CHAPTER – III
PHARMACEUTICAL MARKETING AND PROMOTION IN INDIA

3.1 INTRODUCTION

The Indian pharmaceutical sector has come a long way, being almost non-existent before 1970 to a prominent provider of healthcare products, meeting almost 95% of the country's pharmaceuticals needs.

India currently represents just U.S. $6 billion of the $550 billion global pharmaceutical industry but its share is increasing at 10 percent a year, compared to 7 percent annual growth for the world market overall. Also, while the Indian sector represents just 8 percent of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 percent by value, and its drug exports have been growing 30 percent annually.

The “organized” sector of India's pharmaceutical industry consists of 250 to 300 companies, which account for 70 percent of products on the market, with the top 10 firms representing 30 percent. However, the total sector is estimated at nearly 20,000 businesses, some of which are extremely small. Approximately 75 percent of India's demand for medicines is met by local manufacturing.

India's potential to further boost its already-leading role in global generics production, as well as an offshore location of choice for multinational drug manufacturers seeking to curb the increasing costs of their manufacturing, R&D and other support services, presents an opportunity worth an estimated $48 billion in 2009.

3.1.1 Pharmaceutical Marketing is Unique

Pharmaceutical marketers are unique in the sense that they have a wealth of information that mass marketers lack. Pharmaceutical marketing is the business of advertising or otherwise promoting the sale of pharmaceuticals or drugs. They will have excellent data on how many prescriptions a medical practitioner wrote for a
particular brand. They will also know how many prescriptions medical practitioner wrote for its competitors. They have all this data month by month.

Pharmaceutical marketers will also know how many details and samples the doctor received for the brand in question.

Finally, because pharmaceutical companies rely on medical representatives to deliver their marketing messages through **ETHICAL PROMOTION**, they can call on whom they should as often as they should, as long as the doctors will see them. Pharmaceutical representatives don't have to call on doctors who aren't worth it, assuming the medical representatives know who they are.

Medical representatives can devote extra effort to doctors who will be the most responsive. Most importantly they can, if armed with the right information, call on each doctor according to his or her likelihood of responding to detailing and sampling at that point in time.

The arrival years ago of doctor-level prescribing data should have changed pharmaceutical marketing more than it has. Breakthrough analytical tools make it possible to take this data and quantify each doctor’s unique responsiveness to details and samples for a brand. Instead, the data has been used as just another segmentation tool.

Within the pharmaceutical industry, segmentation results in valuable sales calls going to doctors who are extremely unlikely to write more prescriptions as a result. The analysis of the current study data shows that this is the case for about 40 percent of sales calls. Although some of this can be blamed on Medical representatives going off plan, we've seen many examples where reps have actually done better by cheating on the plan.

3.1.2 The Difference between Pharmaceutical and Consumer Promotion

The immediate difference is the person of contact. It is the doctor in the former and the common man in the latter. Roles correspondingly differ. In consumer marketing, the promotion, the products superiority over that of the
competitor's, its benefits etc., is done by the company through advertisements via television and written media. The consumer salesman's role is to merchandise, display, communicate offers or discounts, attract the customers through free gifts, design slogans, buntings etc. The pharma salesman on the other hand plays the sole part of convincing the doctor to prescribe his brand. All advertisements are done through the representative. The more the doctor is convinced that a particular drug is effective than its competitive brands, greater the sales for the company and the representative gets the reward he is looking for. This also gives the representative work satisfaction.

Also, the marketing strategies of a non-pharma company are driven by the needs of the common man through surveys and other oral means. On the other hand, the doctor is often the person to give feedback to the company to improvise on the product, not the patient. With their clinical experience, doctors can suggest newer indications, modifications of dose, and also suggest different forms of a particular molecule to suit the need for patient's compliance and convenience.

Table 3.1 : The Difference between Pharmaceutical and Consumer Promotion

<table>
<thead>
<tr>
<th>Pharma promotion</th>
<th>Consumer promotion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Representative helps doctor make prescribing decisions</td>
<td>No personal selling involved. Buying decisions are influenced by the advertising in print, electronic and other media</td>
</tr>
<tr>
<td>It is measurable and accountable</td>
<td>Advertising is not as directly measurable</td>
</tr>
<tr>
<td>More loyalty because of direct engagement</td>
<td>Advertising has to do all the hard work</td>
</tr>
<tr>
<td>Talks to well defined, appropriate segments.</td>
<td>Target audience is dispersed and the reach is not as focused</td>
</tr>
<tr>
<td>Engages single doctor in separate individual dialogue or group of doctors</td>
<td>Engages a mass audience</td>
</tr>
<tr>
<td>Doctor involved in the marketing process because of interactive, collaborative activity</td>
<td>Buyer-Seler collaborative activity is minimal</td>
</tr>
<tr>
<td>Medical representative controls the style and force of message</td>
<td>No control possible</td>
</tr>
</tbody>
</table>

3.1.3 **Factors of the Basic Pharmaceutical Promotions**

1. **Personality**
2. **Values**
3. **User-Imagery**
4. **Usage**
5. **Relationships and**
6. **Top of Mind.**

Let us examine each of these in detail:

1. **Personality:** In this exercise, the marketer attempts to assess what kind of human qualities the brand possesses in the minds of the brand user. There are several ways of assessing the brand personality; one way is to ask them questions that if the brand were a human being, would it be male or female? How old would he/she be?

   What newspaper would he/she read...? And so on and so forth. The attempt here is by the marketer to understand what kind of person users think of, when the brand is mentioned.

   This knowledge and understanding gained is then used to enhance the value proposition for the brand. The personality of a pharma brand to a large part is influenced by the nature and quality of the medical representative’s interaction with the doctor. In a consumer promotion situation however, the buyer’s perception of the brand is shaped largely by advertising.

   Therefore, knowledge of how past promotion has shaped pharma promotion. However, the usefulness of the personality building exercise in pharma promotion is debatable.

2. **Values:** The brand also says something about the manufacturer’s values. Just as Mercedes stands for well-engineered products, likewise the efficacy and safety of a pharma brand would invest these very qualities onto the brand - and therefore the manufacturer. However, given the current commoditised nature of pharma brands and the consequent brand parities, the values differentiator
could be more the nature of the manufacturers strategic thrust, viz; his image as being an original research company, reverse engineering expert, presence in number of foreign market, a me-too manufacturer etc. Hence, in a pharma situation, the company would have to rely substantially on the kind of the image it has built for itself over the years, and what new strategic thrust it has adopted to meet the challenges of the times.

3. **User Imagery:** This element seeks to find out what the usage of the brand makes the prescriber feel. Frequently used by the MR by citing peer usage to boost prescriber self esteem.

4. **Usage:** Since the promotion is not to end-user, the prescriber makes the decision on his behalf. Therefore, usage convenience is not a directly experienced brand value. Hence, this element may not be as important as in consumer promotion.

5. **Relationship:** As in consumer promotion, relationship with the brand is a function of the various types of efforts made by the company to build bonds with the user - which in the pharma case is the prescriber. Pharma companies off late are also making attempts at reaching out to the patient himself by making personal visits to them to ensure adherence to drug regimen. In both instances, the principal strategy driver is the MR, and next in importance come the nature of the company’s strategic initiatives, and their effective implementation by the MR. These factors would determine the nature of the prescribers as well as the patient’s relationship with the brand.

6. **Top of the mind:** In this case again, the MR’s own initiatives, the effectiveness of the company’s sales promotional material and its effective use by him, would determine how successfully the objective is achieved.

### 3.1.4 Brand Establishment Priorities

It would be evident then, that to effectively establish pharma brands, companies would have to give priority to the following areas:
• Comprehensive training in strategic and tactical sales and behavioural skills to the sales force
• Devising creative strategic (not only tactical) strategies
• Producing imaginative communication aids to translate the strategy into practice.

3.1.5 Ethical Promotion is Different and Unique and Depends on Number of Factors

Promotion efforts in pharmaceutical industry are typical, as it is not directed to the end user but the influencer – the physician.

Promotion of pharmaceutical products can traditionally be done with four techniques viz:
1. Personal selling
2. Advertising
3. Sales promotion and
4. Publicity.

Out of these four techniques, only personal selling is the most effective and primarily used techniques of promoting pharmaceutical products.

Other techniques are used but they are used during special circumstances and are used to achieve short-term objectives of the company rather than long-term objectives. Thus, advertising, publicity and sales promotion is used secondary to support the main technique, personal selling.

The term 'promotion' means those informational and marketing activities, the purpose of which is to induce prescribing, supply or administration of medical products. It includes the activities of medical representatives and all other aspects of sales promotion such as journal and direct mail advertising; participation in conference exhibitions; the use of audio-visual materials; the provision of drug samples, gifts and hospitality for medical profession and seminars.
3.1.6 Drug Promotion and Doctor

The prescription of a drug is an event in which the doctor is decision maker for the ultimate user - the patient. The industry had a powerful influence on prescribing habits and is often blamed for its marketing practices.

Pharmaceutical companies are not allowed to publicly market their products. Marketing has to be restricted to promotional campaigns, advertisement only in medicinal magazines, journals etc., through medical representatives. It is not a mean of mass communication, which is usually applicable to consumer products. In the process of pharmaceutical marketing, market segmentation, targeting and brand differentiation is considered to be challenging compared to the consumer marketing.

Unlike any other businesses, marketing mix and its operatives for pharmaceutical industry are very peculiar. The pharmaceutical industry is one of the few which cater to unique situations. Here the decision maker is the prescriber i.e. doctor while actual user of the product is a patient.

Patient purchases product only because of doctor’s advice and hence product should satisfy the conditions of physician. Even if all other parameters are correct, the product might still fail because of improper promotion. Personal selling is the major promotional method in pharmaceutical marketing.

Fig. 3.1 : Drug Requiring Prescription

3.1.7 Drug Requiring Prescription

In this case, the patient – customer - do not have much or any say in purchase of the product, perhaps other than spending the money. The decision makers are the physicians or doctors treating the patient. They will prescribe drug of a particular brand if they are:

- Aware of the product.
- Convinced about the utility and usage of the product.
- Reasonably certain that the prescribed drug can be made available by the drug retailer in required amount of time.

3.1.8 Drug Retailer Plays a Major Role

After following the above logic, the doctor prescribes the drug, but the drug retailer plays a major role in effecting actual sale and he may:

- Not have the prescribed product in the ready stock.
- Not consider that the prescribed product has sufficient demand to stock the product.
- Suggest or just substitute product of the competitor company having similar composition, most of the times without even knowledge of the prescribing doctor.

All this will perhaps happen just because there is less brand awareness as a consequence of less promotional efforts by the product company.

3.1.9 The Patient may be the Purchaser of the Pharmaceutical Product, but the Doctor as the Decision Maker, is the Main Customer for the Pharmaceutical Marketers.

The doctor decides upon the appropriate treatment. The patient may be the purchaser of the pharmaceutical product, but the doctor as the decision maker, is the main customer for the pharmaceutical marketers.
3.1.10 The Customer is Unique

Of course, every customer is “king”. But this customer - the doctor - is particularly special. Doctors enjoy a high standing in society and are generally in the top socio-economic group. Such is the confidence that doctors enjoy, that patients puts their lives in their hands. A good doctor sees many patients each day and can be very busy indeed.

Marketing of prescription pharmaceuticals through mass media is not permissible, and in any case, would be inappropriate for many products. One-to-one communication to doctors is the norm. For this, a pharmaceutical company needs many field staff to regularly meet prospective and existing doctors and promote the company’s products. In this, the principles of salesmanship remain largely the same as elsewhere. Thus the company’s field representative becomes the chief link between the company and the doctor, often being described as the company’s “ambassador” in the field.

3.2 PHARMACEUTICAL MARKET IN INDIA : GROWTH, CHALLENGES AND OPPORTUNITIES

The Indian pharmaceutical Industry has witnessed a robust growth of around 14% since the beginning of the 11th Plan in 2007 from about Rs 71000 crores to over Rs1 lac crores in 2009-10 comprising some Rs62,055 crores of domestic market and exports of over Rs 42,154 crores. This also amounts to around 20% of total volume of global generics.

However, the Industry is quite fragmented and comprises of nearly 10,500 units with majority of them in unorganized sector. Of these, about 300-400 units are categorized as belonging to medium to large organized sector with the top 10 manufacturers accounting for 36.5% of the market share.

The Industry is ranked 3rd globally in volume and 14th in value, supplying around 10% of total global production1. This also amounts to around 20% of total volume of global generics. Thus every 5th Tablet, Capsule and Injectable in generics drugs consumed anywhere in the world is manufactured in India. In fact, India
manufactures 30% of the world requirement of Anti HIV drugs. All of this growth has been with affordable price to the common man – one of the lowest in the world. Going forward, it is expected that the growth will be sustained notwithstanding the recent initial decrease due to global economic slow down as brought out in the decreased growth rate from 18.65% in 2009-10 over 2008-09 to 9.38% in the period 2009-102.

Indian pharmaceutical industry is truly international with leading international manufacturers competing in Indian domestic market and several Indian pharma companies having a significant presence in international market, especially in the generic segment. However, the Industry is quite fragmented and comprises of nearly 10,500 units with majority of them in small sector. Of these, about 300-400 units are categorized as belonging to medium to large organized sector with the top 10 manufacturers accounting for 36.5% of the market share.

The domestic pharmaceutical Industry has grown at around 12% CAGR since the start of the 11th Plan in 2007, from Rs 45,367 crores in 2007 to about Rs 62,055 crores in 2009-10.

3.2.1 This is Sustained by the following Factors

i. Market size increase due to increase in the size of middle level income earning population segment as it grows in size from the current 270 Mn to some 583 Million by 20259;

ii. Increase in purchasing power of this group;

iii. Aging of the Indian population as life expectancy has increased from about 42 years in 1960s to 66.95 years at the beginning of the 11th plan to now 68.45 years in 2010-1110 coupled with the purchasing power of this segment. It is to be noted that people of old age spend around 3 to 4 times more on drugs than people in younger age groups for obvious reasons;

iv. greater market penetration due to increasing spread of private sector medical insurance cover driven by liberalization of the insurance sector of this burgeoning middle class; and
v. Sustained expected growth of the Indian economy in general at a GDP growth rate of some 9% to 9.5% in the 12th Plan period.

Going forward, the above factors for sustained growth will be matched by the inherent ability of the Indian manufacturers to scale up production with less costs and time, as witnessed in the over Rs 29,000 crores of investment in setting up of new manufacturing plants in the country in the 11th plan period.

### 3.2.2 Current Opportunities about India’s Pharmaceutical Market

India’s pharmaceutical market grew at 15.7 per cent during December 2011. Globally, India ranks third in terms of manufacturing pharma products by volume. According to McKinsey, the Pharmaceutical Market is ranked 14th in the world. By 2015 it is expected to reach top 10 in the world beating Brazil, Mexico, South Korea and Turkey. More importantly, the incremental market growth of US$ 14 billion over the next decade is likely to be the third largest among all markets. The US and China are expected to add US$ 200bn and US$ 23bn respectively.

McKinsey & Company’s report, “India Pharma 2020: Propelling access and acceptance, realizing true potential,” predicted that the Indian pharmaceuticals market will grow to US$55 billion in 2020; and if aggressive growth strategies are implemented, it has further potential to reach US$70 billion by 2020. While, Market Research firm Cygnus’ report forecasts that the Indian bulk drug industry will expand at an annual growth rate of 21 percent to reach $16.91 billion by 2014. The report also noted that India ranks third in terms of volume among the top 15 drug manufacturing countries.

Further, McKinsey reports Healthcare grew from 4 per cent of average household income in 1995 to 7 per cent in 2005 and is expected to grow to 13 per cent by 2025.

### 3.2.3 Demand

The demand for pharmaceutical products in India is significant and is driven by many factors like low drug penetration, rising middle-class & disposable income, increased government & private spending on healthcare infrastructure, increasing
medical insurance penetration, changing demographic pattern and rise in chronic lifestyle-related diseases; adoption of product patents, and aggressive market penetration driven by the relatively smaller companies.

3.2.4 **According to CARE research demand triggers for the growth are**

- Between 2010 and 2015 patent drugs worth US$171 bn are estimated to go off-patent leading to a huge surge in generic products.
- High margin pharma export business is expected to grow at a higher rate than domestic market given increased in outsourcing activities.
- Increased M&A activities is set to consolidate the market which widens geographic reach, strengthens distribution network and venture into new therapeutic segments.
- Indian companies files the highest number of ANDA’s with USFDA leading to greater chances of approvals and thereby increasing export to regulated markets especially the US.
- There are currently approximately 175 USFDA and nearly 90 UK-MHRA approved pharma manufacturing plants in India which can supply high quality pharma products globally.
- Growth from rural markets will outstrip overall pharma market growth, albeit at lower margins, given lower penetration of 18-19% coupled with rising income level and awareness.
- Biopharmaceuticals is another potential high growth segment for Indian pharma growing at double digit driven by the vaccines market.

3.2.5 **Major Recent M&As**

- **Sun-Merck JV:** Sun and Merck have formed JV to develop, manufacture and commercialize new combinations and formulations of innovative, branded generics in the Emerging Markets. Under the JV, Sitagliptin and Sitagliptin+Metformin have already been commercialized in the Indian markets.
- **Lupin-Lilly JV:** They entered into collaboration to promote and distribute Lilly’s Huminsulin range of products in India and Nepal.
- **Cadila Bayer JV:** The venture will sell brands from both companies in Indian markets.
• Biocon-Pfizer JV: This collaboration will give Pfizer exclusive rights to commercialize Biocon products globally including co-exclusive rights with Biocon in Germany, India and Malaysia.

• Universal Medicines – Aventis: Aventis has acquired Universal Medicines for over US$ 100mn.

3.2.6 Major Pharmaceutical Companies

India based pharmaceutical companies are not only catering to the domestic market and fulfilling the country’s demands, they are also exporting to around 220 countries. They are exporting high quality, low cost drugs to countries such as the US, Kenya, Malaysia, Nigeria, Russia, Singapore, South Africa, Ukraine, Vietnam, and more. Currently, the US is the biggest customer and accounts for 22 percent of the sector’s exports, while Africa accounts for 16 percent and the Commonwealth of Independent States (CIS) places around eight percent of orders, as per Research and Market report.

For most of the pharma companies, domestic business contributes in the range of 20-50% of the overall revenue. US business contribution stands at 20-30% and remaining comes from the RoW markets.

3.2.7 Leading Indian Players by Sales

Table 3.2 : Leading Indian Players by Sales

<table>
<thead>
<tr>
<th>Company</th>
<th>Sales in US $Mn</th>
<th>Year End</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cipla</td>
<td>6,368.06</td>
<td>March 2011</td>
</tr>
<tr>
<td>Ranbaxy Lab</td>
<td>5,687.33</td>
<td>December 2010</td>
</tr>
<tr>
<td>Dr Reddy's Labs</td>
<td>5,285.80</td>
<td>March 2011</td>
</tr>
<tr>
<td>Sun Pharma</td>
<td>1,985.78</td>
<td>March 2011</td>
</tr>
<tr>
<td>LupinLtd</td>
<td>4,527.12</td>
<td>March 2011</td>
</tr>
<tr>
<td>Aurobindo Pharma</td>
<td>4,229.99</td>
<td>March 2011</td>
</tr>
<tr>
<td>Piramal Health</td>
<td>1,619.74</td>
<td>March 2011</td>
</tr>
<tr>
<td>Cadila Health</td>
<td>2,213.70</td>
<td>March 2011</td>
</tr>
<tr>
<td>Matrix Labs</td>
<td>1,894.30</td>
<td>March 2010</td>
</tr>
<tr>
<td>Wockhardt</td>
<td>651.72</td>
<td>December 2011</td>
</tr>
</tbody>
</table>

Source: Indian Pharma Machinery Manufacturers Association, 2012

3.2.8 Trends

All companies, including MNCs, have increased their field force in the last one year.
• Indian companies are entering into strategic tie-ups with MNCs to strengthen their product portfolio.
• Companies are expanding their presence in rural markets.
• Acquisitions by MNCs to gain quick foothold in the fastest growing Indian pharma market.

Most of the Pharma companies have shown considerable decline in growth in the first half of 2011. The slowdown is widely visible in the Chronic and Acute categories. Anti-infective, pain and gastro together contribute 1/3rd of the total pharma market. The pharma companies have started facing challenges in domestic market due to increase in competition from unlisted MNCs in this segment. They are rapidly expanding their field force to extend their geographical reach. Companies like Cipla, Torrent and IPCA which are mainly focused on Indian market are already feeling the heat. Growth rates of companies such as Cadila, Dr. Reddy and Ranbaxy have already come down. On the other hand Lupin and Sun are showing growth due to the shift of focus towards specialty therapies, where competition is relatively low.

Basing on the changing macro factors and economic growth Emkay Research has expected the growth estimates of the pharma companies to decrease. It cut down the domestic growth estimates for Cadila, Cipla, Dr. Reddy, IPCA, Torrent and Unichem for FY12 and FY 13 by 2% to 5% and retained the growth estimates for Lupin, Ranbaxy, Sun, GSK and Pfizer.

**Table 3.3 : Indian Pharma – Domestic Growth Expectations**

<table>
<thead>
<tr>
<th>Company</th>
<th>FY12 Domestic Growth</th>
<th>Earlier growth estimates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadila</td>
<td>12%</td>
<td>15%</td>
</tr>
<tr>
<td>Cipla</td>
<td>10%</td>
<td>15%</td>
</tr>
<tr>
<td>Dr. Reddy’s</td>
<td>10%</td>
<td>15%</td>
</tr>
<tr>
<td>Glenmark</td>
<td>16%</td>
<td>16%</td>
</tr>
<tr>
<td>IPCA</td>
<td>10%</td>
<td>17%</td>
</tr>
<tr>
<td>Lupin</td>
<td>19%</td>
<td>19%</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Sun Pharma</td>
<td>15%</td>
<td>18%</td>
</tr>
<tr>
<td>Torrent</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Unichem</td>
<td>5%</td>
<td>9%</td>
</tr>
<tr>
<td>GSK</td>
<td>13%</td>
<td>13%</td>
</tr>
<tr>
<td>Pfizer</td>
<td>14%</td>
<td>14%</td>
</tr>
</tbody>
</table>

*Source: IMS Health : 360 Global Pharmaceutical Perspective*
3.3 GOVERNMENT POLICIES: OVERVIEW

Government initiatives in the public health sector have recorded some noteworthy successes over time with focus on investments related to better medical infrastructure, rural health facilities etc.

- 100 per cent FDI is permitted for health and medical services under the automatic route.
- The National Rural Health Mission (NHRM) had allocated US$ 10.15 billion for the upgradation and capacity enhancement of healthcare facilities.
- Moreover, in order to meet revised cost of construction, in March 2010 the Government allocated an additional US$ 1.23 billion for six upcoming AIIMS-like institutes and upgradation of 13 existing Government Medical Colleges.

As a result, FDI inflow in hospital and diagnostic centres was US$ 1.1 billion during April 2000 and November 2011, according to st Department of Industrial Policy & Promotion (DIPP) data. FDI inflow in medical and surgical appliances stood at US$ 472.6 million during the same period. And the drugs and pharmaceuticals sector has attracted FDI worth US$ 5.0 billion between April 2000 and November 2011.

3.3.1 Budget 2012

Union Budget 2012-13, as expected, is positive for the pharmaceutical sector. The government has again increased budgetary allocation for healthcare spending, which would be an overall positive for the sector. Indian pharmaceutical companies have been investing on the R&D front to tap opportunities in the domestic and global markets. To encourage the same, the weighted deduction on R&D expenditure to 200% (in-house research) was extended for a further period of five years. R&D sops would continue to be positive for the sector as a whole.
Table 3.4: Government Policies: Overview - Budget 2012

<table>
<thead>
<tr>
<th>Budget Proposal</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposal to extend weighted deduction of 200% for R&amp;D expenditure in an in-house facility for a further period of five years beyond March 31, 2012.</td>
<td>Positive for all Indian pharmaceutical companies.</td>
</tr>
<tr>
<td>Allocation for NRHM proposed to be increased from Rs 18,115cr in FY2011-12 to Rs 20,822cr in FY2012-13.</td>
<td>Positive for all pharmaceutical companies.</td>
</tr>
<tr>
<td>Proposal to continue to allow repatriation of dividends from foreign subsidiaries of Indian companies at a lower tax rate of 15% up to March 2013.</td>
<td>Positive for all pharmaceutical companies, mainly Indian companies, as they generate the highest revenue from export markets.</td>
</tr>
<tr>
<td>Introduced MAT on partnership firm.</td>
<td>Would negatively impact Cadila Healthcare and Sun Pharmaceuticals. Since we have already factored in higher tax provision for FY2013, we are not changing our FY2013 estimates for both the companies.</td>
</tr>
</tbody>
</table>

Source: TCS Pharma, CIO Report.

3.3.2 Government of India Policy on Developing the Domestic Indian Pharmaceutical Market

According to the governments draft National Pharmaceutical Policy for 2006’s provisions on increasing access to treatments for life threatening diseases, but points out that Western lifestyle diseases are currently providing the major growth in the domestic market.

3.3.3 Laws and Regulations Governing Indian Pharmaceuticals

- *The Drugs and Cosmetics Act, 1940*: This Act regulates the import, manufacture, distribution and sale of drugs in India.

- *Schedule M of the Drugs and Cosmetics Act* specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs.

• **Schedule Y of the Drugs and Cosmetics Act** governs the clinical trials legislative requirements of the Drugs and Cosmetics Act.

• **The Pharmacy Act, 1948**: This legislation regulates the profession of Pharmacy in India. Under the provisions of this act the Central Government constitutes a Central Pharmacy Council of India and the State Governments constitute State Pharmacy Councils.

• **The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954**: This Act provides to control the advertisements regarding drugs and prohibits the advertising of remedies alleged to possess magic qualities.

• **The Narcotic Drugs and Psychotropic Substances Act, 1985**: This is an act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.

• **The Medicinal and Toilet Preparations (Excise Duties) Act, 1956**: An Act to provide for the levy and collection of duties of excise on medicinal and toilet preparations.

• **The Drugs Price Control Order (DPCO), 1995**: This is an order issued by the Government of India under the Essential Commodities Act, 1955 to regulate the prices of drugs. The Order provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Government and penalties for contravention of provisions among other things. For the purpose of implementing provisions of DPCO, powers of the Government have been vested in the National Pharmaceutical Pricing Authority (NPPA).

• **Good Clinical Practice (GCP) Guidelines**: The Ministry of Health, along with Drugs Controller General of India (DCGI) and Indian Council for Medical Research (ICMR) has come out with draft guidelines for research in human subjects. These GCP guidelines are essentially based on Declaration of Helsink, World Health Organization (WHO) guidelines and International Conference on Harmonization (ICH) requirements for good clinical practice.
3.3.4 The following are some of the Other Laws which have a bearing on Pharmaceutical Manufacture, Distribution and Sale in India

- The Industries (Development and Regulation) Act, 1951
- The Trade and Merchandise Marks Act, 1958.
- The Indian Patent and Design Act, 1970
- Factories Act

3.3.5 Regulatory Bodies

The Ministry of Health & Family Welfare (MoHFW) and the Ministry of Chemicals and Fertilisers (MoC&F) of the Government of India play a major role in regulating the pharmaceutical sector in the country.

3.3.6 Ministry of Health & Family Welfare (MoHFW)

- Department of Health: The following are the main agencies of the department which deal with key issues including drug approvals:
  - Central Drugs Standard Control Organisation (CDSCO): As an agency of the Department of Health, the CDSCO works both at the Central and the State level and is responsible for ensuring safety, efficacy and quality of drugs supplied to the public. The agency performs the above mentioned functions with the Drugs Controller General of India (DCGI) as the executive head.
  - Drugs Controller General of India (DCGI): The DCGI is an apex body in the pharmaceutical industry governing issues such as product approval and standards, clinical trials, introduction of new drugs, import licenses for new drugs and enforcing new drug legislation.

The following are the major acts which the Department of Health administers:

- The Drugs & Cosmetics Act, 1940
- The Prevention of Food Adulteration Act
- The IMA Act
- The Tobacco Control Act
3.3.7 Ministry of Chemicals and Fertilisers (MoC&F)

The Ministry of Chemicals & Fertilizers constitutes bodies such as the Department of Chemicals & Petrochemicals and the National Pharmaceutical Pricing Authority (NPPA). These departments are entrusted with the responsibility of policy making, planning, development and regulations relating to Chemicals, Petrochemicals and Pharmaceuticals.

- Department of Chemicals & Petro-Chemicals: This department is the concerned authority for formulating and implementing policies and programmes for achieving growth and development of pharmaceuticals in the country. In order to attract investment into the sector, the Department has undertaken several initiatives, the major being the Pharmaceutical Policy with the objective to strengthen the production, export & R&D.

The first comprehensive pharmaceutical policy in India was formulated in 1978. The national pharmaceutical policy has seen a number of changes through new policy guidelines issued in 1986, 1994 and recently in 2002.

Pharmaceutical Policy 2002 –

- The main objectives of the policy are:
  - To ensure availability of good quality essential pharmaceuticals at reasonable prices for mass consumption.
  - To strengthen the indigenous capability for cost effective quality production and export of pharmaceuticals by reducing trade barriers in the pharmaceutical sector.
  - Quality control system for pharmaceutical production and distribution to make quality an essential attribute of the domestic industry.
  - Encouraging pharmaceutical R&D that is compatible with the country's needs.
  - To encourage new investment in the pharmaceutical industry and the introduction of new technologies and new drugs.
3.3.8 Draft Pharmaceutical Policy 2006

The Department of Chemicals has released the draft of the New Pharmaceutical Policy 2006 which is waiting for approval by the Indian Government. The draft National Pharmaceutical Policy, 2006 seeks to strengthen the Drug Regulatory System and Patent offices in the country. It focuses on research and drug development with clinical trials. The policy aims at providing a better access to anti-cancer and anti-HIV/AIDS drugs to the patients. It seeks to rationalize the excise duty on pharmaceuticals and to streamline the system of bulk procurement of drugs by the Government besides promoting the generic medicines.

3.3.9 National Pharmaceutical Pricing Authority (NPPA)

It has been entrusted with the task of fixation / revision of prices of bulk drugs and formulations, enforcement of provisions of the Drugs (Prices Control) Order and monitoring the prices of controlled and decontrolled drugs in the country.

3.3.10 Drugs Price Control Order (DPCO), 1995

The Drugs Price Control Order (DPCO), 1995 is an order issued by the Government of India under the Essential Commodities Act, 1955 to regulate the prices of drugs. DPCO controls the domestic prices of major bulk drugs and their formulations with an aim to provide patients with medicines at affordable prices. DPCO ascertains, as per Drug Policy guidelines, the bulk drugs (and their formulations) to be kept under price control.

- At the State level, the State Food and Drug Administrations (FDAs) monitor the drug manufacture, sale, and testing by companies in their jurisdiction.

- There are also two main statutory bodies formed by Parliament:
  - the Drugs Technical Advisory Board, whose technical experts advise the Central and State Governments on special technical matters involving drug regulation, and the Drugs Consultative Committee, where Central and State drug officials ensure that drug control measures are enforced.
Ninety-four percent of all private health spending is out of pocket, mostly at the time of the incident, and more than 40 percent of hospitalized people borrow money or sell assets in order to cover their expenses. The remaining 6 percent of spending is provided by insurance -3.7 percent social, 1.6 percent employer-sponsored and 0.7 percent private insurance. Just 15 percent of the population has some form of insurance; an estimated 800,000,000 people in India have none.

The health insurance market was opened up to the private sector in 2000 and, since then, growth has been fast, with nearly 10.3 million policies sold in 2003-04 compared to 7.5 million in 2001-02. A 40 percent compound annual growth rate (CAGR) is forecast for the health insurance sector over the coming years, making it a significant driver of the domestic health care market, which analysts at McKinsey believe could be worth $40 billion by 2012.

Rising levels of population and incomes, plus the arrival of new products, will continue to grow the domestic market around 10 percent a year, but there will be no dramatic change unless there is help to improve people's access drugs.

Privatization of health insurance and India's fast-growing middle class will certainly boost consumption. India's fastest-growing product segments last year were for lifestyle-related diseases and the MNCs can produce innovative, patented treatments for these conditions, as well as develop treatments for developing-world diseases such as malaria, TB and HIV/AIDS.

### 3.4 PHARMACEUTICAL MARKETING: ADVANTAGE INDIA

i. **Competent workforce:** India possesses a skilful work force with high managerial and technical competence.

ii. **Cost-effective chemical synthesis:** The track record for development, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules is excellent.

iii. **Legal & Financial Framework:** India is a democratic country with a solid legal framework and strong financial markets. There is already an established international industry and business community.
iv. *Information & Technology:* It has a good network of world-class educational institutions and established strengths in Information Technology.

v. *Globalization:* The country is committed to a free market economy and globalization. Above all, it has a 70 million middle class market, which is constantly growing.

vi. *Consolidation:* After many years, the international pharmaceutical industry has discovered great opportunities in India. The process of consolidation, which has become a popular phenomenon in the world pharmaceutical industry, has started taking place in the Indian pharmaceutical industry as well.

Indian pharmaceutical industry is climbing up the value chain from bringing a pure reverse engineering industry focus on domestic market. The industry is moving towards basic research driven expert oriented global presence and providing wide range of value added quality product and services.

India's pharmaceutical industry has been growing at record levels in recent years but now has unprecedented opportunities to expand in a number of fields. The domestic industry's long-established position as a world leader in the production of high-quality generic medicines is set to reap significant new benefits as the patents on a number of blockbuster drugs are scheduled to expire over the next few years. In addition, more and more governments worldwide are seeking to curb their soaring prescription drug costs through greater use of generics. These opportunities are presenting themselves not only in India's traditional wealthy client markets such as the U.S. and European Union nations but also in emerging economies with vast populations such as Africa, South America, Asia, and Eastern and Central Europe.

In addition, India's long-established position as a preferred manufacturing location for multinational drug manufacturers is quickly spreading into other areas of outsourcing activities. Soaring costs of R&D and administration are persuading drug manufacturers to move more and more of their discovery research and clinical trials activities to the subcontinent or to establish administrative centers there, capitalizing on India's high levels of scientific expertise as well as low wages.
Both multinational and local drug manufacturers could eventually benefit from the market potential of India's population of over one billion.

A large market will likely open up as the result of a projected boom in health insurance, an area in which the country is currently woefully underdeveloped. New government initiatives seek to enable the majority of the population to access the life-saving drugs they need, while even greater opportunities may be presented by the rise of the new Indian consumer. This group-urban, middle class and wealthy-live fast-paced, Western-style lives and, as a result, they are beginning to suffer from Western, lifestyle-related illnesses, for which they want, and can afford, innovative drug treatments.

This untapped domestic market is also highly attractive to the pharmaceutical MNCs, which recently have returned to India in large numbers (many had left when the regime allowing process patents only was introduced in the early 1970s). Now, MNCs and domestic companies are starting to work together, utilizing each other's strengths for their mutual benefit. For the foreign firms, this includes not only the Indian companies' research and manufacturing capabilities and their much lower operational cost levels, but also comprehensive marketing and distribution networks operating throughout India's vast territories.

There are, however, a number of uncertainties, particularly the effects of India's new product patent system, which was introduced on January 1, 2005. Previously, only process patents were granted, a situation that led to India's current role as a world leader in the production of high quality, affordable generics. The new regime may spell the end for the domestic sector's smaller players, while for others it could represent unprecedented opportunities.

At the same time, a number of the country's largest pharmaceutical companies are attaining global-player status as existing markets expand, and new ones open up, for high quality, affordable generic drugs. Indian firms have embarked on an unprecedented shopping spree of overseas acquisitions to establish themselves in these highly lucrative markets and boost their capacities, as demand continues to grow.
Partnerships will also be key for Indian firms' development in their home market. Multinational companies that have re-entered the market since the new product patent system seek out the domestic industry's skills and infrastructures to boost their research and manufacturing activities in the subcontinent and also open up this vast, virtually untapped market.

However, India's market development will depend, more than anything, on government moves to increase the population's access to medicines, which is now extremely limited. Further price controls are not the answer; Indian prices for essential drugs are already the lowest in the world. Instead, the solution lies with proactive measures such as publicprivate partnerships and encouragement of R&D; for example, through industry-academia collaborations and an official system of grants, which have proved to be of great benefit to industry and patients elsewhere in the world.

3.5 CONCLUSION

India will move towards an integrated and robust healthcare financing system, as already articulated recently by Mr. Montek Singh Ahluwalia, Deputy Chairman of the Planning Commission of India, which will usher in the following changes:

Doctors will no longer be the sole decision makers for prescribing drugs to the patients and the way they will treat the common diseases. Ministry of Health/Healthcare providers/ Medical insurance companies will start playing a key role in these areas by providing to the doctors well thought out treatment guidelines.

With major changes within the Indian pharmaceutical industry, it may not be easy for the local players to adapt to the new paradigm sooner and compete with the global players on equal footing, even in the branded generic space. In my view, those Indian Pharmaceutical companies, who are already global players in their own right and relatively well versed with the nuances of this new ball game, will have a significant competitive edge over other domestic players. The global-local companies, in my view, will offer a tough competition to the local-global players, especially, in
the branded generic space and at the same time will be able to bring down their marketing expenses significantly.

So far as other domestic players are concerned, the fast changing environment could throw a new challenge to many of them, accelerating the consolidation process within the Indian pharmaceutical industry.

We all should be well aware, just as today’s pharmaceutical business dynamics in India are not replica of what these were in the yesteryears, tomorrow’s pharmaceutical business dynamics of the country will not be a replica of what these are today. Thus Indian pharmaceutical companies should invest in R&D as well as human resources to take cognisance of the new emerging scenario.