ICRA Rating Feature

Rating Methodology for Entities in the Pharmaceutical Industry

This rating methodology updates and supersedes ICRA's earlier methodology note on the sector, published in December 2017. While this revised version incorporates a few modifications, ICRA's overall approach to rating entities in the sector remains materially similar.

Overview

ICRA categorizes those entities under 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.).

Formulations – the finished pharmaceutical product – is the end product of the pharmaceutical value chain, ready for consumption by the patient. Active pharmaceutical ingredients (APIs, also known as bulk drugs) are converted to formulations when the dosages are fixed in a form ready for human consumption such as tablets, capsules, syrups, drops, ointments or injectables using additional inactive ingredients/ excipients. Formulations are marketed either under a brand name (known as branded formulations) in case of innovator/ patented drugs; or as generic finished dosages with therapeutic equivalence (same dosage, safety, strength, and quality and for the same intended use) to branded formulations and sold under brand names (known as branded generics); or as generic finished dosages with therapeutic equivalence to branded formulations and sold under their chemical names (known as generics).

The Indian formulations industry is largely a branded generic industry with presence of a limited number of patented drugs, predominantly self-reimbursing in nature and largely physician-influenced. The industry continues to be fragmented, regionally diverse with large number of players both national and regional– small as well as big, with focus on different therapeutic segments. Indian formulation companies have presence in both the domestic market as well as regulated and semi-regulated international markets. Rising cost pressures being faced by innovators as well as generic drugs manufacturers have provided a significant opportunity for outsourcing of bulk drugs. to bulk drug players, India being a low-cost producer.

Rating Methodology

This rating methodology provides a reference tool for investors and entities to understand ICRA’s approach to 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 to analyzing quantitative and qualitative risk characteristics that are likely to affect rating outcomes. ICRA’s risk analysis framework for the pharmaceutical entities can be broadly divided into the following factors –

- ***Industry Risk Assessment***
  - Regulatory Risk
  - Competitive Landscape

- ***Business Risk Assessment***
  - Scale of Operations and Market Position
  - Business Profile and Diversification

  - Extent of integration / diversification across business segments
  - Product, therapeutic and brand diversification
  - Geographic diversification
  - Customer Diversification
- R&D Strength and Product Pipeline
- Manufacturing Infrastructure and Compliances

- ***Management Risk***

- ***Financial Risk Assessment***
  - Profitability
  - Working Capital Intensity
  - Leverage and Coverage Indicators
  - Liquidity
  - Foreign Currency Risks
  - Tenure Mismatches, and Risks Relating to Interest Rates and Refinancing
  - Debt Servicing Track Record
  - Contingent Liabilities / Off-Balance Sheet Exposures
  - Accounting Quality
  - Adequacy of Cash Flows

- ***Other Consideration***
  - Event Risk
  - Parent Support

ICRA also assesses the entity's management for its growth plans, risk appetite and financial policies.

Industry Risk Assessment

Regulatory Risk

The domestic pharmaceutical industry is regulated on three aspects: Product Quality, Price and Patents. Regulatory developments like the Drug Price Control Order, patent protection regulations, adherence to various guidelines on manufacturing practices, etc. could have credit implications for the Indian pharmaceutical entities. Entities (Formulation, API or CRAMS) with presence in highly regulated overseas markets (especially USA and Europe) tend to face 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 and growth products. 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 USA and European markets tend 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 issued by various Healthcare authorities. Further, possible punitive damages for breaching various regulatory norms in certain markets is also evaluated for companies under investigation.

As for pricing controls, the domestic formulation manufacturers have to follow the norms set by NPPA (National Product Pricing Authority) in the form of price cap on essential drugs (as defined under National list of Essential Medicine - NLEM) as well as maximum permissible annual price increases (price control) on 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 entity's portfolio under NLEM vis-a-vis 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. Further, Government focus on driving generic prescription through policy change may entail change in business model for domestic formulation companies. For other markets

where price cuts (e.g. Japan) are announced at pre-defined regular intervals by regulatory authorities, entities ability to continuously launch new products or optimised existing production costs remains critical.

Indian pharmaceutical entities largely cater to the generic/branded generic segment globally and have to adhere to the guidelines on patent protection by respective countries as violation of same could result in lawsuits and large penalties. The entities that follow high risk high reward strategy of patent challenges in 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 at-risk (under litigation) Para IV launches 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 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 presence of a large number of players – small as well as big, with focus on different therapeutic segments – across acute (Anti-Infectives, Pain management) as well as chronic (Cardio Vascular, Central Nervous System etc.). 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.

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 supply of bulk volumes at relatively lower prices. All developed countries have been focusing on driving generic prices down through various price control measures such as faster approvals or compulsory price cuts or tendering system among others. 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 and manufacturing quality ensures better margin profile. Thus, ability of the company to offer large product basket along with strong volume market share in majority of the products offered reflects its competitive position in such markets. Consolidation of supply chain concentrated in the hands of few players can also exert pricing pressure as seen for the US market. Exports to semi-regulated markets are generally branded generic in nature and competitive landscape is similar to 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 their 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 New Chemical Entities (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 varied range of contract research and contract manufacturing services, competitive differentiation arises on number of factors including size and breadth of product portfolio; relative expertise, costs of optimising chemical processes and long-standing relationships with clients which acts 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 payors for their developed market operations. Ceteris paribus, a large scale pharmaceutical 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, market 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. For formulators, the same is measured through company's business ranking in each of the key markets it operates in.

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 analyzed 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 analyzed.

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 commoditization and face risks related to high capital intensity and usually limited product portfolios. On the other hand, the formulators may face high competitive intensity 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.

- ***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' with diversified presence in CRAMS or formulations are considered credit positive. Additionally, formulation entities that are backward integrated with 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 commoditization as the product ages) and also enables faster filing of product dossiers for the targeted markets.

- ***Product Portfolio, Therapeutic and Brand Diversification***: Most of the Indian pharmaceutical entities have a presence in "branded generics" segment, largely in the domestic, semi-regulated markets, with a few large players having sizeable exposure to regulated markets in the 'generics' segment. For the entities focused on branded formulations segment of 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 low growth or mature therapeutic areas therapeutic segments face risk of declining revenues and profitability. Additionally, a suitable mix of acute and chronic therapies coupled with presence in other fast growing therapeutic segments/ niches may bring in stability in financial performance. Notwithstanding the need for therapeutic and product 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, ICRA evaluates diversity across therapeutic segments diversity for formulation players and different molecules for API players. While analyzing 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 ability to launch new products/ combinations/ dosages are also critical. For CRAMS entities involved in contract research work - relative expertise, quality and costs of identifying and optimising lead compounds and speed & 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 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 ability to offer a reasonably diverse product basket favours the credit profile. In the past, some of the Indian pharma entities focused on filings that targeted marketing exclusivity resulting 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, proportion of revenues from complex generics (that has limited competition) / specialty products or presence in branded formulations segment and 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 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. ICRA evaluates the concentration of revenues with Top customers to arrive at concentration risk.

- ***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, 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. Indian pharmaceutical entities with presence in largest generic markets of USA faced steep pricing pressure during FY2017-2019 period owing to supply chain consolidation and faster ANDA approvals. Thus, while evaluating geographic diversification, regulatory landscape is also assessed to arrive at credit risk. ICRA evaluates the dependence of companies for procuring raw material and high dependence on any single country or single party is generally viewed as credit negative. Mitigating factors such as maintaining adequate level of stocks to tide over short term crisis are also taken into account.

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) and 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 IPR (Intellectual Property Rights) related issues.

While product development across the pharma segments is critical, the focus areas of generic formulation entities in recent periods has 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 R&D spend of over 7-8% of revenues with a pipeline spread across generic filings, NDDS (New Drug Delivery Capabilities) 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 early monetization route for its investments by out-licensing or milestone based payments based on research outcomes. Given sizeable R&D as well as capex investments, the ability of the company to absorb these losses in case of failure or delay in getting product approvals is also assessed.

The API entities R&D efforts is focused in the areas of new products for renewing product portfolio and introduce derivatives with market potential as well as improve 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 characterized by high competitive intensity 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 from a business sustainability perspective. 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 necessary technical skills and financial resources.

To develop a healthy pipeline of drugs, entities need to draw up their R&D investments well into the future, targeting products with patent expiry of upto 7-8 years into the future. A proxy for the product pipeline can be represented by regulatory filings (DMFs, ANDAs, NDAs, marketing authorization 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 filings 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 entities to maintain systems and processes to ensure product quality. 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. Companies which have only a single manufacturing facility remain exposed to asset concentration risks, with force majeure incidents, or issues like labour unrest, political uncertainties, warning letters, import alerts etc. likely to disrupt the operations significantly. On the other hand, Pharma companies which have a relatively diversified manufacturing presence, are able to offset this risk to some extent.

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 US FDA, 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. 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 toward 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 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 entities 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). Entities 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 ANDA filings for the product. Generic entities 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 focused on the domestic branded formulation market with presence in 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 entities 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 entities.

Leverage and Coverage Indicators

ICRA's assessment of the financial risk profile of the company is based upon the ability of a company 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 Outside Liability-to-Tangible Networth) and Total Debt-to-OPBDITA multiple. A strong Total Debt-to-OPBIDTA multiple is a credit positive as it reiterates the ability of the company to service its debt obligations, fund growth opportunities through R&D & market expansion and improve its competitive position without being overly reliant on external sources.

The interest coverage and DSCR indicator reflects the ability of the company to fund the cost of external borrowings as well its repayment after meeting all operating expenditure requirements. It is an important rating consideration as a weak OPBDITA-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:

Generally, Formulation companies have moderate working capital intensity while API layers have relatively high level of working capital intensity led by the need to maintain critical raw material inventory levels for maintaining uninterrupted supply. Further, companies with exposure to less regulated markets also display high level of debtor days. 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 liquidity position if the company is not successful in getting the award.

Liquidity

ICRA also evaluates the liquidity profile of the company to assess its ability to meet short-term financing requirements. The existence of adequate buffers of liquid assets and bank lines are viewed as a credit positive, and the same is evaluated alongside the drawing power available with the company, to assess its ability to meet temporary shortfalls in funding requirements. While evaluating the liquidity profile of a company, ICRA takes into consideration the monthly working capital utilisation (with unutilised sanctioned limits imparting greater protection during periods of liquidity strain), the unencumbered cash balances and liquid investments available to the company and its internal cash generation capability. ICRA evaluates the free cash flows of the company and its variability to determine the company's ability to meet cash obligations like debt repayments and investments from its own internal cash flows. Additionally, any fluctuations in working capital cycle, especially during peak requirements, and the availability of back up lines to finance seasonal requirements are also monitored.

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 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. ICRA evaluates the extent of such mismatches and the mitigating factors therein. One source of mitigation could be the existence of adequate buffers of liquid assets/committed bank lines to meet short-term obligations. Another source of mitigation could be the entity's strong financial flexibility to be able to garner fresh funds at a short notice or a potent ability to refinance. Further, ICRA evaluates the extent to which an entity might be impacted by movement in interest rates.

Financial Flexibility

Pharmaceutical entities financial flexibility (or the lack thereof) is reflected in its ability to access the capital or the money markets at short notice, attract diverse and marquee investors and enjoy the confidence of banks, financial institutions and intermediaries. A strong financial flexibility allows an entity to raise fresh borrowings or refinance existing ones in quick time and whenever required. Financial flexibility could emanate from factors such as an entity's large scale of operations with strong financials, large unencumbered cash flows, unencumbered assets and the flexibility to borrow against such assets, or strong parentage or linkages with a strong group. In contrast, among the various measures of an entity's depleting financial flexibility, one relates to a high share of pledged promoter shareholding. A sign such as this may imply that the entity might be persuaded to distribute high dividends or support the promoter group through other means to the detriment of its own credit profile. If the promoters fail to repay their loans (availed by pledging of shares) or top up collateral when required, the lenders could sell the pledged shares. In some cases, this could trigger a change-of-control clause in the rated entity's bond indentures or loan documents and require it to redeem its debt ahead of schedule, creating a liquidity squeeze, besides affecting fresh capital raising ability.

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 ability of the company to honour its debt obligations during period of cyclical stress.

Contingent Liabilities/Off-Balance Sheet Exposures

The likelihood of devolvement of contingent liabilities/ off-balance sheet exposures especially with respect to patent litigations and the financial implications of the same are evaluated for this.

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. ICRA also look at the funding requirements of a company and the funding options available to it.

Others

Event Risk

The pharmaceutical industry has experienced a large number of corporate actions like acquisitions for geographic diversification, backward/ forward integration, product portfolio/ pipelines, manufacturing assets, strengthening technical strengths to name a few. These activities funded by debt often having material impact on the credit profile of a company.

Parent Support

While the credit rating of an entity is a function of its standalone credit profile, in certain cases, the entity's credit quality can also be driven by the relationship with its parent or the promoter group (henceforth referred to as the parent). If the parent's credit profile is relatively stronger than the rated entity, ICRA assesses the ability and the likelihood of the parent extending extraordinary support to the entity. Support here means financial support from the parent expected to be available to the entity in the form of loans, equity, extended credit period, advances etc in times of credit or liquidity stress on the entity. Support here

does not mean operational support in the form of new business opportunities, technology sharing, distribution network sharing and so on as these aspects are factored in the standalone credit profile assessment itself. It may be noted that promoters in their individual capacity, or private equity firms/ other financial investors are generally not treated as parents for assessing the likelihood of extraordinary financial support coming in. If the parent's credit profile is relatively weaker than the rated entity, the entity's rating may be lower than what its standalone credit profile assessment would have merited, given the possibility that the entity may at some point of time be bound to extend financial support to its weaker parent, possibly to the detriment of its own credit profile[1].

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.

[1] For more details on this, readers may refer to the document titled, "Impact of Parent or Group Support on an Entity's Credit Rating", published on ICRA's website.

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