Intra Legem

Pharmaceutical Industry

July 2, 2016

Globally, the India Pharmaceutical Industry ranks 3rd in terms of volume and 14th in terms of value[1]. Branded generics dominate the pharmaceuticals market, constituting nearly 70% to 80% of the Indian market[2]. Apart from being a front runner on the home ground, India is also the largest provider of generic drugs globally, with Indian generics accounting for 20% of global exports in terms of volume[3]

1. Report by Business Standard- http://www.business-standard.com/content/b2b-chemicals/success-strategies-for-indian-pharma-industry-in-an-uncertain-world-114021701557_1.html
2 http://www.ibef.org/industry/pharmaceutical-india.aspx
3 http://www.makeinindia.com/sector/pharmaceuticals

In the coming years, the Indian pharmaceuticals industry is slated to grow to $55 Billion by the year 2020 making it only second to USA, in terms of volume (*of course there is always some potential for more!)*[4]. India is home to 523 US-FDA compliant manufacturing plants, highest for any country outside the USA[5].

The Pharmaceutical sector being a highly sensitive sector is subject to significant regulation and control right from the manufacturing stage to its marketing, promotion and consumption stage.

Critical licenses required for setting up a Pharma business in India

Apart from the standard licenses required for an entity to operate any business in India (e.g. PAN/TAN/ local licenses), the most critical license for setting up a pharmaceutical business in India is the drug license from the Food and Drug Administration ("FDA") department. The Central Drug Standard Control Organization and the State Drug Standard Control Organization control the issue of drug license in India. Separate licenses are required for every plant where the drug is being manufactured and also for every type of product (such as tablets, syrups, injections etc.). Also, before any person can import or export drugs in India, he must register himself as an importer or exporter as the case may be i.e. an IEC number (Import Export Code Number) is obtained from the office of Director General of Foreign Trade office to operate as an importer and exporter in India.

Overview of Foreign Direct Investment in Pharma

Bulk drugs or active pharmaceuticals 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% 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 the specific cell/tissue targeted formulations, provided it involves manufacturing from basic stage[7].

4. file:///C:/Users/ashish/Downloads/India_Pharma_2020_Propelling_access_and_acceptance.pdf
5 http://www.ibef.org/industry/pharmaceutical-india.aspx
6. Schedule M part 1F
7. Press note 2 of 2000

It was in the year 2001 that India threw open the pharmaceutical sector to 100% FDI[8] thereby making India an attractive destination for investment in the pharma sector. 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 the upward growth graph, the Pharmaceutical sector was placed under the Special Focus Sector for National Manufacturing Policy 2011 as it enjoyed comparative and competitive advantage [9]

Immediately thereafter, the concept of "Greenfield" and "Brownfield" investment was introduced vide Press Note 3 of 2011[10]. Greenfield investment is foreign direct investment in a new pharmaceutical venture in India whereas Brownfield investments refer to foreign direct investments in an existing company engaged in the pharmaceutical activity. Until recently, FDI in pharma sector was permitted to the extent of 100% under the automatic route for Greenfield investments and FDI in Brownfield [11] investment was permitted to the extent of 100%, albeit under the approval route.

The only conditionality for foreign investment in pharmaceutical sector was the non-allowance of non-compete clauses in both the routes of investment. Such clauses will be allowed only in special circumstances with the prior approval of the FIPB. This restriction has been reserved in order to protect the domestic companies.

8 Press note 4 of 2001 series. Provided the activity does not attract compulsory licensing or involve use of recombinant DNA technology, and specific cell / tissue targeted formulations. FDI proposals for the manufacture of licensable drugs and pharmaceuticals and bulk drugs produced by recombinant DNA technology, and specific cell / tissue targeted formulations required prior Government approval

9. Press note 2 of 2011 series

10. http: ://dipp.nic.in/English/acts_rules/Press_Notes/pn3_2011.pdf

11. Vide press note 3 of 2011, a Brownfield company means an existing company

With various policy changes, the sector has seen huge foreign investments, which is evident from the following table

Sector	2013-14 (April - March)	2014-15 (April-March)	2015-16 (April,15 – March, 16)
DRUGS & PHARMACEUTICALS	7,191 (1,279)	9,052 (1,498)	4,975 (754)

Source: http://dipp.nic.in/English/Publications/FDI_Statistics/2016/FDI_FactSheet_JanuaryFebruaryMarch2016.pdf

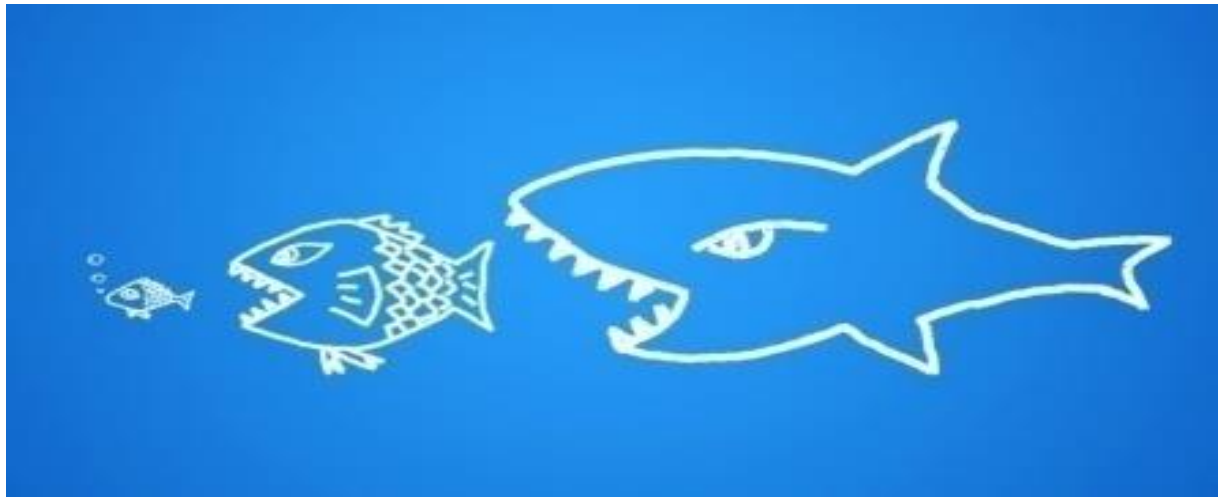
FDI in pharmaceuticals sector involves more of Brownfield Investment which involves Mergers and Acquisitions ("***M&A***"). Apart from complying with the FDI Policy, an M&A has to be in compliance with various laws like the Companies Act, Income Tax Act, SEBI, Foreign Exchange Management Act, Competition Act, etc The objective behind heavy regularization is to craft deals with transparency and investor protection Also, M&A transactions have far reaching effect on competition and there is always a fear of MNCs dictating the markets on their terms and formulating their own policies.

In spite of several regulations, Indisa has, in recent times, witnessed a surge in M&A so much so that these transactions are now the 'new-normal' for the sector.

Company (Acquirer)	Company (Target)	For Amount
Daiichi Sankyo (Japan)	Ranbaxy (India)	$4.6 billion
Abbott (USA)	Piramal (India)	$3.72 billion
Sanofi Aventis	Shantha (India)	$783 million
Mylan (USA)	Matrix (India)	$736 million
Reckitt Benckiser	Paras(India)	$724 million
Hospira	Orchid(India)	$400 million
Fresenius Kabi (German)	Dabur Pharma (India)	$219 million
Abbott (USA)	Wockhardt (India)	$22.5 million

Source: http://www.academia.edu/10549999/Merger_and_Acquisitions_in_Pharma_sector_in_India

The reasons which can be attributed to this increased activity in the M&A space are multi-fold. Synergies in products and R&D offer greater access to product patents, deeper market penetration boosts consumer base resulting in reduced manufacturing costs, and cross border M&A facilitate in altering the global rankings. *The phenomenon of the big fish eating the smaller fish!*



Our View

With the recent amendment by way of a Press Note 5 of 2016 released by the Department of Industrial Policy and Promotion, 74% FDI is now allowed in the Brownfield Investment under the automatic route. 100% FDI will continue to be allowed under the automatic route for Greenfield investments. Apart from the restriction on non-allowance of 'Non-compete' clause which was present earlier as well, additional conditionalities with respect to Brownfield investments have been prescribed. FDI in Brownfield investment under both automatic and government route is subject to maintaining the production levels of National List of Essential Medicines drugs, consistency in Research and Development expenses and providing complete information about technology transfer to the administrative authorities. While the fine print to this relaxation has been released with some conditionalities, one can still expect to see a significant increase in M&A and private equity transactions in the Pharmaceutical space in the coming months.

Contributed by:
Poorvi Sanjanwala, Partner: poorvi@rajaniassociates.net
Zil Shah, Associate: zshah@rajaniassociates.net

Contact Us

Rajani Associates
Advocates & Solicitors

Krishna Chambers
59 New Marine Lines
Mumbai 400020, India
t: +91 22 4096 1000
e: intralegem@rajaniassociates.net
w: www.rajaniassociates.net

AREAS OF PRACTICE

| Capital Markets | Private Equity | Mergers and Acquisitions | Corporate Litigation & Arbitration | Projects & Project Finance |
| Real Estate & Trust | Corporate & Commercial | Banking & Finance | Structuring | TMT | IPR | Employment |