Confederation of Indian Industry

Pharma summit 2012

India Pharma Inc.

Gearing up for the next level of growth

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Foreword

Welcome to the CII Pharma Summit 2012.

The Indian pharma industry is showing signs of healthy growth and is likely to be in the top 10 global markets by value by 2020. In order to drive profitable growth in the future, companies will have to rethink the way they do business today.

Recent trends like mobile health along with innovations in health insurance and medical technology are enabling the industry to deliver superior healthcare services. Further, the industry has seen many regulatory interventions over the last one year, which will require careful consideration by pharma companies as they plan their future strategies.

In this report, we look at the different types of growth levers that have fuelled the growth of the Indian market, emerging new business models, as well as the key success factors that need to be kept in mind to achieve sustainable long-term growth.

We hope this report presents an overview of some of the issues facing the industry today and throws light on the road ahead for all stakeholders, to realise its full potential.

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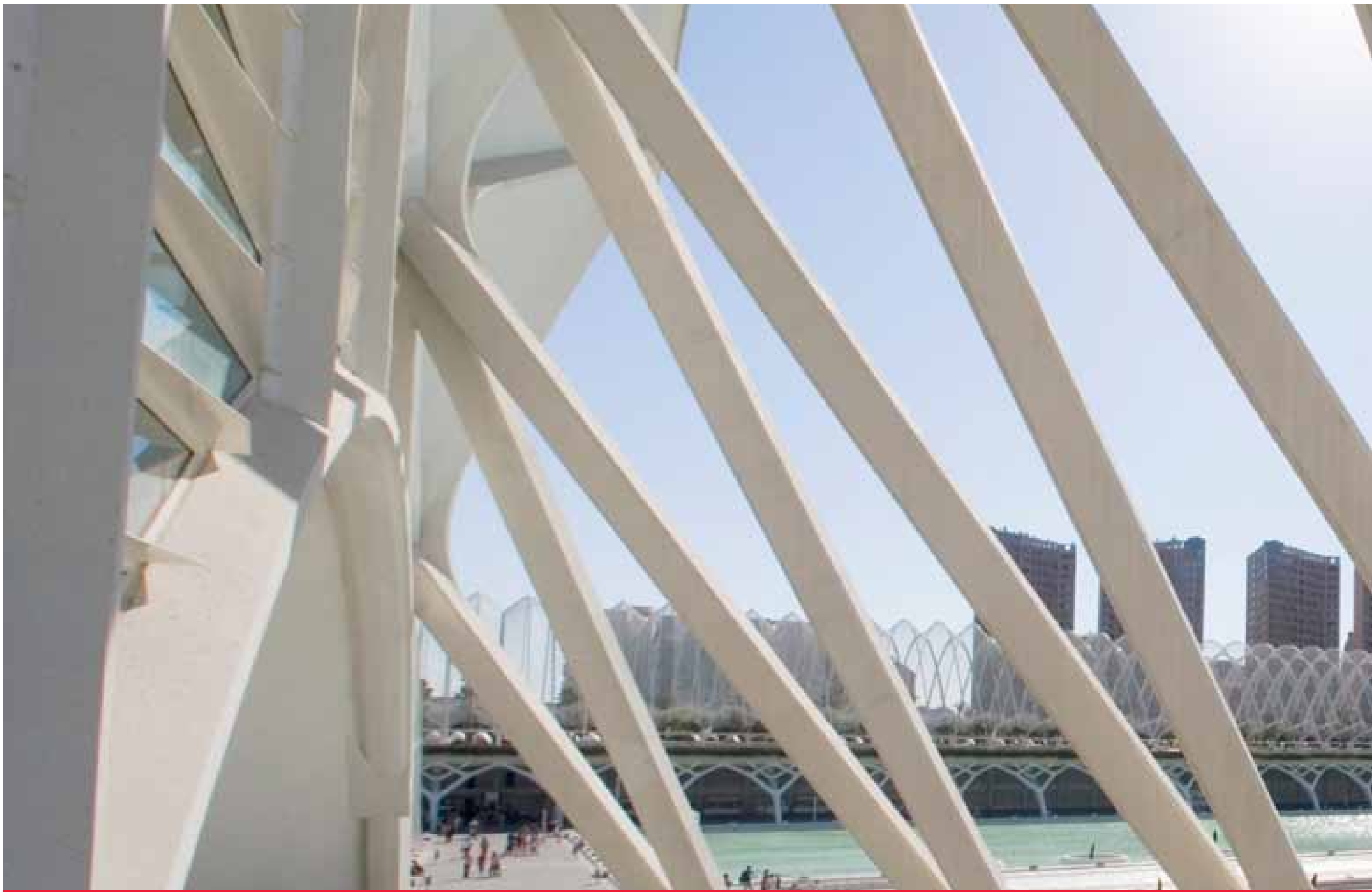

Executive summary

Globally, the scientific foundation on which the pharma industry rests has improved vastly over the years. Technologies for collecting and synthesising biological data are improving and becoming much cheaper and more efficient. However, in the short term, the industry continues to face challenges like patent cliff, rising drug discovery cost, harsher regulations and price controls, coupled with spiralling healthcare cost.

The worldwide sales of medicines reached 1.08 trillion USD in 2011 (an increase of 7.8% over the previous year) and are expected to reach 1.5 trillion USD by 2020[1]. The emerging markets represent the fastest-growing segment of the global pharma industry. Sales in the four BRIC countries (Brazil, China, India and Russia) were up by 22.6%[2] over the previous year, indicating that real surge in growth will come from the emerging markets. Most of the projected increase in revenues will come from branded generics rather than innovator products[3].

The Indian pharma industry is on a good growth path and is likely to be in the top 10 global markets by value by 2020. High burden of disease, good economic growth leading to higher disposable incomes, improvements in healthcare infrastructure and improved healthcare financing are driving growth in the domestic market.

Pharma companies are growing both organically and inorganically. Inorganic growth is happening through licensing and partnerships as high valuation of assets is making acquisitions difficult. Further, companies are organically improving their operations and productivity by increasing field force sizes, penetrating in Tier II and III cities and by expanding their product portfolios.

However, in order to sustain the growth in the long run, companies will need to modify their business models and connect with their customers faster and work on innovative ideas to serve them better.

Indian pharma companies have also capitalised on export opportunities in regulated and semi-regulated markets by growing at a CAGR of 21.5%[4] over from 2005 to 2011 and will continue to grow in these markets.

Other trends like increase in coverage of health insurance, advancement in medical technology and penetration of mobile health services will give further impetus to the growth of the Indian pharma industry.

The government of India is also considering a proposal to increase public expenditure on drugs from 0.1% of GDP to 0.5% of GDP[5] and provide free essential medicines to all. Further reforms are required in the insurance sector to include coverage of outpatient expenses and drug-related expenditure.

The Indian pharma industry has been facing several regulatory challenges like foreign direct investment (FDI) policy, pricing policy, patent protection, regulatory approvals and compulsory licensing, which require careful consideration by the companies as they think through suitable strategies in their pursuit of growth.

*Pharma 2020; Global perspective**

**This section contains excerpts from PwC's iconic Thought Leadership Paper 'Pharma 2020: From vision to decision' which will be released in November 2012*

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Our new report titled 'Pharma 2020: From vision to decision'[6] envisages a positive outlook for the industry. Globally, the industry is at the crossroads of many challenges and, at the same time, seeing new trends in technology that will help it break through some of the barriers that have previously held it back. Major scientific and technological advances, coupled with socio-demographic changes and increasing demand for medicines will revive the pharma industry's fortunes in another 10 to 20 years. But it will all depend on the decisions pharma companies will take between now and the end of the decade to capitalise on the opportunities the next decade holds.

Industry continues to face the classic problems:

- *The 'patent cliff'*
  Between 2012 and 2018, generic erosion will wipe an estimated 148 billion USD[7] off the pharma industry's revenues.
- *Rising drug discovery cost*
  Developing new medicines is becoming an increasingly expensive business[8]. Annual output of the pharma industry has effectively flatlined over the past years.
- *Increasing government pressure with harsher price controls and taxes*
  The rules governing the development and manufacturing of medicines are getting tighter. Both the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) now focus more heavily on risk management. The FDA is building an active surveillance system to monitor the safety of all medicines in the US market.
- *Greater collaboration of the regulators across the world*
  Regulators around the globe are working closely with each other, which means that a product rejected in one region is more likely to be rejected in others.
- *Changing marketing and sales model*
  The traditional marketing and sales model is becoming completely inadequate in large parts of the world.

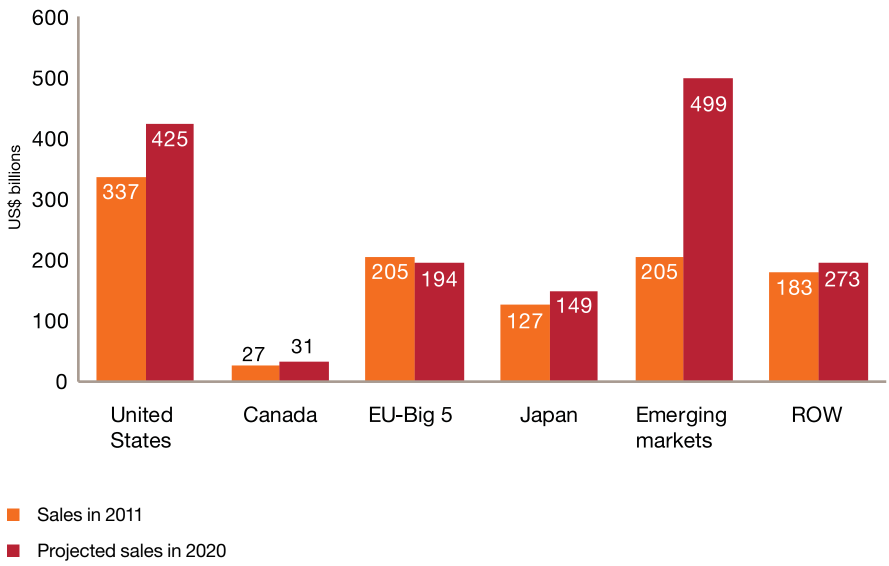
- *Spiralling healthcare cost*
  Healthcare expenditure as a percentage of gross domestic product (GDP) is rising. The steepest rise is seen in the mature markets, where the industry has historically earned most of its revenue.

Emerging economies are driving the growth

In 2011, worldwide sales of medicines reached 1.08 trillion USD, with an increase of 7.8% over the previous year, and are expected to be worth 1.5 trillion USD by 2020[9]. (please see the side chart)

The emerging markets represent the fastest-growing segment of the global pharma industry. As per industry estimates, the total expenditure on healthcare in these markets is likely to grow from 205 billion to 499 billion USD by 2020[10] with most markets expected to grow at double digit rates.

Global pharmaceuticals market could be worth dollars 1.5 trilions by 2020



Source : Business Monitor International

Demand drivers

Growing & ageing global population

- In 2010, there were an estimated 6.9 billion people in he world. By 2020 the world population will be more than 7.6 billion[11]
- By 2020, more than 13% of the population in world will be 60 or older[12].

Growing sick population

- Patients are demanding better treatment.
- Sedentary lifestyle and age are causing many illnesses.

Rising incidence of non-communicable & infectious diseases

- World Health Organisation predicts that, by 2020, non-communicable diseases will account for 44 million deaths a year – 15% more than in 2010[13].

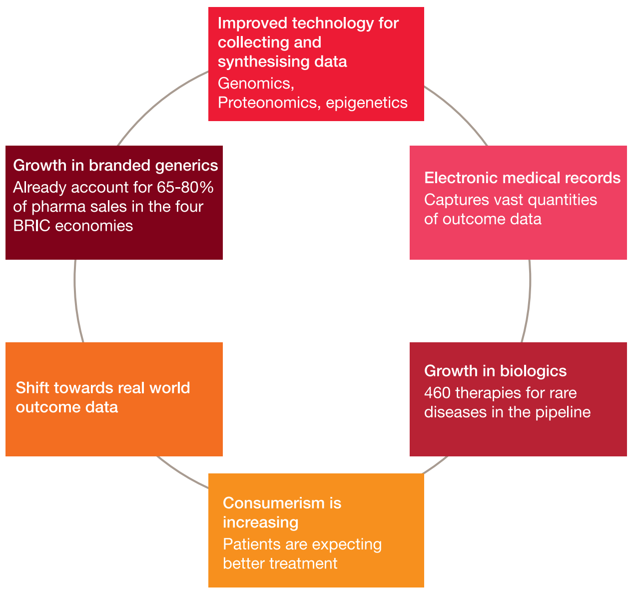
Improved access to healthcare

- More people have access to healthcare than ever before.
- Emerging economies are working hard to improve access to healthcare.
- China is on track with a 125 billion USD programme to extend health insurance cover to more than 90% of the population by the end of 2012[14].

Higher affordability

- The growing middle-class population with higher disposable income is able to afford quality healthcare.
- By 2020, more than 40% of all households in China, India and Indonesia will be 'middle-class' – defined as those with annual incomes of between 5,000 and 15,000 USD[15].

Newer trends benefiting the pharma industry



The Affordable Care Act of 2010

Upheld in June 2012 by the US Supreme Court, the Act aims to improve access to healthcare by bringing another 30 million[16] citizens within the insurance net. It also aims, among other things, to reduce out-of-pocket expenses on pharmaceuticals, which should enhance compliance. In addition, it establishes a regulatory pathway for approving biosimilars. The law is expected to cut revenues from branded products by 112 billion USD[17] over the next decade (excluding the impact of the act on biosimilars).

This Act will have a huge impact on the pharma industry. Companies will price their product on the basis of the value that buyers accord them rather than unit price that they think. Leading to a longer relationship with the healthcare community, this will last till the entire duration of treatment.

Road to 2020

As the industry embarks on its road to 2020, it has taken a giant leap in understanding the newer technologies of genomics, proteonomics, etc., which have led to the production of new medicines, diagnostic tools and lines of research. However, there is still a lot to learn about the human body and even better things lie ahead.

Companies will have to re-evaluate their product portfolio, pipeline and development strategy. They will need to revise their budgeting and forecasting processes, billing and payment systems, and almost everything about the way they have been going to the market.

We believe there are a number of things companies can do to equip themselves for the journey to 2020 and increase their chances of reaching the end of the road in a good shape.

Companies in emerging economies can focus on the following issues:

- Designing products specifically for people in the lower part of the pyramid
- Spotting and serving completely new needs
- Scaling out, not up—i.e., involving a wider range of people in production and distribution
- Using mass-market techniques to deliver complex services
- Making old tools do new tricks—using mobile technologies to improve compliance

Going forward, companies can make impressive gains in the growth markets, but they won't be enough to offset price erosion and patent expiries in the mature markets.

Riding on a good growth wave

02

The Indian pharma industry has been consistently growing at a CAGR of more than 15% over the last five years. The healthy growth reflects the inherent strengths of the industry and improving healthcare standards in the country. If this trend continues, the Indian pharma industry is likely to be one of the top 10 global markets by value by 2020.

Growth in the market will be driven by the following factors:

1. *Changing disease profile and favourable demographics*

   In India, socio-economic changes and urbanisation along with sedentary lifestyle are leading to rapid epidemiological transition. As a result, the Indian population is becoming affluent, living longer and increasingly suffering from lifestyle-related ailments such as obesity, heart disease, stroke, cancer and diabetes. The number of Indian people suffering from these diseases is set to double by 2020. This change in patient demographics will fuel the demand for quality and affordable treatment in the domestic market.

2. *Active participation by foreign pharma companies*

   Over the years, foreign pharma companies have tapped the Indian pharma market through a series of major acquisitions, launches of new products (especially in the branded segment with India-centric pricing) and expansion of field force. Further, MNCs have adopted India-centric strategies such as differential pricing strategy to strengthen their presence in India and address the issue of affordability. MNCs are launching patent-protected drugs in India at lower price points than those in developed markets. Drugs such as Diovan (Novartis), Januvia (Merck, Sharp & Dohme), and Galvus (Novartis) are being sold at 20% of global prices.[18]

3. *Exports to regulated and semi regulated markets*

Exports have made significant contribution to Indian pharma industry's growth story, with the critical market of US generics driving the growth. 148 billion USD worth of patent expiries are expected between 2012 and 2018[19]. In addition, the healthcare reforms initiated by the US government, aimed at reducing healthcare spending and covering a larger proportion of population under public healthcare, are also likely to provide impetus to growth in the generics market.

Apart from the developed markets, the Indian pharma companies have strengthened considerable presence in some of the other fast-growing semi-regulated markets of Russia, South Africa and some in Latin American countries (Brazil, Mexico, etc.) and South-East Asia. These emerging markets offer strong growth prospects for Indian players given that some of these are branded generics markets, with high out-of-pocket expenditure on healthcare (unlike developed markets). Some markets have relatively easier regulatory pathway.

4. *Growing alliances in emerging markets*

Indian companies have also been partnering with MNCs in emerging markets. Such alliances benefit from the R&D (formulation development) and manufacturing capabilities of the Indian partners and the extensive marketing and distribution footprint of the MNCs in those markets.

There is also an increasing trend among MNCs for partnering in the domestic market, where marketing and distribution footprint of Indian companies and the product portfolio of MNCs is being leveraged upon.

Hence, going forward, India should leverage its strengths in the supply of low-cost, quality medicines across the world and partner with foreign companies to drive growth and play a larger role in global pharma market.

Sustaining a robust growth till 2020 03

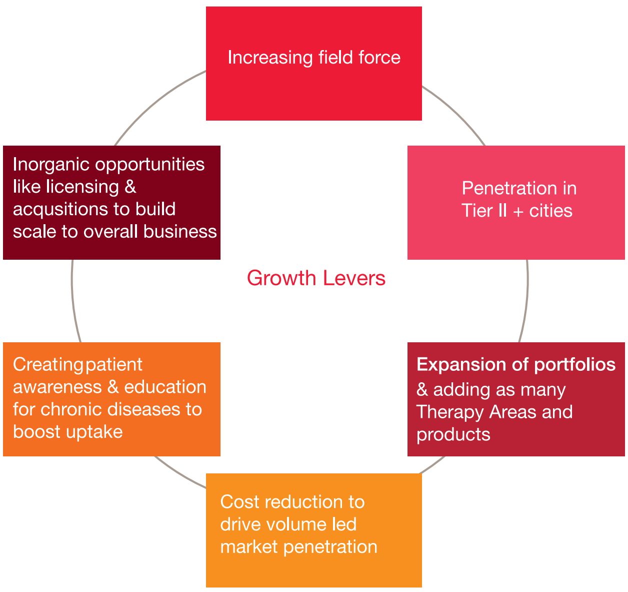
In order to sustain a robust growth rate of 15 to 20% till 2020, companies will have to rethink the way they do business.

Over the years, pharma companies have grown inorganically through acquisitions, but due to higher valuations seen in the sector over the last two years, they have been exploring newer methods of partnerships such as joint ventures and licensing of innovator products and technologies.

Companies are focusing on improving operational efficiencies and have also used the traditional growth levers to drive growth (see the side chart). These initiatives have yielded results but some have also brought in new set of challenges, which companies will have to address for achieving profitable and sustainable growth.

For instance, companies have traditionally increased the field force to penetrate newer markets. This has helped companies to expand but sometimes below expectations. As increase in field force

Growth levers



has not yielded expected productivity, it is becoming difficult for the companies to derive a fair return on investment (ROI) due to reduced profitability and higher cost. For example, from 2008 to 2011, the sales of top pharma companies grew by approximately 16 % and the number of sales representatives increased by almost 11 % but the productivity per representative grew only by 4.5 %.[20]

In another such instance, companies have looked at portfolio expansion for gaining a larger share in the Indian market. However, this has not only led to a wider portfolio, but also one with a portfolio with a large tail with more than 80 to 90% of brands not even crossing the INR 1 crore (0.2 million USD) mark. As a result, companies are now worried about future growth and have started planning strategies that would provide the required growth in this competitive market.

The Indian pharma market is changing, and the need to service this market is changing drastically. To sustain the robust growth for the future, the companies will have to adapt to new business models to serve their customers better. The companies that will adapt to the newer dynamics of the market are more likely to be successful. The companies that will reach patients faster and develop innovative ideas to cater to the changing needs of patient will succeed in the near future.

To register robust growth in the future companies need to think through the following:

1. *Higher volumes through lower prices*

   As we have seen that chronic diseases are setting in early, a large majority of the population will be still working, and this is going to increase the burden on the patients. Pharma companies will have to work around a pricing strategy that will try and reduce the prices appropriately, so that they can rely more on volumes, with larger population suffering from chronic diseases. The chances of 'penetration strategy' working successfully would be determined by 'higher volumes through lower prices. Some MNCS have looked at differential pricing while launching their global drugs in India.

2. *Collaboration with new stakeholders in the super-speciality and speciality segments*

   Companies will have to work closely with key stakeholders like the payers and providers to improve patient compliance especially in speciality and super-speciality segments. In a country like India, the diagnosis rate is low and a compliance rate is lower in the treatment of almost all chronic diseases. Creating awareness about the disease and its implications will improve the diagnosis rate and improved efforts from companies through key stakeholders will improve compliance drastically. Improved compliance will dramatically increase sales of some drugs and, in turn, will drive growth for the companies.

3. *Customising for Indian market*

   Indian market is different from the developed markets in terms of epidemiology, awareness, treatment protocols, and compliance and, above all, pricing. The innovator companies when launching new products will have to customise their strategies for the Indian market in order to make the product accessible and affordable to the masses.

4. *Shifting towards prevention*

   The market will change from treatment to prevention, like other evolved markets. Indian companies will have to look into the healthcare management, work with various stakeholders, and use advanced technology to reach out to more patients. These include use of information and communication technologies such as mobile phones.

5. *Launching patient programmes*

   In India the awareness and literacy rates are on the rise. The patient is more informed, aware and well read than before. As a result, the treatment modality is changing from doctors to self care. So when the treatment is shifting from hospital to primary care or from doctor to self care, there is a tremendous need to connect directly with the patient and pass more information to them. Patients will require new services such as home delivery, etc. Companies will have to come up with innovative ideas to service these patients which, in turn, will increase the patient base and boost sales and growth.

6. *Realigning field force strategy*

   In order to improve sales force productivity, companies will have to revisit the field force strategy, make changes if required and build in new skill-sets. For instance, they will need to provide employees skill sets such as serving patients as customers, look for penetration into newer geographies by piggy-riding on the experience of other industries like FMCG, etc. Thus, in this changing market scenario, the companies will have to change their strategies, adopt newer business models, modify or re-visit the old models and look for incremental growth from areas, wherever possible.

Recent trends

04

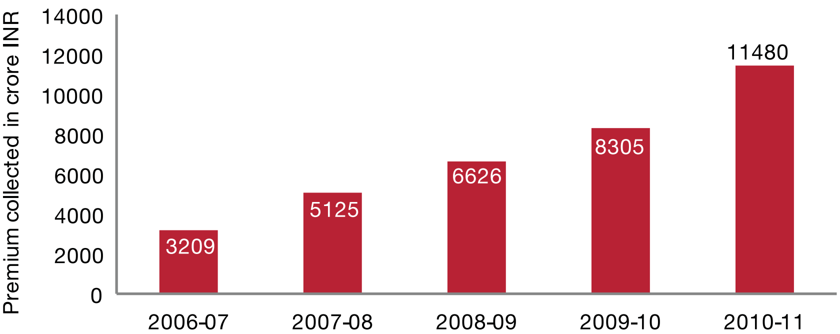
Industry is witnessing newer trends such as health insurance, mobile technology and growth of medical devices industry, which is further giving the impetus to the growth of pharma industry.

Health insurance

Health expenditure in India is largely funded out of the pocket, and this is reflected in the poor per-capita expenditure on health in India. Health insurance is thus critical to the growth of the healthcare market in India, in general, and to the growth of the pharma market in India, in particular.

The government of India initiated reforms in the insurance sector in 2000. Private insurance companies were allowed to operate in India and permission was granted for foreign direct investment to the extent of 26% in the insurance sector. But recently, government has been considering a proposal to increase the limit to 49%.

Health insurance premiums



Health insurance is a significant part of the total portfolio of insurance companies. Gross premiums collected for health insurance products has increased steadily from INR 3,209 crore (USD 642 million) in 2006-07 to INR 11,480 crore (USD 2.29 billion) in 2010-11[21].

The government introduced the National Rural Health Mission in 2005 to improve healthcare delivery in 18 high-focus states. Many state governments have also introduced health insurance programs from 2007. The government also launched the Rashtriya Swasthya Bima Yojana in 2010 to provide healthcare to families living below the poverty line.

These initiatives have resulted in a steady fall in the share of out-of-pocket expenditure in the total healthcare expenditure from 78% in 2004 to 60% in 2009.[22]

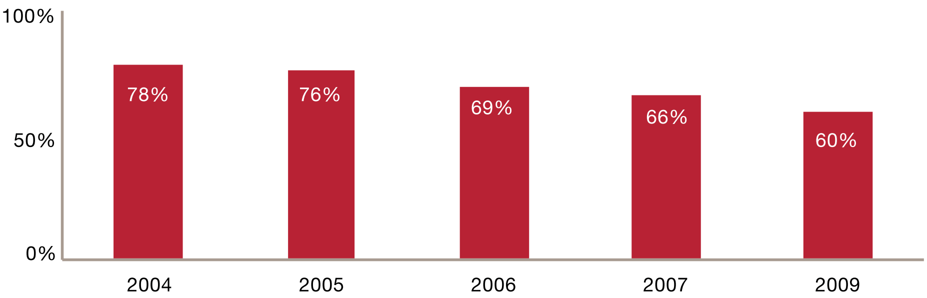
Regional differences exist within the states and even between urban and rural areas. The total out-of-pocket expenditure is about 77% in urban areas and 69% in rural areas[23]. Further reforms are required in the insurance sector to include coverage of outpatient expenses, including drug-related expenditure.

Government of India scheme to enhance access to medicines

The government of India has constituted an expert committee under the chairmanship of Dr K Srinath Reddy to look at the possibility of Universal Health Coverage in India. This committee has given detailed recommendations to the government of all components of healthcare in India.

One of the key recommendations of this committee is to increase public expenditure on drugs from 0.1% of GDP to 0.5% of GDP and provide free essential medicines to all.

Out of pocket expenditure as a % of health expenditure



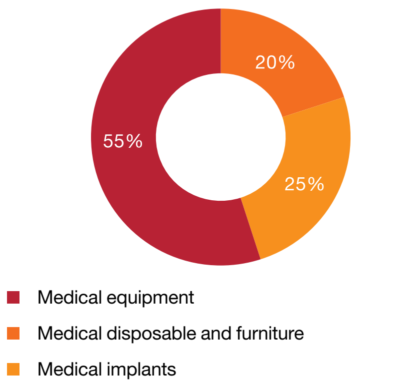
Medical technology

The medical technology sector, which plays a vital role in the delivery of healthcare services in India was valued at 2.75 billion USD in 2008[24] (NIPER Ahmedabad) and is expected to reach 14 billion USD in 2020 at a compounded annual growth rate of approximately 15% (Industry analysis and PwC estimates).[25]

The medical equipment segment forms the largest share of the medical technology sector with over 55% of the total size of the market. This segment includes the following:

- Imaging equipment like SPECT, MRI, CT
- In-vitro diagnostic equipment
- Equipments used for therapy like linear accelerators, gamma knife and cath labs

Niper Ahmedabad medical devices sector analysis 2009



The medical implants segment constitutes the next biggest segment with over 25% of the market. This segment includes the following:

- Cardiac implants such as stents, pacemakers, heart valves
- Orthopaedic implants for knee, hip, spine, etc.
- Eye implants such as intra-ocular lenses
- Ear implants such as cochlear implants
- Dental implants

Medical disposables and furniture constitute around 20% of the market and comprise items such as the following:

- Medical disposables:
  - Catheters
  - IV cannula, infusion sets
  - Medical drapes
  - Surgical masks
  - Sutures
  - Syringes
- Medical furniture:
  - Patient beds and examination couches
  - Patient trolleys
  - Operating tables
  - Wheel chairs

- Many Indian and overseas medical technology companies are launching innovative products for the Indian market. Innovation in the medical technology is crucial for the Indian healthcare system to improve access, enhance quality and reduce costs.
- Innovation in medical technology requires a vibrant and participative ecosystem comprising patients, medical centres, universities, the industry, health insurance companies and the government.

mHealth

There are 913 million mobile subscribers in India as per the estimates of Telecom Regulatory Authority of India (TRAI) for August 2012. The ubiquitous mobile phone offers opportunities for pharma companies in a variety of ways:

- Improving awareness
- Enhancing compliance
- Performing authentication

Improving awareness

Pharma companies can use mobile devices to deliver information about their products to physicians. The mean time for interactions between the medical representatives and the physicians is falling steadily and the mobile phone provides an alternate channel to deliver product information to physicians in a format and at a schedule that can be customised to individual preferences

The increasing penetration of mobile phones allows pharma companies to use this device as an effective marketing tool for OTC products.

Ensuring compliance

Reminders for taking medicines delivered through SMS enhance patient compliance to the medication regimen. Specialised devices are also being developed to help patients improve their adherence to medication schedules.

Performing authentication

Counterfeit drugs are a major source of worry for pharma companies. In response, pharma companies have started fitting special codes on medicine packages to tackle this menace. When a customer buys a bottle or strip of medicine, he/she sends the code as a text message or a scanned image to a specified phone number. A return message verifies whether the medicine purchased is counterfeit or not. Service providers like Sproxil and PharmaSecure have partnered with telecom operators to offer this service in emerging markets where the threat of counterfeit drugs is high.

Policy & regulatory landscape 05

Over the past year, there have been interventions at the regulatory level such as compulsory licensing, FDI policy, pricing policy, marketing code and regulatory approvals, which will require careful considerations as companies think through commercial strategies for future growth.

Pricing policy

The National Pharmaceutical Pricing Authority (NPPA), monitors and controls pricing in the Indian market for essential medicines, through the Drug Price Control Order (DPCO).

There are changes being discussed in the revised proposal, called the Draft National Pharmaceutical Pricing Policy (NPPP) 2011, which seeks to increase price control from 18% to 35% by expanding the span of control from 74 to 348 drugs in the National List of Essential Medicines (NLEM) including 654 formulations[26] of specified strength, while excluding combinations. The revised proposal is to shift from cost-based pricing to market-based pricing by using the weighted average price of all brands in a segment with more than 1% of market share by volume.

The All India Drugs and Chemists Association has estimated that the overall impact on the industry is likely to be at 2.3%.

Compulsory licensing

India's first compulsory license has been granted by the Controller General of Patents, Designs and Trade Marks to Natco for Bayer's kidney-cancer drug Nexavar in March 2012. This allowed Natco to sell a low-cost version at 3% of the original medicine's price on the grounds that the 2.8 lakh INR (5,600 USD)[27] charged by Bayer for a month's dosage was too high for patients in India.

According to legal experts compulsory licensing has been granted on the following grounds under Section 84 of the Indian Patent Act: (1) the drug did not meet the reasonable requirements of the public, (2) the drug was not reasonably affordable and (3) the patent was not being sufficiently 'worked' in India because it was not locally manufactured.[28]

This has evoked mixed response from the industry, policy makers and NGOs. Pharma companies will have to carefully examine its implication on future commercial strategies.

Enforcement of marketing code in the pharma industry

In an attempt to streamline marketing efforts, the Department of Pharmaceuticals (DoP) has released a code of marketing practices for the industry in 2011. The DoP code lays down strict guidelines on the most common and well-known areas of violation, like exaggerated claims; audiovisual promotions; activities of medical representatives (MRs); and provision of samples, gifts, hospitality and sponsorships by pharma companies. The code was voluntary, but in a recent meeting convened between the key industry stakeholders, the industry agreed in principle to enforce a code that will restrict them from offering gifts or other sops to doctors in order to prescribe their medicines.

DoP intends to review its implementation after a set interval of time. If it believes that the code has not been implemented effectively by the pharma associations or companies, it would consider making it a statutory code. The time is right for India to set its own specific guidelines on selling and marketing practices.

There has been parallel development on the tax front with respect to deductibility of expenses on sales and marketing activities. Please see the side bar for details on the CBDT circular.

Delay in approvals for clinical trials

Although India has 15% of the world's population and 20% of the global disease burden, less than 2% of global clinical trials take place in India. This is because of the regulatory uncertainty with regard to the conduct of clinical trials in the country (especially the bioavailability and bioequivalence (BA/BE) studies), which is affecting the growth of the clinical research organisation (CRO) industry and also bears a major ramification for the future of research and development (R&D) in India.

According to data from the Drug Controller General of India (DCGI), new drug approvals dropped by 56.25% during 2011 to 98 from 224 in 2010.[29] Since last year, the DCGI has withdrawn from its role of approving drug trials in the country and has handed over the responsibility to a 10-member new Drug Advisory Committee (NDAC). This year, the NDAC has approved only nine drugs for clinical trials.

Even while India is a cheaper destination to conduct clinical trials as compared to many countries, frequent regulatory delays raise the costs to levels comparable with US or EU levels. As a result, some CROs are looking to increase focus on other geographies like Malaysia and east European countries like Poland.

Given the tremendous opportunity in the sector, the industry can benefit from speedy approvals and stronger ethical infrastructure for conducting trials in India.

FDI in pharma

The government recently decided to take stock of the decade-old FDI policy for the pharma sector. This decision was in response to the potential threat of dominance from foreign players and a general rise in overall drug prices in the country, arising from a spate of acquisitions of Indian companies by MNCs starting in 2006. The most notable ones are the acquisition of Matrix Labs by Mylan, followed by Daichii Sankyo's acquisition of Ranbaxy, Sanofi Aventis's acquisition of Shanta Biotech and Abbott Labs' acquisition of Piramal Healthcare.

As a direct reaction to the takeovers, the government through the Ministry of Commerce and Industry (Department of Industrial Policy and Promotion) amended the FDI policy in November 2011 by permitting FDI up to 100% for investments in existing companies in the pharma sector through the Foreign Investment Promotion Board (FIPB) approval route. At the same time, FDI up to 100% under the automatic route was continued for greenfield investments in the pharma sector.

The FIPB has laid out conditions for approving future proposals. MNC firm looking at buying a stake higher than 49% in an Indian pharma company will have to maintain the same level of investment in research activities and production of NLEM drugs for next five years.[30]

However, it is still at the proposal stage and the final decision is expected soon from the Prime Minister's office.

However, the broad consensus amongst the stakeholders in the pharma sector remains that FDI reforms in this sector should not curtail investments.

The Central Board of Direct Taxes (CBDT) with a view to capture the freebies given to doctors under the tax net has recently issued circular no. 5/2012 dated 1 August, 2012 (circular). The Circular directs the tax officers to disallow expenses in nature of freebies incurred by pharmaceutical or allied health sector industries which have provided such freebies and also to consider them as taxable in the hands of doctors.

The Medical Council of India (Council), in exercise of its statutory powers, had earlier amended the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 on 10 December, 2009 imposing a prohibition on the medical practitioner and their professional associations from taking any gift, travel facility, hospitality, cash or monetary grant from the pharmaceutical and allied health sector industries. The CBDT, in the aforesaid Circular, has provided that freebies to medical practitioners and their professional associations is in violation of the regulations issued by Council, which is a regulatory body constituted under the Medical Council Act, 1956.

As per section 37 of the Income-tax Act, 1961 (the Act) any expense, incurred for a purpose which is either an offence or prohibited by law is not allowed as a deduction. Considering that the provision of freebies to doctors is in violation of regulations issued by the Council, the CBDT has noted that such expense would be inadmissible under section 37(1) of the Act being an expense prohibited by law.

The issue which would need consideration is the nature of freebies which could get covered within the ambit of the above Circular. There are business exigencies for which Companies may have to incur expenditure to make doctors aware of availability of drugs in the market in relation to the cure of a particular affliction, to educate doctors about the new technology through seminars, conferences, training etc which would result in incurring such expenditure and that the Company may have appropriate documentation in place to substantiate the expenditure.

Couple of places which require clarification is date of applicability of the aforesaid Circular i.e. whether from December 10, 2009 i.e. the time of imposition of prohibition by the Council or would it be applicable from the date of issue of Circular i.e. August 1, 2012, as it may impact those years where assessments are open.

Conclusion

The Indian market provides significant growth opportunities for the pharma industry. However, for the industry to sustain a robust growth rate of 15–20% till 2020, companies will have to rethink the way they have been doing business.

Pharma companies will continue to grow inorganically through alliances and partnerships. They will continue to focus on improving operational efficiency and productivity. However, to meet the requirements of changing business environment, they will have to adopt new business models and think of innovative ideas to service their evolving customers faster and better.

Developments in the health insurance sector, medical technology sector and mobile telephony can help the growth of the pharma industry by removing financial and physical barriers to healthcare access in India.

Overall, the various regulatory interventions require careful consideration by the pharma industry. How companies adjust to the regulatory environment as they seek to capitalise on the opportunities provided by the Indian market will be an interesting space to watch in the coming months.

As emerging markets become increasingly important and as India's role among these markets becomes progressively significant, both domestic and pharma MNCs will need to adapt their business models, organisations and processes and create customised strategies.

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