RATING METHODOLOGY – PHARMACEUTICALS

February 2026

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This rating methodology updates and supersedes ICRA's earlier methodology document on this subject, published in February 2024. While this revised version incorporates a few additional clarifications and editorial changes, ICRA's overall approach to rating entities in the sector remains materially similar.

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Overview

Indian pharmaceutical industry can be classified based on business activity involving manufacturing and marketing of pharmaceutical products (all or any of intermediates, active pharmaceutical ingredients (APIs) or formulations), providing contract research and manufacturing services (CRAMS) or those engaged in manufacturing and marketing of alternative medicines (such as ayurveda, homoeopathy etc.)

Formulations – the finished pharmaceutical product – is the end product of the pharmaceutical value chain, ready for consumption by the patient. APIs are the active ingredients with therapeutic properties (also known as bulk drugs) are converted into formulations using additional inactive ingredients/ excipients to make them viable for human consumption, such as tablets, capsules, syrups, drops, ointments or injectables. Formulations are marketed either under a brand name (known as branded formulations) in the case of innovator/ patented drugs or as generic finished dosages with therapeutic equivalence (identical dosage, safety, strength, and quality and for the same intended use) to branded formulations. In some markets, particularly emerging economies such as India, the generics are also sold under brand names (known as branded generics).

The Indian formulations industry is largely a branded generic industry with the presence of a limited number of patented drugs, predominantly self-reimbursing in nature and largely physician-influenced. The industry continues to be fragmented with a large number of players, encompassing both national and regional entities, ranging from small to large, each focusing on different therapeutic segments. The Indian formulation companies have a presence in both the domestic market as well as regulated[1] and semi-regulated export markets.

Rating Methodology

This rating methodology serves as 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. Its aim is to help entities, investors and other market participants understand ICRA's approach to analysing quantitative and qualitative risk characteristics that may impact rating outcomes. This document does not include an exhaustive discussion of all the rating factors that our analysis considers but provides an overall perspective on the considerations that are usually the most important. ICRA's risk analysis framework for pharmaceutical entities can be broadly divided into the following factors –

[1] Regulated markets largely comprise patented products or generics, unlike the Indian market which is dominated by branded generics

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Industry Risk Assessment

Regulatory risks

The domestic pharmaceutical industry is regulated across four aspects: new product approvals, product quality, pricing and patents. Regulations and guidelines concerning manufacturing practices, the Drug Price Control Order (DPCO), the patent protection regulations and others could have credit implications for Indian pharmaceutical entities. While regulatory oversight aims to enhance the industry's sustainability, it can also raise compliance costs and restrict pricing flexibility, potentially impacting profitability. Pharmaceutical entities exporting to highly regulated markets (especially the US and Europe) encounter increased levels of scrutiny from regulatory agencies regarding adherence to manufacturing quality norms. Any adverse observations during such scrutiny can significantly impact an entity's performance, affecting both current business operations and future approvals and consequently, the growth prospects. Depending on the severity of lapses, it can also result in potentially large penalties arising from a failure to supply.

As for pricing controls, the domestic formulations manufacturers must follow the norms set by the National Pharmaceutical Pricing Authority (NPPA) pertaining to the price cap on essential drugs (as defined under the National List of Essential Medicines - NLEM) as well as the maximum permissible annual price increases (price control) on the rest of the portfolio. For the API and the CRAMS players, the pricing is indirectly influenced to some extent, based on the pricing regulations on the formulations. ICRA evaluates the share of an entity's portfolio (to the extent the information is available) under the NLEM. Further, policy changes such as the enhanced focus of the Government of India (GoI) on driving unbranded generic prescriptions are also relevant to analysis from a credit perspective, as these could drive changes in business models of domestic formulation companies. For the export markets, where price cuts are announced by regulatory authorities at defined intervals, entities' ability to continuously launch new products or optimise existing production costs remains critical. Further, any import restrictions, or tariffs imposed on exports from India, could impact the industry due to its large export dependence.

Competitive landscape

The domestic pharmaceutical formulations industry is largely a branded generic industry, with the presence of a limited number of patented drugs. It is predominantly self-reimbursing in nature, as patients pay for medicines, and is characterised by relatively low entry barriers and strong physician influence. The industry is fragmented, with the presence of a large number of players – small as well as big, with a focus on different therapeutic segments – across acute (anti-infectives, pain management) as well as chronic (cardiovascular, central nervous system, etc.) segments. 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 cumulatively created significant opportunities for the generic formulations manufacturers.

Although the Indian pharmaceutical market has predominantly been a branded generic drug market, unbranded generic drugs containing the same active ingredients as their branded counterparts are gaining traction among Indian patients due to GoI initiatives and lower costs. At present, the penetration of unbranded generic drugs is relatively lower. However, if it scales up materially over the medium term, it could increase the competitive intensity for pharmaceutical entities that derive a majority of their revenues from the sale of relatively saturated/ high competition branded generic drugs in the domestic market. Nonetheless, the leading pharmaceutical entities are mostly well diversified in terms of geographical revenue split, mitigating the effects of heightened competition. These entities continue to introduce new products regularly in the domestic market that also include complex branded generics, providing them with a competitive advantage over generic drugs.

Apart from the domestic presence, several Indian formulation players have a presence in the regulated (developed economies) and semi-regulated markets. Indian entities largely cater to the generic segment in these markets, characterised by the 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 product approvals, compulsory price cuts or tendering systems, among others. This has led to intense competition with downward pressure on prices, although the entry barriers in the form of strict

compliance requirements with respect to product registrations and manufacturing quality support margins. Consolidation of the supply chain with fewer players can also exert pricing pressure, as witnessed in the US market. Exports to semi-regulated markets are generally branded generic in nature and the competitive landscape is similar to the domestic formulations industry.

The bulk drug (API) industry is fragmented, and standalone bulk drug players also face competition from large formulation players that have in-house API manufacturing for captive use as well as external sales. Given the commoditised nature of the product, the competitive intensity is higher, and thereby the pricing flexibility is limited compared to the domestic formulation industry.

India is emerging as a major destination for CRAMS, driven by strong chemistry capabilities, skilled manpower with low manufacturing and R&D costs and a large patient population, providing a diverse pool for clinical trials for new chemical entities (NCE). Many domestic formulation players outsource manufacturing of formulations to third-party contract manufacturers for a part of their sales while focussing on new product development and marketing. Although a small number of large players have emerged as leaders within the industry, the domestic CRAMS market remains fragmented, leading to intense competition.

Business Risk Assessment

Scale and market position

The scale of operations, as measured by operating income, is one of the critical drivers of success across segments of the pharmaceutical industry. Large scale typically provides better bargaining power with suppliers and 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 can negotiate better pricing with the drug wholesalers and drug payors for their regulated 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) be better able to absorb the cost of litigations[2], and d) foray into complex products/ therapies.

In addition to the aforementioned factors, for players involved in CRAMS particularly, a large scale enhances their ability to offer product extensions/ different delivery systems while supporting faster product filings on account of regulatory expertise. The entity's market position in its operating geographies or segments enhances rating comfort, as it influences revenue visibility to a large extent. For the formulation manufacturers, the same is measured through the entity's business ranking in the key market/ segments it operates. In case of API players, the strength of a business model is a function of the competitive risk and the degree of the entry barriers that it is exposed to. In general API players with requisite approvals to supply to regulated markets such as USA and Europe; and those with capabilities to manufacture complex molecules enjoy higher barriers to entry, when compared to manufacturers which supply only to semi or unregulated markets. Typically, entities with a large scale and strong market position tend to demonstrate steady performance and hence are important aspects to be analysed.

Business diversification

Entities operating in different segments of the 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 usually limited product portfolios on account of the highly capital-intensive nature of business. Formulation entities that are backward integrated with presence in APIs are assured of timely and quality supply of raw materials, to a large extent. Besides, this enables them to be cost competitive (especially on account of commoditisation as the product ages) and facilitates faster filing of product dossiers for the targeted markets. Conversely, formulation manufacturers face intense competition, with entry barriers linked to therapeutic coverage, portfolio strength, brand equity with prescribers and supply chain efficiencies.

- **Therapeutic coverage and diversity:** Most Indian pharmaceutical entities have a presence in the branded generics segment, largely in the domestic and semi-regulated markets, with a few large players having sizeable exposure to the regulated markets in the generics segment. For pharmaceutical entities, portfolio diversity evaluation is important as the ability of these entities to continually capture larger market and reduce dependence on select therapies. A suitable mix of acute and chronic therapies, coupled with a presence in the fast-growing therapeutic segments/ niches aids stability in financial performance. Notwithstanding the need for diversification, strong market share in key therapy segments through brand recognition among specialists and extensive doctor 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 for formulation players and across products for API players. While analysing the product portfolio, ICRA also attempts to evaluate the price control coverage of the company's portfolio, as higher coverage would constrain profitability.

Similarly, CRAMS entities with reasonably diversified product portfolios and catering to customers with strong brand positions would generally be well positioned to demonstrate stable business performances. Additionally, the ability of CRAMS entities

2 The Indian pharmaceutical entities largely cater to the generic/ branded generic segment globally and must comply with patent protection guidelines in the respective countries as violations could result in lawsuits and large penalties.

to offer products across dosage forms (solids, liquids, injectables, creams, gels, ointments) and help launch new products/ combinations/ dosages are also critical.

It is important for a pharmaceutical entity to distinguish itself from competition and sustain its market share without compromising on profitability. Products that are difficult to replicate or have higher entry barriers, along with a reasonably diverse product basket, strengthen the credit profile. Moreover, a meaningful proportion of revenues from complex generics (that have limited competition)/ speciality products also allows pharmaceutical entities to withstand the pricing pressures in the generics segment.

- **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 they are dependent only on a few customers (in case of business loss/ discontinuation). Customer diversification is important, given the long lead time associated (on account of process validation, technology transfer and site audits by pharmaceutical marketing entities) for new business awards. ICRA evaluates the concentration of revenues with the top few customers to assess the customer 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 an entity to withstand regulatory uncertainties or market conditions related to any single market. In the past, Indian entities forayed into the generics market of European countries either organically or through acquisitions, however, the change in market dynamics (for instance, the 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 a presence in the largest generic markets of the US have faced steep pricing pressure in the recent years, impacting their profit margins. Thus, while evaluating geographic diversification, any adverse impact of regulatory developments on the entity's performance is also assessed to arrive at the credit risk.

R&D capabilities and portfolio strength

As a strong product pipeline is essential for sustainable earnings, an evaluation of company's R&D expenditure is done. While product development across therapeutic areas is critical, the focus areas of generic formulations entities in recent periods has been on newly off-patent product/ combination/ delivery system launches. The higher rated entities normally have an R&D spend of 6-7% of revenues with a pipeline spread across generic filings, new drug delivery systems (NDDS) and complex/ speciality products.

The R&D efforts of API entities are focused on new product development to expand their portfolio and improve process efficiencies to become more competitive as the products mature. Moreover, ICRA also attempts to evaluate if API entities' manufacturing operations are well spread across generic filings as well as products which are yet to go off-patent.

Most large formulation entities from India have significant revenue and profit dependence on regulatory 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 III, IV challenges, developing non-infringing processes), complex products, speciality/ niche products are often better placed from a business sustainability perspective. In the biosimilar space, the presence of Indian pharmaceutical companies has so far been limited. However, a large number of biosimilars are going off-patent in regulated markets over the medium term, which provides an attractive opportunity for companies with requisite technical skills and financial resources.

To develop a healthy pipeline of drugs, entities need to draw up their R&D investments well in advance, targeting products with patent expiry of up to seven to eight years into the future. In the domestic market, entities work on developing a product pipeline for their branded generic business. ICRA also attempts to evaluate the product pipeline (nature of filings, for instance,

abbreviated new drug applications (ANDAs) with Para IV certification, new drug application (NDA) filings for improvised/ new delivery systems in the US market etc.).

Regulatory Approvals for manufacturing

While low-cost manufacturing capability as well as chemistry and process engineering are the strengths of Indian pharmaceutical entities engaged in both formulation and API manufacturing, 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 the regulatory authorities of the countries where the products are exported (FDA for the US market, MHRA for supplies to UK, ANVISA for supplies to Brazil, etc). Entities with only a single manufacturing facility are exposed to asset concentration risks, making them vulnerable to disruptions from force majeure incidents, labour unrest, political uncertainties, warning letters, import alerts etc. In contrast, entities with diversified manufacturing footprints can offset this risk to some extent.

Upgrading and maintaining a manufacturing facility that meets the standards of the regulated markets calls for significant financial commitments. Also, inspection and approvals being a time-consuming process, entities with existing facility approvals from regulators like the 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 the USFDA even for reputed Indian as well as global generic entities, maintaining manufacturing standards has become critical for entities with sizeable exposure to the US and Europe. There have been instances where such regulatory actions have resulted in manufacturing disruptions and penalties from customers arising from a failure to supply, thus impacting revenues and profitability. In case of adverse regulatory action, ICRA attempts to evaluate the entities' approach to mitigate these risks through remedial measures undertaken, including investments in upgrading systems, manufacturing processes, etc. by gathering inputs through management interactions and evaluating strategies like dual location filings (filing for approvals to manufacture the same product from two different facilities).

Summary of the Salient Business Risk Factors - Formulations

	Strongest		Weakest
Scale	The entity has large scale of operations with revenues more than Rs. 10,000 crore	⇨	The entity is a small player in the industry with revenues less than Rs. 300 crore
Market Position	The entity is among the top 10 players in each of the key market segments (US Generics, Branded Formulations in India etc.) it operates in	⇨	The entity has extremely low presence/brand equity among various stakeholders
Geographic Diversification	The entity is highly diversified with no single country/region accounting for >40% of its revenues	⇨	The entity has high concentration with key market accounting for >70% of revenues
Therapeutic Coverage & Diversity	Top 3 TAs[3] contribute <50% to revenues from key branded generic market for the entity	⇨	Top 3 TAs contribute 80-90% to revenues from key branded generics market for the entity
Portfolio Strengths	No. of ANDA filings > 100 with sizeable no. of filings offering limited competition, competitive advantage on account of complexity, Para IVs & FTF[4] filings	⇨	The entity's product portfolio comprises of commoditised products with limited scope of differentiation
R&D Capabilities	The entity's R&D spend is >7% of revenues and activities are well spread across generic filings, NDDS, differentiated products and NCEs.	⇨	The entity's R&D spend is <1% of revenue
Regulatory Approvals for manufacturing	The entity's facilities are approved by multiple regulatory authorities (i.e. US FDA, MHRA, TGA etc.). Clean track record of inspections with no import alert or product ban	⇨	The entity's facilities approved by local/international authorities but several instances of non-compliances

3 *Therapeutic areas*
4 *First to file*

Summary of the Salient Business Risk Factors – APIs

	Strongest	Weakest
Scale	The entity has large scale of operations with revenues more than Rs. 4,000 crore	The entity is a small player in the industry with revenues less than Rs. 150 crore
Geographic Diversification	The entity is highly diversified with no single market accounting for >30% of its revenues	The entity has high concentration with key market accounting for >70% of revenues
Competitive Position	The entity has strong presence in majority of regulated markets (i.e. US, Europe & Japan)	The entity is supplying to small sized players locally
Product Diversity	The entity derives <20% of its revenues from its top three products in key market	The entity derives >90% of its revenues from its top three products
Client Diversification	Top 3 clients contribute <30% to revenues for the entity	Top 3 clients contribute >30% to revenues for the entity
R&D Capabilities	The entity's R&D spend is >7% of revenues	The entity's R&D spend is <1% of revenues
Regulatory Approvals for manufacturing	The entity's facilities are approved by multiple regulatory authorities (i.e. US FDA, MHRA, TGA etc.). Clean track record of inspections with no import alert or product ban	The entity's facilities are approved by local/international authorities but several instances of non-compliances

Financial Risk Assessment

The various financial metrics assessed by ICRA could be divided into four categories viz., profitability, leverage, coverage and liquidity. This document provides a brief summary of why ICRA considers these ratios to be important. For a more detailed description, readers may refer to the note titled, *Rating Approach - Financial Ratio Analysis* available on ICRA's website.

ICRA also draws up projections on the company's likely financial position 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. Depending on the uncertainty around how the various credit drivers could evolve in the future, ICRA also carries out sensitivity analysis to assess the impact of key variables on various financial metrics.

Consolidated financial analysis

The pharmaceutical industry in India comprises several large players with a presence across diverse business segments and geographies through various subsidiaries and associate companies. While evaluating the financial risk profiles of such companies, ICRA analyses consolidated/ group-level financial indicators in terms of capital structure, debt coverage indicators and future funding requirements. For more information on the approach, readers may refer to the methodology titled *Rating Approach – Consolidation* available on ICRA's website.

Profitability metrics

The complexity of products, therapeutic mix, and the geographic market a company operates in, besides operating efficiency, are the key determinants of its profit margins. For APIs and generic formulations players, 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 high market share and hence higher margins). Entities manufacturing products involving less complex and easily replicable processes are often subject to intense competition, and this is reflected in their usually low gross margins. Margins are also typically moderate for entities 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 higher regulated markets in general offer better operating profit margins, price erosions can be steep depending on the number of ANDA filings for the product. Generic entities creating a balanced portfolio of commoditised generics, exclusivities as well as limited competition products are in a better position to sustain/ improve their profitability than those focused only on commoditised products. Entities focused on the domestic branded formulations market with a 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.

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.

Validation of business risk through profitability metrics

[Indicative Metrics[5]]

	Strongest	Weakest
RoCE	>=25%	<10%
Volatility in RoCE	<=10%	>55%

[5] The indicative financial metrics mentioned here and elsewhere in the document are intended to provide a broad overview to the readers regarding what ICRA generally considers as 'relatively strong' or 'relatively weak' metrics. It is, however, possible that an entity has relatively weaker metrices on one or more financial parameters, but its credit risk is assessed to be low because of other mitigating factors, including (but not limited to) stronger metrices on other financial parameters, a healthy business risk profile, strong financial flexibility or a strong promoter group that is willing to extend distress support to it.

Leverage

Financial leverage is a measure of an entity's dependence on borrowed funds. A lower the dependence on borrowings indicate a lower (better) leverage. When an entity borrows, it is obliged to pay both the interest as well as the principal to the lenders as per a defined schedule. This increases the fixed cost burden on the borrowing entity and, in extreme cases, raises default risk. While high leverage may imply higher risk from a credit perspective, it is often adopted by shareholder-oriented management, as high leverage in favourable times can lead to higher returns on equity capital. An entity's financial leverage may thus reflect its management's financial policy and risk tolerance, besides being a point-in-time indicator of its business and financial choices. An entity with lower leverage is better equipped to withstand volatility in cash flow generation arising from competitive challenges, unexpected costs or regulatory changes. A low total debt-to-OPBIDTA multiple is viewed favourably as it reflects the company's ability to comfortably service its debt obligations, fund growth opportunities through R&D and invest in market expansion to improve its competitive position. The financial policies and the risk appetite of the management remain key rating factors. Leverage levels for some API and/or CRAMS companies is relatively higher due to high capex intensity of the business. Whereas leverage levels for formulation companies would be relatively lower as the spend is primarily on product development, funded largely through cashflow generation.

Assessment of Leverage

[Indicative Metrics]

	Strongest		Weakest
Indebtedness Ratio	**<=0.9x**	→	**>3.0x**
Debt to Profit Ratio	**<=0.5x**		**>5.0x**

Coverage

Coverage is a measure of an entity's debt-servicing ability and is calculated as the ratio of profits to the debt-servicing obligations in a given time period. The higher the ratio, the greater the cushion available to withstand variability in profits while meeting financial obligations. Coverage is a function of an entity's profits, leverage and debt characteristics (in terms of cost of debt and repayment schedule). The interest coverage indicator reflects the company's ability to fund the cost of external borrowings after meeting all operating expenditure requirements. The debt service coverage ratio (DSCR) is a measure of an entity's debt-servicing ability and is calculated as the ratio of profits to debt-servicing obligations in a given period. Entities with higher profitability and lower leverage will generally have better coverage ratios and thereby healthier financial risk profiles.

Assessment of coverage

[Indicative Metrics]

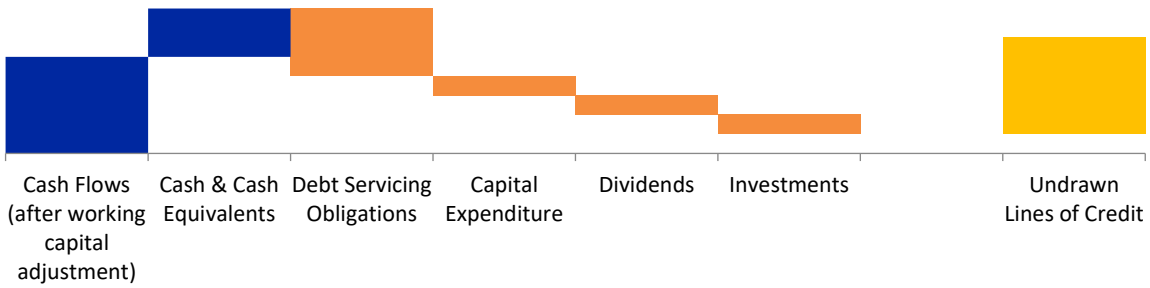
	Strongest		Weakest
Interest Coverage	**>=18.0x**	→	**<2.0x**
DSCR	**>=4.0x**		**<1.1x**

Liquidity profile

Liquidity is the measure of an entity's ability to meet its short-term cash obligations from various internal or external resources. Internal resources include cash flows from operations, unencumbered cash and cash equivalents on the balance sheet and cash inflows expected from the monetisation of physical and financial assets. External resources include undrawn lines of

credit or equity capital. The short-term obligations include both the committed as well as the contingent claims on an entity's cash, including the debt servicing obligations, working capital requirements, capital expenditure and other investment outlays, dividend and share buyback-related outflows, besides the sudden demand arising from the crystallisation of discrete events such as unfavourable outcome of an ongoing litigation. Within the pharmaceutical industry, API manufacturers typically exhibit relatively higher working capital intensity owing to bulk procurement of key starting materials (KSMs) and elevated inventory buffers arising from import dependencies and relatively longer process cycles. Their capex requirements are also moderately high. The funding requirements are met through a mix of working capital facilities such as cash credit, working capital demand loans and packing credit in foreign currency, term loans and internal accruals. In comparison, formulations manufacturers have relatively moderate working capital intensity and capex requirements. However, companies with a larger share of exports to regulated markets (especially North America) have higher working capital requirements. The funding requirements for formulations manufacturers are primarily met through internal accruals. The higher the cushion available between the resources available (especially internal resources) and the obligations, better the liquidity profile of an entity. Liquidity is generally assessed in conjunction with the vulnerability of an entity to timely refinance/renew short-term sources of funding. Depending on the circumstances, an entity that has a relatively modest liquidity profile but a strong refinancing ability may not be viewed too unfavourably. ICRA also notes that the liquidity available with an entity may be for a temporary period and hence an entity's overall policy towards maintaining adequate liquidity (given the trade-off between returns and liquidity) is accorded due importance in the analytical approach[6].

Liquidity snapshot over any defined period



Cash flows

The rating exercise is primarily focused on assessing the future debt-capability. As cash is required to service debt obligations, a detailed cash flow analysis is undertaken to evaluate external funding requirements and the likely financial position going forward. A cash flow statement represents the sources from which cash is generated and its deployment. Analysed here are the trends in an entity's fund flow from operations, cash consumed to fund the working capital, the retained cash flows after paying out dividends or carrying out share buybacks, and the free cash flows after meeting debt repayment obligations and capital expenditure needs. Indian pharmaceutical companies adopting the high-risk high-reward strategy of patent challenges in the US (referred to as Para IV filings), which entail significant uncertainties regarding the final outcome, are exposed to large cash outflows due to litigation. ICRA attempts to assess the financial impact arising from the same.

Capital expenditure and investment plans

The capital expenditure plans of a pharmaceutical entity reflect its plans for capacity expansion, localisation, complying with regulatory norms and new product development. Investment related to increasing the level of indigenisation is generally a positive, as it would result in improved levels of profitability and lower reliance on imports going forward. New product development also highlights the commitment of the entity to enhance its product portfolio. The quantum of capital

[6] For more details on how ICRA assesses liquidity, readers may refer to the document titled, "Liquidity Analysis of Entities in the Non-Financial Sector" published on ICRA's website

expenditure and funding plans for the same are also evaluated to understand their impact on the financial risk profile of the entity.

Foreign currency risks

Foreign currency risks for pharmaceutical entities primarily arise on account of export revenues, KSM/intermediate/ API imports and foreign currency denominated liabilities (including debt). While taking into consideration the hedging policy of the entity 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. Foreign currency risk for an entity is measured by considering its un-hedged net liabilities [= foreign currency receivables – foreign currency payables – foreign currency debt] and assessing the magnitude of such exposure, relative to the entity's profits.

Tenure mismatches, and risks relating to interest rates and refinancing

Large dependence on short-term borrowings to fund long-term investments or other long-term funding requirements can expose an entity to significant re-financing risks, especially during periods of tight systemic 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 could be the entity's strong financial flexibility to raise 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 the movement in interest rates.

Other elements of credit risk assessment

Parentage/ group support

The credit rating of an entity is a function of its standalone credit profile. However, 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 entity's credit profile is relatively stronger than the rated entity, ICRA assesses the ability and likelihood of extraordinary financial support. Such support may include loans, equity, extended credit periods or advances during stress. It does not signify 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. This is given the possibility that the entity may at some point in time be bound to extend financial support to its weaker parent, possibly to the detriment of its credit profile[7].

Financial flexibility

An entity's 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, whenever required. Financial flexibility could depend on 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

7 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.

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. Financial flexibility could also be impacted in cases of adverse industry developments, weakening business profile, or management and governance concerns, which could translate into a sharp decline in market capitalisation or spike in bond yields and consequently constrain an entity 's ability to raise fresh capital or materially increase its cost of capital.

Debt servicing track record

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 and willingness. Nevertheless, the reason behind past defaults is also analysed, which could also be due to adverse demand situations. A company's ability to honour its debt obligations during a period of cyclical stress is also factored in.

Event risk

ICRA recognises the possibility of events such as unrelated diversification, mergers and acquisitions, business restructuring, asset sales and spin-offs, litigations, equity infusion and refinancing, which could have a material impact on the credit profile of an entity. Incorporating the impact of such discrete events in the credit rating, from the beginning, is often difficult. To make rating decisions in such cases, ICRA applies its analytical judgment based on the rated entity's track record, the credibility of the management and the experience of having seen similar situations play out in other entities. However, given the nature of such events, it is possible that the rating may undergo a material change later, upon the occurrence of the event.

Contingent liabilities/ off-balance sheet exposures

ICRA analyses the likelihood of devolvement of contingent liabilities/ off-balance sheet exposures and its impact on the entity's financial metrics while factoring the mitigants such as a strong liquidity cushion.

Accounting quality

ICRA reviews accounting policies, notes to accounts, auditors' comments and other disclosures in the Annual Report. Deviations from accounting standard/ practices are assessed and the financial statements of the entity are adjusted where feasible, to reflect the impact of such deviations. Significant deviations may be indicative of weak corporate governance practices in the entity.

Management Quality Assessment

In addition to the industry, business and financial risk analysis, all credit ratings incorporate an assessment of the quality of the rated entity's management and its financial policies.

Quality of management and financial policies

As a part of its process, ICRA undertakes discussions with the rated entity's management to understand its views on past performance as well as its future plans and strategies, besides the outlook on the industry. Some of the points assessed are:

- Experience of the promoter/ management in the industry
- Commitment of the promoter/ management to the rated entity
- Risk appetite of the promoter/ management and risk mitigation plans
- Policies on leveraging, managing interest rate and currency risks
- Management's past success in introducing new projects and managing changes in the external environment
- Management's plans on new projects, acquisitions and expansions

- Periodic interactions with the management help ascertain the shifts, if any, in their financial policies.

Assessment of Environmental, Social and Governance (ESG) Risks

The assessment of ESG risks by ICRA involves a broad range of considerations that pertain to the sustainability of an entity with a focus on aspects that can have a material impact on its credit quality. E&S risks may be sectoral or entity-specific and influenced by external factors such as regulation or demographics, while G risks are largely entity-driven. The impact of the E&S risks on an entity's credit profile tends to be asymmetric. If the ESG risks are material but unmitigated, these generally translate into pulling down the rating, but generally, the ratings are not pushed up even when the ESG context is favourable.

Environmental (E) and Social (S) risks

As this methodology highlights, while undertaking credit assessment of entities, ICRA seeks to incorporate all relevant credit considerations into its rating decisions while taking a forward-looking view of the risks and the mitigants. The relevant credit considerations include (sometimes overtly, sometimes covertly) the E&S factors that could affect the rated entity/ transaction. While ICRA's analytical approach does not explicitly disaggregate these risks to assess their impact on the rating, these risks are often assessed broadly. Further, it is not always feasible to disaggregate the sub-components of E&S risks fully or precisely in credit analysis since these considerations often tend to overlap.

The materiality and time horizon of E&S risks vary across sectors and entities. In some cases, risks may be material but offset by other fundamental strengths. In other cases, the adverse impact of the E&S risks is expected to play out in the distant future, and hence these considerations do not necessarily weigh on the rating at present. The expectation is that when these risks manifest in future, the rated entity by then would possibly adapt itself by realigning its business model.

While evaluating E&S risks, ICRA's objective is only to assess the direct and indirect risks that an entity faces and how it already is intends to mitigate the impact of such risks on its credit profile. As an example, ICRA only assesses whether an entity is exposed to physical climate risks, or carbon transition risks such as those arising from changes in regulations or other environmental and social risks and seeks to understand the various mitigation and adaptation approaches that the entity is implementing to mollify these risks.

Pharmaceutical entities do not face any major physical climate risk. However, they are exposed to tightening environmental regulations regarding breaches of waste management and pollution norms, particularly API manufacturers, which can lead to an increase in operating costs and capital costs. Capital investments may need to be incurred to upgrade the effluent treatment infrastructure to reduce waste generation. Overall, entities in the industry have a moderate exposure to environmental risks.

Pharmaceutical entities face high social risks relating to product safety and quality wherein lapses could result in both reputation damage as well as litigation costs. They also face risks relating to their ability to retain qualified personnel for R&D and process engineering, and maintenance of high manufacturing compliance standards. Moreover, price controls (through DPCO) and increasing focus on generics drugs are also social risks faced by industry participants.

Governance practices

A sound corporate governance structure should clearly delineate the roles and responsibilities of the Board of Directors and the management. The composition of an entity's Board, its involvement in strategic decision making and the entity's compliance with the legal and regulatory requirements are factored in during credit assessments. ICRA also seeks to gain a qualitative understanding of the entity's commitment to follow transparent and credible practices, as reflected in the presentation of the financial statements, timeliness and depth of disclosures, consistency in communication and the openness about sharing information during the rating process. Additionally, factors such as the complexity of the corporate group structure, related party transactions, instances of financial support to group entities at the expense of debt holders, and any abrupt resignations of auditors or independent directors are evaluated.

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 near-to-medium term and the adequacy of such cash flows vis-a-vis its debt servicing obligations and other funding requirements. ICRA's approach to rating pharmaceutical entities also incorporates an assessment of the company's market position, product, therapeutic area, geographic and customer diversification, R&D and manufacturing capabilities, regulatory risks and competitive landscape.

ANNEXURE

Summary of rating factors and an example to illustrate the key building blocks of a credit rating for a formulations entity

		Strong	Comfortable	Adequate	Moderate	Weak
Industry Risk	Industry Position					
Business Risk	Scale					
	Market Position					
	Geographic Diversification					
	Therapeutic Coverage & Diversity					
	Portfolio Strengths					
	R&D Capabilities					
	Regulatory Approvals for Manufacturing					
Financial Risk	Profitability and Earnings Stability					
	Leverage					
	Coverage					

		Enhance	Support/ Neutral	Hinder
Do these factors enhance or hinder the credit profile?	Diversification			
	Refinancing Dependence, Liquidity and Financial Flexibility			
	Currency Risk			
	Financial Policy			
	Management, Governance & Reporting			

		Very High				High				Moderate				Low	
Parent Support	Likelihood of Parent Support														
	Rating of Parent	AAA	AA+	**AA**	AA-	A+	A	A-	BBB+	BBB	BBB-	BB+	BB	BB-	B/ C category
	Final Rating	**AAA**	**AA+**	**AA**	**AA-**	**A+**	**A**	**A-**	**BBB+**	**BBB**	**BBB-**	**BB+**	**BB**	**BB-**	**B/ C category**

The graphic above is only for illustrative purposes and does not depict an actual rating outcome generated by a framework. The rating process typically involves the use of a framework as a reference tool to provide a broad indication of an entity's credit profile based on factors generally considered important for credit risk assessment. However, given the specific nuances and unique characteristics of individual entities, the framework may not always adequately capture all relevant considerations evaluated by the rating committee while assigning the ratings. Consequently, the ratings assigned by the rating committee may differ from the framework's indicative assessment.

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About ICRA Limited:

ICRA Limited was set up in 1991 by leading financial/investment institutions, commercial banks and financial services companies as an independent and professional investment Information and Credit Rating Agency.

Today, ICRA and its subsidiaries together form the ICRA Group of Companies (Group ICRA). ICRA is a Public Limited Company, with its shares listed on the Bombay Stock Exchange and the National Stock Exchange. The international Credit Rating Agency Moody's Investors Service is ICRA's largest shareholder.

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