Rating Methodology – Pharmaceutical Sector

[In supersession of "Rating Methodology - Pharmaceutical Sector" issued in June 2017]

Industry Overview

Globally, the pharmaceutical industry is considered as one of the defensive sectors, largely immune to the economic cycle. The global pharmaceutical industry is one of the largest industries in the world consisting of branded, generic, finished dosage formulations and non-prescription or over-the-counter (OTC) medicine. The global pharma industry is historically dominated by the United States of America (USA), Western Europe and Asia Pacific countries. The developed markets led by USA, the dominant five European markets (France, Germany, Italy, Spain and United Kingdom) and Japan are the principal countries that have driven the growth, while the emerging pharmaceutical markets will contribute to growth over the next five years.

Indian Pharmaceutical Industry (IPI) has achieved high growth rate largely in terms of volume during the last two decades. Indian pharmaceutical sector has a strong footprint globally in generic segment and is the third largest in terms of volume and thirteenth largest in terms of value. Out of the total exports by Indian pharmaceutical companies, sales to the USA were about one third in FY2018-19 (refers to the period April 1 to March 31). Today, Indian pharmaceutical companies are facing a variety of challenges which are leading to change in their business dynamics. The critical one in the current scenario is drug regulatory system and regulatory legislations, in both domestic as well as in export markets.

Rating Methodology

CARE Ratings has a detailed methodology for rating of companies belonging to the manufacturing sector. CARE's rating process begins with the evaluation of the economy/industry in which the company operates, followed by the assessment of the business risk factors specific to the company. This is followed by an assessment of the financial and project-related risk factors as well as the quality of the management. This methodology is followed while analysing all the industries that come under the purview of the manufacturing sector. However, considering the size and diversity of the manufacturing

sector, CARE Ratings has developed methodologies specific to various industries within the sector. These methodologies attempt to bring out factors, over and above those mentioned in the broad methodology, which are considered while analysing companies belonging to a particular industry.

CARE Ratings considers the following factors as critical determinants of credit risk associated with Indian pharmaceutical companies.

1. Business/ Operations Risk: Business segment and product portfolio, Geographical diversification in terms of presence in regulated and semi-regulated market, R&D focus, Regulatory and Legal compliances (both domestic and exports)
2. Financial position
3. Project-specific challenges

1. Business/ Operations Risk

1.1 Business Segment and Product Portfolio

- Based on the business segment, the companies are broadly classified into bulk drug / Active Pharmaceutical Ingredients (APIs) manufacturing companies, formulation manufacturing companies or companies having integrated operation, ie, engaged in manufacturing of APIs and formulations as well as into contract manufacturing. Bulk drugs are APIs used to manufacture formulations.
- Therapeutic segments: CARE Ratings looks into the therapeutic segmentation of products, viz, Acute or Chronic. Acute therapeutic segment (like anti- infective and pain management) constitutes major share of pharmaceutical sales in domestic market as well as exports in less regulated markets. On the other hand, the chronic therapeutic segments (like cardiovascular and anti-depressants) command a major share in the regulated markets. Companies having products largely in chronic segment are viewed favourably as these products provide long-term sustainability to their revenue visibility. Further, while analysing a company based on therapeutic segment, CARE Ratings looks into the details regarding the company's presence in different therapeutic segments, percentage of the company's revenue from top therapeutic segments, market share in particular therapeutic segment, degree of criticality of the top therapeutic segments and company's past track record and future strategy to diversify or broaden its therapeutic presence.

- Product portfolio: CARE Ratings also analyses the product portfolio of the pharmaceutical company, total number of products in its portfolio, % of total revenue from top 10 products, diversity of products in terms of dosage form, company's past track record of developing and adding new products in product portfolio and pipeline of products for future growth prospects. In addition to it, CARE Ratings also analyses the year on year growth rate of existing products in terms of value as well as volume which indicates the product's life cycle.
- Therapeutic-wise and product-wise analysis helps in better understanding about the sustainability of revenue and profitability going forward.
- Formulation companies: Additionally, while analysing formulation companies, it is important to assess their market positioning by understanding the company's market share in particular therapeutic segment as well as diversification in the product portfolio. This will enable assessment of the stability or sustainability of its future growth. Moreover, CARE Ratings considers the marketing and distribution setup of the company which plays a key role in assessing the market penetration and future growth prospects of the company. The formulation companies can be classified into patented and generic formulations. Further, generic formulations can be further divided into branded and non-branded in the Indian context. Indian Pharmaceutical companies have large presence in generic business. CARE Ratings looks favourably at companies having branded generic formulation as they command higher margins with better market positioning in particular therapeutic segments in light of low entry barriers.
- Bulk drug/ API companies: The bulk drug/API companies are relatively capital intensive & fragmented in nature with threats from cheaper imports; CARE Ratings also analyses the cost efficiency, technical up gradation of plant, manufacturing capabilities, third party tie-ups, customer base and its diversification, product concentration, etc. Over dependence for the raw material on any one country or few suppliers can create significant supplier concentration risk for the company. Diversification in supplier base without geographical concentration is viewed favourably by CARE Ratings.

1.2 Geographical Diversification

- Indian pharmaceutical company's revenue is derived from domestic sales or export sales. The companies with diversified revenue streams, ie, exports to different markets, are considered favourably as they provide more opportunity for growth as well as mitigate the risk related to any change in the regulation in any particular market. Furthermore, since last couple of years, it is observed that the companies having better capabilities gradually diversify revenue stream to exports market. However, the companies would also continue to focus on the domestic market in order to derive revenue growth on account of potential growth opportunities available backed by lifestyle diseases, demographics, increased healthcare awareness, improving infrastructure and various government incentives.
- On the basis of export markets, Indian pharmaceutical companies can be broadly divided into those who export to regulated markets or those that export to semi-regulated markets. Both these markets have different dynamics in terms of regulation, competition, quality, manufacturing standards, patents, etc. Regulated markets (like USA, UK, Japan, Canada, Europe {excl. Russia and CIS countries}, and Australia) are those where regulations are more stringent, while less regulated markets (like Latin America, Africa, Russia & CIS countries) have less stringent regulations. There is a trade-off between the risk and return as far as exports to regulated market or to semi-regulated market are considered.
- For exports to the regulated market, companies earn a higher profitability; however, they are required to follow more stringent regulation compliances related to patent and drug laws of those countries. Moreover, regulated market offers Indian pharmaceutical companies a huge opportunity to grow in the generic segment on back of patent expirations scheduled in the coming years. To analyse the company's strength and presence in regulated market, CARE Ratings takes into cognizance receipt of regulatory approvals from various regulatory authorities like The United State Food and Drug Administration (USFDA), The Medicines and Healthcare Products Regulatory Agency (MHRA), The European Directorate for the Quality of Medicines & Healthcare (EDQM), etc. Approvals from regulatory authorities such as these not only allow these companies to tap the generic opportunity but also open up opportunity in the Contract Research and Manufacturing Services (CRAMS) business. Furthermore, for companies pursuing

the generic opportunity in the regulated markets, CARE Ratings looks at the number of ANDA (Abbreviated New Drugs Application) filing and approvals received. Apart from number of ANDAs, CARE Ratings also analyses the quality of a company's product pipeline. CARE Ratings considers the size of the therapeutic segment, the level of unmet medical need, competitive environment, and government policy on healthcare amongst other factors in particular country.

1.3 Research and Development (R&D) Focus

- In the current scenario, with increasing competition in the domestic as well as global markets and changing business dynamics of pharmaceutical sectors, there is a need for companies to focus more on R&D. This plays a significant role in diversification of therapeutic segments/ product portfolios with improvement in the quality of products which is important for sustainable growth in the long run to achieve overall business strategies with respect to products and markets.
- CARE Ratings looks at the trend in R&D expenditure as a percentage of sales and compares the same with industry averages as well as comparable peers. CARE Ratings also looks into the past track record of company's capability to develop new molecule or to develop new dosage forms/ new drug delivery system or develop new combination of drug, etc. Knowing R&D budget as a percent of sales helps understand if the company is creating strong pipeline of future growth. It is observed that in last couple of years Indian pharmaceutical companies have increased their R&D expenses to establish niche, complex and speciality product portfolios for the future and sustain the market position in competitive business scenario.
- R&D for domestic and less regulated markets: For these markets, the focus is on the development of new combination of existing formulation as well as developing formulation for new therapy classes and APIs. Indian pharmaceutical companies have grown consistently by launching new products in the domestic market and responding to the changing demand.
- R&D for regulated market: Higher investment is required in R&D for supporting company's presence in the regulated markets. For companies following the generic strategy, key focus area includes research for ANDAs, Drug Master Files (DMFs) and other such regulatory filings. CARE Ratings in its analysis assesses the product

development of the entity across various therapeutic segments and its focus areas on recent off-patent drug, combination of products, etc.

- 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 developments.
- 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 drug. This also may entail development of a novel delivery system for an existing drug. Since new drug development activity is characterised by huge cost and low success rates, it is generally not feasible for a single company to take a molecule from lab to 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. This arrangement helps the companies to mitigate the risk to certain extent.
- Generally, mid to large-sized pharmaceutical companies in India spend nearly 7%-9% of their annual sales towards R&D activities. Hence, companies having relatively higher R&D spend are generally expected to provide greater sustainability to business operations.

1.4 Regulatory and Legal Compliances

- In the current scenario, regulatory and legal compliance is one of the big challenges for Indian pharmaceutical companies operating in domestic as well as export markets. Regulatory aspects is extremely crucial for rapid and ongoing changes at the global level, largely with reference to good manufacturing practices (GMP), good clinical practices (GCP) and good laboratory practices (GLP). Along with that, it is an extremely important aspect for healthy supply of quality drugs at affordable prices. In the domestic market, price controls and delays in getting product approvals have been pulling down pharma sales growth in the recent past.
- Part of rating exercise involves assessing the track record of inspections carried out at the manufacturing facilities by various regulatory authorities of countries to which the products are exported such as USFDA for suppliers to USA market, EDQM for European market, MHRA for UK, ANVISA for Brazil, etc. Further, post such inspections, the observations if any made by the regulatory authorities along with company's response

and remedial measures taken by it are evaluated. CARE Ratings analyse the instances of any product re-call in past as well as any instances of ban or import alert for any of the manufacturing facility of the companies by any regulators and the company's response to the same and access the risk accordingly.

- CARE Ratings also evaluates the revenue share contributed by a specific manufacturing facility and the products affected due to failure in observing the regulatory compliances and carries out the sensitivity analysis accordingly. Since the legal cost of any such litigation and the time for re-inspection are high, the revenue and profitability of the companies may be impacted; hence, trigger of such regulatory-concerned events are critical from the credit perspective. Moreover, the company having multiple manufacturing plants/ facilities with each plant having regulatory approvals, and capability of manufacturing variety of products is generally viewed favourably. In the domestic market, the prices of essential drugs are controlled by the Drug Price Control Order (DPCO). CARE Ratings looks at the extent of price control on the domestic product portfolio of the company vis-á-vis its impact on profitability. Furthermore, the National Pharmaceutical Pricing Authority (NPPA), which was set up in 1997 to implement DPCO, announced the DPCO 2013. By virtue of that order, the National List of Essential Medicines (NLEM) expanded to more than 800 formulations as on March 31, 2019, from just 74 under the DPCO 1995. CARE Ratings analyses the company's revenue and the percentage share of revenue it derives from NLEM products which restricts its pricing flexibility.
- For companies having presence in the regulated market, stricter compliance is required with regards to drug quality, manufacturing process, patent and other related regulations. Non-compliance can result in non-approval of company's regulatory submission which in turn would restrict company's presence in these markets. Companies having ANDA filing 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 generic by Governments in the regulated market and the emergence of India as a key drug manufacturer in the global generic space, Indian generic companies are being subject to greater scrutiny by the regulatory

authorities of developed markets. Indian companies having presence in generic space in the regulated markets are exposed to risk of non-compliance with 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.

- For API manufacturing companies, non-compliance with respect to laid down environmental and pollution control norms could attract action from the concerned regulatory authorities which may even lead to shut down of their units. The risk is relatively high in case of small and mid-size API manufacturing companies compared to organised companies that generally make necessary investment in pollution control infrastructure. Recent changes in environment rules in China have led to disruption in production in China and in turn increased the cost of raw material for Indian pharma companies. Hence, companies having vertically integrated operation with relatively low reliance on import provide greater operating flexibility and sustained profitability.

2. Financial Risk

- CARE Ratings 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.*

3. Project Specific Risk

- For pharmaceutical companies, nature of capital expenditure would be driven by the strategic decision pertaining to products and market that the company wants to cater.
- In the recent past, many Indian pharmaceutical companies have acquired overseas assets for expanding their product/ market reach and gaining access to intellectual property of such companies. CARE Ratings looks at the realisation of the envisaged benefit and the extent of debt funding used for such acquisition.
- For capital expenditure 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 exert pressure on its cash flows especially if such project is significantly debt funded.

Conclusion

Overall credit risk profile of companies in pharmaceutical sector is driven by its relative position in the domestic as well as in export markets, geographical diversification and presence across therapeutic segments, its product portfolio, and the ability to handle the regulatory challenges and focus on R&D.

CARE Ratings analyses each of the above factors to arrive at the overall assessment of credit quality of the Issuer. Credit rating is a futuristic assessment and the rating outcome is ultimately an assessment of the fundamentals and the probabilities of change in the fundamentals in future. Moreover, for arriving at the rating outcome, CARE Ratings also considers future estimation of company's financials based on past trends and future strategies, competition, industry trends, economic condition and other considerations.

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