



Life Sciences Consulting and Outsourcing



Market Access Opportunities in India
Kinapse Consulting, 2011



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India has long fascinated the world – be it cultural heritage or unprecedented economic growth. A similar fascination is excited by India’s healthcare market which Kinapse observes being sometimes written off as just a self-pay generics-based market. In this paper, Kinapse uses its global market access experience and India presence to explore the Indian healthcare market. We identify opportunities for Indian Market Access, and weave a kundliⁱ for the margadarshanⁱⁱ of multinational companies looking to optimise access in India.

1 Significant present and future commercial opportunities

India, as the land of diversity, encompasses everything from a large population in poverty to a significant demography of wealthy individuals with first-world lifestyle disease prevalence. This diversity encompasses much more than a volume market for generics. Though this seems complex to outsiders it can be parsed to provide specific, commercially attractive opportunities in India.

While Indian companies dominate the US generic market with 33 per cent of 419 Abbreviated New Drug Application (ANDA) approvals from the US FDA in 2010¹, India’s own market is increasingly being penetrated by high technology products beyond off-patent small molecules, such as biosimilars and medical devices. Biosimilar sales in India are around \$200 million, and expected to grow to \$580 million by 2012² and the Indian medical devices and equipment market was valued at \$3.6 billion in 2010 and is expected to reach \$6.41 billion by 2014.³ Additionally, in spite of the lack of a public reimbursement system in India, Indian patients prove they can afford to pay out of their own pockets for patented molecules like Roche’s Pagasys for Hepatitis C and GSK’s Tykerb for breast cancer.

The Indian pharmaceutical market has witnessed a successful growth rate of 21.3 per cent for the 12 months ending September 2010⁴. However, it is not just a growth story as the \$12.6 billion⁵ Indian pharmaceutical market

is currently the world’s second largest by volume⁶. From Kinapse’s research based on BSE (Bombay Stock Exchange) filings for the financial year 2010 – 2011, Cipla is the leading pharmaceutical company in 2010 (Table 1) while GSK is the top multi-national pharmaceutical company in India. As we can see, there are only 2 non-Indian companies in the Top 10 – and those low down – suggesting a clear competitive space for an MNC (Multinational Company) pharmaceutical with the right access strategies.

Company	Revenue (Rs. billion)	Revenue (USD billion)
Cipla	63.18	1.33
Ranbaxy (Acquired by Daichi Sankyo)	56.72	1.20
Dr. Reddy’s Laboratories	53.04	1.12
Lupin Ltd.	45.09	0.95
Aurobindo Pharma	41.33	0.87
Sun Pharmaceutical	31.05	0.66
Cadila Healthcare	29.20	0.62
GSK	23.74	0.50
Ipca Laboratories	18.81	0.40
Aventis Pharma	11.60	0.24

Table 1: Top 10 pharmaceutical companies in India, 2010

ⁱ “Horoscope”

ⁱⁱ “Guide”

¹ Article in Business Standard on “Indian pharmaceutical remains top in US generics”, January 2011

² Article in Pharmatech on “India To Become A Biosimilar Powerhouse”, February 2011

³ Article in Pharmabiz on “Value of Indian medical devices market to touch US\$ 6.41 bn by 2014: Cygnus”, March 2011.

⁴ Quoted from a PwC report

⁵ IBEF report – a trust by the Ministry of Commerce, India

⁶ “Pharma to topple IT as big paymaster”. The Economic Times Jun 2010.

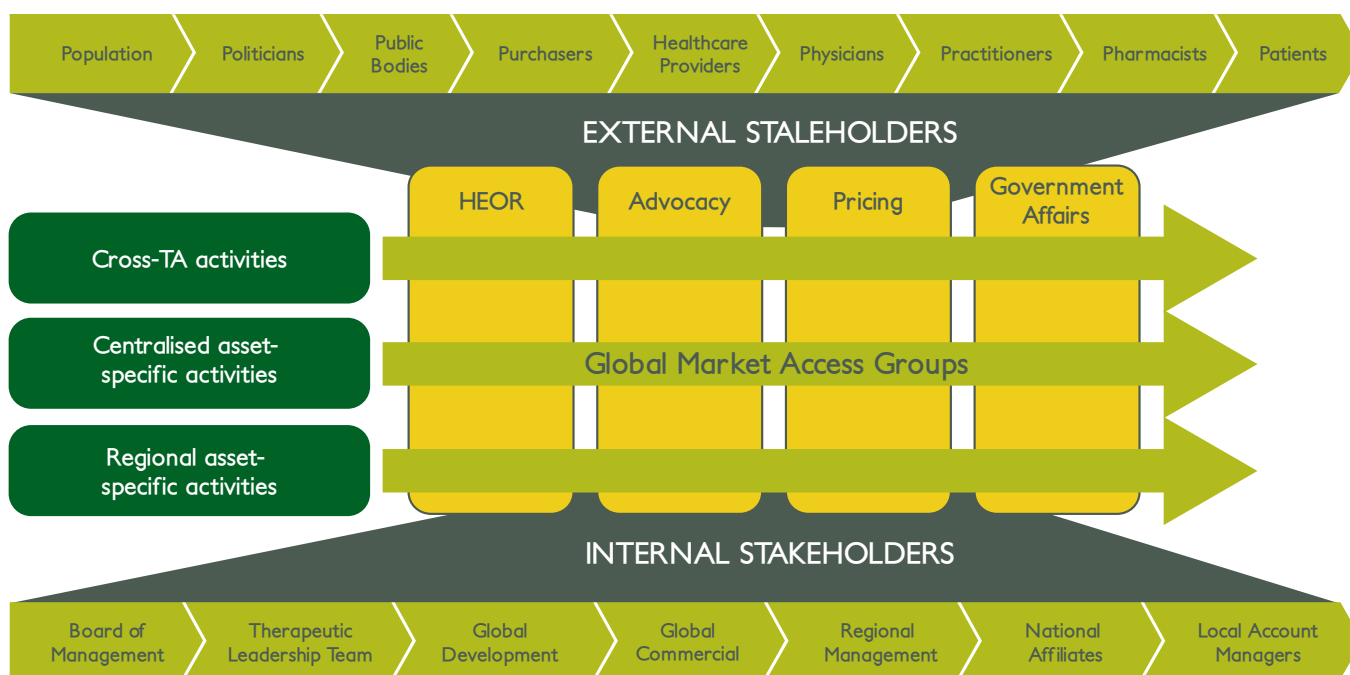


2 Market access landscape in India

The Indian pharmaceutical market is dominated by self-pay generics so the market access disciplines familiar with mature Western markets like health economics and outcome research (HEOR), patient advocacy and reimbursement are in their infancy. However, government affairs and pricing functions can play a very important role in the Indian scenario.

The ambitious health goals for the country demand the need for an alternate system, which encourages private and non-state players to engage in partnerships with the state-run healthcare delivery institutions⁷. With India investing enormously in healthcare infrastructure, government has been inviting public private partnerships⁸ and many companies have adopted the public private partnership (PPP) model to establish themselves in India. The PPP model has largely contributed to GE Healthcare's success in India as attested by Mr. Chaitanya Sarawate, Head of Market Access India where he credited recent commercial success to partnerships made with the government and with educational institutions.

Figure 1: Kinapse framework for market access



2.1 HEOR

The local need for HEOR is almost nonexistent in India. Due to absence of a public reimbursement system or significant HTA body, physicians, who are free to prescribe a generic or a branded product as they please, are the direct customers of a pharmaceutical company. This is the reason why physician marketing remains a dominant lever for driving prescriber uptake in India.

2.2 Government Affairs

The government of India is increasingly investing to improve the healthcare infrastructure in India, hence government affairs today plays an important role.

2.3 Pricing

While India is not just a market for low priced medicines, it is crucial to be affordable here, because it is largely a self-pay (non-reimbursement) market. However, a shift attributed to rising incomes has created a section of society that is ready to pay a premium price for differentiated treatments and increased benefits.

As Mr. Sandeep Duttgupta, Market Access and Pricing, Emerging markets, Pfizer Inc. observed to us, "In India, you are not deemed professionally successful unless you are a little bit obese!" Combining this cultural characteristic with a young educated middle class with fast-growing disposable incomes and increased incidence of heart attacks in the under-35 age group⁹ provides a valuable opportunity for higher-priced branded healthcare products who can justify their price.

⁷ Public Private Partnerships for Healthcare Delivery in India, Journal of world health and societal politics, September 2010

⁸ Public Private Partnership to promote healthcare in India, December 2010

⁹ Article in Economic Times, September 2006

However, as confirmed by the head of Medical Affairs in India of a top 10 pharmaceutical MNC, with many products outside the price control which is exercised in India by DPCO (Drugs Price Control Order), market forces play a greater role than in countries with a broader national pharmaceutical pricing scheme. However, regulations allow the government to intervene to control prices in the public interest even where the product lies outside the explicit scope of the DPCO.

Contrasting pricing strategy by Roche

While other MNCs in India were selling their products at discounted rates, Roche pursued premier pricing to position itself as an innovative brand for its anti-retroviral drugs. However, this exceptional strategy failed and instead attracted criticism following which they had to reduce their prices.

At the time of publication of this paper, Roche have just announced a new strategy of “tiered pricing” for emerging markets after pilots in Egypt and Brazil.

Since medical devices and patented products are often highly priced in India, the Indian government is planning additional interventions. The NPPA (National Pharmaceutical Pricing Authority) has proposed to negotiate the prices of patented medicines based on an external reference pricing system¹⁰. Prices of the same medicines in other countries with comparable per capita incomes or purchasing power parity will be used as references.

2.4 Patient advocacy

India is a democracy where people's movements have implemented lasting change. From the freedom struggle to the latest anti corruption movement – India has exhibited tremendous people power.

With a 67% percent broadband subscriber growth per year, India is looking for information on the net like never before¹¹. This cultural characteristic and technological trend combine with the fact that multiple agencies including regulatory bodies, scientific review committees, ethics committees and NGOs are all working towards improved patient rights and protection in India.

Kinapse assesses that the conditions are right for patient advocacy to have a great impact on the Market Access scenario in India. Talking to Kinapse, the Head of Market Affairs of a top 20 pharmaceutical MNC in India reinforced

Successful Patient Advocacy campaigns in India

While campaigns by AIDS Healthcare Foundation (AHF) forced Cipla - world's largest generic AIDS drug producer to lower prices of its anti retroviral drugs by 20%, the Cancer Patients Aid Association (CPAA) helped reject exclusive marketing rights for Glivec (by Novartis) in India.

this with his view that patient advocacy is a major power that influences parliamentarians and government policies in India.

2.5 Reimbursement

Health insurance similar to that in the United States is beginning to emerge in India for selected populations – however outpatient prescriptions still remain out of the scope of reimbursement. In 2006, out of pocket expenditures made up over 75% of the total healthcare spend¹², essentially due to the poor quality of public healthcare facilities and the nascence of private insurance.

Gross health insurance premiums collected for FY11¹³ increased by 33% and are expected to grow with the expanding middle-high income bracket (>\$2000 per year).

Health insurance in the future may 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. Health insurers are keen to provide drug coverage, but face a massive, paper-based distribution system with thousands of points of dispensation.

Mr. Chaitanya Sarawate foresees the role of government change from “provider” to “payer” in future. That would of course trigger significant changes to the reimbursement, pricing and patient advocacy landscape in India.

¹⁰ Article in Business Standard, June 2011

¹¹ India: Digital Market Overview, 2009

¹² WHO report on country specific health expenditures, 2009

¹³ India Brand Equity Foundation, August 2011

3 Drawing analogies from other industries

Foreign companies have been active in India since the liberalisation of 1991. One of the most successful MNCs in India, Unilever understood that India is a country where both the middle and lower-end segments are critically important. As an example of reaching the lower segment, Hindustan Lever, created a new category for personal hygiene products and expanded the market considerably by offering single-use, low priced sachets of shampoos.

At the same time, some of the successful MNCs have also realized that price is not the only factor driving purchase decisions. Value conscious consumers will pay a premium if the benefits of features and quality are seen to outweigh their cost. LG for example, has reengineered its TV product specifications in order to develop a no-frills model to expand the market at the low end and a premium LED for the middle segment.

India-centric strategies by GSK

India-specific pricing: GSK is selling many of its drugs at prices well below those charged in developed countries, retaining profitability by shifting manufacturing to India.

Emphasis on customized product line: GSK has selectively marketed drug products that align well with the disease profiles in India. It has strategically focused on anti-infectives, acute care products and gastrointestinal products and has created a dominant position in these therapeutic groups.

Finally, these companies have displayed immense commitment in dealing with the local government regulation. Regulations governing the India mobile-telephony sector, for example, have been amended several times since 1994. Although most multinationals left when the regulations changed, Hutchison Whampoa continued to invest in India. Today, Hutchison Essar (now Vodafone) is one of the top three mobile services companies in the country in terms of market share.

We agree that solutions applicable to other industries do not always precisely fit to pharmaceuticals. A similar opinion was provided by Mr. Sandeep Duttgupta, who told us that “companies can reverse engineer to produce an electronic device with less functionality, but can’t launch a pharmaceutical compound without one part of its chemical structure”. However, we believe analogies can be drawn, and not just in medical devices where the end product can be customized. For example, Glaxo SmithKline (GSK) stands out from the rest because of its flexibility to cater to the requirements of the Indian pharmaceutical market. It is the top MNC in India with respect to revenue generation (Table 1 in this document). There was a time when people failed to recognize it as a foreign company.

4 Key considerations for optimising access in India

Kinapse recommends that multinational companies consider the following key levers to gain competitive edge for market access in India:

1. Develop a considered pricing strategy:

As India is still a long way from a widespread shift to an insured payer model, pricing remains a sensitive issue in India. Pharmaceutical companies coming into India usually consider differential pricing. For e.g. Merck & Co. has launched differential pricing through Januvia, its anti-diabetic drug, which is priced at approximately US\$1 per dose in India – a fifth of its price in the U.S.¹⁴. However, a contrary perspective is provided by Mr. Sandeep Duttgupta with his observation that “There is a tendency of companies in India to slash prices of drugs; however such a strategy is not sustainable”

The increasing middle class which is expected to be around a third of the population by 2015 provides a great opportunity to the MNCs to sell their premium products in India. One source estimates that at least 60 million Indians – a market as big as the UK – can already afford to buy Western medicines.¹⁵

2. Overcome generic competition through patient advocacy support:

The evidence to date shows that patient advocacy has been used against the pricing strategies of MNC pharmaceutical companies. However, Kinapse sees an opportunity for the industry to partner more positively with advocacy groups in India for mutual benefit.

3. Target the new growth opportunity areas

India has a small biotechnology hub based largely in Karnataka. The leading domestic biotechnology players include Serum Institute of India (2008 – 09 revenue \$242 million) and Biocon (2008 – 09 revenue \$198 million)¹⁶. As leaders in generics, biosimilars seem to be a natural follow on business in India, providing the only alternative to expensive patented biologics.

With medical tourism growing in India, demand for high end medical instruments and devices is expected to increase. A well known example is the Indian government supporting an initiative by well known heart surgeon Dr. Naresh Trehan to build a “Medi City” in Gurgaon, which is a high growth business headquarter in the same National Capital Region as Kinapse India. The compound will support 17 super specialties and medical colleges. The project is expected to cost an estimated \$493 million¹⁷.

Conclusion

Having considered the market access landscape, successful strategies and had discussions with Indian Market Access leaders, Kinapse concludes that India is a market with tremendous potential that cannot be ignored. While a rising per capita income provides an opportunity for global companies to launch their premium products, lack of a public reimbursement system calls for a careful pricing strategy. India will not be a developing nation for ever and MNCs aiming for success in India should increasingly deploy the disciplines of market access to get their share of that inevitable growth.

¹⁴ The Economist, May 2008

¹⁵ India's Pharmaceutical Industry on course for globalisation (Deutsche Bank Research), April 2008 ¹⁶ Biospectrum ABLE ,2009

¹⁷ PWC report on Healthcare in India, 2007



About the Authors

Gavin Outteridge, Kinapse Vice President

Gavin leads the Kinapse Market Access service line and, since joining Kinapse from Pfizer in 2005, has led a variety of Market Access organisational strategy projects for major global healthcare companies, in addition to a range of market- and product-specific work, with a focus on access in emerging markets.

Kamalika Nandi, Kinapse Senior Analyst

Kamalika since joining Kinapse in 2009, has worked on a variety of HTA and Market Access projects. She has also worked extensively in R&D data analytics designing, creating and maintaining Key Performance Indicators.

Ravi Mehta, Kinapse Intern

Ravi is a student of M. Tech Biotechnology Engineering from the India Institute of Technology, Delhi.

Participating Industry Thought Leaders:

Mr. Sandeep Duttgupta, Market Access and Pricing, Emerging Markets, Pfizer Inc.

Mr. Chaitanya Sarawate, Head of Market Access in India, GE Healthcare

About Kinapse

Kinapse provides consulting and outsourcing services to life sciences organisations, focusing within our development and commercialisation consulting service lines.

The Kinapse Market Access team recognizes that reducing pricing, reimbursement and market access risk has become a key priority so we work with our clients to:

- ▶ Demonstrate positive health economic benefits and secure uptake
- ▶ Optimise resources
- ▶ Develop Market Access strategies

Typical projects for clients in the four market access disciplines of HEOR, Advocacy, Pricing & Reimbursement and Government Affairs include:

- ▶ Organisation and interface design
- ▶ Resource planning and management
- ▶ Performance management including scorecards and benchmarking (the “value of value”)
- ▶ Process redesign
- ▶ Decision-maker and market analyses.

For more information please visit www.kinapse.com or email kamalika.nandi@kinapse.com

Kinapse Ltd.
Tuition House
27-37 St George's Road
Wimbledon, London SW19 4EU

Phone: +44 20 8946 7600
Web site: www.kinapse.co.uk

