2.1. INTRODUCTION: THE ISSUES

It is now globally recognized the health of the people plays a significant role in the overall economic and social development of a nation. The efficacy of the health system of a nation depends on the propagation of good health, appropriate prevention and curative remedies for various diseases. Given the vital importance of a healthy nation, ever since Independence, Indian planners have aimed at achieving an efficient health system. Since the beginning of our national economic planning, the Bhore Committee (Government of India, 1946) formed the basis for adopting a model of the health system which mainly relied on the State’s investment which in turn is determined by outlays allocated to health in the Five Year Plans.

2.1.1. Major Partners and Division of Responsibility

Basically, the health sector in India consists of three major players that are catering to the health of the country’s population. These include public sector (comprising Central, State and local governments and their institutions), private for profit sector and private not for profit sector Non-Governmental Organizations (NGOs). The public sector health services in the country are further categorized in terms of primary, secondary and tertiary care. These are provided respectively by sub-centers (SCs) and primary health centers (PHCs) (primary care), community health centers (CHCs) and district hospitals (secondary care) and teaching and speciality hospitals (tertiary care). The three tiers of the Government, viz., Central, States and local, contribute to the overall public sector spending on health care.

The primary responsibility of health care in the Indian Constitution, however, rests with the States. In general, a major chunk of the public expenditure (almost 90 per cent) on the health care sector in the country
comes through the State’s budget. However, there is also a certain degree of financial dependence of States on the Centre with regard to the health sector expenditure. First, central funding enables the States to run the family planning programmes (including leprosy, malaria, and tuberculosis), immunization, nutrition schemes and the components of primary health care, rural water supply and sanitation which fall under the minimum needs programme of the centre. The funding from the Central Government to the States comes either as cent per cent grants or partly through matching grants. In the later, the States have to contribute through a matching contribution from their budgets. Secondly, the Central Government provides the total funds for medical research and education in the Centrally-funded institutions.

2.1.2. Evolution of the System

The investment in the health sector has been guided by the priorities laid down in each of the five year plans in the country. Our first national economic planning exercise, viz., the First Five Year plan (1951-56), laid emphasis on some health-related issues like malaria control, preventive care in rural areas, maternal child health (MCH) services, family planning and population control, and water supply and sanitation. Vertical programmes in the form of separate preventive schemes pertaining to malaria, Tuberculosis (TB), filariasis, leprosy and venereal disease were also mooted in the priorities listed in the First Five Year Plan. These vertical programmes and other health sector priorities were again listed in the Second Five Year Plan (1956 – 61).

As the health system evolved, the subsequent five year plans had their own focus. Accordingly, a major shift in focus from preventive programmes to family planning was witnessed in the Third Plan (1961-66). The strengthening of the rural Primary Health Centers (PHCs) and existing vertical programmes became the core focus of the Fourth Plan (1969-74). A slight shift in the Fifth Plan (1974-79) occurred with an attempt towards
integration of the peripheral staff engaged in vertical health programmes. Further, the Alma Ata declaration in 1978 and Indian Council of Medical Research/Indian Council of Social Science Research (ICMR/ICSSR) report Indian Council of Social Science Research (ICSSR, 1980) shaped the health sector priorities in the later years. These had an impact on health priorities in the Sixth Plan (1980-84). Accordingly, the Sixth Plan policy objective was to integrate the development of the health system with the transformation in the overall milieu of socio-economic and political scenario of the country.

A major guideline for the health sector in the country evolved with the formulation of the National Health Policy in 1983. This policy reflected the commitment of India to attain the goal of “Health for All by the Year 2000 Anno Domini (AD)” while emphasizing the need for universal, comprehensive, and primary health services, the policy documents provides a list of goals to be attained by 2000 Anno Domini (AD). However, actual achievements were much less than these listed goals.

In the Seventh Plan (1985 – 90) and the Eight Plan (1992 – 97) there was a notable shift in health targets with major focus being put on rural health programmes and private sector’s contribution to the health sector. The structural adjustments and less expenditure on health in the initial Plan years coupled with international funding of vertical programmes changed the focus of the five year plan priorities towards increased private sector participation in the health sector. The Subsequent plan periods of 1997 – 2002 (Ninth plan) and 2002 – 07 (tenth plan) emphasized primary care, referral services and decentralization in the health care sector. Again in 2002, Government of India (GOI) brought out a new National Health Policy (NHP 2002) which listed the achievements in the health sector between the years 1951 – 2000.

Based on achievements so far and keeping in view new threats from diseases like Human Immuno Deficiency Virus and Acquired Immune
Deficiency Syndrome (HIV and AIDS); National Health Policy (NHP) 2002 listed the new goals to be achieved between the years 2000 – 15.

Some of the other notable features of National Health Policy (NHP) 2002 were: the recognition of the need for enhanced health facilities and organizational restructuring of the national public health initiatives to provide a more equitable access to health care facilities, emphasis on control of diseases contributing to high mortality Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (e.g., Malaria, HIV/AIDS) and the need of women, children, aged persons, tribal’s and other socio-economically backward sections of society.

2.1.3. Major challenges

Notably, India has achieved important milestones due to sustained planned efforts. As a result, during 1974 – 2004, life expectancy has doubled from 32 years to 64.6 years. Also Infant Mortality Rate (IMR) has fallen by over 70 per cent, while cases of malaria incidence have been reduced to the extent of 20 lakh. Diseases like smallpox and guinea worm are non-existent leprosy and polio will soon be eliminated. Despite all these achievements with the prevailing National and state health policies and the systematic five year plan health sector priorities, there are numerous disconcerting features and new emerging issues in the health care sector in India. The distressing facts that emerge are: our total population (16.5 per cent of global total population) accounts for one fifth of the world’s share on disease; a third of the diarrhoeal disease, Tuberculosis (TB), respiratory and parasitic infections; a quarter of poor maternal conditions; a fifth of nutritional deficiencies, diabetes, venereal disease; and the second largest number of Human immunodeficiency virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) cases after South Africa Government of India (GOI 2005).
Besides this high disease burden, the overall state financing of health sector in India, as noted earlier, has been inadequate resulting in an unsatisfactory distribution of infrastructure and resources in the health care sector. This as lead to undesirable outcomes. There is widespread disparity in health care services in rural and urban areas, poor and rich States and a notable neglect of some of the emerging health needs of the society. As we developed health system based on the recommendations of the Bhore Committee Government of India (GOI, 1946), the major responsibility for the health services should have been dependent on the basic infrastructure of the public hospitals and Primary Health Centers (PHCs) built over the last few decades. However, instead of playing this major role, public sector investment has led to set up a less efficient health care system thus providing a major impetus to the private sector for an investment which is more equitable and less regulated. Even the low public investment is largely spent (nearly 70 per cent) towards recurring expenditure (including wages and salaries). Thus, literary a very small amount spent on drugs and medicines for patients care. After taking into account the inflationary factor, real per capita health care expenditure is Rs. 120 only. The overall low spending in public sector has adversely affected the availability and quality of health care in the public sector. Based on final outcomes indicators, concern is being raised regarding efficient utilization of this low public sector spending.

As per the study of aegis of the National Commission on Macroeconomics and Health (NCMH), Government of India (GOI, 2005), poorly performing States (like Madhya Pradesh, Orissa and Uttar Pradesh) in terms of Infant Mortality Rate (IMR) and safe deliveries actually spent more between (45-74 per cent) on primary care relative to the better performing southern States of India. In terms of international comparisons, countries like Bangladesh and Indonesia, which spend relatively less on health care than India, Have lower Infant Mortality Rate (IMR) in contrast to India (World
Bank 2003). According to recent data presented in the World Health Report (WHR 2005), India’s health related indicators are indeed lower than similarly placed countries like Bangladesh, Sri Lanka and Nepal.

2.2. MEASUREMENT OF EFFICIENCY OF HEALTH CARE

An overview of health care sector outcomes in India, from 1974 to 2004, presents many features of which some are quite impressive and other disconcerting. It is impressive, for instance, that life expectancy has doubled from 32 years to 64.6 years. While Infant Mortality Rate (IMR) has fallen by over 70 per cent, the cases of malaria incidence have been reduced to 20 lakhs. Diseases like smallpox and guinea worm have become nearly extinct and the near elimination of leprosy and polio has been achieved. Despite these achievements, it is disconcerting that India’s total population (16.5 per cent of global total) accounts for one – fifth of the world share of diseases, viz. a third of the diarrhoeal diseases, Tuberculosis (TB), respiratory and parasitic infections; a quarter of maternal conditions; a fifth of nutritional deficiencies, diabetes and venereal diseases; and the second largest number of South Africa, Government of India (GOI 2005). According to the data presented in the World Health Report (WHR 2005), India’s health related indicators are lower than compared to similarly placed countries like Bangladesh, Sri Lanka and Nepal. In fact, India has a higher infant mortality per thousand and a lower life expectancy than countries like Sri Lanka and China United Nations Development Programme (UNDP 2006).

Even within the country, there has emerged considerable inequity in terms of health achievements. As presented in National Health Financing Scheme (NFHS-3) survey, infant mortality rate (IMR) has been higher in rural areas relative to their urban counterparts. There is a notable disparity between better performing States like Kerala, Maharashtra and Tamil Nadu (TN) and lower performers like Orissa, Bihar, Rajasthan, Uttar Pradesh (UP) and
Madhya Pradesh (MP) National Health Financing Scheme (NHFS-3: 2005-06). Benefits from the public health system have also been uneven across different segments of the society. Particularly women, children and the socially disadvantaged sections of society (the Scheduled castes and Scheduled tribes) have not received the health benefits in an equitable manner and this is reflected in higher values of Infant Mortality Rate (IMR) for these groups of society. Besides the above noted inequity, there exist simultaneous presence of communicable and infectious diseases, and the newly emerging threat of Human Immunodeficiency Virus /Acquired Immune Deficiency Syndrome (HIV/ AIDS). Given the current trends, the cases of the later are likely to be trebled by 2015.

2.2.1. Conceptual Framework for Economic Performance Measurement and Efficiency of Health System

Generally, health system performance could be monitored with either of efficiency, effectiveness, or economy. Efficiency is defined as the extent to which a health agency or health system maximizes the output produced from a given set of inputs or minimizes the input cost producing a given set of outputs. Effectiveness is the extent to which programme and services (outputs) of a system achieve the desired outcomes. Economy refers to buying appropriate quality resources or inputs in the most economic manner.

2.3. COMMUNICABLE DISEASES

Communicable and infectious diseases constitute a major cause of premature death in India, killing over 2.5 million children below the age of five and an equal number of young adults every year. Despite significant progress achieved in the overall quality of life, and a reduction in absolute poverty, the proportion of total deaths on account of communicable disease, maternal and prenatal conditions, high at 42 per cent.
Between 1950 and 1990, there was a significant improvement in health indicators, mainly because of rising incomes and expanding access to health care. But a range of non-health determinants environmental pollution, unsafe water, poor sanitation practices, malnutrition, behavioural attitudes, illiteracy, climatic conditions, and poverty continue to be responsible for the persistence of pre-transition disease. The successful control of these dynamic and resilient diseases, driven by a complex network of ecological, social, political, and economic factors, demands the skillful negotiation of all these factors by an efficient public health system.

Since the global eradication of smallpox, thirty new pathogens have been identified, including Human Immunodeficiency virus/Acquired Immune Deficiency Syndrome (HIV/AIDS), Hepatitis C and E, and new strains of Vibrio Cholera. The resurgence of infections and of Malaria, Dengue, and Tuberculosis (TB) in forms difficult to control or treat, and the exponential rate of the development of Human Immunodeficiency virus/Acquired Immune Deficiency Syndrome (HIV/AIDS), have all imparted a new sense of urgency to disease control. Additionally, with some infections not responding favourably to commonly use and economical anti-microbial agents, the management of these infections has become difficult, long, and expensive.

While current efforts will ensure the elimination of leprosy and polio within the next five years, environmental and social factors impose severe constrains on the eradication of malaria, Tuberculosis (TB), or Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS). Thus efforts will have to be aimed at reducing disease transmission, minimizing drug resistance, and imperative as it is the poor who suffer the most.
The assessment is being made of the disease burden in India caused by the principal diseases—malaria, Tuberculosis (TB) and leprosy—and strategies formulated to contain them. It also identifies the programmatic issues for future direction of policy.

2.3.1. Disease Burden: An Overview

Infectious and parasitic disease accounted for 34.6 per cent of the total 269 million Disability Adjusted Life Year (DALYs) lost and 33 per cent of 9.3 million deaths in 1998. India’s Biochemical Oxygen Demand (BOD) on account of communicable disease is almost three times that of China’s and accounts for 23.3 per cent of global Disability Adjusted Life Year (DALYs) lost. From the very First Five Year Plan, the control of communicable disease has been a priority. Despite limited technical manpower, weak health infrastructure, and modest financial resources. India was able to bring down its diseases load and eradicate smallpox and guinea worm. The cause of death time trends for 1961-99 show an overall decline in mortality due to infectious and parasitic diseases and digestive disorders except in the case of Tuberculosis (TB) and respiratory infections. There has been some reduction in overall morbidity and mortality. Of the ten leading causes of Biochemical Oxygen Demand (BOD) and mortality, almost 50 per cent were on account of respiratory infections, diarrhoeal diseases, Tuberculosis (TB), and measles.

2.3.2. Malaria and Other Vector-Borne Disease

2.3.2.a. Malaria

Initial efforts aimed at malaria eradication brought down the caseload from an estimated 75 million to a record 1,00,000 cases in the 1960s, with negligible deaths. But various financial, administrative, technical, and logistic factors ensured that this success was short-lived. Constrains included the disbanding of malarial teams to assign them duties such as family planning;
the failure to supply several recurrent critical components that states were to provide under the pattern of assistance; reports of drugs and insecticide resistance, particularly from Assam; and an overall sense of compliancy, affecting the required level of vigilance. These and other factors contributed to the resurfacing of malaria in 1976 to a high of 6.47 million cases. A modified plan of operation was launched in 1977 to contain the disease, with the three main objectives of preventing deaths, reducing morbidity, and consolidating gains. By 1984, malaria was brought down to about 2.18 million cases. With the three main objectives of preventing deaths, reducing morbidity, and consolidating gains. By 1984, malaria was brought down to about 2.18 million cases. Efforts towards a further reduction were not successful due to vector and parasite resistance to conventional insecticides and drugs respectively in some high endemic areas, environmental changes caused by development activities such as irrigation projects, rapid urbanization, as well as continuing financial and management constraints.

Several local outbreaks of malaria were once again witnessed in 1994, resulting in high mortality due to a multiple set of reasons: poor disease management, increasing malarial risk factors, and an overall failure of the health system caused by the gradual depletion of trained personnel. The data is not complete enough to be conclusive but it seems fairly clear that the emergence of parasite resistance to drugs and vector resistance to insecticides is a key factor. A major cause of concern is that between 1995 and 1999, plasmodium falciparam (Pf), the more dangerous strain of malaria, increased from 38.84 per cent to 49.96 per cent.

The average caseload of about two to three million malarial cases hides the wide state differentials in disease prevalence. Overall, ten states account for 93 per cent of the total disease burden. While Madhya Pradesh, Orissa, Rajasthan, Bihar, Andhra Pradesh, and Maharashtra account for over 80 per
cent of total case load, Madhya Pradesh and Orissa alone account for 50 per cent of mortality.

On the basis of recommendations from an expert committee, high-risk malarial areas within high endemic states were identified for more focused control measures. A three pronged strategy was drawn up, now being implemented throughout the country under the Native American Mentoring Programme (NAMP). Twenty-nine cities/towns, 318 districts, 10 per cent of primary Health Centres (PHCs), and about 24,844 villages (roughly a population of 200 million) were identified as high risk on the basis of the following parameters:

- A doubling of Slide Positivity Rate (SPR) for 2-3 years and Slide Positivity Rate (SPR) of 5 per cent or more;
- Proportion of plasmodium falciparam(Pf) malaria more than 30 per cent;
- Chloroquin resistant plasmodium falciparam(Pf); and
- Tropical aggregation of labour and new settlements.

The main strategy objective is the interruption of disease transmission by:

- The reduction of the reservoir of infection to humans through early detection and prompt radical treatment;
- The reduction of the vector population through selected vector control, using anti-adult (use of Diptheria-Diphenyl-Trichloro-Ethane (DDT), malathion and synthetic pyrethroids in Diptheria-Diphenyl-Trichloro-Ethane (DDT)-and malathion-resistant areas) and antilarval (spraying of larvicides and use of larvicides and use of larvicidal fish) measures; and
- The enhancement of community-based action (bio-environmental control and personal prophylactic measures).
This strategy is being implemented as centrally sponsored scheme under three different packages of assistance: in the north-eastern states, the centre provides 100 per cent assistance to cover insecticide and drug supply, spray operations, contingencies for Polarization (POL) and other operational expenses; in non-high-risk areas, the package is based on a 50-50 sharing basis, with the centre providing drugs and some insecticides, but no operational expenditures; in high-endemic areas, 100 per cent central assistance is provided under the World Bank-assisted Enhanced Malarial Control Project (EMCP) for synthetic pyrethroids in triple resistance pockets (states are expected to fund malathion fully Diptheria-Diphenyl-Tricholro-Ethane (DDT) partially for other areas), impregnated bed nets for personal protection, rapid diagnostic kits and Artiomisinin injections, vehicles, microscopes, consumables and supplies, and funds (for contracting lab technicians, International Electrotechnical Commission (IEC), and special mobilization activities).

The Enhanced Malarial Control Project (EMCP) covers the 100 most endemic districts in Andhra Pradesh, Orissa, Jharkand, Gujarat, Madhya Pradesh, Chhattisgarh, Maharashtra, and Rajasthan, and nineteen cities/towns, all of which together account for 90 per cent morality. Over 90 per cent of plasmodium falciparam (Pf) malaria cases occur in tribal areas characterized by, weak health systems, poor communications and above all, extreme poverty. The Enhanced Malarial Control Project (EMCP) strategy reflects the shift from Native American Mentoring Programme (NAMP) reliance on chemical control to integrated methods. The three specific initiatives of Enhanced Malarial Control Project (EMCP) are epidemic planning for rapid response to inter-sectoral coordination, strengthening of institutional management, and personal protection through the use of medicated bed nets. In addition, meteorological data regarding rainfall, temperature, and humidity, along with epidemiological information are being
monitored for the first time since 1977, to assess mosquitogenic potential and for warn states. Under implementation only since 1977, Enhanced Malarial Control Project (EMCP) had a slow start for operational reasons and is now getting into gear. However, difficulties in ensuring male health workers to deliver services (the responsibility of state governments) continue to plague the programme.

The urban malaria vector Stephensi (anopheles stephensi) breeds in stored water and domestic containers; construction activities and the aggregation of labour also provide a conducive environment for breeding. Implemented in 131 towns, the strategy for tackling urban malaria consists of early case detection and treatment; recurrent anti – larval measures through conventional larvicides in towns; minor engineering method such as source reduction, channelization and deweeding; and biological control using lavivorous fish at appropriate breeding sites. The success rate has not been promising: from 1997 – 1999, malaria – positive cases have increased from 1,74,000 to 2,89,000 and the proportion of cases has doubled from 15,627 to 53,619. Tamil Nadu, West Bengal and Delhi accounted for more than 80 per cent of this increase. Native American Mentoring Programme (NAMP) also covers other vector – borne disease - leishmaniasis or kala-azar, lymphatic filariasis, dengue hemorrhagic fever (DHF), and Japanese emphatics (JE).

2.3.2.b. Kala - Azar

This disease was controlled with mass insecticidal spraying in 1985 but resurfaced due to the lack of insecticidal pressure on the vector population. Reappearing in four districts of Bihar in 1974, it spreads to become endemic in thirty – six districts of Bihar, and ten of West Bengal. Currently nearly 101 million are at risk; the annual average is about 15,000 cases and 200 deaths. The number of cases declined between 1993 and 1996, but increased again in 2000. The kala – azar strategy consists of the interruption of transmission
through vector control by residual spraying in affected areas, early diagnosis and treatment in Primary Health Centers (PHCs), and community participation. The central government provides the entire requirement of sodium stibogluconate vials, pentamidine vials, amphotericin-B and Diptheria-Diphenyl-Trichloro-Ethane (DDT). Subsequent to the report of a recent expert committee, efforts are underway to eliminate this disease in a time bound manner. Control has been tardy, partly because of weak implementation. Health system deficiencies are already high in the endemic areas, and the capacity for optimal utilization of assistance low. However, the time bound control of this disease will be enhanced if the new drug miltifocin proves to be successful.

2.3.2.c. Lymphatic Filariasis

After a marginal decline, the rate of this disease has increased from 1.01 per thousand in 1989 to 2.33 in 2000. During the same period, the microfilarial rate decreased from 2.02 to 1.11. About twenty-nine million people are estimated to be disease carriers, and other twenty-two million non-infective. The National Filaria Control Programme provides assistance to all eighteen endemic states (454 million people); the most endemic begin Andhra Pradesh, Orissa, Uttar Pradesh, West Bengal, Tamil Nadu, Kerala, and Bihar. Originally conceived as an urban programme, anti-filarial measures are being implemented through the 206 filaria control units and 199 clinics. Since 1994, the anti-filarial drug diethycarbamazine (DEC) is available in rural Primary Health Centres (PHCs) for the treatment of acute and chronic cases of filariasis. Since 1997, a pilot project to study the feasibility of annual single dose diethycarbamazine (DEC) mass drug administration is in operation in thirteen districts of seven states. The central government provides larvicides and anti-filaria drugs, while operational and equipment costs are borne by the states. The strategy – vector control, environmental engineering, and antiparasitic measures–has not led to any
appreciable reduction in disease rates despite the mass single annual dose administration of diethycarbamazine (DEC) in thirteen pilot districts. The co-administration of diethycarbamazine (DEC) and Albendazole for the elimination of lymphatic filariasis in a few districts of Kerala, Orissa and Tamil Nadu, is now being considered. The strategy consists of early case identification and treatment in view of the absence of effective chemoprophylaxis or cost-effective vaccines.

2.3.2.d. Japanese Encephalitis (JE)

This vector-borne disease is prevalent in about sixty-five districts in ten endemic states; the annual caseload is about 2,500 cases and 500 deaths, mostly of children below the age of five. Nearly 90 per cent of cases are reported from Andhra Pradesh, Uttar Pradesh, Karnataka and West Bengal, with 50 per cent of deaths consistently reported from Andhra Pradesh and Karnataka since 1997. But Japanese Encephalitis (JE) spreading to non-traditional areas as well: in 1996 Kerala reported 105 Japanese Encephalitis (JE) cases and thirty-one deaths, and the numbers have been steadily increasing in the last four years. Control strategies continue to focus on early diagnosis, case management, vector control (two rounds of residual insecticidal spraying), fogging by malathion insecticide, segregation of pigs and promotional of personal prophylaxis. While high costs limit the use of vaccination, no effective chemoprophylaxis continues to be an option, as early reports of trials in highly endemic areas indicate safety as well as high level of protection.

2.3.2.e. Dengue Haemorrhagic Fever

There was an outbreak of Dengue Haemorrhagic Fever (DHF) in 1996 in nine states with 16,517 cases and 545 deaths. Preventive action has brought down the caseload to 605 and mortality to about seven in 2000. Intensive
training and standardized patient management have helped reduce case fatality by 50 per cent. Inadequate epidemiological information, however, hinders drawing definitive conclusions.

### 2.3.3. Hindrances in Control Strategies

Despite a plethora of schemes and activities, and in spite of nationwide strategies implemented on a war footing, the success rate in controlling vector-borne diseases has not been satisfactory. There are six essential problems in the implementation of the vector control programmes:

- Weak and dysfunctional health system;
- Poor surveillance in endemic areas;
- Delayed supply of inputs due to time consuming procurement procedures;
- Weak logistic monitoring;
- Inadequate allocation and delayed release of recurring budgets; and
- Inadequate research on vector and human behavior, anthropological and operational issues, drug and parasite resistance.

### 2.3.3.a. Tuberculosis (TB)

The Indian Council of Medical research (ICMR) nationwide survey of Tuberculosis (TB) conducted during 1955-99 covered 40 per cent of the population and indicated an active prevalence level of 1.5 per cent. These estimates continue to be used. Given the socio-economic changes over the past five decades, a new nationwide study to estimate the rate of Asia Research Institute (ARI) has been launched by the National Tuberculosis Institute and the Tuberculosis Research Centre (TRC) Chennai. This should enable a more accurate estimation of the prevalence of Tuberculosis (TB). India accounts for one-third of global Tuberculosis (TB), and the largest
number of persons suffering from active Tuberculosis (TB). About 2.2 million persons are added each year to the existing load of about fifteen million active Tuberculosis (TB) cases; of these, about 4,50,000 die. Tuberculosis (TB) is the leading cause of death among women in the reproductive age group of 25-44 years, more deaths than those due to all the causes of maternal mortality. Tuberculosis (TB) accounts for almost 7.57 million Disability Adjusted Life Year (DALYs) lost World Health Report (WHR 1998). About 20 per cent of fifteen-year-olds are reportedly infected with the bacteria. Since every sputum-positive case has the potential to infect 10-15 individuals in a year, and since Tuberculosis (TB) is one of the important opportunistic infections of Human Immunodeficiency Virus (HIV), it is feared that due to Tuberculosis (TB) can up to four million in the next decade if not controlled.

The National Tuberculosis Control Programme (NTP) was launched in 1962, and an impressive infrastructure of 446 District Tuberculosis (TB) centers 330 Tuberculosis (TB) clinics, 764 hospitals, and 47,600 beds were established. These hospitals diagnose nearly 1.3 million patients and treat 2,50,000 sputum positives every year. But despite an annual expenditure of about Rs 300 crore by these institutions, double what is spent on the National Tuberculosis (TB) programme covering the whole country, the outcome is unsatisfactory due to poor diagnosis, inappropriate regimens and the lack of patient evaluations or follow-up. Despite expert committee’s reviews in 1975 and 1988, the Tuberculosis (TB) programme languished for want of a credible strategy and political and administrative support, as well as low resource allocation not exceeding Rs 20 crore per year. An exhaustive review of the National Tuberculosis (TB) Programme was taken up in 1992 and the findings showed:

- Completion of treatment for less than 40 per cent of patients;
- Inadequate budget and a chronic shortage of drugs, enough only for one-third of detected cases;
- Emphasis on X-ray diagnosis, resulting in inaccurate diagnosis, centralization to Tuberculosis (TB) district centre and more expense;
- Poor quality sputum microscopy due to poorly trained technicians and non-supply and irregular supply of consumables;
- Multiplicity of treatment regimens administered primarily by an unregulated private sector; and
- Insufficient managerial capacity and weak technical leadership.

The World Health Organization (WHO) extended technical support to pilot-test the Directly Observed Treatment Short-Course (DOTS) strategy to detect at least 70 per cent of sputum-positive patients, and cure at least 85 per cent. Based on these reviews and the results of controlled pilot projects, the Revised National Tuberculosis Control Programme (RNTCP) was formulated with the Directly Observed Treatment Short-Course (DOTS) strategy as its cornerstone. The Directly Observed Treatment Short-Course (DOTS) strategy is based on five principles:

- Case detection among patients spontaneously attending health facilities, primarily by the microscopic examination of sputum;
- Ensuring adequate drug supply;
- The administration of Short-Course Chemotherapy (SCC) under direct observation;
- Systematic monitoring and accountability for every patient diagnosed; and
- Political will.

The Dots strategy is now implemented under the Revised National Tuberculosis Control Programme (RNTCP) in about 200 districts covering 350 million people. External funding of about Rs 7.47 billion has been mobilized; Tuberculosis (TB) units are being established at sub-district level of every 5,00,000 people. Each unit oversees the work of five microscopy centers, with
a trained laboratory technician in each, and is provided with state-of-the-art binocular microscopes and reagents. Units are given a vehicle each, along with funds to meet recurring costs and ensure close supervision of quality, reliability and prompt reporting by microscopy centers. Most critical to this strategy is the high priority given to microscopy as the appropriate technology to identify patients most likely to spread Tuberculosis (TB) and most likely to die if untreated.

About half a million people have been treated under The Directly Observed Treatment Short-Course (DOTS) during 2000; there has been a qualitative improvement in diagnosis, with a ratio of 1.2 per smear negative pulmonary Tuberculosis (TB) for every case of smears-positive Tuberculosis (TB). The cure rate has doubled from less than 40 per cent to 80 per cent, though not uniformly. The death rate has also been reduced to 4 per cent, compared to at least 20 per cent under the National Tuberculosis Control Programme (NTP). These achievements of Revised National Tuberculosis Control Programme (RNTCP), over a short three-year implementation period, are due to the quality training given to health staff; the increasing involvement of Non-Government Organizations (NGOs); improved management systems and the standardization of treatment regimens according to patient typology to ensure the uninterrupted supply of drugs in patient typology to ensure the uninterrupted supply of drugs in patient-wise boxes; increased availability of sufficient funds with districts societies and intensive monitoring. The Directly Observed Treatment Short-Course (DOTS) strategy is to be expanded throughout the country by 2005; and successful implementation will improve cure rates, reduce mortality, prevent multi-drug resistance, and control the dual epidemic of Human Immunodeficiency Virus (HIV) and Tuberculosis (TB).

The National Tuberculosis Control Programme (NTP) is implemented along with Revised National Tuberculosis Control Programme (RNTCP) in
the remaining parts of the country with the Central Government providing drugs for Short-Course Chemotherapy (SCC). The results continue to be poor in these districts, for want of adequate inputs, irregular supply of drugs, low budgets, poor supervision, and weak monitoring.

Despite the impressive results of Revised National Tuberculosis Control Programme (RNTCP), the future scenario of Tuberculosis (TB) control appears because of:

- Low coverage: Directly Observed Treatment Short-Course (DOTS) covers only about 20-25 per cent of Tuberculosis (TB) patients; expansions is constrained by weak institutional capacity, low budgets and the dangers of Medical Device Reporting (MDR) due to unplanned expansion;
- Weak health system, particularly in urban areas without primary health care infrastructure;
- Unsupervised private practitioners following their own lines of treatment, contribution to Medical Device Reporting (MDR);
- The implementation of multiple systems of Tuberculosis (TB) control, Short-Course Chemotherapy (SCC), with different financing mechanism; and

The threat of a dual epidemic: Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) and Tuberculosis (TB) as an opportunistic infection with a potential to increase the number of cases substantially.

The expansion of Directly Observed Treatment Short-Course (DOTS) to cover the country by 2005 is apriority. The achievement of this goal will depend on how soon and how well constraints are overcome. It will depend on the required infrastructure-microscopy centers, trained personnel, and
regular supply of drugs and funds-being ensured. Finally, it will also depend on the mobilization of political and administrative will.

2.3.3.b. Leprosy

Available estimates indicate a leprosy caseload of about two million cases, of which 20 per cent are infectious. 50.39 per cent are Multibacillary (MB), 37.28 per cent are other bacillary, and 12 per cent are single skin lesion cases. In the two Modified Leprosy Eradication Programme (MLEC) surveys conducted in 1998 and 2000, 4.63 and 2.13 lakhs new cases were detected. Systematic efforts to eliminate leprosy (prevalence rate less than one per 10,000 populations) by March 2000 have had success in about a quarter of the country; in another 15 per cent, the prevalence rate is between one and two per 10,000. The major states with a high prevalence of leprosy now are Bihar, Orissa, Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Andhra Pradesh. Only twelve districts have a prevalence rate of more than twenty per 10,000; nine are Bihar, two in Orissa, and one in Madhya Pradesh. Bihar has the highest number of Multibacillary (MB) cases, while Orissa has the highest number of single skin lesion cases.

The National Leprosy Eradication Programme (NLEP) was launched in 1965 when prevalence rate was 57 per cent 10,000 persons. The programme, which was strengthened with the introduction of Multi Drug Therapy (MDT), is vertically driven. Implementation is through an impressive infrastructure of 778 Leprosy Control Units, 907 Urban Leprosy Centres, 5,744 Treatments Centres and 350 Mobile Leprosy Centres, Leprosy Treatment Units. The control strategy includes active as finding, Multi Drug Therapy (MDT), and rehabilitation of cured cases for economic productivity. Its strength has been low treatments costs, verticalized implementation structure up to the sub-district level, and active participation of about 300 Non-Government Organizations (NGOs). Disease elimination stage has been reached in ten
states; nearly 8.9 million people have been cured in the last two decades. At the current level of implementation, leprosy elimination is likely in most parts of the country in a few years. The programme, however, must be sustained to ensure that the disease does not resurface. Accordingly, in areas where leprosy is less than one per 10,000, the programme is high integrated with the Primary Health Centres (PHCs), with staff provided at the district level of monitoring.

2.3.3.c. Other Infections

Acute diarrhea, dysentery, worm infestations, and digestive tract infections are soil-transmitted, or caused by the consumption of contaminated water. Hence, the need to promote community hygiene and healthy living is imperative. Comprehensive health education that cuts across sectors is the key to eliminating these diseases; the campaign to eradicate guinea worm demonstrates the success of this strategy. The high morbidity and mortality of water- and sanitation-related diseases continue due to the absence of such convergence at the field level. Data on the prevalence and spread of helminth disease are not routinely monitored at the state or central levels and hookworm to cause anaemia. The fatality caused by these soil-transmitted parasites may not be substantial, but they pose a serious health hazard to small children. In 1999-2000, the National Institute of Communicable Diseases (NICD) carried out pilot studies to estimate the prevalence and intensity of soil-transmitted helminthes among 9-10 year old children in seven ecological zones of the country.

Water related and helminthic diseases have a debilitating impact on the immunity system, particularly among the malnourished. Hence the need to make adequate investments in health education as well as water supply, sanitation, and sewage systems. Locally elected bodies must be involved in the maintenances of water supply sources. Since poor children suffer most with
infections affecting physical and mental growth, investments in community-level chemotherapeutic interventions must be considered.

2.3.4. Programmatic Issues

Technical strategies for disease control seem to be efficacious and affordable, yet India continues to struggle to bring down diseases incidence. The wide gap between policy statements, technical prescriptions and actual implementation persists. While gross deficiencies in the primary health care system explain much of the unsatisfactory implementation of disease control programme, correcting shortcomings would certainly improve implementation quality.

2.3.4.a. Need to Intensify Rigour in Programme Monitoring

Preliminary studies carried out by the Medical Research Council (MRC) and Indian Council of Medical Research (ICMR) indicate a range of factors contributing to the poor implementation of the malaria programme: poor supervision; poor monitoring of drug quality and improper storage facilities; lack of evidence-based planning of malaria control activities; and lack of coordination among different sectors and research inputs. Vector control activities seem particularly affected by:

- Untimely and inadequate procurement of insecticides;
- Low limits for the payment of wages and non-availability of recurring budgets to engage labour for spraying operations;
- Lack of systems for the evaluation of insecticide application equipment;
- Inadequate monitoring of insecticide resistance against malaria;
• Lack of evidence-based data on vectors responsible for malarial transmission period;

• Lack of evidence for the introduction of new insecticides; and lack of control on the free availability and use of anti malarial; delayed slide examinations and lack of information on the status of drug resistance.

A field survey of the Tuberculosis (TB) programme under the Short-Course Chemotherapy (SCC) was conducted by the All India Institute of Hygienic and Public Health (AIHIPH), Kolkata, for an estimated population of 8.6 million with 37,703 reported cases, and about 23,457 new cases in 2000-01.

• Laboratory reagents and ethambutol were inadequate in 28 per cent of the centres;

• Supplies of rifampicin pyrizinzmid, and streptomycin were inadequate in 42 per cent of the centres;

• Drug regimens were being adapted to suit actual availability of the drugs;

• Action to retrieve defaulting patients by letter or visit was rare;

• Default registers were not available in 71 per cent of the centres, lab registers in 42 per cents, and transfer forms were inadequate in about 28 per cent;

• Client satisfaction was low, with 50 per cent of the patients saying that the timing of the centers were not convenient;

• Default usually happened between the fourth and the seventh month due to toxicity of drugs/side effects.
2.3.4.b. Inadequate Budgets and Poor Utilization

The central budget allocation for the control of communicable diseases as a percentage of total health budgets has gradually reduced during the period 1998-2001, from 58 per cent to 47 per cent. This is the matter of grave concern. Under-funding is most acute in the malaria control programme, with no real increase in budget utilization over the past few years. From 1992 – 93 till date, the programme has not been able to incur an average expenditure not more than Rs 150 crore, the highest being Rs 193 crore during 2000-01. While allocations do not get spent, the Malathion needed in north-eastern and other endemic states resistant to Diptheria-Diphenyl-Tricholro-Ethane (DDT) is not provided. An analysis of the causative factors and of areas of high endemicity suggests an ‘epidemiological polarization’. A mapping of disease occurrence across geographical areas and sub-populations establishes a convergence of illness, poverty, malnutrition, the denial of access to basic needs and low economic development. Not surprisingly, the least development states of Bihar, Uttar Pradesh, Madhya Pradesh, Rajasthan, Orissa and Assam account for the highest percentage of morbidity and mortality due to communicable diseases.

The lack of adequate recurring budgets leads to a disruption of activities. Inadequate resources present a problem in states as well; the analysis of budgetary allocations in a god-performance state like Tamil Nadu, showed that during 1995-96 and 1996-97, the percentage of allocation for public health fell from 40 per cent to 38.7 per cent. The budget allocated for disease control constituted only 15.4 per cent and 18.1 per cent of the total public health budget. The central share is also low-only about 7.6 per cent of the total budget for disease control. To ensure timely availability and quicker absorption of funds, state-and district-level societies have recently been constituted under each disease control programme. Funds are released to these societies directly by the Centre.
2.3.4.c. Need of Involvement of Private Practitioners

Almost 80 per cent of Out Patient (OP) care is provided by private practitioners, making their involvement in the control of major communicable disease such as Tuberculosis (TB) and malaria an obvious requirement. A study, conducted on the role of private practitioners in the resurgence of malaria in Mumbai, showed that practitioners had poor qualification, and adopted diagnostic and treatment practices inconsistent with guidelines. Few of those practicing in low-income areas relied on peripheral blood smear tests for diagnosis. They commonly resorted to injectible anti-malarial and broad-spectrum antibiotics for febrile patients, with the justification that patients could not afford a blood smear test or a full prescription.

2.3.4.d. Delayed Procurement and Poor Monitoring of Logistics

Timely procurement and supply of inputs affects implementation of all national programmes; yet Central procurement appears to be an advisable option for economy of scale. In the best of cases, the average time required for the procurement process is not less than 6-8 months; starting the process a year before is not possible because the budget is not sanctioned. With more flexibility, the Centre can consider procurement for state governments that make a specific request, or lack institutional capacity. Besides procurement, delivery, and utilization, close monitoring and inventory control to ensure timely diversion of surplus stocks to deficit areas need to given equal attention.

2.3.4.e. Need for Comprehensive Surveillance System

Planning programme formulation based on partial data may lead to faulty design. The poor enforcement of compliance to report notifiable diseases is a serious gap. The wide difference in the quantum of ‘missing data’ can be gauged from a review of two districts, where surveillance teams have
been trained in field epidemiology and provided with computers. In Udaipur, Rajasthan (population 2.08 million), information against the list of notifiable disease is collected only from government facilities; in Kottayam, Kerala (population 1.82 million), information is received from both public private facilities. Misreporting, delayed reporting, and under-reporting from government facilities are aggravated by lack of infrastructure, Udaipur has no public health laboratory, while Kottayam had laboratory facilities for cholera, viral hepatitis. Dengue meningococcal meningitis, typhoid fever, diphtheria, and water bacteriology. The absence of a surveillance system affects the ability to recognize early warning signals and take timely measures in the event of outbreak of disease.

**Table 2.1. Reported Number of Cases due to Selected Diseases in Tamil Nadu, 2000-03**

<table>
<thead>
<tr>
<th>Years</th>
<th>Malaria</th>
<th>Japanese Encephalitis</th>
<th>Dengue</th>
<th>Leptospirosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>43053</td>
<td>116</td>
<td>81</td>
<td>1801</td>
</tr>
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<td>2001</td>
<td>31551</td>
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<td>2002</td>
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<td>1232</td>
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<tr>
<td>2003</td>
<td>43604</td>
<td>163</td>
<td>1610</td>
<td>3634</td>
</tr>
</tbody>
</table>

Note: Figures in parentheses indicate the new cases reported per 10,000 populations.

Source: Health information of India, Various years and performance Budget, Department of Health and Family Welfare 2005-06.
2.3.4.f. Low Priority to Health Education and Community Involvement

Health education has always occupied a lower priority in Indian public policy: its allocation under different programme budgets, taken together, is not more than 1-2 per cent of the annual health budget. A lack of information as one of the major barriers to the effective access of services. The Pulse Polio Campaign is an example of how people change behaviour in response to information. An activity associated with health education is the securing of social support to enable the effective implementation of disease control measures. The inclusion of health concerns with water and sanitation programmes, adult literacy, poverty alleviation, and developmental projects is limited. So is the co-option of local bodies and Non-Government Organizations (NGOs) to share responsibility, except in the cases of the leprosy and Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) control programmes. For example, in a highly
community-based and localized programme such as malaria. The involvement of local bodies is almost non-existent whether in introducing bio-environmental control methods, or ensuring compliance to sanitary laws, or providing the required administrative and political leadership. Such involvement of the community and local bodies at both village and town levels, is emerging as an imperative for effective control of communicable diseases.

2.3.4.g. Impact of Campaigns

Campaigns cost money; they can also distort priorities and exhaust the staff. Even so, there has been a growing tendency to use campaigns, even or routine tasks. Campaigns can be useful, but they need to be applied selectively, as a means to mop up residual cases. For example, the entire health staff was busy for two months with in campaign after another-the catch-up round, the third round of the pulse polio, family health awareness, tetanus. Needless to say, this affected routine work on malaria surveillance or leprosy.

2.3.5. Policy Issues: Future Directions

On the basis of the analysis of programmatic issues, recommendations for future action include the following:

- Revise public policy for quick epidemiological transition: policy revision must aim to ensure, in the short term, the elimination of leprosy and kala-azar, and the control of malaria, Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) and Tuberculosis (TB), targeting a drastic reduction in mortality.
• Increase total quantum of funds: Central funding to states is at present Rs 3-5 per capita for all four major communicable disease control programmes.

• Consider a more direct central intervention in actual implementation: if necessary, the deployment of trained personnel, on a contractual basis, will offset poor institutional and managerial capacity for programme implementation in weak – performance states.

• Revise procurement systems suitably: the Central Government must consider the decentralization of procurement to states and districts by developing requisite capacity.

• Consider the inclusion of hepatitis vaccination in Universal Immunization Programme (UIP): though hepatitis does not kill, it contributes to disease load that is expensive to treat; also, the vaccine is now more affordable.

• Invest on improving public health institutions and enhance the quality of laboratory support.

• Establish a comprehensive surveillance system: a high priority in all districts, this should be done with central funding for a period of ten years.

• Develop protocols and regulations to co-opt the private sector into reporting and treatment in disease control programme.

• Increase investment and put a set of incentives in place: this will improve the functioning and accountability of the health system; incentives and disincentives will help worker motivation and discipline.
- Undertake more evidence-based research: the priority is drug and insecticide resistance, given the exorbitant costs of alternatives.

- Strengthen technical units related to disease control: this should be done at both Central ministry and state levels to enhance the capacity for impact assessment studies.

- Monitor and supervise at close intervals: this should be substantially intensified at Centre, state and district level.

- Focus on Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS): this will help control associated infection that may become unsustainable for the health system to cope with later.

- Focus on Health programmes: Popular participation and empowerment can be strengthened with more intensive use of mass media channels, as well as interpersonal communication.

2.4. INDIANS SYSTEMS OF MEDICINE ON HEALTH CARE

No discussion of the Indian Systems of Medicine (ISM). India has an incomparably rich heritage in ancient systems of medicine that make up a veritable treasure house of knowledge for both preventive and curative health care. These systems, through their safe, effective, and inexpensive treatments, have the potential to make a significant contribution to the health care of the common people. But their true potential is still largely unrealized, despite a large and well-dispersed infrastructure.

The term Indian Systems of Medicine (ISM) comprises six different systems: ayurveda, siddha, unani, yoga, naturotherapy, and homeopathy. In terms of registered practitioners, ayurveda is the dominant system in Indian Systems of Medicine (ISM). Homeopathy, though German in origin, has a
large Indian clientele, and is second only to ayurveda among the Indian Systems of Medicine (ISM).

2.4.1. Ayurveda

Ayurveda means the ‘science of life’ in Sanskrit. It is one of the oldest and the best documented among the ancient systems of medicine. The documentation of ayurveda is referred to in the Vedas (1500 Before Christ BC) -500 Before Christ (BC), said to be the oldest recorded wisdom in the world. It derives from the charakasamhita (600 Before Christ (BC) and the susrutasamhita (500 Before Christ (BC). The approach is essentially philosophic, holistic, and humanistic. Ayurveda emphasizes life and health more than disease and treatment. It presents a comprehensive life science and encompasses total health – physical, mental, and spiritual – in a holistic way. The system is based on the laws of nature, and the individual human being regarded as a miniature replica of the universe. The individual and the universe are both essentially pancamahabhuta, or made up of the five basic physical factors or elements: akasa (ether/space), vayu (Air, motion), teja (fire/radiant energy) jala (Water/cohesive factor) and prthvi (earth/mass). The individual (purusa) and the universe (loka) remain in constant interaction with each other, and as long as this interaction is wholesome and optimal, the human being enjoys good health.

In these sense, ayurveda is a system of medicine very close to nature.

The five physical attributes of pancamahabhuta constitute three major biological components of living body called tridosa, i.e. vata, pitta and kapha. All ailments arise out of imbalance of the three dosas or humors, and the role of medicine is to assist the natural healing powers of the body.

It is not possible to deal with the various aspects of this ancient system. Suffice it to say that it is a complete and well-developed promotive,
preventive and curative system of medicine with eight major clinical specialties: Kayacikitsa (internal medicine), salyatantra (surgery), salkya Ear, Nose and Throat (ENT), kaumarabhrtya (pediatrics, obstetrics, and gynaecology), bhutavidya (psychiatry), agadatantra (toxicology) and rasayanatantra (nutrition, rejuvenation, and geriatrics).

Ayurvedic drugs are usually soft medications, acting as molecular nutrients for different organs and tissues. Their action is explained more in terms of nutrition dynamics rather than actual pharmoco dynamics. All preparations are from natural sources; most of them are herbal, but the system also makes extensive use of minerals and ashed metals.

2.4.2. Siddha

Siddha, an equally ancient system, is similar to ayurveda in its fundamental principles. But there is considerable difference in the way the two systems have evolved. The siddha system got its name from the ancient masters, who, besides practicing medicine, also performed many miraculous acts. Siddha means a master; thus the name denoted the mastery of such practices. The most famous of the Siddhas was Nagarjuna, whose rasatantraforms the basis of this system. The literature of Siddha is in Tamil, unlike Ayurveda, where the ancient texts are all in Sanskrit. The system flourished in south India and Sri Lanka, and at present, it is practiced primarily in the state of Tamil Nadu. The distinctive features of Siddha are its reliance on minerals and metallic compounds, and its emphasis on rejuvenative therapies.

2.4.3. Unani

The Unani system originated in the fourth and fifth century Before Christ (BC) in Greece under the patronage of Hippocrates (460 Before Christ (BC)-377 Before Christ (BC)) and Galen. It gradually absorbed the experience
and wisdom of many ancient cultures, including those of Egypt, Arabia, Persia, China, Syria, and of course, India. The system was documented in Al anoon by Sheikh Bu-Ali Sina Anno Domini (AD) 980-1037 and in AlHAVIBY Razi Anno Domini (AD) 850-923. The system is based on the humoural theory that good health depends on the balance of the four humours, blood, phlegm, yellow bile, and black bile. Like ayurveda, this is holistic system including promotive, preventive, and curative interventions. But unlike ayurveda it relies overwhelmingly on herbal preparations.

2.4.4. Yoga

Yoga is not really a system of medicine. Its objectives are self-realization and spiritual union with the all-pervasive divine cosmic power. But certain intermediary practices and yogic attitudes have proved beneficial for reducing stress, preventing many lifestyle-related diseases, and promoting general health and well being. It has also proved useful in the treatment of many chronic and intractable ailments. Along with medication, this is by far the most popular ancient system globally.

Essentially, yoga is devoted to the integration of the physical, mental, intellectual, and spiritual dimensions of one’s being. The technology of the practice of yoga is based on Patanjali’s yoga Sutra (around 200 Before Christ (BC), containing the scheme of astanga yoga (eight limbic yoga) with the cosmic force. Meditation is an essential ingredient of yoga. However, in common parlance, yoga is associated with certain postures (asana) and breathing exercises (pranayama), which have wide and varied beneficial influences on both physical and mental health.

2.4.5. Naturopathy

Naturopathy is based on the fundamental principles of ayurveda. While ayurveda uses medicines in addition to bio-purificatory and dietary
practices, naturopathy relies solely on the latter. The basic tenet of naturopathy is to live according to the laws of nature: disease occurs due to the accumulation of toxins in the body, and to cure the ailment, the body is purified with the use of natural methods. Dietary regulation and exercise. Naturopathy uses mud, water, heat, and air as the instruments for therapy, but never any drugs.

2.4.6. Homeopathy

Homeopathy is fundamentally different from other Indian systems. It is based on a specialized method of treating diseases-administering potentized drugs in very high dilutions, which have been empirically established to have the power of relieving the very symptoms which they normally cause in healthy human being when administered in their gross form. Homeopathy was discovered by a German physician, Dr. Christian Frederic Hahnemann, in the seventh century. Homeopathy is also holistic system, and it treats the patients as a whole, not merely the diseased organ. It is particularly useful for constitutional ailments for which modern medicine has few remedies. It is safe, inexpensive and easy to use, and as a result, many households maintain a small chest of homeopathic medicines, which they use on their own for common ailments, particularly those of children. Homeopathy is, by far, the most popular Indian Systems of Medicine (ISM) system across the country, although other systems have their areas influence in designated parts of the country.

2.4.7. Underlying Similarities

While there are significant differences among the Indian Systems of Medicine (ISM) systems, there are some important underlying commonalities in basic approaches and fundamentals, particularly between ayurveda, siddha, unani, yoga and naturopathy. These are:
• All the systems adopt a holistic approach, attempting to treat the patient as a whole rather than the affected organs.

• The systems are more life oriented than disease oriented.

• All of them emphasize promotive and preventive aspects.

• All of them believe that disease is a consequence of disharmony between man and the nature that disturbs the balance between biofactors/humours.

• All systems use Natural substances, predominantly herbal preparations used as nutritional supplements rather than drugs.

• All systems emphasize appropriate diet.

• Ayurveda, siddha, and unani rely, to a great extent on pulse reading for diagnosis.

2.4.8. Infrastructure

There is vast infrastructure of hospitals, dispensaries, teaching institutions and registered practitioners under different systems of Indian Systems of Medicine (ISM). Different systems are dominant in different parts of the country. Ayurveda is more popular in Kerala, Himachal Pradesh, Gujarat, Karnataka, Madhya Pradesh, Rajasthan and Orissa. Unani has a greater following in Andhra Pradesh, Karnataka, Tamil Nadu, Bihar, Maharashtra, Madhya Pradesh, Uttar Pradesh, Delhi, and Rajasthan. Homeopahy is more widely practiced in Uttar Pradesh, Kerala, West Bengal, Orissa, Andhra Pradesh, Maharashtra, Punjab, Tamil Nadu, Bihar, Gujarat, and the North-Eastern states.
2.4.9. The potential of Indian Systems of Medicine (ISM)

With its vast infrastructure and cultural acceptance it would be logical to expect Indian System of Medicine (ISM) to play a major role in Indian health care. But contrary to expectations recent surveys seem to point towards a complete dominance of allopathy, with over 90 per cent of illness episodes being treated with that system. These surveys also indicate that practitioners of Indian Systems of Medicine (ISM) are increasingly resorting to treatment of their patients with allopathic drugs.

All the same, the fact remains that Indian Systems of Medicine (ISM) systems can make a major contribution to health care in the following areas:

- In the changing demographics and epidemiological scenario, longevity has increased, and people are more vulnerable to chronic ailments requiring long-term and expensive therapies unaffordable in poor country.

- More important, the epidemiological transition has increased the burden of National Council on Disability (NCDs), which has major cost implications in poor country.

- With their vast infrastructure and outreach, Indian Systems of Medicine (ISM) could make a significant contribution to public health programmes and supplement health care facilities, particularly in under-served areas.

- The rich range of remedies in Indian Systems of Medicine (ISM) could provide leads to the discovery of safer and more effective drugs to support the human battle against disease.

- Indian Systems of Medicine (ISM) could provide a growing market for export with the rising demand for Complementary Alternative Medicine (CAM) in the industrialized world.
2.4.10. Neglect of Indian Systems of Medicine (ISM) in India

We are far from realizing the potential benefits of Indian Systems of Medicine (ISM) given the centuries of its neglect in the country. With the advent of British rule, the indigenous systems lost official patronage and support: the colonial masters considered these systems unscientific and unreliable. Following the example of their masters, the Indian elite shifted to modern medicine and, consequently, Indian Systems of Medicine (ISM) suffered a major setback with both the state and affluent clients withdrawing their support. The result was an unequal competition between modern medicine and Indian Systems of Medicine (ISM).

There was some recognition of the potential of Indian Systems of Medicine (ISM) after Independence, but very little was done by way of follow-up. An institutional framework was indeed established, to standardize education and drugs and to promote research, but inadequate attention by policy makers and insufficient financial support made these initiatives largely ineffective.

2.4.11. Alternative Medicine in Industrialized Countries

The second half of the nineteenth century saw the beginnings of a technological revolution in modern medicine, with the germ theory of disease contributed by the work of Pasteur and Koch, followed by the establishment of the microbial origins of infections.

As a parallel stream, the development of vaccines, beginning with Jenner’s first vaccination two centuries ago, brought down child mortality significantly. This, coupled with advances in surgery, seemed to promise that modern medicine had answers to all health problems. Naturally, nobody thought it was worthwhile to look at traditional medicine, since it was not
validated by modern science. As a result, most traditional medicine was clubbed with quackery.

Attitudes, however, began to change with the shift in the disease profile, and with the realization of the limitations of modern medicine. With an aging population, the burden of disease shifted to chronic constitutional problems, for which there were, as yet, no solutions in modern medicine.

2.4.12. The Impact of Western Interest on India

Since the West finds Indian’s treasure of traditional remedies interesting, the Indian elite has also begun to perceive these remedies as valuable. This is most welcome, to the extent that this perception encourages support from the government and others to the realization of the true potential of Indian Systems of Medicine (ISM). This also means new commercial opportunities but it presents, at the same time, some new challenges. First, the tendency of Western commercial interest to patent traditional knowledge to enjoy monopoly rights needs to be effectively countered. Second, the rising demand for herbal products could lead to over-exploitation of scarce species, consequently endangering their existence and availability.

2.4.13. Creation of Separate Department for Indian Systems of Medicine (ISM)

The creation of a separate department in the ministry of health and family welfare in 1995, in response to along pending demand, seems to have given new visibility and importance to Indian Systems of Medicine (ISM). This is reflected in a major step-up in financial allocations. The plan allocations for the department of Indian Systems of Medicine (ISM) have increased from merely Rs. 40 lakhs in the first plan period 1951-55 top Rs 386 crore in the ninth plan period 1997-2002. The increasing importance given to
Indian Systems of Medicine (ISM) can be gauged from the fact that plan allocation more than doubled between the seventh (1985-90) and eighth plan (1992-97) periods from Rs 129 crore to Rs 382 crore.

2.4.14. Major Challenges

2.4.14.a. Failure to Concentrate on Identified Strengths

One of the major weaknesses of Indian Systems of Medicine (ISM) arises from its failure to concentrate in its strengths, and in trying to dabble in areas where it lacks a comparative advantage. Indian Systems of Medicine (ISM) must clearly identify its strengths and limitations, and concentrate on developing the former. This would lead to better targeting of resources and concentration of both research and training on their areas of specialization.

2.4.14.b. Integration

There has been a great deal of debate on the question of integration of all systems on the Chinese model, but very little progress has been made. The disadvantages of uncoordinated development of parallel streams are obvious. The large manpower and institutional resources of Indian Systems of Medicine (ISM) are completely divorced from public health activities, which is huge waste in a poor country. On the other hand, even where Indian Systems of Medicine (ISM) remedies are potent and cost-effective, they are not being used in the health care institutions supported by public funds.

Several alternatives have been suggested. Some scholars have advocated complete integration on the Chinese model, with a common course of medical education and a common pharmacopoeia, with the most cost-effective remedies of Indian Systems of Medicine (ISM) being incorporated as first choice treatments in modern medicine.
The modern medicine professionals are also not enthusiastic about Indian Systems of Medicine (ISM) being made a part of the Bachelor of Medicine/ Bachelor of Surgery (MBBS) curriculum. They feel this would take away precious time from the more pressing requirements of teaching modern medicine, which has to enlarge its scope to accommodate expanding scientific horizons and new disease.

Apart from all this, synthesis requires the right climate to evolve. All public pronouncements but health must aim at convincing people of the need to evolve a national system that would bring together the best in all systems. Broadly, such a synthesis would involve the following steps:

- The curriculum in each stream should familiarize students with the basic principles and important remedies in the other.

- An intensive effort must be launched to evaluate, by modern scientific methods, the well known remedies of Indian Systems of Medicine (ISM) and incorporate those that show a comparative advantage in essential drug lists and treatment protocols for public medical institutions.

- All Indian Systems of Medicine (ISM) practitioners in public institutions should be given short courses to enable them to participate in major public health programmes such as control of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS), Tuberculosis (TB), malaria, Asia Research Institute (ARI), and diarrhoeal diseases.

- While the streams may continue on their parallel courses, their need to be strong cross representation on educational and research bodies from both sides.
2.4.14.c. Research

Under the chairmanship of the minister for the health and family welfare, are mandated to promote and oversee research in their respective fields. Although clinical research has also been pursued for the last fifty years, half-heartedly, the results do not command creditability due to an absence of scientific rigour and application. All remedies to be incorporated in the public health care system need to be scientifically evaluated on the basis of accepted principles of research.

There is another aspect of Indian Systems of Medicine (ISM) research that deserves specific mention. Based on Indian Systems of Medicine (ISM) texts, some attempts have been made in the past to isolate the active principle of herbs for purposes of new drug development.

One major issue in Indian Systems of Medicine (ISM) is the standardization of education, and this has been engaging government attention for several decades. The Central Council of Indian Medicine (CCIM), constituted in 1970, is the statutory authority for laying down standards for ayurveda, siddha, and unani, while this function is discharged by the Central Council for Homeopathy (CCCH) for homeopathic institutions.

2.4.14.d. Standardization of Drugs

The standardization of Indian Systems of Medicine (ISM) drugs is a matter of even greater complexity. With hundreds of texts and the varying interpretations and diverse treatment modules followed by hereditary practitioners, the development of the pharmacopoeias is indeed a daunting exercise.
2.4.14.e. Medicinal Plants

The growing commercial interest in Indian Systems of Medicine (ISM) remedies the world over has raised concerns about over-exploitation of natural herbal resources. According to report of the Export Import Bank of India (1997), the value of the trade related to medicinal plants in India is of the order of $5.5 million, and growing rapidly. Forests have traditionally been the source of medicinal herbs and plants, but now these herbs are threatened in two ways: first, the forest cover is fast shrinking; and second the demand for these products has been rising sharply. In the absence of timely action, certain species are in danger of becoming extinct. The ministry of environment has already recommended a ban on the use of twenty-nine endangered species of medicinal plants.

2.4.14.f. Patents

The increased commercial interest in herbal products, coupled with the introduction of the World Trade Organization (WTO) mandated Intellectual Property Rights (IPR) regime, has led to many well-known medicinal uses of plants being patented abroad. This point to the need for vigilance, and for contesting these patents in appropriate Courts.

Indian Systems of Medicine (ISM) has to make up for centuries of neglect. Besides strengthening the infrastructure, some major initiatives must be taken to promote the synthesis of different systems, and to encourage the scientific evaluation of traditional remedies. Above all, a change of mindset is required to make Indian Systems of Medicine (ISM) modern and forward looking in outlook without loosening its traditional roots. The new slogan for Indian Systems of Medicine (ISM) should be ‘tradition with modernity’.
2.5. NATIONAL RURAL HEALTH MISSION- THE VISION

- The National Rural Health Mission (2005-12) seeks to provide effective healthcare to rural population throughout the country with special focus on 18 states, which have weak public health indicators and/or weak infrastructure.

- These 18 States are Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Himachal Pradesh, Jharkhand, Jammu and Kashmir, Manipur, Mizoram, Meghalaya, Madhya Pradesh, Nagaland, Orissa, Rajasthan, Sikkim, Tripura, Uttaranchal and Uttar Pradesh.

- The Mission is an articulation of the commitment of the Government to rise public spending on Health from 0.9 per cent of Gross Domestic Product (GDP) to 2-3 per cent of Gross Domestic Product (GDP).

- It aims to undertake architectural correction of the health system to enable it to effectively handle increased allocations as promised under the National Common Minimum Programme and promote policies that strengthen public health management and service delivery in the country.

- It has as its key components provision of a female health activist in each village; a village health plan prepared through a local team headed by the Health and sanitation Committee of the Panchayat; strengthening of the rural hospital for effective curative care and made measurable and accountable to the community through Indian Public Health Standards (IPHS); and integration of vertical Health and Family Welfare Programmes and Funds for optimal utilization of funds and infrastructure and strengthening delivery of primary healthcare.
• It seeks to revitalize local health traditions and mainstream Ayurveda, Yoga, Unani, Siddha, and Homeopathy (AYUSH) into the public health system.

• It aims at effective integration of health concerns with determinants of health like sanitation and hygiene, nutrition, and safe drinking water through a District Plan for Health.

• It seeks decentralization of programmes for district management of health.

• It seeks to address the inter-State and inter-district disparities, especially among the 18 high focus States, including unmet needs for public health infrastructure.

• It shall define time-bound goals and report publicly on their progress.

• It seeks to improve access of rural people, especially poor women and children, to equitable, affordable, accountable and effective primary healthcare.

2.5.1. Goals

• Reduction in Infant Mortality Rate (IMR) and Maternal Mortality Ratio (MMR)

• Universal access to public health services such as Women’s health, child health, water, sanitation and hygiene, immunization, and Nutrition.

• Prevention and control of communicable and non-communicable diseases, including locally endemic diseases

• Access to integrated comprehensive primary healthcare.

• Population stabilization, gender and demographic balance.
• Revitalize local health traditions and mainstream Ayurveda, Yoga, Unani, Siddha, and Homeopathy (AYUSH)

• Promotion of healthy life styles.

2.6. HEALTH INDICATORS

• Tuberculosis and malaria cases

• Disability (in seeing, in speech, in hearing, in movement and mental)

• Antenatal checkup, availing two Tetanus Toxoid (TT), received International Fiscal Association (IFA) received full antenatal care

• Home delivery and safe delivery

• Complication during pregnancy and post delivery and treatment sought

• Breast feeding

• Diarrhoea and pneumonia

• Acquired Immune Deficiency Syndrome (AIDS) cases Human Immunodeficiency Virus (HIV) Sero-positive (per cent) in Ante-Natal Care (ANC) attendees

• Human Immunodeficiency Virus (HIV) Positive percentage at Prevention of Parent to Child Transmission (PPTCT) Centres 2004

• Human Immunodeficiency Virus (HIV) infection prevalence (per cent) in Sexually transmitted Diseases (STD) for years 2002 to 2005

• Full vaccination

• Nutritional status of children (0-36 months)

• Adolescent anemia

• Population per bed ratio and population per doctor ratio
Awareness about Respiratory Tract Infection/Sexually Transmitted Infection (RTI/STI) and Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) Respiratory Tract Infection/Sexually Transmitted Infection (RTI/STI) symptom experienced Nutrition centers and beneficiaries of Integrated Child Development Services (ICDS) Institutions functioning under Family Welfare Programme.

2.7. DRUG POLICY AND REGULATIONS

The aspects of drug policy that directly impact healthcare. Only the following aspects have been specifically addressed:

- World Trade Organization (WTO) mandated Intellectual Property Rights (IPR) regime and its impact on the availability and prices of drugs.
- Price controls, their impact, and relevance;
- Drug control regulations and their enforcement;
- Institutional infrastructure for quality control; and
- Rational use of drugs.

2.7.1. Pharmaceutical Industry in India

Though the World Trade Organization (WTO) mandated legislation to recognize product will be brought into force only in the year 2005, the pharmaceutical industry is already feeling the impact of globalization. Indian companies such as Dr. Reddy’s Laboratories, Ranbaxy, Wockhardt, Sun Pharmaceuticals and Cipla have begun making significant investments in product research in anticipation of the new Intellectual Property Rights (IPR) regime. Multinational companies (MNCs), such as Pfizer, Glaxo, and Smith Kline Beecham, are making aggressive plans to introduce their latest drugs in the Indian market.
The global trends mergers and acquisitions, and high investment in Research and Development (R&D) with an increasing role for new technologies such as biotechnology, genomics, and combinatorial chemistry are also likely to exert considerable influence on Indian industry. The smaller companies, unable to keep pace with newer technologies, may be bought over by larger or utilized for contract manufacturing.

2.8. GOVERNMENT SUBSIDY SCHEME FOR MEDIUM SIZED PHARMACEUTICAL COMPANY

Under another programme for the small scale sector, known as the credit linked capital subsidy scheme, the department of pharmaceuticals and the department of micro, small and medium enterprises are offering 15 per cent capital subsidy assistance for projects worth up to Rs.1 crore.

2.9. POLICIES REGARDING FOREIGN DIRECT INVESTMENT (FDI) IN THE PHARMACEUTICAL SECTOR

The foreign pharmaceutical firms in India have met a restrictive environment. There used to be performance requirements for the foreign firms investing in the Indian pharmaceutical industry, in order to create linkages between foreign and domestic firms.

2.10. IMPACT OF TRIPS

The agreement on Trade Related Aspects of Intellectual Rights (TRIPS) came into force with the formation of the World Trade Organization (WTO) in January 1995. Trade Related Aspects of Intellectual Rights (TRIPS) require all developing countries to provide a twenty-year patent protection for novel, non-obvious, and useful inventions, whether products or processes, in all fields of technology including pharmaceuticals. India had till recently recognized only process patents in pharmaceuticals; legislation for
compliance with World Trade Organization (WTO) obligations has only recently been passed in Parliament. India should now actively explore ways in which the advantages the new regime can be maximized and disadvantages minimized.

Product patents compromise a highly imperfect instrument to provide incentives for new drug discoveries, which are very expensive, risky and time consuming. Comanor estimated that the process of introducing a successful new product in the United States (US) can take as many as ten or more years and cost more than $250 million. Product patents limit competition, grant monopoly power, and encourage high prices.

In this formative year, the Indian Pharmaceutical industries took full advantage of the absence of product patents due to its technological strengths. Through the process of reverse engineering, it was able to provide new drugs introduced in the industrialized countries into the Indian consumer with a time lag of only 5-10 years and at a fraction of their cost.

Having enjoyed the benefit of new drugs at affordable cost in the old regime, the impact of Trade Related Aspects of Intellectual Rights (TRIPS) on the price of new patented drugs is bound to be significant in India but some mitigating features are likely to moderate this impact.

- Skills in reverse engineering will still be useful in producing generics for drugs going off patents and in cases of compulsory licensing.
- Most life-saving drugs are off patents, and there should be little impact on their prices in the new regime.
- In most cases, the monopoly power of patented drugs is contained by competition from other medicines that treat the same condition.
- All new patented medicine need not provide significant therapeutic gains.
United States Food and Drug Administration (USFDA) divides new
drugs into three categories: A (significant), B (moderate) C (of little or no
therapeutic gain). The prices also vary significantly for each category.

The policy options to the government to minimize the adverse impact
of Trade Related Aspects of Intellectual Rights (TRIPS).

The first option is to have the entire Trade Related Aspects of
Intellectual Rights (TRIPS) regime reviewed by the World Trade Organization
(WTO).

The other options within the four corners of the existing Trade Related
Aspects of Intellectual Rights (TRIPS) regime are compulsory licensing and
parallel trade. The latter attracted considerable attention, consequent to the
judicial challenge by multinationals to the parallel importation of anti-
retroviral for Acquired Immune Deficiency Syndrome (AIDS) patients by
South Africa, from middle-income countries such as Spain and Portugal.

Two basic preconditions for compulsory licensing:

- The prospective license is unable to obtain, within a reasonable
  period of time, authorization from the patent holder to use the
  patented innovation on reasonable commercial terms and
  conditions.
- Compulsory license must be predominantly for the supply of the
  domestic market of the authorizing nation and its user must pay to
  the patent holder adequate remuneration taking into account the
  economic value of the authorization.

It is apparent that the right to compulsory licensing is heavily
circumscribed, and that the rather vague formulation of relevant articles
could mean varying interpretations and conclusions.
The Declaration on the Trade Related Aspects of Intellectual Rights (TRIPS) Agreement and Public Health adopted at the Ministerial Conference at Doha on 14 November 2001 is a major landmark towards recognition by the international community of the need to reconcile the demands of intellectual property protection with the urgent and growing requirement of poor countries for new tools to fight diseases impacting public health.

First, it unambiguously establishes the right of every nation to use the compulsory licensing mechanism flexibly to protect public health of its citizens. Second, it explicitly recognizes that compulsory licensing facility may not be helpful for countries having a weak pharmaceutical industry and enjoins on the World Trade Organization (WTO) to find a way out for them by the end of 2002. Finally, it extends the deadline for product patents under Trade Related Aspects of Intellectual Rights (TRIPS) agreement for the least developed countries from 2006 by a full decade.

2.10.1. Drug Price Control

Most countries drug prices one way or the other. In India, we have inherited a rather complex system that covered around 70 per cent of the market prior to the Drug Policy of 1994. It was administered directly by the ministry of chemicals and fertilizers on the advice of the Bureau of Industrial Costs and Prices (BICP).

The system was characterized by delays and arbitrariness, and it generated strong protests from the drug industry. The Drug Policy of 1994 simplified the system considerably and reduced its coverage to be around 50 per cent of the market.

The ‘Pharmaceutical Policy-2002’, announced on 15 February 2002, is a major step forward the rationalization and liberalization of price controls initiated with the 1990 policy. The overall coverage, estimated by the new
policy to be presently at around 40 percent, is expected to come down to 25 per cent or less after the issue of the new Drug Price Control Order. For the first time, price control has been restricted to only essential and important drugs for public health programmes as determined by the health ministry.

2.10.2. Drug Policy and Administration

The administration of drugs and pharmaceuticals is divided between the ministry of chemicals and fertilizers (MCF) and the ministry of health and family welfare (MHFW). The former is responsible for drug policy, regulation of industry, and price control, while the latter is responsible for laying down standards, quality control, introduction of new drugs, and enforcement of relevant laws and regulations.

The J.J. Hathi Committee (1975) that provided the basic policy framework for drugs for two decades till the basic policy of 1994 recognized this dichotomy. It suggested setting up of an independent National Drug Agency that would over all drug-related functions being performed by the two ministries at that time. The Drug Policy of 1994, while suggesting the setting up of a National Drug Authority (NDA), confined its role to the functions presently assigned to the Central Drug Standard Control Organizations (CDSCO) in the ministry of health and family welfare (MHFW) prescribing standards, enforcing quality control, and promoting rational drug use.

The National Drug Authority (NDA) should be the single agency with jurisdiction over all aspects of pharmaceutical industry. This will develop a long-term, holistic vision and policy. It should be supported by small cess on the manufacture and import of pharmaceuticals, access that could be conveniently collected along with excise and customs duties. Given the large
turnover of domestic production and imports, the cess could be small enough not to impose a noticeable burden on either the industry or the consumer.

2.11. NATIONAL DRUG POLICY

The Drug Policy of 1986, which was titled "Measures for Rationalisation, Quality Control and Growth of Drugs and Pharmaceuticals industry in India" was evolved under the dynamic guidance and leadership of late Shri Rajiv Gandhi. This was done after a detailed examination of the various issues. The main objectives of the Drug Policy, 1986 are as under:

a. ensuring abundant availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality;

b. strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;

c. creating an environment conducive to channelising new investment into the pharmaceutical industry to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs; and,

d. strengthening the indigenous capability for production of drugs.

2.11.1. The Regulatory System for Drugs

The constitution of India places drugs and cosmetics in the Concurrent List which allows jurisdiction to both the centre and the states on this subject. In the case of drug regulation and enforcement, we would advocate a stronger central role for three reasons:
• A substandard/spurious drug manufactured in one state can be sold and consumed in all parts of the country. Hence enforcement of quality standards cannot be left to the mercy of individual states.

• The states are unlikely to find adequate resources for investment in laboratories and infrastructure for enforcement of drug loss without central help.

• The state would not be able to provide, at their level, the expertise required to lay down and monitoring standards of drugs, or to determine the rationality of new drug combinations.

The import, manufacture, distribution, and sale of drugs and cosmetics in India are regulated by Drugs and Cosmetics Act of 1940. The Act specified that the Central Government is responsible for the constitution and functioning of the Drugs Technical Advisory Board, which advises the Drugs Controller General (DCG) all the technical matters, and the Drugs Consultative Committee, which is the institutional mechanism for Centre-State coordination. The Central Government has the power, in consultation with the Drugs Technical Advisory Board, to make rules and specify the different types of offences in relation to import of drugs. The responsibility of the state governments, as regard as the manufacture, distribution, or sale of drugs.

The prevailing system has led to a chaotic situation with nearly 50,000 to 60,000 drugs licensed to be marketed in India. The central government, realizing the consequences of indiscriminate licensing of drugs provided, by an amendment in the Rules, for joint responsibility for the licensing vaccines.

Even otherwise, the Drugs and Cosmetics Act 1940 has become outdated and needs to be replaced with a new law that takes into account
changed circumstances as well as the need for an enhanced role for the central government.

The Central Drug Standard Control Organization (CDSCO) is the designated organization Centre to administer the Drugs and Cosmetics Act, 1940. The main functions of Central Drug Standard Control Organization (CDSCO) include the quality control of imported drugs, the coordination of the activities of the state drug control authorities, the approval of new drugs proposed for import into or manufacture in the country, the laying down of regulatory measures and standards of drugs; and acting as the license approving authority for blood and blood products, large volume parenterals, sera and vaccines.

The state drug controllers bear the responsibility for ensuring that pharmaceutical manufacturers are following good Manufacturing Practices (GMP). By and large, the states have neither organization nor the inclination to enforce these standards, and their performance, as in most health-related matters is extremely uneven. As result, the market is full of sub-standards spurious drugs playing havoc with people’s health.

The licensing of chemist is also the responsibility of the state drug controllers. Each chemist is supposed to employ a qualified pharmacist, but this requirement is rarely met.

2.12. PATENTS OF PHARMACEUTICAL INDUSTRY IN INDIA

As it expands its core business, the industry is being forced to adapt its business model to recent changes in the operating environment. The first and most significant change was the January 1, 2005 enactment of an amendment to India’s patent law that reinstated product patents for the first time since 1972. The legislation took effect on the deadline set by the World Trade Organization (WTO’s) Trade-Related Aspects of Intellectual Property Rights
(TRIPS) agreement, which mandated patent protection on both products and processes for a period of 20 years. Under this new law, India will be forced to recognize not only new patents but also any patents filed after January 1, 1995. Indian companies achieved their status in the domestic market by breaking these product patents, and it is estimated that within the next few years, they will lose $650 million of the local generics market to patent-holders.

In the domestic market, this new patent legislation has resulted in fairly clear segmentation. The multinationals narrowed their focus onto high-end patients who make up only 12 per cent of the market, taking advantage of their newly bestowed patent protection. Meanwhile, Indian firms have chosen to take their existing product portfolios and target semi-urban and rural populations.

2.13. INDIA IN PATENTS REGIME IN PHARMACEUTICAL INDUSTRY

Trade-Related Aspects of Intellectual Property Rights (TRIPS), the intellectual property component of the Uruguay round of the General Agreement on Tariffs and Trade (GATT) Treaty, have given rise to an acrimonious debate between the developed countries and less developed countries (LDCs). Business interests in the developed world claimed large losses from the imitation and use of their innovations in less developed countries (LDCs). They also asserted that Intellectual Property Rights (IPRs) would benefit the developing countries by encouraging foreign investment, by enabling transfer of technology and greater domestic Research and Development (R&D). On the other side, less developed countries (LDC) governments were worried about the higher prices that stronger Intellectual Property Rights (IPRs) would entail and about the harm that their introduction might cause to infant high tech industries. India was very actively involved in opposing the Trade-Related Aspects of
Intellectual Property Rights (TRIPs) component of the General Agreement on Tariffs and Trade (GATT) agreement, especially the proposal for product patents of pharmaceutical innovations. Indira Gandhi succinctly summed up the national sentiment at the World Health Assembly in 1982: "The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death." Now that India has signed the treaty, though most unwillingly, it is committed to introducing pharmaceutical product patents 2004, a value analysis i.e. cost-benefit analysis of this move is essential for India.

2.13.1. THE INDIAN PATENTS ACT 1970

This legislation implemented in 1972 made pharmaceutical product innovations, as well as those for food and agrochemicals, unpatentable in India thus greatly weakening Intellectual Property Rights (IPR) protection. It allowed innovations patented elsewhere to be freely copied and marketed in India. Therefore foreign firms did not find patenting in India worthwhile. This act further restricted import of finished formulations, imposed high tariff rates and introduced strict price control regulation with the 1970 Drugs Price Control Order. This gave a boost to the Indian pharmaceutical industry.

2.13.2. India Beyond 2004

In granting patents, there is a trade-off between the costs incurred by the country granting the patent due to monopoly pricing and the gains accruing to it due to encouragement to innovative efforts.

2.14. PATENT REGIME AND PHARMACEUTICAL INDUSTRY IN INDIA

With the nearing of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) deadline, the pharmaceutical industry in India is gearing up to
face new challenges. The product patent regime is no longer the challenge - it is a reality that the Indian pharma industry has accepted.

The new set of challenges stem from the deeper implications of the imminent product patent regime. With the exception of a few, most Indian pharma companies are unfamiliar with the nuances of complex patent prosecution strategies. The research-based pharmaceutical companies, on the other hand, have firsthand knowledge of successfully designing and implementing, sophisticated patent prosecution strategies. Therefore, the first hurdle for the Indian pharma industry is unevenness in the domain knowledge on patents. One of the ways to overcome this is to learn the use of patents as a business tool. The unrealistic defence against the global norms on patents is perhaps the most critical post Trade-Related Aspects of Intellectual Property Rights (TRIPS) challenge faced by the Indian pharmaceutical industry.


"Evergreening" or what the pharmaceutical companies often refer to as ‘life cycle –management plans’ refers to patent term extension strategies. Using the intricacies of patent prosecution procedures, pharmaceutical companies develop ‘bullet proof’ patent portfolios around million dollar drug molecules. Typically, multiple patents are secured covering a variety of inventive aspects in respect of a basic invention without attracting double patenting rejections. This plurality of patents directed at divergent inventive aspects can at times lead to the extension of patent terms, provided the national patent law allows such flexibilities.

On a rough estimate, the Mail Box contains over 5,000 patent applications filed under Section5 (2) of the Act. Therefore, these 5,000 patent
applications presumably contain claims directed at ‘substances capable of being used as food, medicine or drug’. The number of new drug molecules discovered in the last 5 years is roughly estimated at 40-45. That being the case, a certain section of Indian pharma industry argues that a majority of these patent applications are claiming secondary inventive aspects. Here again the basic question is, the extent to which, the patent statute can declare inventive aspects as unpatentable, while complying with the obligations under Article 27 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

According to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the term of protection for patent is 20 years counted from the filing date. As a patent prosecution and management strategy, ‘Evergreening’ enables patent term extension by developing a portfolio of patents around a basic invention. The child patents may be directed at any one of the various ancillary inventive aspect explained in the earlier section.

Adding new claims to a basic patent disclosure is permissible in certain jurisdictions. This is achieved by the effective use of patent prosecution routes including continuation patent application, divisional patent application, continuation-in-part patent application, and application for patent of addition. It is also possible to build on chains of priority from a basic patent disclosure to preserve novelty. The limitations or restrictions in the criteria of patentability and the exclusions of certain subject matters from the scope of patentability can impose serious limitations on patent prosecution strategies aimed at ‘Evergreening’.

A number of fundamental issues come in sharp interplay when structuring patent prosecution aimed at ‘Evergreening’. Unless the later applications disclose independent inventions (or inventive aspects), though linked to the invention disclosed in the basic application, the allowance of the
later applications can lead to double patenting. On the other hand, inclusion of multiple inventive aspects (consequently multiple independent claims) in a single application can lead to ‘unity of invention’ issues. In India, the Patents (Amendment) Act, 2002 brought in an amendment to Section (10) (5) introducing ‘single inventive concept’. However, the Indian patent offices are yet to start allowing multiple independent claims. Consequently, dividing out applications is considered a normal patent prosecution step. As the effective date of filing of a divisional application is the same as the date of filing of the basic application, this may not contribute to patent term extension or ‘Evergreening’.

In the absence of multiple prosecution avenues, where the applicant has the scope of working around various prosecution routes, the Indian Patents Act is rather rigid as to the time lines for priority, patent term and patentable subject matters. Hence, ‘Evergreening’ may not acquire serious dimensions in India.

While the discussion in this article is confined to the above three issues that the Indian pharmaceutical companies face in the anvil of the new Trade-Related Aspects of Intellectual Property Rights (TRIPS) compliant regime, the transition from a limited term process patent regime to the product patent regime can have several other far reaching implications. The impact of this transition will become evident in the years to come. In the meantime, the Indian pharmaceutical industry must gear up to face the challenges. Creation of a level playing ground is possible the moment the domain knowledge of patents is even among all the players in the Indian market place. To begin with, the efforts to achieve parity in knowing the rules of the game can be confined to India. But sooner or later the Indian pharmaceutical companies will have to transform into knowledge-based organizations capable of producing research-based medicine at prices affordable to the Indian people.
2.15. BIG PHARMA LICENSING STRATEGIES

As competition in the pharmaceutical market continues to grow, effective business development strategies become critical to maintain momentum and improve global market share for the leading pharma companies. As the illustrative chart in Figure 2.1 shows, an increasing proportion of revenues are expected to be generated from licensed products and as a result licensing will become an ever more important component of the overall business development mix.

Figure 2.2. Projected Pharmaceutical Industry Growth by Strategic Activity

2.15.1. Licensing Activity

Licensing activity for the Top 20 pharma companies steadily increased in the decade between 1988 and 1998, but has since started to flatten off (Figure 2.2). Indeed, recent evidence would suggest that we have started to witness a declining trend in licensing activity, in particular late-stage deal making. To a large extent this reflects the increasing cost of securing access to late-stage development candidates, with companies now shifting their focus to securing rights to products in earlier-stage clinical development where such a premium price does not have to be paid.

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As would be expected, there is a considerable difference between the extent of licensing activity across big pharma companies and the focus on early (pre-clinical to proof-of-concept) and late stage licensing activity.

Clearly, licensing strategies for big pharma companies are constantly evolving based on specific individual circumstances. Licensing activity remains a key component of the business development mix at the vast majority of big pharma companies.

2.16. PRICING IN PHARMACEUTICAL INDUSTRY

The price of pharmaceuticals has become a highly volatile issue, particularly in the United States where many consumers, over the past few years, have been alarmed to find that the prices of drugs, manufactured largely by United States (U.S) companies, are consistently higher in the United States (U.S) than in other industrialized countries. Shareholders of a
number of pharmaceutical companies have developed resolutions that would reign in drug prices for retail customers.

Recent studies found that eight antidepressants and anti-psychotic drugs cost, on average, twice as much in the United States (U.S) as in Canada or the European Union. The high prices of prescription drugs hit the elderly and underinsured hardest, due to a pricing structure that favours large health management organizations and government agencies.

Religious institutional shareholders, including religious-based healthcare providers, sponsored shareholder resolutions with ten companies for this proxy season concerning their drug pricing policies. The coalition is administered by the Interfaith Center on Corporate Responsibility (ICCR), a shareholder advocacy organization of 275 religious and other institutions representing $100 billion in assets.

Concern about the high price of prescriptions for those who are uninsured or under-insured are what inspired the Interfaith Center on Corporate Responsibility (ICCR) to support these resolutions, as it was widely publicized that people were having to choose between food or other necessities and needed drugs.

This is not the first time drug companies have been challenged for their pricing policies, but it has been a few years since the last attempts, between 1993 and 1995. A handful of resolutions came to a vote, such as with Upjohn and Johnson and Johnson, but most of them were withdrawn when the shareholders were satisfied with concessions from the companies.

Unfortunately, shareholders are no longer appearing to be satisfied with corporate attempts to placate them. With United States (U.S) spending on prescription drugs rising 12 per cent per year, more than double the 5.1
In 1994, shareholders won a major precedent when the Securities Exchange Commission (SEC) decided that drug pricing could not be omitted by the company on the grounds that it was "ordinary business." In 2000, the filers won another major victory when the Securities Exchange Commission (SEC) decided in their favour on an issue of misleading information raised by two companies.

Bristol-Meyers Squibb Co. and Warner-Lambert Co. challenged the resolutions' wording of the 12 percent rise in drug spending, citing other factors such as increased consumer activity or increased number of products that could account for the rise. But the Securities Exchange Commission (SEC) allowed the resolutions to stand, contingent on minor changes in the text, bolstering the legitimacy of the issues in them.

Several of the drug pricing resolutions are part of an ongoing dialogue between shareholders and company management at many large pharma companies. None of these companies has shown to be positioned to make concessions on the shareholders requests, although some of them cited their patient assistance programmes and the management of Merck at least agreed that there was a problem.

In 2000, shareholders withdrew their drug pricing resolution with Pfizer, due to demonstrated moderation in price changes and a public forum on their commitment to fair pricing policy. The company indicated an average price increase of 2.5 per cent for 2000, and subsequent years have also been relatively low.

The renewed attention to unfair drug pricing policy is a fitting subject for socially responsible shareholder advocacy, and a significant step toward a
more humane society. It remains to be seen how broad shareholder support is on the issue verses their financial interests.

2.17. A Rational Drug Policy

Pharmaceutical companies have an important place in medical care, especially in India, a country where the mortality and morbidity due to various diseases of deprivation, communicable diseases in particular, are very high. Every year hundreds of people still die from malaria for which chloroquine is a cheap but effective remedy; thousands go blind due to lack of vitamin A, and millions suffer from endemic goitre due to iodine deficiency. We have also the largest number of people suffering from tuberculosis and leprosy in the world. At the same time, India is technologically developed enough to be self-reliant, with research capability for the discovery of new drugs. Unlike most other countries, responsibility for the pharmaceutical sector in India is shared by two ministries, the Department of Chemicals and Petrochemicals under the Ministry of Industry and the Directorate of Drugs Control under the Ministry of Health and Family Welfare.

2.17.1. Development of the Drug Industry in India

The foundation of the modern Indian pharmaceutical industry dates back to 1901 when the Bengal Chemical and Pharmaceutical Works were established in Calcutta (now Kolkata). However, till Independence, the country was dependent largely on drugs imported from Europe. After Independence, pharmaceutical manufacturers in India were encouraged to take up the manufacturing of basic drugs. Collaborations were established with manufacturers in the United States (US), Switzerland, (West) Germany, Italy and the United Kingdom (UK). During the 1950s and 1960s many manufacturing units were set up throughout India. The Soviet Union helped set up five units for manufacturing synthetic bulk drugs and intermediate
chemicals, antibiotics, vitamins and hormones, surgical instruments and medical equipment under the public sector.

Today, in India, about 20,000 firms have licences to produce drugs and pharmaceuticals. Of these, about 200 units are responsible for over 40 per cent of total drug production. Over the past few decades, the Indian drug industry has seen phenomenal growth and emerged as an exporter. It is estimated that the Indian drug market, at present, is worth more than Rs 100000 million.

2.17.2. A Drug Policy

The first national drug policy emerged from the findings of the Hathi Committee which was commissioned to study the operations of multinational drug companies indigenous companies and public sector undertakings. The committee’s recommendations, released in 1975, included: nationalisation of multinational units, diluting foreign equities of companies coming under the Foreign Equity Regulations Act; earmarking some drugs for public sector undertakings; strengthening Research and Development (R&D) activities; abolishing brand name drugs; issuing licences for formulations of only 117 drugs which the committee considered sufficient for the treatment of the majority of diseases in India; measures for drug quality control; disseminating unbiased drug information to prescribers and consumers; monitoring of adverse drug reactions, etc. However, the Hathi Committee also recommended differential mark-ups for essential and non-essential drugs. This recommendation had a lasting undesirable impact.

According to the World Health Organization (WHO), a national drug policy should be based on relevant background information including the country’s morbidity, mortality, health system, human resources, and the organisation of the drug sector. A (rational) national drug policy should include: a list of essential drugs; use of generic names of drugs; criteria for
drug registration based on safety, efficacy, quality, health needs and cost; regulation, control and monitoring of drug prices and drug promotion; centralised bulk purchase of drugs using international tenders (for countries lacking manufacturing facilities), and national legislation on patents to exclude pharmaceutical products from patent protection.

2.17.3. The 1978 Drug Policy

In 1978, the Government of India declared a drug policy supposedly based on the Hathi Committee report. However, the government diluted some of the Committee's recommendations and rejected others. This was soon followed by the declaration of the Drug Prices Control Order (DPCO, 1979) which brought 347 drugs under price control, dividing them into four categories according to how essential they were deemed to be, allowing maximum profit margins to the least essential drugs. The idea was that the lower profit margins from life-saving and essential drugs (Categories I and II) would be compensated for by the higher margins for Categories III and IV drugs. However, the result was that drug companies decreased and even stopped the production of life-saving and essential drugs and concentrated on the more profitable ones.

2.17.4. Drug Policies 1986 and After

Some stated goals of the 1986 Drug Policy were to ensure availability of essential life-saving and prophylactic medicines at reasonable prices; strengthen quality control and promote the rational use of drugs; encourage investment in new technologies and cost-effective production; and strengthen the indigenous capacity for production of drugs. The 1987 Drug (Prices Control) Order reduced the number of price control drugs from 347 to 142 and increased the maximum profit margins for these drugs. Special concessions to ayurvedic drugs resulted in thousands of such formulations,
with some well-known allopathic formulations being marketed as ayurvedic drugs. The 1995 Drug Prices Control Order (DPCO) dropped the following drugs essential for public health: ferrous sulphate for anaemia, and most drugs for tuberculosis, malaria, leprosy, rheumatic heart disease, rabies vaccine, cancer, tetanus, etc.

The pharmaceutical policy (2002) calls for further relaxation of production and price controls. Production controls have now mostly gone except for bulk drugs produced by the use of recombinant Deoxyribo Nucleic Acid (DNA) technology, bulk drugs requiring in vivo use of nucleic acids, and specific cell/tissue targeted formulations. It is expected that less than 40 drugs will remain under price control.

2.17.5. The Results

In the absence of a clear, comprehensive and rational drug policy, we continue to see a distorted pattern of drug production and the proliferation of non-essential, irrational and harmful drugs. Indian markets are flooded with over 1,00,000 formulations; there is no system of central registration of these formulations. These drugs are sold under numerous brand names rather than their generic names. There has also been a phenomenal increase in drug prices.

Despite the phenomenal growth of the drug industry during the past five decades, the availability of modern drugs is still low. For example, in 1984 only 5 per cent 6 per cent of the population could afford the modern drugs they needed; another 25 per cent had limited access to essential drugs. A majority of the people living in rural areas and urban slums, the main victims of endemic and epidemic diseases, had little or no access to modern drugs. With the predicted increase in the cost of drugs after joining the World Trade Organization (WTO), the problems are likely to go out of control.
Since 1983, the government has issued various orders banning several harmful and or useless formulations marketed in India, but too little effect. Drug and health activist organisations, under the auspices of the All India Drug Action Network (AIDAN), went to the Supreme Court demanding implementation of the ban. Some constituent bodies publish drug information bulletins for prescribers. In general, representatives of pharmaceutical companies are the only source of information to prescribers in remote areas. The government has taken little initiative to fulfil its statutory function to monitor manufacturers promotional literature and has taken no steps to supply objective and unbiased drug information to prescribers.

Drug and health activist organisations have recently intervened in a petition challenging the government’s recent move to further curtail the number of drugs under price control. At the heart of these efforts is the principle of entitlement. Neither the Constitution nor the National Health Policy guarantees the right to health or to medical care including affordable and appropriate drugs. The community of health professionals must recognise this right and help people exercise it.

The Mashelkar Committee, which studied the various aspects of the growing threat from spurious drugs, submits an interim report recommending stringent punishment for offenders.

The Indian pharmaceutical industry has a domestic turnover of more than Rs.20,000 crores and exports over Rs.10,000 crores. It is also growing at the rate of over 10 per cent for the last decade and is said to be the fourth in the world in terms of volume. But a consumer has good reasons to be concerned about the lack of availability of safe and genuine medicines. For, the problem of spurious and substandard drugs in the country is quite rampant, as is evident from periodic reports in the media on seizures and confiscation of fake drugs from large consignments or godowns. These,
however, would constitute only a small fraction of the real extent of the illegal activity, which perhaps is no different from the extent of counterfeit trade in other commercial products.

2.18. R.A. MASHELKAR, CHAIRMAN OF THE COMMITTEE ON DRUG REGULATORY SYSTEM.

Monitoring of, and control over, pharmaceuticals, however, ought to be much more stringent since it concerns the health of the citizens and the harm that spurious drugs can cause is far more serious than that caused by any other consumable good. There have been the usual platitudes in the drug policies announced over the years. Members of Parliament too do not fail to make their customary quota of appropriate noises in the House. But beyond these there have been no concrete enforcement measures or regulatory mechanisms to bring about a change in the ground reality. The current status of the regulatory apparatus in the country.

One would recall the serious case of Intravenous (IV) fluid contamination at J.J. Hospital, Mumbai, in 1988-89 and the famous Lentin Commission Report on the incident. The commission had made pertinent observations, and recommended appropriate changes in the drug regulatory system. The result was an amendment to the rules to provide for a dual licensing mechanism in December 1992, with a Central Licence Approving Authority (CLAA) and the States being the licence issuing authorities. The idea was to implement uniform norms but the change has not had the desired impact. Indeed, a repeat of the incident was witnessed in Delhi about four years later but there was no perceptible action by the government to improve the monitoring, testing and control system.

More recently, the Supreme Court and the National Human Rights Commission too have expressed their concern about improving the drug
regulatory system. In response to this growing concern, the Central government constituted, on January 27, an expert committee under the chairmanship of R. A. Mashelkar, Director-General of the Council for Scientific and Industrial Research (CSIR), to examine all aspects of the regulatory infrastructure. The committee was also required to evaluate the extent and problem of spurious and substandard drugs in the country. Its mandate was to suggest a road map for implementation of the recommended measures.

The Committee had as its members an eminent scientist, an eminent lawyer, a former Drugs Controller-General of India (DCGI) and a former police commissioner, and officials representing key Central and State Departments/Ministries, drug manufacturers, trade, consumer and professional associations. The present Drugs Controller-General of India (DCGI) was its member-secretary. Two sub-committees looked at specific and distinct terms of reference of the main committee. The deliberations had the benefit of presentations by scientists, such as Nityanand, Ranjit Roy Choudhary and Anant Narayana, and representatives of the Indian Medical Association (IMA), the Delhi Pharmaceutical Trust, Ahmadabad-based Consumer Education and Research Centre (CERC) and the Confederation of Indian Industry (CII). The core issues, the report said, have remained unresolved despite the numerous recommendations made by committees constituted by the government from time to time, which have been implemented partially. The Drugs and Cosmetics Act (D&CA) of 1940, it observed, had not been reviewed in a comprehensive manner at all since its enactment. The Hathi Committee Report of 1975, for example, had recommended measures to strengthen and streamline the Central and State Drug Control Organisations. While the Centre has implemented a few of the recommendations, the States have hardly implemented them. The committee had also called for the setting up of a National Drug Authority, a concept that
has been reiterated in different forms at different times, the latest being by the Pharmaceutical Research and Development Committee (PRDC) in 1999, but little progress has been made on that front.

Among the recommendations made by the committee, the one recommending an enhanced maximum punitive action possible for the manufacture or sale of spurious drug from life imprisonment to death penalty has attracted greater attention and media publicity. The death penalty provokes a lot of debate, and the same is likely to ensue in the case of punishment for producing and selling spurious drugs too. But, in arriving at this recommendation the committee has noted that there is a discernible trend of organised crime taking over the manufacture and sale of counterfeit and spurious medicines and that so far not a single prosecution has resulted in life imprisonment. The committee felt that only an enhanced punishment can serve as a deterrent and instill fear among offenders.

According to the report, interestingly, there is no mention of spurious drug offences in the Indian Penal Code. Also, the existing provisions are bailable and cognizable and are not in consonance with the provisions of The Drugs and Cosmetics Act (D&CA), the committee has observed. It has recommended that it be made non-bailable and cognizable and that the prosecution may be instituted by any police or Central Bureau of Investigation officer not less than the rank of a sub-inspector (instead of an inspector in the extant provision).

The case, according to the committee, should be tried by the court of the rank of a Session Judge or above whereas the extant provision provides for a trial by a metropolitan magistrate or a first class judicial magistrate or above. The committee noted that most of the cases relating to spurious drugs remained undecided for years and has suggested a separate provision for speedy trials of such offences.
The legislative provisions in different countries cited by the committee make for interesting comparison. Death penalty seems to be rare among the countries that the committee has studied. The only countries that have death sentence as punishment for the offence are Vietnam, the United Arab Emirates, Oman, Bahrain, Kuwait and Qatar. In the Indian context, the recommendation appears to be more in the nature of a substitute for an ineffective regulatory-cum-judicial system. The committee has called for amendments to The Drugs and Cosmetics Act (D&CA) incorporating these legal provisions.

Even though the menace of fake drugs has been around for decades and is widespread in the country, it is indeed startling that there is no authentic data on the extent of the problem. The Mashelkar Committee too fails to throw any light on the issue except admitting that there is no data and referring to unconfirmed media reports. It is, indeed, a telling commentary on the regulatory framework, the public health system and the law enforcement machinery of the country that there are no records of confiscations and no periodic surveys of drug manufacturers and wholesale and retail outlets conducted to get a measure of the problem. It is also surprising that industry associations, considering their economic losses, too do not have any reliable data.

"Everyone knows where counterfeit drugs are sold in Delhi, for example," says a scientist of the Delhi Science Forum, a non-governmental organisation. "Anyone can go to Baghirath Place and buy any medicine you want including empty capsules at a fraction of their actual price and no action has ever been taken." The authorities just don't want to address the problem. The reason is widespread corruption in the drug control system in the country.
According to the report, the figures quoted in the media and by different sources on the extent of spurious drugs have varied from 0.5 per cent and 35 per cent. Obviously, given the variation, the data are unreliable. The lower limit is based on the samples tested by the State authorities for the period 1995-2003. The upper limit is from a report in the medical journal Lancet in 2001 by an Indian journalist, ostensibly based on World Health Organization (WHO) figures, which had claimed that 35 per cent of world's counterfeit drugs came from India, the fake drug market of which itself was over Rs.4,000 crores (about 20 per cent of the total turnover).

World Health Organization (WHO), the report was released - clarifying that there was no study conducted by World Health Organization (WHO) that had said that 35 per cent of world's spurious drugs are produced in India. Interestingly, the World Health Organization (WHO) letter went on to add: "The Indian pharmaceutical market, with annual sales ranging between $7 billion and $8 billion, ranks third in the world, and the majority of the Indian pharmaceuticals are produced by large manufacturers according to World Health Organization (WHO) Good Manufacturing Practices (GMP)" It could be noted that these figures differ from the government's own figures.

The presentation by the Confederation of Indian Industry (CII) representative in July too was based on media reports as the organization was unable to provide any evidence for its figures. The Confederation of Indian Industry (CII) used an arbitrary fraction of 18 per cent of the turnover as being spurious and concluded that the revenue loss to the industry was over Rs.4,000 crores.

The Committee has noted that while appropriate regulatory and legislative systems exist, there is considerable non-uniformity of interpretation of the provisions of the laws, and enforcement standards followed by State drug control authorities. The Central Drugs Standards
Control Organization (CDSCO), headed by the Drugs Controller-General of India (DCGI), discharges the functions allocated to the Central government. The State Drug Control Organizations exercise the functions of the States. However, the infrastructure facilities and the number and quality of drug inspectors, testing facilities, and support systems vary from State to State.

While in some States the organization is headed by a technical person, others have administrators, police or medical persons as heads, the report points out. Only a few States have well-equipped testing laboratories, while most have no laboratory or have a small one with scant testing facilities. As per the data collected by the committee, only 15 of the 26 States surveyed have functioning testing laboratories of which only seven were reasonably well equipped and staffed.

The number of inspectors is also not sufficient to meet the work load and to monitor the quality of drugs. A government task force set up in 1982 had recommended one inspector for every 25 manufacturing units and one for every 100 sales premises. The committee has also noted that only 10 States have so far set up intelligence-cum-legal cells as recommended by the Hathi Committee.

This says the report, has the potential to lead to many inter-State complications and open up the possibilities of continuous proliferation and movement of substandard drugs. As a result, a drug manufactured in a State, with a weak regulatory mechanism is sold in another State freely as well as in the export market. A comparison of legislative provisions in other countries as given in the report shows that only in India is the subject of drugs controlled at the State level. According to the report, the Ministry of Health and Family Welfare had made proposals for the expansion of Central Drug Standard Control Organizations (CDSCO). The government, in turn, created several new posts in 1992. Apparently, these posts could not be filled due to
"administrative complexities" and have since lapsed. Efforts made to revive these posts have borne no fruit, says the report.

The 1999 Pharmaceutical Research and Development Committee (PRDC), also headed by Mashelkar, had recommended a comprehensive strengthening of the Central Drug Standard Control Organizations (CDCSO) to enable it to carry out the multifarious activities that the department was expected to perform, especially in the post-2005 World Trade Organisation - Trade-related aspects of Intellectual Property Rights (WTO-TRIPS) situation. In order to facilitate the above, it had envisaged a new structure for the Central Drug Standard Control Organizations (CDCSO). The report has observed that, although three years have elapsed since the Pharmaceutical Research and Development Committee (PRDC) recommendations, "no infrastructural improvement whatsoever in respect of manpower had occurred in the Central Drug Standard Control Organizations (CDCSO”).

The concept of a National Drug Authority, as envisaged in the Hathi Committee, did not find favour with the government and hence the first national drug policy in 1978 did not refer to a National Drug Authority. However, the concept surfaced in the 1986 Drug Policy as National Drug and Pharmaceutical Authority (NDPA) but without clear enunciation of its functions. The Drug Policy of 1994 once again called for an autonomous body by an Act of Parliament called the National Drug Authority (and not NDPA) to strengthen the drug control system and to enforce appropriate quality standards and Goods manufatureing Practices (GMPs). It was intended to perform the specific function of quality control and quality assurance with emphasis on monitoring and policing.

The Mashelkar Committee has observed that the above functions were already mandated to be carried out by Central Drug Standard Control Organizations (CDCSO) and the State Drug Controllers. The Health Ministry
too considered the proposal at various stages during 1994-2000 and drafted a bill for the creation of the Authority to be funded by levying a cess as envisaged. However, because of administrative complexities involved in such a structure, the idea was, apparently, dropped.

The 2002 Drug Policy called for setting up of a "world-class Central Drug Standard Control Organizations (CDSCO) by modernising, restructuring and reforming the existing system" rather than the National Drug Authority. The Mashelkar Committee too sent out a questionnaire to all the States seeking their views on the matter. Apparently, 15 States responded saying that if the Central Drug Standard Control Organizations (CDSCO) could perform the statutory functions efficiently, there was no need for a National Drug Authority.

Based on these considerations, the committee has concluded in the interim that, while the existing infrastructure at the Centre and in the States is not adequate to perform the assigned functions efficiently, creating an additional authority will not solve the problem. It has, therefore, recommended a strong, well-equipped and professionally managed Central Drug Standard Control Organizations (CDSCO), which could be the accorded the status of Central Drug Administration (CDA), as the most appropriate solution.

The Committee proposes to do so without basic data on the extent of the problem is not clear because the proposed survey by the Non-Government Organizations (NGO) is expected to be completed in three to four months. Also, whether a well-run Central Drug Administration (CDA) is sufficient to eradicate the menace of spurious drugs remains to be seen because the fundamental problem in all social maladies in the country is that of corruption. That needs to be tackled first; the Mashelkar Committee would
do well to recommend strong punitive action against those involved in drug-related cases of corruption.

2.19. EVOLUTION OF PHARMACEUTICAL INDUSTRY IN INDIA

The Indian pharmaceutical industry is the world's fourth-largest by volume and is likely to lead the manufacturing sector of India.

The earliest pharmaceutical companies in India are Bengal Chemicals, Pharmaceutical Works, Indian Drugs and Pharmaceutical Limited (IDPL) etc. which still exist today as one of 5 government-owned drug manufacturers. 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. However, economic liberalization in 1990s by the former Prime Minister P.V. Narasimha Rao and the then Finance Minister, Dr. Manmohan Singh 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.

India's biopharmaceutical industry clocked a 17 per cent growth with revenues of Rs.137 billion ($3 billion) in the 2009-10 financial year over the previous fiscal. Bio-pharma was the biggest contributor generating 60 percent of the industry's growth at Rs.8,829 crore, followed by bio-services at Rs.2,639 crore and bio-agri at Rs.1,936 crore.
2.19.1. Pharmaceutical Statistics

Table 2.2. Top 10 Pharmaceuticals in India as of 2010

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Revenue 2010 (Rs crore)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Ranbaxy Laboratories</td>
<td>4,198.96</td>
</tr>
<tr>
<td>II</td>
<td>Dr.Reddy’s laboratories</td>
<td>4,162.25</td>
</tr>
<tr>
<td>III</td>
<td>Cipla</td>
<td>3,763.72</td>
</tr>
<tr>
<td>IV</td>
<td>Sun Pharmceutical</td>
<td>2,463.59</td>
</tr>
<tr>
<td>V</td>
<td>Lupin Ltd</td>
<td>2,215.52</td>
</tr>
<tr>
<td>VI</td>
<td>Aurobindo Pharma</td>
<td>2,081.19</td>
</tr>
<tr>
<td>VII</td>
<td>GlaxoSmithkline</td>
<td>1,773.41</td>
</tr>
<tr>
<td>VIII</td>
<td>Cadila Healthcare</td>
<td>1,613</td>
</tr>
<tr>
<td>IX</td>
<td>Aventis Pharma</td>
<td>983.80</td>
</tr>
<tr>
<td>X</td>
<td>Ipca laboratories</td>
<td>980.44</td>
</tr>
</tbody>
</table>

Source: Pharmaceutical Industry and the needs of developing Countries

Figure No.2.4. Revenue of Top 10 pharmaceutical companies in India Year 2010

Source: Pharmaceutical Industry and the needs of developing Countries
2.19.2. Pharmaceutical Industry Today

The number of purely Indian pharma companies is fairly low. Indian pharma industry is mainly operated as well as controlled by dominant foreign companies having subsidiaries in India due to availability of cheap labour in India at lowest cost. In 2002, over 20,000 registered drug manufacturers in India sold $9 billion worth of formulations and bulk drugs. 85 per cent of these formulations were sold in India while over 60 per cent of the bulk drugs were exported, mostly to the United States and Russia. Most of the players in the market are small-to-medium enterprises; 250 of the largest companies control 70 per cent of the Indian market. Thanks to the 1970 Patent Act, multinationals represent only 35 per cent of the market, down from 70 per cent thirty years ago.

In terms of the global market, India currently holds a modest 1-2 per cent share, but it has been growing at approximately 10 per cent per year. India gained its foothold on the global scene with its innovatively engineered generic drugs and Active Pharmaceutical Ingredients (API), and it is now seeking to become a major player in outsourced clinical research as well as contract manufacturing and research.

2.19.3. Patents

As it expands its core business, the industry is being forced to adapt its business model to recent changes in the operating environment. The first and most significant change was the January 1, 2005 enactment of an amendment to India’s patent law that reinstated product patents for the first time since 1972. The legislation took effect on the deadline set by the World Trade Organization (WTO’s) Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which mandated patent protection on both products and processes for a period of 20 years.
Under this new law, India will be forced to recognize not only new patents but also any patents filed after January 1, 1995. Indian companies achieved their status in the domestic market by breaking these product patents, and it is estimated that within the next few years, they will lose $650 million of the local generics market to patent-holders.

2.19.4. Product Development

Indian companies are also starting to adapt their product development processes to the new environment. For years, firms have made their ways into the global market by researching generic competitors to patented drugs and following up with litigation to challenge the patent. This approach remains untouched by the new patent regime and looks to increase in the future. Local firms have slowly been investing more money into their Research and Development (R&D) programmes or have formed alliances to tap into these opportunities.

2.19.5 Challenges

All of these changes are ultimately good for the Indian pharmaceutical industry, which suffered in the past from inadequate regulation and large quantities of spurious drugs. They force the industry to reach a level necessary for global competitiveness. However, they have also exposed some of the inadequacies in the industry today. Its main weakness is an underdeveloped new molecule discovery programme. Even after the increased investment, market leaders such as Ranbaxy and Dr. Reddy’s Laboratories spent only 5-10 per cent of their revenues on Research and Development (R&D), lagging behind Western pharmaceuticals like Pfizer, whose research budget last year was greater than the combined revenues of the entire Indian pharmaceutical industry. This disparity is too great to be explained by cost differentials, and it comes when advances in genomics have made research equipment more expensive than ever.
The drug discovery process is further hindered by a dearth of qualified molecular biologists. Due to the disconnect between curriculum and industry, phamas in India also lack the academic collaboration that is crucial to drug development in the West.

2.19.6. Research and Development

Both the Indian central and state governments have recognized Research and Development (R&D) as an important driver in the growth of their pharma businesses and conferred tax deductions for expenses related to research and development. They have granted other concessions as well, such as reduced interest rates for export financing and a cut in the number of drugs under price control. Government support is not the only thing in Indian pharma’s favour, though; companies also have access to a highly developed Information Technology (IT) industry that can partner with them in new molecule discovery in Research and Development (R&D).

2.19.7. Labour Force

India’s greatest strengths lie in its people. India also boasts of well-educated, English-speaking labour force that is the base of its competitive advantage. Although molecular biologists are in short supply, there are a number of talented chemists who are equally as important in the discovery process. In addition, there has been a reverse brain drain effect in which scientists are returning from abroad to accept positions at lower salaries at Indian companies. Once there, these foreign-trained scientists can transfer the benefits of their knowledge and experience to all of those who work with them. India’s wealth of people extends benefits to another part of the drug commercialization process as well. With one of the largest and most genetically diverse populations in any single country, India can recruit for clinical trials more quickly and perform them more cheaply than countries in the West. Indian firms have just recently started to leverage.
2.19.8. Comparison with the United States (U.S)

The Indian biotech sector parallels that of the United States (U.S) in many ways. Both are filled with small start-ups while the majority of the market is controlled by a few powerful companies. Both are dependent upon government grants and venture capitalists for funding because neither will be commercially viable for years. Pharmaceutical companies in both countries have recognized the potential effect that biotechnology could have on their pipelines and have responded by either investing in existing start-ups or venturing into the field themselves. In both India and the United States (U.S), as well as in much of the globe, biotech is seen as a hot field with a lot of growth potential.

2.19.9. Government Support

The Indian government has been very supportive. It established the Department of Biotechnology in 1986 under the Ministry of Science and Technology. Since then, there have been a number of dispensations offered by both the central government and various states to encourage the growth of the industry. India’s science minister launched a program that provides tax incentives and grants for biotech start-ups and firms seeking to expand and establishes the Biotechnology Parks Society of India to support ten biotech parks by 2010.

The government has also taken steps to encourage foreign investment in its biotech sector. An initiative passed earlier this year allowed 100 per cent foreign direct investment without compulsory licensing from the government. In April, a delegation headed by the Kapil Sibal, the minister of science and technology and ocean development, visited five cities in the United States (U.S) to encourage investment in India, with special emphasis on biotech.