

CRISIL Ratings' criteria for the pharmaceuticals industry

February 2021

Criteria contacts

Somasekhar Vemuri

Senior Director
Rating Criteria and Product Development
Somasekhar.vemuri@crisil.com

Rama Patel

Director
Rating Criteria and Product Development
rama.patel@crisil.com

Venkata Sumanth Devarapalli

Analyst
Rating Criteria and Product Development
Venkatasumanth.devarapalli@crisil.com

Ramesh Karunakaran

Director
Rating Criteria and Product Development
ramesh.karunakaran@crisil.com

Chaitali Nehulkar

Associate Director
Rating Criteria and Product Development
chaitali.nehulkar@crisil.com

In case of any feedback or queries, you may write to us at Criteria.feedback@crisil.com

Executive summary

The Indian pharmaceutical industry covers manufacturers of bulk drugs and formulations, and healthcare segments such as medicines and diagnostic kits. Bulk drugs comprise active pharmaceutical ingredients that are used to manufacture 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 macro-economic fundamentals have a strong influence on overall demand, demand for pharmaceutical products is relatively independent of such parameters, which is reflected in the fairly steady growth rate reported by domestic players. On the other hand, overseas markets, specifically the US, have witnessed moderation in growth during recent years owing to rising competition, pricing pressure and fewer products going off-patent.

Scope

While the broader criteria of manufacturing companies¹ applies to entities in the pharmaceutical sector as well, this article² focusses on CRISIL Ratings' analysis of government policies and regulatory issues, and the market position and operating efficiency of pharmaceutical companies.

Business risk

Government policies and regulatory issues

Impact of changes in government policy and regulations

The pharmaceutical industry has been highly regulated worldwide, by virtue of its direct bearing on public health. In India too, government policies have played 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 the patent regime with global markets.

Indian regulations explicitly regulate prices of few drugs through the drug price control order (DPCO). While DPCO ensures these drugs are available at reasonable prices, it restricts the pricing flexibility of companies and thus affects their profitability adversely.

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

² For accessing previous published document on 'Rating criteria for the pharmaceuticals industry', kindly follow the link: https://www.crisil.com/content/dam/crisil/criteria_methodology/health-care/archive/CRISIL-Ratings-criteria-pharmaceutical-industry_2007_2.pdf

The new pharmaceutical policy, notified in 2013, brought 348 essential drugs in the National List of Essential Medicines (NLEM), under price control. Subsequent revisions added more drugs to this list, and brought nearly a fifth of the pharmaceutical market by value, under price control by fiscal 2017.³

For analysing the impact of pricing controls on the profitability of companies, CRISIL Ratings looks at the percentage of a company's sales that comes 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.

As far as quality is concerned, no drug can be imported, manufactured, stocked, sold or distributed in India unless it meets the quality standards specified in the Drugs Act, 1940. In 2016, the union health ministry banned 344 fixed-dose combination (FDC) drugs (including several antibiotics and analgesics) on the recommendations of an expert committee as these were allegedly irrational combinations. Despite a stay order on the ban and the matter remaining sub judice, several pharmaceutical companies have withdrawn contentious FDC drugs because of the impact on prescriptions by medical practitioners.

Furthermore, pharma companies engaged in exports 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 as well as new product launches from those facilities. In response, the companies may have to incur remediation costs, which could adversely impact their profitability. Moreover, restrictions on new product launches from the affected plants could adversely impact future revenue potential from the US market.

The impact of post-product patent regime

Product patents in pharmaceuticals were introduced in the country from January 1, 2005, with an amendment of the Patents Act, 1970, in conformity with the Trade-Related Aspects of Intellectual Property Rights agreement. Indian companies are now no longer allowed to introduce the latest patented drugs without licensing agreements with the patent owner. Prior to this, 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 to 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, some of which are listed below:

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

CRISIL Ratings, in its assessment of the impact, 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

³ Source: CRISIL Research

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 respective company's financial structure and business prospects (such as exports).

Other issues

CRISIL Ratings' analysis also factors in issues such as tariffs, taxes and non-tariff barriers such as reduction in customs duty, excise duty exemptions, and ban on bulk drug imports. The analysis covers the impact of changes in indirect and income tax rules, on competitiveness of companies, and takes into account how sensitive the company's performance is to such changes. CRISIL Ratings also assesses various litigation and lawsuits pertaining to the developed markets and its impact on the companies' financial risk profile.

Market position

Product mix

Market position of a pharmaceutical company is largely determined by the product mix and competitiveness of products. CRISIL Ratings examines the company's overall sales mix in terms of bulk drugs and formulations, and the break-up of domestic and export sales.

Factors affecting market position for bulk drug manufacturers:

- **Pricing ability:** Given the intense competition, market position is largely determined by pricing ability that is linked to the company's operating efficiencies and economies of scale.
- **Product quality:** Quality of products and reliability of services also act as key differentiators.
- **Product range:** According to CRISIL Ratings, diversity of the product range and presence of 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 few products can adversely impact the company.
- **Geographical diversity:** Regulated markets such as the US and Europe, which are characterised by high entry barrier, offer a substantial premium over realisations in other markets. Exports to different markets not only enhance the company's risk profile, but also minimise event risks associated with adverse market conditions in a specific country.
- **Access to developed markets:** Given the intense competition in the domestic bulk drug market, access to developed markets lends significant business diversity to a pharmaceutical company. 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 are necessary for them to tie up as suppliers to established drug manufacturers in developed countries. CRISIL Ratings evaluates a 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 witnessed pricing pressures – on the domestic segment due to price controls; and on the export segment due to wholesale consolidation. NLEM (2015) brought in a large number of drugs related to chronic ailments and cancer treatment under price control, thus impacting the domestic segment. Export markets witnessed healthy growth of nearly 14% in compound annual terms during fiscals 2012-16, with blockbuster drugs going off-patent and increased insurance coverage in developed markets. However,

wholesale consolidation (merger of drug distributors) in the US eroded the bargaining power of formulators. In light of such regulatory and market developments, some of the key determinants of performance according to CRISIL Ratings are:

- **Strategy:** With falling patent expiries and increased competition in developed markets, pharmaceutical companies have begun to focus increasingly on complex generics or bio-similar products, niche molecules or therapeutic market segments, and growth through Para IV filings. Several companies are also focusing on semi-regulated markets such as Brazil or Russia, where out-of-pocket expenditure on healthcare is high (unlike developed markets). Penetration in these markets, in terms of distribution channels and product portfolio, is necessary for companies to leverage upon 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 few key therapy areas. Furthermore, companies are also focusing on niche segments of biosimilar and specialty pharma segments, which have relatively lower competition and high profit margins. CRISIL Ratings, in its assessment, evaluates the level of risk-mitigation followed by companies in their growth strategies. CRISIL Ratings considers the level of 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 benchmarked against industry norms.
- **Therapeutic segment coverage:** One of the unique feature of the formulations business is the large 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 pressures. 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 fairly well entrenched in their respective therapeutic segments considerably 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. Though less common in the past, Indian companies operating in niche and complex molecule segments have in recent years 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 therapies, which either replace older therapies or fulfill unmet therapeutic needs, presence of new therapies/molecules in the company's product basket is another key determinant of the overall competitive position. Newer therapies/molecules, specifically in the biosimilar and specialty pharma segments, typically command a premium over older therapies and witness fairly high 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. In case of Indian subsidiaries of international pharmaceutical majors, 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 in which 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 in nature, whereas making formulations involves mere 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 involved in the process. A product that requires a high degree of complexity to manufacture, such as that involving fermentation technology in bulk drugs as well as biosimilars, is typically characterised by high entry barrier and thereby presence of fewer players.

Extent of backward integration

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

Cost of production

Given the commoditised nature of certain bulk drugs, no analysis of the company's operating efficiencies is complete without a comparative assessment of the costs of production vis-à-vis the landed costs of imports.

Quality standards

While assessing the operating efficiencies 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 increase in thrust of Indian companies towards exports, and higher regulatory scrutiny of the US FDA after implementation of GDUFA.⁴

R&D

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

In the past, R&D activities by most Indian companies were restricted to process reengineering for new drugs introduced worldwide, development of new dosage forms and better drug delivery mechanisms. However, with the changes in patent regime from process to product patents in 2005, importance of basic R&D efforts in the Indian context has increased. Pharma companies have made concerted efforts to step up their R&D activity. Apart from getting a regulatory clearance for generic introductions, companies have focused more on new drug delivery systems,

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

biosimilars and new chemical entity research. Some of these activities involve extremely high 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 in their efforts to reduce overall R&D cost. This offers ample opportunities for Indian companies, given their process 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, with long gestation including monetisation of pipeline or finding a strategic partner for joint development.

Financial risk

For the analysis of the financial risk 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 pharma 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 website.

Conclusion

Thus, in CRISIL Ratings' opinion, key success factors for the pharmaceutical sector include the presence of:

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

About CRISIL Limited

CRISIL is an agile and innovative, global analytics company driven by its mission of making markets function better. We are India's foremost provider of ratings, data, research, analytics and solutions. A strong track record of growth, culture of innovation and global footprint sets us apart. We have delivered independent opinions, actionable insights, and efficient solutions to over 100,000 customers.

We are majority owned by S&P Global Inc., a leading provider of transparent and independent ratings, benchmarks, analytics and data to the capital and commodity markets worldwide.

About CRISIL Ratings

CRISIL Ratings pioneered the concept of credit rating in India in 1987. With a tradition of independence, analytical rigour and innovation, we set the standards in the credit rating business. We rate the entire range of debt instruments, such as, bank loans, certificates of deposit, commercial paper, non-convertible / convertible / partially convertible bonds and debentures, perpetual bonds, bank hybrid capital instruments, asset-backed and mortgage-backed securities, partial guarantees and other structured debt instruments. We have rated over 33,000 large and mid-scale corporates and financial institutions. We have also instituted several innovations in India in the rating business, including rating municipal bonds, partially guaranteed instruments and infrastructure investment trusts (InvITs).

CRISIL Ratings Limited ("CRISIL Ratings") is a wholly-owned subsidiary of CRISIL Limited ("CRISIL"). CRISIL Ratings Limited is registered in India as a credit rating agency with the Securities and Exchange Board of India ("SEBI").

For more information, visit www.crisil.com/ratings

CRISIL Privacy Notice

CRISIL respects your privacy. We may use your contact information, such as your name, address, and email id to fulfil your request and service your account and to provide you with additional information from CRISIL. For further information on CRISIL's privacy policy please visit www.crisil.com