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Pharmerging shake-up

NEW IMPERATIVES IN A REDEFINED WORLD



INDIA PHARMA SUMMIT 2012 IPS

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More than three years have passed since IMS Health first coined the term "pharmerging market" in recognition of the major shift in growth away from the mature, developed economies to the seven fast-growing emerging economies of China, Brazil, Russia, India, Mexico, Turkey, and South Korea. Meanwhile, major developments and global recession have driven disparate rates of evolution in each of these countries. With a new raft of pharmerging markets now rapidly rising to the fore, the need for action and informed direction has never been greater. In response to the unprecedented change, and marking a major redefinition of the pharmerging market opportunity, IMS provides the clearest pointers yet to the selection criteria, investment priorities, and critical factors for long-term success.

YESTERDAY'S OUTLOOK

In November 2006, IMS Health recognized a seismic shift in the pharmaceutical markets of the world; a geographic swing away from the major developed powers of the U.S., Japan, France, Germany, Italy, the UK, Spain and Canada to a set of new, dynamic, "pharmerging" markets. Those singled out for their exceptional performance and outstanding prospects for growth – China, Brazil, Russia, India, Mexico, Turkey and South Korea – were expanding at twice the world average rate at that time. Importantly, they were expected to represent 12% of the global pharmaceutical market by 2011 and contribute close to 20% of global pharmaceutical growth from 2006-2011[1] marking a critical signpost to the future direction of the pharmaceutical business worldwide.

Such was the promise of the pharmerging markets in 2006 that each was forecast to grow in excess of 7.5% through 2011, collectively representing US$58bn in new growth. The biggest potential rewards were seen in China, anticipated to be the sixth largest pharmaceutical market by 2011, growing at a compound annual growth rate of 14% from 2006-2011.

TODAY'S REALITY

In the three years since the pharmerging markets were first called out for their high growth potential, ongoing change and new developments have continued to roil the commercial pharmaceutical landscape: patents have been expiring at a significant rate while the industry has struggled to find new sources of revenue to fill the gap; generics have been increasing their volume penetration; the biotech industry – a key growth area – has become chronically underfunded; and everywhere governments have been applying tighter restrictions on their pharmaceutical markets. At the same time, performance in the major developed markets has continued to slow, further widening the regional gap in pharmaceutical growth contribution.

The worldwide economic crisis has also made its mark to varying degrees, adding a new layer of complexity to the already challenging environment. In many of the emerging countries, the level of patient self-pay versus public funding is high and unprecedented pressures have driven significant shifts in healthcare policy. Hardest hit have been countries that are highly dependent on oil and natural resources. Russia, for example, with 40% of GDP driven by revenue from oil and gas, has felt the impact of the recession considerably and is now facing change on a number of fronts including a pending realignment of pharmaceutical prices, potentially tighter restrictions on promotional activity, and a redistribution of influence through the supply chain.

Turkey, too, has been hit by recent events. Decreased prices, strict cost-containment measures, and further pending changes to pricing and reimbursement are

[1] IMS Market Prognosis 2006-10

challenging levels of profitability for pharmaceutical manufacturers, driving down expectations of growth in this market to around 5% through 2013. The Mexican market, while sustaining opportunities from an ageing population, expanded healthcare coverage and incidence growth in key diseases, is also feeling the impact of several issues. These include government pressure on pricing, growing use of generics, and lower brand loyalty to original brands that are due to go off-patent.

Other markets, meanwhile, have continued to gather pace. China's high economic and healthcare growth, for example, has accelerated. The market achieved absolute growth of 27% through 2009, 13% more than was anticipated in 2006, making its profile quite distinct from all other pharmerging markets. South Korea, too, has been gaining ground, now sharing characteristics of the major developed nations. In aggregate, the seven pharmerging markets contributed 29% of global growth in 2009 compared to the 20% anticipated, underscoring the highly dynamic nature of this sector.

Positive developments elsewhere in the world are also helping to reshape the pharmaceutical landscape. In regions as far flung as Latin America and Asia, Eastern Europe and North Africa, a new set of emerging economies are now rapidly rising to the fore. From Poland to Pakistan, Venezuela to Vietnam, a further 13 nations have now reached a threshold of economic development and volume of future growth that warrant close and immediate attention.

Collectively, the pharmerging markets undoubtedly offer high potential, with rising GDPs, expanding access to healthcare and an improving IP and regulatory environment in many cases. Nevertheless, they are fraught with hurdles. Local companies are strong and entrenched, domestic products well-established, and generics dominate the market in a growing number of countries. Patients invariably bear the highest share of healthcare spend, making issues of willingness and ability to pay key in these low income countries. And, going forward, a stronger focus on cost-containment and tighter government controls over pricing can be expected.

Against this background of change and challenge, the need for clarity and informed direction has never been greater.

PHARMERGING OPPORTUNITY REDEFINED

In a major re-classification of global pharmaceutical markets, IMS has conducted a groundbreaking new analysis to bring the clearest characterization yet of the current prospects and future priorities for pharmerging market growth.

The study first divided the global economy into developed and emerging sectors, using a per capita GDP threshold of US$25,000. Countries classified as emerging were then sub-divided using a composite of macroeconomic metrics and market data including GDP and forecasts from IMS Market Prognosis, which are based on a rigorous evaluation of the key events impacting the pharmaceutical and healthcare industries worldwide. The new and refined definition ranked pharmerging markets on the basis of their minimum anticipated added value to the total pharmaceutical market between now and 2013 (Figure 1).

Tier 1: China – in a league of its own

With absolute GDP of US$7.9 trillion in 2008 and a pharmaceutical market that is expected to drive US$40 billion in growth through 2013, the powerhouse of China is positioned firmly at the forefront of the pharmerging markets. Currently the third largest world economy and rapidly moving closer to Japan, it is predicted to surpass the U.S. in GDP to become the world's leading economy by 2027[2]. China is already the largest market for several key industry sectors, including automobiles, mobile phones and TVs.

Fueled by a massive population of 1.3 billion people, aggressive government spending on healthcare and an increasing demand for drugs to treat chronic diseases, China's pharmaceutical sector grew by an astonishing 26% in 2008. At the heart of its healthcare transformation is a landmark US$125 billion incremental government funding, targeting substantial improvement to the nation's healthcare infrastructure and near universal health coverage by 2011 – a move that is projected to double the size of China's pharmaceutical market through 2013. Nevertheless, the operating environment remains complex and challenging, exacerbated by increased local competition, evolving government intervention on drug pricing and uncertainty around healthcare reforms.

[2] BRICs and Beyond, Goldman Sachs Global Economics Group, 2007

Tier 2: Brazil, Russia, India – hot on the heels
With GDP of between US$2-4 trillion in 2008, Brazil, Russia and India are each expected to add US$5-15 billion to the pharmaceutical market through 2013. Prospects aside, balancing the relative benefits and risks of these markets will be paramount to developing a clear position for successful entry or expansion.

Brazil has achieved consistent double-digit pharmaceutical growth over the last few years, continuing at 20% in 2008. The market benefits from a high percentage (85%) of city dwellers, where access to medicines is higher, public health insurance covering around 90% of the population, and increased uptake of supplementary private health insurance. However, out-of-pocket healthcare costs are high and income distribution is poor, limiting the number of people who can pay for innovative therapies. The local environment has seen a number of recent changes, including growing competition from generic medicines, increased government investment in state-owned pharmaceutical plants, and greater emphasis on cost-containment initiatives which tend to favor local companies.

The Russian market has also experienced high double-digit growth in recent years and offers clear potential from increased private insurance and positive developments in the reimbursement system. Physician education is also improving although poor knowledge of prevention, diagnosis and treatment at primary care level and the overall lack of clinical standards and guidelines still impede successful management of chronic disease. High prices, increasing government influence over drug prescribing, and powerful lobbies in favor of local manufacturers are also a feature of this market.

In India, a number of recent developments have been of benefit to outside manufacturers, not least the establishment of Intellectual Property Rights (IPR), as well as a rising middle class population, emerging rural markets and improvements in medical infrastructure.

FIGURE 1. REDEFINING PHARMERGING MARKETS

TIERS	COUNTRIES		2008 GDP[1] ($ TRILLION)	INCREMENTAL PHARMA MARKET VALUE GROWTH[2] FROM 2008-13 ($ BILLION)
TIER 1	1 CHINA		8	40B+
TIER 2	2 BRAZIL 3 RUSSIA 4 INDIA		2-4	5-15B
TIER 3	5 VENEZUELA* 6 POLAND 7 ARGENTINA 8 TURKEY 9 MEXICO 10 VIETNAM 11 S. AFRICA	12 THAILAND 13 INDONESIA 14 ROMANIA 15 EGYPT 16 PAKISTAN 17 UKRAINE	<2	1-5B

Source: [1]IMF GDP PPP in 2008; [2]IMS Market Prognosis Oct 2009, *For Venezuela, pharma value added is 5B+ but mainly attributed to unusual inflation and currency changes. Countries in the table are arranged in descending order of incremental market value growth

Tier 3: Fast followers

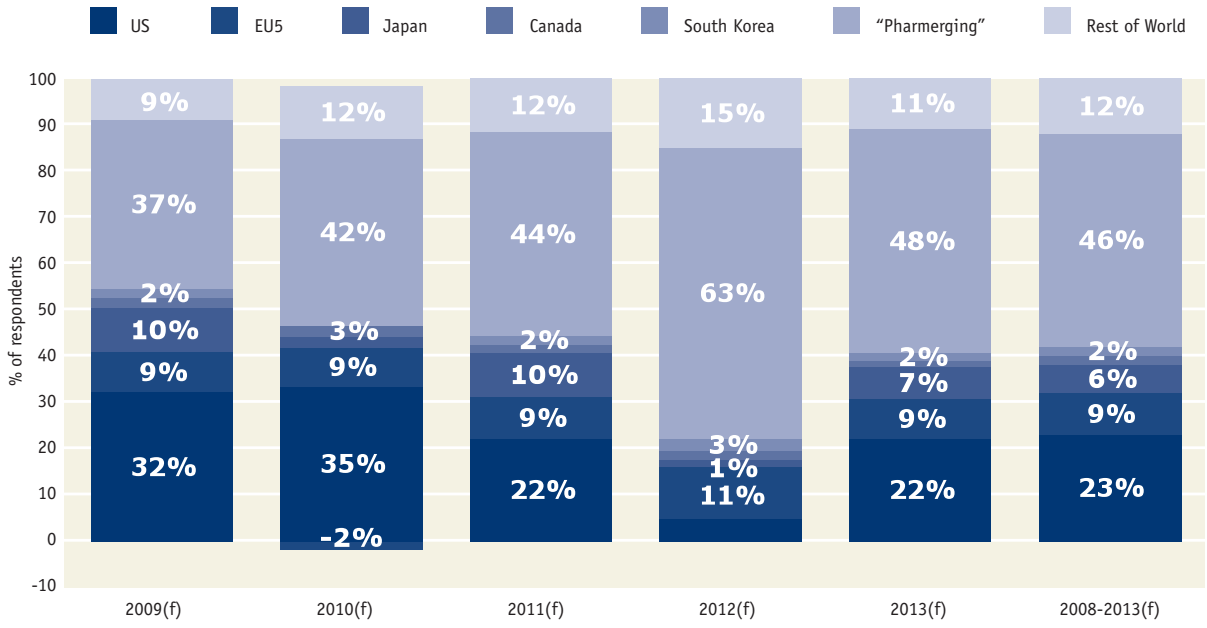
Following fast in the wake of the Tier 1 and Tier 2 markets are a group of 13 far flung nations ranging from Argentina to Egypt, Pakistan to Poland, and the Ukraine to Vietnam. Generating GDP of under US$2 trillion in 2008, with an anticipated cumulative contribution in each market of US$1-5 billion through 2013, these hitherto lesser known pharmaceutical markets offer rich opportunities for growth.

Romania, for example, has been a consistently high-performing market relative to its Central and Eastern European (CEE) peers and is currently growing at nearly 23%. Notwithstanding a reduction in the healthcare budget and challenging new price regulations, a number of major changes will positively impact the pharmaceutical sector over the next few years. These include improvements in public hospital quality, increases in health insurance contributions, healthcare decentralization, expanded reimbursement for pensioners, and healthcare screening for chronic diseases.

Although highly fragmented and with ongoing concerns over drug registration and IP protection, Vietnam is also an attractive market. There are expanding opportunities in the 65+ patient category, an enlarging private insurance market, and increased public funding that will significantly boost growth in the hospital sector.

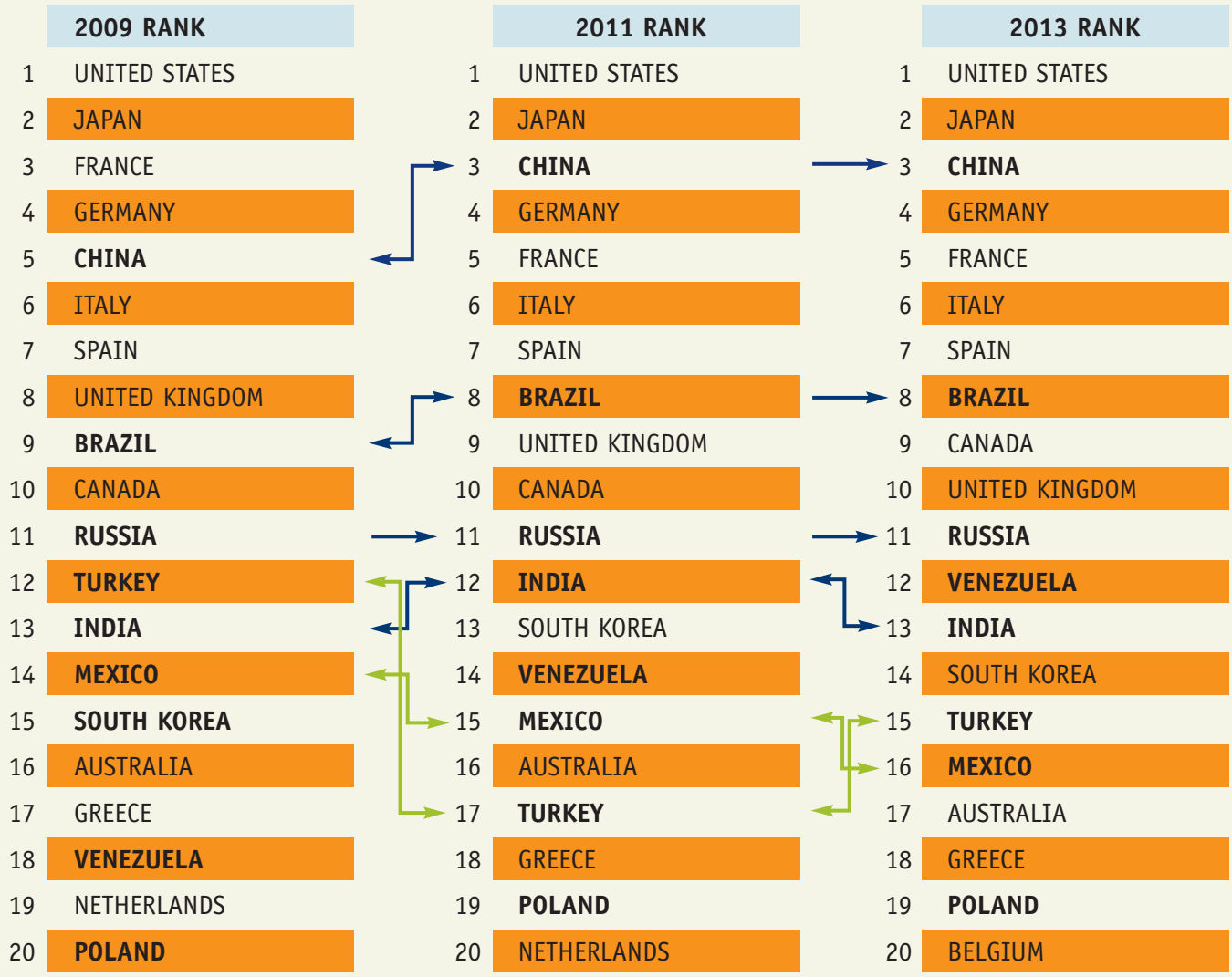
Egypt, too, while long overdue for increased healthcare investment and tighter IP regulations, offers rising potential with a fast-growing population, widespread access to healthcare, significant growth in the dominant retail market and a relatively quick drug approval process. And Argentina's combination of high healthcare spending, an attractive market access environment, and expanding elderly population are all conducive to increased sales growth, despite IP issues, public sector inefficiencies and a sizeable number of uninsured patients.

FIGURE 2. THE PHARMERGING MARKETS WILL BE THE BIGGEST CONTRIBUTOR TO GLOBAL GROWTH IN THE NEXT FIVE YEARS.



Source: IMS Health, Market Prognosis, Oct 2009

FIGURE 3. OLD ORDER GIVES WAY TO A NEW WORLD RANKING OF PHARMACEUTICAL MARKETS.



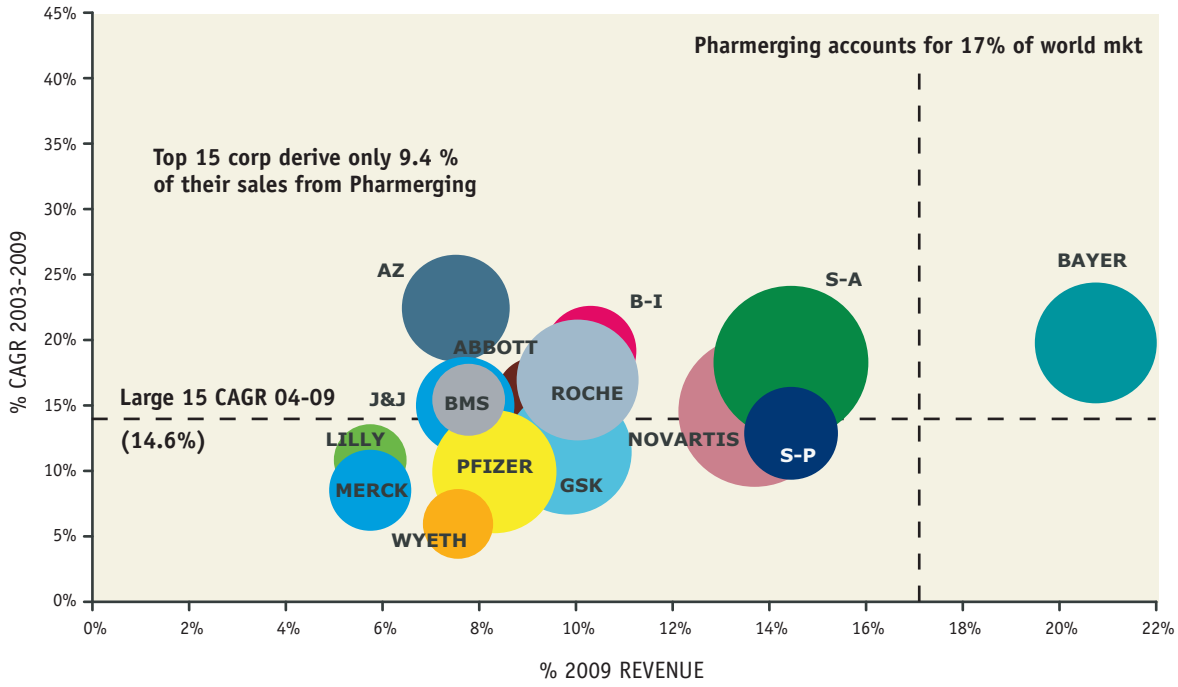
Source: IMS Health MIDAS, Market Prognosis October 2009. Market size ranking in Constant US$.

POWER SWING GATHERS MOMENTUM

The huge swing of power to the 17 pharmerging markets is set to intensify as they continue to gain share at the expense of the U.S. and top five European markets. Superpowered by China, shored by Brazil, Russia and India, and spurred by the impetus of the new Tier 3 fast followers, these markets have delivered an outstanding 37% of global growth in 2009, and are forecasted to reach as much as 48% by 2013 (Figure 2).

With the key essentials in place to drive the market forward, these traditionally peripheral economies are gearing up to turn the tables on the established pharmaceutical world order (Figure 3). For many years simply a minor concern, the pharmerging market segment is fast becoming the platform that will carry global pharmaceutical performance through the next decade and beyond.

FIGURE 4. TOP 15 LARGE PHARMA COMPANIES ARE UNDER-PERFORMING IN THE PHARMERGING MARKETS



Source: IMS MIDAS MAT Sep 2009. Bubble size shows Pharmerging market sales.

IMPERATIVE FOR ACTION

The dramatic change in the rank order of countries that will drive future growth brings a renewed sense of urgency to the management agenda of an industry already under pressure. Experience points to clear advantages for the early movers; companies that take the lead in market entry can often reap the benefits of more discernible differentiation and earlier local entrenchment compared to those that choose to wait. For all pharmaceutical manufacturers comes the need to look afresh at their pharmerging strategy; fundamentally reassess their geographic portfolios to take account of the complexities of each market and their likely evolution over time; and determine where, when and how to capture business before the growth opportunities plateau. Three key elements will be critical to success:

1. Acknowledge and address the urgency

To date, multinational performance in the pharmerging sector has been mixed. A few high-profile pharmaceutical companies have been quick to gain a foothold, several with notable success in generating growth. Among the early movers were Swiss-based Nycomed which, having entered the Russian market in the early 1990s is now ranked number 11 among Russian pharmas. Bayer, too, has achieved much of its recent growth from investments in China and Turkey.

Elsewhere, there are signs that more companies are positioning themselves to build or buy market share in the pharmerging markets. Recent examples include the Sanofi-Aventis acquisition of generics manufacturers in Brazil (Medley) and Mexico (Kendrick), making the French company Latin America's leader in this market; similarly, GSK's expanded partnership with Aspen has paved the way for its increased access to the wider African market; more recently still, Novartis has committed to major investments in China, including US$1bn on R&D over the next five years and $125 million to buy an 85% stake in a privately held vaccine company.

Overall, European pharmas have generally fared better than their U.S.-based counterparts in establishing a local presence. Novartis, Bayer and Novo Nordisk, for example, have all achieved good penetration in Russia while many U.S. players have yet to play catch up. Again, there are signs of positive change in this direction, heralded by Pfizer's recent announcement of a greater push into emerging markets, including China, Mexico, Turkey, Brazil, and India, as well as Russia.

By and large, however, most global drug companies remain under-exposed and under-performing in the pharmerging markets, despite the fact that these new growth engines account for nearly half of the global population. In 2009, the world's top 15 pharmaceutical manufacturers derived just 0.9% of their combined sales from China; 2.9% from the Tier 2 markets of Brazil, India and Russia; and 5.6% from the Tier 3 markets.[3] In many cases, this reflects a continued focus on the premium section of the market rather than the typically larger branded generics segment. There are signs that this is beginning to change with some manufacturers now exploring options for operating in the generics sector.

Clearly, however, securing only single-digit percentages of annual sales from markets that offer a virtual clean slate for pharmaceutical investment leaves significant potential untapped. Companies must act now and act fast to respond to the market changes and seize the opportunities within them.

2. Understand and embrace the complexity

Getting to grips with the many factors that differentiate the pharmerging markets, not only from those in the developed sector but also from each other, is a key priority. Dynamic, volatile and liable to rapid change, these are highly complex and disparate markets and companies in search of fast and easy gains will find themselves on perilous ground.

Despite the fact that Argentina, Poland, and Thailand, for example, are all expected to add between US$2-3 billion in sales through 2013, from an economic, healthcare, regulatory, P&R and market access perspective they are quite divergent. Where Argentina's drug approval process is among the fastest in the world, in Thailand registration typically takes one to two years; while the Polish market is dominated by public health insurance, in Argentina patients and their employers bear the lion's share of total healthcare costs in the form of insurance premiums and out-of-pocket payments; and while Thailand is only just increasing its focus on containing drug costs through pricing, in Poland reimbursed drugs are already subject to regular discretionary price cuts.

Similarly, disease profiles, treatment paradigms and diagnostic rates in the pharmerging markets are not only noticeably different from those of the major developed countries but also subtly distinct between the various tiers. Discrete differences in key market segments, including the role of generics, are a further challenge. Even at country level within the different groupings, disparities are apparent. Each environment is unique. Thus, what is important in China will be very different to what matters in Russia, Indonesia and elsewhere.

Extensive geographic diversity within countries adds a further layer of complexity. Russia, for example, is a vast and diverse geography with 26 regions and pockets of wealth but many much poorer cities; equally, the wide differential between areas and cities across China, each with their own characteristics, physician attitudes, drivers of prescribing, and levels of income and affordability underscores the importance of building city and region-based strategies when expanding in this market. Lack of uniformity in implementing government guidelines is also an issue, making on-the-ground knowledge of each local situation critical.

The competitive arena in pharmerging markets is also very different to that in the mature countries, with power in the hands of local companies who know the operating environment well. While the large multinational pharmaceutical companies have no doubt increased their presence in China, for example, they continue to be outnumbered and outperformed by local manufacturers with their strong geographic reach, wide distribution networks, flexible promotional methods, and close engagement with local governments and hospitals.

Understanding the divergence and distinctiveness of the pharmerging markets will be essential to judicious and rewarding investment in the opportunities they offer. Due focus on generating timely, relevant, on-the-ground insights into their health system dynamics, the national and local economic situation, the degree of infrastructure development, regulatory or government controls, pricing and market access issues, and evolving competitive dynamics will be key to this process.

3. Adapt and tailor your strategy

Since every pharmerging economy is unique and no one country can be defined as a single market, adaptability and customization are key. This means choosing the right portfolio to ensure alignment with the high growth opportunities and local customer needs; building the right sales and distribution model, with the right balance of depth and breadth to increase productivity and ROI;

[3] IMS MIDAS MAT Sept 09

setting the right pricing and market access strategies that will maximize product value; and establishing the right people and leadership to ensure successful execution on the ground.

As companies look to accelerate their plans for investment they must focus quickly on differentiation and use this to drive the value of their business forward. Already there are benchmarks and models for success:

- In Latin America, Novartis and AstraZeneca have taken innovative steps to improve market access through discounts and extra customer service, introducing customer service cards to drive more prescriptions in the region.
- Novo Nordisk has raised its profile in Russia by increasing disease awareness of diabetes in the form of a mobile test center accessible to all parts of the population.
- Local adaptation has enabled Novartis to become the leading player in Russia. The company's strong focus on OTC and generics, its local acquisitions, the solid base of human resources it has built and its strong commitment to the establishment of local government relationships have been key to the company's success.
- The ability to adapt to the local market has been central to Bayer's success in China; by continuously investing in mature products such as Glucobay (for diabetes) and Adalat (for hypertension) the company has been able to achieve a dominant position in these high-growth therapy areas and now derives 3% of its global revenue from China. Superior local execution capabilities and a stable senior leadership team have also played an important role in Bayer's performance in this market.

GOING FORWARD

As current growth trends continue to materially alter the size and structure of the global pharmaceutical landscape, the dramatic swing in power to the pharmerging markets, which was first brought to light by IMS Health in 2006, will only intensify.

Despite some detours in their rate and pace of evolution since then, the fundamentals of these burgeoning economies remain strong. Comprehensive reanalysis of the market indicates that 17 high-performing pharmerging nations, amounting to around 16% of the total world market or US$123 billion in 2009, are about to overturn the established pharmaceutical world order. Rich in opportunities and growth potential, no company can afford to ignore them. But theirs is a constantly evolving story; more changes can be expected, competitive pressures are increasing, the challenges are many and the clock is ticking fast.

Success in the new world order requires an urgent and major reassessment of strategic goals in recognition of the fact that the future pharmaceutical industry will be a very different one from the past. Companies must focus their time and energy on re-evaluating their priorities in the pharmerging markets and building the necessary organizational competencies to embrace the complexities, tailor their portfolios, and adapt their business models accordingly.

With the right fundamentals in place, and the ability to fulfill tactical execution efficiently, they can be positioned to pursue and leverage the pharmerging markets as the major source of growth they represent.

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OUR MISSION

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To enhance efficiency and global competitiveness of Indian industry and to expand business opportunities both in domestic and foreign markets through a range of specialised services and global linkages.

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EGA

The EGA is the official representative body of the European Generic medicines and Biosimilar medicines pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector.
Formed in 1993, the EGA represents generic pharmaceuticals companies and their subsidiaries from throughout Europe, either directly or through national associations. Companies represented within the EGA provide approximately 150,000 jobs in Europe. Costeffective generic medicines save EU patients and healthcare systems over €30 billion each year, thus helping to ensure patient access to essential medicines and providing urgently needed budget headroom for the purchase of new and innovative treatments.
The EGA plays an important consultative role in European healthcare policy-making.The EGA and its members work with the European national governments and the EU institutions to develop affordable solutions for pharmaceutical care and to increase Europe's competitive strength in the global pharmaceutical medicines market.

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