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Background

The global pharmaceutical industry is regarded as one of the most resilient sectors, largely unaffected by economic fluctuations. This vast industry encompasses branded and generic products, finished dosage formulations, and over-the-counter (OTC) medicines. Historically, the pharmaceutical market has been dominated by the United States of America (USA), Western Europe, and Asia-Pacific countries. Primary growth drivers have been developed markets, particularly the USA, the United Kingdom (UK), the leading European countries (France, Germany, Italy and Spain), and Japan. In the next five years, emerging pharmaceutical markets are expected to significantly contribute to the industry's growth.

Several factors contributed to growth of the domestic market. There was a significant increase in demand in both acute and chronic segments. Revisions in pricing, permitted under the National Pharmaceutical Pricing Authority (NPPA), positively impacted overall revenue growth. Introduction of new products also drove growth. Therapies for cardiac conditions, diabetes, and central nervous system (CNS) disorders experienced lower double-digit growth, with other therapeutic areas also performing strongly.

Indian pharmaceutical companies are encountering challenges that are altering business dynamics. A critical issue in the current scenario is the drug regulatory system and regulatory legislation, both domestically and in export markets. For long-term sustainable growth, the industry must enhance domestic manufacturing of bulk drugs, intermediates, and key starting materials (KSM) while gradually reducing dependence on imports from specific countries or regions. The Government of India has initiated measures to incentivise domestic bulk drug manufacturing through a production-linked incentive scheme and the establishment of dedicated bulk drug parks with shared infrastructure. However, reliance on imports for active pharmaceutical ingredients (APIs) and intermediates from China remain significantly high.

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 assessment of the business risk factors specific to the company. This is followed by an assessment of financial and project-related risk factors, and management quality. This methodology is followed while analysing all industries under the purview of the manufacturing sector. However, considering the size and diversity of the manufacturing sector, CARE Ratings has developed methodologies specific to industries within the sector. These methodologies attempt to bring out factors, above those mentioned in the broad methodology, which is considered while analysing companies belonging to an industry.

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

1. Business/ Operational Risk: Business segment and product portfolio, geographical diversification in terms of presence in 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, companies are broadly classified as bulk drug /API manufacturing companies, formulation manufacturing companies or companies having integrated operation, that are engaged in manufacturing APIs and formulations and in contract manufacturing. Bulk drugs are APIs used to manufacture formulations.

Therapeutic segments: CARE Ratings looks into the therapeutic segmentation of products, including Acute or Chronic. The acute therapeutic segment (such as anti-infective and pain management) constitutes a major share of pharmaceutical sales in the domestic market and exports in less-regulated markets. On the other hand, chronic therapeutic segments (such as cardiovascular, oncology, diabetes 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. While analysing a company based on the therapeutic segment, CARE Ratings looks at details regarding the company's presence across therapeutic segments, percentage of revenue from top therapeutic segments, market share in the particular therapeutic segment, degree of criticality of top therapeutic segments, and track record and future strategy to diversify or broaden its therapeutic presence.

Product portfolio: CARE Ratings also analyses the pharmaceutical company's product portfolio, including total number of products, percentage of the total revenue from top 10 products, diversity in terms of dosage form, past track record in developing and adding new products in product portfolio and pipeline of products for future growth prospects. CARE Ratings analyses year-on-year growth rate of existing products in terms of value and volume, which indicates the product's life cycle. CARE Ratings also analyses expected launch of new products in the year, their market size and expected revenue growth. 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 sustainability of revenue and profitability going forward.

Formulation companies: While analysing formulation companies, it is important to assess their market positioning by understanding the company's market share in a particular therapeutic segment and diversification in product portfolio. This enables the assessment of stability or sustainability of its future growth. CARE Ratings further considers the company's marketing and distribution setup, which plays a key role in assessing market penetration and future growth prospects. Formulation companies can be classified as 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 considering low entry barriers. Moreover, to assess operating efficiency of formulation companies, CARE Ratings analyses gross margin and productivity of its sales forces.

Bulk drug/ API companies: Bulk drug/API companies are relatively capital intensive and fragmented with threats from cheaper imports; CARE Ratings also analyses cost efficiency, technical upgrades of the plant, manufacturing capabilities, third-party tie-ups, customer base and its diversification, and product concentration, among others. CARE Ratings analyses revenue from top products and customers to arrive at concentration risk. Over-dependence for raw material on a particular country or few suppliers can create significant supplier concentration risk for the company. The Indian pharma companies heavily depend on China for their raw material requirement, KSM and Bulk drug/ API. From FY18-FY24, import of KSM and API from China accounts for nearly 66-68% of total imports of KSM/ API. During the COVID-19 pandemic, Indian pharma companies faced supply disruption due to 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, exports to different markets, are considered favourably as they provide more opportunity for growth and mitigate the risk related to change in the regulation in 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, among others. Regulated markets are those where regulations are more stringent, while less-regulated markets have less-stringent regulations. There is a trade-off between risk and returns as far as exports to a regulated market or a semi-regulated market are considered.

For exports to the regulated market, companies 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 considering patent expirations scheduled in the coming years. To analyse the company's strength and presence in a regulated market, CARE Ratings takes into cognisance receipt of regulatory approvals from regulatory authorities of respective nations. Approvals from regulatory authorities allow these companies to tap the generic opportunity and open opportunity in the Contract Research and Manufacturing Services (CRAMS) business. For companies pursuing the generic opportunity in regulated markets, CARE Ratings looks at the number of Abbreviated New Drugs Application (ANDA) and approvals received. Apart from several ANDAs, CARE Ratings also analyses quality of a company's product pipeline.

1.3 Research and Development (R&D) Focus

In the current scenario, with increasing competition in domestic and 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 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 it with industry averages and comparable peers. CARE Ratings also looks at the past track record of the company's capability to develop new molecules or new dosage forms/ new drug delivery systems or develop a new combination of drugs, among others. 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, focus is on the development of a new combination of existing formulations and 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 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. In its analysis, CARE Ratings assesses product development capability of the entity across therapeutic segments and its focus areas on the recent off-patent drugs, and combination of products, among others.

For companies offering contract research and manufacturing services (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 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 costs and low success rates, it is viewed carefully.

Generally, mid-to-large sized pharmaceutical companies in India spend nearly 6%-7% of their annual sales on R&D activities, thus 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 and export markets. The regulatory aspect is extremely crucial, given 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 performance track record on inspections carried out at manufacturing facilities by regulatory authorities of respective countries. Post such inspections,

observations made by regulatory authorities and the company's response and remedial measures taken by it are evaluated. CARE Ratings analyses instances of product recall in the past, and instances of ban or import alert for manufacturing facilities of companies by regulators and its 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 legal cost of such litigations and the time for re-inspection is high, revenue and profitability of companies may be impacted; hence, the trigger of such regulatory-concerned events are critical from a 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, and labour unrest, among others, may disrupt the company's operation significantly. In the domestic market, 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 against its impact on profitability. CARE Ratings analyses the company's revenue and 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 price control measures is also observed in developed markets. In prominent developed markets, it is witnessed that consolidation of the supply chain in the hands of a few large distributors also puts pressure on product pricing.

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 laid-down environmental and pollution control norms could attract action from the concerned regulatory authorities, which may even lead to shutting down 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 such as zero liquid discharge facility. It is observed that 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 financial risk of companies in the pharmaceutical sector. Refer to CARE Ratings' Rating Methodology for 'Financial Ratio - Non-Financial Sector', which is available on <http://www.careratings.com>.

3. Project-specific Risk

For pharmaceutical companies, nature of capital expenditure would be driven by 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 realisation of the envisaged benefit and extent of debt funding used for such acquisition.

For capital expenditure pertaining to setting up a new manufacturing facility, necessary regulatory approvals are required. If the facility is being set up for catering to regulated markets, delays in receiving 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 size of the ongoing/ proposed project in proportion to its net worth, past track record of handling and 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 and risk of time and 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 being implemented by the entity.

Environmental Risks: Pharmaceutical entities do not face major environmental-related risk except for entities engaged in the API business. These entities are required to follow stringent pollution control norms set by the regulatory authorities considering gas emission, water use and waste generation. Violation in compliance with pollution control norms or strengthening of these norms would adversely impact operations. Entities which are gradually investing/ upgrading their auxiliary infrastructure to reduce carbon footprint, air/ water pollution and hazardous waste and efficiently use the natural/scarcce resources, would be viewed favourably.

Social Risks: 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. Compliance with labour laws, adequate safety for workers, ensuring customer privacy and fair marketing practices provide long-term sustainability.

Governance Risks: 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. Quality of disclosure related to financial statements, related-party transactions and transparency in sharing information with stakeholders are also helpful to gauge corporate governance practices.

Conclusion

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

CARE Ratings analyses each of these factors to arrive at the overall assessment of the issuer's credit quality. Credit rating is a futuristic assessment, and the rating outcome is ultimately an assessment of fundamentals and probabilities of change in 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 2022](#)]

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