

**INNOVATIVE PRICING AND MARKET ACCESS
STRATEGIES IN PHARMA EMERGING MARKETS**

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1 Introduction

Global Pharmaceutical Companies are increasing their presence in the lives of more and more consumers as companies seek to expand and promote their products to a still wider range of markets globally. As markets change and develop, so does the strategy used to enter them, and companies must be able to choose the correct way to enter markets in order to remain competitive. As most of the developed or so called “mature markets” are getting saturated due to increasing pricing pressure and impact of healthcare reforms, Pharmaceutical companies are shifting their focus on the Emerging markets to get their revenues due to its huge population, technological advancement, increasing insurance coverage and high growth rate.

This study takes a look at What Strategies Global Pharmaceutical companies adopt to make their drugs successful, specifically in emerging markets. In order to gain an understanding of this, the study looked at four specific markets, namely Brazil, Russia, India, and China (BRIC). Also, Africa was included in the study as many companies believe that in long term plans Africa needs to be targeted. The study attempted to answer if the way companies approached emerging markets is in keeping with what would be expected. Additionally it tried to comprehend the disparity that exists between these emerging markets among themselves and also in comparison with mature markets. Analysis of these five markets was also carried out to get deeper insights.

An ability to adapt and tailor specific strategies to individual markets gains more importance, especially with regard to emerging markets, as the difficulties and obstacles presented when entering these markets often proves both new and unique. In many cases there are difficulties in underdeveloped markets, specifically concerning consumer spending power, brand awareness, logistics & infrastructural inadequacies, diverse Regulatory Environment, uncertainty in pricing and reimbursement system and taxation structure compared to western markets which serves to make the correct approach to entering emerging markets of high importance. The methods first employed when entering emerging markets

were often unsuccessful and needs to be modified as market knowledge is gathered and opportunities present themselves.

In the five markets analyzed in the study to illustrate emerging markets- Augmentin, Mabthera, Januvia, and Galvus were used as an example drugs present in all five markets. Pricing and Markets access strategies used by companies for these 4 drugs in 5 markets (BRIC and Africa) were analyzed and the reasons for their success or failure as well as the lessons learned are discussed. In importance, this study contributes to the understanding of what pricing and market access strategies pharmaceutical companies made in past along with the challenges they faced. Also, the study tries to answer very critical question that what needs to be done in future in order to explore the potential of the emerging markets.

At last, our concluding research suggests 3A's strategy- Affordability, Availability and Awareness that needs to be implemented together, not in parts (mistake done by many big companies) to achieve success in Emerging markets. The study also includes the innovative access and pricing models under each Affordability (Tiered Pricing, Micro Insurance, Micro finance, Dual Brand, Patient assistance program, Loyalty card), Availability (Local Players, Capital Investment, Govt. Partnership, Voluntary Licensing, Joint Venture) and Awareness (Education, Information) section that can be used to execute the suggested strategy in an efficient way.

2 Review of Literature

Pharmaceutical companies are changing priorities as growth patterns in developed market continue to flatten. The companies have started shifting their focus on emerging markets as new sources of revenues and profit. Emerging markets have long been regarded as the “promised land” of the pharmaceutical industry. They are expected to amount to nearly a third of the global pharmaceutical market by 2017, and it is anticipated that they will play a vital role in sustainable growth in the industry. With huge populations, increasing prosperity, and improving longevity (albeit at differing rates), these markets are very attractive to those companies suffering from the stagnation of mature markets, patent expirations, and increased regulatory hurdles. As a consequence of growing prosperity and better nutrition, disease patterns in emerging markets are rapidly changing and shifting toward “lifestyle” diseases that are more common in mature markets.

However, although these regions offer huge untapped potential, they display a wide diversity in their stages of development, particularly with regard to their healthcare infrastructure. For this reason, there can be no “one-size-fits-all” approach to emerging markets. Even among the three main clusters of markets — the BRICMT economies (those of Brazil, Russia, India, China, Mexico, and Turkey); second-tier countries such as those of Southeast Asia; and finally Africa — there are local idiosyncrasies that make bespoke approaches to these markets essential.

The emerging markets can be divided into three clusters: ^[4]

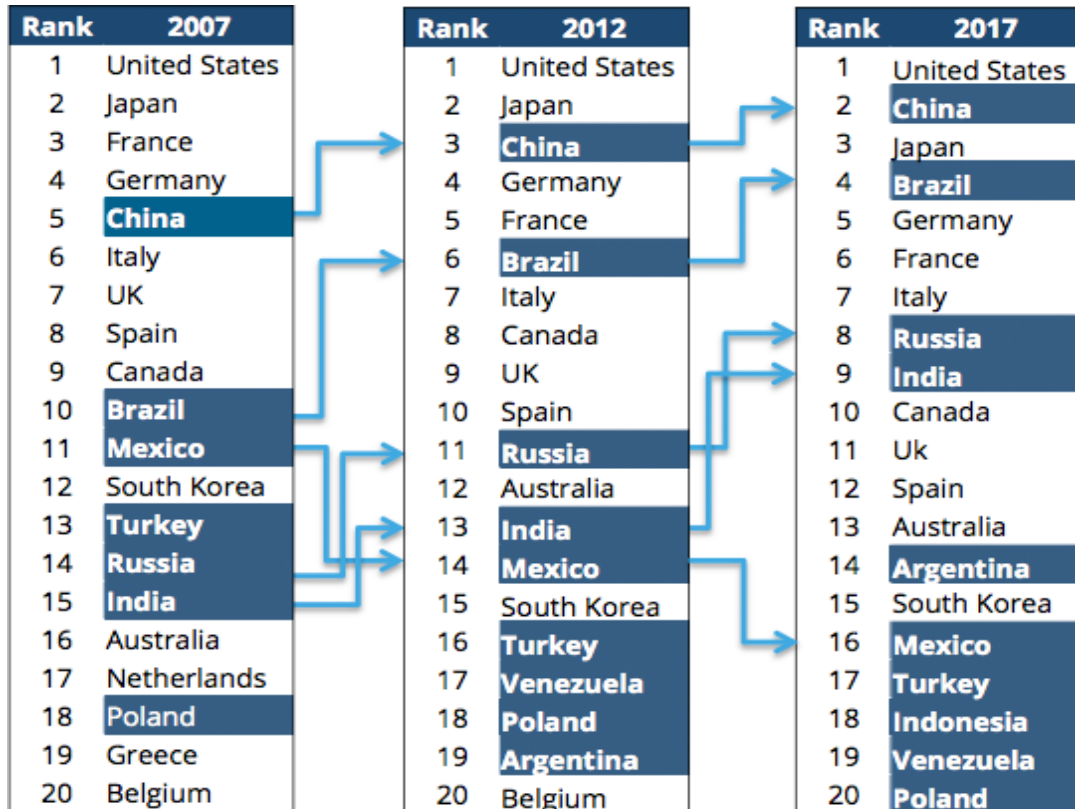
The **BRICMT group**, which comprises Brazil, Russia, India, China, Mexico, and Turkey, has demonstrated strong growth in the past. These countries are developing into markets that are comparable in size and nature to their mature western counterparts. At the same time, these economies are becoming increasingly more stable, making them even more attractive. As a result, the BRICMT countries are occasionally referred to as “growth” markets, rather than “emerging” markets.

The “**second-tier**” emerging markets are a diverse group of more mature economies in Eastern Europe and the CIS (Commonwealth of Independent States, formed from the former Soviet bloc), as well as in more dynamic “threshold”

countries such as those in Southeast Asia. Based on the size of their populations and growth forecasts, their future potential is attractive.

The **third group** is made up of African markets, which are highly populous but have relatively smaller market sizes at the moment. They possess significant future potential. Africa does not yet play a significant role in pharmaceutical sales, since South Africa, Egypt, Algeria, and Nigeria are the only markets in the region where the volume of the pharma market exceeds \$1 billion. However, in the coming years, as sub-Saharan Africa develops economically, the long-term potential offered by this vast continent will be huge. For this reason, we have included Africa in study.

These markets, particularly the BRIC nations (Brazil, Russia, India and China), have experienced significant and rapid change. In 2005, China and Brazil constituted just 5 percent of the total pharmaceutical market of the top 10 nations; by 2017, however, at least one projection is that the four BRIC nations will all be in the top 10 of global pharmaceutical markets and will constitute 30 percent of the top-10 market.



*Source: IMS Health Report

Fig. 1: Forecasted rankings of EM by 2017 ^[7]

Total global spending on medicines will exceed one trillion U.S. dollars for the first time in 2014 and reach almost \$1.2 trillion in 2017.^[8] The next five years, however, also sees a continuing growth split between developed markets and pharmerging markets. The developed markets of North America, Europe, and Japan will see very modest single-digit spending growth, due to a combination of economic and healthcare austerity measures and the savings realized from the growing availability of lower cost generic versions of brands following their patent expiry. Many (but not all) leading pharmerging markets, in contrast, show much higher double-digit growth rates due to a combination of economic growth, demographic and epidemiologic changes, and improved state and private insurance funding for healthcare and medicines. Across the major developed markets, uncertainty exists to an unusual extent. The last five years in Europe have seen greater adoption of generics and more restrictive policies that have made patients in almost all European countries less likely to gain access to innovative medicines. In the next five years, whether Europe sees a widespread, patchy or severely limited economic recovery will have a profound impact on the overall contribution this important group of developed markets makes to overall innovative medicines spending.^[5]

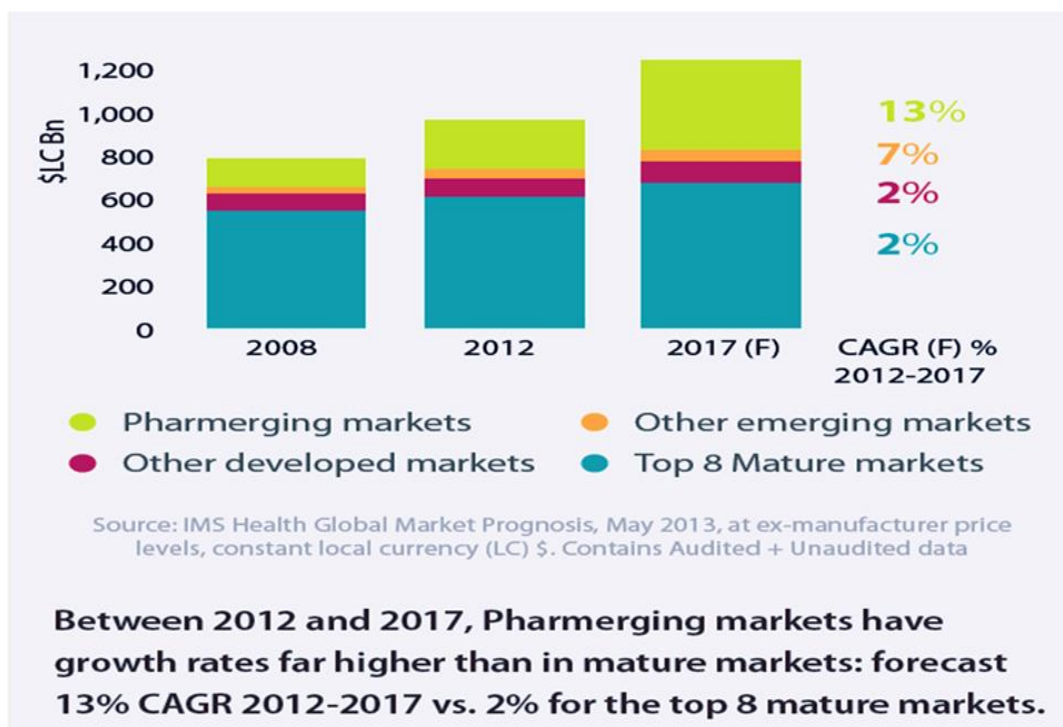


Fig. 2: Global Pharma Sales^[4]

Meanwhile, in the U.S. the next five years will see the greatest impact of the implementation of the Affordable Care Act. With it, this brings uncertainty ranging from the level of enrollment of the currently uninsured to the speed with which the payment system changes from one based on fee-for-service, to one based on performance and patient outcomes. The rapid shifts in service delivery including the corporatization of medical care has yet to fully play out, including the relative negotiating power between payers and providers. Such structural changes will impact medicine spending, though the direction and magnitude of the impact is difficult to predict with certainty. In Japan, the key variable driving different scenarios is the successful establishment of an effective generic market, driven by the Japanese Ministry of Health, Labour and Wealth's goal of increasing generic volume as a percentage of generic and listed drugs to 60% in 2018. By taking on this challenge, Japan aims to achieve a more rapid increase in generic utilization levels than has previously been achieved in any country.

Medicines spending growth in the IMS Health-defined pharmerging markets is very heavily influenced by the prognosis for the Chinese market, as the largest and one of the fastest growing emerging markets for prescription medicines. Chinese healthcare provision is in the process of massive expansion, with the goal being universal healthcare coverage by 2020. During this huge transformation, it is inevitable that segments of the medicines market will also transform. The most positive outcome of current change would be the development of a much larger high quality, low unit price locally-sourced medicines market, with a compensatory growth in the protected innovative medicines sector, funded by a rise in private health insurance.^[7]

India, China, Brazil, and many other countries are undergoing the kind of economic transformation that South Korea, Japan, and the nations of Europe experienced during the post-World War II boom. Economic progress in emerging markets is happening at an accelerated pace due partly to advances in technology, sound economic policymaking, and reduction in poverty as a result of health, education, and other social reforms. In fact, from 1996 to 2010, emerging markets countries grew at more than twice the rate of developed countries—about five percent versus two percent annual GDP growth, respectively. Even more

impressive is that, recently, income disparity between certain emerging markets and developed markets is declining rapidly.

When we speak of emerging markets, just what countries are we talking about?

It depends on whom you ask: The FTSE Group identifies 22 emerging markets, split between “advanced” and “secondary.” Standard & Poor’s, which rates the sovereign debt of 126 different countries, classifies 19 of them as emerging markets.

Perhaps not surprisingly, the ubiquitous success of the term BRICs (Brazil, Russia, India, China) has spawned a whole new set of alphabet-soup-like terms for different groupings of emerging markets. One is the EAGLEs, defined as the 10 emerging and growth-leading economies. Others are the 12 countries of the Big Emerging Markets (BEM), and the rather unwieldy CIVETS, which includes Colombia, Indonesia, Vietnam, Egypt, Turkey, and South Africa. No matter how they are sliced and diced, most emerging markets will continue to enjoy growth that dwarfs that of the developed markets. The International Monetary Fund and the World Bank project that, in 2025, the pace of growth in emerging markets still will be double that of developed markets. ^[7]

2.1 What are Emerging Markets?

The term “emerging markets” describes a dynamic, yet highly diverse group of countries and regions. In 2010, IMS Health redefined the ‘Pharmerging’ markets by identifying the 17 key geographies based on macroeconomic metrics and pharmaceutical market forecasts^[4]. In the latest IMS Health evaluation, it increased the count to 21 countries with the addition of Algeria, Colombia, Saudi Arabia and Nigeria. These 21 Pharmerging countries will together add \$187bn in annual sales between 2012 and 2017. This is two thirds of global pharma growth and will increase the pharmerging markets’ global share from 23% in 2012 to 33% in 2017, with all 4 BRIC (Brazil, Russia, India, and China) countries in the top 10 by sales value. Also, Pharmerging markets will move from representing a fourth of the global pharma market in 2012 to a third by 2017, with growth mainly driven by government healthcare investment, private and out-of-pocket spend, and the increasing burden of chronic disease. ^[4]

Pharmerging markets are most commonly divided into Tier1, Tier 2, and Tier 3 as shown in the Figure:



Fig. 3: Pharmerging Markets

Tier 1:

China: As per projection, China will alone account for nearly half of Pharmerging market growth and is expected to become number two in the world pharma rankings in 2015 (including formulated traditional Chinese medicines). It is one of the world's fastest growing pharma markets with a CAGR of 16.7% forecast between 2012 and 2017. ^[4] Despite the recent EDL (Essential Drug List) revision and associated policies, growth will be driven by the additional investment in healthcare from the Chinese government and the rising affluence of patients paying out-of pocket for premium products. The government is implementing a four-year plan (2012 to 2015) for the prevention and control of chronic diseases which already account for the bulk of healthcare spending in the country.

Tier 2:

Brazil: Despite a slowdown in economic growth, price pressures and government cost containment measures, private healthcare, consumer medicines and the enhancement of current public healthcare provision will continue to drive forecast growth of a CAGR of 12.7% between 2012 and 2017. ^[5]

India: India is forecast to grow at a CAGR of 12.5% between 2012 and 2017. By 2016, health insurance is planned to reach half of the Indian population (630 million people), mainly by broadening basic healthcare provision to families living below the poverty line. Urban middle class private healthcare plans will also expand further. Both are helping to drive growth. ^[5]

Russia: IMS forecasts 10.1% CAGR between 2012 and 2017. This is mainly due to a significant investment in healthcare by the government, which announced plans to increase healthcare spending from 5.6% of GDP in 2012 to 7.5% by 2020, including a national health insurance scheme covering drugs in the retail setting. Growth is, however, slowing due to price controls and a slowdown in the overall economy, which is heavily dependent on oil and gas export prices. ^[5]

Tier 3:

These 17 markets represent a wide array of income levels, growth rates and healthcare sophistication. In this study, we classify Tier 3 countries into two groups based on average pharmaceutical spend per capita to highlight differences between them.

- **Countries with 2012 pharma sales above \$85 per capita:** Poland, Argentina, Turkey, Mexico, Venezuela, Romania, Saudi Arabia and Colombia. IMS forecasts these eight countries will grow at 9% CAGR in 2012-2017 reaching a combined market size of \$82bn in 2017. ^[7]
- **Countries with 2012 pharma sales below \$85 per capita:** Vietnam, South Africa, Algeria, Thailand, Indonesia, Egypt, Pakistan, Nigeria and Ukraine. IMS forecasts these nine countries will grow at 11% CAGR reaching a combined market size of \$45bn in 2017. ^[7]

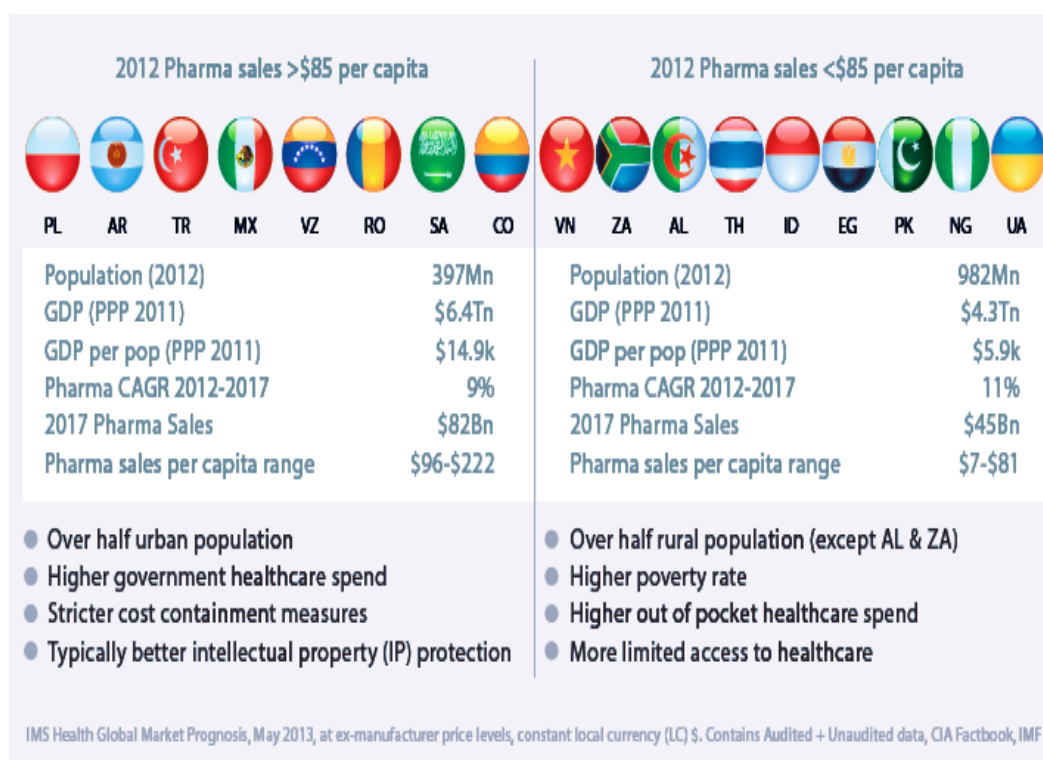


Fig. 4: Pharma Sales Per Capita in Tier 3 Countries (2012)

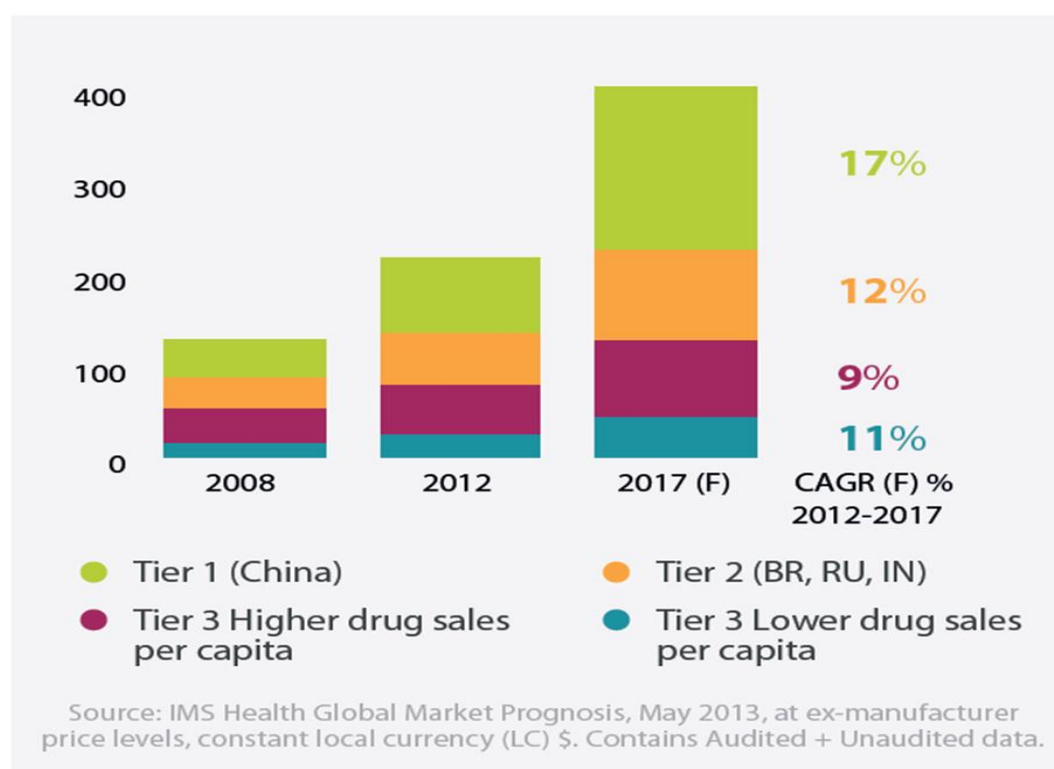


Fig. 5: Pharmerging Market Sales

2.2 Frontier countries

In addition to Pharmerging markets, further business opportunities can be seen in the ‘Frontier markets’. Frontier markets have the potential to become important markets as companies look for further growth opportunities. Combined, IMS forecasts these markets will add an additional \$9.1bn in annual sales by 2017. With half of the Frontier markets in Africa and the Middle East, the potential of this region is becoming more evident ^[5].



Fig. 6: Emerging Markets Geographical Footprint

Expected sales increase 2012-2017	Country	Pharma Sales 2012	CAGR 2012-2017
Asia Pacific \$2.2Bn incremental	Philippines	\$3.0Bn	3.8%
	Malaysia	\$1.6Bn	8.3%
	Bangladesh	\$1.3Bn	10.4%
Latin America \$2.5Bn incremental	Chile	\$2.3Bn	8.2%
	Peru	\$1.5Bn	7.8%
	Ecuador	\$1.3Bn	8.6%
East Europe \$0.8Bn incremental	Kazakhstan	\$1.3Bn	10.3%
Middle East \$1.7Bn incremental	Iran	\$2.6Bn	5.0%
	U.A.E	\$1.3Bn	8.9%
	Lebanon	\$0.8Bn	6.6%
Africa \$1.9Bn incremental	Morocco	\$1.2Bn	4.5%
	Tunisia	\$0.8Bn	10.0%
	Ghana	\$0.8Bn	12.4%
	Kenya	\$0.5Bn	16.9%
	Ethiopia	\$0.4Bn	10.0%

Table 1: Frontier Countries

Companies that already have significant presence in Pharmerging markets have begun to increase their investments in Frontier markets, which will become more important drivers of growth. Frontier markets, plus the least developed Pharmerging countries such as Vietnam, Pakistan and Nigeria, will continue to offer the promise of huge populations and high growth rates. However, they also present the operational challenges of working in undeveloped healthcare systems and often difficult business environments.

Today, many seem to regard emerging markets as the pharma industry's "promised land." By 2017, they are expected to account for nearly a third of the global pharma market. They offer large and growing populations, increasing levels of prosperity, improving longevity, and increased demand, with a shift from basic to more affluent "lifestyle diseases." It's no surprise that these markets are attractive to companies suffering from mature market stagnation, patent expirations and increased regulatory hurdles

2.3 Challenges to Growth in Emerging Markets

There has been a lot of talk about potential of Emerging markets, but it's not as simple as it sounds. Pharmaceutical companies face a lot of barriers while doing business in emerging markets. While executives share a long list of concerns, each pharmaceutical company needs to evaluate them in the context of its specific portfolio. For example, a lack of healthcare infrastructure and affordability can be expected to be a bigger challenge for the producers of expensive specialty care than for those companies that manufacture primary-care products. [7][8]

- Price pressure is aggravated by domestic competition, as local companies typically receive support from their governments, a phenomenon also often seen in public tenders across emerging markets. This situation is further exacerbated by the fact that local companies are typically generics manufacturers that will also benefit from the approaching patent cliff.
- Legal and Regulatory issues are reflected in the lack of intellectual property (IP) protection. The absence of transparency, lengthy processes surrounding tendering and contracting, and compliance challenges also are factors.
- Talent management is known to be a significant hurdle for companies in emerging markets.

- IP protection issues can significantly influence the go-to-market strategies and tactics of pharmaceutical companies.

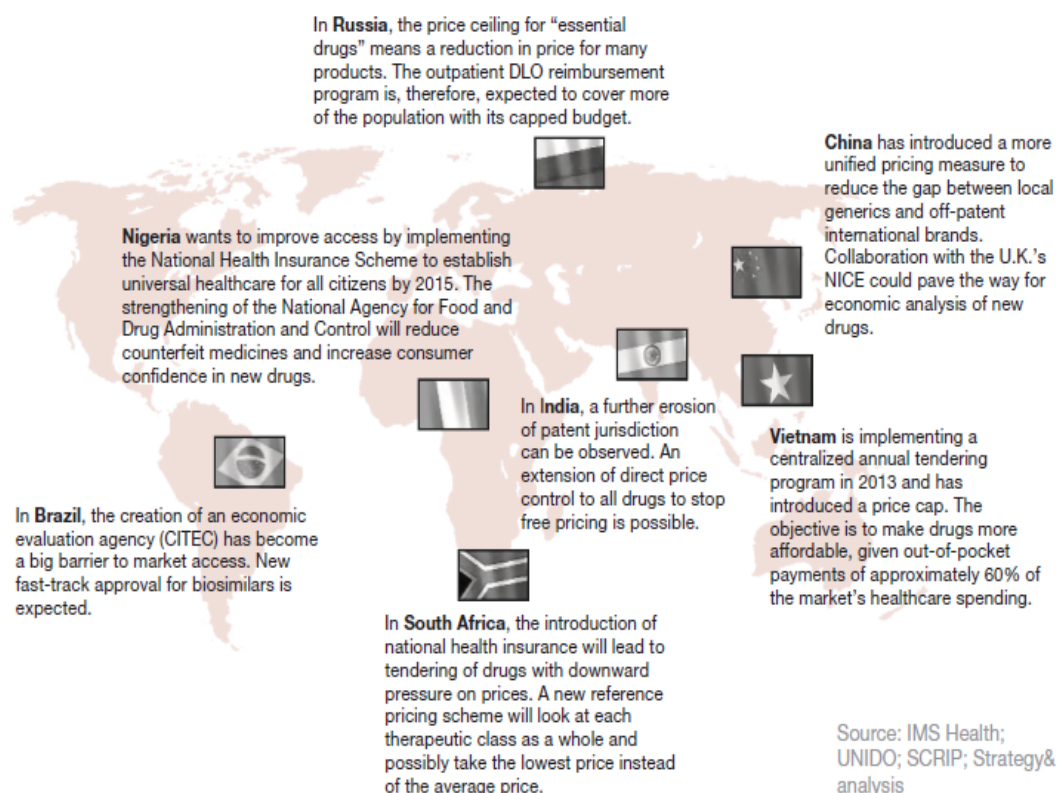


Fig. 7: Examples of healthcare policy changes for selected emerging markets

India is a good example of how tough the situation can be with regard to intellectual property protection. The subcontinent is known to legally support generics companies in order to provide the Indian population with affordable medication. This support is given even when it goes against existing patent laws and corresponding rules of the World Trade Organization (compulsory licensing). For example, despite valid patent protection, Bayer’s Nexavar, a treatment for hepatocellular carcinoma, is facing competition from Natco Pharma ^[9]. Due to the inability to afford Nexavar among the general population, the Indian government granted compulsory license to Natco for manufacturing and marketing rights for the drug. Natco pays only 6 percent in royalties and is able to provide Nexavar at therapy costs of around \$170 per month, while Bayer’s Nexavar therapy costs amount to \$5,500 per month.

- Boehringer Ingelheim (BI) markets its patented HIV drug Viramune in India, although it faces competition from local generics manufacturers. To protect its brand, BI made a commitment not to pursue lawsuits, as long as local manufacturers adhere to good manufacturing practice (GMP), to ensure a level of quality for the marketed product.
- Roche entered a partnership with India's Emcure Pharmaceuticals in 2012 in order to increase affordability and access to some of its blockbuster products. The latter would produce Roche's breast cancer drug Herceptin and its lymphoma and rheumatoid arthritis treatment MabThera for domestic sale — under different names and at significantly lower prices. However, the Indian government nevertheless started the process of granting a compulsory license on Herceptin in January 2013; it had already stripped the patent from Roche's hepatitis C therapy Pegasys in 2012. ^[51]

2.4 What are the barriers to effective execution of an emerging-markets strategy?

Selling and operating in these markets presents numerous difficulties. A variety of market access elements such as supply chain planning, manufacturing and distribution can become more complex when selling to markets in emerging economies. The regulatory environment, including taxation and import regimes, can be a significant barrier to growth, both in terms of working across borders and in terms of tracking the continuously evolving patchwork of laws and rules. The need for more effective monitoring of pricing and reimbursement may increase. Talent shortages can also be obstacles to growth.

Thus, although “expansion into emerging markets” is now a popular topic for boards at many life sciences companies, it is time to turn the talk into effective action in order to stay competitive and win. ^[1]

Here are few major barriers that hinder growth of Pharmaceutical companies in Emerging markets as shown in Fig. 8:

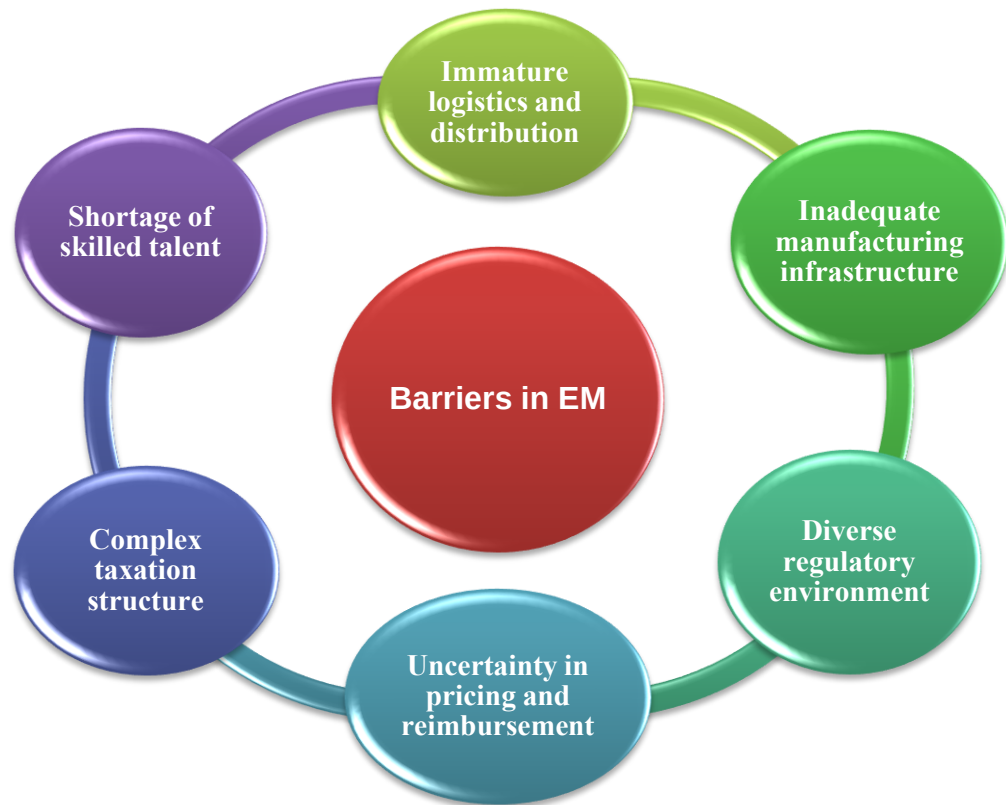


Fig. 8: Barriers in effective execution of emerging markets strategy^[1]

2.4.1 Immature logistics and distribution

Life sciences companies generally have available to them a spectrum of distribution options as they seek access to markets in BRIC countries. One challenge that companies typically face in this area is that the distribution value chain in emerging markets is often immature—inefficient, mostly inflexible and highly fragmented. Take the example of the typical Chinese distribution system which, by Western standards, is complex and much more restrictive, with a large number of distribution companies operating at all levels. Many distributors are province based or city-based and few cover more than just a small area of the country. Five primary distribution centers supply more than 200 provincial-level wholesalers, which in turn supply around 3,000 local distributors. Such a distribution system may have the advantage of simplicity, but it can also be highly inefficient.

China now has a large number of distribution companies operating at all levels. In theory, all products could be distributed through the state-controlled system, but many local companies establish their own preferred methods of purchasing and

distribution. Direct selling by manufacturers and wholesalers at all levels is increasingly becoming the norm. Many suppliers desire to gain broad geographic coverage but find themselves restricted by strong regional governments and poor transportation and communication systems which, in effect, make China a collection of independent and fragmented markets.

The situation is similar in India, with many companies encountering complexity and fragmentation in the distribution chain at every level. A typical distribution value chain in India goes through a distribution network that may involve 30 clearing and Forwarding Agents (CFAs), 60,000 stockists and 550,000 pharmacies in addition to substockists, hospitals and non-government organizations (NGOs). Thus, as in China, the distribution networks in India are exceedingly complex.

In Russia, a large number of small regional drug wholesalers exist, but these are sometimes losing out to a smaller number of national wholesalers. The national wholesalers are typically more efficient and better capitalized. Because they are generally based in Moscow or St. Petersburg, they may be better placed to deal with overseas companies. The distribution system situation in Brazil is more in line with that of a developed market. Brazil has about 300 drug wholesalers and five major pharmacy chains in addition to other players. The five pharmacy chains comprise 49 percent of the market but have only 10 percent of the outlets in the country. Those numbers may continue to fall due to mergers and acquisitions. For example, in September 2011, Drogaria São Paulo, the leader in the state of São Paulo, and Drogarias Pacheco, the leader in Rio de Janeiro, announced a merger, creating the largest pharmacy chain in Brazil, DPSP, with a combined 691 outlets located in five states. Furthermore, lack of adequate cold-chain capabilities across the country has contributed to serious gaps in distributing drugs that require specialized handling. The market does not have distributors or logistics players who have cold-chain capabilities across the entire country. These kinds of constraints may need to be addressed to improve market access in emerging economies.

2.4.2 Inadequate manufacturing infrastructure

Different emerging economies have very different levels of maturity in terms of fully developed manufacturing ecosystems. Although most of the manufacturing

bases in the BRIC countries are focused on providing Active Pharmaceutical Ingredients (APIs) and preparations (China and India), and manufacturing generic products (all BRICS), a great deal of fragmentation exists among pharmaceutical manufacturers. For example, in India, no single company has more than 7 percent of market share; in China by contrast, 70 percent of the players have revenues of less than \$45 million. India is ahead of other emerging economies in formulations due to their domestic generic manufacturing capabilities.

In Russia, manufacturing has often not been able to cope with the growing needs of the Russian market. Currently, local pharmaceutical companies are able to meet only a small percent of the country's requirements; therefore, reliance on imported pharmaceuticals is growing. Around 80 percent of the public procurement budget for additional medicines is spent on foreign pharmaceuticals. Further analysis suggests that the local industry's falling market share may be rooted in part in the inability of Russian manufacturers to produce innovative drugs. Some producers blame the high costs associated with drug development, clinical evaluation, marketing and promotion and the uncertainty of the return on their investment. In Russia, the cost of developing and launching a new drug is estimated at between US\$100,000 and US\$5 million. Some manufacturers therefore claim that they need to acquire licenses for the reproduction of fully established generic products. Another problem often lies with a lack of financing for R&D. Many Russian scientific research institutes that were previously solely responsible for the end-to-end process of developing and launching new products now tend to be involved only in the initial drug-discovery stage. After that point in the process the project is often shelved due to extensive laboratory and clinical evaluation costs, as well as marketing and sales expenses. If a new drug is successfully developed, insufficient laboratory and clinical testing as well as non-compliance with international Good Manufacturing Practices (GMP) standards could prevent it from entering the international market place.

In Brazil, some companies have focused on encouraging more effective collaboration between contract manufacturers and pharmaceutical companies. Due to the strong Brazilian currency, companies can find it infeasible to produce drugs in Brazil for export. This situation, in turn, can result in underutilization of manufacturing capacity.

Russia faces challenges in becoming GMP compliant because only 12 percent of local facilities are GMP certified. India, on the other hand, has many GMP-certified facilities, but faces challenges because many players of all sizes have been exposed as being, in practice, nonadherent to norms. Many large multinationals prefer to invest in captive facilities in these markets to increase the availability of high-quality and compliant local manufacturing partners. In the future, more manufacturing facilities may become GMP compliant across the emerging economies.

2.4.3 Diverse regulatory environments

Successful expansion in emerging markets can depend on a comprehensive understanding of the different regulatory environments of these nations. For example, gaining approvals for new products typically takes longer in the BRIC countries than in developed markets. Approval times can range from about 18 months in Russia to more than three years in China—over and above the timelines for registration in the United States and the European Union.

The costs and processes associated with seeking approvals in these markets typically also vary significantly. China accepts pharmacokinetic bridging clinical studies along with global clinical data, while Russia requires enrollment of local patients in clinical trials. Despite a generally low cost of patient recruitment and a typical ability to run concurrent trials in India along with global trials, many large companies prefer not to engage in Phase I clinical trials because some companies believe that regulations regarding data exclusivity are not strong enough to guarantee protection of preclinical data.

Intellectual property rights for pharmaceutical products are also regularly evolving, with many local governments seeking to strike a balance between World Trade Organization (WTO)-related norms and local patient needs for access to affordable and innovative drugs. Although compulsory licensing may not yet be a significant threat in most emerging markets, other factors such as the scope of patentability for new products in India and patent review processes in Brazil have had an effect on the creation of patent-protected products in these markets.

Regulators in the BRIC markets are often aware of the delay in making innovative medicines available to patient populations. Some regulators are working toward

rationalizing approval timelines to reduce this lag. Brazil is looking at initiating a fast-track approval process for lifesaving drugs, while China and Russia are looking for multinational cooperation in the area of clinical trial regulation to reduce the time and cost associated with repeating clinical trials with the local population. Although these changes may help life sciences firms gain faster market access, companies can still benefit from recognizing that patent laws in these markets may not readily evolve to a stage where patent recognition will be at par with that of developed markets such as the United States and the European Union. Thus, for life sciences companies to be successful in these markets, they may need to become more selective about their portfolio choices. In general, firms may benefit from gaining detailed knowledge of local regulatory policies and putting in place a dedicated workforce to liaise with the local regulatory bodies—an approach that can improve speed to market.

2.4.4 Uncertainty in pricing and reimbursement

Achieving success in emerging markets requires a deeper understanding of how pricing and reimbursement systems work in the different regions. Although each market employs some combination of free-market pricing and price controls, pricing and reimbursement in general can vary significantly across markets and is in part a reflection of local economic conditions and the government's role in healthcare provisioning. For example, although both Brazil and India have similar market sizes in terms of value, drug prices in India are only a fraction of the prices in Brazil. Although a large portion of the market by value is unregulated in Russia and India, resulting in positive price evolution, the reverse is true for Brazil and China, with the latter experiencing negative price growth. In China, government-mandated cuts of about 20 percent every three years are becoming common place. In terms of government reimbursement, both Russia and India are largely self-pay markets with limited coverage for pharmaceutical products. By contrast, both Brazil and China have established reimbursement systems through a combination of social insurance and government funding. Outpatient drug reimbursement is also fairly common in Brazil and China, while many patients in Russia and India must pay themselves for drugs used outside of a hospital stay.

Reimbursement listing can improve market access in many markets. In China, in addition to reimbursement listing, companies generally focus on getting their products listed on the formularies of hospitals. Even then, two to three years may be required before bids for such products are invited. Similarly, in India, winning a tender does not necessarily guarantee that the product will succeed. Sales teams are often called upon to work with hospital formularies to generate regular orders. Given the trend of increased public healthcare spending in emerging markets, some regions are experiencing increasing demand for skilled resources in areas such as tendering and auctioning. Shortages of experienced professionals in these areas often result in more cross-industry recruitment and training.

The countries with better-established reimbursement markets—including China and Brazil—may see stagnation or erosion in prices because the healthcare systems in these countries are generally facing increasing cost pressures and budget constraints. Although the non-regulated retail markets in Russia and India may see positive price evolution, increased pressures from patient and activist groups are likely to result in more monitoring of prices, especially for innovative lifesaving drugs and medications for chronic illnesses, which can impose a significant burden on the self-paying patient population. Calls for greater reimbursement coverage in Russia may not occur for some time, while India may remain a self-pay market for the foreseeable future. When setting their pricing strategies, life sciences firms should be cognizant of consumers' disposable incomes in these emerging markets. Company also may benefit from focusing on improving the cost effectiveness of their supply chains to maintain suitable gross margins. For more on the current situation in BRIC countries with regard to pricing and reimbursement, and on future trends, see the summary chart in Table 2 and Table 3:

Pricing	Brazil	Russia	India	China
Extent of price control	All drugs	EDL (567 DRUGS) & DLO (covers 7 life threatening diseases	348 drugs covered under DPCO	NRDL (2400 molecules) ~ 60% of the market by value
Price control mechanism	International reference pricing (10 countries) and reference to local existing products	International reference pricing (20 European countries) and reference to local existing products	Avg. pricing; of those having market share of more than 1% in similar segment	Patented products prices negotiated individually by NDRC and manufacturers
Pricing norms for generics	At least 35% discount to innovator brands	Average of last 12 months price	~ 95% market is 'branded' generics	First to market enjoys premium over laggards
Price Increases/trends for price controlled products	Regulated based on inflation and generic penetration	Allowed only for locally manufactured products	Reviewed periodically for cost escalation and price increases granted	Prices cut every 3 years (10% to 20%)
Pricing trends for non-controlled products	-	Free pricing, controlled by competitive forces	>10% increase per year not permitted	-
Pricing for government purchases	Compulsory discounts (24%), bulk purchases and reverse auctions	Local made products enjoy a 15% price premium over similar imported products	Purchased through sealed tenders primarily driven by price	Average tender price drops by 2% to 3% each year
Channel margins	Average wholesale margin 10%, retail margin 26%	Margins vary by federal district and product price	DPCO: Wholesale 8% and Retail 16%, non-DPCO: 10% and 20%	NDRC applies maximum margins based

			respectively	on manufacturer's price
Price comparison	(500 mg Ciprofloxacin) - Cost of a 7 day course (2 tabs a day)	(500 mg Ciprofloxacin) - Cost of a 7 day course (2 tabs a day)	(500 mg Ciprofloxacin) - Cost of a 7 day course (2 tabs a day)	(500 mg Ciprofloxacin) - Cost of a 7 day course (2 tabs a day)
Generics	\$15.6	\$4.6	\$1.7	\$3.1
Innovator	\$106.5	\$47.6	\$2.0	\$129.2

Table 2: Comparing pricing environments in the BRIC countries ^[3]

Reimbursement	Brazil	Russia	India	China
Scope of government reimbursement	Vast coverage with full reimbursement for a range of life saving and chronic therapy drugs	Limited drug coverage (DLO affects only 5% of the population)	Only inpatient coverage for government employees	Widespread coverage with a mix of full reimbursement and patient copayments
Private health insurance coverage (outpatient costs)	Few plans provide coverage for outpatient drug usage	No coverage for outpatient drug usage	No coverage for outpatient drug usage	No coverage for outpatient drug usage

Table 3: Comparing reimbursement environments in the BRIC countries

2.4.5 Complex taxation structure

Taxation and import regulations also have important roles to play in attracting large, multinational life sciences companies to emerging markets. R&D and innovation have contributed to the implementation of specific tax incentives in many of the emerging and developed markets. Many local government bodies are trying to attract investments in their regions by setting up tax-free zones and by

providing access to better infrastructure and resource pools. In Brazil, many of the manufacturing and allied industries are currently focused in the São Paulo region because that area provides better access and varying tax plans compared with the rest of Brazil. This situation may be changing, however, because the state of Rio de Janeiro is now attracting pharmaceutical companies as well. Brazil's tax structure on pharmaceutical products, 34 percent, is considered high. Strict import regulations typically prevail, as do mandates to manufacture locally to promote exclusivity of the drugs. Similarly, in Russia, the Kaluga Oblast region is preferred by many industries as a source of innovation and the region's industrial parks are attracting pharmaceutical companies that include Berlin-Chemie. In Russia, about 80 percent of drugs are imported; so many pharmaceutical companies are being provided special status to promote manufacturing in Russia. For example, in the Skolkovo region (near Moscow) residents are offered exemptions on VAT and property taxes. The region also has a highly discounted social tax structure.

In India, some individual states are providing tax incentives in special economic zones for pharmaceutical companies to set up operations in their regions. India offers incentives including a deduction of 100 percent of eligible expenditures for the same year. In addition, the long-awaited move from state tax to Goods and Services Tax (GST) may bring dramatic changes in the way supply chains function within India. Because GST provides a more transparent version of taxation, it may be a force for change for pharmaceutical companies and for the entire life sciences industry. In China, the government is being aggressive in providing deductions. It provides a deduction of 150 percent on qualifying R&D expenditures. Although some multinational companies have already begun planning to use China as a global sourcing base, many companies have also started setting up R&D labs in different cities in China. Easing the norms on market access for imported drugs is also seen as a welcome move by some multinationals who wish to keep manufacturing outside China. Because the need to provide incentives at country, province and city levels may increase, life sciences companies should consider working to learn from similarities across borders and also to learn from industries that have been successful in emerging economies. This can help them design a more tax-efficient operating model. Such a model can help provide better cost

efficiency which can be important to competing more effectively in a highly competitive and fragmented market.

Regulatory	Brazil	Russia	India	China
New product registration	New Drug take more than 2 years, while generics are approved within 1 year	Actual approval usually takes > 18 months although official timelines are far lower	New products take more than 2 years, while generics are approved within 6-12 months	NCEs face 3 to 4 years than the US or EU to be approved
Intellectual property protection	Patent review timelines ~ 8 years. Review by patent office and medicines agency. No explicit Data exclusivity regulations	Russia became a WTO member in 2011 and patent law is still evolving	Issues concerning Data Exclusivity regulations, and scope of patentability which often lead to rejection of applications	Issues concerning Data Exclusivity regulations which can allow generics access to clinical data
Clinical trials	Trial Protocols are approved by multiple agencies with timelines stretching to > 10 months	Minimum of 2000 local patients need to enrolled on trials for marketing approval	Phase I trials allowed only if compound originates in India or pre-clinical data is submitted for review	Bridging pharmacokinetic studies allowed with 100 patients
Manufacturing	GMP norms implemented in the '90s. Stricter norms for APIs (in line with US and EU) implemented since 2010	< 12% local units are GMP certified. Some MNCs prefer to setup captive facilities in Russia	Although many facilities are GMP and even FDA compliant, adherence to norms remains questionable	All manufacturers will need to comply with GMP norms by 2015

Future trends	• Potential introduction of a fast track approval process for life saving drugs • Patent office indicates aims to reduce review timelines to 4 years • Post marketing surveillance rules including ADR reporting may get more stringent	• Mutual new product registration between Russia, Belarus and Kazakhstan designed to reduce approval timelines and grant faster market access • May see mutual recognition of clinical trials between the EU and Russia reducing clinical trial timelines and costs • Some manufacturing units may not achieve GMP compliance by 2014, leading to some consolidation among local manufacturers	• Establishment of a National Medicines Agency as the sole approval authority may happen in the distant future • Clinical trial requirements, including patient consent and ADR reporting may get more stringent	• Regulatory cooperation is being explored with Asian countries for harmonization of clinical trial regulations and reduction of trial timelines • Manufacturing regulations governing API manufacture may become more stringent • Government may resort to compulsory licensing in the area of ARVs
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Table 4: Comparing the regulatory environments in the BRIC countries

2.4.6 Shortage of skilled talent

Availability of skilled talent may be a challenge for life sciences firms seeking to expand into emerging markets. As the emerging markets grow, the competition for skilled talent will be intense. Based on a recent Economist Intelligence Unit survey about talent challenges in emerging markets, most of the surveyed executives feel that retention of employees and domestic recruitment will be significant issues for them over the next three years. As the emerging markets grow, the need for new

skills increases in areas such as cold chain management, biologics manufacturing, demand planning and pricing analytics. The support structure to provide a good stream of skilled talent is being developed but, at the moment, demand is outpacing supply. Even though the emerging markets produce plentiful talent from their universities, too few candidates are industry ready.

In India, where skills shortages are particularly acute, many companies are looking for ways to bring uneducated workers into their organizations, then working with non-governmental organizations (NGOs) to improve the skills those workers need to become productive. In the supply chain talent area, companies are either casting their net widely into related industries such as consumer packaged goods (CPG) or going beyond their own borders to recruit talent. In another strategy, the India School of Business at its Mohali Campus (near Chandigarh) has joined with an Indian Conglomerate Hero group to start Munjal Global Manufacturing Institute, which has a mission of focusing on developing manufacturing skillsets across industries based on industry needs.

The talent challenge is real and will help to determine whether companies and emerging markets can realize their full potential. The Economist Intelligence Unit survey on talent compared BRIC nations and found that most of the key talent issues across the countries are similar. The most important issues that China, India and Russia are facing are, first, higher salary expectations because of shortage of talent and, second, increased demand for critical skills. This situation is causing higher employee attrition, something that creates skill gaps and high overhead for companies. Skills gaps and inability to meet salary expectations are a kind of “chicken and egg” situation; one cannot be resolved without resolving the other.

Maturity Parameters	Brazil	Russia	India	China
Distribution	Highly fragmented, regionally focused, low visibility	Highly concentrated, Further consolidation expected	Highly fragmented, multiple layers, unionized channel, low visibility	Highly fragmented, multiple layers, low visibility
Manufacturing (Compliance)	Local regulation compliant	Low GMP compliance Universal compliance only by 2014	Majors follow GMP, monitoring of adherence to norms is critical	GMP compliance is an issue, universal compliance only by 2015
Manufacturing (Reliance on Imports)	Heavy reliance on imports (80% APIs imported)	Heavy reliance on imports (> 75% of the market)	Predominant local manufacturing (local players)	Predominant local manufacturing (including MNCs)
Availability of niche skills	Limited availability of niche supply chain skills	Skills availability is not an issue at present	Skills available, but LS not a preferred choice	Limited availability of niche supply chain skills
Technology Usage (LS Firms)	Localized systems	High Usage, ERP systems	High Usage, ERP Systems	Legacy Systems
Technology Usage (Channel Partners)	Basic technology used by channel partners	ERP used by large channel partners	Basic technology used by channel partners	Basic technology used by channel partners

Table 5: Comparison of the maturity of life sciences value chain elements across the BRIC markets

2.5 What can be done in Emerging markets?

2.5.1 Think customer clusters: The importance of submarkets.

Each emerging market is a combination of diverse segments requiring differentiated treatment. Companies should consider plotting their access strategies by thinking of customers and clusters of customers (also known as “submarkets”) rather than focusing only on countries and continents. This approach can enable companies to have more targeted and effective customer centric strategies.

2.5.2 Find cross-border similarities.

Elements of the value chain appear to be at similar maturity levels across multiple emerging and/or developed markets. Firms may benefit from creating solutions that are better positioned to cross geographic borders by exploiting these similarities.

2.5.3 Establish global reach with local relevance.

It is important to standardize globally whenever possible to gain economies of scale, but also to customize where appropriate to achieve local relevance. Solution themes can benefit from cross market applicability, but the implemented design may need customization to address market-specific nuances at the local or regional levels.

2.5.4 Create effective and rapid execution capabilities.

The ability to understand the customer and to execute solutions across markets that are aligned with customer needs in a timely and cost-efficient manner can be a key to success and competitive differentiation. This is a difficult goal for many companies because many still operate within functional silos of supply chain, R&D and commercial, rather than working toward one common goal according to one strategy.

Most of the BRIC markets are still at low levels of maturity in terms of distribution capabilities, infrastructure, manufacturing, supply chain skill availability and technology adoption. Establishing and running supply chain

operations in emerging markets is a challenging proposition. It may be difficult to gain penetration down to the last mile in the market, navigating through the complex networks of cities and towns and the vast geographic span. There are also significant differences in the level of economic and infrastructure development as focus shifts from cities to smaller towns and then to rural areas which are typically not well-connected from an infrastructure perspective to the more urban economic centers.

Overcoming these challenges to the overall value chain may require innovative approaches such as focusing on customer clusters, leveraging solutions across markets with local flavor and executing with speed in an effort to maximize the business opportunities that these markets offer to life sciences players.

3 Rationale

When the numbers of emergent markets are so large and diverse the question becomes what markets are worth taking a closer look at in order to define the problems and challenges Pharma Industries facing and to test their pricing and market access strategies. In this study we have taken the approach of looking at the five largest emerging economies, namely Brazil, Russia, China, India and Africa who amongst them represents a significant percentage of the world population as well as the world market. The size of these markets make them more interesting than smaller markets which has less influence on the world, since these countries could very well be the engines that drive the economy of tomorrow. Additionally, the five markets shows themselves to be interesting in the context that they, despite their large size, shows significant differences in their market structure as well as the challenges entrants and domestic companies face.

The study will be helpful to gain deep insights & findings on what Strategies Global Pharmaceutical companies adopt to make their drugs successful, specifically in emerging markets. In order to gain an understanding of this, the study looks at four specific markets, namely Brazil, Russia, India, and China (BRIC). Also, Africa has been included in the study as many companies believe that in long term plans Africa needs to be targeted. The study attempts to answer if the way companies approached emerging markets is in keeping with what would be expected. Additionally it tries to comprehend the disparity that exists between these emerging markets among themselves and also in comparison with mature markets.

4 Aim and Objective

A great deal has been written about the potential of the Emerging markets yet Pharma companies shy away from investing there. The reason behind this is that the CEOs are well aware of the complexity of these markets to do business successfully. The theoretical aspect says that emerging markets are the new land of revenues for Pharma companies but in practice, it is not happening. There are risks, in fact a lot of risks in investing in these markets. Starting from entry to remain competitive later, Companies need to do everything strategically.

This study will therefore contain a comprehensive analysis of 5 major emerging markets in order to offer a better indication of the challenges Pharma companies face when entering emerging markets in general. Also, the study will suggest the pricing and access strategies that need to be implemented in order to win game in these markets. It tried to include the existing pricing models and precedents in EM which can be used strategically for success in these markets.

The aim of the study is to make a contribution to the “understanding of the challenges and problems associated with emerging markets” and “Is the way companies approached emerging markets is in keeping with what would be expected”. In order to shed light on this subject, the study will analyze 4 drugs- Augmentin, Mabthera, Januvia, Galvus in 5 major Emerging markets- Brazil, Russia, India, China and Africa. The **main objective** of the study is to:

- *“Generate Overview of existing Pricing and access models in low GDP and self-pay markets”*
- *“Conclude a strategy based on this research to explore the potential of Emerging Markets in future”*

The **secondary objective** of the study is:

- *“To comprehend the disparity that exists between these emerging markets among themselves and also in comparison with mature markets”*

5 Methodology

Current Pricing and market access models restricts access in Emerging markets, where affordability, availability and awareness of innovative medicine is a key issue. Hence, this work stream tries to generate an overview of existing business models and review applicability to Pharmaceutical business in low GDP and self-pay markets. Business Models include but are not limited to: portfolio deals, beyond the product offerings, innovative financing models (insurance, micro financing, donations from NGOs), stakeholder engagement strategies, effective value communication, Patient Access Programs (PAP), Managed Entry Agreements (MEA).

A desk research was carried out on existing models and precedents in emerging markets to identify the best practices (also infrastructure/Distribution channels) that have been or can be used to achieve the desired results in emerging markets. In order to gain an understanding of this we looked at four specific markets, namely Brazil, Russia, India, and China (BRIC). Also, Africa was included in the study as many companies believe that in long term plans Africa needs to be targeted. Additionally we try to comprehend the disparity that exists between these emerging markets among themselves and also in comparison with mature markets. Analysis of these five markets was also carried out to get deeper insights.

In the five markets analyzed in the study to illustrate emerging markets- Augmentin, Mabthera, Januvia, and Galvus were used as an example drugs present in all five markets. Pricing and Markets access strategies used by companies for these 4 drugs in 5 markets (BRIC and Africa) were analyzed for success factor, price cut, disease area, business model etc. The results obtained were concluded into a strategy that can be used by companies for approaching in emerging markets.

5.1 Selection of Cases for Analysis

When the numbers of emergent markets are so large and diverse the question becomes what markets are worth taking a closer look at in order to define the problems and challenges Pharma Industries facing and to test their pricing and market access strategies. In this study we have taken the approach of looking at the five largest emerging economies, namely Brazil, Russia, China, India and Africa who amongst them represents a significant percentage of the world population as

well as the world market. The size of these markets make them more interesting than smaller markets which has less influence on the world, since these countries could very well be the engines that drive the economy of tomorrow. Additionally, the five markets shows themselves to be interesting in the context that they, despite their large size, shows significant differences in their market structure as well as the challenges entrants and domestic companies face.

This means, that these markets will give a fairly representative picture of the numerous challenges faced by the companies operating in emerging markets.

In addition to the above mentioned reasons for our study, Looking at the cases in a more scientific view, we consider the Brazil, Russia, Chinese and Indian markets to be diverse cases with regard to wealth, which is evident by the differences in GDP per capita in the four countries. As

Rank	Country	GDP per capita	Country	GDP growth rate
1	<i>Taiwan</i>	\$31.900	China	9,8%
2	Czech Republic	\$26.100	Peru	9,2%
3	<i>South Korea</i>	\$26.000	Argentina	7,1%
4	<i>Hungary</i>	\$19.800	Egypt	6,9%
5	<i>Poland</i>	\$17.300	India	6,6%
6	Russia	\$15.800	Indonesia	6,1%
7	Malaysia	\$15.300	Russia	6,0%
8	Chile	\$14.900	Morocco	5,9%
9	<i>Mexico</i>	\$14.200	Pakistan	5,8%
10	Argentina	\$14.200	<i>Brazil</i>	5,2%
11	Turkey	\$12.000	Malaysia	5,1%
12	<i>Brazil</i>	\$10.100	<i>Poland</i>	4,8%
13	<i>South Africa</i>	\$10.000	Philippines	4,6%
14	Colombia	\$8.900	Chile	4,0%
15	Thailand	\$8.500	Czech Republic	3,9%
16	Peru	\$8.400	Thailand	3,6%
17	China	\$6.000	Colombia	3,5%
18	Egypt	\$5.400	<i>South Africa</i>	2,8%
19	Morocco	\$4.000	<i>South Korea</i>	2,5%
20	Indonesia	\$3.900	<i>Taiwan</i>	1,9%
21	Philippines	\$3.300	Turkey	1,5%
22	India	\$2.800	<i>Mexico</i>	1,4%
23	Pakistan	\$2.600	<i>Hungary</i>	-1,5%
Countries in italic type are Advanced Emerging Countries				
Source: CIA 2009 and www.ftse.com				

Table 6: GDP per capita and growth rate for Emerging Countries

can be seen from Table 6 above, the Russian GDP per capita was estimated at \$15,800 in 2008, the Chinese \$6,000 and the Indian \$2,800 (CIA 2009). At the

same time, Africa has shown considerable growth in recent years and is part of emerging markets strategy of various companies.

Type of study: Secondary, Desk Research

Data & Fact collection: Various self-studies, Published reports, Expert Interviews & other confidential resources

Study duration: 3 months

6 Market Analysis of Emerging Markets

6.1 Brazil

Brazil is the largest pharmaceutical market in Latin America. Pricing pressure, cost control, and product portfolio management are among the issues facing its life sciences sector in 2014. Brazil is the largest pharmaceutical market in Latin America and the 10th-largest in the world, accounting for about two percent of overall demand. 2012 sales were an estimated \$36.9 billion (including taxes). Pharma sales are forecast to grow to \$48.7 billion by 2017, supported by rising household incomes but somewhat constrained by government efforts to hold down the prices of patented drugs.

Pricing pressure occurs on two fronts: Manufacturers must submit all proposed drug prices to an independent organization, the Regulation Drug Market Committee (CMED), whose final market price may be lower than what the manufacturers submitted. Also, Brazil has a strong local generics industry (the largest in Latin America), which is supported by government policies aimed at extending the availability of medicines to low income consumers. These pressures are prompting life sciences companies to employ various strategies to identify the optimal price for their key products. Brazil's product registration and launch process through ANVISA, the national health agency, is complex and expensive; to control costs, life sciences companies need to carefully consider country-specific conditions (e.g., competitive offerings, proposed distribution system, regulatory issues) before moving forward with new market offerings.

Some life sciences companies in Brazil operate discount programs, which can present portfolio management challenges. Discount programs allow patients to buy drugs at a reduced cost, encouraging adherence. Companies usually have several discount programs for each product, which can complicate pricing and distribution. To address these and other challenges, life sciences companies are investing in new processes and technologies, such as tools that can control and evaluate market pricing performance. Furthermore, companies are starting to implement new business models to optimize the regulatory process at ANVISA.

6.2 Russia

Almost 80 percent of drugs in the Russian market are imported. This share is decreasing but not very rapidly. Most multinational pharma companies have constructed or are in the process of constructing factories in Russia to avoid losing their share in the hospital segment, where the Russian government is trying to restrict access for imported drugs. Since 2011, Russia's pharmaceutical market has undergone major expansion and is expected to continue growing steadily. Annual pharmaceutical sales are forecast to rise to almost \$32 billion by 2017, an average growth rate of 16.7 percent per year. The main task that lies ahead of the Russian government is to satisfy the market with Russian medicines, increase their quality, and contain their price increases.

However, an imperfect pricing system, a lack of companies operating in accordance with the European GMP standard, divisiveness in the creation of a list of vitally important medicines, and many other issues remain unresolved. The government's target program, "Development of the pharmaceutical and medical industry of the Russian Federation," details the goals to achieve by 2020: the share of Russian-manufactured medicines in the list of strategic medicines and vitally important medicines must reach 90 percent; the share of local medical drugs in the pharmaceutical market in monetary terms must be 50 percent; the share of local medical products and medical equipment in monetary terms must be 40 percent; and 75 percent of pharmaceutical and 85 percent of medical companies should be modernized.

The government has already introduced and plans to add a series of measures to restrict the access to state tenders for imported medicines — particularly in the hospital segment, which is supported by government purchases — in order to stimulate local manufacturing. However, pricing pressures, imperfect legislation, insufficient state financing of health care and manufacturer support, lack of spending capacity among the population, corruption at all stages from production to distribution, and a weak consolidation of local manufacturers create difficult conditions for manufacturing pharmaceuticals in Russia. While some pharma companies believe that current and projected market growth justify the higher costs of producing drugs in Russia, others are cautious and prefer to use a contract manufacturing model or place their manufacturing facilities outside the country.

Pharma companies will need to select their preferred business model in the near future or risk losing their share of sales in the growing hospital segment.

6.3 China

Recent allegations of malpractice by certain companies in their go-to-market conduct have sparked organizations to tighten their compliance programs, particularly those associated with Anti-Bribery Anti-Corruption (ABAC) Act and Foreign Corrupt Practices Act (FCPA) regulations. 2014 is anticipated to be a positive year for life sciences in China.

Pharmaceutical sales are forecast to grow an average of 17.7 percent per year in 2013-17, reaching \$166 billion in 2017. By 2016, the value of pharma sales in China is expected to be greater than that in Japan, currently the world's second-largest market. From an economic perspective, the central government spent an additional \$125 billion in health care expenses above and beyond its planned expenditures over the past three years, and is further increasing its 2013 health care budget by 27 percent to \$41 billion. In addition, China's well-documented, rapidly rising income level has crossed a critical threshold — \$5,000/year in GDP per capita — at which point overall consumption tends to spike.

Fig. 9: Forecast Growth of Chinese market spending on medicine



Also, China's rapid rise in both internet and mobile phone usage is changing patient access and awareness of different types of care. The number of Internet users in China reached more than 540 million at the end of 2012, taking Internet penetration to above 40 percent of the population. Looking at demographic trends, China's population is aging, bringing attendant health conditions and creating demand for life sciences products. In addition, China is becoming increasingly urbanized — the proportion of urban population has grown from 36 percent in 2010 to 52.6 percent in 2012. Urbanization and continued westernization of the population have driven lifestyle changes centered on an increasingly western diet, high prevalence of smoking, and increased pollution, which have materially changed the profile of disease in China. Despite a generally positive outlook, China's life sciences sector faces a number of uncertainties in 2014; chief among them the level of government spending.

China's overall health care expenditures have been highly reliant on public spending. Public hospitals account for more than 90 percent of patient traffic, and public insurance has grown to achieve near-universal coverage over the past decade. In its effort to enhance access and affordability, the Chinese government has consistently increased its health care budget. This spending, however, correlates closely to China's overall GDP growth. The uncertainties surrounding China's much-publicized economic "soft-landing" may impact the continued growth of China's overall health care environment. Fortunately, the rapid expansion of private health care offers attractive opportunities for providers, payers, manufacturers and investors.

Another challenge is continued downward pricing pressure. In response to rapidly growing health care expenditures and continued concern over the pricing of branded generic products, the National Development and Reform Commission (NDRC) have adjusted drug price caps downward five times since 2011. The latest round effectively lowered prices an average of 15 percent for more than 400 drugs, with expectations that high-priced and high-margin ones are subject to further price cuts. NDRC also indicated that Chinese herbal medicine will be the next priority for price adjustments in 2013. Unsurprisingly, the latest revision of the EDL list from National Health and Family Planning Commission (NHFPC, previously MOH) is also expected to be coupled with significant reductions in the

price ceilings for newly enlisted drugs, which could be 40 percent or even higher than the price drop the sector saw in 2009. Hospital budget constraints are also exerting pricing pressure: The growing usage of Diagnosis Related Groups (DRG) and prescription caps across hospitals has further limited prescription frequency and duration by patient type and disease area. These programs have resulted in significant changes in hospital spending and prescription volumes. To meet China's health care goals and address its growing challenges, the public and private sectors will need to develop innovative solutions within a very distinct operating environment. The government will need to continue to alter investments and policies to meet the country's growing demand for access and quality of health care; payers will need to build networks and develop products specific to the country's consumer demographics and needs; and life sciences companies will need to develop innovative products to balance affordability and treatment applicability.

6.4 India

India has a fragmented life sciences industry, with stiff price competition, government price controls, and limited availability of infrastructure. Nonetheless, MNCs are increasing their operations in India and creating opportunities to drive industry growth in the country.

India's pharmaceutical sales were \$22.6 billion in 2012. They are expected to rise to \$23.6 billion in 2013 and reach \$27.0 billion in 2016. As a percent of health care expenditures, pharmaceutical sales were 22.6 percent in 2012; they are expected to reach 23.6 percent in 2013 and 27 percent by 2016. India is among the top five pharmaceutical emerging markets. The double digit growth registered by India's life sciences and health care industry can be attributed to several socio-economic factors, including increasing sales of generic medicines, continued growth in chronic therapies, and a greater penetration in rural markets. Other growth drivers are heightened health awareness, increasing affluence, changing lifestyles resulting in higher incidence of lifestyle diseases, increasing government expenditure on health care, and a nascent, yet fast growing health insurance industry.

In addition, the nation's low cost of production and R&D boosts the efficiency of Indian pharmaceutical companies and its comparative cost advantage enhances Indian pharmaceutical exports. The worldwide demand for cost-effective generic drugs is leading India to rise as a hub of generic drug manufacturing. India accounts for over 10 percent of global pharmaceutical production, with over 60,000 generic brands across 60 therapeutic categories; it manufactures more than 400 different active pharmaceutical ingredients (APIs). The country is the front-runner in a wide range of specialties involving the manufacture of complex drugs. A number of pharmaceutical companies are increasing their operations in India, which has ~180 manufacturing sites approved by the U.S. FDA, the highest in any foreign country. The main focus of the Indian companies is on countries with aging populations such as Japan, Africa, and Latin America, which need cheaper drugs. It is estimated that Indian companies will benefit by about \$40 billion as 46 U.S. drug patents expire in 2012-15. Despite the exponential growth, India's life sciences and health care industry still faces challenges. The outcome of new product patents, drug price control, poor regulatory enforcement, inadequate health care infrastructure, shortage of skilled workforce, increasing patient expectations, ever-changing technology, and quality management and conformance to global standards act as critical barriers in delivering products and services in a sustainable manner. The major challenges being faced by the Indian life sciences sector are:

- **Affordable pricing of drugs:** The government of India is close to having 348 drugs under price control, up from an earlier 74, which is set to impact the retail price of drugs. The move would have far reaching implications on brand-name pharmaceutical manufacturers with patented products rather than generics manufacturers, which are mostly domestic companies whose products are already available at relatively low prices.
- **Poor health care infrastructure:** India's primary health care infrastructure and physician base remain inadequate despite the Ministry of Health and Family Welfare (MoHFW) expanding access into tier 1 and 2 cities through the National Rural Health Mission (NHRM). Also, a high out-of-pocket-expenditure of patients (>70 percent of total health care costs)¹⁰¹ implies that many of them living in underinvested areas either do not have access to health care, or have to pay

significantly higher for treatment because they travel to larger cities and often get treated at a later stage of the disease.

- **Fragmented supply chain:** In India, both pharmaceutical manufacturing and distribution remain fragmented, creating several inefficiencies for the broader system. Lack of effective inventory management systems results in high inventory holding costs, returns, etc. Lack of scale at the retail end of the value chain due to the domination of small chemists also results in lack of economies of scale and higher prices to consumers. In line with the trends, issues, and challenges in the global and Indian life sciences sector, Indian companies need to focus on accelerating drug discovery, advancing clinical trial efficiencies, actualizing end-to-end medical products, increasing manufacturing productivity, enhancing supply chain visibility, improving sales and marketing effectiveness, improving operational efficiencies and reducing costs. Among the measures taken by Indian companies are increasing IT investments to facilitate real time communication and visibility between the R&D and marketing sectors; collaborating with IT companies for services and solutions covering the entire life sciences value chain; and channelizing their sales and marketing initiatives.

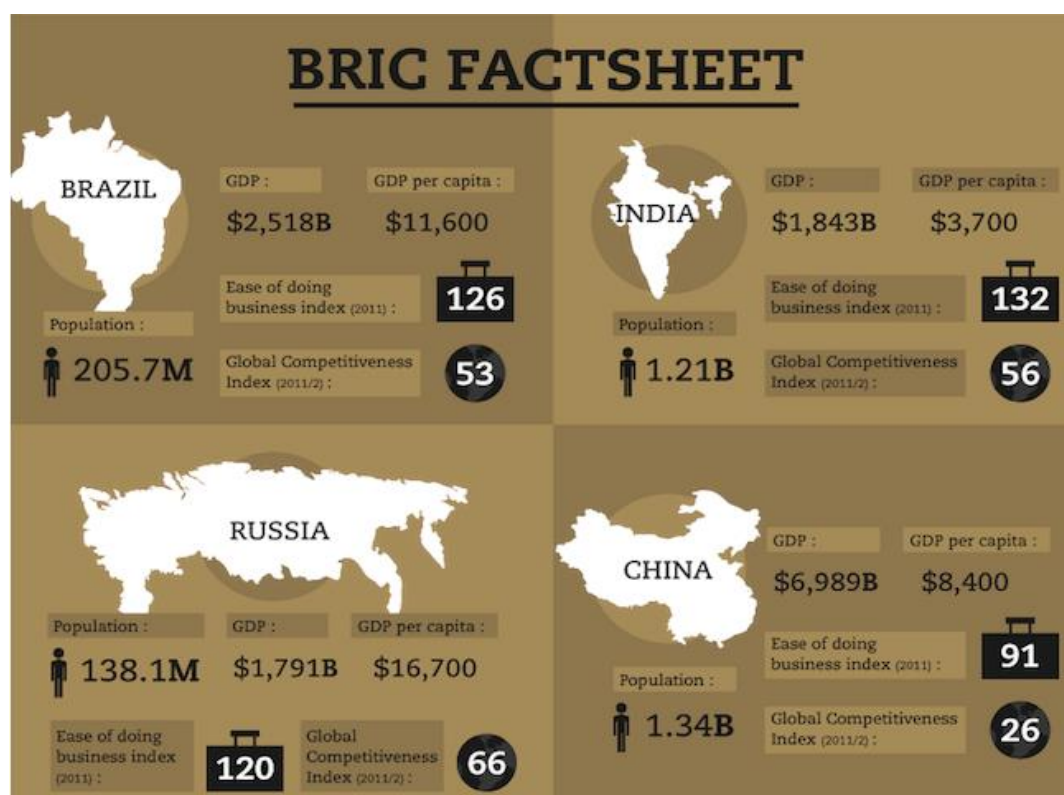


Fig. 10: Summarizing the BRIC nations

6.5 Africa

Africa's potential will reward commitment, engagement and a business model that strengthens the path to market and patient. Hurdles notwithstanding, there is a very real opportunity for the pharmaceutical industry in Africa. This will require long-term commitment and willingness to navigate the complexities and make difficult decisions to optimize margins, volumes and the investment required to build the path to market and patient. Engagement with this market now and in the long term will provide a robust platform for companies to shape the pharmaceutical industry dynamics alongside the broader healthcare environment in Africa.

As mentioned earlier, two African clusters (sub-Saharan Africa and the North African states) are expected to be among the three groups of emerging markets with the highest increase in importance. "We're thinking hard about what happens when those emerging markets start to slow because they are not going to continue growing at the rate that they're growing forever," Joseph Jimenez, chief executive officer of Novartis, recently told the news agency Reuters, "and a place where we're putting a lot of our attention is Africa."

Many consider Africa to be the final frontier of emerging markets. The continent is vast, highly diverse, and full of great potential — but it also presents great challenges. Although sub-Saharan markets are currently embryonic, their expected relative increase in importance is significant and not far behind that of Southeast Asia. This evolution of the continent is defined by a multitude of factors:

- In 2009, the United Nations stated that the population of Africa had hit the 1 billion mark, making it the most populous continent after Asia. This means that around 14 percent of the world's population lives in Africa.
- With a combined GDP of \$2.9 trillion, Africa as a whole ranks fifth in the world — behind Germany, but ahead of France and Brazil.
- Although Africa obviously starts from a lower baseline than other continents, the United Nations Conference on Trade and Development predicts an 82 percent growth in direct foreign investment in Africa between 2012 and 2014, compared with a significantly lower figure of 36 percent in Asia.
- In addition, Africa is attempting to strengthen its economy by leveraging its own resources: The infrastructure ministers of the 15 Southern African Development

Community countries have approved an investment program of \$500 billion for the transport, water supply, communications, and tourism sectors, to take effect by 2027.

- Africa has a growing middle class, with an expected annual disposable income of more than \$1 trillion by 2023.
- As is the case with second-tier markets, South Africa and Northern African countries boast GDPs per capita between \$6,000 and \$11,000.
- Nearly 70 percent of HIV/AIDS patients live on the African continent. This is a huge burden on a growing economy and an impediment to more rapid economic development. An estimated 14 million children in Africa have been orphaned as a result of HIV/AIDS. In addition, infant mortality rates are the highest in the world, at about 109 per 1,000 in some parts of sub-Saharan Africa.

Of course, doing business in Africa poses its own challenges: Africa comprises 54 countries in various stages of economic evolution, medical care facilities, healthcare policy, and population wealth. Sub-Saharan nations, in particular, have a limited economic base from which to kick-start their development, and thus a considerable way to go before they can match the economic pace of the wealthier areas of the continent. The lack of healthcare infrastructure and the unaffordability of medication are the biggest hurdles to growth in the African markets.

As part of the anticipated general economic growth, the African pharmaceutical market is expected to achieve a year-on-year growth rate of 10.6 percent by 2020, resulting in pharmaceutical sales of \$45 billion in 2020. Above and beyond the general economic development, pharmaceutical growth is also driven by governments striving to improve access to healthcare for their citizens. For example, Nigeria, Africa's most populous country, is aiming to implement its National Health Insurance Scheme to provide universal healthcare for all citizens by 2015.

Taking these factors into account, leading participants in the pharmaceutical field consider South Africa and the Northern African economies to be as important for their businesses as second-tier emerging markets. Although sub-Saharan markets are currently awarded the lowest priority, their expected relative increase in importance is the second highest among all of the emerging-market regions, after Southeast Asia.

As a result of the improving standards of living and the more Westernized lifestyle, the World Health Organization predicts that disease patterns in Africa will shift significantly. Infectious diseases, maternal and perinatal conditions, and nutritional deficiencies currently account for nearly two-thirds of Africa's overall disease burden. The incidence of "basic" health issues, such as infant mortality, will decrease.

African markets require tailored approaches. Executives are reluctant to follow a long-term investment strategy in these markets, and in a reflection of their skepticism, they prefer flexible solutions and commit themselves only for the short term.

6.6 Points to be noted

- In 2012, the developed markets in aggregate reduced their medicine spending for the first time, due to a raft of patent expiries and austerity measures, along with policy changes to increase generic penetration.
- Growth in developed markets will rebound from around negative \$3Bn in 2012 to \$20-25Bn by 2017, even as the European economic recovery lags that of the U.S. and Japan.
- The U.S. will resume increased spending levels in 2014 after 2 years of reduction, due to expansion of healthcare access and lower patent expiry levels.
- Growth in Pharmerging markets will increase from \$26Bn in 2012, to \$30-50Bn in 2017, primarily due to increased access to medicines as infrastructure and health systems evolve.
- Pharmerging markets may account for 284USD billion by 2017; a big opportunity for Pharma companies.
- Pharmerging markets will be in the Top 10 spenders on pharmaceuticals by 2017.

Annual spending growth will reach a low point in 2013, followed by increased growth particularly in developed markets

Global Growth, 2008-2017

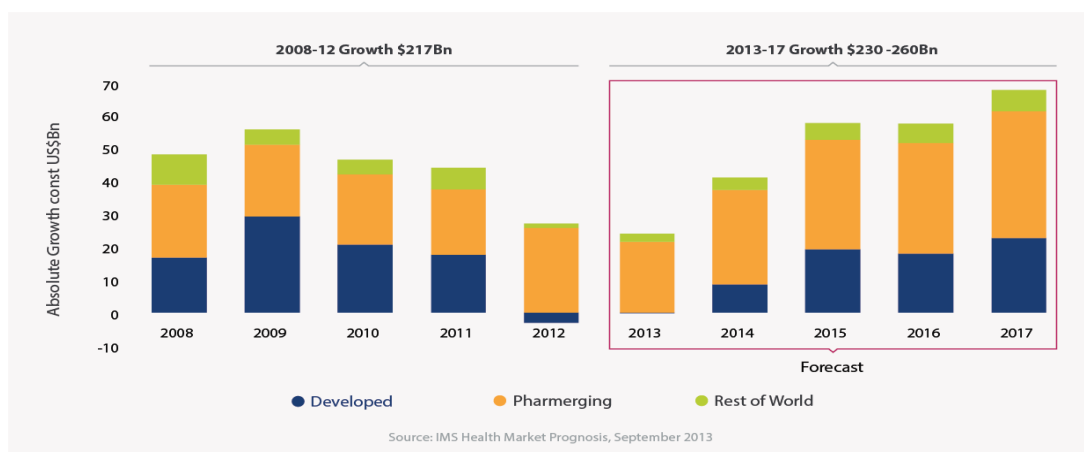


Fig. 11: Global growth of spending on Pharmaceuticals, 2008-2017

7 Results

The study revealed many existing innovative pricing and market access models which are currently in strategies of various pharma companies. It was found that companies made a lot of effort to remain competitive in these markets but there was some gap in their understanding of emerging markets. The study tried to connect the dots to reach a much clearer picture.

The result of the study has been split into 3 sections to make it clearer.

The **first section** includes the overview of existing innovative pricing and access models that are currently used by the companies in emerging markets.

The **second section** includes the complete case studies of 4 drugs- Augmentin, MabThera, Januvia and Galvus in major emerging markets.

And, the **third section** will tell about suggested strategy through the research done which can help the global companies to achieve success in these emerging markets.

Various examples have been included with every model to make it easier to understand.

7.1 Existing pricing and market access models

There are various innovative pricing models which are in practice by Pharma companies. These includes Dual Brand, Voluntary Licensing, Local player partnership, Local govt. partnership, Joint ventures, Capital investment, Tiered pricing, collaboration with insurance companies, micro financing, Patient assistance program, Health Education and awareness. The use of different models depends on various factors like the market where the drug is going to be launched, revenues, reputation, purchasing power parity etc. The study tried to illustrate every model in the best possible way.

All the effective pricing models with their approach cycle are shown in the Figure.

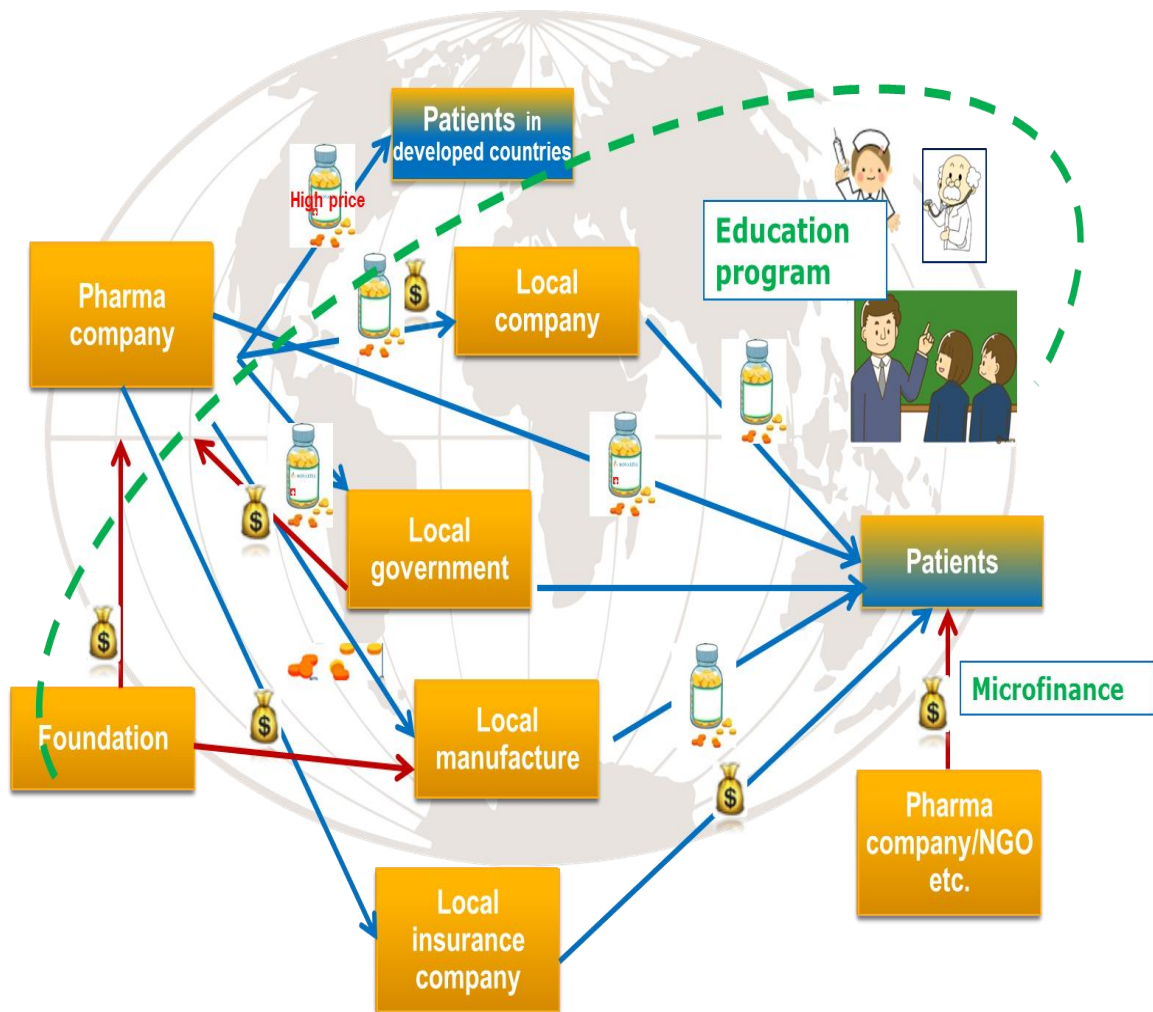


Fig. 12: Pricing and Market access models in EM

7.1.1 Tiered Pricing:

Through tiered pricing, companies adjust prices to assure affordability of products in different social segments. While tiered pricing is nothing new for the pharmaceutical industry, much of the momentum for the current trend towards more systematic pricing strategies in developing markets. It can be either tiered pricing models in the same market (Intra Country Tiered Pricing) or a tiering across market in-between countries and/or regions (Inter Country Tiered Pricing).

GlaxoSmithKline, Gilead and Merck & Co - have all established inter-country tiered pricing policies, based on affordability, in developing countries covered by the Index and for a number of Index Disease products. For example Gilead has developed a tiered pricing system for its HIV medicines, Viread® (tenofovir

disoproxil fumarate) and Truvada® (emtricitabine and tenofovir disoproxil fumarate), through which pricing discounts are given in low- and lower middle-income pricing tiers based on a country's ability to pay. The main criteria used in determining the tier in which a specific country falls are economic status (using gross national income per capita) and HIV prevalence. Gilead's system for pricing its ARVs, Viread (tenofovir disoproxil fumarate) and Truvada (emtricitabine and tenofovir disoproxil fumarate) has two primary tiers, charging a monthly price of \$17.00 for Viread and \$26.25 for Truvada in low-income countries and charging a monthly price of \$30.00 for Viread and \$45.00 for Truvada in lower middle-income countries. Also, Gilead has established partnerships with 13 Indian companies, providing a full technology transfer to enable them to produce and distribute quality, low-cost generic versions of Gilead's HIV medications in 95 developing countries. These inter country pricing model helped Gilead success in both lower and middle income countries.

GSK has been identified as a leading practitioner, committing to price reductions for several of its patented non specialty and specialty medicines across a wide range of Index Diseases. For example in the LDCs, notes GSK's 2010 Corporate Responsibility Report, the company reduced the price of its antibiotic (amoxicillin + clavulanate) by around one third in Francophone West Africa early that year. Six months later, volumes had increased by roughly two thirds. Similar approach is adopted by GSK and others in these cases:

- GSK dropped the price of its allergic rhinitis treatment Avamys (fluticasone furoate) by an average of 45 percent across more than 40 middle-income countries. The results have been “outstanding”, said Abbas Hussain, president, emerging markets and Asia Pacific. The unit sales of Avamys nasal spray for allergies have increased 5 times since a price cut for emerging markets four years ago, while revenue from its enlarged prostate treatment Avodart have swelled 76%. GSK's sales in China were up 20% to 1 billion pounds (\$1.52 billion) last year and up 5.6% to £1.56 billion (\$2.4 billion) across all emerging markets. That was 3.8% of its total revenue, Bloomberg said.
- GSK launched an allergy remedy in Mexico at a 50% discount and, with that cut-rate price, won over a 50% share of that drug's market. Price reductions in emerging markets put Avodart, the prostate drug, on a trajectory to 76% sales

growth. One of Witty's reasons for remaining bullish on India--despite recent moves against Big Pharma IP--is that tiered pricing there has worked for the company.

- In Indonesia, GSK has halved the price of its top-selling inhaled lung drug Seretide, also known as Advair, and its antibiotic Augmentin was slashed by 50% in Brazil in 2010.

Roche had run a successful pilot program in Brazil offering a “really high, substantial double-digit” discount on its cancer drug MabThera (rituximab). The deal was on condition that the Brazilian government covered the cost of the drug, expanding access beyond the previously targeted richer segments of the population who could afford to pay out of pocket.

All these price cuts were made in the expectation that cheaper products would sell better – a strategy has paid off for many companies. But Tiered pricing “is inferior to competition for achieving the lowest sustainable prices; it often involves arbitrary divisions between markets and/or countries, which can lead to very high prices for middle-income markets; and it leaves a disproportionate amount of decision-making power in the hands of sellers vis-à-vis consumers”. Also, a second flaw, the analysis contended, is that “no clear international norm” has been established for setting price tiers, nor is there a “simple or satisfactory” way to allocate payment for R&D costs across various developing countries...

So, the companies are now adding something extra to just “tiered pricing” to improve access. One such innovative model seen is Hybrid model (Tiered pricing & Reputation building) adopted by GSK for African market. In this, GSK's two-year-old least developed countries (LDC) unit was explicitly charged with a dual role - to focus 50 percent on business and 50 percent on reputation across 40 countries in Africa and 10 in Asia. This can be successful for brand conscious market as seen in philippines where GSK got benefited of the brand conscious nature of the Philippines market.

Innovative financing Models: *Affordability is always a concern for pharmaceutical companies while moving towards Emerging markets. Now few companies have started giving financial support to patients with the aim of increasing the access in deeper region of markets. The research found that Micro-*

Finance, Micro-Insurance and Patient assessment programs are commonly used Finance models by companies. Here is some illustration of these:

7.1.2 Micro-Finance

- GSK is introducing a microfinance program to extend access yet further in Indonesia and the Philippines. Christophe Weber, head of GSK's Asia business, described this as a way of helping "patients on a low or unpredictable income". A critical micro financing component that aims to make the treatment affordable. It extends the cost of the 24-week pegylated interferon regimen for patients over a period of 24 to 36 months via equal monthly installment payments of a maximum of INR 5400 (\$89) per month.

7.1.3 Micro-Insurance

- Uplift India Association, an association of NGOs established in 2004, implemented the UpLift Health Mutual Fund (HMF), which has successfully tackled some of these challenges. The fund decreases the financial shock of an unexpected health emergency for community members through community risk-pooling. The scheme allows people to share risk by contributing a small amount (\$2 per person per year). When an emergency occurs, a lump sum amount (max. \$334) can be made available to meet the hospitalization expenditure and to smooth the financial shock. The success of the system relies strongly on the community, which is responsible for setting up the fund. Communities also handle claim management, a model that has been shown to lower transaction costs and reduce the risks of adverse selection, moral hazard and fraud. UpLift's model relies on being healthy and taking preventive care so that the health risks are minimized. This includes a 24x7 helpline and preventive talks. The program works with over 300 health care providers including public and private hospitals and has an ongoing membership of more than 120,000 people. Partnerships with NGOs, a Mutual Insurance Company and an IT company have helped the programme's evolution.
- A system of broad private or public health insurance is essential to improve access to medicines and diagnostics. However, in a number of countries, there is limited health coverage which means that the bulk of costs are paid out-of-pocket by

patients or their families. To help address this, Roche is working closely with local insurance companies in countries such as China, Brazil, the Philippines, Hong Kong, Mexico, Peru and Russia to develop and launch affordable cancer insurance policies, through which patients can now receive appropriate and affordable cancer care.

7.1.4 Patient assessment program

Pharmaceutical companies now run Patient assistance programs to provide free or discounted medications to people who cannot afford to buy their medicine. This increased the access of their drugs in market and also, reputation building for further growth. Pfizer, J&J, Roche, Novartis and BMS have Patient assistance programs for their few drugs from HIV and oncology portfolio.

The few PAP model used by companies are:

Structured PAP:

1: Fixed-Quantity Model: In this type of structured PAP, the number of vials/doses given free is fixed regardless of a patient's financial state.

2: Financial Model: The patient's ability to pay for the drug determines the assistance he or she can get.

Unstructured PAPs:

1: Unstructured PAPs are based purely on doctor recommendation.

Here are some examples of PAP models currently in market:

- **Pfizer:** Oncologists praised this program for delivering the drugs to patients on time. Initial treatment is given for free, and the duration depends on the longevity of patient. The entire treatment is free for patients who live below the poverty line. Other patients receive free vials if they buy a specific number of vials. According to doctors surveyed, the program had little red-tape. However, this PAP is quite fluid; it changes from patient to patient depending on whether the patient can afford the drugs. VCare is the third-party agency that runs this program, although some doctors said they did not know of the agency's involvement
- **Dr. Reddy's Laboratories:** The Sparsh PAP is based on doctor recommendation; they decide who is eligible for assistance. Poor patients get the second vial free

after paying for the first one. Patients do not need to produce a bill to prove they have bought the first vial. For patients with better financial standing, the program offers two-plus-one and one-plus-one/three-plus- three options. To ensure the program is not abused, the company follows up with patients after the drugs are delivered. Doctors praised the transparent way the program is run by the Sparsh Foundation.

- **BMS** sprycel used in oncology has been assisted by company to patients. Bayer asks to fill a form available on their sprycel patient assistance program site website and the assistance is decided as per the case. It depends on the income and insurance status of the person
- **Novartis:** GIPAP is the pioneer in PAPs in India and is the most widely publicized assistance program, with a large patient base. Patients are screened based on their ability to pay and are offered different schemes, e.g., pay for three months and get nine months free or pay for two months and get nine months free. According to doctors surveyed, introducing the eligibility criteria has diluted the effect of the program.

Company	Brand (Molecule)
BMS	Sprycel (dasatinib)
Merck Serono	Erbitux (cetuximab)
Novartis	Glivec (imatinib)
Pfizer	Sutent (sunitinib)
GSK	Votrient (pazopanib)
Sanofi	Aashayein (docetaxel)
Roche	Tarceva (erlotinib)
	Herceptin (trastazumab)
	Mab Thera (rituximab)

Table 7: Patient assistance programs by different companies

7.1.5 Loyalty Cards

- **Pfizer:** An important element of sales volume gains in emerging and developing markets is drug adherence – an issue that must be addressed in countries where large numbers of patients pay for drugs out of pocket. To deal with this issue, Pfizer launched the eCard. This functions similarly to a retail loyalty card. In this case, the customer receives discounts as rewards for adherence to Pfizer's medicines. The level of discounts is determined by how well the patient adheres to the drug regimen, as tracked by the supplying pharmacist. The eCard programme affords customers a 30% – 60% discount on prescription medicine, and also includes educational materials aimed at helping a patient understand and manage their conditions, as well as to understand the importance of adherence. Designed as a programme for emerging markets, the eCard was launched six years ago in the Philippines, where 2.2 million patients are now in the system. It was subsequently replicated in Indonesia and Malaysia, where it respectively reaches 110,000 and 18,000 customers today. Future areas of planned expansion include Russia, Mexico, Brazil, Venezuela and Ukraine.

7.1.6 Dual branding

- In order to increase affordability and access to some of its blockbuster products, Roche entered a partnership with India's Emcure Pharmaceuticals in 2012: The latter would produce Roche's breast cancer drug Herceptin and its lymphoma and rheumatoid arthritis treatment MabThera for domestic sale—under different names and at significantly lower prices. However, the Indian government nevertheless started the process of granting a compulsory license on Herceptin in January 2013; it had already stripped the patent from Roche's hepatitis C therapy Pegasys in 2012.
- Sanofi has used a variant of the "second brand" strategy to keep costs down in poorer countries. For instance, it sells both branded Plavix and its generic version, clopidogrel, in Indonesia, and it's experimenting with two malaria drug pricing tiers in Morocco.

7.1.7 Local players involvement

Local manufacturing, Local operations, local sales force all play a vital role in emerging market strategy. A lot of success has been achieved by pharmaceutical companies by involving local players in their strategy. The good example of this is what done by Novartis for galvus/Eucreas, Novartis found allies in USV Ltd., India's number one company in the oral anti-diabetes drugs segment, and Piramal Enterprises Ltd. which had one of the largest armies of medical representatives across India which increased its access and the sales of Galvus/Eucreas considerably well. The blockbuster drug Januvia and janumet which did exceptionally well in western world was outperformed by the Eucreas and Galvus in Emerging markets. Though Merck allied with Sun pharma later, But it was too late to unseat Eucreas/Galvus.

Local partnerships are already a common effective tool for companies to enhance their position in emerging markets, as is illustrated by a number of examples:

- In January 2014, Biogen Idec and UCB announced that they have signed exclusive agreements granting UCB the right to commercialize Biogen Idec products in South Korea, Hong Kong, Thailand, Singapore, Malaysia and Taiwan, and to develop and commercialize Biogen Idec products in China. Biogen strategy was to leverage UCB's extensive resources, expertise and infrastructure in Asia, which will allow Biogen to grow its footprint in critical Asian markets, get its therapies to patients more quickly and create a foundation for further commercial success in this region.
- In November 2011, Bristol-Myers Squibb announced a technology transfer agreement with the Brazilian Ministry of Health to expand access to Reyataz® (atazanavir sulfate) in Brazil. The agreement is designed to build the capacity and skills required for the Brazilian government to produce a sustainable, high quality supply of atazanavir and will enable the government to become, over time, the sole source of atazanavir in Brazil. The agreement transfers the manufacture and distribution of atazanavir sulfate 200 mg and 300 mg capsules in Brazil from Bristol-Myers Squibb to Farmanguinhos, a technical-scientific unit of Fundação Oswaldo Cruz (Fiocruz) and the largest official pharmaceutical laboratory of the Brazilian Ministry of Health, and Nortec Quimica, a local manufacturer of active pharmaceutical ingredients (API).

- *Russia:* In an effort to become a part of the national immunization calendar, GlaxoSmithKline supplies bulk vaccines and provides technology and expertise to Binnopharm, which then undertakes the filling and packaging. The agreement includes oncological drugs, medication for rotavirus, and pneumococcal vaccines. Pursuing the same goal, Pfizer and NPO Petrovax Pharm have been co-manufacturing pneumococcal vaccine since 2011, and Pfizer provides technology transfer and expertise to increase production quality among local producers, in accordance with GMP standards.
- *India:* Roche has formed a partnership with Emcure Pharmaceuticals to enable affordable versions of its oncology drugs Herceptin and MabThera. The repackaged and rebranded products are expected to launch in 2013.

7.1.8 Capital investment

A lot of companies are now investing in emerging countries as a long term investment. GSK has a relatively long-term investment horizon, so that instead of seeking a return on investments in just one- to two-years, it is planning for three- to four-year time horizons, and perhaps even longer for large programmes. Recognizing that a weak health care infrastructure is a significant barrier to access, the business unit reinvests 20% of its profit into host countries' health care infrastructure, through partner NGOs such as Save The Children, the African Medical and Research Foundation (AMREF), and CARE.

- In November 2012, Sanofi laid the foundation for an industrial facility in King Abdullah Economic City in Saudi Arabia. It would be the first global pharmaceutical company to establish a manufacturing plant with 100 percent foreign direct investment in the country. This project highlights how important Sanofi considers the rapid expansion of its presence in emerging markets in order to maximize revenue-earning opportunities. The corporation also recently received a land concession for a planned investment of \$93 million in Sidi Abdellah, near Algiers, the largest French pharmaceutical complex in the Middle East and North Africa region. Medicine production should begin within three years.
- The manufacturing expansion fits well with the company's strategy for emerging markets, where China plays a big role. "Obviously, China and Brazil drive the

majority of our growth and the majority of our business in the BRIC markets,” Dominic Caruso J&J’s VP of Finance and chief financial officer said.

7.1.9 Govt. partnerships

Government partnership is among the top 5 strategies as per the PWC report. This can be explained by the following example MSD, Qiagen, and the government of Rwanda launched a comprehensive national cervical cancer prevention program in 2011. MSD provided more than 2 million doses of the vaccine Gardasil at no cost. In exchange, MSD was included in the publicly funded routine vaccination scheme.

Other companies going with similar approach are:

- Biogen Idec and partner Swedish Orphan Biovitrum have pledged to donate a whopping one billion international units (IUs) of clotting factor to treat haemophilia in the developing world. The donation should enable doctors to treat more than 75,000 joint bleeding episodes and over 2,000 life-threatening bleeds as well as conduct thousands of elective surgical procedures
- In August the government of Yemen introduced rotavirus vaccines in its national immunisation programme to help prevent thousands of children’s deaths from severe diarrhoea. GSK to supply GAVI with up to 132 million doses of our rotavirus vaccine over the next five years and a minimum of 480 million doses of our pneumococcal vaccine over the next ten years. The vaccines are priced at a small fraction of developed world prices, as they are intended to reach children in the world’s poorest countries where the burden of illness is often the highest. By partnering with GAVI, our vaccines can reach more children. The arrangement provides us with security around high volume and long term supply, allowing us to operate a sustainable business model.
- GSK struck a deal with the Brazilian government. In exchange for knowledge and technology transfers, the state guarantees GSK both a set price and set volumes for its pneumococcus vaccine for children.
- The Swiss drug maker Roche signed a cost-sharing deal with Chinese Government to provide Herceptin, an expensive, breakthrough drug at a 75 percent discount.

7.1.10 Voluntary licensing

Many companies including GSK, Merck, J&J etc. are now sharing their patent rights through voluntary licensing with generic manufacturers. It helps them to increase their medicines access in developing markets.

- GSK plans to share more than 800 drug patents with others seeking new cures for neglected tropical diseases and is cutting prices of more than 100 patented medications by 45% in the world's poorest countries.
- In June 2011, Merck granted two VLs to Indian generic manufacturers, Emcure Pharmaceuticals Ltd. and Matrix Laboratories Ltd., for the manufacture and commercialization of its ARV - raltegravir in 60 Low Income and sub-Saharan African countries. In March 2012, Merck granted two non-exclusive licenses for diabetes medicines to Sun Pharmaceuticals.

7.1.11 Joint Venture

Now this has become a trend in pharmaceutical world. Joint venture helps in penetration into the market. To get into the emerging markets, it seems to be a good strategy.

- Merck to form a joint venture with the objective of providing Chinese patients significantly enhanced access to quality therapies. The partnership will initially focus on branded pharmaceutical offerings for treating patients suffering from cardiovascular and metabolic diseases. In the area of cardiovascular disease, the partnership will offer a combined portfolio of drugs, which includes Merck's Zocor (simvastatin), Cozaar (losartan) and Renitec (enalapril) and Sincere's Xinta (levamlodipine) and Shufutan (rosuvastatin). In the metabolic disease area, the partnership aims to maximise access in China to sitagliptin, a DPP-IV inhibitor for the treatment of type 2 diabetes. This partnership is another step forward in Merck's strategy to grow our business in China.
- In addition, Sincere is also working on a heart drug that BMS had let go idle in its pipeline. If approved, Sincere has exclusive rights to sell it in China but will share proceeds with Bristol-Myers on sales in the rest of the world.
- Pfizer Inc. and Zhejiang Hisun Pharmaceuticals, a leading Chinese pharmaceutical company, launched Hisun-Pfizer Pharmaceuticals Co., Ltd. (hereafter referred to as Hisun-Pfizer), a joint venture formed between the two companies to develop,

manufacture and commercialize off-patent pharmaceutical products in China and global market. This will help expand the product portfolio in therapy areas where Pfizer is weak while lending sales and distribution muscle to penetrate those second- and third-tier urban centers—China has some 160 cities with more than one million people.

7.1.12 Ensure Proper Distribution

- Novartis' SMS for Life pilot project is a PPP with the Roll Back Malaria Partnership, Vodafone, IBM, Google and the Ministry of Health in Tanzania. Its objective is to minimize stock-outs of life-saving malaria drugs, utilizing mobile phones, SMS, Google mapping, and easy-to-use websites to track and manage the supply of drugs. The project is not reliant on Internet access; it is 100% mobile-based, a crucial feature when Internet connections are unreliable. It enables stock tracking and reporting from the central medical store all the way to individual health facilities, ensuring that life-saving medicines are available as needed. A forecasting function uses malaria incidence projections to help determine when a medical store will run out of stock. SMS for Life rewards health facilities for timely response to weekly stock requests with free airtime, and uses a simple code to relay information. To ensure sustainability, an annual subscription to the service has been developed with an affordable fixed \$100 price point for each health centre. This fee allows providers to cover their costs and helps Novartis improve their manufacturing forecasts while reducing the frequency of expensive emergency airfreight deliveries to Tanzania. In pilot districts, stock-out rates have been reduced from 87% –93% to 0% –47% within 21 weeks. Supported by the Swiss Agency for Development and Cooperation, the Medicines for Malaria Venture (MMV) and Novartis, the system has been rolled out nationwide in Tanzania and is today used by over 4,600 health facilities on a weekly basis. Pilots supported by Swiss Tropical Health Institute and Novartis are ongoing in Ghana and Kenya.

7.1.13 Education and Information

The problem with the emerging countries is lack of awareness. People in rural area are not aware of the treatments available in the market which affect both the

people and the pharmaceutical companies. Therefore, many companies came up with the awareness program and had been very successful in increasing market access.

- MSD has embellished its promotional efforts through a comprehensive disease management approach for diabetes using the "Sparsh" (which translates into "Touch" in English) helpline that follows-up with patients for glycemic controls and helps them manage their disease
- GSK working with community organisations, schools, mothers' groups, local doctors, pharmacies, and mobile vans to provide advice and education on health and nutrition in remote rural communities where up to 70% of the population lives. Through this network, GSK is also working with local healthcare providers to increase these communities' access to key medicines to treat diseases that greatly worsen the blight of malnutrition. The Portfolio includes medicines such as Zentel for worm infestations, Fesovit for iron deficiency, other vitamin and mineral supplements and treatments for respiratory problems.
- Counterfeit drugs are a widespread problem, particularly in low income markets. These products either lack active ingredients or contain incorrect or inaccurately measured ingredients. Patients are often unaware of the existence of counterfeits or lack the means to distinguish them from quality products. They suffer from the consequences, in some cases fatally. Pharmaceutical manufacturers, in turn, lose market share since counterfeits are sold for less and contribute to a lack of trust in their products and services. Exacerbating the problem, proper drug legislation, regulation and enforcement are often lacking. Sproxil is a social enterprise that supports pharmaceutical companies in addressing this challenge with an innovative service: an SMS verification system. To verify the authenticity of a drug, customers scratch off a silver panel to reveal 12-digit code on each blister, which is sent via text message using any cell phone. The customer gets an instant response confirming the brand's authenticity. The service is free for users. In cooperation with Sproxil and Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), GlaxoSmithKline (GSK) has successfully applied this service for its antibiotic Ampiclox, which sells a couple of million units a year in Nigeria. Expansion into additional markets in Africa is being considered.

- Novo Nordisk has established an exceptional reputation in the diabetes arena in such pharmerging markets as China, where it has secured a high market share within some of the country's more remote regions, and in India and Russia, where it has achieved major reach with physician and patient disease awareness programs including a 'diabetes bus' and mobile test centers (in Russia).
- Abbott's Indian division, Piramal Healthcare, works to expand access to health care among India's rural villages and urban poor. To this end, Abbott makes use of unconventional communication means, sponsoring a wide range of educational events and health fairs. Allowing locals to learn first-hand about important health topics in their native language has proven more effective than relying solely on advertisements or billboards that require literacy. These fairs also bundle services: Free diagnostics tests, screenings, and advice for both acute and chronic diseases are offered. They are often sponsored in conjunction with a local partner, such as the Indian Epilepsy Society, to raise awareness of specific diseases and provide solutions for patients. Aiming to provide education and information rather than market specific products, these fairs, funded by Abbott's Global Citizenship department, are not part of a business model. They do, however, lay the foundation for market creation.

7.1.14 Opposite Attract: Business-NGO Partnership

Partnership to reduce poverty, improve general conditions, increase access and quality of healthcare and to reduce counterfeit.

- For example: Unilever is integrating social innovation strategies in its business operations. In India, it teamed up with NGOs to create Shakti, a rural network that sells products adapted to rural customers in more than 100,000 villages, employing 31,000 women. In Indonesia, it teamed up with Oxfam to research and assesses the impact of production and distribution processes on poor communities.
- Electricité de France is reaching people in rural areas without electricity through a range of partnerships. Its Energy Access program is carried out with the World Bank, UN agencies, other multilateral and bilateral donors, NGOs and civil society to create small, locally run companies to provide electricity, water, gas and telephone services that stimulate local economic activity and contribute to wealth

creation. The potential is huge: worldwide, 2 billion people still have no access to electricity.

7.1.15 Collaboration with Mobile Phone Companies

Collaboration with Vodafone and other mobile companies to improve patient access has been an effective strategy for many Pharma companies.

For example: mHealth initiatives for data collection, monitoring and treatment support. mHealth is the use of mobile technology i.e. smartphones and tablet computers, to support the practice of medicine and public health, through text messages and apps. 59% of patients in emerging markets use mHealth, compared to 35% in developed markets. Majority of mHealth programs focused on remote data collection or monitoring but also diagnostic and treatment support

- Novartis has ConTacto APP in LACan region offering concierge services for patients through APP.
 - E-Pay: Patient will be able to purchase through ConTacto APP.
 - Express Registration: Enrolment through this app will allow patients to have a faster way of registration.
 - Virtual Card: will be downloaded with a bar code that will be effective at POS
 - Pharmacy Location: Real time information on the location of the nearest pharmacy to patients.
 - Pill Reminder: As all concierge should do, this notification will remember patients to take their medication.
 - Basic Screening Tests: Through APP.

7.2 Case Studies

As said in the previous chapter that BRIC nations and Africa have the potential to be at the top of the Global Pharmaceutical spending list in the coming years, We tried to visualize some interesting and innovative strategies model adopted by some big companies by taking examples of few drugs including Augmentin, Mabthera, Januvia and Galvus. The reason for including these drugs in analysis was the unique approach the company came up with in emerging markets which was quite different from what they did in mature markets for the same drug. The bold and interesting approach makes them an intriguing case for analysis.

7.2.1 Augmentin

Augmentin was launched by GSK in 1984 as an Oral antibacterial combination consisting of the semisynthetic antibiotic amoxicillin (present as amoxicillin trihydrate and amoxicillin sodium) and the β -lactamase inhibitor clavulanate potassium (the potassium salt of clavulanic acid). Augmentin is indicated in the treatment Lower Respiratory Tract Infections, Otitis Media, Sinusitis, Skin and Skin Structure Infections, Urinary Tract Infections. As per IMS Pharmerring markets 2012 report, Augmentin was within top 10 drugs by sales in EMAP. According to GSK 2013 sales report, Augmentin sales grew 5% to £630 million with strong growth in EMAP. It is still growing at the rate of 20%. The approach by GSK for Augmentin in Emerging market was very innovative. They made different strategies according to the markets traits.

We examined the strategies adopted by GSK country by country to have a deeper vision at what happened exactly?

Augmentin in Philippines

Company Strategy: Tiered pricing

- In Philippines, the price of Augmentin was cut by roughly 50%, bringing it close to the branded generic prices.
- Within 18 months of the implementation of the new pricing policy, unit sales of Augmentin had doubled and GSK had reversed the decline of Augmentin market share. But something else occurred as well, the overall value of the amoxicillin market declined

Point to note

- The success of Augmentin in Philippines should also include the fact that Augmentin already benefited from significant brand recognition (the Philippines is a relatively brand-conscious market) and from a high critical mass of “script churn”—that is, doctors who were already frequent Augmentin prescribers responded to price cuts by prescribing it for a greater number of patients presenting with infection—patients who might otherwise have been prescribed a generic.

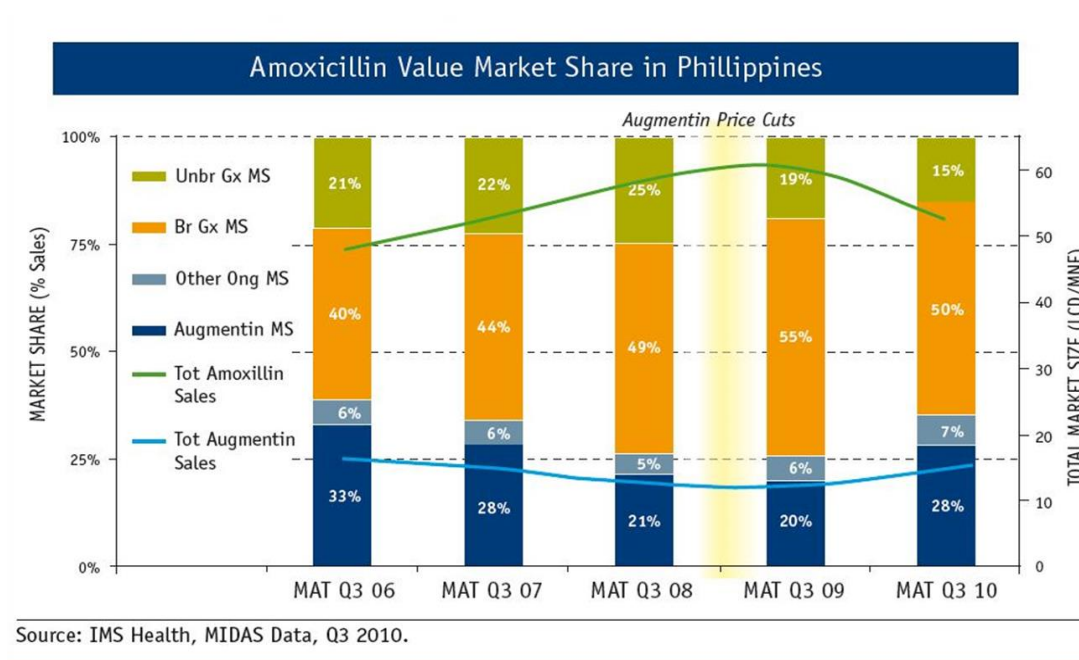


Fig. 13: The price cut effectively reduced the value of the overall market, and share from (unbranded) generics dropped

Results:

- “Decrease in price” resulted in “increase in sales/Volume”. Also, GSK got benefited of the brand conscious nature of the Philippines market.

Reasons for success:

- The Filipino economy expanded faster than that of any Asian country except China, at a rate of 6.5 percent. In 2000, the average Filipino spent less than \$30 a year on healthcare. By 2012, that number had gone up to more than \$100 per year.
- Philippines is the brand conscious market.

Augmentin in Africa:

Company Strategy: Hybrid model strategy (Focus the volume and building the reputation)

- GSK took a different approach by focusing on reputation building in addition to volume-based strategy.
- GSK's two-year-old least developed countries (LDC) unit was explicitly charged with a dual role - to focus 50 percent on business and 50 percent on reputation across 40 countries in Africa and 10 in Asia
- Of the 20 multinational corporations working in Egypt, GSK has the cheapest average price per unit and the highest patient access (heavy price cut)
- GSK in June 2011 entered into an alliance with Dr. Reddy's & in 2009, it bought a stake in Aspen, a generic maker in South Africa to develop and sell selected products across emerging markets which increased its market access more than the other companies which were relying only on their own brands

Result:

- GSK is winning the game of "volume" in the African market and Augmentin is its leading brand.

Reasons for success:

- Africa has 24 percent of the world's health problems and just 1 percent of the budget. Also, it is the second most populous continent on Earth.

Augmentin in Brazil:

Company Strategy: Blanket Cut Pricing

- The strategy includes price cut and collaboration with local manufacturers to increase market access.
- GSK decreased the price of the antibiotic treatment Augmentin by up to 50% in 2010 and volumes increased year-on-year across the range by over 50%
- GSK collaborated with Brazil's Fiocruz which provide access to the country's national immunization program

Result:

- Brazil was GSK's largest market with sales of \$421m equivalent to 32% of the company's total BRIC sales. It had modest single digit growth of 3.6% in this market, Augmentin was the leading anti-infective brand.

Reason:

- Brazil is the fifth largest country in world. Therefore, has high volume.

Augmentin in Indonesia:

Company Strategy: Blanket Cut Pricing

- Company strategy was to increase the affordability and accessibility of Augmentin in Indonesia; a volume based pricing strategy. While lowering the price undoubtedly increased the affordability levels, the coordinated augmentation of sales force and distribution capabilities were important company strategies.
- In 2008, GSK cut the price of its Augmentin by up to 50% in Indonesia.
- While lowering the price increased affordability levels of Augmentin, the coordinated augmentation of sales force and distribution capabilities were critical companies strategy. In fact, GSK astutely increased its sales force headcount and geographical coverage in Indonesia by over 50%.

DEPLOYMENT CONSIDERATIONS FOR GSK'S PRICE CUT IN INDONESIA

Product	Patient Journey	Patient Journey	P-V Strategy*	Deployment Considerations*
• Augmentin • Zinnat • Zantac • Seretide • Avodart • Lamictal • Actifed • Tykerb	• Origination • Awareness/ Presentation • Diagnosis • Referral • Treatment • Fulfillment • Adherence	• Awareness • Accessibility • Affordability	• Blanket Price Cut • Payer-Specific Discount • Income-based Patient Discount • Volume-based Patient Discount • Form-Specific Discount • Second Brand	• Geographic Coverage • Distribution Network • Sales Force Sizing • Segmentation and Targeting • Marketing Campaigns • KPI/Performance Metrics • Initiative Roll-Out • Pricing Risks

Fig. 14: Deployment considerations for GSK's price cut in Indonesia

Result:

- Within a year of Price-cut, Augmentin had rebounded to pre price cut levels. By the third year, GSK had expanded the overall amoxicillin market, while continuing to see an increase in Augmentin's value share.

Reason:

- Indonesia is among top 5 pharmerging markets
- It is fourth most populous country in the world; therefore, Pharmaceutical industry go for volume based strategy in Indonesia

Augmentin in India:**Company Strategy:** Tiered Pricing

- GSK tried to penetrate into the market by taking rural initiative and investing Rs. 850 crore in a new manufacturing facility in India
- In addition to traditional price cuts, GSK has also entered in partnership with NGOs to increase accessibility of drugs in India. Also, GSK took rural initiative named as "Reach Initiative" to increase accessibility In Indian rural markets.
- GSK reduced the price of Augmentin by 44% due to pricing pressure & competition in 2013.
- GlaxoSmithKline plc announced an offer in which it intends to buy about 25% stake in its Indian subsidiary, The move will take the company to 75% stake in the Indian firm, the maximum allowed for promoters under existing laws.
- GSK's strategy also includes using its field-force promoting pharmaceuticals market.

Results:

- In 2010, Augmentin was the highest selling drug in Indian domestic retail market.

Reasons:

- It is the second most populous country on Earth. Also, India's pharmaceutical sales were \$22.6 billion in 2012.They are expected to rise \$27.0 billion in 2016.



Fig. 15: Top 10 products in each market by dollar sales

Augmentin in China:

Company Strategy: Tiered Pricing

- In addition to price cut, GSK strategy in china was to expand the sales force. The number of medical reps were increased by about 1,000 compared with 18 months ago.¹²
- GSK continues expansion in China with the acquisition of Nanjing MeiRui Pharmaceuticals in China.

Reason

- High in terms of volume as it is most populous country in the world
- Pharmaceutical sales are forecast to grow an average of 17.7 percent per year in 2013-17 in china; thereby attracting many pharmaceutical Industries

7.2.2 Mabthera

Mabthera is a monoclonal antibody against the protein [CD20](#), which is primarily found on the surface of immune system [B cells](#). Mabthera destroys B cells and is therefore used to treat non-Hodgkin's lymphoma or chronic lymphocytic leukemia launched by Roche. It is also used for symptomatic treatment of adult rheumatoid arthritis, granulomatosis with polyangiitis (Wegener granulomatosis), and microscopic polyangiitis (MPA).

- Proactive actions along with local factors like political pressure, government focus and compulsory licensing influenced sales performance in Emerging Markets
- Contributes 26% (\$6,445.23 Mn.) of total oncology sales (\$25,236.30 Mn.) and ranks third amongst top 10 oncology products
- 10% (\$658 Mn.) of total sales (\$6368.4 Mn.) comes from emerging markets (Yr. 2013)

Mabthera in Brazil:

Company Strategy

- Starting with a price drop from 2010 onwards. The average price of Mabthera in 2011 was \$1751.21
- Local presence of the company allowed swift capitalization of contributing factors

Contributing Factors:

- Political and media attention to drug in 2011 as the President, diagnosed with cancer and utilized Mabthera

Reasons:

- Listing in Social Security fund for employed people IMMSS formulary
- Direct reimbursement under “Exceptional Medicines” list [Unified health system (SUS) listing]

Comments:

- Price drop wasn't the only factor for sales increase, since price drops in 2012 and 2013 didn't result in further sales increase

Indicators:

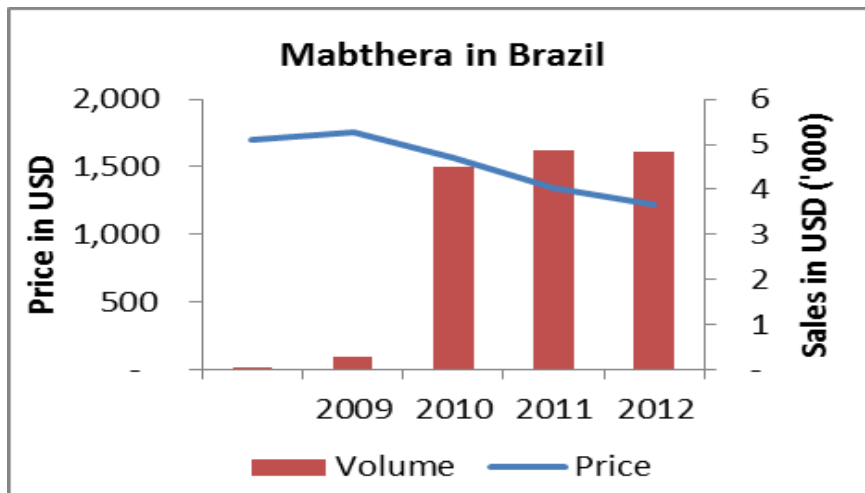


Fig. 16: Mabthera in Brazil

Mabthera in Mexico:

Company Strategy:

- Dual brand Kikuzubam launched in partnership with Probiomed in 2011; at 17% lesser price than Mabthera

Contributing Factors:

- Government favoring active substitution of originators therefore Faster approval for Kikuzubam
- Despite of safety issues it continued in market

Reasons:

- Local partner Probiomed won US\$14.4 Mn. tender of State Employees' Social Security and Social Services in 2011

Comments:

- Dual brand launched as substitute to the originator can gain faster approval
- Prices still have to compete with other biosimilars

Indicator:

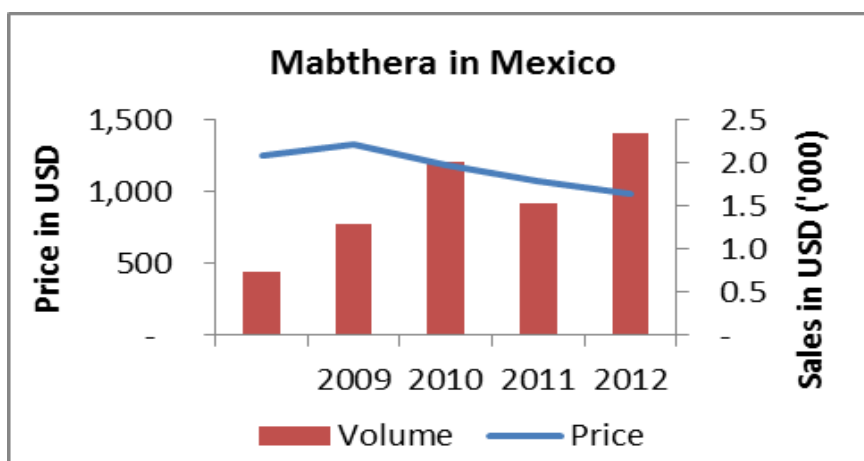


Fig. 17: Mabthera in Mexico

Mabthera in India

Company Strategy:

- Voluntary licensing as a reactive strategy to competitive biosimilar

Contributing Factors:

- Grant of Compulsory licensing caused further decrease in price
- Overall sales for all 3 products declined Q2-Q3

Reasons:

- Dr. Reddy's launched biosimilar Reditux
- Roche launched Ikdar with Emco pharma at 11% lower price than Reditux
- Intas won compulsory license and launched Mabtas at 20% lower price than Ikdar

Comments:

- Voluntary licensing and dual brand could not overcome the challenge of compulsory licensing

Indicator:

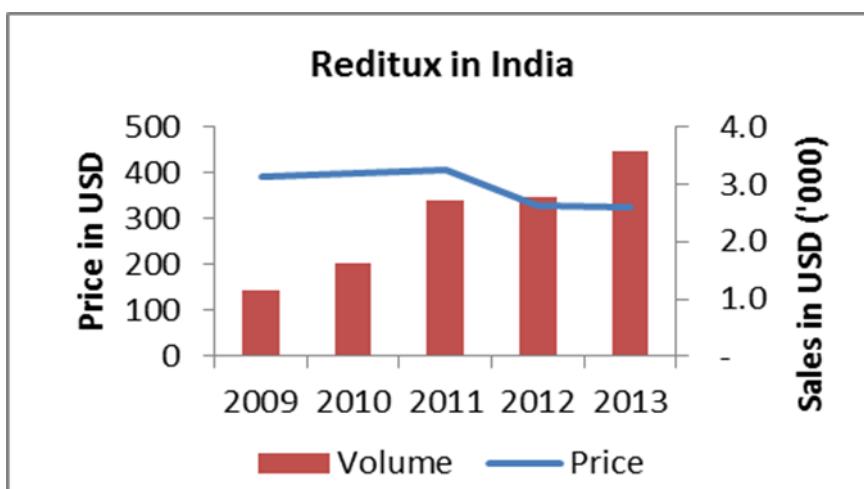


Fig. 18: Reditux in India

Mabthera in Russia:

Company Strategy: Local partnership with Pharmastandard helped to reduce price of MabThera by 15% in Russia.

Contributing Factors:

- Government actively promoting local manufacturing

Reasons:

- Mabthera reimbursed under Programme for seven rare expensive diseases' in 2011

Comments:

- Local partnership can help reimbursement
- Market is price sensitive

Indicator:

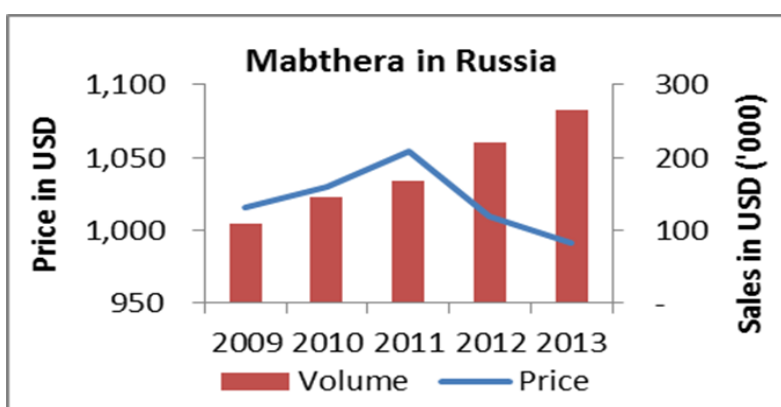
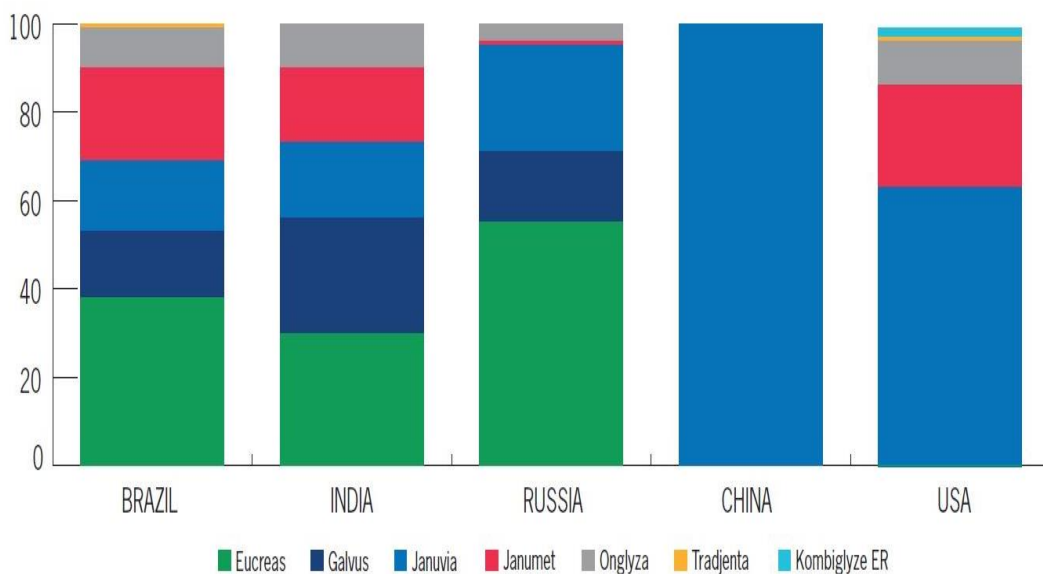


Fig. 19: Mabthera in Russia

7.2.3 Januvia v/s Galvus

Januvia was approved in 2006 as a treatment for Type II diabetes, Januvia was a first-in-class oral dipeptidyl peptidase-4 that was greeted enthusiastically at launch by prescribers, payers and patients. One of the most notable drug launches in recent years, Januvia's market entry was impressive for not only how quickly it got to the market but also how quickly it was embraced by the marketplace. The product exceeded \$750 million in sales in its first full year on the market and hit blockbuster status in 2008, its second year on the market. Januvia's rapid market acceptance was the result of years of pre-launch work to educate the key stakeholders in the diabetes therapeutic area: KOLs, physicians, payers and patients. Given Januvia's new method of action, Merck understood the need to educate - in a cascading manner - these critical groups with targeted messages that related Januvia to each stakeholder's needs.

In emerging markets, Novartis's Galvus and Eucreas account for more than 50% of the DPP-IV market. Share, by country, according to 2011 sales*



* Galvus launched Jan. 2012 in China, so no sales data as yet. Galvus and Eucreas not launched in US. Indian sales include all local brands.

Source: IMS Health MIDAS MAT Dec 2011

Fig. 20: A second chance to unseat the champ

Januvia's dramatic launch was all about speed. Within 24 hours of approval, physician consultants began delivering talks to educate the medical community about the drug. Within 36 hours, reps began making their first sales calls. Within 48 hours, webcasts were broadcast to more than 1,000 scientific leaders. Within

eight days, pharmacies began to receive shipments of the drug, and an estimated 70 percent of target physicians had been brought up to speed on the product. At the same time, Novartis Galvus (also used in treatment of Type- II diabetes) approval was delayed by FDA due to questions of Side effects. So, Januvia was the first DPP-IV inhibitor in the market. With the advantage of first in the market, Januvia dominated sales of DPP-IV products in developed markets. Later launches in the class—such as Onglyza and Galvus have been unable to unseat Januvia from its leadership position.

After that Merck launched its Januvia in Emerging markets, just after that Novartis launched its combination product Eucreas (vildagliptin/metformin), concurrently with its plain product, Galvus in Emerging markets. In contrast, Merck delayed launching its fixed-dose combination product, Janumet (sitagliptin/metformin) until a year after Januvia, its single-compound product, was on the market. Surprisingly, the story was totally different from what happened in mature markets. Though the Januvia was the first to be launched in the Pharmedging markets, Nevertheless, Galvus and Eucreas outperformed Januvia and Janumet considerably.

MERCK'S Strategies (Januvia/Janumet)	NOVARTIS' Strategies (Galvus/Eucreas)
➤ Differential pricing • In India, Januvia was priced at one fifth of cost as it is sold for in US market but still it was 10 times more expensive than the cost of other branded Generics. ➤ Responsible Pricing Strategy • Merck carefully carved out a “responsible pricing” strategy in India by connecting with doctors and patients, winning it a high level of credibility in the community.	➤ Under separate deals, Novartis allowed USV to market vildagliptin under the brand <i>Jalra</i>, and the Piramal Healthcare team – now part of Abbott Laboratories Inc. – markets vildagliptin as <i>Zomelis</i> (Novartis Aimed Double Edged Attack with Galvus and Jalra to Take on Merck's Januvia in India). Novartis executives sensed that to take on an established brand like Januvia, the Swiss pharma needed to have deeper penetration across the country rather than simply focusing on big cities
➤ Aiming to make the most of the growing disease burden in India, Merck has charted out an aggressive growth plan for Januvia, pushing the product through a burgeoning sales force of more than 300 medical representatives out of about 1,700 that it has employed.	➤ Novartis promoted Galvus more heavily than Merck promoted Januvia. Novartis realized the importance of local knowledge means that “going it alone” may not be an effective strategy.
➤ MSD has also embellished its promotional efforts through a comprehensive disease management approach for diabetes using the "Sparsh" (which translates into "Touch" in English) helpline	➤ Novartis also emulated Merck and decided to kick off its own patient management program under the name Praayas, which means “endeavor” in English

that follows-up with patients for glycemic controls and helps them manage their disease. It made a strong impact on Indian Physicians.	
➤ Merck aligned with Sun Pharma via a joint venture to develop and commercialize products as part of its emerging markets strategy.	➤ In late 2008. Novartis found allies in USV Ltd., India's number one company in the oral anti-diabetes drugs segment, and Piramal Enterprises Ltd. which had one of the largest armies of medical representatives across India.
➤ Merck Identified and targeted innovative physicians who would step beyond current treatment paradigms. The idea of targeting innovators is nothing new; in fact, it is an integral part of most launch preparations. What is new, however, is the exponential increase in companies ability to identify and understand innovative physicians as a target group. In the past, companies had to run market research with a limited number of GPs to define segments and then rely on their sales force to categorize prescribers. For instance, before launching Januvia, its type 2 diabetes treatments, Merck had its reps categorize the GPs they visited as "innovator," "conservative," or "traditionalist." With the	➤ Novartis launched its two vildagliptin-based products together (whereas Merck launched Janumet after Januvia).

wealth of information now available, companies can calculate an “innovativeness score”.	
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Table 8: Comparison of Merck and Novartis Strategies

Merck did not capitalize on its first to market position, but waited until after Novartis launched Galvus to increase its sales force. Eventually, three years after launching Januvia and more than two years after the Novartis/USV agreement, Merck partnered with Sun Pharma. Together they launched local brands, Istamet and Istamel, in 2011. This was too late to unseat Novartis’s products, however. In 2011, Novartis’s family of products had secured 56 percent of the Indian DPP-IV market, compared with 34 percent for Merck’s family of products.

NOVO NORDISK	GLENMARK	ELI LILLY
➤ An alternative, but equally successful approach by Novo Nordisk was to focus on more of a blanket strategy, mostly in commoditized segments in diabetes (e.g. insulins, biguanides) to get access to the vast Tier 1/ Tier 2 market populations. Successful Pharma players have launched their entire diabetes portfolio in emerging markets, offering a wide range of product options, building strong physician loyalty with heavy emphasis on education and promotion, and successfully targeting and penetrating areas beyond the large urban centers.	➤ Glenmark Pharmaceuticals has managed to rake in Rs16 crore (according to data available with All India Organization of Chemists and Association) in just eight months since it launched Zita and Zitamet. Glenmark has priced these drugs 30 per cent cheaper than its competitors, a move that's likely to rattle this market in a big way in future. Zita and Zitamet are the generic versions of Sitagliptin, a class of drugs known to fight the insulin levels better than the old-class of diabetes drugs.	➤ Eli Lilly announced plans to set up a team of about 70 diabetes educators to provide counselling services to patients and health-care providers in India.
➤ Spurred by first mover advantage		

and continuing high investment, Novo Nordisk has established an exceptional reputation in the diabetes arena in such pharmerging markets as China, where it has secured a high market share within some of the country's more remote regions, and in India and Russia, where it has achieved major reach with physician and patient disease awareness programs including a 'diabetes bus' and mobile test centers (in Russia).		
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Table 9: Other Companies approach in EM for Diabetic portfolio

8 Recommendations

The major reason behind failure of most of the Pharma companies in emerging markets was improper execution of the pricing and access models. We simplified all the pricing models in 3 sections: Affordability, Availability and Awareness.

Affordability

- 1) Tiered pricing
- 2) Micro-Finance
- 3) Micro-Insurance
- 4) Patient assistance program
- 5) Loyalty Cards
- 6) Dual branding

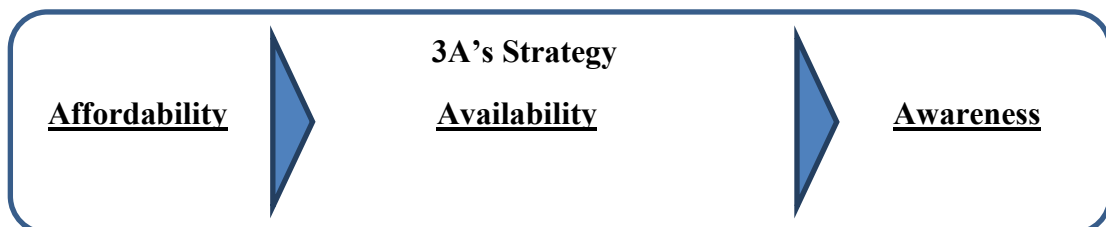
Availability

- 1) Local Players
- 2) Capital Investment
- 3) Govt. Partnership
- 4) Voluntary Licensing
- 5) Joint Venture

Awareness

- 1) Education
- 2) Information

Though all the models were very innovative but the point which most of the companies missed was execution. The strategies followed by most were Affordability or Availability or Awareness. For success in Pharmedging markets, these must be followed in combination, not in parts (mistake done by many big pharma). Our concluding research suggests 3A's strategies to achieve success in this part of the world.



First, the drug to be launched in the emerging markets must be made affordable which is the major concern in EM as there is very low purchasing power parity of people in EM. The companies should focus on the volume not on the value.

As most of the people in EM doesn't have access to the medicines due to improper distribution or supply chain especially in rural areas. Therefore, Companies should put their efforts on ensuring proper distribution in EM to increase patient access.

The problem with the emerging countries is lack of awareness. People in rural area are not aware of the treatments available in the market which affect both the people and the pharmaceutical companies. Therefore, last but not the least; Pharma

companies should do initiatives to make people aware of the disease and available treatment by educating them.

If this 3A's strategy= Affordability + Availability + Awareness will be followed, there are definitely more chances of success for Pharma companies in EM.

The only company we found which executed this was Sanofi:

Sanofi, a leading global pharmaceutical company and manufacturer of malaria medication, and the Drugs for Neglected Diseases Initiative (DNDi), entered into a public-private partnership in December 2004. The partners sought to jointly develop a safe, rapidly acting fixed-dose combination (FDC) to treat malaria in Africa. The result was called ASAQ. The strategies adopted were:

Affordability: From the partnership's inception, acceptable price levels were set at \$1 for three-day adult treatment and \$0.50 for children. No patent would be issued. To reduce the risk of product diversion, ASAQ has a different trade name, branding and distribution channels than Coasucam, a regular pharmacy retail product that has the same active ingredient combination and strength, but higher prices.

Availability: The partnership was set up to produce ASAQ mainly for institutional buyers such as the Global Fund, which typically work through national governments or NGOs to make it available to patients

Awareness: Information and education tools for patients and health care providers give guidance on using the drug safely and effectively along with other services provided by Sanofi's Impact Malaria Program

The collaboration between Sanofi and DNDi reduced the financial burden for each partner and enabled them to combine expertise. Sanofi's annual financial contribution ranged from €6 to €10 million between 2002 and 2009. DNDi supported the project with €8 million collected from various donors. Each partner provided considerable expertise within its own domain: DNDi did much of the preclinical and clinical work with various academic institutions around the world, including in target countries, and subsequently convened an independent panel of experts to provide independent advice on ASAQ distribution and appropriate patient drug use. Sanofi developed the process required to enable production on an industrial scale, conducted pre-clinical pharmaco-toxicology studies, put together the registration files in countries where malaria was endemic, prepared the launch in these countries, and conducted follow-up clinical studies to strengthen local pharmacovigilance

capacities. The results speak for themselves. ASAQ was launched in 2007, one year earlier than Sanofi could have managed independently. The product is WHO pre-qualified, and the business model is sustainable, with 45 million patients treated in 2010.

Interviewed to CEO of a fortune company, on his strategy in EMs; He replied-
“We are the number two in China, as you know. We have the fastest, or one of the fastest, growth rates there and China is now second largest national market on a global basis, so very exciting development there. But also very good results in other markets in the emerging market region. For emerging markets overall, firstly, with China, you can see here strong growth has continued. If we look at the MIT IMS share in China, essentially we were double the market growth rate. So, again, we feel very confident about our business in China. We often get asked are you too reliant on China. You can see here this is the growth rate of emerging markets outside of China ex-factory and there is a nice trend there as we start to see the growth platforms have an increasing share of the business in emerging markets.”

Acc to Mark Clark, MD Deutsche Bank- *“Seeking current trend of Global Pharma industry & emerging markets as well, any pharmaceutical company investing in EMs or aligned markets are only moving to double digit growth. Markets like EU or US are now saturated for revenue generation”*

9 Discussion and Findings

The scope of this research study was to find out all the existing and precedent Pricing models in Pharma industry and using that information conclude a strategy that needs to be adopted to fill the gaps that exist in current pharma pricing strategy. In this desk research, 60 drugs of 18 Pharmaceutical companies from 11 disease areas were included to gather the required information on Business models, Public/Private sector, Price cut, Date of implementation, Specialty/Non-Specialty, Company etc. into an excel file using many different public & private data sources. As per our finding; Tiered Pricing, Capital Investment, Discount cards, Dual brand, Micro finance, Micro Insurance, Health Education & Awareness, Local Partnerships, Joint Ventures, Voluntary Licensing, Patient assistance program were the innovative pricing and access models used by different companies in Emerging markets.

The market analysis of major Pharmedging markets including Brazil, Russia, India, China and Africa were done to find out the complexity in pricing and reimbursement environment, Taxation structure, Distribution channels, Regulatory environment and some other issues that are specific with these markets. We also performed thorough research of 4 drugs in 5 markets as shown in result section the study to get deeper insights.

It was found that the difference in emerging and the mature markets is huge. Therefore, most of the companies did not get the desired success in emerging markets as they went with “one size fits all” approach. Though the existing pricing models used by various Pharma companies were quite unique and innovative. But, the execution lacked the connectivity. Broadly, the three major problems with these low GDP Countries were found to be - Availability, Affordability and Awareness. The study tried to connect the dots to overcome this problem. For example; If a company use “tiered pricing model” to make a drug affordable in combination with “Partnership with local company” and “Health education and awareness” models for increasing its Availability and Awareness respectively; will definitely be more effective than using it alone. So, the study suggests some innovative pricing and access models under all the three sections- Availability, Affordability and Awareness which can be used in combination to eliminate the hurdles in EM. It was also found that Emerging markets are changing very fast;

therefore, the Pharma Company which enters these markets much early with proper pricing strategy will get more benefitted than others.

The following lessons can be learned from previous launches in emerging markets:

First-to-market products:

1) Capitalize on the position: promoting heavily prior to the launch of competitors—and launch combination products quickly in mature markets to reduce the opening for rivals.

2) Leverage pharmerging markets: Form alliances with local companies and consider local branding. Local partners can help shield a product from negative attitudes directed toward the sponsor.

3) As competitive products enter, emphasize homogeneity in the class as a whole, since physicians tend not to switch patients off of existing therapy for a clinically comparable product.

Late-to-market products

1) Look beyond the largest markets for sales opportunities. Pharmerging markets may present opportunities to be first, especially for combination products.

2) Ensure that points of differentiation are really clinically relevant. This will be an issue for the follower DPP-IV and SGLT-2 brands, the majority of which KOLs have had trouble distinguishing.

3) Ensure that other differentiators, such as those that deliver patient convenience, will be recognized and appreciated by prescribers and patients.

10 Conclusion

Global Pharma companies are now increasingly dependent on expansion into emerging markets due to saturation of mature markets. Out of all the emerging markets, BRIC nations seems to be have the highest potential, as per IMS report, it is predicted to be in the top 10 of the world's global pharmaceutical markets by 2017. Many companies face significant challenges in executing this emerging-market strategy, however, including market access elements such as manufacturing, distribution, supply chain planning, pricing, taxation regulation and talent. These challenges explain why even the top pharmaceutical companies in the world are having difficulty breaking through to greater success. Many have no more than 10 percent to 30 percent of revenues coming from these regions. The major mistake done by companies was treating the Emerging markets same as the mature markets and extrapolating the same strategies in EM. Emerging markets are different from mature markets in almost everything; therefore, strategies should also be different while entering these markets.

This study has presented an analysis of different hurdles in approaching Emerging markets. Also, it tried to fill the gap that exists between what companies did in EM? And what should be done in EM? This analysis can give Pharma companies the basis for re-look and modifying their own strategies in EM.

The study recommends a 3As strategy to overcome these challenges and grow revenues in the Emerging markets.

- 1) *Affordability*: The life sciences companies should make their drug more affordable in EM as most of the people in EM can't afford expensive medicines. Effective use of tiered/Differential pricing, Loyalty cards, Patient assistance programs, Micro-insurance and Micro-finance models can be done to achieve this.
- 2) *Availability*: Due to improper supply chain and large out of packet purchase, medicines are not easily available in these markets unlike the mature markets. Therefore, Pharma companies can collaborate with local companies, local govt. or do some capital investment to increase availability of their medicines in EM.
- 3) *Awareness*: Many people in EM are not educated, especially in rural areas. They don't know much about the disease and available therapy. Therefore, life sciences companies need to reach out to people in EM and try to make them aware of their medicine.

Companies that are more advanced in areas such as manufacturing infrastructure, logistics, distribution, regulation, tax and talent management— and, of course, in understanding consumer needs and behaviors—can gain an edge in achieving high performance.

11 Limitations of study

- Using paid sources involve money, acted as constraint at some point of time.
- Interviewing people especially regarding study impart biasness in their views.
- Non availability of latest Data & facts for some areas of study.
- Exclusion of respective local players in markets studied.

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14 Glossary

Developed Markets

Developed markets are defined as the U.S., Japan, Top 5 Europe countries (Germany, France, Italy, Spain, UK), Canada and South Korea.

Pharmerging Markets

Pharmerging countries are defined as those with >\$1Bn absolute spending growth over 2013-17 and which have GDP per capita of less than \$25,000 at purchasing power parity (PPP). Tier 1: China; Tier 2: Brazil, India, Russia; Tier 3: Mexico, Turkey, Venezuela, Poland, Argentina, Saudi Arabia, Indonesia, Colombia, Thailand, Ukraine, South Africa, Egypt, Romania, Algeria, Vietnam, Pakistan and Nigeria.

Compounded Annual Growth Rate (CAGR)

CAGR is the year-over-year growth rate of an investment over a specified period of time. The compound annual growth rate is calculated by taking the nth root of the total percentage growth rate, where n is the number of years in the period being considered.

This can be written as follows:

$$CAGR = \left(\frac{\text{Ending Value}}{\text{Beginning Value}} \right)^{\left(\frac{1}{\# \text{ of years}} \right)} - 1$$

Ex-manufacture/Ex-factory price

Ex-factory pricing is the exact amount a manufacturer charges for the products as they leave the production line. Often distributors and wholesale companies purchase these goods directly from the factory floor or loading docks, providing their own shipping. This practice helps sellers regulate their prices when working with a third party. The ex-factory figure is determined solely by the manufacturer. The price does not include taxes, surcharges or shipping and handling fees. It is often a lower price than a buyer can receive when dealing with a secondary shipping service as a go-between and therefore is preferred by major retailers trying to keep price margins within a certain range.

Gross Domestic Product (GDP)

The gross domestic product (GDP) is one the primary indicators used to gauge the health of a country's economy. It represents the total dollar value of all goods and services produced over a specific time period - you can think of it as the size of the economy. Usually, GDP is expressed as a comparison to the previous quarter or year. For example, if the year-to-year GDP is up 3%, this is thought to mean that the economy has grown by 3% over the last year.

GDP per Capita

A measure of the total output of a country that takes the gross domestic product (GDP) and divides it by the number of people in the country. The per capita GDP is especially useful when comparing one country to another because it shows the relative performance of the countries.

Purchasing Power Parity

The theory that, in the long run, identical products and services in different countries should cost the same in different countries. This is based on the belief that exchange rates will adjust to eliminate the arbitrage opportunity of buying a product or service in one country and selling it in another.

Good Manufacturing Practices (GMP)

Good manufacturing practices are the practices required in order to conform to guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products, and active pharmaceutical products. These guidelines provide minimum requirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public.

ANVISA

The National Health Surveillance Agency (in Portuguese, Agência Nacional de Vigilância Sanitária, **ANVISA**) is a regulatory body of the Brazilian government.

Patent

When a pharmaceutical company first develops a new drug to be used for a disease condition, it is initially sold under a brand name by which the clinicians can prescribe the drug for use by patients. The drug is covered under patent protection, which means that only the pharmaceutical company that holds the patent is allowed to manufacture, market the drug and eventually make profit from it.

Brand-name Drug

A drug that has a trade name and is protected by a patent (can be produced and sold only by the company holding the patent)

Generic Drug

A generic drug is identical--or bioequivalent--to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Once a patent expires, other drug companies then have the right to manufacture and market the generic drug. However, they must market it under a different brand name, or under its generic name.

Ease of doing business Index

The ease of doing business index is an index created by the World Bank Group. Higher rankings (a low numerical value) indicate better, usually simpler, regulations for businesses and stronger protections of property rights.

Global Competitiveness Index

The GCI measures “the set of institutions, factors and policies that set the sustainable current and medium-term levels of economic prosperity” (in other words, those factors that facilitate or drive productivity)

Food and Drug Administration

The Food and Drug Administration (FDA or USFDA) is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements,

prescription and counter pharmaceutical (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.

Compulsory Licensing

Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner

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