Rating Methodology – Pharmaceuticals

[Issued in July 2022]

Background

Globally, the pharmaceutical industry is considered 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 the 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 a high growth rate largely in terms of volume during the last two decades. Indian pharmaceutical sector has a strong footprint globally in the generic segment and is the third largest in terms of volume and thirteenth largest in terms of value. The present market size of IPI stands at around USD 47-49 billion in FY22 (refers to the period April 1 to March 31) which grew at around 5-7% in FY22 over FY21. The pharmaceutical exports stood at USD 24.60 billion in FY22. The growth of IPI was largely driven by higher domestic consumption while export sales remained stable. Further, the export to the United States of America (USA) constituted nearly 34% of total exports during FY22 registered a growth of 2% in USD terms while export to the Rest of the Word (ROW) saw a decline of 7%.

Today, Indian pharmaceutical companies are facing a variety of challenges which are leading to changes in their business dynamics. The critical one in the current scenario is the drug regulatory system and regulatory legislations, in both domestic as well as in export markets. Apart from that, for long-term sustainable growth, the industry must boost the domestic manufacturing for bulk drugs, intermediates & key starting materials (KSM) & gradually reduce its dependency on imports from a particular country or geography. The government of India has already started to incentivise domestic bulk drug manufacturing by way of a production-linked incentive scheme and dedicated bulk drug parks with common infrastructure.

Rating Methodology

CARE Ratings Limited (CARE Ratings) has a detailed methodology for rating companies belonging to the manufacturing sector. CARE Ratings' 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 is considered while analysing companies belonging to an 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 the regulated and semi-regulated markets, R&D focus, regulatory and legal compliances (both domestic and exports)

2. Financial position
3. Project-specific challenges
4. Environmental, social and governance (ESG) risk factors

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, i.e., engaged in the manufacturing of APIs and formulations as well as in 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. The acute therapeutic segment (like anti-infective and pain management) constitutes a major share of pharmaceutical sales in the domestic market as well as exports in lessregulated 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 the chronic segment are viewed favourably as these products provide long-term sustainability to their revenue visibility. Furthermore, 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 the particular therapeutic segment, degree of criticality of the top therapeutic segments and past track record and future strategy of the company to diversify or broaden its therapeutic presence.

Product portfolio: CARE Ratings also analyses the product portfolio of the pharmaceutical company i.e., the total number of products in the portfolio, percentage of the total revenue from the top 10 products, diversity of products in terms of dosage form, past track record of the company in developing and adding new products in product portfolio and pipeline of products for future growth prospects. CARE Ratings 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. In addition to it, CARE Rating analyses the expected launch of new products during the year, the market size of those products and expected revenue growth from new products. A company's ability to produce speciality or complex products, such as injectable, topical drugs, and biosimilars are also viewed favourably.

Therapeutic-wise and product-wise analysis help in better understanding 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 the particular

therapeutic segment as well as diversification in the product portfolio. This will enable the 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, branded generic and generic formulations. Indian Pharmaceutical companies have a large presence in branded generic and generic business. CARE Ratings looks favourably at companies having branded generic formulations as they command higher margins with better market positioning in particular therapeutic segments in light of low entry barriers. Moreover, to assess the operating efficiency of the formulation companies, CARE Ratings analyses the gross margin and productivity of its sales forces.

Bulk drug/ API companies: The bulk drug/API companies are relatively capital intensive & fragmented with threats from cheaper imports; CARE Ratings also analyses the cost efficiency, technical upgradation of plant, manufacturing capabilities, third-party tie-ups, customer base and its diversification, product concentration, etc. CARE Ratings analyses the revenue from top products and customers to arrive at concentration risk. Over-dependence for the raw material on a particular country or few suppliers can create significant supplier concentration risk for the company. The Indian pharma companies are heavily dependent on China for their raw material requirement i.e., KSM and Bulk drug/ API. Over FY18-FY22, import of KSM and API from China accounts for nearly 66-68 per cent of total imports of KSM/ API. During the Covid-19 pandemic, Indian pharma companies faced supply disruption due to Covid-19-led lockdown in China. Diversification in supplier base across geographies is viewed favourably by CARE Ratings.

1.2 Geographical Diversification

The revenue of Indian pharmaceutical companies is derived from domestic sales or export sales. The companies with diversified revenue streams, i.e., 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 market.

Based on export markets, Indian pharmaceutical companies can be broadly divided into those that 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 are those where regulations are more stringent, while lessregulated markets have less-stringent regulations. There is a trade-off between the risk and return as far as exports to a regulated market or a semi-regulated market are considered.

For exports to the regulated market, companies earn higher profitability; however, they are required to follow more stringent regulation compliances related to patent and drug laws of those countries. Moreover, the regulated market offers Indian pharmaceutical companies a huge opportunity to grow in the generic segment on the back of patent expirations scheduled in the coming years. To analyse the company's strength and presence in a regulated market, CARE Ratings takes into cognizance receipt of regulatory approvals from various regulatory authorities of respective nations. Approvals from regulatory authorities 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) and approvals received. Apart from several ANDAs, CARE Ratings also analyses the quality of a company's product pipeline.

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 sector, there is a need for companies to focus more on R&D. This plays a significant role in the 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 concerning 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 the company's capability to develop new molecules or to develop new dosage forms/ new drug delivery systems or develop a new combination of drugs, etc. Knowing the R&D budget as a percentage of sales helps understand if the company is creating a strong pipeline of future growth. It is observed that in the 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 a competitive business scenario.

R&D for domestic and less regulated markets: For these markets, the focus is on the development of a new combination of existing formulations as well as developing formulations 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 the regulated market: Higher investment is required in R&D for supporting the company's presence in the regulated markets. For companies following the generic strategy, the 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 capability of the entity across various therapeutic segments and its focus areas on the recent off-patent drugs, 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 with them for early-stage drug discovery and developments.

At the apex of the R&D pyramid, is research about New Chemical Entity (NCE) and Novel Drug Delivery System (NDDS). This involves the development of a novel drug which is a likely candidate for being granted a patent and becoming a blockbuster drug. This also may entail the development of a novel delivery system for an existing drug. Since new drug development activity is characterised by huge costs and low success rates, it is viewed carefully.

Generally, mid to large-sized pharmaceutical companies in India spend nearly 6%-9% of their annual sales on R&D activities, thus the companies having relatively higher R&D spend are generally expected to provide greater sustainability to business operations.

1.4 Manufacturing facilities and Regulatory and Legal Compliances

In the current scenario, regulatory and legal compliance is one of the larger challenges for Indian pharmaceutical companies operating in domestic as well as in export markets. The regulatory aspect is extremely crucial given the rapid changes at the global level, largely concerning good manufacturing practices (GMP), good clinical practices (GCP) and good laboratory practices (GLP).

Part of the rating exercise involves assessing the performance track record on inspections carried out at the manufacturing facilities by various regulatory authorities of respective countries. Furthermore, post such inspections, the observations, if any, made by the regulatory authorities along with the company's response and remedial measures taken by it are evaluated. CARE Ratings analyses the instances of any product recall in the past, as well as any instances of ban or import alert for any of the manufacturing facilities of the companies by any regulators and the company's response to the same.

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 reinspection is high, the revenue and profitability of the companies may be impacted; hence, the trigger of such regulatory-concerned events are critical from the credit perspective. Companies having multiple manufacturing plants/facilities with each plant having regulatory approvals, and capability to manufacture a variety of products is generally viewed favourably. Companies having only a single manufacturing facility carry a risk of asset concentration. Force majeure incidents, warning letters, import alerts, labour unrest, etc., may disrupt the company's operation significantly 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. CARE Ratings analyses the company's revenue and the percentage share of revenue it derives from the National List of Essential Medicines (NLEM) products which restricts its pricing flexibility. The phenomenon to bring down the prices of generics formulations through various price control measures is also observed in the developed markets. Further in the prominent developed markets, it is witnessed that the consolidation of the supply chain in the hands of a few large distributors also puts pressure on product pricing.

The 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.

For API manufacturing companies, non-compliance with respect to the laid-down environmental and pollution control norms could attract action from the concerned regulatory authorities which may even lead to shutting down of their units. The risk is relatively high in the case of small and

mid-size API manufacturing companies compared to organised companies that generally make the necessary investment in pollution control infrastructure. It is observed that the changes in environmental rules in major economies have led to disruption in production and increased the cost of raw materials for Indian pharma companies. Hence, companies having a vertically integrated operation with relatively low reliance on imports have provided greater operating flexibility and sustained profitability.

2. Financial Risk

CARE Ratings follows its standard ratio analysis methodology for manufacturing companies to assess the financial risk of companies in the pharmaceutical sector. Refer to CARE Ratings' Rating Methodology for 'Financial Ratio - Non-Financial Sector' which is available on the website http://www.careedge.in

3. Project-specific Risk

For pharmaceutical companies, the nature of capital expenditure would be driven by the strategic decision pertaining to products and the market that the company wants to cater to.

In the recent past, many Indian pharmaceutical companies have acquired overseas assets for expanding their product/ market reach and gaining access to the 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 a new manufacturing facility, necessary regulatory approvals are required. If the facility is being set up 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.

CARE Ratings also analyses the size of the ongoing/ proposed project in proportion to its net worth, past track record of handling & executing a similar size the project, means of finance (debt: equity ratio of the project), status of financial closure, impact on future financial performance post consideration of project risk as well as risk of time & cost overrun in the project among others.

4. Environmental, social and governance (ESG) risk factors

CARE Ratings in its overall credit rating framework directly or indirectly analyses the critical ESG risks and their impact on the credit profile of the entities. CARE Ratings analyses the materiality of ESG risk factors and mitigating factors, if any, being implemented by the entity. Pharmaceutical entities do not face major environmental-related risk except for the entities engaged in API business. These entities are required to follow stringent pollution control norms set by the regulatory authorities on account of gas emission, water use and waste generation. Any violation in compliance with pollution control norms or strengthening of these norms would adversely impact operations. The entities which are gradually investing/ upgrading their auxiliary infrastructure to reduce carbon footprint, air/ water pollution and hazardous waste as well as efficiently use the natural/scarce resources, would be viewed favourably.

Pharmaceutical entities face a high social risk related to the safety of the consumers. CARE Ratings analyses the regulatory audit track record and instances of litigations and product-recall apart from quality of manpower to assess the social risk. The pharmaceutical sector is exposed to reputation risk related to the quality of the product/ services. Further, compliance with the various labour laws, adequate safety for workers, ensuring customer privacy and fair marketing practices provide long-term sustainability.

CARE Ratings looks at the composition of the board of directors and track record of legal and statutory compliance by its management/ directors to understand the corporate governance structure. Further, the quality of disclosure related to financial statements, related party transactions and transparency in sharing information with various stakeholders are also helpful to gauge the corporate governance practices.

Conclusion

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

CARE Ratings analyses each of the above factors to arrive at the overall assessment of the 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 the company's financials based on past trends and future strategies, competition, industry trends, economic conditions, and other considerations.

[For the previous version please refer to 'Rating Methodology – Pharmaceuticals Sector' issued in July 2020**]**

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