production of the total formulation, with exports accounting for a larger share. In contrast, in the case of bulk drugs, domestic consumption accounts for only 10-20 percent of the total production. Hence, the Indian pharmaceuticals industry is dominated by exports (in both, bulk drugs and formulations), which contributed about 60 percent to the industry's sales in 2013-14. Formulations are exported either through contracts (supply) or directly sold (retail) in the market. Similarly, bulk drugs are either supplied under a contract, in the case of patented drugs, or are sold outright, in the case of off-patent drugs. In the coming years, Indian pharmaceutical manufacturers are poised to extend their presence in on-patent regulated markets, while maintaining a strong foothold in the generics (off-patent drugs) market as well.

Exhibit 2: Manufacturing by Indian Pharmaceutical Players



Over 100,000 drugs, across various therapeutic categories, are being produced in India. The domestic formulations industry is highly fragmented, in terms of both the number of manufacturers and the variety of products. There are 300-400 organized players and about 15,000 unorganized players in the manufacturing of pharmaceuticals. However, organized players dominate the formulations market, in terms of sales.

Industry Performance

Globally, the Indian pharmaceutical industry is ranked third largest in volume terms and 10th largest in value terms (2.5 percent of global share). The size of the Indian pharmaceutical industry is pegged at US$ 33.9 billion, having grown at roughly 13 percent CAGR over a 5-year period up to 2018-19. One of the reasons for the lower rank in terms of value, and higher rank in terms of volume is the low-cost drugs manufacturing in India; the price differential is estimated to be ranging from 5 percent to 50 percent lower as compared to developed countries. The industry has attained self-reliance in the production of formulations and produces almost 70 percent of bulk drug requirements of the country. India is also one of the major producers of generic drugs in the world.

Export

Indian pharmaceutical companies have not been affected much by the global slowdown, largely because of cost advantages in production. Notwithstanding this, performance on the export front has been rather modest; exports of pharmaceutical products increased by 1.2 percent in 2017-18 over the previous year.

Table 1: India's Export Destinations for Pharmaceutical products

2017-18			2018-19		
Importers	**uS $ million**	**% Share**	**Importers**	**uS $ million**	**% Share**
U S A	1248.9	24.1	U S A	3445.8	30.9
U K	269.4	5.2	Russia	535.9	4.8
Russia	259.0	5.0	South Africa	474.0	4.3
South Africa	203.3	3.9	U K	400.8	3.6
Nigeria	167.0	3.2	Nigeria	337.8	3.0
Germany	116.9	2.3	Germany	222.2	2.0
Ukraine	116.2	2.2	Kenya	215.7	1.9
Vietnam	102.6	2.0	Netherlands	185.5	1.7
Sri Lanka	100.2	1.9	Australia	173.6	1.6
Kenya	99.5	1.9	Brazil	161.4	1.4
Total	**5190.7**		**Total**	**11139.9**	

Source: Ministry of Commerce & Industry, GOI; Exim Bank Analysis

However, exports witnessed a complete turnaround, growing by a healthy 18.5 percent from US$ 8.7 billion during 2017-18 to US$ 10.3 billion during 2018- 19, and in the following year by 25.1 percent to US$ 12.9 billion. However, in recent years, though there has been an increase in exports in terms of absolute value, y-o-y growth has shown a declining trend in USD terms mostly due to the weakening of the rupee. The share of pharmaceuticals in India's total exports has increased from 2.1 percent in 2009-10 to 4.7 percent in 2017-18.

The major export destinations for India's drug formulations and biological products during 2018-19 were: USA (with a share of 30.9 percent) followed by Russia (4.8 percent), South Africa (4.3 percent), UK (3.6 percent) and Nigeria (3 percent). As can be seen from Table 4.1, the USA and Russia have retained their positions as major destinations for Indian pharmaceuticals since 2017-18. However, during 2018-19, the Netherlands, which is considered as a gateway market for the EU emerged as a major market for Indian formulations and biological products. Other markets that have emerged as major markets during the year are Australia and Brazil. These countries have replaced Asian countries, such as Sri Lanka and Vietnam.On the other hand, major export destinations for India's bulk drugs and intermediates during 2018-19 were USA (14.2 per cent), followed by Germany (5.3 per cent), Brazil (4.5 per cent), UK (3.7 per cent), and Japan (3.5 percent).

Table 2: R&D Expenditure of Select Indian Pharmaceutical companies

company Name	2017-18			2018-19		
	` Million		R& D as % of sales	` Million		R&D as % of sales
	Sales	R&D Expenses		Sales	R&D Expenses	
Dr. Reddy'S Laboratories Ltd.	83946	6947	8.3	97938	10391	10.6
Cipla Ltd.	82974	3638	4.4	94821	5119	5.4
Lupin Ltd.	71508	7099	9.9	89776	9294	10.4
Aurobindo Pharma Ltd.	55695	2085	3.7	72695	2551	3.5
Ranbaxy Laboratories Ltd.	60615	4491	7.4	68783	5279	7.7
Cadila Healthcare Ltd.	30943	4427	14.3	36916	4358	11.8
Torrent Pharmaceuticals Ltd.	27672	1263	4.6	33586	1455	4.3
Ipca Laboratories Ltd.	28287	887	3.1	32966	1244	3.8
Sun Pharmaceutical Inds. Ltd.	24522	2725	11.1	29959	3752	12.5
Glaxosmithkline Pharmaceuticals Ltd.	27425	24	0.1	26650	26	0.1
Divi'S Laboratories Ltd.	21444	240	1.1	25330	254	1.0
Glenmark Pharmaceuticals Ltd.	20479	929	4.5	24387	1214	5.0
Abbott India Ltd.	16709	13	0.1	23252	16	0.1
Biocon Ltd.	19833	714	3.6	22393	705	3.1
Orchid Chemicals & Pharmaceuticals Ltd.	19183	842	4.4	19183	842	4.4
Sanofi India Ltd.	16128	24	0.1	18549	43	0.2
Alembic Pharmaceuticals Ltd.	15014	743	4.9	18515	1164	6.3
Wockhardt Ltd.	24770	2010	8.1	18108	1985	11.0

Source: CMIE Prowess, Exim Bank Analysis

Patents

The patents filed by, and granted to Indian companies have been increasing significantly. Indian companies have filed a large numbers of Drug Master Files and Abbreviated New Drug Applications (ANDA) with the US-FDA. According to the Indian Patent Office, during 2017-18, a total of 43,674 patents were filed, of which only around 6.8 per cent were filed in the drug and pharmaceutical sector; and of the

total 4126 patents that were granted in the year, around 8.3 per cent share was forpharmaceuticals.

R&D

In the recent years, Indian pharmaceutical companies have significantly increased theirR&D budgets in view of their growing focus both on regulatedmarketsandcomplexmolecules/therapy segments.In2018-19,mostoftheleadingpharma players spent anywhere between 5 billion to12billiononR&D,whichrepresentedanincrease, both in absolute terms as well as in proportion to net revenues (8-11 per cent ofsales).

Indian Pharmaceutical Industry – Key challenges

At present, India accounts for about 40 percent of generic drugs, over-the-counter products, and 10 percent of finished dosages used in the USA. The ongoing and ensuing patent cliff is projected to offer more opportunities for the Indian pharmaceutical industry, particularly in generic and biosimilar. The generic market is projected to grow at a rate of 9.5 percent to US$ 432 billion by 2018. However, recently, the Indian drug industry has come under increased scrutiny by the US-FDA, mainly due to the following two reasons:

Data Integrity – Data integrity practices followed in many of the US FDA-approved units of Indian pharmaceutical companies have emerged as a major challenge for the industry in recent times. According to the US-FDA, data integrity matters because properly recorded information is the basis for manufacturers to assure product identity, strength, purity, and safety. Evidence of misrepresented data or problems with batch records found during a preapproval inspection has been the prime factor leading to delays in market approval, and the audits have led to warning letters and blacklisting of the units.

The credibility of Clinical Trial Data - The credibility of 'Clinical Trial Data' generated by the Indian pharmaceutical industry has also become a cause of great concern. In many ways, India is the ideal location to conduct clinical trials given its diverse pool of patients with diverse treatment needs, and access to a large, scientifically skilled, workforce. This has caused a huge growth in the number of clinical trials undertaken in the country; however, the capacity to regulate clinical trials has not kept pace with this growth leading to a number of reported unethical practices such as limited patient compensation for adverse events; approval of drugs without clinical trials; and lapses in informed consent procedures. Though the Government of India has enhanced the regulatory control measures, in the form of mandatory trial registration, and the creation of numerous committees tasked with overseeing trial approval, trial execution, and ethical treatment of patients, the delays in new drug approvals as a result of the new regulatory control regime has been also forcing some multinational pharma companies to rethink their clinical trial activities in India.

IPR- - Intellectual property rights (IPR) in the pharma sphere have been a contentious issue globally. The (Indian) Patents Act was enacted in 1970 and inter alia contains provisions relating to pharmaceutical patents. A major change in the patent laws in India was the enactment of the Patent (Amendment) Act, 2005, which made patent laws in

India compliant with the TRIPS Agreement. Though there was an overall improvement in patent protection in India, recent issues such as the granting of compulsory licenses (CLs) have been contentious. Under the Indian Patent Law, CLs can be awarded, inter alia, if:

The reasonable requirements of the public with respect to the patented invention have not been met;or

- The patented invention is not available to the public at a reasonably affordable price;or
- The patented invention is not worked in the territory ofIndia.

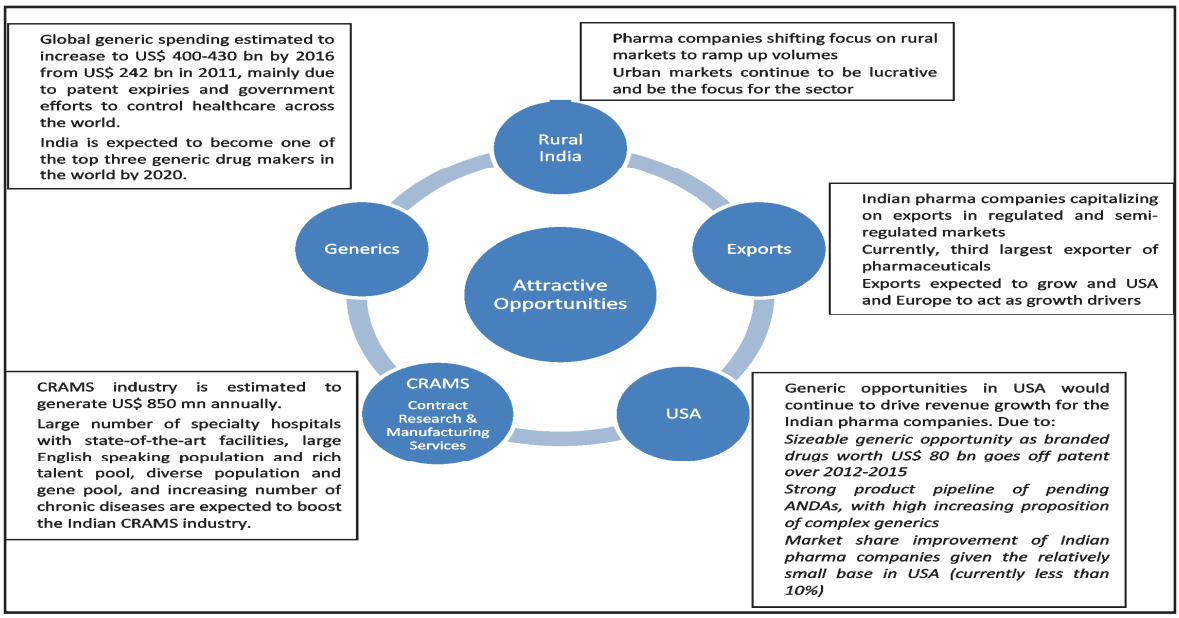
In contract research, collaborative research projects, out-licensing, and in-licensing partnerships Indian firms have been partners of subordinate status who perform piecemeal projects in drug research, and they are not exposed to the whole process of new drug development. In these collaborations, the scope for transfer of technology and joint ownership of technology is also very limited. The subordinate status of the Indian firms, in the long run, may result in a dependency relationship of Indian firms with the MNCs. This may have deleterious consequences to the industry in many ways. Being trusted allies in the global strategy of MNCs, Indian companies may lose interest in those therapeutic areas which do not have a global presence (for example, tropical country diseases). These allies might also withhold themselves from exercising compulsory licensing provisions, the TRIPS instrument to counter abuse of patent monopoly rights as well as to address national health emergencies.

The limited capacity of Indian firms in developing new drugs, both in terms of S&T skills and financial resources leaves them with no other option but to collaborate with MNCs. In the earlier policy regime, the public sector companies and public sector laboratories had played a major role in augmenting the S&T skills of the private sector industry. Under the new policy regime, the public sector companies have been relegated and a few of them have already been closed down. The aversion to indigenous innovations at the regulatory approval stages and at promotional stages further encourages Indian firms to develop new drugs in collaboration with MNCs.

The liberalization measures, on the other hand, have attracted foreign investment in pharmaceutical R&D in India. But it has been observed that the bulk of foreign investment in R&D in the pharma sector has been in the clinical phase, especially in phase III trials, and not much in the biology and chemistry research for new drug development. Phase III requires a large number of human subjects in the trials. MNCs are attracted because India provides a large size of the population that is ethnically diverse and suffering from various ailments. The English speaking human power and a well-developed communication network with information technology capabilities are also advantageous for India in clinical trials.

In addition, the Indian pharmaceutical industry is also witnessing regulatory challenges with respect to uncertainties over the FDI policy, the new pharmaceutical pricing policy, a uniform code for sales and marketing practices, and compulsory licensing. These challenges have been slowing down the growth of the industry.

Exhibit 3: Opportunities for Indian Pharmaceutical Industry



Source: Express Pharma, Aranca research

Research and Development

The present R&D efforts of the Indian pharmaceutical industry are mainly targeted towards therapeutic areas of global interest like diabetes, cardiovascular diseases, central nervous system disorders, and oncology. However, diseases local to India and other tropical countries, for example, tuberculosis and malaria, are getting less attention due to economic reasons. To promote the novel research and development in these areas, there is a need for short/medium/long term policy to further incentivize the private sector for new drug development and bringing down the commercialization barrier in these areas.

Presently, apart from strengthening the intellectual property protection system, the Government of India is providing soft loans, grants, and tax benefits to promote R&D activities. Public-Private Partnerships (PPPs) initiated by the Department of Science & Technology (DST) and Council of Scientific and Industrial Research (CSIR) are providing avenues for risk-sharing and better collaboration between public research facilities and the private sector for the development of the National College of Engineering (NCEs). These partnerships need to be more commercially oriented and proactive in bringing innovations to market. To commercialize new drugs developed for neglected tropical diseases, there is also a need to promote them by providing incentives to the private sector in the form of subsidies or drug assistance programs, or by reviving public sector manufacturing for these drugs.

Clinical Research & Trials

To address unethical practices in clinical research and encourage clinical trials in India, the approval mechanisms for protocols need to be more transparent and time-efficient. In addition, a policy promoting clinical research and innovation needs to be supported by action at various levels:

•**Rational regulations**: Regulations and guidelines developed through a multi-stakeholder consultative approach that is based on science and highlight a commitment to patient safety, ethics, and confidentiality, in line with globally accepted practices are the need of the hour. There are situations unique to India like literacy, socio-economic considerations, and social-cultural norms, which must also be taken into cognizance in the development of guidelines so that no one is denied the right to participate in research because of these challenges.

•**Capacity building**: There is a need for more trained resources within the Central Drugs Standard Control Organization (CDSCO) to ensure the smooth rollout and governance of clinical research in the country.

•**Accreditation**: To address the concerns that have been raised about the conduct of clinical research in India, there is a need for an objective system to accredit investigators, sites, and ethics committees. The accreditation should be provided by an independent third party and reviewed at periodic intervals.

•**Infrastructure development**: For sustained growth of clinical research in the country and to ensure a healthy balance of research across geographies, investments are needed in bettering infrastructure particularly at government-run hospitals and institutions. Many patients do not have the option of participating in clinical research in many areas of India, because, the majority of these sites being ill-equipped and most of the investigators are not trained in clinical research.

•**Public education and awareness**: MIS-reporting and sensationalism of clinical research in India have created fear and suspicion amongst the public at large. A key requirement is public education and awareness not just about clinical research in general but also about the rights and responsibilities of those who participate in a clinical trial. There is a need to create an environment where patients have the confidence and trust that their participation in a trial is not only beneficial to them, but also to other patients in the world.

•**Transparency and Openness**: Greater transparency and openness by the regulators will go a long way in restoring trust amongst various stakeholders.

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