

Accenture Life Sciences

Five Branded Generics Strategies to Master for Global Pharmaceuticals in Emerging Markets

By Tina Gilbert, Arda Ural and Myriam Lopez

High performance. Delivered.



000001

Exhibit 1137
IPR2017-00807
ARGENTUM



Introduction

Emerging markets can be tricky for pharmaceutical players that are more comfortable operating in a developed market environment, but coming to terms with the unique challenges these markets hold may separate winners from losers—especially as the competitive battlefield shifts to a more global footing. Emerging markets are home to more than 70 percent of the world's population, covering 46 percent of its landmass and are generating 31 percent of its GDP¹. Thus, they represent the next big growth engine for the industry. What's more, a recent study² forecasts that by 2016, emerging markets—including Brazil, China, India, Indonesia, Mexico, Russia, and Turkey—will account for 30 percent of international pharmaceutical spending. As a result, cracking developing markets has become an agenda-topper for many industry CEOs. Emerging markets are further complicated by the fact that no two countries are the same. Brazil has different market and consumer dynamics than China or India due to socio-demographic, economic, governmental and regulatory factors.

Pharmaceutical market dynamics are fundamentally different in emerging markets compared to developed ones. The underlying reasons for these differences include different or virtually nonexistent reimbursement systems, limited access to healthcare and unique pricing and distribution aspects. In addition, multinational companies (MNCs) face compliance risks that require management in accordance with strict policies, including the U.S. Foreign Corrupt Practices Act (FCPA) and its UK equivalent. In some cases, failure to comply has led to high turnover among emerging market general managers, especially in countries that have entrenched, corrupt business practices.

But perhaps the most important difference in these markets is that big pharma companies often feel a need to compete more aggressively with a class of products

known as branded generics. These are generic versions of products sold either by the original manufacturer of the patented drug or by generic manufacturers that build up brand equity for their generic versions of the medication, which they introduce right after the patent expires on the original product. The original manufacturers attempt to build on the name recognition of the branded drug to maintain market share in face of the generic manufacturer(s). On the other hand, generic manufacturers strive to build their brand equity with support from their sales, marketing and medical organizations.

Given these realities, global pharmaceutical companies, with a core competency in commercialization and R&D, need to either compete with or against the branded generics to be successful in the emerging markets.

Why branded generics matter in emerging markets

The genesis of branded generics in emerging markets is a pragmatic response to some hard local market realities. Historically, pharmaceutical companies—much as they do in developed economies—have attempted to enforce intellectual property (IP) rights in these regions as their economies became more globally integrated. From the start, however, big pharma players often had to compete against generic versions of their own medications, which in many developed countries are protected by law. The Indian market, for example, is inundated with copycat generic drugs and low-cost chemically similar versions due to historically weak patent laws and government-induced pricing controls.³

These market conditions, coupled with lower consumer disposable income levels and the inability of emerging market governments to afford novel medications⁴ at developed country prices, helped to foster a new, branded generics product segment.

Just how well do branded generics measure up against branded and pure generic products from a profitability perspective? The popularity of branded generics over pure generic products also varies by country with branded ones enjoying a higher price leading to more favorable margins when compared to pure generics. In India, branded generics and originator (off patent) brands dwarf pure generic products, whereas in many developed markets such as the United Kingdom and United States, unbranded generics make up about half the overall category total. Branded generics typically offer higher margins than either over-the-counter (OTC) or pure generic offerings.

The favorable margins of branded generics can provide room for a meaningful amount of promotional spending. Our research shows that emerging market healthcare providers trust branded generic products the same way they rely on other novel medications because they have been in use for a long time—in some cases for decades. And given the often-global reputations of the MNCs, there is also an element of intrinsic trust in both the quality of branded generics and the companies that sell them.





Key success factors with branded generics in emerging markets

While the branded generics play in emerging markets offers pharma players opportunities to expand, success is not certain. To improve the odds, MNCs should consider the following five winning elements of successful branded generics strategies.



1.

Establish sustained local capabilities with strong local talent

Establishing local capabilities in emerging markets can be a challenge for global pharma players, but the benefits can be significant. Local production can help organizations shorten supply chains, avoid currency fluctuations and better understand a market's unique aspects, including distribution oddities. Furthermore, setting up local R&D capabilities can help companies attune their product portfolios to meet the urgent needs in the country, and hiring and retaining local talent can enable firms to benefit from emerging markets' resources. While these opportunities are not exclusive to branded generics, they are important for a successful branded generics strategy.

Manufacturing and distribution

In developed markets, supply chains often function best when guided by a central command center that has a clear view of the global supply and demand capacity of a company's product portfolio. This setup works well for many MNCs, which typically employ a refined sales and operations planning (S&OP) process enabled by enterprise resources planning (ERP) systems. This combination enables them to allocate capital efficiently, acquire raw materials, optimize their manufacturing architecture and move inventory while optimizing the cash position.

However, in an emerging market setting, the central command center approach often faces some unique challenges. For example, supplying the market cheaply and quickly can be an important success factor in these markets because it can foster an environment in which the shelves in the pharmacies remain stocked. Across many

emerging markets, pharmacies are owned and operated by individuals and thus offer a less predictable order horizon than pharmacy chains. Even where there are large pharmacy chains, such as in Latin America, Russia, and China, companies sometimes move smaller quantities on a constant basis, which calls for more of a just-in-time approach to distribution. Given the fact that accounts receivable (A/R) is often a major stumbling block and a risk of doing business in all emerging markets, with days sales outstanding (DSO) levels reaching as high as 180 days or more, the agility of the supply chain can play a much more critical role here than it does in developed markets that benefit from established processes and systems.

Retail pharmacies in developed markets typically both distribute and dispense medicine. In emerging markets, pharmacists can be active care providers and can often—if the consumer is willing to pay—offer for-prescription remedies in absence of any medical training. As a consequence, they can play an influential role as to which medications are dispensed, even if the patient does not have a prescription—a situation that occurs very frequently.⁵ The pharmacist thus suggests, and in many cases decides, which generic product to dispense, if an option is available. In effect, if the patient cannot afford the branded original product due to its higher price, the pharmacist can offer the next-best product, such as a branded generic supplied by a local manufacturer. And while having a trained pharmacist intervene in the medication regimen can provide certain benefits, especially for chronic conditions such as hypertension or diabetes, it is not uncommon to see even pharmacist assistants playing this critical role.

Given this local decision point, MNCs should explore ways to incentivize and train pharmacists to dispense their own branded generics instead of locally produced alternatives in these situations. Economically, branded generics can be more profitable for pharmacists, since they typically offer better payment terms and larger discounts when compared to novel branded medications.

However, MNCs could be at a disadvantage here, since they—unlike some local producers—can face stricter reporting standards regarding their accounts payable terms.

MNCs should endeavor to understand that the distribution picture could change dramatically from country to country. In Mexico, for example, supermarkets have begun to carry pharma products, and drug-store chains are also emerging. Distributors in Russia tend to enjoy high levels of influence due to the market's network of regional formularies, and the Indian distribution network and marketplace are both highly fragmented. Dealing with these dynamics can be a challenge for MNCs trained to operate in developed markets, but unless they understand and act to overcome them, their branded generics initiatives could be less effective than anticipated. Critical factors for creating an effective emerging market distribution network strategy include cultivating a deep understanding of consumer needs in areas such as credit and supply predictability, as well as providing adequate assurances that this is a genuine product, not a counterfeit.

Having a local manufacturing or distribution center presence can be the key to continued participation in a number of emerging economies, and some governments even require companies to establish in-country operations to gain access to the market at all. Other countries, such as Brazil, make it very difficult for companies without local operations to compete by imposing import duties or tariffs that often boost import prices far beyond those charged by local competition.⁶ As a result, localization has been a key element of the Brazilian pharmaceutical market, and numerous global pharmaceutical companies are now using Brazil as a production platform. Additional benefits of local production can include local and national tax advantages and lower production costs. The cost to manufacture a drug in India, for example, is about 40 percent lower than in a developed country.⁷ Russia and China are also evolving into even stronger examples of the need for local manufacturing.

Research and development

The announcement in December 2011 that Merck planned to establish a new research and development (R&D) headquarters in China as part of a \$1.5 billion investment over five years represents a milestone in MNC attempts to establish an integrated presence in the emerging market landscape. As most MNCs move into China, this strategy can be interpreted two ways. First, it allows companies to gain access to an educated local workforce, enabling them to dial up discovery functions at a lower cost. And second, establishing the company as a net investor in an emerging market can boost its influence with local governments, which almost always act as monopsony players (i.e., a single buyer with multiple sellers) in countries that lack a healthy commercial insurance segment. The case of China in particular, is a good example, where drugs developed locally often enjoy a semi-official fast track for reimbursement by local authorities that may save them years in the process.

While pharmaceutical industry R&D has traditionally been a slow process, in India the adoption of reverse pharmacology has provided production efficiency gains, helped manufacturers to test generic drugs more quickly and thus helped to increase the speed to market. The ability to bring relevant products quickly to market at low price points has been instrumental for domestic players in shaping the Indian market on their terms.

Another recent development is the practice of enrolling ever-larger patient populations from emerging markets for clinical trials. Doing so can help to speed up patient recruitment, which appears to have been an operational obstacle for clinical stage development. Due to lower treatment rates in emerging markets, the ability to find more eligible patients has often attracted drug developers (and the contract research organizations they use) to these geographies to perform Phase II and III clinical trials. This practice can also help to speed up the approval process with emerging market regulatory authorities, because many submission packages are mandated to include clinical outcomes data for local populations. However, MNCs should consider striving for full transparency in such trials which can help to avoid the potentially negative perception that they are taking advantage of local populations, whose protections from negative outcomes may be lower than those in developed markets. This issue is exemplified by claims made by an African government concerning clinical trial recruitment for an antibiotic tested by a large global pharma company, and led to a major public relations issue that was drawn out over many years.

Becoming involved locally can actually enhance a big pharma player's image in the eyes of local healthcare providers, positioning it as a progressive and innovative company that supplies high quality products. However, companies should consider weighing the costs and benefits associated

with establishing local R&D capabilities. Many other factors can play into this equation, including nationalistic protectionism, which promotes investments in local technologies by blocking the entry of MNCs and negative popular perceptions of government officials caused by their pricing, payment and coverage decisions that focus on containing healthcare costs.

Local talent

Since both MNCs and local branded generic manufacturers invest heavily in emerging markets, the war for talent is a key success factor. However, this pervasive demand for talent can make the cost of hiring individuals with the right skill sets disproportionately expensive. In some cases, this trend has actually reversed net immigration flows to developed markets.

Talent acquisition costs are also increasing steadily, bringing the fully-loaded cost of a pharma sales rep in China, for example, closer to developed country levels. In some Eastern European countries and Russia, it is a common practice to hire physicians as sales reps, because doctors can often earn multiples of their government-paid salaries.

Continuing education, training and sustainable career paths in a MNC remain important attributes in the war for local talent. However, MNCs may be slowly losing this edge to local branded generic manufacturers, which historically have attempted to lure talent away from big pharma companies once people complete their initial training and gain hands-on multi-national commercialization experience. Now, the local players offer similar perks and career paths as well. In general, rates of attrition seem to be uncharacteristically high in emerging markets, since companies do not shy away from stealing trained talent from anyone, anywhere.

Partner with local players

Successful MNCs often create partnerships with local companies with deeper expertise in the local market and perhaps more support from the local government. Bayer HealthCare, for example, recently launched a joint venture with Cadila, one of India's largest privately held pharmaceutical companies. These ventures are also often designed to establish a new base for expansion into other emerging markets. In 2009, GSK signed an agreement with India's Dr. Reddy's to develop and market selected products across a variety of emerging markets.⁸

2. Engage in portfolio marketing

The ability to create strong brand equity by engaging in portfolio marketing is a key factor for success with branded generics in emerging markets. The strength of the sales and marketing organization and its capabilities in terms of field sales, promotions, market research and medical services can play a critical role in creating such brand equity.

Physician engagement and the creation of brand equity can be even more important for the success of the branded generic when the original drug has been off-patent for some time and other generics have already been launched in the market.

Companies with a branded generics portfolio tend to have divisions focused on certain therapies. This can foster the opportunity for them to increase their depth in a specific therapy by conducting focused market research and to develop a good understanding of a market's medical needs, which in turn can help them to gain recognition among physicians. For example, Sandoz remains the leader in tuberculosis therapy in India because it has the most relevant portfolio, which it markets as a comprehensive package.

Leveraging a portfolio of products can allow companies to benefit from synergies as they execute their strategy and develop a market presence. Engaging in portfolio marketing can generate efficiencies by enabling field sales teams to promote multiple products with physicians, further improving their ability to succeed in this competitive market with a branded generic. The MNCs' know-how regarding the specific therapies and the market can further improve their speed to market, thus building their local brand equity. Novartis' business in India is a perfect example of this approach, as most of the investment has been focused on creating awareness of diseases among local populations in rural settings under an umbrella brand, Arogya Parivar, which means good family health in Hindi.

Promotional activities can help MNCs maintain the relevance of branded generic offerings in a market, and doing upfront portfolio lifecycle planning and taking steps to understand target segment needs can place the MNC in a strong commercial position with its branded generic offerings.

Sponsor certification and training programs

Pharmaceutical companies can build their emerging market presence by sponsoring local certification and training programs in collaboration with local and international institutions. Educating customers about a company's products and the diseases they address can raise awareness and generate new revenue opportunities in markets that may have less understanding of Western medicine. One avenue involves the creation of training regimens to "certify" physicians in the use of a company's product. Novo Nordisk, for example created the Changing Diabetes in Children Program (CDiC) which addresses barriers for children living with diabetes in developing countries. The program provides free insulin and supplies, in addition to a comprehensive training manual for healthcare professional and diabetes educators.⁹

3. Recalibrate regulatory affairs

The regulatory affairs department of a MNC typically plays a different role when dealing with branded generics in emerging markets than it does generally in developed countries. In fully industrialized economies the regulatory affairs function primarily focuses on providing guidance about a new product's labeling and seeks to optimize the ability to promote products on a post-approval basis while ensuring full compliance. In emerging markets, on the other hand, the ability to accelerate the company's go-to-market capability by moving the branded generic application dossier through multiple bureaucratic hurdles is a key capability that regulatory affairs personnel must master. Turkey, for example, can be a difficult market for pharma players due to its challenging regulatory environment, which causes a significant backlog in the registration process—typically from 18 to 36 months.¹⁰ Likewise, the strong influence of the Chinese government and the uncertainty around future healthcare regulatory reforms make China a complex market for MNCs.

In many markets, established relationships are an important element of regulatory affairs performance and it is not unusual for former government officials and/or regulators to join the ranks of local or multi-national companies—a practice common in India. MNCs are often required to navigate these cultural norms and manage the risks to which they may be exposed concerning their governing compliance policies, while at the same time being clear when it comes to intent and desired outcomes.

Overall, MNCs that play in the branded generic space often benefit from a versatile regulatory affairs function that can enable smooth and agile go-to-market performance.

Give back

Non-profit engagements can offer a way for pharmaceutical players to build brand strength in emerging markets that is consistent with their corporate philosophy of improving healthcare. Contributing to the local economy or infrastructure can help build goodwill and winning over a customer base that recognizes a company's brand. It also can become a vehicle to elevate the corporate image to attract and retain local talent who feel particularly proud about working for the company.



4. Bolster the sales force with multi-channel engagement

In-person, face-to-face interactions remain a core strategy for marketing products to providers in emerging markets. Many MNCs are investing in sales reps, who play a vital role in product education and relationship building. However, as emerging markets grow and an increasing number of individuals have access to healthcare in these markets, MNCs should consider taking an integrated, multi-channel approach.

A well-executed multichannel approach can achieve goals and accelerate results by extending the sales force through digital and on-line interactions. For example, China has 120 cities with populations that exceed one million, and 832 million people in more rural areas now have access to healthcare.¹¹ Even faster growth rates appear to be occurring in mid-size cities. While many MNCs have been aggressively pursuing market access in China, few have successfully penetrated the Chinese market and achieved sales or geographic scale.¹² To keep pace with the rate of change, to maximize their growth potential and effectively compete with local firms, MNCs should consider leveraging non-traditional channels that go beyond the individual sales rep.

A multi-channel marketing strategy leveraging newly adopted channels (such as digital access) has the potential to reach a broader audience to deliver core branded generics messaging. One key goal of this strategy is instilling trust and recognition among health care providers and consumers for the pharmaceutical parent company. Sales reps may then have an opportunity to focus on reinforcing this messaging in strategically important markets where providers may be more likely to be receptive to e-Detailing and e-Learning applications. In the case of China, for example, it has been said that reps should focus on the cities with the largest, most technologically advanced populations.^{13, 14}

In general, providers in emerging markets will likely continue to rely on individual interactions with sales reps as a means to gain trust and educate practitioners about a product. However, specifically for branded generics, an integrated multi-channel strategy can enhance the brand and provide lower-cost solutions that align with these lower priced markets.

Innovate to access health care providers

Some pharma players are experimenting with innovative ways to reach health care providers. For example, pharmaceutical sales reps in China often have difficulties meeting with doctors in person due to high patient loads, time pressures and a variety of other factors. In addition, in Turkey and Russia, there is an emerging trend by governments to limit sales rep access to physicians. As a consequence, some companies are exploring new ways to reach doctors through digital channels such as the Internet and email.

5. Enhance contracting capabilities

In many emerging markets, the contracting or tendering process is an area of focus for MNCs. As a result, cultivating effective contracting capabilities is a strategy that can help MNCs win the branded generics game. Currently, the emerging market tendering process is typically low-tech and reactive rather than proactive. In many markets, the individuals in charge of contracting and tendering processes simply use Microsoft Excel® spreadsheets to track historical bid prices, and decision-makers lack ready access to data or the tools they need to drive actionable insights.

In order to compete with local players in India such as Ranbaxy and Dr. Reddy's, MNCs could benefit from viewing contracting and tendering as a commodities game involving a robust and dynamic pricing capability, rather than one focused on brands. Additionally, the tendering process for off-patent products includes the additional complexity of dealing with generic competitors whose price points are generally unknown. Preparing multiple bidding scenarios can help MNCs

deal with the potential inconsistencies that can arise when customers have low levels of influence over the prices they pay. One often-valuable discounting strategy involves offering incentives for purchases across an MNC's portfolio of products, which can help companies sell both patented and off-patent drugs and MNC's can incorporate as appropriate in the local market. MNCs can gain market share and potentially create positive prescribing spillover for off-patent drugs, which is often difficult to execute in a low transparency market.

Tenders, typically the main source of high-volume sales opportunities—often gain even more importance in the overall commercial plan. As a consequence, identifying tenders by investing in third-party aggregating services or by establishing data-sharing relationships with distributors may be essential to finding profitable opportunities in this product segment. MNCs are largely dropping out of this game (e.g., in Brazil) and where they continue to play (e.g., China), the pressure is intensifying.

Understand generic drug pricing

Pharmaceutical companies should also cultivate a better understanding of the generic drug markets in target countries. Many have strict government-enforced pricing measures including reference pricing that would use an average of prices in a basket of low-price countries as a benchmark to determine the price in the home country. The Chinese government, for example, has created an Essential Drug List (EDL), which has reduced pricing on many off-patent Western drugs, and many hospitals and pharmacies are restricted to providing only generic products from the EDL. Such price limits, as well as large low-income consumer populations, tend to favor generic drugs.



Conclusion

Branded generics in emerging markets present a viable avenue for potential growth for big pharma players, but companies need to understand the often-unique challenges they face in pursuing this opportunity. With the increasing pressure on government budgets and cost containment, the window of opportunity that the branded generics present may not stay open for long. Therefore, MNCs should consider exploring and pursuing a select combination of the strategies discussed in this publication with a sense of urgency.

The five elements of a winning branded generics game-plan described here can help leaders identify potential gaps in their go-to-market plans, and help prepare them for the sometimes unconventional aspects of doing business in many of these markets.



End notes

- 1 *Credit Suisse Global Investment Returns Yearbook 2010*, Elroy Dimson, Paul Marsh, Mike Staunton, Jonathan Wilmot.
- 2 IMS Health, "The Global Use of Medicines: Outlook Through 2016," July 2012, Page 3.
- 3 "India: Good Endings, Good Beginnings," *Pharmaceutical Executive*, September 2011.
- 4 Drugs that offer benefits that are differentiated from those offered by other products in the market.
- 5 "Use of antibiotics without medical prescription," Dalton Espíndola Volpato, Bárbara Vicente de Souza, Luana Gabriela Dalla Rosa, Luiz Henrique Melo, Carlos Antonio Stabel Daudt, Luciane Deboni, *Brazilian Journal of Infectious Diseases*, Vol. 9 no.4 Salvador, August 2005.
- 6 "2011 National Trade Estimate Report on Foreign Trade Barriers—Brazil," Office of the United States Trade Representative.
- 7 *India's Potential as Part of a Global Pharmaceutical Value Chain*, Alexander Meyer auf der Heyde, Sriram Shrinivasan, Sebastian Schweitzer, Accenture.
- 8 *Fast Forward to Growth*, Rob Hayward, Armen Ovanessoff, Athena Peppes, Kuangyi Wei, Paul Nunes, Mark Purdy, Matthew Robinson, Mark Spelman, Vanessa Rossi, Accenture, January 25, 2012.
- 9 "Novo Nordisk to Reach 2500 Children in India with Free Insulin and Diabetes Care," Novo Nordisk Press Release, September 7, 2011.
- 10 "Country Report; Turkey", Steve Kretschmer, Pharmaceutical Market Europe, May 2011.
- 11 "Digital Channels Reaching Doctors in China," Anne O'Riordan, Kher Tean Chen, Accenture, December 21, 2011.
- 12 *What it Takes: Launching Successful Products in China's Pharmaceutical Market*, Anne O'Riordan, Kher Tean Chen, Andrew Yu, Accenture, July 19, 2011.
- 13 *Digital Channels Reaching Doctors in China*, Anne O'Riordan, Kher Tean Chen, Accenture, December 21, 2011.
- 14 *What it Takes: Launching Successful Products in China's Pharmaceutical Market*, Anne O'Riordan, Kher Tean Chen, Andrew Yu, Accenture, July 19, 2011.



About the authors

Kristina Gilbert is a senior executive in Accenture's Management Consulting practice. Kristina brings over 14 years of experience consulting with global Life Sciences clients on strategy, new commercial models and emerging markets growth opportunities, including building commercial capabilities for new markets, customers, and go-to-market approaches. She is based in Philadelphia, Pennsylvania.

kristina.l.gilbert@accenture.com

Arda Ural is a senior manager in Accenture's Life Sciences Strategy practice. Prior to joining the firm, he was a VP Strategic Marketing at Becton Dickinson (BD) and served as the SVP Marketing & Sales for a start-up biotechnology company Eyetech (later acquired). He started his career at Pfizer in Turkey and over 10 years had global and US commercial responsibilities. Arda is based in New Jersey.

arda.ural@accenture.com

Myriam E. Lopez is a senior manager in Accenture's Management Consulting practice. She brings over 12 years of Life Sciences experience in industry and consulting. Myriam has focused on helping organizations with the creation of their growth strategy, market expansion approach, emerging markets penetration plan, and capabilities development roadmap. She has led the global launch of several medical device products. Myriam is based in New Jersey.

myriam.e.lopez@accenture.com

Contact us

Kher Tean Chen (陈科典) is a senior executive in Shanghai, China.

kher.tean.chen@accenture.com

Marcelo Duerto is a senior manager based in Buenos Aires, Argentina.

marcelo.v.duerto@accenture.com

Sriram Shrinivasan is a senior executive in Mumbai, India.

sriram.shrinivasan@accenture.com

The authors would like to thank Olivier Jarry—3xBL Consulting—for contributing to this article.

About Accenture

Accenture is a global management consulting, technology services and outsourcing company, with 257,000 people serving clients in more than 120 countries. Combining unparalleled experience, comprehensive capabilities across all industries and business functions, and extensive research on the world's most successful companies, Accenture collaborates with clients to help them become high-performance businesses and governments. The company generated net revenues of US\$27.9 billion for the fiscal year ended Aug. 31, 2012. Its home page is www.accenture.com.

Life Sciences Practice

Accenture's Life Sciences practice is dedicated to helping companies rethink, reshape or restructure their businesses to deliver better patient outcomes and drive shareholder returns. We provide consulting, outsourcing and technology around the globe in all strategic and functional areas—with a strong focus on R&D, Sales & Marketing and the Supply Chain. We have a long history of working hand in hand with our clients to improve their performance across the entire Life Sciences value chain. Accenture's Life Sciences practice connects more than 10,000 skilled professionals people in over 50 countries who are personally committed to helping our clients achieve their business objectives and deliver better patient outcomes for people around the world.

