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Pharmaceutical Market Entry in India

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Executive Summary

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 (MNCs) in the Indian pharmaceutical market. This paper sets out to address the questions and concerns of multinational pharmaceutical manufacturers contemplating entry and growth in India as a market for their products.

It is tempting to view the Indian market with an explorer's eye, like Columbus sailing off to discover new lands and great wealth. While such voyages are exciting and hold the promise of boundless opportunities for trade, there is an element of uncertainty when sailing into unknown waters. As Columbus discovered, a *large* element of uncertainty. Explorers may have a greater than average appetite for risk, but in the end, people undertake these voyages because the expected benefits outweigh the risks posed by uncertainty.

The growth of the Indian pharmaceutical market is accompanied by uncertainty around the IP/regulatory environment, disease trends, prescription patterns, domestic research & development (R&D) capability, healthcare spending, and enablers like health insurance and distribution infrastructure. These market factors tend to influence each other, further complicating the picture of the future for the market. For instance, while the increasing prevalence of chronic diseases in the Indian population is fairly certain, the market for chronic treatments depends on such factors as the growth of disposable income and availability of health insurance. The introduction of health insurance with prescription drug coverage, currently nonexistent in India, could open up the market for patented drugs to a broader population. Will it happen? Maybe – there are signs that new insurance products are being developed in the Indian market, but the vast, paper-based pharmaceutical distribution system remains a hurdle. Similarly, distribution consolidation could not only aid development of an insurance system, it could also increase the reach of MNCs into semi-urban and rural markets, but consolidation depends on development of basic infrastructure as well as non-protectionist government policies.

What will the future hold for pharmaceuticals in India? In this complicated business environment, the uncertainty is such that a change in assumptions could invalidate a company's basic approach to creating and capturing value. A bet on one breakthrough strategy carries with it the risk of destroying the company, but not pursuing a breakthrough strategy sacrifices all the potential upside. These strategic risks take the form of questions. Will MNCs dominate the market with novel, patented drugs in a supportive regulatory environment or will local pharma companies fight back with large scale investments in R&D? Historically, most domestic companies have been focused on generics with limited research capabilities. However, an analysis of the drug pipelines of a few of the domestic companies challenges this view. In an intensely competitive environment, will consumers and physicians develop brand loyalties or flock to generics? Will the government adopt policies to keep prices low and make drugs widely available? It is possible that a restrictive environment will stifle growth and neither multinationals nor domestics will prevail. So much of the future of the Indian pharmaceutical market depends, directly or indirectly, on favorable government policies and regulations, yet the past thirty years are nothing if not a warning about the fluid nature of Indian politics.

Each of these questions portends a different future for the Indian pharmaceutical market and a different opportunity for MNCs, yet these questions lack clear answers. How can you build a strategy without a better idea of which assumptions will prove to be correct? If you bet on the wrong assumptions, you could risk catastrophe. If you wait until the answers are known, it might be too late to make the investments and develop the capabilities to realize the opportunity. The uncertainty could paralyze a company or lead it to develop a compromise, middle-of-the-road strategy that won't expose it to ruin but won't achieve breakthrough results under any possible future conditions. The challenge is not to look for a superior prediction of the future because it doesn't exist—most of the uncertainty is outside the company's control and even subject to random events. The challenge is to manage the strategic risks embedded in these questions.

In such a complex and uncertain environment, there is no single "right" strategy. Therefore, traditional strategic commitment must yield to Strategic Flexibility. Strategic Flexibility 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 strategic choices implicit in each scenario. Using Strategic Flexibility planning, a company could articulate the range of uncertainty the future might hold and may reduce the unknown to a manageable number of outcomes.

The second half of this paper describes how the Strategic Flexibility framework could be applied to four plausible scenarios for the Indian pharmaceutical market in 2015:

- **Stop Go. Go Stop:** Key drivers change little
- **Innovation Triumphs:** MNCs claim a majority of the market share through novel products
- **All Around Growth:** Domestic companies stave off MNC competition
- **Modernization Slows:** The Government intervenes with populist measures

Under these four scenarios, we estimate the Indian small-molecule pharmaceutical market could range from a low of \$10 billion to a high of \$24 billion.¹ The challenge for senior management is to formulate a portfolio of strategies against these scenarios. MNCs need to place their bets in such a way that, as the future becomes clearer, they have a range of options to exploit available opportunities while effectively managing their exposure to the downside risks. Strategic Flexibility is not a choice but an imperative for companies that wish to be profitable in the Indian life sciences market.



India at a Crossroads

The Indian economy has entered an exciting period of sustained growth that will positively impact all key sectors, including pharmaceuticals. However, the future of the pharmaceutical market in India is contingent upon a combination of seven key drivers. In addition to the health of the Indian economy and consequent 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 environment, and domestic R&D capability will govern growth and shape the market opportunity for MNCs. Some of these factors will tend to work in concert with each other. All are outside the direct control of MNCs.

What Will Drive Future Growth?

Indian Economy – Surging Ahead

India is second only to China in terms of real Gross Domestic Product (GDP) growth and is expected to be the fifth largest economy in GDP by 2017.² Since 2003, the Indian economy has seen robust growth driven by liberal government policies, investment in IT, increased volume as well as breadth of international trade, a maturing financial sector, and creation of special economic zones (SEZs). In addition, there has been a definite surge in productivity driven by the movement of capital and surplus labor away from low-productivity agriculture to high-productivity industry and services.³

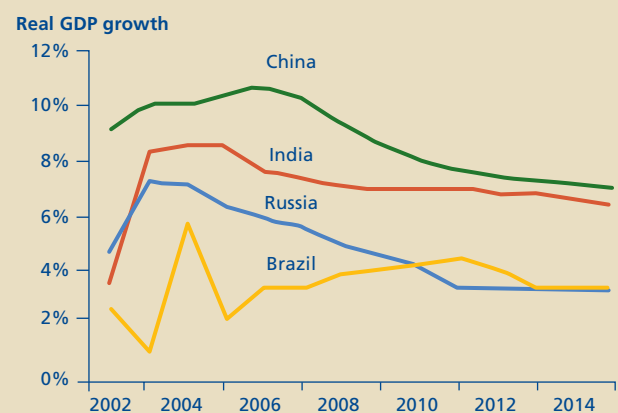
We expect that the shift of resources toward higher-productivity activities will sustain growth in the Indian economy for the next several years.⁴ As a result, per capita disposable income is expected to increase 220 percent by 2015.⁵ Healthcare spending per capita is rising directly with increasing per capita disposable income and is expected to double by 2015.⁶

While we believe the outlook for the Indian economy is positive, there are risks. Compared to its emerging market neighbor China, India may have a real risk of political instability. As the world's largest democracy, policy in India has a history of swinging toward populism leading to positions that do not always align with the interests of MNCs. In addition, administrations formed out of coalitions of multiple parties are susceptible to in-fighting and instability. As the past 30 years illustrate, the Indian government is also capable of large-scale reforms, and reversals, that dramatically affect the business climate.

Environmental degradation, supply-side constraints, education, and other market reforms could negatively impact growth.

If the Indian economy continues to grow, so will healthcare spending, positively impacting both the affordability of prescription drugs and investment in the healthcare infrastructure. The question for MNCs: will India's robust growth continue?

Figure 1. Emerging market GDP growth



Source: EIU Reports and FAPRI data.

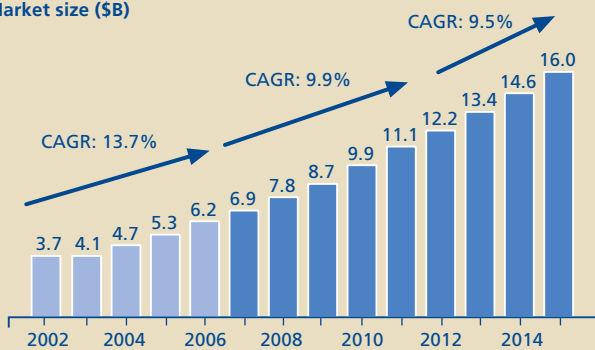
The Pharmaceuticals Market

Although the Indian pharmaceutical market is attractive,⁷ it is more than a little bit crowded with over 20,000 pharmaceutical firms, 60,000 distributors and 700,000 to 800,000 retailers competing for the pharmaceutical dollar.^{8, 9, 10} The top 10 companies control about 30% of the market and 250 companies control 70% of the market.¹¹ Fortunately for MNCs, whose limited portfolios make brand-building essential, there are still opportunities to build and sustain brands in the market despite intense competition and fragmentation. In a market where doctors are free to prescribe any drug (whether branded or generic), any broad shifts in prescription patterns will radically impact revenues.

Pharmaceutical sales are rising faster than growth in real private consumption¹² and will continue to grow, driven by both increased healthcare spending per capita and a larger proportion of spend going toward pharmaceuticals. While acute therapies have historically dominated the market and epidemics provide spurts of growth, chronic therapies are growing at a faster rate and have witnessed significant price increases at a time when overall pricing in the domestic pharmaceutical industry has been fairly stable.¹³ The price increase can be attributed to increasing disposable income among chronic patients, prescription “lock in” with few equivalent brands, and novel technologies that differentiate treatments and deliver increased value to patients.

Figure 2. India retail pharmaceutical market

Market size (\$B)

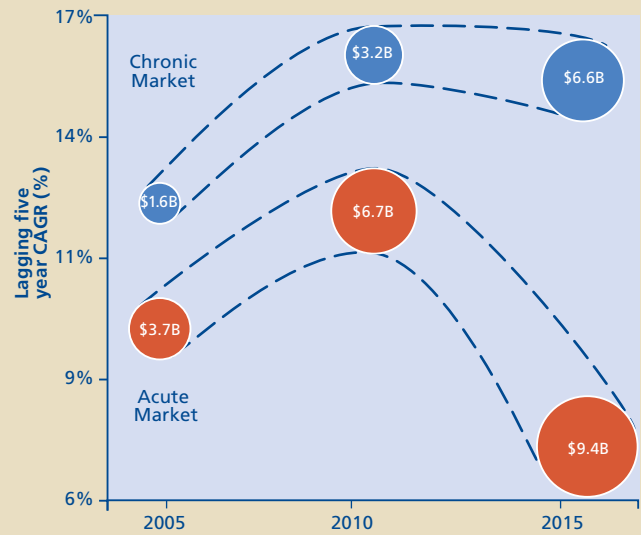


Source: EIU Report, Datamonitor, primary interviews, Deloitte Consulting LLP analysis

Domestic pharmaceutical sales stood at \$6.2 billion at the end of 2006¹⁴ and even under current conditions (minimal patent protection, unconsolidated distribution network, and an undeveloped health insurance system), are expected to grow at a rate of 9.5-10% annually, to reach \$16 billion, by 2015.¹⁵ Despite this seemingly certain growth, the real uncertainty for MNCs is whether doctors will prescribe their brands or consumers will demand their brands when generic options exist.

Strategic Risk: How will prescription patterns change if Indian companies match the MNC value proposition at competitive prices?

Figure 3. Disease patterns: A surge in chronic therapies



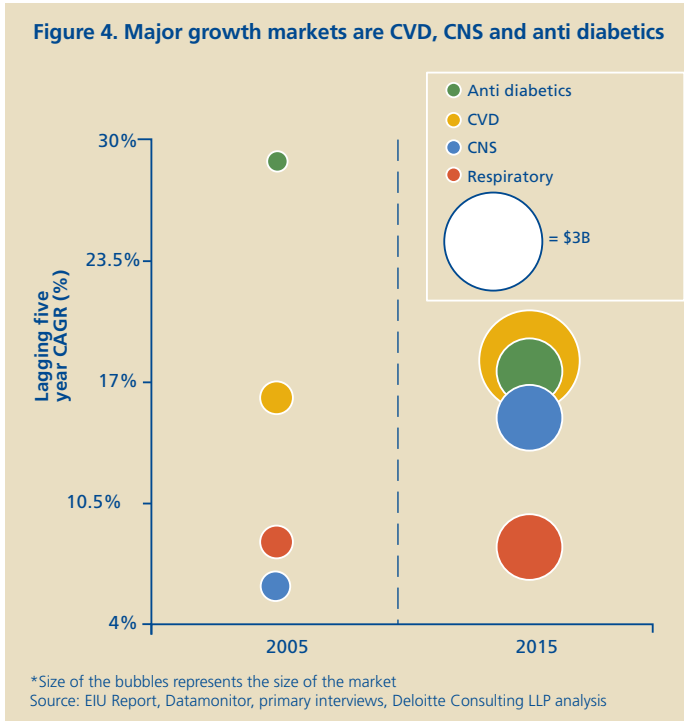
*Size of the bubbles represents the size of the market
Source: EIU Report, Datamonitor, primary interviews, Deloitte Consulting LLP analysis

Disease Patterns

Demand for pharmaceutical products in the Indian market is beginning to mirror demand in the global market, primarily as a result of a shift in disease patterns from acute to chronic disorders due to the increasing urbanization and unhealthy lifestyles of the Indian population. According to World Health Organization (WHO) estimates, India's mortality due to chronic disease will increase 18% by 2015.¹⁶

- Cardiovascular disorders (CVD) are expected to rise as a result of coronary heart disease (CHD) which is driven by risk factors including diabetes and hypertension, both of which are rampant in India.
- India's diabetic population is 37 million strong and growing rapidly. WHO estimates that diabetes-related mortality could increase 35% by 2015.^{17, 18} New therapies and innovations in delivery and disease management will bridge treatment gaps and command price premiums.
- Although India has the largest population of HIV/AIDS sufferers,¹⁹ we do not expect the cost of highly active anti-retroviral treatment (HAART) to rise significantly. Even if the more expensive second line regime (protease inhibitors, fusion inhibitors) is introduced by international agencies, the government may use heavy subsidies and generics to keep the cost of therapy low.
- Cancer is becoming more prevalent as a result of increasing tobacco consumption and will be an important driver because of the high cost of therapy.
- Alzheimer's disease and other dementias, epilepsy, Parkinson's disease, etc. are expected to continue to drive demand for central nervous system (CNS) drugs.

Figure 4. Major growth markets are CVD, CNS and anti diabetics



Chronic diseases like cardiovascular disease and diabetes are expected to drive demand for new drugs. Companies operating in these therapeutic areas should be able to price their products higher for two reasons: 1) Once a chronic patient is brought on therapy, that patient will likely continue using the product throughout their lifetime; 2) Chronic disease therapies are newer molecules with relatively less brand clutter and better patent protection.

An important but less-discussed trend is the development of India-specific innovations to address infrastructure issues and patient behaviors. For example, the absence of cold chain distribution in much of the country led Emcure to launch heat stable Emletra for HIV patients. Other innovations include fixed dose combinations such as Sanofi-Aventis' Combiflam and sustained release once-a-day formulations like Abbott's Ganaton OD.

While the increased prevalence of chronic diseases in the Indian population is expected, their effect on the market will depend on the affordability of treatments, a favorable IP environment and physician and consumer preferences for brands versus generics. Chronic therapies currently represent a small share of the market.

Strategic Risk: Will an unpredicted rise in demand for acute therapies push India-specific innovation in chronic therapies to the back seat?

Health Insurance

Health insurance similar to that in the United States is just beginning to emerge for select populations; prescription drug coverage does not yet exist. In 2005, private, out of pocket, expenditures made up over 77%²⁰ of the total healthcare spend essentially due to the poor quality of public healthcare facilities and the nascence of private insurance. However, increasing prosperity has resulted in greater demand for health insurance coverage (as approximated by premium growth). Between 2002 and 2005, total health insurance premiums grew at an annual rate of 36.2% and will continue to grow with the expanding middle-high income bracket (>\$2000 per year). The middle income bracket is predicted to include 800 million people by 2015.²¹

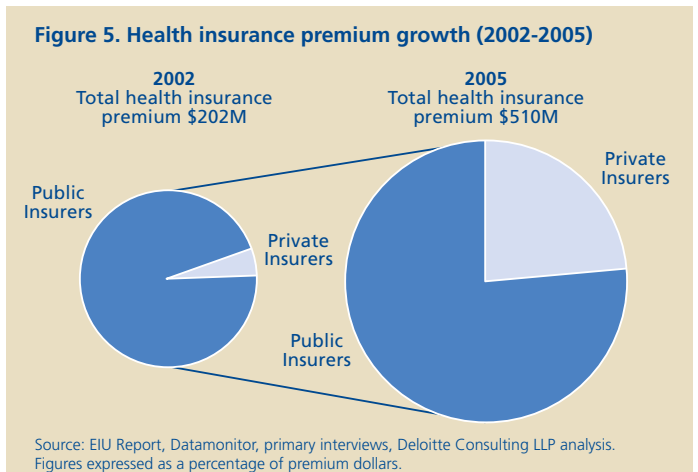
We believe health insurance should facilitate demand by making high-cost prescription drugs more affordable. Although per capita disposable income is rising, the modest income of most of the population keeps specialty medicines unaffordable. With the enforcement of product patents, drugs will become costlier. Patented, high cost drugs are expected to push spend on drugs to over 15% of total health care spend.²² Therefore, sales of expensive niche drugs depend on the growth and maturity of the health insurance sector.

If the health insurance industry does not mature, the market for patented drugs will probably shrink. The next three to five years will see significant growth and change in the Indian health insurance space as new players and insurance products respond to the increased demand. Health insurers are keen to provide drug coverage, but face a massive, paper-based distribution system with little flow of information and hundreds of thousands of points of dispensation. Automation of billing and records at the pharmacy level and development of formularies would go a long way toward making prescription drug coverage possible but will likely depend on retail consolidation and integration between retail chains and insurance providers.

Because health insurance is such an important enabler for future demand in the Indian market, MNCs will need to work with the health insurance industry as it matures but must also be prepared for this to occur very slowly.

Strategic Risk: Will the lack of systems and infrastructure act as a bottleneck in the spread of health insurance? What would be the disruptive innovation²³ to shift to a next-generation pharmacy benefit management model (similar to telecom in Eastern Europe)?

Figure 5. Health insurance premium growth (2002-2005)



Distribution Consolidation

The Indian pharmaceutical distribution system is fragmented and disorganized with 60,000 distributors and 700,000 to 800,000 retailers,²⁴ many of them “mom and pop” drug stores. An archaic, multi-layered tax structure with multiple excise, inter-state and local sales taxes led to the establishment of a layer of carrying and forwarding (C&F) entities solely to avoid taxation. Additionally, many parts of the country lack cold chain distribution.

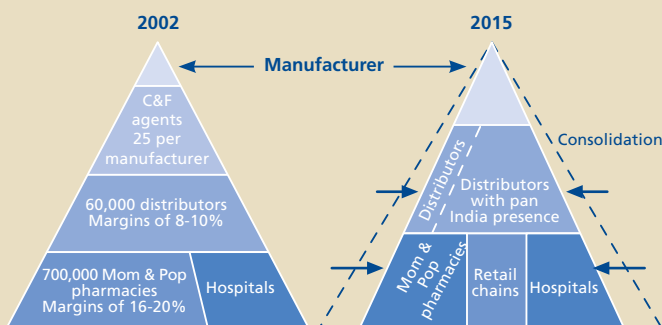
The current tax structure is being reformed with the goal of instituting a goods and services tax (GST) to replace the excise, value added tax (VAT), central and local taxes. The VAT/GST are exchange taxes levied on the value added at each exchange in the production of goods and services rather than a sales tax on the total value of the exchange. They are collected from the seller rather than the consumer and are neutral with respect to the status of the buying and selling entities and to the number of transactions between producer and final consumer.

In all probability, India will end up with a dual VAT/ GST system at the state and Federal level by 2010. When implemented, the VAT/GST should eliminate much of the incentive for tax evasion and with it, the need for an entire layer of carrying and forwarding agents. In the interim, some states have not implemented VAT and the others set their own VAT rates so distortions still exist. The advent of third party logistics providers, the growth of organized retail chains, and the impending entry of large US distributors should further drive consolidation in the Indian distribution system.

Organized retail and distribution consolidation will enable greater demand by reducing systemic inefficiencies and increasing reach in the semi-urban and rural markets. Although distribution and retail consolidation is likely, enough impediments exist to limit or stall consolidation. Well-entrenched trade unions, specifically the All India Organization of Chemists & Druggists (AIOCD), a representative body with 550,000 members, are expected to try to protect the interests of small distributors and “mom and pop” drug stores. In addition, the pace of distribution consolidation will be governed by the rate of infrastructure growth, especially cold chains and road networks. Finally, the future of retail consolidation will depend upon the government’s willingness to allow foreign investment into organized retail.

Strategic Risk: Will protectionist policies be effective in restricting retail consolidation?

Figure 6. Retail consolidation, 2002 – 2015



Source: Primary interviews, Express Pharma Pulse, Deloitte Consulting LLP analysis

Government Regulations

As a democracy governed by coalition, the Indian government has tended to shift policy from favorable to unfavorable in a short period of time. Although MNCs dominated the Indian pharmaceutical market before 1970, the government balked at the high drug prices that resulted from respecting the international patent regime. In 1970, the Indian Patent Act invalidated product patents, allowing domestic companies to copy innovative drugs by reverse-engineering and making small changes to the processes. This effectively ended the dominance of MNCs in India.

In 2005 the government shifted policies again, reintroducing product patents to honor commitments to the World Trade Organization (WTO). Despite the reintroduction of product patents, there is still cause for concern:

- The Indian Patents Amendment Act of 2005 excludes patentability for derivatives of known substances, unless it is proved that the efficacy is significantly greater than the original substance.²⁵
- Lack of guaranteed data exclusivity allows generic companies to continue to introduce competing products without doing their own safety and efficacy tests.
- In a tilt back toward protectionism, a proposed 2006 pharmaceutical policy brought 354 essential drugs under price control.
- In August 2007, the High Court rejected a challenge to the 2005 Act, effectively shutting the door on product patents for new versions of drugs introduced prior to 2005 and supporting the continued production of less expensive generic versions.²⁶

Inefficiency in patent processing and regulations surrounding clinical trials combined with a history of protectionist policies could affect the potential for MNCs in the Indian market. There is hope, however, that together with the growing economy, the government’s relaxation of price controls and adherence to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), will open up opportunities in the Indian pharmaceutical industry. However, if populist measures are employed, MNCs may stop launching innovative products in the Indian market.

Given the magnitude of change previously made by the government, the uncertainty surrounding the IP and regulatory environment in India is one of the most critical for a MNC to manage going forward.

Strategic Risk: Will the Indian government bow to pressure from Domestic industry lobby and limit IPR reforms?

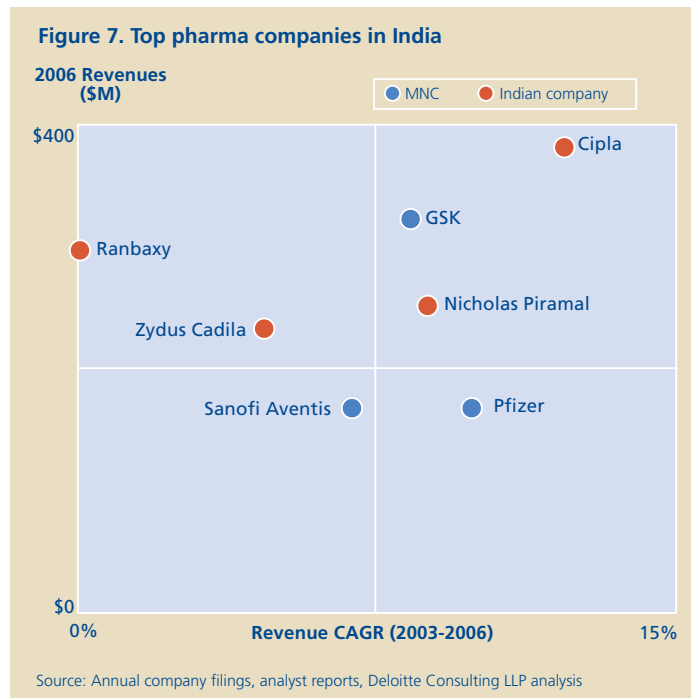
Table 1. Regulatory history

	Before 1970	1970-2005	2005 Onwards
Patent laws	<ul style="list-style-type: none"> • Recognized product patents • Patent term 14 years 	<ul style="list-style-type: none"> • Excluded product patent coverage • Limited process patent to 7 years 	<ul style="list-style-type: none"> • Recognized product patents • Data exclusivity not guaranteed
Pricing and royalty	<ul style="list-style-type: none"> • Limited consideration regarding royalty rates • Limited price ceilings 	<ul style="list-style-type: none"> • Royalty rates reduced to 4% • Price ceilings on most drugs in the market 	<ul style="list-style-type: none"> • “Reasonable” royalty rates • Reduction in the number of drugs under price ceiling
Regulatory	<ul style="list-style-type: none"> • Drugs & Cosmetics Act • Essential Commodities Act 	<ul style="list-style-type: none"> • Ex-factory based excise duty levy • Phase I clinical trials allowed only when foreign trial data is available 	<ul style="list-style-type: none"> • VAT implementation • Dual VAT/GST system • MRP based levy • Concurrent trials possible

Source: Economic Aspects of Access to Medicines after 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry, Padmashree Gehl Sampath, United Nations University-Institute for New Technologies (UNU-INTECH), The Tiger Awakens: The tumultuous transformation of India’s patent system and the rise of Indian pharmaceutical innovation, Janice M. Mueller, University of Pittsburgh Law Review, Vol 68:491, 2007, Deloitte Consulting LLP analysis.

A Snapshot of MNCs In India

The Indian competitive landscape is changing rapidly. With the promise of patent protection under TRIPS and the lure of double-digit growth, MNCs are re-entering the market, and many have already launched patented products. MNCs can target attractive therapeutic areas by bridging gaps in their product portfolios, but achieving profitable results in the Indian market will also require innovations in pricing and marketing.



Pricing challenges and government regulations have acted as a barrier to introducing blockbuster drugs in India while heavy “me too” brand clutter has made it difficult for companies to differentiate in the doctor’s office. Mid-size companies have employed aggressive pricing and higher sales incentives to claim market share, but MNCs are limited by the global floor prices set to avoid parallel imports. The pricing decision is a direct function of product uniqueness and the willingness to price below the global floor. MNCs must either skim the market with high-priced specialty drugs and biologics or use tactical strategies like changing brand and packaging to overcome price floor restrictions. Pricing in India is further complicated by the fact that the government can introduce price controls over any drug.

MNCs have been able to garner price premiums through differentiation including brand-building, education and innovations. Examples of India-specific product innovations include:

- A leading MNC brand for Chronic Obstructive Pulmonary Disease (COPD) brought in a different inhalation mechanism to reduce cost and bring within reach of larger consumer base.
- Effexor™ was released as extended release (ER) in tablet form because tablets have a longer shelf life than capsules. Pharmacies, especially in semi-urban areas prefer stocking tablets.

The pricing premium which MNCs can command will increase if India makes the expected transition to a differentiated market. However, improved patent protection brings its own uncertainty for the competitive landscape. Restrictions on replicating patented products will give domestic companies greater incentive to invest in R&D. If domestic pharmaceutical manufacturers are effective at launching their own patented products, their knowledge of the Indian market and history of physician relationships would hinder market penetration for MNCs.

Strategic Risk: How will M&A, alliance and licensing activities affect product portfolios and the overall market dynamic?

GlaxoSmithKline



Knowledge of the Indian market, a strong distribution network and a multi-pronged strategy for patented molecules have positioned GlaxoSmithKline (GSK) to continue to be profitable in the Indian market. With well-known brands, a strong vaccine portfolio and an aggressive pricing strategy, GSK is currently the largest MNC in India in terms of revenues.²⁷ When product

patents were invalidated in 1970, GSK stayed in the Indian market, and over the years, built a distribution network with a sales force of 2,000 representatives and over 4,000 distributors.

Since 2005, GSK has embarked on a new Indian strategy which involves both organic and in-organic growth:

- **In-licensing:** GSK has previously focused on acute therapies and has gaps in key chronic areas like CVD, CNS and diabetes. In the short term, it plans to license molecules from other MNCs and employ its existing distribution muscle.
- **Vaccines portfolio growth:** GSK has an India-specific vaccine strategy with vaccines for diseases like malaria, tuberculosis and leishmaniasis. In its pipeline are four new clinical entities (NCEs) expected to launch between 2007 and 2009. Additionally, new vaccines for malaria, dengue and tuberculosis are expected to be released post-2010.
- **New molecules:** GSK has been cautious in introducing blockbuster drugs from its global portfolio, but this is expected to change as they become more confident with the patent protection laws.
- **Acquisitions:** As the Indian pharmaceutical industry enters a consolidation phase, GSK plans to acquire promising brands from small domestic players.

Strategy Formulation

Uncertainties in the market

The uncertainties inherent in a complex, growing market like India make forming and committing to one strategy difficult because the assumptions the strategy was built on may well change. A company that has been committed to a breakthrough strategy may face catastrophe if the underlying assumptions change. Strategic risk is the danger of change so profound that a company's basic approach to creating and capturing value is threatened. The challenge is not to look for a superior prediction of the future, because it doesn't exist—most of the uncertainty is outside the company's control. The challenge is to manage the strategic risk.

We believe uncertainty in four areas leads to strategic risk for the CEO of any MNC contemplating entry into the Indian market:

- **Government Regulations and IP Environment:** How will the government regulations evolve? Will they become more restrictive? Will the government exercise greater price control? Will IP infrastructure mature sufficiently to enable introduction of novel, patented drugs? Will the IP/regulatory environment turn sour for MNCs?
- **Domestic Competition and Pricing:** If the market shifts in favor of MNCs, how will domestic companies react to save their turf? Will domestic companies commit to large-scale R&D investment? What happens if Indian companies match the MNC value proposition at competitive prices? How will M&A, alliance & licensing activities change product portfolios and alter market dynamics?
- **Enablers (Insurance and Distribution):** Will the health insurance industry mature in time to provide coverage for high cost patented drugs? Will organized distribution and retail chains overcome the infrastructure and governmental barriers to consolidation? Will the lack of systems and infrastructure act as a bottleneck in the spread of health insurance? Will protectionist policies be effective in restricting retail consolidation?
- **Disease and Prescription Patterns:** What are the diseases of the future as India becomes more urbanized? Will the demand for acute therapies push innovation in chronic therapies to the back seat? Will physicians be biased towards MNC products or towards generics? How will the more informed consumer influence physician prescriptions?

Each of these questions portends a different future for the Indian pharmaceutical market and a different opportunity for MNCs, yet these questions lack clear answers. How can you build a strategy without a better idea of which assumptions will prove to be correct? If you bet on the wrong assumptions, you may risk catastrophe. If you wait until the answers are known, it may be too late to make the investments and develop the capabilities to realize the opportunity. The uncertainty may paralyze a company or lead it to develop a compromise, middle-of-the-road strategy that may not expose it to ruin but may also not achieve breakthrough results under any possible future conditions.

Traditional planning and financial decision-making tools are inadequate in an environment where threats and opportunities develop quickly or where change is slower but masks a fundamental shift in assumptions. A different approach to strategic planning is required, one that allows MNCs to articulate and bound the uncertainty to make sense of the possible future for India and to pursue bold strategies while effectively managing the company's exposure should the assumptions about government policies or distribution improvements prove to be inaccurate. Over the next several pages, we will try to shed light on the future of the Indian pharmaceutical market using the Strategic Flexibility approach (see sidebar).

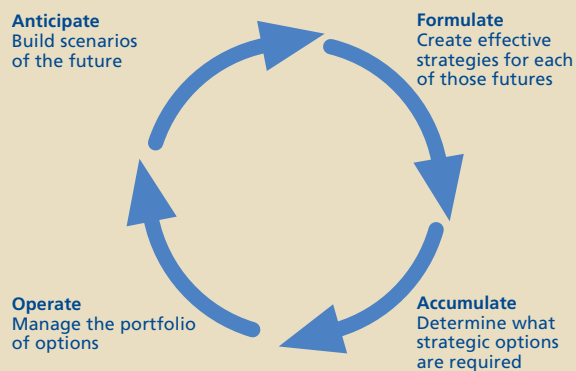


Strategic Flexibility Approach

The Deloitte Consulting Strategic Flexibility Framework²⁸ 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.

Figure 8 illustrates the Strategic Flexibility Framework which uses a continuous four step process to identify uncertainties and develop the options needed to mitigate strategic risk while exploiting opportunity.

Figure 8. Strategic Flexibility Framework



Source: Deloitte Research

Scenario ideation

Any strategy is based on a set of assumptions about the underlying drivers and enablers. Scenarios organize the market uncertainties into sets of competing assumptions about the future environment MNCs will face. The first step of applying the Strategic Flexibility Framework is to identify the drivers of change, define the range of possible futures, and develop scenarios that describe these futures. The following pages explore four likely scenarios, their impact on the Indian market and the potential opportunity for MNCs. Developing strategic responses for each scenario is dependent on the unique capabilities and challenges of each company and is beyond the scope of this paper. It is our hope to spur MNCs to abandon the notion of a single, silver bullet, “best” strategy and to adopt a new perspective on strategic planning for India’s complex pharmaceutical market.

The strategic flexibility approach begins with anticipating strategic questions and mapping them to drivers that could change the direction of the Indian pharmaceutical market. The strategic questions posed by the uncertainties in the market lead us to identify seven key drivers that we believe will shape its future:

- **Disease trends and consumer preferences.** The increasing prevalence of, and focus on treating, chronic diseases will drive demand for novel new drugs. Consumer preferences (and limitations) will necessitate India-specific innovations. MNCs and domestic companies will compete to claim value in these relatively-uncluttered therapeutic areas.

- **Economic growth.** 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.
- **Prescription patterns.** In a market like India 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. Both differentiated treatments and better-informed consumers could influence prescribing physicians for products excluded from strong patent protection.
- **Intellectual property, policies and regulatory environment.** These key enablers 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.
- **Distribution and retail environment.** Changes in the distribution and retail system could impact both supply and margins. The entry of large, organized distributors and retailers may drive efficiencies and force competition but is dependent on overcoming other infrastructure challenges.
- **Health insurance.** 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 nascent health insurance industry and government intervention to address infrastructure barriers.
- **Domestic R&D capability.** 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, thereby impacting the market share of MNC players.

Summary of the scenarios

The strategic questions articulated the uncertainties underlying the Indian market and led to the drivers that should shape the future opportunity for MNCs in India. Now that you know the seven key drivers, how can you begin to develop an effective strategy against so many moving parts? The answer is to develop plausible alternate scenarios of the future as described by the key drivers. This requires defining the range of possible values for each driver, effectively bounding the possibilities. To facilitate this analysis, we assigned values to the drivers that represent alternate, believable answers to the key strategic questions.

In practical terms the possible combinations of values are limited. Changes in one driver may influence other drivers. For instance, Disease trends could range from *acute* to *chronic* but are unlikely to be *chronic* if the IP/regulatory environment is *protectionist*. Based on our understanding of the Indian market, we also believe some conditions are much more likely than others. Growth in healthcare is a key driver but it is tightly connected to the overall economic growth in India which is expected to be robust for several years. After analyzing the various combinations of values for the seven drivers, significant differences emerge based on the uncertainty about the regulatory environment, prescription patterns, and the demand enablers (health insurance and distribution). Table 2 summarizes the values of the drivers for four plausible scenarios for the Indian pharmaceutical market in 2015.

Table 2. Scenarios for the Indian pharmaceutical market in 2015

Scenario	Disease Trends	Economic Growth	Prescription Patterns	Regulatory Environment	Demand Enablers	Domestic R&D Capability
1. Stop Go. Go Stop.	Acute	Robust	Generics	Protectionist	Limited	Intermediate
2. Innovation Triumphs	Chronic	Robust	Favoring MNC	Liberal	Favorable	Intermediate
3. All Round Growth	Chronic	Robust	Generics	Liberal	Moderate	Advanced
4. Modernization Slows	Chronic	Robust	Generics	Protectionist	Limited	Intermediate

After defining states for each driver, we predicted the impact (ranging from favorable to unfavorable and including “neutral”) of each driver’s state on MNC market presence, MNC pricing and generic competition intensity to better understand the effect of the assumptions on the MNC opportunity. Each scenario in Figure 9 presents a distinctly different future business environment which a MNC entering India might face.

Figure 9. Scenario business environment

Scenario 1 Stop Go. Go Stop.	Scenario 2 Innovation Triumphs
<p>Key drivers change little</p> <ul style="list-style-type: none"> Patent enforcement remains weak, discouraging companies from introducing novel drugs MNCs do not get enough pricing flexibility Health insurance market remains under-developed 	<p>MNCs claim a majority of the market share through novel products</p> <ul style="list-style-type: none"> Domestic companies are unable to introduce generic variants MNCs price drugs attractively and within the reach of the population Domestic health insurance market offers coverage for expensive drugs
Scenario 3 All Around Growth	Scenario 4 Modernization Slows
<p>Domestic companies stave off MNC competition</p> <ul style="list-style-type: none"> Domestic companies invest in R&D Domestic companies in-license drugs and price aggressively Domestic companies challenge MNC patents and introduce generic variants 	<p>The Government intervenes with populist measures</p> <ul style="list-style-type: none"> The government tries to soothe public sentiment on drug safety and prices through DPMAA Current price controls (MAPE) are extended to a wide range of drugs Regulatory procedures become more stringent, making it more expensive to introduce novel drugs

At this point, each scenario may be possible. As time passes, more information becomes available about the likelihood of each scenario which allows a company to commit more heavily to one or more scenarios. When events occur which answer or partially answer an uncertainty, the strategic risk is reduced and a strategy can be executed.

Indian Pharmaceutical Market Forecasting Model



We’ve talked a lot about uncertainties, but what are the stakes involved? Scenarios are useless without a sense of the real impact of each scenario playing out. We used a robust mathematical model combined with regression analysis and Monte Carlo simulation to forecast the size of the Indian market in 2015 under the four scenarios. We:

1. Determined drivers of growth: Chronic disease trends, Growth in healthcare spend, and Demand enablers for patented products.
2. Identified proxies for each driver: For disease trends, we used a Price Volume (PV) indicator for six major diseases, for growth in healthcare we used healthcare spending (\$B), and each of the demand enablers was assigned a numeric value (1-100).
3. Derived a regression equation based on historical proxy values against the pharmaceutical market size in those years.
4. Determined the ranges of Monte Carlo simulation for 2015: The PV indicator was projected forward from 2006 at the rate of inflation and then a multiplier was applied to represent pricing premiums in any disease. The values of the demand enablers were changed to represent the conditions of each scenario.
5. Performed Monte Carlo simulations to factor in uncertainty and predict market size.

Scenario 1: "Stop Go. Go Stop."

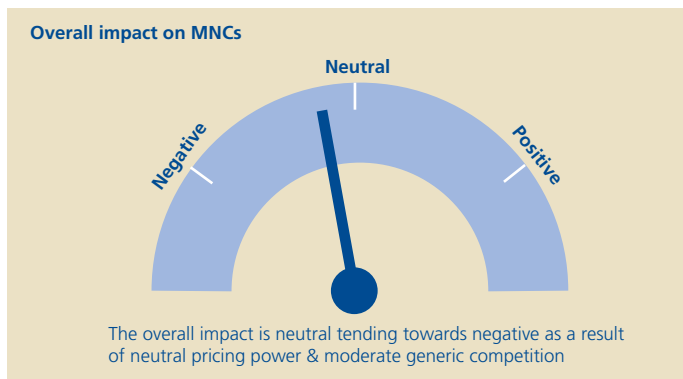
Robust economic growth drives demand but minimal patent protection and protectionist regulations act as a deterrent to novel drug entries and investment in the market. Disease trends remain weighted toward acute therapies and demand enablers like health insurance and distribution consolidation see limited development through 2015. Overall the market continues to grow, but Scenario 1 is not particularly positive for MNCs.

Impact on MNC market presence: Although the strong economy drives greater per capita spend on drugs, the lack of confidence in patent protection persists. MNCs do not introduce novel drugs and do not gain market share.

Impact on MNC pricing: The continuing tendency to prescribe generic alternatives and limited growth in demand enablers like health insurance limit pricing power for MNCs.

Generic competition intensity: Domestic players continue to exploit loopholes in patent protection laws to provide generic formulations thereby negatively impacting MNCs.

Market size estimate: The market maintains current trajectory with a greater than 9.5% CAGR to reach US \$16 billion in 2015.



Scenario 2: "Innovation Triumphs"

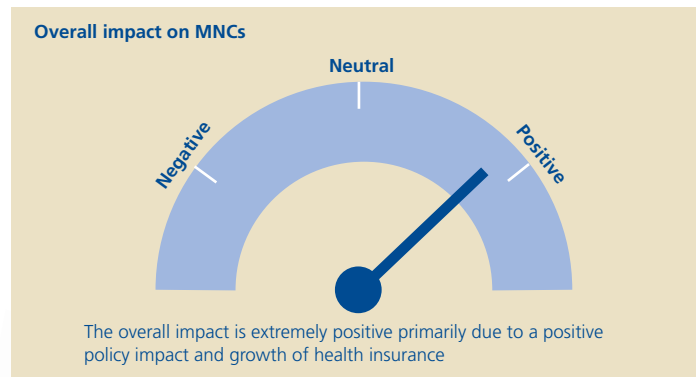
MNCs maintain market presence and price leadership and dominate the Indian market. Through a combination of novel drug introductions, a supportive regulatory environment and mature demand enablers, MNCs take market share from domestic companies as the market overall continues to grow. Domestic companies 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.

Impact on MNC market presence: A trend toward treating chronic diseases favors the global drug portfolios of MNCs. Favorable developments in demand enablers like distribution consolidation and health insurance help MNCs maintain a dominant market presence. Distribution consolidation removes systemic inefficiencies and increases reach; insurance coverage for expensive drugs acts as a revenue multiplier.

Impact on MNC pricing: Although pricing is always a challenge in the Indian market, price sensitivity diminishes significantly. Increasing income prosperity, lack of me-too drugs and a mature health insurance infrastructure that provides coverage for high-cost drugs gives MNCs pricing power.

Generic competition intensity: A liberal regulatory/IP environment that respects IP rights dampens generic competition intensity. With strong patent regulation in place, MNCs can launch novel products from their global portfolios.

Market size estimate: Driven by expensive patented molecules and increased demand from chronic drugs, the market is expected to approach US \$24 billion. This is far greater than the expected US \$16 billion market under the "Stop Go. Go Stop." scenario.



Scenario 3: "All Around Growth"

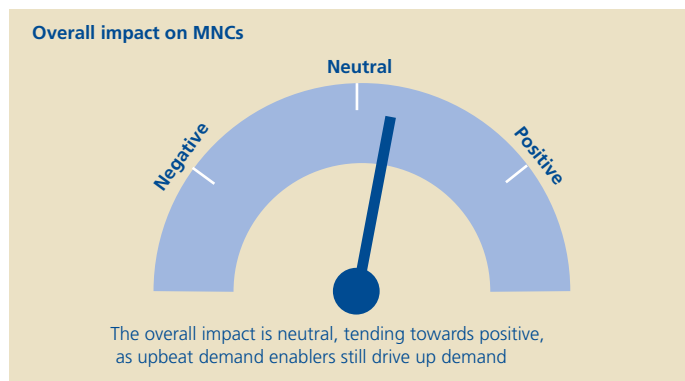
Domestic players build significant R&D capabilities to challenge MNC dominance and conserve market share with aggressive pricing. Domestic players take advantage of a liberal regulatory environment that supports patented molecules by in-licensing drugs from MNCs. Better knowledge of the Indian market 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.

Impact on MNC market presence: Although chronic disease trends and moderate developments in demand enablers like distribution consolidation and health insurance make the market attractive, a strong domestic R&D capability impedes MNC market presence. Prescription patterns tilt toward generic drugs. MNCs bring only select drugs from their global portfolios.

Impact on MNC pricing: A neutral regulatory environment coupled with locally-produced novel drugs enables domestic players to price aggressively. MNCs are forced to match prices to compete.

Generic competition intensity: The trend toward generic prescribing coupled with domestic players R&D capabilities and strength in the market increases the intensity of domestic competition with more small players competing for drug spend.

Market size estimate: The market is expected to approach US \$20 billion. This is greater than the US \$16 billion expected under the "Stop Go. Go Stop." scenario, but less than "Innovation Triumphs."



Scenario 4: "Modernization Slows"

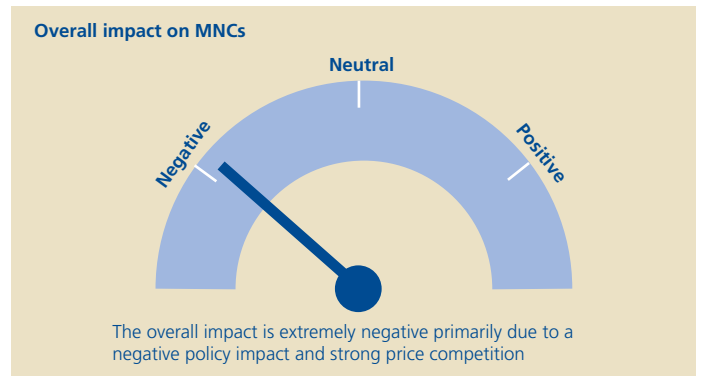
Lack of drug affordability for millions of Indians drives the government to adopt a restrictive and protectionist regulatory policy and to employ price ceilings which severely limit the market for MNCs. Stringent regulatory procedures also make it more expensive to introduce new drugs. The overall market slows in response to these restrictions, and Scenario 4 is a lose-lose for both multinational and domestic pharmaceutical companies.

Impact on MNC market presence: Although the disease trend is still chronic, a protectionist regulatory environment discourages the introduction of novel drugs in chronic therapeutic areas. The regulatory environment also stifles developments in the demand enablers, thereby limiting the MNC market presence.

Impact on MNC pricing: Severe price controls take pricing power away from the MNCs. Underdeveloped demand enablers reinforce the extreme price sensitivity. MNCs will not introduce novel drugs in India.

Generic competition intensity: Though the restrictive environment also limits the market for domestic companies, regulations favor domestic companies, allowing them to continue to compete through generics. Prescription patterns likewise lean toward generics and generic competition intensity will be high.

Market size estimate: The market is expected to be about US \$10 billion. This is far lower than the US \$16 billion expected under the "Stop Go. Go Stop." scenario.



The four scenarios demonstrate that there is ample upside for MNCs in the Indian pharmaceutical market. However, the ability to exploit the uncertainty in the Indian market may well differentiate the winners from the losers. The size of the opportunity for MNCs varies widely depending upon 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.

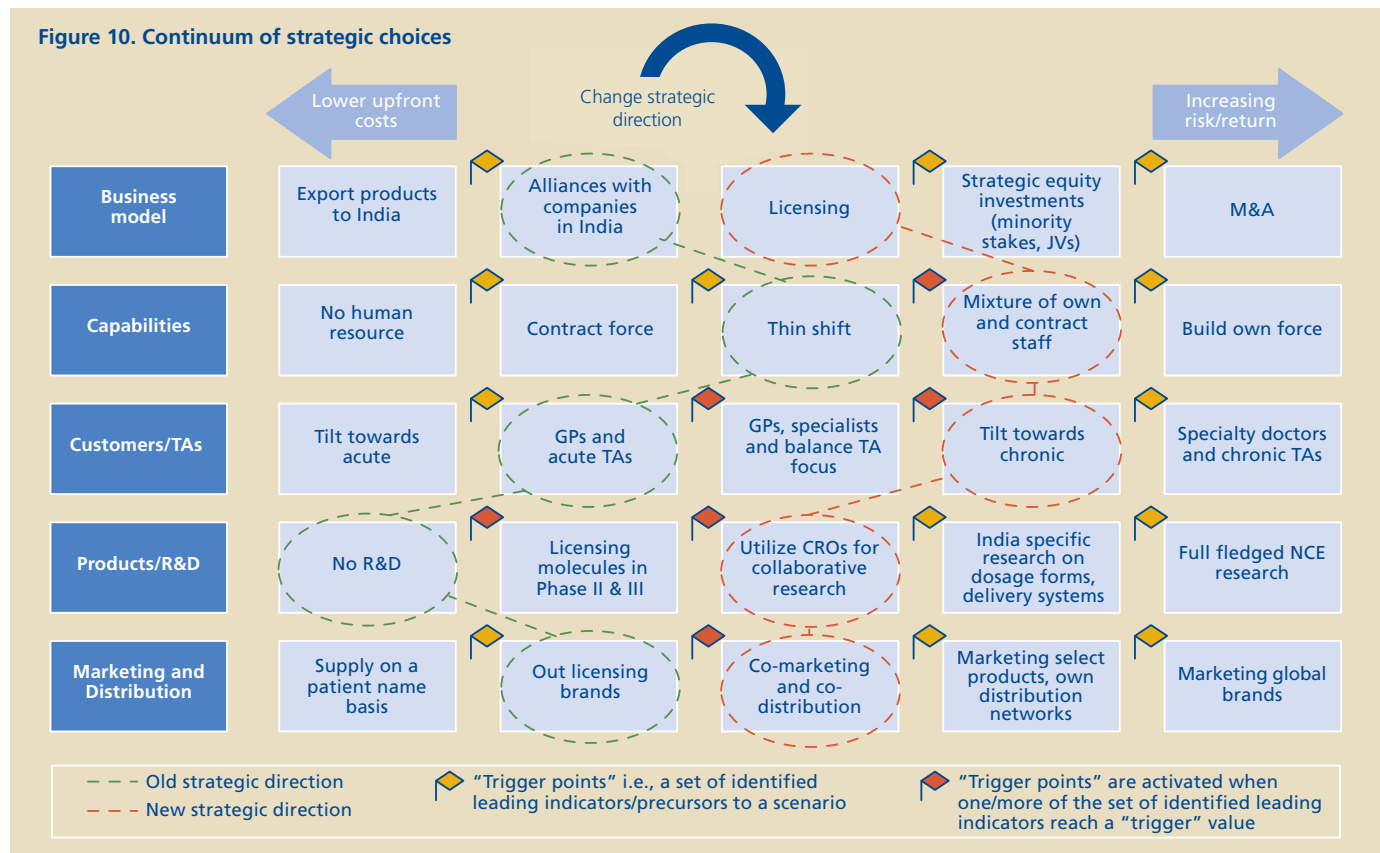
Steps in Strategy Formulation

Step 1: Choose a strategic direction and identify trigger points.

Multinational pharmaceutical companies planning to enter or re-enter India have a pool of strategic choices available to them related to business model, capabilities, customers, products and marketing/distribution. The strategic choices range across a continuum of investment risk and reward. Choosing a subset out of this pool establishes your strategic direction and depends on numerous factors specific to the company such as the capacity to invest upfront, risk appetite, capabilities like technology and people, operational competencies, and knowledge/experience of the Indian market or a comparable emerging market. Your strategic direction also depends on which scenario of the future you believe is most likely. Figure 10

depicts a continuum of strategic choices with two different strategic directions highlighted.

Trigger points are a set of leading indicators that precede a scenario. When the indicator reaches a predetermined value or state, the trigger point is activated, signaling that a key driver has changed and certain scenarios have become more likely. The company needs to change their set of strategic choices when a trigger point is activated. A company may even jump over several sets of strategic choices at one trigger depending on risk appetite. Companies can move back and forth across the continuum, although it becomes difficult to move from a higher risk state to a lower risk state due to commitments such as technology, manpower, capital, and land.



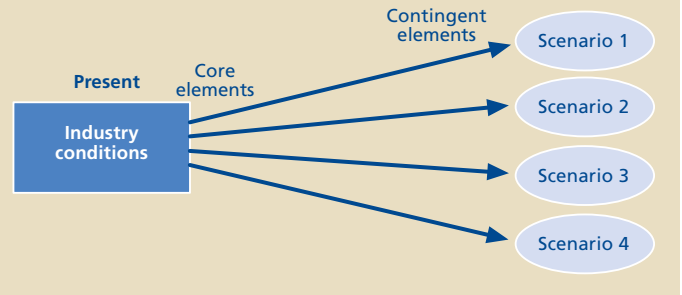
Step 2: Formulate core and contingent strategy elements within the strategic direction

After choosing a strategic direction and establishing trigger points, the next step for a MNC is to use conventional strategic planning to define the strategy it would employ to achieve its desired results under each of the competing scenarios. For instance, you might think that the “All Around Growth” scenario is most likely; however you will define the most appropriate strategies for your company under each of the other scenarios as well.

Comparing the four strategies, executives can see which elements or initiatives appear in all strategies and which occur in only one or two. Those that appear in all scenarios are designated “core elements” and the company can invest in developing these capabilities because they will be valuable under any future scenario. Those that exist in only one or two scenarios are “contingent elements”—while crucial to one strategy, they may be unnecessary or even counterproductive under a different scenario. By defining contingent strategy elements for each of the possible outcomes and identifying the necessary investments to pursue those elements, companies are poised to move quickly as events occur that make one or more of the futures more likely. If conditions intrinsic to one of the other scenarios emerge (signaled through a trigger point), the company must overhaul the strategy to account for the new assumptions.

The core and contingent elements provide functional guidance. Figure 12 illustrates how core and contingent strategy elements work across the value chain. For example, within product development, a company should benefit from streamlining developmental processes through IT platforms regardless of future conditions. Therefore, streamlining developmental processes is a core strategy element and should be implemented immediately. Focusing on development of acute therapies would only benefit the company in the “Stop Go. Go Stop.” scenario so it is designated a contingent strategy and should only be implemented if conditions shift toward that scenario.

Figure 11. Strategic Flexibility Framework



Step 3: Create and manage real options for each contingent strategy element

Once core and contingent elements have been defined for all of the scenarios, which contingent strategies should an MNC implement? A company cannot possibly invest in developing the capabilities for all of the contingent elements, nor typically will it be able to implement new strategies rapidly enough to change course if the assumptions about the Indian market change, no matter how adaptable your organization. In some cases, contingent elements will even be at cross purposes to each other.

The concept of real options, like financial options, is that the company will have secured the right but not the obligation to quickly adopt a new direction if conditions change. Practically, this means the company will invest just enough to keep a foot in the door of other technologies, market segments, relationships or products suggested by alternate scenarios without committing the company to those strategies. If conditions change, the company can more rapidly switch to the relevant contingent strategy elements to address the new assumptions.

Consider an MNC that has committed to a particular strategic direction. Its product development strategy might be to create a

Figure 12. Core and contingent elements

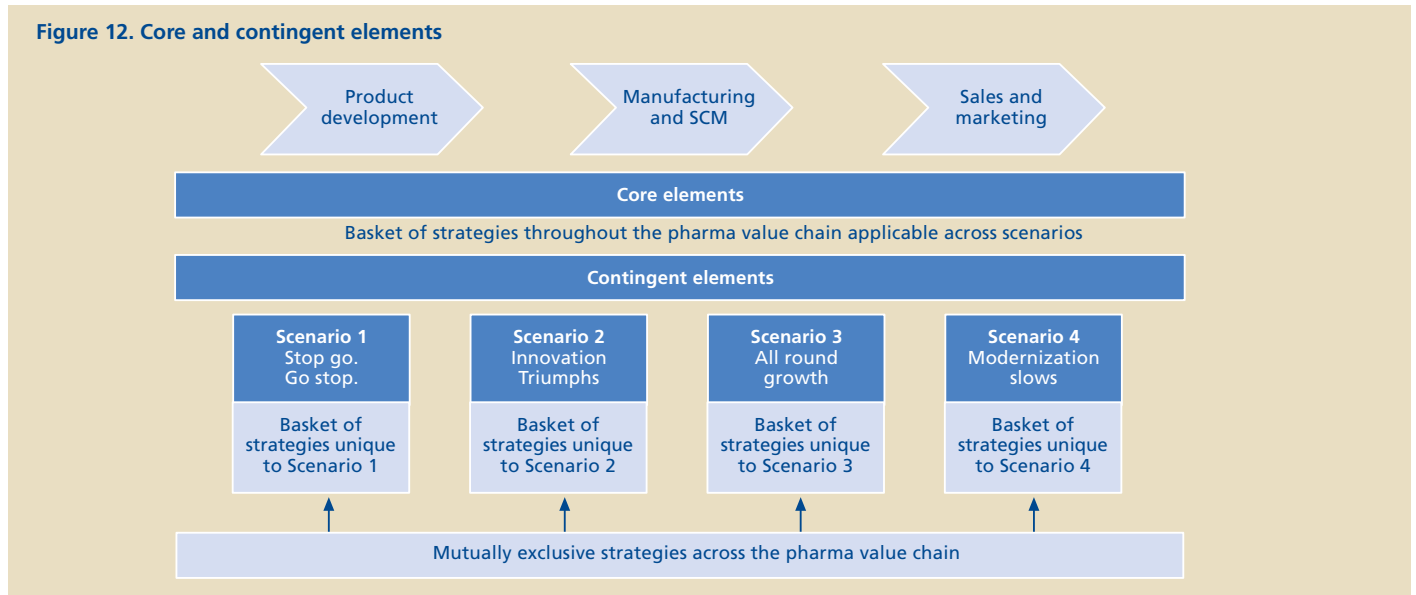
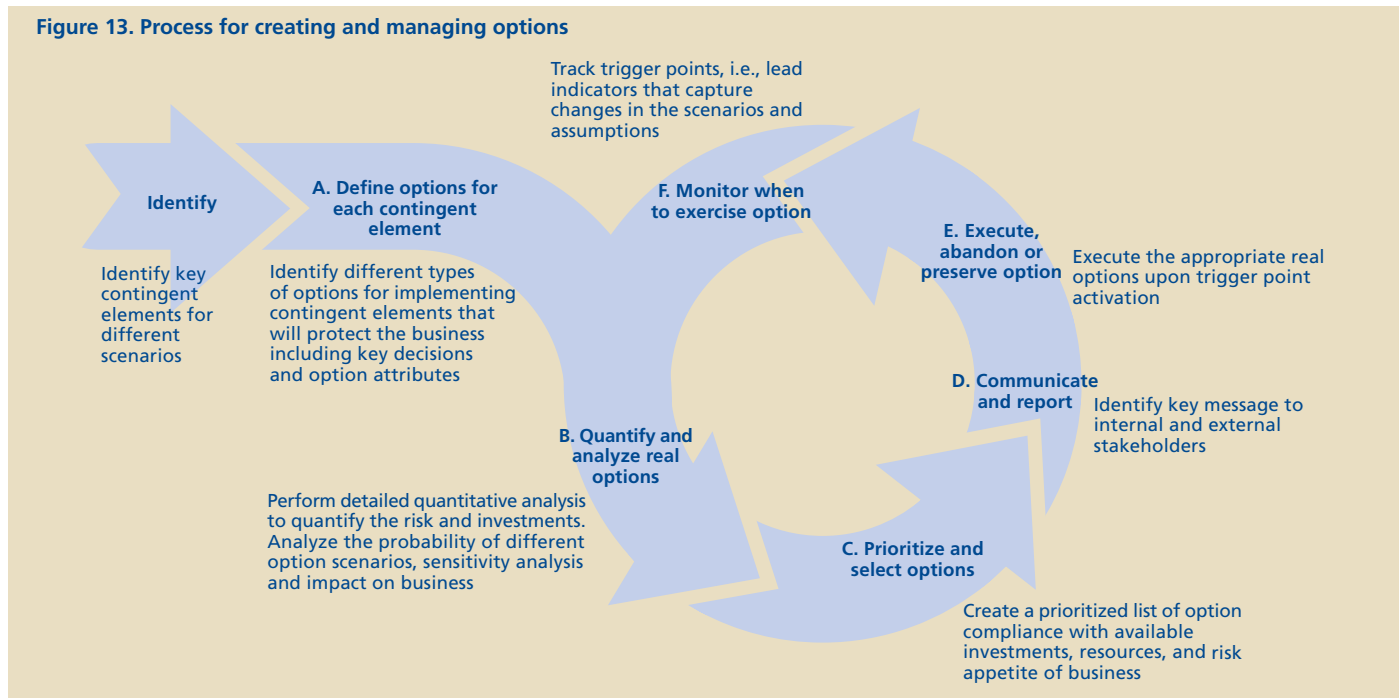


Figure 13. Process for creating and managing options



formulation technology barrier through heavy patent filing. At the same time, a contingent product development strategy for “All Around Growth” might be to achieve a competitive cost structure by acquiring low cost research facilities. The company might hedge its bets by entering in a partnership in a low cost research facility for a single niche product with the idea that the capability and facility could be quickly ramped up across other product lines if conditions changed toward the “All Around Growth” scenario. The investment required is less than would be required to pursue all competing strategies. In some cases, viable real options may not exist and a company must accept the associated risk, responding to it only if the need arises.

Like the core and contingent elements, real options are entirely company-dependent and must account for the resources, assets and capabilities of the company and its appetite for risk. Devising this portfolio of real options and determining the appropriate level of investment in each is the challenge for the senior leadership team while the functional leadership pursues the designated strategy without concern for the inherent uncertainties.²⁹

Creating and maintaining options is not without cost. Options should be fully defined to include key decisions and should be backed by quantitative analysis to understand the investments required and the associated risk. Options can be exercised or abandoned depending on how the market uncertainties unfold as signaled by defined trigger points. Figure 13 illustrates the iterative process of creating and actively managing options.

Step 4: If triggered, change direction and implement contingent strategy elements

A trigger point represents a changed scenario or assumptions. The company should stick to the chosen strategic direction unless a trigger point is activated indicating that conditions have changed. When a trigger point is activated, the company implements the appropriate contingent strategies by exercising the real options underlying those contingent strategies. A change in strategic direction may also mean that one scenario is no longer plausible and the company should abandon options related to that scenario.

Glenmark, a domestic pharmaceutical company



Established in India in 1977, Glenmark’s story is one of developing strategic options through building capabilities, balancing risks and moving aggressively in niche segments. By having a flexible strategy, Glenmark has become one of the fastest growing pharmaceutical companies in India.

For its first 20 years, Glenmark specialized in dermatology and focused almost entirely on the Indian market. From 1998 to 2003, the company began developing its manufacturing and research capabilities, including building a research center in Navi Mumbai and acquiring an API manufacturing facility in Ankaleshwar. The company’s process capability in API helped it develop its formulation business by backward integration. In 2003 Glenmark set up Glenmark Pharmaceuticals Inc. to facilitate entry into the US market. Since 2000-01, Glenmark has followed an aggressive expansion strategy and has balanced its risk portfolio to maintain a constant revenue stream:

- **Mix of Para III and Para IV Abbreviated New Drug Applications (ANDA):** In a Para III filing, a generic company acknowledges the existence of a patent and files an ANDA to enter the market after the date of patent expiry passes. In a Para IV filing, the generic company challenges the validity of a patent, and if successful, gains a 180-day exclusivity to market the drug. Para III filings are less profitable but offset the risks of Para IV litigation with a consistent stream of revenues.
- **Niche segments:** In the US, Glenmark has focused its generic on segments like dermatology. The barriers to entry are high because of a few strong players but profitability is better than other highly competitive segments.
- **Growth through acquisition:** The acquisition of the Czech firm Medicamenta gives Glenmark a strategic entry point to two of Europe’s fastest growing markets– the Czech Republic and Slovakia.
- **NCE pipeline development:** Glenmark has two NCEs in Phase II and four others in Phase I and preclinical trials.

The Final Word on India

How can you realize your desired results?

Uncertainty and risk are inherent in the Indian market – the type of game-changing unknowns that had Columbus carting home potatoes from the New World when he meant to be trading in silk and spices from the Far East. While these uncertainties should give you pause—the inherent uncertainties in market drivers make effective strategy formulation extremely challenging—let's not lose sight of the potential. The pharmaceutical market in India is at the cusp of an exciting period of sustained growth driven by growing prosperity and a shift in disease patterns.

The question is not: Is there opportunity in India? The question is: How can you realize your desired results?

First, discard the notion that you can identify and pursue a single “right” strategy in India. At the same time, to realize the potential upside of the Indian market, you must choose a strategy and commit to it; a middle of the road strategy is unlikely to gain an advantage in this highly competitive market. Traditional strategic commitment must give way to strategic flexibility.

Anticipating plausible scenarios, making strategic choices in the face of uncertainty and formulating core and contingent strategy elements is challenging. Such a framework of creating, preserving, and exercising real options requires a new approach on the part of senior management. It also implies a new understanding of the role of the corporate office and its relationship with business units. Realizing your desired results depends on knowing 1) which options to take; 2) how much to invest in these options; 3) how to manage the options over time; and 4) when and how to exercise or abandon these options. This strategy will continue to evolve as the market and environment matures – it is not a static decision.

Finally, given the plethora of uncertainties in the Indian market, it is essential that you test the robustness of your strategies and gauge the impact of “what if” variations. Thus, strategic flexibility is not a choice but an imperative for companies that wish to be profitable in the Indian market.

Endnotes

- ¹ While ample opportunity exists for biotechnology manufacturers in India, we have not contemplated them in the present analysis due to limited share in the Indian market.
- ² China and India: Boom, Boom, Andrew C. Schneider, Feb 2007- Kiplinger.Com Article, Deloitte Consulting LLP Analysis
- ³ Goldman Sachs Global Economics Paper No. 152, Jan 2007
- ⁴ Goldman Sachs Global Economics Paper No. 152, Jan 2007
- ⁵ EIU Reports, Deloitte Consulting LLP Analysis
- ⁶ Deloitte Consulting LLP Analysis
- ⁷ Growing at an annual average of 13.7% from 2002-07
- ⁸ "Ready for the Medical Boom", Biju Govind, Hindu.com Article, June 2006
- ⁹ "Time for a Makeover", Nandini Patwardhan, Expresspharmaonline.com Article, Nov 2006
- ¹⁰ "India meets Doha", white paper from Deloitte Research and the Deloitte Life Sciences and Health Care global industry practice
- ¹¹ *ibid.*
- ¹² EIU Report - India: Healthcare and pharmaceuticals forecast, 2006
- ¹³ Deloitte Consulting LLP primary interviews
- ¹⁴ EIU Report - India: Healthcare and pharmaceuticals forecast, 2006
- ¹⁵ Deloitte Consulting LLP analysis
- ¹⁶ WHO Chronic Disease Report: The Impact of Chronic Disease in India.
- ¹⁷ *ibid.*
- ¹⁸ WHO Data, NCMH Background Papers: The Burden of Disease in India, 2005, Deloitte Consulting LLP Analysis
- ¹⁹ In July 2007, the Associated Press reported India has roughly 2.5 million sufferers, less than half what was previously estimated. However, we are using the earlier reported estimates.
- ²⁰ WHO Data, Deloitte Consulting LLP analysis
- ²¹ IRDA/NCAER Surveys, Deloitte Consulting LLP analysis
- ²² Deloitte Consulting LLP primary interviews
- ²³ Clayton M. Christensen, Michael E. Raynor, *The Innovator's Solution Creating and Sustaining Successful Growth*, Harvard Business School Press, 2003.
- ²⁴ "Ready for the Medical Boom", Biju Govind, Hindu.com Article, June 2006
- ²⁵ A "Calibrated Approach": Pharmaceutical FDI and the Evolution of Indian Patent Law, Katherine Connor Linton and Nicholas Corrado, USITC Journal of International Commerce and Economics, July 2007, Deloitte Consulting LLP Analysis
- ²⁶ "Indian Court Rejects Patent Challenge", Amelia Gentleman, New York Times, Aug 2007
- ²⁷ "The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market", William Greene, USITC Office of Economics Working Paper, May 2007
- ²⁸ Michael Raynor, *The Strategy Paradox: Why Committing to Success Leads to Failure (and What to Do About It)*, Currency/Doubleday, 2007.
- ²⁹ Requisite Uncertainty describes the allocation of responsibility for managing elements of strategy based on time horizon and degree of uncertainty. Middle management makes strategic commitments with the greatest potential for growth but does not focus on uncertainties. Senior management creates real options to mitigate the strategic risks created by uncertainty over a longer time frame. Functional managers execute the strategy that is given them with a short term focus. The board balances shareholder returns with corporate survival.

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