



KNOWLEDGE PARTNERSHIP PROGRAMME

Impact of Merger & Acquisitions in Indian Pharma on Production, Access and Pricing of Drugs

HEALTH & DISEASE CONTROL

Summary

Policy Context: The pharmaceuticals sector in India is currently open for 100% Foreign Direct Investment (FDI) in both Greenfield (Initiation of new venture and facilities) and Brownfield (Purchasing of an existing facility to begin new production) investments. Mergers and Acquisitions (M&A) can act as a source of capital, productivity and innovation but can potentially jeopardize the capability of Indian pharmaceutical industry in relation to 'Access to Medicines', which is one of the major goals of the health system. In order to objectively evaluate impact of M&A on access to medicines, an analytic study was commissioned under the Government of UK's Department for International Development (DFID) supported Knowledge Partnership Programme (KPP).

Current Status: The opening of pharma sector for FDI has directed lots of capital and interest into Indian pharmaceuticals. However, critics point out that more than 90% of FDIs are currently for Brownfield projects E.g. \$989 million during April 2012-April 2013 was Brownfield compared to just \$87.3 million for Greenfield investments. One of the primary reasons pointed out by industry is complex and time consuming approval regime for Greenfield pharmaceutical investments.

Concerns: There are concerns over the acquisitions in Indian pharma sector around:

- Potential for price increase

- Limited availability of priority products
- Consolidation of market share; leading to anticompetitive behavior
- Reduction in availability of generics
- Availability and affordability of off-patent/generics with patent cliff
- Lack of challenge to Multinational Corporation (MNC) patents

Project Details: Six recent major acquisition cases in pharmaceuticals sector were analyzed. Analysis was carried out for three years before & after the acquisition to allow for sufficient grounding for conclusions. The framework for evaluation is constructed along four broad areas: Pricing, Production and Availability, R&D and Social Consequences.

Recommendations: Industry needs to participate in developing and sharing supporting infrastructure to ensure availability of medicines in rural areas is not impacted even after strategic changes such as M&A. Industry needs to engage government in a dialogue to ensure commercial viability is maintained on innovator drugs. Policymakers should consider ways to promote competition in selected molecules where competition is lower and public health priority is higher. Also, molecule level price monitoring post-acquisition for a defined time period should be done by appropriate governing bodies.

The Findings

Pricing

- Changes in prices for selected molecules for acquired company in comparison to the reference market - Negative
- Changes in prices across portfolio for acquired company in comparison to the reference market - Positive
- Changes in prices for medicines under specific Therapeutic Areas & comparison with the reference market - Positive

Availability

- Product Profile (Focus on API vs. Formulations): Negative
- Domestic vs. Export focus: Negative
- Pace of new launches: Positive
- Discontinuation of products: Positive
- Town class coverage: Negative
- Product Portfolio Changes: Neutral

Research & Development (R&D)

- R&D Expenditure: Negative
- Local market orientation: Positive
- Innovative drug launches: Neutral
- Transfer of technology: Neutral

Social Consequences

- Employment Generation: Positive
- Salaries and employees' related expenditure: Neutral

Positive - Favourable; Negative- Not Favorable; Neutral- No Impact

Background

The Indian pharmaceutical industry ranks 13th in the world by value of pharmaceutical products and is highly fragmented, currently having more than 20,000 registered companies. The top 1.25% companies (approximately 250) control 70% of the overall market. The Indian domestic pharmaceutical players enjoy certain advantages which attracts M&A in the country: Lower cost of operations, R&D and capital expenditure, proven track record in bulk drug and formulation patents, strong domestic support in production, from raw material requirements to finished goods, and an attractive Indian market.

The rise of the competition, the financial liberalization allowing capital outflows and the rapid technological advances are the main drivers of the globalization process extensively favouring the influence, presence and participation of foreign owned, multinationals and new domestic companies in national economies.

The global pharmaceutical industry is witness to declining R&D productivity, expiring patents on blockbuster products and relentless downward pricing pressure forcing companies to look closely at the bottom line. One effect of this slowdown has been an upsurge in the level of M&A activity as players within the industry consolidate to cut costs, expand research pipelines and lengthen geographic footprints.

Current Scenario

All pharmaceutical companies want to grow bigger, have better products and expand market share. Often, companies acquire smaller companies, or form joint venture agreements, to gain control of their patent rights, technologies, products, R&D (research & development) facilities, manufacturing facilities, and, at times, their marketing/distribution channels. The pharma sector is currently open for 100 percent Foreign Direct Investments (FDI) in both Greenfield and Brownfield projects. Greenfield investments are under the automatic route of Department of Industrial Policy & Promotion (DIPP). The Government last introduced substantial changes in the FDI policy in November 2011 whereby stating that



“Brownfield investments (i.e. investments in existing companies)” would require prior approval from the Foreign Investment Promotion Board (FIPB). Invariably there is preference for Brown field investments so as to cut down perceived long gestation period. One of the primary reasons pointed out by industry is the complex and time consuming approval regime for Greenfield pharmaceutical investment which at times takes upto 3-5 years and 30+ regulatory approvals.

The opening of pharma sector for FDI has directed lots of capital and interest into Indian pharmaceuticals from foreign investment point of view. However, critics point out that more than 90% of FDIs are currently for Brownfield Projects which has already led to the loss of local production of many important drugs. E.g. \$989 million during April 2012-April 2013 was Brownfield compared to just \$87.3 million for Greenfield investments.

Concerns over the recent spate of M & A in Indian Pharma Industry by foreign investors have been articulated at different forums.

Some of these concerns:

- Potential for drug prices to go up,
- Limited availability of high priced specialty products
- Limiting the power of government to grant Compulsory License (CL)
- Reduction in availability of generics (of the acquired company) in the market

Study Purpose

M&A can act as a source of capital, productivity and innovation but can potentially jeopardize the capability of Indian

pharmaceutical industry in relation to ‘Access to Medicines’, which is one of the major goals of the health system. “Access” in this context is defined as availability of quality and affordable existing and new essential medicines in India and other countries, especially developing economies. Therefore, an objective quantitative evaluation of effect of M&A is required to

suggest safeguards against the same without denying access of capital and technology to domestic players.

In the background of such scenario and recent inward M&A especially in niche segments (injectable, oncology etc.) it would be prudent to understand impact of M&A with special reference to access to quality essential drugs at affordable costs.

Government of UK’s Department for International Development (DFID) under its Knowledge Partnership Programme commissioned a review of recent M&As and assessed impact on key parameters. A framework for measuring impact was developed and agreed. The data for study was obtained from IMS Health proprietary data base on drug sales and pricing, annual reports. Similarly other secondary sources are accessed for gathering required information.

The present study covers only foreign owned companies acquiring domestic pharmaceutical companies which are covered under the purview of FDI. The study only covers deals completed till last year (therefore recent deals and domestic acquisitions are out of purview).

Primary information has been used to supplement the secondary analysis and bridge the gaps where ever it was possible. Along with this quantitative analysis, qualitative comments, annual and analyst reports, press releases were also studied to assess “commitment” and long term aspect of all areas under evaluation.

Around six acquisition case-studies have been included in the study, namely- (i) Ranbaxy’s acquisition by Daiichi Sankyo, (ii) Fresenius

Kabi's acquisition of Dabur Pharma (iii) Piramal Healthcare's acquisition by Abbott (iv) Matrix Laboratories' acquisition by Mylan (v) Generic Injectable Business of Orchid Chemicals by Hospira and (vi) Acquisition of Shantha Biotechnics by Sanofi Pasteur.

Three year period has been used for analysis before & after acquisition in each case. In some cases where data for three years pre and/or post was not available, analysis has been done on available time period and indicated in footnotes. Also, for few indicators such as new launches etc. post-acquisition data for more than three years has been analyzed as impact on these can be analyzed over a longer time frame.

The analytical framework captures and compares data from companies having undergone a complete, partial or business unit acquisition from global pharmaceutical companies. The framework is constructed along four broad areas of focus covering the range of company activities that experts consider most relevant to access to medicine. Within each area, the framework assesses performance along with commitment.

M&A in Indian Pharma Industry

Advantages of the Indian pharma:

1. Low cost of innovation and capital expenditure
2. Proven track record in bulk drug and formulation patents
3. Strong domestic support in production
4. Hub for contract and clinical research
5. Focus on reverse engineering and development of processes

India had opened the sector to foreign investments up to 100 percent on the automatic route (without prior approval either of the Government or the Reserve Bank of India) in 2002. However certain restrictions were imposed after an intense debate following a spate of acquisitions of Indian companies by global drug makers including the takeover of biggest domestic company Ranbaxy by Daichi Sankyo.

The government then introduced distinct norms for FDI in Greenfield and Brownfield projects amid fears that consumers in India will be denied cheap medicines if foreign multinational companies continued to buy large domestic pharma companies.

As a result, all forms of FDI including foreign portfolio investments in existing Indian pharma companies have since required prior approval from the Foreign Investment Promotion Board and need to meet certain conditions to ensure the local company

dependence on China for bulk drugs and is looking at measures to boost productivity in the sector.

During the last decade, Indian pharmaceutical companies have become the main source of low-priced quality generics for developing countries. For example, India has a dominant global market share of Antiretroviral (ARVs) (80%), pediatric ARVs (90%), anti-TB drugs (70%-80%), and Artemisinin-based Combination Therapy (ACTs) - (70%-80%).

India also provides up to 70% of vaccines procured by UNICEF for developing countries. Thus any disruption in pricing, availability and R&D efforts for low cost drugs have a potential impact on global public health especially in developing countries.

However, there is a need to strike a **balance between public health concerns of India and developing countries and attracting FDI** in the pharmaceutical sector.

The Indian pharmaceutical industry has developed through a range of governmental incentives and, foreign firms that have invested in the industry, have additionally contributed to the growth.

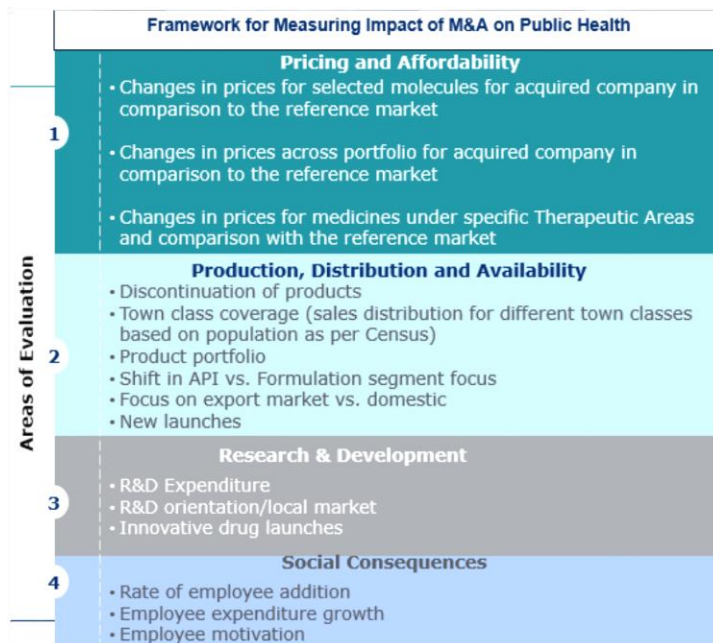
additionally contributed to the growth.

Firms with foreign ownership have been seen to experience **higher productivity levels**. Also, there is **expectation that this will lead to quicker access to patented medicines** for patients in India and developing countries since many of these acquirers may be holding patents. Also, possible technology transfer and quality focus of large MNC's can potentially raise profile for Indian pharma industry.

The cumulative effect of all these drivers makes the Indian pharma industry attractive to the foreign pharmaceutical majors.

Study findings

They are organized as per key elements such as pricing, availability, research, development and social consequence of recent M&As.



continues to produce essential drugs.

Investors also have to give a commitment to manufacture and make available essential drugs post acquisition for five years, besides increasing expenditure by five percent on research and development for diseases prevalent in India.

Non-compete clause (agreement not to enter into or start a similar profession or trade in competition against another firm) is not allowed either, except in special circumstances. Interestingly, Ranbaxy Laboratories, whose acquisition had fuelled strong protectionist concerns, has since been acquired by another large Indian firm, Sun Pharmaceuticals.

The government recently moved medical devices sector out of the approval route even in case of Brownfield investments, indicating it may not be averse to dropping some restrictions. India is keen to draw investments into the sector to reduce the country's

IMPACT OF MERGER & ACQUISITIONS IN INDIAN PHARMA ON PRODUCTION, ACCESS AND PRICING OF DRUGS

Merger and Acquisition- Foreign Acquisition in Indian Pharma Sector

Indian Company	Foreign Company	Amount (mn US\$)	Year
Matrix Lab	Mylan (USA)	736	Aug 2006
Dabur Pharma (Oncology)	FreseniusKabi (Singapore)	219	April 2008
Ranbaxy Labs	Daiichi Sankyo (Japan)	4600	June 2008
Shanta Biotech (Vaccines)	Sanofi Aventis (France)	783	June 2008
Orchid Chemicals (Injectables)	Hospira (USA)	400	Dec 2009
Piramal Healthcare	Abbott (USA)	3720	May 2010
Paras Pharmaceuticals	Reckitt Benckiser (UK)	726	Dec 2010
Wockhardt	Danone (France)	350	Sep 2011
Arch Pharmalabs	Mitsui (Japan)	26.7	Sept 2012

Impact of M&A in pharmaceutical sector on public health and society depends on four key levers - Pricing, Availability, R&D focus and social commitments. The overall impact based on our analysis is positive in terms of availability and affordability but some considerations and concerns on monopolization of certain molecules after these transactions. Key findings from study across these areas are:

Pricing

Pricing or affordability is one of the major attributes of access to medicines, which can be explained in terms of the ability of the patients to pay for the medicines. As per the relevance of the study, following indicators have been chosen to evaluate the impact of M&A on price of medicines:

- **Changes in price levels** across portfolio: The analysis of price variation on the products existing in the company portfolio suggests that all the companies included in the analysis have shown a decrease in price growth across portfolio during post acquisition period.
- **Therapeutic Area (TA) price change** for acquired company in comparison to market: The analysis suggests that the price levels at therapeutic area have decreased in overall context during post acquisition period.
- **Trends in price change for molecules** where acquired companies have high market share: The analysis of molecule wise price growth data suggests shown a negative impact of M&A i.e. price growth of molecules where acquired companies had high market share is higher during post acquisition period. E.g Losartan Potassium for high blood pressure.

Availability

Availability of required medicines by the patients at the right time is a critical element to ensure the access to medicines in India and other developing countries. To evaluate the impact of M&A on medicine availability, following parameters have been analysed:

- **Product Profile** (Focus on API): Sales of APIs have increased in post-acquisition period with a faster growth rate compared to pre-acquisition. This can be critical in reducing dependency on for raw materials
- **Domestic vs. Export focus:** Domestic sales and exports have both grown in post-acquisition period for companies under acquisition. However, during post acquisition; growth rate for exports has increased at a higher rate in all cases indicating higher focus on export.
- **Pace of new launches (new brands but non innovative molecules - incl. NLEM (National List of Essential Medicines) & Non-NLEM new launches):** The overall impact of M&A over the pace of new launches in India is positive as companies have added new products in portfolio.
- **Discontinuation of products:** The impact of M&A on discontinuation of product has shown a positive impact. Post-acquisition, number of overall and essential medicine discontinuations has both decreased. The products that were discontinued were having small market share and therefore did not impact availability.

- **Availability and sales of drugs in different town class levels:** (classification of towns and cities as per Census based on population) (Town class coverage): Post M&A, rate of growth for companies has increased for tier 1-2 towns; whereas, a lower growth rate is seen in lower town class as compared to pre-acquisition period. This can be attributed to industry view that lower tier markets are much more complex to penetrate and present less profitable opportunities in short term.

Research & Development

Investment in Research & Development and Innovation is one of the critical aspects of 'access to medicine'. To understand the impact of M&A on research and development following parameters have been studied during pre and post-acquisition period for companies:

- **R&D Expenditure:** R&D expenditure as a percentage of sales during pre and post-acquisition has been used to evaluate the impact of M&A on research and development. The analysis suggests that the overall impact of M&A over R&D is negative during post acquisition period, as most companies have reduced share of investment on R&D.
- **R&D - Local market orientation:** Couple of companies under consideration have launched a New Chemical Entities (NCE's) / newer drugs from their global portfolios based on local disease pattern. However, largely, the impact of M&A over R&D orientation has not been as per expectations but still can be termed as positive due to extremely low/negligible base of earlier locally oriented innovations.
- **Innovative drug (new molecules) launches:** The number of patented drugs introduced after acquisition is used to evaluate the impact of M&A on this areas. This has been found to be neutral as none of the companies under study have launched any innovative drug in post-acquisition phase.
- **Transfer of technology:** One of the critical expectations at time of allowing FDI into a particular sector is around potential technology gain that local companies receive from global acquirers. However, in case of Pharma M&A, there is no evidence that post acquisition, acquiring company has transferred process improvement, operation management practices, IT system and quality control measures to Indian companies. None of the studied parent companies have brought any significant technology pertaining to drug discovery in India.

Social Consequences

M&A brings a structural change in the organization that leads to consequences for individuals, productivity and quality. To understand social consequence of M&A in Indian pharmaceutical industry, following parameters have been studied:

- **Employment Generation:** The impact of M&A over the employment generation has been found positive. Post-acquisition companies have generated new job opportunities and appointed manpower from India which posed a positive impact.
- **Salaries and other employees' related expenditure per employee:** Post acquisition the average salary of the employees has been increased, but the analysis also found that the employee expenditure per employee has reduced. So the overall impact was found to be neutral for this parameter.

Recommendations and Conclusions

Key principles for designing any policy for minimizing negative and maximizing positive impact of M&A should be based on the desired outcome for patients in India and other developing countries and industry. From a patient perspective the desired outcome is better access to medicine.

From an industry perspective, the desired outcome is commercial sustainability and incentive for future innovation. The broader objective is around better health outcomes for all, a stronger economy and equitable access.

Interventions are required from industry on:

- **Pricing of Molecules with High Market Share for Acquired Companies:** Industry and enabling policy environment needs to be much more considerate to public health needs of India and other developing countries when it comes to setting prices of medicines especially in molecules where competition is lower and acquired companies have high market share.
- **Availability in Lower Town Classes:** From a commercial standpoint, lower income countries, lower tier markets and rural areas provide a tremendous opportunity for pharmaceutical companies. However, these require long term view and investment and are much tougher markets to penetrate due to lack of supporting infrastructure, supply chain and prescribing specialist doctors. Industry needs to participate in developing and sharing supporting infrastructure to ensure availability of medicines in rural areas is not impacted even after strategic shifts such as M&A.
- **Launch of Patented Drugs:** Industry needs to engage government in a dialogue to ensure commercial viability and premium is maintained on innovator drugs and at the same time access to critical drugs is not denied to patients in India and other developing countries. This will ensure one of the arguments in favour of M&A with regards to faster availability of patented drugs is validated.

- **Focus on R&D Specific to Developing Country Needs:** Industry should ensure that development of innovation ecosystem must be prioritized and areas such as nurturing R&D talent, supporting research education institutes must be top priority so that R&D focus is locally relevant

Suggested Policy Roadmap to Maximize Positive Public Health Impact of M&A in Pharmaceuticals Sector

This roadmap can serve as a framework for supplementing the existing mechanisms such as Competition Commission of India and FIPB and their respective guidelines to ensure specific issues related to pharmaceuticals are taken under consideration at the time of acquisition. For successful implementation of the framework it is suggested that a joint committee comprising of Government Officials, drawing from the likes of the Ministry of Health and Family Welfare, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority (NPPA), Department of Industrial Policy and Promotion (DIPP) and Competition Commission of India can be formed. This committee should take the framework forward to develop the detailed policy interventions for the country in consultation with the key stakeholders. Following are the suggested key items that the committee may consider:

- **Promote competition in molecules with high market share of one or two companies:** Identify molecules where competition is lower and public health priority of India and other developing countries is higher so that adequate incentives can be provided for private sector to increase competition in selected molecules with the expectation that adequate competition under existing pricing policy will ensure affordability.
- **Molecule level price monitoring post-acquisition for a defined time period:** In consultation with NPPA and Competition Commission of India (CCI), adequate capabilities and capacities are built to ensure molecule level price monitoring is possible for a defined time period after acquisition. This will ensure any molecule specific pricing shocks are minimized for India and other developing countries.
- **Incentivize Lower Town Class and Rural Availability:** Establish cost-effective methods to incentivize and support private sector (in terms of necessary supply chain and infrastructure requirements) to ensure quality medicines are available across India and in other developing countries.
- **Incentivize Availability of Innovator Drugs:** Even though price setting mechanisms of patented innovator drugs needs to be clearly laid out and in favour of ensuring affordable access, there should be adequate room for industry to ensure commercial viability and incentive for innovation. A representation mechanism should be formulated so that dialogue can be initiated with industry on this issue.
- **Harmonization among National Drug Regulatory Agencies in Developing Countries:** To ensure there is incentive and commercial pressure on pharmaceutical companies, there should be harmonized efforts from all developing countries to ensure new patented specialty products are timely launched at affordable prices in all countries
- **Incentivizing Exports to Meet Medicine Access Needs across the Globe:** With increasing focus of China to penetrate generic formulations market across developing countries, India has to incentivize exports and focus on export promotion to maintain market leadership and ensure access to medicines in these countries.

Very recently Government of India has allowed 100 percent FDI in medical devices sector to give a boost to manufacturing of medical devices in country. This along with policy initiatives for attracting FDIs is likely to give further impetus to M&As in India. Universal Health Coverage is going to one of the major sustainable development goal and access to quality essential medicines at affordable costs is going to be key element. Also, further market monitoring is required to understand implications of domestic acquisitions as well on access of medicines.

Recommendations as above should be taken on board for calibrating policy measures to minimize negative and maximize positive consequences.

KPP is a South-South cooperation programme promoting knowledge sharing in the areas of Food Security, Resource Scarcity and Climate Change; Health and Disease Control; Trade and Investment; and Women and Girls. KPP is funded by the Government of UK's Department for International Development (DFID) and managed by a consortium led by IPE Global Private Limited under its Knowledge Initiative. The main objective of KPP is 'Gathering and uptake of evidence on issues central to India's national development that have potential for replication in LICs and impact on global poverty'.

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