Rating Methodology for Entities in the Pharmaceutical Industry

Overview

This rating methodology provides a reference tool for investors and entities to understand ICRA's approach in assessing the business and financial risk profiles of entities in the pharmaceutical sector. It aims to help entities, investors and other market participants understand ICRA's approach in analysing quantitative and qualitative risk characteristics that are likely to affect rating outcomes. ICRA categorises those entities under the pharmaceutical industry whose primary business activity involves manufacturing and marketing of pharmaceutical products (all or any of: intermediates, active pharmaceutical ingredients (APIs) and formulations), providing contract research and manufacturing services (CRAMS) and those engaged in manufacturing and marketing of alternative medicines (such as ayurveda, homeopathy etc).

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Industry Risk Assessment

Regulatory Risk

The domestic pharmaceutical industry is regulated on three aspects: Patents, Price and Product Quality – regulatory developments like the Drug Price Control Order, patent protection regulations, adherence to various guidelines on manufacturing practises, etc. have long-term implications on Indian pharmaceutical entities. Entities (Formulation, API or CRAMS) with presence in highly regulated overseas markets (especially USA and Europe) are facing an increased level of scrutiny for adhering to manufacturing quality norms by the regulatory agencies from these countries. Any adverse observations during such scrutiny can have a significant adverse impact on a company's performance as it can impact both current business as well as future product approvals. Depending on intensity of lapses, it can also result in potentially large penalties going forward. In view of these intensified regulatory scrutiny, entities with relatively high dependence on the USA and the European markets would need to dedicate higher resources in managing regulatory compliance, therefore, adding pressures to the cost structures. ICRA evaluates the sensitivity of pharmaceutical entities to manufacturing compliance through availability of requisite approvals (USFDA, TGA, MHRA etc.) and past track record of instances of regulatory non-compliance such as material audit observations, warning letters and import alerts.

For pricing controls, the domestic formulation manufacturers have to follow the norms set by the National Product Pricing Authority (NPPA) in the form of price cap on essential drugs (as defined under the National list of Essential Medicine - NLEM) as well as maximum permissible annual price increases (price control) on the rest of the portfolio. For API and CRAMS players, the pricing gets indirectly influenced based on the pricing regulations on the formulations. ICRA evaluates the share of the entity's portfolio under NLEM vis-a-vis the industry for the domestic formulation market and its track record of launching new products, which are out of such price caps through R&D efforts. For other markets where price cuts (e.g. Japan) are announced at pre-defined regular intervals by regulatory authorities, the entities' ability to continuously launch new products to maintain economies of scale benefits remains critical.

Indian pharmaceutical entities largely cater to the generic/branded generic segment globally and have to adhere to the guidelines issued on patent protection by respective countries as violation of the same could result in lawsuits and large penalties. The entities that follow the high risk high reward strategy of patent challenges in the US (referred to as Para IV filings), with significant uncertainties relating to the final outcome, are exposed to large cash outflows on account of litigation. ICRA evaluates the financial risks arising from potential rejection/ launches at risk for Para IV and the ability of the company to absorb such downsides.

Overall, ICRA evaluates the sensitivity of pharmaceutical entities to various regulatory requirements, past track record of compliance and mitigating factors available to them.

Competitive Landscape

The domestic Indian formulations industry is largely a branded generic industry with the presence of a limited number of patented drugs, predominantly self-reimbursing in nature, low entry barriers and largely physician-influenced. The industry is fragmented, with the presence of a large number of players – small as well as big, with the focus on different therapeutic segments – across acute as well as chronic. Factors such as changing lifestyle patterns with rising incomes, higher prevalence of chronic ailments, ageing population and government intervention for cost-effective healthcare treatments have together created significant opportunities for generic formulations manufacturers. Thus, ICRA evaluates the strength of the rated entity with respect to its presence in diversified therapeutic areas, consistency in maintaining market share and new launches to assess its competitive position in the domestic formulation industry.

Apart from domestic presence, Indian formulation entities have exports presence in the regulated and semi-regulated markets. Indian entities largely cater to the generic segment for developed exports market characterised by the supply of bulk volumes at relatively lower prices. This has led to high competitive intensity with downward pressure on prices though entry barriers in the form of strict compliance requirements with respect to product registrations, manufacturing quality ensures better margin profile.

Thus, the company's ability to offer a large product basket along with strong volume market share in majority of the products offered reflects its competitive position in such markets. Export semi-regulated markets are generally branded generic in nature and the competitive landscape is similar to the domestic formulation industry. In line with formulations, the bulk drug (API) industry is also fragmented with low entry barriers and entities ability to develop low cost manufacturing, high process chemistry skills and requisite manufacturing facilities defines its competitive position. The bulk drug players also face competition from in-house API manufacturing of large formulation players for captive consumption as well as sales to external formulation players.

India is emerging as a major destination for CRAMS, driven by strong chemistry capabilities, skilled manpower, cost value proposition with low R&D cost and large patient population providing a diverse pool for clinical trials for NCE. While a small number of large players have emerged leaders within the industry, the domestic CRAMS market remains fragmented. While there are several organisations providing a varied range of contract research and contract manufacturing services, competitive differentiation arises on a number of factors including size and breadth of product portfolio; relative expertise, quality and costs of identifying and optimising potential lead compounds; speed, costs of optimising chemical processes and long-standing relationships with clients which act as an entry barrier.

Business Risk Assessment

Scale of Operations and Market Position

Scale of operations, as measured by operating income, is one of the critical drivers of success across segments of the pharmaceuticals industry. Large scale typically provides better bargaining power with suppliers and also allows improvement in competitiveness by way of entailing cost and manufacturing process efficiencies. Moreover, it enables better equity with prescribers as well as distribution channels for branded formulation entities. Additionally, large pharmaceutical entities are able to negotiate better pricing with the drug wholesalers and drug payers for their developed market operations. Ceteris Paribus, a large scale pharma company is likely to be better positioned to a) make continued investments in R&D for maintaining a healthy product pipeline b) undertake capacity additions to support future growth c) allocate budgets for litigations relating to product filings (pertaining to Para IV in the US market) and d) foray into limited competition launches. The benefits also support the renewal and expansion of product portfolio by development of derivatives, especially for API manufacturers. In addition to the aforementioned factors, for players engaged in CRAMS particularly, large scale enhances their ability to offer different product extensions / delivery systems and supports faster product filings on account of regulatory expertise. Further, a strong position of the entity (which is determined by the product portfolio strength and extent of competition) in the geographies in which it operates enhances the rating comfort as the same influences the revenue stability to a large extent.

In case of CRAMS entities, in addition to the share of wallet with their customers for specific products, the latter's market position in those products are analysed to understand the vulnerability of revenues of the customers and in turn of the CRAMS player. Typically, entities with large scale and strong market position tend to demonstrate stable revenue profile and cash flow generation and hence are important aspects to be analysed.

Business Profile and Diversification

Entities operating in different spheres of pharmaceutical industry face risks associated with that particular segment. For example, API manufacturers may face pricing pressure on account of commoditisation and face risks related to high capital intensity and usually limited product portfolios. On the other hand, the formulators may face intense competition on account of relatively less fixed capital intensity and entry barriers are largely on account of therapeutic coverage, portfolio strength, brand equity with prescribers and supply chain efficiencies (on account of high working capital intensity).

- ***Business Segment Diversification / Extent of Integration***: Business segment diversity enables entities to better withstand segment-specific risks by shielding them from sharp revenue volatility by

way of reducing dependence on the performance of one segment. For instance, API manufacturers' initiatives to diversify their presence in CRAMS or formulations are considered credit positive. Additionally, formulation entities that are backward integrated with their presence in APIs also are assured of timely and quality supply of raw material. Besides, this enables them to be cost competitive (especially on account of commoditisation as the product ages) and also enables faster filing of product dossiers for the targeted markets.

- ***Product Portfolio, Therapeutic and Brand Diversification***: Indian pharmaceutical entities have a presence in "branded" products largely in the domestic, semi-regulated markets with a few large players having sizeable exposure to regulated markets. For the entities focused on branded formulations segment of the Indian market, product maturity and portfolio diversity evaluation is important as the ability of pharmaceutical entities to continually add new products in line with the emerging medical needs remains critical in sustaining revenues and cash flow generation. Entities with significant exposures to mature or declining therapeutic segments face the risk of declining revenues and profitability. Additionally, a suitable mix of acute and chronic therapies coupled with the presence in other fast growing therapeutic segments/ niches may bring in stability in financial performance. Notwithstanding the need for therapeutic and brand diversification, a strong market share in their key therapy segments through brand recognition with key opinion leaders/ specialists as well as exhaustive doctor/specialist penetration remains critical. Specifically for the domestic market, while stronger brands usually prove more profitable for entities, high product concentration can significantly increase risks. Thus, a product portfolio diversified across therapeutic segments and different molecules is a credit positive. While analysing the product portfolio, ICRA also looks at the price control coverage of the company's portfolio as higher coverage would constrain profitability.

  Similarly, CRAMS players (contract manufacturers) with reasonably diversified product portfolio across growing therapeutic segments, delivery systems and catering to customers with strong brand position, would generally be well positioned to demonstrate stable business performance. Additionally for CRAMS entities, ability to offer products across dosage forms (solids, liquids, injectables, creams, gels, ointments) and to launch new products/ combinations/ dosages is also critical. For CRAMS entities involved in contract research work - relative expertise, quality and costs of identifying and optimising lead compounds and speed and costs of optimising chemical processes remains critical.

  ICRA assesses the strength of a generics company by its ability to distinguish itself from competition and sustain its market share without compromising on profitability. Thus, for the Indian entities that have significant revenue dependence on the US generic market, product and therapeutic diversity is critical as the generic products remain exposed to price competition, especially for simple delivery forms like tablets and capsules. Thus, diversity across delivery forms (extended release, injectables, inhalers, patches, hormonal contraceptives)/ having products that are more difficult to replicate / with higher barriers to entry in addition to its ability to offer a reasonably diverse product basket favours the credit profile. In the past, some of the Indian pharma entities focused on filings targeting marketing exclusivity resulted in significant jump in revenues and earnings in the years such products were launched followed by steep contraction as other players forayed resulting in steep pricing pressure. Thus, a balanced portfolio of filings comprising of plain vanilla generics, niche products (delivery forms or complex to manufacture) and an annuity of filings for exclusivity (arising from large number of filings and strong R&D and regulatory capabilities) aids stable revenues and earnings. Moreover, a proportion of revenues from complex generics (that has limited competition) or presence in the branded formulations segment and the OTC segment in the regulated markets also allows the pharmaceutical entities withstand price erosions in the generics segment. Increasingly, the Indian pharma entities with substantial revenues from developed markets, especially the US, are investing in R&D to focus on complex generics where the competition is limited, resulting in better pricing power.

- ***Customer diversification for CRAMS / API players***: Entities engaged in CRAMS / APIs business require significant upfront investments in creating manufacturing / research infrastructure and thus, may face high business risks if dependent on few customers. Customer diversification remains a challenge given the long lead time associated (on account of process validation, technology transfer and site audits by pharmaceutical marketing entities) for business awards.

- ***Geographic diversification:*** In the backdrop of the stringent regulatory landscape for pharmaceutical entities in terms of regulatory approvals (facility, product), pricing and intellectual property rights, a geographically diversified revenue mix, besides addressing market risks, allows the company to withstand regulatory uncertainties or market conditions related to any single market. In the past, Indian entities had forayed into the generics market of European countries either organically or through acquisitions, however, the change in market dynamics (for instance, German market that was a branded generic market turned into a tender based market with healthcare reforms being implemented) on account of budget constraints of healthcare payors, resulted in significant pricing pressures. Thus, the European operations of many players became unviable. In contrast, Indian pharmaceutical entities, with presence in markets like the US and Japan have benefited from the robust generic business in these markets. Thus, while evaluating geographic diversification, the market opportunity as well as regulatory landscape is also assessed to arrive at credit risk.

While evaluating the business profile of pharmaceutical entities, attention is also paid to the company's exposure in the emerging markets that are witnessing fast growth. This would involve assessment of the country risks such as - political risks, local economic conditions and currency risk, regulatory regime (patent regulations and product approvals, quality and manufacturing compliances, pricing policies) credit risks associated with key participants in the pharma distribution chain.

R&D Focus and Product Pipeline

As a strong product pipeline is essential for sustainable earnings, an evaluation of company's R&D efforts, R&D team and infrastructure as well as consistency/ growth in budgetary allocations are evaluated. A strong R&D team also needs people who are adequately experienced in dealing with Intellectual Property Rights (IPR) related issues.

While product development across the pharma segments is critical, the focus areas of generic formulation entities in recent periods have been on newly off-patent product/ combination/ delivery system launches with some of them also targeting new chemical entity development (NCE). The higher rated entities, normally have an R&D spend of over 9% of revenues with a pipeline spread across generic filings, New Drug Delivery Capabilities (NDDS), and differentiated products.

NCE research, by nature, has significant risks and given the long gestation period needs high R&D budgets. While most Indian entities lack the balance sheet size to carry on NCE research, some of the entities have been somewhat successful in NCE research, adopting the early monetisation route for its investments by out-licensing milestone-based payments. Given the sizeable R&D as well as capex investments, the company's ability to absorb these losses in case of failure to get product approvals is also assessed.

The API entities R&D efforts are focused in the areas of new products for renewing product portfolio and introducng derivatives with market potential as well as improving process efficiencies to become more competitive as the products mature. CRAMS entities focus on development of new formulation/ combinations/ drug delivery systems as an early mover advantage can support profitability.

Most large generic entities from India have significant revenue and profit dependence on developed country markets, which are typically characterised by intense competition and low pricing power for vanilla generics. In these markets, entities with focus on products targeting exclusivity (Para IV challenges, developing non-infringing processes), complex products, specialty/ niche products are often better placed. In the biosimilar space, the presence of Indian players has so far been limited, largely to less regulated markets. However, a large number of biosimilars are going off patent in regulated markets over the medium term, which provides an attractive opportunity for players with the necessary technical skills and financial resources.

To develop a healthy pipeline of drugs, the entities need to draw up their R&D investments well into the future, targeting products with patent expiry of up to seven to eight years into the future. A proxy for the product pipeline can be represented by regulatory filings (DMFs, ANDAs, NDAs, marketing authorisation

applications, certificate of suitability of the European Pharmacopoeia or CEP, etc). Assessing the diversity of the pipeline (nature of filings, for instance, ANDAs with Para IV certification, NDAs filed targetting exclusivity under 505 (B)(2) for improvised/ new delivery systems in the US market etc.), however, remains critical.

Manufacturing Infrastructure and Compliances

While low-cost manufacturing capability as well as chemistry and process engineering are the strengths of Indian pharmaceutical entities, it is also critical for these entities to maintain systems and processes to ensure product quality. ICRA, therefore, assesses the systems followed by the company during manufacturing and testing. The rating process involves assessing the inspection track record of manufacturing facilities by Indian regulatory authorities and regulatory authorities of countries where the products are exported (FDA for US market, MHRA for supplies to UK, ANVISA for supplies to Brazil, etc). Moreover, the observations of the inspectors (for instance, observations issued during the USFDA inspection in the form of 483s), the company's response and corrective actions taken by the management are gauged.

Upgrading and maintaining a manufacturing facility that meets the standards of the regulated markets call for significant financial commitments. Also, inspection and approvals being a time-consuming process, entities with existing facility approvals from regulators like the USFDA, UK MHRA, among others have a crucial time advantage over others. With the heightened scrutiny levels and stringent product quality standards evident from imposition of warning letters/ import alerts by USFDA even for reputed Indian as well as global generic entities, maintaining manufacturing standards has become critical for players with sizeable exposure to the US and Europe (revenues as well as product pipeline based on innovator products expected to go off patent). There have been instances where such regulatory actions have resulted in manufacturing disruptions with a significant impact on revenues and profitability. To mitigate such risks related to production/ profitability loss in case of adverse regulatory action, ICRA evaluates the entities' approach towards investments in upgrading systems, documentations, IT and manufacturing processes through management interactions, besides strategies like dual location filings.

Backward integration is an increasingly crucial factor in sustaining cost advantages in exports, especially for commodity generics in the regulated markets. For instance, some Indian manufacturers have been able to sustain profitability even after over 90% price erosion on generics, through focus on operating efficiencies and effective cost control measures. Besides, entities with quality manufacturing facilities coupled with strengths in process re-engineering can also leverage potential opportunities in the field of contract manufacturing and custom synthesis.

Management Quality

All debt ratings necessarily incorporate an assessment of the quality of the entity's management, as well as the strengths/weaknesses arising from the entity's being a part of a "Group". Also of importance are the entity's likely cash outflows, arising from the possible need to support other group entities, in case the entity is among the stronger ones within the group. Usually, a detailed discussion is held with the management to understand its business objectives, plans and strategies, and views on past performance, besides the outlook on the (entity's) industry. Some of the other points assessed are:

- Experience of the management in the line of business concerned
- Commitment of the promoter/management to the line of business concerned
- Attitude of the promoter / management to risk taking and containment
- The entity's policies on leveraging, interest risks, commodity risks and currency risks
- The entity's plans on new projects, acquisitions, expansion, etc.
- Strength of the other entities belonging to the same Group as the entity
- The ability and willingness of the parent/ group to extend extraordinary financial support to the entity, if the latter faces cash flow pressures; or infuse capital to fund the latter's capex commitments

Financial Risk Assessment

Profitability

The complexity of products, therapeutic mix, and the geographic market a company operates in, besides operating efficiency, are the key determinants of a company's profit margin. For APIs and generics, profitability is also influenced by the particular stage a product has reached in its lifecycle (mature, commoditised products usually offer low margins) and the time of its market entry (early entry often yields a relatively large market share and hence higher margins). manufacturing products involving less complex and easily replicable processes are often subject to intense competition, and this gets reflected in their usually low gross margins. Margins are also typically moderate for players targeting less regulated markets, as relatively lenient requirements for product registration and manufacturing facility approval also imply low entry barriers and, therefore, intense competition. While better regulated markets in general offer better operating margins, price erosions can be steep, depending on the number of ANDA filings for the product. Generic creating a balance portfolio of commoditised generics, exclusivities as well as limited competition products are able to sustain/ improve their profitability better than those focused on commoditised products. Players focussed on the domestic branded formulation market with its presence in the lifestyle drugs segment with stronger brands tend to enjoy better profitability than ones that may have relatively higher coverage of their portfolio under price control. ICRA places emphasis on product pipeline strength, as that can even out the large price fluctuations inherent in exports to regulated markets.

For into contract research (including custom synthesis and clinical research) and manufacturing, the risks associated with large upfront investments are often mitigated by profitable long-term contracts from large innovator .

Leverage and Coverage Indicators

ICRA's assessment of the financial risk profile of the company is based upon the company's ability to generate healthy cash flows to reinvest in the business as well as meet the debt servicing obligations. The financial policies and the risk appetite of the management remain key rating factors.

Leverage ratios are an indicator of the degree of financial flexibility a company enjoys in terms of its ability to raise funds from alternative sources. Such flexibility is reflected in a company's gearing (Total Debt-to-Tangible Networth) and Total Debt-to-EBDITA multiple. A strong Total Debt-to-EBIDTA multiple is a credit positive as it reiterates the company's ability to service its debt obligations, fund growth opportunities through R&D and market expansion and improve its competitive position without being overly reliant on external sources.

The interest coverage indicator reflects the company's ability to fund the cost of external borrowings after meeting all operating expenditure requirements. It is an important rating consideration as a weak EBITDA-to-interest multiple indicates that the company is not generating adequate revenues to meet its interest and debt obligations from its operational cash flows, and may signal a default risk.

Working Capital Intensity and Liquidity Profile:

In addition to long-term financial flexibility the liquidity profile of the company is equally important to understand the company's ability to meet short-term financing requirements. Thus, evaluation of working capital requirements with respect to the receivables and inventory is critical. A high level of inventory and receivables with respect to stagnant revenues may not reflect well on the company. For instance, a significant inventory pile-up in anticipation of orders in tender business can materially affect the liquidity position if the company if it proves unsuccessful in getting the award. The working capital requirements and funding sources are evaluated from the monthly working capital utilisation of the company and the available drawing power.

Foreign Currency Risks

The foreign currency risks for pharmaceutical entities primarily arise on account of export revenues, intermediate/ API imports and foreign currency denominated liabilities (including debt). While taking into consideration the hedging policy of the company towards mitigating such foreign currency risks, ICRA also focuses on the impact of the adverse movement in foreign exchange rates on the cost structures, profits or incremental cash outflows for such entities.

Tenure Mismatches, and Risks Relating to Interest Rates and Refinancing

Large dependence on short-term borrowings to fund long-term investments can expose a company to significant re-financing risks, especially during periods of tight liquidity. The ratings factor in the existence of adequate buffers of liquid assets/bank lines to meet short-term obligations and the extent to which the company could be impacted by interest rate movements on such borrowed funds.

Debt Servicing Track Record

The debt servicing track record of the company forms an important rating consideration. Any history of past delays or defaults in meeting interest and principal repayment obligations reduces the comfort level with respect to the company's future debt servicing capability. ICRA also factors in the company's ability to honour its debt obligations during a period of cyclical stress.

Contingent Liabilities/Off-Balance Sheet Exposures

ICRA also looks at the quality of accounting practises followed by a company based on interactions with the Statutory Auditors as well as studying the Auditors' Report and other Notes to Accounts disclosed by a company in its Annual Report. Some of the key factors looked at include- auditor qualifications with respect to internal control systems, debt servicing and asset liability mismatch; contingent liabilities and other off balance sheet items and the method of revenue recognition and depreciation policy of a company in comparison with industry peers.

Accounting Quality

ICRA reviews the accounting Policies, notes to accounts, and auditor's comments as available in the financial statements of the entity. Any deviation from the Generally Accepted Accounting Practices (GAAP) is noted and the financial statements of the entity are adjusted to reflect the impact of such deviations.

Adequacy of Cash Flows

Cash is required to service obligations. Cash flows reflect the sources from which cash is generated and deployed. ICRA analyses the trends in the entity's Funds Flow from Operations (FFO) after adjusting for working capital changes, the Retained Cash Flows, and the Free Cash Flows after meeting debt repayment obligations and capital expenditure needs. The cash flow analysis also helps in understanding the external funding requirement that an entity has to meet its maturing debt obligations. ICRA also draws up projections on the likely financial position of the company based on the expected movements in operating performance factoring in capex and investment requirements as well as upcoming debt obligations to study the impact on revenue growth and profitability, cash flows, leverage as well as debt protection indicators. We also look at the funding requirements of a company and the funding options available to it.

Other Considerations

Event Risk

The pharmaceutical industry has experienced corporate actions like acquisitions for geographic diversification, backward/ forward integration, product portfolio/ pipelines, manufacturing assets to name a few. These actions, often debt-funded, have a material impact on the credit profile of a company.

Summing up

ICRA‘s credit ratings are a symbolic representation of its opinion on the relative credit risk associated with the instrument being rated. This opinion is arrived at following a detailed evaluation of the entity‘s business and financial risks, its competitive strengths, its likely cash flows over the life of the instrument being rated, and the adequacy of such cash flows vis-a-vis its debt servicing obligations. As highlighted in the note, ICRA evaluates the business segment, product, therapeutic area and customer diversification, R&D and manufacturing capabilities, brand strength, geographical diversification, regulatory risks and competitive landscape of the entity in the pharmaceutical industry and capability of the entity to generate cash over the lifetime of the instrument being rated, to arrive at an opinion on the credit risk associated.

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