McKinsey&Company

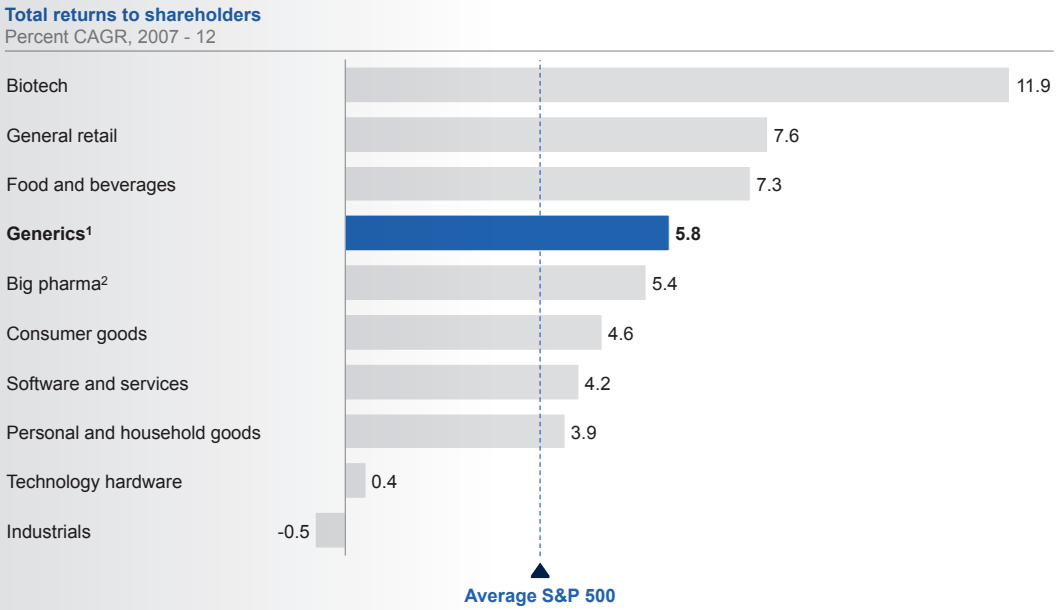
Insights into Pharmaceuticals and Medical Products

Generating value in generics: Finding the next five years of growth

Global Generics Interest Group

The generics industry has enjoyed a remarkable run over the past decade, with companies generating above-average shareholder returns (Exhibit 1). The industry has a long track record of strong, steady growth, often at double-digit rates. From 2009 to 2012, net revenue grew at an average 8 percent per year – one and a half times faster than the 5 percent posted by small-molecule originators. Generics companies had an average EBITA in 2011 of 20 percent and an ROIC north of 30 percent, putting them in striking distance of originators' profitability.

Generics companies have generated above-average returns



1 Based on top 25 publicly listed generics companies ranked by 2012 revenue
2 Based on top 15 pharmaceuticals companies ranked by 2012 market cap

SOURCE: Datastream

Exhibit 1

The challenges ahead

Although there is still room for growth in generics, delivering it has become more complex. Given that penetration rates are as high as 80 percent in the US and 70 percent in central and eastern Europe, significant potential exists for volume penetration in many markets. In addition, between $20 and $60 billion of originator sales will continue to go off-patent each year. However, generics companies face considerable challenges to their profitability and growth:

- **Commoditization, combined with extensive reforms in both regulated and unregulated markets, is increasing pressure on prices.** Although healthcare reforms have boosted sales of generics in recent years, many governments are looking to reduce their generic drug expenses. More and more countries have seen a dramatic shift in their business model as payors become key stakeholders through the implementation of tenders.

- **Product portfolios are becoming increasingly complex.** The share of hard-to-make and specialized drugs going off-patent – including drug/device combinations, sterile injectables, and biologics – will increase. By 2016, eight of the top 10 pharmaceutical drugs will be biologics.

- **Managing the business while maintaining a lean structure and striving for cost leadership has become more complex.** The top two global players each have up to 1,000 compounds on the market and even more products in the pipeline covering oral solids, biosimilars, respiratory, sterile injectables, and patches.

- **Quality control in manufacturing remains challenging.** Comparing generics players with originators illustrates the scale of the problem. For example, 1.4 percent of batches are rejected for generics companies as compared with 0.4 percent for originators, and there are 72 deviations per 1,000 batches for generics players as compared with 53 for originators. In comparison with other industries, generics players also have clear room to improve their obsolescence rates and service levels. For instance, pharmaceuticals have roughly the same obsolescence rate as milk, despite having a much longer shelf life. Similarly, a drug takes an average of 75 days to go from packaging into the customer's hands, while a Lenovo laptop takes only a week to reach the customer after assembly.

- **New players are intensifying competition.** New entrants in the generics market include electronics companies such as Samsung and Fuji in certain segments, as well as originators such as Abbott and Sanofi.

As a result of these challenges, financial markets are less optimistic than they were about the outlook for generics. Industry leaders expect growth in the global generics market to slow to 6 to 7 percent per year.

Although companies in the industry exhibit a broad range of performance levels, the overall stock market outlook for them is pessimistic. An analysis of current share prices indicates that implied long-term growth for top generics companies is negative, and margins are expected to shrink to below the median for the S&P 500 industrial companies. Return on capital without goodwill has also slipped, indicating that M&A may not be delivering as it did in the past.

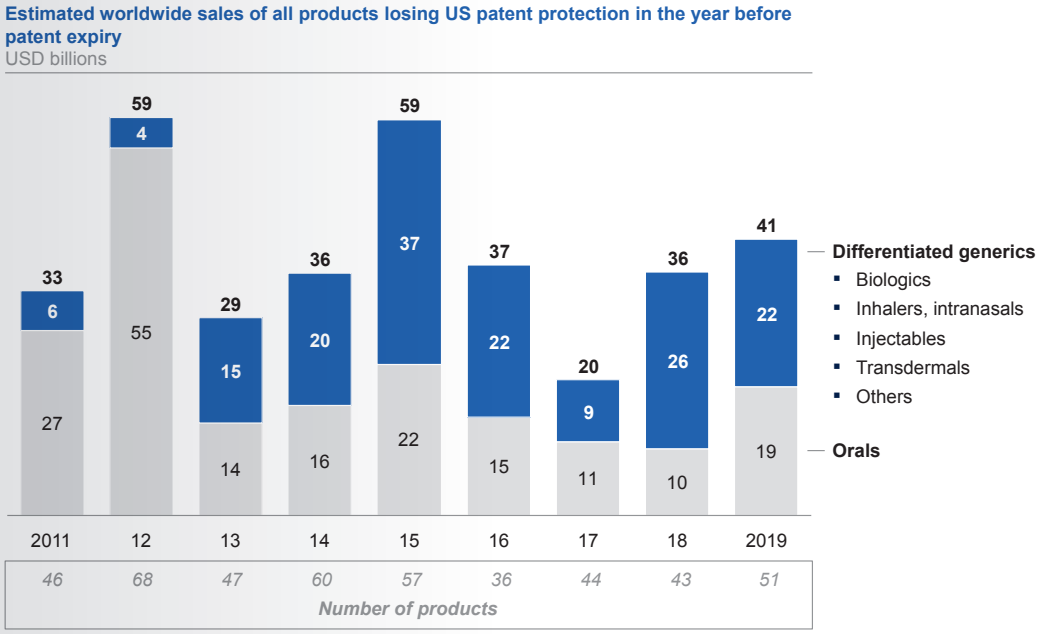
Choosing where to play

Some might say that generics companies will find it increasingly difficult to launch new products now that originator products coming off-patent are becoming harder to develop, produce, and commercialize. However, if we compare the situation of generics companies with that of telecommunications or industrial companies, say, it is clear they have a wide field of opportunities to choose from. Some $217 billion worth of originator products will lose their patent protection by 2018, and they span the full range from oral solids, biologics, inhalers, and sterile injectables to over-the-counter (OTC) medicines (Exhibit 2).

The opportunities in these categories will vary in value and timing (Exhibit 3). For instance, biosimilars will be a large opportunity with cyclical openings driven by the patent expiries of major products, while sterile injectables will be a smaller opportunity by value, but with a steady stream available each year. Each product opportunity will also vary in terms of its regulatory context, manufacturing requirements, and commercialization challenges.

Industry estimates suggest that generics are likely to have the luxury of nearly $60 billion in net growth in the next six years. Companies should make a careful assessment of where to invest before deciding

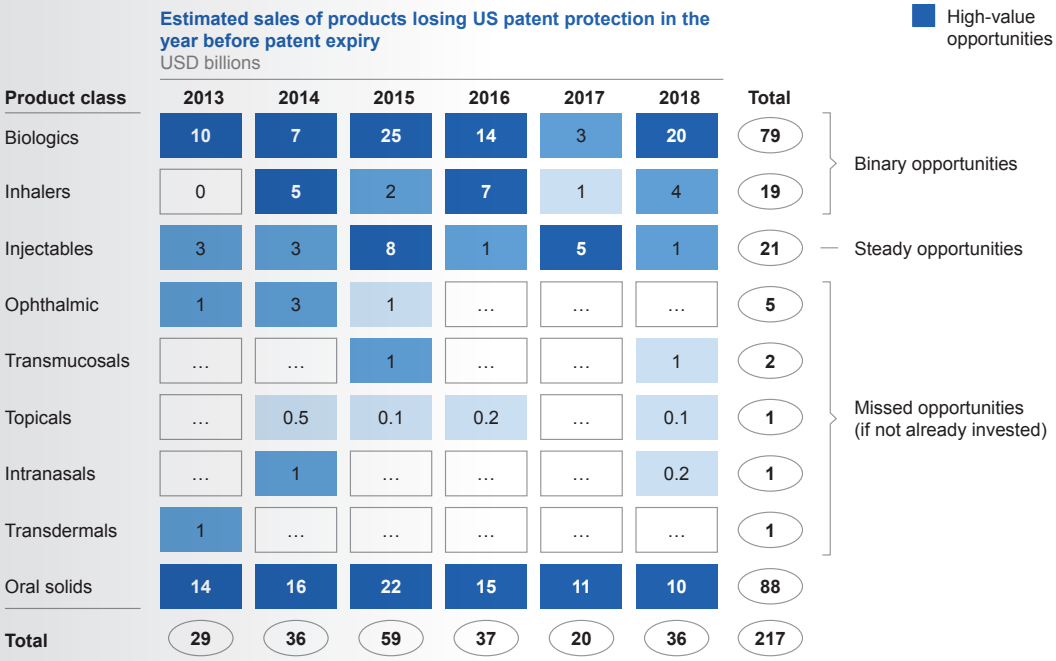
Upcoming LOE opportunities will be dominated by differentiated generics products



SOURCE: Evaluate, 2013

Exhibit 2

Opportunities by product class will vary over time



SOURCE: Evaluate, 2013; McKinsey analysis

Exhibit 3

on their development programs. Opportunities and challenges vary enormously from one product category to another.

Oral solids: Cost game or branding game?

Oral solids are still the largest source of growth, with $88 billion going off-patent by 2018. In the United States and United Kingdom, where they have become a pure cost game, players are finding it increasingly difficult to compete. In markets such as Germany and the Netherlands, tough price competition has been exacerbated by the introduction of tenders, which has led to discounting of more than 95 percent on some products. To succeed in these markets, generics companies will need to ramp up their operational and manufacturing performance and establish seamless supplier networks. Emerging leaders tend to be large generics players or Indian companies.

On the other hand, cost is only one of the success factors in many emerging markets, where competition is still a branding game with attractive margins. Even so, optimism about the sustainability of the branded generics model has been waning in recent years. For instance, the game has changed in central and eastern Europe as health systems move closer to western European models.

Biosimilars: Attractive but uncertain

After oral solids, biosimilars will be the second-largest source of growth, with $79 billion of originator sales going off-patent by 2018. The industry continues to debate what the impact will be, with market size predictions for 2020 ranging from $2 billion to $20 billion. Regulatory pathways have developed around the world, biosimilars are becoming more widely accepted, and investments are at an all-time high, with more than 200 players involved. However, questions remain over the regulatory requirements for biosimilars, particularly in the US, as well as their commercial prospects.

- **Unclear regulatory requirements.** Since the US accounts for about half of all global branded biologics sales, worth $160 billion in 2012, success here will make or break the business case for most entrants. To date, no biological product has been approved through the abbreviated biologic license application (aBLA) pathway, and the Food and Drug Administration (FDA) has been vague about some aspects of approval, such as indication extrapolation and interchangeability. The biggest hurdle to approval is seen as the intellectual property provisions in the aBLA. Moreover, only a handful of players will be able to fulfill the requirements for technical development, analytical characterization, clinical trials, and manufacturing capabilities. Some companies appear to be reconsidering their investments in biosimilars; for instance, Merck recently terminated its partnership with Korea's Hanwha to develop a biosimilar for Enbrel.

- **Limited commercial success to date.** The industry continues to debate how profitable biosimilars can be in view of the level of investment required. Some skeptics wonder whether follow-on originator products such as T-DM1 for Roche's Herceptin will be able to convert the market before biosimilars players can enter. However, analysts expect innovation to increase sales rather than take share from first-generation biologics. The emerging belief in the industry is that the first few players to enter will make money, but later entrants will struggle.

Respiratory products: Sizeable, but tough to crack

Inhalers are a sizeable opportunity, with $19 billion going off-patent by 2018. However, only a few players are likely to have the capabilities to gain approval in regulated markets, and commercial success is uncertain. Product development is complicated by the drug delivery platforms, with an average seven to 10 patents per inhaler product.

The regulatory approval process is unclear in the US, as there are no published guidelines for substitutable generic inhalers, and draft guidelines for dry powder inhalers promise difficult and expensive development programs. Established guidelines exist in Europe, but bioequivalence requirements are stringent. As one industry leader put it: “Not even different batches from one of the originators would fulfill these requirements.”

Commercial costs are expected to be even higher for respiratory products than for biologics, given the level of promotional spending by originators. However, pockets of opportunity do exist outside the US and Europe. For instance, an Algerian generics company has established a program with local authorities to get approval for a generics version of Seretide. The country has significant medical needs, but no generics guidelines for inhalers.

Sterile injectables: Differentiation is key

The industry consensus is that sterile injectables remain an attractive, high-margin segment with significant potential: about $10 billion of growth is expected up to 2018 from a $20 billion base. Growth will be driven by loss of exclusivity (LOE), improvements in product formulation, and demand from emerging markets. The key factors for players to consider include:

- **Quality.** This needs to be a priority for all players. Regulatory scrutiny has increased and the list of setbacks is long; over the past few years, 12 of the top 15 players have experienced serious manufacturing issues. As a result, the future of many companies is on the line, especially if they operate old plants that pose greater quality risks. Several of the world’s largest facilities are more than 20 years old.

- **Need for differentiation.** As new capacity (primarily in India and China) and upgraded capacity (in the US and Europe) come on stream in the next few years, undifferentiated sterile injectables are likely to suffer overcapacity and will become less interesting unless the increase in capacity is offset by a surge in demand, as is happening in some emerging markets. Despite the need for differentiation, players appear to be underinvesting and should look for development opportunities in the LOE pipeline. The main sources of differentiation are likely to be product types such as emulsions, liposomes, and APIs with complex structures or specific fill-finish forms, such as pre-filled syringes and dual-chamber bags.

- **Emerging markets.** Few global players are focusing on emerging-market opportunities, leaving the field open for strong local players.

The key success factors in generic sterile injectables include the nature and degree of portfolio differentiation, the scale and age of manufacturing facilities, the level of manufacturing and quality assurance talent, and the ability to refine the commercial model in an increasingly competitive market. A strategic player with the right product can still outperform over time. Overall, the winners in this product class are likely to be big players with large portfolios and low costs, and small players with truly differentiated offerings.

OTC: Pockets of opportunity

The OTC opportunity is large, with revenues of $130 billion in 2012, and attractive because of the stability of its cash flows and longevity of its brands. Profit margins are muted at 15 to 25 percent, and overall growth rates are in the mid to low single digits, but there are pockets of faster growth such as tonic drinks, vitamins, and dietary supplements.

The market is highly fragmented, spanning a range of business models and categories. For instance, generics players in the pharmacy channel in France and Germany are moving into OTC as an adjacent business. On the other hand, those in out-of-pocket retail markets with mostly branded generics, such as Russia and Brazil, are staying closer to their core operating model and taking advantage of their capabilities in brand building, allocation of promotion investment, distribution, and rapid development of small innovations. Successful OTC brands built by generics players in Russia, for instance, include Pharmstandard's Arbidol (one of the market's biggest retail products), Sandoz's Linex, and Teva's Gastal.

Successful generics companies are less likely to be able to tap into this opportunity in mature and INN (international nonproprietary names) type markets, where the core skill set of OTC players will be very different from their own. One solution could be for them to establish partnerships with heritage consumer companies that can commercialize the products in mass retail and pharmacies, while the generics companies themselves manufacture the products cost-efficiently and adapt quickly to new formulation requirements and incremental innovations. Teva is a pioneer in establishing new collaborations to win in OTC, having established a joint venture with P&G to develop and market OTC drugs. The new entity, PGT Healthcare, combines P&G's expertise in consumer understanding, branding, and merchandising with Teva's leading brands and pharmacy distribution capabilities.

For most large generics players the development of OTC products and capabilities will compete with other opportunities and may not be a priority, given the relatively small market footprint of these products. Players that focus primarily on branded generics markets may be an exception, since the greater degree of overlap with their core business makes the business case more attractive.

Emerging markets: A mixed picture

Emerging markets are the most important geographical growth driver for generics, as for many other industries. Between 2005 and 2010, they contributed 30 percent to global GDP, but 70 percent to GDP growth. In the generics market, they are expected to grow at 8 percent per year between 2012 and 2017, outperforming developed countries, at 3 percent.

Although global players have invested heavily in leading emerging markets, they have not been able to keep up with incumbents' rate of growth. The main challenges they face– beyond ensuring compliance with high ethical standards and winning the battle for talent – are the need to understand individual markets in depth and withstand increasingly frequent attempts by governments to protect local industry. With the exception of Russia, where Teva and Sandoz are among the top three generics players, the major generics companies do not have a strong presence in BRIC markets.

Such a situation makes inorganic moves inevitable, but with high valuation levels, M&A is difficult to justify. There are hopes in the industry that a few global players will eventually succeed in these markets. Meanwhile, there is growing interest in opportunities in Africa, the Middle East and second-tier markets in Latin America and Asia.

Africa: Attractive, but not for the faint hearted

The continent of Africa is becoming a large opportunity. The broader pharmaceuticals market, currently estimated at $18 to $19 billion, is expected to grow to about $50 billion by 2020, representing an annual growth rate of 12 percent. Generics is one of the most vibrant sectors of the market. Worth $4 billion, it is expected to reach $18 billion by 2020 on annual growth of 22 percent.

Growth is being driven by strong socioeconomic momentum and interventions such as import quotas in Algeria, substitution laws in South Africa and Nigeria, and governmental purchasing in Morocco. A granular analysis shows that both multinational and local players need to be selective: most growth is expected to come from 10 to 12 countries in well-defined regions. These regions present an opportunity to invest in large anchor countries (Kenya in the east, South Africa in the south, Nigeria in the Economic Community of West African States (ECOWAS), Algeria in Maghreb, and Angola in Portuguese Africa); to leverage trading blocs, common languages, and improving regional distributor networks; and to establish small regional offices to capture bordering markets. Regulation, ease of operation, and infrastructure quality make some anchor countries, such as Kenya, more accessible. By contrast, Nigeria requires longer lead times and more investment.

There is consensus that pharmaceuticals and generics players need to establish themselves now in order to capture the coming growth. However, Africa is not for those with a faint heart or a short-term outlook. A long-term commitment is needed since benefits can be reaped only over a five- to seven-year horizon. That is fast compared with the three decades or more that such players as GlaxoSmithKline have dedicated to Africa, but slow compared with the average timelines given to managers at multinationals.

The winners will take decisive and patient steps to create the market. Generics companies should build strong tactical partnerships (for secondary manufacturing, for instance) and establish end-to-end solutions such as fully integrated supply chains and turnkey disease solutions. They should also tailor their product portfolio and pricing to local needs, and “go big” in a few selected markets.

Companies need to answer a few key questions quickly. Where are regulations going and where will local manufacturing and ownership be needed? What does the return on investment look like at national and regional level? What mechanism of tiered pricing makes most sense across the continent? What is the best way to choose and manage African distributors? How should portfolios be tailored at regional and country level? What kind of support do particular governments look for from pharmaceuticals companies?

Latin America: A fight for Brazil and Mexico

Latin America has emerged as a priority region. The pharmaceuticals market is large, with $71 billion in revenue in 2011. Entry barriers are lower than in China and Russia. However, substantial differences in healthcare systems, intellectual property arrangements, and emerging middle-class wealth mean that companies should undertake a country-by-country assessment of attractiveness.

The top six countries – Brazil, Mexico, Venezuela, Argentina, Colombia, and Chile – account for 80 percent of the Latin American pharmaceuticals market, but differ widely in their economic conditions. Brazil and Mexico are the most stable and sought-after opportunities, but still require high levels of investment.

Accordingly, some multinationals have shifted their focus to medium-sized countries such as Columbia, which they are entering mostly through M&A.

However, an industry consensus has yet to emerge on the attractiveness of markets such as Colombia, Venezuela, and Argentina, and many multinationals are still assessing the opportunity. In Argentina, for instance, local companies can be highly successful and profitable, yet multinationals struggle. As in all emerging markets, the key to success lies in thoroughly understanding local rules and tailoring the approach to local requirements while capturing synergies on a regional level.

China: Tough for global players

China is a highly fragmented market with more than 4,000 drug manufacturers. Market access is complex and favors local players. Several global generics players have entered China either solo or via joint ventures, but so far these moves seem to be small-scale efforts to figure out what approach could be successful.

For originators, China is a highly successful market. For the top 10 multinational prescription drug companies, the total field force has increased from 5,500 in 2005 to a whopping 25,000 in 2012, albeit at lower productivity levels. However, global generics companies struggle. Slow registrations, difficulty in winning highly competitive provincial tenders, and hospital listing requirements make it difficult for them to gain share.

If we take planned reforms at face value, we might expect the environment to evolve in favor of global players, given the introduction of new manufacturing standards, higher compliance requirements, and accelerated generics substitution. However, companies face a challenge in differentiating their products on the basis of quality. Generics manufacturers will face increasing pressure on prices and margins, especially for products on the essential drug list. In addition, it is open to question whether raising standards for good manufacturing practice and compliance will benefit global generics players or make Chinese players more competitive internationally, especially in sterile injectables.

The emerging belief in the industry is that the government's attempts to protect local companies is likely to prove an insurmountable barrier for multinationals in the long term. Strategies based on mergers and acquisitions will be particularly difficult given the quality compliance issues and commercial practices of local players.

Functional excellence: A precondition for success

Generics companies aspiring to capture these growth opportunities must ensure they have functional excellence in place. They will need to master a staggering set of capabilities in product development, supply, and commercialization. In particular, excellence in technical operations causes CEOs many a sleepless night.

The industry is managing a combined $60 billion in cost of goods sold, which will double by 2020. Generics companies have already made great strides in managing costs: the unit cost of a generic product is on average 44 percent of that of an originator product. The same low-cost mindset is apparent in, for instance, the relative modesty of the buildings at generics companies' headquarters.

For some companies, achieving operational excellence is a matter of survival. Consider the Indian generics players that have transformed their manufacturing operating models and undertaken ambitious lean programs in recent years. The keys to success include having a clear operations agenda, building centers of competence, ensuring an open environment, creating opportunities for their best talent, and constantly searching for the next extraordinary goal. As a result, Indian companies are among the leaders in the generics industry, and their manufacturing plants are among the world's top-performing facilities, with conversion costs per production unit of less than 10 percent of the industry median.

As players reflect on where their priorities should lie, they should beware of three common myths about manufacturing excellence.

First, there is a widespread belief that factor costs should be the main focus of attention. Proof to the contrary comes from the fact that many well-managed European sites feature among the industry leaders.

Second, some players maintain that low manufacturing costs and high quality are incompatible. In practice, though, a few companies have eliminated the need for this classic trade-off by developing plant operating systems that ensure both high maintenance productivity and excellent reliability.

Third and finally, there is a belief that big is beautiful when it comes to operations. On the contrary, scale alone does not confer advantage. Benchmarking results for a Fette 2090 tablet press show that the variations in performance for different tablet presses within a given company are much larger than variations between companies. The next S curve in manufacturing capabilities will include active lifecycle management of the product portfolio, a simple end-to-end supply chain, a decisive partnership approach with suppliers, design-to-value so as to provide tailored solutions for the least affluent customer groups, and investment in organizational health.

Though confronted by a tough capital market outlook and a multitude of challenges, generics companies can still generate substantial value and capitalize on abundant growth opportunities. Should they risk the uncertainties of the biosimilars opportunity, try to crack the respiratory market, focus on the stable OTC arena, or pursue differentiation in sterile injectables? Choosing the right opportunities is equally crucial when deciding where to compete, and rather than trying to establish a presence in every market from Africa to China, companies should focus on countries where they believe they can succeed. To emerge as winners, they need to make clear judgments about products and markets, forge partnerships and join forces, and invest in building new capabilities.

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