CRISIL Ratings

CRISIL Ratings criteria for the pharmaceuticals industry

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Executive summary

The Indian pharmaceutical industry comprises manufacturers of bulk drugs and formulations. Bulk drugs comprise active pharmaceutical ingredients used to produce formulations (end product). While multinational companies (MNCs) dominated the domestic pharmaceutical industry till the early 1980s, the late 1980s and early 1990s saw the emergence of Indian companies.

The pharmaceutical industry remains relatively immune to economic cycles, unlike other industries where demand is influenced by macroeconomic fundamentals. This is reflected in the steady growth rate of domestic pharmaceutical players. On the other hand, overseas markets, specifically the US generics market, have seen growth moderate in recent years owing to rising competition and pricing pressure. As a result, players are gradually diversifying into biosimilars and complex/specialty products, where competition is lower.

Scope

While the broader criteria for manufacturing companies[1] applies to entities in the pharmaceutical sector as well, this article[2] focusses on the CRISIL Ratings analysis of government policies and regulatory issues, and the market position and operating efficiency of pharmaceutical companies.

The criteria document highlights the parameters that are relevant for assessing the credit profile of issuers within the sector. These parameters serve as illustrative guidelines. The relevance of specific parameters varies based on the issuer's unique circumstances. For instance, if the liquidity of the company is weak, industry risk or other business-related factors may exert minimal influence on the final rating. Likewise, business parameters that hold substantial importance for one issuer may be less pertinent for another, potentially being encompassed within the broader category of industry risk.

Business risk

Government policies and regulatory issues

Impact of changes in government policy and regulations

The pharmaceutical industry is highly regulated worldwide, by virtue of its direct bearing on public health. In India, too, government policies play a key role in regulating the performance of companies, with patents, prices and quality acting as the three cornerstones.

In January 2005, in compliance with the World Trade Organization, India shifted to the product patent regime from the process patent regime, thereby harmonising its patent regime with global markets.

Indian regulations explicitly regulate prices of some drugs through the Drug Price Control Order (DPCO), which ensures the drugs are available at reasonable prices. This restricts the pricing flexibility of companies, thereby affecting their profitability.

[1] The detailed criteria 'Rating criteria for manufacturing and services sector companies' and 'CRISIL's approach to financial ratios'—are available on the CRISIL Ratings' website under the section, 'Criteria and Methodology'.

[2] For accessing the previous published document on 'Rating criteria for the pharmaceuticals industry', kindly follow the link: https://www.crisilratings.com/content/dam/crisil/criteria_methodology/health-care/archive/CRISIL-Ratings-crieria-pharmaceutical-industry_2007-feb2021.pdf

The new pharmaceutical policy notified in 2013 brought 348 essential drugs in the National List of Essential Medicines under price control. More drugs were added subsequently to this list, bringing over a fifth of the pharmaceutical market by value under price control by fiscal 2023.[3]

For analysing the impact of pricing control on the profitability of a company, CRISIL Ratings looks at the percentage of the company's sales under the purview of pricing controls. However, considering the large number of players, competitive pressures, rather than regulations, could be the key determinant of prices in many segments over the medium term.

In terms of quality, no drug can be imported, manufactured, stocked, sold or distributed in India unless it meets the quality standards specified in the Drugs Act, 1940. The Union Health Ministry banned 344 fixed-dose combination (FDC) drugs (including several antibiotics and analgesics) in 2016 and 14 additional FDCs in 2023 on the recommendations of an expert committee, as these FDCs had no therapeutic justification.

Furthermore, pharmaceutical companies exporting to developed markets (such as the US) need to comply with the United States Food and Drug Administration (US FDA) guidelines for manufacturing facilities and processes. They are subject to periodic inspection and scrutiny — any adverse observation could impact product supply and new product launches from those facilities. In response, the companies may have to incur remediation costs, which could impact their profitability. Moreover, restrictions on new product launches from the affected plants could constrain future revenue potential from the US market.

The impact of product patent regime

Product patents for pharmaceuticals were introduced in India on January 1, 2005, with an amendment to the Patents Act, 1970, in conformity with the Trade-Related Aspects of Intellectual Property Rights agreement. Indian companies are no longer allowed to introduce the latest patented drugs without licensing agreements with the patent owners. Earlier, India recognised only process patents, wherein patents were granted based on the production process and not the end product. The process patent regime helped manufacturers develop strong formulation skills. India’s entry into the product patent regime marked the end of the protected era and signalled a new phase in integration of domestic players into the global market.

This integration saw Indian manufacturers strengthening their presence in the domestic and international markets through various strategies, including:

- Setting up manufacturing and marketing joint ventures abroad
- Tapping the generic (patent expired) market of developed countries
- Conducting clinical trials in India, thereby reducing development cost for new drugs
- Research and development (R&D) tie-ups with international majors
- Forming alliances (co-marketing/licensing arrangements) with MNCs for new drug launches

CRISIL Ratings considers the strategies that companies have adopted to maintain the pipeline of new products. The total worth of drugs going off-patent globally and growing population of the aged in developed markets present a sizeable opportunity for Indian players to export bulk drugs and generics. Hence, CRISIL Ratings considers the impact of such strategies on the financial structure and business prospects (such as exports) of the company.

[3] Source: CRISIL Research

Other issues

The CRISIL Ratings analysis includes issues such as tariffs, taxes and non-tariff barriers such as reduction in customs duty and excise duty exemptions. It covers the impact of changes in indirect and income tax rules on competitiveness and considers how sensitive the company's performance is to such changes. CRISIL Ratings also assesses litigations and lawsuits pertaining to the developed markets and their impact on the company's financial risk profile.

Market position

Product mix

The market position of a pharmaceutical company is largely determined by its product mix and competitiveness. CRISIL Ratings examines the overall sales mix of the company in terms of bulk drugs and formulations, and the break-up of sales between the domestic, regulated and semi-regulated markets.

Factors affecting market position for bulk drug manufacturers

- **Pricing ability:** Given the intense competition, market position is largely determined by pricing ability, which is linked to the company's operating efficiency and economies of scale.
- **Product quality:** Quality of products, reach of the distribution network and reliability of services are key differentiators.
- **Product range:** Product diversity and presence in molecules that are complex to manufacture significantly mitigate competitive pressures and support performance in terms of sales growth and profitability. This becomes more essential in the light of price caps and FDC bans, as reliance on a few products can adversely impact the company.
- **Geographical diversity:** Regulated markets (such as the US and Europe), which have high entry barriers, offer a premium over realisations in other markets. Exports to different markets not only enhance the credit profile of the company, but also minimise risks associated with adverse market conditions in any country.
- **Access to developed markets**: Given the intense competition in the domestic bulk drug market, access to developed markets lends significant business diversity. However, to tap such markets, Indian companies need to get their manufacturing facilities approved by regulatory agencies such as the US FDA and its counterparts in other markets. While compliance with current Good Manufacturing Practices requires higher capital and R&D investments, it enables pharmaceutical companies to file for Drug Master Files, which is necessary to tie up as a supplier to established drug manufacturers in developed countries. CRISIL Ratings evaluates the company's strategy and progress on these fronts to determine future benefits.

Factors affecting market position for formulators

The formulations segment (both domestic and exports) has been witnessing pricing pressure (the quantum keeps varying) — due to addition of drugs under price control in the domestic segment, and due to buyer group consolidation, increased approvals of abbreviated new drug applications and intense competition in overseas markets. Some key determinants of performance are:

- **Geographical and product diversification strategy:** With increased competition in the developed markets, pharmaceutical companies have begun to focus more on complex generics, biosimilar products,

niche molecules or therapeutic market segments, and growth through Para IV filings. Several companies also focus on select semi-regulated markets of Africa, Asia and Latin America, where out-of-pocket expenditure on healthcare is high. Penetration in these markets, in terms of distribution channels and product portfolio, is necessary to leverage this opportunity. On the domestic front, companies are targeting growth through new product launches and pushing volume by increasing sales efforts and consolidating their focus on a few key therapy areas. Furthermore, companies are focusing on niche segments of biosimilar and specialty products, which have lower competition and higher profit margin. CRISIL Ratings evaluates the level of risk mitigation followed by companies in their growth strategies and considers the diversity in revenue streams from different product segments and geographies.

- **Distribution set-up:** For domestic and semi-regulated markets, CRISIL Ratings assesses the company's marketing and distribution set-up in terms of geographical reach and linkage between the medical representative sales force and doctors. Productivity of the sales force is also considered.
- **Therapeutic segment coverage:** A unique feature of the formulations business is the number of therapeutic segments. Each segment assumes characteristics of a separate industry and varies in terms of growth rate, loyalty of usage, rate of new drug discovery and competitive pressure. CRISIL Ratings assesses the company's strategy to increase its presence in fast-growing segments.
- **Market share:** CRISIL Ratings examines the company's position in therapeutic segments in terms of relative market share, growth rate and presence of strong brands.
- **Brand loyalty:** Another key feature of the formulations business is the premium and loyalty of the medical fraternity associated with brands. Large brands that are well entrenched in their respective therapeutic segments strengthen the company's business position and render stability to sales. In analysing the relative position of companies on this aspect, CRISIL Ratings looks at the number of strong brands in the company's portfolio and their contribution to overall sales. In recent years, Indian companies operating in niche and complex molecule segments have started selling their own or acquired brands through their distribution channels in developed markets (such as the US).
- **New product launch:** In an industry driven by discovery of new product segments/therapies, which either replace older products/therapies or fulfil unmet therapeutic needs, presence of new therapies/products in the company's product basket is another key determinant of the overall competitive position. Newer therapies/molecules, specifically in the biosimilar and specialty pharmaceutical segments, typically command a premium over older therapies and witness higher growth rates, often at the expense of older therapies. This has implications on the company's growth and profitability prospects. To assess the company's capabilities in this respect, CRISIL Ratings looks at its track record of introducing new products and their contribution to overall turnover. For Indian subsidiaries of international pharmaceutical majors, the level of new product launches is guided by research strengths of the parent company and the latter’s policy of differential pricing for developing countries such as India. CRISIL Ratings also examines various strategies adopted by the company, such as co-marketing and licensing arrangements with patent holders of new generation drugs.

Operating efficiency

Technological capability

Manufacturing involves two stages, the first where bulk drugs are produced, and the second where these bulk drugs are formulated into various dosage forms such as tablets, capsules and syrups. Manufacturing of bulk drugs is technology- and capital-intensive, whereas making formulations is simpler and involves physical processes such as mixing, adding binders and packaging, with relatively small capital requirement.

In analysing the operating efficiencies of a bulk drugs manufacturer, CRISIL Ratings considers the chemical synthesis capabilities and process complexities. A product with high manufacturing complexity, such as that involving fermentation technology in bulk drugs as well as biosimilars, typically has high entry barriers and hence fewer players.

Extent of backward integration

CRISIL Ratings also looks at the level of backward integration for formulation companies and flexibility to manufacture a wide range of bulk drugs. Backward integration helps improve operating margin, pricing flexibility and control over quality standards, compared with smaller players. On the flip side, it may constrain ability to capitalise on cheaper intermediate and raw material sources.

Cost of production

Given the commoditised nature of certain bulk drugs, analysis of the company's operating efficiency is incomplete without a comparative assessment of the costs of production vis-à-vis the landed costs of imports.

Quality standards

While assessing the operating efficiency of a formulator, CRISIL Ratings considers the level of automation and certification of the company's facilities by regulatory authorities in the US and Europe. This is critical, given the increasing focus of Indian companies on exports and the higher regulatory scrutiny by the US FDA after the implementation of the Generic Drug User Fee Act.[4]

R&D

Internationally, lifecycles of pharmaceutical products necessitate that companies keep up a steady stream of new product launches. This is critically linked to the company's R&D capability. Consequently, most leading companies dedicate a large proportion of their resources (in terms of people, funding and time) for discovering new molecules that will drive future growth. Resource commitment to R&D is justified by the high return on investment on account of pricing flexibility and patent protection for new products.

In the past, R&D by most Indian companies was restricted to process reengineering for new drugs introduced worldwide, development of new dosage forms and better drug delivery mechanisms. However, with the changes in the patent regime (to product from process) in 2005, importance of basic R&D in the Indian context has increased. Pharmaceutical companies have made concerted efforts to step up their R&D activity. Apart from getting a regulatory clearance for generic introductions in the regulated markets, companies are focusing more on new drug delivery systems, biosimilars and new chemical entity research.

Some of these activities involve large expenditure with uncertain outcomes. Companies have been managing this risk through various strategies, which include partnering and out-licensing. International pharmaceutical companies have also begun to focus on collaborative research and outsourcing of research activities to contract research organisations to reduce overall R&D cost. This offers ample opportunities for Indian companies, given their process

[4] Generic Drug User Fee Amendment – A law introduced by the US FDA that requires the industry to pay user fee to supplement costs of reviewing generic drug applications and inspecting facilities.

strengths and access to skilled manpower at a lower cost. For assessing a company's ability to capitalise on these opportunities, CRISIL Ratings examines the quality of scientific and technical manpower, annual spend on R&D, and adequacy of R&D facilities. CRISIL Ratings also examines the risk-mitigation strategies followed in undertaking large R&D expenditure, given the long gestation, including monetisation of pipeline or finding a strategic partner for joint development.

Financial risk

For the analysis of the financial risk profile of a pharmaceutical company, CRISIL Ratings follows the standard criteria used for all manufacturing companies. The criteria is presented in detail in our publications, ‘Rating criteria for manufacturing and services sector companies' and 'CRISIL's approach to financial ratios'.

Management risk

To analyse the management risk of a pharmaceutical company, CRISIL Ratings follows the standard criteria used for all manufacturing companies, as detailed in ‘Rating criteria for manufacturing and services sector companies’ under the ‘Criteria and Methodology’ section on the CRISIL Ratings website.

Conclusion

CRISIL Ratings believes that the key success factors for the pharmaceutical sector include:

- Strong R&D capabilities
- Diversity in product mix and presence of molecules involving complex manufacturing
- Geographical diversity and brand equity

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