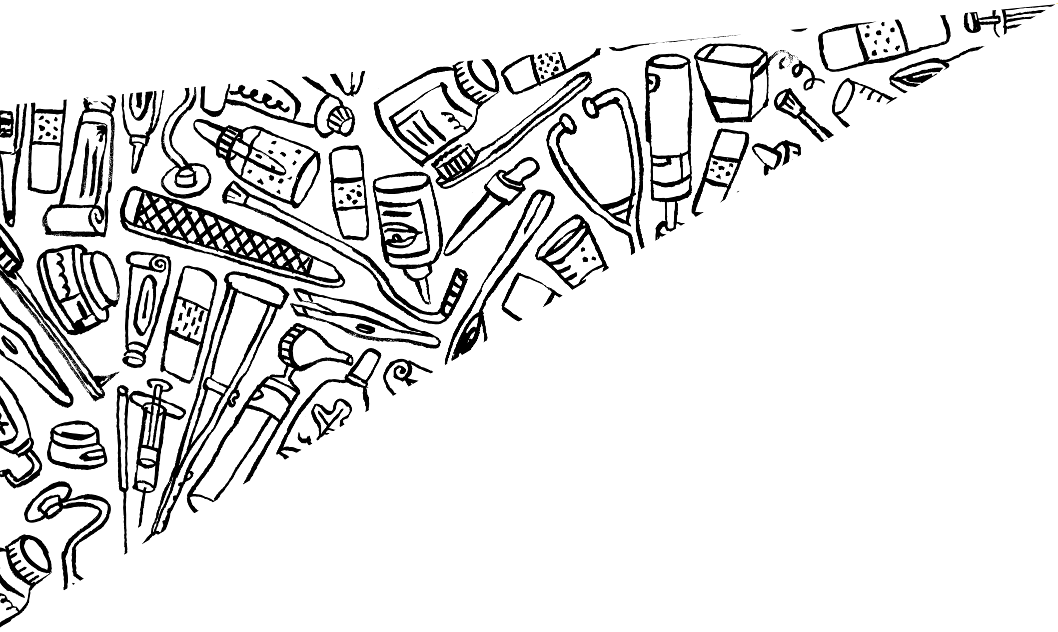
India emerging

Pharma's evolving business models



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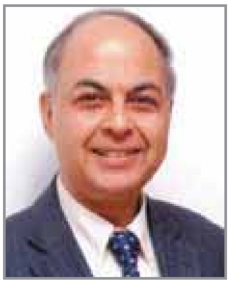
Foreword



Ranjit Shahani
Vice Chairman and Managing Director
Novartis India Limited
President, OPPI

India emerging: Pharma's evolving business models is the third part in a series of reports by the OPPI and Ernst & Young that focuses on India as a pharmaceutical destination. The focus of the report is to understand the increasing importance of India as an emerging market and the models that companies might need to adopt in order to succeed in this market.

In an interview Mr. Ranjit Shahani, Vice Chairman and Managing Director, Novartis India Limited and President, OPPI presents his point of view on India as an emerging market and the models and critical success factors for this market

Q) How important are emerging markets to global pharma and which are the areas where you believe emerging markets will have a role to play in the future-market, sourcing, innovation?

A) GDP is one of the main determinants of health spending. As economies grow and mature, they begin to spend more on health related issues. Emerging markets will represent 95% of all population growth contributing ~ 40% of the GDP 10 years from now and will add 500mn new consumers, making pharma and healthcare markets in these economies very highly valued. However there are multiple challenges in tapping these markets as there is variable infrastructure, lack of reimbursement, pricing, poor awareness etc in these emerging economies. Amongst the emerging economies China and India, have a key role to play in sourcing. While China and India both have good chemistry knowledge, China is also investing significantly in biologics. The economic shift taking place will also warrant a change in the innovation model to cater to the requirements of the emerging economies. This has already begun with some recent studies indicating the rebalancing, with the centre of gravity of innovation shifting from developed to developing countries and the Asian countries beginning to take a lead over the west in terms of overall innovation over the last few years across multiple industries and renewed interest in pharma innovation.

Q) Where does India stand as compared to the key emerging markets esp. Brazil, China and Russia?

A) Over the last 5 years investments and focus have been on China, Brazil, Russia and India in that order. However even though the next few years will continue to see China as focus, India will increasingly become an important market. Recent economic forecasts have indicated that India would become the world's third largest economy in 2012 by overtaking Japan in terms of gross domestic product (GDP) measured according to the domestic purchasing power of the rupee, otherwise called purchasing power parity. India's demographics, rising income levels, changing attitudes towards health and lifestyle all augur well for the industry. While India will continue to attract the attention of the world for sourcing, as far as research innovation is concerned the question is that will India be a center of it? The answer today is not a resounding yes unless the ecosystem is built which will change key aspects such as education, investments in research and industry collaboration and of course a strong IPR implementation on the ground etc. Global economies are recalibrating as developed nations try to increase productivity. One of the things that will lead this rebalancing is the fact there is need for frugal innovation and this is something that Indians are good at and we must certainly leverage. Clearly there needs to be an emerging market model towards innovation and research and India can certainly have its place in the sun provided we get some key determinants in place which include a world class Intellectual Property system, good infrastructure when the promise of having the coming decade – the decade of innovation for India can be fulfilled.

Q) Do you see an increase in M&A, collaboration or in-licensing in the future? Which of these approaches do you feel will be more prevalent?

A) I believe, the M&A space will continue to see significant activity, so will collaboration and in-licensing. While the rationale for M&A can be to gain market share or access a new technology platform or management efficiency, the key to getting collaborations to work will be execution to meet the objectives initially set out.

Q) What are the critical success factors to operate in a market such as India?

A) We have one of the lowest priced medications available in India but as a market the most pivotal driver still remains investments in healthcare infrastructure to achieve accelerated growth and improved access. Investments in rural markets are needed for building access – this includes roads, improved sanitation, drinking water, nutrition, vaccination etc. In addition the entire health ecosystem will need to be upgraded with increasing number of medical and nursing schools, diagnostic labs, insurance penetration, PPP, schools of public health etc. Significant investments are also needed in infrastructure for logistics and distribution. Pharmaceutical companies have an opportunity to participate with players in the existing eco-system and even beyond the eco-system. Telecom companies and FMCG players have reached the remote corners of India and pharma companies will have to find innovative ways of partnering to deliver medicine and thereby improve access. While the task of the government is to invest in creating infrastructure, the private sector can work towards access and affordability. This is truly a social business model.

Foreword

Tapan Ray
Director General
OPPI

Encouraging economic performance of the emerging markets has transformed the global opportunity landscape across various industries. These markets are estimated to contribute significantly to the global economic growth.

Such a transformation in the world economy is enabling companies to realise the need to adapt and evolve their business models to leverage and sustain growth opportunities in a competitive environment.

The pharmaceutical industry has equally been confronted with challenges and constraints from patent expiries, falling R&D productivity to reducing healthcare costs by the developed countries together with the global financial crisis since 2008. The sector has witnessed increased focus on emerging markets. This has prompted many companies to start pondering on how to reinvent their business models and diversify in terms of both products and markets to gain cutting edge advantage.

Many companies have sensed the opportunities at various levels and structured their internal organisations, resources and partnerships to customize market access and gain customer share. Technology and pricing levers are also being used differentially by these companies to reposition themselves in different markets within the region.

Accordingly, we at the Organisation of Pharmaceutical Producers of India (OPPI), in our continued commitment to the pharmaceutical sector of India in particular and the region at large, have partnered with Ernst & Young to undertake a research study, which talks about the importance of emerging pharmaceutical markets, opportunities in India as one such market and various paths that companies have already started pursuing and will further need to consider to succeed in these markets.

I thank the members of the Global Sourcing Committee of OPPI and the Ernst & Young team for preparing this important research report aimed at offering significant value to the stakeholders in pursuit of excellence.

Foreword

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India emerging: Pharma's evolving business models is an attempt to take forward our discussion on India's potential as a pharmaceutical destination which we had initiated with our previous 2 reports; Taking wings: The coming of age of the Indian pharmaceutical industry and Successful partnerships: Insights on working with Indian pharmaceutical service providers. The objective of this year's report is to understand the increasing importance of India as an emerging market and the models that companies might need to adopt to succeed in this market

The importance of emerging markets to the pharmaceutical industry has been growing with each year - something that has been evidenced by the increase in M&A and partnerships one has witnessed. No more is it a "nice to have" for a global pharma company to have an effective emerging market strategy. With 40% of the growth in the pharma industry coming from these markets and the future looking quite the same, it will be the driver of growth in the industry.

The pharma industry has had to evolve at a speed which perhaps it has not had to in the past. One of the key dimensions is the broadening of the ecosystem beyond R&D, manufacturer, supplier, distributor etc to a broader health outcomes ecosystem. In this context the importance of accessing and succeeding in emerging markets will prove even more crucial as global pharma learn to combine traditional wisdom and strategy with what works in a market. This has been reflected in changes in organisation structures amongst most global pharma companies to allow for local market expertise to influence corporate strategy more definitively.

While the pharma industry does have a lot in common around the world, the approach to access markets varies quite significantly. One of the key reasons for including a piece on emerging markets as part of the "Global Sourcing" initiative of OPPI was the increasing congruence between sourcing and markets. Even until a few years ago there was quite a distinction between pure-play manufacturing businesses (who supplied product to pharma companies) and pharma companies. The lines are now graying. It is clear that in order to sustain a strong manufacturing business one must have access to products. It is also clear that access to a strong portfolio of products in emerging markets is a prerequisite.

We would like to thank the leadership of the OPPI, members of the OPPI Global Sourcing Committee and the Ernst & Young team of Rajiv Pillai, Ruchi Malhotra, Rohit Srivastava, and Rahul Ambadkar for their effort during this process.

Executive summary

The global pharma market is in a state of transformation with its focus changing from a blockbuster drug (Pharma 1.0) to a healthy outcome (Pharma 3.0)-based approach.

The industry is responding to the challenge of a patent cliff, decreasing R&D productivity, pricing pressures, globalization and changing demographics with the implementation of new strategic initiatives.

- **Market:** Penetrating emerging markets and their growing middle class to drive future growth
- **Science:** Invigorating pipelines, breaking down silos, collaborating with biotech companies and licensing in late stage molecules
- **Customer:** Moving from a product to a customer-centric approach

The industry is now on the cusp of another transformation, "Pharma 3.0," spurred by the convergence of new trends including health care reform, demographics, health information technology (IT) and consumerism.

This transformation has been an evolutionary process, with each business model fueling the next, and subsequent models drawing from the strengths of their predecessors. Depending on each company's strategy, these models may co-exist at different times.

The contribution of emerging markets to the growth of the pharma market has increased five-fold (8% in 2003 to 40% in 2010) over the last decade.

- The global pharma market has grown to US$835 billion in 2010, although its growth rate has halved over the last seven years. However, there has been double-digit growth in markets including Asia, Africa and Australia (AAA) and Latin America.
- Four countries in emerging markets are slated to figure in the list of the top 10 pharma markets by value (up from two countries in 2003).
- China has emerged as the leading market with Brazil, India and Russia constituting the next tier of emerging markets.
- It will therefore be imperative to prioritize these markets and define the timeframe for their access and penetration.
    - **Short term:** It is important to be in China in the near term, given its size and rate of growth.
    - **Short to medium term:** Since India and other markets are expected to reach a critical size over the next five to seven years, it will be critical to develop an understanding of these markets now and establish a base in them within the next two to three years.

Companies are looking at leveraging this opportunity and intend to garner a significant share of their revenues from emerging markets.

- European and US companies have taken the lead in tapping these opportunities while Japanese companies have joined in relatively late. Market leaders are already recording more than 20% of their revenues from emerging markets.
- While leading companies had a 5.5% market share in emerging markets in 2008, within a span of two years, their average share went up by almost three times to ~15% in 2010.
- Leading multinationals have set ambitious targets for themselves and most of them are expecting at least 20% of their revenues to be generated by emerging markets.

Companies have adopted various combinations of the strategic options below to address these markets:

- **Organizational structure changes:** Companies are increasingly restructuring their existing organization structure to accommodate dedicated business units that are focused on emerging markets.
- **M&A:** Considering speed the vital element for success, inorganic activity gathered steam in emerging markets and peaked in 2010 with 27 cross-border deals. China and India have emerged as the top two destinations for acquisitions. While China witnessed the largest number of acquisitions, some supernormal valuations have actually been paid for companies that were based in India. The success of companies depends on their ability to integrate and leverage an acquired company's capabilities.
- **Collaboration:** Collaboration gained popularity as a low-risk model when multinational companies began collaborating with local companies to augment their product portfolios and increase their reach. In terms of the nature of deals, India has seen the largest number of in-incensing deals, while China has witnessed more co-marketing and distribution deals.

In addition to collaborating with local companies in emerging markets, Big Pharma has also focused on emerging markets, especially China and India, as destinations for outsourcing and off-shoring, across the pharma value chain — from NCE research to late stage manufacturing. India has been the preferred choice for outsourcing in the area of late stage drug discovery, shared services and complex manufacturing while China has been the preferred market for building blocks and intermediates (APIs).

While each of the emerging markets presents diverse growth opportunities, they are structurally distinct and need a tailored approach.

- Russia and Brazil have seen a high multinational presence, reliance on imports and a large share of patented products. Markets such as India and China have strong local home-grown companies that have dominated the market.
- While China and India have an increasing chronic market, companies that aims to grab a significant market share will also need to have equally competent acute portfolios of products.

Having established the role that emerging markets are likely to play in next few years, it is important to respond to the key challenges relating to the following:

- Awareness
  - Investment in primary and preventive healthcare will be critical from India and China's point of view, since a large proportion of ailments are still unreported in these countries.
- Access
  - A large part of the population in BRIC countries, barring Russia, still does not have access to adequate health care facilities. Therefore, it will be critical to focus on strengthening supply and distribution networks to achieve growth in these countries.
  - Effective use of technology and adoption of novel partnership models will be critical to resolve access-related challenges in emerging markets.
- Affordability
  - A win-win situation needs to be created for the industry and customers by enabling a platform for income-based differential pricing.
  - Moving pricing closer to target markets and achieving greater control of the cost base will be important.

High-performing companies that have approached India have a deep understanding of their target customers. They have broadened the range of their products, adopted unconventional partnership models to increase access and tested new pricing and marketing approaches.

The Indian market is expected to reach US$24 billion (pessimistic) to US$49 billion (optimistic) by 2020. India-specific challenges are largely in the area of pricing and access to new products and markets.

Pricing has been and is expected to continue being the key strategic decision in India.

- Not only does India have lower price points than some western markets, it also has lower price points as compared to other emerging markets.
- It is important to consider that India is one of the few markets where drug prices are expected to increase over the next few years, unlike in several other developed markets.
- Multinational companies have been successful in launching products at a premium price, and yet garner a high market share in India. While these products are priced at a premium in the country, they have been launched at a differential price as compared to developed and other emerging markets.
- Ability to differentiate brand and align product pricing with market dynamics will be critical for garnering a substantial market share.
- Despite the great disparity between the US and India's per capita income, (per capita income of the US — US$47200 as compared to India's US$3500), there is a sizeable population in India that has significantly high income levels.

Therefore, an intra-country differential pricing may create a win-win situation, whereby the lower income group population will gain access to new medicines and pharma companies may be able to launch products at higher price points for the higher income population. Companies have launched patented products to facilitate access to advanced and new drugs and have adopted various models to increase their market penetration.

- Although Indian companies were able to launch most of patented products in the pre-2005 era, the enforcement of the product patent regime has led to near cessation of on-patent drug launches (21% of on-patent product launches in 2005–2010 as compared to 55% in 2000–2005).
- While a few MNC companies have expressed their apprehension on enforcement of the patent regime in India, others have successfully launched patented products in the country's market. This clearly indicates waning of IP risk in the Indian market.

Companies are testing non-traditional models to tap tier 2 and rural markets to leverage India's large untapped rural and semi-urban market.

- A large untapped opportunity exists in tier 2 and rural markets, with the majority of high to medium purchasing power households (67%) residing in these areas. At the same time, these markets contribute only 39% of the current market, which indicates that there is significant headroom for expansion in them.
- Companies have adopted novel approaches for patient engagement in these areas. Allying with FMCGs and using mobile communication technology are some of the initiatives taken by them to reach out to potential customers.
- Technology-enabled initiatives such as e-health and m-health are considered the key drivers to address access-related challenges in a vast country such as India. These initiatives received a fillip when the Government of India sanctioned ~US$6 billion for e-health and m-health initiatives.

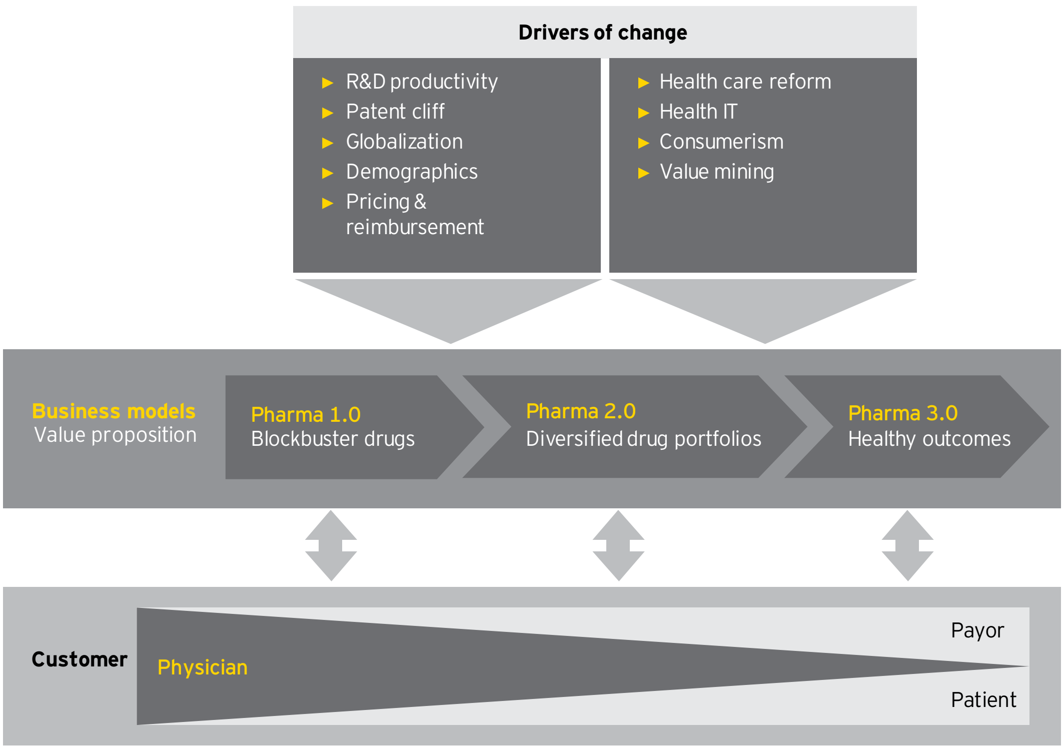
In conclusion, as emerging markets become increasingly important and India's role among them becomes more significant, pharmaceutical companies will need to adapt their business models, organizations and processes to align with these new environments. Companies have adopted multiple levers to tap emerging markets for product portfolios, sourcing or innovation. However their ability to understand these markets and drive revenue growth will be the key determinant of the extent of their investment and participation. Companies will be increasingly required to integrate their internal organizations and collaborate with the external environment in line with emerging market realities. This will help to accelerate learning and implementation as competition in these markets increase significantly. There will be a necessity to partner with health ecosystems and companies will be required to develop business models that will facilitate enhanced access and more market-realistic pricing, which are important factors for succeeding in emerging markets. The business case for these models will need to consider non-traditional approaches to increase access to hitherto untapped segments of the population, e.g., partnering with governments through the PPP mode, as well as with health insurance providers, diagnostic providers and NGOs; improving patient awareness, literacy, etc. While the challenges are manifold, the opportunities are significantly attractive for the pharmaceutical industry to participate in market creation and growth, and ultimately help in the creation of a better and healthier world for the future.

Section 1

- The global pharmaceutical industry, which was earlier product-centric, now has a diversified product and market portfolio.
- The industry is witnessing transition across three areas:
  - Science
  - Customer
  - Markets
- While emerging markets offer attractive opportunities for growth, it is important to prioritize entry into them. China has emerged as the tier1 market, attracting significant foreign capital. India, Brazil, Russia and Venezuela are the next in line and also offer substantial growth opportunities. M&A has emerged as the preferred model for entry into emerging markets, but with there being relatively few attractive targets, companies are compelled to pay high valuations. Over a period of time, collaboration may be viewed as a more viable option for companies.

1A. The global pharma market is in its transformation phase, with its focus changing from a blockbuster to a healthy outcome-based approach.

Figure 1: Evolution of the pharma market

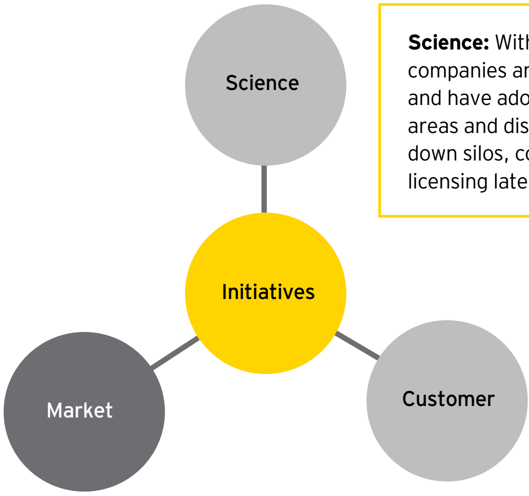


Source: Ernst & Young, Progressions Building Pharma 3.0

1A.1 Pharmaceutical companies now have a diversified product and market portfolio as compared to a blockbuster-based one.

The patent cliff, decreasing R&D productivity, pricing pressures, globalization and changing demographics are trends that have been compelling pharmaceutical companies to reinvent their business models. They have focused their efforts on three areas to complete their transformation:

Figure 2: Key areas for initiatives

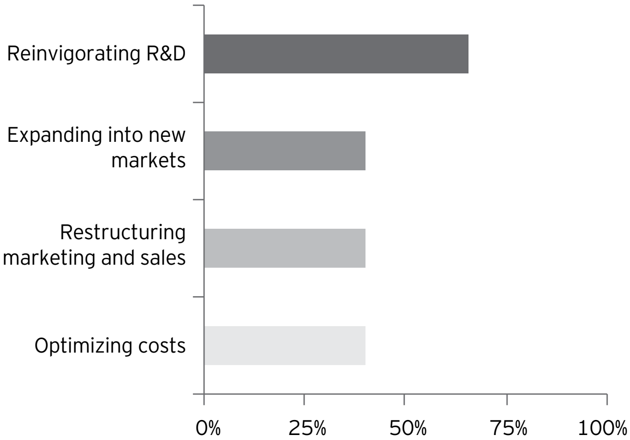


Science: With the impending patent cliff, most companies are trying to invigorate their pipelines and have adopted measures to prioritize therapeutic areas and disease categories. They are also breaking down silos, collaborating with biotech companies and licensing late stage molecules.

Market: Drug companies are counting on emerging markets and their increasing middle class to drive their future growth. They are looking at extending the life of their mature products and are also identifying strategies to approach patients who are at the middle and bottom of the income pyramid.

Customer: There is increasing focus on understanding the needs of the customer (payor, provider and patient) and moving from a product- to a customer-centric approach.

Figure 3: Key initiatives of global pharma companies



Source: Ernst & Young report, Progressions: executing for success , based on interviews with 40 senior executives of 15 companies worldwide

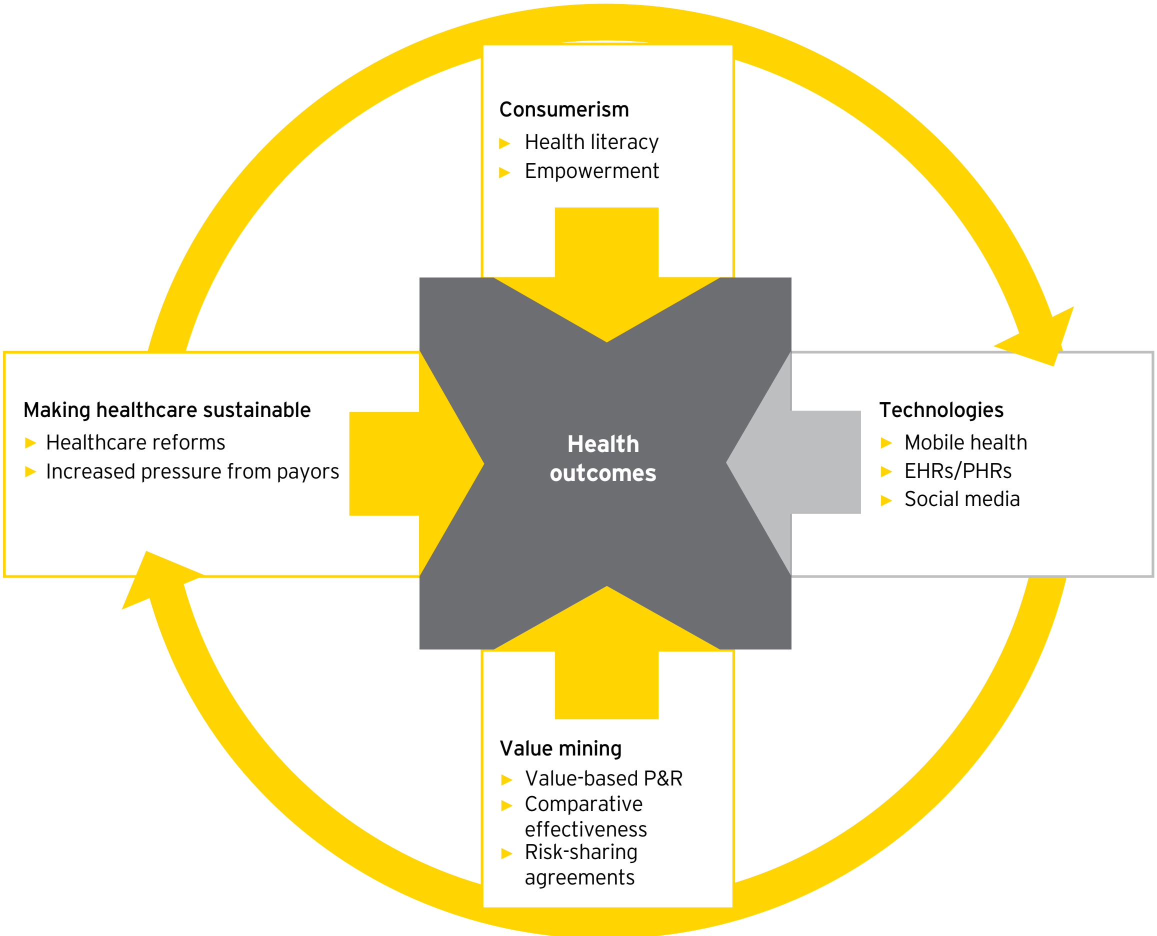
Out of all the initiatives for transforming their businesses, invigorating R&D and expanding into new markets have emerged as the top two initiatives of pharma companies worldwide.

These initiatives have led companies to evolve from a traditional vertically integrated blockbuster model – Pharma1.0 – to a cost-efficient, diversified product and market model with a focus on emerging markets and finding new ways to service underserved patients – Pharma2.0

1A.2 Even as pharma companies are adjusting to these challenges; they are being propelled to an environment in which they need to align their initiatives to potential health outcomes.

The industry is now on the cusp of another transformation – Pharma 3.0, spurred by the convergence of new trends such as health care reform, demographics, health information technology (IT) and consumerism. Pharma 3.0 is an ecosystem wherein companies are likely to move from simply producing new medicines to demonstrating improvements in health outcomes and creating new and effective business models. Their success will be driven by not just how many units they are able to sell, but also on their ability to improve health outcomes, with patients and payers being at the center of their model.

Figure 4: Drivers for tranformation to pharma 3.0



This transformation is being driven by the the following:

- Pressure to create a sustainable, affordable and accessible health care system
- New technologies such as mobile applications and text messaging platforms that can enhance access for patients in rural areas and emerging markets
- Customers being increasingly empowered through technological advances – social media such as PatientsLikeMe and Medscape Physician that provide data on outcomes and efficacy
- Widespread use of electronic health records can help to mine data to compare the efficacy of different treatments

This transformation has been an evolutionary process with each business model fueling the next, and subsequent models drawing from the strengths of their predecessors. Pharma 1.0 has been and is still a highly successful model that has driven the industry's growth, producing margins unmatched by other sectors. Pharma 2.0 has helped the industry change its approach to customers, alleviating some present day pressures and laying the ground for Pharma 3.0 and a collaborative, outcome-centered perspective. Depending on each company's strategy, these models may co-exist at different times.

Although various initiatives are underway both from the Pharma 2.0 and Pharma 3.0 perspective, the focus of this document is on how companies are looking at entry into new (emerging) markets and leveraging these to drive their health outcome agenda.

1A.3 The contribution of emerging markets to the growth of the pharma market has increased five times over the last decade.

Figure 5.1: Global pharma market size and growth rate

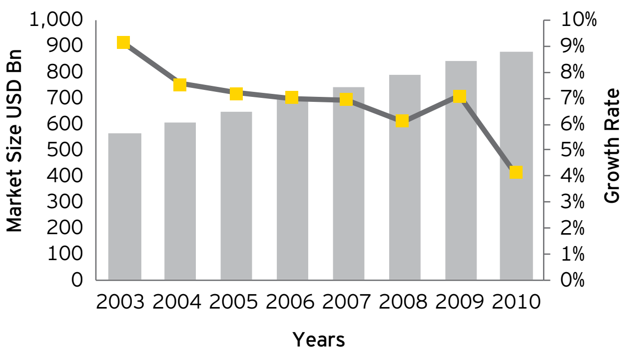
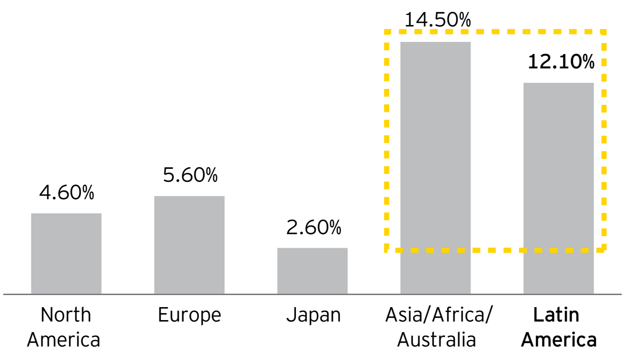


Figure 5.2: Growth of pharma market, 2006-2010 (region wise)



Source: IMS Health Market Prognosis, March 2011

While the global pharma market grew to US$ 835 billion in 2010, its growth rate has been halved over the last seven years. This has been due to the low single digit growth in the largest markets, e.g., North America, Europe and Japan. However, the bright spot has been the double-digit growth rates witnessed in markets such as Asia, Africa and Australia (AAA) and Latin America.

Figure 6.1: Region wise pharma market past and present- US$

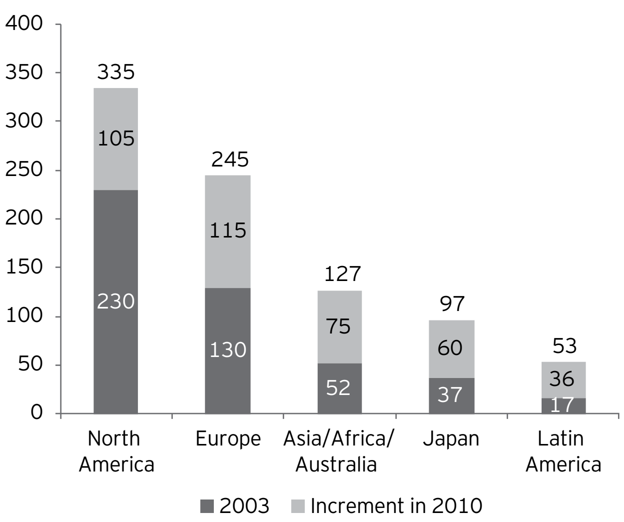
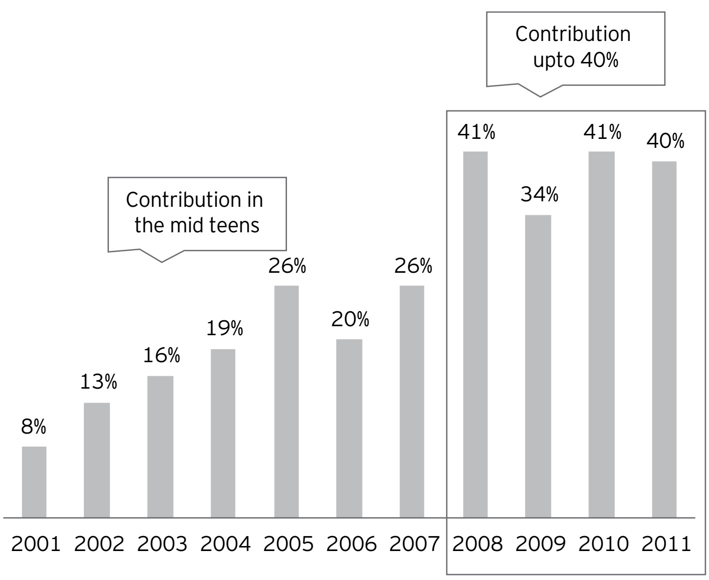


Figure 6.2: Contribution to growth from emerging markets



Source: IMS Health Market Prognosis, March 2011

These markets have become increasingly important destinations for pharma companies due to the former's contribution to the overall pharma market doubling from 11.6% in 2003 to 21% in 2010. At the same time, their contribution to the growth of the pharma market has increased from 8% in 2003 to 40% in 2010.

1A.4 The growth of these markets is expected to lead to a new world order in the pharma industry.

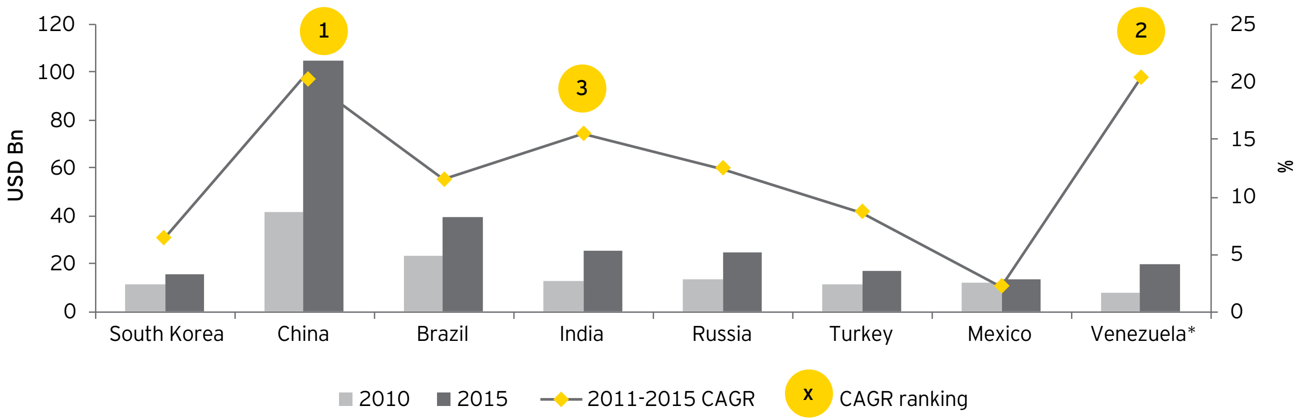
Leading markets by sales:

Rank	2003	2010	2015
1	US	US	US
2	Japan	Japan	Japan
3	Germany	China	China
4	France	Germany	Germany
5	Italy	France	France
6	UK	Italy	Brazil
7	Spain	Spain	Italy
8	Canada	Brazil	India
9	China	UK	Spain
10	Brazil	Canada	Russia
11	Mexico	Russia	Canada
12	Australia	India	UK
13	India	South Africa	Venezuela
14	Poland	Venezuela	Turkey
15	Netherlands	Mexico	Korea

Source: IMS Health, Market Prognosis 2011

Historically (in 2003), China and Brazil were the only two countries that featured among the top 10 pharma markets worldwide. However, by 2015, 4 of these emerging markets are expected to rank among the top 10 global pharma markets, with China and India emerging as the largest gainers. The other major emerging markets are forecasted to be Brazil, Russia, Venezuela, Turkey and Korea. Mexico, on the other hand, is likely to drop out of the list of the top 15 markets during this period.

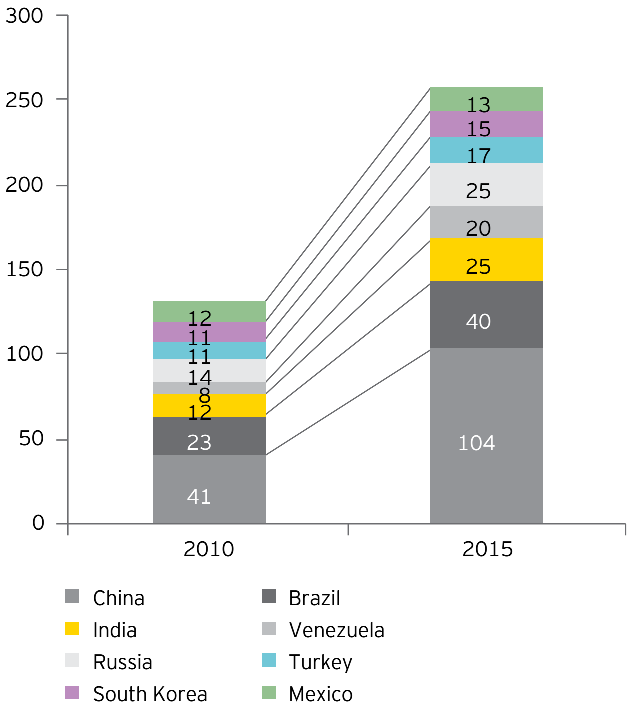
Figure 7: Emerging markets: today and tomorrow, market size, growth rates



Source: IMS Market Prognosis, 2015, market sizes averaged, Ernst & Young analysis

Out of these markets, China and Venezuela are expected to be the fastest growing (by more than 20%), while India and Russia are predicted to rank in the next tier with double-digit growth rates. Mexico, which is expected to grow at a CAGR of 2.2%, is expected to lose out to some of these fast-growing markets.

Figure 8: Market growth



Source: IMS health prognosis, 2011; Ernst & Young analysis

Each of these markets is growing. They can be classified into three tiers, based on their contribution to the growth of the market in absolute terms.

Tier 1: China is expected to make the largest contribution to the growth in the global market, contributing around US$63 billion.

Tier 2: Brazil, India, Venezuela and Russia are expected to contribute more than US$10 billion between 2010 and 2015.

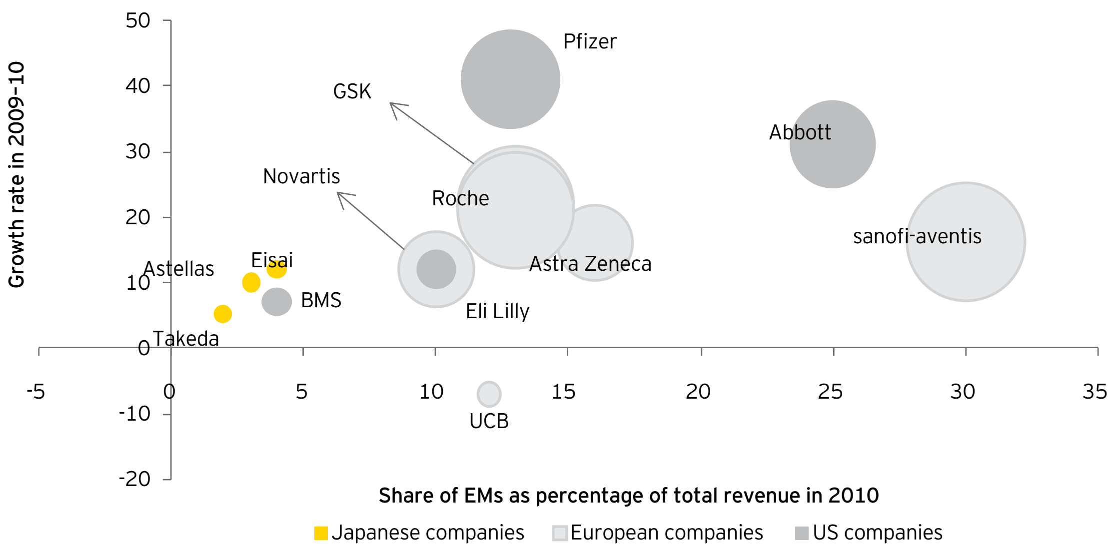
Tier 3: Turkey, South Korea and Mexico are expected to contribute less than US$6 billion.

While Venezuela has emerged in the tier 2 category, its growth is driven by inflation (of almost 30%) as well as due to currency fluctuations. As a result, while its market is growing, it is facing several challenges.

1A.5 Companies are looking at leveraging the opportunities mentioned earlier and intend to garner a significant share of their revenues from emerging markets.

Pharma companies have realized the importance of these markets and are clearly focusing on emerging market requirements.

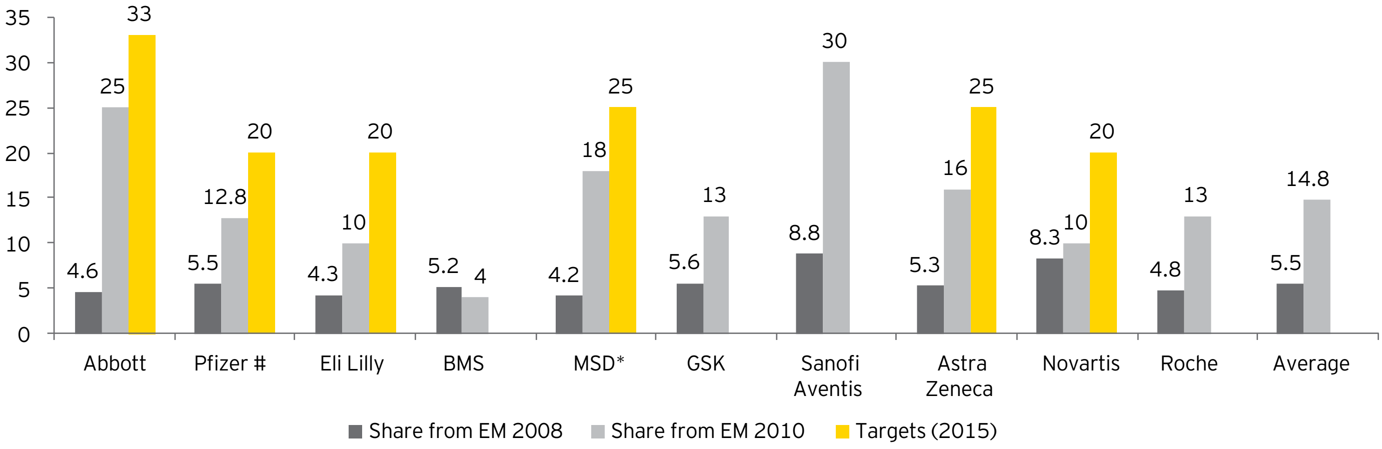
Figure 9: Companies' relative positions in emerging markets



Sources: Annual reports, News Reports, Ernst & Young analysis

European and US companies have taken the lead in tapping these opportunities, while Japanese companies joined in relatively late. Although most Japanese companies generate less than 5% of their revenues from emerging markets, more than 10% of the revenues of most US and European organizations emanate from emerging markets. sanofi-aventis and Abbott are the leaders in terms of their share of revenues from emerging markets, with both already generating more than 20% of their revenues from these markets. One of the exceptions is BMS, which had sold its assets in emerging markets (Indonesia, Pakistan, Egypt and Latin America) to other companies.

Figure 10: Emerging markets: aspirations



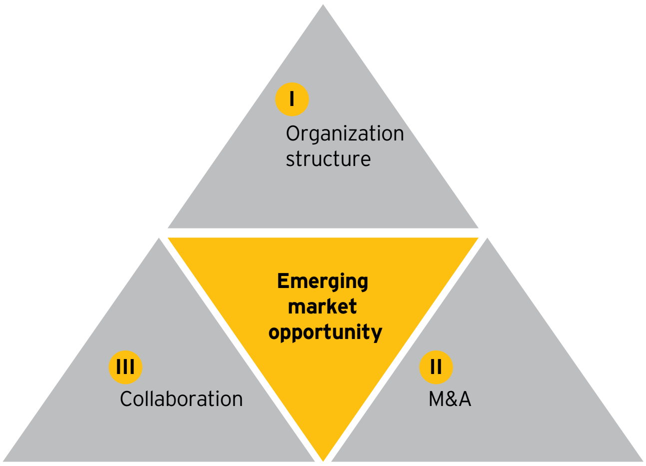
Sources: 2008 figures: IMS MIDAS MAT DEC 2008, 2010 figures and 2015 targets (if available): annual reports, company newsletters and other news reports
Note: Every company may have a different definition of the emerging market, [#] stated target for 2012, [*] stated target for 2013

While the companies generated 5.5% of their revenues from emerging markets in 2008, in a span of two years, their average share went up almost three times to ~15% in 2010. Abbott, sanofi-aventis and AstraZeneca have been among the top gainers and have seen a more than threefold increase in their revenue share from emerging markets.

They are also looking at increasing their revenue share from emerging markets in the future —companies such as Abbott aim to achieve almost one-third of their revenues from these geographies. Most other companies expect at least 20% of their future revenues to come from emerging markets (refer to graph above).

1B. In order to tap these opportunities, companies have adopted a three-pronged strategy to realign their organizational structure, increase M&As in these markets and collaborate with local companies.

Figure 11: Key strategies



I – Organizational structure

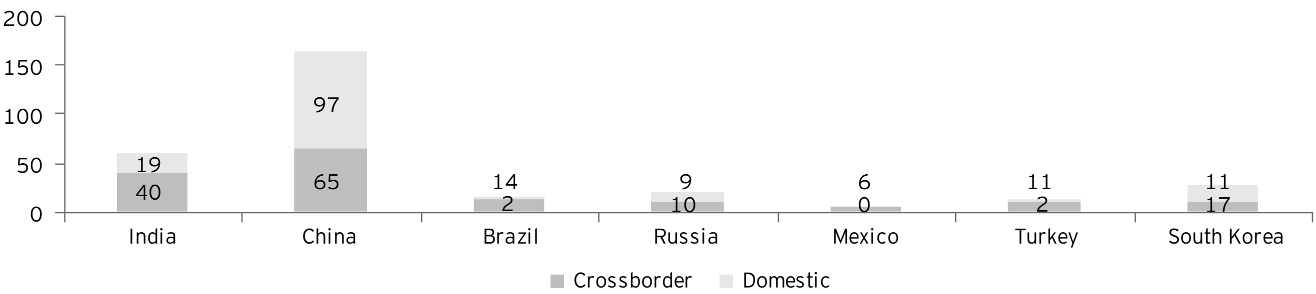
Companies have established business units that are focused on emerging markets. In addition, in the case of organizations that have not set up separate business units to focus on these geographies, a team has been identified internally, whose mandate is to evaluate opportunities in these markets and identify potential growth options in them.

An analysis of the top 10 big pharma companies indicates that half of them preferred establishing emerging market-specific business units to capture market opportunities, whereas the other half preferred a region-specific structure with an increasing focus on emerging markets.

II – M&A

Companies have been increasingly using acquisitions as a strategy to increase their presence in emerging markets.

Figure 12: Distribution of M&A deals

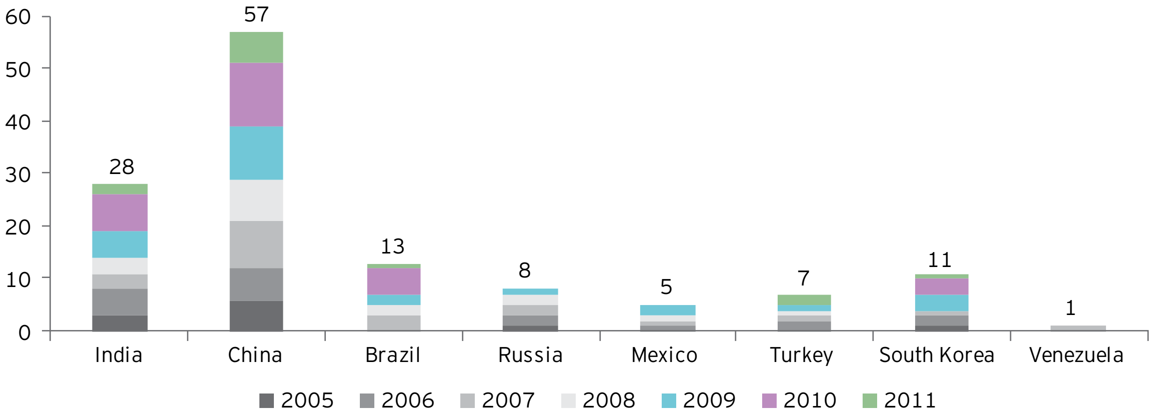


China and India have emerged as the top two destinations for acquisitions for local and multinational companies. China has seen the largest percentage (60%) of domestic acquisitions.

China has also witnessed the largest number of the cross-border deals, accounting for 67% of the total acquisitions made in major emerging markets in the last six years (refer to graph below).

Looking at year-wise trends, CY 2010 emerges as the year that saw M&A activity at its peak, with 27 deals. This is closely followed by 2009 and 2007, with 24 and 21 deals, respectively.

Figure 13: Major cross-border M&As in major emerging markets*



Source: Merger Market,*Does not include targets and acquirers residing in the same market or the acquisition of a stake by a private equity firm.

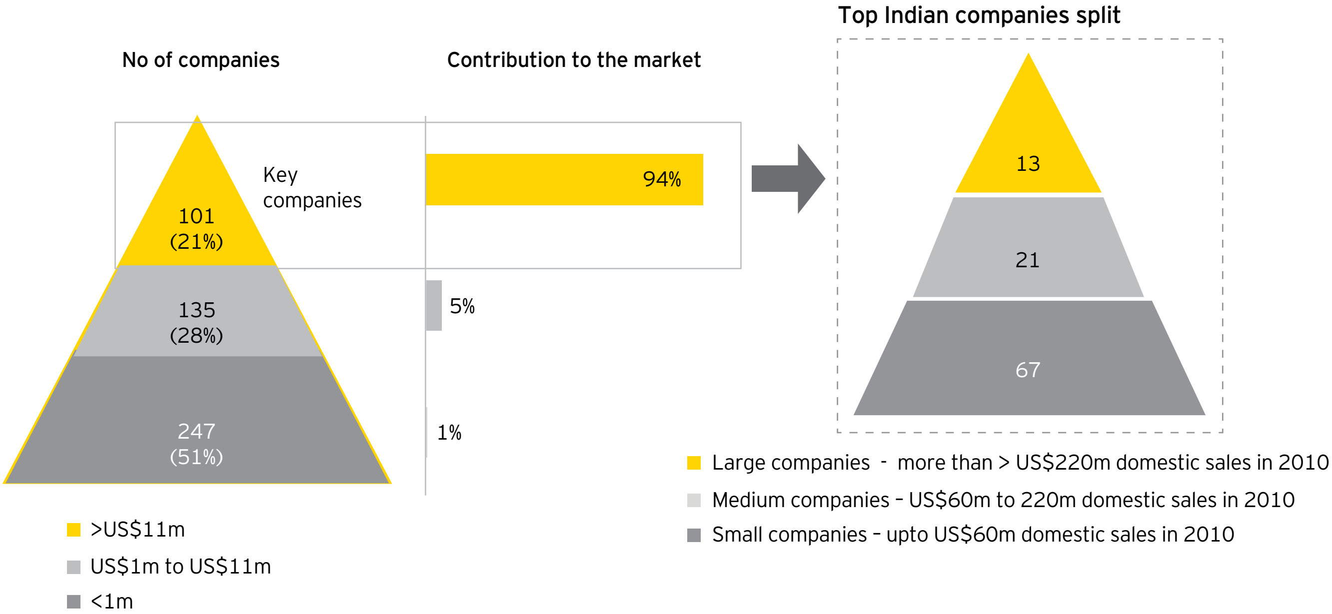
Major deals focusing on emerging markets

Year	Bidder –target	Deal value	Valuation	Rationale
2011	J&J –JB Chem	US$0.26 b	More than 5 X revenue	▸ JB Chem's business – more than 50% of its revenues coming from Russia and CIS countries ▸ Strong OTC brands in Russia
2011	Takeda–Nycomed	US$14.00 b	Not yet completed	▸ Nycomed – 39% of its revenues coming from emerging markets ▸ Nycomed's strengths in COPD
2011	Amgen –Bergamo	US$0.215 b	2.7 X revenue	▸ Bergamo's strong presence in Brazil in the areas of hospital supplies and oncology medicine
2010	Reckitt – Benckiser Paras	US$0.724 b	8.1 X revenue 30.1 X EBIDTA	▸ Firm foothold in OTC pharma market with Paras brands ▸ Material health care synergies in India
2010	sanofi-aventis – BMP Sunstone	US$0.52 b	3.0 X revenue 28.8 X EBIDTA	▸ BMP Sunstone's strong platform in the cough and cold, and women's health segment in China ▸ Enhanced presence in consumer health care market
2010	Abbott –Piramal	US$3.72 b	8.7 X revenue	▸ Expansion into Indian market by leveraging Piramal's 7000+ salesforce and 350 branded generic products
2009	Abbott –Solvay	US$6.20 b	1.7 X revenue 7.9 X EBIDTA	▸ Solvay – 75% of revenues from other than the US ▸ Around 70% of revenues from branded generics ▸ Expansion into emerging markets in Eastern Europe and Asia
2009	Novartis – Zhejiang Tianyuan	US$0.125 b	5.9 X revenue	▸ Tinayun – strengths in Chinese vaccine market expected to strengthen its product portfolio and expand its innovation capabilities
2008	sanofi-aventis –Zentiva	US$2.91b	3.7 X revenue 17.5 X EBIDTA	▸ Zentiva's generics capabilities ▸ Reach in Central and Eastern European (CEE) markets, Turkey and Russia
2008	Daiichi – Ranbaxy	US$5.48b	4.9 X revenue 37.9 X EBIDTA	▸ Access to Indian market ▸ Leveraging Ranbaxy's generic portfolio for Japanese market

Sources: Merger Market, Press releases, news reports

While China has witnessed the maximum number of acquisitions, some supernormal valuations have been for companies that were based out of India, e.g., Abbott's acquisition of Piramal at 8.7 times the latter's revenues, Reckitt's acquisition of Paras at 8.1 times the latter's revenues and Daiichi's acquisition of Ranbaxy at 4.9 times the latter's revenues. These high valuations can be attributed to the limited availability of attractive assets in these countries.

Figure 14: Market share analysis of companies



Source: Ernst & Young analysis

Out of the overall Indian market, 101 companies (with revenues of more than US$11 million) control over 94% of the market. However most of these companies are too small to provide either a product portfolio or reach out to foreign companies. Since most MNCs have shown an interest in companies that provide reach and have a large product portfolio, only the top 13 companies (with revenues of US$220 million) have emerged as likely candidates for acquisitions. This has resulted in the market becoming a seller's market and driving up valuations.

III. Collaboration

In addition, companies have tried to align their product portfolios with the requirements of emerging countries by collaborating with local companies. The following key approaches have been adopted.

In – licensing products

MNCs have typically in-licensed their products for two reasons.

1. Despite their significant interest in emerging markets, many companies had a product portfolio that was more aligned to western markets. In order to operate in emerging markets, they have in-licensed products from companies, especially in countries such as India, to augment their portfolios.
2. In addition, because of increasing genericization due to patent expiry and austerity measures adopted by governments in their own countries, they have in-licensed products, even for the US and European markets.

Licensing deals

Year	Deal partners	Therapeutic areas	Geographic focus
2011	Bausch & Lomb – Micro Laboratories	Eye care	India
2011	Nycomed –Roche	Bonviva (treatment of osteoporosis)	China, Hong Kong, Malaysia, Australia, New Zealand, the Philippines, Singapore, Taiwan and Vietnam
2011	sanofi-aventis – Glenmark	Crohn's disease, multiple sclerosis	North America, Europe, Japan, Argentina, China , Uruguay, Brazil, Russia and India
2010	Abbott – Zydus Cadila	Pain, cancer, cardiovascular, neurological and respiratory	Fifteen high-growth emerging markets
2010	AstraZeneca – Torrent Pharma	18 generic products	Nine emerging markets

Sources: Press releases, news reports

R&D and co-development

Companies have further entered into R&D and co-development deals to develop drugs targeted at the emerging markets. Such deals would drive synergies through the branded generics R&D capabilities of the local companies and the clinical, registration and geographical footprint of the Big Pharma.

R&D and co-development

Year	Deal partners	Therapeutic areas	Geographic focus
2011	Bausch & Lomb – Micro Laboratories	Eye care	Emerging markets
2010	Merck – Sun Pharma	Developing, manufacturing and commercializing branded generics	Emerging markets
2009	Eli lilly – Zydus Cadila	Cardiovascular	-
2009	GSK – DRL	Cardiovascular, diabetes, oncology, gastroenterology and pain management	Emerging markets including Africa, the Middle East, Latin America and the Asia Pacific, excluding India
2008	J&J – Advinus	Metabolic, inflammatory and neglected diseases	-

Sources: Press releases, news reports

Co-marketing

The success of a product's introduction depends on its ability to reach out to a large segment of doctors. Since several MNC pharma companies tend to have small sales teams and are focused on a few geographies, they have been forging co-marketing agreements to help them increase their product reach in the market and thereby the sale probability of these products. China has seen a relatively large number of deals in the marketing and distribution segments. Around 38% of all deals in China are co-marketing and distribution transactions.

Co-marketing deals

Year	Deal partners	Therapeutic areas	Geographic focus
2011	Bayer – Zydus Cadila	Women's health, diagnostic imaging, cardiovascular diseases, diabetic treatment and oncology	India
2010	Merck – Sinopharm	HPV and other vaccines	China
2010	MSD – Adcock –Ingram	OTC and selected prescriptions	South Africa
2010	GSK-Dong A pharma	Proprietary, generics and biologics	South Korea
2009	GSK – Amgen	Post-menopausal osteoporosis	Emerging markets including China, Brazil, India and South Korea

Sources: Press releases, news reports

1C. In addition to collaborating with local companies in emerging markets, big pharma companies have also been focusing on emerging markets, especially China and India, as destinations for outsourcing and offshoring across the pharma value chain from NCE research to late stage manufacturing.

Outsourcing and offshoring: India vs China

Company name	Drug discovery				Drug development				Manufacturing			
	India		China		India		China		India		China	
	Off	Out	Off	Out	Off	Out	Off	Out	Off	Out	Off	Out
Pfizer		√		√	√		√	√	√	√	√	√
Abbott									√	√		
Novartis			√		√		√			√		√
sanofi-aventis						√		√	√	√	√	√
Roche						√	√	√				
BMS						√						
Eli Lilly	√	√	√	√		√		√			√	√
GSK			√		√	√	√		√	√	√	√
AstraZeneca							√	√	√	√	√	√
Merck		√							√	√	√	√
Novo Nordisk		√	√					√				
J&J		√										
Amgen		√										
Bayer							√					
Takeda (Nycomed)										√		

Sources: Annual reports, press releases, news reports
Note: Off - offshoring, Out - outsourcing

Preferences differ on sourcing from India and China across the drug value chain.

- India has been the preferred choice for outsourcing in the area of late-stage drug discovery, although is only marginally better than China in terms of outsourcing development activities (including clinical trials). The country has taken the lead in providing IT-enabled R&D services in areas including clinical data management, biostatistics and medical writing to one or more Indian service providers.
- India scores in complex manufacturing (formulations), whereas China is preferred for building blocks and intermediates (APIs). However China has taken the lead in the area of biologics.
- China has seen more offshoring than India across most areas. This can be attributed to the country's better infrastructure and the incentives provided by its government.

In summary

Trend	Imperative
▸ Pressures of pricing, R&D productivity and patent cliff, among others, are driving pharma companies to a diversified product/market model — Pharma 1.0 to Pharma 2.0. ▸ Companies are also facing a changing environment of increasing health care reforms , technological advances and a customer-focused approach — Pharma 2.0 to Pharma 3.0.	▸ While the pharma industry is evolving from Pharma 1.0 to Pharma 3.0, these models continue to coexist successfully. ▸ Companies are expected to align their strategies with these models, depending on the maturity of the markets in which they operate. ▸ In addition, they will need to tap opportunities to leverage new technologies to overcome issues relating to access, affordability and awareness.

▸ Seven out of the top 15 markets are expected to be emerging ones by 2015.
▸ China has emerged as the leading emerging market, with Brazil, India and Russia featuring in the next tier of emerging markets.
▸ European and US companies have a stronger focus on emerging markets as compared to Japanese companies.
	▸ Emerging markets are not an option but a necessity.
	▸ Companies need to prioritize the markets they want to address first:
	  ▸ Short term: It is important to be in China today, given its size and growth.
	  ▸ Short to medium term: Since India and other markets are expected to reach a critical size over the next five to seven years, it is important to develop an understanding of these markets now and establish a base in them within the next two to three years.

▸ Companies are increasingly establishing business units that are focused on emerging markets. ▸ M&A has emerged as one of the key strategies in the last two to three years to gain a foothold in emerging markets with several big ticket acquisitions. ▸ However, some of the these acquisitions have been at high valuations due to the paucity of attractive targets. ▸ Companies are also collaborating to increase their penetration and augment their product portfolios.	▸ Since success in this market also depends on the speed with which companies are able to establish their presence in them, companies have been increasingly adopting acquisitions as a strategy in the last few years. ▸ However, these acquisitions have taken place at high valuations due to the few attractive candidates present in markets such as India. The success of companies depends on their ability to integrate and leverage the capabilities of the acquired companies. ▸ In addition, companies have continued to collaborate with organizations in India to augment their product portfolios and increase their reach in emerging markets. Since this is a low-risk model, it is expected to continue being a viable option for growth in these markets over the long term.

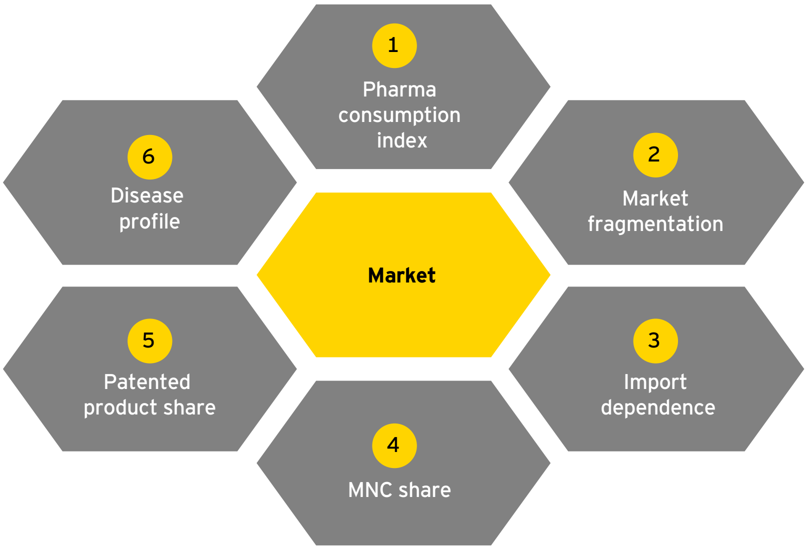
Sources: Press releases, news reports

Section 2

While each of the emerging markets provide opportunities for growth, they have diverse characteristics, and companies need to utilize the market levers of awareness, access and affordability differently to tap these opportunities

2A. Each of the markets can be characterized by the following:

Figure 15: Market characteristics

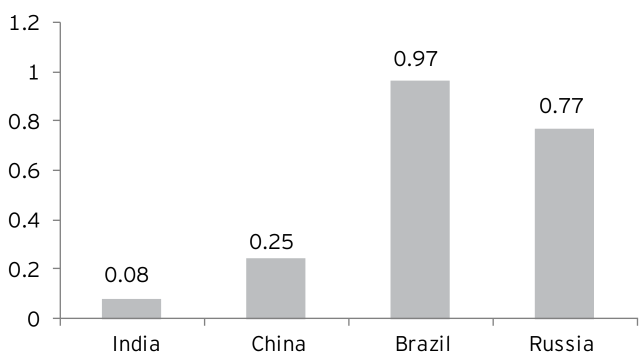


As a result of their evolution, emerging markets exhibit different characteristics.

1. Pharma consumption index of a country – ratio of contribution to world pharma market to world population

Although more than 17% of the world's population lives in India, it constitutes only 1.4% of the world pharma market. On the other hand, Brazil has one-sixth of India's population, but its contribution is almost double of India's. This demonstrates the low per capita consumption of medicines in India, which implies an attractive opportunity for the growth of the country's pharma market.

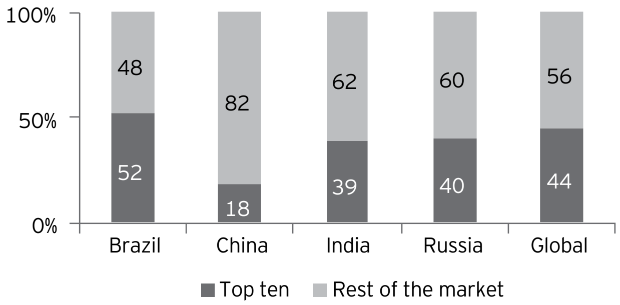
Figure 16: Pharma consumption index



Source : CIA world fact book, IMS Health prognosis, Ernst & Young analysis

2. Fragmentation of market

Figure 17: Share of top 10 companies

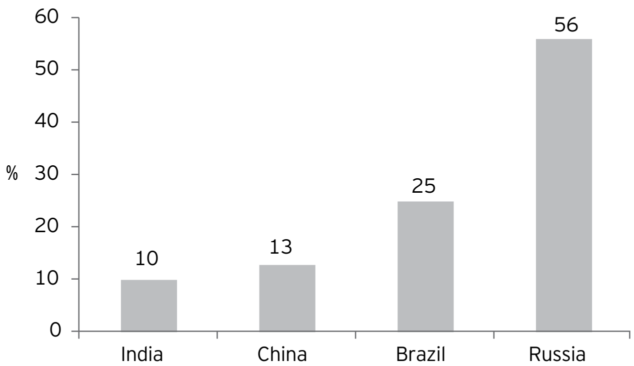


Note: Base year: 2009
Source: Ernst & Young insights

China and India have the highest level of fragmentation among the BRIC countries, and thus, see high competitive intensity. This is reflected by the comparatively low share of the top 10 companies in the countries. As a result, it is difficult to enter these markets and garner a significant market share in them. Companies have therefore been following an acquisition-led strategy to gain a foothold in these markets.

3. Dependence on imports – total imports/domestic market

Figure 18: Import dependence

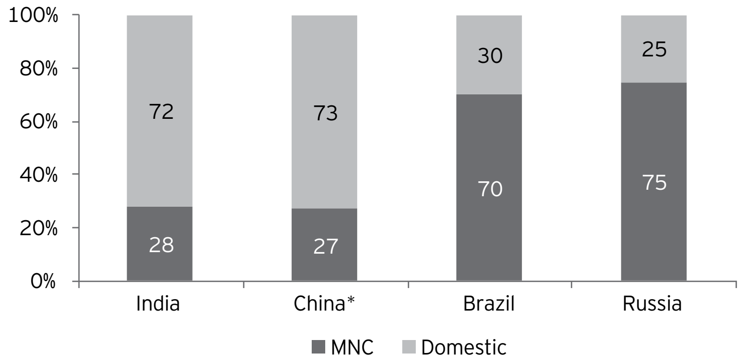


Source: United Nations Comtrade Database DESA/UNSD

India has the lowest dependence on imports to service the needs of the domestic market. This is due to the strength of Indian companies in developing and manufacturing products. This, along with high competitive intensity in the country, results in low price points of product in the Indian market. Companies that enter this market therefore primarily need to have local manufacturing facilities in order to be competitive, especially in the case of mature products.

4. MNC share

Figure 19: Share of MNCs vs domestic companies in BRIC markets

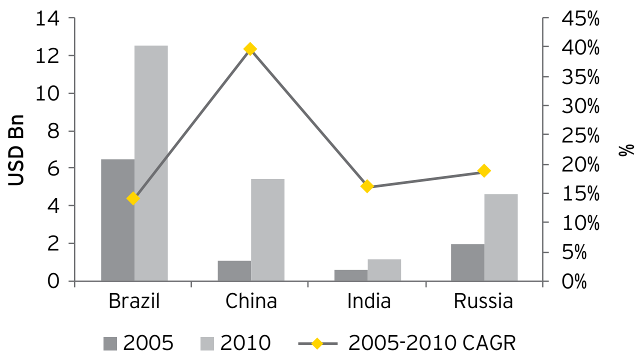


Source: BMI, Ernst & Young research, pharmaonline.com,
Note*: Indicates that sale through formal hospital channel do not include Traditional Chinese Medicine (TCM).

While Indian and Chinese markets witness less than 30% contribution from MNCs, Russia and Brazil are dominated by the latter. This indicates the strength of the countries' domestic pharma industries as well as the policies that have encouraged MNC participation in them. It also reflects that there is ample headroom for expansion in both these markets.

5. On-patent products

Figure 20: Share of patented products

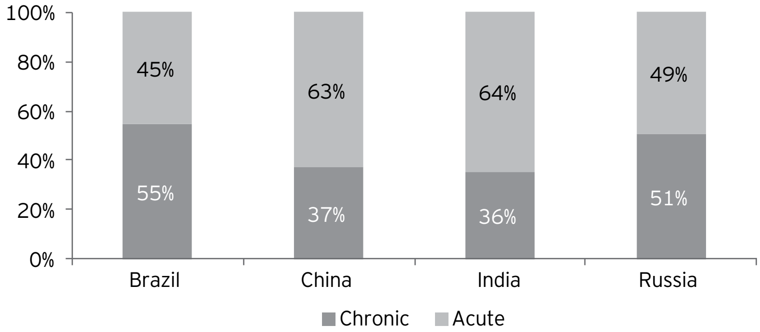


Ernst & Young Analysis

Among the four markets that have implemented the product patent regime, India is the latest entrant. This is reflected in the lower share of revenues accruing from patented products in India vis-a-vis that of any of the other markets. Brazil, on the other hand, witnesses almost 60% of its sales from patented products. Since MNCs have seen the successful launch of patented products in countries such as India in the recent past, it is expected that more patented products will be launched in India in future and their contribution will continue to grow.

6. Disease profile

Figure 21: Chronic vs acute distribution of diseases in BRIC countries



Source: Datamonitor, 2009, Ernst & Young Analysis

Rising middle class incomes and lifestyle changes have a direct bearing on the disease profile of a country. Emerging markets are therefore seeing a gradual shift from acute diseases to chronic ones. Metabolic, cardiovascular, respiratory, CNS and infectious diseases, as well as gastroenterology disorders, are expected to be the leading therapy areas in these markets. Although there is a shift toward chronic diseases, India and China still witness the prevalence of acute diseases. Consequently, companies entering these markets will need to have product portfolios that are focused on the acute disease segment as well.

In summary

Factors	India	China	Brazil	Russia	Point of view
Pharma consumption index	0.08	0.25	0.97	0.77	India offers one of the largest opportunities for growth, with its relatively lower consumption of pharmaceutical products among BRIC countries.
Market fragmentation	38%	18%	40%	48%	High competitive intensity in countries such as China are leading to increasing consolidation in their markets. These are expected to see increasing consolidation over the next few years, with companies needing to make multiple acquisitions to become significant players.
Dependence on imports	10%	13%	25%	56%	India and China have a strong local manufacturing base, which contributes to its low dependence on imports. As MNCs become more comfortable in launching niche products in these markets and the ability of local generic companies to launch products decreases, the market may see the enhanced contribution of imports.
Disease profile	36%	37%	55%	51%	While China and India are witnessing an increase in the prevalence of chronic diseases, companies that aim to secure a significant market share in these countries will need to have a strong product portfolio in this as well as the acute disease segment.
Share of MNCs	28%	27%	70%	75%	Russia and Brazil are dominated by MNCs; the Chinese and Indian markets offer ample headroom for expansion.
Patented product share	8%	10%	60%	26%	As of date, Brazil has a relatively high level of acceptance for patented products.

Russia and Brazil have evolved into markets that are more attractive for MNCs as compared to India and China, and as a result, they have seen a higher MNC presence, dependence on imports and share of patented products. On the other hand, markets such as India and China have stronger local companies that have been dominating their markets.

While India offers one of the largest opportunities for growth, it is also one of the most challenging markets to enter and grow. Since its market is expected to grow significantly over the next five to seven years, it is important for companies to be present early in the market to become familiar with its nuances and build their reach in the market, so that they can grow with it and secure a significant market share.

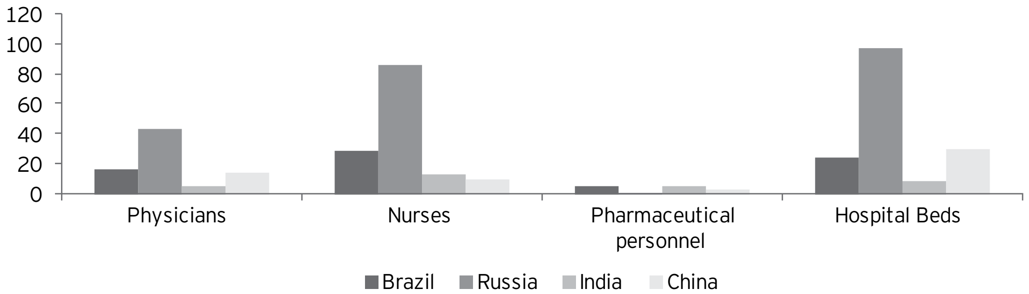
2B. Having established the role emerging markets are likely to play in the next few years, every country needs to have a different approach, which goes beyond figures and is aimed at developing a deeper understanding of the levers of awareness, access and affordability. It is important to be flexible yet cautious.

2B.1 Access

Access can be defined as the convenience with which a patient can avail of health care services. Accessibility to health care services in any country is the function of its infrastructure and its distribution across the country. This is in terms of physical infrastructure and the people to man it, e.g., physicians, nurses and pharmaceutical personnel. Russia has clearly emerged as a leader in terms of health care infrastructure, while India lags behind in terms of its number of physicians and hospital beds per patient.

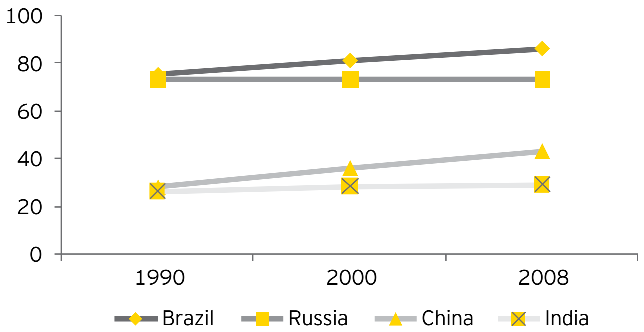
Figure 22: Levers for market growth

Figure 23: Health care infrastructure



All figures are per '0000s except hospitals, averaged between 2000 and 2009
Source: World health statistics 2011, WHO

Figure 24: Percentage of urban population



Source: WHO database

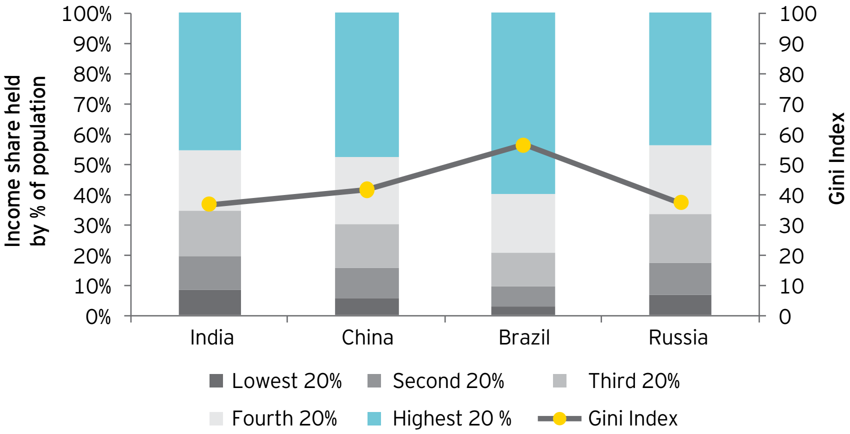
This problem becomes exacerbated when we move to semi-urban or rural areas where there are few health care facilities. Countries such as India and China, which have the bulk of their population living in non-urban areas, witness low access to health care facilities on the whole. It is estimated that almost 80% of specialist and medical facilities in these countries are located in urban areas.

2B.2 Affordability

Affordability is the ability to buy medicines and pay for health care services. According to the Gini Index*, although India has the most equal distribution of income among BRIC countries, on closer examination we find that a large part (20%) of the population command almost 45% of the total income in India. This is also the case in China and Russia. Brazil has the most inequitable distribution of income.

While there is inequality of income in BRIC countries,at the same time, private expenditure on health care is almost 71%, 53%, 35% and 56% in India, China, Russia and Brazil, respectively. In addition, insurance penetration, especially in India, is very low at only 12%. All of these factors limit the capacity of people to spend on health care, especially those in the lower income strata.

Figure 25: Income distribution in BRIC countries



Source: World Bank , Note [*] Gini Index reflects inequality in income distribution.
An index value of 0 reflects absolute equality, while an index value of 100 implies total inequality

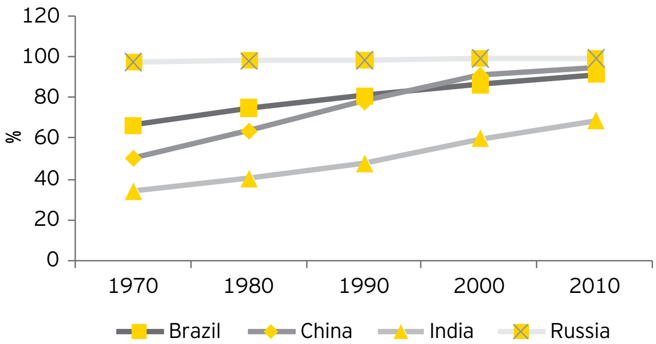
2B.3 Awareness

It is important that diseases are reported and patients receive proper treatment. This problem is more acute in Asia and Africa, where disease is unreported and unattended. The low level of awareness is reflected by something as basic as levels of immunization in these regions. Among BRIC countries, India has the lowest levels of immunization, revealing a lack of understanding of the importance of health care. Traditionally, India has been a sick-care market, although there is a gradual transition toward a health care mindset.

All data relates to percentage of vaccination coverage amongst one year olds.

Country	BCG(typhoid)	DTP-3	HepB3	Measles
Brazil	99	99	98	99
Russia	96	98	97	98
India	87	66	21	71
China	97	97	95	94

Figure 26: Literacy rate in BRIC countries



Source: UNESCO report, 2010

One of the main reasons for a low level of awareness is inadequate literacy levels in these countries. Among BRIC countries, Russia has the highest literacy rate and India the lowest. However, the literacy rate in India has grown the fastest in the last decade (+14% absolute growth) and the country is catching up with other BRIC countries. As literacy levels in India improve, there is expected to be higher levels of awareness. Technology can also act as an enabler to improve access and awareness. Initiatives that such as mobile health care, along with the increasing spread of mobile phones in the country will help to improve awareness of healthcare. (India has seen a CAGR of 44% in mobile subscription between 2006-2010.)

In summary

Factors	India	China	Brazil	Russia	Implication for pharma companies	Implication for the Government
Awareness	L-M	M	H	H	▸ India and China are still largely sick-care countries with a large part of ailments still going unreported.	▸ Investment in primary and preventive health care ▸ Effective use of technology and novel partnership models
Access	L-M	M	M	H	▸ Large part of population in BRIC countries, barring Russia, still do not have access to health care, and therefore, it will be critical to focus on strengthening the health care supply and distribution network to achieve growth.	▸ Evaluation of PPP models to create required infrastructure
Affordability	L-M	M	H	H	▸ There is a need to move pricing closer to target markets and achieve greater control of the cost base.	▸ Creation of a win-win situation for industry and customers by providing platform for income-based differential pricing

Note: L - Low, M - Medium, H - High

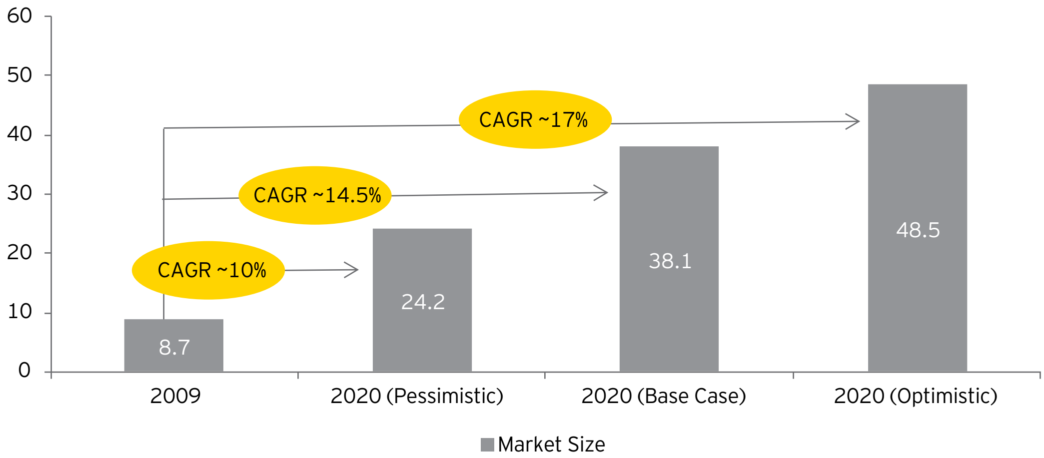
Section 3

High-performing companies that have approached India have a deep understanding of their target customers. They have broadened the range of their products, adopted unconventional partnership models to increase access and tested new pricing and marketing approaches.

3. Despite the challenges, the sheer size of the Indian market and potential growth opportunities create a compelling proposition for investment in the country.

The Indian market is expected to reach US$24 billion (pessimistic estimate) to US$49 billion (optimistic estimate) by 2020. Even if we assume the base case, the market presents an opportunity of almost US$ 25-US$30 billion over the next eight to nine years.

Figure 27: Indian pharmaceuticals market by 2020



Source: Sanofi and Kantar health presentation at EphMrA

In light of the opportunity mentioned above, companies have evolved strategies to overcome key challenges they have faced in the Indian market. These have been largely in the following areas:

- Pricing
- Access to new products
- Access to new markets

Companies have adopted a combination of strategies to deal with the above.

3A. Pricing

Pricing continues to be one of the most complex decisions pharma companies have to take to gain a market share and grow. Differential pricing, moving production closer to the target, achieving greater control of supply chain, etc., have been some of their considerations.

3A.1 India has among the lowest priced formulation products worldwide.

Not only does India have lower price points than western markets such as the US and Europe, but it also has lower price points in comparison with other emerging markets. This also holds true for comparisons across innovator and generic products. Intense competition and a price regulator have played a key role in this, and therefore, average revenue per brand is relatively low in the country. For example, while the price of ciprofloxacin in India is almost three to four times lower than in Russia (figures 1 and 2), the differential is much higher if we compare it with European and US markets.

Figure 28.1: Retail prices of generic ciprofloxacin 500mg

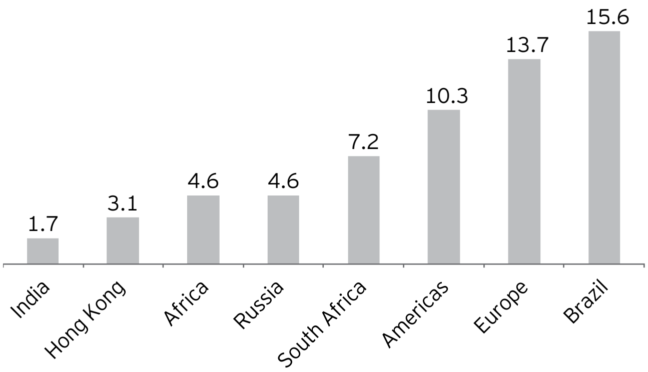
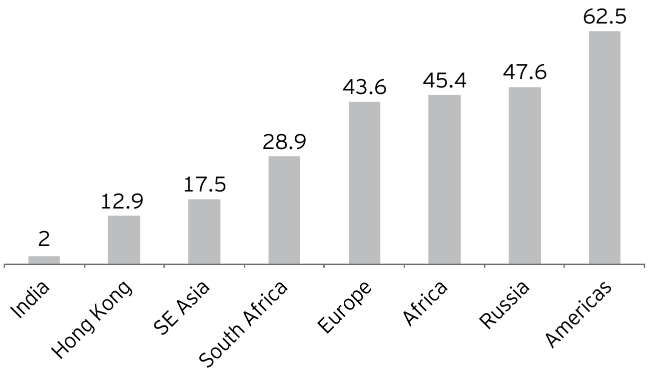


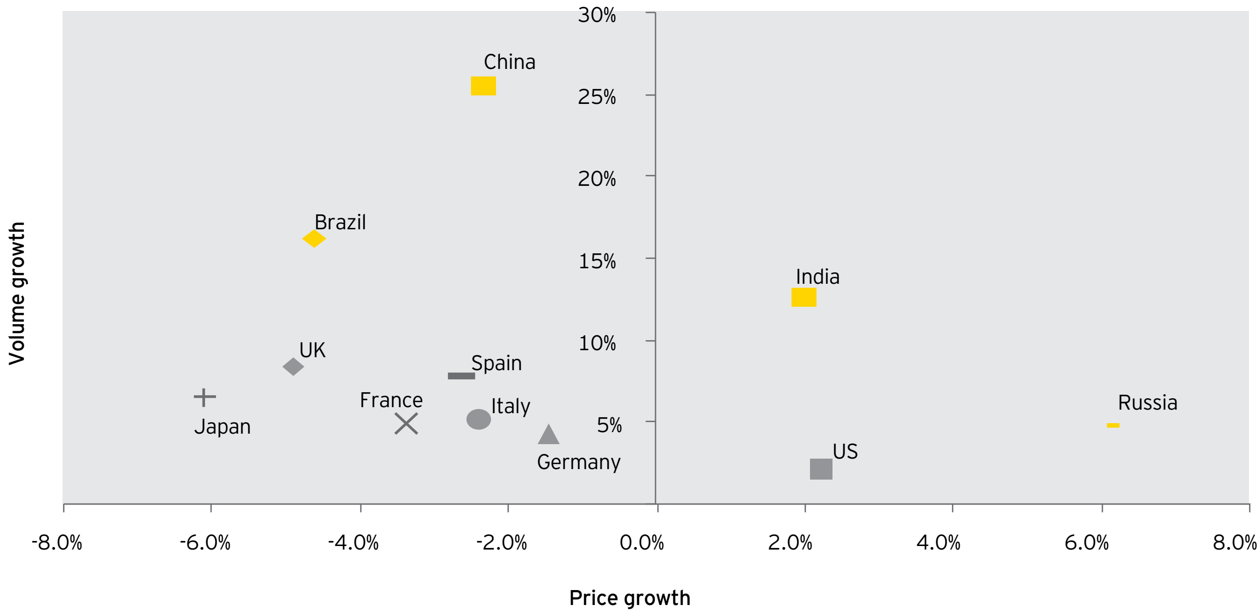
Figure 28.2: Retail price of innovator ciprofloxacin 500mg



Source: Health Action International, as of 30 November 2009, 14 doses

It is equally important to consider that India is one of the few markets where drug prices are expected to increase over the next few years, unlike in several other developed markets.

Figure 29: Value-volume growth (CAGR 2010-14)



Source: Ernst & Young Analysis

3A. 2 Multinational companies have been successful in launching products at premium prices and yet garner a larger market share.

The introduction of new products, both patented and generic, is outside price control at this point, and therefore, individual companies are free to price their products, depending on market dynamics. Although there is intense pricing pressure in India, there is also scope for brand differentiation and premium pricing. Accordingly, having launched products at higher price points, MNCs have been successful in garnering an enhanced market share.

Selected examples of premium-priced products

Molecule name	Pricing strategy	Market share (by value)
Glimepiride	High-priced brand with 3% premium as compared to the next high-priced brand	~33%
Amlodipine	High-priced brand with 38% premium to the next high-priced brand	~18%
Phenytoin	High-priced brand with 55% premium as compared to the next high-priced brand	~90% market share

Source: Ernst & Young analysis, price points and market share as of September 2010

3A. 3 While these products are priced at a premium in India, they have been launched at differential prices in comparison with developed and emerging markets.

Price differential – India vs the US

Product name	Therapy	Price in India in INR	Price in US in INR	Discount
Januvia	Anti-diabetic	43	219	80%
Lyrica	Neuro/CNS	55	121.5	54%
Nexium	Gastro-intestinal	7	29	76%
Levemir Flexpen	Anti-diabetic	953	1480.5	34%
Travatan	Ophthalmology	652	1100	41%

Source: Ernst & Young analysis, price points and market share as of September 2010

Companies have adopted a differential pricing strategy to make their products more affordable to the Indian population. They have launched their products at significantly lower price points as compared to the price of the product in the US market. The products are priced lower as compared not only to the US markets, but also to emerging markets as well. Although they have been launched at lower price points, they may not still be affordable for a large segment of the Indian population.

Price comparison among emerging markets

Drug	Generic/Branded	Dosage form	Price in Brazil (INR)	Price in India (INR)	% discount
Alprazolam	Generic	1 mg, 20 capsules	556	65	88%
		0.5 mg, 20 capsules	313	33	89%
Amaryl	Brand	1mg, 30 capsules	661	54	92%
		2 mg, 30 capsules	1236	112	91%
Clexane	Brand	20 mg, 2 pre-filled syringes	1227	551	55%
		40 mg, 2 pre-filled syringes	2382	879	63%
Lansoprazole	Generic	30mg, 7 enteric coated caps	780	29	96%
Lantus	Brand	100 IU cartridge 3ml x 1	2593	460	82%
Galvus	Patented	50mg, 28 tabs	2290	491	79%

Source: Brazilian Pharmacy Guide, Ernst & Young analysis
Exchange rate: 1 BRL = INR26.97
Retailer margins in India assumed to be 18% on an average

Case study: BMS

Bristol Myers Squibb(BMS) is one of the largest pharmaceutical companies in the world and witnessed sales of US$19.5b in 2010. The company is focused on and has more than 18% of its turnover invested in R&D. It has adopted collaboration as a strategy for innovation and has global strategic partnerships with companies such as Pfizer and AstraZeneca. Its considers India a market and an offshoring destination.

Offshoring through collaboration across the R&D value chain

BMS is active in the R&D space in India through its research partnership with Biocon via its subsidiary Syngene since 1998, to develop integrated drug discovery and development capabilities. BMS has one of the largest research centers (BMS- Biocon Research Centre (BBRC) outside the US in Bengaluru in India. The center is spread over 200000 sq ft and can accommodate upto 450 scientists in it. R&D work at the facility spans initial hit to lead optimization, early pharmaceutical development and clinical phase studies.

In addition, the company has a dedicated global pharmacovigilance center operated by Accenture in Chennai, with more than 600 employees. Realizing India's competence in IT-enabled services, BMS has outsourced its IT, financial services and global biostatics work to Accenture in Chennai.

Launch of patented products to tap market opportunity...

India has emerged as one of the first markets, sometimes only second to the US, in which BMS launches new products. After the introduction of the patent product regime in 2005, the company has introduced 10 products from its global pipeline in India with half of them are under patent protection.

Today, BMS' brands rank among the top three in therapies in areas such as oncology, Hepatitis B, rheumatoid arthritis, anti-infective and pain. In addition, it has entered a partnership with AstraZeneca, considering the market potential for diabetes in countries such as India. This alliance will develop and commercialize two compounds (discovered by Bristol-Myers Squibb) for the treatment of type 2 diabetes. The company has also increased its market presence by ramping up its sales force from 20 to 300 between 2005 and 2010.

.. in addition to differential pricing

Understanding the price-sensitive nature of the Indian market, BMS has introduced products at India- specific pricing. It has launched its diabetes product, Onglyza (saxagliptin), at one-fifth its price in the US. To address the issue of issue of affordability in economically backward sections, it has adopted an innovative model through which it provides Baraclude, its chronic leukemia (cancer) medicine, free of cost for every two purchases if a patient is poor, thereby ensuring one-third price reduction.

Source: Taking Wings- Coming of age of the Indian pharmaceutical outsourcing industry, BMS website, Biocon website, Financial Express, March 23, 2009

Despite the great disparity between India and the US' per capita incomes (India — US$3500 and US —US$ 47,200), there is a sizeable part of India's population that has achieved high income levels. Considering the magnitude of the Indian population, this high-income segment can be compared in size to that of several European countries put together.

Income distribution in India

Households	<US$1000 per month	US$1000 - US$2000	> US$2000
%	66%	22%	12%
Number	108m	36m	20m

Source: Credit Suisse Emerging Consumer Survey, 2011

Therefore, an intra-country differential pricing may create a win-win situation in which the lower income group population in India has access to new medicines, and pharma companies may be able to launch products at higher price points for population segments that can afford these.

Novartis has adopted differential pricing for Coartem for the public and the private sector, whereby the public and the NGO sector receives the medicine at a price that is much lower than at which it is provided to the private sector

Differential pricing: Coartem

Segment	Price point
Public sector	US$0.3 -1.30
Non-premium private sector	US$8-12
Private sector	US$8-12
Developed world	US$50

Source: Novartis, 2009

The same medicine is also made available as Riamet (Europe) at a price of around US$50 for a smaller population that travels to countries where malaria is endemic. While there are challenges in terms of leakages between segments, different packaging has allowed better tracking and monitoring of such leakages.

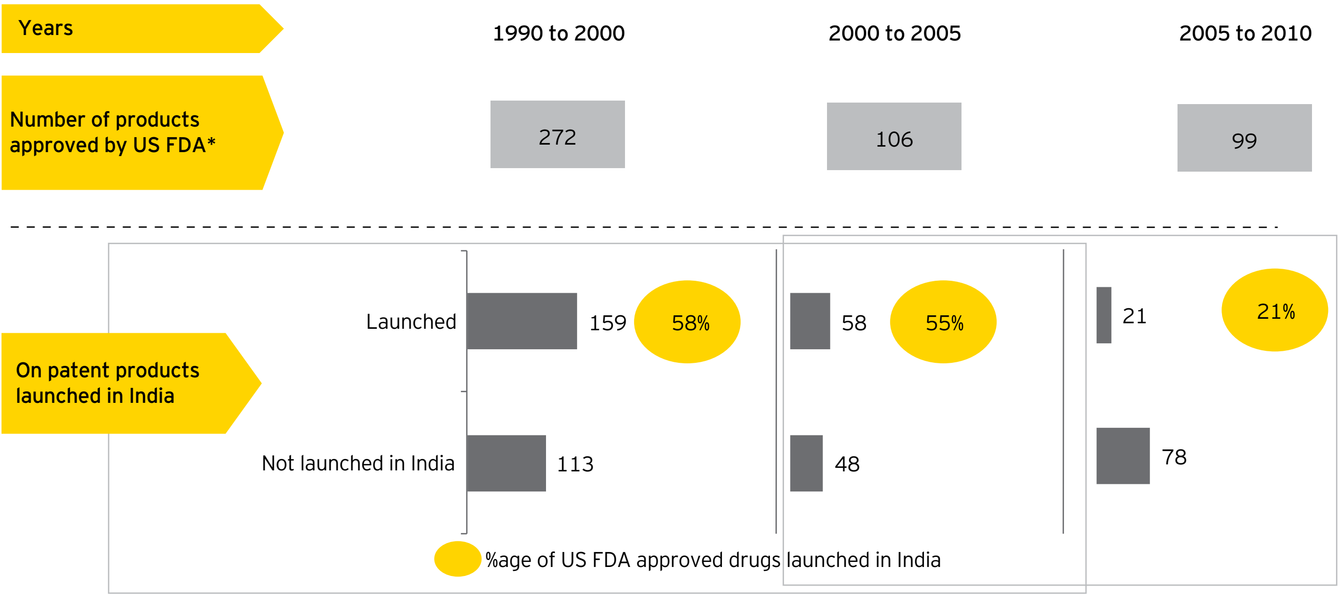
3B. Access to new products

3B.1 Companies have launched patented products to enable access to advanced and new drugs, and have adopted various models to increase their market penetration.

While a few MNCs have expressed their apprehension regarding patent regime enforcement in India, others have successfully launched patented products in the Indian market.

Although Indian companies were able to launch most patented products in the pre-2005 era, enforcement of the product patent regime has led to the decline of on-patent drug launches.

Figure 30: On patent products launched in India



Source: Drug@FDA (CDER U.S.FDA), Ernst & Young analysis
Note : Includes NMEs, new ester from new salt or other non-covalent derivatives; products approved but subsequently discontinued excluded from the analysis

India has seen a fall in the number of on-patent products launched in the country due to the implementation of the patent regime. While during the 1990 to 2005 period, almost 55%-58% of the products approved in the US were launched in India, this number fell sharply to only 21% from 2005 to 2010.

3B.2 MNCs have been able to successfully launch products in India, indicating a waning of the IP risk.

Despite concerns relating to data protection and exclusivity, companies have continued to launch on- patent products in the Indian market over the last five years.

List of on-patent product launches

Company name	Brands
Pfizer	Vfend, Viagra, Lyrica, Caduet, Genotropin, Champix
GSK	Windia, Coreg, Arixtra, Flutivate - E , Boostrix, Infranix, Tykerb
Roche	Tamiflu, Avastin, Tarceva, Pegasys
sanofi-aventis	Aprovel, Stilnox
MSD	Lucentis, Januvia
Novartis	Lescol XL

Note: Indicative list of brands

3C. Access to new markets

3C.1 Companies are developing non-traditional models to tap tier 2 and rural markets.

Large companies in India typically follow the model of focusing on the top 20–25%[1] of the doctors that generate the maximum number of prescriptions. This is due to the fact that detailing to doctors becomes unprofitable for a company below a minimum prescription volume. Given that most Indian companies are present in metro and the tier 1 markets and have reached out to this set of doctors, the next opportunity for growth may arise in tier 2 and rural markets.

On analyzing tier 2 and rural markets, it is clear that a large opportunity exists in these, with the majority of high to medium purchasing power households (67%) residing in such areas.

At the same time, these markets contribute only 39% of the current market. This indicates that there is significant potential for expansion in these markets (Figure 6).

Rural markets: alliances with FMCGs

FMCGs were the first to harness the potential of rural markets in India and are looking to reach the next strata. They have launched differentiated products and smaller pack sizes in rural areas.

Pharma companies such as Ranbaxy and Pfizer have tied up with FMCG major ITC in India for their OTC business to replicate the success of FMCGs in these areas.

Deals such as these will enable enhanced reach through the robust supply chains of FMCGs and provide access to profitable opportunities.

Source: MoneyControl, 11 July 2011, via Dow Jones Factiva

Figure 31: Tier-wise market split

		No. of towns/villages	Population (mn)	Households with high-medium purchasing power	Current market split
Tier 1	Metro	35	108 (11%)	39	27%
	Class I/IA	359	88 (9%)		34%
Tier 2	Class II-IV	3792	89 (9%)	11	20%
Rural	Rural	593,807	743 (72%)	56	19%

Metro: >1 mn population, Class I towns: 0.1-1 mn, Class II-IV: 5000 – 0.1 mn, Rural: less than 5000 ; Tier 1 markets: Metros and Class I towns, Tier 2 markets: Class II-VI towns and Rural areas *High – medium purchasing power – Annual income is Rs. 1 lakh and above

This is reflected by the high growth exhibited by the rural market, which grew at ~19% for the one-year period ended April 2011.[2] This was even higher for the month of April 2011, when it grew at 29% as compared to 12.4% in April 2010.[2]

However, there are still challenges in tapping these markets due to the scarcity of doctors and inadequate infrastructure in rural India

Examples of companies that have adopted different measures to tap into these markets:

1. Novartis

Novartis launched its Arogya Parivar program, which focused on rural markets, in 2006. The company's focus is on gastro-intestinal disorders, respiratory infections, TB, diabetes and gynaecology. It undertook initiatives to increase awareness, availability, affordability and acceptability to tap the rural market. It is now present in 300,000 villages across 202 districts and 11 states in the country. Novartis provides access to health care to around 42 million customers. It has also been exploring options to increase access by making drugs available through local post offices.[3]

Source: [1] Credit Suisse, India Pharmaceutical Sector 5 March 2010,
[2] Economic Times June 18, 2011
[3] Novartis company website, annual reports

2. sanofi-aventis

sanofi-aventis established a separate 200-250 strong division, focused on tier 2 markets, to target these markets. This division focuses on gastrointestinal diseases, infection and general antibiotics. Furthermore, the company established super-stockists in selected states to increase its level of reach and penetration.[1]

Use of non-traditional platforms

In addition to the initiatives undertaken by pharma companies, various non-pharma companies have developed applications and systems to capture information from patients due to the rapid development of digital and communication channels in the country. This will enable enhanced access to health care.

1. eUNO R10: Maestros Mediline Systems Limited's mobile ECG application allows doctors to receive real-time heart data of patients from their Blackberries. This service has been launched in one hospital (Mumbai's Nanavati Hospital) — a patient calls paramedic who visits with the eUNO, and records and sends ECG data to a server. This is sent to a cardiologist. Cardiologists access it on Blackberry applications, diagnose ECGs and convey to the paramedic the action to be taken.[2]

2. Screening for oral cancer[3] (Narayana Hrudayalaya, Mazumdar Shaw Cancer Centre and SANA — a research group at Harvard/MIT): Trained general physicians and nurses screen individuals using automated questionnaires encoded on phone and high-quality lesion pictures using phone cameras. Their condition is diagnosed either by using the in-built decision support algorithms on phones or by uploading data on Narayana Hrudayalaya's electronic medical record system for specialists, to enable them to provide feedback. Treatment or counselling is recommended for patients through interactive videos on phone, or if required, they are referred to specialist.

3. Health Management and Information System (HMIS)[2] (Media Lab Asia): Mobile or handheld devices are used for data collection, ensuring relevant and up-to-date data flow to authorities for decision-making. A centralized server is used to store collected data in a central database and analyze it, using statistical methods. This serves as an input to health planning and decision-making at the higher levels of the Directorate of Health Services (DHS). Digitized name- based data is maintained at the PHCs or CHCs level. The data at PHCs or CHCs is digitally updated from that on handheld devices. This system is deployed at 20 locations (15 PHCs, 3 BPHCs and 2 CHCs) of Tirur Taluk, Mallapuram, Kerala. The total number of beneficiaries under this deployment include 780,000 people.

Case in focus: Government's impetus to e-health and m-health

Going forward, the use of technology to solve access and awareness- related problems is critical for a country such as India. In a bid to bridge the gap between the quality of health care available for city dwellers and for the country's rural population, several hospitals have been planning to introduce electronic health records (EHRs). These are digital records and facilitate information exchange between geographical locations, and support medical professionals in rural areas. Doctors are provided with patient data, including past history, provided by Electronic Medical Records (EMRs) and up-to-date medical knowledge and literature, which helps doctors make an accurate diagnosis.

These initiatives have been further bolstered through the Government's e-health and mobile health initiatives in the recent past. The Technology Development Board, Department of Science & Technology, Ministry of Science & Technology has sanctioned US$6 billion (INR2,69 billion) for e-health and mobile initiatives.[4]

Source: [1] sanofi-aventis company website, annual reports
[2] company website
[3] thehindu.com, 29 August 2010
[4] PR Newswire Europe, 4 August 2011, via Dow Jones Factiva

In summary

Trend	Imperative
‣ Delay in generic product launch due to onset of product patent regime in the country ‣ New product (generic and patented) launch still outside price control in India ‣ Economic prosperity and growing middle class providing sizeable target market	‣ Potential to launch patented products to address medical needs, which were in the past serviced by generics ‣ Ability to differentiate brand and align product pricing with market dynamics critical for garnering market share
‣ Around 65% of Indian population still unable to access modern medicine ‣ Reach in tier 2 and tier 3 markets limited, even for domestic pharmaceutical companies	‣ Huge growth potential in semi-urban and rural markets ‣ Exploring partnerships with non-traditional partners to be the key determinant of success — mode of structuring deals and valuation of each partner's contribution to be important ‣ Competitive success more likely in the case of companies that achieve the optimal balance between their customer reach, operational agility, cost competitiveness and stakeholder confidence

Notes

Notes

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