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A quarterly newsletter for the  
life sciences industry



# Life sciences insights

Winning in emerging markets

# Life sciences insights: winning in emerging markets

As the life sciences industry continues to gain complexity, the Ernst & Young Global Life Sciences Center is dedicated to providing timely insights to help life sciences companies explore the evolving business models and execute for success. Our work with companies around the world helps us stay in tune with the opportunities and issues of strategic importance. Each quarterly issue of *Life sciences insights* aims at covering timely topics to help you stay ahead of the important developments in an industry in transformation. In this issue, we focus on winning in emerging markets, and we stand ready to help you as you navigate your way forward.



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Analysts have sent the pharmaceutical industry clear signals that emerging markets are expected to see double-digit growth in healthcare spend in the next three years. We are noticing a global trend with the recent increase in government regulations and healthcare reform initiatives that will surely impact the pharmaceutical industry in emerging markets.

Government regulations have been enacted on a wide scale to make local companies more competitive, to increase the safety of pharmaceutical consumers

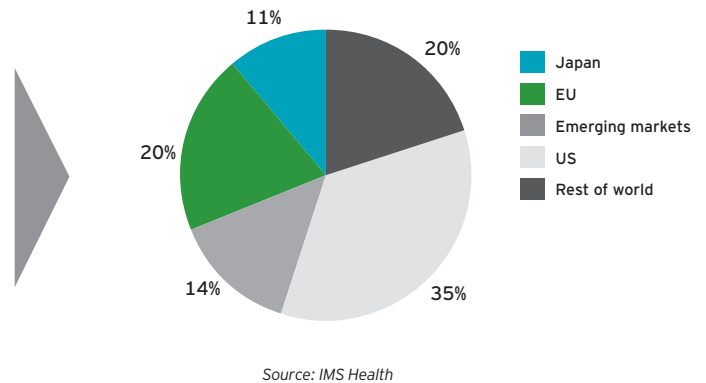
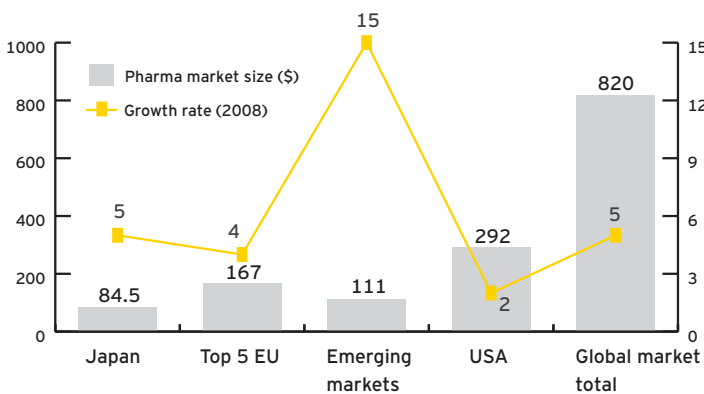
and to bring healthcare to a larger percentage of the population. China's recently passed healthcare reform, which aims at providing 90% of its citizens with healthcare coverage, along with reforms in Mexico and Russia, could yield lucrative new markets for companies to penetrate. To achieve their goals, governments have put in place costly safety requirements for drug-manufacturing facilities, spurring speculation that small-scale facilities may have to shut down because they are unable to comply

# Regulatory reforms could change the pharmaceutical landscape

As economies develop and wealth increases, governments place a higher degree of importance on healthcare. As a result, emerging pharmaceutical markets are growing very rapidly. Recently announced government reforms in emerging markets aimed at bringing healthcare to a larger portion of the population will further

support the growth of these markets and could have far reaching effects for the global pharmaceutical industry. These universal healthcare programs are only just beginning, but could potentially provide multinational pharmaceutical companies with huge opportunities in key geographic markets.

Pharmaceutical market size and estimated growth rate



With a total value of more than US\$111 billion, representing about 14% of the global pharmaceutical market, emerging markets are expected to grow at a rate of 14.5%. Newly enacted reforms would help increase this rate over the next few years.

with more costly operations. If that occurs, there will be a demand for new facilities and a renewed focus on effective capital allocation.

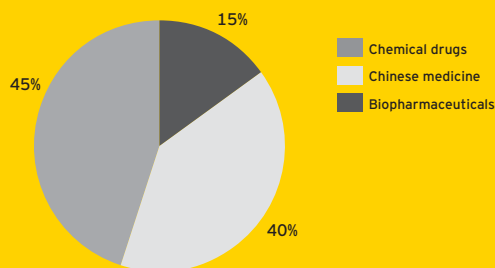
The current economic environment has been a challenge for companies and governments around the world. A noteworthy consequence has been the strengthening of the dollar and the decline of the currencies of key emerging markets, such as India, Brazil, Mexico and Russia. This could have a significant impact on the revenues of the industry.

Positive commitments to the pharmaceutical industry from emerging market governments will have significant implications for the industry, but operating effectively in these markets will require companies to assess the reforms and carefully consider the strategic choices. We invite you to continue reading as we present perspectives to help you leverage the opportunities ahead.

## Spotlight on China

- ▶ Population: 1.3 billion
- ▶ Gross Domestic Product (GDP): US\$4.2 trillion (at official exchange rate)
- ▶ GDP per capita: US\$3,166 (at official exchange rate)
- ▶ GDP 2008 growth rate: 9.8%
- ▶ Pharmaceutical market size (2007): US\$43.1 billion
- ▶ Regulators require that clinical trials be conducted in China (and drugs be tested on Chinese citizens) before compounds are approved, regardless of overseas clinical trials and foreign registrations.
- ▶ The Chinese government is planning to provide basic medical care and health services to all citizens by 2020.
  - ▶ In January 2009, the State Council passed national healthcare reform, the so-called "Healthy China 2020" strategy, which will speed up the creation of a universal medical insurance system and significantly relieve the medical cost burden on patients. By 2011, the medical insurance coverage is to reach more than 90% for both rural and urban dwellers.
- ▶ The pharmaceutical industry in China started out strong in 2009, posting an average 13.5% year-on-year growth in January and February (the fastest growth among 12 major industries).
- ▶ China's pharmaceutical market is dominated by foreign and domestic generic manufacturers, which account for an estimated 75% of sales in value terms and up to 90% in terms of volume.
- ▶ Despite some recent progress, including a pledge to implement intellectual property legislation, significant problems remain:
  - ▶ Patent legislation is rarely enforced. This enforcement may accelerate, though, as new Chinese research and development facilities become successful.
  - ▶ The Chinese legal system is not equipped to deal with complicated technological issues involving patents.
  - ▶ Drug counterfeiting is a major cause for concern in China and is responsible for significant revenue losses for the pharmaceutical industry.

### Chinese medicines industry



Source: Global Insight Report: China (Health care and Pharma), Global Insight, 5 December 2008.

According to the latest available estimates, the Chinese medicine industry consists of several sectors. Biopharmaceuticals and chemical drugs make up about 60%, or about US\$26 billion.



"Healthy China 2020," China's mid- to long-term plan for healthcare development through 2020, is an important instrument designed to achieve universal access to essential healthcare services. China's State Council passed this national healthcare reform plan in January 2009, allocating 850 billion yuan (US\$124 billion) for five reform priorities to address soaring medical costs, the cost and quality gap between urban and rural healthcare and inequities of funding and resource allocation. The strategy will be implemented in three phases:

- ▶ In Phase I, which runs from now to 2010, a framework will be established for an essential healthcare system covering rural and urban patients, to meet the government's overarching goals and targets of the eleventh Five-Year Plan on health development and to reach universal healthcare coverage. A key priority is to increase the government subsidy for residents' medical insurance coverage by 50% per person by 2010. The plan will also increase the reimbursement ratio and maximum limit and the starting line for premium payment. By 2011, this plan will cover 90% of rural and urban residents.
- ▶ Phase II will span 2010 to 2015, during which the government will increase the quality and capacity of its healthcare services with the goal of exceeding the services that are offered by other developing countries.
- ▶ Phase III will span 2015 to 2020, to achieve a fully operational healthcare system with universal coverage, offering essential healthcare services with the goal of offering healthcare services that are on par with more developed countries.

In each phase, priority areas will be identified based on economic development, public health and major risk factors. From these priority areas, action plans will be created and implemented. The success of each phase of Healthy China 2020 will be evaluated using specific indicators and initiatives, including such indicators as average life expectancy, control of major communicable diseases and chronic diseases, accessibility of health services and the scale of health service delivery and health spending.

What do China's actions mean for manufacturers of pharmaceutical products?

Given the country's low rate of insured individuals and large population, China's healthcare reform will create a huge growth market for the pharmaceutical industry. Forty-five percent of China's planned \$850 billion yuan (US\$124 billion) investment in healthcare is earmarked to improve national insurance coverage, which is expected to translate into a significant increase in drug consumption.

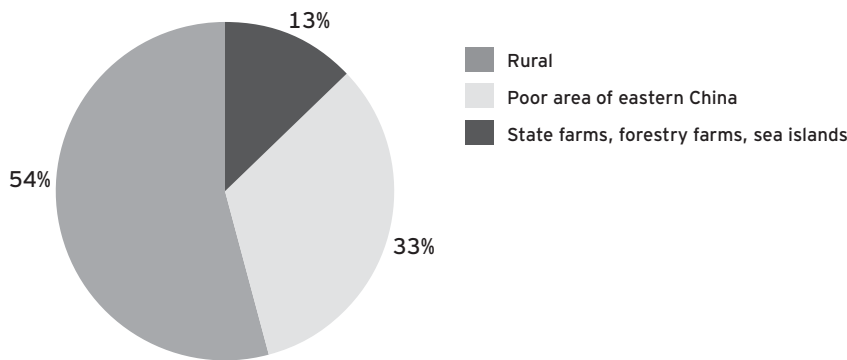
During Phase I, urban residents are expected to experience the fastest growth in drug consumption with a Compound Annual Growth Rate (CAGR) of 128% over the next three years, compared with

the national average of 38%. Rural residents and urban employees are expected to consume the largest volume of medicines, or 268.7 of the 344 billion yuan, 78%, over the next three years. For pharmaceutical companies, the reforms mean pricing pressures from the government offset by increased sales volume of drugs. In China, branded pharmaceuticals are classified as an innovative category of medicines compared to generics. The government has proposed removing this innovative category, placing products currently being paid for at a premium price at risk of being reimbursed at lower

prices. But the government may consider a quality argument – that innovative products are of higher quality – as a rationale for a differentiated price. The industry may want to consider aligning with industry organizations, such as the Research and Development-based Pharmaceutical Association in China (RDPAC), to demonstrate that the innovative category for reimbursement is of value to the health of the Chinese people.

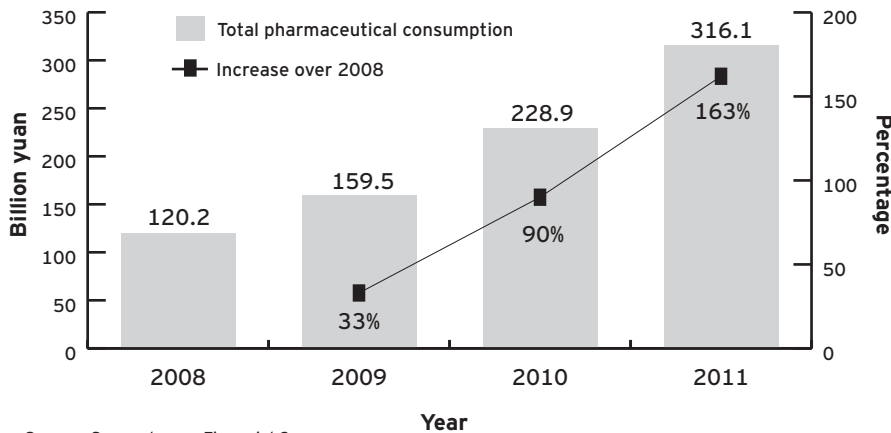
### Distribution of rural healthcare funds

4.8 billion yuan



Source: Derrick Sun, "China Health (Industry outlook)," BNP Paribas, 23 January 2009, via Thomson Research

### China's post-reform pharmaceutical consumption



Source: Susquehanna Financial Group

Phase I of China's healthcare reform is anticipated to result in a 38% three-year national CAGR of pharmaceutical consumption.

## Did you know?

### Tax rebates in China

On 18 November 2008, China's State Administration of Taxation announced that it would raise export-tax rebates for 3,770 products, including major Active Pharmaceutical Ingredient (API) exports such as paracetamol, analgin, acetylsalicylic acid, barbiturate, ciprofloxacin hydrochloride and some cardiovascular drugs. The export-tax rebate increase was the central government's third in 2008, and it is intended to boost the flagging domestic economy.

The hike in rebates is designed to help increase the profitability of China's major API-exporting companies. APIs account for 34% of China's medicine industry by sales. The export-tax rebate on affected APIs, which rose from 5% to 9%, took effect in December 2008.



### Mexico

The Mexican government has also taken steps to improve healthcare for its citizens with a pledge to cover 85% of the country's population under the public healthcare system by 2012. In September 2008, the Health Secretariat noted that it would need to invest up to 100 billion pesos (US\$9.5 billion) to achieve this objective. Much of this investment will be needed to improve the healthcare system's infrastructure, which will expand demand for healthcare products and services.

To further enhance the competitiveness of the pharmaceutical market in Mexico, in mid-2008, President Felipe Calderón officially authorized the amendment of Article 168 of Mexico's Health Supplies Regulations to remove the stipulation that only companies with a local manufacturing plant could market drugs in Mexico. The amendment opens up the Mexican market to a far wider range of imported drugs. In October 2008, Mexico's Senate approved a modification of the health law to oblige Cofepris, Mexico's drug regulator, to supervise the quality of new drug imports. The increase in competitiveness has brought a hike in mergers and acquisitions and entry into drug discovery in Mexico.



### Russia

The Russian public healthcare administrator, the Federal Mandatory Health Insurance Fund, is reforming the system to include coverage for prescription drugs by 2010, enforce national standards in a bid to erase regional inequalities and increase state monitoring to stamp out inefficiency and corruption in the social insurance system. The plan also includes the decentralization of reimbursement decisions, shifting power from the central government to the local regions.

Universal coverage for prescription drugs will expand the already strong demand for retail prescription drugs in Russia, nearly all of which are paid for out-of-pocket under the current system. Although domestic pharmaceutical companies will be the preferred suppliers under the reform plan, the limited number of Russian production plants will likely be unable to meet the demand.



### India

India's National Pharmaceutical Pricing Authority (NPPA) recently established a system to track the supply levels of drugs in the market. The system will allow NPPA to anticipate drug supply shortages and take appropriate action at the earliest opportunity. As part of its plan to oversee drug supply, NPPA has also implemented a new pricing mechanism whereby prices will be set in consultation with the drug manufacturers. This may cause the prices of some drugs to rise, thus providing incentives for pharmaceutical companies to increase drug supplies in India. India's previous policy of government-regulated pricing was a main cause of drug shortages because low reimbursements for drugs facing increased prices for imported raw materials reduced profit margins.

## Final thoughts

The recent reforms have been extensive and will have a profound impact on the future of the pharmaceutical industry in emerging markets. These reforms – China's passage of Phase I of its "Healthy China 2020" strategy, Mexico's expansion of its healthcare system, Russia's proposal of universal coverage for prescription drugs and India's pricing and tracking system – are just a few indications that emerging markets are beginning to see healthcare as a key issue and the creation of a strong and sustainable pharmaceutical industry as an important priority.

The reforms in emerging markets also signify the government's commitment to substantial industry expansion in traditionally overlooked markets. In addition, the reforms present possibilities to boost large-scale Research and Development (R&D) and introduce higher prices for innovative drugs. Although some of the reforms aim primarily to benefit domestic companies, they will also create new chances for development collaboration for multinational corporations (MNCs). Opportunities for MNCs to build new facilities in these markets may arise to meet the increased demand as a greater percentage of the population will have access to healthcare coverage and life-saving medicines.

## Issues to consider

**Customer transformation.** Penetrating, gaining and sustaining access to emerging markets are key challenges for multinational corporations, but commercialization efforts are often targeted primarily at the top 5% to 15% of the wage-earners in those countries. The remaining 85% to 95% of the population represent a much larger-than-average share of the whole and thus represent significant untapped demand for a whole range of products and services. Today, patients in emerging markets who earn less than US\$3 per day purchase more than US\$50b worth of medicines. Designing and developing customer-centric segmentation plans for local markets include a focus on the economics, product/service mix, sales and marketing strategies and infrastructure challenges in those countries and would require a team with local knowledge and insight.

**Pricing strategies.** Often, pricing strategies have put the most beneficial drugs out of the reach of average individuals in emerging markets. Finding the intersection between competing stakeholder objectives and maximizing market penetration and revenue while at the same time covering costs often require considerable time and effort for an organization to arrive at sustainable and dynamic pricing policies. Current pricing policies often focus on infectious diseases and none yet exists for noncommunicable or chronic diseases. Drug donation programs coexisting with strong pricing policies have often been pursued. But how productive are

drug donation programs in emerging markets for individuals other than the very poor? Do they erode market share that could be gained through more aggressive pricing strategies – particularly as these societies become more affluent?

**Sustainable business models.** Healthcare reform measures are sweeping through emerging markets just as quickly as through developed markets. They are challenging the established norms of pharmaceutical access, use and distribution. Each major player in healthcare is being forced to reexamine traditional service delivery mechanisms and policies. These transformational times require transformational execution to achieve new and sustainable commercial models that may be unique for each business entity. Just as governments are improving access to healthcare through healthcare reforms, initiatives to provide access to medicine, such as drug immunization programs, improve MNCs' outreach to rural or previously uninsured populations. Can such initiatives be converted into sustainable value creation by identifying the opportunities for long-term commercial benefits for the organization? What does the business model look like and what combination of products and services should companies be offering their customers?

**Addressing neglected diseases.** The pharmaceutical industry is beginning to recognize the need for and the opportunity represented by developing new treatments and delivery models for neglected diseases. There is an increased level of R&D activity

aimed at addressing such diseases, including collaborations between pharmaceutical companies, research institutes and private funding sources and organizations, many of which have expertise in developing countries (e.g., World Health Organization). For pharmaceutical companies, recognizing the opportunity these diseases present and developing cost-effective treatments and formulations require a paradigm shift to more nimble and agile R&D activities and greater emphasis on a network of business collaborations to share in the risk and reward.

**Agreements with generics manufacturers.** A key focus of healthcare reform is reducing healthcare costs, which often includes the use of national essential-drug lists that favor domestic and generic drugmakers. Through voluntary licensing agreements with generic drug manufacturers, companies maintain ownership of their patented products while reducing the negative perception often associated with higher-priced branded drugs. Licensing has been used for treatments for infectious diseases, many of which have been applied to HIV/AIDS. The Access to Medicine Foundation has found that this licensing trend is on the rise in developing countries although most branded pharmaceutical companies have yet to develop key performance indicators to measure the effectiveness of the agreements. How is your company responding to this trend, and what business strategies are in place to address the market shift?

# Regulatory compliance stresses manufacturing facilities

Governments appreciate the relative resiliency in consumer demand for healthcare products and have made healthcare a funding priority. Even in the face of the economic downturn, emerging market governments are trying to create an environment that will help foster the growth of pharmaceutical industries that are both locally productive and globally competitive.

In addition to more widespread health insurance coverage and stronger intellectual property protection, governments are beginning to implement reforms aimed directly at the manufacturing sector. Normally, such reforms would be a boon to local industry, but in certain instances, financial realities have changed the game. Because of the high costs of compliance with new regulations, small and medium-sized pharmaceutical companies in emerging markets are facing greater financial pressure and are often unable to adapt to the new requirements. As a result of new regulations aimed at current Good Manufacturing Practices (cGMP), it is expected that, over time, many manufacturing plants will close. This, along with the growth of pharmaceutical markets in key emerging countries, presents a unique opportunity for MNCs to meet increased demand for cGMP-compliant facilities and products.

India has very ambitious plans for increasing pharmaceutical exports and becoming a global manufacturing outsourcing hub. This goal has resulted in stricter regulations that present compliance challenges for small-scale drug players. Since 2005, India – with

more than 80 US FDA-approved plants, the largest number in any country outside the US – has required strict compliance with cGMP regulations and a minimum 200-million-rupee (US\$4 million) turnover to participate in government drug tenders. This has led more than 1,000 small-scale Indian drug manufacturing companies, employing more than 100,000 people, to cease operations. An additional 2,500 companies face imminent closure, with the potential for more if the global economic downturn results in fewer outsourcing activities as companies become more frugal with their R&D budgets.

Like India, Russia hopes to increase its own pharmaceutical production by reducing the dominance of imported medicines. The Russian government is implementing a new cGMP compliance regulation that could lead to the widespread closure of pharmaceutical production plants. According to the Association of Russian Pharmaceutical Producers (ARFP), as many as 70% of the country's drug production plants (300 to 349 facilities) could be forced to shut down by 2010 because of the companies' inability to afford the upgrade needed to meet the new requirements. Russia's pharmaceutical industry has already seen a great deal of consolidation in recent years, and new cGMP compliance rules could further reduce the number of Russian pharma companies operating inside the country.

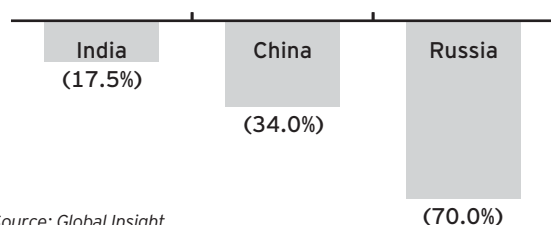
In China, new environmental protection regulations will require drug manufacturers to restrict their upper limit for chemical oxygen demand (a measure of water pollution) to just

120 mg per liter by July 2009. Since this will cause a 5% to 10% rise in production costs, many small and medium-sized drug manufacturers will struggle to meet the new controls, possibly resulting in the closure of their plants. Because implementing cGMP standards has been difficult for the estimated 5,000-plus pharmaceutical manufacturers in China, analysts are forecasting that approximately one-third of the manufacturing industry will disappear. These small, mostly state-owned companies will not be able to absorb the associated increase in operating costs and will not be protected by the state. Big pharma MNCs won't feel the impact due to the nature of their business. The new circumstances will, however, give them an edge against local competitors in the market.

## Questions to consider

- ▶ With cGMP regulations changing, are your affected plants in compliance?
- ▶ Are your API, excipient, intermediate, packaging and parts suppliers in compliance, and when was the last time a vendor audit was conducted?
- ▶ How can the risk of supplier loss be mitigated?
- ▶ Are there opportunities to collaborate or acquire small and medium-sized firms in emerging markets?
- ▶ Would acquiring local firms make strategic sense?

## Expected plant closings due to current reforms



Source: Global Insight

## Issues to consider: supply chains in distress and manufacturing alliances

**Supply chain risk.** The financial stability of key suppliers is critical to the successful operation of a pharmaceutical company. For most companies, supplier stability has not been an area of concern over the last several decades. However, today's financial landscape has brought into question the long-term viability of even the most financially secure companies because their ability to manufacture, operate and deliver in both developed and emerging markets has been compromised by factors outside of their control. Many in the industry have not taken the time to evaluate the exposure and level of risk associated with key suppliers that lack the financial health to deliver contracts for key components in the manufacturing and supply chain process. Executives should consider the following supplier stress indicators:

- ▶ A request for improvement in payment terms
- ▶ Substantial compensation/piece-price increase for a commodity or other consideration(s)

- ▶ Extended credit terms with its supply base either formally or through nonpayment
- ▶ Use of factoring or a request to implement reverse factoring
- ▶ A pledge of some of the supplier's stock
- ▶ Major and/or multiple sale-leaseback transaction(s) in an effort to monetize its assets and generate liquidity
- ▶ Turnover in top management positions within the past six months
- ▶ News that a subsidiary/sister company of the supplier's has just filed for bankruptcy or has been liquidated
- ▶ A delay in some investments
- ▶ Increased involvement in litigations with third parties
- ▶ Noticeable difficulties dealing with trade unions
- ▶ A sudden rise in defects and quality issues, on-time delivery concerns and/or expedited freight deliveries
- ▶ A spike in activity in acquisitions/divestitures/plant closings
- ▶ A change in ownership in the past six months

**Manufacturing alliances.** Emerging markets may represent opportunities for developing manufacturing alliances and joint ventures at the local level to meet local market demands. Creating such business partnerships can be a complex venture from many perspectives, including deal structuring, governance, regulatory compliance and total quality and safety. How prepared is your organization to address and consider the multitude of options that may be presented by such alliances?

**Operating performance and cash flow.** Global pharmaceutical companies have taken on some of the attributes of global trading companies with a complex supply chain that has thousands of "goods and services" crossing hundreds of borders every day. Pharmaceutical companies can reduce their overall tax burden by enhancing operating performance and cash flow through identifying customs and duty cost/penalty reduction opportunities in their global trade flows. Another source of tax relief can come from proactive planning around a tax-effective supply chain and transfer pricing regimes that reflect the new business model realities.

# How foreign exchange (forex) can drive the pharma industry in 2009

In a challenging economic environment, pharmaceutical companies of all sizes are adapting their product development strategies. R&D investment and cash reserves are often considered in assessing the effect of the economy on the global pharmaceutical industry. However, another factor – foreign currency valuations – has had a significant impact on the industry and is likely to continue to do so. In fact, Deutsche Bank predicts that currency valuation will be one of the main drivers of pharmaceutical companies' earnings in 2009.

The US dollar has grown stronger in 2009 as the economic downturn spread throughout the world. US companies with a significant foreign market presence are

experiencing declining earnings as the US dollar strengthens. This is because a weaker local currency means fewer US dollars when revenues denominated in local currencies are repatriated to the US and converted into US dollars. All exporting pharmaceutical companies will feel this pinch when selling products to markets that are seeing their currencies depreciate against the company's home currency.

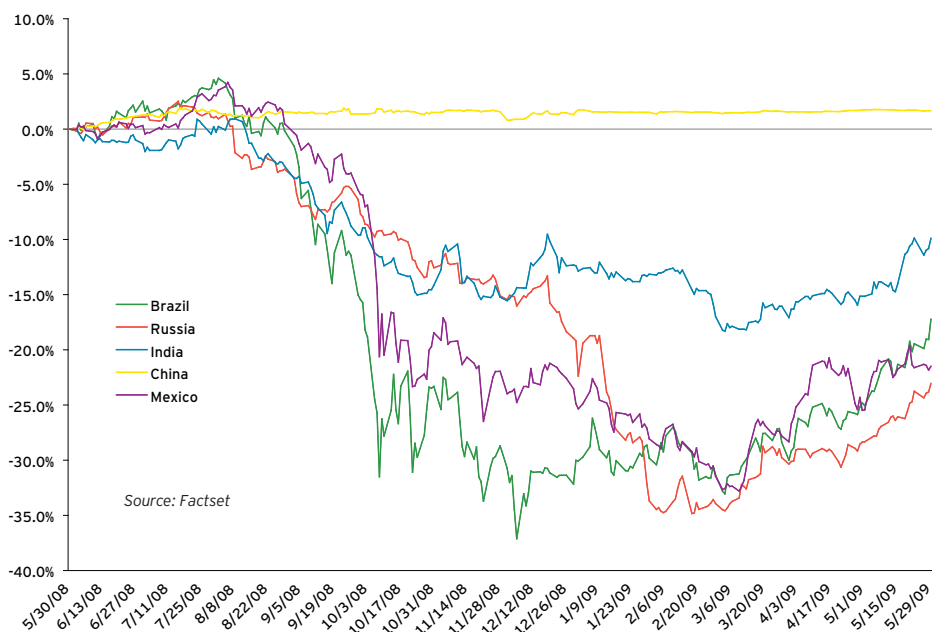
A continued decline of emerging market currencies will have a widespread effect on the global pharmaceutical industry. For big pharma, this means that foreign goods, including raw materials, will become cheaper.

In emerging markets, however, exports will likely drop as the local prices of imported

drugs rise due to currency valuations. In addition, locally based pharmaceutical companies will see their costs, especially for the import of APIs, rise considerably. These companies could see the costs of imported goods, including raw materials, increase by 30% or more. Because of increased costs, companies may be forced to look for cheaper manufacturers and will have to consider producing some products and ingredients in-house or through local partnerships.

The recent depreciation of the Russian ruble against the US dollar has had a significant impact on the price of medicines in Russia, where the average price pack was predicted to rise by 20% in the first half of 2009. The ruble depreciation is affecting imported

## Indexed change in US dollars against selected foreign currencies



Source: Factset

Over the past 12 months, emerging market currencies, aside from that of China, have depreciated significantly against the US dollar, some by more than 25%. This could have significant implications for the revenues of big pharma and the operating costs of locally based companies.

## Questions to consider

- ▶ How much gain/loss comes from foreign currency valuations?
- ▶ What level of exposure do you have to foreign currency fluctuations?
- ▶ What percentage of your business is denominated in foreign currencies?
- ▶ Does your company effectively use derivatives to control the currency risk related to business transactions?
- ▶ Are foreign currency hedging contracts used to mitigate risk? Are they effective?
- ▶ How active is the foreign government in influencing the value of its currency?
- ▶ Is your company exposed to currency risk related to foreign investments?
- ▶ Can your current facilities in emerging markets take advantage of foreign exchange and export?

medicines as well as domestic manufactured medicines whose manufacturers are reliant on imported APIs.

The global financial crisis has also affected several Indian pharmaceutical companies as the decreased valuations for the Indian rupee against the US dollar have led to the increased cost of imported raw materials and a subsequent reduction in profits. India is a net exporter of raw materials and API intermediates and excipients, and therefore the effect has been considerable. Normally, a sliding rupee would help an export-oriented sector like the pharmaceutical industry because exports are cheaper and thus sell better. But these gains are being offset as imports, including raw materials, have become more expensive and are squeezing margins. The Pharmaceutical

Export Promotion Council of India estimated that in the absence of the financial crisis, pharmaceutical exports would have grown 23.87% in Indian rupee terms and 13.89% in US dollar terms in 2008.

Currencies in Mexico and Brazil have also depreciated against the Euro and US dollar, causing the domestic prices of imported goods from those markets to rise. The devaluation of the Brazilian and Mexican currencies should support the competitiveness of their exports. Neither country, however, is a net exporter of pharmaceutical products although the governments of both nations have implemented reforms aimed at making their local pharmaceutical industries more competitive globally.

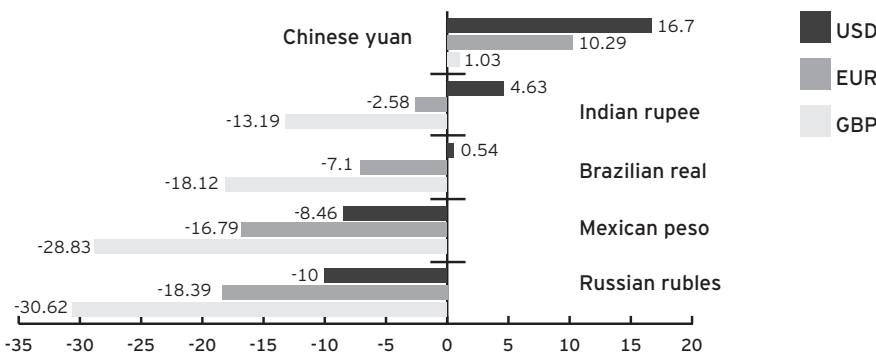
## Issues to consider: currency fluctuations

**Hedging.** Companies with significant revenue coming from overseas operations naturally have the most foreign exchange risk. This is a necessary cost of doing business in the global economy, but companies should take advantage of hedging options to mitigate the risk as much as possible through hedging with forward exchange contracts. Successful hedging strategies and the unstable state of many financial institutions will require counterparty risk analyses to ensure that the institution will be able to meet its contractual obligations over the term of the hedge.

**Tax considerations.** MNCs or companies with foreign branches must consider tax planning and currencies for tax return reporting requirements, data collection requirements and processes to help mitigate the effects of foreign currency gains and losses and potential dual consolidated losses.

**Acquisitions.** Pharmaceutical companies may be in a strong position to look for acquisitions, raw materials and even finished goods from emerging markets whose currencies have been depreciating.

Currency rate fluctuation (%)



Source: OANDA Corporation

The currencies of several emerging markets have depreciated significantly against the US dollar and the Euro, but have remained stronger against the beleaguered British pound.

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