

c) National Pharmaceutical Pricing Authority

A National Pharmaceutical Pricing Authority (NPPA) has been established to oversee and regulate the pricing of pharmaceutical drugs in India. Its objective also includes liberalising the climate for collaboration between foreign and Indian companies and the promotion of the rational use of drugs.

The principles and objectives of the Drug Policy which have not changed since the 1977 Drug Policy are outlined below:

- 1) to develop self-reliance in drug technology;
- 2) to provide a leadership role to the private sector;
- 3) to aim at quick self-sufficiency in the output of drugs with a view to reducing imports;
- 4) to foster and encourage the growth of the Indian sector;
- 5) to ensure that the drugs are available in abundance in the country to meet the health needs of India;
- 6) to ensure quality of production;
- 7) to offer special incentives to firms which are engaged in research and development;
- 8) to provide other parameters to control and regulate the activity of foreign companies in accordance with national objectives and priorities.

Drug Prices Control Orders (DPCO) is the title given to India's pricing laws. The DPCO comes under the auspices of the NPPA. The drug price controls have been relaxed since the last drug policy of 1986. However, the policy of limiting the profits of pharmaceutical firms to 8-13% of pre-tax sales remains.

To encourage more domestic R&D, the drug policy exempts companies that conduct in-house bulk drug R&D and who develop a new drug delivery system from price controls for a period of 10 years. In addition, new drugs introduced into the country for the first time, either by foreign or domestic firms, are exempted for 5 years.

The new drug policy allows for the elimination of price controls on drugs meeting certain sales specifications. Price controls can be eliminated if:

- sales are under Rs40 million (Cdn \$1.6 million) annually
- for drugs with annual turnover greater than Rs10 million (Cdn \$0.4 million) no single formulator has a market share greater than 90%
- drugs for which there are at least 5 bulk producers and 10 formulators, none with a market share greater than 40%.