Start-ups and pharma industry

Poorvi Sanjanwala, Partner and **Zil Shah**, Associate, Rajani Associates, give an overview on the growth drivers in the pharma industry and the role of start-ups in furthering progress

THE INDIAN pharmaceutical industry has been growing phenomenally. It is globally ranked third in terms of volume and 14th in terms of value[1]. Nearly 70 to 80 per cent of the Indian market[2] is constituted of branded generics. Apart from being a front runner on the home ground, India is also the largest provider of branded generic drugs globally, with Indian generics accounting for 20 per cent of global exports in terms of volume[3]. The Indian pharma industry, which is expected to grow over 15 per cent

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per annum between 2015 and 2020, is also expected to outperform the global pharma industry, which is set to grow at an annual rate of five per cent between the same period.[4]

The pharma sector is highly sensitive and hence is subjected to significant control and regulation, right from the manufacturing stage to its marketing, promotion, storage and consumption.

Critical licences to set up a pharma business in India

The most critical licence for setting up a pharma business in India is the drug licence from the Food and Drug Administration (FDA) department. The Central Drug Standard Control Organization (CDSCO) and the State Drug Standard Control Organization (SDSCO) control the issue of drug license in India. Separate licences are required for every plant where the drug is being manufactured, and also for every type of product (such as tablets, syrups, injections etc).

Moreover, in order to import or export drugs in India, a person must have an Import Export Code (IEC) number. It is obtained through registeration as an importer or exporter. The number is received from the office of the Director General of Foreign Trade.

Apart from these, standard licences are required for an entity to operate any business in India (e.g. PAN/TAN/local licences).

Growth prospects

According to data from the Ministry of Commerce and Industry, India has maintained its lead over China in pharma exports with a year-on-year growth of 7.55 per cent to \$12.54 billion in 2015[5]. India is clearly enjoying an important position in the global pharma market. With a large pool of human resources (both qualified and unqualified) and the gradual efforts put in by the Government of India, there is potential to steer the industry to a higher level. Relaxations in foreign direct investments in India are also expected to provide an impetus to the growth of this industry.

Bulk drugs or active pharma ingredients[6] are those components in a medicine that gives it the therapeutic effect. Up until the year 2000, foreign direct investment (FDI) was allowed up to 74 per cent in the case of bulk drugs, their intermediaries and formulations under the approval route. Any FDI which exceeded this threshold was considered on a case-to-case basis for

(i) manufacture of bulk drugs from basic stages and their intermediates; and

(ii) bulk drugs produced by the use of recombinant DNA technology as well as specific cell/tissue targeted formulations, provided it involves manufacturing from basic stage[7].

The pharma sector was unbolted for 100 per cent FDI in the year 2001[8] making India an attractive destination for investments. This relaxation coupled with India's low cost of production, availability of skilled workforce, lower cost of labour, rising levels of education resulting in increased health awareness, increase in patient pool, etc. has aided in an unprecedented growth of this industry.

Further, with escalating growth, the sector was placed under the Special Focus Sector for National Manufacturing Policy, 2011 as it enjoyed comparative and competitive advantage.[9] From then on, the concept of greenfield and brownfield investment were introduced vide Press Note 3 of 2011[10].

Greenfield investment is foreign direct investment in a new pharma venture in India whereas brownfield investments refer to foreign direct investments in an existing company engaged in pharma activity.

Up until 2016, FDI in pharma sector was permitted to the extent of 100 per cent under the automatic route for greenfield investments and FDI in brownfield[11] investment was permitted to the extent of 100 per cent under the approval route. The only condition for foreign investment in this sector was the non-allowance of non-compete clauses in both routes of investment. Such clauses were allowed only in special circumstances, with prior approval of the FIPB. This restriction has been reserved in order to protect domestic companies.

With a recent amendment by way of a Press Note 5 of 2016, released by the Department of Industrial Policy and Promotion (DIPP), 74 per cent FDI is now allowed in brownfield investment under the automatic route. 100 per cent FDI will continue to be allowed under the automatic route for greenfield investments. Apart from restriction on the inclusion of a non-compete clause which was present earlier, additional conditionalities with respect to brownfield investments have been introduced. FDI in brownfield investment, under both automatic and government route, is subject to maintaining the production levels of National List of Essential Medicines (NLEM) drugs, consistency in research and development (R&D) expenses and providing complete information about technology transfer to administrative authorities.

The fine print to this relaxation has been released with some conditionalities. Considering that conditions levied on FDI in brownfield investment has been relaxed, one can still expect to see a significant increase in mergers and acquisitions (M&A), private equity transactions and entry of new players in the pharma space.

Sector: DRUGS & PHARMACEUTICALS Year	Amount in ₹ crores ($ in millions)
2013-14 (April - March)	7,191 (1,279)
2014-15 (April-March)	9,052 (1,498)
2015-16 (April,15 – March,16)	4,975(754)[12]

Opportunities to look out for

In any industry, growth and sustainability assume importance. The pharma industry will also need to focus on improving operational facilities and productivity which will have to be achieved without triggering any consequential cost increase which may then result in increase in prices. India is highly dependent on China for bulk medicines; nearly 75 per cent of its bulk drugs come from China[13]. The Government of India had decided to come up with a policy which would help boost manufacturing of bulk drugs. This would have not only reduce our dependence on China but also help in advancement of the domestic pharma sector. However, it appears that the government is now intending for the states to come up with bulk drug parks which will help boost manufacturing of bulk drugs[14].

Research is a vital aspect of the pharma industry. In the Union Budget 2015-16, the government has provided various incentives for industry private sponsored research programmes like a weighted tax deduction to assesses under section 35 (2AA) of the Income Tax Act as well as a weighted deduction of 200 per cent for any sum paid to a national laboratory, university or institute of technology, or specified persons with a specific direction, subject to certain conditions. Further, there is a separate provision for benefits to companies engaged in manufacturing with in-house R&D centers under section 35 (2AB) of the Income Tax Act for both capital and revenue expenditure incurred on scientific R&D[15]. Such incentives pave the way for more development and expansion. Amongst the new entrants in the field of R&D is Vitas Pharma. Incorporated in 2011, it has involved in drug discovery and development[16].

The hiccups

Every industry has its own strength and weakness, and the pharma industry is no different. India's pharma industry has grown to become a global competitor. However, in recent years, Indian companies have been facing credibility issues in terms of manufacturing practices, quality etc. with the US-FDA[17].

Start-ups have been exploring the e-commerce space in the pharma industry, for instance, the online pharmacies concept. However, ambiguity about whether online pharmacies can exist and operate in the space that they currently operate persists. This necessitates the need for defined clarity in the form of a regulatory framework.

There is no doubt that the pharma industry has major growth opportunities, however, pharma companies will have to revamp their business strategies to increase as well as sustain growth levels. They will also need to adopt innovative or refined business models. Progress in medical and mobile technology has the ability to provide further impetus for growth of the pharma industry. Though the pharma industry may face certain legal issues, it also has tremendous potential to grow manifold and continue to participate in enhancing global confidence in India's growth story.

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