India Pharma Inc.

Enhancing value through alliances and partnerships

Confederation of Indian Industry

Pharma summit 2011

pwc

Contents

Foreword

The social, demographic and economic context in which the global pharmaceutical industry operates is rapidly changing. Globally, pharma companies are facing pressure from governments and taxpayers alike for reducing prices of drugs and initiating outcome-based pricing. Simultaneously, there is a vast decline in R&D productivity, diminished pipeline for new drugs, increased drug discovery costs as well as increased regulatory measures that companies need to contend with.

The Indian pharma industry is showing signs of robust growth. The domestic pharma market is expected to grow at a CAGR of 15% to 20% to reach a value anywhere between US$ 50 billion and US$74 billion by 2020.[1]

Foreign multinational companies along with Indian pharma companies are partnering together to tap opportunities in the fast growing emerging economies(BRIC nations) and the larger established markets in the West and Far East (Japan). Acquisitions, alliances and partnerships are some of the tools used to penetrate and capture a larger share of the potential opportunity in these markets.

We are also seeing companies collaborating outside the realm of manufacturing and R&D with players in health insurance, medical technology, Information Technology and mobile technology to deliver superior sustainable healthcare services. These developments bode well for the pharma industry and society as a whole who stand to benefit from such alliances and partnerships through reduced costs and streamlined supply chains.

Some Indian pharma companies are looking to increase the value of services they provide by moving early on in along the value chain into biotechnology, drug discovery & development, which have primarily been the domain of large innovator companies. In this report, we look at the different types of alliances and partnerships that have taken place in the Indian market, the synergies and benefits to the parties involved as well as the key success factors which need to be kept in mind to achieve productive and cohesive long term collaboration.

Sujay Shetty
Executive Director - India Pharmaceuticals and Life Sciences Leader - PwC

Jai Hiremath
Chairman - CII Pharma Summit 2011 and
Vice Chairman & Managing Director - Hikal Ltd.

Executive summary

The social, demographic and economic context in which the global pharmaceutical industry operates is changing. Developed economies with spiralling healthcare costs are looking to rein in healthcare expenditure. Payers are demanding a reimbursement model based on healthcare outcomes. The impending patent cliff and declining R&D productivity threaten the sustainability of the pharma industry's current business model. Emerging markets in general and India in particular offer a ray of hope for the global pharma industry. India's large domestic market, product development skills and scientific talent are being increasingly sought by pharma MNCs to tackle the challenges of growth and innovation. Indian pharma companies are also looking to move up the value chain and change the perception of India as a cheap manufacture base to that of a genuine intellectual contributor.

One of the main ways MNCs enter the Indian market is through acquisitions. However, given the scarcity of assets, valuations in the sector have increased over the last 12 to 18 months. Companies are now exploring other ways of collaboration through alliances and partnerships. Such collaboration began with product sourcing and has now blossomed into other areas such as drug discovery, clinical development and marketing and sales. Collaboration between big pharma companies and Indian drug

firms has proved beneficial not just to the two parties but to the Indian patient society as a whole.

A PwC survey of opinion leaders in the Indian pharma industry revealed that quality as a key determinant of the success of alliances and partnerships. Other issues impacting success include management control, valuations, corporate governance, cultural differences and awareness of local regulations.

The key point of note for these companies looking to do deals is to choose an alliance partner after conducting a thorough due diligence. While financial diligence is a standard and integral part of all deals and alliances, the pharma industry needs a more thorough operational due diligence prior to partner selection. No one size will fit all and companies will have to choose and implement the collaboration initiatives that best meet their strategic objectives.

With increasing pressure on healthcare costs all over the world, pharma players will have to pay attention to cost reduction efforts. Efficient management of operations, supply chain and transfer pricing are thus issues of paramount importance.

Pharma companies will also have to strengthen collaboration with key players outside the industry such as health insurance, medical technology and information and communication technologies. In addition, they will have to devise strategies for inclusive and sustainable growth.

The pharmaceutical industry in India is poised for a period of robust growth driven by alliances and partnerships. Success in the market will be dependent not only on the pharma companies but also on other stakeholders like healthcare providers, health insurance companies, medical technology companies, government, patient groups as well as society at large, acting in concert. How well they do will determine the future of the industry.

Growing through alliances and partnerships

Why partnerships

The global context

As population grows and ages, new areas of medical need emerge. The diseases in the developing countries are growing increasingly similar to those of the developed world.

Demand for new anti-infectives is mounting, especially for diseases like multi-drug resistant tuberculosis. Global warming can bring diseases such as malaria, cholera, diphtheria and dengue fever to more developed regions. These changes will generate opportunities for the global pharma industry over the next decade.

Despite robust demand for its products, the industry is facing unprecedented challenges. The impending patent cliff which could see big companies lose over US$ 118 billion worth of patented drug sales by 2015[2] is a cause of great concern. Compounding this is the increased cost for developing new drugs and requirements of regulators for enhanced safety and efficacy monitoring.

The governments of developed economies with huge fiscal deficits are also under pressure to reduce spiralling healthcare costs. At the same time, healthcare payers and providers everywhere have recognised that current

Trends shaping the global industry

- Emphasis will be on outcomes.
- Compliance monitoring will become a win-win for patients, payers and providers.
- Focus will shift from treatment to prevention.
- New technologies will drive R&D.
- The current linear phase R&D process will give way to in-life testing and live licensing.
- There will be greater international regulatory cooperation.
- The blockbuster sales model will disappear.
- The supply chain functions will generate revenue.
- More sophisticated direct-to-consumer distribution channels will diminish the role of wholesalers

healthcare expenditure levels are also unsustainable unless they deliver more demonstrable care and cost benefit over the long term. Payers are demanding evidence of outcomes from pharma companies before including the medicines in pharma benefit plans.

According to PwC's pharma 2020 report, **Challenging business models**, global pharma companies will have to fundamentally change their operating model to capitalise on future growth opportunities.

Most large companies have traditionally done everything from R&D to commercialisation themselves. By 2020, however this model may no longer work for many organisations. If they are to prosper, they will need to improve their R&D productivity, reduce costs, tap the potential of emerging economies and switch from selling medicines to managing outcomes. Alliances and partnerships with firms within and outside the pharma industry is a key requirement of the pharma operating model of the future.

Bristol Myers Squibb (BMS) uses a slew of alliances, partnerships and acquisitions to complement its internal capabilities in drug discovery and development.

BMS calls its string of pearls strategy in which each transaction will be aligned to the company's focus on specific disease areas.

40% of BMS patents and 50% of revenue come from such alliances.[3]

Lilly is currently transforming itself from a traditional fully integrated pharmaceutical company into a fully integrated pharmaceutical network, so that it can draw on a range of resources beyond its own walls. Lilly hopes teaming up with other organisations to create virtual R&D programmes will enable it to get better access innovation, reduce costs, manage risks more effectively and enhance productivity. For example, the Chorus Project is a virtual organisation to take molecules quickly to proof of concept. Lilly also uses external networks comprising third parties such as Piramal Life Sciences, Hutchison MediPharma, Suven Life Sciences in the development of molecules .[4]

Several pharmaceutical firms like Lilly and BMS have already begun to use more collaborative models. The pressure to change to new business models, triggered by internal and external factors has led to increasing mergers, acquisition, alliances and partnerships in the pharmaceutical sector.

The Indian context

The Indian pharma industry is today, the third largest market globally in terms of volume and 14th largest by value. According to PwC's report **Capitalising on India's growth potential**, the domestic pharma market is expected to grow at CAGR of 15 to 20% annually to be a USD 49 billion to 74 billion market by 2020.[5]

India is an attractive market for a variety of reasons:

- India's economy continues to show signs of robust growth. The increased spending on healthcare needs is expected to drive revenue growth for pharma companies.
- The emergence of chronic diseases like cancer, diabetes, Cardio Vascular System (CVS) and Central Nervous System (CNS) disorders is likely to drive demand for newer therapies.
- With increasing pressures on curbing healthcare costs in the US, India's low-cost manufacturing capabilities coupled with attention to quality (India has the highest number of FDA-approved manufacturing plants outside the US.) will be sought by MNCs.
- India has a large pool of scientific manpower which can be used in drug discovery, development and clinical trials.
- India's diverse genetic pool of treatment-naive population is attractive for clinical trials.

Indian generic pharma companies have strong product development skills and have set up world-class active pharma ingredients (API) and formulation manufacturing facilities to cater to the price-sensitive India market and global generics market. Many of these dominate India's domestic market through a large sales team, strong relations with physicians and medical institutions. Indian pharma companies are now seeking to move up the value chain to drug discovery and development by leveraging the country's scientific talent. Given the strengths of Indian and and global pharma companies, it makes sense for them to come together to develop India's domestic market, source products for global market and to discover & develop new drugs and therapies. .

MNCs and Indian companies are stepping up their play in the market through various kinds of partnerships to achieve the following:

- Capitalise on the opportunities provided by the Indian market
- Make the most of India's capabilities in drug discovery, product development and sourcing to serve overseas markets.

This chapter explores the different kind of partnerships in the Indian pharma space, the challenges faced in creating and sustaining such partnerships and the benefits of these partnerships to various stakeholders.

Government announces new norms for FDI in pharma

As of 2011, FDI through the automatic route was allowed in the pharmaceutical sector in India. Currently, 100% FDI is permitted via the automatic route.

Given the trend of acquisitions of domestic pharma companies by global players, the government has expressed concerns about the accessibility and affordability of medicines in the Indian market.

To ensure that such deals do not result in monopolies and an increase in drug prices, the government is now mulling over placing a cap on FDI in the pharma sector.

A high-level committee has been appointed by the government of India to look into this.

Government has decided the following: [6]

- 100 % FDI through the automatic route would be allowed for Greenfield projects
- 100% FDI through the FIPB approval route for Brownfield investments in the pharma sector for a period of six months
- During these six months, necessary enabling regulations will be put in place by the Competition Commission of India (CCI) for effective threshold limits on mergers and acquisitions to ensure that there is a balance between public health concerns and attracting FDI in the pharma sector
- After six months the oversight will be done by the CCI entirely in accordance with the competition laws of the country (FIPB nod will not be required)

Serving the Indian market

Given the growth slowdown in developed countries, pharma companies are keen to address the opportunities offered by the growing Indian market.

a. Mergers and acquisitions (M&A)

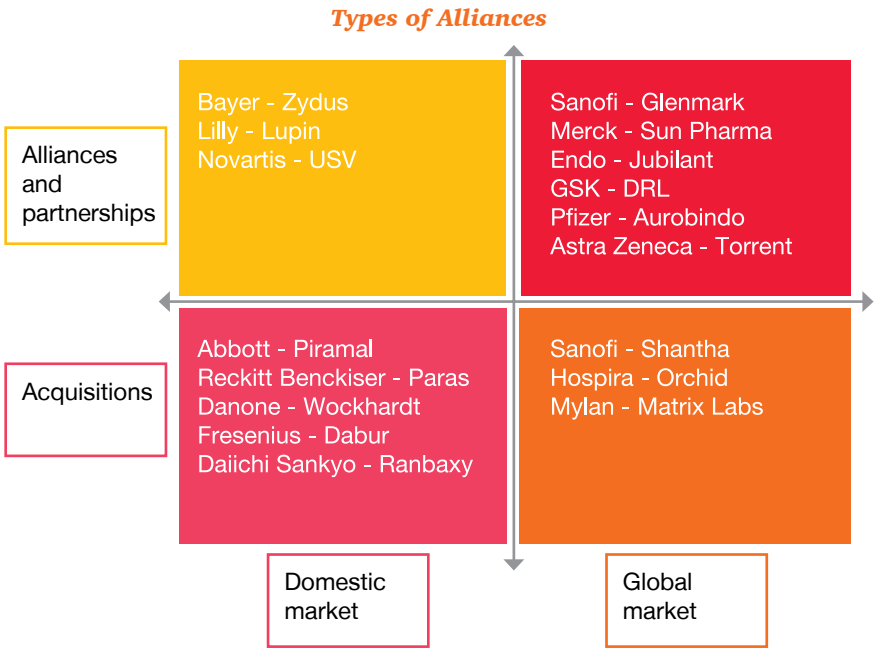
The Abbott acquisition of Piramal Healthcare's domestic formulations business in 2010 is a good example. Other examples include Reckitt Benckiser's acquisition of Paras Pharmaceuticals and the acquisition of the nutrition business of Wockhardt by Danone in 2011. Addressing the opportunities in the Indian market was also one of the key drivers behind the acquisition of Ranbaxy by Daiichi Sankyo (though Ranbaxy did have a global presence).

Recent M&A for addressing the Indian market

However, given the scarcity of assets, valuations in the sector have gone up over the last 12 to 18 months. Companies are now exploring other methods of partnership.

b. Alliances and partnerships (A&P)

Germany's Bayer Healthcare announced a 50-50 joint venture with Zydus Cadila to create a new company, Bayer Zydus Pharma focussed on the India market. Bayer Healthcare's pharma division will contribute its sales and marketing business in India to the new company while Zydus will contribute its women's health products, diagnostic imaging and other products.[7]



Year	*Indian player*	*MNC*	*Nature of deal*
2011	Wockhardt	Danone	Acquisition for US$ 350 million
2010	Paras Pharma	Reckitt Benckiser	Acquisition for US$ 726 million
2010	Piramal Healthcare	Abbott	Acquisition of domestic formulations business for US$ 3.7 billion
2008	Dabur (*)	Fresenius	Acquisition of 73.3% stake for Euro 139 million
2008	Ranbaxy (*)	Daiichi Sankyo	Acquisition for US$ 4.6 billion

Source: Industry reports, PwC analysis
(*) While these deals were predominantly aimed at gaining access to the domestic market, they also provided a platform for the acquirers to target global markets.

Lupin has signed a deal with Eli Lilly for anti-diabetic drugs. Under the deal, Lupin will market and distribute the entire range of Huminsulin brand of Eli Lilly in India and Nepal. Lupin will deploy 300 sales representatives from its formulations business to promote the product and will also provide education to physicians and patients.[8]

Novartis has signed a deal with USV Ltd to market Galvus(Vildagleptin) in the Indian metros. USV will manage marketing activities in Tier II and Tier III cities in the next phase.[9] Also entering the fray is Belgium's Omega Pharma, which formed a JV with Modi-Mundipharma Group to create Modi Omega Pharma India. Eight brands from Omega's product portfolio will be manufactured in India by the Modi-Mundipharma Group. The marketing strategies and sales team will be provided by Modi Omega Pharma India. [10]

Serving the global market

Pharma MNCs are facing challenges of impending patents and rising R&D expenditure. They are looking for opportunities to increase the drug pipeline and reduce costs. In addition, given the pressures of reducing healthcare costs and the increasing use of generics, pharma MNCs are also looking to partner with companies with superior product development capabilities. At the same time, Indian companies are also looking to move up in the value chain by discovering new drugs. These drivers have created the need for collaboration between MNCs and Indian pharma companies to target global opportunities.

a. Mergers and acquisitions

Pharma MNCs have acquired Indian companies to maximise their capabilities in serving the global market. The acquisition of Matrix Laboratories by Mylan in 2006 is one of the earliest examples of this trend.[11] More recent examples include the acquisition of the injectables business of Orchid Chemicals by Hospira[12] and Sanofi's acquisition of Shantha Biotechnics.[13]

Mergers and acquisitions to target global opportunities

Year	*Indian player*	*MNC*	*Nature of deal*
2009	Shantha Biotech	Sanofi-Aventis	Acquisition for US$ 781 million
2009	Hospira	Orchid	Acquisition for US$ 400 million
2006	Mylan	Matrix	Acquisition for US$ 736 million

Source: Industry reports & PwC analysis

b. Alliances and partnerships

Previously, A&P were formed to source out products. Today, it has expanded in R&D as well.

Research and development

Pharma MNCs are looking for opportunities to co-develop drugs, buy or in-license molecules from Indian companies. Such deals have helped India shed the tag of a cheap manufacturing base and gain the title of a genuine intellectual contributor.

Glenmark Pharmaceuticals became the first Indian company to out-license a biological product. The company licensed its biotech drug, which has the potential to generate revenue worth US$ 613 million,[14] to French company Sanofi Aventis. Glenmark sold the marketing rights for North America, Europe, Japan, Argentina, Chile and Uruguay, while it retained co-marketing rights for Russia, Brazil, Australia and New Zealand. In India, the company retained its exclusive rights.

Another example is of Jubilant. The company entered into a three-year drug deal with US-based Endo Pharmaceuticals for developing oncology drugs.[15] Under the deal, Jubilant will receive research funding and milestone payment on successful completion of predetermined targets. Endo will own the developed drugs and will pay royalties to Jubilant on the successful commercialisation of the drugs.

Other deals for R&D

Indian company	*Pharma MNCs*	*Products*
Glenmark	Forest Laboratories	Asthma and anti-lung infection
Piramal Research	Merck	Cancer
Glenmark	Eli Lilly	Pain relief
Serum Institute of India	MSD	Pneumococcal conjugate vaccine

Source : Industry reports & PwC analysis

Importance of Japan

The Japanese pharmaceutical market stands at US$ 96.5 billion.[21] This market is largely innovator-based with the generics component contributing about 25% of sales by volume. In contrast, the generics component of the US and UK stand at 88% and 71%[22] respectively.

The Japanese market is fast shifting its focus towards generics, driven by the government's fiscal pressures and an ageing population.

The government of Japan has been aggressively promoting generics by providing incentives to the industry and physicians.

Hence, we see an increasing number of Japanese pharma companies seeking partnerships with Indian generics manufacturers.

Product sourcing

Manufacturing deals are common in India because of the country's legacy in research chemistry, efficient production and cost advantage manufacturing. These skills coupled with the fact that India has the highest number of USFDA-approved plants outside the US, make manufacturing alliances an attractive proposition. There are several examples of such alliances in India.

GlaxoSmithKline (GSK) expanded its market share by striking a deal with Dr Reddy's Laboratories[16] and gaining access to a portfolio of more than 100 drugs. For Dr Reddy's, the deal will help increase its product reach in regions where, till now, it only had negligible market presence.

Similarly, Pfizer signed licensing deals with Aurobindo Pharma[17], Claris Life Sciences[18], Biocon[19] and Strides Arcolab. The deal will strengthen Pfizer's position in emerging markets and expand its medicine portfolio in established products business units (EPBU). The Indian companies will benefit from a steady revenue flow and the possibility of receiving significant upfront payment and royalties.

Sun Pharmaceutical Industries and Merck and Co Inc entered into a JV agreement to develop, produce and market innovative generics in emerging markets.[20]

Japan is an upcoming market for collaborations given the opening-up of generics market by the Japanese government. Please see the side bar for details.

A&P for product sourcing

Indian players	*MNCs*	*Nature of deal*
Aurobindo Pharma	AstraZeneca, Pfizer	Supply of generic medicines for developed and emerging markets
Strides Arcolab Ltd	Pfizer	Supply of 67 generic drugs to Pfizer with focus on oncology
Torrent Pharmaceuticals	AstraZeneca	Supply of 18 products for various markets
Indoco Remedies	Aspen	Range of ophthalmic products for 30 emerging markets
Indoco Remedies	Watson Pharmaceuticals	Development and manufacture of generic drugs with market size of US$ 670 million
Cadila Healthcare	Altana, Zyban	JV structure for the manufacture of patent drugs
Torrent Pharmaceuticals	Novo-Nordisk	Contract manufacturing of formulations
Strides ArcolabLimited	GSK	Supply of drugs for semi-regulated markets

Source : ICRA Limited. 'CRAMS India: Overview & Outlook'. June 2011

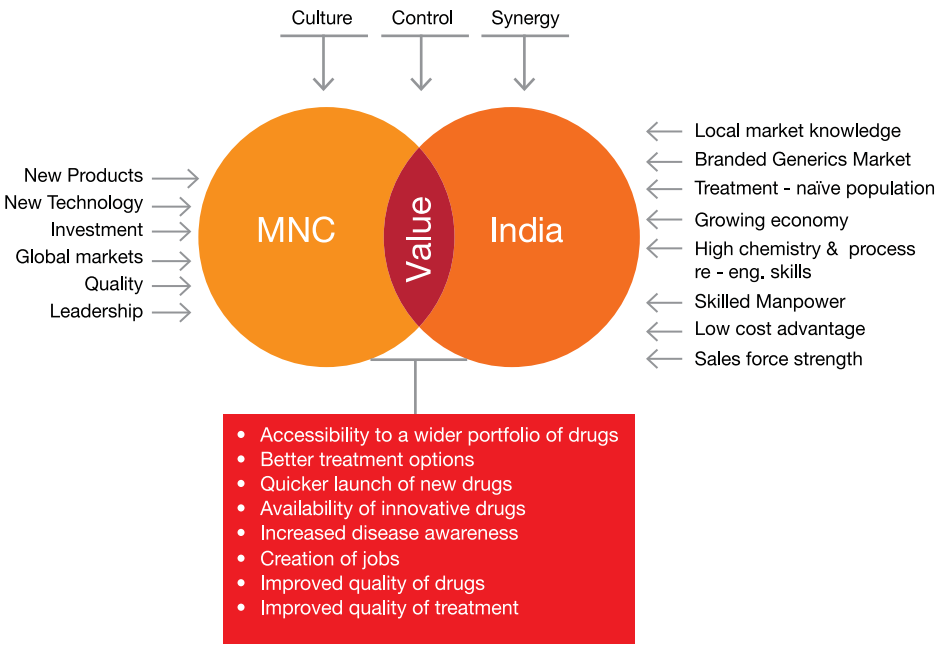
Benefits of collaboration

Pharma MNCs collaborating with Indian companies bring to the table new products, latest technology, higher investments, quality systems and the knowledge of regulatory processes. On their part, Indian companies provide local market knowledge, cost advantage and local scientific talent. Such alliances have the potential to bring significant benefits to both parties and add value to society as a whole. Such partnerships bring in new drugs and therapies to the market and increase patient's awareness about diseases and wider treatment choices available.

Success drivers

PwC's survey of opinion leaders in the Indian pharma industry revealed that issues related to quality, management control, corporate governance, valuations, cultural issues and understanding local regulations were crucial for any form of collaboration.

Benefits of collaboration



Success Drivers

1. Importance of quality

As a result of increasing alliances and the growing importance of Indian pharma globally, prominent Indian pharma companies have come under the scanner of the US Food and Drug Administration (USFDA) for varying degree of quality issues.

In India, USFDA audits and pre-approval inspections typically focus on the following:

- Management roles, responsibilities and training of personnel operating in USFDA-approved facilities
- Filed application integrity with specific attention to records, manufacturing systems and laboratory test results
- Monitoring of impurities in APIs and drug products
- Stability studies and investigation of out-of-specification (OOS) incidents
- Safety and integrity of the supply chain

While the impact of this regulatory crisis on alliances formed cannot be muted, the more critical issue is its impact on future alliances and on the overall image of the Indian pharma industry.

Given the mounting internal and external pressures on pricing and healthcare costs, MNCs are still bound to look at India as a low-cost manufacturing destination as well as a strategic partner for specific operations. The key consideration for such MNCs is to choose a partner after conducting a thorough investigation and with due diligence. While financial diligence is a standard and an integral part of all deals and alliances, the pharma industry needs a more in-depth operational approach prior to selecting a partner.

Aspects to focus on include the following:

- Historical review of internal and external regulatory audit data
- Extent to which audit findings have been remediated
- Mechanisms put in place to ensure implementation of adequate corrective and preventive actions
- Regulations in place to ensure sustainability of quality system improvements
- Overall review of quality systems implemented

Companies often require domain specialists to understand the true nature of the above issues. A thorough operational diligence can help understand the appropriate measures that can be implemented to mitigate any risks associated with quality.

2. Transaction-related drivers

In addition to quality related issues, attention needs to be focussed on the following determinants too. These need to be discussed and resolved to the satisfaction of both the parties involved in the A&P:

- Management control
- Corporate governance
- Expectations of valuation
- Cultural differences
- Local regulations

M&A along with A&P have a major role to play in changing the dynamics of the industry and taking it to the next level of growth.

A&P are likely to be more popular, as they are mutually beneficial to both stakeholders. It can help Indian companies scale the innovation curve, while at the same time helping to increase the drug pipeline curve for global players. India's low-cost manufacturing capabilities will also help pharma MNCs meet the increasing global demand of generics.

To ensure successful partnerships, issues such as quality, valuations, management control, corporate governance and cultural differences need to be identified, discussed and resolved through an in-depth financial, tax and operational diligence.

No one size will fit all and companies will hav eto choose and implement the path that best meet their strategic objectives.

Bringing cost efficiencies

With increasing pressure on the global healthcare industry to cut costs, pharma companies will have to look at different avenues to achieve it. Efficient operations, management of the supply chain and transfer pricing are key areas where cost efficiencies can be achieved.

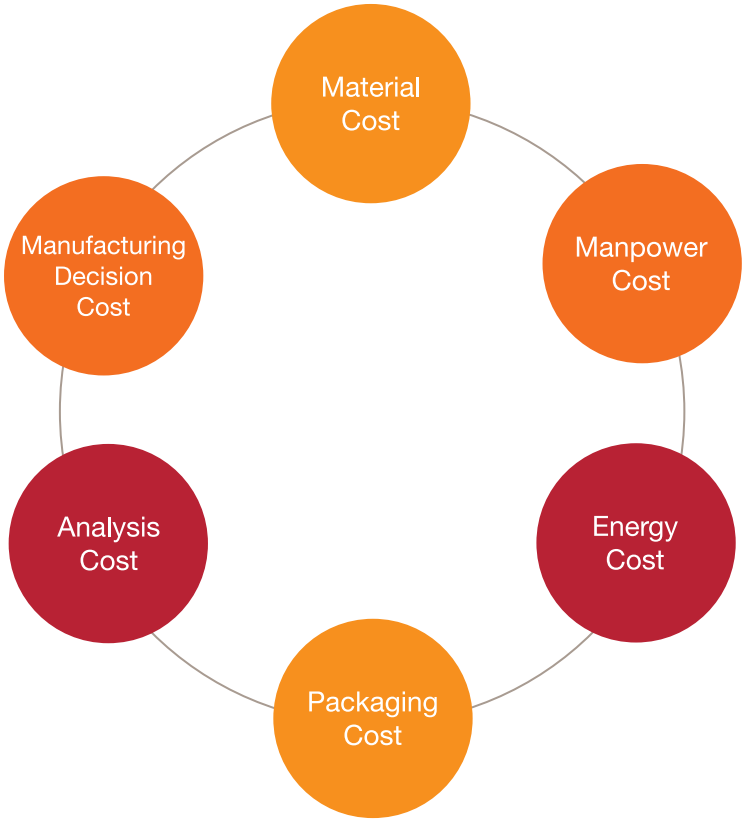
Operations improvement

Pharmaceutical companies can achieve year-on-year cost reduction in their overall spending by rigorously identifying and eliminating wastes in their manufacturing and business processes.

Today, for many companies, manufacturing costs, as a fraction of overall costs, is considerably higher. Therefore, it is quite logical to start with a cost reduction exercise in manufacturing.

Elements of cost reduction

Like any other industry, pharmaceutical cost has several direct and indirect costs:



Currently, pharma companies are taking a hard look at various cost elements and are coming up with various innovative ways to reduce them.

Material cost: Around, 60 to 70%[23] of pharma manufacturing cost is influenced by raw materials. Therefore, controlling material costs is one of the most important areas that companies need to focus on. Leading pharma companies are launching several improvement programmes to control these costs.

While the sourcing teams focus on getting materials at a competitive landed cost, many leading API players are undertaking initiatives to improve batch yields and the consumption of critical input materials.

Project teams use the DMAIC methodology to understand the reasons behind yield loss and implement an action plan towards improvement. Today, companies set year-on-year targets for improvements in yield, which in turn get converted to the budgeted

yield numbers in the next financial year. This acts as a financial control for ensuring sustenance.

API companies use various levers and also fundamentally question the type and quantity of solvents required in the process. Companies have in several instances been able to improve the recovery of solvents by identifying and addressing the source of loss. Some companies have also adopted a better solvent management process and have been able to eliminate a few solvents, either by adopting an alternate solvent or by an alternate manufacturing process.Similar efforts are initiated by formulations players in terms of improving their rolled throughput yields. Companies are looking at various factors including breakages, powder losses, etc to improve yields. They are also effectively embracing various concepts of lean to eliminate wastes in their processes.

Manpower cost: Like others, the pharma industry also faces challenges such as an average 15%[24] growth in salaries and an approximate 20%[25] attrition rate at operative and executive level. This puts pressure on manpower costs, as the costs of recruitment constantly increase.

Therefore, controlling manpower cost is becoming an important agenda item for the top management. On an average, the pharma industry spends around 7 to 10% on manpower costs. This is slightly higher as compared to the overall average.

Most companies struggle with the question as to what is the right manning number. The industry defines manning for each function based on certain thumbrules (like 'x' chemists per HPLC, 'y' scientists per project, etc.), that make it difficult to identify the right number. Moreover, the industry is also struggling with increased requirement for casual labour. A majority of the pharma companies have started to think in terms of defining manning norms. From a shop-floor viewpoint, the more the number of people on the shop-floor, the greater are the chances of error and mix-ups.

These questions exist for all levels of staffing:

- Managerial
- Operative
- Casual

Leading companies are controlling cost by defining manning norms. In PwC's own experience, a correct manning exercise involves the following:

- Activity driver based work load analysis
- Shared services and resource analysis
- Span of control studies
- Process improvement for work simplification

Energy: The pharma industry uses a variety of utility equipment, including boilers, air compressors, chillers, brine units, air handling units (AHU), vacuum pumps, DG sets, etc. These machines use electricity, coal and furnace oil as sources of energy, all expensive and subject to active cost reduction exercises.

Savings in operating these units primarily result from ensuring efficiency of these machines and preventing wastage. Companies typically look at generation, consumption and distribution efficiencies.

Benchmarking key performance parameters, such as efficiency, power consumption per unit generated, etc, of utility machines can give insights into corrective actions required. Utility requirements are very specific to the process and companies can do well to link utility consumption with production planning to optimise consumption and reduce wastage. PwC's experience suggests that energy costs can be dramatically reduced by synchronising planning and averaging out peak loads through proper scheduling.

Most organisations today carry out rigorous energy audits and take several steps including replacement of old energy-guzzling equipment with new state-of-the-art energy-efficient equipment. Companies are adapting themselves to green technologies to save energy costs.

This also contributes towards sustainability.

Packing costs: Packing costs are typically higher for formulations as compared to API. Packing costs can be reduced by at least 10%[26] by reducing packing rejections and by value-engineering the packing design. Companies use several factors for reducing packaging cost. These include strip dimensions, number of colours used, packing material thickness, optimal fitment of tablets within strips, number of ply, shipper sizes, etc. PwC's experience suggests that while primary packaging is a function of stability, companies do well by addressing elements of dimension and wastages in primary packing.

However, packing designs generally have a long gestation period as they are subject to customer approval. Hence, the benefits of these normally accrue over multiple years.

Analysing costs: Quality costs (QC) in most organisations were not tracked and it is only recently that organisations have started looking into this.

Today, organisations have gone beyond the scope of production and have tried to implement cost containment in quality control functions by reducing cost of analysis. Companies use factors such as material substitution, optimising quantities drawn for sample analysis, reduced testing, standardising makes of chemicals across sites, clubbing samples to be cost-effective, while at the same time adhering to delivery dates, enhancing equipment utilisation and identifying optimum manning norms.

Cost of manufacturing decisions: Cost of manufacturing decisions work primarily at the strategic and tactical domain, where the companies take decisions on the following:

Strategic	• Where should the plant be located? • What are the RM and FG transportation costs? • What is the technology and infrastructure such as reactors, layout, material handling systems, etc. to be utilised? • What is the planned capacity utilisation of the plant?
Tactical	• What should be the batch sizes to operate? • How much should be the inventory in process? • What is the production planning philosophy to be used? • Which are the products or intermediates to make or buy?

Planned versus actual capacity utilisation will have an impact on product costing in terms of apportioning fixed costs over the quantity produced. Planning during the project phase ensures minimum time and cost overruns. This reduces the cost of setting up the project. The cost of these decisions is high, and so is the impact they have in the medium to long term.

Companies need to evaluate their make-buy decisions more rigorously on the back of contribution earned. Appropriate technology selection, plant location and layout and production planning influence cost of production.

Levers for cost reduction

Companies do implement manufacturing cost reduction programmes using levers such as process improvements, shared services, standardisation, first principle costing, efficiency improvement, etc.

Each of these levers needs to be addressed along two dimensions, strategic and operational. Decisions for strategic cost reduction will have a long- to medium-term impact. However, the complexity will be high. In operational cost reduction, the impact will be for the immediate or medium-term but relatively less complex.

Many progressive companies use lean management as a concept to identify and eliminate wastes in the process, thereby resulting in additional throughput and better service levels at a lower cost. Companies have realised 10 to 15%[27] reduction in overall costs and improvement in bottom-line savings by implementing structured cost reduction programmes.

The Indian scenario

Riding on the back of 12 to 13%[28] year-on-year growth, the Indian pharma industry is going through a very interesting phase. It is rapidly achieving a distinctive position in the global pharma space with generics, Contract Research and Manufacturing Services (CRAMS) and clinical trials. Also as foreign MNCs fight for a share of the market, the fragmented domestic market is poised for consolidation. In this scenario of increased competition, companies will try to differentiate on the basis of speed-to-market, cost competitiveness, quality, customer orientation and distribution reach in domestic markets. With these challenges, the Indian pharma industry is seriously evaluating the ways and means to reduce operation costs.

The recently concluded lean implementation in the pharma industry survey conducted by the Organisation of Pharmaceutical Producers of India (OPPI) and PwC revealed some interesting evolving trends. Almost all participants cited improving service levels to the customer as one of their prime business needs, while reducing cost and improving profitability came a close second. So, while companies today are focussing on customer-centric metrics, they are also focussing on delivering customer value at lower costs.

The survey reveals that companies are targeting improved service levels but at competitive costs.

It is clear that the Indian scenario is a peculiar one and delivering service and cost competitiveness need to go hand-in-hand. To achieve sustainable improvement programmes, companies need to execute holistic programmes. The journey is difficult, but the rewards are fast and considerable.

Supply chain efficiencies

As Indian companies look forward to market growth on one side and the need to reduce costs on the other, an agile, customised and cost-efficient supply chain is of paramount importance. Companies in many industries have taken pruning shears to their supply chains to support profitable growth. Until recently, pharmaceutical companies did not embrace this trend. However, the industry can no longer afford a laissez faire position on the operation of their supply chains.

Why focus on the supply chain

The contributors to growth of the Indian pharma market such as increasing disposable incomes, greater health insurance penetration and a gradual shift in disease profile pose several questions on the existing supply chain configuration:

- Is the existing supply chain capable of supporting market creation (e.g. a supply chain that supports reach and coverage in the growing peri-urban markets, cold chain for biotech, etc)?
- Is there a need to tailor the supply chain across markets (Tier I, Tier II and rural) and disease profiles to support varied approaches in terms of products, pricing and sales coverage?

The nature of distribution such as fragmented channel, channel power of stockists, limited visibility and push-based supply also acts as a tipping point for overhauling the supply chain.

Key concern areas

Some of the key concern areas with the supply chain include the following:

- High logistics cost ranging from 4.72 to 6.22% of sales as against 0.5% in the US and 2% in Europe.[29]
- Ineffective control over channel inventory: 46 days for a pharmaceutical company as against 26 days for an FMCG company.[30]
- Low ARPUs per stockist and retailer
- Porous supply chain facilitating easy entry of counterfeits
- Sub-optimal penetration of the rural market
- Inadequate access to secondary and tertiary sales information critical to planning processes
- Inadequate infrastructure to support compliance to CGMP in the distribution chain

Analysis of the reasons behind the failure of the supply chain in meeting challenges of market growth points to a variety of practices within the Indian pharma industry. These need to be addressed if efforts to create an agile, responsive, customised and cost-effective supply chain are to be met.

- *Pharma supply chains operate on a pure push:* Salvage net is the cost incurred by a pharma company due to expiry and breakages of products in the market or at other storage locations. This is created due to the multiplying effect of inefficiencies in the supply chain. Some of the key reasons behind this include the following:
- Push-based supply to depots, stockists and retailers
- Misalignment between sales and supply chain organisation on timing (start and end) of promotions
- Budget-driven forecast leading to forecast bias, mismatched planning horizon on account of sales visibility and supply lead times
- Sub-optimisation at each stage of supply chain impacting inventory velocity
- Inventory imbalance across stock points
- Lack of visibility on products nearing expiry

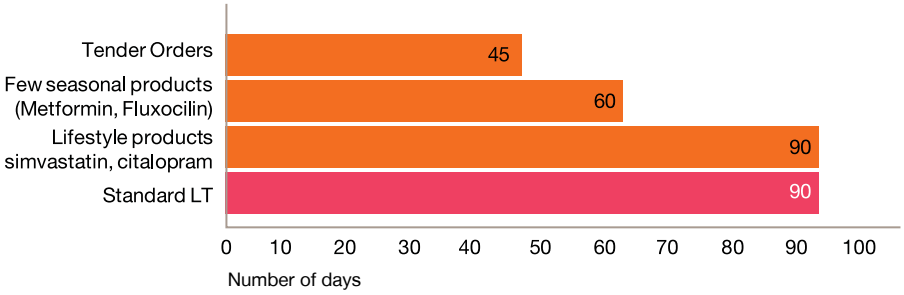
- Inefficient warehousing processes related to storage, handling and retrieval
- Batch size economics in transportation, manufacturing and procurement

PwC believes that effective synchronisation between the supply chain function and other organisational functions like sales and marketing, finance and IT can lead to a reduction in salvage net.

- *Homogenous supply chain catering to varying customer needs:* A homogenous supply chain operating on a standardised lead time restrains pharma companies from effectively capitalising on all business opportunities. The lead time required by the customer varies across product and markets. The figure below illustrates an example of how lead time expectations vary across products and markets.

Pharma companies will have to tailor their supply chain strategy after understanding the requirements along the cost and responsiveness frontiers.

Lead time in number of days



Goods and services tax (GST)

As seen in our previous report, India Pharma Inc: Capitalising on India's growth potential, GST is a comprehensive value-added tax (VAT) on the supply of goods or services. The GST will bring with it opportunities to realise efficiencies and related challenges.

The pharma industry (including FMCG)is significantly affected by GST, since it disadvantages the classic manner of concentrated manufacturing and disaggregated distribution across a national level C&FA/warehousing mechanism.

At present, the biggest challenge for a pharma distribution company is the movement of goods across India, to cater to the need of each state and thus save the CST payable otherwise on such inter- state movement.

Also, several entities set up warehouses in attractive locations like Daman as the CST rate at such locations was previously lower than the rates prevalent in other states.

This logistical challenge and the added cost of compliance will become a focal point of attention, post GST.

The distribution team needs to re-ascertain the warehousing locations from a commercial and logistic point of view rather than from a pure tax-saving perspective. Reduction in such warehouses will reduce the cost of distribution.

It is important for the pharma sector to understand the implications and challenges arising out of GST and to ensure that the business model and supply chains are re-engineered to maximise benefits.

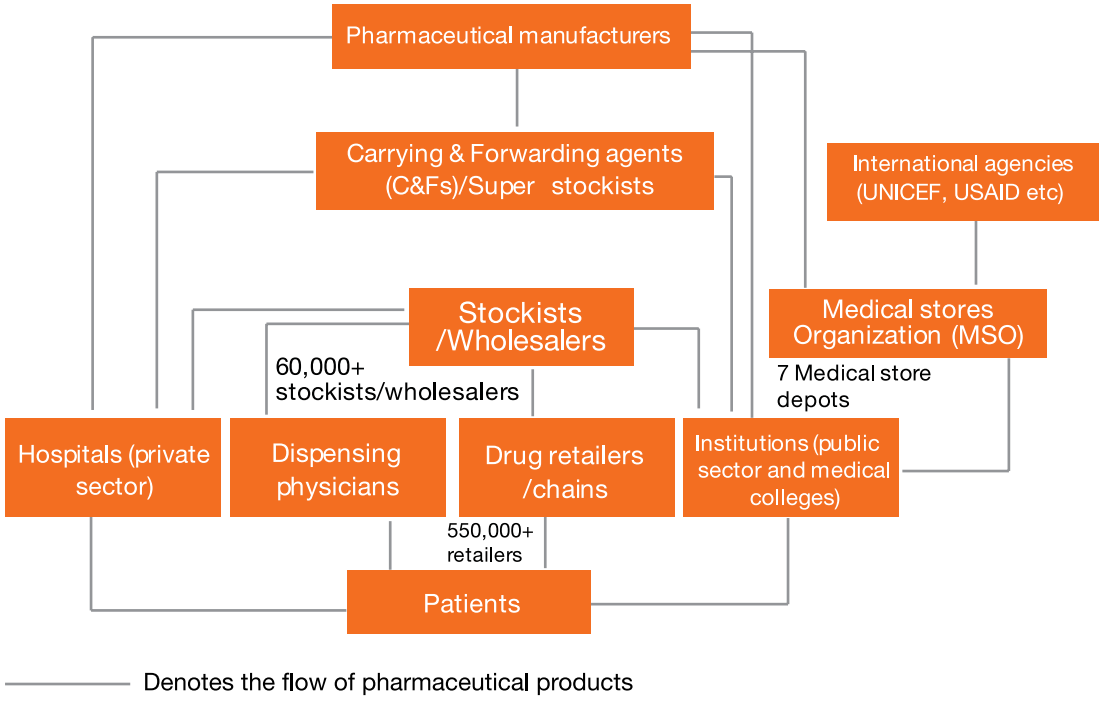
- *Sourcing from a perspective of aligning demand to supply often overlooked:* Production plans at pharma companies are governed by the availability of raw materials rather than being aligned to customer demand. The lack of a diversified supplier network constrains the pharma company from aligning demand and supply, thereby creating inefficiencies in the supply chain.

All these factors lead to significant value erosion. To participate in future growth, the pharma supply chain will need to focus on the following dimensions:

- Channel management
- Supply chain planning
- Supplier relationship
- Outsourcing
- Security and compliance
- IT

Mitigating fraud in the Indian pharma supply chain

The worldwide scale of pharmaceutical operations is creating supply chains that are extensive and globally dispersed. This introduces heavy reliance on third parties and increases the risk of fraud. In particular, India's supply chain uses a fragmented distribution network depicted in the chart below:



Source: Overview of the Indian Pharmaceutical Market (2010) published by Datamonitor

A typical organisation loses 5% of its annual revenue to fraud. When applied to the estimated 2010 size of the Indian pharma market, this figure translates to a potential total fraud loss of more than US$ 600 million. Managing risks and fraud is therefore a key area of concern for Indian and global pharma companies.

Fortune 500 pharma companies have established whistleblowing reporting mechanisms which allow employees to raise concerns and seek guidance. They have also initiated the concept of anti-retaliation protection to ensure that all employees can safely report potential violations.

These companies are developing robust compliance programmes based on their 'dipstick assessment' of business conducted by subsidiaries or affiliates in Brazil, Russia, India, China (BRIC) and east European countries. Such programmes are being rolled out worldwide to ensure consistency in compliance globally with specific focus on entities that were rated unsatisfactory in the dipstick assessment.

To identify processes vulnerable to fraud, companies are conducting an enterprise-wide assessment of existing fraud risks on a pro-active basis. This assessment considers risks involved and the potential schemes to circumvent existing control activities.

So, to avoid fraud and risk, companies need to adopt many of the general tenets of good supply chain management. They need to establish a culture that supports control efforts and whistleblowing with clear, ethical guidelines. They need to build loyalty within the organisation, give employees the confidence to do the right things and identify clear conditions for those who commit fraud.

Managing transfer pricing (TP)

Introduction of the concept of "Transfer Pricing ('TP')" is a measure adopted by the governments to ensure the protection of the tax base of their respective countries. TP refers to the basis adopted by a company while transacting with its group companies such that the same reflect pricing and conditions similar to those adopted in transactions undertaken between third parties.

In current times, where pharma companies are espousing austerity measures on several counts to remain cost-competitive, it is important for companies to understand TP issues and prepare an upfront defence so as to mitigate future litigation. TP principles will also aid phama companies to effectively plan their business operations.

This chapter digs deeper into the overview of the current Indian TP environment, key TP challenges for the pharma industry and planning opportunities using TP principles.

TP environment in India

Introduced in 2001, Indian TP regulations are broadly modelled in line with global practices including TP guidelines issued by the Organisation for Economic Cooperation and Development (OECD).[31] Indian revenue authorities have so far completed six rounds of audit and have made an astronomical adjustment of about Rs 54,999 crore.

Prominent TP challenges faced by Indian pharma companies:

- Comparison of import price of original API with price of generic API
- Comparison of the export price of the product(s) with its price in the domestic market
- Benchmarking clinical trial support services provider with clinical research organizations (CROs) and thereby expecting higher mark-ups
- Expectation of higher mark-ups for contract R&D services provided
- Seeking justification or commercial rationale for the payment of royalty or management fee by the Indian taxpayer and
- Alleging creation of marketing intangibles due to the promotional spends incurred by the Indian taxpayer

Key TP issues in the pharma industry

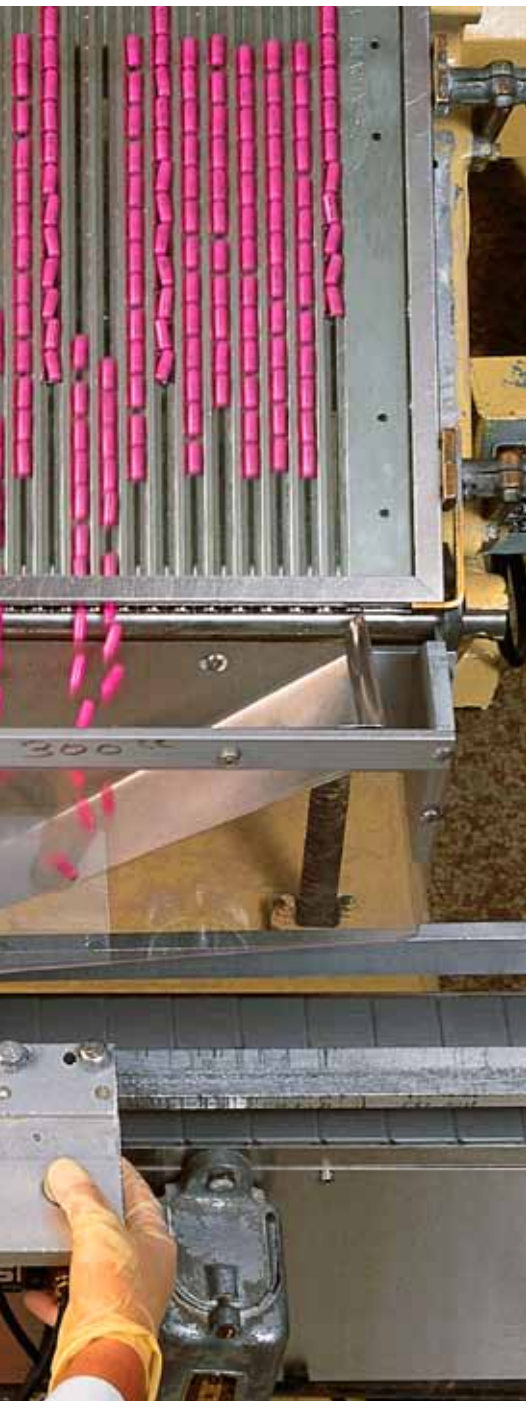
Owning significant intangible property deployed across geographies) coupled with the multitude of cross-border transactions, Pharmaceutical industry has been exposed to some of the most significant TP litigation over the years. From an Indian TP perspective, following are the prominent challenges faced by the Pharma companies: Please see the side bar for details.

Possible solutions

- *API prices comparison*

Globally, the comparison of original (branded) API with generic API is one of the most contentious issues faced by pharma companies. The same has taken centre stage in the Indian TP context with the Income-Tax Appellate Tribunal (ITAT)[32] ruling on the issue in case of UCB[33] and Serdia.[34] While in the case of UCB, ITAT ruled that original API cannot be compared with generic, in the case of Serdia, ITAT upheld the validity of such a comparison.

These rulings raise the question if such a comparison is valid and if not, how the arm's length nature of the imported API (branded) should be established. Instead of focusing on the technical difference (such as quality, efficacy, potency, etc.) in the two APIs, one can establish the appropriateness of the margins earned by the Indian company with regard to its functional profile



(i.e., functions performed, assets employed and risks assumed).

- *High mark-up for support and facilitation services*

A possible defence for the high mark-ups anticipated by the tax authorities for the support services (such as clinical trial support, procurement support etc.) provided by Indian taxpayer lies in demonstrating the level of the activities performed by the Indian taxpayer and its relative contribution in the value chain.

To develop a transfer pricing defence, the actual business conduct should be in sync with the underlying characterisation and should be supported by robust documentation.

- *Business restructuring*

Business restructuring, involving cross border redeployment of functions, assets and risks is often undertaken by the pharma companies to streamline their business operations. Commercial reasons such as increased competition, cost optimization, elimination of duplicative functions, need for centralisation, proximity to market etc. compel the pharma companies to adopt restructuring. Business restructuring often results in achieving significant tax optimisation by realigning the distribution of profits across geographies.

The objectives and practical implementation of a business restructuring are effectively achieved by the application of TP principles i.e., an entity's remuneration is linked to the function it performs, risks it assumes and the assets it employs.

While business restructuring offer business advantages, such exercise also pose significant risks, including the potential for significant transfer pricing adjustment. Therefore, it is imperative that any restructuring is undertaken after duly considering the established TP principles.

The road ahead

Going by the trend, the challenge of audit and the level of dispute (from tax authorities) faced by this industry will increase. Therefore, it is in the best interest of pharma companies to adopt a more proactive approach to set and monitor their TP policies. They should also maintain robust documentation to support the basis for setting these policies. Apart from being viewed as compliance requirement, TP should be used to optimise business operations too. Given the nexus of TP to both tax and business, effective coordination between an organisation's tax and business functions is required to make the best use of TP principles. TP is not about documenting the end result, but about documenting the journey.

Newer growth trends

Pharma companies will need to create meaningful partnerships with organisations in other industries like health insurance, medical technology and IT to drive growth. In addition, they will have to devise strategies to make growth inclusive and sustainable.

Health insurance

Less than 15% of the Indian population is covered under any form of health insurance, including government-supported schemes. Only around 2.2% of the population is covered under private health insurance. The awareness of health insurance schemes in rural areas is disturbingly low. Health insurance is, however, expected to grow at a CAGR of 15% by 2015.[35] Given the diversity of India's population and its limited purchasing power, innovative insurance products at multiple price points are needed to tap the market.

The union government rolled out an insurance plan for the poor, Rashtriya Swasthya Bima Yojana (RSBY) which provides medical cover for families below the poverty line (BPL). It includes hospitalisation, out-patient treatment and surgical treatment in select hospitals. The medical insurance provides an annual cover of Rs 30,000 per household and covers five members of a family. Plus, transport allowance of up to Rs 1,000 a year is given to BPL families. The scheme is administered through biometric smartcards with two smartcards issued to each family. One of the cards makes it possible for a worker based in a particular state to move to another place and continue to be part of the scheme. The premium amount of the scheme is shared by the union and state governments in 75:25 ratio, with a nominal amount of Rs 30 being paid annually by the beneficiary. Till date, RSBY has been successfully extended to 23 million poor families in 330 districts in 27 Indian states.[36] Beneficiaries are free to avail of healthcare from any empanelled government or private hospital of their choice.

Two private trusts, the IFMR Trust that provides rural finance to 1.7 lakh households and the Manipal Education and Medical Group covering 80,000 families, were recently given the approval to participate in the RSBY scheme. The two trusts together will add nearly 2.5 lakh families, a development that promises to alter the delivery of healthcare to the poor.

The government is examining the possibility of turning its two important social sector programmes--old age pension scheme for the BPL and the Aam Aadmi Bima Yojana (AABY) targeting the rural landless--into universal schemes covering the unorganised sector in phases. The two schemes will be linked with the smartcards given under the RSBY scheme. If implemented well, they can help beef up the grossly inadequate social security cover available to the poor in the country.

RSBY is attracting a slew of entrepreneurs to set up hospitals primarily targeted at the rural population. Looking at the trend of private hospitals' participation, the government wants to introduce public-private partnerships, wherein the role of the government will change from that of a provider to that of a payer.

In a recent PwC publication Healthcare Unwired, we have listed recommendations and specific solutions to improve the reach of health insurance. Some of these measures include creation of a new business model, reducing premiums and collection costs, switching from patient cure to preventive care and simplifying policies and regulatory reforms in the healthcare and health insurance space. Initiating these measures will result in increased penetration and improved coverage of health insurance in India.

Medical technology

Medical technology plays a pivotal role in improving access to affordable healthcare services. It also helps early diagnosis of diseases and creating personalised therapies for the Indian population.

The Indian medical technology industry, which comprises medical equipment, medical implants, medical disposables and furniture, is expected to grow from US$ 2.75 billion in 2008 to US$ 14 billion[37] in 2020, at a compounded annual growth rate of approximately 15%.

Innovative initiatives[38]

- Transasia Biomedicals has developed in-vitro diagnostic equipment through its R&D base in Mumbai.
- Sushrut Adler Group has developed an external fixator through its facility in Pune.
- Johnson & Johnson has developed a knee implant suitable for the Indian market as well as a reusable stapler for use in surgeries, both at amenable price points for the Indian market.
- Roche Diagnostics has developed a screening device for cardio-vascular disease suitable for use in rural settings too.
- GE Healthcare has developed a low-cost ECG machine and a low-cost ultrasound machine for the Indian market.
- Philips Healthcare is using its recent acquisitions in India to develop and launch a low-cost cath lab for the Indian market.

Post independence, India adopted an import substitution policy for the development of indigenous industries under the umbrella of a strong public sector. The medical technology sector, however, was not on the list of government priorities. Also, no pathbreaking effort was made to build domestic capabilities in R&D and manufacturing. The seeds of import reliance were thus sown in the early years of free India. The reliance on imports continued in the subsequent years in spite of high import duties and tariffs. Today, 80% of the medical technology market is through imports.

The last few years have seen an increase in the domestic manufacture of medical equipment. With impetus from the government, India is finally being recognised as a manufacturing destination for sophisticated medical technology. International medical technology companies are also using India as a manufacturing base by either setting up facilities of their own or by acquiring domestic manufacturers.

There is also a strong need of innovation in the medical technology market given its ground realities. Innovation in medical technology, however, faces challenges that need to be addressed by the government. Some of the steps which the government can take include the following:

- Increase public spending in healthcare from 1% of GDP to 3%.
- Usher further reform in the insurance sector to stimulate health insurance.
- Set up a venture investment fund to address the lack of early stage venture capital.
- Ensure a level playing field for all companies with a distinct regulatory pathway for medical technology free of ambiguities.
- Make research a rewarding career option.
- Reform the medical education system to include medical technology education with assistance from institutes like National Institute of Pharmaceutical Education and Research (NIPER).
- Evolve medical technology clusters with common facilities for the benefit of small entrepreneurs who want to set up companies focusing on medical technology.
- Assist existing manufacturers to upgrade their quality systems to match international standards.

Medical technology is a nascent sector in India and the opportunities for innovation-led growth are immense. Innovation in medical technology requires a vibrant and participative ecosystem comprising patients, medical centres, universities, the industry, health insurance companies and the government. All stakeholders have to act in concert for the sustained growth of the industry and the benefit of patients.

Information technology (IT)

Many pharma companies have entered into strategic partnerships with Indian IT companies in areas of pharmacokinetic modelling, data management and validation, pharmacovigilance, etc.

Pharma	*IT*	*Objective*
BMS	Accenture	Clinical data and document management, pharmacovigilance and scientific writing
GSK	Tata Consultancy Services	Clinical data management and clinical submission support
AstraZeneca	Cognizant Technology Services	Clinical data management, clinical study set-up for electronic data capture, medical coding, adverse event reconciliation
Elan	Infosys	Co-creation engagement model to design and implement research informatics system
Eli Lilly	HCL	Co-innovation hub to accelerate the process of bringing ideas to fruition

Source: Industry & PwC Analysis

Mobile health

Mobile technologies are also finding their way into areas like disease awareness, disease management, patient compliance to drug schedules, etc.

Mobility solution provider	*Pharma application*
Nokia	Diabetes disease management
Univercell	Medi alert
Sproxil	Mobile product authentication

Source: Industry & PwC Analysis

Sustainability

In recent years, addressing various sustainability issues has become increasingly important for the pharma industry. Sustainability is about long-term value creation not only for businesses but also for all stakeholders such as employees, customers, the industry sector, investors and the communities where the company operates.

Indian companies have started sustainability programmes on the lines of their global counterparts. They are at various stages in their journey on sustainability reporting. An analysis of the sustainability reports of these firms identifies similar trends as those initiated by global majors. They develop CSR programmes which focus largely on improving environmental performance of their operations and providing better access to medicines.

Companies are also partnering with suppliers to improve their sustainability performance. Most other companies have programmes focusing on social initiatives to improve local infrastructure, economic and social conditions, organising various medical camps, providing free consultations and treatments and raising awareness about HIV-AIDS.

Companies report extensively on their initiatives and performance, but do not focus on how to improve their communication and the reach of their sustainability programmes in India.

Conclusion

The Indian pharma industry is on a major growth trajectory and is expected to reach US$ 74 billion by 2020. In order to realise the full potential of the market and tap growing global opportunities, companies operating here will have to collaborate in a mutually beneficial manner.

As we move into the next decade, mergers and acquisitions, partnerships and licensing will drive future growth. MNCs will not be averse to acquisitions but high valuations will make M&As expensive in India. Alternatives such as alliances and partnerships will actually prove to be more flexible and value-enhancing in the long term.

MNCs can benefit from the local market knowledge of Indian companies, the strength of their sales force and significant cost advantage across drug development and the manufacturing process. Global pharma companies have the capability of bringing in newer products, technology, capital and quality leadership. They can help their Indian counterparts in their desire to ascend the innovation curve.

However, alliances and partnerships face significant challenges of quality, valuation,

management control, corporate governance as well as cultural issues. Success will depend on thorough due diligence of quality aspects, appropriate valuation and synergy derived from the association.

Given the price-sensitive nature of the Indian consumer as well as cost pressures from developed economies, pharma companies will have to focus on improving operational efficiencies. Creating an agile and responsive supply chain that is operationally efficient and minimising the incidents of supply chain fraud will be of significant importance.

At the same time, companies entering cross border transactions should proactively set /monitor their TP policies and maintain robust documentation. This will assist companies in optimising their business operations.Health insurance is a significant driver for the growth of the overall healthcare market by improving access to state-of-the-art medicines and therapies. Medical technology can also help improve access to quality healthcare delivered in a cost-effective way. Medical technology will also help drive the trend towards personalised medicine. The medical technology sector needs to reduce its import reliance as well as create innovative products and solutions keeping in mind the realities of the Indian market. Government and industry must work together to reduce the barriers to innovation and create a vibrant innovation ecosystem to deliver patient-centric solutions.

In meeting the challenges of growth, pharma companies will have to ensure that it is sustainable. Pharma MNCs as well as large Indian companies are taking an interest in sustainability by implementing initiatives and reporting on their success in the areas of energy and water consumption, emissions and waste treatment and handling, access to medicine by using differential pricing and voluntary licensing.

The pharmaceutical industry in India is poised for a period of robust growth driven by alliances and partnerships. Success in the market will be dependent not only on pharma companies but also on other stakeholders like healthcare providers, health insurance companies, medical technology companies, government, patient groups as well as society at large acting in concert. How well they do will determine the future of the Indian pharma industry.

References

1. PwC Report-India Pharma Inc.: Capitalising on India's Growth potential, 2010
2. EP Vantage, 'Patent storm gathering strength' 28 January 2011
3. Redefining the Meaning of a Successful 21st Century BioPharma Company, "BioPharma and the String of Pearls"
4. PwC Report – Pharma 2020; Challenging Business Models, 2009
5. PwC Report – India Pharma Inc: Capitalising on India's growth potential, 2010
6. PTI, 'FDI in Pharmaceuticals to pass through filter', The Economic Times, 10 Oct, 2011
7. Bayer Healthcare Press release: 'Bayer and Zydus Cadila sign Joint Venture Agreement to strengthen pharmaceutical business in India' 28th Jan, 2011
8. Lupin Pharma Press release: 'Eli Lilly India and Lupin announce strategic collaboration to help fight the battle against diabetes' 29th July, 2011
9. Nina Mehta, 'Novartis ties up with USV to market Galvus in India' The Economic Times, 27th Nov, 2008
10. Khomba Singh, 'Modi Mundipharma in JV with Belgian co', Economic Times, 29th April, 2009
11. TNN, 'US pharma major Mylan buys Matrix Labs', The Economic Times, 29 August, 2006
12. Mohit Bhalla and Khomba Singh, 'US-based Hospira to buy Orchid Chemicals' injectables biz for $400 mn', The Economic Times, 16 December, 2009
13. ET Bureau, 'Sanofi-Aventis buys Shantha for Rs.3,740 cr', The Economic Times, 28 July, 2009
14. Glenmark Press release: 'Sanofi-Aventis and Glenmark Pharmaceuticals Sign License Agreement', 3 May, 2011
15. Jubilant Biosys Ltd Press release: 'Jubilant and Endo Pharmaceuticals announce Late Stage Discovery Milestone in Oncology Program' 20 June, 2011
16. GlaxoSmithKline Press release: 'GSK announces a strategic alliance with Dr. Reddy's to further accelerate sales growth in emerging markets', 15th June, 2009
17. Aurobindo Pharma Press release: 'Aurobindo Pharma Inks Marketing Deal With Pfizer For Finished Dosage Products', 3rd May 2009
18. Vishal Dutta: 'Pfizer ties up with Claris for injectables' Economic Times, 20 May, 2009
19. Biocon Press release: 'Biocon and Pfizer enter into Global Commercialization Agreement', 18th October, 2011
20. Merck & Co. Press release: 'Merck & Co., Inc., and Sun Pharma Establish Joint Venture to Develop and Commercialize Novel Formulations and Combinations of Medicines in Emerging Markets', April 11, 2011
21. IMS Health Market Prognosis, March 2011
22. Generics and Biosimilars initiative: 'Hospira looks to biosimilars and increased use of generics for growth' 16 September, 2011
23. PwC analysis, Moneycontrol website
24. C.H. Unnikrishnan, "Pharma salaries up 12% as India turns into top priority", 21 Dec 2010
25. C. H. Unnikrishnan, Rediff business, "High attrition plagues Indian pharma sector", August 2006
26. PwC analysis
27. PwC analysis
28. PwC report: India Pharma Inc.: Capitalising on India's Growth Potential
29. Eric Langer & Abhijeet Kelkar, 'Pharmaceutical Distribution in India', India Today (BioPlan Associates), September 2008
30. Sapna Dogra, 'Revamping the distribution network', Express Pharma, 1-15 May 2006
31. TP: Transfer Pricing Guidelines for Multinationals and Tax Administrations issued by Organisation for Economic Cooperation and Development
32. ITAT stands for Income-tax Appellate Tribunal which is a second level appellate authority
33. UCB India Private Limited v. ACIT 317 ITR 292 (2010)
34. Serdia Pharmaceuticals (India) Private Limited - ITANos:2469/Mum/06,3032/Mum/07 and 2531/Mum/08
35. NIC has 20 % share in BPL health insurance scheme, Hindu, Provider: Kasturi & Sons Ltd, March 2011
36. Private healthcare in rural areas gets RSBY push, Economic Times, May 12, 2011
37. NIPER Ahmedabad, Industry Analysis, PwC estimates
38. PwC Report: Enhancing access to healthcare through innovation, June 2011

Acknowledgements

We would like to express our gratitude for the input and help we received from the following experts who so generously donated their time towards the survey conducted for the report:

- S Kalyanasundaram – Chief Executive Officer, Sun Pharma Industries Ltd.
- K V Subramaniam - President & Chief Executive Officer, Reliance Life Sciences
- Prashant K Tewari - Managing Director - USV Ltd
- Ranjit Shahani - Country President, Novartis India Ltd.
- Satish Khanna - Chairman, Fullife Healthcare Pvt.Ltd.
- Vivek Mohan - Managing Director, Abbott India Ltd.

We also take this opportunity to thank all the following team members from PwC for their contributions to this report:

- Arun S Saripalli - Sr. Manager, Tax
- Darshan Patel - Associate Director, FAS
- Deeksha Vatsa - Associate Director, FAS
- Krishnakumar Sankaranarayanan - Managing Consultant, Consulting
- Nikhil Patil - Principal Consultant, Consulting
- Nisha Vishwakarma - Manager, India Pharmaceuticals & Life Sciences
- Madhur Rathaur - Director, PwC PRTM
- Prahalad Chadrasekharan - Managing Consultant, Consulting
- Suneel Aiyar - Associate Director, Consulting
- Shubhra Jain - Manager - FAS
- Vinita Vasanth - Experience Associate, PwC PRTM
- Malvika Singh - Brand and Communication

The views expressed herein are personal and do not reflect the views of the organisations represented by the individuals concerned.

About CII

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the growth of industry in India, partnering industry and government alike through advisory and consultative processes.

CII is a non-government, not-for-profit, industry led and industry managed organisation, playing a proactive role in India's development process. Founded over 116 years ago, it is India's premier business association, with a direct membership of over 8100 organisations from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 90,000 companies from around 400 national and regional sectoral associations.

CII catalyses change by working closely with government on policy issues, enhancing efficiency, competitiveness and expanding business opportunities for industry through a range of specialised services and global linkages. It also provides a platform for sectoral consensus building and networking. Major emphasis is laid on projecting a positive image of business, assisting industry to identify and execute corporate citizenship programmes. Partnerships with over 120 NGOs across the country carry forward our initiatives in integrated and inclusive development, which include health, education, livelihood, diversity management, skill development and water, to name a few.

CII has taken up the agenda of "Business for Livelihood" for the year 2011-12. This converges the fundamental themes of spreading growth to disadvantaged sections of society, building skills for meeting emerging economic compulsions, and fostering a climate of good governance. In line with this, CII is placing increased focus on Affirmative Action, Skills Development and Governance during the year.

With 63 offices including 10 Centres of Excellence in India, and 7 overseas offices in Australia, China, France, Singapore, South Africa, UK, and USA, as well as institutional partnerships with 224 counterpart organisations in 90 countries, CII serves as a reference point for Indian industry and the international business community.

Contacts

Charu Mathur
Regional Director
Confederation of Indian Industry (WR)
105, Kakad Chambers
132, Dr A B Road, Worli,
Mumbai - 400018
Phone: +91 22 24931790
Fax: +91 22 24945831 / 24939463
Email: charu.mathur@cii.in

Dev Ranjan Mukherjee
Head - CII Gujarat State and Head - Conference
Confederation of Indian Industry
Western Region - Gujarat State Office
CII House
Gulbai Tekra Road
Near Panchwati
Ahmedabad – 380 006
Tel: 079 40279900 - 10
Fax: 079 40279999
Email: dev.mukherjee@cii.in

About PwC

PwC firms help organisations and individuals create the value they're looking for. We're a network of firms in 158 countries with close to 169,000 people who are committed to delivering quality in assurance, tax and advisory services. Tell us what matters to you and find out more by visiting us at www.pwc.com.

In India, PwC (www.pwc.com/India) offers a comprehensive portfolio of Advisory and Tax & Regulatory services; each, in turn, presents a basket of finely defined deliverables. Network firms of PwC in India also provide services in Assurance as per the relevant rules and regulations in India.

Providing organisations with the advice they need, wherever they may be located, our highly qualified, experienced professionals, who have sound knowledge of the Indian business environment, listen to different points of view to help organisations solve their business issues and identify and maximise the opportunities they seek. Our industry specialisation allows us to help co-create solutions with our clients for their sector of interest.

We are located in these cities: Ahmedabad, Bangalore, Bhubaneshwar, Chennai, Delhi NCR, Hyderabad, Kolkata, Mumbai and Pune.

Contacts

Sujay Shetty
Executive Director,
India Pharmaceutical & Life Sciences Leader - PwC (India)
Email: sujay.shetty@in.pwc.com
Phone: +91 22 6669 1305

Nisha Vishwakarma
Manager, India Pharmaceutical & Life Sciences - PwC (India)
Email: nisha.vishwakarma@in.pwc.com
Phone: +91 22 6669 1100

www.pwc.com/india

This publication does not constitute professional advice. The information in this publication has been obtained or derived from sources believed by PricewaterhouseCoopers Private Limited (PwCPL) to be reliable but PwCPL does not represent that this information is accurate or complete. Any opinions or estimates contained in this publication represent the judgment of PwCPL at this time and are subject to change without notice. Readers of this publication are advised to seek their own professional advice before taking any course of action or decision, for which they are entirely responsible, based on the contents of this publication. PwCPL neither accepts or assumes any responsibility or liability to any reader of this publication in respect of the information contained within it or for any decisions readers may take or decide not to or fail to take.

© 2011 PricewaterhouseCoopers Private Limited. All rights reserved. In this document, "PwC" refers to PricewaterhouseCoopers Private Limited (a limited liability company in India), which is a member firm of PricewaterhouseCoopers International Limited (PwCIL), each member firm of which is a separate legal entity.

MS 239- October 2011 Pharma report .indd
Designed by: PwC Brand and Communications, India