Chapter 3- Pharmaceutical Industry in India

3.1 Indian Pharmaceutical Industry: Growth Story

A pharmaceutical company, or drug company, is a commercial business whose focus is to research, develop, market and/or distribute drugs, most commonly in the context of healthcare. They can deal in generic and/or brand medications. They are subject to a variety of laws and regulations regarding the patenting, testing and marketing of drugs. From its beginning at the start of the 19th Century, the pharmaceutical industry is now one of the most successful and influential, attracting both praise and controversy.

Drug & pharmaceutical industry plays a vital role in the health care of the any country. The pharmaceutical industry in India is among the most highly organized sectors. This industry plays an important role in promoting and sustaining development in the field of global medicine. Due to the presence of low cost manufacturing facilities, educated and skilled manpower and cheap labor force among others, the industry is set to scale new heights in the fields of production, development, manufacturing and research.

The Indian Pharmaceutical Industry today is in the front rank of India’s science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously. India's pharmaceutical industry is now the third largest in the world in terms of volume
and stands 14th in terms of value. According to data published by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the total turnover of India's pharmaceuticals industry between September 2008 and September 2009 was US$ 21.04 billion. Of this the domestic market was worth US$ 12.26 billion.\(^1\) India’s pharmaceutical industry currently comprises more than 20,000 licensed companies employing approx 500,000 staff.\(^2\) The leading 250 pharmaceutical companies control 70% of the market.

The first pharmaceutical company is Bengal Chemicals and Pharmaceutical Works, which still exists today as one of 5 government-owned drug manufacturers. **Bengal Chemical & Pharmaceutical Works Ltd. (BCPW)** is precursor of the present Company, **Bengal Chemicals & Pharmaceuticals Ltd (BCPL)**. Acharya P C Ray took a rented house at 91 Upper Circular Road, Calcutta and started business with a meager capital of Rs 700.00. Since inception of the Company he was very much quality conscious and produced various products of British Pharmacopoeia standard. Eminent Doctors with nationalistic feeling like Dr R G Kar, Dr N R Sarkar, Dr S P Sarbadhikari, Dr Amulya Charan Bose, etc. came forward and patronized the products. The reputation of the Company started enhancing rapidly, when Acharya P C Ray felt of pumping more fund in the Company to produce on a large scale. This idea transpired to convert into a Limited Company and on 12th April, 1901 the name of the Company was styled as **Bengal Chemical and Pharmaceutical Works Ltd. (BCPW)**, retaining the same premises at 91 Upper Circular Road, Calcutta.\(^3\)

For the next 60 years, most of the drugs in India were imported by multinationals either in fully-formulated or bulk form. The government started
to encourage the growth of drug manufacturing by Indian companies in the early 1960s, and with the Patents Act in 1970, enabled the industry to become what it is today. This patent act removed composition patents from food and drugs, and though it kept process patents, these were shortened to a period of five to seven years. The lack of patent protection made the Indian market undesirable to the multinational companies that had dominated the market, and while they streamed out, Indian companies started to take their places. They carved a niche in both the Indian and world markets with their expertise in reverse-engineering new processes for manufacturing drugs at low costs. Although some of the larger companies have taken baby steps towards drug innovation, the industry as a whole has been following this business model until the present.

India is a major generic pharmaceutical producer and exporter and has acquired the role of pharmacy for the developing world. Indian drugs and pharmaceuticals are sold at affordable price and have been found to be safe, efficacious and of good quality. Therefore, the action taken by DGFT is in order to re-assert India’s claim as a credible generic pharma supplier and at the same time to mandate an internal discipline upon the exporting community. India exports medicine worth more than US $ 9 billion annually. The Indian pharmaceuticals industry has grown from a mere Rs. 1,500 crores turnover to approximately Rs. 1,00,611 crores in 2009-10 (upto sept., 2009). The country now ranks 3rd in the terms of volume of production (10% of global share) and 14th largest by value. Indian pharmaceutical industry growth has been propelled by exports which have grown from Rs. 6,225 crores in 1998-99 to rs. 39,821 crores in 2008-09. The domestic pharma sector has been expanding and has crossed Rs. 55,000 crores in 2008-09 from Rs. 32,000 crores in 2003-04. Indian
exports are destined to various countries around the globe including highly regulated market of USA, Europe, Japan and Australia.\(^4\)

Figure 3.1.1 Market size of Indian Pharmaceuticals Industry over the years

![Graph showing market size of Indian Pharmaceuticals Industry over the years]

<table>
<thead>
<tr>
<th>Year</th>
<th>Domestic Market</th>
<th>Exports</th>
<th>Imports</th>
<th>Total Market Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002-03</td>
<td>30365</td>
<td>12826</td>
<td>2865</td>
<td>42326</td>
</tr>
<tr>
<td>2003-04</td>
<td>32575</td>
<td>15213</td>
<td>2956</td>
<td>47332</td>
</tr>
<tr>
<td>2004-05</td>
<td>34128</td>
<td>17857</td>
<td>3139</td>
<td>52029</td>
</tr>
<tr>
<td>2005-06</td>
<td>39989</td>
<td>22216</td>
<td>4515</td>
<td>62566</td>
</tr>
<tr>
<td>2006-07</td>
<td>45367</td>
<td>24942</td>
<td>5867</td>
<td>68442</td>
</tr>
<tr>
<td>2007-08</td>
<td>50946</td>
<td>30760</td>
<td>6734</td>
<td>78610</td>
</tr>
<tr>
<td>2008-09</td>
<td>55454</td>
<td>38433</td>
<td>8552</td>
<td>89335</td>
</tr>
</tbody>
</table>

Source: Department of Pharmaceuticals, Ministry of Chemicals & Pharmaceuticals, Government of India.

The top twenty export destinations of Indian Pharmaceutical products during recent years are:

Table No. 3.1.1
Export destinations of Indian Pharmaceutical Products

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Importing Country</th>
<th>2006-07</th>
<th>2007-08*</th>
<th>2008-09*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>USA</td>
<td>4,479.00</td>
<td>5,839.35</td>
<td>7,103.27</td>
</tr>
<tr>
<td>2</td>
<td>Russia</td>
<td>1,321.64</td>
<td>1,243.81</td>
<td>1,519.20</td>
</tr>
<tr>
<td>3</td>
<td>Germany</td>
<td>1,343.83</td>
<td>1,448.01</td>
<td>1,441.87</td>
</tr>
<tr>
<td>4</td>
<td>Austria</td>
<td>80.13</td>
<td>111.38</td>
<td>1,417.15</td>
</tr>
<tr>
<td>5</td>
<td>UK</td>
<td>901.60</td>
<td>1,146.52</td>
<td>1,233.09</td>
</tr>
<tr>
<td>6</td>
<td>South Africa</td>
<td>501.57</td>
<td>684.27</td>
<td>1,126.75</td>
</tr>
<tr>
<td>7</td>
<td>Canada</td>
<td>562.45</td>
<td>789.15</td>
<td>1,090.43</td>
</tr>
<tr>
<td>8</td>
<td>Brazil</td>
<td>777.03</td>
<td>771.61</td>
<td>1,018.89</td>
</tr>
<tr>
<td>9</td>
<td>Nigeria</td>
<td>629.80</td>
<td>671.24</td>
<td>1,001.74</td>
</tr>
</tbody>
</table>
The export of drugs, pharmaceuticals and the fine chemicals as per Govt. of India sources for the year 2007-08 stood US$ 7.24 billion. This is 22.45% growth over previous year 2006-07 stood US$ 5.94 billion.\textsuperscript{5} Shri Anand Sharma, Union Minister of Commerce and Industry, while addressing the Indo-Africa Pharma Business Meet in Hyderabad on 25 Sep 2009, has stated that the exports of drugs, pharmaceuticals and fine chemicals for the year 2008-09 stood at Rs.39,538 crore (around US $ 9.35 billion), registering a growth of about 29% over the last year. “In recent times the Indian pharmaceutical sector has emerged as one of the major contributors to Indian exports with export earnings rising from a negligible amount in early 1990s to Rs.29,139.57 crore (US $ 7.24 bn) by 2007-08. The exports of Drugs, pharmaceuticals & fine chemicals of India have grown at a compounded annual growth rate of 17.8% during the five-year period 2003-04 to 2007-08”, the Minister added.\textsuperscript{6}

The composition of India’s exports of pharmaceuticals products in 2007-08 was found as, 43% of basic drugs, fine chemicals and intermediates; 55% of formulations; and 2% of herbals.

<table>
<thead>
<tr>
<th></th>
<th>Country</th>
<th>Exports 2007-08</th>
<th>Exports 2008-09</th>
<th>Growth %</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Ukraine</td>
<td>519.67</td>
<td>497.14</td>
<td>687.22</td>
</tr>
<tr>
<td>11</td>
<td>Israel</td>
<td>538.97</td>
<td>456.80</td>
<td>686.22</td>
</tr>
<tr>
<td>12</td>
<td>Netherlands</td>
<td>480.63</td>
<td>522.69</td>
<td>669.98</td>
</tr>
<tr>
<td>13</td>
<td>Spain</td>
<td>466.73</td>
<td>501.42</td>
<td>620.02</td>
</tr>
<tr>
<td>14</td>
<td>Turkey</td>
<td>470.30</td>
<td>502.10</td>
<td>614.20</td>
</tr>
<tr>
<td>15</td>
<td>China</td>
<td>686.55</td>
<td>879.42</td>
<td>561.53</td>
</tr>
<tr>
<td>16</td>
<td>Kenya</td>
<td>310.27</td>
<td>366.60</td>
<td>543.86</td>
</tr>
<tr>
<td>17</td>
<td>Vietnam</td>
<td>415.06</td>
<td>483.56</td>
<td>536.62</td>
</tr>
<tr>
<td>18</td>
<td>Belgium</td>
<td>178.44</td>
<td>273.28</td>
<td>520.90</td>
</tr>
<tr>
<td>19</td>
<td>Italy</td>
<td>504.54</td>
<td>471.28</td>
<td>57.85</td>
</tr>
<tr>
<td>20</td>
<td>Mexico</td>
<td>455.56</td>
<td>442.49</td>
<td>501.54</td>
</tr>
</tbody>
</table>

*Figures are provisional
Source: Department of Pharmaceuticals, Ministry of Chemicals & Pharmaceuticals, Government of India.
The Director General of Foreign Trade in the Department of Commerce has issued a Public Notice No. 21 (RE-2011)/2009-2014 dated January 10, 2011 mandating that all exports of pharmaceuticals and drugs from India would be made under a trace and track surveillance system. This would be done at primary, secondary and tertiary levels of packaging labels following GS-1 global standards. The system would be made effective from July 1, 2011. It may be recalled that last year some consignments of pharmaceuticals and drugs exported to Africa from China were seized by African regulatory authorities on the grounds of their being sub-standard or spurious. These consignments though had originated in China had labels of ‘Made in India’ pasted on them. This had created some adverse publicity for Indian generic pharmaceuticals and India had to specifically take this up with the African drug regulatory authorities and the Chinese Government. The Chinese Government had informed the Government of India that these consignments had been sent from China and the relevant
exporters had been criminally prosecuted and cases against them in Courts were pending.\(^7\)

As per D.G.C.I.S. statistics imports of medicinal and pharmaceuticals products for the last three years have been seen as\(^8\)

<table>
<thead>
<tr>
<th>Year</th>
<th>Import of Medicinal &amp; Pharmaceuticals Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006-07</td>
<td>Rs. 5866.27 Crores</td>
</tr>
<tr>
<td>2007-08</td>
<td>Rs. 6734.15 Crores</td>
</tr>
<tr>
<td>2008-09</td>
<td>Rs. 8674.80 Crores</td>
</tr>
</tbody>
</table>

There have been no reports of shortage of Drugs & Pharmaceuticals in recent years in India. The country is almost self-sufficient in case of formulations. The imports are essentially consists of some bulk drugs & intermediaries and some formulations that are being imported on quality & economic considerations and not necessarily non-availability from domestic source.

One report published by OPPI and YES BANK titled “Indian Pharmaceutical Industry: Vision 2015” projects Indian Pharmaceutical Industry to grow to nearly US$ 50 billion by 2015.\(^9\)

Figure 3.1.3 Indian Pharmaceutical Industry by 2015
The global pharmaceuticals market is estimated at US$ 773 billion, of which the US accounts for 38%. This share is expected to decrease to 34% by 2013 when drug sales will reach US$ 987 billion. The global market for generic drugs was estimated to be worth US$ 84 billion in 2009, of which the US accounted for about 42%. India’s contribution is about US$ 19 billion, but India ranks 3rd worldwide with volume of production at 10% of global share and 14th largest by value (1.5%). One reason for lower value share is the lower cost of drugs in India ranging from 5% to 50% less as compared to most other countries. A comparison of prices of some of the formulation packs in India vis-à-vis other countries depicts this clearly.

Table No. 3.1.3
Prices of formulation packs in India vis-à-vis other countries

<table>
<thead>
<tr>
<th>Drugs</th>
<th>India</th>
<th>Sri Lanka</th>
<th>Zimbabwe</th>
<th>U.K.</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciprofloxacin HCL</td>
<td>US$</td>
<td>0.81</td>
<td>1.16</td>
<td>1.5</td>
<td>11.4</td>
</tr>
<tr>
<td>500 mg 10’s tabs</td>
<td>Ruppes</td>
<td>39</td>
<td>55.68</td>
<td>72</td>
<td>547.2</td>
</tr>
<tr>
<td>Times Costlier</td>
<td></td>
<td>1.4</td>
<td>1.8</td>
<td>14.0</td>
<td>46.6</td>
</tr>
<tr>
<td>Diclofenac Sodium</td>
<td>US$</td>
<td>0.19</td>
<td>1.38</td>
<td>1.2</td>
<td>1.32</td>
</tr>
<tr>
<td>50 mg 10’s tabs</td>
<td>Ruppes</td>
<td>9</td>
<td>66.24</td>
<td>57.6</td>
<td>63.36</td>
</tr>
<tr>
<td>Times Costlier</td>
<td></td>
<td>7.4</td>
<td>6.4</td>
<td>7.0</td>
<td>107.8</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>US$</td>
<td>0.12</td>
<td>0.84</td>
<td>1.1</td>
<td>5.9</td>
</tr>
<tr>
<td>Product Description</td>
<td>Unit Price</td>
<td>Quantity</td>
<td>Gross Profit</td>
<td>Costlier Times</td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>------------</td>
<td>----------</td>
<td>--------------</td>
<td>----------------</td>
<td></td>
</tr>
<tr>
<td>150 mg 10’s tabs</td>
<td>Ruppes</td>
<td>5.98</td>
<td>40.32</td>
<td>6.7</td>
<td></td>
</tr>
<tr>
<td>Times Costlier</td>
<td>US$</td>
<td>1.67</td>
<td>1.85</td>
<td>2.1</td>
<td></td>
</tr>
<tr>
<td>Omeprazole</td>
<td>40 mg 10’s tabs</td>
<td>80</td>
<td>88.8</td>
<td>100.8</td>
<td></td>
</tr>
<tr>
<td>Times Costlier</td>
<td>Ruppes</td>
<td>1.1</td>
<td>1.3</td>
<td>6.6</td>
<td></td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>US$</td>
<td>0.73</td>
<td>0.99</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>75 mg 10’s tabs</td>
<td>Ruppes</td>
<td>34.88</td>
<td>47.52</td>
<td>1263.84</td>
<td></td>
</tr>
<tr>
<td>Times Costlier</td>
<td>US$</td>
<td>0.0</td>
<td>5.6</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>Simvastatin</td>
<td>20 mg 10’s tabs</td>
<td>94.52</td>
<td>169.44</td>
<td>120</td>
<td></td>
</tr>
<tr>
<td>Times Costlier</td>
<td>US$</td>
<td>0.0</td>
<td>5.6</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B. Vaccine</td>
<td>1 ml</td>
<td>3.54</td>
<td>0.0</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>R Human Insulin</td>
<td>US$</td>
<td>3.29</td>
<td>4.38</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>100 IU</td>
<td>Ruppes</td>
<td>158</td>
<td>210.24</td>
<td>480</td>
<td></td>
</tr>
<tr>
<td>Times Costlier</td>
<td>US$</td>
<td>1.3</td>
<td>3.0</td>
<td>1.7</td>
<td></td>
</tr>
</tbody>
</table>

Source: Department of Pharmaceuticals, Ministry of Chemicals & Pharmaceuticals, Government of India.

There are five Central Pharma Public Sector Undertakings (CPSUs) named:

- IDPL: Indian Drugs & Pharmaceuticals Limited.
- HAL: Hindustan Antibiotics Limited.
- BCPL: Bengal Chemicals & Pharmaceuticals Limited.
- RDPL: Rajasthan Drugs and Pharmaceuticals Limited.
- KAPL: Karnataka Antibiotics & Pharmaceuticals Limited.

The combined comparisons of Production, Sales Turnover and Gross profit of all the above over the recent years can be seen as:\(^{11}\)
Table No. 3.1.4
Production, Sales and Profit of CPSUs

<table>
<thead>
<tr>
<th>Production, Sales and Profit of CPSU’s (Rs. Crores)</th>
<th>2006-07</th>
<th>2007-08</th>
<th>2008-09</th>
<th>2009-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production</td>
<td>340.24</td>
<td>539.49</td>
<td>641.79</td>
<td>875.00</td>
</tr>
<tr>
<td>Sales Turnover</td>
<td>289.14</td>
<td>507.77</td>
<td>612.42</td>
<td>875.00</td>
</tr>
<tr>
<td>Gross Profit</td>
<td>-57.31</td>
<td>-17.17</td>
<td>-10.50</td>
<td>15.62</td>
</tr>
</tbody>
</table>

Source: Department of Pharmaceuticals, Ministry of Chemicals & Pharmaceuticals, Government of India.

In 2009, India had more than 120 US FDA-approved plants in addition to 84 UK MHRA-approved plants. Most of these plants have multiple approvals from regulatory authorities in Canada, Australia, Germany and South Africa. These approved sites aptly demonstrate the ability of Indian companies to deliver quality products worldwide and serve as platforms for CRAMS players.12
According to the first “Directory of Pharmaceuticals Manufacturing Units in India,” brought out by the Department of Pharmaceuticals, there are 10,563 pharmaceuticals manufacturing units in the country. The share of top 5 states in the terms of no. of pharmaceuticals manufacturing units is depicted below.

Source: Directory of Pharmaceuticals Manufacturing Units in India, 2007, National Pharmaceutical Pricing Authority, Govt. of India. New Delhi; http://www.nppaindia.nic.in
The complete state-wise figures of the 10,563 pharmaceuticals manufacturers can be seen in table below.

Table No. 3.1.5
State wise distribution of Pharmaceuticals Manufacturing Units

<table>
<thead>
<tr>
<th>S.N.</th>
<th>State</th>
<th>Formulation</th>
<th>Bulk Drugs</th>
<th>Total</th>
<th>% Share</th>
<th>Cumulative % Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Andhra Pradesh</td>
<td>520</td>
<td>199</td>
<td>727</td>
<td>6.9</td>
<td>6.9</td>
</tr>
<tr>
<td>2</td>
<td>Assam</td>
<td>34</td>
<td>2</td>
<td>36</td>
<td>0.3</td>
<td>7.2</td>
</tr>
<tr>
<td>3</td>
<td>Bihar</td>
<td>95</td>
<td>3</td>
<td>98</td>
<td>0.9</td>
<td>8.2</td>
</tr>
<tr>
<td>4</td>
<td>Chhatisgarh</td>
<td>12</td>
<td>1</td>
<td>13</td>
<td>0.1</td>
<td>8.3</td>
</tr>
<tr>
<td>5</td>
<td>Delhi</td>
<td>414</td>
<td>126</td>
<td>540</td>
<td>5.1</td>
<td>13.4</td>
</tr>
<tr>
<td>6</td>
<td>Goa</td>
<td>41</td>
<td>7</td>
<td>48</td>
<td>0.5</td>
<td>13.8</td>
</tr>
<tr>
<td>7</td>
<td>Gujarat</td>
<td>1129</td>
<td>397</td>
<td>1526</td>
<td>14.4</td>
<td>28.3</td>
</tr>
<tr>
<td>8</td>
<td>Haryana</td>
<td>294</td>
<td>21</td>
<td>315</td>
<td>3.0</td>
<td>31.3</td>
</tr>
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<td>9</td>
<td>Himachal Pradesh</td>
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<td>3.5</td>
<td>34.8</td>
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<td>10</td>
<td>Jammu &amp; Kashmir</td>
<td>36</td>
<td>2</td>
<td>38</td>
<td>0.4</td>
<td>35.1</td>
</tr>
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<td>11</td>
<td>Jharkhand</td>
<td>21</td>
<td>0</td>
<td>21</td>
<td>0.2</td>
<td>35.3</td>
</tr>
<tr>
<td>12</td>
<td>Karnataka</td>
<td>221</td>
<td>74</td>
<td>295</td>
<td>2.8</td>
<td>38.1</td>
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<tr>
<td>13</td>
<td>Kerala</td>
<td>232</td>
<td>12</td>
<td>244</td>
<td>2.3</td>
<td>40.4</td>
</tr>
<tr>
<td>14</td>
<td>Madhya Pradesh</td>
<td>344</td>
<td>70</td>
<td>414</td>
<td>3.9</td>
<td>44.3</td>
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<tr>
<td>15</td>
<td>Maharashtra</td>
<td>1928</td>
<td>1211</td>
<td>3139</td>
<td>29.7</td>
<td>74.1</td>
</tr>
<tr>
<td>16</td>
<td>Manipur</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>0.0</td>
<td>74.1</td>
</tr>
<tr>
<td>17</td>
<td>Orissa</td>
<td>90</td>
<td>2</td>
<td>92</td>
<td>0.9</td>
<td>75.0</td>
</tr>
<tr>
<td>18</td>
<td>Punjab</td>
<td>233</td>
<td>30</td>
<td>263</td>
<td>2.5</td>
<td>77.4</td>
</tr>
<tr>
<td>19</td>
<td>Rajasthan</td>
<td>157</td>
<td>24</td>
<td>181</td>
<td>1.7</td>
<td>79.2</td>
</tr>
<tr>
<td>20</td>
<td>Tamil Nadu</td>
<td>472</td>
<td>98</td>
<td>570</td>
<td>5.4</td>
<td>84.5</td>
</tr>
<tr>
<td>21</td>
<td>Tripura</td>
<td>10</td>
<td>0</td>
<td>10</td>
<td>0.1</td>
<td>84.6</td>
</tr>
<tr>
<td>22</td>
<td>Uttar Pradesh</td>
<td>414</td>
<td>32</td>
<td>446</td>
<td>4.2</td>
<td>88.9</td>
</tr>
<tr>
<td>23</td>
<td>Uttrakhand</td>
<td>255</td>
<td>6</td>
<td>261</td>
<td>2.5</td>
<td>91.3</td>
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<tr>
<td>24</td>
<td>West Bengal</td>
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<td>62</td>
<td>756</td>
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<td>98.5</td>
</tr>
<tr>
<td>25</td>
<td>Chandigarh</td>
<td>6</td>
<td>0</td>
<td>6</td>
<td>0.1</td>
<td>98.6</td>
</tr>
<tr>
<td>26</td>
<td>D &amp; N Haveli</td>
<td>24</td>
<td>1</td>
<td>25</td>
<td>0.2</td>
<td>98.8</td>
</tr>
<tr>
<td>27</td>
<td>Daman &amp; Diu</td>
<td>67</td>
<td>0</td>
<td>67</td>
<td>0.6</td>
<td>99.4</td>
</tr>
<tr>
<td>28</td>
<td>Puducherry</td>
<td>57</td>
<td>4</td>
<td>61</td>
<td>0.6</td>
<td>100</td>
</tr>
<tr>
<td>29</td>
<td>Total</td>
<td>8174</td>
<td>2389</td>
<td>10563</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

Source: Directory of Pharmaceuticals Manufacturing Units in India, 2007, National Pharmaceutical Pricing Authority, Govt. of India. New Delhi; http://www.nppaindia.nic.in
Indian government created the Department of Pharmaceuticals in the Ministry of Chemicals and Fertilisers on 01-07-2008 to provide greater focus on the growth of the Pharmaceuticals industry. The following main works have been allocated to the Dept. of Pharmaceuticals:\(^{14}\)

- Drugs and Pharmaceutical, excluding those specifically allotted to other departments.
- Promotions and co-ordination of basic, applied and other research in the areas related to the Pharmaceuticals sector.
- Development of infrastructure, manpower and skills for the Pharmaceuticals sector and management of related information.
- Education and training including high end research grant of fellowship in India and abroad, exchange of information and technical guidance on all matters relating to Pharmaceutical sector.
- Promotion of public-private-partnership (PPP) in pharmaceutical related areas.
- International cooperation in Pharmaceutical research, including works related to international conferences in related areas in India and abroad.
- Inter-sectoral coordination including coordination between organisations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.
- Technical support for dealing with national hazards in pharmaceutical sector.
- All matters relating to National Pharmaceutical Pricing Authority (NPPA) including related functions of price control/ monitoring.
- All matters relating to National Institutes for Pharmacy Education and Research (NIPER).
• Planning, development and control of and assistance to, all industries dealt with the Department.
• IDPL: Indian Drugs & Pharmaceuticals Limited.
• HAL: Hindustan Antibiotics Limited.
• BCPL: Bengal Chemicals & Pharmaceuticals Limited.
• RDPL: Rajasthan Drugs and Pharmaceuticals Limited.
• KAPL: Karnataka Antibiotics & Pharmaceuticals Limited.

Union Budget of Government of India gives provision in 2011 Annual Budget for the Pharmaceutical Industries as follows:¹⁵
### Table No. 3.1.6

GOI’s provision in 2011 Annual Budget for the Pharmaceutical Industries

**Department of Pharmaceuticals**

A. The Budget allocations, net of recoveries, are given below:

<table>
<thead>
<tr>
<th>Major Head</th>
<th>Actual 2009-2010</th>
<th>Budget 2010-2011</th>
<th>Revised 2010-2011</th>
<th>Budget 2011-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plan</td>
<td>Non-Plan</td>
<td>Total</td>
<td>Plan</td>
</tr>
<tr>
<td>Revenue</td>
<td>77.41</td>
<td>31.25</td>
<td>108.66</td>
<td>125.00</td>
</tr>
<tr>
<td>Capital</td>
<td>24.49</td>
<td></td>
<td>24.49</td>
<td>40.00</td>
</tr>
<tr>
<td>Total</td>
<td>101.90</td>
<td>31.25</td>
<td>133.15</td>
<td>165.00</td>
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</tbody>
</table>

1. Secretary-Economic Services  9451  0.25  5.06  5.31  0.25  7.34  7.59  0.25  7.46  7.71  0.25  7.64  7.89

**Industries**

1. National Institute of Pharmaceutics Education and Research (NIPER)
2. National Pharmaceutical Pricing Authority (NPPA)
3. Pharmaceutical Export Promotion Scheme (PEPS)
4. Pharmaceutical Promotion & Development Scheme (PPDS)
5. Other Revenue

<table>
<thead>
<tr>
<th>Major Head</th>
<th>Actual 2009-2010</th>
<th>Budget 2010-2011</th>
<th>Revised 2010-2011</th>
<th>Budget 2011-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plan</td>
<td>Non-Plan</td>
<td>Total</td>
<td>Plan</td>
</tr>
<tr>
<td>Total</td>
<td>77.15</td>
<td>26.17</td>
<td>103.32</td>
<td>108.25</td>
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</tbody>
</table>

Total Industries

<table>
<thead>
<tr>
<th>Major Head</th>
<th>Actual 2009-2010</th>
<th>Budget 2010-2011</th>
<th>Revised 2010-2011</th>
<th>Budget 2011-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plan</td>
<td>Non-Plan</td>
<td>Total</td>
<td>Plan</td>
</tr>
<tr>
<td>Total</td>
<td>31.26</td>
<td>31.26</td>
<td>62.52</td>
<td>62.52</td>
</tr>
</tbody>
</table>

B. Investment in Public Enterprises

<table>
<thead>
<tr>
<th>Major Head</th>
<th>Actual 2009-2010</th>
<th>Budget 2010-2011</th>
<th>Revised 2010-2011</th>
<th>Budget 2011-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plan</td>
<td>Non-Plan</td>
<td>Total</td>
<td>Plan</td>
</tr>
</tbody>
</table>

C. Plan Outlay

<table>
<thead>
<tr>
<th>Major Head</th>
<th>Actual 2009-2010</th>
<th>Budget 2010-2011</th>
<th>Revised 2010-2011</th>
<th>Budget 2011-2012</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plan</td>
<td>Non-Plan</td>
<td>Total</td>
<td>Plan</td>
</tr>
<tr>
<td>Total</td>
<td>101.81</td>
<td>101.81</td>
<td>203.62</td>
<td>103.00</td>
</tr>
</tbody>
</table>

Source: Government of India, Union Budget and Economic Survey; http://indiabudget.nic.in/vol2.asp
3.2 Marketing Mix (4Ps) of Pharmaceutical Products

James P Orlowski (M.D., F.C.C.) and Leon Wateska (R.Ph., M.S.) in the official journal of the American College of Chest Physicians named CHEST published a researched article titled “The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns* There’s No Such Thing as a Free Lunch” in July 1992. The surprisingly findings of the research were indicating how the marketing efforts by the Pharmaceuticals companies changes the habit of prescriptions of drugs by doctors. They examined the impact on physician prescribing patterns of pharmaceutical firms offering all-expenses-paid trips to popular sun-belt vacation sites to attend symposia sponsored by a pharmaceutical company. The impact was assessed by tracking the pharmacy inventory usage reports for two drugs before and after the symposia. Both drugs were available only as intravenous preparations and could be used only on hospitalized patients. The usage patterns were tracked for 22 months preceding each symposium and for 17 months after each symposium. Ten physicians invited to each symposium were interviewed about the likelihood that such an enticement would affect their prescribing patterns. A significant increase in the prescribing pattern of both drugs occurred following the symposia. The usage of drug A increased from a mean of 81 ±44 units before the symposium to a mean of 272 ± 117 after the symposium (p<0.001). The usage of drug B changed from 34 ± 30 units before the symposium to 87 ± 24 units (p<0.001) after the symposium. These changed prescribing patterns were also significantly different from the national usage patterns of the two drugs by hospitals with more than 500 beds and major medical centers over the same period of time. These alterations in prescribing patterns occurred even though the majority of
physicians who attended the symposia believed that such enticements would not alter their prescribing patterns.\textsuperscript{15}

Marketing is an essential function in any business without which the surviving of business is critical. As the marketing theorist Theodore Levitt observes, “There can be no effective corporate strategy that is not marketing oriented, that does not in the end follow this unyielding prescription: The purpose of business is to create and keep customer.” However, Levitt should also add that businesses must also develop products and services that customers want and at prices they are willing to pay. Marketing broadly conceived includes, then, making decisions about what products or services to put on the market, who are the potential customers for these goods, how to reach the target markets and induce them to buy, how to price the product or service to make is attractive to these customers, and how to deliver the goods physically to the ultimate consumers. These matters are often expressed as the four Ps of marketing: Product, Price, Promotion and Place. Let us describe these 4 Ps comprehensively relating to Indian Pharmaceutical Industry.

\textbf{3.2.1 Product}

Here we talk about the need category of the consumers, types of products, their development, testing, packaging, leveling and branding etc and related things which are the topics of concern to offer anything, any drug in market.

In India, the import, manufacture, distribution and sale of drugs and cosmetics are regulated by the \textit{Drugs and Cosmetics Act} (DCA) and its subordinate legislation, the \textit{Drugs and Cosmetics Rules 1945} (DCR) and Drugs and Magic Remedies Act, 1954.\textsuperscript{17}
Anti-infective is estimated to be the major therapeutic segment accounting for 14.7% of the total pharma market in India. The major sub-segments within this category are Cephalosporins, Quinolones, Penicillin and Macrolides. Cardiovascular drugs are the next major therapeutic segment contributing 11.1% of the total sales. The major sub-segments under this category include anti-hypertensives, statins and anticoagulants. Gastrointestinal and respiratory are the next leading therapeutic segments accounting for 10.7% and 10.5% in 2005-06.

Table No. 3.2.1.1
Therapeutic Segmentation of Pharmaceutical Market in India

<table>
<thead>
<tr>
<th>Therapeutic Segments</th>
<th>%ge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti Infectives</td>
<td>14.70%</td>
</tr>
<tr>
<td>CVS</td>
<td>11.10%</td>
</tr>
<tr>
<td>Gastro Intestinal</td>
<td>10.70%</td>
</tr>
<tr>
<td>Respiratory</td>
<td>10.50%</td>
</tr>
<tr>
<td>Analgesics</td>
<td>9.60%</td>
</tr>
<tr>
<td>Vitamins/ Food Supplements</td>
<td>9.20%</td>
</tr>
<tr>
<td>Dermatology</td>
<td>5.40%</td>
</tr>
<tr>
<td>CNS</td>
<td>5.40%</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>5.00%</td>
</tr>
<tr>
<td>Anti Diabeticcs</td>
<td>4.60%</td>
</tr>
<tr>
<td>Others</td>
<td>13.80%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100.00%</td>
</tr>
</tbody>
</table>

Figure 3.2.1.1 Therapeutic Segmentation

Source: Cygnus Research; ASSOCHAM 2006; A white paper on Indian Pharma Industry: Quest for Global Leadership.
The major classification of drugs on the basis of prescriptions is: Prescription Drugs and Non-Prescription Drugs.

1. **Prescription Drugs:** Prescription drugs are drugs that are not locally available without a physician's prescription. A prescription drug is a licensed medicine which is obtained only by prescription. The prescription drugs are regulated by legislation. In India, "Rx" is often used as a short form for prescription drug. In European countries, any kind of prescription drug has a monograph or Patient Information Leaflet (PIL) that gives detailed information about the drug. Prescription-only drugs are those medicines that are listed in Schedules H and X appended to the Drug and Cosmetics Act & its Rules. Drugs listed in Schedule G (mostly antihistamines) do not need prescription to purchase but require the following mandatory text on the label: “Caution: It is dangerous to take this preparation except under medical supervision”. Drugs falling in these 3 schedules are currently not advertised to the public under a voluntary commitment by the pharmaceutical industry.

2. **Non Prescription Drugs:** These are medicines, which can be bought at a pharmacy without the prescription of a doctor, at the pharmacist's advice. These are also known as over-the-counter (OTC) medicines. ‘OTC Drugs’ means drugs legally allowed to be sold ‘Over The Counter’, i.e. without the prescription of a Registered Medical Practitioner. In India, though the phrase has no legal recognition, all the drugs that are not included in the list of ‘prescription only drugs’ are considered as non-prescription drugs (or OTC drugs). Currently, non drug-licensed stores (e.g. non-chemists) can sell a few medicines classified as ‘Household
Remedies’ listed in Schedule K of the DCA&R in villages whose population is below 1,000. OTC proprietary drugs registered as ‘Ayurvedic Medicines’ (= traditional Indian medicines containing natural / herbal ingredients) are also regulated by the DCA and DCR. However, as they do not require a drug licence they can be sold by non-chemists. Some of the top OTC brands in India (e.g. Vicks VapoRub, Amrutanjan Balm, Zandu Balm, Iodex, Moov Pain Cream, Itch Guard Cream, Eno Fruit Salt, Vicks Cough Drops, Halls Lozenges, etc.), are registered as ‘Ayurvedic Medicines’ because of their plant-based natural active ingredients. There are no price controls on ‘Ayurvedic Medicines’.

**List of Prescription Drugs**

1. Anti-convulsant Drugs
2. Anti-Obesity Drugs
3. Anti-Angina Drugs
4. Anti-Fungal Drugs
5. Anti-Itch Drugs
6. Anti-Viral Drugs
7. Anti-Diabetic Drugs
8. Anti-Asthmatic Drugs
9. Anti-Hypertensive Drugs
10. Antibiotics
11. Anti-Migraine Drugs
12. Anti-Rheumatic Drugs
13. Anti-Protozoal Drugs
14. Tricyclic Anti-depressants
15. Anti-Arrhythmic Drugs
16. Anti-nausea Drugs
17. Anti-Parkinson Drugs
18. Anti-Psychotic Drugs
19. Muscle Relaxants
20. Digitalis Drugs
21. Anti-Gastroesophageal Reflux Drugs
22. Anti-Retroviral Drugs
23. Anti-Tuberculosis Drugs
24. Anti-Ulcer Drugs
25. Anti-Hemorrhoid Drugs
26. Anti-Spasmodic Drugs
27. Anti-malarial Drugs
28. Non-steroidal Anti-inflammatory Drugs: Some can be bought over the counter; others are available only with a prescription from a physician or dentist.
29. Immuno-Suppressant Drugs
30. Anti-Insomnia Drugs
31. Anti-helminthic Drugs
32. Central Nervous System Stimulants
33. Decongestants: Some decongestant products require a physician's prescription but there are also many non-prescription (over-the-counter) products.
34. Anti-Coagulant Drugs
35. Bone Disorder Drugs
36. Infertility Drugs
37. Topical Antibiotics: Some topical antibiotics are available with a prescription only.
38. Diuretics
39. Vasodilators: In the forms used for treating high blood pressure (tablets or injections), these drugs are available only with a physician's prescription.
40. Blood-viscosity Reducing Drugs
41. Beta Blockers
42. Corticosteroids
43. Benzodiazepines
44. Cephalosporins
45. Expectorants: Some products that contain are available only with a physician's prescription
46. Sulfonamides
47. Calcium Channel Blockers
48. Gout Drugs
49. Anti-histamines: Some Anti-histamine products are available only with a physician's prescription.
50. Penicillins
51. Barbiturates
52. Laxatives
53. ACE inhibitors
54. Anti-anxiety Drugs
55. Urinary Anti-infectives
56. MAO Inhibitors
57. Opioid Analgesics
58. Bronchodilators
59. Ophthalmic Antibiotics
60. Smoking Cessation Drugs: Some products are available only with a prescription.
61. Protease Inhibitor
62. Anti-depressant Drugs
63. Alpha1-adrenergic Blockers
64. Tetracyclines

**List of Non-Prescription Drugs**

1. Anti-Hemorrhoid Drugs
2. Herbal / Ayurvedic Medicines.
3. Topical Antibiotics: Some topical antibiotics are available without a prescription
4. Cough-Suppressants
5. Anti-acne Drugs
6. Non-steroidal Anti-inflammatory Drugs: Some can be bought over the counter; others are available only with a prescription from a physician or dentist.
7. Antiseptics
8. Analgesics
9. Decongestants: Some decongestant products require a physician's prescription but there are also many non-prescription (over-the-counter) products.
10. Aspirin
11. Vasodilators: Some Vasodilators such as Minoxidil are sold without prescription.
12. Antacids
13. Expectorants: Many expectorants are available without a physician's prescription.
14. Anti-fungal Drugs
15. Anti-Histamines: Some can be bought without prescription.
16. Anti-gas Agents
17. Smoking Cessation Drugs: Many drugs can be bought over the counter, without prescription.

**Trade Names** of the drugs are mandatory although sometimes generic names of molecules only is enough to buy the drug in the market. Trade names are regulated by the *Trade and Merchandise Marks Act* (TMMA). The TMMA provides for registration of trademarks for a period of seven years at a time, renewable after each period. For any item, trademarks should not be objectionable from a religious or social point of view. They should not contravene the *Emblems and Names (Prevention of Improper Use) Act*, 1950. They should also not yet be registered or applied to be registered in India. The trademark can be registered even if the item is not produced or sold in India at present.

A foreign trademark can be used without any restriction. Foreign companies can license their trade mark to their local subsidiaries or joint ventures. The *Indian Copyright Act* also provides protection for unique logos and designs on packaging.

Pass-off or look-alike copies of popular OTC drugs are a major issue because the license to manufacture and sell drugs is issued by state-level FDAs who do not verify whether they issues a manufacturing and selling license to a pass-off drug. However, the Indian courts are known to provide quick and corrective
action against a pass-off product, although the burden of search and taking the pass off manufacturer to court falls on the individual affected company.

**Patent information and labeling** is again mandatory to sell the pharmaceuticals in India. Ethical (prescription only) pharmaceuticals label is nothing but information compiled about a product that is provided by a manufacturer and approved by drug controller of India. The label would contain necessary information for safe and effective use of a drug and is written primarily for healthcare professionals. Pharmaceutical labels are important aspects of a product, as they carry information related to the product identity, product usage and shelf life, apart from source and regulatory information. Rule 96 of the DCR (‘Manner of Labelling’) mandates the information which needs to be put on the label of all medicines other than homeopathic medicines. This includes:

- a) proper (generic) and trade (brand) name
- b) net contents and content of active ingredients,
- c) name and address of manufacturer including manufacturing license number,
- d) distinctive batch number, etc.

Rule 97 requires on-label caution statements for the different drug schedules. For example, drugs falling under Schedule G require “Caution: it is dangerous to take this preparation except under medical supervision”. Schedule H drugs need the symbol ‘Rx’ as well as “Schedule H – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only”.23
There are no separate labelling requirements for OTC drugs. Under the Packaging Commodities Act, most packaged consumer products including drugs are required to have the Maximum Retail Price (MRP) printed on the label. The selling of any product at a price higher than the MRP is not permitted.

According to the United States Pharmacopoeia (USP), the term "labeling" designates all labels and other written, printed, or graphic matter upon an immediate container of an article or upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of labeling upon the immediate container.\textsuperscript{24}

It is observed that in India the pharmaceutical labels are not comprehensive, as regulatory guidelines cover only partial aspects of labelling. For instance, it is optional to carry the product usage and related information for the patients. Besides, it was found that the labels in the Indian market are grossly and inadequate from the point of view of the patient and health care professional. Hence, there is a need to form national guidelines with proper regulations. The labeling guidelines should be implemented uniformly throughout the nation. This could help in avoiding medication error and assist in quality use of medicines.

In most developed countries, the regulatory agencies have established comprehensive guidelines and rules for the content and format of labeling. For example in the United States these are set in the Code of Federal Regulations under Title 21 concerning the Food and Drug Act. 21 CFR 201.56 defines the major topical sections to be included as:\textsuperscript{25}
In India the rules specify the indication of the proper name of the drug in a more conspicuous manner than the brand name, correct statement of the net contents, details of active ingredients, address and name of the manufacturer, distinctive batch number, manufacturing license number, expiry particulars, information related to storage or manner of use and general information like physician's sample, not for sale. However, there is no specific rule regarding the inclusion of auxiliary (cautionary and advisory) labels, therapeutic indication, dose, side effects and other relevant information regarding the drug on the package label. A N Nagappa, N K Srivastava, M Varghese, S K Rupani and S Poojee all associated with Department of Pharmaceutical Management, Manipal College of Pharmaceutical Sciences, Manipal, India, suggest some requirements about labeling of drugs in India as: 26
Recommended label wording can offer advice about:

- Timing of doses in relation to food
- Completing the course of treatment
- What to do if a dose is missed
- The correct storage of a medicine
- Dissolution of the medicine in water before taking it
- Limits to the number of tablets that should be taken in a given time

Recommended label wording can offer warnings about:

- Effects of the medicine on driving or work (e.g. through drowsiness)
- Foods or medicines that should be avoided
- Avoidance of exposure of the skin to sunlight or sun lamps
- Medicines that can discolor the urine
- Medicines that can stain clothes or skin

They also suggest that the incorporation of these labels will not only reduce the occurrence of errors, but also optimise the drug therapy. They recommended wording of cautionary & advisory labels like:

**Warnings**

- May cause drowsiness
- May cause drowsiness. If affected do not drive or operate machinery
- Avoid alcoholic drink
- Follow the printed instructions you have been given with this medicine
- Causes drowsiness which may continue the next day. If affected do not drive or operate machinery. Avoid alcoholic drink
- This medicine may colour the urine
Instruction for usage

- Take at regular intervals. Complete the prescribed course unless otherwise directed
- Dissolve or mix with water before taking
- Allow to dissolve under the tongue. Do not transfer from this container. Keep tightly closed. Discard 8 weeks after opening.
- with or after food
- half to one hour before food
- an hour before food or on an empty stomach
- sucked or chewed
- swallowed whole, not chewed
- dissolved under the tongue
- with plenty of water
- To be spread thinly

Dos and don'ts

- Do not take indigestion remedies at the same time of day as this medicine
- Do not take indigestion remedies or medicines containing iron or zinc at the same time of day as this medicine
- Do not take milk, indigestion remedies, or medicines containing iron or zinc at the same time of day as this medicine
- Do not stop taking this medicine except on your doctor's advice
- Avoid exposure of skin to direct sunlight or sun lamps
- Do not take anything containing aspirin while taking this medicine
- Caution flammable: keep away from fire or flames
- Do not take more than…in 24 hours
- Do not take more than…in 24 hours or…in any one week
- Do not take more than 2 at any one time. Do not take more than 8 in 24 hours
- Do not take with any other Paracetamol products
- Contains aspirin and Paracetamol. Do not take with any other Paracetamol products
- Contains aspirin
- Contains an aspirin-like medicine

Some internationally used Pharmaceutical Abbreviations which may be used in prescriptions, advertising and labeling are cited below: 27
Table No. 3.2.1.2
Internationally used Pharmaceutical Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
<th>Latin</th>
</tr>
</thead>
<tbody>
<tr>
<td>ad.lib.</td>
<td>freely as wanted</td>
<td><em>ad libitum</em></td>
</tr>
<tr>
<td>aq.</td>
<td>Water</td>
<td><em>Aqua</em></td>
</tr>
<tr>
<td>b.i.d.</td>
<td>twice a day</td>
<td><em>bis in die</em></td>
</tr>
<tr>
<td>cap.</td>
<td>Capsule</td>
<td><em>Capula</em></td>
</tr>
<tr>
<td>c with bar on top</td>
<td>With</td>
<td><em>Cum</em></td>
</tr>
<tr>
<td>div.</td>
<td>Divide</td>
<td><em>Divide</em></td>
</tr>
<tr>
<td>eq pts.</td>
<td>equal parts</td>
<td><em>equalis parties</em></td>
</tr>
<tr>
<td>gtt.</td>
<td>a drop</td>
<td><em>Gutta</em></td>
</tr>
<tr>
<td>h.</td>
<td>Hour</td>
<td><em>Hora</em></td>
</tr>
<tr>
<td>no.</td>
<td>Number</td>
<td><em>Numero</em></td>
</tr>
<tr>
<td>O.</td>
<td>Pint</td>
<td><em>Octarius</em></td>
</tr>
<tr>
<td>p.r.n.</td>
<td>as occasion requires</td>
<td><em>pro re nata</em></td>
</tr>
<tr>
<td>q.s.</td>
<td>a sufficient quantity</td>
<td><em>quantum sufficiat</em></td>
</tr>
<tr>
<td>q4h</td>
<td>every 4 hours</td>
<td><em>quaque 4 hora</em></td>
</tr>
<tr>
<td>q6h</td>
<td>every 6 hours</td>
<td><em>quaque 6 hora</em></td>
</tr>
<tr>
<td>q1d</td>
<td>every day</td>
<td><em>quaque 1 die</em></td>
</tr>
<tr>
<td>q1w</td>
<td>every week</td>
<td></td>
</tr>
<tr>
<td>q.i.d.</td>
<td>four times a day</td>
<td><em>quater in die</em></td>
</tr>
<tr>
<td>s.i.d.</td>
<td>once a day</td>
<td><em>semel in die</em></td>
</tr>
<tr>
<td>Sig., S.</td>
<td>write on the label</td>
<td><em>Signa</em></td>
</tr>
<tr>
<td>stat.</td>
<td>Immediately</td>
<td><em>Statim</em></td>
</tr>
<tr>
<td>tab.</td>
<td>a tablet</td>
<td><em>Tabella</em></td>
</tr>
<tr>
<td>t.i.d.</td>
<td>three times a day</td>
<td><em>ter in die</em></td>
</tr>
</tbody>
</table>

Table No. 3.2.1.3
Weights and measures used in prescribing and toxicology:

**The Metric System**

**Weight**
- 1 picogram (pg) = $10^{-12}$ gram
- 1000 picograms = 1 nanogram (ng) or $10^{-7}$ gram
- 1000 nanograms = 1 microgram (ug) or $10^{-6}$ gram
- 1000 micrograms = 1 milligram (mg) or $10^{-3}$ gram
- 1000 milligrams = 1 gram (g)
- 1000 grams = 1 kilogram (kg)

**Volume**
- 1000 milliliters (ml) = 1 liter (L)

*Be able to interconvert all of these values*

*Prefixes for volumes correspond to those for weight.*
IMPORTANT: Know that 1 part per million (ppm) is a frequently used term in toxicology and drug residue discussions. For example, the following are 1 ppm: 1 mg/kg, 1 mcg/g. An analogy is "Percent" that represents 1 part per hundred, i.e., 1 g/100 g = 1% w/w. The expression "w/w" indicates that the amount of both substances is on a weight basis. It is assumed that ppm is w/w unless otherwise specified.

Table No. 3.2.1.4
The Apothecaries' System

The Apothecaries' System

Weight
20 grains (gr) 1 scruple ( )
3 scruples 1 dram( ) = 60 grains
8 drams 1 ounce ( ) = 480 grains

Volume
60 minims (m) 1 fluid dram ( )
8 fluid drams 1 fluid ounce ( )
16 fluid ounces 1 pint (O.)

Table No. 3.2.1.5
Conversion Equivalents

<table>
<thead>
<tr>
<th>Approximate</th>
<th>Exact</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 milligram</td>
<td>1/60 grain</td>
</tr>
<tr>
<td>1 gram</td>
<td>15 grains</td>
</tr>
<tr>
<td>1 kilogram</td>
<td>2.2 pounds*</td>
</tr>
<tr>
<td>1 milliliter</td>
<td>15 minims</td>
</tr>
<tr>
<td>1 liter</td>
<td>1 quart</td>
</tr>
<tr>
<td>1 grain</td>
<td>60 milligrams</td>
</tr>
<tr>
<td>1 dram</td>
<td>4 grams</td>
</tr>
<tr>
<td>1 ounce</td>
<td>30 grams</td>
</tr>
<tr>
<td>1 pound*</td>
<td>450 grams</td>
</tr>
<tr>
<td>1 minim</td>
<td>0.06 milliliter</td>
</tr>
<tr>
<td>1 fluid dram</td>
<td>4 milliliters</td>
</tr>
<tr>
<td>1 fluid ounce</td>
<td>30 milliliters</td>
</tr>
<tr>
<td>1 pint</td>
<td>500 milliliters</td>
</tr>
<tr>
<td>1 quart</td>
<td>1000 milliliters</td>
</tr>
<tr>
<td>1 drop</td>
<td>1 minim</td>
</tr>
<tr>
<td>1 teaspoonful</td>
<td>5 milliliters</td>
</tr>
<tr>
<td>1 dessertspoonful</td>
<td>8 milliliters</td>
</tr>
<tr>
<td>1 tablespoonful</td>
<td>15 milliliters</td>
</tr>
</tbody>
</table>

Note: Where possible, use suitable units rather than decimal fractions, e.g., 10 mg not 0.010 g. When a decimal fraction is used the decimal point must be preceded by a zero, e.g., 0.5 not .5. *= avoirdupois pound (the one used in the USA!)
Table No. 3.2.1.6
Conversion factors for obtaining approximate equivalents

<table>
<thead>
<tr>
<th>To convert</th>
<th>To</th>
<th>Multiply by</th>
</tr>
</thead>
<tbody>
<tr>
<td>gr/lb</td>
<td>mg/lb</td>
<td>60</td>
</tr>
<tr>
<td>gr/lb</td>
<td>mg/kg</td>
<td>143</td>
</tr>
<tr>
<td>mg/lb</td>
<td>gr/lb</td>
<td>0.015</td>
</tr>
<tr>
<td>mg/lb</td>
<td>mg/kg</td>
<td>2.2</td>
</tr>
<tr>
<td>mg/kg</td>
<td>gr/lb</td>
<td>0.007</td>
</tr>
<tr>
<td>mg/kg</td>
<td>mg/lb</td>
<td>0.45</td>
</tr>
</tbody>
</table>

Table No. 3.2.1.7
Commonly used abbreviation in product information leaflets and literature: 28

1 ACE  Angiotensin converting enzyme  56 IVU  Intravenous urography
2 ACTH  Adreocorticotropic hormone  57 JVP  Jugular venous pressure
3 ADH  Antidinratic hormone  58 LA  Left atrium
4 ADHD  Attention deficit hypersensitivity Disorder
5 AF  Atrial fibrillation  59 LBBB  Left bundle branch block
6 AIDS  Acquired immunodeficiency syndrome
7 ALL  Acutelymphoblastic leukemia  60 LDH  Lactate dehydrogenase
8 ALT  Alanine Transaminase  61 LDL  Low density lipoprotein
9 AML  Acute myeloid anaemia
10ANF  Antinuclear factor  62 LFT  Liver function test
11ASD  Atrial septal defect  63 LH  Lutenizing hormone
12ASO  Antistreptolysin O  64 LVF  Left ventricular failure
13AST  Aspartate Transaminase  65 MCV  Mean cell Volume
14ATN  Acutetubular necrosis  66 MI  Myocardial infarction
28 OCP  Oral contraceptive pill

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15 BBB  Bundle branch block
16 BMT  Bone marrow transplant
17 CABG  Coronary artery bypass graft
18 CAPD  Chronic ambulatory peritoneal dialysis.
19 CCF  Congestive cardiac failure
20 CCU  Coronary care Unit.
21 CEA  Carcinoembryonic antigen
22 CLL  Chronic lymphoblastic leukemia
23 CML  Chronic myeloid leukemia
24 CMV  Cytomegalovirus
25 COLD  Chronic obstructive lung disease
26 CRF  Chronic renal failure
27 CSF  Cerebrospinal fluid
28 CT  Computed tomography
29 CVA  Cerebrovascular accident
30 CVP  Central venous pressure
31 CXR  Chest X-ray
32 DIC  Disseminated intravascular Coagulation
33 DM  Diabetes mellitus
34 DU  Duodenal Ulcer
35 DVT  Deep Venous Thrombosis
36 EBV  Esptein - Barr Virus
37 OGTT  Oral glucose tolerance test
38 PA  Pulmonary Artery
39 PABA  Para- amino benzoic acid
40 PAS  Para-amino salicylic acid
41 PCP  Pneumocystis carini phenmonia
42 PCV  Packed cell volume
43 PDA  Patent ductus arteriosus.
44 PEEP  Positive-end expiratory pressure
45 PEFR  Peak expiratory flow rate
46 PPD  Purified protein derivature
47 PTH  Parathyroid hormone
48 PT  Prothrombin tune
49 PTT  Partial thromboplastin time
50 PUO  Pyrescia of unknown origin
51 RA  Rheumatoid arthritis
52 RAD  Right anis deviation
53 RAG  R antigen
54 RAST  RAdioallergrosorbent test
55 RVF  Right ventricular failure
56 SBE  Subacute bacterial endocarditis
57 SLE  Systemic Lupus Erythrematosus
58 SVT  Supraventricular tachycardia
<table>
<thead>
<tr>
<th>No.</th>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>37</td>
<td>ELISA</td>
<td>Enzyme-linked immunosorbent assay</td>
</tr>
<tr>
<td>38</td>
<td>EMG</td>
<td>Electromyography</td>
</tr>
<tr>
<td>39</td>
<td>ESR</td>
<td>Erythrocyte sedimentation rate</td>
</tr>
<tr>
<td>40</td>
<td>FFP</td>
<td>Fresh frozen plasma</td>
</tr>
<tr>
<td>41</td>
<td>FTA</td>
<td>Fluorescent treponemal antibody test</td>
</tr>
<tr>
<td>42</td>
<td>FVC</td>
<td>Forced Vital Capacity</td>
</tr>
<tr>
<td>43</td>
<td>GABA</td>
<td>Gamma aminobutyric acid</td>
</tr>
<tr>
<td>44</td>
<td>GFR</td>
<td>Glomeruler filtration rate</td>
</tr>
<tr>
<td>45</td>
<td>HBV</td>
<td>Hepatitis B Virus</td>
</tr>
<tr>
<td>46</td>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
</tr>
<tr>
<td>47</td>
<td>HOCM</td>
<td>Hypertrophic obstruction Cardiomyopathy</td>
</tr>
<tr>
<td>48</td>
<td>HSV</td>
<td>Herpes Simplex Virus</td>
</tr>
<tr>
<td>49</td>
<td>IBD</td>
<td>Inflammatory bowel disease</td>
</tr>
<tr>
<td>50</td>
<td>ICP</td>
<td>Intracramial pressure</td>
</tr>
<tr>
<td>51</td>
<td>IDL</td>
<td>Intermediate density lipoprotein</td>
</tr>
<tr>
<td>52</td>
<td>IHD</td>
<td>Ischemic heart disease</td>
</tr>
<tr>
<td>53</td>
<td>INR</td>
<td>International normalised Ratio</td>
</tr>
<tr>
<td>54</td>
<td>ITP</td>
<td>Idiopathic thrombocytic purpura</td>
</tr>
<tr>
<td>55</td>
<td>IVC</td>
<td>Inferior Venacava</td>
</tr>
<tr>
<td>93</td>
<td>TIA</td>
<td>Transient ischemic attack</td>
</tr>
<tr>
<td>94</td>
<td>SVC</td>
<td>Superior Venacava</td>
</tr>
<tr>
<td>95</td>
<td>TPHA</td>
<td>Treponema pallidum hemagglutination</td>
</tr>
<tr>
<td>96</td>
<td>TPN</td>
<td>Total parenteral nutrition</td>
</tr>
<tr>
<td>97</td>
<td>TRH</td>
<td>Thyroid Releasing Hormone</td>
</tr>
<tr>
<td>98</td>
<td>TSH</td>
<td>Thyroid stimulating hormone</td>
</tr>
<tr>
<td>99</td>
<td>TURP</td>
<td>Transurethral resection of prostate</td>
</tr>
<tr>
<td>100</td>
<td>U&amp;E</td>
<td>Urea and Electrolyte</td>
</tr>
<tr>
<td>101</td>
<td>UC</td>
<td>Ulcerative colitis</td>
</tr>
<tr>
<td>102</td>
<td>URTI</td>
<td>Upper respiratory tract infection</td>
</tr>
<tr>
<td>103</td>
<td>UTI</td>
<td>Urinary tract infection</td>
</tr>
<tr>
<td>104</td>
<td>US</td>
<td>Ultrasound</td>
</tr>
<tr>
<td>105</td>
<td>VDRL</td>
<td>Venereal disease research laboratory</td>
</tr>
<tr>
<td>106</td>
<td>VF</td>
<td>Ventricular fibrillation</td>
</tr>
<tr>
<td>107</td>
<td>VLDL</td>
<td>Very low density lipoprotein</td>
</tr>
<tr>
<td>108</td>
<td>VSD</td>
<td>Varticular septal defect</td>
</tr>
<tr>
<td>109</td>
<td>VT</td>
<td>Ventricular tachycardia</td>
</tr>
<tr>
<td>110</td>
<td>WPW</td>
<td>Wolf - Parkinson – white</td>
</tr>
</tbody>
</table>
Clinical trials are the core of research-based pharmaceutical industry. No new drug can come into the market without clinical trials. Global clinical trials are relatively new to India. No wonder there are several misconceptions on the subject. The companies conducting research need to proactively publicize their commitment to protecting the rights, safety and well being of trial participants. The development of new therapies to treat disease and improve quality of life is a long and complex process. A critical part of that process is the conduct of clinical trials. Clinical trials may involve already marketed product(s) and/or investigational products. A clinical trial is defined in the International Conference on Harmonization Guideline for Good Clinical Practice [ICH-GCP E6 (R1)] as any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. Clinical trials (Phase 1 to Phase 4) involve both potential benefits and risks to the participants and are conducted with the primary aim of bringing to patients new medicines with a favorable benefit–risk ratio. Clinical trials are conducted to answer specific questions and some aspects of the therapeutic profile (benefits and risks) of the product(s) tested may not be fully known without study in humans. In August 2009 OPPI has published the OPPI Code Of Clinical Trials which guides the producers and practiceners of Pharmaceuticals products about how and what precautions should be taken care of in developing new drugs.

OPPI also published Anti-Counterfeiting Guidelines. A report was published by Dr Milind Joshi, President –Global Regulatory Management (12 May 2007, www.jbcpl.com © Copyright 2005 J. B. Chemicals Pvt. Ltd.) on “Effect of
Counterfeit on Pharma Exports” in which it was found that WHO has estimated that 10% of global pharmaceutical commerce, or $21 billion, involves counterfeit drugs. 35% of all detected cases of counterfeits originate from India.\textsuperscript{30} Although it is found CHINA has the major role in it and they even labels the products made in INDIA. A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products:

- With correct ingredients but fake packaging
- With the wrong ingredients
- Without active ingredients
- With insufficient active ingredients

A counterfeit drug is an imitation/substitute/illegal drug that is made with intent to deceptively represent its content or origins. OPPI guidelines help in establishing requirements that facilitate authentication and discourage counterfeiting and re-cycling of original manufacturer’s packs. These Guidelines can be adopted by companies that are engaged in manufacturing, distributing or marketing of medicinal products. This Guide addresses the following anti-counterfeiting measures:\textsuperscript{31}

- Overt (visible) features
- Covert (hidden) features
- Design of packaging components.
- Other design considerations.
- Control of components.
- Incident management

The production model for pharmaceuticals is complex because many of its constituents can be variable, such as:\textsuperscript{32}
• Raw materials which may vary between batches (e.g., quality, potency, purity)
• Formulas and routings that can change as a result of a process schedule
• Yield requirements
• Co-product and by-product production
• Recycle considerations and waste issues

Not only can input elements vary, but so can the end products due issues like packaging variations. As the variations of inputs and outputs increase, so do the number of Bills of Material (BOMs), and managing them becomes complex. In addition, tolerances of certain ingredients require the BOM to handle a high degree of precision (up to 6 decimal places). Because the BOM is dynamic, the actual process of production is dynamic and consequently planning and scheduling is done with a short-term horizon.

The drug discovery and development Timeframes and costs for process stages across the value chain for R&D and development of an FDA approved drug can be seen below.

Figure 3.2.1.2 Drug discovery and development Timeframes

Source: An Introduction to the Indian Pharmaceutical Industry, An In-Depth Study of India’s Domestic and Outsourced Pharmaceutical Market, October 2007; ba_indian_pharmaceutical_market_research_report_10_07; BOSTAN Research Group.
The value chain of Pharmaceutical Industry can be easily understood by figure given below:

Figure 3.2.1.3 Value chain of Pharmaceutical Industry

- **Research Biology**: Includes target identification and target validation which involve choosing a molecule to target with a drug and testing the target and confirming its role in the disease.

- **Research Chemistry**: Includes compound generation, screening and lead optimization which involve creating molecules/compounds and testing hundreds and thousands of them against the target to identify any that might be promising and then further optimizing them to be more effective and safer.

- **Pre-clinical Development**: Includes lab and animal testing to determine if the drug is safe enough for human testing.

- **Clinical Development Phase I-III**: Includes performing the testing in humans by increasing the number of patients on which the drug is tested in each stage.

- **Phase IV**: The drug after being introduced to the market is monitored and if there are any alterations that are essential, the drug is brought back into the clinical development phases for further modifications.

- **Chemical Synthesis**: Includes extraction or fermentation which is used to make the active drug substance or active pharmaceutical ingredient (API).

- **Formulation**: Includes the processes to manufacture the pill or dosage.

- **Packaging**: Includes processes like packaging and labeling of the final drug.

Source: An Introduction to the Indian Pharmaceutical Industry, An In-Depth Study of India’s Domestic and Outsourced Pharmaceutical Market, October 2007; ba_indian_pharmaceutical_market_research_report_10_07.; BOSTAN Research Group.
Indian drug manufacturing business attracts many foreign companies in India. India is the outsourcing hub for pharmaceutical manufacturing in the world. It is projected by 2015, India is poised to become a favorable destination for pharmaceutical outsourcing activities (*illustrative*).

Figure 3.2.1.4 Attractiveness of Indian Pharmaceutical outsourcing Industry

<table>
<thead>
<tr>
<th>Key Factors</th>
<th>Discussion</th>
<th>India in 2007</th>
<th>India in 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talent availability</td>
<td>Increase in number of graduates relevant to the pharmaceutical industry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of skill</td>
<td>With better exposure, the quality of skill is improving</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wage rate</td>
<td>Lower cost of skill across the value chain activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competency to deliver</td>
<td>Good talent quality coupled with better infrastructure helps in improving the competency to deliver</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory environment</td>
<td>Better regulatory environment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Govt. support</td>
<td>Increasing support for life sciences park</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to market</td>
<td>Round the clock operations/consultants help in reducing the time to market</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distribution Network capability/last mile reach</td>
<td>Improving distribution networks in Tier II and Tier III cities helps reach the last mile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>All these factors combine to make India an attractive pharmaceutical outsourcing destination</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Source: An Introduction to the Indian Pharmaceutical Industry, An In-Depth Study of India’s Domestic and Outsourced Pharmaceutical Market, October 2007; ba_indian_pharmaceutical_market_research_report_10_07.; BOSTAN Research Group.*

Experts say the causes of India’s rise in outsourcing in Pharmaceutical business are its expertise in chemistry and data management services which are backbone of pharmaceutical manufacturing through the value chain.
### 3.2.2 Price

Price controls are carried out on certain drugs by virtue of the *Drugs (Prices Control) Order 1995* (DPCO), in the framework of the *Essential Commodities Act* (ECA). The DPCO is the responsibility of the *Ministry of Chemicals and Fertilisers* and is supervised by the *National Pharmaceutical Pricing Authority* (NPPA). It outlines the classification of price-controlled products and methods.
of price fixation and revision. The NPPA monitors drug prices by fixing and revising them. The 347 price-controlled drugs under the *Drugs (Prices Control) Order 1979* were brought down to 143 in the *Drugs (Prices Control) Order 1987*. Under the DPCO-1995, there are 74 bulk drugs and their formulations under price control covering around 40% of the total pharmaceutical market in India. Only a few OTC actives, e.g. acetylsalicylic acid and ephedrine and its salts, fall under the current DPCO price control.\(^{36}\)

Under the *National Pharmaceutical Policy 2006*, the government intended to:

- Strengthen the Patent office infrastructure,
- Focus on Research & Development strategies to increase access to anti-cancer and anti-HIV drugs,
- Rationalise the Excise Duty schemes in order to promote access to drugs for the poor,
- Set up a Drugs Price Monitoring Awareness and Accessibility Fund
- Create a Pharma Advisory Forum and
- Increase the range of price controls.

However, at the beginning of 2007 the Policy was still under review by a government-appointed high level committee of cabinet ministers.

The stockist / wholesale and retail margins on medicinal products are fixed by an agreement of Industry Associations including OPPI and the All India Organisation of Chemists & Druggists (AIOCD) whereby a 10% margin on the Maximum Retail Price (MRP exclusive of all taxes & duties) is provided for the stockist/wholesaler and 20% for retailers for non-price-controlled drug products.
For price controlled products 16% margin for Retailers is mandated by the DPCO. Generally, Stockists retain between 5-6% of margin while passing on the balance 3-4% margin to wholesaler or bulk retail buyer.\(^{37}\)

The consumer price or Maximum Retail Price (MRP) build-up for non-price-controlled medicines and Ayurvedic medicines is as follows:

<table>
<thead>
<tr>
<th>Article</th>
<th>%</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer’s selling or ex-factory price (MSP)</td>
<td>100.0</td>
<td>60.4</td>
</tr>
<tr>
<td>Central VAT (16% of 57.5% of the MRP)</td>
<td>113.2</td>
<td>69.7</td>
</tr>
<tr>
<td>State VAT (4% of the MRP)</td>
<td>121.8</td>
<td>73.7</td>
</tr>
<tr>
<td>Stockist / Wholesale price (margin = 10% of the MRP)</td>
<td>136.6</td>
<td>82.6</td>
</tr>
<tr>
<td>Maximum Retail Price (MRP) (margin = 20% of MRP1)</td>
<td>165.3</td>
<td>100.0</td>
</tr>
</tbody>
</table>

1 excluding taxes.

Currently 74 bulk drugs and the associated formulations are under price control. The prices are fixed and revised by the National Pharmaceutical Pricing Authority (NPPA). MRP, Inclusive of All Taxes, regime introduced since October 2, 2006.\(^{38}\) The price of formulations in India is fixed on the basis of the following formula on which a 4% value added tax (VAT) is imposed-

$$MRP = Ex\text{-factory Cost} + 100\%\ MAPE \text{ on Ex-factory Cost} + ED + VAT + Other\text{ tax (If any)}^{39}$$

\([MRP = Maximum\ Retail\ Price, \ MAPE = Maximum\ Allowable\ Post\text{-}manufacturing\ Expense\ (100\%), \ ED = Excise\ Duty\ (16\%) \ - \ With\ an\ abatement\ of\ 40\%\ on\ MRP, \ VAT = Value\ Added\ Tax\ (4\%).]\)

India is recognised lowest priced drug manufacturer and marketer of pharmaceuticals products domestically and internationally. One reason for lower value share is the lower cost of drugs in India ranging from 5% to 50%
less as compared to most other countries. A comparison of prices of some of the formulation packs in India vis-à-vis other countries depicts this clearly.

Table No. 3.2.2.2
Prices of formulation packs in India vis-à-vis other countries

<table>
<thead>
<tr>
<th>Drugs</th>
<th>India</th>
<th>Sri Lanka</th>
<th>Zimbabwe</th>
<th>U.K.</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciprofloxacin HCL</td>
<td>US$</td>
<td>0.81</td>
<td>1.16</td>
<td>1.5</td>
<td>11.4</td>
</tr>
<tr>
<td>500 mg 10’s tabs</td>
<td>Ruppes</td>
<td>39</td>
<td>55.68</td>
<td>72</td>
<td>547.2</td>
</tr>
<tr>
<td>Times Costlier</td>
<td></td>
<td>1.4</td>
<td>1.8</td>
<td>14.0</td>
<td>46.6</td>
</tr>
<tr>
<td>Diclofenac Sodium</td>
<td>US$</td>
<td>0.19</td>
<td>1.38</td>
<td>1.2</td>
<td>1.32</td>
</tr>
<tr>
<td>50 mg 10’s tabs</td>
<td>Ruppes</td>
<td>9</td>
<td>66.24</td>
<td>57.6</td>
<td>63.36</td>
</tr>
<tr>
<td>Times Costlier</td>
<td></td>
<td>7.4</td>
<td>6.4</td>
<td>7.0</td>
<td>107.8</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>US$</td>
<td>0.12</td>
<td>0.84</td>
<td>1.1</td>
<td>5.9</td>
</tr>
<tr>
<td>150 mg 10’s tabs</td>
<td>Ruppes</td>
<td>5.98</td>
<td>40.32</td>
<td>52.8</td>
<td>283.2</td>
</tr>
<tr>
<td>Times Costlier</td>
<td></td>
<td>6.7</td>
<td>8.8</td>
<td>47.4</td>
<td>123.1</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>US$</td>
<td>1.67</td>
<td>1.85</td>
<td>2.1</td>
<td>11</td>
</tr>
<tr>
<td>40 mg 10’s tabs</td>
<td>Ruppes</td>
<td>80</td>
<td>88.8</td>
<td>100.8</td>
<td>528</td>
</tr>
<tr>
<td>Times Costlier</td>
<td></td>
<td>1.1</td>
<td>1.3</td>
<td>6.6</td>
<td>11.8</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>US$</td>
<td>0.73</td>
<td>0.99</td>
<td>0</td>
<td>26.33</td>
</tr>
<tr>
<td>75 mg 10’s tabs</td>
<td>Ruppes</td>
<td>34.88</td>
<td>47.52</td>
<td>1263.84</td>
<td>921.6</td>
</tr>
<tr>
<td>Times Costlier</td>
<td></td>
<td>1.4</td>
<td>0.0</td>
<td>36.2</td>
<td>26.4</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>US$</td>
<td>1.97</td>
<td>3.53</td>
<td>2.5</td>
<td>24.48</td>
</tr>
<tr>
<td>20 mg 10’s tabs</td>
<td>Ruppes</td>
<td>94.52</td>
<td>169.44</td>
<td>120</td>
<td>1175.04</td>
</tr>
<tr>
<td>Times Costlier</td>
<td></td>
<td>0.0</td>
<td>5.6</td>
<td>1.5</td>
<td>6.0</td>
</tr>
<tr>
<td>Hepatitis B. vaccine</td>
<td>US$</td>
<td>3.54</td>
<td>0.0</td>
<td>20</td>
<td>5.48</td>
</tr>
<tr>
<td>1 ml</td>
<td>Ruppes</td>
<td>170</td>
<td>960</td>
<td>263.04</td>
<td>1025.76</td>
</tr>
<tr>
<td>Times Costlier</td>
<td></td>
<td>5.6</td>
<td>1.5</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td>R Human Insulin</td>
<td>US$</td>
<td>3.29</td>
<td>4.38</td>
<td>10</td>
<td>5.48</td>
</tr>
<tr>
<td>100 IU</td>
<td>Ruppes</td>
<td>158</td>
<td>210.24</td>
<td>480</td>
<td>263.04</td>
</tr>
<tr>
<td>Times Costlier</td>
<td></td>
<td>1.3</td>
<td>3.0</td>
<td>1.7</td>
<td>195.8</td>
</tr>
</tbody>
</table>

Source: Department of Pharmaceuticals, Ministry of Chemicals & Pharmaceuticals, Government of India

The National Pharmaceutical Pricing Authority (NPPA) was established as an independent body of experts under the Ministry of Chemicals and Fertilizers by Gazette notification dated 29-08-1997. The authority is entrusted with the task
of price fixation/revision of the 74 scheduled drugs and formulation containing any of the scheduled drugs under Drugs (Prices Control) Order, 1995 as well as monitoring and enforcement of prices. NPPA provides inputs to the Government for policy formulation and in the other specific issues concerning affordable medicines to the consumers.

The functions of the NPPA are:

1. To implement and enforce the provisions of the Drugs (Price Control) Order (DPCO), 1995 in accordance with the power delegated to it.
2. To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.
3. To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
4. To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.
5. To render with all legal matters arising out of the decisions of the Authority.
6. To render advice to the Central Government of changes/revisions in the drug policy.
7. To render assistance to the central Government in parliamentary matters relating to drug pricing.
The performance of NPPA since inspection (upto 30-11-2009) is as under:

The NPPA has fixed/ revised the prices of scheduled bulk drugs in 470 cases, which includes 300 bulk drugs and 170 derivatives of scheduled bulk drugs since its inspection. Of these, the prices of 10 scheduled bulk drugs and 8 derivatives and 1737 formulations were fixed/ revised during the period from 01-04-2009 to 30-11-2009 which are given and summarized below:

Table No. 3.2.2.3
Fixing of prices of scheduled bulk drugs by NPPA

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Cases Where Bulk Drugs Price Decreased</td>
<td>8</td>
<td>9</td>
<td>22</td>
<td>8</td>
<td>116</td>
</tr>
<tr>
<td>No. of Cases Where Bulk Drugs Price Increased</td>
<td>42</td>
<td>50</td>
<td>9</td>
<td>8</td>
<td>333</td>
</tr>
<tr>
<td>No. of Cases Where Bulk Drugs Price Fixed for First Time</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td>No. of Cases Where There was no change</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td>65</td>
<td>31</td>
<td>18</td>
<td>470</td>
</tr>
</tbody>
</table>

Table No. 3.2.2.4
Fixing of prices of Formulation Packs

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. of Packs Approved</td>
<td>1020</td>
<td>2012</td>
<td>1577</td>
<td>1737</td>
<td>10253</td>
</tr>
<tr>
<td>Price Increased</td>
<td>131</td>
<td>78</td>
<td>190</td>
<td>169</td>
<td>1294</td>
</tr>
<tr>
<td>Price Decreased</td>
<td>340</td>
<td>422</td>
<td>89</td>
<td>437</td>
<td>3286</td>
</tr>
<tr>
<td>Price Fixed for the First Time</td>
<td>522</td>
<td>1429</td>
<td>1256</td>
<td>1107</td>
<td>5404</td>
</tr>
<tr>
<td>No Change in Prices</td>
<td>27</td>
<td>83</td>
<td>42</td>
<td>24</td>
<td>269</td>
</tr>
</tbody>
</table>
### Table No. 3.2.2.5
Prices of the Scheduled Bulk Drug/ Derivatives Fixed/ Revised By NPPA during 2009-2010

<table>
<thead>
<tr>
<th>S. No.</th>
<th>NAME OF THE DRUG</th>
<th>SO No.</th>
<th>Existing</th>
<th>Revised</th>
<th>%</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tolnaftale</td>
<td>1046(E)</td>
<td>4121</td>
<td>2500</td>
<td>-39.34</td>
<td>Decrease</td>
</tr>
<tr>
<td>2</td>
<td>Iodo Chloro Hydroxy Quinoline (ICHQ)</td>
<td>1047(E)</td>
<td>788</td>
<td>933</td>
<td>18.40</td>
<td>Increase</td>
</tr>
<tr>
<td>3</td>
<td>Glipizide</td>
<td>1048(E)</td>
<td>29244</td>
<td>26114</td>
<td>-10.70</td>
<td>Decrease</td>
</tr>
<tr>
<td>4</td>
<td>Rifampicine</td>
<td>1049(E)</td>
<td>3428</td>
<td>3742</td>
<td>9.76</td>
<td>Increase</td>
</tr>
<tr>
<td>5</td>
<td>Betamethasone Alcohol Micronised</td>
<td>536(E)</td>
<td>181</td>
<td>167</td>
<td>-7.73</td>
<td>Decrease</td>
</tr>
<tr>
<td>6</td>
<td>Betamethasone 17 Valerate</td>
<td>536(E)</td>
<td>171</td>
<td>160</td>
<td>-6.43</td>
<td>Decrease</td>
</tr>
<tr>
<td>7</td>
<td>Betamethasone Disodium Phosphate</td>
<td>536(E)</td>
<td>145</td>
<td>133</td>
<td>-8.28</td>
<td>Decrease</td>
</tr>
<tr>
<td>8</td>
<td>Betamethasone Dipropianate</td>
<td>1910(E)</td>
<td>106</td>
<td>90</td>
<td>-15.09</td>
<td>Decrease</td>
</tr>
<tr>
<td>9</td>
<td>Bethametasone Acetone</td>
<td></td>
<td></td>
<td>93</td>
<td>12.06.09</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Para Chloro Meta Xyenol (PCMX)</td>
<td>1943(E)</td>
<td>273</td>
<td>305</td>
<td>11.72</td>
<td>Increase</td>
</tr>
<tr>
<td>11</td>
<td>Cloxacillin Sodium (Oral)</td>
<td>536(E)</td>
<td>1346</td>
<td>1409</td>
<td>4.68</td>
<td>Increase</td>
</tr>
<tr>
<td>12</td>
<td>Cloxacillin Sodium (Sterile)</td>
<td>536(E)</td>
<td>1891</td>
<td>1707</td>
<td>-9.73</td>
<td>Decrease</td>
</tr>
<tr>
<td>13</td>
<td>Dextropropoxyphere HCL</td>
<td>536(E)</td>
<td>3693</td>
<td>3361</td>
<td>-8.99</td>
<td>Decrease</td>
</tr>
<tr>
<td>14</td>
<td>Dextropropoxyphere Napsylate</td>
<td>536(E)</td>
<td>4995</td>
<td>5535</td>
<td>10.81</td>
<td>Increase</td>
</tr>
<tr>
<td>15</td>
<td>Naproxen Sodium</td>
<td>536(E)</td>
<td>1312</td>
<td>1585</td>
<td>20.81</td>
<td>Increase</td>
</tr>
<tr>
<td>16</td>
<td>Cephazoline Sodium (Sterile)</td>
<td>536(E)</td>
<td>1415</td>
<td>1617</td>
<td>14.28</td>
<td>Increase</td>
</tr>
<tr>
<td>17</td>
<td>Doxophylline</td>
<td>536(E)</td>
<td>5915</td>
<td>6773</td>
<td>14.51</td>
<td>Increase</td>
</tr>
<tr>
<td>18</td>
<td>Dextropropoxyphere Napsylate</td>
<td>2905(E)</td>
<td></td>
<td>1487</td>
<td>17.11.09</td>
<td></td>
</tr>
</tbody>
</table>

Since Inspection of NPPA

| Bulk Drug | 300 |
| Derivative | 170 |
| Total     | 470 |

| First Time | 16 Cases |
| No Change  | 5 Cases  |
| Increase   | 116 Cases |
| Decrease   | 333 Cases |

Source: Department of Pharmaceuticals, Ministry of Chemicals & Pharmaceuticals, Government of India
3.2.3 Promotion

In recent years, pharmaceutical companies throughout the world have been targeted by critics for their marketing practices, particularly, with regard to their transactions with the doctors. Doctors around the world were known to be pampered by the pharmaceutical industry with expensive gifts and holidays to exotic locations. Critics felt that in doing so, the companies were influencing the doctors to prescribe their products that may not be in the patient's best interests.

Research conducted in India as well as other countries found that, though most of the doctors said that they were not influenced by these incentives, they admitted that their colleagues were influenced by such promotions. 43

Many countries like the US, Australia, and some European countries, have put in place regulations that ban doctors from accepting gifts and other favors from pharmaceutical companies. Companies find it hard to generate prescriptions based solely on science. Relying on published datasheets issued by the inventing companies reduces the scope of a drug because of the inconvenience of contraindications, precautions, drug interactions, and adverse effects. Sometimes, for purely promotional purposes local data are generated, as happened with letrozole, which was given to over 430 young women to test its efficacy in inducing ovulation. 44 The commercial needs of countless, fiercely competing pharmaceutical companies have led them to depend on the tried and tested 3Cs: convince if possible, confuse if necessary, and corrupt if nothing else works. 45
In 2005, the Indian National Commission on Macroeconomics and Health labelled 10 out of 25 top selling brands of medicines in the country as being either “irrational or non-essential or hazardous.”\(^{46}\) Those brands are listed in the table below and include a number of market leaders. These issues are important in developed and developing countries but are particularly pressing in developing countries where each dollar that is misused is a dollar that can’t easily be replaced.

Table No. 3.2.3.1
Irrational or Non-essential or Hazardous Brands of Medicines

<table>
<thead>
<tr>
<th>Rank</th>
<th>Brand</th>
<th>Producer</th>
<th>Headquarters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Becosules</td>
<td>Pfizer</td>
<td>USA</td>
</tr>
<tr>
<td>3</td>
<td>Corex</td>
<td>Pfizer</td>
<td>USA</td>
</tr>
<tr>
<td>9</td>
<td>Liv-52</td>
<td>Himalaya</td>
<td>India</td>
</tr>
<tr>
<td>11</td>
<td>Dexorange</td>
<td>Franco-Indian</td>
<td>India/ France</td>
</tr>
<tr>
<td>12</td>
<td>Digene</td>
<td>Abbott</td>
<td>USA</td>
</tr>
<tr>
<td>17</td>
<td>Combiflame</td>
<td>Aventis</td>
<td>France</td>
</tr>
<tr>
<td>20</td>
<td>Polybion</td>
<td>E. Merck</td>
<td>Germany</td>
</tr>
<tr>
<td>21</td>
<td>Glucon-D</td>
<td>Heinz</td>
<td>USA</td>
</tr>
<tr>
<td>22</td>
<td>Evelon</td>
<td>E. Merck</td>
<td>Germany</td>
</tr>
<tr>
<td>25</td>
<td>Revital</td>
<td>Ranbaxy</td>
<td>India</td>
</tr>
</tbody>
</table>

Source: Drugs, Doctors and Dinners, How drug companies influence health in the developing world, ISBN: 1-902391-59-4, Published by Consumers International in October 2007 ©Consumers International

Health professionals in developing countries work in overstretched and under resourced sectors on low pay and in difficult conditions. In such conditions the promotions from the drug companies are inviting.\(^ {47}\) Disparities in health spending between the world’s richest countries and the world’s poorest countries are such that a relatively cheap promotion in a developing country will generate much more interest there than it would in a developed country.
The aim of drug promotion is to persuade people to buy more drugs and/or to pay higher prices. This is done by increasing the perceived value of the drug via one or more of several approaches including:

- Increasing the perceived frequency and/or severity of the indications.
- Widening the indications to include more people.
- Increasing the perceived likelihood and magnitude of benefits.
- Decreasing the perceived likelihood and magnitude of harms.
- Increasing the use of the drug for longer durations.

The World Health Organization defines drug promotion as including: “all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.”  

The main aim of promotion is not to inform but to persuade. Consumer goods advertisements rarely convey much information about the features of the product. Instead the emphasis of much advertising is on associating consumption of the product with positive feeling.

The table below provides an overview of the key promotion methods used to target doctors:
Table No. 3.2.3.2
Promotion Methods used by Pharmaceutical Companies

<table>
<thead>
<tr>
<th>Type</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical</td>
<td>Advertisements</td>
</tr>
<tr>
<td></td>
<td>• Brochures</td>
</tr>
<tr>
<td></td>
<td>• Sponsored articles</td>
</tr>
<tr>
<td></td>
<td>• Internet</td>
</tr>
<tr>
<td></td>
<td>• Sponsored journals subscription or textbooks</td>
</tr>
<tr>
<td>Personal Selling</td>
<td>• Visits by medical representatives</td>
</tr>
<tr>
<td></td>
<td>• Sponsored events with “key opinion leaders” in the field. Most of the</td>
</tr>
<tr>
<td></td>
<td>time, these company sponsored guest speakers use presentation slides</td>
</tr>
<tr>
<td></td>
<td>provided by the company for their talk.</td>
</tr>
<tr>
<td>Trade promotion</td>
<td>• Gifts</td>
</tr>
<tr>
<td></td>
<td>• Gimmicks and incentive schemes based on number of prescriptions</td>
</tr>
<tr>
<td></td>
<td>• Product samples</td>
</tr>
<tr>
<td>Sponsorship</td>
<td>Academic activities</td>
</tr>
<tr>
<td></td>
<td>• Symposiums</td>
</tr>
<tr>
<td></td>
<td>• Exhibition booths</td>
</tr>
<tr>
<td></td>
<td>• Registration fees</td>
</tr>
<tr>
<td></td>
<td>• Tutoring sessions</td>
</tr>
<tr>
<td></td>
<td>• Journal clubs</td>
</tr>
<tr>
<td></td>
<td>• Free textbooks and journal subscriptions</td>
</tr>
<tr>
<td></td>
<td>Non-academic activities</td>
</tr>
<tr>
<td></td>
<td>• Entertainment</td>
</tr>
<tr>
<td></td>
<td>• Excursions</td>
</tr>
<tr>
<td></td>
<td>• Travelling expenses</td>
</tr>
<tr>
<td></td>
<td>• Meals</td>
</tr>
<tr>
<td></td>
<td>• Family-related activities</td>
</tr>
<tr>
<td></td>
<td>• Donations or support for facilities used in offices i.e. fax machine,</td>
</tr>
<tr>
<td></td>
<td>printer, furniture, etc.</td>
</tr>
<tr>
<td></td>
<td>• CASH</td>
</tr>
</tbody>
</table>

Health professionals are targeted by companies mainly via medical representatives and advertisements placed in medical journals or brochures that are sent directly to the doctors. The main conduits of promotion in India are: advertising, detailing (visits from sales representatives), direct mail, sales promotion, publicity and public relations. Among them, detailing dominates most along with the given promotional methods in table above.
Currently, there is no specific law which prohibits the advertising of prescription drugs although industry practice is not to advertise prescription-only drugs. The DCGI’s office is considering coming out with a notification prohibiting the advertising of any drug which legally requires a doctor’s prescription for its supply.

The following OTC medicines advertising can be seen on TV in India:

- Digestives
- Antacids
- Antiflatulent
- Cold rubs and analgesic balms/creams
- Vitamins/ tonics/ health supplements (especially herbals and Ayurvedic-Registered)
- Medicated skin treatment
- Analgesic /cold tablets
- Antiseptic creams/liquids
- Glucose powders
- Cough liquids
- Throat lozenges
- Medicated dressings (band-aids)
- Baby gripe water. Etc.

**OPPI Code of Pharmaceutical Marketing Practices 2010**

The Organisation Of Pharmaceutical Producers Of India (OPPI), established in 1965, is a premier organisation of pharmaceutical manufactures consists of companies with international collaboration and large Indian companies. OPPI

Objective of OPPI Code of Pharmaceutical Marketing Practices 2010 is stated as “The Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that, companies’ interactions with healthcare professionals are appropriate and perceived as such.”

For the purposes of the Code: “pharmaceutical product” means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body. “promotion” means any activity undertaken, organised or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet and mobile SMS etc. “healthcare professional” means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product. “company” means any pharma company that is a member of OPPI that agrees to abide by this code.
This Code does not seek to regulate the following activities: promotion of prescription only pharmaceutical products directly to the general public (i.e. direct to consumer advertising); promotion of self-medication products that are provided “over the counter” without prescription; pricing or other trade terms for the supply of pharmaceutical products; the engagement of a healthcare professional to provide genuine consultancy or other genuine services to a member company; The conduct of clinical trials (which are governed by separate GCP guidelines); The provision of non-promotional information by member companies.  

The general principles of the code are as follows:  

- **Basis of Interaction**: Companies' relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education.  

- **Independence of Healthcare Professionals**: No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing
practices or would influence their professional integrity and autonomy or will compromise patients’ interest in any manner.

Healthcare professionals should not be influenced to endorse any drug or product of any pharmaceutical company publicly.

- **Appropriate Use**: Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

- **Regulations**: In all cases, all relevant laws and regulations must be observed and companies have a responsibility to check requirements, in advance of preparing promotional material or events.

- **Transparency of Promotion**: Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programmes and post authorisation studies must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.

- **Pre-approval Communications and Off-Label Use**: No pharmaceutical product shall be promoted for use until the requisite approval for marketing for such use has been given.
This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

To clarify the Standards of Promotional Information OPPI Code identifies:

- **Consistency of Product information**: It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labelling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with approved product information.

Healthcare professionals in India should have access to similar data to those being communicated by the same company in other countries.

- **Accurate and Not Misleading**: Promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion,
exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as 'safe' and 'no side effects' should generally be avoided and should always be adequately qualified.

- **Substantiation**: Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

The definitions of and guidelines for different promotional terms given by OPPI Code are as follows:

**Printed Promotional Material**: Where regulations or codes are in force, which define requirements, those take precedence.

**All Printed Promotional Materials including Advertisements**: All Printed Promotional Materials including Advertisements other than those covered in *Reminder Advertisements* below must be legible and include:

- the name of the product (normally the brand name);
- the active ingredients, using approved names where they exist;
• the name and address of the pharmaceutical company or its agent responsible for marketing the product;

• date of production of the advertisement; and

• “abbreviated prescribing information” which should include an approved indication or indications for use together with the dosage and method of use, and a succinct statement of the contraindications, precautions and side effects.

Reminder Advertisements: A “reminder” advertisement is defined as a short advertisement containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For “reminder” advertisements, “abbreviated prescribing information” referred to in Printed Promotional Materials above may be omitted.

Electronic Materials, Including Audiovisuals: The same requirements shall apply to electronic promotional materials as applied to printed materials. Specifically, in the case of pharmaceutical product related websites:

• the identity of the pharmaceutical company and of the intended audience should be readily apparent;

• the content should be appropriate for the intended audience;

• the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
• Information should comply with Drugs & Magic Remedies Act.

Interactions with Healthcare Professionals:

Events:

Scientific and Educational Objectives: The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an “Event”) for healthcare professionals organised or sponsored by a company should be to inform healthcare professionals about products and/or to provide scientific or educational information.

Promotional Information at Events: Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

• The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place.

• Promotional material (excluding promotional aids) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally.
• Promotional material which refers to the prescribing information (indications, warnings etc.) authorised in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally and

• An explanatory statement should identify the countries in which the product is registered and make it clear that it is not available locally.

**Travel Facilities:** No travel facilities to be extended to a healthcare professional as a , inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc. for self and family members for vacation or for attending conference, seminars, workshops, CME programs, etc.

**Payments for Speakers and Presenters:** Payments of reasonable fees and reimbursement of out-of-pocket expenses, including travel and accommodation, may be provided to healthcare professionals who are providing genuine services as speakers or presenters, other than delegates.

**Affiliation:** A healthcare practitioner may work for the pharmaceutical company in advisory capacities as consultants, as researchers, as treating doctors or any other professional capacity. Such affiliation would ensure the following:

(i) Professional integrity and freedom of healthcare professionals are maintained.
(ii) Patients’ interest are not compromised in any way.

(iii) Such affiliations are within the Law and fully transparent and disclosed.

**Hospitality:** No hospitality, like hotel accommodation, for self and family members under any pretext to be provided to healthcare professionals other than as mentioned in sections *Payments for Speakers and Presenters* and *Affiliation* above.

**Appropriate Venue:** All Events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. The additional requirements set forth in Article 7 of this Code also apply accordingly.

**Limits of Hospitality:** Hospitality, wherever applicable, should be limited to refreshments and/or meals incidental to the main purpose of the Event and should only be provided:

- To participants of the Event and not their guests; and

- If it is moderate and reasonable as judged by local standards.

- As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves.
**Entertainment:** No stand-alone entertainment or other leisure or social activities should be provided or paid for by companies. At Events, entertainment of modest nature which is secondary to refreshments and/or meals, wherever applicable, is allowed.

**Cash, Gifts and Promotional Aids:**

**Cash:** No cash or monetary grants for individual purpose in individual capacity under any pretext to be provided to healthcare professionals. Funding for medical research study, etc. can only be given through approved institutions by modalities laid down by law / rules / guidelines adopted by such approved institutions in a transparent manner and as mentioned in section Affiliation above.

**Gifts:** Gifts to the healthcare professionals (including, but not limited to, music CDs, DVDs, sporting or entertainment tickets, electronic items) must not be provided or offered.

**Promotional Aids:** Promotional aids or reminder items may be provided or offered to healthcare professionals and appropriate administrative staff, relevant to the practice of the healthcare professional.

**Samples:**

**Samples Permitted:** In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to healthcare
professionals in order to enhance patient care. Samples should not be resold or otherwise misused.

**Control and Accountability:** Companies should have adequate systems of control and accountability for samples provided to healthcare professionals including how to look after such samples whilst they are in possession of medical representatives.

It is expected by OPPI that Companies should establish and maintain appropriate procedures to ensure full compliance with relevant codes and applicable law and to review and monitor all of their promotional activities and materials. A designated company employee, with sufficient knowledge and appropriate scientific or healthcare qualifications should be responsible for approving all promotional communications. Also, a senior company employee could be made responsible, provided that scientific advice is taken. OPPI strongly encourage their members to adopt procedures to assure adherence to the Code.

**3.2.4 Place**

Industry, market and customer trends are creating both challenges and opportunities for increasing business and profitability and for making more and more profits in competitive and trendy pharmaceutical industry, companies are deploying a plethora of marketing and distribution strategies to target the different customer segments.
The downstream Supply Chain of pharmaceutical products is unique. Not only in India but over the globe medicines and healthcare facilities are generally distributed and sold by the non-user customers of the drugs and pharmaceutical products, reputedly known in society as Doctor/s. This is doctor/s mostly who prescribe the pharmaceutical product/s to the real-user customer poorly known in society as Patient (ill person) or friends/relatives of the patient. In the pharmaceutical and healthcare industries, a complex web of decision-makers determines the nature of the transaction (prescription) for which direct customer of pharmaceutical industry (doctor) is responsible. Essentially, the end-user (patient) consumes a product and pays the cost. Which drug to transact, from where to transact, in what quantity to buy etc. etc. all are directed by the doctor which is consumed by the patient and pays the cost. Doctors plays the direct role in transaction of drugs through prescriptions so are the Direct customers of the pharmaceutical companies while patients play indirectly although they pay the price essentially, are indirect customers of the pharmaceutical companies.

Pharmaceutical companies use the sales force of Medical Representatives (sophisticated designed in hierarchy) for marketing products to doctors and to exert some influence over others in the hierarchy of decision makers (for procurement, buying, prescribing) has been a time-tested tradition. Typically, sales force expense comprises an estimated 15 percent to 20 percent of annual product revenues, the largest line item on the balance sheet. Despite this other expense, the industry is still plagued with some very serious strategic and operational level issues.

It is also a fact that Indian consumers confidently self-treat a wide range of common ailments such as cough, cold, fever, pain & sprains, heartburn,
indigestion and diarrhoea. With a strong heritage of Ayurveda and alternative medicines, the usage of home remedies is quite high in Indian households. In fact, more than 30% of the time Indian consumers use home remedies. When suffering from an ailment, consumer behaviour is as follows:\textsuperscript{57}

- Go to the pharmacist: 45%
- Go to the doctor: 24%
- Self-medication: 23%
- Do nothing: 9%.

But when generally doctors prescribe the medicines to the patients after diagnosing the problem, send them to the chemists’ (pharmacist) shops where drugs can be bought easily.

**Prescription** (*pre*-before, *script*-written): A prescription is a healthcare plan implemented by any physician /registered medical practitioner in form of instructions which govern the plan of care of an individual patient. It is denoted by symbol "**Rx**". A registered pharmacist dispenses medication according to the prescription only.\textsuperscript{58}
When a prescription is presented to a pharmacist, he / she needs to exercise a few basic steps as cited below: 59

- While receiving prescription, no comments or discussion over therapeutic efficiency of prescription should be there.

- While receiving prescription, a pharmacist should not show any expression of astonishment or alarm, thereby causing anxiety in patients or their agents regarding their prescription, diseased state or physician even.
• A pharmacist should ask the patients or their agents for

  • Any known allergic drug reactions
  • Chronic conditions
  • Other drugs patient is taking including OTC drugs like aspirin, antacids etc.

• A pharmacist should review or screen the prescription, should refer to physician if he/she has any queries regarding :

  • drug dosage
  • Length of treatment

• Any question on a prescription should be answered with every caution and care.

• A pharmacist is not supposed to add, omit or substitute any ingredient or alter any composition of the prescription without the consent of prescriber.

• While dispensing of the prescription a pharmacist needs to use correct weights & measures, avoid any guess work or approximation.

• A pharmacist should avoid usage of sub-standard or spurious drugs and should not dispense schedule G, H & X drugs without prescription.

• While refilling a pharmacist should abide by instructions of the prescriber.
• It is the moral duty of pharmacist to counsel patient about proper drug administration, correct dosage and time.

• A pharmacist should encourage the patient to show compliance with the prescription.

• A pharmacist needs to be very careful and judicious while dealing with drugs which can be poisonous or carry abuse potential.

• A pharmacist should charge the right price from the patient including the applicable taxes, prescription handling charges etc.

Generally two types of diseases, *Chronic* and *Acute*, ask the pharmaceutical players to adopt different types of model of supply chain or distribution for the sales of the products. While most of the top Indian companies have focused on antibiotics and anti–infectives (acute), many companies operate in niche formulations (chronic) segments such as psychiatry, cardiovascular, gastroentology and neurology. The level of competition in very high in Acute segment on day to day basis however the degree of competition in not as much as high in Chronic therapy area on day to day basis. As doctor has to prescribe drug for a long time in chronic cases and patient is suppose to consume it without any change of brand. While in acute cases doctor is changing brands on day to day basis.  

The pharmaceutical distribution channel is indirect with usually three channel members i.e. depot/C&F, stockiest and chemist. Pharmaceutical companies appoint one company depot or C&F agent usually in each state and authorized
stockist(s) in each district across the country. Company depot/C&F sends stocks to authorized stockists as per the requirement. Retail chemists buy medicines on daily or weekly basis from authorized stockiest as per demand. Patients visit chemists for buying medicines either prescribed by a doctor or advertised in the media or due to word of mouth promotion (which is unique in case of India where everyone who has any experience of medicine tries to suggest everyone suffering from same type of problem). Here patient is end customer and doctor is direct customer for any pharmaceutical company. But for doctor customer is more important so he wants an effective supply chain management from prescribed company. And for pharmaceutical companies their customer that is doctor is more important that’s why they emphasize more on supply chain management. Ultimately end-customer is benefited out of this.

Pharmaceuticals companies generally exercise two models of distributions to market their products based on two greatly known Push and Pull strategies of Marketing for distribution and promotion.

(i) **M-D-P-R-S-C or Pull Model or Super Core Model** involving the search for, and distribution of a small number of drugs from **Chronic Threapy Area** that achieve substantial global sales. The success of this model depends on achieving large returns from a small number of drugs in order to pay for the high cost of the drug discovery and development process for a large number of patients. Total revenues are highly dependant on sales from a small number of drugs.

(ii) **M-SRD-C or Push Model or Core Model** in which a larger number of drugs from **Acute Threapy Area** are marketed to big diversified markets. The
advantage of this model is that its success is not dependant on sales of a small number of drugs but on large and voluminous.

In Chronic therapy segment pharmaceutical companies generally use the pull strategy and design the Supply Chain accordingly, which may be seen below as:

**Figure 3.2.4.2 M-D-P-R-S-C or Pull Model**

**M-D-P-R-S-C:** Marketing & Sales Team influences the Doctors, Doctors prescribes the products to Patients, Patients buys the products from Retailers, Retailers ask the products from the Stockists and Stockists from carry and Forwarding Agents or Depot Level of the Pharmaceutical Company. In this model companies pull the demand for the product/s.
While in the Acute therapy segment pharmaceutical companies use push strategy to design the Supply Chain.

**Figure 3.2.4.3 M-SRD-C or Push Model**

**M-SRD-C**: Marketing and Sales Team stocks the products at stockist or make sure the availability of products to them from C & F or Dept level, at the same time Marketing and Sales Team also influences the Doctors and Retailers to prescribe and keep stock of the products. For promotional items retailers also influences the doctors for the prescription of particular brand and sometimes Clinicians also keep stock of the product in the clinic or near by retailer’s store, which is ultimately prescribed and sold to Patient. In this model of supply chain companies pushes the products to the end-users.

Generally Pharmaceutical Representatives place product orders from their stockist on the basis of following formula:

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CLOSING STOCK * 2 – OPENING STOCK = ORDER
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For temperature sensitive Pharmaceutical product, the Drug Controller General of India, Dr. Surinder Singh recognises the need for Cold Chain Management. Realising this critical need, the Materials Management Committee of OPPI has prepared the comprehensive booklet titled ‘OPPI Guidelines on Cold Chain Pharmaceutical Products’, which covers Standard Operating Procedures (SOPs) for various stakeholders. According to OPPI those medicines are cold chain medicines that require special temperature-controlled cold storage to maintain their quality and efficacy. There are two commonly recommended temperatures specified on the labels of cold chain products:

1. Products requiring temperatures of between 2°C and 8°C
2. Products requiring temperatures of around (-10°C) and (-20°C)

A cold chain is a temperature-controlled supply chain. It is used help extend and ensure the shelf life of products such as fresh agricultural produce, processed foods, photographic film, chemicals and pharmaceutical drugs. A cold chain for pharmaceutical products is an uninterrupted series of storage and distribution activities that maintains products at a required temperature range of 2°C and 8°C or between -10°C and -20°C as per their requirements.

Cold chain management in pharmaceuticals is important to ensure that the right quality is maintained during storage and transportation, and also to meet the regulatory commitments. Regulatory guidelines and standards around the world focus on the right storage and transportation, and adhering to these standards is important.
OPPI has given detailed guidelines to maintain cold chain such as:

1. Guidelines related to Storing and Handling Cold Chain Pharmaceuticals at Seaports and Airports.
2. Guidelines related to Customs Clearance and Sample Testing of Cold Chain Products by the Assistance Drug Controller office.
5. Guidelines for Retailers / Chemists for Handling Cold Chain Pharmaceutical Products.

Pharmaceutical Products have their own supply chain system which ensures the delivery of drugs to end-users at given cost for given quality. Being a good partner in the ecological system it is necessary to be a good member of the Supply Chain at your place wherever you stand in the overall value chain or distribution system. Organizational objectives can only be achieved well when particular maintains its supply chain strategically.
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