ICRA Indonesia Rating Feature

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Rating Methodology for Pharmaceutical Companies*

Overview

Indonesian pharmaceutical sector has grown by double digits since 2009 driven by the demand from the growing population. The value of the country's pharmaceutical industry was estimated at USD 6.5 billion in 2014 with an annual growth rate of 12.5%. The growth level is expected to continue till 2018 on the back of implementation of the national social security system or Sistem Jaminan Sosial Nasional (SJSN). The system was introduced in January 2014, whereby the government has planned to extend health cover by 2019 to all the citizens. This universal health care scheme aims to provide better standards, regulations, accress and cost effectiveness. The initiative will increase the number of individuals who have access to health institutions, thereby leading to the catapulting volumes and increasing need for further investment in the pharmaceutical industry.

Being the fourth most populated country in the world with growing middle class, Indonesia offers an attractive market for pharmaceutical industry since the industry is still in the stages of development. For example, in 2008, the per capita expenditure on healthcare (including pharmaceutical drugs) in the country was USD 61 and increased to USD 108 in 2012. As the level remains below Philippines (USD 119), Thailand (USD 215) or Malaysia (USD 410) as per the World Health Organization (WHO), the room for growth is promising. In 2014, the number was estimated at USD 125 (Pharmaphorum.com) and is expected to increase to USD 150 by end of 2015 ('Pacific Bridge Medical' report).

The growth of the Indonesian pharmaceutical sector is largely contributed by domestic generics and formulations that are estimated to hold more than 70% of the total market share. This is mainly due to the high cost of branded drugs that only selected groups of the society can afford. The sector is highly fragmented and competitive with more than 200 players within the industry, of which around 60 are foreign players. The industry has also been actively exporting its generics to unregulated and semi-regulated markets (regulation here refers to the quantum of control of the government/domestic regulatory institution over new drug discovery, generics development, clinical/pharmaceutical research and development, clinical trials, reviews and evaluation of the trials, controlling environment, licensing norms, etc) in Africa and Asia. Some of the export destinations for generics include Thailand, Japan, India, South Korea, etc, whereas the country also exports formulations to unregulated markets such as Ghana, Zimbabwe, Nigeria, Mozambique, etc. The export potential however lies significantly in the ASEAN countries through ASEAN Free Trade Area (AFTA), if the industry is able to scale up its production (which is still low as 95% of production is consumed domestically).

Internationally, the pharmaceutical industry is characterised by regulatory controls—that is, controls both on products and manufacturing facilities, and price controls in some markets—besides large and continuing investments. ICRA Indonesia's analysis of pharmaceutical companies involves studying the prospects in the major markets that the companies operate (or propose to operate) in, the companies' manufacturing and R&D capabilities, their product portfolios (including drugs in the

pipeline), their marketing and distribution strategies, and their market presence across various types of drugs and therapeutic segments. Future business strategy is a key area of focus, especially in view of the emerging challenges in the product patent regime juxtaposed with the available financial resources with the pharmaceutical companies. Some of the key issues that are examined while analysing the credit quality of pharmaceutical companies, as listed below, are discussed at some length in this report.

- Product Portfolio and Pipeline
- Market Diversification
- Domestic Market Presence
- R&D Investment
- Legal and Regulatory Risks in Exports
- Impact of Product Patent Regime
- Impact of Price Control
- Manufacturing Facility
- Management Quality
- Financial Risk

Product Portfolio and Pipeline

Age, revenue potential and diversity of product portfolio are key rating factors. Thus, the ability of pharmaceutical companies to continually add new products in line with the emerging demand patterns is an important rating factor. Unlike in the case of international “branded” pharmaceutical companies, Indonesian companies are not exposed to “patent expiries”, which can result in a significant drop in product prices, leading to a drop in revenues. At the same time, generic companies operate in a highly competitive environment characterised by lower entry barriers in the absence of any patent protection, with the result that the margins are also low. Maintaining a profitable product pipeline, keeping in view the manufacturing complexities and competitive pressures, remains a challenge.

Indonesian pharmaceutical companies have a presence in “branded” products largely in the domestic and a few semi regulated markets. Domestic companies have branded presence mainly in nutritional and consumer health care products. In drugs segment, the production skews more towards generics. While larger brands usually prove more profitable for companies, high product concentration can significantly increase risks. Companies with significant exposures to mature or declining therapeutic segments would be exposed to higher degrees of risk. On the other hand, companies that are able to update their product portfolios in line with the therapeutic needs of the market would experience more robust earnings growth. Companies with strong domestic marketing infrastructure would also be exploring in-licensing opportunities to augment their product pipelines. Having a strong product pipeline is essential to sustain future earnings for a pharmaceutical company. The more aggressive players would also target specialty/niche products, and tailor their pipeline.

Market Diversification

Presence in multiple markets is positive from the credit perspective. Low entry barriers in the unregulated markets make companies serving these markets vulnerable to considerable pricing pressures. Companies targeting exports to unregulated markets alone are often characterised by low margins, long credit periods, and low returns on capital employed, with the result that they are likely to have significantly low coverage numbers. However, a company’s ability to sustain its presence in various markets is an issue that ICRA Indonesia evaluates by considering its track record, its R&D investments, its approved manufacturing capacities, its current product portfolio and pipeline, its current and proposed distribution arrangements, and such other factors.

Domestic Market Presence

Strong domestic market presence is considered positive by ICRA Indonesia. The highly fragmented nature of the domestic pharmaceutical market imposes strong low-cost manufacturing discipline,

which is a key strength in this industry. Also strong distribution network and brand presence may open up in-licensing opportunities from original patent holders targeting the Indonesian market. ICRA Indonesia's assessment of domestic market presence includes analysis of the therapeutic mix of the domestic sales of the company. A diversified therapeutic presence, relatively strong market position in key segments, and focus on new product introductions are considered positive by ICRA Indonesia. On the other hand, high therapeutic or product concentration exposes a company to significant business risks. The movement in market share data and ranking in the relevant segments over the years are also analysed to understand the trend and consistency in the company's performance. Strong sales network and first-mover advantage in a segment hold the key to developing a strong brand, and are given adequate weightage by ICRA Indonesia.

R&D Investment

Although the Indonesian pharmaceutical industry consists primarily of generic players, R&D will increasingly play an important role in the future product development. R&D infrastructure and qualified and experienced manpower are two key ingredients for pharmaceutical research. Going forward, with competition increasing for limited experienced manpower, retention of technical personnel would be an important aspect of R&D initiatives of companies. A strong R&D team also needs people who are adequately experienced in dealing with patent related issues.

In terms of financials, ICRA Indonesia looks at the total R&D spend (both revenue and capital) by the company over last three to five years as an indicator of the company's commitment to R&D. ICRA Indonesia also evaluates R&D productivity, taking into account the measurable milestones reached by the company through past R&D efforts.

Legal and Regulatory Risks in Exports

Currently, Indonesia exports to semi-regulated and unregulated pharmaceutical markets within Asia and Africa. Since the exported drugs are generics, market dynamics will largely be based on price competition. However, more and more unregulated markets are streamlining their controls and increasing the qualitative and documentation requirements. As a result, as the pharmaceutical companies expand their international presence, they could be subject to an increasing risk with respect to patent infringement or product liability risks --initially due to changes in the regulations of existing markets and later on as they expand their catchment area. In this regard, a strong balance sheet and diversified product profile would act as risk mitigating factors.

Impact of Product Patent Regime

Indonesia, by virtue of being a signatory to the General Agreement on Tariffs and Trade (GATT), is required to comply with Trade Related Intellectual Property Rights (TRIPS). The TRIPS agreement requires Indonesia to recognise product patents for food products, pharmaceuticals and agro-chemicals. This has impacted the government's goal of providing low-cost drugs and has affected general price levels of all the drugs, making them substantially costlier.

In future, introduction of patented drugs by Indonesian companies would be possible largely through in-licensing arrangements with patent holders. In rating a pharmaceutical company, ICRA Indonesia assesses the impact of the product patent regime on the current product portfolio of the company concerned. ICRA Indonesia's analysis also includes a critical assessment of the strategy being pursued by the company in terms of in-licensing, contract manufacturing, R&D efforts, and exports. The strategy is evaluated in the context of financial resources, R&D and manufacturing capabilities, and depth of management resources of the company.

Impact of Price Control

A 2012 decree of minister of health controls the prices of commonplace generics in the country. A lower dependence of the revenue profile on the price-controlled drugs will be viewed positively by ICRA Indonesia. However, the scope of price control is subject to revisions and re-evaluations by the

ministry which will impact the dynamics of pharmaceutical industry within Indonesia over the coming years. ICRA Indonesia would monitor these developments on an ongoing basis to assess their impact on the industry participants.

Manufacturing Facility

The comparative cost of manufacturing will play a determinant role in product pricing as well as entry into export markets. While Indonesian drug prices have historically been higher on account of raw material import among others, the emergence of local pharmaceutical raw materials suppliers is expected to grow given the upcoming opportunities in the sector. In analysing peers across the industry, thus the cost of manufacturing as well as the technological facilities would play a major role. ICRA Indonesia, therefore, assesses the systems followed by the company during manufacturing, its testing facilities, the quality of its trained manpower, and the quality of its documentation during manufacturing. Backward integration may be crucial in sustaining cost advantages in exports, as that usually provides for greater value addition.

Upgrading and maintaining a manufacturing facility that meets the standards of the export markets call for significant financial commitments. Also, inspection and approvals are time-consuming processes. Companies with existing facility approvals will have a significant time advantage over its competitors.

Management Quality

The pharmaceutical industry operates in a very dynamic environment, with significant events in one market—like product development, patent expiry and regulatory changes—often impacting players in other markets. Exports opportunities also throw up complex management challenges, with profitability (and price erosion) being influenced by niche opportunities, unique chemistries or dosage forms, and complex legal and marketing issues. These have become particularly relevant, given the retaliatory strategies increasingly being adopted by innovator companies to thwart generic challenges.

Quality of management remains a key factor for all credit ratings. Lack of a seasoned management team in areas like R&D, regulatory affairs, business development and manufacturing can significantly increase the business risks of a pharmaceutical company. Going forward, there would be increasing competition for the trained-manpower available, especially in critical areas like R&D and business development. Therefore, professional management structure and focus on human resources would be of crucial importance for the industry.

Financial Risk

Moderate debt levels, high gross margins and return of capital employed (ROCE) have historically proved to be essential in coping with the uncertainties related to investments in product development and entry into regulated markets. A strong balance sheet also gives a company favourable access to both the equity and debt markets, which in turn allows flexibility in funding growth plans and managing liquidity. Besides strong balance sheets, higher rated entities in the industry exhibit stable cash flows through revenue streams that are diversified among markets and product categories, stable product pipelines, and strong distribution networks. With the investment requirements being large, lack of economies of scale can also significantly impair a company's risk profile, especially in the emerging product patent regime.

Complexity of products, therapeutic mix, and the market a company operates in, besides operating efficiency, are the key determinants of its profit margin. Additionally, profitability is also influenced by the particular stage a product has reached in its lifecycle (matured, 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). Companies manufacturing products involving less complex and easily replicable processes are often subject to intense competition, and this gets reflected in their usually low margins. Also, in highly commoditised segments, large capacity build-ups in low cost

locations like China can severely bring down prices and margins. Margins are also likely to be stretched 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 after "exclusivity periods", if any. Also, less complex molecules can invite many players, with the result that the margins may be very low. ICRA Indonesia also places emphasis on product pipeline strength. Diversification of client base is also necessary to mitigate risks. At the same time, successful relations with innovator companies can provide greater protection to margins for Indonesian manufacturers.

ICRA Indonesia evaluates profitability before R&D investments, as increased R&D expenditure is likely to be a long term positive and is thus evaluated separately. ICRA Indonesia's analysis of financials therefore adjusts for differences that can arise because of the employment of different accounting methods.

Working capital is a key factor in ICRA Indonesia's analysis. High levels of receivables and inventory may be reflective of poor quality earnings, which may require write-offs in future. At the same time, build-up of inventory can also result from one-time events like product launches scheduled for the immediate future; such build-up would be considered necessary investment.

Exchange risk for pharmaceutical companies could originate from imports of raw materials and exports of pharmaceutical products. The extent of exchange risk that a company faces would be determined by its net imports/exports position. ICRA Indonesia looks into the import/export mix of the company to assess its exchange risk, the hedging strategy it has adopted, and the implications of such strategy, while evaluating the company's performance.

Conclusion

The Indonesian pharmaceutical industry is at a milestone in its growth trajectory; the opportunities afforded by the new social security system are enormous. On the other hand, the factors such as non availability of key raw materials domestically, fragmented markets and necessity to pump in adequate resources have inhibited the growth of the industry to its full potential. The AFTA too affords substantial opportunities for Indonesian pharmaceuticals to move forth. Thus, the ability to move proactively in anticipating market requirements, expand the product offering and diversify offerings across therapeutic segment remains critical to the success of the industry. Further, with the growing opportunities in the export market, the ability to conform to the local regulatory and manufacturing standards would also be critical.

*Adopted and modified from ICRA Limited's Rating Methodology for Pharmaceutical Companies