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

Introduction

- The Indian pharmaceutical industry ranks 14th in the world by value of pharmaceutical products and is highly fragmented, currently having more than 20,000 registered manufacturing units. Nearly 250 units are controlling 70% of the overall market.
- The pharmaceuticals sector in India is currently open for 100 per cent FDI in both Greenfield and Brownfield projects. 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.
- There is a need to strike a balance between public health concerns 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. Firms with foreign ownership have been seen to experience higher productivity levels.

- However, there have been concerns articulated at different forums over the sudden rush for M&A in Indian Pharmaceuticals Industry through FDI route.
- Considering access to affordable and quality essential medicines is an integral component of Universal Health Care, apprehensions about hiking drug prices, limited availability of high priced specialty products, limiting the power of government to grant Compulsory License (CL) and reduction in availability of generics (of the acquired company) in the market. In order to find answers to these questions an analytic study was commissioned under a DFID supported Knowledge Partnership Programme.

Study Methodology

- Six recent major acquisition cases in the pharmaceuticals sector were analysed using a framework. Analysis was carried out for three years before & after the acquisition in each company, to allow for sufficient grounding for conclusions. Some of the recent acquisitions were not considered due to limited post-acquisition data. Also, cases where only specific categories were acquired and these categories were not of public health importance (nutrition, consumer products, veterinary etc.) were not considered.

The framework is constructed along four broad areas of focus which cover the range of company activities that experts consider most relevant to access to medicine. These areas of focus are: Pricing, Production and Availability, Research and Development and Social Consequences and were studied before and after the acquisition to study the impact of M&A on these variables.

Overall Assessment Impact of M&A on Pharmaceuticals Sector

Pricing -Changes in price levels across portfolio(price increase much less than annual inflation) Positive -Therapeutic Area (TA) price growth for acquired company in comparison to market: Positive -Trends in price growth in selected molecules: Negative	**Research & Development** -R&D Expenditure (percentage to total sales): Negative -Local market orientation: Positive Innovative drug launches: Neutral -Transfer of technology: Neutral
Availability -Product Profile (Focus on API vs. Formulations): Positive (faster growth of APIs) -Domestic vs. Export focus: Negative -Pace of new launches: Positive -Discontinuation of products: Positive -Town class coverage: Negative -Product Portfolio Changes: Neutral	**Social Consequences** -Employment Generation: Positive - Salaries and other employees' related expenditure per employee: Neutral

(Positive : Favorable, Negative :Not Favorable Neutral: No Impact)

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Recommendations for Industry

On Pricing

• Monitor Pricing in Molecules with Lower Degree of Competition: There is room for more affordable pricing where companies enjoy high market share and prices need to be rationalized for ensuring patient affordability.

The study highlights high price growth in specific molecules where the acquired company had high market share and low competition.

On Availability

• Industry needs to take a long term view on sharing supporting infrastructure for SCM in Tier-III cities and big towns. The focus of companies after acquisition has increased on metros and Tier I&II towns.

The rate of growth in lower tier towns and rural areas has decreased in comparison to market growth which can be partially attributed to lesser focus from companies due to limitations of prescribing potential and purchasing power in rural areas.

On R&D Initiatives

• Industry should focus on increasing investments in R&D for drugs required to treat common diseases.

R&D investments for acquired companies have come down post-acquisition due to increased focus on generics and API manufacturing. However much would also depend on the guidelines for conducting clinical trials.

Social Consequences

• Managing Employee Distress during M&A: Companies and line managers should develop a plan to communicate the relevant changes to all employees. Managers typically communicate too little or the wrong information, or communicate too late to mitigate uncertainty and anxiety.

Policy Directions

Overall Pharmaceuticals Sector

• Incentivize timely innovative drug launches.

• Incentivize access in lower town classes/rural areas for pharmaceutical companies.

• Price monitoring at a molecule level where market share is greater than a threshold for combined entity to negate any monopolistic/oligopolistic effect.

On Pricing

• Monitor Monopolistic/Oligopolistic Nature of Specific Molecule markets in country.

• Coordination between Competition Commission of India and National Pharma Pricing Authority on cartelization of certain molecules, use of anti-compete clause and to limit concentration in post-acquisition pricing strategies.

On Availability

• Incentivize availability in town and rural areas; focus on availability of doctors/specialists at public health facilities.

On R&D Initiatives

• Incentivize availability of innovative drugs within a stipulated time to ensure patients in India get access to super specialty drugs.

• Address perception of "low confidence on Indian IP regime" owing to provisions of compulsory licensing, denial of patents for incremental innovation etc. and providing appropriate guidelines and grievance redressal mechanisms. Move for pre-authorisation meeting of all stakeholders and dedicated benches in courts are in the right direction.

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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