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China journeys from imitation to innovation

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With a population of over 1.3 billion, China is poised for continued growth in the life sciences sector. There are several factors that will contribute to this growth, including overall rise in economic condition, increase in middle-class population, elaborate healthcare reforms, an aging population, and boom in medical infrastructure. All these factors are results of sustained increase in government research budgets, investment by multinational pharma companies, and government healthcare funding initiatives.

China, due to its geography, has a highly fragmented drug distribution industry which has witnessed consolidation in the last couple of years. This has happened as part of the government's 12th Five-Year Plan (FYP) 2011-15 to strengthen the national drug distribution industry by actively supporting acquisitions, mergers, and reorganizations.

On March 14, 2011, China's National People Congress approved the 12th FYP which focuses on key "strategic emerging industries" (SEIs) that will benefit from preferential government support. The plan focuses on seven SEIs, including areas such as energy, information and communication technology, and biotechnology.

By developing a strong industrial base and encouraging pharmaceutical research and development (R&D), the nation believes that it can simultaneously develop an economic engine for the future, while improving the quality of life for its citizens.

The Ministry of Health (MoH) also announced lowering of drug prices a top priority for health authorities in 2011. The National Development and Reform Commission (NDRC) implemented two rounds of drug price reductions in 2011. In August 2011, the NDRC issued a notice stating an average 14 percent price cut on 82 types of drugs, involving more than 400 formulations. The price cut, effective from September 1, 2011, affected endocrine, nervous system, and hormonal drugs. Most of these drugs were manufactured by multinationals.

The government is keen on expansion of the national essential drug list (NEDL) this year to cover nearly all government-sponsored grass-root health institutions. This brings a strong opportunity for pharmaceutical companies, especially for the domestic firms. In July 2011, the MoH revealed that, as part of the country's universal health coverage program, it may introduce mandatory licensing policy to secure cheaper drugs for HIV/AIDS patients.

In March 2011, the World Health Organization (WHO) announced that the Chinese State Food and Drug Administration (SFDA) and its affiliated institutions meet WHO indicators for a functional vaccine regulatory system. Subsequently, in July 2011, WHO sanctioned SFDA to approve domestic vaccines for international use.

Chinese vaccine manufacturers' products can now obtain WHO prequalification in one-to-two years. The successful applicants can supply vaccines to the United Nation Children's Fund (Unicef), which will then distribute the products to developing countries. Receiving prequalification will help Chinese firms to rake in international deals.

After five years of amendments and two rounds of public consultations, the SFDA issued good manufacturing practice (GMP) for drugs, effective from March 1, 2011. As per the guideline, the newly built drug manufacturers and reconstructed or extended workshops of drug manufacturers shall comply with GMP requirements.

Improving the situation of existing facilities, the SFDA has instructed that the existing drug manufacturers will be granted a transition period of five years to meet stage-by-stage new version of GMP in accordance with the product risk level. The SFDA has also started to inspect overseas manufacturing facilities in November 2011, as the agency seeks to align its practices with international standards.

Bribery continues to remain a significant problem in China's hospitals. Hence, in November 2011, the health ministry increased its efforts to eliminate collaboration between doctors and sales personnel from pharmaceutical and medical equipment companies. Doctors, if found guilty, will face a two-year ban on practicing in their respective hospitals.

Industry size

According to IMS Health, the pharmaceutical market for 2011 stood at $40.8 billion registering a growth of 17.1 percent. Business Monitor International (BMI) has estimated the pharmaceutical expenditure in 2011 at $66.7 billion which will go up to $81.3 billion in 2012, registering a growth of 21.6 percent. BMI also estimates that the healthcare sector in China will rise from $290 billion in 2011 to $324 billion in 2012, with a growth rate of more than 16.6 percent in terms of US dollar. Additionally, the medical devices market will reach $24.7 billion in 2012 from $21.6 billion in 2011, a growth of more than 14.5 percent.

The Chinese market represents many opportunities for foreign business, and if new regulatory reforms prove successful and the inadequacy of rural healthcare is effectively addressed, then the number of previously untapped consumers makes China an attractive market.

The vast pool of people in China pose an attractive proposition for carrying out large-scale clinical research studies. China's colossal healthcare expenditure, coupled with a burgeoning middle class and the rise of chronic diseases, presents a

platform for double-digit growth that cannot be matched in western economies.

China has emerged as a favorable destination for drug discovery and manufacturing with influx of investments and significant reforms imbibed in the country's policy.