Governments and public health policy makers around the world have long struggled with providing access to affordable health care while at the same time promoting life science innovation. China is no different. Its pharmaceutical landscape today has been shaped by the government’s quest to achieve universal health care through a national health care system. And the evolving industry landscape and the government’s pro-innovation policies are driving indigenous innovation in its life science industry.

China is a market too large to be ignored—this has long been a saying among those considering doing business in the country. But increasingly, multinational corporations see China as a hub of nascent innovation in life sciences, and have been setting up research and development (R&D) centers for new drug candidates that target global markets. To be sure, there are some challenges. This month’s Asia Insight explores China’s path in this arena.

**China’s Pharmaceutical Landscape**

It’s hard to overlook China’s pharmaceutical market given its size and growth rate. Public and private expenditure on pharmaceuticals totaled US$76 billion in 2014, and this is expected to reach US$315 billion at a compound annual growth rate of 23% by 2020, which would make it the second-largest pharmaceutical market in the world after the U.S. Both China’s central and local governments have played an integral role in shaping the current landscape of the fragmented pharmaceutical market. The focus on affordable health care has led to the prevalence of generic drugs, which have taken over 80% of the market. Domestic and multinational pharmaceutical companies have pursued very different strategies. Multinational companies have focused on patented drugs and some drug originators that enjoy preferential pricing premiums under the existing drug pricing system. Domestic companies, on the other hand, have not invested much in R&D, and have focused predominantly on making generics.

The most successful domestic companies have focused on branded generics, which are generic drugs marketed under a company’s proprietary brand name. This has been a profitable approach due to the limited scope of R&D investment and price premiums. But generic drug makers often have to participate in government tendering, and face intense competition and government price cuts. They rely on their knowledge of tiered markets and extensive distribution networks to achieve economies of scale.

**Essential Medicines**

Essential medicines are defined by the World Health Organization as those that satisfy the priority health care needs of the population. In 2009, China’s Ministry of Health published its first list of essential drugs, which are subsidized by local and central governments. China’s fragmented domestic pharmaceutical industry includes approximately 5,000 drug manufacturers, with the top 100 drug makers comprising just one-third of the market. Going forward, the regulatory environment is increasingly shifting against sub-scale inefficient generic players due to the more intense pricing pressure from the expanding Essential Drug List (EDL) and higher compliance costs.
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The EDL was initially designed to make medicine more affordable for low income patients, and was implemented at grassroots, mostly rural, facilities. In 2013, the government expanded the coverage of EDL to larger and better-equipped hospitals mainly located in urban areas. It required EDL drugs to reach 40% of Class 2 hospitals and 25% of Class 3 hospitals in revenues to ensure better access to affordable drug nationwide. While the plan has helped improve access to basic medicine, the central and local governments are incentivized to contain the growth of drug costs through price ceilings, price cuts, and zero mark-up policy. Drugs on the essential list are expected to increase as a percentage of total pharmaceutical sales value from 12% in 2011 to 28% by 2020. So the business model of focusing solely on the EDL tender is likely to become less profitable. Non-differentiated generic drug manufacturers will increasingly face more pressure as the segment’s share of total pharmaceutical sales is expected to decrease from more than 50% to one-third during the same period.

Raising quality standards among drug manufacturers is another cornerstone of China’s health care reform initiatives. The China Food and Drug Administration (CFDA) has significantly increased quality standards for pharmaceutical products by standardizing certain operating procedures and the management of manufacturing records. Changes were also made to better align good manufacturing practices to those of the World Health Organization. However, many small pharmaceutical companies make less than 1.5 cents per pill and have had trouble keeping up with rising compliance costs. As a result, more and more industry consolidation has taken place in which larger companies with better resources are acquiring attractive drug candidates from small companies or purchasing the companies outright. CFDA estimates that new regulations could shut down as many as 500 small- and medium-sized drug producers for non-compliance issues.

At the same time, demand for patented drugs is growing because of increasingly affluent populations. That said, R&D investment in innovative drugs has been rising. While China’s life sciences sector may still be quite young, it holds the potential to become a global leader in innovation. However, the process of building and strengthening its life science ecosystem will take time. The commercialization of a single drug alone can take 10 to 15 years from initial development. Encouragingly, over the last decade, we’ve witnessed the development of different elements conducive to the growth of innovation in China’s life science sector. In the coming decades, we expect to see the emergence of more pioneering Chinese drug businesses.

Recognizing that moving up the value chain is the key to sustaining future economic growth, China has prioritized biotechnology as one of seven strategic industries. In this quest, it has been making significant investment in infrastructure and basic research to promote China as an R&D destination for life sciences. Since China’s 12th Five-Year Plan, 22 national life science parks were built, accounting for two-thirds of China’s total life science industry production. The ability to access state-of-the-art research facilities and tap public and private funding sources has created numerous life science clusters in recent years. Beijing/Tianjing, Yangtze River Delta and Guangdong provinces are the leading hubs in terms of innovation because of their R&D capabilities, access to talent pools and track record in commercialization and have attracted both domestic and foreign life science firms. In addition to infrastructure investment, R&D rigor has been elevated as local talent pools improve, and as Chinese professionals, who have worked and studied abroad, return with extensive experience, bringing with them knowledge over best global practices.

The number of researchers in China has tripled since 1995 and, in 2007, China overtook the U.S. as the world leader in the number of doctoral degrees awarded in the natural sciences and engineering. There are sufficient doctoral graduates available to conduct R&D at a fraction of the cost of U.S. and European peers. The quality of the research has also been improving. In the last decade, academic publications from China in premier industry journals have increased six-fold. In addition to hiring locally and cultivating local talent, the government is actively recruiting overseas Chinese to return home for work on patents in areas like nanotechnology and cellular biology. The returnees, referred
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to as hai gui (sea turtles), have played multiple roles in the ecosystem. Some act as entrepreneurs, starting their own companies and investing in others. Many lead the Chinese operations of pharmaceutical multinational corporations. These returnees have helped bridge cultural gaps while also facilitating cross-border licensing and acquisition agreements.

Patent Incentives

The government is promoting a culture of innovation in life sciences—and the willingness to take risks and allow for a healthy process of trial and error. Typically, the cost of developing a new drug from discovery to commercialization takes over a decade and costs hundreds of millions of dollars. In China, researchers are empowered to test ideas and make mistakes because the government sees failure as a necessary learning curve. Patents in China are typically owned by individual professors. In an interview with the National Bureau of Asian Research, Yiwu He, a senior program officer at Bill & Melinda Gates Foundation recollected a conversation he had with the president of a major university in China. In his university, professors who started their own companies could have a major ownership stake. This idea is that the direct alignment of interests helps encourage the translation of innovation from ideas to business opportunities. In contrast, in the U.S., a patent created by a professor typically belongs to the university that employs the individual.

Beijing Genomics Institute

One of the best-known examples of an innovative Chinese life science firm is the privately held firm BGI, previously known as the Beijing Genomics Institute. First created under the Chinese Academy of Science in 1999, BGI has become one of the world’s top genome-sequencing centers with one-third of total global capacity. Offering a global platform for new drug discoveries and advanced genetic research, BGI boasts a management team has been educated abroad, scientists that are published in international journals, and relationships with well-reputed Western institutions. Wang Jun, BGI’s chief executive, describes BGI as a new model of an international Chinese organization.

Last October, Johnson & Johnson Innovation—a division of the global health care firm that focuses on accelerating early-stage innovation worldwide and forming collaborations between entrepreneurs—launched an Asia Pacific Innovation Center in Shanghai. At the same time, it also initiated several R&D partnerships with universities in China. The center works with the entire ecosystem, encompassing academics, start-ups, venture capitalists and government agencies. The multinational is just one of many that are increasingly allocating R&D resources to China. For China and its life science industry, this collective expertise is tremendously beneficial in helping to cultivate indigenous, rather than imported, innovation.

To be sure, there are challenges to China’s path to becoming an innovative leader in global life sciences. A lack of intellectual property (IP) protection continues to be a major concern. Serial entrepreneurs with experience overseeing entire drug development chains are also lacking. Chinese authorities, however, have been working on ways to better develop IP protection and address the shortage of skilled corporate leaders. The transformation will be a lengthy process because the industry is still young. The industry as a whole only started taking shape in the past decade.

Market forces and governmental policies are increasingly shifting China’s life science industry from one of generics to one that includes more innovative drugs. Over the coming decades, we should witness rising indigenous innovation from China, helping its companies up the global pharmaceutical value chain. Considering how much progress China has already made, I expect there to be ample opportunities for investors with long-term horizons to participate in this exciting secular trend.

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