CHINA: INVESTING IN PHARMACEUTICAL RESEARCH CAPACITY TO COMPETE GLOBALLY

In a Nutshell

The WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement has brought momentous changes to China and its pharmaceutical sector. The country can no longer rely solely on reverse engineering patented medicines for its 1.3 billion people. Further, mortality from chronic diseases such as cancer is rising, the population is ageing and the health needs of the poorest pose an ongoing challenge – all factors that will test China's health science capacity.

This case highlights the response of the Chinese government and scientific community to changing internal and external circumstances, and the actions they have taken to develop capacities for pharmaceutical research and development (R+D). This has included the promotion of collaborations between the government, academia and industry; the facilitation of foreign joint ventures in contract research and manufacturing; and legal and institutional reforms.

The Story

Disease and health trends largely dictate manufacturing as well as research and development priorities in the pharmaceutical and biotechnology sector. Over the past decades, China has been in the midst of an epidemiological transition from an overwhelming infectious diseases burden to a rising incidence of uncommunicable, chronic illnesses.

Already considerable in size, China's pharmaceutical industry is one of the fastest growing in the world. However, research and development investment has been barely 2-4 per cent of revenue, compared to 20 per cent among the multinational pharmaceutical companies that hold the majority of high-value intellectual properties in novel chemical entity discovery. Consequently, 90 per cent of the modern medicines distributed in China is estimated to be reverse engineered. With pharmaceutical product trade liberalization and the WTO's strict patent protection requirements, the Chinese health science industry has no choice but to raise research and development capacity to compete and survive. Government as well as industry initiatives are well underway.

There are a number of promotional efforts by the government to enlarge research capacity through academia and then commercialize the outputs. The Ministry of Science and Technology is spending $600 million over five years to promote biotechnology and genomics research, for example. State and local governments are also a part of the funding channels. The Shanghai Center of Research and Development for New Drugs, for instance, provides assistance and financing for joint ventures and commercializes discoveries in the region. In the arena of genomic chips, companies and universities, with the active encouragement of the government, are racing to develop these building blocks for research and development on new medicines. Collaboration in this area is creating a cluster effect in the form of knowledge-intensive, high-tech industry cropping up around academic institutions.

China has also encouraged joint ventures between research and development entities, and technology- and cash-rich foreign companies. Many of the world's top pharmaceutical firms have already set up manufacturing as well as research and development operations, attracted by a large pool of skilled scientists. Many have trained at world-class universities in the US and Europe, and returned to China with government incentives. Foreign corporations are also eyeing a growing domestic market opening for foreign competition and offering cost advantages. In 2001, $1.8 billion of foreign direct investment as well as domestic public and private financing poured into the pharmaceutical sector.

The dynamics of the global pharmaceutical industry provide China a window of opportunity for capacity development. The international contract manufacturing market is close to $10 billion in size, with an average of $800 million spent over ten years by big pharmaceuticals for every successfully commercialized molecule. Significant cost pressures, coupled with high attrition rates and an acute shortage of specialized labour in biopharma, mean that today's discovery research efforts take place in multiple transnational locations. Contract research forms an integral part of product development efforts as multi-country, multi-centre clinical research is conducted on a global scale.

These global contracts are often based on strict quality conditions that require a regulatory agency's certification for good manufacturing, clinical and even agricultural practice. The conditions are accompanied by on-site training and

sometimes a sponsor's investment in clinical facilities and equipment. Despite this expensive outlay, research outsourcing is on the rise, constituting a major financing and capacity-building source for many small- and mid-size research-oriented companies worldwide. The completion of the Human Genome Project, for example, has generated a huge research need for linking the workings of thousands of genes to diseases through functional genomics and proteomics. Many pieces of the research and development puzzle require informatics capability and labour-intensive laboratory work, making outsourcing a necessity. To capitalize on this trend, Chinese institutions are building modern bioinformatics capacity. In addition, since China was one of two Asian countries participating in the International Human Genome Sequencing Consortium, some Chinese research and development institutions have existing collaborative research projects with advanced foreign companies.

Another notable factor driving pharmaceutical capacity development in China is research to unearth the scientific basis of traditional Chinese medicines. The potential value of these can be significant, making research on them a priority among China's research and development entities. In conformity with the international regulatory approval requirements, some Chinese traditional medicines have already been taken through the formal drug discovery and development process, with scientific documentation and modern technologies to investigate their efficacy and safety.

The initiatives described above have evolved based on a widely accepted consensus that it has been necessary to propel competitiveness in knowledge-based industries while the overall Chinese economy has grown. This has been supported by landmark legislation, further accelerating capacity development. Examples include reforming pharmaceutical regulatory requirements in line with international standards; revamping the State Drug Administration; ensuring quality standards for drug safety; providing government incentives for building pharmaceutical and biotechnology capacity; protecting product patents; setting up strong enforcement measures; and deregulating imports and exports and the distribution of pharmaceutical products.

Some argue that these reforms are double-edged in that they remove certain safeguards from the fledging domestic pharmaceutical industry, exposing it to direct competition with powerful global companies. In an environment where regulatory approval of novel drug discovery is becoming increasingly difficult, it is likely that many initiatives will face consolidation. However, the steps currently underway in China to develop capacity will likely allow it to skilfully manage this transition.

Results and Critical Factors

China's experience offers practical insights and realistic approaches to capacity development in the pharmaceutical R&D sector. Critical factors that have contributed to its many achievements include:

- The government's determination not to hide behind reverse engineering but to accept international standards and the rules of the game, combined with competitive pressures acting as a motor for innovation
- Collaboration between the government, academia and industry that has nurtured new scientific, technological and human capacity, enabling China's R&D efforts to leap forward towards the discovery of new molecules for pharmaceuticals and research on unearthing the scientific basis of traditional Chinese medicines
- Multiple government reforms ranging from the regulation of medicines to enforcement of patent protection to pharmaceutical industry liberalization
- A large market, to which the investment capital for R&D and future return on equity is linked (In the past, big markets, like in Brazil, China or India, have stimulated development of pharmaceutical capacity outside the developed world.)

Further information

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