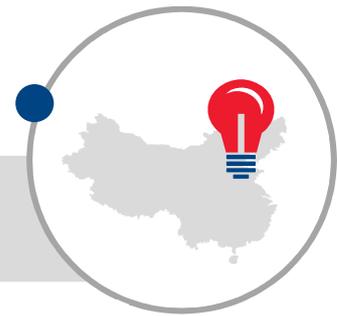


GPS Healthcare Quarterly

Innovation in China, “Made in China 2025” and Implications for Healthcare MNCs

July 2018



This paper considers the market, competitive and regulatory dynamics driving homegrown innovation in healthcare in China, details the key “Made in China 2025” policy as it applies in healthcare, and outlines the impact these developments are having on multinational healthcare firms in China.

Context



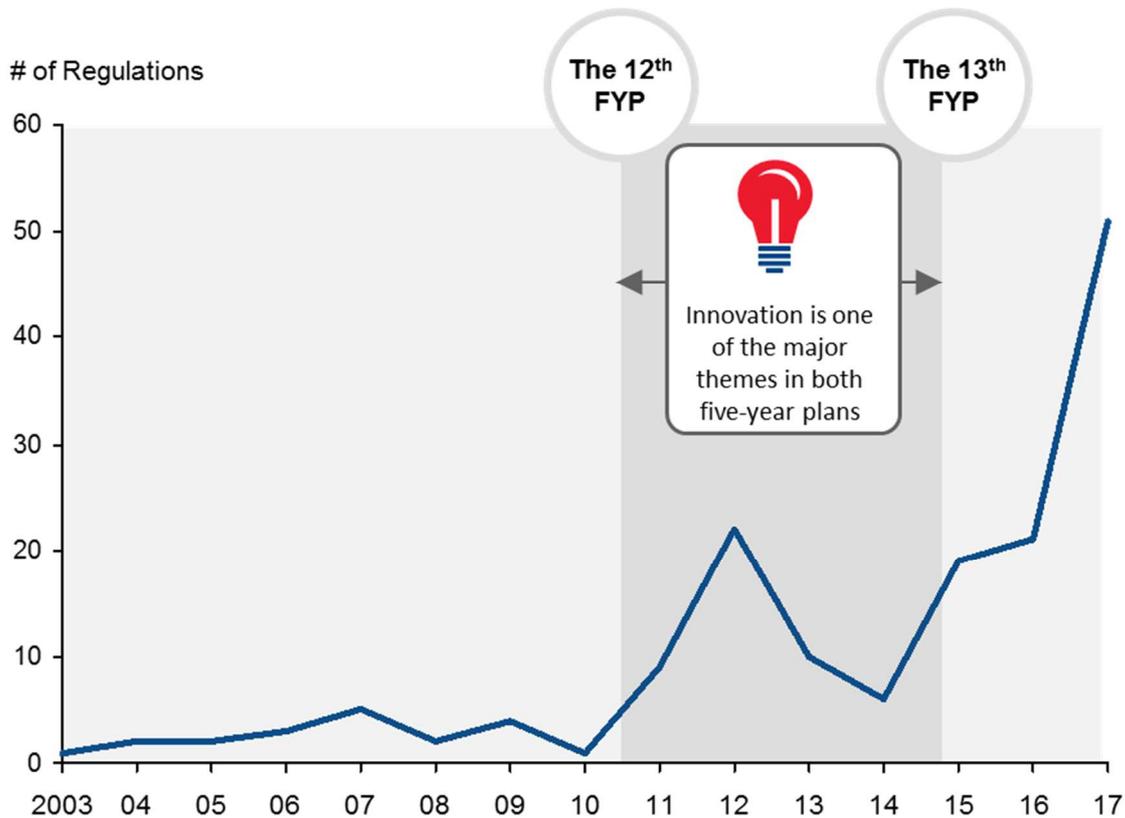
During the past four decades, China’s economy has rocketed to become the second-largest in the world. Now, however, it is facing different challenges: The working-age population has peaked, employment costs continue to rise rapidly, and the RMB has become stronger. As a result, China is finding it difficult to maintain its stellar growth on the basis of being a low-cost manufacturing center. In their efforts to avoid the middle income trap that affects many emerging economies, China’s leading policymakers have focused on raising productivity and bolstering innovation to upgrade China’s economy.

During the past decade, innovation, especially domestic innovation, has been gaining attention and driving government and private investment into biopharmaceuticals, medical technology and healthcare delivery.

In transitioning to a higher-value-added ecosystem, China’s government has introduced healthcare system reforms in wide-ranging areas including government funding for research and development, overhaul of market authorization requirements, product accreditations, procurement evaluations, management of the distribution channel, pricing, and payment. While these reforms are certainly intended to be beneficial in the domestic market, some are seen as controversial — especially those with an industrial policy dimension where China is sponsoring indigenous development of technologies that are destined to become competitive in the global marketplace.

China’s government has unleashed round upon round of reform to promote healthcare innovation (see Chart 1).

Chart 1: Innovation regulations published over time



Note: Includes nine administrative regulations issued by the State Council and 153 other regulations issued by other national departments

Source: CNKI, L.E.K. research and analysis

What is “Made in China 2025”?

The single most influential policy now driving innovation is “Made in China 2025” (“MiC2025”), whose scope and scale is now becoming clear three years after launch. As a result of “MiC2025”, foreign companies in the healthcare sector are re-evaluating their business models, market positions, technologies and product pipelines for China. This report will focus on “MiC2025” and its impact on multinational healthcare companies operating in China.

Made in China

Today, China’s high-end drugs and medical products markets are dominated by multinational companies (MNCs) equipped with innovative technologies, while domestic companies mostly produce components for those systems or lower-quality products that are not widely accepted outside China and developing markets.

In May 2015, the Chinese government unveiled “MiC2025”, a blueprint calling for investment of as much as RMB 8 trillion¹ (~US\$1.2 trillion) and intended to transform China into a global high-end manufacturing powerhouse over the next decade. “MiC2025” is broad-reaching and covers 10 high-technology fields — including biopharma and high-

¹ <http://www.scmp.com/news/china/economy/article/1814281/made-china-smart-revolution-blueprint>.



performance medical products — where China’s government has identified an opportunity for domestic manufacturers to participate in the global value chain.

Support for innovation is one of five guiding principles² for “MiC2025”, and the policy envisions innovation and demonstration centers that will build a foundation for industrial development and generate a greater variety of competitive products and technologies. With “MiC2025” acting as an “umbrella” policy, there are also indirect-but-important policy changes in other areas, such as tax incentives, government and public funding, and promotion of talent programs.

For the biopharma and medical device sectors, “MiC2025” establishes specific goals and projects in support of indigenous innovation (see Chart 2). For example, “MiC2025” aspires to achieve the industrialization of 20-30 innovative drugs by 2025. As for medical devices, “MiC2025” explicitly seeks 50% usage of local products in county-level hospitals by 2020 and 70% by 2025. These targets could be interpreted as overly ambitious but they do set the stage for pursuit of ambitious policy change and investments.

Chart 2: “Made in China 2025” for biopharma and high-performance medical devices

	Objectives/Targets	Focus products	Focus projects
 Drug	<ul style="list-style-type: none"> Increase drugs registered in developed countries, 10-20 chemical drugs, 3-5 Chinese Medicine, 3-5 biologics in 2020; 5-10 innovative drugs approved by FDA/EU in 2025 Turn 90+% patent-expired critical drugs into generics in 2020 Breakthroughs in 10-15 key technologies by 2020; industrialize 20-30 innovative drugs by 2025 	<ul style="list-style-type: none"> Drugs for critical diseases Antibody-drug conjugates Chemical drugs with new MoA or targets, for CAR-T and more 3D printing for tissue engineering and regenerative drugs Generics for expiring patented drugs 	<ul style="list-style-type: none"> Develop large and high-tech R&D bases, national-level translational medicine centers, collaborative innovation centers driven by specialized colleges and biopharma companies
 Medical Device	<ul style="list-style-type: none"> Increase mid-to-high-end domestic medical device usage to 50% by 2020 (70% by 2025) Increase market share of domestic core medical device components to 60% by 2020 (80% by 2025) 	<ul style="list-style-type: none"> Medical imaging equipment Clinical diagnostic equipment Advanced treatment equipment High-value implantables Health monitoring, remote medicine and rehabilitation equipment 	<ul style="list-style-type: none"> Launch and implement the Innovative Medical Device Application Demonstration program, to encourage usage by healthcare institutions Develop innovative medical device industrial clusters in BJ-TJ-HB, Yangtze River Delta, and Pearl River Delta regions

Source: State Council, “Made in China 2025” key areas technology road map, L.E.K. analysis

National and local governments have developed industry regulations to drive on-the-ground implementation and encourage the onshore development of healthcare products. Medical devices, in particular, have been on the radar of Chinese regulators. For example, the government initiated three rounds of equipment performance evaluations for domestic

² The other four guiding principles of “MiC2025” are quality over quantity, green development, industry structure optimization and human talent cultivation.



products in 2014, 2016 and 2017. These offered official recognition of quality levels, and limited the scope for hospitals and physicians to reject the products.

Some provinces and municipalities have been even bolder in changing procurement patterns: Sichuan, Zhejiang and Jiangxi officially require the purchase of certain types of domestically manufactured medical equipment in middle and higher tier healthcare institutions. Many MNCs also indicate that sometimes even though their products can be listed for use, their domestic counterparts eventually win because of cheaper prices and/or stronger government connections, as well as fit for customer needs.

China's policies also limit the use of imported products via payment systems and budget caps. For example, the introduction of payments to hospitals based on Diagnosis-Related Groups (DRGs) will strongly incentivize hospitals to procure and use cheaper, typically domestically manufactured products. Under such circumstances, some foreign companies even consider exporting second-tier products to China to gain access to hospitals.

“MiC2025” for healthcare MNCs

MNCs operating in China have been wrestling in particular with the somewhat nebulous definition of what it means to be “Made in China” in the context of complex, often global, supply chains.

At a practical level, there is, for example, currently no clear threshold for the proportion of value that should be added within China in order to qualify a product as “local”; “local” can still mean just the last step of production taking place in China (国产).

It seems also that the idea of a “local” product or company covers multiple aspects of the product and company — not only related manufacturing. When considering whether a company is “local”, a variety of factors can be considered, including investments, brand, intellectual property and ownership.

So ... being “local” is a continuous spectrum, and where any given company sits on that spectrum is movable and subjective, even though its legal status under Chinese law may remain unchanged.

Being “local”, however, comes with tangible benefits. Companies that are more “local” tend to receive more support from local governments, such as tax deductions, special procurement channels, R&D grants, etc. Nimble Chinese firms can take advantage of these schemes, whereas established MNCs need to balance complex trade-offs — considering local in-China benefits with potential dis-synergies in the rest of their operations, for example from operating multiple nodes in a manufacturing network or an innovation system.

In most cases, the most important lever of being “local” remains the status of the business in China under Chinese law. MNCs with interests in China have long been accustomed to the requirement for compliance with the “Catalogue of Industries for Guiding Foreign Investment” (《外商投资产业指导目录》) — now in its ninth edition, with its determinations as to whether investment by foreign companies is “encouraged,” “restricted” or “prohibited”. While in principle there seem to be fewer restrictions with each new edition of



the catalogue, the rising effectiveness of other forms of market management means that ownership remains key to being deemed “local”.

In the future, foreign enterprises — particularly those in the ten “MiC2025” sectors — will likely face an important trade-off between market opportunity and control. Whereas a Chinese joint venture partner can confer certain commercialization benefits (from market knowledge, relationships, etc.) that could be valued by its foreign partner, the scope for this continues to expand as economic participation and control over the business by the MNC declines. Adopting a minority position as an MNC could create increased market competitiveness and commercial opportunities and engender more favorable government treatment. The trade-off is complex and the right answer is unique to each situation.

Domestic innovation as an opportunity

The development of a bigger and better innovation ecosystem in China is creating a further competitive challenge for healthcare MNCs, but also an opportunity.

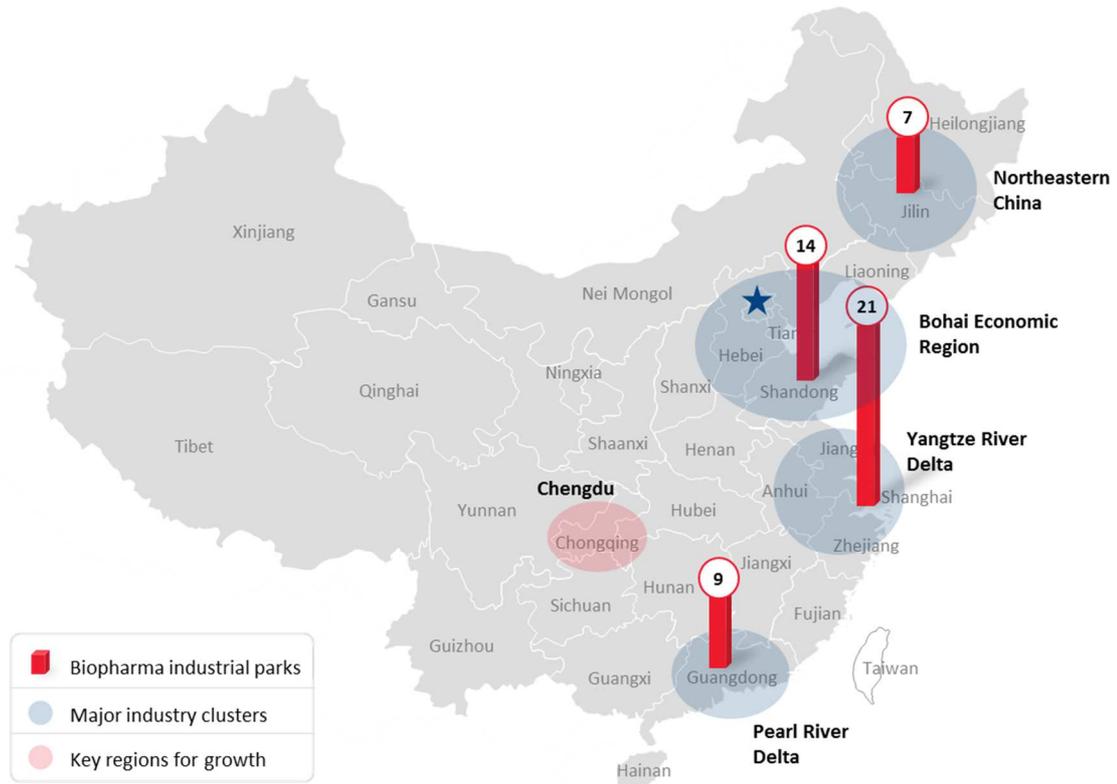
Increasing emphasis on “buying local” allows domestic manufacturers to focus more on product innovation as a lever for developing their business. For example, in the medical device market, the opportunities for MNCs to target lower tier hospitals are becoming increasingly proscribed by procurement regulation. China’s domestic device manufacturers are gearing up to provide less-expensive local alternatives with improved quality; they will be more competitive with MNCs going forward.

In the short term, the changes supporting Chinese healthcare innovation seem positive for foreign healthcare companies. China’s more innovation-friendly environment benefits innovators of many origins: Faster registration allows the value of innovation to be realized sooner, acceptance of foreign clinical data mitigates development costs associated with China opportunities, and a new Market Authorization Holder regime reduces investment and complexity.

Over the longer term, however, these changes will also support China’s healthcare companies in emerging and competing with their global peers.

The pharmaceutical industry is widely known for its reliance on and investment in R&D. However, the fragmented market in China has long limited the country’s pharmaceutical companies’ ability to develop innovative drugs requiring tremendous consolidated resources. This is also one of the reasons that “MiC2025” encourages the development of key biopharma clusters (see Chart 3), integrating R&D capabilities, supervisory government departments and biopharma companies to create a sound ecosystem accelerating innovation and clinical trials.

Chart 3: Location of large biopharma industry clusters



Source: L.E.K. analysis

In some segments, such as CAR-T³, China is already a global leader in terms of the number of therapies under development or in clinical trial. While this is currently an isolated example, China's biopharma companies are growing rapidly in scale and capability.

Reflecting the evolving ecosystem in which they operate, some leading MNCs have actively shifted their approach to innovation for China and in China. For example, Medtronic established a China Healthcare Technology Venture Investment Fund with Sequoia and Suzhou-BioBay (a bio-tech accelerator), providing capital and resources to local Chinese start-ups with potential to succeed in local and global markets. By contrast GSK shuttered its Neuroscience R&D Centre in China in 2017, instead, leaning towards R&D activities more closely aligned with China's needs, and also in 2017 AstraZeneca spun out its China R&D operations into a collaboration with Shanghai's municipal government.

³ CAR-T therapy: also called chimeric antigen receptor T cell, a type of treatment/therapy in which a patient's T cells (a type of immune system cell) are changed in the laboratory so they will attack cancer cells. T cells are taken from a patient's blood.



Conclusion

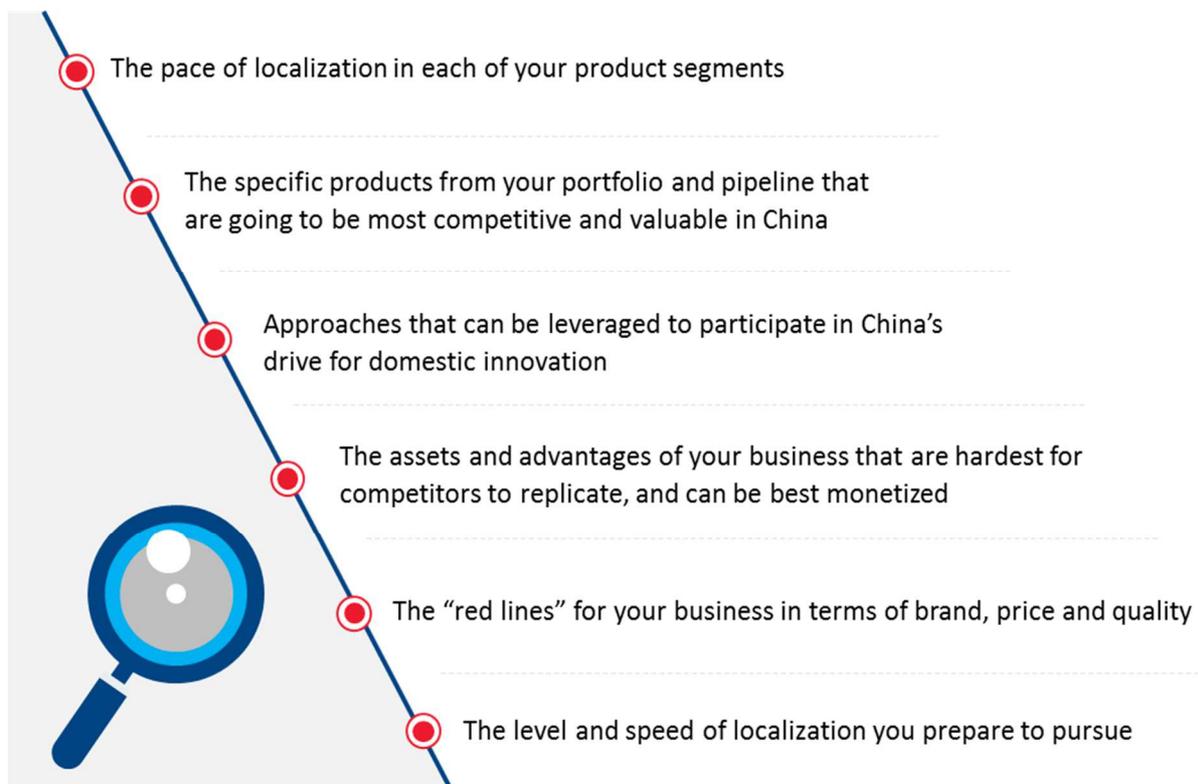


China still has a long way to go before it achieves some of the lofty goals of “MiC2025”, but the journey is clearly well underway and the direction of travel is clear. Upgrading China’s production capabilities and bolstering innovation are essential to moving China up the value chain toward the sophisticated industrial ecosystem to which the leadership aspires; it is not a passing fad.

Foreign businesses in China have always faced challenges, as seen in annual business sentiment surveys compiled by AmCham Shanghai and other business associations. Concerns over unequal regulatory oversight and enforcement by government remain a consistent theme. “MiC2025” has been particularly controversial as it appears to tacitly sponsor, elevate and therefore exacerbate these difficulties. That may be a key reason behind the reduction during June 2018 in emphasis on the “MiC2025” policy in the domestic press and from policymakers. The government’s objective, however, remains clear and can be expected to persist.

In a situation where China’s industrial policy is further accelerating and adding nuances to an already breakneck pace of change, healthcare MNCs seeking opportunities in China need to continually elevate their performance and dynamically adapt their strategies to compete. As Darwin noted, it is those most adaptable to change who survive.

There are a range of internal and external factors that MNC healthcare businesses need to understand to determine their optimal strategy. These include:



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AmCham Shanghai's Government Policy Support (GPS) Program is dedicated to helping members navigate the impact of industrial policy on business. Drawing from the knowledge of industry experts in business, academia and government, GPS provides members with the latest policy developments and valuable insights into how these translate into commercial opportunities and challenges for companies.

This report is the first in a series of quarterly healthcare reports available exclusively to GPS Program members. For more information, please contact gps@amcham-shanghai.org.

