

The changing dynamics of pharma outsourcing in Asia:

Are you readjusting your sights?



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Introduction



The dynamics of pharma outsourcing and location decisions in Asia are changing. Cost reduction is being augmented and will gradually be eclipsed by ‘footprint growth’ as a key factor shaping decisions. Companies need to set their strategic sights on a future world where Asia is not just a market and manufacturing powerhouse for the pharma industry, but could make a key contribution to drug discoveries as well.

In this publication, we examine the strategic forces that are shaping outsourcing and other location decisions in the region. We find that companies need to balance a number of factors, ranging from the forces that are affecting current and future pharmaceutical business models to the opportunities and constraints posed by the dynamics of growth, convergence and divergence at work in the Asia region. We look at how outsourcing in Asia is moving up the value chain, and at the expansion of clinical trials and manufacturing activity.

We follow up this strategic perspective with a discussion of the main factors companies need to take into account in their outsourcing and location decisions. We provide an overview of the region by ranking individual territories against three key dimensions - cost, risk and the market opportunity present in each territory. Finally, we review each territory in detail. Our main focus is on the hot spot territories: China, India and Singapore, but we also consider the mature markets: Japan and Australia and other Asian territories: Korea, Taiwan, Malaysia, Thailand, Indonesia and the Philippines.

PricewaterhouseCoopers (PwC) works in all of the territories covered by this report. In China alone, for example, we have over 11,000 personnel. Our teams have expert insight into market conditions, participants and trends. We conclude the report with a summary of how we can help companies to successfully identify, select and make the most of sourcing opportunities in the region.

Strategic context of outsourcing and location decisions in Asia



Outsourcing decisions have traditionally been driven by cost factors. However, with the wider global economic balance shifting from west to east, and with the growing importance of end-markets in Asia being matched with increasing Asian pharmaceutical expertise across the value chain, cost is just one of a range of factors that companies need to consider when taking outsourcing decisions in Asia.

Increasingly, such decisions need to be informed by strategic as much as tactical considerations. The outsourcing steps that companies make today cannot be divorced from the footprint strides they will need to make over a 10-20 year time period¹. We have identified four clusters of factors that are relevant to the decision-making context faced by multinational pharmaceutical companies when they consider outsourcing in Asian territories. These factors are also equally relevant to the outsourcing carried out by fast-growing Asia-based pharmaceutical companies.



Cluster one: pharma revenue constraints

The big global pharmaceutical companies face an array of forces that constrain revenue growth, and in turn, the shareholder value they can create. These are driving the need for companies to look for new ways that they can boost drug discovery potential, reduce time to market and squeeze costs along the whole value chain.

The patent expiry time bomb

In 2006, more than 90% of Big Pharma's total pharmaceutical revenues came from medicines that had been on the market for more than five years². Yet the patents on many of these products are due to expire quite shortly, exposing an estimated US\$157 billion worth of sales (measured in 2005 terms) to generic erosion.

The need for R&D productivity

Only nine of the new treatments launched in the US in 2006 came from the laboratories of the 13 companies that comprise the Big Pharma universe³, a pattern that has changed very little over the past few years. Even allowing for inflation, the industry was investing twice as much in R&D in 2006 as it was a decade earlier but

only producing two-fifths of the new medicines it then produced⁴.

Pricing pressures in healthcare markets

By 2020, the OECD (Organization For Economic Cooperation and Development) territories, excluding the US, will spend 16% of their GDP on healthcare, while the US will spend a huge 21%. In all, they will spend US\$10 trillion on healthcare⁴. In this context, pressures are increasing on pharmaceutical companies to demonstrate the value of their products or risk coming under huge pressure to cut prices.

Quest for improved margins and growth

The combination of Big Pharma's lack of recent R&D productivity and pricing pressure in current major markets puts a premium on the search for cost reductions that can improve margins and the need to tap into growth in new markets. This is all the more urgent given poor financial performance in the past few years. Big Pharma's total shareholder returns have charted a downward path with weighted average TSRs (Total Shareholder Returns) of -2.4% a year between January 2001 and March 2007.

Cluster two: Asia growth forces

A range of factors are propelling pharmaceutical companies to step up their presence in Asia. As well as the increasing importance of Asia as an end-customer market, growth in manufacturing and human capital capabilities are also providing compelling reasons to build direct or outsourced capacity in the region.

Growth in Asian pharma markets

China could overtake the US in around 2025 to become the world's largest economy and will continue to grow to around 130% of the size of the US by 2050. India could grow to almost 90% of the size of the US by 2050⁶. Such economic growth would create major pharmaceutical markets. On a pharmaceutical market annual growth assumption of 10% to 15% in Asia compared to between 5% and 7% a year in G7 territories, China would be the second or third biggest pharmaceutical market in the world by 2020 and India might well be in the top 10.

Growth in Asian pharma manufacturing capability

Asian contract manufacturing organisations (CMOs) account for an ever-expanding share of global pharmaceutical manufacturing and is expected to account for around US\$3.3 billion of the total projected US\$23 billion CMO market by 2010⁷. A growing number of CMOs have obtained US Food and Drug Administration (FDA) approval for their operations and completed good manufacturing practice (GMP) certification. Asian territories provide a significant cost advantage with manufacturing savings that can range from 50-80% of the cost that would be incurred if the manufacturing was performed in western territories⁸.

Growing Asian scientific base and capability

The number of doctorates awarded in the natural sciences and engineering has leveled off or declined in the US, UK and Germany since the late 1990s. Conversely, it has been rising steadily in Asia. In some Asian territories, pro-active government policies are boosting the knowledge and talent base. In Singapore, for example, a major public programme has been successful in attracting industrial, intellectual and human capital investment in bio-medical sciences. Such initiatives are underpinning the growth of Asia as a force in research and clinical development as well as manufacturing.

Patient pool

Asia accounts for more than 60% of the world's population. Around a third of the world's population live in China and India alone. The population base for clinical trials is vast and has the advantage of being relatively 'treatment naïve'. Locating clinical trials in lower cost territories such as China and India can potentially save up to 60% on costs and reduce patient enrolment time by as much as 30%⁹.

Cluster three: East/West convergence/divergence trends

Much of the historical impetus for manufacturing outsourcing comes from the economic development gap between Asia and developed territories as manifested in lower wages and other costs. On the other hand, the gap in regulatory standards between many Asian territories and the west has acted as a brake on R&D outsourcing. In the future, there is likely to be a closing of these gaps between east and west with a consequent impact on the cost-benefit of outsourcing different parts of the value chain.

Intellectual property and legal landscape

Intellectual property protection (IPP) is one of the primary requirements for outsourcing any patented drug manufacturing or drug R&D to a territory. IPP in Asian territories has fallen short of western standards. However, there has been significant progress made by some key Asian territories to enforce IPP and implement patent laws. Singapore has established a strong track record for IPP while China and India have made significant progress in the field. IPP still has some considerable ways to go in Asia but legislation concerning intellectual property rights (IPR) continues to be developed and improved.

Clinical trials and pharma regulation

The cost of clinical trials in India is about 50% less than in the US. Total R&D cost savings can be similarly large¹⁰. However, regulatory barriers offset these cost advantages and significant delays can hinder the development of clinical trials in many Asian territories.

Currently, Singapore offers the shortest time to gain approval to start clinical trials at two to three months.

East/West disease profiles

Differences in ethnic origin, diet and environmental factors have produced marked variations in the nature and incidence of diseases which populations suffer from in Asian territories compared with the West. However, with rising incomes, urbanisation and convergence of tastes and lifestyles, this East/West disease divergence is reducing. Chronic diseases, for example, are becoming more common as a cause of death in the East compared with infectious diseases.

Labour and other overhead costs

Cheaper labour costs and other lower overheads, such as property costs, remain key factors in most outsourcing decisions. However, as economies develop, the gap between different territory costs will narrow. Indeed, some Asian territories already are the victims of their own success with growth resulting in tight labour markets and higher wages. In Singapore, for example, labour costs are comparable to developed territories in the West and are significantly higher than those in India or China. Wage costs in the Indian drugs industry on the other hand are just 30% of the European level or 20% of that in the US¹¹. However, India finds it difficult to recruit in certain areas - such as clinical research professionals.

Cluster four: technological/business model forces

The technological possibilities open to the pharmaceutical companies are fast-changing, spurred by changes such as the US Food and Drug Administration's move to risk-based regulation. This change is enabling companies to move away from batch manufacturing, to modernise manufacturing, and to create greater integration between manufacturing and R&D.

More flexible manufacturing

The number of products major pharmaceutical companies make are likely to increase and become more diverse, with the advent of combination therapies, diagnostics, biomarkers and treatments targeted at patients with specific disease subtypes. The technologies they use to manufacture some of these new therapies will become much more complex. The manufacturing process will have to become much more flexible, with different manufacturing routes for different kinds of products and a move to real-time manufacturing.

Closing the gap between R&D, manufacturing and patients

There is likely to be greater integration of R&D and manufacturing with shared technologies such as process analytical technology (PAT). Companies will seek to close the gap between R&D and manufacturing to reduce cost and speed up the time to market or new drugs. As well as closing the gap between R&D and manufacturing, pharmaceutical companies will be seeking to close the gap between drug development and the patient. Feedback loops will give continuous information on the effectiveness and bioavailability of individual treatments and link directly into both manufacturing and R&D.

Company vision of core vs non-core activities

Each company's vision of what activities it needs to keep in-house at the core of its operations and what is regarded as non-core is also vital to outsourcing decisions. However, increasingly, the boundary between the two will become less rigid as companies build strategic relationships with contractors. For example, some pharmaceutical companies lack the skills required to manage turnkey operations and perform specialist manufacturing, and thus, may decide to outsource most of their production to contract manufacturers. In turn, this will require much greater collaboration. Instead of treating such firms as contract manufacturers, they will need to treat them as strategic partners for the duration of the product lifecycle.

Networked business models

The pharmaceutical business model is moving away from a fully integrated company structure towards a future where companies use a wide range of outsourcing, partnership initiatives, and other contractual and relationship arrangements to create networks of collaboration and discovery. Outsourcing in Asia is a vital component of this networked future as demonstrated by the Eli Lilly case example (see Eli Lilly Snapshot on p11).

Implications of the ‘four clusters’ for Asia outsourcing

Snapshot:

Eli Lilly - Asia outsourcing in a networked future

Eli Lilly has made considerable progress in transforming itself from a fully-integrated pharmaceutical company - the old ‘FIPCO’ model - into what it refers to as a fully-integrated pharmaceutical network—or ‘FIPNET’. In the new model, it draws on a broad range of resources outside the company’s walls—to increase effective capacity and access to external capabilities, to reduce its level of risk and accelerate development, and ultimately to help lower the average cost of R&D per molecule.

Some of this transformation involves fairly traditional outsourcing—for example, the early-stage development work of its ChemExplorer and PharmExplorer partnerships in China, and its discovery efforts with Jubilant in India. At the same time, the company is pioneering new ways to share risks and rewards, such as its partnership with Nicholas Piramal. In exchange for milestone payments, and a royalty if a product reaches the market, this India-based company is developing selected molecules from Eli Lilly’s pipeline up to the end of phase II—during which time there is the option to bring them back into the Eli Lilly portfolio.

Eli Lilly has a similar risk-sharing collaboration with Sugen Pharmaceuticals in Hyderabad that will be expanded in 2008. It has also entered into a partnership in the pre-clinical arena with China’s Hutchison MediPharma, focused on targets in oncology and inflammation. The emergence of Eli Lilly as the hub of a ‘FIPNET’ is expected to contribute as well to productivity gains across the company’s business.

(Source: Eli Lilly and Company 2007 Annual Report)

The effect of these four clusters of forces is to create two key challenges for pharmaceutical companies. First, companies face the challenge of deciding how best to maximise value chain productivity and minimise costs. Second, they need to judge how to maximise the opportunity presented by growing pharmaceutical markets in Asia and the growth in Asian pharmaceutical expertise.

Outsourcing offers answers to both these challenges; however, as we see from the East/West divergence trends, the outsourcing landscape in Asia is complex. The regulatory landscape is uneven with concerns about IPP still unresolved in many territories. Moreover, the cost advantage cannot always be taken as a given as local labour markets converge with the increasingly globalised market for skilled professionals. Decisions on optimal locations for outsourcing entail difficult trade-offs. Singapore, for example, has a level of IPP comparable with Western territories but also has labour costs to match. China and India provide much lower labour costs and immense market growth but greater IP and other regulatory uncertainty. We look at these and other trade-offs in greater detail in Chapter IV.

In addition to these overall location factors, companies need to carry out extensive scrutiny of potential outsourcing candidates. Absolute confidence in the reliability and quality of supply and service from the outsourced entity is a critical consideration for any pharmaceutical company considering outsourcing. Moreover, the choice of candidate and the type of outsourcing relationship needs to fit with the company’s future ambition and strategy. The choice of outsourcing partner might be very different if, for example, the goal of outsourcing is to help accelerate a company’s move to more flexible, modern manufacturing and use of more advanced process technology compared with the goal of reducing costs on end of patent products.

Moving up the value chain: the changing nature of pharma outsourcing in Asia

The outsourcing trend started off with the outsourcing of non-core support functions such as IT, HR and finance. In pharmaceuticals, outsourced contract manufacturing and contract research have become the norm for many pharmaceutical companies. Asian contract manufacturing organisations (CMOs) and contract research organisations (CROs) compete with their European and North American counterparts in a world-wide CMO and CRO marketplace.



The trend towards high end innovation

Much of the outsourced pharma market has been for routine work such as later stage clinical trials and low cost manufacturing of established drugs but, increasingly, outsourcing is moving up the value chain. Industries such as IT, automotive and aviation are already sourcing significant elements of high end work in Asia. The motivation for such moves extends beyond cost. General Motors, for example, now uses its design studio in Bangalore to develop blueprints for new models. Darwin Allen, director of product communication with GM in Detroit, points out: "Obviously you are aware of [cost savings], but the real motivation is to find people with expertise" ¹².

Intellectual property concerns have inhibited this trend in pharma; however, increasingly, such concerns are being overcome and major moves are being made by big pharma companies to step up their drug discovery investment in Asia. Such investment is taking various forms. As we saw in the Eli Lilly snapshot, the company is developing a range of higher end relationships in a 'networked' model. Direct investment in the establishment of their own research and innovation centres has been the route followed by companies such as AstraZeneca with its tuberculosis research centre in Bangalore, India, and more recently, GlaxoSmithKline (GSK) with an investment worth US\$100 million in the first year, in a new neuroscience research centre in China (see Shanghai Snapshot).

As well as these examples of 'insourcing', capturing the benefits of an Asian location through an in-house investment, companies are also turning to research-based partnerships as a way of sourcing high end expertise and building up drug discovery investment in Asia. For example, US company Merck and Indian company Advinus Therapeutics, are collaborating on early-stage development of drugs for metabolic disorders with Merck retaining the right to advance the research into late-stage trials ¹³. In addition, Asian pharma companies such as Ranbaxy and Dr Reddy's in India, who have grown through cheap generic drug manufacturing, are seeking to compete in new drug discovery, and elsewhere, many private equity funds are taking stakes in the higher end activities of Asian pharma companies.

Snapshot: Shanghai – the next seedbed for future discoveries

GlaxoSmithKline (GSK) is the latest big pharma company to locate research activities in Shanghai, China. GSK has decided to increase its focus in neurosciences with a significant investment in the city. The company is building a fully integrated, end-to-end R&D centre that will employ more than 1,000 staff by 2010. In an announcement to investors, GSK points out: "China's growing talent pool of scientific expertise is leading to the rapid development of excellence in life sciences in general and neuroscience in particular."

Moncef Slaoui, GSK's Chairman of Research and Development, emphasised: "Neuroscience is one of the most complex and challenging areas of research and development. For us, China is not about outsourcing and cheap labour. We don't want to give them the crumbs. It's about different science. We will link our fate to their fate. Within five to 10 years we will be moving from 'made in China' to 'discovered in China'."

The GSK decision came after a six-month analysis around the world co-ordinated by Mr Slaoui to identify "the next seedbed for future discoveries." He concluded that "qualitatively and numerically, China came out on top," especially in oncology and neurology. GSK's R&D expansion in China will build on ongoing work in neural stem cell research and natural product compound libraries. It will focus on neurodegeneration (Alzheimer's and Parkinson's disease) and neuroinflammation (MS).

The GSK investment follows moves by a number of pharmaceutical companies to open R&D centres in China. Roche, AstraZeneca, Novartis, NovoNordisk, Sanofi-Aventis and other companies are also investing significantly in R&D in China, with the majority concentrated in Shanghai.

(Source: GlaxoSmithKline London Stock Exchange announcement, 13 December 2007; Financial Times, 13 December 2007.)

Rapid expansion of clinical trials in Asia

The volume of clinical trials being conducted in territories outside of Europe, North America and Japan has been growing rapidly in recent years as emerging markets grow. Asian territories have led much of the growth with the number of trials taking place in China and India, in particular, growing fast as a result of recent moves to strengthen IPP laws. Cost has been a critical factor alongside IPP improvements. Clinical trials are estimated to be up to 50% cheaper in India, for example, compared to the US ¹⁰.

According to Clinicaltrials.gov, a website operated by the US National Institute of Health, the number of ongoing clinical trials in India increased from 40-50 in 2003 to around 270 by 2007. Big pharma companies now active in India include Amgen, Biogen, Johnson & Johnson, Roche and GSK ¹⁴. However, data from the same website shows that China has overtaken India as one of the fastest growing locations for drug trials. By June 2008, China had 428 clinical trials registered on the website as under way and a cumulative total of 870 completed or ongoing trials compared with 737 in India.

The need to enroll more patients for longer periods in trials in order to satisfy regulatory requirements has led companies to look to territories such as India and China with large populations of patients who are able to participate in studies. Many such patients are 'treatment naïve', and therefore, fulfill the needs of many trials.

Another key advantage of conducting trials in some Asian territories is that many hospitals or doctors are serving large numbers of patients. So companies can recruit more quickly from a smaller number of sites. However, speedier recruitment can be offset by delays in securing local regulatory approval in certain territories. Delays of up to 12 months are not uncommon in China, and despite recent moves to streamline processes, nine month waits are typical in India. In contrast, approval times in Singapore are around three months.

The expectation is that approval times will continue to shorten as governments seek to remove barriers to investment in trials. At the same time, there is a focus on stepping up measures to prevent the risk of fraud or poor quality data, which would make trials unreliable. The US Food and Drug Administration (FDA) recently established an office in China, and other regulators are also stepping up inspections. Local regulators are also committed to measures that bring the prospect of standards gradually moving to match those in Europe and North America. However, as we see in the next chapter, there is wide variation in standards in the region with territories like Singapore already matching international standards and others much further behind. As with trials in any location, ethical issues require careful management; however, with low income populations, additional issues arise such as ensuring that participants give truly informed consent and post-trial access to treatment.

Manufacturing scales up

Asian territories provide a significant cost advantage for pharmaceutical manufacturing. The overall costs of drug manufacturing in India, for example, are up to 50% cheaper than in western industrialised territories¹¹. Cost savings on this scale present a compelling reason for manufacturing outsourcing to Asian CMOs. However, cost savings are nothing compared to the need to ensure quality and safety. Recent reports of deaths linked to contaminated heparin in the US sourced from China highlight the critical issue of quality. The general trend, however, is of ever-increasing quality of work from Asian territories.

The region has a large pool of educated and appropriately qualified talent with the ability to run manufacturing plants equalling western complexity and quality. Several CMOs operating out of Asia have obtained approval from the FDA gaining credibility for their quality standards. In India, there are more than 100 FDA-approved pharmaceutical facilities – the largest number in any territory outside the US¹⁵. China completed Chinese Good Manufacturing Practice (GMP) certification as far back as July 2004 on all the drug manufacturers in the territory. At the end of 2005, more than 5,000 Chinese drug manufacturers had obtained their Chinese GMP certificates¹⁶. There is an ongoing effort in China to increase inspections on already certified manufacturing sites, in response to evidence that some of the certified manufacturers have not consistently adhered to GMPs in the past.

With an increased commitment to international standards, Asian CMOs are securing more outsourcing orders from big pharmaceutical companies. The commitment to Western standards is also being reflected in the modernisation of plants, and moves to innovate through the development of technologies, such as PAT are necessary to ensure facilities are ready to meet future manufacturing needs.

Snapshot: AstraZeneca ramps up API sourcing from Asia

China's attractiveness for API manufacturing has convinced companies like AstraZeneca to step up outsourcing investment. David Brennan, chief executive, said all "active pharmaceutical ingredients" (API) would be produced externally within a decade as part of his strategy of "maximising the efficiency of our supply chain while maintaining the highest possible standards of quality and security of supply."

AstraZeneca plans to increase its outsourcing drastically from China and India. The firm has set up a dedicated sourcing centre in Shanghai. AstraZeneca currently spends US\$9bn a year on purchasing and will use the China sourcing centre to make purchasing savings of 10% over the next three years. The centre, which has so far made US\$25 million worth of purchases, will be ramped up to achieve total purchases valued at US\$100 million in 2010¹⁷.

(Source: quote from Financial Times, 16 April 2008; in-PharmaTechnologist.com, 5 July 2007)

Evaluating the landscape: the location context for outsourcing decisions

Choice of location as well as choice of partner is crucial to outsourcing decisions. The labour market and regulatory environment are critical influences on operations, while the logistics of the locations need to fit within the markets. The territories in the Asia region are diverse with a range of market, regulatory, geo-political and economic circumstances. They are also characterised by widely varying stages of evolution. Understanding the risks and opportunities associated with each territory is an important element in choosing a destination for outsourcing or any location decision. In this chapter we assess the different territories on an index of risk before reviewing each territory in more detail.



The risk context

A territory cannot be assessed on a single standalone factor. A combination of various parameters need to be considered. In broad terms, the major key dimensions for assessing the outsourcing competitiveness of any territory are cost factors, a range of risks associated with the territory environment, and the extent of the market opportunity. These three key dimensions can be further split into different sub-factors. To compare territories on the same scale we have assigned weights to each of these sub-factors in the figure below.

Figure 2: Framework for evaluating outsourcing destinations

	Weights
A. Cost factor	33%
1. Compensation and wages	15%
2. Infrastructure costs	8%
3. Tax and regulatory costs	10%
B. Risk factor	37%
1. Geopolitical risks	6%
2. Human capital risks	10%
3. Economic risks	7%
4. Legal risks	8%
5. Infrastructure risks	6%
C. Market opportunity factor	30%
1. Current and future needs of healthcare in terms of ageing population	15%
2. Current pharmaceutical market size	7%
3. Market growth rate	8%

Outsourcing index methodology and sources

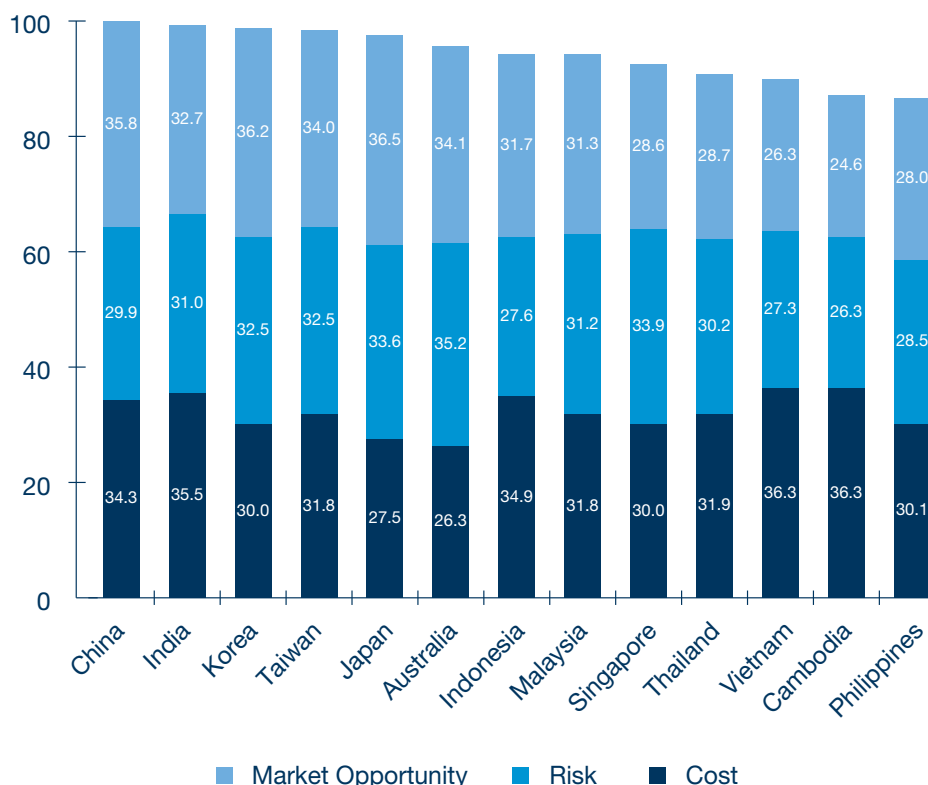
The component parameters of the index and their respective weightings are listed in Figure 2. The weights were assigned after detailed analysis of the relative importance of the factors and sub-factors based on PwC pharmaceutical practitioner experience and industry research papers. A set of data points/metrics were identified for each factor and sub-factor. The following criteria were used for the identification of a metric. i) The metric can be measured objectively and is linked to the corresponding factor; ii) the data for the metric is available from an authoritative source; iii) the metric is not used for any other factor to prevent duplication.

A territory is suitable for outsourcing if it has a good mix of all the parameters involved and has a well balanced score on each of them. The outsourcing index charts in this chapter provide a measure of the degree of readiness and attractiveness of a territory as a potential outsourcing destination for pharmaceutical R&D and manufacturing. This index has been prepared to assess emerging outsourcing destinations and to rank these territories in terms of their suitability to outsourcing. The exact weighting can be varied to reflect the exact context of an individual outsourcing decision. For example, the weight given to market opportunity will depend on the extent to which an outsourcing decision is part of a strategy to capitalise on local market growth in a territory or whether it is serving other needs. In the following sections, we look at how Asian companies rank across the factors as a whole, and against each of the three individual key dimensions.

Risk and opportunity overview

Taking all the parameters into account, China tops the table as the best outsourcing destination followed by India, Korea and Taiwan respectively. Both China and India, although not leaders in all the factors, score strongly across a sufficient range to emerge as the leading destinations. In particular, the lower costs and greater market opportunity in these two territories outweigh the higher risk compared with the more established and mature regulatory regimes of Australia, Japan and Singapore. Strong market growth potential is a key reason for Korea's third place spot while Taiwan's active promotion of the biotech industry, supported by incentives and tax breaks, helps put that territory into fourth position. The Taiwanese government hopes to establish the territory as a leading location for CRO activities in Asia.

Figure 3: Outsourcing index - ranking of Asian territories across all factors



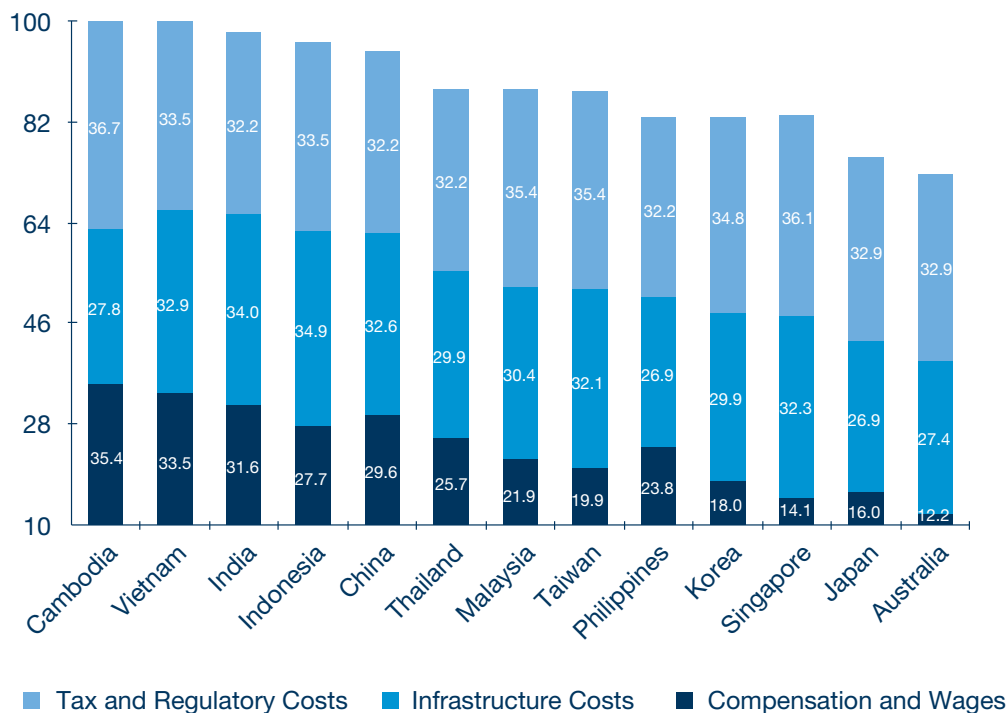
(Scores are 'normalised' with the best ranking territory = 100. Thus, higher scores indicate lower costs, lower risks and greater market opportunity.)

Evaluating territory costs

In the past, cost has been the primary driver for outsourcing. Cost continues to be a key factor but no company would base a sustainable decision on cost alone. Indeed, in a converging world where the scale of cost differences will ultimately diminish in significance and in the context of the trends discussed in the preceding chapters, cost reduction is, more often, an additional validating factor for decisions that need to make sense on wider grounds. In this respect, cost is a vital underpinning factor rather than the lead driver for decisions.

Thus, while Cambodia emerges as the lowest cost location, it lags behind significantly on the other factors. Between India and China, each has relative cost advantages over the other across wages and infrastructure costs depending on the actual city location. On the other hand, Malaysia, Singapore, Korea and Australia, although being potentially more expensive outsourcing destinations in Asia, score favorably in terms of the risk parameters (see next section).

Figure 4: Cost ranking of Asian territories



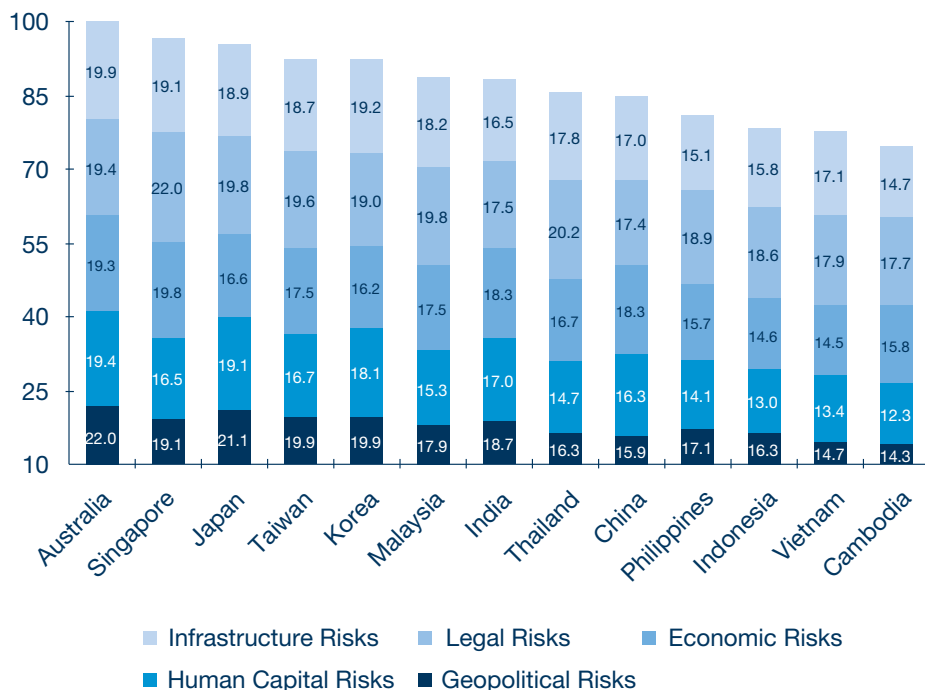
(Scores are 'normalised' with the best ranking territory = 100. Thus, higher scores indicate lower costs.)

Wider risk factors

The ranking pattern of risk vs cost illustrates starkly the trade-offs involved in location decisions. The territories emerging as the most expensive destinations also emerge as the most attractive destinations when evaluated on the risk parameters. This is primarily due to better legal systems, well managed infrastructure and stability in the political and economic system.

The trade-off between cost advantage vs wider risk also highlights the way in which cost reduction gains gradually recede over time as territories modernize and converge with international standards. Benefits come in the form of a more favourable regulatory environment but convergence occurs in terms of cost as well. Singapore illustrates this trend well. A couple of decades ago, the gap between this destination and more expensive territories was much wider. For example, average earnings in Singapore just five years ago, in 2003, were just 62% of US average earnings. By 2007 the gap had almost halved to 77% of US average earnings ¹⁸.

Figure 5: Wider risk ranking of Asian countries

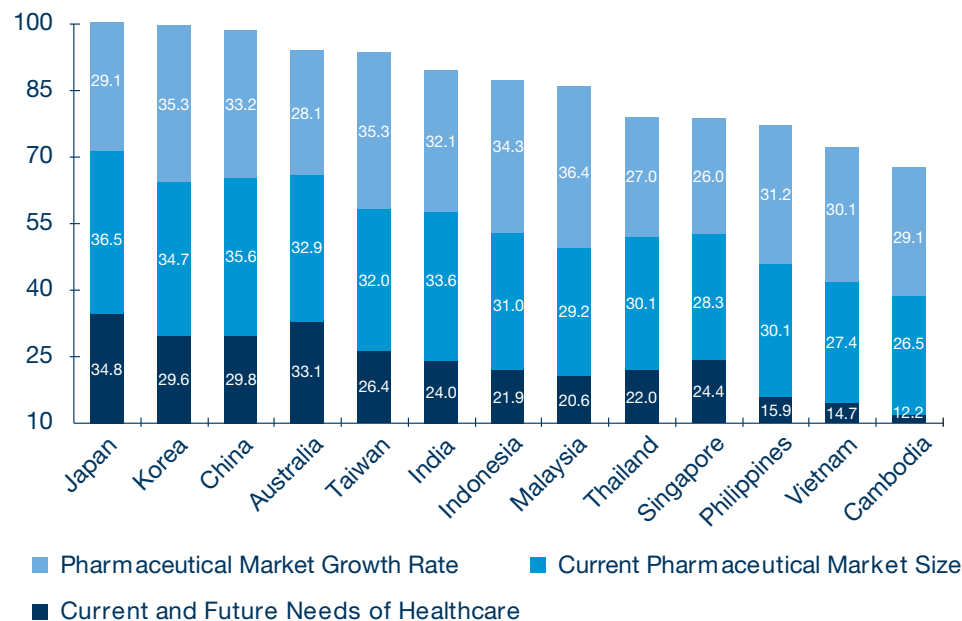


(Scores are 'normalised' with the best ranking territory = 100. Thus, higher scores indicate lower risks.)

Market opportunity

Outsourcing has ceased to be just a cost driven activity. Instead, strategic and market opportunity factors are playing an increasingly significant role in deciding the attractiveness of an outsourcing destination. The pharmaceutical market in Korea is experiencing double digit growth helping put the territory close to Japan at the top of the market opportunity rankings followed by China in third place. India holds the promise of significant future market potential but this is constrained by the fact that its current healthcare market is smaller than that of Japan, China and Korea, hence its middle ranking position in the table.

Figure 6: Market opportunity ranking of Asian territories



(Scores are 'normalised' with best ranking territory = 100. Thus, higher scores indicate greater market opportunity.)

These rankings are no more than indicators, providing the starting point of a framework for outsourcing and other location decisions. They provide an overview and are not, for example, adjusted to take account of the purchasing preferences of individual populations. Actual decisions by companies need to be the result of a rigorous evaluation of locations, markets and potential outsourcing candidates. Such an evaluation is likely to involve scrutiny and comparison of individual territories. In the next chapter, we provide an overview of each territory. We group them in the following sections - the hot spots: China, India and Singapore, the mature markets: Japan and Australia and other Asian territories: Taiwan, Malaysia, Korea, Thailand, Indonesia and the Philippines. Our main area of focus and discussion is on the 'hot spot' territories.

Territory review



Hot spots: China, India and Singapore

China

Labour

China has a large pool of skilled scientists. There are about 128 universities and colleges of medicine and pharmaceuticals, complemented by 53 tertiary vocational-technical colleges. There are about 666 institutes dedicated to science and technology. In total, as of 2007, there were over 1.6 million science and engineering graduates (including undergraduate, masters and PhD students) and about 7.7 million enrollments for doctoral and masters study programmes.

IP protection and regulation

China joined the World Trade Organisation in 2001 and agreed to uphold the Trades-Related Aspect of Intellectual Property Rights (TRIPS) Accord. However, IPR protection and corruption remain key issues. Recent legal and enforcement moves are encouraging - Pfizer won a law suit against Beijing Huirui Biotechnology Ltd. for trademark infringement, and in another ruling, Aida Pharmaceuticals, Inc., a local company, won a law suit against four counterfeit drug suppliers. Restrictions over drug pricing are a cause of concern to pharmaceutical players with drug prices regulated and revised every two years. However, the State Food and Drug Administration (SFDA) is considering deregulating prices of certain drugs in order to improve the situation.

Tax

The Chinese government is encouraging foreign investment in R&D activities by granting tax incentives, providing financial subsidies and offering other incentives. The possible tax incentives, subject to registration and approval by the relevant authorities, for qualified R&D activities include:

- Business tax exemption on qualified technology transfer, technology development and related technical consulting and services;
- 150% deduction of R&D expenses incurred in relation to new products, new technologies or new techniques;
- A reduced corporate income tax (CIT) rate of 15% for high and new technology enterprises (HNTE);
- A tax holiday comprising a two-year exemption and three-year half reduction if the HNTE is established in specified areas (Shenzhen, Zhuhai, Shantou, Xia'men, the Hainan Special Economic Zone and the Shanghai Pudong New Area);
- CIT exemption/reduction on income derived from technology transfer;
- Duty free import of capital equipment or VAT refund on local purchased equipment used for R&D activities.

Various criteria need to be met by enterprises wishing to gain from HNTE status. These include possession of IP rights over the core technology, the development of products or services that are covered by the state's list of high and new tech domains, a highly qualified workforce and having a certain concentration of R&D expenditure within China.

Drug discovery

Chinese pharmaceutical players are spending more on R&D in recent years. Hengrui Pharmaceuticals holds 12.5% market share in the territory's anti-tumor market. Hengrui has had four new drugs approved by the territory's SFDA, and spends approximately 7-8% of its revenues on R&D. Another company, Zhejiang Huahai, has evolved from being solely an API manufacturer to an integrated pharmaceutical company ¹⁹.

Biology research

Pre-clinical development revolves around basic biology, chemistry and developing the drug into safe dosages for humans. Chinese government institutes have some proven skills in core biology. Vendors are capable of offering services in protein expression, stem cell research and genomics. Johnson & Johnson has been outsourcing basic biology work to Chinese vendors. SiBiono Genetech has developed an injectible therapy – Gendicine - for cancer treatment in China, exemplifying China's capability in genomics.

Chemistry research

China offers acceptable basic chemistry services such as analytical and combinatorial chemistry. The number of service providers providing chemistry services is not large but is continuously growing at a rapid pace. Capabilities currently reside mostly with governmental institutes, who also cater to outsourcing requirements. GSK outsources its basic chemistry requirements to Shanghai Institute of Materia Medica (SIMM).

Pre-clinical development

Pre-clinical services in China are provided by government institutes as well as private CROs. Private entities and government institutes possess extensive animal testing capabilities covering a wide variety of species. The Institute of Pharmacology and Toxicology in China provides pre-clinical services with the support of the government. There are about 20 'GLP certified' labs.

Clinical trials

Chinese CROs offer a range of services and have partnered with other Asian CROs to offer a complete suite of R&D services. For example, Indian company Suven Life Sciences Limited's clinical research division, Asian Clinical Trials (ACT), has entered into a strategic alliance with VPSCRO, a CRO based in Beijing, China to conduct clinical trial services in India and China. Chinese CROs have also formed domestic alliances to mutually benefit from each others' capabilities. In June 2007, three CROs, Sundia MediTech, United PharmTech and HD Biosciences, formed a CRO service alliance (CROSA) to offer pre-clinical development services. Covance is expanding its clinical trial operations in China in collaboration with Excel PharmStudies and offers drug development services. AstraZeneca will invest US\$14 million in Wuxi PharmaTech for synthesis of 150,000 compounds. Almost all foreign CROs operating in China are providing clinical trial services and some domestic CROs have started offering biology and chemistry as well as pre-clinical and clinical trial services ²⁰.

Snapshot:

The Chinese CRO market

The Chinese CRO market has been rapidly growing over the last few years with growth rates of 52% and 38% in 2006 and 2007 respectively. This was mainly fuelled by global R&D outsourcing (rather than domestic outsourcing). In 2007 the contract research market in China was estimated at US\$186 million. The Chinese market is expected to grow at a CAGR of 33% over the next five years to reach US\$791 million in 2012. By that time, Chinese CROs will account for an estimated 2.3% of the global CRO market.



(Source: Goldman Sachs, *United States: Healthcare Services: CROs*, December 2007.)

Raw material sourcing

China has been a major source of raw materials for drug manufacturers due to cheaper prices. However, in 2007/8 the export incentives offered by the Chinese government were reduced to 7% from 13% in 2006/7, which resulted in increasing prices of raw materials being exported from China ²¹. As a result, big pharmaceutical companies are integrating backwards by producing their own raw materials or APIs in China and domestic SME units in the outsourcing territories are being seen as viable sources of raw materials. China is extremely rich in basic medicinal raw material. Exported raw herbs, for example, account for 20% of the territory's annual harvest.

APIs and bulk drugs

The Chinese fine chemicals industry has traditionally focused on basic intermediaries, commodity APIs and bulk drugs. However, companies are increasingly moving on to offer complex services such as custom synthesis*. Chinese bulk drugs and API producers are among the largest in the world and are known for their lower prices. China's API companies made sales of just under US\$6 billion in 2007 and are expected to bring in nearly US\$10 billion by 2010, through an annual increase of 17.6%. Exports of Chinese API and bulk drugs have mostly been in the form of antibiotics, vitamins, amino acids and organic acids. The largest export markets are the EU, the US, India and Japan, which jointly account for around 60% of the total Chinese API exports. China's attractiveness for API production is highlighted by AstraZeneca's moves to step up its Chinese manufacturing (see AstraZeneca Snapshot on p15).

* Custom synthesis is the manufacture of compounds based on specific client requirements. Synthesis means combining two or more elements to form a new compound.

Finished drugs

Chinese drug makers are eager to enter the finished drugs market, both as contract manufacturers and as patent holders. China has a small presence in the finished drugs export market with finished drug exports estimated at about US\$700 million in 2007 ²².

Figure 7: China API export value

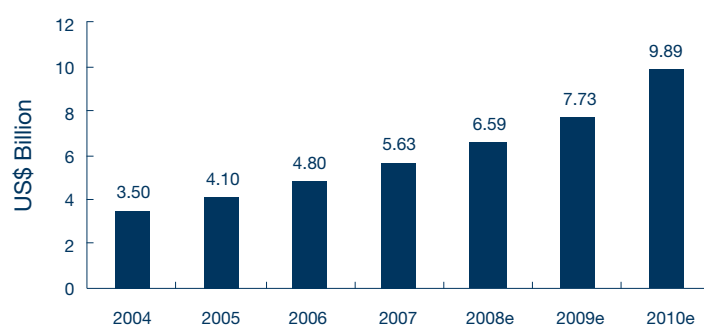
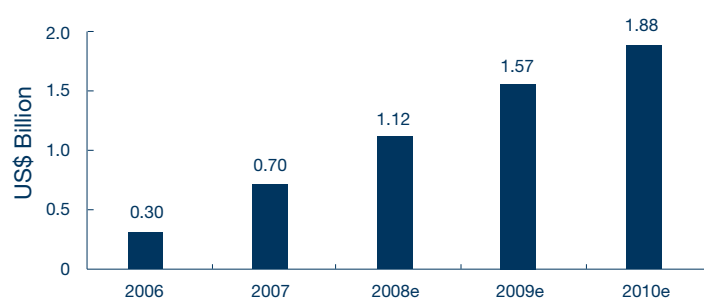


Figure 8: China's finished drugs export value



India

Labour

In India, about 300,000 postgraduates and 1,500 PhD students qualify annually in biosciences and engineering and around 150,000 MSc students graduate in chemistry alone. The number of fresh scientists and engineers available every year is 700,000 according to a Confederation of Indian Industries (CII) study. Despite these numbers, India finds it hard to recruit sufficient clinical research professionals. An Indian Planning Commission report highlights a “looming shortage of clinical research personnel, estimated at 30,000-50,000”. Labour costs in India are around one-seventh of those in the US²³. Another benefit is the talent pool's proficiency with the English language.

IP protection and regulation

Until 2005, India recognized only process patents. IPR protection altered significantly in 2005 when India became TRIPS-compliant and formally recognised product patents with retrospective application to 1995. This move has encouraged drug discovery. CROs in India are capable of offering complete discovery and development outsourcing solutions. The priority of drug research has been refocused from reverse engineering to new molecular entities (NMEs).

Tax

The effective aggregated tax rate for companies in India is around 20% based on a study analyzing actual rates paid by a sample of thirty-two companies²⁴. In-house R&D expenditure qualifies for a weighted deduction of 150%, which can be claimed up until March 2012. Clinical trials of new drugs have been exempted from

service tax in order to give impetus to R&D²⁵. Certain geographical zones within India have been allowed tax holidays for defined periods resulting in significant incentives for investors. Single digit tax rates are achievable for research, resulting in minimal tax outgoings.

Biology research

India is efficient in bioinformatics due to the practitioners' well-established IT skills. However, the territory lacks capability to offer complex biology services. Government institutes offer basic biology services but the extent of innovation is less. Looking ahead, private players will need to partly/completely own or share technology with available CROs in order to achieve innovative results. Examples of research include IBM's funding of protein structure research and AstraZeneca's investments in target identification and validation studies for developing a NME for treating tuberculosis.

Chemistry research

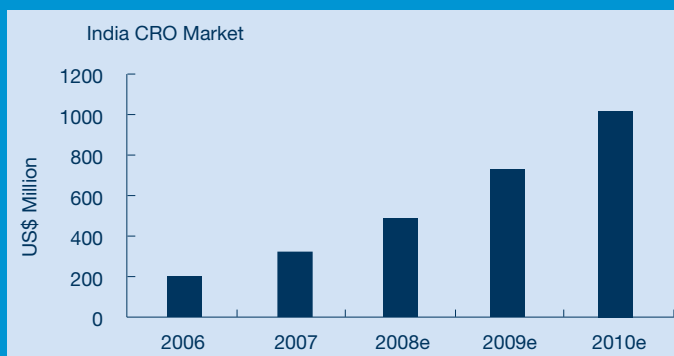
India has widely accepted chemistry skills and can offer complex services well. The services offered match global standards. CROs have been co-developing drugs along with multi-national pharmaceutical companies. Examples of outsourcing chemistry services from India include GSK-Torrent Pharma and AstraZeneca-Ranbaxy.

Pre-clinical development

India offers capabilities for pre-clinical trials in rodents, and limited for dogs with almost none for primates. The capabilities mostly reside with Indian pharmaceutical companies, developed through in-house R&D programmes as opposed to government organisations. There are 12 'GLP-certified' laboratories but this number is expected to increase.

Snapshot: The Indian CRO market

The total CRO market in 2007 was about US\$323 million and is expected to grow at around 49% CAGR up to 2010. Government support and funding are being extended to improve the segment's potential and serviceability. Funding through private equity and venture capitalists, though at a very nascent stage, has improved the credibility of Indian pharmaceutical research. Private equity investor Barings, for example, has bought a 30% share in Siro Clinpharm. Indian pharmaceutical companies tend to follow the model of keeping simple, low-cost operations at home and taking complex operations offshore. Indian pharmaceutical company Nicholas Piramal is expected to be ranked among the top ten outsourcing companies in the world after its acquisition of Pfizer's UK facility. It will also secure the largest share in Pfizer's outsourcing pie.



(Source: Zinnov, Deutsche Bank, Biospectrum Asia, PwC Analysis; India Outsourcing, Pharma Scene.)

Clinical trials

India has several experienced CROs offering services across all clinical trial phases. The CROs have been successfully adhering to quality standards and the output is similar to that of developed markets. The territory has very strong data management capabilities and IT skills. There are significant cost and patient enrollment advantages. India offers a large 'treatment naïve' patient population. Patient population is vast and diseases are diverse in nature but similar to the epidemiological profile of mature markets. Due to the lack of penetration of effective medical treatment, patient enrollment is high with minimal attrition. They can be recruited for less than one-third the time taken in the US. The average number of patients per site is fifty, which is five times higher than that in the US. However uneven infrastructure and shortage of clinical research assistants could hamper future growth in the outsourcing of clinical trials.

Raw material sourcing

India has a well-established chemicals and extraction industry capable of supplying raw materials to the global and domestic pharmaceutical industry. However, it faces stiff price competition from Chinese raw material producers. In response, Indian CMOs are exploring collaborative tie-ups with their Chinese counterparts for the supply of raw material products. For example, Hikal is sourcing key raw materials through a Chinese joint venture with Sinochem-Jiangsu Chemstar Industries. Around 340 plant species yielding raw materials are used by the industry on a regular basis or in substantially large quantities. Among these, around 40 are imported from other territories and the rest are available domestically ²⁶.

APIs and bulk drugs

With export sales of US\$1.7 billion in 2007, the Indian API manufacturing industry is the third largest in the world and is expected to make export sales of US\$2.8 billion by 2010, an average yearly growth rate of 19.3%. Globally, India comes fifth in terms of API manufacturing ¹⁷. India has more than 100 FDA-approved plants - the largest number of such plants outside the US.

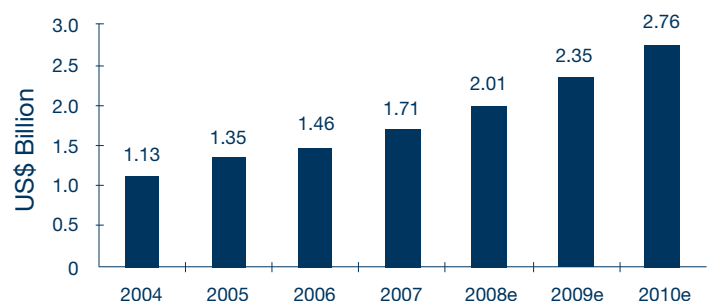
Certain therapy drugs are driving sales. The production of APIs has mainly been for areas like antibiotics, anti-infectives, anti-inflammatory drugs, cardiovascular system drugs, central nervous system drugs, respiratory drugs, and anti-diabetes drugs. India has limited technical capabilities in biomanufacturing. Although the expanded scope of IPP does cover biologics, companies are still reluctant to outsource patented biologic APIs.

Western companies have been reluctant to outsource API manufacturing of in-patent drugs to India. However, a few companies have realised that API manufacturing in India is no longer as risky as in the past. Outsourcing API manufacturing of patented products has gradually increased with companies such as Solvay

and AstraZeneca signing API contract manufacturing agreements with Indian CMOs. Hikal recently signed a long term API-supply deal for lifestyle drugs with Pfizer. Another Indian CMO, Arch Pharmed Labs, has signed a long-term deal with DSM Anti-Infectives of the Netherlands to supply generic APIs ²⁷.

The Indian bulk drug market is fragmented, with the top ten companies contributing 44% of the market and the remaining companies accounting for the balance. Nearly 70% of bulk drugs are manufactured for the export market. The pharma CMO market as a whole in India in 2010 is expected to reach US\$916 million from US\$492 million in 2007. By 2010, the Indian bulk drugs export market is projected to grow to about US\$6.54 billion ²⁸.

Figure 9: India's API export value

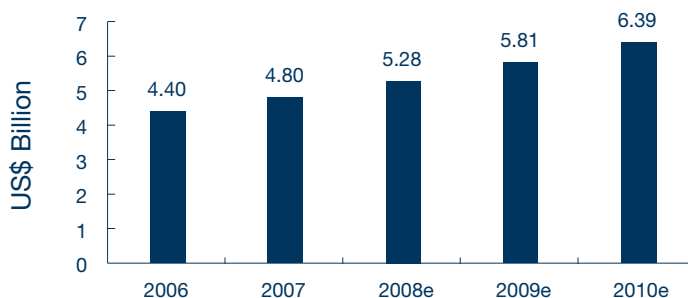


Finished drugs

Generic drug manufacturing and export lead the way in finished products. Finished generics supplied from India account for 20% of the global generics market. Most of the earlier growth of pharmaceutical companies has been based on generics. It is only of late that Indian players have extended their offerings across to the manufacture and export of patented drugs. In 2007, finished drugs constituted about half of total pharmaceutical manufacture exports in value terms. The balance was bulk drug exports.

Indian CMOs have expanded their service offering domestically as well as globally by setting up new facilities and acquiring existing facilities from large pharmaceutical companies in order to gain ready access to the market, pre-approved facilities and clients. Bought-out deals by CMOs provide a ready made solution to cater to the problems of outsourcing clients. DRL, for example, recently added its seventh finished dosage plant to serve the international market for the treatment of cancer, hormonal imbalances and other diseases ²⁹. Kemwell has bought Pfizer's FDA-approved plant in Uppsala, Sweden in order to gain access to the European market. The plant continues to make anti-inflammatory drugs, and at the same time, enables Pfizer to outsource production without shutting down the facility ³⁰.

Figure 10: India's finished drugs export value



Singapore

Labour

Singapore's total research scientific and engineering personnel pool increased by 6% to 26,436 in 2006³¹. The availability of a skilled talent pool, with a density of 93 per 10,000, is on par with mature markets such as the US and Japan. English is an official language in Singapore and therefore not a barrier. Labour costs are comparable to those in developed territories in the West and significantly higher than in India or China, resulting in the outsourcing of mainly high-end complex tasks to Singapore. Although the territory benefits from a multi-racial population, the small population base of 4.5 million limits the recruitment of patients for clinical trials.

IP protection and regulation

The Singaporean market has extremely well-regulated IPR protection, and considered one of the best among all Asian territories in terms of regulatory compliance. It has complied with the TRIPS regulations since 1999. Along with Australia, Singapore has consistently topped the rankings as the top Asian territory for IP protection and enforcement. Compared to China and India, Singapore offers the shortest time to gain approval to start clinical trials. The average regulatory approval period is four weeks followed by an additional four to six weeks for site-level IRB/ethics committee (EC) approval³². This short timescale makes Singapore an even more attractive destination for clinical trials in Asia.

Tax

Besides having the necessary operations and regulatory infrastructure, Singapore also has an attractive tax regime. Singapore's corporate income tax rate, in effect from 2007 is 18%, one of the lowest in the region³³. The income tax rate can be further reduced through incentives offered by the Singapore government. In a further effort to boost Singapore as an R&D hub, the Singapore government's 2008 budget proposals include a tax deduction for 150% of the expenses incurred for R&D activities carried out in the territory (whether in-house or outsourced to a contract R&D service provider). This enhanced tax deduction scheme will be available for five years starting from 2009³⁴. In addition, there are a few other tax incentive schemes to encourage R&D activities in Singapore, such as R&D tax allowance and R&D incentive for start-up enterprises. Also, in order to encourage companies to go overseas to recruit foreign talent (including scientists and engineers), the Singapore government allows a double tax deduction for expenses that companies incur in recruiting foreign talent, including relocation expenses, subject to prescribed limits. This scheme is currently available until 2013³⁵.

Biology research

Singapore has well-established biology research services in terms of protein expression, bioinformatics, molecular biology and genomics. Several initiatives have been taken by the Singaporean government to promote the pharmaceutical industry. These include the establishment of Biopolis, an international research and development centre located in Singapore for biomedical sciences. Private investment in this and other areas is being attracted by extremely lucrative regulatory incentives by the government. For example, Fluidigm Corporation has a captive R&D facility in Singapore for developing biochips. The quality of research offered by Singapore is of international standard due to the expatriate talent. Expatriates are being offered good remuneration and career opportunities in order to pursue R&D in Singapore.

Chemistry research

Singapore is capable of offering end to end chemistry services such as analytical and medicinal chemistry and chemical synthesis. Albany Molecular Research Inc (AMRI) offers discovery and medicinal chemistry, as well as some custom synthesis.

Pre-clinical development

Singapore offers good capabilities for trials using rodents and primates. However, the cost of subjects, especially genetically modified ones, is sometimes high. Most labs used for pre-clinical development are 'GLP certified' and are capable of offering complete pre-clinical development services. For example, Maccine is a CRO providing innovative discovery support and safety assessment services. It provides pharmacokinetic services and pharmacodynamic services on primates along with toxicology and efficacy testing.

Clinical trials

Singapore has a very small population base and, with a large proportion of the population having access to good medical facilities. There are fewer opportunities for 'treatment naïve' trials. The patient population in Singapore is diverse in nationality and origin. Clinical trials capabilities exist with government and private institutions. The National University of Singapore conducts trials jointly with Eli Lilly for candidate drugs in various therapeutic areas. Being the secretariat for the Asia Pacific Economic Cooperation (APEC) Coordinating Centre for Good Clinical Practice (GCP), Singapore has also been the focal point for the development of GCP in Asia, steering many initiatives such as the training of clinical research personnel and the creation of a conducive environment for multi-site clinical trials in the region.

Snapshot: The Singaporean pharma market

The pharmaceutical market in Singapore totalled US\$600 million³⁶ in 2007. Besides offering the basic essentials, such as a stable business environment and an excellent communications infrastructure, the territory also offers an established regulatory infrastructure, a strong IPP regime and a pool of highly skilled manpower. In 2006, Singapore's expenditure on research and development hit US\$3.15 billion (2.39% of GDP) and is on its way to meeting the government's target of 3% of GDP by 2010. According to The National R&D Survey 2006, the private sector's expenditure on R&D increased by 8.6% during 2005 to US\$3.2 billion in 2006. Biomedical R&D expenditure increased from US\$523 million in 2005 to US\$662 million in 2006.

(Source: Business Monitor International, Singapore Pharmaceuticals and Healthcare Report Q1 2008)

Raw material sourcing

Singapore imports most of its basic raw material requirements from China and other territories. In order to compete with neighboring Asian territories and to improve self-sufficiency in raw materials, Singapore has initiated research to improve productivity in the extraction and formulation of raw materials. The Crystallisation and Particle Science programme at the Institute of Chemical and Engineering Sciences (ICES) aims to develop a fundamental understanding of crystallisation and formulation science. The crystallisation team has the ability to invent highly efficient separations to provide high purity, specific size and control of form and physical characteristics. This isolation is often a critical step that determines the downstream processability and the final product quality ³⁷.

APIs and bulk drugs

Singapore's infrastructure and IPP make the territory a suitable offshore location for pharmaceutical and biotech companies alike. However, costs are comparable to Western territories. Singapore is well recognized for the quality of its API and bulk drugs. Companies from mature markets enjoy significant comfort when using contract manufacturing in Singapore. For example, Lonza has entered into a joint venture with Bio*One Capital to build a commercial mammalian cell culture manufacturing plant with around 80,000 litres of capacity. The new plant will supplement Lonza's existing mammalian cell culture plant based in New Hampshire in the US. The investment totals around US\$250 million and employs around 300 staff. The final plant is expected to be operational in 2009. Looking ahead, companies may have to consider the possibility of capacity constraints given the small size of the territory. However, it is clear that Singapore is well-suited for complex and technology intensive manufacturing (as required in biotechnology), and among the 'hot spot' territories, Singapore has access to the best technology and funding for outsourcing high-technology intensive products.

Finished drugs

Singapore's pharmaceutical manufacturing output was about US\$16.5 billion ³⁸ in 2007. The annual output growth in the pharmaceuticals segment was around 30% ³⁹. Singapore exported US\$5.27 billion worth of medicinal products in 2006 ⁴⁰. This is the highest amongst the other hot spots like India and China, which exported finished drugs worth US\$4.4 billion and US\$0.3 billion respectively. Technologically advanced facilities and strong legal infrastructure make it increasingly possible to outsource complex and patented drug manufacturing to Singapore. However, Singapore faces the threat of ever increasing labour costs which offset some of its comparative advantages in technology and legal infrastructure.

Snapshot: Pfizer's new R&D facility in Singapore

Pfizer's Clinical Research Unit (CRU) in operation since mid-2007, is the largest clinical research facility in Singapore. The company also operates a manufacturing facility in the territory. The CRU is one of three such facilities operated by Pfizer around the world.

Occupying a floor area of more than 3,000m² and housing more than 50 inpatient beds at Raffles Hospital, the new CRU is three times larger than Pfizer's previous facility at Singapore General Hospital (SGH). The unit conducts multi-therapeutic research to facilitate the rapid introduction of new medicines. The new facility is connected via the latest IT systems to other Pfizer facilities (headquarter facilities in the UK and the US) in the world to enable real-time, cross-territory synchronisation of research data.

The facility highlights the importance of Asian research capability to Big Pharma. Pfizer alone is involved in partnerships with many of Asia's leading research organizations. In the 18 months prior to the official opening of the CRU, for example, Pfizer entered into more than 45 research and technology transfer agreements with universities, research institutions and companies in the region.

(Source: Biomed Singapore - Pfizer News on 5 Feb 2008)

Figure 11: The ‘hot spot’ territories: overview of capabilities across the pre-manufacturing value chain

Process	China	India	Singapore
Biology Research	<ul style="list-style-type: none"> • Innovative capabilities, with government institutes • Established skills in basic molecular biology and protein expression • More than 100 small companies are servicing multinational companies some services • There are new players continuously coming on the market and expanding rapidly • Innovative research in stem cells, biochips, and gene sequencing • Expanding biology talent pool 	<ul style="list-style-type: none"> • Innovative capabilities lie mainly with government institutes • About five companies with proven skills in basic molecular biology and protein expression • Few multinationals present, mostly with captive biology investment • Innovative research focused on bioinformatics and biochips • Limited biology talent pool owing to historic focus on generics 	<ul style="list-style-type: none"> • Innovative capabilities lie mainly with government and private companies • Limited but high quality talent pool, government extensively supports foreign talent recruitment • Private investment in these areas in being attracted by extremely lucrative incentives by the government • Skilled in protein expression, bioinformatics, molecular biology and genomics
Chemistry Research	<ul style="list-style-type: none"> • Capabilities residing mostly with government institutes; few small private companies with a track record, but the number of companies and their size is growing rapidly • Established basic-chemistry skills moving to more complex offerings, but limited end to end capabilities • Large and growing pool of raw talent, limited language skills 	<ul style="list-style-type: none"> • Large pool of vendors with full services and track record of efficient capabilities • Extensive multinational activities with top-tier vendors • Vast pool of skilled and low-cost chemists 	<ul style="list-style-type: none"> • Well developed chemistry skills, capable of offering end to end complex capabilities • IPR protection is strong and well acknowledged • Many multinational pharmaceutical companies are already present and more are expected to source from Singapore • Skilled chemists available

Figure 11: The ‘hot spot’ territories: overview of capabilities across the pre-manufacturing value chain (Cont'd)

Process	China	India	Singapore
Pre-clinical Development	<ul style="list-style-type: none"> • Capabilities in pre-clinical trials in a wide variety of species • Capabilities residing with government-sponsored institutes and privately owned companies • Approximately 20 labs with good laboratory practice (GLP) certification; new regulations should boost that number 	<ul style="list-style-type: none"> • Good capabilities for pre-clinical trials in rodents, limited for dogs, almost none for primates • Capabilities residing mostly with Indian pharmaceutical companies, developed through in-house R&D programmes • Approximately 12 GLP-certified labs, expected increase in the number • Government increasingly supportive and relaxing hurdles, though restrictions persist (for example, on exporting blood samples) 	<ul style="list-style-type: none"> • Extremely supportive government • Good capabilities for pre-clinical trials in rodents and primates • Sufficient number of GLP certified labs to carry out development studies
Clinical Trials	<ul style="list-style-type: none"> • Experienced contract research organizations and growing vendor pool providing full spectrum of services • High-quality SFDA-approved hospitals exist • Several multinationals conducting global trials at Chinese sites • Low-cost and efficient enrollment compared with the United States and Europe • Trial approval times may stretch long 	<ul style="list-style-type: none"> • Experienced contract research organizations with full service range and output of similar quality to that of developed markets • Strong data-management capabilities and track record • Many multinationals conducting global trial activities • Greater advantage in cost and patient enrollment • Uneven infrastructure and shortage of clinical research assistants might hamper future growth 	<ul style="list-style-type: none"> • Well experienced CROs capable of delivering as per international standards • Low patient pool due to low population base of 4.5 million people • Skilled labour needs to be sourced externally • CROs also work more in collaboration with other Asian CROs

Mature markets: Japan and Australia

Japan

Japan ranks second in terms of its pharmaceutical market size after the US. Per capita healthcare spending is among the highest in the world. Skills and technology available in Japan are easily comparable to western standards. Japan is recognised worldwide for its innovation and advanced technological standards. In turn, the very stringent standards expected by both regulators and end customers mean that the role of Japanese contract manufacturers is very important to international pharma companies seeking to capitalise on the market.

Labour

Labour in Japan is skilled but at a cost comparable to western territories. Cost structures in Japan have largely converged with those of developed pharmaceutical markets.

Intellectual property rights

Japan has a developed IPR protection system. However some issues, such as data exclusivity for new drug applications, remain unresolved. Generic manufacturers may collate data without much difficulty. The Pharmaceutical Affairs Law (PAL) allows generic manufacturers to use a patented drug's data to conduct R&D activities.

Tax

Companies can claim a tax credit of 8-10% for R&D on the total cost base. The precise applicable rate is determined by the R&D cost ratio i.e. R&D costs/average sales. Tax credit on joint R&D with the government is restricted to 12% of specific R&D costs. Tax credit based

on the increased R&D cost base is up to 5% of the excess R&D costs, which is over annual average of R&D cost for the last three years. In all cases, the maximum tax credit allowed is 20%⁴¹.

Services offered

Services are offered across the value chain. Biology and chemistry services are mostly offered by government institutions. Other services mostly sought are clinical trial services, data management and statistical analysis. The population is 127 million and is not 'treatment naïve', which limits the patient pool for trials.

Raw material

Japan imports most of its raw material requirement for pharmaceutical extracts from other Asian territories such as China and India. Being smaller in size, the amount of organic raw material available in Japan is insufficient to meet the pharmaceutical industry's demand.

APIs and bulk drugs

In 2007, about 70% of Japan's API requirement, worth US\$5 billion, was manufactured domestically. The remaining 30%, worth about US\$2 billion, was outsourced to foreign markets⁴². The contract manufacturing industry in Japan is relatively young. There are only around 10 dedicated CMOs among the 100 or so companies that conduct contract manufacturing. Most of the 10 have been spun out of large parent drug manufacturers. The remainder are largely companies that undertake contract manufacturing alongside their own, largely generic operations.

Australia

The Australian pharmaceutical market was worth approximately US\$10 billion in 2005-06⁴³ and was the third largest market in the region after Japan and Korea.

Labour

Labour available within the Australian market is skilled and comparable with its developed world peers in terms of remuneration.

Intellectual property rights

Australia is a highly developed, regulated, and westernized market. Products have effective patent terms of 20 years, bring domestic procedures largely in line with international norms. Patent holders receive an advance notice of patent-infringing products entering the market, allowing them time to act to address the situation. However, Australia passed legislative measures penalizing companies for misleading claims⁴⁴.

Tax

A 175% R&D tax break came into force in July 2007. This can be utilized irrespective of where global biotechnology and pharmaceutical firms hold their intellectual property. However, corporate taxes (30%) in Australia are higher than other territories for foreign investors⁴⁵.

Services offered

Services are offered across the value chain through a number of certified labs and CROs. Capabilities rest with government and private players alike. Being a developed market, services outsourced to Australia are usually complex services requiring a skilled workforce. The quality of services offered matches those of other Western territories. Clinical trials have been increasing and have been recognized as some of the best in the Asia Pacific region.

Contract manufacturing in Australia is not very developed due to the small size of the market and its inability to compete as a major export hub compared to other Asian territories. However, it is on par with developed Western pharmaceutical markets in terms of technology. There is also not a huge price difference between generic and branded drugs; however, this may change with the recently introduced PBS (Pharmaceutical Benefit Scheme) Reforms which have mandated a 25% price cut for generics from August 2008. The territory also has good regulatory systems in place. The Australian pharmaceutical market is more of an import intensive market with Big Pharma companies operating large sales and marketing operations. In 2006-07, Australian pharmaceutical exports totalled US\$2.8 billion in comparison to imports of US\$5.9 billion⁴⁶, and Australia's broader pharmaceuticals market spent US\$573 million on R&D in 2005-06.

Raw material

Intense competition exists against cheaper imports. Drug manufacturers prefer to outsource raw material supply and import to maintain consistency, quality and price. Medicinal herb cultivation in Australia is hard to quantify due to inconsistency in production volume. In addition to this, farmers switch to other crops to yield better returns as prices offered for medicinal herbs are not competitive.

APIs and bulk drugs

All API and bulk drug manufacturing facilities are 'GMP compliant.' There is a lot of API licensing activity in Australia. Companies in-license and cross-license many of their APIs from other generics/pharmaceutical companies. Companies such as Sigma, Arrow and Alphapharm are reliant on in-licensing their API from other generics companies.

Finished drugs

The standard of technology available in Australia is high and can suit complex drug outsourcing requirements. However, the biotechnology industry is not very developed. Government efforts are trying to change this. A few multinationals, such as GSK, Pfizer and Baxter, have located manufacturing facilities in Australia. The trend of outsourcing manufacturing to Australia is low, given competition from Asian territories and the high level of imports in the market. Contract manufacturing is used for domestic consumption rather than exports from Australia. Eighty percent of all generic drugs sold in Australia are manufactured domestically but this is likely to decrease as more use is made of lower cost sourcing abroad.

Other Asian territories: Korea, Taiwan, Malaysia, Thailand, Indonesia and the Philippines

Korea

With a rapidly growing pharmaceutical industry comprising over 2,000 companies operating in the manufacture of drugs, quasi-drugs and cosmetics, Korea has experienced a double digit pharmaceutical market growth and is second only to Japan in terms of market potential in Asia. Annual pharmaceutical market growth is around 10% and the market is expected to reach almost US\$15 billion by 2010, reflecting a wealth of opportunities in market and R&D cooperation for foreign investors and future R&D partners ⁴⁷.

Labour

Korea offers a large patient population and highly qualified pools of medical facilities and practitioners. There are nearly 225 well-equipped hospitals accredited as clinical institutes with a pool of 83,000 nurses and 75,000 physicians ⁴⁸. Global clinical trials have grown substantially with the increasing number of researchers and field experts.

Intellectual property rights

In order to comply with the TRIPS agreement, Korea revised its relevant domestic laws in 2001 to meet international standards to improve IPR protection including the protection of pharmaceutical test data and to prevent the issuance of marketing approvals for patent-infringing products. These reforms have helped increase transparency in the pricing and reimbursement system, which had previously been a cause for concern. There have also been positive changes in the regulatory climate that have allowed smoother and earlier market access for new, innovative drugs.

Tax

Effective from January 2008, the Korean government offers a tax credit on investment in the pharmaceutical industry to help strengthen the quality control system of pharmaceutical manufacturers ahead of the anticipated free trade agreement with the US. Pharmaceutical companies will be allowed to credit 7% of their investment in certain qualified facilities against their corporate income tax due for the concerned tax year.

Services offered

While Korea's pharmaceutical industry is competitive in terms of chemical and synthesizing technologies, it is considered less competitive in drug screening, safety evaluation, clinical development and marketing. Therefore, companies have found partnering to be an ideal way in which to become more involved in R&D. Korean companies are pursuing strategic alliances with multinational firms to finance R&D for new products or for cross-licensing existing technologies with open support from the government. The Korean government has pushed ahead with its plan in consolidating and expanding Korea's infrastructure for the development of new drugs as well as for ameliorating the current drug-related systems for safeguarding the safety of drugs.

Regulatory and other issues

In the past, foreign companies with unique products have faced several disadvantages in Korea's pharmaceutical market, including the lack of transparency in the pricing and reimbursement processes, 'unequal' registration treatment and, often, a lack of coverage by the Korean national medical insurance system. However, the Korean government is making great strides towards liberalising and deregulating its pharmaceutical market to conform to the International Conference on Harmonization guidelines as well as improving the transparency and efficiency of its regulatory processes.

In keeping pace with the efforts of the industry, the Korean government has selected pharmaceuticals and biotech as key sectors. The government has announced it will streamline regulations that limit competition in the medical industry including the implementation of a set of drug-related policies designed mainly to foster pharmaceutical production for a more stabilized supply of drugs in parallel with the development phases of the domestic pharmaceutical industry. This has led to increased foreign investment taking place in Korea which is expected to improve the infrastructure available for the pharmaceutical industry.

Raw material

Less than 10% of this segment constitutes domestic production. However, with a concentrated effort on new drug R&D, many companies have made heavy investments for the development of major exportable items, which has resulted in an increase in the import of necessary intermediates.

Snapshot:

Pfizer invests US\$300 million in Korean R&D

Pfizer announced in June 2007 its plans to invest significantly in R&D in Korea over the next five years. Pfizer CEO, Jeff Kindler, and Korea's Vice Health and Welfare Minister, Byun Jae-jin, signed a memorandum of understanding on joint R&D investment under which Pfizer will spend US\$300 million on developing new drugs, animal testing and clinical research. It is the single-largest R&D investment by a foreign company in Korea.

Over the past year, Pfizer has been focusing investment on clinical trials and drug development in Korea. The company has designated four hospitals (Seoul National University Hospital, Yonsei University Severance Hospital, Samsung Medical Center and Asan Medical Center) to serve as major clinical research services (CRS) providers. Pfizer Pharmaceuticals Korea Limited said that the designated CRS providers "will carry out about 50% of the initial stages of Pfizer's clinical trials. That means Korea will serve as a hub for many other territories"⁴⁹.

In April 2008, the company announced that it would set up the world's first PK/PD Modeling and Simulation Training Center in Korea. This will ultimately decrease the costs and time for drug development by predicting the effectiveness of new drugs under development through a simulation program.

The government and Pfizer also agreed to establish an Office for Strategic Alliance in Pfizer's R&D headquarters to nurture Korean talent in the development of new drugs. Pfizer's investment is expected to generate synergies to strengthen Korea's competitiveness in new drug development.

(Source: PRA International February 2007)

Taiwan

Services offered

Taiwan's government has taken several initiatives in recent years to promote the biotech industry and new drug development. The territory has a large pool of bio-scientists and high-tech talent, as well as an impressive medical research base. As a result, Taiwan's biotech industry is on a strong upward path, and is increasingly becoming an attractive destination for outsourcing drug development. In recognition of Taiwan's progress in CRO-conducted clinical trials, NASDAQ-listed Parexel International Corp. acquired Taiwan's largest CRO, APEX International Clinical Research Co. Ltd., in 2007.

A key measure was the replacement in 2000 of local registration trial requirements with bridging study evaluations that follow international standards. This prompted leading pharmaceutical companies to include Taiwan in their development plans for early phase clinical trials. It also provided fertile ground for the emergence of domestic CROs offering a full range of services for all drug development phases, including pre-clinical development and studies, clinical data and trial management, and pre-market IND and NDA approval applications. Their operations are fully compliant with GCP standards, and are routinely inspected by Taiwan's Department of Health and Food and Drug Authority, among others.

Tax and regulatory issues

The government has introduced tax incentives to encourage Taiwanese pharmaceutical companies to employ CROs by allowing them to claim R&D tax credits on payments to CROs and also grant either a 5-year tax holiday to CROs or shareholder tax credits to their shareholders. CROs have also been given the right to represent sponsors in applying for INDs under a new approval system, which was introduced in 2007 as part of the government's ongoing efforts to ensure a more transparent and efficient regulatory environment for drug development. However, Taiwan has not yet established patent linkage in the regulatory procedures for approving generics and does not provide adequate data exclusivity to the full range of eligible products. These long-standing intellectual property issues could undermine innovator companies' willingness to introduce new drug products into the Taiwan market. In response, Taiwan's Department of Health has started to evaluate the implementation of patent linkage and is also in the process of reviewing and refining procedures for conducting specialised clinical trials.

Malaysia

Services offered

The main focus is on clinical trial services. The Clinical Research Center of Malaysia (CRC) ⁵⁰ provides clinical trial services through a network of 17 hospitals. Services such as study monitoring, safety surveillance, data management, protocol development and biostatistics are provided through the CRC. The CRC acts as single window for all clinical trial management activity. There is one 'GLP certified' laboratory. Although labour may be available at a lower cost than in China, the skills and language proficiency is relatively untested. The patient pool, with a population of 24 million, is larger than Singapore but does not offer the same large diversity in terms of epidemiological profile.

Regulatory and other issues

Malaysia provides data exclusivity for a period of five years for NMEs and three years for modified drugs. All drug development data may be accessible to competitors after the expiry of these terms. There have also been several cases involving registration of generic versions of pharmaceuticals that are still subject to patent protection ⁵¹. This reflects poorly on Malaysia's potential as a market for patented drugs. An effective 'patent linkage' mechanism to prevent the regulatory approval of generic versions of patented products is required. Such a mechanism would prevent the registration of a generic form of a patented medicine while the patent is still in force. Quality checks for the drugs already in the market are not enough to deter counterfeits. Also, not all generic drugs are required to prove their bioequivalence to patented drugs. These act as entry barriers for multinational companies willing to introduce patented drugs and enter the Malaysian market.

Thailand

The Thai pharmaceutical market was estimated at US\$2.3 billion in 2007 and is expected to increase to US\$3.4 billion by 2010. Thailand has emerged as a strong pharmaceutical growth market in Asia, growing at 16% last year and at a CAGR of 17.2% during 2002-2006⁵².

Labour

Thailand offers a large patient pool and its policy to become the medical hub of Asia has spurred the growth of research and specialist centres as well as internationally-accredited medical facilities. However, an inadequate number of practitioners and human resources in healthcare relative to the size of the population is likely to persist in the near future. The density of four physicians per 10,000 population is considered comparatively low even though most public and private universities throughout the territory offer specialist medicine and pharmacy courses.

Intellectual property rights

Despite the fact that Thailand has a world-class set of IP laws complying with TRIPS, their interpretation and enforcement are far from desirable. There is no patent linkage system between the Food and Drug Administration (FDA) of the Ministry of Public Health and the Patent Office. While drugs being distributed to the market are required to gain the approval of the FDA, the FDA generally does not concern itself with patent or intellectual property matters and has no intentions

to create the patent linkage system. The FDA leaves it to the courts to resolve infringement disputes. Thus, patent holders would face a significant drop in revenue from generic competition and any ongoing litigation. The FDA does provide a Safety Monitoring Program (SMP), covering a two to four year period, depending on how long it will take for the expert to provide judgement, during which time sales are restricted to hospitals and clinics, i.e. no drugstore sales.

In January 2007, Thailand's interim military government issued compulsory licenses for three drugs. This subject has dominated the Thai pharmaceutical industry agenda and the newly elected government has promised to end the practice. However, the new public health minister was almost forced to resign as a result of his decision to review the compulsory licensing enforcement and the practice is still in place. Not a single multinational company has invested in building their R&D centres in Thailand, although a few are involved in clinical trials and some R&D projects. One such project is the three year R&D venture started in 2005 between Novartis and BIOTEC, a government agency. According to the company's representatives, it was attracted to Thailand because of the territory's research facilities, the quality of its researchers and its commitment for further development of its research capacity. The government agency has stated its intention to actively promote clinical trials and R&D capabilities especially in the areas of tropical diseases (malaria, dengue fever, and tuberculosis research) and pharmaceutical genomics. It is currently working with Singapore on outsourcing clinical trials for some global pharmaceutical companies.

Services offered

Public universities (with strong medical schools) have been carrying out clinical trials in the past. However, with the dramatic growth in new drugs being trialed in developing territories, the Thai private sector has entered the industry (albeit in a late response compared to Singapore and Taiwan) through joint ventures or collaboration with foreign CROs (e.g. Bio-Innova, a joint venture of Thai investors and Synchron of India) and a local public university (e.g. Mahidol University). Thailand's ambition to become a regional medical hub has also helped spur this trend. There are currently about 15 CROs in Thailand most of which are set up within public universities. Services offered include Phase I, II, III, IV clinical trials, bio-equivalence studies, pharmaceutical testing, pharmacokinetics, bio-availability, bioanalytical method development and validation, bio-analysis, drug-release profiling and stability studies, statistical analysis and data management. Main areas of clinical trials in Thailand are: cancer, cardiovascular, DM, digestive system diseases, hepatitis, HIV/AIDS, infectious diseases and mental disorders.

Tax

The Board of Investment (BOI) is a government agency in charge of investment promotion in Thailand. The BOI grants tax and non-tax incentives to investors in the pharmaceutical and biotechnology sectors. For pharmaceutical manufacturing companies, producing medicines or active ingredients, tax incentives cover exemption from import duty on machinery; exemption from corporate income tax for five, six or seven years according to the location zone subject to a cap on the amount of investment; and exemption or reduction from import duty on raw material and essential parts, again according to the location zone in the country. Non tax incentives cover rights on land ownership and foreign

exchange remittance as well as work permit and visa incentives for foreign staff. Similar incentives are in place for pharma research organisations and biotech companies and, for both these categories of companies, the corporate income tax exemption is for eight years regardless of location zone with no cap on the amount of investment. In the case of biotech companies, if the project is located in the Science and Technology Park of Thailand, the promoted project will obtain an additional 50% corporate income tax reduction for five years after the end of corporate income tax exemption period.

Regulatory and other issues

To ensure Thai CROs' international competitiveness, they need to comply with international clinical trials/ research standards such as the International Conference of Harmonization (ICH)'s Good Clinical Practices (GCP) Guidelines, and OECD's Good Lab Practice (GLP). None of the CROs in Thailand have been accredited with OECD-GLP, ICH-GCP officially. However, they are all in the process of compliance preparation to reach the standards through practice. There are a few companies, for example, Bio-Innova and International Bio Services, that have applied for the accreditation of GLP and are being audited by the Bureau of Laboratory Quality Standards. By law, Thai CROs are not bound to comply to OECD-GLP/GCP.

Raw material

Thailand's domestic manufacturers focus on formulating drug products from imported active ingredients and

Indonesia

manufacturing generics. In contrast to other territories in the region, no API is produced in Thailand.

The Indonesian pharmaceutical market was estimated at US\$2.7 billion in 2007 and is expected to increase to US\$4.2 billion by 2012⁵³. Per capita healthcare spending is still as low as US\$12. The retail sector received a major boost in 2007 when the government launched a programme to increase the availability of cheap, locally-made versions of patented pharmaceuticals. Foreign direct investment has continued growing due to Indonesia's economic development. During the first month of 2007, the pharmaceutical industry received foreign direct investment worth US\$6.9 billion. The increase in healthcare demand and rapid population growth will provide opportunities for the Indonesian drug market.

Labour

The low cost and availability of labour is still the main attraction for investors in Indonesia. However, unskilled labour dominates. Only 6.2% of the population has a college or university degree. There are 32 pharmacy schools for students seeking a career in pharmacology. Most of the government universities have medicine and pharmacy departments providing graduate specialists in those areas.

Intellectual property rights

The National Agency of Drug and Food Control has developed an IPR protection system, which has helped accelerate the drug approval process and improved transparency. However, a focus on the protection of local industry leads to slow progress and inefficiency when it comes to implementation. The labelling of local generic drugs is also one of the main key concerns with some aspects of the labelling law contradicting Pharmaceutical Research and Manufacturers of America regulation.

Tax

Expenses related to R&D conducted in Indonesia are tax deductible. The Indonesian tax authorities apply a progressive corporate tax rate up to a maximum of 30%. The following tax facilities are available for the pharmaceutical industry (for certain products including biotechnology raw material):

- A reduction in net income of up to 30% of the amount invested, given at 5% for 6 years of the commercial production provided that the assets invested are not transferred within 6 years;
- Acceleration of fiscal depreciation;
- Extension of tax loss-carry forward up to 10 years;
- A reduction to 10% in the withholding tax on dividends paid to non-residents.

Services offered

Services are limited due to the scarcity of financial resources of most local firms. Biology and chemistry services are offered by government institutions on limited activities. In early 2007, a foreign institute developed a clinical research facility which focuses on R&D treatments for common tropical diseases, recruiting local experts and gaining direct access to hospitals and patients.

Raw material

There is a government reduced tariff on pharmaceutical raw material for local pharmaceutical companies. Some materials are available in the territory, but the rest has to be imported from other Asian territories such as China and India.

APIs and bulk drugs

In 2006, new government regulations forced producers to cut 10-70% of the original price. This involved 34 APIs, and affected 1,400 prescription products in the market.

Philippines

The Philippines pharmaceutical market is projected to reach US\$1.4 billion in 2008⁵⁴, equal to nearly US\$15 per capita. In terms of the overall market, this is comparable to the market size of Thailand. The Philippine pharmaceutical market is highly dependent on import of raw materials to manufacture drugs. About 95% of the materials compounded in the territory are imported, and the industry is concentrated on manufacturing products discovered and developed elsewhere. Compared to other more developed territories that have established themselves in the formulation of breakthrough pharmaceutical products, innovation and discovery of drugs in the territory is relatively small business.

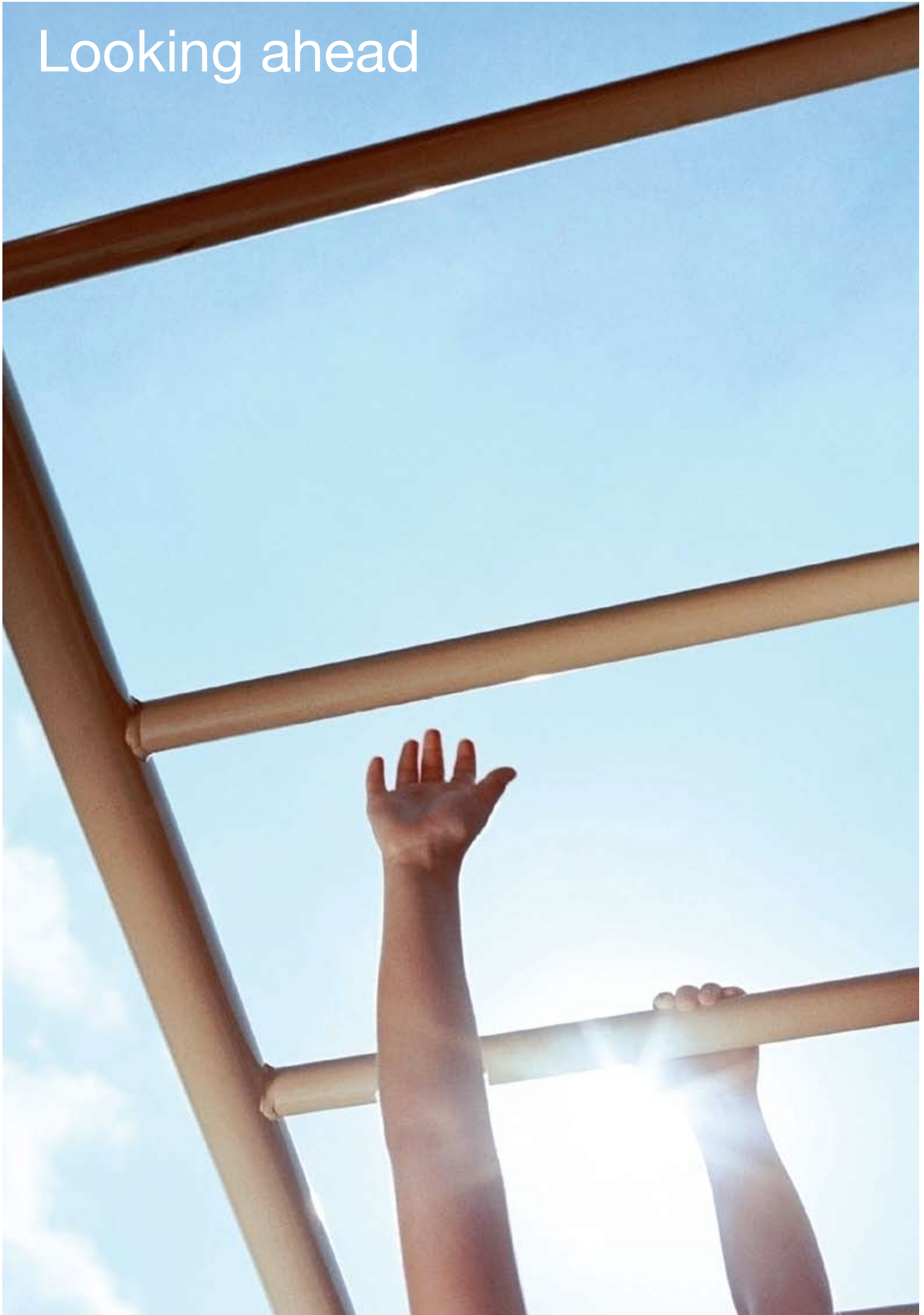
Services offered

Basic research services and clinical trials are offered in this territory. The healthcare system suffers from funding shortages. The migration of experienced medical workers to other territories has been a significant problem. The government has stepped in with various initiatives to stem this 'brain drain' and this is starting to have some effect. Language proficiency is good. Most Filipinos in urban areas are bilingual with English as a dominant language.

Regulatory

Philippines is committed to follow TRIPS. In June 2008, the government introduced the Universally Accessible Cheaper and Quality Medicines Act which allows parallel imports. The impact will most likely be felt by the larger pharma companies whose patented medicines may be more expensive to produce and distribute than those medicines that might be procured via parallel import. Patent linkage is absent, thereby allowing generics to register despite in-force patents for drugs.

Looking ahead



Looking ahead, China and India will spearhead growth in the Asian pharmaceutical sector. Of the two, China is likely to set the pace with growth spurred by the territory's low costs and immense market potential. Foreign direct investment, contract research and contract manufacturing will continue to grow in both territories.

Alongside China and India, Singapore will maintain its position as a centre for research and innovation. While the trio of China, India and Singapore will maintain their position as the 'hotspots' of the Asian pharmaceutical sector, other territories, notably Korea and Taiwan, will also be increasingly significant.

Outsourcing and its 'insourcing' relation will continue to move up the value chain. The balance of pharmaceutical investment in the region and worldwide will gradually

shift towards a future where high end drug discovery in Asia will play an increasingly significant role alongside the region's traditional manufacturing role. Insourcing will remain the preferred model for higher end activities although, increasingly, this will be supplemented by strategic partnerships and collaboration with outside companies.

The companies that will be the most successful will be those that are most adept at managing and mixing a range of contractual relationships and partnerships across a number of different locations. There will be no 'one size fits all' approach. Different companies and, indeed, different activity centres within the same company will utilise a mix of approaches. They will look to make the most of the strengths of different locations and opportunities for different parts of the value chain.

How PricewaterhouseCoopers can help

To be competitive in a highly volatile global market, pharmaceutical and life sciences companies should consider these questions:

- Are outsourcing and offshoring R&D and manufacturing operations strategically appropriate for my company?
- Are we making the most of new opportunities for collaborative networking?
- Is my current outsourcing strategy cost-effective and yielding maximum ROI?
- Are we well prepared with access to the right tools to evaluate our potential outsourcing partners and location decisions?



PricewaterhouseCoopers' (PwC) pharmaceutical outsourcing professionals bring in-depth industry experience and global market knowledge to support outsourcing needs by providing a full suite of services across each phase of the outsourcing lifecycle.

- PwC helps you save money and time evaluating and implementing global outsourcing partnering by using our established database and proven methodologies.
- PwC has trusted global advisors with deep pharmaceutical industry knowledge and experience and with strong local industry connections.

Strategy alignment: How to evaluate risks and benefits in an outsourcing strategy

- Facilitate outsourcing requirements gathering processes
- Perform outsourcing risk assessment
- Conduct macroeconomic research for targeted territories/regions
- Create an outsourcing plan for desired business objectives

Partnership selection: How to select a CRO/CMO partner to meet short and longterm business goals

- Identify, interview, analyze and screen potential partners
- Perform technical and financial due diligence
- Coordinate and manage due diligence site visits

Collaborative partnering: How to make the most of opportunities to create collaborative networks

- Identify networking opportunities
- Establish the right protocols, contractual and working arrangements
- Create systems for collaboration and maximise networking gains

Outsourcing transaction: How to form and maximize the value of business alliances

- Develop request for proposal (RFP) and manage selection process
- Establish contract agreement process and manage contract negotiation
- Provide tax advisory service for maximized benefits

Operational transition: How to effectively manage change and outsourcing implementation

- Develop service management function
- Manage outsourcing transition
- Manage communication and organizational change management

Partnering optimization: How to achieve continued success through proper outsourcing governance

- Perform periodic risk and compliance audit
- Benchmark operations and identify gaps for improvement
- Optimize existing arrangements

Appendix

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