Rating Methodology - Pharmaceutical Sector

[In supersession of "Rating Methodology - Pharmaceutical Sector" issued in December 2016]

Industry Overview

Globally, the Pharmaceutical Industry is considered as one of the most defensive sectors, largely immune to the economic cycles. North America, Europe and Japan are the three largest pharmaceutical markets in the world with a combined share of over 80%. These markets are classified as 'Regulated Markets' on account of stringent healthcare regulatory norms prevailing in the countries belonging to these regions. While growth in the top-3 markets has moderated over the years, emerging markets of Asia and Latin America are witnessing higher growth rates than the industry average due to a number of factors.

The Indian Pharmaceutical Industry (IPI) has grown at a robust pace over the past decade with strong growth in exports. The IPI is not only meeting the majority of the demand for drugs in India but is also increasingly catering to the global demand. The dynamics of the IPI changed following the recognition of product patents from 2005 onwards. The emergence of new threats and opportunities has significantly altered the risk profiles of Indian pharmaceutical companies. CARE believes that the following factors are critical determinants of credit risk associated with Indian pharmaceutical companies.

- Product portfolio & segments catered
- Domestic market position
- Presence in export markets
- R&D focus
- Legal and regulatory risk
- Management competence
- Financial risk
- Project specific risk

1. Product Portfolio & Segments Catered

Based on products manufactured, the IPI can be broadly classified into API (active pharmaceutical ingredients)/bulk drug companies, finished dosage formulation companies and integrated companies manufacturing both formulations and APIs.

CARE looks at therapeutic segmentation of product portfolio of formulations as well as bulk drug companies. While acute therapeutic classes (like anti-infectives and pain management) constitute a major share of pharmaceutical sales in India and other less-regulated markets, chronic therapeutic classes (like cardiovascular and anti-depressants) command a major share of the regulated markets. In India, chronic therapeutic classes have been growing at a higher rate compared to acute therapies and their share is likely to increase in the future due

to changing lifestyle of the Indian population. Companies having products for treatment of chronic diseases in their portfolio are viewed favourably by CARE.

Formulations manufactured by IPI can be further classified into branded and generic formulations. CARE examines the strength of the branded product portfolio of formulation companies for domestic and less-regulated markets. CARE also looks at the market share of formulations (branded as well as generic) within its therapeutic segment in order to assess the company's market position. Further, companies manufacturing niche/complex products can command better margins due to relatively low level of competition in such product segments.

2. Domestic Market Position

Revenue from domestic market constitute significant portion of total revenue for many Indian pharmaceutical companies. Stability of revenue stream coupled with growth prospects of the domestic market are critical to overall growth of such companies.

For formulation companies, CARE assesses their position by looking at their overall market share in the Indian formulation market. Apart from strength of branded product portfolio, CARE also looks at the marketing and distribution setup of a company which plays a key role with regards to market penetration and coverage. For API companies in the domestic market, CARE considers factors like cost efficiency, manufacturing capabilities, customer base and concentration, product concentration and market share in the domestic market for products manufactured. Though the share of revenue from domestic market has been declining for most top pharma companies due to diversification to export markets, CARE believes that companies would continue to focus on

the domestic market in order to drive revenue growth in the future as the same offers good potential in light of changing lifestyles & demographics and improving healthcare access.

3. Presence in Export Markets

Export markets for Indian pharma companies can be divided into two categories based on degree of regulation pertaining to drug quality, manufacturing standards and patents. Regulated markets (like US, UK, Europe {excl. Russia & CIS countries}, Japan, Canada, Australia) are those where such regulation is more stringent, while less-regulated markets (like Latin America, Africa, Russia and CIS countries) have lesser or negligible regulation. Entry into regulated markets requires strict compliance with patent and drug laws of those countries and serves as an entry barrier for small and mid-size pharmaceutical companies. Prices of drugs are highest in the regulated markets due to patent protection and other factors compared to the less-regulated markets. Moreover, regulated markets offer huge opportunity for generic companies due to large number of patent expirations scheduled in the coming 5 years.

CARE looks at risks and rewards associated with the two broad strategies followed by Indian pharma companies for regulated markets viz. generics and contract research and manufacturing services (CRAMS). CARE favourably views companies which have received

approvals from regulatory authorities like USFDA, MHRA, EDQM etc. as this not only allows these companies to tap the generic opportunity but also opens up opportunities in the CRAMS business.

For companies pursuing the generic opportunity in the regulated markets, CARE looks at the number of ANDA (abbreviated new drug application) filings and approvals received. While ANDAs filed under Para-III allow companies to launch generic drug on the day the patent expires, Para-IV filings, if successful, allow companies to launch generic drug before expiration of patent by challenging and invalidating the same. However, Para-IV filings expose generic companies to significant litigation risk.

4. R&D Focus

R&D has assumed greater significance for Indian pharma companies with the advent of product patent regime. Indian companies have started investing in R&D infrastructure in order to support their overall business strategies with respect to products and markets. CARE looks at the trend in R&D expenditure as a percentage of sales and compares the same with industry peers. CARE also looks at the effectiveness of company's R&D function vis-à-vis its pursued growth strategy. A company's R&D function would be driven by its current and future strategy with regards to products and markets. The following broad R&D strategies are followed by IPI.

(a) R&D for domestic and less-regulated markets:

For these markets the focus is on development of new combinations of existing formulations, formulations for new therapy classes and APIs. Indian pharma companies have grown consistently by launching new products in the domestic market and responding to the changing demand.

(b) R&D for regulated markets:

Higher investment is required in R&D for supporting company's presence in the regulated markets. For companies following the generic strategy, key focus areas include research for ANDAs, DMFs and other such regulatory filings. For companies offering CRAMS, R&D is focused on process research, synthetic chemistry and other services that they offer to global pharma companies for partnering them for early stage drug discovery and development. At the apex of the R&D pyramid is research pertaining to NCE (new chemical entity) and NDDS (novel drug delivery system). This involves development of a novel drug which is a likely candidate for being granted a patent and becoming a blockbuster. This also entails development of a novel delivery system for an existing drug. Since, new drug development activity is characterized by huge costs and low success rates it is generally not feasible for a single company to take a molecule from lab to the market. Hence, it looks for partners to do so by out-licensing a molecule after a certain stage of development to another company which takes up further development of the drug and eventually to the market. The new product patent regime encourages companies to take up NCE research; however, the strategy is highly risky due to uncertainties associated with it.

5. Legal and Regulatory Risk

CARE assesses the overall impact of the regulatory environment in the markets in which companies operate. In the domestic market, the prices of essential drugs are controlled by the DPCO (Drug Price Control Order), 1995. CARE looks at the extent of price control on the domestic product portfolio of the company.

The current patent law in India and similar laws in other countries give rise to litigations which can hamper a company's plans to launch new products and cater to new markets. In India, the foreign pharmaceutical companies can launch patented molecules, which would restrict Indian companies to manufacture and sell the generic version of such products in the Indian market, thereby curtailing their growth opportunity.

However, the penetration of global patented molecules in India has been very low so far .For companies having presence in the regulated markets, stricter compliance is required with regards to drug quality, manufacturing process, patents and other related regulations. Non-compliance can result into non-approval of company's regulatory submissions which in turn would restrict company's presence in these markets. Companies having ANDA filings under Para-IV are subject to significant litigation risk as they look to invalidate the innovator company's existing patent before its expiration. For CRAMS players, non-compliance with manufacturing processes and drug quality can lead to termination of supply contracts and regulatory authorities imposing other penalties. With increasing emphasis on use of generics by Governments in the regulated markets and the emergence of India in the global generic space, Indian generic companies are being subject to greater scrutiny by the regulatory authorities in the developed markets. Hence, Indian companies having presence in the generic space in the regulated markets are exposed to risk of non-compliance with the regulatory norms of those countries resulting in banning of products which in turn may disrupt their operations in the short-term as well as hurt their reputation in the regulated markets. CARE looks at instances of non-compliance raised by regulatory authorities in the past, and the company's response to the same, in order to access this risk.

For API manufacturers, non-compliance with regards to laid down environmental & pollution norms could attract action from the concerned regulatory authorities which may even lead to shut-down of their units. This risk is relatively high in case of small & mid-size API manufacturers

compared to organized companies who generally make necessary investments in pollution control infrastructure.

6. Management Competence

Management competence assumes greater importance in the Indian pharmaceutical industry which is constantly evolving and becoming highly integrated with the global pharmaceutical industry. Top management's composition, industry experience, technical prowess and vision are critical to developing business strategies which will drive the long-term growth of the company. An experienced and well qualified management is important for companies to adapt to the dynamic nature of the industry and respond to the developing trends. CARE looks at the past track record of the management in devising strategies and successfully implementing the same. CARE interacts with the top management during the rating process in order to understand the challenges and opportunities facing the company and likely strategies that will drive the growth of the company.

7. Financial Risk

CARE follows its standard ratio analysis methodology for manufacturing companies in order to assess the financial risk of companies in the pharmaceutical sector. *Refer to CARE's Rating Methodology for Manufacturing Companies for this section.*

8. Project Specific Risk

For pharmaceutical companies, nature of capital expenditure would be driven by the strategic decision pertaining to products and markets that the company wants to enter. In the recent past, many Indian pharma companies have acquired overseas assets for expanding their product/market reach and gaining access to intellectual property of such companies. CARE looks at the realization of the envisaged benefits and the extent of debt funding used for such acquisitions.

For capex pertaining to setting up of new manufacturing facility, necessary regulatory approvals are required. If the facility is being setup for catering to the regulated markets, any delay in receiving the approvals can delay the project which in turn can put pressure on cash flows if such a project is significantly debt funded.

Pharma companies also invest in development of new products and processes which get reflected as intangible assets on the balance sheet. CARE assesses the riskiness of such development expenditure based on the certainty of outcome of such activity. Significant time and costs are involved for development of product pipeline for biogenerics (biosimilars), which despite being generics, have to undergo a long development and approval process. Funding of such investments through debt may lead to cash flow mismatches if the development pipeline does not progress as envisaged. Overall, project specific risk for pharma companies is posed by acquisitions, investment in new facilities and development of new products.

Conclusion

The changes in the regulatory environment in the domestic market and the state of the global pharmaceutical industry are shaping the future for IPI. In the current product patent regime and increasing competition in the domestic market, it is imperative for Indian pharmaceutical companies to diversify geographically as introduction of new products would become more and more difficult. Companies focusing on generics in the regulated markets and CRAMS are better placed than those focusing solely on domestic market.

For companies in the domestic market, responding to the changing demand and new therapeutic segments would be critical for growth. Formulation manufacturers, being closest to the market, are at a higher point in the pharmaceutical value chain compared to API and intermediate manufacturers and hence, are likely to have a superior business risk profile. Overall credit risk profiles of companies in the pharmaceutical sector would be driven by effective geographic diversification and strengthening of position in the domestic market, both supported by strong R&D function.

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