

Industries
Pharmaceutical

Gearing up for a global gravity shift*

growth, risk and learning in the Asia
pharmaceutical market



*connectedthinking

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Introduction

The centre of gravity of the global pharmaceutical industry is shifting. Not only is Asia set to be the largest pharmaceutical market in the world but many Asian territories will be powerhouses of the industry. The shift started as economies grew and low cost manufacturing in the region expanded. Now, companies are, increasingly, also seeking to site research, development and clinical trial activity in Asian territories.

Multinational pharmaceutical companies are building up their presence in the region. In parallel, many Asian pharmaceutical companies are looking outward and extending their own international reach. Within the region, there is a plethora of domestic companies with the likelihood of substantial consolidation. The region is far from homogenous and each market has its own unique challenges and opportunities. The risk landscape is complex and, while there has been significant progress on many fronts, major concerns remain.

Against this background, PricewaterhouseCoopers has conducted 185 interviews with MNC and domestic pharmaceutical companies across nine territories. The report provides insight into how their companies are *Gearing up for a global gravity shift* and their views on the growth, risk, learning and outsourcing challenges that lie in front of them. The results highlight the way the industry is changing in the region and the issues that concern companies most. It also looks at the lessons companies have learned along the way and how the two sets of companies, domestics and MNCs, can learn from each other.

PricewaterhouseCoopers has a presence across the region and works with a range of companies, both domestics and MNCs, engaged in many different parts of the pharmaceutical industry. Throughout the report, we also take a look at some of the individual markets and, in a series of focus panels, we examine some of the key dilemmas that companies are facing and how they can be resolved.

Key highlights

The shifting global centre of gravity

The pharmaceutical industry in Asia is gearing up to be at the centre of the global market and most expect this shift to happen fast. Fifty five per cent of multinational companies (MNCs) and 62% of domestic companies in our survey believe the centre of gravity of the global pharmaceutical market will be in Asia rather than North America and Europe in the near future. China, India, and Singapore will be key countries.

Sights set on outward and inward expansion

Three-quarters of respondents from the region's domestic pharmaceutical companies report that exporting outside their local market is a key goal with 65% seeing increased global market share as important to their companies. A third of MNCs have immediate 12 months plans to further expand within the region through acquisitions or their own 'greenfield' sites.

The region receives a mixed risk report

Both MNCs and domestic companies report progress towards risk reduction in the region. But this is tempered with continuing concerns over intellectual property rights (IPR), corruption and pricing. More than half of domestic companies are worried about unfair competition from generic brands and over three quarters of MNCs report worries about IPR and legal risk. Corruption is regarded as inescapable with 67% of companies saying that it is an endemic part of the landscape and they do not expect it to be eliminated soon.

Companies seek to step up two-way learning

MNCs report that their learning curve in the region has been smoother than they had expected. Some anticipated problems were not such issues in reality. Some MNCs feel they still lack the knowledge, skills and insight to gain the most presence in the region. This finds echo with their domestic counterparts who list a number of lessons that they feel MNCs could learn from them, such as understanding the local business environment better and appreciating the professionalism of local companies. In return, domestic companies also emphasise the gains they can get from MNCs.

Outsourcing trends reflect a changing business model

The focus for outsourcing is extending beyond manufacturing, towards research and development (R&D), clinical trials and analytical services. These trends reflect increased capability in the region and a changing MNC business model. MNCs are increasingly focusing on sales and marketing at the centre with other activities outsourced. It is clear that outsourcing has a long way to run. A majority of companies thought that most of the industry still does not see outsourcing in a sufficiently dynamic way and is missing opportunities for shared development, learning and improvement.

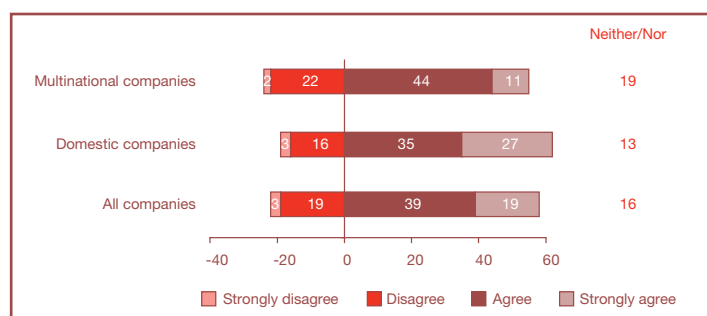
Growth

The Asia Pacific pharmaceutical sector continues to exhibit dynamic growth both as a base to serve the global healthcare market and as a market in its own right. The strength of the region is reflected in the fact that more than half of the respondents in our survey believe the global centre of gravity will be in Asia in the near future. Fifty eight per cent agreed with this view with a third of these registering strong agreement (see Figure 1).

The rise of Asia pharma

The view that the centre of the pharmaceutical industry is moving away from North America and Europe and towards Asia is shared by multinational companies and Asia-based companies alike. Fifty five per cent of MNCs and 62% of domestic companies agreed with the statement. Indeed, less than a quarter of MNCs and less than a fifth of domestic companies voiced any disagreement with the prospect of such a shift in the global centre of gravity of the industry.

Figure 1: The centre of gravity of the global pharmaceutical industry will be in Asia rather than North America or Europe in the near future (All respondents)



China, India and Singapore are poised to become leading countries in the Asia pharmaceutical space. Indeed, India and China have emerged as major suppliers of several bulk drugs, producing these at lower prices compared to the formulation producers worldwide. Other territories, notably South Korea,

Malaysia, Thailand, Taiwan and Hong Kong are also building strong domestic pharmaceutical bases although MNCs currently dominate these markets.

The race is very much on between countries to lure international pharmaceutical players to set up base in their respective territories by offering grants, incentives and infrastructure support. The interest of MNCs in setting up more R&D facilities and conducting more clinical trials in certain Asian countries is increasing. Competition and the need to harness expertise and reduce costs is also leading the big pharmaceutical companies to explore partnerships and merger & acquisitions (M&A) opportunities in the region. At the same time, region-based pharmaceutical companies are seeking to expand their geographical footprint and become pan-regional and, in some cases, global players.

Sights on expansion

These trends are evident in the responses of companies surveyed by this report. A third of MNCs already in the region have plans to immediately expand within the next year either through their own 'greenfield' sites or acquisitions. Not surprisingly, China and India head the list of target countries for expansion, with Singapore and South Korea next in the sights of MNCs. Half of those considering joint ventures (JV) are prepared to accept minority stakes in cases where local regulations limit the presence of foreign companies. It is the development of their sales and marketing, and manufacturing that are the main motivations behind this growth.

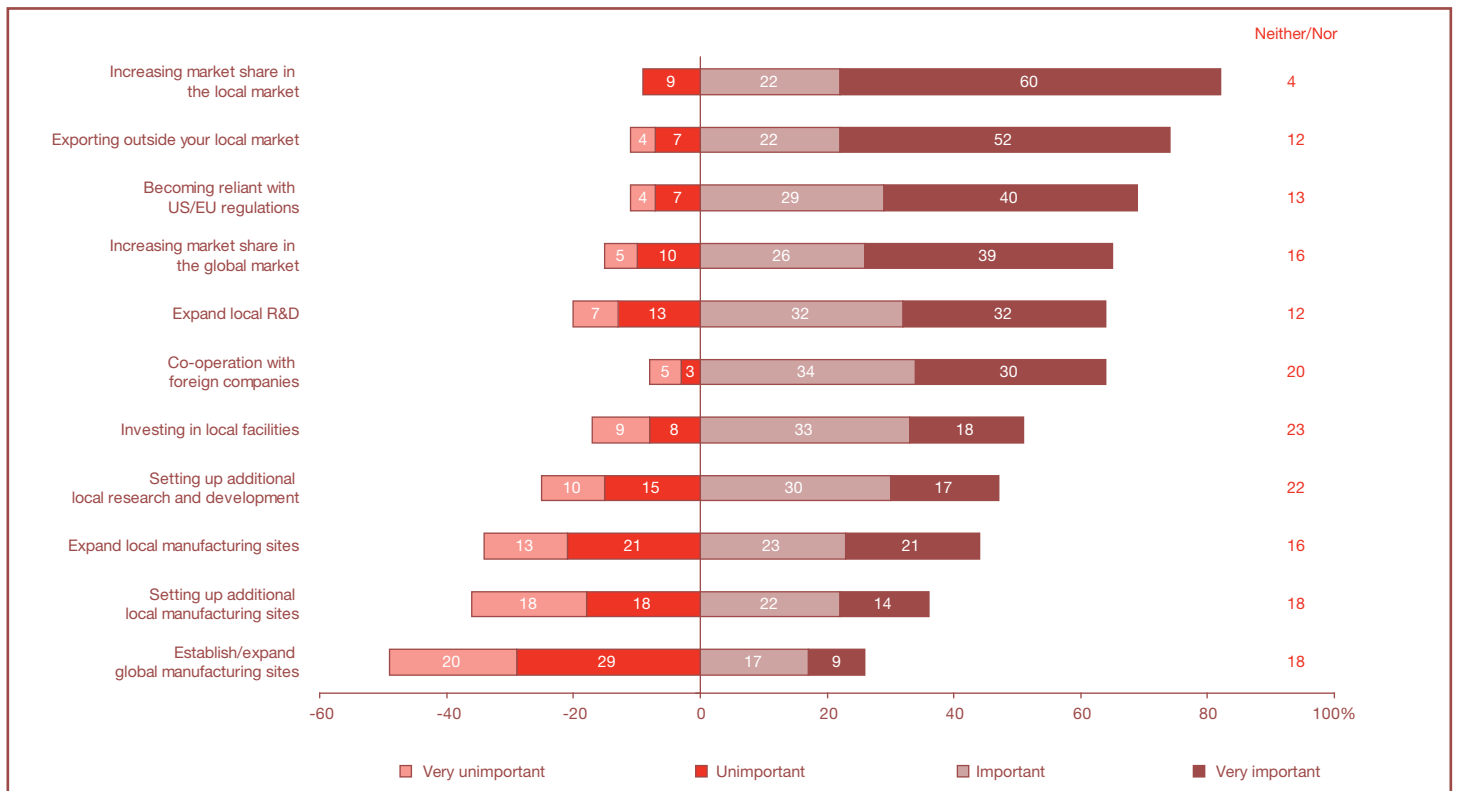
MNCs report that two thirds of the staff they use to research and assess JV and other acquisition prospects are deployed from their regional headquarters with only one third being situated in the target country. Could these companies gain from placing more emphasis on local intelligence which, in turn, might help ensure a better and quicker integration?

MNCs are seeking to achieve better market penetration within the region for their existing products and back this up with the development of new products. This twin focus reflects the existing footprint of MNCs in the region with sales and marketing, distribution and R&D heading the list of current activities, undertaken by 94%, 45% and 41% of companies respectively. Manufacturing is more likely to be outsourced by MNCs in the region but just under a third of the MNCs surveyed, 30%, undertake finished drug manufacturing and 15% API manufacturing.

The appetite for growth is equally evident among domestic companies. Just over a third, 34% of domestic companies are looking to acquire pharmaceutical companies. Two thirds of these companies are on the acquisition trail in order to

expand their domestic presence but more than half, 52% are seeking to acquire international market share. At present, fewer than half, 45% of the domestic companies surveyed had an international presence but international growth, both within the region and globally, is high on their agenda. Indeed, when asked about the objectives underpinning their business growth, 74% of all the domestic companies surveyed said that exporting outside their local market is a key goal; with 65% identifying increased global market share as 'important' or 'very important' to their companies. A similar percentage stated that cooperation with foreign companies is a key objective (see Figure 2).

Figure 2: How important are the following objectives to you in terms of your business growth? (Domestic companies)



Growth

Capital constraints

Capital constraints can be a significant brake on growth for domestic pharmaceutical companies. While some are not seeking acquisitions because such a strategy does not fit with their companies' current priorities, 27% of the domestic companies who are not on the acquisition trail report that it is money that is holding them back. The implication is that, with the right access to funding, they would be seeking acquisition opportunities, meaning that around half of all the domestic pharmaceutical companies we surveyed in the region might be looking for deals if funding obstacles could be overcome. There are few specialised venture capital funds to support start-up biopharmaceutical companies in Asia. These companies don't have access to a supportive stock market environment, such as in a junior market like London's Alternative Investment Market (AIM).

Just over a third, 36%, of domestic companies would consider selling all or part of their company to foreign investors in order to raise funds. Not surprisingly, the majority, 58%, of these companies cite the need to raise cash for other investment as the main reason for considering such a sale although a significant 30% say that such a move would help them gain experience in a foreign market. Many domestic companies are also looking towards IPOs as a fundraising route. Thirty eight per cent of those surveyed are already listed but, among those that are not, a further 36% have plans to raise capital from foreign capital markets by way of either a public or private share issue.

The main focus for investment by domestic pharmaceutical companies is R&D. Fifty five per cent of companies seeking to attract investment from selling stakes in their companies are looking to strengthen their R&D activities compared to 45% looking to invest in sales and marketing and 24% in manufacturing. This reflects the overall strength of the domestic pharmaceutical companies in manufacturing, with 70% already having manufacturing presence, and their relative weakness, compared to MNCs, in R&D.

Country contrasts

There are some interesting contrasts between domestic companies in the three countries – India, China and Singapore – which contained the majority of domestic companies in the survey. Indian companies had the strongest appetite for acquisitions and the least appetite for divestments. Forty eight per cent of Indian pharmaceutical companies were considering acquisitions compared to 31% in Singapore and just 17% of Chinese companies. In turn, 46% of Chinese companies and 44% of Singaporean companies were open to foreign investment in their companies compared to just 20% of the Indian companies surveyed. Between 30-40% of the non-listed companies in all three countries had plans to raise capital through private or public issues in overseas markets.

Growth

Insights: market growth – assessing the landscape

Seventy four per cent of domestic pharmaceutical companies consider exporting outside their local market as an important objective. A third of our surveyed MNCs are planning to acquire a domestic company, enter into a new joint venture or set up a new greenfield operation within the next twelve months. What are the key considerations for such market entry or expansion?

Market studies – assessing the size of the market, both now and in the future, in terms of volume, value, key product characteristics, growth rates, share of major players, and product evolution.

Understanding the regulatory framework – this is as crucial for Asian companies looking towards the EU, North America, Australia or Japan as it is for MNCs expanding in Asia. Companies need to understand key points of influence as well as the operational impact of regulation.

Competitor and target assessment – mapping the performance of current players, profiling them, understanding their competitive strengths, interviewing their customers and channel partners to probe their strengths and weaknesses, assessing them as potential acquisition targets, and analysing their ownership and financial performance.

Industry competition structure – understanding capacity issues, cost structure issues, and identifying the key success factors for market entry.

Supply assessment – identifying the availability of materials needed for supply, assessing import alternatives, evaluating suppliers to understand the robustness of the future supply chain and understanding the consequences of the associations being entered into.

Location studies – gathering and analysing data to select the optimal location, including analysis of the macro environment, the supplier base, any tax and incentive packages offered by development zones, and developing a shortlist of preferred locations.

Focus: China

Major pharmaceutical MNCs are fast investing and building their businesses in China attracted by a highly skilled, low cost workforce and, of course, the enormous potential Chinese market. Clinical trials conducted in China provide access to data for a different ethnic population who will comprise the world's largest market. Total pharmaceutical sales of US\$13.6bn are forecast to more than double to US\$28.3bn by 2010 (Economist Intelligent Unit). By the middle of the century drug sales in China are forecast to outstrip those in every other region.

In late 2006, Novartis announced a US\$100m investment in a new R&D centre in Shanghai's Zhangjiang Hi-Tech Park close to Roche's R&D centre, while at the same time building a new API plant in Jiangsu province. Earlier in 2006, AstraZeneca set aside US\$100m for a new R&D centre to start operations by the end of 2009, while also investing heavily in their manufacturing site in Wuxi. Baxter, Bayer, Roche and Pfizer are all investing in new or existing manufacturing sites. DSM formed a joint venture with North China Pharma Group and is investing more than US\$100m while building a new facility for nutritional supplements. These companies are all following the example of Xian Janssen (Johnson & Johnson) who came to China in the early eighties.

China joined the World Trade Organization in 2001 and agreed to uphold the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Accord. However, IPR protection and corruption remain key issues. The June 2006 Beijing court ruling in favour of Pfizer in a long-running dispute over the Chinese patent for Viagra

was an encouraging event for other research-based MNCs seeking to launch their products in China. The Chinese Government is taking steps to clean up the health industry but anti-bribery laws and practice will take time to get embedded in the normal business procedures and behaviour of sales teams.

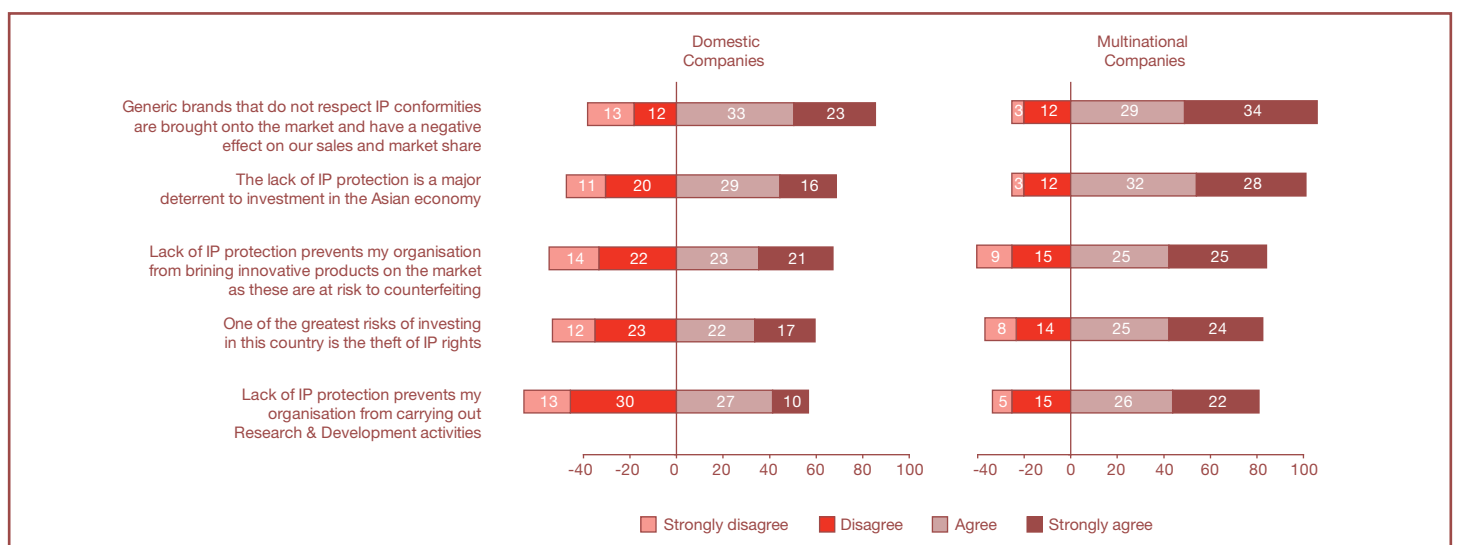
Domestic pharmaceutical companies play a major role in what is a highly fragmented market where foreign-invested companies account for only 20-30% of sales (EIU). Until recently, China's pharmaceutical industry was largely focused on generic manufacturing of brand-name drugs and researching traditional Chinese medicine. The Chinese Government has stated its intention to boost the prospects for indigenous pharmaceutical companies. In June 2006, the National Development and Reform Commission (NDRC) signalled reforms in tax, financial support, government procurement and intellectual property rights protection to motivate pharmaceutical enterprises to increase investment in drug innovation and to encourage them to set up technology centres.

Pharmaceutical companies operating in Asia Pacific territories report important progress being made to reduce their exposure to a number of key risks. Indeed, MNCs seeking to expand in the region believe Asia Pacific carries less risk, in general, than other developing markets. Behind the headline of optimism, however, lies a more mixed picture including a significant degree of concern over regulation and corruption.

Intellectual property

Intellectual property rights (IPR) protection and uncertainty over legal systems remain key concerns. Seventy six per cent of MNCs report such concerns, with half saying they are ‘extremely concerned’ about IPR and legal risk. Indeed, of those companies reporting concerns, IPR is named by MNC companies as the biggest reason to consider leaving the region. Nearly two thirds, 63%, say that their sales and market share is suffering as a result of the uneven application of IPR protection and competition from generic brands that do not conform with IPR requirements. Sixty per cent believe that the lack of IPR protection is a major deterrent to investment in the region (see Figure 3). These sentiments find echo with domestic companies with 56% of domestic companies expressing concern about unfair competition from generic brands and 45% viewing IPR issues as a major deterrent to investment.

Figure 3: To what extent do you agree with the following statements in relation to Intellectual Property (IP) rights?

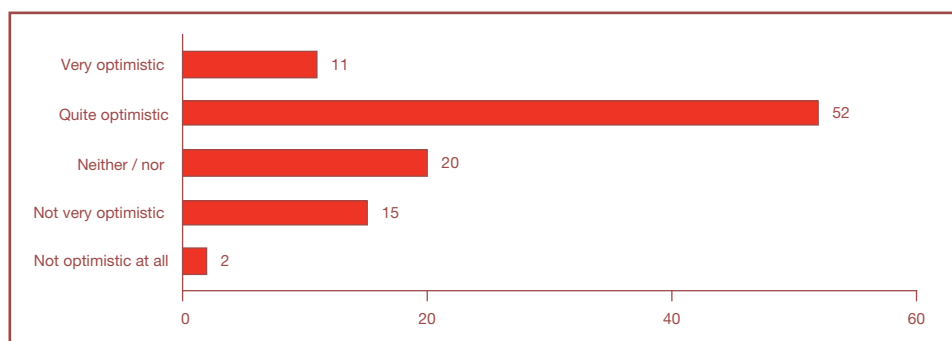


Risk

However, three quarters, 74% of MNCs and 79% of domestic companies say they have seen an improvement in IPR protection in the past five years, primarily as a result of the introduction of new IP laws underpinned by a stronger government emphasis on IPR protection and more rigorous application of existing laws. Equally encouraging is that, of those MNCs reporting an improvement, a majority believe that this will continue over the next five years (see Figure 4). Among the domestic companies seeing an improvement, 68% report that this has had an impact on them bringing more innovative drugs to the marketplace, 62% have established more R&D capability in the local market and 52% indicate that it has encouraged them to implement anti-counterfeiting measures such as RFID tags.

In general, domestic companies are more optimistic about progress on IPR protection than MNCs – 56% believe more IP laws have been introduced and 48% report an increased emphasis on IPR protection from governments compared with only 43% and 23% of MNCs. Clearly MNCs do not feel that current progress is sufficient and many would like to see it stepped up.

Figure 4: How optimistic are you that IP Protection will improve in the next 5 years? (Multinational companies)

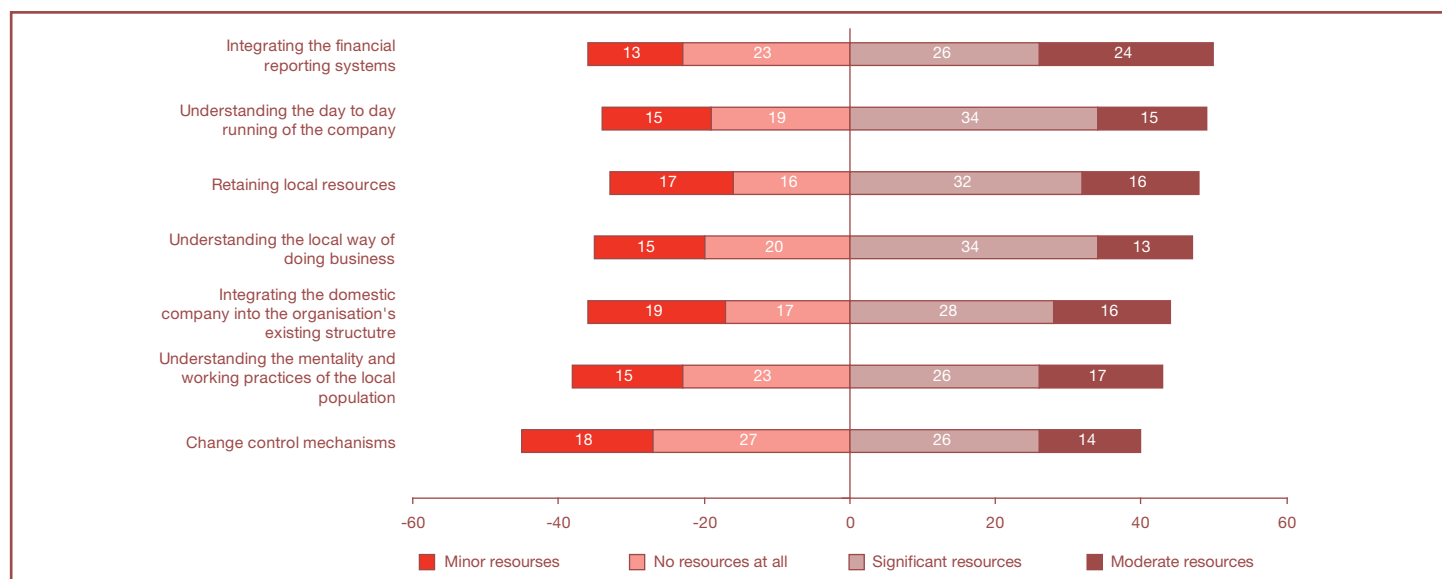


Corruption and management risk

Corrupt practice is a key anxiety. Indeed, both MNCs and domestic pharmaceutical companies see it as an inescapable part of the landscape they have to operate in. Two thirds of companies accept the presence of corruption and do not feel the situation will change soon. Sixty seven per cent of companies agreed with the statement “corruption is an endemic part of the business system in Asia and it is not realistic to expect it to be eliminated in the near future.” Domestic companies were rather more inclined to concur with this view – with 70% of them agreeing versus 60% of MNCs. Only 21% of MNCs and 14% of domestic companies disagreed.

The concern about corruption and related risk is reinforced in the responses of MNCs who are seeking to acquire local pharmaceutical companies. Seventy one per cent of these MNCs are concerned about management risk; highlighting the importance of rigorous pre-deal assessment, but also reflecting more general unease about corruption. In the light of such anxiety, it is perhaps surprising that more MNCs have not invested significant resources in reforms such as tightening change control mechanisms and integrating financial reporting systems. While these were important priorities for 40% and 50% of MNCs respectively, the remainder report that little resource was being invested in better change control and understanding of their JV or country-specific entities (see Figure 5).

Figure 5: To what extent has your company deployed resources in order to set up your joint venture/domestic takeover? (All multinational respondents)



Risk

Impact of the Foreign Corrupt Practices Act

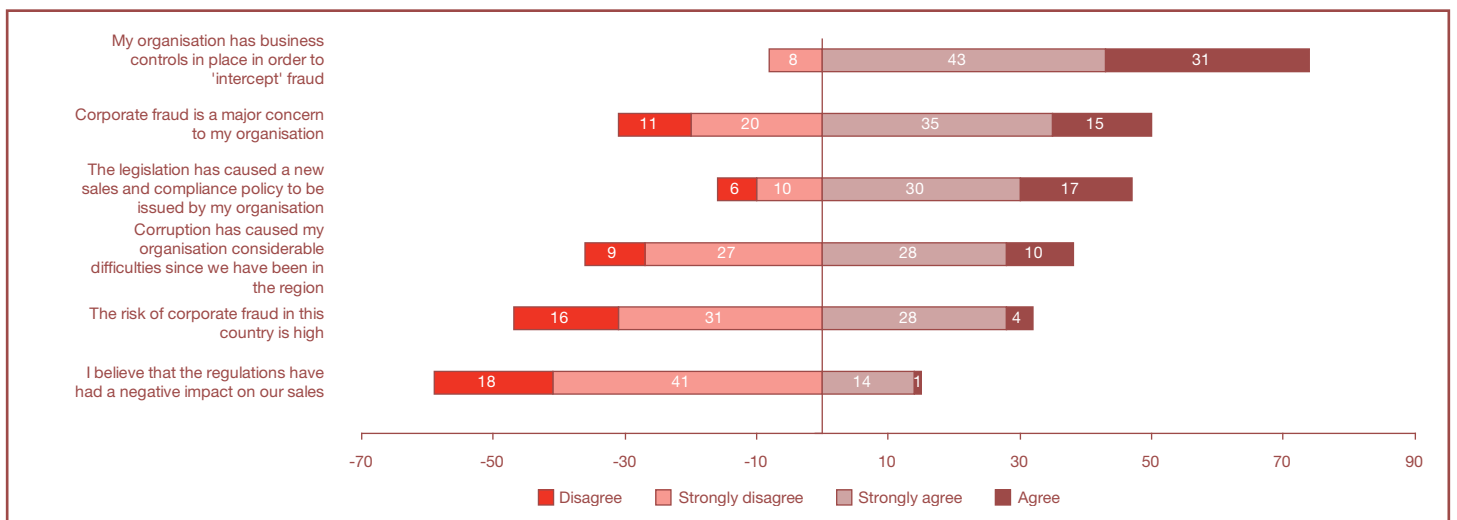
Worries about fraud and corruption are also reflected in MNC responses to the US Foreign Corrupt Practices Act (FCPA) and the different national European legislations.

While the vast majority of MNCs felt that they had mechanisms in place to intercept fraud, 50% viewed corporate fraud as a major concern and 38% said that corruption had caused their organisation considerable difficulties since they moved to the region (see Figure 6).

The responses from domestic pharmaceutical companies make it clear that, if progress is to be made in respect of fraud and corruption, it ultimately has to come from within. Domestic companies take a rather

more remote view of internationally-targeted overseas legislation such as the FCPA. Only 15% of domestic companies expect that the FCPA would change the way they do business and 57% say that they do not regard their companies as obliged to follow overseas legislation but, instead, would continue to take their cue from domestic law (see Figure 6). Nonetheless, it does appear to be having a significant impact on changes to sales and compliance policies with half of domestic companies reporting changes as a result. Some may feel that the uneven impact of the FCPA between MNCs and domestic companies might be a source of competitive advantage for domestic companies. However, domestic companies are divided on whether this would be the case.

Figure 6: To what extent do you agree with the following statements in relation to the Foreign Corrupt Practices Act (FCPA) and the different national European legislations? (All multinational respondents)



Insights: managing IPR uncertainty

IPR uncertainty is the biggest threat to growth identified by pharmaceutical MNCs. Their concerns are shared by domestic pharmaceutical companies. While many are optimistic that improvements to protection are happening, none of them expect such moves will resolve their worries. How can companies best manage risk in an uncertain IPR world? What are the strategies that need to be employed?

The key starting point for companies is to assume that the answer will not come from law and regulation. A more valid assumption, based on research evidence analysed by PricewaterhouseCoopers ⁽¹⁾, is that low cost producing countries and the core dynamics of globalisation may continue to pose a unique set of high risks to IP in the future.

In this environment, companies should reduce their dependence on conventional IP mechanisms by complementing this with an approach that places IP strategy within a broader context of value creation and business strategy. This makes good sense, particularly because the forces that contribute to accelerated and more pervasive value erosion include many that IPR protection alone cannot address.

This is not to say that companies should give up on pressing for improvements to IP laws. Examples of important action include:

- Careful selection of an IP holding location as well as examination of the tax implications of IP migration and revenue from future exploitation

- Structuring for R&D, cost sharing and royalty arrangements
- Incentive planning, strong documentation and TP studies
- Continuing to engage with the related central government agencies to improve their knowledge and law enforcement capability-exercises
- Aligning interests with local government parties because much infringement is local in nature
- Engaging in local standards debates and elevating protection initiatives in international standards groups
- Organising government education efforts that stress and quantify the benefits of IPR protection, especially for future R&D, patients and healthcare delivery
- Encouraging local IP holders to support the cause of IP protection
- Nurturing alliances with researchers, academics and policy advisers and helping them expand their knowledge and influence

(1) PricewaterhouseCoopers, Redefining IP Value: the case of China, 2005.

Focus: India

The Indian pharmaceutical market is one of the fastest growing markets in the world. Sales increased by 17.5 percent to US\$7.3bn in 2006 (IMS Health). Many factors, including the acceptance of intellectual property rights, a strong economy and the country's growing healthcare needs have contributed to the country's accelerated growth.

The Indian clinical trials market is worth about US\$120m currently and expected to reach US\$1bn by 2010 (Infomedia). Contract manufacturing, US\$350m currently, is also expected to reach US\$1bn by 2010 (Crisil). There are 85 US-FDA approved API & formulation plants located in India, the highest such number outside the US.

Indian companies are going global. Local generic companies such as Ranbaxy and DRL have expanded through acquisition in Western markets aggressively in 2006. DRL acquired Germany's Betapharm for US\$570m. Ranbaxy led the way with eight acquisitions and is aspiring to be a US\$2bn company by 2007 (Media).

From January 2005, the country became TRIPS compliant and formally recognised product patents. This has triggered a growth in Indian clinical trial activity by MNCs and contract research organisations (CROs). Government taxation incentives are also boosting R&D in India.

The Indian pharmaceuticals industry has risen above the generics label and is now undertaking serious drug discovery contract research for big pharmaceutical companies. Global pharmaceutical alliances with Indian drug firms are finally beginning to look like a two-way street with major R&D deals being struck such as:

- Glenmark Pharmaceutical with Dyax to identify biological entities for its three targets in cancer treatment
- Glenmark Pharmaceutical with Merck KGaA for its prospective diabetes molecule GRC 8200
- GSK with Ranbaxy Laboratories for identifying new targets
- Nicholas Piramal with Eli Lilly for drug development in metabolic disorders
- GSK with TCS for data management through global drug development support centre in Mumbai

Learning

Just like the growth of the pharmaceutical industry in Asia, movement along the learning curve for companies in the region has been fast. The environment facing companies has changed and the actual experience of MNCs coming to the region has, in some respects, been different from what they anticipated. Both MNCs and domestic companies in our survey believe they have a lot that they can learn from each other.

A changing environment

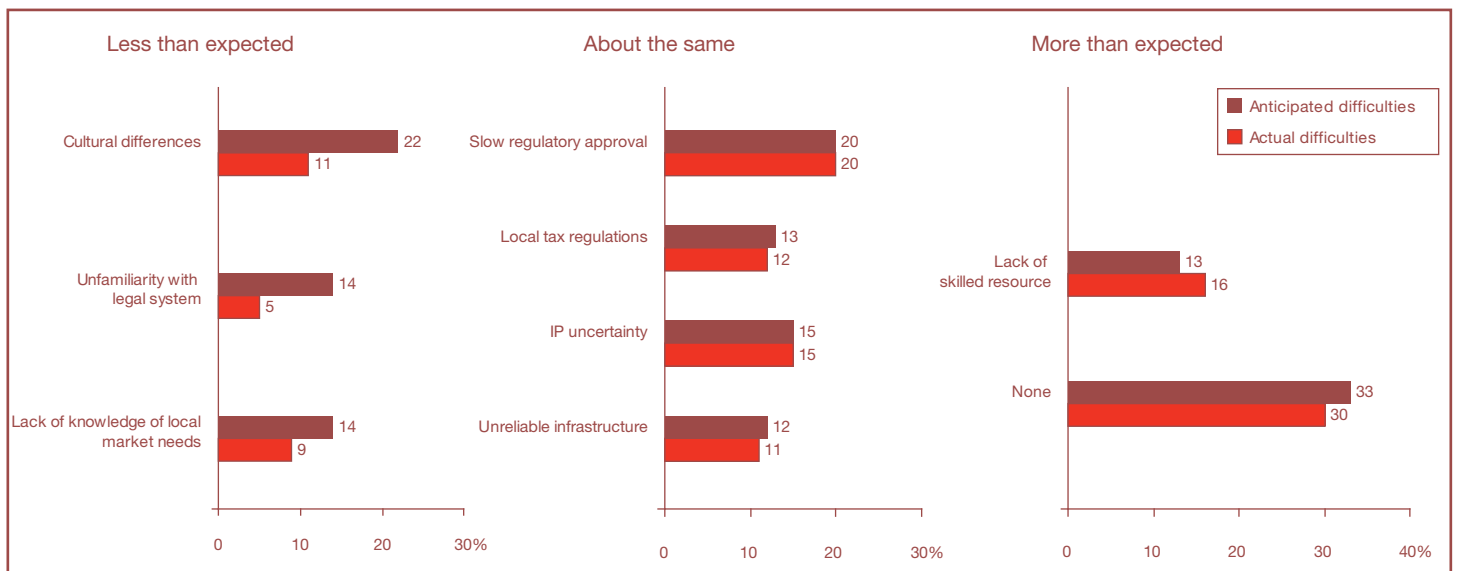
The dynamics of the risk are changing fast as the various markets mature. Many of the new top risks are the result of growing, competitive marketplaces. This is reflected in MNC companies' views on how risks have changed over the last ten years. Pharmaceutical companies are now less worried about market knowledge and cultural differences. Many of the risks that are judged to be higher now than a decade ago arise from greater competition and complexity in the marketplace. For example, with more companies in the sector, MNCs are more worried about choosing the wrong partner. They also cite market competition, innovation and price pressures pose greater risk than a decade ago. In common with our overall findings, human risk, including corruption, fraud and union

relations, are rated higher than ten years ago. However, the biggest change over ten years is that MNCs are now much less concerned with cultural differences. Only 14% thought this posed a higher risk than a decade ago compared with 86% saying it was less significant.

Actual vs anticipated experience

Multinational pharmaceutical companies are becoming much more comfortable about conducting operations in Asia. Key issues that some MNCs were initially concerned about have proved less of a worry in reality (see Figure 7). Only half the companies that expected cultural differences to be a problem found this to be the case in reality. Familiarisation with different legal systems was an issue for barely a third of the companies that were anticipating difficulties and lack of knowledge of local market needs similarly faded in significance as an issue in reality. However, difficulties such as slow regulatory approval systems, IP uncertainty, tax regulations and unreliable infrastructure all presented the same problems in practice as companies had anticipated in advance. Indeed, no doubt as a symptom of a growing and more crowded sector, finding skilled resources has proved more a problem than expected for some companies.

Figure 7: Anticipated vs actual difficulties encountered by MNCs pharmaceutical companies establishing presence in the Asia Pacific region



Learning

33% of MNCs report that they did not expect to find any difficulties and 30% found that this was their experience in practice. Of the two-thirds of companies, however, who had experienced difficulties, 28% felt that it could be potentially serious enough to make them exit the country in question. While this is only 16% of all the MNCs interviewed, it does indicate the continuing importance of market and regulatory reform to ensure a favourable environment for companies to operate in.

Working together

However, despite their increased comfort, MNCs feel that, on balance, they lack the knowledge, skills and insight to gain the most of their presence in Asian countries. Forty two per cent of MNCs agreed with this proposition versus 38% disagreeing. Domestic companies felt more strongly with 51% of domestic companies believing MNCs could not do it alone versus 19% disagreeing. It is clear that MNCs and domestic companies can learn a lot from each other. Domestic companies were asked about things that they had gained from working with MNCs and, also, the lessons that they felt that MNCs could learn from them. The opportunities for further mutual gain appear significant. As well as the obvious gains of access to international markets, finance and growth, domestic companies value the training and development and ideas exchange that flow from working with MNCs. They also highlight improvements in working methods and better management techniques, among other things (see Table 1).

Table 1: Top ten strengths of working with MNCs as reported by domestic pharmaceutical companies

Increased access / exposure to / knowledge of international markets
Exchange of ideas / ability to learn from each other / training & development of staff
Improve working methods / processes
Access to finance / capital / investment
Technology
Improve management techniques / processes
Experienced Research & Development
Branding
Reputation / image
Opportunity to grow the company

Learning

Domestic companies, though, emphasise that learning has to be two-way and that there are many issues on which MNCs can gain knowledge and insight from domestic companies. In particular, they feel that MNCs could work harder to understand the local business environment, culture and regulatory requirements (see Table 2). They also point to the potential for adopting more flexible management methods and processes and understanding the professionalism of local companies. Poor communication and shortcomings in cultural awareness headed the list of main difficulties in working with foreign companies (see Figure 8). There was a broad similarity of responses across the various territories covered in the survey, although respondents in China place some added emphasis on the need for good communications and rationality in decision-making by MNCs.

Governments, of course, are a key player in the market landscape, particularly in the pharmaceutical sector. As we have seen, many pharmaceutical companies believe that improvements in the regulatory landscape have been made and, for example on IPR, there is optimism about future progress. However, domestic companies identify a range of issues on which they would like further progress to be made as a top priority – corruption, improvements in drug pricing, more efficient product registration and funding to support R&D (see Figure 9). Approvals for clinical trials, for example, can take a long time in some territories – up to twelve months in China and, until recent improvements, some nine months in India.

Table 2: Top five lessons that foreign companies could learn from domestic companies (as reported by domestic pharmaceutical companies)

An understanding of the local business environment
Culture
Regulation / legislation
Flexible management methods / processes
Reduction in costs of products / professionalism of local companies / integration of management processes / techniques

Figure 8: What would you consider to be the main difficulties in working with foreign companies? (Domestic companies)



Figure 9: What issue do you think should be a top priority for local government to resolve in respect to business in your sector?

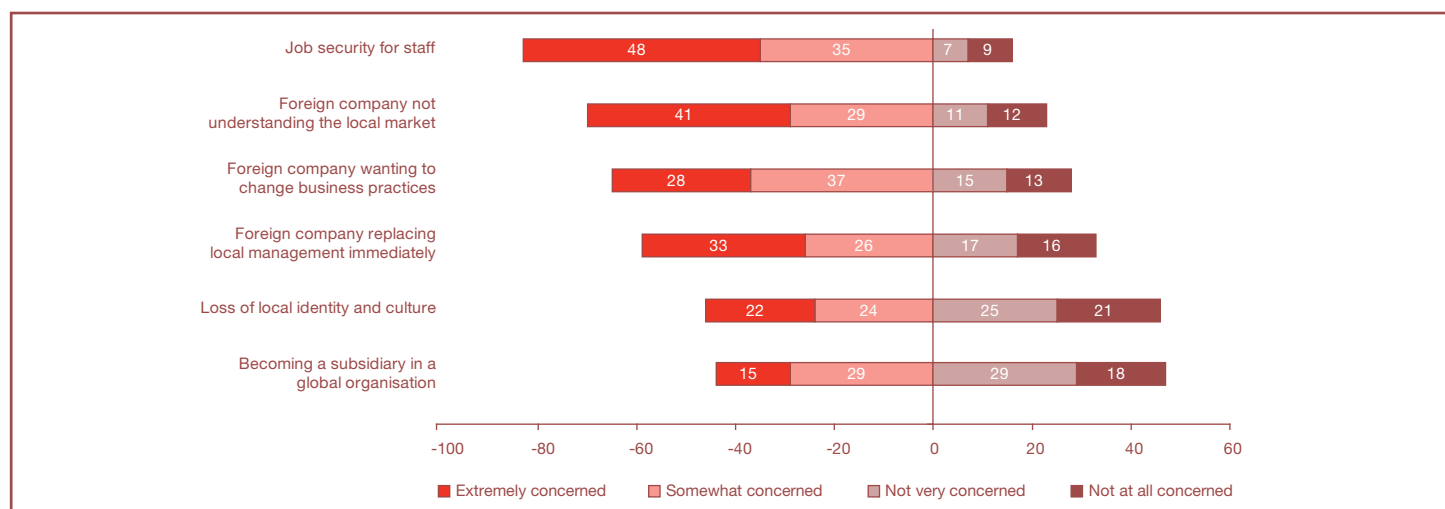
Reduction in taxation / tax guidelines	Government support for / development of business sector	Improved clarity / understanding of legislation
Restructure / completion of legislation	Financial investment / support	Enforcement of legislation
Improve administration / product approval & registration efficiency	Industry regulation	Pricing policy
Reduce protectionism / allow for fair competition	A change of government policy	Local government / company corruption

Learning

Combining together

Of course, in some cases MNCs and domestic companies do more than work together - they combine together following takeovers. Takeovers have inherent risk and uncertainty. Indeed, research shows that, across business as a whole, around 70% of transactions fail to achieve their intended value. Certainly the resultant change can create anxiety in the target company and this, in itself, can be a brake on value. Such anxieties were expressed by respondents in the domestic pharmaceutical companies that we surveyed (see Figure 10). The biggest concern after a potential takeover is job security (83%) but there are also considerable worries that the foreign company would implement change that is either too hasty or would not take good account of the local market and business environment. However, respondents were less concerned about the loss of local identity and becoming a subsidiary in a global organisation.

Figure 10: How concerned would you be about the following potential risks to your organisation that may arise after a takeover by a foreign company? (Domestic companies)



Insights: evaluating investment opportunities

Value can easily be lost in takeovers. The domestic pharmaceutical companies in our survey express concern that the purchasing entity would not judge change correctly. They fear that inherent value could be lost. The MNCs are split on how best to invest resources to gain best results from joint ventures or domestic company takeovers. Forty four per cent, for example, would invest moderate or significant resources to integrate the domestic company's structure into the organisation's existing structure but 36% would not. How can companies gain best value from joint ventures and takeovers?

It is imperative to include an assessment of the operational capabilities of the target when evaluating and pricing a deal. Failure to do so can lead to unforeseen capital expenditure and makes the effective integration of business units, processes and systems problematic. In addition, companies which fail to develop well structured integration plans find themselves beset by project delays, synergy losses, and distractions from their business plans that quickly drain value from the transaction.

In China, investments often take the form of strategic minority stakes, or leaving management to operate on a standalone basis. Working practices and culture differ significantly from international practice and reliable data is often not available. These issues add further complexity to the challenge of making a deal succeed.

Early identification of key deal and integration issues and close control over execution to achieve improved performance with reduced levels of risk are vital. An effectively structured approach begins with operational, financial and tax due diligence at the deal evaluation stage. It continues through execution with a tightly managed process for rectifying deficiencies, integrating processes and driving longer term performance improvement across the business. Achieving your objectives requires addressing a number of critical success factors:

- A clear vision for the end state
- Commitment and leadership
- Operational due diligence to identify issues and risks
- Integration plans aligned with business strategy
- Effective project management and communications
- Cultural issues addressed and key talent retained
- Structured approach to execution and benefits tracking
- Regulatory compliance due diligence

Focus: Singapore

Singapore has enjoyed phenomenal growth over the last four decades despite its small size and population of 4.4 million (UN Population Division). It has become recognized as a premier global hub in Asia for the manufacturing of pharmaceuticals. Leading companies like Aventis, GSK, MSD, Schering-Plough and American Home Product (AHP), have invested over US\$1.3bn in plants to produce active pharmaceutical ingredients and finished products for worldwide markets.

The growth of Singapore as a base for pharmaceutical activities is boosted by the country's IPR protection record. Singapore achieved full compliance with the WTO's Trade-Related Aspects of IPR Agreement by 1999. It also has been ranked by the Political and Economical Risk Consultancy as having the best IPR protection in Asia since 1997.

Singapore's base of pharmaceutical manufacturing activities has expanded from primary manufacturing by companies such as Aventis and GSK to introduce secondary manufacturing such as tableting, formulation and finishing by Merck and Wyeth, and nutritional manufacturing by Wyeth. Schering-Plough also has added biotechnology lyophilization into Singapore's host of high value-added manufacturing activities. Many companies, like Novartis, Eli Lilly and Bristol-Myers Squibb have invested in R&D activities ranging from basic research to clinical development. There are at least ten MNC pharmaceutical manufacturing facilities in Singapore.

Biomedical manufacturing is enjoying strong growth in Singapore, with a significant 30.2% manufacturing output growth to S\$23 billion in 2006 (Biomed). Within a short span of six years from 2000, biomedical manufacturing output has grown fourfold. Pro-active government policy is spurring this growth. The Singapore Biomedical Sciences (BMS) initiative was launched in June 2000 to develop the biomedical sciences cluster as one of the key pillars of the Singapore's economy, alongside electronics, engineering and chemicals.

Biologics is a fast growing segment of the global BMS industry and is a key part of the expansion of Singapore's biopharmaceuticals manufacturing base. Biologics manufacturing is the large-scale production of therapeutic proteins (in contrast to chemical-based drugs) to treat a variety of diseases. Genentech, one of the world's leading biotechnology companies, is in the process of establishing a commercial scale microbial-based biologics manufacturing facility in Singapore. This will be Genentech's first such facility in Asia. Lonza Group and Bio*One Capital have also established a large-scale commercial mammalian cell culture manufacturing facility at Tuas Biomedical Park.

Singapore is now home to some thirty biotechnology companies, which include a growing number of local start-ups such as S*BIO, CordLife, ES Cell International and Merlion Pharmaceuticals as well as international companies like ViaCell and Proligo. In common with South Korea and China, Singapore has built up substantial research experience in stem cell research.

Outsourcing

Competition from generics and pricing pressures in the healthcare market continue to create pressures for reduction in costs in all parts of the pharmaceutical value chain. Outsourcing to lower cost but highly effective companies in Asia has become a common response to these pressures. The outsourcing trend has still some way to run. So far much of the focus has been on outsourcing drug manufacturing but, increasingly, companies are turning their attention to R&D and clinical trials.

Momentum strong but full potential yet to be grasped

A majority of the pharmaceutical companies that we surveyed think the industry is failing to fully grasp the potential for outsourcing and are missing opportunities for shared development and improvement. A majority, 56% of companies agreed with the statement that “companies do not see outsourcing in a dynamic way and miss real opportunities for shared development learning and improvement”, and only 19% disagreed with this. There is a broad consensus between MNCs and domestic companies on this topic (see Figure 11) with, for example, only 21% of MNCs and 17% of domestic companies disagreeing.

Momentum for outsourcing remains strong with 71% of MNCs having considered outsourcing of one kind or another. Among these companies, the main reason for such a move has been the desire to source lower cost manufacturing (39% of companies) and lower cost research capacity (24% of companies) (see Figure 12). In addition, a considerable proportion, 48%, identified strong underpinning factors in their decision such as more effective time usage, lower HR cost and the benefit of being able to focus on core strengths.

Figure 11: Many companies do not see outsourcing in dynamic way and miss real opportunities for shared development learning and improvement

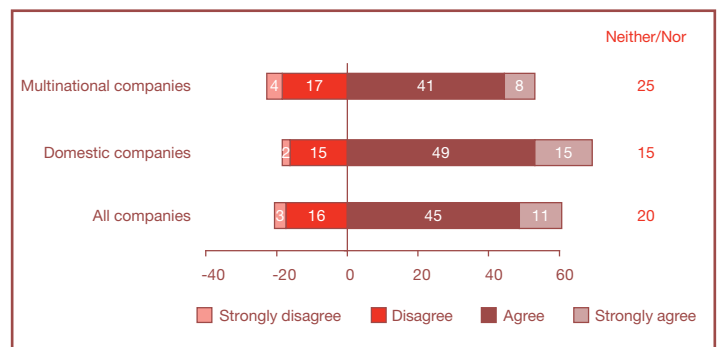
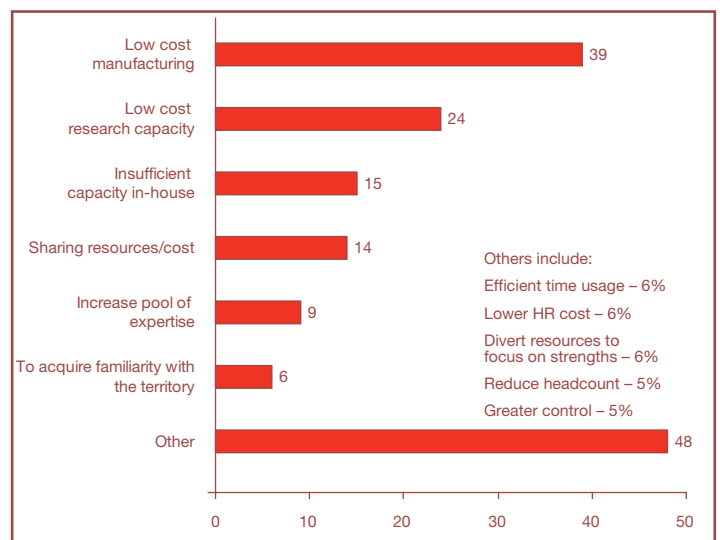


Figure 12: Main reasons for outsourcing (MNCs that have outsourced)



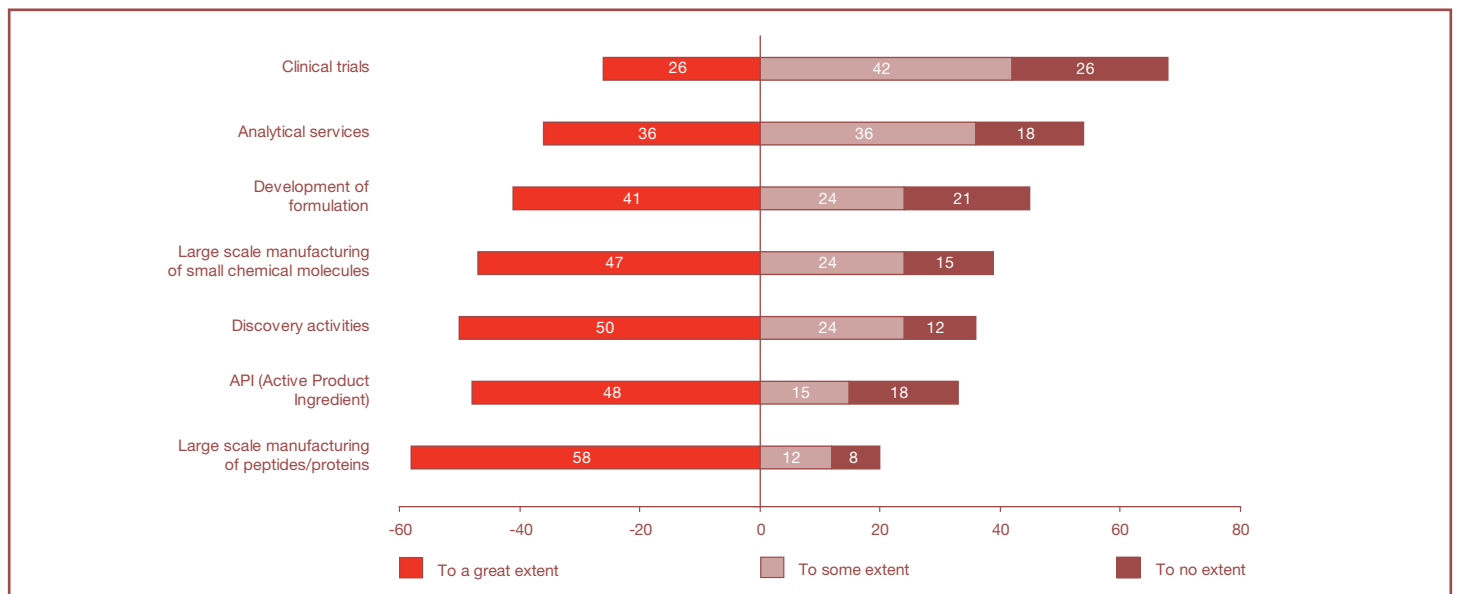
Outsourcing

A changing business model

Looking ahead, companies see a lot of room for continued outsourcing growth in the Asian pharmaceutical sector. Many MNCs are moving towards a future where a new business model will be more common. In such a model, the focus of the MNC is on sales and marketing with other activities outsourced. Not surprisingly, as the industry moves to this future model, strategic partnerships or long-term partnerships are the preferred route, favoured by 82% of the multinational pharmaceutical companies we surveyed who outsource. Only a small number, 13%, felt that buyer/vendor set-ups were preferable. This has important implications for domestic companies. They need to ensure sufficient effort is into understanding their potential partner because what they are looking for is almost “a partner for life”.

When pharmaceutical MNCs were asked about what activities they were considering outsourcing, the focus moved away from manufacturing towards clinical trials and analytical services (see Figure 13). This highlights the trend towards a changed business model in the pharmaceutical sector and the move of R&D and clinical trials closer to a growing main consumer marketplace. More than half of the world’s population is in Asia. Companies are moving research closer to the consumer to contain the cost, manage risk and make the most of a future where therapies may be more closely aligned to patient segments. It also highlights the importance of the right regulatory climate in individual territories if those territories are to make the most of the growth opportunity. At present, for example, there are significant differences in the time required to gain approval for clinical trials. Those territories that minimise bureaucracy and delay are likely to benefit. Territories in the region need to invest more in regulatory manpower resources to overcome these problems, both in the area of trials and in IPR enforcement.

Figure 13: To what extent have you considered outsourcing the following services? (Multinational respondents)



Outsourcing

Attitudes towards shared services centres

Forty per cent of multinational and 22% of domestic pharmaceutical companies have set up or are considering setting up a shared services centre (SSC). IT, employee training, payroll and the recruitment side of HR are the services that companies most favour outsourcing to such centres. They see scope for greater efficiency and effectiveness as well as cost control by pursuing an SSC outsourced route. Interestingly, some companies feel they can gain better control of these functions in an SSC. Twenty four per cent of the MNCs who had made the decision in favour of an SSC report that “improved control” was a key factor in the choice with 19% mentioning “improved reporting structures”.

However, many companies, especially domestic companies, currently feel that an SSC is not right for them. Three quarters of domestic companies are not considering SSCs, mainly because they are either too small to feel that it would be beneficial or because they are satisfied that their current structure works well. Among MNCs, again a majority, 53%, are not considering SSCs with the main reason being satisfaction with current arrangements. However, among both MNCs and domestic companies, it is clear that pressure of resource and other business priorities are a key barrier to examining the case for an SSC. Forty five per cent of MNCs and 56% of domestic companies feel that they simply don't have the time to currently investigate the pros and cons of SSCs.

Outsourcing

Insights: maintaining control of outsourced activities

Worries about loss of control are a key factor holding pharmaceutical companies back from outsourcing. Of those who have decided not to outsource, 54% of MNCs believe it is more difficult to monitor the performance of outside companies and 79% report that they prefer to keep everything in control inside their organisation. What should companies be doing to ensure control and compliance is not a worry?

Whatever the outsourced activity, the following areas are crucial:

Good partnership selection

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

Maximise the value of the alliance

- Develop request for proposal (RFP) and manage selection process
- Establish contract agreement process and manage contract negotiation
- Acquire tax advice for maximised benefits

Effective outsourcing implementation

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

Continued partnering optimisation

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

The increasing move to outsource clinical trials re-emphasises the importance of pharmaceutical and life sciences companies assessing their global clinical compliance risk, companies are able to promote and achieve a consistently high level of compliance with good clinical practices.

They need to ensure that outsourced arrangements are also comprehensively covered – just because the trial is outsourced does not immunise them from the effects of any non-compliance. Non-compliance exposes corporations to heightened risks such as hefty fines, significant trial delays, endangered patient safety, wasted resources, and potential litigation resulting from withdrawn products.

Focus: Territory round up

South Korea is a major player in the emerging Asia pharmaceutical landscape. It has the fourth highest overall healthcare spending in Asia, behind Japan, China and India. There are sizeable opportunities for foreign firms in a rapidly growing pharmaceuticals market. Most of foreign companies have been engaged in wholesale business in Korea. Thus, manufacturing and R&D activities by the foreign companies are limited in Korea. The leading two domestic companies - Dong-A and Yuhan - had revenue of US\$601.2m and US\$433.4m respectively in 2006 against US\$376.5m and US\$311.5m for the two leading foreign MNCs, GSK and Pfizer (LG Life Sciences).

As in many Asian territories, the domestic market in South Korea is highly fragmented and the rising profile of foreign pharmaceuticals companies in South Korea is likely to force reorganisation. The country is seeking to forge a future in innovative pharmaceuticals. It is pushing forward, for example, on stem cell research and a South Korean team cloned the first human embryo in 2004.

The accession of Taiwan to the WTO in 2002 eased concerns from MNCs about unequal treatment and, indeed, foreign companies dominate this market. Total pharmaceutical sales are estimated at US\$4.4bn in 2007 (EIU). However, drug price adjustments by the Bureau of National Health Insurance are limiting growth. Most major multinational pharmaceutical companies have a sales and marketing presence in Taiwan. Taiwanese domestic companies tend to concentrate on generics and bulk drug manufacturing. There is government encouragement to upgrade local producing standards and foster biopharmaceuticals. Taiwanese producers are having success in getting more orders from western markets due to success in meeting Good Manufacturing Practice (GMP).

Thailand has a very high pharmaceutical spend per capita growth rate – US\$19m in 2004 projected to rise to US\$36m by 2009 (Source: IMS 2005). Future annual growth of Thailand's pharmaceutical industry is expected to be about 10-15% per year over the next 5 years. Over 60% of drugs consumed in Thailand are manufactured domestically, the rest are imported. Multinational drug makers account for over 70% of sales in terms of value.

Global consolidation and outsourcing are affecting the industry structure of the smaller regional markets like Thailand. MNCs now only have sales and marketing in Thailand with no manufacturing or R&D. In the past, as many as ten MNCs manufactured in the country. Domestic manufacturers focus on formulating drug products from imported active ingredients and manufacturing generic products. Some export to the neighbouring territories and Middle East. No API is produced in Thailand.

In the Philippines, total pharmaceutical sales are comparable with Thailand but growth is more limited. Foreign MNCs dominate the market and there is limited domestic production. Import restrictions force most MNCs to have a manufacturing presence in the country. United Laboratories is the largest domestic producer of pharmaceuticals.

The market for pharmaceutical sales in Malaysia is much smaller than the Philippines but domestic producers, mainly in generics, are present alongside MNCs.

The pharmaceutical market in Vietnam is still in its infancy with per-capita spending on drugs among the lowest in the region. However, a large population of 81 million does mean that, subject to economic growth, there is significant growth potential. WTO accession, which began at the start of 2007 for the pharmaceutical market, will take place in stages. Foreign investment is growing. Domestic producers are already seeing sales erode by higher-quality foreign imports.

Looking ahead

The demand for drugs in the developing world is continuously growing and, as territories in the region grow wealthier, Asia will become the biggest pharmaceutical market in the world. A presence in these markets today gives companies market knowledge and the opportunity to adjust to the environment. Each market is at a different stage of development, has different needs and requires different company approaches and tactics.

Local market knowledge gives companies competitive advantage. It allows them to adjust product portfolios to market requirements and to understand future needs better in a context that is continuously and rapidly changing. The significance of the Asian market in the global pharmaceutical landscape makes it advantageous to conduct clinical trials in the region. This enables data to be obtained for different ethnic populations. In some territories, for example China, it is mandatory to have clinical trial data from within the country before a drug can be registered.

Domestic companies are 'hungry' for cash to invest. There is also a great deal of room for consolidation among domestic companies. The scope for mergers and acquisitions is considerable. Foreign pharmaceutical companies and the larger domestic entities will be key players but investment might also come from private equity funds. Combined entities will need to judge well the reorganisation and change that is needed to secure best value from transactions. In the case of private equity, reform may be considerable.

Our survey highlights many factors that companies need to consider with, for example, domestic companies believing that one-way reform that does not recognise indigenous strengths may damage rather than boost future potential. Again local insight is valuable and purchasers would do well to get closer to the target market – at present, for example, most staff involved in acquisitions by MNCs are located in HQ and not in the target country itself.

As well as the move to outsource non-core IT, HR and other services in shared services centres, big pharmaceutical companies are moving to outsource activities such as R&D that were previously considered core to their business. The pattern of change to this new model will, in part, be determined by progress towards better IPR protection. The IPR landscape will be an important factor in the growth of R&D outsourcing in particular territories. Nonetheless, companies will also need to be successful in managing an imperfect IPR environment by handling IP strategy within a broader context of value creation and business strategy.

Companies that use outsourcing in the right way, and at the right pace, look set to get ahead of the game. Some are already moving towards setting up a complete virtual supply chain, making use of the low cost Asian environment while minimising risk. Without doubt, as we look ahead, the pharmaceutical landscape for both MNCs and domestic companies alike in Asia will look radically different in the medium term.

Appendix

Methodology

The Pan-Asian survey used a quantitative technique. Between January and March 2007, a telephone survey measured and quantified market opinions on future developments in the pharmaceutical industry in the Asian region. The research was carried out by Synovate (Asia) on behalf of PricewaterhouseCoopers and all analysis was carried out by PwC's International Survey Unit (ISU). A total of 185 interviews were conducted in the following nine territories: China, India, Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam.

To produce a valid sampling frame for the telephone survey, PwC carried out extensive research on pharmaceutical companies operating in the Asian market and a regional list was compiled of the most prominent domestic and multi-national organizations in each territory. These business executives were then sent a personal invitation to participate in the survey, resulting in 185 telephone interviews – an overall response rate of 24%.

Using industry knowledge from across their networks, PwC designed a 30-minute telephone questionnaire, structured around the following headings:

- Business growth
- Risks to growth
- Regional presence
- Intellectual property
- Outsourcing
- Raising capital
- Regulation and legislation

The respondents were also given the opportunity to provide more personal feedback on their particular territory in open-ended questions throughout the questionnaire.

All of the telephone interviews were conducted under the management of PwC's International Survey Unit, which operates under the guidelines of the Market Research Society's Code of Conduct. They are also accredited under the Interviewer Quality Control Scheme (IQCS), which is the industry quality standard for fieldwork and analysis.

Appendix

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