THE RIGHT SPICE

Poised on the cusp of an exciting period of growth, the Indian pharmaceutical market is big and getting bigger, driven by growing prosperity and a shift in disease patterns. Since 2005, a number of intellectual property (IP) and regulatory reforms have unlocked new opportunities for multinational companies. Glenn Snyder, Rob Jacoby and Laveshni Reddy of Deloitte explore the options.

The future of the pharmaceutical market in India rests on a combination of seven key drivers. In addition to the health of the economy and growth in healthcare spending, factors such as disease trends and prescription patterns, development of the health insurance industry, consolidation of retail and distribution networks, regulatory and intellectual property (IP) environment, and domestic R&D capability will govern growth and shape market opportunity for multinational companies (MNCs). Some of these factors will work together; all are outside the direct control of MNCs.

The Indian economy – surging ahead

India's economy witnessed robust growth during 2007–08, although the growth rate moderated in comparison with the previous year. India registered an average GDP growth rate of 8.4% during 2003–08. The size of the Indian pharmaceutical industry is around $8 billion and is expected to touch $16 billion by 2015. Healthcare spending per capita is rising directly with increasing per capita disposable income and is expected to double by 2015.

The increasing prevalence of, and focus on treating, chronic diseases will drive demand for novel new drugs. Consumer preferences will necessitate India-specific innovations. MNCs and domestic companies will compete to claim value in these relatively uncluttered therapeutic areas. The sustained growth of the Indian economy may lead to twofold increases in disposable income, which is tied directly to healthcare expenditure and affordability. India's overall economic performance may impact public and private investments in healthcare infrastructure.

More widely available health insurance and coverage for prescription drugs used to treat chronic conditions should improve affordability. The availability and coverage of insurance will possibly depend on new offerings from the emerging health insurance industry and government intervention to address infrastructure barriers. In this market where domestic pharma companies rapidly introduce generic formulations and drug spend is largely out-of-pocket, shifts in doctors' prescription patterns may radically impact revenues. Differentiated treatments and better-informed consumers could influence prescribing physicians for products excluded from strong patent protection.

IP, policies and regulations will possibly impact the ease of doing business and the attractiveness of the market yet are unpredictable and out of MNCs' immediate control. The Indian government has given mixed signals on whether future policies and regulations will be supportive of multinational competition or protective of domestic players. Changes in the distribution and retail system could impact supply and margins. The entry of organised distributors and retailers may drive efficiencies and force competition but is dependent on overcoming other infrastructure challenges. Increased demand for more expensive chronic therapies coupled with improved patent protection will create a stronger incentive for domestic companies to enhance their R&D capabilities and introduce novel drugs of their own, impacting the market share of MNC players.

It is possible that a restrictive environment will stifle growth and neither multinationals nor domestics will prevail. Much of the future of the Indian pharmaceutical market depends, directly or indirectly, on favourable government policies and regulations. There are a number of assumptions about the market and it is unclear which will prove to be correct, making it hard to build a strategy.

Strategic flexibility

In such a complex and uncertain environment, there is no single 'right' strategy. Traditional strategic commitment must yield

RISK: INDIAN PATENT LAW

Although IP laws have been strengthened, India remains on the USTR Priority Watchlist. There are 200 pre-grant oppositions pending, most of which relate to pharmaceutical products.

India's patent law does not recognise incremental innovation: molecules that are esthers, salts, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes combinations and other derivatives of known substances are considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

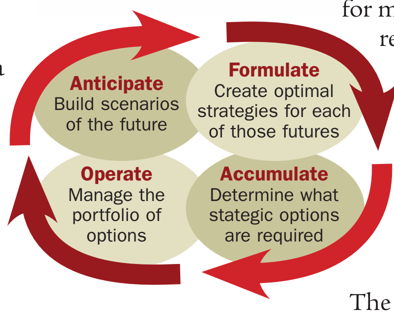
The most noted case involved a large multinational where the Indian courts ruled against incremental patents. The patent ruling prevents companies from making slight modifications to obtain a patent, drugs must be new or significantly different. In response, this company has moved the majority of its investment away from the county.

However, the IP environment in India may be improving. In December 2007, the first patent application of a HIV/AIDS drug was granted, although post-grant patent opposition from local manufacturers still could result in the overturning of the decision.

Source: Deloitte Consulting analysis, Datamonitor to strategic flexibility. This combines scenario planning with real options to provide a framework for identifying uncertainties and developing the options needed to not just manage uncertainty but exploit it for competitive advantage. MNCs contemplating entry or expansion in India should consider a range of scenarios and study the choices implicit in each scenario.

The Deloitte Consulting Strategic Flexibility 3 Framework combines scenario planning with real options, to help companies in their efforts to formulate strategies that effectively exploit market uncertainties for competitive advantage while mitigating strategic risks. Scenario-based planning is a forward-looking methodology that reduces a multitude of future unknowns to a manageable number of outcomes. A real option is an investment that establishes an opportunity, but not an obligation, for the company to make additional investments in the future, keeping the door open to other strategic directions. Each scenario should present a distinctly different future business environment that an MNC entering India might face:

The Strategic Flexibility Framework uses a continuous four-step process to identify uncertainties and develop the options needed to mitigate strategic risk while exploiting opportunity.



Scenario 1: Stop go. Go stop. Robust economic growth drives demand but minimal patent protection and protectionist regulations act as a deterrent to novel drug entries and investment in the market. The continuing tendency to prescribe generic alternatives and limited growth in demand enablers like health insurance limit pricing power for MNCs. Domestic players continue to exploit loopholes in patent protection laws to provide generic formulations thereby negatively impacting MNCs. The market maintains trajectory with a greater than 9.5% CAGR to reach $16 billion in 2015. The market continues to grow, but Scenario 1 is not particularly positive for MNCs.

Scenario 2: Innovation triumphs. MNCs maintain market presence and price leadership and dominate the Indian market. Through a combination of novel drug introductions, a supportive regulatory environment and mature demand enablers, MNCs take market share from domestic companies as the market overall continues to grow. Domestic companies are unable to compete due to limited development of R&D capability, and strict enforcement of IP laws prevents them from introducing cheaper generic variants. Driven by expensive patented molecules and increased demand from chronic drugs, the market is expected to approach $24 billion.

Scenario 3: All around growth. Domestic players build significant R&D capabilities to challenge MNC dominance and conserve market share with aggressive pricing. Domestic players take advantage of a liberal regulatory environment that supports patented molecules by in-licensing drugs from MNCs. Better knowledge of the Indian market and the regulatory environment enables them to retain their market share. Scenario 3 maintains a balance between MNCs and domestic players as the overall market continues to grow. The market is expected to approach $20 billion.

Scenario 4: Modernisation slows. Lack of drug affordability for millions of Indians drives the government to adopt a restrictive and protectionist regulatory policy and to employ price ceilings, limiting the market for MNCs. Stringent regulatory procedures also make it more expensive to introduce new drugs. The overall market slows in response to these restrictions, and Scenario 4 is a lose-lose for multinational and domestic pharmaceutical companies. The market is expected to be about $10 billion.

The four scenarios demonstrate that there is ample upside for MNCs in the Indian market. However, the ability to exploit uncertainty may well differentiate the winners from the losers. The size of the opportunity for MNCs varies widely depending on the condition of key market drivers. While scenarios are independent of the company, the most effective strategies to address those scenarios are unique to each company. Breakthrough results require committing to the most appropriate strategy for the expected future while maintaining the ability to adjust and respond quickly should the future not turn out as expected.

Uncertainty and risk are inherent in the Indian market, but there is potential. The pharmaceutical market is on the cusp of an exciting period of sustained growth driven by growing prosperity and a shift in disease patterns. Getting the desired results depends on knowing which options to take, how much to invest in these options, how to manage the options over time, and when and how to exercise or abandon these options. This strategy will continue to evolve as the market and environment matures. Given the plethora of uncertainties in the Indian market, it is essential that strategies are tested and the impact of 'what if' variations are gauged. Strategic flexibility is not a choice but an imperative for companies that wish to be profitable in the Indian market. WPF

Deloitte

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