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Prescription for healthier growth

Shaping China's life sciences market

Life Sciences

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Prescription for healthier growth

Shaping China's life sciences market

By Chee Hew

Change is in the air for China's life sciences industry, as is continued growth. This climate, as well as the government's heavy investment in healthcare reform and its goal to create a more innovative and competitive industry, will greatly impact the market's key players. We examine the implications for those operating in China and outline recommendations in the key areas of innovation; manufacturing quality; and sales, marketing and distribution.

Executive summary

China's life sciences industry is viewed as a key growth engine both within China, as well as globally. In the new economic environment, selected segments such as the pharmaceutical and medical devices markets are still projecting year–to-year double-digit growth, largely fueled by increased consumer demand. The real attention, however, is focused on the longer-term potential of China's markets. Currently the sixth-largest pharmaceutical market, China is predicted to become the world's third largest by 2011.[1]

The life sciences market in China is undergoing massive changes, due partly to China's intention to invest 850 billion RMB (approximately US$125 billion) in healthcare reform, which is expected to bring immense opportunities for key players.[2] The government is also setting up a more transparent and efficient environment for all stakeholders in the healthcare ecosystem. In this paper, we discuss the impending changes and highlight the major implications for life sciences players. We believe:

- Increased social insurance for healthcare will lead to more accessible and affordable services for three major consumer groups: rural populations, migrant workers and urban residents.
- There will be more efficient and effective delivery of healthcare services. Introduction of primary care in urban areas and a three-tier rural healthcare system will result in new customers and changes to the channel mix, requiring new capabilities from life sciences players.

- There will be increased attention on pricing controls, availability and safety of prescription drugs due to changes in regulations and the establishment of national pricing, listing and bidding guidelines.

The life sciences industry is also being shaped by the Chinese government's efforts to boost innovation and the level of competition, particularly among domestic players. These efforts to promote innovation are increasing the focus on and consolidation of research and development (R&D) resources. We believe this will lead to a more vibrant R&D market that attracts further investments and growth in China. In addition, revision of China's good manufacturing practices (GMP) and good supply practices (GSP) will increase quality and compliance standards, lifting requirements for and expectations of manufacturers and distributors. Elimination of weaker players and further industry consolidation will help raise the competitive threshold of the survivors. Overall, we expect the life sciences market to become more mature and competitive.

The objective of this paper is to provide organizations already operating in China with practical insights on how to succeed in China's rapidly growing and changing life sciences market. We recommend they focus on increasing capabilities in three key operational areas:

- Innovation – Strengthen R&D capabilities to leverage local talent, regional capabilities and incentives, and national attention. This can be achieved by building up R&D presence through external collaboration and strengthening in-house capabilities through talent development and management programs.
- Manufacturing quality – Achieving high-quality and compliant manufacturing is no longer a differentiator, but a prerequisite. Companies need to enhance manufacturing capabilities to increase production efficiency, lower operational costs and achieve effective compliance across the supply chain.
- Sales, marketing and distribution – Key players need to achieve more effective market access, affordability, quality and safety through improved channel and logistics management. Building effective sales management and channel strategies is critical for success. Tighter collaboration between manufacturers and distributors is also required to improve efficiency.

Prescription for healthier growth

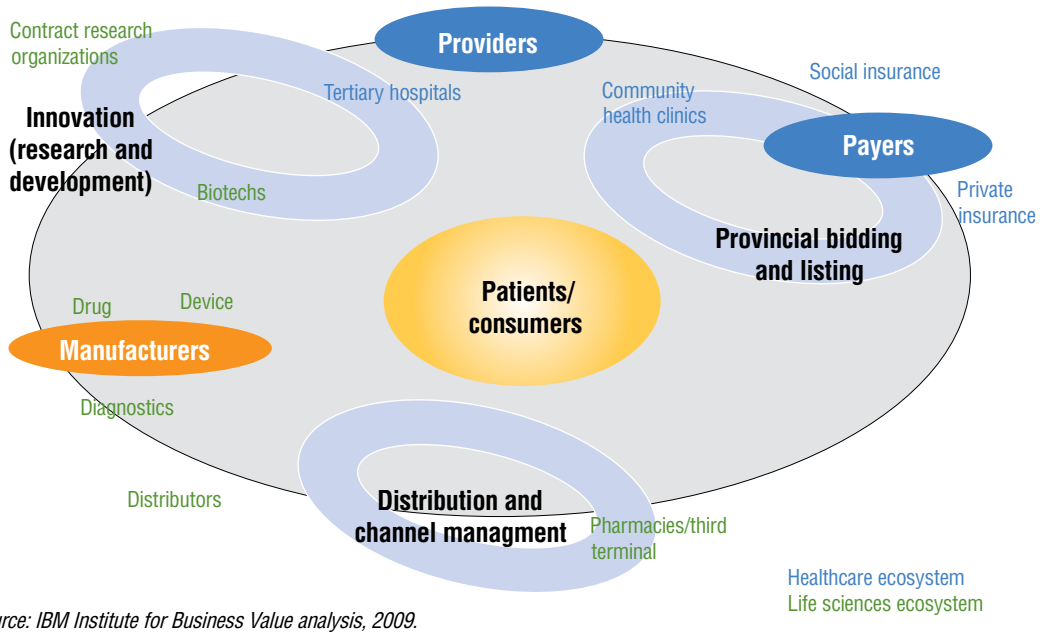
Shaping China's life sciences market

Defining the life sciences market

We define the life sciences market to broadly include key players in the extended healthcare ecosystem (see Figure 1). Each supports or provides services related to pharmaceuticals or other medications, medical devices, diagnostics services or equipment ultimately related to patient care. This includes innovation (R&D), manufacturing, and marketing and distribution.

China's life sciences industry is a bright spot of growth in a global economy where many industries are facing declining growth rates. For instance, the pharmaceutical market is viewed by some to be recession proof and has been capturing attention due to its immense growth potential. In 1997, the market size for branded and over-the-counter (OTC) drugs in China reached only US$3.7 billion, whereas in 2010, it is expected to reach US$22 to US$25 billion.[3] In 2009, China's pharmaceutical market projects year-to-year growth of 25 percent, which is higher than other emerging markets that predict approximately 15 percent growth and significantly higher than the approximate 5 percent growth predicted in developed countries.[4] However, what is really catching worldwide attention is the projection that branded and OTC drug sales in China will reach US$220 billion by 2020, making it the second largest market globally, only behind the United States.[5]

FIGURE 1.
Definition of life sciences market.



Source: IBM Institute for Business Value analysis, 2009.

China's life sciences market is undergoing both growth and change, due in part to the government's large investment in healthcare reform.

The life sciences market will experience further boosts through China's healthcare reform and the government's commitment to create a more innovative and competitive industry. In this new "healthier" yet more regulated environment, life sciences players will need to adapt their roles to better meet patient needs and evolve into true leaders in the global market.

Implications of China's healthcare reform on the life sciences industry

China is making unprecedented investments in reforming its healthcare system. As part of its efforts to provide affordable, higher-quality healthcare to all citizens, the State Council announced in January 2009 that it will invest 850 billion RMB (approximately US$125 billion) over the next two years in healthcare.[6] Given the important role of pharmaceuticals in the healthcare system, this investment will have a significant impact on key players in the life sciences system, including pharmaceutical manufacturers, medical device companies and distributors.

More accessible and affordable healthcare will increase healthcare expenditures, resulting in increased demand for drugs and medical devices.

A major objective of the healthcare reform is to address the problem of Chinese citizens unable to afford healthcare due to lack of medical insurance. Building on the significant progress made in the last few years, China has set a goal that more than 90 percent of Chinese citizens will be covered by public insurance by 2010.[7] This will require expanding coverage in cities through the urban employee and urban medical insurance funds, as well as in the rural areas through the new rural cooperative program.[8]

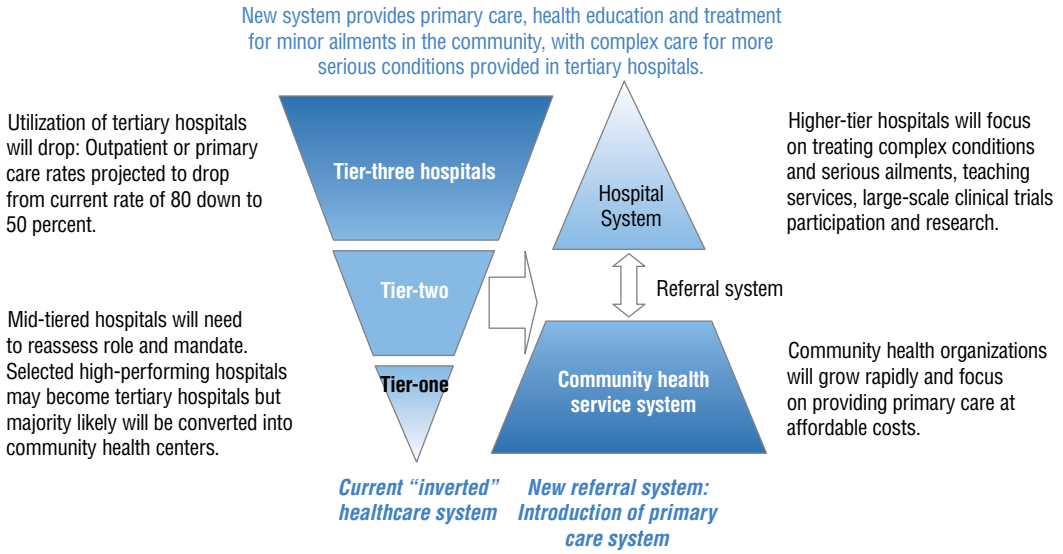
In addition to increasing the number of individuals covered, the government will increase the level of subsidies per individual. For instance, the government subsidy for the urban medical insurance program will increase from 80 to 120 RMB per individual, whereas the government's contribution for rural residents will triple from 40 to 120 RMB per individual. While these increases might seem insignificant on an individual basis, the impact on healthcare expenditures across the nation will be immense due to the large population size. Analysts predict the impact of increasing healthcare coverage will expand the subsidized funds for drug expenditures from 165 billion RMB to as high as 333 billion RMB by 2011.[9] It is almost a unanimous belief among industry spectators that increasing insurance coverage will further spur the growth of pharmaceutical sales in the next two years.

More efficient and effective delivery of healthcare services will change the current channel, product and customer mix for life sciences organizations.

"Inverting the pyramid" in the cities places new emphasis on the community healthcare organization.

The proposed healthcare reform also aims to address the issue of inefficient use of healthcare resources (including healthcare professionals, beds, facilities etc.), particularly in the cities.[10] A new referral system has already been piloted in China and now will be implemented on a national basis (see Figure 2). The main principle of this new structure is to introduce a primary care system through which patients are treated in their communities at lower costs for common ailments. In cases where specialty care is required, patients will be referred to tertiary hospitals.

FIGURE 2.
Reform of the healthcare service delivery system in cities.



Source: IBM Institute for Business Value analysis, 2009.

This marks a significant change from the current system, which concentrates patients in tertiary hospitals, primarily in the large tier-three hospitals. In the new model, higher-tier hospitals will have a new mandate to focus on treating complex conditions and serious ailments, teaching and conducting research. It is expected that utilization of higher-tier hospital resources will drop. For instance, outpatient rates are expected to drop from the current 80 percent down to 50 percent.[11] Mid-tier hospitals will need to change their current role and mandate by assessing their core services and either evolving into tertiary services or specializing in community health.

The emergence of community health organizations is a significant development in introducing primary care in China. Community health organizations will focus on treating common ailments, promoting wellness and providing disease control services at affordable costs. By 2010, China expects to have 67,000 community health organizations across Chinese cities, almost three times as many as in 2007. The goal is for one community health center (CHC) to be set up per 30,000 to 100,000 citizens in urban areas and for a CHC to be linked up to several Community Health Service Stations (CHSS), which are essentially smaller satellite offices.[12]

The rapid expansion of the community health organizations has significant impact on both healthcare providers and life sciences players who are focused on primary care. There is an urgent drive to quickly recruit and train sufficient qualified medical professionals to staff these organizations. Medical device companies will see an increased demand in sales, as

CHCs are projected to spend up to 30 percent of the national investment to equip their facilities with common medical equipment.[13] Sales of commonly used drugs, particularly generics, should also see a significant boost.

Creation of a three-tier rural healthcare system will introduce additional customers and channels for life sciences organizations.

A new three-tier healthcare system is also being set up in rural areas to allow rural residents to treat common ailments within the village and major ailments within the county. The county-level hospital will act as the "specialty hospital in the rural area," providing basic healthcare services along with treating specialty diseases. County hospitals also have the mandate to train and provide guidance to doctors and healthcare workers in village health stations. Starting in 2009 and expected to expand for three years, the government will invest in more than 2,000 county hospitals, ensuring that there is at least one hospital per county that reaches defined standards and requirements.[14]

Similar to community health organizations, rural healthcare providers represent relatively new channels and markets for pharmaceutical manufacturers, medical device companies and distributors. The emergence of these markets will impact both the volume and types of drugs sold, as well as the current channel mix.

Reforms surrounding the prescribing, distribution and sales of drugs will require operational changes within life sciences organizations.

Medication, particularly how it is prescribed, procured and distributed, has long been a highly debated topic in healthcare system reform discussions. While detailed policies affecting the use and sales of drugs have yet to be released in China, the updated healthcare reform mandate highlights potential means to increase transparency in drug sales and usage while reducing overall costs to the healthcare system (see Figure 3).[15]

FIGURE 3.
Predicted impact of various levers to control medicine use and sales.

Lever	Likely impact on life sciences organizations
National list: Categories drugs according to level of reimbursement.	• Will increase need for strong government relationship programs. • Could spur growth of traditional Chinese medicine sector.
Pricing: National guidance on maximum pricing for drugs.	• Generic drugs will have significant cost pressures, while innovative branded drugs likely to be allowed higher margins. • Foreign generic drugs possibly adjusted downwards.
Procurement: Open bidding for listing of drugs and centralized procurement at provincial level.	• Drug prices will be reduced in open transparent bidding system, requiring companies to have better control of quality and costs.
Distribution: Goal for direct distribution of basic drugs to 80 percent of community health organizations/rural healthcare providers.	• The number of layers of distributors will be reduced, encouraging consolidation and growth of larger regional and national players. • Manufacturers and distributors will need to become more cost effective.
Usage: Enforce restrictions on prescription restrictions, particularly for community healthcare providers and basic drugs.	• Will encourage use of low-priced drugs, further propelling growth of generic markets. • Will "standardize" prescription use among healthcare providers.

Source: IBM Institute for Business Value analysis, 2009.

China's healthcare reform will create significant changes for life sciences players, including shifts in channel and customer segments.

Core to the reform is the introduction of a national drug list that will organize and group types and brands of drugs into three major categories, each with different pricing and reimbursement profiles. Category A drugs include mostly "basic" drugs that are 100 percent reimbursed by government-subsidized medical insurance. Category B drugs are partially covered, and Category C drugs are not covered by government insurance. Local governments will have some flexibility to adjust the categorization of drugs according to particular regional needs. The national list will also provide suggested price caps – or maximum prices – for drugs, although provincial governments will retain the ability to negotiate and set final pricing.[16]

Under the new plan, all community health organizations are expected to adhere to the published lists for all drug prescriptions, while other healthcare providers (e.g., tertiary hospitals) will prescribe Category A drugs as their first choice.[17] Other ways to use the drug list to further control costs have been suggested, such as adding retail pharmacies that would be eligible for reimbursement by social insurance for listed drugs. The objective is to further bring down prices by expanding consumer choice regarding where to purchase medications, thus encouraging free-market competition.

Another major proposed change involves each provincial government setting up a not-for-profit centralized drug procurement platform in which all state-owned healthcare providers would be required to participate. The new system would likely include online group purchasing and competitive pricing incentives and improve transparency of the procurement process. Provincial governments would be expected to establish a methodical approach to evaluating bids, placing increased emphasis on factors such as effectiveness, quality and safety, price and services, as well as the overall reputation of the manufacturer. At the same time, healthcare providers would be urged to improve standardization in medication prescribing protocols to improve quality and regulate prescription patterns among healthcare personnel.[18]

Some local governments, Guangdong for example, have already started to implement various aspects of the proposed changes.[19] These changes have forced both manufacturers and distributors to gain better control of quality and costs. It is expected that the distributor market will also be impacted by the goal to have direct distribution of basic drugs to 80 percent of community health organizations or rural healthcare providers.[20] The achievement of this goal likely will lead to consolidation and, as a result, growth of larger regional and national players.

China's healthcare reform will shift current channel and customer segments.

China's healthcare reform brings about significant change and opportunities for life sciences players. Drug manufacturers (especially those with primary care focus), medical device manufacturers and vaccine manufacturers are most likely to benefit from the government's increased spending on public health, broader medical insurance coverage and expansion of the primary care system. Traditional Chinese medicine (TCM) manufacturers can also expect added attention and sales, as the national drug list is expected to comprise up to 50 percent TCM products.[21]

The change in channel mix and customer segments is another key element of healthcare reform. Up to 20 percent of total volume is predicted to shift from the traditional market, which includes hospital and retail pharmacies, to the third-terminal market, which includes channels such as county hospitals, community health organizations, clinics, health wellness centers, etc.[22] We note the emergence of three distinct market segments, requiring companies to build up different capabilities to successfully market, sell and distribute to each segment (see Figure 4).

The increased control of drug sales and usage through initiatives such as the national drug list and controlled drug prices through open bidding implies that pharmaceutical manufacturers and distributors need to have more visibility and control over sales and distribution. Companies will also need to build up and strengthen expertise to better manage government relations with emphasis on pricing, reimbursement and listing.

Creation of a more competitive and innovative life sciences market

The life sciences industry in China is continuing to evolve, becoming ever more competitive and innovative. The Chinese government has initiated a variety of actions to drive innovation and is using increased standards and requirements to change the playing field. This aligns to China's overall goals to support domestic companies that utilize innovation to move up the value chain and to enhance the ability of local enterprises to more effectively compete both in China and international markets. The result is a more competitive innovation market for life sciences organizations, as well as a more attractive market for multinational players.

FIGURE 4.
Emergence of three distinct market segments in China.

	Premium	Value	Volume
Target organization	• Tertiary and secondary hospitals	• Community healthcare organizations	• Rural healthcare providers
Product offering	• Secondary care • Chronic and acute conditions	• Primary and secondary care • Mainly chronic conditions	• Primary care • Chronic conditions
Operational capabilities	• R&D capabilities required to develop leading products • Smarter, more focused sales force to market to specialists	• Intense marketing and sales to target primary care physicians • Expertise in accelerated launch • Quick and responsive market access abilities	• Operational excellence – low costs, high service levels in marketing and distributing drugs • High level of integration between manufacturers and distributors

Source: IBM Institute for Business Value analysis, 2009.

The government has initiated a number of programs to increase standards, drive competition and spur innovation.

Focused efforts to promote innovation will result in China-led innovation, creating a more vibrant R&D market that attracts further global investments.

Recognizing the potential for China to become a global player in the life sciences industry, the Chinese government has identified biopharmaceutical (biopharma) as a priority industry,[23] estimating that by 2020, the biopharma industry will account for more than 4 percent of total gross domestic product (GDP).China's most recent five-year plan placed particular emphasis on the growth of innovative R&D within China's pharmaceutical industry, specifically on owning intellectual property to newly developed drugs.[24]

A key national program started in 2008 to boost innovation is the New Drug Creation and Development program, designed to accelerate drug research and development among domestic companies. Goals planned to be achieved by 2010 include:

- Establish ten to twenty new drug incubation bases.
- Form eight to ten drug innovation alliances.
- Establish between five and ten new companies.
- Invest 6.6 billion RMB (US$960 million) between 2008 and 2010.
- Have at least thirty new drugs in the pipeline by 2010 with plans for several of them to enter European or U.S. markets.
- Make breakthroughs in twenty to thirty key technologies, including those used in new chemical drug discovery, biotechnology and TCM quality control.[25]

The program is being implemented in two phases, with phase one focused on developing "incubator bases" at corporate development research centers. In 2008, six corporate incubator sites were identified, including Beijing Pharma, Huabei Pharma, Shijiazhuang Pharma, Zhejiang Pharma, Tianjin Tasly Pharma and Jiangsu Hengrui Pharma, as well as two new drug discovery research centers to be set up in Beijing Pharma, Tongrentang. Additional objectives in phase two (started in 2009) include research on key technologies required for new drug development, discovery work on innovative drugs and development of a drug discovery research platform.

One of the key benefits of the program is that it provides much-needed focus in terms of defining research areas and concentrating domestic research and development efforts within China. For instance, the program outlines the focus on researching drugs to treat the ten most critical diseases, accelerates modernization of TCM and places emphasis on further expanding China's strength in biologics. Developing corporate research centers across China will help consolidate funding and resources on promising domestic firms. Recognizing that the expensive "blockbuster" R&D model that many multinationals are now struggling with is not suitable for China, Chinese companies are trying to develop a China-specific drug development model. While the ultimate answer is not yet clear, it is evident that domestic firms need to raise their capabilities significantly to be competitive globally. Even within China today, there is intense competition to attract the best people and form strategic alliances with leaders in academia and biotechnology, as multinationals increasingly look to China as a key source of innovation.

Recognizing the potential of the life sciences industry to introduce higher-value manufacturing and employment, many local governments have set ambitious targets to become key hubs within China. Tianjin, for instance, aims to have 100 R&D projects, attract 100 entrepreneurs and institutes, and generate 500 billion RMB of industry scale to transform Binhai New Area to a biopharma base with proprietary intellectual property rights.[26] As another example, Wuhan hopes to generate sales value of 130 billion RMB annually by 2020 from its biology industry base.[27]

It is obvious that these hubs are not meant to attract manufacturing investments but to increase activities such as R&D and outsourcing services. The competition for these hubs is highly intense, with more than 100 regions vying to be key biopharma bases and 50 approved "bioparks" already being built in China. In comparison, the United States has 16 key biopharma hubs, while France has only 14. The challenge is compounded by the fact that many multinationals have already invested in R&D sites, particularly in major hubs such as Beijing and Shanghai.

Local governments are also playing a key role in promoting innovation. A number of strategies have helped provide focus and consolidate resources to drive innovation (see Figure 5).

Continued refinement and consistent adoption of good practice (GxP) standards will benefit the industry.

China has been revising and implementing GxP standards for all operational aspects. In R&D, international good clinical practice (GCP) and good laboratory practice (GLP) standards are being adopted in China, especially among contract research organizations and other R&D organizations that are working with global partners. Currently, GMPs and GSPs in China are different from those in the United States and the European Union, with China revising and lifting standards to meet local safety and quality requirements. The government's raising of GMP and GSP standards will have the most impact in terms of leveling the playing field between multinational companies (MNC) and domestic manufacturers.

FIGURE 5.
Examples of local governments driving innovation.

Consolidate and leverage existing R&D resources to focus innovation	Guangdong Provincial Department of Science & Technology consolidated resources from leading academia and four private companies, investing 1 billion RMB in a virtual South China New Drug Development Center.
Leverage unique strengths in traditional Chinese medicine to identify new compounds	Yunnan will leverage locally unique flora that are currently used by minority tribes for medicine. Yunnan intends to strengthen quality standards in selecting, harvesting and processing Chinese herbs for medicine usage and research.
Focus on biotechnology/biologics; Explore research service market	Beijing intends to leverage unique strengths and critical mass in biologics and biotechnology to develop biotechnology research service opportunities.
Build and enhance collaborative ecosystem	Shanghai has built up a strong ecosystem of R&D players, including multinational pharma and biotechnology companies and contract research organizations, and invested in leading academic institutions. There has been extensive collaboration through strategic alliances and research outsourcing within the ecosystem.

Source: IBM Institute for Business Value analysis, 2009.

Updated good practice standards will further raise the quality and competitive levels of Chinese manufacturers.

Strengthening GMP standards will require manufacturers to improve quality systems at existing operations.

China has, in fact, been increasing the scope and level of scrutiny in implementing GMP standards. A significant milestone occurred in 2004 when China ordered production halts to 1,800 manufacturers that failed GMP certifications, mostly due to lack of sufficient financial and human resources. This move greatly improved quality management among enterprises and promoted structural adjustments in the industry.

The government plans to implement updated GMP standards in 2010, further raising the quality and competitive levels of Chinese manufacturers. The focus of the revamp will be on increasing nonfacility requirements for manufacturers and reviewing GMP standards to help ensure they complement guidelines on drug registration and drug recall administration. Major changes include:

- Evaluation of how well manufacturers adhere to drug supervision, registration and recall regulations when they apply for GMP certification.
- Requirements that manufacturers conduct annual quality inspections and are responsible for product recalls.
- Expanded documentation requirements for new concepts such as drug quality assurance, design validation and change control. (Current GMP standards only require manufacturers to document the main steps or key areas in the production process, while the new standards will probably entail filing of details for every stage of production before products are sent to distributors.)[28]

These updated standards will further contribute to product quality and safety levels of drugs, forcing manufacturers to improve core quality and compliance of manufacturing systems. Drug manufacturers will also need to have better visibility of the distribution process, requiring tighter collaboration with distributors to help ensure compliance with new guidelines for product recalls.

For Chinese manufacturers that intend to manufacture drugs for export, it is essential to make the investments necessary to meet not only Chinese but also international quality and compliance standards. An attractive strategy for domestic pharmaceutical manufacturers seeking higher value-added growth is to move from manufacturing active pharmaceutical ingredients (API) to exporting finished drugs. A prerequisite, however, is the ability to meet international standards. Currently less than 20 Chinese manufacturers have achieved certification for European Union current good manufacturing practice (cGMP) standards, and only one company, Zhejiang Huahai Pharmaceutical Co., has received certification for exporting finished medicine to the United States. In fact, Huahai's successful approval in 2007 for product fully manufactured in China is seen as a major milestone for Chinese manufacturers.

A success story: Approval to export finished medicine

Established in 1989, Zhejiang Huahai has become a leading domestically listed pharmaceutical manufacturer in China specializing in manufacturing active pharmaceutical ingredients, most of which are exported to drug companies in more than 30 countries. In 2007, Huahai became the first Chinese company to obtain U.S. Food and Drug Administration (FDA) approval for a finished medicine – an AIDS drug. The application process was not easy and required significant investments – more than 100 million RMB. The entire process took Huahai five years and spanned from initiating the plan to preparing paperwork to an on-the-spot FDA investigation. The benefits, however, justify the investments made. Although Huahai must wait until the U.S. patent expires in May 2012 to export its medicine, having the FDA's official approval should make it easier for Huahai to get approvals from other countries and also increase its ability to attract international drug partners. In fact, in 2008, Huahai was selected by Merck Sharp & Dohme as its original equipment manufacturer in China.[29]

Revision of GSP standards will further accelerate the maturation of the distribution industry.

China has also released a new version of GSP for consultation, proposing higher requirements for manufacturers and distributors. Proposed changes include:

- Stricter monitoring. There are more severe punishments for companies that violate GSP, such as suspension/withdrawal of certificates and operating licenses.
- Increased emphasis on traceability. There are requirements that information technology systems monitor the procurement, storage and sales of drugs to improve quality control of the entire process, as well as increased requirements on monitoring the source of each drug.
- Increased regulations on management of manufacturers and distributors. For instance, there will be stricter requirements on a distributor's infrastructure and facilities (for example, storage space should be no less than 15,000 square meters).[30]

The distribution industry has experienced a lot of consolidation in the last few years, with the majority driven by expansion of coverage at the regional, not national, level. The top three players in China have close to 20 percent of the Chinese medical distributor market. While still in sharp contrast compared to the 95 percent and 65 percent that the top players hold in the United States and Japan respectively, it is viewed as a critical turning point for the industry. Proposed GSP changes call for key players to have bigger and better infrastructures and, more importantly, to implement effective operating processes and systems to help ensure compliance. This might require putting in place traceability solutions similar to e-pedigree requirements in Europe and the United States that can track the source of drugs throughout production and distribution cycles.[31] As smaller players unable to meet requirements are forced to close down or consolidate, the entire competitive threshold of the survivors will be raised.

In summary, we anticipate domestic players will become more innovative and competitive, changing the China life sciences industry (see Figure 6). Multinational players can also benefit from seeking more partnership opportunities, not only within R&D but also potential manufacturing outsourcing within China.

Both domestic and multinational companies can benefit from the changes occurring.

FIGURE 6.
Likely changes in the life sciences industry.

Current	Future
• **Domestic innovation efforts are fragmented and "commoditized."** – Major domestic players focused on developing "mass market" generics, resulting in uncompetitive product portfolio. – R&D resources (finances and human resources) spread thinly over domestic pharma and academia.	• **Focused efforts in drug development will result in "China-led innovation."** – Consolidation of existing R&D resources. – Leverage China's strengths – for example, in biologics, traditional Chinese medicine, etc. • **More vibrant R&D market attracts further investments and growth.** – Multinationals continue to invest in China given large market potential and build up of critical mass. – China-based contract research organizations further grow and expand.
• **Manufacturer and distributor markets are highly fragmented, with many unable to meet GxP requirements.**	• **"Survival of the fittest" eliminating weaker players and furthering industry consolidation.** – Increased GMP & GSP requirements raise the competitive threshold of the "survivors" who are better positioned to compete with multinationals and enter international markets.

Source: IBM Institute for Business Value analysis, 2009.

Prescription for change: Recommendations for participants in China's market

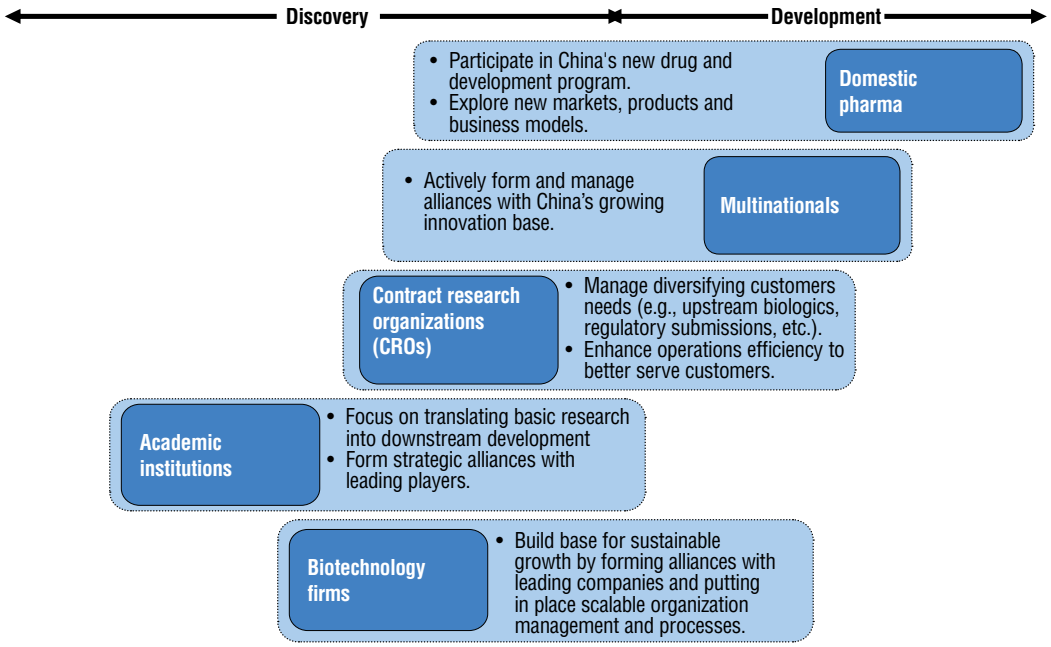
To succeed in this rapidly changing market, key players in the life sciences sector need to prepare themselves by establishing and strengthening capabilities in three key operational pillars: innovation; manufacturing quality; and sales, marketing and distribution.

Innovation: Organizations should strengthen R&D capabilities, taking advantage of national and regional attention and China's immense talent reserves.

Life sciences players can expect R&D activities to continue to intensify in the short term. Aside from the focused domestic innovation previously outlined, multinational pharmaceuticals likely will continue to invest in R&D to capitalize on the market growth. Life sciences organizations can expect innovation initiatives to become more sophisticated and comprehensive in nature, particularly in the discovery area. Essentially, each player will have specific challenges to address (see Figure 7).

As China evolves to become a critical innovation hub within the global pharmaceutical industry, there are two common challenges. First, building and strengthening in-house capabilities requires appropriate talent recruitment, retention and management programs, particularly as competition intensifies in hubs such as Beijing and Shanghai. Second, an increasingly prevalent and effective model for innovation within the industry today involves extending R&D capabilities through external collaboration. These are the same capabilities that R&D organizations have to manage globally. In a recent IBM survey, approximately two-thirds of chief executive officers (CEOs) concur that people skills will cause the most changes for life sciences companies over the next three years.[32]

FIGURE 7.
Different challenges for key players involved in innovation.



Source: IBM Institute for Business Value analysis, 2009.

Domestic companies can adopt different strategic options to develop their own model of innovation.

For domestic pharmaceutical firms, the evolution from generics to innovation will require a gradual build up of human talent and expertise, as well as financial resources. Outlined below, we have identified various strategic options for domestic companies to slowly develop their own model of innovation:

- Adopt the hybrid model. Exploit the low cost base in China to offer outsourcing services to third parties to subsidize the revenue required to fund R&D activities. For instance, Hisun Pharmaceuticals manufactures a tuberculosis drug for Eli Lilly to help finance its own R&D efforts.[33]
- Form strategic alliances. Pursue strategic alliances and licensing deals with multinationals and academia to develop and market a profitable portfolio, with an eventual goal of moving toward global markets. For example, North China Pharmaceutical Group New Drug Research & Development Co. Ltd. has formed alliances with Yunnan Institute of Microbiology and Hans-Knöll-Institute in Germany to conduct anti-cancer drug research.[34]
- Move into the "branded generics" space. Be first to market by launching branded generics in local markets. Simcere Pharmaceutical Group, for instance, adopted a "first-to-market generic" strategy and introduced Bicun, one of the only two injectable neuroprotective stroke management medications.[35]

While each player will face different innovation challenges, all should focus on strengthening R&D capabilities.

- Seek export markets. Enter export markets with niche finished generic products like Huahai has done. Aside from FDA approval to export AIDS drugs to the United States, Huahai is also working to export a finished dosage Alzheimer drug to Europe by early 2008.[36]
- Find new markets in which China has a unique advantage. There is an increased focus on development of biosimiliars for commercialization both domestically and overseas. Examples include interferons, erythropoietin growth factors, human insulins, etc. Dragon Pharmaceuticals is an example of a company with local expertise that larger biosimilar companies might find beneficial.[37]

MNCs should further leverage China's growth capabilities in R&D to augment the global pipeline and accelerate time to market.

Many multinationals have already made significant investments in R&D in China over the last few years, with commitments of up to several hundred million U.S. dollars to build R&D centers, some with global innovation mandates. Given the importance of the China domestic market to sales and the potential of China's innovation abilities, MNCs should evaluate opportunities to actively source within China's innovative base. Leveraging China's contract research organizations' capabilities can accelerate time to market.

Multinationals should put into place an effective biopartnering strategy addressing three key elements:

- Start from a position of strength. The MNC China R&D team should proactively search for partners in China, including leading research institutes, biotechnology companies, etc. and build a reputation for being a partner of choice.
- Search for the win-win. Understand the unique interests of Chinese R&D organizations and cater to them (e.g., offer more influential roles for academic scientists).
- Practice appropriate alliance management. Facilitate interaction with partners that are starting to work with global teams to reduce unnecessary conflicts, etc. Collaboration techniques and cultural considerations will be important.[38]

Leading multinationals are also tapping into China's research strengths, natural heritage and extensive history, looking for sources of new drugs from TCM, focusing on areas such as infectious diseases and biologics, and capitalizing on China's large disease populations (e.g., hepatitis and oncology) to contribute to global R&D efforts.

Manufacturing quality: Companies must transform their manufacturing capabilities to move toward proactive quality management, lower operational costs and effective regulatory compliance.

In an environment where GMP standards are being increasingly refined, improved and enforced, achieving high-quality and compliant manufacturing is no longer a differentiator, but a prerequisite. If managed appropriately, high-quality and compliant manufacturing will add value through better production efficiency and lower operational costs.

Leading domestic pharmaceutical companies can improve compliance and increase quality by putting in place required prerequisites:

- Be familiar with compliance requirements, particularly if entering international markets. If Chinese companies intend to enter the U.S. market, they need to be familiar with and understand the operational implications of the legal requirements of U.S. Code of Federal Regulations-21 part 210 (current good manufacturing practice in manufacturing, processing, packing or holding of drugs). For example, electronic batch records management not only fulfills key regulatory requirements, but also can dramatically improve overall quality and efficiency.
- Set up and implement effective quality management processes and systems. It is important to think of improving quality by setting up systems (including process, facilities, etc.) as opposed to focusing on individual products. The U.S. FDA describes this in terms of 12 core quality systems and will perform inspections based on risk assessments of those systems.
- Maintain training records and resource qualifications. Consider the readiness of organizations and which people can deliver the required quality performance. Document management is also a core competence of modern manufacturers and covers areas such as standard operating procedure management, corrective action/preventative action and master batch records.

Leading domestic pharmaceutical companies should also take a structured approach to managing compliance strategically and tactically:

- *Strategic* – Analyze risk diagnostics to identify root causes of failure, quantify product risk and measure revenue impact. This will allow companies to prioritize, schedule and justify the best actions to reduce and manage risks.
- *Tactical* – Transform the industrialization process by building quality into products and processes using science, systems and technology.
- *Technology* – Create a compliance-centric architecture by aligning people, processes and technology for quality, efficacy and safety.

Sales, marketing and distribution: Commercial operations can improve access, scalability, affordability, responsiveness and safety through improved channel and logistics management.

Life sciences players are being challenged to provide affordable, quality, safe drugs. In addition to building and expanding effective sales management and channel strategies, there is a need for tighter collaboration between manufacturers and distributors for efficient channel and logistics management.

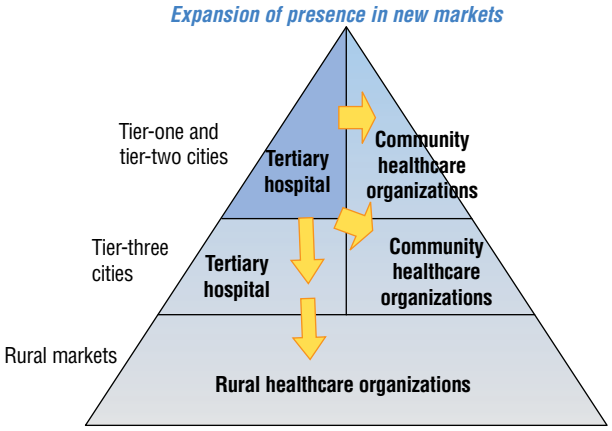
The complexity of China's market makes it more challenging for sales and marketing to get the right information and data to the right people at the right time. For instance, building strong government relationships at national and provincial levels is now required to succeed in this new environment. In addition, healthcare reform introduces new primary care customers – in addition to the traditional specialist doctors at tertiary hospitals. Community and rural healthcare professionals have very different practice needs and prescribing patterns. A key challenge for companies is determining how to cost effectively expand their presence in new community and rural markets (see Figure 8).

Domestic companies should closely scrutinize manufacturing capabilities, and all should reassess sales, marketing and distribution operations.

FIGURE 8.
Key considerations in expanding presence in new community and rural markets.

Key considerations

- **Product portfolio:** How does the current portfolio meet needs of new markets? How does pricing need to be adjusted? Should MNCs enter branded generics market?
- **Sales coverage model:** How can new channels be covered effectively? How is a rapidly expanding sales force best managed?
- **Market access:** How can listing of products be accelerated? What additional skillsets are required within the company?
- **Sales channel:** How can visibility be improved, especially as new markets are entered?
- **Distribution:** How can various distribution models (e.g., direct to store, intra warehouse, re-dispatch, etc.) be mixed effectively and efficiently?



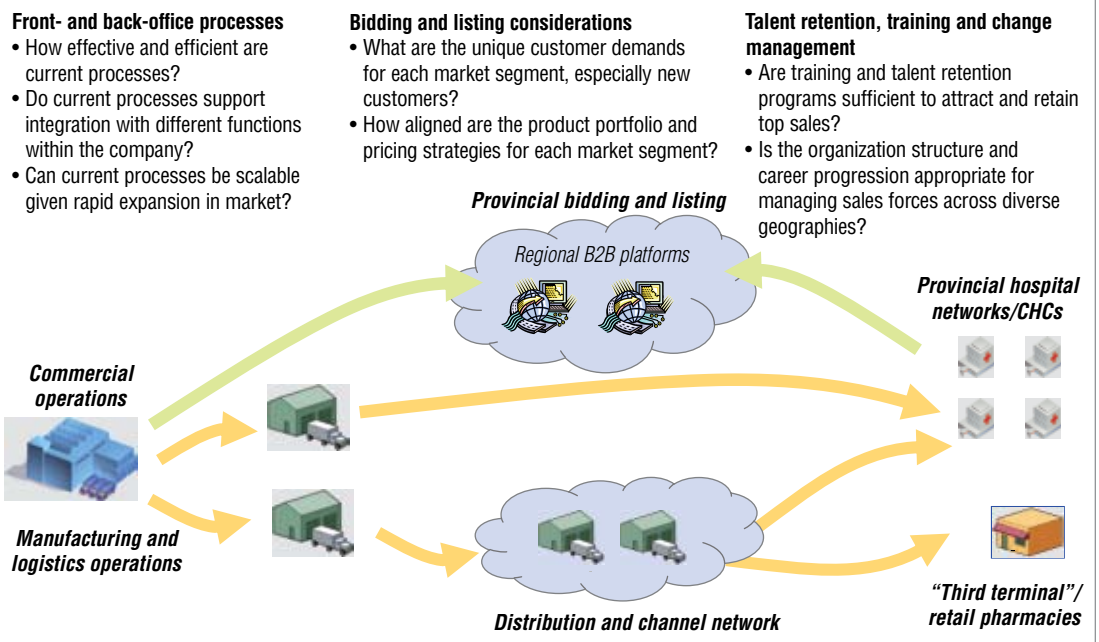
Source: IBM Institute for Business Value analysis, 2009.

To address these changing market needs, life sciences companies need to assess how sales and marketing should operate today by looking at some key capabilities:

- *The ability to bid and list products effectively* – Prepare socio- and health-economic viewpoints supporting inclusion in the essential and enhanced drug listings, and develop flexible pricing schemes and strategies to meet provincial variations.
- *The ability to assemble aligned and professional sales teams* – Sales teams likely will need to be realigned to address a broader community of healthcare providers. Companies will need to develop relationships in more regions outside the major cities, as well as with new key opinion leaders.
- *The ability to implement expanded marketing programs* – Companies will need to gradually adapt to new stakeholder structures in the hospital system. For instance, medical and patient education programs should be enhanced for community healthcare organizations.

Effective channel management requires an integrated view of strategy, processes, organization and supporting systems.
With the increasing complexity and mix of potential channels, there is a need to proactively understand and manage channel partners. This extends across all aspects of an organization, including operating models, processes and supporting systems (see Figure 9).

FIGURE 9.
Integrated view of sales and channel management.



Source: IBM Institute for Business Value analysis, 2009.

Rationalization of China's distribution networks will require closer, more strategic relationships between manufacturers and distributors.

Maintaining a hands-off approach to product distribution to the end patient is no longer a viable option, as manufacturers are being requested to take responsibility for product integrity and safety throughout the distribution chain. In China's current distribution network, companies lack visibility of actual patient demand and product movement. However, such visibility throughout the distribution network is increasingly a regulatory, commercial and operational imperative, and tighter collaboration with distributors will be required to achieve it.

Increased visibility and improved internal efficiency will help distributors provide better and higher-value services to customers, including healthcare providers and pharmaceutical manufacturers. Distributors need to develop efficient internal processes to facilitate timely delivery and processing of drugs (for example, the ability to quickly and efficiently handle drug returns and recalls). Improving overall quality of service is essential.

Distributors should also equip themselves to provide more value-added services by investing in more sophisticated and integrated information technology systems. For instance, effective data collection enables distributors to

The China life sciences market's new environment brings great opportunities for those who can successfully navigate the areas of innovation; manufacturing quality; and marketing, sales and distribution.

provide information to pharmaceutical companies that helps them better track and monitor sales in a timely manner. Integration with customers' tracking systems will help further improve visibility of products. Serialization, or "track and trace" solutions, can improve traceability of drugs throughout the distribution chain to help ensure drug safety and quality. Such systems will also assist distributors in fulfilling proposed GSP requirements.

Conclusion

The China life sciences market is facing unprecedented change and growth. The overall environment is undoubtedly becoming more regulated and demanding for key players – but also more healthy. This healthier environment brings immense opportunities and allows for more sustainable growth – growth that benefits patients, the various levels of governments and, in the long run, the life sciences industry.

Today's ongoing healthcare reform in China sets the stage for life sciences players to make required operational changes that will redefine and shape the role of how medicine and medical devices are used in the future healthcare system. The key challenge is how to adapt and compete in a fast-growing marketplace that is simultaneously facing a major transformation in terms of customers, markets and channels.

The maturity level of the life sciences market in China is also changing. The drive toward a more innovative industry will spur higher-value growth for domestic companies and create a more vibrant R&D environment for other participants involved in innovation, research and development. Raising GxP standards will drive increased compliance, quality and efficiency, not only improving competitiveness within China, but also opening the door to global markets.

As leading players prepare to compete in one of the world's largest markets, they can look to our recommendations to assist them in executing efficiently and effectively in three key areas: innovation; manufacturing quality; and marketing, sales and distribution.

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