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New Rules for Winning in China's Pharmaceutical Market



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New Rules for Winning in China's Pharmaceutical Market

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January 2014

AT A GLANCE

The pharmaceutical market in China is in the midst of a fundamental shift that will dramatically alter the winning strategies of both multinational corporations (MNCs) and local companies.

HEALTH CARE REFORM IS REMAKING THE MARKET

China's government is using various measures to reform health care, including compressing pharmaceutical prices and enhancing insurance coverage.

LOCAL COMPANIES ARE INCREASINGLY COMPETITIVE

The quality gap between products manufactured by MNCs and those made by local players will narrow. And consolidation is yielding more-formidable local companies.

STRATEGIES FOR SUCCESS MUST CHANGE

Market reforms will put pressure on previously fast-growing drug segments—in particular, the off-patent-product portfolios of MNCs.

THE RULES OF THE game are being rewritten in the pharmaceutical market in China. Some basic truths about the Chinese pharmaceutical market will remain unaltered, including the fact that it is a large, vitally important market that boasts robust growth prospects—but little else will remain static. In fact, the Chinese pharmaceutical market is in the midst of a fundamental shift that will dramatically alter the winning strategies of both multinational corporations (MNCs) and local companies.

Certainly, industry growth will remain healthy, driven by the aging population, urbanization, increasing wealth, and the government's commitment to spending more on health care. At the same time, however, two significant market-oriented factors are at play. The first is health care reform, which is both expanding coverage for the Chinese population and creating stronger budgetary controls and price pressure. The second is the emergence of local players as more formidable competitors, a development that has major implications for MNCs operating in China.

The result: companies need to develop new strategies and skills. MNCs will find that they can no longer rely on their off-patent-product portfolios, a segment that has generated tremendous growth over the past decade thanks in part to the Chinese government's policies. And local companies, meanwhile, have a tremendous opportunity to take share from MNCs. But capitalizing on that opening will require new approaches, including in some cases a shift from their focus on simple, nondifferentiated generics—which are off-patent, commodity drugs—to a more differentiated product portfolio and the development of more-effective go-to-market strategies.

Powerful Forces Are Changing the Chinese Health-Care Environment

The pharmaceutical market in China will continue to grow at a rapid pace thanks primarily to two potent trends.

The first is the ongoing demographic shift, which is driving demand. The Chinese population is aging: in 2020, 33 percent of the total population will be 50 years of age or older, up from 24 percent in 2010. In addition, chronic illnesses are becoming more prevalent: in 2020, about one-third of adults will have hypertension, for example, and about one-tenth will suffer from type 2 diabetes. Importantly, the number of people in the middle-class and affluent populations is growing significantly, and the number of small to midsize cities is exploding, expanding access to modern health care.

The pharmaceutical market in China will continue to grow at a rapid pace.

At the same time, the Chinese government has committed to picking up a greater portion of the nation’s health-care bill. In particular, government-funded health insurance has been made available to virtually all Chinese citizens. And although the depth of coverage varies significantly across the three public insurance funds within China and across the various provinces (some provinces have larger funds because of their greater wealth levels), it is generally being deepened to cover more types of treatments for individuals.

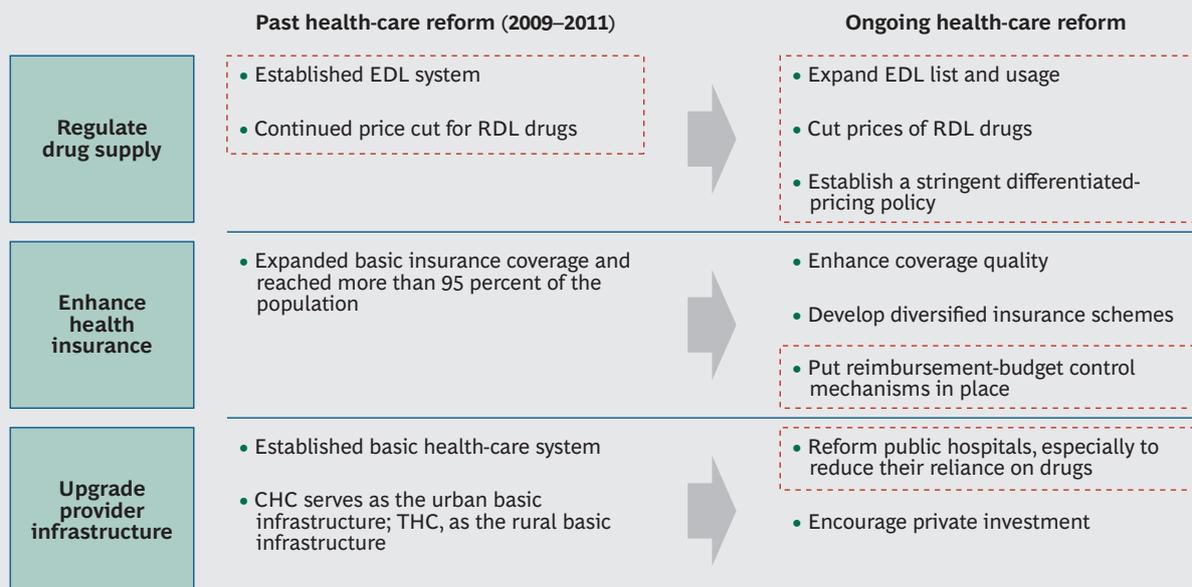
These factors will drive overall health-care spending at a 14 percent compound annual growth rate through 2020, with health care accounting for about 7 percent of Chinese nominal GDP in that year, up from 5.1 percent in 2011. These same trends will power compound annual growth in the pharmaceutical sector of 13 to 15 percent from 2011 through 2020, a robust expansion by any measure, albeit slower than the 20 percent annual pace from 2008 through 2011.

Underlying the double-digit growth, however, is significant change wrought by ongoing health-care reform. The Chinese government has the twin objectives of reducing inefficiencies in the health-care-delivery system and paring the relative cost of major elements of health care; drugs are the most prominent. (See Exhibit 1.)

The impact of reform will be felt in five key areas:

Compressed Drug Prices. The Chinese government seeks to lower drug prices—both retail prices (prices paid by individuals for drugs) and bidding prices (prices

EXHIBIT 1 | Ongoing Health-Care Reform Will Emphasize Drug-Related Cost Containment



 Drug-related cost-containment initiatives

Source: National Health and Family Planning Commission.

Note: CHC = community health-care center, THC = township health-care center; EDL = essential-drug list, RDL = reimbursement-drug list.

paid by public hospitals for drugs). This effort is primarily focused on generic drugs and off-patent originator drugs, which are previously patent-protected products that are now sold off-patent by the companies that originally developed them. The government has paid high premiums for off-patent originator drugs since 2001.

A key element in the government's drive to provide quality, low-cost pharmaceuticals to the entire population is the essential-drug list (EDL). The EDL is the list of drugs originally intended for use in China's primary-care system of community health-care centers in cities and township health-care centers in rural areas; drugs that are on this list are used in large volumes. Drugs on the list, which was created in 2009 and has been expanded to include more than 500 medicines, have no price premiums over generics. As a result, many MNCs have passed on bidding to be suppliers of the drugs listed on the EDL. The prices for EDL drugs are determined through tendering (the process by which provincial governments select drug suppliers for public health-care institutions). In addition, the government is pushing for the EDL to be used not just in primary-care settings such as community and township health-care centers—where it is firmly established—but also in county and city hospitals. That means that in these hospital settings—which account for the majority of pharmaceutical sales—premium-priced MNC products could be increasingly displaced by lower-cost EDL products.

In parallel, the National Development and Reform Commission (NDRC), which regulates health care prices in China, will work to reduce the prices of drugs on the original reimbursement-drug list (RDL). The RDL, the comprehensive list of drugs reimbursed by the government, includes many off-patent originator products. As a result, MNCs will find not only that increased use of EDL products will reduce the use of their premium-priced off-patent originator drugs but also that the premiums will be reduced over the next few years to a maximum of 30 percent over local generics.

Moreover, the NDRC will be stricter about granting a price premium to off-patent drugs in general. This includes not only the off-patent originator products but also differentiated generics, which are generics that have some unique feature or attribute that has entitled them to premium pricing and which are sold by companies other than the original developer. In the future, the NDRC will allow premium pricing only for products that are first to market in their category or have true clinical differentiation, such as a unique form of administration.

Finally, for drugs on either the EDL or the RDL, the actual tendering process, which is already managed by the provinces, has become more intense; decisions are increasingly based on price.

Reduced Hospital Reliance on Drug Revenues. Historically, hospitals earned much of their operating income from drugs as a result of skewed incentives that encouraged doctors to prescribe more-expensive drugs—and to overprescribe in general. Health care reform, however, will reduce and eventually eliminate those incentives. Among the measures that will drive that change: constraints on the percentage of total hospital revenues that can come from drugs and changes in the amount of a drug's markup that goes to the hospital, the way that overall drug budgets are set, and the sharing of budget overruns by the government and the hospitals. These

In hospital settings, premium-priced MNC products could be increasingly displaced by lower-cost EDL products.

measures will limit not only the use of high-priced off-patent originator drugs in cases where there are alternative cost-effective local generic products but also the use of some expensive innovative drugs.

Enhanced Quality of Coverage and Diversified Insurance Schemes. The Chinese government has made concrete efforts to expand basic insurance to cover the entire population; currently, more than 95 percent of the population is covered. The focus now is on enhancing coverage quality and diversifying insurance coverage to enable broader patient access to more costly therapies. Four levels of coverage are available:

For both MNCs and local companies, compliance has emerged as a critical issue.

- *Basic Insurance.* Although the coverage of expenses remains somewhat limited and patients are still required to pay a large amount of their health-care costs out of pocket, basic coverage is improving. The funding that backs it will double from 2011 through 2015.
- *Major-Disease Insurance (MDI).* In 2012, the central government created and funded insurance aimed at providing better coverage for serious, life-threatening diseases. Under MDI, which the provinces offer and manage, the government covers some costs for patients suffering from certain diseases if those patients' out-of-pocket treatment costs have exceeded a certain threshold.
- *Negotiated Reimbursement.* A limited number of provinces and cities provide some coverage for very expensive drugs, such as oncology treatments, based on negotiated terms with the pharmaceutical manufacturer. The number of provinces and cities providing such coverage is expected to expand, as is the number of therapies covered.
- *Private Insurance.* Although the number of privately insured people is small and is expected to remain limited over the medium term, private insurance will grow under new government policies intended to open up the market. This coverage will support the use of innovative therapies.

Increased Emphasis on Corporate Compliance. For both MNCs and local companies, compliance has emerged as a critical issue. Recent investigations into the sales practices of several companies in China highlight this widespread problem; many competitors will have to adjust their sales and marketing practices. We expect that the government will continue to audit and monitor all players in the industry. Both MNCs and local companies will have to pay more attention to the ways they approach the market and perhaps adjust the channels of promotion and marketing that they use.

Strengthened Local Companies. The Chinese government has moved on a number of fronts to strengthen the competitiveness of local companies. New regulations defining good manufacturing practices were introduced in 2011, and the government requires all manufacturers to meet those standards by the end of 2015. The upshot is that the quality gap between products manufactured by local companies and those manufactured by MNCs will narrow. The Chinese government has also supported local innovation through such measures as providing funds to local companies and accelerating the approval of products involving local intellectual

property. And the government is promoting the emergence of larger local players by pushing pharmaceutical-industry consolidation, particularly through deals involving government-owned companies.

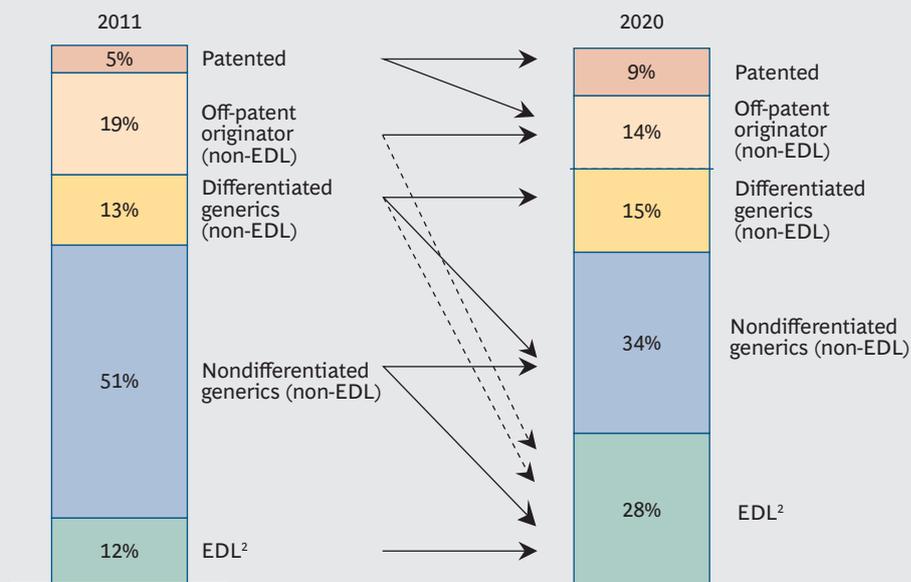
Government Policies Shift the Dynamics for Key Market Segments

As the impact of the government’s health-care reform becomes evident, the competitive dynamics in various segments of the pharmaceutical market will shift. This means more intense competition along with price deterioration in some areas of the market and improved prospects in others.

A Shift in Drug Segment Fundamentals. Consider the impact of reform on individual drug segments. (See Exhibit 2.) The patented-drug segment, for example, will see strong sales growth as several new, potentially high-selling products—including biological drugs—launch. At the same time, the government will continue to support innovation through steps such as the development of diversified insurance schemes that will improve access to more innovative and more expensive medicines. Even without enhanced reimbursement, rising incomes will mean that patented drugs will be more affordable.

EXHIBIT 2 | Pharmaceutical-Market-Segment Shares Will Shift As Health Care Reform Evolves

Breakdown of the Chinese pharmaceutical market by segment based on sales value¹



----- A limited number of drugs from this category will move onto the EDL

Sources: China’s Health Statistics Yearbook 2012; National Health and Family Planning Commission; China Food and Drug Administration; EvaluatePharma; literature search; BCG modeling and analysis.

Note: EDL = essential-drug list.

¹Excludes the retail channel and traditional Chinese medicines.

²The EDL consists mostly of nondifferentiated, generic drugs.

Meanwhile, off-patent originator drugs that are not on the EDL will enjoy volume growth thanks to improved insurance coverage, better affordability due to rising incomes, and reduced price premiums over local generics as the government presses to lower prices on those products.

The group of differentiated generics that are not on the EDL will continue to post robust growth, partly driven by looming patent expirations. But although first-to-market generic drugs will initially enjoy a premium relative to competing generics that are likely to come to market later, over time that broader set of follow-on generics will trigger fairly rapid price erosion.

The segment of nondifferentiated generics not on the EDL will likely contract. Either these drugs will migrate to the EDL, or their production will become concentrated among a smaller number of companies that can use scale to produce high-quality generics at a low price.

Finally, the EDL segment will experience strong growth owing to the addition of more drugs to the list and the increased use of those drugs across all city and county hospitals, as well as throughout the basic health-care system.

A Change in Customer Dynamics. It is critical for pharmaceutical companies to understand how health care reform in China is changing the way that three key customer groups (city hospitals, county hospitals, and the basic health-care system) operate—and therefore changing the composition of the market. (See Exhibit 3.)

City hospitals will account for about 50 percent of growth from 2011 through 2020. These hospitals provide better economics, relative to county hospitals and community and township health-care centers, for pharmaceutical companies thanks to their strong demand for pharmaceuticals and the reasonable costs that pharmaceutical companies incur in selling to these organizations. As a result, city hospitals will continue to be a hotly contested market among MNCs and local companies.

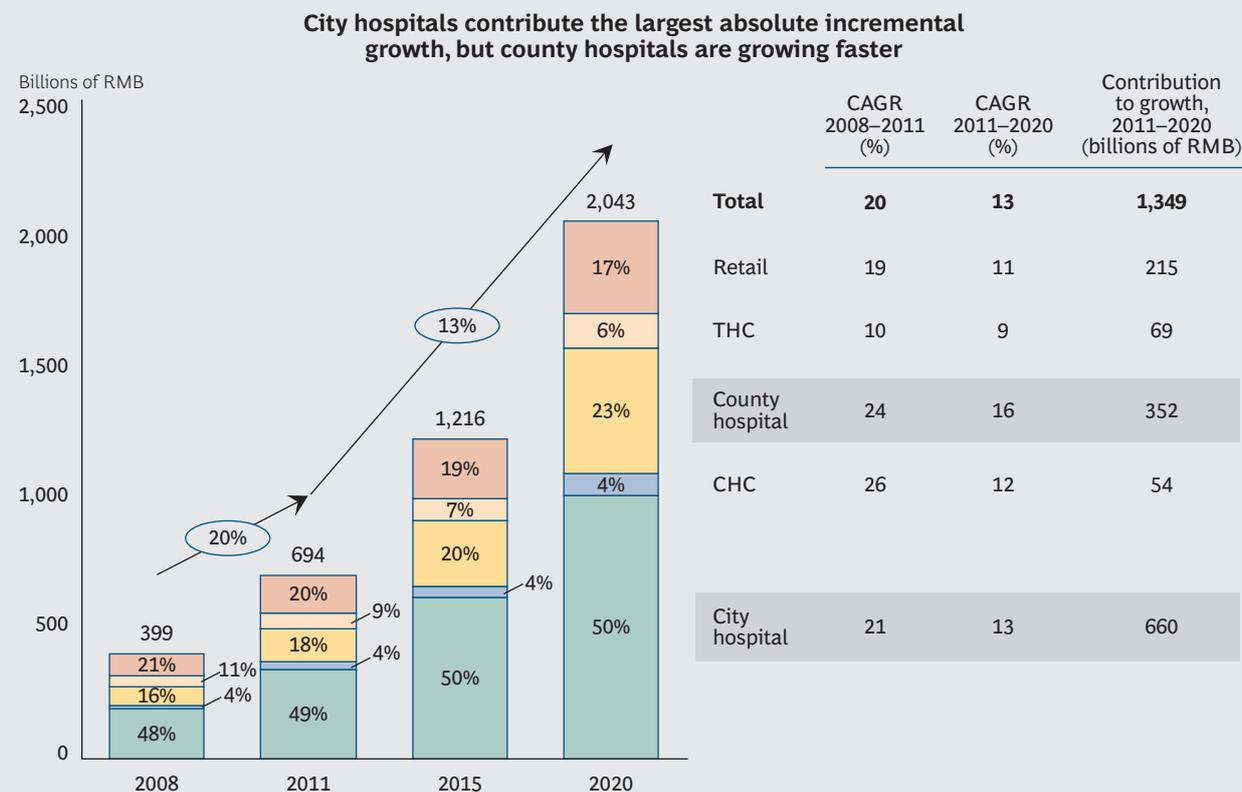
City hospitals will continue to be a hotly contested market among MNCs and local companies.

County hospitals, however, will become an increasingly important market. The government is increasing its investment in new infrastructure and physician training to improve county hospitals' capabilities and is adopting reimbursement policies that encourage people to go to the county facilities instead of the big-city hospitals. That's why county hospitals are expected to grow faster than city hospitals—at a 16 percent compound annual growth rate from 2011 through 2020 versus a 13 percent rate for city hospitals over the same time period. But competing in this category comes with real challenges: lower profitability caused by dispersed distribution across locations and lower sales per hospital.

The broader basic health-care system is made up of community health-care centers in cities and township health-care centers in rural areas. This primary-care system will be the key area of competition for EDL drugs.

A Need to Understand the Factors That Drive Success. Adapting to new market forces requires a keen understanding of both the competitive dynamics in key drug segments and the challenges facing customers. Four sectors are of particular

EXHIBIT 3 | City Hospitals Are the Most Attractive Channel, but County Hospitals Will Become Increasingly Important



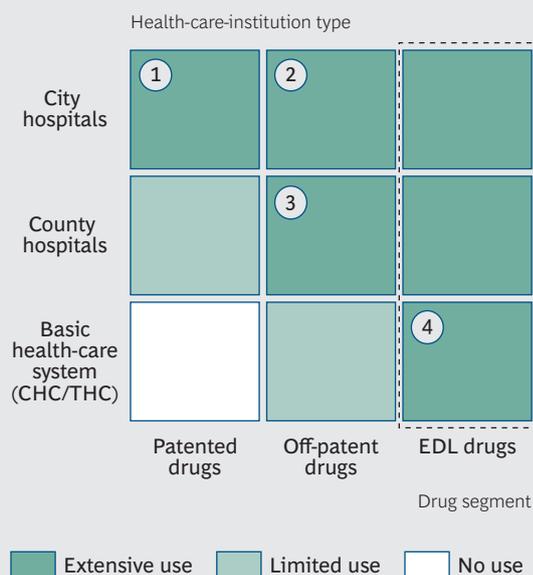
Sources: China's Health Statistics Yearbook 2012; National Health and Family Planning Commission; Economist Intelligence Unit, literature search; BCG modeling and analysis.
Note: Based on institution purchase prices. CHC = community health-care center, THC = township health-care center, EDL = essential-drug list.

importance for pharmaceutical companies in the Chinese market—and what it takes to win in each sector is changing. (See Exhibit 4.)

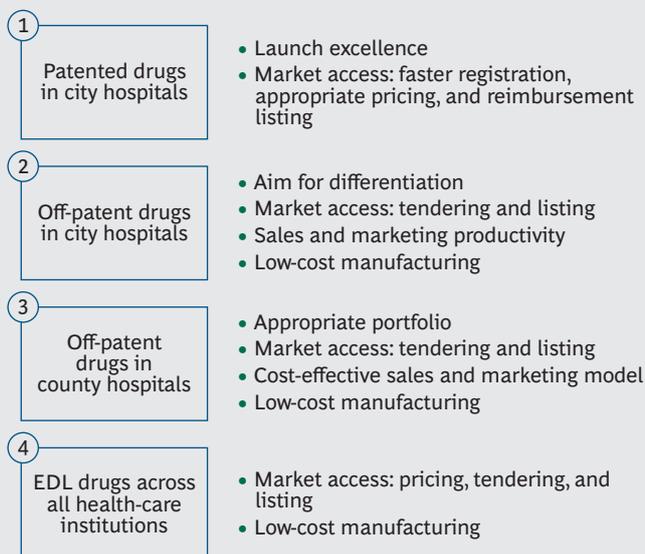
- Patented Drugs in City Hospitals.** This sector, long dominated by MNCs, has experienced relatively slow growth over the past few decades because of the long wait times to gain approval and reimbursement in China and because of MNCs' focus on off-patent drugs. Increasingly, local companies will push to develop competitive patented products. We expect that this sector will grow faster than before but that MNCs will continue to dominate.
- Off-Patent Drugs in City Hospitals.** Both MNCs and local companies compete in this sector, but MNCs in particular will feel the impact of changes. That's because MNCs built large sales forces for single-line detailing, a high-cost sales operation that was focused on city hospitals and was supported by the high premiums garnered by off-patent originator drugs. Going forward, those premiums will erode, making it harder to support the expensive (and increasingly less effective) sales practices, and off-patent originator drugs will face increasing competition from cost-effective branded generics marketed by local companies.

EXHIBIT 4 | Key Success Factors Vary by Target Sector

Companies need clear strategies to choose where to compete and what portfolio to bring



Key factors determine success by target sector



Source: BCG.

Note: CHC = community health-care center, THC = township health-care center, EDL = essential-drug list.

- *Off-Patent Drugs in County Hospitals.* The county hospital market remains much smaller than the city hospital market and has been dominated by local pharmaceutical companies. MNCs have expanded to some large county hospitals in wealthy counties with select off-patent originator drugs. Going forward, however, the fast-growing county-hospital sector will become an important market for both MNCs and local companies. But the sector has its share of challenges: county hospitals are at the center of government reform, which includes a shift to eliminate markups on drugs, and local companies will fight aggressively for share with lower-priced drugs.
- *EDL Drugs in All Health-Care Institutions.* Although MNCs have generally not participated in the EDL market in the past, the EDL sector will become harder to ignore. That's because it will grow much larger and use of EDL drugs will be enforced more aggressively in both city and county hospitals. But there will be significant price cuts for EDL drugs. As a result, this will remain the least profitable of the four key sectors.

MNCs Must Follow a New Roadmap

MNCs need to address two basic questions in setting their strategies for selling pharmaceuticals in China. The first is where to compete. The second is how to compete.

Determining where to compete rests on a company's current and future position in each of the four sectors listed previously and encompasses expected changes in the overall competitive environment. So, a key factor will be the health of the company's drug pipeline. For a company whose pipeline contains a plethora of new, innovative, patent-protected products that are ready to launch, it may be reasonable to put lesser resources into the highly competitive off-patent segments. Most companies, however, will need to achieve a balance between the patented and off-patent segments.

Over time, though, MNCs will likely find the greatest rewards in the patented-drug segment. It seems clear that Chinese companies will continue to dominate in the generic-drug segment, in part because of local companies' low-cost position and willingness to live with lower returns (as is typical of EDL products). That position is likely to be strengthened as government policy promotes consolidation among local players with the aim of creating several larger, more powerful Chinese companies. This won't happen immediately, but we believe that by 2020 there will be many Chinese companies of considerable scale able to compete successfully in all segments but particularly in the EDL and off-patent- drug segments.

On the issue of how to compete, the answers for patented and off-patent drugs will be quite different. And while any individual company's strategy will depend on its product mix and competitive advantage, five key levers can be used:

Enhancing the Patented-Drug Business. The goal for any company competing in this segment is to maximize the sales of products during the period of patent protection. MNCs should be aware, though, that the traditional sales-force model will become more challenging; the restricted access to doctors that is already commonplace in more-developed countries is likely to become the norm in China as well. Companies must ensure the rapid and effective launches of new patented drugs. They must also strengthen their ability to gain market access by striking new reimbursement agreements with provincial governments, for instance, particularly for expensive innovative drugs.

Transforming the Business for Off-Patent Originator Drugs. MNCs will have to determine what new business models they should adopt and what new capabilities they need to build in light of the fact that a large sales force doing single-line detailing will no longer work in this segment. The changes required to adapt will encompass all aspects of the commercial model: sales, marketing, and market access. As premiums on off-patent products disappear, sales efforts may have to evolve; rather than focusing on specific drugs, companies may need to focus on broad disease categories. At the same time, marketing must be made more cost-effective through the use of tools for reaching out to physicians, such as digital communication channels. And market access will need to evolve as well, moving beyond a simple focus on gaining reimbursement to developing a broad effort that includes a team with the ability to manage the tendering processes run by the provincial governments.

Entering the Generics Business. Some MNCs have looked to the generics segment—including both differentiated and nondifferentiated generics—to build new

By 2020 there will be many Chinese companies of considerable scale able to compete successfully in all segments.

“legs” for their businesses. We believe it is unlikely that MNCs, as standalone businesses, will be able to compete successfully in pure generics. Should they wish to enter this segment, they will need to forge alliances or joint ventures with local companies. Hisun and Pfizer have formed a joint venture called Hisun-Pfizer Pharmaceuticals, for example. The reasons why MNCs will need to make such moves to compete in this segment are straightforward. We believe that the Chinese government intends for local companies to supply the bulk of generic drugs in China; therefore, local companies will likely be favored in the tendering process and in gaining market access. In addition, the economics of the generics business are better suited to the lower costs of Chinese organizations and their willingness to tolerate lower returns.

Having local manufacturing sites can be a positive factor in government negotiations for reimbursement.

Leveraging Manufacturing and R&D. MNCs need to think strategically about where they locate manufacturing and the extent to which pharmaceutical R&D is integrated into operations in China. Having local manufacturing sites, for example, can be a positive factor in government negotiations for reimbursement. And the launches of new products can be accelerated in some cases if multicenter clinical trials include sites in China. The importance of speeding up launches can't be overstated given that companies must maximize revenues during the period of patent protection.

Building an Organization with the Right Skills and Expertise. The right strategy is meaningless if it cannot be effectively executed. MNCs must take a hard look at their organization and identify where gaps exist. Functions such as market access, for example, will become more critical, and companies must invest either to improve existing capabilities or to develop them where they are lacking.

Local Players Can Seize New Opportunities

Local companies, although they typically operate from a position that is diametrically opposed to that of the MNCs, will nonetheless need to address the same core questions about their strategy going forward.

The locals are mostly present in the less-differentiated end of the market. Thus, for local companies, determining where to compete means examining how robust their patented- and differentiated-drug portfolios are in terms of breadth as well as how competitive their off-patent-drug operation is in terms of cost.

When it comes to assessing how to compete, the specific capabilities that local players will need to enhance or develop will depend on the segment or segments in which they intend to participate. But regardless of their chosen market focus, it is clear that many companies have critical gaps when it comes to the skills and abilities required to compete.

If local companies continue to play in the off-patent, nondifferentiated drug segments, they will clearly need to continue to improve their manufacturing and commercial operations to be able to compete on cost and efficiency. They will also need to achieve improvements in overall product quality and market access. Stronger local players that are able to achieve scale (as noted, we expect several such companies to develop by 2020) will be successful competitors in the off-patent drug seg-

ments. Moreover, quite a few leading local companies that are focusing on the nondifferentiated end of the market are state-owned enterprises and have not fully integrated recent acquisitions. Improving areas such as corporate governance is critical for business integration that will improve efficiency and avoid a duplication of efforts.

In the patented-drug and differentiated-generic-drug market segments, on the other hand, local companies will need to consider how to enhance R&D capabilities to speed up drug development, or they can explore external sourcing opportunities. We already see several leading Chinese players investing in R&D to better compete in the differentiated-generic-drug and patented-drug segments. These local companies are unlikely to have the breadth and depth of products in the patented-drug segment that MNCs enjoy, but they will still gain some presence. In addition, local companies in the patented-drug and differentiated-generic-drug segment will find it critical to develop effective brand-building skills and improve their product-marketing and product-sales capabilities.

Adapting to an Altered Landscape Is Paramount

The changes being wrought by demographic, regulatory, and competitive forces in the Chinese market are far reaching. And the changes required to compete will be just as significant.

For MNCs, this will require nothing short of a fundamental rethinking of strategies in the Chinese market. Most have built significant businesses mainly on the strength of off-patent originator drugs. That business will essentially disappear over the next five to ten years, making it critical for MNCs to focus on bringing truly innovative products to the market. At the same time, however, many of the most innovative MNC drugs are very expensive, so securing reimbursement is an uphill battle. Certainly, the enhanced and diversified reimbursement schemes that the government is putting in place will cover some of the expense, but the majority of the costs for these drugs will still be paid out of pocket by patients.

Compounding those difficulties is the likelihood that MNCs will not be able to launch new patented drugs in China rapidly enough to fully offset the declines in the off-patent portfolio, in part because of their weak new-product pipelines. And some of their most innovative drugs, which are biologics, will be challenged by local companies offering less-expensive similar versions that manufacturers claim are equivalent to the original patented product.

All of this means that MNCs will be trying to maximize the sales of their off-patent products even as many of those medicines move onto the EDL. In some cases, this will mean focusing on cities where the pricing is a bit higher for those drugs or refraining from bidding to be on the EDL altogether, a step that will result in lost market share over time.

For some MNCs, these shifts are prompting a move into the generic-drug business—both differentiated and nondifferentiated—through joint ventures or possibly as standalone competitors. It will be difficult, however, for MNCs to compete as

The changes being wrought by demographic, regulatory, and competitive forces in the Chinese market are far reaching.

standalone entities in this space in part because of the explicit intention of the Chinese government to promote the development of local pharmaceutical champions in both the innovative and the generics markets. Even without that factor, MNCs will find that their business models—particularly their current sales forces—are not suited to the economics of the generics business.

For the local players, the evolution of the market presents more opportunity than challenge. That’s because the expansion of the generics segment is likely to drive significant growth, albeit growth that favors stronger players as the government seeks to consolidate the sector to reduce the number but increase the strength of local companies.

There will also be more opportunities for innovation as local companies enhance their scale and invest more in R&D, even if much of this investment will be along the lines of the “me too” development focus that we see today. And while “me too” biologics present clear opportunities for local companies, generic small-molecule products will continue to account for the bulk of the market. As a result, local companies that have large-scale, high-quality operations will have a true competitive advantage.

Whether the changes create new openings or new hurdles, the ability to adapt will be paramount. Those that do not adjust will be left behind.

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Acknowledgments

The authors would like to thank Shanshan Wang and Leo Xu for their contributions in data analysis. They also thank Kathryn Sasser and Amy Barrett for their assistance in the report's conceptualization and writing, and Katherine Andrews, Gary Callahan, Catherine Cuddihee, Kim Friedman, and Sara Strassenreiter for their editing and production assistance.

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