

Issues Monitor

Sharing Knowledge on the Pharmaceuticals Industry

KPMG INTERNATIONAL

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Welcome to the January edition of *Issues Monitor*. Each edition pulls together and shares our firms' industry-wide knowledge to help you quickly and easily get briefed on the issues that impact your sector.

John Morris
Global Head of
Pharmaceuticals



Keeping up to date with the very latest and most pressing issues facing your business can be a challenge and, while there is no shortage of information in the public domain, filtering and prioritizing the knowledge you need can be time consuming and unrewarding. I hope that you find *Issues Monitor* useful and welcome the opportunity to further discuss the issues presented and their impact on your business.

ISSUE 1: Supply chain management and tax efficiency

The continuously expanding global marketplace has vastly increased the international reach of companies in the pharmaceuticals industry. While being a significant growth opportunity, this trend has also made the supply chains more complicated and vulnerable to transfer pricing issues and other risks. Furthermore, various other factors such as the oncoming wave of patent expirations, low returns on heavy R&D investment and dry pipelines are forcing branded drug manufacturers to reduce costs by restructuring their supply chains. In this situation, it is critical for multinational pharmaceuticals manufacturers to implement tax-efficient supply chain management (TESCM), a business

model that considers tax issues while executing supply chain restructuring initiatives.

- 02 Supply chain challenges
- 06 TESCM and its potential benefits
- 09 Conclusion

ISSUE 2: The drug discovery industry in China and India

The outsourcing of drug discovery and related activities to low cost destinations is currently one of the most important trends in the pharmaceuticals industry. China and India are the clear frontrunners, as they offer the advantages of relatively cheap skilled labour, vast patient pools and rapidly growing domestic markets. Additionally, in the past few years these

countries have witnessed significant improvements in their regulatory environments, particularly with regards to patent protection. However, some concerns still remain, especially around stringent implementation of patent protection laws and unethical manufacturing practices. Both countries have their sets of advantages and disadvantages as outsourcing destinations, and companies need to evaluate these comprehensively according to their specific requirements.

- 11 Market overview
- 14 Public private partnerships for drug research
- 16 Drivers and inhibitors
- 22 China vs India: A comparison
- 23 Best practices

1

Supply chain management and tax efficiency

Pharmaceutical companies have been keen on embracing globalization because of their continuously expanding global marketplace. Effectively aligning tax strategies with supply chain restructuring initiatives by implementing tax-efficient supply chain management (TESCM) needs to be a key focus for pharmaceutical companies globally. This article talks through some of the challenges faced by the pharmaceutical industry as it manages paying tax in varied locations, and discusses what a tax-efficient supply chain process is about in this environment.

Supply chain challenges

In addition to ensuring high-quality products and lowering operating costs, companies also now need to focus on optimally managing the tax obligations that result from multinational operations. In the current highly competitive scenario, companies need to examine each aspect of their supply chains, as outlined below.

Where...	Who...	How...
<ul style="list-style-type: none"> ...goods are purchased from 	<ul style="list-style-type: none"> ...buys the goods 	<ul style="list-style-type: none"> ...the goods are routed through the supply chain
<ul style="list-style-type: none"> ...they are manufactured 	<ul style="list-style-type: none"> ...takes ownership of the inventory at various stages 	
<ul style="list-style-type: none"> ...they are delivered to 		
<ul style="list-style-type: none"> ...they are stocked 		
<ul style="list-style-type: none"> ...value is added to the goods 		
<ul style="list-style-type: none"> ...engineering and design is done 		

Source: Tax Efficient Supply Chain Management for Diversified Industrials, KPMG, June 2008



Regulatory authorities are seeking to monitor the expanding pharmaceutical supply chains more rigorously.



Each one of the above is both a supply chain consideration and a tax issue. Any significant change in the supply chain, or change in the tax regulations within the jurisdictions that a company operates in, must be considered in terms of both supply chain and tax implications. Failure to do so may expose a company to risks or potential missed opportunities.¹

These considerations are particularly important for the pharmaceutical industry which has a vertically integrated international business model. In a bid to save costs, leading pharmaceutical companies are outsourcing some of their drug discovery activities to lower-cost off-shore destinations such as China and India. New emerging markets are becoming increasingly important with growing demand for products, and pharmaceutical companies are carrying out marketing and sales-related activities through numerous affiliates around the world to meet these new needs. This global business model has the potential to generate a number of supply chain issues related to tax efficiency.²

As pharmaceutical companies move parts of their businesses to multiple locations, they may become exposed to varying, and in some cases, contradictory regulatory guidelines. Furthermore, the pharmaceutical industry is attracting more regulatory attention than ever before, as the authorities seek to monitor the expanding supply chains more rigorously.³

Declining margins and market shares of patented drug manufacturers have initiated significant supply chain restructuring initiatives within the industry. These structural changes in the supply chain may initiate regulatory action to govern these transactions.⁴



A September 2008 survey revealed that managing costs is the top priority for pharmaceutical supply chain decision makers.

Patent expiry and generics expansion

The expiry of blockbuster drug patents remains, without a doubt, the most critical problem faced by global pharmaceutical majors. The direct result of such expirations is rising competition from generics which is leading to pricing pressure and a subsequent drop in both sales and revenues. The scenario is expected to be especially testing for branded drug manufacturers during the next few years. The annual US sales of leading industry players are also expected to drop by US\$67 billion between 2007 and 2012 due to patent expirations and the resulting generics competition, which is roughly half of their combined 2007 US sales.⁵ In addition to revenue losses, there are also some indirect consequences of this development.

- **Increased focus on R&D:** Companies are looking to combat patent expirations by strengthening their pipelines, which is resulting in a greater focus on drug discovery. To achieve this, many are seeking to become leaner, more efficient, research-based organizations and are rationalizing their global manufacturing facilities. Furthermore, as R&D is usually one of the most cost-intensive links in the supply chain, the trend of saving costs by outsourcing and off-shoring drug research has quickly been adopted by pharmaceutical companies.
- **Reducing supply chain costs:** As part of a broader cost control program, reduction in supply chain costs is one of the primary concerns for manufacturers. A September 2008 survey conducted by UPS highlighted that managing supply chain costs was the number one priority for supply chain decision makers in the pharmaceutical industry.⁶
- **More efficient sales and marketing:** Following the patent expiry of a drug, many companies seek to launch their generic versions of those drugs, either on their own or through collaborations with regional partners. To ensure the success of these products, companies need to enhance their sales and marketing efforts.



These challenges have significant tax implications for supply chain management (SCM). The most challenging of these are issues related to transfer pricing, which are guided by the regulatory authorities' perception of the stage at which value is created. Moreover, varying tax laws in different regions pose the risk of double taxation for manufacturers.⁷

- If R&D is carried out in a particular country, the authorities in that region may be of the view that product value is created at the beginning of the supply chain.
- On the other hand, the regulatory authorities in any of the countries where the product is sold may perceive the value as being created by the marketing strategies of the company in that region.

Transfer pricing issues

Pharmaceutical companies with operations in multiple locations usually utilise elaborate transfer pricing models to avoid double taxation. However, while many countries are encouraging companies to invest in different supply chain activities by offering tax incentives, the frequency of transfer pricing audits has increased dramatically in the pharmaceutical sector for a number of reasons, including the following.

- The industry's global reach has increased its risk profile considerably with respect to tax authorities who are becoming more aggressive in identifying intangibles (marketing and service) and other transfer pricing issues.⁸
- The rapidly increasing trend of outsourcing key value chain activities is attracting further regulatory attention, particularly with respect to transfer pricing.
- There are significant variations in the views of regulatory bodies in different countries regarding transfer pricing guidelines. Although most follow the principles outlined in the Organization for Economic Co-operation and Development (OECD) Transfer Pricing guidelines to evaluate transfer prices, their interpretations of the rules are not uniform.⁹
 - In Germany, a recent legislation allows a broad definition of what must be paid when business functions are relocated from the country.
 - China's views on the use of a parent company's intellectual property (IP) by its Chinese subsidiary are much narrower than the international standards.
- The scope and stringency of transfer pricing audits have also increased. Previously, authorities focused mostly on restructuring that led to effective shifts in profit to low-tax jurisdictions. However, with the increasing complexity of the supply chain giving rise to SCM initiatives, activities such as plant closures and movement of manufacturing operations to reduce costs are also likely to attract tax authority attention. The recent German legislation mentioned above is a clear example of this trend.¹⁰



The industry's global reach has increased its risk profile considerably with respect to tax authorities.



GSK paid approximately

US\$3.4

billion

to the IRS to settle a transfer pricing dispute in September 2006.

Are tax considerations part of your supply chain strategy?



Over the past few years, many of the top global pharmaceutical companies have had to pay billions of dollars to settle legal issues related to transfer pricing in various geographies.

- In June 2008, GlaxoSmithKline (GSK) Canada lost a transfer pricing case that is likely to cost the company millions of dollars in back taxes, penalties and interest.¹¹ Earlier, GSK had to pay approximately US\$3.4 billion to the Internal Revenue Service (IRS) of the US to settle a transfer pricing dispute in September 2006.¹²
- Indian drug company Ranbaxy Laboratories is also currently in the middle of a transfer pricing dispute with the Income Tax Appellate Tribunal (ITAT) of India. In January 2008, the ITAT reported that the company had under-assessed its income by approximately US\$57 million¹³ (INR 2245 million) during 2004 – 05 by not pricing appropriately goods and services sold to its sister concerns abroad.¹⁴
- In February 2007, Merck & Co. was penalized close to US\$2.3 billion by the IRS in order to settle various transfer pricing disputes.¹⁵
- It is reported that Pfizer's ongoing legal battle in Pakistan also has transfer pricing issues at its heart. The case raises concerns for other manufacturers as governments and regulators are becoming more aware and stringent about transfer pricing outside the developed countries.¹⁶

TESCM and its potential benefits

The first step for companies looking to avoid tax issues related to supply chain reconfiguration is to better understand the specific challenges and realize the potential pitfalls of ignoring tax considerations. TESCM is a business model approach that incorporates tax considerations into designing a supply chain strategy. Under this model, any current and future supply chain restructuring strategy is aligned with the tax structure, resulting in potential profitability enhancement opportunities. Some of the key focus areas of TESCM are outlined below.¹⁷

- Creating a more centrally coordinated SCM process, both from a strategic and tactical point of view.
- Managing the international tax implications of operational changes to the supply chain, such as the flow of goods, the location of the tangible and intangible assets used when operating the supply chain, as well as the underlying organizational structures.
- Reducing the effective direct tax rate on income derived from the supply chain.
- Optimizing the effect of indirect taxes triggered within the supply chain, such as value-added tax (VAT) and custom duties.



How does it work?

The TESCM model is built on the fundamental principle that direct tax is dependent on profits, which in turn are a function of those operations that are considered as “value addition” by tax authorities. These include functions such as brand management and strategic policy setting, along with risk management activities such as working capital decisions and pricing. TESCM essentially entails combining risk management activities with “value added” activities to develop a new supply chain configuration. The focus is to change the physical location of where the risk is incurred or where “value addition” takes place, which directly affects the value of the tax paid. By identifying and centralizing these key activities, companies enjoy freedom to choose where and how they need to pay the bulk of their tax, and herein lies a significant opportunity to save tax costs.¹⁸

Some of the key tools developed in TESCM are outlined below.¹⁹

- **Shifting risk:** This may be achieved by converting a buy/sell distributor to a commissionaire or a stripped distributor and/or transforming a manufacturing company into a contract manufacturing arrangement.
- **Off-shoring functions:** Activities such as back-office operations may be relocated to lower-cost countries such as China or India.
- **Relocating IP:** This may involve a shift in research base through cost-sharing agreements and contracting R&D.

In addition to the above, centralized purchasing is considered the latest TESCM tool for multinational companies (MNCs). Under this model, the purchasing function is consolidated under a single central entity. The centralized purchasing agent purchases goods and services on behalf of its affiliates. The following precautionary guidelines should be considered while centralizing the purchasing function.²⁰



Companies that have incorporated tax considerations during restructuring have seen up to

25%

improvements in profitability.



The centralized model of TESCO has enabled companies to reduce the effective tax rate by up to

20%.



The potential savings for the top 13 European pharmaceutical firms after implementing TESCO could be over €200 million a year.

- Consolidated group operating profits should improve after the change is introduced.
- Local subsidiary operating profits should not suffer as a result of the changes.
- The beneficiaries of any post-restructuring excess profits should be decided at the outset.

Potential benefits

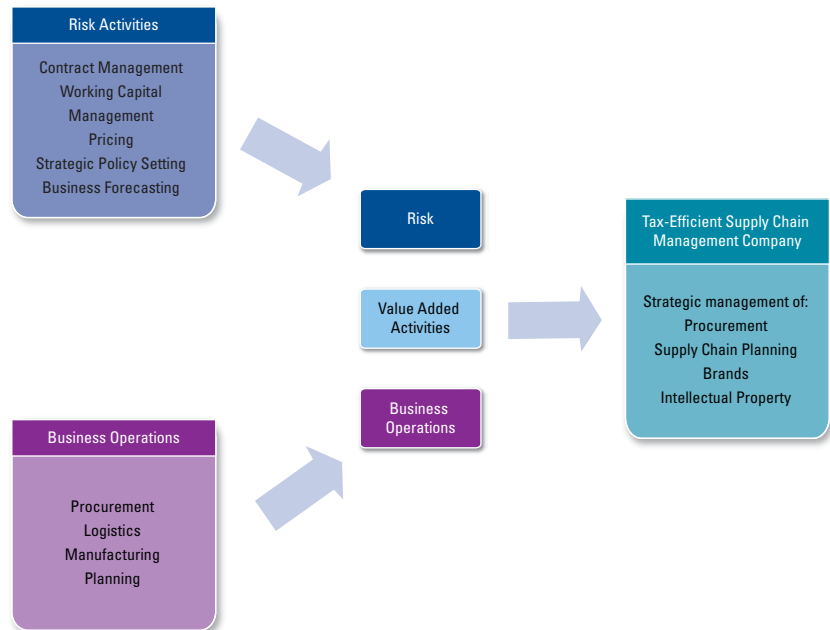
As evident from the principles of TESCO, there is potential for generating significant tax-related benefits, leading to increased overall operational efficiency.

- Across all industries, companies that have restructured their business operations while incorporating tax considerations have seen substantial improvements in profitability levels (up to 25 percent) and are also looking to improve profit margins.²¹
- The centralized model of TESCO has enabled companies to considerably reduce effective tax rates. In some cases, the decrease has been as much as 20 percent following TESCO restructuring.²²
- The centralized purchasing model in the pharmaceutical supply chain holds many potential benefits, including labor cost savings, greater volume discounts, increased efficiency in currency risk management and improvements in effective quality control.²³
- According to a research by Capgemini on the European pharmaceuticals industry, companies could generate savings of up to 5 percent of the turnover by including tax considerations in their supply chain strategies. The potential savings for the top 13 pharmaceutical firms after implementing TESCO could be more than €200 million a year.²⁴



Figure 1 outlines the creation of a centrally managed tax-efficient supply chain company.

Figure 1: Creation of a centrally managed tax efficient supply chain company



Source: Uncovering Supply Chain's Hidden Taxes, Supply Chain Europe, August 2006

Conclusion

TESCM is highly useful for multinational pharmaceutical companies looking to reduce the overall effective tax rates, while also achieving efficiency gains in relation to the supply chain. Therefore, the tax and business aspects of a supply chain should be considered on an integrated basis, from both strategic and tactical perspectives. As transfer pricing disputes continue to impose a threat if the supply chain is not managed tax-effectively, companies should avoid the pitfall of ignoring tax considerations while implementing supply chain restructuring initiatives.²⁵

"In the rapidly changing global economy, multinational companies should be seeking to constantly evolve to stay ahead of the competition. Major business transformation programs aimed at improving efficiency, reducing risk, and building global structures should deliver clear bottom-line and shareholder value. The integration of TESCM into these programs helps the best multinationals to improve the benefits available through transformation."

– Andrew Underwood, European TESCM Advisory Leader, KPMG in the UK

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- *The Tablet: KPMG's views on supply chain management and tax efficiency in the pharmaceutical industry*

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Managing Transfer Prices

Dealing effectively with tax authorities is complicated by differences in transfer pricing regulations and practices. With each new announcement of transfer pricing enforcement initiatives, the development of transfer pricing policies that meet corporate objectives, satisfy each of the tax authorities at issue, and reduce the risk of double taxation becomes increasingly more complex. KPMG's Global Transfer Pricing Services practice helps companies develop and implement economically supportable transfer prices, document policies and outcomes, and respond to tax authority challenges.

Indirect taxes and cross-border transactions

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2

The drug discovery industry in China and India

The global pharmaceuticals industry is going through a restructuring phase with the aim to position itself better against the ongoing wave of patent expirations, decreasing R&D productivity and high costs of drug development. Companies are faced with the challenges of reducing costs while simultaneously retaining focus on drug discovery to replenish their weakening pipelines. As a result, the outsourcing of drug discovery activities to low-cost destinations is one of the most significant trends in the industry currently, and is likely to become even more prominent in the future. China and India are the clear frontrunners as outsourcing destinations for drug discovery because of their vast pools of skilled and low-cost labor. Other than this, the thriving domestic markets and a vast patient pool for the purpose of conducting clinical trials are also contributing significantly to the growth of drug discovery in these regions.

This article covers the challenges and benefits of relocating parts of the drug discovery process to China or India, and provides a comparison of the two locations.

Market overview

Recently, the outsourcing of drug-discovery-related activities, including drug research and clinical trials, has increased rapidly. In Asia, China and India have emerged as the preferred destinations for drug development. Many Big Pharma companies have already moved some of their R&D operations to Asia and are partnering with contract research organizations (CROs) to undertake various aspects of drug discovery, including trial monitoring, project management, data management, safety reporting, drug distribution and central laboratory services.²⁶ The global CRO market is expected to exhibit stronger growth, and the focus is likely to increasingly shift to Asia.





The Asian CRO sector is predicted to grow from

US\$1.2 billion

in 2006 to US\$2 billion in 2010 at a CAGR of 13.6%.



Global players such as GSK, Roche, Novartis and AstraZeneca have set up R&D centers in Shanghai.

- An August 2008 report by Goldman Sachs predicted the global CRO market to grow at a compound annual growth rate (CAGR) of 12.6 percent, and increase in value from US\$16.3 billion in 2007 to US\$29.4 billion by 2011.²⁷
- Approximately 40 percent of these revenues are generated outside the US, and approximately 25 percent of all R&D expenditure is outsourced. This is expected to increase further, as the trend of conducting clinical trials globally catches up.²⁸
- According to a Frost & Sullivan report, the Asian CRO sector generated revenues of US\$1.2 billion in 2006, and is predicted to grow at a CAGR of 13.6 percent to reach US\$2 billion in 2010.²⁹

China

China has been an important source of active pharmaceutical ingredients (APIs) that are used by multinational pharmaceutical players in the manufacturing of both prescription and over-the-counter (OTC) drugs. Until a few years back, drug companies were wary of conducting drug research and clinical trials in China due to its reputation of a weak intellectual property (IP)-protection regime. However, during the current decade, the country has sought to remedy this, and its entry into the World Trade Organization (WTO) in December 2001 has been a significant step in this direction. As a result, China has acquired a significant role in drug discovery during the past three years or so, and is expected to grow further.³⁰

- The growth of drug discovery in China started off slowly as companies were skeptical of the strength of IP protection in the country. However, the initial experiences of Big Pharma companies revealed that this was mostly a problem with perception and not the actual scenario.³¹
- As a result, the market is now developing rapidly, with major global players including GlaxoSmithKline (GSK), Roche, Novartis and AstraZeneca setting up full-fledged R&D centers in Shanghai. Many outfits are now beginning to offer the entire range of services, from early lead generation to mass production.³²





Pfizer announced plans to expand operations in China from 110 cities to more than 650 cities.

- The number of Chinese CROs offering drug discovery services has grown significantly. The pricing structures are also changing as these CROs are increasing both in number and the range of services offered. When CROs were first established in China, the payment structure was basically a set fee-for-service scheme. This has, however, evolved into a structure whereby CROs offer a variety of pricing schemes. Full time equivalent (FTE) pricing is still popular, but companies are experimenting with risk-sharing models.³³
- Beijing, Shanghai and Guangzhou are already home to a number of world-class pharmaceutical research facilities. In addition to these, there has been large-scale investment in China in research facilities by a number of Big Pharma companies,³⁴ including the following.
 - Novartis is currently in the process of constructing an R&D facility expected to employ 500 scientists.
 - In September 2007, AstraZeneca, one of the first Big Pharma companies to engage in large-scale clinical trials in China, entered into a partnership with Peking University Third Hospital to establish its first clinical pharmacology unit in China, focused on Phase I clinical research. The company has also announced an investment of US\$100 million for R&D in China over the next few years.³⁵
 - In 2007, GSK opened an R&D center in Shanghai to work on drug discovery and development for many major ailments, including Multiple Sclerosis, Parkinson's disease and Alzheimer's disease.³⁶
 - In April 2008, Genzyme announced an investment of US\$90 million for the construction of an R&D facility in Beijing. The company is the first US-based biotech firm to set up R&D operations in China.³⁷

India

India's image as a destination for quality clinical trials and drug discovery has undergone a noticeable change over the past decade. Undoubtedly, the most significant catalyst for this change has been the improvement in the patent protection scenario for drugs in the country. The 2005 decision to extend patent protection to drugs has encouraged many global pharmaceutical players to outsource more work to India. Many of them now regard the country as a critical part of their long-term plans to evolve into leaner, research-based organizations. Companies such as Pfizer, Novartis, AstraZeneca, Eli Lilly, GlaxoSmithKline, Aventis, Novo Nordisk, Bristol-Myers Squibb, Roche and Amgen have expanded their existing clinical research investment and infrastructure in India. According to the Asia Times, the market for outsourced clinical trials by Indian companies has grown from US\$70 million in 2002 to US\$200 million in 2007. The growth of the drug discovery market in India has been an amazing story of transformation.³⁸



The India Patents Act of 2005 has encouraged many global pharmaceutical players to outsource more work to India.

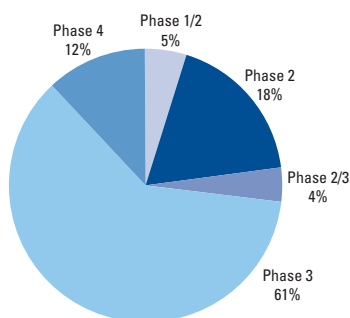


McKinsey predicts the global clinical trial outsourcing market in India to grow to approximately

US\$2 billion by 2010.

- The CRO market in India was practically nonexistent a decade ago due to a combination of factors, including an unfriendly regulatory environment and the lack of skilled researchers and clinical trial professionals.³⁹
- A collective initiative by the industry and regulatory bodies resulted in the issuance of Ethical Guidelines for Biomedical Research on Human Subjects in 2000 by the Central Ethics Committee on Human Research (CECHR) of the Indian Council of Medical Research (ICMR).
- In 2001, the Central Drugs Standard Control Organization (CDSCO) took an initiative to develop good commercial practices (GCP) guidelines for India in line with various international standard practices. Currently, the foremost priority from a regulatory perspective is the revision of Schedule Y, which deals with regulations relating to clinical trial requirements for the import, manufacture and marketing of new drugs in India. The successful enforcement of the revised Schedule Y will be a major step in establishing India's reputation as a reliable destination for clinical trials.⁴⁰
- Currently, there are more than 70 Indian companies that offer services and solutions related to clinical trials and R&D to multinational pharmaceutical corporations. According to a McKinsey & Company report, the global clinical trial outsourcing market in India will grow to approximately US\$2 billion by the year 2010.⁴¹
- Indian CROs are following in the footsteps of some of their Western counterparts and developing full-service offerings for their pharmaceutical clients. This includes the drug discovery phase of the drug development process through clinical research and manufacturing.
- Other sources indicate that India-based researchers have registered around 467 clinical trials to date in the US.⁴² Recently, there has been speculation of the US Food and Drug Administration (FDA) establishing a formal presence in India. Although unconfirmed, the news is a testimony to India's increasing maturity as a global drug discovery destination.⁴³

Figure 2: Distribution of clinical trials in India by phase of trial



Source: India's Clinical Trials Market Accelerates, BioPharm, May 2008

Figure 2 depicts the breakdown of clinical trials conducted in India by phase.

Public private partnerships for drug research

A recent development in the drug discovery market worldwide is the forging of public private partnerships (PPP) to support drug research activities. The ever-increasing pressure on pharmaceutical manufacturers to reduce R&D costs and simultaneously develop innovative products has given rise to the concept of PPP. Under this initiative, private manufacturers leverage the technical know-how and capabilities of research institutes and combine it with their infrastructure and industrial knowledge to facilitate the process of drug development. The governments of various countries have also pledged support to companies in this endeavor through tax and other incentives, and in some cases, even partial funding of the research.⁴⁴ Owing to their vast networks of high-quality research institutes and vast reservoirs of talent, China and India stand to gain from PPP initiatives.

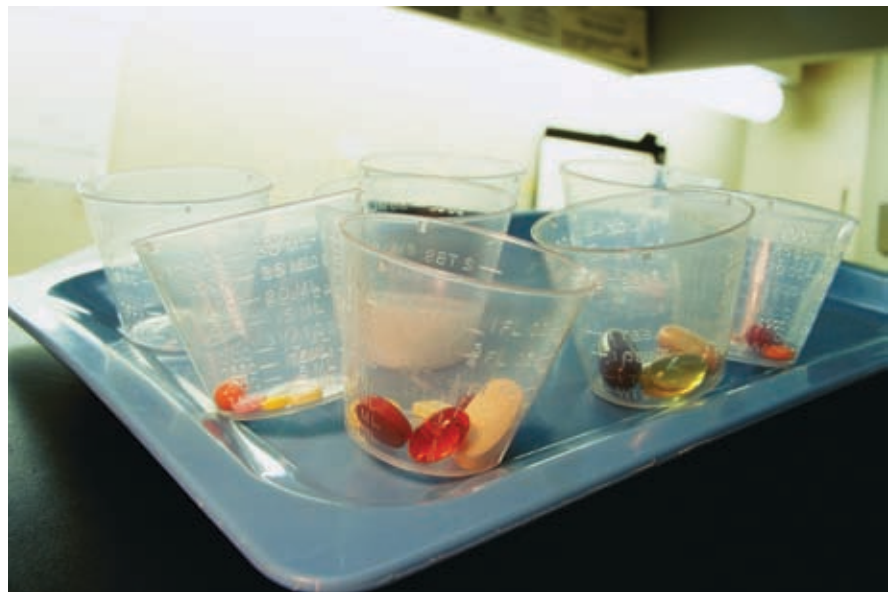


The Indian government has assigned

30%

of the Department of Biotechnology's budget for funding PPP-related activities.

- The Indian government has set aside 30 percent of the Department of Biotechnology's (DBT) budget for funding PPP-related activities. Many industry players have also taken steps toward building a collaborative effort between the private and the public sectors. Although resources have been allocated for PPP, a lack of awareness is preventing the optimal use of these resources. To this end, the government needs to take initiative not just with regard to funds, but also to popularize the concept to ensure its successful implementation.⁴⁵
 - In February 2008, Nicholas Piramal Research & Development Ltd (NRDL) and the DBT signed the first public private drug discovery agreement in India. The project envisages a mega-scale screening program for various environmental isolates, as part of which the industry and the academia will work together to screen a large number of bacterial isolates.⁴⁶
- In China too, national programs have supported interdisciplinary research funding and infrastructure setup for clinical research. In order to facilitate the R&D of drugs, PPPs in clinical research have been adapted. The recently concluded Third Annual Drug Development China Conference also included PPPs for drug research as one of the main topics for discussion. Ling Chen, the director general of the Guangzhou Institute of Biomedicine and Health (GIBH), said that the institute has selected developing vaccines and drugs for infectious diseases, cancer and metabolic diseases as one of its top priorities.⁴⁷





Drivers and inhibitors

As has been already outlined above, the most prominent factor driving drug discovery activities in China and India is cost-cutting by multinational pharmaceutical companies. However, as the drug discovery markets in these two countries mature, the drivers for R&D outsourcing have become more varied and intricate. On the other hand, some of the issues that initially restricted multinational companies (MNCs) from conducting full-fledged research in Asian countries continue to plague growth. These need to be addressed in order to tap the full potential of drug discovery in China and India.

Drivers

- **Cost-cutting:** Challenged by blockbuster patent expirations, increasing R&D costs and weak pipelines, Big Pharma companies are seeking to leverage the vast pool of inexpensive and skilled talent in China and India to conduct cost-effective drug research. In addition to cutting R&D costs, many companies are also seeking to reduce financial risk by limiting in-house investment, and are therefore partnering with offshore CROs to develop drugs at a much lower cost. Big Pharma companies are vigorously seeking ways to reduce the cost of bringing a drug to market, a process that costs an average of US\$1.2 billion in the US.⁴⁸ Although salaries have risen in recent years in China and India, the cost of outsourcing work to these countries remains significantly lower than in developed countries.
 - Clinical trials in India are considerably cheaper compared to those in the developed countries. According to estimates, companies can achieve cost savings of up to 50 percent in Phase I clinical trial studies, and up to 60 percent in Phase II/III studies.⁴⁹
 - In China, the cost of carrying out clinical trials is 15 percent less for Phase I, and up to 20 percent less for Phase II/III compared to that in developed countries.⁵⁰



Companies can achieve cost savings of up to

60%

by conducting Phase II/III clinical trials in India.



In China, around 100,000 students are enrolled for chemistry and another 120,000 for medical sciences annually.

- **Accelerating drug development:** Companies are trying to strengthen their weakening drug pipelines by finding new products to reduce the financial impact from the number of the drugs that are coming off-patent during the next few years. To this end, they are trying to streamline the R&D process, and partnering with CROs for drug discovery has been established as a highly effective way.
 - In 2007, the Chinese State Food and Drug Administration (SFDA) announced plans to shorten the drug approval time for innovative new medicines. Under the proposed rules from the SFDA, regulatory authorities are aiming to reduce approval time from the current 8-to-12 months to a maximum of 4 months.⁵¹
 - India boasts of a robust IT industry offering services and solutions to help companies reduce the time-to-market of drugs.
- **Large talent pool:** As graduates in the US and EU are increasingly abandoning scientific careers for more lucrative options, pharmaceutical companies are looking up to the huge pool of scientific talent in China and India for a more efficient drug discovery process.⁵²
 - India has the fourth largest reservoir of scientific manpower in the world, producing nearly 150,000 chemistry graduates per year.
 - In China, each year, an estimated 100,000 undergraduate/graduate students are enrolled for chemistry, another 120,000 for medical sciences and approximately 60,000 for biological sciences.
- **Availability of patients for trials:** Both China and India offer a large patient pool at a time when patient recruitment is becoming increasingly difficult globally. In addition, the increasing westernization of these countries in terms of diets and habits is leading to similarity in the nature of ailments affecting the population. China, in particular, also faces the problem of an aging population, similar to that in Western countries.⁵³
- **Growth opportunities:**⁵⁴ China and India are projected to be among the top 10 largest pharmaceutical markets by 2015. Companies are seeking to reduce the time taken for drugs to reach these rapidly growing local markets by conducting trials in these countries. In terms of demand for pharmaceutical products, China and India are likely to be at par with the rest of the world in due time. Increasing urbanization is leading to more unhealthy lifestyles in these countries and thereby shifting the disease patterns from acute to chronic disorders, along the lines of the trend in developed countries. In China, about 50 – 70 million people are likely to be affected by clinical depression by 2015. In India, the diabetic population is approximately 37 million and is growing rapidly. Additionally, China is also facing the consequences of an aging population due to the strict one-child policy that was followed for a long time. Approximately 40 percent of the Chinese population will be over the age of 50 by 2020. All these factors are likely to fuel the growth of the pharmaceutical market in the two countries.



China and India are projected to be among the top 10 largest pharmaceutical markets by 2015.

How effective is drug patent protection in China and India?



- China's gross domestic product (GDP) growth rate is the highest in the world, and the country is projected to overtake the US and become the largest economy by 2035.⁵⁵
- Over the past few years, the Indian economy has entered a period of sustained growth that has an obvious positive effect on the pharmaceutical sector. India is second only to China in terms of real GDP growth and is expected to be the fifth largest economy in terms of GDP by 2017.⁵⁶
- **Regulatory initiatives:**
 - Regulatory authorities have implemented a number of initiatives in recent years to improve IP protection laws to encourage greater confidence and investment.
 - » Some of the regulatory initiatives taken in India to ensure ethical practices in drug research, including the adherence to GCP guidelines and the revision of Schedule Y, have been mentioned above. In addition, the Indian government extended the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the WTO to pharmaceutical products in 2005. The agreement sets minimum levels of protection for many forms of IP, including drugs. This was a watershed development in the bid to establish a secure IP environment for drug discovery activities in the country.⁵⁷
 - » Anticipation of more regulatory changes has strengthened the attraction of China as the best location in Asia for conducting clinical trials. It has also been revealed that the US FDA will begin accepting data that has been derived entirely from clinical trials in China as the basis for granting marketing approval. These new measures will allow domestic and MNCs to develop medicines in China, and effectively shorten the commercialization process for newly developed blockbuster drugs.⁵⁸ However, keeping in mind the geographical variations in legal requirements, the FDA is also taking certain precautionary steps.⁵⁹
 - The agency has agreed to accept data from overseas trials not conducted under an investigational new drug application (IND). It has even approved a few drugs solely on foreign studies.
 - In April 2008, the FDA published a final rule, slated to go into effect in October 2008, clarifying that drug trials conducted overseas must follow GCPs, including approval by an independent ethics committee or institutional review board (IRB).
 - FDA Commissioner Andrew von Eschenbach's "Beyond our Borders Initiative" has been launched in order to gain from on-the-ground regulatory offices in critical parts of the world and establish familiarity with political and scientific issues affecting foreign drug development. The FDA plans to open offices in Beijing, Shanghai and Guangzhou by the end of 2008 to work with local regulatory authorities and better track the enforcement activities.



The US FDA is expected to begin accepting data derived from clinical trials in China for granting marketing approval.

- » In early 2007, a Chinese court overturned a 2004 ruling that allowed local companies to sell generic versions of Pfizer's erectile dysfunction drug Viagra. This decision bolstered confidence in the country's IP environment and in government pledges to improve IP protection.⁶⁰
- » Following its entry into the WTO in December 2001, China is now obligated to enforce foreign international patents in accordance with the TRIPS Agreement on Intellectual Property Rights of 1995. This agreement mandates that drugs receive at least 20 years of patent protection.⁶¹
- In addition to securing the IP environments, the governments of both countries have raised efforts to attract heavier flows of R&D and clinical trial investment through incentives such as tax concessions and favorable regulatory reforms.
 - » China's State Drug Administration (SDA) introduced new GCP rules in 2003, allowing CROs for the first time to undertake clinical trials on behalf of clients. The consequential increase in CRO activities in the country helped develop China's research infrastructure. Major international CROs such as Quintiles Transnational Corps (US) and Bridge Pharmaceuticals (US) began large-scale operations in the country, which in turn improved China's image as a low-cost base for drug trials.⁶²
 - » In 2002, the Indian government relaxed duties on materials imported for clinical trials. Amendments made to Schedule Y of the 1945 Drugs and Cosmetics Rules permitted drug firms to undertake clinical trials in India and overseas simultaneously for the first time. Previously, at least one trial phase for an innovative drug was required to be repeated inside the country, which undermined the cost- and time-saving aspects of undertaking clinical studies overseas.⁶³





India's Patents Act of 2005 has certain peculiar provisions that differ from the WTO TRIPS agreement.

Inhibitors

Despite a range of factors favoring R&D investment in China and India, ongoing concerns over IP protection continue to constrain the development of the drug research industry. A number of regulatory initiatives have been implemented in the area of IP protection, as outlined above.

- Although there has been a considerable improvement in the patent protection scenario in China and India, certain concerns remain, stemming particularly from regional variations in enforcement of guidelines. For instance, although the Patents Act of 2005 enforced in India is largely based on the WTO TRIPS Agreement, it has certain peculiar provisions which should be carefully noted by drug companies. One such provision is Section 3(d), which states that derivatives of known substances cannot be patented unless they can be shown to differ in terms of efficacy. No such provision features in the TRIPS Agreement.⁶⁴
 - In August 2007, a ruling by an Indian court permitted generic drug makers to override Novartis' international patent for its cancer treatment drug Glivec. The court refused to acknowledge the argument that "incremental innovation" to an existing drug by the company merits a patent.⁶⁵

Other factors that need to be addressed to make the environment more conducive for drug research include the following.

- The data exclusivity laws in these countries are still not deemed entirely effective by foreign firms, resulting in a sense of insecurity regarding the confidentiality of clinical data extracted from trials.



Melamine contamination in milk powder sold by Chinese company Sanlu caused severe illness among over 1,200 babies.



The Indian Planning Commission has said that there is a shortage of skilled clinical research personnel in the country.



Domestic companies dominate the Chinese pharmaceuticals market with approximately 70 percent market share.

- Unethical practices in other industries also affect the reputation of the regulatory regime as a whole. Very recently, the melamine contamination in milk powder sold by China's biggest manufacturer Sanlu caused severe illness among over 1,200 babies, resulting in death in some cases. Sanlu's joint venture partner Fonterra, a food giant based in New Zealand, has also alleged that it tried to make Sanlu recall the product on several occasions, but "the local authorities in China would not do it."⁶⁶ Before this, in 2007, numerous quality control glitches surrounding export toys, pet food and consumer products raised concerns about the effectiveness of regulations. A number of pharmaceutical products were also affected.⁶⁷
 - Reports of a leukemia drug contaminated with another cancer-fighting material that affected hundreds of patients led to a highly publicized and embarrassing recall.
 - Concerns were also raised over tainted supplies of Heparin.
- In China, international firms face the issue of distinctly different regulatory processes for international trials and those taking place in that country exclusively.⁶⁸
 - For international multicenter trials, drugs can be brought from overseas and used in any hospital the trial initiator deems qualified without undergoing the complicated, time-consuming and costly SFDA registration procedures. These can include drugs that have been licensed in Europe but not yet in China.
- The process is more complicated for using overseas comparator drugs in Chinese domestic clinical trials. Comparator drugs used either for clinical trials that are part of a process of new drug registration (including drugs to be imported into China), or that are being employed under a domestic multicenter program, must be registered with the SFDA. These drugs must be licensed in China as well, even if they are not meant to be sold in the Chinese market. Failing this, the drugs will need to be registered as imports, a very time-consuming and costly process.
- Although both countries are making considerable efforts to improve their clinical trials infrastructure, they have a long way to go before they can be counted among the leading regions for drug testing. The number of research-trained physicians capable of running trials is still small compared to that in the Western world and relative to populations of the countries.
 - According to a recent report released by the Indian Planning Commission, there is a shortage of trained and experienced clinical research personnel in the country, which may serve as a major hurdle in its race to become the preferred destination for outsourcing of clinical trials.⁶⁹
- Despite the high growth rate of the pharmaceutical market in China, it is still largely fragmented, which is a challenge for all companies, particularly for MNCs. Domestic companies dominate the market with approximately 70 percent market share, and the market share of the leading players is only around 2 percent.⁷⁰

Which is a better destination for conducting drug research?



The use of English as an official business language is a significant advantage for India.



China has a more comprehensive set of regulatory reforms for IP protection compared to those in India.

- The traditionally poor patent protection scenario for drugs in China and India is at least partly due to the cultural differences between Eastern and Western countries, which are reflected in their attitude toward patent protection. In China, for instance, patent protection for drugs is a novel concept; as drugs have traditionally been considered a special commodity to save lives, they do not require patents. This sometimes leads to unnecessary political influence over proper enforcement of regulations, which is already a tricky process. In addition, intellectual theft in China appears in numerous forms, including reverse engineering, and copying and counterfeiting.⁷¹

China vs. India: A comparison

Although most of the growth drivers in the drug discovery market are common to China and India, there are many notable differences between the two countries that require slightly different approaches on the part of pharmaceutical companies. In a nutshell, China has a more comprehensive set of regulatory guidelines for patent protection and also a potentially more lucrative domestic drug market. However, the use of English as an official business language and less complicated drug approval processes are significant advantages for India.⁷² Furthermore, the recent cases of drug recalls have highlighted the lack of proper enforcement of regulations in China.

Table 1 depicts a comparison between China and India as potential outsourcing destinations for drug discovery.

Table 1: Comparison between drug discovery markets of China and India

Country	Advantages	Disadvantages
China	<ul style="list-style-type: none"> • Rapid expansion in healthcare sector presents more opportunities • More comprehensive set of regulatory reforms for IP protection compared to that in India • Entry of Big Pharma and major international CROs testimony to improving image 	<ul style="list-style-type: none"> • Regulatory processes for international trials significantly more complicated compared to those taking place in China • Concerns over quality control due to recent drug recalls • Communication issues due to lack of a English-speaking population
India	<ul style="list-style-type: none"> • Improved patent protection after 2005 • Easier approval process for international drugs, fast-track approval for studies already approved in developed countries • Use of English as an official language, a major advantage 	<ul style="list-style-type: none"> • IP protection not deemed as efficient as that in China • Potentially less lucrative domestic drug market compared to that in China • Overall infrastructure poor compared to China's



Companies should be vigilant in maintaining comprehensive documentation for the drugs involved.

Best practices

- Companies planning to carry out drug research in China and India should be vigilant in maintaining comprehensive documentation for the drugs involved. This is imperative for securing their supply chains, ensuring consistency and safety, as well as the ultimate success of the trial.⁷³
- Proper documentation is also vital if the drugs are already registered in any of the developed markets or have been used in an international multicenter program elsewhere. Detailed records of these proceedings could expedite the registration process and enable companies to avoid certain procedures.⁷⁴
- Companies also need to compare and contrast the drug discovery scenarios in the two countries, compare with their specific requirements and then devise a comprehensive strategy. For instance, the process for approvals is less complicated in India, but the Chinese domestic market is potentially more profitable. Accordingly, the factors under consideration would be the target markets, the risk of IP leakage and the optimal time to market.



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Companies mentioned in this issue

Amgen	13
AstraZeneca	12, 13
Aventis	13
Bristol-Myers Squibb	13
Eli Lilly	13
Frost & Sullivan	12
Genzyme	13
Goldman Sachs	12
GSK	6, 12, 13
McKinsey & Company	14
Merck & Co.	6
Nicholas Piramal	15
Novartis	12, 13, 20
Novo Nordisk	13
Pfizer	6, 13, 19
Ranbaxy	6
Roche	12, 13
Sanlu	20, 21

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